The effectiveness of transcutaneous electrical nerve stimulation (TENS) therapy on shoulder impingement syndrome: A systematic review

By

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Dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic

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I, Shrishti Maharaj, hereby do declare that this dissertation is a representation of my own work in both conception and execution.

23 – 03 - 2021

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Approved for final submission

23 - 03 - 2021

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Dedication

I dedicate this dissertation to my parents.

Acknowledgments

I would like to thank my parents, Rajendra and Akashni, for being my role models in academia and in life. The passion that drives the both of you to be the best in your respective professional fields has been the motivation behind the completion of my studies.

To my brother Kiash, you were my pillar of strength whenever I felt overwhelmed throughout this research process. Thank you for being there through the stress and excitement of my degree. I will forever appreciate all the advice and kindness I have received from you over the past few years.

To my supervisor, Dr Charmaine Korporaal. Thank you for being such an inspiration and for shaping me to become the chiropractor and researcher that I am today.

To all my reviewers from around the world, Prof Peter McCarthy, Prof Henry Pollard, Prof Kristian Leisegang, Dr Clinton Daniels, Dr Amy Minkalis and Dr Dillon Cuppusamy, it has been an absolute honour and pleasure having you collaborate on my study. Thank you for taking time out of your busy schedules to assist with the review process of this study. I am profoundly grateful.

Thank you to Mrs Segarani Naidoo and Mrs Avenal Finlayson, for all your assistance with my article search.

To Ms Sunitha Kissoon, thank you for taking the time out of your busy schedule to proof-read my thesis. It is highly appreciated.

To anyone choosing to pursue a systematic review as a thesis, its not impossible. You can do it!

Abstract

Background

Shoulder impingement syndrome (SIS) is a common condition that causes pain and functional impairment in the shoulder. There have been various studies assessing methods of pain management in SIS, however, the knowledge around the association between transcutaneous electrical nerve stimulation (TENS) and SIS management has been found to be limited. A systematic review of the literature will provide healthcare providers and the public with an evidence-based summary of evidence regarding the effectiveness of TENS in treating SIS pain.

Objective

To systematically assess and review the methodological rigour of all available studies that have used TENS to treat SIS in order to provide evidence-based knowledge to either support or refute its use in clinical practice.

Methods

A literature search was conducted on electronic databases Google, Google scholar and DUT Summons (Pubmed, MEDLine, Mantis, ScienceDirect). The relevant key search words used at this stage of the study included the term “TENS” and each of the following: shoulder pain, frozen shoulder, calcific tendonitis, shoulder impingement syndrome, shoulder myofascial pain syndrome, brachial dysfunction, shoulder dysfunction and shoulder bursitis. It was identified that SIS would be the focus of this study and therefore, full-text articles relevant to SIS and TENS were included, based on the inclusion and exclusion criteria outlined in the study design. The final list of included articles was reviewed by a total of seven reviewers using either the PEDro and/or Newcastle-Ottawa scale, in order to establish the methodological rigour of the studies.

Results

During the data collection process that took place between August 2019 to January 2020, 106 articles were screened for eligibility. Patients included in these studies were adults who were required to have been diagnosed with SIS. These articles

included randomized controlled trials (RCTs), non-RCT's, case studies and case reports. The 106 articles were reduced to 20 articles meeting the inclusion criteria, consisting of 19 RCTs and 1 non-RCT. Following the conclusion of the data collection process, the articles collectively were divided into three groups. Screening and review of the articles were conducted by the three reviewers allocated to each group. Each article was then ranked according to the criteria outlined in the PEDro and/or Newcastle-Ottawa scale, and the limitations of each article were stated. Following this process, the findings of all articles were collated, with the results indicating that there is limited evidence to support the use of TENS in the management of SIS.

Conclusion

Even though TENS has been found to be effective in inducing pain relief in a variety of conditions, clinicians should use TENS with caution as the limited and conflicting evidence available does not advocate for its use (alone or in combination with other therapies) in treating SIS. Thus, there is a demand for more high-quality studies pertaining to TENS and SIS clinical subcategories. It is however recognised that the findings of this study may be limited to a specific time period and could be influenced by more recently published studies not included.

Key words

Shoulder pain, Frozen shoulder, Calcific tendonitis, Shoulder impingement syndrome, shoulder myofascial pain syndrome, Brachial dysfunction, shoulder dysfunction, shoulder bursitis, transcutaneous electrical nerve stimulation

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Definitions

Adhesive capsulitis: A condition in which there is fibrous scar tissue creating adhesions around the glenohumeral joint, which results in the presence of a chronic response to inflammation in the shoulder joint. This condition affects 5% of the general population yearly (Page and Labbe, 2010). Commonly associated features of adhesive capsulitis include; joint stiffness, pain and loss of shoulder range of motion (Le et al., 2017). This shoulder pathology can occur as a result of an underlying disease such as thyroid dysfunction or diabetes, or it can occur secondary to shoulder injury. It presents in three different stages and the condition usually clears up, with a resultant increase in range of motion after a period of 5-26 months (Chan et al., 2017).

Frozen shoulder: A synonym for adhesive capsulitis (Yuan et al., 2017, Chan et al., 2017, Page and Labbe, 2010).

Meta-analysis: A statistical, objective and scientific method of quantifying and synthesizing relevant evidence on various types of studies pertaining to a specific topic in order to derive conclusions related to the research question (Ahn and Kang., 2018, Lee, 2018). The advantage of producing a meta-analysis is that it is able to quantify and consolidate complex pools of data in order to answer a research question (Higgins and Green., 2011) and to improve the strength in terms of the contribution from smaller or inconclusive studies (Ioannidis and Lau., 1999). A disadvantage of this study type is that it can only utilize studies of a similar type (usually randomized controlled trials), that have at least one common clinical outcome that is measured at approximately the same time intervals. This makes the meta-analysis prone to bias (given small study numbers but larger patient pools that fit fairly specific criteria) that may lead to erroneous conclusions (Higgins and Green, 2011).

Rotator cuff injuries: A common cause of shoulder pain, affecting between 30-50% of the adult population over the age of 50 years (Longo et al., 2019). It is often characterized by either a strain, tendonitis or tear of one of the rotator cuff muscles (Schuldt, 2009) as a result of a traumatic incident to the shoulder in adolescents, and as a result of weak tendons and persistent micro-traumas in the older population

resulting in an associated decrease in blood supply to the shoulder joint (Carvalho et al., 2016).

Shoulder impingement syndrome (SIS): A condition with a simultaneous presentation of multiple causes of orthopaedic shoulder pain (rotator cuff tears, calcific tendinitis, tendinosis and subacromial bursitis) occurring often at the same time. This cause of shoulder pain is often found to be the most common disorder affecting the shoulder girdle in adults (Watts et al., 2017; Baskurt et al., 2011) and is mostly characterized by progressive loss of range of motion, shoulder pain and disability. This study focused on shoulder impingement syndrome as it is the most common disorder of the shoulder, with a prevalence of 44-65% (Ucurum et al., 2018 and Consigliere et al., 2018) and results in the greatest amount of upper extremity disability due to pain, loss of motion and biomechanical disruptions (Hakguder et al., 2011).

Sub-acromial impingement syndrome (SAIS): A common cause of shoulder pain that affects approximately 48% of the population. SAIS occurs as a result of impingement of the rotator cuff tendons as a result of the acromion, coracoacromial ligament or the acromioclavicular joint (Dhillon, 2019). SAIS can further include pathologies such as rotator cuff tears, tendinosis, subacromial bursitis and calcific tendinitis affecting the tendons of the rotator cuff muscles (Koester et al., 2005). Pain presenting as a result of SAIS occurs on the anterior and lateral aspect of the acromion, with radiation of pain extending down towards middle of the humerus. The pain is noted to be worse at night and exacerbated by pressure placed on the affected side when lying down (Koester et al., 2005, Dhillon, 2019).

Systematic review: A systematic review is a precise and methodological process in which systematic and explicit methods are used to answer a clearly formulated research question (Moher et al., 2009). Multiple primary studies are synthesized by using study specific strategies that reduce risk of bias and random errors (Gopalakrishnan and Ganeshkumar., 2013). This process encompasses a rigorous literature search that includes both published and unpublished literature in order to identify articles that are relevant to the research question (Hemingway and Brereton., 2009). The articles are then critically evaluated in terms of extent, nature and quality of evidence in relation to the research question (Siddaway et al., 2019). Critical

appraisal of the relevant articles is conducted using scales specific to each study type (Liddle et al., 1996; Wells et al., 2003 and PEDro Scale., 1999) in order to accurately summarise the conclusive findings in each review. A well conducted systematic review provides reliable estimates regarding the efficacy of treatment interventions which result in conclusions that are defensible (Gopalkrishnan and Ganeshkumar., 2013).

Transcutaneous electrical nerve stimulation: A form of electrostimulation that follows the principles of the pain control theory proposed by Melzack and Wall (Melzack and Wall., 1965) in which the stimulation of the skin results in nerve impulses being transmitted to the spinal cord allowing for electroanalgesia to occur, at various frequencies. This form of electroanalgesia is also an inexpensive, non-invasive and safe form of pain management used in the treatment of various conditions (Johnson., 2008).

Abbreviations

ACJ:	Acromioclavicular joint
ACL:	Acromio-clavicular ligament
ASD:	Arthroscopic subacromial decompression
CAL:	Coraco-acromial ligament
CCL:	Coraco-clavicular ligament
CMSP:	Chronic mechanical shoulder pain
DCML:	Dorsal-column medial lemniscal
DOMS:	Delayed onset muscle soreness
EERT:	External rotation resistance test
GABA:	gamma-Aminobutyric acid
HF TENS:	High-frequency transcutaneous electrical nerve stimulation
LF TENS:	Low-frequency transcutaneous electrical nerve stimulation
LLLT:	Low-level laser therapy
Non-RCT/ n-RCT:	Non-randomised controlled trials
NOS:	Newcastle-Ottawa scale
NSSP:	Non-specific shoulder pain
PAG:	Periaqueductal gray
PEMF:	Pulsed electromagnetic field
PICOC:	Population, Intervention, Comparison, Outcomes and Context
PRISMA:	Preferred Reporting Items for Systematic reviews and Meta-analyses
PT:	Physical therapy
RCT:	Randomized controlled trials
ROM:	Range of motion
RVM:	Rostral ventromedial medulla
SAIS:	Sub-acromial impingement syndrome
SASD:	Sub-acromial-sub-deltoid
SCJ:	Sterno-clavicular joint
SCM:	Sternocleidomastoid
SIS:	Shoulder Impingement Syndrome
TENS:	Transcutaneous electrical nerve stimulation
VAS:	Visual Analogue Scale

1. Chapter One

1.1 Introduction to Chapter One

This chapter outlines the aims, objectives, rationale and benefits of performing a systematic review to assess the literature available to substantiate the use of transcutaneous electrical nerve stimulation (TENS) in treating shoulder impingement syndrome (SIS). The limitations of this study is clearly defined along with an outline of chapters found in this research dissertation

1.2 Introduction to the study

Shoulder pain has been identified as the third highest ranking complaint of musculoskeletal origin (Steuri et al., 2017, Artus et al., 2014) with an estimate of 7-34% of cases presenting annually (Tien and Tan, 2014). Shoulder impingement syndrome (SIS) (Natsis et al., 2007) is one of the most common causes of shoulder pain complaints with a prevalence of 44-65% in the general population (Ucurum et al., 2018, Haik et al., 2016). This condition of the shoulder often results in a progressive loss of function and increased pain and disability (Michener et al., 2003).

The types of treatment available are dependent on the severity and duration of the type of SIS. The more acute the SIS symptoms are, the less invasive the treatment methods (Garving, 2017). Literature reported conservative treatments for SIS including exercise therapy, extra-corporeal shock wave therapy and taping (Steuri et al., 2017, Haik et al., 2016). The surgical procedure for SIS, arthroscopic subacromial decompression, is routine, minimally invasive and highly recommended (Draghi et al., 2015, Dong et al., 2015, Khan et al., 2019).

In manual therapy clinical practice however, practitioners have been reported to utilise interferential current therapy (Nazligul et al., 2017) ultrasound therapy (Yildirim et al., 2013) and dry needling (Arias-Buria et al., 2017). This mismatch between the literature and clinical practice has several ethical consequences, which include:

- The inability of the practitioner to provide adequate information to the patient regarding interventions for SIS (Munthe et al., 2012)

- the inability of the patient to make an informed judgement and provide informed consent for treatment protocols (Munthe et al., 2012)

- the inability of third party payors / medical insurance agencies / medical aids in being able to adequately re-imburse practitioners or patients for care rendered (Goold, 2001)

- the incursion of costs to patients, third party payors and companies as a result of ineffectual treatment plans through the use of modalities that have not necessarily shown any benefit (Munthe et al., 2012, Goold, 2001).

Similarly, other surgical interventions have been known to include treatments such as open subacromial decompression (OSD) which has been identified as less effective than ASD (Dong et al., 2015). Because of this disparity between literature reported and practical clinical contexts, treatments related to SIS and shoulder pain in general can result in financial burden to the patient, company and society as it may increase the amount of sick days a patient takes due to pain (Virta et al., 2012), or increase the cost as a result of ineffectual treatment plans that are not evidence based. As the direct and indirect costs of treatment can be quite high, this systematic review looks at the use of transcutaneous electrical nerve stimulation (Aarskog et al., 2007) therapy as a form of treatment for SIS, as it has the ability to be utilised in practice care programmes as well as home care programmes (Searle et al., 2009).

Transcutaneous electrical nerve stimulation is an easily accessible, non-invasive, cost-effective device (Searle et al., 2009) that is used to treat pain related to a multitude of musculoskeletal conditions (Bjordal et al., 2003, Robinson, 1996). The effectiveness of TENS in the treatment of non-specific shoulder pain, inclusive of SIS, has been inconclusive by previous systematic reviews due to the high prevalence of low-quality randomised controlled studies assessing the effectiveness of TENS (Hawk et al., 2017, Steuri et al., 2017). Therefore, this systematic review aimed to assess the methodological quality of all available studies to either promote or discourage the use of TENS in managing pain related to SIS, through enabling identification of the gaps in the known literature about the use of TENS in SIS patients.

An appropriate definition of a systematic review, that is both accepted and used by the Cochrane Collaboration is “a review of a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to

collect and analyse data from the studies that are included in the review" (Higgins and Green, 2011, Moher et al., 2009). A systematic review attempts to collate all empirical evidence that fits a pre-specified, eligibility criteria that answers a specific research question. It is a reproducible piece of observational research that uses a specific protocol, which sets out an explicitly objective, systematic method for the conduct of the research, in order to minimize bias. This, therefore, provides reliable findings from which conclusions can be drawn and decisions made (Liberati et al., 2009, Wormald and Evans, 2017).

Systematic reviews are an essential tool for summarizing evidence accurately and reliably. It provides a means of keeping clinicians informed of current research and allowing policy makers to render correct judgement calls by providing them with adequate information to judge a risk-benefit ratio in terms of harms associated with health care interventions (Hemingway and Brereton, 2009). Systematic reviews also provide a summary of current research that is relatable to the general public, which is composed of patients, consumers and care-givers, all of whom, require the summary to be of a level that is easy to interpret as compared to most published articles (Liberati et al., 2009).

Therefore, the purpose of this study was to review and examine the quality and quantity of evidence available for the use of transcutaneous electrical nerve stimulation (TENS) in the treatment of shoulder pain related to SIS and to enable practitioner education, informed consent processes and guideline formation for third party payors (Hemingway and Brereton, 2009).

1.3 Aim

The aim of this study was to determine the level of evidence and provide an accurate, transparent (Page and Moher, 2017) and reliable summary of evidence to provide to health care practitioners regarding the use of TENS in the treatment of shoulder pain as a result of SIS (Liberati et al., 2009). This was done by using an evidence-based, non-biased critical analysis of studies including RCT's (Bhogal et al., 2005, Olivo et al., 2008) non-randomised clinical trials (Deeks et al., 2003) case reports and observational studies (Kempen, 2010, Murad et al., 2018)

1.4 Objectives

The objectives of the study were:

1. To determine the level of methodological rigour of studies investigating TENS therapy as a treatment for shoulder pain due to SIS.

2. To determine whether the use of TENS has a positive or negative clinical outcome in patients treated for shoulder pain due to SIS.

3. To determine the level of evidence to support the use of TENS therapy for shoulder pain due to SIS.

4. To make recommendations for further investigations and RCT's in order to determine the effectiveness of TENS therapy for shoulder pain due to SIS.

1.5 Rationale and benefits

Shoulder pain is a common musculoskeletal disorder, which is commonly seen in primary healthcare and is known to cause significant pain, disability, care costs and work loss for many patients around the world (Joo et al., 2017). It is a type of dysfunction that can have a debilitating effect on a person's quality of life. (Walker, 2014). Shoulder pain is often seen as a challenging phenomenon to treat due to the potential mismatch between pathology and perception of pain (Struyf et al., 2015).

Shoulder impingement syndrome is one of the most common, often overlooked causes of shoulder pain that can result in biomechanical dysfunction in the upper extremity (Ucurum et al., 2018, Haik et al., 2016, Steuri et al., 2016). Understanding SIS as a cause of shoulder pain can be difficult, as the term "SIS" is a generic term that accounts for injury to structures within the sub-acromial space (Steuri et al., 2016) such as rotator cuff tears, tendinosis, calcific tendinitis and subacromial bursitis (Koester et al., 2005). In the acute stages of SIS, exercise therapy is often seen as the first line of treatment, in conjunction with nonsteroidal anti-inflammatory drugs (NSAIDs), electrotherapy and kinesio-taping.In chronic cases, surgery is usually the recommended treatment, with surgical decompression being the first choice after a period of conservative treatment (Dong et al., 2015, Consigliere et al., 2018). However, the knowledge behind the use of TENS in the treatment of SIS symptoms is limited and therefore, a review to understand the evidence-based strengths or weaknesses of this treatment modality will aid the clinician in providing an effective form of treatment for the resultant shoulder pain that occurs due to SIS.

This systematic review aimed to evaluate the use of TENS as a treatment for shoulder pain as a result of SIS. The reason for the evaluation of this specific modality is that it is an inexpensive, non-invasive and safe modality, with no major side effects (Searle et al., 2009). Due to the ease of use and inexpensive nature associated with a TENS device, medical professionals can recommend that patients use it at home (Loh and Gulati, 2015).

Transcutaneous electrical nerve stimulation is also known to relieve a wide variety of acute non-malignant and chronic conditions throughout the body (Tashani and Johnson, 2008), including the treatment of post-surgical shoulder pain (Albright et al., 2001); but evidence is limited in terms of effective treatment of shoulder pain as a result of SIS. Individual studies have shown that TENS has provided variable relief in multiple shoulder pain dysfunctions (Vrouva et al., 2019, Mahure et al., 2017, Korkmaz et al., 2010, Soibam, 2005). This range includes work-related musculoskeletal disorders (Suh et al., 2015) to post stroke hemiplegic shoulder pain (Ekim et al., 2008); but evidence is limited in terms of effective treatment of shoulder pain as a result of SIS. In addition, most studies do not provide specific settings on the TENS unit to clarify which setting provides optimal results for any one pathology.

Systematic reviews are essential in summarizing the efficiency, effectiveness, and reliability of a health care intervention (Liberati et al., 2009). This systematic review seeks to evaluate and provide an accurate and reliable summated format of the available evidence in the use of TENS in SIS. In doing so, it would assist the clinician / patient / third party payor to either reject or accept the use of TENS in the treatment of SIS. Collating the evidence in an objective and explicit manner aids the public, health care providers and policy makers in making well-informed and calculated decisions in terms of treatment protocols and other investments (Hemingway and Brereton, 2009).

Therefore, a systematic review assessing the efficiency of TENS in the treatment of SIS is both beneficial and essential as it will contribute to the current knowledge of healthcare professionals who are treating and managing shoulder pain in patients that has occurred as a result of SIS.

This study included all relevant literature pertaining to SIS, in the form of randomized controlled trials, non-randomized controlled trials, case studies and case reports. This allows all publications to be reviewed for determining the methodological rigor of each of the studies included in this review. Studies outside of those pertaining to RCTs have

tended to show increased support for more recent interventions; even though they do not have a high level of scientific credibility, but most closely approximate clinical practice settings (Harris, 2013).

1.6 Limitations

The limitation of this study was that only pain involving the shoulder girdle as a result of SIS was included and not as secondary occurrence due to disease or surgery. The reason for the focus of this study being on SIS is because the use of TENS as a post-surgical pain intervention has already been reviewed and pain secondary to disease cannot be classified as primary shoulder pain from SIS directly.

Another limitation is that only English articles were used. This was done in order to prevent translation bias in this study (Balk et al., 2013). However, articles that were already translated into English were used in this study. It is suggested that future systematic reviews include the use of non-English articles as the result of exclusion of such articles may introduce a language bias, which can lead to erroneous conclusions (Morrison et al., 2012).

The articles included were limited to peer reviewed and published grey literature. There has been reluctance in the use of grey literature (literature that is found outside the scope of academic publishing) due to the absence of peer-review for unpublished literature (Moher et al., 2010). However, research outside peer-reviewed publications, other publications, such as case reports, case studies and non-randomized controlled/clinical trials were included, as data from such publications may provide new evidence for this review and may form the basis for future research endeavours. In general, it is accepted that many RCTs are only published when they have demonstrated favourable outcomes (Higgins and Green, 2011). Therefore, different types of reporting bias may affect the interpretation of articles which leads to publication bias, that can possibly impact the results of a systematic review (Moher et al., 2010). Therefore the inclusion of various publication types may assist in negating the publication bias in RCTs (Higgins and Green, 2011)

Other systematic reviews pertaining to the treatment of shoulder pain with the use of TENS were also excluded from this study. A systematic review is based on the analysis of primary articles only (Charrois, 2015), therefore this study excluded other systematic

reviews but did not exclude any articles that may have been utilized in those systematic reviews.

The scales (Pedro., 1999 (Appendix E) and Wells et al., 2003b (Appendix F)) provided to reviewers were accompanied by an explanatory guide, however there was room for subjective interpretation during the review process. This may or may not have indirectly affected the interpretation of the methodological rigour and may impact on the conclusive outcome of this study. The researcher was available to clarify any queries pertaining to theinterpretation of the scales without assisting in the interpretation of the individual study. In addition, every article reviewed in this systematic review was reviewed by three reviewers, with the requirement for consensus or at minimum majority consensus in terms of the interpretation of the scale outcomes per article.

This study is defined as a systematic review as stated in the Cochrane Handbook in which it is “A review of a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, to collect and analyze data from the studies that are included in the review” (Higgins and Green, 2011, Moher et al*.,* 2009). This study does not identify itself as a meta-analysis, which is identified as “A quantitative, formal, epidemiological study design used to systematically assess the results of previous research to derive conclusions about that body of research” (Haidich, 2010).

This systematic review purely assessed the methodological rigor of the articles reviewed concerning the research topic. It does not entail the statistical analysis, as one would find in a meta-analysis. This systematic review looked at the effect of TENS therapy in the treatment of pain related to SIS. This study is not able to include a meta-analysis in the review due to the inclusion of studies other than RCTs; and according to Rodseth and Marais (2016), a meta-analysis is “an attempt to increase the statistical power of clinical trials studying an intervention.” (Rodseth and Marais, 2016).

1.7 Outline of chapters

The main points of this study are covered in the overview presented in this chapter. Chapter Two includes a literature review, which outlines shoulder pain as a result of SIS and TENS as well as the mechanism of review. Chapter Three entails the research methodology, which outlines the research design and methods followed. Chapter Four contains the results once all data was collected and reviewed. Chapter Five is a discussion

of results and Chapter Six is the conclusion of the study and recommendations that may be beneficial to future researchers.

2. Chapter Two – Literature Review

2.1 Introduction

This chapter presents a review of the literature pertaining to the anatomy, physiology, clinical assessment and diagnosis of shoulder impingement syndrome. Further, an explanation regarding the use of Transcutaneous Electrical Nerve Stimulation (TENS) is provided, along with the perceived benefits it has presented in healthcare and its role in the treatment and management of SIS. The use of a systematic review is explained, in terms of its importance in determining the validity and rigour of studies pertaining to the use of TENS in the treatment of SIS, as well as in identifying the limitations found in the relevant reviewed studies.

2.2 Anatomy of the shoulder

The human body comprises of two shoulder girdles that allow for the connection of the upper limb to the axial skeleton (Tortora and Derrickson, 2011). The anatomy pertaining to the shoulder girdle is complex in both structure and function (Kadi et al., 2017). It comprises a dynamic and sequential bone-muscle-ligament relationship, all of which allow for the greatest range of motion in the human anatomy (Terry and Chopp, 2000).

Anatomical constituents of the shoulder girdle include the clavicle anteriorly and the scapula posteriorly (see Figure 2.1). The position of these bony structures determines the type of movement permitted in the shoulder and provides a namesake for each type of muscle attached to these bones. Each bone in the shoulder girdle has individual anatomical variabilities that promote articulations between each structure. The shoulder girdle does not have osseous articulations with the vertebral column, instead it is stabilized and supported by a large set of muscles that extend from the spinal column and ribs to the scapula (Tortora and Derrickson, 2011, Engin, 1980).

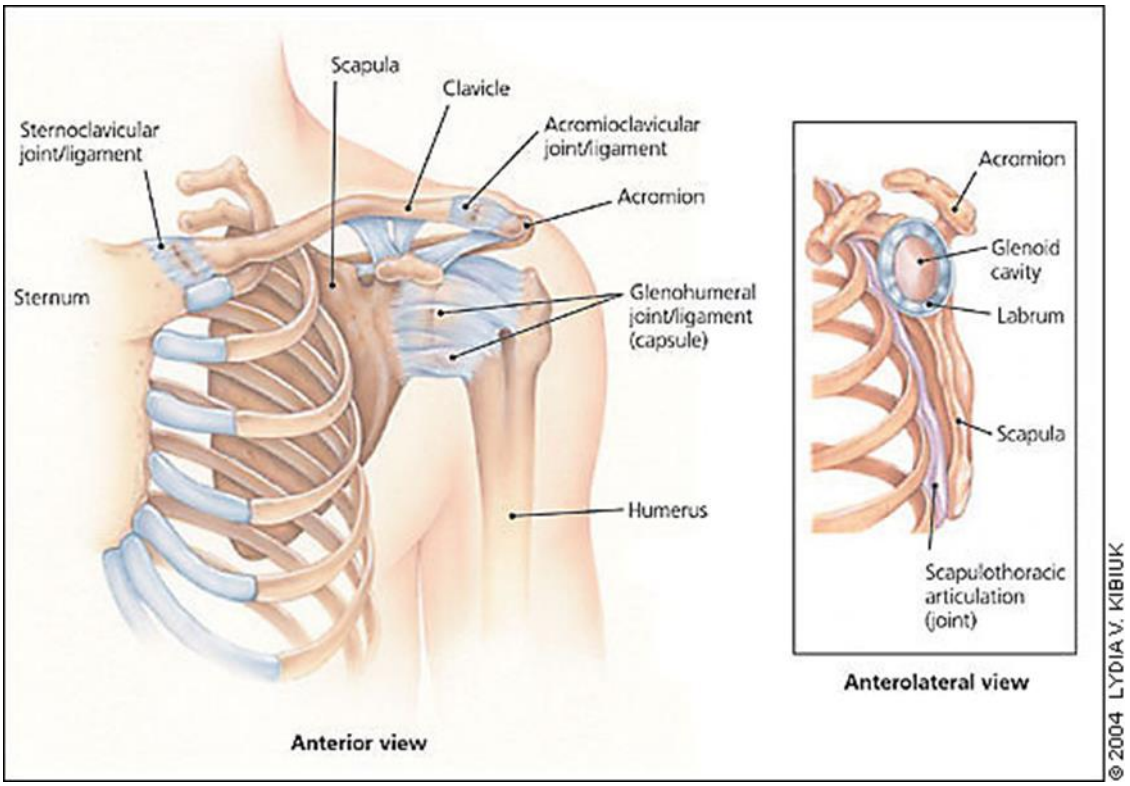


Figure 2.1: Anatomy of the shoulder girdle (reproduced with permission from the illustrator (see Appendix G))

2.2.1 The clavicle

The clavicle is also commonly known as the collarbone and is found on the anterior aspect of the shoulder girdle. It is classified as a sigmoid-shaped long bone (Hyland and Varacallo, 2019), which is horizontally orientated and located on the superior, anterior aspect of the thorax just above the first rib (see Figure 2.1).

2.2.1.1 The structure of the clavicle

Structurally, the clavicle can be divided into two portions, an external flattened portion and an internal cylindrical portion.

The external flattened portion of the clavicle has two surfaces (upper and lower) and two borders (anterior and posterior). The upper surface is seen to be a rough, flattened surface with an anterior demarcation for the attachment of the deltoid muscle and a posterior marking for the attachment of the trapezius muscle (Marieb, 2015, Gray, 2013).

The lower surface is flattened, with a rough eminence protruding from the posterior border which gives rise to the conoid tubercle. This osseous structure is a point of attachment for

the conoid ligament, which plays a pivotal role in attaching the clavicle to the scapula (Tortora and Derrickson, 2011, Marchese and Bordoni, 2020).

The anterior border of the flattened external clavicle is a rough, concave structure that limits the insertion of the Deltoid (Table 2.3) and gives rise to the deltoid tubercle. The posterior border is more convex than the anterior border and provides the attachment for the Trapezius muscle (Marieb, 2015, Gray, 2013).

The internal cylindrical portion of the clavicle is a curvy structure that is convex anteriorly and concave posteriorly and contains three different borders (Table 2.1) that separate three different surfaces (Table 2.2) of the clavicle.

Table 2.1: Internal clavicular borders (Gray, 2013)

Border	Description	Muscle attached to border
Anterior border	Smooth portion of clavicle that corresponds to the osseous interval between the Deltoid and Pectoralis major attachments	Clavicular portion of the Pectoralis major
Superior border	Smooth and round, separating the anterior and posterior surfaces	The sternocleidomastoid (SCM) muscle
Posterior border	Divides the posterior and inferior clavicular surfaces; extends from conoid tubercle to the rhomboid depression	Forms part of the posterior groove for the subclavius muscle

Table 2.2: Internal clavicular surfaces (Gray, 2013)

Surface	Description	Muscle attachment involved
Anterior surface	Triangular in shape, surface faces inferior and anteriorly	Anteriorly – Pectoralis major Posteriorly – Sterno-cleido mastoid (SCM)
Posterior surface	Smooth, flat and faces posteriorly	Attachment at the sternal extremity – Sterno-hyoid muscle
Inferior surface	The internal surface is narrow but the width of the surface increases externally. Contains facet for articulation with the first rib	Subclavius muscle

2.2.2 Articulations of the clavicle

The articulations of the clavicle include the sterno-clavicular (SC) joint, which is found medially, along the upper border of the sternum, at the manubrium. The SC joint is a saddle-type synovial joint, which allows for the elevation, depression, forward and backward translation and posterior rotation of the clavicle (Armfield et al., 2003). Superior to this articulation, the inter-clavicular ligament can be seen connecting the ipsilateral and contralateral clavicles to ensure positional maintenance of the bones (Gray, 2013).

Laterally, the clavicle articulates with the acromion process of the scapula, which results in the formation of the acromio-clavicular joint (ACJ). The AC joint is a plane joint that allows for a restricted amount of translation and rotation of the corresponding clavicular and acromion surfaces (Armfield et al., 2003). Both joints are covered by fibro-cartilage and contain an intra-articular disc that is held in place by the corresponding ligaments. The ACJ is stabilized and supported by three main ligaments, the acromio-clavicular ligament (ACL), the coraco-acromial ligament (CAL) and the coraco-clavicular ligament (CCL) (Hyland and Varacallo, 2019), all of which provide joint stability between the scapula and clavicle (Armfield et al., 2003). When there are degenerative changes at the inferior aspect of the ACJ, which affects the CAL, impingement results due to the encroachment of the bone on the subacromial space (see Section 2.3) (Umer et al., 2012).

Another noteworthy ligament is the coracohumeral ligament, which separates the subacromial space into two divisions. The first division comprises the sub-deltoid/sub-acromial bursa and is in close proximity to the anterior acromial surface and the CAL (Lazaro, 2005). The supraspinatus outlet is located in this region and is a common cause of impingement by a type three acromion (see Section 2.3.) due to the fact that the supraspinatus tendon passes through this outlet and can easily be compressed (Fongemie et al., 1998).

The CAL is a common cause of shoulder impingement. It is acts as a bridge between the acromion and coracoid process of the scapula, in which it connects the two osseous structures, forming the coracoacromial arch that works to prevent excessive displacement of the humeral head superiorly. Impingement of the subacromial bursa and rotator cuff tendons often occur between the humeral head and the coracoacromial arch (Rothenberg et al., 2017, Michener et al., 2003).

2.3 The scapula

The scapula is a triangular bone found on the posterior aspect of the ribcage – between the first and eighth ribs (see Figure 2.1). This osseous structure has three angles (superior, anterior and inferior), three borders (superior, lateral/axillary and the medial/vertebral) as well as two surfaces (anterior and posterior) (Gray, 2013, Marieb, 2015, Standring, 2016).

The scapula gives rise to a prominent ridge called the spine of the scapula, and laterally it gives rise to a flattened expansive bony process called the acromion. Another noteworthy feature is called the coracoid process, which is a thickened and curved extension of the scapula which arises from the broad base of the neck of the scapula (Marieb, 2015, Standring, 2016).

The subacromial space is found within this region and is bordered by the humeral head inferiorly, the ACJ superiorly, the CAL and the ventral aspect and inferior surface of the acromion. Between the humeral head and the acromion, with a distance of 1 to 1.5 cm between the structures, rest the rotator cuff tendons, long head of biceps tendon, the subacromial bursa and the CAL, which easily becomes irritated at the first indication of abnormality within the shoulder (Umer et al., 2012). Normal subacromial space measurements found on radiographs have been measured to be 10.2 mm in men and 9.5 mm in women and when there is a reduction in this space, the possibility of impingement increases (Petersson and Redlund-Johnell, 1984).

A common cause of narrowing of the subacromial space is the size and shape of the acromion (Umer et al., 2012). The shape of the acromion often affects and irritates the associated soft tissue structures in the shoulder, resulting in impingement (Inklebarger et al., 2017). According to Bigliani et al., (1986), the acromion shape can be classified according to three types, i.e; Type one which is flat, Type two which is curved and Type three, which is hooked (Bigliani et al., 1986, Stehle et al., 2015). Type two and three acromion have been commonly identified to be the cause of impingement in the shoulder (Natsis et al., 2007, Balke et al., 2013, Inklebarger et al., 2017), often due to the presence of degenerative osteophytes (Nyffeler and Meyer, 2017). These factors (subacromial space encroachment and the acromion shape and type) have been identified as extrinsic causes of shoulder impingement (Consigliere et al., 2018).

A reversed curved acromion which is described as a Type four acromion morphology was identified and described to have an inferior surface that is convex (Vanarthos and Monu, 1995). However, it has been noted that Type four acromion morphology is not implicated in the development of impingement syndrome (Natsis et al., 2007, Bigliani et al., 1986).

The os acromiale, a rare condition in which the primary ossification centres of the acromion fail to fuse, which may lead to shoulder pain and associated limited range of motion of the ACJ and scapula-thoracic joint. This occurs when the affected patient is performing overhead motions, as the os acromiale is constantly forced into flexion, resulting in impingement type symptoms (Hurst et al., 2019).

Scapula articulations include the scapula-thoracic joint, scapulo-clavicular and the gleno-humeral joint. The glenoid cavity is located on the anterior angle of the scapula which gives rise to the head of the scapula. On the head of the scapula, a pyriform, superficial depression is present, which provides the point of articulation for the glenoid cavity (Gray, 2013).

The most important role of the scapula is the biomechanical movement that occurs at the points of articulations which result in movement of the upper extremity. These movements are commonly a result of the corresponding muscles found on the scapula, which are known as the rotator cuff muscles. These muscles dynamically stabilize the scapula, whilst simultaneously appropriately locating the glenoid in line with the humerus to provide efficient range of motion at the gleno-humeral joint (Paine and Voight, 2013).

2.3.1.1 The scapula-thoracic joint

The scapulothoracic joint can be defined according to Seth et al., (2016) as “the kinematics of a joint frame on the scapula with respect to a joint frame on the thorax body”. The scapula-thoracic joint is not considered to be a “true joint” but rather the point at which the scapula slides along the thoracic cage. Movement at the scapula-thoracic joint is essential for the movement of the upper axial skeleton as well as providing stability to the glenohumeral joint (GHJ) (Armfield et al., 2003). The most defining motion of the scapula-thoracic joint is the superior rotation of the scapula (Seth et al., 2016). Expected movements that occur at the scapula-thoracic joint during elevation of the arm include superior rotation, posterior tilting, and either internal or external rotation at the scapula-thoracic joint (Ludewig and Braman, 2011). Movement in the scapula-thoracic joint occurs

as a result of coupled motions between the acromioclavicular and sternoclavicular joints, which provide smooth and efficient movements of the shoulder (Ludewig and Braman, 2011).

The scapula-thoracic joint does not comprise an osseous articulation between the thoracic spine and the scapula, as it depends on ligamentous and muscular structures to provide stability which therefore results in a variety of movements occurring at the scapula, allowing for maximum mobility within the upper extremity (see Figure 2.1). These movements include retraction, protraction, depression, elevation, tilt in the anterior and posterior planes, and rotation which takes place internally, externally, superiorly and inferiorly. These movements contribute to the biomechanical and kinetic functioning of the shoulder girdle (Paine and Voight, 2013).

One of the most important roles of the scapula is to provide stability to the glenohumeral joint (Kibler, 1998). The movement of the scapula is dependent on the position of the glenoid as this is the anatomical point of reference for movement in the shoulder girdle. Since the scapula does not have any bony articulations with the thoracic spine, the main stabilizing muscles of the scapula to the spine include the subscapularis and serratus anterior muscles as these have a suctioning mechanism that keeps the scapula from performing unnecessary movements and maintaining stability in the upper extremity (Paine and Voight, 2013). Poor kinematics due to weak and incorrectly activated muscles and an unstable joint, would result in superior migration of the humeral head, leading to limited movement in abduction and external rotation. This would increase the compressive forces at the glenohumeral joint thus increasing pain due to impingement (Consigliere et al., 2018).

A review by Ludewig and Reynolds (2009) identified common scapula-thoracic abnormalities in patients with SIS. These abnormalities included dorsal tilting of the scapula-thoracic joint, limited superior rotation of the joint, while the internal rotation of the scapula-thoracic joint was increased and finally, a surge in clavicular elevation in conjunction with thoracic cage movements (Ludewig and Reynolds, 2009). It has been identified that these abnormalities result in a reduction in the sub-acromial space, which reduces the space between the rotator cuff tendons and the humeral head, leading to impingement (Ludewig and Braman, 2011). This type of impingement is often described as

an anterior subacromial impingement (Lazaro, 2005), and repetitive movements at the shoulder under these conditions can result in pain.

The scapulo-humeral rhythm on the lateral aspect of the body provides coordinated movement between the glenohumeral joint and scapula to allow for maximum joint movement, whilst simultaneously providing stability to the scapula. The scapulohumeral rhythm is an important factor in the movement of the upper extremity as it allows fluid and coordinated arm movement while keeping the glenohumeral joint in alignment to allow for maximum joint stabilization (Paine and Voight, 2013).

2.3.1.2 The glenohumeral joint

The glenohumeral joint is made up of two bones, the humerus and the glenoid fossa of the scapula. The glenoid fossa of the scapula is found at the anterior angle, along the head of the scapula. The glenoid cavity has a thick fibrous band attached around the circumference of the fossa. This band aids in deepening the fossa for articulation with the humeral head, while protecting the osseous edges. This joint has a synovial membrane covering the fossa, allowing for smooth, frictionless movement (Gray, 2013).

The glenoid rim has been noted as a contributing factor towards impingement. This is due to translation of the humeral head either in the superior or anterior direction as a result of posterior capsule tightness. This results in abnormal scapular kinematics and approximation of the acromion inferiorly towards the subacromial space (Umer et al., 2012). Posterosuperior glenoid rim impingement as stated by Lazaro (2005) involves the entrapment of the rotator cuff and labral fibers found posteriorly and superiorly, between the greater tuberosity of the humerus and the posterior superior aspect of the glenoid (Lazaro, 2005).

In terms of traumatic lesions to the shoulder, the shoulder joint is well-known to be a highly unstable joint and has an increased reliance on the rotator cuff muscles (see Table 2.3) for stability and for prevention of humeral head upward translation. Therefore, any form of high magnitude force placed on the joint could result in glenohumeral joint dislocations, which can either be unidirectional, bi-directional or multidirectional, with unidirectional dislocations being the most common in the shoulder (Sheehan et al., 2013).

2.3.2 Muscles of the rotator cuff

The movement of the pectoral girdle differs according to the location. These muscles can be divided into four subgroups : Anterior thoracic muscles, Posterior thoracic muscles and the scapulo-humeral muscles that move the scapula and the humerus (Tortora and Derrickson, 2011).

A less common type of impingement known as coracoid impingement syndrome, is when the subscapularis muscle (see Table 2.5) tendon is impinged between the coracoid process and the lesser tuberosity of the humeral head (Okoro et al., 2009). In the tables below, each muscle group will be explained according to origin, insertion, action and corresponding nerve supply.

Table 2.3: Muscles that move the humerus (Moore et al., 2010, Tortora and Derrickson, 2011)

Muscles	Origin	Insertion	Action	Nerve Supply
Pectoralis Major	Clavicular head – Dorsal surface of the medial half of clavicle Sternocostal head – Dorsal surface of sternum, superior six costal cartilages	Greater tubercle and lateral lip of intertubercular sulcus of humerus	Adducts and medially rotates the humerus while drawing the scapula anterior and inferiorly Individually – Clavicular head flexes the humerus Sternocostal head- extends humerus from the flexed position	Medial and lateral pectoral nerves Clavicular head (C5; C6) Sterno-costal head (C7-T1)
Pectoralis Minor	3rd-5th ribs	Medial border; superior surface of the coracoid process of the scapula	Stabilizes the scapula by suctioning it inferiorly and anteriorly against the wall of the thoracic spine	Medial pectoral nerve (C8-T1)
Subclavius	1st rib and its corresponding costal cartilage	Inferior aspect of the middle third of the clavicle	Anchors and depresses the clavicle	Nerve to subclavius (C5-C6)
Serratus anterior	1st to 8th ribs	Vertebral border and inferior aspect of the scapula	Protracts the scapula whilst simultaneously holding it against the rib cage; rotates the scapula	Long thoracic nerve (C5-C7)

Table 2.4: Muscles of the posterior thoracic wall (Moore et al., 2010, Tortora and Derrickson, 2011)

Muscle	Origin	Insertion	Action	Nerve Supply
Trapezius	Medial third of superior nuchal line; External occipital protuberance; Nuchal ligament; spinous process of C7-T12	Lateral third of the clavicle, acromion and the spine of the scapula	Superior fibers: rotate the scapula upward Middle fibers: Adducts scapula Inferior fibers: depress Inferior and Superior fibers: rotate the scapula upward Superior fibers: Extends head	Motor fibers: Accessory spinal nerve XI Pain and Proprioception: C3 and C4 cervical nerves
Levator Scapulae	Transverse processes of C1 – C4	Superior vertebral border of the scapula	Elevation of the scapula; inferior rotation of the scapula	Dorsal scapula nerve (C5) and cervical spinal nerve C3-C5
Rhomboid Major	T2-T5 spinal processes	Vertebral border of scapula; from the spine to inferior angle of the scapula	Elevates and adducts the scapula; inferiorly rotates the scapula	Dorsal scapula nerve (C4-C5)
Rhomboid Minor	C7- T1 spinal process	Vertebral border of the scapula superior to the spine	Stabilizes the scapula	
Latissimus Dorsi	T6-T12 spinous processes; thoracolumbar fascia; iliac crest; ribs 9-12	Floor of intertubercular groove of humerus	Adducts, extends, medially rotates the humerus	Thoracodorsal nerve (C6-C8)

Table 2.5: The scapulo-humeral and rotator cuff muscles (see Figure 2.2)

(Moore et al., 2010, Tortora and Derrickson, 2011, Standring, 2016)

Muscle	**Origin**	**Insertion**	**Action**	**Nerve Supply**
Deltoid	Acromion; spine of scapula and lateral third of clavicle	Deltoid tuberosity on the humerus	Lateral fibers: Abducts arm Anterior fibers: Flexes and medially rotates arm Posterior fibers: Extends and laterally rotates the arm	Axillary nerve (C5-C6)
Subscapularis	Subscapular fossa	Lesser tubercle of humerus	Medially rotates arm; helps hold humeral head in glenoid cavity	Upper and lower subscapular nerve (C5-C7)
Supraspinatus	Supraspinatus fossa	Greater tubercle of humerus	Assists the deltoid in abduction of arm	Suprascapular nerve (C4-C6)
Infraspinatus	Infraspinatus fossa	Greater tubercle of humerus	Laterally rotates arm	Suprascapular nerve (C5-C6)
Teres Major	Posterior aspect of inferior angle of scapula	Medial lip of intertubercular sulcus of humerus	Extends, adducts and medially rotates arm at the shoulder joint	Lower subscapular nerve (C5-C6)
Teres Minor	Inferior aspect of lateral border of scapula	Greater tubercle of humerus	Laterally rotates arm	Axillary nerve (C5-C6)
Coracobrachialis	Coracoid process of the scapula	Medial surface of shaft of humerus	Flexes and adducts arm	Musculocutaneous nerve
Long head of biceps	Supraglenoid tubercle of the scapula, located at the apex of the glenoid cavity	Posterior aspect of the radial tuberosity	Supination of forearm, flexes elbow and slight flexion of shoulder. Contributes to superior translation of humeral head during deltoid contraction	Musculocutaneous nerve (C5-C6)

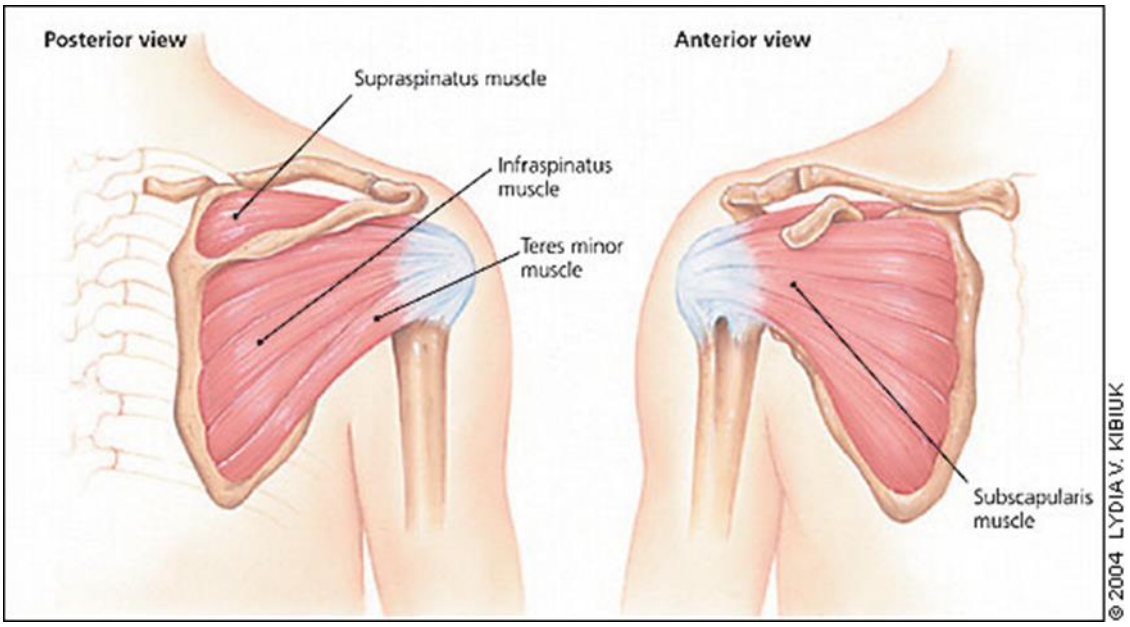


Figure 2.2: Muscles of the rotator cuff (Reproduced with permission from the illustrator (see Appendix G))

2.4 Biomechanics of the shoulder girdle

The ability of the shoulder to move in multiple directions is due to the many interactions between the major articulations (viz. sternoclavicular joint, the acromioclavicular joint, scapulothoracic joint and the glenohumeral joint) and muscular connections, which react to particular mechanical stimuli, which causes the shoulder complex to respond accordingly (Lugo et al., 2008).

Multiple movements occur at the shoulder complex and each movement works in correlation with two or more joints. The major movements of the shoulder complex include abduction, adduction as well as upward/downward rotation, all of which occur along the scapula-thoracic, acromioclavicular and sternoclavicular joints (Culham and Peat, 1993). The upward rotation of the scapula, occurs as a result of the action of the Trapezius and the Serratus anterior muscles which aid in the motion of arm elevation (Culham and Peat, 1993). The major articulations that provide movement in the shoulder complex is the sternoclavicular joint, the acromioclavicular joint, scapulothoracic joint and the glenohumeral joint.

2.5 Neuroreceptors in the shoulder complex

The shoulder complex, due to its irregular bony composition, results in disruption to the skin, muscle, fascia, capsule of the joints and ligaments upon movement of the joint (Bachasson et al., 2015). In order to ensure that the shoulder complex is dynamically stable during movement, the coordination of muscle movements along with the corresponding sensory input need to be functioning at optimum level (Diederichsen et al., 2002). The tissues around the shoulder capsule contribute significantly to shoulder stability, and is balanced by muscle force which is aided by neuromuscular feedback (Guanche et al., 1999).

The neuromuscular feedback in the shoulder is regulated by the Golgi tendons, Ruffini endings, Pacinian and Meissner corpuscles and free nerve endings (Guanche et al., 1999, Dean et al., 2013), which are neuroreceptors that provide the brain with data regarding the body's position, balance and kinesthesia (Bachasson et al., 2015). Each of these sensory neurons are located in different aspects of the shoulder girdle; the majority of the Ruffini endings were located in the coracoacromial ligament and the rotator cuff, the Pacinian corpuscles were found to be frequently located in the joint capsule, while the Golgi tendon organs were specifically located in the musculotendinous junction of rotator cuff muscles, specifically subscapularis and supraspinatus muscles (Diederichsen et al., 2002). A study by Morisawa et al., showed that majority of these mechanoreceptors were found in the subacromial bursa of the shoulder as compared to the rotator cuff and coracoacromial ligament (Morisawa et al., 1996).

Collectively, these neural elements in the body are termed proprioceptors. Proprioception is defined as "the cumulative neural input to the central nervous system from specialized nerve endings called mechanoreceptors, which are located in the ligaments, joints, capsules, muscles, tendons and skin" (Ribeiro and Oliveira, 2011). These proprioceptors provide different information to the brain, specific to the different type of joint and body movement. The Ruffini endings provide neural feedback pertaining to the end range of rotatory movements; however, they require a significantly longer period of time to adapt to the movement. The Pacinian corpuscles are rapidly responsive in providing feedback concerning acceleration, vibration, and deformation in the joint and surrounding tissues. The Golgi tendon organs are similar to the Ruffini endings regarding the slow adaptation

time. It aids in the identification of joint position sense and direction of movement in the body (Guanche et al., 1999).

