Advances in Technology-Based Eyelid Skin Rejuvenation

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Recent advances in technology present new options for eyelid rejuvenation. Some of these techniques produce novel outcomes not previously achievable, whereas others induce favorable changes formerly accomplished through longer recovery times. Noninvasive skin tightening, fractional skin resurfacing, and plasma skin resurfacing can all play a role in eyelid rejuvenation. Successful application of these devices requires a thorough understanding of their capabilities and limitations.

The effects of dermal heating are well recognized to include modification of collagen structure and stimulation of neocollagenesis. These changes can help improve the appearance of fine rhytides or skin that has begun to lose its elasticity.[1-3] Dermal heating may be achieved directly via ablative laser skin resurfacing or indirectly through an intact epidermis via a process referred to by various terms, such as "nonablative skin resurfacing" and "subsurface resurfacing." A host of devices has been used to accomplish noninvasive dermal heating. The 1320-nm Nd:YAG was the first device developed specifically for noninvasive dermal heating and has proven highly useful in the treatment of acne scars, depressed scars, and fine wrinkles.[4-5] Many lasers emitting in the midinfrared portion of the electromagnetic radiation spectrum have subsequently been developed to accomplish similar objectives. Some of these devices include the long-pulsed 1064-nm Nd:YAG, the 1450-nm Nd:YAG, and the 1540-nm Er:glass, among others.[6-8] Primarily, most of these infrared lasers exert a relatively superficial effect, which can be good for treating fine wrinkles and acne scars but not for producing deep dermal tissue tightening. In general, to achieve more dramatic skin tightening, deeper heating is required.

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Dr. Biesman has received research support from Alma Lasers, Reliant Technologies Inc, Rhytec, Inc, and Thermage, Inc.

Presented in part at the 5th meeting of the American Society of Cosmetic Dermatology & Aesthetic Surgery, Las Vegas, Nevada, December 1, 2006.

NONINVASIVE TIGHTENING OF EYELID SKIN

A number of approaches have now been developed to achieve this goal. Currently available devices that heat the deeper dermis utilize radiofrequency (RF) energy alone, RF energy plus infrared laser energy, and near- and midinfrared pulsed-light devices. A monopolar RF device was the first to be developed specifically for skin tightening. There is thus more basic scientific and clinical information available about this device than about any of the others.

Electric energy can be advantageous for deep dermal heating as the movement of electrons is not impeded by tissue proteins, unlike light energy. RF energy heats tissue by creating electric fields between 2 electrodes, thereby causing molecules to rotate or move. In the case of a monopolar electrode, the charge changes rapidly (as much as 6 million times per second) from positive to negative, alternately attracting and repelling electrons and charged ions. This induces rotation of the polarized molecules, and the resistance to this movement creates heat. Resistance varies with the nature of the tissue (eg, skin vs fat), temperature, and water content (eg, infiltration with tumescent solution). Bipolar electrodes function by passing current between 2 electrodes positioned relatively near one another. In passing between the electrodes, the electric energy flows through the skin, thereby heating it as described above.

RF devices were used for many years in a variety of surgical applications to accomplish hemostatic dissections. The energy delivery systems of these established monopolar devices used a conductive coupling delivery system in which energy was concentrated at the periphery of the electrode. Although this system was not of clinical significance for incisional applications, it posed a problem for noninvasive rejuvenation, since the accumulation of energy at the electrode's periphery would produce localized high concentrations of heat and, thus, burns.

To circumvent this problem, the ThermaCool® device was created. This device is a monopolar RF delivery system that includes a unique capacitive coupling device that permits uniform energy distribution across the entire electrode surface, with subsequent volumetric tissue heating.

The ThermaCool device delivers RF energy with a maximum fluence of 225 J/cm^2, heating tissue in a uniform fashion, with peak temperatures centered approximately 2 to 3 mm beneath the surface. The temperature to which the tissue rises is not known exactly, but histopathologic findings suggest that a temperature of 55°C to 70°C is achieved. Another unique feature of the ThermaCool device is the cooling system that is integrated into the handpiece. Upon activation of the device, cryogen spray is used to internally precool the electrode. The cryogen continues to be delivered during (parallel cooling) and after (postcooling) the energy delivery. The first treatment tip released with this system took a total of 6 seconds to complete a cycle, but a recently released model completes the cycle in only 1.9 seconds. When the ThermaCool device is used, it is extremely important to keep the handpiece perpendicular to the skin at all times. The operator must avoid lifting part of the electrode off the skin's surface, since doing so allows for accumulation of RF energy and can produce a burn.

