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Bipolar Radio Frequency as an Adjunct to Face and Body Contouring: A 745-Patient Clinical Experience

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Abstract

Background: Radiofrequency (RF) technology has ushered in a new paradigm in body contouring for patients with mild to moderate skin laxity who desire fat removal without exacerbating skin laxity issues. The authors utilized a bipolar internal RF device as an adjunct to liposuction and found the device to simpler and more accurate than previous technologies.

Objectives: Our study aims to review our clinical experience with bipolar RF assisted liposuction (RFAL).

Methods: A review of our large experience with bipolar RFAL was completed, with evaluation of the nuances from appropriate patient selection and specific treatment areas. The authors treated 745 patients from January 2017 to January 2020 at two centers. A retrospective chart review was performed of the first and last 50 patients treated at each center (for a total of 100 patients in each group), to assess trends in outcomes and adverse events.

Results: Results were generally excellent from physician evaluation, and overall patient satisfaction was high (96%). The two most common adverse events were temporary swelling (9%) and nodules (8.5%). Selected examples of a variety of cases are reviewed.

Conclusions: The ability to tighten skin with a minimally invasive tool adds much to the contemporary approach to the body contouring patient with skin laxity. Adverse events were minimal and greatly decreased after an initial short learning curve. Bipolar RFAL is a strong addition to our surgical armamentarium and has become one of the essential tools for our practices.

The addition of energy devices to liposuction has evolved since ultrasound assisted liposuction (UAL) was first introduced in the 1990's.[1] Initial reports of UAL suggested better skin tightening through a suspected skin heating mechanism than with traditional liposuction,[2] but lack of temperature monitoring and difficulties with the delivery of ultrasound energy led to inconsistent results.[2,3] Power assist devices (PAL) were subsequently introduced and allowed rapid fat removal but without skin heating and skin tightening.[4,5] The technology evolved from initial UAL and PAL devices to laser assisted liposuction (LAL), which was the first energy-based technology to include precise temperature monitoring and subsequently improve the consistency of results.[6–9] Radiofrequency (RF) devices emerged as an adjunct to liposuction, with precise internal temperature monitoring and external camera temperature monitoring, and completely changed the way we approach skin tightening with liposuction. Initial monopolar RF devices with external monitoring and thin probes increased the popularity of RF as a modality in the skin tightening arena.[10,11]

Bipolar RF assisted liposuction (RFAL) was first introduced in 2009[11] but was not approved in the United States until late 2016. We have been using the latest generation of bipolar RF devices (InMode) since early 2017 and have noticed an evolution in the way we approach patients and areas treated. Patients who were previously considered not ideal candidates for traditional liposuction, due to age and issues with skin laxity, could be effectively treated with this technology. A trend towards treating smaller areas under local anesthesia was also noticed as this type of anesthesia became more requested. In our clinical experience using the latest bipolar RF devices, a consistent approach for achieving high quality results was developed using this technology in a variety of treatment areas. The mechanism of bipolar RF contouring, the bipolar device used, as well as a review our preferred approach to using bipolar RF in a variety of situations will be discussed here. We hope this paper will serve as a guide to the use of bipolar RF, for surgeons interested in expanding liposuction in patients with mild to moderate skin laxity, both in common areas and those not routinely treated.

METHODS

All patients treated using the InMode bipolar radiofrequency system (BodyTite, FaceTite, AccuTite, InMode Corporation, Lake Forest, CA) from January 2017 through January 2020 at two centers (Sanctuary Plastic Surgery, Boca Raton, FL and New Jersey Plastic Surgery, Montclair, NJ) were included for this study. Patient selection was based on the clinical judgement and experience of our senior authors. Patients were excluded if they

were considered poor candidates for bipolar RF, such as those with areas of hanging skin more amenable to excisional treatment. Basic demographic data was obtained for all patients. Patients undergoing retreatment of previously treated areas were excluded from this study, so that all unique treatment areas could be counted separately. A retrospective chart review was performed of the first and last 50 patients treated at each center (for a total of 100 patients in each group), in order to assess trends in outcomes and adverse events. At both centers, patient satisfaction was assessed during routine surgical follow-up and recorded for this chart review. Statistical comparisons between groups were performed using Fischer's Exact Test and Student's t-test, where appropriate. This study was conducted in compliance with the Declaration of Helsinki[12] and all patients provided their written informed consent.

Technology

A brief overview of the InMode bipolar RF platform is helpful in order to understand its use in the present study. The initial device was 20-watts and had two bipolar applicators – a body handpiece called BodyTite (Figure 1A) and a smaller face handpiece called FaceTite (Figure 1B). The device was upgraded to 40-watts within the first year and additional handpieces were introduced to take advantage of this increased power. Subsequently a smaller handpiece called AccuTite was also introduced (Figure 1C). Table 1 describes the different dimensions and properties of each handpiece. With all bipolar RF handpieces, RF energy flows between the internal and external electrodes (Figure 2). The depth of flow, or cone of energy, can be controlled using a spring mechanism on the handpiece. This variable mechanism allows for a deep flow of energy to the underlying fibrous tissue network (Figure 3) for "vertical" tightening, as well as a transdermal application of thermal energy for "horizontal" skin tightening.[7]

Technique

Tumescent fluid infiltration is performed for all areas undergoing bipolar RF treatment, both under general and local anesthesia with IV sedation. Our preferred tumescent fluid is: 50cc of 1% lidocaine and 1 mg epinephrine mixed into 1 liter of lactated Ringer's solution.[13] Fractional volumes are prepared for smaller areas, and we increase the concentration of lidocaine for procedures performed under local or IV sedation. We adhere to the American Society of Plastic Surgeons guideline for maximal lidocaine during tumescent liposuction (35 mg/kg body weight),[14] taking into account any additional lidocaine used for a concurrent local procedure. Small stab incisions are made using a 14-gauge needle or an 11-blade scalpel, and infiltration is performed using a 14-gauge infiltration cannula (Black & Black Surgical, Inc., Tucker, Georgia) until turgor of the overlying soft tissues is achieved.

