

## Original Article

# Clinical evaluation of a topical formulation to help prevent stretch marks during pregnancy

## Avaliação clínica de uma formulação de uso tópico como auxiliar na prevenção de estrias na gestação

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### ABSTRACT

**Introduction:** Stretch marks occur due to the rapid stretching of the skin, which is typical in pregnancy. Several topical treatments to prevent them have been studied.

**Objective:** To evaluate the effectiveness of a topical formulation (lactic acid and sodium lactate in an emulsion with caprylic and capric acids' triglycerides) in the prevention of stretch marks.

**Methods:** Seventy-five pregnant women aged 18–40 were assessed. The treated area was the abdomen and the control area was the inner forearm, with and without the application of the tested product. Softness, hydration, and elasticity – and biophysical measurements for hydration and elasticity – were evaluated.

**Results:** Of the 52 women who completed the study, 9.6% presented stretch marks in the treated abdominal area. There was a significant improvement in all clinical parameters assessed ( $p < 0.001$ ). There was a significant improvement – compared the control area – in the instrumental measurements of hydration and elasticity in the abdomen. A significant improvement was also verified in the treated forearm area compared to the untreated forearm area for both parameters evaluated ( $p = 0.001$ ).

**Conclusions:** The formulation improved the skin's elasticity and hydration, reducing the striae incidence more than previously reported in the literature.

**Keywords:** striae distensae; pregnancy; relaxin.

### RESUMO

**Introdução:** As estrias ocorrem pelo rápido estiramento da pele, típico da gestação. Tratamentos tópicos vêm sendo estudados para prevenir seu aparecimento.

**Objetivo:** avaliar a eficácia preventiva de estrias de uma formulação tópica.

**Métodos:** Avaliaram-se 75 gestantes entre 18 e 40 anos. A área tratada foi o abdome, e a área-controle, a face interna do antebraço, com e sem o produto de teste, avaliando-se: maciez, hidratação e elasticidade além de medidas biofísicas para elasticidade e hidratação.

**Resultados:** Das 75 gestantes, 52 finalizaram o estudo; destas, 9,6% apresentaram estrias na área abdominal tratada. Houve melhora significativa em os todos parâmetros clínicos avaliados ( $p < 0,001$ ). Nas medidas instrumentais, houve melhora significativa da hidratação e elasticidade na área abdominal, superior à da área-controle; quanto ao antebraço, também houve melhora significativa da área tratada em relação ao controle para ambos os parâmetros avaliados ( $p = 0,001$ ).

**Comentários e Conclusão:** A associação dos ingredientes da formulação (ácido láctico e lactato de sódio em emulsão com triglicerídeos do ácido caprílico e cáprico) foi capaz de aumentar os níveis de elasticidade e hidratação, reduzindo a incidência de estrias em comparação ao relatado em literatura.

**Palavras-chave:** estrias de distensão; gravidez; relaxina.

## INTRODUCTION

Stretch marks (*distensae striae*) are caused by the rupture of collagen and elastic fibers in the dermis, when subjected to fast and intense distension. They can occur in any individual during situations of cutaneous distension, such as weight gain, physical exercise with fast increase in muscle volume, corticosteroids use etc. However, they are especially common in pregnancy.<sup>1,2</sup> Stretch marks occur in up to 90% of pregnancies, especially in the third quarter, being a multi-factorial phenomenon. They can be linked to constitutional pre-disposition, weight gain, and the age of the mother.<sup>3</sup>

The appearance of stretch marks is clinically characterized by linear macules that are initially erythematous or violaceous. They may present mild pruritus, and then progress to atrophic areas of pearly appearance. They can be variable in size and number, and sometimes lead to deformities, causing psychological disorders in the patient.<sup>4</sup> There are several treatment modalities for attenuating striae distensae, however once they have occurred, their complete eradication from atrophic areas is still virtually impossible.<sup>5</sup> For this reason, some studies have been conducted with the aim of assessing the value of topical treatments ineffectively preventing the formation of stretch marks during pregnancy. Topical formulations that could act on the mechanical properties of the skin – especially on elasticity – could possibly mitigate the onset of stretch marks.<sup>6</sup>

