Patient-Reported Outcomes and Perceptions Following Use of Compounded Scar/Burn Cream: Interim Results from an Observational Survey Study

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Background

In addition to aesthetic implications, scar tissue can cause symptoms including pain, itching, tenderness, physical deformities, and psychological effects, and can interfere with daily activities.[1, 2] Therefore, collection of patient-reported outcomes and perceptions is important in the study of scar treatments.

Objectives

This pre-planned interim analysis of an observational survey study (IRB-approved, informed consent) involving 31 sites across the United States, evaluated patient-reported outcomes and perceptions regarding use and effects of treatment with compounded scar/burn creams over 4 months.

Methods

Adult patients (18-64 years old) with scar/burn tissue ≥1-month old, healed, closed, and not infected and using one of two formulations of compounded scar tissue treatment (Collagenase 200U/gm, Naltrexone 1% 10mg/gm, Aloe Vera freeze-dried 1:200 3mg/gm in Pracasil Plus gel; OR Naltrexone 1% 10mg/gm, EGCG 1%, Dimethyl Sulfone 5%, Caffeine 1%, in anhydrous gel) were enrolled. Surveys were administered at each visit, with a section for the clinician, and a section for the patient to complete. Interim results (collected 2014/2015) report on paired analyses (n=110) from Survey 1 (baseline) to Survey 3 (visit 3).

Results

Table 1. Patient Characteristics

	Mean ± SD	Range
Female/Male (n), n=109	97/12	
Age at Survey 1 (years), n=110	43.2 ± 10.2	19.4 - 63.6
Race, n=110	White/Caucasian: 76 Hispanic/Latino: 20	Black/African American: 8 Other: 6
How long had scar/burn (n), n=108	1 month: 12 2-6 months: 14 6-12 months: 9	1-5 years: 30 >5 years: 43
Time between Surveys 1 & 3 (days), n=110	127.7 ± 24.9	70 - 170

SD = standard deviation

Table 2. Changes in Pain Medication Use from Survey 1 to Survey 3 (n=103, paired data)

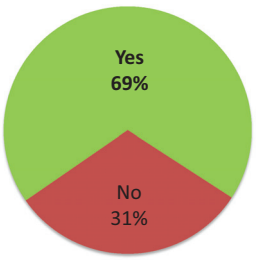
Current Medication Usage	Survey 1 (%, n)	Survey 3 (%, n)
Yes	63.1, 65	*19.4, 20
None	36.9, 38	80.6, 83
	*P<.001, a 69.3% decrease in medication use	

Table 3. Patient-Reported Side Effects from Scar Medication* (n=108)

Side Effect	%, n
None	90.7, 98
Rash or redness at scar site	3.7, 4
Other (not specified)	3.7, 4
Skin dryness	1.9, 2

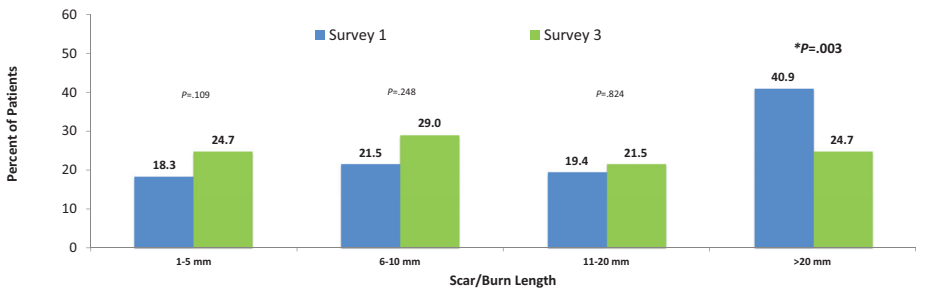
*No serious AEs were reported.

Figure 1. Have you noticed a reduction in the size of the scar since you started the medication? (n=109)



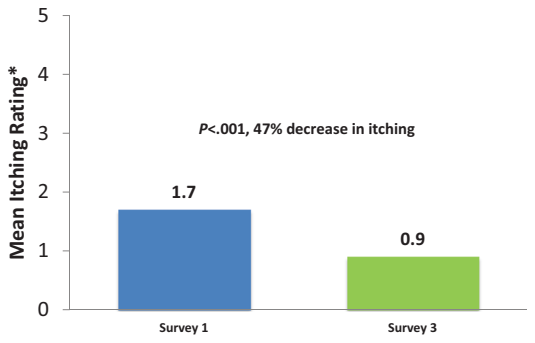
Of note, at Survey 3, a higher proportion of patients with scar <1 year indicated scar size reduction (79.4%, 27/34) compared to patients with scar >1 year (63.0%, 46/73), however the difference was not statistically significant (P=.090).

