

A Proposed Method for Upper Eyelid and Infrabrow Tightening Using a Transcutaneous Temperature Controlled Radiofrequency Device With Opaque Plastic Eye Shields

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ABSTRACT

BACKGROUND: Laxity of the eyelid and periorbital area, a common manifestation of aging, is usually addressed via blepharoplasty and/ or fat transfer. Given the trend toward safer, less invasive treatments preferred by those patients reticent to undergo more invasive procedures, viable alternatives have been sought. Transcutaneous temperature controlled radiofrequency (TTCRF) integrates non- invasive super cial RF treatment with automatic temperature feedback control of energy deposition, as a stimulator of overall collagen remodeling; however, the globe of the eye is particularly sensitive to RF energy. The purpose of the study was to propose a method by which TTCRF and other non-ablative modalities could be used to treat evelid and infrabrow laxity, with autoclavable opaque black haptic scleral contact lenses protecting the globe of the eye. METHODS: Subjects (n=40, 36 women and 4 men, age range, 33-72) with mild to moderate laxity of the eyelid and infrabrow were treated with TTCRF using black plastic eye shields (Oculoplastik, Montreal, Quebec, Canada) to protect the globe of the eye from heat and RF energy. With the shields in place subjects were treated with the 10 mm small monopolar emitter of the ThermiSmooth device (Thermi, Irving, Tex.), using small circular looping motions to safely elevate the temperature of target tissue to the therapeutically rel- evant range for approximately 6 minutes; tissue temperature was measured in real time using the device's forward-looking infrared imaging. RESULTS: No major adverse events were recorded. Treatment was safe and tolerable for all subjects. CONCLUSION: The use of autoclavable opaque black plastic eye shields provides a safe method of treating the upper eye lid and infrabrow using TTCRF. J Drugs Dermatol. 2016;15(11):1302-1305.

INTRODUCTION

Laxity of the eyelid and periorbital region is a universal and early manifestation of aging which increases over time, often addressed by blepharoplasty and/or transfer of autologous fat to remove lax skin and restore lost volume.¹ While safe, effective, and commonly performed, many younger patients may be reticent to undergo these invasive procedures, especially in the presence of safe, effective alternatives with reduced risk and downtime.¹⁻² Trends such as these across the industry regarding the advent of less invasive methods have, in fact, been noted.³ Less invasive modalities such as intense focused ultrasound (IFUS)^{1,4} and fractional CO2 laser⁵ have been demonstrated to be valid alternatives for upper lid and periorbital treatment.A brief review of blepharoplasty alternatives by Bae-Harboe and Geronemus⁵ suggested RF as a potential non-invasive therapy with low downtime but variable degree of improvement limited to tightening and lifting. RF technology works by harnessing the impedance of skin when electrical current is passed through it, generating thermal energy to stimulate collagen contraction and neocollagenesis.⁶ Subsequent inflammatory response leads to other beneficial effects, ultimately causing collagen remodeling and a tightening effect. The technology has been demonstrated safe and effective for tightening in younger patients or as adjunct to

facelift surgery (as a touch-up or maintenance treatment). Javate and colleagues used non-ablative, noninvasive RF for periorbital rhytides with some success in a 2014 study.⁷One potential RF-based alternative is transcutaneous temperature controlled radiofrequency (TTCRF). The ThermiRF device (Thermi, Irving, TX) is designed to perform different iterations of radiofrequency (RF) treatments; ThermiSmooth is a transcutaneous mode of the device. Using the ThermiSmooth small probe with its 10 mm active tip monopolar RF emitter (requiring a grounding pad), skin temperature in small areas such as the periorbital region might be elevated to and held at the scientifically determined, therapeutically relevant temperature range of 40°C to 45°C to stimulate collagen remodeling and tightening. Integrated temperature monitoring allows automatic adjustment of RF energy emission by the device based on real time tissue temperature readings, which promotes

maximum safe energy deposition. For transcutaneous applications forward-looking infrared (FLIR) thermal imaging is employed for this purpose.8While RF may seem to be an ideal modality for the periorbital area, the eyes are among tissues known to be extremely susceptible to damage by RF energy; any RF-based therapy to the periorbital area would have to account for this.⁶ Carruthers and Carruthers used a small-tip RF device in a 2007 study and used opaque black plastic shields to protect the globe of the eye during treatment; safety was demonstrated but outcomes were described as mild to moderate at best.² Opaque black haptic scleral contact lenses (Oculoplastik, Montreal, Quebec, Canada) are autoclavable plastic shields designed for blepharoplasty procedures, protect the globe of the eye from heat and RF energy. These are placed on the eye via suction cup handle designed for that purpose. Shields themselves come in four sizes (extra small/XS, small/S, medium/M, and large/L) and are good for up to 50 autoclave cycles. The purpose of this study is to propose a method for applying TTCRF to the upper eyelid, periorbital area, and infrabrow and demonstrate its safety for future use in investigations.

