Background

- Scarring can cause functional, cosmetic, and psychological morbidity.
- The clinical symptoms of scars include tenderness, discoloration, pruritus, and disfigurement.
- Remodeling treatments used for scars include surgery, laser therapy, steroid injections, and topical products such as onion extract gel and silicone gel.
- The use of silicone gel sheets for treating burns has revealed that skin grafts refrain from shrinking, while the area around the burns heals by epithelialization without hypertrophy.
- Silicone gels and sheets are widely considered as first-line treatment for scars.

Objectives

- To evaluate the safety and efficacy, in terms of appearance and symptoms, of a 100% silicone gel (Recedo™) compared with an onion extract-containing gel (Mederma®) in adult subjects with post-surgical scars.

Methods

Study Design

- Randomized, evaluator-blinded, single-center, 16-week, active-comparator clinical study (Figure 1).
- All subjects had post-surgical scars that were 2 weeks to 4 months old.
- The initial treatment was applied to the affected scar at the baseline visit (day 0) by a designated device dispenser at the site who was not responsible for any subject or scar evaluations.
- All remaining treatments were applied by the subject.
- Study visits were scheduled for baseline (day 0, first investigational product application), week 2, week 8, week 12 (end of treatment), and a final evaluation at week 16 (follow-up or early termination).

Efficacy Assessments

- Vancouver Scar Scale (VSS) total score: Change from baseline to week 16 (including ratings of vascularity, pliability, and height, with scores of 0-3 for each; total potential score range was 0-9).
- Pain and itch scores:
  - Change from baseline to week 16 (including ordinal ratings of 0-3 for each, and visual analog scale (VAS) scores of 0-10 cm for each).
  - Investigators’ and Subject’s Global Assessment of Scar Treatment: Assessed at weeks 8, 12, and 16 (4-point assessments: 1=very good, 2=good, 3=moderate, and 4=unsatisfactory).
- Comparison between the 2 study groups in the Subject’s Global Assessment of Scar Treatment at weeks 8, 12, and 16.

Safety Assessments

- Adverse events (AEs) and serious AEs.

Results

Baseline Characteristics

- Subjects were well matched, with no significant differences between study groups for age, gender, ethnicity, race, or age of scar (Table 1).
- 1 subject in the onion-extract-containing gel OD group was lost to follow-up after the baseline visit.

Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Gender</th>
<th>Silicone gel BID (n=24)</th>
<th>Onion extract-containing gel OD (n=24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>13 (54.2)</td>
<td>10 (41.7)</td>
</tr>
<tr>
<td>Female</td>
<td>11 (45.8)</td>
<td>14 (58.3)</td>
</tr>
<tr>
<td>Age, mean, years</td>
<td>61.7</td>
<td>60.5</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
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<tr>
<td>Hispanic or Latin</td>
<td>6 (25)</td>
<td>5 (20.8)</td>
</tr>
<tr>
<td>Non-Hispanic or Latin</td>
<td>18 (75)</td>
<td>19 (79.2)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>20 (83.3)</td>
<td>20 (83.3)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>4 (16.7)</td>
<td>3 (12.5)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0 (0)</td>
<td>1 (4.2)</td>
</tr>
<tr>
<td>Age of scar, mean, days</td>
<td>45</td>
<td>52.4</td>
</tr>
</tbody>
</table>

VSS Score

- The mean VSS score increasingly improved (decreased) from baseline for both groups during the course of the study (Figure 2).
- The improvement was significantly greater for the 100% silicone gel BID group at week 2 (P<0.01) and at the end of the study at week 16 (P<0.05) compared with the onion-extract-containing gel OD group.

Figure 2. Improvement in Mean VSS Score From Baseline

Pain and Itch Assessments

- There was a significant reduction in subject-reported itch from baseline in the 100% silicone gel BID group but not in the onion-extract-containing gel OD group.
- Mean VAS scores:
  - 100% silicone gel BID: 0.3 at baseline, 0 at week 16 (P<0.02).
  - Onion extract-containing gel OD: 0.2 at baseline, 0.09 at week 16.
- There were no significant differences between groups in subject-reported pain.
- There were no significant differences from baseline or between groups in reported pain.

Conclusions

- Both the 100% silicone gel and the onion extract-containing gel were effective and safe in improving the appearance of post-surgical scars.
- As assessed by the VSS, the 100% silicone gel BID was significantly more effective than the onion extract-containing gel OD at improving post-surgical scars.
- The 100% silicone gel BID was better tolerated than was the onion extract-containing gel OD, as nearly one-quarter of the onion-extract-containing gel OD subjects had mild-to-moderate itching at the site of application, versus no subjects receiving 100% silicone gel BID.

References