Clinically, the ThermaCool device has US Food and Drug Administration (FDA) clearance for skin tightening of the periorbital region, the full face (including the neck), and the body. Since the energy is concentrated 2 to 3 mm below the skin's surface, the ThermaCool device should not be used on the eyelids within the orbital rim for fear of injury to the eyes or some of their supporting vital structures. A shallow treatment tip that may safely be used on the eyelids has been developed and tested, and has recently been granted FDA clearance for use on the eyelids. Treatment of other anatomic regions, such as the abdomen, arms, and breasts, has been reported to produce varying degrees of success.[9]

The first US study performed with the ThermaCool device was a multicenter study in which patients underwent treatment of the periorbital region.[3] Patients received a single treatment to the crow's-feet and forehead regions. Fitzpatrick wrinkle scores improved by at least 1 point in 83% of treated periorbital areas. After 6 months, 50% (43 of 86) of patients indicated their satisfaction with periorbital wrinkle reduction. (This, of course, meant that 50% were not satisfied with their outcomes.) In addition, in 61.5% (40 of 65) of patients with sufficient follow-up, eyebrows were lifted by at least 0.5 mm.

These initial studies were performed using high fluences and relatively few treatment spots. The initial treatments were extremely painful, and, in a small but significant number of cases (including one of my own), subcutaneous fat atrophy developed. Although some areas resolved spontaneously, others did not. These problems led to a great deal of negative press about the technology. Today, however, it is unfair to evaluate the performance of the ThermaCool device based on this early experience, since both treatment-tip technology and the treatment algorithm have changed dramatically over the past few years. Advances in the disposable-tip technology have decreased the treatment cycle duration from 6 to 1.9 seconds, making it possible to treat large areas more efficiently. It has also been demonstrated clinically that more passes performed at lower fluences are better tolerated by patients and produce greater, more predictable skin tightening, with a 10-fold lower risk of subcutaneous fat atrophy (estimated risk based on incidents reported to the manufacturer, 1/10,000 cases) (Thermage, Inc, personal communication, April 2006). Electron microscopic studies performed by Zelickson et al[1] have confirmed that more passes at lower fluences may produce changes in dermal collagen at least as significant as those produced at higher fluences. Up to 10 passes are currently performed clinically. Treatments are typically administered without topical anesthesia or intravenous sedation and are titrated to a visible clinical end point. Approximately 90% of patients treated with the multiple-pass and low-fluence algorithm demonstrate visible skin tightening at the time of treatment (M. Kaminer, MD, oral communication, September 2005).

In my opinion, the greatest clinical efficacy is produced with treatment of the mid face, lower face, and neck. Often overlooked is the qualitative improvement in skin quality related to enhanced collagen production. Despite these improvements, clinical results can still vary widely. Some patients achieve marked tissue tightening, lifting, or both, whereas others demonstrate less dramatic results.

In my own research, we have successfully demonstrated safety and efficacy in treating eyelids within the orbital rim using a specially designed 0.25-cm^2 treatment tip. This tip heats less deeply than the medium-depth tips typically used on the face, abdomen, and other areas. Our first goal in developing this tip was to ensure that it was indeed safe to use near the eyes. We

began by treating piglet eyelids, measuring treatment effects on both the eyelid skin and the eyes themselves over a range of treatment settings. We also measured temperature change at the ocular surface to ensure that dangerous temperatures were not reached during treatment. We concluded that the shallow treatment tip would be safe for use on human eyelids.

To investigate further, we treated ex vivo human eyelid tissue over a range of settings extrapolated from the piglet study. Again, we found no deleterious effects associated with monopolar RF treatment with the shallow tip. Next, we treated in vivo human eyelids immediately prior to surgery. The treatments were well tolerated without supplemental anesthesia and did not cause injury to the eyelids or to any of the delicate structures within or next to the eyes.[10] Specially designed plastic corneoscleral protective lenses were used during these studies.

