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Helium Plasma-Driven Radiofrequency in Body Contouring

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Abstract

Consumer demand for a minimally invasive alternative to dermolipectomy-based excisional procedures has been driven by interest in risk reduction, reduced scarring in the treatment region, and significant lessening of recovery time. While minimally invasive liposuction is a common approach, limitations can include residual skin laxity and irregular skin contour. The current literature suggests that radio frequency energy is superior in achieving non-excisional soft tissue and skin shrinkage without surgical skin resection. Monopolar and bipolar radiofrequency-based devices have been available for 10 years. Recently, a plasma-driven radiofrequency device, Renuvion, was introduced and FDA cleared for soft tissue coagulation. The device uses a pressurized helium tank to drive radiofrequency energy into a hollow cannula. As measured skin temperature rarely exceeds 38°C, the safety profile of the device is optimized. The use of helium-driven plasma energy is a new and promising resource for achieving non-excisional soft tissue and skin tightening. Because the device rapidly heats subcutaneous collagen, strong immediate contraction is generated within fractions of a second. This treatment is followed by very visible improvement at the 24 hour post-op mark. Results can continue to improve over a year, as infiltration of new collagen within the adipose stroma occurs.

Keywords: skin tightening, radiofrequency, impedance based, minimally invasive, helium plasma

1. Introduction

For decades, the ability to reshape the human body was limited to dermolipectomy-based excisional procedures with long scars. Consumer demand for a minimally invasive alternative has been driven by interest in risk reduction, reduced scarring in the treatment region, and significant lessening of recovery time so that patients can return to work or regular activity within a short time span. Liposuction appeared to be the golden solution for many. While this minimally invasive procedure is a common approach, limitations can include residual skin laxity, an irregular skin contour, and little improvement in regions that were pendulous prior to the procedure. Subcutaneous tone is generally not improved with traditional suction-assisted lipectomy (SAL). Goals other than fat reduction include significant skin and soft tissue contraction in a smooth and even manner. While

ultrasound and laser-assisted lipoplasty have been recommended for this purpose following liposuction, consistent outcomes have not been able to be achieved. The current literature suggests that radiofrequency (RF) energy is superior in achieving non-excisional soft tissue and skin shrinkage without surgical skin resection. By targeting the subcutaneous collagen matrix instead of just the skin, practitioners of body contouring are able to achieve up to 36% measured skin surface area contraction at 1 year following treatment with RF-assisted liposuction. While monopolar and bipolar radiofrequency-based devices for this purpose have been available for 10 years, only recently has a plasma-driven radiofrequency device been introduced. The Renuvion device is FDA cleared for the purpose of soft tissue coagulation. The device is a modification of a standard Bovie electrocautery unit. The new configuration has a pressurized helium tank attached to the energy delivery system, so that helium plasma-driven energy is emitted from a hollow cannula when the device is activated. The handpiece is moved in the subdermal plane in a manner similar to that of a liposuction cannula. Emitted energy is fractional. Small fragments of stromal collagen are heated very quickly to 85°C, causing a reduction in fiber length of 40–50%.

Because the measured skin temperature rarely exceeds 38°C, the safety profile of the device is optimized. Soft tissue treatment is usually performed following liposuction, but it can also be used in the subcutaneous plane without liposuction when skin contraction alone is desired. The use of the device for these purposes is considered off label.

2. History of suction-assisted lipectomy (SAL)

Patient and physician interest in limiting incisions and complications led to the development of liposuction in the late 1970s [1]. While Illouz [2] has commonly been given credit for coming up with liposuction as a new procedure, other surgeons before him used a combination of sharp cannulas without tumescent fluid to remove fat. German surgeons Schrudde, Meyer, and Kesselring performed liposuction in the early to the mid-1970s in such a manner [3]. Blood loss was significant, and clinical outcomes were not ideal.

The Fischers, a father and son team, developed a blunt liposuction cannula in the mid-1970s [4].

They treated only the thigh area. Frenchmen Illouz and Fournier spread the technique to other body regions and to other esthetic surgeons [5]. During the late 1970s, they began combining injection of intravenous fluid and hyaluronidase for the purpose of improving the ease of dissection. The term they used was “wet technique.” Klein [6] is credited with the concept of tumescent fluid, which differs from the French wet technique by adding both epinephrine (to reduce intraoperative blood loss) and lidocaine (for pain reduction during the procedure, so that it could be performed while the patient was awake). Sodium bicarbonate was added to the injectable fluid in order to reduce burning on injection when general anesthesia was not used. The safety of infusing large volumes of this solution was documented in studies performed by the dermatologic surgery contingent, who focused on lidocaine toxicity [7]. The complication rate with liposuction was significant though [8], and the ASAPS recommended limiting large volumes of infusion and lipoaspirate over 5 L to the hospital setting [9].

Liposuction rapidly gained popularity but did not replace dermolipectomy, as limited skin surface area contraction was noted with SAL alone [10]. The development of energy-assisted liposuction was rapid and included ultrasound, laser, power, water-jet, shock wave, and radiofrequency-assisted liposuction [11–16].

While many new devices have been utilized during the past 20 years, few have attained the simultaneous goal of significant and esthetically acceptable skin contraction in the treatment region.

For decades, practitioners and patients alike have been focused on treating “skin laxity” without considering the true cause of the problem. Recent publications [17] show that the adipose/stromal framework of the skin may be a better treatment target. Rubin noted [18] that skin follows the substructure. If the scaffold or framework that the skin rests upon is weak or ptotic, the skin will follow, as it has no ability to hold a fixed shape on its own. If a practitioner chooses a device or treatment that does not target the framework, also known as the fibroseptal network (FSN), the goal of improving a pendulous structure will not be met without an excisional approach.

How does the skin become lax? Facial aging studies show that the average person loses 235 cc of bony mass during a lifetime [19]. Certainly, there is associated muscle and fat atrophy with aging [20, 21]. While fat loss in the face and neck is a normal part of the aging process, these factors do not explain the loss of soft tissue tone. Serial scanning electron micrographs were taken from volunteers of various ages and similar skin types [22]. These show that with age, weight gain and loss, and genetic predilection, the stromal portion of the adipose framework for the overlying skin becomes weak, due to loss of the fibrocollagenous matrix and involution of the vascular network.

While mechanical stimulation of the FSN with liposuction can create an 8% skin surface area contraction at 1 year posttreatment [23], the firm tone and defined shape of youthful body contours are not re-established. A thermal regenerative solution for this dilemma has been the focus of my energy-based device studies over the last decade.

