

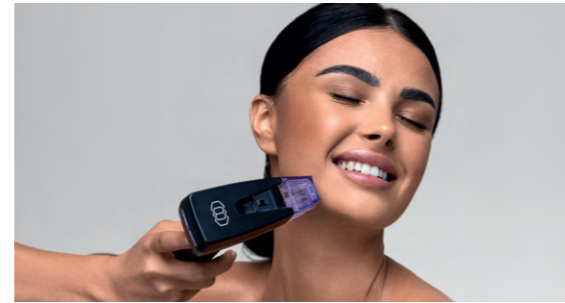
MORPHEUS8

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MEHR ALS 3 Millionen Behandlungen WELTWEIT

Morpheus8: Die ultimative Microneedling-Behandlung.

Die Hautverjüngung entwickelt sich ständig weiter – und Morpheus8 steht an der Spitze dieser Transformation. Durch die Kombination aus fraktionierter bipolarer Radiofrequenz und Mikronadeln hat sich Morpheus8 zur beliebtesten Behandlung zur Verbesserung der Hautfestigkeit und -struktur entwickelt – die ultimative Microneedling-Behandlung.

Weltweit wächst die Nachfrage nach Morpheus8 stetig weiter: Über 18.000 Anwenderinnen und Anwender vertrauen auf diese Technologie, um sichtbare und sichere Ergebnisse zu erzielen. Neben der Neudefinition des Standards für Hautverjüngung optimiert das innovative System auch Gesichts- und Körperbehandlungen und ermöglicht dadurch effektivere und individuellere Therapien.

MORPHEUS8: PRÄZISION, INNOVATION UND TECHNOLOGIE

Morpheus8 kombiniert die Kraft des Microneedlings mit fraktionierter bipolarer Radiofrequenz und erzielt so eine tiefgehende und effektive Remodellierung sowohl der Dermis als auch des subdermalen Gewebes. Dank seiner fortschrittlichen Technologie, die Tiefen von 5 bis 7 mm erreichen kann, ist dieses Gerät darauf ausgelegt, eine breite Palette ästhetischer Bedürfnisse zu behandeln. Von feinen Linien, Narben und Falten bis hin zu Hauteschlaffung verbessert Morpheus8 die Hautstruktur und den Hautton mit sichtbaren und langlebigen Ergebnissen.

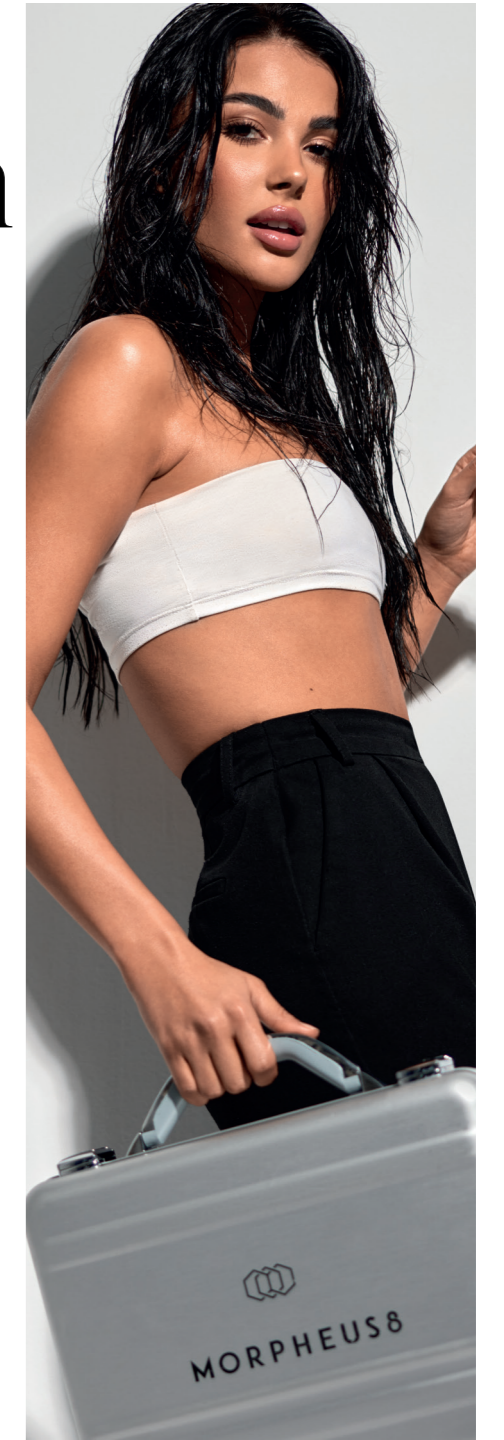
Was macht Morpheus8 einzigartig? Seine Vielseitigkeit verdankt es den verschiedenen Einstellungen, die an jeden Patienten und jeden Behandlungsbereich angepasst werden können. Morpheus8 verfügt über unterschiedliche Aufsätze mit 12, 24 und 40 Mikronadeln, wodurch die Verfahren individuell angepasst werden können, um in verschiedenen Gesichts- und Körperbereichen optimale Ergebnisse zu erzielen.

Die Forschungs- und Entwicklungsabteilung von InMode befindet sich in kontinuierlicher Weiterentwicklung und entwickelt Optimierungen, die die höchsten Standards in Qualität, Wirksamkeit und Sicherheit gewährleisten. Als Ergebnis dieser Innovation sind im Laufe der Zeit verschiedene Versionen von Morpheus8 entstanden:

Morpheus8 Body 3D, Morpheus8 Burst und Morpheus8 Burst Deep, die jeweils für spezifische Bedürfnisse entwickelt wurden, erweitern die Behandlungsmöglichkeiten.

Mehr als nur eine Technologie! Morpheus8 hat die traditionellen ästhetischen Grenzen durchbrochen und sich zu einer eigenen Behandlungskategorie sowie zu einer Referenz für Ärzte, Prominente und Patientinnen und Patienten weltweit entwickelt. Die Zahlen sprechen für sich: über 3 Millionen durchgeführte Behandlungen, mehr als 18.000 Anwender und Präsenz in über 90 Ländern. Schließe dich der ästhetischen Revolution an: Morpheus8.

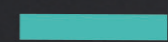
MORPHEUS8
burst | burst deep



Einzigartiges Sicherheitsprofil. Technologie mit FDA-Zulassung für die Straffung von Weichgewebe mittels Mikronadeln und Radiofrequenz (RF)



MORPHEUS 8 KLINISCHE STUDIEN



INMODE



ADJUSTABLE DEPTH FRACTIONAL RADIOFREQUENCY COMBINED WITH BIPOLAR RADIOFREQUENCY: A MINIMALLY INVASIVE COMBINATION TREATMENT FOR SKIN LAXITY

Erez Dayan, MD; Christopher Chia, MD; A. Jay Burns, MD; and Spero Theodorou, MD

Abstract

Increasingly, patients are seeking minimally invasive methods to tighten skin and remodel adipose tissue. A large treatment gap exists among 3 types of patients: (1) the younger demographic, who increasingly desire soft tissue tightening without traditional operations, scars, and downtime; (2) patients with soft tissue laxity who are not “severe enough” to justify an excisional procedure, but not “mild enough” to rely on liposuction with soft tissue contraction alone; and (3) those with recurrent laxity who already underwent traditional excisional procedures. In these populations, plastic surgeons risk under- or overtreating with traditional methods. The purpose of this supplement is to describe the utility of radiofrequency (RF) microneedling (Fractora modified to Morpheus8 InMode Aesthetic Solutions, Lake Forest, CA) in combination with bipolar RF (FaceTite/BodyTite, InMode Aesthetic Solutions). By combining these procedures, the aforementioned treatment gap can be addressed. The RF microneedling allows for subdermal adipose remodeling and skin tightening. Addition of bipolar RF also tightens the skin by contraction of the underlying fibroseptal network in addition to induction of neocollagenesis, elastogenesis, and angiogenesis at skin surface temperatures of 40° to 50°C. In our experience, these technologies have been effective and safe in these patient populations.

Level of Evidence: 4

Editorial Decision date: February 14, 2019.



Minimally invasive skin tightening and adipose reduction has long been an elusive goal of aesthetic surgery.¹⁻⁵ Multiple energy-based technologies including laser, high-intensity focused ultrasound, and radiofrequency (RF) have evolved to meet this rising demand.^{1,6-12} RF technology has steadily gained popularity since the early 2000s with consecutive increases in use of 10% or more annually.¹¹⁻¹³ These gains encompass aesthetic surgery as well as numerous nonaesthetic applications (tissue electrodissection, cardiac catheter ablation, ophthalmic surgery, etc.).¹¹

Public demand for minimally invasive skin tightening continues to grow.¹¹ This has been in response to a widening treatment gap prevalent among 3 cohorts of patients:

(1) the younger demographic, who increasingly desire soft tissue tightening without traditional operations, scars, and downtime; (2) patients with soft tissue laxity who are not

Dr Dayan is a Plastic and Reconstructive Surgeon, Division of Plastic Surgery, Massachusetts General Hospital/Harvard Medical School, Boston, MA. Drs Chia and Theodorou are Plastic and Reconstructive Surgeons, Division of Plastic Surgery, Manhattan Eye, Ear, Throat Infirmary, New York, NY. Dr Burns is a plastic and reconstructive surgeon in private practice in Dallas, TX.

Corresponding Author:

Dr Erez Dayan, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02144, USA.
E-mail: erezdayan1@gmail.com; Twitter: [@ErezDayanMD](https://twitter.com/ErezDayanMD)

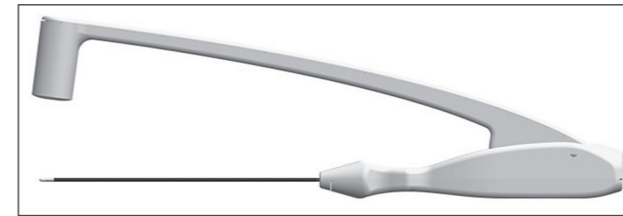


Figure 1. Bipolar radiofrequency device (Facetite, InMode Aesthetic Solutions, Lake Forest, CA).

“severe enough” to justify an excisional procedure, but not “mild enough” to rely on liposuction with soft tissue contraction alone; and (3) those with recurrent laxity who already underwent traditional excisional procedures. In these populations, plastic surgeons risk under- or overtreating with traditional methods.

RF achieves skin tightening by thermal heating of the reticular dermis, which triggers a healing cascade leading to collagen formation.^{14,15} Tissue resistance of electrical current allows for variable impedance and rates of heat generation. For example, fat is an insulator and has high resistance to current flow (producing more heat), and water is closest to a pure conductor (producing less heat).^{4,16} New collagen, elastin, and blood vessel formation occurs as skin surface temperatures reach 40° to 45°C.^{1,2,17-19} In contrast to laser, RF is chromophore independent and has a better safety profile for all skin types in terms of pigmentation changes.¹⁶ There are different types of RF for medical utilization including monopolar, bipolar, fractional, and multipolar energy modes. Monopolar RF utilizes one emitting pole with the body serving as a ground. In the bipolar RF devices, there are 2 electrodes at a set distance with a current flowing between them (Figure 1). Multipolar RF utilizes multiple electrodes to emit energy at various changing directions to allow for deeper as well as more superficial penetration of energy.

Non-energy-based devices such as microneedling serve as a minimally invasive method to induce dermal collagen formation and skin resurfacing through induction of an inflammatory cascade while preserving the epidermal barrier. This technology was first introduced by Orentreich in 1995 for the treatment of atrophic scars and rhytids. It has since been successfully employed for acne, melasma, photodamage, transcutaneous drug delivery, alopecia, and skin rejuvenation.^{6,9,20-23} The local injury induced by dermal penetration of the microneedles releases growth factors (ie, TFG-alpha, beta, VEGF, PDGF) that stimulate collagen and elastin fiber production, as well as angiogenesis.

RF microneedling systems advance existing technology by adding heat at controlled depths (Figure 2). Similar to fractional laser, fractional RF microneedling treats segments of the skin and soft tissue, leaving islands of untreated areas to reduce recovery time. Studies have shown active dermal remodeling by 10 weeks post-procedure with increased



Figure 2. Radiofrequency microneedling device (Morpheus8, InMode Aesthetic Solutions, Lake Forest, CA).

reticular dermal volume, hyaluronic acid, and elastin content.^{8,24} This purpose of this manuscript is to describe the utilization of RF microneedling (Fractora modified to Morpheus8, InMode Aesthetic Solutions) with or without bipolar RF (FaceTite/BodyTite, InMode Aesthetic Solutions).

RADIOFREQUENCY MICRONEEDLING

The Morpheus8 (InMode Aesthetic Solutions) is a fractional RF device with programmable penetration depth and energy delivery (Figure 2). The 24 coated needles penetrate into the subdermal tissue, leading to coagulation of fat as well as contraction of the reticular dermis and surrounding connective tissue. At the same time, directional RF energy stimulates neocollagenesis, elastogenesis, and angiogenesis (Figure 3). The adjustable penetration depth and energy settings allow the clinician to customize treatment. In the face, treatment may be 1 to 2 mm, whereas for body areas a 3-mm to 4-mm depth penetration would be appropriate. There is an additional 1-mm zone of heat effect that should be accounted for when planning treatment.

Depth	Treatment areas	Depth of penetration	RF energy level	Treatment mode (cycle/fixed)	No. of sessions	Weeks between sessions	Downtime (days)
Periorbital	Bony areas, periorbital, forehead, chin	2 mm	15-30	Cycle	1-3	3-6	2-5
Facial	Soft tissue, neck	3 mm	20-40	Cycle/fixed	1-3	3-6	2-5
Body	Body areas	4 mm	25-40	Cycle/fixed	1-3	3-6	2-5

RF, radiofrequency.

Treatment Procedure

Pretreatment

A detailed history and physical are obtained to determine if there are any contraindications to treatment (ie, collagen disorders, active infection, immunocompromised state, pregnancy, poor wound healing, unrealistic expectations). Valacyclovir is recommended for patients with a history of herpes simplex.

Anesthesia

Numerous anesthesia options are available depending on energy employed, depth of treatment, and patient tolerance. Topical anesthesia applied for 45 to 60 minutes can be utilized if energy is limited and tolerated by the patient. Some patients require nerve blocks or local anesthesia for higher energy settings.

Treatment

RF microneedling treatment parameters are (Table 1):

- Depth: automatically set for the anatomic area
- RF energy: varies from 5 to 62 kw
- Cycle mode: needles penetrate the skin and retract from the skin with every pulse
- Fixed mode: needles are inserted into the skin and energy is delivered when the footswitch is activated. The needles retract from the skin and energy stops once the footswitch is released. This can be employed for stacking of pulses when desired.
- Repetition mode: single pulse mode or autorepeat mode when pulses are delivered automatically with predetermined pulse repetition rate.

The handpiece is applied firmly and perpendicular to the treatment area. The footswitch is pressed to deliver RF energy: one press for each pulse for sensitive and small areas like the periorbital region, or continuous press for fixed mode. The handpiece is moved to the adjacent area with an overlap of approximately 50%. The handpiece should be completely released from the skin rather than sliding the needles to avoid abrasions. Then 1 to 2 additional pulses may be applied at the same site (stacking) in fixed mode. However, pulses should not be stacked over bony areas such as the forehead, periorbital, jawline, etc. (Video 1). Minor pinpoint bleeding may be

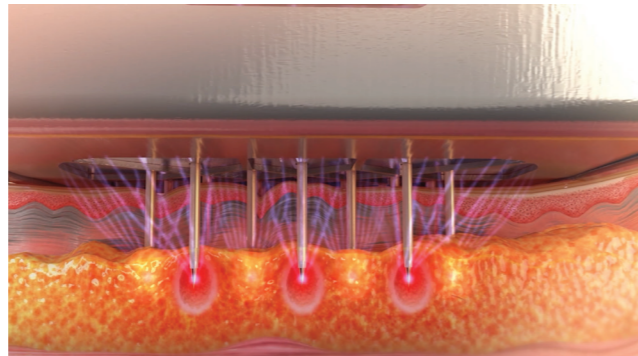


Figure 3. Illustration of radiofrequency microneedling depth and effect.

encountered. Treatment may be applied to all skin types. It is important to restrict energy when treating dark Fitzpatrick skin types by starting at 15 kw or lower, adding 5 kw of energy gradually with each treatment course (to a maximum energy level of 40 kw over soft tissue, 25 kw over bone). Higher RF energy can be applied to deeper treatment areas. When working on thin skin (ie, neck) or in bony areas (ie, forehead, jawline), energy should be reduced by 20% and stacking of pulses should be avoided.

Post-Treatment

Cooling of the skin immediately post-procedure can reduce discomfort and erythema/edema. Antibiotic ointment is typically applied 1 to 3 days post-procedure. During this time, patients should refrain from other topical agents (ie, sunscreen or makeup). Once the microneedle holes close (within 1-3 days), makeup, moisturizer, and sunscreen may be applied.

EXAMPLES OF CLINICAL APPLICATIONS OF RF MICRONEEDLING

Early Facial Aging and Recurrent Laxity After Facelift

Increasingly, young patients present with early facial aging (ie, jowls, neck skin laxity) and are not yet optimal candidates for a traditional facelift. Additionally, there is a large population of patients who already



Figure 4. (A) Preoperative view of this 55-year-old woman with submental and jowl skin laxity. (B) Postoperative view of the patient 6 months after radiofrequency microneedling to jowls and submental area demonstrating improved skin laxity.

underwent a facelift and suffer from recurrent laxity. These groups are ideal candidates for RF microneedling, which reliably and safely achieves skin tightening and subdermal adipose remodeling. Similarly, in this group of patients, conventional liposuction of the neck and mandibular border often leads to unpredictable soft tissue contraction.

We have noticed in our clinical practice that patients respond best to RF microneedling combined with bipolar RF (Embrace Protocol, InMode Aesthetic Solutions). The RF microneedling component allows for tightening of the skin and remodeling of the subdermal adipose tissue, and the bipolar RF (FaceTite, InMode Aesthetic Solution) produces deep tissue heating (pre-superficial-musculo-aponeurotic-system/platysma) to tighten the overlying fibroseptal network. This combination of deep and superficial energy delivery optimizes treatment and soft tissue response (Figures 4 and 5; Video 2).

We prospectively evaluated 247 patients (224 female, 23 male; mean age, 55 years; range, 26-67 years) undergoing

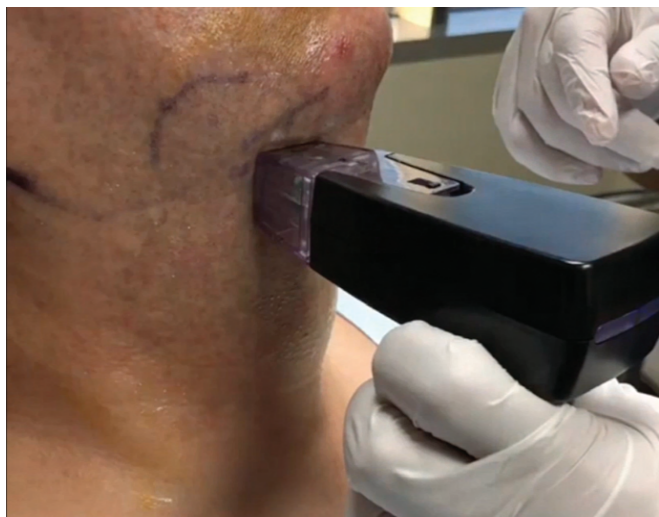
this combination RF therapy for neck laxity and jowling. Their pretreatment average Baker Face Neck Classification was 3.1 (standard deviation \pm 1.4). The post-treatment objective improvement was 1.4 points (standard deviation \pm 1.1), and 93% of patients indicated they were pleased with their results and would undergo the procedure again. Complications included prolonged swelling >6 weeks (4.8%, 12/247), hardened area >12 weeks (3.2%, 8/247), and neuropraxia (1.2%, 3/247), which all resolved without further intervention.

Brachioplasty

According to the 2017 American Society of Aesthetic Plastic Surgery Data Bank, approximately 18,000 arm lifts were performed, up 20.1% from the prior year.¹² Despite this increasing number, brachioplasty is limited by poor scarring, dehiscence, seroma, and infection. There are often focal areas of adiposity proximal to the elbow as well as of the lateral chest that are challenging to treat



Figure 5. (A) This is a 47-year-old woman with abdominal skin laxity. (B) Six months after bipolar radiofrequency and radiofrequency microneedling treatment of anterior abdomen. Note preoperative supraumbilical skin laxity that is improved with radiofrequency treatment and not suction assisted liposuction alone.



Video 1. Demonstration of radiofrequency microneedling technique.



Video 2. Embrace™ Protocol (InMode Aesthetic Solutions, Lake Forest, CA) combining radiofrequency microneedling with bipolar radiofrequency.



Figure 6. (A) This is a 44-year-old woman who was bothered by backrolls. (B) Six months after treatment of backrolls with bipolar radiofrequency and radiofrequency microneedling.

with traditional arm-lift and lead to contour deformities. Ultrasonic and laser-assisted liposuction have attempted to solve this problem with superficial application of heat to induce skin tightening. However, these have been complicated by inadequate tightening (ie, inadequate generation of heat) and high risk for contour deformities.

Theodorou et al described near circumferential (270 degrees) RF-assisted liposuction of the upper arms in 40 patients.^{3,4} An objective plastic surgeon evaluated the results as good to excellent tightening of the soft tissue envelope in the majority of patients. There were minimal complications in this cohort (1 seroma resolved with aspiration and 1 burn treated with wound care).³ In our clinical experience, the addition of RF microneedling to this protocol serves to augment the tightening effect of bipolar RF as well as broadens the ability to treat challenging areas such as fat pads proximal to the elbow or at the arm/axillary junction (Figure 6).

Focal Areas of Excess Skin Adiposity

Common areas of localized adiposity include the axillary rolls, soft tissue proximal to the knee, as well as supra and infraumbilical region. These areas are especially challenging in patients with poor skin elasticity who do not desire skin excision but also would not retract with traditional liposuction techniques. The large number of these “in between” patients represents a treatment gap that has been shown to benefit from RF microneedling. These areas benefit from deeper treatment (4000 μm) to ablate the adipose tissue as well as maximally tighten the skin, with or without bipolar RF tightening of fibroseptal networks.

DISCUSSION

The addition of RF microneedling to bipolar RF in the face and body has allowed for a safe, reliable, and effective treatment of patients who fall into the aforementioned treatment gap. In properly selected patients, we have combined these technologies to the application of RF heat from the superficial and deep directions and achieved satisfactory results without increased complications.

Bipolar RF provides deep heat generation to the overlying soft tissue and ultimately reticular dermis. Utilizing a parachute analogy, the heat contracts the strings (fibroseptal network) holding the parachute (ie, skin) in place, leading to a uniform and concerted contraction effect from below. The addition of RF microneedling augments our results by heating tissue from the superficial surface directly to the dermis and subdermal elements. One significant advantage of the RF microneedling treatment is the ability to directly generate heat in the subdermal adipose tissue and impact the contour of fat in this region while tightening the overlying dermis.

Numerous clinical studies support the efficacy of RF therapy for aesthetic skin tightening of the face and body. The goal of RF therapy is not to replace excisional procedures when indicated, but rather to achieve skin tightening in the “treatment gap” population, broadening the plastic surgeon’s armamentarium. Seo et al compared facial soft tissue laxity improvement with RF vs surgical facelift employing blinded grading of photographs. They demonstrated a 49% improvement in skin laxity relative to baseline for surgical facelift compared with 16% for fractional RF. Further, the mean laxity improvement from a single fractional RF treatment was 37% of the surgical facelift.²⁵ Peterson et al also

studied objective measurements of mechanical skin properties and demonstrated a statistically significant improvement (5%-12% decrease in Young's modulus and 10%-16% decrease in retraction time) as well as 1.42 grade improvement on the Fitzpatrick scale for wrinkles and 0.66 on the Alexiades scale for skin laxity, increasing to 1.57 and 0.70, respectively, improvement at 6 months. Patient satisfaction was noted to be "very high" for > 90% of patients.¹⁷

As demonstrated in this manuscript, our clinical experience has shown that the combination of bipolar RF and RF microneedling can achieve substantial skin tightening and subdermal adipose coagulation and necrosis in patients who are not candidates or prefer to not undergo surgery. Complications are rare when employed judiciously in the appropriately selected patients; however, they may include thermal burns, contour deformities, and superficial nerve injury. There are a number of limitations to our study including the subjectivity of the Baker face scale as well as patient satisfaction survey. There are more objective scales that are currently being applied to prospectively collected data including the Fitzpatrick wrinkle scale and Alexiades skin laxity scale as well as surface area measurements.

CONCLUSIONS

The demand for minimally invasive solutions to avoid traditional operative treatment continues to increase. RF technology has emerged as an effective method to safely tighten skin and reduce underlying adipose tissue. As our armamentarium expands, we have the opportunity to treat large portions of the population who were previously considered premature or borderline candidates for excisional operations. In our experience, combination RF technology (RF microneedling and bipolar RF) advances and broadens our ability to achieve tissue retraction that does not reliably occur with other energy-based devices and liposuction alone.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

Disclosures

Dr Dayan is a Consultant to InMode Aesthetic Solutions and Owner of wikiPlasticSurgery.com. Drs Chia and Theodorou are Consultants to InMode Aesthetic Solutions. Dr Burns is a Consultant to Allergan, HINTMD, InMode Aesthetic Solutions, and Sciton.

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THE ROLE OF FRACTIONAL RADIOFREQUENCY IN LONG-TERM ACNE REMISSION AND REDUCTION OF ACNE SCAR LOAD

Fadi Hamadani, MD; and Neil M. Vranis, MD

Abstract

Background: Acne is an inflammatory skin disease afflicting the majority of the world's population at some point in their lifetime, and is seen to be chronic in about 50% of cases. Acne leads to significant social withdrawal, depression, and disfiguring scars in many cases. Available treatments are characterized by high rates of relapse, dangerous side effects, and social stigma, which often leads to poor patient compliance and treatment failure.

Objectives: The aim of this article was to discuss and share the authors' experiences utilizing fractional radiofrequency (RF) (Morpheus8; InMode Ltd., Lake Forest, CA) in the treatment of both active acne and acne scars.

Methods: A retrospective review was conducted comparing 3 treatment modalities. In total, 356 patients received acne scar treatments. The cohort comprised a high-dose isotretinoin topical therapy series (n = 128, 36%), a 6-session ablative laser series (n = 89, 25%), and a 3-session fractional RF microneedling series (n = 139, 44%).

Results: Of the patients with extended 3-year follow-up, the relapse rates were: isotretinoin group, 36 of 54 (67%); laser group, 12 of 16 (75%), and fractional RF microneedling group, 7 of 29 (24%).

Conclusions: In treating older acne scars, fractional RF microneedling technology has served as an effective tool to tighten skin and fill in atrophic scars when used in conjunction with other techniques. This technology is very effective and very safe for treating all skin types with acne and acne scars.

Editorial Decision date: July 8, 2024.

Acne is the most common skin disease globally, with over 85% of the world's population having been afflicted at least once in their lifetime.¹ Increasingly, acne is being recognized as a chronic disease, as it waxes and wanes in over 50% of sufferers and often continues into adulthood.² The complexity of the disease, its well-documented social impact, and the lack of consistent and safe treatments have led an ongoing search for new therapies.^{3,4}

The pathogenesis of acne is a complex interplay of genetic predisposition, hormonal imbalances, and environmental triggers that leads to hyperkeratinization of the pilosebaceous unit, follicular desquamation, colonization by *Cutibacterium acnes* (formerly *Propionibacterium acnes*), and an inflammatory cascade of cytokines.⁵⁻⁷ There

is mounting evidence that acne has a strong autoimmune component in over 50% of cases.⁸

The social impact of acne is also well documented. Many patients suffer from disfiguring scars that lead to social withdrawal and depression, often because they fail to seek early treatment.⁹ The stigma surrounding many

Dr Hamadani is a plastic surgeon in private practice, Ramallah, Palestine. Dr Vranis is a plastic surgeon in private practice, Beverly Hills, CA, USA.

Corresponding Author:

Dr Fadi Hamadani, Division of Plastic and Reconstructive Surgery, H Clinic Hospital, Al-Irsal Street, Ramallah, Palestine.
E-mail: fhamadan@gmail.com; Instagram: [@drfdhamadani](https://www.instagram.com/drfdhamadani)

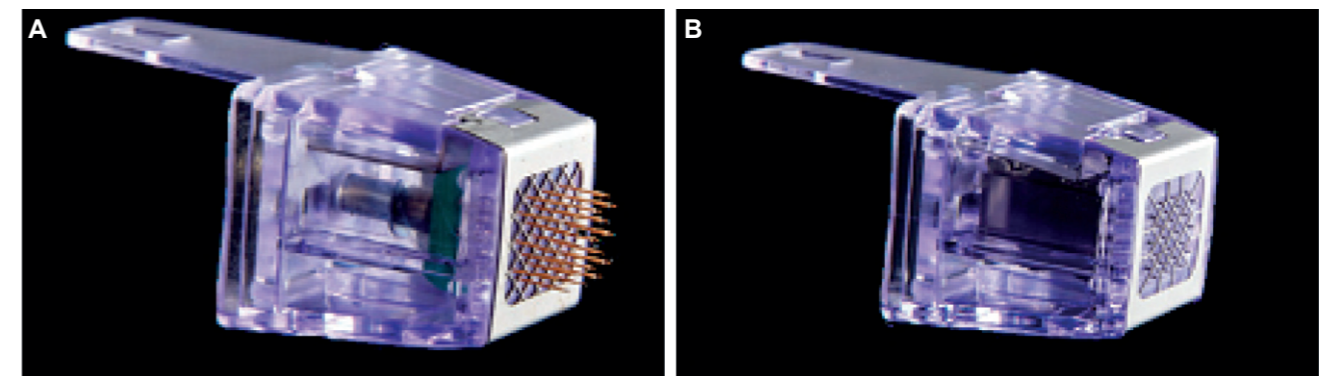


Figure 1. Fractional radiofrequency tips. (A) Morpheus8. (B) Morpheus8 T Resurfacing (InMode Ltd, Lake Forest, CA).

acne treatments, together with an unfavorable side-effect profile, has led many patients to self-medicate or to receive ineffective therapies.¹⁰ Traditional therapies have included oral and topical retinoids and antibiotics, hormonal medications, and a large selection of topical keratolytics.^{11,12} There has been a drive to find new and effective therapies for both active acne and acne scars because of the huge market potential.¹³

Some of the alternative therapies for acne that have shown promise include lasers, fractional techniques, chemical peels, and light therapies,^{14,15} but none have been consistent in their results and there are high levels of relapse. Microneedling, a technique that was developed in the 1990s, utilizes fractional and controlled-depth penetration of the skin with different types of microneedles. Microneedling has been shown to induce a wound-healing cascade of growth factors and cytokines that can improve acne scars, wrinkles, and striae,¹⁶ but has a very limited number of applications in treating active acne.

