Pilot Evaluation of Radio-Frequency Assisted Liposuction (RFAL™)

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Abstract: This pilot study was conducted to evaluate the thermal effect and immediate response of human adipose tissue to RF energy applied during minimally invasive liposuction. The preliminary investigation showed efficiency of RF energy in creating the desired thermal effect, specifically effective pre-aspiration thermal coagulation of adipose and vascular tissue with uniform heating of the skin during a liposuction procedure.

Introduction

Liposuction is the most popular cosmetic surgical procedure. In the United States alone, nearly 750,000 lipoplasty procedures are performed annually. Lack of skin elasticity remains one of the most common relative contraindications for liposuction.

There are many non-invasive devices which can demonstrate some skin tightening after thermal cutaneous treatment using transepidermal RF and laser energy. Incorporating this thermally mediated dermal and soft tissue contraction effect into a liposuction procedure may provide significant skin tightening benefits for patients.

Recently, LAL, specifically Smartlipo™ has received a lot of media attention and gained strong physician popularity in cosmetic surgery [1-4]. The main reason for the surge in popularity is the proposition and expectation of a gentler contouring procedure and skin tightening improvement as result of laser thermal effect on collagen and connective tissue.

LAL is based on manual coverage of the subcutaneous treatment volume with optical fiber delivering laser radiation through a very small area fiberoptic, having diameter of 600 microns.

The main reported limitation of the LAL is relatively long treatment time [5] and focal burns.

In this current report, we summarize our preliminary data on the use of RF energy for simultaneous lipolysis, vascular coagulation and skin heating. The underlying concept of the treatment is based upon accurate, monitored and controlled pre-aspiration thermal destruction and coagulation of the adipose and vascular tissue with sub-necrotic heating of the dermis using RF energy.

Materials and Methods

The RFAL™ procedure was performed on 4 patients using the BodyTite™ system (Invasix Ltd.). The internal electrode was inserted into the adipose tissue at the desired depth as shown in figure 2.

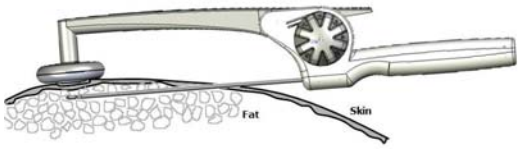

Figure 1. Bipolar RF hand piece inserted into the body.

This insulated internal electrode probe emits the RF current through a small conductive tip. The external electrode has a larger contact area and is applied to the skin surface creating lower power density in the skin than in the adipose tissue. 40 Watts of RF power was applied between the two electrodes.

The BodyTite device provides online, continuous skin temperature measurements with a negative feedback loop control of power

During the treatment the parameters of the BodyTite device were set so that the system would reach 40-42°C and maintain that target temperature for a consistent period of time.

In the current study we did not have objectives to evaluate the long term clinical effects, as our primary purpose was to test a new technology and its ability to create a uniform thermal effect of the treated area in a consistent and time efficient manner. We believe that this is the basis for effective lipolysis and skin tightening without significant risk of dermal injury. 4 patients underwent RFAL. All patients were female, with an average age of 42 years old. Two patients underwent outer thigh procedures and two hip and abdomen RFAL treatments.

We made evaluation of technologies using two treatment protocols:

1. In the first case we divided treatment areas of thermal zones with size of 5x5cm. Each zone was treated until skin temperature reached the end point of 40°C. The same thermal grid protocol was used in the LAL treatment.
2. The thermal elevation was so fast with the small 5 X 5cm grid protocol, that a second evaluation of larger thermal zones of 10x15cm were treated with the same thermal end point.

For both cases skin temperature was monitored by thermal camera and confirmed with a hand held infrared thermometer.

In order to assess the optimal parameters, efficacy, and safety while avoiding any side effects to the skin, the treatments were initially performed on two pre-excision abdominoplasty specimens, with a fat layer of 25-30mm. Tumescent anaesthesia was applied prior to the RFAL treatment. After confirmation of parameter safety and efficacy , RFAL was performed on 4 patients.

