



The Effect of Magnesium Chloride Liquid on Post-Inflammatory Hyperpigmentation

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SIGNATURE



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ABSTRACT

Introduction: Post-Inflammatory Hyperpigmentation (PIH) in higher Fitzpatrick skin phototypes is a challenging condition to treat, and existing treatment modalities may exacerbate PIH post treatment. Post Inflammatory Hyperpigmentation (PIH) is reported to have a negative impact on the quality of life of those affected. Topical treatments are available to improve the appearance of PIH, but may not be suitable for use in a Somatology clinic as they are classed as scheduled drugs and require a prescription. The need to treat PIH in populations with higher phototypes remains unmet. Studies have shown that Magnesium Chloride is effective in treating inflammatory conditions, however there is paucity of data validating the effects of MgCl₂ liquid on PIH.

Aim: The aim of this research was to investigate the effects of MgCl₂ liquid on PIH in higher Fitzpatrick skin phototypes.

Objectives: The objectives of the study were:

- To determine the clinical effect of topical magnesium chloride liquid on PIH in higher phototypes.
- To evaluate the tolerability of massaged magnesium chloride on higher phototypes
- To explore the impact of post-inflammatory hyperpigmentation on quality of life.

Methodology: The research followed a quantitative, experimental research design. The study was conducted in Cape Town, Western Cape, at SCIN Medispa in Wembley Square. The study included twenty (n= 10) participants who had completed participant questionnaires and Quality-of-Life questionnaires. The participant's skin was cleansed with a micellar water and the MgCl₂ liquid was applied onto the cheeks in weekly intervals for three months. The participants underwent six skin analysis sessions. Session one was the baseline measurements and follow up measurements were conducted on a monthly basis for six months. The skin analysis was done using a Visia® Skin Complexion Analyser. Descriptive data was collected using Pain Intensity Scales, Pigmentation Severity Scales and Erythema Grading Scales.

Results: The results of the study yielded a statistically significant difference in the Quality of Life before versus after ($t(9) = 2.400, p = 0.040$). The mean difference of 4.300 (95% CI [0.253, 8.347]) indicates a substantial increase in the Quality of Life post-intervention. A substantial reduction in the erythema scores was observed ($t(9) = 4.810, p < 0.001$). The mean difference of 1.200 (95% CI [0.636, 1.764]) signifies a substantial reduction in erythema post-intervention. Oedema scores did not reveal a statistically significant difference ($t(9) = 1.410, p = 0.193$). The mean difference of 0.300 (95% CI [-0.183, 0.783]) suggests a minimal change in Oedema post-intervention. Overall disease severity scores did not yield a statistically significant difference ($t(9) = 1.460, p = 0.177$). The mean difference of 0.500 (95% CI [-0.273, 1.273]) indicates a modest change in Overall Disease Severity post-intervention. Pigmentary intensity scores did not reveal a statistically significant difference ($t(9) = 1.410, p = 0.193$). The mean difference of 0.300 (95% CI [-0.183, 0.783]) suggests a marginal change in pigmentary intensity post-intervention. No discernible change was noted in scores denoting the area of hyperpigmentation ($t(9) = 0.000, p = 1.000$). The mean difference of 0.000 (95% CI [-0.337, 0.337]) suggests no discernible change in the Area of Hyperpigmented Lesions post-intervention. Contrastingly, the pain intensity scoring revealed a statistically significant improvement ($t(9) = 3.000, p = 0.015$). The mean difference of 1.000 (95% CI [0.246, 1.754]) denotes a considerably positive impact on tolerability post-intervention.

Conclusion: Magnesium Chloride liquid used in the treatment of PIH in higher phototypes displays tolerability with frequent usage and an increase in the quality of life however, minimal effect on the reduction of PIH. This study contributes valuable insights into the effects of MgCl₂ liquid on PIH in higher skin phototypes. While improvements in quality of life, pain intensity, and erythema were notable, the study underscores the necessity for further research to optimize treatment outcomes, address patient satisfaction, and increase overall understanding of dermatological interventions for higher skin phototypes. The findings create avenues for future research, aiming to bridge the existing gaps in knowledge and provide safer and more effective treatments for individuals with PIH in higher skin phototypes.

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- The Almighty, the most sufficient as Disposer of Affairs.

ABBREVIATIONS AND ACRONYMS

In the context of the study, the following acronyms and abbreviation apply:

PIH: Post-Inflammatory Hyperpigmentation

DEJ: Dermal-Epidermal Junction

MgCl₂: Magnesium Chloride

TYR: Tyrosinase

TYRP-1: Tyrosinase Related Protein- 1

TYRP-2: Tyrosinase Related Protein- 2

UV: Ultraviolet

UVA: Ultraviolet A

UVB: Ultraviolet B

HQ: Hydroquinone

Nd:YAG: Neodymium-doped Yttrium Aluminium Garnet

SPSS: Statistical Package for Social Sciences

DEFINITION OF TERMS

In the context of the study, the following definitions of terms apply:

Cutaneous: In relation to the skin.

Pathogens: Micro-organisms causing a disease.

Psychometric Scale: A standardized scale with multiple questions, measuring psychological traits, behaviours or emotional states.

Reactive Hypermelanosis: Hyperactivity of melanin activity in response to stimuli.

Cytotoxicity: The ability of a substance being poisonous or toxic, causing cells to die.

Carcinogenesis: The transformation of healthy cells into cancerous cells.

Exogenous Ochronosis: A complication of blue/black pigmentation resulting from long term usage of skin lightening creams.

Fitzpatrick Scale: A numerical scale which classifies skin phototype according to the reaction of the skin on exposure to the sun.

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CHAPTER ONE

INTRODUCTION

Post-Inflammatory Hyperpigmentation is a laborious condition to treat, with more common and severe cases showing in higher phototypes as these individuals naturally carry an increased epidermal melanin load (Bae et al., 2020). Higher phototypes are more likely to experience PIH due to an increase in the production or deposition of melanin into the epidermis or dermis by labile melanocytes (Davis & Callender., 2010). The Fitzpatrick system for phototyping classifies higher phototypes as skin types IV-VI (Lawrence and Aboud., 2020). According to the Fitzpatrick skin typing system, these individuals tan with minimal to no burning from exposure to the sun (Farage et al., 2010). As stated by Frazier et al. (2023), individuals with skin of colour constitute a diverse population of ethnic/racial backgrounds, including but not limited to American Indian or Alaska Native, Black or African American, Hispanic or Latino, Asian American or Pacific Islander, and Middle Eastern or North African (Iwuala et al., 2022; Dadzie., 2009). According to Anvery et al. (2022), the prevalence of PIH in Hispanic and Black patients is 46% and 65% respectively, compared to White patients at a low 25%. The need to treat PIH in the population of higher phototypes is still unmet (Silpa-archa et al., 2017). The condition is also more common during the adolescent and young adult phase ranging from 18-25 years of age (Akinboro et al., 2018).

1.1 BACKGROUND

Post-inflammatory hyperpigmentation is a cutaneous inflammatory condition characterised by small, to large scattered hyperpigmented patches and macules of skin (Davis & Callender., 2010). It is a challenging condition to treat. PIH varies in colour from brown, tan, dark brown to blue grey depending on whether the pigmentation is found in the epidermis or whether it extends into the dermis (Davis & Callender., 2010). Chemical peels and laser therapy are considered the common advanced treatments for PIH, however may not be suitable for all skin phototypes as these treatment modalities may exacerbate existing PIH, increasing the risk of scarring, and are therefore, not suitable for higher skin phototypes (Bae et al., 2020). While topical treatments are available to improve the appearance of PIH, however, these treatments are usually classified as prescription drugs and require a prescription, or, when applied clinically, are best carried out under

the supervision of a dermatologist (Rendon et al., 2010). According to Ambrosio (2018), there is a need in South Africa for somatologists to adopt a more medical approach in the skin care sector. In an attempt to avoid undesirable side effects when treating darker phototypes, such as Fitzpatrick phototypes IV-VI, with current treatment modalities, suboptimal results may be produced (Desai., 2014). Furthermore, PIH has been reported to negatively affect the affected individual's quality of life (Bae et al., 2020). The need to treat PIH in populations with higher phototypes remains unmet (Silpa-archa et al., 2017).

In South Africa, many skin care clinics offer treatments to improve the appearance of PIH. These treatments, however, may be costly over a period of time as hyperpigmentation therapy requires repetitive treatments ranging from four to six sessions (Kaufman et al., 2018, Quiñonez et al., 2022). According to SAFacts (2022), entry level peels in South Africa cost R690 per session. Conducting this research was paramount to determine a possible treatment modality for PIH which is long-lasting, tolerable, and has a positive impact on quality of life. The research also determined whether $MgCl_2$ is a viable and safer treatment modality suitable for use in a somatology clinic.

1.2 STATEMENT OF RESEARCH PROBLEM

Post-Inflammatory Hyperpigmentation is amongst the most common skin conditions that higher phototypes seek help from a dermatologist for (Pararajasingam et al., 2019). Inflammatory conditions such as impetigo, atopic dermatitis and acne vulgaris are common triggers of PIH in darker phototypes (Lawrence and Aboud., 2020). Cutaneous insults such as trauma or iatrogenesis procedures may also result in PIH (Wong & Richer., 2021). Post-Inflammatory Hyperpigmentation has a significant psychosocial impact on people with higher phototypes as the frequency of PIH in these individuals is higher, the duration is longer and the occurrence has a greater severity (Pararajasingam et al., 2019). Treatment options available for PIH such as chemical peels, laser therapy and depigmenting agents can incite further hyperpigmentation, making the process extremely onerous and discouraging (Bae et al., 2020). Chemical peels and laser therapy are considered the common advanced treatments for PIH (Silpa-archa et al., 2017), however these procedures pose a risk to Fitzpatrick skin types IV to VI as an increase in production and deposition of melanin may cause these phototypes to be more likely to develop PIH post-procedure (Dayal et al., 2019). In the case of laser therapy, different phototypes absorb variable amounts of photons emitted and is based purely on the amount of melanin present (Liebert et al.,

2012). The more melanin-rich the skin is, the more photons are absorbed (Liebert et al., 2012). Melanin production is one way in which the skin protects itself from trauma therefore, when the melanocytes are excited by interventions which are absorbed deeper within the skin, the risk for exacerbation exists (Mohania et al., 2017). The same phenomenon is noticed when developing a tan in reaction to UV exposure (Mohania et al., 2017). Studies have shown that MgCl₂ is effective in the treatment of inflammatory conditions, however there is paucity of data validating the effects of MgCl₂ on PIH (Last., 2020; Veronese et al., 2022; Shahi et al., 2019).

1.3 SIGNIFICANCE OF THE STUDY

Post-Inflammatory Hyperpigmentation amongst higher phototypes has become a growing concern over time. Techniques posing a potential risk have become the popular choice for the treatment of the condition. The need to educate higher phototypes about the alternate, safer and correct way to treat their PIH is yet to be met. The intricacy of treatment versus disease burden in darker phototypes highlights the uniqueness in the choice of treatment modality and the requirements for a skin of this nature. Additionally, individuals classed as higher phototypes are more inclined to display negligible behaviours such as overexposure to the sun due to the lack of or decreased sensation of burning experienced in comparison to lighter phototypes. Over time, the condition worsens, resulting in a prolonged course of treatments and a greater financial impact. Akinboro et al., (2019) denoted that depression, reduced self-esteem, anxiety and emotional distress were the most common subjective psychological feelings among higher phototypes burdened with facial pigmentation. Additionally, Misery et al., (2020) states that psychological impairment associated with skin disease burden may also result in suicidal ideations. Resultantly, skin diseases have a great impact on one's quality of life (Montero-Vílchez et al., 2022).

Magnesium chloride has been shown to effectively treat inflammatory conditions but the paucity of data underscores the need for additional research to improve and ensure the validity of PIH. Conducting research of this nature serves to bridge the gap between, not only, understanding the correlation between the quality of life and the impact of skin disease burden but also the exploration of new interventions to safely treat PIH in individuals with higher phototypes.

1.4 SUMMARY AND ORGANIZATION OF THE STUDY

The study consists of five chapters covering the following content:

Chapter 1

Chapter 1 has provided the reader with the conceptual framework of the study.

Chapter 2

Chapter 2 will provide a comprehensive review of the literature relevant to the study and will emphasize the gap in existing research due to insufficient prior studies.

Chapter 3

Chapter 3 will focus on the methodology of the research covering all areas related to the practicality of the study.

Chapter 4

Chapter 4 will present the results of the statistical analysis.

Chapter 5

Chapter 5 will discuss the study's results.

Chapter 6

Chapter 6 will conclude the study, outlining its limitations and providing recommendations for further research.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

The objective of this literature review is to provide the reader with an extensive overview of PIH. The chapter will focus on topics such as the pathophysiology of PIH, existing treatment modalities as well as current information regarding the use of $MgCl_2$.

2.2 THE INTEGUMENTARY SYSTEM AND ITS COMPONENTS

The integumentary system is the largest organ of the body responsible for protection and maintenance by creating a physical barrier between the internal and external environments of the body, namely the skin (Kim et al., 2019). Additionally, the integumentary system performs key functions such as regulating body temperature, providing immunity against pathogens, maintaining fluid and electrolyte balance, synthesising vitamin D, and detecting stimuli (Kim et al., 2019). This system consists of three layers: the epidermis, dermis, and (Figure 1).

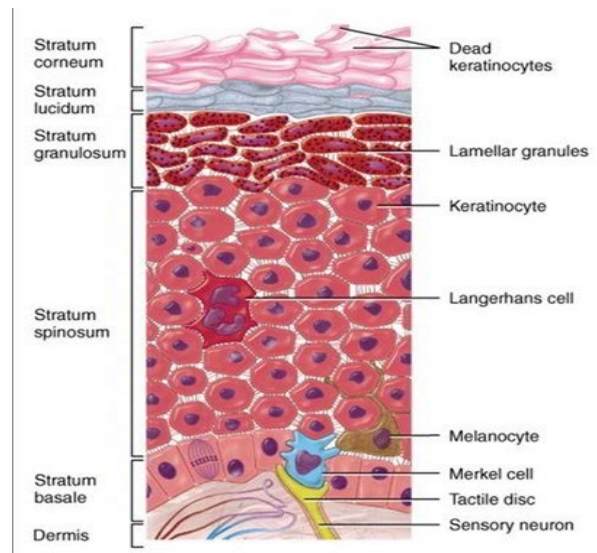


Figure 1: The Layers of The Skin (Anon, 2019).

2.2.1 THE EPIDERMIS

The epidermis is the outermost layer of the skin, made up of five layers (stratum corneum, stratum lucideum, stratum granulosum, stratum spinosum and stratum basale), which are nourished by the blood supply of the dermis (Chambers et al., 2020). The two main specialised specialised cells in this layer are the keratinocytes and melanocytes, which also include Merkel cells and Langerhans cells (Chambers et al., 2020). The keratinocytes protect the skin against mechanical and non-mechanical stress whilst the melanocytes protect the skin by producing melanin in response to ultraviolet radiation, inflammatory stress or injury (Moreiras et al., 2021). Langerhans cells provide the skin with immunity and are regarded as the skin's first line of defence against pathogens while Merkel cells are responsible for sensory function (Yousef et al., 2020).

2.2.2 THE DERMIS

The dermis is the connective tissue layer found between the epidermis and the hypodermis, performing functions such as sensation, thermoregulation and supporting and protection of protecting the skin (Brown & Krishnamurthy., 2019). It consists of two layers composed of collagen and elastin fibres the papillary and reticular layer (Yousef et al., 2020). The papillary layer contains loose connective tissue and is highly vascular whilst the reticular layer forms the bulk of the dermis and contains thick connective tissue (Yousef et al., 2017). In the papillary layer, there are dermal papillae extensions into the epidermis which form the dermal-epidermal junction (DEJ) (Aleemardani et al., 2021). According to Brown et al., (2022), the dermis houses many cells, two of these cell types being histiocytes and mast cells. Histiocytes are macrophages (when discussing pigmentation, we refer to these as melanophages) and mast cells which are inflammatory cells, are important in inflammatory reactions and wound healing (Brown & Krishnamurthy., 2019).

2.2.3 THE HYPODERMIS/ SUBCUTANEOUS LAYER

The hypodermis is the layer of the skin located directly below the dermis and serves to connect the skin to the underlying fascia (Zimoch et al., 2021). Whilst this layer is commonly considered the 'fat' layer due to its adipocyte content, it also contains nerves and vasculature. According to Zimoch et al., (2021), the hypodermis plays a critical role in the maintenance of the mechanical

and thermoregulatory properties of the skin. Zimoch et al., (2021) also stated that the hypodermis supports wound healing and keratinocyte and fibroblast proliferation.

2.3 PROCESS OF CELL TURNOVER

The epidermis renews itself by a process called 'cell turnover', occurring approximately every 28 days (Hoff., 2021). The stratum basale contains keratinocytes in their least differentiated form (Freeman & Sonthalia., 2019). According to Freeman et al., (2022), these keratinocytes undergo mitosis and proliferation, a process involving cell division resulting in the maturation, differentiation and superficial migration of keratinocytes to produce keratin. During this process, keratinocytes migrate to the stratum corneum, where they form a horny layer and become anucleated, meaning they no longer contain a nucleus and are classified as dead cells that desquamate or slough off (Hoff., 2021).

2.4 PATHOPHYSIOLOGY OF MELANIN PRODUCTION

The melanocytes are found in the basal layer of the epidermis and produce the pigment melanin (Shier et al., 2007). Melanin is produced as a protective mechanism for the skin, but overproduction of melanin due to internal or external inflammatory conditions results in PIH by means of a process called melanogenesis (Kaufman et al., 2018). Melanogenesis takes place in the melanosomes which are the organelles found in the cytoplasm of the melanocytes (Fu et al., 2020). Melanosomes contain enzymes such as tyrosinase (TYR), tyrosinase-related protein 1 (TYRP-1) and tyrosinase-related protein 2 (TYRP-2) which are key players in the regulation and production of pigments in the skin (Fu et al., 2020). When the process of melanogenesis is activated by internal and external inflammatory conditions (exposure to UV radiation, acne, contact dermatitis), TYR (a rate-limiting enzyme) converts the amino acid L-tyrosine to dopaquinone, a precursor of melanin, initiating the process of melanin synthesis (Roulier et al., 2020). Dopaquinone is converted to pheomelanin (yellowish-reddish brown melanin) in the presence of adequate concentrations of cysteine (a tyrosinase inhibitor) and glutathione (a free radical scavenging antioxidant) (Charoo., 2022). In the absence of adequate concentrations of cysteine and glutathione, dopaquinone transforms into eumelanin, a melanin which is brown to black in colour (Charoo., 2022). These processes take

place through a series of oxidative chemical reactions within the melanocyte (Bolognia et al., 2018). The melanin produced is transferred to the nearby keratinocytes in the epidermal layer, which travels to the surface of the skin and presents as hyperpigmentation (Bolognia et al., 2018).

