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- 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 to be used with compatible electrosurgical generators owned by Apyx Medical (specifically BVX-200H, BVX-200P, APYX-200H, APYX-200P, APYX-RS3, and APYX-JS3).
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Combining Helium Plasma-Driven Radiofrequency with Nanofat for Contouring

Diane Irvine Duncan

Abstract

Many energy sources have been utilized to optimize tissue behavior following traditional liposuction. Peer-reviewed data to date show that radiofrequency has been shown to cause more skin and soft tissue contraction than other energy sources. While external RF can improve skin quality and create new collagen formation, tissue contouring has not been successful with topical energy application. However, the use of subdermal RF has been utilized to generate directional shaping and contouring in addition to skin tightening. An understanding of the way soft tissue contracts over time as collagen fibers develop is based on both the science of soft tissue energy response and experience in treating large numbers of patients. The Apyx Renuvion device is 510(k) cleared for soft tissue coagulation. In most cases of facial and body contouring, the ability to add volume in specific regions is as important as the skill to remove it. Since some liposuction is commonly performed as a part of the Renuvion contouring process, frequently this lipoaspirate is used to augment focal depressions or areas of soft tissue atrophy. The recent development of mechanical processing of macrofat into smaller particles, as well as nanofat, has widened the scope of the use of adipose-derived tissue.

Keywords: radiofrequency, plasma, nanofat, minimally invasive, neck, facial contouring

1. Introduction

Radiofrequency-assisted liposuction (RFAL) has been performed since 2008 [1]. Early devices were used to heat tissue prior to lipoaspiration, and the early cannulas performed both tissue heating and liposuction. Users gradually changed the order of the steps in the procedure, as it became clear that removing some of the adipose insulation prior to heating enhanced soft tissue contraction. Original versions of cannulas contained heating elements in a bipolar configuration that are allowed for treatment at multiple depths. A new, smaller version of radiofrequency was introduced in 2014. This device was monopolar and utilized a 10 or 15 cm wand-like cannula that was placed under the skin. Best suited for smaller areas, the device was capable of targeted nerve ablation as well as soft tissue coagulation. Both devices are considered “bulk heaters” as the subcutaneous cannula tip heats the soft tissue in gradients, hotter near the cannula tip and cooler away from the device tip [2]. The mechanism of action was the coagulation of the lax stromal collagen fibers, which resulted in overlying skin contraction as an indirect effect. In 2016, a helium

plasma-driven radiofrequency device created for laparoscopic cutting and coagulation was used externally for skin resurfacing. An esthetic surgeon then placed the device under the skin, causing soft tissue coagulation and subsequent skin tightening in this region. Instead of targeting a large area of soft tissue, this device emits very small multidirectional pulses of RF energy that are impedance driven. The energy is delivered in a fractional manner. All subdermal RF devices cause mild soft tissue contraction initially, followed by gradual ingrowth of a new stromal collagen scaffold over time in the treated region. Safety is optimized with the helium plasma device, as the external skin temperature rarely reaches 39 degrees C. The treatment target is the fibroseptal stroma, not the overlying dermis.

Nanofat has been used for many purposes including enrichment of traditional fat grafts, in combination with myostimulation, and intradermal injection in patients who desire skin resurfacing without epidermal ablation. While the FDA considers nanofat or SVF produced with collagenase a drug, mechanical instead of chemical tissue manipulation does not fall into the “drug” or maximally manipulated category [3]. Mechanical devices must obtain a 510(k) clearance and are single use only. However, the individual devices cost quite a bit less per use than a tissue processing laboratory within the operating room would. Examples of nanofat processing units include the Nanocube (Lipocube, London) and Tulip devices (Tulip Medical, San Diego, CA). Nanofat is created from fatty lipoaspirate, and the cells that remain are fragile, prone to death when desiccated or roughly handled. The solution can be combined with particulate fat in order to enhance the quality of fat grafts. It can be injected intramuscularly following myostimulation. Nanofat can be injected into regions with radiation damage in order to lessen the deterioration of the skin and soft tissue. Also injected directly into the skin, nanofat can improve the quality of aging skin by stimulating dermal fibroblasts. It is not recommended to apply nanofat topically as very few cells will survive in this environment.

