

## ABSTRACT

**Objectives:** Patients are increasingly seeking nonsurgical treatment for the aging face. The purpose of this study was to evaluate the clinical efficacy and outcomes of a thermistor-controlled subdermal skin tightening device (ThermiTight) as a treatment modality for the aging face.

**Study Design:** Retrospective chart review.

**Methods:** A retrospective analysis of 12 patients was completed on patients having undergone ThermiTight for midface and neck skin tightening. The ThermiTight probe was set at a designated temperature and maintained using a thermistor integrated electrode. Two blinded reviewers assessed photographs taken at baseline and post-procedure using a standardized skin laxity scale. Patient charts were reviewed to assess for complications up to six months post-treatment.

**Results:** The mean age of treated patients was 53.2 years, and all 12 patients were female. Three (25%) patients treated with ThermiTight were also treated with injectables (Botox, Juvéderm) simultaneously. One (8.3%) patient developed a wound complication. Three (25%) patients complained of incisional site pain at their first postoperative visit that subsequently self-resolved. On a five-point scale to assess facial skin laxity, there was an average improved score of 0.65 per patient ( $p < 0.001$ ). Two blinded reviewers correctly categorized photographs as either being “baseline” or “post-procedure” 88% of the time. There was no significant difference between the skin laxity scores by the blinded reviewers ( $p = 0.31$ ).

**Conclusions:** ThermiTight is a new technology used for nonsurgical treatment of the aging face. Short-term outcomes demonstrate the safety and efficacy of the procedure. Complications are rare for ThermiTight for the treatment of aging face.

**Level of Evidence:** 4

## INTRODUCTION

Facial soft tissues undergo age-related changes in volume, shape and position. 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, jowling along the mandibular border, and excessive skin laxity resulting from a decline in collagen and elastin.<sup>1</sup> As demand for a youthful appearance has increased, face lifting and contouring have received attention as promising procedures in the field of facial plastic surgery.

A widely used non-invasive skin tightening solution has been transcutaneous thermogenesis, which is achieved using ultrasound, radiofrequency, or light. These techniques exert a thermo-mechanical effect to induce neocollagenesis, denaturation of multi-chain collagen crosslinks, activation of wound healing pathways, collagen contraction and increased collagen fibril size.<sup>6,7</sup> A major disadvantage of transcutaneous thermogenesis is the poor penetration of energy into deeper dermal and subdermal tissues, which can result in uneven contouring and scar formation.<sup>8</sup> Another potential drawback to transcutaneous thermogenesis technologies is that the temperature required to cause an epidermal burn is lower than the temperature required to remodel the subdermal layers. A newly emerging approach that provides precise and controlled subdermal heating is thermistor-controlled subdermal skin tightening (ThermiTight, ThermoAesthetics, Southlake, TX). This approach uses a percutaneous treatment probe to administer radiofrequency directly to dermal and subdermal tissue. Subdermal temperatures are monitored and controlled by a thermistor integrated within the thermocoupled handpiece.<sup>9</sup> Concurrently, epidermal temperatures are monitored using an infrared camera system. Therefore, both subdermal and dermal collagenous tissue reaches therapeutic temperature thresholds necessary for collagen remodeling. With this in mind, we sought to evaluate the outcomes and clinical efficacy of ThermiTight for reversing neck and lower face skin laxity.

## METHODS

Following institutional review board (IRB) approval, we retrospectively reviewed 12 patients undergoing ThermiTight treatment to rejuvenate neck and lower face skin under local anesthesia. Treated sites included the submentum and jowls.

Two blinded reviewers assessed photographs taken at baseline and three months post-procedure. Reviewers were presented with both photographs at the same time and asked to label each photograph as either the “baseline” or “post-procedure” image. Blinded grading was performed using a quantitative five-point grading scale to assess changes in skin laxity (Table 1).

## METHODS, CONTINUED

Patient charts were reviewed for the six months following ThermiTight treatment to evaluate for any complications. Complications included infection, wound breakdown, patient dissatisfaction, or uneven contour.

