The effect of an innovative gel in the prevention and treatment of striae distensae. *(Stratamark® gel)*

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Abstract

Despite the heavy use of cosmetic products for the prevention and treatment of stretch marks, Striae Distensae (SD) remains prevalent amongst pregnant women, to date little clinical evidence has been published to support their use. **Objective:** The objective of this study was to evaluate the clinical efficacy of a novel medical device (Stratamark® gel) for the prevention and treatment of striae distensae in a study cohort of 303 women. **Results:** 148 pregnant women with no existing striae distensae used Stratamark® in the **Prevention arm.** Only 18.2% developed striae distensae at the endpoint of the study, which were graded as mild (9.46%), mild – moderate (6.08%), moderate (2.03%), moderate – severe (0.68%) with no severe or very severe cases reported. 155 women with existing striae distensae used Stratamark® in the **Treatment arm.** 80% experienced an improvement in their existing striae distensae. Both outcomes were found to be statistically significant. **Conclusions:** Stratamark® is effective in the prevention and treatment of striae distensae in the studied cohort. Further studies to confirm these results are recommended.

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Introduction

Striae distensae (SD) are common and clinically present as pathological linear atrophic scars[15] that have several different classifications – SD is the generic term for stretch marks, Striae Rubrae (SR) describes early red scarring that occurs in the epidermis, Striae Albae (SA) describes the stretch marks as they become mature, whiter and depressed, and Striae Gravidarum (SG) describes stretch marks that occur due to pregnancy. The prevalence of SG reported in the literature is wide ranging, between 50% in some studies, and as high as 90%, or "most women" in some medical text books. Most published studies report between 60% to 70% of pregnant control groups develop SG, depending on the ethnic group studied, the type of placebo cream used and the measurement criteria used.[1–4] The measurements used to determine the development of SG varies from self-reported questionnaires in some studies, through to health care professional examination. In pregnancy, SG commonly starts to occur late in the second trimester, although a considerable percentage (43%) develop prior to 24 weeks gestation. This same study, reported that even a 15% of the studied cohort developed SG before week 15 of pregnancy. [6] SG most frequently affects all four quadrants of the abdomen and appears less commonly on the breasts, buttocks, hips, arms and thighs.[1,2]

Macroscopically, SD appear as slightly raised pink to purple linear bands (SR) that eventually mature to become pale, atrophic scars with finely wrinkled lines (SA).[1,4,9,10,12] Microscopically SD are scars with a thin, flattened, atrophic epidermis and flattening of the rete ridges. There is loss of the normal random collagen distribution to the level of the mid-dermis or deeper. Elastin stains reveal scarce or absent elastin fibres and reduced fibrillin in the papillary and reticular dermis. Elastin fibres that are present reside in clumps around the periphery of the scar and appear tangled and frayed.[2,4–6,9,10,15] The histology of a SD is that of a scar, and the development of SD has been likened to that of wound healing or abnormal scar formation.[14]

The pathogenesis of SD is still not fully understood, but most authors agree that there are definitive changes in the extracellular matrix, especially changes in collagen, elastin and fibrillin.[5,6,16–18] Gene expression studies have suggested that SD skin shows decreased fibroblast metabolism compared to normal skin, with decreased levels of collagen, elastin and fibronectin gene expression.[5,6,16] Elastolysis and mast cell degranulation has also been implicated in the early stages of SD leading to destruction of elastin and collagen fibers.[10,19]

In support of the above findings Mitts, et al looked at the histological difference between 3 groups – SD

skin, patients with normal looking skin that had SD areas and normal skin. They showed the fibroblasts of SD skin were dysfunctional producing less elastin, fibrillin, collagen I, and fibronectin. In addition, they reported that all aberrant features were reversible including the SD fibroblasts. [36]

Chang, et al postulated that SD may be caused by a defect in the basic structure of elastic tissue leading to an abnormal response to stretch in susceptible individuals. This theory was posed after a relationship was found between SG and increased vaginal lacerations at birth.[6] An extracellular matrix defect may also explain why overstretched tissue leads to ruptured collagen fibers and hence SD in some individuals who experience rapid weight change such as pregnancy or Cushing's syndrome.[13]

Treatment modalities for the reduction and/or prevention of SD include phototherapy, CO_2 fractional laser therapy, pulsed dye laser, pulsed light therapy, cocoa butter, topical tretinoin and various other hydrants creams, topical massage, oil and herbal remedies. Several products are available on the market claiming to improve SD with no clinical evidence or assessment of efficacy. Of those products that have been studied for efficacy and tolerability, results for different modalities vary depending on age of the SD at the time of treatment and/or the patient skin type studied. SA have the reputation of being notoriously difficult to treat.[3,20]

Materials and Methods

Recruitment and selection

A volunteer sample of 303 women, presenting to 61 different Obstetricians in Czech Republic for obstetric care participated in the study. All subjects were in good health with no chronic skin conditions or severe co-morbidities that were likely to interfere with the study outcome. All patients were over 18 years of age.