In order to accurately evaluate this possible affect, biophysical measurements of parameters such as skin elasticity and hydration can be gathered using safe, accurate, and non-invasive equipment.<sup>7,9</sup> Alpha-hydroxy acids have been studied for their therapeutic effect on stretch marks via topical use or peeling. Their safety profile at low concentrations is encouraging for use during pregnancy.<sup>10</sup> The product evaluated in the present study is an emulsion containing lactic acid. To date, there is an absence of studies on the preventive effects of the alpha-hydroxy acid molecule on striae distensae. The present study is aimed at evaluating the efficacy of a topical formulation containing lactic acid in preventing stretch marks during pregnancy.

## METHODS

This was a prospective, controlled, comparative study, conducted between May and September 2010, at a private clinical research laboratory in the city of Osasco (SP), Brazil. Seventy-five pregnant women aged 18–40, without previous abdominal striae, were assessed. The patients were invited to take part in the study, from immediately after their third full month of pregnancy (13 + 1 completed weeks) and ending at the beginning of their 36th week of pregnancy. Patients who had not attended prenatal care, those carrying twins, those considered high-risk by the assistant obstetrician, those with hormonal disorders or using oral or topical corticosteroids (as well as any type of hormone) were not included in the study.

At baseline, the skin of all patients was evaluated using the clinical parameters of smoothness, hydration and elasticity, and was classified according to a four-grade scale of intensity, with the higher grades representing higher intensities. Biophysical

measurements were collected using a Cutometer® MPA 580 (Courage & Khazaka, Germany) device, designed for the evaluation of elasticity. The stratum corneum's hydration was assessed with a Corneometer® MPA 580 (Courage & Khazaka, Germany) device. The instrumental measurements were then repeated at the last study visit. The treated area (for ethical reasons) was the abdomen. In order to evaluate skin elasticity, random sections of the inner right or left forearm were chosen as the control area, and areas both with and without the application of the tested product were compared. In addition to the initial assessment, three more clinical and subjective evaluations were carried out during the course of the study (at 28 + 2 days, at 70 + 2 days, and at 140 + 2 days), corresponding to approximately 120 days of continued use of the product in the tested areas.

The evaluation of stretch marks that emerged on the patients during the study followed a five-grade rating scale, which included size, color, and depth of stria, where Grade 1 corresponded to the highest intensity of the parameter and Grade 5 corresponded to the lowest (the latter meaning improvement of the striae). A specific abdominal area (the lower right and left quadrants located near the umbilicus) was chosen for the observation and counting of the stretch marks. The use of the product was standardized at one to two times daily. The study protocol, as well as the Free and Informed Term of Consent, was previously approved by an independent Ethics Committee.

## RESULTS

Of the 75 pregnant women invited for the study, seven did not meet the criteria for inclusion and/or exclusion. The study began with 68 volunteers; one was excluded for not using the product as instructed and eight gave up participating for personal reasons unrelated to the study, which proceeded with 59 volunteers going forward. Of those, two patients had their data disregarded for not returning for the final evaluation. Of the 57 remaining, five developed adverse events during the study, resulting in valid data collected from 52 pregnant women who completed the study. The mean age in the study group was 28.4 years. Adverse events observed are detailed in table 1:

## EFFICACY EVALUATION

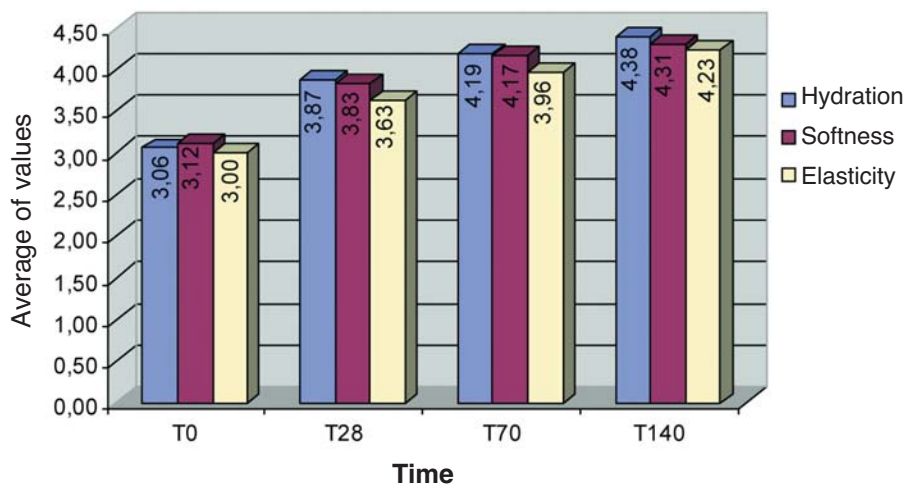
Statistical evaluation: All data was statistically analyzed using a Student's t-test, with a 5% significance level.

### 1. Clinical evaluation

All parameters evaluated clinically (hydration, softness and elasticity), presented a statistically significant increase ( $p < 0.001$ ), as shown in figure 1.

**Table 1: Adverse reactions observed (n=59)**

Adverse reaction	Number of patients
Spontaneous abortion	01 (1.7 %)
Preterm birth	03 (5.0 %)
Pregnancy prurigo	01 (1.7 %)
TOTAL	05 (8.4%)



**Graph 1:** Clinical Evaluation: average scores taken at experimental time frames for hydration, softness, and elasticity. Abdominal area (n = 52)

## 2. Striae occurrence

The counting of new striae was carried out in the right and left lower quadrants of the abdomen, and only in the clinical evaluations of return visits: Visit 2 (T28 + 7 days), Visit 3 (T70 + 7 days) and Visit 4 (T140 + 7 days).

Of the 52 volunteers who completed the study, five patients developed striae (9.6%) when using the product. Table 2 details the data obtained.

Striae with sizes and depths considered moderate were observed, with 11.2 new striae having emerged, on average.

## 3. Instrumental evaluation

### Measurement through corneometry:

There was a significant increase of the corneometric average between the initial and final time frames of the study, therefore meaning greater skin hydration. This data is depicted in graph 2.

In the forearm control area, the measurements of the two sites (those with and without the formulation applied) were taken at the beginning and end of the study. Although there was improvement in the control area, it was not considered significant when compared to observations of the treated site ( $p < 0.001$ ), as shown in graph 3.

### Measurement of elasticity through cutometry:

The elasticity parameter in the abdominal area presented a statistically significant increase of the values obtained, as shown in figure 4.

The elasticity parameter was evaluated in the forearms (in the treated and in the untreated areas), evidencing a significant increase in elasticity over time ( $p = 0.001$ ) in the areas where the product had been applied, as compared with the control area, as shown in figure 5.

## DISCUSSION

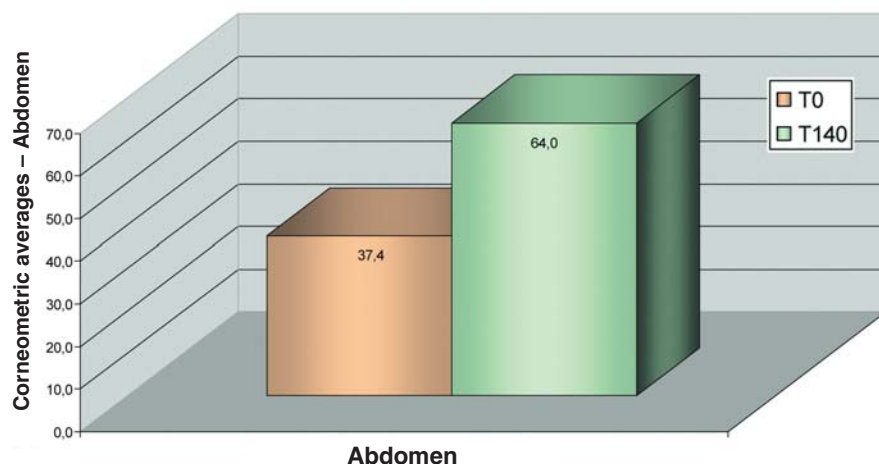
The occurrence of striae distensae during pregnancy can be attributed not only to mechanical effects, but also to hormonal estrogenic alterations and the activity of relaxin, as well as to some constitutional (e.g. age group) and genetic components.<sup>11,12</sup>

