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The Basic Science of Radiofrequency-Based Devices

Michael Kreindel and Stephen Mulholland

Abstract

This chapter outlines the basic science and specific principles of operation for radiofrequency (RF) technologies with a focus on minimally-invasive applications enhancing liposuction procedure. Before discussing the parameters, settings and techniques for radiofrequency-assisted lipolysis (RFAL) and fractional RF subdermal treatment, it is important to understand the fundamentals of the basic science of RF technologies and applications. The chapter accurately describes the physics of the processes occurring during RF-based treatment, and the factors affecting its safe and efficacious outcome. The discussion of RF-based devices will use terminology and definitions provided by FDA guidance for electrosurgical devices. Measurements and computer simulations conducted by the authors to illustrate importance of different parameters for the specific treatments of skin and subcutaneous fat are also presented.

Keywords: radiofrequency, monopolar, bipolar, RFAL, micro-needling

1. Introduction

1.1 RF treatment effect

The method of operation for the vast majority of esthetic energy-based devices (EBD's) is through the generation of heat causing physiologic modifications to the human tissue. RF energy is a method to deliver heat into the human body at a level and distribution required for the specific application. For sub-necrotic thermal applications, this heat can be a relatively low temperature for fibroblast stimulation and metabolism acceleration (hands free RF devices). Alternatively, the heat can be more aggressive, ablative coagulative and necrotic in nature (RF assisted lipolysis or Fractional micro-needling technology). It may occur that during the same treatment, RF energy effects will be both non-ablative on the skin and ablative-coagulative sub-dermally.

In most instances with RF, microwave and light-based technologies, heat is the result of a common pathway for the desired thermal effects. This understanding has given rise to an entire generic category of esthetic and medical EBD's. A variety of technologies and devices have been developed based on thermal treatment of tissue, either ablative or non-ablative, selective, or non-selective, using optical energy, RF electrical current, focused ultrasound to generate the heat. The common outcome of these devices leads to some heat-assisted transformation of local tissue. This thermally stimulated tissue alteration or remodeling typically results from:

- Selective thermal targeting of tissue by focusing energy at the desired spot internally or externally. Energy can be delivered to the selected volume in a

minimally invasive manner by focusing energy to penetrate the tissue under the skin surface. An example of a minimally invasive treatment is electro-surgical devices which deliver thermal energy into the body via a tiny cannula or needle. Alternatively, electrocautery devices focus the energy on the tissue surface, ablating the tissue in proximity of the tip of the instrument to dissect the a soft tissue.

- Non-selective bulk heating, used mostly for sub-necrotic heating to stimulate natural processes in the body leading to increased production of collagen, elastin and ground substances. The result may include tissue tightening, circumferential reduction and wrinkle reduction.

RF energy is an important part of the armamentarium for treatment options comprising tissue cutting and coagulation, minimally invasive selective tissue targeting and bulk heating. RF current is the accepted type of energy used in four out of five surgeries conducted in the world and most industry leaders in the aesthetic field employ RF energy in at least one of their applications.

2. What is electromagnetic energy?

Electromagnetic (EM) energy travels in waves and spans a very broad wavelength spectrum from DC voltage, to very short wavelengths in gamma radiation (**Figure 1**).

RF energy is small part of electromagnetic spectrum having frequencies in the range of Kilohertz to Gigahertz. The shorter wavelength and the higher frequency, the more energetic are quanta of EM radiation and the more destructive it can be for the tissue. RF energy, Microwaves, Infrared and Visible Light has relatively low frequencies and represent non-ionizing radiation which is not able to modify the DNA (genes) inside the cells. High frequency radiation as UV, X-ray and Gamma are ionizing radiation which in natural conditions is generated by plasma or by radiative isotopes.

A very small part of RF spectrum range is used in EBD, and its properties will be the primary focus of the current chapter.

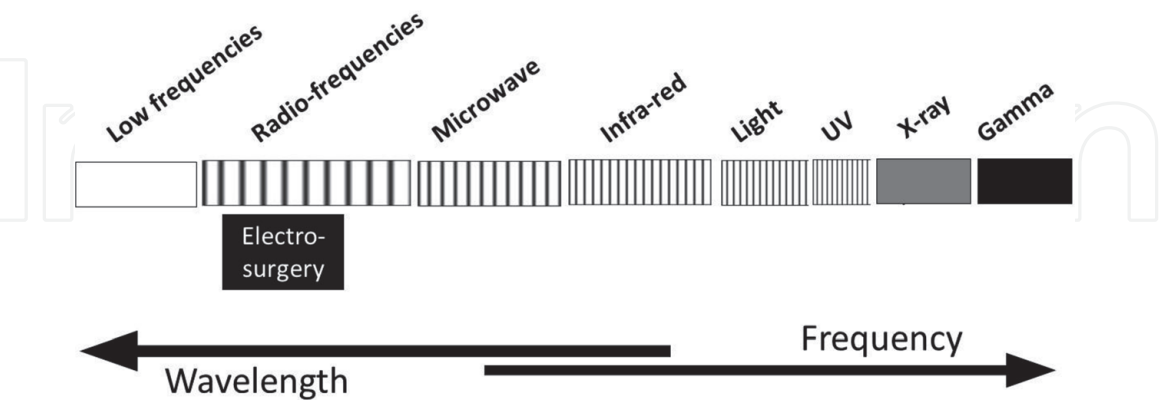


Figure 1.
Electromagnetic Spectrum.