Proprioception is an element that is detected by proprioceptors which send feedback via the dorsal column medial lemniscal (DCML) pathway to the brain for interpretation. Three different order neurons are responsible for the transmission of data from the shoulder to the brain. The first order neurons carry the signals to the brain via the fasciculus cuneatus to synapse with the nucleus cuneatus of the medulla oblongata. The second order neurons deliver information received at the nucleus cuneatus, after decussation within the medulla oblongata, to the contralateral medial lemniscus to synapse with the thalamus. Finally, sensory signals are received in the ipsilateral somatosensory cortex of the brain via the third order neurons. The DCML controls conscious proprioception, while the spinocerebellar tract controls unconscious proprioception of the body (The Ascending Tracts - DCML - Anterolateral – TeachMeAnatomy, 2020).

A dysfunction in the organization of these proprioceptors can result in shoulder pain. A disruption in the neural pathway between the proprioceptors and the brain can indicate possible tissue injury, which would affect the pain threshold and intensity a person would be able to tolerate. This results in an activated sensitization of the peripheral and central pain pathways. The increased sensitization of these pathways has a domino effect by increasing nociception, since pain threshold and intensity in a patient experiencing shoulder pain would be lowered due to injury. Continuous stimulation of these nociceptors in the presence of unmanaged pain symptoms can result in the development of chronic pain (Borstad and Woeste, 2015). Nociceptors are receptors found throughout the body, in areas such as the joints, muscles, skin and capsules that detect pain signals and relays the information to the brain about tissue injury or possible tissue damage present in the body (Bachasson et al., 2015). They are attached to two different types of fibers, myelinated A-delta fibers and unmyelinated C-fibers, which attach to the dorsal horn of the spinal cord. These fibers contribute to peripheral stimulation by responding to painful stimuli. The A-beta fibers communicate with the dorsal horn of the spinal cord to provide non-nociceptive feedback in order to counteract the effects of the A-delta and C fibers (Kandel et al., 2000)

Both peripheral and central sensitization occurs in response to injury in the body. Peripheral sensitization is often seen as a common immediate response to peripheral tissue damage. Prolonged peripheral sensitization leads to the activation of central

sensitization (Borstad and Woeste, 2015). Although peripheral sensitization occurs in majority cases of shoulder pain, central sensitization specifically, has been identified in many cases of unilateral shoulder pain, with shoulder impingement syndrome being one of the most common conditions identified (Sanchis et al., 2015, Borstad and Woeste, 2015). The definition of central sensitization is an “amplification of neural signaling within the central nervous system that elicits pain hypersensitivity” (Sanchis et al., 2015, Woolf, 2011). Central sensitization has been noted as a high contributing factor to chronic pain syndromes (Borstad and Woeste, 2015).

2.5.1 Central sensitization and shoulder pain

Shoulder pain is a common condition that accounts for 1.2% of all general practitioner visits, being only third to neck and back complaints (Green et al., 1999), thereby leading to significant morbidity in patient populations. Shoulder pain can be described as pain located and localized to the anterior and posterior portion of the shoulder complex with the exclusion of the spine and the anterior thoracic cage region. Most causes of musculoskeletal dysfunction can be classified into two categories: structural and functional related dysfunction. Many cases of shoulder dysfunction are a result of poor of biomechanics that result from wear and tear of the joint, either through overhead activity, overuse, or structural abnormalities (Page, 2011).

Sensitization is commonly seen in many musculoskeletal conditions that could lead to chronic pain and guarding of the joint or area. Conditions with a high incidence of sensitization include chronic fatigue syndrome, whiplash, fibromyalgia, patellar tendinitis, low back pain and shoulder pain (Borstad and Woeste, 2015, Sanchis et al., 2015). In the event of recurrent sensitization, the body experiences an exaggerated response to minimal tissue injury, which prolongs the pain experienced. Due to the multiplicity of mechanoreceptors found in the shoulder joint, shoulder impingement syndrome has been identified as one of the most common shoulder conditions to be affected. Clinical symptoms of heightened sensitization in impingement syndrome include referred pain down the forearm, neuropathic pain, dynamic tactile allodynia, hyperalgesia and paranesthesia (Gwilym et al., 2011, Woolf, 2011, Sanchis et al., 2015).

2.5.2 The Gate Control Theory and pain

In 1965, Melzack and Wall proposed the gate control theory to explain the effects of pain on the central nervous system. The authors stated that the substantia gelatinosa, found in the grey area of the spinal cord (Kleiner, 2011), worked as a system to control incoming painful afferents before they affect the central transmission cells found in the dorsal horn. The incoming patterns received by the dorsal horn trigger selective processes of the brain that control the properties of the gate control system. Neural mechanisms are activated following this process by the central transmission cells, which results in a bodily response to pain perception (Melzack and Wall, 1965). The purpose of this pain theory was to explain the mechanism involved in controlling painful stimuli received from nociceptors fibers along the cutaneous sensory pathways of the body (Mendell, 2014).

If there is an increase in the central transmission cells in response to a painful stimulus, the pain threshold decreases in the affected patient, resulting in increased sensitivity to pain. Therefore, a heightened sensitivity to pain implies that the “gate” is open resulting in the increased stimulation of A-delta and C fibers, whereas a reduction of pain experienced indicates that the “gate” is closed to sensory input from painful stimulus (Moayedi and Davis, 2013). A-delta fibers are the first responders to immediate injury to the body whilst C fibers respond to chronic pain stimuli (Deardoff, 2017).

The theory further suggests that a painful sensation perceived by the body as a result of injury can be overridden when there is an addition of a non-painful stimulus to the body. The non-painful stimulus activates the A-beta fibers which forces the nerve “gate” of the central nervous system to close to the sensation of pain, preventing the brain from recognizing the presence of pain within the body (Melzack and Wall, 1965).

2.6 Pathologies related to the shoulder

Shoulder pain varies in presentation and etiology, based on anatomical structure, degeneration or possibly repetitive microtrauma (Garving et al., 2017) (see Section 2.2.2 and 2.3). Shoulder conditions can be classified according to their respective etiologies (see Figure 2.3). Classifications of these groups range from traumatic, which includes micro and macro trauma, shoulder pain secondary to disease, to non-specific causes of shoulder pain. Each type of shoulder pain requires differing approaches to treatment, with varied healing time periods.

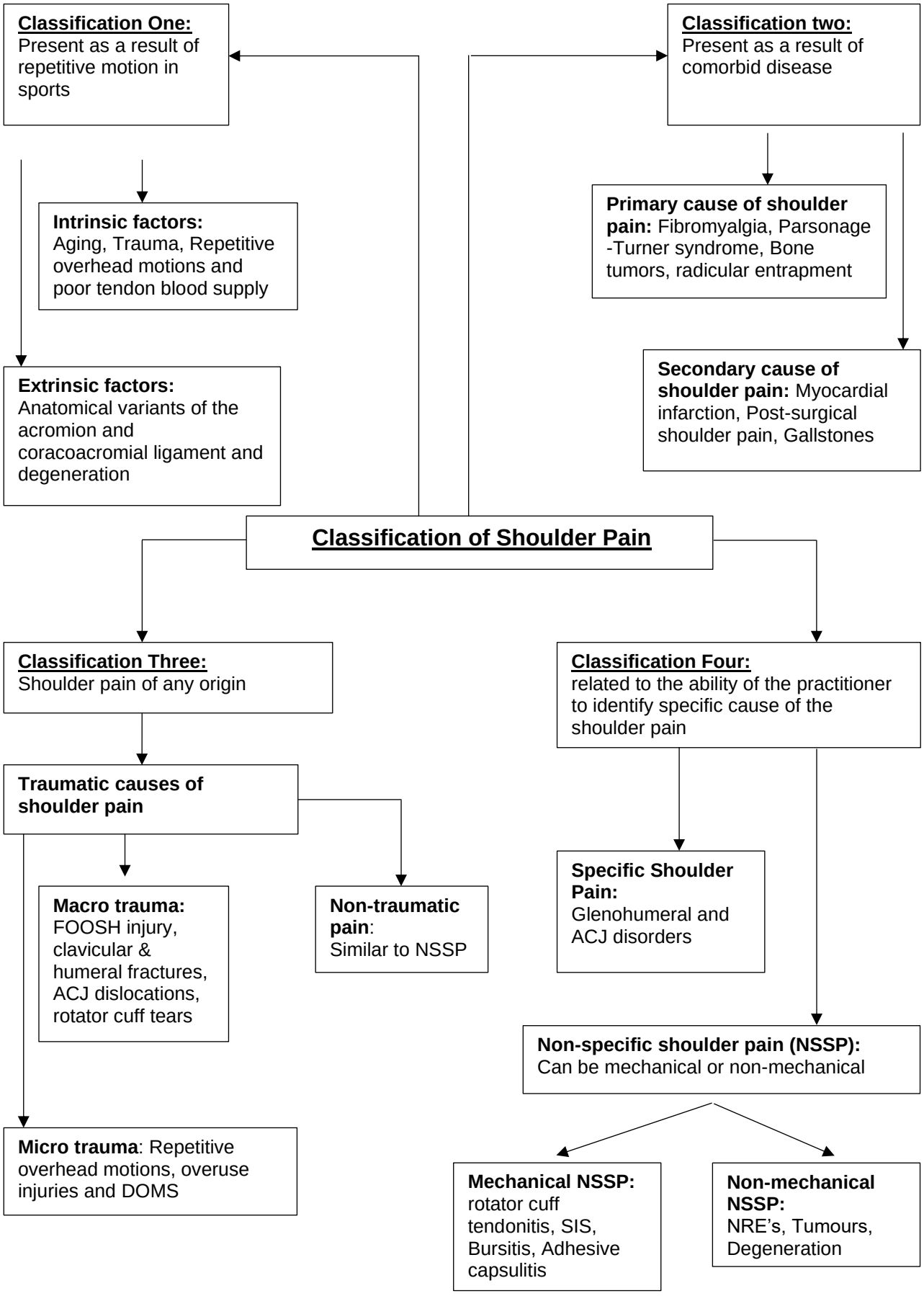


Figure 2.3: Classification of shoulder pain

2.6.1 Traumatic shoulder pain

Traumatic shoulder pain can be divided into two categories: micro-trauma and macro-trauma. Macro-trauma is large scale trauma to the shoulder as a result of high impact collision with a hard surface, as in the case of falling on an outstretched hand (FOOSH) injury resulting in an anterior dislocation of the shoulder or having a large force placed on the GHJ, which may lead to rotator cuff injury that could result in impingement due to decreased motion (see Section 2.3.1.2). Most traumatic anterior dislocations (85-98%) are present in people between the ages of 10 and 20 years (Sheehan et al., 2013). Other common conditions related to trauma include fractures of the clavicle and proximal humerus, acromioclavicular joint injuries and rotator cuff tears (Monica et al., 2016).

Micro-trauma related to the shoulder occurs as a result of overuse of the joint, and the injury therefore occurs over a period of time and is not immediately noticed. Repetitive injuries commonly occur in sporting professions such as volleyball and swimming, with swimming having a prevalence of 80% in competitive swimmers (Bansal et al., 2007), as sports that require repetitive motions at the joint result in microtrauma to the tendons, muscles and ligaments (Mattava, 2019). Another common cause of micro-injury to tissues in athletes and the general public alike, is the presence of delayed onset muscle soreness (DOMS). DOMS is commonly recognized as a type 1 muscle strain, which can range from mild symptoms of muscle pain inclusive of tenderness and pain on palpation to debilitating pain (Cheung et al., 2003). The effect of DOMS due to micro-trauma can spread from the muscle to the connective tissues and can lead to impaired kinematics of the affected joint (see Section 2.3.1.2) (Sonkodi et al., 2020).

2.6.2 Shoulder pain secondary to disease

Many underlying diseases result in the presentation of shoulder pain. Parsonage-Turner syndrome, which is a rare form of brachial plexopathy of idiopathic origin that results in an insidious and acute onset of unilateral shoulder pain with associated neurological abnormalities. It is present in males more than females and affects patients between the ages of 3 months and 75 years (Feinberg and Radecki, 2010). Fibromyalgia, which is often identified as a wide-spread appearance of pain, is diagnosed with an onset of pain four months or longer with associated muscle tenderness and palpatory pain. Fibromyalgia often presents bilaterally and can often begin in the shoulder and the low back, with a high

female to male ratio, affecting approximately 10-11% of the general population (Macfarlane, 1999).

Post-surgical shoulder pain can occur as a result of gynecological laparoscopy as the procedure is known to often irritate the phrenic nerve (Kojima et al., 2004). Mastectomy surgeries in breast cancer patients is a common cause of shoulder pain. This is due to the altered scapula kinematics often seen post-surgery, which results in a diminished range of motion and a heightened sensitivity to pain. Post-surgical mastectomy patients may experience shoulder pain for up to six years post-surgery, with an average of 22-56% of patients complaining of shoulder pain and limited range of motion (Shamley et al., 2012). Laparoscopic cholecystectomy due to the presence of gallstones can also result in the presence of post-surgical shoulder tip pain, however the visceral referred pain prior to surgery has a higher prevalence than post-surgical pain (Dey and Malik, 2015).

Regarding peripheral neuropathies as a cause of shoulder pain, the etiology of such pain can range from infectious and malignant, to traumatic and surgical. The most common cause of peripheral neuropathies in the shoulder is radicular entrapment, which can result in pain, weakness, loss of function and atrophy in the shoulder and corresponding muscles of the arms that is supplemented by the entrapped nerve (Madani and Creteur, 2017).

Due to the underlying pathological causes of shoulder pain in these cases, the understanding of TENS as a source of pain relief for SIS secondary to disease has been excluded from this study (see Chapter three, section 3.3.5). This is due to the fact that the effectiveness of TENS may be limited in such cases, making SIS appear to be recalcitrant to treatment.

2.6.3 Non-specific shoulder pain

Non-specific shoulder pain (NSSP) affects at least 12% of the general population (Miranda et al., 2005) and can be described as pain occurring in the shoulder, that is continuous and debilitating with resultant financial strain on the patient (Peek et al., 2015). It often does not have an easily identifiable cause, with patients complaining of prolonged pain for over a year in duration. When a shoulder complaint has no identifiable physical symptoms and signs or pathology it is therefore termed “Nonspecific shoulder pain” (van den Dolder et al., 2015). Common NSSP conditions include rotator cuff disorders such as tendinitis / tendinosis, shoulder impingement, bursitis and adhesive capsulitis (Mitchell et al., 2005,

Factor and Dale, 2014). These conditions tend to have common overlapping symptoms; however, the etiologies vary per condition.

Due to the prevalence of SIS, which is classified as mechanical NSSP in the general population (see Figure 2.3), and the variance in etiology leading to SIS symptoms, this section is focused on the conditions that are found to be common differentials for SIS. Many of these conditions often overlap or occur as a result of SIS, and therefore adequate physical and radiological assessments may be required in order to differentiate between these conditions (Katsuura et al., 2020).

2.6.3.1 Rotator cuff tendinopathy

A rotator cuff tendinopathy is often associated with a reduction in shoulder elevation and external rotation with accompanying pain and weakness (Lewis et al., 2015). The associated etiology of this condition has been identified as multifactorial in presentation (Seitz et al., 2011). Seitz et al., (2011) attributed the cause of rotator cuff tendinopathy to either intrinsic or extrinsic factors (see Figure 2.3). The prevalence of this condition ranges between 0.5% and 7.4% each year (Littlewood et al., 2013).

Intrinsic factors resulted in tendon degradation due to overload as a result of biological alterations, the blood supply, anatomical structure and mechanistic properties. Extrinsic factors included any cause for infraction onto the subacromial space that would result in impingement of the rotator cuff tendons, such as anatomical variations (see Section 2.3) in surrounding structures of the shoulder girdle complex, variations and alterations in shoulder kinematics, muscle and postural imbalances and limited extension of the posterior aspect of the shoulder. (Roy et al., 2018, Seitz et al., 2011).

2.6.3.2 Subacromial-subdeltoid (SASD) bursitis

A bursa can be described as a sac in the body that is filled with fluid. The fluid in this sac is present in order to prevent friction between joints (Faruqi and Rizvi, 2019). Bursitis is the inflammation of bursa. The SASD bursa is located between the tendons of the rotator cuff and the inferior surface of the acromion, deep to the deltoid muscle and the acromioclavicular joint (Hirji et al., 2011). SASD is prevalent in 70% of patients suffering with osteoarthritis and 90% patients diagnosed with rheumatoid arthritis (Draghi et al., 2015).

Symptoms of bursitis include redness, swelling and pain at the top of the shoulder region as well as at the tip of the shoulder with associated limited range of motion (Faruqi and Rizvi, 2019). Factors such as trauma to the shoulder, degeneration, repetitive stress applied to the shoulder, age, poor posture and infection caused by bacteria, all contribute to the onset of subacromial bursitis and its associated symptoms. Medical imagining such as x-ray, ultrasound and MRI are often used to diagnose this condition (Ma, 2019).

2.6.3.3 Adhesive Capsulitis

Adhesive capsulitis, commonly referred to as frozen shoulder, accounts for 2-5% of the general population's cause of shoulder pain, with an increased risk in people with comorbidities such as diabetes and thyroid disease (Kelley et al., 2009). Adhesive capsulitis is often described as presenting with sudden onset shoulder pain and stiffness, with a noticeable reduction in shoulder range of motion, specifically in external rotation. The condition goes through three phases (painful freezing phase; adhesive phase and resolution phase) and terminates after an average of 30 months after onset (Dias et al., 2005). The precise etiology of this shoulder condition is unknown (Dias et al., 2005, Mezian and Chang, 2019). Adhesive capsulitis is often diagnosed by method of elimination when imaging procedures are used. A medical history and physical examination are required in order for the healthcare professional to be able to make an informed diagnosis (Mezian and Chang, 2019).

The above are differential diagnoses for SIS, which is described in the Section 2.7

2.7 Shoulder impingement

Shoulder impingement syndrome is a clinical syndrome that results in a chronic presentation of shoulder pain, that occurs as a result of soft tissue structures being trapped at the anterior and inferior surface of the ventral third portion of the acromion (Garving et al., 2017, Neer, 1982) as well as due to abnormal biomechanics and anatomical variations (Escamilla et al., 2014). Since SIS is the focus of this research, it will be explained in greater detail below.

2.7.1 Shoulder impingement syndrome as a result of mechanical dysfunction

In the general population, between 44% to 65% of people are diagnosed with SIS (Page, 2011, Creech and Silver, 2020) affecting females and the elderly in large numbers (Michener et al., 2009). Majority of these affected patients are over the age of 40, and have an initial complaint of sudden onset of shoulder pain without a history of macro-trauma (Creech and Silver, 2020, Garving et al., 2017). Nevertheless, SIS is one of the most overlooked shoulder disorders that can result in biomechanical dysfunction in the upper extremity (Ucurum et al., 2018, Haik et al., 2016, Steuri et al., 2016). The diagnosis of shoulder impingement syndrome is a generic term that accounts for injury to structures within the sub-acromial space (Steuri et al., 2016, Koester et al., 2005) and is mostly characterized by progressive loss of range of motion, shoulder pain and disability.

The condition is characterised by the following classification, which is associated with the pathogenesis of the condition.

2.7.2 Neer’s stages of impingement

In 1982, Neer proposed the idea that there are three stages of progression regarding impingement lesions. He stated that in the first stage, excessive overhead activity can result in edema and haemorrhage, appearing in patients below the age of 25 years.

In the second stage, chronic oedema and haemorrhage from repetitive overhead tasks can lead to mechanical dysfunction in the shoulder, which would result in fibrosis and tendonitis. The target age group for this stage was identified to be between the age of 25 and 40 years old. Patients only appear to be symptomatic when there have been excessive overhead motions, leading to a reduction in shoulder functionality.

The third and final stage of shoulder impingement involves the presence of rotator cuff tears and structural bony changes. This is due to continuous wear and tear of the acromioclavicular joint. The affected population are people over the age of 40 years old (Neer, 1982).

2.7.3 Types of impingement

Besides the stages outlined by Neer (1982), shoulder impingement can be further classified according to its cause. There are multiple causes of shoulder pain based on structural changes and repetitive motions (Lazaro, 2005). The most common types of shoulder impingement syndromes include the following (based on the findings by Lazaro, 2005 and Garving et al., 2017):

- Subacromial impingement syndrome
- Subcoracoid impingement syndrome
- Posterior-superior glenoid rim impingement syndrome
- Anterior superior inner impingement

2.7.3.1 Subacromial impingement syndrome (SAIS)

This impingement syndrome affects structures found within the subacromial space. Narrowing of the subacromial space occurs as a result of two different factors; intrinsic and extrinsic causes (Michener et al., 2003). Intrinsic causes of SAIS are related to degenerative changes in the structure of the shoulder due to age or repetitive injury which affect the tendons, resulting in damage and functional impairments (Khan et al., 2013, Michener et al., 2003). Extrinsic causes of SAIS occur as a result of anatomical changes such as os acromiale, shape of the acromion, ossification related changes in the CCL and osteophytic changes in the ACJ (Lazaro, 2005, Michener et al., 2003).

Primary SAIS occurs as a result of bony abnormalities that result in structural changes causing an encroachment on the subacromial space, while secondary SAIS occurs as a result of muscular imbalances and structural abnormalities leading to the malposition of the humeral head (Lazaro, 2005).

2.7.3.2 Posterior glenoid rim impingement

Posterior glenoid rim impingement occurs often in athletes who consistently engage in overhead motions. The compression of the rotator cuff tendons (specifically supraspinatus and infraspinatus tendons) occur as a result of the greater tuberosity of the humeral head rotating posteriorly towards the posterior-superior aspect of labrum of the glenoid (Manske et al., 2013, Lazaro, 2005). This type of impingement occurs when the shoulder is elevated, extended and abducted. Possible causes of this impingement are scapular dyskinesis, posterior capsule contracture and general shoulder instability due to repetitive overhead motions (Khan et al., 2013).

2.7.3.3 Subcoracoid impingement

This type of impingement occurs due to narrowing of the subcoracoid space. This may occur as a result of compression of the tendon of the supraspinatus muscle from elevation of the humerus posteriorly with added internal rotation of the shoulder (Lazaro, 2005). Common causes for this type of impingement are a shortened coracohumeral distance, the possible involvement of the subscapularis tendon in the event of it being ossified or calcified, hypertrophy of the subscapularis muscle, humeral and scapula fractures, displaced humeral head and SCJ dislocations (Osti et al., 2013).

2.7.3.4 Suprascapular nerve impingement

Impingement that occurs as a result of injury to the suprascapular nerve. Possible injury to the nerve includes pathologies affecting the spinoglenoid ligament such as calcification and hypertrophy, as well as structural changes to the nerve regarding the direction of angulation. This type of impingement is known to affect volleyball players who engage in forceful and excessive repetitive motions (Lazaro, 2005).

2.7.4 Additional signs and symptoms related to SIS

Signs and symptoms associated with SIS may vary per individual. This is partially due to the stage, varied presentation and multi-factorial etiologies associated with SIS. Impingement is hall marked by pain that is present upon movement of the shoulder in an arc of elevation and abduction in all stages of impingement, with the pain steadily worsening over time. The pain is further exacerbated at night, when sleeping on the affected arm or resting the affected arm in an overhead position (Koester et al., 2005).

SIS related pain presents along the ventral aspect of the outer acromion. The pain from this syndrome refers down the humerus, along the long head of the biceps muscle. Other associated signs and symptoms include night pain when pressure is applied to the affected shoulder or when sleeping with a raised arm. Overhead activities that occur as part of activities of daily living may be inhibited due to pain and reduced muscle strength in the affected arm (Koester et al., 2005).

According to the stages of Neer's impingement theory (Neer, 1982), each stage varies in the presentation and cause of pain.

2.7.5 Diagnosing shoulder impingement syndrome

Shoulder conditions are most often diagnosed by means of a thorough medical history, physical assessment and orthopaedic examination of the affected part in order to reproduce the pain experienced by the patient.

A detailed history would include questions about the:

- Onset (usually after a period of a repetitive actions, occurring gradually, without the presence of a traumatic event(Creech and Silver, 2020). It may also occur as a result of low-grade chronic inflammation from continuous overhead activity).
- Character (varies per individual)
- Location of pain (SIS related pain presents along the ventral aspect of the outer acromion. Additional referral pain refers down the humerus, along the long head of the biceps muscle (Koester et al., 2005))
- Quality of pain (gradual onset of pain that gets worse over a period of weeks to months (Creech and Silver, 2020, Koester et al., 2005))
- Associated signs and symptoms (include night pain when pressure is applied to the affected shoulder or when sleeping with a raised arm (Koester et al., 2005); additionally, reduced muscle strength as a result of arthrogenic muscle inhibition is also possible (Koester et al., 2005)).

- Past traumatic injuries (fractures of the greater tuberosity, dislocation of the tendon of the long head of the biceps muscle, sports injuries, clavicular fractures (Pedowitz et al., 2008))
- Co-morbidities (such as smoking, diabetes and obesity (Titchener et al., 2014))

and

- Engagement in repetitive overhead activities (Overhead activities that occur as part of activities of daily living may be inhibited (Koester et al., 2005)).

Questions relating to aggravating and relieving factors pertaining to the current pain experience would be able to guide the clinician in a diagnosis of SIS as most often, the exacerbating factors include pain at night and upon added pressure on the shoulder (Creech and Silver, 2020).

The physical examination would include inspection, palpation, range of motion assessment in both active and passive motions and neurological assessment of the muscles regarding the strength and neurological function. Tests would be conducted bilaterally to be able to compare the function of both shoulders at baseline in order to determine what the rate of improvement is at post-treatment.

Inspection:

This would require the patient to be exposed from the waist to the neck. Inspection would include identifying structural abnormalities pertaining to the clavicle, glenohumeral joint and scapula, looking for bruising, inflammation, redness and atrophy on the affected shoulder and rotator cuff and other surrounding shoulder muscles (see Table 2.3 and 2.5) in comparison to the unaffected shoulder. Atrophy of the medial deltoid muscle has been a common finding amongst patients with SIS, as a result of limited shoulder motion and pain (Kronberg et al., 1997, Page, 2011). Identification of scars from recent or previous trauma should also be noted, with attention to the clavicle and GHJ in order to identify any previous clavicular fractures or GHJ dislocations that may affect the symmetry and kinematics of the shoulder girdle (Kooienga and Rasmor, 2016, Woodward and Best, 2000).

Palpation:

Palpation techniques should be applied when assessing the bony structures related to the shoulder like the clavicle, acromion, greater tuberosity of the humerus, GHJ, ACJ, scapula and coracoid. This is to assess for pain and swelling along the osseous structures of the shoulder girdle, along with identifying possible displacement of such structures that may possibly lead to impingement (e.g., superior translation of humeral head in the glenoid cavity (Umer et al., 2012, Kooienga and Rasmor, 2016). Palpation of the muscles and tendons of the shoulder, such as the rotator cuff, long head of biceps and its associated tendon, deltoid and lower trapezius (see Table 2.4) can help to identify shortening and tightening of the muscles leading to scapula-thoracic imbalances, that that may contribute to the migration of the glenohumeral head superiorly, resulting in the development of SIS through postural imbalances (Page, 2011).

Range of motion:

This assessment would include all movements of the glenohumeral and acromioclavicular joints, with particular focus on external rotation and abduction, as these motions present with weakness in impingement syndrome. Forward flexion of the shoulder is assessed for signs of scapular dyskinesis (Creech and Silver, 2020). The presence of instability of the GHJ during shoulder elevation may indicate weakness of the infraspinatus muscle, resulting in a decrease in compressive strength from the rotator cuff in order to maintain dynamic stabilization of the humeral head within the glenoid cavity (Page, 2011).

The physical examination is also refined with the application of orthopaedic test – which include:

2.7.5.1 Orthopedic assessment for SIS

Special tests or orthopedic examinations provide further specificity as regarding the diagnostic aspect of SIS. The use of special tests allows the clinician to isolate the anatomical structure responsible for the cause of the pain and helps to provide conclusive evidence as to whether the cause of SIS is pathological, dysfunctional or due to instability (Michener et al., 2009, Biederwolf, 2013).

There are five special tests that have been determined to provide fair to excellent specificity in identifying and diagnosing SIS (Michener et al., 2009). These are: Hawkins-

Kennedy test, Neer impingement test, Jobe test (empty can test), external rotation resistance test and arc of painful motion (Creech and Silver, 2020).

- Hawkins-Kennedy Test:

The Hawkins-Kennedy test involves forceful passive forward flexion of the shoulder to 90 degrees with accompanying forced internal rotation. The forceful forward flexion jams the greater tuberosity against the anterior and inferior aspect of the acromion, which would result in a pain response (Hawkins and Kennedy, 1980). A positive test result would indicate a supraspinatus tendon impingement or rotator cuff pathology. Multiple tests propose that the Hawkins-Kennedy test does not provide a high level of specificity in the diagnosis of shoulder impingement syndrome when used in isolation (Hegedus et al., 2008, Michener et al., 2009). The sensitivity of the Hawkins-Kennedy test has been identified as 79%, with the statistical specificity being 59% (Phillips, 2014, Hegedus, 2012).

- Neer Impingement Test:

The Neer impingement test involves forceful passive forward flexion of the arm while it is internally rotated, while the clinician prevents the scapula from elevating. A positive test would present with pain on the anterior shoulder (Vind et al., 2011, Woodward and Best, 2000). The Neer test has been investigated and identified as a clinical test with low reliability for the detection of SIS (Ferenczi et al., 2017, Michener et al., 2009). The specificity of the Neer test has been calculated to be 72%, with a sensitivity of 60% (Phillips, 2014, Hegedus, 2012).

- Jobe Test (Empty can test)

The Jobe test is also known as the empty can test and is conducted with the patient's arm at 90 degrees abduction, moved into internal rotation with the thumbs facing inferiorly, and the arm pushed anteriorly to 30 degrees forward flexion (Lasbleiz et al., 2014). The clinician adds a downward pressure to the arm with the patient resisting the movement. A positive result for this test would be pain on resistance with associated weakness of the affected arm (Keener and Levine, 2020). The Jobe test is one of three tests to provide high specificity (90%) (Phillips, 2014) in identifying and diagnosing impingement syndrome in affected patients when used both collectively with other tests or as an individual test. The other tests include the EERT, and the painful arc test (Michener et al., 2009, Vind et al., 2011).

- External Rotation Resistance Test (EERT)

The EERT is conducted by having the patient's elbow flexed to 90 degrees and adducted with no rotation of the arm. A force is applied to the arm that is directed medially towards the trunk, while the patient resists the applied force. A positive test would indicate pain and weakness, especially of the infraspinatus muscle, implying the presence of subacromial impingement (Flynn et al., 2008). There was high specificity for ERRT in detecting a shoulder impingement and therefore it is considered to be one of the most reliable tests used for SIS, when used alone or collectively with the Jobe test and painful arc test (Michener et al., 2009).

- Painful Arc Test

The painful arc assessment is conducted by having the patient actively abduct their shoulder and asking them to report any pain they experience upon movement. A positive result would be present when the pain experienced was between 70 and 120 degrees of abduction movement (Creech and Silver, 2020, Michener et al., 2009). This test is considered to have a high level of specificity at 76% and reliability, with a sensitivity of 53% when used to diagnose SIS (Michener et al., 2009, Hegedus, 2012).

Michener et al., (2009) proposed that diagnosis of SIS required a positive result from three out of the five allocated special tests where used to test for SIS. Due to the varied views on the effectiveness of the Hawkins-Kennedy and Neer impingement test, if the ERRT, painful arc test and the Jobe test combined provide positive results, it would provide enough physical evidence to substantiate the diagnosis of SIS in a painful shoulder (Michener et al., 2009). In contrast, Vind et al., (2011) proposed that the Neer impingement test provides the highest specificity for diagnosis of SIS.

A systematic review by Hegedus et al. (2008) stated that the empty can test provided the highest level of accuracy due to its specificity in the diagnosis of SIS, and this therefore leads to the conclusion that the tests should be collectively conducted in order to provide the highest level of specificity in the diagnosis of SIS. In contrast however, Hegedus (2012) stated that when used in conjunction, all shoulder pain examination tests provide greater accuracy. This though, is still limited and suggested that the history and physical examination play vital roles in the diagnosis of shoulder pain, and in this case, SIS.

The use of these tests in conjunction with the history and a thorough physical examination of the patient's shoulders would provide enough information to lead the clinician towards the diagnosis of SIS. An appropriate treatment approach is important in order to treat the signs and symptoms associated with SIS.

2.7.6 Treatment and management of SIS

According to the three different stages of impingement by Neer, each lesion requires a different approach to pain management. The more acute the impingement lesion, the less invasive the required treatment approach. The acute stages of impingement require conservative treatment and management, while the more severe cases of SIS present as challenging and may require surgery (Neer, 1982). However, the literature is contradictory regarding the precise appropriate treatment for SIS.

2.7.6.1 Invasive methods of treatment

Although surgical interventions are an available option for the treatment of SIS, a systematic review and meta-analysis on surgery for shoulder impingement syndrome stated that long-term effectiveness of surgical procedures were not sustained since there was not a significant reduction in pain and functional outcomes. The study included thirteen RCT's, which collectively pooled a total of 1062 patients who were included in the review (Khan et al., 2019).

Another systematic review looked at the effectiveness of surgical and post-surgical interventions for the treatment of SIS and found that there was a moderate to low quality of evidence to support the use of surgical interventions as a treatment for pain related to SIS. They further concluded that surgical interventions were not superior to conservative therapy in pain management and no singular surgical intervention was superior to another. They recommended the use of conservative treatment as the preferred method of treatment for SIS, and ASD as a possible choice for surgery as it is minimally invasive (Gebremariam et al., 2011).

Another systematic review and meta-analysis by Nazari et al., (2019) supported the use of physiotherapy and exercise as a first-line treatment for SIS, as they concluded that surgery with the addition of physiotherapy yielded no substantial benefits in comparison to the use of physiotherapy and exercise therapy alone.

Apart from the expensive nature of surgical interventions for SIS (Dorrestijn et al., 2009), the procedure alone can often result in complications and functional impairments. Limitations in movement may occur as a result of an ASD or an open arthroscopic acromioplasty. This can occur as a result of damage to the deltoid muscle, where the damage is irreversible, leading to imbalances in the rotator cuff causing abnormalities in humeral head position (Seltzer et al., 1994). Post-operative shoulder stiffness has been noted in 2.8% to 15% of patients (Dhillon, 2019).

Further complications include high rate of post-operative infections. Depending on the depth of the infection, extreme and deep infections can result in damage to the deltoid muscle after an acromioplasty, which can prevent the deltoid from correctly attaching to the acromion (Seltzer et al., 1994, Dhillon, 2019).

Acromion fractures are also known to be prevalent after an acromioplasty, in which there is no union between the acromion ossification centres, leaving the bone susceptible to stress fractures and displacement (Mayne et al., 2016). Other complications include biceps tendon ruptures, pulmonary embolisms and haematomas and avascular necrosis of the humeral head (Seltzer et al., 1994, Dhillon, 2019).

2.7.6.2 Non-invasive methods of treatment

Since the use of conservative therapies have been advised as first line treatment of SIS, irrespective of the stage of impingement, various therapeutic methods have been applied both in practice and at home, which can often be expensive and ineffective.

Home pain management can include the use of exercise therapy and taping techniques which was supported as a treatment method by Steuri et al., (2017). Treatment methods that are specific to patients seeing clinicians in a medical practice include the use of modalities such as ultrasound and low-level laser therapy (LLLT) which are both expensive modalities that cannot be used as a form of home pain management.

According to Neer (1982), the first and second stages of impingement (see Section 2.6.2) require conservative therapy in order to manage the associated pain. Consigliere et al., (2018) stated that conservative therapy such as ultrasound, injections into the subacromial space and exercise therapy, used for a duration of three to six months should provide pain relief and relative positive outcomes. The third stage of Neer’s impingement describes

anatomical deformities/abnormalities that may require surgical interventions, in which Neer recommended the use of acromioplasty and ASD (Neer, 1972, Neer, 1982).

Steuri et al. (2017) stated that conservative interventions that include the use of exercise therapy should be included in the treatment protocol with the accompaniment of electro-modalities such as extra-corporeal shockwave therapy and low-level laser therapy (LLLT) and taping techniques for the shoulder (Steuri et al., 2017). Haik et al., (2016) supported the use of exercise therapy with accompanying mobilization of the shoulder in order to improve pain and range of motion in patients diagnosed with SIS but the study rejected the use of low-level laser, taping or pulsed electromagnetic field (PEMF) treatment modalities to reduce pain (Haik et al., 2016, Dong et al., 2015).

The use of electro-modalities as an adjunct therapy in the management of SIS has been studied. Hawk et al. (2017) stated that there was moderate evidence to support the use of low-level laser and PEMF in managing pain related to SIS. Evidence for studies pertaining to TENS, extracorporeal shockwave therapy and microcurrent stimulation was inconclusive as a limited number of high-quality RCT studies have been done to assess the effectiveness of these modalities (Hawk et al., 2017).

However, the use of TENS has been advocated in multiple conditions due to its inexpensive nature and ease of use (Bjordal et al., 2003, Robinson, 1996). It is also a non-invasive method of treatment that does not contribute to high medical expenses, unlike the surgical interventions mentioned in Section 2.7.6.1. Also, its method of use can be explained to patients as a form of home therapy unlike ultrasound and LLLT (Searle et al., 2009). TENS also has little to no chance of contributing to overdose and toxicity and is available without the need for a medical prescription, further contributing to the reduction of medical expenses that is usually associated with pain (Johnson and Jones, 2017). This study aimed to collate the data available in order to provide a greater understanding of the effects of TENS in treating SIS in order to eliminate the lack of informed understanding among the general population regarding TENS and SIS.

2.8 Transcutaneous electrical nerve stimulation

TENS is a form of electrostimulation that follows the principles of the pain control theory proposed by Melzack and Wall (Melzack and Wall., 1965) in which the stimulation of the skin results in nerve impulses being transmitted to the spinal cord allowing for electroanalgesia to occur, at various frequencies. Micro-impulses are carried through the skin towards the affected area in order to stimulate the mechanoreceptive A-beta fibers to reduce pain (NHS, 2018). The effect of TENS has been likened to the stimulation of non-nociceptive fibres by actively rubbing one own's skin (Johnson, 2014).

The TENS device is a battery-operated unit that has ports to connect between 2 and 4 electrodes which are conducting pads that provide electrical impulses through intact skin (Wheeler, 2017, Johnson, 2014). TENS is a non-invasive device that has been used to treat and manage pain that is both acute and chronic in nature. The TENS device has three different modes of settings, normal, modulate and burst, to accommodate the different nociceptive levels regarding pain by varying the frequencies associated with the duration of pain presented by a patient. However, there is minimal evidence to state that a variation in frequency is superior to that of a constant frequency when treating pain using the TENS device.

Chen and Johnson (2009) stated that frequency modulated TENS has shown to increase the pain threshold experienced by a patient as compared to a constant frequency, and therefore concluded that a high TENS frequency will result in a greater reduction of pain in patients.

2.8.1 Mechanism of TENS

TENS uses a non-invasive method of electrical stimulation by sending impulses through intact skin in order to interfere with the pain signals sent from nociceptors to the brain in order to provide an analgesic effect (Johnson, 2007). Healthcare professionals as well as the general public can buy and use this device in a healthcare setting or at home, with little to no difficulty due to it being inexpensive, widely available and easy to use (Searle et al., 2009). This reduces the need for pharmacological drugs that could result in drug interactions in the elderly and opioid dependence in the younger generation (Johnson, 2007). TENS does not have any recognized drug interaction capabilities, and is therefore

safe to use on patients with pharmacological management of pain and other comorbidities that require medication (Tashani and Johnson, 2009).

TENS devices can be set at either high frequency (HF) or low frequency (LF), depending on the condition being treated. High frequency TENS operates with a frequency of 50 or more Hertz with a maximally high intensity in order to provide motor contractions whilst simultaneously providing an analgesic effect (Sluka and Walsh, 2003). The effect of HF TENS occurs by activating a mechanism in the central nervous system that inhibits internal response to pain. A reduction in central sensitization results in a decrease in the development of chronic pain, along with a reduction in substance P and glutamate, which decreases the possibility of acquiring chronic pain syndrome and reducing opioid dependence after surgical procedures. The use of “conventional TENS” combines HF TENS with a low intensity level to provide pain relief (DeSantana et al., 2008b).

Low frequency TENS has a frequency of less than 10 Hertz and provides an analgesic effect by activating GABA, opioid, serotonin and muscarinic receptors. When there is a high concentration of opioids in a patient’s system, LF TENS is rendered ineffective as interferes with the neuronal pathway of the periaqueductal gray (PAG), the rostral ventromedial medulla (RVM) and the spinal cord (DeSantana et al., 2008b, Vance et al., 2014a). LF TENS is often found to be used in conjunction with a high intensity in order to provide a strong motor contraction, which simultaneously stimulates the opioid receptors in the spinal cord, which provides an analgesic effect (Sluka and Walsh, 2003, DeSantana et al., 2008b). This type of TENS is known as “acupuncture-like TENS”. In a general setting, conventional TENS is the preferred method of treatment, with acupuncture-like TENS only being used when conventional TENS fails in providing effective relief (Johnson, 2014).

An understanding pertaining to the varied frequency settings on a TENS device is required in order to correctly treat a condition. A common problem found among many publications assessing the use of TENS, is that the objective parameters of stimulation vary. These parameters of stimulation include the frequency, duration of the pulsed setting and the intensity of the device when applied. Another often overlooked parameter of measurement is the placement of electrodes in participants who are experiencing pain in the same area (Sluka and Walsh, 2003, Vance et al., 2014).

Systematic reviews show inconclusive evidence for the use of TENS due to the lack of homogeneity found among participants of included RCT’s, resulting in low-quality studies

(Sluka and Walsh, 2003). A critical review by Vance et al., (2014a) stated that due to a lack of high quality studies included in systematic reviews pertaining to the effectiveness of different types of TENS-related frequencies and intensities, it is hard to deduce whether TENS is effective, if at all, in treating a particular condition (Vance et al., 2014a). However, multiple studies have deduced that TENS operates at its highest level of efficacy when the intensity applied during treatment is at its maximum (Aarskog et al., 2007, Serrano-Muñoz et al., 2017, Sluka and Walsh, 2003).

2.8.2 TENS and analgesic tolerance

Studies using rats assessed the analgesic effect of high and low frequency TENS and the time it takes to create tolerance in the nervous system over a period of six days. The authors discovered that the effectiveness of both HF and LF TENS diminished over the six day period and therefore recommended that continuous use of TENS on a daily basis should be avoided (Chandran and Sluka, 2003).

Another study supported the findings of Chandran and Sluka, by investigating the analgesic tolerance of TENS in human subjects. The authors concluded that the effectiveness of TENS decreases after the fourth and fifth day of continuous use, as the modality overstimulates the opioid receptors that confers information to the PAG and RVM of the brain, which contain fewer opioid receptors as compared to the descending pathway of the central nervous system (Liebano et al., 2011). The daily frequency applied to the painful area can affect the rate of tolerance development, and therefore a study in arthritic rats showed that the application of a frequency which is modulated between HF and LF TENS can reduce the speed at which tolerance is developed (DeSantana et al., 2008a).

2.8.3 Electrode placements using TENS

A common issue of contention regarding the use of TENS and its effectiveness, is the placement of electrodes on the affected area. Some studies state that the placement of electrodes on acupuncture points provide an appropriate amount of pain relief in various types of conditions (AminiSaman et al., 2018, Ting et al., 2010, Ely, 2016). However, to establish the true effectiveness of TENS in the treatment of a specific condition, electrode placement needs to be uniform in order to produce results that are homogenous and of high quality.

The argument that Vance et al., (2014) made is that there is no specification in clinical studies regarding the manner in which the electrodes have been placed and whether there was consistency among all participants of the study (Vance et al., 2014). Studies have been identified in placing electrodes either at the injurious area, along the affected dermatome or proximal to the injury (Sluka and Walsh, 2003). Homogeneity among clinical studies assessing the same area would aid in identifying whether electrode placement plays an important role in the clinical effectiveness of TENS.

2.8.4 The Gate Control Theory and Transcutaneous Electrical Nerve Stimulation (TENS)

Melzack and Wall proposed the idea that in order to “close” the gate to stimulation of A-delta and C fibers that are responding to painful stimuli, the A-beta fibers need to be stimulated. Since the A-beta fibers have an activation threshold that is lower than that of the nociceptive fibers, the use of TENS would help to interfere with the pain signals by continuously stimulating the A-beta fibers of the painful area (Tashani and Johnson, 2009). This results in an analgesic effect of TENS, which surpasses the nociceptive threshold experienced by patients in response to pain.

A study by Melzack assessed the effects of TENS on the stimulation of painful trigger points in the body, which found that pain decreased substantially with long lasting effects, which indicates that the strength of TENS overrides the nociceptive response to painful stimuli in both chronic and acute conditions in order to provide non-invasive pain relief that lasts longer than the allocated treatment time (Melzack and Wall, 1982).

The application of TENS has an effect on pain control on both the central and peripheral nervous system. DeSantana et al., (2008) reported that TENS affects the muscarinic receptors, serotonin and opioid receptors in the central nervous system, while it peripherally stimulates the alpha-2 noradrenergic and opioid receptors in order to systematically reduce pain and improve function in the affected area.

2.8.5 The Clinical Effectiveness of TENS

TENS is universally known to be a non-pharmacological, analgesic modality that provides pain relief for a variety of conditions. It has been identified as providing significant pain relief for a period of between two and four weeks in patients experiencing chronic low back pain, when TENS was administered for a < five weeks (Jauregui et al., 2016). The clinical

effectiveness of TENS is highly dependent on the dosage regarding the intensity administered for each condition as mentioned in Section 2.8.1.

A low intensity provides little to no effect in pain management, regardless of the condition being treated. It is important to note that a high but comfortable intensity provides a greater amount of pain relief (Aarskog et al., 2007, Bjordal et al., 2003).

Other factors have a greater influence over the effectiveness of TENS in the management of most painful conditions (see Section 2.8) and these should be taken into consideration when administering a dosage of TENS.

2.8.6 Conditions treated by TENS

TENS has been known for treating a variety of conditions regarding pain, due to the non-invasive nature of this electrical modality. Many chronic and acute conditions treated with TENS have been researched in the past in order to verify its effectiveness. Acute conditions that can be treated with the use of TENS include: post-operative pain (Bjordal et al., 2003), pain related to dysmenorrhea (Parsa and Bashirian, 2013), acute low back pain, orofacial and dental pain (Johnson, 2007), and pain related to musculoskeletal dysfunction (Robinson, 1996).

Chronic pain conditions that are effectively managed with TENS include inflammatory conditions such as soft tissue dysfunction from rheumatoid arthritis, osteoarthritis, chronic low back pain, phantom limb and stump pain, post-herpetic and trigeminal neuralgia, complex regional pain syndromes, diabetic neuropathies, pain from nerve entrapments and chronic localised muscle aches (Johnson, 2007, Robinson, 1996, Johnson and Martinson, 2007).

Shoulder conditions have often been managed with the use of conservative therapeutic methods such as ultrasound, interferential current therapy, low-level laser and TENS. Depending on the condition pertaining to the shoulder, majority of the conditions have been successfully managed with the analgesic use of an electrical modality, however the evidence regarding the effectiveness of TENS in managing pain pertaining to non-specific shoulder conditions has been limited and inconclusive (Hawk et al., 2017, Desmeules et al., 2016).

The use of TENS has been identified in the treatment of various medical conditions. However, the data is limited on the effectiveness of TENS in the treatment of non-specific shoulder conditions (Hawk et al., 2017, Desmeules et al., 2016), with further limitations of studies assessing the effectiveness of TENS in the treatment and management of shoulder impingement syndrome.

Due to the expensive nature and side effects related to surgical interventions (see Section 2.7.6.1), there is a greater need for non-surgical interventions when managing SIS. Since Neer (1972) stated that the first two stages of impingement require conservative therapy, one should also consider the benefits of teaching patients about home therapy and the effectiveness of TENS as a modality to be used at home in managing SIS. Conservative therapy involves a multiplicity of methods of treatment such as taping, ultrasound, LLLT, TENS (see Section 2.7.6.2).

The benefits of using a non-invasive, inexpensive, non-pharmacological form of treatment such as TENS (Stehle et al., 2015, Johnson and Jones, 2017) is that it allows patients to comfortably treat their shoulder related pain from SIS in a space outside of a clinical medical practice, which would reduce cortisol dysfunction on the body. A reduction in cortisol will prevent perpetuation of inflammation and pain within the shoulder (see Section 2.5.1). This allows the shoulder and surrounding muscles to steadily respond to pain modalities such as TENS, thereby reducing the pain that the patient experiences from SIS.

Understanding the effects of TENS in relation to pain experienced from SIS, helps the healthcare provider, patient and policy maker make an evidenced based decision regarding the acceptance or rejection of the use of TENS in treating SIS. This would help the patient save money and the healthcare provider save time in terms of patient management when applying evidence-based practices (Hemingway and Brereton, 2009).

A summary of the most recent and relevant literature is required in order to inform the public and healthcare practitioners on successful management of SIS pain using TENS, since it is a common and easily accessible modality. There are several methods by which this can be achieved, which is discussed in the following section.

2.9 Literature syntheses to address clinical conditions and their treatment

There are different types of reviews conducted in the scientific community, namely a traditional/narrative review, a meta-analysis and a systematic review (University, 2020):

2.9.1 Literature review:

A literature review is a summary of literature published by various researchers and scholars pertaining to a specific topic of interest. (Taylor and Procter, 2011). The benefits of conducting a literature review include being able to use a variety of sources in the review, allows for transparency and reproducibility of the review and can be conducted when time is a limiting factor (Nakano and Muniz Jr, 2018, Auas.org.uy, 2017). The disadvantage of conducting a literature review is that it does not often allow for the inclusion of grey literature, resulting in publication and selection bias and the review lacks information pertaining to the criteria used to include and exclude sources, the appraisal of the literature and the process that led to the conclusion drawn in the review (Nakano and Muniz Jr, 2018, Auas.org.uy, 2017). A traditional review involves reviewing previously published studies and providing a comprehensive summary of the data. This traditional review provides a summary of each article being reviewed.

Limitations of this study include a lack of disclosure regarding the methodological process of the review, inclusive of the inclusion and exclusion criteria of the study, and this lack of information can reduce the quality of the review, resulting in it being of low-quality and irreproducible (Snyder, 2019). Another limitation of this type of review is that the rigour and validity of the review can be affected if the review does not include an adequate sample size of articles included in the study by either limiting the number of articles included or restricting the article years that would be included in the study (Snyder, 2019). There is also the possibility that there would be a high level of subjectivity included in the review, which can lead to the presence of bias in the study and further diminish the quality of the review (Cipriani and Geddes, 2003, Green et al., 2006).

2.9.2 Systematic review:

A systematic review is a precise and methodological process in which systematic and explicit methods are used to answer a clearly formulated research question (Moher et al. 2009). Multiple primary studies are synthesized by using study specific strategies that reduce risk of bias and random errors (Gopalakrishnan and Ganeshkumar, 2013). This process encompasses a rigorous literature search that includes both published and unpublished literature in order to identify articles that are relevant to the research question (Hemingway and Brereton., 2009). The articles are then critically evaluated in terms of extent, nature and quality of evidence in relation to the research question (Siddaway et al., 2019).

Critical appraisal of the relevant articles is conducted using scales specific to each study type (Liddle et al., 1996; Wells et al., 2003 and PEDro Scale., 1999) in order to accurately summarise the conclusive findings in each review. A well conducted systematic review provides reliable estimates regarding the efficacy of treatment interventions which result in conclusions that are defensible (Gopalkrishnan and Ganeshkumar., 2013).

