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A Prospective Trial: Handsfree Thermoregulated Bipolar Radiofrequency for Face and Neck Contouring

Erez Dayan, MD*
Anne Chapas, MD†
Joseph Marte, MD‡
Christopher Chia, MD‡
Spero Theodorou, MD‡

Background: The use of radiofrequency in aesthetic surgery has evolved significantly since it was first introduced in the early 2000s. Nonexcisional correction of the lower one-third of the face and neck has long been a challenging problem. The purpose of this prospective study was to assess the safety and efficacy of the first handsfree thermoregulated bipolar radiofrequency device for face and neck contouring.

Methods: This prospective multicenter (New York, Nevada) IRB-approved study evaluated healthy candidates who desired noninvasive correction of their lower face and neck laxity. The primary objective of this study was to evaluate safety and soft tissue remodeling pretreatment and at 1-, 3-, and 6-months post last treatment. Assessment was made using blinded evaluators, 3D photographic analysis (Quantificare, France), and volumetric measurements. Investigator and subject assessments were obtained using a 0-4 point Likert scale.

Results: A total of 34 patients completed both the cheek and chin applicator treatment series. Average age of patients was 38 (STD 3.4), BMI 27 (STD 2.2), average Baker Face & Neck classification 2.6 (STD 1.1), and average Fitzpatrick type 2.4 (STD 1.2). Mean treatment time was 41 min (STD 3.5) with a temperature of 42°C–43°C. Patient discomfort data were statistically very low based on *t*-test analysis. Satisfaction metrics measured at 1- and 3-month follow-up demonstrated a significant change in subject skin appearance, subject overall satisfaction, and investigator improvement perception. More patients were satisfied at the 3-month follow-up compared with the 1-month follow-up for all three measures. Volumetric data demonstrated an average change of −3.2 cm^3 (STD ±1.2 cm^3) per side for the cheek applicator and −4.1 (STD ±2.3) for the submental applicator. Of note there were cases where volume increases were noted that were believed to be related to soft tissue contraction.

Conclusions: This is the first prospective study to evaluate a handsfree thermoregulated bipolar radiofrequency device for face and neck contouring. This device demonstrates a significant advance in the control and delivery of radiofrequency for aesthetic purposes. With a favorable safety and comfort profile, this device is able to concentrate thermal energy consistently at a depth that allows for fibroseptal network tightening to improve lower third of face and submental soft tissue contraction. *(Plast Reconstr Surg Glob Open 2022;10:e4194; doi: 10.1097/GOX.0000000000004194; Published online 28 March 2022.)*

INTRODUCTION

The multifactorial etiology of facial aging and increasing demand for noninvasive and minimally invasive treatments have led to development of various modalities to address the components of the aging face.[1,2] As a result, industry for noninvasive and minimally invasive facial aesthetics continues to grow at an all-time high, with a current estimated market size of 19 billion USD in 2019. This includes treatments such as skin resurfacing (chemical peels, lasers, microneedling), energy-based devices (radiofrequency, ultrasound), suspension methods (threads),

*From the *Avance Plastic Surgery Institute, Reno/Tahoe, Nev.; †New York, N.Y.; and ‡bodySCULPT, Union Derm, New York, N.Y.*

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and volumizing methods (biologic and nonbiologic fillers).[3–13]

Our current method of aesthetic facial analysis systematically divides the face into horizontal thirds to identify and treat the predictable changes that occur per facial region. Among the most challenging areas to correct has been the lower face and neck. As opposed to the upper thirds of the face where volume deflation is a primary target for correction, the lower third of the face and neck requires correction of soft tissue laxity and descent (jowls and submental region), which has long been an elusive goal for the noninvasive or minimally invasive technologies.[14,15] In fact, even traditional excisional surgery (ie, facelift/necklift) is often challenging due to the tendency for recurrent laxity in these areas postoperatively.[16]

