Journal of Dermatology and Therapies (JDT)

HENDUN RESEARCH ACCESS

Case Report

Evaluation of Radiofrequency Devices in Aesthetic Medicine: A Preliminary Report

Thomas Narsete*[1], Daniel S Narsete[2]

[1] Plastic Surgeon, Denver, Colorado, USA

[2] Medical Device Representative, Denver, Colorado, USA

In recent years, there has been an explosion of non-invasive devices to promote wrinkle, cellulite and fat reduction in patients who do not want invasive surgery. According to the American Society of Plastic Surgery in 2015 the annual number of minimal or non-invasive procedures has nearly tripled since 2000. In 2013, the International Society of Aesthetic Plastic Surgery reported over 1.6 million liposuction procedures were performed globally. During that time, nearly 95,000 non- surgical fat reduction procedures and 294,000 non- surgical skin tightening procedures were done in the USA alone. Many studies are used to promote the sales of non- invasive devices, yet objective peer review studies are scarce. One of the more popular and growing uses of technology in aesthetic medicine is that of Radiofrequency (RF). The purpose of this study is to review the evolution of more commonly used radio frequency (RF) based devices. It also aims to generate a professional opinion on their use and efficacy.

History

The use of Radiofrequency (RF) in medicine is not new concept. The first use was in electro-caudery during the 1920's [1]. They have since been used in everything from ablation for sleep apnea, to general surgery to generate images of the human body (MRI). RF at non-ablation levels are used for non- invasive cosmetic treatments which utilize lower levels of heat and longer durations of time. In contrast, microwaves are a form of electromagnetic radiation which creates a considerable amount of heat. Pulsed electromagnetic fields, PEMF, are non-thermal and have been used to heal bone injuries as well.

Radio frequency based devices are among the more common ones used to promote patient satisfaction as compared to laser based modalities. Gold et al [2] reviewed 56 patients with mild to moderate facial wrinkles who received three full faced RF treatments at 4-6 week intervals. They were evaluated at 12 and 24 weeks after the last treatment. Clinical photographs were reviewed by a clinical investigator and patients using the Global Aesthetic Improvement scale. They found that the Fitzpatrick Wrinkling and Elastosis Score significantly decreased in their patient study. Their conclusion was that the combined bipolar RF and infrared treatments were safe and effective in wrinkle reduction, and improvement in skin tone.

Thermage (Solta), Pelleve (Cynosure), VelaShape/Smooth (Syneron), Pallogen (Lumenis), TiteFx (Invasix), Vanquish and Exilis (BTL) and Venus Freeze/Legacy (Venus Concept) are all RF devices. The basis of patient benefit is a reduction of wrinkles, cellulite and body mass. These devices typically use the synergy of infrared light, mono, bipolar and multipolar radio frequency combined with gentle vacuum suction and mechanical manipulation. The dermal and subdermal effects are designed to improve blood circulation, promote neocollagenesis, enhance lymphatic drainage, and increase the permeability and metabolic rate of fat cells. Heat in the range of 39-44+ degrees Celsius for 5-40+ minutes is generated to stimulate the healing mechanism and new collagen growth. The treatments are designed to achieve a reduction in fat circumference and wrinkle reduction. The side benefit is a relief of minor aches and pains.

Technology

In order for any RF device to work it must have positive and negative poles to create an electrical charge or completed circuit. The general schematic for an RF device consists of a generator and a hand piece with a single or bi-polar electrodes. When placed on the skin these electrodes create an electromagnetic field that causes molecules to oscillate against one another through resistance. This resistance is measured in Ohms and creates significant friction. RF is an electrical current causing ion to collide and will take the path of least resistance to achieve this process. The kinetic energy is converted to heat, designed to control the healing process and tissue regeneration and thus mechanism of action. Some hand pieces include cooling and temperature sensors for heat regulation, while others do not.

Collagen itself is that of a triple helix designed structure held together via hydrogen bonds. When heat is applied at a consistent level and fixed interval the hydrogen bonds break and cause the denaturation of collagen [3]. While light based modalities use temperatures in excess of 65 degrees Celsius for miliseconds most RF based technologies denature collagen at lower temperatures (39-44 degrees Celsius) for longer periods of time measured in minutes versus milliseconds.

