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Internal and External Radiofrequency Assisted Lipo-Coagulation (RFAL) in the Control of Soft Tissue Contraction during Liposuction: Part 1 “Inside Out” Thermal Tissue Tightening

Robert Stephen Mulholland

Abstract

Radiofrequency Assisted Lipo-coagulation (RFAL) BodyTite is a contact, impedance, internal and external thermal regulation controlled, internal, minimally invasive, non-excisional procedure providing soft tissue lipo-coagulation and contraction that has been used for over 10 years to optimize skin and soft tissue contraction during liposuction procedures. The device deploys a bipolar applicator inserted into the liposuction zone. The internal, coated, electrode is positively charged and emits a coagulative, ablative injury that results in adipose liquification and Fibroseptal Network (FSN) contraction. The RF flows from the internal electrode after ablation and coagulation up to the external negatively charged return electrode moving on the skin, which heats and tightens the papillary dermis non-ablatively. The body areas that most benefit from this BodyTite technology and procedure include those areas most in need of non-excision contraction include the abdomen, upper arms, inner thighs, bra-line, neck and jaw line. Studies, show, that the combination of BodyTite internal thermal coagulation and external Morpheus8 (see Part 2) at the time of liposuction can result in 40–70% area skin contraction, greatly improving the soft tissue contours and Body shaping outcomes following lipo-contouring procedures.

Keywords: Liposuction, Radiofrequency, BodyTite, Morpheus8, Soft Tissue contraction, RFAL Skin Tightening, Cellulite, Stretch Marks, Mommy Make overs, Tummy tuck, Armlift, Brachioplasty and Thigh Lift

1. Introduction

This is an opportune time for Dr. Duncan's IntechOpen book on “Enhanced” Liposuction. Liposuction and body contouring is the world #1 surgical procedure. For the modern Liposuctions surgeon, the simple removal of fat has been replaced with adipose contouring in concert with the soft tissue contraction and skin remodeling to deliver body shaping enhancement with an optimized skin

envelope. We might even call this book “Enhanced Lipo-contraction”, as many times, in smaller areas we are not aspirating fat. Our current Lipo-contouring patients include older patients with laxity, younger patient with atrophic striatum and encompasses soft tissue contouring and remodeling of the periocular, perioral, jawline, neck and all body areas, including formally “too risky” zones such as the lax upper arm, bralaine, inner thighs and post weight loss abdomens and mommy tummy’s. In the current body contouring market, the modern liposuction surgeon must invest in energy based internal devices and technology that offers “enhanced liposuction” to address the diverse and challenges needs of suboptimal skin elasticity and contours.

As a result of InMode’s innovations and development of RFAL technology, there has been the creation of a whole new market segment they have call the GAP patients [1]. RFAL or BodyTite treatments can often provide results that are reasonably comparable to a modest tummy tuck, arm lift or thigh lift procedures, but without the extensive scars [2–8]. This RFAL procedure can bridge the gap between non-invasive treatments with very minimal/modest results, minimally invasive treatments that lack the soft tissue contraction, or safety of RFAL and the standard open plastic surgery excisional procedures (**Figure 1**).

The FaceTite, AccuTite RFAL applicators and the Morpheus8 percutaneous OUTSIDE-IN RFAL remodeling tips are all available on the BodyTite workstation, as well as the Embrace RF and EmpowerRF workstations. Each applicator and Hand piece was specifically designed, engineered, produced and sold to serve a very large and growing market segment in the esthetic plastic surgery space; that is, the non-excisional Body contouring, face and neck lift and *GAP skin tightening market*. Non-excisional skin tightening technology and procedure growth has shown 30–40% year-over-year growth rates over the past five to eight years.

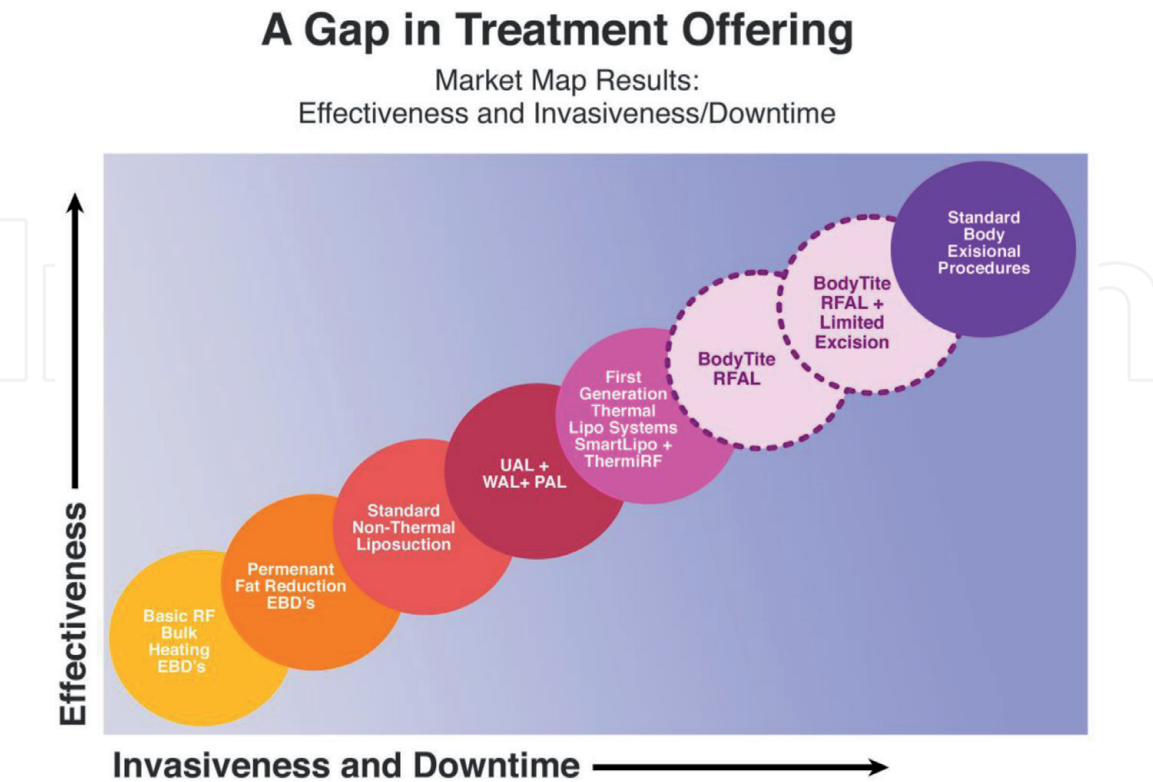


Figure 1. BodyTite RFAL procedures can serve as a GAP procedure between non-invasive, non-thermally invasive and standard excisional procedures.

2. Basic science of RFAL

2.1 Understanding RFAL and “enhanced liposuction”

Over the past 25 years, I have had the benefit of working with virtually every major external and internal energy-based device (EBD). As an EBD physician, I feel fortunate to have been practicing through this 2 decades plus renaissance in the non-excisional EBD face and body contouring. All of the major technologies I have used have their advantages and disadvantages and like all tools, a good tradesman gets good with what they have. The Astute surgeon will quickly be able to see the InMode BodyTite workstation, although not the cheapest, offers the most versatile, safe and effective GAP procedure offerings lipo-coagulation and contraction of the Face, Neck and Body and thus, the extra money of capital outlay, result in a multiple of ROI that make the purchase price differences compared to its competitors worthwhile.

It is now irrefutable that thermal stimulation of the deep subcutaneous and sub-dermal space works to achieve a degree of lipo coagulation and skin contraction that exceeds non-thermal techniques alone. The excellent work of Dr. Barry DiBernardo using a laser lipolysis system (SmartLipo, Cynosure) has shown a good 17% area contraction, 25% increase in dermal thickness and 29% increase in skin elasticity following sub-dermal thermal stimulation using a laser fiber [9]. This SmartLipo study was measuring only the thermal control of the subdermal space and skin contraction. The limiting factor in the 15–20% skin tightening component of soft tissue contraction is the thermal safety features of devices that work directly under the skin. Most of these devices (Vaser, Laser, Plasma or mono-probe RF) you would be hesitant deploying then on the face, eyelids, or neck, or even low-fat content small body areas where the incidence of burns and seromas' would be too high. The medical-legal liability of not using a state-of-the-art enhanced, automated external and internal thermally controlled Lipo-contouring device as the “standard of care” would be a decision that would be very hard to defend.

Because of the risks of thermal injuries and burns, prior to InMode and RFAL, most technologies sell features and tissue effects that work in the deeper adipose tissue. Ultrasound (VaserLipo), Laser (SmartLipo), Plasma (Renuvion) and mono-probe internal RF, are all most safely deployed in the adipose tissue, NOT IN THE immediate Subdermal space. All these competitive energy devices have value and benefit, but I will also highlight in these two chapters why the BodyTite, workstations provide the most effective “Total Tissue thermal contraction” (adipose + Skin) and bulk heating, in the safest construct, with automated feedback RF and thermal control, facilitating the industry leading 60–70% contraction **IN ALL TREATMENT** areas from the delicate eyelid tissue to large abdominal collections. It is this “**Total Tissue**”, bulk heating, thermal control and contraction proposition and the far more **ROBUST ROI from its safety and versatility**, that continues to have InMode as the world's leading Thermal Contraction System **BY FAR** [10–15].

As physician owners you can deploy your AccuTite anywhere on the face, from the brow and lids, midface, perioral region and neck and the Morpheus externally for tightening and wrinkle reduction; the FaceTite on the jawline and neck, upper arms, breasts and BodyTite on all body areas with the Morpheus used in combination from the outside-in. With the BodyTite applicators you get your 20–25% skin contraction with safe predictable subdermal and transdermal work (Morpheus) and the FSN contraction of 40% the RFAL inside applicators.

The BodyTite, FaceTite, AccuTite and Morpheus Contraction Formula = Total Tissue Contraction = the summative effect of

RFAL FSN	30–40%	+
Morpheus Subdermal	15–20%	+
= 60–70% Total Tissue contraction		

2.2 What is RF?

RF, or Radiofrequency energy is part of the electromagnetic spectrum, with a frequency range that is dependent upon the industry and device. In medicine, in general, radiofrequency energy is high frequency alternating electrical current that operates in a frequency in the range of 100 kilohertz to 6 megahertz (**Figure 2**). The most common frequency of medical equipment alternating electrical current is one million cycles per second. The RF deployed in esthetic medicine is generally a pure thermal effect (the InMode BodyFX and Evolve TRIM being the exception, where its effects are both thermal and electroporation). The action potentials of nerves are not sensitive to RF current at the frequencies deployed in esthetic medicine (*one million cycles/second*) [16].

The FaceTite, AccuTite, BodyTite and CelluTite RFAL technology uses an alternating electrical current operating in the frequency of one million cycles per second. When one looks at the electromagnetic spectrum in medicine, very low frequency energies such as iontophoresis are deployed in medical devices. This is followed by radiofrequency energy, microwave, infrared laser and light devices, visible laser and light devices and x-ray systems. In the cosmetic space, radiofrequency energy has been deployed internally for surgery with necrotic and ablative devices, such as monopolar and bipolar electrocautery, or the classic Bovie, as well as non-ablative external devices, such as Thermage or the moving non ablative, temperature-controlled RF system from InMode the Forma.

