The effect of a topically-applied cosmetic oil formulation on striae distensae

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Abstract

Background: Stretch marks or striae distensae are tears in the dermis, above which the epidermis remains intact. Striae result from rapid expansion of the underlying tissue, e.g. during puberty, pregnancy or rapid weight gain. The prevalence of striae is high (up to 80% in most populations). Many of the successful treatment modalities for striae (laser, surgery, prescription-only medication) entail high costs, often with the involvement of private medical practitioners. The objective of the study was to investigate the effect of a topical application (Bio-Oil™) on striae in 20 healthy Caucasian women. The study was performed according to standard good clinical practice guidelines.

Methods: The study was conducted among 20 healthy Caucasian women with bilateral abdominal striae. The women used the test product on one side of their abdomen twice a day for 12 weeks, and their normal moisturising routine on the other side. Assessment methods were: 1) subjective visual self-assessment, using both the Patient and Observer Scar Assessment Scale (POSAS) and a directed difference (i.e. comparison of sides), and 2) objective laboratory visual assessment (blinded) using the same scales.

Results: The subjective visual self-assessment yielded statistical significance at four weeks in terms of improvement of the treated striae when compared to the untreated sites, using both the POSAS and directed difference. Objective laboratory visual assessment, using the POSAS and directed difference, showed a statistical improvement on the treated side from week 2 onwards.

Conclusions: The test product (Bio-Oil™) significantly improved the appearance of striae on the treated side of the abdomen as assessed by both subjective and objective assessments. This study has shown that it is possible to improve the appearance of striae with the topical application of a relatively low-cost, non-medicinal product.

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Introduction

Stretch marks or striae distensae are tears in the dermis, above which the epidermis remains intact.[1] Stretch marks are referred to as striae cutis distensae, striae gravidarum and by many other terms.[1] Throughout this paper, the collective term striae will be used.

Striae appear as elliptical erythematous or blanched areas on the skin. Striae may merge to form an interwoven pattern on the affected area. The internal reflectance of the damaged areas often produces a pearlised appearance. Striae often feel softer and more pliable than the surrounding skin.

Striae result from rapid expansion of the underlying tissue, e.g. during puberty, pregnancy or rapid weight gain.[1] They may also result from a weakening of the dermal tissue. Striae are commonly found on the abdomen (especially near the umbilicus), breasts, upper arms, underarms, thighs, hips and buttocks.[1] The prevalence of striae is high (up to 80% in most populations).[2,3]

Pregnant women are at particular risk of developing stretch marks (striae gravidarum) due to the combination of rapid abdominal growth and hormonal changes. It is estimated that 50% to 90% of women develop some stretch marks during pregnancy.[1,3] The prevalence is higher in women who are already obese prior to pregnancy.[3]

The subject of the prevention of striae gravidarum formation is controversial. Many cosmetic products claim to help prevent the formation of stretch marks, but the ethical issues related to the conduct of clinical studies on pregnant women hinder objective assessment.

Only one published randomised controlled study could be identified which claimed to test whether cosmetic creams prevent the development of stretch marks.[4] This study found that only 34% of the group that used a daily application of a cream containing *Centella asiatica* extract, vitamin E and collagen-elastin hydrolysates developed striae, as opposed to 56% in the control group. In women with a history of striae during puberty, the active cream induced a significant absolute prevention in 89% of the cases, whereas all the women in the placebo group developed striae.[4]

Another study, with an untreated control, examined a cream which contained vitamin E, panthenol, hyaluronic acid, elastin and menthol. Use of the cream was associated with fewer stretch marks during pregnancy versus no treatment.[5]

Treatments that have been used to improve the appearance of existing stretch marks include laser treatments, laser dermabrasion, topical retinoids and exfoliation.[6] Fractional laser resurfacing uses scattered pulses of light on small areas of the lesion, over several treatments. The pulsed laser causes micro-damage and micro-repair, hence the body responds to the treatment by producing new collagen and epithelium. The procedure improved both the texture and appearance of mature, white striae in skin phototypes I to IV.[7]

Tretinoin (0.1%) has been shown to improve the appearance of striae over six months when compared with a vehicle-only group.[9,10] Alpha hydroxy acids (e.g. glycolic acid 15–20%) have also been patented to treat striae.[11] Dermabrasion with sand and/or exfoliation with trichloroacetic acid (15–20%) has also been shown to be effective for improving the appearance of striae in all skin types.[12,13] Perhaps the most drastic approach to the removal of striae is that of surgical removal of the affected areas of skin, e.g. through a "tummy tuck".[1]

