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The Effect of Sodium Shale Oil Sulphonate 1% Shampoo on Dandruff

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ABSTRACT

Dandruff, also known as *seborrhea sicca, pityriasis capitis* or *sicca capitis*, can be defined as chronic non-inflammatory scaling of the scalp, or an abnormality in the desquamation process which occurs on the scalp (Willet, 2010). It is said that dandruff affects at least 50% of the world's adult population and about 15 – 20% of the world's total population (Prambhamanju *et al.*, 2009).

Aim: To ascertain the effect of sodium shale oil sulphonate 1% shampoo on the appearance of dandruff. Forty participants completed the study and participants were of both genders between the ages of 18 and 45. The study compromised of 16 days with 3 visits each 8 days apart.

Methodology: The study design consisted of double-blind, placebo-controlled study where participants were grouped into matching pairs based on the severity of the condition. Participants were then randomly assigned to the treatment or placebo group. At each visit, participants were assessed using the following assessment measures: a Visual Analogue Scale for the participant comprising of scaling, irritation, itching, greasiness and global impression; a Visual Analogue Scale for the researcher comprising of scaling, irritation, greasiness and global impression as well as an Adherent Scalp Flake Score grading completed by the researcher.

Results: Parametric and non-parametric analyses were used and the results of the study demonstrated overall statistically significant improvement in all parameters for the treatment and placebo groups but the extent of improvement was greater in the treatment group. However, at individual visits, only certain parameters expressed statistically significant changes when compared to the placebo group.

Conclusion: It was found that both Sodium Shale Oil Sulphonate 1% shampoo and the control shampoo may contribute significantly to the improvement of the appearance of dandruff with

respect to all of the aforementioned parameters. No significant difference was found between the sodium shale oil sulphonate 1% shampoo and the control shampoo relevant to irritation, itching, greasiness or researcher global impression.

The Sodium Shale Oil Sulphonate 1% shampoo was shown to yield a higher percentage improvement for each measured parameter than the control substance and showed a significant improvement over and above the control shampoo with respect to only the following parameters: scaling (participant rated p=0.012; researcher rated p=0.020) and the global impression (participant rated p=0.048). Higher numbers of participants and longer study periods are however required to verify these results.

INTRODUCTION

Dandruff, also known as *Pityriasis capitis,* is a common condition affecting the scalp. It is estimated that dandruff affects at least 50% of the world's adult population and about 15 – 20% of the world's total population (Nowicki, 2006). Dandruff is caused by increased desquamation and cell growth leading to irritation, marked by flaking and itching of the scalp with associated greasiness (Roger, 2010). Although dandruff is not a cause of major morbidity, as it only affects the scalp, it may be embarrassing and distressing to sufferers leading to low self-esteem and social problems (Nowicki, 2006). The psychological effects of dandruff warrants research into ways in which the problem can be addressed.

Current treatment options for dandruff include many over-the-counter preparations, anti-dandruff shampoos and topical steroid medications. These treatments may be accompanied by side effects and possible aggravation of the condition. Some commonly used ingredients have carcinogenic properties, while others cause increased irritability, dryness and itching of the scalp, allergic reactions (contact dermatitis), endocrine and epithelial cell disruptions, and headaches (Pierard–Franchimont *et al.*, 2001). Options available for the treatment of dandruff are not always effective and can pose the risk of higher recurrence rates. Some only provide symptomatic relief for the condition and include numerous harmful side effects as aforementioned.

Ichthyol® Pale shampoo is a sodium salt of pale sulphonated shale oil in aqueous solution. It has anti-microbial, anti-inflammatory, anti-seborrheic and anti-fungal properties. It combats

dandruff by means of slowing down the desquamation process and regulating cell growth, thus addressing both the cause and symptoms of dandruff (Lunar Pharmaceuticals, 2014). Research on Ichthyol® Pale needs to be conducted in order to evaluate its effect on the treatment of dandruff, as no external research has been done to date.

The use of Sodium Shale Oil Sulphonate 1% shampoo may provide a long term, safer and more effective treatment option for dandruff. Should the study produce positive results, further research on the treatment of dandruff, and other similar conditions, using Shale Oil Sulphonate 1% shampoo can be conducted.