3. History of energy-based devices

Ultrasound-assisted liposuction (UAL) was introduced by Zocchi in 1990 [24]. Reports of complications including seroma, burns, and contour irregularities caused a loss of popularity of this particular device. A current ultrasound-based device, Vaser, is still in regular use but is not targeted toward causing skin contraction. Power-assisted liposuction (PAL) is used by many practitioners who like the vibratory nature of the handpiece for treatment of fibrous areas and in secondary cases. Water-jet-assisted liposuction is excellent for fat grafting harvest, but does not improve the overall liposuction outcome. Laser-assisted liposuction (LAL) was shown to create a 13–17% skin surface area reduction at 3–6 months post-op [12]. Lack of a long-term outcome has led to a loss in popularity of this device. Radiofrequency-based tissue tightening has increased in popularity as longer-term improvement has been shown [23]. A bipolar device with indwelling liposuction capability was introduced in 2008 (Invasix) [16], and a monopolar device was cleared for soft tissue coagulation in 2012 (Thermi) [25]. This device utilized a subcutaneous cannula with an internal temperature probe. In 2012, a new version of the bipolar device (InMode) was introduced that contained both internal and external temperature monitors. A 50% improvement in upper arm pendulosity and a 36% skin surface area reduction at 1 year were seen with this device [26]. In 2016, the J-Plasma device (Bovie Medical) was introduced for the purpose of subdermal coagulation. The device was originally developed as a general surgical/gyn/urological laparoscopic cautery device. In esthetic cases, the cannula with blade retracted has been used in the subcutaneous plane for the purpose of collagen coagulation.

4. Mechanical effects of liposuction

Traditional SAL removes fat. However, the procedure is also a mechanical, nonthermal FSN stimulant. If simple fat reduction in a young patient with no soft tissue laxity is the goal, then fat removal and mechanical stimulation of the soft tissue will cause some reduction of the distended skin and soft tissue mass. Nonthermal trauma to the tissue induces an inflammatory response, which as we know causes inosculation of new blood vessels, generation of fibroblasts, and formation of new collagen or scar tissue within the treated space. Chemokines, cytokines, and growth factors all influence tissue response to mechanical injury [27]. Skin contraction with SAL measures about 10% at 6–8 weeks posttreatment [23] and then relaxes to a measured 8% skin surface area contraction at 1 year.

Practitioners such as specialists like Gasparoni and Toledo used superficial liposuction to optimize skin shrinkage [28]. However, reports of complications resulting from treatment by other surgeons have diminished the popularity of this procedure [29]. Full-thickness skin loss due to aggressive superficial liposuction is still a concern, especially in Central and South America.

5. Thermal effects of heating soft tissue

When heat is added to mechanical stimulation, the soft tissue response changes. Thermal effects of radiofrequency energy can include ablation, coagulation, and collagen contraction [30]. While ablation without adjacent tissue damage is a desired goal in vaporizing tumors or lesions, the esthetic practitioner has more commonly used RF to cauterize blood vessels or to directly shrink soft tissue. Common use of a pencil-type cautery unit includes shrinkage of the SMAS in face lifting or a “popcorn” capsulorrhaphy in breast implant surgery.

A newer concept is that of contraction of collagen fibers, a microeffect of RF energy on the tissue. Genin [31] notes that the native state of triple helical collagen strands change to a transitional state and then become denatured when temperature from the device over time causes the protein to unfold. In a study by Rossman [32], he showed that average collagen fibers measure 290 nm shrank to 101.5 nm when denatured, a contraction of 65%.

The electric properties of tissue are governed by impedance or “resistivity” to energy conductance [33]. When a uniform tissue type is exposed to radiofrequency energy, impedance can be measured using a certain cross section with a measured distance between the electrodes [30]. Blood is highly conductive to RF energy with a slight lowering of impedance between 0 and 6 MHz. Its conductivity coefficient is 0.7 (low impedance), while fat has high impedance with a conductivity coefficient of 0.03. The value of adding tumescent fluid to fat is illustrated by contrasting the impedance of dry and wet skin. Dry skin conducts RF energy at a 0.03 coefficient—the same as fat, while wet skin has a 0.25 coefficient.

If tissue is heating slightly—elevating the temperature from 37°C to 44°C, the metabolic process quickens [34]. At 45°C, there is a structural change in the collagen helix which leads to hyperthermic cell death. At 60–80°C, collagen proteins denature and unfold. At 90°C, tissues become dessicated, and at 100°C, they become thermally ablated.

In treating patients, factors to consider include the “permittivity” of the tissue to heat, and the temperature achieved in the treatment region. These two factors, as well as duration of energy exposure, directly influence clinical outcome. The vascular perfusion to the area is another very important consideration. This can be

compromised in patients who have had previous procedures in the treatment zone. The frequency and type of energy source will also affect tissue response.

6. Radiofrequency energy in esthetic procedures

Energy has been applied in some form to tissue since the beginning of recorded history. The practice of applying heat to tissue through the use of cauters was used for thousands of years as an invaluable method of controlling hemorrhage. Continuous improvement of methods for utilizing the beneficial effects of heat on tissue eventually led to the development of the basic concepts of electrosurgery we know today. In October of 1926, Dr. Harvey Cushing used an electrosurgical unit developed by Dr. William T. Bovie to successfully remove a highly vascularized brain tumor from a patient after previous failed attempts. Today, electrosurgical instruments are used in the majority of surgical procedures performed worldwide [35].

Radiofrequency-based devices for skin rejuvenation became popular in the early 1990s, as a noninvasive device (Thermage) was used to improve tissue tone and texture. Other devices rapidly followed and utilized monopolar, bipolar, and multipolar configurations to treat the skin surface. While the Bovie cautery device has been used for decades in the subcutaneous plane, an open approach was needed. The first subdermal device to be used in a minimally invasive manner was the BodyTite device, which in 2008 had an accompanying liposuction cannula. The monopolar Thermi device utilizes a 10- or 15-cm slender monopolar cannula in a subdermal manner to heat soft tissue at the level of the fibroseptal network. These devices are characterized as “bulk heating” devices and create a radiant pattern of tissue heating from the probe tip outward.

7. Characteristics of bulk heating devices

Traditional subcutaneous monopolar and bipolar radiofrequency devices utilize a small cannula that is placed underneath the skin to heat the adipose tissue. They are called bulk heaters because the thermal energy generated from the tip of the device heats the adjacent tissue from the point of emanation. The surrounding tissue becomes warm gradually in a radiant distribution. Monopolar RF has only a single source of subcutaneous energy, and heat must accumulate in the tissue from this small point. A grounding pad is needed to safely treat the patient (**Figure 1**). Bipolar devices maintain a zone of energy between two sources, in this case, one internal and the other external (**Figure 2**). If the external treatment head is small, it will take a while for the tissue between the two emitters to heat up. Broader external heads create wider fields of heated tissue and are more time efficient. Energy output also influences the speed of tissue heating. Tumesced tissue increases the permittivity of the adipose layer toward heat. If liposuction is indicated, it should be performed prior to energy application. Then, tissue heating is optimized, as the heat-resistant adipose shield will have been removed from the collagen bands of the fibroseptal network, which have lower impedance. Advantages of these device types include ease of use, a known performance history, and many experienced users. Limitations include a long duration of heating if treatment areas are broad. Even with an external sensor such as a FLIR camera or external thermistor, burns and seromas can occur. Clinical endpoints of treatment include warmth, erythema, and a slight tissue reaction when the cannula is moved under the skin. While the internal cannula tip can get to the preset temperature quickly, the surrounding tissue takes time to get warm. Thus, there are “hot spots,” which may