3. The history of RF

RF energy has been used in medicine for over 100 years. Nikola Tesla, (1856–1943), Croatia-born electrical and mechanical engineer, is reputed as being the father of alternating high frequency current. But it was Dr. William Bovie (yes, of

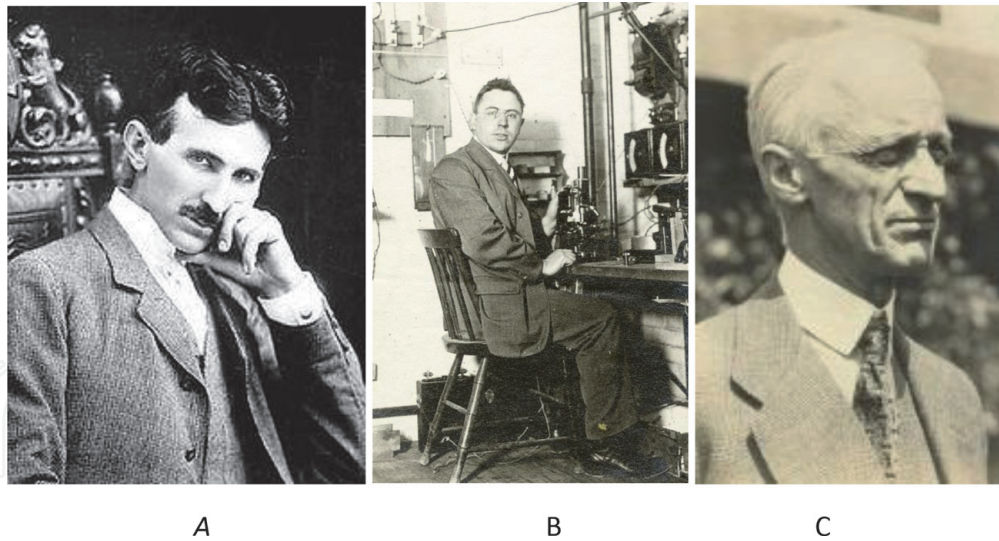


Figure 2.
 The early pioneers of RF energy in medicine, [6] (A), [7] (B) and [8] (C).

the “Bovie cautery fame”) that developed the first electrosurgical device during the period of 1914–1927 at Harvard University [1]. The first reported use of an electro-surgical generator in an operating room occurred on October 1st, 1926 in a surgery performed by Dr. Harvey Williams Cushing [2, 3]. Since Dr. Bovie introduced RF energy and the electrocautery, RF had been used for ablation [4] and coagulation [5] in surgery and medicine. Over the past 20 years, RF energy has evolved and come to dominate esthetic medicine (for good reasons, as will be explained in this chapter). RF was first being used in non-ablative form for skin collagen remodeling and other esthetic applications (Figure 2) [9, 10].

4. Radiofrequency in medicine

The specificity of RF energy in medicine is that it acts as an electrical current flowing through the tissue but differently than radiation. RF energy is associated with electro-surgical devices and can be defined as high frequency alternating electrical current heating soft tissue without significant electrical nerve stimulation. It is critical to minimize nerve impact to avoid electric shock which may cause muscle spasm and cardiac arrest.

It is important to remember that tissue has ion conductivity with the most prominent varieties being Na⁺, K⁺, and Cl[−] (sodium, potassium, and chlorine ions respectively). Nerves are affected as a result of ion penetration through the membrane of neuron. Under normal conditions the nerve is surrounded by electrically neutral liquid where ions with positive and negative charge compensate each other and bound by Coulomb force preventing free diffusion of the electrical charge. As an electrical field is applied the ion starts to move and the nerve stimulating effect depends on ion displacement (D) in alternating electrical field that can be presented as following:

$$D \sim \frac{\mu E}{f} \quad (1)$$

where μ is mobility of ions which is proportional to conductivity of tissue σ ; E is electrical field strength; f is frequency of electric field.

