An In-Depth Examination of Radiofrequency Assisted Liposuction (RFAL)

by
Dr R Stephen Mulholland
MD, FRCS(C)
Plastic Surgeon
Toronto, Canada
and Los Angeles, CA

INTRODUCTION

There are a myriad of liposuction technologies and devices available to physicians to serve the rapidly growing body contouring market. The most successful and appealing of the liposuction technologies are the newer energy-assisted systems, which have evolved from Ultrasound-Assisted Liposuction (UAL) to Laser-Assisted Liposuction (LAL), and, finally, to the newest and most versatile member of the family, Radio Frequency Assisted Liposuction (RFAL), which is a subject of the current evaluation.

TECHNOLOGY DESCRIPTION

RFAL is based on delivering directional RF energy into the subcutaneous fat to coagulate and liquify adipose tissue and gently heat the subcutaneous fibrous matrix and the dermal tissue to sub-necrotic contractile levels. The thermal energy is delivered by an innovative handpiece comprised of two electrodes; the internal electrode is inserted into the fat layer, while the other, which is attached to the hand-piece through an eccentric spring-loaded mechanism, is applied externally to the skin surface (Figure 1). The hand-piece and the internal cannula-electrode is passed through the subcutaneous fat to be contoured as you would with any liposuction cannula.

Figure 2 shows the distribution of RF energy between the internal and external electrodes, demonstrating divergence of current from the small tip of the internal cannula, up towards the external electrode on the skin's surface.

The internal electrode has a dual purpose, first as a source of RF energy and secondly as a concurrent aspirating cannula. The small internal conductive tip delivers RF energy into the fat and houses the proximal aspiration ports that remove coagulated tissue from the body. This simultaneous energy delivery results in coagulation of adipose, fibrous and vascular tissue, followed by their immediate aspiration allowing for a one-stage procedure that increases speed and efficacy and safety of the treatment. The configuration of the two electrodes delivers the RF energy across a large surface area, creating a gentle uniform heating of the subcutaneous and dermal layers. All RF energy applied to the patients' adipose tissue and skin is concentrated between the electrodes and is utilised maximally for adipose coagulation and skin contraction without risk of heating deeper structures.

The RFAL platform is called BodyTite (Invasix Ltd, Israel) and it is the first device in the market to use RF energy for liposuction and skin tightening. The unique features of BodyTite, makes it a safer, faster, more uniform and less traumatic treatment with significant and consistent skin contraction.

To increase safety measures, the BodyTite has real-time skin temperature monitoring through a thermal sensor embedded within the external electrode. The physician can preset the desired temperature level that they wish to heat the skin and the device will automatically switch off RF power when the cut-off temperature is reached and then turn power on when the skin has cooled down below the target temperature or the hand-piece is moved to the area with lower temperature.

This continuous temperature feedback loop allows the surgeon to achieve a target uniform temperature distribution over the treated volume (most often 40-42°C, Figure 3) without localised hot spots or undertreated zones, which is common with laser lipolysis systems. For safe, effective thermal treatment and subsequent skin contraction, it is important to not only reach the desired target thermal effect, but also to maintain it for a period of time to improve consistency without compromising the safety.

The ideal liposuction procedure should have the following features:

1. **Speed of Treatment:** Fast treatment speed, to save time for physicians as well as cost for patients.

2. **Lipolysis:** Effective coagulation and liquefaction of adipose tissue favours a more gentle aspiration and uniform results.

3. **Blood Coagulation:** Coagulation of blood vessels just prior to aspiration helps to avoid significant blood loss during high volume liposuction and reduces post-operative bruising and ecchymosis.

4. **Skin Tightening:** A liposuction system that consistently and effectively induces significant contraction of the skin and subcutaneous envelope can treat patients with larger volumes of fat and/or those with skin laxity.

5. **Safety and Uniformity:** There must be features built into energy assisted liposuction systems that ensures the safe delivery of heat, protection of the skin from burns and uniform energy delivery to avoid hot spots and undertreated zones.

SPEED OF TREATMENT

For optimal three-dimensional soft tissue contraction, it is critical to have adipose and fibrous coagulation through the entire thickness of subcutaneous tissue, and the liposuction technology must be powerful enough to perform the coagulation and aspiration in a reasonable time.

