Under-eye rejuvenation utilizing a novel, topical, skin-conforming material technology

Introduction
Recent decades of medical advances have brought about a surge in minimally invasive procedures that include botulinum toxin injections, injectable fillers and laser-based skin therapies. While these procedures provide dramatic anti-aging results to the treated areas, safe and effective treatments for the under-eye region remain a gap in the facial rejuvenation armamentarium. We now introduce a novel materials technology that complements the leading cosmetic procedures to address unmet needs for under-eye rejuvenation. Strateris™ is a flowable, cosmetically elegant polymeric material system, which is activated to form a breathable imperceptible elastic film that mechanically re-contours the shape of the skin surface. When applied to the under-eye area, periorbital puffiness is dramatically reduced, a result previously achieved only through a surgical lower lid blepharoplasty. To date, our knowledge has been no published scientific reports describing a topical technology providing the results described here.

Materials And Methods
Strateris™ Under-eye Contouring System (Strateris™, LLC, Cambridge, MA) is a two-stage topical formulation technology that the authors have evaluated on 300 subjects. Our experience with these subjects indicates no irritancy, allergy or usage problems. The Contouring Complex (Step 1) is a proprietary dispersion of poly(methylmethacrylate) polymers in an aqueous medium. The Activator (Step 2) is a water-in-oil emulsion that is applied over the Contouring Complex to immediately activate the appearance of lower lid rejuvenation. The effects last all day until Strateris™ is removed.

Blinded photography assessment:
• Standardized photographs of 18 subjects were taken at baseline and 7 hours following application of the Strateris™ Under-eye Contouring System. The photographs were randomized and graded by 5 trained, blinded evaluators located at 2 sites. At each site, the 0 to 4 photo-numerical scales for under-eye wrinkles and bags (see below) were used to quantify the severity of the under-eye bag and wrinkle. Photographs of subjects whose baseline revealed mild to severe under-eye protrusions (bag grades of 2 through 4) were included in the photography assessment of Strateris™ performance. The photographs of 13 subjects qualified for the performance assessment based on this criterion.
• The scores from the two sites were pooled to yield the average wrinkle and bag grades and the corresponding standard error values. The Student’s t-test (Excel, Microsoft, Seattle, Washington) was used to determine the statistical significance of the differences observed at baseline and at 7 hours following Strateris™ application.
• Standardized photography was taken with a digital SLR camera (Nikon D300s, Melville, New York) using a 17–55mm lens (Sigma DC 1.8 4.5 macro HSM, Ronkonkoma, NY) with a circular polarizer. Subjects were illuminated with three 1 ft LED studio panels (LITE-panels 1x1 D-Flood, Van Nuys, CA). Each light provides 1400 lux of 5600 K lighting. To maintain consistency between time-points, subjects are positioned in a chin rest and head clamp for each photo.
• Three-dimensional imaging: A Canfield Vectra 3-dimensional imaging system (Canfield Scientific, Fairfield, NJ) was used to capture skin contour changes at the Strateris™ application site.

Anderson-Gilchrist Wrinkle and Bag Scales (0-4)

<table>
<thead>
<tr>
<th>Score 0</th>
<th>Score 1</th>
<th>Score 2</th>
<th>Score 3</th>
<th>Score 4</th>
</tr>
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<tbody>
<tr>
<td>No wrinkle, no bag</td>
<td>Mild under eye wrinkles</td>
<td>Moderate under eye wrinkles</td>
<td>Severe under eye wrinkles</td>
<td>Prominent under eye protrusion</td>
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With Strateris™

Results

Figure 1: Representative results following Strateris™ Under-eye Contouring System application to the lower lid region (Unstretched image). Contouring of the lower lid region with Strateris™ application is available in the reduced appearance of wrinkles, bag protrusion, and skin surface roughness compared with the corresponding baseline image.

Figure 2: Blinded Photography Assessment of Strateris™ performance at the lower lid application site yields a one-grade improvement (p=0.001) in the under-eye bag severity.

A significant improvement in the appearance of under-eye wrinkles was also observed (p<0.001), with an average 0.8 grade improvement. The error bars correspond to the standard error of the mean.

Figure 3: Increased skin recoil time with Strateris™ application.

The skin retraction times (Dermalab® USB Cortes Technologies, Hadud, Denmark) and the skin conductance values (IBS SkinR-200 Conductance Meter, IBSS Co., Hamamatsu, Japan) were measured on the volar forearms of 5 volunteers at baseline and 4 hours following Strateris™ application. Figure 4 shows a 20% reduction in skin recoil times with Strateris™ applied (p<0.005). Figure 4 reveals a 1.5 fold increase in skin conductance with Strateris™ application compared to petrolatum (p=0.03). Error bars indicate one standard deviation from the mean. In the impact of the mechanical elasticity and the skin moisturization properties on the skin appearance are further visualized below.

Figure 4: Superior Strateris™ skin hydration compared to petrolatum.

The Figures to the left are skin cross-sections, noninvasively imaged using optical coherence tomography (Michelson Vitec OCT, Michelson Diagnostics, Raynham, MA). The white arrows point to spatial markers applied to the treatment site, and track the skin spatial position at baseline and at 4 hours after Strateris™ application to the lower lid region of the first subject shown in the panel above.

Image analysis of the OCT-contrast images were performed using IPLab v3.5 (Scanalytics Software, Ontario, NY). The distance between the two epidermal markers was measured using a straight line. The epidermal surface length was measured by tracing along the unseen epidermal surface on between the two markers. All values are given in pixels, determined by IPLab.

The lower lid section with Strateris™ is longer between the markers than the baseline section, 742 pixels versus 586 pixels, respectively, yielding a correction factor of 0.8. With this correction factor, the surface length becomes 584 pixels versus 626 pixels, or 88% of the baseline length, for the section with Strateris™. While these values may underestimate the actual length of the section with Strateris™, resulting from the surface curvature observed, the decrease in the length measured between the two epidermal markers following Strateris™ application reveals skin surface shrinking, in addition to the skin surface smoothing effects. These preliminary results illustrate the skin tightening, skin conforming, elastic material design parameters underlying this novel polymer system.

Conclusions
The Strateris™ Under-eye Contouring System is a novel material that promises a safe, noninvasive alternative to existing under-eye rejuvenation procedures. The exploratory studies presented here illustrate the myriad skin performance attributes and highlight the potential utility of this novel polymer technology for numerous other applications in dermatology.

• One-grade improvement in the appearance of lower lid protrusions.
• Marked improvement in the appearance of lower lid wrinkles.
• Smoothing of skin surface.
• 1.5x increased skin hydration, compared to petrolatum.
• Augmented skin elasticity via decreased skin retraction times.
• Natural skin appearance.
• Compliance and durability of a once-daily application.
• Safe and self-administered.

References:

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