As has been previously noted,[15,16] this subcutaneous fluid aids in RF conductivity, and the tissue turgor provides a smooth surface upon which to move the device while facilitating adequate coupling between the external and internal electrodes.

The appropriate hand piece is selected based upon treatment area. In general, the 40-watt BodyTite probe is used on the abdomen, flanks, back, arms, thighs, and calves. The FaceTite probe is used selectively for more narrow areas, such as the neck, "bra fat," breast, and knees. The AccuTite probe is limited to the most superficial areas, such as the submental region in patients with "short necks," the jowls, nasolabial folds, and other facial areas. Standard settings for both practices are a set target temperature of 42°C for the external probe and 70°C for the internal probe. Initially, it is recommended to use settings 2 – 4°C less than this during the learning period for most areas. For thinner face and neck tissues, it is common to limit the temperature to 40°C external and 68°C internal.

Once the tumescent fluid has been infused and the appropriate size hand piece has been selected, the internal probe is inserted into the subcutaneous adipose layer and the external probe is positioned on the skin surface (Figure 2). The internal probe heats the tissue and monitors internal temperature. The external "return" electrode monitors external temperature. The device is activated and the handpiece is passed back and forth, using the visual and auditory cues provided by the device to heat the tissue to the setpoint temperatures. Internal and external temperatures are set prior to treatment, and the device automatically modulates RF energy according to tissue impedance and measured temperature, turning on and off as necessary.

Treatment areas are divided into smaller constituent areas to facilitate efficient uniform heating. Once the set temperature is achieved there is no need to "re-treat" or "stack" treatments. Target temperatures are the primary treatment "endpoint;" secondary endpoints include easy gliding of the internal probe through the subcutaneous tissues, and tactile warmth of the treated skin. A thermal camera (FLIR) could be used, however is not necessary with the built-in temperature monitoring of this technology.

After the treatment area has been uniformly heated to the target temperature, liposuction is performed to aspirate the liquified subcutaneous fat and heated tumescent fluid. The exception to this rule would be in cases where autologous fat grafting will be performed, in which case liposuction must be completed *prior* to performing bipolar RF. In all cases, the final step is subcutaneous basket cannula "equalization."[17] All stab incisions are closed with 5-0 Prolene, and all 16-gauge needle holes are allowed to close on their own. Occasionally, cases with minimal fat may receive no additional liposuction.

Aftercare following bipolar RF and liposuction is identical to SAL or PAL in our practice. We utilize foam padding and compression garments for the first 3 – 7 days following the procedure. Lymphatic massage is considered on a case by case basis. Patients resume light activity and exercise at 3 days post procedure, and regular activity after one week. We counsel patients to expect to wait until 6 months after the procedure before they see the final results.

RESULTS

There were 745 patients treated at both centers, including 106 men and 639 women. A total of 608 patients were treated at the Florida center and 137 patients at the New Jersey center. Thirty patients underwent retreatment of previous areas and were not included in this analysis. The average age was 50.5 years (range 18 – 84 years) (Table 2). The total number of treatment areas was 895 and the average number of areas treated per patient was 1.62 (range 1 – 7 areas) (Table 2). The most commonly treated areas were abdomens (218), necks (192), flanks (120), thighs (105), and arms (64) (Table 3). The proportions of areas treated remained relatively stable over time, aside from an increase in the number of necks treated, reflecting the introduction of the AccuTite handpiece and our increasing familiarity with its use (Figure 4). The BMI of the initial 100 patients treated was compared to the last 100 patients to evaluate for differences in patient selection with increased experience (Table 4). The difference between average initial BMI (24.5, range 17.3 – 34.6) and final BMI (24.6, range 17.1 – 36.9) did not reach statistical significance ($p = 0.69$).

General anesthesia was used for 242 patients (32%) and local anesthesia was used for 503 (68%), and this proportion remained stable over time (Table 5). Local anesthesia cases received 1 mg Ativan and 75 Demerol IM preoperatively until December 2019, when MKO melt sublingual tabs (ImprimisRx, San Diego, CA) were used at one clinical site; the other site used Valium 10-20mg and 1-2 Percocet (325mg/5mg) orally. Pro-Nox (CAREstream Medical, Surrey British Columbia, Canada) on demand inhalational nitrous oxide was used in some local anesthesia cases as well, enabling patients to self-administer N_2O during the case.

The first and last 100 patients treated were reviewed retrospectively to assess for the occurrence of complications. In this manner, if there was a true learning curve as evidenced by adverse events, it would be detected. Complication data are listed in Table 6. From the initial 100 patients treated to the final 100 patients in this study, the incidence of adverse events decreased from 21% to 19%, although this did not reach statistical significance ($p = 0.86$) The two most common complications were temporary swelling (9%) and nodules

(8.5%), and these were self-limited. Other minor complications included hyperpigmentation (0.5%) and contour irregularity (1%). In all, 96% of the analyzed patients (n = 192) were satisfied with their treatment. There was a 40% reduction in patient dissatisfaction from the first 100 (5%) to the last 100 patients (3%). Nine (4.5%) of the initial 100 patients had retreatment of selected areas. The final 100 patients sampled did not have any retreatments, perhaps reflecting increased experience with this procedure. Selected examples of a variety of patients and areas treated can be seen in Figures 5 – 8, Supplemental Figure 1, and Supplemental Figure 2.

DISCUSSION

Bipolar RFAL advances an era of finesse liposuction that has completely changed our approach to lipocontouring. Prior to its use, we limited liposuction to younger patients without significant skin laxity, and to the treatment of traditional areas such as the abdomen, flanks, and outer thighs. We frequently treated these larger areas under general anesthesia.