RFAL treatment speed is outlined below for a treatment area of 20x20cm (8"x8"), fat thickness of 2.5cm (1"), and an aspiration volume of 1000cm^3 (one litre). Taking in account that the heat capacitance of fat are similar to water, in order to increase the temperature of this volume of adipose tissue from 30°C up to 50°C, the required energy is approximately 80kJ. In order to complete the thermal and treatment of this area with an RF device generating 50W of power, less than 30 minutes is required and for 75W of RF energy, approximately 15 minutes. Table 1 shows the correlation between device power and treatment times for the above-mentioned volume of one litre in a 2.5cm thick flap.

Table 1: Treatment time for 1L volume vs. device power.

Power (W)	Treatment time (min)
25	52
50	26
75	17

Simultaneous aspiration, coagulation and thermal contraction, makes RFAL a single-stage procedure. By performing liquefaction, blood coagulation, skin tightening and fat aspiration simultaneously, RFAL saves operating time and facilitates more profitable outpatient procedures.

Comparison of RFAL aspiration speed with a standard Mercedes liposuction cannula each with the same diameter, was conducted with a split body treatment. Measurements of aspirated tissue volume after 20 minutes of treatment showed 490ml fat extracted with RFAL, compared with 420ml with the regular cannula. RFAL demonstrated a 17 percent higher aspiration speed in spite of less intensive cannula work. The increased speed of RFAL over SAL is likely the result of the lower viscosity and increased flow following Poiseuille's law.

LIPOLYSIS

The adipose coagulation process is a function of time and tissue temperature. For a period shorter than one second the coagulation temperature of tissue is above 60°C while after applying RFAL for a few minutes duration, it is enough to

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maintain 50-55°C to reach coagulation.

RFAL technology allows the surgeon to monitor and control epidermal temperature to avoid thermal skin damage and maintain a higher internal temperature for as long as required to reach optimal effect. Whereas lasers will get the sub-dermal temperature just to an end point, and stop, RFAL can reach an optimal end point and, through continuous tissue temperature monitoring and power control, maintain the target temperature as long as required. BodyTite is very effective at creating profound, uniform heating of both the subcutaneous adipose fibrous matrix, as well as the sub-dermal envelope. Over-heating of the adipose tissue is prevented by continuous on-line monitoring of the high and low impedances', with RF power cut-off. The coagulation of fat reduces its mechanical integrity and favours a gentle, non-traumatic aspiration. For the patient, the results are less pain, bruising, swelling and downtime. For the physician, pre-aspiration coagulation results in less physical exertion and more uniform fat extraction.

In a comparison of human adipose tissue from an abdominoplasty patient where one side was untreated (Figure 4a) and the other was pre-treated with RF (Figure 4b), it is evident that after the RFAL treatment, the fat structure was more lobular, became less dense, less bloody and the fat layer was contracted. In addition, RFAL aspirate comprises of more fat tissue and less serum and blood, indicating a less traumatic fat aspiration.

Histological observations show the disruption of adipocytes, following the RFAL treatment. Figure 5a shows typical histology of an untreated, controlled fat sample, while Figure 5b illustrates the canal created by the cannula with the debris of fat cells and connective tissue around the canal demonstrating the thermal damage of surrounding tissue.

BLOOD COAGULATION TO REDUCE BRUISING

Blood coagulation is critical to reduce bleeding for high-volume liposuction procedures and for reducing post-operative bruising and ecchymosis. RF power concentrated in vicinity of internal electrode tip creates thermal coagulation of tissue including blood vessels. It is not always possible to totally avoid bleeding during an RFAL procedure, but the haematocrit in the aspirate is always less than in traditional liposuction.

In a histology analysis, Figure 6a shows a strong concentration of haemoglobin and red blood cells in the adipose tissue after traditional liposuction. Blood vessels are mostly damaged due to disruption during the aspiration stage of procedure. After the applying the RF energy, most of the blood vessels are coagulated, as is shown in Figure 6b.

SKIN TIGHTENING

RFAL procedures incorporate efficient heating of the skin and sub-dermal tissue, as well as the vertical fibrous septa of the adipose tissue, causing significant contraction of collagen in the dermis and sub-dermal connective tissue. The initial contraction study shows a 15 percent average linear skin contraction immediately after treatment. In observations of 10 patients, 12 weeks post BodyTite treatment, results show that skin tightening and soft tissue contraction continues steadily during this period with final results from 14 percent to 42 percent with average contraction of 31 percent.