At a cellular level, the alternating current of radiofrequency flows between positive and negatively charged electrodes of the device. The alternating nature

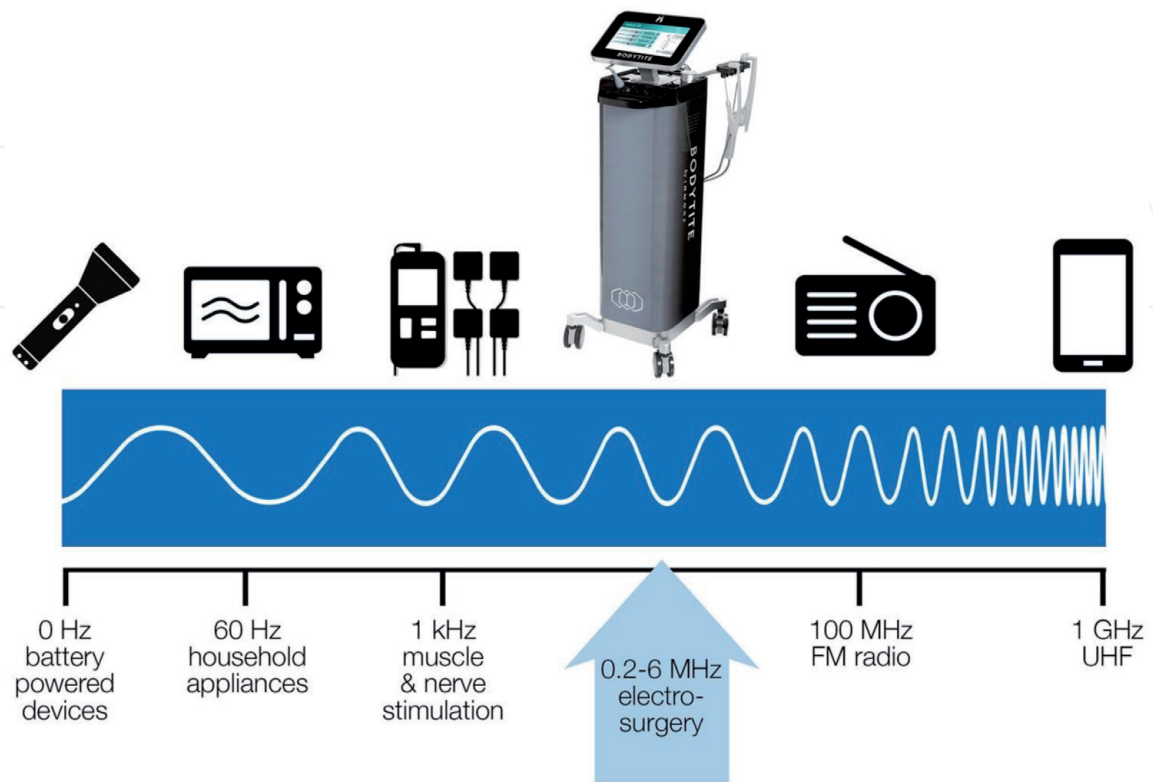


Figure 2.
The electromagnetic spectrum and commercial devices and where RF energy and the esthetic space resides.

of the radiofrequency current causes micro-oscillations in molecules throughout the tissue the RF is flowing through. The micro-molecular motion and micro-oscillation results in heat and heat is a final end pathway to the desired therapeutic effect of radiofrequency energy. There are three main types of radiofrequency thermal effects and InMode through and its various Esthetic workstations, deliver all types of RF injury to tissue and biological systems: (i) RF Ablation of Tissue



Figure 3.
The 40 watt BodyTite RFAL workstation. RFAL heats in an automated fashion the soft tissue at the optimal “rate of rise of temperature per volume of tissue”, an automated BodyTite feature called temperature Surg protection or TSP. optimal thermal volumetric velocity, as determined by in-vivo studies, is <20 degrees Celsius/cm3/second. BodyTite RFAL will deliver just the amount of energy needed to heat a volume of adipose at this rate (rarely the whole 40 Watts are required). TSP is the automated control of this rate of rise. If the rate of rise of temperature rises to between 20 and 35 degrees Celsius, then the BodyTite workstation will automatically drop the power to the system, lower the RFAL energy on tissue until the adipose temperature quickly returns to less than 20 degrees celsius/cm3/second. Importantly, if the rate of rise of adipose tissue is >35 degrees/cm3/second then the energy to the BodyTite workstation is cut-off and the user hears dull, flat “TSP audible”. By the time the BodyTite user repositions the RFAL hand piece and takes the foot of the pedal for a second, the adipose tissue temperature will drop, allowing the physician to begin treatment again.

(ii) RF coagulation of tissue and (iii) RF subnecrotic, non-ablative heating of tissue. The BodyTite workstation provides the physician the versatility of combinations of these 3 tissue effects [1]. (For more on details on the Basic Science of Radiofrequency energy, see Dr. Kriendel chapter on the same in this book.)

2.3 What are the BodyTite and RFAL specifications?

BodyTite is the RFAL (Radiofrequency assisted Lipo-coagulation or Liposuction) applicator used for lipo-coagulation and Suction Assisted Lipoplasty of moderate to larger sized patients. And is powered by the BodyTite Workstation (**Figure 3**). The BodyTite 2.4 mm diameter applicator has an internal electrode that is silicone coated, silastic capped and 2.4 mm in diameter and 17 cm long. In international (in non-USA markets) there is also a BodyTite 3.9 mm diameter internal electrode, with a 25 cm applicator, which shares the exact same thermal and monitored safety features as the 2.4 mm RFAL applicator. The FaceTite is a 1.2 mm internal electrode that is 12 cm long. The Facetite external electrode is proportionately much larger in diameter than the BodyTite 2.4 mm applicator. The smaller RFAL BodyTite applicator external electrode geometry means the power density and RF skin heating capability is much more efficient than the FaceTite (**Figure 4**).

The BodyTite workshop station can emit up to 70 W of energy and this is more than enough for large volume lipo-contouring patients because of the much higher power density of the smaller 2.4 mm RFAL external electrode. 120 seconds of continuous treatment time is allotted before having to double click the foot pedal. The surgeon does not enter the fluence, rather the machine delivers only the amount of RF energy needed to ensure the rate of rise of tissue temperature is <20 degrees Celsius/cm³/second.

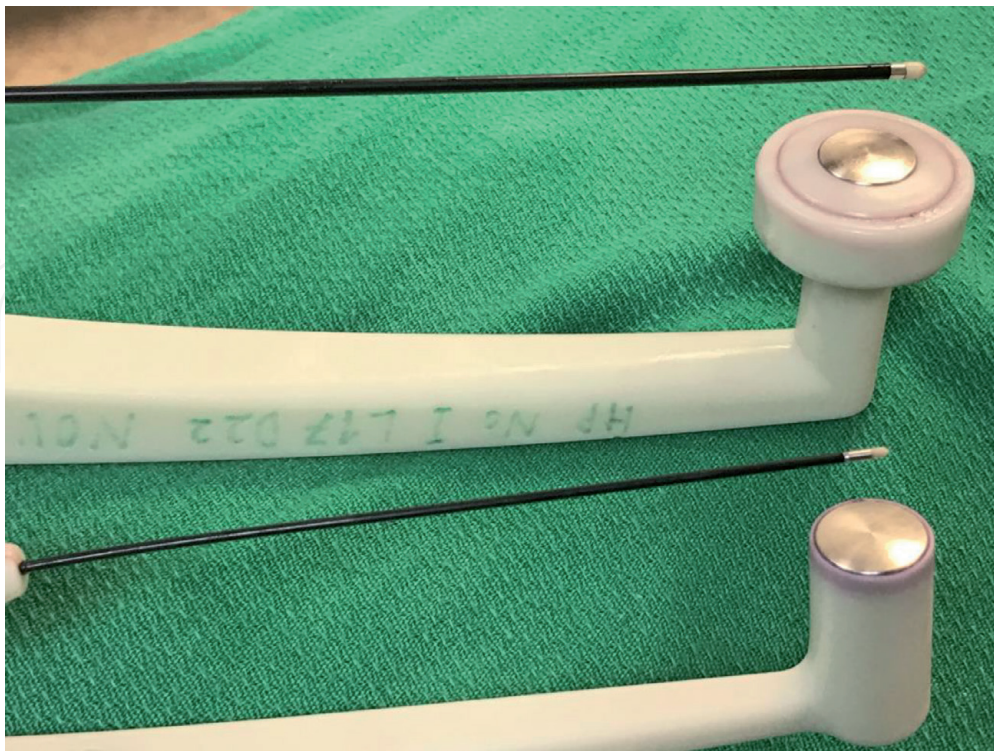


Figure 4. The BodyTite external electrode (top) is much smaller than the FaceTite (bottom), with a larger internal RF emitting electrode (2.4 mm vs. 1.2 mm) and this creates a much stronger power density and coagulation for at the same wattage. Up to 70 W of energy will be emitted automatically, as much as is required (raising and lowering automatically) depending up the rate of rise of adipose tissue.

Unlike the FaceTite, where the distance between the internal and external electrode is controlled simply by pinching the proximal hand piece, which brings the two electrodes closer together to achieve the desired inter-electrode distance, with the BodyTite RFAL hand pieces there is electrode dial to set the desired inter-electrode distance. With the BodyTite, there is an actual dial on the hand piece that controls and fixes the distance between the electrodes. There is a relative scale for the inter-electrode distance (**Figure 5**).

Practically speaking, each number on the Inter-electrode distance dial, corresponds to the number of centimeters between the external and internal electrode (**Figure 6**).

Level	Inter-electrode Distance (approximate)
Level 1	1.0 cm
Level 2	1.5 cm
Level 3	3.0 cm
Level 4	4.0 cm
Level 5	5.0 cm
Level 6	6.0 cm

The high tech, industry leading thermal, high and low impedance, contact sensed, and TSP safety features are the same for the BodyTite as for the FaceTite. The internal electrode is silicone coated with silastic, bullet shaped cap on the end and has thermistor temperature-controlled RF release and adjustable cut off temperatures as high as 70 degrees Celsius. The External electrode houses the contact sensor, external skin thermistor for continuous temperature-controlled skin temperature monitoring, with cut offs ranging from 36 degrees – 42 degrees Celsius, high and low impedance sensor and finally, the Temperature Surge Protection sensor (**Figure 7**).