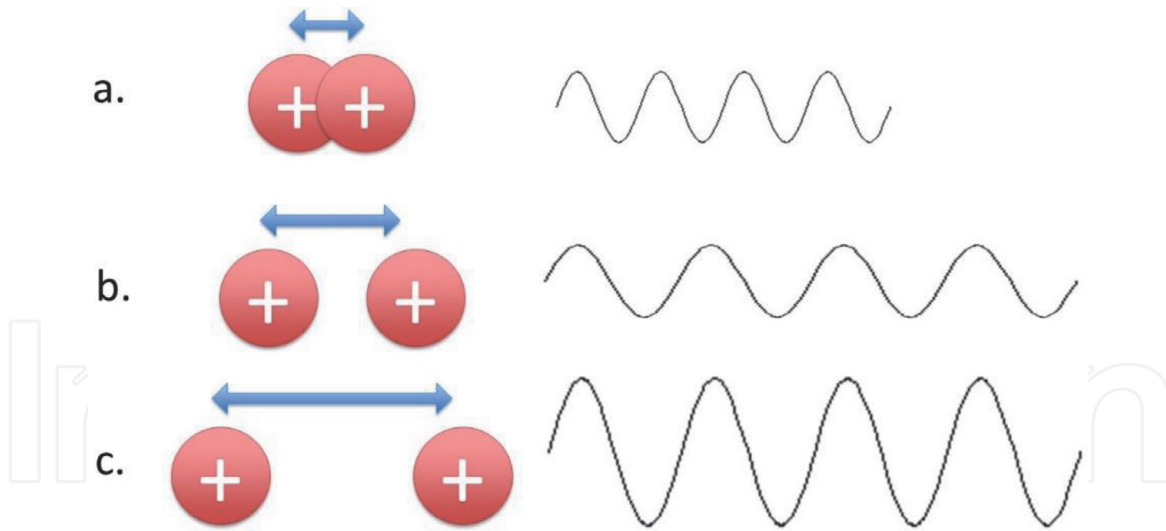


Figure 3.

Ion displacement for a) low amplitude and high frequency of electric field; b) low amplitude and low frequency; c) high amplitude and low frequency.

It is obvious the displacement of the ions is higher when electrical field is stronger and it is applied for longer time (**Figure 3**).

In general, polarity of RF voltage is changed so fast that ions vibrate in the same place without significant movement. However, users of RF may occasionally observe small muscle tweaking when high RF parameters are used. Therefore, RF energy used in electrosurgery is limited by lowest frequency of 100 kHz, while the recently developed esthetic devices operate at frequencies above 300 kHz.

The typical range of RF is 100 kHz to 5 MHz according to the FDA guidance [11]. This is intended to exclude other frequencies that may technically fall within the RF portion of the electromagnetic spectrum, but operate in a fundamentally different manner. However, there are few products with higher RF frequency of up to 40 MHz. If RF is higher than 5 MHz there is significant radiative component with reduced capability to predict the distribution in the patient's body and can even potentially affect the treatment attendant.

The ions oscillating in RF field interact with the surrounding tissue, losing its kinetic energy and generating the heat. The heat generated by electrical current in conductive media is described by Joule's law:

$$H = \sigma E^2 \quad (2)$$

The heat generated in each point of tissue is proportional to tissue conductivity (σ) and square of electric field (E).

The Ohm's law in vector form allows to calculate the density of RF current (j) in each point of tissue:

$$j = \sigma E \quad (3)$$

While continuity equation allows to analyze RF current distribution in the tissue

$$\nabla \cdot j = 0 \quad (4)$$

The Eq. 4 states that electrical current coming into any volume of tissue is equal to the current going out of the same volume (**Figure 4**).

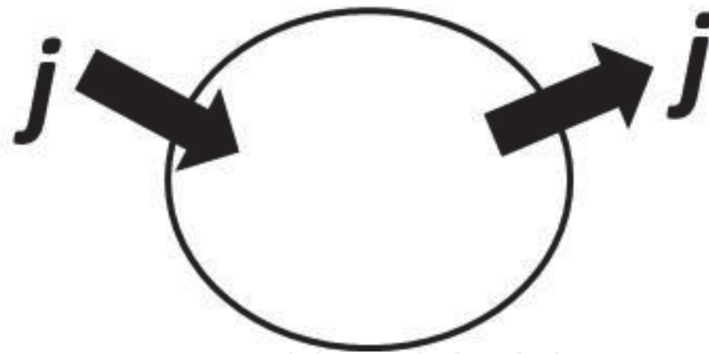


Figure 4.
Schematic illustration of continuity law.

The other conclusion from the charge continuity equation is that all RF current emanating from one electrode into the tissue flows to the other electrode. The current density on the electrode surface depends on the size of the electrode.

5. RF penetration depth

Penetration depth of RF energy depends on the electrode geometry and divergence of the RF current inside the tissue. We will determine RF penetration depth as the depth where RF energy is decreased by exponential factor ($e = 2.71 \dots$) and analyze a few typical cases (Figure 5).

The first case in Figure 5 illustrates small electrode distant from the return electrode. The RF current density and consequently electric field in vicinity of the electrode diverges spherically and current density drops as square of distance from electrodes. Taking into the account that heat is proportional to square of electric field. Therefore, heat created by RF energy can be represented as following:

$$H = \sigma E_o \left(\frac{r_o}{r_o + d} \right)^4 \tag{5}$$

Where E_o is electric field on the surface of semispherical electrode, r_o is radius of electrode and d is distance from the electrode. It is easy to calculate that heating drops by exponential factor at $d = 0.28 r_o$. For the electrosurgical electrode having tip with radius about 0.5 mm the RF penetration into the tissue is about 140 microns. Such small RF penetration depth allows to cut the tissue with minimal thermal damage.