The distribution of melanin is however, not limited only to the epidermis as inflammation that takes place in the epidermis can cause weakening of the keratinocyte basal layer, resulting in 'melanin leakage' and subsequent deposition of melanin into the dermal layer (Hoff., 2021). According to Hoff (2021), the melanin that accumulates in the dermal layer becomes phagocytised by neighbouring melanophages. The process of phagocytosis in dermal hyperpigmentation involves the melanophages engulfing the apoptotic melanin containing keratinocytes. Apoptosis is the programmed death of melanin-containing keratinocytes (Lamb., 2022). The result thereof is melanin accumulating at the site of injury and appearing blue/grey in colour (Hoff., 2021).

2.5 POST-INFLAMMATORY HYPERPIGMENTATION

Post-Inflammatory Hyperpigmentation is a common acquired disorder which occurs after injury or skin inflammation and can affect individuals of all genders (Lawrence and Aboud, 2020). Post-Inflammatory Hyperpigmentation is characterised by melanin overproduction caused by cutaneous inflammation (Kaufman et al., 2018) and presents as hyperchromic skin macules ranging from brown to black (Khelifa et al., 2023). The localisation of the pigment, whether in the epidermis or the dermis, also determines how hyperpigmentation responds to treatment (Elbuluk et al., 2021). Pigmentation resulting from the dermis is harder to treat than pigmentation resulting from the epidermis as the epidermis desquamates every twenty-eight days (Freeman & Sonthalia, 2019). Treatment modalities for PIH include laser and light therapy, chemical peels, depigmenting topical agents and photoprotection (Kang et al., 2022).

2.6 TRIGGERS OF POST-INFLAMMATORY HYPERPIGMENTATION

The most common triggers of PIH in higher phototypes are atopic dermatitis, impetigo and acne vulgaris (Lawrence and Aboud., 2020). Other events, such as trauma or iatrogenic procedures, may also cause PIH (Wong & Richer., 2021). Since PIH is considered a reactive hypermelanosis, an inflammatory response may be triggered by stimuli such as ultraviolet (UV) radiation (Fatima et

al., 2020). Sun exposure exacerbates PIH by further stimulating melanocyte activity, underscoring the importance of sunscreen use (Fatima et al., 2020).

2.6.1 ATOPIC DERMATITIS

Atopic dermatitis (Figure 2) is one of the most common inflammatory skin diseases, with underlying factors including epidermal barrier disruption, genetic predisposition, and immune dysregulation (Kim et al., 2019). The condition is defined as a chronic, pruritic inflammatory dermatosis characterised by recurrent scaling, papules and plaques (Poladian et al., 2019).



Figure 2: Atopic Dermatitis on an Adult Extremity (Frazier et al., 2020).

According to Grayson et al., (2020), atopic dermatitis mostly affects individuals with skin of colour. It is distressing due to its resultant PIH, harming one's psychosocial state and quality of life. In a discussion of a study conducted to treat atopic dermatitis and PIH in a patient with skin of colour, several factors were highlighted. The highlighted factors include: (I) PIH is the second most common diagnosis in patients with skin of colour; (II) atopic dermatitis leads to pigment alteration, which results in increased melanocyte density due to chronic inflammation; and (III) increased melanocyte function explains why inflammatory conditions, such as atopic dermatitis, cause PIH (Grayson et al., 2020).

A study conducted by Skevaki et al. (2021) stated that urbanisation in Sub-Saharan Africa, the growth of cities when people migrate from rural to urban areas, has increased rapidly, resulting in rising rates of environmental transitions associated with high rates of irritants, pollution, climate and allergens; factors which not only trigger, but worsen atopic dermatitis in adults. Case reports by Carman et al., (2023) conducted in Gauteng, highlighted that atopic dermatitis in adults may be triggered by exposure to workplace chemicals, often being misdiagnosed as contact dermatitis.

2.6.2 IMPETIGO

Impetigo (Figure 3) is a superficial bacterial infection that occurs more often in children than in adults (Johnson., 2020).

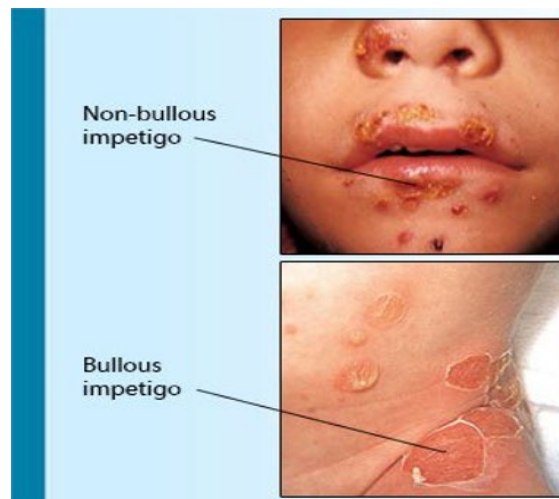


Figure 3: Non-bullous vs Bullous Impetigo (Anon, 2023).

According to Johnson (2020), impetigo has two common variants: non-bullous caused by *Staphylococcus aureus* and *Streptococcus pyogenes* (which together account for 70% of impetigo infections), and bullous, caused solely by *Staphylococcus aureus* (which accounts for 30% of impetigo infections). Non-bullous impetigo presents with crusting while bullous impetigo presents as pustular, containing yellow fluid with brown and yellow crusting (Robinson et al., 2023).

2.6.3 ACNE VULGARIS

Acne (Figure 4) is one of the major causes of PIH in skin of colouru (Callender et al., 2022). Acne exacerbates PIH by stimulating abnormal melanin deposition and excessive melanogenesis (Elbuluk et al., 2021).



Figure 4: Nodulocystic Acne Accompanied by Inflammation and Post-Inflammatory Hyperpigmentation (Sangha., 2021)

The theory of acne induced PIH is still not fully understood; however, it is believed that arachidonic acid, released as an inflammatory response to acne, triggers molecules involved in melanocytic activity (Elbuluk et al., 2021). According to Abad-Casintahan et al., (2016), in a study conducted on 324 subjects quantifying the frequency of acne-related PIH in seven Asian countries, more than half of the subjects had PIH lasting for at least one year and five years for 22.3% of the sample size. Similarly, Abanmi et al., (2019) conducted a prospective, non-interventional study of acne in 262 Middle Eastern patients consulting a dermatologist and reported that 87.2% of the sample had PIH, with 52.6% stating that their PIH had lasted for a year or more.

A study conducted by Perkins et al., (2011), showed the following percentages as an indication of the prevalence of post-acne hyperpigmentation amongst different racial groups: Black (65%), Hispanic (48%), White (25%), Asian (18%) and Indian (10%) with the condition being more bothersome to the black community. Similarly, Elbuluk et al., (2021) reported the following findings on a study displaying the longevity of acne- induced PIH in higher phototypes: 58.2% of the participants from the Southeast Asian population experienced PIH for more than one year and 52.6% of participants from the Middle Eastern population experienced PIH for at least a year

following the acne occurrence. Topical retinoids are among the more favourable treatment options for acne in people with skin of colour; however, tretinoin formulations must be closely monitored, as they can cause skin irritation (Callender et al., 2022).

2.7 THE EFFECT OF POST-INFLAMMATORY HYPERPIGMENTATION ON QUALITY OF LIFE

Post-Inflammatory Hyperpigmentation can last for several years, contributing to emotional distress and a decrease in the overall quality of life (Anvery et al., 2022). In a study conducted by Darji et al., (2017), a psychometric scale was used to quantify the impact of PIH in patients with acne vulgaris. Twenty-five subjects had acne accompanied by PIH, while twenty-three subjects had acne without PIH. Darji et al., (2017), found that patients with acne and PIH had greater statistically significant impairments on questions asked regarding their quality of life. The questions with the most negative scores were related to “feeling self-conscious in the presence of others”, “difficulties with significant others and friends” and “feeling like an outcast” (Darji et al., 2017).

According to Anvery et al., (2022), the increase in disease burden has an impact on the individual’s psychosocial well-being and the management of the disease starts with patient education on risk factors.

2.8 CURRENT TREATMENT MODALITIES

Post- Inflammatory Hyperpigmentation can be treated with depigmenting agents such as hydroquinone, azelaic acid and kojic acid (Davis & Callender., 2010). Other treatments for PIH include ascorbic acid (vitamin C), retinoids, niacinamide, N-acetyl glucosamine, mequinol and soy (Davis & Callender., 2010). Common advanced procedures for the treatment of PIH include chemical peels such as Salicylic Acid (SA), Trichloroacetic Acid (TCA) 10%-35%, Glycolic Acid (GA) 20%-50%, Lactic Acid (LA) 20%-30%, and Mandelic Acid (MA), as well as laser and light therapy (Silpa-archa et al., 2017). These procedures pose a risk for individuals with darker skin types, as they are more likely to develop post-procedure PIH due to greater production and deposition of melanin in higher skin phototypes (Sarkar et al., 2012; Dayal et al., 2019). The

inflammation which may follow an aesthetic intervention may further incite reactive-hypermelanosis (Pararajasingam et al., 2019).

2.8.1 DEPIGMENTING AGENTS

The copper-containing enzyme, tyrosinase, is a key component in the process of melanogenesis in that it acts as a catalyst, accelerating the process (Masum et al., 2019). The inhibition of tyrosinase is therefore, crucial for the regulation of melanin production (Masum et al., 2019). Tyrosinase can be inhibited with the use of depigmenting agents (Shin et al., 2014). Depigmenting agents inhibit melanogenesis (Figure 5) by interrupting the transfer of melanosomes and accelerating the rate of epidermal desquamation and epidermal turnover and may also be used as priming agents in preparation for laser therapy or chemical peels (Kumarasinghe., 2018; Griffiths et al., 2016). As a result, the risk of developing PIH post-procedure may be reduced (Griffiths et al., 2016).

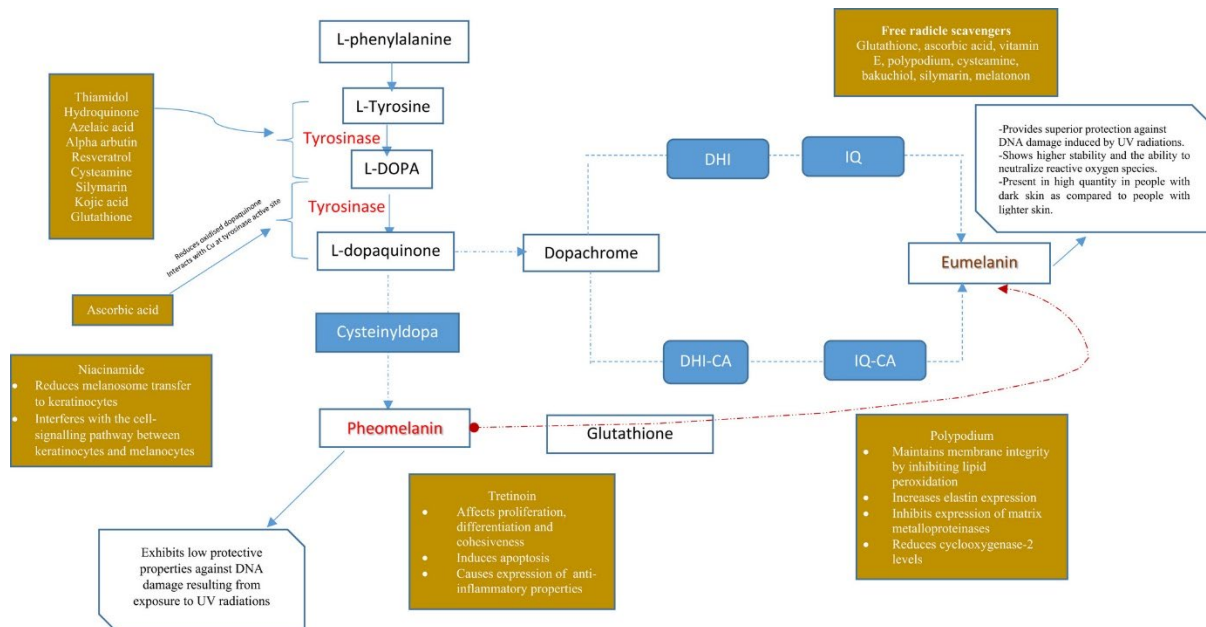


Figure 5: The Mechanism of Action When Using Depigmenting Agents (Charoo., 2022)

Topical agents such as hydroquinone, azelaic acid and kojic acid mainly inhibit tyrosinase activity whereas agents such as niacinamide and soy mainly interrupt melanosome transfer (Kumarasinghe., 2018). Retinoids mainly accelerate the rate of epidermal desquamation

(Kumarasinghe., 2018). Due to a reduced response in the deeper tissue, topical agents are used to treat pigmentation resulting from the epidermis (Elbuluk et al., 2021).

The development of various types of tyrosinase inhibitors are being explored, particularly factoring in aspects such as safety with regular application and knowledge on the use of recommended dosages (Phasha et al., 2022). The use of these agents has previously resulted in reports of cytotoxicity and instability, necessitating further research development into safer formulations (Phasha et al., 2022).

2.8.1.1 HYDROQUINONE

According to Desai (2014), hydroquinone (Table 1) continues to be the preferred treatment option for hyper-pigmentary disorders.

Author	Depigmenting Agent	Source	Route of Administration	Concentration in Topical Formulation	Effects
Moolla et al., 2022	Hydroquinone	Synthetic/ natural	Topical	2%-4%	• Gradually lightens the area
Tan et al., 2022	Retinoids	Forms of Vitamin A	Topical	0.01%-1%	• Induces desquamation of stratum corneum • Disperses pigment granules in the keratinocyte. • Improves epidermal cell turnover

Elbuluk et al., 2021	Azelaic acid	Saturated carbon molecule derived from the fungus <i>Pityrosporum ovale</i>	Topical	15%-20%	● Mainly acts on melanocytes and has minimal effects on the other parts of the skin
Nayak et al., 2019	Kojic acid	Fungal metabolite of <i>Acetobacter</i> , <i>Penicillium</i> and <i>Aspergillus</i>	Topical	1%-4%	● Enhances hydroquinone efficacy
Nayak et al., 2019	Niacinamide	Yeast and root vegetables, derivative of Vitamin b3	Topical	2%-5%	● Assists in the maintenance of normal epidermal thickness against skin barrier disruptors that may cause inflammatory changes
Kalasho et al., 2020	Vitamin C	Fruits and vegetables	Topical	10%-20%	● Reasonably efficient against ultraviolet

					induced hyperpigment ation ● Safe for use
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Table 1: Depigmenting Agents in Melano-Dermo Skin Model (Charoo., 2022)

Roggenkamp et al., (2021) have raised concerns about the systemic absorption, carcinogenesis, and exogenous ochronosis induction of hydroquinone usage (Figure 6).



Figure 6: Depiction of Depigmented Macules After Eight Months of 4% Hydroquinone Usage (Das et al., 2019)

As a result of these safety hazards, the European Union prohibited the use of hydroquinone as an ingredient in cosmetic formulations and in the United States, the Food and Drug Administration is re-evaluating over-the-counter formulations with a 2% hydroquinone content (Roggenkamp et al., 2021). Care should be practiced when applying hydroquinone as an uneven application may result in uneven penetration and therefore, uneven depigmenting of the skin (Hilton., 2020).

2.8.1.2 AZELAIC AND KOJIC ACID

According to Searle et al., (2022), azelaic acid (Table 1) has numerous dermatological properties with the two main properties being anti-inflammatory and anti-oxidative. Azelaic acid displays depigmenting actions through the inhibition of tyrosinase activity and its ability to produce a selective cytotoxic effect on abnormal melanocytes (Elbuluk et al., 2021). Albahlool et al., (2021) states that azelaic acid should be used alongside sunscreen. In a double-blind study conducted on fifty-two subjects over a period of twenty- four weeks, azelaic acid was effective in reducing PIH in skin types IV-VI, however, noticeable burning and stinging was observed (Albahlool et al., 2021).

Kojic acid (Table 1) inhibits tyrosinase activity and has radioprotective, anti-inflammatory, skin-lightening and anti-proliferative properties (Phasha et al., 2022). According to Phasha et al., (2022), kojic acid protects the skin from UV rays, prevents melanin formation and reduces hyperpigmentation. In a study conducted by Wawrzyk-Bochenek et al., (2023), 3% kojic acid was applied to the skin on hyperpigmented areas and the result noticed was an inhibition of cellular activity within the keratinocytes, ultimately producing an anti-melanogenic effect.

2.8.1.3 NIACINAMIDE

Niacinamide (Table 1) is a water-soluble vitamin used in the treatment of skin diseases carrying traits such as antioxidation and apoptosis of keratinocytes (Zhen et al., 2019). A study conducted by Bae et al., (2022) on hyperpigmentation evaluated the results of a split-face study involving 17 patients, comparing the right side of the face treated with a niacinamide patch to the untreated left side. The study was conducted over a period of two weeks on patients with a skin type III-IV and the measurements were taken with an automatic skin analysis device (Bae et al., 2022). The results showed an improvement of the hyperpigmentation on the right side of the face, however, the effects of the niacinamide application reversed after 3 days (Bae et al., 2022).

2.8.1.4 RETINOIDS

Topical retinoids (Table 1) are among the favourable options for the treatment of hyperpigmented lesions in skin of colour (Callender et al., 2022). Retinoids increase cell turnover, which accelerates the skin's desquamation process and provides anti-inflammatory benefits (Lamb., 2022). As stated

by Lamb (2022), retinoids also cause apoptosis. According to Callender et al., (2022), whilst retinoids are a favourable option for the treatment of PIH, its risk of irritability can cause undesired pigmentary changes in the skin.

2.8.1.5 VITAMIN C

Vitamin C (Table 1) has antioxidative effects on the skin and is able to inhibit tyrosinase activity (Kurokawa et al., 2020). The derivative of vitamin C, Isostearyl-L-ascorbic acid, has the distinct characteristic of being highly absorptive by the skin, bypassing the skin barrier, entering the keratinocyte and into the dermis (Kurokawa et al., 2020). A study conducted on sixteen female patients presenting with melasma, compared the application of 5% ascorbic acid (a derivative of vitamin C) and 4% hydroquinone and found a 62.5% and 93% improvement in hyperpigmentation respectively (Wasiullah., 2022). Although hydroquinone showed better improvement results, its efficacy may be due to the combination therapy with ascorbic acid (Wasiullah., 2022).