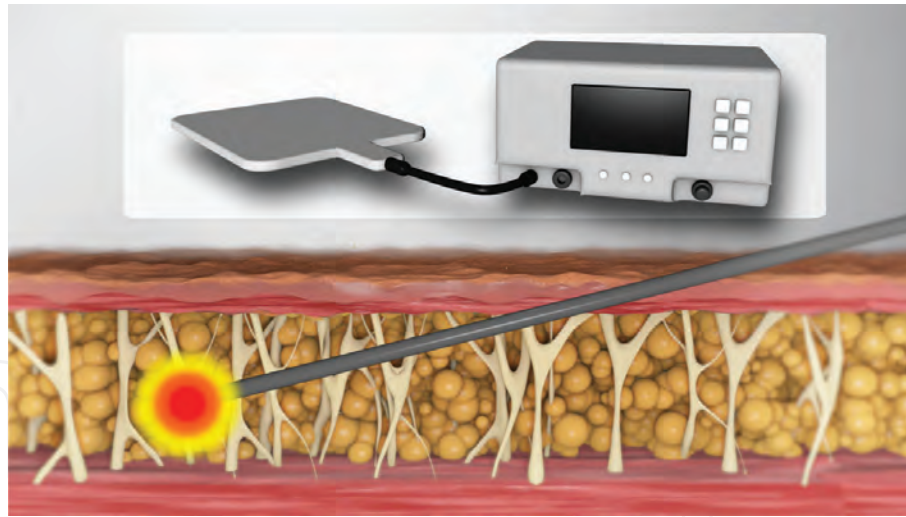


Figure 1. Monopolar soft tissue coagulation device. The heated tissue radius is small, as the cannula tip is not large. There is a central region that heats to a high temperature, but this rapidly drops down at the periphery. A grounding pad is needed in order to safely treat the patient.

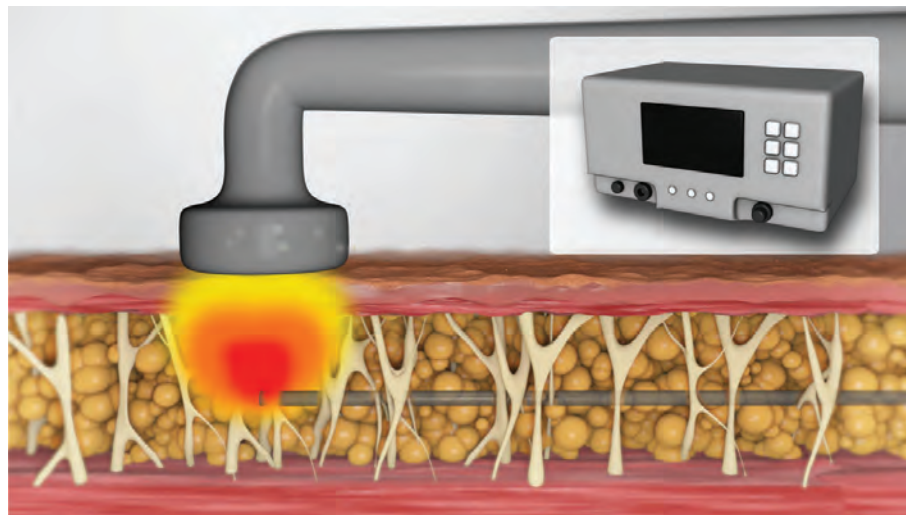


Figure 2. Bipolar configuration of a radiofrequency-assisted tissue tightening device. There is an internal and external heat sensor. The cannula is deployed in the subcutaneous fat in a manner similar to that of a liposuction cannula.

develop seromas, and areas where heating is not optimized. If the operator continues to heat a region that has already been optimally treated, cauterization of the microvasculature can cause ischemia, resulting in fibrosis or a burn. Knowing the amount of energy used is helpful, but a difficulty with any energy-based device is knowing when you are done. Factors that should reduce the amount of time and energy spent include an area with thin skin, a relatively thin layer of fat (such as the neck, face, and decollete), and any degree of existing fibrosis. FLIR studies show that when used in a primary case in the fibrous bra roll region, a bipolar device generated a skin temperature of 45°C for several minutes, even after the device was removed (**Figure 3**), despite the preset skin cutoff temperature being 38°C. A key to success when using these devices is to consider decreasing treatment time and measuring the skin temperature with FLIR in regions that have been previously treated and have some scar tissue and compromised blood supply. In fibrous areas, the physical nature of bulk heating can create a heat sink, due to the slow dispersion of heat. Compromised blood supply due to scarring or physical containment of heat

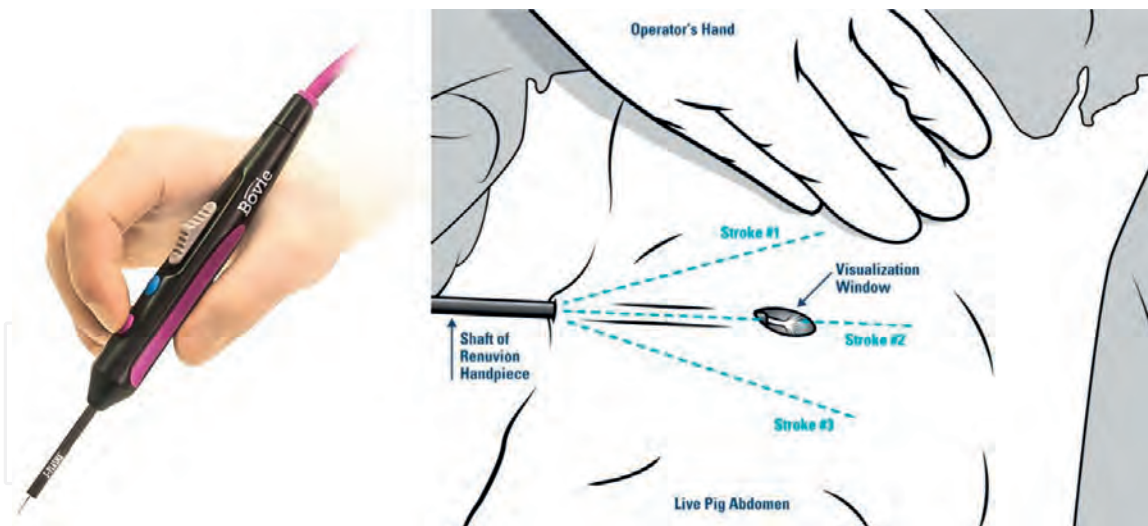


Figure 3.
Illustration of methods used in tissue temperature study.

is a region with fibrous fat which is a relative contraindication to the use of a subcutaneous bulk heating device.