Our objective was to analyze the temperature distribution in the treatment area, assuming the importance of the thermal effect for skin tightening and to ensure early quality outcomes.

Results and Discussion

Small zone treatment

The Initial temperature of the skin prior the treatment was in the range of 27°C to 29°C.

The RFAL device used a power of 40W. Desired temperature was reached in 60sec. After this time period we continued the treatment of the zone for additional 2 minutes. During this maintenance period, the BodyTite device adjusted RF power automatically to maintain skin temperature at predetermined level. Figure 2 shows thermal images of skin surface during the treatment.

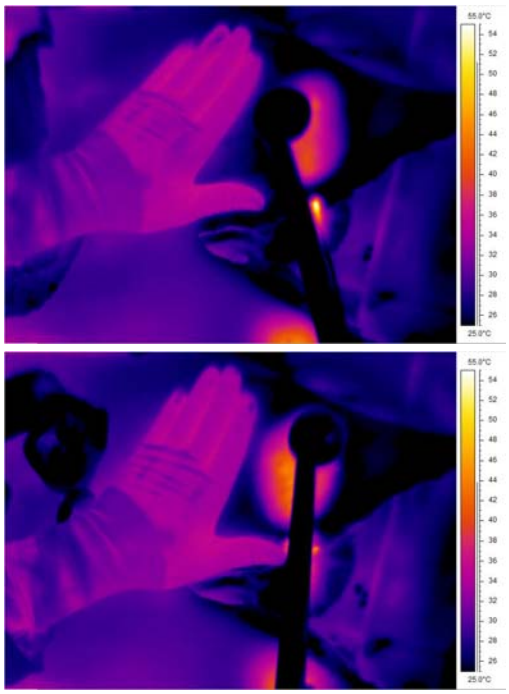

Figure 2. Typical thermal image of the small treated zone at after 30sec (top), 60sec(center) and after 180sec (bottom).

The treatment of such a small Thermal zone was not very efficient because of the difficulty controlling small handpeice movements and the rapid rise in temperature.

Heating to a significant target temperature in each thermal zone was very fast but high speed thermal heating did not result in the appearance of “hot spots”, or areas of focal thermal excess, which is common with LAL. After 60 sec skin temperature reached 40-42°C and this target temperature was able to be maintained for several minutes over the entire treatment areas, with continuous feedback temperature control.

BodyTite treatment protocol

RFAL treatment of a large 15cm X 10cm area was quite effective, fast and uniform . After 5-6 min and an average of 15KJ at 40W, the temperature of the zone reached end point of 40-42°C. Figure 3 shows thermal distribution of treated area before the treatment and after 90sec, 210sec and 300sec after the beginning of the treatment