The Morpheus8 (InMode Ltd, Lake Forest, CA) is a fractional radiofrequency (RF) system that delivers thermal energy to variable depths of the skin through 24 parylene-coated gold-plated pins¹⁷ (Figure 1). Fractional RF microneedling has a well-documented effect on improving the thickness of the reticular and papillary dermis connective tissue and fibers of the skin by inducing a cascade of growth factors, both in the face and body.^{17,18} The distal part of the tip, which is uncoated, creates a compact zone of ablation surrounded by 2 expanded zones of necrotic and subnecrotic nonspecific heating.¹⁷ This leads to a significant tightening of the skin in addition to a noticeable improvement in skin quality via subacute (up to 3 months) neocollagenesis. The treatment acne and acne scars with fractional RF microneedling devices has not previously been described.

The purpose of this Supplement is to introduce the utility of applying fractional RF microneedling for the treatment of acne in all its forms, with the goal of providing long-term remission, considered as a relapse rate of less than 15% in a 5-year period, and effective early scar remodeling.

Furthermore, specific protocols for late acne scar remodeling that utilize fractional RF in combination with other modalities will also be discussed.

DIFFERENCES BETWEEN FRACTIONAL RADIOFREQUENCY TECHNOLOGIES

There are different forms of RF energy with medical applications. Most available systems are bipolar RF, meaning that the energy alternates between positively and negatively charged electrodes situated close together within the system.¹⁹ Most fractional devices on the market today consist of a row of positively charged electrodes positioned parallel to a row of negatively charged ones, so that the RF arc travels a very small distance between the pairs of tips. This configuration results in a very small and superficial zone of ablation, and the induced wound-healing cascade is not very different than standard needling without RF.²⁰

The Morpheus8 bipolar fractional RF microneedling system is designed differently and offers noticeable advantages. The electrode pins are all positively/negatively charged, with the grid surrounding each pin located at the interface of the tip near the skin^{17,20} having the opposite charge. As such, the RF loop is large and induces a bigger and deeper zone of ablation or coagulation that leads to a large quantity of released cytokines and growth factors. Fractional RF treatment spares the epidermis, except for the mechanical injury to the skin, and is considered to be significantly safer in darker skin types.²¹

TREATMENT PROCEDURE FOR ACTIVE ACNE AND EARLY ACNE SCARS

Diagnosis and Pretreatment

Active acne is identified clinically through the identification of well-known lesions on the face such as closed

comedones (blackheads), open comedones (whiteheads), and inflammatory papules and pustules. Often, the lesions lie on a background of erythema with varying degrees of scars depending on the severity of the acne.²² The majority of acne scars fall into the following categories: icepick, boxcar, and rolling.

A detailed family history and physical exam are undertaken with special attention paid to recent use of isotretinoin. Although several studies have demonstrated the safety of both ablative and nonablative energy-based devices for patients on isotretinoin, in darker skin types we opt to reduce the energy by 20%. Contraindications to treatment include high doses of corticosteroids, immunocompromised states, active infections other than acne, pregnancy, and unrealistic expectations.

Skin Preparation and Anesthesia

Before the treatment, the skin is cleaned and exfoliated with a keratolytic toner. At high energies, fractional RF microneedling can be quite painful and it is important to provide safe and appropriate analgesia. Options for anesthesia include application of topical numbing creams, nerve blocks, or local anesthesia. One helpful option for anesthesia comes from administering a modified tumescent solution that consists of 60 mL normal saline, 400 mg lidocaine, and 0.3 mg epinephrine. This is then administered via a special chamber that connects to the syringe and allows the tumescent to flow through multiple small needles. When sufficient anesthesia is achieved, the face is cleaned with alcohol wipes.

Treatment

During the treatment both the standard fractional RF microneedling tip and the “resurfacing tip” were used. Both tips consist of 24 pins, but the former is coated (except the distal 0.5 mm) and can reach depths of 1 to 4 mm, whereas the latter is noncoated and fixed at a depth of 0.5 mm. [Table 1](#) provides an outline of the settings used based on Fitzpatrick skin type. The treatment starts with passes at the deeper layers first and continues superficially. Depending on skin thickness, a depth of 3 mm or 2 mm is chosen to commence the treatment. Once the tip is placed firmly against the skin, a foot pedal is used to activate the device and deliver the pulses of energy. In general, at depths of more than 2 mm, the device is set to “fixed mode,” which enables it to deliver several pulses of RF energy through the pins continuously as long as the foot pedal is engaged. The system delivers an acoustic signal to indicate the delivery of each pulse, and the tip is activated to deliver double-stacked pulses at the predetermined depth. Once the double-stacked pulses are delivered, the handpiece is moved over the skin such that it overlaps 50% with the previous treatment area. A set of double-stacked pulses is delivered to each site.

Table 1. Morpheus8 Treatment Parameters Based on Fitzpatrick Skin Type

Condition	Treatment area	Depth (mm)	RF energy level	Mode
Active acne, skin type I-IV	Forehead	1 mm	25	Cycle
	Cheeks/jaw	2 and 3 mm	30-45	Fixed
	Neck	2 mm	30-40	Cycle
Active acne, skin type V-VI	Forehead	1 mm	20	Cycle
	Cheeks/jaw	2 and 3 mm	25-35	Fixed
	Neck	2 mm	25-35	Cycle
Acne scars	Forehead	1 mm	25	Cycle
	Cheeks/jaw	2 and/or 3 mm	30-40	Fixed

Once the treatment zone has received 1 pass of stacked pulses, a second pass that overlays the previous treatment is conducted. This ensures that the treatment zone has received 2 passes of 2 stacks each. Following this, the more superficial depth is started, to ensure full coverage of the treatment zones. At depths of 2 mm or less, the “cycle mode” is preferred because this reduces the risk of skin surface overexposure to heat. This mode allows for the pins to insert and deliver the preset amount of RF energy before retracting, only to be reintroduced for the second pulse. Once the treatment is completed, a moisturizing lotion is applied.

Posttreatment

Patients are instructed to avoid sun exposure and to moisturize the treated skin multiple times a day. Patients on topical retinols are instructed to avoid using them for at least 1 week. Patients on oral isotretinoin are instructed to continue taking their prescribed medications. Sun protection is emphasized, as is avoiding exposure to any other direct heat sources for at least 30 days. Patients are informed of expected side effects, including swelling, erythema, crusting, and itchiness and are informed that these may last for several days.

TREATMENT PROCEDURE FOR OLD ACNE SCARS

Diagnosis and Pretreatment

Old acne scars are identified according to their clinical morphology, and classified as ice-pick, boxcar, or rolling scars^{1,23} ([Table 2](#)). This nomenclature provides a general outline of scar morphology and is meant to serve as a guide to scar

Table 2. Main Acne Scar Subtypes^{1,23}

Subtype	Description
Ice-pick scars	Narrow and deep scars
Boxcar scars	Broad or narrow, deep or shallow scars with sharp edges
Rolling scars	Broad scars with a sunken appearance and tethering that improve on skin traction

depth. We have found it to be more useful to think of each subtype as existing on a spectrum, starting with pores on one end, through to pits and then ice-picks on the other end. In the case of boxcar scars, they may present as narrow or wide, deep or shallow. Rolling scars have a classical peau d’orange appearance and always improve when light traction is applied to the skin. Although classically associated with rolling scars, it is our experience that all acne scars have a degree of tethering due to fibrotic bands between the skin and subcutaneous tissue, often reaching the muscle.

It is important to note the patient’s skin type, and to determine if active acne is still present. Patients with active acne are encouraged to treat the active lesions with fractional RF microneedling or other modalities before commencing with scar revision. Darker-skinned patients are encouraged to condition the skin with topical retinol or tyrosinase inhibitors for at least 3 to 4 weeks prior to commencing treatment with fractional RF microneedling. Skin preparation and anesthesia are carried out as described above.

Treatment

Ice-pick Scars

Fractional RF microneedling can remodel ice-pick scars because the pins are able to penetrate the skin at varying depths. In our experience, performing a trichloroacetic acid (TCA) or phenol chemical reconstitution of skin scars (CROSS) or even a punch excision of the scar with a disposable 1-mm skin punch device works in synergy with fractional RF microneedling to produce outstanding results for this scar type.^{24,25} A depth of 2 mm in “cycle mode,” with an energy level ranging from 35 to 45, is selected. RF delivery of a single pulse with 75% overlap and 2 or 3 passes is applied.

Boxcar Scars

These scars respond extremely well to fractional RF microneedling and rarely need any adjunctive therapy. Both the depth of the scar and the consistency of the skin improve notably. The same settings and treatment protocol as for ice-pick scars are used.

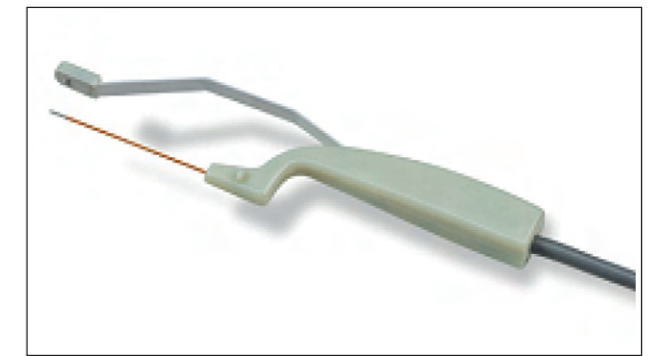


Figure 2. AccuTite handpiece (InMode Ltd, Lake Forest, CA).

Rolling Scars

Almost all atrophic acne scars, by definition, have a certain degree of tethering.²⁶ The most important adjunctive procedure in our experience for this scar type is tumescent subcision.^{26,27} The same anesthesia described above is delivered through a 22G, 70-mm cannula until the skin is turgid. A 2-cm region outside of the mapped scars is anesthetized. Utilizing the same cannula, or a larger caliber one (up to 16G can be used for very fibrotic tissue), repeated gentle strokes parallel to the skin surface are made to break through the bands of the fibrosis.²⁸ The key is to be firm and slow. Multiple strokes, in parallel passes, are made until a full release of the tethering is accomplished. The endpoint is identified as when the ease of the passage of the cannula increases. An audible sound of the bands breaking is often heard. Fractional RF microneedling is then performed, with the tumescent providing the necessary anesthesia. For rolling scars, the energies are often the same as those for ice-pick and boxcar scars. The option to inject an agent for collagen boosting is also available, although we prefer to carry out this step at a later time, at least 2 weeks after the simultaneous subcision and fractional RF microneedling treatment session.^{27,29}

ANCILLARY TECHNIQUE UTILIZING ACCUTITE FOR SUBCISION OF SCARS

The AccuTite handpiece (InMode Ltd, Lake Forest, CA) ([Figure 2](#)) is a smaller version of the FaceTite probe, which has been described previously.^{17,18,30} Both AccuTite and FaceTite handpieces (InMode Ltd, Lake Forest, CA) are minimally invasive bipolar RF devices that produce deep tissue heating to tighten the overlying fibroseptal network. An internal positively charged electrode and an external negatively charged electrode complete the circuit. The AccuTite handpiece consists of a 6-cm cannula, 0.9 mm in diameter, and is used to treat more sensitive areas of the face such as the nasolabial folds and periorbital area.

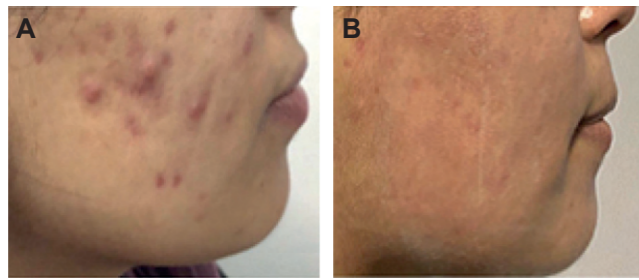


Figure 3. Active acne and early acne scar resolution after a treatment protocol with low-dose isotretinoin (10 mg, 3x per week, 6 months) and 3 sessions of fractional radiofrequency microneedling in a 27-year-old female. (A) Pretreatment. (B) Six months posttreatment.

We have developed a new application for this powerful handpiece, using the internal electrode as an internal cannula for subcision. Once the scar bands are mechanically released, RF is delivered at very conservative temperatures: 50°C internal and 35°C external. When treating acne scars with this technique, it is not necessary to reach the cut-off temperatures, but rather to deliver a few passes in the subcised zone. We have found this to be sufficient for remodeling the skin. **Figure 3** demonstrates a typical result achieved at 6 months follow-up visit after the last treatment. The treatment protocol included 2 sessions of fractional RF microneedling treatments for active acne, followed by 3 sessions of minimally invasive bipolar RF with subcisions as described above. In the final session, the patient was administered a collagen booster (calcium hydroxylapatite, diluted 1:1 with lidocaine 2%; Radiesse, Merz Pharma GmbH & Co., Germany), immediately after this treatment session.

EXAMPLES OF CLINICAL APPLICATIONS OF FRACTIONAL RADIOFREQUENCY FOR VARIOUS ACNE PRESENTATIONS

Results of Treatment of Active Acne and Preventing Acne Scars

Many options exist for the treatment of active acne, but high relapse rates and an unfavorable side-effect profile may lead to poor compliance.³¹ Many patients seek alternative therapies that are able to provide longer remission. Many of our patients had undergone previous treatments and had experienced relapse, including treatments with high doses of isotretinoin. Although isotretinoin has been shown to improve and modulate early acne scars, its ability to do so is limited, especially in cases of severe cystic acne.

We have noticed in our practice that fractional RF microneedling has the added benefit of significantly improving early acne scars and acne rosacea with excellent results



Figure 4. Results of treatment in a patient with acne and rosacea. This 23-year-old female underwent 4 sessions of fractional radiofrequency microneedling spaced 2 months apart. (A, C, E) Pretreatment. (B, D, F) Six months posttreatment.

(**Figures 3, 4**). Most patients have a complete elimination of early scars which are identified by being red and in the early stages of atrophy. We have also noticed higher remission rates of active acne.

Between February 2018 and October 2021, 356 patients received acne and early acne scar treatments at one of our clinics. Of these patients, 128 (36%) opted for treatment with isotretinoin in high doses and a skincare routine. A group of 89 patients (25%) elected for topical therapy involving 6 sessions with a combination of Er:glass and Nd:YAG lasers. The remaining 139 (44%) patients underwent treatment for their active acne with a skin protocol and fractional RF microneedling. The ancillary skincare protocols for the 3 groups were very similar. All patients were prescribed a keratolytic wash, sun protection, and a topical retinoid. Of the 3 groups, a subset of 54 patients of the isotretinoin group, 16 patients of the laser group, and 29 patients of the fractional RF microneedling group have completed a 3-year follow-up since treatment. A large proportion of the patients in the isotretinoin group (36/54, 67%) relapsed within a 3-year period. The laser group had an even higher relapse rate of 75% (12/16 patients). Of the fractional RF microneedling group, 24% experienced relapse (7/29 patients). Satisfaction in this patient group had a mean [standard deviation] of 4.2 [0.4] out of 5. Relapse was defined as patient or practitioner observing worsening of acne or acne scarring after the initial improvement after treatment. There were no adverse outcomes observed—this includes thermal injury to the epidermis, prolonged erythema, or hyper/hypopigmentation.

Although we were unable to objectively quantify the scar burden in all these patients after treatment, the majority of patients treated with fractional RF microneedling were very satisfied with the quality of their skin, whereas patients in the remaining 2 groups would often complain about the scars they were left with after their acne remission.

Results on Old Acne Scars

Old acne scars present one of the most challenging scar types to treat.³² It is difficult to predict response rate and most patients are only able to achieve a modest result.¹ Darker skin types pose a particular challenge as many of the more aggressive laser options lead to severe pigmentary changes.³³ Our experience shows that fractional RF treatment for acne scars is a safe and effective option for all skin types when situated within an acne scar revision protocol that combines multiple modalities.

Some of the most effective treatments for the different scar types have been summarized above. We have found fractional RF microneedling to be a powerful adjunct for acne scar revision. Combining RF energy with the other procedures described helps initiate neocollagenesis and

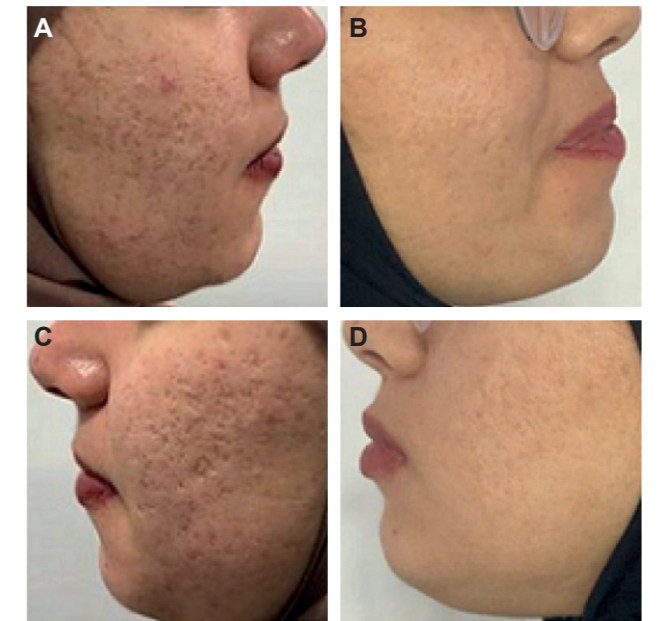


Figure 5. Typical results of acne scar revision protocols utilizing several tools along with fractional radiofrequency microneedling treatment series. In this case, a 25-year-old female underwent punch excision with a 1-mm punch, tumescent subcision, and fractional radiofrequency microneedling. Four sessions were performed every 3 months. (A, C) Pretreatment. (B, D) Nine months after the last session.

dermal remodeling, as well as significant tightening of the skin over time. In addition to lifting the atrophic tissue, neo-collagenesis helps to support the soft tissue architecture surrounding the scar, leading to smoothing and textural improvement.

The ECCA score (échelle d'évaluation clinique des cicatrices d'acné) is a validated acne scar grading system in use since 2007.³⁴ It allows physicians to score acne scars based on number and severity in order to produce an overall score. Between April 2018 and April 2019, 49 patients with average age of 25.4 [5.6] years with varying degrees of old acne scars completed a series of 4 sessions that utilized a combination of treatments together with fractional RF microneedling. After 4 sessions, all patients showed at least a 50% reduction in median ECCA acne scar grading. The average ECCA score for all patients before treatment was 178 [35], but this was reduced after treatment to 132 [17]. Both the number of scars and their depths were significantly reduced, contributing to the overall clinical improvement (**Figure 5**). Most importantly, there were no significant adverse outcomes for these patients. There were no infections, long-term sequelae of thermal injury, or worsening of scars. Satisfaction in this group of patients had a mean of 3.8 [0.5] out of 5. We did not assess the use of fractional RF microneedling alone for old acne scars.

DISCUSSION

Available treatments for acne scars often demonstrate mild improvement, but are frequently inconsistent or fail to present a dramatic outcome.³⁵ The use of fractional RF has been a powerful addition to our armamentarium of tools used for acne and acne scar treatments. Especially when including fractional RF microneedling in combination with other treatments, we have seen excellent results in scar remodeling, well beyond what has been seen with other treatments. This is most likely due to the powerful energy that fractional RF microneedling can deliver, especially when considering the depth of the RF penetration into the tissue. The advantages that the fractional RF microneedling system has over other fractional and microneedling RF systems on the market may be attributed to the fact that the return electrode is on the surface of the skin, thus allowing the RF current to travel a longer distance, thereby creating a larger and deeper heating zone. Other systems situate the positive and negative electrodes in parallel and the RF current achieved occurs in a small and superficial area between the short tips at the very end of the needles.

The high safety profile achieved with fractional RF microneedling in darker skin types can be attributed to the insulation of most of the length of the pin. In their recent consensus paper looking at energy-based devices for acne scars, Salameh et al showed that noninsulated needles produced less effective results.³⁶ One argument is that when the device uses noninsulated needles, the RF spark produced between the positive and negative electrodes occurs along the whole length of the needle. Thus, it produces a more superficial zone of heating, increasing the risk of damage to the skin surface and postinflammatory hyperpigmentation.³⁶ However, when the pins are insulated, except for the tip, RF energy is selectively delivered specifically to the target depth. Inadequate treatment of acne scars occurs when treatments are too superficial and do not reach the deep component of ice-pick or boxcar scars.

In 2014, Kaminaka et al were able to show excellent improvements in active acne when they used RF microneedling.³⁷ Our experience has been the same, with results from fractional RF microneedling being more consistent than when utilizing lasers or isotretinoin alone. We attribute this to the stronger and deeper heat signal produced by fractional RF microneedling, which in turn leads to a more powerful wound healing response. Furthermore, fractional RF microneedling is known to ablate the sebaceous glands in the skin, and has recently been shown to be an excellent treatment for ectopic sebaceous glands.³⁸ Apparently, there is some destruction of the sebaceous glands, resulting in a reduction of sebum overproduction. Histology of adnexal structures in the skin showed higher levels of

collagen remodeling than what is seen with laser treatment.³⁷ This perhaps explains the observation in our cohort of acne patients that treatment with fractional RF microneedling leads to longer remission rates than treatment with lasers.

The excellent results seen in acne scar revision are probably due to the deeper and more powerful heat signature that fractional RF microneedling devices are able to achieve. Several studies have shown that in addition to significant sebum reduction, RF microneedling is able to upregulate TGF β , leading to more collagen remodeling, and to downregulate NF- κ B and IL-1, associated with improved scar remodeling.³⁹ The negative impact of inflammation on scar revision has been well elucidated, and it is apparent that fractional RF microneedling is able to decrease the inflammatory milieu concomitantly with improving collagen remodeling.^{37,39}

The current evaluation demonstrates qualitative improvements, as well as a degree of quantitative improvement measured by ECCA scores. Unfortunately, we are currently unable to objectively measure sebum reduction or to histologically confirm the improvements we noted clinically. Limitations of this study also include the retrospective, observational nature of the data. The study was not designed as a randomized, independent, blinded trial, and the patients themselves often chose which treatment protocol to undergo, based on financial limitations and treatment downtimes, introducing a bias. Patients were not asked to keep diaries and there is no independent mechanism whereby we can confirm treatment compliance. Nevertheless, the treatments were offered in the same clinic and by the same physician with similar treatment parameters/settings. The presented data are for the patients who completed the whole treatment plan. The current data also share the longest follow-up period for patients after completing fractional RF microneedling sessions. Most studies have a follow-up of 12 to 18 months,³⁵ whereas we have followed our patients for over 3 years. Future directions will include performing isolated fractional RF microneedling treatments in addition to combination treatments and a control group to further elucidate the therapeutic benefits of fractional RF microneedling in patients with acne/acne scarring.

CONCLUSIONS

Fractional RF microneedling offers the advantage of effectively treating both active acne lesions and the associated early scars, and results in long-term remission. Fractional RF microneedling has proven to be extremely safe in darker-skinned patients, whereas other modalities have many limitations. In addition, applications of fractional RF microneedling can be very effectively expanded to include treatment of old scars.



Disclosures

Drs Hamadani and Vranis are consultants for InMode Ltd (Lake Forest, CA).

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BODY CONTOURING FINESSE: DYNAMIC DEFINITION LIPOSCULPTURE AND BIPOLAR RADIOFREQUENCY MICRONEEDLING

Alfredo E. Hoyos, MD; Mauricio E. Perez Pachon, MD ; and Neil M. Vranis, MD

Abstract

Dynamic definition liposculpture (HD2) is considered a highly sought after procedure in body sculpting surgery by patients. Radiofrequency microneedling is a cutting edge technology with evidence-based outcomes demonstrating skin tightening and retraction. These ancillary procedures complement and enhance the results of dynamic definition liposculpture. A retrospective review of patient records from 2022 to 2024 was conducted. All patients who underwent high definition (HD) or HD2 in combination with fractional radiofrequency microneedling treatments by the senior author (A.E.H.) were included. Data collected included patient demographics, areas treated, and any complications. A total of 86 patients were included: 16 in 2022, 62 in 2023, and 8 in 2024. The most frequently treated area was the abdomen, followed by the back, face, neck, thighs, and arms. The average age of patients was 40.0 years in 2022, 40.8 years in 2023, and 44.4 years in 2024. The average BMI was 23.9 kg/m² in 2022, 24.3 kg/m² in 2023, and 25.2 kg/m² in 2024. Minimal complications were observed, with some patients requiring further interventions such as scar correction and nevus resection. Avoiding superficial liposuction by relying on radiofrequency microneedling to target the adipose tissue directly beneath the dermis decreases the risk for iatrogenic (cannula related) superficial contour irregularities and makes the overall operation safer and more reliable.

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Following the Industrial Revolution, the rise of technology has been exponential in all industries. Consequently, medicine, and in particular plastic surgeons, have relied on technologic devices and advances to improve the safety and outcomes of clinical practice. Recently, the power of controlled radiofrequency (RF) has been utilized in both microneedling and bipolar devices to target dermal and subdermal collagen disposition and structure. Evidence has shown that this promotes remodeling, tightening, and adipolysis to improve skin texture, thickness, and contour.^{1,2} Surprisingly, these devices have had a great impact on the general outcome after liposuction and moreover have

become an integral component of dynamic definition liposculpture (HD2), previously described by the senior author (A.E.H.).^{3,4} This is an upgrade to the previously published high-definition (HD) liposculpture technique, which carves

Dr Hoyos is a plastic surgeon in private practice, Bogota, Colombia.
Dr Perez Pachon is a research fellow, Mayo Clinic, Rochester, MN, USA.
Dr Vranis is a plastic surgeon in private practice, Beverly Hills, CA, USA.

Corresponding Author:

Dr Alfredo E. Hoyos, Av K 15 #83-33, Suite 203, Bogota, Colombia.
E-mail: alhoyos@gmail.com, Twitter: [@alfredohoyosmd](https://twitter.com/alfredohoyosmd)

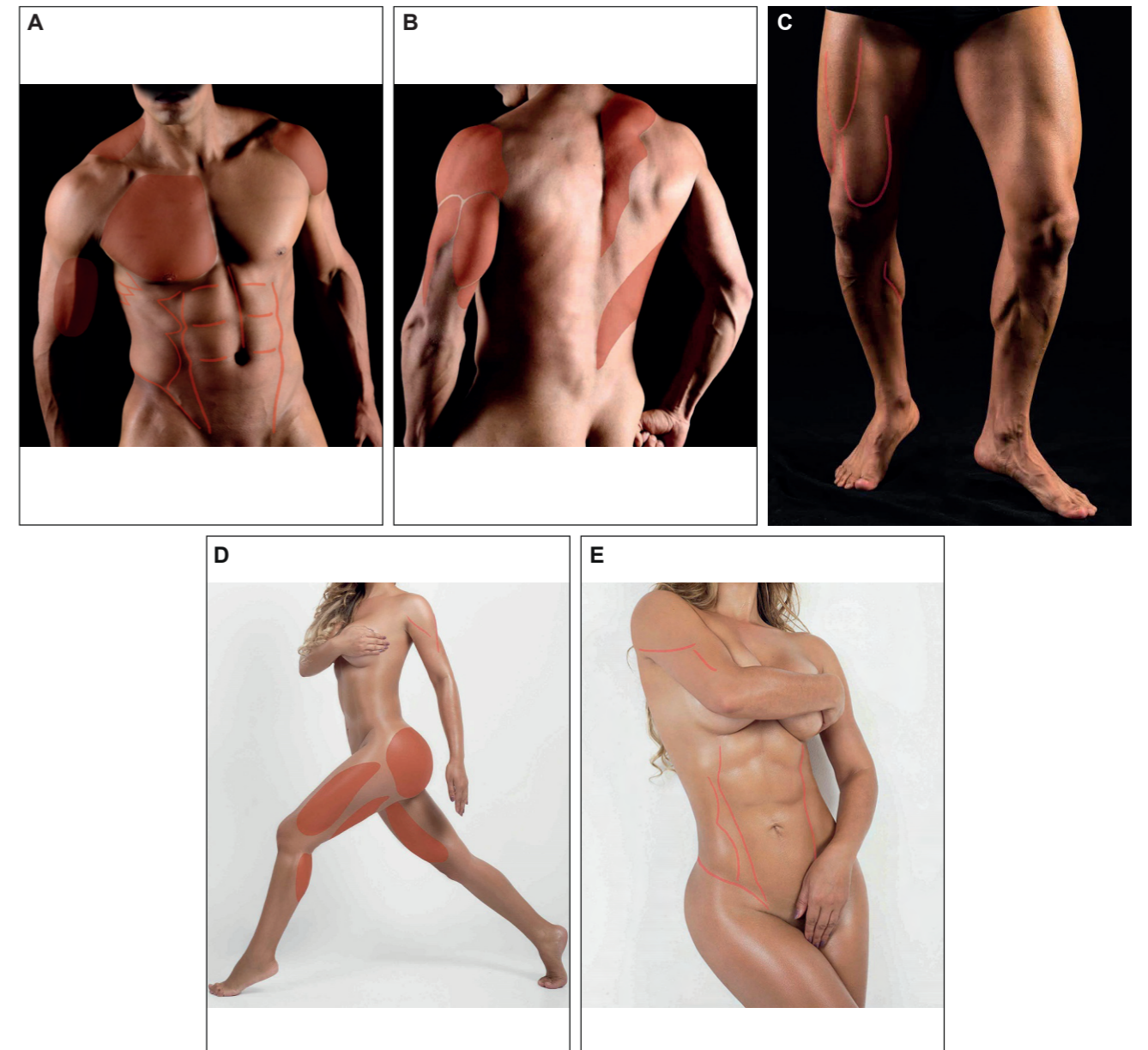


Figure 1. (A) Torso frontal oblique, (B) torso posterior oblique, and (C) lower extremity frontal oblique views of a 28-year-old athletic male model demonstrating cutaneous landmarks of muscle definition. (D) Semilateral and (E) oblique frontal views of a 26-year-old athletic female model. The orange shades are areas of muscular convexity and dotted lines are convex areas between major muscle groups.

the superficial and intermediate adipose layers of the skin and creates controlled contours to achieve an athletic and natural body.⁴

Techniques for advanced liposculpture take advantage of different technologies that allow the surgeon to safely reshape a patient's torso and extremities based on their unique underlying anatomy. Up-to-date concepts in body sculpting finesse consider body phenotype and variable degrees of

muscularization, and safe fat grafting practices have permitted a broader spectrum of possibilities for our patients such that we are now able to plan a procedure that suits not only the patient's anatomy but also satisfies their expectations.⁵ Throughout this supplemental article, we describe our experience in blending dynamic definition liposculpture with radiofrequency microneedling to optimize outcomes of patients undergoing body sculpting procedures.

