

ORIGINAL ARTICLE

Cosmetic

Aesthetic Applications of Radiofrequency: Lymphatic and Perfusion Assessment

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Background: The use of radiofrequency in aesthetics has increased in popularity since the early 2000s. To date, there have been limited studies investigating the effect of thermal energy secondary to radiofrequency treatment. The purpose of this study was to evaluate perfusion and lymphatic assessment tools pre and post bipolar and fractional radiofrequency treatment.

Methods: A retrospective IRB-approved study was conducted between January 2019 and April 2019. Patients who were independently deemed appropriate candidates for radiofrequency soft tissue remodeling were evaluated. Diagnostic perfusion and lymphatic imaging obtained were reviewed using indocyanine green (SPY, Stryker) and optical coherence tomography (Vivosight OCT).

Results: A total of 63 patients were treated during the study period, of which 37 had diagnostic perfusion and lymphatic imaging. Average patient age was 47 (STD 12), 95% (35/37) of patients were women, and no patients were active smokers. In total, 27% (10/37) of patients were post-surgical patients with recurrent laxity, 32% (12/37) did not have enough skin laxity to justify traditional excisions procedures, and 41% (15/37) may have been candidates for excisional procedures but were willing to accept more moderate results to avoid excisions surgery. Indocyanine green perfusion and lymphatic assessment for bipolar and fractional radiofrequency, as well as optical coherence tomography pre and post radiofrequency, did not show compromise from thermal injury.

Conclusions: This study supports safety of radiofrequency in terms of preservation of tissue perfusion and lymphatic drainage. This correlated to our low clinical incidence of burns, prolonged swelling, or tissue ischemia. (*Plast Reconstr Surg Glob Open 2020;8:e3193; doi: 10.1097/GOX.00000000000003193; Published online 26 October 2020.*)

INTRODUCTION

Radiofrequency (RF) has been shown to be safe and efficacious in a variety of medical applications over the past 75 years (ie, electrocautery, cardiac ablations, oncologic therapy, orthopedic joint tightening, etc). ¹⁻⁴ RF use in aesthetic surgery gained momentum in the early 2000s when the Food and Drug Administration (FDA) first approved it for facial wrinkle reduction (ThermaCool, Thermage, Inc., Hayward, Calif.). ⁵ Over the subsequent 15 years, numerous RF devices have come to market. ^{2,4-6} The clinical efficacy of these devices for treatment of skin

and soft tissue laxity has been well documented in a variety of body areas, with high patient satisfaction rates.⁷⁻⁹

As RF energy is applied to different tissue types (ie, muscle, fat, skin), the inherent resistance or impedance leads to the generation of thermal heat. Tissues with higher impedance (ie, fat) generate more heat than tissues with lower impedance (ie muscle). This relationship is dictated by Ohm's law: Energy (J) = current × resistance × time. Unlike laser or light-based therapy, the electromagnetic RF current does not selectively target elements of skin (selective photothermolysis). This nonspecificity

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is advantageous, as RF can be used in all Fitzpatrick skin types.

Two mechanisms for RF-induced tissue tightening have been demonstrated in clinical and animal studies. When dermal temperatures approach 65°C, collagen partially denatures through the breaking of hydrogen bonds in the collagen triple helix structure. This fibril denaturation leads to an immediate collagen contraction and thickening.^{7,10,11} The second mechanism, and majority of the subsequent tightening, is due to the proliferative wound healing response that triggers neocollagenesis, angiogenesis, and elastin reorganization.^{7,10,12} Investigators such as Zelickson et al corroborated these mechanisms by documenting denaturation of collagen fibrils and elevated expression of type I collagen mRNA in skin samples treated with RF.¹³ Meshkinpour and colleagues also showed increased collagen production (type III > type I) in biopsies even 12 months after RF treatment.¹⁴

There are a number of delivery methods of RF energy. The most common are monopolar, bipolar, and fractional. Monopolar RF delivers current using 1 active electrode that contacts the skin and another that acts as a grounding pad.12 The soft tissue envelope contracts secondary to volumetric heating. Often there is a cooling mechanism applied to the skin to protect the epidermis, which also creates a reverse thermal gradient.2 In contrast, bipolar devices transmit electromagnetic current between two oppositely charged electrodes to achieve a more localized volumetric heating. 15,16 An RF cannula is placed beneath the soft tissue to be heated, and there is a second probe on the external surface of the skin. Fractional radiofrequency is delivered by an array of needles with proximal tips that are positively charged and a faceplate on the device that is negatively charged. This application of bipolar energy creates a fractional thermal effect in the subdermal target tissue. Also, hybrid technologies have emerged, which integrate other methods (ie, laser, vacuum) to optimize tissue tightening using less energy.