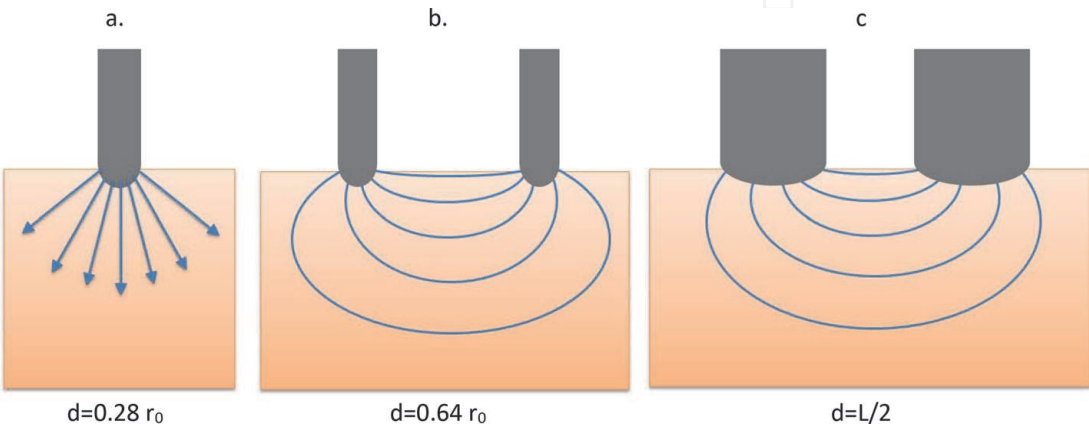


Figure 5.
RF current distribution for typical geometries of electrodes.

Figure 5b shows two long electrodes having cylindrical surface contacting the tissue. The distance between the electrodes is larger than an electrode size. In this case the heat distribution near the electrode can be calculated using the following equation:

$$H = \sigma E_o \left(\frac{r_o}{r_o + d} \right)^2 \quad (6)$$

The heating drops by exponential factor at the distance of $d = 0.64 r_o$. Such configuration of esthetic devices is commonly used, but the penetration depth is limited and most of the energy is concentrated near the electrode.

The case shown in **Figure 5c** represents two parallel electrodes having size comparable with the distance between them. Analysis of heat distribution required computer simulation but RF penetration depth can be estimated as half distance between the electrodes [10].

The thermal measurements conducted for the three cases described above are shown in **Figure 6**.

Thermal experiments were conducted using porcine tissue and a RF generator with the frequency of 1 MHz and 50 W power. The thermal camera FLIR A320 was used for thermography of tissue during RF application.

Heat conductivity, real geometry of electrodes and non-uniformity of tissue effect the thermal imaging but measurements correlate well with theoretical consideration.

6. Tissue conductivity and impedance

The electrical properties of tissue play important role in understanding of RF-tissue interaction.

Tissue conductivity is a strong function of tissue type. The fundamental article of Gabriel et al. [12] summarized data on electrical conductivity for different types of tissue. **Figure 7** shows tissue conductivity of fat and skin in broad range of frequencies.

In the RF range, the tissue conductivity is a weak function of frequency. The tissue has resistive and capacitive properties. The capacitance of tissue in RF diapason is determined by recharging of cell membrane.

The properties of different types of tissue are presented in **Table 1**.

Our measurements in-vivo for tumesced adipose tissue show that fat's conductivity is very similar to the one of skin and is in the range of 1 to 2 S m^{-1} .

Conductivity of tissue is a function of temperature and is changed in the range of sub-necrotic heating by $2\%/^{\circ}\text{C}$ [13]. Our measurements of tissue conductivity

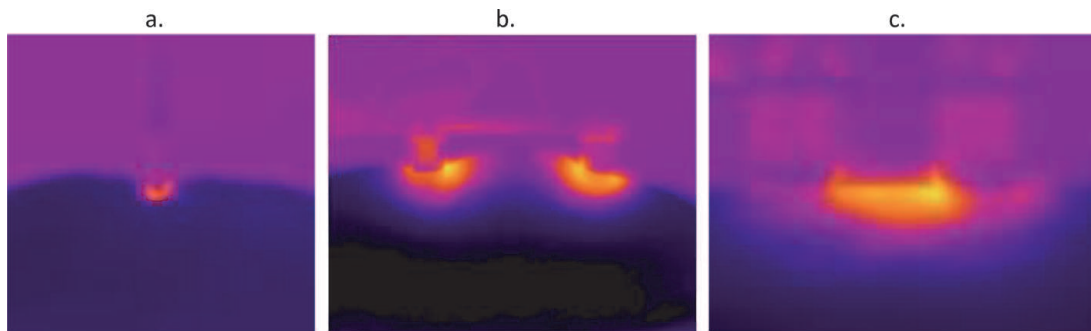


Figure 6.
Thermal measurements of tissue temperature generated by RF current for typical geometries of electrodes.

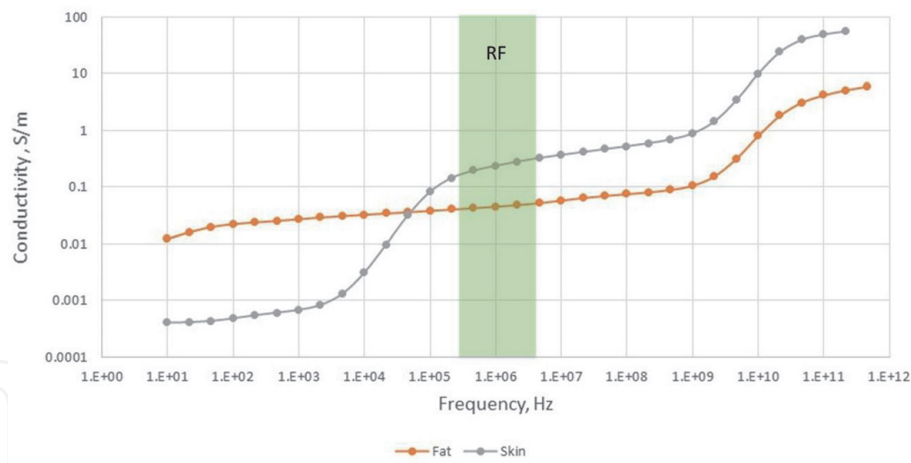


Figure 7.
Electrical conductivity of skin and fat as a function of frequency of electrical current.