2.8.1.6 KLIGMAN'S FORMULA

Kligman's formula is a Triple Combination Cream (TCC) which had previously been referred to as the mainstay treatment for pigmentary conditions for years (AboAlsoud et al., 2022). This formulation consists of hydroquinone, tretinoin and a topical corticosteroid making the depigmenting agent a synergistic, more tolerable and efficacious treatment for hyperpigmentation (Aldhafiri et al., 2021). Studies suggest that Kligman's formula produces the best results in reducing hyper-pigmentary disorders when used in combination with either laser therapy or chemical peeling agents (Sarkar., 2017; Nasimi., 2022). Contrastingly, long term use of corticosteroids and hydroquinone may result in adverse effects such as skin atrophy and ochronosis respectively (Karrabi et al., 2021).

2.8.2 CHEMICAL PEELS

According to Issa et al., (2018), chemical peeling is a means of wounding' the skin in a controlled manner.

2.8.2.1 SUPERFICIAL PEELS

Superficial peels work on the basis of exfoliating the epidermal layer of the skin without surpassing the basal layer (Issa et al., 2018). Common superficial peels are Salicylic Acid (SA), Trichloroacetic Acid (TCA) 10%-35%, Glycolic Acid (GA) 20%-50%, Lactic Acid (LA) 20%-30% and Mandelic Acid (MA). A study conducted by Vemula et al. (2018), denoted the frequency of complications and side effects after conducting superficial peels on patients with a skin type III-VI. Results indicated that the most frequent complications were crusting (2.3%), post-inflammatory hyperpigmentation (1.9%), and erythema (1.9%) (Vemula et al., 2018). All the side effects resolved with eight months of treatment and an adjusted model identified higher skin phototypes with higher odds of side effects (Vemula et al., 2018). Vemula et al., (2018) also emphasised the importance of exercising great care in selecting appropriate patients, choosing suitable peeling agents, and ensuring that the technique used is meticulous.

2.8.2.2 MEDIUM DEPTH PEELS

Medium depth peels induce similar histologic changes within the skin such as epidermal necrosis, dermal inflammation and dermal oedema (Lee et al., 2019). Common medium depth peels include 70% GA in combination with 35% TCA, Jessner's Solution in combination with 35% TCA, 88% phenol and 35% TCA in combination with solid CO₂ (Lee et al., 2019). According to Dayan et al., (2019), when peeling with Jessner's Solution in combination with 35% TCA, the skin may need to be anaesthetized 40-60 minutes prior to the procedure. There is also a downtime of seven to ten days in which the skin sloughs off and re-epithelializes and a six-week period is needed for dermal regeneration (Dayan et al., 2019).

2.8.2.3 DEEP PEELS

Deep chemical peels are achieved through the use of phenols and are used to target conditions such as photo aging, deep scars and wrinkles (Castillo et al., 2022). The eligibility to have deep chemical peels is dependent on patient outcomes following extensive laboratory work such as

hepatic, cardiac and renal testing (Rullan., 2019). According to Castillo et al., (2022), great care should be practised when carrying out deep peels to avoid the high risk of systemic toxicity in patients. According to Rullan (2019), peels of such a sensitive nature require pre-conditioning of the skin up to 4-12 weeks prior to having the treatment done. As stated by Castillo et al. (2022), deep peels in the population of darker phototypes should be avoided as the risk of developing PIH and scarring is high.

In addition to PIH, chemical peels pose a risk of scarring in higher skin phototypes, especially when performed with excessively strong agents, inadequate post-procedure care, or improper technique. A retrospective study conducted by Vemula et al. (2018) evaluating superficial peels in Fitzpatrick III–VI skin reported that although complication rates were relatively low, higher phototypes may also experience crusting, which may develop into scarring if the healing response is disrupted or secondary infection occurs.

2.8.3 LASER THERAPY

A common adverse effect of PIH is observed following laser treatment, especially in individuals with darker skin phototypes (Cheyasak et al., 2015). Dorgham et al., (2020) stated that to avoid the adverse effects in the treatment of PIH in skin of colour, a prolonged pulse width and an extended treatment duration should be used as the parameters when carrying out laser treatment. Long-pulsed Neodymium-doped Yttrium Aluminium Garnet (Nd: YAG), pulsed diode and alexandrite lasers as well as Intense Pulsed Light (IPL) are also the advised phototherapy treatment options, however, these treatment options still remain unclear for patients with skin of colour (Dorgham & Dorgham., 2020).

A study conducted by Arsiwala et al., (2019), has shown that great consideration has to be shown for higher phototypes when choosing more aggressive modalities of treatments to avoid complications such as PIH. The study concentrated on treating post-acne scarring in skin of colour using a fractional carbon dioxide laser. The researchers considered using a low fluence instead of a high fluence, low density instead of a high density, and a long pulse mode to avoid damaging the epidermis (Arsiwala et al., 2019). The study has also shown that interventional priming of the skin, using depigmenting agents is best suggested prior to performing treatments such as chemical peels or laser therapy on a darker phototype (Arsiwala et al., 2019).

A study conducted by Bae et al., (2020) evaluated the efficacy and safety low energy, low density, non-ablative fractional 1927 nm wavelength laser treatment on Fitzpatrick skin types IV-VI suffering from PIH. The researcher made use of the following parameters: fixed spot size of 140 µm, depth of 170 µm, and 5% coverage, fixed fluence at 5 mJ with no use of a priming agent (Bae et al., 2020). Conversely, the results of the study showed a statistically significant improvement in PIH in Fitzpatrick phototypes IV-VI, motivating its safety and efficacy (Bae et al., 2020).

2.9 PHOTOPROTECTION AS A PREVENTATIVE/ TREATMENT MODALITY

The use of UV filters is an integral part in the management of PIH (Puaratanaarunkon et al., 2022). Exposure to UVA and UVB radiation stimulates melanocytic activity and results in pigmentary alterations (Hoff., 2021). Post-Inflammatory Hyperpigmentation is one of the several inflammatory conditions exacerbated by exposure to ultraviolet (UV) exposure, especially in individuals of colour (Fatima et al., 2020). As a result, the perception from the Black and Hispanic populations is that because their risk of skin cancer is lower, there is no need for sun protecting strategies (Buchanan Lunsford et al., 2018). The education emphasizing sun- protective behaviours and the usage of broad-spectrum sunscreen in this population is therefore, crucial (Hoff., 2021). Since PIH is most evident among Fitzpatrick skin types III-IV, exposure to ultraviolet radiation may have a significant impact on the outcome of treatments (Hoff., 2021).

2.10 MAGNESIUM CHLORIDE AS A TREATMENT INTERVENTION FOR POST-INFLAMMATORY HYPERPIGMENTATION

Magnesium salt therapy is one of the oldest techniques for treating unregulated inflammatory responses within the body (Chandrasekaran et al., 2014). A study conducted by Shahi et al., (2019), showed that a deficiency in Magnesium can cause inflammation in the body. Studies have shown that acne vulgaris is a primary inflammatory disease, resulting in PIH and the method of counteraction is the use of anti-inflammatories (Tanghetti., 2013; Rico., 2013).

According to Sircus (2011), the form of magnesium that is most recognizable to the body is $MgCl_2$, which is found in seawater. A study by Last (2020), has validated the effectiveness of $MgCl_2$ for

the treatment of inflammatory conditions such as muscle stiffness, arthritis and acne. A study conducted by (Manoharan et al., 2022), showed that bathing in Dead Sea water was effective for the reduction of inflammation of patients suffering from atopic dermatitis. Dead Sea water is 46% rich in the crystalline form of magnesium chloride (Manoharan et al., 2022).

While there is data to validate the effects of MgCl_2 for the treatment of acne and atopic dermatitis, no data has been recorded regarding the potential anti-inflammatory effects on PIH and its resultant effect on the quality of life on the individual faced with the disease burden.

2.11 AIMS

This study aimed to investigate the effects of MgCl_2 on PIH in individuals with a higher Fitzpatrick skin phototype from a single centre, addressing a significant gap in evidence regarding its potential depigmenting and skin-modulating properties.

2.12 OBJECTIVES

The research sought to:

1. Determine the clinical impact of MgCl_2 on PIH in higher Fitzpatrick phototypes
2. Evaluate the tolerability of massaged MgCl_2 in this target population; an essential aspect for real-world application
3. Explore the broader psychosocial burden of PIH by assessing its impact on the quality of life.

Collectively, these objectives support the skincare industry's need for scientifically substantiated, well-tolerated and inclusive treatment modalities, catering to diverse Fitzpatrick skin phototypes, addressing both clinical and quality-of-life considerations.

CHAPTER THREE

METHODOLOGY

3.1 INTRODUCTION

This chapter explores the methodology executed in this study. Topics such as the hypothesis, aims and objectives, assumptions and limitations, research design and setting, ethical considerations, target population, sampling and recruitment process, data collection tools and process will be covered. The chapter will also cover the statistical analysis of the research.

3.2 RESEARCH QUESTIONS

- What was the clinical effect of topical MgCl_2 liquid on the treatment of PIH on higher skin phototypes?
- Did MgCl_2 display longevity as a treatment modality for PIH 3 months after concluding the application?
- Did the skin become more tolerable to the application of MgCl_2 over time?
- Did the treatment of PIH with topical MgCl_2 improve the quality of life?

3.3 HYPOTHESES

Consistent topical administration of the MgCl_2 is anticipated to produce a progressive reduction in the severity of PIH, with the majority of participants expected to achieve complete lesion resolution by the conclusion of the study period. Topical MgCl_2 demonstrates sustained improvement in PIH after the discontinuation of treatment. Frequent topical application of MgCl_2 will enhance participants' tolerance to the formulation by the conclusion of the study period. A measurable

reduction in the severity of PIH will correspondingly improve participants' quality of life by the end of the study period.

3.4 RESEARCH DESIGN

The research design of a study can be defined as the framework of a study which determines factors such as how participants will be selected, which variables are included in the study and how they are manipulated as well as the manner in which data is collected and analysed for reporting (Dannels-Anderson., 2018). A quantitative, experimental research design was used for this study. This design is also most effective when trying to evaluate the efficacy or cause and effect, of new interventions and treatments that have not previously been done (Thompson et al., 2006). Experimental studies do not involve any randomisation and therefore, all participants receive the same intervention (Ary et al., 2010). Experimental research functions on the basis of measuring independent and dependent parameters (Srinagesh., 2005). All participants received MgCl₂ applied to cheeks and forehead. The dependent parameter of the study was the effect MgCl₂ liquid will have on PIH. The independent parameters were those that could be manipulated by the researcher such as the Fitzpatrick phototype, the age and the sex of the participants enrolled in the study.

3.5 TYPE OF RESEARCH

The study adopted a quantitative research approach. According to Mishra et al., (2011), the quantitative approach involves the systematic experimental analysis of observable-phenomenon via mathematical, statistical or computational techniques to represent data as statistics or percentages. This approach was chosen as the data collected was represented in numerical values to identify the measurable effects of MgCl₂ on PIH.

3.6 STUDY SETTING

The research study took place at SCINMed in Wembley Square, Western Cape. SCIN is a specialist laser and aesthetic Institute whose prime focus is advanced aesthetics such as plastic

surgery but also innovations such as laser therapy, micro-needling and chemical peels. The treatment room used for the duration of the research, had a separate section which allowed for skin analysis with the use of a VISIA® skin analysis device.

3.7 TARGET POPULATION AND STUDY POPULATION

A target population can be defined as the entire population of subjects that the researcher intends to generalise the results of the study for (Hu., 2014). The study population is the sample selected from the target population, with specific selections criteria (Hu., 2014). The study population for this study included participants of any gender who presented with Post Inflammatory HyperpigmentationPIH between the ages of 18-25 years. The participants were also required to reside in Cape Town, have experienced unsuccessful treatment of their PIH and have a Fitzpatrick skin type IV-VI.

3.8 SELECTION CRITERIA

3.8.1 INCLUSION CRITERIA

- Participants with a Fitzpatrick phototype IV-VI presenting with PIH on the face, regardless of time of inception or duration of the condition.
- 18-25 years of age
- Males and femalesMalesandfemales
- Participants residing in Cape Town
- Participants who have experienced unsuccessful treatment for their PIH.

3.8.2 EXCLUSION CRITERIA

- Fitzpatrick phototypes I-III
- Participants who are allergic to seawater
- Participants currently using any form of magnesium supplementation
- Participants on Isotretinoin (Roaccutane, Acnetane, Accutane)

3.9 RECRUITMENT PROCESS

The researcher recruited participants by placing an advertisement on a social media platform such as Instagram. The advertisement (Appendix H) included the inclusion and exclusion criteria for the study and contact details, such as the email address of the researcher. Individuals who wished to partake in the research contacted the researcher via email prior to being recruited based on their inclusion criteria.

3.10 SAMPLING PROCESS

As highlighted in the literature review of this study, PIH is a common occurrence in Fitzpatrick skin types IV-VI, which is prevalent in Asian, Black/ African American and Indian ethnic groups (Iwuala et al., 2022; Dadzie., 2009; Frazier et al., 2023; Anvery et al., 2022). Preliminary screening was conducted on individuals who expressed interest in the study. Interviews were conducted to determine the Fitzpatrick phototype and eligibility based on the inclusion and exclusion criteria of the study. Participant questionnaires and consent forms were administered based on the individual's eligibility. Consequently, purposive sampling was used for the selection of participants for this study. Purposive sampling involves the purposeful selection of traits in a population to represent a sample (Mishra et al., 2011). Prior to the commencement of the study, the researcher tested the intervention on twenty interested individuals who met the inclusion criteria. The MgCl₂ liquid was sprayed as a test patch behind the ear to assess tolerability and potential sensitivity to the medium. The study sample originally consisted of twenty participants, but decreased to ten due to participants dropping out.

3.11 DATA COLLECTION PROCESS

3.11.1 PRE- TREATMENT

All participants who met the inclusion criteria were provided with a letter of information, (Appendix A), a consent form (Appendix B), indemnity form (Appendix C), consent for the release of photographs form (Appendix D).

Baseline tests: Each participant completed a participant questionnaire prompting questions based on demographics, existing or previous skin conditions, skin care regimes and sun exposure (Appendix E), and a quality of life assessment (Appendix F). The researcher used a post-inflammatory hyperpigmentation severity scale adapted from Callender et al., (2012) to grade the PIH (Appendix I) prior to the initial treatment. Photos were taken of each participant using a Visia® Skin Complexion Analyser.s

3.11.2 PROCEDURE

The researcher cleansed the participant's skin with micellar water. The MgCl₂ liquid was applied to the participant's skin and left on the skin to determine the tolerability of the applied medium. The areas of focus were the cheeks and forehead. If the participant experienced a tingling sensation, the researcher applied an aloe vera gel to soothe and comfort the skin. A tingling sensation was an indication of a magnesium deficiency in the body and the sensation diminished with the progression of sessions. Each participant completed a PIS (Appendix O), PSS (Appendix L) and erythema grading scale (N) after the initial treatment.

3.11.3 FOLLOW-UP PROCEDURE

Follow-up sessions were conducted on a weekly basis for three months. Skin analysis was conducted six months after the commencement of the study to identify if the effects of the intervention were long lasting. The participants were required to complete the PIS (Appendix O), PSS (Appendix L), and erythema grading scale (N) once more. After photos were taken using a Visia® Skin Complexion Analyser.s Photos were taken using a Visia® Skin Complexion Analyser after the participants completed the required assessments. A data record sheet was kept for each participant to track the changes in the PIH over the six-month period (Appendix K).

3.12 DATA COLLECTION TOOLS

3.12.1 PARTICIPANT QUESTIONNAIRE (APPENDIX E)

The researcher drafted the participant questionnaire, focusing on extraneous factors that could potentially impact the accurate measurement of the research objectives. The key areas highlighted in the participant questionnaire were the participant's age, gender, lifestyle, medical history and skin care behaviours; factors which all play a role in the severity of the presented PIH and the skin's response to the treatment.

All the participants were required to complete the participant questionnaire prior to commencing the research. The responses to the participant questionnaires were tabulated for the purpose of descriptive analysis.

3.12.2 QUALITY OF LIFE ASSESSMENT (QOL) (APPENDIX F)

The QOL used in this study was adapted from the World Health Organisation Quality of Life Brief Version (WHOQOL BREF), which is a 26-item summarised version of the 100-item original version used for measurement in the medical industry (Vahedi., 2010). The domains included in QOL assessments consisted of physical health, psychological health, social relationships and environmental health (Vahedi., 2010). The researcher's prime focus when compiling the QOL assessment for this research was psychological health and social relationships. Examples of questions included; how badly their skin condition impacted the participant's interactions with others, how badly the skin condition impacted their freedom and how self-conscious the skin condition made the participant feel. The participants were required to answer these questions on a scale from 1-10 based on severity (1= least severe and 10= most severe). These scores were statistically analysed to quantify the effect of PIH on quality of life.

3.12.3 POST-INFLAMMATORY HYPERPIGMENTATION SEVERITY SCALE (PIHSS) (APPENDIX I)

A Post-Inflammatory Hyperpigmentation Severity Scale adapted from (Callender et al., 2012), was used to grade the severity of the PIH. The PIHSS has previously been used in studies assessing

PIH in darker phototypes (Grimes et al., 2006; Callender et al., 2012). The PIHSS grades the following domains from 0- 8 on the basis of severity: overall disease severity, pigmentary intensity of hyperpigmented lesions and the percentage facial area of hyperpigmented lesions. The researcher conducted this measurement as a baseline measurement, followed by a secondary measurement six months after the commencement of the research. Baseline photos from the study conducted by Callender et al., (2012) were used as a reference point to grade the disease severity of the participants of this study.

3.12.4 VISIA® SKIN COMPLEXION ANALYSER (GEN 6)

The Visia® Skin Complexion Analyser is able to document progress over time with the use of a multi-point positioning system with live overlay. The camera system is able to display skin surface characteristics two- dimensionally (Henseler., 2022). A rotating capsule captures the left, right, and front views of the skin. The Visia® Skin Complexion Analysers makes use of cross-polarised light, standardised lights and UV light to highlight skin surfaced characteristic in masked areas (Henseler., 2022). The researcher used the Visia® Skin Complexion Analysers to display comparative photos of the participants at the start and end of the study. Validity and reliability with the Visia® Skin Complexion Analysers are ensured with the assistance of a patient photo positioning grid which ensures that every photo is taken at the same angle ensuring consistency throughout measurements.

3.12.5 PATIENT SATISFACTION SCALE (PSS) (APPENDIX L)

A Patient Satisfaction Scale, adapted from a Likert Scale was used to measure participant satisfaction throughout the treatment intervention period. Likert scales are psychometric scales used to measure psychological constructs in respondents in the form of opinions or feelings about certain aspects (Norman., 2010). A PSS was completed by each participant after the first treatment and at the end of the six-month study period. The PSS was used as an indicator of treatment satisfaction throughout the intervention period.

