



**“Comparative study on the inclusion of *Nigella sativa* oil with
micro-needling for post-acne scarring”**

By

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Submitted in fulfilment of the requirements for the degree

of

Masters of Health Sciences in Somatology
in the Faculty of Health Sciences

at

Durban University of Technology

June 2019

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Declaration

This Master of Somatology is my own work and all primary and secondary sources cited in the thesis have been appropriately acknowledged. The dissertation has not been submitted to any other institution as part of an academic qualification.

This Dissertation is prepared in partial fulfilment of the requiremen for the Master of Somatology at Durban University of Technology, Kwazulu Natal, South Africa.

Signature

June 2019

Dedication

I lovingly dedicate this thesis to my husband Muneeb and family, who supported and encouraged me each step of the way.

To my son Muhammed Hafeez, as an encouragement in the future that with hard work and perseverance success can be achieved.

Acknowledgements

Bismillahi raḥmāni raḥīm, In the name of Allah the most gracious, the most merciful.

First and foremost, I would like to thank and acknowledge my creator for the abundance of blessings and guidance, surely without Him the completion of this thesis's would not have been possible.

To my husband Muneeb for his patience and sacrifice and always believing in me.

To my parents Amina and Mogamat Adiel for always reassuring me that anything is possible. To my colleagues Diana, Khosi, Zuko, Prasidh, and Michael, for your invaluable support and guidance, I am ever indebted to you all.

To my supervisor, Prof. Oluwafemi Oguntibeju, for always believing that I would be able to complete my master's degree, and for offering words of encouragement when most needed. Thank you for the valuable input and words of wisdom. I am forever grateful and blessed for having an outstanding supervisor as yourself.

To my co-supervisor Ms Sinegugu Nkwanyana, who has guided and assisted me through the entire process, thank you for your valued input, assistance and patience.

Abstract

Acne is one of the leading skin disorders resulting in a debilitating physical appearance and psychological distress. Studies have shown that acne, and acne scarring are more common amongst women (76%) than men (24%). The need for acne scarring treatments is ever-rising. Post-acne scarring is a common, permanent, distressing, disfiguring skin disorder, which results from poor healing of active acne vulgaris. Post-acne scarring usually persists for a long time, even after the acne lesions have disappeared, due to its disfigurement leading to visible scarring, and post inflammatory hyperpigmentation. Acne scarring is more than a cosmetic concern, but rather, a medical problem, as it causes psychological problems. The growing interest in the use of botanical ingredients in modern aesthetics has grown phenomenally. This trend had led the researcher to using micro-needling in combination with oil from medicinal plant (*Nigella sativa*), with the aim of providing further insight in the growing interest and use of botanical ingredients.

The aim of the study was to determine whether *Nigella sativa*, along with micro-needling, would provide better results when compared to micro-needling alone. The addition of the botanical oil was used in order to act as a synergist for micro-needling by improving post-acne scarring.

This study employed quantitative research approach with qualitative elements, making use of purposive sampling. A total of 50 female participants with post-acne scarring were recruited into the study, however only 42 completed the study. Participants were consulted and a participant demographic information sheet, post acne scarring grading scale and photographic images were taken at baseline with the Visia Skin Complexion Analyser®. The participant's pain intensity scale, information sheet and satisfaction survey provided descriptive data.

Data saturation was achieved after analysis of the results. The results that emerged from the study indicated an improvement in both the control and experimental group.

The results of this study provided valuable insight into the use of botanical oils, combined with micro-needling. It is important to note that there is lack of research in South Africa in this area, especially on males, as studies have indicated that men have exhibited the same effects as females in relation to scarring. Results from the study indicated improvement in both the control and experimental group, however a significant improvement in scarring along with post-inflammatory hyperpigmentation was observed within the experimental group. This is indicative of the fact that the addition of the *Nigella sativa* oil helped to elicit a significant improvement, when combined with micro-needling. What further emerged from the study was the importance and use of a quality of life questionnaire, particularly in post-acne scarring, as limited research and studies exist. It is important to monitor acne, especially within a clinical setting.

Definition of terms

Keloid scarring: Is a tough, heaped-up scar that rises fairly abruptly above the rest of the skin. It tends to have a smooth top and a pink or purple colour.

Cosmeceuticals: Cosmeceuticals refer to the combination of cosmetics and pharmaceuticals. Cosmeceuticals are cosmetic products, with bioactive ingredients, purported to have medical or drug-like benefits. The "cosmeceutical" label applies only to products applied topically, such as creams, lotions, and ointments.

Botanical oils: Botanical oils are oils obtained from plants that are fatty, dense and non-volatile. These oils are extracted from the root, stem/bark, leaves, flowers, seeds or fruits of a particular plant, tree or shrub, usually cold-pressed, or extracted by heat. Most contain nutritious proteins, minerals, and vitamins.

Chemical peel: A chemical peel is a treatment in which an acid solution is used to remove the damaged outer layers of the skin. In performing chemical peels, physicians apply alpha-hydroxy acids (AHA), trichloroacetic acid (TCA), or phenol to the skin.

Roaccutane: Accutane (isotretinoin) is a form of vitamin A and is used to treat severe nodular acne.

Micro-needling: refers to a procedure that uses fine needles to puncture the skin and create a controlled skin injury for the purpose of rejuvenation. It's also called skin-needling, collagen induction therapy (CIT), and percutaneous collagen induction (PCI).

Microdermabrasion: A type of cosmetic skin treatment in which the outermost or most superficial layers of the skin is removed using a fine abrasive applied very gently.

Dermabrasion: A surgical process by which the skin is resurfaced by planing or sanding, usually by means of a rapidly rotating abrasive tool.

***Nigella sativa*:** black caraway (also known as black cumin, nigella, and kalonji) is an annual flowering plant in the family Ranunculaceae, native to South and Southwest Asia. *Nigella sativa* grows to 20–30 cm (7.9–11.8 in) tall, with finely divided, linear, (but not thread-like) leaves.

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CHAPTER I: INTRODUCTION

This chapter is an overview of this study concerning the development of acne scarring. The psychosocial and physical effects and current treatment interventions available.

1.1 Background

Post-acne scarring is a common, permanent, distressing, disfiguring sequel, skin disorder, which results from poor healing of active acne vulgaris (Ibrahim *et al.*, 2018). This condition usually persists for a long time, even after the acne lesions have disappeared (Porwal *et al.*, 2018; Kornhaber *et al.*, 2018). Due to the disfigurement it causes, acne scarring is more than a cosmetic concern, but rather a medical problem, as it causes psychological problems. Literature indicates high levels of anxiety, stress, difficulty to concentrate at school, less productivity at work and self-consciousness, depression, and sometimes the tendency to commit suicide in people with post-acne scarring (Levy and Zeichner, 2012; Fabbrocini *et al.*, 2010; Brown *et al.*, 2008).

A number of factors could lead to the development of post-acne scars, for example the severity preceding inflammation, stage and nature of treatment, the nature of local manipulation, as well as individual predisposition to scarring (Bhargava *et al.*, 2018; Ibrahim *et al.*, 2018; Goodman, 2011). Post-acne scars are respectively classified into atrophic, hypertrophic, and keloidal scars. Due to loss of dermal collagen, atrophic scars are further classified into ice-pick, rolling, and boxcar scars (Varma *et al.*, 2018; Jacob *et al.*, 2001). Many therapeutic measures, such as micro-needling, skin grafting, chemical peels, soft tissue augmentation, lasers (non-ablative, ablative and fractional), and radio frequency have been performed to improve acne (Varma *et al.*, 2018; Singh and Yadav, 2016; Aslam & Alster, 2014).

Dermabrasion and laser resurfacing using carbon dioxide (CO₂) and erbium-doped yttrium aluminium garnet laser, erbium YAG laser (Er: YAG) lasers have demonstrated significant improvement in facial atrophic scars. However daily activities can be affected due to post treatment downtime and undesired side effects (Varma *et al.*, 2018; Ochi *et al.*, 2017; Cohen *et al.*, 2016). Alternatively, treatment modalities, such as microdermabrasion and non-ablative laser resurfacing, are tolerated better, and have shorter down time, however the response is slow, which could possibly lead to patient disappointment and frustration (Varma *et al.*, 2018; Cohen *et al.*, 2016; Rivera and Spencer, 2007).

Micro-needling has been recently investigated as an alternative treatment intervention for post-acne scars, to overcome the short-comings in certain aesthetic treatment interventions, such as laser and chemical peels. The use of skin needling was initially described by Orentreich (1995) using a technique called subcision, in order to release fibrous strands responsible for depressed cutaneous scars and wrinkles. It was not long after that Dr. Dez Fernandes, developed a drum-shaped device, which has very fine protruding stainless steel needles of 0.25-3 mm in length (Alster and Graham., 2017; Fernandes, 2005). Each needle of the derma roller punctures the skin and forms a channel or 'micro-wound'. This controlled micro-traumatisation of the skin leads to an activation of the healing cascade, along with activation of growth factors and cell proliferation, leading to increased synthesis and deposition of collagen-elastin complex. There is successive transformation of collagen III to collagen I with neo-angiogenesis, and thus accelerated scar remodelling (Fernandes, 2005; Fernandes, 2002). In turn, this induction of collagen improves the tethered scars, skin rejuvenation characterised by improved firmness, texture, and hydration of skin (Bhargava *et al.*, 2018; Alster and Graham, 2017).

Micro-needling is therefore considered a non-invasive aesthetic technique associated with minimal and tolerable side-effects including mild erythema, localised oedema and skin flaking, all of which resolve within a 48-hour period. This makes

micro-needling suitable for people who desire measurable clinical results from treatments, with little to no recovery (Alster and Graham, 2017).

Nigella sativa is a well-known herb and cold-pressed oil, cultivated in the Middle East, Asia and Europe, and it has been found to possess many medical properties, amongst other efficacies (Al-Ghamdi, 2001). Traditionally, its uses are well documented in folk medicine for treating common to chronic ailments, such as eczema, boils, respiratory problems such as bronchitis, asthma, parasitic infections, and inflammatory diseases (Dogra *et al.*, 2014; Yarnell & Abascal, 2011; Mahmoud, El-Abhar and Saleh, 2002; Khan, 1999). *Nigella sativa* oil is a highly regarded medicinal herb, used both topically and orally, for centuries which has demonstrated many antioxidant effects (Ahmad *et al.*, 2013; Sharma *et al.*, 2009; Erkan, Ayranci and Ayranci, 2008; Muhtasib, El -Najjar and Schneider - Stock, 2006; Hajhashemi, Ghannadi and Jafarabadi, 2004; Mabrouk *et al.*, 2002; Al Ghamdi, 2001).

Despite an array of possible treatment modalities, post-acne scarring is challenging to treat, as there is no single intervention that is completely effective. In an attempt to resolve the challenge, this study investigates the effectiveness and safety of micro-needling alone, versus micro-needling combined with topical application of *Nigella sativa* in the treatment of post-acne scarring.

1.2 Statement of the problem

Post-acne scarring is the most common complication in the skin care industry across the globe (Tan and Bhate, 2015). Due to disfigurement it causes as majority of post-acne scars occur on the face. Post-acne scarring is always associated with a range of psychological disorders, thus impacting the quality of life. Improvement of scars is a common request from acne clients visiting skin care clinics. Post-acne scarring is a challenge to treat. A plethora of traditional treatment techniques such as dermabrasion, microdermabrasion, chemical peeling, and laser resurfacing have been reported to improve acne scarring, however, these treatment modalities are invasive and have been reported to have undesirable side effects which result in

disappointment and dissatisfaction (Majid and Imran, 2014; Bernstein *et al.*, 2013; Mahmoud *et al.*, 2010; Rivera, 2008). In pursuit of a safe, minimally invasive and effective treatment intervention for post-acne scarring, acne scar management has always been a challenging task, and an area of interest for skin care professionals for several decades. Cosmetic micro-needling has been introduced as a relatively new treatment modality currently used in the skin care industry for the treatment of various skin related problems including post-acne scars.

Nigella sativa, a natural oil producing plant has been reported to have healing properties, as it has been used to reduce inflammation on conditions such as eczema and dermatitis. In recent years, the skin care industry has shifted to the use of more natural ingredients in creams, lotions, and cleansers. Cosmeceutical companies and modern day societies have come to realise the importance and benefits of herbal ingredients, and have thus capitalised on this, not only for its untapped market, but for its cosmetic benefits. Although the use of *Nigella sativa* is well-documented, there is paucity of data controlled studies comparing micro-needling alongside the application of *Nigella sativa*. It is for this reason that in this study, evaluated the effectiveness of micro-needling alone versus micro-needling and topical application of *Nigella sativa* as the modality for treating atrophic acne scars.

1.3 Aim and objective of the study

1.3.1 Aim

To establish the influence of combined micro-needling and *Nigella sativa* oil in reducing the appearance of acne scars.

1.3.2 Objectives

The primary objective is to compare the difference in results between Group A – micro-needling only (control group) and Group B – micro-needling and sativa (experimental group), which is supported by a number of sub-objectives, namely:

- to evaluate the impact of acne scarring by means of the Acne Scarring Quality of Life Scale (ASQLS);
- to assess any visual difference in acne scars by means of a Visia® pictographic measurement tool;
- to assess the perceived participant's perception on the difference of acne scars through the participant's satisfaction survey; and
- to determine the grading of the post-acne scars by comparing before and after treatments.

1.4 Contribution of the study

Improvement of scars is a common request from acne clients. Scientists in the skin care industry are working tirelessly towards discovering an effective treatment modality for the improvement of post-acne scarring. The study findings have demonstrated, a novel treatment intervention for post-acne scarring, combining therapies of micro-needling, and topical application of *nigella sativa*. This discovery adds to the body of knowledge and also contributes to a wide selection of post-acne treatment interventions, which is suitable for all skin types with less down time.

CHAPTER II: LITERATURE REVIEW

2.1 Introduction

Medical aesthetics used in facial procedures have grown exponentially since 1997. This growth was fostered due to the increased client demand for minimally invasive medical aesthetics interventions (American Society for Aesthetic Plastic Surgery, 2016). According to statistics from the American Society of Plastic Surgery, more than 80% of treatments recorded were minimally invasive, of which common procedures accounted for chemical peel, lasers, micro-dermabrasion, skin resurfacing, dermal fillers and botox. This section therefore draws on past and current methods of application used in the improvement of acne scarring, with a key focus on the combined therapy of micro-needling and *Nigella sativa* oil.

2.2 Micro-needling

Micro-needling has increased in popularity amongst consumers due to its usefulness in improving acne scars, wrinkles, stretch marks, transdermal drug delivery, and especially for its facial rejuvenation activity (Bahuguna, 2013; Doddaballapur, 2009).

Micro-needling in particular is a less invasive treatment option and has proven to be more advantageous than other methods of treatment, such as derma-brasions or laser, which causes a considerable amount of morbidity and downtime interference with the daily activities of the patient (Majid, 2009). One major concern of these treatments are the precipitation or worsening of pigmentation especially on skin types IV-VI (Alster and West, 1996).

However, micro-needling is a relatively new and novel technique in the management of acne scarring. It has been proved that a combination of various treatment modalities, such as chemical peel and micro-needling gives, better results than

using a single method of treatment, and is safe for use on darker Fitzpatrick skin types III-IV with a scar grading of 1-3 (Sharad, 2011).

Micro-needling has not only been used effectively in cosmetic industry, but also for maximising drug delivery systems of medical practitioners, of which 74% were positive with regards to usage and even self-administration (Birchall *et al.*, 2011).

A study by Fabbicini *et al.* (2009) has shown that the severity grade of rolling scars in all patients has improved tremendously, with only two sessions over a year. This has indicated that through digital analysis needling has proven to be advantageous in terms of producing immediate effects on improving acne scars, when compared to other procedures. Many therapeutic approaches have been advocated to treat acne scarring, which include both invasive and noninvasive methods, but unfortunately, even with the most expensive techniques, it is difficult to achieve the goal of complete improvement. Thus, there is an ever-increasing demand for less invasive, highly effective, and affordable therapeutic procedures to treat post-acne scars (Dodgra *et al.*, 2014).

2.2.1 Mechanism of action

In essence, micro-needling's core purpose is to elicit a wound response, much like chemical peels, but it is much safer, as no epidermal destruction of tissues occurs, and minimal down time is required, when compared to laser resurfacing techniques (Majid, 2009).

Micro needling works by traumatically puncturing the skin to create pores in the dermis, which stimulates the release of growth factors and cytokines (Lee, 2016).

A study by Aust *et al* (2008) reported that micro-needling with 0.5 to 1.5 mm long needles, stimulated massive growth of elastin and collagen fibres, along with the formation of new blood capillaries (neovascularisation), which in turn lead to a reduction in and improvement of scars. However, the authors suggested that results are largely based on various factors that would produce favorable results, such as depth and frequency of needle penetration, number of passes and micro-needling

sizes, which can range from 0.1 to 2.5 mm. Similarly, a study by Fernandes and Signorini (2008) noted a vast improvement in the reduction of burns scars and acne scars by removing scar collagen, and replacing it with new collagen when 2-3 mm needling was performed.