SUMMARY OF LITERATURE REVIEW

Structure of the Skin

The skin is the largest organ of the entire human body. Tissues that make up the skin constantly grow, differentiate and renew themselves. The skin acts as a major protection barrier between the internal and external environment (Hull, 2011).

The skin is made up of 3 layers – the epidermis (external layer), the dermis (internal layer), and the subcutaneous tissue – together with blood vessels, nerves and accessory structures (hair, nails and sweat glands) (Hall and Hall, 2010). The skin itself, together with accessory structures, makes up the integumentary system. As with other systems of the body, the integumentary system does not function in isolation. It depends largely on an extensive network of blood vessels as well as sensory receptors in order to complete its functions (Martini and Nath, 2009).

Dandruff

The word *pityriasis capitis* (dandruff), introduced to the world of dermatology by Galen, originates from the Greek word 'pityriasis' which means bran-like (Rastegar, 2009). Dandruff, also known as *seborrhea sicca, pityriasis capitis* or *sicca capitis*, can be defined as chronic non-inflammatory scaling of the scalp, or an abnormality in the desquamation process which occurs on the scalp. Scaling often occurs on the epidermal layer of the skin and can affect individuals to varying degrees (Willet, 2010). The presenting white flakes of dandruff can be constant, recurrent or sporadic and can vary in severity (Pierard–Franchimont *et al*., 2001).

Two types of dandruff are thought to exist: Common or dry dandruff and oily dandruff (Adamski, 2006).

Epidemiology

Dandruff is an age-related condition. It is rarely seen prior to puberty, increases in occurrence in post pubertal individuals, peaks in the early twenties, and declines in frequency in individuals over 50 years. According to American market research, at least 80-90% of people suffer from some type of scaling disorder. Of that, 30-35% of those suffer from dandruff (Robbins, 2012). In terms of the world adult population, at least 50% suffer from dandruff contributing to approximately 15-25% of the total population (Prambhamanju et al., 2009). According to extrapolated statistics of the United States, approximately 8 million South Africans suffer from dandruff (Pray, 2006).

Aetiology

Since the 19th century, many different causes for dandruff have been proposed. Through the years, these propositions have been further studied in order to pin point a single cause of dandruff. The aetiologic factors involved in causing dandruff can be described as multi-factorial, and includes any combination of the Malassezia fungus, lipase activity, presence of sebum, lipid levels as well as other factors such as stress, immune function, genetic susceptibility and humidity (Schwarts, 2003).

Signs and Symptoms

Dandruff is characterized by loosely adherent small white-grey flakes. The flakes are generally noticeable to the sufferer when brushing or combing the hair or on the shoulder area when dark colour clothing is worn (Sage, 2005).

Scaling may be accompanied by itching of the scalp, irritation and also possible hair loss. In rare cases, the skin can also become reddened with greasy patches and minute openings on the scalp that may ooze a yellow liquid which later forms crusts (Jacoby and Moungson, 2005).

Differential Diagnosis

Many different conditions are commonly confused with dandruff as they share similar symptoms as the condition. Conditions that are often wrongly diagnosed include psoriasis, Tinea capitis, atopic eczema, allergic contact dermatitis, head lice and dry scalp (Thomas et al., 2001; Sage, 2005; Hall and Hall, 2010)

Dandruff Severity Measures

The modified Visual Analogue Scale (VAS) is a subjective measure which can be used to evaluate the symptoms of dandruff including: scaling, irritation, greasiness and itching, as well the psychological effect of dandruff on the participant, termed 'global impression' (Stubbs et al., 2000).

According to Baran and Maibach (1998), the Adherent Scalp Flake Score (ASFS) grading is the primary measure used in many anti-dandruff trials. It is based on an 11 point scale of flaking, ranging from 0 to 10 where 0 reveals no scaling and 10 reveals very heavy scaling. The scalp can be divided into either 6 or 8 sections or anatomic sites on the scalp. The hair in each section is parted in order to visualize the severity of the flaking in that particular atomic site on the scalp. Each section is scored from 0 to 10. The scores are then added to give a total score out of 60 or 80 depending on the amount of sections examined. This evaluation method can be used effectively to observe the condition over time (Schwarts, 2012).

