Clinical Efficacy of a Novel Sonic Infusion System for Periorbital Rhytides

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ABSTRACT

Aging skin is a leading concern of most men and women seeking cosmetic dermatologic consultation. Various in-office procedures as well as topical at-home regimens, are generally prescribed to reduce the signs of aging, but relatively few provide immediate clinical benefit.

A novel sonic infusion system that combines sonic micro-massage with an anti-aging serum was studied to determine its immediate effect on a wide range of patients with periorbital rhytides. Clinical improvement of periorbital rhytides was achieved after a single sonic infusion treatment (30 seconds/eye). Patients with more severe rhytides and those older than 40 years of age showed the best clinical results.

INTRODUCTION

The use of topical cosmeceuticals for the reduction of facial rhytides and enhancement of skin’s youthfulness has become increasingly popular over the last decade. Various serums and creams containing antioxidants, retinoids and other ingredients are often prescribed as adjunctive therapy to in-office dermatologic procedures and as integral steps in patients’ skin care regimens for counteracting signs of aging.

In recent years sonic technology has been used for cleansing different parts of the human body. The first such device was the sonic energy powered toothbrush (Sonicare™; Philips Oral Healthcare, Snoqualmie, WA, USA) for oral hygiene. A similarly powered technology for facial cleansing was subsequently developed taking into account the elastic properties of the skin (Clarisonic™; Pacific Bioscience Laboratories, Inc., Bellevue, WA, USA). It involves the application of oscillatory motion of optimal energy to a specified area in order to enhance cleansing of the surface while being gentle enough for at least twice daily use without compromising the skin barrier. The sonic skin cleansing brush applies oscillatory (back and forth) motion at a rate greater than 300 motions per second. This bidirectional motion is at sufficient amplitude to generate a force powerful enough to unclog pores, but low enough to minimize strain to the skin. It has been shown to be effective for skin cleansing and improvement of various skin conditions, including seborrheic dermatitis.

Analogous to the cleansing system, a novel cosmetic sonic infusion system has been developed that combines a soft silicone applicator tip, precision-tuned sonic frequency (127 Hz), and a gentle kneading motion to maximize transfer of serum into the skin (Clarisonic Opal™; Pacific Biosciences, Bellevue, WA). A marine extract and botanical-containing serum is integrated within the device, and its application is enhanced by the gentle oscillations of the applicator tip as it is moved over the skin. No prior published clinical studies have been performed to evaluate the effectiveness of this sonic infusion system on the skin.

The periorcular area is a wrinkle-prone region and is often the first area to show aging. Its delicate nature dictates that a gentle treatment be delivered. The purpose of this study was to determine the immediate effect of the novel sonic infusion system on periorbital rhytides in adult men and women.

MATERIALS & METHODS

A sonic applicator (Clarisonic Opal) and cosmetic serum (Clarisonic Sea Serum) were supplied by the manufacturer (Pacific Biosciences, Bellevue, WA) for use in this study.

The sonic applicator is used to infuse serum into the epidermis by movement of a soft elastomeric tip in an arcuate motion at 127 cycles per second (127 Hz). The infuser motor is tuned to resonate when the tip is lightly loaded against the skin, increasing the amplitude in-use. This amplitude “pick-up” results in a tip motion of 0.030 to 0.050 inches during use. The combination of soft tip amplitude and arcuate motion provides the applicator’s optimal sonic infusion (R.E. Akridge, personal communication, April 18, 2001).

The serum is a blend of marine and botanical extracts specifically formulated to work (and only available) with the sonic applicator. Its ingredients include water, Epilobium angustifolium leaf/stem extract, glycerin, hydrolyzed elastin, glycosaminoglycans, PEG-8 dimethicone, Kigelia africana fruit extract, silanetriol trehalose ether, saccharomyces ferment, Avena sativa (oat) kernel extract, Ceratonia siliqua.
gum, hydrolyzed casein, Laminaria saccharina extract, algal extract, pullulan, Skeletonema costatum extract, acetyl citrull amido arginine, arginine PCA, plankton extract, soluble collagen, Chondrus crispus (Irish moss, carrageenan) extract, niacinamide, ascorbic acid, bisabolol, Zingiber officinale (ginger) root extract, Opuntia coccinellifera fruit extract, sodium PCA, urea, trehalose, sodium hyaluronate, polyquaternium-51, ethyl lauroyl arginate HCl, butylene glycol, acrylates/C10-30 alkyl acrylate crosspolymer, chlorphenesin, disodium EDTA and sodium hydroxide.

Two key properties of the serum formulation are its viscosity (30,000 centipoises) and pH (pH 6.0-6.5). Its gel-like consistency creates a serum reservoir within the well of the applicator tip for targeted application to the area of concern. Because of body heat and the sonic motion, the gel changes into a liquid which then allows for rapid absorption into the epidermis. Unlike many serums that have acidic pH to increase absorption by chemical etching of the stratum corneum, the relatively neutral pH of the sea serum combined with sonic technology results in cutaneous absorption with minimal risk of chemical irritation.

