Onion Extract Gel Versus Petrolatum Emollient on New Surgical Scars: a Prospective Double-Blinded Study

Vinh Q. Chung, MD, Larisa Kelley, MD, Diego Marra, MD, and S. Brian Jiang, MD*

BACKGROUND Cutaneous scars resulting from surgical procedures can be erythematous, hypertrophic, pruritic, painful, or cosmetically unacceptable. An onion extract-based topical gel (Mederma, Merz Pharmaceuticals) has been marketed as a product to improve scar appearance and texture. However, few data are available to substantiate these claims.

OBJECTIVE To compare the efficacy between the onion extract gel and a petrolatum-based emollient (Aquaphor, Beiersdorf, Inc.) in improving the appearance and symptoms of new surgical scars.

METHODS Twenty-four patients with new surgical wounds at least 4 cm in length were enrolled in the study. Using a randomized, double-blinded, split-scar study design, each scar was divided into two equal portions, and each half was assigned treatment with either onion extract gel or petrolatum ointment at the time of suture removal. Each product was applied three times daily for 8 weeks, and patients were evaluated at 2, 8, and 12 weeks following initiation of treatment. A follow-up phone interview was conducted at least 11 months postoperatively.

RESULTS Scar halves were evaluated by blinded investigators for overall cosmetic appearance, erythema, and hypertrophy. Patients also independently rated side-specific erythema, pruritus, burning, and pain. Using the paired t-test and the Wilcoxon sign-rank test, we found no statistically significant difference (p<.1) between the two treatment groups in any of the outcome variables studied.

CONCLUSION Petroleum-based topical agents constitute standard therapy in the management of postoperative wounds. In this side-by-side, randomized, double-blinded, split-scar study, the onion extract gel did not improve scar cosmesis or symptomatology when compared with a petrolatum-based ointment.

Vinh Q. Chung, MD, Larisa Kelley, MD, Diego Marra, MD, and S. Brian Jiang, MD, have indicated no significant interest with commercial supporters. The Mederma gel was provided by Merz Pharmaceuticals (Greensboro, NC, USA).

Scarring from surgical wounds varies from fine and asymptomatic scars to hypertrophic scars to keloids. Results of abnormal and excessive wound matrix deposition, hypertrophic scars, and keloids may cause pruritus, pain, disfigurement, and psychological distress. Various treatment options exist for treating hypertrophic scars and keloids, including intrallesiob corticosteroids, pressure therapy, surgical excision, radiotherapy, cryotherapy, and carbon dioxide laser ablation. These treatments often require multiple visits and have limited success, so prevention of problematic scars is important. In addition to minimizing skin trauma, tension, and infection perioperatively, hydrating the wound through various dressings may also enhance healing.

An over-the-counter topical onion extract-based gel (Mederma, Merz Pharmaceuticals, Greensboro, NC, USA) has been claimed by its manufacturers to improve the appearance and texture of surgical scars (www.mederma.com). Despite its popularity, data

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demonstrating this gel’s efficacy are lacking. This study hopes to determine if this onion extract gel provides any additional benefit to the appearance and symptomatology of postoperative wounds when compared to a hydrating petrolatum-based topical agent (Aquaphor, Beiersdorf, Inc., Wilton, CT, USA) used as standard therapy for postoperative wounds in our dermatologic surgery unit.

Methods

Study Design

This is a prospective, randomized, double-blinded, internally controlled, split-scar study. Informed written consent was obtained from all patients, and the study was approved by the Institutional Review Board of the Beth Israel Deaconess Medical Center (Boston, MA).