8. Characteristics of the helium plasma-driven device

Bovie Medical Corporation's Renuvion[®] (formerly branded as J-Plasma[®]) helium-based plasma technology has FDA clearance for the cutting, coagulation, and ablation of soft tissue. The Renuvion[®] system consists of an electrosurgical generator unit, a handpiece, and a supply of helium gas. RF energy is delivered to the handpiece by the generator and used to energize an electrode. When helium gas is passed over the energized electrode, a helium plasma is generated which allows heat to be applied to the tissue in two different and distinct ways. First, heat is generated by the actual production of the plasma beam itself through the ionization and rapid neutralization of the helium atoms. Second, since plasmas are very good electrical conductors, a portion of the RF energy used to energize the electrode and generate the plasma passes from the electrode to the patient and heats tissue by passing current through the resistance of the tissue, a process known as Joule heating. These two sources of tissue heating give the Renuvion[®] device some unique advantages during use as a surgical tool for the coagulation of subcutaneous soft tissue for the purpose of soft tissue contraction.

8.1 Renuvion[®] instant tissue heating versus bulk tissue heating

Monopolar and bipolar RF devices available for subcutaneous soft tissue coagulation work on the principle of bulk tissue heating. The device is activated until a preset subcutaneous temperature in the range of 65–70°C is achieved and maintained. The tissue being treated must be maintained at that temperature for greater than 120 s for maximal contraction to occur. Although these devices have proven effective in achieving soft tissue contraction [36], the process of heating and maintaining that temperature for extended periods can be time-consuming. In devices without an external temperature monitor, the skin surface can become overheated, causing occasional blisters or burns.

A study conducted on a live porcine model to establish the subdermal tissue temperatures produced by the Renuvion[®] device demonstrated a different philosophy for achieving soft tissue contraction when compared to the RF devices

described above. See **Figure 3** for an illustration of the methods used in this porcine study. The study simulated actual clinical conditions as closely as possible including tumescent infiltration and completion of liposuction on the abdomen of the pig. Prior to beginning treatment with the Renuvion[®] device, an incision was made through the epidermis and dermis into the subdermal plane to serve as a visualization window through which a forward-looking infrared radiometer (FLIR) camera could measure internal tissue temperatures. Multiple treatment passes of the Renuvion[®] device were then conducted using a matrix of various treatment combinations. For each treatment combination tested, a single treatment pass consisted of three strokes of the device in the subdermal plane (see **Figure 3**). The second treatment stroke was performed so that the tip of the Renuvion[®] device passed directly underneath the visualization window. This novel testing method allowed the FLIR camera to capture both internal and external tissue temperatures simultaneously. See **Figure 4** for an example of the images captured by the FLIR camera as the device passes under the visualization window.

Typical results from the porcine study are shown in **Figure 5**. It is important to note that the time shown on the X-axis in this graph is reported in milliseconds.

As shown in **Figure 5**, the Renuvion[®] device heats the tissue to temperatures greater than 85°C for between 0.040 and 0.080 s [17]. Heating the tissue to these temperatures for this period of time is adequate for achieving maximal soft tissue coagulation and contraction. However, unlike with bulk tissue heating, the tissue surrounding the treatment site remains at much cooler temperatures resulting in rapid cooling after the application of the energy through conductive heat transfer. Published studies have shown that the majority of soft tissue contraction induced by subcutaneous energy delivery devices is due to its effect on the fibroseptal network [12, 13]. Because of these unique heating and cooling properties of the Renuvion[®] technology, immediate soft tissue contraction can be achieved without unnecessarily heating the full thickness of the dermis. Practitioners who became used to the need for monitoring skin temperatures with a FLIR camera will find this is not needed with the Renuvion system.

Figure 6 helps to visualize the differences between the bulk tissue heating of monopolar and bipolar RF devices and the instant tissue heating of the Renuvion[®] helium plasma device. The narrow difference between subdermal and epidermal temperatures of the monopolar and bipolar devices (top image in **Figure 6**) results

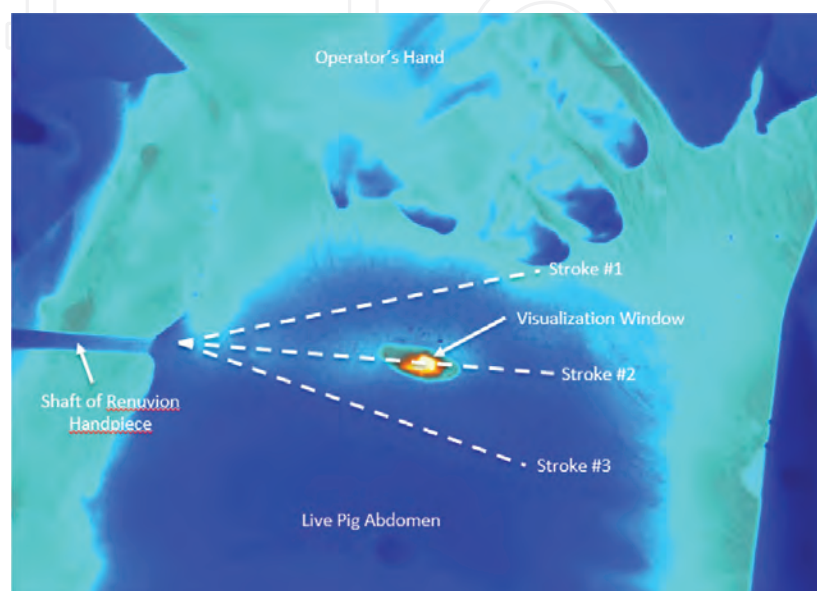


Figure 4.
FLIR camera image.

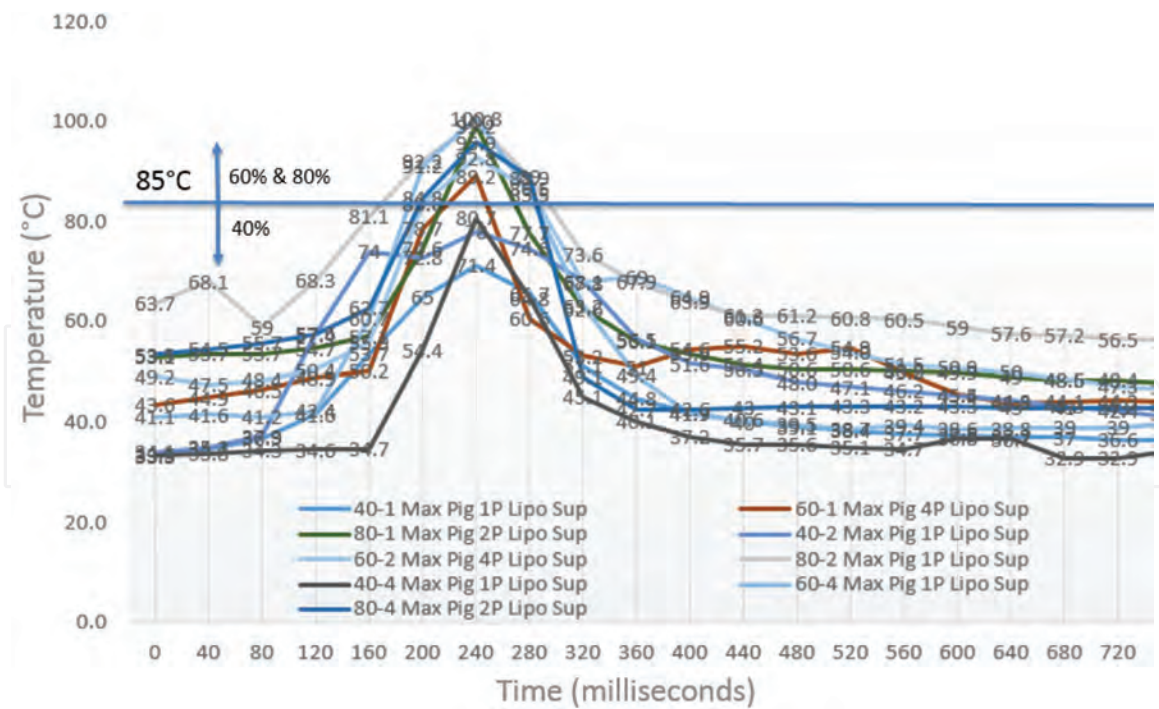


Figure 5.
 Temperature vs. time (in ms) for Renuvion treatment [17].