Conventional Treatment

Treatment options for dandruff may be topical in the form of creams, ointment or shampoos, or they can be taken orally (Gupta et al., 2004). The Consensus of the Expert Group of Polish Dermatological Society Mycological Section has summarized and codified the pharmacological treatment of dandruff. Based on the mechanism of action, anti-dandruff formulas can be classified into three groups - fungicidal substances, cytostatic substances and keratolytic substances - each with specific common active ingredients (Adamski, 2006). Anti – inflammatory substances are also commonly used for the treatment of dandruff.

Sodium Shale Oil Sulphonate/Pale Sulfonated Shale Oil Shampoo

Sodium shale oil sulphonate 1% shampoo, trading as Ichthyol® Pale, is manufactured in Germany, and distributed in South Africa by Lunar Pharmaceuticals. Ichthyol® Pale is a

sodium shale oil sulphonate which originates from keragon-containing sedimentary rock. Through the process of distillation, the keragon rock produces a sulphur-rich shale oil which is purified, refined and neutralized before use (Lunar Pharmaceuticals, 2014). Sodium shale oil sulphonate may be used for the treatment of dandruff, as well as for skin complaints such as acne and blemishes (Sanders, 2008).

According to the literature, pale sulphonated shale oil has widespread dermatological uses as it is believed to have anti-inflammatory, anti-microbial and anti-seborrheic properties (Lunar Pharmaceutics, 2014). Based on its actions, pale sulphonated shale oil can be used for the following:

1. Conditions with overproduction of the oil glands such as acne;
2. Bacterial and fungal infections;
3. Inflammatory conditions such as seborrheic dermatitis, atopic dermatitis and psoriasis;
4. Conditions of excess desquamation such as dandruff;
5. Venous leg ulcers; and
6. Wound healing (Willet, 2010).

METHODOLOGY

Research Sample

A representative sample of 40 participants, suffering from mild to moderate dandruff, were recruited for the study via advertisements. The sample included both males and females between the ages of 18 and 45 years. Advertisements were placed at the University of Johannesburg Health Training Centre notice boards and restrooms, as well as in gyms and hair salons in and around the South of Johannesburg with relevant permission.

Inclusion Criteria

Participants were included if they were: Males and females between the ages of 18 to 45 years; suffering from mild to moderate dandruff with itching, flaking, greasiness, irritation of the scalp and possible hair loss (Kent, 2005); had a baseline Adherent Scalp Flaking Score grading ASFS score of ≥ 24; and had good general health.

Exclusion Criteria

Participants were excluded if they were: Suffering from other conditions such as psoriasis, atopic dermatitis, contact dermatitis or *tinea capitis*; diagnosed with systemic or chronic

diseases; pregnant or lactating; currently on any chronic medication; and/or currently on treatment for dandruff.

Participants were requested to refrain from using any conventional, herbal or homeopathic treatment for dandruff for the duration of the study. Only Sodium Shale Oil Sulfonate 1% shampoo was used as treatment.

3.2 Research Procedure and Design

The research study was performed as a 16-day double-blind, placebo-controlled study design. The research was conducted at the University of Johannesburg, Doornfontein Campus. The initial consult (day zero) consisted of a full description and discussion of the research method with the participant. Thereafter, the participant was requested to read a participant information form and sign a consent form. An evaluation based on the inclusion and exclusion criteria, to determine whether the participant met the criteria for the research study, was performed. A physical and general assessment was conducted to determine vital signs and health status respectively. Thereafter, the participant's dandruff was evaluated using the Adherent Scalp Flaking Score (ASFS) grading, completed by the researcher, and the Visual Analogue Scale (VAS), completed by both the participant and the researcher. The participants were divided into two groups by means of matched pairing, according to the severity of dandruff of their dandruff. Based on the determined group, the participants were given either the experimental (with active anti-dandruff agents) or control (without active anti-dandruff agents) shampoo together with the directions for the use of the shampoo. At the second consultation, which occurred on day 8, the participant's scalp was evaluated using the ASFS grading, completed by the researcher, and the VAS, completed by the participant and the researcher. On day 16 (final consult), a final evaluation of the participant's dandruff was performed, using the same method described as with the second consult. At each consult, all results were recorded. Participants were requested to wash the scalp once every second day, starting from day one till day 16. Reminders to wash the scalp were sent to each participant via SMS the night before they were due to wash their hair.

