Clinical Report

Dynamic Monopolar Radiofrequency for Successful Non-Invasive Treatment of Skin Laxity and Body Contouring.

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Background and Objectives: Multiple devices are currently on the market in the US for treatment of skin laxity. These range from ultrasound to broadband infrared to laser. The most commonly employed, however, are radiofrequency (RF) based devices. (1) Radiofrequency devices include use of the ISM RF bands which are reserved for industrial, scientific and medical uses. We are most acquainted with Wi-Fi radio bands used in the industrial sector, in fact laptop computers communicate on these frequencies.

When used for medical purposes, these radio frequencies comprise an oscillating electrical current forcing collisions between charged molecules and ions, which are then transformed into heat. This RF heating occurs irrespective of chromophore or skin type and is not dependent upon selective photothermolysis but rather heating of water. RF heat has different biological and clinical effects, depending upon the depth of tissue targeted. In the dermis which is comprised of collagen, elastin and ground substances, RF mediated thermal stimulation of this matrix results in an immediate and temporary change in the helical structure of the collagen. (2) It is also believed that RF thermal stimulation results in a micro-inflammatory stimulation of fibroblasts which produces new collagen (neocollagenesis) and new elastin (neoelastogenesis), as well as other substances to enhance dermal structure. (3) RF thermal stimulation of adipose tissue is believed to result in a thermal mediated stimulation of adipocyte metabolism and augmented activity of lipase mediated enzymatic degradation of triglycerides into free fatty acids and glycerol. Induction of apoptosis of fat cells is another proposed mechanism.

Radiofrequency based devices are logically employed to non-invasively manage and treat skin tightening of lax skin, wrinkle reduction, cellulite improvement and body contouring enhancement. There are many devices on the market, each of which has wide ranging methods of RF delivery. Radiofrequency (RF) devices may be monopolar in which the patient is grounded and the RF delivered through the skin, into the body and ultimately to the grounding electrode. These monopolar devices may be static in which a short 1 – 2 second cycle is given while the handpiece is held in place. Alternatively, monopolar RF may be delivered dynamically in which RF is delivered in a continuous pulse with constant movement of the handpiece. In the static method, a single pulse is delivered, the handpiece is then moved to an adjacent marked area and fired again. This is performed for hundreds of pulses until a pre-marked area is treated. With dynamic monopolar, the handpiece is continuously moved and specific areas of laxity can be targeted in a relatively short amount of time.

Other methods of RF delivery include bipolar, in which the RF moves between two poles built into the handpiece. With a specific distance between the electrodes, the depth of penetration and heating is predetermined and is typically confined to within 1 – 2 mm of the skin surface. Another form of delivery is unipolar in which there is one electrode and no grounding pad. With this method, a large field of RF is emitted without the ability to focus on a specific target. This is analogous to a radio tower broadcasting signals in all directions. Some devices now on the market are claimed to be tripolar or multipolar but are variations of the basic three; monopolar, bi-polar or unipolar. Other energy sources such as laser or intense pulsed light can be combined with RF so that a fairly confusing array of technologies claim to cause smoothing and tightening of the skin.

INTRODUCTION

In the field of cosmetic medicine, the Holy Grail is the ability to treat patients with skin laxity or excessive

adipose tissue, which both lead to body contour irregularities, without resorting to surgical methods. Skin excision techniques such as facelifts, abdominoplasty or brachioplasty can provide excellent clinical results when performed by skilled hands. It is the downtime of anesthesia, reduced mobility and wound healing that patients would like to avoid. Potential scars, morbidity and fear of excisional and invasive liposuction procedures keeps a large majority of patients looking for less invasive skin tightening and body contouring procedures. Cosmetically oriented physicians who do not offer alternatives are at a distinct disadvantage.