3.12.6 PAIN INTENSITY SCALE (PIS) (APPENDIX O)

A Pain Intensity Scale was completed by each participant after the initial treatment and at the end of the six-month study period. The PIS was used as an indicator of immediate discomfort and tolerance when applying the MgCl₂ liquid, measuring the tolerability of the application over time. For the purpose of collecting quantifiable data, a Numerical Rating Scale (NRS) was used. Numerical Rating Scales depict the level of pain experienced by the participant in the form of numbers, i.e., 0-10. Ten on the scale, represented 'agonizing' pain and zero represented 'no' pain. Study conducted by Silverberg et al., (2021) supported the use of NRS as an excellent psychometric test, especially in patients suffering from skin conditions.

3.12.7 ERYTHEMA GRADING SCALE (APPENDIX N)

Erythema grading scales play a crucial role in skincare interventions by providing standardised methods to assess skin redness, which is a key indicator of inflammation and treatment response. Assessing erythema in skin of colour is quite challenging, as typical redness is often masked by increased melanin, leading to misclassification of inflammatory skin conditions (Forsyth et al., 2025). Whilst a numerical grading scale was used for this research study, a recent study underscores the development and validation of specialised scales, such as the Kesty Redness Scale (KRS), a 5-point ordinal tool that quantifies facial erythema across varying severities. The KRS, when compared to a numerical erythema grading scale, uses photos as a basis for the respective grading score (Kesty and Kesty., 2025).

3.13 STATISTICAL ANALYSIS

Statistical analysis was completed using the Statistical Package for Social Sciences (SPSS) version 28. All statistical analyses were performed with a 95% level of significance ($\alpha = 0.05$). Parametric testing such as the paired samples t-test was used to determine any significant differences in paired measurements. Cohen's D coefficient was as a statistical measure used, quantifying the effect size of variables measured on various scales.

3.14 STANDARD OPERATING PROCEDURE

At the time of data collection, Covid19COVID-19 restrictions were relaxed. The researcher however, still followed safe practices by ensuring the following:

- A safe distance between the researcher and the participant was maintained where possible.
- The researcher and participants ensured that they washed their hands prior to all sessions and in between where necessary.
- Sanitisers was made available to sanitises in between contact with the skin and any other surface and upon entry to the Medispa.
- The Visia® Skin Complexion AnalyserAnalyser was wiped down with a disinfectant solution in between each consultation.
- The surfaces in the study setting were disinfected between each consultation.
- If participants reported that they were not feeling well or who were in contact with someone who had Covid19, appointments would be rescheduled until such a time that the participant is declared fit or within 14 days of reporting symptoms, as per the minimum self-isolation period.

3.15 ETHICAL APPROVAL AND CONSIDERATIONS

The study received full ethics approval (Appendix M) from the Institutional Research Ethics Committee (IREC number 233/21) at Durban University of Technology to conduct it. To ensure the protection of morality, avoidance of misconduct and guarantee accountability on the researcher's behalf, a set of ethical principles established by The Belmont Report were put into place to guide the researcher and the research study. A set of ethical principles established by the Belmont Report was put into place to guide the researcher and the research study, ensuring the protection of morality, the avoidance of misconduct, and accountability on the researcher's behalf. For the research to be deemed 'ethical', the researcher received the following:

- Gatekeeper permission (Appendix G) was sought by SCIN at Wembley Medispa to make use of the facilities and measurement device to conduct the study. The letter of ethical approval (Appendix M) was provided to the National Director of the data collection site.
- The researcher completed an online ethics course through TRREE (Training and Resources in Research Ethics Evaluation) and received certification (Appendix J).

As part of the ethical considerations, the following principles were followed:

- Confidentiality, truthfulness and anonymity: Each participant was assigned a name in the form of a pseudonym and their eyes were blanked out in photographic data to protect their identity. Confidentiality was maintained by storing electronic copies of participant particulars under lock and key with access restricted to the researcher and the supervisors. Electronic data pertaining to the participants was stored on a password protected drive with access restricted to the researcher and the supervisors. Confidential information pertaining to the participants will be stored for a period of five years, after which physical copies of their data will be shredded, and electronic copies of their data will be erased from all removable drives.
- The researcher will remain compliant with the Protection of Personal Information Act (POPIA) for as long as the researcher has access to the participant's information.
- Autonomy & Informed Consent: Prior to participation in the research, participants were required to complete an informed consent form (Appendix B) as well as a consent to the release of photographs form (Appendix D). After agreeing to partake in the study, the participants were at liberty to withdraw at any point that they wished.
- Beneficence: Prior to the commencement of the research, the participants were informed of the potential risks or adverse effects related to the research which was also stated in the letter of information (Appendix A).
- Non-Maleficence: The researcher made sure the participant received the utmost care during all procedures.
- Social Justice: In this research study, every participant received the same intervention and there was no discrimination of any sort. No remuneration was granted to any of the participants.

3.16 DATA MANAGEMENT AND STORAGE

The data collected in the study were strictly accessible to the researcher and supervisor. The data was kept in the possession of the researcher, and physical data will be discarded after five years by means of either shredding or deletion from the researcher's external drive. Personal data, which consists of various forms, is securely stored in a locked filing cabinet. Participant identities have been protected through the distribution of pseudonyms and blacking out the eye area in photos.

All data generated from the Visia® Skin Complexion Analyser will remain in electronic format and be stored on a removable drive in the possession of the researcher.

3.17 CONCLUSION

Chapter 3 provided the reader with a detailed breakdown of the methodology of the research. An explanation of the research design was provided, along with the target population and how the researcher went about selecting the participants using a specific selections-criteria for the study. The data collection process was explained and the ethical principles that governed the research were provided. The researcher provided insight into the choice of data collection tools and the statistical analysis of the data.

CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

This chapter will contain the analysis, presentation, and interpretation of the study's findings. The data analysed was used to identify the effect of MgCl₂ on Post-Inflammatory Hyperpigmentation (PIH) with reference to the following research objectives:

1. To determine the clinical effect of MgCl₂ on PIH in higher skin phototypes.
2. To evaluate the tolerability of massaged MgCl₂ in higher skin phototypes.
3. To explore the impact of PIH on the quality of life.

The resultant data is presented in the form of tables and is interpreted descriptively.

4.2 DEMOGRAPHICS

Twenty ($N = 20$) participants were enrolled for the study. Despite the initial recruitment of 20 participants, only ten ($n = 10$) participants completed the study. Twenty percent ($n = 2$) of the sample size were aged 19 years, 20% ($n = 2$) were aged 20 years, 10% ($n = 1$) were aged 21 years, 10% ($n = 1$) were aged 22 years, 20% ($n = 2$) were aged 24 years and 20% ($n = 2$) were aged 25 years (Table 2).

Age	Counts	% of Total
19	2	20.0 %
20	2	20.0 %
21	1	10.0 %
22	1	10.0 %
24	2	20.0 %
25	2	20.0 %

Table 2: Frequencies of Age

4.3 DESCRIPTIVE ANALYSIS OF PARTICIPANT QUESTIONNAIRES

Statistic	Age	Allergies	PrevMgUse	Eczema	Acne	MedE lab
Sample Size, N	10	10	10	10	10	4
Missing	0	0	0	0	0	6
Mean	21.900	0.400	0.200	0.300	0.700	
Median	21.500	0.000	0.000	0.000	1.000	
Mode	19.000	0.000	0.000	0.000	1.000	
Standard deviation	2.420	0.516	0.422	0.483	0.483	
Variance	5.880	0.267	0.178	0.233	0.233	
Range	6	1	1	1	1	
Minimum	19	0	0	0	0	
Maximum	25	1	1	1	1	
Skewness	0.145	0.484	1.780	1.040	-1.040	
Std. error skewness	0.687	0.687	0.687	0.687	0.687	
Kurtosis	-1.860	-2.280	1.410	-1.220	-1.220	
Std. error kurtosis	1.330	1.330	1.330	1.330	1.330	

^a More than one mode exists, only the first is reported

<i>Continuing...</i>	SunExpose	Sunscreen	ExfolUse	SkinCareReg	PrevTreatmtPIH	PIHEI ab
Sample Size, N	9	10	10	10	10	7
Missing	1	0	0	0	0	3
Mean		0.400	0.400	0.600	0.100	
Median		0.000	0.000	1.000	0.000	
Mode		0.000	0.000	1.000	0.000	
Standard deviation		0.516	0.516	0.516	0.316	
Variance		0.267	0.267	0.267	0.100	
Range		1	1	1	1	
Minimum		0	0	0	0	
Maximum		1	1	1	1	
Skewness		0.484	0.484	-0.484	3.160	
Std. error skewness		0.687	0.687	0.687	0.687	
Kurtosis		-2.280	-2.280	-2.280	10.000	
Std. error kurtosis		1.330	1.330	1.330	1.330	

Table 3: Descriptives of Participant Questionnaires

4.3.1 ALLERGIES

The participants were required to disclose any allergies that could contraindicate the application of MgCl_2 . A total of 40% ($n = 4$) of the participants stated allergies ranging from papaya to avocado, sweet melon, penicillin, fragranced products, artificial colourants, products containing alcohol and shellfish. Sixty percent ($n = 6$) of the participants indicated no allergies (Table 4).

Allergies	Counts	% of Total
0	6	60.0 %
1	4	40.0 %

Table 4: Frequencies of Allergies

4.3.2 PREVIOUS MAGNESIUM USAGE

Eighty percent ($n = 8$) of the sample size have indicated that they have not previously used magnesium in any form, whilst 20% ($n = 2$) of the participants have indicated that they have previously used magnesium in the form of magnesium carbonate and elemental magnesium (Table 5).

Previous Magnesium Use	Counts	% of Total
0	8	80.0 %
1	2	20.0 %

Table 5: Frequency of Previous Magnesium Usage

4.3.3 ECZEMA & ACNE

Seventy percent ($n = 7$) of the sample size indicated that they currently or have previously suffered from eczema and acne, whilst 30% ($n = 3$) of the participants have stated no previous experience of eczema and acne (Table 6).

Eczema & Acne	Counts	% of Total
0	3	30.0 %
1	7	70.0 %

Table 6: Frequency of Eczema & Acne**4.3.4 SUN EXPOSURE, EXFOLIATOR USAGE & SKIN CARE REGIME**

Forty percent ($n = 4$) of the sample size have indicated that they use sunscreen, exfoliate and have a skin care regime; whilst 60% ($n = 6$) of the participants do not make use of sunscreen, do not exfoliate and do not have an existing skin care regime (Table 7).

Sunscreen, Exfoliator, Skin Care	Counts	% of Total
0	6	60.0 %
1	4	40.0 %

Table 7: Frequency of Sunscreen Usage, Exfoliator Usage & Skin Care Regime**4.3.5 PREVIOUS TREATMENT SOUGHT FOR PIH**

Ten percent ($n = 1$) of the sample size has previously sought treatment for their PIH, whilst 90% ($n = 9$) of the participants have not (Table 8). The responses were as follows:

- Participant 2 had a chemical peel two and a half years ago for the treatment of PIH.

Previous Treatment for PIH	Counts	% of Total
0	9	90.0 %
1	1	10.0 %

Table 8: Frequency of Previous Treatment for PIH

4.4 DESCRIPTIVE ANALYSIS OF MEASURING TOOLS

Statistic	QoLB	QoLA	PSS_B	PSS_A	PIS_B	PIS_A	Eryth_ B	Eryth_ A
Sample Size, N	10	10	10	10	10	10	10	10
Missing	0	0	0	0	0	0	0	0
Mean	32.400	28.100	3.000	3.400	1.800	0.800	1.500	0.300
Median	31.000	26.500	3.000	4.000	1.500	0.000	1.500	0.000
Mode	22.000	27.000	3.000	4.000	0.000	0.000	1.000	0.000
Standard deviation	10.400	9.190	0.000	0.966	1.990	1.690	0.850	0.483
Variance	108.000	84.500	0.000	0.933	3.960	2.840	0.722	0.233
Range	25	31	0	3	5	4	3	1
Minimum	21	18	3	1	0	0	0	0
Maximum	46	49	3	4	5	4	3	1
Skewness	0.337	1.370	NaN	-1.960	0.767	1.780	0.000	1.040
Std. error skewness	0.687	0.687	0.687	0.687	0.687	0.687	0.687	0.687
Kurtosis	-1.730	2.130	NaN	4.190	0.794	1.410	0.107	-1.220
Std. error kurtosis	1.330	1.330	1.330	1.330	1.330	1.330	1.330	1.330

<i>Continuing...</i>	Oedema_ B	Oedema_ A	ODS_ B	ODS_ A	PI_B	PI_A	AHL_B	AHL_A
Sample Size, N	10	10	10	10	10	10	10	10
Missing	0	0	0	0	0	0	0	0
Mean	0.300	0.000	3.900	3.400	2.100	1.800	2.200	2.200
Median	0.000	0.000	4.000	3.000	2.000	1.000	2.000	1.500
Mode	0.000	0.000	4.000	1.000	1.000	1.000	1.000	1.000
Standard deviation	0.675	0.000	1.520	2.120	1.200	1.140	1.400	1.480
Variance	0.456	0.000	2.320	4.490	1.430	1.290	1.960	2.180
Range	2	0	5	6	3	3	4	4
Minimum	0	0	2	1	1	1	1	1
Maximum	2	0	7	7	4	4	5	5
Skewness	2.280	NaN	0.678	0.393	0.738	1.050	1.080	0.871
Std. error skewness	0.687	0.687	0.687	0.687	0.687	0.687	0.687	0.687
Kurtosis	4.770	NaN	0.625	-0.874	0.878	0.394	0.265	-0.513
Std. error kurtosis	1.330	1.330	1.330	1.330	1.330	1.330	1.330	1.330

Table 9: Descriptives of Measuring Tools

4.4.1 QUALITY OF LIFE: QUALITY OF LIFE BEFORE (QoLB) VS QUALITY OF LIFE AFTER (QoLA)

The paired samples t-test (Table 10) comparing the QoLB and QoLA interventions yielded a statistically significant difference ($t(9) = 2.400, p = 0.040$).

	t-statistic	df	p	Mean diff	SE diff	95% Confidence Interval		Cohen's d
						Lower	Upper	Effect Size
QoLB vs QoLA	2.400	9.000	0.040	4.300	1.789	0.253	8.347	0.760

Note. $H_a: \mu(\text{Measure}_1) - \mu(\text{Measure}_2) \neq 0$

Table 10: Paired-samples t-test for QoLB VS QoLA

The mean difference of 4.300 (95% CI [0.253, 8.347]) indicates a substantial increase in the quality of life post-intervention (Figure 6). The effect size, as measured by Cohen's d (0.760), falls within the medium range, suggesting a moderate practical significance.

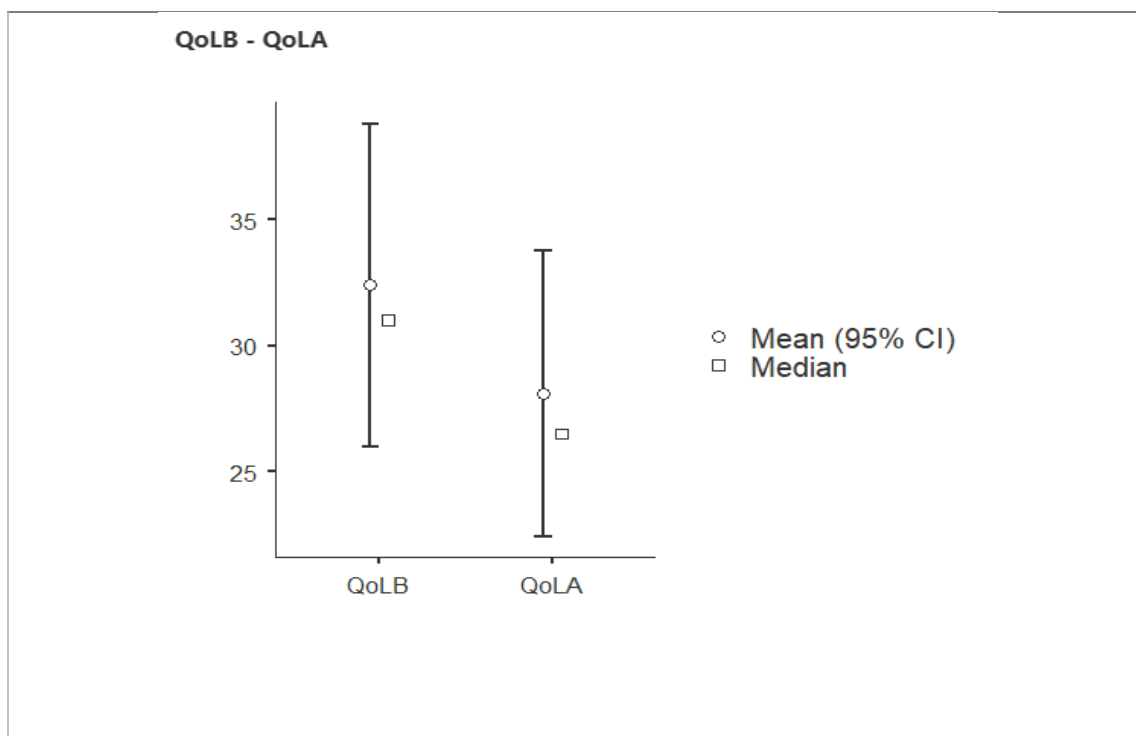


Figure 6: Quality of Life Scores

4.4.2 PATIENT SATISFACTION SCALE: PATIENT SATISFACTION SCALE BEFORE (PSS_B) VS. PATIENT SATISFACTION SCALE AFTER (PSS_A)

Contrastingly, the paired samples t-test (Table 11) for the PSS_B and PSS_A interventions did not reveal a statistically significant difference ($t(9) = -1.310$, $p = 0.223$).

	t-statistic	df	p	Mean diff	SE diff	95% Confidence Interval		Cohen's d
						Lower	Upper	Effect Size
PSS_B vs PSS_A	-1.310	9.000	0.223	-0.400	0.306	-1.091	0.291	0.414

Note. $H_a: \mu(\text{Measure}_1) - \mu(\text{Measure}_2) \neq 0$

Table 11: Paired Samples t-test for PSS_B VS PSS_A

The mean difference of -0.400 (95% CI [-1.091, 0.291]) suggests a negligible change in patient satisfaction scale (Figure 7). The small effect size (Cohen's $d = -0.414$) further supports the limited practical impact.