Tissue	Conductivity, S m ⁻¹
Blood	0.7
Skin	0.25
Fat	0.03
Bone	0.02

Table 1.
Tissue conductivity at 1 MHz [12].

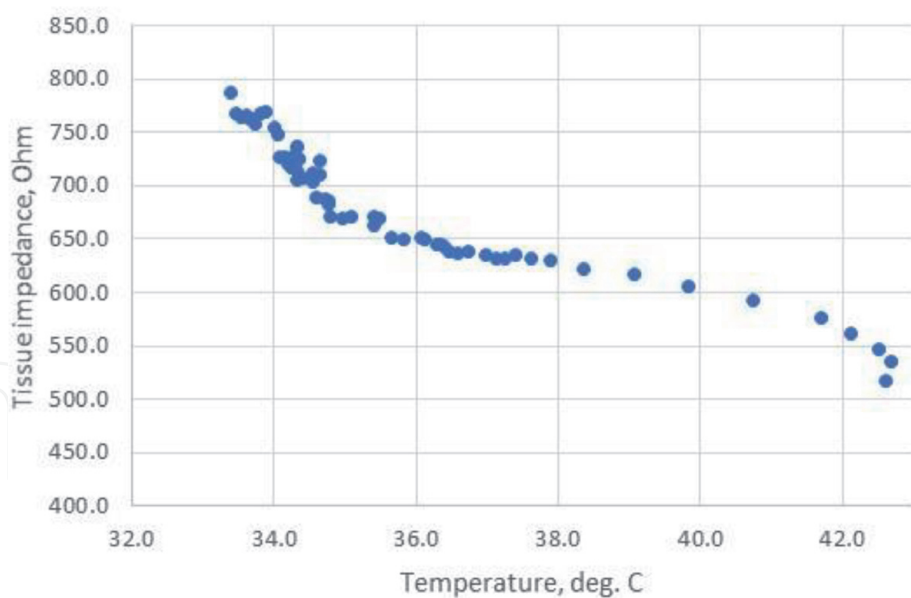


Figure 8.
Impedance of tissue measured between two electrodes applied to the skin surface.

between two electrodes in-vivo showed smaller change for the temperature close to the normal body temperature and larger change when tissue temperature deviated more (**Figure 8**). The tissue was pre-heated to 43 °C during 15 min and then tissue impedance was measured for short RF pulses during two hours as skin cooled down. As tissue is heated to higher temperatures resulting in tissue coagulation and dehydration, the tissue impedance is increased dramatically [10]. Schematic change of tissue impedance as function of temperature is shown in **Figure 9**.

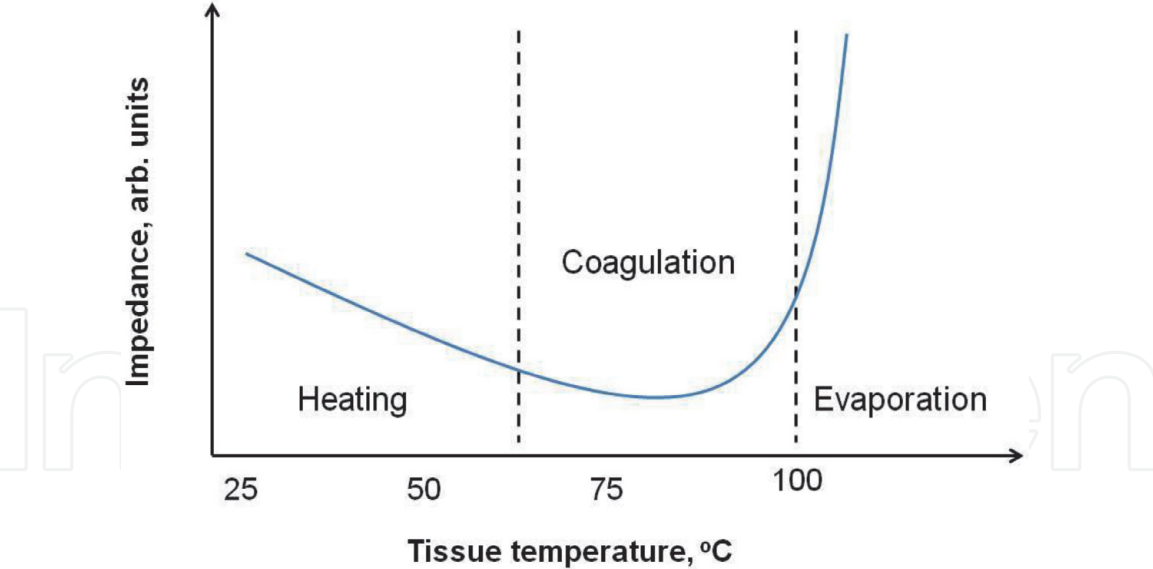


Figure 9.
Schematic impedance behavior as function of temperature.