Numerous energy-based technologies have developed to address aesthetic concerns in the lower third of the face and neck, including laser, cryolypolysis, high-intensity focused ultrasound (HIFU), and radiofrequency (RF).[17–24] Over the past 20 years, RF has emerged as a safe and efficacious method to produce soft tissue contraction through thermal energy.[3,5,14,15,25–29] Today's RF devices allow for closely regulated delivery of electrical currents to achieve precise thermal effect in accordance with Ohm's law (energy = current^2 × impedance × time).[14,15] As RF is applied to different tissue types (ie, muscle, fat, skin), the inherent resistance or impedance leads to generation of thermal energy. Tissues with higher impedance (ie, dermis, fibroseptal networks, fat) generate more heat than tissues with lower impedance (muscle). Once target temperatures are acquired and maintained, RF has been shown to achieve soft tissue remodeling by two mechanisms: (1) cleavage of hydrogen bonds in the collagen triple helix structure, leading to immediate fibril denaturation and contraction/thickening of collagen, and (2) a wound healing cascade is triggered to induce neocollagenesis, angiogenesis, and elastogenesis, leading to long-term soft tissue contraction.[14,15] Clinical and animal studies have both shown that after 10 minutes of exposure to temperatures of 39°C–43°C, the amount of collagen increases from approximately 15% to 20% after a 3-month follow-up period.[30] Other studies have similarly shown through electron microscopy that collagen fibrils had a greater diameter after RF treatment.[31] In addition, Northern blot analysis has confirmed microinflammatory stimulation of fibroblasts and other substances that enhance dermal structure.[31] RF has not only been proved effective for skin tightening, but it has also been shown to trigger apoptosis in adipocytes.[32]

Today's aesthetic RF devices have advanced significantly over the first FDA approved RF device for facial wrinkle reduction in 2004 (ThermaCool, Thermage, Inc., Hayward, Calif.).[33] The major advance has not only been in the RF energy delivery method itself but in depth, control, and consistency of energy delivery. The balance between temperatures that trigger a nonablative wound healing response to remodel collagen as opposed to ablating collagen is relatively narrow.[14,15,29] The depth and degree of energy transferred depends on several factors, including the size and configuration of the treatment device, energy settings, time of treatment, and inherent conductive properties of the tissue.

Takeaways

Question: How does radiofrequency produce soft tissue contraction?

Findings: This prospective study demonstrated safety and efficacy of a handsfree noninvasive bipolar radiofrequency device in soft tissue contraction of the lower face and submental area. Consistent with previous studies, acquisition of temperatures (42°C–43°C) for the duration of the treatments produce soft tissue contraction by stimulation of neocollagenesis and elastin reorganization.

Meaning: Noninvasive bipolar radiofrequency can achieve safe and effective soft tissue contraction of the lower one-third of the face and neck.

The purpose of this study was to prospectively evaluate the first "hands free" thermoregulated noninvasive bipolar radiofrequency technology (EVOKE; InMode, Lake Forest, Calif.) specifically intended to target lower one-third of the face soft tissue laxity. (Fig. 1) To our knowledge, this is the first device designed to provide soft tissue contraction through noninvasive bipolar radiofrequency in an automated delivery process.

METHODS

This multicenter prospective study was IRB approved and complied with the Declaration of Helsinki. Subjects were healthy adults between the ages of 36–75 years with visible signs of facial aging, seeking skin tightening treatments. Three centers conducted this study (New York, N.Y. & Reno/Tahoe, Nev.) with the goal of enrolling 10–20 subjects per site. Exclusion criteria included any type of electrical implant (pacemaker, defibrillator), permanent implant in the treatment areas (metal plates, silicone implants, screws), current or history of skin cancer, immune compromise, history of skin disorders (keloids, wound healing conditions), 6 months post any skin treatment (filler, microneedling, laser), or use of isotretinoin.

The primary objective of this study was to evaluate soft tissue remodeling pretreatment and at 1-, 3-, and 6-months post last treatment. This was assessed using blinded evaluators (objective plastic surgeons not familiar with the device/study), 3D photographic analysis (Quantificare, France), and volumetric measurements. Investigator and subject assessments were obtained using a 0-4 point Likert scale at the 1-, 3-, and 6-month follow-up visits. Baker Face & Neck classification was also utilized to classify patients (Fig 2). Adverse events and treatment discomfort were closely monitored after each treatment. The treatment discomfort metrics were chin discomfort and cheek discomfort at each of the three treatments. The six subject satisfaction metrics were measured on an 11-point scale, where 0 = most comfortable, and 10 = most uncomfortable. The follow-up visit satisfaction metrics were (1) subject skin appearance evaluation, (2) subject