In this largest series to date, our average age was 51 with the oldest being 82. Two thirds of patients were treated under local anesthesia and oral sedation. Generally, one to two areas were treated at a time. It was surprising for us to note that many patients elected to have multiple bipolar RFAL procedures in which small areas were treated under local anesthesia, instead of one larger procedure with multiple areas treated under general anesthesia. Many patients started with one area to see whether they liked the results before proceeding to have additional areas treated.

Approximately one third of patients were treated under general anesthesia, and many of these patients had additional procedures such as breast augmentation performed concurrently. The high percentage of patients treated under local anesthesia appears to be a paradigm shift, with older patients having minimally invasive procedures, and our impression was that these were often new patients who had not previously considered liposuction due to age or aversion to general anesthesia.

The benefits of bipolar RFAL are readily apparent, and we believe this influenced our patients' decisions to undergo this treatment. Many patients who were eventually treated with bipolar RFAL were initially consulted for non-invasive procedures (such as CoolSculpting, SculpSure, Velashape, or Vanquish), but chose bipolar RFAL due to a reduced number of treatments per area, no risk of hypertrophy, and the additional skin tightening provided by bipolar RFAL. It should be noted again that most small area RFAL patients returned to exercise at 3 days post procedure and that garment use was limited – additional reasons, we

surmise, for the increased acceptance of bipolar RFAL. Finally, in contrast to laser energy, which generates heat through selective photothermolysis (eg by targeting a pigment chromophore), bipolar RF works by delivering RF energy directly to the tissue[18,19] and is therefore effectively "colorblind." Although it is possible for thermal energy to result in hyperpigmentation, no patient in this series had skin color changes from the energy placed.

The mechanism of bipolar RF is through the controlled delivery of thermal energy to the dermis and subcutaneous fibro septal network (FSN).[16,18,20,21] The resistance of tissues to the flow of RF energy results in the generation of heat.[18,19] RF energy has been shown to cause thermal-induced contraction of collagen and restructuring of collagen fibers.[11,18,20,22] When thermal energy is delivered to the dermis, it results in skin tightening,[7,16,18,22,23] and when delivered to the FSN it produces volumetric contraction.[16,20] These changes have been shown to occur at around 70°C for the subcutaneous tissues of the septofascial network and FSN,[11,16] and optimally between 39°C and 42°C for the skin in order to avoid thermal injury. In prior work, effective temperatures for tightening were seen to be 47°C by thermal camera surface measurements.[7] There is a correlation between the bipolar RF external probe measurement of 42°C and the thermal camera measurement: these are two different ways to measure the same reading, from a "top down" or "bottom up" perspective.

The advantages of using tightening technology are obvious: avoiding the laxity that occurs with traditional liposuction, and contouring and tightening body areas that are already lax. The areas treated in this large series varied from traditional liposuction areas (such as necks, abdomen, flanks, and thighs) to non-traditional areas (such as jowls, axillary rolls, arms in older patients, banana rolls and calves). The smaller probes were especially useful in treating small areas.

The question arises as to what the advantages of bipolar RFAL are when compared to monopolar RFAL such as ThermiTite (Thermi, Irving, TX) and to LAL. In our opinion, having used both technologies, bipolar RFAL offers simplified external temperature monitoring and more power (and thus faster treatment) when compared to the original generation of monopolar technology. Additionally, the bipolar nature of the RF energy delivered spares nerves by only treating the tissue in between the electrodes (Figure 2). Compared to LAL, bipolar RFAL is a less complex, more solid-state device, with less moving parts and less service issues—this is particularly relevant if the device is to be transported from office to OR. Like laptops, solid state devices contain circuit boards which are not prone to injury from movement. Lasers are complex instruments with mirrors and

light pathways that are very dependent on calibration. Movement can easily alter the precision of these devices, which may then require servicing upon a change in location.

Complications of energy-based devices are mostly due to excessive energy – ie creating a burn or an area of fibrosis. Laser liposuction in particular had many reports of burns which in our opinion was due to inadequate temperature monitoring. With bipolar RF there is constant temperature monitoring and therefore the risk of burns is much lower than with previous techniques. A review of the incidences of adverse events (AEs) for every energy device mentioned in this manuscript would be interesting however this is outside the scope of our paper.

In this series we elected to compare an initial group of patients to a later group to see if there was a learning curve to avoiding complications, and in fact we did see a decrease in adverse events from 21 to 19% (although this did not reach statistical significance). Most of these AE's were self-limited nodules or swelling. There were only two true burns in this large series, minor arm burns which healed uneventfully. These were thought to be from using the 40-watt handpiece in very thin women treated for skin tightening of the arms. We subsequently learned to move this handpiece a bit more rapidly and this eliminated any further issues. It was decided to not quantify the middle 545 patients as there were no major complications and the minor AE's of swelling, nodules, etc. of this middle group did not add any value to this paper. The low incidence of complications may also be due to the senior authors' expertise as both have had many years of experience with energy-based devices.

Novices to energy-based liposuction need to be aware that complications of bipolar RF beyond those of suction assisted lipectomy (SAL) are avoidable with proper technique and deserve mention. An "end hit," or "end dermal hit" occurs when the tip of the internal probe is thrust into the dermis at a perpendicular angle during treatment. It is most often seen when treating around a convex contour, such as a bony prominence. Care must be taken to recognize the contour in these areas and focus on passing the internal electrode parallel to the skin. Manual retraction of the skin is useful to maintain a flat surface (like the process of making a flat surface for a dermatome during a split thickness skin graft). When an "end hit" occurs, it can usually be felt as resistance in the handpiece as the internal probe abruptly stops within the dermis on a pass. The end hit can be seen on the skin surface as a small weal (Figure 9). Treatment is immediate application of ice, and we always have a sterile glove filled with ice cubes on the field for this purpose. If treated promptly, there are no long-term consequences. If untreated, however, the "end hit" could result in a full-thickness burn.