As mentioned above regarding conductivity, heating of tissue reduces its impedance with a rate of about 2% per degree Centigrade [13]. This change is related to reduction of tissue viscosity which is reduced with temperature increase. Coagulation of the tissue causes a chemical change in tissue structure, subsequently changing the trend of impedance behavior. When heating up to 100 °C, the evaporation of liquids dehydrates the tissue, dramatically increasing tissue impedance. Additional heating of the tissue leads to its carbonization. Dependence of tissue conductivity on temperature is utilized by ELOS (Electro optical synergy) technology where tissue is preheated using optical energy creating a preferable path for RF current [14, 15]. This can provide treatment advantages for some applications.

7. RF waveform

The RF energy can be delivered in continuous wave (CW) mode, burst mode and pulsed mode (**Figure 10**).

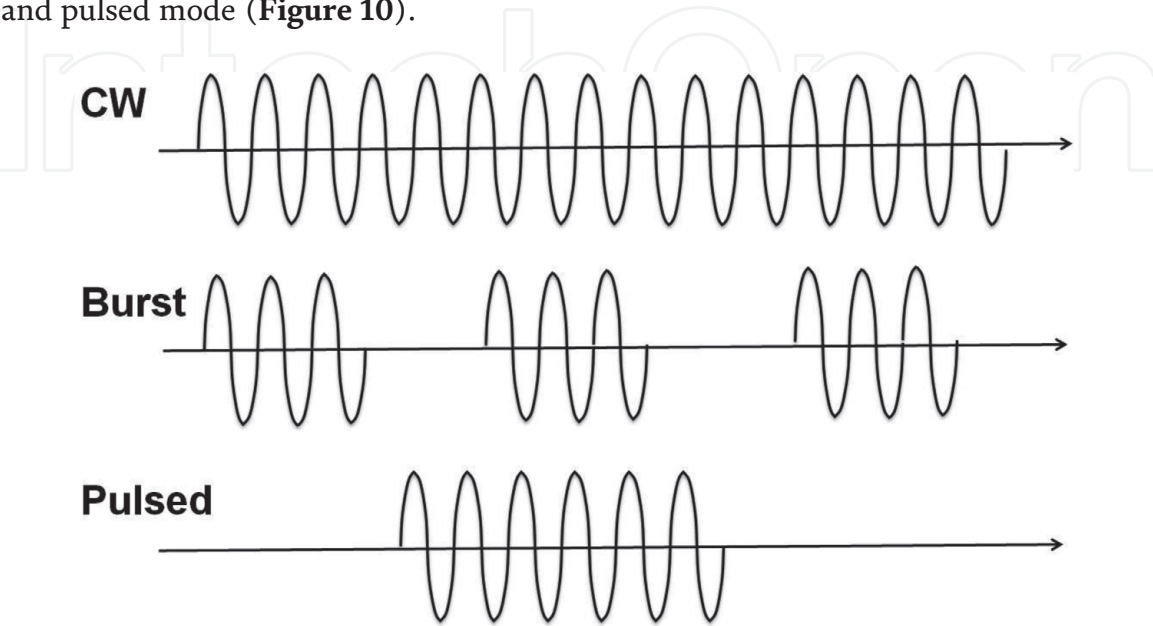


Figure 10.
Typical RF waveforms.

For gradual treatment of large areas, the CW mode is most useful, allowing for the slow increase in temperature in large tissue volume. It is used for treatment of cellulite, subcutaneous fat and skin tightening. CW mode typically delivered in device intended for moving over the treatment area.

The burst mode delivers RF energy with repetitive pulses of RF energy. It is used in applications where peak power is important while average power should be limited. Such an example would be blood coagulation. Also, it is used in hands free devices where energy is added by small portions maintaining the required temperature.

Pulsed mode is optimal when small tissue volume should be affected without heat spreading to the surrounding tissue. Pulsed mode is used in micro-needling devices.

8. Effect of spot size

In order to create tissue ablation, very high energy density is required. In electro-surgical cutting instruments, a very small electrode, or needle type electrode is used to concentrate electrical current to very small area, which increases the energy density to ablative levels. Coagulation instruments, which create energy and thermal profiles coagulating the cells and shrinking the collagen, usually have larger surface area electrodes than ablative devices. Typically, the surface area of such electrodes is a few square millimeters to generate heat in larger volume but at a lower level to create coagulation rather than ablation. Sub-necrotic heating is usually used for treatments related to stimulation of natural processes in the tissue, such as collagen remodeling, revascularization, speeding fat metabolism. In this case the spot size is about 1 square centimeter or larger. Schematical illustration of spot size effect is shown in **Figure 11**.

Generally, the smaller the electrode, the higher the energy density and the effect tends to be ablative (e.g., cutting cautery tips), whereas larger sized electrodes, have a gentler tissue effect, either coagulation (hemostasis) or sub-necrotic tissue heating [16].

