Secret Saviours Stretch Mark Prevention System Clinical Trial 2012 – 2013

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A novel ‘system’ to aid in the prevention of stretch marks during pregnancy: Results of a randomised control trial using a combination of a maternity support device and functional cosmetic formulations.

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Keywords: Striae; Striae gravidarum; Pregnancy; Vector Alignment

Manuscript word count and figures: 2000 words; 2 figures

Conflict of interest: The authors declare that there are no conflicts of interest.

Abstract:

Background: *Striae gravidarum* occur during pregnancy in 50-90% of women and can cause considerable cosmetic concern, leading to psychological distress. Striae initially appear as red or purple lines that gradually fade, leaving white, thin skin. No treatments to date have been shown conclusively to prevent development of striae.

Aims: To assess a novel combination of synergistic topical creams and a specifically padded, skin device utilising the novel "Dermal Support Technology™"

Methods: Women in weeks 12-14 of their first pregnancy were recruited from the Instituto de Maternidad Y Ginecologia, Tucuman, Argentina to this randomised controlled trial. The control group consisted of women who used no creams or device and the treatment group consisted of women who used a combination of the device, day gel and night cream. The skin support device was worn only during the day; participants were recommended to use the day gel twice daily and the night cream once, at bedtime.

Results: Incidence of *Striae gravidarum* in the control group was 66%, while in the treatment group was 34% (OR 3.62, 95% CI 1.70-7.69, p=0.001). Median severity score in the control group was 4 (IQR 0-7), whereas in the treatment group it was 0 (IQR 0-3), p<0.001.

Conclusions: The systems combination of the specifically padded, skin support device and creams resulted in a significant reduction in the development of *Striae gravidarum*.
Contribution to significance of each component was not trialed.

Introduction:

Striae distensae, or stretch marks, develop when integrity of the dermis is compromised, which may occur in rapid growth and/or weight gain. Initially, they appear as raised red or purple striations, which gradually fade to irregular, white, guttered and thinned skin, which remain for life[1]. They are common in pregnancy, here known as *Striae gravidarum*. In a recent study of 2000 primigravidas, incidence was 64%[2], similar to previous reports of 50%-90%[3-5].

Striae gravidarum occur primarily on the lower abdomen after the 20th week of gestation[3]. Physical symptoms are minimal. Women may experience discomfort and itching, but the principal impact is long term cosmetic, which can lead to psychological disturbance[6]. *Striae gravidarum* are likely also, around the breasts, axillae, lower back, buttocks, and upper thighs[7]. *Striae gravidarum* on the abdomen appear perpendicular to Langer's lines, whereas spherical expansion of the abdomen with pregnancy might have been expected to cause striae that mimicked Langer's lines, with expansion of the skin's collagen and elastin bundles therein[8].

Striae gradually fade. This can be *enhanced* by 'treatments' such as laser photocoagulation, dermabrasion, and masking creams[9]. True removal is only possible with abdominoplasty. Additional striae are likely with subsequent pregnancies, multiple births, and familial tendency to formation[9].

There have been no clinical studies involving physical stabilisation of the skin to reduce mechanical shear forces generated in a pregnant abdomen. The present study is the first of this type; a randomised controlled clinical trial of a novel, padded maternity support band, combined with topical agents presented as both a day gel and a night cream, containing agents advocated by others[9-11].

Methods:

Women were recruited from Instituto de Maternidad y Ginecologia, as well as peripheral public clinics in Tucuman, Argentina. Ethics committee approval and informed consent was obtained for each participant. Inclusion criteria were ideally primigravidas but also, some few multigravidas. 159 women were enrolled before 14 weeks pregnancy. After which they were randomly assigned to either a treatment or control group. The treatment group was given a maternity support band and gels to use daily. The control group did not use the gels or band. ***Fig. 1*** shows the support band and how it is worn on the pregnant abdomen.

The day gel and night cream are based on existing skin moisturising creams, but now contain the active ingredients Centella asiatica extract, tocopherol and panthenol. The day gel was formulated using Lubrajel PF (Azelis/United Guardian, USA) as a base. This contains glycerin, aqua and glyceryl acrylate/acrylic acid co-polymer. The glycerin component leaves a slightly tacky residue on the skin, designed to increase adherence of the soft polymer, tacky pads on the support band, to the skin. The garment is derived from a support band commonly used to provide abdominal lift and commensurate relief of lower back pain as frequently encountered in latter stages of pregnancy, but with the addition of soft polymer, tacky pads on the inner surface.

The treatment group were instructed to apply the day gel on all four quadrants of the abdomen, on waking in the morning, after showering, before putting on the support band and at least once more during the day. The night cream was to be used before going to bed, after removing the support band.