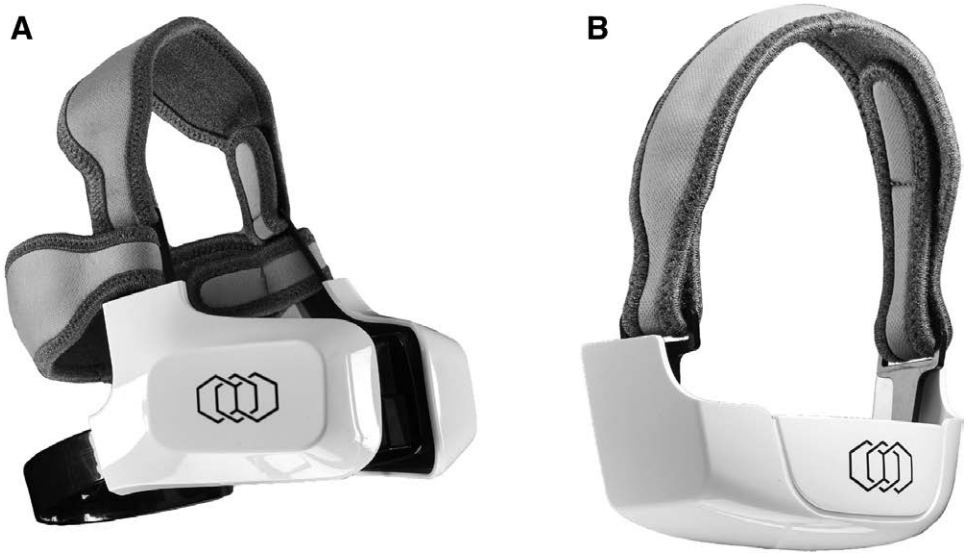

Fig 1. Evoke Bipolar noninvasive radiofrequency device. A, Cheek applicator. B, Chin applicator.

overall satisfaction, and (3) investigator improvement rating. Because follow-up visits occurred twice (1-month follow-up and 3-month follow-up), there were six satisfaction metrics in all. These six metrics were measured along the same scale, where 0 = no change, and 4 = significantly marked improvement.

RESULTS

This study was composed of 40 patients (n = 40) who completed all treatments, of which 34 participants completed at least one follow-up visit. All subjects sought noninvasive treatment for facial aging and were in satisfactory health. Patient demographics included an average age of 38 (STD 3.4), BMI 27 (STD 2.2), average Baker Face & Neck classification of 2.6 (STD 1.1), and average Fitzpatrick type 2.4 (STD 1.2) All patients were treated with both the cheek and chin applicators. Mean treatment parameters include temperature of 42°C–43°C for a mean duration of 41 min (STD 3.5).

Given the nature of this study, the treatment results were reported both descriptively and inferentially. Starting first with the descriptive results, the vast majority of respondents reported no or very low chin or cheek discomfort as a result of the procedure. In general, the discomfort rate improved at each successive treatment. The discomfort was rated on a 1–10 point Likert scale, with 0 being no discomfort and 10 being maximal discomfort (Table 1).

Next, these values were tested inferentially, utilizing a one-sample *t* test against a hypothesized mean. Note that given the above distributions are skewed toward zero, the Wilcoxon signed-rank test was conducted in addition. The conclusions were the same, given the means and medians were closely aligned. Thus, only the one-sample *t* test results will be reported. First, a cutoff/test value of 5 was utilized, as 5 represented the middle value of the scale. For all three time points for chin and cheek measures, the observed means were statistically significantly different. That is, participants evaluated their chin and cheek discomfort well below the middle of the scale (moderate discomfort), indicating low discomfort with the procedures. Decreasing the test value to be 2 (the first quartile cutoff value, a low discomfort level) largely tells the same story, though not all comparisons are statistically different from one another. That is, treatment