Finally, we undertook an efficacy study in which the upper and lower eyelids and crow's-feet region were treated.[9] This study took the form of a multicenter efficacy study that included a total of 4 sites in Mexico, the United States, and Canada. Overall, we found that 85% to 88% of treated patients achieved at least minimal eyelid tissue tightening as judged by the treating physician, independent photographic review, and patient questionnaires. Although there were no significant complications in this study, the major drawback was the total amount of time required to perform the treatment, an average of approximately 70 minutes.

A second multicenter study was then undertaken to evaluate a slightly different algorithm, this time using a combination of the small 0.25-cm^2 shallow-depth tips and larger 1.5-cm^2 medium-depth tips. The small, shallow-depth tips were used to treat the skin overlying the globe itself, and the larger, medium-depth tips were used to treat the skin overlying the bony orbital rim. Although the efficacy remained similar, the time required to complete the treatments was markedly reduced. Safety studies have not been performed with the larger, medium-depth tips on tissue overlying the eye; therefore, we recommend that these tips be used only on eyelid tissue overlying the orbital rim.

Monopolar RF treatment of human eyelid skin is best for patients with mild to moderate dermatochalasis, reasonably good skin tone, and no significant eyebrow ptosis, eyelid ptosis, or herniated orbital fat. Ideal candidates either do not want or do not need blepharoplasty surgery. Patients who have previously undergone blepharoplasty and who experience a gradual development of skin laxity are also good candidates for monopolar RF skin tightening. However, patients should be counseled to expect modest improvement as the amount of tightening achieved can vary dramatically from patient to patient. The factors responsible for this variability remain largely unknown.

One factor to consider when evaluating this type of technology is the cost of the disposable products required for each treatment. The treatment tips are single-use only, as are the return pads that complete the RF circuit. Also required are cryogen, treatment grids, and coupling fluid. In total, the cost of performing a ThermaCool treatment can be relatively low but in some cases may be well above $500, depending on which treatment tip is used.

RF technology has been applied to skin rejuvenation in a very different manner, with light energy in electro-optical synergy. In contrast to the ThermaCool device, electro-optical synergy makes use of a bipolar RF delivery system. The basic concept underlying these devices is that RF or light energy is used to raise the tissue temperature, thus decreasing the amount of additional tissue heating required to accomplish the intended objective. In theory, when light and RF are combined, each modality would require less energy than if either modality were used alone to achieve the desired clinical results.[11-13] Depending on the intended clinical goal and the device in use, the timing of RF current relative to light energy and the pulse parameters will vary. Epidermal protection is provided via a piezoelectric cooling device built into the handpiece. However, the manufacturer recommends additional cooling with cold air when using some if its devices.

These devices use a bipolar as opposed to unipolar system for delivery of RF energy. The size and positioning of the electrodes within the handpiece determine the geometry and depth of penetration of the electric field into the dermis. When these devices are used, care must be taken to keep both electrodes in contact with the skin since failure to do so will result in accumulation of energy and burns.

A device intended for skin tightening that combines bipolar RF energy delivery with laser light has also been developed. A 900-nm diode laser is used to irradiate the tissue in conjunction with a higher-powered RF generator (maximum energy delivery, 100 J/cm^3). This diode-RF device, known as the Polaris™, has different modules, one for treating vascular lesions and the other for reducing wrinkles. These modules differ in the application-tip design (position of the RF electrodes relative to the sapphire window), sequence of firing of the laser and RF generator, and pulse profile. The Polaris device has been used internationally, reportedly with good success both for treatment of vascular lesions and for tissue tightening.[14] As opposed to the ThermaCool device, the Polaris is generally used to provide a series of treatments to accomplish desired end points. Although some investigators feel strongly that the combination of light and RF energies produces a synergistic effect

clinically, this has not yet been confirmed in an objective study. I am told that such studies are currently under way, but, at the time of the preparation of this article, further details about these studies were not available.

A side-by-side comparison of the bipolar and unipolar devices has not yet been performed. Additional clinical evaluations are currently under way in the United States. The Polaris has FDA clearance for treatment of wrinkles, leg veins, and vascular lesions. The laser spot size is 1 cm. Neither the Polaris nor the ThermaCool should be used on the eyelids within the orbital rim without performing safety studies specific to this region. There are currently no reports in the peer-reviewed literature of using the combined RF-diode device for tissue tightening in areas other than the face and neck. Operation of the Polaris, unlike that of the ThermaCool, does not require disposable equipment. Use of the Polaris on the eyelids has not yet been studied.