The benefits of conducting a systematic review is that it follows a distinguished protocol, with clear set objectives and inclusion and exclusion criteria, along with a methodology that provides reasons as to how a conclusion was reached. It is also a comprehensive review that draws on all knowledge regarding a particular topic (Grant and Booth, 2009). This review promotes objectivity and transparency while limiting researcher bias in order to strongly defend the clinical intervention being studied (Mallet et al., 2012). The cons of doing a systematic review are dependent on the manner in which the study was conducted with regard to the types of studies that were included (selection bias), heterogeneity of the studies included and publication bias (Gopalakrishnan and Ganeshkumar, 2013).

Therefore, systematic reviews are usually the method of choice when reviewing large amounts of data as it provides a higher level of rigour and validity in comparison to the narrative reviews along with a well-defined study protocol with a limited possibility of bias (Pae, 2015).

2.9.3 Meta-Analysis:

A statistical, objective and scientific method of quantifying and synthesizing relevant evidence on various types of studies pertaining to a specific topic in order to derive conclusions related to the research question (Ahn and Kang, 2018 and Lee, 2018). The advantage of producing a meta-analysis is that it is able to quantify and consolidate complex pools of data in order to answer a research question (Higgins and Green, 2011) and to improve the strength in terms of the contribution from smaller or inconclusive studies (Ioannidis and Lau, 1999). A disadvantage of this study type is that is prone to bias that may lead to erroneous conclusions (Higgins and Green, 2011).

Given the descriptions above, a systematic review would be best suited to answer the research question of this study (see Chapter one section 1.2) as it has a detailed protocol (see Chapter three) explaining how the conclusion (see Chapter five, section 5.5) was reached, with little to no risk of erroneous conclusions that may often be associated with a meta-analysis due to the statistical pooling of large amounts of data that reduces the possibility of the presence of subjectivity often associated with literature reviews.

Systematic reviews provide an objective, unbiased and methodological approach to summarizing large amounts of data in order to provide an evidenced based conclusion pertaining to a particular intervention, such as TENS, in healthcare. The use of a transparent and rigorous approach to data analysis reduces the degree of bias that is often seen in narrative reviews, while simultaneously increasing the viability for future reproducibility (Mallet et al., 2012).

The summation of evidence provided by a systematic review provides a condensed, factual and consistent understanding of an intervention that both healthcare workers and members of the public can utilise with ease and efficiency, without the trouble of reading multiple articles with contradicting conclusions on the same topic (Hemingway and Brereton, 2009). This allows clinicians to keep abreast with improvements in healthcare interventions. The limited possibility of bias found in a systematic review results in reviews that dictate both the benefits and harms a possible intervention can cause during treatment (Liberati et al., 2009). This allows healthcare professionals to make evidence-based decisions on the best treatment methods for their patients (Gopalakrishnan and Ganeshkumar, 2013).

Systematic reviews have often been regarded as the initial point of commencement for the development of standard guidelines for clinical practice (Moher et al., 2009). The aggregation of evidence pertaining to the use of TENS as a treatment modality in the management of SIS in the form of a review would provide practitioners with an unbiased account of the modality's effectiveness, feasibility and appropriateness (Hemingway and Brereton, 2009). Therefore, a systematic review provides the reader and healthcare provider with the best available evidence (Gopalakrishnan and Ganeshkumar, 2013).

A systematic review of the literature regarding the use of TENS in the treatment of SIS would aid healthcare providers in establishing a treatment protocol that is both effective and evidence based. The current available literature regarding the use of TENS in treating non-specific shoulder conditions is limited, as stated in a systematic review by Hawk et al., (2017); the study further stated that the evidence available for the use of TENS regarding SIS was of low-quality and the results on its effectiveness was inconclusive (Hawk et al., 2017). Another systematic review study by Desmeules et al., (2016) concluded that the level of evidence available regarding the use of TENS in rotator cuff tendinopathy was limited, which further led to inconclusive results. There has been no systematic review that solely assessed the effect of TENS in in treating SIS and therefore, this review aimed to fill in the gap in the literature.

A systematic review addressing the use of TENS in the treatment of shoulder impingement syndrome would provide practitioners with a reference guide detailing whether the modality is cost-effective, clinically effective or harmful to patients (Hemingway and Brereton, 2009). A systematic review by Hawk et al., (2017) assessed the use of TENS as one of multiple modalities used in the treatment of shoulder impingement syndrome. The study found only one article of substantially good quality, comparing active TENS to sham TENS. The outcome for active TENS was favourable with a significant difference between the groups, however the overall evidence to encourage the use of TENS as a treatment for SIS was limited, and therefore the results were inconclusive (Hawk et al., 2017).

A common problem found in clinical trials is that the information provided to the readers regarding the stimulation parameters, electrode placement and intensity are often heterogenous or undisclosed. This diminishes the quality of the study and results in inconclusive evidence to motivate for the use of TENS as a form of adjunct therapy in the treatment of pain related to SIS (Sluka and Walsh, 2003, Vance et al., 2014). Therefore,

this systematic review aims at providing healthcare providers with an assessment of the available literature that is evidence-based, in order to aid the clinical decision-making process.

Due to the high regard of conservative treatment as the first line method of pain management for SIS (Nazari et al., 2019, Gebremariam et al., 2011, Khan et al., 2019), it is important to understand which modalities provide the highest level of pain relief, in order to prevent poor patient management and unnecessary expenditure for healthcare providers and patients alike (Hemingway and Brereton, 2009). There is a need for healthcare providers to provide patients with evidence-based proof that either supports or rejects the use of an intervention. TENS is a well-known treatment modality that is familiar to healthcare providers and the general population. However, informed consent on the use of such a modality regarding the stimulation parameters, intensity and electrode placement in treating pain related to SIS is important in order for patients and clinicians to appropriately apply the use of this type of electrical stimulation (Dagenais et al., 2012).

Therefore, a systematic review on this topic would ameliorate patient outcomes and provide a standard procedure for the application of TENS in the treatment of SIS.

This study is focused on systematically reviewing clinical studies related to the treatment of SIS with the use of TENS, therefore, an explanation of the systematic review process will be explained below.

2.10 Systematic reviews

Systematic reviews help to critically evaluate the literature in order to provide a summary of evidence that is both accurate and reliable (Liberati et al., 2009). The goal of providing a summary of evidence is to help clinicians judge risks, benefits and possible harms encountered to a patient as well as interventions when using a modality to treat a pathology; thus, providing a starting point for clinical evaluation and treatment (Liberati et al., 2009). A systematic review uses explicit and rigorous methodological evaluation of articles in order to critically appraise the available research (Moher et al., 2009).

2.10.1 Procedure for a systematic review

A systematic review requires a well-defined protocol in order to gather articles that is relevant to the topic of interest and the review process. It is important that this protocol is clearly outlined prior to the commencement of the review process, as this allows for a clear understanding among all members of the review team about the process of each step in the systematic review. This allows for a democratic contribution to the study as there is a focus on transparency, accountability, and integrity in the research process, as stated by Moher et al., (2015).

According to Hemingway and Brereton, there are five main steps to conducting a systematic review. These include defining a research question related to the healthcare topic of interest, searching databases for relevant data pertaining to the research question, assessing the data found in identified studies and finally collating the results in order to answer the research question and place the findings in context (Hemingway and Brereton, 2009).

The first step of the systematic review process is defining a relevant healthcare research question. This would require an a priori list of objectives that are well-defined, discussing the target populations, type of intervention and the types of studies that the authors wish to include in the review process in order to collect evidence to answer the research question. The application of the Cochrane acronym PICOC, which stands for population, intervention, comparison, outcomes and context would provide key details that should be considered prior to the commencement of a review (Uman, 2011). These factors would provide the basis for the inclusion criteria applied to the study in order to reach the

appropriate and clearly stated outcomes expected from the study (Hemingway and Brereton, 2009).

The second stage of a systematic review is a review of relevant literature. All forms of data, including published and non-published studies are sorted through and filtered for relevance pertaining to the research questions. All databases are searched for relevant key terms in order to prevent selection bias in the study. Grey literature is often searched for on all available platforms and the inclusion of non- English articles should be accepted, if the authors are able to correctly translate it. Nevertheless, during this process, there is a high possibility of selection bias, language bias and publication bias from occurring (Hemingway and Brereton, 2009, Higgins et al., 2019).

The third stage of conducting a systematic review involves assessing the studies that have been retrieved during the literature review process. This involves comparing the relevance and quality of the study against an established inclusion criterion. At this stage, abstracts are identified, read and are either included or excluded based on the assessment for methodological quality. This rigorous process continues until a final list of acceptable articles that are included in the study is put together. Studies that have been excluded are discussed in a study report, which results in a synthesis of the best available evidence. Articles that are found to be relevant are then reviewed by all included reviewers. The data from the articles are then tabulated, and each reviewer's feedback is recorded in the table. The review process should be conducted by two or more reviewers. This is necessary in order to reduce inclusion bias (Hemingway and Brereton, 2009, Liberati et al., 2009).

The penultimate stage of a systematic review is the aggregation of results. The results from the minimum of two reviewers are pooled together in order to provide evidence to answer the research question. The evidence extracted from the article reviews provide an indication as to whether a particular clinical intervention is effective, feasible, appropriate and meaningful regarding its contribution to healthcare. The aggregation of evidence at this stage is known as evidence synthesis (Hemingway and Brereton, 2009).

The final stage of a systematic review is providing context to the research findings. This would involve the discussion of results and the identification of any inconsistency regarding the results of the review. Placing the research findings into context allows the researcher to identify the presence of heterogeneity within the study and its findings, the impact of possible bias present and would provide a conclusive statement regarding the applicability

of results regarding the focus intervention. These factors would therefore enhance the methodological rigour of the study (Hemingway and Brereton, 2009, Higgins et al., 2019, Uman, 2011).

Systematic reviews provide an objective, unbiased and methodological approach to summarizing large amounts of data in order to provide an evidenced based conclusion pertaining to a particular intervention, such as TENS, in healthcare. The use of a transparent and rigorous approach to data analysis reduces the degree of bias that is often seen in narrative reviews, while simultaneously increasing the viability for future reproducibility (Mallet et al., 2012).

The summation of evidence provided by a systematic review provides a condensed, factual and consistent understanding of an intervention that both healthcare workers and members of the public can utilise with ease and efficiency, without the inconvenience of reading multiple articles with contradicting conclusions on the same topic (Hemingway and Brereton, 2009). This allows clinicians to keep abreast with improvements in healthcare interventions. The limited possibility of bias found in a systematic review results in reviews that dictate both the benefits and harms a possible intervention can cause during treatment (Liberati et al., 2009). This allows healthcare professionals to make evidence-based decisions on the best treatment methods for their patients (Gopalakrishnan and Ganeshkumar, 2013).

Systematic reviews have often been regarded as the initial point of commencement for the development of standard guidelines for clinical practice (Moher et al., 2009). The aggregation of evidence pertaining to the use of TENS as a treatment modality in the management of SIS in the form of a review would provide practitioners with an unbiased account of the modality's effectiveness, feasibility and appropriateness (Hemingway and Brereton, 2009). Therefore, a systematic review provides the reader and healthcare provider with the best available evidence (Gopalakrishnan and Ganeshkumar, 2013).

2.11 Tools utilised in systematic reviews

2.11.1 Systematic analysis of randomized controlled studies (RCT's)

It is common practice for authors of systematic reviews to include randomised controlled trials to prove whether an intervention is effective or not. The methodological quality of an

RCT study is assessed in order to determine the level of bias prevalent in the results of the study (Olivo et al., 2008). There have been many types of scales used within and outside the scope of healthcare interventions. The most recognised and commonly used scales for RCT evaluation include the Jadad scale, the Delphi List, the Pedro scale as well as Downs and Blacks (Maher et al., 2003, Olivo et al., 2008, Armijo-Olivo et al., 2015). The most commonly recognised scales for nRCTs are the Newcastle-Ottawa scale (Balk et al.), ROBINS-I, MINORS, and SIGN (Quigley et al., 2019).

Table 2.6: Table of scales assessing methodological quality of RCTs

Scale	Year	Published in peer-reviewed literature	Scoring system	Study Type	Reliability and Validity
Scales for randomised controlled trials					
Bizzini scale (Bizzini et al., 2003)	2003	Yes	Point system	RCTs	Good reliability and validity (Olivo et al., 2008)
Delphi List (Verhagen et al., 1998a)	1998	Yes	Yes/No	RCTs	Low reliability and validity (Lange et al., 2020, Olivo et al., 2008)
Downs and Blacks (Downs and Black, 1998)	1998	Yes	Point system	RCTs	Substantial to excellent reliability (O'Connor et al., 2015)
Jadad scale (Jadad et al., 1996)	1996	Yes	Five-point scale	RCTs	Low reliability (Clark et al., 1999)
Maastricht scale (Verhagen et al., 1998b)	1998	Yes	Point system	RCTs	Unknown
PEDro Scale (Scale, 1999)	1999	Yes	Yes/No	RCTs	Fair – Good reliability (Maher et al., 2003, Bhogal et al., 2005)
van Tulder scale (van Tulder et al., 2003)	2003	Yes	Yes/No	RCTs	Unknown

The Bizzini scale was limited to interventions pertaining to patella-femoral pain syndrome and was therefore not used in this study (Bizzini et al., 2003). The Maastricht and van Tulder scale both had unknown reliability and validity and was also not used in this research. The Downs and Blacks scale had substantial to excellent ratings, however, it was not used in this research as it is not specifically used for physical therapy interventions (Olivo et al., 2008). The inter-rater reliability of the Jadad scale was identified to be poor (Clark et al., 1999). In contrast, Olivo et al., (2008) stated that the Jadad scale presents with a high level of reliability and validity but is limited when applied to trials related to physical therapeutic interventions.

The Delphi List has often been used to review studies pertaining to physical therapy, however the application of the scale to a study has the potential to lead to bias, affecting

the quality of the study. This therefore led to the scale having a low reliability and validity (Lange et al., 2020, Olivo et al., 2008). The Downs and Blacks scale has an inter-rater reliability that ranges from substantial to excellent, however the Downs and Blacks scale lacks the ability to recognize bias in a study and could potentially skew the results of a systematic review (O'Connor et al., 2015).

However, multiple studies assessing the validity of these scales agree that the PEDro scale provides fair to substantial levels of reliability and fair to good levels validity when assessing RCTs, especially physical therapy interventions (Maher et al., 2003, Olivo et al., 2008). The PEDro scale was identified to be a scale that measured the methodological quality of a clinical trial and is therefore used in many systematic reviews assessing the methodological rigour of physical therapy (Olivo et al., 2008).

2.11.2 Systematic analysis of non-randomised controlled trials

There are multiple scales used to assess the validity of nRCTs, however, only a few are known to be used in health and physical health interventions (Quigley et al., 2019). Table 2.7 below outlines the most commonly used nRCTs and provides information regarding its usefulness in systematic reviews regarding health interventions.

Table 2.7: Tables of scales assessing methodological quality of nRCTs

Scale	Year	Published in peer-reviewed literature	Scoring system	Study Type	Reliability and Validity
Scales for non-randomised controlled trials (Quigley et al., 2019)					
MINORS (Slim et al., 2003)	2003	Yes	Point system	NRS of surgical interventions	Unclear (Quigley et al., 2019)
Newcastle-Ottawa Scale (Wells et al., 2003b)	2003	Yes	Star rating	Non-randomised controlled trials (NRCT's)	Fair (Hartling et al., 2013a, Quigley et al., 2019, Zeng et al., 2015)
Robins-I (Sterne et al., 2016)	2016	Yes	Ranges from serious risk, moderate risk and low risk	NRS of interventions	Unclear (Quigley et al., 2019)
SIGN Checklist (https://www.sign.ac.uk/)		Yes	Yes/No	Cohort studies and case control studies	Unclear (Quigley et al., 2019)

Due to the unclear / unknown validity of the MINORS, SIGN and ROBINS-I checklists (see Table 2.7), these were not used in this systematic review. The Newcastle-Ottawa scale (Balk et al., 2013) is a scale that is used in the assessment of non-randomised controlled

studies. In a commentary by Stang (2010), it was found that the lack of evidence related to the reliability of the scale resulted in the use of the scale being of little value in systematic review and meta-analyses (Stang, 2010). However, in an assessment by Deeks et al., the NOS was found to be easy to use as well as suitable for reuse in systematic reviews (Deeks et al., 2003). Another study stated that the NOS has minimum ability to recognise bias and therefore continuous revisions is required to improve the use of the scale (Hartling et al., 2013b).

The NOS has been accepted and endorsed as a scale to be used in the assessment of cohort and case-control studies by the Cochrane collaboration (Higgins and Green, 2011) and was found to be the most commonly used scale for non-randomised studies (Quigley et al., 2019, Seehra et al., 2016). The inter-rater reliability was high for cohort studies, with the intra-class correlations equating to 0.94. This therefore indicated good reliability and high levels of validity when using the scale (Wells et al., 2003a).

Following the understanding of the various etiologies of SIS (see Section 2.7.3), along with the detailed explanation about the mechanism of TENS (see Section 2.8.1), this systematic review used the PEDro and NOS scales to assess the effectiveness of TENS in managing SIS, using a well-defined and clearly outlined protocol in order to reach an appropriate conclusion. This protocol is detailed in Chapter Three.

3. Chapter Three – Research Methodology

3.1 Introduction

In this chapter, the research methodology pertaining to this systematic review is explained in terms of the methods and materials used. This includes the study design, the data collection process (inclusive of the literature search, identification of the study type and the inclusion and exclusion criteria) followed by the article evaluation and a summarization of findings.

3.2 Research Design

This study is a systematic review looking at the effectiveness of TENS therapy in the treatment of SIS (Natsis et al., 2007). The study design is a qualitative-qualitative paradigm study using a systematic review approach (Higgins and Green, 2011). This study design required that all relevant articles pertaining to the use of TENS in the treatment of SIS be systematically and methodologically screened and methodologically obtained via electronic databases as part of the data collection process, before being critically evaluated for their methodological rigor.

Databases used to search for relevant articles in this systematic review included DUT Summons (which included Pubmed, MEDline, Mantis and ScienceDirect), Google and Google Scholar. The individual databases were screened using specific key search terms relating to the use of TENS in various types of NSSP (See Appendix B) before the study was narrowed down to focus on SIS. Each study type was tabulated based on whether they were RCTs, non-RCTs, case studies or case reports (See Appendix B). In this review, only RCT's and non-RCT's were found and included.

Following the above procedure, the finalized number of relevant articles found for this study was separated according to each study type and allocated to six previously identified reviewers (all of whom agreed to participate in this study and had signed the Memorandum of Agreement (see Appendix D) and the researcher.The articles were reviewed according to the PEDro scale and the Newcaste-Ottawa Scale to establish the methodological rigour of the studies. The feedback of each article review was then received and further analysed for any discrepancies amongst reviewer gradings, following which a conclusive report of findings was created and discussed.

3.2.1 Permissions for this study

- Approval from the Faculty Research Committee (FRC) at the Durban University of Technology was received on the 5th of December 2019, prior to the initiation of the study protocol (See Appendix A).

- Agreement from the selected reviewers was sought and established using a Memorandum of Agreement (Moayedi and Davis, 2013) (Appendix D).

- The study was registered with PROSPERO on the 28th of April 2020 and was allocated the registration number CRD42020162385.

3.3 Research Procedure

3.3.1 Database search

A database search for relevant citations was conducted for the use of TENS in the treatment of orthopedic shoulder pain, which was inclusive of shoulder impingement syndrome. Databases searched were inclusive of those that DUT subscribed to as well as external databases. These databases included:

- DUT Summons (inclusive of Pubmed, MEDLine, Mantis, ScienceDirect)
- Google
- Google Scholar

Database searches commenced in January 2019 and ended in August 2019, at the point of data collection.

3.3.2 Key search terms

The following key search terms were used in each electronic database to search for relevant citations:

- TENS and Shoulder pain
- TENS and Frozen shoulder
- TENS and Calcific tendonitis
- TENS and Shoulder impingement syndrome
- TENS and Shoulder myofascial pain syndrome

- TENS and Brachial dysfunction
- TENS and Shoulder dysfunction
- TENS and Shoulder bursitis

3.3.3 Criteria for inclusion and exclusion of citations (Step One)

Inclusion of citations:

1. All relevant citations were required to be available in electronic format in order to obtain the citations (Huggins et al., 2012).

2. Citations needed to have the following relevant keywords: **TENS and one of the following: Shoulder pain; Frozen shoulder; Calcific tendonitis; Shoulder impingement syndrome; Shoulder myofascial pain syndrome; Brachial dysfunction; Shoulder dysfunction; Shoulder bursitis**

Exclusion of citations:

1. Any citation that could not be obtained by the researcher and/or the librarian; an opinion paper, web articles and unpublished studies (Mahood et al., 2013).

Table 3.1: Number of citations per search engine

Search engine	Summons	Google Scholar	Google
Citation number	8084	69 977	1 447 100

3.3.4 Criteria for inclusion and exclusion of abstracts (Step two)

The citations found per database in Table 3.1 were further reviewed (via abstract) in order to identify which articles met the relevant inclusion and exclusion criteria.

Inclusion of abstracts:

1. The abstract needed to comply with the inclusion and exclusion criteria stated in step one (see Section 3.3.3)
2. The abstract needed to comply with the relevant search terms such as: “TENS”;

"**Shoulder pain"; "Frozen shoulder"; "Calcific tendonitis"; "Shoulder impingement syndrome"; "Shoulder myofascial pain syndrome"; "Brachial dysfunction"; "Shoulder dysfunction"; "Shoulder bursitis".**

3. The abstract needed to identify that TENS is one of the treatment modalities being used in human adult subjects.
4. The abstract needed to state that pain specific to the shoulder region is being treated by TENS.
5. Studies were required to be in English or translated to English (see Section 1.5 in Chapter one).
6. All types of studies included in this review also contained randomised controlled trials, non-randomised controlled trials, case studies and case reports at the abstract stage.

Exclusion of abstracts:

3.3.4.1 Non- English abstracts/articles.

3.3.4.2 The abstracts that stated that the use of TENS was applied to non-human or child participants.

3.3.4.3 The use of TENS was applied to area non-specific to the shoulder region.

3.3.4.4 An abstract that stated that the initially screened citation was a systematic review; commentary paper or meta-analysis.

Table 3.2: Number of included abstracts per search engine

Search engine	Summons	Google scholar	Google
Abstract number	212	176	141

3.3.5 Criteria for the inclusion and exclusion of relevant articles (Step three)

This step included reviewing the above abstracts (Table 3.2) to identify whether they adhered to the inclusion criteria. Due to the large volume of abstracts found for the above key words search, it was identified that shoulder impingement syndrome yielded the greatest number of studies. Therefore, the focus group for the full text article search was specific to "Shoulder impingement syndrome and TENS".

Inclusion criteria

1. The full-text articles were required to be in English or translated into English, in order to reduce time and cost involved in translating and thereby also reducing the possibility of translation bias, from non-English articles (Higgins and Green, 2011).
2. The full text articles had to be acquired from an electronic source in order to access their citations and abstracts or convertible to an electronic medium.
3. Full-text articles had to be obtained from databases within the DUT library and external networks were included.
4. The full-text articles using adults as test subjects only.
5. No specific time period was allocated for the included articles. All articles published were included up to and including January 2020.

Exclusion Criteria

1. Any full-text articles that were not in English.
2. Previously conducted systematic reviews and literature reviews, government gazettes, blogs, websites or articles containing any expert opinions that did not conform to being RCTs, non-RCTs, case studies or case series.
3. Studies involving the treatment of shoulder pain without the use of TENS therapy or with the use of TENS as a sham/placebo.
4. Any shoulder condition that was reported as being secondary to a pathological cause (e.g. shoulder pain as a result of a stroke or secondary to diabetes mellitus).
5. Studies conducted on non-human/ child participants.
6. Duplicate studies found during the search process (i.e. to ensure the same study was not reviewed twice).

Full number of full text articles identified per search engine:

Table 3.3: Number of full text articles available per search engine

Search engine	Summons	Google Scholar	Google
Number of articles	13	5	4

Final number of articles included as part of this review prior to this hand search is 21 (Appendix C).

(Step 4):

A hand search was done and continued through FRC approval of this study on the 5th of December 2019 (see Appendix A) to ensure that compliant full text articles that had not been included were added. These full text articles would also have been screened with the inclusion and exclusion criteria found in steps 1-3 above (see Sections 3.3.3; 3.3.4 and 3.3.5)

In addition, the external reviewers each received a list of articles that were included, and they were requested to include any further articles that to their knowledge met the inclusion criteria for inclusion into this study.

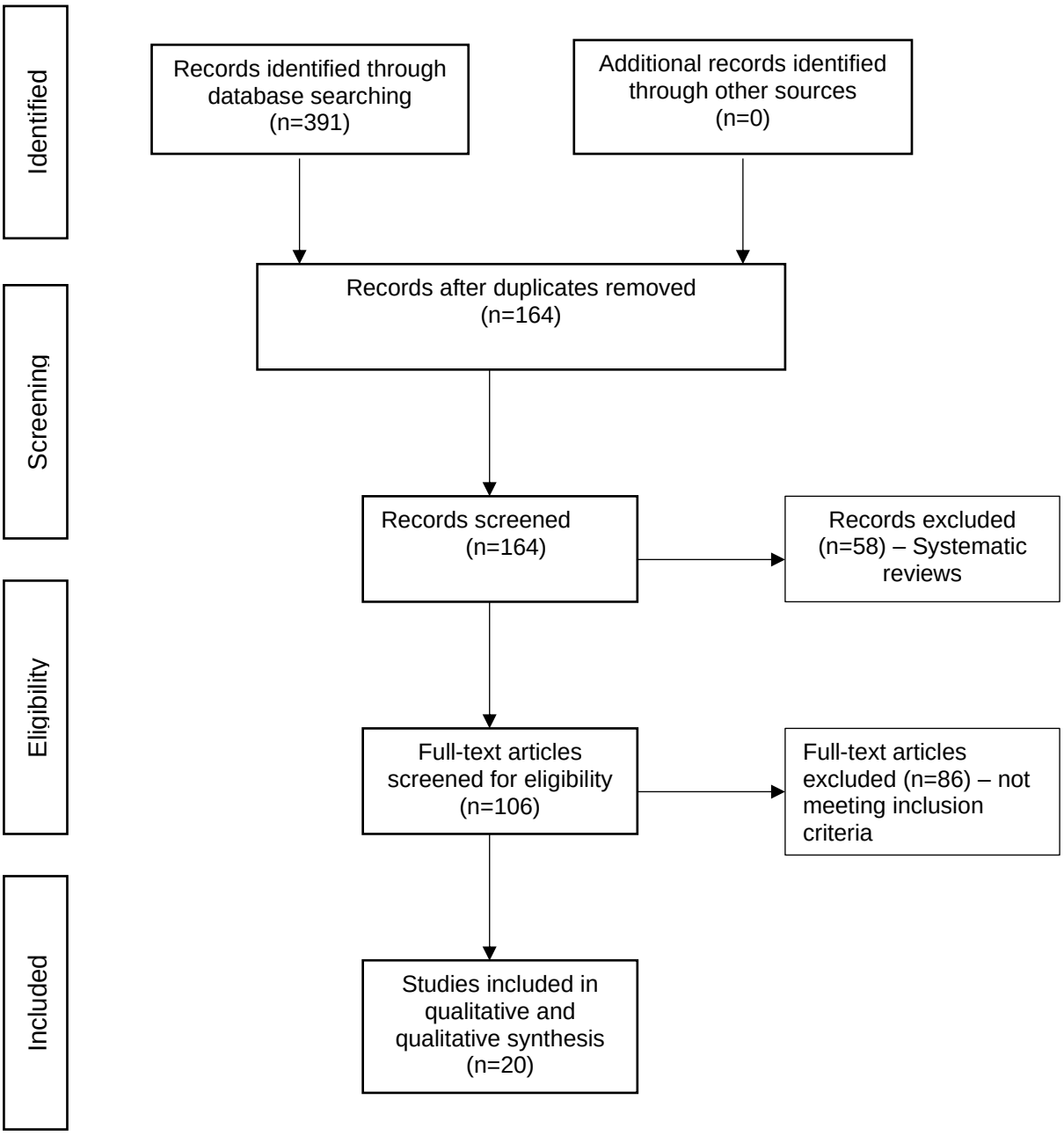
Table 3.3: Number of articles per study type

Study type	RCT's	nRCT's	Observational studies (Case reports/ Case series)
Full number of articles included	20	1	0

A description of steps 1-4 is available on the PRISMA flowchart (Figure 3.1).

During the hand search process, no additional articles were added, however one article by Munday (2014) was removed, as the reviewers agreed that it did not provide any relevant contribution to this study.

Figure 3.1: PRISMA flowchart



Adapted from: Moher, D, Liberati, A, Tetzlaff, J, Altman, D. G, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses*:* The PRISMA Statement. *PLoS Med* 6(7)

3.4 Reviewer appointment process:

Prior to and during the review process, anonymity was upheld throughout the review process. No reviewer was made aware of the names of the other reviewers. This was done in order to reduce the possible risk for bias. The names of the reviewers were also not made public. Most often, reviewer anonymity is upheld in order to provide the reviewers with the freedom of speech regarding their feedback, without the possibility of experiencing negative commentary from other authors. It is also upheld to prevent authors from being influenced by the public or by other reviewers (Ross-Hellauer, 2017).

No comments made on this study were causally linked to a specific reviewer. Any reviewer who is also an author on one of the selected articles for review, was not allowed to review their own study. This was done to reduce the possibility of selective non-reporting or under-reporting of outcomes in their studies that may lead to bias as a result of a conflict of interest (Uttley and Montgomery, 2017, Boutron et al., 2019).

3.4.1 Review procedure steps

Step 1:

Obtained Faculty of Health Research Committee Approval for PG2 on the 5th of December 2019 (Appendix A)

Step 2:

Identification of reviewers for this study was conducted based on the findings of articles as outlined in the research procedure outlined above. Additionally, special interest groups were contacted to determine interest regarding participation in this study. For systematic review specific interest, the Cochrane collaboration centres and Institute for Work and Health (IWH) were contacted. For musculoskeletal/orthopaedic specific interest, the Orthopaedic research society and International Society of Orthopaedic Centres were contacted. In order to prevent reviewer bias (Uttley and Montgomery, 2017), author and reviewer affiliation to topic and publications were taken into consideration.

Step 3:

Six independent external reviewers were approached to participate in this study, with the seventh being the researcher. The six reviewers were:

1. Reviewer A
   PhD with a specialization in sports science

2. Reviewer B
   PhD with a specialization in neurophysiology

3. Reviewer C
   PhD with a specialization in Medical and Clinical Science

4. Reviewer D (MSc with a special interest in clinical research)

5. Reviewer E (MSc with a special interest in sports science)

6. Reviewer F (MTech with a special interest in Chiropractic))

7. Researcher

Step 4:

The above reviewers were contacted via email once the proposal was approved, to ascertain their interest in this systematic review and to outline the following points, by means of the memorandum of agreement (Moayedi and Davis, 2013) (Appendix D):

1. Introduction and description of study.

2. Research procedures – outlining the role and expectation of the reviewers.

3. Process anonymity and blinding.

4. Resolution of research and reviewer discrepancies.

5. Projected timelines for above procedures.

The reviewers received the MoA via email and were asked to read and sign the agreement should they agree to participate and to adhere to the study protocols outlined. The reviewers were expected to either scan and fax or attach a secured pdf version of the signed agreement via email and return it to the researcher. Upon receipt of the signed MoA, the reviewers were placed in the reviewer matrices (Table 3.4 and 3.5), before they

received their allocated articles. A follow up email was sent to confirm receipt of such articles.

The reviewers had an eight-week deadline to review the articles following which they were required to return their feedback to the research supervisor.

After all MoAs were signed and accounted for, the reviewers were allocated to either Group, 1, 2 or 3 based on their qualification, clinical experience, research experience and academic experience. Each group had two reviewers with the researcher being the third reviewer in each group (Moher et al., 2009) to ensure that each article was reviewed three times.

Table 3.4: Table of reviewers

	Group 1	**Group 2**	**Group 3**
Reviewer 1	Reviewer C	Reviewer A	Reviewer B
Reviewer 2	Reviewer D	Reviewer E	Reviewer F
Reviewer 3	(researcher)	(researcher)	(researcher)

Each group was allocated three reviewers, with one PhD and Master's degree graduate allocated to each group. Allocation to each group was concealed in order to reduce the possibility of response bias (van de Mortel, 2008).

Allocation of articles were divided among the reviewers in Groups 1, 2 and 3. Majority of the articles included were randomised controlled trials, with the exception of one non-randomised controlled study, and therefore, Groups 1 and 3 received only RCTs, while Group 2 received a mix of RCTs and non-RCTs.

Table 3.5: Table of reviewers: Individual Aspects

Reviewers	PhD	Masters	Academic	Clinical	Research Experience	Publication Experience	Group Allocation
Reviewer A	X		X	X	X	X	2
Reviewer B	X		X		X	X	3
Reviewer C	X		X	X	X	X	1
Reviewer D		X	X	X	X	X	1
Reviewer E		X		X	X	X	2
Reviewer F		X		X	X		3

For this study, more reviewers were approached than was allocated. The additional reviewers that agreed to participate were asked to be standby reviewers in the instance that any appointed reviewer that was not able to complete their reviews and / or if there was a discrepancy between the reviewer's feedback of a single article. In such a case, the reviewers on stand-by would act as arbitrator reviewers to resolve the differences (Boutron et al., 2019).

Step 5:

Article allocation occurred as according to Table 3.5. Each review group had one PhD and one Masters level researcher in order to introduce variance in terms of the experience of the reviewer both clinically, and in terms of research, so that agreement on reviews was stronger should the reviewers agree (Gallo et al., 2016).

If the reviewer was an author of one of the included articles, it was vital to ensure that this reviewer did not review their own study as this may have skewed the review process and resulted in biased conclusive findings (Moher et al., 2015, Uttley and Montgomery, 2017, Sanz-Cabanillas et al., 2017).

Table 3.6: Article Allocation

Group	Article Allocation
1	1-7
2	8-14
3	15-20

Had the external reviewers included additional articles (as per the hand search) to the review list, these articles would have been distributed to the reviewers equally.

Step 6:

Following the allocation of articles to each reviewer, the reviewer then received the respective checklist and scales such as the PEDro scale for RCT studies (Pedro, 1999) and the Newcastle-Ottawa scale for non-RCT studies (Wells et al., 2003b), depending on the study types that they were allocated. The scales were accompanied by its relevant set of instructions and explanations (Appendices E and F) which clearly indicated how the scales should be used. If there was any issue regarding interpreting the explanation of the scales, the researcher was available to further explain how to use the scales (Moher, 2015; Uttley and Montgomery, 2017).

As stated in the research procedure under reviewer appointment (see Step 3 under Section 3.4.1), this process was a blinded procedure in order to reduce any possibility of bias and to ensure reviewer independence (Moher et al., 2015).

Step 7:

Reviewers were requested to confirm receipt of articles along with a confirmation of understanding and interpreting checklists and scales.

A reminder was provided at week three and week five that the reviews are expected back by week eight.

Whilst the external reviewers were involved in the review process, the researcher was conducting an independent review of the 20 articles. The research supervisor was therefore the recipient of all the results and only handed the results to the researcher once their individual review process had concluded. This was to prevent reporting bias from occurring (Uttley and Montgomery, 2017, Boutron et al., 2019).

If there was a conflict regarding reviewer feedback, an investigation into the matter would have occurred and an additional reviewer would have been requested to step in and review the publication (Uttley and Montgomery, 2017, Resnik and Elmore, 2018). In this study, no conflict was found regarding reviewer feedback.

Upon the completion of the review process, all individual article scale scores were collated and reviewed in terms of the review outcomes. Homogeneity was required amongst review outcomes in order to provide a clear and concise review report. Any abnormalities noted upon receipt of reviews from the reviewers resulted in the researcher meeting with the reviewer group to discuss the abnormality. Once an agreement took place, a new rating was allocated for this review. In this study, all results were found to be homogenous, no reviewer discussion was required.

3.5 Reviewer tools

There are various scales that were used to test the validity and reliability of each article included in this study (Liberati et al., 2009; Kitchenham, 2004; Moher et al., 2015). Each study type has a specific set of scales used to review a particular field of study. An example of this would be the use of the PEDro scale for the assessment of randomised controlled trials (Scale, 1999) whilst the Newcastle-Ottawa scale has been likened to the review process pertaining to non-randomised controlled studies (Wells et al., 2003).

3.5.1 Review tools for RCT's used in physical therapy interventions: (Olivo et al., 2008, Armijo-Olivo et al., 2014)

- Bizzini scale – Patellofemoral pain syndrome
- Delphi List – Physical Therapy
- Downs and Blacks Scale – Public health studies
- Jadad scale – Pain research
- Maastricht Scale – Physical Therapy
- PEDro scale – Physical therapy
- van Tulder scale – Back pain

In this study, the PEDro scale (Scale, 1999) was chosen due to its reliability and validity as identified by Maher et al., (2003) and Olivo et al., (2008) (See Chapter 2, Section 2.10.1).

3.5.2 Review tools for non-RCTs

- Robins-I – designed to assess NRS of interventions (Farrah et al., 2019)
- JBI-MAStARI- designed to assess RCT's and pseudo RCT's, descriptive and case control studies (Quigley et al., 2019)
- MINORS – NRS of surgical interventions (Farrah et al., 2019)
- Newcastle-Ottawa Scale – case control and cohort studies (Wells et al., 2003b, Farrah et al., 2019)
- SIGN- cohort studies and case control studies (Quigley et al., 2019)

The Newcastle-Ottawa scale is the only review tool that has been validated from all of the above (see Section 2.11.2).

3.6 Research Procedure: Data reduction and analysis

The individual articles were critically analysed and individual strengths and weakness were identified using the above scales. Upon receipt of review outcomes from the external reviewers, the data was captured on an excel spreadsheet. The majority consensus was used to rank and link specific outcomes from each study type. A compilation of a tabulated review outcome and a chapter detailing a discussion of results (see Section 4.4 in Chapter Four) was formulated. Ranking of evidence was presented regarding the TENS application procedure (see Section 5.3 in Chapter Five). An unbiased conclusive report of results was conducted in order to appropriately describe the evidential findings from the above process. The Chapter Five analysis and final overview of the evidence assessing the effectiveness of TENS in the treatment of shoulder impingement syndrome is concluded in Chapter Six.

Therefore, each article will fall into one of four categories as outlined in Table 3.7 below:

Table 3.7: Classification of outcomes

	Rigourous study	Poorly structured study
Good clinical outcomes	Well structured study with good clinical outcomes in favour of TENS in the treatment of SIS	Poorly structured study with good clinical outcomes in favour of TENS in the treatment of SIS
Poor clinical outcomes	Well structured study with poor clinical outcomes in favour of TENS in the treatment of SIS	Poorly structured study with poor clinical outcomes in favour of TENS in the treatment of SIS

This ranking of evidence in Chapter Five was done according to the levels of evidence as proposed by Foley et al. (2003), Dagenais and Haldeman, (2012) and the GRADE system (Brozek et al. 2009) where they provide three levels of evidence. These three levels

describe the degree or strength of evidence within a clinical category for a modality (in this case TENS and its various applications in clinical practice for patients with SIS).

Each of these grading systems provide different ways in which to rank evidence based on their specific research domains:

- Foley et al (2003) – shoulder rehabilitation.
- Dagenais and Haldeman (2012) – manual therapy.
- GRADE system (Brozek et al., 2009) – clinical interventions and practice.

Dagenais and Haldeman (2012) along with Foley et al., (2003) present a grading of evidence that works in favour of health care providers and is less complicated compared to the Cochrane GRADE system, which focuses on providing a standardised method of creating healthcare guidelines, which results in an increased level of complexity.

Foley et al., (2003) includes an additional category when compared to the Dagenais and Haldeman (2012) study, in which it is shows whether the evidence presented agrees or conflicts within the clinical category (for example there may be eight studies that provide a high level of evidence but their clinical conclusions are conflicting).

Due to the complexity of the GRADE system, it was not utilised in this study. Since Foley et al., (2003) includes category specific evidence rating as compared to Dagenais and Haldeman (2012), Foley et al., (2003) was utilised in this study to grade the level of evidence to justify the use of TENS in the treatment of shoulder pain – specifically SIS.

3.7 Ethical considerations

In order to ensure that all participants of this study were protected, the four cardinal principles of ethical conduct, which include autonomy, non-maleficence, beneficence and justice were applied.

Autonomy can be defined as an individual's right to self-governance and self-determination (Dryden, 2020). It is the right of a person to make choices based solely on their own judgement without the influence of external factors. In this study, participants were approached regarding their interest in this study. They were given a Memorandum of

Agreement to sign which explained the details of the study in order to gain informed consent from them (see Appendix D).

Non-maleficence is a principle that states no harm had occurred to participants/reviewers during the duration of the study (Jahn, 2011). This systematic review was a blinded review in order to prevent bias and protect all contributors from possible harm.

Beneficence can be defined as a “moral obligation to act for the benefit of others” (Jahn, 2011). Beneficence was upheld by anonymizing the names of the reviewers and gaining the relevant permissions and approvals for this study. In order to prevent any form of bias, article allocation occurred in order to prevent authors from reviewing their own articles.

Justice is defined as a principle that “obliges a person to equitably share the benefits, risks, costs and resources” (Jahn, 2011). Justice was upheld by providing each reviewer with an equal honorarium in order to acknowledge their time and effort that they contributed towards to this study. In the event of this study being published, all contributors will be equally acknowledged with written consent being obtained from all contributors.

4. Chapter Four – Results

4.1 Introduction

This chapter focuses on the feedback provided by the seven reviewers. The feedback has been collected, collated and tabulated into tables titled “Tabulated Feedback Data”. The contents of this table include the scales scores for each individual article type (RCTs or non-RCTs – no relevant case series/reports and observational studies were found, hence the lack of inclusion of such studies), the overall reviewer agreement percentage and the ranking of each individual article. A second table titled the “Analysis of article” follows with information pertaining to the study properties of the article. These include, the form and frequency of measurement, the duration of the study, number of participants, blinding of assessors, use of a control group and the presence of randomization when allocating participants of the study to a specific study group. Further information regarding the limitations of the study found by the reviewers, the outcome of the study regarding the strength of the individual study, along with a discussion and conclusion are also included in this table.

4.2 Data

4.2.1 Primary data

A list of final articles was put together after the primary and secondary searches were completed. The list of included articles was reviewed by three reviewers. The feedback from each reviewer was documented in the table titled “Tabulated Feedback Data”. The content of each table included the scores from each reviewer for each criterion on the relevant scales. A majority score was given, and a majority agreement percentage was calculated to represent the percentage of agreement between the reviewers. Following the allocation of scores for each criterion in the scale, an overall score was allocated to the study based on the reviewer feedback, which led to the calculation of the overall percentage agreement score. The highest percentage score an article could have been allocated was a 100%, indicating that all the reviewers of that specific article were in total agreement of a specific criterion. The lowest percentage score that an article could have been allocated was 33%, which would indicate that there was a lack of agreement between reviewers on a specific criterion. The overall percentage score was calculated according to

the score that was given from majority of the reviewers. A study was considered to be of a high quality, if the overall percentage score was over the 70% scoring range (Liberati et al., 2009). A study with a high overall percentage score indicates that there was homogenous agreement among all reviewers pertaining to the feedback scores provided.

4.2.2 Secondary data search

A secondary search included searching for grey literature such as books, commentaries and news reports and grey data such as online books and unpublished data (Adams et al., 2016), while majority of findings were published journal articles that were found via online databases. Articles that were not available online were sourced via an inter-library loan at the Durban University of Technology (DUT).

4.3 Abbreviations

CMSP: Chronic mechanical shoulder pain

CONSORT: Consolidated Standards of Reporting Trials

DUT: Durban University of Technology

MCID: Minimal clinically important differences

MES: Microcurrent electrical stimulation

Non-RCTs: Non-randomised controlled trials

ORD: Overhead reach distance

RCTs: Randomised controlled trials

SIS: Shoulder impingement syndrome

TENS: Transcutaneous electrical nerve stimulation

TPRF: Transcutaneous pulsed radiofrequency

VAS: Visual Analogue Scale

4.4 Results

The results of this study are separated into two different sections, representing the results pertaining to RCT and non-RCT studies, respectively. Each section includes the tabulated feedback data and an analysis of the results, which includes the ranking of each article individually and a discussion regarding the results, outcomes, and limitations of each article.

4.4.1 Examiner agreement and ranking of articles: Randomised Controlled Trials

Table 4.1: List of table number allocation for RCT feedback and analysis

Tabulated feedback data table	Analysis of article table numbers	Authors (s)	Year	Title
Table 4.3	Table 4.4	Alwesaly and Abdelsalam	2019	Immediate effect of mobilization on pain and overhead reach in patients with shoulder impingement syndrome
Table 4.5	Table 4.6	Ashtiani, Ghiasi, Noraie and Bohloli	2016	Effectiveness of action potential simulation and transcutaneous electric nerve stimulation on pain and function of patients with chronic mechanical shoulder impairment
Table 4.7	Table 4.8	Atya	2012	Efficacy of microcurrent electrical stimulation on pain, proprioception accuracy and functional disability in subacromial impingement: RCT
Table 4.9	Table 4.10	Bae, Lee, Shin, Kim and Lee	2011	Effects of motor control and strengthening exercises on pain, function, strength and the range of motion of patients with shoulder impingement syndrome
Table 4.11	Table 4.12	Baskurt, Baskurt, Ozcan and Yilmaz	2006	The immediate effect of heat and TENS on pressure pain threshold and pain intensity in patients with stage 1 shoulder impingement syndrome
Table 4.13	Table 4.14	Celik	2010	Comparison of the outcomes of two different exercise programs on frozen shoulder
Table 4.15	Table 4.16	Grymel-Kulesza, Polak, Kubacki, Skrzep-Poloczek and Krol	2007	The effect of multi-modality therapy including active exercises, classic massage, cryotherapy and comination if ultrasound and electrical stimulation on rotator cuff injuries
Table 4.17	Table 4.18	Kocyigit, Akalin, Gezer, Orbay, Kocyigit and Ada	2012	Functional magnetic resonance imaging of the effects of low-frequency transcutaneous electrical nerve stimulation on central pain modulation: A double-blind, placebo-controlled trial
Table 4.19	Table 4.20	Koo, Lin, Wang, Tsauo, Yang, Yen and Biswal	2015	Novel noxipoint therapy versus conventional physical therapy for chronic neck and shoulder pain: Multicentre randomized controlled trials

Table 4.2: List of table number allocation for RCT feedback and analysis continued…

Tabulated feedback data table	Analysis of article table numbers	Authors (s)	Year	Title
Table 4.21	Table 4. 22	Korkmaz, Capaci, Eyigor and Eyigor	2010	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: a prospective, randomized study
Table 4.23	Table 4.24	Lin, Chiu, Shih, Lee, Li, Guo, Luo and Pang	2019	Two transcutaneous stimulation techniques in shoulder pain: Transcutaneous pulsed radiofrequency (TPRF) versus Transcutaneous electrical nerve stimulation (TENS): A comparative pilot study
Table 4.25	Table 4.26	Moezy, Sepehrifar and Dodaran	2014	The effects of scapular stabilization-based exercise therapy on pain, posture, flexibility and shoulder mobility in patients with shoulder impingement syndrome: a controlled randomized trial
Table 4.27	Table 4.28	Ozdincler	2005	The effects of TENS and LEL on pain and functional performance of patients with shoulder pain
Table 4.29	Table 4.30	Shehab and Adham	2000	Comparative effectiveness of ultrasound and transcutaneous electrical nerve stimulation in treatment of periarticular shoulder pain
Table 4.31	Table 4.32	Soibam	2005	Comparative study on the effectiveness of ultrasound (US) and transcutaneous electrical stimulation (TENS) in the treatment of periarticular shoulder (PSP)
Table 4.33	Table 4.34	Subasi, Toktas, Demirdal, Turel, Cakir and Kavuncu	2012	Water-based versus land-based exercise programs for the management of shoulder impingement syndrome
Table 4.35	Table 4.36	Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender	2013	The effect of balneotherapy on chronic shoulder pain: A randomized, controlled, single-blind follow-up trial. A pilot study
Table 4.37	Table 4.38	Ucurum, Kaya, Kayali, Askin and Tekindal	2018	Comparison of different electrotherapy methods and exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial
Table 4.39	Table 4.40	Yazmalar, Sariyildiz, Batmaz, Alpayci, Burkan, Ozkan and Cevik	2016	Efficiency of therapeutic ultrasound on pain, disability, anxiety, depression, sleep and quality of life in patients with subacromial impingement syndrome: A randomized controlled study

Table 4.3: Tabulated feedback article for RCT: Article 1

AUTHOR(S):	Alwesaly and Abdelsalam					
YEAR:	2019					
TITLE:	Immediate effect of mobilization on pain and overhead reach in patients with shoulder impingement syndrome					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	0	1	**66%**
3	Allocation was concealed	0	1	1	1	**66%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	0	1	**66%**
5	There was blinding of all subjects	0	1	0	0	**66%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	1	1	1	1	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	0	0	0	0	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	0	0	1	0	**66%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	0	1	1	1	**66%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	1	1	**100%**
	TOTAL SCORE	5	8	6	7	
		OVERALL PERCENTAGE AGREEMENT:				**81%**

Table 4.4: Analysis of RCT: Article 1

AUTHOR(S):	Alwesaly and Abdelsalam
YEAR:	2019
TITLE:	Immediate effect of mobilization of pain and overhead reach in patients with shoulder impingement syndrome

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomization of participants	Ranking	Total Percentage Agreement
Pain intensity – Visual Analogue Scale (VAS) Overhead reach distance (ORD) – Overhead stand reach test	Assessments took place in a pre-test/post-test comparison paradigm evaluation	The duration of the study is not specified - same day is assumed based on the research design	50 male patients with unilateral SIS, were used in this study – 25 participants for each group	The assessors were blinded to group allocation	A control group was used – TENS was used as active control whilst TENS and mobilisation was used in the experimental group	Yes – they had a randomization table that they utilized	7	81%

LIMITATIONS:

A limitation of this study is that the patients recruited for this study were taken from an outpatient clinic of a security forces hospital, including only males with unilateral SIS. The hand dominance association and type of SIS were not noted in this study. This sample size and the group characteristics do not represent the general population. In addition the study population (given their occupation) are more likely to have acquired SIS through trauma as opposed to repetitive strain injuries or related to comorbid conditions.

The study focused mainly on the age group of 24-40 years old. Impairments in this age group, in the armed forces profession, differs from the general public in terms of activities of daily living (Oster et al., 2017) and with all participants being male, will have a higher pain tolerance (Bartley and Fillingim, 2013), indicating that the severity of the SIS may be higher than the general public. In addition, in this age group, men are less likely to have comorbidities (Tran et al., 2018, Oster et al., 2017), which allows for this study to have a very homogenous group of males that may fit the inclusion criteria well but limits the extrapolation of the data to patient groups with comorbidities (and the confounder of the medications taken by these patients).

