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CASE REPORT

A novel non-invasive radiofrequency dermal heating device for skin tightening of the face and neck

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Abstract

Background: Loose, lax skin is a common cosmetic complaint. Previous non-invasive skin tightening devices had modest efficacy and were associated with pain or downtime. New technologies may allow for effective skin tightening with a series of radiofrequency (RF) treatments with no downtime. *Objective:* To evaluate the efficacy and safety of a novel bipolar RF device for skin tightening. *Methods:* Fifteen consecutive female patients were enrolled in the case series; 14 completed the study and were included in the analysis. The device under investigation is a novel, bipolar RF device allowing for achievement and maintenance of optimal dermal temperatures to stimulate collagen remodeling and skin tightening. Patients underwent a series of 4–6 weekly treatments. Three blinded, experienced cosmetic physicians evaluated paired pre-treatment and post-treatment photographs and determined the associated improvement, if any. *Results:* All patients (14/14) were determined to have a clinical improvement, as the pre-treatment and post-treatment photographs were correctly identified by the evaluators. It was observed that 21% (3/14) of patients had significant improvement, 50% (7/14) had moderate improvement, and 29% (4/14) had mild improvement. No pain, side effects, or adverse events were observed. *Conclusions:* This novel bipolar RF device represents a safe, effective treatment option for non-invasive skin tightening.

Key Words: *non-invasive, radiofrequency, rejuvenation, skin tightening*

Introduction

As we age, our collagen and elastic tissue degrade, resulting in excess, loose skin; this is often one of the first signs of facial aging. As a result, surgical rhytidectomy (facelifts) remains a common surgical procedure to help reverse this aging process, with 133,320 facelift procedures performed in 2013, the most recent year for which data is available from the American Society of Plastic Surgeons (1). While facelifts remain an extremely effective method to reduce static rhytids, there has been a dramatic paradigm shift toward non-surgical skin tightening and rejuvenation techniques, as patients seek to achieve skin tightening with no or minimal downtime procedures. In 2013, 293,388 non-surgical skin tightening procedures and 456,613 photorejuvenation procedures were performed, a much higher volume than traditional surgical facelifts, according to the American Society for Aesthetic Plastic Surgery (2). While many technologies including infrared lasers, intense pulsed light devices, and resurfacing lasers have been utilized to heat the deep dermis, thereby resulting in skin tightening, the results have typically been modest (3–5). Recently, intense focused ultrasound has been proposed as a potential option for skin tightening; however, these treatments are associated with pain and downtime (6). An ideal skin tightening treatment would be efficacious, pain free, require no anesthesia, and result in no downtime.

Radiofrequency (RF) technology represents a potentially promising option for non-invasive skin tightening to achieve these ideals. RF devices utilize electrical conductance, in the form of rapidly alternating electrical current (various frequencies can be utilized, but they are typically greater than 1,000,000 cycles per second), to cause oscillation of cellular

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structures that are in the electrical path, thereby increasing intermolecular motion. As the current flows alternatively, molecular collisions increase, thereby creating thermal energy (heat). Thus, RF technology utilizes the impedance (resistance) of tissue to generate heat rather than directly transferring heat. Historically, the majority of RF devices were monopolar devices; however, these initial devices had relatively limited efficacy in skin tightening and could be associated with pain, burns, or other adverse effects (7,8). More recently, bipolar RF devices, incorporating both positive and negative electrodes, have been developed with potentially greater efficacy and an improved safety profile due to the creation of a closed electrical circuit. The depth to which the current penetrates is a function of the distance between the positive and negative electrodes; greater distance between the bipolar terminals results in greater depth of energy penetration. The controlled heat exposure from bipolar RF devices can be directed to the dermis of the tissue, causing controlled dermal heating of collagen, while sparing the epidermis. As the dermis is heated, the triple helical shape of collagen is broken due to disruption of the intramolecular heat-labile bonds connecting the helices, while the heat-stable intermolecular bonds are unaffected. These effects allow the triple helix to unravel and shorten, resulting in tighter, more compact collagen (9). Ultimately, dermal heating results in collagen stimulation and neocollagenesis (10).