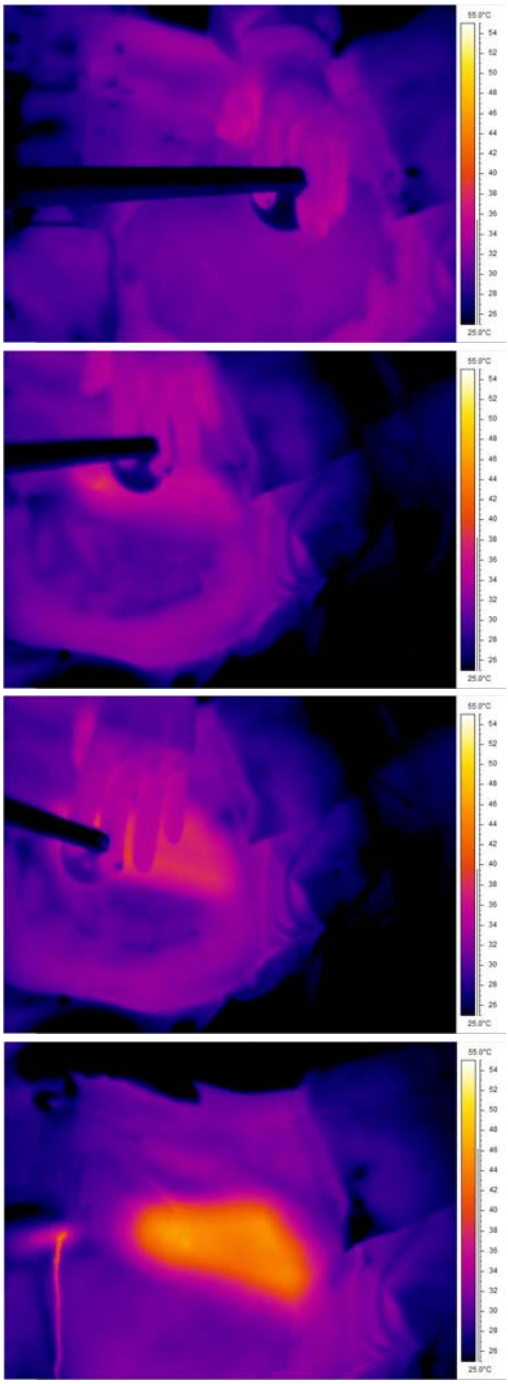

Figure 3. Thermal image of the large treated zone before the treatment and at after 90sec, 210sec and 300sec (from top down).

The thermal video images of the treated zones reveal an extremely uniform temperature distribution. Hot liquefied fat was observed leaking from the incision port on the thermal images.

Observation of the post thermal coagulation and aspirated adipose tissue, shows effective coagulation of fat and blood vessels post RFAL treatment. Figure 4 shows a cross section of abdominal tissue with RFAL treated and non-treated zones.

One can see that after the RFAL treatment blood content is significantly reduced due to coagulation of blood vessels by the RF current, which acts in the same manner as surgical RF bipolar electrocautery. During aspiration of the RFAL cases, the color of fat was devoid of blood after the treatment indicating its coagulation.

We noted that the subdermal vascular plexus and arcade was not damaged and bleeding of the skin was normal indicating safety of the method for the skin.

The four RFAL patients underwent their body contouring procedure without complication. The postoperative reports of pain, discomfort and bruising were remarkably diminished and good early skin contraction was achieved.

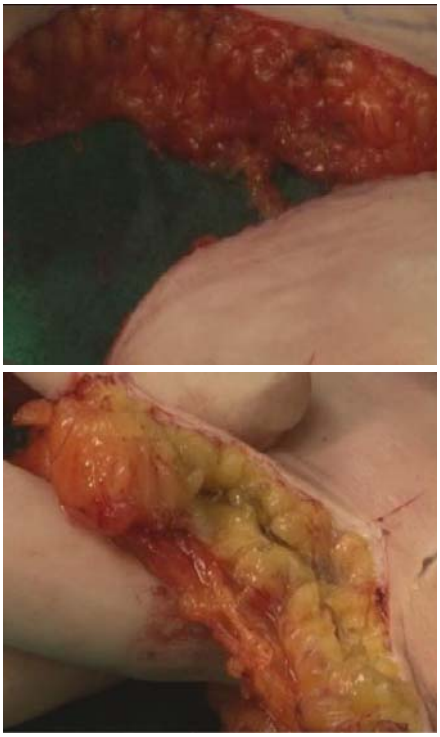

Figure 4. Cross-section of human fat and skin Top-untreated tissue, Bottom-RFAL treated tissue

Figure 5 shows a patient who underwent a RFAL outer thigh reduction with excellent early results and another patent with abdominal and hip contour enhancement and skin contraction.