The RFAL soft tissue contraction was measured as a change in the distance between two points, where either incision ports, umbilical and natural pigment signs were used as marks for tightening measurements. Figures 7, 8 and 9 show patients before the treatment and 12 weeks after the procedure.

Critical to tightening is the ability to effectively deliver a thermal stimulus to the whole thickness of the adipose tissue. This includes the ability to heat the deeper adipose layers uniformly without overheating and then elevating more superficial tissue temperature to a target level of 40-42°C, and maintaining this for the duration of several minutes. The longer a surgeon can keep the tissue at the critical temperature, the better soft tissue contraction treatment results were observed.

SAFETY AND UNIFORMITY

With BodyTite's real-time, continuous measurement of skin temperature and internal impedance, with feedback power control based

upon this target temperature and impedance differences, physicians can be assured they are using the safest and most effective energy assisted liposuction devices on the market.

To further increase safety measures, there are additional built-in impedance measurements. During treatment, BodyTite detects the varying levels of density and fibrotic tissue in the treatment area and automatically adjusts energy output to provide a precise and uniform treatment. High resistance zones (fibrous tissue or boney tissue) will trigger a high impedance default where RF energy is reduced. The energy delivery is cut off if one of the electrodes does not have contact with the skin's surface or is too close to the skin's surface, offering physicians an additional dimension of safety during treatment. Finally, there is anti-carbonisation

Figure 1: RFAL hand-piece with internal electrode at the tip of the cannula, and skin sensor embedded in the external electrode.

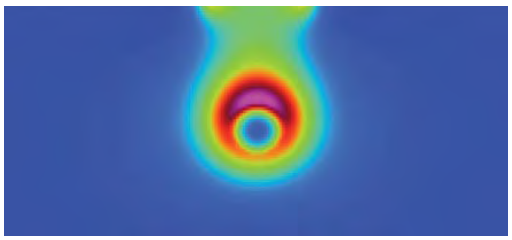

Figure 2: Temperature distribution between internal and external electrodes.

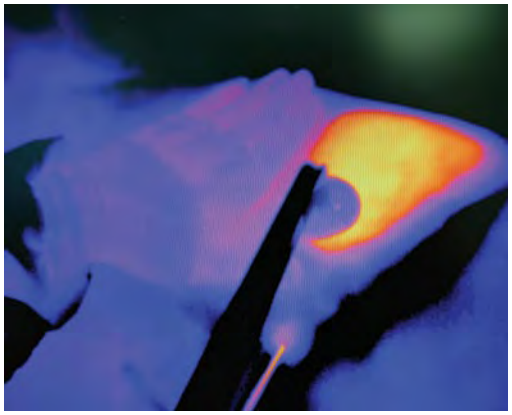

Figure 3: Uniform temperature distribution using RFAL captured with a thermal camera.

Figure 4a: Cross-section of untreated adipose tissue from an abdominoplasty patient.

Figure 4b: Cross-section of RFAL-treated adipose tissue showing more lobular, less dense, less bloody and contracted fat layer.

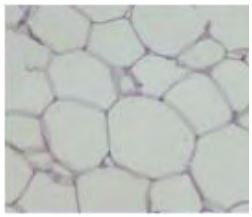

Figure 5a: Histology of controlled fat sample.

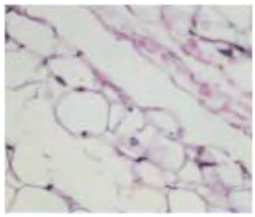

Figure 5b: Histology of fat after RFAL treatment.

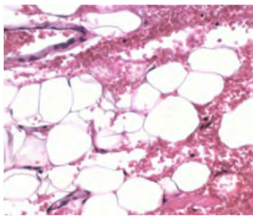

Figure 6a: Histology of fat showing high concentration of haemoglobin and red blood cells after standard liposuction.

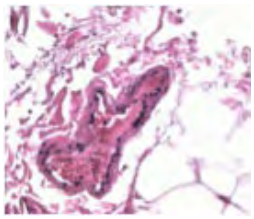

Figure 6b: Coagulation of blood cells after RFAL treatment.

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protection whereby energy is automatically cut-off during treatment if carbonisation builds on the internal electrode.

An audible sound is emitted when the skin temperature is within a few degrees of the desired user-programmed setting. This provides the physician a signal that a critical temperature has been met and there is uniformity of heat. In addition, the physician can focus on treatment, rather than having to refer back to the device screen for temperature measurements.