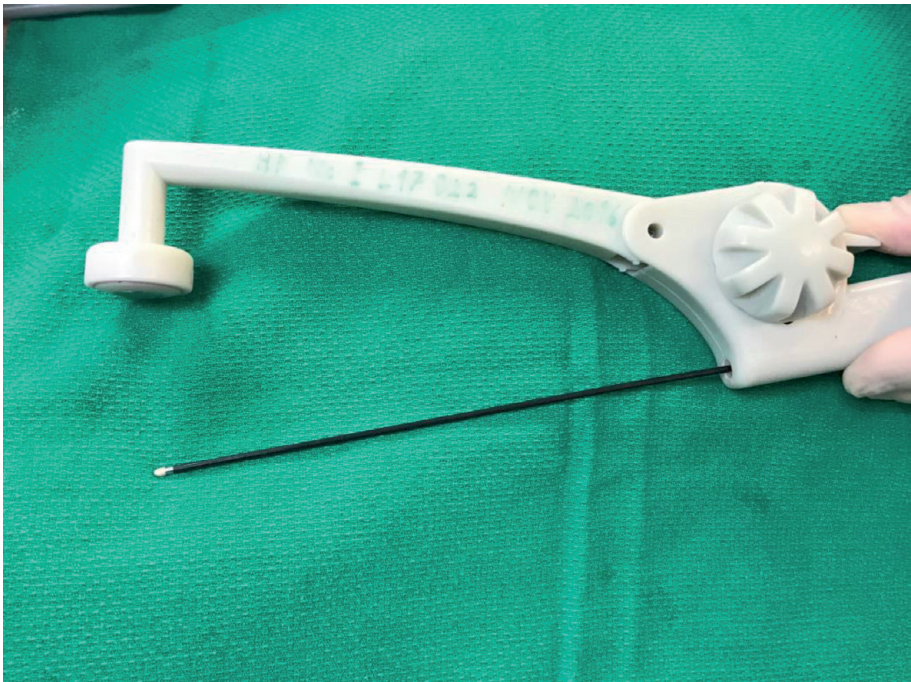


Figure 5.
On the BodyTite RFAL handpieces, there is an inter-electrode distance control dial, numbered 1–6, which determines the distance between the internal and external electrode.

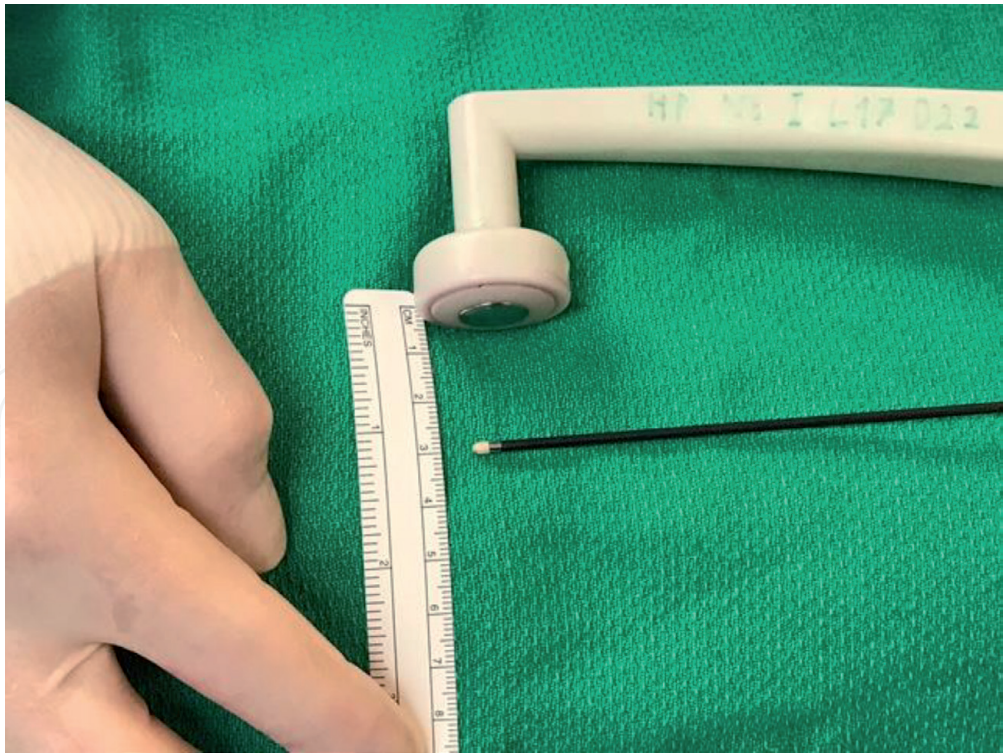


Figure 6.
The dial has settings numbered 1 through 6. Below is the practical inter-electrode distance for each level on the BodyTite dial.

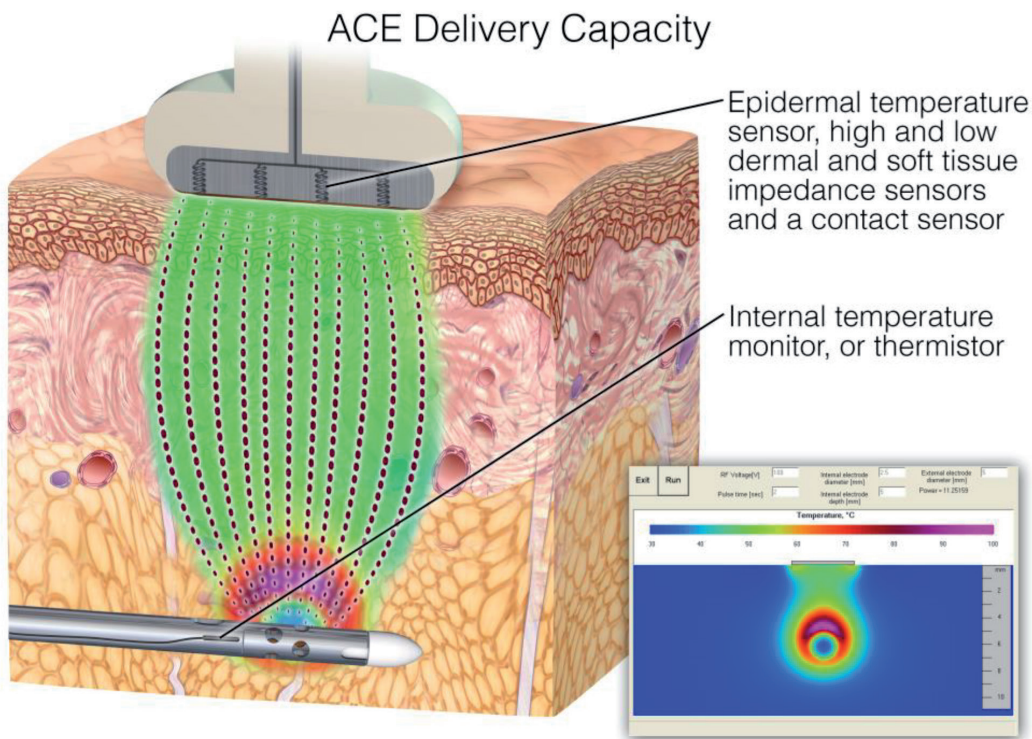


Figure 7.
BodyTite handpiece. RF flows from the internal electrode, where the temperatures are very strong and coagulative, with FSN contraction and adipose liquefaction, to the external electrode where the temperature is more moderate and the effect is a non-ablative heating, remodeling and tightening of the papillary and reticular dermis.

Over the past 10 years, through constant RnD and innovation, InMode has delivered to the marketplace and its physician users increasingly smaller and smaller, more elegant RFAL handpieces, culminating in the AccuTite (and Aviva on the

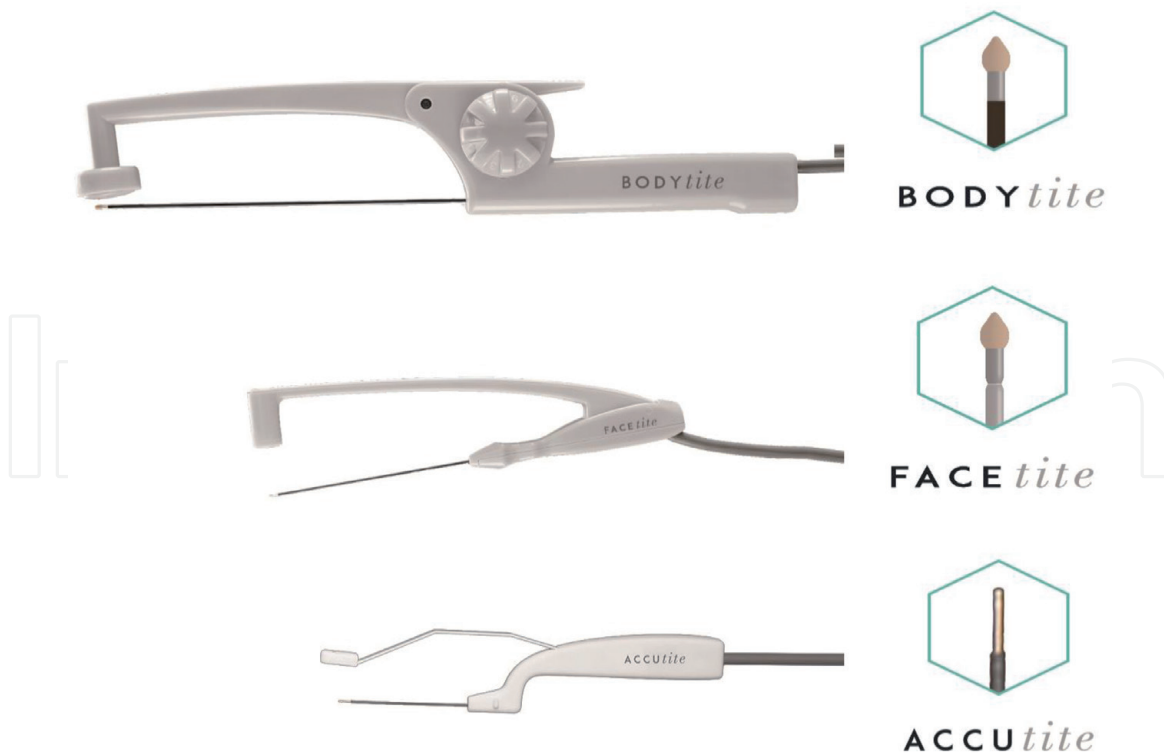


Figure 8.
The InMode RFAL family of handpieces. All the handpieces, even the tiny AccuTite have the same elegantly engineered thermistors and sensors that make the treatments effective and safe.

EmPower RF Gynecologic system), which are no bigger than the palm of your hand (**Figure 8**). All the RFAL applicators, even the tiny ones, operate on the same RF principle and with the same array of thermistors and ACE sensed and automated controlled RF delivery for the responsible delivery of soft tissue heat.

2.4 AccuTite: the injectable skin tightening handpiece

2.4.1 Injectable skin tightening? What does that mean?

The AccuTite RFAL has become so small and easy to use, it has created a whole new category of anti-aging treatment I call, “*Injectable skin tightening*”. What does this mean? The AccuTite RFAL is so small and elegantly engineered, that is now smaller than the microcannula systems I use to inject my soft tissue dermal fillers (**Figure 9**). The microcannula technique facilitates the safe, quick and even injection distribution of Hyaluronic Acid gel fillers into the subcutaneous and supra-periosteal space. With the AccuTite being actually a smaller diameter than my microcannula, I can now use the microcannula port to “inject RF, inject heat, inject subdermal skin remodeling and tightening. What an awesome concept?