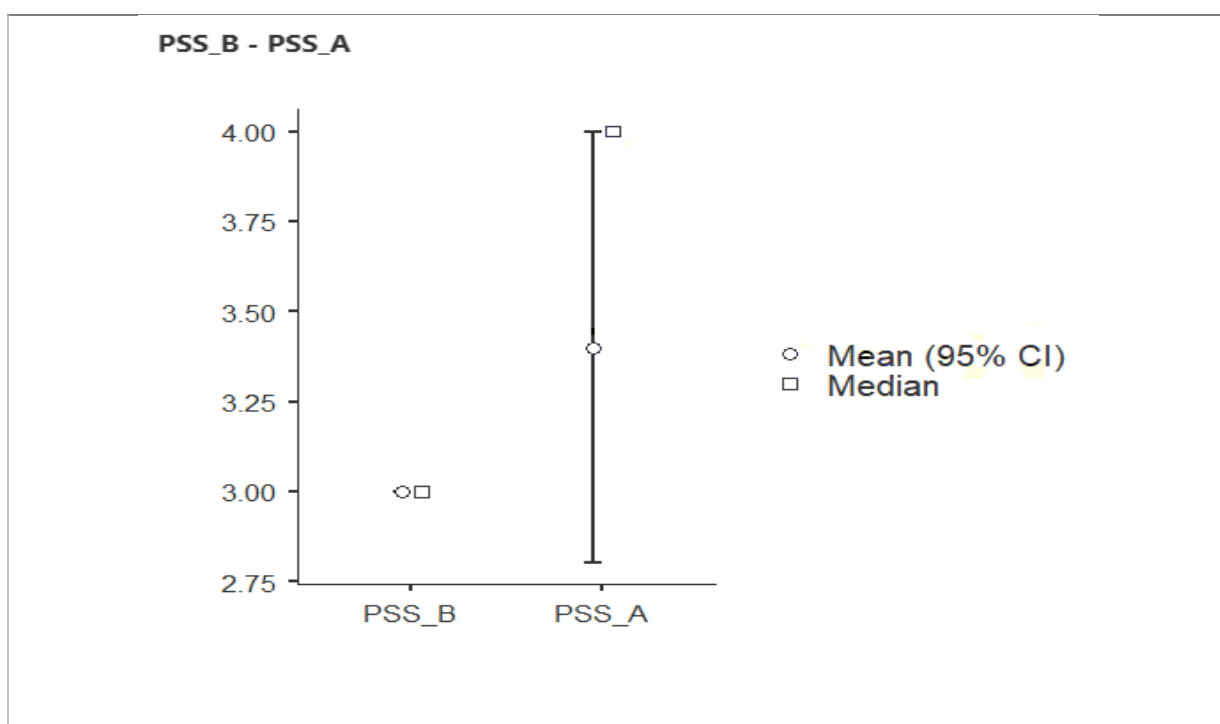


Figure 7: Patient Satisfaction Scale Scores

4.4.3 PAIN INTENSITY SCALE: PAIN INTENSITY SCALE BEFORE (PIS_B) VS. PAIN INTENSITY SCALE AFTER (PIS_A)

The Paired t-test between (Table 12) the PIS_B and PIS_A interventions indicated a statistically significant improvement ($t(9) = 3.000$, $p = 0.015$).

	t-statistic	df	p	Mean diff	SE diff	95% Confidence Interval		Cohen's d
						Lower	Upper	Effect Size
PIS_B vs PIS_A	3.000	9.000	0.015	1.000	0.333	0.246	1.754	0.949

Note. $H_a: \mu(\text{Measure}_1) - \mu(\text{Measure}_2) \neq 0$

0

Table 12: Paired Samples t-test for PIS_B VS PIS_A

The mean difference of 1.000 (95% CI [0.246, 1.754]) denotes a considerable positive impact post-intervention (Figure 8). The effect size (Cohen's $d = 0.949$) is notably large, indicating a substantial practical significance.

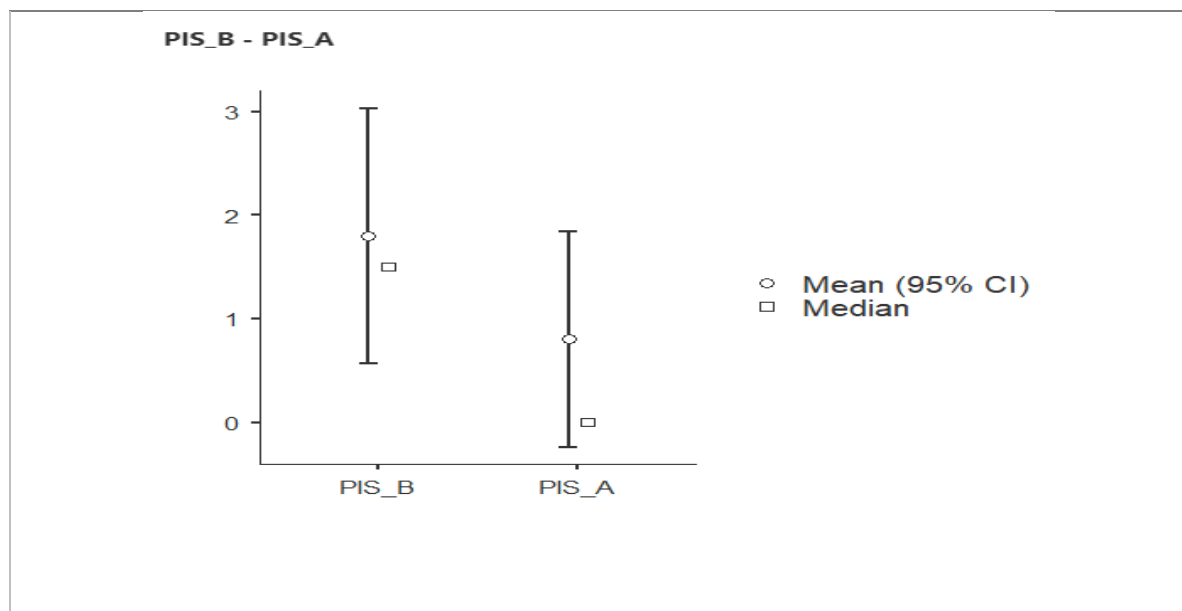


Figure 8: Pain Intensity Scale Scores

4.4.4 ERYTHEMA: ERYTHEMA BEFORE (ERYTH_B) VS. ERYTHEMA AFTER (ERYTH_A)

In the comparison of the Eryth_B and Eryth_A interventions, a highly significant difference was observed ($t(9) = 4.810$, $p < 0.001$). The mean difference of 1.200 (95% CI [0.636, 1.764]) signifies a substantial reduction in erythema post-intervention (Table 13).

	t-statistic	df	p	Mean diff	SE diff	95% Confidence Interval		Cohen's d
						Lower	Upper	Effect Size
Eryth_B vs Eryth_A	4.810	9.000	< 0.001	1.200	0.249	0.636	1.764	1.521

Note. $H_a: \mu(\text{Measure}_1) - \mu(\text{Measure}_2) \neq 0$

Table 13: Paired Samples t-test for Eryth_B VS Eryth_A

The effect size (Cohen's $d = 1.521$) indicates a large and clinically meaningful improvement (Figure 9).

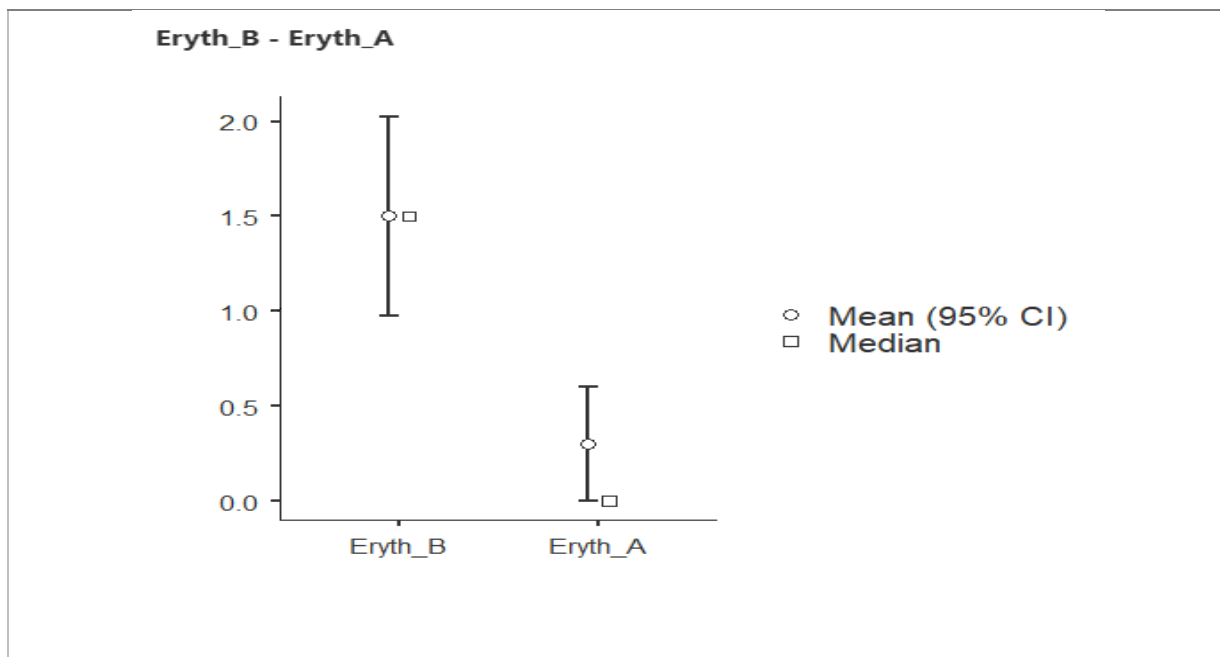


Figure 9: Erythema Scores

4.4.5 OVERALL DISEASE SEVERITY: OVERALL DISEASE SEVERITY BEFORE (ODS_B) VS. OVERALL DISEASE SEVERITY AFTER (ODS_A)

Similarly, the paired t-test comparing the ODS_B and ODS_A interventions did not yield a statistically significant difference ($t(9) = 1.460$, $p = 0.177$). The mean difference of 0.500 (95% CI [-0.273, 1.273]) indicates a modest change in ODS post-intervention (Table 14).

	t-statistic	df	p	Mean diff	SE diff	95% Confidence Interval		Cohen's d
						Lower	Upper	Effect Size
ODS_B vs ODS_A	1.460	9.000	0.177	0.500	0.342	-0.273	1.273	0.463

Note. $H_a: \mu(\text{Measure}_1) - \mu(\text{Measure}_2) \neq 0$

Table 14: Paired Samples t-test for ODS_B VS ODS_A

The effect size (Cohen's $d = 0.463$) is small, suggesting a limited practical significance (Figure 11).

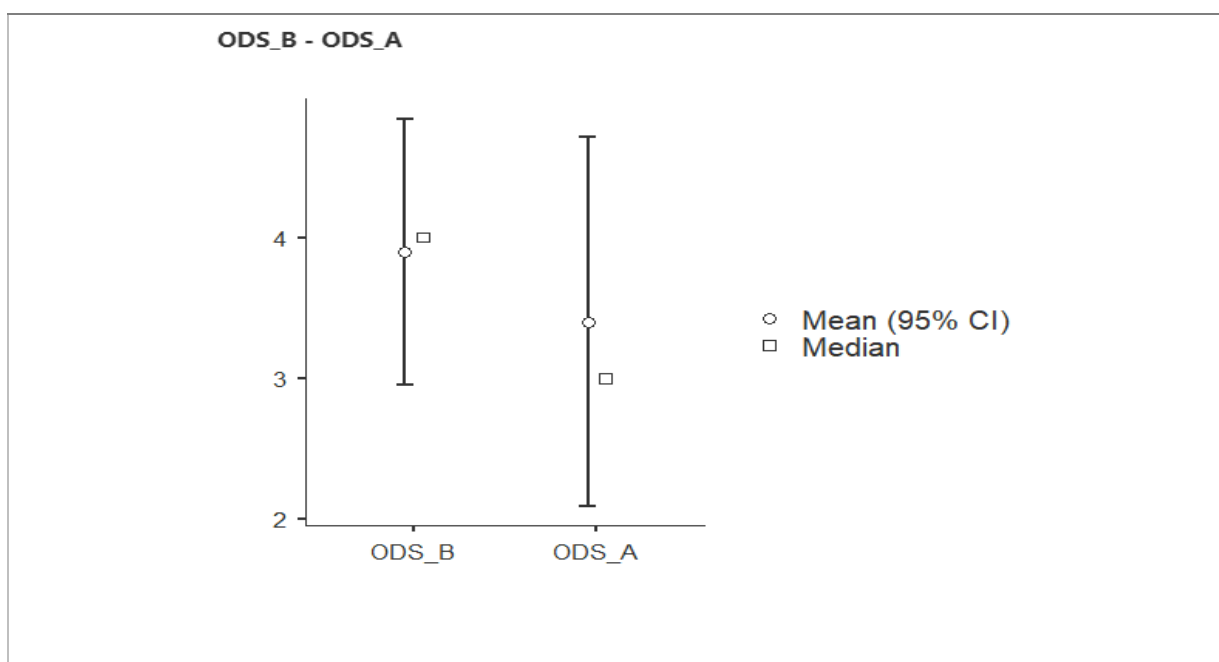


Figure 11: Overall Disease Severity Scores

4.4.6 PIGMENTARY INTENSITY: PIGMENTARY INTENSITY BEFORE (PI_B) VS. PIGMENTARY INTENSITY AFTER (PI_A)

The paired t-test for the PI_B and PI_A interventions did not reveal a statistically significant difference ($t(9) = 1.410$, $p = 0.193$). The mean difference of 0.300 (95% CI [-0.183, 0.783]) suggests a marginal change in pigmentary intensity post-intervention (Table 15).

	t-statistic	df	p	Mean diff	SE diff	95% Confidence Interval		Cohen's d
						Lower	Upper	Effect Size
PI_B vs PI_A	1.410	9.000	0.193	0.300	0.213	-0.183	0.783	0.444

Note. $H_a: \mu(\text{Measure}_1) - \mu(\text{Measure}_2) \neq 0$

Table 15: Paired Samples t-test for PI_B VS PI_A

The effect size (Cohen's $d = 0.444$) is small, indicating a limited practical impact (Figure 12).

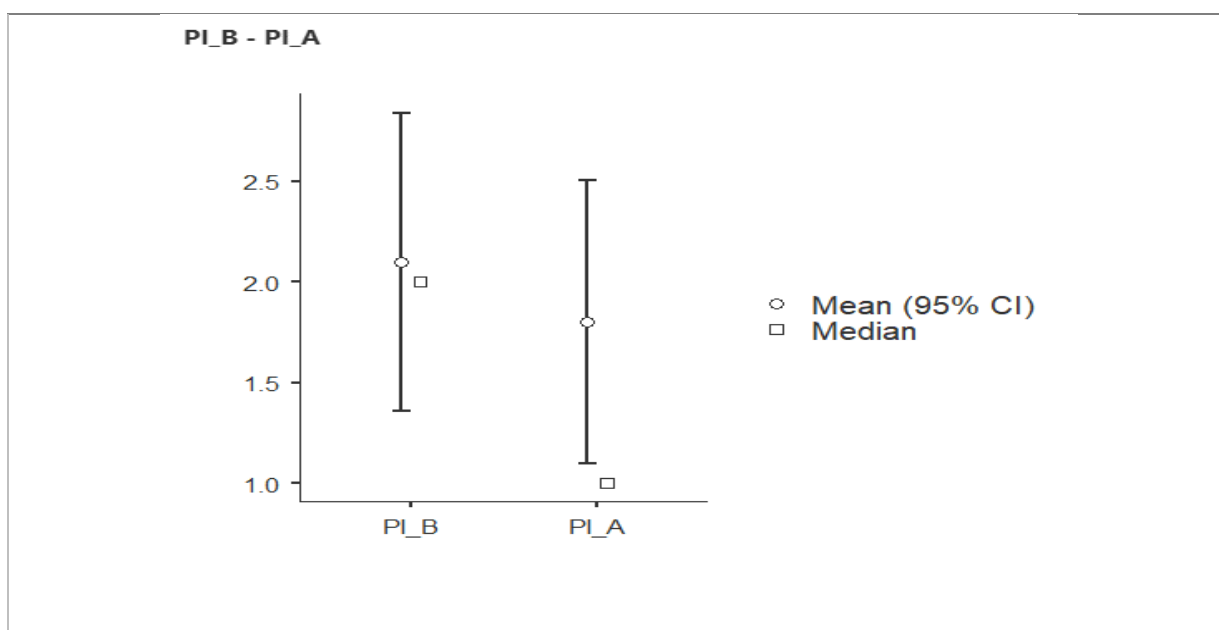


Figure 12: Pigmentary Intensity Scores

4.4.7 AREA OF HYPERPIGMENTED LESIONS: AREA OF HYPERPIGMENTED LESIONS BEFORE (AHL_B) VS. AREA OF HYPERPIGMENTED LESIONS AFTER (AHL_A)

Finally, the paired t-test for AHL_B and AHL_A interventions did not demonstrate a statistically significant difference ($t(9) = 0.000$, $p = 1.000$). The mean difference of 0.000 (95% CI [-0.337, 0.337]) suggests no discernible change in AHL post-intervention (Table 17).

	t-statistic	df	p	Mean diff	SE diff	95% Confidence Interval		Cohen's d
						Lower	Upper	Effect Size
AHL_B vs AHL_A	0.000	9.000	1.000	0.000	0.149	-0.337	0.337	0.000

Note. $H_a: \mu(\text{Measure}_1) - \mu(\text{Measure}_2) \neq 0$

Table 16: Paired Samples t-test for AHL_B VS AHL_A

The effect size (Cohen's $d = 0.000$) confirms the absence of a practical impact (Figure 13).

