

Comprehensive Thermoregulation for the Purpose of Skin Tightening Using a Novel Radiofrequency Treatment Device: A Preliminary Report

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ABSTRACT

Background: Radiofrequency-induced heating of dermal and subdermal tissue promotes skin contracture; however, the temperature threshold for inducing an epidermal burn is lower than the therapeutic temperature thresholds required for collagen remodeling, and therefore, there is the possibility of epidermal burn. Herein, we evaluate a radiofrequency treatment that provides novel real-time subdermal and epidermal temperature monitoring.

Methods: A retrospective chart review of 18 subjects undergoing thermistor-controlled subdermal skin tightening via percutaneous radiofrequency was conducted. During the treatment, epidermal temperature was concurrently monitored by a handheld infrared laser thermometer and a forward looking infrared camera system and peak temperatures readings were reported and evaluated.

Results: Mean temperatures of 43.6 and 38.2°C were reported for the infrared camera and infrared thermometer. The Bland-Altman plot analysis reported a bias of 5.38°C and 95% limits of agreement between 0.60 and 10.15°C. Additionally, the mean difference or bias of 5.38°C was statistically significant ($P < 0.0001$).

Conclusion: Our preliminary data supports a superior form of thermoregulation for the purposes of skin tightening that integrates continuous subsurface and epidermal temperature monitoring.

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INTRODUCTION

The gradual loss of skin quality overtime often becomes a barometer of age, which in turn, fosters the immense patient demand for skin restoration procedures. In 2012, facial rejuvenation treatments, including surgical and minimally-invasive procedures, accounted for an astonishing 74% of all cosmetic procedures performed.¹ Considerations for the cause of skin aging and loss of quality include, but are not limited to, loss of subcutaneous fat, prominence of platysmal banding through muscle laxity, jowling along the mandibular border, and excess skin laxity resulting from a decline in collagen and elastin.² Treatments range from botulinum toxin injections to more invasive surgical procedures. A widely used non-invasive skin tightening solution has been transcutaneous radiofrequency, which exerts a thermomechanical effect to induce neocollagenesis, denaturation of multi-chain collagen cross-links, immunological and wound healing responses, collagen contraction, and collagen fibril size increase.^{3,5} Additionally, shorter, heat-stable intermolecular cross-links are established, which increase rubber-elasticity of the collagen polymer.³

Transcutaneous radiofrequency, through an external applicator, permeates the tissue generating an alternating electromagnetic field that increases the kinetic activity of ions.^{6,7} Increased ion kinetics and oscillations, in turn, facilitates resistive tissue thermogenesis.⁷ However, resistance-induced thermogenesis mandates that an appropriate quantity of energy reach the target tissue without imposing ill-effects on the epidermis.⁸ Accord-

ingly, a major disadvantage of transcutaneous radiofrequency is the poor penetration of radiofrequency energy into deeper dermal and hypodermal layers, which can result in tissue arcing and subsequent scar formation.⁸ Additionally, and of great importance, the temperature threshold for inducing an epidermal burn is lower than the therapeutic temperature thresholds required for collagen remodeling. Accordingly the epidermis and outer dermal layers must be appropriately monitored and cooled to prevent untoward effects. Presently, temperature monitoring is done via a handheld infrared laser thermometer, without proper subdermal temperature monitoring and control.

Based on limited thermoregulation, broad, or volumetric, transcutaneous heating is limited in its ability to effectively treat superficial subdermal layers as well as deep adipose and subcutaneous tissue, without affecting skin integrity.⁸ This is an important limitation because Paul et al, (2011) described tissue contracture as a result of treating subcutaneous collagenous tissue, rather than dermal collagen only.⁹ Subcutaneous collagenous tissue includes the papillary and reticular layer of the dermis; fascia layer between muscle and skin; septal connective tissue segmenting fat lobules and linking the dermis and fascia; and reticular fibers encapsulating adipocytes.⁸

A treatment strategy that may deliver the appropriate subcutaneous heating for optimal skin contracture is thermistor-controlled subdermal skin tightening (ThermiTight) via

percutaneous radiofrequency, which involves the direct delivery of radiofrequency to select hypodermal tissues using a subsurface treatment probe. Additionally, this therapeutic approach provides real-time subdermal temperature monitoring and self-regulation via integration of a thermistor into the thermocouple hand piece. These important thermoregulatory parameters were established based on the use of percutaneous radiofrequency to treat more serious medical ailments: hepatocellular carcinoma, adrenal adenoma, breast cancer, and chronic knee osteoarthritis, thermocoagulation for the treatment of lumbar disc herniation, and management of chronic pain.⁹⁻¹⁴ Applying ThermiTight for skin tightening requires an equally comprehensive thermoregulation for precise heat generation within superficial subdermal layers as well as deep adipose and subcutaneous tissue to preserve the integrity of the skin surface.