	At baseline, the mobilisation group had a greater overhead reach than the control group (noted as borderline significantly different (p=0.056)) and less pain, with the control group having more significantly reduced overhead reach and increased pain. This would have made it potentially more difficult for them to improve in one treatment session (as compared to the intervention group); even though the chances of improvement were potentially mathematically better in the control group. The mobilization group had a higher ROM and therefore had a less chance of improving than the control group (known as the "ceiling effect" (Garin, 2014), making the comparison skewed. Given that there seemed to be a difference in the clinical severity of the groups, it is unclear whether there was any statistical application used to normalize the data prior to the analysis of the results. This difference between the groups could indicate allocation bias as it is not clear whether the person holding the randomisation numbers was the same person that was screening patients for entry into the study. It is also not clear how participants were recruited into the study and whether the participants were naïve as to which intervention was the control and which was the active intervention. The perception of grouping may have negatively affected the results in the control group if they felt that they were not given the "appropriate" intervention for their condition (Krauss, 2018). Given that the one outcome was a subjective outcome and the other was a reach test which required "performance testing", it is conceivable that the control patients (if not naïve and disgruntled) could have influenced the outcome measures. Given the condition of SIS, both groups would usually achieve their best effects over a period of treatment and not just over one treatment. For this study, it would have been better if the number of sessions and the time between pre-test and post-test was indicated. The pre and post-test design paradigm is not effective in adequately assessing the effectiveness of interventions for SIS as a condition. Additionally, it is not clear in which order to treatments were administered; and whether this could have had an impact on the outcome of the mobilization of the outcome group. The lack of a CONSORT diagram indicating the patient recruitment process and screening of the patients entering the study and those subsequently falling out; leaves the reader to assume that all patients that presented were entered into the study until the required population was attained. This lessens the credibility of the homogeneity of the cohort in the study and allows the reader to question whether the patients were screened and that the self-set criteria were adhered to. Lastly, the lack of clarity as regards blinding of the screening doctor, allocation assistant, and outcomes administrator does not allow for reader confidence in whether there was any associated bias in patient screening, allocation, or in the captured data at the end of the study.

	The possibility that the outcomes administered was biased along with the lack of naivety of participants, could have been the principle factors that allowed the mobilization group to improve beyond that of the control, without any treatment effect of the interventions. This could further have been confounded by the handedness / hand dominance of the patient in relation to the group – if the mobilization group had more non dominant handed patients (Lemos et al., 2011), it is likely that their condition was also less severe and more likely to improve with one treatment.
OUTCOME:	The authors suggest that the study outcomes indicate that shoulder mobilization, with the specific use of joint distraction and gliding along with TENS immediately reduces pain and increases overhead reach distance in patients with SIS when compared to those patients just receiving TENS.
DISCUSSION:	Given the context provided in the limitations, it is still possible for a combined intervention to improve to a greater extent when compared to the single intervention; based purely on the fact that one modality addressed pain and the other range of motion; with the combined effect of decreased pain also decreasing arthrogenic muscle inhibition (Palmieri-Smith et al., 2013). However, these conclusions need to be contextualized in the specific context of the study with limited generalization. No conclusion can be made specifically with regards to mobilization by itself, as the possibility of synergistic cooperation of the applied modalities may enhance an otherwise non-clinically useful modality (viz. without TENS, the mobilization may have been no better than placebo). It would therefore have been better to consider a placebo intervention in the control group. In terms of the TENS (control group), it could be stated that this intervention may be potentially as good as the combined treatment of TENS and mobilization in terms of pain and ORD. However, this outcome cannot be made categorically as the control group had more severe pain and greater limitation of movement on ORD than the combined group, meaning that the impact of one intervention would have been less than the group with less severe symptoms. Therefore, a different study control for this would be required to valid this possible outcome. The settings for the TENS was mentioned as being 100 Hz, 150 mA and a time of 20 minutes. Electrode placement was stated as being placed on the anterior and posterior aspect of the shoulder. No further specification was provided. This results in a lack of homogeneity being present among participants as no specific point or muscle was indicated. Since the duration of the study is not specified, we cannot conclude as to whether there was a control for analgesic tolerance because we do not know the number of times that TENS was applied, and we are

	therefore unaware if there was a possibility for analgesic tolerance to occur. Considering the conclusions of the study in terms of the limitations of the context of the study, it is necessary to acknowledge that there was a difference between the groups in terms of the clinical outcome. Given the context, these differences are significantly challenged in terms of the following principles: 1. Severity of the SIS between the groups 2. The equality of the impact of the treatment modalities on the groups 3. The impact of patient perception on the outcomes This makes the outcome tenuous, and with the already limited ability to extrapolate the data to the general patient population, it generates an outcome that has very isolated clinical applicability and subsequently, contextual reality, in clinical practice.
CONCLUSION:	Due to the structure of this study, the reviewers were able to rate this study moderately well, with a methodological ranking of 7 out of a possible 11. However, the study was limited in terms of study population (militia), target age group (24-40 years), gender specification (males only), lack of homogeneity between the control and experimental group and finally, location (hospital recruitment from the military). The poor outcomes demonstrated in this study is limited to a particular population and location and is therefore, not an adequate representation of the general population. Therefore, we have a relatively well-structured study with a poor clinical outcome, indicating that the clinical usefulness of TENS in SIS is questionable (see Table 3.7).

Table 4.5: Tabulated feedback article for RCT: Article 2

AUTHOR(S):	Ashtiani, Ghiasi, Noraie and Bohloli					
YEAR:	2016					
TITLE:	Effectiveness of action potential simulation and transcutaneous electric nerve stimulation on pain and function of patients with chronic mechanical shoulder impairment					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	Percentage Agreement
1	Eligibility criteria were specified	1	0	0	0	**67%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	0	0	0	0	**100%**
5	There was blinding of all subjects	0	0	0	0	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	0	0	1	0	**67%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	0	0	1	0	**67%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	1	1	**100%**
	TOTAL SCORE	4	3	5	3	
		OVERALL PERCENTAGE AGREEMENT:				**91%**

Table 4.6: Analysis of RCT: Article 2

AUTHOR(S):	Ashtiani, Ghiasi, Noraie and Bohloli							
YEAR:	2016							
TITLE:	Effectiveness of action potential simulation and transcutaneous electric nerve stimulation on pain and function of patients with chronic mechanical shoulder impairment							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomisation of participants**	**Ranking**	**Total Percentage Agreement**
The Western Ontario Rotator Cuff Index (WORC), the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) and Shoulder dyskinesia recorded: **Pain**: The scales used assessed pain at 3 different time points **Shoulder mobility rate**: was measured in 3 different movements **Shoulder girdle stability**: This was assessed by measuring the distance between the scapula and spinal cord in 2 different positions **Scapula position**: was measured with the hands alongside the body	Measurements were taken on Day 1 and Day 6 of the study	Six-day period, in which treatment was provided once a day	32 patients participated in this study – the number of participants per group was not stated and due to a lack of a CONSORT, we cannot assume the number allocated per group	The article did not state if the assessors were blinded or not.	No control group was used – it was a relative effectiveness study	Participants were randomly allocated to either a TENS or an APS group	3	91%
LIMITATIONS:	Given that the study did not include a clearly defined eligibility criteria (other than chronic mechanical shoulder pain), there is a							

	possibility that the study groups were not similar at baseline, with regards to: - gender (and the attendant relationship to pain perception) (Franconi et al., 2019) - handedness or dominant hand involvement (over a six-day period comparing a predominantly dominant hand group to a predominantly non-dominant hand group may mask actual improvements in the dominant hand group, simply as a result of daily use). - Functional ability (females tend to be more mobile than males in terms of joint movement) (Czuppon et al., 2017) - There were no indications that there was a wash out period for any prior treatment to the involved shoulder. The above is further compounded in that it is not clear that the baseline outcome measures were the same (or at least not statistically different) at the outset / baseline of the study. This is particularly important given that there is a large variance in age (18-45 years of age), no comment on the presence of comorbid conditions and / or the use of medication. All these factors have an impact on the rate of healing (Guo and DiPietro, 2010) and the possible comparability of the outcomes for each group. Additionally, whether the participants have the ability to be non-homogenous, making it difficult to extrapolate the outcomes of this study to the general population. Due to the lack of homogeneity at baseline, the APS group had lower pain scores than the TENS group, which indicates that the degree of improvement is lower in the APS group as compared to the TENS group, in which the “floor effect” could mask a significant difference in treatment effectivity (Oxford, 2020). This would indicate that the groups would not respond at the same rate to their respective treatment, since one group has a smaller room for improvement. Prior to randomization of participants into the TENS and APS groups, the participants were classified into 4 groups that defined their relevant levels of pain and dysfunction. The sample size of 32 participants leaves one to assume that each of the 4 groups would have an average of 8 participants per group. This sample size per dysfunction is too small in order to be able to properly assess whether the treatment protocols would be effective per “sub-group”. After the classification of the participants into one of

	four groups, the participants were grouped together and randomly divided into either TENS or APS groups. The authors do not state whether there was equal distribution of the participants with varied pain and dysfunction in each of the two groups. This results in further lack of homogeneity at baseline, since each of the 2 groups would have participants experiencing any one of four types of pain and dysfunction. The article did not state whether allocation was concealed or whether there was blinding of the assessors, therapist or participants. This leads to the credibility of the randomization process being questioned and could have possibly resulted in possible bias between the two groups. If the author preferred one treatment over the other, the randomization process could have been manipulated in order to favor the participants with the greatest levels of pain and dysfunction by placing them into the group that the author believed would have benefitted the participants most, resulting in exaggerated optimistic outcomes by means of autosuggestion from the author (Jakovljevic, 2014). Further to the above, a lack of patient naivety has the potential to influence subjective outcome measures, particularly if their previous experience was favorable. This may exaggerate an outcome (favourable if in the perceived active group and not favourable if the intervention seems as non-effective) in this study. With the assessors not blinded, it may have re-enforced the position of naivety / lack of naivety and further skewed the results for one or the other group. Another notable limitation is that the sample size per group was too small, as each of the four categories would have had eight people per group (hyper/hypoactive) and at most 16 per analysis group (assumption that there were equal numbers as there is no CONSORT diagram). This would have led the researcher to use non-parametric statistics to account for the small sample size, which are less strong and categorical than parametric statistics (Frost, 2020a). The smaller the group, along with the unclear inclusion criteria results, lack of blinding and questionable naivety further increases a greater variance between groups. The greater the variance, the more difficult it is to compare each group. A small sample size can also result in a single outlier, such as one out of eight people positively responding to the treatment, over-throwing the results due to its greater influence on the stats of the study (Frost, 2020a). With regards to the outcome measures, the authors state that they measured shoulder girdle stability by measuring the distance between the scapula and the “spinal cord”. In terms of reproducibility, the spinal cord is not an osseous landmark and cannot be

	consistently and reliably measured repeatedly over time. In addition, the authors do not state clearly when the outcome measures were taken in relation to the treatments provided in their protocol. If the measurement outcomes were taken on day 6 directly after treatment, then technically the final outcome measures would have been the direct result of the final treatment session and not the entire protocol. It would have been more appropriate to take the final measurement a day / week after the protocol was completed. The MCID is important in order to evaluate whether the treatment genuinely improves perceived clinical outcomes in patients suffering with chronic mechanical shoulder impingement (Rai et al., 2015). The authors do not explain the scales / outcome measures and their relevant MCID, that they used to assess each outcome. Pain was assessed in both the Western Ontario Rotator Cuff Index (WORCI) and the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), however the validity of pain assessment in the ASES is low (Michener et al., 2002), whilst WORC is only effective in assessing pain during movement (Lopes et al., 2008).
OUTCOME:	Notwithstanding the above limitations, it would seem that both the TENS and the APS showed a statistically significant change over time for pain reduction and movement improvement and only the APS for improved performance. Between the groups, the authors report a significant p-value for all outcome measures in favour of the APS intervention, therefore the authors state that APS is effective in reducing pain and improving shoulder complex functioning for a short duration, when compared to TENS, but that both are effective in the treatment of CMSP.
DISCUSSION:	Given the limitations of the study, the lack of overt explanations of key CONSORT outcomes (Schulz et al., 2010) by the authors and the lack of clarity in terms of the participant homogeneity; the outcomes at best may be an indicator of possible effectiveness of the TENS and APS in the treatment of CMSP and therefore the conclusions need to be accepted with caution and applied within the confined context of the study parameters as the outcomes are not generalizable to the general population. The TENS settings were in this study included a frequency of 150 Hz, with pulse width of 1.2 mA. There is no specifications provided regarding the electrode placement apart from the fact that it was placed on the shoulder and on the painful region found on the shoulder. This would have therefore varied among participants with regards to the most painful area found in the shoulder.

	The application of TENS was conducted for 6 days daily, and this would have led to analgesic tolerance presenting itself among the participants, as Chandran and Sluka (2003) mentioned that after the 4th or 5th day, unless the frequency is varied between high and low frequencies, the possibility for analgesic tolerance setting in is quite high. They had conducted a study over a period of six days to assess tolerance in patients and found that six continuous treatments led to diminished effects from the TENS therapy. There is no statement from the authors with regards to how they may have accounted for this factor, if at all.
CONCLUSION:	This study did not specify important factors that could have affected the outcome of this study, whilst simultaneously not following a detailed protocol when conducting this trial. Due to the points mentioned in the limitation and discussion above, this study was rated as poor, with a methodological ranking of 3 out 11, indicating poor methodological rigour. The outcomes of this study cannot be executed in practice due to the lack of information provided at baseline, lack of homogeneity and the lack of a smaller target age group, resulting in poor clinical outcomes and poor methodological rigour (Table 3.7).

Table 4.7: Tabulated feedback data for RCT: Article 3

AUTHOR(S):	Atya					
YEAR:	2012					
TITLE:	Efficacy of microcurrent electrical stimulation on pain, proprioception accuracy and functional disability in subacromial impingement: RCT					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	Percentage Agreement
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	1	1	1	**67%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	1	1	**100%**
5	There was blinding of all subjects	1	1	1	1	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	1	1	1	1	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	0	0	1	0	**67%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	0	0	0	0	**100%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	0	1	**67%**
	TOTAL SCORE	7	8	8	8	
		OVERALL PERCENTAGE AGREEMENT:				**91%**

Table 4.8: Analysis of Article RCT: Article 3

AUTHOR(S):	A. M. Atya
YEAR:	2012
TITLE:	Efficacy of microcurrent electrical stimulation on pain, proprioception accuracy and functional disability in subacromial impingement : RCT

STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomisation of participants**	**Ranking**	**Total Percentage Agreement**
Pain: Pain assessments were conducted using the Visual Analogue Scale (VAS) **Proprioception Assessment**: An isokinetic dynamometer was used to measure proprioception. A passive reproduction of the joint position test was used as a standard indicator for proprioception accuracy **Functional Disability**: The Shoulder Disability Questionnaire (SDQ) was used to assess disability of the shoulder	Measurements were taken at baseline and after 6 weeks of treatment	Six-week duration with three treatments per week (total 18 treatments)	Forty people with shoulder impingement syndrome participated in this study – 19 males and 21 females. These participants were randomly divided into 2 groups: The experimental group had 19 people who received microcurrent electric stimulation The control group had 21 people who received placebo microcurrent electric stimulation	There was blinding of the assessors	A control was used with the MES not being switched on in the control group	There was randomization of the participants with the use of a computer-generated software	8	91%

LIMITATIONS:	The study's authors need to be credited for the clear exposition of the inclusion and exclusion criteria; however, they have omitted to include the handedness of the participants and the spread of handedness (dominance) between the two groups. Another inclusion / exclusion criterion that was well addressed is the maintenance of patients on their medication to eliminate this as a source of change. However, the study does not report any of the possible comorbidities that the medication was for and whether these comorbidities were equally spread between the groups. This consideration is important as the older population in their study (who are more likely to have comorbidities present (Guo and DiPietro, 2010)) may have had conditions that would negatively have affected the outcome of the intervention for SIS. In terms of the interventions, this study does not indicate the minimum and maximum time periods between the treatments, other than to state that 3 treatments were given within an assumed 7 days (one week). Given this, 18 treatments would therefore take 6 weeks for completion. It is unclear if all patients completed these 6 week / 18 treatment sessions in their entirety (we only know how many participants were included at the start). Given the above lack of clarity, it is further compounded by the fact that the final outcomes measure assessment was seemingly completed on the day of the last treatment – there is no mention of a 19th visit purely for measurement outcomes. This draws into question whether the last measurement is only able to comment of the treatment that was done on that day as opposed to the entire treatment protocol. In terms of blinding processes, the authors must be credited for the blinding of patients and staff administering the outcome measures to the participants; however it is not clear whether the person(s) screening the participants for entry were blinded to the randomization table or whether participants were only allocated to a group after their evaluation for participation and subsequent inclusion. It is also significant that the study was able to ensure that patient naivety was not required for ensuring that the patient's perception was not a factor in the recorded outcomes. The study does not conduct any follow-up assessments past the 6-week mark, which limits this study to the short-term effects of microcurrent electrical stimulation. A follow-up would have benefitted this study to include both long- and short-term effects. This study is also limited to SIS symptoms that are in the subacute and chronic phases in a very limited age group of 30-55 years of age. Lastly, the settings on the MES were specifically set at 10 Hz, which means that the outcome effect is restricted to a low frequency setting.
OUTCOME:	Based on this relatively well structured randomized controlled trial, the authors propose that the outcome of this study supports that micro-current electrical nerve stimulation is a non-invasive method of effectively reducing pain (p= 0.001 over time in intervention group; p=0.015 between groups)

	and increasing shoulder function (p=0.003 over time in intervention group; p=0.007 between groups) but with no change in the proprioception (p=0.067 over time in intervention group; p=0.84 between groups) in patients with subacromial impingement syndrome.
DISCUSSION:	From the discussion under limitations and the reported high-level of blinding, randomization allocation (fairly good procedure) and fairly comprehensive inclusion / exclusion criteria, this study outcomes have a small variance to be influenced by bias. Therefore, this study's outcome seems to be supportive of the conclusion. This study was included in this review even though it does not focus specifically on TENS, but rather MENS. This is because this relatively new form of electric stimulation has similar properties to TENS with regards to the type of parameters present in the device and therefore achieves its clinical outcomes using similar physiological outcomes (Rajpurohit et al., 2010).
CONCLUSION:	This well-planned study had a total ranking of 8 out of a possible 11, with a majority percentage agreement of 91%. This was due to the well-planned and structured details of this study pertaining to the use of microcurrent electrical stimulation in the treatment of SIS. However, due to the small target age group, the lack of information regarding hand dominance, and the non-specified type of impingement lesion present in the study participants, the outcomes of this study can only be applied to a specific population with specific low frequency MES settings. This was a well-structured study; however, the application of the clinical outcomes are poor given the limitations of this study and this therefore results in a rigorous study with poor clinical outcomes (see Table 3.7).

Table 4.9: Tabulated feedback data: Article 4

AUTHOR(S):	Bae, Lee, Shin, Kim and Lee					
YEAR:	2011					
TITLE:	Effects of motor control and strengthening exercises on pain, function, strength and the range of motion of patients with shoulder impingement syndrome					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	0	1	0	0	**67%**
5	There was blinding of all subjects	1	0	0	0	**67%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	0	0	1	0	**67%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	0	0	1	0	**67%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	0	1	**67%**
	TOTAL SCORE	5	5	5	4	
		OVERALL PERCENTAGE AGREEMENT:				**85%**

Table 4.10: Analysis of article RCT: Article 4

AUTHOR(S):	Bae, Lee, Shin, Kim and Lee
YEAR:	2011
TITLE:	Effects of motor control and strengthening exercises on pain, function, strength and the range of motion of patients with shoulder impingement syndrome

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomization of participants	Ranking	Total Percentage Agreement
Pain: The Shoulder Pain and Disability Index (SPADI) **Range of Motion**: A goniometer was used to assess active shoulder range of motion without pain	Measurements were taken at baseline and again after 4 weeks of treatment	The duration of this study was 4 weeks The control group received 3 x 45 min sessions for 4 weeks The experimental group received the same as control group with an additional 30 minutes of exercise therapy	35 participants were selected for this study and were divided into two groups Group 1 had 17 participants while Group 2 had 18 participants	Assessors were not blinded in this study	A control group was used in this study. The control group received conservative physical therapy which comprised of TENS for 20 minutes, Ultrasound for 5 minutes and a hot pack for 20 minutes	Participants were randomly allocated into 2 groups	4	85%

LIMITATIONS:	The authors defined the inclusion and exclusion criteria for the participants in this study, but these criteria did not necessarily enable homogeneity between the two groups. This assertion arises out of the fact that the participants were only expected to have a minimum of one of the three inclusion criterion stated by the authors. In addition to this, the authors do not include handedness, the presence of comorbid conditions and / or whether medication was limited or resulted in exclusion. It would have been more prudent to have well-defined inclusion criteria, which would have ensured that all participants experienced similar pain and disability regarding their shoulder dysfunction; mitigated the effects of comorbid conditions as well as identified the effects of medication (or changes in medication) and the effects of physical activity related to handedness or dominance. Notwithstanding the limitations of the inclusion criteria, the baseline participant characteristics between the groups seems to show that

	they were similar in gender, side of injury (not handedness), age, height and weight (although no p values where presented). Further to this, the study does not state the stage of impingement as specified by Neer (Neer, 1982), or the degree of pain that the patients were required to be experiencing in order to be involved in this study. The lack of specificity regarding the pain stage of participants implies that an acute short-term SIS condition would potentially respond to treatment faster as compared to a long-term chronic SIS condition. Thereby potentially affecting group outcomes differently. The study states that randomization did take place, but there was no mention of allocation concealment or the process by which randomization was affected. No comment is made in terms of participant naivety; therefore this leads to the possibility that prior experience and / or autosuggestion from the researcher(s) could have influenced the outcome of the study (particularly the pain outcomes). Lack of blinding of the person screening the patients, the therapists and the outcomes administrators is a significant flaw in this study as this allows for the credibility of the randomization as well as the credibility of the outcome's measures to be questioned. Concerning the relationship between the treatment and measurement periods, the timeframe for this study was four weeks to retrain motor control patterns in adults experiencing shoulder impingement syndrome. A study by Roy et al., (2009) that used an intervention similar to this study stated that a 4-week intervention is beneficial in patients with SIS between the ages of 29 and 60. However, a study intervention conducted by Worsely et al., (2012) found that motor control retraining in young adults between the ages of 18 and 34 was effective after a 10-week intervention. This brings into question whether a 4-week motor control retraining intervention would be effective in an older population, as compared to a younger population with the same symptoms. Therefore, the clinical outcomes obtainable in this study based on the physiological functional changes would have at best been small and therefore difficult to detect. This would have been compounded by the lack of information available on when outcomes measures were taken – it is assumed that there were 12 interventions over four weeks with a baseline measure. The final set of measurements and their relationship to the final treatment are not clearly spelt out; this means that if taken at the last visit the outcomes may actually reflect the outcomes of the last treatment more accurately than the treatment protocol as a whole. The use of the SPADI questionnaire, although reliable and valid (Thoomes-de Graaf et al., 2015), allows for subjectivity to be included in the results. The weakness of this study is that the results from the questionnaire have not been split between pain and disability. This makes differentiating between the disability and the pain difficult and does not specify which of the two aspects is showing greater levels of improvement in the participants (particularly as some modalities target pain and other improve functional ability (Tiktinsky et al., 2010)). This can be seen in that the

	strength of external rotation at 60 degrees improved significantly in the control group, which cannot be compared to pain changes or functional ability changes specifically as the SPADI is reported as a composite outcome. This is of particular concern, as the effects of arthrogenic muscle inhibition and the effect of the intervention cannot be interrogated. The sample size is small and the use of non-parametric statistical analysis, which accounts for the possibility of outliers and abnormal results at post-test, is most effective. In the study by Roy et al., (2009) a sample size of eight patients were used, so this study improved on that factor by increasing the sample size, however the sample size is still relatively small and could have been negatively affected by dropouts (which are not reported). This study does not have any variability in measurements, which would have been accounted for if the researchers had a follow-up period after post-testing. This limits this study to the fact that there is no indication whether the effects of the treatment protocol are effective in the long-term management of pain.
OUTCOME:	The authors suggest that the outcome of this study indicated that strengthening and motor control exercises were effective in treating patients with shoulder impingement syndrome, better than compared to the control intervention.
DISCUSSION:	Based on the limitations found in this study, we find that the sample size was too small, and patients are likely to not have been similar at baseline, therefore limiting group comparability. The authors did not state the type of impingement that they were focusing their treatment on, and therefore our knowledge on the types of pain patients experienced at baseline is limited. The authors did not state why they had chosen a four-week treatment period for an age group with an average of 48 years, when literature (Roy et al., 2009) shows that a longer period should have been applied. Although TENS was included in this study, its stand-alone effectiveness within the context of SIS is limited as this study's focus was shoulder control and strengthening exercises and not the conservative therapy. The use of TENS was packaged into a control treatment that included both ultrasound and hot packs. The authors did not specify what settings were used in this study with regards to the placement of electrodes, the intensity and frequency, all of which would have contributed to the effectiveness of the modality in the intervention. Therefore, the effectiveness of

	TENS alone was not specified in this study in order to assess whether it would be effective in the treatment of SIS.
CONCLUSION:	Due to the numerous limitations pertaining to this study, a ranking of 4 out of a possible 11 was awarded to this study, with a total percentage agreement of 85%. The outcomes of this study are limited to a specific minority group of people, and the use of TENS was undertaken as part of a packaged treatment and therefore the effects of TENS on SIS was not the focus of this study, resulting in an unclear indication of the effectiveness of TENS. The methodological rigour of this study was poor with poor application of the clinical outcomes in general practice for the use of TENS (see Table 3.7).

Table 4.11: Tabulated feedback data for RCT: Article 5

AUTHOR(S):	Baskurt, Baskurt, Ozcan and Yilmaz					
YEAR:	2006					
TITLE:	The immediate effect of heat and TENS on pressure pain threshold and pain intensity in patients with stage 1 shoulder impingement syndrome					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	0	1	0	0	**67%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	0	1	**67%**
5	There was blinding of all subjects	0	1	0	0	**67%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	0	0	1	0	**67%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	0	0	1	0	**67%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	1	1	**100%**
	TOTAL SCORE	4	6	5	4	
		OVERALL PERCENTAGE AGREEMENT:				**85%**

Table 4.12: Analysis of Article RCT: Article 5

AUTHOR(S):	Baskurt, Baskurt, Ozcan and Yilmaz							
YEAR:	2006							
TITLE:	The immediate effect of heat and TENS on pressure pain threshold and pain intensity in patients with stage 1 shoulder impingement syndrome							
STUDY PROPERTIES								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomisation of participants**	**Ranking**	**Total Percentage Agreement**
Pain intensity was measured using a horizontal Visual Analogue Scale Pain-Pressure Threshold was assessed using the dolorimeter on the antebrachial area (points not specified)	For PPT: measures were taken 3 times and a mean value was recorded For VAS: assessment was done before and after the treatment Both measures were taken pre and post the intervention on the same day	The article does not state the duration of the study – assumption would be pre-post study so one consultation	92 participants were included in this study: 31 participants were placed in the first group in which they received heat therapy for 20 mins 30 people were placed in the second group, in which they received active TENS for 20 mins 31 participants were placed in the last group in which they received heat and TENS for 40 mins	Assessors were not blinded	No control was used for this study	Randomization of participants did take place- although the method of randomization was not stated	4	85%
LIMITATIONS:	The authors do not state a specific inclusion criteria for the study, other than to state that the participants were required to be diagnosed with stage 1 shoulder impingement; without specific orthopedic tests or combination of signs and symptoms (Neer, 1982, Rossi, 1998). Demographic characteristics although comparable between the groups for age, height, weight, and BMI; there are no comparisons for handedness, co-morbid conditions, use of medication and wash out periods for the treatment of the stage one shoulder impingement. To complicate the above, there was also no randomization process noted in this study – although the patients seemed to be comparable at baseline (which the authors mention as a strength of their study), it is unclear whether the factors that most directly impact on the shoulder impingement syndrome were indeed							

	similar. It is assumed that only the pain pressure threshold was taken three times before and three times after the intervention in order to determine the average measures before and after the intervention(s). What is not considered is that the pain pressure threshold dolorimeter may in itself, have been responsible for the phenomenon of “ischemic compression” (Gulick, 2017, da Silva et al., 2020) and inadvertently assisted in improvement in the groups being tested. This may therefore account for the changes in all three groups and there being no significant difference between them at the end of the study. Therefore, assessing the short-term effects of each intervention group (i.e. 24 hours or 48 hours later) would have been beneficial in ensuring that the patients did not simply improve because of chance, but rather because the therapy was effective, resulting in a statistically significant outcome. The study is also subject to bias in that there was no mention of blinding of person screening the patients for inclusion into the study (i.e. there was no concealed allocation), there was no mention that the therapists were different for each of the groups (allowing for therapist bias to be considered, particularly in terms of therapists actions and words suggesting outcome (Jakovljevic, 2014)) and there was no blinding of the assessors recorded in this study. These are significant shortcomings of this study calling into question the outcomes of the study. Lastly the effect of the treatments was not well structured – group 1 – heat application for 20 min; group 2 TENS for 20 min and the last group 3 – heat and TENS were applied for 40 minutes; it is left to the reader to assume that it was 20 minutes for each of the therapies.
OUTCOME:	According to the study, the outcome showed that the TENS group, heat and TENS group + heat group were all equally effective in providing an analgesic effect in patients with stage 1 shoulder impingement syndrome. The combination of heat and TENS as a treatment protocol seemed to reduce pain more than each treatment modality when used individually although this was not statistically significant. In this vein, the authors note in their discussion that most studies do suggest that combination treatment methods have been proven to be much more effective in pain reduction. Even though this may be the case, the effect of combination therapy is dependent on the condition being treated as well as their antagonistic or synergistic effects. As a result, the authors state that this study showed that all three forms of therapy were effective in treating pain in the short term.

DISCUSSION:	Although this study has showed that TENS and heat, used either individually or in combination with each other has been effective in treating shoulder impingement syndrome (stage 1) these results need to be read with caution as: ► there was no mention of more significant co-morbid conditions, medication, handedness and other factors that may affect the outcome of the study. ► the consistency of the screening of participants ► there was no mention of appropriate randomization. ► there was no controlling for various bias' related to the initial participant assessor, the treating person and / or the assessor. ► there is no controlling of autosuggestion and its impact on patient subjective input through the VAS (Javovljevic, 2014) ► study was limited to short-term effects of the treatment. The authors do not state the duration of the study and one assumes that this was simply a pre-test/ post-test assessment of the effects of the therapeutic measures. The interventions (treatment protocol), with concomitant repeated outcome measures could have been repeated more than once (i.e. assumed pre-post measures in this study) with a realistic time period in between treatments and outcome measures (commensurate with the condition), in order to assess the consistency regarding the short-term effects of the treatment on should impingement syndrome. The TENS settings used in this study was stated as being a 100 Hz at 0.1 pulse duration at a tolerable intensity. There was no statement regarding the location of the electrodes in terms of placements and this could indicate a possible lack of homogeneity among patients as electrode placements could have varied and resulted in variation in the results assessing the effectiveness of TENS.
CONCLUSION:	Based on the points outlined under limitations, outcomes and discussion, the article was ranked poorly with an overall agreement percentage of 85% (see Table 4.11). The outcomes of this study favour the use of TENS as a packaged treatment with heat, however due to the multiple factors affecting the validity of this study (inclusion criteria, study duration, lack of blinding), the actual effectiveness of this treatment protocol is questionable at best, which explains the reviewer's agreement in the poor study ranking. Therefore, we can conclude that this study had a low level of rigour with poor clinical outcomes pertaining to the use of TENS in SIS.

Table 4.13: Tabulated feedback data for RCT: Article 6

AUTHOR(S):	Celik
YEAR:	2010
TITLE:	Comparison of the outcomes of two different exercise programs on frozen shoulder

CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	0	1	1	**67%**
5	There was blinding of all subjects	0	1	0	0	**67%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	0	0	1	0	**67%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	0	0	0	0	**100%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	1	1	**100%**
	TOTAL SCORE	**5**	**5**	**6**	**5**	
		OVERALL PERCENTAGE AGREEMENT:				**91%**

Table 4.14: Analysis of Article RCT: Article 6

AUTHOR(S):	Celik
YEAR:	2010
TITLE:	Comparison of the outcomes of two different exercise programs on frozen shoulder

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomization of participants	Ranking	Total Percentage Agreement
Pain measurements were assessed using the Visual Analogue Scale (VAS) Functional results were tested using the modified constant score. Range of motion was assessed using a goniometer	Measurements were taken before the commencement of the study (at baseline), at 6 weeks and at 12 weeks	The duration of the study was 6 weeks, made up of 30 treatment sessions	29 participants were included in this study (22 females and 7 males)	Assessors were not blinded	A control group was used – this included TENS, cold pack, NSAIDS + ROM exercises (without the inclusion of scapulothoracic exercises)	Participants were randomly placed into 1 of 2 groups	5	91%

LIMITATIONS:	The baseline between the two groups seems to have been similar in terms of gender and age (although no *p*=values were given), no report was given in terms of handedness, side involved and treated in the study, co-morbid conditions (other than the diabetes mellitus and thyroid mentioned) and / or associated medications. From Table 1 (Celik, 2010), it is also clear that there was a difference between the groups in terms of primary and secondary adhesive capsulitis (although no *p*=values are noted). Additionally, it is not clear whether there was a wash-out period as a result of treatment outside of the study in order to minimise impact on the study. There is no mention of concealed allocation, intervention administering person being blinded or the assessor being blinded to the group of the participant. This increases the likelihood of bias – whether through the specific allocation of participants to a group, auto-suggestion in respect of the people that the participants interact with and / or the bias of the assessor to a particular group (Torgerson and Torgerson, 2003, Boutron et al., 2019, Jakovljevic, 2014).

	In terms of the interventions, there is limited information in terms of the settings utilized for the TENS, this along with the timing of the measurements in relation to the intervention structure (five weeks of TENS and NSAIDs; six weeks of exercise with measurements only at the baseline, week six and week twelve), it is impossible to determine the impact of the TENS and whether it acted synergistically or antagonistically with the NSAIDS and / or the exercise protocols. A second concern of the treatment protocol is the lack of tracking patient compliance to home exercise therapy. This may skew the results favoring one or another group OR it may indicate that the intervention is actually only due to the TENS, NSAIDS and supervised treatment; therefore, limiting the ability of the study to draw conclusions on the total protocol or the individual therapies included. According to Tables 1 and 3 found in this study (Celik, 2010), it appears that the VAS and ROM scores for both groups were not similar at baseline, with group 2 (the experimental group / secondary adhesive capsulitis) seeming to experience more pain and specifically less motion in internal rotation when compared to the control group. This lack of comparability (which approximates a clinically significant difference for the VAS (Kelly, 2001) and possibly also the internal ROM (Muir et al., 2010), not only indicates that this group was potentially more recalcitrant to treatment on the one side or potentially had the greater chance of improvement on the other hand (Garin, 2014, Oxford, 2020) (as can be seen in Table 1 of this study (Celik, 2010) for the VAS and Table 3 of this study (Celik, 2010) for both outcome measures). This is further compounded by the fact that the intervention strategies are aimed at targeting different clinical outcomes (as their intervention effects are different), it is not possible to actually state that one treatment programme is indeed comprehensively better than the other.
OUTCOME:	This study focuses on the effects of glenohumeral and scapulothoracic exercises in the treatment of frozen shoulder, in addition to a baseline intervention common to both groups, the outcome of the study states that the scapulothoracic exercises in conjunction with glenohumeral exercises contributes significantly to the improvement of joint movement in the frozen shoulder, when in fact both groups improve to a statistically significant degree for the majority of outcome measures.
DISCUSSION:	Therefore, in terms of the study, there are several limitations noted in the: ► Patient homogeneity, condition homogeneity ► Bias in terms of allocation and assessment

	► The specific application of treatment interventions and patient compliance. The above limits the comparability of the two groups as well as the generalizability to the general population. Given these outcomes, and the fact that the smaller group of shoulder impingement syndrome patients within the study were not separately analysed and the specific contribution of the TENS application were not provided; the results of this study cannot provide us with any indication on the effect of TENS in treating those patients with secondary frozen shoulder with type 2 subacromial impingement syndrome. In the context of this systematic review, the participants in this study by Celik (2010) were identified to have shoulder impingement syndrome secondary to adhesive capsulitis (designated as type II subacromial impingement syndrome). This resulted in a small portion of the overall recruited number of patients having shoulder impingement syndrome. Therefore, direct implications of TENS on the shoulder impingement syndrome will be difficult to extrapolate. To complicate this, since TENS was used in both groups (as part of a package of treatment), it is unclear whether the use of TENS alone was effective in treating pain in the shoulder. The use of TENS in this study was not clearly defined in terms of settings. The author states that TENS was used for 20 minutes, however there was no specification regarding the settings, placement and intensity. All these parameters should have been mentioned in order for the reader to be able to apply the findings in clinical practice.
CONCLUSION:	Based on the points outlined under the limitations, outcomes and discussion above, this article was ranked a 5 with a 91% agreement as seen in Table 4.13. The majority consensus regarding reviewer agreement is a direct result of the fact that this study lacked in methodological rigour, which therefore results in the outcomes being questionable and should perhaps be applied in practice with caution. Therefore, we can conclude that this study had poor methodological rigour and poor clinical outcomes (see Table 3.7).

Table 4.15: Tabulated feedback data for RCT: Article 7

AUTHOR(S):	Grymel-Kulesza, Polak, Kubacki, Skrzep-Poloczek and Krol					
YEAR:	2007					
TITLE:	The effect of multi-modality therapy including active exercises, classic massage, cryotherapy and combination of ultrasound and electrical stimulation on rotator cuff injuries					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	0	1	**67%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	0	1	1	**67%**
5	There was blinding of all subjects	0	1	0	0	**67%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	0	0	1	0	**67%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	0	0	1	0	**67%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	0	1	**67%**
	TOTAL SCORE	5	5	5	5	
		OVERALL PERCENTAGE AGREEMENT:				**82%**

Table 4.16: Analysis of Article RCT: Article 7

AUTHOR(S):	Grymel-Kulesza, Polak, Kubacki, Skrzep-Poloczek and Krol
YEAR:	2007
TITLE:	The effect of multi-modality therapy including active exercises, classic massage, cryotherapy and combination if ultrasound and electrical stimulation on rotator cuff injuries

STUDY PROPERTIES

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
Muscle strength was tested using the 5-level Lovett's Scale Muscle damage was assessed using 4 different tests: Jobe's test for the supraspinatus and anterior aspect of the rotator cuff, Test for infraspinatus, test for biceps muscle and test for teres major Humeral joint mobility was assessed with the use of a goniometer with the patient performing 4 movements of the upper limb Assessment of mobility compared the range of the patients arm movements against A. Zembaty's reference values	The study does not state if the patients were assessed at any point other than before and after the therapy was administered	The duration of the study was 6 months – the therapy was performed over a 2-week period with a total of 10 procedures per participant	30 participants, of which 23 were female and 7 were male	Assessors were not blinded	No control was used	Randomization of participants did take place	5	82%

LIMITATIONS:	The study, in its favour includes the handedness of the participants and compares gender, age and average duration of the condition that the participants presented with. They donot however, mention co-morbid conditions, medication and control of previous treatment influencing this

	current study (washout period). These noted favourable and unfavourable inclusions of participants is confounded by the lack of specific inclusion criteria for the participants (although some exclusions are listed). This precludes identifying the stage or degree of the pathogenesis and an inability to understand the homogeneity of the participants in terms of the shoulder complex changes (physiological and anatomical) and therefore the interpretation of results from these participants. This does not specifically allow the reader to understand to what extent shoulder impingement syndromes were included in the groups and whether this was equitable. From a point of view of bias, there is no indication that the person assessing the participants for inclusion applied concealed allocation processes in order to determine how the participants were practically allocated to the respective groups. Additionally, the article does not provide information on whether the assessor of the participants was blinded to the group allocations. One factor in favour of the study includes the fact that all the outcome measures are objective in nature and therefore limits the patient's subjective input into their improvements. This decreases the bias related to patient perception, even that which is possible from auto-suggestion activities / interactions with unblinded assessors and therapists. But it does not exclude the possibility that unblended assessors may have influenced the objective outcomes taken. Assessment of the range of motion of the shoulder does not provide specificity as the rotator cuff muscles perform a variety of synergistic movements that work in combination with other muscles surrounding the shoulder girdle. Therefore, using the range of motion as an outcome measure does not provide a high level of specificity and is therefore not an appropriate outcome measurement. Due to the use of ultrasound and electrical stimulation, deeper muscles would be affected, as compared to cryotherapy in which superficial muscles would only be able to benefit. The use of a combination of therapy with only the use of massage and exercise (non weight bearing and self assisted), as well as TENS / ultrasound or cryotherapy, means that the study can technically only comment on the comparison between TENS / ultrasound and cryotherapy. However, even this commentary is limited by the inability to determine the synergistic or antagonistic relationship between ultrasound and TENS. This paired treatment does not afford the ability to understand the effect on the shoulder of each modality as their effects are different combined and singularly in comparison to cryotherapy. The study does not state the exact point in time that remeasurements were taken after the treatment; causing one to assume it was a pre-test/post-test assessment, which would restrict the study to the immediate effects of electrical stimulation. At baseline, the average duration

	that most participants experienced their symptoms were 4.6 months, meaning that their condition falls under the category of “subacute”, in which these patients would most likely require more follow-up assessments and treatments to show progress and the long-term effectiveness of the treatment modalities that were undertaken in this study (Ucurum et al., 2018), for full impact of the intervention to be realistically assessed. During the assessment, it should be noted that at baseline, passive abduction in Group B was 8 degrees less than that of Group A. This may have been the reason for the result in Group A showing greater improvement than that of Group B (due to the ceiling effect) (Garin, 2014). From the tables of results provided the study only seems to provide information and *p*-values for the change over time within each of the groups, but does not supply a comparison of the changes between the groups and therefore if one group improved significantly over the other group. Furthermore, the statistical improvements within the groups are not linked to the clinically minimally significant difference for each of the outcome measures, so in the absence of the group comparisons, it is also not possible to tell whether there was a clinically significant change in one group versus the other group. This therefore leaves the reader hanging in terms of the actual applicability of the outcomes in clinical practice either in terms of the comparison between the groups or where both show improvement, which has the greater clinical outcomes (with the exception that the cryotherapy group seemed to have not change in terms of night pain). In terms of the small sample size, the use of non-parametric statistics, makes the conclusions drawn in the study weaker, making it difficult to extrapolate to a more general population.
OUTCOME:	According to the study, the researchers stated that they found that a therapy that comprises of the use of combined ultrasound and electric current, active exercises and classic massage or combined cryotherapy, and classic massage is effective in treating rotator cuff injuries. Although there was no control group, it was suggested that the inclusion of the combination treatment was noted as being the key factor in improving muscle strength and movement in rotator cuff injuries as was presented by the results represented in Group A (ultrasound and electric current group) statistics.
DISCUSSION:	This is a good preliminary study that starts to explore the options possible in combination therapy, however the lack of specificity in the diagnosis of the patients, the lack of specific inclusion criteria and the potential lack of homogeneity between the groups (in terms of patients

	and in terms of the physiological effects of the interventions), does not provide information that allows the reader to generalize the study to any one population group(s) and does not allow a comprehensive understanding of when the combination therapy should be used and when (or if) this is better than a single therapeutic intervention (i.e. an application of any one of the modalities utilized in the treatment programme(s)). Thus with the significant amount of uncontrolled for variables within this study, its outcomes, although statistically significant for immediate and short term effect of treatment, can only be accepted with caution, given that the clinical effectiveness and efficacy of the treatment programme has limits in terms of applicability, generalisability and statistical power limiting interpretation. TENS was used at a frequency of 100 Hz, however there was no statement regarding the location and placement of electrodes on the shoulder.
CONCLUSION:	Due to the points mentioned above in the limitations and discussion of the article, this article has been ranked a 5 out of a possible 11 (see Table 4.15). Due to the lack of homogeneity among participants in this study, the outcomes cannot be applied with certainty to any specific population group and the long-lasting effects of the outcomes presented in this study have not been researched to know whether the interventions used would provide long-lasting relief. The use of TENS in this study was studied as part of a combination treatment and therefore, the effectiveness of the modality on its own is unclear. This study has poor methodological rigour based on a poorly structured study and poor clinical outcomes (Table 3.7).

Table 4.17: Tabulated feedback data for RCT: Article 9

AUTHOR(S):	Kocyigit, Akalin, Gezer, Orbay, Kocyigit and Ada					
YEAR:	2012					
TITLE:	Functional magnetic resonance imaging of the effects of low-frequency transcutaneous electrical nerve stimulation on central pain modulation: A double-blind, placebo-controlled trial					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	1	0	**67%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	1	1	**100%**
5	There was blinding of all subjects	1	1	1	1	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	1	1	1	1	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	1	1	1	1	**100%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	0	1	1	1	**67%**
11	The study provides both point measures and measures of variability for at least one key outcome	0	1	0	0	**67%**
	TOTAL SCORE	**7**	**9**	**9**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**91%**

Table 4.18: Analysis of Article RCT: Article 9

AUTHOR(S):	Kocyigit, Akalin, Gezer, Orbay, Kocyigit and Ada
YEAR:	2012
TITLE:	Functional magnetic resonance imaging of the effects of low-frequency transcutaneous electrical nerve stimulation on central pain modulation: A double-blind, placebo-controlled trial

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
FMRI pain measurements were assessed using the Visual Analogue Scale (VAS) Pain perception: 10 central areas of the brain that have been identified as having a connection to pain perception was analyzed bilaterally on fMRI	Pre-treatment and Post-treatment assessment were used for this study	The study does not state the duration	20 participants were included in this study who were divided into 2 groups of 10	Assessors were blinded in this study	A control group in the form of sham-TENS was used	Participants were randomized	8	91%

LIMITATIONS:	The demographical assessment at baseline indicates that the groups were not similar regarding the duration of their symptoms as well as the intensity of their pain. There was a small sample size included in this study (20 participants divided into 2 groups of 10 each) which led to the use of non-parametric statistics, which has a lack of power as compared to parametric statistics. There was a lack of homogeneity in each group as the low-frequency TENS group had participants with ages ranging from 45 to 55 years old, while the sham TENS group had participants between the ages of 24 and 64 years of age. The recruited age group was 25-65 years of age, which would indicate a wide age gap among participants, resulting in varying stages and causes of impingement, according to Neer's stages of impingement (see Chapter two, section 2.6.2) being included in this study. The authors do not state the type or cause of impingement in each participant included in this study either. The inclusion of participants from the age of 45 years and older indicates the possibility of comorbidities being present (Davis et al., 2011). The researchers do not indicate whether

	any co-morbidities were present among patients and if they were medicated for it, however they do state that they ruled out any conditions and medication intake that may interfere with the study design and be a contraindication for the use of TENS. Other noteworthy aspects of this study's design are the fact that every possible measure was taken in order to ensure that blinding of participants to their respective groups was upheld. These measures included omitting participants who were familiar with TENS therapy and using a device with an activator light for both groups. Randomization was conducted in an objective manner, allowing for blinding of assessors to participants of each group, preventing selection bias from occurring in this study (Attia, 2005). The researchers also did note the dominance of the affected arms in this study. In terms of the results anddue to the lack of homogeneity at baseline regarding the type of impingement and age group among both groups, Group 2 showed a significantly higher increase in both these categories as compared to Group 1. However, extra precaution was taken to ensure blinding was upheld. The difference in VAS scores brings into question whether the use of low frequency TENS would have been effective on patients with a higher baseline VAS score.
OUTCOME:	The outcome of this study indicated that one treatment of low-frequency TENS can result in a decrease in pain levels through the modulation of discriminative, affective and motor pathways regarding central pain perception.
DISCUSSION:	This was the first time that fMRI was used to assess the analgesic effect of TENS on the brain in patients with shoulder impingement syndrome. This study indicates that TENS is an effective form of treatment in managing the pain aspect of SIS as was represented on the MRI. An assessment should have been redone on a group of patients with a higher VAS score in order to assess whether severity of pain affects the effectiveness of the TENS in modulating the pain pathways within the brain. The limitations of the study question the true effectiveness of the low-frequency TENS as there was a lack of homogeneity among participants per group and overall. There was no indication of the type or stage of impingement (see Chapter two, section 2.7.2 and 2.7.3), which would result in variance in healing time and response to treatment. Furthermore, the authors do not state the location of electrodes and the consistency of placement among participants, which is an important parameter to deduce the effectiveness of TENS (see Chapter two, section 2.8.3).

	Although the study had favourable results pertaining to the use of low-frequency TENS in the reduction of pain in SIS, there were many factors amiss that could have either negatively impacted the results such as electrode placement, or exaggerated the results, such as the variance in the included age group.
CONCLUSION:	This study was well-designed, taking into consideration important factors that could have negatively impacted the results of the study such as blinding of participants and objective randomization. However, there are many factors that were not taken into consideration such as homogeneity among participants' age group and impingement type. Therefore, this study was ranked an 8 out of a possible 11 due to the well-executed study protocol, but it is limited in application as important parameters pertaining to TENS were not considered in this study. This study, therefore, has a high level of methodological rigour but poor clinical outcomes that limits its use in clinical practice (see Table 3.7).