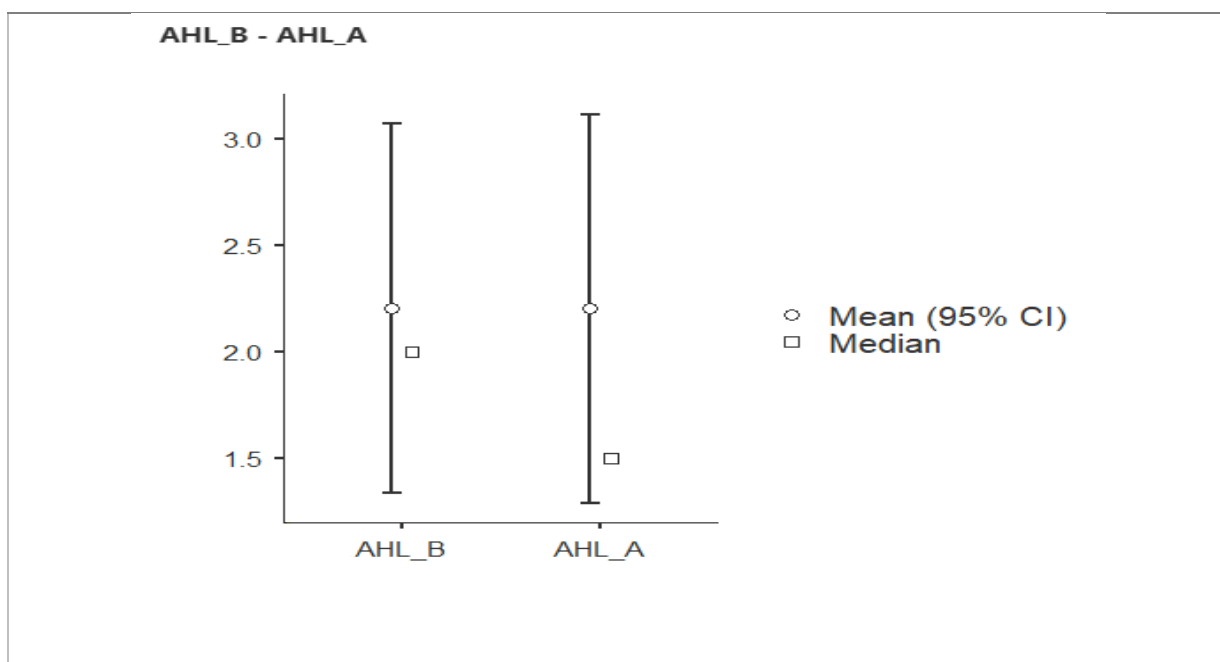


Figure 13: Area of Hyperpigmented Lesions Scores

4.5 VISIA® SKIN COMPLEXION ANALYSER

Pictographic evidence was recorded at baseline (Treatment 1) and at the end of the study at month six using the Visia® Skin Complexion Analyser. Miniscule changes were observed when comparing before and after photos. Whilst the severity of the PIH did not display improvement, the pigmentary intensity displayed slight improvement.

4.5.1 PICTOGRAPHIC DATA

Figure 14 is a depiction of the frontal view of the face of Participant 10. The figure on the left was taken as a baseline measurement (prior to the commencement of the study). The figure on the right depicts the pigmentary changes that have occurred during the course of the study and was taken at month six, the completion of the study.

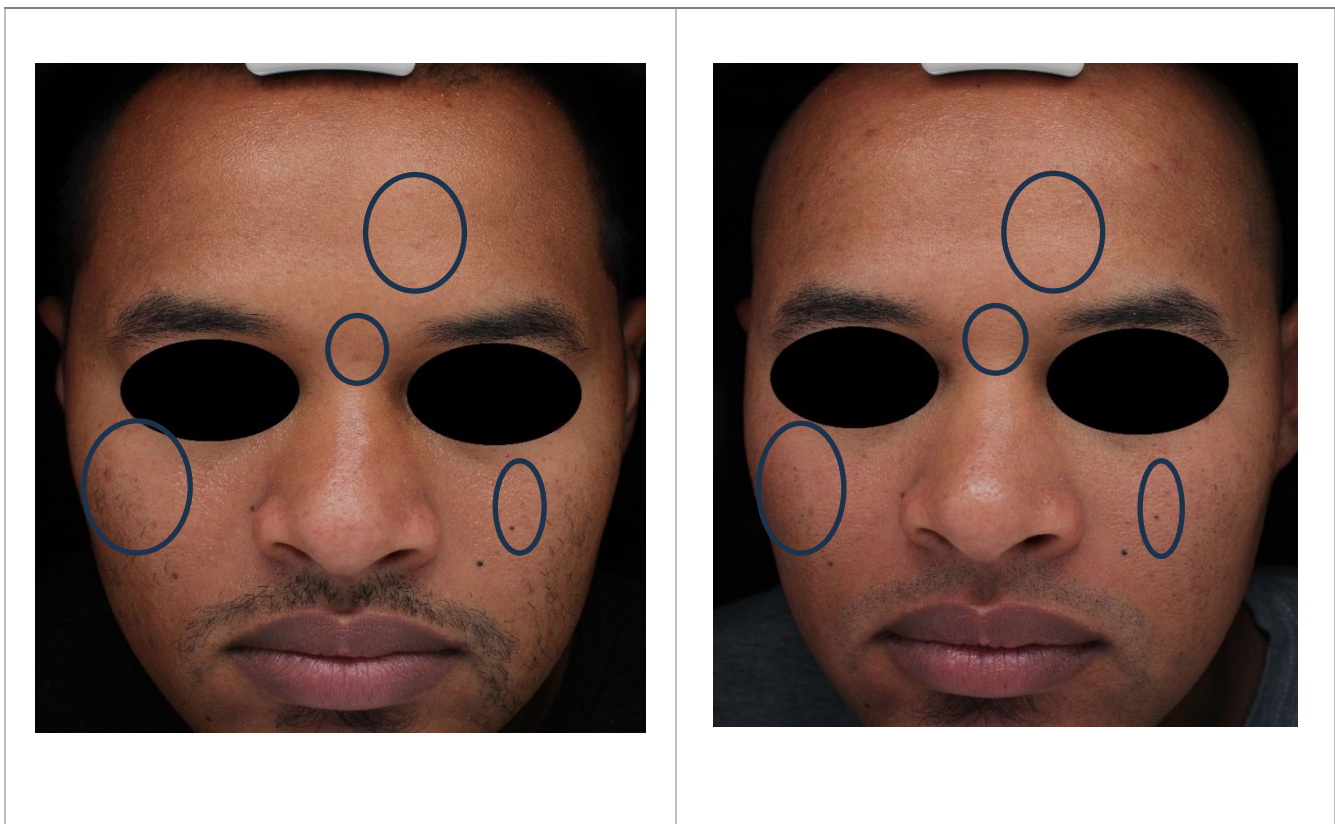


Figure 14: Participant 10- Baseline Front Measurement VS. Completion of Study Front Measurement.

Figure 15 is a depiction of the left side of the face of the face of Participant 10. The figure on the left was taken as a baseline measurement (prior to the commencement of the study). The figure on the right depicts the pigmentary changes that have occurred during the course of the study and was taken at month six, the completion of the study.



Figure 15: Participant 10- Baseline Left Side of Face Measurement VS Completion of Study Left Side of Face Measurement.

Figure 16 is a depiction of the right side of the face of the face of Participant 10. The figure on the left was taken as a baseline measurement (prior to the commencement of the study). The figure on the right depicts the pigmentary changes that have occurred during the course of the study and was taken at month six, the completion of the study.



Figure 16: Participant 10- Baseline Right Side of Face Measurement VS Completion of Study Right Side of Face Measurement.

Figure 17 is a depiction of the frontal view of the face of Participant 1. The figure on the left was taken as a baseline measurement (before the commencement of the study). The figure on the right depicts the pigmentary changes that have occurred during the course of the study and was taken at month six, the study's completion.

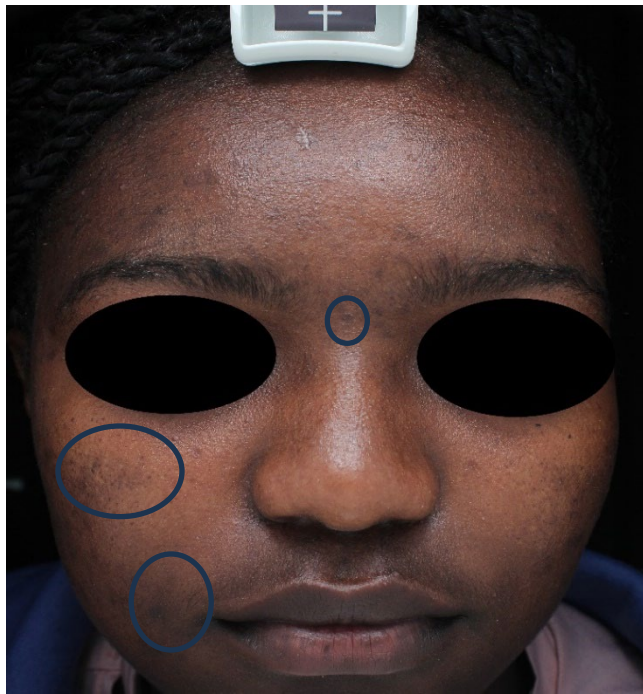


Figure 17: Participant 1- Baseline Front Measurement VS. Completion of Study Front Measurement.

Figure 18 is a depiction of the left side of the face of the face of Participant 1. The figure on the left was taken as a baseline measurement (before the commencement of the study). The figure on the right depicts the pigmentary changes that have occurred during the course of the study and was taken at month six, the study's completion.



Figure 18: Participant 1- Baseline Left Side of Face Measurement VS Completion of Study Left Side of Face Measurement.

Figure 19 is a depiction of the right side of the face of the face of Participant 1. The figure on the left was taken as a baseline measurement (before the commencement of the study). The figure on the right depicts the pigmentary changes that have occurred during the course of the study and was taken at month six, the study's completion.



Figure 19: Participant 1- Baseline Right Side of Face Measurement VS Completion of Study Right Side of Face Measurement.

4.6 CONCLUSION

In summary, Chapter 4 reported the objective findings, elucidating diverse outcomes across the measured variables and underscoring the nuanced effects of the interventions. The findings offer useful insights into the differential impact of interventions across various aspects of health and well-being, informing both clinical practice and future research.

CHAPTER FIVE

DISCUSSION

5.1 INTRODUCTION

Chapter 5 provides a thorough discussion of the study's scope and findings in relation to the research objectives. The discussion elucidates the implications of the research on the treatment of PIH in darker skin phototypes with the use of MgCl₂ liquid. Furthermore, this chapter aims to contribute to scholarly knowledge by offering new perspectives on clinical applications, thereby suggesting avenues for future research.

5.2 DISCUSSION OF FINDINGS

7.2.1 DEOMOGRAPHICS

The range of the age group for the study was 19-25 years. With a mean age of 21.9 years and a median of 21.5, the study was able to streamline results for a late adolescent to young adult age group frequented by PIH and its effects. A skewness of 0.145 depicted a near-symmetrical distribution of ages with a standard deviation score of 2.42, indicating some variability.

Focusing on this specific young adult age group is significant for studying skin conditions such as post-inflammatory hyperpigmentation (PIH) and acne, which often affect individuals in late adolescence and early adulthood. Studies indicate that skin issues like pigmentation and acne are highly prevalent in the 18-25 age demographic, likely driven by lifestyle factors and environmental exposures (Akinboro et al., 2018, Fatima et al., 2020, and Puaratanaarunkon et al., 2022). Pigmentary changes and other related skin concerns in the age group highlight the importance of education on skin health management and addressing dermatological needs using tailored skin care interventions.

7.2.2 ALLERGIES

The mean for the presence of allergies was 0.4, ultimately depicting that less than half of the total participants reported any allergies. A median and mode of '0', supported the most frequent response being 'no allergies present'. The range of data was one. A data range of '1', was a reflection of the binary nature of the allergy status (0 = no allergy or 1 =allergy). The standard deviation of 0.516 and variance of 0.267 depict an average variability in the allergy responses. A skewness value of 0.484 suggests a slight tilt towards non-allergy responses, however, the skewness standard error of 0.687 indicates this skew is not statistically significant. The kurtosis value of -2.280 points to a distribution with lighter tails in comparison to a normal distribution, ultimately indicating fewer extreme values in allergy reporting.

Given the minimal relevant allergies reported in this study, the analysed data support the researcher's careful screening, thereby minimising the risk of allergic reactions. This data highlights participants' adherence to safety.

5.2.3 MAGNESIUM USAGE

The majority of participants in this study reported no prior use of magnesium (80% of the total). Only 20% of participants reported prior use of magnesium, in the form of elemental magnesium or magnesium. This suggests that participants who have indicated no prior use either have no reason to use it or are new to the concept of magnesium use, whether oral ingestions or transdermal application.

The mean value of 0.2 represent the 20% of the total participants who have indicated prior use. Non-usage is reinforced by a zero value for the median and mode. The standard deviations (0.422 and 0.178, respectively) indicate slight variability, but the small sample sizes limit generalizability.

A positive skewness of 1.780 supports the indication of a minority of previous magnesium users . This is further supported by a kurtosis value of 1.410 suggesting a peaked distribution with clustering at zero use.

The limited prior use of magnesium underscores a multitude of considerations, such as a lack of awareness of its associated benefits and applications, potentially altering their impartiality toward treatments that include magnesium as an active ingredient or their willingness to use supplementation. Other forms of magnesium may influence the minority of participants who have indicated prior use.

5.2.4 ECZEMA & ACNE

A considerable 70% of participants reported currently suffering from, or having previously experienced, eczema and/or acne. In comparison, 30% reported no current experience of eczema and/or acne, nor any history of the skin conditions. This statistic supports the high prevalence of post-inflammatory hyperpigmentation in individuals suffering from eczema and/or acne.

The mean value of 0.7 reflects that 70% of participants have eczema and/or acne. The median and mode both indicate a positive central tendency response of 1. The standard deviation of 0.483 and variance of 0.233 highlight the moderate variability in responses. The presence of these skin conditions is further supported by skewness of -1.040 and kurtosis of -1.220 indicating fewer outliers in the skin condition. The importance of skin health management is underscored by the prevalence of hyper-pigmentaryhyperpigmentary triggers, which necessitate ongoing treatment interventions and education.

5.2.5 SUNSCREEN USAGE, EXFOLIATOR USAGE AND SKIN CARE REGIME

Forty percent of the participants reported using both sunscreen and exfoliators, whilst 60% of the participants indicated that they use neither of the two skin care preparations. Based on these findings, more than half of the participants display negligent skin behaviours, and engage in less skin care practices. When asked to comment on sun exposure and the reaction to the sun, mixed responses were noted such as:

- “Sun exposure is avoided”
- “Sun exposure is avoided as it results in erythema”
- “Sun exposure is avoided as the participant experiences hyperpigmentation”

- “Exposure to the sun occurs while driving”
- “Often exposed to the sun”

When asked about frequency of use, some participants reported daily use, whilst others reported weekly use.

The mean value of 0.4 reflects the 40% of participants who frequently use both sunscreen and exfoliators whilst a zero median and mode value depicts non-users. Moderate variability in sun-protectant and exfoliant behaviours among participants is indicated by standard deviations of 0.516 and 0.267, respectively. Whilst the 0.687 standard error of skewness is not highly significant, a skewness of 0.484 indicates a slight tilt towards non-use. Given lower usage rates among 60% of participants, non-use of sunscreen and exfoliators may place these individuals at a higher risk of developing PIH or exacerbating their current PIH.

Similarly, 40% of participants reported having an existing skin care routine, whilst 60% did not. The following responses were obtained from the participants who engaged in structured skin care practices:

- Participant 2: Cleanser & SPF (does not reapply sunscreen after initial application)
- Participant 3: Cleanser, Exfoliator, Toner & Moisturiser
- Participant 4: Precleanser, Masque, Cleanser, Moisturiser, SPF50 (does not reapply sunscreen after initial application)
- Participant 10: Cleanser & Exfoliator

Non-existence of a skin care regime was depicted with a mean value of 0.6. Contrastingly, the mode and median of 1 indicated that those with an existing skin care regimen responded. The standard deviation and variance values of 0.516 and 0.267, respectively, indicate a moderate variation in the responses. A standard error skewness of 0.687 indicates a weak skewness of -0.484, with a leftward tilt, leaning slightly toward participants with a skin care regimen. The absence of skin-protective behaviours increases the risk of PIH formation and severity, thereby prolonging the results, as previously highlighted by Fatima et al. (2020). The use of cosmeceutical products was undertaken by the participant in their personal capacity and was not included in the researcher's study budget.

5.2.6 PREVIOUSLY SOUGHT TREATMENT FOR PIH

Ten percent of the participants (one out of ten participants) indicated having previously sought treatment for their PIH in comparison to 90% of the participants having never pursued any treatment, highlighting that treatment for PIH is uncommon in this group.

The mean value of 0.1 corresponds to the one participant who sought treatment (10). The median and mode of zero reflect a typical 'no' response regarding treatment-seeking behaviour among most participants. The standard deviation and variance of 0.316 and 0.1, respectively, indicate low variability, given a uniform response among most participants. A skewness of 3.160 with a positively skewed distribution and a kurtosis of 10.000 accurately reflect the rarity of treatment-seeking behaviour. The low incidence of treatment-seeking may be due to a range of factors, including accessibility, financial burden, or even lack of awareness, highlighting a gap in the skin care industry.

5.2.7 QUALITY OF LIFE

5.2.7.1 QoL Before Treatment

Before the commencement of the treatment intervention, all the participants collectively, had a mean QoL score of 32.4, a median of 31 and mode of 22, indicating that the QoL levels were moderately spread. The standard deviation and variance of 10.4 and 108, respectively, suggesting a notable variability in individual QoL experiences before treatment. Moderate clustering of scores toward the lower end of the scale were observed with a skewness of 0.337. A flat distribution was indicated by a kurtosis of -1.173.

5.2.7.2 QoL After Treatment

Post-treatment, the QoL score decreased from 32.4 to 28.1, with additional decreases in median and mode scores to 26.5 and 27, respectively. A widening of the range was observed from 18 to 49, whilst the standard deviation and variance reduced to 9.19 and 84.5, respectively, indicating

less variability in post-treatment scores compared to pre-treatment scores. An illustration of a stronger right skew (score of 1.37) and a more peaked distribution (kurtosis score of 2.13) was observed.

The study revealed a significant enhancement in the quality of life score post-intervention, denoting a positive impact on the participants. Not only does this observation address the physical manifestations of PIH but it also suggests a potential influence on the psychosocial well-being of individuals with darker skin phototypes. The observation of QOL scores moving in a positive direction aligns with the broader understanding that skin conditions can significantly affect an individual's self-esteem and overall quality of life (Parna et al., 2015; Cortés et al., 2022). Magnesium chloride liquid, identified as a potential therapeutic intervention, may span beyond its physiological effects, reaching into the realm of psychological well-being.

In addition, the study endorses the use of $MgCl_2$ liquid as an intervention for PIH, complementing existing treatments known for their efficacy in reducing PIH, such as chemical peels, depigmenting agents and the use of sunscreen (Enechukwu., 2019; Piquero-Casals et al., 2023). The study findings emphasize the positive impact on participants' quality of life, which aligns with the broader literature on the structure of psychological well-being. As cited by Dodge et al., (2012), high psychological well-being is defined as a state where an excess of positivity predominates negativity in an individual, and this statement is emphasised by the impact on QOL results depicted in this study. Future research could explore the psychological aspects of PIH treatment, focusing on the intersection of skin care and mental health to gain a more comprehensive understanding of the implications of magnesium chloride liquid in this context.