A combined infrared-bipolar RF device known as the ST has been recently introduced into the marketplace. Clinical data are not yet available for this device, but anecdotal reports are favorable. The ST device has not yet been studied for use on the eyelids.

A skin-tightening device that uses infrared light energy to produce dermal heating, known as the Titan®, produces a thermal profile in the dermis comparable to that of the ThermaCool. The majority of the energy is emitted in the 1100- to 1300-nm range. The handpiece has an integrated cooling system, and treatments, like ThermaCool treatments, are performed at moderate energy settings using a multiple-pass algorithm. The area of the treatment window is 1.5 cm^2. Approximately 4 passes are typically recommended in a given anatomic region during a single treatment session. Several treatment sessions spaced approximately 4 to 6 weeks apart are recommended. Operation of the Titan is similar to that of the Polaris and contrasts with that of the ThermaCool in that the Titan does not require disposable tips or other supplies, although the treatment head needs to be replaced periodically (the initial recommendation was replacement after 10,000 pulses; parameters differ with newer heads). The greatest clinical success has been reported in the lower face and on the abdomen.[15,16] A drawback of this device is the duration of each pulse cycle, which averages approximately 6 seconds but is longer at higher fluences. This limits the number of pulses that can be delivered during a treatment session. Rigid multicenter clinical trials have not been performed with the Titan.[17,18] According to the manufacturer, complications of the Titan device have been limited to superficial blistering without serious scarring. The Titan is commonly used in the periorbital region but should not be used directly on the eyelids.

Another infrared energy–based skin-tightening handpiece that attaches to its basic platform has recently been released. This device, also known as the ST, emits energy in the 800- to 1000-nm range. A pulse train is delivered over 5 to 15 seconds, depending on the fluence. Despite the very long pulse duration, the large size of the sapphire window (6.4 cm^2) still allows the device to be used somewhat efficiently. Experience with this device is limited since it has been available for only a short time. A clinical study I performed suggests that this device can produce clinically significant skin tightening (B.S.B., unpublished data, 2006–2007). More rigid studies are currently under way. This device also may be used in the periorbital region but should not be used on the eyelids themselves.

Another approach to noninvasive skin tightening involves the combination of RF energy and vacuum suction. The Aluma™ uses functional aspiration controlled electrothermal stimulation to induce a conformational change in dermal collagen, with subsequent skin tightening. The suction element is adjustable from 4 to 28 mm Hg and serves to draw the skin between parallel electrodes, where it is then exposed to an electric current passed between the electrodes at a power of 2 to 10 W. Treatment times per pulse vary from 1 to 6 seconds. As with other noninvasive tissue-tightening modalities, supplemental anesthesia is not required. A well-constructed clinical study was performed by Gold et al[19] in which 46 patients were evaluated. Treatments were limited to the upper and lower face. Treatment sessions were administered weekly for 8 weeks, and patients were followed for 6 months after the final treatment. Patient satisfaction was quite high (90%), with modest skin tightening noted in both the upper and lower face. The Aluma device has been used by some clinicians on the eyelids, but ocular safety studies have not yet been performed.

It is clear that noninvasive tissue tightening can produce satisfactory to excellent clinical results with a satisfactory safety profile. However, there are still a number of obstacles to overcome. Patient selection and education remain challenging. The clinical characteristics of those patients who are either ideal candidates or poor candidates have not yet been fully determined. Debate continues about the use of these devices over dermal fillers, although one study in which the ThermaCool device was compared with various fillers suggested that there was no increased risk associated with the treatment and no decrease in the duration of temporary fillers.[20,21] Other obstacles that remain include the determination of ideal treatment parameters and algorithms, management of pain during treatment, judgment of clinical end points, the dependence of results on treatment technique, justification of treatment costs with clinical outcomes, and the further development of applications on the eyelids and other anatomic regions.