Early reports by Orentreich and Orentreich (1995) as well as Camrind and Doucet (1997) concurred with how dermal needling methods helped improve subsequent scarring. This research acted as a catalyst for the development of ground breaking micro-needling procedures that focused on efficacy and safety.

Camirand and Doucet (1997) made their discovery of the introduction of micro-needling, whereby a tattoo pistol containing no ink was used in the treatment of atrophic scarring. Following this, a better procedure in terms of safety and simplicity was developed for the treatment of wrinkles and scars. As opposed to ablative treatments, this treatment could be safely repeated if necessary, and it can be effectively carried out on regions where laser treatments, or deep peelings, cannot be done (e.g., orbital rims or nasolabial folds) (Fulton, 2013).

Micro-needling (also known as percutaneous collagen induction) is a well-recognised procedure in the medical aesthetics field, and used as a facial rejuvenation method, as it offers an anti-aging effect. Micro-needling's core focus is based on the principle of the induction of new collagen and elastin synthesis, combined with the pre-preparation of antioxidants, which is applied topically for at least three weeks prior to post-treatment, as micro-needling allows for the enhancement and absorption of these topical therapies (Iriarte *et al.*, 2017; Badran *et al.*, 2009). The induction of new collagen and elastin occurs when micro-needling repeatedly punctures the epidermis, producing micro-channels that elicit a wound healing cascade response to injury, similar to that of chemical peels (Fernandes and Signorini, 2008). This wound healing cascade produces growth factors, which stimulate the formation and remodelling of the new collagen and elastin fibres (Doddaballapur, 2009).

These growth factors are of primary importance in providing the skin with a plump and youthful appearance (Fernandes and Signorini, 2008). However, over time, this youthful appearance may decrease due to either environmental factors such as ultraviolet sun exposure, which is the leading cause of photo damage, resulting in an accelerated aging process (Farage *et al.*, 2008).

Collagen and elastin synthesis form an important facet in structural integrity, keeping skin plump and youthful in appearance. Therefore, as we age, the structural integrity of these proteins diminishes over time, leading to aging skin. Figure 2.1 is a microscopic slide of the aging process, indicating how the condition of the skin may deteriorate over time. The top part of the picture illustrates a skin biopsy of a 12-year old patient with compact collagen, thick epidermis, and deep dermal papillae, compared to the bottom, a biopsy of 77-year-old patient with elastotic, friable and fragmented collagen, thinned epidermis, and flattened papillae, all of which are well-documented in an aging skin (Fernandes and Signorini, 2008).

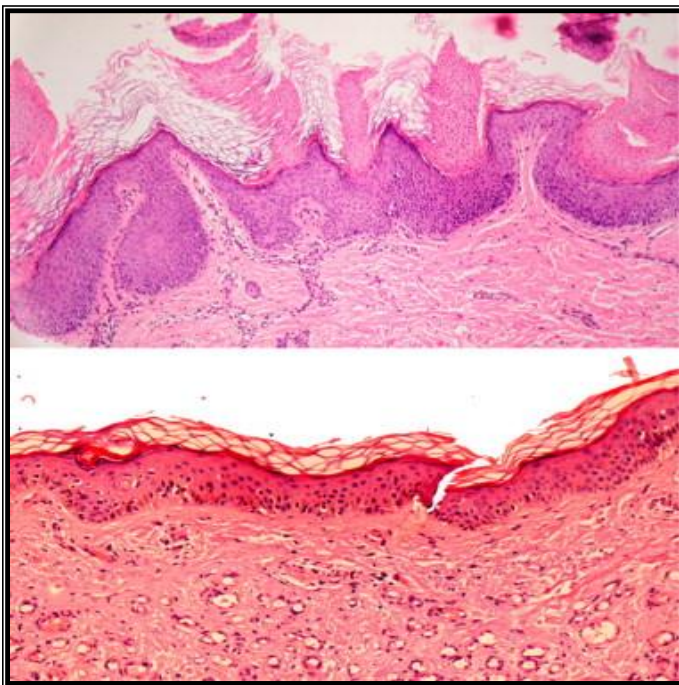


Figure 2.1 Microscopic biopsy of young healthy 12-year-old vs bottom half of a 77-year-old patient (Fernandes and Signorini, 2008)

Percutaneous Collagen Induction may therefore be a very useful intervention in combating scarring as the advantages greatly outweigh the disadvantages of this novel treatment as compared to other available methods which risk far outweigh its benefits in the treatment of post acne scarring (Fernandes, 2005). Table 2.1. below highlights some of the disadvantages and advantages of Percutaneous Collagen Induction which concurs with similar study by Dhollan and Thirunavukkarasu, 2017.

Table 2.1. Disadvantages and Advantages of Percutaneous Collagen

Induction (Dhollan and Thirunavukkarasu, 2017; Fernandes, 2005)

Disadvantages	Advantages
Bleeding may be possible dependent on needle size.	Short healing phase.
Less intense deposition of collagen than laser resurfacing, but repeatable treatments that may last just as long.	Less expensive than laser resurfacing.
Hyperpigmentation is a potential although rare complication.	Can be performed with topical anaesthesia depending on the needle size.
	PCI does not permanently damage the skin.
	Skin does not become sun-sensitive.
	Easy-to-master technique with a tool that has been specially designed in various sizes including those for home use
	Can be used after laser resurfacing or in those with very thin skin.

2.2.2 Pain tolerability

According to Woodrow *et al.*, (1972), pain sensitivity may differ in individuals depending on race, age and sex. For this reason, it is important to consider the use of pain intensity scales in order to monitor patient pain intensity. The study further

concluded that caucasians demonstrated a higher pain tolerance compared to Black, Indian, and Asian patients. Pain intensity scales is essential for monitoring experimental pain during a treatment over long periods. Numerous studies have reported on the use of pain intensity scales as a method of monitoring patients pain tolerability toward clinical or experimental procedures (Hawker *et al.*, 2011; Breivik *et al.*, 2008; Hadjistavropoulos, 2007; Herr, 2004). Another study confirms this notion of pain tolerance in Caucasians as opposed to black individuals (Sheffield *et al.*, 2000). Daddoballapur (2009) reported that micro-needling is a well-tolerated procedure resulting in minimal erythema following the treatment, which usually dissipates in 2-3 days. Micro-needling can be combined with other acne scar treatments such as chemical peels, microdermabrasion, fractional resurfacing, and subcision surgery, thus maximising the benefits to the patients.

A study by Fernandes *et al.* (2008) similarly mentioned micro-needling being tolerable when using a 1 mm roller size. Active bleeding to occurs when using medical grade needling of 3 mm size under local anesthetic as these penetrate well into the dermis of the skin.

2.3 Fitzpatrick skin classification system

Globally, Fitzpatrick skin type classification system is a useful tool in determining who is at risk of photo damage and skin cancer (Ravnbak, 2010; Roberts 2009; Fitzpatrick, 1988). In performing medical aesthetics procedures, it has proven useful to predict certain impending reactions in cosmetic procedures, such as lasers, chemical peels and micro-needling, resulting in hyperpigmentation and scarring (Roberts, 2009 and Sachdeva, 2009). Due to this, post-operative care has become essential when performing these types of cosmetic treatments.

The Fitzpatrick classification systems not only helps to identify reactive skin types, but also to identify those who may be exposed to significant risk of hyperpigmentation, hypopigmentation or scarring when performing these medical aesthetic procedures (Sachdeva, 2009; Astner and Anderson 2004). Fitzpatrick

classification system works by administering and posing numerous questions, and scoring it in relation to individuals tanning habits and reaction towards the sun exposed areas, as well as genetic disposition. Table 2.2 is a representation of the Fitzpatrick skin type classification of sun reactive skin types, while Table 2.3 and Table 2.4 and Table 2.5 pose certain questions, which are then scored. These scores are then indicative of the category in which individuals would be classified as per their Fitzpatrick skin type.

**Table 2.2 Fitzpatrick skin type classification of sun reactive skin types
(Sachdeva, 2009)**

Fitzpatrick skin type classification				
Skin Type	Skin Colour	Hair and eye Colour	Reaction to sun	Common ethnic considerations
Type I	White	Blond hair and green eyes	Always burns, freckles	English, Scottish
Type II	White	Blond hair and green eyes/ blue eyes	Always burns, freckles, difficult to tan	Northern European
Type III	White	Blond/brown hair and blue/brown eyes	Tans after several burns, may freckle	German
Type IV	Brown	Brown hair and brown eyes	Tans more than average, rarely burns, rarely freckles	Mediterranean, Southern European, Hispanic
Type V	Dark Brown	Brown/black hair and brown eyes	Tans with ease, rarely burns, no freckles	Asian & Indian, some African

Type VI	Black	Black hair and brown/black eyes	Tans, rarely burns, deeply pigmented, never freckles	African
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Table 2.3 Reaction to sun exposure (Sachdeva, 2009)

Reaction to sun exposure					
Score	0	1	2	3	4
What happens when you stay in the sun to long?	Painful redness, blistering peeling	Blistering followed by peeling	Burns sometimes followed by peeling	Rare burns	Never had burns
To what degree do you burn?	Hardly or not at all	Light colour tan	Reasonable tan	Tans very easily	Turn dark brown quickly
Do you turn brown within several hours after sun exposure?	Never	Seldom	Sometimes	Often	Always
How does your face react to the sun?	Very sensitive	Sensitive	Normal	Very resistant	Never had a problem
TOTAL SCORE (0- 16)					

Table 2.4 Tanning habits (Sachdeva, 2009)

Tanning habits					
Score	0	1	2	3	4
When last did you expose the body to sun (artificial sun lamp, sun cream)	More than 3 months ago	2-3 months ago	2 months ago	Less than a month ago	Less than 2 weeks ago
Did you expose the area to be treated by the sun?	Never	Hardly ever	Sometimes	Often	Always
Total Score (0-8)					

Table 2.5 Fitzpatrick Skin Type Score

Skin Type Score	Fitzpatrick skin type
0-7	I
8-16	II
17-25	III
25-30	IV
Over 30	V- VI

2.4 Post care photo protection

Post-operative care, particularly the use of sunscreen, has become an important facet in various treatment interventions in medical aesthetics. Sun-screens offer topical photoprotection against UVA and UVB radiation (Jansen *et al.*, 2013).

The use of sun-screens has been cited in numerous articles, and used as a post-care treatment, with an attempts to prevent development of hyperpigmentation and minimise the development of solar damage (Jansen *et al.*, 2013). Particularly in micro-needling, topical application has been encouraged as part of a post care routine (Doddaballapur *et al.*, 2009).

Though some individuals are well-versed in the use of sun-screens, it has been found that individuals have not been compliant with applying sunscreen on a regular basis, which suggests suboptimal use across all age groups (Young *et al.*, 2017 ;Jansen *et al.*, 2013; Lund and Taylor, 2008 Koh *et al.*, 1997; Beverley *et al.*, 1992). The reason for suboptimal use of sunscreen was particularly due to financial reasons, as high quality sunscreens are expensive in nature; cosmetically difficult to use due to their greasiness; impractical in social setting due to whitening; or comedogenic; these factors exist alongside a paucity of education on photo damage (Ulrich *et al.*, 2009). It is therefore important to encourage regular and earlier use of sun-screens as suggested by (Cockburn *et al.*, 1989) as it may not only reduce squamous and basal cell carcinomas by 78%, but may also significantly reduce one's chances of photo damage along with subsequent aging.

2.5 Acne

Acne is one of the leading skin disorders that may affect many individuals. It has been estimated to affect as much as 9.4% of the global population, making it one of the top ten most prevalent skin diseases worldwide (Lim *et al.*, 2017; Tan and Bhate, 2015; Hay *et al.*, 2014). Although this is usually recognised as an adolescence disorder, the referral of patients with post-adolescent acne has significantly increased (Knaggs, 2004; Goulden, Clark and Cunliffe 1997).

Studies have reported that acne, and acne scarring, are more common amongst women (76%) than amongst men (24%), with a mean age for these patients of 35.5 years, ranging from 25-55 years of age (Stern 1992; Goulden, Clark and Cunliffe 1997). According to the Leeds Grading scale, these patients experienced mild or moderate acne consisting mainly of inflammatory lesions (Burke and Cunliffe, 1984).

Shalita and Lee (1983) and Hassun (2002) describes the characterisation of acne as an inflammatory disease response, mainly of the pilosebaceous unit. This inflammatory response is caused by the creation of a prominent anaerobic

environment, in which *Propionibacterium acne* bacteria flourishes. The condition associated with the development of this environment are said to be the hyper-secretion of sebum, and hyper-keratinisation of the follicular ostium, which inherently leads to the development of numerous papules, nodules, and cyst along with the presence of open and closed comedones. Furthermore, acne is generally limited to areas where sebaceous glands are largest and most abundant particularly the face, neck, chest, upper back, and upper arms (Oberemok *et al.*, 2002).

Acne has been found to be particularly troublesome in darker skin types, particularly in later years of life, as many individuals are left with undesirable keloidal scarring and post-inflammatory hyperpigmentation, which is recognised by distinct hyper-pigmented patches of macules (Callender, 2004). Furthermore, it is stipulated that keloidal scarring, along with post-inflammatory hyperpigmentation, is far more evident in darker-skinned individuals (Davis and Callender, 2010; Zulu *et al.*, 2017).

Studies by Rivera and Kirkville (2008), Layton *et al.* (2001), as well as Niemeier, Kupfer and Gieler (2006) have shown that acne may not only bring about physical changes in the form of acne scars, but may also lead to psychological implications e.g., low self-esteem, and depression, which in turn may lead to suicide. Fried and Wechsler (2006) also found a strong link to exist between a patient's emotional state, which may have a negative impact on acne, by exacerbating the condition further via stress.

2.6 Acne complications in individuals with coloured skin

The South African population is not spared from the negative effects that acne or acne scarring has on individuals, reports on the South African population affected by acne or acne scarring has been noted in literature (Buchanan, 2018; Mosam *et al.*, 2005; Sinclair and Jordaan, 2005; Harthorne, 2003).

Many studies on a global context suggest how acne and acne scarring have affected peoples' psychological and emotional state (Tan *et al.*, 2015; Thieboutot *et al.*, 2009; Gollnik *et al.*, 2003). There is, however, a paucity of studies on the effects of acne within the South African population. A study conducted in South Africa investigated this impact and found significant correlation of psychological distress affecting the quality of individuals lives (Tan and Bhate, 2015; Mosam *et al.*, 2005). However, the most commonly reported concern for most individuals was the continuation and development of post-inflammatory hyperpigmentation, particularly for those of a darker skin color (Zulu *et al.*, 2017). A study by Davis and Callender (2010) has suggested that this could be largely due to heightened inflammatory response in darker photo types.

2.7 Acne treatments available

Although acne treatments may be readily available, it is limited by those of a lower socio-economic income group, and especially in economically developing countries. Studies have shown that this alone may impact on quality of life impairment and social advancement of these individuals, resulting in an increase in depression and anxiety in those who have not sought help (Yap, 2012).

Treatment options available are isotetrinoin, retinols, laser, cryogen cooling and phototherapy (Paithankar *et al.*, 2002; Tzung, Wu and Huang, 2004). Most first line interventions for those who seek treatment are in the form of antibiotics, retinoids, salicyclic acid, or oral contraceptives, which are either administered topically or orally for the improvement of skin conditions.

Other studies have found a high prevalence of the use of phytochemicals, botanical plants and leaves for the improvement of acne (Fisk *et al.*, 2014). Most individuals, especially in developing countries and in specific cultures, still rely heavily on natural remedies for the improvement of skin conditions, particularly acne vulgaris (Kapoor and Saraf, 2011). Table 2.6 provides a list of systemic and topical treatment options for acne sufferers.

Table 2.6. Acne treatments (Callender, 2004).

Topical	Systemic
Antibiotics: Erythromycin Doxycycline Clindamycin	Antibiotics: Tetracycline Erythromycin Minocycline Doxycycline Sulfonamides
Retinoids: Tretinoin Adapalene Tazaroten	Retinoids: Isotretinoin
Salicyclic acid Azelaic acid Benzoyl peroxide plus erythromycin Sodium sulfacetamide Benzoyl peroxide Benzoyl peroxide plus clindamycin	Oral Contraceptives and Corticosteroids Prednisone Norgestimate/ethinyl estradiol

2.7.1 Antibiotics

Antibiotics are still recognised as the prescribed means of treating acne, although many studies have indicated that over time, drug resistance has become apparent in these individuals. The negative effects of using of antibiotics is not limited to drug resistance, but the risk it poses for pregnant individuals, as limited information is available on the dangers it may pose on the developing fetus (Guzman *et al.*, 2018; Sinnott *et al.*, 2016).