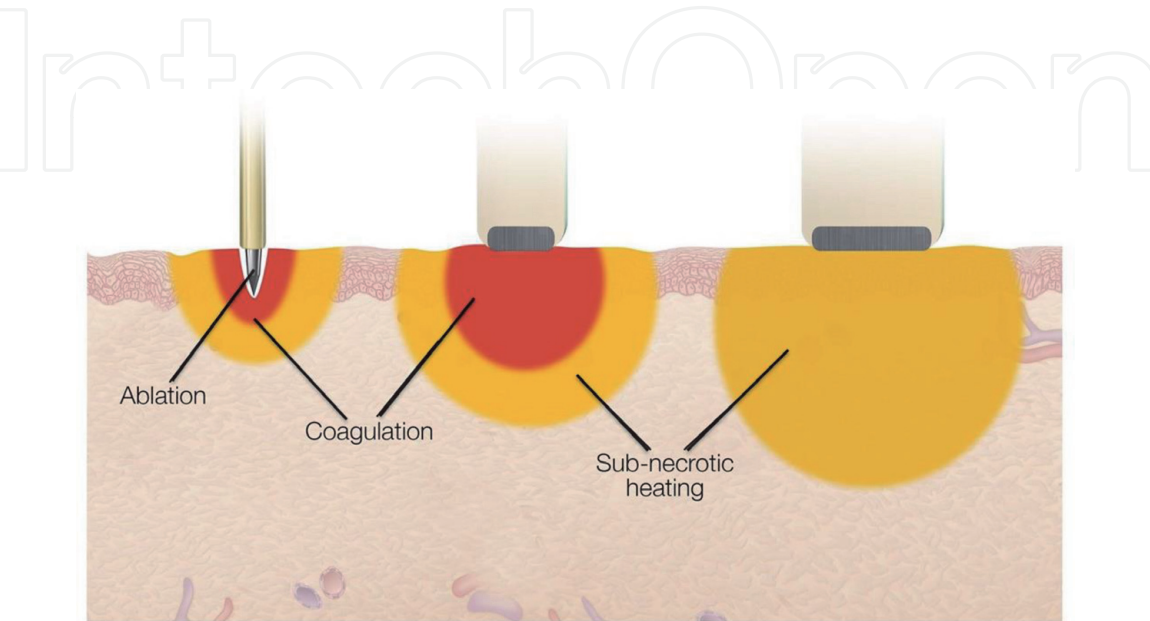


Figure 11.
The effect of electrode size, or spot size on the energy and power density.

9. Monopolar RF systems

RF current always flows between two electrodes having opposite polarity. The FDA definition of monopolar devices relates to the size and position of electrodes in respect to patient during the treatment. According to FDA guidance [11], monopolar is an electrosurgical technique in which the current flows from a single active electrode at the surgical site, through the patient, to a relatively distant return electrode.

The most common feature of a mono-polar device is a single electrode applied in the treatment area while the return electrode has a much larger contact surface and is placed outside of the treatment zone, usually in the form of a grounding pad. In this electrode geometry, the high RF current density is created near the active electrode and RF current diverges toward the large return electrode. The heat zone for this geometry can be estimated using analytic spherical model for continuity equation stating that electrical current flows continuously from one electrode to another.

$$\nabla_r j = 0 \quad (7)$$

Taking into account Ohm's law in differential form (Eq. 3) and the definition of an electric field, Eq. 5 can be rewritten as:

$$\frac{1}{r^2} \frac{\partial}{\partial r} r^2 \frac{\partial \varphi}{\partial r} = 0 \quad (8)$$

Where φ is the potential of the electric field. The solution for this equation provides RF current density distribution between electrodes.

$$j = \frac{\sigma V r_0 R}{r^2 (R - r_0)} \quad (9)$$

Where σ is tissue conductivity, V is voltage between electrodes, r_0 is radius of small electrode and R is the radius of the large electrode.

For the instance when the return electrode is much larger than the active electrode, the equation can be simplified as:

$$j = \frac{\sigma V r_0}{r^2} \quad (10)$$

Correspondently, heat power according to Joule's law can be estimated as:

$$P = \frac{\sigma V^2 r_0^2}{r^4} \quad (11)$$

This simple equation leads to a few interesting conclusions:

Heat generated by RF current near the active electrode does not depend on position of the return electrode when return electrode is much larger in size than the active electrode and located at a distance which is much larger than the active electrode size.

Heating decreases dramatically as distance increases from the active electrode. As was shown before, RF energy penetration depth is about one third of electrode radius (**Figures 5 and 6**). However, heating temperature on the electrode surface may reach hundreds of degrees centigrade and coagulation effect may be extended much larger than RF penetration depth. The other factor enlarging thermal zone is heat conductivity spreading heat around.