We believe the ThermiTight holds several advantages, such as providing an acceptable safety profile for the localized thermal effect while mitigating damage to adjacent normal tissue. Herein, we evaluated, retrospectively, the difference in epidermal temperatures recorded by a forward looking infrared camera (FLIR) and handheld infrared laser thermometer (ILT) for patients having undergone ThermiTight for skin contracture.

METHODS

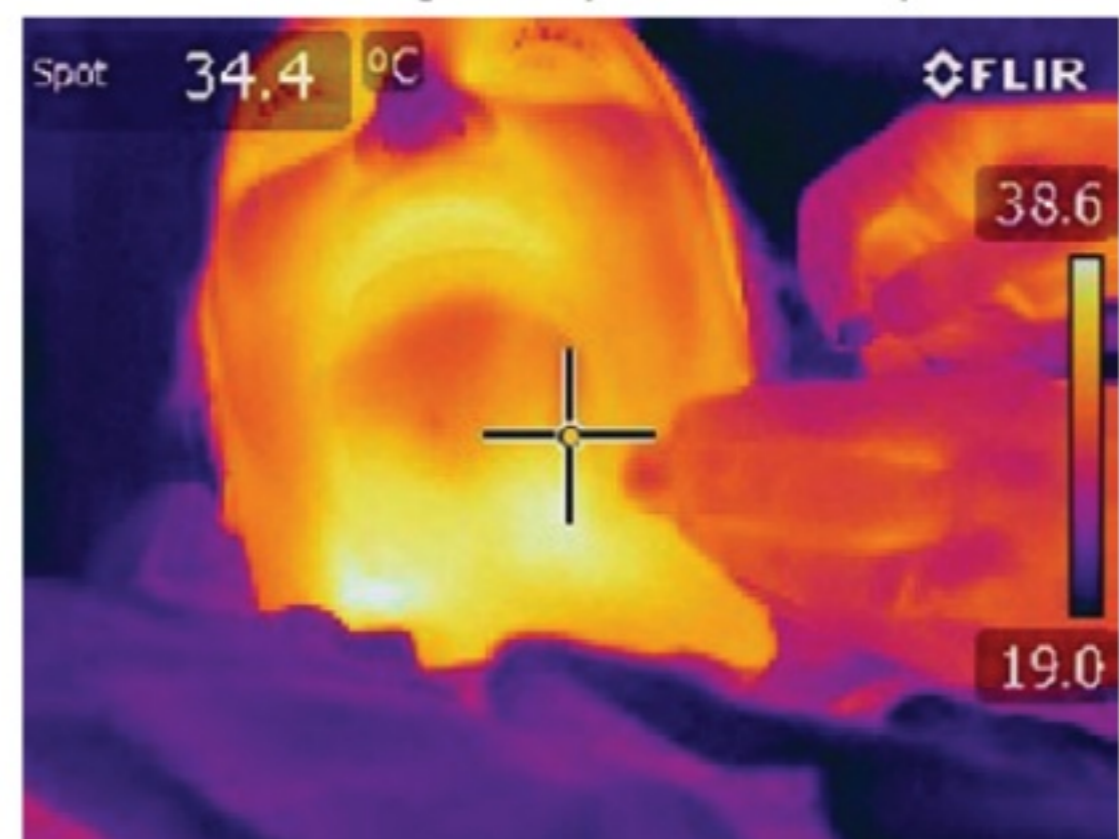
Data reported herein were acquired following a retrospective chart review of 18 patients having undergone ThermiTight for skin contracture. All charts were deemed acceptable based on the criterion that while undergoing ThermiTight, epidermal temperature was monitored with both a FLIR and ILT. No additional inclusion and exclusion criteria were used for chart selection. Treated sites included under-chin, under-chin and jowls, abdomen, upper abdomen, buffalo hump, and above the knees.

