

# FIRST CASE REPORTS OF A NEW RADIO FREQUENCY PR

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## ABSTRACT

Non-invasive cosmetic procedures, characterized by minimal patient recovery periods and low complication rates are preferred over invasive procedures for achieving cosmetic improvements on facial skin. Non-ablative lasers used for this purpose typically require numerous treatments over 6 months to achieve modest cosmetic benefit, primarily due to time required for secondary collagen response to a minor thermal injury. This new radio frequency device is capable of delivering higher energy fluences to a greater volume of tissue than non-ablative lasers, and was evaluated for a number of clinical targets, including periorbital wrinkles, non-invasive eyebrow lifting, sub-mental reduction, and acne scarring.

In this series of pilot case studies, a new non-invasive RF technology (ThermaCool TC™ System) demonstrates significant cosmetic effects one month after a single treatment of facial skin, in a small number of patients. The notable improvements observed within one month of a single treatment are suggestive of a mechanism other than secondary collagen synthesis in response to thermal injury. Primary collagen contraction, similar to that seen with ablative CO2 resurfacing, is postulated as a short-term mechanism of efficacy for this non-ablative radio frequency device. Secondary collagen synthesis response to the thermal injury is predicted over a longer time period. These impressive findings in a small number of patients require additional verification in larger studies, but do indicate the unique potential of this device to cause a primary contraction of underlying tissue with one treatment, without burning the surface of the skin.

## BACKGROUND

A number of non-ablative laser technologies have been purported to cause a deeper thermal injury than traditional resurfacing lasers without damaging the epidermis. The ThermaCool TC System is the first radio frequency (RF) technology to be deployed for the purpose of non-ablative, sub-epidermal heating. This device heats a volumetric zone of dermal tissue while conductively cooling the epidermis and has the theoretical potential to achieve controlled, uniform heating at considerably greater depths than those reported with light-based technologies.

Each treatment cycle of the ThermaCool TC System delivers treatment to tissue in three phases through a RF treatment tip that integrates both volumetric heating and contact cooling functions. Over the course of the 6.3-6.5 second treatment cycle, the skin is exposed to an initial phase of cryogen based pre-cooling, followed by simultaneous heating and cooling, and then post-cooling. The coolant does not come into direct contact with the skin. The depth and volume of thermal injury directly correlate to the geometry of the RF treatment tip, a component that can be selected by the clinician to target a depth of thermal injury desired.

The ThermaCool TC System has been cleared via 510(K) for use in *Dermatologic and General Surgical Procedures for Hemostasis and Electrocoagulation*.

In a previous report, Suzanne Kilmer, MD et al, demonstrated an acceptable pattern of safety in the first deployment of the ThermaCool TC System on human abdominal skin, with minimal incidence of transient side effects. Histological analysis indicated preservation of the epidermis with an absence of findings suggestive of dermal or epidermal scarring. Fibroplasia and other signs of increased collagen formation were seen at various dosing levels. These findings suggested the potential for safe deployment on skin in other areas of the body and at higher doses.

## SUMMARY AND CONCLUSIONS

These promising results and case histories demonstrate the potential of the ThermaCool TC System for tightening facial skin in a single treatment session. The procedure is performed in most patients with topical anesthetic only, with no patient

## OVERVIEW OF STUDY DESIGN AND STUDY POPULATION

**Overview of Study Design:** Under the auspices of the Ethics Committee at the Instituto Dermatológico De Jalisco, a protocol was developed in accordance with Mexican requirements. The scope of this protocol was to evaluate the safe and effective deployment of this new technology on skin in various areas of the body, including facial skin. Outcome criteria included the investigator's clinical observations, photographic evaluations and the patients' self-reported level of satisfaction. Evaluations were performed and photographs were taken at pre-treatment and at selected time intervals over a minimum 6-month follow-up period.

**Study Population:** A total of 93 patients (85 females/8 males) were treated with the ThermaCool TC System at the JuBaGo Unidad de Cirugía Plástica y Reconstructiva in Guadalajara, Mexico. These patients were treated in varying anatomical locations including some on the trunk and some on the face. The distribution of treatments for facial indications is shown below.

Facial Areas Treated	Number of Patients Treated*
Periorbital Wrinkles	45
Acne Scars/Acne	16
Nasolabial Fold	4
Perioral Rhytids	1

\*Some patients were treated in more than one facial area and therefore may appear in more than one category. The data reported herein is limited to the 45 patients who were treated in the periorbital region.

Patients ranged in age from 16 to 79 years (mean 55 years). The majority of the patients had Fitzpatrick Sun-Reactive Skin Type IV (58%) followed by Type III (27%).

Most periorbital patients received 1 treatment (33 patients) and some received up to 4 treatments (12 patients). The longest follow-up available for the group of patients reported herein was 9 months (mean 3 months). Follow-up data and photographs through at least 4 months post-treatment were available for about half (49%) of these periorbital patients.