The improvement in the skin's elasticity could be one of the contributing factors in the partially mitigated appearance of striae, given the multi-factorial nature of this process.<sup>13</sup>

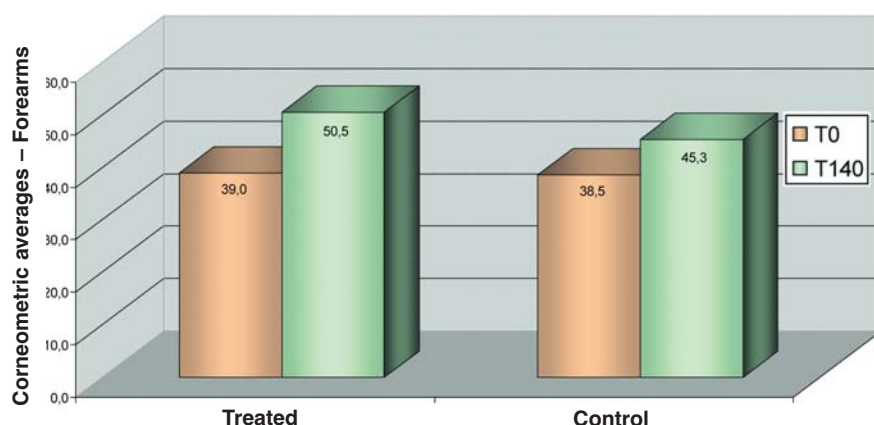
In the latest review article published by The Cochrane Library, there were a few comparative studies (with placebo or control-groups) demonstrating that some compounds have had a positive effect in decreasing the appearance of striae. The use of

**Table 2:** Results obtained in the volunteers who presented recent formation of striae in the abdominal area (n=52).

Number of volunteers	Quantity	Size	Color (Score)	Depth (Score)	Return visit on which it appeared (Score)
23	8	5	2	4	T70+7D
67	16	2	2	2	T140+7D
17	10	2	2	2	T140+7D
12	7	2	2	2	T140+7D
9	15	2	2	2	T140+7D
Média	11.2	2.6	2	2.4	



**Graph 2:** Average of corneometric measurements in the abdominal area at experimental time frames (n = 52) ( $p < 0.0001$ )



**Graph 3:** Average of corneometric measurements between time frames T0 and T140, in the forearms – treated and control areas (n = 52) ( $p < 0.001$ )

Asian centella, tocopherol and collagen hydrolysates, and elastin reduced the occurrence of stretch marks in a group of 130 pregnant women. Another study involving 50 patients assessed the use of a compound containing tocopherol, panthenol, hyaluronic acid, elastin, and menthol, in tandem with massage, and also suggested a reduction in the incidence of striae.<sup>14</sup>

Lactic acid is an alpha-hydroxy acid commonly used in dermatology, for it has the ability to act in the epidermis (desmolytic effect, with increased epidermal turnover) and dermis (stimulation of collagenesis and elastinogenesis), to improve scarring when used in peeling, for example.<sup>15</sup>

Sodium lactate is a molecule with hydration properties superior to those of glycerin, and which also provides micro-exfoliation (keratolysis). As it is the lactic acid's salt form, sodium lactate helps to isolate the activity to the epidermis and prevent the risk of irritation during continued use.<sup>16,17</sup>