An added benefit to the growth of RF in medicine is radiofrequency is not a laser or light based modality. Depending on the wavelength of the photon emitted with a laser it will absorb into a specific color. Anderson [4] demonstrated this principle in the concept of Extended Theory of Selective Photothermolysis. By using lasers selective thermal damage of non-uniformly pigmented structures of biological

Corresponding author: Thomas Narsete, 1221 S. Clarkson Street, Suite 300, Denver, Colorado 80210 USA, Tel: 512-736-3700; Fax: 720-476-4886; E-mail: thomasnarsete@gmail.com

Received: March 03, 2017, 2016; **Accepted:** March 16, 2017; **Published:** March 20, 2017

tissues is possible. It is achievable to destroy specific targets with light based modalities using heat, which is a similar concept to RF based technology. However light based technologies are limited to lower skin types as pigment absorption and in turn melanocyte activity can cause complications. Radiofrequency based tecnologies do not have this limitation as the electromagnetic field is created by the attraction of ions vs absorption into colors. While both concepts strive to tighten tissue, it should be noted that another difference between the two relative concepts is patient comfort. When using, RF based technology it is generally unnecessary to used anesthetics or nerve blocking agents.

Depending on the application and desired result practitioners use the amount of heat, frequency of polarity and pulse duration to determine outcomes. With any bipolar or multipolar RF, half the distance between two electrodes is the maximum potential depth of penetration. If the distance between electrodes is 5cm, the maximum depth of penetration of the RF is 2.5cm. This suggests that the more superficial fat will get more benefit, and skin tightening can result from the treatments. For example, if the RF device is used for "non-invasive body contouring" lipolysis on a micro level can occur in subcutaneous fat, at sustained temperatures above 44+ degrees Celsius. When the skin temperature is raised, body stress hormones are released. Hormone sensitive lipase is released which breaks down triglycerides into fatty acids, which then exits the fat cells into the bloodstream. Thus, the fat cell volume is slowly reduced. Though a novel concept little published data exists to present a consistent result as the depth of penetration in RF is variable, with respect to molecular resistance.

There are significant challenges for hand piece design and application with respect to size and scope of pole distance and placement. If a practitioner is using a device where poles are 5 cm apart it is not practical to use for face, neck and decollate applications. The hand piece is large, cumbersome and covers the entire face. Conversely if a practitioner is using a smaller applicator with poles 1-2 cm apart there is very little utility in covering larger areas such as the abdomen, buttocks or thighs.

Evolution

The first wave of RF based technology came about in the early 2000's with the introduction of monopolar based technology. Monpolar RF uses a ground pad and a pole placed on the skin. The energy travels from the electrode through the skin to the grounding pad. Higher levels of energy (100 watts+) are needed to complete the circuit. Many practitioners found that achieving therapeutic levels of heat was a challenge as patient discomfort can be high.

To combat issues with patient discomfort Bipolar technology was developed. This new concept used a positive and negative electrode which are both placed on the skin. The energy between the two points then completes the circuit. The difficulty with bipolar energy comes when an electrode loses contact with the skin, and an arc is created. Skin burns and blisters can occur. The other change that came about was moving the hand piece around the area treated. This allowed for less patient discomfort and higher temperatures to be achieved.

The third generation of RF based technology was tri-polar RF. Tri polar circuits have two negative and one positive electrode to complete the circuit. RF currents can be applied to the body without discomfort as the current change is too quick to depolarize a nerve. This technology also allows for a theoretical deeper penetration of RF energy as the poles are farther out than that of bi-polar RF.

The fourth generation of RF was multipolar radiofrequency. These treatments are designed to change the direction of the electromagnetic field while the practitioner moves the hand piece. Some hand pieces also include a vacuum to manipulate lymphatic drainage. The concept is to treat at a potentially deeper point into sub-cutaneous fat and induce neocollagenesis with a bulk heating effect. A few of the drawbacks for this technology include having to use mulitple hand pieces to treat separate areas.

One challenge that has remained in the use of radiofrequency is the consistency of results. This is largely due to the resistance of RF in different types and densities of skin. Considering electromagnetic enery will take the path of least resistance there are differing opinions as to why this is. Theories range from skin hydration, sun damage, age, to collagen and elastin densities. As a response to this challenge radiofrequency combined with microneedling has recently come about in what can be described as the fifth generation of RF based technology. This newer technology enables the practitioner to control the depth of the RF in depths up to 3.5 milimeters.

Radiofrequency Technologies

Thermage, Exillis, and Pelleve are all monopolar RF devices that use applications for the face and some use for body, including wrinkle reduction. Thermage was FDA cleared in 2002 and utilizes a cooling compartment to reduce the skin temperature. Technically the depth of the RF wave travels throughout the body to the grounding pad, with the therapeutic depth being very shallow in the epidermis or superficial dermis. This has lead to some significant challenges for the technology as a whole. Studies on tissue cooling have previously been reported [5]. The hand piece for Thermage has different tips for different areas of the body to be treated, and vibration for the patient's comfort. The internet reviews from patients do not support long term use for wrinkle reduction. Other limitations with mono-polar RF reside with small applicators treating large areas such as the abdomen. While this may work for smaller areas such as eyelids it is just not practical from a time standpoint to use for large areas. Another issue with some of the first models of mono-polar RF was temperature control with practitioners having to use external infrared guns to determine temperatures.

