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Evaluation of a Novel Radiofrequency Device for the Surgical Treatment of Loose Tissue of the Upper Eyelid

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Introduction

The natural process of facial aging reflects the cumulative effects of time, gravity, animation, redistribution of fat and loss of elasticity on skin and soft tissues. These changes are particularly evident, and arguably first noticed, in the periorbital region due to the delicate nature of the upper eyelid and minimal tissue thickness. In contrast to the youthful appearance once seen in the first decades of life, the complex effects of aging can result in various functional and cosmetic deformities, including impaired visual acuity, drooping eyelids and a "tired-looking" appearance. Upper eyelid surgery, or blepharoplasty, is a popular procedure that aims to restore a youthful appearance in the upper eyelids by removing excess tissue and addressing skin laxity.[1–4].

Background

Several surgical methods exist today in accomplishing this desired youthful effect, including, traditional scalpel, cautery, electrosurgery, lasers and radiofrequency (RF). Each method carries its own inherent risks and thus, it is important for the clinician to consider each when deciding which is best for their practice. Traditional methods, though aesthetically effective, are unable to both excise and coagulate tissue simultaneously. The inability to provide simultaneous hemostasis results in an increased risk for prolonged bleeding, less accurate visualization of the surgical site and longer procedure times. Additionally, increased intraoperative bleeding has been associated with a high degree of postoperative edema, ecchymosis and discomfort[5]. The emergence of new technologies has effectively resolved this issue and offers the ability to both coagulate and cut tissue simultaneously.

One such technology that is gaining momentum for its surgical innovations is the TempSure Surgical RF device. The 300 watt, 4 MHz frequency device is able to use less heat and simultaneously cut and coagulate tissue resulting in minimal damage to the surrounding tissues, thus lowering the risk for injury and postoperative complications. The ability to produce less heat during the procedure also promotes less postsurgical pain and faster healing and recovery time[6,7]. There are several advantages evident with the use of a radiofrequency device for blepharoplasty over other surgical modalities including, pressureless incisions, more precise cuts and minimal scarring. Currently, the device is cleared by the Federal Food and Drug Administration (FDA) for the treatment of wrinkle reduction, soft tissue coagulation, cutting, blended cutting and coagulation, cellulite reduction and fulguration. The versatility of the device for both surgical and non-invasive aesthetic procedures is an appealing feature of the device platform.

The following study aimed to assess the safety, efficacy and recovery time of the TempSure® Surgical RF device for its use in blepharoplasty procedures.

Methods and Materials

A single site, prospective study was performed to evaluate the safety and efficacy of the TempSure Surgical RF device for the treatment of excess skin in the periorbital region. The inclusion and exclusion criteria included:

Inclusion criteria:

1. Healthy and 18 years of age or older
2. Unwanted loose or excess tissue of the upper eyelid
3. Able to attend all visits and comply with all requirements of the study

Exclusion criteria:

1. Is pregnant or of child bearing potential and not using medically effective birth control or has been pregnant in the last 3 months, currently breastfeeding or planning a pregnancy during the course of the study.

2. Active or localized systemic infections.
3. Enrolled in an investigational drug or device trial, or has received an investigational drug or been treated with an investigational device within the area to be treated 6 months prior to entering this study.
4. Cosmetic treatments in the area to be treated in the past 6 months are cautioned and determined at the discretion of the investigator.
5. History of keloids.
6. Scarring or wounds in the treatment area that would interfere with assessments.
7. Metal implant (such as but not limited to; titanium orbit or metal chin repair) in the face or head or electronic implantable device (such as but not limited to; pacemakers and embedded defibrillators).

A pregnancy test was performed on all subjects of childbearing potential prior to initiating treatment. Subjects were instructed to refrain from applying products or makeup to the general eye area for at least 12 hours before treatment. Proper hydration and avoidance of alcohol was encouraged for optimum results. On the day of treatment, subjects were asked to remove makeup, lotion and sunblock from their face, as this could act as an impedance to energy and diminish results.

The procedures were performed using local anesthetic; lidocaine 1% with epinephrine. Per the Investigator's preference the pedal activated handpiece was used and both the Empire 45° and Ball electrodes at his discretion. The procedure was performed using the following parameters and surgical methods:

Step 1: Neutral pad used per guidelines. CUT at 15W, BLEND at 15W and COAGULATION at 20W. Less bleeding was observed with BLEND at 15W so it was used the majority of the time for the initial incision. The Empire tip offered more control and was easier to maneuver for this particular step.
Step 2: COAGULATION setting at 25W. The Empire needle electrode was used to cut the second layer of tissue in order to widen the gap between the original cut and tissue that was going to be excised.
Step 3: Using the Empire electrode on COAGULATION at 25W the Clinician uses forceps to lift the lateral edge of the flap that will be excised and in a backhanding motion uses the Empire tip to gently separate and remove the skin.
Step 4: Using the Empire electrode at 25W on COAGULATION the Clinician smooths the skin edges and coagulates any vessels that may still be an issue.
Step 5: Using the Ball electrode at 15W on COAGULATION, the Clinician runs the electrode over the tissue and muscle to induce coagulation and tissue tightening. This negates the need to remove any further tissue via scalpel, RF or any other method.
Step 6: Suture (6-0 prolene) and Steri-Strip

Post-treatment, subjects were informed they may experience mild erythema and to avoid hot water when washing or showering until redness subsided. Makeup could be applied immediately post-procedure but was not encouraged. If the treatment area was going to be exposed to the sun, SPF 30 or greater was recommended to prevent sun damage. The Clinician and subjects were asked to complete a questionnaire at this visit evaluating their treatment experience.