Many of the above modalities entail high-cost specialist treatments, often with the involvement of private medical practitioners. Such treatments are not always accessible or affordable to those who have problematic striae. Hence there is a huge market for over-the-counter products that claim to prevent or improve striae. Few studies exist to support the claims made by these products, and most of those that do are not published in peer-reviewed media.[14]

In South Africa, an oil-based cosmetic formulation (Bio-Oil™) has been produced and marketed since 1987.[15] It is also marketed in 17 other countries. A large body of anecdotal evidence regarding product efficacy developed over the years. Consumers found that the product improved the appearance of uneven skin pigmentation, striae and scars. In early 2005 we were approached to design and conduct objective clinical studies on the product to test its efficacy for those skin conditions.

Our laboratory has been involved with the objective assessment of the safety and efficacy of sunscreens and cosmetic products since 1989. This was the first study that we conducted on striae. Striae are in fact scars.[13,16] Consequently, scar assessment methods are appropriate in the study of striae. A protocol was developed in conjunction with the Department of Plastic and Reconstructive Surgery on the Medunsa Campus of the University of Limpopo.

This paper presents the findings of a 12-week study on striae, based on the above protocol and conducted at the Photobiology Laboratory, School of Pharmacy, Medunsa Campus, University of Limpopo, South Africa.

Method

Study objective

The objective of the study was to investigate the effect of 12 weeks of application of topically applied cosmetic oil (Bio-Oil™) on cutaneous striae, under randomised, controlled, observer-blinded conditions.

Sample size

Twenty healthy Caucasians with bilateral striae were included in the study (see below). The sample size was determined on the basis of the size of the expected difference between the test and control sites and also on economics.

Inclusion criteria

- Caucasian
- Aged 18–55
- In good health
- Willing to sign informed consent and attend all appointments
- Having appropriate bilateral striae

Note: as this was an exploratory study, no limit was placed on the age or appearance of the striae.

Exclusion criteria

- Breast-feeding or pregnant
- Currently taking or applying antihistamines, anti-inflammatories, corticosteroids or other medication that may affect skin reactions
- Suffering from diabetes, circulatory problems, malnutrition or other conditions that may adversely affect healing processes

Randomisation and assessor blinding

The product was allocated randomly to either the right or left side of the panellist's abdomen. Allocation was in such a way that 10 panellists applied the product to the left side and 10 to the right. The opposite side of the abdomen was the control site.

The assessors were blinded as to the product-treated side. The randomisation code was based on the study number of the panellist and was only broken at the end of the study, once the data analysis had been completed.

Study panel

Thirty-two potential panellists attended the study briefing. The panellists were briefed orally and given the study calendar and instructions. They completed a health questionnaire and informed consent form for study purposes at the start of the study.

Immediately after the briefing and form completion, a visual assessment was conducted to determine qualification for the study (to ensure that the proposed test sites had suitable striae). Panellists with bilateral abdominal striae were identified so that a half-abdomen study design could be adopted.

Panellist health questionnaires and consent forms were reviewed by the study investigator for eligibility and completeness. Queries, omissions or potential problems on the forms were "flagged" for clarification at the baseline visit.

The 20 most suitable potential panellists were included in the study.

Products and application

Bio-Oil™ contains a mixture of potential actives in a mineral oil, isopropyl myristate and cetearyl ethylhexanoate base. The actives in the product that are known to play a role in skin improvement include retinyl palmitate, tocopherol acetate and glycine soja. In addition, the properties of the following actives could also play a role in the improvements seen – *Lavandula augustifolia* (astringent and antiseptic), *Rosmarinus officinalis* (soothing and antiseptic), *Calendula officinalis* (regenerative), and bisabolol (anti-inflammatory).

The target application quantity was 2 mg/cm^2 of product, which is a standard application quantity in similar skin studies. Measurement of the application dose was performed using a 1 ml syringe. For some panellists this quantity proved cosmetically unacceptable (i.e. excessive),

hence the panellists were allowed to apply as much as was acceptable. Application quantities were monitored through product weight.

The panellists were instructed to apply the test product in the morning and at night, after their normal hygiene routines. They otherwise followed their normal cleansing and moisturising routine, except that the test product was used as a substitute for their normal moisturiser on the treated side of the abdomen. Hence, whilst the assessors were blinded as to the identity of the treatment sites, the panellists were aware which side was treated with the test product and which had undergone their regular moisturising routine.