In 2005 VelaShape ™ was the first non- surgical FDA cleared device for non- invasive face and body contouring using bi-polar RF. The contour improvement required three stages designed to reduce circumferential fat and cellulite reduction with a maximum depth of 1.5 cm. The procedure can be performed anywhere in the body, and patients with a BMI below 30 were preferred. The VelaShape combines four different technologies: infrared light, bipolar radiofrequency, a pulsed vacuum, and mechanical rollers. The vacuum technology lifts targeted tissue closer to the energy source, and the bipolar RF evenly distributes the heat to targeted cells. The rollers help mechanically reduce cellulite. The VelaShape™ is more powerful 50W than the VelaSmooth™ (25W). [6] The infrared component of the devices target dermal water and the radiofrequency target deeper layers of the skin. The thermal energy results in skin tightening.

Sadick and Mulholland [7] reported 40% improvement in cellulite and a large percentage of thigh circumference in 35 patients undergoing VelaSmooth treatments. Alster and Tanzi [8], reported 90% improvement in thigh and buttock, and cellulite reduction in 20 patients who underwent VelaSmooth treatments, twice weekly for 3 weeks. Sadick and Magro showed a reduction in thigh circumference in 71.9% of treated patients after 4 weeks of treatments using VelaSmooth. However, the study did not show improvement at 8 weeks follow up. In a series of 29 postpartum women, Brightman et al, [9] showed significant reduction in upper arm and abdominal circumference at 1 and 3 month follow ups following VelaShape treatments.

A challenge that has come about with bi-polar RF is that the practitioner is only treating one depth of skin or subcutaneous fat. With only targeting one level of dermis the surrounding tissue is largely unaffected leading in some instances to lackluster results. This problem lead to the development of the third-generation RF using three poles or tri-polar RF. Pollogen™ (Lumenis) came about to attempt and solve this problem and was FDA cleared in 2011. While many modalities of RF can only treat the face or body with different hand pieces, the idea behind this technology is to be able to treat both the face and body. By having three poles spread out further than that of bi-polar RF the practitioner is also treating different levels of the skin based on the movement of the hand piece and the distance of the RF poles. The issue with arching is also solved within this concept as the polarity direction can change fast enough to overcome the issue.

Another issue that came about in the evolution of RF was that of depth of penetration. The Venus Freeze ™ is a device that in 2011 attempted to solve this issue. It delivers multi polar radiofrequency and PEMF to the skin to produce a dense and uniform heat matrix. There are two hand pieces. The larger head uses eight poles in a concentric circle with equally distanced apart and a smaller hand piece with four poles and max depth of 2.75 cm. The second smaller hand piece has four poles shaped in a diamond configuration and a treatable depth of up to .75 cm. Conceptually the algorithm of polarity changes rapidly (1 HZ) from opposing poles changing the direction of the electromagnetic field. The treatment is designed to promote collagen synthesis and contraction. It was the first FDA cleared technology to combine multipolar RF and PEMF.

In 2013 the Venus Legacy ™ also approved by the FDA, added two new hand pieces. The first is a large hand piece using eight poles on an outer circle and four on an inner circle with a vacuum and a temperature sensor. It has a potential maximum depth of 4.25 cm and was designed to treat sub-cutaneous fat along with skin tightening. The second addition was a smaller hand piece with a max penetration of 1.75 cm, also using suction. The device delivers PEMF with multi-polar radio frequency with a hand-held device.

Microneedling (MN) with RF has recently been added for new technology. The new INFINI (Lutronic) and Vivace (Aesthetics Biomedical) were FDA Cleared in 2016 for the treatment of facial wrinkles. Where non-invasive RF struggles with consistency in depth of penetration microneedling precisely controls the depth of collagen denaturation. It is designed to address wrinkles and sagging skin by applying RF directly into the dermis through micro needling and insulated needles. By coating the needles of inserted into the skin the RF can only travel from non-insulated pole to non-insulated pole. This insulated needle approach allows for the practitioner to control the depth of RF delivery. It also has a coagulative effect for hemoglobin and allows for practitioners to introduce Platlette Rich Plasma and other cascade based regenerating serums. This is possible because the channels created by the needles remain open for a period of time. Previous RF technologies delivered the energy current from the outside of the skin, the advantage of this technology is direct stimulation of the dermis. The benefit is based on direct denaturing of dermal collagen with controlled heat and depth. The microneedling uses very small, sterile needles to gain entrance to the dermis.