2.7.2 Retinoids

Topical retinoids are fundamentally one of the most commonly prescribed form of treatment for acne sufferers by dermatologist (Leyden *et al.*, 2017). In the United States, this accounts for 63% more than any other medical prescriptions alone (Zhang, Silverberg and Kaffenberger, 2017). Their early use is advocated by many dermatologists, along with anti-microbial therapy, in combatting the acne pathogenesis (Shalita, 2001).

2.7.3 Phototherapy

Phototherapy is one of the most common technologies used in the skincare industry for the treatment of acne. Studies using light-emitting diodes (LED) blue light, intense pulsed light (IPL), photo-dynamic therapy (PDT) and lasers have revealed a great improvement in acne, particular the inflammatory lesions, however there is a paucity of evidence regarding the long-term effects of these acne treating devices (Alba *et al.*, 2017; Antoniou *et al.*, 2016; Park *et al.*, 2015).

2.7.4 Hormone therapy

Hormone therapy, in the form of contraception, is fundamentally still the chosen root for prevention and treatment to control non-inflammatory and inflammatory acne lesions (Huber and Walch, 2006). Studies have found that hormones, in particular, the hormone androgen, plays an integral part in the production of sebum, as well as in the pathological development of acne (Lam and Zaenglein, 2014; Zouboulis, 2004). Therefore, the use of oral contraceptives such as estrogen, estradiol and progesterone are still used as an effective means of treatment for the control of the androgen hormone which helps in reducing the development of acne lesions (Lam and Zaenglein, 2014).

2.8 Post-acne scarring aetiology

Scarring is said to arise on the face due to a number of causes, from trauma to the skin due to scratching or picking of papules and pustules, although the commonest cause is acne vulgaris (Rivera, 2008). Acne scarring is a permanent disfiguring sequel, which can accompany morphological changes in the normal healing cascade (Sobanko and Alster, 2012).

The formation of scarring may differ vastly from individual to individual, presenting itself as either atrophic or hypertrophic in nature (Fabbrocini *et al.*, 2009). Atrophic scarring is commonly associated with post-acne scarring individuals, which is a deterrent as a result of the inflammatory response process, while scarring in post-acne suffers involves a complete destruction of collagen, which may be categorically

and objectively defined as either being icepick, box, or rolling-type scars (Sobanko and Alster, 2012; Jacob, Dover and Kaminer, 2001). Figure 2.2 depicts a universally accepted classification system used in identifying various types of scarring.

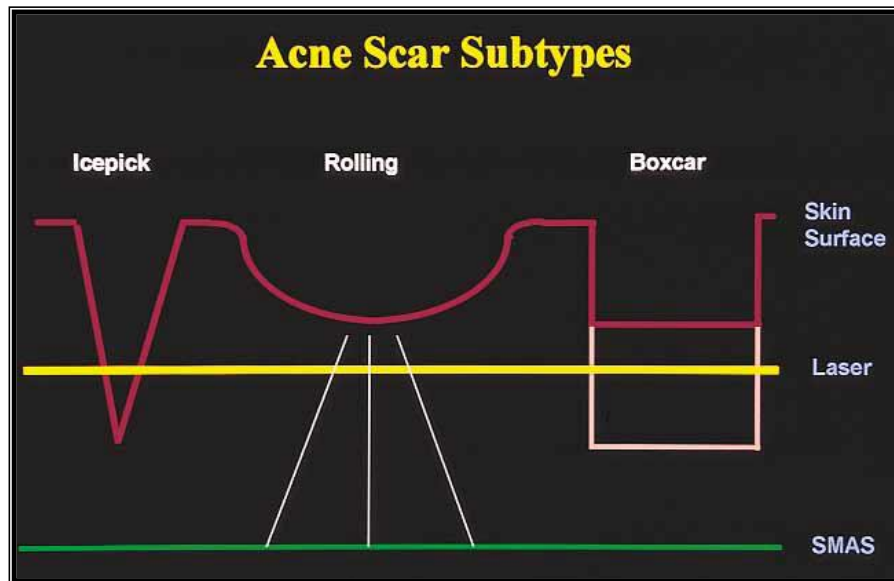


Figure 2.2 Scarring classification system (Jacob, Dover and Kaminer, 2001)

2.9 Methods employed in identifying acne scarring and its effects on quality of life

2.9.1 Grading scales and assessments for acne scarring

According to Durani *et al.* (2009), the purpose and usefulness of validated scales are to effectively monitor changes in any scar quality over time, and to compare changes. This globally suggested scale comprises all morphological types of post-acne scars, and uses this simple tool to grade scars before and after treatments.

Goodman & Baron, (2006) devised a qualitative global standard for assessing and recognising the severity of post-acne scarring. This grading system utilises a simple and effective way to help investigators compare cases more accurately, where various intervention methods have been employed owing to a more accurate

discussion of these treatment methods for the improvement of acne scarring patients.

2.9.2 Digital Photographic Analysis - Visia Skin Complexion Analyser®

The Visia Skin Complexion Analyser® is an effective imaging tool that photographically monitors the progress of the skin when using products or devices to improve its condition, which has led to a better understanding, as well as educating individuals with regards to their skin concerns, or any underlying conditions (Goldberry, Hanke and Hanke, 2014).

Abramovitz (2003) supports the notion and use of non-invasive imagery tools, as these high-resolution diagnostic tools offer specialists the ability to effectively provide treatment options best suited to treat and monitor various cutaneous skin diseases or disorders.

The Visia Skin Analyser is a non-invasive, computerised tool that generates a comprehensive report. The report generated identifies, ultra-violet spots, brown spots such as pigmentations and texture, which is either raised or depressed in certain facial areas, smoothness, wrinkles, red areas of inflammation, pores, and porphyrins (Canfield, 2017).

Visia Skin Analysis therefore use of IntelliFlash® and Canfield's RBX® technology, which involves cross-polarised and UV light, making it possible to record and measure surface and subsurface skin conditions. The UV photography thus provides the most complete data set available for sun damage assessment and analysis, including UV fluorescence imaging, to reveal porphyrins (bacterial). The technology also separates the unique colour signatures of red and brown skin components for the visualisation of conditions that result in colour concentration, such as post-inflammatory hyperpigmentation (Linming *et al.*, 2018).



Figure 2.3 Visia Complexion Skin Analyser® (Visia Skin Analysis| Canfield Scientific, 2017).

2.9.3 The effects of quality of life in post-acne scarring individuals

The researcher turned towards several studies done on quality of life on acne, as this helped provide insight as to how it would affect individuals that presented with post-acne scarring, as a paucity of studies on post-acne scarring affecting quality of life exist.

Acne scarring has proven to be worrisome, especially when this concerns the face. Brown *et al.* (2008) reported acne scarring to have a significant negative impact on those suffering from post-acne scarring. These negative associations (anger, pain, low self-confidence and inflammation) often to lead to immense psychological and physical distress, leading to high levels of anxiety, low sense of self-worth, and self-consciousness. It was further reported that the stigma associated with acne scarring affected their lives, and how various coping mechanisms were implemented. These coping mechanism often lead to difficulty in having relationships, leading to unsociable behaviour by avoiding social events, or public places where they will be

observed and judged. This indicated an 82% significance regarding how acne scarring can affect quality of life.

A study by Tan, Vasey and Fung, 2001 and Harris and Carr (2001) further reported females experiencing more psychosocial distress than males. The psychological and physical impact of scarring is further depicted below in Figure 2.3 below.

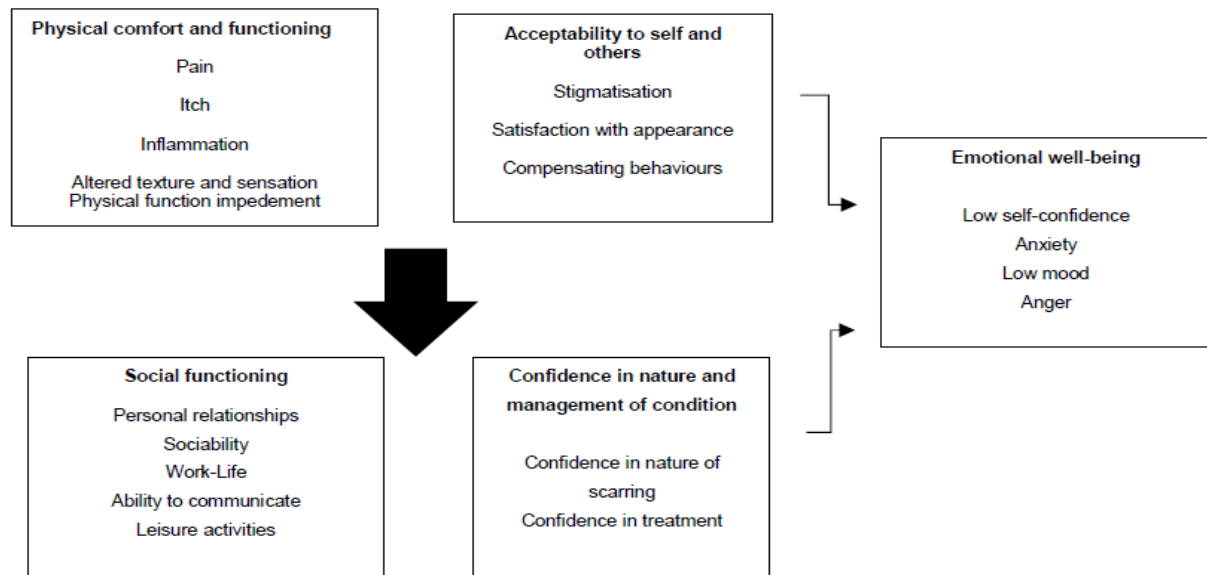


Figure 2.3 The hidden cost of scarring (Brown *et al.*, 2008)

2.10 Treatment interventions for acne scarring

2.10.1 Chemical peels

Chemical peel processes involve the use of peels of various strengths and formulations with a core purpose eliciting an exfoliating response by removing superficial lesions within the skin layers. The application of chemical peels helps to improve the appearance of the skin, by improving the skin texture and minimising the appearance of fine lines and wrinkles, presenting a smoother, more youthful appearance (Ghersetich *et al.*, 2003). Chemical peel treatments are commonly performed on acne vulgaris, pseudo folliculitis barbae, post inflammatory hyper pigmentation, melasma, photo damage, and acne scarring (Roberts, 2004).

Although they have their limitations, chemical peels have been used extensively, not only for post-inflammatory hyper-pigmentation, but also for acne scarring. Lawson *et al.* (2015) states that peels with concentrations of 20-30% salicylic acid have been deemed safe to be used on darker skin types (Fitzpatrick skin type IV – VI). However, adverse effects such as erythema, itching, flaking, dryness or burning sensation on the skin may arise (Jarritum *et al.*, 2014).

A number of treatments for these areas have been advocated for the management of scarring. These include simple excision, suturing, percutaneous collagen induction with 20% trichloroacetic acid as well as alternating with fraxel lasering and the application of chemical peel with the addition of vitamin C applied directly to the skin following a chemical peel, this method of combining various management therapies enhances the outcome in minimising the appearance of scarring (Leheta *et al.*, 2014; Khee *et al.*, 2017).

Many other methods of treatment for acne scarring may also be modified for an improved benefit such as chemical reconstruction of scars described by (Lee *et al.*, 2016). Jemec and Jemec (2004) explain how some of these methods have largely been replaced, especially in the UK. For instance, dermabrasion has been replaced by laser therapy, due to the health risks associated with the aerosol produced by dermabrasion.

2.10.2 Lasers

Laser therapies work by making use of electromagnetic waves that effectively ablate the upper most skin layers being the epidermis and partial layers of the dermis. Laser therapy, topical de-pigmenting agents, and microdermabrasions are also effective in treating acne scarring, however there is still much controversy surrounding these expensive procedures, as they could worsen the pre-existing condition if sufficient precaution is not taken (Briganti *et al.*, 2003).

In modern medical aesthetics, lasers are inherently considered the gold standard method in skin rejuvenation and has been an effective treatment for those suffering from post-acne scarring, as this method stimulates the formation of new collagen

thereby improving the appearance of scarring. However, lasers have many short comings, such as causing scar formation, de-pigmentation, keloid formation, severe heat damage to the top layers, as well as being deemed unsafe for certain race groups or skin types, e.g., Fitzpatrick skin type IV-VI (Jemec and Jemec, 2004; Harmon, 2001). It is for this reason that lasers, particularly the Fraxel CO₂ laser, is not often employed in Japan (Omi *et al.*, 2011).

Other means of improving scarring particularly those associated with hyper pigmentation have been employed such as topical de-pigmenting creams, which contain hydroquinone, however these creams contain harmful ingredients that may lead to toxicity if not used correctly and should be used under the advisement of a dermatologist (Dadzi and Petit, 2009).

2.10.3 Vitamin C

The most intensively studied antioxidants involved in skin oxidative damage are vitamin C (ascorbate), vitamin E (particularly α -tocopherol) and carotenes (β -carotene) in animal subjects (Lopez-Torres, 1998, Rozman and Gašperlin, 2007). Vitamin C plays an important role in the epidermis, since it promotes collagen synthesis, and assists in wound repair. The body does not synthesise vitamins E and C, and whilst working synergistically, they form a useful combination when applied topically. It must be remembered that the efficacy of a topically applied antioxidant is limited by its penetration (Podda and Grundmann-Kollmann, 2001). Vitamin C has inherently received considerable attention as a natural occurring antioxidant when topically applied. Vitamin C has been advantageous in promoting collagen synthesis, lightening of hyperpigmentation, and improvement of inflammatory conditions, along with photo protection from ultraviolet A and B.

The antioxidant defence mechanism of the skin has been extensively researched (Kohen, 1999), and the topical applications of low molecular weight antioxidants (LMWA) have been investigated (Kohen and Gati, 2000).

2.11 Botanical oils

Today, consumers have become increasingly more selective about the products and treatments they use. Their concerns have shifted to not only using natural alternatives, but also, affordable environmental friendly products (Happi, 2009). Because of this, natural and environmentally friendly products have strengthened their place in the cosmetic market. Numerous journal articles support the notion of this growing trend (Kapoor, 2005; Lall and Kishore, 2014; Aburjai, 2003; Chiu and Kimbal, 2003). White and De Groot (2006) further suggested a link between the use of non-natural cosmetic substances, and skin related allergies. Thus, cosmetic preparation of natural origin has been proven to be more effective, showing significantly lower incidence of skin reactions (Ahshawat and Saraf, 2008).

Topical application of botanical oils has long been investigated as a strategy for minimising skin damage and helping improve the exogenous cutaneous protection system of the skin, therefore helping to improve its overall condition (Oresajo *et al.*, 2008; Masaki, 2010; Afaq and Mukhtar, 2006, Podda and Grundmann- Kollmann, 2001; Kohen and Gati, 2000).

Research of plant oils and antioxidants has thus increased phenomenally, owing to the cutaneous healing capabilities these have on the skin, as well as to the protection they may provide against environmental damage (Newman and Cragg, 2012; Wakefield and Elias, 2011; Grazul-Bilska *et al.*, 2009). Plant extracts such as Aloe vera have been widely used in a variety of cosmetics products as well on its own, as it possesses de-generative skin properties, by stimulating the synthesis of collagen and elastin (Davis *et al.*, 1994).

Numerous studies have reported the effective use of aloe vera when applied topically for the treatment of burns, sunburns, inflammatory skin disorders, and wounds. The action of aloe vera as a moisturising agent has become a popular concept, and is now used in many formulations as a highly effective skin hydrator (Dal'Belo *et al.*, 2014). Binic *et al.* (2013) reported on its skin lightening properties,

along with Vitamin C, which has been found to play an important role in the epidermis, since it promotes collagen synthesis, and assists in wound repair. For this reason, many botanical extracts have been coupled with micro-needling and chemical peeling (Fernandes, 2006).

Katiyar (2003) conducted a study investigating photo-protection, as well as the antioxidant and immune-modulating effects of green tea. In this study, it was found that topical and oral ingestion of green tea contain, phenols that are photo protective in nature, which can be used as a preventative measure in solar-induced skin disorders, such as photo-ageing.

Therefore, studies on green tea polyphenols have grown substantially, as these phenols are capable of absorbing UV radiation. Lipid peroxidation has also been reduced in mice, with the topical application of green tea sun-screen, proving its protective abilities to solar exposure (Katiyar and Nichols, 2010).

Several other botanical plant oils have shown to contain high concentrations of antioxidants, which make them resistant to oxidation and free radical damage (Oguntibeju *et al.*, 2009). Topical application of botanical oils rich in antioxidant properties may prove valuable in protecting the skin against environmental damage, especially oxidative and degenerating processes, which is not provided by dietary supplementation. Therefore, plant oils may act as a supplemented reserve against oxidative stress (Pinell, 2003).

