Forearm histology showed complete epidermal healing at 1 day. Both treatments produced an outward migration of pigment, with sustained pigment removal at 14 days post-treatment. The laser + topical regimen showed comparatively decreased inflammation and increased pigment removal.

Facial treatments with both regimens showed mild-moderate improvement in all benefit areas assessed, including fine lines, skin texture, dyschromia, and overall appearance. Clinical efficacy in dyschromia and overall appearance trended higher in the laser + topical group at all time points. Subject self-recorded diaries indicated resolution of redness, swelling, and heat sensation 2 days earlier with laser + topical as compared to laser alone.

The combination of efficacious photoaging treatment modalities suggests improved clinical results over individual regimens. The 1927nm laser in combination with the topical antioxidant serum demonstrated mild to moderate improvement with a high safety profile. Additionally, duration of post-treatment side effects was reduced with laser + topical in comparison with laser alone. These results demonstrate that this combinational treatment of laser with topical is safe and leads to more efficacious clinical results with decreased downtime in comparison to laser alone.
**Figure 1. Repair of microscopic thermal zones.**

Hematoxylin and Eosin Y staining showed the formation of microscopic thermal zones (MTZs) comprised of both an epidermal and dermal component. At 1 day post treatment, there was complete epidermal regeneration and healing of the basement membrane. The thermal damage also resulted in the formation of microscopic epidermal necrotic debris (MENDs).

At 14 days post treatment, the MENDs were found to be above the stratum corneum demonstrating near complete exfoliation. The dermal component of the MTZ showed ongoing dermal remodeling.

**Figure 2. Outward migration and sustained removal of pigmentation.**

At 1 day post treatment, Fontana Masson staining showed the outward migration of melanin (stained black) via the epidermis into the microscopic epidermal necrotic debris (MENDs) to be exfoliated off.

At 14 days post treatment, the epidermis overlying the MTZs remained devoid of pigment while the adjacent areas showed pigment in the basement membrane.
CLINICAL RESULTS

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Erythema (Redness)</th>
<th>Edema (Swelling)</th>
<th>Heat Sensation</th>
<th># of Days Resolved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser Alone</td>
<td>1.64 ± 0.9</td>
<td>0.96 ± 0.8</td>
<td>0.87 ± 1.0</td>
<td>Day 7 (after treatment)</td>
</tr>
<tr>
<td>Laser + Topical</td>
<td>1.66 ± 0.9</td>
<td>1.05 ± 0.9</td>
<td>1.10 ± 1.0</td>
<td>Day 5 (after treatment)</td>
</tr>
</tbody>
</table>

Table 1. Subjects self-reported side effects 1 day after treatment. Subjects reported side effects including redness, swelling, and heat sensation for up to 7 days after treatment. Side effects were scored using a 0-3 severity scale (0=none, 1=mild, 2=moderate, 3=marked). Up to 90% of subjects reported redness at Day 1 in both groups, 68% reported swelling, and 60% reported heat sensation. No unanticipated side effects or adverse events were observed or reported. Average duration of side effects in the laser + topical group resolved 2 days earlier (by Day 5) than the laser alone treatment group (by Day 7).

Figure 3. Investigator-assessed improvement.

Investigator assessed improvement of patients after a series of six facial 1927-nm laser treatments alone (Group 1) and in combination with topical (Group 2). Investigators rated improvement in fine lines, skin texture dyschromia, and overall appearance at 1-week, 1-month and 3-months after final treatment. Quartile Improvement Scale, 0-4 (0=none, 1=minor/mild, 2=moderate, 3=marked, 4=very significant). N=18 (Group 1), N=19 (Group 2).

Subjects in both groups (laser alone and laser + topical) reported slightly higher scores (moderate to marked improvement) than Study Investigators in self-assessments of fine lines, skin texture, dyschromia, skin radiancy, skin firmness and elasticity, and overall appearance at all time points. Additionally, the laser + topical subjects reported slightly higher improvement scores than the laser group alone at 1-week, 1-month and 3-months post treatment regimen.

Subject satisfaction with treatment results were high, with over 90% of all subjects being either satisfied or very satisfied with treatment results.
CLINICAL RESULTS

Figure 4. Laser Alone
Photographs of a subject in the laser alone treatment group at baseline (left) and at 1-month after the completion of a series of six treatments (right). Treatment using the 1927nm laser demonstrated improvements in skin tone and texture.

Figure 5. Laser + Topical
Photographs on a subject in the laser + topical treatment group at baseline (left) and at 1-month after the completion of a series of six treatments (right). Combination treatment using the 1927nm laser followed by the topical regimen demonstrated improvements in skin tone, texture, and dyschromia.

CONCLUSIONS

The 1927-nm wavelength laser was utilized alone and in combination with an aqueous antioxidant serum to observe the effect of post-treatment wound healing and longer term clinical efficacy in prospective, single-site, clinical study. Forearm sample histology results revealed a wound healing response consistent with expectations taken from experience with the higher power 1927nm laser wavelength. Outward migration of pigment was evident by 3 days post treatment. By 14 days post treatment there was complete healing of the basement membrane, indication of MENDs exfoliation, sustained pigment removal, and deposition of newly synthesized collagen. Subject diaries self-recorded for 7 days after each facial laser treatment indicated resolution of redness, swelling, and heat sensation 2 days earlier with laser + topical as compared to laser alone. Additionally, facial treatments with both regimens showed mild-moderate improvement in all benefit areas assessed, including overall appearance, with clinical improvement in dyschromia and overall appearance trending higher in the laser + topical group. No unanticipated side effects or adverse events were observed or reported during the course of the study.

The combination of efficacious photoaging treatment modalities suggests improved clinical results and reduced post-treatment downtime over individual treatment regimens.