A Retrospective Evaluation of Subsurface Monopolar Radiofrequency for Lifting of the Face, Neck, and Jawline

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BACKGROUND Subsurface monopolar radiofrequency (SMRF) has emerged as a new method for reducing skin laxity via the controlled delivery of thermal energy below the skin using a radiofrequency probe.

OBJECTIVE To evaluate the overall efficacy of the treatment and satisfaction ratings of subjects who underwent a single SMRF treatment to the face, neck, or jawline (or some combination).

MATERIALS AND METHODS A retrospective, single-center study was conducted in which data were obtained via subject follow-ups at 90 and 180 days posttreatment.

RESULTS A total of 35 subjects, 6 men and 29 women, underwent a single SMRF treatment. Overall, 77% of subjects reported improvement, and 64% reported satisfaction with the treatment site at Day 180 posttreatment.

CONCLUSION Subsurface monopolar radiofrequency represents an effective modality to achieve skin tightening of the face, neck, and jawline. The data suggest that there is an energy delivery threshold, above which a higher percentage of subjects report satisfaction. Analysis of treatments parameters suggests an optimal treatment time and tissue temperature that should be achieved to maximize results.

The authors have indicated no significant interest with commercial supporters. The equipment used was loaned by Thermi Aesthetics.

Increasing skin laxity with age is a common concern among subjects presenting to a cosmetic dermatology practice. This finding most typically presents in the lower face and neck but can also affect body sites such as the posterior upper arms, the periumbilical abdomen, the outer and inner thighs, and the knees. Apart from rare genetic conditions, such as cutis laxa and Ehlers-Danlos syndrome, the etiology of lax skin is a result of natural aging processes, such as gradual degradation of cutaneous structural integrity and loss of subcutaneous tissue and muscular support, as well as others processes such as cumulative ultraviolet radiation exposure.

To combat progressive age-related skin laxity, a multitude of energy devices (ablative and nonablative lasers, microfocused ultrasound, and radiofrequency) have been developed with demonstrated clinical and histological efficacy. The principle mechanism of action of these devices is the delivery of thermal energy to target tissue, causing both immediate collagen contraction and denaturation with subsequent remodeling and regeneration of de novo collagen.[1–4] A novel method of delivering radiofrequency energy to the subdermal interface via real-time thermistor-controlled probe has been developed to address skin laxity (ThermiRF; Thermi Aesthetics, Irving, TX). Using this technology, exact surface and subsurface temperatures can be monitored in real time, allowing controlled and tunable energy delivery to specific tissue planes beneath the skin. Preliminary data have supported the efficacy of this treatment in improving age-related skin laxity.[5,6] However, optimal treatment parameters have yet to be clearly defined.

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In this retrospective study, the authors evaluate the safety and efficacy of thermistor-controlled subsurface monopolar radiofrequency (SMRF) for lifting and tightening the face, neck, and jawline. The authors also present an analysis on various factors that may contribute to optimal treatment results.

Materials and Methods

Subject Population

A retrospective chart review at a single center was conducted to identify subjects who had undergone SMRF treatments to the face, neck, and jawline over a 6-month period. These subjects were taken from a pool of 4 treating physicians. The principles of the 1975 Declaration of Helsinki were followed, as subjects expressed willingness to participate in the study.

Treatments

Subsurface monopolar radiofrequency was delivered to various body sites that were characterized by excessive skin laxity. These sites included multiple combinations of the face, cheeks, jawline, and neck. After thorough cleansing of the treatment area with 4% chlorhexidine gluconate solution, dilute lidocaine solution consisting of 3 parts 1% lidocaine with epinephrine and 7 parts bacteriostatic normal saline was administered via subdermal cannula so that the entire treatment area was adequately anesthetized but not tumesced. Depending on treatment area, the volume of anesthetic solution used varied between 50 and 100 mL. Throughout the treatment procedure, the epidermal temperature was continuously monitored via an external infrared camera to minimize the chance of inadvertent burn by allowing the operation to cool the skin immediately if a temperature above 42°C was noted. The subsurface temperature target was set between 55°C and 65°C. Clinical end point was determined when a uniform subsurface target temperature was achieved.