Inclusion criteria for ThermiTight treatment were: good health and mild to severe skin laxity. Exclusion criteria were: any injection history such as silicone, fat or collagen; bleeding or coagulation disorder; history of a hypertrophic scar or keloid; compromised immune system; history of impaired wound healing; or collagen vascular disease. Patients were required to be available for post-treatment follow-up evaluations. ThermiTight treatments were performed by the two senior authors (HK, RH). The procedure was performed as previously described by Key.<sup>10</sup>

## RESULTS

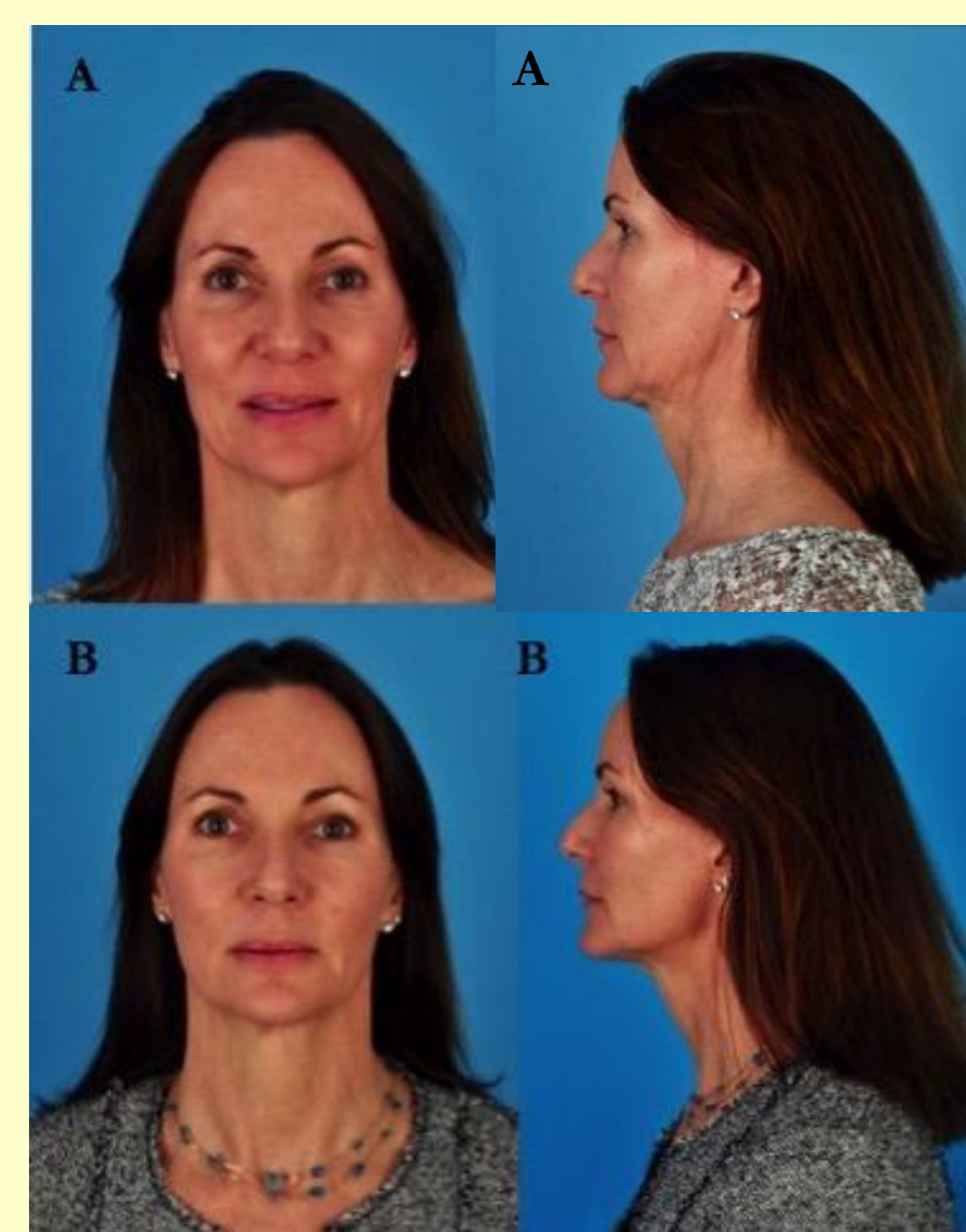
Grade	Descriptive Parameter	Laxity
0	None	None
1	Mild	Localized to NL folds
1.5	Mild	Localized, NL and early ML folds
2	Moderate	Localized, NL/ML folds, early jowls, early SM
2.5	Moderate	Localized, prominent NL/ML folds, jowls, and SM
3	Advanced	Prominent NL/ML folds, jowls and SM, early neck strands
3.5	Advanced	Deep NL/ML folds, prominent jowls and SM, prominent neck strands
4	Severe	Marked NL/ML folds, jowls and SM, neck redundancy and strands

**Table 1. Skin Laxity Severity Scale**

NL = Nasolabial, ML = Melolabial, SM = submental/submandibular  
 Ref: Alexiades-Armenakos M. A quantitative and comprehensive grading scale for rhytides, laxity, and photaging. *J Drugs Dermatol* 2006;5:808-809.

