An Efficacy Assessment of a Novel Skin-Cleansing Device in Seborrheic Dermatitis

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Cleansing of the face is important for optimal hygiene and proper skin exfoliation. The cleansing process is a delicate balance between the desirable removal of excess sebum, old cosmetics, and environmental dirt and the maintenance of the stratum corneum barrier. It requires preservation of the intercellular lipids while minimizing skin colonization by *Pityrosporum* species, *Demodex folliculorum*, and *Propionibacterium acnes*, all of which contribute to skin disease. The importance of facial cleansing creates the need for a system that cleans and exfoliates the skin while maintaining optimal physiologic function.

Nowhere is this truer than in conditions such as seborrheic dermatitis, which is caused by the overgrowth of *Pityrosporum*. Seborrheic dermatitis requires the thorough removal of the fungus, sebum, and skin scale to normalize the facial skin. Removal of the fungus prevents the release of free fatty acids that cause facial skin irritation resulting in hyperproliferation. Excellent cleansing can aid in treatment and prevent recurrence. A study was undertaken to evaluate the effect of a mechanized oscillatory sonic face brush on the traditional treatment of seborrheic dermatitis.

Technology Development

The oscillatory sonic brush takes advantage of the skin's elastic properties to effect facial cleansing without exceeding its physical limits by using an optimal amplitude and frequency range.[1] Sonic energy has been used in powered toothbrushes to provide effective cleansing and improved oral health. The optimized amplitude and frequency selected for sonic toothbrushes have been proven more effective than manual tooth brushing for many individuals. The concept of optimized sonic technology has now been applied to cleansing the skin. The oscillatory sonic face brush was optimized with the elastic modulus of the skin in mind.[1]

According to Short et al,[2] the skin's mechanical organization may be thought of as large numbers of loose collagen fibers connected at randomly distributed nodal points. The mechanical behavior of this system is similar to that of a woven material, such as a nylon stocking. As the material stretches, the fibers initially straighten and become oriented in the direction of the stress. Eventually, some fibers become fully aligned in the direction of the stress and then carry stress directly. Further deformation will result in the recruitment of ever increasing numbers of collagen fibers to support the stress. The modulus of elasticity (ie, the stiffness of the skin) increases rapidly as this process continues, until it matches the stiffness of the collagen fibers. The modulus of elasticity in this region is typically $3–5\times10^3$ N/mm.[2]

The sonic skin brush was designed so that the differential motion applied to the skin is of sufficient amplitude to create pore-opening forces to loosen and dislodge sebaceous plugs and other debris but low enough to minimize stretching of collagen fibers in the skin.[1,3] The brush head has 2 distinct zones of action.[1] The first zone is between the outermost oscillating row of bristles and the innermost stationary bristles. This deep-cleansing zone causes the skin to flex rapidly. The inner bristle action of the second zone sweeps away surface debris to provide topical cleansing. The sonic skin brush has proven safe and effective at cleansing the skin, particularly in patients with uneven skin texture associated with acne scarring or various dermatologic conditions.[4,5,6] It was postulated that this bristle action might provide superior cleansing and skin scale removal in patients with seborrheic dermatitis.

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Methods

Twenty adult subjects with mild to moderate seborrheic dermatitis were enrolled in the 2-week skin-cleansing device study. Subjects were randomly assigned by the study coordinator to 2 treatment groups of 10 subjects each; one group used the cleansing device at home twice daily with the prescribed cleanser (sodium sulfacetamide cleanser), and the other group was assigned to twice-daily use of the prescribed cleanser alone. Subjects provided a self-assessment at each visit rating the amount of facial scaling, redness, extent of disease, and itching/burning on a scale of 0 to 3 (none, mild, moderate, and severe, respectively). At the baseline visit, the dermatologist, blinded to treatment, performed a medical assessment and physical examination of the face. The amount of facial skin scaling, erythema, extent of involvement on the face, and overall assessment of seborrheic dermatitis were rated on the same scale as the subjects' self-assessments. Photographs of the frontal face, right face, and left face were taken. Noninvasive transepidermal water loss (TEWL) and Corneometer® measurements were taken from both sides of the face. Subjects in the device treatment group were instructed by the research coordinator on proper use of the cleansing device with the sodium sulfacetamide cleanser, using a quarter-sized dab of cleanser with a dampened brush according to the manufacturer's instructions. Subjects with seborrheic dermatitis affecting the ears were instructed to cleanse their ears with the brush for 10 seconds. Subjects in the cleanser-only treatment group were instructed to use a quarter-sized dab of cleanser to cleanse the face manually. Further evaluations occurred at days 3, 7, and 14.