PATIENTS AND METHODS

Subjects (n=40, 36 women and 4 men, age range, 33-72) presented with mild to moderate laxity of the eyelid and infrabrow. Exclusion criteria included any anatomically nearby metallic implants or microelectronic implants, such as a pacemaker. The study was conducted using Good Clinical Practice Guidelines and informed consent was obtained from all subjects prior to inclusion. Any makeup, false evelashes, and contact lenses were removed prior to treatment. The subject is placed in a supine position with the RF grounding pad placed on exposed clean skin (shaved of excessive hair) on the upper back. Eye shields were cleansed with soap and water followed by chloroxylenol 3% wash before autoclaving prior to treatment, and were inspected thoroughly for rough or lagged edges before placement. The suction cup applicator was placed on the convex surface of the shield for placement and one drop of lubricant (mineral oil 42.5%, petrolatum 57.3%) was applied to the concave inner surface of the shield. A single drop of proparacaine 0.5% ophthalmic solution was applied to the treated eye; after 10 to 20 seconds the upper eyelid was then gently lifted using gauze and while the patient looked downward, the lubricated shield was placed onto the globe of the treated under the then lower lid using еуе upper,

FIGURE 1. Digital photographs of a woman (age, 54 years) before (left) and after (right) 6 treatments one month apart with TTCRF for the eyelid and infrabrow, using opaque black plastic eye shields to protect the eye during treatment. Photos courtesy of Douglas Key MD.



FIGURE 2. Digital photographs of a woman (age, 60 years) before (left) and after (right) 5 treatments one month apart with TTCRF for the eyelid and infrabrow, using opaque black plastic eye shields to protect the eye during treatment. Photos courtesy of Douglas Key MD.



the suction applicator handle. After shield insertion, the patient closed their eyes and the applicator handle was removed by applying gentle pressure to the upper eyelid and easily dislodging the suction cup. A thin layer of ultrasound gel was then applied to the eyelid and periorbital region. The upper eyelid as well as the periocular and suprabrow areas are then treated using the small probe of the ThermiSmooth RF device. Using continuous movement in a small circular 'daisy-chain' motion to prevent overheating of any one area, the skin temperature was elevated to and held between 39°C and 41°C for approximately 6 minutes. FLIR thermal imaging was used to monitor skin temperature to maximize proper management of RF energy application and prevent hotspots. The tear trough and lower lid were avoided to mitigate the potential for unwanted subcutaneous fat reduction. Each periorbital region was treated in sequence separately. Upon completion of treatment the suction cup is applied to the shield and the patient is asked to open their eyes widely, to facilitate shield removal. If needed patients may flush the eyes with carboxymethylcellulose sodium 0.5% ophthalmic solution to remove excess lubricant. Follow-up occurred 2-3 months after treatment.

RESULTS AND DISCUSSION

There were no major adverse events recorded. Treatment was safe and tolerable for all subjects. Figures 1 and 2 represent before and after photographs of patients undergoing treatment as per study protocol. One of the challenges with this study was obtaining consistent clinical photography to record and measure improvement in lid laxity and brow ptosis. Challenges with comparative photography in matching upper lid laxity are affected by facial expression, brow position, and consistent lighting and positioning of the subject.Further refinement of safe methods for studying TTCRF for upper lid and infrabrow laxity would benefit from validated objective methods to accurately rate improvement, given the small size of the treatment area and possible subtlety of the outcomes. A 2014 study by Javate, et al¹ proposed the use of a multipoint facial positioning and imaging systems (Canfield Reveal, Canfield Scientific, Fairfield, NJ) to document outcomes of an RF therapy for periorbital rhytides. The imaging protocol provides a reproducible method of documenting outcomes by using software to analyze and combine photographs taken at a variety of angles at each treatment or follow-up session; changes are rendered graphically on a computer screen with measurements that can be statistically analyzed. Subjects (n=12) received 1 to 2 treatments and the imaging system showed average evebrow lifting of 2.05 mm and average superior evelid crease elevation of 0.98 mm after treatment, with average 3.52 mm and 1.84 mm eyebrow lifting and superior eyelid crease elevation, respectively, at 8-week follow-up. Results were statistically significant. Future study using this or similar technologies capable of objectively documenting subtle results for areas such as the

periorbit would be the logical next step, although these modalities may not be available in every practice.

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CONCLUSION

The use of autoclavable opaque black plastic eye shields provides a safe method of treating the upper eye lid and infrabrow using TTCRF.

DISCLOSURES

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