In esthetic non-invasive medicine, for too long now, we have *tended to over inject* our patients suffering from skin laxity with soft tissue fillers to provide and lift and tightening effect. And while this Filler, VolumaLift, Liquid Lift (many names) strategy works for modest laxity and in certain facial zones, when laxity increases, we use more fillers and end up with the dreaded “**FILLER FACE**”, or “**PILLOW FACE**”, an unattractive, over injected, over-filled look. Would it not be nice to tailor our treatments and Inject Skin Tightening where required and volume only where needed and only to replace what was lost..... **AND THAT IS THE CONCEPT OF ACCUTITE, the INJECTABLE SKIN TIGHTENER. NO SUCTION NEEDED! Just simple AccuTite injection of RF thermal skin contraction in the subdermal space (Figure 10).**

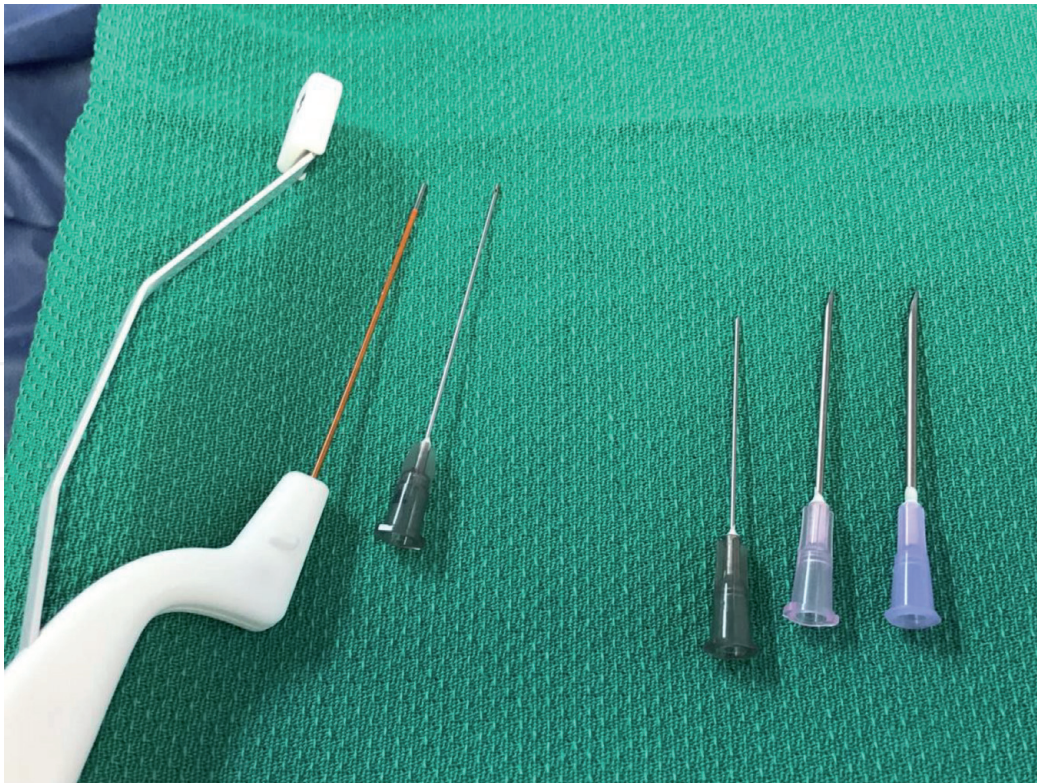


Figure 9.

The AccuTite RFAL handpiece is smaller than the actual microcannula I use to inject my soft tissue dermal fillers (a 22 g, 2 inch, Dermasculpt, blunt tipped, rigid cannula).

Now, when treating the aging skin envelope of the face or neck, I will add the necessary neuromodulator to shape the face, use the *AccuTite to Inject Skin and Soft Tissue Tightening* where needed and, using the same access port, I will use my #22 g microcannula to add the necessary judicious and artistic soft tissue filler. Add to that Formula, fractional RF skin resurfacing, and you can now achieve truly amazing non-excisional, minimally invasive skin rejuvenation.

2.5 Where can we use the AccuTite injectable skin tightening procedure?

The following areas all respond well to using the AccuTite, with safe and effective soft tissue skin tightening and significant esthetic improvement (**Figures 11 and 12**).

i. AccuTite and the Face

- a. Brow
- b. Upper and Lower lids
- c. Nasolabial and labiomental folds
- d. Pre-Jowls and Jowls
- e. Jawline, submentum and Turkey Neck

ii. AccuTite and the Body

- a. Upper arms
- b. Breast Tail

- c. Supra umbilical abdomen
- d. Inner thigh
- e. Suprapatellar knee skin
- f. Orange peel, mild cellulite

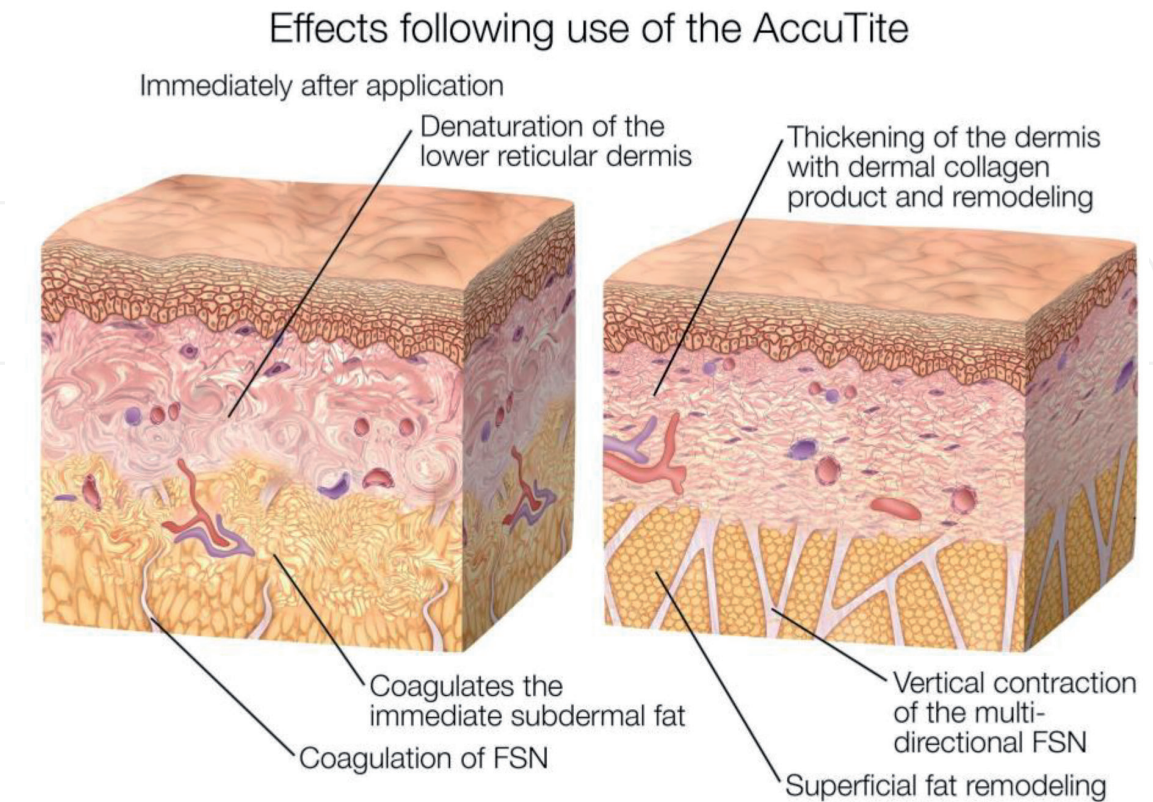
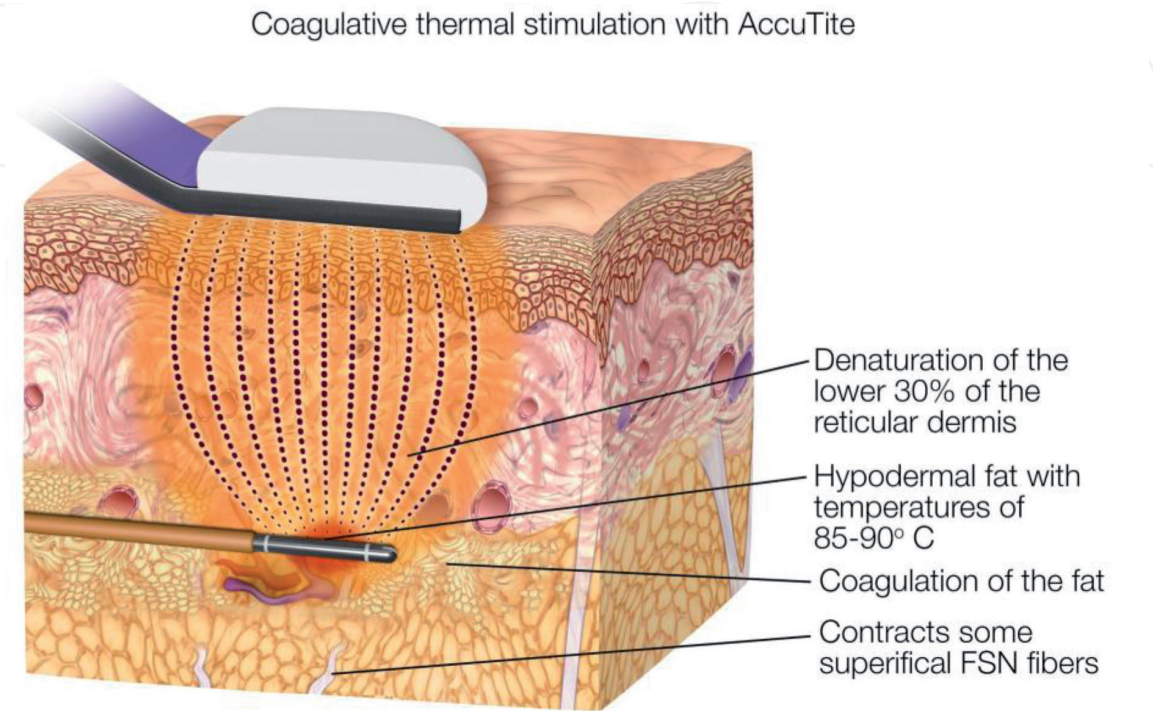


Figure 10.
The AccuTite thermal coagulation ablative and non-ablative effects (top) and the soft tissue contraction and remodeling effects of the AccuTite Injectable skin tightening.