Twenty-four patients with new surgical wounds at least 4 cm in length were enrolled from June 2003 to April 2004. All the patients had recently undergone Mohs or excisional surgery at the Dermatologic Surgery Unit at the Beth Israel Deaconess Medical Center and had tested negative for allergic reaction to the onion extract gel and the petrolatum ointment by a 48-hr patch test on their forearms. Each scar was divided into two equal portions, and each half was randomly assigned treatment with either onion extract gel or petrolatum ointment at the time of suture removal. Patients were given the treatments in two identical opaque syringes that were labeled “Top,” “Bottom,” “Left,” or “Right” to designate the scar half. From the day of suture removal, the products were applied three times daily for 8 weeks, and scars were independently evaluated by patients and Mohs surgeons (SBJ and LK) at 2, 8, and 12 weeks following initiation of treatment. A phone interview was conducted at least 11 months after the surgery.

Physician Evaluation

At each visit, blinded investigators (SBJ and LK) used a 10-cm visual analog scale (VAS) to rate each scar half for redness and thickness from 0 (absent) to 10 (severe). The investigators also determined whether the overall cosmetic appearance of one half was better than the other and rated the difference on a VAS from 0 (no difference) to 10 (significant difference).

Patient Evaluation

At each visit, patients used a 10-cm VAS to rate each scar half for redness, itchiness, burning, and pain from 0 (absent) to 10 (severe).

Phone Interview

Patients, who were still blinded to the treatment assignment, were interviewed over the phone. They were asked whether one scar half was better than the other in overall cosmetic appearance. If one half was reportedly better, patients were asked to assess whether the difference was “minimal,” “moderate,” or “significant.” Patients were also asked to assess whether the entire scar was “poor,” “okay,” or “excellent” in its overall appearance.

Statistical Methods

We have determined that a sample size of 24 scar halves, or 12 patients, would allow us to achieve 90% power to detect a mean difference of at least 2.0 cm in the VAS score between the two treatment groups, using an unpaired 2-tailed t-test with a 0.05 significance level and assuming a standard deviation (SD) of 1.5 cm.

Results

Patient Demographics

Seventeen (71%) male and 7 (29%) female patients were enrolled in the study and followed up at 2 weeks. Twenty-two patients were followed up at 8 weeks, and 14 patients followed up at 12 weeks. Twenty-one patients were successfully contacted in the phone interview. None of the patients developed an allergic reaction owing to the treatments.

All the patients were Caucasians who had undergone Mohs or excisional surgery for either basal cell carcinoma or squamous cell carcinoma. The ages of the patients ranged from 45 to 90 years, with an average age of 65 years. Twelve (50%) scars were located on the head, 7 (29%) on...
the trunk, and 5 (21%) on the extremities. The scar lengths ranged from 4 to 18 cm, with an average of 7.1 cm (Table 1).

Physician Evaluation: Overall Cosmetic Appearance
At 2 weeks, 8 (33%) of the onion extract-treated scar halves were determined to be better in overall cosmetic appearance, while 5 (21%) of the petrolatum-treated scar halves were better. At 8 weeks, 6 (27%) of the onion extract-treated scar halves were determined to be better in overall cosmetic appearance, while 4 (18%) of the petrolatum-treated scar halves were better. By 12 weeks, no difference in overall cosmetic appearance was found between the scar halves in 12 (86%) of cases. Only 1 (7%) case of petrolatum-treated scar half and only 1 (7%) case of onion extract-treated scar half were found to be superior. At all three points of evaluation, the differences in overall cosmetic appearance between the two treatment groups were not statistically significant (Table 2).

Physician Evaluation: Redness and Thickness
At 2, 8, and 12 weeks, minimal redness and thickness (<2) were found, with a time-related improvement in redness and thickness in both treatment groups. There was no statistical difference in redness or thickness between the onion extract-treated and the petrolatum-treated scar halves (Table 3).

Patient Evaluation: Redness, Itchiness, Burning, and Pain
There was no statistical difference in redness, itchiness, burning, or pain between the two treatment groups. By 12 weeks, all the criteria were rated as minimal, less than 1 out of 10 (Table 4).