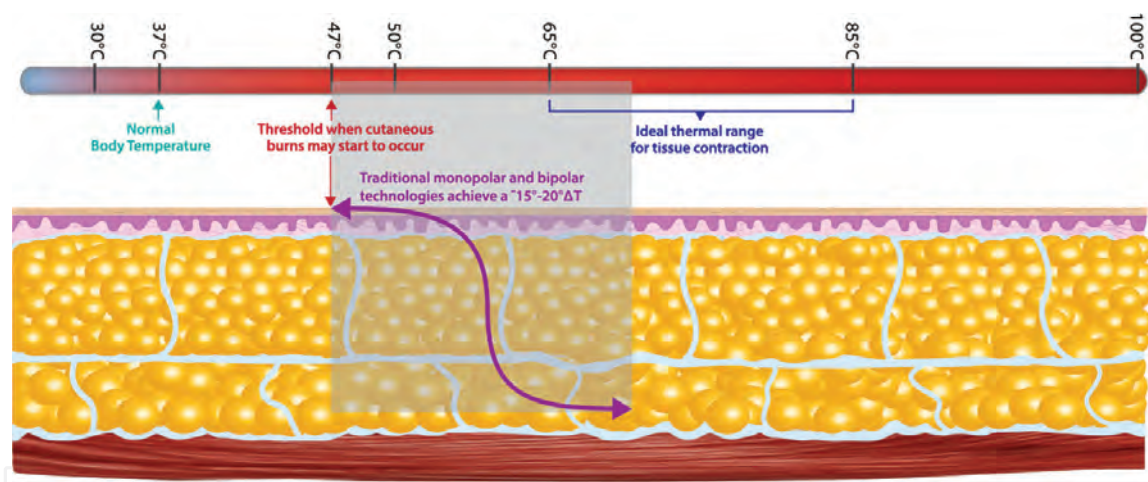


Figure 6.
 Differences in epidermal and subdermal temperatures for monopolar and bipolar RF devices (top) and Renuvion® helium plasma device (bottom). Author's note: while a skin temperature of 45°C was noted in the porcine model, the maximum FLIR reading on a human subject's epidermis has been 38°C.

in a delicate balance between achieving the subdermal temperatures needed for soft tissue contraction and maintaining safe epidermal temperatures, resulting in the need for constant internal and external temperature monitoring. A much larger difference between internal and external tissue temperatures for the Renuvion® device (bottom image in **Figure 6**) achieves maximal tissue contraction while maintaining safe skin temperatures without the need for temperature monitoring.

8.2 Renuvion®—360° tissue treatment

It is known that electrical energy takes the path of least resistance. RF energy flows through the conductive plasma beam generated by the Renuvion® system. This conductive plasma beam can be thought of as a flexible wire or electrode that

“connects” to the tissue that represents the path of least resistance for the flow of the RF energy. This tissue is typically either that which is in the closest proximity to the tip of the Renuvion[®] device or the tissue that has the lowest impedance (is the easiest to pass energy through). When used for the coagulation of subcutaneous soft tissue, this means that the energy from the Renuvion[®] device is not directed or focused in any set direction when activated in the subdermal plane. As the tip of the Renuvion[®] device is drawn through the subdermal plane, new structures are introduced to the tip of the device, and the path of least resistance is constantly changing. As the energy is constantly finding a new preferred path, the plasma beam quickly alternates direction, seeking out new structures to heat (see **Figure 7**). This allows for 360° tissue treatment without the need for the user to redirect the flow of energy. Since the collagen framework of the FSN is typically the closest tissue to the tip of the Renuvion[®] device, the vast majority of the energy delivered by the device results in coagulation and contraction of the fibroseptal bands. Maximizing the energy flow to the FSN expedites the soft tissue contraction process.

8.3 Renuvion[®]—consistent power output

The design of the electrosurgical generator for the Renuvion[®] plasma device is fundamentally different from that of monopolar and bipolar devices. As shown in **Figure 8**, monopolar and bipolar devices have limited power output in tissues with higher impedance, such as fat. The Renuvion[®] device was designed to maintain consistent power output over a wide range of impedances. When used for the coagulation of subdermal tissue, the Renuvion[®] output is not self-limiting and provides unencumbered delivery of power regardless of the tissue impedance.

8.4 Renuvion[®]—minimal depth of thermal effect

Not all RF energy is created equal. Experienced RF users know that you can achieve very different tissue results at the same power setting by simply changing from an RF waveform designed for cutting to an RF waveform designed for coagulation. The proprietary oscillating waveform of the Renuvion[®] device has much lower current than typical monopolar RF devices. In most cases, the current of the Renuvion[®] device is an order of magnitude lower. The current of the Renuvion[®] waveform flows through the conductive plasma beam to create additional beneficial Joule heating of the target tissue. However, since the current is so low, it is dispersed before it is able to penetrate deep into the tissue. This allows for soft tissue heating with minimal depth of thermal effect. This low current also prevents the tissue from being overtreated when subjected to multiple treatment passes. As the tissue is treated, it coagulates and desiccates resulting in an increase in tissue impedance. The lower current of the Renuvion[®] device is unable to push through higher impedance tissue. As the Renuvion[®] device passes in proximity to previously

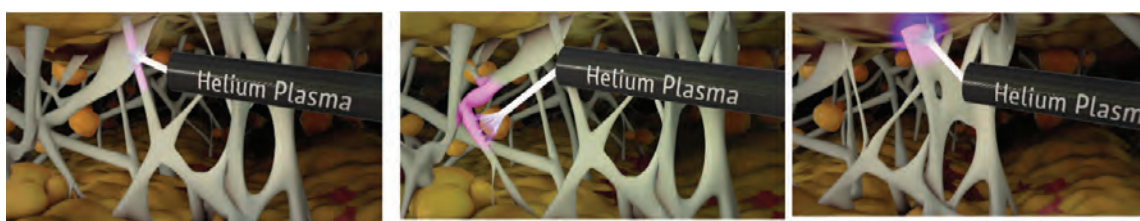


Figure 7. The Renuvion[®] plasma beam quickly alternates between treating the different tissues surrounding the tip of the device. Instead of treating all tissue in the field, the approach is fractional. By targeting low impedance targets, tissue shrinks well without excessive heating.

