Accepted: 16 March 2021

DOI: 10.1111/jocd.14094

ORIGINAL ARTICLE

JCD Journal of Cosmetic Dermatology WILEY

Topical oil formulation of plant extracts and vitamins as effective treatment for stretch marks and xerosis—An observational longitudinal study

Mariateresa Cantelli MD | Elisa Camela MD | Claudio Marasca MD | Giuseppina Fontanella MD | Chiara Blasio MD | Gabriella Fabbrocini MD

Section of Dermatology, Department of Clinical Medicine and Surgery, University of Naples Federico II, Napoli, Italy

Correspondence
Mariateresa Cantelli, Section of Dermatology, Department of Clinical Medicine and Surgery, University of Naples Federico II, Via Pansini 5, 80131 Napoli, Italy.
Email: mariateresacantelli@gmail.com

Abstract

Background: Stretch marks are linear scars that result from elastic fiber destruction. They usually occur as the consequence of rapid change in the body mass (weight gain and loss, pregnancy, weightlifting), long-term steroid use, or endocrinopathies. Treatment is challenging and mainly based on topical and procedural therapies, although the standard of care is still under debate.

Purpose: To evaluate the efficacy and tolerance of a topical oil formulation of plant extracts and vitamins on the aesthetic improvement of stretch marks and xerosis.

Materials and methods: Fifty male and female patients, aged between 14 and 45 years, with stretch marks referring at the University Hospital Federico II, Naples, were enrolled between March and November 2019. Topical application of plant extracts and vitamin-rich oil was performed twice daily on affected skin for 4 months. Patients were monitored at baseline (T0), and at two-month (T1) and 4-month (T2) follow-ups, through clinical and dermoscopic assessment, confocal microscopy, cutaneous ultrasound, MoistureMeterEpiD, and X-Rite spectrocolorimeter. Primary endpoints were as follows: 70% clinical improvement of stretch marks and 3-point decrease in clinical score from baseline to T2. Secondary endpoints were as follows: change in the T0 parallel pattern of collagen fibers at confocal microscopy, cutaneous thickness increase at ultrasounds, cutaneous hydration increase at MoistureMeterEpiD, erythema reduction at X-Rite spectrocolorimeter, and safety and adverse events (AEs).

Results: At 4-month follow-up, stretch marks improved objectively and subjectively in all patients ($p < 0.001$). In detail, there was a 29% and 71% improvement in clinical appearance of stretch marks at T1 and T2, respectively, as documented dermoscopically and by the 3-point reduction in the assessor's mean clinical score at each follow-up visits [from 8.1±0.7 at baseline to 5.7±1.0 at T1 and 2.3 ±0.5 at T2 ($p < 0.001$)]. Erythema decreased by 15% and 30% and in parallel hydration increased by 25% and 71%, at T1 and T2, respectively ($p < 0.001$). At T2 confocal microscopy of stretch marks, dermal collagenous fibers assumed casual disposition with reticular pattern and refractivity, as signs of collagen remodeling and neocollagenesis, and also the T2

cutaneous ultrasound revealed increased epidermal thickness and decreased dermal hypoechogenicity as for a higher skin hydration.

Conclusion: Our study showed that a topical oil formulation rich in plant extracts and vitamins appears to be effective and safe in treating stretch marks and xerosis.

KEYWORDS
confocal microscopy, cutaneous ultrasound, dermoscopy, MoistureMeterEpiD, oil, spectrocolorimeter, Stretch marks, topical treatment, xerosis

1 | INTRODUCTION

Striae distensae (SD), also known as stretch marks, are linear scars present on body sites under excessive stretching that determines dermal damage.[1] They may occur at any age although they are more frequent during adolescence and pregnancy, and predominantly affect women.[1] Their management is challenging as guidelines are lacking and dedicated randomized clinical trials are scant.[1] Therefore, we conducted a longitudinal study with the purpose to assess the efficacy and safety of a topical cosmetic product containing plant extracts and vitamins in an oil formulation applied twice daily on stretch marks of a sample of 50 young, affected patients. The product is a cosmetic oil containing vitamins A and E, and a mixture of oils, that is, calendula, lavender, rosemary, chamomile, and PurCellin Oil™ that overall have anti-inflammatory, anti-oxidating, and soothing properties, and stimulate neocollagenesis.