Studied product

Stratamark® stretch mark gel (manufactured by Stratpharma AG, Basel, Switzerland) is a film-forming gel in the form of a self-drying silicone, developed from advances in polymer technology, for management and prevention of SD, resulting from pregnancy, exogenous and endogenous glucocorticoids, obesity and other conditions resulting in SD formation. Stratamark® when used as directed dries to form a very thin silicone gel sheet. Stratamark® forms a gas permeable, waterproof and durable membrane that protects and hydrates the skin surface.

Procedure

Subjects were divided into two arms: **Prevention:** 148 pregnant women with no existing SD, and **Treatment:** 155 women with existing SD (both SA and SR) prior to their study participation. Within the Treatment arm some women started their treatment during their current pregnancy as they had pre-existing SD and some patients started their treatment as late as post-delivery. 9.03% of women had SA; Means SD over 90 days of age. Many of the women recruited into the Treatment arm did not have existing SD, had declined participation in the prevention group, and as they developed SD during their pregnancy and/or post-delivery, requested to become part of the Treatment arm. See Table 3.

All women were instructed not to use other creams or lotions during the study period. All women were asked to apply the gel once per day, and it was explained that the best results were expected if the product was in contact with the skin 24 hours a day 7 days a week (24/7). Those that used the gel less than 6 days per week were excluded from the study.

Measurements

Patients in both the Prevention and Treatment Arms were asked to fill in a questionnaire on their experience using the gel - this included tolerability, ease of use and feel on their skin using a Likert scale of 1 to 5 (1 = unsatisfactory, 2= satisfactory, 3 = good 4 = very good , 5 = excellent). Patients in the Prevention arm were assessed qualitatively for the development of SD post-partum by their obstetrician. Those patient who developed SD were further assessed to rate the severity of their new SD using a scale from 1 to 7 (0= no SD, 1= mild, 2= mild –moderate 3 = moderate, 4 = moderate – severe, 5 = severe, 6 = very severe and 7= worst imaginable SD).

Patients in the Treatment arm were assessed by the obstetrician prior to their first Stratamark application to determine change in color, visibility and pruritus of their current SD using a scale (-4 significant deterioration, -3 considerable deterioration, -2 deterioration, -1 slight deterioration, 0 no change, +1 slight improvement, +2 improvement, +3 significant improvement, +4 disappearance). Severity of their SD pre and post treatment was rated by the investigator using a scale from 1 to 7 (0= no SD, 1= mild, 2= mild –moderate, 3 = moderate, 4 = moderate – severe, 5 = severe, 6 = very severe and 7= worst imaginable SD).

Severity, color and visibility were rated by the investigator comparing the SD to surrounding skin and pruritus was rated by the patient.

Statistical Analysis

For subjective evaluation of the product both arms were added up. A value of 61% was chosen as the background prevalence for the development of SG as demonstrated by Osman et al.[1]

Data found not to be normally distributed were summarized using medians and analyzed using non-parametric Wilcoxon Rank Sum Test. Chi-Square Test for qualitative SD prevention against literature prevalence was used. ANOVA one way was used to determine variables and risk factors influencing the outcomes. A two tailed p- value of < 0.05 was considered significant.

Results

Prevention Arm:

The average gestational age of the first Stratamark® application was during week 21 of pregnancy (std= 6.44 weeks). 23.8% of the deliveries were cesarean sections, 76.2% of participants underwent a vaginal delivery. Of the 148 women the average week of delivery was 38.9 (std= 2.06 weeks).

Of the 148 women who participated in the Prevention arm 18.2% of these patients developed SD as assessed by their obstetrician post-delivery in contrast with published 61% prevalence (p<0.001).[1] Details regarding the severity of these new SD are shown in Table 1. The prevention of SD development with Stratamark® use was neither influenced by the gestational age at starting gestational age of application (p = 0.77) nor by the gestational age at delivery (p = 0.94), nor the delivery method (p = 0.76), nor the location of the investigation (p = 0.5).