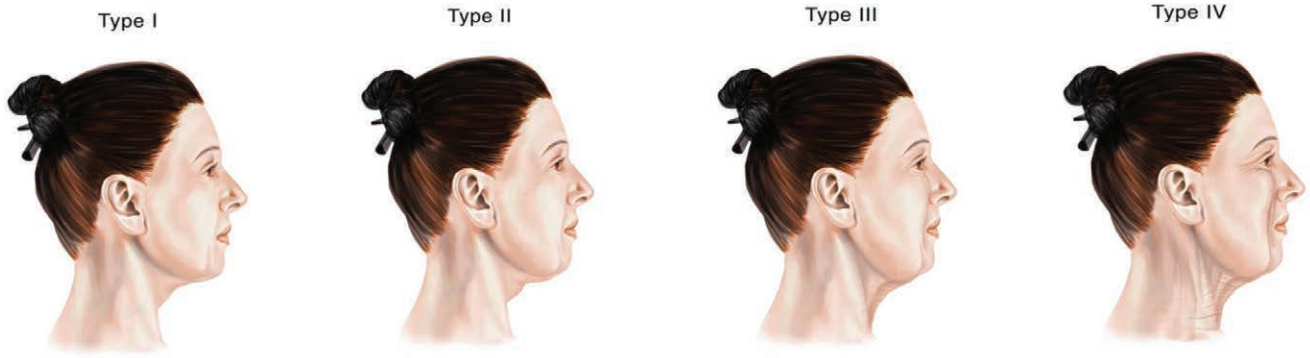

Fig. 2. Baker face and neck classification.

Table 1. Chin and Cheek Discomfort Metrics at Each Treatment Interval

	Chin			Cheek		
Discomfort	Treatment 1	Treatment 2	Treatment 3	Treatment 1	Treatment 2	Treatment 3
0	52.5%	59.5%	65.7%	53.8%	54.1%	70.6%
1	7.5%	8.1%	8.6%	15.4%	16.2%	14.7%
2	17.5%	10.8%	11.4%	7.7%	10.8%	2.9%
3	7.5%	8.1%	0.0%	7.7%	8.1%	5.9%
4	2.5%	2.7%	2.9%	5.1%	5.4%	2.9%
5	7.5%	5.4%	5.7%	5.1%	5.4%	2.9%
6	2.5%	2.7%	0.0%	0.0%	0.0%	0.0%
7	2.5%	2.7%	5.7%	2.6%	0.0%	0.0%
8	0.0%	0.0%	0.0%	2.6%	0.0%	0.0%

1 of the chin discomfort evaluation did not differ from a hypothesized cutoff value of 2 (though it was near the 0.05 *P*-value threshold, indicating marginal significance); thus, the discomfort caused by this treatment can be considered low. The time 2 and 3 chin discomfort evaluations were below a *P*-value of 0.05, indicating the discomfort levels were considered very low. The other three cheek discomfort evaluations were nearly identical. The mean difference for the first evaluation was marginally different from the hypothesized value of 2, indicating the discomfort caused by this procedure was considered low. For the second and third treatments, the mean differences were significantly lower than 2, indicating the discomfort in these visits was considered very low. The following table demonstrates the means, *t* scores, degrees of freedom, and *P*-values of the size tests utilizing the cutoff values of 2 and 5 (Table 2).

Post-treatment Satisfaction and Evaluation Metrics

As previously mentioned, the satisfaction metrics, measured at 1-month follow-up and 3-month follow-up, were (1) subject skin appearance evaluation, (2) subject overall satisfaction, and (3) investigator improvement rating, all along the same scale. The majority of respondents/investigators identified some to significant change compared with no change; thus, the descriptive statistics are reported (Table 3), accordingly. That is, at 1-month, 3-month, and 6-month follow-up, subject skin appearance, subject overall satisfaction, and investigator improvement perception were in agreement; more people reported some to significant change compared with those who reported no change, by a large plurality. There is also anecdotal evidence to suggest more people were satisfied at the 3-month follow-up compared with the 1-month follow-up for all three measures.

One-sample *t*-tests against hypothesized means were conducted for the following nine comparisons. The one-sample *t*-test results were consistent with the descriptive statistics results. The hypothesized mean value used in this series of tests was 0, as 0 represented no change. Each of the nine tests was significant, indicating that for each metric, at all three time points, there was an observed improvement compared with the hypothesized baseline (no change). Another one-sample *t*-test was conducted using the hypothesized mean value of 0.5; all tests were also statistically significant, which indicates that all metrics were better compared with even a slight change. In other words, subjects at all time points and for all measurements reported larger improvements compared with minor improvement. The following table represents the one-sample *t*-test results for the hypothesized comparison value of 0.5 (Table 4).

