

# LETTER TO THE EDITORS

## Research Letter

Dear Editor,

### *The use of an innovative film-forming topical gel in preventing Striae Gravidarum and treating Striae Distensae*

Striae distensae are atrophic scars of the dermis with coinciding epidermal atrophy. Striae distensae commonly occur during pregnancy, striae gravidarum, with a reported prevalence ranging from 55% to 90%.<sup>1,2</sup> Pathologically, a loss of normal collagen distribution occurs to the level of the dermis, with a reduction in elastin and fibrillin.<sup>3</sup>

From a patient perspective, striae gravidarum are abnormal scars that can cause significant disfigurement and psychological distress.<sup>4</sup> Clinically, the demand from patients for effective products to treat and prevent striae gravidarum is increasing. A recent survey showed that 78% of pregnant women used at least one topical product to prevent or reduce striae gravidarum during pregnancy and over one-third of women reported using two or more products.<sup>5</sup>

Evidence concerning efficacy of products is, however, lacking. The latest Cochrane review reported no evidence to support the use of topical preparations for the prevention of stretch marks during pregnancy.<sup>6</sup> Ud-Din *et al.*<sup>7</sup> concluded that no topical formulation is effective in treating or improving striae. This review also reported that the majority of trials did not discuss results on product efficacy in relation to early striae rubra or later striae alba. A recent study by Malkova concerning a topical treatment reported statistical significance in the prevention ( $N = 148$ ) and treatment ( $N = 155$ ) of striae gravidarum during pregnancy.<sup>8</sup>

The aim of this study was to confirm or reject the recent claims for this product during pregnancy and post-partum.

This prospective, multicentre study was ethically approved and conducted at the Women's and Children's Hospital and North Eastern Community Hospital in Adelaide, Australia. Informed consent was appropriately obtained for each patient.

Two groups of patients were included: pregnant women without stretch marks recruited from 26 weeks of gestation (prevention) and post-partum women with stretch marks

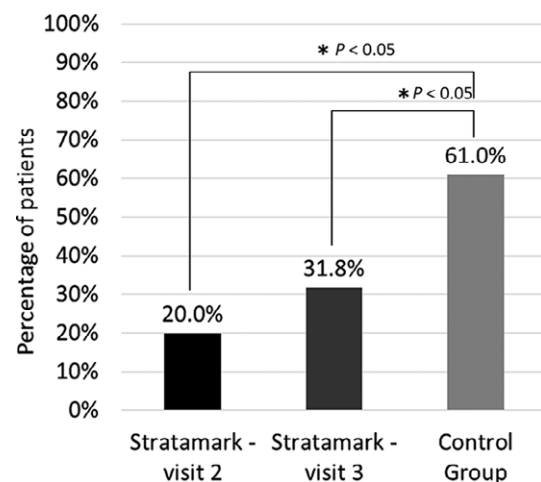
from any cause treated for 6 months (treatment). The study device was a topical, film-forming gel (Stratamark®, Stratpharma, AG - Basel, CH).

In the prevention group, striae gravidarum frequency and severity were measured. A historical background prevalence of 61% was used.<sup>1</sup>

In the treatment group, striae distensae age, severity, colour and pruritus were measured. In both groups, patients assessed efficacy, tolerability, ease of use and feel on the skin of the trial product. Significance was set as  $P$  value of  $<0.05$  and power of 0.80.

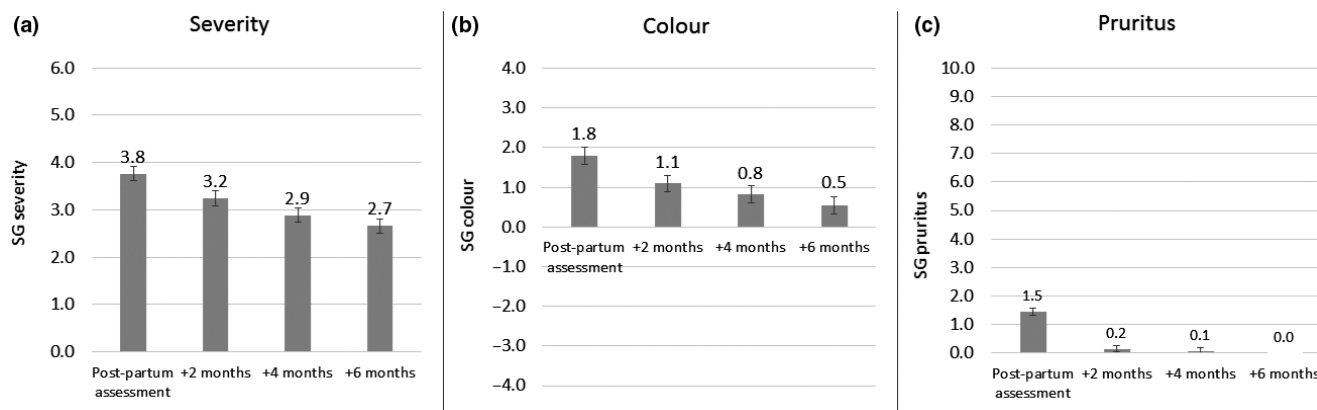
A total of 272 subjects were analysed (139 prevention, 133 treatment). Within the prevention group (Fig. 1), the device was statistically significant in preventing the occurrence of striae gravidarum vs. control population (20.0% at 36–40 weeks and 31.8% at 6–8 weeks post-delivery; both values were statistically significant vs. 61%,  $P < 0.05$ ). Within the treatment group, a statistically significant improvement in old and new striae distensae features of severity (23.5%), colour (54.4%) and pruritus (95.6%) was found over treatment time (Figs 2,3). Statistical significance was shown for improvement of severity in patients with striae distensae  $\geq 1$  year old, at 2 months post-partum (19.1%,  $P = 0.005$ ). A subjective assessment of the gel's efficacy, tolerability, ease of use and feel on the skin was favourable. Each item was rated as 'excellent' by the majority of patients.