Another adverse event seen with bipolar RF is hardened areas or nodules. Although this complication was rare in our series (8.5%), we did obtain a biopsy of one such lesion, which was consistent with fat necrosis. If these "hard areas" (or nodules) indeed represent fat necrosis, then this underscores the importance of evacuating liquified fat after bipolar RF.

All suction lipectomy procedures may cause contour irregularities and result in the need for further surgical or nonsurgical contouring, however adverse events (AE's) were extremely rare in this series. It should be noted that both senior authors had extensive experience with energy devices prior to using bipolar RFAL, and this may have contributed to the lack of AE's. However, both senior authors have trained many physicians with this technology and have kept in contact with the physicians they trained, and minimal issues have been reported. Our recommendation still stands that proper training is essential, but the learning curve is short, and bipolar RFAL technology is very safe.

One limitation of bipolar RFAL is its potential inability to achieve maximal skin tightening. The physician or patient may feel their results are adequate for a minimal incision procedure, but expectations should be tempered to not expect "surgical" (ie excisional) tightening from the device. Another limitation is consistency from patient to patient. Although we have shown very good results in our photos, there is variability in most tightening technologies and even surgeries, due to differences in age, sun damage, dermal thickness, genetic factors, and unknown reasons. Fortunately, by setting proper expectations during preoperative consultation, and with adequate patient selection from experience, the vast majority of patients are satisfied with the results. We have learned from this series that patient selection is key to achieving successful outcomes—that patients with hanging skin, who are truly in need of surgical excision, will never tighten to the point of not needing surgery. Conversely, marginal patients without hanging skin who would surely sag from traditional liposuction will maintain their tissue integrity with the addition of radiofrequency. In other words, this technology tightens them enough to provide a nice appearance without causing worsening of their skin laxity. Younger patients with good elasticity have universally excellent results.

The limitations of this study include its retrospective design and lack of objective outcome data (such as volumetrics or measurements of two-dimensional skin tightening). The homogeneity of our sample population was limited by including patients treated at two centers, but this larger group is more representative of the overall population undergoing these procedures. We also did not perform a pre hoc power analysis prior to making statistical comparisons between groups. However, this study was not designed to experimentally assess

the technology used, but rather to provide a thorough clinical review of the authors' experience using the device.

CONCLUSIONS

With the popularity of social media, patients are increasingly discerning about their appearance. As a result, plastic surgeons are now faced with higher expectations and more subtle goals. For these patients, the concept of body contouring has evolved to encompass improvements to the aesthetic appearance of all parts of the body, with a premium placed on treatments that are incisionless, and carry a minimal amount of pain and "down time."

We have shown that the combination of bipolar RF and focused liposuction can provide for impressive results under both general and local anesthesia. The limitations of our study include its retrospective design and lack of quantitative outcome metrics. Nonetheless, we believe our experience in this largest series reported to date can serve as an indicator to surgeons seeking to achieve similar results. Bipolar RF can be used to achieve elegant outcomes in patients with mild to moderate skin laxity and focused adiposity, enabling surgeons to achieve finesse in lipocontouring.

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Table 1. Probe Dimensions

	Length (cm)	Diameter (mm)	Energy Depth (cm)
BodyTite	17	2.2	2-6
FaceTite	10	1.3	1-2
AccuTite	6	0.9	< 1

Table 2. Demographic Information for All Patients

Number of Patients	745
Female	639 (86%)
Male	106 (14%)
Average age (years)	50.5 (range 18 – 84)
Average areas treated per patient	1.62 (range 1 – 7)

Table 3. Number of Treatments Performed, by Area

	Total	First 100	Last 100
Abdomen	218	26	27
Thighs	192	22	8
Neck	120	21	45
Flanks	105	17	16
Back	64	17	3
Arms	62	14	11
Banana rolls	27	8	1
Axilla	26	5	5
Knees	17	5	1
Chest	16	2	0
Breasts	15	1	2
Mons	14	1	1
Jowls	10	0	0
Buttocks	9	0	1
Total:	895	139	121

Table 4. BMI Comparison, First and Last 100 patients

	Site 1			Site 2			Combined		
BMI	First 50	Last 50	Combined	First 50	Last 50	Combined	First 100	Last 100	Combined
Average	22.7	23.3	23.1	26.1	25.8	26	24.5	24.6	24.5
Min	17.3	17.1	17.1	19.4	19.1	19.1	17.3	17.1	17.1
Max	34	29.3	34	34.6	36.9	36.9	34.6	36.9	36.9

Table 5. Anesthesia by Category

	All Cases (%)	First 100	Last 100
General Anesthesia	242 (32.5)	30	29
Local Anesthesia	503 (67.5)	70	71

Figure Legend

Figure 1. A) BodyTite handpiece. B) FaceTite handpiece. C) AccuTite handpiece.

Figure 2. A) Schematic depicting the flow of RF energy between the internal and external electrodes, and B) Idealized image of radiofrequency energy transfer within tissue.

Figure 3. Deep fibrous tissue target for RF energy (reproduced with permission from Diane I. Duncan)

Figure 4. Number of treatments performed by area for the first 100 and last 100 patients.

Figure 5. 53-year-old female patient– neck treated with FaceTite – 1 month, A) Before and B) After.

Figure 6. 61-year-old female – FaceTite treatment to circumferential breast with calibrated measurements – 3 months, A) Before and B) After.

Figure 7. 48-year-old. female – axillary "bra fat" treated with liposuction and FaceTite – 3 months, A) Before and B) After.

Figure 8. 61-year-old. female – back and flank treated with VASER and BodyTite – 3 months, A) Before and B) After.