FRACTIONAL AND PLASMA SKIN RESURFACING OF THE EYELIDS

None of the noninvasive skin-tightening treatments adequately address fine wrinkling and dyspigmentation of the eyelid skin, common patient complaints. For patients seeking improvement in these areas, other solutions must be sought. Available options include chemical peels, ablative laser skin resurfacing, fractional skin resurfacing, and plasma skin resurfacing. Superficial peels do not produce sufficient clinical improvement, and deep peels and ablative skin resurfacing techniques are associated with prolonged posttreatment recovery. In an effort to develop an effective approach to fine eyelid wrinkling with minimal associated downtime, I have studied fractional resurfacing and plasma resurfacing of the eyelids.

Fractional resurfacing may be accomplished with a number of different devices. The Fraxel® laser is a 1550-nm diode-pumped erbium fiber laser that is FDA approved for skin resurfacing and for treatment of melasma, periorbital wrinkles, and scars created by acne or surgery. This device coagulates tissue in multiple 75- to 150-µm microthermal zones, with depth of injury extending up to 750 µm. Re-epithelialization typically occurs within 24 hours. Owing to technical limitations, the Fraxel device had not been previously used on the eyelids. To facilitate use on the lids, a special treatment tip was developed. This tip has the same diameter as the existing small treatment tip but extends several millimeters from the housing to permit manipulation on the eyelids and other small areas.

To evaluate the safety and efficacy of the Fraxel laser treatment on the eyelids, a 2-phase study was designed.[22] In the first phase, ex vivo testing was performed on human eyelid skin removed during routine blepharoplasty to determine acceptable treatment parameters. Once this phase was completed, 20 patients with Fitzpatrick skin types I through III were recruited to participate in the second phase in which 4 treatment sessions were conducted at approximately 2-week intervals. All treatments were performed under topical anesthesia, with follow-up at 1 and 3 months after the final treatment. There were no serious complications after any of the treatments. The average time to return of everyday activities was 2 to 3 days.

At this time, final data analysis is not complete. However, preliminary data suggest significant reduction of wrinkles and substantial improvement in surface texture and overall eyelid appearance. Fractional resurfacing of the eyelids with the Fraxel laser appears to hold significant promise in eyelid rejuvenation. Although there are many other fractional resurfacing devices available, care should be taken to avoid extrapolating the data and applying results to devices that have not been carefully tested on the eyelids themselves. Preliminary evaluation of the Affirm™ Anti-Aging Workstation suggests that this device is also safe and effective for use on the eyelids.

Plasma skin resurfacing involves the creation of high-energy plasma via the delivery of a pulse of ultra–high-frequency RF energy to inert nitrogen gas. When the plasma thus generated is delivered to the skin, a rapid molecular energy transfer occurs, with transmission to dermal layers. The depth of effect is determined by the amount of energy delivered per pulse.

Differences between plasma skin-resurfacing and laser skin-resurfacing techniques include lack of chromophore dependency and maintenance of the structural integrity of treated tissue after delivery of plasma energy. Similar to ablative skin resurfacing, zones of thermal damage and thermal modification are produced following delivery of plasma energy to the skin. The zone of thermal damage is ultimately sloughed, while the zone of thermal modification recovers. Maintenance of an intact epidermis overlying the area of injured tissue appears to support shorter healing times relative to ablative skin-resurfacing techniques. The greater the energy delivered, the deeper the plasma is delivered to the dermis.

There is only one plasma skin-resurfacing device commercially available. The Portrait® is FDA cleared for use in treating facial and nonfacial rhytides, superficial skin lesions, actinic keratoses, seborrheic keratoses, and viral papillomata. Until recently, this device was not formally evaluated for its safety and efficacy in treating the eyelids. I recently completed a study in which this device was used to treat the eyelids of 24 patients.[23] Patients included in this study had more substantial photoaging and lid laxity than those included in the fractional resurfacing eyelid study. After a series of ex vivo eyelid treatments were performed, parameters were selected to treat the remaining patients. Some treatments were performed at low-energy settings, and others were performed at high-energy settings. Most treatments were accomplished with topical anesthesia only. Recovery typically ranged from 4 to 10 days. Final data analysis has not been completed, but preliminary evaluation suggests that most patients achieved marked skin tightening and wrinkle reduction.

SUMMARY

There is an increasing number of technology-based options that provide the aesthetic specialist with new choices for eyelid rejuvenation. The key to using these procedures successfully lies in the ability to match a clinical scenario with an appropriate treatment and to counsel patients in such a manner that expectations are set appropriately.

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