2 | MATERIALS AND METHODS

A longitudinal observational study was conducted on 50 male and female patients (aged 14–45 years) affected by stretch marks, attending our dermatology clinic of the University Federico II, Naples, from March to November 2019. The study procedures are illustrated in Table 1. Enrolled patients had to apply a topical oil formulation rich in plant extracts and vitamins on affected areas, twice daily for 4 months. The improvement in stretch marks was evaluated clinically, dermoscopically, and through non-invasive techniques (digital pictures, MoistureMeterEpiD, X-Rite spectrocolorimeter, reflectance confocal microscopy [RCM], and cutaneous ultrasound [US]), at baseline (T0), and two-month (T1) and four-month (T2) follow-ups. Moreover, the investigator had to assign SD a clinical score (0–10) according to severity at each visit. Inclusion criteria were as follows: presence of striae rubrae, thin striae albae (<1 mm), and age of 14–45 years. Exclusion criteria were as follows: presence of thick (>1 mm), old, and deep striae albae. Primary endpoints were as follows: 70% clinical improvement of SD and a 3-point decrease in clinical score from the baseline to T2. Secondary endpoints were as follows: cutaneous hydration increase at MoistureMeterEpiD, erythema reduction at X-Rite spectrocolorimeter, change in the T0 parallel pattern of collagen fibers at RCM, cutaneous thickness reduction at US, and safety and AEs. The study was drawn according to the ethical standards laid down in the World Medical Association Declaration of Helsinki (June 1964) and its later amendments and was approved by the local ethical committee.

3 | STATISTICS

All data analyses were performed using SAS software version 9.4 (SAS Institute) and R software (R Foundation for Statistical Computing) version 3.6.0. STROBE guidelines were followed. Data are presented as total and percentage number for categorical variables and means–standard deviation (SD) or median (range) for the continuous variables, as appropriate. For the three main outcomes, that is, clinical score, cutaneous hydration, and erythema, the

TABLE 1 Study procedures: screening, baseline (T0), and 2-month (T1) and 4-month (T2) follow-ups

Study period, T	Procedures
Screening	Assessment of inclusion and exclusion criteria If eligibility, planning enrollment
Baseline T0	Enrollment (providing written informed consent) Clinical assessment and scoring of SD Digital (clinical and dermoscopic) pictures MoistureMeterEpiD X-Rite spectrocolorimeter Ultrasound evaluation RCM Start of treatment with bio-oil
Month 2 T1	Clinical assessment and scoring of SD Digital (clinical and dermoscopic) pictures MoistureMeterEpiD X-Rite spectrocolorimeter Ultrasound evaluation RCM Evaluation and record of AEs
Month 4 T2	Clinical assessment and scoring of SD Digital (clinical and dermoscopic) pictures MoistureMeterEpiD X-Rite spectrocolorimeter Ultrasound evaluation RCM Evaluation and record of AEs

percentage difference in values between T0 and T2 was calculated, considering as significant at least a 70% and 30% reduction in clinical score and erythema, respectively, and a 40% increase in cutaneous hydration. Statistical significance was set as at $\alpha = 0.05$.

4 | RESULTS

A total of 50 patients were enrolled in the study: Mean age at baseline was 20.2 ± 6.3 years (14–45 years), with a female-to-male ratio of 8.8:1.2 (Table 2). All subjects (100%) completed the study. At T2, stretch marks improved objectively and subjectively in all patients ($p < 0.001$). In detail, there was a 29% and 71% improvement in clinical appearance of SD at T1 and T2, respectively (Figures 1-2; Table 3). Accordingly, the investigator's mean clinical score reduced by 3 points at each follow-up visit, from 8.1 ± 0.7 at baseline to 5.7 ± 1.0 at T1 and 2.3 ± 0.5 at T2 ($p < 0.001$). Moreover, erythema decreased significantly from 19.6±4.2 at baseline to 16.7 ± 3.5 at T1, to 13.7 ± 3.4 a T2, with a mean percentage reduction of 15% and 30%, respectively ($p < 0.001$). Such findings were in line with those of the dermoscopy (Figure 3). In parallel, hydration increased by 25% and 71% at T1 and T2, respectively ($p < 0.001$) (Table 3). At T0 confocal microscopy of SD, dermal collagenous fibers showed a parallel pattern along the skin tension lines that, by contrast, at T2 assumed casual disposition with reticular pattern and refractivity, as signs of collagen remodeling and neocollagenesis (Figure 4).

Likewise, the T0 US of SD revealed a thin epidermis and a dermal high-grade hypoechogenicity, which reflected the altered organizations of elastic fibers. Conversely, at T2, epidermis thickness increased and the hypoechogenicity reduced as for a higher skin hydration (Figure 5).