Figure 9. Dermal end hit, immediate intraoperative appearance (arrow) in a 42-year-old female.

Figure_1A

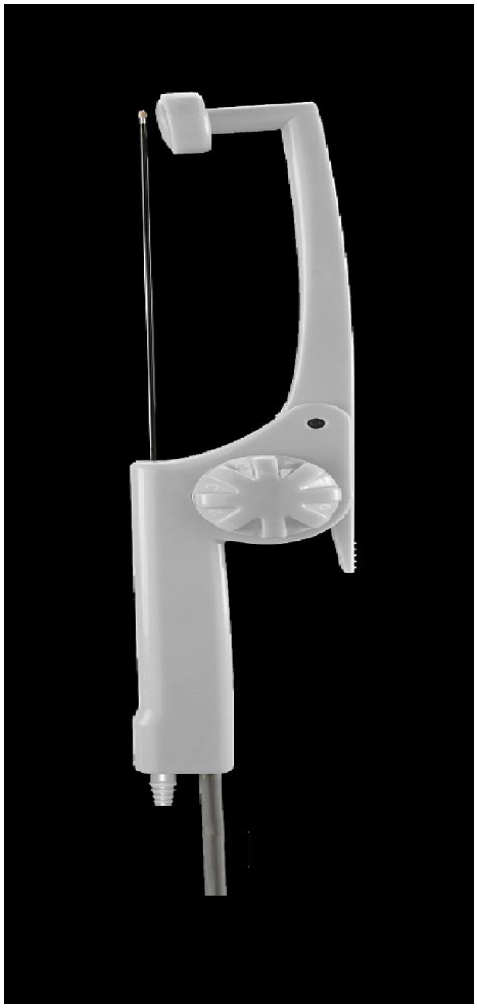

Figure_1B

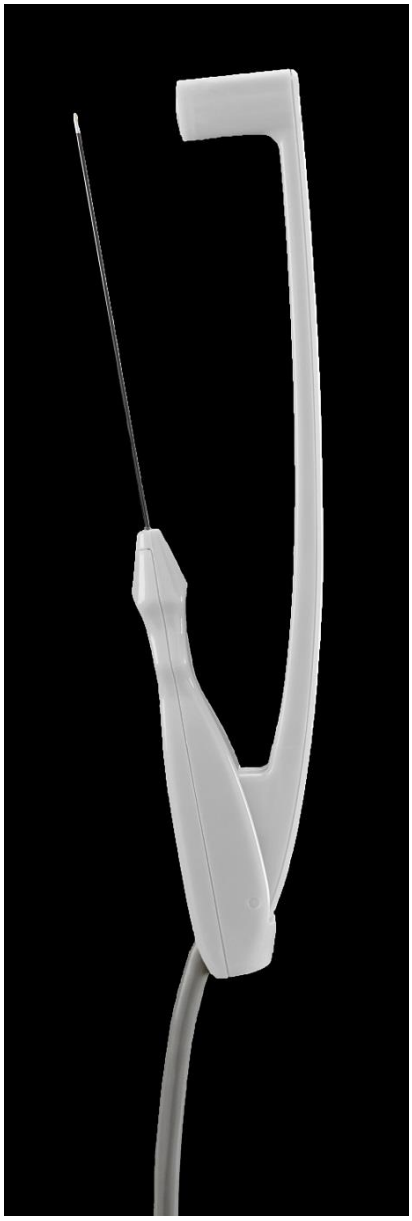