Study participants were solicited over a one-week period in a busy dermatologic practice. All adults with visible periocular rhytides presenting for skin consultation were considered for study entry. Men and women over 18 years of age with any skin phototype were eligible for inclusion. Any patient who had signs of eye infection or irritation or who were receiving periocular treatment that could interfere with the investigators’ ability to make an accurate assessment of the patient was excluded from study entry.

Removal of moisturizer, sunscreen and makeup in the periocular region was achieved with a hypoallergenic, noncomedogenic cleanser and water. Baseline clinical assessments of the periocular regions were made independently by the investigators using a mild, moderate, severe photographic index scale. Baseline clinical photographs of each periocular area (alone and together) were obtained using a digital imaging system (Canfield Mirror Image, Fairfield, NJ) under controlled lighting and positioning conditions. The study examiner (SS) applied a pea-sized amount of serum on the sonic applicator tip (Figure 1). Using light pressure and a circular motion of the device tip, the serum was uniformly applied in a 30 second treatment to the lateral canthus and infraocular region of each eye. Any excess serum present on the skin after the sonic infusion was gently removed with tissue after treatment.

Post-treatment clinical photos were obtained and the study examiner assessed the severity of periocular wrinkling using a mild, moderate, severe photographic scale. Both the subject and study examiner assessed the degree of improvement of each periocular region (compared with baseline) using a quartile grading scale (1=0-25%, 2=26-50%, 3=51-75%, 4=76-100% improvement).

RESULTS

Fifty-three patients (41 females, 12 males) were enrolled in and completed the study. The patients ranged in age between 29 and 65 years (mean 48 years). A wide range of skin phototypes were represented (Table 1).

No side effects were observed during the course of the study, including erythema, edema, dermatitis or other adverse sequelae. Patients did not report any pain or tenderness in the treatment areas during or after treatment.
TABLE 3.

Clinical Improvement Scores

<table>
<thead>
<tr>
<th>% Improvement (Score)</th>
<th>Patient Rating (&lt;40 years)</th>
<th>Investigator Rating (&lt;40 years)</th>
<th>Patient Rating (&gt;40 years)</th>
<th>Investigator Rating (&gt;40 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-25 (1)</td>
<td>9</td>
<td>8</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>26-50 (2)</td>
<td>6</td>
<td>6</td>
<td>15</td>
<td>14</td>
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<tr>
<td>51-75 (3)</td>
<td>2</td>
<td>3</td>
<td>13</td>
<td>16</td>
</tr>
<tr>
<td>76-100 (4)</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Total Patients</td>
<td>17</td>
<td>17</td>
<td>36</td>
<td>36</td>
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<tr>
<td>Mean Score</td>
<td>1.6</td>
<td>1.7</td>
<td>2.3</td>
<td>2.3</td>
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**FIGURE 2.** Mild rhytides in a 32-year-old woman before a) and after b) sonic infusion treatment (clinical improvement score: 2).

**FIGURE 3.** Moderate rhytides in a 48-year-old woman before a) and after b) sonic infusion treatment (clinical improvement score: 3).

Patient clinical improvement rating scores ranged from 1 (0-25%) to 3 (50-75%) with an average score of 1.6 for those patients younger than 40 years of age and from 1-4 (average 2.3) for those older than 40 years of age. (Figures 2a, 2b, 3a and 3b) These were consistent with the independent investigators’ scores, which ranged from 1–3 (average 1.7) and from 1–4 (average 2.3) for those patients younger than 40 years and older than 40 years, respectively (Table 3).

**DISCUSSION**

This study demonstrated the clinical efficacy and tolerability of a novel sonic infusion system for the temporary treatment of periocular rhytides. Most patients showed moderate clinical improvement after a single 60-second treatment (30 seconds per eye). Patients older than 40 years of age had greater clinical responses than those younger than 40 years. This disparity is presumably due to the difference in wrinkle severity at baseline, with patients older than 40 years showing more severe rhytides compared to younger patients. Results were independent of gender and skin phototype.

This study supports the use of a novel sonic infusion system in the temporary reduction of periocular rhytides. Given the increased consumer-driven market, the plethora of topical wrinkle reduction products available, and the superlative claims of many of the manufacturers of these products, it is especially important to provide clinically relevant and reproducible studies. The results of this initial study show promise for this at-home device for the effective improvement of periocular rhytides. Additional research is necessary to determine the longevity of clinical results, as well as to further assess its role in daily skin maintenance and for the treatment of other cutaneous conditions.

**CONCLUSION**

A novel sonic infusion system can be used to effectively and safely improve the clinical appearance of periocular rhytides in adult men and women. Patients older than 40 years of age with more moderate-to-severe wrinkling show greater clinical smoothing of wrinkles.

**DISCLOSURES**

Equipment was supplied by Pacific Biosciences (Bellevue, WAS).

The authors have no further conflicts of interest to disclose.

**REFERENCES**