While either procedure alone has benefit, the combination of helium plasma-driven RF to treat soft tissue for localized volume reduction plus nanofat-enriched grafts for focal volumetric enhancement corrects most deformities in the subdermal region. The addition of intradermal nanofat injection helps to enhance the appearance of aging skin without creating any superficial injury.

2. Background

Initially, the purpose of adding radiofrequency energy to traditional liposuction was to prevent the inevitable postoperative skin laxity in cases of moderate to large volume reduction. The Vectra measurement of skin surface area contraction [4] showed 26% surface area reduction at 6 weeks posttreatment and 36% at 1 year. Corresponding measurements of skin contraction obtained with mechanical stimulation after SAL showed contraction of 10% at 6 weeks and only 8% at 1 year. While laser-assisted liposuction did tighten the skin surface area more effectively than SAL at 13–17% measured skin tightening [5, 6], none of the other energy assists generated significant measured associated skin tightening. As patient expectations continue to grow, these also drive both technical and clinical development. Demands for a smooth, taut contour following treatment have encouraged surgeons to adopt techniques that will result in better outcomes than were common a decade ago. Changes that have been noted during this development phase include lower power settings, fewer passes—but passes at multiple depths—and more contouring in regions that need more attention. As with other energy-based devices, the RFAL procedure has evolved from a basic company guideline of three to five passes per region to more of a sculpting approach. Because

most surgeons also perform excisional techniques, the ability to visualize which region needs 33% skin contraction or less is a good guideline for treatment. If there is a localized region with extreme pendulosity, skin excision might be recommended. In order to transition from simple skin tightening to directional shaping, both vision and experience help to guide the practitioner in the therapeutic application of RF energy.

The popularity of using nanofat has grown rapidly over the past several years. With FDA-cleared devices for mechanical production of progenitor cells, the process has become affordable for most physicians and patients. Nanocube™ has been cleared for mechanical adipose tissue processing. This device produces millifat, microfat, and nanofat. The harvested macrofat is serially transferred through a cutting screen. The cube is rotated between ports 1 and 2 to produce millifat. Microfat is produced following several passes through the screen between ports 2 and 3. Nanofat production requires passage of the adipose tissue through ports 3 and 4. There is an average of between 50,000 and 70,000 MSCs in each cc of this particular nanofat, though no adipocytes remain.

3. Materials and methods

The Apyx Renuvion device has recently obtained a 510(k) clearance for a new handpiece that is significantly smaller in diameter than the original footprint (**Figure 1**). A bullet nose contour at the tip aids in a precise placement, and the two-side firing ports achieve a 360-degree directional energy placement. The handpieces are slightly flexible for ease of use in curved regions. As the energy is emitted just proximal to the handpiece tip, end hits are prevented. At a 3 mm diameter, instead of the previous 5 mm, the device can now be introduced through a small port created with a 16-gauge needle. Erythema and mechanical abrasion at the access port are reduced due to a graduated indicator system near the handpiece tip, warning the user that the device tip is near. More access points can now be placed without