According to Afaq and Mukhtar (2006), botanicals have been extensively researched, particularly for their photo protective and powerful antioxidant abilities. The usage of botanical oils for their curative properties dates back at least 5000 years (Swerdlow and Johnson, 2009). Thus, the use of essential oils has been well documented.

A study by Simon (2014) has shown that more than 400 botanical plant extracts are used for their therapeutic and medicinal properties. Another study by Biswas *et al.* (2009) supports this notion of the important benefits of botanical plants, such as *Azadirachata Indica A*, commonly known as neem, which is used within the Indian population, has been used for its benefits on skin infections for more than 2000 years. This versatile plant extract is known for its anti-inflammatory and antibacterial properties, where clinical studies have shown effectiveness in curing scabies, ringworm, and eczema.

Botanical oils have therefore have become an important facet especially for the environmental friendly and health conscious consumer, leading to an increase in the sale of organic face and hair care products (Kim and Chung, 2011).

2.12 South African use of botanical oils and plants

To date, Africa and South Africa boast a rich use and presence of botanicals (Van Wyk, De Wet and Van Heerden, 2008). Due to this diversity and benefits the use of medical plants, oils and herbs are still common practice amongst many rural communities within Africa (De wet *et al.*, 2013; Mahomoodally, 2013, Mahwasane, 2013). To date many of these plants and oils have been commercialised by pharmaceutical companies for their medicinal purposes, particularly in Africa and South Africa (Street and Prinsloo, 2012; Diederich, 2012). However the uses of these plants and oils are not only limited to the improvement of various skin conditions, but include other ailments as well, including colds and flu, wounds, sunburn, and high blood pressure (Van Wyk, De Wet and Van Heerden, 2008; Thring and Weitz, 2006). Table 2.7 depicts the most commonly used South African indigenous plants for medicinal purposes.

Table 2.7 Commonly used indigenous plants for medical purposes in South Africa (Van Dyk, 2011)

Species; Family; Common name(s)	Uses
Gethyllis spp.; <i>Amaryllidaceae</i> ; <i>kukumakranka</i>	Digestives, tonics
<i>Gunnera perpensa</i> L.; <i>Gunneraceae</i> ; river pumpkin, gobo, ughobo	Uterotonic, stomach ailments, menstrual pain, rheumatic fever, topical application for wounds and psoriasis
<i>Harpagophytum procumbens</i> (Burch.) DC. ex Meisn.; <i>Pedaliaceae</i> ; devil's claw	Arthritis, painful joints, dyspepsia and loss of appetite, topical application for wounds
<i>Helichrysum nudifolium</i> (L.) Less.; <i>Asteraceae</i> ; <i>hottentotsteebossie</i> le+	Colds, chest ailments
<i>Hypoxis hemerocallidea</i> Fisch. & Avé-Lall.; <i>Hypoxidaceae</i> ; <i>inkomfe</i> , "African potato"	Traditional tonic, benign prostate hyperplasia
<i>Kigelia africana</i> (Lam.) Benth.; <i>Bignoniaceae</i> ; sausage tree	Skin care, cosmetics
<i>Helichrysum odoratissimum</i> (L.) Sweet; <i>Asteraceae</i> ; <i>imphepho</i> , Nguni incense	Ritual incense Sedative inhalant, aromatherapy

2.13 *Nigella sativa*

Nigella sativa is a well-known herb and cold-pressed oil cultivated in the Middle East, Asia and Europe found to possess many medical properties. Traditionally its uses are documented in folk medicine for treating common to chronic ailments. It has been vastly used in treating skin conditions such as eczema, boils and pigmentation, along with respiratory problems such as bronchitis and asthma, rheumatism,

inflammatory diseases and as a treatment for parasitic infections (Dogra *et al.*, 2014, Yarnell and Abascal, 2011; Mahmoud, El-Abhar and Saleh, 2002; Khann,1999).

Nigella sativa is highly regarded for its use as a medicinal herb both topically and orally (Ahmed et al., 2013; Sharma et al., 2009). Studies have shown it possesses an antioxidant and inflammatory effect, especially when applied topically (Erkan, Ayranci and Ayranci, 2008). Mabrouk *et al.* (2002) advocated its nutraceutical capabilities in the fight against oxidative stress when supplemented within one's diet. Furthermore, studies have revealed and supported the notion of use by exhibiting anti - inflammatory properties (Amin and Hosseinzadeh, 2016; Hajhashemi; Ghannadi and Jafarabadi, 2004; Al Ghamdi, 2001). Similar studies have noted great improvement in post acne scarring when using micro needling combined with various forms of antioxidants eg vitamin C, A and E (Rozman and Gasperlin, 2007; Lopez-Torres, 1998).

Nigella sativa oil not only possesses antioxidant and anti inflammatory properties but has been seen to elicit antimicrobial abilities which has been beneficial in the treatment of acne vulgaris. It has also been deemed a much safer alternative compared to other main stream methods of treatment such as topical and oral antibiotic and systemic retinoids which possess significant risk to users resulting in dryness, peeling and local irritation to the skin (Guzman *et al.*, 2018; Leyden et al., 2017; Sinott *et al.*, 2016; Ameer and Al-hachan, 2010; Charakida *et al.*, 2007; Heffernan et al., 2007). Though there are a few well researched articles on the effects of *nigella sativa*, a paucity of research exists on the potential abilities *nigella sativa* oil may have on post acne scarring skin, for this particular reason and in the hope of further identifying and accelerating research into the use of *nigella sativa* oil in conjunction with micro needling for the improvement of post acne scarring has the researcher chosen the use of *nigella sativa* oil as an added benefit.

CHAPTER III: METHODOLOGY

3.1 Introduction

This chapter describes the methodology used in the research process, method of participant selection, data collection, data management and ethical considerations, and limitations of the study. The study employed a quantitative research approach with elements of qualitative research focusing subjectively on the meaning of the participant's experience of the treatment with the use of a satisfaction survey and pain intensity scale, as well as how post acne scarring has impacted their lives with the use of acne scarring quality of life scale.

3.2. Type of research

The research study was a clinical trial making use of quantitative research with elements of qualitative comments that follows a positivist paradigm theorem (Cresswell, 2016; Mertens, 2015; Tashakkori and Teddlie, 1998; Mackenzi and Knipe, 2006). According to Feldon and Kafai (2008), the use of quantitative and qualitative research focuses on collecting, analysing and mixing both types of data in a single study or series of studies. The premise is that the combination of the data provides a greater understanding of the research problem than either data type would provide alone.

The approach used for the research study therefore gathered quantitative and qualitative data, which assisted the researcher to obtain an understanding of participant's perceptions on post-acne scarring, data triangulation, and validation of quantitative photographic data. According to LeCompte and Schensul (1999), a research design may be seen as a detailed blueprint encompassing various variables which can be manipulated by selecting the appropriate study sample, analysing and interpreting the results.

Photographic data was gathered from the computerised Visia® complexion analysis, which photographically compares the difference in the post-acne scarring

from baseline (start) to end of the six-month treatment period. The Visia Skin Complexion Analyser® is an effective tool in tracking skin changes overtime (Visia Skin Analysis| Canfield Scientific, 2017).

Further data has been provided through sequence of questions from the participant demographic information and participant self-evaluation scale, which provided valuable input with regards to participant's perceived outcome of the treatment and acne-scarring scales, providing subjective quantitative data. The study included the use of the pain intensity scale, which was utilised at each and every treatment procedure, in order to ensure that tolerance was monitored throughout the duration of the study. This was especially important from an ethical standpoint in protecting the participant from any foreseeable concern and congruently implementation a safe and secure practice. The safe practice in protecting individuals includes a numbering code, and provides anonymity, by keeping individual particulars confidential (Belmont report, 1979). The pain intensity scale was used and presented in accordance to the numeric rating scale for pain that may be experienced during the research study. It was easy to administer, taking only one minute, and is acceptable for use in adults, as well as various culture and language groups (Hawker *et al.*, 2011).

3.3. Ethical approval and its implications

Ethical approval has been obtained from the Research Ethics Committee of Durban University of Technology (reference number: 109-17) (see Appendix G).

3.4. Permission and ethical clearance

Informed consent plays an integral and equally important role in a research design. According to Murphy and Dingwall (2007); Flory and Emmanuel (2004), the researcher should ensure that those involved in the research should not only agree and consent to participating in the research, but should do so of their own accord, without being pressurised or influenced, they should also be well informed on the bases of the proposed research study entails.

As per the National Health Act No 61 of 2003, research involving human participants is based on a moral commitment to advancing human welfare and knowledge (Department of Health, 2014). It is the duty of the researcher to conduct scientifically sound research, while acting in the participant's best interests, and respecting and protecting the participant's autonomy. As many guiding principles of ethics are respect for: human dignity, autonomy, informed consent, confidentiality, the lack of harm and maximum benefit. Bearing this in mind, voluntary participation was emphasised amongst all participants. This involved providing an information letter made available to all participants (see Annexure B) detailing the following main points:

- the identification of the researcher and contact details;
- a statement that participation was completely voluntary;
- an assurance of anonymity and confidentiality;
- possible risk or discomfort involved; and
- a declaration statement whereby participants signed when in agreement to participate in the research study.

3.5. Study population

The clinical trial consisted of a study population comprising of female participants from all race groups, which included females of black, caucasian, Indian or coloured ethnicity, for the purpose of the study.

3.5.1 Inclusion criteria

- Inclusion was based on diagnosis of moderate to severe post-atrophic acne scars on the face with females aged 18-37, as several studies have noted a high incidence of post-acne scarring in this age group (Chawla, 2014; Dogra *et al.*, 2014; Fabbrocini *et al.*, 2010).

3.5.2 Exclusion criteria

- The following criteria were used to excluded individuals from the study on the bases of having the presence of active acne, previous history, or presence of post inflammatory hyperpigmentation. The use of oral isotretinoin in the last six months – one year.
- The use of facial treatments such as laser/chemical peel or surgery in the last year.
- The presence of, or common occurrence of herpetic infection, warts, or any other active infection of the adjacent skin.
- Any coagulopathies or anticoagulating therapies. Individuals being treated with chemotherapy, radiotherapy, or corticosteroids at high doses. Individuals with diabetes mellitus or impaired wound healing abilities. Individuals with the inability to understand the goals and risks of treatment.
- Those with the presence of skin cancer or actinic keratoses.
- Any previous history of photosensitivity or photosensitive diseases such as systemic lupus erythematosus or xeroderma pigmentosum.
- Pregnancy or lactating females and the use of drugs that may induce hyperpigmentation, such as: amiodarone, clofazimine, minocycline, or chloroquine.
- Gender (males excluded).

3.6 Sampling technique

According to Joubert *et al.* (2007), it may be improbable and impractical to study individuals of an entire population. Therefore, a sample size should be collected to thus reflect or represent the study population in order to make an informed and consensus conclusion about the whole population. Therefore, taking in account previous studies investigating post-acne scarring methods the researcher recruited 50 participants, as various studies made use of individuals ranging from a minum of 10 to a maximum of 36 individuals per study which provided statistical significance (Dogra *et al.*, 2014; Chandrashekar *et al.*, 2014; Majid, 2009; Fabbrocinni *et al.*,

2009;). Fifty participants were recruited, however only 42 participants met the criteria after which stratified random sampling method was applied. Following the randomising of the sampling, participants were further subdivided into two groups: namely, Group A $n = 21$ (control) and Group B $n = 21$ (experimental group). Therefore, a total of 42 ($n = 42$) participants completed the study as per Figure 4.1.

This study employed the use of stratified probability sampling, as suggested by Cresswell (2003) and Dalenius (1992) as this method of sampling is best suited when dealing with a homogenous population group. The researcher ensured that the study focused on particular characteristics of a population namely females between ages of 18–37 years with presence of post-acne scarring, as similar studies indicated a high incidence of post acne scarring in females compared to males Etikan, Musa and Alkassim (2016) and Collier *et al* (2008). Trait homogeneity of the participants was necessary to ensure similar gender, age, and the presence of acne-scarring was present as these were pertinent to the study. This entailed the use of implementing generalisation, that is, an act of reasoning that involves drawing broad inferences from particular observations in line with Polit & Beck (2013).

3.7 Participant Recruitment Process

The study entailed the participation of female individuals. Recruitment was done at local spas, beauty clinics, and beauty/somatology institutions, as a high percentage of females frequent these places, and are enrolled at these particular establishments. Permission has been sought before a poster advertisement was placed (see Appendix A).

3.7.1 Advertisement

The poster advertisement included all necessary contact details of researcher, including telephone and email; place of research at which participants received a comprehensive analysis of their skin; and specific criteria on age, gender and presence of post-acne scarring were stated in order to simplify the process (see Appendix D).

3.8 Data collection tools

3.8.1. Visia Skin Complexion Analyser®

According to Prado *et al.* (2013) evaluating the skin requires well-defined and efficient methods to diagnose various skin diseases and disorders. These methods should include the use of technological and validated devices and scales. The Visia Skin Complexion Analyser® is a computerised system that digitally captured each participant's facial images from baseline. These baseline images are then compared with the final images taken post 6th treatment on conclusion of the study.

The Visia Skin Complexion Analyser® is a comprehensive, computerised system making use of standardised, fix lighting with a three point fixed positioning system, allowing the researcher to capture left, right and frontal facial views. This digital photographic system can easily recognise surface and subsurface findings that is not easily articulated by the naked eye, or by means of standard photographic cameras. Once a thorough cleanse was performed, removing all traces of any debris or makeup, the Visia Skin Complexion Analyser® was used.

3.8.2 Post-acne scarring grading scale (PASGS)

The post-acne scarring grading scale was used in order to identify scarring from baseline (1st treatment) as well as on the completion of the study (6th treatment) (see Appendix F) (Goodman and Baron, 2006).

3.8.3 Participant pain intensity scale (PPIS)

The pain intensity scale was used during treatment in order to monitor participants pain tolerance towards the micro-needling procedure, especially for those who have not experienced such a treatment before. The participant pain intensity scale was administered during the treatment process. Participants were asked to rate the treatment from 0-10. Participants were then instructed to indicate the level at which they experienced the micro-needling treatment, the visual analogue and numeric rating scale when combined have been deemed far more superior than the four -

point verbal rating scale when measuring subjective feeling of the intensity of pain right now or present pain intensity (Breivik *et al*, 2008).

- 0 - No sensation;
- 1- 3 mild sensation;
- 4 - 6 moderate sensation;
- 7- 9 severe; and
- 10 worst pain imaginable (Appendix E)

3.8.4 Participation demographic information sheet (PDI)

The participant demographic information sheet was administered to all participants. The researcher posed a series of questions to participants, relevant to the study. The participant demographic information sheet provided descriptive data such as demographics, age groups and various open-ended and closed-ended questions, probing into the participant's lifestyle and skincare use (Appendix C).

3.8.5 Acne scarring quality of life scale (ASQLS)

The quality of life scale for post-acne scarring identified the impact acne scarring has physically and psychologically on individuals. The acne scarring quality of life scale was completed by participants, which provided an overview on the implications post-acne scarring has on the quality of life as a paucity on the matter exist and was included in the results chapter (see Appendix G) (Chuah and Goh, 2015).

3.8.6 Participant satisfaction survey (PSS)

The participant satisfaction survey provided subjective data. The participant satisfaction survey was administered to all participant's $n = 42$ at the end of the study. Participants were asked to score perceived difference in the acne scars. These two data sets from Group A and Group B were then compared with one another and statistically analysed (see Appendix H) Warnock (1992).

3.9.5 Home care

Participants were encouraged to avoid sun exposure, sun beds and self-tanning applications; to avoid products that causes skin to become photo sensitive such as Vitamin A based products Retinol/Retinoic acid, both orally and topically; and to refrain from the use of abrasive and exfoliating methods (mechanical or manual) post treatment procedures following micro needling may cause increased sensitivity (Alster and Graham, 2018).

3.9. Treatment Procedure and Frequency

3.9.1 Prior to commencement of treatment

Prior to commencement of the treatment participants were consulted once they were screened by the researcher in meeting the criteria participants were then provided with a letter of information and informed consent detailing the process of the study.

Baseline tests included: A comprehensive Visia Skin Complexion analysis was conducted at Cape Peninsula University of Technology in which the researcher made use of the Visia Skin Complexion Analyser® which scanned and photographically captured each participants skin condition from baseline, followed by the post-acne scarring grading scale (PASGS) and participant's demographic information sheet (PDI). These digital images were sent to a dermatologist for grading of the post-acne scarring and confirmed the presence of acne scarring.

An allergy test was carried out by the researcher, where the sun-screen and *Nigella sativa* oil was placed in separate inner corners of the arms. The researcher made contact with the participant in the 72 hours following application, to note any worrisome changes that may hinder the usage of a sun-screen or the use of *Nigella sativa* oil.