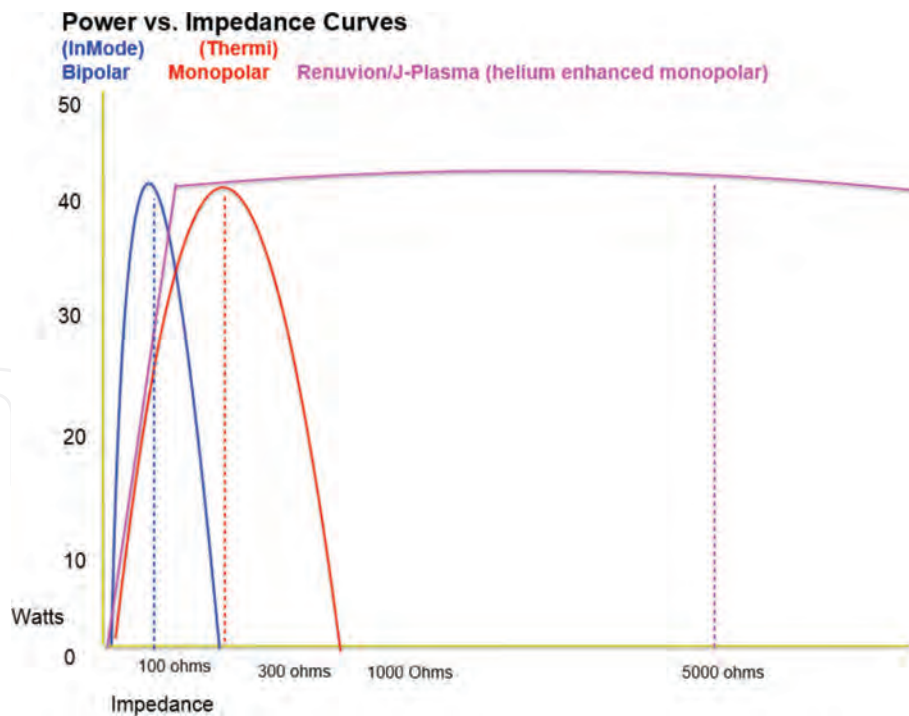


Figure 8.
Output power vs. impedance curves for subdermal energy devices.

treated tissue, the energy will follow the path of least resistance (lower impedance) and preferentially treat previously untreated tissue. This prevents overtreatment of any one particular area with multiple passes and maximizes the treatment of untreated tissue. **Figure 8** shows a comparison of power versus impedance curves for bulk heating devices versus the plasma fractional RF device.

8.5 Renuvion[®]—helium

Although other inert gases can and have been used in plasma devices for medical applications, the Renuvion[®] device uses helium due to its unique properties which translate into certain clinical advantages. Helium has a simple molecular structure consisting of only two electrons. This simple structure allows helium to be ionized using very low input of energy. The ionization of helium is therefore very controlled and produces a precise and stable output of energy. Helium facilitates the use of the low-current, proprietary RF waveform from the Renuvion[®] generator.

In summary, the Renuvion[®] helium-based plasma device from Bovie Medical has technological features that result in a unique and effective method of action for subdermal coagulation and contraction of soft tissue. These features are as follows:

1. The Renuvion[®] device achieves soft tissue coagulation and contraction by rapidly heating the treatment site to temperatures greater than 85°C for between 0.040 and 0.080 s [15].
2. The tissue surrounding the treatment site remains at much cooler temperatures resulting in rapid cooling after the application of the energy through conductive heat transfer.
3. Focused delivery of energy on immediate heating of the FSN resulting in immediate soft tissue contraction without unnecessarily heating the full thickness of the dermis.

4. 360° tissue treatment without the need for the user to redirect the flow of energy due to electrical energy taking the path of least resistance.
5. Unencumbered delivery of power regardless of the tissue impedance due to the unique power output from the electrosurgical generator.
6. Low-current RF energy resulting in minimal depth of thermal effect and prevention of overtreating tissue when performing multiple passes.

9. Indications

Indications for treatment with plasma-driven RF include focal lipodystrophy with mild to moderate soft tissue laxity. Post-bariatric patients can be treated if the need for skin contraction is less than 33% and if pendulosity of the tissue is mild. If the patient's focus is skin quality without excision, or improvement in poor soft tissue tone, the addition of this energy can improve outcomes. Patients who have given birth and want to restore their physique can also be helped, but diastasis recti can only be slightly improved with subcutaneous RF stimulation of the lax fascia. Breast lifting can be achieved to a significant degree, but the technique works best in patients with grade I and II ptosis and size C cup or less. The addition of a suspension suture can improve the outcome, especially for the subareolar and lower pole contour. Other popular treatment regions include the lower face and neck, upper arms, axilla, bra roll, abdomen and pubis, flanks, and circumferential thighs and knees.

10. Contraindications

Patients who should not be treated include:

1. Women who are pregnant or breastfeeding
2. Those with unrealistic expectations
3. Patients with an open sore in the treatment region
4. Patients with compromised healing such as oxygen dependence, diabetes if poorly controlled, and autoimmune disease
5. Severe pendulosity or skin/soft tissue laxity in the treatment region
6. Patients with significant skin compromise such as striae, scars, scleroderma, or lupus
7. Patients with previous treatments in the region of focus, thick or depressed scars, or poorly vascularized tissue

11. Operative technique

Patients are marked in an upright position. Depressions are marked, and protuberances are highlighted. The patient is asked to look down and note what she or he sees as the most important set of goals as far as fat reduction and skin tightening. This perspective may be somewhat different from the evaluating surgeon's view.

Steps in treatment include evaluation and marking, sterile prep and drape, and administration of anesthesia, which always includes tumescent infusion and can also include oral sedation, IV sedation, or general anesthesia. Liposuction, if indicated, of the treatment region is then performed. Treatment with subcutaneous heating of the Renuvion device follows. “Strokes” are considered as an insertion and slow withdrawal of the device. Ideally, the speed of withdrawal should be about 1.5 cm/s. A “pass” is considered to be a series of strokes performed from a single access point at the same depth. Lab studies show that in the typical treatment region, a series of three multidepth passes is required in order to see significant soft tissue and skin contraction within 24 h. In areas with a small surface area or limited amount of localized fat, two passes may be sufficient. Of course, in regions where adipose thickness is 3 cm or more, up to five passes at multiple depths may be needed in order to achieve the optimal outcome. Unless the treatment region is very thick, more than five passes in one region may be overtreatment.

Clinical endpoints with the Renuvion device are different from those with bulk heating treatment. There will be little localized warmth or erythema, because it is not a bulk heating device. A visible contraction of the skin surface with the handpiece slightly angled up upon withdrawal is an indicator of good response. Because there is not an energy expended measurement on the current generator, a good indicator is activated time on the tissue. I usually treat a 10 × 15 cm segment of the tissue with 5 kJ, which correlates to 5 min of handpiece activation time per region.

Some controversy exists regarding “cross-hatching” or creating a perpendicular series of passes in the same treatment zone. Because the device seeks out low impedance tissue to briefly heat, the “woven” or “crisscross” method is not routinely needed. However, in large areas or in regions needing optimal soft tissue contraction, this approach is recommended.