Women were photographed at the start of the trial and at term. The treatment group was given a questionnaire at the end of the trial to assess the system's usage. Photographs were assessed to provide contemporaneous control data of incidence and severity of *Striae gravidarum* in this population. At completion, photographic data were randomised and independently analyzed, blindly, by six clinicians and scientists, none of whom were connected to, or participated in, the study; inclusive of; a consultant dermatologist, qualified dermatology research fellow, two consultant surgeons, a consultant obstetrician, and a PhD scientist. A visual analogue 'scale' was fashioned using photographs of women in the study to provide 'icons' rating the *Striae gravidarum* from "0" - no *Striae gravidarum*, to "10" - an abdomen entirely covered with red/purple *Striae gravidarum*; as shown in ***Fig. 2***.

Statistical Analysis:

Differences between proportions were analysed with Fischer's Exact test and odds ratios were calculated with Mantel-Haenszel Estimate. Median comparisons were analyzed with Mann-Whitney U test. Intra-class Correlation Coefficient of the six raters was calculated to identify reliability. Comparison of control and treatment group was performed on an intention-to-treat basis. All p values were two sided and were considered significant when <0.05. Statistical analysis was performed on IBM SPSS version21.

Results:

There were 60 participants in the treatment group and 59 in the control group. 56 of the treatment group completed the questionnaire. 57% used the maternity support band and creams, as instructed, throughout pregnancy. For some women the band became too tight, or too hot to wear (during the trial local temperature often exceeded 35°C). The night cream was preferred over the day gel, due to it being more akin to a standard skin moisturiser, whereas the day gel was tacky. This resulted in the following observations throughout the trial; at least one change up in size of maternity support band was required to allow for comfortable, yet firm, skin grip with increasing abdominal girth. Two or three (100mls) day gel bottles and one or two (100mls) night cream bottles were required throughout the pregnancy.

Incidence of *Striae gravidarum* in the control group was 66%, compared to 34% in the treatment group (OR 3.62, 95% CI 1.70-7.69, p=0.001). An approximate 50% reduction in incidence of *Striae gravidarum* with this system use. Median severity score of *Striae gravidarum* was 4 (IQR 0-7) and 0 (0-3), p<0.001 in the control group and treatment group respectively. Severity scores were gathered from six independent observers. Analysis was undertaken to correlate the likelihood of one observer scoring the *Striae gravidarum* the same as the next. Score correlation between judges was deemed 'excellent' (intra-class correlation coefficient of 0.94 (95% CI 0.92-0.95, p=0.001).
However, in both user and control groups, 10% scored nine or ten.

Discussion:

Few controlled studies focus on the prevention of *Striae gravidarum.* *Striae gravidarum* are incomplete wounds principally caused by stretching, influenced by other factors such as increased hormone receptor activity[12], elevated levels of relaxin[13], multiple pregnancies and a familial tendency, with the early redness part of an inflammatory response in the damaged dermal layer[3, 14]. *Striae gravidarum* seem to form perpendicular to Langer's lines. This observation can potentially be explained using the hypothesis whereby striae start at a 'point focus' of stress in abdominal skin. Similar to how a small chip in a car windscreen can be the focus for later propagation to a crack, this 'point focus' in the skin might allow a stria to form and thereafter propagate vertically downwards along a line of least resistance if stretching continues.

This hypothesis also accounts for why striae are less common with subsequent pregnancies, if *Striae gravidarum* did not develop during the first pregnancy[15].

This hypothesis formed the basis of the 'system' approach to help prevent *Striae gravidarum* forming in pregnancy. A device was fashioned to support the abdominal wall skin evenly, across its entire surface, equalising and minimizing those forces in the skin that if unchecked, might have allowed a 'stress focus' to form and initiate a stria.

The maternity support band was made to give firm support to the skin, aided by placement of tacky, soft polymer pads on the skin-facing side, placed in such a way that should a 'stress focus' still form, no line of least resistance could be followed downwards to allow the *Striae gravidarum* to propagate. This was termed "Vector Alignment". Functional cosmetic preparations were designed to introduce those few agents in to the skin, regularly, throughout pregnancy, shown by others to help prevent *Striae gravidarum*. The day gel was designed counter-intuitively to leave a tacky surface residue to enhance the grip of the maternity support band pads. At night, the maternity support band would not be required, as gravity would tend to de-stress the abdominal wall when lying flat. The night cream introduced the same key ingredients in to the skin overnight, yet allowed the woman to feel that her skin was 'soft and supple', through use of the same base moisturizer.