All these RF application methods generate thermal injury to tighten existing collagen and induce neocollagenesis over the subsequent 3–4 months. The balance between temperatures that trigger a nonablative wound healing response to remodel collagen as opposed to ablate collagen is relatively narrow. One of the major clinical concerns with RF is the ability to control temperatures and avoid injury to soft tissue elements. The depth and degree of energy transferred depends on several factors, including the size and configuration of the treatment device, energy settings, time of treatment, and inherent conductive properties of the tissue.

The purpose of this study was to objectively evaluate soft tissue perfusion and lymphatic function after treatment with bipolar RF as well as fractional RF. To our knowledge, this assessment has not been described in the literature.

METHODS

A retrospective IRB-approved study was conducted at a private plastic surgery practice (Dallas Plastic Surgery Institute, Dallas, TX) over a 4-month time period (January 2019–April 2019). Patients who were independently deemed appropriate candidates for radiofrequency skin tightening by a plastic surgeon (E.D.) voluntarily enrolled. No incentives were offered to patients for participating. Selection criteria included patients who desired skin tightening of the face, neck, or body areas. Three types of patients were treated: (1) patients who had a prior excisional procedure with recurrent laxity, (2) patients whose skin laxity was not severe enough for an excisional procedure, or (3) patients who preferred to not undergo traditional surgery and were willing to accept a more modest result with RF. All procedures were performed by a single surgeon to control for technique variation.

Patients were with treated with bipolar radiofrequency (Accutite/BodyTite/FaceTite, InMode, Lake Forest, Calif.) or fractional radiofrequency (Morpheus8 InMode, Lake Forest, Calif.), or both depending on the evaluating plastic surgeon's clinical assessment of soft tissue laxity. Patients with more severe soft tissue laxity were typically treated with both RF modalities. Exclusion criteria included patients with wound healing disorders, autoimmune conditions, infection, HIV, pregnancy, pacemaker devices, active smokers, and elderly patients with thin skin.

Treatment Protocol

Local Anesthetic/Tumescent Infiltration Technique

Once treatment areas were marked and maximal areas of laxity were identified, the patient was prepared and draped in the standard fashion, with chlorhexidine solution. Tumescent infiltration technique commenced, as previously described by Theodorou and Chia. The tumescent solution (1000 mg lidocaine with 1.5 ml epinephrine and 10 ml bicarbonate in 1 L of Ringer's lactate) was slowly injected into the deep and intermediate subcutaneous space with a 14-gauge cannula. The infiltration began deep into the superficial fascial system. Once the deep subcutanteous space was infiltrated, the more superficial infiltration commenced. This ensured that subsequent application of RF (with or without subsequent liposuction) was pain-free for the patient while awake. No patient had a lidocaine load exceeding the recommended maximum of 35 mg lidocaine/kg body weight. Patients were given 10 mg diazepam, 500 mg cephalexin, and 5/325 mg of hydrocodone/acetaminophen orally 1 hour pre-procedure.

Bipolar Radiofrequency Technique

Patients who desired soft-tissue tightening of the face/neck or body areas underwent treatment with bipolar radiofrequency (AccuTite/FaceTite/BodyTite; Inmode, Lake Forest, Calif.) under local anesthesia.

The device parameters (AccuTite/FaceTite/BodyTite; InMode, Lake Forest, Calif.) were set with an internal cuttoff temperature of 68°C and external cutoff temperature of 38°C in all cases. Sterile water-soluble ultrasound gel was applied liberally over the treatment area to improve RF conduction and electrode movement over soft tissue surface. The treatment area was divided into segments for systematic heating. An 11 blade was used to make a 2-3 mm

access incision. The internal RF probe was placed under the skin at approximately 1–3 cm depth depending on the treatment area. The bipolar RF device was then moved in a radial manner antegrade and retrograde to pre-tunnel. Once pre-tunneling was complete, the bipolar device was passed systematically from segment to segment to achieve aforementioned target temperature. The bipolar RF was engaged via a foot pedal only on the retrograde motion of the handpiece for optimal control. RF was stopped within approximately 1 cm of the entry port to prevent overheating with each pass. Audible alerts from the bipolar device indicated when target temperature was reached, at which point heat continued to be applied for approximately 30–60 seconds.