3.9.2 Procedure

Following baseline procedures, statistical randomised sampling method was applied and participants were further divided in two groups namely:

Experimental: group A

Which included the intervention: *Nigella sativa* oil was applied to the entire facial area post micro needling of about 15 min. Frequency = 1x every 4 weeks.

Duration = 3 months.

Control: group B

Received micro needling only for 15 min. Frequency = 1x every 4 weeks

Duration = 3 months

The participant's facial area was cleansed free from makeup and debris. Following the cleansing procedure was the application of emla (a topical numbing cream) applied on the participants face. This allows for ease and comfort during the micro needling process (Fernandes et al., 2008).

The topical numbing cream was allowed to settle into the skin for 20 mins. Thereafter, the 1 mm micro-needling was applied to the facial area. Participant's facial area was rolled with the micro-needling roller both vertically and horizontally, overlapping each section five times, gloves were worn throughout the process which were in line with health and safety protocol at the Department of Somatology at Cape Peninsula University of Technology. Participants were monitored throughout the process of micro-needling with the use of a pain evaluating sheet which the participants completed (see Appendix E) this data was later descriptively analysed.

The treatment procedure was the same for both the control and experimental group, with the exception of the application *Nigella sativa* oil post treatment. The use of sunscreen was encouraged to be applied twice daily post-treatment.

3.9.3 Pre and Post micro needling facial analysis

A facial analysis was conducted with the use of the Visia Skin Complexion Analyser®. Thereafter, the treatment was conducted using a 1 mm micro-needle, according to Fernandes and Signorini (2008). With the use of a 1mm micro-needle participant will experience a flushed appearance of the skin, which dissipates in 24 hours. Minimal redness, accompanied by peeling and skin tightening was experienced in the first 24hr to 72 hours' post-treatment.

3.9.4 Post-care

Post-care included the application of sun-screen, applied twice daily. An SPF30 sun-screen containing zinc oxide (physical blocker of ultra violet rays) was supplied to all participants by the researcher in order to protect the skin from sun damage thereby providing no therapeutic effect other than protection from sun damage caused by ultra violet rays (Dlova *et al.*, 2018). The encouragement and use of a sun- screen pre and post micro needling has been deemed particularly important as micro needling should be avoided on recently sun exposed skin which shows visible signs of tanning as use may lead to the development of post treatment dyspigmentation (Alster and Graham, 2018).

3.10 Data management and storage

The researcher, supervisor, co-supervisor had access to the raw data. The data was kept in the possession of the researcher, and will be discarded after five years by shredding the documents. In the interim, all personal evaluation forms and record cards are locked in a secure office based at the Cape Peninsula University of Technology, Department of Somatology. All images taken via the Visia Skin Complexion Analyser® will be kept in an electronic format and stored on a hard drive in possession of the researcher. Participant records and pictures were given a code only known to the researcher to protect participant identities. All eyes were also blacked out on photographic data.

3.11 Statistical analysis

Data from the study was recorded and statistically analysed using Statistical Package for Social Sciences (SPSS) version 24.0. The quantitative and qualitative (descriptive) data that emerged from the study was presented in a series of graphs and figures as illustrated in the results section. An analysis for statistical significance was represented as $p < 0.05$. Inferential techniques included the use of the chi-square test and the t-test in order to identify significance in the presented results. The study focused on both quantitative as well as qualitative aspects. Quantitative data emerged from the participant's demographic information sheet and post acne scarring grading scale where as qualitative data emerged from the subjective responses to questions that participants answered from the acne scarring quality of life scale, participant satisfaction survey and participants pain intensity scale, furthermore the Visia Skin Complexion Analyser ® allowed for the comparison of photographic data taken at baseline and at the completion of the study.

CHAPTER IV: RESULTS

This chapter presents the data from the study population $n = 42$ groups in the research study. It further presents the findings of the study collected through a series of information sheet, questionnaires, participant's self-evaluation surveys and photographic images.

4.1 Section A: Biographical information

4.1.1 Demographics

Figure 4.1 below illustrates the ethnic distribution of the study population. A dominant representation of coloured (mixed race) was observed (40.5%), followed by African (23.8%), caucasian (19%) and Indian (16.7%).

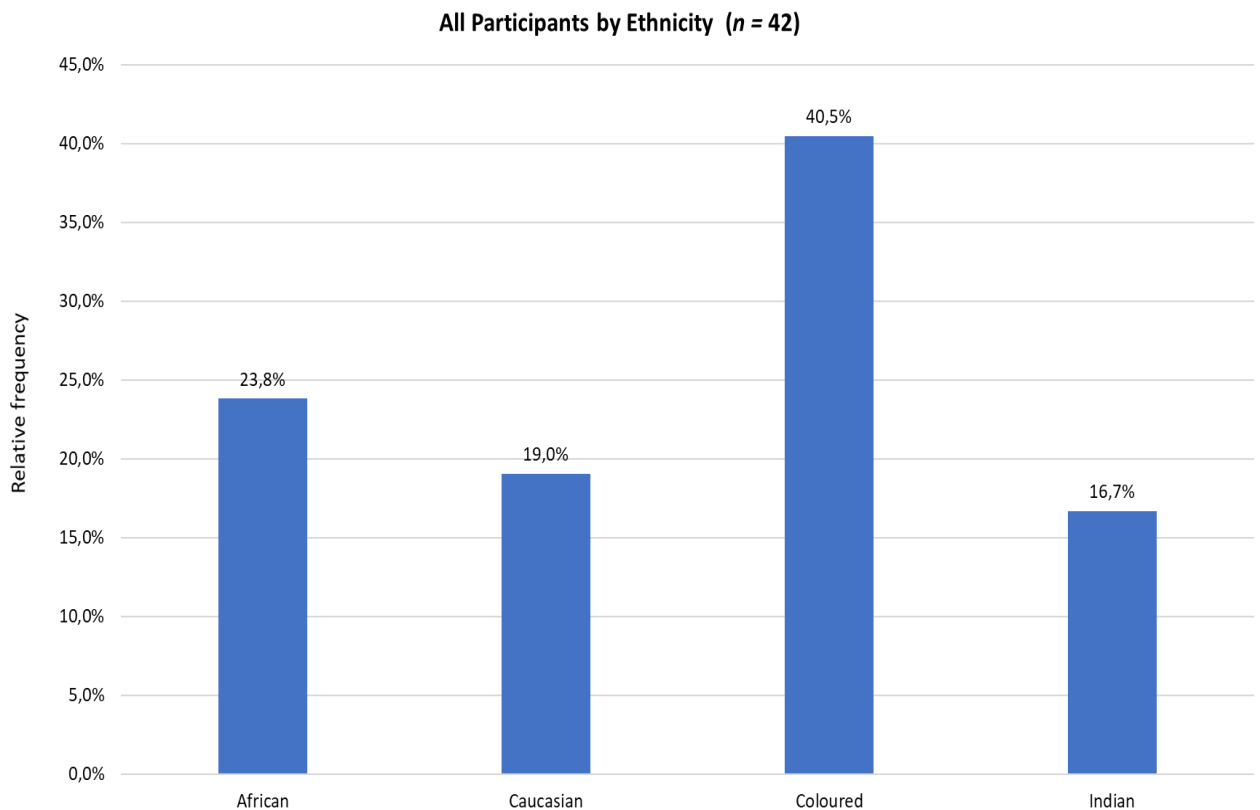


Figure 4.1: Ethnic distribution of participants ($n=42$)

4.1.2. Age distribution

The study population consisted of participants that ranged from 18-37 years. Figure 4.2 demonstrates a high prevalence in the age distribution 22-25 years of age (28.6%), following 26-29 years of age (26.2%), 30-33 years of age (19%), 18-21 years of age (16.7%), and with the least being 34-37 years of age (9.5%).

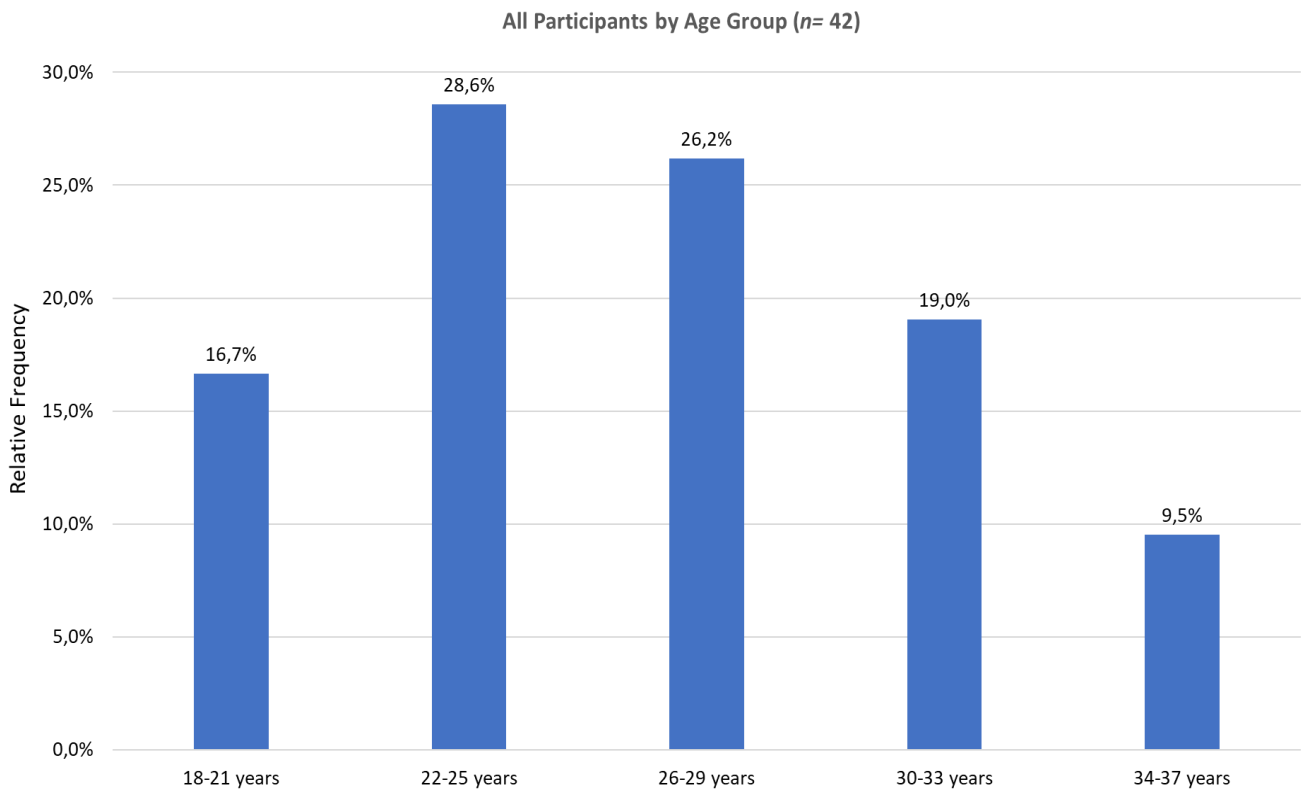


Figure 4.2 Age distribution of participants (n=42)

4.2 Section B: Medical Information

Following Section, A, participants were asked a series of medical-related information as depicted below:

4.2.1 Fitzpatrick skin type classification

Figure 4.3 below illustrates the frequency of skin type of the 42 participants. Skin Type IV accounted for 40.5%, Skin Type V accounted for 21.4%, Skin Type II 11.9%, Skin Type VI 9.5%, and Skin Type I 2.4%, respectively.

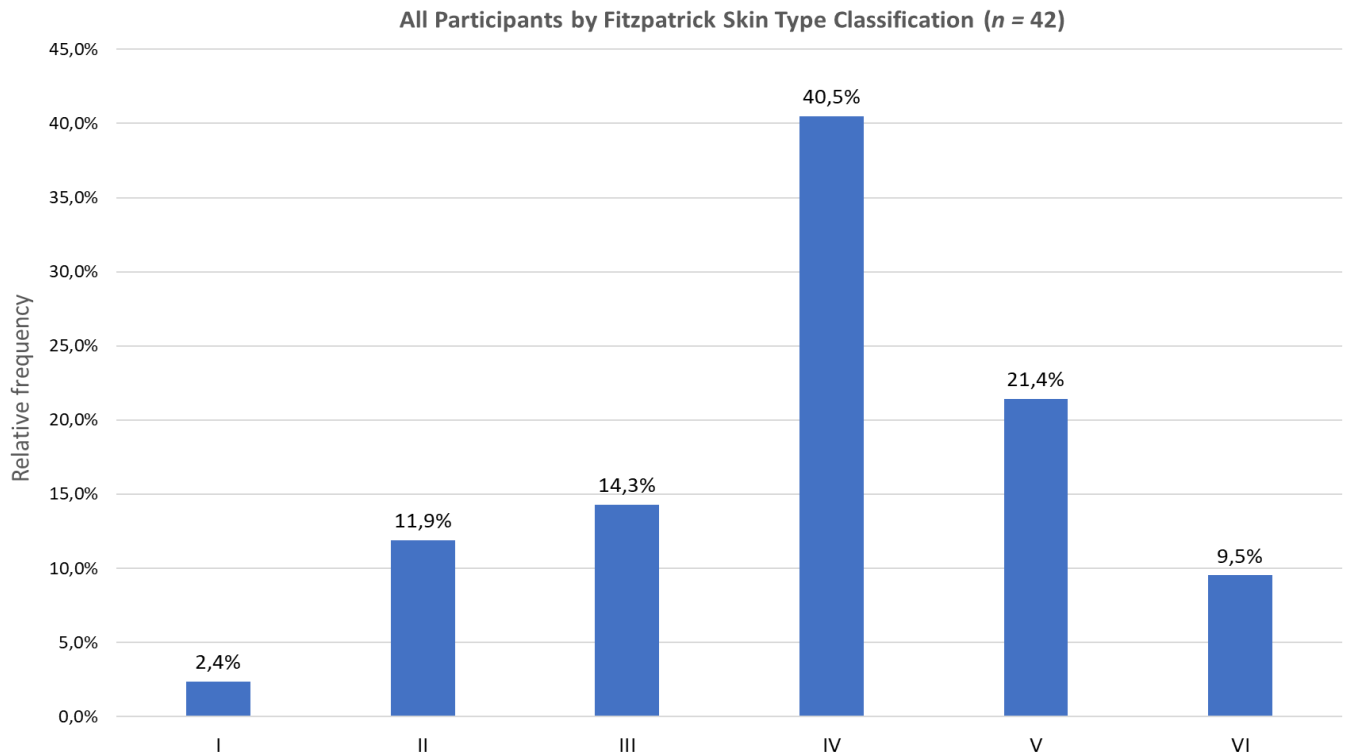


Figure 4.3 Fitzpatrick skin type classification (n=42)

4.3 Section C: Lifestyle and skin related information

4.3.1 Ultra-violet photo protection

Study findings indicated that of the 42 participants, only 25 participants (59.6%) wore a sunscreen, of which 17 participants (40.5%) did not. In Figure 4.4, it was further noted that of the 25 participants that wore sunscreen, the majority only seem to apply it once a day (76%), compared to (24%), who applied twice daily.

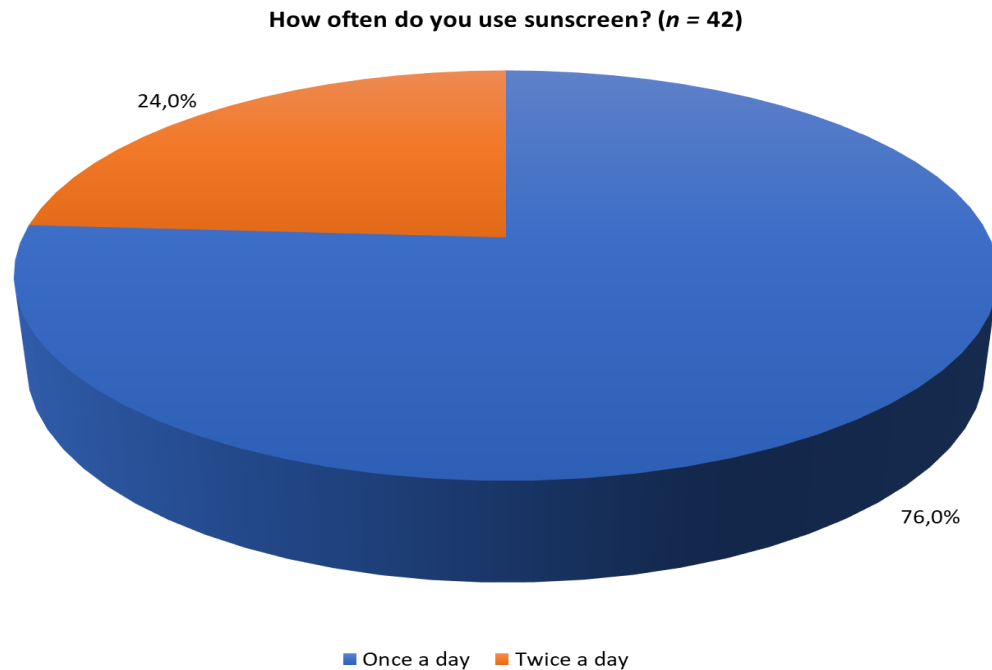


Figure 4.4 Sunscreen practice (n=42)

4.4 Acne scarring quality of life scale (ASQLS)

The acne scarring quality of life questionnaire depicted a significant correlation between present scarring, and the quality of life of both the control and the experimental group. Figure 4.5 indicates the mean score of all participants answering the ASQL questionnaire.