Patients were infiltrated with preheated tumescent solution (37°C) containing 0.125% lidocaine and 1:800,000 epinephrine. Incisions were made using an 11 blade and dilated with a 16-gauge dilator, permitting the blunt 10 cm long, 18 gauge percutaneous treatment probe to traverse the dermal plane. The distal end of the treatment probe administered the radiofrequency and possessed a temperature sensor that initiates an automatic feedback loop to maintain subdermal tissue temperature (ThermiRF™, ThermiAesthetics, Southlake, TX). Therefore, the device used provided, concurrent, dual temperature monitoring of the subdermis and epidermis (Figure 1). The ThermiTight probe was set at a default temperature range, between 50 to 60°C. Additionally, syringe assisted fat aspiration was performed with both 16 and 14 gauge Klein micro cannulas. Temperature monitoring was conducted using a FLIR (FLIR E40, FLIR Systems, Inc, Wilsonville, OR) and ILT (TN400L1 Economy Laser Thermometer, Metris Instruments, Los Gatos, CA). The FLIR system allows for radiometric IR-video streaming with thermal monitoring of the entire physical field rather than a single spot (Figure 2).

FIGURE 1. Dual temperature monitoring device.



FIGURE 2. IR thermal image taken by the FLIR camera system.



The ILT was positioned perpendicular to the surface of the treatment site at an approximate distance between 2 to 6 inches. At all times, the ILT remained directly above the portion of the treatment site that was currently receiving treatment. The FLIR was fitted to a tripod positioned at the base of the surgical lift table. The camera's position in reference to the treatment site placed the center of the treatment zone at the center of the camera's image. During the case, for each area of treatment, the highest observed temperature peak, for the FLIR and ILT, was recorded.

Statistical Analysis

Agreement between recorded temperatures for the FLIR and ILT was evaluated using the Bland-Altman method. Additionally, a *t*-test for paired samples evaluated the difference between the reported temperature means.

RESULTS

Subject mean and median age was 54.3 and 54.5 years, respectively. Of the 18 subjects evaluated, nine patients received under-chin/jowl treatment; five, under-chin only; and one, for each of the remaining anatomical sites (abdomen, upper abdomen, above the knees, and buffalo hump). Only 12 subjects had subcutaneous adipose tissue aspirated, and for these 12 subjects, a mean aspirate volume of 5.6 ml was observed.

For the FLIR, the mean and median peak temperatures reported were 43.6 and 43.8°C, and for the ILT, a mean and median temperature of 38.2 and 38.8°C was observed. Comparison of the two independent group means reported a difference of 5.38 (13.2% difference), which was statistically significant ($P < 0.0001$). The Bland-Altman plot reported a bias, or mean difference, of 5.38°C and 95% limits of agreement between 0.60 and 10.15°C (Figure 3). When evaluating each treatment region individually, a difference of $\geq 4.60^\circ\text{C}$, with the exception of the upper abdomen, was observed (Table 1).

Mean and median subdermal temperatures observed were 54.4 and 55.0°C, respectively. A linear regression model comparing subdermal and peak epidermal temperatures (reported by FLIR) shows a weak correlation between the two variables (Figure 4).

Before and after images illustrate the clinical response following treatment. In the first image, a 42-year-old female underwent ThermiTight combined with subcutaneous aspiration of 0.5 ml (Figure 5). The second patient is a 55-year-old female undergoing ThermiTight with 14.0 ml of subcutaneous aspiration. The third patient is a 79-year-old female that underwent ThermiTight without aspiration (Figure 7).

The treatment was well tolerated with patients experiencing mild erythema, which persisted no more than 12 hours. No pigmentary alterations, blistering, erythematous papules, or scarring was observed. Additionally, there were no reports of a burning, sore, or achy sensation that were sufficient to require analgesics post treatment.

FIGURE 3. Bland-Altman plot of reported ILT and FLIR temperatures.