The product was issued to the panellists immediately after the baseline assessment had been performed. The panellists were instructed how to apply to product and the initial application was performed under the supervision of a staff member not involved in the assessment. Supervised application was performed on the first two days of the study (Thursday and Friday), then on the following Monday, and then at weekly intervals for the first four weeks and thereafter every two weeks.

The product was smoothed gently onto the skin and allowed to be absorbed, with no massage. As massage can play a role in the condition of skin, the panellists were instructed to apply the test product as they would apply their normal moisturiser, hence the role of massage was minimised.

Product application continued twice daily at home. An application diary was issued to the panellists to record the time of each application.

The product containers were weighed at the beginning and end of the study to monitor product use.

Assessment

Assessments were conducted by study staff with several years experience in skin assessment.

The assessment of the striae was carried out by means of a recognised scar assessment grading scale, the Patient and Observer Scar Assessment Scale (POSAS).[16] A directed difference of relative striae condition was also performed.

A detailed description of the assessments follows:

Visual evaluation – objective and blinded

The POSAS Scar Scale is intended to be used by adding the individual scores from the scale's components and obtaining a total. Any improvement in the scar or stria will reflect as a lower total.

The POSAS covers five parameters (vascularisation, pigmentation, thickness, relief, pliability), each graded on a scale of 1 to 10. The higher the number, the worse the stria or scar (i.e. a potential total of 50 for the worst possible stria).

The change in parameters was calculated as follows:

Change in parameter (delta)

= (score of untreated striae at time t - score of treated striae at time t) - (score of untreated striae at time baseline - score of treated striae at baseline) Equation 1

Using *Equation 1,* a positive value reflects an improvement in the striae on the treated side, over time, relative to the untreated side.

A simple directed difference was used to assess the relative condition of the test sites in terms of whether the right site was much worse, worse, the same, better or much better than the left site.

Visual evaluation – subjective

A subjective evaluation was performed by each panellist under the supervision of a study assistant, using the subjective POSAS and directed difference.

Data analysis

The visual data were discrete data, therefore a non-parametric statistical test was used. The Wilcoxon Sign Rank Test was applied to the scores. In addition, the number of panellists in each group who had improved, remained the same or worsened was calculated.

All data were recorded manually and then entered into an Excel spreadsheet. Proofreading was performed after data entry. After sorting the data according to the treatment, statistical analysis was performed. After the baseline assessment, the study continued for 12 weeks. The data for weeks 0, 4, 8 and 12 are presented below.

Ethical considerations

The study was conducted in accordance with the 'Guidelines for good practice in the conduct of clinical trials in human participants in South Africa'.[17] These guidelines are comprehensive and are based on the ICH Tripartite Guidelines for Good Clinical Practice (1997) and the Declaration of Helsinki (2000).[17]

Permission to conduct the study was granted under the protocol approval for project MC 81/2005 of the Medunsa Campus Research and Ethics Committee of the University of Limpopo.

Results

Panellist compliance

One panellist (number 7) was discharged after week 8 for protocol violation. This panellist had abdominal liposuction between weeks 8 and 12.

Product application quantities varied between the panellists, but were relatively consistent on the two sides of any given panellist. An average of 2.75 g of product was applied per day (or 1.375 g per application). Hence, if the average application area was 900 cm^2, that equates to an application quantity of approximately 1.5 mg/cm^2.

Adverse events

There were no adverse reactions to the test product or to the panellists' normal products.

Visual evaluation – objective POSAS

The objective POSAS showed no difference between the treated and untreated sides at week 0 (see Table I). Overall there was a relative improvement on the treated side, with significance from week 4 ($p = 0.5$).

Visual evaluation – objective directed difference

The directed difference was considered by the assessors to be the simplest as well as the most reliable method of comparison. The directed difference indicated an improvement on the treated side (see Table II). The improvement was statistically significant ($p \leq 0.05$) at weeks 4, 8 and 12 using the Wilcoxon Sign Rank Test.

Table I: Objective POSAS score summary

Week	Number in panel	Treated score (mean)	Untreated score (mean)	Difference	p value
0	20	10.9	10.8	-0.1	0.8
4	20	11.2	12.5	1.3	0.05
8	20	12.2	13.8	1.6	0.09
12	19	10.3	12.3	2	0.01

Note: See *Equation 1* and Discussion for rationale for using difference between scores rather than raw scores

Table II: Directed difference summary

Week	Number of panellists				p value (Wilcoxon)
	Number in panel	Treated site better	Treated site worse	No difference	
0	20	5	5	10	1
4	20	13	5	2	0.05
8	20	13	5	2	0.03
12	19	14	4	1	0.02

Visual evaluation – subjective POSAS

The subjective evaluation showed a perceived improvement from baseline that was statistically significant from four weeks onwards (a lower score equates to a better condition) (see Table III).