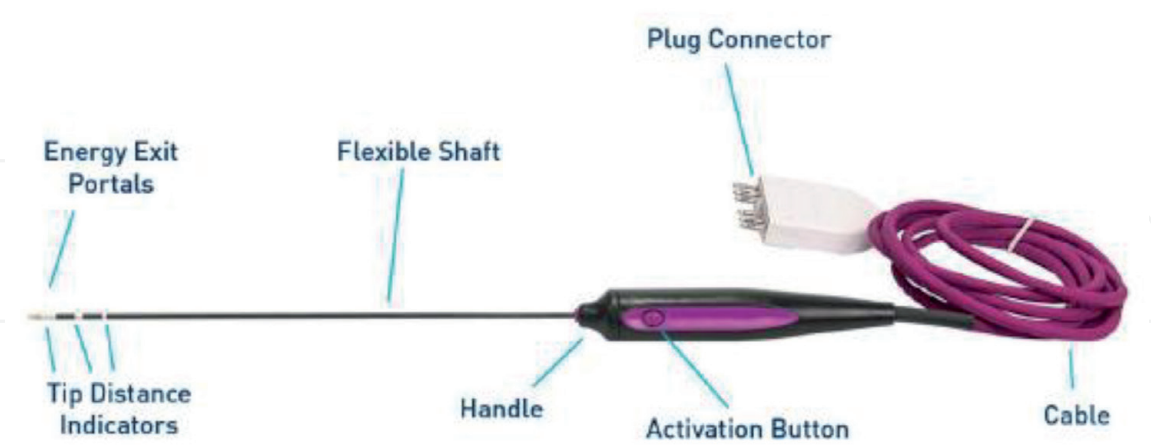


Figure 1. New handpiece is approved by the FDA for soft tissue coagulation: side port configuration of tip—testing demonstrated that the first locations of highest external tissue temperatures were treatment transition areas (i.e., transitions from treated tissue to untreated areas) when energy was delivered distally from tip of the device. Based on the results of this testing, the APR handpiece was designed to have plasma discharged radially from the side ports of the tip as opposed to distally; indicator lines on tip of device—the second location where the external tissue temperatures were the highest was areas within approximately 40 mm from the incision site providing access to the subdermal plane. There is a risk of this area being overtreated since the treatment strokes of the device converge at the incision site. In order to prevent overtreatment of this area, indicator lines were included on the shaft of the Renuvion APR device to provide awareness to the user that the tip is nearing the incision site. The user is also instructed to stop activation of the device when the indicator line becomes visible at the incision site; and epidermal marking templates—provided in device packaging as a mean for the user to mark 40 mm from the incision site on the patient. This will prevent possible overtreatment where treatment passes converge at the incision site.

concern for pronged visible erythema. Also, more regions can be easily treated with the redesigned handpiece. The lower face, arms including the elbows, knees, and ankles are excellent targets for HPDRF treatment. There is no requirement for liposuction; soft tissue contraction in such areas as the neck, breast, arms, knees, and axilla can be performed following tumescent infusion.

Optimal settings range from 60 to 80% power and 1.5 to 3 L/min helium flow rate. While a minimum of three passes per region is recommended for the average treatment region, thin areas such as the nonfatty neck, upper arms, décolleté, and knees should be treated with no more than two passes per region in order to avoid postoperative fibrosis.

While general anesthesia reduces the need for large volumes of tumescent fluid infusion, small areas can be treated under local anesthesia. Patients may find that the inhalation of nitrous oxide can reduce perceived discomfort during tumescent infusion. The limitations of local/ tumescent anesthesia include possible lidocaine toxicity and increased sensitivity to discomfort when the second region is being treated.

Following sterile prep and draping, access ports that were pre-marked in the upright position are injected with local anesthetic. A small 20-gauge infusion cannula is used to infuse standard Klein's solution into the treatment region at multiple levels. The recommended fluid ratio is 1:1, meaning that approximately 1 cc of lipoaspirate is planned for each cc of tumescent infused. Because helium plasma RF is impedance driven, too little fluid creates a high-resistance field, while too much fluid does not allow the tissues to heat optimally. Liposuction is performed prior to RF heating in cases where it is indicated. If no liposuction is performed, pre-tunneling with a 3 mm cannula is recommended in order to establish the proper planes prior to application of RF energy. It is strongly recommended that at least three communicating access ports be created, so that helium gas is allowed to escape. Postoperative crepitus can be reduced by aspirating from each access port following RF heating. Three to five passes are recommended in each treatment region if the area is moderately lipodystrophic. In patients with very thick fat layers, up to eight passes can be performed at multiple varying depths. It is possible to create a seroma if depths are not varied. If energy is applied only superficially, the lax adipose layer will not reattach to the underlying fascia, and an optimal correction will not be achieved. It is important not to scrape the underside of the skin in an effort to achieve skin contraction. This can cause linear depressions that are very difficult to correct. Recommendations to stay at least 5 mm under the base of the dermis will improve the possibility of a smooth skin surface postoperatively. When performing a secondary case, marking of any preoperative depressions in the standing position is ideal. Following any revisional liposuction of the protruding areas, any treatment with RF heating

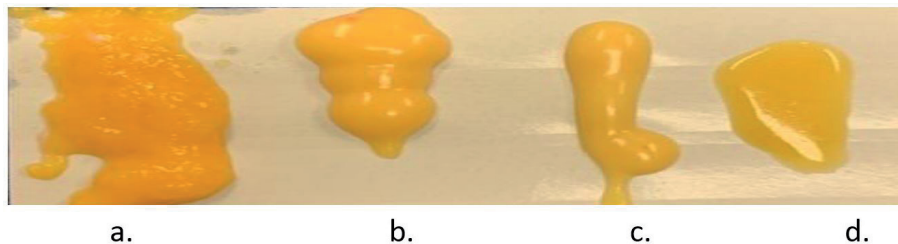


Figure 2.