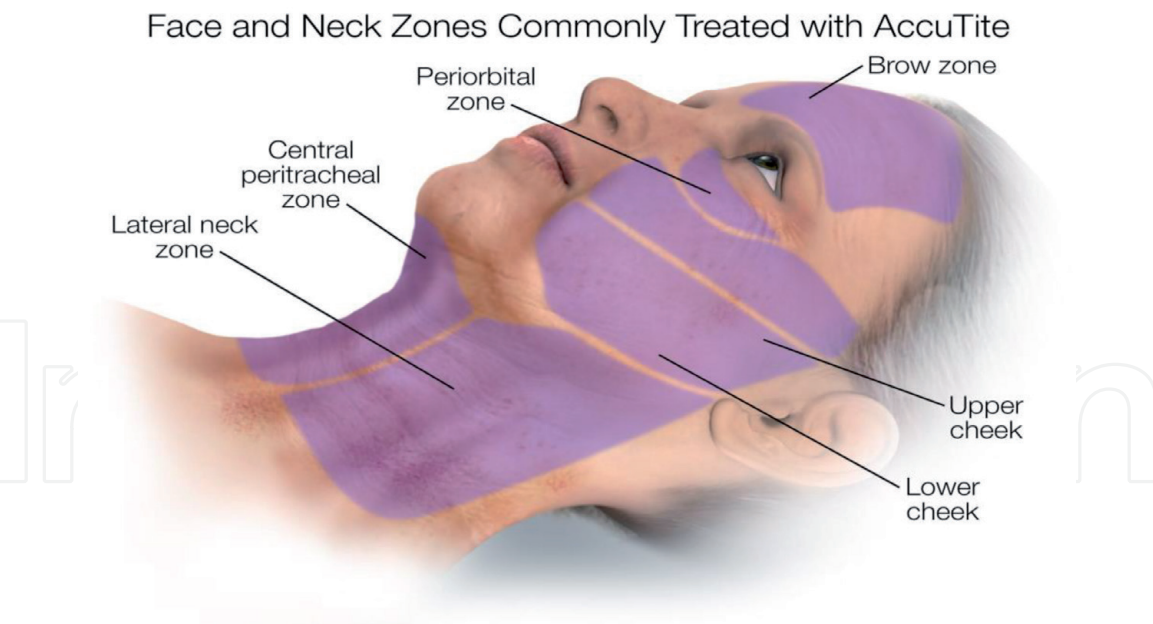


Figure 11.
Common facial areas treated with the AccuTite injectable skin tightening.

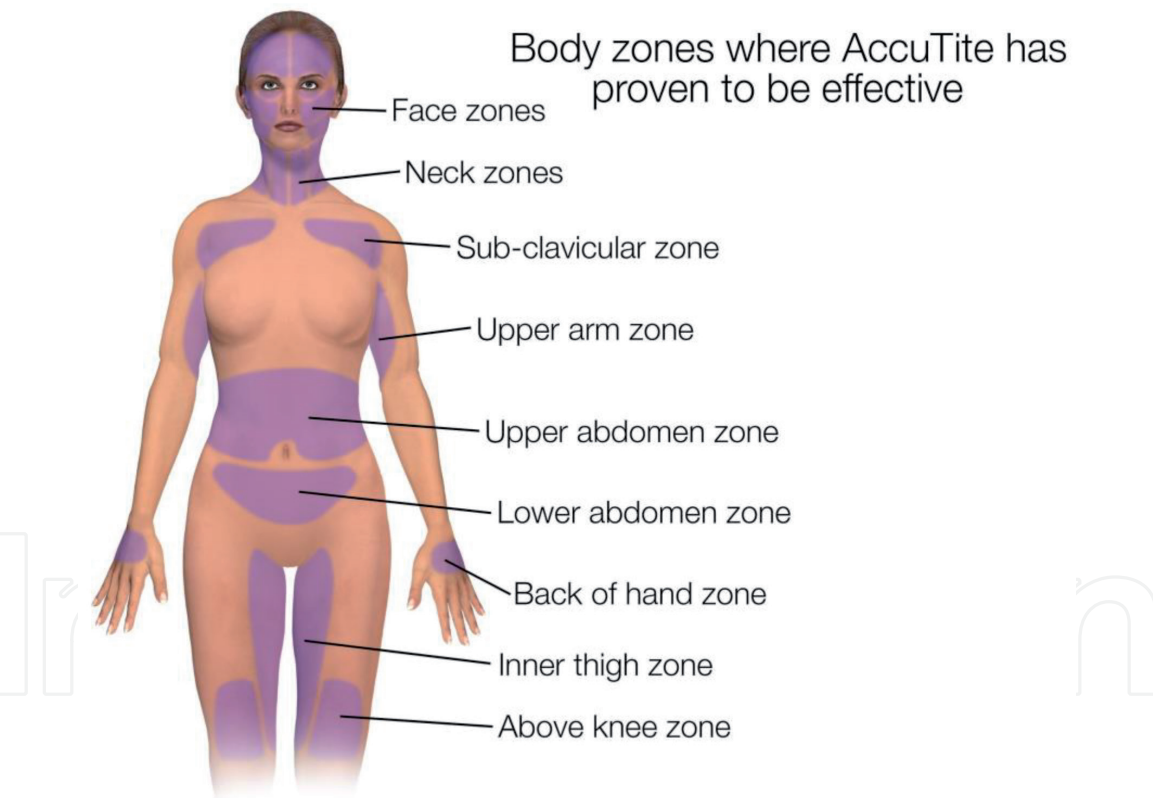


Figure 12.
Body areas where AccuTite injectable skin tightening can be very effective.

3. RFAL adipose FSN contraction

With the BodyTite RFAL applicators, BodyTite, FaceTite, AccuTite (and CelluTite internationally), RF flows from the small uncoated region of the 2.4 mm or 3.9 mm electrode, just proximal to the silastic cap and flows through the adipose tissue from the internal electrode to the external. Up to 70 watts of energy will be delivered automatically by the BodyTite workstation to ensure the most efficient and optimal rate

of rise of adipose temperature, which is 20 degrees Celsius/cm³/second. The external electrode moves smoothly along the surface of the skin, in tandem with the internal electrode in a bipolar configuration. The RF provides a strong ablative and coagulative effect on the adipose tissue, vascular tissue and the multi-directional Fibroseptal network (FSN) within 1 cm of the internal electrode, the temperatures are coagulative in intensity (70 degrees Celsius) with FSN and tissue contraction and adipose liquefaction (**Figure 10**). The FSN contracts optimally and maximally at 69 degrees Celsius [15]. At higher temperatures, that are prolonged, the chemical damage to the adipose tissue can result in fibrotic changes to the soft tissue. The RF flows from the internal to the external electrode is strongly ablative and coagulative within 1–2 cm of the internal electrode (**Figures 7 and 10**). As the RF current flows from the internal ablative tissue effect to the external electrode, which is much wider, the diameter of RF thermal heating increases, and the tissue heating becomes non ablative, gentle bulk heating when the RF reaches the external electrode. The smaller “relative” diameter of the 2.4 mm and 3.9 mm external electrode means a higher power density and more efficient RF flow and heating of the soft tissue and skin and temperature end points are achieved much faster than with the 1.2 mm FaceTite, which has the larger external electrode.

The BodyTite is used prior to or after performing SAL on those patients who:

- i. need optimal soft tissue contraction to enhance contour and minimize the risk of loose skin
- ii. for small venule and arterial vessel coagulation of these small vessels to minimize post op ecchymosis
- iii. to coagulate and liquefy the adipose tissue for easy extraction and less post-operative swelling and pain.
- iv. Need to achieve a multi-level, sequential stimulation of the FSN and dermal tightening, combined with Morpheus Fractional external RFAL on the dermis and sub-dermal envelope for an overall 60–70% area contraction [10–15].

3.1 RFAL electrode geometry

RFAL is intended for simultaneous coagulation of adipose tissue, blood vessels and sub-necrotic heating and contraction of the **soft tissue FSN** (Fibro-septal Network) matrix and, summatively, the subdermal space and dermal skin collagen (**Figure 13**). This technology combines some of the best features of surgical RF coagulators and non-invasive skin tightening devices. RFAL technology utilizes a geometry shown in **Figure 14**.

By slowly moving the RFAL applicators (AccuTite, Aviva, FaceTite and BodyTite) back and forth through the intended treatment area, uniform ablation and coagulation of adipose and vascular tissue and FSN is achieved. While the external electrode is always moved over the skin surface, the internal electrode should pass through the deep, intermediate and/or superficial fat layers to treat the adipose tissue between 1.5-5 cm. The internal electrode Lipo-coagulation, results in liquefaction of the adipose tissue, vessel coagulation of small venules and arterioles and stimulates the contraction and shortening of adjacent vertical, oblique and horizontal fibers of the FSN, or Fibro-septal network that connects the overlying soft tissue to the underlying muscle.

The hand piece of the RFAL device has a cannula/probe/electrode (internal electrode) with a conductive tip and external electrode with significantly larger surface area. Electrical current through both electrodes is the same but the *resistance for smaller electrode is much higher*.

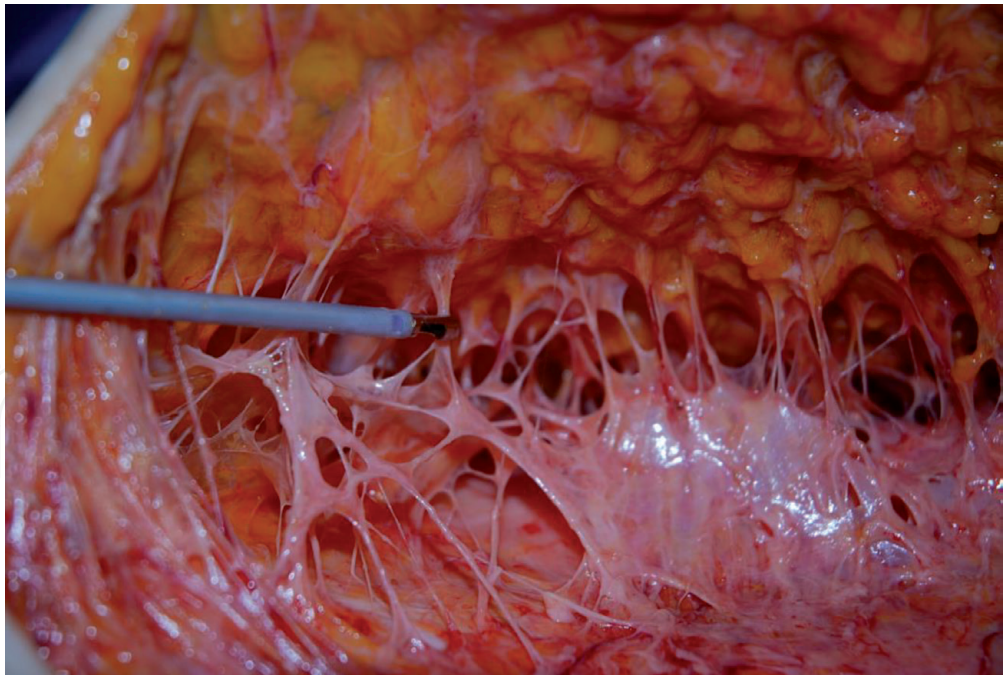


Figure 13.
The vertical, oblique and horizontal fibrous septa of the FSN is the vehicle for RF mediated contraction. The vertical, oblique and horizontal fibers act like “check rein ligaments” holding our skin to the underlying muscular fascia. Heating these fibers to 69 degrees results in contraction of up to 40% immediately. Over 6 months the entire soft tissue envelope remodels and demonstrates 25% contraction, which increases to 40–50% at 12 months and, if you add the Morpheus8 multi-level, multiple pass combination protocol 60–70% soft tissue contraction can occur. The reticular and papillary dermis will be heated, non-ablatively to between 36 and 42 degrees and will also deliver some horizontal soft tissue contraction.