An important observation is noted (1.9762), indicating the impact scarring has on the participant's social interaction e.g., socialising with others at parties, and feelings of self-consciousness when in the presence with others. This is followed closely by the impact it has on relationships i.e., with close friends (1,6429) and feelings of rejection with romantic partners (1,5714), and with difficulty in relationships with spouse/partner. On the contrary, feeling like an outcast (1,1190) and the ability to find the job that you like (1,2619) have the least impact.

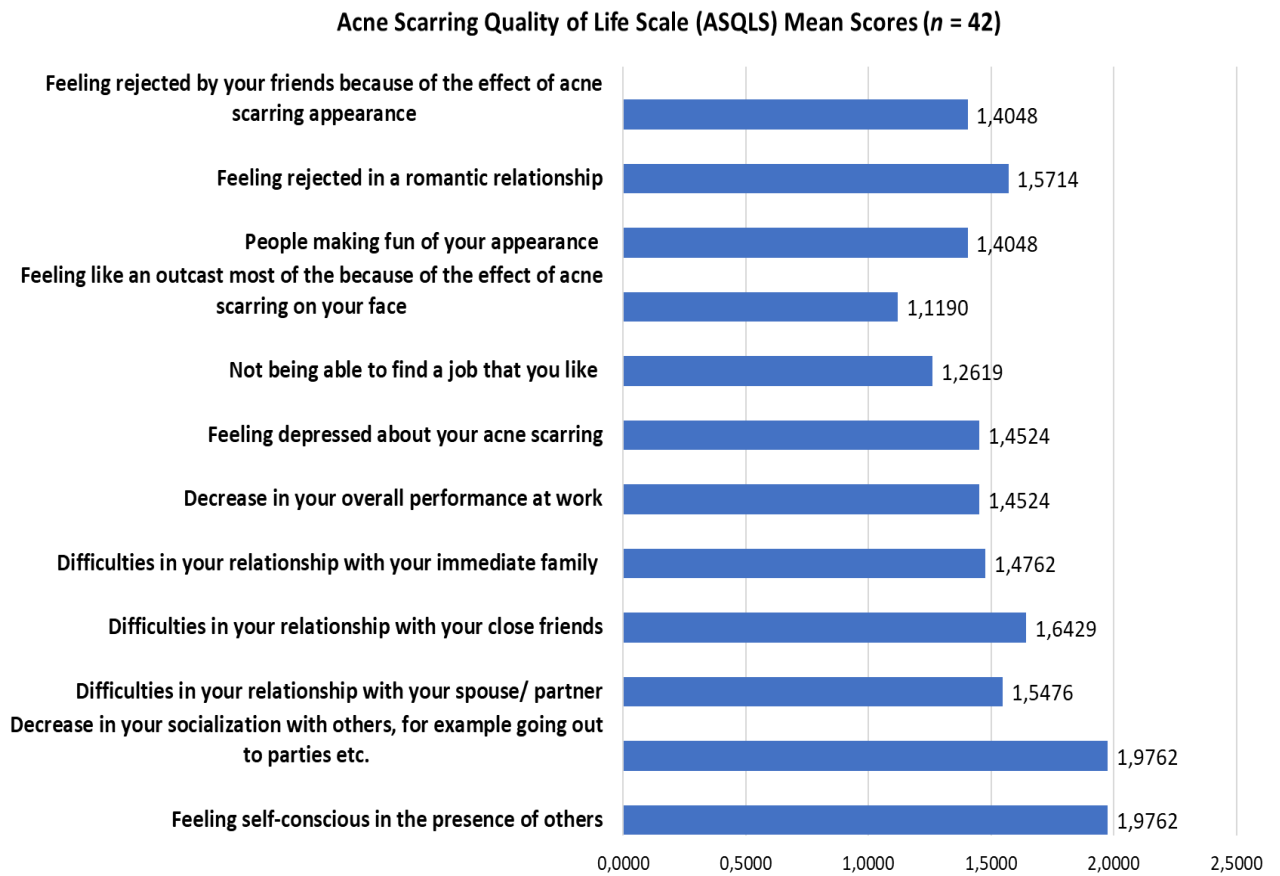


Figure 4.5 Acne scarring quality of life mean scores (n= 42)

4.5 Post-acne scarring grading scale (PASGS) control and experimental group, before vs. after treatment

A chi-square test was used to compare the post-acne scarring grading before the treatment commence, verses after the completion of the study, in both the control and experimental group. The test indicated a significance of $p < 0.001$. Figure 4.6 represents the control group within the study. Pre-treatment grading was performed, and demonstrated that 24% of participants had Grade 1 post-acne scarring, 62% had Grade 2 post-acne scarring, and 14% had Grade 3 post-acne scarring. A post-treatment grading was performed on the completion of the study, The post-treatment grading indicated an improvement in those who presented with Grade 2 post-acne

scarring, which thus resulted in a positive shift, increasing the Grade 1 post-treatment grading to 33%, and decreasing the amount of Grade 2 (52%) post-acne scarring individuals. It was evident that no significant improvement was observed in those who presented with Grade 3 post-acne scarring.

Figure 4.7 represents the experimental group. A pre-treatment grading was performed, and indicated (14%) having Grade 1 post-acne scarring, (62%) having Grade 2 post-acne scarring and (24%) indicated Grade 3 scarring. Post-treatment grading revealed in the experimental group a decrease in the Grade 2 post grading to (38%), which resulted in an increase in having Grade 1 to (48%) post-acne scarring, due to a positive shift. Minimal decrease was observed in the Grade 3 post treatment grading, which observed a 10% decrease from the initial 24% percent.

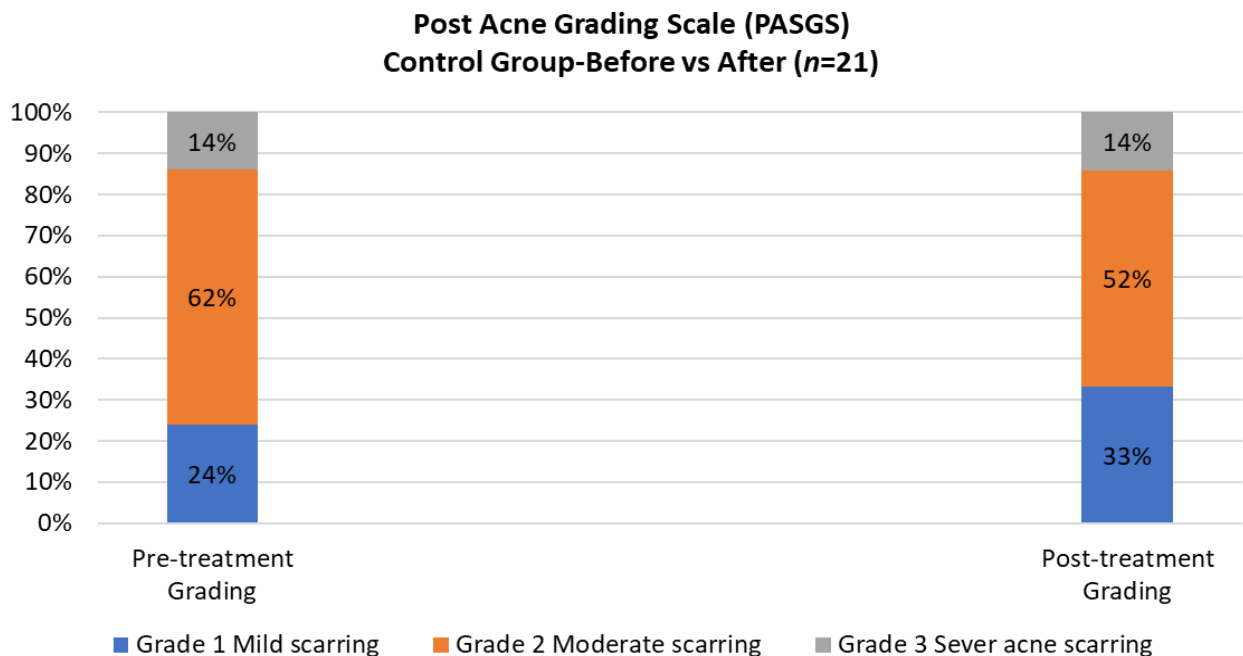


Figure 4.6 Post-acne scarring grading scale before versus after treatment Control Group (n=21)



Figure 4.7 Post-acne scarring grading scale before versus after treatment Experimental Group (n=21)

4.6 Participant Pain Intensity Scale (PPIS)

A pain intensity scale during the treatment was used in order to monitor participants' pain tolerance towards the micro-needling procedure. The pain intensity scale was administered during each treatment, and equated to a total of six. The graph below demonstrates the tolerability of the participants towards the micro-needling. Figure 4.7 shows that a negative correlation exists between the perceived pain intensity score and the number of treatments ($p < 0.01$). As the number of treatments increases, the perception of pain decreased.

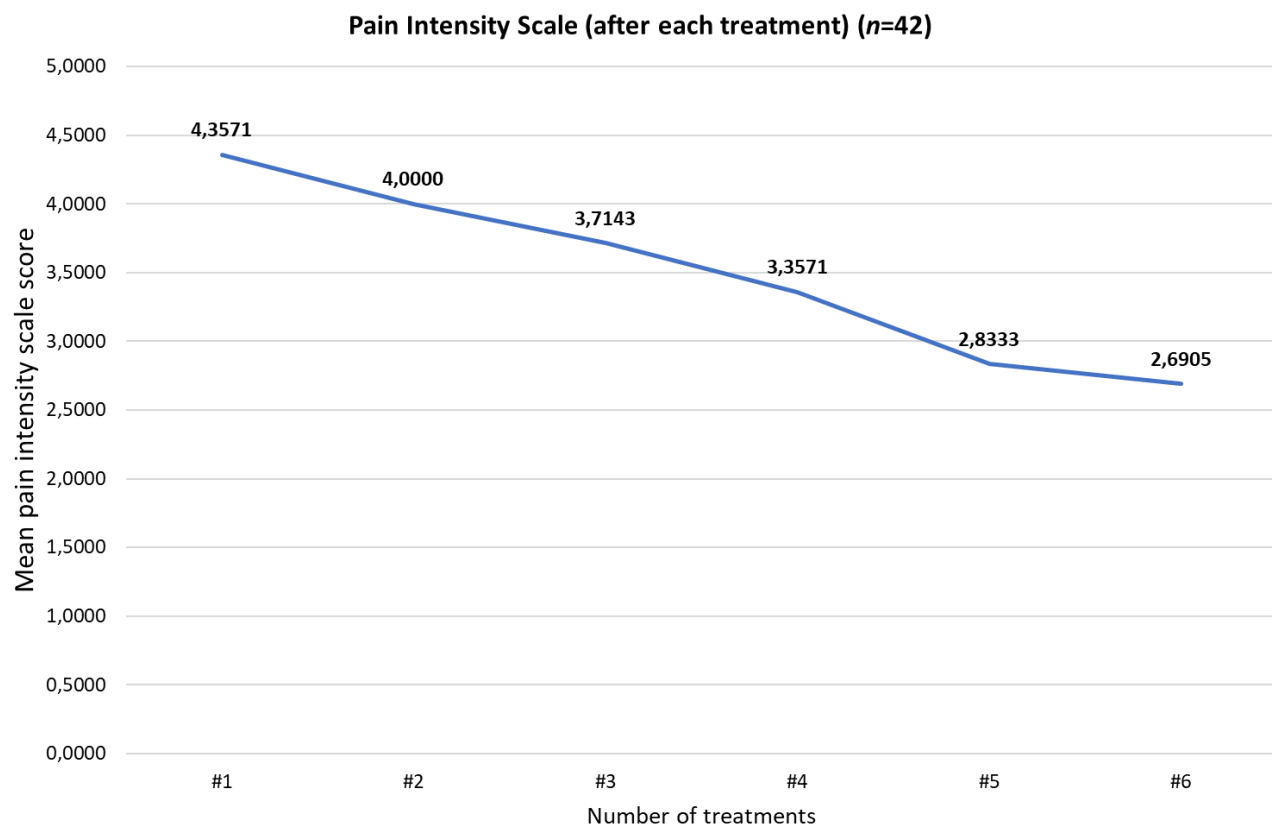


Figure 4.8 Pain intensity scale after each treatment (n= 42)

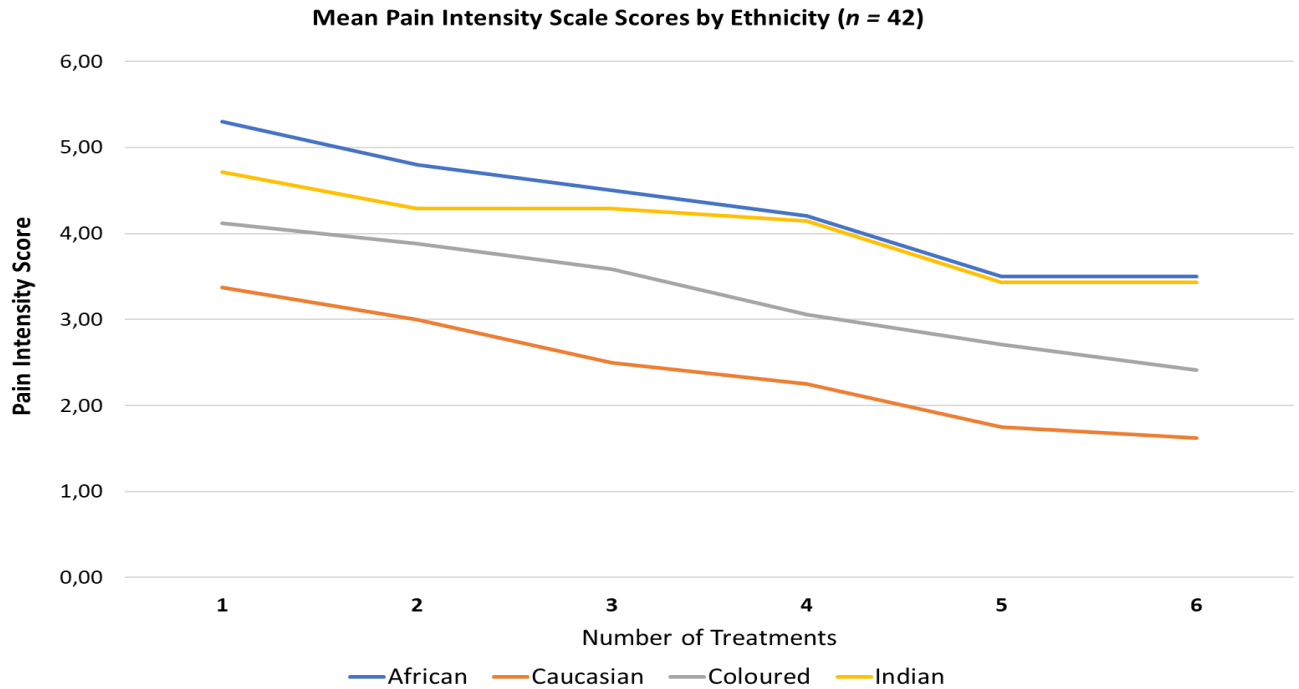


Figure 4.9 Pain Intensity Scores by Ethnicity (n= 42)

As shown previously in Figure 4.7, as the number of treatments increases, the perception of pain intensity decreases. This inverse relationship is uniform across all the ethnic groups ($p < 0,0001$), although the fastest decline is in the African ($\beta_1 = -0,3771$, $t = -10,4683$), followed by caucasian ($\beta_1 = -0,3643$, $t = -14,8257$), coloured ($\beta_1 = -0,3597$, $t = -18,3503$) and then Indian ($\beta_1 = -0,2612$, $t = -5,8587$). These are all highly statistically significant observations, with p values under 0,0001. Initial pain thresholds are, however, different in experience. This further demonstrates that African (5,30) experienced more pain, followed by Indian (4,71), coloured (mixed race) (4,12) and lastly caucasian (3,38) experiencing least amount of pain.