(a) Macrofat: Best for structural repair and contains stroma and fat >2 mm particle size. (b) Millifat: Obtained with first pass through Nanocube. 2 mm particle size. (c) Microfat: Obtained with second pass through Nanocube. Able to inject into the dermis. (d) Nanofat: This solution has progenitor cells but no adipose and can inject intradermally with a 30-gauge needle.

should remain at the Scarpa's fascia or below in order to avoid creating more superficial fibrosis. After the use of RF heat, fat grafting should be performed with slight overcorrection in the depressed regions. Specific regional contouring descriptions are given below.

Nanofat was processed following the harvest of fat using traditional liposuction techniques with negative pressure of only 10 mm Hg. In order to reduce extravasated free fatty acid contents, filtration rather than centrifugation was used for initial fat processing. Macrofat (particles measuring >3 mm) was then processed in the Nanocube in order to produce millifat, microfat, and nanofat (**Figure 2**). Macrofat was injected in regions needing more structure, such as the bra roll depression, chin, and the prejowl sulcus. Millifat was injected in the infraorbital hollows in order to avoid lumpiness. Microfat can be injected with a 25-gauge needle and is used for supporting the deep dermis or for mixing with biostimulatory agents such as hydroxyapatite.

Nanofat can be combined with all types of particulate fat and also can be injected by itself with a 30-gauge needle. The stimulation of dermal fibroblasts is the primary purpose with superficial nanofat injection.

4. Results

The combination of using helium-driven plasma in the subcutaneous space for contouring has been enhanced with the development of a new handpiece. Ease of use, especially in areas with thin skin, striae, and small surface areas, has made the operative procedure more straightforward. Due to the slightly flexible nature of the cannula, directional shaping in regions such as the jawline, neck, lateral breast and axilla, upper arm, and knees has become possible.

The use of Renuvion is no longer limited to skin surface area contraction, though this use is off-label. The ability to shape soft tissue is difficult, even with traditional surgical techniques. If the fibroseptal network can be manipulated in such a way that a new form with defined shape is possible without skin excision, the stage is set for optimized outcomes.

The addition of fat grafting in certain regions also enhances results. For example, many women have skin pendulosity as well as localized lipodystrophy in the bra roll region. Frequently, there is an associated depression, due to the tethering of the dermis to the midlevel Scarpa's fascia. By releasing the tether and creating a superficial subdermal tunnel that is then filled with transferred fat, the deformity can be fully corrected without surgical skin excision (**Figure 3**).

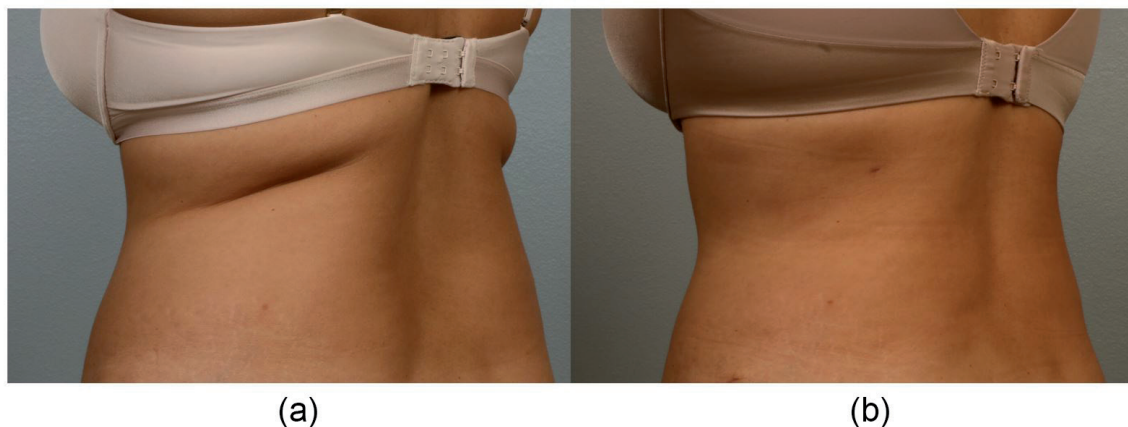


Figure 3.
(a) 38-year-old before surgery. (b) 3 months post-Renuvion treatment of bra roll and flanks.