The analysis of volumetric data obtained from our imaging software (Quantificare, France) provided valuable insights to soft tissue changes resulting from this treatment. The research grade camera used digitally generates volumetric changes (Fig. 3). The RF technology used in this study produced two effects seen on the volumetric imaging: (1) soft tissue contraction and (2) adipose remodeling. The average volume changes from the initial

Table 2. One-Sample *t*-test Statistics Results

Measure	*t*	df	*P*	Mean	Mean Difference
		Test value = 2			
T1 chin discomfort	**−1.816**	**39**	**0.08**	**1.44**	**−0.563**
T2 chin discomfort	−2.273	36	0.03	1.27	−0.73
T3 chin discomfort	−2.587	34	0.01	1.11	−0.886
T1 cheek discomfort	−1.919	38	0.06	1.37	−0.628
T2 cheek discomfort	−3.519	36	0.001	1.11	−0.892
T3 cheek discomfort	−6.181	33	<0.001	0.65	−1.353
Test value = 5					
T1 chin discomfort	−11.504	39	<0.001	1.44	−3.563
T2 chin discomfort	−11.617	36	<0.001	1.27	−3.73
T3 chin discomfort	−11.347	34	<0.001	1.11	−3.886
T1 cheek discomfort	−11.082	38	<0.001	1.37	−3.628
T2 cheek discomfort	−15.355	36	<0.001	1.11	−3.892
T3 cheek discomfort	−19.885	33	<0.001	0.65	−4.353

Table 3. Post-treatment Satisfaction and Evaluation Metrics

Measure	n	% No Change	% Some to Significant Change
1MFU sub skin appearance	33	33.3%	66.7%
3MFU sub skin appearance	26	19.2%	80.8%
6MFU sub skin appearance	14	21.4%	78.6%
1MFU sub overall sat	33	24.2%	75.8%
3MFU sub overall sat	26	15.4%	84.6%
6MFU sub overall sat	15	20.0%	80.0%
1MFU invest improve	31	35.5%	64.5%
3MFU invest improve	27	33.3%	66.7%
6MFU invest improve	14	35.7%	64.3%

treatment to 6-month follow-up were −3.2 cm^3 (STD ±1.2) per side for the cheek applicator and −4.1 (STD ±2.3) for the submental applicator. Interestingly, there were cases where volume increases were noted (Fig. 4). Although this could be due to weight gain, analysis of the images indicates that that contraction of the soft tissue envelope caused the imaging software to identify a volume increase rather than soft tissue contraction.

In all, there is significant evidence to suggest this noninvasive RF treatment is effective from treatment to treatment (by way of the chin and cheek discomfort measures) and 1-, 3-, and 6-month follow-up (by way of the subject skin appearance, subject overall satisfaction, and investigator improvement rate). The descriptive statistics results largely align with the results of the one-sample *t*-tests.

DISCUSSION

The noninvasive thermoregulated bipolar radiofrequency device evaluated in this study represents significant development in the delivery and control of RF energy. As opposed to prior RF devices, this is the first device to provide a handsfree treatment modality. This means that the device could be placed on the patient, pre-set to target temperatures, and activated, not requiring manual provider application. The device automatically reaches target temperature within 1–2 minutes and regulates electromagnetic current delivery to achieve the predetermined temperature settings consistently throughout the treatment. This feature eliminates user variability previously seen with other manual RF deliver methods, leading to inconsistent energy delivery and outcomes.[3,5,14,25]

Another unique feature is the use of deep bipolar RF energy, which reaches 4-mm depth and targets the lower one-third of the face and submental laxity through two separate components (cheek and submental). Each side of the cheek headpiece contains four applicators, and the submental headpiece has three applicators, with each applicator comprising three electrodes (Fig. 1). The bipolar RF travels directionally from the central electrode to outer electrodes to achieve a volumetric bulk heating at approximately a 4-mm depth, which impacts fibroseptal networks between the superficial musculoaponeurotic system and dermal layers. Intervening thermostats were engineered between the electrodes to be in contact with the skin and achieve real-time and responsive temperature monitoring (Fig. 5). As opposed to other RF devices, surface cooling is not necessary due to the tight thermal control, and depth of heat achieved with this device configuration. The purpose of this configuration was to maximally impact fibroseptal network contraction, which has been shown to be more effective than only subdermal heating. The deep heating effect further allows for a wider gradient of volumetric heat to be applied. The electrode size and coverage area also allows for bulk heating of the entire anatomic subunit. Rather than prior devices that claim a "lift" effect, it has become clear that RF does not induce "lift," but rather soft tissue contraction. Thus, a wider treatment area is required to achieve a clinically impactful effect.

Traditionally, noninvasive energy-based aesthetic devices have produced modest results due to the limited amount of energy that can be delivered safely at the dermal/subdermal level without causing ablative injury to the skin surface. Without precise temperature control, predecessor devices either were "underpowered" and caused a few complications with limited to no results, or conversely the devices were "overpowered" and led to unacceptable percentage of thermal injuries. Radiofrequency microneedling devices were a partial solution to this by bypassing the skin level and delivering deeper RF energy; however, most of these devices had energy concentrated between the needle tips, thus not volumetrically heating the soft tissue envelope.