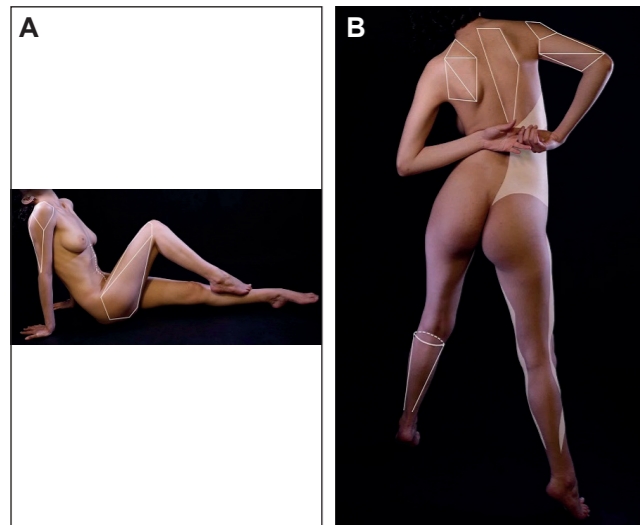


Figure 2. (A) Semilateral and (B) oblique frontal views of a 26-year-old athletic female model. The orange shades are areas of muscular convexity and dotted lines are convex areas between major muscle groups.

RADIOFREQUENCY MICRONEEDLING TECHNICAL ASPECTS

In the basic science and clinical literature, it has been reported that bipolar fractionated RF microneedling devices (Morpheus8, InMode, Lake Forest, CA) have decreased the amount of subdermal adipose tissue while tightening dermal and subdermal connective tissue through a process of remodeling and neocollagenesis.^{1,2} The operator can manipulate depth of microneedle penetration (1-7 mm of depth), the degree of energy delivered per pulse, and the number of pulses delivered to a certain area (pulse count/cm²). Targets include the epidermis, dermis, and subcutaneous adipose tissue. The particular device the senior author (A.E.H.) prefers in his practice comes with a choice of handpiece. The head of the handpiece contains 12, 24, or 40 sharp, stainless steel, gold-coated microneedles. These are selected based on anatomic area, thickness of dermis and subcutaneous tissue, and the magnitude of desired treatment effect. The goals of treatment include fat liquefaction, contraction of the reticular dermis, and remodeling of the connective tissue (fibroblast stimulation). The more laxity and the less adipose tissue, the less energy and depth are applied. Typical settings are, for the periorbital area, 2 mm, 15W to 30W; face, 3 to 4 mm, 25W to 40W; and body, 2 to 7 mm, 25W to 50W. Burst mode is preferred for HD due to the vulcanization technology that allows multiple depths in the same pulse, which creates cross links between long collagen fiber molecules in a stratified depth.²

Table 1. Protocol for Prevention of Thromboembolic Events

Protocol steps
1. Suspend OCPs and HRT 3 weeks before surgery and resume after 2 weeks.
2. Avoid prolonged periods of sitting 24-48 hours before surgery.
3. For patients whose travel time is ≥ 8 hours, delay surgery for 48-72 hours.
4. Use intermittent pneumatic compression boots during surgery.
5. Use compression stockings for 5-7 days after surgery.
6. Patient early mobilization, preferably first 4-6 hours after surgery.
7. Guide chemoprophylaxis by preoperative Caprini score.

HRT, hormone replacement therapy; OCPs, oral contraceptives.

ARTISTIC ANATOMY

Power vs Definition

Muscles are individual bundles of muscle fibers that share a common origin and insertion. The ratio of muscle size to overlying skin and subcutaneous thickness determines the degree of visible definition. A patient's physique can be altered by manipulating both factors. Removing subcutaneous adiposity and creating any degree of volume enhancement or projection with intramuscular or subcutaneous adipose grafts improves the overall muscular appearance. For HD2, we have divided the muscles according to gender (Figure 1). Definition muscles are those requiring sharp edges and demarcated limits to provide a "shredded" perception of the body. Certain muscles are considered "masculinizing" and would distort the delicate, soft, feminine appearance. These muscles include the deltoids, trapezius, triceps brachialis, gluteus medius, pectoralis major, latissimus dorsi, and serratus anterior.

Feminizing Facets of the Torso

Feminizing facets of the torso are conceived as planes over different body segments that interact with each other to give the body a natural feminine silhouette (Figure 2). These facets differ from the sharp edges of male body sculpting, and can be found at the posterior arm; with shadowing here more of a delicate diamond shape. In the posterior torso the scapulae and trapezius muscle interact to form different planes. Laterally, in the waist area, the flanks act as a rhomboid wraparound with a smooth transition to the latissimus dorsi. Anteriorly, the rectus abdominis transitions from the rib cage with more shadowing laterally because the external oblique forms a gentle concavity.

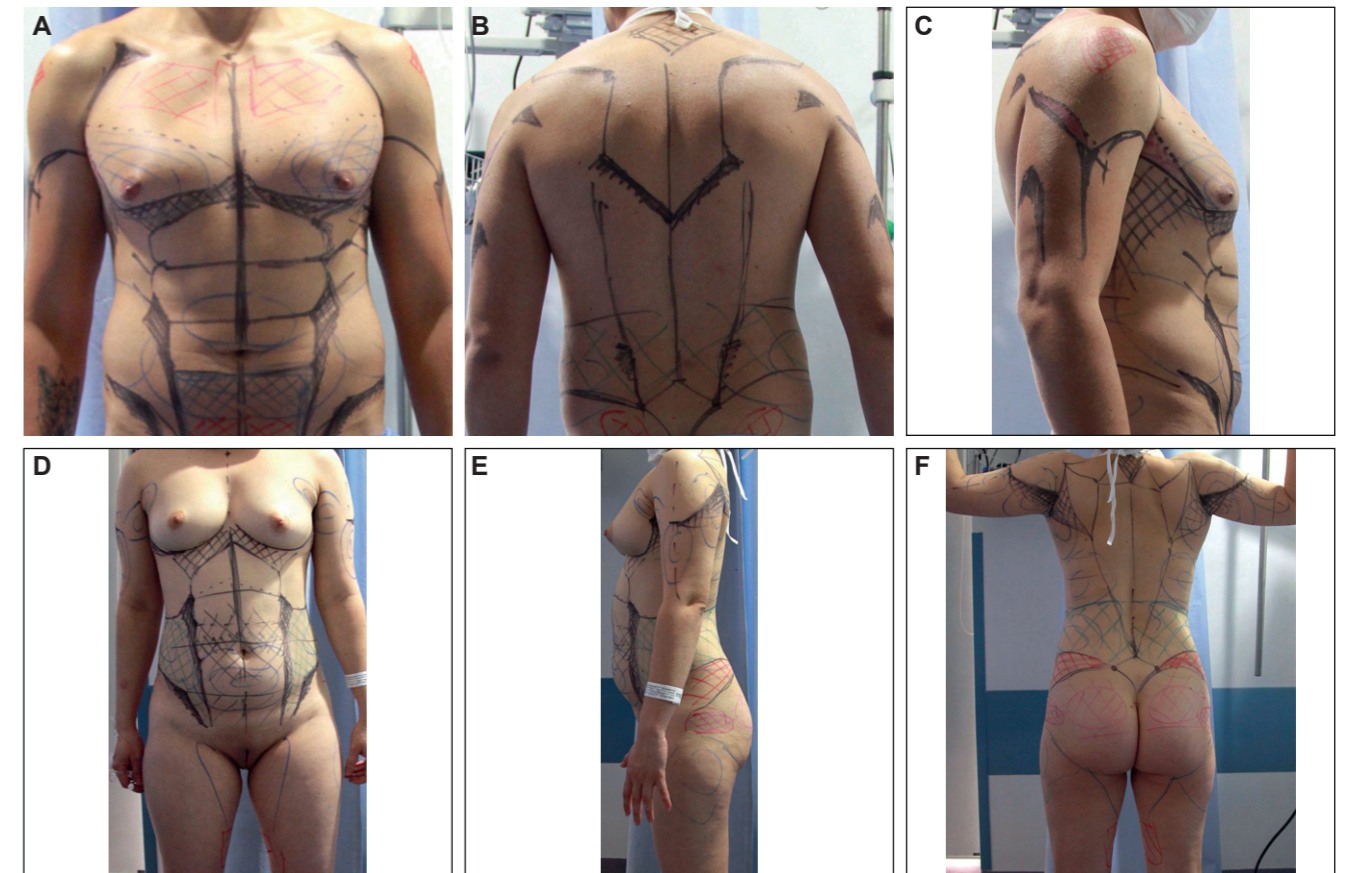


Figure 3. (A) Frontal, (B) posterior, and (C) lateral views of a 35-year-old male patient. (D) Frontal, (E) lateral, and (F) posterior views of a 29-year-old female patient. Black/blue lines are preoperative markings to delineate intersection of major muscle groups and will translate to lines of definition. Line thickness notes areas of widened negative contouring, and cross-hatched areas are diffuse areas of liposuction debulking.

METHODS

We conducted a retrospective review of patient records from the last 3 years at a single center in Bogotá, Colombia. Our aim was to identify patients who underwent HD or HD2 in combination with bipolar fractionated RF microneedling treatments. All procedures were performed by the senior author (A.E.H.). Data collected included patient demographics, areas treated, and any noted complications. Specifically, we analyzed the distribution of treatment areas and documented the frequency of each area treated across the years 2022, 2023, and 2024.

Preoperative Considerations

Patient Evaluation

The principles of the Declaration of Helsinki were followed, including obtaining written informed consent from all participants. Similar to any surgical procedure, the consultation included a thorough past medical history and a detailed physical examination to determine the patient's BMI, areas

of excess adipose deposits, muscular structure, and body biotype. We preferred to utilize an abdominal wall ultrasound when scars were present over the abdominal wall or abdominal hernias were suspected. Patients were required to stop any tobacco products for at least 2 weeks before and 2 weeks after surgery. Heavy smokers or those experiencing cessation difficulties were referred to their primary care provider for more extensive cessation strategies.

Medical exclusion criteria for undergoing HD2 included patients with a high BMI (≥ 30 kg/m²), significant cardiovascular pathology requiring intervention or treatment, blood clotting disorders, active smokers, ASA III, a history of psychiatric disorders (eg, body dysmorphic disorder), and a hemoglobin ≤ 10 g/dL. Relative contraindications included an age greater than 65, autoimmune or immunodeficient disorders, and patients with preoperative hemoglobin levels between 10 and 12 g/dL.

Intraoperative Safety Protocols

HD liposculpting became extensively popular worldwide in the late 2000s and currently is considered a safe and

Table 2. Protocol for Hypothermia Prevention in High Definition Liposculpture (HD) and Dynamic Definition Liposculpture (HD2)

Protocol steps
1. Turn off the air conditioning inside the operating room (OR) before the patient enters.
2. One-hour patient prewarming with a Bair Hugger (3M, Saint Paul, Minnesota) before admission to the OR (warm air at 38°C/100.4 °F).
3. Insert esophageal thermometer (after endotracheal intubation) for continuous temperature monitoring.
4. Air conditioning inside the OR must be set to 22°C-23°C (68-71.6 °F).
5. Keep both intravenous fluids and tumescent solution for infiltration at 37.5°C (99.5 °F). ^a
6. Use the Blanketrol (Gentherm, Northville, MI) system during the entire procedure. ^b
7. Keep the surgical blankets as dry as possible: decrease non-sensible temperature loss.
8. Turn off the OR air conditioning about 30 minutes before the procedure termination.
9. Use the Bair Hugger (at 38°C/100.4°F) to keep the patient in normothermia after surgery.

^aWe use the ANOVA precision cooker (ANOVA Applied Electronics, Inc., San Francisco, CA) to keep fluids at this temperature in a bain-marie.

^bBlanketrol is a temperature regulation system (computer-controlled heater + circulation pump + water-filled blanket) that is placed beneath the clothing of the surgical table.

effective technique for body contouring surgery. Strict protocols for patient preparation and intraoperative measures are in line with evidence-based medicine that have been customized for our practice. For thromboembolic event prevention, preoperative risk stratification is paramount. Calculating the Caprini score allows for modifiable risk factors to be addressed before surgery (ie, weight loss, regular exercise, quitting smoking, suspending oral contraceptives). Lower extremity compression socks, intermittent pneumatic compression devices, normothermia, early ambulation, and shortened operative times were well accepted interventions to reduce the risk of postoperative embolic events. For patients with Caprini scores of 3 or greater, chemoprophylaxis was usually administered postoperatively (Table 1).

Intraoperatively, we optimized hemostasis with epinephrine and tranexamic acid in the tumescent fluid in addition to careful hemostasis for incisional procedures. Constant communication with the anesthesiologist was maintained throughout the procedure to avoid hypothermia and perioperative hemodilution. We considered transfusion only if the hemoglobin was less than 9 g/dL and the patient was symptomatic, or if the hemoglobin dropped below 7 g/dL.

Surgical Planning

Markings

All markings were done with the patient in the standing position. Anatomic landmarks were outlined for reference, including negative spaces, forbidden areas (adhesion zones), fat deposits, transition and dynamic zones, and those for deep and superficial liposuction. Sharp muscular edges were etched for males, and curvilinear, gentle transitions were drawn for females (Figure 3). A color code that each surgeon was familiar with was utilized and is recommended; for example, green indicated negative spaces, red was for adhesion and transition zones, blue for fat deposits, black for anatomical landmarks, crossed lines for fat grafting, and so forth.

Degree of Muscular Definition

Aesthetic standards for muscular contours and definition differed by the individual's gender, identity, and body image preferences. Preoperative markings and intraoperative execution were tailored on a case by case basis. To perform these surgeries, we introduced a new variable of basic (B), moderate (M), or extreme (X) muscular definition.⁴ This was not only determined by the patient's desire but also had to comply with the patient's body biotype and underlying musculoskeletal structure.^{6,7} To put this in clinical perspective, ectomorph patients could elect for any of the 3 degrees of muscular definition (BMX), but endomorph patients and mesomorph patients had to choose between 2 (BM and MX, respectively). This was because of the unnatural appearance that would result from an exaggerated deviation of a patient's underlying body type.^{8,9, 10}

Intraoperative Considerations

Hypothermia Prevention

Harmful effects following hypothermia include increased risk of surgical site infection, coagulopathy (platelet dysfunction), myocardial complications (arrhythmias and ischemia), prolonged recovery times, among others. Table 2 outlines the senior author's (A.E.H.) protocols for maintaining normothermia during the procedure.

Stealth Incisions

Minimal access incisions (5 mm) were placed over hidden areas or along skin creases to mitigate postoperative stigmata. The most common stealth incisions included the anterior axillary fold, posterior axillary fold, distal elbow, nipple (for male patients) and inframammary fold (female patients), umbilicus, inguinal crease, intergluteal crease, infragluteal crease, knee, popliteal, Achilles, lateral thigh, and posterior neck midline.

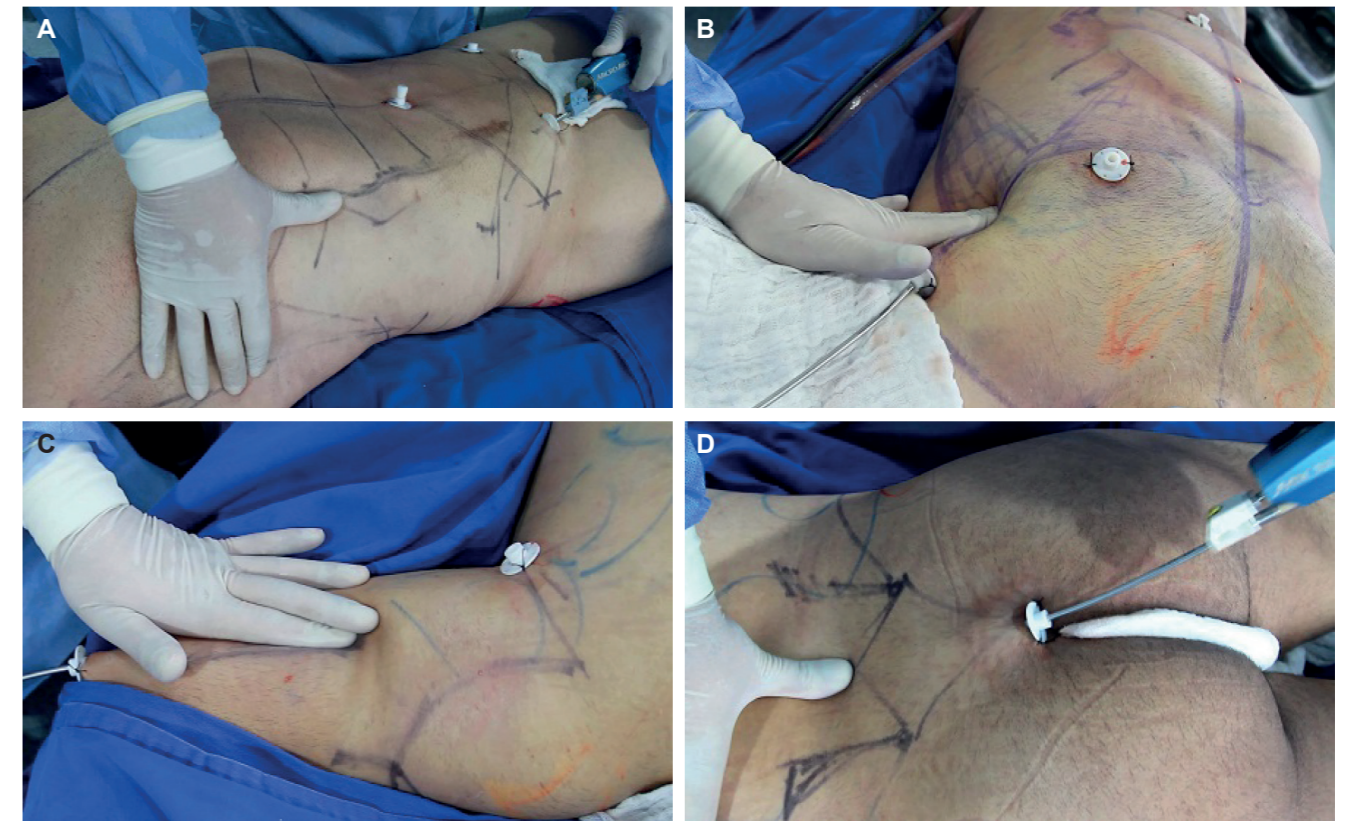


Figure 4. Intraoperative photographs of (A, B) abdomen, (C) flank, and (D) back liposuction of a 35-year-old male patient.

Tumescent Solution

A standard mixture of epinephrine, lidocaine, and tranexamic acid were added to lactated ringers, with 1 mg of epinephrine per liter of tumescent solution (ideal dose: 0.15 mg/kg). To prevent the non-sensible absorption of epinephrine, we did not exceed 9 mg of epinephrine in total. Lidocaine concentration peaked in the plasma an average of 12 to 24 hours after infiltration. It was therefore imperative to monitor patients for toxicity or complications for up to 24 hours after surgery. We abided by the standard maximum dose for lidocaine of 35 mg/kg. Patients remain in the recovery room for a minimum of 6 to 12 hours after surgery with clear instructions to watch for both lidocaine intoxication and pulmonary edema. Infiltration was allowed to sit for 5 to 10 minutes for an even solution distribution before starting emulsification (local vasoconstrictive effect).

Ultrasonic Emulsification

The operation began with emulsification of the superficial layer. Back and forth gentle movements of the probe were performed until resistance was decreased to minimal effort. A pulsed mode of 70% to 80% was set for the anterior and posterior torso (superficial layer) and a pulsed mode of 50% to 60% for the arms and thighs (both superficial and deep layers) and in young patients without fibrosis. The

continuous mode of 70% to 80% was reserved for the deep layer in bulky areas over the anterior and posterior torso. The 3 endpoints for successful ultrasonic emulsification (VASER; Solta Medical–Bausch Health Companies Inc., Bothell, WA) treatment were (1) time, 1- to 2-minute maximum per 100 mL of infiltrated solution; (2) decreased or minimum tissue resistance; and (3) temperature, when the palpable tissue was warmer than the surgeon's hand.

Fat Extraction

Surgeons prefer liposuction systems such as PowerX (Solta Medical–Bausch Health) and MicroAire power-assisted liposuction (MicroAire Surgical Instruments, Charlottesville, VA) to minimize operator fatigue. Suctioning the deep layer revealed the gross anatomy, and superficial layer liposuction unveiled the anatomical details and artistic landmarks (Figures 4, 5). In males we began with superficial liposuction of the definition lines with a small cannula (3 mm) to mitigate risk of contour irregularities and then slowly progressed to larger cannulas (4-5 mm) for deeper suctioning. In females focus was initially on creating gentle valleys and shadows with 3- to 4-mm cannulas. Once the negative spaces were defined, anatomic regions were evenly debulked to an endpoint determined by the surgeon.



Figure 5. Intraoperative photographs of abdomen (A, B) abdomen, (C) back, and (D) flank liposuction of a 29-year-old female patient.



Figure 6. Intraoperative photograph depicting use of the Morpheus8 microneedling radiofrequency device after completion of liposuction in a 29-year-old female patient.

Fat Transfer

The following tenets were created by the senior surgeon (A.E.H.) as a result of extensive experience and were routinely followed: (1) intramuscular fat grafts must be placed as superficial as possible; (2) applying the Mathes and Nahai vascular classification system, always direct the cannula perpendicular to the direction of the main muscle

pedicle; and (3) access point entry should penetrate the muscle fascia as far as possible from the main pedicle.¹¹ The most common large muscles that we have fat grafted for muscle augmentation are the deltoids, pectoralis major, biceps, trapezius, gluteus maximus, gluteus medius, vastus lateralis, and medial and lateral gastrocnemius.

After fat harvest with the power liposuction systems, lipos aspirate was decanted and washed. After fat processing, a peristaltic pump was utilized for EVL (expansion vibration lipofilling).¹² This technique has been widely accepted as safe and efficacious for high-volume lipofilling. This was performed with a blunt-tip 3-mm cannula, injecting in a constant retrograde fashion. Aliquots of fat were deposited with a multiple-layer approach. The subcutaneous plane was compulsory at the gluteal region, and the intramuscular, subfascial plane was preferred for augmenting most power muscles.¹³

Microneedling Radiofrequency Application

A thorough preoperative assessment of the skin and subdermal thickness and its laxity through pinch tests was imperative to stratify patients. Patients with suboptimal inherent skin elasticity or thickness were indicated for simultaneous microneedling radiofrequency treatment in



Figure 7. Intraoperative photograph of a 29-year-old female patient depicting use of the Morpheus8 microneedling radiofrequency device on the (A, B) flanks and (C, D) abdomen after completion of liposuction. (E) The "grid" pattern of the microneedling is expected after completion of the microneedling RF treatment.

addition to the detailed liposuction procedure. For thin skin flaps the power variable was decreased, and we did not perform superficial burst shots. This mitigated the risk of thermal damage to the dermis and epidermis.

Meticulous technical execution also decreased risk of thermal injury. The handpiece must be firmly positioned over the treatment area and make complete contact with the skin (Figure 6). Complete contact of the head of the handpiece completes the circuit that is critical to maintaining the bipolar nature of the device. Once the handpiece

was positioned appropriately, with approximately 30% overlap with the previous area, the pedal was pressed to deliver the RF energy. The operator could choose to toggle between a single press-release for the cycle mode or continuous pressing of the pedal for the fixed and burst mode (preferred).

We began this portion of the procedure over the zones where more flaccidity was seen. Typically this involved the proximal posterior arm, lower abdomen, top lateral posterior torso, medial thigh, and infragluteal region (Figure 7).

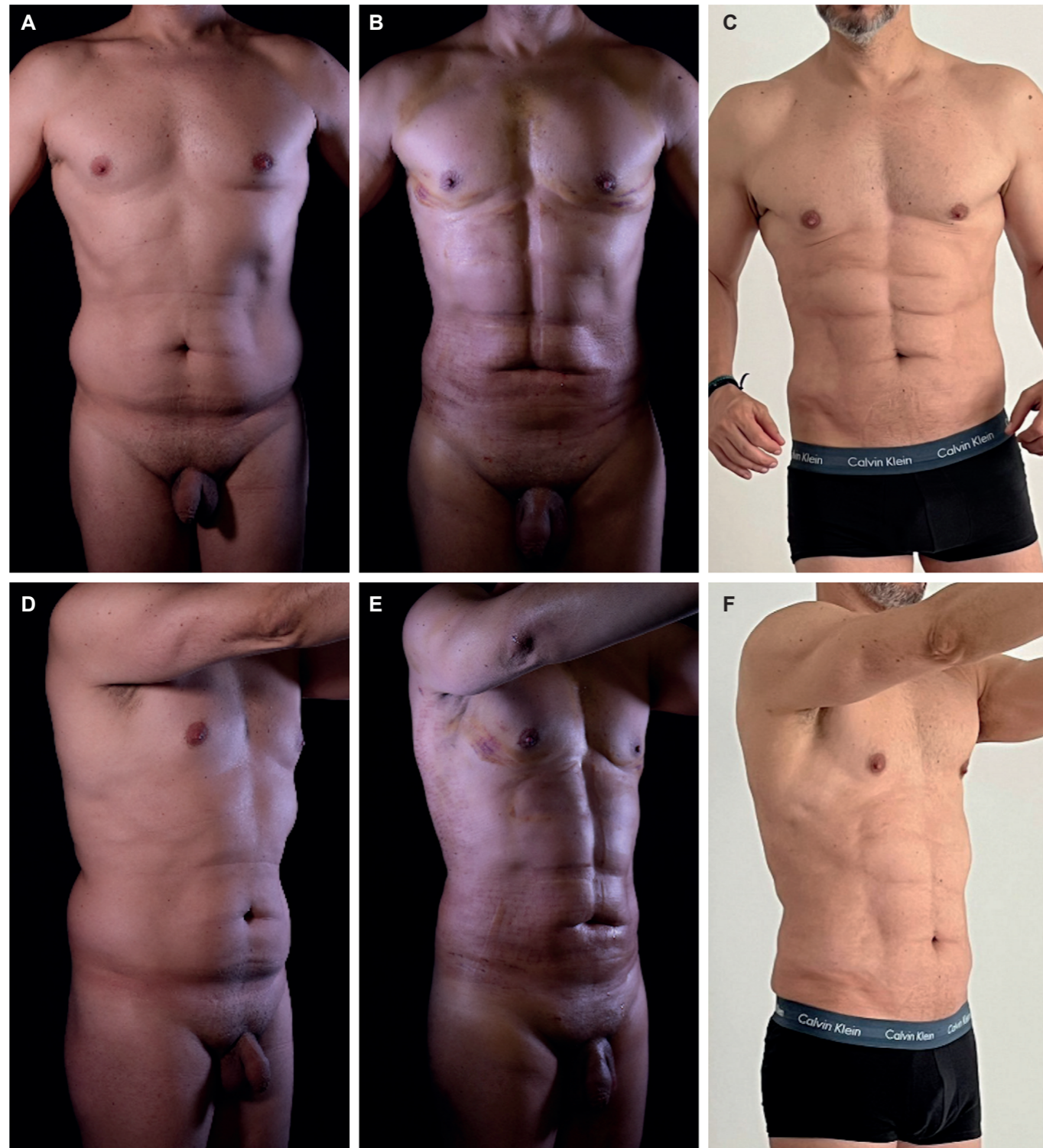


Figure 8. A 47-year-old male underwent high-definition liposuction combined with microneedling radiofrequency (RF) of the abdomen. (A, D) Based on the skin sagging in the lower abdomen, this patient might typically be considered for a miniabdominoplasty. However, the combination of high-definition liposuction with intraoperative microneedling RF improved skin retraction and eliminated the need for lipectomy. This improvement can be seen in (B, E) the early 48-hour photographs and (C, F) the final result 6-month postoperatively, after 2 additional sessions of RF.

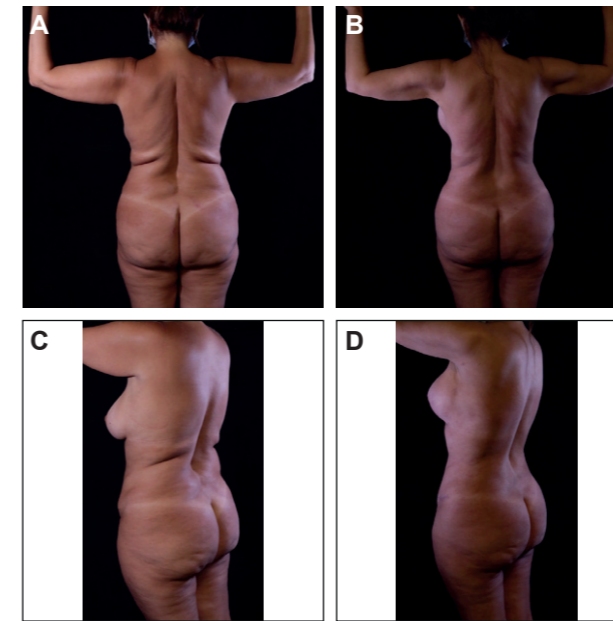


Figure 9. A 42-year-old female who underwent high-definition liposuction (HDL) and intraoperative microneedling radiofrequency (RF) of the arms and the back. Both HDL and RF helped improve the skin tightening of the arms and the posterior torso by almost disappearing the back rolls and improving the slim definition of the arms. This is well appreciated by comparison of (A, C) the preoperative photographs with (B, D) the 6-month follow-up postoperative photographs.

Next, the negative spaces and the muscle limits of definition muscles were targeted to accentuate transition muscle zones. Delivery of RF energy was avoided over the muscles in which fat transfer was performed. We usually left some space in between shots to fill with a new one with a different depth or energy. The depth and energy must be customized to the patient's skin quality and subdermal thickness. The following settings were frequently chosen and can serve as reference points for the reader:

- Arms and thighs: 30W to 35W power, starting at a 6-mm depth, then 4 mm and 2 mm.
- Torso: Burst mode at 40W power, starting at a 7-mm depth, then 5 mm and 3 mm.
- Submandibular region: 50W, 40W, and 30W at 4 mm, 3mm, 2mm.

Postoperative Considerations

Patients were closely monitored after surgery, with the first appointment usually 24 to 48 hours after surgery and then at 1 week, 1 month, 3 to 6 months, and 1 to 2 years. Results may take up to 6 months to be completely appreciated given the time it takes for the edema to resolve, the fat transfer to remain viable, and neocollagenesis to occur (Figures 8-11).



Figure 10. A 46-year-old female who underwent high-definition liposuction (HDL) and intraoperative microneedling radiofrequency (RF) of the arms and the back. Both HDL and RF helped improve the skin tightening of the arms, abdomen, flanks, and posterior torso. Note the improvement in back rolls, abdominal definition, and slim definition of the arms. This is well appreciated by comparison of (A, C) the preoperative photographs with (B, D) the 6-month follow-up postoperative photographs.

Patients are advised to apply cooling to the treated area to reduce erythema and discomfort. Topical antibiotic and anti-inflammatory ointments are applied to incision sites or areas of potential thermal injury. Overall this will prevent local contamination and decrease swelling. Hyperbaric oxygen therapy is recommended for patients with flap ischemia or altered perfusion over any body area, usually 24 to 72 hours after surgery. Skin moisturizers (body and face lotions) and sunscreen may be started after 24 hours. Manual lymphatic drainage begins 24 hours after surgery, and external ultrasound therapy and pressotherapy are provided 24 to 48 hours after surgery. This is avoided in areas where fat grafting was performed.

Additional external RF can be performed 10 to 15 days after surgery to promote second-phase healing. Additional sessions—up to 3, 1 month apart—of radiofrequency microneedling can be performed in the office under topical anesthesia if additional skin tightening is required.