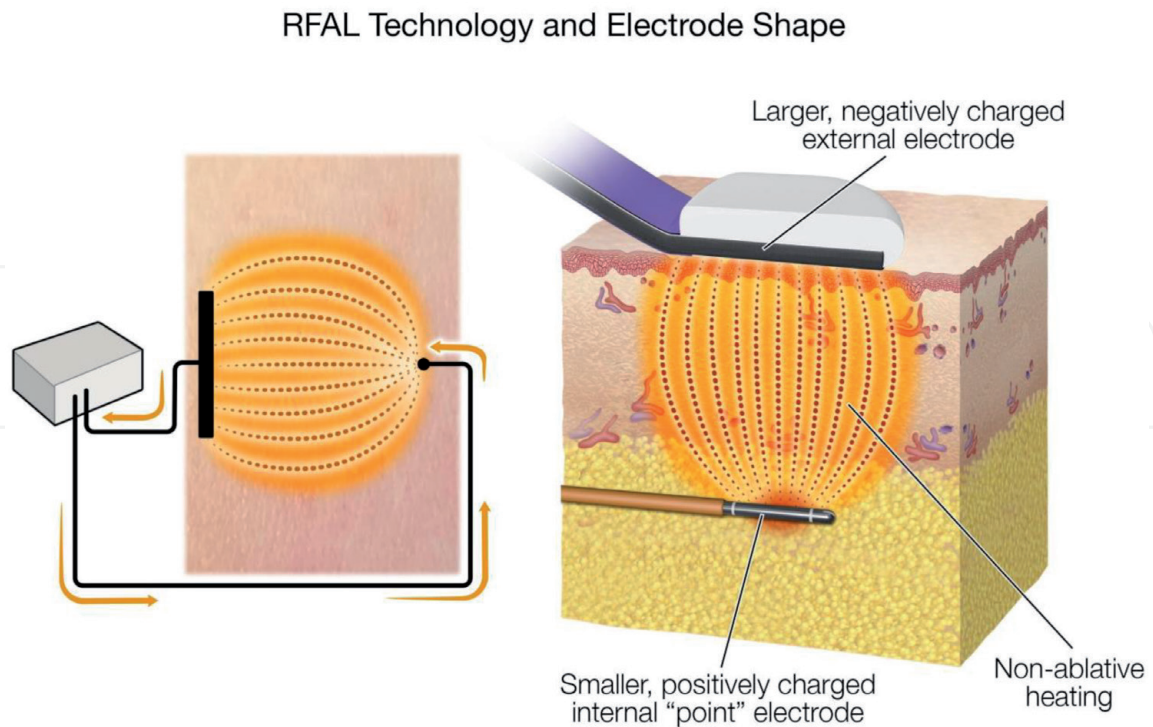


Figure 14.
In the RFAL technology (and the Morpheus family of tips) the RF flows back and forth from the very small tip of an internal, silicone coated, positively charged “point type” electrode, which is placed in the deeper subcutaneous adipose, where the thermal effect is ablative, to a larger, negatively charged electrode that moves along the skin surface, in tandem with the internal electrode and creates a gentle, non-ablative bulk heating effect on the dermis (with the Morpheus, of course, the tip sits on the skin and is static during RF application).

Initial temperature of the patient body after tumescent anesthesia is about 28–30 degrees Celsius. Desired skin temperature is 38–42 degrees Celsius and required fat temperature is 68–70 degrees Celsius.

The desired thermal coagulative temperatures for adipose coagulation, FSN contraction and small venule and arterial coagulation is 70 degrees. The maximum thermal cut-off in the internal thermistor of the FaceTite and NeckTite is 70 degrees. As RF flows to the relatively large geometrical configuration of the external electrode, a gentle non-ablative, non-necrotic heating of the papillary and reticular dermis occurs with denaturation of the collagen occurs for remodeling and thermal tightening. This bipolar configuration allows the double benefit of internal FSN coagulation and contraction, as well as gentle trans-epidermal papillary and reticular dermal remodeling from the external electrode.

The InMode BodyTite, FaceTite and CelluTite user screen allows the physician user to set the cut-off temperature for the external epidermal monitored electrode as well as the internal coated electrode. The desired endpoint generally, internally is 70 degrees, while externally the desired cut off is between 36 and 42 degrees Celsius, depending upon the soft tissue laxity of the target soft tissue (**Figure 15**).

The silicone coated internal electrode prevents direct thermal stimulation and injury to the external access port and the silicone cap at the end of the FaceTite, NeckTite and BodyTite electrodes is bullet shaped, facilitating easy passage through soft tissue and minimizing the risk of end-dermal hits when going around a curved surface.

3.2 RFAL safety monitoring

One of the risks of any thermal treatment (laser or radiofrequency) is the possibility of a thermal skin injury [17]. Thermal treatment in subcutaneous or subdermal layers may create full thickness skin burn. Therefore, one of the most significant advances InMode has been able to develop and patent, are the contact, thermal, and impedance measurements and software algorithms of automatized RF cut-off feedback control that allow for the most controlled, effective and safest thermal delivery.

3.2.1 Skin temperature measurements and the importance of sensing

Non uniform treatment or over-heating the treatment area may result in the risk of unwanted thermal damage to the skin during the treatment. To avoid or minimize this risk of a skin burn, online real time thermal measurements are necessary. There are two basic methods of skin temperature measurements:

- *Infrared (IR) thermometers measuring IR radiation of heated object.*
- *Contact measurements using a thermocouple, thermistor or thermo-transistors.*

Advantages of IR thermometers is the speed of measurements and they do not need to be built into the device and are independent of the treatment. The obvious weakness of this method is collecting IR radiation from relatively large area which depends on distance from the measured area. You are also relying on a third party that is not linked in time of space to the thermal treatment being performed. Most importantly, you are not measuring the internal thermal profile.

A typical IR thermometer measured area is about 1cm² or larger and allows you to monitor average skin temperature in treatment area but does not protect from

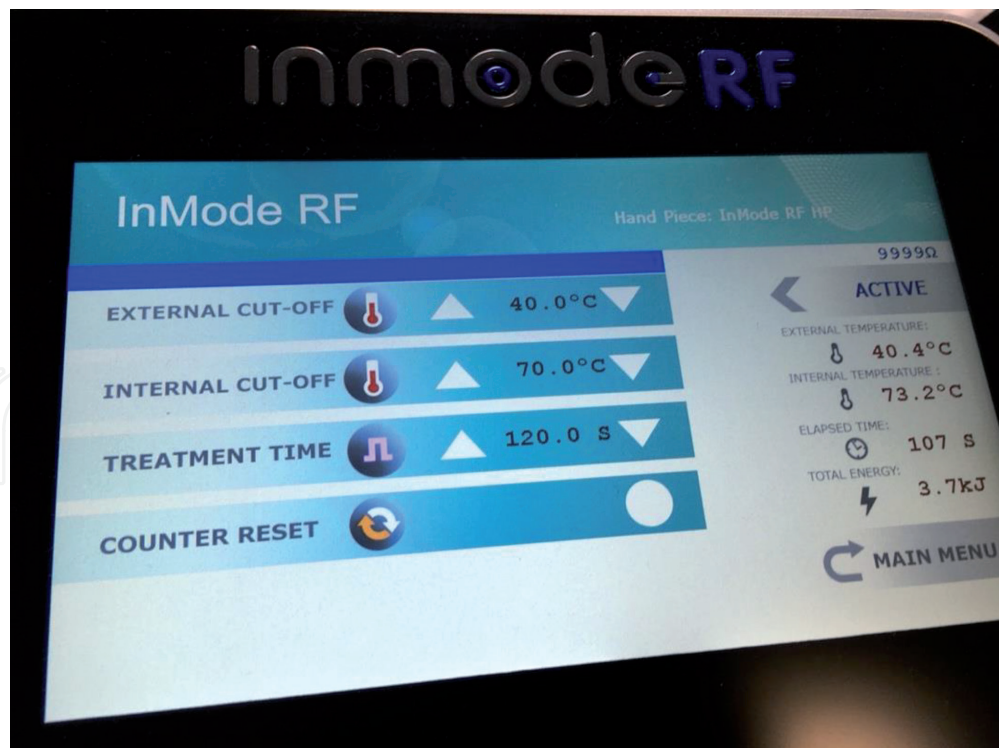


Figure 15.

The InMode FaceTite and BodyTite physician treatment screen with the internal thermistor set to cut off at 70 degrees celsius and the external RF temperature cut off at 40 degrees celsius and the treatment time to 120 seconds. The real time temperatures on the right-hand side show the epidermal cut off temperature of 40 degrees and internally of 70 degrees have both be reached. The treatment time is allotted in renewable 120 second allotments (and FDA requirement) and, when the system indicates a time down, a simple release and the depression of your foot starts automatically another 120 seconds are allotted. The BodyTite workstations (FaceTite, BodyTite and CelluTite), release just enough energy to ensure the rate of rise of temperature is 20 degrees celsius/cm3/second. If the rate of rise of temperature is between 20 and 35 degrees celsius/cm3/second, the energy emitted from the system is automatically reduced to ensure the rate of rise is 20 degrees/cm3/second. If the rate of rise of temperature is >35 degrees celsius/cm3/second, the first of thermal injury is unacceptably high and the energy to the applicator is automatically interrupted and a low, flat audible will sound and you will see temperature Surg protection (TSP) on the screen. Simply take your foot off the pedal, re-position the applicator, put your foot on the pedal and begin treatment again. The exquisite safety feature (TSP) has just minimized the risk of the thermal injury.

appearance of small hot spots that lead to the full thickness skin burns. The current “Standard of Care” would now be based upon the advanced on-board, built in InMode thermal, impedance and contact controls and not a third-party IR skin monitoring system. The synchronous and simultaneous measurement of internal and external thermal temperatures and cut-off targets, electrode contact sensing, high and low impedance sensing and rate of rise of temperature sensing and RF cut-off control is the “state of the art” InMode thermal control. All these “sensed” safety features are designed in the software to regulate the flow of RF to the emitting electrodes and is present on all the RFAL family of electrodes (BodyTite, FaceTite, AccuTite and Aviva), the external non-ablative RF devices (Forma, Plus, BodyFx, Evolve Tite, Evolve Trim and Evoke Jawline and Sub-mentum AND is present on the Morpheus Resurfacing and Remodeling tips. NOW that is one smart line of products!