Figure_1C

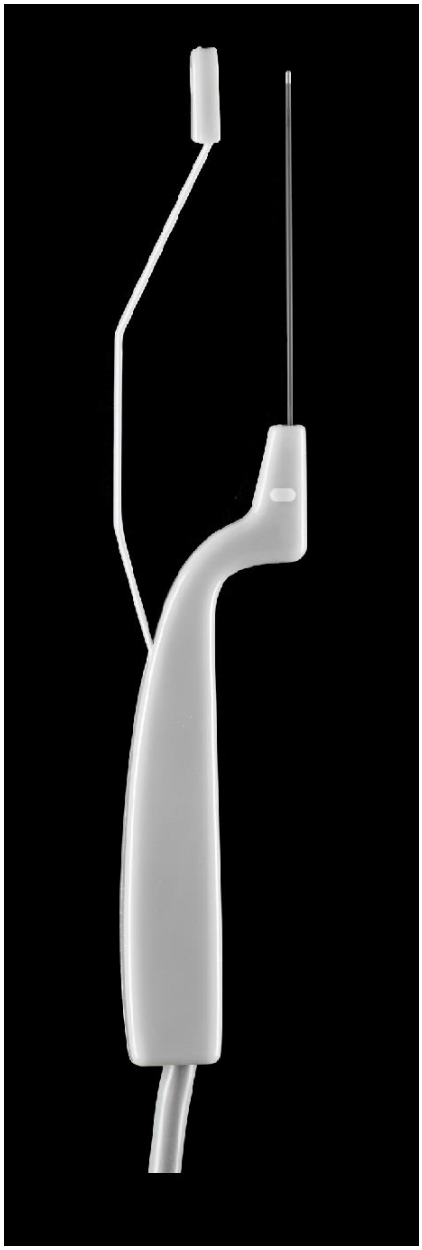

Figure_2A

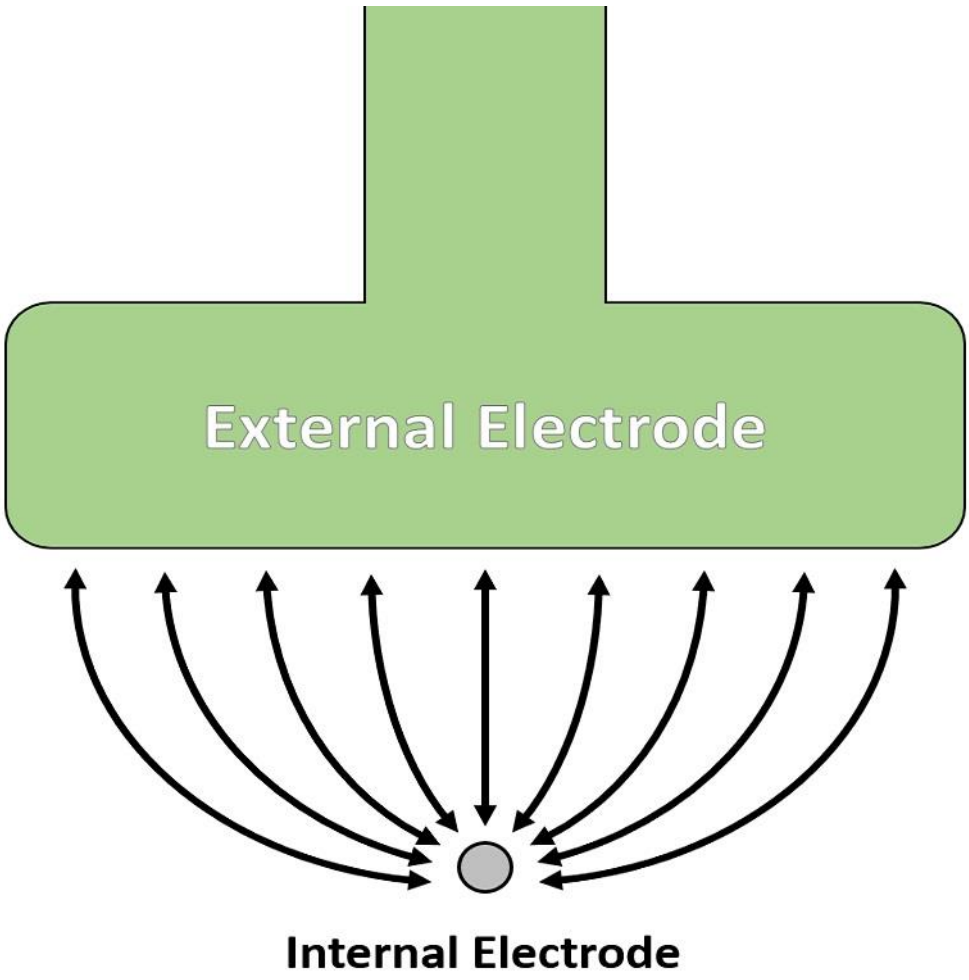

Figure_2B

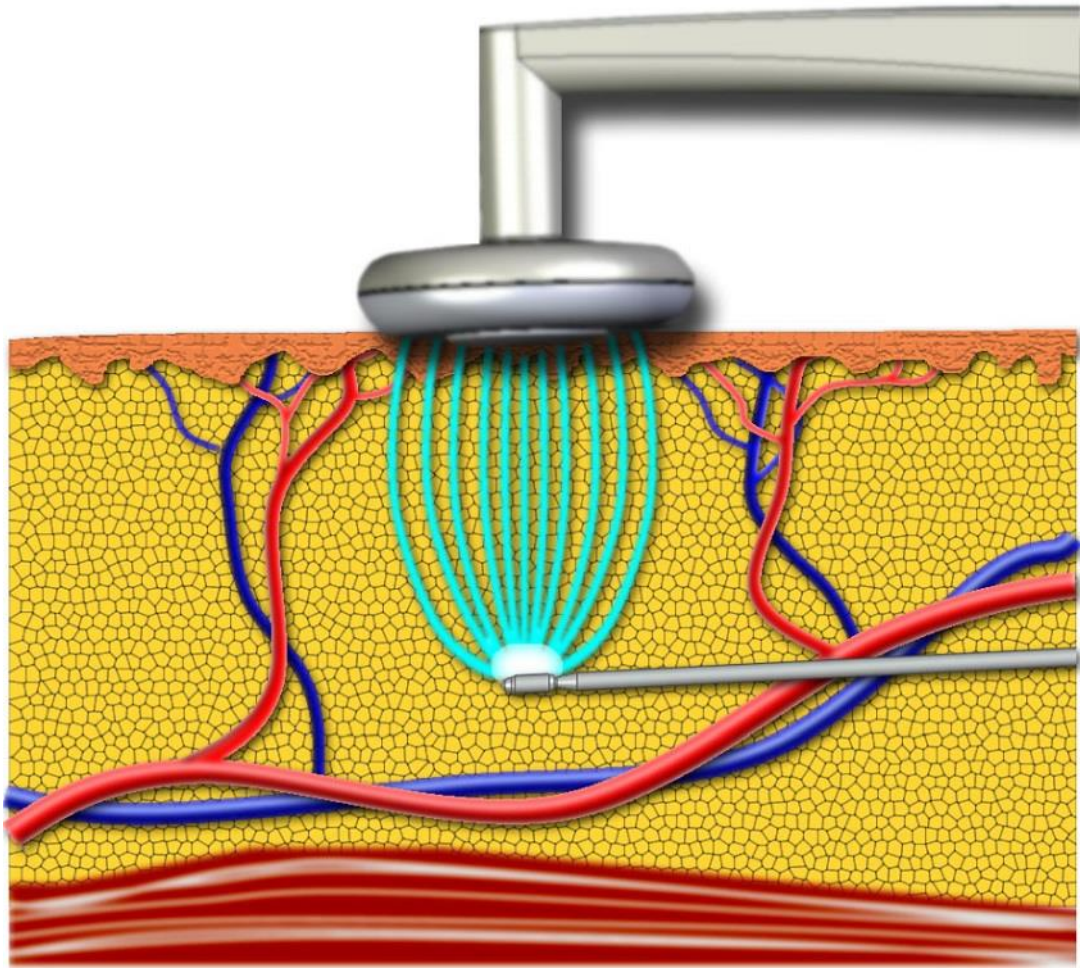