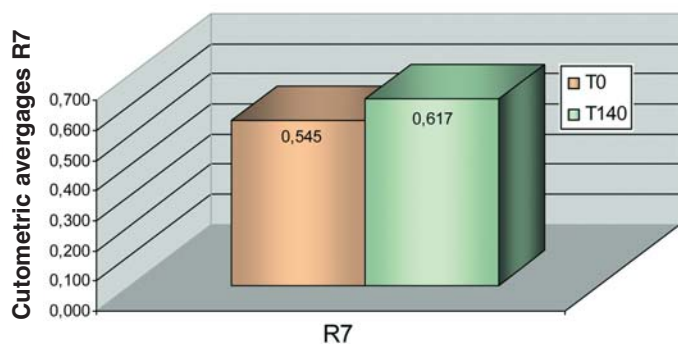
Caprylic and capric acids' triglycerides are oils of natural origin with emollient activity and are used extensively in cosmetics due to their compatibility with the skin, making them safe for use during pregnancy.<sup>18</sup> The formulation evaluated in the pre-

sent study contained lactic acid and sodium lactate combined in an emulsion containing mainly triglycerides of caprylic and capric acids, as well as glycerin, all of which are compatible for use on the skin.

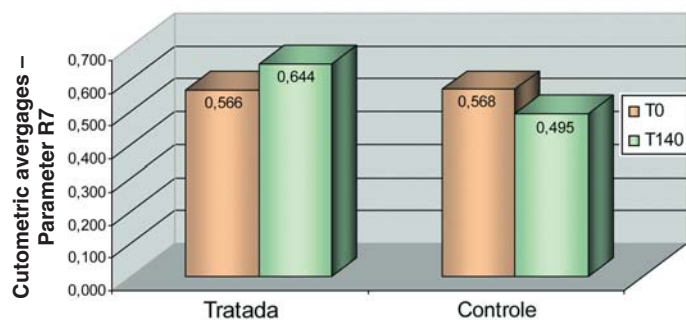
At the clinical evaluations, significant improvement in the amount of hydration, skin elasticity, and softness was observed in the treated area. Although there is no evidence that preventing dryness helps to avoid the formation of striae distensae, the comfort provided by the application of the emulsion did improve the patients' adherence to the continued use of the product, favoring its potential effect on skin elasticity.

Approximately 9.64% of pregnant women in the studied group developed stretch marks, which were observed mainly during the 20 weeks of evaluation. Such incidence is lower than that reported in the literature (around 70% in women under 25-years-old, and about 29% in women above 25-years-old).<sup>16</sup>

There is evidence that improved levels of elasticity are correlated to the integrity and functionality of elastic and collagen fibers. A recent study suggests there is a correlation between cutaneous distention capacity and cutometric and elasticity mea-



**Graph 4:** Average of cutometric measurements of elasticity (R7) at experimental time frames - statistically significant increase ( $p = 0.008$ )



**Graph 5:** Average of cutometric measurements of elasticity (R7) in the forearms - significant improvement in the treated area ( $p = 0.001$ )

surements. The ability to increase elasticity seems, therefore, to be present throughout the tegument, both in the distended and in the control area (which has not undergone distension) in pregnant women who are less prone to develop striae.<sup>17</sup>

In the present study, the significant increase in the elasticity of the skin treated (both in the abdomen and forearm) when compared to the untreated area, allows us to infer that the use of the formulation has a positive influence on the improvement of elasticity. This in turn may also be an influencing factor in the lower incidence of stretch marks in the group of patients studied.

## CONCLUSION

The studied formulation led to a significant reduction in the occurrence of stretch marks in the population studied when compared to the literature. This preventive effect is possibly related to the improvement in the skin's elasticity level in the application areas, meaning it has interfered with one of the striae distensae's etiological factors. ●

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