Table 4.19: Tabulated feedback data for RCT: Article 10

AUTHOR(S):	Koo, Lin, Wang, Tsauo, Yang, Yen and Biswal					
YEAR:	2015					
TITLE:	Novel noxipoint therapy versus conventional physical therapy for chronic neck and shoulder pain: Multicentre randomized controlled trials					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	1	1	1	1	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	0	1	**67%**
5	There was blinding of all subjects	1	1	1	1	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	1	1	1	1	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	1	1	1	1	**100%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	1	1	**100%**
	TOTAL SCORE	**10**	**10**	**9**	**10**	
		OVERALL PERCENTAGE AGREEMENT:				**97%**

Table 4.20: Analysis of Article RCT: Article 10

AUTHOR(S):	Koo, Lin, Wang, Tsauo, Yang, Yen and Biswal							
YEAR:	2015							
TITLE:	Novel noxipoint therapy versus conventional physical therapy for chronic neck and shoulder pain: Multicentre randomized controlled trials							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomization of participants**	**Ranking**	**Total Percentage Agreement**
Pain, functional impairment and quality of life: All of these outcomes were assessed using the Basic Pain Inventory Short form (BPI- SF) **Range of motion (Kronberg et al.):** A goniometer was used to assess the participants change in ROM	Measurements were taken at: 1. Baseline 2. Before and after each individual treatment 3. 4 weeks after final treatment 4. 4 months after final treatment session on random patients	The intervention of this study in Study One was 3 sessions of 90mins a session. Study Two had a maximum of 6 sessions at 90 mins per session	The number of participants included in Study One was 34 Study Two had 44 participants included in the study at baseline Follow-ups were conducted 8 weeks after baseline and 4 months later on randomly selected patients	Assessors and patients were blinded in this study	A control was used in the study, named PT-TENS The control treatment comprised of TENS, infrared therapy, manual therapy and range of motion exercises	Randomization of participants took place by means of a compute-r generated sequence	10	97%
LIMITATIONS:	This study assesses the effect of Novel noxipoint therapy (NT) on patients suffering with chronic neck and shoulder pain. This study by Koo et al., (2015) included three different studies, Study one which focused on patients with chronic shoulder and neck pain, Study two, which focused on chronic neck pain only and Study three, which looked at animal testing. The focus of this review was solely on Study One, as Study Two did not include shoulder pain patients and Study Three included the use of animal testing, which falls under the exclusion criteria of this study (see Chapter Three, Section 3.3.4 and 3.3.5). Although an eligibility criterion was stated, it was not specific regarding each area of assessment. The demographic age group included in this								

	study was wide (18-64 years of age), creating a possible lack of homogeneity among participants. The conditions included in this study for both the neck and the shoulder varied as the authors stated that most participants had an idiopathic diagnosis of neck or shoulder pain at baseline. However, patients with comorbidities were included in both the shoulder and neck pain categories, and the authors do not state the type of comorbidities included and the medications taken by patients to manage such conditions. This would limit the readers understanding of the effectiveness of the interventions and their interactions with various comorbidities and associated medications. There was also an uneven distribution of shoulder pain and neck pain patients between the study arms in Study One, with the NT arm having 25% of patients with shoulder pain, which translated into 6 patients and the PT-TENS arm having only 20% of shoulder pain patients included, which translated to only 2 patients. This indicates that the number of shoulder pain patients in each arm in study one was not similar at baseline and may confound the results, as a smaller sample size can be easily influenced by individual factors lending to the possible presence of outliers skewing the results (Frost, 2020b). The lack of a defined inclusion criterion resulted in majority of patients having idiopathic causes of pain, along with the inclusion of patients who have experienced a significant traumatic injury in the past or are currently suffering with degenerative joint disease. Due to the poorly defined inclusion criteria, there is a lack of clarity regarding the type of shoulder pain conditions that were included in this study, which shoulder was the affected arm, whether the dominant arm was affected and if impingement was present, the type and stage of impingement that was included. This creates uncertainty as to whether these interventions would effectively treat SIS. Regarding all the included patients, their occupationand method of recruitment was not indicated. Due to the lack of homogeneity among participants in both arms of study one, each participant's response to treatment would vary, based of their etiology of pain. This would indicate that some participants may respond quicker to the treatment in comparison to others who's conditions are worse, resulting in the floor effect (Oxford, 2020). Taking the above into consideration, the lack of homogeneity and target population makes the application of the outcomes from this study questionable. Patients were required to have been heavily pre-treated for their respective conditions, prior to inclusion into this study – this was to assess the effect of NT and PT-TENS on patients with chronic conditions that were previously managed unsuccessfully. The objective of this study was to indicate whether NT and PT-TENS, acting as non-pharmacological analgesics, provided effective pain relief, improved function and a greater quality of life in a manner that was non-invasive. Due to the chronic nature of conditions included in this study, the outcome measures would have required a long period of time to be assessed, as compared to a hypothetical situation in which acute patients were included. Therefore, this study is biased towards patients who have been treated before and does not consider the effect of the therapy on patients who have not

	been treated for their conditions before. There is also a lack of a washout period from previous treatments which would have ensured that there was no overlap in treatment and management of the included conditions. These further questions the credibility of the intervention as a wash-out period would have ensured that, although the patients included were heavily dosed, their previous treatments would not have impacted on the rate of healing of the NT and PT-TENS. At baseline, it was also noted that the groups in Study one differed in terms of the accumulated functional impairment scores that they presented with. The NT group had a higher level of dysfunctional impairment as compared to the PT-TENS group, which would affect how effective the treatment would appear to be between the two groups. The NT group had a collective score of 10.8, while the PT-TENS group had a collective score of 5.2, which is almost a 50% difference between the groups. The result found at post-test for this outcome would not be a true comparison due to the discrepancy between the groups at baseline. There was a difference in sample size between both the studies, with Study one having 34 participants at baseline in the USA, whilst Study two in Taiwan had 44 participants divided almost equally into the 2 arms. At post-test, due to the option of a crossover in this study, the participants were able to change the treatments that they received. The 4-week washout period was negated in the study since the participants were in extreme pain and felt that the PT-TENS group did not provide pain relief. This crossover in the study was done prior to allocated crossover period, before the last PT-TENS treatment was to be carried out, which resulted in a reduced number in the PT-TENS group. At baseline, the NT group had 24 participants while the PT-TENS group had 10. The sample size was unequal and small in the PT-TENS group, which indicates that the authors did not accommodate the possibility of dropouts prior to the commencement of the study. This would affect the statistical findings regarding the outcomes, as a smaller sample size had a greater chance of exaggerating a positive/negative effect of a treatment and dropouts could skew the data. Another concern pertaining to this study, is that NT therapy was compared to an existing treatment plan. The problem with this, is that patients who were heavily treated prior to the commencement of this study would have been familiar to the effects of the PT-TENS and therefore may have already had previous negative experiences with the therapy, biasing the effectiveness of the PT-TENS and exaggerating the effects of NT therapy. This would result in self-reporting bias among participants that may skew the statistical data, leading to incorrect outcomes (Althubaiti, 2016). This study included the intention to treat principle to measure impact of treatment post-baseline from all participants that were included in the

	study. This was conducted as a last observation carried forward (LOCF) assessment of the data, however research has shown that this principle affects the treatment effect as it provides a biased outcome of the results. This principle does not take into consideration the effect the treatment had on the patient prior to their dropout, which provides a generalized assessment of the outcome, which is optimistically significant and biased, as it assumes that the patient has the same change in outcome as prior to the application of the intention to treat principle. This means that plateauing of the outcomes is not accounted for and expressed an overly optimistic outcome (Salim et al., 2008). This does not provide a valuable effect to the results presented in a study using this principle (Molnar et al., 2008). The researchers should have included a greater sample size in order to account for the potentially high drop-out rates. The inclusion of TENS with infrared, exercise therapy, manual therapy, and range of motion exercises, limits our knowledge on the effectiveness of the individual modalities in treating shoulder pain. The authors did not separate the neck and shoulder pain results in this study and therefore our knowledge on the effectiveness of the control group regarding shoulder pain is limited. The authors did state that they did not take into consideration the settings for the TENS due to the literature being limited on its effectiveness. However, the frequency settings were set to be constant per study i.e 80-100Hz for Study two and 10-90Hz for Study one. The authors do however state later on that both the frequency and intensity of the TENS machine were set to patient comfort. The frequency of TENS does affect pain outcomes as different frequencies affect the body differently (Vance et al., 2014b) (see Chapter Two, section 2.8.1). The use of high frequency TENS in Study two would have had different effects in comparison to the use of low frequency TENS in Study one. The authors also mentioned that the TENS intensity settings would have differed according to patient, when a lack of progress was observed by the therapist conducting the treatment – so it appears that there was a lack of consistency regarding the settings on the TENS machine. The follow-up period at 4-months was conducted on random patients, so it can only reflect the 2nd treatment interventions on top of the first. Post treatment randomly assessed patients from the NT group. This group included patients who crossed over from the PT-TENS group at 4-weeks, and randomly selecting them would further skew the results as there would be irregularities amongst participants due to the different lengths of treatments that they received. With regard to cultural differences, Study one and Study two were conducted on two different continents (USA and China) with differing views on pain perception and functional impairments. The study relied on patient feedback in order to assess the effectiveness of the interventions. Culturally, each group would have different points of view on pain and pain management. In China, it is common to find patients experiencing

	extreme levels of pain in silence, based on their belief systems. Many Chinese patients refuse to take any form of medications based on their religious beliefs of needing to endure pain in silence, or avoiding potential addiction to medication (Tung and Li, 2015). Therefore, these patients, were they included in the study, would have under-reported their pain levels or the effectiveness of the treatment due to their own beliefs, which could have further resulted in self-reporting bias, unlike that of American patients (Althubaiti, 2016).
OUTCOME:	The conclusion of findings in this study states that NT greatly reduced chronic pain in neck and shoulder patients, while simultaneously restoring function and improving quality of life in these patients over a long-term period.
DISCUSSION:	Based on the limitations of this study, the lack of homogeneity between participants and their conditions affects the outcome of this study. This is due to the small sample size, the poorly defined inclusion criteria and the lack of clarity of the included conditions and progression of disease each participant was at, at baseline of this study. There was greater variation among groups due to the differing levels of pain experienced by each participant, therefore one participant would have responded much quicker to the treatment as compared to someone with a greater degree of pain. The authors did not specify the type of neck and shoulder pathologies that were included in this study and this contributed to the different response rate to the therapy. The outcome is not substantiated by evidence (Heneghan et al., 2017) regarding the type of conditions that the patients who responded favorably were experiencing. It does not state how effective the treatment was in managing neck pain versus shoulder pain, or the types of shoulder pain that was included. Although the outcomes were favorable, the study design and the information provided does not provide adequate information in order to apply this technique in an evidenced based practice setting. The use of TENS as a treatment method was limited by the variation of settings among participants. The authors did not state the location of electrodes, stating only that general areas were used as sites for placement and the frequency varied among both study groups. TENS was used as a combination treatment and this further makes it difficult to deduce the impact of TENS alone in treating both shoulder and neck pain in Study one. The use of TENS was limited based on the abovementioned points. Keeping the frequency and electrode placement consistent is a key factor in identifying the effectiveness of TENS as an electrical modality (see Chapter two, section 2.8.2 and 2.8.3), therefore the outcome found in this

	study is limited in its benefit due to the omission of important data related to the inclusion of patients and types of disease and injury that they are dealing with. The lack of consistency with the use of TENS does not allow the reader to deduce a positive result regarding the application of TENS in shoulder and neck pain and therefore this study has concluded that TENS does not provide adequate pain relief as part of a packaged treatment, making it an unfavourable choice of modality.
CONCLUSION:	Although the study design covered important criteria required for an RCT to be classified as a high quality study, which would equate to a 10/11 points on the PEDro scale (see Table 4.19) with a 97% agreement among reviewers, it lacked in important aspects that would have been relevant for this systematic review. The lack of adequate information and consistency pertaining to the use of TENS and the limited knowledge regarding the type of shoulder conditions included in this study makes the relevance of this study regarding TENS in the management of SIS almost irrelevant as one cannot make a statement regarding the effectiveness of TENS in SIS, as the shoulder pain specifications were not disclosed in the inclusion criteria. The outcomes of this study may favor the use of Novel-noxipoint therapy but due to the limited knowledge on the target population at baseline and the wide age group that was included in this study, the application of the outcome is limited in its benefit. This leads to the conclusion that the methodological rigour of the study was of a high quality, however the clinical outcomes are poor in terms of its application (see Table 3.7).

Table 4.21: Tabulated feedback data for RCT: Article 11

AUTHOR(S):	Korkmaz, Capaci, Eyigor and Eyigor					
YEAR:	2010					
TITLE:	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: a prospective, randomized study					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	0	1	**67%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	1	1	**100%**
5	There was blinding of all subjects	0	0	0	0	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	1	1	1	1	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	1	1	1	1	**100%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	1	1	**100%**
	TOTAL SCORE	**8**	**8**	**7**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**97%**

Table 4.22: Analysis of Article RCT: Article 11

AUTHOR(S):	Korkmaz, Capaci, Eyigor and Eyigor
YEAR:	2010
TITLE:	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: a prospective, randomized study

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
Pain assessment was measured using the Visual Analogue Scale (VAS) Range of motion was tested using a goniometer Disability was assessed using the Shoulder Pain and Disability Index (SPADI) Quality of Life was assessed using the Short Form 36	Measurements were taken at baseline, at week 1, 4 and 12 post treatment	The duration of the study was 12 weeks	40 participants were included in this study and were randomly divided into 2 groups; 20 in a group receiving pulsed radiofrequency and exercise interventions 20 participants in a group receiving TENS and an exercise intervention	Assessors were blinded in this study	No control group was used for this study	Randomization of participants occurred	8	97%

LIMITATIONS:	Notwithstanding the positive points in this study, which include blinding of the assessors, appropriate randomization of patients (although the technique was not fully described), a well-defined exclusion criteria, and mention of shoulder dominance, the limitation of this study is that it does not state a specified inclusion criterion. This lack of inclusion criteria calls into question whether all participants were equal at baseline. The study included patients that had shoulder pain as a result of partial tears of the supraspinatus tendon, supraspinatus tendon and acromioclavicular joint osteoarthritis. These variations in etiologies of shoulder pain may affect the results of each group as the authors do not state results pertaining to patients with individual conditions, which may indicate that one cause of shoulder pain may have responded more or

	less favourably to each of the treatment interventions as compared to another. This creates a lack of homogeneity among groups. The distribution of each shoulder condition was mostly equal with the exception being acromioclavicular joint osteoarthritis having only one participant in the TENS group and none in the pulsed radiofrequency group, further contributing to the lack of homogeneity Shoulder pain at baseline was generalized to three specific diagnoses: suprascapular tendinopathy, acromioclavicular osteoarthritis and partial tears of the supraspinatus tendon. The average duration of symptoms related to the above pathology was 8 months for patients in the TENS group and 10 months for patients placed in the pulsed radiofrequency group. Since the inclusion of patients indicated that symptom duration of a minimum of three months was included, the patients in this study would have ranged from subacute to chronic, which would indicate that each category of pathology may have responded differently to the treatment as the subacute patients would improve at a faster rate as compared to the chronic patients (Chanda et al., 2011). Provision of the consort was good and showed that the authors had utilized the CONSORT (Schulz et al., 2010) as a basis for the structure of their study, however the lack of homogeneity in the pathology in terms of chronicity and the differences in passive IR and active ER (which may be significant at baseline but are not reported on) have significant implications for the outcomes of the study and therefore its generalizability and application in clinical practice as a practitioner using this study as guideline would be unaware which shoulder condition experienced the greatest loss of motion.The MCID for the SF-36 o.61, which further indicates that there was a lack of homogeneity at baseline (Strand et al., 2008).
OUTCOME:	The researchers on this study have found that there was no difference between the use of TENS and pulsed radiofrequency in the treatment of shoulder pain. The impact of the limitations is that the target population was not homogenous at baseline and therefore would have responded at variable rates to the treatment interventions included in this study. Had the researchers kept their target population to one specific shoulder condition, the homogeneity between groups would have contributed favourably towards the application of outcomes in clinical practice. However, it is not possible to apply these outcomes to patients with the three aforementioned etiologies that were included in this study as we are unaware which etiology of shoulder pain benefitted most from the two interventions.

DISCUSSION:	The rigour of this study was good as it had randomly allocated participants into 2 groups, with no dropout numbers. The study had also indicated that assessors were blinded to the treatment protocols which prevented any form of bias from occurring. Researchers also used both point and variability measurements to assess the short- and long-term effects of both interventions, which is useful when treating patients with chronic painful shoulder symptoms. Since shoulder impingement was not a prime focus of this study (although such patients were included), it was not possible to deduce whether the use of TENS on the patients that had been diagnosed with suprascapular tendinopathy benefitted more than those suffering with partial tears of the supraspinatus tendon or acromioclavicular osteoarthritis. We are also unaware of the etiology behind the suprascapular tendinopathy and cannot assume that impingement was the sole cause of the tendinopathy. The study should have stated a detailed inclusion criterion apart from mentioning ultrasonography and X-rays being used in order to better provide the reader with more detail regarding what the researchers considered to fall under the umbrella term of “painful shoulder”. The authors were consistent in their use of TENS on each patient as the frequency was set at a 100Hz which is indicative of conventional TENS settings. Electrodes were said to be placed on the anterior and posterior aspect of the shoulder joint, but they do not state which muscles were being stimulated and this could have therefore varied among participants based on factors such as their posture, height, weight, etc. However, the consistency with regards to the settings of the HF-TENS was a favourable aspect of this study, as well as the consistency that was kept when using the pulsed radiofrequency.
CONCLUSION:	To conclude, the study did have multiple favourable aspects however the heterogeneity of the participants included in this study could have negatively altered the results. Each shoulder pain condition included in this study could have varied in intensity and since the authors state that the minimum requirement for inclusion into this study was pain present for a minimum of three months, there was a mixture of subacute and chronic patients, meaning that each individual could have reacted differently to the treatment (Chanda et al., 2011). The study protocol was favourable apart from the lack of a well-defined inclusion criteria and that is why this study was rated an 8 out of a possible 11 on the PEDro scale. The use of TENS in this study produced favourable results based on the parameters that were taken into consideration during the application of TENS on participants. However, it can be concluded that TENS has a favourable effect on shoulder pain, but it is unclear as to whether SIS solely, would respond the same way. This study has therefore been identified as having a high level of methodological rigour with

	good clinical outcomes, making it a good, rigorous study (see Table 3.7).

Table 4.23: Tabulated feedback data for RCT: Article 12

AUTHOR(S):	Lin, Chiu, Shih, Lee, Li, Guo, Luo and Pang					
YEAR:	2019					
TITLE:	Two transcutaneous stimulation techniques in shoulder pain: Transcutaneous pulsed radiofrequency (TPRF) versus Transcutaneous electrical nerve stimulation (TENS): A comparative pilot study					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	1	1	1	1	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	1	1	**100%**
5	There was blinding of all subjects	1	1	1	1	**100%**
6	There was blinding of all therapists who administered the therapy	1	1	1	1	**100%**
7	There was blinding of all assessors who measured at least one key outcome	1	1	1	1	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	1	1	1	1	**100%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	1	1	**100%**
	TOTAL SCORE	**11**	**11**	**11**	**11**	
		OVERALL PERCENTAGE AGREEMENT:				**100%**

Table 4.24: Analysis of Article RCT: Article 12

AUTHOR(S):	Lin, Chiu, Shih, Lee, Li, Guo, Luo and Pang							
YEAR:	2019							
TITLE:	Two transcutaneous stimulation techniques in shoulder pain: Transcutaneous pulsed radiofrequency (TPRF) versus Transcutaneous electrical nerve stimulation (TENS): A comparative pilot study							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomisation of participants**	**Ranking**	**Total Percentage Agreement**
3 assessment questionnaires were to be completed: 1. The first questionnaire was based on the treatment comfort level and that was to be filled after the treatment 2. The second questionnaire was the Constant-Murley Shoulder (CMS) score 3. The third questionnaire was the PEG score (pain, enjoyment of life and general activity score)	Measurements were taken at baseline, post-test, after week 1, after 1-month post-therapy and again at 3 months post-therapy	The duration of this study was 3 months	50 people participated in this study and were randomly allocated to 2 groups; 25 participants were allocated to the TENS group and 25 participants were allocated to the TPRF group	There was blinding of both assessors and patients in this study	No control group was used for this study	Participants were randomized and allocation was concealed	11	100%
LIMITATIONS:	A positive aspect of this study is that it utilized the CONSORT flow diagram (Schulz et al., 2010) to report the study and formulate the basis for the design of the study, which improves the rigour of the study. However, limitations in this instance often relate to the patients that are admitted and the measurement outcomes used to measure improvement.							

	One of the limitations of this study is that there is possible heterogeneity among the two groups. The age gap of 25-65 years of age indicates that there are possible variations regarding health status and presence of possible comorbidities that were not mentioned in this study. There is a possibility that some patients may have been experiencing subacute symptoms while the older population may be prone to experiencing chronic symptoms which would react differently to the treatment intervention, especially the reaction time regarding healing (Chanda et al., 2011); especially since the inclusion criteria stated a history of shoulder pain for a period of more than three months. In this case some patients could have been experiencing pain for years in comparison to a person experiencing pain for three to six months, contributing to the lack of homogeneity in the study. The authors do not state whether there was stratification of patients with varying pain durations in each group either. The authors do not state which arm was affected and whether the dominant shoulder was affected more than the non-dominant shoulder. With regards to the tendinitis included, they do not state what caused the tendonitis, although tendonitis of the shoulder is often associated with SIS. The inclusion stated that participants were included if they were on medications apart from non-opioid medication. They do not further state how they worked to ensure that there was no overlap between the medication and the effect of the interventions of the study nor do they state if they had tracked and recorded the use of these medications during the study. There is no mention as to whether the participants were asked to stop taking their medication either. If this factor was not controlled, then the results from the study would most likely be affected by the influence of the medication that the patients were on. The lack of control regarding the use of medication during this study would result in the medication largely influencing the perception of pain when used with the respective interventions. This could have therefore impacted and influenced the subjective outcomes of this study. Another limitation of this study is that the outcomes that were assessed were purely subjective, with the use of three different questionnaires. This limits the understanding of the effectiveness of treatment as lack of patient naivety could have influenced the results if the patients had been exposed to either of the treatments prior to being included in the study – this could possibly result in performance bias (Torgerson and Torgerson, 2003) which may lead to reporting bias from participants when filling out the questionnaires (Boutron et al., 2019). The study does not assess range of motion or shoulder disability and focuses primarily on the pain reduction factor as well as on the improvement of activities of daily living. This subjective assessment limits the focus of this study and does not provide the reader with details on whether the use of TENS or TPRF aids in muscle functioning and range of motion from an objective standpoint. The focus of pain alleviation is dependent on a patient's pain tolerance level and therefore does not provide a concrete ground for comparison to the general public. Lastly, the

	focus of this study is solely on patients with chronic shoulder tendonitis and does not therefore indicate whether the treatment would be effective on patients with acute shoulder tendonitis, thus generalizability is limited.
OUTCOME:	The authors of this study have concluded that both TENS and TPRF are safe and effective to use in the treatment of shoulder pain. The effect of TPRF was stated as being greater than that of TENS; however, the superiority of TPRF over TENS tends to diminish over time. The difference between the two interventions was noted to be statistically significant based on the PEG and CMS scores as these indicated a greater improvement from TPRF over TENS.
DISCUSSION:	The study appears to have only subjective key outcomes and no objective outcomes. Subjectivity in research can be influenced by various factors, with one of the biggest factors being patient naivety (Torgerson and Torgerson, 2003). The study did not state that the patients had never experienced this form of therapy before, and if they did, they would have been able to predict the outcome based on previous experience. The study should have assessed a key objective outcome such as range of motion to ensure that the treatment was effective both objectively and subjectively to prevent any form of bias affecting all the results pertaining to the outcomes of the study. With regards to the use of TENS in this study, consistency was upheld regarding the settings as conventional TENS settings were used with a high frequency of 150 Hz, which stimulates both the skin and muscle as stated by the authors. However, the authors located a maximally tender region on the shoulder on each patient for the placement of the first electrode. This would have varied between participants and therefore reduces the possibility of studying the collective effect of TENS in a group setting. The second electrode was mentioned to have been randomly placed on an area inferior to the deltoid muscle insertion on the same shoulder. The lack of consistency of the placement of the TENS among the group participants means that there was no consistency and adherence to the stipulated parameters (see Chapter two, section 2.8.1) required to achieve an effectively positive result from the use of TENS.
CONCLUSION:	The study design formulated for this research was of a high standard and received the highest possible ranking of 11 on the PEDro scale, with a 100% agreement among reviewers (see Table 4.23). However the limitations of this study indicate that the outcomes may have been influenced by potential bias (performance and reporting bias) which could have resulted in possible exaggeration of results regarding TPRF over TENS, since TENS is a commonly used and easily accessible device (Searle et al., 2009) that the patients could have been exposed to

	prior to the commencement of the study. The variation in electrode placement among participants of the TENS group could have also affected the collective outcome of TENS in the TENS group. Along with the fact that SIS was not mentioned as a specific included etiology in this study, we cannot state that TENS was effective in reducing pain relating to SIS in this study. This study demonstrated a well-structured study protocol based on the results in the PEDro scale in Table 4.23, leading to a high methodological rigour. However, this study demonstrated poor clinical outcomes due to the limitations found pertaining to TENS and SIS.

Table 4.25: Tabulated feedback data for RCT: Article 13

AUTHOR(S):	Moezy, Sepehrifar and Dodaran					
YEAR:	2014					
TITLE:	The effects of scapular stabilization-based exercise therapy on pain, posture, flexibility and shoulder mobility in patients with shoulder impingement syndrome: a controlled randomized trial					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	1	1	**100%**
5	There was blinding of all subjects	1	1	1	1	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	1	0	**67%**
7	There was blinding of all assessors who measured at least one key outcome	1	1	1	1	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	1	1	1	1	**100%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	0	1	**67%**
	TOTAL SCORE	**9**	**9**	**9**	**9**	
		OVERALL PERCENTAGE AGREEMENT:				**94%**

Table 4.26: Analysis of Article RCT: Article 13

AUTHOR(S):	Moezy, Sepehrifar and Dodaran
YEAR:	2014
TITLE:	The effects of scapular stabilization based exercise therapy on pain, posture, flexibility and shoulder mobility in patients with shoulder impingement syndrome: a controlled randomized trial

STUDY PROPERTIES:

Form of measurement	Frequency of measurement	Duration of study	Number of participants	Assessors blinded	Control used	Randomisation of participants	Ranking	Total Percentage Agreement
Pain: Participants were asked to rate their pain according to the Visual Analogue Scale (VAS) **Shoulder Range of Motion**: Active shoulder motion in external rotation and abduction were assessed in both shoulders of participants **Forward Head Posture**: Lateral photograph of the cervicothoracic region was taken using a Canon camera **Mid-thoracic curve**: A flexi-ruler was placed at T2 to T12 and the curve was transferred to a blank	The study was a pre-test/ post-test design and the assumption is that measurements were taken at baseline and after 6 weeks of treatments (3 treatments per week for 6 weeks) However, the authors do not state clearly what the frequency of measurement is apart from being a pre-test and post-test assessment	The duration was 6 weeks	According to Flowchat 1, 72 participants were initially randomized into 2 groups, after drop-out numbers were removed, the final number of participants were 68. 33 people were allocated into the exercise group and 35 people were placed into the physical therapy group	Assessors were blinded in this study	No control group was used in this study	Randomization of participants took place with the use of a random number table and block random sampling	9	94%

sheet of paper, in which a metric ruler measured the length, while the flexi ruler measured the height of the curve **Forward Shoulder Translation**: The anterior tip of the acromion was marked and with the use of a square combination ruler, the distance between the wall and the tip of the acromion was measured. **Pectoralis Minor Length**: An anthropometric measurement of the length of the Pectoralis Minor. A caliper was used to measure the distance between the medial inferior angle of the coracoid and a landmark lateral to the sternocostal junction of the inferior aspect of the 4th rib								

LIMITATIONS:	The limitation of this study is that less than 20% of the included participants were males. The ET group had double the number of males included as compared to the PT group, which means that there was an uneven distribution of genders in each group. Males respond to pain and pain modalities differently as compared to females (Bartley and Fillingim, 2013) and this may have had an effect on the outcome of this study due to the uneven distribution. Therefore, this study does not accurately reflect whether the treatment protocols are as effective in the management of male patients suffering with shoulder impingement syndrome as compared to females. Other noteworthy limitations of this study pertaining to the demographics include the lack of data provided regarding the inclusion of patients suffering with comorbidities. The study did not state if there were patients who suffered from any comorbidities and no mention was made of the patient being medicated for it. The use of medications for other health conditions could affect the outcomes of this study by influencing patient's response to treatment. Since there was a rather broad age range of 18-75 years of age included in this study, there would have been variations among participants regarding the stage of impingement experienced, as stated by Neer (see Chapter two, section 2.7.2). With the possible presence of comorbidities in the older age group, those patients would have reacted less favourably to the treatment as compared to the younger age group between 25 and 50, in which Neer's stages 1 and 2 would have been prevalent and most responsive to conservative management. The older age group would experience delayed tissue healing due to age and possible comorbidities which results in delayed response to treatment (Guo and DiPietro, 2010). Patients were also recruited from a hospital setting which suggests that their symptoms more severe than the average SIS patient. The use of the CONSORT flowchart was beneficial as it provided information regarding the research process pertaining to this study. Another positive was the fact that hand dominance and affected arms were stated in the study. The pre-test/post-test design does not provide an accurate account of the rate of improvement that occurs in clinic practice. This design paradigm does not allow the reader to see at which stage (in terms of weeks) the physical therapy treatment stopped being effective / or was most effective. We are also unaware of which week showed most improvement in range of motion due to the fact that there is no data stating what each week's measurements were. There is also no follow-up period (short / long term) to look at the how long the effects of the exercise and physical therapy last. This therefore limits this study, as it does not take into account the affects of activities of daily living on posture and flexibility, as these factors play the biggest roles in changing posture and length of pectoralis minor. This is compounded by the fact that it usually takes six to eight weeks for changes to

	occur in muscle strength and/or length (Loenneke et al., 2019) and up to three months (12 weeks) for changes in related fascia (Fraser, 2008). In terms of the study design related to the exercise group, the author states that two types of stretching exercises were performed with 10 repetitions for 30 seconds. It is unclear whether the researcher asked the participants to perform each exercise for 30 seconds, repeating it at a minimum of 10 times, or if they meant that the entire stretch (inclusive of repetitions) were performed in a timeframe of 30 seconds. Performing stretching exercises at a rapid speed does not allow for the appropriate effects to take place as there is an inversely proportional relationship between the duration of a stretch and the effect it has on flexibility (Page, 2011). The longer the static stretch duration, the more flexible the targeted muscle becomes (Islamoglu et al., 2016). This study packaged TENS with Ultrasound and Laser, in conjunction with pendulum exercises and shoulder range of motion exercises, which does not indicate whether TENS was effective in providing pain relief to patients. The author of the article suggested that TENS as a therapy on its own is ineffective in the treatment of SIS, based on the findings of Johansson et al., (2002) which stated that there was not enough evidence in their systematic review to substantiate the use of TENS for treating subacromial pain and it therefore was packaged as a therapeutic treatment with multiple other modalities.
OUTCOME:	The authors indicated that the outcome of the study showed that scapular stabilization-based exercises used as a treatment intervention in the management of shoulder impingement syndrome, is successful in increasing shoulder external range of motion and abduction, while simultaneously decreasing forward head and shoulder postures, with the added benefit of increased pectoralis minor flexibility. It was also noted that apart from increasing flexibility, range of motion and correcting posture, the scapular exercises are beneficial in reducing pain. The authors stated under post test results that in the PT group there was a reduction in scores related to VAS, shoulder abduction, external rotation, forward shoulder translation and pectoralis minor length. However, the ET group showed a greater degree of improvement in the above outcomes. The VAS score and scapular rotation and symmetry showed no difference between the groups. No mention was made regarding the electro-modalities used in the treatment of the PT group.
DISCUSSION:	This article did not assess the effectiveness of TENS alone in the treatment of SIS. It was a combination treatment that was seen to be less effective than the exercise therapy in aiding shoulder movement. However, the VAS scores reduced significantly in the physical therapy group,

	similar to that of the exercise therapy group and it can be noted that although TENS was used in conjunction with ultrasound, laser and focused exercise therapy, it does seem that these modalities do play a role in providing an analgesic effect on patients with shoulder impingement syndrome. This study looks at multiple outcomes but does not assess how long the effects of these treatment modalities last. This is an important factor that should have been assessed as posture and flexibility is generally affected by most activities of daily living and this study is limited based on the duration the researchers had decided to perform this study for. Due to the difference in number of participants included per gender, the study should have tried to include equal number of males and females in order to adequately assess the effectiveness of the treatment protocol in both genders, which would have been an appropriate representation of the general population. As it stands now, the study is predominantly made up of females (80%) and this does not allow practitioners referring to this article to ascertain whether this therapy is effective in treating men as it is in treating females (Bartley and Fillingim, 2013). Although the study seems to have been sound, except for the fact that TENS was used as a packaged treatment in managing SIS, the effects of TENS as part of the programme is limited. This is because the authors do not state which of the electro-modalities provided greater pain relief which makes determining the effect of TENS solely in this study, not possible. Regarding the settings used in this study, the study made use of conventional TENS which is known to provide effective pain relief as it stimulates both superficial and deep muscles (see Chapter two, section 2.8.1). However, the electrodes were placed on maximally painful areas that were identified by the patient. This means that there was variation of electrode placement in each patient, and this could have also changed among participants each time the intervention was administered. This would diminish the effect of TENS as electrode placement contributes largely to how effective TENS is in providing pain relief.
CONCLUSION:	This study was ranked a 9 out of a possible 11 on the PEDro scale, with a 94% total percentage agreement (see Table 4.25). Although this study had many positives with regards to the study design, the use of a COHORT flowchart, and stating the hand dominance in each study group, there were many key factors that were also outstanding. The lack of data regarding the inclusion of patients experiencing comorbidities, the types of medication they were taking, the impingement type, the broad age range and the use of TENS as a packaged treatment reduced the quality of this study. We are unable to determine the effect of TENS on SIS, based on it being a packaged treatment, with randomized electrode placement, making it impossible for us to determine whether TENS was effective in contributing to pain relief in patients with SIS. Due to the

	broad age range, even if we were able to deduce whether TENS was genuinely effective in treating SIS, we would not be aware as to which age group and stage of impingement benefitted most, further reducing the quality of this study. Therefore, this study had a high methodological rigour but the clinical outcomes pertaining to TENS and SIS was poor.

Table 4.27: Tabulated feedback data for RCT: Article 14

AUTHOR(S):	Ozdincler
YEAR:	2005
TITLE:	The effects of TENS and LEL on pain and functional performance of patients with shoulder pain

CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	0	1	1	1	**67%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	0	1	1	**67%**
5	There was blinding of all subjects	0	0	0	0	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	0	0	1	0	**67%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	1	0	0	0	**67%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	0	0	0	**67%**
11	The study provides both point measures and measures of variability for at least one key outcome	1	1	1	1	**100%**
	TOTAL SCORE	**5**	**3**	**5**	**4**	
		OVERALL PERCENTAGE AGREEMENT:				**85%**

Table 4.28: Analysis of Article RCT: Article 14

AUTHOR(S):	Ozdincler							
YEAR:	2005							
TITLE:	The effects of TENS and LEL on pain and functional performance of patients with shoulder pain							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomisation of participants**	**Ranking**	**Total Percentage Agreement**
Pain: The use of the Visual Analogue Scale (VAS) **Active Shoulder Range of Motion**: A universal goniometer was used to assess the following shoulder ROM's: shoulder flexion, abduction, external and internal rotation **Functional Assessment**: The use of Constant's Shoulder index, which assesses pain, activities of daily living (O'Connor et al.), ROM and poverty	Measurements were taken before the treatment, after the treatment and a control assessment was done after 30 days of home exercise therapy	3 weeks, consisting of 15 therapy sessions, with home exercise therapy for 30 days after the conclusion of the study	45 participants (30 females and 15 males) were divided into 3 groups; Group 1 received TENS only Group 2 received LEL only Group 3 received combination therapy (TENS and LEL)	Assessors were not blinded in this study	No control group was used in this study	There was randomization of the participants into 3 groups	4	85%

LIMITATIONS:	A limitation of this study is that the author does not state whether the participants, assessors or clinicians performing the treatment were blinded. If no blinding has taken place, with no allocation concealment, it would be easy for the assessor to manipulate the groups by placing participants with more severe symptoms into the group that is most favorable, resulting in auto-suggestion occurring (Jakovljevic, 2014) hence putting the study at risk for subversion bias (Torgerson and Torgerson, 2003). This ipoint is further compounded by the fact that the author does not state the method that resulted in the randomization of participants at baseline, which results in the possibility of selection bias (Boutron et al., 2019). The study does not provide statistical data representative of demographic data at baseline. No specific age group was specified for this study, nor was there any data provided to tabulate the participant's age, height, weight, and BMI. The authors stated that no cardiac and respiratory diseases were included and exclusion of patients experiencing inflammatory conditions was maintained. The authors do not specify the age group of recruited patients and therefore, we are unaware of the target population of this study. With the elimination of severe cardiac, respiratory and inflammatory conditions, they did not rule out possibility of infectious diseases and conditions such as diabetes mellitus and liver disease, in which patients would have been medicated for. These conditions may negatively impact neurological functioning and pain reporting (Schreiber et al., 2015). The inclusion criteria do not specify the type of shoulder pain included in this study; however, they do mention that only right upper extremity dominant patients were included.The inclusion criteria stated that the participants were expected to have unilateral shoulder pain with a right hand dominant upper extremity. However, it is unclear whether the researchers expected the pain to be presented on the right shoulder only or if pain present on either of both shoulders were included in this study. This contributes to the lack of homogeneity among participants, apart from the fact that there was no specific target population or specified type of shoulder pain. The lack of specification of the type of shoulder pain would result in difficulty in the clinical application of outcomes in general practice. Since the type of shoulder pain and target population is unspecified, we cannot assume that this study focused on shoulder impingement syndrome and if it did, we are unaware of the types and stages of impingement included in this study. The author does not indicate how many males were in a group as compared to females. Since the ratio of males to females is 2:1, this information is important as we do not know whether the data in one group favored one gender over the other and whether the conclusive outcome of this study can be applied to the general population of males and females, or if it benefits one group over the other. Due to the fact

	that males and females respond to pain and pain interventions differently, this may skew the results and affect the outcome of this study (Bartley and Fillingim, 2013). The statistical data that was supplied in this study, represented by table 1 and 2 of the study conducted by Ozdincler (2005), do not provide comparisons of each group specifically at baseline. This is an important factor to note as there could have been variations in types of shoulder pain with some patients experiencing pain for three months whilst others for six months, resulting in different responses to healing. Therefore, the possibility of the floor and ceiling effects influencing the study is high (Oxford, 2020, Garin, 2014). If the range of motion and pain levels were low and high respectively at baseline, then those patienst would have benefitted greatly from the treatments they received as compared to someone with a low pain rating and limited range of motion. The authors do state that there was no significant difference between groups at baseline but provide no data to substantiate this statement. The lack of transparency in this regard can lead to reporting bias from the researchers (Torgerson and Torgerson, 2003). The data provided compares the three measurements that was taken collectively from all participants at baseline, post-test and at control assessment, which does not provide any data stating which group benefitted the most from what treatment. The tables do not provide information specific to each group, so the reader is unaware what the VAS scores were for each group. The reader was further unaware as to what the degree of range of motion was in each group and the Constant's scores for each group individually. This limits our understanding of the effectiveness of the individual treatments. The author compares the statistical findings for each outcome by grouping them as a "general population" instead of dividing them into the treatment groups that were being assessed in this study. This does not provide any useful data as the author does not explain the statistical findings in the tables. Grouping the data does not show any difference in the individual treatments being used in this study. This is a limitation because the author does not show the degree of improvement in the TENS and LEL groups and simply explains that the combination treatment had more favorable results as compared to TENS and LEL individually. Due to the limited information provided in the tables, this study does not indicate if all participants completed the study and if there were any dropouts, and how they accounted for a dropout rate, if this was the case. This RCT did not indicate any method following CONSORT guidelines (Schulz et al., 2010), which further introduced a lack of information regarding how the researchers accounted for the drop-out rates, if any.

OUTCOME:	The outcome as stated in the study is that combination therapy of TENS and LEL is more effective in the treatment of shoulder pain as compared to TENS and LEL being used separately. The use of combination therapy showed a greater reduction in pain, and an increase in range of motion, which allowed the participants to exercise regularly, resulting in an increased functional performance. According to the study, the TENS group showed greater improvement in pain as compared to the LEL group, however the combination group showed the greatest improvement in both pain and range of motion.
DISCUSSION:	Due to the limitations of this study, the outcome above was not presented in a manner that would be considered in line with the CONSORT reporting guidelines. There was a lack of statistical data presented to the reader to understand the degree of difference between baseline, after treatment and control assessments. The lack of demographic data in this study indicates a possibility of non-homogeneity at baseline. The researcher stated that all participants were homogenous at baseline, regarding only outcome measures based on the explanation provided in the study, but rovides no information of age, weight, comorbidities, affected arm and other demographic information required in order to understand the target group of this study. Providing a generalized picture of improvement in this study does not prove to be effective since this study was divided into three groups randomly and was not a singular group assessment. Although the conclusion states that the combination treatment was the most effective of all three outcomes, there is no quality data provided to know exactly why this was the case. The lack of blinding, appropriate randomization measures and appropriate statistical data results in an outcome that is not adequately justified and a poor-quality study. The use of TENS in this study regarding parameters pertaining to electrode placement was not stated. Unlike the LEL, in which the author states that the electrodes were placed on certain tender points, there is no mention of electrode placement for the TENS group. The author stated that the use of continuous TENS was applied in this study, with a consistent frequency of 80Hz, which was a positive, but without clearly stated electrode placements for the participants, we cannot assume all participants received TENS in the same manner and on the same area.
CONCLUSION:	This was a poorly designed and executed study based on the limitations mentioned above and the scoring of 4 out a possible 11 on the PEDro scale, with an 85% total percentage agreement from all three reviewers (see Table 4.27). Since the author does not state the type of shoulder

	pain included in this study, we cannot assume that SIS, was present in this study. The lack of a target age group results in an inability of practitioners to be able to apply the outcome provided in this study in clinical practice. The lack of an age group also indicates that, if SIS was present among participants in this study, the stage and type of impingement would be unknown. The use of TENS without stating the location for placement of electrodes further diminishes the quality of the study and does not provide enough information to substantiate the point made by the author regarding TENS being superior to LEL but inferior to combination treatment. The only manner that would allow the author to conclude that TENS is superior to LEL in this study, is if the electrodes placed in LEL were located in the same area as those of TENS. However, we are unable to assume this fact and therefore we can conclude that the structure and methodological rigour of this study is poor. The clinical outcomes of this study are also found to be poor and lacking in evidence.

Table 4.29: Tabulated feedback data for RCT: Article 15

AUTHOR(S):	Shehab and Adham					
YEAR:	2000					
TITLE:	Comparative effectiveness of ultrasound and transcutaneous electrical nerve stimulation in treatment of periarticular shoulder pain					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	0	1	**67%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	0	0	0	0	**100%**
5	There was blinding of all subjects	0	0	0	0	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	0	1	0	0	**67%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	0	1	1	1	**67%**
11	The study provides both point measures and measures of variability for at least one key outcome	0	1	0	0	**67%**
	TOTAL SCORE	**3**	**6**	**3**	**4**	
		OVERALL PERCENTAGE AGREEMENT:				**88%**

Table 4.30: Analysis of Article RCT: Article 15

AUTHOR(S):	Shehab and Adham							
YEAR:	2000							
TITLE:	Comparative effectiveness of ultrasound and transcutaneous electrical nerve stimulation in treatment of periarticular shoulder pain							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomization of participants**	**Ranking**	**Total Percentage Agreement**
Pain: The use of a Visual Analogue Scale (VAS) described the level of pain the participants were experiencing **Shoulder Range of Motion**: Shoulder flexion and abduction was assessed using a standard goniometer	Measurements were taken before and after treatment. The author does not state if this is for each individual treatment or at the end of 13 sessions	The study was performed with the participants receiving treatment 3 to 5 times a week for 13 sessions – the assumption would be that the study lasted approximately 12-13 weeks at most, as the authors do not state the time period specifically	50 female participants were included and randomly divided into 2 groups; Group 1 had 26 participants receiving TENS Group 2 had 24 participants receiving Ultrasound	There was no blinding of the assessors	There was no control group in this study	Participants were randomly placed into one of two groups	4	88%
LIMITATIONS:	This study focused on females and therefore the outcome are only relevant to the management of female patients. The mean age group of these women were 50 years old; the authors do not state what the actual age range was beside stating that the females were 50 years old (±5.89). The limitation to the inclusion of this particular age group is that tissue healing is slower and less responsive as compared to younger individuals and there is age-related delays in physiological processes involved with tissue healing (Gould et al., 2015). This age group is also more likely to be experiencing menopause, which may have hormonal impacts on tissue healing as a lack of estrogen production is known to delay healing in the							

	body (Ashcroft et al., 2003). A lack of eligibility criteria for this study draws out the question about homogeneity of the groups in order to compare them and then also the ability of the outcomes to be applied to a similar sample of patients in practice. The age group that this study included has a potentially high risk of comorbidity prevalence that may influence their individual etiologies regarding their painful shoulders, which would ultimately affect their response to treatment. The other impacting factor is that there is no mention of medication in terms of exclusion and whether or not medication change was monitored throughout the study (or for that matter allowed to have happen). This could have resulted in participants not being similar at baseline in terms of their demographic data and their condition, resulting in an inability to fairly compare the groups. The study states that most patients suffered with supraspinatus or bicipital tendonitis and subdeltoid bursitis, which does not clarify what the rest of the participants, were diagnosed with. There was no statement regarding how these patients were diagnosed. Therefore, there is a possibility that there is a lack of consistency among included participants, resulting in a heterogeneity in the study group. The variation in etiologies and consistency in diagnosis may affect the response to treatment and the outcome of this study. The authors state that the included participants were based in a hospital setting and this would therefore indicate that the probable severity of the shoulder conditions experienced by participants were high. The location for recruitment of participants brings into question whether the patients are an accurate representation of the general public who require conservative management prior to hospital admission or if the included participants were at an advanced state of dysfunction and impairment, which would not be an accurate representation of the general population. The study stated that the only inclusion requirement was that the participant had a minimum duration of 1 month of pain and dysfunction, which means that this study is limited to only acute patients or patients experiencing an acute exacerbation of a chronic condition, and not aimed at those in the subacute and chronic stage of shoulder dysfunction. The acute stage of any condition responds more favorably as compared to the subacute and chronic stages – even just with natural history (Guo and DiPietro, 2010). Acute in terms of pain, is always worse than a persistent pain associated with a chronic condition so the degree of improvement for the acute patient is consistently greater than that of a chronic patient. This study does not provide demographic data stating the weight, height and BMI of these participants, neither do they state which arm was affected in each group, as dominance may affect the type of injury sustained and may influence the effectiveness of the treatment. We are also unaware of the professions associated with these patients which may have contributed

	to the development of the acute shoulder pain. Furthermore, in terms of shoulder impingement, we are unaware if patients diagnosed with SIS were included in this study, and if they were, the types and stages of impingement that were present was not specified. Participants were randomized but there is no statement as to how randomization occurred. The author does not state whether the assessor was able to gain access to the randomization table and due to the fact that there was no blinding in this study, the possibility of selection bias from the assessor regarding the modality that is most favorable to them, is high (Torgerson and Torgerson, 2003). The other issue regarding the lack of blinding is that the results of the study could have been easily influenced by the researcher by placing participants with pain that is more severe in a particular group as this would then not impede improvement due to the floor effect (Oxford, 2020) which further contributes to the possibility of selection bias (Torgerson and Torgerson, 2003). The fact that participants were not blinded through naivety, and the fact that an appropriate exclusion criteria was not provided, leads to the question as to what the level of patient naivety in this study was, and were the participants able to influence the outcome of the study based on whether they have had good / unchanged or adverse reactions to ultrasound or TENS therapy before, all of which could have resulted in the participants engaging in reporting bias, which further biases the outcomes of this study (Torgerson and Torgerson, 2003). The assumption regarding the frequency of measurement is that this study was a pre-test post-test study design, so one can assume that a measurement was taken at baseline and the again after 13 sessions. The authors state that 3 to 5 sessions were done per week for a duration of 13 sessions. There is no information regarding the rest period between these sessions, as this could have possibly influenced the effectiveness of the treatment. Since the statement of 3 to 5 treatment sessions per week was used; the question arises as to whether every participant received the same number of sessions per week in each group, as variance in this would result in differing outcomes (i.e. at 5 sessions per week the patient would complete the programme in under three weeks, with three sessions per week the patient would complete the programme in five weeks, which would indicate a very big difference in terms of healing time and potential differences in the outcomes as a result). The use of TENS at the same dose on a daily basis results in analgesic tolerance and can alter the effectiveness of the study protocol (Vance et al., 2014a) hence the authors should have stated how frequently their treatment sessions took place. If the frequency of treatment per week was five consecutive days, this would have resulted in a reduce effect of TENS as it is known that analgesic tolerance occurs after the fourth or fifth day of continuous use (see Chapter two, section 2.8.3), this would therefore have effected the outcomes of this study. The authors state that the intensity on the TENS machine was kept at 50Hz for 30 min. In order to avoid analgesic tolerance to TENS, the authors should have varied

	between high and low frequency in order to delay the effect of analgesic tolerance. The use of non-parametric statistics in this study is not justified since each group had over 20 participants, and parametric statistics would have been able to produce reliable results in the event of skewed data. The author does not explain why the variables were skewed, and this leads to the question as to whether there was uniformity of all baseline parameters. The lack of a focused age group, along with generalized inclusion of patients experiencing acute shoulder pain, with no specific etiology of the pain, could have possibly resulted in skewed results at baseline. If the variability of groups were significant at baseline, nonparametric statistics could have provided results that are not reliable (Frost, 2020a). The lack of adherence to CONSORT reporting makes it difficult to evaluate the study and reduces the quality of the study.
OUTCOME:	The outcome of this study, as indicated by the authors, is that both modalities, TENS and Ultrasound, used in combination with ice packs and exercise therapy are effective in the treatment of peri articular shoulder pain, with ultrasound resulting in a better range of motion.
DISCUSSION:	Based on the reporting of this study, it seems to reflect a pragmatic study with the limitations mentioned above, therefore the rigour and application of the CONSORT principles in this study are questioned. There was valuable information missing in this study that negatively affected the ability for the study to be adequately reviewed – as the rigour is dependent on overt reporting of the CONSORT criteria (Schulz et al., 2010). Shoulder impingement specifically was not noted as a condition being treated in this study (although the possibility of its inclusion cannot be excluded), so the outcome is unclear as to whether the use of TENS is effective in treating dysfunction that could have occurred as a result of SIS. The study does not state clearly how often TENS and Ultrasound were used on a weekly basis and whether there was a rest period in between use. These are contributing factors to the effectiveness of the modalities, with specific focus on TENS as mentioned by Vance et al., (2014). Exercise therapy and ice packs were also used in both groups, but the authors do not explain what type of range of motion exercises were used in this study and how often they were performed. The application of this treatment protocol by a professional in rooms would be difficult since timing and type of stretching exercises were not provided and the intensity of the modalities was not noted. These are important factors as stretching exercises also known to contribute to pain alleviation, even though it was used in both groups.

	As mentioned in the discussion, the TENS settings were kept consistent at 50 Hz and used for a period of 13 sessions, which may indicate the possibility of analgesic tolerance being present in the TENS group after the fourth or fifth day of treatment, if there was no rest period in between. Furthermore, exact electrode placement was not specified apart from mentioning that the electrodes were placed on the anterior and posterior aspect of the shoulder. We do not know if there was consistency among patients regarding placement of the electrodes and if there was consistency in each treatment session. Therefore, we cannot assume that these factors did not affect the outcome of this study pertaining to the use of TENS.
CONCLUSION:	Based on the limitations of this study regarding the use of one specific gender population, the lack of information pertaining to the type of shoulder patients included in the study (especially since we do not know whether patients diagnosed with SIS were included in this study), the possible presence of comorbidities, the small sample size, location of this study and the consistent use of TENS which may have possibly resulted in the presence of analgesic tolerance affecting the outcome, this study was ranked poorly with a score of 4 out of a possible 11 on the PEDro scale, with an 88% total percentage agreement. This study does not allow practitioners to apply the outcomes in clinical practice due to its limitations and does not provide enough information to state whether TENS is effective in treating SIS. It has therefore been determined that this study is poor both in methodological rigour and in clinical outcomes.