Other areas that benefit from this combination are the lower face and jawline. A common problem with aging is bony resorption of the maxilla and mandible. This process causes visible jowling due to skin and stromal laxity as well as hollowing of the prejowl sulcus and gonial notch. The process of soft tissue aging is characterized by gradual loss of the scaffold, or fibroseptal network, in the fatty layer (**Figure 4**). The use of radiofrequency energy in the multiple levels of adipose stroma will regenerate this framework over the period of 1 year.

Hollow regions tend to be focal instead of diffuse. Known regions of accelerated aging include the prejowl sulcus, gonial notch, oral commissures, distal nasolabial folds, and medial infraorbital regions. Temporal hollowing, also known as the “old horse” phenomenon, also creates an aged appearance even in younger patients. By restoring the smooth and full contour of the face and jawline, apparent age reduction can be accomplished with a process known as microlifting [7].

A third novel use of combined RF energy plus nanofat-enriched grafting is in male body contouring. Formerly reserved for liposuction plus etching [8], the addition of myostimulation plus fat transfer to the male contouring armamentarium has broadened the scope of male body contouring. By combining electromagnetic energy [9] with stem cell tissue enrichment, muscle volume can be enhanced in ways not achievable in the gym. **Figure 5** shows results of a man treated 2 years ago with Renuvion and his 2-year result.

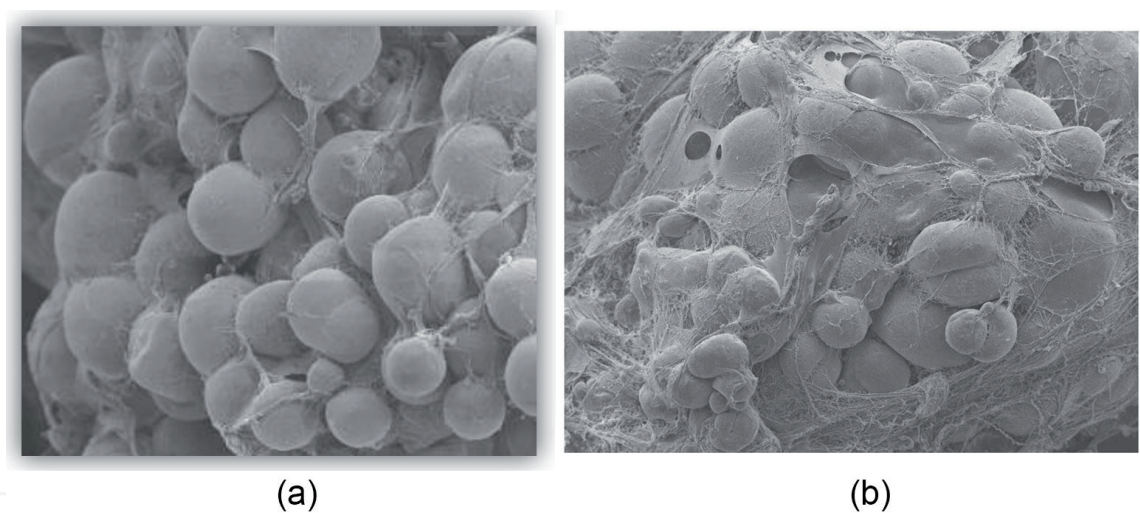


Figure 4. (a) SEM of aging adipose tissue. Note the lack of collagen support network. (b) 3 months post-RF treatment of the adipose layer; the collagen binding network is restored.