N=12	Baseline	Post-Procedure	Difference
Mean +/- SD	2.69 +/- 0.93	2.04 +/- 0.76	-0.65 (p<0.001)

**Table 2. Reported Mean Change in Skin Laxity Severity Scores When Comparing Baseline and Post-Procedure Scores.**



**Figure 2.** 49 year female who underwent ThermiTight for submental skin laxity and jowling. Pre-operative (A) and 3 months post-procedure (B) front and profile views.



**Figure 3.** 55 year female who underwent ThermiTight for submental skin laxity and jowling. Pre-operative (A) and 3 months post-procedure (B) front and profile views.

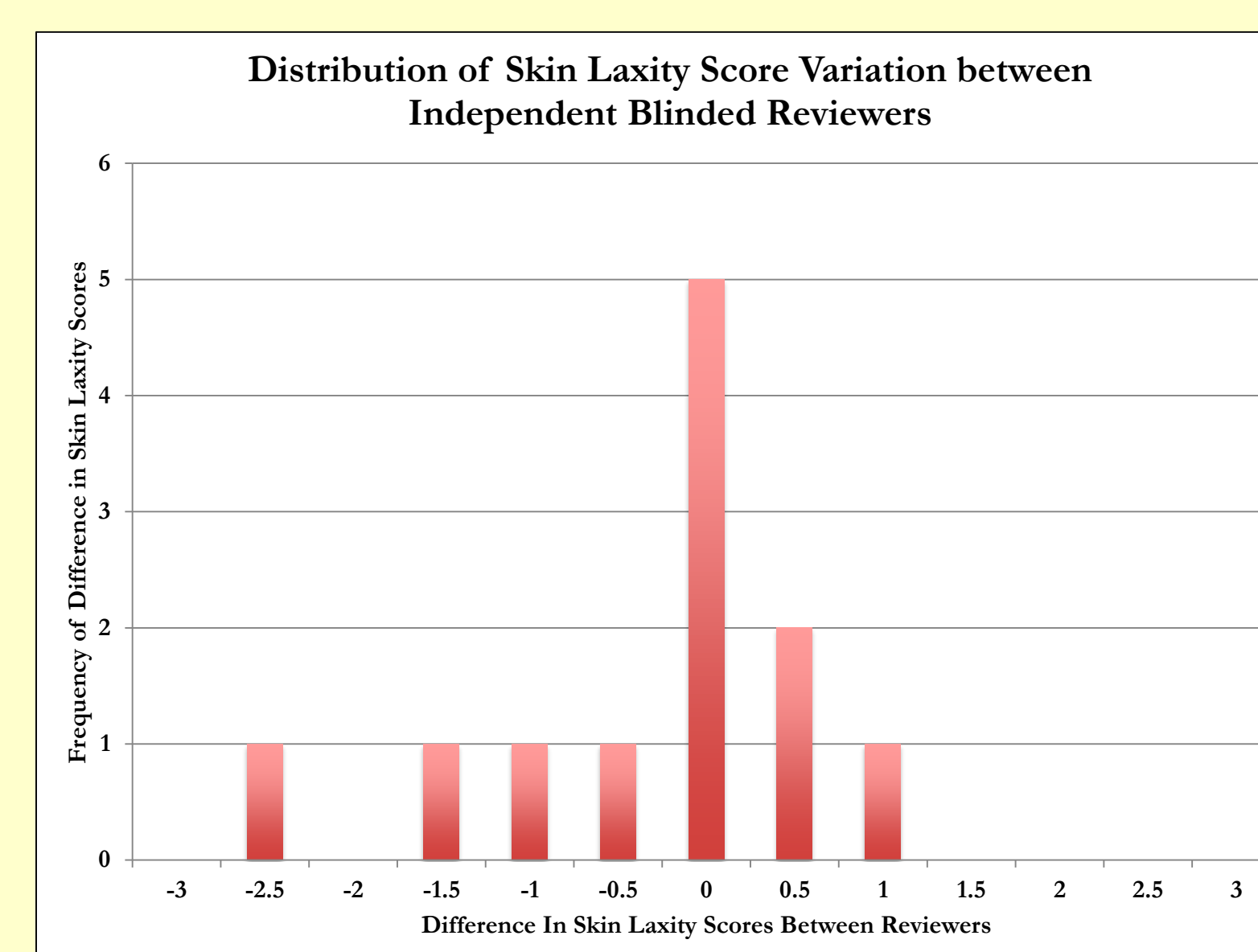
## Safety

One patient (8.3%) developed a facial abscess after ThermiTight, which required an incision and drainage and overnight admission for intravenous antibiotics. Three patients (25%) complained of incisional site pain at their first post-operative visit, all of which resolved spontaneously by their subsequent appointment. There were no complications of wound breakdown, surface irregularities, numbness, or patient dissatisfaction. Patients could return to their normal activity immediately after treatment.