Table 4. One-Sample *t*-test Statistics Results (Test Value = 0.5)

Measure	t	df	*P*	Mean	Mean Difference
1MFU skin appearance	3.04	32	0.01	1.06	0.56
1MFU overall sat	4.56	32	0.00	1.64	1.14
1MFU invest improvement	2.72	30	0.01	0.94	0.44
3MFU skin appearance	4.41	25	0.00	1.39	0.88
3MFU overall sat	4.64	25	0.00	1.77	1.27
3MFU invest improvement	2.99	26	0.01	1.07	0.57
6MFU skin appearance	2.96	13	0.01	1.29	0.79
6MFU overall sat	2.28	14	0.04	1.07	0.57
6MFU invest improvement	2.14	13	0.05	1.07	0.57

Fig 3. Volumetric image analysis (Quantificare, France).

Fig. 4. Increased volumetric assessment due to soft tissue contraction.

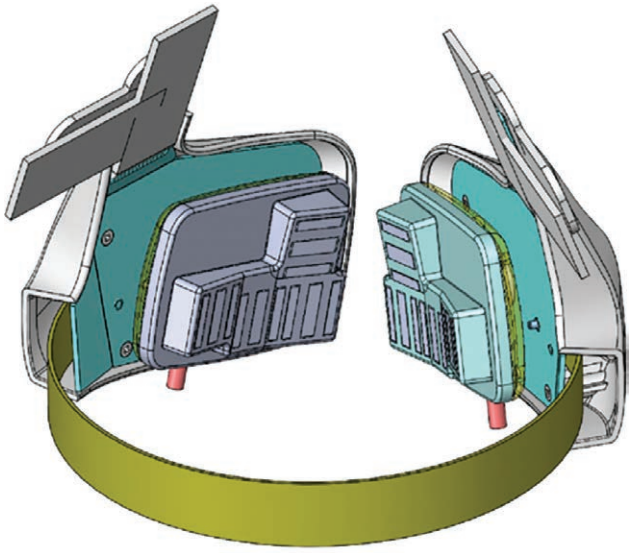

Fig. 5. Thermostats between electrodes.

The aesthetic application of radiofrequency energy delivery stimulates neocollagenesis functions through an Arrhenius time versus temperature relationship (Fig. 6). Studies suggest that for millisecond exposures, the shrinkage temperature is above 85°C, whereas for exposures for several seconds, the shrinkage temperature is in the range of 60°C–65°C.[31,34] For every 5°C decrease in temperature, a 10× increase in time is required to achieve a comparable collagen contraction.[31,34] Although the "ideal time" has been elusive, it has been well established that using lower temperatures (fluence) for a longer period of time is more effective at collagen stimulation, rather than using higher temperatures and shorter time.[14,15,29] Further, it has been postulated that lower temperatures may additionally stimulate fibroblasts to form collagen. Seo et al compared facial soft tissue laxity improvements with RF versus surgical facelift using blinded grading of photographs.[35] They demonstrated a 49% improvement in skin laxity relative to baseline for the surgical facelift compared with 16% for bipolar RF. Further the mean laxity improvement form a single bipolar RF treatment was

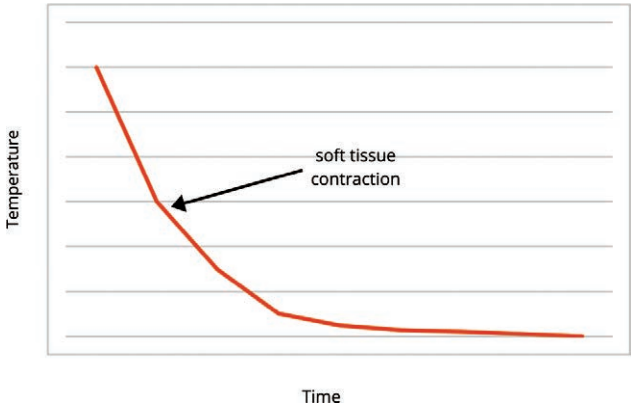

Fig. 6. Arrhenius time versus temperature relationship.