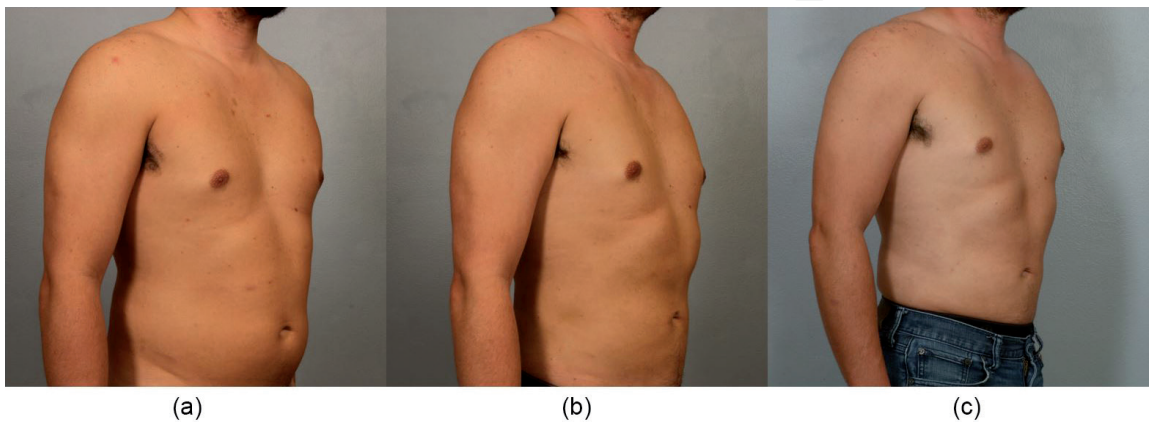


Figure 5. (a) 38-year-old before surgery. (b) Early result 6 weeks post-op. (c) Result at 2 years post-op.

Myostimulation with radiofrequency energy combined with nanofat injection can also enhance the small muscles of the face. As we age, the combination of bone atrophy, muscle thinning and atrophy, and soft tissue volume loss [10] can lead to the development of a negative facial expression [11]. The combination of RF myostimulation at subcoagulative levels combined with intramuscular injection of progenitor cells can result in shortening of the long, attenuated upper lip by 3 mm or more without a “bullhorn” skin excision (**Figure 6**). The addition of erbium laser resurfacing can definitively optimize the long-term outcome in patients ≥ 60 years of age. In patients with mild to moderate neck laxity, the use of plasma-driven radiofrequency in the neck and submental region can be an alternative to a surgical neck lift, even with patients over 60 (**Figure 7**).



Figure 6.
(Above) 73-year-old woman before surgery. (Below) 6 months post-laser resurfacing, fat grafting, and RF myostimulation to the upper lip.



Figure 7.
(Above) 61-year-old before treatment. (Below) Same patient 3 months post-Renuvion-assisted neck lift. No skin was excised.

5. Discussion

Regenerative medicine is rapidly gaining a large market share of the esthetic market [12]. The procedures that utilize the patient’s own tissues make sense to most people, and the ability to generate a prolonged improvement without significant temporary deformity or downtime resonates with potential customers. As the popularity of minimally invasive or noninvasive procedures soars [13], esthetic practices are enthusiastically seeking solutions that are safe and effective. By understanding the causes of apparent aging as well as minimally or noninvasive options for skin and soft tissue restoration, esthetic practitioners are able to address these concerns in ways that patients identify with. The optimal combination of electromagnetic and RF energy plus nanofat-enriched fat transfer can optimize long-term outcomes of rejuvenative procedures.

The use of subdermal RF energy can restore the framework or scaffold that supports the overlying skin. With commonly used liposuction techniques, especially superficial liposuction, the integrity of that framework can be compromised, and a cannula defect or localized depression can result. Even with subdermal radiofrequency devices, if the cannula is used to scrape the underside of the dermis, interrupting the subdermal fibroseptal network, the adjacent soft tissue contraction will paradoxically amplify the defect as the soft tissue near the injury contracts. A uniform network of contractile hypodermis is needed for a smooth postoperative surface.

The combination of subcutaneous tissue contraction and stabilization and regeneration of the overlying skin will provide the optimal outcome in most facial and body contouring efforts. If underlying muscle laxity is a contributing factor to the deformity, electromagnetic stimulation of the affected muscle is recommended. Restoration of the stromal/skin complex’s attachment to the underlying fascia can be achieved by applying RF energy at the junction of these two layers. **Figure 8** shows a patient treated with plasma-driven RF in the abdominal region. Treatment of the lower diastasis can improve the midline gap up to 5 cm. This is a minimally invasive alternative to an abdominoplasty in suitable patients.

Care must be taken to not overtreat here in the abdominal region, as a seroma can develop. Overtreatment can also cause fibrosis which can compromise the gliding of the skin surface.