SD classification in Prevention Arm	All cases (n=148)	n (%)	SD cases (n=27)
0	121	81.76	0
1	14	9.46	14
2	9	6.08	9
3	3	2.03	3
4	1	0.68	1
5	0	-	0
6	0	-	0
7	0	-	0

Table 1 *Severity of SD according to the scale in the Prevention arm*

0= no SD, 1= mild, 2= mild –moderate, 3 = moderate, 4 = moderate – severe, 5 = severe, 6 = very severe and 7= worst imaginable SD

Treatment Arm:

155 women who participated in the Treatment arm had SD prior to this study. The age of the SD was distributed as shown in Table 2. From the 96 cases of SD under 2 weeks of age, 81 cases happened during pregnancy and 15 post-delivery. The rest of the studied population (74 subjects) applied Stratamark® for the first time post-delivery.

Average severity of SD prior to beginning treatment with application of Stratamark® scored 3.50 (from 1 to 7) and ended at 1.84 (std respectively 1.62 and 1.10). This improvement was found to be significant (p-value <0.001).

Age of SD	Cases (n)	n(%)
<(less than) 2 weeks	96	61.94
>2 weeks <4 weeks	6	3.87
>4 weeks <8 weeks	26	16.77
>8 weeks <12 weeks	13	8.39
>12 weeks	14	9.03
Total	**155**	**100.00**

Table 2 *Age of studied SD in Treatment arm*

Ad Hoc analysis of subgroups is shown in Table 3. Subgroups include the analysis of the treatment of those SD developed and treated during pregnancy; those SD developed during or after pregnancy but treated post-delivery; those SD with an age over 90 days and those SD subcategorized under severe (Mean severity score before treatment > 4)

Color, visibility and pruritus of SD pre and post treatment are summarized in Table 4.

Color assessment of SD in comparison to surrounding healthy skin pre and post treatment demonstrated that 1.97% (3/152) had a disappearance of SD color; 38.16% (58/152) had a significant improvement in color, 33.55% (51/152) showed an improvement, 14.47% (22/152) showed a slight improvement, 7.24% (11/152) showed no change; 1.32% (2/152) showed a slight deterioration; 1.97% (3/152) showed a deterioration; 0.00% (0/152) showed a considerable deterioration and 1.32% (2/152) showed a significant deterioration; as assessed by their obstetrician.

For visibility pre and post treatment comparison as assessed by the patient's obstetrician post-delivery 3.36% (5/149) showed a disappearance of SD,

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28.86% (43/149) a significant improvement, 37.58% (56/149) showed an improvement, 16.11% (24/149) showed a slight improvement, 9.40% (14/149) showed no change; 2.01% (3/149)showed a slight deterioration; 2.01% (3/149) showed a deterioration; 0.00% (o/149) showed a considerable deterioration and 0.67% (1/149) showed a significant deterioration; as assessed by their obstetrician.

And for pruritus rating – 19.21% (29/152) reported the disappearance of pruritus, 31.13% (47/152) a significant improvement, 25.17% (38/152) showed an improvement, 7.95% (12/152) showed a slight improvement, 15.23% (23/152) showed no change ; 0.00% (0/152) showed a slight deterioration; 0.00% (0/152) showed a deterioration; 0.00% (0/152) showed a considerable deterioration and 1.32% (2/152) showed a significant deterioration; as per patient self-assessment.

A risk factor analysis influencing the outcome was performed in the Treatment arm and none of the studied variables had an influence in the improvement of existing SD with Stratamark® treatment. Age of the SD (p = 0.06), delivery method (p = 0.55) and location of investigation (p = 0.65) respectively.

Patients evaluation

Tolerability, Ease of Use and Feel on the Skin of Stratamark® rated by the patients for both the Treatment and Prevention arms are summarized in Table 5. 302 women answered the questionnaire regarding tolerability, and 298 answered the questionnaire regarding ease of use and feel on the skin respectively.

	*Sample size	(n%)	Mean severity (Before)	Mean severity (After)	Z-score
All cases	153**	100.00	3.503	1.837	-9.044
Treatment start during pregnancy	69	45.39	2.986	1.928	-4.537
Treatment start post-delivery	72	47.37	4.014	1.847	-7.645
Old SD (> 90 days)	14	9.21	4.429	2.214	-3.354
Severe cases (> 4–7)	60	39.47	5.200	2.450	-9.075