Cross-hatching is contraindicated in areas such as the lower face, jowls, jawline, submentum, or décollete. Thin upper arm skin may also not need two perpendicular approaches.

Treatment depths generally include the deep suprafascial zone, the midlevel of the adipose layer which corresponds to Scarpa’s fascia, and the immediate subdermal region. In patients with thin skin, striae, or a previous procedure in the treatment zone, a conservative two layer approach is recommended. In necks, a supraplatysmal and a subdermal approach are recommended.

Multiple treatment levels are recommended to reduce the amount of adipose gliding that is seen with age, a decrease in the stromal collagen binding of fat, and hormonal change [37].

Patients who note a disconnection of the soft tissue from the rectus fascia when leaning forward can gain some readherence with multilevel treatment. Suprafascial heating of the abdominal midline can decrease diastasis recti up to 1 cm. Further studies are needed to show the duration of this response.

Enhancement of tissue response can be achieved by reducing local impedance with infusion of tumescent fluid and by removing the insulating adipose tissue. Undertumescing will decrease tissue response. An infusion ratio of 1:1 is recommended for most regions. By optimizing treatment temperature, the stromal fibrous collagen bands will contract more intensely and more quickly. A variety of optimal temperatures are shown in the biomechanical literature, ranging from 60 to 80°C. At lower temperatures, tissue contraction is slower. Perfusion is the most influential factor, as well as the most difficult to measure and influence. Good perfusion can be enhanced by avoiding overtumescing as the closing venous pressure will be exceeded. Using warm fluid is helpful. Vasodilators are not indicated. Perfusion can be compromised by mechanical factors such as tissue location in a fibrous area (flanks and bra roll). A frequently overlooked consideration is

treatment in secondary cases. The presence of scar tissue in a patient who has undergone a previous procedure should be noted. The use of another energy-based device prior to the use of the primary heating device adds risk, such as liposuction using PAL or Vaser.

It is important to consider the effect of adding pressurized gas when treating the secondary patient. Fibrosis, whether induced by previous minimally invasive procedures or by surgery, will change the direction of the gas, which will follow the path of least resistance. While not clinically dangerous, the creation of temporary subcutaneous crepitus can be disconcerting to the patient. Careful and thorough tunneling of the treatment region will allow for gas egress in these cases. The use of more than one access port is imperative. Tunnels should be created in such a way that they communicate with one another, and aspiration of gas at the end of the procedure will improve patient comfort.

12. Results

Significant improvement in the contour and pendulosity of skin and soft tissue has been seen with the combination of liposuction and helium plasma-driven radiofrequency energy.

Interestingly, clinical endpoints are different with this device compared with bulk heaters. Because the skin does not heat up in broad regions, neither erythema nor warmth at the treatment site is an indicator of a completed treatment. However, early improvement can be seen as early as the next day.

While the presence of some fat in the neck to be treated with bulk heating devices is desired, it is not necessary when using the Renuvion device. **Figure 9** shows a 49-year-old woman with no fat in her neck preoperatively. A nice correction of her skin laxity is seen at 2 months post-op.

Figure 10 shows a 37-year-old man with gynecomastia and abdominal lipodystrophy. The device is quite good for treating larger surface areas on men or women, as the rapid heating of soft tissue has been shown to decrease overall operative time. Good definition without contour irregularities is noted postoperatively.

The use of energy-based devices has been somewhat limited in the older patient. Because both skin quality and cohesiveness of the subcutaneous tissue can be compromised, these patients are usually offered excisional procedures. **Figure 11**

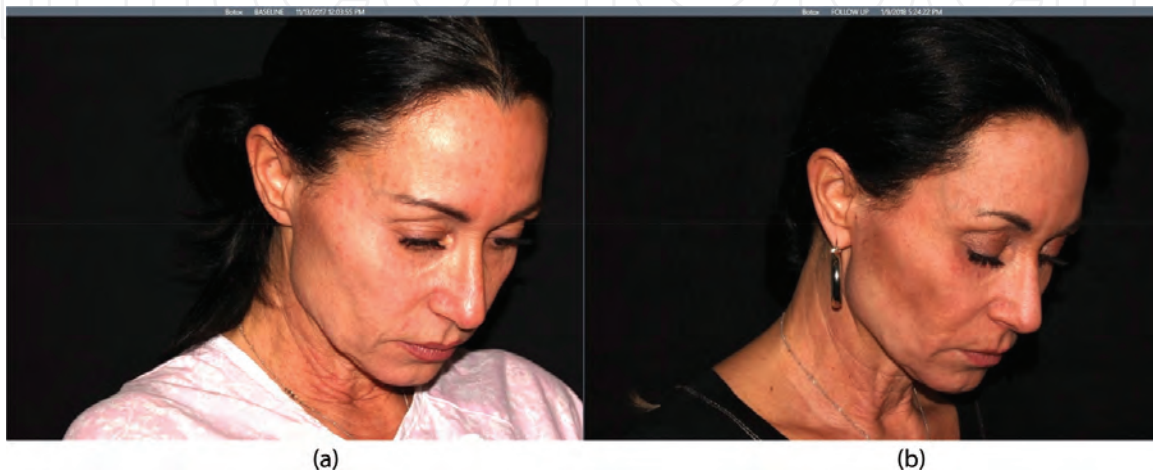


Figure 9.
(a) A 49-year-old patient with neck laxity and (b) a patient 2 months following tumescent infusion and subcutaneous heating with Renuvion. No liposuction was performed.



Figure 10.
(a) A 37-year-old man with lipodystrophy of the abdomen, flanks, and chest and (b) a patient 3 months post treatment with liposuction and Renuvion soft tissue heating.

shows a 65-year-old woman who underwent circumferential liposuction and Renuvion RF tightening. She has excellent reduction of the skin envelope with improvement of skin tone and texture.

Figure 12 shows a 37-year-old man who had multiple areas of lipodystrophy, despite an active job. He was treated with liposuction and helium-driven plasma RF tightening of the fibroseptal network in the chest, abdomen, and flank region. New technology shows the directional lift achieved in the lower abdomen that corrects the preoperative pendulosity. Skin compression diagram shows relative tightening of the skin in the treatment region (**Figure 13**).

13. Risk reduction in energy-assisted lipocontouring

Side effects can be seen when using any energy-based device. With radio-frequency, most of these are thermal. There is a difference between expected sequelae and adverse sequelae.



Figure 11.
A 65-year-old woman with pendulosity of the volar upper arm (above). Below, a patient 3 months after circumferential liposuction and treatment with Renuvion. Pendulosity measurement decreased by 40%.



Figure 12. This 38-year-old man had gynecomastia, abdominal lipodystrophy with pendulosity, and flank and waist fatty hyperplasia and tissue contraction at 6 weeks. (a) A patient before treatment and (b) a patient 6 weeks after liposuction plus Renuvion.