Table III: POSAS subjective score summary

Week	Number in panel	Mean of total POSAS score (treated)	Untreated score (mean)	Difference	p value
0	20	25.0	24.2	-0.8	0.25
4	20	16.4	19.7	3.35	0.003
8	20	14.5	21.8	7.35	< 0.001
12	19	18.0	22.9	4.89	0.02

Visual evaluation – subjective directed difference

The panellists assessed the striae in overall terms by completing the directed difference assessment (see Table IV). These scores confirmed the POSAS totals in that they showed a perceived improvement on the treated side.

Table IV: Directed difference (subjective) summary

Week	Number in panel	Overall treated score (mean diff)	Overall untreated score (mean diff)	Difference	p value
0	20	8.0	7.6	-0.4	0.07
4	20	5.7	7.4	1.7	0.02
8	20	4.0	6.8	2.8	0.0001
12	19	3.6	4.5	0.8	0.14

Discussion

Both visually and instrumentally, striae are very difficult to assess.[18] Their appearance is often pearly, and it changes depending on the angle of light. Striae vary considerably in size and colour, from small white pearly ellipses to large, contiguous pink/red dappled "zebra-stripe" lines.

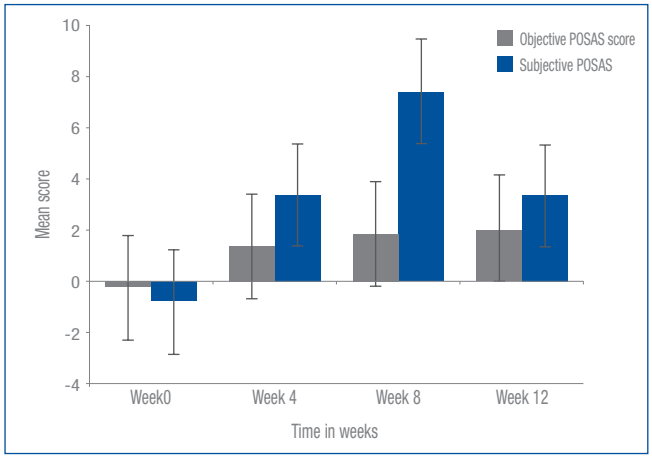
A 12-week study was implemented in order to allow sufficient time for the effect of the product to become apparent.

The scores on the POSAS cover a relatively wide range, from 1 to 10. Hence it is difficult to achieve consistency on the scale from week to week (e.g. the same parameter scored as a 6 in one assessment week may be rated as a 5 at the following assessment). Using *Equation 1* allows for any drift in assessment to be eliminated, as assessment is narrowed down to a relative difference between the two sites.

Both the subjective assessment grades peaked at week 8. This phenomenon is difficult to explain, even with the loss of one panellist between weeks 8 and 12.

The following graph summarises the improvements, scored on the POSAS scale, as perceived by the panellists (subjective) and the blinded assessors (objective):

Figure 1: Mean improvement in scores of treated sides over untreated sides: POSAS objective (expert assessor) and subjective (panellists)



From Figure 1, it is interesting to note that the subjective assessment of the improvement of the treated side, relative to the untreated side, was considerably greater than that of the objective assessment. The difference could be due to one of two factors:

1. The panellist's knowledge of which side was treated may have led to a positive bias. However, the panellists were predominantly experienced participants in clinical studies. Many were professional women with either postgraduate or administrative qualifications. As such, their opinions should be relatively objective and critical.
2. The more likely explanation is that the panellists had a completely different visual perspective of the striae from that of the assessors. The assessor was seated in front of the panellists and the panellists were viewed frontally, with the assessor swivelling the panellists to obtain a balanced view. The panellists, on the other hand, were in a standing position and observed their abdomens from above, hence their angle of observation was relatively consistent for each side. It may have been easier for the panellists to make a direct side-by-side comparison than it was for the assessor.

The simple, directed difference measures were the most effective comparators.

Conclusion

Bio-Oil™ significantly improved the appearance of striae on the product-treated side of the abdomen, as assessed by both subjective (POSAS and directed difference) and objective (POSAS and directed difference) means. The improvements were observed after four weeks of treatment and peaked at six to eight weeks ($p = 0.05$).

This study has shown that it is possible to improve the appearance of striae through the topical application of a relatively low-cost, non-medicinal product.

Competing interests

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