5.2.8 PATIENT SATISFACTION

After the commencement of the first treatment, uniformity in satisfaction among all participants was depicted by a score of 3 for the mean, median, and mode. Satisfaction ratings were neither high, nor low, with no variability as the standard deviation and variance both depicted a zero value. A lack of variability prohibited the calculation of skewness and kurtosis. An overall improvement in patient satisfaction was observed at the end of the study period with mean scores increasing to 3.4, median and mode scores increasing to 4.

A standard deviation of 0.966 and a variance of 0.933 indicated post-treatment variability, with a range from 1 to an unspecified upper limit. A strong left skew was observed (skewness = -1.960), further supported by a positive kurtosis of 4.190, indicating a peaked distribution with a cluster of satisfaction scores toward the higher end. Most scores were high, but some participants reported lower satisfaction rates, possibly due to their perception of the treatment outcome.

Despite the anticipated positive impact on patient satisfaction, as measured by the Patient Satisfaction Scale (PSS) (Appendix L), the post-intervention results did not demonstrate a statistically significant difference in scores. This minuscule change suggests that while participants experienced physical improvements in the treatment of PIH, their overall satisfaction with the process remained relatively stable.

5.2.9 PAIN INTENSITY

After the commencement of the first treatment, a mean score of 1.8 was reported, with a median and mode of 1.5 and 0, respectively. The pain score ranged from 1 to 5, with some participants experiencing moderate pain and others experiencing none. Considerable variability in pain levels were depicted in the standard deviation and variance scores of 1.99 and 3.96, respectively. A positive skewness of 0.767 supported some participants reporting lower pain scores, while others reported higher tendencies. A broad spread of pain scores with a relatively flat distribution was noted with a negative kurtosis value of -0.794.

Post-intervention, a decrease in pain intensity score to 0.8 and a median and mode value of 0, indicated no pain experienced at the end of the intervention. The range experienced a slight shift from 1-5 to 1-4 with a slightly reduced standard deviation and variance of 1.69 and 2.84, respectively. As a result, less variability was observed compared to the data after treatment one. A kurtosis score of 1.41 and skewness of 1.78 indicates a peaked distribution with clustering at lower pain intensity values.

The findings revealed a statistically significant improvement in pain intensity scores post-intervention. This suggests a potential contribution to pain alleviation associated with PIH, thereby enhancing the overall treatment experience. This promising result prompts further exploration of

the mechanisms behind magnesium chloride's analgesic properties in skin care, creating avenues for future investigations (Yin et al., 2013; Enechukwu., 2019; Roggenkamp et al., 2021; Callender et al., 2021).

5.2.10 Erythema & Oedema

5.2.10.1 Erythema & Oedema Before Treatment

After the commencement of the first treatment, erythema scores showed mean and median of 1.5, with a mode of 1, whilst oedema scores had a mean of 0.3, a median and a mode of 0. The range of scores for erythema were between 0 and 3, suggesting either no presence of erythema or moderate presence whilst oedema scoring ranged from 0 to 2, suggesting no oedema or very mild cases thereof. Moderate variability in erythema severity was observed, with a standard deviation of 0.85 and a variance of 0.72. Some variability was noted in oedema with standard deviation and variance scores of 0.675 and 0.456, respectively. A skewness of 0 and kurtosis of 0.107 suggests a distribution fairly close to zero for erythema, whilst a skewness of 2.280 for oedema indicates very low oedema score with the presence of outliers with higher scores.

Post-intervention, a significant decrease in the mean was noted (0.3), with a median and mode indicating that participants experienced little to no erythema. The range decreased to 0-1, whilst the standard deviation and variance decreased to 0.483 and 0.233, respectively. These findings depicted a decreased variability in responses. Low scoring, with some participants still experiencing mild erythema was observed with a skewness of 1.04. A flat distribution was observed with a negative kurtosis of -1.22. No variability in oedema was observed because the score decreased to zero, indicating that no oedema was experienced post-treatment.

The notable reduction in mean, median, and mode scores post-treatment suggests that the application of MgCl₂ does become tolerable over time, proving safety with usage. The significant reduction of oedema to none at all further supports the treatment intervention's ability to manage PIH with minimal discomfort. In the long-term management PIH, a multifaceted approach is necessary, encompassing topical agents, dietary considerations, and photoprotection. These factors all play a role in the skin's inflammatory response resulting in erythema. UV light exposure exacerbates PIH, highlighting the importance of photoprotection (Callender et al., 2021). While

various treatments show potentiality in reducing hyperpigmentation and mitigating erythema scores associated with PIH, further research relating to MgCl₂ is needed to optimise treatment strategies, particularly in diverse patient populations (Callender et al., 2021; Enechukwu., 2019; Taylor et al., 2009).

5.2.11 OVERALL DISEASE SEVERITY

5.2.11.1 Disease Severity Before Treatment

A median and mode score of 4 was seen among all the participants, with an overall disease severity score of 3.9. Overall disease severity scoring ranged from 2 to 7, a range reflection of a moderate to severe of disease impact. The standard deviation and variance of 1.52 and 2.32, respectively, illustrate the moderate variability in severity across the sample. A slight positive skew (0.678) is seen with severity scoring toward the lower end of the scale. Moderation clustering of score around the mean with a slightly peaked distribution is highlighted with a kurtosis of 0.625.

5.2.11.2 Disease Severity After Treatment

Mean disease scoring and the median decreased to 3.4 and 3, respectively indicating improvement. A mode of 1 depicted frequent reporting of lower severity. An increase in variability of responses was noted with a range increasing slightly to 6. The standard deviation and variance increased to 2.12 and 4.49, respectively indicating severity scores of a broader spread. A slightly less pronounced positive skew was noted with a reduction in skewness of 0.393, and a flatter distribution was seen with a kurtosis value of -0.874.

The finding indicate an overall reduction in severity scoring post-treatment, showing a positive intervention improvement in disease status. Whilst a positive treatment effect for a substantial subsets was reinforced by changes in the mode scores, the increase in variability in treatment responses depicted a marked improvement in some participants, but persistence or no change in others.

5.2.12 PIGMENTARY INTENSITY

5.2.12.1 Pigmentary Intensity Before Treatment

Before the commencement of the intervention, mean pigmentary intensity scores of 2.1, a median of 2 and a mode of 1 was observed. Mild to moderated changes in pigment were noted with a range score of 1 to 4. Moderate variability was reflected by a variance and standard deviation of 1.43 and 1.2, respectively. A tendency toward lower pigment scores was noted by a positive skewness of 0.738. A flatter distribution was highlighted with a negative kurtosis of -0.878.

5.2.12.2 Pigmentary Intensity Post-Treatment

The decline in mean and median pigmentary intensity scores, 1.8 and 1.0, respectively, underlines a shift towards a reduction in pigment intensity. A stable mode of 1 before and after the treatment intervention depicts a common low pigmentary intensity but median shifting support the movement toward a reduced pigmentary intensity. Although some participants presented with a more persistent pigmentary intensity, an increased skewness of 1.05 depicted clustering at lower intensity values with a standard deviation of 1.14 showing a slight decrease in variability. These findings align with the fact that the greater majority of participants do not have any substantial skin care regimen which could potentially support the efficacy of the treatment intervention.

5.2.13 AREA OF HYPERPIGMENTED LESIONS

The analyses of the data suggests that although the average lesion area remained stable across all participants, a reduction of the area of hyperpigmented lesions was noted in some participants post-intervention. The decrease in median and mode, along with subtle shifts in distribution, revealed individual variability among the participants in their treatment response. Improvements in median lesion size were highlighted, suggesting treatment benefits to the participants however, the mean lesion size displayed no change with a score of 2.2 before and after the treatment intervention. Median scores depicted a slight decreased from 2.0 to 1.5, and the mode remained at 1, an indication that a reduction in lesion size was experienced by more than half of the

participants. A slight increase in variability post-intervention was highlighted by the standard deviation increasing marginally from 1.4 to 1.48 and the range remaining consistent from one to five. A mild shift toward smaller lesion sizes was noted with a positive skewness decrease from 1.08 to 0.87. a flatter distribution was observed with a kurtosis changing from 0.265 to -0.513. Evidenced by lower median scoring and reduced skewness post-treatment, the findings suggest that although no change was seen in the average lesion size among all participants, improvement in the reduction of hyperpigmentation lesion areas was noted for a portion of the group.

5.3 CONCLUSION

The aim of the study was to determine the clinical effect of topical MgCl₂ liquid on PIH in higher skin phototypes, factoring in objectives such as tolerability of the massaged medium considering aspects such as erythema, oedema and pain intensity.. Significant improvements in quality of life, pain intensity, and erythema and overall tolerability were notable however, the study underscores the necessity for further research to optimise treatment outcomes, address patient satisfaction, further observe substantial pigmentary changes in addition to overall disease severity and increase overall understanding of skin care interventions for higher skin phototypes. The findings create avenues for future research, aiming to bridge the existing gaps in knowledge and provide safer and more effective treatments for individuals with PIH in higher skin phototypes. The results of this research study have been disseminated in an article submitted to PLOS One for peer review (Appendix P). The journal article is titled '*The effects of magnesium chloride liquid on post-inflammatory hyperpigmentation in higher Fitzpatrick skin phototypes: A pilot study*' and was co-written by Ashurah Scheepers, Michael Paulse and Nomakhosi Mpofana.

CHAPTER 6

CONCLUSION AND RECOMENDATIONS

6.1 INTRODUCTION

The purpose of the chapter is to address the challenging prospect of treating PIH in individuals with higher skin phototypes, an area where existing interventions present limitations and risks. Focusing on the potential of MgCl₂ liquid, the study aimed to investigate its effects on PIH, exploring aspects of efficacy, tolerability, and impact on quality of life. The panoramic approach involved a quantitative, experimental research design, spanning three months and engaging participants in a Somatology clinic setting in Cape Town, Western Cape.

6.2 CONCLUSIONS

The study demonstrated a significant improvement in quality of life scores post-intervention, highlighting the broader impact of MgCl₂ liquid beyond its dermatological effects. This finding suggests that a potential positive impact on PIH may lead to improved quality of life scores. The identified enhancement in quality of life is in line with the study's broader goal of contributing to treatments that address not only physical symptoms but also the broader impact on individuals' lives. The successful management of PIH is due in part to the strength of the 'patient–therapist' relationship. In the treatment of individuals suffering from PIH, somatologists must work with these individuals to locate the most suitable treatment options and establish reasonable expectations for PIH and the treatment thereof. In a skin condition that disproportionately affects patients of colour, utilising patient-centric language that is both culturally and racially sensitive is vital to effectively communicate the available treatment options, the possibility of experiencing side effects, and proper treatment use

Distinctly, the study revealed a statistically significant improvement in pain intensity scores post-intervention. This outcome indicates that although MgCl₂ liquid is stimulating as a skin preparation, consistent use and adherence to the application lead to better skin tolerability and reduced

discomfort over time. While the study showcased a significant decrease in erythema scores, indicating an improvement in redness associated with PIH, the impact on overall disease severity and pigmentary intensity displayed practical limitations. This nuanced outcome prompts questions about the comprehensive effectiveness of MgCl₂ liquid as a stand-alone intervention in addressing all aspects of PIH. The findings emphasise the complexity of PIH and suggest potential avenues for future research, including exploring combinations of MgCl₂ liquid with other therapeutic agents to effectively treat PIH as a long-term solution.

6.3 CONTRIBUTIONS TO SCHOLARLY KNOWLEDGE

This study contributes to scholarly knowledge by:

1. **Highlighting the Multifaceted Impact of PIH Treatment:** Beyond the visual improvements, the study highlights the psychological and analgesic aspects of MgCl₂ liquid treatment, expanding the understanding of holistic dermatological interventions.
2. **Addressing the Gap in Treatment for Higher Fitzpatrick Skin Phototypes:** The research underscores the limited existing literature on safety and efficacy of PIH treatments tailored to individuals with higher skin phototypes, identifying a critical need for further research in this niche.

6.4 LIMITATIONS OF THE STUDY

A small sample size, coupled with a high participant dropout rate, may have impacted the skewness of the results, especially since those who discontinued from the study differed in age and the severity of PIH in comparison to those participants who completed the study. The robustness of the findings may have been affected by a high dropout rate as a result of COVID-19 barriers, impacting the willingness to participate. The age restriction of 18-25 years of age may have limited the applicability of results to older populations, especially since younger skin has a tendency to heal faster and therefore, respond better to treatment interventions. A potential bias was introduced by the absence of a placebo-controlled arm, making it difficult to determine whether the observed improvements were solely due to the MgCl₂ liquid or to external factors. The use of

non- disease specific measurement tools may have lacked the sensitivity to detect the subtle changes in the PIH, which may have underestimated the true treatment effects. Differing habits and product ingredients in the various skincare routines amongst the participants may have influenced the severity of PIH, impacting treatment outcomes.

6.5 RECOMMENDATIONS FOR FURTHER RESEARCH

6.5.1 ADHERENCE TO TREATMENT

Participant compliance with the recommended application frequency and duration is a crucial aspect requiring attention in future research. Adherence to treatment regimens plays an important role in determining the effectiveness of interventions across diverse medical conditions (Hamine et al., 2015). Poor adherence has been associated with negative impacts on disease-specific clinical outcomes and the management of chronic conditions (Hamine et al., 2015; Perwitasari et al., 2022). In specific dermatologic contexts such as PIH, adherence to treatment assumes greater importance. Successful reduction of PIH is linked to the use of specific inhibitors and cosmetic products (Roggenkamp et al. 2021; Bae et al. 2019), contingent upon participant adherence to the prescribed application frequency and duration. Non-adherence to treatment for conditions like acne and mild to moderate acne leads to poor clinical improvement (de Lucas et al., 2015; Fernandez-Lazaro et al., 2019).

In skin care, the association between adherence and clinical improvement has been extensively explored. The monitoring of adherence to topical therapy in children and young people underscores its importance in achieving favourable treatment outcomes (Green et al. 2022). Additionally, the use of ablative lasers in facial melasma treatment minimizes PIH, placing emphasis on the significance of treatment adherence in attaining optimal clinical results in darker phototypes (Morais et al. 2013).

In summary, participant adherence to the prescribed treatment regimen intricately influences the impact of MgCl liquid on PIH. Existing literature consistently points out the important role of adherence in achieving favourable clinical outcomes across various medical conditions, particularly in dermatologic contexts such as PIH.

Building upon the study's outcomes, future research could explore combination therapies involving MgCl_2 liquid and other topical agents or procedures to optimise treatment efficacy. Long-term follow-up studies could offer questions about the sustainability of improvements observed, while investigations into the psychosocial impact of dermatological conditions may enhance our understanding of the relationship between skin health, mental well-being, and quality of life.

Understanding the multifaceted factors that contribute to patient satisfaction is crucial for adherence to treatment and overall success. Future investigations should explore the influence of patient expectations, communication, and perceived treatment effectiveness in shaping patient satisfaction levels. Qualitative research methods may provide a greater understanding of patient experiences, enriching our comprehension of the complexities that surround physical outcomes and subjective satisfaction.

Examining the chemical composition of MgCl_2 , is essential in the detection of potential contamination and implications for certain applications (Pownceby et al. 2010). The study on the solid-liquid phase equilibrium of aqueous ternary systems involving MgCl_2 contributes insights into its phase behaviour, enriching our understanding of its properties and potential applications (Ge et al. 2020). Additionally, the ability to image local ionic concentration in magnesium corrosion processes has implications for understanding corrosion involving magnesium (Izquierdo et al. 2013).

Although MgCl_2 liquid did not significantly affect patient satisfaction after the intervention, future studies should consider various factors, such as measurement methods and chemical composition, to explore its role in patient satisfaction outcomes.

6.6 SUGGESTIONS FOR FURTHER RESEARCH

6.6.1 Long-Term Follow-Up Studies

A longitudinal investigation with extended follow-up periods would give evidence about the sustainability of the improvements observed and the potential long-term effects of MgCl_2 treatment.

6.6.2 Psychosocial Impact of Dermatological Conditions

Further research could explore the psychosocial impact of dermatological conditions, examining the interplay between skin health, mental well-being, and quality of life.

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Appendix A: Letter of Information



LETTER OF INFORMATION

Title of the Research Study: The Effect of Magnesium Chloride on Post-Inflammatory Hyperpigmentation

Principal Investigator/s/researcher: Ashurah Scheepers (BTech: Somatology)

Co-Investigator/s/supervisor/s: Dr Nomakhosi Mpofana (PhD: Medicine [Dermatology])

Good Day

I am a postgraduate student at Durban University of Technology (DUT), doing my Master's degree in Somatology. The topic of my research is *The Effectclinical of Magnesium Chloride on Post-Inflammatory Hyperpigmentation. in higher Fitzpatrick skin phototypes*

Brief Introduction and Purpose of the Study:

Post-inflammatory hyperpigmentation (PIH) is an inflammatory condition that may occur in all skin types but is common among darker skin phototypes (Farage et al., 2010). PIH is characterized by the

overproduction of melanin caused by skin inflammation (Kaufman et al., 2018) and can be identified by small, scattered hyperpigmented macules to large hyperpigmented patches of skin (Callender et al., 2011).

Darker-skinned individuals are more likely to experience PIH due to an increase in the production or deposition of melanin (Callender et al., 2011). Current interventions include the use of laser therapy or chemical peels. These treatment modalities may not be suitable for darker skin types as they pose the risk of exacerbating the condition post treatment (Doyal et al., 2019).

In South Africa, there are many skin care clinics offering treatments to improve the appearance of PIH. These treatments however, may be costly over a period of time as hyperpigmentation therapy requires repetitive treatments. Conducting this research may yield results in favour of providing a treatment for PIH which may be long-lasting, non-invasive and cost effective with little to no side effects and ease of access.

Studies have shown that Magnesium Chloride is effective in the treatment of inflammatory conditions, specifically arthritis, muscle stiffness and acne (Last, 2020). There is a paucity of data validating the effects of Magnesium Chloride Liquid on Post-Inflammatory Hyperpigmentation.

I would like to invite you to participate in this research. Understanding the purpose and scope of the research is crucial before making your decision. I am therefore, providing you with the following information in which you should take time to read carefully.

Outline of the Procedures: The research aims to determine the effects of magnesium chloride solution on post-inflammatory hyperpigmentation.