RESULTS

A total of 86 patients underwent HD and HD2 in combination with fractional bipolar RF microneedling over the 3-year

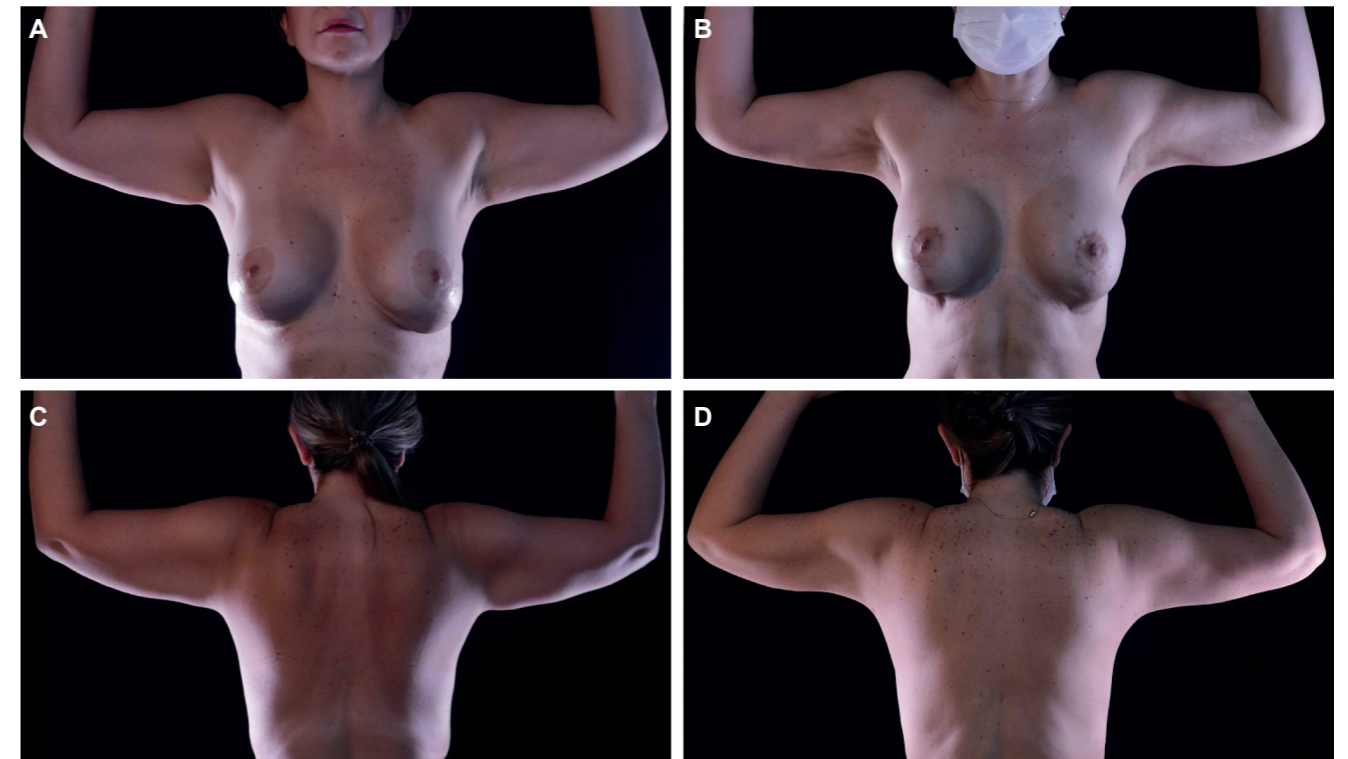


Figure 11. A 39-year-old female who underwent high-definition liposuction (HDL) and intraoperative microneedling radiofrequency (RF) of the arms and the back. Both HDL and RF helped improve the skin tightening of the arms. Circumferential arm reduction and improved definition can be appreciated by comparison of (A, C) the preoperative photographs with (B, D) the 6-month follow-up postoperative photographs.

period from 2022 to 2024. The cohort included 16 patients in 2022, 62 patients in 2023, and 8 patients in 2024. The distribution of patients across these years accounted for 18.6%, 72.1%, and 9.3% of the total, respectively. The average age of patients was 40.0 years in 2022, 40.8 years in 2023, and 44.4 years in 2024. The interquartile range (IQR) for age showed variability, with 13.8 years in 2022, 9.5 years in 2023, and 17.5 years in 2024. The average BMI of patients slightly varied across the years, being 23.9 kg/m² in 2022, 24.3 kg/m² in 2023, and 25.2 kg/m² in 2024, with respective IQRs of 3.3 kg/m², 3.5 kg/m², and 1.9 kg/m². The weight of patients averaged 64.9 kg in 2022, 66.5 kg in 2023, and 70.0 kg in 2024, with weight ranges showing considerable variability. The average volume of lipoaspirate was 3346.4 mL in 2022, 3227.6 mL in 2023, and 3793.8 mL in 2024, with IQRs indicating a broad range of lipoaspirate volumes across the years (Table 3). Complications observed during the study period included a single thermal injury on the right arm immediately after ultrasound-based liposuction in 1 patient, and 1 patient with a mild asymmetry, none of them related to the combination of treatments but rather isolated events. These findings indicate a consistent application of the procedure with notable variations in patient demographics and treatment outcomes over the study period,

alongside some instances of postprocedure complications that required additional medical attention.

DISCUSSION

Bipolar fractional RF microneedling has gained significant attention in recent years as a versatile and effective treatment modality for skin tightening and rejuvenation. When combined with HD or HD2 liposculpture, as seen in our study, it enhances the overall aesthetic outcomes by promoting skin contraction and improving the texture and tone of the treated areas.

Our retrospective cohort shows the efficacy and safety of this combined approach. The results indicated consistent application and positive outcomes across a diverse patient population. In our series, the most frequent treatment areas were the abdomen, followed by the back, face, neck, thighs, and arms. This distribution aligned with the common anatomical regions in which skin laxity and contour irregularities are most noticeable. Bipolar fractional RF microneedling in these areas facilitated significant skin retraction, which was crucial for achieving the desired definition and contouring in liposculpture procedures. Moreover, it seemed it might be helpful

Table 3. Patient Demographics

Year	2024	2023	2022
No. of patients	8	62	16
Male	1	54	13
Female	7	8	3
Percentage of total	9.3	72.1	18.6
Average age (years)	44.4	40.8	40.0
Age IQR	17.5	9.5	13.8
Age range	38.0	35.0	26.0
Average BMI (kg/m ²)	25.2	24.3	23.9
BMI IQR	1.9	3.5	3.3
BMI range	3.6	11.1	10.3
Average weight (kg)	70.0	66.5	64.9
Weight IQR	15.0	15.5	13.0
Weight range	33	62	43
Average lipoaspirate (mL)	3793.8	3227.6	3346.4
Lipoaspirate IQR	2112.5	3247.5	2725.0
Lipoaspirate range	5600	6100	6200
Area treated (n)			
Abdomen	3	15	16
Back	2	10	8
Face	1	9	8
Neck	1	5	6
Thighs	1	6	3
Arms	3	5	0
Other areas	2	12	2

BMI, body mass index; IQR, interquartile range.

to move to more conservative treatments for patients with mild to moderate skin laxity. The average BMI and weight also showed variability, indicating that the combined treatment was suitable for patients with different body compositions. Complications were usually not associated with the combination of treatments but rather the result of each procedure alone. These findings underscored the importance of meticulous technique and careful patient selection to minimize adverse outcomes. The low complication rate also highlighted the safety of combining bipolar fractional RF microneedling with liposculpture. This adjunct technology has proven to be an effective adjunctive treatment in body contouring surgeries. Its ability to enhance skin tightening and improve

surface texture complements the fat reduction and contouring achieved through liposculpture. The synergistic effect of these treatments results in superior aesthetic outcomes, with high patient satisfaction and minimal downtime.

Limitations

Our study had several limitations. The retrospective design limited causal inferences, and the data relied on potentially incomplete patient records. With the study conducted at a single center with all procedures performed by 1 surgeon, the findings may not be generalizable. The small sample size, especially in 2024, affects statistical robustness. Variable follow-up periods and potential patient selection bias also limited the study. Future larger, multicenter, prospective studies are needed to validate these findings.

CONCLUSIONS

Bipolar fractional RF microneedling treatments are increasingly popular as stand-alone therapies for skin tightening or in conjunction with other procedures to augment the surgical result. We have found it a worthy adjunct to HD and HD2 lipo-contouring procedures in patients who require additional skin tightening or dermal thickening. Surgeon must be aware of safe settings and carefully select patient indications to maximize outcomes and mitigate complications.

Disclosures

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DERMATOLOGIC FACIAL APPLICATIONS OF MORPHEUS8 FRACTIONAL RADIOFREQUENCY MICRONEEDLING

Aleksi J. Hendricks MD | Sheila Z. Farhang MD

¹Division of Dermatology, Department of Medicine, University of Arizona, Tucson, Arizona, USA

²Avant Dermatology and Aesthetics, Oro Valley, Arizona, USA

Correspondence

Sheila Z. Farhang, Avant Dermatology and Aesthetics, 8580 N. Oracle Rd. Suite 140, Oro Valley, AZ 85704, USA.
Email: drsheilafarhang@avantdermatology.com

Abstract

Dermatologic patients are expressing increasing interest in minimally invasive procedures to address a wide range of common concerns from skin laxity to acne and scarring. Fractional radiofrequency (RF) microneedling offers an effective method for addressing a variety of dermatologic conditions with reduced downtime compared with historically more invasive procedural approaches. This article aims to describe the technology utilized in fractional RF microneedling (Morpheus8, InMode Aesthetics) and its studied applications in dermatology for treatment of the face.

KEYWORDS

microneedling, radiofrequency, resurfacing, skin aging, skin laxity

1 | INTRODUCTION

Radiofrequency (RF) technology employs low-frequency electromagnetic waves in the range of 100kHz to 5 MHz, which create an electromagnetic field within the skin when delivered via alternating current.^{1,2} This electromagnetic field generates thermal heating of the dermis and promotes neocollagenesis, elastin formation, and angiogenesis in the healing process.³ Pulsatile RF waves impart differential heating across distinct tissue types according to Ohm's law, where $(energy = current^2 \times impedance \times time)$.⁴ As different tissue types demonstrate unique impedance to electrical currents based on density and water content, RF energy can be adjusted for the target tissue (e.g., fat vs. dermis).² For example, adipose tissue is less conductive than water (higher impedance) and leads to the generation of temperatures higher than those generated by muscle over a set time period. Soft tissue temperatures of 50°C and skin surface temperatures of 40–42°C induce the production of collagen, elastin, and blood vessels.⁴ Compared with laser technology relying on chromophore targeting, RF is chromophore-independent and can deliver energy into the dermis with less risk of post-inflammatory hyperpigmentation resulting from epidermal injury, and therefore is safely applicable in all skin types.^{3,4}

RF microneedling allows for variable depth delivery of heat, thus broadening the range of anatomical locations and tissue types that can be effectively treated. Fractional RF microneedling (Morpheus8,

InMode Aesthetics) provides fractional treatment of the skin, leaving untreated segments of skin dispersed among treated segments to decrease time required for healing. Inducing micro-injury to the cutaneous tissue spurs new formation of collagen, elastin, and blood vessels that result in dermal contraction and thickening, while retaining a fraction of the skin as untreated to expedite healing of treated areas from adjacent tissue.^{3,5}

The Morpheus8 handpiece includes interchangeable tips with varied pin configurations including 12- or 24-pin microneedle tips for use on the face. Standard Morpheus8 tips (discussed in this article) have 24 pins insulated at the tips allowing for energy at the deepest point of the skin, capable of up to 4mm penetration with an additional 1mm of tissue heating ability.⁶ The partially insulated tips allow the use of high energy and bulk heating with minimal inadvertent epidermal heating. Morpheus8 Prime tips are ideal for small, delicate areas, or sharp facial contours. The smaller tip surface area provides precision treatment with 12 semi-insulated pins, similar to the standard tips but with a smaller footprint for use in sensitive regions such as the periorbital area, upper lip, and forehead when needed. Morpheus8 Resurfacing tips are designed for superficial skin resurfacing with 24 blunt, uncoated (non-insulated) pins with a depth of 0.5mm. The non-insulated needles of the resurfacing tip allow for RF energy to be emitted over the entire surface area. Variable depths (0.5–4mm) on these handpiece tips enable customizable treatment for delicate, thinner-tissue regions of the face such

as the periorbital area and areas with more subcutaneous adiposity as in the jowls and submental region.⁶

The Morpheus8 system has dual treatment modes for further customization of treatment. Cycle mode involves microneedles penetrating and retracting from the skin with each energy pulse. In fixed mode, microneedles are inserted into the skin with energy delivered at a fixed repetitive pulse rate by footswitch activation, followed by retraction from the skin and cessation of energy delivery upon footswitch release. Fixed mode can be utilized for pulse stacking when targeting adipose tissue remodeling in the lower face, such as the jowls or submental area.^{3,6}

Fractora is a similar, earlier technology from InMode for fractional RF microneedling, but involves manual pulses.⁷ Compared to manual stamping with Fractora, auto-ejection of microneedles with Morpheus8 provides improved control and precision for selective depth targeting and allows for even distribution of bulk heating. Morpheus8 pins are also capable of subdermal adipose remodeling due to increased pin depth compared with the Fractora microneedle tip.

While alternative modalities targeting undesired adiposity can result in increased skin laxity posttreatment,^{8,9} the adjustable treatment depth and energy output of Morpheus8 provide the added benefit of simultaneous skin tightening and subdermal fat reduction for contouring.¹⁰ The fractional RF microneedling technology of Morpheus8 is a versatile treatment modality capable of skin resurfacing, tightening, and subdermal adipose remodeling with a strong safety profile in all skin types, making it widely appealing to both clinicians and patients.

2 | DERMATOLOGIC APPLICATIONS OF RF MICRONEEDLING FOR FACIAL TREATMENT

2.1 | Skin aging and laxity

In the process of aging, skin loses thickness and elasticity as a result of collagen and elastin degeneration and impaired production over time.¹¹ Skin laxity may be especially apparent on the face due to a confluence of factors including ultraviolet exposure, facial movement and expression, and change in facial fat distribution with aging. As aptly discussed by Dayan et al.,¹² RF technology addresses the treatment gap specific to those candidates who have skin laxity deemed too mild to require a more invasive traditional facelift, those who have had a prior facelift but desire additional skin tightening, and those aiming for alternatives to invasive surgical procedures.

RF microneedling is best studied in the context of skin laxity and adipose remodeling. Several studies have demonstrated effective skin tightening with enduring results and high subject satisfaction. In a study of patients with premature redevelopment of facial skin laxity within 5 years of surgical facelift, combined use of InMode AccuTite RF-assisted lipolysis and Morpheus8 fractional RF microneedling resulted in significant clinical improvement in jowl and neck laxity as assessed by blinded investigators as well as marked improvement by self-assessment in a majority of subjects.¹³ A larger study of 247

patients evaluated combination treatment with bipolar RF (InMode FaceTite) and fractional bipolar RF (InMode Fractora) and found statistically significant improvement in Baker Face/Neck classification rating in 100% of subjects.¹² In addition, 93% of subjects reported satisfaction with posttreatment improvement in facial laxity.¹²

In our largely nonsurgical aesthetic-based practice, RF microneedling fulfills the need of those who (1) are not interested in injectables including filler or neuromodulator products and (2) those who have existing filler but remain unsatisfied with their skin laxity, texture, and/or quality. In the age of excessive and improperly placed filler used to achieve facial lifting and tightening, the demand for RF technology has exponentially increased in those for whom additional volume is not recommended.

In our clinical practice, Morpheus8 RF microneedling is popular for both the younger and the older male and female demographic with a high satisfaction rate. The Morpheus8 24-pin microneedling tip is used on the face and jawline to achieve skin tightening and facial remodeling according to the protocol delineated in Table 1 in our Fitzpatrick I-IV patients. Generally, delicate bony areas of the face including the forehead, periorbital, zygomatic, nasal, and perioral regions are treated with at least two passes at decreasing depths (2mm followed by 1mm) and lower energy levels in the range of 15 to 25. To achieve both skin tightening and/or subdermal adipose reduction in areas such as the mandibular cheek, jowls, and submental region (Figure 1), several passes (5 to 7) are used at varied depths of 1 to 4mm and higher energy levels ranging from 20 to 45.

Typically, our goal is to achieve at least 500 pulses when treating the face; however, in patients with severe rhytides and laxity and who are tolerating the procedure well, we will treat up to 1000 pulses. Scientifically and clinically, it is ideal to treat several depths (1–3mm) to most effectively improve skin laxity.

2.2 | Skin resurfacing

In addition to addressing skin laxity by targeting the dermis and subdermis with the traditional 24-pin microneedling Morpheus8 tip, the recently launched 0.5mm resurfacing tip is ideal in candidates who aim to achieve epidermal resurfacing including improvement in shallow acne scars, fine lines, skin texture, and large pores. In our clinical practice, the 0.5mm resurfacing tip is an easily added adjunct to the traditional 24-pin tip which has a depth range of 1–4mm. This is largely used in our acne and acne scarring patients as detailed in their respective sections below.

2.3 | Acne vulgaris

Acne vulgaris is among the most frequently encountered concerns in dermatology patients. While a broad range of treatment modalities from topical to systemic to light-based therapies are available for acne, these may be poorly tolerated due to skin sensitivity, side effects, or difficulty in regimen adherence. RF microneedling offers

TABLE 1 Generalized Morpheus8 settings for Fitzpatrick I-IV skin types for skin laxity

Facial subunit	Depth	RF energy levels	Mode	Stacked
Periorbital	1st pass: 2 mm *	20	Cycle	Yes
	<i>Will repeat if deep</i>			
	2nd pass: 1 mm *	15	Cycle	Yes
	<i>Will repeat above two passes if severe laxity and rhytides present</i>			
Zygoma	1st pass: 2 mm	20	Cycle	No
Infraorbital (including nasolabial fold)	1st pass: 2 mm	20-30	Cycle	Yes
	2nd pass: 1 mm	15-25	Cycle	Yes
Mandibular (soft tissue area between zygoma and mandible)	1st pass: 2 mm	20-30	Cycle	Yes
	2nd pass: 3 mm	30-40	Cycle	Yes
	3rd pass: 2 mm	20-30	Cycle	Yes
	4th pass: 3 mm	30-40	Fixed	Yes
	5th pass: 1 mm	15-20	Cycle	No
Jowl (adipose tissue)	6th pass: 4 mm	40-45	Cycle	Yes
	7th pass: 4 mm	40-45	Fixed	Yes
Perioral	1st pass: 2 mm	20-25	Cycle	No
	2nd pass: 1 mm	15-20	Cycle	No
	<i>Will repeat if deeper rhytides and actinic texture change</i>			
Nasal	1st pass: 2 mm	20-25	Cycle	No
	2nd pass: 1 mm	15-20	Cycle	No
Forehead	1st pass: 2 mm	20-25	Cycle	Yes
	2nd pass: 1 mm	15-20	Cycle	Yes
	<i>Will repeat if deeper rhytides and texture change</i>			
Jawline (soft tissue underneath)	1st pass: 3 mm	30-40	Cycle	Yes
	2nd pass: 2 mm	30-35	Cycle	Yes
	3rd pass: 1 mm	20-25	Cycle	Yes
Submental (adipose tissue)	4th pass: 3 mm	40-45	Fixed	Yes
	5th pass: 4 mm	40-24	Fixed	Yes
	<i>Will repeat if targeting fullness and adipose tissue</i>			

a noninvasive approach with little to no downtime or risk of adverse effects in acne patients who have exhausted or desire an alternative to traditional acne treatments. RF microneedling is thought to be beneficial in acne vulgaris by decreasing sebum production following micro-insults to sebaceous glands and promoting dermal and follicular epithelial remodeling.¹⁴ In practice, target depths of 0.5–2 mm are utilized to target the sebaceous gland depth of approximately 1 mm.

Fractora, the predecessor to InMode's Morpheus8 fractional RF microneedling technology, has been evaluated in acne patients. In a retrospective analysis of eight subjects undergoing four treatments with Fractora fractional RF at monthly intervals, 100% of subjects experienced improvement in acne severity with decrease in inflammatory lesion burden and reduction in acne scarring with decreased histological scar depth.¹⁵ Four of the aforementioned subjects were reevaluated at 1–2 years posttreatment for long-term efficacy of fractional RF in treatment of acneic lesions and scarring, with some

subjects undergoing an additional 1–3 fractional RF sessions following the initial four-treatment regimen. Long-term follow-up analysis demonstrated durable improvement in active acne lesions and in severity of acne scarring.¹⁶

A study of 18 Korean patients with moderate inflammatory acne found 88% to have clinical improvement following two RF microneedling sessions at 1-month intervals, with no subjects experiencing worsening of acne severity.¹⁴ A similar evaluation of 25 subjects with moderate-to-severe acne vulgaris treated with RF microneedling three times at monthly intervals demonstrated decrease in both inflammatory and non-inflammatory acne lesions and statistically significant reduction in sebum production ($p < 0.05$).¹⁷

Morpheus8 has become a popular and effective option for our patients who are not able to tolerate topical prescription acne medications, are not responding to topicals and/or prefer to avoid prescription oral medication. Fractional RF microneedling has been shown to provide reduction in both number and severity of



FIGURE 1 Skin laxity before and after. Note improvement in texture with reduction of rhytides and skin tightening with improvement in jowl and jawline contour

inflammatory acne lesions in as few as two treatment sessions (Figure 2).¹⁴ In addition, RF microneedling is a well-tolerated treatment approach for acne in darker IV-VI skintypes with less potential for hyperpigmentation compared to CO₂ fractional ablative laser.¹⁸

2.4 | Scarring

Post-traumatic, post-procedural, and acne scarring are common aesthetic concerns bringing patients to dermatologic evaluation. Scar formation results from dense, thickened collagen and decreased vascularity at the site of prior skin insult and can manifest as either hypertrophy or atrophy at the healed site with tethering to deep dermal structures causing inconsistent skin texture. RF microneedling disrupts the preexisting abnormal collagen structure and stimulates neocollagenesis and angiogenesis to establish a more regular dermal matrix.¹⁹

Among all types of scarring, treatment of acne scarring via RF microneedling is best characterized in the literature. Boxcar (U-shaped) and rolling (M-shaped) acne scars have been found to be amenable to RF microneedling, while icepick (V-shaped) acne scars show less improvement following treatment.¹⁹ RF microneedling has also been studied with adjuvant therapies for acne scarring,

including subcision²⁰ and topical poly lactic acid,²¹ in both cases, combination therapy was found to be superior to RF microneedling alone for treatment of atrophic acne scarring.

In our experience, treating several depths targeting the epidermis, dermis, and subdermis yields optimal results (Figure 3). In these cases, we add the resurfacing tip and treat superficially at 0.5 mm depth in addition to 1–3 mm depths with multiple stacked passes at high energy levels (above 30).

2.5 | Periorbital treatment

Skin laxity, infraorbital fat pad prolapse, and impaired lymphatic drainage contribute to aesthetic concerns of periorbital edema and undereye discoloration. Fractional RF microneedling is thought to stimulate vascular endothelial growth factor, which has been shown to promote lymphangiogenesis and angiogenesis in animal models.²² Stimulation of lymphatic and blood vessel formation helps to improve drainage and localized edema, especially in the periorbital region. Thermal energy generated by RF has been demonstrated to have no disruptive effect on preexisting lymphatics and vascular perfusion²³ and is safe for use in the periorbital region for skin tightening, targeting of infraorbital fat, and promoting lymphatic drainage.

FIGURE 2 Acne vulgaris and acne scarring before and after. Note reduction of inflammatory papules and improvement in skin texture and enlarged pores. There is also notable improvement in rolling, boxcar, and icepick acne scarring



A randomized split-face study conducted in a population of 15 Chinese subjects compared fractional RF microneedling technology to non-ablative fractional erbium-doped glass 1565nm laser treatment of the infraorbital region at monthly intervals for a total of three treatments.²⁴ Clinical response was evaluated by two blinded investigators and by facial imaging analysis, with similar improvement in volume elevation, elevation area, and maximum depth as well as depth and length of orbital fat following both fractional RF microneedling and non-ablative fractional laser. Subject satisfaction rate was greater than 47%.²⁴ While both treatments yielded similar improvement in undereye bags, fractional RF microneedling may be more widely suitable for patients of all skin types given risk of post-inflammatory hyperpigmentation following laser therapy in darker-skinned patients.

Morpheus8 has become a popular periorbital treatment with high satisfaction in our practice due to ease of treatment for both the patient and the clinician. In our experience, treating several depths targeting the dermis and subdermis with multiple passes yields optimal results (Figure 4). While topical anesthesia is utilized on most of our patients undergoing periorbital RF microneedling, we have found that injecting 1–2 cc of lidocaine with epinephrine superficially around the eye further eases discomfort. In these cases, we use the 12-pin microneedling Prime tip and treat on the orbital bone while stretching the upper and lower eyelids. Typically, our protocol includes two passes at 2 mm depth with 20–25 energy and two passes at 1 mm depth with 15–20 energy. Our goal is to achieve at least 100 pulses on each eye. Although downtime with RF microneedling is

FIGURE 3 Scarring before and after. Note softening and smoothing of the scar texture on the upper lip, central forehead, and lateral canthus



FIGURE 4 Periorbital treatment before and after. Note improvement in fine periorbital rhytides, reduced infraorbital skin laxity with smoothing and improvement of edema in the tear trough region



lower compared with other energy-based devices, pinpoint bruising and swelling is more common in this area after treatment.

2.6 | Rosacea

Rosacea is characterized by chronic cutaneous inflammation of the central face with several clinical presentations including

erythematotelangiectatic, phymatous, and papulopustular. Treatment of rosacea varies according to the clinical phenotype and encompasses a wide range of interventions including lifestyle modification for trigger avoidance, topical or systemic antibiotics, immunomodulators, and laser and light-based therapies.²⁵ Fractional RF microneedling technology has been reported as an effective treatment for rosacea in a prospective, randomized split-face trial, specifically for the papulopustular subtype.²⁶

Immunohistochemical analysis following fractional RF microneedling in rosacea subjects demonstrated reduced expression of mediators of inflammation, innate immunity, and angiogenesis in treated compared with non-treated skin, suggesting that decrease in cutaneous inflammation and blood vessel formation underlie clinical improvement in erythema.^{26,27}

Given that most of our patients exhibit overlap of multiple rosacea variants (Figure 5), we treat those with the papulopustular subtype with Morpheus8 in addition to traditional intense pulsed light (IPL) (Lumecca, InMode) that targets and ablates dermal blood vessels. Notably, in our experience, patients treated with IPL monotherapy demonstrate less improvement compared to those treated with combination therapy, as there appears to be a synergistic effect of fractional RF microneedling and IPL in treatment of rosacea.

2.7 | Applicability of fractional RF microneedling in patients with melasma

Melasma is a disorder of facial hyperpigmentation seen most frequently in female patients with skin of color. Therapies targeting hyperpigmentation in melasma must be used judiciously due to risk of hyperpigmentation and worsening of melasma in patients of darker skin tones. RF microneedling is thought to improve melasma by way of reduced inflammation, angiogenesis, and mast cell activity resulting from dermal remodeling and formation of microperforations to allow melanin clearance from the skin.^{27,28}

While limited studies have been published on RF microneedling for treatment of melasma,^{28,29} as Tan et al.²⁷ described in their recent comprehensive review of RF microneedling, it is important to note that in our clinical practice, we are confident that melasma does not worsen in our RF-treated patients, as this is often a concern given the thermal energy generated by RF. Melasma patients have demonstrated improvement in hyperpigmentation after Morpheus8 as part of a multimodal therapeutic strategy with concurrent use of treatments ranging from topical to oral medication in addition to sun protection. Additional high-quality studies are needed to confidently recommend fractional RF microneedling as a therapeutic option for melasma.

2.8 | Applicability of fractional RF microneedling in Fitzpatrick IV-VI skintypes

Historically, thermal energy and light-based treatment modalities have been limited to use in lighter skin types due to increased risk of post-inflammatory hyper- or hypopigmentation and scarring. Fractional RF therapies mitigate this risk by reducing the fraction of skin surface area treated and sparing areas to provide a starting point for expedited healing posttreatment. Battle et al. evaluated 35 subjects with Fitzpatrick type VI skin undergoing a series of three fractional RF treatments with the InMode Fractora device at 4-week intervals.³⁰ Subjects demonstrated improvement in



FIGURE 5 Rosacea before and after. Note improvement in erythema, telangiectasias and papules over the nasal dorsum, nasal tip and malar cheeks

several components of facial skin texture including rhytides, pores, acne scarring, and active acne lesions, with continued improvement through 12-week follow-up. No subjects experienced adverse effects of posttreatment pigment alteration or scarring.³⁰

The ability to treat darker skin types with Morpheus8 has been a great asset in our clinical practice with high satisfaction rates for treatment of skin laxity, skin tone, acne, acne scarring, pseudofolliculitis barbae, and striae. While the risk of post-inflammatory hyperpigmentation is low, it is important to note that energy settings at superficial depths such as 1 mm should be set 20%-30% lower and the 0.5 mm resurfacing tip should be used with caution or avoided in V-VI skin types.



While energy-based treatments for darker skin types have previously been scarce due to concern for these adverse outcomes, fractional RF microneedling has been shown to be safe and effective in Fitzpatrick type VI patients and is a promising therapeutic option when used appropriately in patients of darker skin.

2.9 | Peri-procedural anesthesia for fractional RF microneedling

Patient comfort is critical to good outcomes, necessitating a reliable anesthesia protocol for fractional RF microneedling treatment at high energy settings. In our practice, 23% lidocaine with 7% tetracaine in a plasticized gel base is applied in office for 1–2 h prior to the procedure. We have had success with section-by-section removal of topical numbing gel immediately prior to treatment of a specific area to maximize anesthetic efficacy compared to removal of numbing gel from the entire face before treatment commences. Of note, thorough removal of topical anesthetic with alcohol on a gauze pad is critical to avoid product inadvertently being pushed into the dermis with microneedles, potentially causing a hypersensitivity reaction. In addition, we offer inhaled nitrous oxide to ameliorate procedure-associated discomfort and anxiety. This protocol has been highly effective with excellent patient satisfaction, and very rarely do we need to utilize nerve blocks or any form of sedation.

3 | CONCLUSIONS

Fractional RF microneedling offers a versatile treatment modality for a wide range of dermatologic concerns and is safe for use in patients of all skin types. The adjustable depth and microneedle pin configurations available with the InMode Morpheus8 allow clinicians to address varied tissue targets and regions of concern on the face. The ease of use for practitioners, minimal posttreatment recovery time and enduring results make fractional RF microneedling an increasingly attractive option for patients desiring minimally invasive options. This technology boasts a growing range of applications with study-proven efficacy and an excellent safety profile that is likely to encourage continued and broadened use in the field of aesthetic dermatology.