Our overall results support the findings by Malkova.<sup>8</sup> The described results were achieved by topical application of the studied gel as monotherapy, and there were no patient-reported adverse events related to the device.

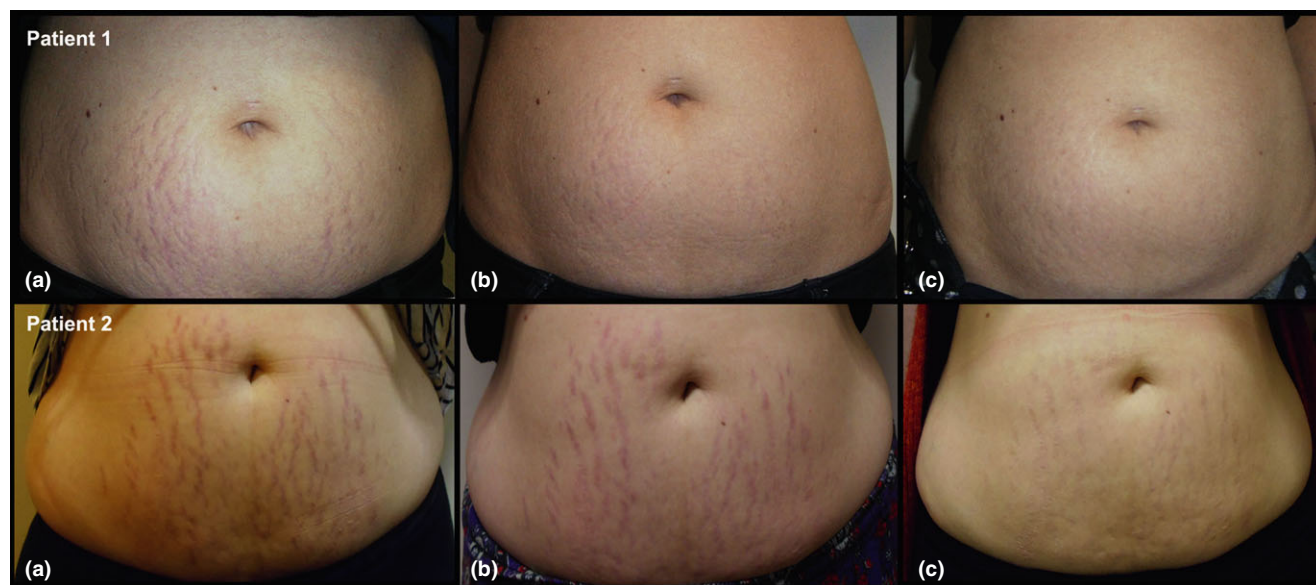


**Figure 1** Prevalence of subjects that developed striae gravidarum (SG) using the studied device versus control group.

Conflict of interest: The study product was supplied by Stratpharma AG, Switzerland free of charge to subjects. The academic institute received remuneration for the employment of a clinical research nurse.



**Figure 2** Investigator evaluation of striae distensae severity (a), colour (b) and pruritus (c) in the treatment group at each assessment. Scores are presented as mean values  $\pm$  SEM.



**Figure 3** Severity and colour of striae distensae in 2 subjects in the treatment group. (a) 2 months post-partum, visit 1. (b) 4 months post-partum, visit 2. (c) 6 months post-partum, visit 3.

Striae alba are a particularly challenging condition to treat. Invasive treatments, such as chemical peels, radiofrequency and laser therapy, can achieve different levels of results.<sup>7,9</sup> Maintenance treatments are recommended to sustain the cosmetic outcome, bearing an economic burden for the patient.<sup>10</sup> A subgroup analysis on severity improvement with old striae  $\geq 1$  year showed at 2 months postdelivery a strong statistical improvement. This finding was notable, as old striae distensae are characterised by permanent breakdown of collagen and elastin and do not improve over time.<sup>7,9</sup> It is probable that the improvement in the severity of old striae distensae is due to the application of the gel, or due to a synergistic effect with the gel causing scar remodelling during the finite hormonal window induced by pregnancy.

Considering other effective topical products and invasive procedure are contraindicated during pregnancy,

this gel currently sits as a standalone topical treatment that is efficacious and safe. Based on the results, healthcare professionals can be confident in recommending it to women who wish to prevent and/or treat striae.

Whilst the results are promising, this study is limited by small number of patients and high dropout rate.

Christopher David Gildas Hughes<sup>1</sup> | Amanda Hedges<sup>2</sup>  
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