Figure 2. Change in Scar/Burn Length from Survey 1 to Survey 3—As Measured by Clinicians (n=93, paired data)



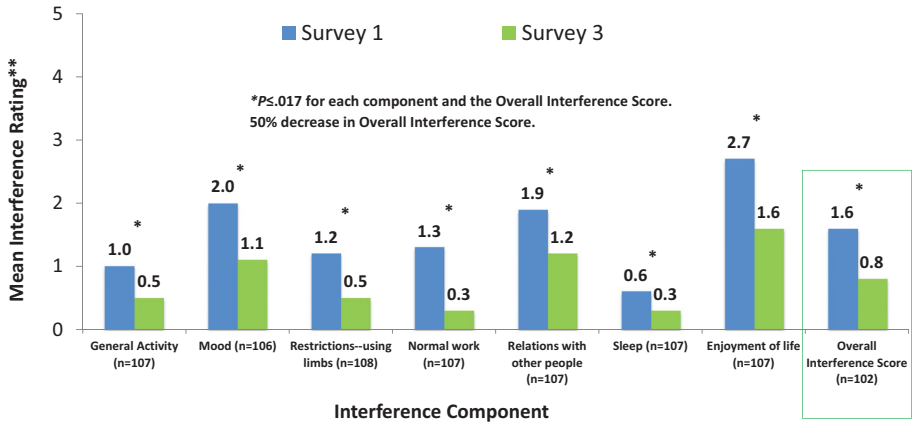
*Statistically significant decrease.

Figure 3. Has there been itching associated with your scar/burn during the last 7 days? (n=104, paired data)



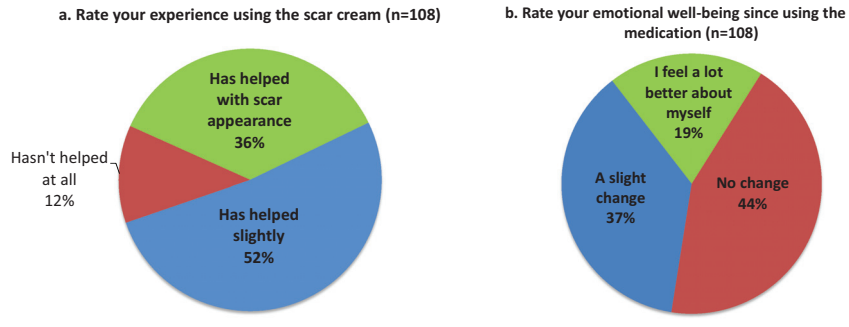
*Rating scale: 0=None, to 10=Continuous itching

Figure 4. Changes in Scar/Burn Interference Ratings from Survey 1 to Survey 3 (paired data)



**Scale: 0=Does not Interfere, to 10=Completely Interferes

Figure 5. Patient-Reported Observations on Scar Cream Use at Survey 3



Conclusions

- **Results from this interim analysis suggest that the compounded scar/burn creams used by adults in this study may reduce scar/burn:**
  - **Size (as measured by clinicians and as perceived by patients)**
  - **Itching**
  - **Mood/daily living interference scores**
  - **Pain medication use**
- **A majority of patients believed that the compounded creams helped scar appearance and improved their emotional well-being.**
- **The compounded scar/burn creams were safe and well-tolerated.**
- **Results from the interim analysis warrant and justify continuation of the trial.**

References

1. Ahn et al. Topical silicone gel: A new treatment for hypertrophic scars. *Surgery*. 1989;106:781–7.
2. Ahn et al. Topical silicone gel for the prevention and treatment of hypertrophic scar. *Arch Surg*. 1991;126:499–504.

Limitations

- This was an interim analysis. A more detailed analysis will be conducted at the conclusion of the study.
- This is an observational survey study. Changes observed cannot definitively be attributed to the scar/burn creams. Further study is therefore required.

Study funded by:

Advantage Medical and Pharmacy, Hattiesburg, MS, USA
Advantage Medical Infusion, Hattiesburg, MS, USA
Annie's Apothecary, Kerrville, TX, USA
Annie's Apothecary, Boerne, TX, USA
Boothwyn Pharmacy, Boothwyn, PA, USA
Cypress Compounding Pharmacy, Houston, TX, USA

Financial Disclosures

H. J. Visser: Honoraria paid by Clarity Research and Consulting, LLC
E. Harris: Consultant to Clarity Research and Consulting, LLC
P. Hurwitz: Study funded by the 6 pharmacies listed above
D. Dietze: Analysis paid by Clarity Research and Consulting, LLC
C. Viereck: Analysis paid by Clarity Research and Consulting, LLC