Statistical Analysis

Ordinal data were analyzed statistically using the Mann-Whitney test for differences between the 2 groups, whereas the Wilcoxon signed rank test was used to analyze pairwise comparisons for improvements from baseline scores for each group. For comparisons with missing data points (2 subjects in the sonic brush group missed the day 3 appointment), the Mann-Whitney test was used. For numeric data, 2-tailed Student *t* tests were performed on paired data (differences from baseline) and unpaired data (between groups or when data points were missing from the data sets).

Results

All 20 subjects completed the study; no adverse events occurred. Subjects in both treatment groups began to assess statistically significant reductions in itching by day 3, with continued reduction in itching throughout the 2 weeks of the study (sonic brush group, $P=.013$; cleanser-only group, $P=.012$). A trend toward statistically significant reduction in skin scale began to be observed in the sonic brush treatment group by day 7, with statistically significant reductions in scaling characteristics ($P=.034$), facial redness ($P=.031$), and extent of scaling ($P=.05$) by day 14. Comparisons between the 2 groups reported no statistically significant differences at any time point or parameter. While some improvement was noted in both treatment groups, greater improvement from baseline scores were reported in the sonic brush treatment group for scaling characteristics, redness, and extent of scaling, reaching statistical significance at day 14 only in the device treatment group.

These results were confirmed by the dermatologist investigator assessments (Figure 1). The investigator began to note statistically significant reductions in skin scaling, redness, extent of involvement on the face, and overall assessment by day 7 in both treatment groups, with continued and significant reductions in the sonic brush group continuing to day 14. At day 14, improvement from baseline was statistically significantly greater in the sonic brush group over the cleanser-only group for erythema ($P=.001$), extent of involvement on the face ($P=.005$), and overall assessment ($P=.008$). While no statistical differences between the 2 treatments were noted for scaling at day 14, the sonic brush group did show statistically significant improvements in scaling over baseline scores ($P=.02$), and a trend toward improvement was noted in the cleanser-only group ($P=.106$).

No statistically significant increases in TEWL were noted at any evaluation time point during the study (Figure 2A). Mean baseline TEWL values were randomly higher in the sonic brush treatment group (19.2 ± 7.9) than in the cleanser-only group (14.9 ± 5.3), with little change in either group at 2 weeks (20.2 ± 6.1 and 15.1 ± 4.3, respectively). This indicates that the cleansing device did not damage the skin barrier and supports the safety for device use in patients with seborrheic dermatitis. Skin hydration was measured using a Corneometer. No reduction in skin hydration was observed in either treatment group (Figure 2B). Mean baseline hydration measurements for the sonic brush (298.9 ± 73.3) and cleanser-only (265.3 ± 46.9) groups changed little during the 2 weeks of the study (309.9 ± 91.6 and 303.4 ± 74.6, respectively); however, a temporary increase in skin moisture was observed in both groups at day 3 (sonic brush, $P<.001$; cleanser only, $P=.023$) and day 7 (sonic brush, $P=.033$; cleanser only, $P=.013$). These results