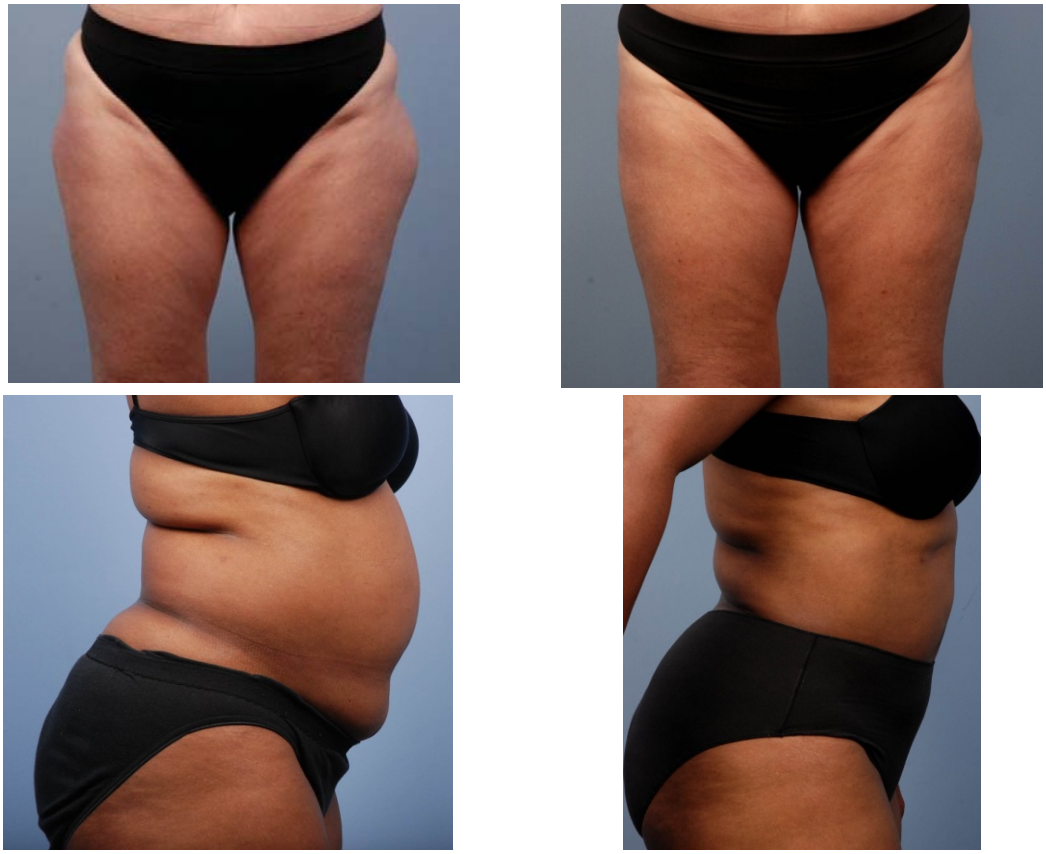

Figure 5. Before (left) and 6 weeks post treatment (right) images for 2 patients treated with RFAL.

Conclusion

In this study we witnessed some significant advantages using RFAL technology including its ability to heat uniformly both small and larger thermal areas. RFAL demonstrated a very rapid adipose heating speed with excellent uniformity. Our early clinical experience suggests signification skin contraction, but more quantitative and objective measurements of the effect of tissue heating on skin tightening and the healing process will be reported in further investigations. Skin contraction aside, we believe that a more uniform thermal adipose tissue and blood vessel coagulation allows for a less traumatic fat aspiration with less bleeding and less post operative bruising, edema and pain. The RFAL technology demonstrated a tremendous ability to heat skin and sub-dermal fat to the desired temperature and then, with a feedback control loop, maintain that temperature for prolonged periods of time. It is both the absolute temperature and the duration of exposure that will determine skin contraction after heating based liposuction procedures. We believe that the safe, effective and rapid RF thermal component incorporated in RFAL™, minimally invasive body contour procedures represents a significant advance in less morbid liposuction procedures and affords optimal skin contraction for those patients with questionable skin laxity.

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