The heating of collagen can be modeled by the principles of the Arrhenius equation, indicating that the reaction rate of heating collagen is dependent both on time and temperature (11,12). If high dermal temperatures are achieved, low exposure times are necessary. At a temperature of 85°C, an exposure time of ~1 ms is enough to induce structural changes to collagen (13). Historically, static (or "Stamping") RF devices utilized relatively higher peak temperatures with low exposure times; however, high peak temperatures also increase the risk of burns and other adverse events. Alternatively, according to the Arrhenius equation, lower peak temperatures could be utilized to reduce the risk of side effects, but this would require longer exposure periods in order to effectively remodel collagen. As an example, at a temperature of 43°C, an exposure time ranging from ~90 s to 5 min is necessary to induce collagen remodeling. Recently, novel dynamic (or "Moving") RF devices have been developed, which utilize lower peak temperatures with longer exposure times; these devices require that the handpiece is moved across the skin surface during the treatment to sustain the dermal matrix at an elevated temperature. Historically, RF devices had difficulty in uniformly achieving and maintaining these constant temperatures for several minutes to effectively remodel collagen, thereby limiting the effectiveness of these dynamic RF devices (14). In this case series, we utilize a novel RF device capable of achieving and uniformly maintaining dermal temperatures to effectively remodel collagen and improve the signs of aging.

Study methods

Patients

Fifteen consecutive female patients who were interested in undergoing RF skin tightening agreed to participate in this case series. The mean age of the patients was 62.1 (range: 47–76) years, and the patients had skin type I–III.

Exclusion criteria for the case series included history of abnormal scarring or skin healing, active systemic or local infections, botulinum toxin administration within the previous 3 months, soft-tissue augmentation within the previous 6 months, ablative or non-ablative laser rejuvenation procedures within the previous 6 months, and any other dermatologic procedures during the treatment period.

Equipment

Forma (InMode Inc, Richmond Hill, ON, Canada, North America) is an FDA-approved, bipolar, non-invasive RF device that generates controlled dermal heating. The device incorporates multiple novel technologies to allow for prolonged, controlled dermal heating while limiting the potential for side effects. The device handpiece incorporates two central rows of 7 smooth RF-emitting positive electrodes (14 polar) with current flowing from the positive electrodes to the two negative side electrode bars (Figure 1). The RF current travels to a maximum depth of half the distance between the electrodes and is thus confined to the dermis, creating a uniform dermal heating pattern (Figure 2).

The device also allows the treating physician to determine and set the optimal dermal temperatures (in Celsius) to be maintained throughout the treatment, as well as the energy delivered via the handpiece (in millijoules). In order to achieve and maintain

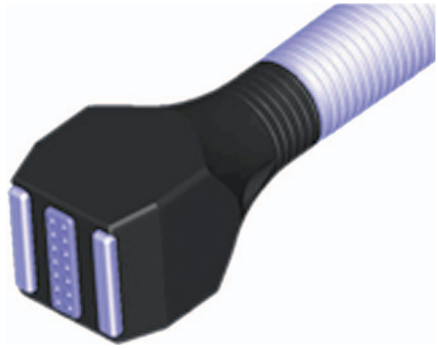

Figure 1. RF handpiece with two central rows of 7 smooth RF-emitting positive electrodes (14 polar) with current flowing from the positive electrodes to the two negative side electrodes.

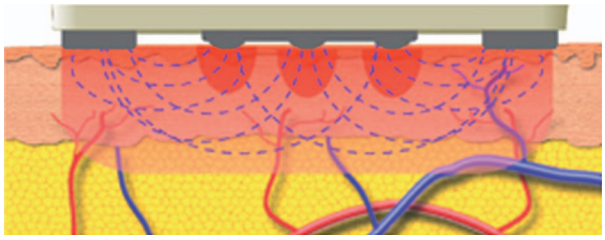

Figure 2. Representation of alternating current flowing between the positive (central) electrodes and negative (side) return plates. Note the multiple layering of different levels of RF current based on the distance between the plates, resulting in effective heating of the entire dermis.