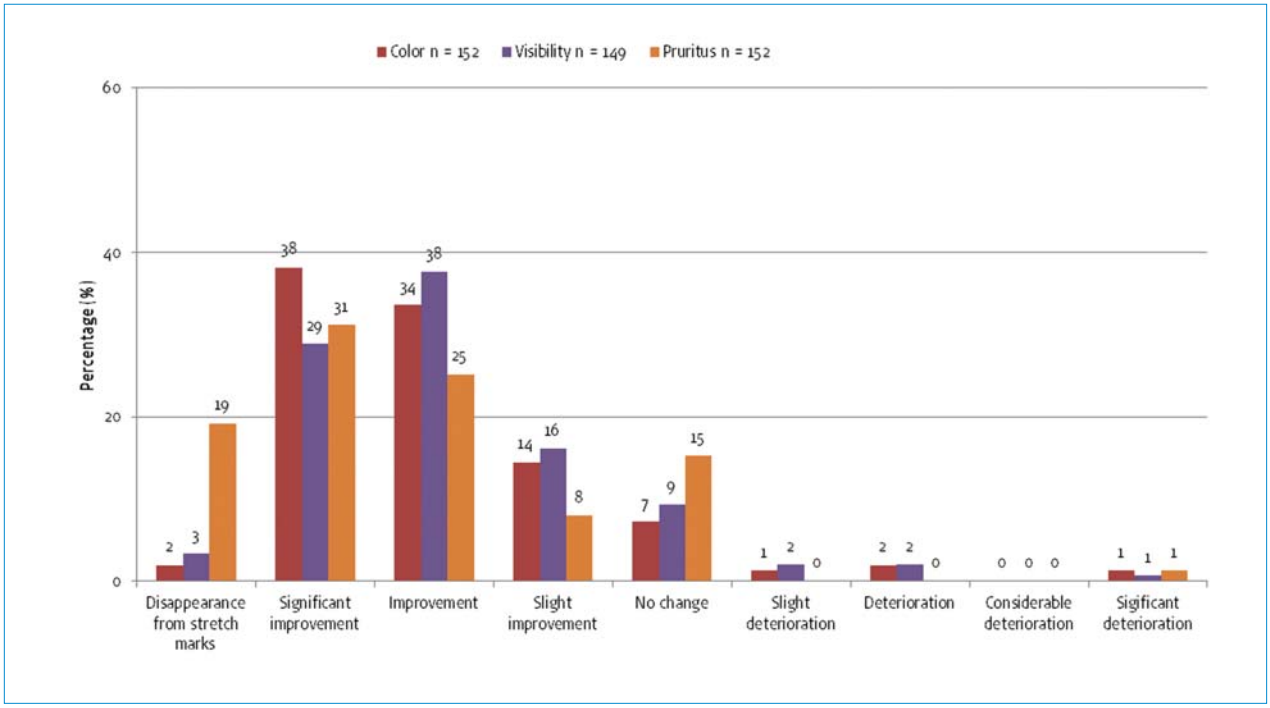
Table 3 *Treatment arm; Ad Hoc analysis of subgroups after Stratamark® use*

** The total sample does not add up as some subjects are present in more than one subgroup at the same time.*

***2 women were not assessed for severity by investigators.*

	Color		Visibility		Pruritus	
	n (total=152)	n (%)	n (total=149)	n (%)	n (total=152)	n (%)
Disappearance from SD	3	1.97	5	3.36	29	19.21
Significant improvement	58	38.16	43	28.86	47	31.13
Improvement	51	33.55	56	37.58	38	25.17
Slight improvement	22	14.47	24	16.11	12	7.95
No change	11	7.24	14	9.40	23	15.23
Slight deterioration	2	1.32	3	2.01	0	0.00
Deterioration	3	1.97	3	2.01	0	0.00
Considerable deterioration	0	0.00	0	0.00	0	0.00
Sigificant deterioration	2	1.32	1	0.67	2	1.32

Table 4 *Color, visibility and pruritus of SD before and after Stratamark® treatment*



24 women reported applying the product less than 6 days per week in the Treatment arm and 29 women in the Prevention arm. Both non-compliant groups were excluded from data analysis based on the eligibility criteria. Application frequency of the product was 1.55 times per day in the Treatment arm (std = 0.63) and 1.38 times per day in the Prevention arm (std = 0.55).

There were no significant adverse events reported from either study arm. A total of 3 women withdrew from the study or discontinued using the gel due to reasons sighted as: dryness sensation or unknown reasons.