Medication administration

Each participant was given 200 ml of either Sodium Shale Oil Sulphonate 1% shampoo or placebo shampoo for use over 16 days. Participants were requested to wash the scalp once every second day (day 1, 3, 5, 7, 9, 11, 13, 15). Each time the scalp was washed, the participant

was instructed to use only 25ml of the shampoo which was measured out using a standard 25ml measuring cup supplied. No other shampoo was used for the duration of the research.

Sodium Shale Oil Sulphonate 1%

Each bottle of the shampoo using the trade name Ichthyol Pale® contained 1% of Sodium Shale Oil Sulphonate as the active anti-dandruff ingredient. The shampoo was produced by Lunar Pharmaceutics which is a registered pharmaceutical company that maintains good manufacturing procedures and is registered with the Pharmacy Council of South Africa. The shampoo was produced, packaged and labelled by Lunar Pharmaceutics. The labels consisted of the numbers '1' and '2' to ensure that neither the participant nor the researcher was aware of which batch contained the active ingredient and which batch contained the placebo. This was only determined at the end of the study. The control shampoo was manufactured to look and feel the same as the experimental shampoo but without the active anti-dandruff ingredient, sodium shale oil sulphonate. The participants were given a particular bottle using matched pairing according to the severity of the dandruff, to ensure a parametric distribution of the participants across the two groups.

Reliability and validity measures

The Adherent Scalp Flake Score (ASFS) grading is one of the best methods for the assessment of seborrheic dermatitis and dandruff as validated by various research trials and practice (Bacon, 2012). It is also used in private practice by dermatologists to evaluate the extent of such conditions (Schwarts, 2012).

The Visual Analogue Scale (VAS) is the most commonly used scale of measure in terms of healthcare research (Johnson, 1997). Both self-perception and clinical assessment using VAS is regarded as a valid subjective measure for participant's evaluation of dandruff, as it exhibits a rational degree of reliability (Stubbs *et al.,* 2000)

Ethics

All information regarding procedures, duration and requirements of the study was provided and explained to the participants as per the participant information form. In order to participate in the study all participants were requested to sign the participant consent form. All participation in the study was voluntary and withdrawal from the study could take place at any time. There were no anticipated risk factors to the use of the shampoo. However, participants

were advised to discontinue the shampoo if any adverse reactions occurred and to contact the researcher. Privacy and confidentiality of the participant was guaranteed by providing private consultations with the researcher, and all information will be kept in a secure storage facility for five years to which only the researcher and supervisor has access to. Anonymity was upheld by replacing the use of participant names in the research with case numbers. Researcher and supervisor contact details were made available to the participants should any further questions arise. In the event that results were requested by the participant, they were made available. In case of any unforeseen circumstances or outcomes, participants were referred to the relevant healthcare practitioner. In the case of favourable data in the experimental Group as compared to the control Group, the participants in the control Group were provided access to the shampoo at the end of the study. This study was approved by the University of Johannesburg, Faculty of Health Sciences Higher Degrees and Research Ethics committees.

RESULTS

On completion of the study, Lunar Pharmaceutics disclosed the ingredients in the bottles labelled '1' and '2' for the purpose of the researcher to determine which participants were in the control and experimental groups. All data was collated and an Exploratory Data Analysis (EDA) was performed to determine group normality and comparability of the data. The Shapiro – Wilk test was performed to assess the normality of the data. Thereafter, parametric or non – parametric tests were employed based on normality. Parametric intergroup analysis included the independent sample T- test, followed by intragroup analysis using the repeated measures ANOVA test. Non-parametric intergroup analysis included the Mann-Whitney U test, while intragroup analysis involved the Friedman or the Wilcoxon Signed-Ranks test (Van Staden, 2014).

A total of 42 participants were assessed for eligibility from which none were excluded as they all met the participation requirements and were included to participate in the study. Of the 42 participants, 18 were given the active shampoo and 24 were given the placebo shampoo randomly based on matched pairing on the basis of the severity of their dandruff. One participant was lost from group 1 (treatment group) and one participant was also lost from group 2 (control group). Therefore, 17 participants were analysed in group 1 and 23 participants were analysed in group 1.

Data collected for scaling was normally distributed according to the Shapiro Wilk test allowing for parametric data analysis. All other variables showed an abnormal distribution of data, therefore non-parametric tests were used in order to analyse the data.