Table 4.31: Tabulated feedback data for RCT: Article 16

AUTHOR(S):	Soibam					
YEAR:	2005					
TITLE:	Comparative study on the effectiveness of0 ultrasound (US) and transcutaneous electrical stimulation (TENS) in the treatment of periarticular shoulder (PSP)					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	1	1	**100%**
5	There was blinding of all subjects	0	0	0	0	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	1	1	1	1	**100%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	0	1	1	1	**67%**
	TOTAL SCORE	**6**	**7**	**7**	**7**	
		OVERALL PERCENTAGE AGREEMENT:				**97%**

Table 4.32: Analysis of Article RCT: Article 16

AUTHOR(S):	Soibam							
YEAR:	2005							
TITLE:	Comparative study on the effectiveness of ultrasound (US) and transcutaneous electrical stimulation (TENS) in the treatment of periarticular shoulder pain (PSP)							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomization of participants**	**Ranking**	**Total Percentage Agreement**
Pain: Measurement of participant's pain levels were assessed with the use of the Visual Analogue Scale (VAS) **Shoulder Range of Motion**: Shoulder flexion and abduction was assessed using a universal goniometer **Functional Assessment**: The use of the Shoulder Pain and Disability Index (SPADI) was given to the participants to assess functional performance regarding pain and	Pre and post therapy measurements of each outcome was taken from all participants on the 1st, 7th and 13th day	The duration of the treatment was 13 days	40 participants were included in this study; 26 males and 14 females; these participants were divided into 2 groups, Group A received ultrasound therapy for 10 minutes Group B received TENS therapy for 30 mins. Both groups received cold therapy and range of motion stretching exercises	The assessors were not blinded in this study	No control group was used in this study	There was randomization of the participants into 2 groups of combined males and females	7	97%

disability								
LIMITATIONS:	This study is limited to the management of peri articular shoulder pain (inclusive of supraspinatus tendonitis, bicipital tendonitis and adhesive capsulitis) in the acute phase. Similar to Shehab and Adham's study in 2002 on the same condition, this study does not have a follow-up period that extends beyond the 13th session. Therefore, this study is limited to the short-term effects of TENS and ultrasound in the treatment of acute shoulder pain. This study does not account for the effect of TENS and Ultrasound in medium and long term periods. The inclusion criteria do not state a specific age range; however, it is mentioned in the results as being between 20 and 72 years of age. The broad age range is an important factor to take into consideration as variation in age groups would result in a variation in healing time (Bartley and Fillingim, 2013, Guo and DiPietro, 2010). The inclusion of patients over the age of 40 also results in the possible presence of comorbidities among participants that could have contributed to the shoulder pain that the patient was experiencing (Tran et al., 2018). There is no mention of whether the patients were medicated for other conditions unrelated to the shoulder. These factors could impact the outcome of this study. Due to the lack of blinding in this study, patient naivety is questioned. If the patients had received either of the modalities as treatment in the past, it would influence how they would respond to the treatment that they were given as part of this study. A patient may respond more favorably to a treatment if they are familiar with it, conversely, they could respond negatively to a modality that did not produce favorable results previously. These preconceptions could have been acquired for treatment from any previous injury that they were treated for and not specific to the shoulder and would thus result in reporting bias from the patient (Torgerson and Torgerson, 2003). There was a lack of baseline similarities presented in this study. The height, weight and BMI of the included participants were not stated. There was no mention of affected arm dominance as this factor could have influenced the rate of healing and muscle response to the modalities due to the different muscle motor recruitment patterns. The non-dominant shoulder would have a higher muscle recruitment pattern as compared to the dominant shoulder (Lemos et al., 2011). The professions of the included patients were not stated either and we are therefore unaware if their shoulder condition occurred as a result of a repetitive injury or not (Linaker and Walker-Bone, 2015). With regards to the frequency of measurements in this study, the methods suggest that the VAS was taken before and after each treatment session on days 1, 7 and 13. This results in the patient being exposed to treatment outcome assessments on more than one occasion. This could result in the patients reporting favourable outcomes due to overexposure of pre and post testing (a total of six times). It was also noted							

	that there is no mean difference of more than 2 points (decrease) between the different reported time frames (1, 7 and 13 pre-post treatment), which means the treatments have not achieved a clinically significant change in one treatment (Boutron et al., 2019, Bird and Dickson, 2001), but this seems to have been achieved overall (5 point difference in both groups on the VAS). Another noteworthy problem that was presented in this study is that the application of both TENS and US modalities were targeting two different points on the shoulder for the same/similar condition between the patients. Variation of modality application in patients would result in the outcome data being skewed as these modalities are not treating the same area of the shoulder. This further results in a false comparison of outcomes between groups. The author does not state their choice for the use of non-parametric statistics as compared to parametric statistics. In the study by Shehab and Adham., (2000), they had chosen to use non-parametric statistics because they had found that their variables were skewed. In the current study, the author used 2 types of non-parametric statistics without an explanation. The sample size was large enough to justify the use of parametric statistics. This study would have benefitted from sample t-testing as it would have collated the data collected by the researcher in an organized manner. The author states that osseous anatomical landmarks were used to identify the location of palpatory points to use when applying the goniometer to assess the differences in range of motion. This is not a specific method of measurement as there is no manner of knowing whether there was a 100% accuracy at pre-test and post-test as palpation can lead to variation. A more reliable method such as a henna dye spot would have provided the assessor with greater accuracy when performing the goniometer measurements, reducing the possibility of variation at post-testing.
OUTCOME:	The authors report that, the outcome of this study was that both TENS and Ultrasound are effective interventions – the intragroup comparisons with readings from day 1 to day 13 showed statistically significant results for both groups, however there was no statistically significant difference between groups, in the treatment of peri articular shoulder pain, as both the interventions increased range of motion and functional performance, whilst simultaneously reducing pain.
DISCUSSION:	This study was exactly the same as Shehab and Adham (2000), regarding the choice of treatment interventions and modality settings, however

	whilst Shehab and Adham's study focuses on the effect of TENS and Ultrasound in the treatment of peri articular shoulder pain in females, this study included males as well. Demographic data was not presented and dominant arms that were affected was not established, which limits our understanding as to how effective the treatment intervention is, since motor recruitment patterns differ on either side of the body. The previously conducted study by Shehab and Adham (2000), did not provide a concise inclusion criterion as compared to this study. This study had a thorough inclusion and exclusion criteria that specified which conditions would and would not be included for assessment. This study did not take into consideration the recommendation for a double-blind study to be conducted as stated by Shehab and Adham (2000).. There was no blinding and the intensity settings for TENS were not stated either. A positive aspect of this study is that measurements were taken multiple times in order to assess rate of progress of the treatment interventions. This is helpful in understanding the rate at which the shoulder responded to the modalities. The reason behind the use of non-parametric statistics was not explained by the authors. The TENS settings were kept consistent among participants with 50 Hz at 30 min per session. The electrode placements were not clearly indicated in this study, the author simply states that TENS was applied on the anterior and posterior aspect of the glenohumeral joint. This does not provide specification as to which muscle was being stimulated and if there was consistency among all participants in the group for all treatment sessions. The participants received 13 sessions of treatment and the author does not specify whether the treatment was conducted for 13 days consecutively. If this was the case, analgesic tolerance (Chandran and Sluka, 2003) would have occurred as there was no variation in frequency, This study was an improvement on Shehab and Adham's study, however it still is limited in terms of the TENS settings used, the possibility of analgesic tolerance being present and the lack of information regarding electrode placement, all of which are important parameters in assessing whether TENS would truly be effective in treating shoulder pain. If the author adhered to regulating these parameters among participants, there may have been a statistically significant difference between groups.
CONCLUSION:	To conclude, although there were many benefits in terms of study design and an improvement in score ranking, with this study ranking 7 on the PEDro scale (see Table 4.31) while Shehab and Adham (2000) ranking a 4 (see Table 4.29), it is still limited in terms of the exact types of

	shoulder pain included and not being specific to SIS as well as the use of TENS and its settings having short-comings that could have affected the effectiveness of treatment among participants. Therefore, the outcome of this study can be applied in practice, with caution. However, it is still unclear as to whether TENS is effective in treating patients with SIS. The methodological rigour of this study is of a high-quality, however the clinical outcomes are poor based on the explanation presented in Table 3.7.

Table 4.33: Tabulated feedback data for RCT: Article 17

AUTHOR(S):	Subasi, Toktas, Demirdal, Turel, Cakir and Kavuncu					
YEAR:	2012					
TITLE:	Water-based versus land-based exercise programs for the management of shoulder impingement syndrome					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	0	1	**67%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	1	1	**100%**
5	There was blinding of all subjects	0	0	0	0	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	0	1	0	0	**67%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	0	1	1	1	**67%**
11	The study provides both point measures and measures of variability for at least one key outcome	0	1	1	1	**67%**
	TOTAL SCORE	**4**	**7**	**5**	**6**	
		OVERALL PERCENTAGE AGREEMENT:				**88%**

Table 4.34: Analysis of Article RCT: Article 17

AUTHOR(S):	Subasi, Toktas, Demirdal, Turel, Cakir and Kavuncu							
YEAR:	2012							
TITLE:	Water-based versus land-based exercise programs for the management of shoulder impingement syndrome							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomisation of participants**	**Ranking**	**Total Percentage Agreement**
Pain: The use of the Visual Analogue Scale (VAS) assessed pain intensity in included subjects **Changes in severity of disease**: The Western Ontario Rotator Cuff (WORC) index was used to assess and monitor progression and recovery from rotator cuff lesions **Pain and Disability**: Both of these factors were assessed with the use of the Shoulder Pain and Disability Index (SPADI)	Measurements were taken at baseline, after the treatment (which was the 1st follow-up) and 3 months after the beginning of the treatment – which is 2 months after completion of intervention- this was the 2nd follow-up	The duration of the exercise therapy was 3 months, this included: 20 treatment sessions carried out 5 times a week for 1 month. A follow-up period, 3 months after the commencement of the study was also included.	57 patients were recruited and divided into 2 groups. The Land Group had 28 patients (7 males and 21 females) and the Water Group had 19 patients (14 males and 15 females)	The assessors were not blinded	There was no control group in this study	There was randomization of participants	6	88%
LIMITATIONS:	This study had many positive aspects such as the fact that they assessed both the short and long-term results of their included interventions. The authors also provided an extensive exclusion criterion detailing all conditions that they would not include in the study. Limitations of this study includes the fact that a clearly defined inclusion criteria to specify how shoulder pain patients were recruited for this study was not provided. An extensive assessment of possible candidates for this study did take place, but there was a failure to provide an inclusion criterion for this study. The statement in which the author stated that “70 shoulders were assessed in 57 patients” did not provide an explanation as to why they had chosen to assess 70 shoulders out of 114 shoulders being present in this study.							

	There was no statement claiming that some patients had bilateral shoulder impingement syndrome. If both shoulders were affected, the question of allocation arises. They do not state whether both shoulders received the same treatment. There is no indication that there was any patient blinding in this study, so patients were fully aware of the treatment protocol that they would be receiving. If there is a possibility of allocation of 2 shoulders into 2 separate groups, then there would have been a reduction in patient naivety, as the patient could have favored one treatment method over the other leading to reporting bias from the patients (Torgerson and Torgerson, 2003). The authors do not state shoulder dominance, and this would affect the response rate of the selected shoulder to the treatment method, since motor recruitment patterns in each arm differs (Lemos et al., 2011). The presence of bilateral SIS suggests that the patient is more likely to be older, have more co-morbid conditions and consume medication to a greater degree as a result (Burner et al., 2014). These factors were not mentioned as part of the inclusion criteria, the authors did not state if any of the patients experienced any other comorbid conditions and if these patients were medicated prior to commencement of this study. There is no mention of the profession and type or stage of impingement present in participants of this study either. This limits the reader's knowledge regarding which type of shoulder impingement benefits most from this intervention. This is further compounded by the fact that an age range is not provided, however the authors state that the mean age of inclusion was over 55 years old in each group. This age group indicates a high possibility for the presence of comorbidities (Tran et al., 2018). In the case of a participant receiving treatment on both arms, in comparison to an individual receiving treatment on one arm, there would be a lack of homogeneity at baseline, and this could influence the results received. The changes in pain and severity of disability and dysfunction on one arm can easily be monitored by an individual when the other arm is functioning relatively normal. However, the patient that has both shoulders affected, they have no baseline normal to compare the dysfunctional shoulder to and this would skew the results regarding the VAS, SPADI and WORC questionnaires, which are purely subjective. This study relies purely on subjective feedback from patients who received the therapy in each group, which could bias patient feedback if one patient had two shoulders receiving two different interventions. The multitude of subjective outcome measures questions the reliability of the data. There were no objective measures to clearly assess whether the treatment was effective, regardless of the subjective findings noted and presented by patients through the questionnaires provided. The difference in

	measurements seen in Table 3 in the study by Subasi et al., (2012), in the total SPADI score, shows that the water group had a significant improvement as compared to the land group in the first and second control reading. If patient naivety influenced the outcomes of these results, then patients who received the water-based exercise may possibly have favored this over the land exercise, purely because this type of therapy is “different” from conventional exercise therapy as in the case of the land-based exercise therapy. Another difference between land and water based exercise is the fact that in terms of mechanics, the water based exercises work against the resistance between the person and the water and there is no effect from gravity, which results in the patients modulating their exercises according to their pain levels. The land-based exercises would be more difficult to do as gravity does not provide the same fluidity and dynamic as the resistance from water. Another factor to take into consideration in this study is the climatic effect on the programmes. This study was conducted during spring, in which Turkey, Istanbul experiences warmer weather. This would have influenced patient participation, as they would have favoured cooler water temperatures in comparison to the warmer ambient temperatures that they would have experienced in the land-based group. The temperature of the cooler water may also have negated the inflammatory after-effects of the exercise which the land based did not have. Thermal water has shown to be more beneficial in reducing pain and disability as compared to tap water temperatures, and therefore the temperature of the water would have also played a contributing role in affecting the outcomes (Kulisch et al., 2009). Another possible influence on the statistically significant scores seen in the VAS, SPADI and WORC questionnaire scores under tables 2, 3 and 4 (Subasi et al., 2012), is the adherence to home exercise therapy. There is no indication by the author stating that there was a way of controlling or monitoring adherence to home exercise therapy, such as an exercise log sheet or diary. If patients were more enthusiastic about one treatment method, such as the water exercise therapy, over the land exercises, they would be enthusiastic in ensuring they conducted the home exercises that they were expected to do. The authors stated that adherence to home exercises were assessed at each follow-up, however the timeframe between each follow-up is not conducive in ensuring that the home exercise programmes were strictly followed, as was expected of the participants. This could have negatively impacted the land- based group’s second control outcomes, as compared to the water-based group. Patient preference was not taken into consideration when allocating patients to land or water-based groups. If a person had an aversion to water and did not enjoy swimming, they could have performed the exercises incorrectly or on land and skewed the results.

	The author also does not state what type of range of motion stretching and strengthening exercises were conducted in each group. If both exercises were the same, the author does not state whether the exercises in the water group were conducted under the water or if the patients were simply standing in the water, performing the same exercises as the land group. Since the pool was 1.4m in depth at its deepest point, the height of each participant of the water group should have been documented, as this would have affected the outcome of the results in this group. Although it is important to mention that irrespective of the water height the patient could still have been suspended in the water whilst doing the exercises, but a patient with an aversion to water would have performed the exercises incorrectly and not as directed. All these factors provide possible ways in which patients could have performed these exercises incorrectly, which would have influenced the outcome of this study if there was no control of such factors. The weight of the dumbbells was also not stated – as such, water would have made the weights lighter while gravity would have made it heavier. The weight of the dumbbells would have affected the performance of each person differently, based on their weight and BMI. Although the shoulder pathology was the same at baseline, the weight of the dumbbells and the resistance of the water / gravity, would have contributed to the effectiveness of the exercise performed by the participants. This study does not focus on TENS as a form of analgesic treatment on its own, it is used in combination with ultrasound, heat packs, and exercise therapy, and therefore we cannot conclude as to how effective TENS was in this study.
OUTCOME:	The outcome of this study states that land and water-based exercise therapy used in conjunction with physical therapy can have a favorable effect on pain, range of motion and quality of life in the treatment of SIS. However, it was noted that the water-based exercise group that included the use of physical therapy was clinically significantly effective as compared to the land-based approach towards the treatment of SIS.
DISCUSSION:	Although this study has many benefits by comparing the effectiveness of land versus water-based treatment, it lacked objective outcome measures that would have provided a more precise assessment of the quality of this treatment protocol. The authors did provide tabulated information about the participants at baseline, however when exercise therapy is involved, information about height, weight and BMI would be useful.

	The lack of blinding of participants in this study can result in a lack of patient naivety negatively influencing the outcomes in this study. The use of home exercise therapy is difficult to monitor and contributes to the subjectivity of this study. Range of motion should have been assessed with a universal goniometer so that patient adherence could have been adequately assessed and documented. Based on the limitations of this study and the fact that TENS was used in both groups, the findings of this study do not contribute to whether TENS is effective in managing SIS. Regarding the outcome of this study, we can agree that at first control, both groups experienced improvement in pain, range of motion and functional performance; however, the water-group showed greater improvement and was the more favorable of the two treatments. Due to the high level of subjectivity of this study, there is no objective basis to properly substantiate the findings of this study in order for it to be applicable in a health professional's treatment protocol. TENS settings in this study showed that a conventional method was used with a consistent frequency of 60 Hz and a consistent period of time of 20 mins a day 5 times a week for 1 month. There is no mention of electrode placement stated apart from the electrodes being placed on the area of shoulder pain, which is non-specific and could have varied among all patients, leading to a lack of homogeneity. Furthermore, TENS was used consistently on a daily basis for a month, which could have led to possible analgesic tolerance, which would have affected the outcomes of this study. Given these facts, there is an obvious deviation from adherence to important TENS parameters to assess effectiveness.Therefore,, given these factors and that TENS was used in combination therapy, it is difficult to determine whether TENS was actually effective in treating SIS related pain.
CONCLUSION	Although there were a few positive aspects of this study such as the study design, the detailed exclusion criteria and the assessment of both long and short-term effects of the interventions included in this study, there is still important factors mentioned in the limitations and discussion of this study that reduced the its quality.. The most notable short-coming of this study is the incorrect use of TENS and the high possibility of analgesic tolerance affecting the outcome of this study. There were multiple aspects that led to a lack of homogeneity among participants and therefore the outcome provided may not be applicable to a target population in clinical practice. This study has therefore been classified as having poor methodological rigour and poor clinical outcomes as outlined in Table 3.7.

Table 4.35: Tabulated feedback data for RCT: Article 18

AUTHOR(S):	Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender					
YEAR:	2013					
TITLE:	The effect of balneotherapy on chronic shoulder pain: A randomized, controlled, single-blind follow-up trial. A pilot study					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	100%
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	100%
3	Allocation was concealed	0	1	0	0	67%
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	1	1	100%
5	There was blinding of all subjects	0	0	0	0	100%
6	There was blinding of all therapists who administered the therapy	0	1	0	0	67%
7	There was blinding of all assessors who measured at least one key outcome	1	0	1	1	67%
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	100%
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	1	1	1	1	100%
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	100%
11	The study provides both point measures and measures of variability for at least one key outcome	0	1	1	1	67%
	TOTAL SCORE	**7**	**9**	**8**	**8**	
		OVERALL PERCENTAGE AGREEMENT:				**88%**

Table 4.36: Analysis of Article RCT: Article 18

AUTHOR(S):	Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender							
YEAR:	2013							
TITLE:	The effect of balneotherapy on chronic shoulder pain: A randomized, controlled, single-blind follow-up trial. A pilot study							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomisation of participants**	**Ranking**	**Total Percentage Agreement**
Primary objectives: **Pain:** The use of the Visual Analogue Scale (VAS) to assess pain on movement and at rest **Pain and Disability**: Both outcomes were assessed using the Shoulder Pain and Disability Index (SPADI) questionnaire **Secondary Objectives**: Quality of Life: This outcome was assessed using the Short Form-36 Health Survey (SF-36) and the EuroQol-5D Quality of life questionnaire **Range of Motion**: Active and passive glenohumeral range of motion was assessed using a goniometer	Measurements were taken at baseline, post-treatment at week 4 and then again at week 7 and 13	The duration of this study was 4 weeks, technically 13 weeks as last measurement was at 14 weeks The control group received exercise therapy and TENS 2 to 3 times a week for 4 weeks, for a total of 10 sessions The experimental group received the same as the control group + balneotherapy for 4 weeks, with a total of 15 sessions	46 participants were randomly divided into 2 groups 23 participants were allocated per group	The assessors were blinded in this study	A control group receiving exercise therapy and TENS was used	A computer system randomized the allocation of participants into one of two groups	8	88%
LIMITATIONS:	Limitations found in this study include the fact that this study had a small sample size, and the groups varied at baseline regarding multiple							

	outcomes in the SF-36 questionnaire and on the EQ-5D scores. However, many of the other outcomes had similar measurements at baseline and the patients included in this study were similar regarding key prognostic indicators. The inclusion of a broad age range of 30-75 years of age indicates the possibility of comorbidities being present among participants over the age of 40 years old (Tran et al., 2018), which means that ±55% of participants could have been suffering with comorbid conditions that could have affected the outcomes of this study. The effect of medications in the management of comorbid conditions could have further influenced the results of this study and should have been considered by the authors. Another important factor to take into consideration is that the authors state that the target group for inclusion is patients who are suffering with chronic shoulder pain, however, the inclusion criteria states that the patients should have shoulder complaints for a minimum of two months. Chronic pain is defined as pain presenting for a period that is greater than three months (King, 2013), so the effectiveness of the treatment is not necessarily only chronic pain patients, as the study includes patients who could be categorized as subacute, instead of chronic (King, 2013). No definition for the term “chronic” was provided by the authors of this study. This means that the generalisablility of the outcomes may not be to the group of patients as reported by the authors but rather both categories of patients. This further raises the question about the homogeneity of the patients in each group with respect to the duration of their complaint (in order to be able to compare them) and then how reflective the groups are of patients in general practice as most of the patients seemed to be hospital based patients. Muscle recruitment patterns vary between the dominant and non-dominant shoulders and therefore, hand dominance should have been taken into consideration, which it was not in this study. This could have led to variation in results and response to the treatment of the shoulders included in this study (Lemos et al., 2011). No indication of patient occupation or possible engagement in overhead activity was mentioned in this study, which would have been contributing factors towards the development of shoulder pain, with particular focus on SIS (Linaker and Walker-Bone., 2015). This study incorporates the use of home exercise therapy, patient compliance to home exercises is questionable and there is no method of ensuring the exercises are done timeously on a daily basis such as making use of an exercise diary. Poor compliance could negatively affect the outcome of the study (Argent et al., 2018). Unlike the study by Subasi et al., (2012), who only included subjective outcome measures, this study to its credit included the goniometeric measures of range of motion (an objective outcome), but on the down side, they do not actually indicate how the measurements were taken in

order to allow for reproducibility of the study. Also, they have a very low minimum on the VAS (25 points / mm); meaning that those patients who had 25% pain had a lesser chance of improving resulting in the floor effect (Oxford, 2020).

The statistical analysis of the results showed that between the two groups at baseline, the role limitations due to physical health in the SF-36 quality of life questionnaire were significantly different. The control group demonstrated greater disability, with a low score of 21, as compared to the treatment group who had a score of 34. This was reflected in similar non-significant trends related to pain reporting as well. Therefore, the conclusions of the effectiveness of the treatment is questioned in influencing the quality of life of a patient, since the group that received the treatment demonstrated less disability and therefore improved much faster than the control group, resulting in the ceiling effect (Garin, 2014). However, conversely it is also recognized that the lesser pain and disability in the treatment group may also have masked the effects of treatment and resulted in a poorer reflection of treatment outcomes compared to the control. A possible reason for the control group demonstrating greater disability is the fact that randomization of the groups may have led to majority of older participants being placed into the control group.

In the results relating to the active shoulder girdle range of motion and the passive glenohumeral joint range of motion, at baseline the participants demonstrated significant difference in active anteflexion, with the treatment group demonstrating a greater range of motion than the control group. This affected the results of the group, as the treatment group improved at the same rate as the control group; however, the statistical results indicated that the range of motion of the group after the treatment was better. This difference between groups may lead to the ceiling effect occurring, affecting the results of both groups, with the treatment group having better figures at baseline, showing greater improvement as compared to the control group (Garin, 2014).

The intention to treat – although necessary when patients are unable to complete the study and place the study at a disadvantage, does not account for improvement or regression of the patient from the point of departure, as the assumption is that the patient will continue with the same clinical trajectory as the patient had presented prior to their point of departure, this does on occasion, not reflect clinical reality (Salim et al., 2008). The advantage of the current study is that there were equal numbers of patients in the respective groups that had the above mentioned mathematical formula applied to their outcomes, which may have potentially negated the negative effect of these statistics.

The focus of this study was not on the effect of TENS but rather the effect of balneotherapy on chronic shoulder conditions. The use of TENS in conjunction with exercise, limits how effective the modality was in this this study, as we are unable to separate the effects of TENS from exercise

	therapy. Therefore, we cannot conclude whether TENS on its own would have provided a different outcome in the control group.
OUTCOME:	According to the findings presented in this study, it was found that balneotherapy used in conjunction with TENS and exercise therapy is more effective than TENS and exercise therapy on its own, in treating chronic shoulder pain.
DISCUSSION:	Even though the study has tried to comply with the CONSORT criteria for the reporting of the study there are limitations, which may affect the outcomes of the study, related to the patient recruitment, allocation and the measurement of the clinical outcomes (particularly the objective outcomes). The question as to whether the patients included in this study were in the subacute pain stage, may affect the outcome of this study in assessing the effectiveness of this treatment protocol in the management of chronic pain. However, we can agree the treatment group responded more favorably to the treatment as compared to the control group. Due to the limitation of this study, in which TENS was not used as the main form of therapy in either group, this study is limited in its relevance in assessing whether TENS is effective in treating SIS related pain. However, a positive aspect of this study is that there was a two-week washout period for patients who received TENS prior to the commencement of this study, which indicates that no previous treatment results could have interfered in the outcomes of this study The positive aspect of this study regarding the use of TENS is that the application of the device was used for only 2-3 sessions per week, which eliminates the possibility of analgesic tolerance affecting the outcome of this study (Chandran and Sluka, 2003). The frequency of the TENS was kept at 100 Hz consistently for 15 mins per patient which indicates that conventional TENS was used and there was homogeneity among participants in that regard. However, there is lack of information regarding where the exact location of the TENS electrodes were placed and this introduces a lack of homogeneity among participants, as the authors simply state that the pads were placed on the anterior and posterior aspect of the shoulder joint. This therefore results in variation among patients and does not indicate if TENS was effective in treating a specific aspect of the shoulder. Although there were multiple follow-up assessments, the effectiveness of TENS would not have been clear as it was used as a combination

	treatment in a long-term trial study.
CONCLUSION:	This study was a well-designed RCT, with multiple positive aspects such as randomization of participants, blinding of assessors and prevention of possible analgesic tolerance from TENS by using it only 2 to 3 times a week. However, there were quite a few limitations as outlined above that could have negatively impacted the outcomes to favor one group over another and this reduces the quality of the study as a whole. This study was ranked moderate to good with a score of 8 on the PEDro scale, with a total percentage agreement of 88%. However, it does not answer the research question regarding the effectiveness of TENS in treating SIS, which limits its use in this study. Therefore, this study has a high methodological rigour with poor clinical outcomes.

Table 4.37: Tabulated feedbacl data for RCT: Article 19

AUTHOR(S):	Ucurum, Kaya, Kayali, Askin and Tekindal					
YEAR:	2018					
TITLE:	Comparison of different electrotherapy methods and exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	0	0	0	**100%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	1	1	**100%**
5	There was blinding of all subjects	0	0	0	0	**100%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	1	1	1	1	**100%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	0	1	1	1	**67%**
	TOTAL SCORE	**6**	**7**	**7**	**7**	
		OVERALL PERCENTAGE AGREEMENT:				**97%**

Table 4.38: Analysis of Article RCT: Article 19

AUTHOR(S):	Ucurum, Kaya, Kayali, Askin and Tekindal							
YEAR:	2018							
TITLE:	Comparison of different electrotherapy methods and exercise therapy in shoulder impingement: A prospective randomized controlled trial							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomisation of participants**	**Ranking**	**Total Percentage Agreement**
Pain: The Visual Analogue Scale (VAS) was used to assess pain intensity **Quality of Life**: The authors chose to use the Short Form-36 **Shoulder Functional Assessment**: The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire was used	Measurements of the outcomes were taken before treatment, after 4 weeks of treatment and at a follow-up 3 months later	The treatment protocols were carried out over a period of 4 weeks, with 3 sessions of treatment a week. A follow-up was conducted 3 months later. Total study duration was 3 months.	79 participants were included and randomly divided into 4 groups; all of whom completed the study	The assessors were not blinded in this study	The control group in this study was Group 1, as they received exercise therapy and hot packs and did not receive any treatment from a modality	Subjects were randomized into 4 groups	7	97%
LIMITATIONS:	This study had a well-defined inclusion and exclusion criteria which a positive aspect to note. It included an age range of 18-55 years of age that was smaller than other included RCTs in this systematic review. However, the authors do not provide information regarding the presence of any comorbidities that may have been prevalent among the included population in this study. The participants were expected to stop all pain medication; however, no mention of any medication unrelated to the SIS was mentioned and controlled. The inclusion of SIS was stated, however the type and stage of impingement was not noted by the authors. A positive aspect of this study is that arm dominance among participants was tabulated and indicated. This is an important factor to note as it could affect the outcomes of this study as muscle recruitment patterns vary between each arm and since this study focuses solely on unilateral shoulder symptoms (Lemos et al., 2011). The control group had the highest number of unaffected left shoulders that were included in the group,							

	which creates heterogeneity among groups as the highest level of variation among groups was found in the control group. Therefore, the control group indicates a different cohort of patients as compared to the other groups. Among the other groups in this study, the TENS group had the highest group of involved right sided arms being treated – making this group the most different from the control. The other two groups tended to be closer to the TENS in terms of patient presentation, which results in a lack of homogeneity among patients at baseline, affecting the outcomes of this study. Also, to note, arm dominance was mentioned, however there was no statement to indicate which arm (dominant/non-dominant) responded more or less favourably to treatment. Another limitation of this study is that the author does not state the method of randomization used to divide the participants into the 4 groups. Since there was no blinding in this study, the researcher could have favored one outcome over the rest, or had a negative opinion of one modality as compared to the others and hence placed the participants with severe pain in the groups that were favored by the researcher, which could have resulted in selection and reporting bias (Torgerson and Torgerson, 2003, Boutron et al., 2019). The above statement regarding possible bias towards a particular modality could be the reason why the TENS group had lower VAS scores as compared to the three other groups at baseline. A lower score at baseline can indicate that there was no homogeneity amongst the participants regarding pain severity, which may be as a result of the fact that there was variation among dominant and non-dominant shoulders being affected. The TENS group also showed less disability as indicated by the DASH scores, as compared to the other groups. This leads to the question as to whether the TENS group demonstrates limited pain and disablity because they are forced to use their affected dominant arm more so than the other patients in the other groups. If this is the case, the limited pain and disability in the TENS group could have resulted from mechanical stimulation of the arm through movement, which may result in the amelioration of the symptoms experienced by these patients. It appears that participants experiencing less pain and disability were placed into the TENS group. The lower scores result in the floor effect occurring (Oxford, 2020), as there is limited room for improvement as compared to the other groups. In this case, there is almost 50% less room for improvement in the VAS scores as compared to the other groups. The above complexities in being able to compare the groups may have occurred due to the process of group allocation – the process is indicated as randomized, but there are no specific details on how this was actually done. It may have been better to utilize a stratification process to ensure greater homogeneity between the groups. This leads to the possibility of bias occurring in this study due to the lack of allocation concealment and blinding (Lewis and Warlow, 2004).

	Much like the study by Subasi et al., (2012), this study focuses on subjective outcomes, which affects the rigour of the study; as the outputs are all patient reporting based and subject to influence, auto-suggestion, pain tolerance, pain perception and prior experience of the same or similar treatment (Torgerson and Torgerson, 2003, Jakovljevic, 2014). The subjectivity of the questionnaires regarding how effective the participants found the treatment can often be influenced by depressive factors pertaining to pain, regardless of whether the treatment worked or not. This is indicated by greater disability scores in the DASH questionnaire (Wolfensberger et al., 2016). Patients were asked to perform home exercise therapy; however patient adherence was not being monitored (e.g. exercise diary), and this could have affected the outcome of the results at the 3-month follow-up period as poor compliance could have resulted in a negative outcome (Argent et al., 2018). It should have been noted at the 3-month follow up, which arm benefitted most from treatment in terms of dominance and which did not. Another limitation of this study is that the VAS scores at rest for Group 3 were much lower than all the other groups, resulting in the floor effect (Oxford, 2020) occurring. This further contributes to the fact that the groups were not equal at baseline and this variation disadvantaged Group 3 as there was no statistically significant changes present at post testing and follow-up measures.
OUTCOME:	The outcome of this study showed that TENS, interferential current and ultrasound treatments, used in conjunction with exercise therapy and heat, had similar effects in treating SIS; however, they do not vary much in comparison to the control. The control group used in this study was a different target population with a different affected side as compared to the other groups, resulting in erroneous conclusions. All groups showed improvements regarding pain, function and the physical component of quality of life. However, interferential current provided better outcomes regarding the mental component of quality of life, with no difference in application tie noted.
DISCUSSION:	Based on the limitations of this study, regarding the baseline differences of participants receiving TENS, we cannot assume that TENS was as effective in treating SIS, as compared to ultrasound and interferential current therapy, due to the 50% difference of baseline VAS and DASH scores. The settings on the TENS machine used on the participants were not stated as compared to the frequency stated for interferential current and the intensity stated for ultrasound. This limits how practitioners would be able to apply the findings from this study in a health care practice. This study also focused on subjective outcomes, which do not provide evidence to indicate that range of motion and functional assessments had

	improved in an objective manner. The use of three different questionnaires results in the possibility of bias from the patients based on their emotional response to pain. This study did not question participants regarding history of treatment with modalities, if patients were given an option of joining one of four groups, then previous negative experiences with a modality would have resulted in poor feedback, and positive previous encounters could have resulted in a patient exaggerating outcomes in the subjective feedback. If patients were familiar with a treatment modality prior to this study, they would have preconceived expectations of how effective the modality would be and based on the high level of subjectivity in this study, their lack of naivety could have either positively or negatively affected the outcomes. This leads to further possibility of selection and reporting bias in this study, making the quality of this research questionable (Jaovljevic, 2014, Torgerson and Torgerson, 2003, Boutron et al., 2019). The authors mentioned that conventional TENS was used in this study, however the authors do not specify what frequency was applied, the placement of the electrodes and how they controlled for possible analgesic tolerance in patients with prior experience with TENS. The TENS group was also not uniform with other groups, demonstrating lower VAS at rest scores and could not therefore provide any statistically significant results. The TENS group also demonstrated the greatest amount of difference from the control group, due to the high numbers of right-hand dominant arms included.
CONCLUSION:	This study was ranked 7 out of a possible 11 on the PEDro score, with a high total percentage agreement of 97% among reviewers. Although this study demonstrated some positive aspects such as indicating arm dominance and equal distribution of genders among groups, the high level of subjectivity and the lack of accountability in terms of controlling possible patient naivety that may affect outcomes, reduces the methodological rigour of this study. This study also had a high degree of variation regarding the TENS group and the control group, which makes comparison between these two groups difficult. Due to the variation in the TENS group and the control group, we cannot clearly state whether TENS was effective in treating SIS. The methodological rigour of this study is however good but the clinical oucomes are poor.

Table 4.39: Analysis of Article RCT: Article 20

AUTHOR(S):	Yazmalar, Sariyildiz, Batmaz, Alpayci, Burkan, Ozkan and Cevik					
YEAR:	2016					
TITLE:	Efficiency of therapeutic ultrasound on pain, disability, anxiety, depression, sleep and quality of life in patients with subacromial impingement syndrome: A randomized controlled study					
CRITERION:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
1	Eligibility criteria were specified	1	1	1	1	**100%**
2	Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	1	1	1	1	**100%**
3	Allocation was concealed	0	1	0	0	**67%**
4	The groups were similar at baseline regarding the most important prognostic indicators	1	1	1	1	**100%**
5	There was blinding of all subjects	0	1	1	1	**67%**
6	There was blinding of all therapists who administered the therapy	0	0	0	0	**100%**
7	There was blinding of all assessors who measured at least one key outcome	0	0	0	0	**100%**
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	1	1	1	1	**100%**
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”	1	1	0	1	**67%**
10	The results of between-group statistical comparisons are reported for at least one key outcome	1	1	1	1	**100%**
11	The study provides both point measures and measures of variability for at least one key outcome	0	1	0	0	**67%**
	TOTAL SCORE	**6**	**9**	**6**	**7**	
		OVERALL PERCENTAGE AGREEMENT:				**88%**

Table 4.40: Analysis of Article RCT: Article 20

AUTHOR(S):	Yazmalar, Sariyildiz, Batmaz, Alpayci, Burkan, Ozkan and Cevik							
YEAR:	2016							
TITLE:	Efficiency of therapeutic ultrasound on pain, disability, anxiety, depression, sleep and quality of life in patients with subacromial impingement syndrome: A randomized controlled study							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomisation of participants**	**Ranking**	**Total Percentage Agreement**
Pain and Disability: This was assessed using the Shoulder Disability and Pain Index (SPADI) **Anxiety and Depression**: Assessment of these outcomes were assessed using the Hospital Anxiety and Depression Scale (HADS) **Sleep Quality**: Measures of 7 different sleep components were assessed using the Pittsburgh Sleep Quality Index (PSQI) **Quality of Life**: Six different components of health were assessed using the Nottingham Health Profile (NHP)	Measurements of relevant outcomes were conducted at baseline and at the end of three weeks of treatment. Treatment sessions were conducted five times a week for three weeks	The duration of the study was three weeks. The last measurement was taken after 3 weeks	51 participants were initially enrolled into this study and divided into two groups. Group 1 had 26 participants, receiving continuous ultrasound + control Group 2 had 24 participants and received sham ultrasound + control This study had one drop out from Group 2.	Assessors were not blinded	Each group received TENS and an exercise program as a control	There was a computerized method of randomization regarding the participants	7	88%
LIMITATIONS:	This study had positives such as a detailed inclusion and exclusion criteria, the presence of assessor blinding and an objective method of randomization. However, there were multiple factors that limited the quality of this study. The age range included in this study was broad, which indicates the possibility of variation in types and stages of impingement involved. The presence of comorbidities outside the specified list in the							

	exclusion criteria are also much more likely in patients over the age of 40 (Tran et al., 2018), which means that there is lack of homogeneity concerning impingement type and health status of included individuals. This makes the application of outcomes difficult to do in a general clinical setting as there is no specification as to which age group benefitted the most from this treatment. Furthermore, with the presence of comorbidities and pain comes the possibility for medication – either to manage the pain related to SIS or to manage the underlying comorbidity. These factors could have influenced the outcome of this study if they were not controlled. The inclusion criteria stated that patients were recruited for this study if they presented with tendinitis, tendinosis and partial tears of the supraspinatus tendon. The severity of pain between the tendinitis and tendinosis patients would be different from those with partial supraspinatus tears, and this would therefore create variation between groups and among individuals in each group. The authors do not state whether the patients with partial tears were equally distributed in each group, and this variation could negatively impact the outcome. Another aspect to note regarding patient recruitment is the fact that patients were included in this study as long as they had presented with pain for a period of 3 months or more. This means that there was inclusion of both subacute and chronic patients, which results in variation in response to healing (Chanda et al., 2011, Guo and DiPietro, 2010). If there were older patients with chronic symptoms, then healing time would take much longer as compared to a 20-year old, due to the fact that age affects healing response in tissues (Gould et al., 2015). This study recruited patients from two university hospitals physical medicine and rehabilitative centres. The location of this study leads to the question as to whether the outcomes of this study can be applied to the general public as there is no statement from the author stating the severity of each individuals SIS symptoms. The more severe the symptoms are, the more likely these patients were to be admitted for surgery. If these patients represented hospital admission patients, then it would limit the outcomes of this study to patients with advanced SIS and not to the general public. The subjects of this study were not similar at baseline, given the differences in the pre and post intervention statistics (although these were noted as not being statistically significant) for the NHP pain and sleep scales, which means that the degree of dysfunction in all the participants were not similar. Shoulder dominance was also not stated, and in cases where sleep disturbances were being assessed, the dominance of the shoulder would affect the quality of sleep. The authors should have also questioned the participants on which sleeping position is favored as this would also affect pain during sleep. In this study, data was collected at two different hospital sites. The authors do not state how they accounted for the homogeneity when applying

	the intervention protocol and they do not state how randomization was applied in the two different hospital recruitments centres. The appropriate measure of handling randomization in this study is to have recruited all participants from both hospitals and created one list, in which the computer-generated randomization would divide them among two groups. However, no mention of this was presented in this study and the possibility of selection and chance bias from the authors could occurr (Torgerson and Torgerson, 2003). Patient naivety was not taken into consideration. There is no mention that the authors took into account the possibility of the patients having experienced or been treated with same modalities that were used in this study. The possibility of a patient having a preconceived opinion on the modalities used in this study would have affected the outcomes due to reporting bias (Torgerson and Torgerson, 2003; Boutron et al., 2019). This is especially possible due to the fact that purely subjective outcomes were used in this study to determine the effectiveness of the intervention. The limitations of this study are that all the outcomes being assessed are subjective. The SPADI questions the patient's state of pain and disability, but there is no assessment of the range of motion / use of the algometer / use of diagnostic ultrasound / MRI to assess whether the pain and disability experienced by the participants are justified. Patients associate pain with a limited range of motion, so if the TENS and exercise therapy was useful in improving the range of motion, the SPADI pain scores should have decreased by more than ±30 points, while the SPADI disability scores should have decreased by more than ±25 points, since the patients would have noticed a visual change in function, which would have decreased the pain experienced by them. There is a noticeable difference, although not significant in pre-intervention scores for the NHP-pain and sleep scores, with Group 1 having higher scores than Group 2, making them unequal at baseline. If one group has less pain and sleep dysfunction than the other, it would not be appropriate to assess the effectiveness of the treatment on those factors, since one group has more room for improvement as compared to the other group (Oxford, 2020). This study makes use of descriptive statistics which limits the projected effect the outcomes of this study may have on larger populations. This then further limits the findings of this study to only the population included within it (Frost, 2020). This makes application of findings even more difficult apart from the fact that there is a lack of homogeneity at baseline among participants regarding their age, time frame for their shoulder pain and variation in etiology.

OUTCOME:	The outcome of this study indicates that ultrasound is not effective in treating subacromial impingement syndrome. The TENS and exercise programs have shown to beneficial in reducing pain, disability and sleep disturbances in SIS patients, however it is not effective in treating anxiety, depression and fatigue.
DISCUSSION:	Many of the outcomes assessed in this study are subjective, while all the forms of measurement are subjective (similar to the previous studies by Subasi et al., (2012); and Ucurum et al., (2018)), by using questionnaires to assess pre and post test differences. This does not provide substantial evidence (as there are many influencing factors as were also applicable to Subasi et al., (2012) and Ucurum et al., (2018) to promote the use of the included treatment modalities in managing SIS. It also appears that patients included in this study was recruited from a hospital setting and there is no mention of the public being recruited. This further indicates that the outcomes would be limited to hospital patients rather than the general public. TENS was not the focus of this study; however, it was proven to be effective when used in combination with exercise therapy to improve pain, disability and reduce sleep disturbances. Disability could have been assessed with the use of a universal goniometer, in order to provide an objective outcome. This study does not provide adequate evidence to state that TENS on its own is effective in treating SIS. In this study, TENS was used in conjunction with an exercise program, as a form of control in both groups. Although this study has found that this control was effective in treating pain, disability and sleep disturbances associated with SIS, we do not know whether TENS on its own, would be effective in managing pain and dysfunction associated with SIS. With regards to the use of TENS settings, there was no mention of the settings used regarding TENS application on the shoulder of patients in this study. The only mention of settings was that conventional TENS was used and for a period of 20 minutes. There is no statement regarding electrode placement, the exact frequency used, how intensity was measured and if there was any method of controlling analgesic tolerance as the TENS was applied daily, five days a week for three weeks. All of these factors could result in the ineffective use of TENS with analgesic tolerance affecting possible outcomes.

CONCLUSION:	This study was ranked 7 on the PEDro scale, with a total percentage agreement from reviewers being 88%. Although this indicates that the quality of this study was good, the above limitations and the fact that the application of outcomes is limited to a small population based on the use of descriptive statistics, this study can be categorized as being a poor study with low rigour and not supportive for the use of the intervention in clinical practice. This study is not specific to the use of TENS and due to the lack of important parameters not being taken into consideration, we cannot state whether TENS was an effective contributing factor in reducing pain from SIS. There is a need for further studies to address the above shortcomings, by having a smaller age range, including a specific type of impingement, using TENS correctly and stating the settings associated with the patients in the study as well as making use of inferential statistics which would help project the effectiveness of the outcomes on a larger population. Therefore, to conclude, this study has a low level of methodological rigour and poor clinical outcomes.

4.4.2 Summary of findings

Table 4.41: Outcome and Methodological Ranking of Randomised Controlled Trials (n=19)

Study Type			Randomised Clinical Trials		
Authors	**Year**	**Reported Outcome**	**Methodological Ranking**	**Outcome as determined by reviewers:**	**Clinical outcomes of the study for TENS use in SIS**
Alwesaly and Abdelsalam	2019	Shoulder mobilization along with TENS immediately reduces pain and increases overhead reach in patients with SIS	7	Good	Poor
Ashtiani et al.,	2016	Both TENS and Action Potential Stimulation (APS) reduce pain and improvement in chronic mechanical shoulder pain patients. APS is however, superior to TENS.	3	Poor	Poor
Atya	2012	Micro-current electrical nerve stimulation effectively reduces pain and increases shoulder function in patients with SIS	8	Good	Poor
Bae et al.,	2011	Strengthening and motor control exercises were effective in treating patients with SIS, better than compared to the physical therapy (TENS, Ultrasound and hot pack)	4	Poor	Poor
Baskurt et al.,	2006	TENS, heat and TENS + heat are all equally effective in providing an analgesic effect in patients with stage 1 SIS	4	Poor	Poor
Celik	2010	The outcome of the study states that the scapulothoracic exercises in conjunction with glenohumeral exercises contributes significantly to the improvement of joint movement in the frozen shoulder. No assessment of TENS effectiveness was made in this study	5	Good	Poor
Grymel-Kulesza et al.,	2007	Combination therapy that comprises of the use of combined ultrasound and electric current, active exercises and classic massage or combined cryotherapy, active exercises and classic massage is effective in treating rotator cuff injuries	5	Good	Poor
Kocyigit et al.,	2012	One treatment of low-frequency TENS can result in a decrease in pain levels through the modulation of discriminative, affective and motor pathways regarding central pain perception in patients with SIS.	8	Good	Poor

Authors	Year	Reported Outcome	Methodological Ranking	Outcome as determined by reviewers:	Clinical outcomes of the study for TENS use in SIS
Koo et al.,	2015	Novel noxipoint therapy showed improved chronic pain, function and quality of life as compared to physiotherapy with TENS, in paitients with chronic shoulder and neck pain	10	Excellent	Good
Korkmaz et al.,	2010	There is no difference between the use of TENS and pulsed radiofrequency in the treatment of shoulder pain.	8	Good	Poor
Lin et al.,	2019	TENS and Transcutaneous Pulsed Radiofrequency (TPRF) are safe and effective to use in the treatment of shoulder pain. The effect of TPRF is greater than TENS, however the superiority of TPRF over TENS tends to diminish over a period of time.	11	Excellent	Poor
Moezy et al.,	2014	Scapular stabilization-based exercises used as a treatment intervention proves to provide successful management of shoulder impingement syndrome. No mention of the effectiveness of TENS was present in the outcomes.	9	Excellent	Poor
Ozdincler	2005	Combination therapy of TENS and Low Energy Laser (LEL) is more effective in the treatment of shoulder pain as compared to TENS and LEL being used separately	5	Good	Poor
Shehab and Adham	2000	Both TENS and Ultrasound, used in combination with ice packs and exercise therapy are effective in the treatment of peri articular shoulder pain, with ultrasound resulting in a better range of motion.	4	Poor	Poor
Soibam	2005	TENS and Ultrasound are effective interventions in the treatment of perarticular shoulder pain	7	Good	Poor
Subasi et al.,	2012	Water-based exercise group that included the use of physical therapy (TENS, ultrasound and hot pack) was clinically significantly effective as compared to the land-based approach towards the treatment of SIS.	6	Good	Poor
Tefner et al.,	2013	Balneotherapy used in conjunction with TENS and exercise therapy is more effective than TENS and exercise therapy on its own, in treating chronic shoulder pain.	8	Good	Poor
Ucurum et al.,	2018	TENS, interferential current and ultrasound treatments, used in conjunction with exercise therapy and heat, had similar effects in treating SIS, however they do not vary much in comparison to the control.	7	Good	Poor

Yazmalar et al.,	2016	Ultrasound is not effective in treating SIS. TENS and exercise programs have shown to be beneficial in reducing pain, disability and sleep disturbances in SIS patients, however it is not effective in treating anxiety, depression and fatigue	7	Good	Poor

Based on the findings in Table 4.41 above, it is evident that majority of the studies included in this review did not provide good clinical outcomes regarding the use of TENS in treating SIS. Each article was categorised according to the categories in Table 3.7, which divided articles into either a rigorous or poor study based on clinical outcomes and methodological rigour. We can deduce from Table 4.42 that 19 out of 20 studies did not provide good clinical outcomes, either as a result of not focusing on TENS as a sole method of treatment, or not including SIS patients as the sole focus of the study. The methodological rigour of the studies, however, vary between excellent to poor. The outcomes above indicate that there is not enough evidence to support the use of TENS in treating SIS, as the number of studies that focus on SIS related pain is limited as is the number of studies using TENS as a treatment intervention by itself.