The use of fat grafting in facial, neck, and body contouring is well established [14]. Coleman is considered the father of fat grafting, popularizing the technique in the early 1990s [15]. He notes that the range of “take” of the fat grafts can range from 10 to 90% [16], depending on the technique and postoperative compliance of the recipient. The enhancement of graft take can be achieved by avoiding large-volume injections, by stratifying the fat injections at multiple levels, and by pulsing

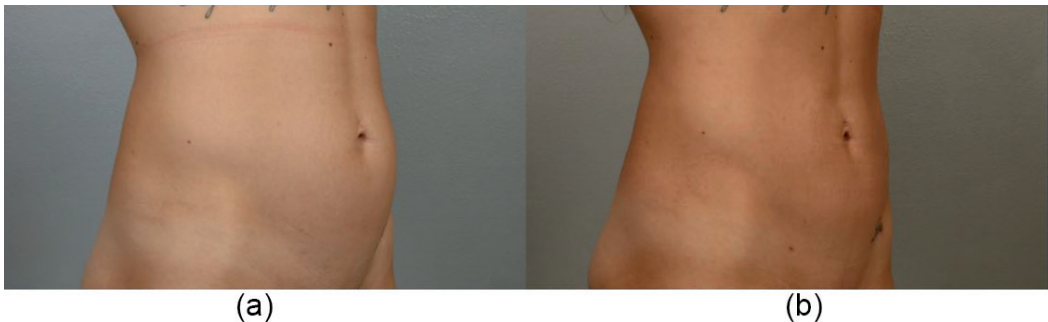


Figure 8. (a) 35-year-old mom with diastasis recti. She declined abdominoplasty. (b) 3 months post-Renuvion-assisted liposuction. Significant improvement of her rectus diastasis was obtained.



Figure 9.
(a) 58-year-old before treatment. (b) 3 months following laser resurfacing, fat grafting, and intradermal injection of nanofat.

small volumes at a time so that a “string of pearls” effect is achieved. If there is a significant component of liquefied fat in the injectable fat, this will reduce graft take. The traumatized fat or desiccated fat is less viable than the fat harvested at low pressure and kept in a closed container. A current common practice is the topical application of nanofat following nonthermal microneedling, RF microneedling, or fractional laser resurfacing. There is little uptake of progenitor cells with these methods, as the aDSCs are prone to desiccation and traumatic death. A recent publication [17] advocates the use of a biocrete to enhance cell viability. Future development of the novel use of nanofat for skin enhancement will no doubt optimize the technique so that consistent outcomes can be achieved.

An interesting use of nanofat is the injection of the substance intradermally. **Figure 9** shows a patient treated in the infraorbital region using this method. Since the particulate size is very small, the solution can be injected with a 30-gauge needle. The effect of intradermal nanofat improves with time, so that outcomes at 1-year post-injection are much more remarkable than early changes [18]. Regions that can be significantly improved with intradermal nanofat include the upper lip and the infraorbital region. By adding nanofat to the traditional macrofat grafts, the outcomes, especially in facial regions, are enhanced. By milling macrofat into millifat, lumpiness in regions with skin can be reduced.

6. Conclusion

Regenerative medicine has become a popular antiaging resource that patients are actively seeking. Helium plasma-driven fractional radiofrequency energy can restore the lost fibroseptal scaffold in many regions of the face, neck, and body. While FSN contraction can reconstruct a framework of cohesive fatty stroma upon which the skin can rest, aged skin will not be appreciably improved as it is not directly addressed. Instead of using damaging resurfacing techniques such as laser ablation or thermal microneedling, the regenerative restoration of dermal fibroblasts as well as the generation of a new blood supply helps to thicken the dermis as well as improve the tone, texture, and wrinkles. Little downtime is seen with the use of nanofat injections, and there is very little temporary deformity. The addition

of nanofat to traditional fat for grafting enhances both structural and vascular response. As with most esthetic procedures, combination therapy is superior to the use of a single modality when an optimal outcome is desired. The use of helium plasma-driven radiofrequency energy for soft tissue contouring and skin tightening is an excellent approach for the restoration of the supportive fibroseptal network. Nanofat plus more traditional approaches can optimize the correction of volume deficiencies as well as the correction of thin, structurally deficient skin. As research and development of both of these techniques evolves, biological restoration of the aging soft tissues is predicted to become more popular than other surgical or injectable approaches.

Author details

Diane Irvine Duncan
Private Practice in Fort Collins, Colorado, USA

*Address all correspondence to: momsurg@aol.com

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