Fractional Radiofrequency Technique

Patients who required soft-tissue tightening of the face/neck or body areas underwent treatment with fractional radiofrequency (Morpheus8; InMode, Lake Forest, Calif.) either as a standalone treatment or in addition to bipolar radiofrequency. When fractional radiofrequency was performed as the only treatment, topical anesthesia was used (Lidocaine/Prilocaine). In cases where bipolar radiofrequency was concomitantly performed, prior local tumescent anesthesia was used. Variable depth settings on the fractional RF device were adjusted based on body area (periorbital: 2mm; face: 3mm; body: 4mm). The fractional radiofrequency technology involves 24 coated needles delivering RF energy only through the exposed 0.5 mm distal end. The thermal field is stretched between the needle tips and the skin surface. After treatment areas were identified and analgesia was confirmed, the device was firmly pressed against the soft tissue and engaged via a footpedal. Double-stacked pulses were applied at an energy setting of 30, and the device was advanced with 50% overlap until the treatment area was completely covered.

Lymphatic Assessment

Lymphatic function was assessed by the use of a 0.2-cc subdermal injection of indocyanine green dye in 3–4 locations surrounding the treatment area. The SPY PHI imaging system (Stryker, Kalamazoo, Mich.) was utilized to map the subdermal lymphatic function to local lymph node basins. This technique has been well described in the assessment of lymphedema and lymph node mapping.¹⁷

Lymphatic Assessment of Bipolar Radiofrequency and Combination Bipolar and Fractional Radiofrequency

Lymphatic assessment of bipolar radiofrequency and combination bipolar and fractional RF treatment was performed post-treatment only. Prior trials demonstrated erroneous spreading of subdermal ICG secondary to compression and tandem movement of the internal cannula and external electrode, which confounded imaging when performed pre-treatment. In bilateral treatment areas, the contralateral side was injected pre-treatment to obtain a baseline of lymphatic function for post-treatment comparison of the treatment area. Subsequent to this lymphatic

mapping, the contralateral side was treated with RF as previously described.

Lymphatic Assessment of Fractional Radiofrequency

Lymphatic assessment of fractional radiofrequency treatment was dynamically evaluated pre-, during, and post-treatment. Subdermal injections of 0.2-cc ICG were performed pre-treatment in 3–4 locations surrounding the treatment area. In bilateral areas, the contralateral side was injected pre-treatment, and lymphatic function was mapped to obtain a baseline lymphatic map. Subsequent to this data collection, the contralateral side was treated with fractional radiofrequency.

Perfusion Assessment

Two methods were independently used to determine subdermal perfusion assessment. Indocyanine green (ICG) was injected intravascularly (0.3 cc) once target temperature was reached with the bipolar RF device and after treatment with the fractional radiofrequency device. This provided a real-time visualization of soft tissue perfusion. Video was obtained of this dynamic perfusion assessment to determine any areas that may have suboptimal perfusion. The Vivosight optical coherence tomography (Kent, United Kingdom) imaging system was additionally utilized on a subgroup of our cohort as a second imaging modality to measure subdermal perfusion pre and post RF treatment. This noninvasive imaging system generates cross sectional images of soft tissue, including a dynamic subdermal vascular plexus assessment.

RESULTS

A total of 63 patients were treated with bipolar and/or fractional radiofrequency for aesthetic concerns between January 2019 and April 2019. Of these patients, 37 had diagnostic lymphatic and perfusion assessment, as outlined above. Average patient age was 47 (STD 12), 95% (35/37) of patients were female, and no patients were active smokers. In total, 27% (10/37) of patients were post-surgical patients with recurrent laxity, 32% (12/37) did not have enough skin laxity to justify traditional excisional procedures, and 41% (15/37) may have been candidates for excisional procedures, but were willing to accept more moderate results to avoid traditional surgery. Demographic data of this cohort can be found in Table 1. Of these 37 patients included in our study cohort, 27% (10/37) were treated only with bipolar radiofrequency, 12 (32%) were treated only with fractional radiofrequency, and 40% (15/37) were treated with both modalities in one treatment session. Treatment areas and device settings can be found in Table 2.