CONFLICT OF INTEREST

SZF serves as a consultant for InMode Aesthetics, CellFX, GlacialRX and Procter & Gamble. AJH has no conflicts of interest to declare.

ETHICS STATEMENTS

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

ORCID

Aleksi J. Hendricks  <https://orcid.org/0000-0003-3448-5555>

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A CLINICAL STUDY TO EVALUATE THE SAFETY AND EFFICACY PERFORMANCE OF THE MORPHEUS8 APPLICATOR FOR THE TREATMENT OF CELLULITE: A CASE SERIES

Nkemjika Ugonabo MD, MPH | Rachael Ward MD, MPH | Anne Chapas MD

1 | INTRODUCTION

Cellulite is a significant cosmetic concern for post-pubertal females and has been reported to affect 85% to 98% of post-pubertal females across all races.¹ The demand for treatment of cellulite has been on the rise in recent years. Recently, a multicenter clinical trial demonstrated improvement in cellulite of the upper thigh using microneedling with fractional radiofrequency (RF) to the dermal and subcutaneous area.² It is proposed that the microneedle RF induces a wound healing response at the level of the subcuticular junction or dermis, potentially disrupting the excessive tension placed by perpendicular fibrous septae. The microneedle RF is thought to induce new collagen, elastin, and HA at the subcuticular junction, further preventing fat herniation into the dermis.² Additionally, adding microneedling to radiofrequency enhances dermal heating by delivering energy through pins/needling that penetrate to a predetermined desired depth.³

Previously, the Morpheus8 (InMode Aesthetics, Lake Forest, CA) handpiece (24-pin tip up to 4mm depth) received FDA clearance for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. The Morpheus 40-body tip (InMode Aesthetics, Lake Forest, CA) with a depth of 6mm was introduced to stimulate contraction and collagen formation while simultaneously affecting adipose tissue and fibro-septal network. However, this specific technology had not been previously published for the treatment of cellulite. Hence, our objective was to evaluate the safety and efficacy of the Morpheus8 Body 40-pin tip at a depth of up to 6mm for treatment of the thighs to improve cellulite appearance, skin laxity, and subcutaneous fat deposits. Subjects self-assessed their outcome at each follow-up visit using 5-point Likert scales for Subject Satisfaction Scale (2: Very Satisfied, 1: Satisfied, 0: Neutral, -1: Dissatisfied, -2: Very Dissatisfied) and Subject Improvement Scale Global Aesthetic

Improvement (GAI) scale (0: No change, 1: Slight Improvement, 2: Moderate Improvement, 3: Marked Improvement, 4: Significantly Marked Improvement). Similarly, investigators assessed improvement on a GAI scale (0: No Change, 1: 1%-24%, 2: 25%-49%, 3: 50%-74%, 4: 75%-100%), and a Skin Laxity/Tightening Improvement Scale (0: No tightening/firmness, 1: Slightly visible tightening/firmness, 2: Visible tightening/firmness, 3: Very visible tightening/firmness).

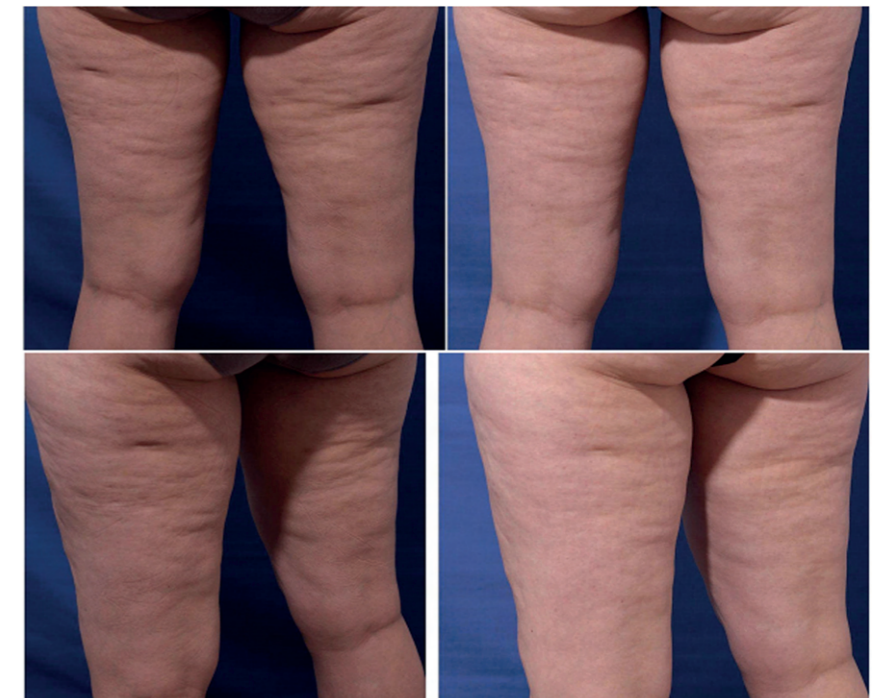
2 | CASE 1

Patient 1 was a 57-year-old female with a history of moderate-to-severe cellulite affecting posterior thighs and buttocks (Figure 1). The treatment area was marked by the investigator and measured approximately 20x20cm in size on the posterior thighs only. For the first treatment, topical 30% lidocaine was applied to the treatment area in addition to the use of Pro-Nox™ for patient comfort. For the second treatment, a combination of topical 30% lidocaine as well as 12 ccs of injectable lidocaine 1% with epinephrine 1:100000 was used (i.e., 6 ccs per side) for anesthesia. The patient received two monthly treatments, 4 weeks apart with the following settings: First session: Energy 15J, Treatment mode: Fixed, Depth 6mm for 1 pass with 105 pulses on the right thigh and 185 pulsed on the left thigh followed by Depth 3mm for 1 pass with 175 pulses on the left thigh. Second session: Energy 15J, Treatment mode: Fixed, Depth 6mm for 1 pass with 137 pulses on the right thigh and 135 pulses on the left thigh followed by 3mm for 2 passes with 236 pulses on the right thigh and 253 pulses on the left thigh. The patient was seen at 4 follow-up visits at 1, 3, 6 and 9 months post treatment. At 9-month follow-up, the patient scored her satisfaction level as "satisfied" or 1 and improvement as "moderate improvement" or "2" on the Subject Improvement Scale

FIGURE 1 Patient 1 at initial visit and 9-month follow-up visit (lateral view)



FIGURE 2 Patient 2 at initial and 3-month follow-up visit



GAI Scale. At 9-month follow-up, the physician rated the improvement as 25%-49% or "2" on the GAI scale and "visible tightening/firmness" or "2" on the Skin Laxity/Tightening Improvement Scale.

3 | CASE 2

Patient 2 was a 50-year-old female with a history of moderate-to-severe cellulite affecting posterior thighs and buttocks (Figure 2).

The treatment area was marked by the investigator and measured approximately 16x16cm in size on the posterior thighs only. For patient's comfort, local infiltration of tumescent solution consisting of 250ml of normal saline, 25ml of 1% lidocaine with epinephrine, and 3 cc of 8.4% sodium bicarbonate was used for anesthesia, with a total of 125cc injected to each posterior thigh using a Klein pump prior to treatment. The patient received two monthly treatments, 4 weeks apart with the following settings: Energy 15J, Treatment Mode: Fixed, Depth 6mm for 2 passes followed by Depth of 3mm for

3 passes. At the first session, a total of 304 pulses were applied at the 3 mm depth of the right thigh and 245 pulses at the depth of 6 mm. A total of 316 pulses were applied on the left thigh at the depth of 3 mm and 245 pulses at the depth of 6 mm. At the second session, a total of 317 pulses were applied at the 3 mm depth of the right thigh and 201 pulses at the depth of 6 mm. A total of 306 pulses were applied on the left thigh at the depth of 3 mm and 179 pulses at the depth of 6 mm. The patient was seen at two follow up visits at 1 and 3 months post treatment and is scheduled for additional follow up at 6 and 9 months. A 3-month follow-up, the patient scored her satisfaction level as “very satisfied” or “2” and improvement as “marked improvement” or “3” on the Subject Improvement Scale GAI Scale. Similarly, at 3-month follow-up, the physician rated the improvement as 50%–74% or “3” on the GAI scale and “very visible tightening/firmness” or “3” on the Skin Laxity/Tightening Improvement Scale.

4 | DISCUSSION

Microneedle radiofrequency (RF) creates thermal and mechanical effects of the skin to increase collagen, elastin, and hyaluronic acid (HA), leading to improvements in skin laxity and rhytids. This technology provides direct and controlled delivery of thermal injury at controlled penetration depth to the junction of the deep reticular dermis and superficial subcutis.^{3,4} Multiple microneedle electrodes enter the tissue to deploy bipolar radiofrequency energy to the assigned treatment depth. Heat in this technique is generated from the resistance of tissue components to the movement of charged molecules within the radiofrequency field.³

More recently, the indication of microneedling with radiofrequency has been broadened to include the treatment of cellulite. Cellulite is a localized disorder of subcutaneous tissue that is characterized by the protrusion of adipose within fibrous connective tissue septae into the dermis, causing a modification of skin topography.¹ Microscopically, differences in septae orientation are noted with women having perpendicularly oriented septae compared to men.¹ Fat protrusion into the dermis is a result of continuous and progressive tension placed on these septa, which are located in the hypodermis of the skin.¹ The Morpheus8 device can potentially lead to tension disruption of the fibrous septae at the subcuticular junction with higher depth use. Additionally, its use at deeper settings is known to deliver direct heat which disrupts adipocytes.⁵ Its use may promote new collagen, elastin, and HA induction aimed at prevention of dermal fat herniation at medium depth use.

The literature on the use of microneedling in the treatment of cellulite is relatively scarce. Alexiades et al.² performed a multicenter clinical trial of subcutaneous microneedle RF for the treatment of cellulite. Patients with cellulite were enrolled and received one subcutaneous microneedle RF treatment of the posterolateral thighs. Efficacy of treatment was assessed based on blinded dermatologists and investigators by grading photos at baseline, 1, 3, and 6 month follow ups. Number of dimples present on each photograph and the severity of undulation irregularities were assessed using a 5-point

scale and Nurnberg–Muller scale. Subjects also rated their treatment results using the same 5-point scale and additionally, satisfaction was assessed using the 5-point Likert scale. Overall, the study found an average reduction of at least one dimple at both 3- and 6-month follow-up visits by both blinded and treating physicians. The reduction in undulation severity was also similar for blinded and treating physicians at 3 months (0.83 vs. 0.86) and better for treating physicians at 6 months (0.60 vs. 1.02). Investigator improvement assessment distribution revealed that most subjects at 3- and 6-month follow-up obtained a score in the moderate-to-good improvement categories. Satisfaction results at 3 and 6 months were slightly higher for the investigators (85% and 89% chose “satisfied”) than for the subjects (70% and 75% chose “satisfied”).²

In a case study performed by Yu et al. in 2018, the use of RF microneedling to improve skin laxity and cellulite in a 39-year-old woman was evaluated.⁶ Two sessions of RF microneedling were performed 5 months apart on the bilateral medial thighs. The study was conducted using the Profound device and was administered in two passes at a depth of 5.8 mm. The study reported a five-point improvement on the Hexsel and Dal’Forno Cellulite Scale score, and the patient reported satisfaction with the results. In the Alexiades et al. study, treatments were also conducted using Profound Sub-Q device, which delivers microneedles into the dermis with an exposed portion extending from 3.9 to 5.8 mm beneath the skin surface. In both studies, each patient was treated at one treatment depth. Treatments in our study were conducted using the Morpheus8 Body 40-pin tip. This particular device is the first to be FDA-approved to provide treatment to penetrate subdermal tissue up to 7 mm. Importantly, both patients in our study were treated at a depth of 6 mm followed by a depth of 3 mm for a total of 2 sessions. Treatment at both medium and deeper depths in our study may have led to better targeting of the reticular dermis and subcutaneous tissue and subsequently more effective heating and remodeling of the dermis in addition to the disruption of adipocytes and fibrous septae tension. Side effects in both patients were limited to minimal transient bruising.

It should also be noted that in our study, local infiltration of tumescent solution was used for anesthesia in patient 2 due to severe pain experienced by the first patient. This ultimately enabled the treating physician to complete more treatment passes; nonetheless, the patient still reported pain rated as “none.” Contrarily, patient 1 received topical lidocaine 30% and Pro-Nox™ for comfort and rated her pain level as “severe.” This suggests that use of tumescent anesthesia can result in more treatment pulses, which could potentially lead to better treatment outcomes and improved patient and provider satisfaction as was the case with our patient.

Limitations of this case series include lack of assessment by blinded investigators and lack of a validated scale to assess the improvement in cellulite. Regardless, our study further adds to the growing body of literature that supports the safety and effectiveness of RF microneedling for the treatment of cellulite. We further highlight the increase in benefit that can be attained with use of the Morpheus8 Body 40-pin tip, which can achieve an increased depth and therefore deeper subdermal adipose tissue remodeling as

compared to other devices. Additional controlled studies are needed to further support these findings.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

ETHICAL APPROVAL

This material has not been previously published elsewhere and represents the original work of the authors. It is not currently being considered for publication elsewhere and credits the meaningful contributions of all co-authors.

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CORRECTION OF AGE-RELATED CHANGES IN THE SKIN AT THE DERMAL AND SUBDERMAL LEVEL USING RADIOFREQUENCY MACRONEEDLING THERAPY

Elena Flegontova MD, PhD | Michael Kreindel PhD | Neil M. Vranis MD | R. Stephen Mulholland MD

¹Moscow Clinical Hospital by Speransky, Moscow, Russia

²Laboratory Angiopharm Private Clinic, Moscow, Russia

³InMode Inc., Yokneam, Israel

⁴Division of Plastic Surgery, Department of Surgery, Cedars Sinai Hospital, Los Angeles, California, USA

⁵Private Practice, Ghavami Plastic Surgery, Beverly Hills, California, USA

⁶Private Practice, SpaMedica Plastic Surgery Center, Toronto, Ontario, Canada

Correspondence

R. Stephen Mulholland, Private Practice, SpaMedica Plastic Surgery Center, Toronto, ON, Canada.

Email: smulholland@drm2.com

Abstract

Background: The negative effects of skin aging are primarily related to the destruction of dermal architectural structure. More specifically, this includes changes in the spatial arrangement of collagen, elastin fibers, mucopolysaccharides, proteoglycans, and ground substances.

Aims: The purpose of this study is to investigate the histologic effects of dermal and subdermal tissue after a controlled single treatment with radiofrequency (RF) macroneedling. This therapy provides a controlled, localized, thermal effect on the dermis whereby triggering the body's own healing processes of extracellular matrix remodeling. Clinically benefits include skin tightening.

Methods: Biopsies were obtained for histologic evaluation from four patients ($n=4$), 4 weeks after completing a single RF macroneedling facial treatment.

Results: Age-related changes of the dermal and subdermal architecture were observed at baseline. After treatment, all biopsies demonstrated an increase in epidermal cells, collagen, elastin, fibroblasts, vasculature, and a decrease in inflammatory cells.

Conclusions: The results of this histologic study confirm a significant "subsurfacing" thermal effect from the noncoagulative ascendant thermal injury. The obtained results characterize RF macroneedling therapy as an effective method for correcting age-related changes in facial skin.

KEYWORDS

age-related skin changes, bipolar radiofrequency, collagen fibers, macroneedling therapy, subdermal remodeling,

1 | INTRODUCTION

As humans age, there is a predictable change in the structure of our skin. Thinning of the epidermal layer is due to atrophic changes in keratinocytes, which leads to increased trans-epidermal water

loss and increased skin dryness. In addition, the two main components of the extracellular matrix—collagen and elastin—which are responsible for tensile strength and elasticity of the skin, respectively, undergo significant changes during aging.¹ There is a decrease in the amount of collagen due to a reduction of its

synthesis. Collagen also becomes less functional due to an increase in structural fragmentation, which is presumably associated with the increased expression of matrix metalloproteinases (MMP) found in aging skin.²

Currently, about 28 distinct types of collagen have been described, which are encoded by more than 40 genes. Type I collagen (80%–90% of all skin collagen) and type III collagen are predominantly found in the skin. The relative amount of type III collagen increases significantly during the initial phase of wound healing. This has been observed after fractional CO₂ or radiofrequency epidermal-dermal ablative resurfacing treatments that activate the neo-collagenases cellular wound healing pathway. Type IV collagen forms a flat network of collagen fibers at the border of the epidermis and dermis responsible for maintaining integrity of the basement membrane (basal laminae). Collagen type V is combined in fibrils with collagen types I and III. It helps to regulate the diameter of the fibers. An important function is performed by type VII collagen, the main component of anchoring fibrils in order to provide adhesion between the epidermis and the underlying dermis.³ Anchoring fibrils protect the skin from excessive stretching.

Elastin is an inert protein produced at an early age, so, there is virtually no new elastin formation during a human's lifetime. Any changes in elastin fibers that occur with aging tend to be permanent,^{4,5} since the half-life of elastin is approximately 70 years. Consequently, only a minimal amount of this protein is synthesized during one's lifetime given the slow process of elastin genesis. It is estimated that only about 1% of elastin peptides are renewed per decade.⁶ However, the fate of elastin is similar to all other types of protein found in humans—with age elastin is damaged and degraded.⁷ Due to the extremely slow innate regeneration process, the degradation of elastin fibers is a practically irreversible and irreparable.⁸ The increased activity of proteases associated with aging in elastin-rich tissues leads to the degradation of elastin and, simultaneously the increase of calcium deposits creating calcification of the soft tissues.⁹ Changes in the quality and quantity of elastin fibers dramatically affect the skin's function, appearance, and ultrastructure. This decrease in elasticity accounts for the clinical classic age-related changes such as wrinkles and laxity.

As a result of ultraviolet (UV) radiation, photodamage of the skin is a known consequence. In vivo and in vitro studies have shown that UV radiation activates the elastin promoter and qualitative/quantitative changes in elastin fibers occur with a massive deposition of thickened, tangled, and amorphous fibers (solar elastosis). Unfortunately, this phenomenon is also facilitated by the formation of free radicals, which stimulate the synthesis and accumulation of abnormal elastin fibers.¹⁰ Controlled damage is one of the most potent stimuli to remodel the dermal layer, thus, various technologies that harness this concept have been developed and applied in aesthetic medicine. In recent years, the delivery of thermal energy through high frequency oscillating, electrical current (radiofrequency energy) devices has become among one of the most popular.

1.1 | The use of the radiofrequency (RF) current in aesthetic medicine

Radiofrequency (RF) electric current was first used for medical purposes in 1926. During an operation, Dr. Harvey Williams Cushing used an electrosurgical generator developed by Dr. William Bovie to coagulate tissues. Since then, RF electric current has routinely been used in all surgical specialties as an ablative instrument. More recently, alternating RF electric current has found broader application in aesthetic medicine. When applied, the RF current causes vibrations of tissue molecules with a frequency of 1000000Hz/s. As a result of micro-oscillations of tissue molecules, intermolecular, and intramolecular motion, kinetic energy is generated. This becomes converted into thermal energy. Heating of tissues at high temperatures can be ablative and coagulative, but, at a lower temperature it is nonablative. When applied at lower temperatures, thermal stimulation induces inflammation triggering neo-collagenesis and neo-elastogenesis. The main objective of this approach is to establish a dose-response thermal curve to safely heat targeted structures while mitigating the risk of irreversible thermal injury.¹¹

Over the past 15 years, RF technology has undergone significant evolution. By changing the configuration and size of the electrodes and fractionating the delivery, one can control the energy density and, as a result can achieve the desired clinical effects while minimizing the risks of thermal injury.

Depending on the configuration of the electrodes, there are several main types of RF devices:

- **Monopolar devices:** energy is delivered through one active electrode with a relatively small contact surface, which is superimposed on the targeted area. The passive electrode, which is much larger than the active one is located at a certain distance from the treatment area. Monopolar systems affect the dermis and subcutaneous fat almost equally. With such a large radius, it is difficult to control the temperature and exposure level, thus, the risk of thermal damage is higher.
- **Bipolar devices:** these consist of two electrodes with different polarities ("+" and "-"). The advantage of bipolar systems is that the thermal effect is limited within the zone between the two electrodes. Therefore, when the electrodes come in contact with the skin's surface, the affected layers include the epidermis and partially the dermis, while the subcutaneous layer can be selectively targeted as needed.
- **Multipolar devices:** have more than two electrodes in the operating handpiece that change their polarity during exposure. At any given time, there are two bipolar electrodes activated. The continuous modification in trajectory and direction of the electric current between alternating electrodes reduce the risk of burns and provides uniform heating of the soft tissue under the handpiece.¹²

Most technologies that deliver controlled thermal damage aesthetic medicine target the dermal layer. However, if the energy

source is applied externally, the epidermal layer receives a significant amount of energy also. The epidermis is much more sensitive to heat; thus, thermal exposure of the epidermis entails an increased risk of complications and requires downtime.

Obstacles often serve as a stimulus to innovation and technological advancement. In the process of creating a device for precise and targeted RF energy delivery, radiofrequency microneedling technology was born: the needles were modified to become electrodes. In this case, the RF impact depends on the needle electrode length and their coating. Furthermore, the concept of Macro-RF needling, or using longer, more powerful, monopolar, coated electrode-pins to penetrate more deeply to the subdermal adipose tissue was the next generation of innovation.

These new technologies made it possible to focus fractional, coated electrode-macro-needle RF energy on another target—the subcutaneous fat layer. Therefore, in addition to treating the dermis, there is a synergistic effect on deeper soft tissue contraction, adipolysis, and overall tightening.¹³ The subcutaneous fat layer is divided into lobules, separated by connective tissue septa forming the fibro-septal network (FSN) designed to connect the dermis securely to the underlying muscle fascia (Figure 1).

Each of the needle electrodes of the applicator are positively charged and emit RF current only from the tip. The operator can precisely control depth of penetration into the dermis and/or adipose tissue. Maximum depths on the Morpheus8 device (InMode, Lake Forest, CA) are 8mm for coagulation/heating and 7mm for ablation. At these maximum depths the delivery of energy targets the subcutaneous adipose tissue as well the FSN. Importantly, a built-in safety mechanism ensures that the tips of each electrode-pin are positively charged while the negative return electrodes remain on the surface. Since the negative electrodes cover a much larger surface area, the superficial thermal zone of injury is minimized allowing for a greater amount of deeper energy to be delivered. For each fractional electrode needle, the RF emission produces three zones of thermal injury in the nearby deep tissues—an ablation zone, a zone of reversible coagulation (when

introduced into the fat layer, these two zones cause a shortening and contraction of the FSN) and finally, a large zone of noncoagulative, nonablative tissue heating created by the RF current flowing from deep inside the adipose tissue up to the negative electrodes on the surface of the skin. (Figure 2).

The ablation zone is created when tissue is heated beyond 100°C and can range from 100 to 500 microns in diameter, while the reversible coagulation zone is created when the temperatures reach 60–85°C and can be 600–800 microns in diameter. After ablative damage to adipose tissue, the RF current flows back to the negative return electrode on the skin surface, gently heating the dermis and epidermis. This nonablative, coagulative, and noncoagulative thermal stimulation is what we term “fractional RF sub-surface remodeling.” It should be thought of as an “upside down cone” caused by the bipolar RF flowing back to the negative electrode from the internal, positively charged ablative positively charged electrode to the larger surface area, negatively charged plate. This nonablative, coagulative, and noncoagulative heating serves as the thermal stimulation for the formation of new collagen and elastin.^{11,14} The heating of the skin surface does not exceed 42°C which has been found to be the threshold for irreversible epidermal thermal injury.

After RF exposure, an immediate shortening of the FSN fibers occurs. The horizontal, oblique, and vertical connective tissue fibers simultaneously contract to achieve a three-dimensional shrink-wrap effect. Additionally, soft tissue contraction and skin thickening can reach 40%–70% (30%–40% due to FSN + 20%–30% secondary to dermal contraction). The thermal energy delivered reduces thickness of adipose tissues affecting external contours in addition to reducing/eliminating overlying wrinkles, folds, scars (including post-acne scarring), uneven skin texture, pores and stretch marks.

The purpose of this study is to investigate the histologic effects of dermal and subdermal tissue after a controlled single treatment with RF microneedling. We anticipate that there will be histologic

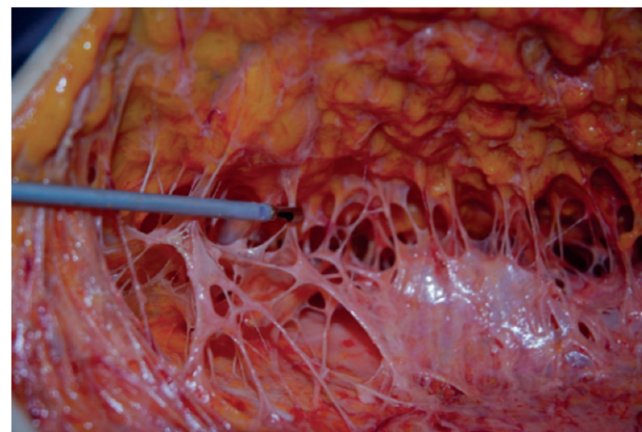


FIGURE 1 Fibers of the fibro-septal network (FSN) of adipose tissue.

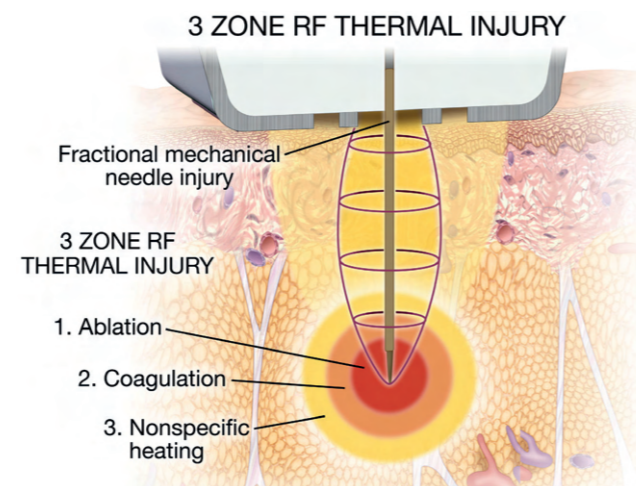


FIGURE 2 Three different thermal zones of injury produced by the Morpheus8 device (InMode, Lake Forest, CA).

evidence that correlates with the clinical observations of skin tightening and skin thickening.

2 | MATERIALS/METHODS

Each needle electrode of the Morpheus8 device (InMode, Lake Forest, CA) has a gold coating except for the distal 500 microns, where the RF energy is emitted. The tip of each electrode-needle is positively charged, and the larger, flat, planar designed negative side-rail electrodes stay on the surface of the skin. The RF energy flows from the tips of the microneedles to external electrodes set on the skin surface. The patented pulse of RF energy ablates and coagulates the subdermal adipose tissue and more importantly, shortens the FSN's horizontal, oblique, and vertical connective tissue fibers. (Figure 3). The pulse duration has been calibrated by the manufacturer to account for thermal relaxation time of the dermis and subcutaneous tissue in order to maximize energy delivery and minimize risk of irreversible thermal injury.

Ablative and coagulative injury was meticulously delivered to soft tissues at the various subcutaneous levels, with noncoagulative, nonablative thermal stimulation of the reticular and papillary dermis from the “bottom up”, or “Fractional RF Sub-Surfacing” while protecting the epidermis from thermal damage. The settings were consistent for all patients in this study to minimize variables and maintain consistency of treatment parameters.

2.1 | Post-treatment reduction of age-related skin changes and their morphological characteristics

Patients volunteered for the study and consent was obtained in accordance with the Declaration of Helsinki. To assess changes in skin structure after Morpheus8 (InMode, Lake Forest, CA) RF macroneedling therapy, we conducted a clinical study involving subjects of the following two age groups:

- Group 1: 35–40 years old (subjects 1–3);
- Group 2: > 40 years old (subject 4, 69 years old).

The facial area of the participants was treated with the facial applicator using the following single pass parameters: 2 mm depth and 22 mj/pin of energy. This was selected because all patients were Fitzpatrick type 2 and 3 without excess subcutaneous adiposity.

Before and after the procedure, eight biopsies from the treated area were obtained from subjects. All biopsies were taken 28 days after the procedure at the 4-week follow-up visit. During the histological examination, the following parameters were evaluated:

- The thickness of skin layers;
- Number of fibroblasts and inflammatory cells (lymphocytes and macrophages);
- Surface area of vessels in the papillary and outer layers of the reticular dermis;
- The density of collagen and elastin fibers in the dermis, as well as the degree of fragmentation of elastin fibers (analyzed by semi-quantitative scoring method on a 5-point scale, where 0—none, 4—maximum intensity).

The pathologist used the following collagen degradation scale to determine the “Fiber Score.” Score = 0: Collagen bundles are not visualized, they are disintegrated into individual fibers. Score = 1: Bundles are loosely arranged, fibers within are moderately loosened. Score = 2: Bundles are arranged with moderate density, there are areas of loosening of individual fibers. Score = 3: Bundles are arranged closely to each other, there are small areas of loosening of individual fibers. Score = 4: Bundles are densely arranged, fibers are tightly packed, parallel to each other. Five visual fields were analyzed in each sample, and about 50 measurements were made for each parameter.

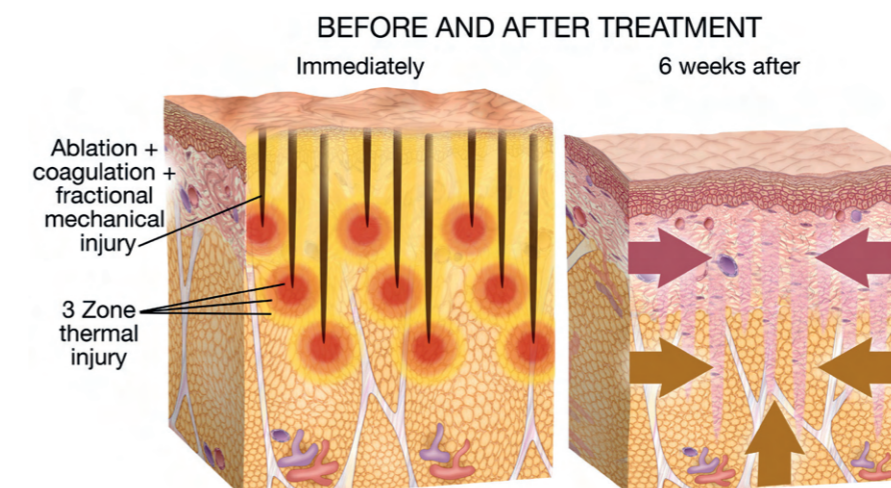


FIGURE 3 Multiple passes of Morpheus8 (InMode, Lake Forest, CA) at different depths results in horizontal and vertical fractional remodeling of adipose tissue and FSN. This also leads to dermal remodeling for optimal skin tightening, contouring, and soft tissue contraction.

3 | RESULTS

3.1 | Comparison of the morphological characteristics of the skin of subjects before the fractionated RF macroneedling procedure

Table 1 presents data as mean values ± standard error of the mean or as median values and interquartile range (in the case of score evaluation). At baseline, subject 4 (69 years old) had a

lower epidermal thickness (28.2% less) compared to subjects aged 39–40 years, while the thickness of the dermal layers was unchanged (Figures 4–9).