Phone Interview
Twenty-one patients were successfully contacted for a phone interview at an average of 16 ± 4 months (range, 11–20 months) after the surgery. Three patients were unable to be reached despite multiple attempts. Nineteen of the 21 patients reported that no difference exists between the two scar halves in overall cosmetic appearance. The petrolatum-treated half was reported to be better in both cases where a difference existed. In one case, the reported difference was "minimal." In the other case, the reported difference was "moderate." All 21 patients reported that the entire scar was "excellent" in overall cosmetic appearance (Table 5).

Discussion
Overall, our patients tolerated both treatments well, with no incidence of allergic reaction. All of the criteria—redness, itchiness, burning, pain, and thickness—were generally rated as minimal or absent with time-related improvements. We found no signifi-
ONION EXTRACT VERSUS PETROLATUM FOR SURGICAL SCARS

TABLE 3. Physician Evaluation of Scar Halves: Redness and Thickness. Each Scar Half was Rated for Redness and Thickness on a 10-cm Visual Analog Scale from 0 (Absent) to 10 (Severe)

<table>
<thead>
<tr>
<th>Time (Weeks)</th>
<th>Characteristic</th>
<th>Onion Extract</th>
<th>Petrolatum</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Redness</td>
<td>1.50 ± 0.44</td>
<td>1.80 ± 0.44</td>
<td>.5898</td>
</tr>
<tr>
<td></td>
<td>Thickness</td>
<td>0.03 ± 0.03</td>
<td>0.13 ± 0.09</td>
<td>.2294</td>
</tr>
<tr>
<td>8</td>
<td>Redness</td>
<td>0.95 ± 0.30</td>
<td>1.1 ± 0.42</td>
<td>.5811</td>
</tr>
<tr>
<td></td>
<td>Thickness</td>
<td>0.25 ± 0.11</td>
<td>0.83 ± 0.24</td>
<td>.1080</td>
</tr>
<tr>
<td>12</td>
<td>Redness</td>
<td>0.39 ± 0.36</td>
<td>0.16 ± 0.13</td>
<td>.3356</td>
</tr>
<tr>
<td></td>
<td>Thickness</td>
<td>0</td>
<td>0</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

There was no statistically significant difference in redness or thickness between the two treated groups.


<table>
<thead>
<tr>
<th>Time (weeks)</th>
<th>Characteristic</th>
<th>Onion Extract</th>
<th>Petrolatum</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Redness</td>
<td>2.45 ± 0.50</td>
<td>2.50 ± 0.44</td>
<td>.9414</td>
</tr>
<tr>
<td></td>
<td>Itchiness</td>
<td>1.58 ± 0.63</td>
<td>1.09 ± 0.38</td>
<td>.2841</td>
</tr>
<tr>
<td></td>
<td>Burning</td>
<td>0.77 ± 0.34</td>
<td>0.85 ± 0.35</td>
<td>.8483</td>
</tr>
<tr>
<td></td>
<td>Pain</td>
<td>0.69 ± 0.29</td>
<td>0.68 ± 0.29</td>
<td>.4259</td>
</tr>
<tr>
<td>8</td>
<td>Redness</td>
<td>1.21 ± 1.72</td>
<td>1.59 ± 0.47</td>
<td>.4732</td>
</tr>
<tr>
<td></td>
<td>Itchiness</td>
<td>0.72 ± 0.43</td>
<td>0.30 ± 0.11</td>
<td>.3225</td>
</tr>
<tr>
<td></td>
<td>Burning</td>
<td>0.9 ± 0.43</td>
<td>0.19 ± 0.06</td>
<td>.3288</td>
</tr>
<tr>
<td></td>
<td>Pain</td>
<td>0.47 ± 0.26</td>
<td>0.30 ± 0.14</td>
<td>.3056</td>
</tr>
<tr>
<td>12</td>
<td>Redness</td>
<td>0.29 ± 0.11</td>
<td>0.29 ± 0.13</td>
<td>.9142</td>
</tr>
<tr>
<td></td>
<td>Itchiness</td>
<td>0.86 ± 0.047</td>
<td>0.57 ± 0.027</td>
<td>.4533</td>
</tr>
<tr>
<td></td>
<td>Burning</td>
<td>0.043 ± 0.02</td>
<td>0.043 ± 0.02</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>Pain</td>
<td>0.043 ± 0.02</td>
<td>0.043 ± 0.02</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

Each scar half was rated for redness, itchiness, burning, and pain on a 10-cm visual analog scale from 0 (Absent) to 10 (Severe). There was no statistically significant difference between the two treated groups for any of the variables.