A total of 40 participants completed the study. Of the 40 participants, most of which were from Indian race, 33 (82.5%) were females and 7 (17.5%) were males. With respect to age, all participants were aged between 18 and 45 years. The ages between the participants were comparable as the *p* value was 0.161 and there is no statistical significance in the age between the two groups.

Comparability was reported with respect to primary visit scores for all the parameters assessed by both the participant and the researcher.

Scaling

Over the duration of the study, the scaling in the treatment group was found to improve by 76.9% ($p = <0.001$), and by 45.1% in Group 2 ($p = <0.001$) when considering the participant evaluation. Despite significant improvements for both groups over the course of the study, it was revealed that there was still a significant difference ($p = 0.012$) between the groups at the last visit (visit 3). Since both groups had comparable degrees of scaling at visit 1, this result suggests that both groups experienced improvement with respect to the appearance of scaling, but that the treatment group (Group 1) appeared to gain a more significant improvement.

With respect to the same criteria using the researcher evaluation, a similar trend was observed where an overall improvement of 64.6% in scaling occurred in Group 1 ($p = <0.001$) whereas Group 2 showed an improvement of only 43% ($p = <0.001$). Although both groups showed significant improvements during the study, a statistically significant difference ($p = 0.019$) was found at visit 3 between the two groups. At visit 1 both groups were comparable with regards to scaling therefore, similar to the participant evaluations, there was a greater improvement in the appearance of scaling for Group 1 when compared to Group 2.

Irritation

For Group 1, irritation (scored by the participant) improved by a total of 74.8% ($p = <0.001$), whereas for Group 2, a total of 52.8% improvement occurred ($p = <0.001$). Groups 1 and 2 both demonstrated a statistically significant improvement, which shows that both groups

improved significantly in the scores for irritation. However, despite the improvement of both groups there was shown to be no statistically significant difference between the two groups at visit 2 and 3 (p = 0.697 and p = 0.249).

When scored by the researcher, the total improvement for irritation improved in Group 1 by 78.8% (p = 0.001) and in Group 2 by 77.3% (p = <0.001). There was found to be no statistical significance in irritation between the two groups at visit 2 and 3 (p = 0.483 and 0.412, respectively).

Itching

Although both Group 1 and 2 displayed statistically significant improvements in itching, Group 1 (76.8%) had a higher overall improvement when compared to group 2 (54.7%). The p value for Group 1 was <0.001 similar to <0.001 of Group 2 indicating that both the treatment and placebo shampoo assisted in significantly reducing the presence of itching on the scalp.

Group 1 and 2 were comparable at visit 1 and by visit 2 and 3, there still appeared to be no statistical significance (p = 0.418 and 0.749 respectively) in the presence of itching.

Greasiness

Both Group 1 and 2 had a total improvement for greasiness according to the participant evaluations. Group 1 improved by 79.3% (p= <0.001) compared to group 2 with a 61.2% (p = 0.001) improvement. Both groups yielded a p value of <0.05 indicating a statistically significant change in greasiness over the period of the study. This indicates that both shampoos produced similar results with regards to greasiness. Similar to visits 1, no statistically significant difference occurred between Group 1 and 2 by visit 2 and 3 (p = 0.468 and 0.115 respectively).

Overall improvements for greasiness were present in the researcher results for Group 1 with an 80.5% (p = 0.001) improvement and Group 2 with a 74% (p = <0.001) improvement. Similar to the participant evaluations, no statistically significant differences occurred between the 2 groups at visit 2 and 3 (p = 0.141 and 0.307 respectively)

Global impression

The overall participant global impression rating for both groups showed significant improvements for Group 1 of 65% (p = 0.001). On the other hand, Group 2 showed less than half the improvement of Group 1 (30.6%) with no statistical significance (p = 0.033).

Both groups were comparable with respect to global impression at visit 1. On the contrary, at visit 3 significant differences (p = 0.048) in the average global impression occurred between the 2 groups.

As indicated in the researcher results, Group 1 produced an overall average improvement of 56% (p = 0.001) whereas Group 2 produced an overall improvement of 42.2% (p = 0.002) in global impression. Although both groups showed improvements, at visit 3 (p = 0.209), no significant difference was found between the 2 groups contrary to the results obtained in the participant evaluation.