4.4.3 Non-randomised controlled studies

4.4.3.1 Examiner agreement and ranking of articles: Non-randomised controlled trials

Table 4.42: List of feedback analysis of N-RCT articles

Tabulated feedback data table	Analysis of article table numbers	Authors (s)	Year	Title
Table 4.44	Table 4.45	Hakguder, Tastekin, Birtane, Uzunca, Zater and Sut	2019	Comparison of the short-term efficacy of physical therapy in subacromial impingement syndrome patients with stage 1 and stage 2 magnetic resonance imaging findings

Table 4.43: Tabulated feedback data for RCT: Article 8

AUTHOR(S):	Hakguder, Tastekin, Birtane, Uzunca, Zater and Sut					
YEAR:	2011					
TITLE:	Comparison of the short-term efficacy of physical therapy in subacromial impingement syndrome patients with stage 1 and stage 2 magnetic resonance imaging findings					
CRITERIA:		**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**Majority**	**Percentage Agreement**
Selection:	1. Is the case definition adequate?	1	1	1	1	100%
	2. Representativeness of the cases	1	1	1	1	100%
	3. Selection of controls	0	0	0	0	100%
	4. Definition of controls	0	0	0	0	100%
Comparability:	5. Comparability of cohorts on the basis of design or analysis	0	1	0	0	67%
Exposure:	6. Ascertainment of exposure	0	1	0	0	67%
	7. Same method of ascertainment for cases and controls	1	1	0	1	67%
	8. Non-response rate	0	1	1	1	67%
	TOTAL SCORE	**3**	**6**	**3**	**4**	
		OVERALL PERCENTAGE AGREEMENT:				**74%**

Table 4.44: Analysis of Article RCT: Article 8

AUTHOR(S):	Hakguder, Tastekin, Birtane, Uzunca, Zater and Sut							
YEAR:	2011							
TITLE:	Comparison of the short-term efficacy of physical therapy in subacromial impingement syndrome patients with stage 1 and stage 2 magnetic resonance imaging findings							
STUDY PROPERTIES:								
Form of measurement	**Frequency of measurement**	**Duration of study**	**Number of participants**	**Assessors blinded**	**Control used**	**Randomisation of participants**	**Ranking out of 9**	**Total Percentage Agreement**
Pain: The Visual Analogue Scale (VAS) was used at three different time points **Pain and Function**: The University of California, LA (UCLA) and Constant Shoulder Score Scale were used to assess pain and function in the participants. The Constant Score assesses pain and function by scoring parameters related to Activities of Daily Living (ADL), Range of Motion (ROM), pain and strength	Measurements were taken at baseline (Visit 1), after treatment (visit 2) and at a one-month follow-up after visit 2 (visit 3)	The duration of the study was one month. The patients received 15 sessions of physical therapy, 5 days a week for 3 weeks. A follow-up was conducted one month after post-testing at the first visit	48 patients were initially enrolled into the study and divided into 2 groups, based on the degree of rupture. 5 participants dropped out of the study and the final participant number was 43, with Group 1 having 17 participants and Group 2 having 26 participants	There was blinding of the assessors in this study	No control group was used in this study	There was no randomization of participants. Participants were divided into 2 groups, depending on whether they had a partial supraspinatus tendon rupture or not	4	74%

LIMITATIONS:	A limitation of this study is that the sample size was too small, with only 43 participants included in this study, 17 participants were allocated to the partial tears group (Group One), while 26 participants were allocated to the group that had no partial tears present (Group Two). The small sample size results in the use of non-parametric statistics being used, which reduces the possibility of detecting an effect in the study (Frost, 2020). The study also had more than double the number of females as compared to males. The females were not equally distributed between the groups, as Group one had 13 females and Group two had 18. Group Two also had double the number of males as Group One. The use of non-parametric statistics in this study would focus on the outcomes achieved mainly by females as compared to the males, as the sample size of females is greater than that of males. With regard to hand dominance, no mention was made. This is an important factor to take into consideration considering muscle recruitment patterns of the dominant hand is different from the non-dominant hand (Lemos et al., 2011). The authors do state the number of left and right shoulders that were affected in each group, they were not noted to be equally distributed, however. Therefore, we are unaware if hand dominance played a contributing factor in the response to treatment. There is no mention regarding comorbidities prevalent in the included patients, and due to the fact that the age range in both groups starts from ± 40 years of age to the maximum age of 76, there would be a high possibility that these patients would be diagnosed with a comorbidity (Tran et al., 2018). There is no statement regarding whether these patients were medicated for their comorbid conditions, or if they were on analgesics prior to admission into this study. Analgesic intake was permitted and controlled post-treatment, but we are unaware as to whether consumption during the study intervention affected the results. Although there is a mean time frame to indicate the duration of time the participants experienced their symptoms (10 months for group one and 8 months for group two), there is no specification as to whether the symptoms presented as an acute, subacute or chronic condition. The mean age between the groups varied by 10 years, which would affect the study as age affects the structure and function of tendons in humans (Kannus et al.,

	2005). This would contribute to a lack of homogeneity regarding demographic factors at baseline. This means there is a lack of homogeneity among individuals regarding the duration of symptoms, and this is an important factor to take into consideration as variation in pain duration means there is variation in response to treatment, which would affect the outcome of this study. This study does not include control groups to assess the efficacy of the treatment in each of the stages of subacromial impingement individually. This therefore only addresses the relative effectiveness in a pragmatic study, which reduces the rigour of the study. There is no benchmark (control) to assess the progress that was achieved by each group with the use of the physical therapy. The groups were just compared to each other, which would greatly reduce any possibility of detecting a positive effect (and possibly detecting an erroneous difference as the one group had more severe pathology than the other), since the groups were not similar regarding baseline prognostic indicators (e.g. the VAS: the VAS scores different at baseline at rest, with Group one having higher scores that Group two). With the VAS score having been significantly different between the groups to start with, the floor effect of the lower group (group 2), may have enhanced the difference over time between the groups (i.e. group 1 had a greater ability to improve as compared to group 2). This is an artificial significant difference which can lead to the authors drawing the incorrect conclusion (Oxford, 2020). Hence the need for a control group of patients with a similar pathology stage would have strengthened the rigour of the study (Oxford, 2020). There is also a comparison of two different pathologies, with partial supraspinatus tears in one group and no partial tears in another group. Each of these conditions would respond differently to treatment and their duration in healing time would be different. This indicates a lack of homogeneity between groups in order to make an informed and accurate comparison. The physical therapy used in this study is a packaged treatment, in which TENS was one of many components. This reduces any possibility of identifying whether TENS had a positive individual effect in managing pain related to the two stages of subacromial impingement in either of the groups, as the effects of the physical therapy was assessed as a combined treatment. Unlike many studies, the authors indicated the frequency

	settings on the TENS machine was set at 100Hz at a 0.2 pulse duration and tolerable frequency. The authors do not state what ROM and stretching exercises were used in this study. This limits our knowledge on what the combination treatment entails in order to provide improvement in patients experiencing subacromial impingement syndrome. There was also no long-term follow-up period conducted on patients in this study, and therefore the outcome of this study is limited to the short-term effects of physical therapy. With regards to assessment, the use of purely subjective outcomes were applied in order to assess the effectiveness of the study. This could be greatly influenced by patient naivety and bias which could have led to reporting bias from the patient (Torgerson and Torgerson, 2003). This reduces the effectiveness of the outcomes provided as we cannot state whether the treatment interventions were really effective in managing pain related to SIS type 1 and 2, due to the lack of objectivity.
OUTCOME:	The authors found that there was no significant difference regarding assessed outcomes in Stage 1 and Stage 2 subacromial impingement syndrome patients who received the physical therapy treatment protocol. However, in the conclusion they state that the SIS with partial rupture did benefit more from the treatment interventions --- which implies that they did better than the other group, however, we cannot assume to know whether this improvement was better than placebo or natural history due to the lack of a control to test the interventions against.
DISCUSSION:	Given the limitations of this study, such as variation in baseline prognostic factors, variation duration of symptoms, lack of information regarding presence of comorbidities that may have influenced the outcome and, the small sample size and lack of control groups limits the study's outcomes in terms of treatment efficacy and relative effectiveness. Although age difference between the two groups was factored into the statistical calculations, the effects of age on the tendons in the participants would affect the outcome of the treatment (Kannus et al., 2015). In this study, TENS was used as part of a combination treatment that consisted of more than one electromodality, and not on its own. This makes it difficult to assess whether TENS was effective in providing analgesic relief. The settings used in this study was stated with an intensity of 100Hz and

	a pulse width of 0.2 m/s. Intensity was controlled based on the patient's pain tolerance. However, the electrode placement was stated as being located around and on the shoulder region. There is no specification as to where exactly the electrodes were placed, which results in a lack of homogeneity among participants as the placement could have varied between individuals. There was no control for possible analgesic tolerance as the intervention was applied 5 times a week for 3 weeks, without variation in the frequency (Chandran and Sluka, 2003). Due to the packaged use of TENS, the lack of control regarding analgesic tolerance and the lack of information regarding the electrode placement among participants, we cannot clearly ascertain whether TENS is effective in treating either Stage 1 or 2 SIS.
CONCLUSION:	This study was ranked a 4 out of a possible 9 on the NOS. Although there were favourable factors included in this study such as a well-defined inclusion and exclusion criteria, mentioning of the pathological shoulders affected and providing a flow-diagram regarding patient follow-up, it did not provide adequate information regarding TENS and its effectiveness in treating SIS. The study had a low rigour but the clinical outcomes were poor, due to the lack of homogeneity at baseline and lack of proper control group, to compare the outcomes against.This study is therefore categorized as having low methodological rigour and poor clinical outcomes as based on the categorization in Table 3.7.

4.4.4 Summary of Findings

Table 4.45: Outcome and Methodological Ranking of Non-Randomised Controlled Trials

Study Type		Non- Randomised Controlled Trials			
Authors	**Year**	**Reported Outcome**	**Methodological Ranking**	**Outcome as determined by reviewers:**	**Clinical outcomes of the study for TENS use in SIS**
Hakguder et al.,	2011	TENS was used as a combination treatment along with superficial heat, ultrasound, Codman's pendulum exercises, assisted ROM and posterior capsule stretching and strengthening exercises. No significant difference regarding assessed outcomes in Stage 1 and Stage 2 SIS patients who received the combination physical therapy treatment protocol was noted	4	Poor	Poor

Based on the findings of Hakguder et al., (2011), the evidence is limited in stating whether TENS is effective in treating SIS related symptoms. Both the methodological rigour and clinical outcomes was found to be poor in this study, which means that there is not enough evidence to support the use of TENS in treating SIS in a general sense, as these findings correlate to those found in the RCTs included in this study (Table 4.41).

4.5 Conclusion

Chapter Four revealed the findings of the reviewers regarding the methodological rigour, outcomes, limitations, discussion and conclusion for each study included in the review.

Each study was scored according to their respective scales with RCTs being scored according to the PEDro scale (PEDro, 1999) and non-RCTs being scored against the Newcastle Ottawa Scale (NOS) (Wells et al., 2003b).

In the next chapter (Chapter Five), an explanation as to whether the studies provided evidence to support the use of TENS in treating SIS will be provided based on the findings in this chapter.

5. Chapter Five - Discussion of Results

5.1 Introduction

In this chapter, a discussion of the results, found in Chapter Four,is presented in order to assess the level of evidence provided by the literature to either accept or reject the use of Transcutaneous electrical nerve stimulation (TENS) in the treatment of shoulder impingement syndrome (SIS).

This review will be completed in two ways:

1. Review by evidence available for the use of TENS as a single therapy intervention versus the use of TENS in a combination therapy intervention.
2. Outlining the listed specifications of the TENS and its clinical application and the evidence for these different situations.

5.2 Review and classification of articles based on the individual and combined use of TENS in treating SIS

Following the review of articles included in Chapter Four, it was clear that TENS was used in both individual and combination therapy treatments. As such, the articles will be divided and tabulated based on the manner in which TENS was used in the reviewed studies.

To facilitate this, the articles used to review the effectiveness of TENS in treating SIS were divided between studies that used TENS as an individual treatment and those that used TENS as a combination treatment (see Tables 5.1 and 5.2 respectively). The articles were reviewed and ranked using the Pedro scale (PEDro, 1999) and the Newcastle-Ottawa Scale (Wells et al., 2003b).

Table 5.1: Articles in which TENS was used as an individual treatment

Authors and Year	Article Title	Interventions compared
Alwesaly and Abdelsalam, 2019	Immediate effect of mobilization on pain and overhead reach in patients with shoulder impingement syndrome	Conventional TENS TENS versus mobilization
Ashtiani, Ghiasi, Noraie and Bohloli, 2016	Effectiveness of action potential simulation and transcutaneous electric nerve stimulation on pain and function of patients with chronic mechanical shoulder impairment	TENS versus APS
Atya, 2012	Efficacy of Microcurrent Electrical Stimulation on Pain, Proprioception Accuracy and Functional Disability in Subacromial Impingement: RCT	MES versus Placebo MES
Baskurt, Baskurt, Ozcan and Yilmaz, 2006	The immediate effect of heat and TENS on pressure pain threshold and pain intensity in patients with stage 1 shoulder impingement syndrome	TENS versus Heat versus TENS + Heat
Kocyigit, Akalin, Gezer, Orbay, Kocyigit and Ada, 2012	Functional magnetic resonance imaging of the effects of low-frequency transcutaneous electrical nerve stimulation on central pain modulation: A double-blind, placebo-controlled trial	Low-frequency TENS versus Sham TENS
Korkmaz, Capaci, Eyigor and Eyigor, 2010	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: a prospective, randomized study	Conventional TENS versus Pulsed radiofrequency
Lin, Chiu, Shih, Lee, Li, Guo, Luo and Pang, 2019	Two transcutaneous stimulation techniques in shoulder pain: Transcutaneous pulsed radiofrequency (TPRF) versus Transcutaneous electrical nerve stimulation (TENS): A comparative pilot study	TENS versus TPRF
Ozdincler, 2005	The effects of TENS and LEL on pain and functional performance of patients with shoulder pain	TENS versus LEL versus TENS + LEL
Shehab and Adham, 2000	Comparative effectiveness of ultrasound and transcutaneous electrical nerve stimulation in treatment of periarticular shoulder pain	TENS versus Ultrasound
Soibam, 2005	Comparative study on the effectiveness of ultrasound (US) and transcutaneous electrical stimulation (TENS) in the treatment of periarticular shoulder (PSP)	TENS versus Ultrasound
Ucurum, Kaya, Kayali, Askin and Tekindal, 2018	Comparison of different electrotherapy methods and exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial	TENS versus IFC versus Ultrasound versus Heat and exercise

Table 5.2: Articles in which TENS was used as part of a combination treatment

Author and Year	Article Title
Bae, Lee, Shin, Kim and Lee, 2011	Effects of motor control and strengthening exercises on pain, function, strength and the range of motion of patients with shoulder impingement syndrome
Celik, 2010	Comparison of the outcomes of two different exercise programs on frozen shoulder
Grymel-Kulesza, Polak, Kubacki, Skrzep-Poloczek and Krol, 2007	The effect of multi-modality therapy including active exercises, classic massage, cryotherapy and comination if ultrasound and electrical stimulation on rotator cuff injuries
Hakguder, Tastekin, Birtane, Uzunca, Zater and Sut, 2011	Comparison of the short-term efficacy of physical therapy in subacromial impingement syndrome patients with stage 1 and stage 2 magnetic resonance imaging findings
Koo, Lin, Wang, Tsauo, Yang, Yen and Biswal, 2015	Novel noxipoint therapy versus conventional physical therapy for chronic neck and shoulder pain: Multicentre randomized controlled trials
Moezy, Sepehrifar and Dodaran, 2014	The effects of scapular stabilization-based exercise therapy on pain, posture, flexibility and shoulder mobility in patients with shoulder impingement syndrome: a controlled randomized trial
Subasi, Toktas, Demirdal, Turel, Cakir and Kavuncu, 2012	Water-based versus land-based exercise programs for the management of shoulder impingement syndrome
Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender, 2013	The effect of balneotherapy on chronic shoulder pain: A randomized, controlled, single-blind follow-up trial. A pilot study
Yazmalar, Sariyildiz, Batmaz, Alpayci, Burkan, Ozkan and Cevik, 2016	Efficiency of therapeutic ultrasound on pain, disability, anxiety, depression, sleep and quality of life in patients with subacromial impingement syndrome: A randomized controlled study

5.3 Ranking criteria for the evidence available to support or reject the use of TENS in treating SIS

A criteria outlined by Dagenais and Haldeman (2012) and Berkman et al., (2013) is used to rank the evidence available in this study. The ranking criteria are presented as follows:

- **Strong:** There was a consistent and generally high level of evidence found among multiple high quality RCT studies.
- **Moderate:** Findings among studies were consistent with similarities being present in at least four or more low quality RCTs or two or more high quality RCT studies.
- **Limited/Low:** The presence of only one RCT study (either high or low quality), or a non-experimental study (non-RCT) to support the findings, or findings that were inconsistent among four or more low quality RCT studies
- **No evidence/insufficient:** The articles provided no evidence to support the outcomes.

The quality of the RCTs as based on the PEDro scores are ranked as follows (Roopchand, 2014):

High quality: 9-11/ 11 on the PEDro scale

Average quality: 6-8/11 on the PEDro scale (does not provide adequate evidence to support or rebuke the effectiveness of a treatment intervention.)

Poor quality: 0-5/11 on the PEDro scale

5.4 Evaluation and ranking of evidence for TENS used as an individual and combination treatment for SIS

5.4.1 TENS as an individual treatment for SIS

In all the studies mentioned in Table 5.1, the authors used TENS as an individual treatment intervention and compared its effectiveness to other modalities in the treatment of SIS. Many of these studies provided evidence either for or against the use of TENS and had varied methodological rigour.

Table 5.3: Level of evidence for TENS as an individual treatment intervention for SIS

Author and Year	Type of study	PEDro Ranking	Clinical Outcome for TENS	Level of evidence					
				Strong	Moderate	Limited	No Evidence	Consistent clinical outcomes	Mixed clinical outcomes
Alwesaly and Abdelsalam, 2019	RCT	7	In favour						
Lin, Chiu, Shih, Lee, Li, Guo, Luo and Pang, 2019	RCT	11	Not in favour						
Ucurum, Kaya, Kayali, Askin and Tekindal, 2018	RCT	7	In favour						
Ashtiani, Ghiasi, Noraie and Bohloli, 2016	RCT	3	Not in favour						
Atya, 2012	RCT	8	In favour						
Kocyigit, Akalin, Gezer, Orbay, Kocyigit and Ada, 2012	RCT	8	In favour			X			X
Korkmaz, Capaci, Eyigor and Eyigor, 2010	RCT	8	Not in favour						
Baskurt, Baskurt, Ozcan and Yilmaz, 2006	RCT	4	In favour						
Ozdincler, 2005	RCT	5	In favour						
Soibam, 2005	RCT	7	Not in favour						
Shehab and Adham, 2000	RCT	4	Not in favour						

Based on the above table (Table 5.3), it can be seen that there are mixed clinical outcomes pertaining to the singular use of TENS in treating symptoms related to SIS, however, the majority of the articles in Table 5.3 show a trend in favour of the use of TENS

to treat SIS as an individual treatment intervention. Understanding the literature available to support the individual use of TENS is important as this electromodality is a widely available, inexpensive and easy to use form of therapy to bring about analgesia in patients experiencing pain related to SIS (Searle et al., 2009). The implications of the findings in Table 5.3 is that the literature trend suggests that there is a slightly larger proportion of literature to indicate that TENS can be used as an individual treatment intervention for SIS, the available evidence to support this conclusion is limited, based on the fact that only six out of the eleven articles in Table 5.3 were in favor of TENS. Therefore, TENS as a treatment method on its own, has limited well structured studies with a favourable clinical outcome to provide a solid basis for making clinical reccomendations. This does not provide adequate evidence-based support for practitioners who are using this as a sole treatment intervention in the treatment of SIS. This may also suggest that the solitary use of TENS as a home therepy independent of adjunctive care within the clinical setting may not provide the patient with positive outcomes.

A possible reason for the outcome attained is that the use of TENS is highly dependent on the placement of the pads as well as the settings utilised when applying the unit. This is therefore discussed in Section 5.4.3

Notwithstanding this, further high-quality studies related to this area of pain management are required, particularly as this modality is non-invasive and inexpensive (Searle et al., 2009), practitioners utilise it in clinical practice and often advocate home care use of this modality. Both these clinical scenarios come at an expense to the patient and if there is no shown clinical benefit, the cost benefit ratio in the long-term cannot reasonably be justified.

Reccomendations for future studies should therefore consider the following shortcomings of the high-quality studies in order to improve the reliabiliaty of the outcomes attained in the articles reviewed in this study.

- Many of the high-quality studies presented with weaknesses that related to patient homogeneity between the groups or they did not provide a comprehensive baseline comparison for the reader to be able to judge comparability.

- Inconsistency among patients resulted in varied responses to treatment and therefore did not provide an accurate indication as to the effectiveness of the

treatment modality used.

- A large contributing factor towards the lack of patient homogeneity is the fact that there was no consistency applied across the literature in terms of patient recruitment – (examples include the influence of handedness / dominance, occupation, side treated, large age ranges, clinical categorisation of the type of SIS). These factors influence not only the severity of the presentation, but also affect the rate and manner of improvement of SIS over time.

- There is a need for better clinical assements (both physical assessments and special investigations) to be used, for identifying patients with particular subcategories of SIS, so that treatment groups may be more homogenous in terms of their clinical presentation. This would ssist in developing clinical prediction rules for specific categories of patients that fall into this SIS diagnoses group and allow for better clinical application of specific treatment programmes both within a research context and a practical clinical context.

- There is a need for better clinical outcome measures that match with the particular subgroups of SIS within a particular study.

Lastly, studies that were found to be of low quality were identified as not having followed the CONSORT principles (Schultz et al., 2010) and therefore lacked transparency and limited data was available to the reader in order to explain how the conclusions of each study were reached. The lack of transparency led to the assumption that bias (selection, allocation, and reporting bias (Torgerson and Torgerson, 2003, Bourton et al., 2019)) may have influenced the results and therefore led to inaccurate and poor outcomes.

5.4.2 TENS as a combination treatment for SIS

Table 5.4: Level of evidence for TENS as part of a combination treatment intervention for SIS

Author and Year	Type of study	PEDro/ NOS Ranking	Clinical Outcome for TENS	Level of evidence					
				Strong	Moderate	Limited	No Evidence	Consistent clinical outcomes	Mixed clinical outcomes
Yazmalar, Sariyildiz, Batmaz, Alpayci, Burkan, Ozkan and Cevik, 2016	RCT	7	In favour						
Koo, Lin, Wang, Tsauo, Yang, Yen and Biswal, 2015	RCT	10	Not in favour						
Moezy, Sepehrifar and Dodaran, 2014	RCT	9	In favour						
Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender, 2013	RCT	8	In favour						
Subasi, Toktas, Demirdal, Turel, Cakir and Kavuncu, 2012	RCT	6	Not in favour			X			X
Bae, Lee, Shin, Kim and Lee, 2011	RCT	4	Not in favour						
Hakguder, Tastekin, Birtane, Uzunca, Zater and Sut, 2011	NRCT	4	Not in favour						
Celik, 2010	RCT	5	Not in favour						
Grymel-Kulesza, Polak, Kubacki, Skrzep-Poloczek and Krol, 2007	RCT	5	Not in favour						

Based on the findings in Table 5.4, it is evident that there is limited evidence to support the use of TENS in treating SIS, even as a packaged treatment intervention. Only three higher quality studies proposed that TENS used in combination with other treatment modalities may be beneficial in providing pain relief relative to SIS. Six lower quality studies (with the exception of one high quality study) were not in favour or did not provide enough evidence regarding the role of TENS as an effective treatment intervention. This indicates that 67% of the studies were not in favour of TENS as part of a combination treatment, which results

in TENS presenting with limited evidence to support its use in treating SIS in this clinical scenario.

Given the outcomes that there is limited conflicting evidence for the use of TENS in combination or as a stand alone treatment (see Table 5.3 and 5.4), it is suggested that is would perhaps be clinically more appropriate to integrate the use of TENS into a clinical treatment package where the benefit of the various interventions may collectively provide an appropriate clinical outcome; which would therefore have a positive impact on the patient, the practitioner and policymakers (Hemingway and Brereton, 2009).

In terms of the research implications identified from the outcomes of the higher quality studies in Table 5.4, it can be deduced that the following factors should be taken into consideration in order to improve the status quo of TENS utilised in a clinical combination setting:

- Similar to studies that were assessing the individual effect of TENS in treating symptoms related to SIS, the lack of patient homogeneity has been the biggest weakness of studies that were identified to be “good”.

- There is a need for more appropriate and specific clinical assessments, both physical and special investigations, in order to identify pathologies being included in a study. This should be done to ensure that there is specificity and homogeneity regarding patients that are included in the study, and to ensure that the subcategories of SIS are specified. This would aid in the development of clinical prediction rules for specific categories of patients that are diagnosed with SIS and allow for better clinical application of specific treatment programmes both within a research context and a practical clinical context.

Weaker studies require a more rigorous application of the CONSORT principles (Schultz et al., 2010) in order to promote transparency and avoid possible bias. Furthermore, studies that have multiple treatment interventions should be more conscious of choosing appropriate measurement tools that can assist in differentiating the contribution of the different interventions within a treatment programme and not focusing on one singular aspect such as pain, for exampleThe effect of TENS settings and placement on clinical outcomes.

5.4.3 The effect of TENS settings and placement on clinical outcomes

Table 5.5: Evidence of TENS settings and electrode placement for TENS used as an individual treatment intervention

Author and Year	Type of study	PEDro Ranking	Clinical Outcome for TENS	TENS settings reported in study	TENS settings	Electrode placement specified
Alwesaly and Abdelsalam, 2019	RCT	7	In favour	Reported	100 Hz	Yes
Lin, Chiu, Shih, Lee, Li, Guo, Luo and Pang, 2019	RCT	11	Not in favour	Reported	150 Hz	Yes
Ucurum, Kaya, Kayali, Askin and Tekindal, 2018	RCT	7	In favour	Not reported	None	No
Ashtiani, Ghiasi, Noraie and Bohloli, 2016	RCT	3	Not in favour	Reported	50 – 100 Hz	No
Atya, 2012	RCT	8	In favour	Reported	10 Hz	No
Kocyigit, Akalin, Gezer, Orbay, Kocyigit and Ada, 2012	RCT	8	In favour	Reported	3 Hz	No
Korkmaz, Capaci, Eyigor and Eyigor, 2010	RCT	8	Not in favour	Reported	100 Hz	Yes
Baskurt, Baskurt, Ozcan and Yilmaz, 2006	RCT	4	In favour	Reported	100 Hz	No
Ozdincler, 2005	RCT	5	In favour	Reported	80 Hz	No
Soibam, 2005	RCT	7	Not in favour	Reported	50 Hz	No
Shehab and Adham, 2000	RCT	4	Not in favour	Reported	50 Hz	No

Based on the findings in Table 5.5, it is evident that there is inconsistency regarding the TENS settings applied in order to produce favourable outcomes. Alwesaly and Abdelsalam (2019) and Baskurt et al., (2006) used a high frequency of 100 Hz each to produce favourable results to support the use of TENS, whilst Atya (2012) and Kocyigit et al., (2012) used a low frequency which resulted in similar positive outcomes. This therefore leads to the conclusion that the settings used does not have to be specific to high or low frequency TENS in order to produce a favorable result. These outcomes may be linked to the clinical pathogenesis of the patient's condition and / or the placement of the TENS on

the patient in relation to tissues implicated in the SIS that presents. It is however not possible to comment on this relationship as approximately 77% of the studies do not report on electrode placement. As noted in the discussion in Section 5.4.1 and 5.4.2, the studies have shown a consistent lack of SIS subcategory reporting and a lack of patient homogeneity. This assertion is supported in that, electrode placement was reported in the high-quality studies as compared to the lower quality studies, which means that electrode placement does play a contributing role in enhancing the methodological rigour and leads to more precise clinical outcomes when TENS is used as an individual treatment intervention.

Table 5.6: Evidence of TENS settings and electrode placement for TENS used as part of a combination treatment intervention

Author and Year	Type of study	PEDro/ NOS Ranking	Clinical Outcome for TENS	TENS settings reported in study	TENS settings	Electrode placement specified
Yazmalar, Sariyildiz, Batmaz, Alpayci, Burkan, Ozkan and Cevik, 2016	RCT	7	In favour	Not reported	-	No
Koo, Lin, Wang, Tsauo, Yang, Yen and Biswal, 2015	RCT	10	Not in favour	Reported	10 – 90 Hz	No
Moezy, Sepehrifar and Dodaran, 2014	RCT	9	In favour	Reported	90-130 Hz	Yes
Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender, 2013	RCT	8	In favour	Reported	100 Hz	No
Subasi, Toktas, Demirdal, Turel, Cakir and Kavuncu, 2012	RCT	6	Not in favour	Reported	60 Hz	No
Bae, Lee, Shin, Kim and Lee, 2011	RCT	4	Not in favour	Not reported	-	No
Hakguder, Tastekin, Birtane, Uzunca, Zater and Sut, 2011	NRCT	4	Not in favour	Reported	100 Hz	Yes
Celik, 2010	RCT	5	Not in favour	Not reported	-	No
Grymel-Kulesza, Polak, Kubacki, Skrzep-Poloczek and Krol, 2007	RCT	5	Not in favour	Reported	100 Hz	No

Based on the evidence from the settings and electrode placement used when TENS was used as part of a combination treatment intervention (Table 5.6), we can see that three out of the nine included studies did not indicate the settings used in the study, whilst the three higher quality studies indicated the specific settings in the study. The trend that is noticeable in Table 5.6 is that high frequency TENS provided greater outcomes than low frequency TENS as seen in outcomes from Moezy et al., (2014) and Tefner et al., (2013). However, due to the fact that three out of the seven studies that were not in favor of the use of TENS in SIS, did not provide settings for TENS, we cannot provide an accurate conclusion regarding the effects of the frequencies on the effectiveness of TENS.

In terms of electrode placements, majority of the studies did not specify the location in which the electrodes were placed. Therefore, we are unable to conclude if the electrode placements affected the study and clinical outcomes when TENS was used as a part of a combination treatment.

More research is required regarding the application of electrodes and settings of TENS, particularly in populations that are vulnerable to neurological compromise as a result of comorbid conditions that can often present with SIS (Tran et al., 2018, Titchener et al., 2014, Davis et al., 2011). As seen in Table 5.7 below, there is limited evidence in both categories of TENS intervention to support its use in treating SIS effectively. The limitations of the studies included in this review were consistent in terms of the lack of information regarding the following:

- The specific category of the SIS and cause as this was only noted by Hakguder et al., (2011).
- The homogeneity of the groups in terms of SIS severity.
- The homogeneity of the groups in terms of age, occupation, handedness / dominance (Lemos et al., 2011), co-morbid conditions, medication use and the effect on the outcome of the study.
- The location of the studies also impacts the application of clinical outcomes to the general population. An example is that of Alwesaly and Abdelsalam (2019), where their study population was recruited from the military, causing their outcomes to be limited to a specific population.

- The wash-out periods from the previous treatment for shoulder pain in patients included in the study.

  Majority of the studies had a small sample size, which is not an adequate depiction of the general population, leading to smaller effect sizes and therefore inconclusive results within studies and withint he evidence collectively.
- TENS settings were not appropriately used or specified and there was variation regarding electrode placement which resulted in homogeneity in majority of the articles.
- TENS was used as a packaged treatment in just under 50% (45%) of the studies included in this review, which implies that there is limited evidence for the stand alone use of TENS before even evaluating the rigour of the studies and their contribution to our knowledge on the effectiveness of TENS for SIS.

5.5 Conclusion

The analysis of the articles conducted in Chapter Four and the grouping and explanation of the outcomes in Chapter Five, along with the ranking of evidence based on the individual articles found in this study, indicates that the level of evidence to support the use of TENS in treating SIS is limited at best (see Table 5.7). In addition, reccomendations for the use of specific TENS frequencies or placement canot be made, as the evidence is either not available or conflicting where available resulting in inconclusive evidence to support any one particular position with the use of TENS as a stand alone treatment or a combination treatment.

The findings in this study agrees with those of Hawk et al., (2017) who stated that there was inconclusive evidence to support the use of TENS in the treatment of SIS. Although this study included articles that were excluded from the study by Hawk et al., (2017), the results were the same. The conclusion from the study by Desmeules et al., (2016) that stated that there was inadequate evidence to support the use of TENS in treating rotator cuff tendinopathy was also found to be in agreement with the findings of this study.

Table 5.7: Level of evidence for the use of TENS in the treatment of SIS

Interventions	Level of evidence				Consistent clinical outcomes	Mixed clinical outcomes
	Strong	Moderate	Limited	No Evidence		
The use of TENS as an individual treatment intervention in treating SIS			X			X
The use of TENS as a combination treatment intervention in treating SIS			X			X
Placement			X			X
TENS settings			X			X

The conclusions drawn in this study, do require contextualisation within the methods and associated limitations of this particular study.

- This systematic review only included studies that mentioned the diagnosis of SIS within either participant group, which implies that the SIS considered for this study was not secondary to pathological disease or surgery. This would have limited the focus of this study to a significantly smaller target group.
- Only the methodological rigour of each article was assessed and not the statistical rigour, which may have impacted the effectiveness of the outcomes found in clinical trials.
- Therefore, a meta-analysis is recommended for the use of TENS, although it is understood that only a small sample of the studies in this review could be used due to the varied outcome measures utilized and the manner in which they were utilized (Haidich, 2010).
- The end date for inclusion of articles was the end of August 2019, therefore any recently published literature could affect the outcomes of a similar systematic review.
- Articles included in this study were restricted to only those that were published in English, indicating that any evidence available in other languages was note considered.

If the above limitations of this study are taken into consideration, future systematic reviews regarding the effectiveness of TENS in treating SIS may differ in their findings.

6. Chapter Six

6.1 Introduction

In this Chapter, the conclusion of this study as well as further recommendations are made regarding for future studies and application of findings.

6.2 Conclusion

The aim of this study was to determine whether transcutaneous electrical nerve stimulation (TENS) was effective in treating shoulder impingement syndrome (SIS) by critically analysing the research that was available pertaining to this topic. A study design was drawn up and a set of inclusion and exclusion criteria were established to compare the available body of knowledge against, in order to differentiate studies that were relevant to the research topic from those that were not. After a thorough search of the databases and hand-search procedures were conducted, a list of twenty articles that met the inclusion criteria were included in this study.

These articles were reviewed by the researcher and six other external reviewers with various qualifications and levels of expertise, using the PEDro scale (PEDro, 1999) for the nineteen RCTs that were included in this study and the Newcastle-Ottawa Scale (Wells, et al., 2003b) for the one non-RCT in this study. All results were individually tabulated, and each article was analysed with regards to the level of methodological rigour present in the study and the limitations associated with each study that affected the outcomes and quality of the study overall. The collective results were then grouped into individual and combination use of TENS interventions, and these groups were assessed based on the AGREE outcomes (Dagenais et al., 2010) and with consideration to TENS settings and electrode placements.

There was a variation in results concerning the methodological rigour of the included studies. Some studies were ranked extremely high in terms of quality while others were of poor quality. Collectively, the available evidence to substantiate the use of TENS in treating SIS was limited in both categories (Chapter Five, Section 5.4) due to the

limitations outlined in Chapter Four, and this therefore indicates that there is a demand for more high quality studies that solely assess the effectiveness of TENS in treating SIS.

Therefore, the conclusion suggests that there is a need for more in-depth and TENS specific studies regarding specific subcategories of SIS. Due to the current limitations presented in available research and the subsequent lack of knowledge regarding the use of TENS in SIS treatment limits its application in general practice in term of the evidence based practice approach and practitioners need to clearly spell out to patients that there is limited evidence in support of the use of TENS in SIS, even though from a anatomical and physiological standpoint it is argueable that TENS should assist in the improvement of the condition (Johnson, 2007). Due to the non-invasive and inexpensive nature of TENS (Searle et al., 2009), more studies should be conducted as it would contribute to a decrease in cost and pain experienced by patients suffering with SIS.

6.3 Recommendations

6.3.1 Recommendations to improve this study

Future systematic reviews should include articles that are non-English by increasing the budget to allow for a translator, forward translation and backward translation processes to minimise the impact of translation related biases.

Time delays could be improved, by providing reviewers with the chance to familiarize themselves with the scales prior to review eg, giving them a trial review would aid in hastening the review process and return of reviews from the external reviewers.

Future studies could also include a meta-analysis to provide the statistical rigour along with the methodological rigour of included studies.

Lastly, the limitations noted for the TENS when used as an individual intervention and the TENS when used as part of a combination treatment intervention need to be considered to improve the overall rigour of the studies in order to generate conclusive clinical outcomes.

6.3.2 Recommendations for future research

There were multiple factors that presented as limitations in the articles being reviewed (Chapter Four, Section 4.4.2 and Chapter Five, Section 5.4). Future studies should ensure compliance with the CONSORT guidelines for study reporting, including but not limited to the following:

- That there is no possibility of reporting bias from patients who are familiar with the interventions.
- Patient homogeneity should be ensured by making use of specific and accurate physical assessments and spcial investigations to ensure consistency in outcomes.
- Blinding and randomization techniques should be clearly outlined and stated in the study in order to rule out possibility of selection bias being present in the study.
- Included age ranges should be smaller in order to target a specific population group and eliminate variation in response to treatment.
- Authors should specify the type and stage of SIS being included in the study as each stage and type presents and responds differently to treatment interventions.
- Indicating the presence of comorbidities and the associated medications should be taken into consideration prior to the study.
- The dominance and handedness of individuals included in a study pertaining to the shoulder and SIS, should be indicated as the response varies between dominant and non-dominant arms.
- Finally, TENS settings should be stated clearly regarding intensity, frequency, pulse width, electrode placement and methods of preventing analgesic tolerance from occurring.

The above would would improve the analysis of the rigour of the studies, their contribution to the evidence and more clearly define the application of clinical outcomes for easier and more effective use in general clinical practice.

6.3.3 Recommendations for practitioners

Based on the conclusion (see Chapter Six, Section 6.2), and the limitations that were outlined in this study (see Chapter Four and Five), the evidence is limited regarding the

effectiveness of TENS in treating SIS. More research and high-quality studies are required in order to provide a greater body of evidence to support / no in support of the use of TENS.

Therefore, healthcare providers should take the limited evidence into consideration when applying the use of TENS to treat SIS – specifically with respect to the requirements of informed consent for the patient and evidence-based practice principles in terms of practice guidelines and third-party payor requirements.

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Appendix A

DUT DURBAN UNIVERSITY OF TECHNOLOGY

FACULTY OF HEALTH SCIENCES

5 December, 2019

Ms S Maharaj
Student No: 21415800

22 58th Avenue
Umhlatuzana
4092

Dear Ms Maharaj

MTECH: CHIROPRACTIC

I am pleased to advise that:

1. The Faculty Research Committee approved the following:

    (i) Your research proposal and dissertation title, being:

The effectiveness of transcutaneous electrical nerve stimulation (TENS) therapy on shoulder impingement syndrome: A systematic review.

Please note: ANY PROPOSED CHANGES in the DISSERTATION TITLE require the approval of your supervisor and the Faculty Research Committee.

    (ii) Supervisor – **Dr C Korporaal**

2. Your request for funding totalling **R 8 000.00** subject to any literature referred to in Section A of the PG 4a form being accessioned by this University, and any equipment purchased shall become the property of the department.

NOTE: - This funding is not paid directly to you but is controlled by the Faculty Office. Any proposed changes to this funding allocation needs the approval of your supervisor, and Faculty Research Committee

The University Research Committee has stipulated that:

(a) Ownership of any patent registered in respect of the results of your Master's studies is retained by you as the initiator of the project;

(b) Should you make any drift from the results of your Master's studies, you will be required to repay pro rata, the **R 5 000.00** investment which the University Research Committee has made in approving your request for funding;

(c) If the Durban University of Technology provided the equipment/materials for the creation of artefacts, this cost would be refunded to the University if such artefacts were sold and

(d) Durban University of Technology is given first refusal in respect of any possible future sale by you of any patent that may be registered in respect of your said project.

(e) All journal articles, referenced in your dissertation, are to accompany your ring-bound copies when submitting for examination purposes.

Should you experience any problems relating to your research studies, your supervisor must be informed as soon as possible. If the difficulty persists, you must then approach your Head of Department and thereafter the Executive Dean of the Faculty.

Yours sincerely

FACULTY RESEARCH OFFICER

06/12/2019

Student's signature in acceptance of the conditions contained herein.

Date:

Appendix B

Database Search Tables

Database: Summons (EBSCOHost, Pubmed, Medline, ScienceDirect)						
Search Term	Number of Articles	Number of articles included	Author	Year	Article Title	Study type
TENS and shoulder pain	3481	23	Acedo, Antunes, Santos, Olveira, Santos, Colonezi. Fontana, Fukuda	2015	Upper trapezius relaxation induced by TENS and interferential current in computer users with chronic nonspecific neck discomfort: An electromyographic analysis	RCT
			Anandkumar and Manivasagam	2014	Multimodal physical therapy management of a 48-year-old female with post-stroke complex regional pain syndrome	Case report
			Barr, Weissenbuehler, Cleary	2004	Effectiveness and Comfort of Transcutaneous Electrical Nerve Stimulation for Older Persons with Chronic Pain	NRCT
			Butera, George, Borsa, Dover	2018	Prolonged Reduction in Shoulder Strength after Transcutaneous Electrical Nerve Stimulation Treatment of Exercise-Induced Acute Muscle Pain	RCT
			Chuang, Chen, Chen, Li, Wang, Hsu, Chang	2017	Effect of EMG-triggered neuromuscular electrical stimulation with bilateral arm training on hemiplegic shoulder pain and arm function after stroke: a randomized controlled trial	RCT
			Gemmell and Hilland	2010	Immediate effect of electric point stimulation (TENS) in treating latent upper trapezius trigger points: A double blind randomised placebo-controlled trial	RCT
			Koo, Lin, Wang, Tsauo, Yang, Yen, Biswal	2015	Novel Noxipoint Therapy versus Conventional Physical Therapy for Chronic Neck and Shoulder Pain: Multicentre Randomised Controlled Trials.	RCT
			Korkmaz, Capaci, Eyigor, Eyigor	2010	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: a prospective, randomized study	RCT
			Lin, Chiu, Shih, Lee, Li, Guo, Luo, Lin, Hsu, Pang and Pang	2019	Two Transcutaneous Stimulation Techniques in Shoulder Pain: Transcutaneous Pulsed Radiofrequency (TPRF) versus Transcutaneous Electrical Nerve Stimulation	RCT

					(TENS): A Comparative Pilot Study	
			Ottoson and Lundeberg	1988	Pain treatment by TENS: transcutaneous electrical nerve stimulation a practical manual	Book
			Pan, Chou, Chiou, Ma, Lee, Chan	2003	Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study	RCT
			Rawat, Eapen and Seema	2016	Effect of rotator cuff strengthening as an adjunct to standard care in subjects with adhesive capsulitis: A randomized controlled trial	RCT
			Razavi and Jansen	2004	Effects of acupuncture and placebo TENS in addition to exercise in treatment of rotator cuff tendinitis	NRCT
			Rodriguez-Fernandez, Garrido-Dantofimia, Grieta-Rodriguez and Fernandez-de-las-Penas	2011	Effects of Burst-Type Transcutaneous Electrical Nerve Stimulation on Cervical Range of Motion and Latent Myofascial Trigger Point Pain Sensitivity	RCT
			Sandberg, Sandberg and Dahl	2007	Blood Flow Changes in the Trapezius Muscle and Overlying Skin Following Transcutaneous Electrical Nerve Stimulation	RCT
			Smania, Corato, Fiaschi, Pietropoli, Aglioti and Tinazzi	2005	Repetitive magnetic stimulation A novel therapeutic approach for myofascial pain syndrome	RCT
			Taverner, Loughnan and Soon	2014	Transcutaneous pulsed radiofrequency treatment for patients with shoulder pain booked for surgery: a double-blind, randomized controlled trial	RCT
			Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender	2013	The effect of balneotherapy on chronic shoulder pain. A randomized, controlled, single-blind follow-up trial. A pilot study	RCT
			Ucurum, Kaya, Kayali, Askin and Tekindal	2018	Comparison of different electrotherapy methods and exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial	RCT
			Vas, Perea-Milla, Mendez, Galante, Madrazo, Medina	2005	Acupuncture and rehabilitation of the painful shoulder: study protocol of an ongoing multicentre randomised controlled clinical trial	RCT
			Wang, Gowda, Barad, Mackey and Carroll	2009	Serratus muscle stimulation effectively treats notalgia paresthetica caused by long thoracic nerve dysfunction: a	Case series

					case series	
			Yu, Chae, Walker, Hart and Petroski	2001	Comparing stimulation-induced pain during percutaneous (intramuscular) and transcutaneous neuromuscular electric stimulation for treating shoulder subluxation in hemiplegia	RCT
			Zhou, Li, Lu, Wu and Pei	2018	Efficiency of Neuromuscular Electrical Stimulation and Transcutaneous Nerve Stimulation on Hemiplegic Shoulder Pain: A Randomized Controlled Trial	RCT
Frozen shoulder and TENS	696	16	Celik	2010	Comparison of the outcomes of two different exercise programs on frozen shoulder	RCT
			Chuang, Chen, Chen, Li, Wang, Hsu, Chang	2017	Effect of EMG-triggered neuromuscular electrical stimulation with bilateral arm training on hemiplegic shoulder pain and arm function after stroke: a randomized controlled trial	RCT
			Gulick, Borger and McNamee	2007	Effect of analgesic nerve block electrical stimulation in a patient with adhesive capsulitis	Case Report
			Hanchard, Goodchild, Thompson, O'Brien, Davison and Richardson	2010	A questionnaire survey of UK physiotherapists on the diagnosis and management of contracted (frozen) shoulder	Survey study
			Karel, Scholten-Peeters, Thoomes-de-Graaf, Duijn, van Broekhoven, Koes, Verhagen	2016	Physiotherapy for patients with shoulder pain in primary care: a descriptive study of diagnostic- and therapeutic management	Observational study
			Khan, Akhtar, Ayyub, Aziz, Iqbal, Shafaat	2018	Intra-articular corticosteroids vs physiotherapy in the management of adhesive capsulitis	RCT
			Lilje, Genberg, Aldudjaili and Skillgate	2014	Pain relief in a young woman with adhesive capsulitis after manual manipulation of the acromioclavicular joint for remaining symptoms after mobilisation under anaesthesia	Case Report
			Maryam, Zahra, Adeleh and Morteza	2012	Comparison of corticosteroid injections, physiotherapy, and combination therapy in treatment of frozen shoulder	RCT
			Poh, Seo, Cho, Park, Park and Baek	2010	Clinical effectiveness of bee venom acupuncture and physiotherapy in the treatment of adhesive capsulitis: a randomized controlled trial	RCT
			Rawat Eapen and Seema	2016	Effect of rotator cuff strengthening as an adjunct to standard care in subjects with adhesive capsulitis: A	RCT

					randomized controlled trial	
			Scudds, Scuuds, Baxter, Mcdonough and Walsh	2009	Transcutaneous electrical nerve stimulation for the treatment of pain in physiotherapy practices in Hong Kong and United Kingdom. A survey of usage and perceived effectiveness compared with other painrelieving modalities	Survey study
			Taverner, Loughnan and Soon	2013	Transcutaneous Pulsed Radiofrequency Treatment for Patients with Shoulder Pain Booked for Surgery: A Double-Blind, Randomized Controlled Trial	RCT
			Taverner and Loughnan	2014	Transcutaneous Application of Pulsed Radiofrequency Treatment for Shoulder Pain	Observational study
			Vas, Ortega, Olmo, Perez-Fernandez, Hernandez, Medina, Seminario	2008	Single-point acupuncture and physiotherapy for the treatment of painful shoulder: a multicentre randomized controlled trial	RCT
			Vas, Perea-Milla, Mendez, Galante, Madrazo, Medina	2005	Acupuncture and rehabilitation of the painful shoulder: study protocol of an ongoing multicentre randomised controlled clinical trial	RCTj
Shoulder Impingement syndrome and TENS			Hakguder, Tastekin, Birtane, Uzunca, Zater, Sut	2011	Comparison of the Short-Term Efficacy of Physical Therapy in Subacromial Impingement Syndrome Patients with Stage I and II Magnetic Resonance Imaging Findings	NRCT
			Joo, Lee, Shin, Lee, Kim, Koh, Park, Song, Cho and Ha	2017	Medical service use and usual care of common shoulder disorders in Korea: a cross-sectional study using the Health Insurance Review and Assessment Service National Patient Sample	Cross sectional study
			Kocyigit, Akalin, Gezer, Orbay, Kocyigit and Ada	2012	Functional Magnetic Resonance Imaging of the Effects of Low-frequency Transcutaneous Electrical Nerve Stimulation on Central Pain Modulation A Double-blind, Placebo-controlled Trial	RCT
			Koo, Lin, Wang, Tsauo, Yang, Yen, Biswal	2015	Novel Noxipoint Therapy versus Conventional Physical Therapy for Chronic Neck and Shoulder Pain: Multicentre Randomised Controlled Trials	RCT
			Razavi and Jansen	2002	Effects of acupuncture and placebo TENS in addition to	NRCT

					exercise in treatment of rotator cuff tendinitis	
			Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender	2013	The effect of balneotherapy on chronic shoulder pain. A randomized, controlled, single-blind follow-up trial. A pilot study	RCT/Pilot
			Ucurum, Kaya, Kayali, Askin and Tekindal	2018	Comparison of different electrotherapy methods and exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial	RCT
			Vas, Ortega, Olmo, Perez-Fernandez, Hernandez, Medina	2008	Single-point acupuncture and physiotherapy for the treatment of painful shoulder: a multicentre randomized controlled trial	RCT
			Vas, Perea-Milla, Mendez, Galante, Madrazo	2005	Acupuncture and rehabilitation of the painful shoulder: study protocol of an ongoing multicentre randomised controlled clinical trial	RCT
			Zhou, Li, Lu, Wu and Pei	2018	Efficiency of Neuromuscular Electrical Stimulation and Transcutaneous Nerve Stimulation on Hemiplegic Shoulder Pain: A Randomized Controlled Trial	RCT
Calcific tendonitis and TENS	213	5	Analan, Leblebici, Adam	2015	Effects of therapeutic ultrasound and exercise on pain, function, and isokinetic shoulder rotator strength of patients with rotator cuff disease	RCT
			Karel, Scholten-Peeters, Thoomes-de-Graaf, Duijn, van Broekhoven, Koes, Verhagen	2017	Physiotherapy for patients with shoulder pain in primary care: a descriptive study of diagnostic- and therapeutic management	Descriptive study
			Pan, Chou, Chiou, Ma, Lee, Chan	2003	Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study	RCT
			Serrano-Aguilar, Kovacs, Cabrera-Hernandez, Ramos-Goni and Garcia-Perez	2011	Avoidable costs of physical treatments for chronic back, neck and shoulder pain within the Spanish National Health Service: a cross-sectional study	Observational study
			Taverner, Loughnan and Soon	2014	Transcutaneous Application of Pulsed Radiofrequency Treatment for Shoulder Pain	Observational study
Shoulder bursitis and	452	6	Chuang, Chen, Chen, Li, Wang, Hsu, Chang	2017	Effect of EMG-triggered neuromuscular electrical stimulation with bilateral arm training on hemiplegic	RCT

TENS					shoulder pain and arm function after stroke: a randomized controlled trial	
			Joo, Lee, Shin, Lee, Kim, Koh, Park, Song, Cho and Ha	2017	Medical service use and usual care of common shoulder disorders in Korea: a cross-sectional study using the Health Insurance Review and Assessment Service National Patient Sample	Observational study
			Taverner, Loughnan and Soon	2014	Transcutaneous Pulsed Radiofrequency Treatment for Patients with Shoulder Pain Booked for Surgery: A Double-Blind, Randomized Controlled Trial	RCT
			Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender	2013	The effect of balneotherapy on chronic shoulder pain. A randomized, controlled, single-blind follow-up trial. A pilot study	RCT
			Vas, Perea-Milla, Mendez, Galante, Madrazo	2005	Acupuncture and rehabilitation of the painful shoulder: study protocol of an ongoing multicentre randomised controlled clinical trial	RCT
			Vas, Ortega, Olmo, Perez-Fernandez, Hernandez, Medina	2008	Single-point acupuncture and physiotherapy for the treatment of painful shoulder: a multicentre randomized controlled trial	RCT
Shoulder-related myofascial dysfunction and TENS	272	6	Farina, Casarotto, Benelle, Tinazzi, Goldoni and Smania	2004	A randomized controlled study on effect of two different treatments (FREMS and TENS) on myofascial pain syndrome	RCT
			Gemmell and Hilland	2011	Immediate effect of electric point stimulation (TENS) in treating latent upper trapezius trigger points: A double blind randomised placebo-controlled trial	RCT
			Kim, Yoon, Park, Jin, Jin, Schepis and Yoon	2014	Comparison of NSAID Patch Given as Monotherapy and NSAID Patch in Combination with Transcutaneous Electric Nerve Stimulation, a Heating Pad, or Topical Capsaicin in the Treatment of Patients with Myofascial Pain Syndrome of the Upper Trapezius: A Pilot Study	RCT
			Koo, Lin, Wang, Tsauo, Yang, Yen, Biswal	2015	Novel Noxipoint Therapy versus Conventional Physical Therapy for Chronic Neck and Shoulder Pain	RCT
			Rodriguez-Fernandez, Garrido-Dantofimia, Grieta-Rodriguez and Fernandez-de-las-Penas	2011	Effects of Burst-Type Transcutaneous Electrical Nerve Stimulation on Cervical Range of Motion and Latent Myofascial Trigger Point Pain Sensitivity	RCT