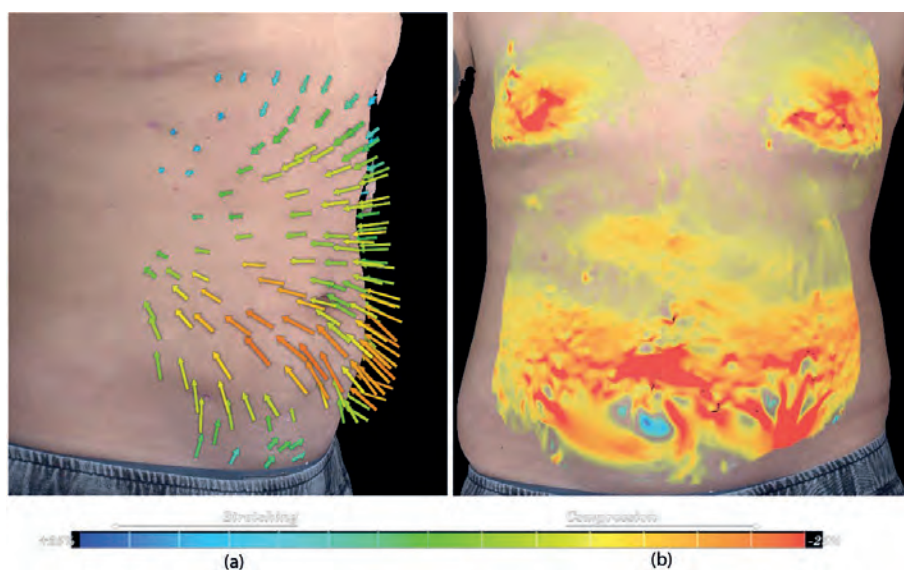


Figure 13. (a) Postoperative analysis of directional lift following liposuction and Renuvion RF assisted tissue tightening. (b) Compressive tissue analysis of the same patient following treatment with abdominal liposuction and Renuvion tissue tightening.

Expected sequelae include erythema, swelling, and redness and small scar at the access port sites. Bruising may be prolonged, and a temporarily modest improvement due to post-op swelling is expected. Patients may note they cannot fit into their regular size of clothing for a few weeks. Less than hoped for improvement in the early weeks is expected. Tissue contraction really becomes noticeable about 3 months post-op and continues for a year or more. Pre-existing asymmetry will not be totally corrected. Crepitus or air in the tissue due to residual helium is common, even if gas is expressed or suctioned at case end.

Adverse sequelae can include persistent tissue pendulosity if present preoperatively. Creases or folds in the skin can occur if the patient is not careful about compression garment application. Small burns or blistering can occur but this is rare. If heat or ice is applied to the treatment region postoperatively, an area of full-thickness skin loss can occur. Unsatisfactory scarring at the access port sites may occur. Rarely, fibrosis can occur in overtreated regions. Undertreatment may result in residual lipodystrophy, a hooded umbilicus, or focal skin contour irregularities.

These irregularities can also occur if fat pad thickness is not checked for uniformity prior to closure. Overly aggressive liposuction, especially if superficial, can leave an unattractive skin surface.

Top 10 technical tips for achieving good outcomes:

1. Use DocMatter. The device company has set up a discussion forum, DocMatter. This website is easily accessible and promotes an open review of techniques and outcomes.
2. Initial assessment is critical. If the patient has a significant diastasis recti or needs more than 33% skin contraction, especially in a localized area, the treating physician should explain the limitations of a minimally invasive approach.
3. Treatment of multiple tissue layers is important. Dr. Sonja Sattler notes that the soft tissue regions have a gliding aspect in which the skin and superficial fat become disconnected with the deep fascia with aging. When performing abdominoplasty, I have noted that many patients have very little attachment of the deep fat to rectus fascia. Therefore, in order to reconnect the soft tissue to underlying fascia, it is optimal to treat several levels—suprafascial, midlevel, or Scarpa's fascia and the immediate subdermal fat—with the Renuvion device. Clinical laboratory studies show that 3–4 passes (several ray-type strokes in a given region) will give optimal soft tissue and skin shrinkage in the average treatment region.
4. In regions with less fat, such as the neck, decollete, some arms, knees, and lower faces, only two levels of treatment are needed. Less is more here.
5. Because the current iteration of Renuvion does not measure energy expended, it can be difficult to understand the clinical endpoint. Clinical lab studies have shown that 1 min of activated handpiece time on the tissue is equivalent to 1 kJ of energy. If a 10 × 15 cm region is demarcated, an average of 5 min time on the tissue is optimal. This is equivalent to about a hand-sized region.
6. In regions where the skin is thin, less energy is needed. In the neck and jawline, 3–5 kJ total is recommended. A region of risk is the central cervicomental angle. By marking this area, and avoiding repeated passes, the risk of a burn is diminished.
7. Compression is king. Patients are informed that the best outcomes are obtained when a team approach is adopted. The surgeon can only influence the outcome during the surgical procedure and in the office during postoperative visits. It is the patient's responsibility to perform proper aftercare. By utilizing serially smaller compression garments and kinesiology tape where indicated, the desired smooth contour can be optimized.
8. Dr. Adam Rubenstein notes that patient selection is the most important aspect of treatment. Choosing a patient with a mild to moderate amount of subcutaneous fat and associated skin laxity is key. Managing expectations should be done at the outset in order to avoid postoperative disappointment. By reminding the patient that minimally invasive procedures cannot achieve the degree of change seen with skin excision, patient understanding of expected outcomes is optimized.
9. Dr. Ed Zimmerman recommends venting the access port not in use with a 1 cc syringe and plunger removed. This saves time as little gas is retained.

10. Dr. Gerhard Sattler likes to use a bit more tumescent fluid in a secondary treatment, as well as the PAL handpiece. This approach optimizes tunneling through fibrous tissue and allows for more thorough liposuction, tissue protection from overtreatment, and creation of regions of low impedance recipient tissue.

14. Conclusion

The use of helium-driven plasma energy is a new and promising resource for achieving non-excisional soft tissue and skin tightening. The use of the device for skin tightening is off label. This versatile treatment can be used in multiple regions, and its safety profile is strong. Because the subcutaneous fibroseptal network is the treatment target, there is no real focus on heating overlying skin. Clinical FLIR measurements show that in an average treatment region, skin temperatures get to about 38° when treated with Renuvion, as opposed to 45° and higher with bulk heating devices. Because the device rapidly heats a small segment of subcutaneous collagen to 85°C, strong immediate contraction is generated within 0.044 s. A rapid post-liposuction tissue treatment is followed by very visible improvement at the 24 h post-op mark. Results can continue to improve over a year, as infiltration of new collagen within the adipose stroma occurs. Restoration of the adipose framework can recreate a firm rather than flabby feel of the soft tissue, along with a defined shape.


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- *The Renuvion® APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma where coagulation/contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue.*
- *The Renuvion APR Handpiece is intended for the coagulation of subcutaneous soft tissues following liposuction for aesthetic body contouring.*
- *The Renuvion APR Handpiece is indicated for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region.*
- *The Renuvion APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue during open surgical procedures.*
- *The Renuvion APR Handpiece is intended to be used with compatible electro-surgical generators owned by Apyx Medical.*