TABLE 2 Study population characteristics

	Value
No. patients	50
Sex, female, *n* (%)	44 (88%)
Age (mean), years Range, years	20.2 ± 6.3 14–45

FIGURE 1 Clinical pictures of stretch marks on the breast A) before (T0) and B) after treatment (T2)

5 | DISCUSSION

Striae distensae (SD) or stretch marks are linear scars affecting about 80% of the population, with female preponderance.[1] Striae rubrae are the earliest presentation of SD and are characterized by an erythematous-to-violaceous color evolving over time into striae albae, which appear hypopigmented, atrophic, and scar-like.[2,3] Diagnosis is clinical although many non-invasive techniques have been used with the purpose of not only increasing knowledge on SD pathogenesis as for investigation, but also monitoring the epidermal and dermal changes before and after the treatment.[4]

Concerning treatment, the therapeutic arsenal comprises topical and procedural treatments that aim at improving clinical aspect, reducing symptoms (if present), and preventing the development of new lesions. Above all, procedural therapies seem to be the most effective. Their mechanism of action consists in the induction of a minimal controlled damage to the dermis that promotes fibroblast proliferation and collagen production.[1] Anyway, although minimally, they are invasive and may transitorily cause discomfort, pain, bleeding, erythema, and pruritus, thus being not univocally suitable for all patients. By contrast, topicals are easily accessible to any patient, easy to use, and characterized by few or even no side effects, making its employment straightforward in clinical practice. In this scenario, we conducted a longitudinal study with the purpose to assess the efficacy and safety of a topical oil formulation rich in plant extracts and vitamins twice daily applied on stretch marks in a young, affected sample population over 4-month treatment. Strikingly, all patients experienced a significant improvement as documented clinically and dermoscopically, but also through non-invasive diagnostic tools such as X-Rite, MoistureMeterEpiD, RCM, and cutaneous US, which objectively revealed significant erythema reduction, increased cutaneous hydration and thickness, and deep structural changes in stretch marks. Interestingly, our RCM results were in line with those reported by Mazzella et al that observed the same changes in collagen bundle orientation after treatment: from parallel to skin tension lines at baseline to casual and cross-linked at the end of the study.[5] Likewise, increased cutaneous thickness at ultrasound was reported by Bogdan et al, after 6-week topical application of a cream.[6]

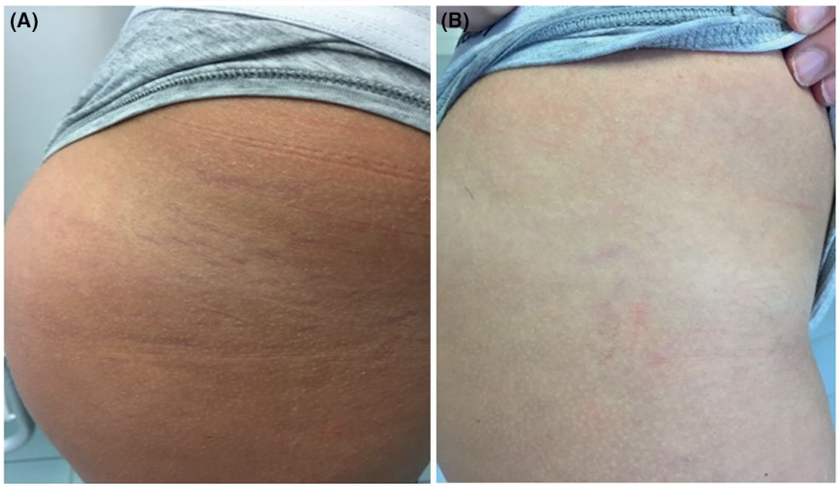

FIGURE 2 Clinical pictures of stretch marks on the gluteus A) before (T0) and B) after treatment (T2)

	T0	T1	T2	ΔT1-0	ΔT2-0
Clinical score (mean±SD), *n*	8.1 ± 0.7	5.7 ± 1.0	2.3 ± 0.5	−29%	−71%
Hydration (mean), %	34%	42%	50%	25%	71%
Spectrocolorimeter (mean)					
L^*	61.9 ± 5.1	63.9 ± 5.5	67.1 ± 5.9	3%	8%
C^*	19.6 ± 4.2	16.7 ± 3.5	13.7 ± 3.4	−15%	−30%
h°	54.4 ± 8.9	60.5 ± 9.5	62.6 ± 9.8	7%	15%

TABLE 3 Study outcomes at T0, T1, and T2

L*: LIGHTNESS; C*: CHROMA; h°: HUE ANGLE; according to the commision internationale de l'Eclairage