These “sensed” features are measured through the engineering and insertion in each applicator and handpiece an elaborate array of thermistors and sensors and they consist of the following:

3.2.1.1 Internal and external thermal measurement

Internal and external contact methods of thermal measurement allow the device and user to measure the temperature of small areas, both inside and

out. The internal thermistors are only on the internal minimally invasive RFAL applicators. The internal thermistor will measure the tissue temperature around the ablative internal tip of the electrode, while the external thermistor measures the skin temperature. The user can set independent internal and external cut-off temperatures that will automatically control the flow of RF energy to the internal electrode when the external and/or internal target temperature has been achieved. The disadvantage of this method is that the response time of the sensor is limited by thermal conductivity. Typical response times can vary by as much as 1 second. When the internal probe is moving quickly and in a uniform heated area the temperature response of the sensor is not sufficiently fast enough to monitor tissue temperature in real time and the clinical technique needs to be modified for slow and steady movements to ensure the most accurate thermal, contact and impedance feedback.

3.2.1.2 Rate of rise of temperature and temperature surge protection (TSP): Optimal safety and efficacy

The InMode RFAL applicators and non-invasive RF handpieces also measure the rate of rise of temperature, each millisecond and which can help overcome the moving applicators and the thermal end point limitations mentioned above. The optimal rate of rise of temperature, as determined by in-vivo abdominoplasty specimen measurements is 20 degrees Celsius/cm³/second. The current InMode RF devices no longer allow the user to enter the RF energy, but rather, deliver just the right amount of RF power, to allow the rate of rise of tissue temperature to be 20C/cm³/second. When this rate of rise of tissue temperature is 20-35C/cm³/second, then the RF energy is reduced until the rate of rise is <20C/cm³/second. When the rate of rise of tissue temperature exceeds 35C/cm³/second, then the RF energy is cut-off, the user hears a temp surge alarm and the user's foot must be released from the pedal and then re-applied to start the flow of RF again, which is enough time for the rate of rise of tissue temperature to drop below 20C/cm³/second.

3.2.1.3 Contact sensing

All InMode RFAL applicators and non-invasive RF handpieces have an external contact sensor and, if contact is broken between the external electrode and the surface of the skin, or is reduced significantly, but lifting the electrode partially off, the contact sensor will alarm and RF energy to the internal electrode will be cut-off. This contact sensing helps prevent arch burns or injuries.

3.2.1.4 Impedance sensing and control of RF output

The BodyTite RFAL system (**and Morpheus**) deploys a very sophisticated, online, Realtime impedance regulatory system to help control clinical circumstances where high thermal temperatures may occur. There are several RFAL procedural situations when the contact sensing, external and internal tissue temperature and rate of rise of temperature measurements and RF energy control may require the additional of impedance measurement and control as well.

Tissue impedance measurements may improve procedural efficiency and safety of the treatment. Below are a few examples of how continuous, online impedance monitoring and control, in addition to external and internal thermal end point control, contact control and temperature surge protection control can prevent adverse effects.

- When the external electrode exhibits bad contact with the skin surface, high current densities occur on the skin surface, leading to rapid rise in temperature and a sudden drop of impedance (resistance to RF flow through tissue) and this can result in skin damage. The sudden impedance drop can often be “sensed” or “measured” before the internal or external tissue temperature end points or, even the rate of rise of temperature is measured. Occasionally, especially in fibrous areas, the internal electrode may bend slight off the path of the overlying external electrode leading to high impedance on the skin surface and the risk of the burn. By monitoring high impedance, or resistance to flow, as well as the various thermal measurements and limiting power, or turning of the RF power when a high impedance levels are detected, the user reduces the risk of thermal skin side effects significantly from bad external electrode contact or when the internal electrode strays laterally from under the path of the overlying external electrode.
- Touching the under surface of the dermis from the inside by internal electrode may cause thermal skin damage. When this occurs, the impedance will suddenly drop, and the temperature will rise possibly leading to a low impedance burn. By placing a silastic cap on the tip of the internal electrode, this risk of a subdermal injury is greatly minimize, but, as you get close to the subdermal space, by monitoring tissue impedance and limiting lower impedance levels, the device switches off RF power when distance between electrodes is too small and impedance is low, thereby reducing the risk of low dermal internal electrode impedance burns.

Coagulation of tissue is often accompanied by tissue dehydration and carbonization and eschar will accumulate on the internal electrode, which will increase the impedance between the electrodes. When this occurs, the impedance will rise and the Impedance measuring system is adjusted to switch off RF power when tissue is dehydrated, and carbonization or eschar begins to occur near the internal electrode. That prevents eschar effect and increase efficiency of RF power delivery and save surgeon time. *It is also why you will never have to clean eschar off the internal electrode with the BodyTite RFAL system.*

4. The thermal evidence for soft tissue contraction using RFAL

RFAL has been available internationally for 12 years and most recently, in 2016, has been approved for the intended use of soft tissue coagulation, by the FDA in the United States. There is a large body of literature that validates the use of internal thermal stimulation for soft tissue contraction, over and above what non-thermal techniques can deliver, as well as the increased efficiency and efficacy of using radiofrequency energy.

The first question most surgeons will ask is, does RFAL and heat really work to enhance soft tissue contraction?

Internally applied RF energy also travels preferentially up and down the vertical FSN, especially with RFAL, as the current is already flowing vertically from the deep electrode to superficial electrode direction, parallel to the vertical FSN. These concepts were outlined in a number plastic surgery, peer reviewed articles [13–15]. The FSN acts as the conduit for low impedance transport of radiofrequency energy from the internal electrode up to the external electrode. The vertical fibrous septa comprise the vertical encasing septa of the adipose tissue and thus the casing around the adipose tissue is more selectively and rapidly heated by the vertical FSN.

The FSN acts as the conduit for RF conduction and experience a higher concentration of the RF power density and result in more efficient vertical contraction. *It is the vertical, oblique and even horizontal contraction of the FSN that leads to most of the thermal contraction effects of the soft tissue* [4]. This contraction of the FSN, in the vertical, oblique and horizontal vectors lead to a 3-dimensional contraction in the X, Y and Z axis. The bipolar-contained energy in the RFAL configuration leads to more efficient bulk heating of soft tissue with no dissipation of heat below the electrode. Dissipation of RF energy and mono-probe RF systems such as ThermiRF and the diffuse radiant heat of laser, although effective and provide heating and certainly when end points are achieved result in tightening, are less efficient than the RFAL bipolar patented configuration of InMode RF.

There is a large body of evidence in peer-reviewed articles that shows the highly efficient nature of the RFAL contraction experience [13–15]. An article published in 2011 in *Esthetic Plastic Surgery*, using perfused abdominoplasty specimens and the RFAL bipolar electrode applicators to heat the internal soft tissue to various temperatures [15].

The various named horizontal fascia fibers throughout the soft tissue such as camper's and Scarpa's fascia in the abdomen need to be heated to approximately 61.5 degrees Celsius to exhibit contraction and the contraction is in the order of 14%. *This is certainly substantial contraction, but it turns out that the vertical, oblique and horizontal fibrous septa, the vertical, oblique and horizontal FSN, when heated to 69.4 degrees Celsius resulted in an on-the-Table 33% 3-dimensional contraction. And 60–70% contraction measured overtime and with superficial thermal RFAL treatment as well* [10–15]. This paper was the first to point out that internal thermal stimulation to a temperature of 70 degrees can result in immediate contractions in the range of 33% [2]. Using even smaller internal electrode FaceTite applicators in the order of 1.2 mm, contractions of up to 43% -50% have been reported.

4.1 The role of RFAL in superficial skin tightening and dermal remodeling

RFAL also works on tightening the superficial soft tissue and dermis. In fact, in many areas of the body and in many patients, there may not be much subcutaneous fat, which means less FSN. In other patients, there is lots of fat and FSN, but the soft tissue is very loose (tummy, inner thigh and upper arm) and the clinician must tighten the deeper adipose tissue and FSN as well as the superficial fat layers and provide safe and effective dermal heating to optimize “best in class” contraction. Technologies, such as Plasma (Renuvion), Vaser Ultrasound (Sound Surgical), Laser (Cynosure) cannot provide a safe subdermal and superficial subcutaneous thermal control and become dangerous in these body areas. When it comes to the jawline, face, upper and lower lid, the AccuTite and FaceTite are unparalleled for subdermal skin tightening and “best in class” thermal contraction and cosmetic outcomes. Add to the list, the Morpheus 8, which also comes loaded on your BodyTite or Embrace workstation and no wonder, InMode RFAL technology is by far the *worlds #1 thermal soft tissue contraction system*, as it adds so much certainty to the patient and the physician practice that deploys it.

The external electrode and the RFAL system provide gentle heating through non-ablative, sub-necrotic remodeling of collagen. There is biopsy-proven evidence in published papers on the nature of this gentle trans-epidermal heating and sustaining epidermal temperatures to 38 to 42 degrees over a series of treatments can result in increased messenger RNA up regulation of 35%. When between four and eight treatments are provided, increased collagen contents of 8–15% have been demonstrated [7–9]. *Combining the FSN RFAL contraction with superficial subcutaneous and dermal remodeling and, even Morpheus, 60–75% soft tissue contraction can be achieved* [10–15].

When we combine the internal RFAL, vertical, oblique and horizontal FSN 33–43% 3-dimensional contraction produced on the table, with the gentle trans-epidermal, dermal, papillary dermal or reticular **10–25% remodeling**, significant soft tissue, non-excisional, contraction can be achieved with RFAL technology. An excellent published paper that documents accurately the effect of RFAL skin tightening was published by editor of this Intech Open book, Dr. Diane Duncan in the Esthetic Surgery Journal in 2013 [17, 18]. In Dr. Duncan's article she replicated the study performed by Dr. Barry DiBernardo except this time using RFAL bipolar radiofrequency heating technology; the FaceTite and NeckTite and replicating the same clinical protocol (**Figure 3**). India ink tattooed rectangles were made on each side of the lower abdomen. On one side, after tumescent anesthesia, RFAL was performed heating the deep subcutaneous tissue to 69 to 70 degrees with an epidermal end point of only 36–38 degrees Celsius. Following heating to these thermal end points, standard suction-assisted lipoplasty was performed. On the contralateral side, after tumescent anesthesia, standard suction-assisted lipoplasty was performed without RFAL thermal stimulation or coagulation.

Dr. Duncan followed these abdominal-tattooed soft tissue individuals for six months and twelve months. Dr. Duncan's article is the only long-term thermal contraction study in the literature. Many physicians raised the question that perhaps internal thermal stimulation led to short-term contraction, but by one year perhaps there was no appreciable effect and the Dr. Duncan article this was refuted this quite demonstrably. What she found on the SAL non-thermal side was a 14% contraction at six months, which had fallen to 6% at 12 months showing the stress relaxation of the non-thermal aspiration technique. Six percent contraction by subdermal stimulation and stimulation of the viscoelastic fibers in the adipose tissue can be important, especially in those individuals who have inherently good skin tone. For those individuals, however, who have decreased skin tone or elasticity and laxity, 6% contraction at 12 months will not be enough.