When compared, the results obtained from the ratings for global impression indicate that the participant evaluations showed a greater improvement than the researcher evaluations.

Adherent Scalp Flake Score grading

According to the results, it is indicated that both groups 1 and 2 showed significant improvements of 67.9% (p = <0.001) and 50.6% (p = <0.001) respectively in the ASFS grading over the period of the study.

At visit 1 there appeared to be no statistically significant difference for the inter group analysis as both groups were comparable with regards to ASFS grading. However, at visit 3, as indicated in the results the p value was 0.035 indicating a statistically significant difference in the mean ASFS of the 2 groups.

DISCUSSION

Results obtained displayed changes in both groups with regards to scaling. However, the significant change in scaling for the treatment group may be explained by the presence of the active ingredient – which is reported to successfully treat scaling and desquamation disorders (Willet, 2010) - in the shampoo. A standard protocol was employed with respect to the

frequency of hair washes. Although the control group showed changes in scaling, such changes were not statistically significant but the increased frequency of hair washes may provide an understanding as to why the control group showed a decrease in scaling as well (Gerson, 2004).

Changes in irritation were reported for both the treatment and control group, such changes may be explained by the presence of certain ingredients in the shampoo which provide relief from irritation (Barel *et al.,* 2010) as well as the presence of sodium shale oil sulphonate in the treatment shampoo which has been reported to possess anti-inflammatory properties (Willet, 2010).

Similar changes in itching were noted for the treatment and control group. Ingredients such as sodium shale oil sulphonate, found in the treatment shampoo, as well as sweet almond amphoacetate, found in both the treatment and control shampoo, both contain anti-fungal properties (Brown, 2010 and Willet, 2010). Almost all fungal infections are characterised by the presence of itching (Hall and Hall, 2010), the presence of anti-fungal ingredients in both the treatment and control shampoo may explain why the treatment and control shampoo performed similarly with respect to itching.

The results reported for greasiness can be explained by the increased frequency of washing (Gerson, 2004) which controls greasiness of the scalp. Usage of styling products – which may contribute significantly to greasiness of the scalp (Ahmed *et al*., 2007) - was prohibited during the course of the study which may also explain the decrease in the greasiness for both the treatment and control group.

According to Sage (2005), the psychological effects of dandruff are noteworthy due to the increased concern in society regarding appearance. The most visible symptom of dandruff is the presence of flakes or scaling either on the scalp or over the shoulders. Therefore, the significant change in global impression may be explained by the significant change in scaling reported previously. However, the researcher and participant evaluation seemed to differ as a significant change was only reported by the participant evaluations. Such a result may be explained by the greater social impact of the condition on the sufferer when compared to the view of an outsider viz. the researcher in this case.

The ASFS grading results, assessed by the researcher, displayed significant changes in favour of the treatment group. This result may also be explained by the significant change in scaling reported above. The increased frequency of washing which removes excess sebum accumulation (Nina, 2013) may provide an explanation as to the decrease in scaling which consequently results in a decreased ASFS grading.

CONCLUSION

It was found that both sodium shale oil sulphonate 1% shampoo and the control shampoo may contribute significantly to the improvement of the appearance of dandruff with respect to all of the aforementioned parameters. No significant difference was found between the sodium shale oil sulphonate 1% shampoo and the control shampoo relevant to irritation, itching, greasiness or researcher global impression.

The sodium shale oil sulphonate 1% shampoo was shown to yield a higher percentage improvement for each measured parameter than the control substance and showed a significant improvement over and above the control shampoo with respect to only the following parameters: scaling (participant rated $p = 0.012$; researcher rated $p = 0.020$) and the global impression (participant rated $p = 0.048$). Comparable to the results presented for scaling, significant changes in ASFS grading occurred overall at visit 3 for the sodium shale oil sulphonate 1% (67.9%) versus the control shampoo (50.6%) ($p = 0.035$). Higher numbers of participants and longer study periods are however required to verify these results.

The improvements in scaling, significant global impression recorded by the participant and ASFS grading reported by the researcher could imply that sodium shale oil sulphonate 1% shampoo may decrease the appearance of scaling in a relatively short period of time (16 days). Wide scale research and further verification of these is mandated prior to the finalisation of any claim of beneficial improvement**.**

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