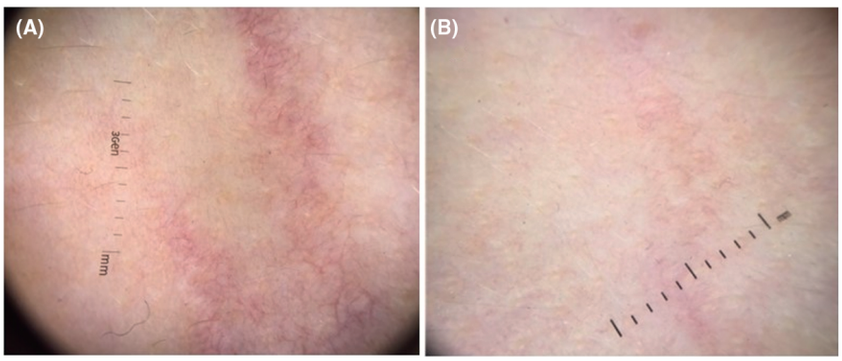

FIGURE 3 Dermoscopy of stretch marks A) before (T0) and B) after treatment (T2)

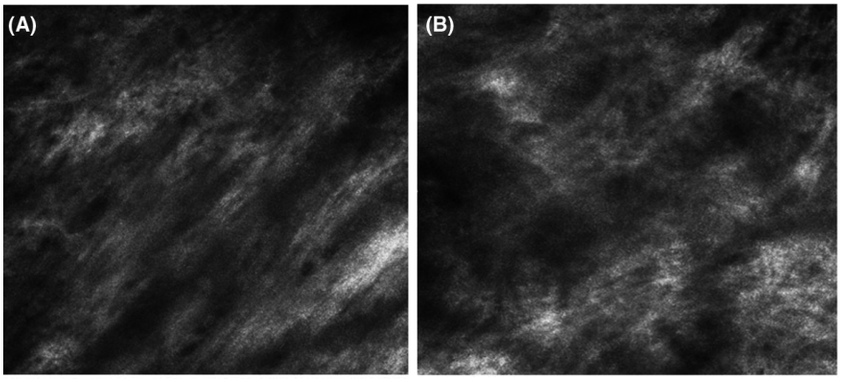

FIGURE 4 Confocal microscopy of stretch marks A) before (T0) and B) after treatment (T2)

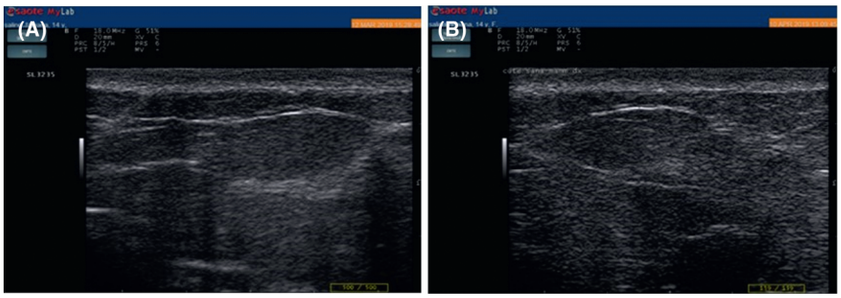

FIGURE 5 Cutaneous ultrasound of stretch marks A) before (T0) and B) after treatment (T2)

Moreover, no AEs were registered over the whole study period, thus making it suitable for patients at any age. Such findings are in line with those reported by Summers et al, which run a randomized, controlled, observer-blinded study on 20 non-pregnant Caucasian women that had to apply the product twice daily for 12 weeks on a side of the abdomen, leaving the other untreated.[7] They reported a significant objective and subjective improvement in treated stretch marks compared with non-treated ones.[7] Hence, we support the use of the tested product in the treatment of stretch marks and cutaneous xerosis as it showed to be effective and safe. Anyway, more research on the topic is needed through dedicated and randomized clinical trials that may compare treatment modalities on larger sample of patients and longer follow-up periods.

CONFLICT OF INTEREST

None to declare.

ETHICAL STATEMENT

This study received approval by the local ethical committee.

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How to cite this article: Cantelli M, Camela E, Marasca C, Fontanella G, Blasio C, Fabbrocini G. Topical oil formulation of plant extracts and vitamins as effective treatment for stretch marks and xerosis—An observational longitudinal study. *J Cosmet Dermatol.* 2021;20(Suppl. 1):9–13. https://doi.org/10.1111/jocd.14094