Lymphatic Assessment

Bipolar Radiofrequency Lymphatic Assessment

Subdermal lymphatic function was assessed following bipolar radiofrequency treatment (internal temperature: 68°C, external temperature: 38°C). Subdermal injection of 0.2 cc of indocyanine green dye in 3–4 locations

Table 1. Demographic Data

No. Patients Enrolled in the Study	n = 37
Average age	47 (STD 12)
Female/Male	35/37 (95%)
Smokers	0
Post-surgical patients with recurrent laxity	10/37 (27%)
Post-surgical patients with recurrent laxity Not enough skin laxity for traditional excisional	12/37 (32%)
procedure	
Patients did not desire traditional excisional	15/37 (41%)
procedures	

Table 2. Treatment Areas and Parameters

	Total No. Patients	Treatment Area	
Bipolar radiofrequency	10	Lower face/neck	3
(accutite, facetite, body)		Arms	4
		Thighs	2
		Abdomen	1
Fractional radiofrequency	12	Lower face/neck	7
(morpheus8, InMode)		Arms	3
•		Thighs	1
		Abdomen	1
Both bipolar and fractional	15	Lower face/neck	8
radiofrequency		Arms	3
,		Thighs	3
		Abdomen	1

surrounding the treatment area was performed and the SPY PHI imaging system (Stryker, Kalamazoo, Mich.) was utilized to map the lymphatic function to local lymph node basins. Early attempts to map subdermal lymphatic function pre-treatment proved futile, as the internal and external electrode compression and movement erroneously spread the ICG dye. In bilateral treatment areas, the contralateral side was injected pre-treatment to assess baseline lymphatic function. All patients demonstrated normal appearing contralateral lymphatic channels and peristaltic function. No patients demonstrated venous insufficiency or subclinical lymphedema. This served as an internal control for comparison to the post-treatment lymphatic imaging of the treatment side. Subsequently the contralateral area was treated with bipolar RF. Posttreatment lymphatic mapping demonstrated an equivalent peristaltic function of lymphatic channels and migration toward local lymph node basins as the control side. Lymphatic transit time measurements were variable, but had no major subjective discrepancy among individual patients. In all patients, discrete lymphatic channels were visualized, as opposed to previously described 'stardust' appearance of dysfunctional lymphatics. $^{18\mbox{-}20}$ Of note, in 3post-surgical patients, the ICG dye did not transit a portion of the previous incision.

Fractional Radiofrequency Lymphatic Assessment

As opposed to bipolar radiofrequency lymphatic assessment, the fractional radiofrequency impact on lymphatics was evaluated pre-, intra, and post-treatment. Subdermal injections of 0.2-cc ICG were performed before RF in 3–4 locations surrounding the treatment area. Fractional

radiofrequency treatment then commenced. The near infrared SPY PHI camera was utilized to assess movement of the ICG through the local lymphatic channels throughout treatment. (Video 1) (See **Video 1** [online], which displays lymphatic imaging pre/post fractional radiofrequency treatment)

Assessment of ICG demonstrated that the fractional radiofrequency needles reached the subdermal space and migrated the ICG dye to subsequent treatment areas in a similar fractional array as the needles. Upon close examination, ICG dye that was migrated to adjacent treatment areas by the RF needles entered local lymphatic channels and moved toward local lymph node basins. Discrete lymphatic channels were subjectively visualized in all cases. Resolution or concentration of the ICG was not high enough to visualize peristaltic function of the lymphatic channels; however the unidirectional movement toward local lymph nodes suggests that there was peristaltic function intact, and lymphatic function of treatment area was not impacted or minimally impacted by thermal energy.

Perfusion Assessment

Two methods were independently used to determine soft tissue perfusion assessment. ICG was injected intravenously (0.3 cc) once target temperature was reached with the bipolar RF device and after treatment with the fractional radiofrequency device. This provided a realtime visualization of soft tissue perfusion. (Video 2) (See Video 2 [online], which displays perfusion assessment after bipolar and fractional radiofrequency.) This method of perfusion assessment has been well documented in reconstructive surgery, particularly in flap planning and assessment.²¹⁻²³ In bilateral cases we found no difference between RF-treated tissue and contralateral baseline pretreatment tissue in terms of subjective evaluation of perfusion using ICG SPY PHI system. This correlated with clinical findings showing no indication of soft tissue vascular compromise (ie, soft tissue loss, epidermolysis). It was noted however that the brightness of the ICG dye was relatively blunted. This was attributed to the epinephrine's vasoconstrictive effect in our wetting solution as adjacent body areas not treated with wetting solution did have brighter ICG signal. Despite this, the control side and treatment side demonstrated no subjective difference.

To further visualize subdermal perfusion, we used the optical coherence tomography (Vivosight Kent, United Kingdom) imaging system in 10 patients pre and post combination bipolar and fractional RF treatment to assess cross sectional dynamic subdermal perfusion. (Video 3) (See Video 3 [online], which displays perfusion assessment with optical coherence tomography.) Subjective comparison demonstrated equal perfusion after reaching target external and internal temperatures in all cases.