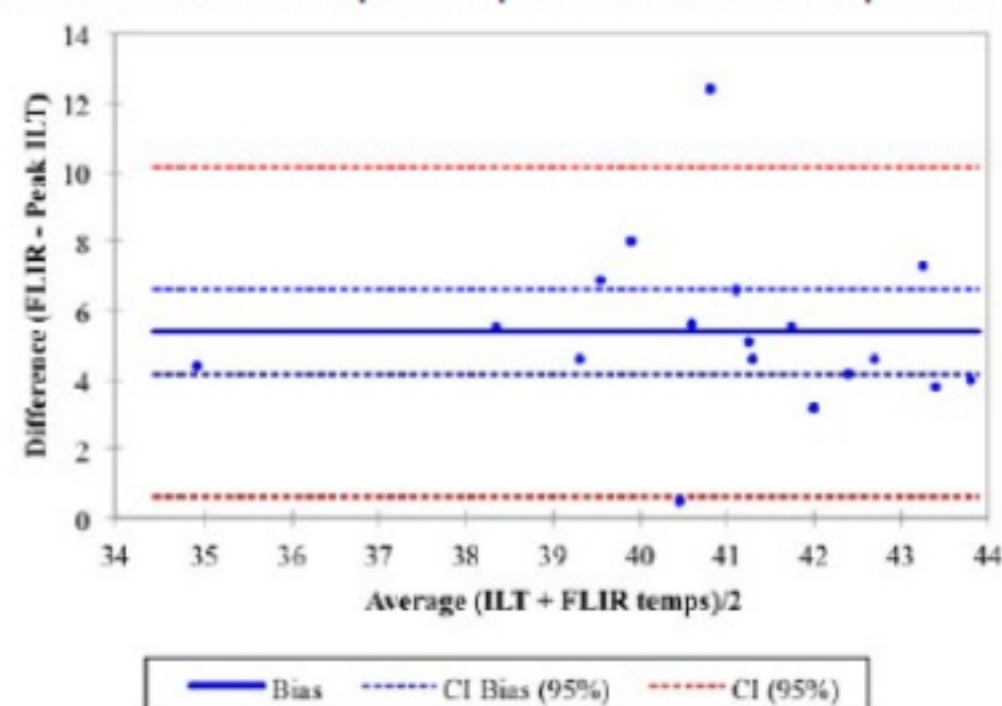


FIGURE 4. Linear regression of the subdermal and epidermal recorded temperatures.

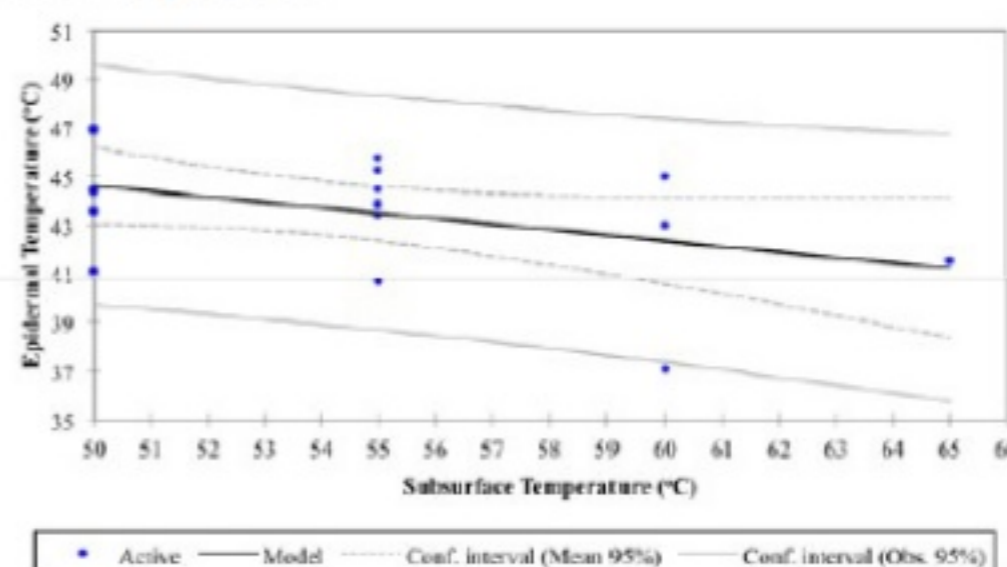


FIGURE 5. Baseline and 50 day post-procedure images of submental skin tightening following ThermiTight.



TABLE 1.