The objectives of the study will be:

- To determine mine the clinical effect of $MgCl_2$ liquid on PIH in higher phototypes
- To evaluate the tolerability of massaged $MgCl_2$ liquid on higher phototypes
- To explore the impact of PIH on quality of life

Inclusion Criteria:

- Participants with a Fitzpatrick phototype IV-VI presenting with PIH on the face will be enrolled in this study.
- 18-25 years of age
- Males and females
- Residents of Cape Town

Exclusion Criteria:

- Fitzpatrick phototypes I-III
- Individuals with a sea water allergy
- Individuals currently using any form of magnesium supplementation
- Individuals on Isotretinoin (Roaccutane, Acnetane, Accutane)

Twenty participants are required for the research. Every participant will receive the same intervention (magnesium chloride liquid applied to their face). For the initial treatment, 45 minutes are required from you. During the 45 minutes, we will complete and discuss your consent form, indemnity form, consent for release of photographs form, a participant questionnaire and a quality-of-life questionnaire. Photos will be taken using a Visia® Skin Complexion Analyser Gen 6, and the Disease Severity will be graded at Wembley SkinMed. Your initial treatment will then proceed with me applying the magnesium chloride liquid to your face and an aloe vera gel (should you not be able to withstand the tingling/burning sensation of the magnesium chloride liquid).

It is your responsibility to ensure that you do not wear makeup prior to the treatment and to arrive on time so as to respect the time allowed for research by the institution. The research will be conducted over a period of 6 months. The magnesium chloride solution will be applied to your skin once a week for 3 months and follow-up measurements will take at the 6 month mark, at the end of the study.

Risks or Discomforts to the Participant: There are no risks involved in this study. You may experience a tingling or burning sensation after the magnesium chloride has been applied to your skin. This sensation does however diminish after a few minutes.

Reasons for withdrawal from the study: Participation in this research is voluntary and you may withdraw at any point. Should you decide to withdraw from the research, your withdrawal will be noted. I will request to continue using your data in the research and report findings on the data collected up and until the point of withdrawal. Should you not allow further use of your information, all of your information will be erased/discarded of.

Your participation in the research may also be terminated for reasons such as non-compliance, adverse reactions, not falling within the inclusion criteria or if it may not be in your best interest to participate. In this case, your termination will also be noted and all of your information will be erased/discarded of.

Benefits: The research will potentially help you gain insight on how to go about treating post-inflammatory hyperpigmentation. Should the research yield favourable results, you will have first-hand experience of a cost effective, long-lasting and non-invasive solution to post-inflammatory hyperpigmentation. As a result, the findings may positively influence your quality of life.

Remuneration: You will not be remunerated for your participation in this research as your participation is voluntary

Costs of the Study: There are no costs involved in your participation in this study. Note that participation in this research is voluntary, and you will therefore be responsible for your travelling costs to the institution where the research will be carried out.

Confidentiality: Confidentiality and privacy will be maintained by assigning you with a pseudonym in place of your name. An example of this would be to call you 'Participant A or Participant 1' as opposed to using your name. When taking photographs of your face, your eyes will be blocked out in the photos where they are visible. All of your information will be stored either in a filing cabinet under lock and key or on a

computer hard drive protected by a password. The only individual who will have access to your information will be myself and my supervisors. In this way, your identity will remain confidential.

Results: The results of the study will be provided to you should you be interested and will also be available to other scholars who have access to Durban University of Technology's repository. A desired outcome of the research is also for it to be published in an accredited journal. Should there be any significant and new findings in the study, all the results will be compiled and made available to you at the end of the study.

Research-related Injury: Research injuries will be mitigated as far as practically possible. The research is however, still governed by the terms and conditions of the indemnity form that you will be required to complete prior to taking part in the study. Note that your well-being is still the main priority.

Storage of all electronic and hard copies including tape recordings: All hard copies of your information will be kept in a filing cabinet under lock and key. Electronic data will be stored on a computer protected by a password. All information will be kept for a period of 5 years after the study has been conducted and only myself and my research supervisors will have access to your information. After 5 years, all of your confidential information will be completely erased from my computer storage and hard copies will be shredded.

Persons to contact in the Event of Any Problems or Queries: Please contact the researcher Ashurah Scheepers (084 248 0786), my supervisor Dr SNomakhosi Mpofana (078 608 7119) or the Institutional Research Ethics Administrator on 031 373 2375. Complaints can be reported to the Director: Research and Postgraduate Support Dr L Linganis on 031 373 2577 or researchdirector@dut.ac.za.

Appendix B: Consent Form



CONSENT

Full Title of the Study: The Effect of Magnesium Chloride on Post-Inflammatory Hyperpigmentation

Names of Researcher/s: Ashurah Scheepers

Statement of Agreement to Participate in the Research Study:

- ☐ I hereby confirm that I have been informed
by the researcher, Ashurah Scheepers
, 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 computerized 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, Ashurah Scheepers, herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the study.

_____	_____	_____
Full Name of Researcher	Date	Signature

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

_____	_____
Full Name of Legal Guardian (If applicable)	Date

	Signature

Appendix C: Indemnity Form



INDEMNITY FORM

I, the undersigned hereby agree as follows:

- I am aware of the dangers of personal injury to which I may be exposed as a result of my participation in any research projects and I understand and accept that my participation in such activities is at my own risk for which I accept all responsibility.
- I indemnify and agree to hold Wembley ScinMed and DUT Department of Wellness Sciences, its members and employees, blameless in the event of any injury to myself, whilst participating in any research at Wembley ScinMed, including travelling to or from any of these activities.
- I hereby waive all claims of any nature that I have or may in the future have against Wembley ScinMed and DUT Wellness Sciences arising out of my participation in the MHSc thesis dissertation.
- I declare that I am medically fit to attend the activity, and I do not pose any threat or risk to myself.
- Should I be injured whilst participating in the thesis dissertation at the Wembley ScinMed, I authorise any first-aid qualified members of staff to perform first aid medical treatment at the activity. I further hereby appoint and authorise the activity leader to consent to my undergoing medical treatment. I further undertake to pay the cost of the treatment.

I hereby confirm that I have read and understood this agreement prior to signing it and I am aware that by signing this agreement I am waiving certain legal rights which I may have against Wembley ScinMed and DUT Department of Wellness Sciences.

Full Name of Participant:

Date:

Time:

Signature:

Full Name of Researcher:

Date:

Signature:

Appendix D: Consent for The Release of Photographs



CONSENT FOR RELEASE OF PHOTOGRAPHS

I hereby state that:

- I understand that photographs will be taken by the researcher.
- I consent for these photographs to be used within the dissertation by the researcher.
- I understand that my eyes will be blocked out in photographs where they may be visible

Full Name of Participant:

Date:

Time:

Signature:

I, Ashurah Scheepers, herewith confirm that the participant has consented to the release of their photographs for the purpose of the study.

Full Name of Researcher:

Date:

Signature:

Appendix E: Participant Questionnaire



PARTICIPANT QUESTIONNAIRE

Biographical Information	
Participant:	
Age:	
Gender:	
Race:	

Medical History	
Do you have any allergies?	
Have you previously used any form of magnesium? If yes, state what the purpose of your usage was for.	
Do you suffer from eczema?	
Do you suffer from acne?	

Skin Care	
Are you often exposed to the sun and how does your skin react to prolonged sun exposure?	
Do you wear sunscreen? If so, do you reapply throughout the day?	
Do you make use of an exfoliator/facial scrub? If so, how often do you exfoliate?	
Do you follow a skin care regime? If so, state what products you are using	
Have you had any facial treatments to treat your post-inflammatory hyperpigmentation before? If so, state what treatments you have had?	

Appendix F: Quality of Life Assessment (QOL)



QUALITY OF LIFE ASSESSMENT (QOL)

1. On a scale from 1-10, how frustrated are you about your skin condition?

2. On a scale from 1-10, how self-conscious are you about your skin condition?

3. On a scale from 1-10, how embarrassed are you about your skin condition?

4. On a scale from 1-10, how much does your skin condition affect your interaction with others?

5. On a scale from 1-10, how much does your skin condition affect your participation in leisure/social activities?

6. On a scale from 1-10, how much effort do you put into concealing your skin condition?

7. On a scale from 1-10, how much does your skin condition affect your sense of freedom?

Appendix G: Gatekeeping Permission to SCIN At Wembley Medispa



8 February 2022

Wembley Square North

Solan Road

Cape Town

8001

Dear Jeanette van Staden

Request for Permission to Conduct Research

I trust this letter finds you well!

My name is Ashurah Scheepers and I am a postgraduate student enrolled at Durban University of Technology. The research I wish to conduct for my Master's dissertation is *The Clinical Effect of Magnesium Chloride Liquid on Post-Inflammatory Hyperpigmentation in Higher Fitzpatrick Skin Phototypes*.

As I will be studying remotely, I am hereby seeking consent to conduct my research at SCIN at Wembley Medispa. The research will require the use of the facility at which to apply the topical Magnesium Chloride to the participant's skin and the use of a skin analysis device such as the Visia®. Twenty participants will be recruited to take part in the research. Treatments will be carried out once per week over a period of 3 months and skin measurements will take place once per month for 6 months. Should consent be granted, convenient dates and times for data collection can be arranged to ensure that the research does not interfere with activities and schedules already in place at the institution. All the data collected will be strictly confidential, only allowing access to the researcher and the research supervisors. On completion of the research, the results will be reported in a research dissertation which will be made available to all the participants of the study. Provided is a copy of the research proposal, along with the attachment of appendices such as a letter of information, consent form, indemnity form, consent for the release of photographs, participant questionnaire and Quality of Life assessment pertaining to the research process. The Pg2a form as part of the application process of this research has been provisionally approved by the Durban University of Technology's Institutional Research Ethics Committee (IREC) subject to the approval from the data collection site.

Thank you for your time and consideration in this matter!

Yours sincerely

Ashurah Scheepers

0842480786

Ashurah96@gmail.com

Appendix H: Recruitment Advertisement



The Effect of Magnesium Chloride Liquid on Post-Inflammatory Hyperpigmentation

Concerned about dark spots? Previously sought treatment but were unsuccessful? Are you willing to be part of a research study to potentially determine a cost effective, long-lasting and easily accessible solution to post-inflammatory hyperpigmentation?

We are looking for individuals residing in the Cape Town area between the age of 18-25 years with a tan- very dark skin tone who present with dark spots on the face regardless of the duration on the face.

Exclusion Criteria:

- Fair to beige skin tones (individuals who burn on exposure to the sun)
- Individuals with a sea water allergy
- Individuals currently using magnesium supplements
- Individual on Isotretinoin (Roacutane, Accutane, Acnetane)

Participants will be required to:

- Fill in questionnaires and various consent forms
- Avail themselves once per week for 3 months for treatments and 6 months after the initial treatment for follow-up measurements to be done at SCIN at Wembley Medispa.

Interested or unsure if you meet the requirements?

Contact: Ashurah Scheepers
ashurah96@gmail.com

Appendix I: Post-Inflammatory Hyperpigmentation Severity Scale (PIHSS)

POST INFLAMMATORY HYPERPIGMENTATION SEVERITY SCALE			
GRADE	OVERALL DISEASE SEVERITY	PIGMENTARY INTENSITY OF HYPERPIGMENTED LESIONS	AREA OF HYPERPIGMENTED LESIONS (% FACIAL AREA)
0	Normal	None	None
1	Present, but <mild	Trace (mild and localized)	Trace (1-10%)
2	Mild (slightly noticeable)	Mild (mild and diffuse)	Mild (1-25%)
3	Between mild and moderate	Moderate (moderate and diffuse)	Moderate (26-40%)
4	Moderate (noticeable)	Marked (moderate and dense)	Marked (41-50%)
5	Between moderate and marked	Severe(prominent and dense)	Severe (>50%)
6	Marked (distinctive)	-	-
7	Between marked and severe	-	-
8	Severe (very distinctive)	-	-

Appendix J: Introduction to Ethics Certificate



**Zertifikat
Certificat**

Promouvoir les plus hauts standards éthiques dans la protection des participants à la recherche biomédicale
Promoting the highest ethical standards in the protection of biomedical research participants

**Certificado
Certificate**



Certificat de formation - Training Certificate
Ce document atteste que - this document certifies that
Ashurah Scheepers
a complété avec succès - has successfully completed
Introduction to Research Ethics
du programme de formation TRREE en évaluation éthique de la recherche
of the TRREE training programme in research ethics evaluation

Release Date: 2021/05/13
CID : Xafphtu2W

Professeur Dominique Sprumont
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[REV : 20170110]

Appendix K: Data Record Sheet

Participant Data Record Sheet	
Registration	Information Letter
	Indemnity Form
	Consent Form
	Consent for Release of Photographs
	Participant Questionnaire
	Quality of Life Assessment
Baseline Measurements	PIH Severity Scale
	Visia® Photos
Initial Treatment	Treatment 1
Baseline Measurements Post-Initial Treatment	Patient Satisfaction Scale
	Pain Intensity Scale
	Erythema Grading Scale
3 Month Treatment Intervention	Treatment 2
	Treatment 3
	Treatment 4
	Treatment 5
	Treatment 6
	Treatment 7
	Treatment 8
	Treatment 9
	Treatment 10
	Treatment 11
	Treatment 12
	Treatment 13
	Treatment 14
Measurements at Month 6	PIH Severity Scale
	Visia® Photos
Final Measurements at Month 6	Patient Satisfaction Scale
	Pain Intensity Scale
	Erythema Grading Scale
	Quality of Life Assessment

Appendix Lppendix: Patient Satisfaction Scale

PARTICIPANT SATISFACTION SCALE				
Rate from 1-5 how satisfied/unsatisfied you are with the outcome of your treatment				
Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied
1	2	3	4	5

Appendix M: Ethics Approval



31 May 2022

Ms A Scheepers
4 Oryx Street
Eastridge
Mitchell's Plain
7785

Dear Ms Scheepers

The Effect of Magnesium Chloride Liquid on Post-Inflammatory Hyperpigmentation
Ethical Clearance number IREC 233/21

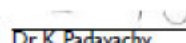
The Institutional Research Ethics Committee acknowledges receipt of your gatekeeper permission letter.

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.

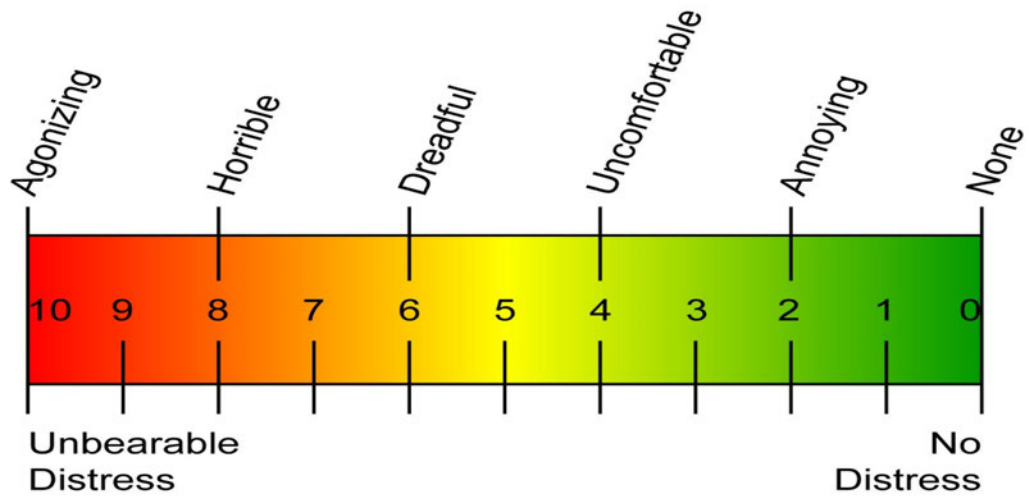
Yours Sincerely


Dr K Padayachy
Deputy Chairperson: IREC

Appendix N: Erythema Grading Scale

ERYTHEMA SCORE	DESCRIPTION
0	None, Normal colour
1	Minimal, light pink, indistinct
2	Mild, bright pink/pale red, distinct
3	Moderate, bright red, distinct
4	Severe, dark red, pronounced

Appendix O: Pain Intensity Scale (PIS)



Appendix P: Journal Article Submission for Peer Review

PLOS One

The effect of magnesium chloride liquid on post-inflammatory hyperpigmentation in higher Fitzpatrick skin phototypes: A pilot study --Manuscript Draft--

Manuscript Number:	PONE-D-26-18403
Article Type:	Research Article
Full Title:	The effect of magnesium chloride liquid on post-inflammatory hyperpigmentation in higher Fitzpatrick skin phototypes: A pilot study
Short Title:	The effect of magnesium chloride liquid on post-inflammatory hyperpigmentation
Corresponding Author:	Ashurah Scheepers, MHSc Durban University of Technology - Ritson Campus Durban, SOUTH AFRICA
Keywords:	post-inflammatory hyperpigmentation; hyperpigmentation; magnesium chloride; Fitzpatrick; higher phototypes; quality of life
Abstract:	Abstract Background Post-inflammatory hyperpigmentation in higher Fitzpatrick skin phototypes is a challenging condition to treat, and existing treatment modalities may exacerbate PIH post-treatment. The need to treat post-inflammatory hyperpigmentation in populations with higher phototypes ensuring safety and efficacy remains unmet. Objectives The study objectives were to determine the clinical impact and evaluate the tolerability of massaged magnesium chloride on post-inflammatory hyperpigmentation in higher Fitzpatrick phototypes. Additionally, the broader psychosocial burden of post-inflammatory hyperpigmentation on the quality of life was assessed. Methods The recruitment commenced from the 6th of June 2022 until the 23rd of June 2022. All the participants recruited for the study provided written consent for their participation. Ten participants received a topical application of magnesium chloride liquid on the cheeks in weekly intervals for three months. Psychosocial data was collected through the use of quality of life questionnaires. Skin analysis was done using a Visia® Skin Complexion Analyser in monthly intervals for six months. Descriptive data was collected using Pain Intensity Scales, Pigmentation Severity Scales, and Erythema Grading Scales. Statistically significant differences in paired measurements were recorded through the use of a T-test. Results The results of the study yielded a statistically significant difference in the Quality of Life before versus post-intervention. A substantial reduction in the erythema scores was observed. OedemaThe pain intensity scoring revealed a statistically significant improvement. Conclusion Consistent use and adherence to the application of magnesium chloride leads to better skin tolerability and reduced discomfort over time. Beyond the dermatological effects of magnesium chloride on post-inflammatory hyperpigmentation, a broader impact is highlighted by quality of life scoring before and after the intervention. The use of magnesium chloride for the treatment of post-inflammatory hyperpigmentation in combination therapies for higher Fitzpatrick phototypes should be explored.
Order of Authors:	Ashurah Scheepers, MHSc Nomakhosi Mpofana, PhD: Medicine(Dermatology) Michael Paulse, PhD: Business Sciences
Opposed Reviewers:	
Additional Information:	
Question	Response