this temperature, the device handpiece incorporates several sensors, including high and low impedance sensors, a contact sensor, and an epidermal thermal sensor. The device measures skin temperature, impedance, and epidermal contact 10 times per second allowing for real-time feedback. When the treatment area reaches the predetermined temperature, or if the tissue impedance drops quickly or contact is broken, the device immediately, automatically, and temporarily terminates the delivery of RF energy to this area. Once the temperature of this treatment area drops to 0.1°C below the set target temperature, or as the physician moves the treatment applicator over a new area, which has not yet reached the predetermined temperature, the device automatically reactivates the RF energy. This real-time immediate feedback allows for the physician to achieve, control, and extend the thermal treatment while limiting the potential for adverse effects. As a result, the physician is able to safely, comfortably, and effectively achieve uniform heating of large treatment areas (Figure 3), while minimizing pain and the potential for burns or other adverse effects.

Experimental procedure

Four treatment areas were identified for patients: [1] left cheek, nasolabial fold, and lower eyelid, [2] right cheek, nasolabial fold, and lower eyelid, [3] left jowl, neck, and submental area, and [4] right jowl, neck, and submental area. The treatment areas were cleansed with alcohol prior to the treatment. No anesthesia, including topical anesthesia, was utilized during this case series.

Ultrasound gel was applied to all treatment areas. The handpiece was then gently applied to the treatment area to create constant, uniform coupling. As a safety feature, if this coupling was broken during the treatment, the device withheld RF energy until the coupling was reestablished. The treatment parameters were set as follows: treatment target temperature of 43.0°C and energy of 60 mJ. The probe was guided over each treatment area in small circles to uniformly heat the area. Each treatment area was heated in this manner to a temperature of 43.0°C, and maintained at that temperature for 5 min. The patients underwent a series of 4–6 weekly treatments with these settings. Any subjective and objective side effects of treatments were monitored by the treating physician (AAN).

Clinical photographs of the face and neck were taken using a digital camera before treatment and at approximately 2 weeks after the final treatment. Frontal, 45°, and 90° still digital photographs of the face and neck were obtained. Baseline photographs were displayed in a computer monitor for the photographer to match the positioning of the patient as closely as possible when taking follow-up photographs. All treatments were performed under the direction of a single study author (AAN) and performed in a single outpatient facility.

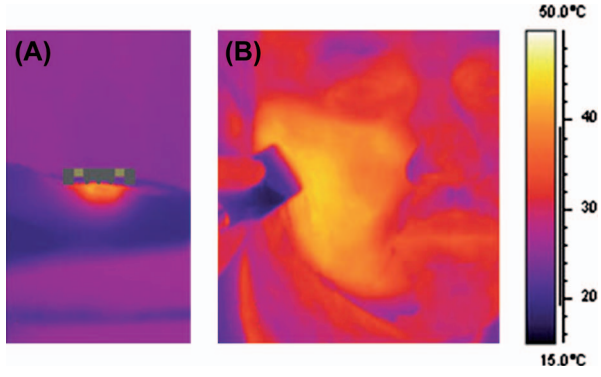

Figure 3. In vivo thermal view showing the initial application of Forma handpiece (A) and following treatment, a uniform heat distribution at 43°C across an entire right cheek (B).

Assessment techniques

Three blinded, experienced laser dermatologists evaluated each paired pre-treatment and post-treatment series of photographs of the subjects in a randomized fashion (pre-treatment and post-treatment photographs not identified as such) to determine whether discernible clinical improvement was noted. All available frontal, 45°, and 90° still digital photographs were shown to the evaluators when performing this assessment. If a particular masked reviewer detected a change, the reviewer was asked to identify the pre-treatment and post-treatment images. If the pre-treatment and post-treatment images were correctly identified, then the assessment from the reviewer was considered to be a clinical improvement; if the reviewer incorrectly identified the pre-treatment and post-treatment images, the assessment from the reviewer was considered to be a clinical worsening. If the masked reviewer could not distinguish the pre-treatment and post-treatment images, then the assessment from the reviewer was considered to be no change. Once each of the reviewers had separately examined the sets of photographs, the results were compiled and the majority opinion was considered

definitive; if two or more reviewers noted improvement, the patient's condition was said to have improved, and if two or more noted worsening, the patient's condition was said to have worsened.