## Efficacy

Average skin laxity score as assessed by two blinded reviewers improved from 2.69 pre-procedure to 2.04 post-procedure, an average change of 0.65 points ( $p < 0.001$ ). (Table 2) Highest average score improvement was 1.5 points, and lowest average score improvement was -0.25 points, indicating that one patient’s average skin laxity score was slightly higher following ThermiTight treatment. 91.7% of patients’ post-procedure photos were rated as having improved skin laxity.

The two-blinded reviewers had improvement scores within one point of each other in 83.3% of patients, and had perfect agreement in 41.7% of cases. (Figure 1) No significant difference between reviewer assessments of change was detected by t-test ( $p = 0.31$ ).



**Figure 1.** Distribution of skin laxity score variation between independent blinded reviewers.

## DISCUSSION

Skin laxity and abnormal fat accumulation are highlighted in the aging face and neck through the submental area, jowls, lateral nasolabial folds, lateral labiomental folds, and lateral mental areas.<sup>11</sup> These changes lead to morphological disruption, resulting in an older appearance. ThermiTight is a new technology for lipolysis and contouring, which can cause neocollagenesis via radiofrequency energy applied directly to target tissues. Collagen molecules are organized as fibrils, whose tensile properties are caused by intermolecular cross-links.<sup>12</sup>

When collagen is denatured by heat, the hydrogen bonds rupture, and the triple helices unwind, resulting in randomly coiled molecules. This heat-modified collagen undergoes remodeling associated with fibroplasia and new collagen synthesis.<sup>13</sup> Lin et al. noted that collagen fibers began to curve at 52 – 55C.<sup>12</sup> On the basis of these theories, we set the maximum temperature of 60C, which was measured by a micro-thermosensor inside the tip of the cannula. When the internal temperature was close to 60C, the epidermal temperature measured with an external infrared thermometer was set to a max of 42C.

Key retrospectively analyzed 18 patients who were treated with ThermiTight in the under-chin/jowl area, abdomen, above the knees and buffalo hump and assessed for reliability of the FLIR system reporting temperature differences between the epidermal and dermal regions. One of the drawbacks to the ThermiTight device is that the device has no ability to suction fat.

One patient in our series had an adverse event: facial abscess after ThermiTight. To the authors’ knowledge, this is the first reported ThermiTight complication. Interestingly, the patient was a 60 year old female who three years prior underwent a facelift. Her post-operative course for the facelift was complicated by facial cellulitis. She did not have any underlying immunologic deficiency, diabetes, autoimmune disease, or wound healing history. She was seen at her first post-operative visit six days after ThermiTight treatment, admitted to the hospital and started on intravenous antibiotics. A CT scan demonstrated cellulitis of the left face without a drainable collection. She did not improve on intravenous antibiotics and a bedside incision and drainage was performed. 15 cc of pus was drained from the ThermiTight treatment site and cultures grew methicillin-resistant staphylococcus aureus (MRSA). She was discharged home the following day with an oral antibiotic regimen. She did not have any other sequelae from treatment and subjectively was satisfied with her result.

In our experience, the use of a subsurface radiofrequency thermistor produced significant improvement for lower face and neck contouring in the aging face with a minimal side effect profile. Theoretically, an ideal subdermal skin tightening device should: 1) affect subdermal tissues without compromising the viability of the overlying skin-soft tissue envelope, 2) cause soft-tissue envelope contraction around the area of the treated tissue, 3) be safe to use on patients under local anesthesia, and 4) lead to minimal bruising and swelling, allowing for quick return to daily activities without significant downtime. ThermiTight fulfills all of these aforementioned criteria, and led to reliably improved skin laxity scores. The authors recommend ThermiTight for the aging face based on our early data. A limitation of this study is the retrospective design and small number of patients.

## CONCLUSION

In this study, we evaluated the safety and clinical efficacy of a subsurface radiofrequency thermistor for non-surgical treatment of the aging face in 12 patients. Patients and surgeons were satisfied with the clinical efficacy of the procedure. Short-term complications are rare but possible for ThermiTight for the treatment of aging face.

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## CORRESPONDING AUTHOR

Akshay Sanan MD  
 Department of Otolaryngology – Head and Neck Surgery  
 925 Chestnut Street, 6<sup>th</sup> Floor  
 Philadelphia, PA 19107  
 Akshay.Sanan@Jefferson.edu