Consumer demand for non-invasive methods for skin tightening, wrinkle reduction, body contouring and cellulite reduction is continuously growing. We have seen this even in times of an uncertain economy, especially since patients cannot afford downtime for fear of not being in the office and losing their job. Similarly, patients need to look better and younger for fear of being replaced by younger colleagues in a very competitive job market. There is great demand to diminish skin laxity non-invasively and smooth irregular body contours non-invasively and to be cost effective.

While there are many options in the skin tightening and body contouring arena, there are very few that have a relatively short treatment cycle, minimal cost consumables and a high degree of patient comfort during the treatment. Competitive technologies include vacuum massage, infrared laser technologies, high frequency focused ultrasound, cavitation frequency ultrasound, radiofrequency energy and various hybrid energy devices combining some or all of the above. The RF in the device described in this paper rapidly excites molecules (2 - 3 million times per second) to create desirable heating effects on collagen and subcutaneous tissues. It uses an ideal combination of heat and cooling to non-invasively deliver RF energy to specific depths in tissue which produces a predictable response, notably collagen remodeling, to achieve desired cosmetic results for wrinkle reduction, tissue tightening and body contouring.

THE EXILIS® DEVICE

This paper introduces a novel RF dynamic monopolar device, the Exilis® (BTL, Boston, MA) that combines focused monopolar RF delivery with a number of built-in safety features.

The Exilis® system delivers the energy through two different applicators and the goal of treatment is to raise the surface temperature to 40 – 42 °C for 4 to 5 minutes for each region treated. When this temperature is reached, the patient feels a comfortably warm sensation. The handpiece is in continuous motion so that the areas of skin with the most laxity can be specifically targeted. This has been termed dynamic monopolar RF. Additionally, Peltier cooling can be adjusted up or down to allow targeting of skin or subcutaneous tissue. For example, to drive heating more deeply the skin is cooled and protected allowing heat to reach into subcutaneous fat. Alternatively, to get maximum effect on skin laxity, cooling is turned off and heating of skin occurs very quickly with minimal effect on subcutaneous fat. For the large applicator, temperature is monitored by an on-board infrared temperature sensor which continuously displays skin temperature. When the device senses spikes in RF delivery, these spikes are automatically reduced. Constant monitoring of energy flow through tissue (impedance) detects tip contact with skin. Specifically, the device, using a complex algorithm, calculates energy delivered and energy returned, thus providing continuous monitoring of energy flow. If there is any disruption of contact of tip to tissue, the device will decrease the amount of energy being delivered or completely shut off, virtually eliminating the risk of serious burns. This feature is termed; the energy flow control system. The advantage is that energy flow control allows use of high power (Watts) which then leads to faster treatment times while ensuring the greatest level of safety and comfort. The device also warns when RF is not being delivered.

Experiments have shown that the increased temperature effect is seen as much as 2 cm below the skin. The primary advantage of this system is the ability to target skin laxity or contour deformities. With a precise depth of penetration combined with the focused thermal effect due to advanced controlled cooling, the device can be utilized for full face and total body applications. This paper reviews our clinical experience with the Exilis® utilizing dynamic monopolar RF heating of skin and subcutaneous tissues in the treatment of skin laxity, rhytids, as well as circumferential contouring of the arms, thighs, knees and other areas.

MATERIALS AND METHODS

The study is a cohort study of 30 patients that were treated with the Exilis® device on the jowls and neck for rhytids and laxity as well as submental fat pad reduction. 28 patients were female and 2 patients were male. The age range was 31 - 66 years old. Additionally, 14 of the facial treatment patients were also treated for 'jiggly' fat pads or loose skin on the arms between the shoulder and elbow. Circumference was measured mid-

arm. The treatment target was fat pad and circumferential reduction and/or tightened skin. Patients were weighed and photographed before and after the study and were instructed to continue with their current lifestyle and not to change their nutrition, caloric intake or physical activity routines.