After this initial assessment of the photographs, the same three clinicians reevaluated the series of photographs that were determined to represent clinical improvements. The reviewers were then asked to score the degree of skin laxity improvement according to the following categories: mild improvement (improvement of superficial laxity), moderate improvement (focal improvement of structural laxity with or without improvement of superficial laxity), and significant improvement (overall improvement of structural laxity with or without improvement of superficial laxity).

None of the evaluators were involved in the treatment of the patients; one reviewer is listed as an author of this paper (GPL), while the other two evaluators were unrelated to the study. A similar protocol has recently been used to assess and validate intense focused ultrasound technologies for facial skin tightening (15,16).

Results

Fourteen of the fifteen patients completed all treatments and follow-up visits, and were included in the analysis. One patient was excluded from the study, as she required an unrelated dermatologic diagnostic procedure (shave biopsy) in a treatment area during the study period.

Based on the primary endpoint for efficacy of skin tightening, all of the subjects were judged to have a clinical improvement. 12 of the 14 sets of patient photographs (85.7%) were properly identified as pre-treatment and post-treatment images by all three evaluators and therefore determined to have achieved clinical improvement. Two of the fourteen sets of patient photographs (14.3%) were properly identified as pre-treatment and post-treatment images by 2 of the 3 evaluators; these patients were also determined to have achieved clinical improvement, as outlined in the primary endpoint definition.

Three of the fourteen patients (21%) were assessed to have a significant improvement by the physician evaluators (Figure 4). Seven of the fourteen patients (50%) were assessed to have a moderate improvement (Figure 5), while the remaining 4 of 14 patients (29%) were assessed to have a mild improvement.

All subjects developed transient mild erythema and edema immediately following the treatment. Patients reported a warm sensation throughout the treatment, but none of the patients reported pain requiring termination or shortening of any of the treatments. None of the patients reported post-procedure pain, and no cases of scarring or dyspigmentation were noted. No other adverse events were observed.

