Treatment of Keloids and Hypertrophic Scars with a Novel Polymer-based Skin Coating

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OBJECTIVE
The purpose of this study was to evaluate a polymer-based film-forming technology as a treatment for mature hypertrophic scars and keloids in a 16-week clinical trial. The product is an aceton and polymer-based skin coating that is applied to the skin as a liquid that rapidly dries (~15 – 30 seconds) to form a thin film. The polymer formulation contains no silicone.

The primary efficacy endpoint was the Vancouver Scar Scale (VSS). Study participants also provided self-assessment of itching.

BACKGROUND
Silicone sheeting is used as a non-invasive treatment for keloids and hypertrophic scars. However, silicone dressings often adhere poorly, can be difficult to affix to skin, can induce irritation on adjacent non-injured skin, and have inherent cosmetic deficiencies. This study was designed to evaluate the efficacy of a polymer-based skin coating to treat hypertrophic scars and keloids.

METHODS
Forty volunteers having a mature (>7 months old) keloid or hypertrophic scar met inclusion/exclusion criteria and were randomized to either silicone sheeting or polymer coating treatment groups. Study participants self-administered the polymer coating treatment twice daily for the duration of the 16-week study period, and those randomized to the silicone sheeting group used the product consistent with instructions from the manufacturer. Scar measurements and subjective evaluation by the participants were completed at baseline and weeks 4, 8, and 16.

The Vancouver Scar Scale (Table 1), which provides a composite score for vascularity, pliability, and height, and an ordinal score for pigmentation, was used to assess scars. Study participants also provided self-assessment of itching (Table 2).

RESULTS
Subjects treated with the polymer coating showed a statistically significant difference in VSS index score from baseline at weeks 4 (p<0.006), 8 (p<0.001) and 16 (p<0.001), demonstrating progressive improvement over the study period (Figure 1). Changes in scar pigmentation approached significance at week 4 (p<0.083) and continued treatment led to significant differences observed at week 16 (p<0.009).

Scars treated with the polymer coating showed significant and continual improvement over the four-month period. A disproportionately high number of patients dropped out of the study due to dissatisfaction and discomfort associated with the silicone sheeting. Similar dropout did not occur in those treated with the polymer coatings.

In order to minimize any effect of spontaneous scar resolution, only subjects with scars that were at least seven months old were enrolled in the study. In addition, there was no upper limitation placed on the age of the scar; as a result, many of the scars that were treated were several years old and reportedly refractory to previous modalities, including silicone sheeting. Better results may be expected in newer scars.

CONCLUSIONS
These novel polymer-based coatings are an effective treatment for mature keloids and hypertrophic scars.

**RESULTS (continued)**

Table 1. Vancouver Scar Scale

<table>
<thead>
<tr>
<th>Pigmentation</th>
<th>0 Normal</th>
<th>1 Hypopigmentation</th>
<th>2 Mixed</th>
<th>3 Hyperpigmentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascularity</td>
<td>0 Normal</td>
<td>1 Pink</td>
<td>2 Red</td>
<td>3 Purple</td>
</tr>
<tr>
<td>Pliability (Capacity to bend/twist)</td>
<td>0 Normal</td>
<td>1 Supple (flexible with minimal resistance)</td>
<td>2 Yielding (giving way to pressure)</td>
<td>3 Firm (resists to manual pressure)</td>
</tr>
<tr>
<td>Height</td>
<td>0 Normal (flat)</td>
<td>1 &lt; 2 mm</td>
<td>2 2.0 to 5.0 mm</td>
<td>3 &gt; 5 mm</td>
</tr>
</tbody>
</table>

Table 2. Scale for Self-Assessment of Itching

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 No itchy sensation</td>
<td>1 Sometimes itchy</td>
</tr>
<tr>
<td>2 Occasionally itchy: moderate and tolerable</td>
<td>3 Severe itchy sensation or constant itch with signs of scratching</td>
</tr>
</tbody>
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