Surveys

Subjects' feedback was obtained at Days 90 and 180 posttreatment. Subjects were prompted to provide feedback on the following: pain during treatment, pain after treatment, edema, bruising, numbness, nodules/induration, and any other adverse events. Subjects were then asked to rate the improvement of the treated area and their satisfaction. Both pain ratings were recorded using a Numeric Rating Scale 0 to 10, with 0 being no pain and 10 being the worst pain. Severity of edema, bruising, numbness, nodules/induration, and other adverse events were reported as none, mild, moderate, or severe. Duration of these events in days was also recorded. Improvement was reported using the Subject Global Aesthetic Improvement Scale (SGAIS), with subjects classifying the treated areas as very much improved (>75%), moderately improved (25%–75%), somewhat improved (<25%), the same as before, or worse than before. Data were recorded using a numeric rating scale of "very much improved" = 1 to "worse than before" = 5. Similarly, subjects' degree of satisfaction was reported as very satisfied, somewhat satisfied, neutral, somewhat dissatisfied, or very dissatisfied, with the numeric rating scale of "very satisfied" = 1 to "very dissatisfied" = 5.

Data on adverse events were collected once at either 3 or 6 months posttreatment, whereas SGAIS and satisfaction ratings were recorded at both 3 and 6 months posttreatment.

Subjects' feedback was analyzed in correlation with treatment parameters, including total treatment time and total energy delivered (as calculated by the weighted average subsurface target temperature during the treatment multiplied by the total treatment time in seconds).

Results

A total of 35 subjects, 6 men and 29 women, underwent a single SMRF treatment. Subjects ranged from 42 to 85 years old, with an average age of 63 years. Set internal probe temperatures ranged from 55°C to 65°C, with an average of 59.9°C. Total treatment times varied with the surface area of the treatment site, ranging from 8 to 38 minutes with an average of approximately 19 minutes. Of the 35 subjects who underwent treatment, feedback data

were successfully obtained from 28 (80%). These demographics are represented in Table 1. The majority of subjects reported both improvement and satisfaction at both Days 90 and 180 posttreatment (Table 2, Figure 1).

Subject satisfaction data were analyzed as a factor of treatment time and total energy delivered (treatment time multiplied by average probe temperature). Subjects who received total treatment energy above 90,000 (°C × seconds) (Group 1) reported approximately 22% and 29% higher satisfaction rates than those whose treatment registered below that threshold (Group 2) (Figure 2A,B).

Adverse Events

The most common reported side effects were tenderness (63.0%), edema (88.9%), bruising (51.9%), numbness (81.5%), and nodules or induration (18.5%). These adverse effects were described as mild and transient (Figure 3A,B). Additionally, 2 subjects experienced temporary marginal mandibular nerve palsy, which resolved within 14 days without intervention.

Epidermal Temperature

With set probe temperatures ranging from 55°C to 65°C, epidermal temperatures ranged from 35°C to 48°C. Although every effort was made to maintain epidermal temperatures below 43°C, brief seconds of increased temperature occurred rarely and were immediately addressed with application of cold saline wipes to cool and protect the epidermis. One subject experienced a mild, transient, unilateral burn, which resolved without sequelae.

TABLE 1. Study Demographics

Variable	*N*	*Mean*	*Range*
Age, years	35	63	42–85
Gender, *N* (%)			
Male	6 (17.1)		
Female	29 (82.9)		
Subjects responded, *N* (% of total subjects)			
Overall	28 (80.0)		
3 months	19 (54.3)		
6 months	22 (62.9)		
Treatment parameters			
Time, minutes		19.4	8.0–38.3
Probe temperature, °C*		59.9	55.0–65.0

*Weighted average.