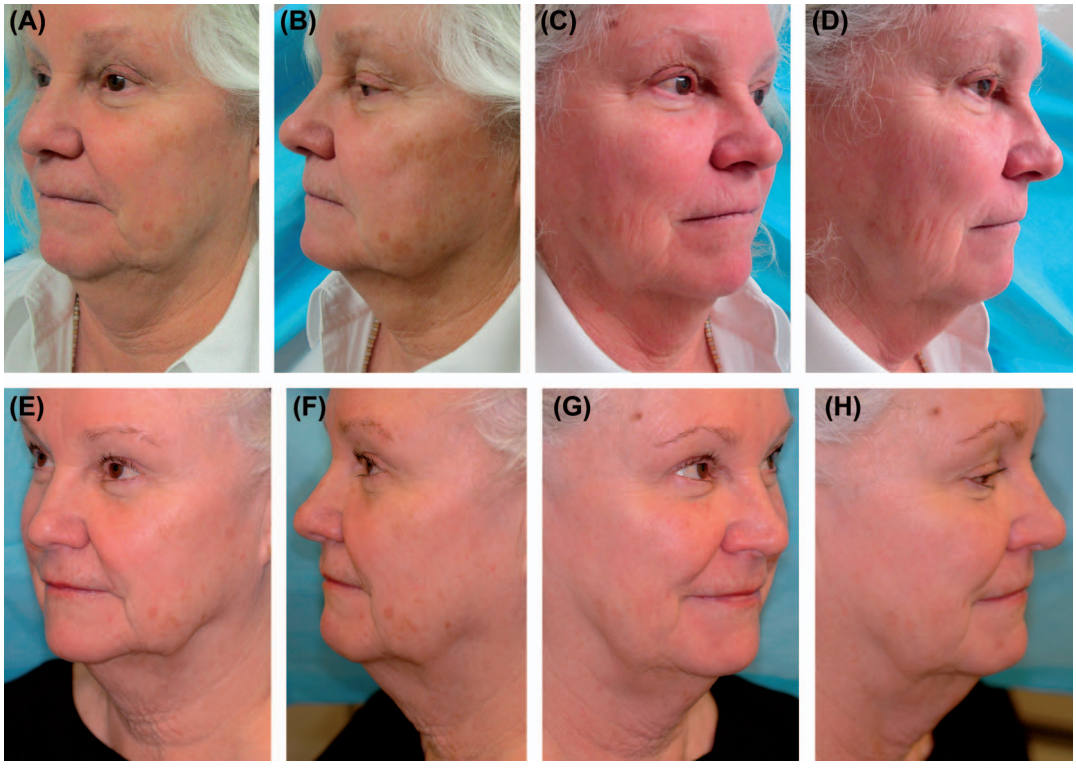

Figure 4. 65-year-old female with significant improvement in skin tone and texture following a series of 4 non-ablative RF skin-tightening treatments (Figure 4A–D are taken before treatment, and Figure 4E–H are taken after treatment).

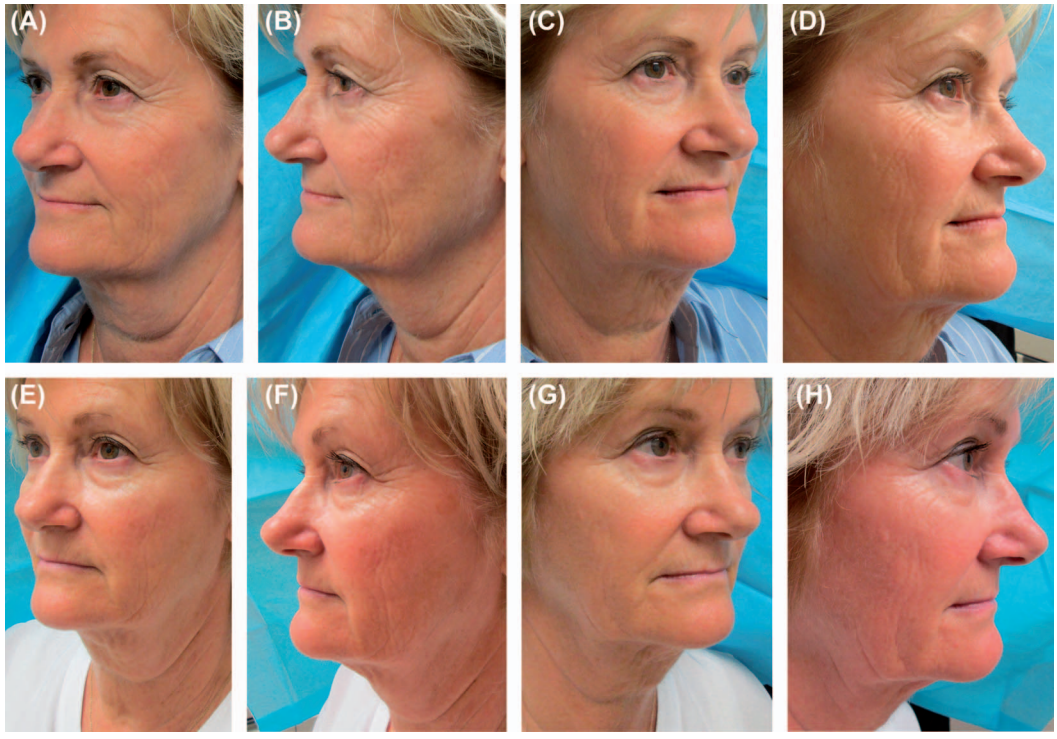

Figure 5. 68-year-old female with a moderate improvement in skin tone and texture following a series of 5 non-ablative RF skin-tightening treatments (Figure 5A–D are taken before treatment, and Figure 5E–H are taken after treatment).

Discussion

Non-invasive skin tightening represents a rapidly emerging area in cosmetics, as patients increasingly seek to avoid facelifts and other invasive procedures. Non-ablative heating of the dermis and subcutaneous tissue offers the potential for skin tightening and rhytid reduction with minimal pain, downtime, and low risk of scars or other adverse events. Multiple non-invasive technologies including intense pulsed light, lasers, RF, and ultrasound have been studied as therapeutic options; however, the clinical efficacy of these modalities has been limited and difficult to reproduce on a consistent basis. Additionally, several devices, such as focused ultrasound, have been associated with significant pain and/or downtime.