37% of the surgical facelift.[35] Peterson et al[36] also studied objective measurements of mechanical skin properties and demonstrated a statistically significant improvement (5%–12% decrease in Young's modulus and 10%–16% decrease in retraction time), as well as 1.42 grade improvement on the Fitzpatrick scale for wrinkles, and 0.66 on the Alexiades scale for skin laxity, increasing to 1.57 and 0.70 improvement at 6 months.[36] Patient satisfaction was noted to be "very high" for more than 90% of patients.[36] Multiple other studies have corroborated these findings by showing efficacy of nonablative multisource RF as a single modality for face/body contouring.[37–39] Similar to the findings of Mulholland and Hruza et al, this technology allows for thermal stimulation from an "inside-outside" method, directing the heat gradient from 4 mm of depth toward the dermis.[10] The patient comfort and 1-, 3-, and 6-month follow-up measurements utilized in this study (subject skin appearance, subject overall satisfaction, and investigator improvement rate) all are statistically consistent with this explanation. The 3D volumetric data obtained in this study demonstrate that the soft tissue contraction effect of the RF supercedes volume loss. One consideration that arises with the use of this technology is the possibility that RF will impact adipocyte viability and lead to undesireable volume loss. This is of concern, as modern aesthetics aims to revolumize facial fat compartments that decrease with age. However, our volumetric data demonstrate that some volume loss in the lower one-third of the face is aesthetically desirable, especially when combined with a more significant soft tissue contraction (Figs. 7, 8). (**See figure, Supplemental Digital Content 1**, which displays (A) before and (B) after results EVOKE (InMode, Lake Forest, Calif.). **http://links.lww.com/PRSGO/B967**.)

There were a number of limitations to this study. Although this study was appropriately powered for statistical analysis, there were only 34 patients who completed the entire study follow-up period. We would have preferred a larger sample size to obtain more information on the efficacy of this treatment on various age brackets to better ascertain expectations for treatment and who is the ideal candidate. The volumetric data obtained by the 3D camera system used did not account for soft tissue laxity, and data may have been confounded by changes in soft tissue laxity that may skew volume readings. It also would have been preferable to exclude patients who had any procedure on their faces/neck in the past as some patients may have had lingering effects (ie, filler) that would have confounded the effect of RF alone. Also, there are more objective scales that are currently being applied to future prospective studies, including the Fitzpatrick wrinkle scale and Alexiades skin laxity scale as well as surface area measurements.

This is the first prospective study to evaluate a handsfree thermoregulated bipolar radiofrequency device for face and neck contouring. This device demonstrates a significant advance in the control and delivery of radiofrequency for aesthetic purposes. With a favorable safety and comfort profile, this device is able to concentrate thermal energy consistently at a depth that allows for fibroseptal