**Skin Preparation and Pain Management:** A topical anesthetic, **ELA-Max® 5** (lidocaine 5%), was applied to the targeted treatment area and occluded for about an hour before treatment. Additionally, for a few cases, a nerve block was administered to the forehead to control discomfort. The target treatment area was then marked with a grid pattern composed of contiguous squares corresponding with the size of the RF treatment tip. A conductive fluid was spread onto the skin just prior to treatment.

**Treatment:** Energy was applied to the marked squares in the treatment area on the forehead skin, beginning just above the eyebrows, down to the lateral canthal areas, and extending up to the hairline above these two areas. It was postulated that lifting or tightening this skin would diminish the appearance of the periorbital wrinkles. For the squares located directly on an epidermal wrinkle, the treatment fluence was set to a lower level of energy. For all other treatment areas, fluences were titrated to maximum tolerable pain levels or a set maximum,

down time. Clinical observations reveal that the majority of patients had some degree of improvement as evidenced by softer periorbital wrinkles, lifted eyebrows or a more open angle to their eyebrows. Objective measurements made from the eye to the eyebrow quantify these changes and support these observations of skin

# PROCEDURE TO NON-INVASIVELY CONTRACT FACIAL SKIN

Universidad De Guadalajara, Mexico; Pamela Buckman, RN, MS, and Mitchell Levinson, MS, ME, of Thermoage™, Hayward, CA.

whichever was less. Higher fluences were thought to be associated with primary tissue tightening. Typically, 50 to 80 applications of energy were delivered for each treatment session.

## RESULTS

**Safety Data:** A total of 4147 applications of energy were delivered to the 45-periorbital patients. Of these, 6 applications (0.1%) resulted in a superficial, second degree burn for 2 patients (4.4%). These burns presented immediately after treatment as edema and/or erythema. These findings typically resolved within a few days and in some cases, within a month. No other complications or unanticipated adverse events have occurred during the course of this study.

**Efficacy Data:** Clinical observation of the treated areas revealed that the majority of patients (about 60%) showed some degree of improvement. Rhytids appeared to be softer or not as deep as before treatment. Eyebrows seemed to be lifted and in some cases, the angle of the eyebrow was more open. Hooding of the upper eyelids was less pronounced in some patients. These observations support the hypothesis that tightening the skin above the periorbital area "pulled" the skin below, similar to the effect seen with an invasive brow lift.

Satisfaction data was available for 14 periorbital patients who had completed their 6-month visit. Of these 14 patients, 12 (86%) reported that they were satisfied or very satisfied with the treatment. Patients frequently commented that the treated area felt tighter and that family members and friends noticed a difference in their appearance.

## CASE HISTORIES

**Case History #1:** SCN 405 is a Hispanic female who was 57 years old at the time of treatment and has Fitzpatrick Skin Type II. She had previously used Retin A, but not within several months of treatment. She was treated twice in the periorbital region within 60 days. Her treatment was uneventful with no reports of untoward reactions. At 1 month after the first treatment, she reported that her skin felt "more young and fresh". At 6 months, she was very pleased with the outcome and had been told by family and friends that she looked younger. The difference in her appearance is apparent when comparing photographs taken at pre-treatment and at 8 months after treatment (Figures 1 and 2).



Figure 1  
Pre-Treatment



Figure 2  
8 Months Post-Treatment  
SCN 405

**Case History #2:** SCN 406 is a Hispanic female who was 53 years old at the time of treatment and has Fitzpatrick Skin Type III. She has previously used Retin A and other vitamin products but not within several months of treatment. She was treated twice in the periorbital region within 60 days. Her treatment was uneventful with no complications. At 1 month after the first treatment, she reported that her skin felt "tighter". At 6 months, she was told by family and friends that she looked younger and had fewer crow's feet. This improvement is apparent when comparing photographs taken at pre-treatment and at 6 months post-treatment (Figures 3 and 4). Histological analysis of a biopsy specimen taken from the treated area at 4 months after treatment shows epidermal thickening and increased dermal density as compared to baseline (Figures 5 and 6), corroborating the clinical observations. Measurements taken at 6 months reveal that her eyebrows were raised by 1.7mm for her right eye and 2.4mm for her left eye for an average change of 2.0mm for both eyes.



Figure 3  
Pre-Treatment



Figure 4  
6 Months Post-Treatment

Eyebrow Lift Measured 6 Months Post-Treatment  
Right eyebrow raised: 1.7mm  
Left eyebrow raised: 2.4mm  
Average lift for both eyes: 2.0mm



Figure 5  
Pre-Treatment



Figure 6  
4 Months Post-Treatment  
Histology

tightening. Furthermore, changes in appearance were corroborated histologically with findings of thickened epidermis and increased density of the dermis post-treatment. These findings warrant further evaluation of this potentially promising technology for cosmetic skin procedures and suggest the ability to "lift" tissue in a

manner only seen previously with invasive procedures involving tissue excision. A multicenter clinical study is currently ongoing in the US to further evaluate the safety and efficacy of ThermoCool TC System treatment for the reduction of periorbital wrinkles.