All subjects were given a diary to complete for 7 days post-treatment and were asked to document adverse events and symptom severity [1: "mild", 2: "moderate", 3: "severe"] in order to assess recovery time. They were instructed to return for follow up at 1 day, 1 week, 1 month and 3 months. Adverse events were evaluated by the clinician at each visit and subsequently until they resolved. Standardized photography was performed at baseline and all follow up visits to assess efficacy.

Subjects were responsible for costs of procedure and given $2800 for their participation in the study.

Results

10 subjects were enrolled in the study and received a single treatment to the upper eyelids with the Tempsure RF surgical device. One month data was not available for 2 subjects so they were not included in the final safety analysis. Similarly, 1 subject did not complete the symptom diary and was not included included in the subjective recovery time analysis.

Subjects were generally very pleased with their results with all reporting they were satisfied or extremely satisfied with the treatment. When asked if they felt nervous throughout the procedure the majority reported they were not, with most reporting high levels of overall comfort during the treatment. Subjects most enjoyed the ease and quickness of the procedure with one subject stating "it was nice to be awake" during it. Subjects least enjoyed "the smell" and "noise" associated with treatment as well as the idea of having "surgery". 80% reported they would return for another treatment after their experience, with the remaining 20% stating "maybe" or "to be determined".

The clinician performing the procedure reported the setup was easy and, overall, felt comfortable using the reusable handpiece, especially once the plastic covering was removed. He reported that subjects were generally very comfortable during the procedure, though 2 subjects needed reapplication of lidocaine for added comfort.

The most common adverse events observed by the clinician were: Swelling (88%), Redness (88%) and Bruising (88%) followed by Bleeding (25%) and Crusting (25%). There were no reports of infection or blistering during the study. Overall, symptoms were mild to moderate and all reduced in severity to mild by the 1 week follow up visit.

Only 1 subject met the criteria for experiencing “severe” swelling, which reduced to “mild” by the 1 week follow up and completely resolved by the 1 month visit. The majority of subjects had complete resolution of their symptoms within 1 month post treatment.

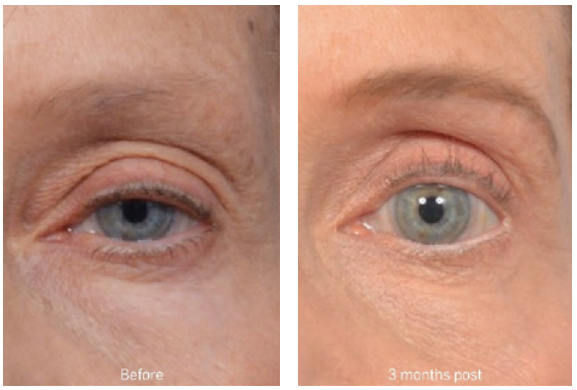
Subjects most frequently reported: Swelling (100%), Redness (100%), Discomfort (89%), Bruising (89%) and Bleeding (67%) immediately post-treatment and the day following. By day 6, the number of patients experiencing Swelling, Redness and Bruising reduced to 67%, 89% and 67%, respectively. Bleeding completely resolved by day 3 and discomfort completely resolved by day 6. Itching was most frequently reported between days 2-5 but also resolved by day 6 (Figure 1). Overall, subjects reported improvement of symptoms over the 7 day period with many having complete resolution. Most symptoms were perceived as mild to moderate initially with the majority improving to “mild” by day 6 (Figure 2).

Discussion

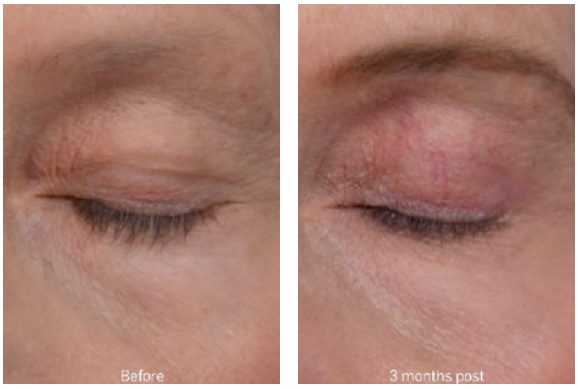
For the past 20 years, blepharoplasty has firmly remained a popular choice for both cosmetic and functional alteration of the upper eyelids, always ranking in the top 5 for surgical procedures. In 2018 alone, 115,508 blepharoplasties were performed, similar to what has been reported in preceding years. The procedure is similarly sought out by both male and female patients, ranking 3rd and 5th, respectively, for most frequently performed based on gender. It was also the most common procedure in adults over the age of 65 years old, which given the nature of the condition and its correlation with aging, is not surprising[8]. These steady trends confirm the prevalence of this issue among older adults and highlights the need for a continued focus on the safest and most effective treatment modalities. Recent advancements in device technology, as seen with the TempSure Surgical RF device, offer a safe and efficacious option for patients seeking to undergo upper eyelid surgery.