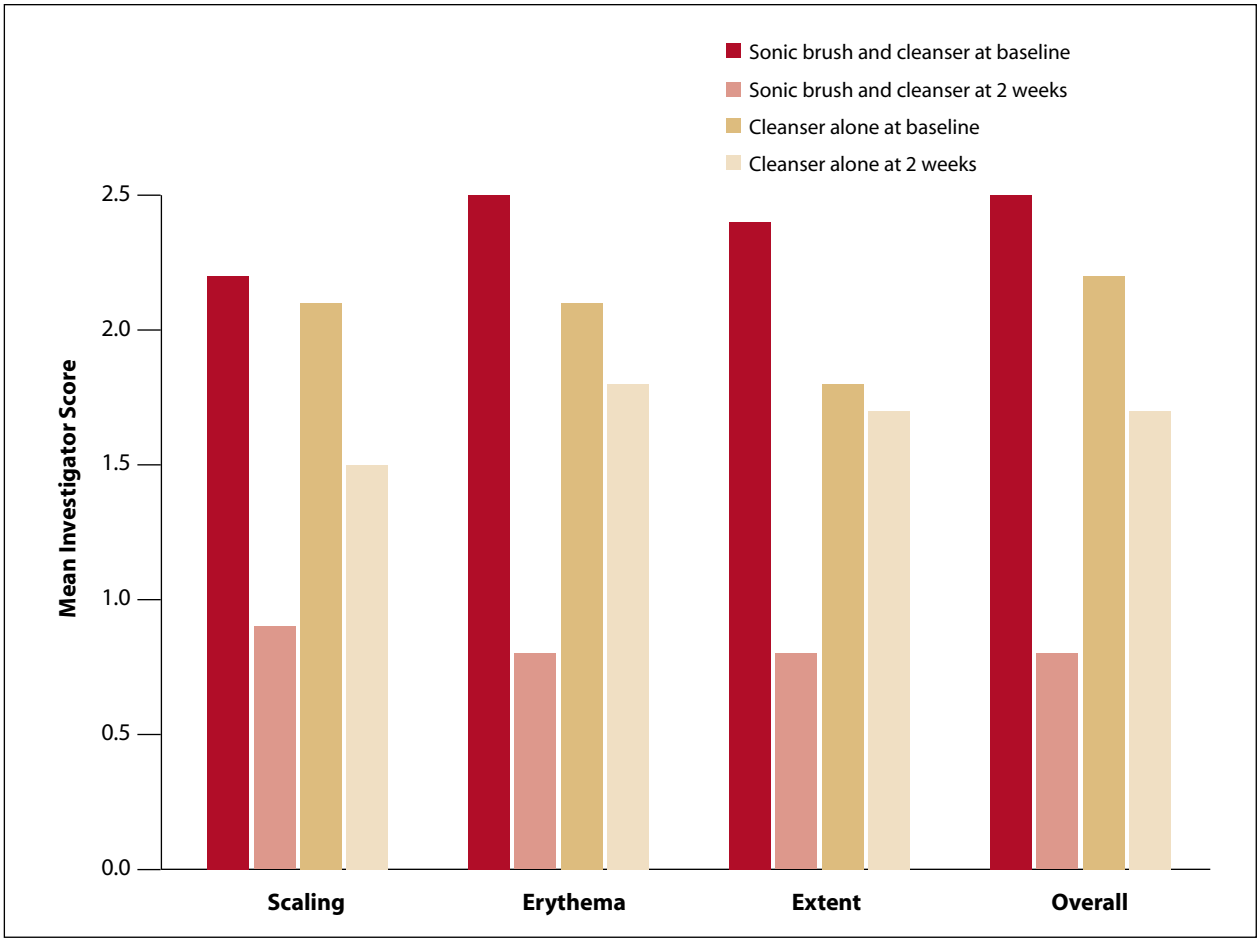

Figure 1. Mean investigator assessments (blinded) of scaling, erythema, extent of scaling, and overall severity of sebborheic dermatitis before and after 2 weeks' use of a sonic skin care brush plus study cleanser or study cleanser alone. The assessments were rated on a scale of 0 (none) to 3 (severe).

indicate that the sonic skin care brush does not damage or dry the skin and confirms that it may be safely used by patients with seborrheic dermatitis.

Discussion

Skin cleansing is a complex interaction between the skin, the cleanser, and the cleansing implement. For many years, the traditional method of facial cleansing was the use of bar soap and a washcloth. While this cleansing method may be adequate for normal skin, it may not be ideal for people with skin diseases such as seborrheic dermatitis, who may have a need for specialized cleansing. The most socially disabling part of seborrheic dermatitis for patients is the facial scaling and erythema, both of which might be improved with an optimal facial-cleansing regimen.

True soaps efficiently remove sebum but may also remove the intercellular lipids in dry-complected individuals, leading to increased facial scaling. Newer cleansers, such as the sulfacetamide cleanser used in this study, incorporate synthetic detergents that are less apt to damage the barrier through intercellular lipid removal. This fact was confirmed by the relatively constant TEWL readings obtained after initiation of the cleanser and brush combination. In addition, the study cleanser selected incorporated sodium sulfacetamide, a topical antifungal agent effective in reducing the skin surface fungus operative in the etiology of seborrheic dermatitis.

The cleanser and brush combination allowed for more efficient delivery of the cleanser in and around the sebaceous-rich pores that provide a nutritional source for fungal growth. The cleanser also helped to loosen skin scale, which was subsequently dislodged by the sonic brush action and rinsed away with water. Thus, ideal cleansing involves both chemical and physical effects on the skin surface (Figure 3).