CONCLUSION

RFAL technology shows superior coagulation and contraction results in comparison to other liposuction methods without compromising treatment speed. The ability to liquify fat, coagulate blood vessels and tighten skin safely and effectively while simultaneously aspirating makes BodyTite the most effective body contouring device on the market.

The added value of RFAL technology for lipo-contouring physicians is the ability to treat patients with higher volume of adipose tissue with mild to moderate skin laxity. In addition, BodyTite can provide skin-tightening benefits in difficult areas such as the arms, inner thighs, bra line, knees and neck. The patient benefit of RFAL is less pain, bruising, swelling and optimised skin contraction.

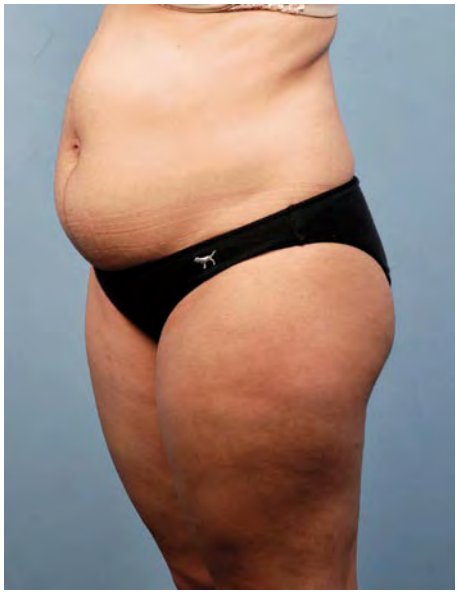
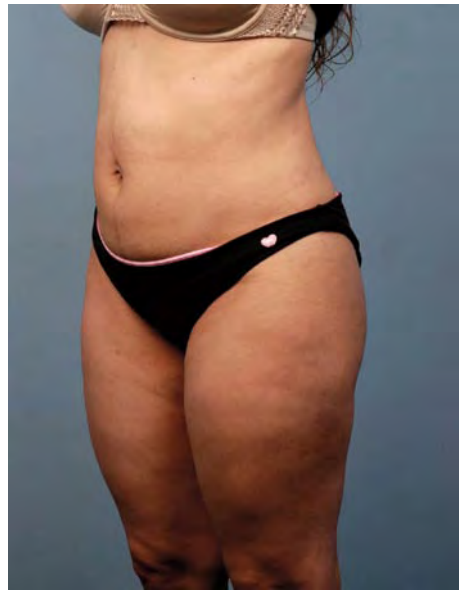


Figure 7: BEFORE



AFTER

Figure 8: BEFORE

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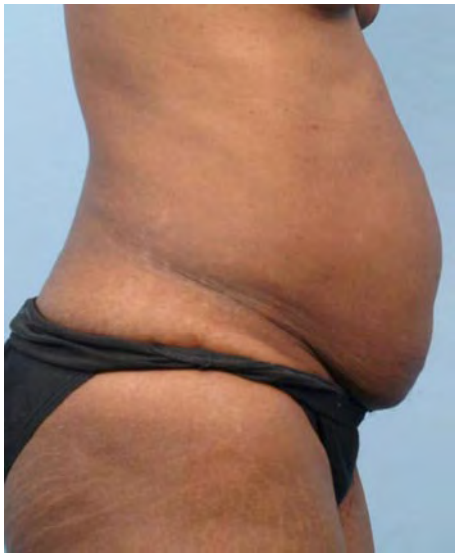
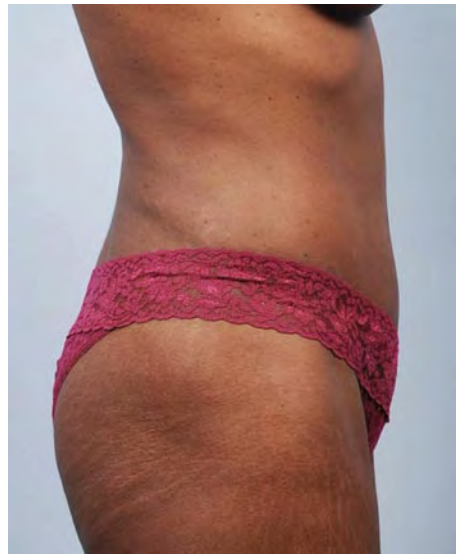


Figure 9: BEFORE



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