DISCUSSION

Since the first monopolar RF device was approved by the FDA in 2002 (ThermaCool; Thermage. Inc., Hayward, Calif.), more sophisticated RF devices have been developed to deliver RF energy in different manners (ie, bipolar, multipolar, fractional, etc) with more safety features. 4,6,12 Clinical studies and animal studies demonstrate that subdermal temperatures from 65–68°C and skin surface temperatures ranging from 38–42°C are required to obtain optimal contraction. Further, it has been proposed that the mere act of heating fibroblasts may stimulate increased collagen production. 24

If temperatures exceed a critical heat threshold, there is the potential for collagen ablation and full thickness burn. 13,25 There is no single target shrinkage temperature for collagen contraction. 13,26 The delivery of RF energy is a function of time and temperature to allow for maximal epidermal protection while optimally heating the dermal collagen. For example, studies suggest that for millisecond exposures, the shrinkage temperature is above 85°C, while for exposures of several seconds, the shrinkage temperature is in the range of 60-65°C. 13,26 For every 5°C decrease in temperature, a 10X increase in time is required to achieve a comparable collagen contraction. 13,26 RF volumetric dermal heating is favorable, as it avoids targeting specific dermal elements and instead leverages various tissue impedances to generate desired heat and contraction. 27

The safety and efficacy of RF has been demonstrated in numerous animal and clinical trials. 1,8-10,12,27,28 However, to our knowledge, objective assessment of perfusion and lymphatic function of soft tissue have not been performed in aesthetic applications of RF. In the authors' cumulative experience with RF, there have been infrequent complications related to burns or prolonged swelling/seromas indicative of perfusion or lymphatic compromise (1%-3%). This begs the question, why undergo such a study if there is no perceived clinical problem? With the rise of popularity of these devices, it is critical to understand implications of treatment before clinically significant manifestations-particularly in the elective aesthetic setting. In our study, we found that both lymphatic function and soft tissue perfusion was not significantly impacted by electromagnetic RF induced heat to 68°C internally and 38°C externally.

Evaluations of bipolar and fractional RF independently and in combination demonstrated no demonstrable impairment on lymphatic function. In fact, studies suggest that thermotherapy may in fact augment or improve lymphatic function. Investigators hypothesize that increased flow with heat is associated with a reduction in the concentration of proteins, which could suggest increased fluid in the cellular interstice, greater capillary arterial filtration, and consequently greater hydration of the interstice leading to the formation of less-concentrated lymph. This concept of thermotherapy, or heating soft tissue to 40°C at the surface is utilized for the treatment of lymphedema.²⁹ Thus, we would not expect negative impact on lymphatic function at our treatment parameters.

The potential for full thickness thermal injury is of clinical concern for practitioners not experienced with aesthetic radiofrequency techniques. The bipolar (accutite, facetite, bodytite; InMode, Lake Forest, Calif.) and fractional bipolar RF (Morpheus8; InMode, Lake Forest, Calif.) devices used in this study have regulation of thermal

energy with features such as continuous internal and external temperature monitors as well as impedance control that will shut down RF energy past pre-set parameters. Despite this, it is useful to visualize any potential compromise of subdermal perfusion. In our study, imaging with ICG and Vivosight OCT subjectively demonstrated maintained perfusion post-RF treatment. This is consistent with the clinical findings without any evidence of burns or epidermolysis post-procedure.

There are a number of limitations in our study. Overall, the number of patients included in this study was limited. The 37 patients included were spread among a variety of body areas. Dermal thickness and local perfusion as well as lymphatic drainage can be variable and was not controlled for in this study. These patients were imaged after uncomplicated radiofrequency treatments. There is a possibility that in cases where thermal injury may occur there would be findings of compromised lymphatic flow or perfusion. Locations of ICG injection for lymphatic assessment were not standardized and may confound results. Also, 10/37 patients had RF treatment for recurrent laxity after surgical excision, which was not controlled for. The use of epinephrine in the tumescent fluid may have potentially masked changes in perfusion, although, when applicable, contralateral treatment areas were used as an internal control to assess for changes in perfusion, assuming the control side was within normal limits. This study data are based on one clinician's technique and settings for RF treatment. Thus, the data may not be applicable for the diverse array of treatment techniques or energy/ time settings.

CONCLUSIONS

The results of this study demonstrate that bipolar and fractional bipolar radiofrequency do not appear to impact subdermal lymphatic flow or perfusion either in isolation or in combination. More studies are needed on these increasingly popular technologies to ensure safety and efficacy.

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