Conclusion

The results of this study validate the device’s usefulness in treating a common cosmetic and functional issue for older adults. The subjects were generally comfortable prior to and during the procedure and due to the reduced risk of intraoperative bleeding were able to be treated in the office setting, adding to the ease of treatment for both the clinician and subjects. Overall, the study revealed that treatment was well tolerated with minimal recovery time and yielded high subject and clinician satisfaction. Of the adverse events that were reported, most were mild and transient in nature and resolved or improved by the 1 month follow up visit. The TempSure Surgical RF device is a safe and efficacious option for those seeking to improve the appearance of loose periorbital tissue.



courtesy of B. DiBernardo, MD



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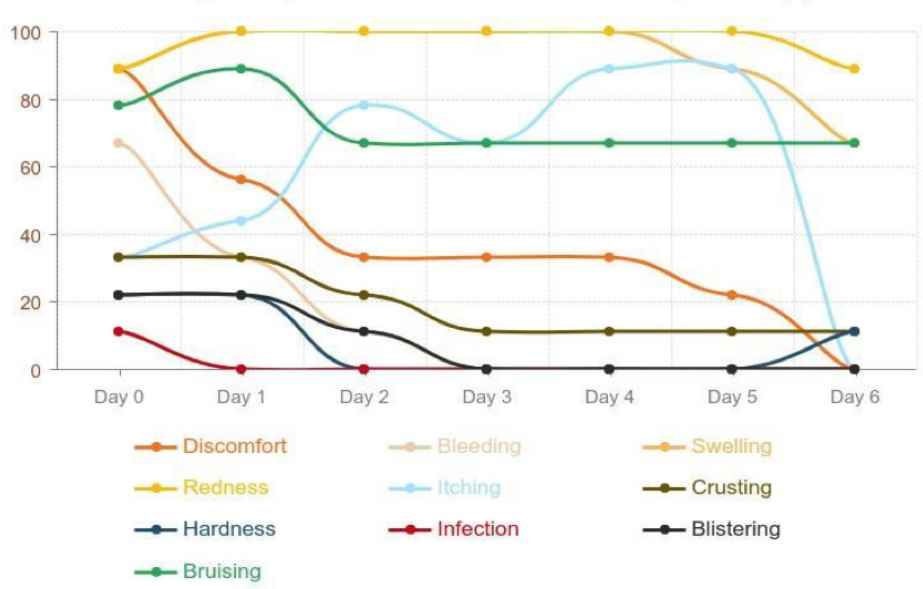
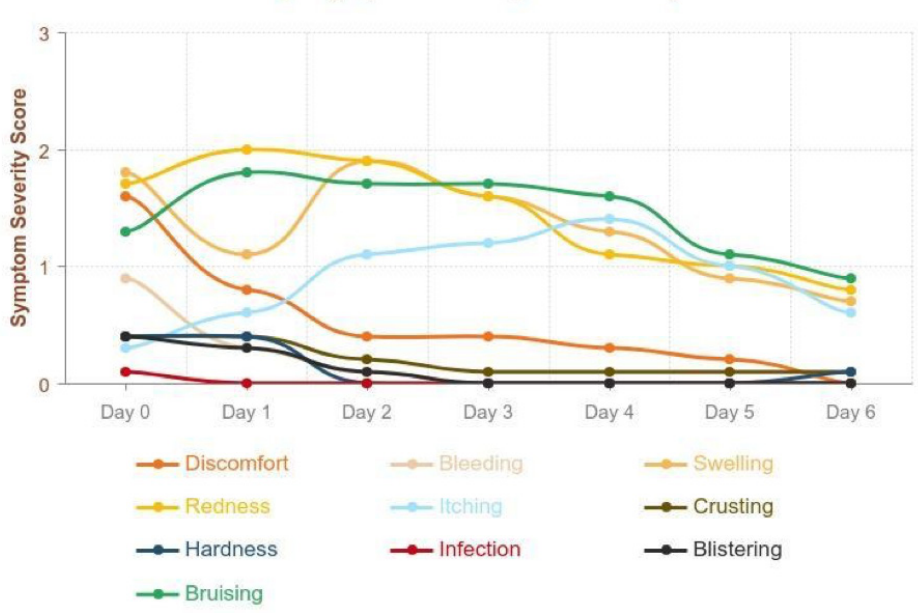
Subject Reported Adverse Events Over 7-Day Period (%)



Average Symptom Severity Over a 7-Day Period



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