The bipolar RF device studied in this series is a novel, safe, and effective technology for inducing skin tightening. In this series, all treated patients were determined to have an effective treatment resulting in skin tightening and rhytid reduction following a series of 4–6 weekly RF treatments; over 70% of treated patients were observed to have a moderate or significant clinical improvement. This represents an extremely high response rate, as well as significant level of improvement not seen with previous RF and other non-invasive skin-tightening technologies.

This RF device offers several advantages over currently available technologies, which likely explains this high level of clinical efficacy. The Forma device utilizes real-time temperature-monitoring mechanisms, assessed by measuring tissue impedance, temperature, and epidermal contact throughout the treatment. This allows the device to continuously monitor the targeted tissue, and adjust the delivery of the RF energy to create a uniform heating exposure. The device is also able to maintain this constant uniform heating exposure for prolonged periods over relatively large treatment areas, such as an entire unilateral cheek. This uniform, long exposure is likely more effective at inducing collagen remodeling and neocollagenesis. Additionally, since the thermal exposure can be extended and prolonged, lower temperatures that do not induce any pain can be utilized. Rather than applying high, painful temperatures for seconds, this device allows for controlled, comfortable dermal heating to be maintained for several minutes to induce collagen tightening and remodeling. The use of lower temperatures over a longer exposure period allows for the treatment to be pain free with no downtime. In contrast to many other devices, when using the device under investigation, none of the subjects in this series required any anesthesia, including topical, and none required stopping the treatment or reducing the treatment parameters. Thus, this device represents a safe and effective non-invasive option for facial skin tightening.

Our series, of course, has its limitations. Face tightening, particularly of the lower face, is difficult to assess with quantifiable measures. There are no fixed anatomic structures that lend themselves well to measurement on the lower face to determine lift or tightening effects. As a result, we utilized

randomized photographic comparisons in this study, similar to other peer-reviewed skin tightening clinical studies. In the future, perhaps it will be possible to develop and validate more objective measures for lower face tightening and rhytid reduction. This study was also conducted in a single center, with a female study population; this may impact the generalizability of the data to larger, more diverse populations. Finally, the long-term impact of the treatments on skin tightening over the course of years is not yet known.

This case series also leads to several interesting questions for future studies. Is the effectiveness of non-invasive skin tightening related to the dermal thickness of the treatment area? In this study, distinct anatomic areas such as the periorbital area and eyelids, which are much thinner, were treated in conjunction with thicker targets such as the malar cheek. In addition to the variability in dermal thickness, these distinct areas have varying compositions of collagen, fat, and the superficial muscular aponeurotic system; does this variability impact the effectiveness of non-invasive RF skin tightening? Unfortunately, in this initial case series, it was not possible to assess the relative effectiveness of the Forma device on these distinct areas. In this study, each treatment zone was heated to the predetermined temperature of 43°C and maintained at that temperature for 5 min, and significant clinical improvement was observed. However, as previously discussed, the effectiveness of non-invasive RF skin-tightening treatments is dependent on both temperature and treatment time. Therefore, in the future, additional clinical studies utilizing a variety of temperatures and exposure times should be performed to determine the ideal treatment parameters. Finally, follow-up data over several years is necessary to determine the long-term effectiveness of the treatment series.

This initial clinical case series demonstrates the effectiveness of the Forma device for non-invasive skin tightening. This novel RF device represents a safe and effective new treatment option for non-invasive skin tightening and rejuvenation, with no downtime.

Financial disclosure

Drs. Nelson and Lask have spoken regarding several medical devices at national meetings and local meetings. In some cases, InMode Inc., the manufacturer of the device in this study, has provided travel expenses and honoraria. Drs. Nelson and Lask have future stock options in InMode Inc. Dr. Beynet has no declarations/conflicts of interest to report.

Declaration of interest: The authors report no declarations of interest other than the financial disclosures listed above. The authors alone are responsible for the content and writing of the paper.

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