The older aged individual demonstrated a decrease in the average number of epidermal cells (38.4% less), fibroblasts (29.5% less), and inflammatory cells (73.7% less). Age-related changes in the vascular area were also observed. A decrease in the density of collagen fibers (33.3% less) and an increase in the degree of fragmentation of elastin fibers (33.3% more) were visualized on histology.

TABLE 1 Morphometric analysis of morphological features in skin biopsies of subjects of different ages before and after treatment.

Morphological signs	Subjects 1-3 (35-40 y.o.)		Subject 4 (69 y.o.)	
	Before treatment	After treatment	Before treatment	After treatment
Layer thickness (µm)				
Epidermis	58.2 ± 2.8	56.9 ± 2.2	41.8 ± 2.5	35.7 ± 1.2
Papillary dermis	87.3 ± 3.2	98.4 ± 3.3	80.9 ± 3.8	61.03 ± 4.5
Reticular layer of the dermis (outer part)	302.3 ± 5.6	318.2 ± 9.6	321.4 ± 9.2	314.8 ± 13.5
Cellular composition (pcs)				
Epidermal cells	150.4 ± 6.1	162.6 ± 7.8	95.7 ± 2.3	91 ± 5.1
Fibroblasts	117 ± 10.4	141.7 ± 7.6	82.5 ± 3.8	85.8 ± 3.5
Inflammatory cells	67.7 ± 7.6	51.8 ± 6.8	17.8 ± 4.6	10.2 ± 1.5
Vessels (µm ²)				
Vessels surface area	3064 ± 538.3	5597 ± 1089	2349 ± 680.4	3996 ± 739.1
Fiber (score)				
The density of collagen fibers	3 (3; 3)	4 (3; 4)	2	2
The density of elastin fibers	2 (2; 2)	3 (2; 3)	2	4
Fragmentation of elastin fibers	2 (2; 3)	1 (1; 1)	3	1

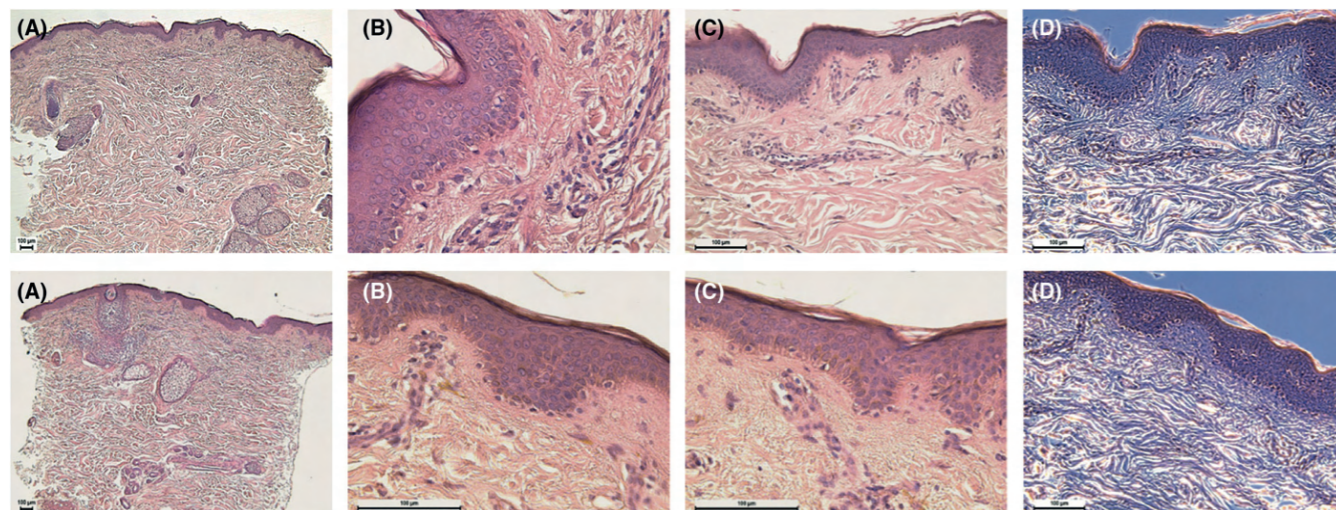


FIGURE 4 Top Row: Histological structure of the skin biopsy of subject one before treatment, stained with hematoxylin-eosin: (A) general view of the epidermis, reticular, and papillary dermis; (B) moderate dystrophic changes in the cells of the epidermis and a slight perivascular inflammatory infiltration in the papillary dermis; (C) the structure of the papillary and reticular layers of the dermis; (D) thin and loose fibers in the papillary layer and thicker bundles of fibers in the reticular layer. Bottom Row: Histological structure of the skin biopsy of subject one after the procedure, stained with hematoxylin-eosin: (A) general view of the epidermis, reticular, and papillary dermis; (B) Weak dystrophic changes in the cells of the epidermis and a slight perivascular inflammatory infiltration in the papillary dermis; (C) the structure of the papillary and reticular layers of the dermis; (D) a denser arrangement of thin fibers in the papillary layer.

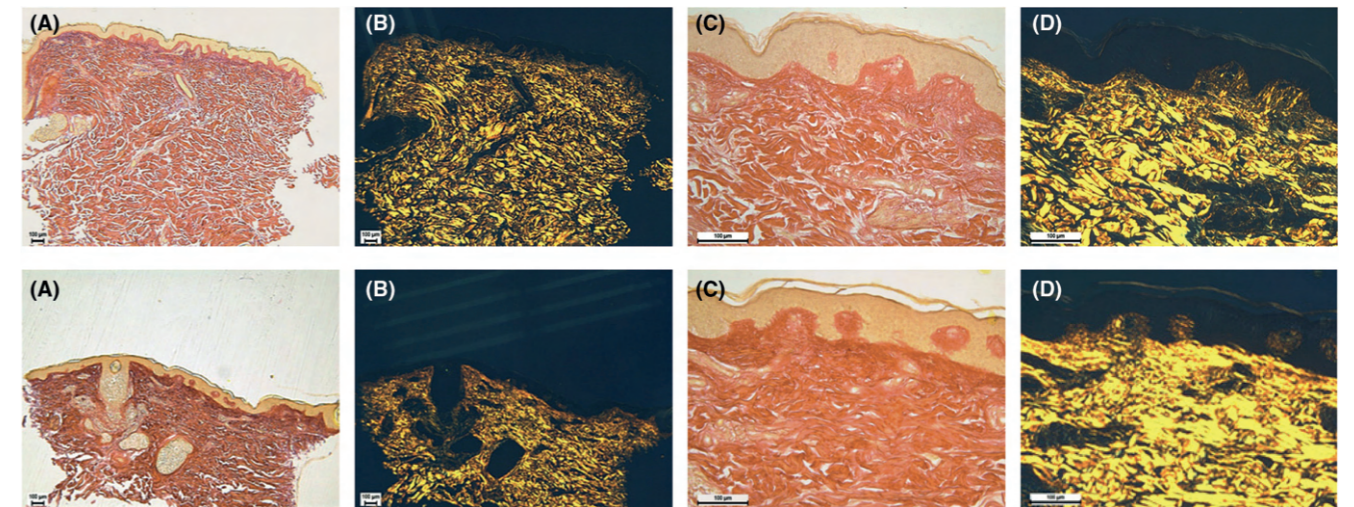


FIGURE 5 Top Row: Histological structure of collagen fibers in the skin biopsy of subject one before treatment, stained with picosirius red: (A) collagen fibers of the reticular and papillary dermis are stained red; (B) collagen fibers give yellow anisotropy; (C) thinner and looser collagen fibers are located in the papillary dermis, and thicker bundles of collagen fibers are visible in the reticular layer; (D) collagen fibers give yellow anisotropy of varying intensity depending on the thickness and density of collagen fibers in different layers of the dermis. Bottom Row: Histological structure of collagen fibers in the skin biopsy of subject one after the procedure, stained with picosirius red: (A) collagen fibers of the reticular and papillary dermis are stained red; (B) collagen fibers give yellow anisotropy; (C) thinner and looser collagen fibers are located in the papillary dermis, and thicker bundles of collagen fibers are visible in the reticular layer; (D) collagen fibers give yellow anisotropy of varying intensity depending on the thickness and density of collagen fibers in different layers of the dermis.

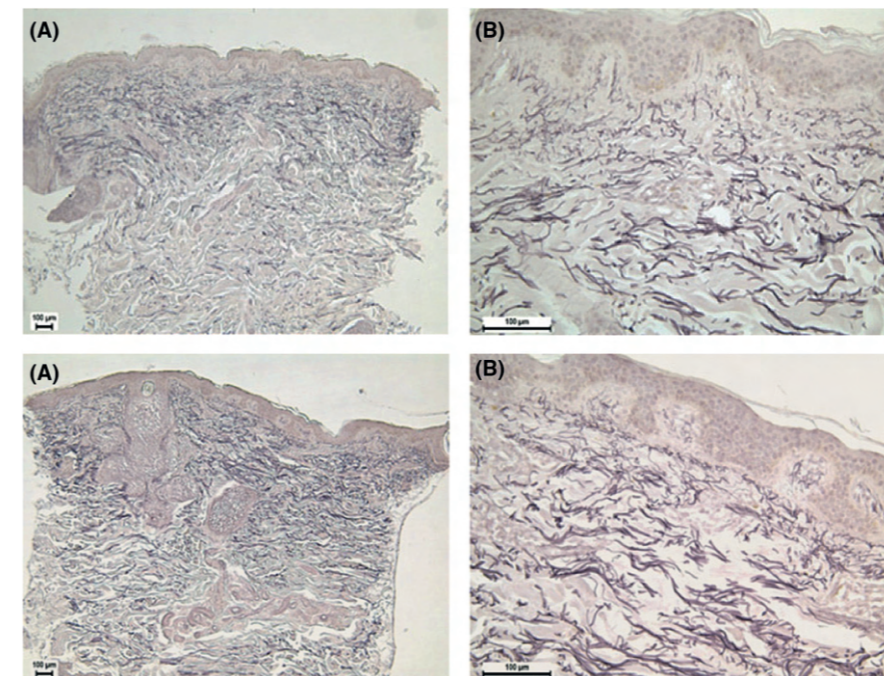


FIGURE 6 Top Row: Histological structure of elastin fibers in the skin biopsy of subject one at baseline, pretreatment, stained with orcein: (A) collagen fibers of the reticular and papillary dermis are stained black; (B) thinner and shorter elastin fibers are seen in the papillary dermis and thicker and loosely located elastic fibers are seen in the reticular layer. Bottom Row: Histological structure of elastin fibers in the skin biopsy of subject one after the procedure, stained with orcein: (A) collagen fibers of the reticular and papillary dermis are stained black; (B) an increase in the content of elastin fibers in the layers of the dermis, their longitudinal orientation in the reticular layer.

3.2 | Comparison of the morphological characteristics of the skin of subjects after the Morpheus8 procedure

After the procedure, the younger cohort (Group 1) representing subjects 1–3, displayed an increase in the number of epidermal cells (by 8.1%) and fibroblasts (by 21.1%) as well as a decrease in

the number of inflammatory cells (by 23.5%). In cohort 2, subject 4, after treatment, a decline in the number of inflammatory cells (by 42.7%) was observed.

In all subjects, regardless of age, a significant increase in the area of the vessels was observed: in the group of subjects 1–3, by 1.8 times, and in subject 4, by 1.7 times (Graph 1). In the group of younger subjects, 1–3, after the procedure, there was an increase

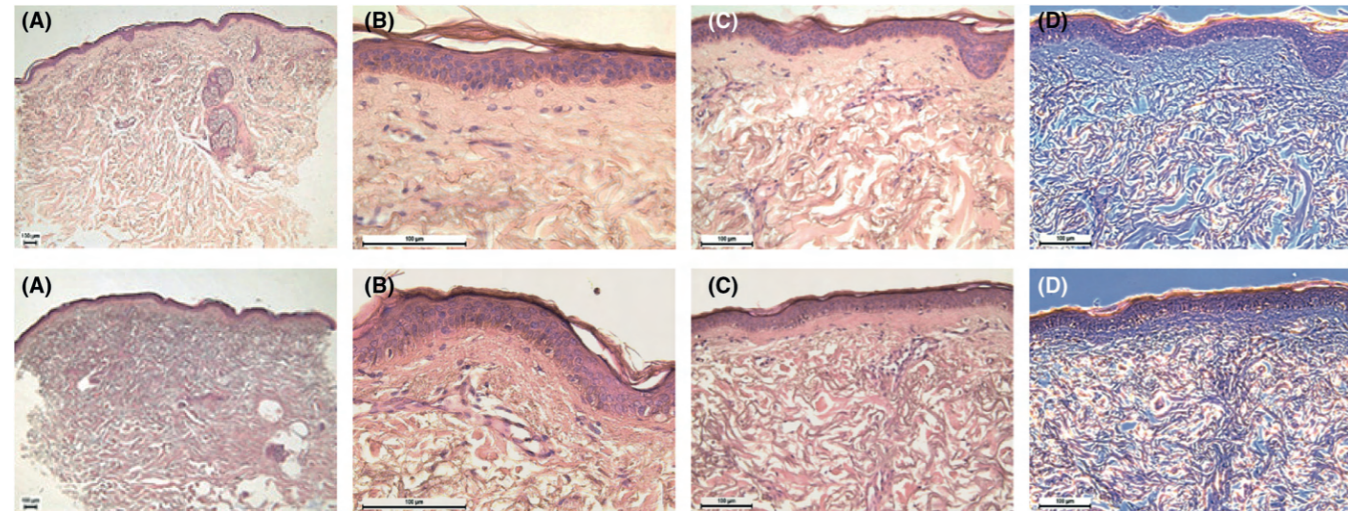


FIGURE 7 Top Row: Histological structure of the skin biopsy of subject four (69 years old) before the treatment, stained with hematoxylin-eosin; (A) general view of the epidermis, reticular, and papillary layers of the dermis; (B) thinned epidermis, thickened papillary dermis; (C) inadequate vascularization and moderate perivascular inflammatory infiltration in the dermis; (D) the same area with phase-contrast microscopy. Bottom Row: Histological structure of the skin biopsy of subject four after the procedure, stained with hematoxylin-eosin; (A) general view of the epidermis, reticular, and papillary layers of the dermis; (B) a thin layer of the epidermis and papillary layer, an increase in the content of blood vessels in the papillary layer; (C) the structure of the papillary and reticular layers of the dermis with increased range of blood vessels; (D) the same area with phase-contrast microscopy.

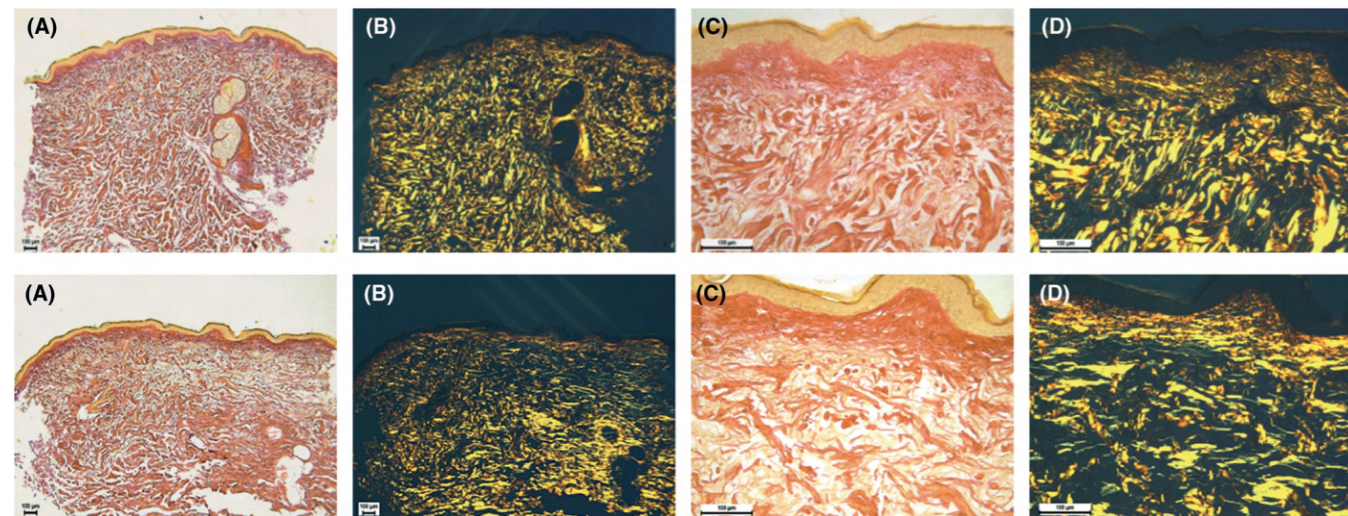


FIGURE 8 Top Row: Histological structure of collagen fibers in the skin biopsy of subject four (69 years old) before the procedure, stained with picrosirius red; (A) collagen fibers of the reticular and papillary dermis are stained red; (B) collagen fibers give yellow anisotropy; (C) dense arrangement of thin collagen fibers in the papillary dermis, loose structure of bundles of collagen fibers in the reticular layer; (D) collagen fibers give yellow anisotropy of varying intensity depending on the thickness and density of collagen fibers in different layers of the dermis. Bottom Row: Histological structure of collagen fibers in the skin biopsy of subject four (69 years old) after the procedure, stained with picrosirius red; (A) collagen fibers of the reticular and papillary layers of the dermis are stained red; (B) collagen fibers give yellow anisotropy; (C) increase in the content of collagen fibers in the papillary dermis; (D) increased anisotropy of collagen fibers in the layers of the dermis.

in the density of collagen (by 25%), elastin (by 33.3%) fibers and a decrease in the degree of fragmentation of elastin fibers (by two times) were observed. In subject 4, after treatment, there was an increase in the density of elastin fibers (2 times) and a decreasing degree of fragmentation (3 times).

4 | DISCUSSION

Recent research has validated the effects of the Morpheus8 (InMode, Lake Forest, CA) on the RF-induced FSN tightening and adipose-related soft tissue contraction which is significant. This

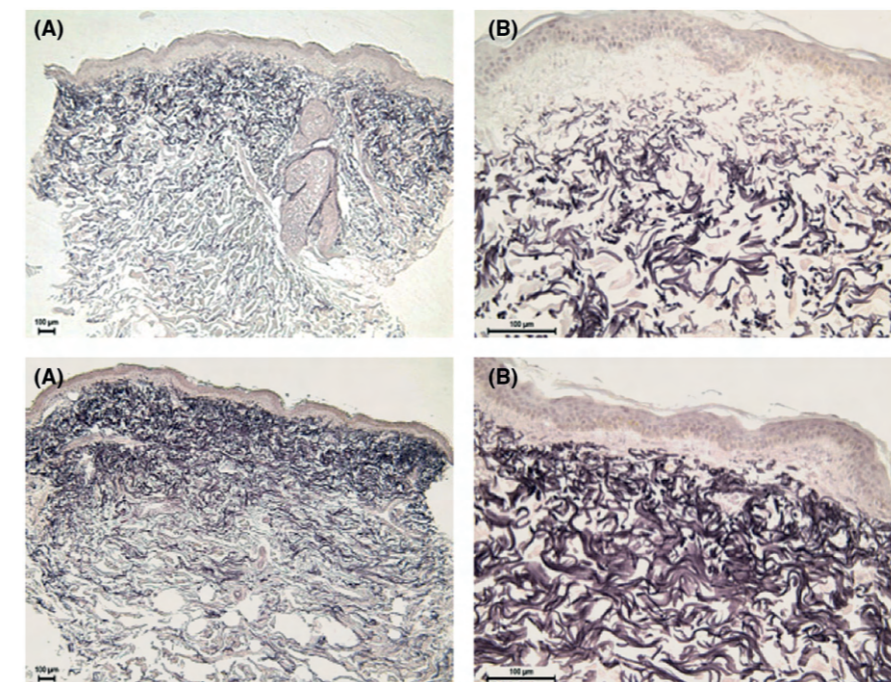
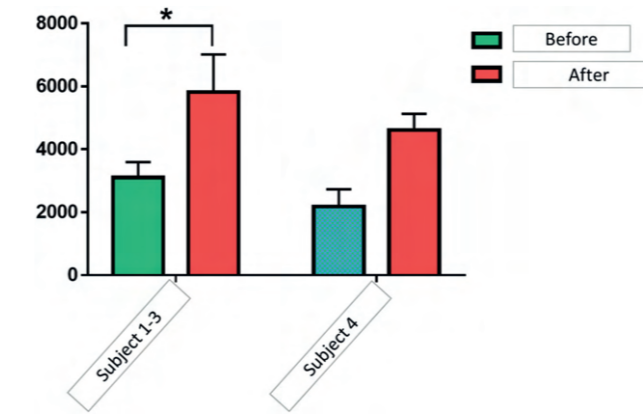


FIGURE 9 Top Row: Histological structure of elastin fibers in the skin biopsy of subject four (69 years old) in the initial state, stained with orcein; (A) collagen fibers of the reticular and papillary layers of the dermis are stained black; (B) hypoelastosis and fragmentation in the papillary dermis with evidence of hyperelastosis and fragmentation in the reticular dermis. Bottom Row: Histological structure of elastin fibers in the skin biopsy of subject four (69 years old) after treatment, stained with orcein; (A) collagen fibers of the reticular and papillary layers of the dermis are stained black; (B) hyperelastosis in the reticular layer of the dermis.



GRAPH 1 Change in the vascular area in subjects of both age groups after the Morpheus8 procedure. $P < 0.05$.

focused on the dermal histologic effects of the novel adipose thermal ablation and coagulation. We found that, at baseline, in the initial state, the skin of subjects aged 35–40 was characterized by moderate dystrophic changes in the epidermis cells. In the papillary dermis, collagen fibers were primarily thin and loosely arranged, while elastin fibers were also light, sparse, and fragmented. Sometimes in the papillary layer, there were separate areas of noticeable fibers loosening with increased content of lymphocytes and macrophages, as well as foci of compaction and tissue homogenization (fibrosis and hyalinosis).

In the reticular dermis, collagen fibers formed bundles and were denser; elastin fibers were also thicker, often fragmented, and unevenly distributed. The cellular composition of the dermis was mainly represented by fibroblasts and a few vessels with moderate perivascular infiltration from lymphocytes and macrophages.

A month after RF treatment, dystrophic changes in epidermal cells were almost not detected. There were no areas of sharp loosening of the fibers, as well as foci of fibrosis and hyalinosis in the dermis. In the papillary dermis, the density of collagen fibers increased, elastin fibers were located more evenly, and their degree of fragmentation decreased. In the reticular layer, there was an increase in the content of collagen and elastin fibers with a simultaneous decrease in their fragmentation. The number of fibroblasts and vessels in the dermis increased, while the amount of lymph-macrophage infiltration was minimal.

In a skin biopsy of the older subject (69 years old), a pronounced thinning of the epidermis was observed before the procedure. In the thickened papillary dermis, thin collagen fibers were very densely packed, while significantly fewer elastin fibers (hypoelastosis) and their fragmentation were observed. In the reticular dermis, a loose arrangement of bundles of collagen fibers was noted. In the outer areas of the reticular layer, hyperelastosis was detected, and in deeper areas, the density of elastin fibers decreased, and fragmentation increased. The content of fibroblasts and vessels in the layers of the dermis was reduced while only few lymphocytes and macrophages were noted.

Most of these histological changes cannot be just attributed to the mechanical injury of the single pass microneedling as the increased vasculature in the reticular dermis, the notable neo-elastogenesis and reorganized and compacted papillary and reticular dermis have not been noted in published, nonthermal, microneedling papers. Thus, we postulate that the strong noncoagulative heating of the return RF traveling from the deep positive ablative and coagulative electrode up to the negative electrode created this “subsurfacing” or “upside down” thermal remodeling. This subsurfacing effect is not present with the typical RF microneedling design where the needles penetrating into the deep dermis or superficial adipose are alternating rows of positive and negatively charged bipolar electrodes. The

ablative and coagulative index for these RF microneedling bipolar arrays is small compared to the Morpheus8 (InMode, Lake Forest, CA), and there is no RF flow up to negative electrodes on the surface of the skin, which generates the reticular and papillary thermal effects.

It would be interesting to extend this study with additional subjects to achieve greater power to determine if these trends would persist. Additionally, it would be valuable to determine if a depth at 1 mm, would the “subsurfacing” effect be just as dramatic. It would also be of value to compare the subdermal and transdermal effects of Radiofrequency-Assisted Liposuction (RFAL) which involves AccuTite, FaceTite, and BodyTite (InMode, Lake Forest, CA).

After radiofrequency macroneedling therapy, the structure of the epidermis did not fundamentally change; the content of vessels and elastin fibers in the papillary layer increased. The most significant changes occurred in the reticular layer, with a strong predominance of densely located elastin fibers (hyperelastosis) over loosened collagen fibers. Thus, the radiofrequency microneedle therapy had a beneficial effect on the skin condition of subjects of different ages: a decrease in the severity of age-related changes and increased regenerative properties were observed. In order to maintain consistency in this case series, all patients were treated with a single pass at 2 mm depth and 22 mj/pin of energy. This mitigates confounding variables such as stacking pulses and multiple passes. Clinically, most patients will receive multiple passes and pulses at multiple depths. Thus, these changes are even more impressive when considering it is due to a single shot of RF delivered by the macroneedles in a given area.

In skin biopsies after the procedure, an increase in the number of epidermal cells, fibroblasts, and blood vessels was noted, the density of collagen and elastin fibers in the dermis layers increased, dystrophic changes in cells and inflammatory infiltration were minimal. It should be noted that in older subjects, the effectiveness of treatment was more pronounced due to the pronounced stimulation of elastogenesis in the reticular layer of the dermis.

5 | CONCLUSION

The Morpheus8 (InMode, Lake Forest, CA) device can deliver a deep and profound FSN and adipocyte ablative and coagulative injury resulting in FSN soft issue contraction and adipose destruction and liquification with the resulting soft tissue tightening and adipose reduction and contouring.¹³ The results of this histologic study confirm a significant “subsurfacing” thermal effect from the noncoagulative ascendent thermal injury and. The obtained results characterize radiofrequency macroneedling (micro electrode) therapy as an effective method for correcting age-related changes in facial skin in subjects of different age groups. A study with a larger sample size is needed to confirm the statistical significance of the recorded changes in skin condition.

AUTHOR CONTRIBUTIONS

All authors have read and approved the final version of the manuscript. EF and MK were involved in study design, data collection and

histologic analysis. RSM and NV were involved in writing and editing the manuscript.

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CONFLICT OF INTEREST STATEMENT

Dr. Mulholland is a paid consultant and shareholder of InMode. Dr. Kreindel is the chief technology officer of InMode. Dr. Vranis and Dr. Flegontova have no disclosures.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

All procedures were performed according to the standard of care at the time of service. Data was collected retrospectively and the patient data was immediately de-identified and essentially anonymous.

ORCID

Neil M. Vranis  <https://orcid.org/0000-0003-4015-5130>

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PLUME EFFECT OF FRACTIONAL RADIOFREQUENCY VERSUS LASER RESURFACING: CONSIDERATIONS IN THE COVID19 PANDEMIC

Erez Dayan, MD, Spero Theodorou, MD, Jay Burns, MD, Bruce Katz, MD, and Jeffrey S. Dover, MD, FRCP

Introduction: The COVID-19 pandemic requires us all to re-evaluate aesthetic practices to ensure optimal patient safety during elective procedures. Specifically, energy-based devices and lasers require special consideration, as they may emit plume which has been shown to contain tissue debris and aerosolized biological materials. Prior studies have shown transmission of viruses and bacteria via plume (i.e., HIV and papillomavirus). The purpose of this study was to evaluate plume characteristics of the Er:YAG resurfacing laser (Sciton; Palo Alto, CA) and compare it to the Morpheus8 fractional radiofrequency device (InMode; Lake Forest, CA).

Methods: Five patients who underwent aesthetic resurfacing and/or skin tightening of the face and neck were treated with the Er:YAG (Sciton Joule, Palo Alto, CA) and/or fractional radiofrequency (Morpheus8, Lake Forest, CA) between April 1 and May 11, 2020. Data collected included patient demographics, past medical history, treatment parameters, adverse events, particle counter data, as well as high magnification video equipment. Patients were evaluated during treatment with a calibrated particle meter (PCE; Jupiter, FL). The particle meter was used at a consistent focal distance (612 inches) to sample the surrounding environment during treatment at 2.83 L/min to a counting efficiency of 50% at 0.3 μ m and 100% at >0.45 μ m. Recordings were obtained with and without a smoke evacuator.

Results: Of our cohort ($n=5$), average age was 58 years old (STD ± 7.2). Average Fitzpatrick type was between 2 and 3. Two patients received Er:YAG fractional resurfacing in addition to fractional radiofrequency during the same treatment session. Two patients had fractional radiofrequency only, and one patient had laser treatment with the Er:YAG only. There were no adverse events recorded. The particle counter demonstrated ambient baseline particles/second (pps) at 8 (STD ± 6). During fractional radiofrequency treatment at 1-mm depth, the mean recording was 8 pps (STD ± 8). At the more superficial depth of 0.5 mm, recordings showed 10 pps (STD ± 6). The Er:YAG laser resurfacing laser had mean readings of 44 pps (STD ± 11). When the particle sizes were

broken down by size, the fractional radiofrequency device had overall smaller particle sizes with a count of 251 for 0.3 μ m (STD ± 147) compared with Er:YAG laser with a count of 112 for 0.3 μ m (STD ± 84). The fractional radiofrequency did not appear to emit particles >5 μ m throughout the treatment, however, the Er:YAG laser consistently recorded majority of particles in the range of 510 μ m. The addition of the smoke evacuator demonstrated a 50% reduction in both particles per second recorded as well as all particle sizes.

Conclusion: Re-evaluation of the plume effect from aesthetic devices has become important during the COVID-19 pandemic. Further studies are required to characterize viability of COVID-19 viability and transmissibility in plume specimens. Based on this pilot study, we recommend that devices that generate little to no plume such as fractional radiofrequency devices be used in Phase I reopening of practice while devices that generate a visible plume such as Er:YAG laser resurfacing devices be avoided and only used with appropriate personal protective equipment in addition to a smoke evacuator in Phase IV reopening.

Key words: COVID19; laser plume; radiofrequency; predictive

INTRODUCTION

The COVID-19 pandemic requires us to re-evaluate aesthetic practices to ensure optimal patient safety during elective procedures [1]. Specifically, the energy-based devices and lasers require special consideration, as they may emit plume, which has been shown to contain

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

*Correspondence to: Erez Dayan, MD, Avance Plastic Surgery Institute, 5570 Longley Lane, Suite A, Reno, NV 89511.

E-mail: drdayan@avanceinstitute.com

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tissue debris and aerosolized biological materials [1–9]. The U.S. Occupational Safety and Health Administration (OSHA) currently has no regulatory requirements for protection against plume emission from these devices. However, several professional societies, including the American Society for Lasers in Medicine and Surgery (ASLMS) have recommended guidelines to protect patients and practitioners.