Fractional RF with microneedling has recently been studied to treat acne scars. Chandreshekar [10] evaluated 31 patients with acne scars using fractional RF with microneedling. Their study group received four microneedling RF treaments with 6 weeks interval for 6 months. Topical anesthesia and nerve blocks were used for patient comfort. Goodman and Baron's Global acne scar improvement chart was used to grade the results. 80.64% showed qualitative improvement by two grades, and 19.35% by 1 grade. Quantitative improvement showed 58% with moderate improvement, 29% with minimal improvement, 9% with good improvement and 3% with very good improvement. Long term studies are not available to assess the effectiveness of microneedling compared to other RF modalities.

It should be noted that while microneedling with RF is promising for advancements it does have some drawbacks. One is that it is too superficial for fat reduction [11]. The depth of penetration is too superficial to be effective for fat reduction. There is a pain element to consider as it is necessary to use topical anesthetics when using one of these devices. However preliminary online feedback from patients suggests this new technology may have some promising results.

Sasaki studied the depth of microneedling, the time of medication delivery and efficacy of treatment. Esthetic microneedling has demonstrated skin permeability to cosmetic ingredients by creating reversible skin channels in the skin. He excised microneedled skin and determined the depth of microneedling penetration. The depth of penetration matched the 1.0mm settings, and less consistently over 1.5mm, and platelet rich plasma(PRP) was delivered through the needle marks into the dermis [12]. The optimum time for medication delivery was 5-30 minutes after the microneedling. Their study showed statistically significant improvement in wrinkle effacement, skin laxity, scar softening and hairgrowth. They concluded that MN and PRP was an effective and safe treatment according to their guidelines.

Conclusion

There are many benefits and challenges associated with the use of RF in aesthetic medicine. Hand piece size alongside treatment area, permeation of RF into the skin and consistency of results are all challenges. It seems evident that challenges associated with RF arching and temperature control have improved significantly in recent generations of technology.

It is clear that the use of Radiofrequency in medicine for cosmetic purposes continues to evolve and is likely to stay. Starting with the introduction of mono-polar RF now to multi-polar and even micro needling with RF aesthetic medicine has progressed through a technological evolution. Over the last 15 years there have been five separate generations RF with the most recent developments occurring in 2016. All of these studies show improvement in wrinkle and fat reduction. However, long term data has not been established. Further studies are needed in that area.

References

1. Loulis MS, Goldberg DJ (2012) Radiofrequency in Cosmetic Dermatology: A Review. *Dermatol Surg* 38: 1775-1776.
2. Gold AH, Pozner J, Weiss R (2016) A fractional Bipolar Radiofrequency Device Combined with a Bipolar Radiofrequency and Infrared Light Treatment for Improvement in Facial Wrinkles and Overall Skin Tone and Texture. *Aesth Surg J* 36: 1058-1067.
3. Sadick N (2008) Tissue tightening technologies: fact or fiction. *Aesthet Surg J* 28: 180-188. [crossref]
4. Altshuler GB, Anderson RR, Manstein D, Zenzie HH, Smirnov MZ (2001) Extended theory of selective photothermolysis. *Lasers Surg Med* 29: 416-432. [crossref]
5. Mulholland RS, Paul MD, Chalfoun C (2011) Noninvasive body contouring with radiofrequency, ultrasound, cryolipolysis, and low-level laser therapy. *Clin Plast Surg* 38: 503-520. [crossref]
6. Nassab R (2015) The evidence behind noninvasive body contouring devices. *Aesthet Surg J* 35: 279-293. [crossref]
7. Sadick NS, Mulholland RS (2004) A prospective clinical study to evaluate the efficacy and safety of cellulite treatment using the combination of optical and RF energies for subcutaneous tissue heating. *J Cosmet Laser Ther* 6: 187-190. [crossref]
8. Alster TS, Tanzi E (2005) Cellulite Treatment using a novel combination Radiofrequency, infrared light, and a mechanical tissue Manipulation Device. *J Cosmet Laser Ther* 7: 81-85.

9. Brightman L, Weiss E, Chapas AM, et al. (2009) Improvement in arm and postpartum abdominal and flank subcutaneous fat deposits and skin laxity using bipolar radiofrequency, infrared, vacuum and mechanical massage device. *Lasers Surg Med* 41: 791-798.

10. Chandreshekar (2014) Evaluation of Microneedling Fractional Radiofrequency Device for Treatment of Acne Scars. *J Cutaneous and Aesthetic Surgery* 7: 93-97.

11. Sadick N, Magro C (2007) A study evaluating the safety and efficacy of the VelaSmooth system in the treatment of cellulite. *J Cosmet Laser Ther* 9: 15-20. [crossref]

12. Sasaki (2017) Micro-Needling Depth Penetration, Presence of Pigment Particles, and Fluoroscein Stained Platelets: Clinical Usage for Esthetic Concerns. *J Aesth Surg* 37: 71-83.