Temperature Difference Between ILT and FLIR Reported for Individual Treatment Sites

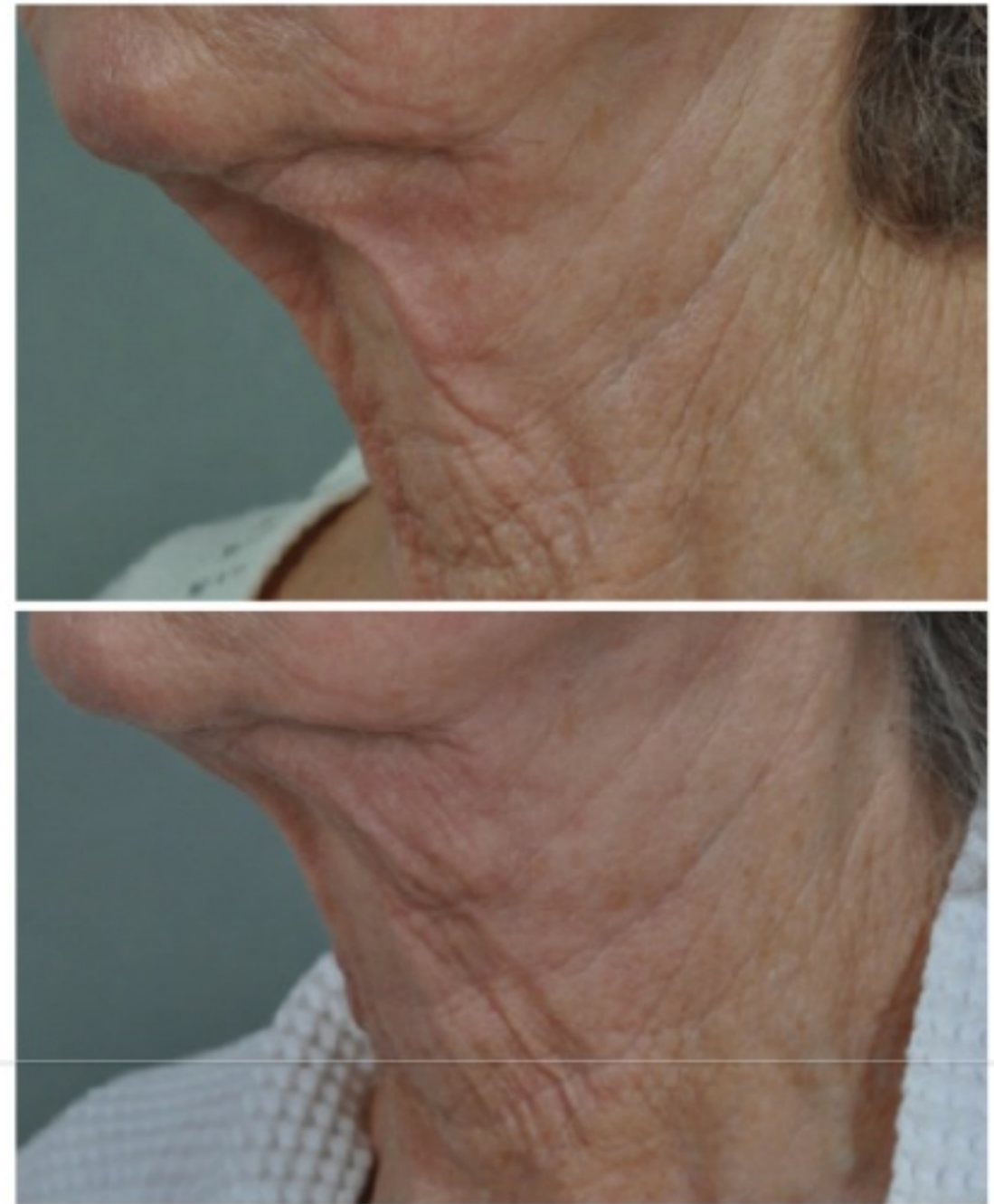
	Under-Chin/Jowl	Under-chin	Abdomen	Buffalo Hump	Above the Knees	Upper Abdomen
Difference	5.389	5.240	4.6	12.4	4.6	0.5
P-value (Two-tailed)	0.001	0.001	N/A	N/A	N/A	N/A

FIGURE 6. Baseline and 60 day post-procedure images of submental skin tightening following ThermiTight.

DISCUSSION

These data raise an important question concerning the reliability of ILTs for epidermal temperature monitoring. Based on our analysis, the recorded ILT temperatures were within a safe temperature range; however, FLIR recordings revealed epidermal temperatures approaching burn thresholds. Accordingly, pushing upper treatment temperature limits while monitoring with ILT alone could inadvertently produce temperatures beyond the safe range. The Bland-Altman analysis reported 95% limits of agreement between 0.60 and 10.15°C, which is the predicted difference between the two temperature monitoring systems for any future recordings. In turn, ILT epidermal temperature readings can be 0.6 to 10.15°C lower than the actual temperature, according to our findings. Nevertheless, further studies are warranted to validate our finding. A substantial limitation of our study was that a single ILT brand was utilized, and it could be argued that more precise and accurate ILTs are available. Although the FLIR and ILT devices used in this study share a similar accuracy of $\pm 2.0^\circ\text{C}$, the FLIR provides temperature monitoring of the entire physical field rather than a single spot. Accordingly, with an image resolution of 160 x 120 pixels, this is equivalent to using 19,200 ILTs simultaneously.¹⁸ Furthermore, the ILT requires a distance to spot size ratio of 9:1, indicating a strong dependence on the proper position from the surface for an accurate reading.¹⁹