When newly pregnant women review information, principally on the internet, incidence of *Striae gravidarum* most often quoted is 70%-90%. Incidences of 52%[3] and 61%[4] have been reported for primiparous women and 71.1% for both primigravidae and multigravidae[9, 16]. However, it is not clear if the quoted incidences are simply for 'present' or 'absent' as opposed to the more relevant, present and severe. A few, small, narrow streaks are less likely to be emotionally troublesome than an abdomen covered in broad, red/purple, and jagged marks. Use here of the 'icons' to give an overall visual scale of *Striae gravidarum* is deemed useful and allows additional measure of efficacy for the system described. The scoring methodology was perhaps open to significant variation from how one observer might score *Striae gravidarum* from photographs but correlation between judges was 0.94.

The major finding of this study is that incidence of *Striae gravidarum* forming was significantly reduced when compared with contemporaneous controls (34% vs 66%). Furthermore, median severity score of Striae gravidarum was significantly reduced in the treatment group, with a

median score of 0 as compared with 4 in the control group. Effects of the maternity support band in isolation and its attributes versus the topical preparations is indeterminate. However, studies showing beneficial effects of the key ingredients in isolation did not exhibit results as significant as the results obtained in this trial. The dual system approach of the support band and creams has produced a statistically significant means of preventing *Striae gravidarum* forming in pregnancy.

Minor, yet relevant, findings from the study were noted from the answers of the questionnaire. There was a general consensus that the maternity support band was easy to put on and comfortable to use. Inherent firm support (and skin pads) kept it in place during wear and had an additional effect of providing substantive relief of back pain, especially during the third trimester. Anecdotal confidence in its efficacy came from the results for 'would you use it again?', 'would you recommend it to a friend?' and 'do you think the band helped diminish the incidence of *Striae gravidarum*?' Less encouragingly, the maternity support band was often deemed too hot to wear, reflecting its construction from nylon and elastane, with printed polymer pads. Cotton-rich materials, silk-like synthetic materials, or the addition of wicking agents to the garment, could be taken into consideration for future devices. The day gel was not as popular as the night cream; the deliberately tacky residue left on the skin to enhance grip was counter-intuitive to what women would expect and want from a moisturiser. This was soon overcome through education – once the purpose of the tacky residue was explained, regular use was achieved. The night cream was very much favored, being far more akin to a high quality skin moisturiser. Moreover, its frequent use over other body areas in addition to the abdomen, was found to be widespread. Although this is the first published study evaluating the effects of a physical 'support' for the skin during pregnancy, there is a limitation of this study. Effects of the active ingredients in the topical agents cannot be evaluated in isolation and furthermore, effects of simple massage and 'moisturisation' alone cannot be discounted[17]. The fact remains that we are unclear as to how and why *Striae gravidarum* form. Clearly, not a simple, mechanical only event, but one that is influenced by several other, most likely complex, factors. Findings evidencing this statement further is that almost 10% of women in the treatment group and control group ended their pregnancy with severe *Striae gravidarum*, scored at 9/10, for which we have no immediate explanation.

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Acknowledgements:

Funding: No one is directly funding the publication. The trial has been funded entirely by a small UK-based start-up company, run by three private individuals, one of which is Mr Stephen Barker. The other two individuals have had no direct input to the study whatsoever.

Contribution to Authorship: Dr Rossana Chahla is the Director of the Obstetric Institute who presented the protocol to the Ethics Committee for approval, gained approval from the Committee and allowed the study to take part in the facility. She asked and encouraged the local Consultant staff to participate and helped collate the final results. Dr Manuel Perez Gorena recruited in to the study and actively encouraged his colleagues to do the same, liaised directly with Professor Manson as the overall 'CRO' and acted as the local 'CRO'. Professor Manson has coordinated the project from the outset following requests from Mr Stephen Barker to do so. He has been responsible for presenting the protocol to the Director of the Obstetric Institute, translating all from English to Spanish, visiting the Institute on several occasions to gather and coordinate information, to encourage participation and to review and collate questionnaires. Dr Dimitri Raptis has reviewed the statistics for the paper and advised originally on the design of the trial. Miss Rebecca Perris, Miss Fatima Malik, Dr Sunil Chopra and Dr Sunit Ghatak have been responsible for the analysis of data and writing the paper. Miss Rebecca Perris has also been responsible for the final formatting of the paper.

Details of Ethics: The Instituto de Maternidad Y Ginecologia approved the trial on 8th July 2011.

Reference images of support band and scoring icons

Figure 1 (a) The maternity stretch mark support garment;
(b) Worn on pregnant abdomen

Figure 2 Benchmark ‘icons’ for the stretch mark scoring system,
(a) score 0;
(b) score 4;
(c) score 6;
(d) score 8.