			Smania, Corato, Fiaschi, Pietropoli, Aglioti and Tinazzi	2005	Repetitive magnetic stimulation A novel therapeutic approach for myofascial pain syndrome	RCT
Brachial dysfunction and TENS	801	3	Afsar and Karatas	2018	Case of an Unusual Suprascapular Neuropathy: Case Report and Literature Review	Case report
			Wang, Gowda, Barad, Mackey and Carroll	2009	Serratus muscle stimulation effectively treats notalgia paresthetica caused by long thoracic nerve dysfunction: a case series	Case Series
			Zhou, Li, Lu, Wu and Pei	2018	Efficiency of Neuromuscular Electrical Stimulation and Transcutaneous Nerve Stimulation on Hemiplegic Shoulder Pain: A Randomized Controlled Trial	RCT
Shoulder dysfunction and TENS	1630	9	Anandkumar and Manivasagam	2014	Multimodal physical therapy management of a 48-year-old female with post-stroke complex regional pain syndrome	Case report
			Harini, Kumari, Madhavi	2013	Effect of Low Frequency Vibratory Stimulation on Biceps Brachii Spasticity in Subjects with Hemiplegia	RCT
			Karel, Scholten-Peeters, Thoomes-de-Graaf, Duijn, van Broekhoven, Koes, Verhagen	2017	Physiotherapy for patients with shoulder pain in primary care: a descriptive study of diagnostic- and therapeutic management	Observational study
			Koo, Lin, Wang, Tsauo, Yang, Yen, Biswal	2015	Novel Noxipoint Therapy versus Conventional Physical Therapy for Chronic Neck and Shoulder Pain	RCT
			Ottoson and Lundeberg	1988	Pain treatment by TENS: transcutaneous electrical nerve stimulation: a practical manual	Book
			Perennou, Leblond, Amblard et al	2001	Transcutaneous electric nerve stimulation reduces neglect-related postural instability after stroke	NRCT
			Vas, Perea-Milla, Mendez, Galante, Madrazo	2005	Acupuncture and rehabilitation of the painful shoulder: study protocol of an ongoing multicentre randomised controlled clinical trial	RCT
			Zhao, Wang, Li et al	2015	Efficacy and safety of transcutaneous electrical acupoint stimulation to treat muscle spasticity following brain injury: a double-blinded, multicenter, randomized controlled trial.	RCT
			Zhou, Li, Lu, Wu and Pei	2018	Efficiency of Neuromuscular Electrical Stimulation and Transcutaneous Nerve Stimulation on Hemiplegic Shoulder Pain: A Randomized Controlled Trial	RCT

Database: Google Scholar						
Search Term	Number of articles	Number of articles included	Author	Year	Article title	Study type
TENS and shoulder pain	22 500	25	Barr, Weissenbuehler, Cleary	2004	Effectiveness and comfort of transcutaneous electrical nerve stimulation for older persons with chronic pain	NRCT
			Baskurt	2006	The immediate effects of heat and TENS on pressure pain threshold and pain intensity in patients with Stage I shoulder impingement syndrome	RCT
			Chuang, Chen, Chen, Li, Wang, Hsu, Chang	2017	Effect of EMG-triggered neuromuscular electrical stimulation with bilateral arm training on hemiplegic shoulder pain and arm function after stroke: a randomized controlled trial	RCT
			Dewan and Sharma	2011	Effectiveness of transcutaneous electrical nerve stimulation and interferential electrotherapy in adhesive capsulitis	RCT
			Dissanayaka, Pallegama, Suraweera, Johnson and Kariyawasam	2016	Comparison of the Effectiveness of Transcutaneous Electrical Nerve Stimulation and Interferential Therapy on the Upper Trapezius in Myofascial Pain Syndrome: A Randomized Controlled Study	RCT
			Ekim, Armagan and Oner	2008	Efficiency of TENS treatment in hemiplegic shoulder pain: a placebo-controlled study	RCT
			Graff-Radford, Reeves, Baker, Chiu	1989	Effects of transcutaneous electrical nerve stimulation on myofascial pain and trigger point sensitivity	RCT
			Herra-Lasso, Mobarak, Fernandez-Dominguez, Cardiel and Alarcon-Segovia	1993	Comparative effectiveness of packages of treatment including ultrasound or transcutaneous electrical nerve stimulation in painful shoulder syndrome	RCT
			Kocyigit, Akalin, Gezer, Orbay, Kocyigit and Ada	2012	Functional Magnetic Resonance Imaging of the Effects of Low-frequency Transcutaneous Electrical Nerve Stimulation on Central Pain Modulation: A Double-blind, Placebo-controlled Trial	RCT
			Korkmaz, Capaci, Eyigor,	2010	Pulsed radiofrequency versus conventional	RCT

			Eyigor		transcutaneous electrical nerve stimulation in painful shoulder: a prospective, randomized study	
			Leandri, parodi, Corrieri and Rigardo	1990	Comparison of TENS treatments in hemiplegic shoulder pain.	RCT
			Marco, Duarte, Vila, Tejero et al	2007	Is botulinum toxin type A effective in the treatment of spastic shoulder pain in patients after stroke? A double-blind randomized clinical trial	RCT
			Moniruzzaman, Salek, Shakoor, Mia, Moyeeuuzaman	2010	Effects of Therapeutic Modalities on Patients with Post Stroke Shoulder	RCT
			Ozdincler	2005	The effects of TENS and LLL on pain and functional performance of patients with shoulder pain	RCT
			Pan, Chou, Chiou, Ma, Lee, Chan	2003	Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study.	RCT
			Perennou, Leblond, Amblard et al	2001	Transcutaneous electric nerve stimulation reduces neglect-related postural instability after stroke	NRCT
			Rodriguez-Fernandez, Garrido-Dantofimia, Grieta-Rodriguez and Fernandez-de-las-Penas	2011	Effects of burst-type transcutaneous electrical nerve stimulation on cervical range of motion and latent myofascial trigger point pain sensitivity	RCT
			Sandberg, Sandberg and Dahl	2007	Blood flow changes in the trapezius muscle and overlying skin following transcutaneous electrical nerve stimulation	RCT
			Smania, Corato, Fiaschi, Pietropoli, Aglioti and Tinazzi	2005	Repetitive magnetic stimulation - A novel therapeutic approach for myofascial pain syndrome	RCT
			Sonde, Gip, Fernaeus, Nilsson, Viitanen	1998	Stimulation with Low Frequency (1.7 Hz) Transcutaneous Electric Nerve Stimulation (Low-Tens) Increases Motor Function of the Post-stroke Paretic arm	RCT
			Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender	2013	The effect of balneotherapy on chronic shoulder pain. A randomized, controlled, single-blind follow-up trial. A pilot study	RCT
			Wang, Gowda, Barad, Mackey and Carroll	2009	Serratus muscle stimulation effectively treats notalgia paresthetica caused by long thoracic nerve dysfunction: a case series	Case series

			Yoshimizu, Teo, Masahiko, Kosuke and Takashi	2012	Relief of Chronic Shoulder and Neck Pain by Electro-Acupuncture and Transcutaneous Electrical Nervous Stimulation: A Randomized Crossover Trial	RCT
			Zhou, Li, Lu, Wu and Pei	2018	Efficiency of neuromuscular electrical stimulation and transcutaneous nerve stimulation on hemiplegic shoulder pain: a randomized controlled trial	RCT
Frozen shoulder and TENS	4090	8	Dewan and Sharma	2011	Effectiveness of transcutaneous electrical nerve stimulation and interferential electrotherapy in adhesive capsulitis	RCT
			Eyigor, Eyigor and Korkmaz	2009	Are intra-articular corticosteroid injections better than conventional TENS in treatment of rotator cuff tendinitis in the short run? A randomized study	RCT
			Hanchard, Goodchild, Thomson et al	2010	A questionnaire survey of UK physiotherapists on the diagnosis and management of contracted (frozen) shoulder	Observational study
			Kraal, Visser, Sierevelt, Beimers	2016	How to treat a frozen shoulder ? A survey among shoulder specialists in the Netherlands and Belgium	Observational study
			Rizk	1983	Adhesive capsulitis (frozen shoulder): a new approach to its management.	RCT
			Schneider	1989	Restricted Shoulder Movement: Capsular Contracture or Cervical Referral — A Clinical Study	Case report
			Taverner, Loughnan and Soon	2014	Transcutaneous Application of Pulsed Radiofrequency Treatment for Shoulder Pain	Retrospective audit
			Taverner and Loughnan	2013	Transcutaneous Pulsed Radiofrequency Treatment for Patients with Shoulder Pain Booked for Surgery: A Double-Blind, Randomized Controlled Trial	RCT
Shoulder impingement syndrome and TENS	5500	6	Kocyigit, Akalin, Gezer, Orbay, Kocyigit and Ada	2012	Functional magnetic resonance imaging of the effects of Low-frequency Transcutaneous Electrical Nerve Stimulation on central pain modulation: A Double-blind, Placebo-controlled Trial	RCT
			Baskurt	2013	The immediate effects of heat and TENS on pressure pain threshold and pain intensity in patients with Stage I shoulder impingement syndrome	RCT
			Ucurum, Kaya, Kayali,	2018	Comparison of different electrotherapy methods and	RCT

			Askin and Tekindal		exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial	
			Ozdincler	2005	The effects of TENS and LLL on pain and functional performance of patients with shoulder pain	RCT
			Karel, Scholten-Peeters, Thoomes-de-Graaf, Duijn, van Broekhoven, Koes, Verhagen	2017	Physiotherapy for patients with shoulder pain in primary care: a descriptive study of diagnostic- and therapeutic management	Observational study
			Soibam	2005	Comparative study on the effectiveness of ultrasound (us) to transcutaneous electrical stimulation (tens) in the treatment of periarticular shoulder pain(psp)	RCT
Calcific tendonitis and TENS	987	5	Eyigor et al	2010	Are intra-articular corticosteroid injections better than conventional TENS in treatment of rotator cuff tendinitis in the short run? A randomized study	RCT
			Lin et al	2019	Two Transcutaneous Stimulation Techniques in Shoulder Pain: Transcutaneous Pulsed Radiofrequency (TPRF) versus Transcutaneous Electrical Nerve Stimulation (TENS): A Comparative Pilot Study	RCT
			Pan, Chou, Chiou, Ma, Lee, Chan	2003	Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study	RCT
			Razavi	2004	Effects of acupuncture and placebo TENS in addition to exercise in treatment of rotator cuff tendinitis	NRCT
			Vas, Ortega, Olmo, Perez-Fernandez, Hernandez, Medina	2008	Single-point acupuncture and physiotherapy for the treatment of painful shoulder: a multicentre randomized controlled trial	RCT
Shoulder bursitis and TENS	2510	5	Herra-Lasso, Mobarak, Fernandez-Dominguez, Cardiel and Alarcon-Segovia	1993	Comparative Effectiveness of Packages of Treatment Including Ultrasound or Transcutaneous Electrical Nerve Stimulation in Painful Shoulder Syndrome	RCT
			Lin, Chiu, Shih, Lee, Li, Guo, Luo, Lin, Hsu, Pang and Pang	2019	Two Transcutaneous Stimulation Techniques in Shoulder Pain: Transcutaneous Pulsed Radiofrequency (TPRF) versus Transcutaneous Electrical Nerve Stimulation (TENS)	RCT
			Ozdincler	2005	The effects of TENS and LLL on pain and functional performance of patients with shoulder pain	RCT

			Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender	2013	The effect of balneotherapy on chronic shoulder pain. A randomized, controlled, single-blind follow-up trial. A pilot study	RCT
			Ucurum, Kaya, Kayali, Askin and Tekindal	2018	Comparison of different electrotherapy methods and exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial	RCT
Shoulder-related myofascial dysfunction and TENS	4180	4	Gemmell and Hilland	2011	Immediate effect of electric point stimulation (TENS) in treating latent upper trapezius trigger points: A double blind randomised placebo-controlled trial	RCT
			Kim et al	2014	Comparison of NSAID Patch Given as Monotherapy and NSAID Patch in Combination with Transcutaneous Electric Nerve Stimulation, a Heating Pad, or Topical Capsaicin in the Treatment of Patients with Myofascial Pain Syndrome of the Upper Trapezius: A Pilot Study	RCT
			Rodriguez-Fernandez, Garrido-Dantofimia, Grieta-Rodriguez and Fernandez-de-las-Penas	2011	Effects of Burst-Type Transcutaneous Electrical Nerve Stimulation on Cervical Range of Motion and Latent Myofascial Trigger Point Pain Sensitivity	RCT
			Rou et al	2002	Immediate Effects of Various Physical Therapeutic Modalities on Cervical Myofascial Pain and Trigger-Point Sensitivity	RCT
Brachial dysfunction and TENS	10 600	3	Wang, Gowda, Barad, Mackey and Carroll	2009	Serratus muscle stimulation effectively treats notalgia paresthetica caused by long thoracic nerve dysfunction: a case series	Case report
			Yu et al	2001	Comparing stimulation-induced pain during percutaneous (intramuscular) and transcutaneous neuromuscular electric stimulation for treating shoulder subluxation in hemiplegia	Observational study
			Zhou, Li, Lu, Wu and Pei	2018	Efficiency of Neuromuscular Electrical Stimulation and Transcutaneous Nerve Stimulation on Hemiplegic Shoulder Pain: A Randomized Controlled Trial	RCT
Shoulder dysfunction and TENS	19 400	11	Barr, Weissenbuehler, Cleary	2004	Effectiveness and Comfort of Transcutaneous Electrical Nerve Stimulation for Older Persons with Chronic Pain	NRCT
			Chan et al	2014	A Home-Based Program of Transcutaneous Electrical Nerve Stimulation and Task-Related Trunk Training	RCT

					Improves Trunk Control in Patients With Stroke: A Randomized Controlled Clinical Trial	
			Chuang, Chen, Chen, Li, Wang, Hsu, Chang	2017	Effect of EMG-triggered neuromuscular electrical stimulation with bilateral arm training on hemiplegic shoulder pain and arm function after stroke: a randomized controlled trial	RCT
			Kim et al	2013	Task-related training combined with transcutaneous electrical nerve stimulation promotes upper limb functions in patients with chronic stroke	RCT
			Korkmaz, Capaci, Eyigor, Eyigor	2010	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: a prospective, randomized study	RCT
			Herra-Lasso, Mobarak, Fernandez-Dominguez, Cardiel and Alarcon-Segovia	1993	Comparative Effectiveness of Packages of Treatment Including Ultrasound or Transcutaneous Electrical Nerve Stimulation in Painful Shoulder Syndrome	RCT
			Moniruzzaman et al	2010	Effects of Therapeutic Modalities on Patients with Post Stroke Shoulder	RCT
			Perennou et al	2001	Transcutaneous Electric Nerve Stimulation Reduces Neglect-Related Postural Instability After Stroke	NRCT
			Schroder et al	2008	TENS and optokinetic stimulation in neglect therapy after cerebrovascular accident: a randomized controlled study	RCT
			Vas, Ortega, Olmo, Perez-Fernandez, Hernandez, Medina	2008	Adding single-point acupuncture to physiotherapy for painful shoulder improved function and reduced pain	RCT
			Zhou, Li, Lu, Wu and Pei	2018	Efficiency of Neuromuscular Electrical Stimulation and Transcutaneous Nerve Stimulation on Hemiplegic Shoulder Pain: A Randomized Controlled Trial	RCT
Database: Google						

Search term:	Number of articles	Number of articles included	Author	Year	Article title	Study type
TENS and shoulder pain	416 000	35	Ashtiani	2016	Effectiveness of Action Potential Simulation and Transcutaneous Electrical Nerve Stimulation on Pain and Function of Patients With Chronic Mechanical Shoulder Impairment	RCT
			Bello and Amedzo	2010	Relative Effectiveness of Transcutaneous Electrical Nerve Stimulation and Hot Packs in the Management of Hemiplegic Shoulder Pain	RCT
			Butera, George, Borsa, Dover	2018	Prolonged Reduction in Shoulder Strength after Transcutaneous Electrical Nerve Stimulation Treatment of Exercise-Induced Acute Muscle Pain.	RCT
			Chuang, Chen, Chen, Li, Wang, Hsu, Chang	2017	Effect of EMG-triggered neuromuscular electrical stimulation with bilateral arm training on hemiplegic shoulder pain and arm function after stroke: a randomized controlled trial	RCT
			Dewan and Sharma	2011	Effectiveness of transcutaneous electrical nerve stimulation and interferential electrotherapy in adhesive capsulitis	RCT
			Dissanayaka, Pallegama, Suraweera, Johnson and Kariyawasam	2016	Comparison of the Effectiveness of Transcutaneous Electrical Nerve Stimulation and Interferential Therapy on the Upper Trapezius in Myofascial Pain Syndrome: A Randomized Controlled Study.	RCT
			Ekim, Armagan, Oner	2008	Efficiency of TENS treatment in hemiplegic shoulder pain: a placebo-controlled study	RCT
			Eyigor, Eyigor and Korkmaz	2010	Are intra-articular corticosteroid injections better than conventional TENS in treatment of rotator cuff tendinitis in the short run? A randomized study.	RCT
			Hendley	2014	Manual Therapy with Transcutaneous Electric Nerve Stimulation in a Patient with Frozen Shoulder: A Case Report	Case report
			Herra-Lasso, Mobarak, Fernandez-Dominguez, Cardiel and Alarcon-	1993	Comparative Effectiveness of Packages of Treatment Including Ultrasound or Transcutaneous Electrical Nerve Stimulation in Painful Shoulder Syndrome	RCT

			Segovia			
			Kaada	1984	Treatment of peritendinitis calcarea of the shoulder by transcutaneous nerve stimulation	NRCT
			Kocyigit, Akalin, Gezer, Orbay, Kocyigit and Ada	2012	Functional magnetic resonance imaging of the effects of low-frequency transcutaneous electrical nerve stimulation on central pain modulation: a double-blind, placebo-controlled trial	RCT
			Koo, Lin, Wang, Tsauo, Yang, Yen, Biswal	2015	Novel Noxipoint Therapy versus Conventional Physical Therapy for Chronic Neck and Shoulder Pain: Multicentre Randomised Controlled Trials	RCT
			Korkmaz, Capaci, Eyigor, Eyigor	2010	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: a prospective, randomized study.	RCT
			Leandri	1990	Comparison of TENS treatments in hemiplegic shoulder pain	RCT
			Lin, Chiu, Shih, Lee, Li, Guo, Luo, Lin, Hsu, Pang and Pang	2019	Two Transcutaneous Stimulation Techniques in Shoulder Pain: Transcutaneous Pulsed Radiofrequency (TPRF) versus Transcutaneous Electrical Nerve Stimulation (TENS): A Comparative Pilot Study	RCT
			Marco	2007	Is botulinum toxin type A effective in the treatment of spastic shoulder pain in patients after stroke? A double-blind randomized clinical trial	RCT
			Mayo clinic	Accessed 2019	Frozen shoulder - Diagnosis and treatment	Web article
			Moniruzzaman, Salek, Shakoor, Mia, Moyeeuuzaman	2010	Effects of therapeutic modalities on patients with post stroke shoulder pain.	RCT
			Ottoson and Lundeberg	2012	Pain Treatment by Transcutaneous Electrical Nerve Stimulation (TENS)	Book
			Ozdincler	2005	Effects of TENS and LEL on Pain and Functional Performance of Patients with Shoulder Pain	RCT
			Pan, Chou, Chiou, Ma, Lee, Chan	2003	Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study	RCT
			Patil, Sudha, Sidharth	2018	Comparative efficacy of transcutaneous electrical nerve	RCT

					stimulation (TENS) and pendular exercises v/s ultrasound and rhythmic stabilization in clinically diagnosed frozen shoulder (adhesive capsulitis) using SPADI scale. A random study	
			Poenaru, Cinteza, Popescu, Ionita and Mateescu	2008	Shoulder pain management in stroke	RCT
			Qureshi, Ahmed and Qureshi	2013	Suprascapular nerve block (SSNB) vs Transcutaneous Electrical Nerve Stimulation (TENS) in hemiplegic post stroke shoulder pain with adhesive capsulitis.	RCT
			Rodriguez-Fernandez, Garrido-Dantofimia, Grieta-Rodriguez and Fernandez-de-las-Penas	2011	Effects of Burst-Type Transcutaneous Electrical Nerve Stimulation on Cervical Range of Motion and Latent Myofascial Trigger Point Pain Sensitivity	RCT
			Sandberg, Sandberg and Dahl	2007	Blood Flow Changes in the Trapezius Muscle and Overlying Skin Following Transcutaneous Electrical Nerve Stimulation	RCT
			Shehab and Ahdam	2000	Comparative effectiveness of ultrasound and transcutaneous electrical stimulation in treatment of periarticular shoulder pain	RCT
			Suh, Kim, Han	2015	The Effects of High-Frequency Transcutaneous Electrical Nerve Stimulation for Dental Professionals with Work-Related Musculoskeletal Disorders: A Single-Blind Randomized Placebo-Controlled Trial	RCT
			Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender	2013	The effect of balneotherapy on chronic shoulder pain. A randomized, controlled, single-blind follow-up trial. A pilot study	RCT
			The Good Body	2018	TENS Unit Uses: The Definitive Guide	Web article
			Tiwari	2015	Role and Efficacy of TENS versus SWD in the management of periarthritis shoulder	NRCT
			Ucurum, Kaya, Kayali, Askin and Tekindal	2018	Comparison of different electrotherapy methods and exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial	RCT
			Yoshimizu, Teo,	2012	Relief of Chronic Shoulder and Neck Pain by Electro-	RCT

			Masahiko, Kosuke and Takashi		Acupuncture and Transcutaneous Electrical Nervous Stimulation: A Randomized Crossover Trial	
			Zhou, Li, Lu, Wu and Pei	2018	Efficiency of Neuromuscular Electrical Stimulation and Transcutaneous Nerve Stimulation on Hemiplegic Shoulder Pain: A Randomized Controlled Trial	RCT
				2018	Zapped! Does TENS work for pain?	Web article
Frozen shoulder and TENS	221 000	12	Dewan and Sharma	2011	Effectiveness of transcutaneous electrical nerve stimulation and interferential electrotherapy in adhesive capsulitis	RCT
			Gachibowli's Best Physiotherapy	Accessed 2019	Electrical Stimulation	Web article
			Gillott	2017	Frozen shoulder - what you need to know	Internet article
			Healthmate Forever treatment solutions	Accessed 2019	Pain treatment - Painful shoulder	Web article
			Hendley and Lucado	2014	Manual Therapy with Transcutaneous Electric Nerve Stimulation in a Patient with Frozen Shoulder: A Case Report	Case Report
			Korkmaz, Capaci, Eyigor, Eyigor	2010	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: a prospective, randomized study.	RCT
			Mayo Clinic	Accessed 2019	Frozen shoulder	Web article
			National Institute of Arthritis and Musculoskeletal and Skin diseases	Accessed 2019	Shoulder Problems	Web article
			Ozdincler	2005	Effects of TENS and LEL on Pain and Functional Performance of Patients with Shoulder Pain	RCT
			Patil, Sudha and Sidharth	2018	Comparative efficacy of transcutaneous electrical nerve stimulation [TENS] and pendular exercises v/s ultrasound and rhythmi stabilization in clinically diagnosed frozen	RCT

					shoulder [Adhesive Capsulitis] using SPADI scale. A random study	
			Sharaf, Ahmed and Abdel-Aziem	2013	The efficacy of designed physical therapy program on frozen shoulder syndrome	RCT
			Tiwari et al	2015	Role and Efficacy of TENS versus SWD in the management of periarthritis shoulder	RCT
Shoulder impingement syndrome and TENS	74 700	11	Alsewaly and Abdelsalam	2019	Immediate effect of mobilization on pain and overhead reach inpatients with shoulder impingement syndrome	RCT
			Ashtiani, Ghiase, Noraie and Bohloli	2016	Effectiveness of Action Potential Simulation and Transcutaneous Electrical Nerve Stimulation on Pain and Function of Patients with Chronic Mechanical Shoulder Impairment	RCT
			Hakguder, Tastekin, Birtane, Uzunca, Zater, Sut	2011	Comparison of the Short-Term Efficacy of Physical Therapy in Subacromial Impingement Syndrome Patients with Stage I and II Magnetic Resonance Imaging Findings	NRCT
			Keblawy et al	2018	Low level laser versus acupuncture like TENS in chronic shoulder impingement syndrome	NRCT
			Korkmaz, Capaci, Eyigor, Eyigor	2010	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: A prospective, randomized study	RCT
			Lin, Chiu, Shih, Lee, Li, Guo, Luo, Lin, Hsu, Pang and Pang	2019	Two Transcutaneous Stimulation Techniques in Shoulder Pain: Transcutaneous Pulsed Radiofrequency (TPRF) versus Transcutaneous Electrical Nerve Stimulation (TENS): A Comparative Pilot Study	RCT
			Ozdincler	2005	Effects of TENS and LEL on Pain and Functional Performance of Patients with Shoulder Pain	RCT
			Razavi and Jansen	2002	Effects of acupuncture and placebo TENS in addition to exercise in treatment of rotator cuff tendinitis	NRCT
			Tefner, Kovacs, Gaal, Koroknai, Horvath, Badruddin, Borbely, Nagy and Bender	2013	The effect of balneotherapy on chronic shoulder pain. A randomized, controlled, single-blind follow-up trial. A pilot study	RCT
			Ucurum, Kaya, Kayali, Askin and Tekindal	2018	Comparison of different electrotherapy methods and exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial	RCT

			Vas, Ortega, Olmo, Perez-Fernandez, Hernandez, Medina	2008	Single-point acupuncture and physiotherapy for the treatment of painful shoulder: a multicentre randomized controlled trial	RCT
Calcific tendonitis and TENS	22 800	5	EBSCO Health Library	Accessed 2019	Shoulder calcific tendinitis	Web article
			Kurt, Aktas and Yilmaz	2018	Acute Calcific Tendinitis of the Subscapularis Tendon: A Rare Case Diagnosed by Ultrasound Imaging and Treated Successfully?	Case Report
			Lin, Chiu, Shih, Lee, Li, Guo, Luo, Lin, Hsu, Pang and Pang	2018	Two Transcutaneous Stimulation Techniques in Shoulder Pain: Transcutaneous Pulsed Radiofrequency (TPRF) versus Transcutaneous Electrical Nerve Stimulation (TENS): A Comparative Pilot Study	RCT
			Pan, Chou, Chiou, Ma, Lee, Chan	2003	Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study.	RCT
			Lowe	2017	Calcific Tendonitis	Web article
Shoulder bursitis and TENS	88 300	8	Butera, George, Borsa, Dover	2018	Prolonged Reduction in Shoulder Strength after Transcutaneous Electrical Nerve Stimulation Treatment of Exercise-Induced Acute Muscle Pain	RCT
			Colorado.gov	1998	Transcutaneous Electrical Nerve Stimulator for Pain Treatment	Book
			HealthQuest	2018	How TENS Therapy Helps Alleviate Bursitis Pain	Web article
			Herra-Lasso, Mobarak, Fernandez-Dominguez, Cardiel and Alarcon-Segovia	1993	Comparative Effectiveness of Packages of Treatment Including Ultrasound or Transcutaneous Electrical Nerve Stimulation in Painful Shoulder Syndrome	RCT
			iRelieve	Accessed 2019	Using electrotherapy for acute shoulder pain	Web article
			Ozdincler	2005	Effects of TENS and LEL on Pain and Functional Performance of Patients with Shoulder Pain	RCT
			Seol et al	2015	Scapulothoracic Bursitis in a Patient with Quadriparesis	Case report

			TENS Machine Pro	2018	Using TENS to treat bursitis	Web article
Shoulder-related myofascial dysfunction and TENS	68 300	14	Amjad, Shahid, Batool, Ahmad and Ahmed	2016	A comparison on efficacy of transcuatneous electrical nerve stimaulation and therapeutic ultrasound in treatment of myofascial trigger points	RCT
			Azatcam, Atalay. Akkaya et al	2017	Comparison of effectiveness of Transcutaneous Electrical Nerve Stimulation and Kinesio Taping added to exercises in patients with myofascial pain syndrome	RCT
			Benedetti, Zati, Stagni, Fusaro, Monesi and Rotini	2016	Winged scapula caused by rhomboid paralysis: a case report	Case report
			Dissanayaka, Pallegama, Suraweera, Johnson and Kariyawasam	2013	Comparison of the effectiveness of Transcutaneous Electrical Nerve Stimulation and Interferential Therapy on the upper trapezius in myofascial pain syndrome: A randomized controlled study	RCT
			Farina et al	2005	A randomized controlled study on the effect of two different treatments FREMS and TENS on myofascial pain syndrome	RCT
			Ingraham	2018	Zapped! Does TENS work for pain?	Web article
			Jeon, Jung, Lee, Choi, et al	2012	The Effect of Extracorporeal Shock Wave Therapy on Myofascial Pain Syndrome	RCT
			Koo, Lin, Wang, Tsauo, Yang, Yen, Biswal	2015	Novel Noxipoint Therapy versus Conventional Physical Therapy for Chronic Neck and Shoulder Pain: Multicentre Randomised Controlled Trials	RCT
			Rajalakshmi, Sathish Kumar, Ivvala Anand et al	2013	Effect of Transcutaneous electrical nerve stimulation in trapezitis	RCT
			Rodriguez-Fernandez, Garrido-Dantofimia, Grieta-Rodriguez and Fernandez-de-las-Penas	2011	Effects of Burst-Type Transcutaneous Electrical Nerve Stimulation on Cervical Range of Motion and Latent Myofascial Trigger Point Pain Sensitivity	RCT
			Sandberg, Sandberg and Dahl	2007	Blood Flow Changes in the Trapezius Muscle and Overlying Skin Following Transcutaneous Electrical Nerve Stimulation	RCT
			Smania, Corato, Fiaschi, Pietropoli, Aglioti and	2005	Repetitive magnetic stimulation - A novel therapeutic approach for myofascial pain syndrome	RCT

			Tinazzi			
			Suh, Kim and Han	2015	The Effects of High-Frequency Transcutaneous Electrical Nerve Stimulation for Dental Professionals with Work-Related Musculoskeletal Disorders: A Single-Blind Randomized Placebo-Controlled Trial	RCT
Brachial dysfunction and TENS	189 900	7	Khalili, Jain, DeCastro	2019	Brachial Neuritis	Book
			Munhoz, Hanajima, Ashley et al	2003	Acute Effect of Transcutaneous Electrical Nerve Stimulation on Tremor	NRCT
			NORD	2019	Parsonage-Turner Syndrome	Web article/Report
			Saiz-Sapena et al	2019	Treatment of Neuropathic Pain in Brachial Plexus Injuries	Book
			Torres et al	2019	Brachial Plexitis (Parsonage Turner Syndrome, Brachial Neuropathy, Brachial Radiculitis)	Book
			Wang, Gowda, Barad, Mackey and Carroll	2009	Serratus muscle stimulation effectively treats notalgia paresthetica caused by long thoracic nerve dysfunction: a case series	Case series
			Zhou, Gou, Xu et al	2012	Clinical research of comprehensive rehabilitation in treating brachial plexus injury patients	RCT
Shoulder dysfunction and TENS	313 000	14	Ashtiani, Ghiasi, Noraie et al	2016	Effectiveness of Action Potential Simulation and Transcutaneous Electrical Nerve Stimulation on Pain and Function of Patients with Chronic Mechanical Shoulder Impairment	RCT
			Bello and Amedzo	2010	Relative Effectiveness of Transcutaneous Electrical Nerve Stimulation and Hot Packs in the Management of Hemiplegic Shoulder Pain *	RCT
			Butera, George, Borsa, Dover	2018	Prolonged Reduction in Shoulder Strength after Transcutaneous Electrical Nerve Stimulation Treatment of Exercise-Induced Acute Muscle Pain	RCT
			Chuang, Chen, Chen, Li, Wang, Hsu, Chang	2017	Effect of EMG-triggered neuromuscular electrical stimulation with bilateral arm training on hemiplegic shoulder pain and arm function after stroke: a randomized controlled trial	RCT
			Ekim, Armagan and Oner	2008	Efficiency of TENS treatment in hemiplegic shoulder pain: a placebo-controlled study	RCT
			Herra-Lasso, Mobarak,	1993	Comparative Effectiveness of Packages of Treatment	RCT

			Fernandez-Dominguez, Cardiel and Alarcon-Segovia		Including Ultrasound or Transcutaneous Electrical Nerve Stimulation in Painful Shoulder Syndrome	
			Koo, Lin, Wang, Tsauo, Yang, Yen, Biswal	2015	Novel Noxipoint Therapy versus Conventional Physical Therapy for Chronic Neck and Shoulder Pain: Multicentre Randomised Controlled Trials	RCT
			Korkmaz, Capaci, Eyigor, Eyigor	2010	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: A prospective, randomized study	RCT
			Leadnri, Parodi, Corieri and Rigardo	1990	Comparison of TENS treatments in hemiplegic shoulder pain	RCT
			Moniruzzaman, Salek, Shakoor, Mia, Moyeeuuzaman	2010	Effects of therapeutic modalities on patients with post stroke shoulder pain.	RCT
			Ozdincler	2005	Effects of TENS and LEL on Pain and Functional Performance of Patients with Shoulder Pain	RCT
			Poenaru, Cinteza, Popescu, Ionita and Mateescu	2008	Shoulder pain management in stroke	RCT
			Shehab and Adham	2000	Comparative effectiveness of ultrasound and transcutaneous electrical stimulation in treatment of periarticular shoulder pain	RCT
			Zhou, Li, Lu, Wu and Pei	2018	Efficiency of Neuromuscular Electrical Stimulation and Transcutaneous Nerve Stimulation on Hemiplegic Shoulder Pain: A Randomized Controlled Trial.	RCT

Appendix C:

Master List:

	Author (s)	Year	Title	Reference	Study Type	Included
1	Alsewaly, I and Abdelsalam, M	2019	Immediate effect of mobilization on pain and overhead reach inpatients with shoulder impingement syndrome	Alsewaly, I. and Abdelsalam, M., 2019. Immediate effect of mobilization on pain and overhead reach inpatients with shoulder impingement syndrome. *International Journal of Advanced Research*, 7(2), 321-328	RCT	YES
2	Ashtiani, A, Ghiase, R, Noraie K and Bohloli, B.	2016	Effectiveness of Action Potential Simulation and Transcutaneous Electrical Nerve Stimulation on Pain and Function of Patients With Chronic Mechanical Shoulder Impairment	Ashtiani, A.,Ghiase, R., Noraie, K., and Bohloli, B., 2016. Effectiveness of Action Potential Simulation and Transcutaneous Electrical Nerve Stimulation on Pain and Function of Patients With Chronic Mechanical Shoulder Impairment. *Physical Treatments*, 6(2), 79-84.	RCT	YES
3	Atya, A	2012	Efficacy of Microcurrent Electrical Stimulation on Pain, Proprioception Accuracy and Functional Disability in Subacromial Impingement: RCT	Atya, A., 2012. Efficacy of Microcurrent Electrical Stimulation on Pain, Proprioception Accuracy and Functional Disability in Subacromial Impingement : RCT. *Indian Journal of Physiotherapy and Occupational Therapy*, 6(1), 15-18.	RCT	YES
4	Bae, Y, Lee, G, Shin, W, Kim, T and Lee, S	2011	Effect of motor control and strengthening exercises on pain, function, strength and the range of motion of patients with shoulder impingement syndrome	Bae, Y., Lee, G., Shin, W., Kim, T., Lee, S.,2011. Effect of motor control and strengthening exercises on pain, function, strength and the range of motion of patients with shoulder impingement syndrome. *Journal of Physical Therapy Science*, 23(4), 687-692.	RCT	YES
5	Baskurt, Z, Baskurt,	2006	The immediate effects of heat and	Baskurt, Z., Baskurt, F., Ozcan, A.,	RCT	YES

	F, Ozcan, A and Yilmaz, O		TENS on pressure pain threshold and pain intensity in patients with Stage I shoulder impingement syndrome	Yilmaz, O.,2006. The immediate effects of heat and TENS on pressure pain threshold and pain intensity in patients with Stage I shoulder impingement syndrome. *The Pain Clinic*, 18(1), 81-85		
6	Celik, D	2010	Comparison of the outcomes of two different exercise programs on frozen shoulder	Celik, D., 2010. Comparison of the outcomes of two different exercise programs on frozen shoulder. *Acta Orthopaedica et Traumatologica Turcica*, 44(4), 285-292.	RCT	YES
7	Grymel-Kulesza, E, Polak, A, Kubacki, J, Skrzep-Poloczek, B, Krol, P.	2007	The effect of multi-modality therapy including active exercises, classic massage, cryotherapy and a combination of ultrasound and electrical stimulation on rotator cuff injuries	Grymel-Kulesza, E., Polak, A., Kubacki, J., Skrzep-Poloczek, B., Krol, P., 2007. The effect of multi-modality therapy including active exercises, classic massage, cryotherapy and a combination of ultrasound and electrical stimulation on rotator cuff injuries. *Fizjoterapia Polska*, 7, 107-123.	RCT	YES
8	Hakguder,A., Tastekin, N., Birtane, M., Uzunca, K., Zater, C., Sut, N.	2011	Comparison of the Short-Term Efficacy of Physical Therapy in Subacromial Impingement Syndrome Patients with Stage I and II Magnetic Resonance Imaging Findings	Hakguder, A., Tastekin., N, Birtane, M., Uzunca, K., Zater, C., Sut, N.,2011. Comparison of the Short-Term Efficacy of Physical Therapy in Subacromial Impingement Syndrome Patients with Stage I and II Magnetic Resonance Imaging Findings. *Turkish Journal of Rheumatology*, 26(2), 127-134.	nRCT	YES
9	Kocyigit,F., Akalin, E.,Gezer, N., Orbay, O., Kocyigit, A., and Ada, E	2012	Functional Magnetic Resonance Imaging of the Effects of Low-frequency Transcutaneous Electrical Nerve Stimulation on Central Pain Modulation A Double-blind, Placebo-controlled Trial	Kocyigit, F., Akalin, E., Gezer, N., Orbay, O., Kocyigit, A., Ada, E.2012. Functional Magnetic Resonance Imaging of the Effects of Low-frequency Transcutaneous Electrical Nerve Stimulation on Central Pain Modulation. *The Clinical Journal of Pain*, 28(7), 581-	RCT	YES

				588.		
10	Koo, C., Lin, R., Wang, T., Tsauo, J., Yang, P., Yen, C Biswal, S.	2015	Novel Noxipoint Therapy versus Conventional Physical Therapy for Chronic Neck and Shoulder Pain: Multicentre Randomised Controlled Trials	Koo, C., Lin, R., Wang, T., Tsau, J., Yan, P., Yen, C., Biswal, S 2015. Novel Noxipoint Therapy versus Conventional Physical Therapy for Chronic Neck and Shoulder Pain: Multicentre Randomised Controlled Trials. *Scientific Reports*, 5, 16342.	RCT	YES
11	Korkmaz, O., Capaci, K., Eyigor, C., Eyigor, S	2010	Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: a prospective, randomized study	Korkmaz, O., Cpaci, K., Eyigor, C., Eyogor, S., 2010. Pulsed radiofrequency versus conventional transcutaneous electrical nerve stimulation in painful shoulder: A prospective, randomized study. *Clinical Rehabilitation*, 24(11), 1000-1008.	RCT	YES
12	Lin, M., Chiu, H., Shih, Z.., Lee, P., Li, P., Guo, C., Luo, Y., Pang, W	2019	Two Transcutaneous Stimulation Techniques in Shoulder Pain: Transcutaneous Pulsed Radiofrequency (TPRF) versus Transcutaneous Electrical Nerve Stimulation (TENS): A Comparative Pilot Study	Lin, M., Chiu, H., Shih, Z., Lee, P., Li, P., Guo, C., Luo, Y., Pang, W., 2019. Two Transcutaneous Stimulation Techniques in Shoulder Pain: Transcutaneous Pulsed Radiofrequency (TPRF) versus Transcutaneous Electrical Nerve Stimulation (TENS): A Comparative Pilot Study. *Pain and Research Management*, 2019, 1-9.	RCT	YES
13	Moezy, A, Sepehrifar, S, Dodaran, M	2014	The effects of scapular stabilization-based exercise therapy on pain, posture, flexibility and shoulder mobility in patients with shoulder impingement syndrome: a controlledrandomized clinical trial	Moezy, A., Sepehrifar, S and Dodaran M., 2014. The effects of scapular stabilization- based exercise therapy on pain, posture, flexibility and shoulder mobility in patients with shoulder impingement syndrome: a controlledrandomized clinical trial. *Medical Journal of the Islamic Republic ofIran (MJIRI)*, 28.87, 1-15.	RCT	YES
14	Munday, S	2014	The efficacy of shoulder adjustments	Munday, S., 2019. *The efficacy of*	RCT	YES

			on patients suffering from shoulder impingement syndrome	*shoulder adjustments on patients suffering from shoulder impingement syndrome*. Masters. Durban: Technikon Natal.		
15	Ozdincler, A	2005	The effects of TENS and LLL on pain and functional performance of patients with shoulder pain	Ozdincler, A., 2005. The effects of TENS and LLL on pain and functional performance of patients with shoulder pain. *Journal of Medical Science*, 5(4), 328-332.	RCT	YES
16	Shehab, D and Adham, N	2000	Comparative effectiveness of ultrasound and transcutaneous electrical stimulation in treatment of periarticular shoulder pain	Shehab, D., Adham, N., 2000. Comparative effectiveness of ultrasound and transcutaneous electrical stimulation in treatment of periarticular shoulder pain. *Physiotherapy Canada*, 52(3), 208-210, 214.	RCT	YES
17	Soibam, I	2005	Comparative study on the effectiveness of ultrasound (us) to transcutaneous electrical stimulation (tens) in the treatment of periarticular shoulder pain(psp)	Soibam, I., 2005. *A comparative study on the effectiveness of ultrasound (us) to transcutaneous electrical stimulation (TENS) in the treatment of periarticular shoulder pain (psp)*. Masters. Karnataka, Bangalore: Rajiv Gandhi University of Health Sciences.	RCT	YES
18	Subasi, V, Toktas, H, Demirdal, U, Turel, A, Cakir, T and Kavuncu, V	2012	Water-Based versus Land-Based Exercise Program for the Management of Shoulder Impingement Syndrome	Subasi, V., Toktas, H., Demirdal, U., Turel, A., Cakir, T., Kavuncu, V 2011. Water-Based versus Land-Based Exercise Program for the Management of Shoulder Impingement Syndrome. *Turkish Journal of Physical and Medical Rehabilitation*, 58, 79-84.	RCT	YES
19	Tefner, I., Kovacs, C., Gaal, R., Koroknai, A., Horvath, R., Badruddin, R., Borbely, I, Nagy, K,	2013	The effect of balneotherapy on chronic shoulder pain. A randomized, controlled, single-blind follow-up trial. A pilot study	Tefner, I., Kovacs, C., Gaal, R., Koroknai, A., Horvath, R., Badruddin, R., Borbely, I., Nagy, K., Bender, T., 2015. The effect of balneotherapy on chronic shoulder	RCT	YES

	and Bender, T			pain. A randomized, controlled, single-blind follow-up trial. A pilot study. *Clinical Rehabilitation*, 34, 1097-1108.		
20	Yazmalar, L, Sariyildiz, M., Batmaz, I., Alpayci, M., Burkan, Y, Ozkan, Y, Cevik, R	2016	Efficiency of therapeutic ultrasound on pain, disability, anxiety, depression, sleep and quality of life in patients with subacromial impingement syndrome: A randomized controlled study.	Yazmalar, L., 2016. Efficiency of therapeutic ultrasound on pain, disability, anxiety, depression, sleep and quality of life in patients with subacromial impingement syndrome: A randomized controlled study. *Journal of back and musculoskeletal rehabilitation*, 29, 801-807.	RCT	YES
21	Ucurum, S, Kaya, D Kayali, Y, Askin, A, and Tekindal, M	2018	Comparison of different electrotherapy methods and exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial	Ucurum, S., Kaya, D., Kayali, Y., Askin, A., Tekindal, M., 2018. Comparison of different electrotherapy methods and exercise therapy in shoulder impingement syndrome: A prospective randomized controlled trial. *Acta Orthopaedica et Traumatologica Turcica*, 52, 249-255.	RCT	YES

Appendix D:

Memorandum of Agreement

Title of the study: The effectiveness of transcutaneous electrical nerve stimulation (TENS) therapy in the treatment of shoulder pain: A systematic review

Principle Investigator:	Miss Shrishti Maharaj		(Researcher)
Co-investigator:	Dr. C. Korporaal	M.Tech:Chiropractic	(Supervisor)

Brief introduction and description of the study:

This study is a systematic review of literature pertaining to the use of Transcutaneous Electrical Nerve Stimulation (TENS) therapy in the treatment of shoulder pain as a result of shoulder impingement syndrome (SIS). Articles are collected electronically from online databases by the researcher. The articles included in this study are divided into different study types; non-randomised controlled studies, randomised controlled clinical trials; case series/reports; observational studies; all of which are included in this study. Grouped articles are to be reviewed by a panel of seven (7) reviewers using rating scales (specific to the study types listed above) and feedback from reviewers are collated and presented in a statistical presentation.

Outline of procedures:

Reviewers will receive articles which are grouped according to study type (RCT's/Case series/reports/Observational studies and Non-randomised controlled studies) as well as the corresponding scale rating sheet (RCT's-PEDro Scale, Case series/reports and Observational studies- Newcastle-Ottawa Scale and Non randomised controlled trials- Liddle scale) as well as an explanation sheet for each scale. The reviewer will then eventually rate the articles according to its corresponding scale. Rating sheets are collected and collated for statistical analysis. A determined time period will be recommended for each article/group of articles review for feedback.

Reviewer Requirement: A biosketch/CV outlining each reviewer's qualifications and experience will be obtained from each reviewer, upon agreement from the reviewer to partake in this study. The biosketch/CV is required for purposes of record keeping in this study in order to have evidence to support that the proposal guidelines have been followed.

Benefits: Publication of the study: should this study be published, all persons participating in the study will be included in the publication as the author. Should the reviewer wish to be exempt from this, please strike through the paragraph and initial alongside.

Remuneration: An honorarium of R 1000.00 is awarded to each reviewer in appreciation of their time and dedication to this project.

Contact persons: Please do not hesitate to contact either the supervisor and/or researcher regarding any questions or queries via the following methods:

Dr. Charmaine Korporaal (Supervisor):		Ms Shrishti Maharaj (Researcher):
Telephone:	031 373 2611	Cell no: 079 596 9762
Cell no:	083 246 3562	Email: shrishti.maharaj@gmail.com
Email:	charmak@dut.ac.za	

Statement of Agreement to Participate in the Research Study:

I …….. (Subject's full name),

……(Identity number / passport number),

have read this document in its entirety and understand its contents. Where I have had any questions or queries, these have been explained to me by.....to my satisfaction. Furthermore, I voluntarily agree to participate in this study
as a reviewer.

Reviewer's name .....

Reviewer's Signature: …….. ..... Date: ……

Supervisor name.....

Supervisor Signature: …….. ..... Date: ……

Researcher name.....

Researcher Signature: …….. ..... Date: ……

Copies of the signed documents will also be sent to the reviewers for reference.

Appendix E

PEDro Scale:

Scale for the assessment of randomized controlled trials (RCT's)

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (*Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41*). The list is based on "expert consensus" not, for the most part, on empirical data.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

All Criteria	**Points are only awarded when a criterion is clearly satisfied**. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	*Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented
Criterion 4, 7- 11	*Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5-7	*Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An *intention to treat* analysis means that, where subjects did not receive treatment (or the control

	condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group □ time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
Criterion 11	*A point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.

PEDro scale

Reviewer:

Article title:

1. eligibility criteria were specified	no ❑ yes ❑ where:
2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no ❑ yes ❑ where:
3. allocation was concealed	no ❑ yes ❑ where:
4. the groups were similar at baseline regarding the most important prognostic indicators	no ❑ yes ❑ where:
5. there was blinding of all subjects	no ❑ yes ❑ where:
6. there was blinding of all therapists who administered the therapy	no ❑ yes ❑ where:
7. there was blinding of all assessors who measured at least one key outcome	no ❑ yes ❑ where:
8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no ❑ yes ❑ where:
9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no ❑ yes ❑ where:
10. the results of between-group statistical comparisons are reported for at least one key outcome	no ❑ yes ❑ where:
11. the study provides both point measures and measures of variability for at least one key outcome	no ❑ yes ❑ where:

Adapted from PEDro scale online. (1999)

Appendix F

Newcastle-Ottawa Quality Assessment Scale

Non-randomised controlled trials

Reviewer:	
Article Title:	

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Selection

1) Is the case definition adequate?
   a) yes, with independent validation □
   b) yes, eg record linkage or based on self-reports
   c) no description

2) Representativeness of the cases
   a) consecutive or obviously representative series of cases □
   b) potential for selection biases or not stated

3) Selection of Controls
   a) community controls □
   b) hospital controls
   c) no description

4) Definition of Controls
   a) no history of disease (endpoint) □
   b) no description of source

Comparability

1) Comparability of cases and controls on the basis of the design or analysis
   a) study controls for_____(Select the most important factor.) □
   b) study controls for any additional factor □ (This criteria could be modified to indicate specific control for a second important factor.)

Exposure

1) Ascertainment of exposure
   a) secure record (eg surgical records) □
   b) structured interview where blind to case/control status □
   c) interview not blinded to case/control status
   d) written self report or medical record only
   e) no description

2) Same method of ascertainment for cases and controls
   a) yes □
   b) no

3) Non-Response rate
   a) same rate for both groups □
   b) non respondents described
   c) rate different and no designation

Adapted from Wells et al. 2003. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analyses

Appendix G

Gmail Shrishti Maharaj <shrishti.maharaj@gmail.com>

Copyright permission for use of images
3 messages

Shrishti Maharaj <shrishti.maharaj@gmail.com> Wed, Aug 19, 2020 at 6:45 PM
To: "lydia.kubiak@nih.gov" <lydia.kubiak@nih.gov>

Good day

My name is Shrishti Maharaj and I am currently conducting a Master's level thesis study titled "The effectiveness of transcutaneous electrical nerve stimulation (TENS) therapy on shoulder impingement syndrome: A systematic review" at the Durban University of Technology in South Africa.

I have come across the study titled "Acute shoulder injuries" by David. M. Quillen, Mark Wuchner and Robert. L. Hatch by the American Family Physician 2004;70:1947-54 (as attached) and wanted to request permission to use the following images in my study as part of my Chapter two: Literature review:

Figure 1: Bony anatomy of the shoulder on page 1948 and

Figure 8: Muscles of the rotator cuff on page 1953 - both of which was illustrated by Lydia. V. Kibiuk

My request for the use of these images is purely for research use as part of a Master's of Technology in Chiropractic thesis and will receive no commercial gain after publication. All credit would be given to the authors of this study and the illustrator.

I have been advised by the copyright office at AAFP to request your permission as you are the illustrator. Please could you advise me further on this.

Kindest regards,

Shrishti Maharaj

Sent from Mail for Windows 10

Kibiuk, Lydia (NIH/OD/ORS) [E] <kibiukl@mail.nih.gov> Wed, Aug 19, 2020 at 7:42 PM
To: Shrishti Maharaj <shrishti.maharaj@gmail.com>

Dear Shrishti,
Than you for asking permission to use art. Yes, please feel free to use. Permission granted. Good Luck to you!
Lydia

Sent from my iPhone

> On Aug 19, 2020, at 12:46 PM, Shrishti Maharaj <shrishti.maharaj@gmail.com> wrote:
>
> [Quoted text hidden]