	Tolerability Sample size	(n%)	Ease of use Sample size	(n%)	Feel on the skin Sample size	(n%)
Total	302	100.00	298	100.00	298	100.00
Excellent	194	64.24	150	50.34	134	44.97
Very good	75	24.83	92	30.87	115	38.59
Good	25	8.28	43	14.43	37	12.42
Satisfactory	5	1.66	7	2.35	6	2.01
Unsatisfactory	3	0.99	6	2.01	6	2.01

Table 5 *Subjective evaluation of Stratamark®. Prevention and Treatment arm.*

Discussion

The analysis indicated that Stratamark® was efficacious for both preventing the development of SG during pregnancy and for treating those with previous SD whilst currently pregnant, and post-delivery.

Prevention

There are many unproven products on the market tried by many women for SD prevention. Women lack of clinically relevant information regarding their choice of treatment to prevent SD. It is important, therefore, to systematically assess the evidence on the effectiveness of these creams and preparations in the prevention of SD.

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18.2% of women (27/148) developed SD versus 61% of standard prevalence literature. As mentioned in the introduction, the frequency of SG is reported as high as 90%, but for this analysis we have used a conservative figure of 61%. This study was chosen as the measurements were performed by health professionals, not self-reported. Many reported prevalence rates are based on self-assessment questionnaires. This was based on the data published by Osman et al, 2007 who looked at 110 primiparous women with singelton gestations and no previous SD. Assessment was undertaken by 3 researches using a validated scale. All women were assessed prior to discharge and were included regardless of attempts to avoid development of SG. 61% of patients had used one cream or lotion in an attempt to avoid getting SG and 17% had used more than 1 cream or lotion. Whilst this is not an ideal study to determine prevalence versus one where no creams or lotions were used by subjects, Osman et al found no correlation between cream used and SG development. Secondly, Osman et al looked at 3 anatomical areas – abdomen, breasts and thighs where most studies report only the abdomen. Osman et al found that 1 in 4 women develop SG of the breasts or thighs.
For this study the authors were pleasantly surprised at the low prevalence rate achieved with this gel for the prevention group. To our knowledge there is no published studies thus far that report a prevalence rate this low for a single treatment modality.

Treatment

80% (124/155) of women demonstrated a significant level of improvement in their SD. Pruritus disappeared completely from SD in 19.21% of cases and improved in different degrees in up to 64.24% of cases. Pruritus in pregnancy can be severe and psychologically distressing and is commonly not addressed adequately by current therapy options. Attention also needs to be drawn to the point that only 6.62% of the questioned participants with SD did not consider the gel could have helped prevent SD (9.93% were not sure). This reveals an overall high believe in the efficacy of Stratamark® in this cohort. 83.87% of questioned participants consider the gel would help prevent SD, and this was further confirmed in the Prevention arm. With respect to the Treatment arm, we believe that further, more detailed studies are required based on the age of the SD and its potential cause, as SA are significantly more refractory to treatments. In addition, the length of time for treatment requires further investigation. In our study we used a compliance of 6 or more days per week and an end point of 60 days post-delivery, but many women reported still seeing improvements in their SD at our study end point.
The safety component of the study was of no surprise given the extensive amount of literature and medical experience with silicone gels. Stratamark® is a class I silicone based medical device, does not contain alcohol, fragrances or parabens and is suitable for pregnant women, breastfeeding mothers, children and people with sensitive skin.
SG are a type of atrophic scarring for which it is postulated that there is a reversible dysfunction of the components of the extracellular matrix (ECM) and dermal cells, specifically fibroblasts. Research into keloid and hypertrophic scarring suggests that growth factors such as the FGF family play an important role in regulating this production. In addition, it is well established that hydration and protection of the skin promotes this normal homeostasis. We believe that Stratamark through its physical mechanisms of protection and hydration aids in restoring the ECM and correcting fibroblast regulation. Future research would also ideally require biopsing the SD site, which is unlikely to be achieved in a pregnancy cohort.

Limitations

Limitations to this study include subjects and obstetricians not being blinded to their treatment. In addition, a more rigorous study controlling for variables such as parity and anatomical site of SD are necessary. There is a need for robust randomized trials involving larger sample sizes to confirm the efficacy of Stratamark® on the prevention and treatment of SD in pregnancy.

Conclusion

Although many kinds of creams and lotions are sold and used in an attempt to prevent and treat SD, their use is not linked with a reduction in SD for treatment nor for prevention.[37] Stratamark® was effective at preventing and treating SD in the study cohort. In the prevention Arm 18.2% women developed SD as assessed by their obstetrician post-delivery in contrast with published 61% prevalence ($p<0.001$). In the Treatment arm 80% experienced an improvement in their existing SD ($p<0.001$).

Conflicts of interest: Stratamark® tubes were provided free of charge by Stratpharma AG, The author had no financial interest in Stratamark® or support from Stratpharma AG, Switzerland.

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