For over 40 years, the plume from electrosurgical units, commonly known as Bovie (Bovie Medical Corp., Melville, NY) has been shown to be similar to other pathogenic smoke, behaving as a carcinogen, mutagen, as well as a vector for active aerosolized biologic material [10–14]. Despite this, there has been a long-standing complacency among providers regarding this smoke and its potential toxicity. Most aesthetic energy-based devices function by generating heat (e.g., ultrasound, radiofrequency, and ablative lasers) [15–20]. Depending on the duration of exposure and temperatures generated, tissue proteins may coagulate and eventually vaporize by superheating intracellular water content. The result is the disintegration of cell integrity and aerosolization of cellular debris [18,19,21,22]. Studies have shown that smoke generated from ablative laser resurfacing of 1g of tissue to be equivalent to smoking three unfiltered cigarettes [23]. The plume of laser devices has been shown to contain both inert and biologically active particulate matter, such as viruses [2,6–8]. For example, papillomavirus has been identified in vapor from bovine warts treated with laser-derived material as well as electrosurgical cautery [7]. Of the two, more viral load was present in the laser-derived material. Smaller particulate matter is considered to be most harmful and typically bypasses surgical masks, reaching the alveolar level of the respiratory system. These particles are usually less than 5 μ m in size [1,5,8,23].

The purpose of this pilot study was to evaluate and compare plume particle emission and size between two popular types of aesthetic devices: Erbium:YAG laser ablative resurfacing (Sciton, Palo Alto, CA) and fractional radiofrequency needling (InMode, Lake Forest, CA). With the knowledge of the plume characteristics of these devices, we are able to assess the potential risks of these devices and better understand how to protect ourselves and the patients.

METHODS

Five patients underwent aesthetic resurfacing and/or skin tightening of the face and neck and were treated with the fractional Er:YAG (Sciton Joule) and/or fractional radiofrequency (Morpheus8; InMode) between April 1 and May 11, 2020. All patients signed informed consent for the treatments and for participation in the study. Data collected included patient demographics, past medical history, treatment parameters, adverse events, particle counter data, as well as high magnification video during treatment. All aesthetic device settings were standardized among the cohort based on the most typical treatment

parameters. The fractional Er:YAG laser was set at 100 μ m depth in coagulation mode with a density of 20% and scan area of 10 mm². The fractional radiofrequency treatment was performed at a depth of 0.5 mm, followed by 1 mm at level 30 energy and double-stacked pulses at 50% overlap. Patients were evaluated during treatment with a commercial-grade calibrated particle meter (PCE-PQC 10US, PCE Instruments, Jupiter, FL). The particle meter was used at a consistent focal distance (6–12 inches) to sample the surrounding environment during treatment at 2.83 L/min to a counting efficiency of 50% at 0.3 μ m and 100% at >0.45 μ m. The plume particle characteristics were recorded throughout the treatment and compared among the different technologies. Recordings included an overall reading of the number of particles per second (pps) as well as the categorization of particles by size range (0.30, 0.50, 1.00, 2.50, 5.00, and 10.00 μ m). A 6 K camera (Blackmagic, Victoria, Australia) was utilized at $\times 10$ magnification to visualize the plume during treatment for correlation to the particle meter data. The aforementioned recordings were obtained with and without the use of a Bovie Smoke Shark evacuator (Bovie Medical Corp.). The smoke evacuator had a 7/8" tubing attachment and was set at "medium" with the efficacy of approximately 4.5 cubic feet per minute. The smoke evacuator was held within 1–3 inches of the treatment area.

RESULTS

Of our cohort ($n=5$), the average subject age was 58 years old (STD ± 7.2). There was one Fitzpatrick type I, two type II, and one type III subjects. Indications for treatment included cosmetic improvement of skin tone/texture and improvement of facial rhytids. Subjects were all deemed appropriate candidates for fractional radiofrequency and/or laser aesthetic treatments without significant past medical history, excluding them from treatment (such as autoimmune conditions or active infection). None of the subjects included had prior aesthetic facial treatment over the prior 4 months. Two subjects received Er:YAG fractional resurfacing in addition to fractional radiofrequency during the same treatment session. An approximate 30-minute interval passed between these two treatments for ambient room particle reading to return to baseline. The fractional radiofrequency was performed first in both cases. Both modalities were used because these subjects required correction of skin laxity primarily targeted by radiofrequency and resurfacing of deeper rhytids primarily targeted by the Er:YAG laser. Two subjects had fractional radiofrequency only, and one had laser treatment with the Er:YAG only. There were no adverse events recorded during or after treatment.

The particle counter demonstrated ambient baseline particles/second (PPS) at 8 (STD ± 6). During fractional radiofrequency treatments at 1 mm depth, the mean recording was 8 pps (STD ± 8). At the more superficial depth of 0.5 mm, recordings showed 10 pps (STD ± 6). During the Er:YAG laser resurfacing laser treatments, the mean

readings was 44 pps (STD \pm 11). When the particle sizes were broken down by size, the fractional radiofrequency device produced overall smaller particle sizes with a count of 251 for 0.3 μ m (STD \pm 147) compared with Er:YAG laser with a count of 112 for 0.3 μ m (STD \pm 84). The fractional radiofrequency did not appear to emit particles $>$ 5 μ m throughout the treatment; however, the Er:YAG laser consistently recorded a majority of particles in the range of 5–10 μ m. The addition of the smoke evacuator demonstrated a 50% reduction in both particles per second recorded as well as all particle sizes. High magnification videographic data of the treatments were analyzed and demonstrated a clearly visible plume from the Er:YAG laser compared with no visible plume from the fractional radiofrequency device.

DISCUSSION

The risk of plume exposure generated by electrosurgical devices has been investigated since the 1980s [24]. It has been shown that as particle size increases, so does the risk for pathogen transmission. Laser tissue ablation has been shown to generate particles with a mean size of 0.31 μ m, which is larger than traditional surgical electrocautery devices [12,13,25]. This is consistent with clinical findings, suggesting that the plume from resurfacing lasers is more hazardous than electrocautery smoke [1,5,8,23]. To our knowledge, the plume profile from fractional radiofrequency has not been reported in the literature.

This study is timely given the COVID-19 pandemic, as the biologic transmission of pathogens has been shown to occur through plume particles [1]. As a group of providers, we are actively seeking reentry guidelines to best serve patients [26]. Clinical and animal studies on the dangers of plume exposure have shown mutagenic and potentially carcinogenic effects, as well as infectious risks by the transmission of biologic pathogens [2,3,6,7,8,11,13,23]. Concern about the transmission of pathogens led to a study that identified human immunodeficiency virus DNA in laser smoke plume, demonstrating its transmission to cultured cells [2]. Furthermore, reports of human papillomavirus DNA developing on unusual sites (i.e., face, nasopharynx, and larynx) of laser operators who removed plantar and anal warts [7]. In addition to viruses, in vitro experiments have cultured bacteria from laser plume [3].

In this study, we used a commercial-grade particle analyzer to indicate the rate of particle emission (i.e., particles per second) as well as to categorize particle sizes. Our data demonstrated that the Er:YAG resurfacing laser emits more than four times the particles when compared with fractional radiofrequency (Er:YAG; 44 pps vs. fractional radiofrequency; 10 pps). Fractional radiofrequency treatment did not emit plume significantly above ambient baseline particle readings of the exam room environment. When recordings were performed at two different depths of the fractional radiofrequency, there was a slight trend toward more particles in the 0.5 mm treatment depth compared with the 1.0 mm treatment depth, suggesting

that the more superficial the treatment, the more potential particle emission. This appears to be a logical finding as fractional radiofrequency treatment focuses energy at the deeper portion of the applicator. In the bipolar configuration of the device tested, the radiofrequency energy travels half the distance between the subdermal electrode and the external electrode. The temperatures generated are not high enough and the duration of each pulse not long enough to cause vaporization of cellular water content and proteins. In contrast, the Er:YAG laser functions to target the skin surface water chromophore at 2940 nm wavelength energy. This wavelength is absorbed by water 20 times more than the predecessor CO₂ laser, which led to more collateral heat generation. Both the particle reader, as well as the videographic data, show a more substantial plume visualized during treatment, with a larger number and size of particles emitted. Consistent with previous studies, the smoke evacuator did favorably reduce particle emission recordings as well as all sizes of particles by approximately 50% [12,13].

There are a number of limitations to this study. A larger cohort subdivided by age would have provided statistical substantiation to the data and a better understanding of age/dermal thickness relationship to plume emission. The recordings obtained were useful to understand the number of particles emitted per unit time as well as the size of these particles. However, further analysis of the composition of particles beyond particle size would best elucidate the potential biologic activity of the plume, clarifying the risk of pathogenic transmission. In relation to COVID-19, much is left unknown in terms of transmission patterns and viral temperature tolerance. Namely, a more thorough understanding of COVID-19 transmissibility via cutaneous particles is critical. This information is a key component of risk assessment during these treatments.

The aim of this pilot study was to evaluate the particle sizes emitted during treatment with Er:YAG laser resurfacing and compare it to fractional radiofrequency. Our data do suggest that plume emission is greater using a resurfacing laser compared with fractional radiofrequency. Based on this preliminary data, we recommend that all providers working with resurfacing lasers use a smoke evacuator in addition to appropriate personal protective equipment (mask, eye protection) to minimize the risk of plume-associated pathogen transmission.

CONCLUSION

Re-evaluation of the plume effect from aesthetic devices has become important during the COVID-19 pandemic. Further studies are required to characterize the viability of COVID-19 and transmissibility in plume specimens. Based on this pilot study and prior studies, personal protective equipment such as masks, eye protection, and smoke evacuation systems should be used with Er:YAG laser resurfacing due to potential viral and bacterial transmissibility via plume particles.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

POST-HYALURONIC ACID RECURRENT EYELID EDEMA: PATHOPHYSIOLOGIC MECHANISMS AND A PROPOSED TREATMENT PROTOCOL

Justin Karlin, MD, MS ; Neil Vranis, MD; Erez Dayan, MD; and Kami Parsa, MD

Abstract

Background: Hyaluronic acid (HA) filler injections for facial augmentation are commonly administered but can lead to post-hyaluronic acid recurrent eyelid edema (PHAREE). The pathophysiology of this condition has not been fully understood.

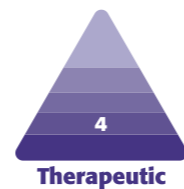
Objectives: To report the successful treatment of PHAREE using serial hyaluronidase and fractionated radiofrequency microneedling, with additional carbon dioxide laser skin resurfacing in selected patients.

Methods: Five patients with PHAREE were treated with serial hyaluronidase injections and fractionated radiofrequency microneedling, with 2 patients receiving carbon dioxide laser treatment. The patients were followed up for a minimum of 24 months.

Results: All patients reported a resolution of PHAREE signs/symptoms with no adverse effects or recurrence. One patient demonstrated complete resolution after a single treatment; 4 required a series of treatments.

Conclusions: The proposed treatment protocol may provide advantages over hyaluronidase alone for PHAREE. The impermeable malar septum, vulnerable eyelid lymphatics, and potential immunogenicity of HA fragments likely contribute to PHAREE pathophysiology. Further research on pathophysiologic mechanisms is warranted.

Level of Evidence: 4



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Facial volume augmentation with hyaluronic acid (HA) filler gel injection ranks among the most common aesthetic non-surgical procedures performed worldwide. One estimate reports that the number of procedures of soft-tissue injection of HA fillers increased from 1.2 million in 2012 to 3.6 million in 2020.¹ This increase in popularity can be attributed to high patient satisfaction, immediate results, social media marketing campaigns, perceived high safety profile (reversibility² and biocompatibility³), and the low barrier to entry (low overhead, quick procedure time, and minimal technical demand). If these factors are coupled with high profit margins and low financial burden (compared with

surgical procedures), then the HA filler injection procedure becomes a lucrative adjunct to the practices of facial surgeons, dermatologists, nonsurgical general doctors,

Dr Karlin is Assistant Professor of Ophthalmology at the Stein and Doheny Eye Institutes, University of California, Los Angeles; Dr Vranis is a plastic surgeon in private practice, Dr Dayan is a plastic surgeon in private practice, Dr Parsa is an oculoplastic surgeon in private practice.

Corresponding Author:

Dr Kami Parsa, 465 N Roxbury Dr, Ste 1011, Beverly Hills, CA 90210, USA.

E-mail: kamiparsa@gmail.com

dentists, and physician extenders (ie, nurse injectors, nurse practitioners, and physician associates).

As expected, a rise in the frequency of facial HA filler injection procedures portends a corresponding rise in associated complications.⁴⁻¹² These complications can present early or late; be transient, intermittent, or persistent; and include mechanical, inflammatory, or ischemic etiologies. Common nonischemic, noninflammatory complications include contour abnormalities (static or dynamic), skin discoloration, localized excessive tissue expansion, or panfacial “overfill.” Inflammatory nonischemic complications may include mycobacterial infection, foreign body granuloma formation, and facial cellulitis. Complications secondary to vascular compromise^{13,14} have gained significant attention, given the severity and need for emergent medical evaluation. Persistent or intermittent malar and eyelid edema is an underreported complication that is poorly understood^{15,16} but can be quite distressing to both patient and injector. There is a knowledge gap in understanding how post-hyaluronic acid recurrent eyelid edema (PHAREE) develops and a skills gap in how to treat this condition.

PHAREE and related conditions have been associated with a periocular injection of HA fillers. The common sites of periocular HA injection include effacement of the inferior orbital rim hollow,¹⁵ colloquially referred to as the “tear trough injection,” and augmentation of the midface,¹⁷ that is, expansion of the suborbicularis oculi fat (SOOF) pocket by injecting filler material into the prezygomatic space. There have been numerous reports of edema of the lower eyelid and midface following HA filler injection.^{15,16,18-21}

Key anatomic and histologic features of the lower eyelid and midface can render this region susceptible to short- and long-term complications such as PHAREE. Anatomically, these features include an abrupt transition between the thin skin of the eyelid and the thick skin of the cheek,²² which may result in visible irregularities beneath the eyelid skin, with even a slightly superficial injection²³; variable extent of the arcus marginalis and orbital septum, making inadvertent orbital filler injection possible, worsening rather than camouflaging steatoblepharon; and the orbicularis oculi’s sphincter-like muscle orientation, which, in the case of inadvertent intramuscular injection, may result in dynamic irregularities during animation.²³ Histologically, the contributing factors to PHAREE are the impermeability of the malar septum,²⁴⁻²⁶ which can act as a barrier to retain fluid, especially in the setting of lymphatic damage or the presence of hydrophilic filler material; the eyelid’s delicate, superficial valveless lymphatics,²⁷ which are vulnerable to damage at the sites of injection (mechanical obstruction secondary to external hydrostatic pressure compression); and the propensity of filler material (especially low-molecular-weight hyaluronic acid and crosslinking agents) to stimulate idiosyncratic inflammation,²⁸⁻³² resulting in a T-lymphocyte-mediated response that may

irreversibly damage the lymphatic drainage apparatus, resulting in lymphedema.³³

Festoons, a related clinical entity,³⁴⁻³⁶ may bear some resemblance to PHAREE but have a different pathophysiologic mechanism. Festoons are characterized by a laxity of the zygomatic-cutaneous ligaments, orbicularis oculi muscle, and overlying skin, a laxity that both leads to and is caused by co-existing tissue edema. Although the exact triggers and pathophysiology of festoons are an active area of research, several treatment modalities have been employed with variable success rates. These include surgical intervention (midface lift and/or lower blepharoplasty),³⁷ ablative lasers,³⁸⁻⁴⁰ chemical peels,⁴¹ sclerosing agents,^{42,43} radiofrequency (RF) devices,⁴¹ or a combination thereof.⁴⁴

In this report, we couple the principles and concepts of festoon management with the ability to dissolve the inciting HA filler with hyaluronidase and RF to develop a treatment protocol that can be effective for managing the manifestations of PHAREE. We propose that management should include dissolution of a previously placed filler along with a gradual and controlled retraction of the surrounding soft tissue. A slow and serial dissolution of the filler, while allowing for a synchronous contraction of the soft tissue, prevents skin redundancy and rapid volume loss. Anecdotally, from the experience of the senior author, patients who simply undergo hyaluronidase without simultaneous soft-tissue management often report dissatisfaction because of the presence of deflation and new rhytides. Through this case series, we demonstrate clinical resolution with acceptable aesthetic outcomes of PHAREE in 5 patients. We employ a protocol that combines hyaluronidase (Hylenex; Halozyme Therapeutics, San Diego, CA) injections with fractional RF energy (Morpheus-8; InMode, Irvine, CA) treatments. Carbon dioxide laser (DEKA; Innate Ability, Calenzano, Italy) resurfacing was also performed on 2 patients who demonstrated a low-risk Fitzpatrick skin type.

METHODS

Five patients with a clinical diagnosis of PHAREE were identified. All included patients reported a history of multiple HA filler injection events to the malar region and orbital rim hollow. The patients initially presented to the senior author’s practice during the period between 2018 and 2021. Subsequently, each patient reported bilateral, recurrent, and persistent malar edema. Ultrasound (Clarius, Vancouver, BC, Canada) was performed in all patients to confirm the presence of HA fillers in the prezygomatic, premaxillary, and/or orbital rim hollow region. Demographics, relevant medical history, clinical photographs, and the treatment protocols are presented in [Table](#). All patients were instructed to initiate lifestyle changes, including lower salt diet, facial massage with a jade roller, and sleep hygiene (ie, sleeping on the back and with the head elevated to 15 degrees). After the completion of the individualized

Table. Demographics, Relevant Medical History, Clinical Photographs, and the Treatment Protocols Are Presented

Case	Age	HA filler type (if known)	Triggering event (if known)	Treatment regimen overview	Treatment settings
1	52		Autologous fat transfer to the midface	Three rounds of treatment with 30 U hyaluronidase, with concomitant fractionated radiofrequency, 3 to 6 weeks apart	Radiofrequency First pass: depth 2 mm, energy level of 20 Second pass: depth 3 mm, energy level of 25 88 total shots (44 each side)
2	64		Autologous fat transfer	One treatment of 30 U hyaluronidase, with concomitant fractionated radiofrequency and CO ₂ laser skin resurfacing	Radiofrequency First pass: depth 2 mm, energy level of 12 120 total shots (60 each side) CO ₂ laser 10W, dwell time 500 μm, spacing 450 μm
3	54	Juvederm Plus (Allergan, Irvine, CA)	Sculptra injection (Galderma, Dallas, TX)	Two rounds of treatment with 75 U hyaluronidase, with concomitant fractionated radiofrequency	Radiofrequency First pass: depth 1 mm, energy level of 15 Second pass: depth 3 mm, energy level of 25 100 total shots (50 each side)
4	58	Juvederm (Allergan, Irvine, CA), Restylane (Galderma, Dallas, TX), Voluma (Allergan, Irvine, CA)		One treatment of 50 U hyaluronidase with concomitant fractionated radiofrequency and CO ₂ laser skin resurfacing	Radiofrequency First pass: depth 2 mm, energy level of 18 Second pass: depth 3 mm, energy level of 18 100 total shots (50 each side) CO ₂ laser First pass: 6 W, dwell time 500 μm, spacing 450 μm Second pass: 9 W, dwell time 500 μm, spacing 450 μm
5	49			Five rounds of treatment with 30 U hyaluronidase, with concomitant fractionated radiofrequency	Radiofrequency First pass: depth 1 mm, energy level of 25 Second pass: depth 2 mm, energy level of 25 Third pass: depth 3 mm, energy level of 25 90 total shots (45 each side)

treatment plan, all patients were followed up for a minimum of 24 months to assess for recurrence. Written consent was provided, by which the patients agreed to the use and analysis of their data. This study was approved by the Institutional Review Board of the University of California, Los Angeles.

RESULTS

Case 1

A 52-year-old woman presented with a history of multiple HA filler injection events to the midface and orbital rim hollow in the 15 years prior to presentation. Five years prior to presentation, she had undergone an autologous fat transfer procedure to the midface by an external plastic surgeon. She developed persistent eyelid and midfacial edema immediately post-procedure. She was referred for the evaluation and treatment of eyelid and malar edema (Figure 1 and Video).

Her treatment regimen included 3 treatments of the following protocol: injection of Hylenex (hyaluronidase enzyme; Halozyme Therapeutics), 30 units on each side, combined with Morpheus-8 (fractionated RF microneedling; InMode) treatments. A period of 3 to 6 weeks elapsed between each treatment. The concurrent Morpheus-8 treatments included treating the lower eyelids and the midface. The RF treatment settings were as follows: the first pass was set to a depth of 2 mm with an energy level of 20 and the second pass was set to a 3 mm depth and an energy level of 25. The patient received a total of 88 total shots (44 on each side).

Case 2

A 64-year-old female presented with a 3-year history of intermittent, recurrent, and painless edema of her malar region (Figure 2). She reported a history of filler injection to the lower eyelid orbital rim hollow 5 years prior to

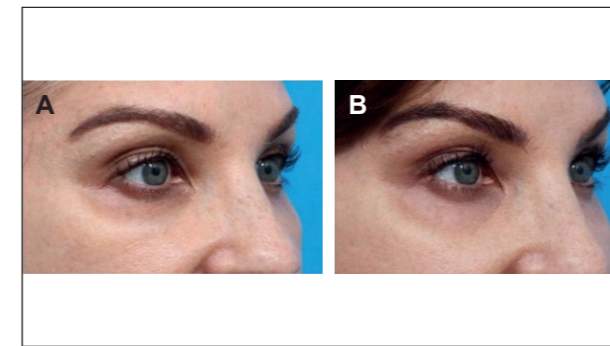


Figure 1. Oblique view of a 52-year-old female patient described in Case 1. (A) Pretreatment photograph and (B) posttreatment photograph. Note the presence of lid–cheek junction edema and blue discoloration of the pretreatment photograph, features that are no longer present in the posttreatment photograph (captured 28 months later).

presentation. The edema had developed immediately after lower eyelid fat transfer 3 years before presentation.

The patient was treated with 1 round of Hylenex (Halozyme Therapeutics) injection, 30 units on each side, and Morpheus-8 (InMode), with concomitant carbon dioxide laser skin resurfacing. The RF treatment was performed at 2 mm depth with 120 shots (60 per side) in the periocular region. A single pass of fractionated carbon dioxide laser skin resurfacing was performed at a power of 10 W, dwell time of 500 μm, and spacing of 450 μm.

Case 3

A 54-year-old female presented with 4 years of malar edema. She reported a history of HA filler injection to the midface and orbital rim hollow 5 years prior to presentation. She stated that the edema had first developed 4 years prior to presentation, immediately following a facial injection of Sculptra (Galderma, Dallas, TX).

The patient was treated with 2 rounds of injection of Hylenex (Halozyme Therapeutics), 75 units, coupled with simultaneous fractionated RF microneedling (Morpheus-8; InMode) to the midface with the following settings: 1 mm depth and an energy level of 15 and 3 mm depth and energy level of 25. The patient received a total of 100 shots (50 per side; Figure 3).

Case 4

A 58-year-old female with a history of multiple HA filler injections over a 10-year period to the midface and orbital rim hollow presented reporting several years of fluctuating edema of the bilateral lower eyelids. The patient denied

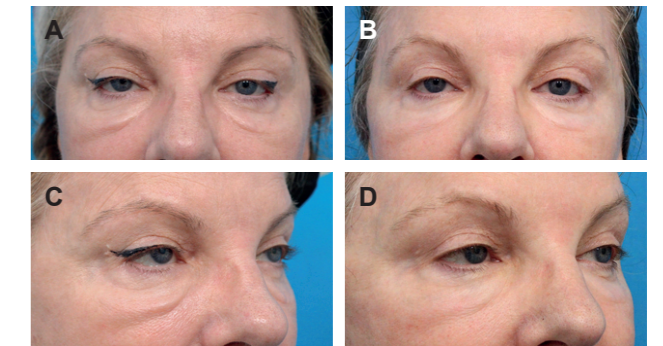


Figure 2. (A, C) Preoperative front facing and oblique photographs of a 64-year-old female (Case 2) presenting with signs of post-hyaluronic acid recurrent eyelid edema and symptoms including intermittent malar edema. (B, D) One year after a single treatment session of enzymatic degradation of a previously placed hyaluronic acid filler, along with fractionated radiofrequency microneedling and carbon dioxide laser skin resurfacing, there was a resolution of symptoms in addition to clinical aesthetic improvement.

experiencing pain and erythema. The edema was noted to be worse in the mornings and exacerbated by the consumption of salty foods or alcohol (Figure 4).

This patient underwent 1 round of treatment with Hylenex (Halozyme Therapeutics), with 50 units injected into the midface and cheek on each side, with concomitant fractionated RF treatment (Morpheus-8; InMode). The RF microneedling settings were as follows: 1 pass at a depth of 2 mm and a second pass at a depth of 3 mm, and at both times, the energy level was set to a power of 18, with a total of 100 shots (50 each side). Additionally, given her favorable skin type, fractionated CO₂ laser resurfacing (DEKA; Innate Ability) was performed. Two passes were done with the following settings: a power of 6 and 9 W, dwell time of 500 μm, and spacing of 450 μm.

Case 5

A 49-year-old female presented for the evaluation and treatment of “under-eye bags,” which had worsened considerably in the month prior to first presentation. She noted fluctuation in severity but could not identify any triggers. She reported a history of multiple episodes of HA filler injection to the cheek and orbital rim hollow, at 10 years, 5 years, and 1 year prior to presentation (Figure 5).

She underwent a series of 5 treatments with the following protocol: injection of 30 units of Hylenex (Halozyme Therapeutics) to the orbital rim hollow region on each side, followed immediately by fractionated RF treatment (Morpheus-8; InMode) to the orbital rim and malar region. The RF microneedling settings were as follows: 1 pass at a depth of 1 mm, a second pass at a depth of 2 mm, and a third pass at a depth of 3 mm; the energy level was set to a power of 25 for all passes.



Video. Watch now at <http://academic.oup.com/asjopenforum/article-lookup/doi/10.1093/asjof/ojad102>.

Summary of Results

All 5 patients were females with an average age of 55.4 years (range 49-64). All included patients experienced a resolution of the signs and symptoms of PHAREE and all of them reported satisfaction over the treatment provided. Resolution was determined by clinical examination from a board-certified oculoplastic surgeon and upon a review of standardized medical photography that demonstrated a smooth lid–cheek junction transition. Additionally, subjective reports from each of the patients emphasizing the resolution of the intermittent eyelid and malar edema confirmed these clinical observations. The efficacy of treatment lasted a minimum of 24 months after the final treatment (follow-up time averaged 26 months with a range of 24-28 months). There was no recurrence of malar edema and no complications of treatment were observed. Two patients experienced resolution after a single treatment and 3 patients required multiple treatments (range 2-5 treatments). Notably, 3 patients reported that the edema had first developed immediately after a facial procedure was performed in the setting of a previously injected HA filler to the same area. In 2 patients, the triggering procedure was autologous fat injection, and in another, it was an injection of Sculptra (Galderma) triggered PHAREE.



Figure 3. (A) Full-face photograph of a 54-year-old female prior to post-hyaluronic acid recurrent eyelid edema treatment showing chronic swelling over the orbital rim hollows and malar region. Focused periorbital photographs of the same patient, (B) before and (C) 6 months after treatment with hyaluronidase and fractionated radiofrequency microneedling treatment outlined in Case 3.

DISCUSSION

In this case series, we report the cases of 5 patients with PHAREE who were treated with serial hyaluronidase injection and fractionated RF, and, out of these, concomitant carbon dioxide laser skin resurfacing was performed in 2 patients. All these patients experienced a resolution of the recurrent malar and eyelid edema, and all expressed satisfaction with the treatment. We review the literature examining HA-filler-related eyelid and malar edema, discuss the pathophysiology of this entity, and describe the principles underlying our proposed treatment protocol.

Review of Prior Reports of HA-Filler-Related Eyelid and Malar Edema

HA fillers have been in use as an injectable agent for facial volume augmentation for 25 years. In this time, several groups have noted the clinical patterns of eyelid and midfacial edema. Goldberg and Fiaschetti¹⁵ described the results of cheek, eyebrow, and zygomatic/septal-confluence/orbital rim hollow HA filler injection in 120 patients. In this report, 15% of patients ($n = 18$) reported “fluid buildup” in the malar region. The authors describe this edema

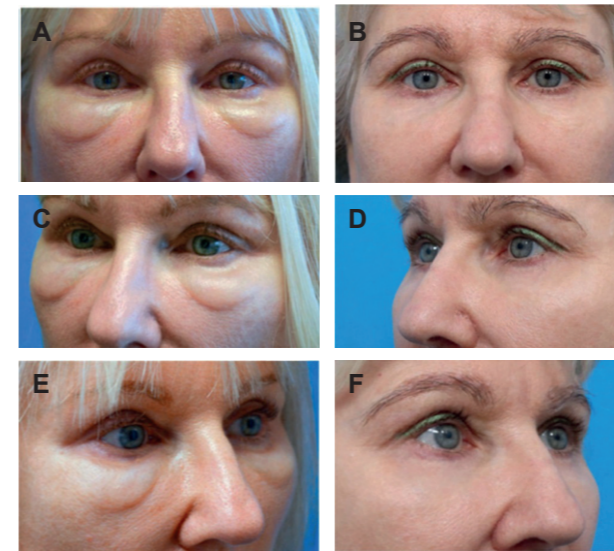


Figure 4. A 58-year-old female with post-hyaluronic acid recurrent eyelid edema was treated with a combination of hyaluronidase, fractionated radiofrequency microneedling, and CO₂ laser resurfacing (Case 4). (A, C, E) Bilateral oblique and frontal pretreatment views. (B, D, F) The posttreatment photographs were captured 9 months after treatment.

as having particular features—“cold” inflammation occurring in the malar region and often persisting for weeks to months. This is identical to what has been observed in patients with PHAREE. The authors in that study speculate that this edema might be related to lymphedema, and that patients with pre-existing malar triangle edema were at a higher risk for developing this complication.

Griepentrog et al¹⁶ reviewed the charts of 51 patients who underwent periocular lower eyelid HA filler injection and noted 12 patients (~24%) who demonstrated prolonged periorbital edema. The authors note that the observed periorbital edema lacked inflammatory features. Of note, the majority of patients (10/12, 83%) in that series with periocular edema had received Juvederm (Allergan, Irvine, CA) injections, and 3 patients (3/12, 25%) reported a history of seasonal allergies. The authors speculate that the increased hydrophilicity of Juvederm may have been responsible for the tendency of patients who received this filler to develop edema.

Prior case reports have described delayed onset eyelid edema after HA filler injection. Iverson and Patel²¹ described a patient who had developed eyelid edema 1 year after HA filler injection. Dubinsky-Pertzov et al²⁰ described 17 patients who had developed upper eyelid and brow edema 6 to 24 months (mean 13.8 months) after upper eyelid or brow filler injection.