TABLE 5. Phone Interview

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is one scar half better than the other in overall cosmetic appearance?</td>
<td>Onion extract</td>
<td>Petrolatum</td>
</tr>
<tr>
<td>Which half is better than the other?</td>
<td>Minimal</td>
<td>Moderate</td>
</tr>
<tr>
<td>How much better is one scar half than the other?</td>
<td>Poor</td>
<td>Okay</td>
</tr>
<tr>
<td>How does the entire scar look overall?</td>
<td>Poor</td>
<td>Okay</td>
</tr>
</tbody>
</table>

Patients were asked whether one scar half was better than the other in overall cosmetic appearance. If one half was reportedly better, patients were asked to assess whether the difference was "minimal," "moderate," or "significant." Patients were also asked to assess whether the entire scar was "poor," "okay," or "excellent" in its overall appearance. Patients' actual answers to this question were "Top," "Bottom," "Left," or "Right."

While none of the scars in our study became hypertrophic or keloidal at least 11 months after the surgery, it is uncertain whether the patients would have developed hypertrophic scars or keloids without treatments. Answering this question would require having a third group in our study that received no treatment. However, we believe that this study design would have been substandard of care, since keeping the wound moist has been shown to be beneficial. Whether our patients' scars will become problematic years later is also uncertain, since keloids may not develop until years after the event.

The nature of the trauma and the patient demographics in the study may have contributed to the excellent outcome of the scarring, in addition to any benefit from the treatments. From our experience, most scars from Mohs surgery are well healed, of good cosmetic appearance, and asymptomatic. All the patients in the study were elderly Caucasians, as is the vast majority of patients requiring Mohs or excisional surgeries at our institution. This group is at a lower risk for developing hypertrophic scars and keloids than younger patients with darker skin.
or patients with scars secondary
to burns. In addition to the type of surgical scar and demographics, the fact that all 21 patients rated the overall scars as excellent may reflect a selection bias. Patients who give informed consent to participate in the study are probably more likely to have good rapport with the staff and thus report positive results.

One potential confounder in our study could be that treatment on each scar half may have diffused to the other side, giving the entire scar a homogenous appearance. This is unlikely, since one would also expect a tapering effect difference towards the opposite end of the scar if diffusion was indeed occurring. Furthermore, despite the simplicity of the study design and our effort to ensure proper treatment for each scar half, patients could have inadvertently applied the gels to the wrong sides. Whether this happened in our study is uncertain, but we know that split-scar studies, such as that by Baumann and Spencer, can effectively demonstrate differences in two topical agents applied side by side. We have selected the split-scar study design because of the optimal internal control. Both scar halves have the same location on the same patient and have experienced the same trauma.

Our finding that onion extract gel does not improve healing of scars when compared to petrolatum agrees with previous animal and clinical studies. Jackson and Sheltom's study of 17 patients with new scars resulting from Mohs surgery found no statistically significant difference between pre- and post-treatment evaluation of scar erythema and pruritus in patients using the onion extract gel. Saulis et al. found no significant difference in scar hypertrophy or erythema in the onion extract gel-treated scars compared with untreated scars in the rabbit ear model. Clarke et al.'s prospective double-blinded study of 99 patients with scars ranging from 3 weeks to 8 years old found no difference in physician assessment of scar improvement between placebo-treated and onion extract gel-treated scars.

While our study did not detect a statistically significant difference between the two treatments, a benefit might exist in a higher risk population. Future studies on a younger patient population with non-surgical scars may be helpful.

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References


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