TABLE 2. Subject-Graded Improvement and Satisfaction

SGAIS Classification	*N (%)*	
90 days, *N* = 19		
Very much improved	4 (21.1)	Total improved: 84.2%
Moderately improved	7 (36.8)	
Somewhat improved	5 (26.3)	
No change	2.5 (13.2)	
Worse	0.5 (2.6)	
180 days, *N* = 22		
Very much improved	5.5 (25.0)	Total improved: 77.2%
Moderately improved	8.5 (38.6)	
Somewhat improved	3 (13.6)	
No change	3 (13.6)	
Worse	2 (9.1)	
Subject Satisfaction	*N (%)*	
90 days, *N* = 19		
Very much improved	7 (36.8)	Total satisfied: 68.4%
Moderately improved	6 (31.6)	
Somewhat improved	2 (10.5)	
No change	1 (5.3)	
Worse	3 (15.8)	
180 days, *N* = 22		
Very much improved	5.5 (25.0)	Total satisfied: 63.6%
Moderately improved	8.5 (38.6)	
Somewhat improved	3 (13.6)	
No change	3 (13.6)	
Worse	2 (9.1)	

SGAIS, Subject Global Aesthetic Improvement Scale.

Discussion

In this retrospective study, the authors evaluate the safety and efficacy of SMRF for treatment of skin laxity to the face, neck, and jawline, in a cohort of paying subjects. Moderate satisfaction with the procedure was identified at both 3- and 6-month follow-up time points, with approximately 64% of subjects reporting satisfaction while approximately 77% noticed improvement. Previous retrospective studies have evaluated externally applied

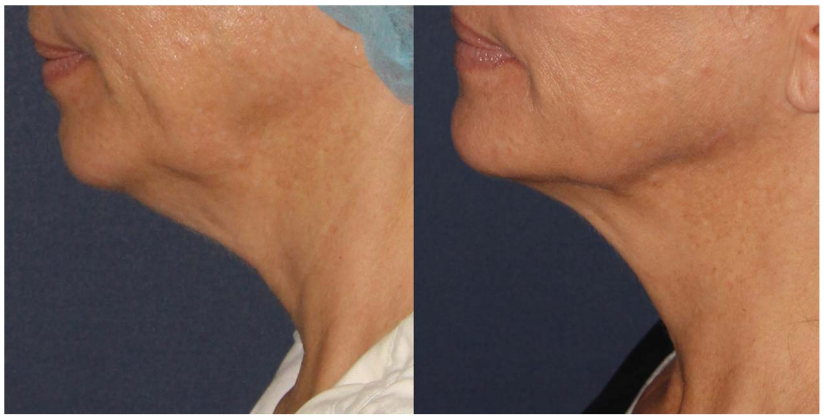

Figure 1. Before and 180 days after 1 subsurface monopolar radiofrequency treatment to the jawline and neck.

radiofrequency (Thermage CPT System; Solta Medical, Hayward, CA), in which 80% (n = 51) of subjects reported some degree of correction of skin laxity,[5] and microfocused ultrasound resulting in approximately 60% of subjects reporting satisfaction and 80% reporting improvement.[6] Each of these modalities can induce collagen contracture, neocollagenesis, and skin tightening, but further prospective trials are required to determine comparable efficacy. Furthermore, the incongruences between patient-reported satisfaction and improvement are potentially because of variable patient expectation, as this procedure is aimed at treating skin laxity over other characteristics, such as volume loss and static wrinkles.

Adverse events were mild and transient. Additionally, these data indicate a possible energy threshold necessary for yielding optimal results and increased subject satisfaction. Increasing total treatment time can contribute to increased total energy delivery, as analysis demonstrated that treatments longer than 25 minutes in duration yielded higher satisfaction rates. Combining these 2 analysis points, a possible set of optimal treatment parameters for treatments to the face, neck, and/or jawline is a minimum of 25 minutes, with a minimum set probe temperature of 60°C. Continued studies are warranted to determine optimal parameters for treatments to other areas, and if manipulating, either treatment time or set probe temperature has a greater effect on the