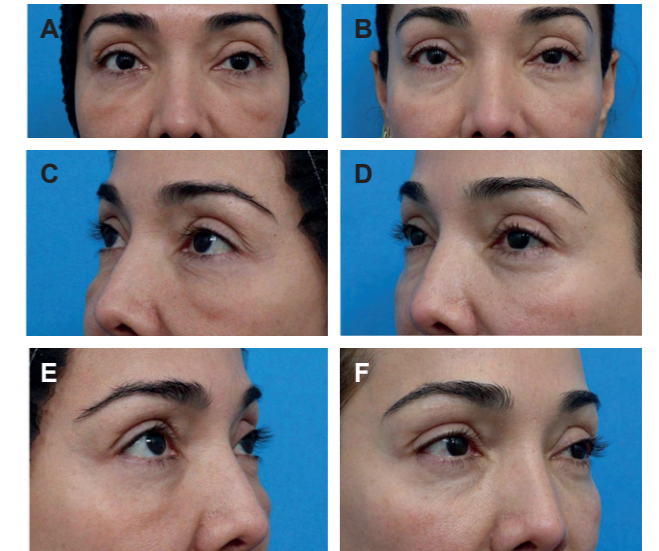


Figure 5. A 49-year-old female with post-hyaluronic acid recurrent eyelid edema was treated with a combination of hyaluronidase injection and fractionated radiofrequency microneedling. (A, C, E) Pretreatment bilateral front facing and oblique views. (B, D, F) The posttreatment photographs were captured 1 year after treatment.

The Anatomic and Pathophysiologic Basis of Posthyaluronicacid Recurrent Eyelid Edema (PHAREE)

Valveless Lower Eyelid Lymphatic System

The lymphatic anatomy of the eyelid and midface is potentially relevant to PHAREE in 2 key ways. First, histologically, the superficial cutaneous lymphatics are a sparse and delicate network that for the most part lack intraluminal valves.²⁷ Second, periocular lymphatic drainage in the region of the malar septum forms a watershed region (Dayan and Parsa, unpublished data, 2023).

The lymphatic system is a generally unidirectional network of vessels that collect and transmit interstitial fluid from the peripheral tissues to the central venous system. Interstitial fluid of the lower eyelid and midface, deposited through a leak from the lymphatic capillary bed, is collected through an “oak leaf” network of lymphatic absorbing capillaries that, at their tips, harbor a valve that regulates fluid entry. The fluid that enters the lumen is transported through a paranasal superficial network that extends from the medial canthus to the submandibular nodes and a lateral superficial network from the lateral canthus to the preauricular nodes. There is also a deep network laterally that drains into the preauricular parotid nodes.

Focusing on the histology of the superficial vessels, in order of increasing luminal diameter, we find that the



Figure 6. Watershed area of the midface and lower eyelid. The ovals depict the location of the lymphatic drainage pathways serving the lower eyelid and malar region, spanning from the lateral canthus toward the preauricular nodes, and from the medial canthus toward the submental nodes. The trapezoid highlights the watershed region of the midface and lower eyelid.

superficial network consists of 3 interconnected plexuses—the (1) dermal capillary and (2) dermal precollector vessels, and (3) a subcutaneous collector vessel network. Plexus (1) and (2) are valveless and drain into (3) which has valves. Given the lack of intraluminal valves, cutaneous superficial lymphatics are unique in that they may be subject to multidirectional flow depending on pressure gradients. A compromise of the lymphatic drainage distal to the superficial network (for instance with HA filler injection) could increase intraluminal pressure, resulting in the slowing or reversal of interstitial fluid clearance from the eyelid skin. Ultimately, downstream subacute or chronic effects of this dysfunction lead to increased dermal and subcutaneous thickness.

The deep network begins when channels penetrate the orbicularis to connect Plexus 3 (see above) to a deep network of valved lymphatic vessels.⁴⁵ This deep network courses inferolaterally, penetrating the orbicularis-retaining ligament along the orbital rim and entering the deep SOOF. These channels then traverse the superior portion of the prezygomatic space and, at the level of the zygomatico-cutaneous ligament (“McGregor’s Patch”), penetrate deeper into the preperiosteal fat layer near the origin of the zygomaticus. These channels continue laterally at this level, ultimately draining into the preauricular nodes within the parotid. Notably, there is a connection between the tarsal conjunctival lymphatics with the superficial networks and the lateral deep network through channels that penetrate the tarsus.

Conventional descriptions of the lower eyelid and midface lymphatic networks describe a medial network traveling in the paranasal region toward the submandibular nodes and a lateral network traveling along the body of the zygoma toward the preauricular nodes (Figure 6). In this model, as these 2 lymphatic networks diverge toward their nodes (submandibular and preauricular, respectively),

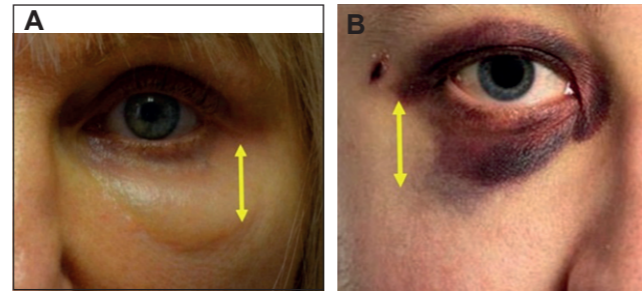


Figure 7. The barrier function of the malar septum. The left image demonstrates periocular ecchymosis and the right image is a closeup of the post-hyaluronic acid recurrent eyelid edema patient described in Case 4. The yellow arrows demonstrate the inferolateral portion of the malar septum. Note the stark transition between (A) ecchymosis and normal tissue and the (B) stark transition between edema and normal tissue (right).

a watershed region of the midface forms between the 2 networks. This watershed region happens to correspond to the central and lateral portions of the malar septum, the region of fluid accumulation appreciated in patients with PHAREE.

Relatively Fluid-Impermeable Midface Osteocutaneous Septa

The development of PHAREE may be related to the intrinsic anatomy of the lower eyelid and midface. Pessa and Garza described a fibrous septal structure, the “malar septum,” as a “relatively impermeable membrane ... that traps tissue fluid and hemoglobin pigment and acts as a functional and structural barrier.” This fibrous thickening spans the lower eyelid and midface, separating the oral cavity and lower face from the orbit and the upper face.²⁶ This structure originates at the inferomedial orbit in the region of the anterior lacrimal crest, and fans out laterally, with attachments along the anterior inferior orbital rim (ie, the orbicularis-retaining ligament), and inferolaterally (ie, the zygomatico-cutaneous ligament), with strong attachments at the inferolateral tip of the body of the zygoma, in the region of “McGregor’s patch.” The malar septum separates the SOOF into superficial and deep layers. The development of lower eyelid festoons and also the appearance of triangular malar mounds are to some extent related to the unique anatomy of this region,¹⁵ because osteocutaneous malar septum attachments are not uniform across this anatomic area. Skin laxity or edema will thus result in the development of troughs, in which osteocutaneous attachments are dense, and crests, in which there are no attachments.

Teleologically, 1 may hypothesize that the malar septum (a fibrous, relatively impermeable structure in the midface) acts as a barrier that isolates the orbit from the oral cavity. The evolutionary benefits of the malar septum may include

preventing the translocation of oral pathogens superiorly toward the orbit, which is similar to the orbital septum, which prevents the translocation of the bacterial cellulitis of the face (preseptal) from invading vital structures within the orbit (orbital cellulitis). The barrier function of the malar septum is starkly illustrated in patients who present with periocular ecchymosis, after trauma (Figure 7), in which an abrupt transition corresponding to the thickest attachments of the malar septum exists between the ecchymotic skin of the eyelid and the normal skin of the cheek. Likewise, in patients with PHAREE, the eyelid edema is often noted to accumulate above with an abrupt transition along the lid–cheek junction (zygomatico-cutaneous ligament), at the site of the attachments of the malar septum.

Immune Regulation of Lymphedema

An accumulating body of evidence suggests that lymph stasis leads to inflammation, which, in turn, perpetuates permanent damage to the lymphatic system, causing chronic lymphedema. The 3 hallmarks of chronic lymphedema are morphologic adipose deposition, fibrosis, and lymphatic destruction. This process may be regulated by CD4⁺ T cells. In a mouse model of tail lymphedema, CD4⁺ T-cell knockout mice were protected from chronic lymphedema.⁴⁶ In a subsequent paper, the same group identified the proinflammatory cytokine interleukin-6 as a key regulator of adipose deposition in the setting of lymphedema.⁴⁷ Garcia Nores et al showed that lymphatic injury leads to CD4⁺ T-cell activation in regional lymph nodes, and that these T cells migrate to the site of the initial injury.⁴⁸ One might then assume that lymphatic damage creates a pathologic cycle in which migrating CD4⁺ T cells worsen the original lymphatic insult.

Although the exact role of immune-mediated regulation of lymphatic damage in the development of lower eyelid and midfacial edema in the setting of HA injection is still not known, certainly a scenario is possible where HA filler breakdown products might trigger an idiosyncratic T-cell response⁴⁹ that might, in turn, cause lymphatic damage (fibrosis, adipose deposition). This would lead to stasis and, in some cases, permanent lymphatic damage. Similarly, it is possible to imagine a situation where, irrespective of immunologic HA-induced inflammation, a repeated injection of HA fillers to the lower eyelid or midface will cause tissue compression, mechanical lymphatic obstruction, lymph stasis, and localized lymphedema in the delicate superficial lymphatics. These 2 scenarios are not mutually exclusive. Interestingly, in the 2 patients in whom the injection of a non-HA substance triggered PHAREE (Case 1—autologous fat injection, and Case 3—Sculptra), a dissolution of HA fillers and fractionated RF treatment led to PHAREE resolution, suggesting that the presence of HA filler material in certain individuals is necessary but not sufficient to trigger PHAREE.

PHAREE Treatment Rationale

Injected HA fillers can act as a tissue expander. Goldberg et al⁵⁰ and Zamani et al⁵¹ have reported using the tissue expanding effect of injected HA fillers to treat lower eyelid retraction, using the fillers to stretch and support soft tissues in 3 dimensions, counteracting eyelid descent. When HA fillers are injected into healthy noncicatrized periorbital tissue, it is reasonable to anticipate that these fillers will have a similar (if not more robust) tissue expansion effect. Modern HA filler products are being manufactured with high levels of crosslinking, in an effort to impart elasticity and enhance product longevity.^{52,53} Products with increased elasticity, by definition, have greater tissue expansion effects. The tissue expander effect of HA fillers, in theory, can stretch native tissues beyond their intrinsic capacitance, causing a fragmentation of elastin and collagen within the dermis and loss of an innate ability to return to baseline.⁵⁴ Following dissolution of the filler, either naturally or deliberately, the overexpanded skin may not return to the elasticity of its prefilled state, leading to a deflated appearance, clinically diagnosed as volume deflation and rhytids. Counteracting deflation is a principle underlying the treatment of PHAREE.

Lymphatic dysfunction plays an integral role in the development of PHAREE. In 1 study, the authors showed that, compared with filler-naïve patients (control patients), patients with a history of filler injection to the cheek or orbital rim hollow (or both) had a dysfunctional lymphatic system characterized by a starburst pattern at the lid–cheek junction by near infrared indocyanine green (ICG) lymphoscintigraphy.⁵⁵ The authors observed a localized retention of the dye that lasted for more than 48 h, compared with less than 24 h for the control patients. Interestingly, 2 patients included in the present study (Cases 1 and 3) reported to appear normal after having HA fillers injected to the inferior periorbital area; it was not until after they subsequently underwent a second procedure without dissolving the previously placed filler (Case 1 underwent autologous fat grafting and Case 3 Sculptra injection) that they began experiencing PHAREE. It is possible that in susceptible patients after an initial trigger (ie, HA fillers injected in the cheek, orbital rim hollow, or both), a subsequent inflammatory or injuring insult (fat grafting, lower blepharoplasty, Sculptra, etc) may further disturb the lymphatics beyond a threshold, resulting in PHAREE.

RF microneedling devices can induce remodeling and contraction of dermal and subdermal soft tissues.⁵⁶ A major benefit of RF microneedling is that, unlike ablative lasers that can cause permanent pigmentation changes⁵⁷ in darker-skinned individuals,⁵⁸ these devices can be safely used on patients with higher Fitzpatrick skin types.⁵⁹ A systematic review, which included 2 randomized control trials by Kleidona et al,⁵⁹ affirmed that the use of fractionated RF

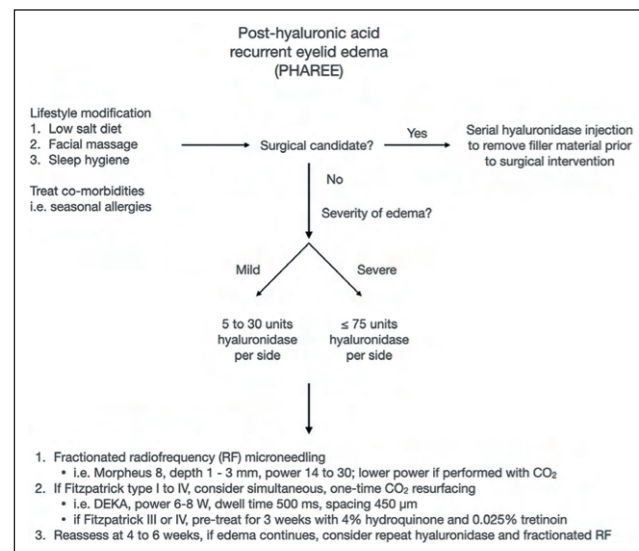


Figure 8. Flowchart outlining the post-hyaluronic acid recurrent eyelid edema treatment protocol. For surgical candidates, the process starts with multiple sessions of hyaluronic acid filler dissolution through hyaluronidase, and then proceeds to surgery. For nonsurgical candidates, the protocol combines low-dose hyaluronidase with fractionated radiofrequency microneedling for gradual filler dissolution and tissue contraction. Optional adjustments include even lower hyaluronidase dosage for mild edema or rhytid prevention and a one-time ablative fractional CO₂ laser for patients with Fitzpatrick skin Types I to IV. Reassessment every 3 to 6 weeks is essential for nonsurgical candidates.

led to improvements in skin wrinkles, laxity, and patient satisfaction. Note that there have been reports of hyperpigmentation after RF microneedling, but these cases are rare and transient.^{60,61} RF energy delivered to the intra- and subdermal layers induces localized tissue heating, in turn, inducing collagen contraction and collagen synthesis.⁶² RF devices with insulated needles theoretically are able to achieve depth-controlled effects without causing collateral thermal injury to the epidermis or other layers superficial to the desired treatment depth. Fractionated RF devices have been used as a noninvasive modality to improve periorbital rhytids and for the treatment of malar mounds and festoons.⁶³ Interestingly, Hsu et al have demonstrated that fractionated RF microneedling can even cause a destruction and dissolution of intradermal and subdermal hyaluronic acid filler material.⁶⁴

Recent data from our group⁵⁵ have demonstrated that patients with HA-filler-related edema demonstrate a delayed clearance of ICG injected into the midface. This is suggestive of slowed lymphatic drainage. Interestingly, ICG clearance improved following the use of hyaluronidase and RF microneedling treatments.⁵⁵ These data support the assertion that hyaluronidase injection, along with fractionated RF, resolves PHAREE by improving lymphatic drainage.

In treating PHAREE, it is first important to determine whether a patient is interested in availing surgical treatment. If so, treatment should involve a combination of HA filler dissolution with hyaluronidase, often with multiple sessions. This should be followed by lower blepharoplasty, possible canthoplasty, and possible midface lift, along with possible simultaneous adjunctive treatments such as fractionated RF microneedling or carbon dioxide laser skin resurfacing or both.

In PHAREE patients who are not surgical candidates, we believe that it is important to avoid the deflation and tissue laxity that can occur when dissolving the filler using hyaluronidase alone, because this can result in an aged, hollowed appearance. As such, we recommend combining gradual filler dissolution using low doses of hyaluronidase, with synchronous fractionated RF microneedling, to allow for incremental filler dissolution with simultaneous soft-tissue contraction. In patients in whom edema is mild, or in patients who communicate their desire to avoid the formation of rhytids, an even lower dose of hyaluronidase may be injected. Note that fractionated RF microneedling is used not only for its tissue contraction effect, but also for its ability to potentiate the dissolution of HA filler material.⁶⁴ In patients with favorable skin types, a 1-time ablative fractional CO₂ laser can be incorporated to further optimize tissue contraction, as illustrated in Case 4. Our protocol requires reassessment every 3 to 6 weeks after the initiation of treatment, to determine whether the patient requires further hyaluronidase dissolution with fractionated RF microneedling. Figure 8 is a flow chart describing our treatment protocol in detail.

Study Limitations

Although all patients in this series reported a resolution of their symptoms, the series' small sample size limits the generalizability of the findings. Moreover, the lack of a control group (for instance, patients who underwent hyaluronidase injection alone) prevents a comprehensive assessment of the relative contribution of fractionated RF microneedling or laser resurfacing to the treatment of PHAREE. To impart more objectivity and generalizability to the findings, future studies could include standardized outcome measures such as consistent photography with an objective facial edema grading system.

CONCLUSION

Although the etiology and pathophysiology of recurrent and persistent malar and eyelid edema following HA filler injection are multifactorial, lymphedema plays a major role. In this case series, we have identified and described a therapeutic modality for PHAREE that involves enzymatic degradation of the HA filler, coupled with fractionated

RF microneedling (Morpheus-8; InMode), and, in select patients, ablative carbon dioxide laser (DEKA; Innate Ability). We have observed a durable resolution of PHAREE signs and symptoms with a restoration of aesthetic periorbital anatomy, ostensibly due to RF- and laser-mediated tissue contraction and RF-mediated restoration of lymphatic function. Ultimately, managing these rare yet challenging sequelae of HA fillers in the periorbital region with precise multimodal treatments that address the underlying inciting factor, in addition to the overlying soft tissue, results in high levels of patient and surgeon satisfaction.

Supplemental Material

This article contains [supplemental material](#) located online at www.asjopenforum.com.

Disclosures

Dr Karlin is a consultant for Horizon Therapeutics (Dublin, Ireland) and a member of the Speakers' Bureau. Dr Parsa is a consultant for Inmode Inc. (Irvine, CA) and is a member of the Speakers' Bureau. The other authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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RADIOFREQUENCY FOR FAT REMOVAL AND SKIN TIGHTENING OF THE BODY

Erez Dayan, MD, Joseph Marte, Spero Theodorou, MD

KEYWORDS

- Radiofrequency • Bipolar radiofrequency • Minimally invasive • Aesthetic technology • Body
- Soft tissue tightening • Skin tightening • Soft tissue remodeling

KEY POINTS

- Significant advancements in minimally invasive body contouring have been made over the past 10 years.
- Increasingly, patients are seeking minimally invasive methods to tighten skin and remodel adipose tissue. A large treatment gap exists among 3 types of patients: the younger demographic, who desire soft tissue tightening without traditional operations, scars, and downtime; patients with soft tissue laxity who are not “severe enough” to justify an excisional procedure, but not “mild enough” to rely on liposuction with soft tissue contraction alone; and those with recurrent laxity who already underwent traditional excisional procedure. In these populations, aesthetic surgeons risk undertreating or overtreating with traditional methods.
- Through impedance of electromagnetic current, radiofrequency (RF) waves lead to differential heating across distinct tissue types consistent with Ohm’s law ($\text{energy} = \text{current}^2 \times \text{impedance} \times \text{time}$). For example, adipose tissue is less conductive than water (higher impedance) and leads to the generation of higher temperatures than muscle. Once soft tissue temperatures reach 50°C and skin surface reaches 40°C to 42°C, there is a trigger to induce neocollagenesis, angiogenesis, and elastogenesis. Through different applications of RF energy (eg, monopolar, bipolar, multipolar, and RF microneedling), subdermal adipose remodeling and long-term soft tissue contraction can be safely and consistently achieved.
- The procedure may be performed safely and effectively under local anesthesia with an excellent safety profile and return to daily activities within 24 to 36 hours.

 Video content accompanies this article at <http://www.advancesincosmeticsurgery.com>.

PREOPERATIVE STEPS

Analysis

- A thorough history and physical examination should be performed with a focus on previous procedures, significant weight changes, pregnancy status, and a preoperative analysis to identify areas of subcutaneous excess, dermal striae, and tissue laxity [1–5].
- Areas of volume excess and areas of significant laxity are marked preoperatively with the patient in the standing position with the target areas in the dependent position to facilitate intraoperative accuracy.
- For upper extremities, the forearm is flexed at 90° and the humerus is parallel to the floor to demonstrate areas of maximal laxity in the upper posterior arm.

- Preoperative photography is essential for postprocedural analysis.
- When indicated, laboratory values, including complete blood count, chemistry profile, coagulation tests, and urine pregnancy tests in women of child-bearing age, are obtained.
- Thirty to 45 minutes preoperatively, the patient is given oral medications, including an antibiotic, sedative, and pain reliever.

OPERATIVE STEPS

1. Tumescent infiltration

- Following standard preparation and drape, the previously identified access points are injected with 1% lidocaine with epinephrine.
- Access incision is made with either a 14-gauge needle or a number 11 blade scalpel.
- Standard infiltration cannula is used to deliver the tumescent fluid (Box 1) into the deep subcutaneous space at a low speed.
- Once the deep and intermediate subcutaneous fat spaces are adequately infiltrated, the cannula is placed into the superficial fat space in order to obtain complete analgesia of all layers with the most densely innervated subdermal space injected last.
- It is important to tumesce at least 1 to 2 cm beyond the marked areas to achieve full analgesia in the treatment zone.
- In the awake patient, slow infiltration speed will achieve a comfortable state for the patient because the rate of distension correlates with discomfort.
- Infiltrate “low and slow”: begin with the tumescent injected into the less richly innervated deep subcutaneous fat space at a low speed.
- Only progress to the next step once complete analgesia is achieved.

2. Application of radiofrequency (RF) energy (Video 1)

- The same access incisions are used that were made for tumescent infiltration.
- Zones of heating are identified for maximally efficient tissue heating.
- External and internal temperature maximum values are entered on the RF generator (typically 65°C –68°C internally and 35°C –38°C externally).
- Sterile ultrasound gel is used to maintain good conduction between the external electrode and the surface of the skin.
- The internal electrode is carefully placed into the subcutaneous fat space at the desired depth (ie,

BOX 1

Modified Tumescent Fluid (0.1% Lidocaine Concentration)

- 1000 mL normal saline
- 1000 mg lidocaine (50 mL of 2% plain lidocaine)
- 10 mL sodium bicarbonate
- 1.5 mL 1:1000 concentration epinephrine

intermediate layer) while maintaining at least 5-mm distance between the electrode tip and the underside of the dermis.

- A fan pattern of heating from the access point is made as both the internal and the external temperatures of the soft tissues in between the 2 electrodes are gradually heated toward their respective maximum temperature goals.
- To avoid overheating and creating “hot spots,” there is no heating within 1 to 2 cm of the access point.
- Keeping the internal electrode parallel to the skin is important when treating areas where anatomic prominences can cause unintended superficial treatment resulting in “end hits” where the electrode abuts directly against the dermis.
- Adjust the speed of the heat application and/or the amplitude of the strokes when heating the tissues in order to gradually increase the temperatures of both the internal and the external tissues.
- In general, the more quickly the hand piece is moved and the longer the distance of the strokes, the more quickly the external temperature will rise.
- Conversely, the more slowly the hand piece is moved and the shorter the amplitude of the strokes, the more quickly the internal temperature will rise.
- Once the proper cadence is found specific for the patient area treated, the more efficiently the heat can be transferred without the generator’s safety features defeating the delivery of the energy.
- Once the therapeutic temperatures both internally and externally are achieved, maintain the maximum temperatures for the clinically appropriate amount of time (typically 30–60 seconds).
- For large volumes of fat that are subjected to the heating, such as the abdomen in large patients, it is recommended that aspiration of the emulsified fats that are liberated by the heat is

performed in order to remove excess oil and fatty acids that can slightly increase the rate of seroma formation and fat necrosis if left for too long.

- Fractional bipolar RF is commonly performed at the same stage with the Morpheus8 device (InMode, Lake Forest, CA, USA). This device achieves subdermal adipose tissue remodeling in addition to bipolar thermal injury, leading to reorganization of the reticular dermis.
 - Fractional RF is subsequently used at a depth of 4 mm (double stacked) and energy of 35 with 50% overlap. The hand piece is applied firmly and perpendicular to the treatment area before delivery of RF energy pulses. In patients with thinner skin or darker Fitzpatrick types, energy settings are reduced by 20%.
3. Liposuction contouring
- Following application of RF energy, suction-assisted lipectomy may be performed.
 - Manual or power-assisted liposuction may be used.
 - Some practitioners may wish to perform liposuction in larger patients with substantial subcutaneous fat before application of the RF energy in order to save time in heating the soft tissues.
 - If fat is to be harvested for transfer, liposuction must be done before RF heating, which will cause lipolysis.
 - If the fat aspirate portion of any single anatomic area treated exceeds 1000 mL, consider



FIG. 1 A 27-year-old woman pre-RF- and 4 months post-RF-assisted liposuction.

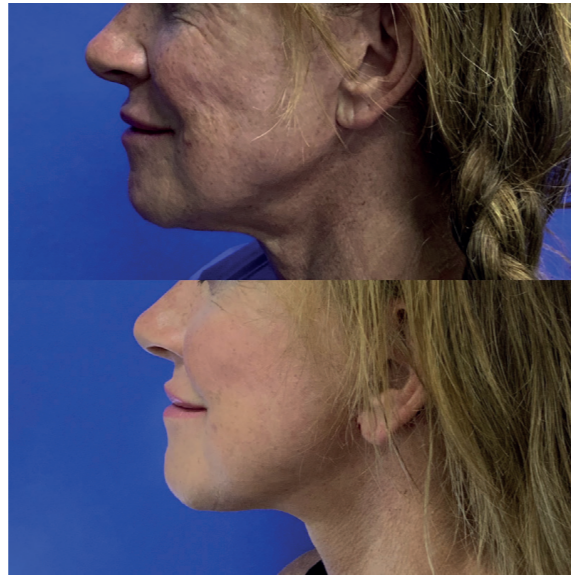


FIG. 2 A 54-year-old woman pre-RF- and 6 months post-RF-assisted liposuction of the lower face/neck.

placement of a closed suction drain to reduce the risk of seroma formation.

POSTOPERATIVE CARE

- Standard compression garments following liposuction are routinely worn by the patient for 10 to 14 days.
- Patients are instructed to not use any skin products for the first 3 to 4 days after fractional RF treatment.
- Except for the avoidance of high-salt foods, there are no dietary restrictions.
- Patients are encouraged to walk as soon as possible.
- Heavy lifting and exercise should be held off for 2 to 3 weeks.
- Sutures are removed between 7 and 10 days.

SUMMARY

- Significant and reproducible soft tissue tightening may be achieved with the application of RF to the skin and underlying fibroseptal network.
- This allows inclusion of patients for minimally invasive contouring with liposuction who may otherwise be deemed noncandidates because of the risk of unacceptable laxity postoperatively.
- In patients with good elasticity, it allows more aggressive and detailed liposuction to be performed.
- The procedure may be applied to nearly limitless areas of the body in addition to the trunk and

extremities, to include the face, neck, upper and lower eyelids, forehead, and any other areas of soft tissue laxity where conventional excisional operations may not be indicated or wanted by the patient at the time. Preprocedure and postprocedure results for body (Fig. 1) and face/neck (Fig. 2) areas demonstrate satisfactory soft tissue remodeling and contraction using bipolar RF assistance.

CLINICS CARE POINTS

- Radiofrequency has emerged as a safe and reliable method for minimally invasive skin tightening in the face and body areas under local anesthesia.
- Close temperature control over a period of time is essential for optimal fibroseptal network tightening.
- Bipolar radiofrequency technology allows for superior directional volumetric heating of tissue.

DISCLOSURE

E. Dayan: Book royalties: Thieme, Elsevier; Consultant: InMode; Co-Owner: CoreAesthetics. J. Marté: none. S.

Theodorou: Book royalties: Thieme; Consultant: InMode.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found online at <https://doi.org/10.1016/j.yacs.2021.02.001>.

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MORPHEUS & VORHER & NACHHER



INMODE



Lumecca & Morpheus8: Dr. S. Farhang



Morpheus8: esmé, the medspa



Morpheus8: esmé, the medspa



Lumecca & Morpheus8: Dr. S. Farhang

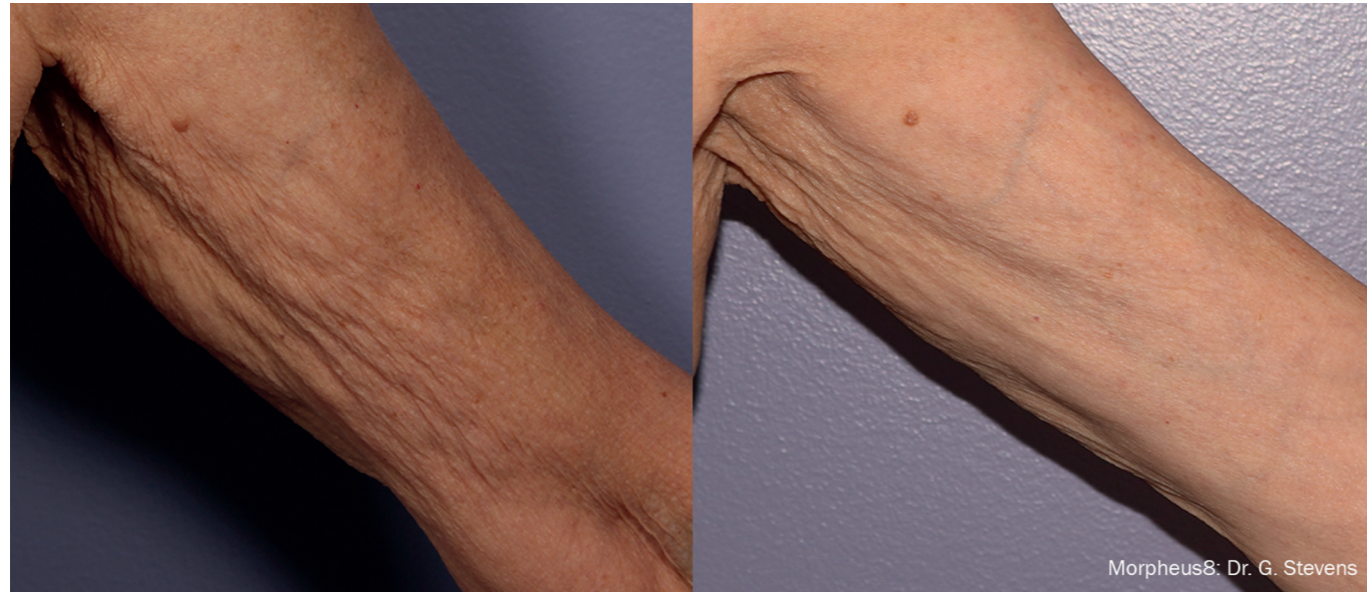


Morpheus8: Dr. R. Westreich



Morpheus8: Dr. G. Stevens





MORPHEUS8

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