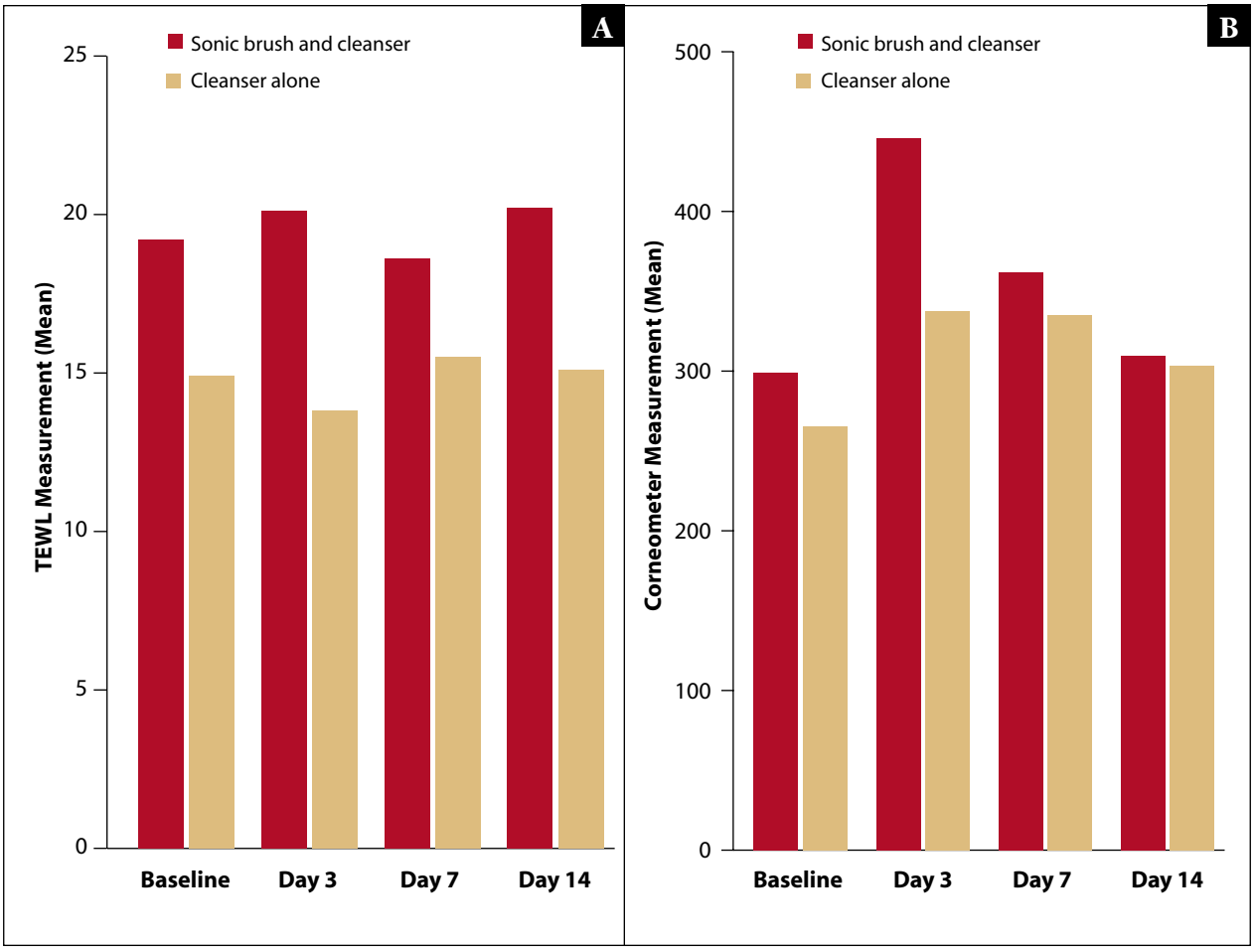

Figure 2. Mean transepidermal water loss (TEWL)(A) and skin hydration (B) at baseline and after 3, 7, and 14 days' use of a sonic skin care brush plus study cleanser or study cleanser alone.

Figure 3. Male subject before (A) and after (B) 2 weeks' use of the sonic skin care brush plus study cleanser.

This was a small pilot study of only 20 subjects, yet statistically significant improvement from baseline was seen at both 1 and 2 weeks in the signs and symptoms of seborrheic dermatitis, particularly in the sonic brush group. The main goal of the study was to determine if the sonic brush was safe for use in diseased skin; that goal was met. Furthermore, there is a strong indication that combining the cleanser with the brush may lead to more significant improvement in resolution of seborrheic dermatitis than cleanser use alone. Now that this study has provided a preliminary safety assessment and suggests that the sonic brush may enhance treatment regimens, further controlled studies with larger population sizes and increased duration may be performed to evaluate the usefulness of sonic cleansing in a variety of skin conditions.

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