Observer-Blinded, Randomized Study to Determine the Safety and Efficacy of a Silicone Gel (Recedo™ Gel) Versus a Gel Containing Onion Extract (Mederma® Advanced Scar Gel) for the Appearance and Symptoms of Surgical Scars

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Background

- Scarring can cause functional, cosmetic, and psychological morbidity[1]
- The clinical symptoms of scars include tenderness, discoloration, pruritus, and disfigurement
- Remedial treatments used for scars include surgery, laser therapy, steroid injections, and topical products such as onion extract gel and silicone gel[2]
- 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[3]
- Silicone gels and sheets are widely considered as first-line treatment for scars[2]

Objectives

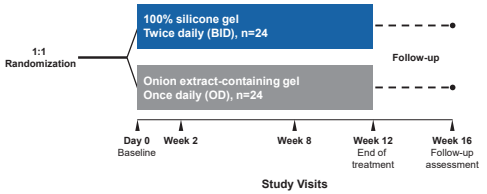
- To evaluate the safety and efficacy, in terms of appearance and symptoms, of a 100% silicone gel (Recedo™) compared with an onion extract-containing gel (Mederma®) in adult subjects with postsurgical scars

Methods

Study Design

- Randomized, evaluator-blinded, single-center, 16-week, active-comparator clinical study (**Figure 1**)
- All subjects had postsurgical 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 that 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)

Figure 1. Study Design



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)
- Investigator's 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

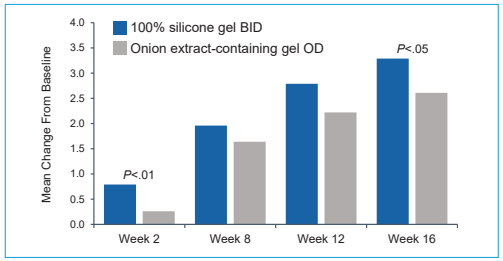
	100% silicone gel BID (n=24)	Onion extract-containing gel OD (n=24)
Gender, n (%)		
Male	13 (54.2)	10 (41.7)
Female	11 (45.8)	14 (58.3)
Age, mean, years	61.7	60.5
Ethnicity, n (%)		
Hispanic or Latino	6 (25)	5 (20.8)
Non-Hispanic or -Latino	18 (75)	19 (79.2)
Race, n (%)		
White	20 (83.3)	20 (83.3)
Hispanic	4 (16.7)	3 (12.5)
Black/African American	0 (0)	1 (4.2)
Age of scar, mean, days	45	52.4

Efficacy Evaluations

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*<.01) and at the end of the study at week 16 (*P*<.05) compared with the onion extract-containing gel OD group

Figure 2. Improvement in Mean VSS Score From Baseline



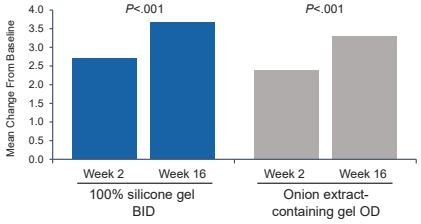
Pain and Itch Assessments

- 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*<.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 itch
- There were no significant differences from baseline or between groups in subject-reported pain

Investigator's Global Assessment of Scar Treatment

- The mean change from baseline for the Investigator's Global Assessment of Scar Treatment increased significantly from week 2 to week 16 in both groups (*P*<.001 for each) (**Figure 3**)

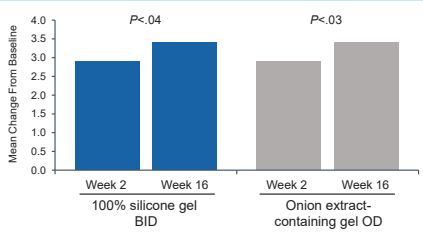
Figure 3. Mean Change From Baseline in Investigator's Global Assessment of Scar Treatment



Subject's Global Assessment of Scar Treatment

- Similar to the Investigator's Global Assessment, the mean change from baseline in the Subject's Global Assessment of Scar Treatment increased significantly from week 2 to week 16 in both groups (*P*<.04 for 100% silicone gel BID and *P*<.03 for onion extract-containing gel OD) (**Figure 4**)

Figure 4. Mean Change From Baseline in Subject's Global Assessment of Scar Treatment



Safety Evaluation

- 10 subjects experienced AEs during the study
- The most common treatment-related AE was mild-to-moderate itching at the site of application, which was reported by 5 subjects (21.7%) in the onion extract-containing gel OD group and 0 subjects in the 100% silicone gel BID group (*P*<.02)
- Application-site tenderness (recorded as burning, tingling, or sensitivity) occurred in 2 subjects (6.3%)
- No serious AEs occurred during the study

Conclusions

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

References

1. Bock O, et al. *Arch Dermatol Res.* 2006;297(10):433-438.
2. Monstrey S, et al. *J Plast Reconstr Aesthet Surg.* 2014;67(8):1017-1025.
3. Perkins K, et al. *Burns Incl Therm Inj.* 1983;9(3):201-204.

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