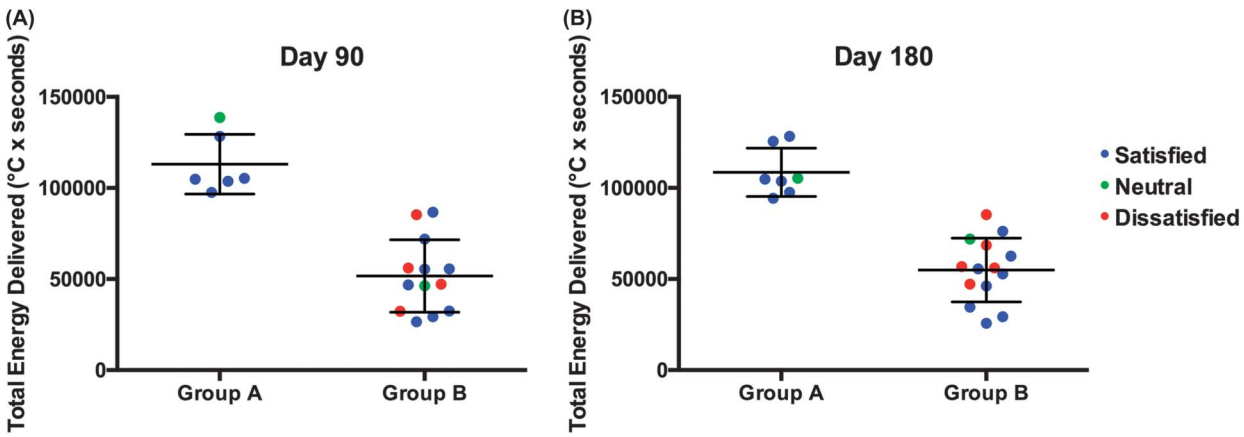

Figure 2. Total energy delivered per treatment correlated with subject satisfaction. Calculated as total treatment time in seconds × average subsurface target temperature. (A) At 3 months posttreatment, treatments >90,000 (°C × seconds) (Group 1), N = 6 yielded an 83.3% satisfaction rate versus <90,000 (°C × seconds) (Group 2), N = 13 yielded a 61.5% satisfaction rate. (B) At 6 months posttreatment, treatments >90,000 (°C × seconds) (Group 1), N = 7 yielded an 85.7% satisfaction rate versus <90,000 (°C × seconds) (Group 2), N = 14 yielded a 57.1% satisfaction rate.

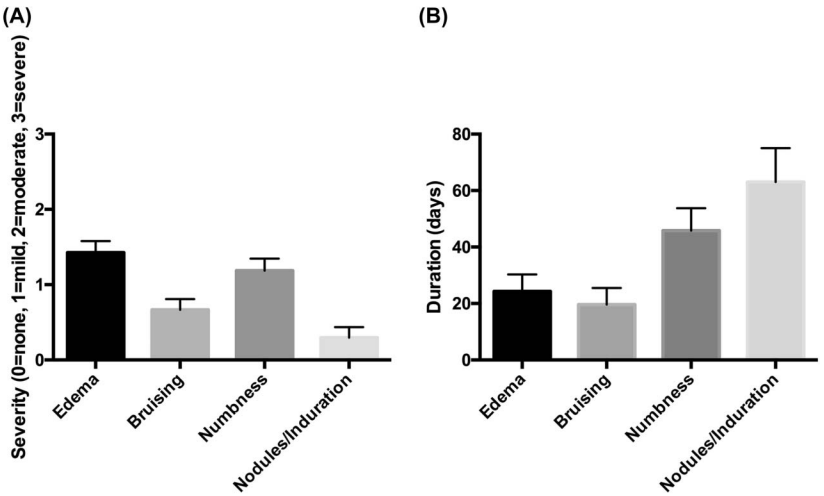

Figure 3. Subject-reported adverse events. (A) On average, subjects only experienced mild-to-moderate adverse effects from treatment. (B) Adverse effects varied in duration, with nodules/induration lasting the longest (although of the least severity).

outcome. Subject feedback indicates limited adverse effects from SMRF treatments.

Two previous studies demonstrated the safety of SMRF for minimally invasive skin tightening.[7,8] Mild but significant improvements in skin laxity were reported, complimenting the satisfaction ratings presented in the current study.

The limitations of this study were related to its retrospective design, which resulted in the potential for memory bias and nonuniformity of treatment parameters. However, despite these limitations, these data provide valuable insights about this new therapeutic modality and may serve as the basis for directing future prospective trials.

Conclusion

This retrospective evaluation demonstrates the safety and efficacy of the SMRF technology in reducing skin laxity. Additionally, data from subjects who received treatment to the face, jawline, and/or neck regions suggest a minimum energy threshold per treatment area to achieve optimal subject satisfaction.

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