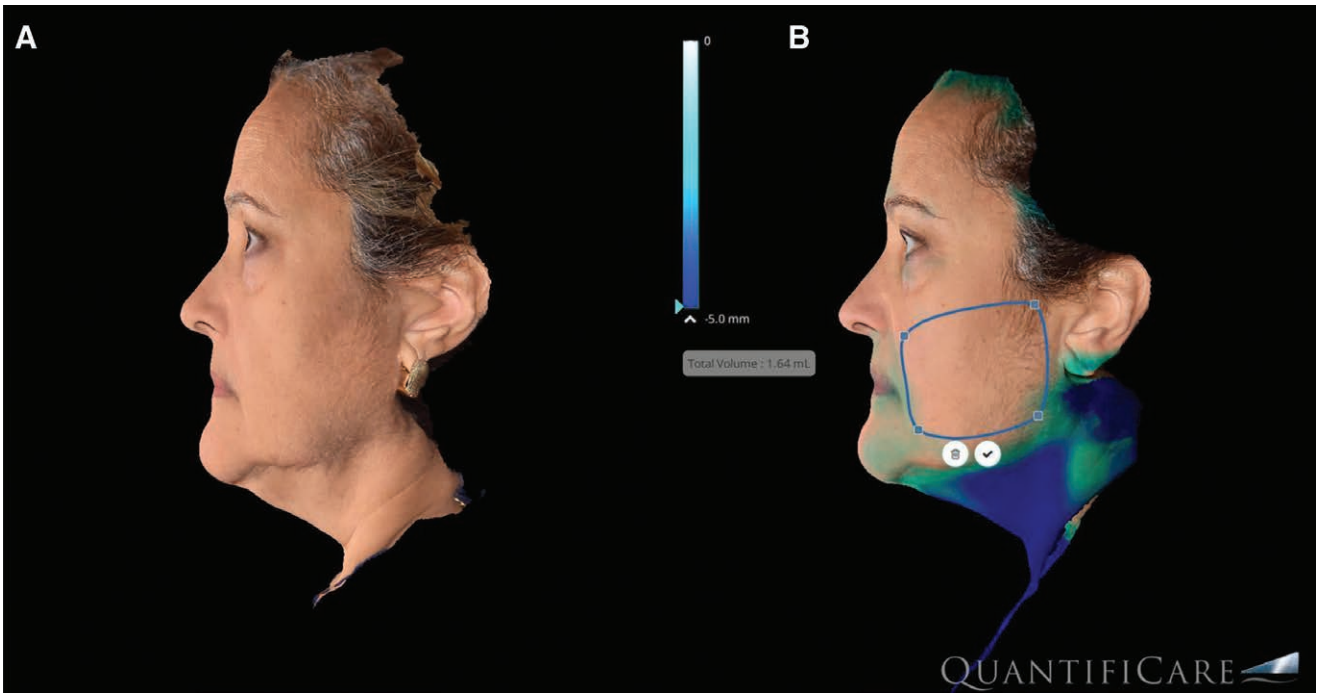

Fig. 7. A 52-year-old female patient before (A) and after (B) Evoke treatment.

network tightening to improve lower third of face and submental soft tissue contraction.

Erez Dayan, MD
Avance Plastic Surgery Institute
Reno/Tahoe, NV
E-mail: drdayan@avanceinstitute.com

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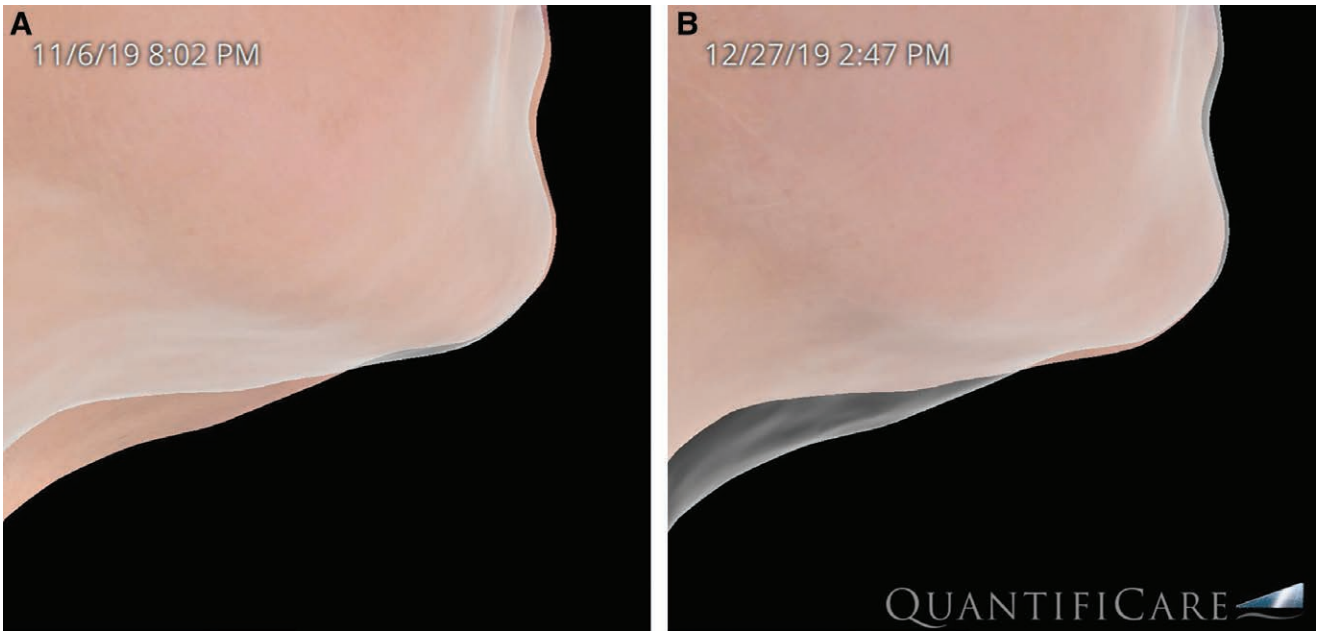

Fig. 8. A 54-year-old female patient 7 weeks before (A) and after (B) EVOKE treatment.

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