4.7 Participation satisfaction survey

A comparative analysis was performed on the participant satisfaction survey (PSS) following the completion of the study. Participants had to complete a satisfaction survey, ranking their perception of improvement by choosing either of the following:

- 1 Worsening (acne score worse than before treatment)
- 2 No effect (no visible changes of acne scarring)

- 3 Mild (decrease in visible acne scarring with some visible borders)
- 4 Moderate (marked decrease in visible acne scarring with some moderate borders)
- 5 Excellent (a complete loss of visible abnormal acne scarring).

Subjectively, according to the participant's perception, the experimental group showed a significance of $p < 0.001$ when compared to the control group.

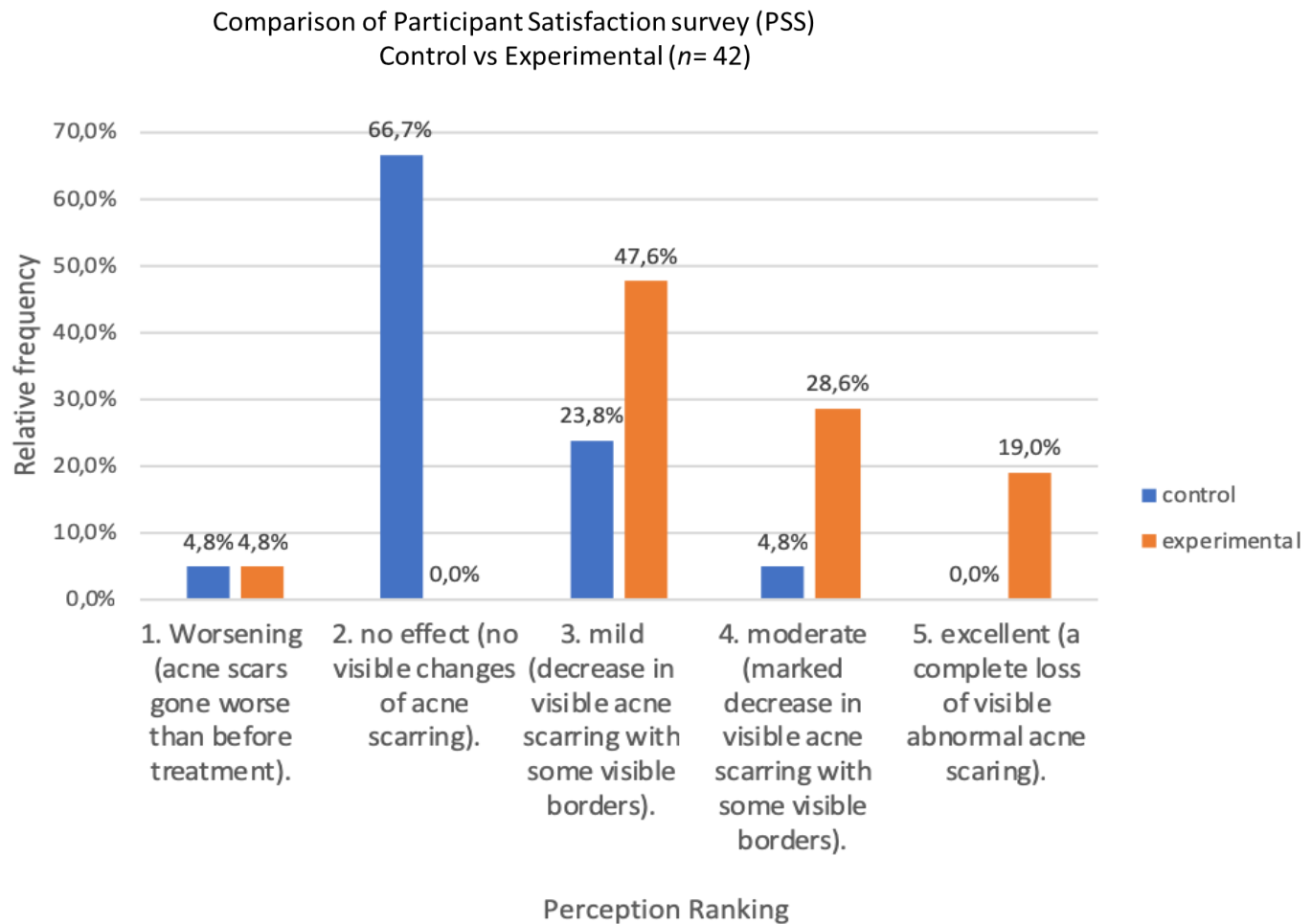
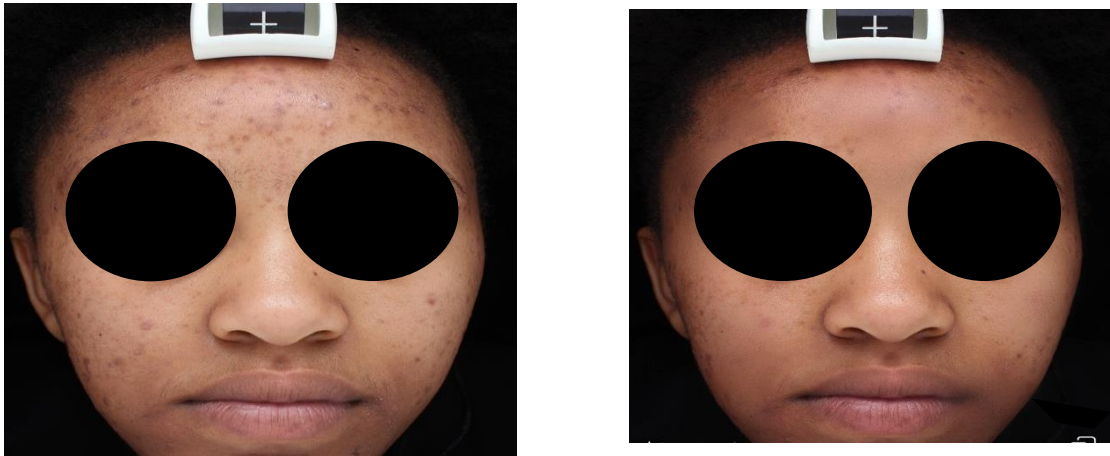


Figure 4.10 Comparison of Participant satisfaction survey control vs. experimental group (n= 42).

4.8 Visia Skin Complexion Analyser®

Photographic evidence was gathered from the Visia Skin Complexion Analyser®. Pictures were taken at baseline (before the commencement of the 1st treatment), and at the end of the 6th treatment (completion of study). The Visia Skin Complexion Analyser® demonstrated improvement in both groups, However, remarkable improvement was demonstrated in the experimental group (Figure 4.15, 4.16, 4.17 and 4.18) when compared to the control group (Figure 4.11, 4.12, 4.13 and 4.14). A marked improvement in the post inflammatory hyperpigmentation within the experimental group, shown below, was observed.

4.8.1 Photographic Data: Control Group (Micro- needling only)



**Figure 4.11 Illustration of post-acne scarring on African skin type.
Comparison of Before (left picture) versus After (right picture).**



**Figure 4.12 Illustration of post-acne scarring on Caucasian skin type.
Comparison of Before (left picture) versus After (right picture).**



**Figure 4.13 Illustration of post-acne scarring on Caucasian skin type.
Comparison of Before (left picture) versus After (right picture).**



**Figure 4.14 Illustration of post-acne scarring on Coloured skin type.
Comparison of Before (left picture) versus After (right picture).**

**4.8.2 Photographic Data: Experimental Group (Micro-needling and
Nigella sativa oil)**



**Figure 4.15 Illustration of post-acne scarring on African skin type.
Comparison of Before (left picture) versus After (right picture).**



Figure 4.16 Illustration of post-acne scarring on Coloured skin type. Comparison of Before (left picture) verses After (right picture).



Figure 4.17 Illustration of post-acne scarring on Indian skin type. Comparison of Before (left picture) verses After (right picture).



**Figure 4.18 Illustration of post-acne scarring on Coloured skin type.
Comparison of Before (left picture) versus After (right picture).**

CHAPTER V: DISCUSSION

The discussion focused on quantitative data with elements of qualitative research that focuses on the perception of participants through the use of the acne scarring quality of life scale, participant pain intensity scale and participant satisfaction survey. The chapter culminates in bringing together these two different perspectives in order to offer breadth and depth, while providing richness, accuracy, and insight to the findings of the study (Tashakrri and Teddlie, 1998; Cresswell, 1993) when combining these types of data sets.

The two main data sets discussed in this chapter are the control and the experimental groups. The control group involved only the micro-needling treatment, whereas the experimental group involved micro-needling with the application of *Nigella sativa* oil.

The quantitative section comprised of data elements emanating from the participant questionnaire, namely the participant demographic sheet. Other quantitative data includes photographic evidence and the post-acne scarring grading scale.

The scales in the research study provided ordinal data. This section pertains to information relating to biographical information, medical information, acne scarring quality of life, participation satisfaction, and pain intensity scale. The qualitative section comprises opinions, perceptions and insights of the participants with respect to all quantitative data above.

5.1. Biographical Information

The highest demographic information for ethnicity in the research study was of mixed-race coloured (40.0%). This is in line with the census released in 2011 indicating that Cape Town has a high majority of coloured ethnicity of 42.4% (SA Statistics). Furthermore, the census indicated that the ethnic diversity for this geographical region makes the study particularly relevant, given the closeness

($p < 0.05$) of the research study ethnic sample to census population parameters, as indicated in Figure 4.1, which indicates a larger population group of mixed race.

The largest percentage (28%) of participants were between the ages of 22 and 25, closely followed by participants who were between the ages of 26 and 29, which is reflected in Figure 4.2. The significance of these age groups was highlighted by Ster (1992), Goulden, Clark and Cunliffe (1997), which indicated that the mean age for the prevalence of the development of acne and acne scarring to be between the ages of 22 and 55. Furthermore, this age group developed mild to moderate inflammatory acne, which lead to a high rate of scarring in this age bracket. This justifies why the majority of sampled participants were in this age group, as well as why the chosen probability sampling technique was used.

A study by Cunliffe and Goulden (1979) pointed to the observation that only 5% of female participants between the ages of 40 and 49 had inflammatory acne. This could be the possible cause for the research study observation that no participants were older than 37 (0.00%), as well as due to the small sample size.

According to Table 4.1., the results of the chi-square test show a significant relationship between the participants' ethnicity and Fitzpatrick skin type classification ($p < 0.01$). The mixed race (40.5%) results are consistent with the Fitzpatrick skin type classification IV (40.5%), which is classified as Coloured or mixed race. Furthermore, (21.4%) and (9.5%) of participants were classified as skin-type V and VI, which could account for the ethnic groups, African and Indian, in the study. A lesser percentage (2.4%) and (11.9%) were observed as Fitzpatrick skin type classification I and II respectively, which can account for the low percent (19.0%) of Caucasians in the research study. This is consistent with the census done (SA Statistics).

5.2 Ultra violet photo protection

As expressed in Figure 4.4, the findings indicated a large percentage of participants (40.5%) did not wear any sunscreen. The results further noted that those who indicated the use of a sunscreen only applied it once a day. These findings suggest

suboptimal use of sunscreen, which is consistent with the studies by Ulrich *et al.* (2009), Koh *et al.* (1997) and Iannacone *et al.* (2014), which indicated suboptimal use of sunscreen protection in life.

This could be due to numerous reasons, as suggested by Ulrich *et al.* (2009). One reason expressed is that individuals find it cosmetically displeasing to apply sunscreen, due to the difficulty they experience to rub in, being greasy, impractical in terms of its whitening effect, or its comedogenic nature. There appears a paucity of education with regard to photo damage. This would suggest a future educational gap could be explored to raise awareness of the use and importance of sunscreen from a young age (Stein *et al.*, 1986).

5.3 Acne scarring quality of life scale (ASQLS)

Results of the study indicated a strong significance of the impact of scarring in affecting quality of life of the participants, particularly within a social setting. The results further indicated how the presence of scarring negatively influenced individuals when building or maintaining romantic relations. Results reported feelings of rejection, self-consciousness in the presence of others. Similar sentiments were reported by (Brown *et al.*, 2009; Brown *et al.*, 2008) and Carr and Harris (2001). It worth taking into account the effects scarring has on quality of life, which has largely been neglected. Many studies focused on treating the physical appearance of post-acne scarring, but little has been done regarding the physiological implications this has on individuals. However, it has been suggested that when treating acne scarring, that quality of life needs to be taken into account by physicians in a clinical setting, in order to create a well-developed and validated scale for future use.

5.4 Comparative analysis of the post-acne scarring grading scale (PASGS) pre- and post-treatment

A comparison of the results was done using the chi-square analysis. Both the control and experimental group observed a significance. However, a difference was

observed in the post-acne scarring grading, particularly Grade 1, Grade 2 and Grade 3, where the control group observed a significance of $p < 0.05$, and the experimental group observed a significance of $p < 0.001$. This significance was observed through a decrease in the scarring after the completion of the study in both the control and more so in the experimental group. These findings concur with previous studies, which suggested improvement of post-acne scarring with the use of a micro-needling device (Birchall *et al.*, 2011; Fabrocinni *et al.*, 2009), however, the experimental group findings suggested a marked difference in the improvement of post-acne scarring noted in the results chapter (see Figure 4.6, 4.15 - 4.18) compared to those of the control (see Figure 4.5, 4.11 - 4.14). This is indicative of the fact that a combination treatment with the use of micro-needling and *Nigella sativa* oil significantly decreased the visible scarring, especially in the Grade 1, Grade 2 and Grade 3 post-acne scarring, compared to those participants in the control group, where micro-needling was used alone.

It is noteworthy though that minimal improvement was demonstrated in Grade 3 post-acne scarring, this could have been influenced by the difference in needle sizes used for the study. In this study, a 1 mm micro-needle was used, whereas in previous studies, needles of greater sizes (1.5 mm and bigger) were suggested to maximise the results (Aest *et al.*, 2008, Fernandes and Signorini, 2008).

5.5 Participant pain intensity scale (PPIS)

The tolerance levels varied amongst the different ethnicities. Figure (4.5) shows that African (5,30) participants experienced more pain, followed by Indian (4,71), coloured/mixed race (4,12), and lastly caucasian (3,38) participants, experiencing the least amount of pain. This finding is in accordance to a study done by Woodrow *et al.* (1972) and Sheffield *et al.* (2000), who found that caucasians demonstrated a higher pain tolerance compared to black, Indian and Asian race groups. This further indicated that pain intensity vary in accordance to race. For this reason, especially within a clinical experimental setting, it is important to monitor pain tolerability.

5.6 Participant satisfaction survey (PSS)

Participant satisfaction surveys gathered data upon the completion of the study. The total percent (66.7%) of the control group felt that the scarring did not improve as much as anticipated. This data speaks to the data in Figure 4.6 (PASGS) that similarly showed that scarring did improve on micro-needling alone. However, a small percentage (4.8%) felt their scarring to have worsened. Participants totalling 19% felt that the scarring improvement was excellent, similarly, 28.6% indicated a moderate decrease in their overall scarring, and 47.6% felt that there was a mild decrease in scarring. This is in agreement with Figure 4.7(PASGS), in which the experimental groups showed a better improvement.

5.7 Photographic data

A visual analysis is an important factor to consider when comparing surface findings. This is especially important as these surface findings may not be easy to be articulated by the naked eyes. The use of the Visia Skin Complexion Analyser[®] allows one to compare accurately these surface and subsurface findings from baseline (Goldsberry, Hanke and Hanke, 2014). Furthermore, this photographic technology makes use of standard fixed facial positioning points eliminating any variance in the pictures taken. This concurs with studies done by Linming *et al.*, (2018) and Chen *et al.* (2009), who advocates the use of imaging systems to track patient progress and subsequently educating patients on underlying conditions.

Pictures from the Visia Skin Complexion Analyser[®] revealed a significant improvement in post-acne scarring from both groups. However, participants from the experimental group (Figure 4.12 to 4.15) responded better when compared to participants from the control (Figure 4.8 to 4.11). These visual differences were assessed by the physician and coincides with the results from the subjective data analysis from Figure 4.7. Subjectively, the experimental group (Group B) regarded themselves as having improved better compared to the control group (Group A). This suggest that improvement was significant when using micro-needling and

Nigella sativa oil, as compared to micro-needling alone. It would be of significant interest to see the histological interaction of the oil with skin cells.

CHAPTER VI: RECOMMENDATIONS AND CONCLUSION

6.1 Conclusion

Post-acne scarring is a common, permanent, distressing, disfiguring skin disorder (Ibrahim *et al.*, 2018). Due to the disfigurement it causes, acne scarring is more than a cosmetic concern, but rather, a medical problem, as it causes psychological problems. Literature indicates high levels of anxiety, stress, difficulty to concentrate at school, less productivity at work, self-consciousness, depression, and in some cases tendency to commit suicide (Saitta *et al.*, 2011; Fabbrocini *et al.*, 2010; Brown *et al.*, 2008).