To reach a desired clinical outcome, a specific subdermal temperature threshold must be reached. However, without complete thermoregulation, generating a higher subdermal temperature may, in turn, result in a higher epidermal temperature. Using a linear regression model we did not demonstrate a strong linear dependence between subdermal and epidermal temperatures. For instance, a reported subdermal temperature of 65°C corresponded to an epidermal temperature of 41.6°C, with a subdermal temperature of 50°C demonstrating

FIGURE 7. Baseline and 30 day post-procedure images of submental skin tightening following ThermiTight.

an analogous epidermal temperature of 41.1°C. Accordingly, the rigorous thermoregulation of the subdermis, epidermis, and subcutaneous and facial tissue planes enables clinicians to deliver therapeutic subdermal temperatures without adversely modulating epidermal temperatures.

In aesthetics, radiofrequency ablation generally administers frequencies between 300 kHz and 3.0 MHz. At these frequencies, displacement of the electric current becomes negligible, and more elaborate mathematical equations to calculate the generation of heat, like the bioheat equation, is not necessary. Instead, tissues are viewed as resistive and the conversion of electric energy into heat is based on the principles of Joule's law. Accordingly, the distributed heat source is given by:

1. Where q is the Joule loss (distributed heat source); J is the current density (A/m^2); and E is the electric field intensity (V/m).¹⁶ Additionally, Laplace's equation is required to evaluate current density and electric field intensity:
2. Where V is the voltage (V) and σ is the electrical conductivity (S/m). According to equations 1 and 2, the generation of heat is based on tissue electrical conductivity - the measure

in which tissue conducts an electric current – and electric field intensity in tissue. Electrical conductivity and density of tissue varies across the subdermal tissue landscape. Additionally, factors such as hydration can modulate tissue conductance. As a result, sudden changes in tissue density and conductivity will affect radiofrequency induced thermogenesis. Royo de la Torre et al, (2011) discussed sudden heat peaks resulting in a burning sensation while administering radiofrequency for the treatment of skin laxity.²⁰ A critical tool for mitigating rapid subdermal temperature fluctuation is a thermistor integrated within a negative feedback circuit. A thermistor is a temperature-sensing element that changes in resistance when exposed to small temperature changes. As the Thermistor's resistance changes, the negative feedback loop modulates output current accordingly, maintaining a specific subdermal tissue temperature. ThermiTight via percutaneous radiofrequency incorporates this type of temperature feedback circuit. Accordingly, ThermiTight not only provides real-time epidermal temperature monitoring via the FLIR, but also subdermal temperature monitoring and self-regulation through the thermocouple integrated thermistor.

Temperature regulation, in turn, may improve the safety profile and quality of care for radiofrequency. For traditional radiofrequency treatment methods, there have been reports of achy, sore, and burning sensations.²⁰ Additionally, Alster et al, (2004) reported erythematous papules in 6% of treated patients.²¹ Further studies are presently being conducted to elucidate the complete safety profile and improved quality care for ThermiTight. Nevertheless, preliminary data reports side effects concomitant to any subsurface treatment approach with no reports of epidermal blistering or burning sensation. Additionally, the procedure, performed under local tumescent anesthesia without the need for systemic sedation, reported a high degree of patient comfort. Lastly, additional studies are underway to objectively quantify the improvement in skin laxity.

CONCLUSION

Comprehensive real-time epidermal and subdermal tissue temperature monitoring mitigates the risk of untoward effects associated with radiofrequency. Current radiofrequency solutions lack the ability to effectively monitor subdermal tissue temperature. Additionally, our data raises important questions about the viability of ILT epidermal temperature monitoring. Although further studies are necessary, our preliminary data supports a superior form of thermoregulation by amalgamating continuous subsurface and epidermal temperature monitoring.

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DISCLOSURES

The author has not disclosed any relevant conflicts of interest.

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