On the RFAL side, she found there was a 24% contraction at six months, and this had increased to 35% area contraction at 12 months. This excellent peer-reviewed and randomized, blinded trial using an extremely accurate contraction instrument, the Vectra 3D and proved quite conclusively that RFAL definitely provides long-term contraction. 35% area soft tissue contraction at 12 months is by far the industry-leading thermal coagulation system. This long-term contraction of 35% (single level FSN RFAL) can give significant non-excisional tightening to the neck, jawline and face as well as body areas where laxity-post contouring or without fat contouring at all is one of the primary clinical outcomes of the esthetic intervention. *However, what is even more impressive, the 35% area contraction at 12 months in this study, was achieved without superficial subdermal work at skin temperatures of only 36 degrees Celsius. By adding superficial RFAL and subdermal work, together with the Morpheus8 studies have shown 60–70%, 12-month soft tissue contraction is achieved* [10–15].

Additional thermal contraction can be provided by not only superficial and subdermal RFAL, but by the simultaneous use of the Morpheus and/or the Fractora, particularly the silicone-coated applicator, and radiofrequency ablative needling and radiofrequency ablation. Simultaneous Fractora with the 24-pin coated will provide a deep papillary and reticular ablation that can be combined with the ablative and necrotic experiences soft tissue effects of the internal electrode combined with a non-ablative bipolar heating of the FaceTite RFAL external electrode (**Figure 16**). Simultaneous use of the Morpheus 8 or Fractora combined with FaceTite, NeckTite and even BodyTite is outlined in chapter are an additional soft tissue coagulation tightening tool to optimize clinical results [19–21].

Combination therapy using FaceTite and Fractora

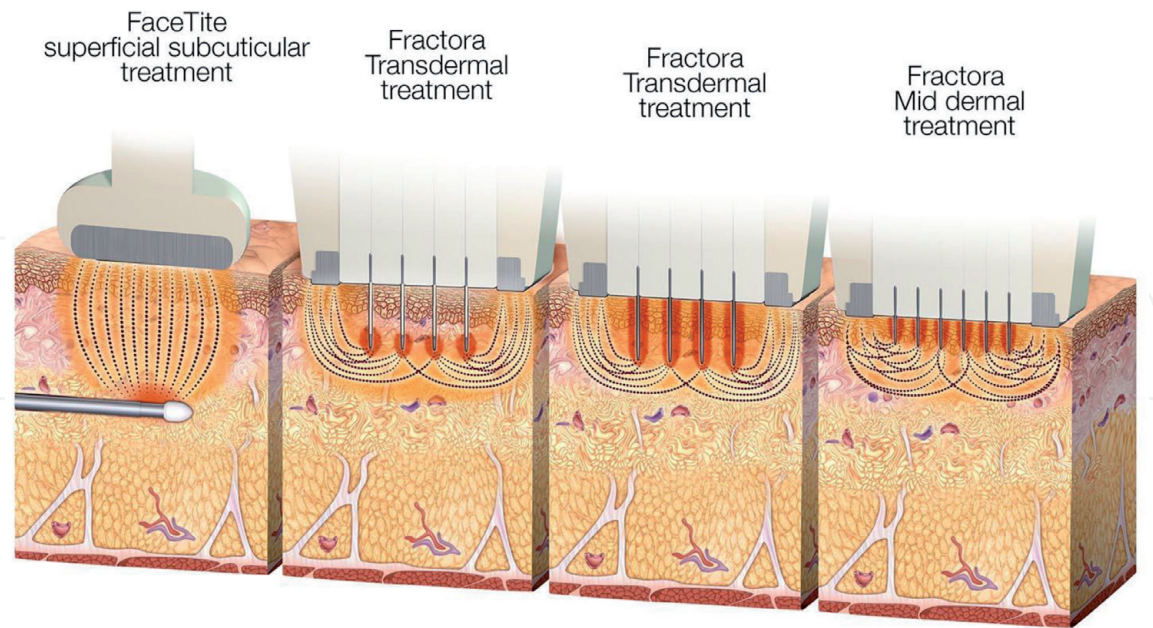


Figure 16.
Optimal soft tissue contraction and tightening can be achieved by combining the 35% contraction with RFAL and the Fractora dermal contraction following fractional RF resurfacing being performed immediately after RFAL.

4.2 How much soft tissue contraction can RFAL applicators deliver?

Excellent peer reviewed studies show that, depending upon characteristics of the patient’s soft tissue, anatomic location (high or low FSN zones) and degree of dermal and skin elastosis, *soft tissue contraction and skin tightening of 35–70% (30–40% FSN + 20–30% sub-dermally and dermally) can be achieved (Figure 17). WOW, and with exquisite and elegant thermal control leading to a very, very low incidence of thermal injury [10–15, 22, 23].*

In the next chapter, Part 2 of the RFAL phenomenon, we will explore the external RFAL applicator, or “Outside-In” RFAL, the Morpheus 8 and how it works. Part 2 will also synthesize the combination of the Inside out RFAL and outside in Morpheus 8 RFAL to deliver an amplified Lipocoagulation and “enhanced Liposuction.

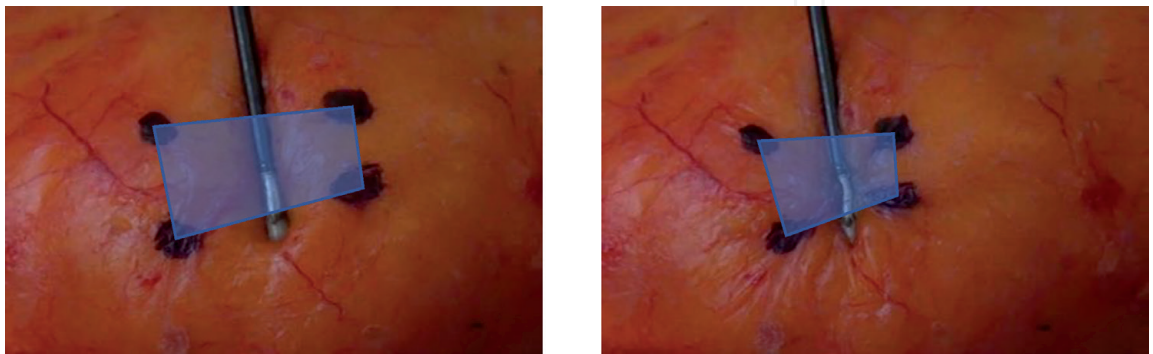


Figure 17.
Excellent peer reviewed articles, from multiple authors and continents have confirmed that RFAL can deliver 40–70% soft tissue area contraction, through combination of adipose coagulative ablation, FSN contraction and non-ablative dermal remodeling.

4.3 My experience with other enhanced liposuction devices

The modern face and body contouring surgeon must embrace energy-based devices to offer advanced “enhanced” liposuction and soft tissue contouring through the face, neck and body. The ability to deliver adipose, FSN and dermal modeling with or without fat aspiration has emerged as a critical factor in the treatment of both delicate face and neck rejuvenation as well as body contouring in challenging soft tissue envelopes. Like the editor and the world renowned authors, I have deployed energy-based technologies in offering “enhanced liposuction for over 20 years. The evolution in my “enhanced” liposuction work mirrored the development of more sophisticated energy-based technologies that minimized the trauma of fat extraction and optimized the contraction and, hence control of the overlying soft tissue envelop.

For a number of years, Ultrasonic Liposuction (Vaser) and Water-assisted Lipoplasty (Waterjet) offered my patients less bruising and ecchymosis and viable stem cells, but both lacked efficient, predictable and significant soft tissue contraction. The emergence of thermal assisted lipo-contouring, with laser lipolysis (Smart Lipo, Cynosure and Lipolite, Syneron) combined the coagulation of small vessels, minimized ecchymosis, edema and recovery, while offering, for the first time, a subdermal and FSN thermal contraction and was my favored technology for a number of years. However, the suboptimal efficiency of laser transmission in adipose resulted in only modest soft tissue contraction and the lack of integrated external and internal thermal controls resulted in thermal complications in less trained hands. Thermigen’s monopolar RF coagulation device ushered in radiofrequency “enhanced” liposuction in the USA. Although small and less effective for most moderate to large zone “enhanced” liposuction zones, the incorporation of a 3rd party infrared monitor on the skin and internal thermistor temperature monitoring made this technology safe in small zone and facial contouring, as well, as motor nerve to the corrugator ablation. The FDA pathway with Thermi opened the regulatory door for the FDA’s approval of BodyTite and RFAL. BodyTite’s integrated, automated RF controlled thermal adipose and dermal bulk heating lead to industry soft tissue contraction and control. The addition of the Morpheus to the BodyTite workstation, with external RFAL, fractional superficial fat and dermal contraction (see next chapter, Part 2) has allowed me total thermal control of the skin dermis and superficial subdermal fat tightening, as well as the well documented deeper FSN and adipose contraction. In my hands, the BodyTite experience offers, a truly versatile face, neck and body “enhanced” liposuction and contour system. While all the “enhanced” liposuction technologies I have used and covered so expertly in this book offer undeniable advantages over traditional SAL, we must control **BOTH THE ADIPOSE AND SKIN** contraction to produce the most consistent and optimal results from the eyelids down to the inner and anterior thighs and all lax and suboptimal soft tissue in between. In my hands, the BodyTite experience offers, the most versatile and successful face, neck and body “enhanced” liposuction and contour system.

5. Conclusions

It has become imperative for the modern liposuction surgeon to include an energy based surgical device that facilitates “enhanced liposuction”. The emergence of a market segment of consumer, The GAP patients, who are looking for significant non-excisional soft tissue tightening, contraction and wrinkle reduction has created a whole next market opportunity for esthetic physicians. These GAP patients want more than the non-invasive market of toxins, external non-invasive body contouring energy-based devices can offer, but also wants to avoid the scars, recovery and

stigma of more extensive excisional procedures. InMode has created the technology to serve this GAP market with the internal and external RFAL applicators, the BodyTite, FaceTite, AccuTite and Morpheus8. Non excisional, minimally invasive procedures can now be offered under local anesthesia in your office and the face and body options are impressive. In the Operating room, even many excision procedures can be enhanced, the outcomes improved or the scars reduction with the soft tissue contraction and wrinkle reduction results of the RFAL technology.

This “Enhanced Liposuction” InTech open book is well timed, as this kind of technology is not only here to stay, but in the case of RFAL, has created a whole new market segment of face and body consumers, the GAP patients. In Part 2 of the RFAL technology, External lipocoagulation and “lipocontouring” using an external adipose fractional ablative device, the Morpheus 8 and its role in “enhanced liposuction” will be outlined.

Conflict of interest


The Author is a paid workshop consultant for the company, co-patent developer and a founding shareholder.

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