Figure_3

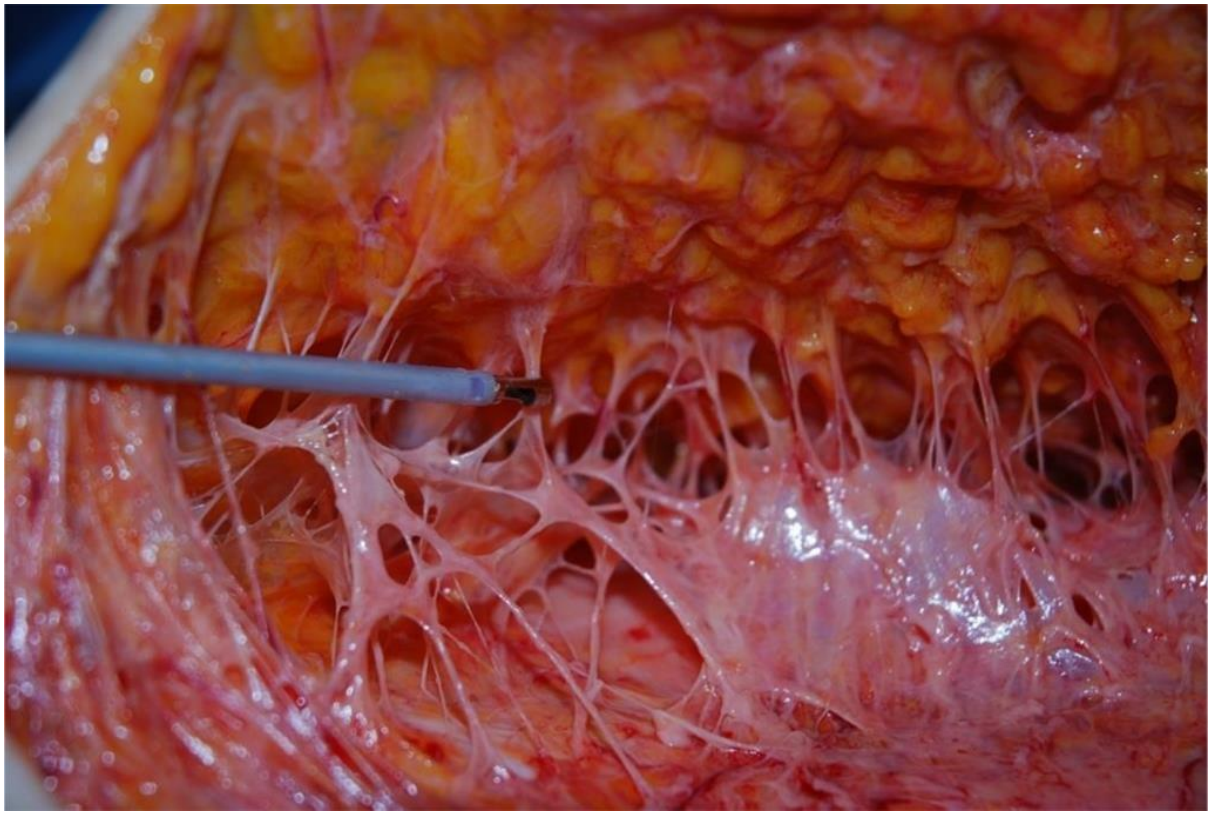

Figure_4

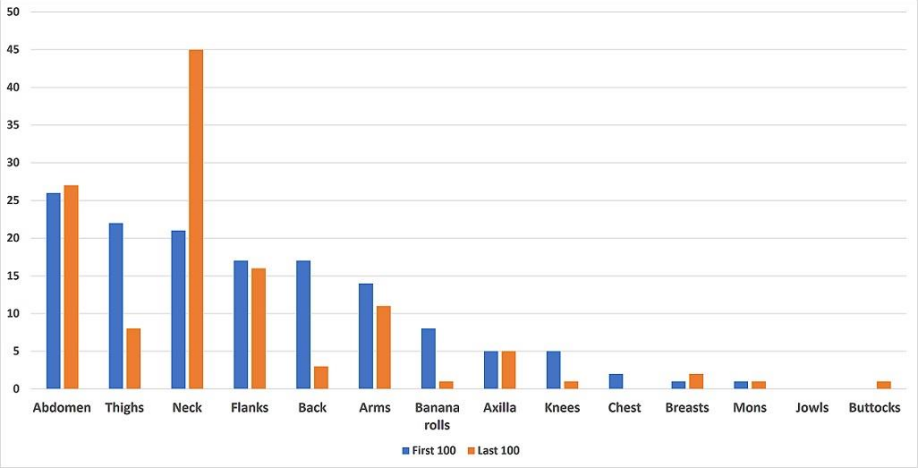

Figure_5A

Figure_5B

Figure_6A

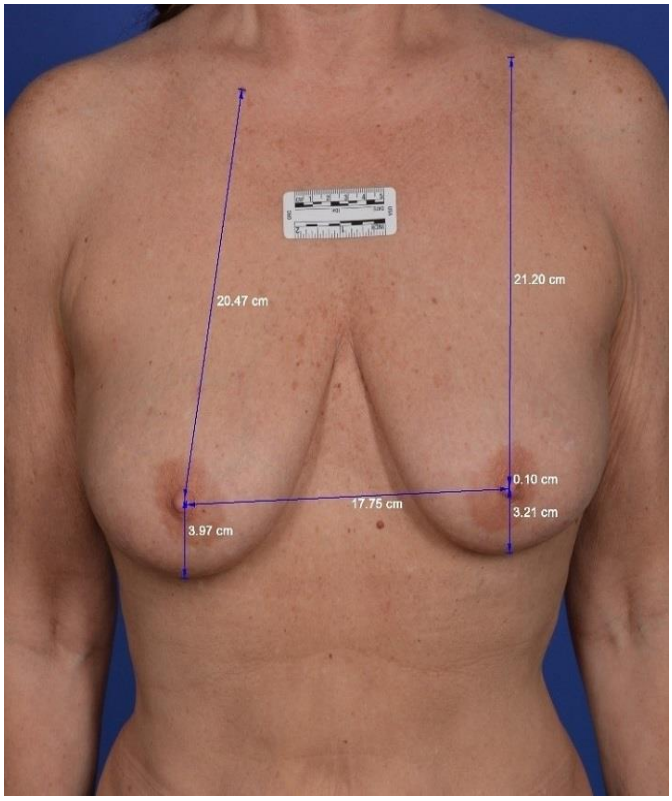

Figure_6B