All study patients were treated for 4 treatments with each treatment per 7 - 10 days following our standard protocol. Arm areas were treated for 10 minutes for a 20 X 25 cm area, maintaining surface temperatures of 40 – 42 °C, but not higher. Facial treatments were performed for 5 minutes for each side of the face and 5 minutes for the underside of the neck maintaining temperatures of 40 – 42 °C but never exceeding 43 °C. Skin temperatures at the end of a treatment cycle were typically 40 °C which rapidly dropped at the conclusion of the treatment. The patients were treated lying down comfortably, with the treatment area exposed. Water based gel (face) or mineral oil (body) was applied to the treatment area prior to the onset of treatment. Baseline temperature prior to treatment was typically 32 °C.

The energy and treatment times were adjusted according to the area being treated. For the face typically 30 W with 100% duty cycle was used. For the body 50 – 80 W with 100% duty cycle was used. The RF applicator was applied to the skin, maintaining contact with the skin through each 30 second treatment cycle. Circular motions or two and fro motions were utilized to keep the tip moving over the treatment area. The key was not to allow the RF applicator to stop moving and to focus on areas of greatest concern. According to patient feedback the energy was adjusted up or down, as tolerated, to achieve a sustained surface temperature of 40 - 42 °C with a rapid slope up from baseline. Photographs using the Canfield Omnia system as well as circumferential measurements of the arms were two important endpoints. Photographs were taken prior to commencing treatment and at the final treatment day. Patient satisfaction was also queried.

RESULTS

All patients completed 4 facial and neck treatments in the study and final photographs were taken at the final treatment. Photographs were judged for wrinkle reduction, reduction of laxity and degree of improvement of submandibular fat. Significantly less laxity was observed in 14/15 patients (Fig. 1). A majority showed a reduction in the submandibular fat pad (Fig. 2). Cheeks and jowls demonstrated moderate to significant improvements in laxity and facial contours. In some cases rhytids were also less visible.

The average circumferential reduction for the arm contour patients was 2.1 cm (range 1.4 cm – 3.4 cm) (Fig. 3). All the treatments were well tolerated. There were no complaints of significant pain or discomfort during any treatment. During a treatment if the patient stated that an area was getting too hot then the treatment tip was moved to any adjacent area. No complications were reported, there were no skin burns. Typically minor erythema lasted 5 - 10 minutes. About 5% of patients reported soreness lasting less than 24 hours.

CONCLUSIONS

The use of a dynamic monopolar RF device (Exilis®) produces consistent and demonstrable improvement of skin laxity in our experience. It leads to circumferential reduction of the arms and reduction of submandibular fat pads. When compared to other RF devices on the market, the Exilis® appears to have the following advantages:

1. Exilis® works quickly to achieve the temperature elevation required for skin tightening.
2. Soft tissue heating is controlled by movement of the handpiece (dynamic) and is therefore virtually pain free, feeling more like a warm massage.
3. Skin safety with built-in circuitry to limit surges, continuous monitoring of skin temperature and timed application delivery.
4. Very low risk of side effects with none seen after hundreds of treatments.
5. Exilis® has versatile clinical applications; face and neck jowls and laxity can be treated, and body contouring can be performed.
6. Consistent, effective and desirable non-surgical outcomes are realized.
7. Ergonomically designed applicators are easy to use with less operator strain.
8. No expensive one-time use tip cost to the practice (minimal cost of grounding pad).

Exilis® dynamic monopolar RF tightening and contouring treatments can be a versatile, efficacious and economical addition to an aesthetic practice with a high benefit to cost ratio.

REFERENCES

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3. Hantash BM, Ubeid AA, Chang H, et al. Bipolar fractional radiofrequency treatment induces neoelastogenesis and neocollagenesis. Lasers Surg Med. 2009;41:1-9.

APPENDIX: BEFORE AND AFTER PHOTOS

Figure 1. Reduction of skin laxity.

Figure 2. Reduction of submandibular fat.

Figure 3. Reduction of arm circumference and arm laxity.