The aim of the study was to establish whether the addition of *Nigella sativa* oil would prove beneficial when combined with micro-needling on post-acne scarring individuals, since there is scarcity of information regarding the combined effect of *nigella sativa oil* and micro-needling. The study indicated a statistical significance in the experimental group (micro-needling and *nigella sativa* oil) compared to those of the control group (micro-needling only) as indicated in section 5.4. This along with the photographic evidence shows significant improvement of acne scarring and hyperpigmentation in the experimental group, when compared to the control group.

6.2. Recommendations

Improvements and validation of the results could be achieved through the following recommendations:

1. For future studies, it is suggested that a longer follow-up period should be allowed.
2. Use a larger sample size and include male participants.
3. To look at the histology of the cells before and after treatment.
4. Investigate further the effects acne and acne scarring may have on the quality of life particularly within South Africa.

6.3 Limitations of study

1. The study cannot be generalised to the larger population due to the small sample size.
2. The non-inclusion of male participants as studies have indicated a prevalence of post-acne scarring in males.
3. A lack of research and understanding on the black and coloured skin types in South Africa, particularly with the use of micro-needling.

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Appendix A - Ethics Clearance Letter



28 May 2018

Ms M Ismail
1 Briand Way
Strandfontein

Dear Ms Ismail

Comparative study on the combination of Nigella sativa oil with micro needling for post acne scarring

The Institutional Research Ethics Committee acknowledges receipt of your gatekeeper permission letters.

Please note that FULL APPROVAL is granted to your research proposal. You may proceed with data collection.

Any adverse events [serious or minor] which occur in connection with this study and/or which may alter its ethical consideration must be reported to the IREC according to the IREC Standard Operating Procedures (SOP's).

Please note that any deviations from the approved proposal require the approval of the IREC as outlined in the IREC SOP's.

Yours Sincerely,

Professor J K Adam
Chairperson: IREC



Appendix B - Letter of Information and consent

Title of the Research Study:

Comparative study on the combination of nigella sativa with micro-needling for post-acne scarring

Principal Investigator: Moeneeba Jacobs, MHSc Somatology

Co-Investigator/supervisor:

Supervisor: Professor O. Oguntibeju, Biomedical Sciences.

Co-supervisor: S. Nkwanyana, Masters Somatology

Brief Introduction and Purpose of the Study:

Cosmetic micro-needling is considered a relatively new skin rejuvenating treatment modality currently used in the cosmetic industry for the treatment of acne scars, stretch marks, pigmentation fine lines and wrinkles. It is a simple painless device, with no down time period affecting ones daily activities and has found to be a relatively affordable modality compared to most cosmetic procedures offered for the improvement of acne scarring.

There have been attempts to help address acne scarring but the problem still persist (as no gold standard has been achieved). Various types of medical treatments, lasers and light, cosmetic peels as well as natural therapies have been tempted. Although these are effective treatments, there have been numerous problems experienced as these methods have fallen short by being costly and have shown to bring about longer recovery period which may impact on individuals' daily activities. Many of these medical treatments produce adverse effects ranging from dryness, scaling, erythema, burning, irritation, pruritus and edema and are particularly negative when attempted on darker skin photo skin types.

The purpose of this study is to provide a deeper understanding on the benefits of combining *nigella sativa* oil with cosmetic micro-needling for the treatment of mild to moderate acne scarring in an attempt of maximising treatment outcome.

Outline of the Procedures:

The researcher intends to conduct a qualitative study and incorporate an experimental clinical trial design.

A 24-hour allergy test will be carried out on each participant at the start of the study. Digital photo images of each participant using the Visio scope® Imager will be taken, pre and post-treatment. Digital images of each participant's acne scars will be sent to a Dermatologist for grading.

A pre and post questionnaire will need to be completed by each participant during the course of the study

The Visio scope® imager, will be used to monitor and analyse the skin parameters required. Data will be analysed using the statistical software SPSS (version 24).

A 1mm micro-needling device will be used on the area of the skin that presents itself with post-acne scarring. Method of application included the rolling of the micro-needling roller vertically and horizontally covering all areas about 4-5 times. The entire process will take about 30-40 minutes as application.

Each participant will therefore have a marked (according to participant number as an identifier) micro needle hand piece that will correlate to that specific participant. Micro needling devices will be stored systematically in a locked facility at the Somatology department at Cape Peninsula University of Technology.

All Procedures including consultation, digital photo imaging and micro needling application which will be carried out by the researcher will take place at Cape Peninsula University of Technology.

A maximum of 30 – 45mins will be required of the participant upon treatment of micro needling and photo imaging analysis.

Participant needs to be aware that they may form part of either being the experimental or control group whereby one group will receive micro-needling

application only and the other group will receive application of *nigella sativa* oil as well as micro-needling.

Risks or Discomforts to the Participant:

Slight redness may be experienced during and after the application of micro needling device on the skin for about 24-72 hours.

Flaking of the skin may or may not be experienced by the participant during the study as a result of the micro needling

Benefits: In relation to participation to the study, participants acne scarring may improve, results of the study may be used for publication

Reason/s why the Participant May Be Withdrawn from the Study: Participation of the study is voluntary. Therefore in the event of illness and non compliance individuals may withdraw from the study at any given time without being held accountable.

Remuneration: Participants will not receive any form of compensation/remuneration during the course of the study.

Costs of the Study: No cost will be required by the participant at any point during the study.

Confidentiality: All personal information including (name, surname, sex, occupation etc.) collected during the study will be processed anonymously into a study report.

Technical safeguards will be used where by only researcher and respective supervisor will have access codes to view progress of the research.

All eyes will be blacked out in the photo imaging process when the skin is analysed by the computerised Visia analysis.

Research-related Injury: As researchers we take utmost care in seeing no harm may come to any participants during the course of the study. **Please note** in the event of should any problem or injury related concern arise, all representative being supervisors and researchers as well as prospective premises will not be held accountable for as participants are entering the study and premises at own risk.

Persons to Contact in the Event of Any Problems or Queries:

Please contact the researcher Moeneeba Ismail (tel no. 0735781056), my supervisor Professor Oguntibeju (tel no 021 953 8495) or the Institutional Research Ethics administrator on 031 373 2900. Complaints can be reported to the DVC: TIP, Prof F. Otieno on 031 373 2382 or dvctip@dut.ac.za.

General:

Potential participants must be assured that participation is voluntary and the approximate number of participants to be included should be disclosed. A copy of the information letter should be issued to participants. The information letter and consent form must be translated and provided in the primary spoken language of the research population e.g. isiZulu.

CONSENT FORM

Statement of Agreement to Participate in the Research Study:

I hereby confirm that I have been informed by the researcher, _____
(name of researcher), about the nature, conduct, benefits and risks of this study -
Research Ethics Clearance Number: _____,

I have also received, read and understood the above written information (Participant
Letter of Information) regarding the study.

I am aware that the results of the study, including personal details regarding my sex,
age, date of birth, initials and diagnosis will be anonymously processed into a study
report.

In view of the requirements of research, I agree that the data collected during this
study can be processed in a computerised system by the researcher.

I may, at any stage, without prejudice, withdraw my consent and participation in the
study.

I have had sufficient opportunity to ask questions and (of my own free will) declare
myself prepared to participate in the study.

I understand that significant new findings developed during the course of this
research which may relate to my participation will be made available to me.

_____	_____	_____	_____
Full Name of Participant	Date	Time	Signature / Right Thumbprint

I, _____ (name of researcher) herewith confirm that the above participant has been fully
informed about the nature, conduct and risks of the above study.

_____	_____	_____
Full Name of Researcher	Date	Signature

_____	_____	_____
Full Name of Witness (If applicable)	Date	Signature

Full Name of Legal Guardian (If applicable) Date

Signature

Please note the following:

Research details must be provided in a clear, simple and culturally appropriate manner and prospective participants should be helped to arrive at an informed decision by use of appropriate language (Grade 10 level - use Flesch Reading Ease Scores on Microsoft Word), selecting of a non-threatening environment for interaction and the availability of peer counselling (Department of Health, 2004)

If the potential participant is unable to read/illiterate, then a right thumb print is required and an impartial witness, who is literate and knows the participant e.g. parent, sibling, friend, pastor, etc. should verify in writing, duly signed that informed verbal consent was obtained (Department of Health, 2004).

If anyone makes a mistake completing this document e.g. wrong date or spelling mistake a new document has to be completed. The incomplete original document has to be kept in the participant file and not thrown away and copies thereof must be issued to the participant.

References:

Department of Health: 2004. Ethics in Health Research: Principles, Structures and Processes. Available at:

<http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/>

Department of Health. 2006. South African Good Clinical Practice Guidelines. 2nd Ed. Available at: http://www.nhrec.org.za/?page_id=14

Appendix C – Letter of Permission to conduct study

Keizergraght and
Tenant Street
Zonnebloem
PO Box 652
Cape Town
8000

Date: 12 May 2017
Dr N Brooks
Head of Department of Somatology

RE: Permission to conduct research study at the Cape Peninsula University of
Technology Wellness Clinic: Somatology Department

Dear Dr N Brooks

I am writing to request permission to conduct a research study at the Wellness Clinic Somatology Department. I am currently enrolled for Masters in Somatology at Durban University of Technology. The study is titled the effectiveness of *Nigella sativa* oil along with cosmetic micro needling on post- acne scarring in females aged 18- 35 in Cape Town

Once approval is granted, data collection will take place. No costs will be incurred by the Department of Somatology, CPUT.

Your approval to conduct this study will be greatly appreciated. I am happy to answer any questions or concerns that you may have at any time. You may contact me at my email address: mnmismail7@gmail.com.

If you agree, kindly sign below

Sincerely,
Moeneeba Ismail
Researcher

Approved by:

Nicole Brooks

26/07/2017

Print your name and title here Signature

Date

Appendix D – Research Poster

Appendix 2c

Let scarring become a thing of the past!!

Do you struggle with facial scarring?

Are you between the ages of 18-35?

Then you are kindly invited to partake in a research study that may help improve the appearance of post-acne scarring with the use of Micro needling and Nigella sativa oil

The research study will be conducted at the Cape Peninsula University of Technology, Cape Town Campus, Somatology Department for approximately 30 – 40 minutes every 3-4 weeks after first initial screening criteria

*For more information contact researcher:
Moeneeba Ismail
Whatsapp: 0735781056
Email: mnmismail7@gmail.com*



Appendix E - Post-acne scarring grading scale (PASGS)

Assessment of post-acne scarring

The following table will be used to assess the grade and number of lesions present on each participant facial area:

Participant number: _____

Grade before treatment: _____

Grade after treatment.

Scarring Grade	Number of lesions present: 1-10 lesions	Number of lesions present: 11- 20	Number of lesions present: 21	majority of facial area covered by lesions
Grade 1 Mild scarring (Macular/Flat in appearance and hyper pigmented) can be covered with makeup and colour corrective not noticeable 1 metre away				
Grade 2 Moderate scarring (indentation of small scars varying in sizes of no less than 5mm in diameter) somewhat noticeable when covered with makeup and corrected colour, can be seen 1 metre away				
Grade 3 Sever acne scarring (Indentation of scarring more than 5 mm in diameter (hypertrophic in nature), noticeable ice pick scarring and roughed texture) can be seen clearly within 1 metre with or without makeup, post-inflammatory hyperpigmentation.				

Appendix F - Participant Pain Intensity Scale (PPIS)

Purpose: To monitor pain intensity during the application micro needling treatment.

Participant No: _____

Treatment number: _____

Please indicate the post applicable intensity from the Numeric scale:

0- 1- 2- 3- 4- 5- 6- 7- 8- 9- 10

Outcome:

Description of the scale

0 no sensation

1 - 3 mild sensation

4 - 6 moderate sensation

7- 9 severe

10 worst pain imaginable

Appendix G – Participant demographic information

Participant Information sheet

Topic: A comparative study on the application of Nigella sativa oil along with micro needling on post acne scarring.

* General information cross (x) where applicable.

Participant No:

Section A: Biographical information

1. Ethnicity:

Mark only one oval.

- ☐ African
☐ Coloured
☐ Indian
☐ Caucasian
☐ Other: _____

2. Age:

Mark only one oval.

- ☐ 18-21 years
☐ 22-25 years
☐ 26-29 years
☐ 30-33 years
☐ 34-37 years

Section B: Medical information

3. Fitzpatrick skin type classification:

Mark only one oval.

- ☐ I
☐ II
☐ III
☐ IV
☐ V
☐ VI

4. Do you have/ suffer from any of the following conditions:

Check all that apply.

- ☐ Skin Disorders
- ☐ Allergies
- ☐ Adrenal conditions (Thyroid, Poly cystic ovarian syndrome, endometriosis)
- ☐ Keloids
- ☐ None

5. If you answered yes to any of the above conditions please specify;

6. Are you currently taking any of the following medication:

Check all that apply.

- ☐ Multi-vitamins
- ☐ Supplements
- ☐ Herbal medications
- ☐ Oral contraceptive
- ☐ Hormonal medication to assist pregnancy
- ☐ Interventions to control acne (topical or oral)
- ☐ None

7. If you answered yes to any of the above medications please specify;

8. Are you currently on any form of Retinol (vitamin A):

Mark only one oval.

- ☐ Yes
- ☐ No

9. If you answered yes to any of the above question please specify the medication;

Section C: Lifestyle and skin related information

10. How would you rate your general health:

Mark only one oval.

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

11. Are you a smoker:

Mark only one oval.

- ☐ Yes
☐ No

12. If you answered yes to the above question please specify how many cigarettes you smoke a day;

Mark only one oval.

- ☐ 1-3 cigarettes a day
☐ 4-6 cigarettes a day
☐ 7 or more cigarettes a day

13. Have you ever had a reaction to skincare products or sun protection factors:

Mark only one oval.

- ☐ Yes
☐ No

14. If you answered yes to the above question please specify the product;

15. 10. Do you use sunscreen:

Mark only one oval.

- ☐ Yes
☐ No

16. Please specify how often you use sunscreen:

Mark only one oval.

- ☐ Once a day
☐ Twice a day
☐ More than three times a day

17. Have you ever received any form of treatment for the improvement of your scarring:

Mark only one oval.

- ☐ Yes
☐ No

18. If you answered yes to the above question please specify the treatment;

19. If you answered no to question 13, please indicate why not;

20. Do you currently have a skin care routine:

Mark only one oval.

- ☐ Yes
☐ No

21. If you answered yes to the above question please specify how many times a day you carry out the skincare routine;

Mark only one oval.

- ☐ Once a day
☐ Twice a day
☐ Three times a day
☐ Other: _____

22. Do you use any form of facial products regularly:

Check all that apply.

- ☐ Face wash / cleansers
☐ Facial scrubs
☐ Facial masks
☐ Facial oils / serums
☐ SPF
☐ Toner
☐ None

23. With ageing as a skin concern, which treatment route are you mostly like to follow:

Mark only one oval.

- ☐ Doctor's consultation (Dermatologist, Plastic surgeon or general practitioner)
☐ Professional consultation (Somatologists, professional skin care therapists or medical aesthetic practices)
☐ DIY home remedies (social media: YouTube, Pinterest or Instagram)
☐ Natural botanicals (essential oils or plant base active ingredients)
☐ Pharmacist
☐ None
-

Appendix H - Acne Scarring Quality of Life Scale (ASQLS)

Please indicate to what extent you have experienced the following as a result of your acne scarring. Choose one most appropriate number in each case, using the following four-point rating scale:

0 = not at all

1 = mildly

2 = moderately

3 = very markedly

	0 (not at all)	1 (mild)	2 (moderately)	3 (very markedly)
Feeling self-conscious in the presence of others.				
Decrease in your socialisation with others, for example going out to parties etc.				
Difficulties in your relationship with your spouse/ partner .				
Difficulties in your relationship with your close friends.				
Difficulties in your relationship with your immediate family				
Decrease in your overall performance at work .				
Feeling depressed about your acne scarring.				
Not being able to find a job that you like.				
Feeling like an outcast most of the because of the effect of acne scarring on your face.				
People making fun of your appearance.				
Feeling rejected in a romantic relationship.				
Feeling rejected by your friends because of the appearance of acne scarring.				

Appendix I- Participants Satisfaction Surveys (PSS)

Participant's satisfaction surveys will include an assessment of the treated area and will be performed at the completion of the study period. Participants will score any perceived difference in acne scars by themselves. The assessment will be scored as follows:

- (1) worsening (acne scars gone worse than before treatment).
- (2) no effect (no visible changes of acne scarring).
- (3) mild (decrease in visible acne scarring with some visible borders).
- (4) moderate (marked decrease in visible acne scarring with some visible borders).
- (5) excellent (a complete loss of visible abnormal acne scarring).