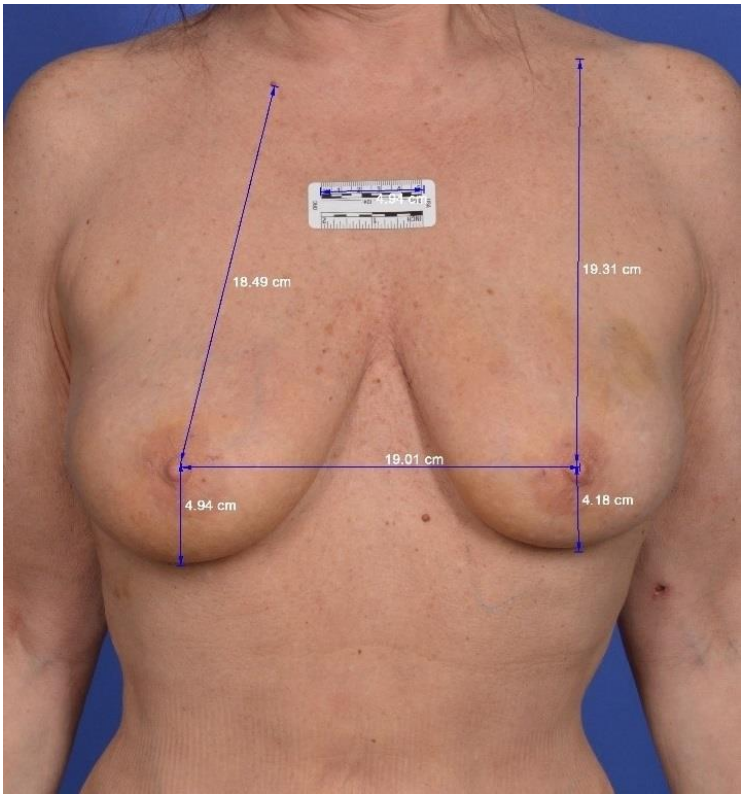

Figure_7A

Figure_7B

Figure_8A

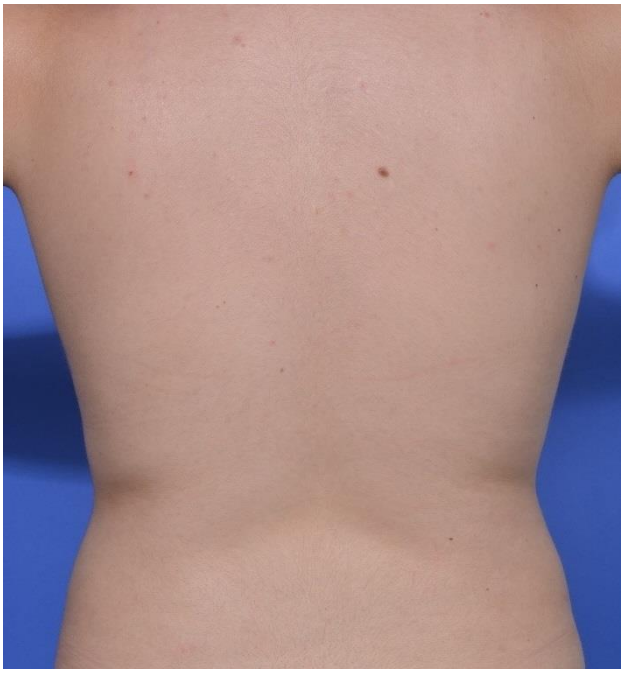

Figure_8B

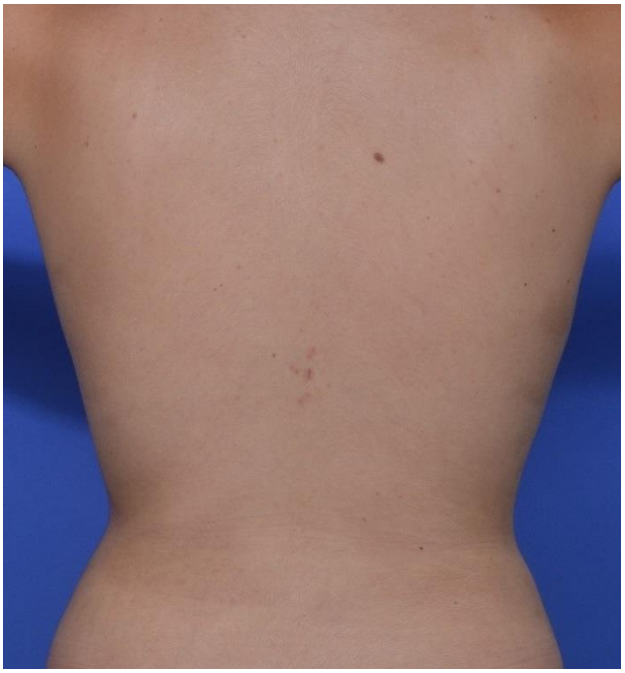

Figure_9