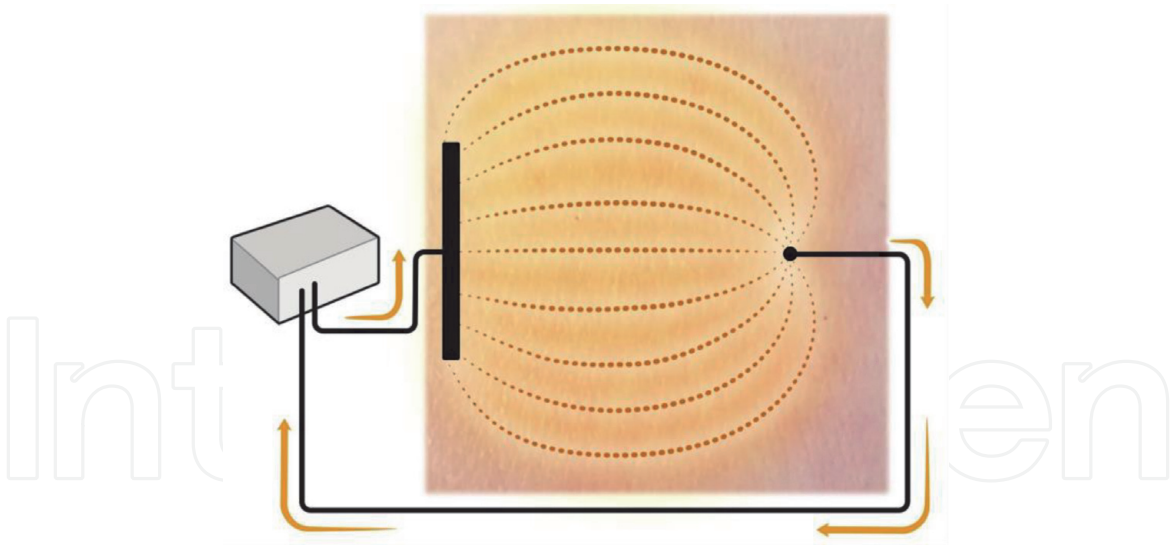


Figure 12.
Schematic RF current distribution between electrodes for monopolar system.

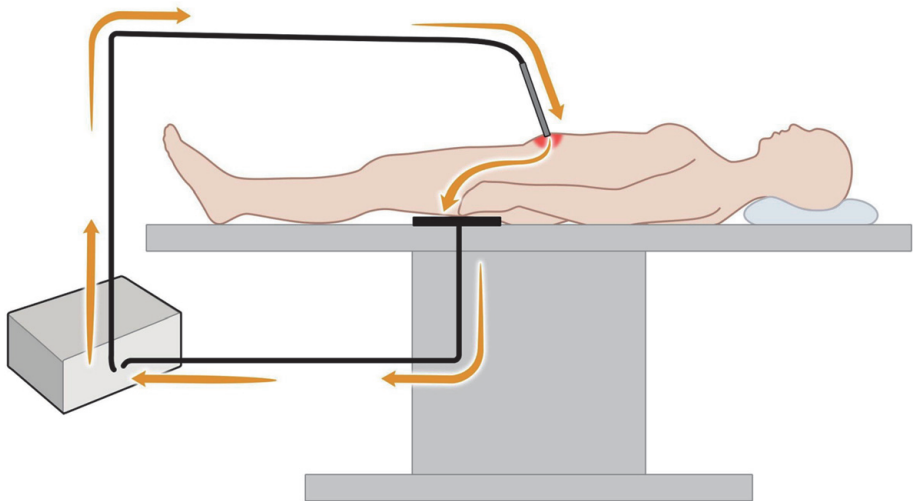


Figure 13.
Electrical current flowing through the patient and monopolar electrosurgical device.

RF current behavior in the body for monopolar systems is visualized schematically in **Figure 12**.

RF current is concentrated on the active RF electrode and rapidly diverges toward the return electrode.

Monopolar devices are most commonly used for tissue cutting. Schematically, the RF current flow through the patient for monopolar devices is shown in **Figure 13**.

The RF current is always flowing through a closed loop via the human body. As we showed above, the current density out of the vicinity of the return electrode is negligible. However, a malfunction where some low frequency current escapes out of a monopolar configuration holds high risk because the entire body is exposed to the electrical energy. Most commercially available devices have isolated output to avoid any unexpected RF current path to the surrounding metal equipment.

Treatment effects with monopolar devices depend on RF power and size of electrode. The classic use of monopolar technique is tissue cutting and ablation while occasionally it is used for soft tissue coagulation or sub-necrotic heating [9, 17–19].

The main features of monopolar devices are:

- Predictability of thermal effect near the active electrode
- Ability to concentrate energy on a very small area
- High non-uniformity of heat distribution which is strong at the surface of the active electrode and is reduced dramatically at a distance exceeding the size of electrode, thereby limiting penetration depth

10. Bipolar RF systems

According to FDA [11], bipolar is an electrosurgical device in which the current flows between two active electrodes placed in close proximity. In bipolar devices both electrodes create a similar thermal effect and are applied to the tissue treatment area (**Figure 14**). Bipolar devices create larger thermal zones and this circuit is used in electro-coagulators. The advantage of bipolar systems is the localization of all RF energy in the treatment zone (**Figure 14**).

Bipolar devices concentrate all RF energy between electrodes in the treatment area. This geometry is more suitable than a monopolar system to create uniform heating in larger volume of tissue. In order to understand heat distribution between electrodes the following three rules should be taken into the account:

- Heating is always higher near the electrode's surface and reduces with a distance because of current divergence. Divergence of RF current between electrodes reduces current density and correspondently generated heat.
- For any geometry, RF current density is higher along the line of shortest distance between the electrodes and reduced with distance from the electrodes.
- RF current is concentrated on part of the electrode having high curvature creating the hot spots.

A schematic distribution of electrical currents in uniform media in bipolar device is shown in **Figure 15**.

In bipolar devices, both electrodes create an equal thermal effect near each of the electrodes and the divergence of RF current is not as strong because of the small

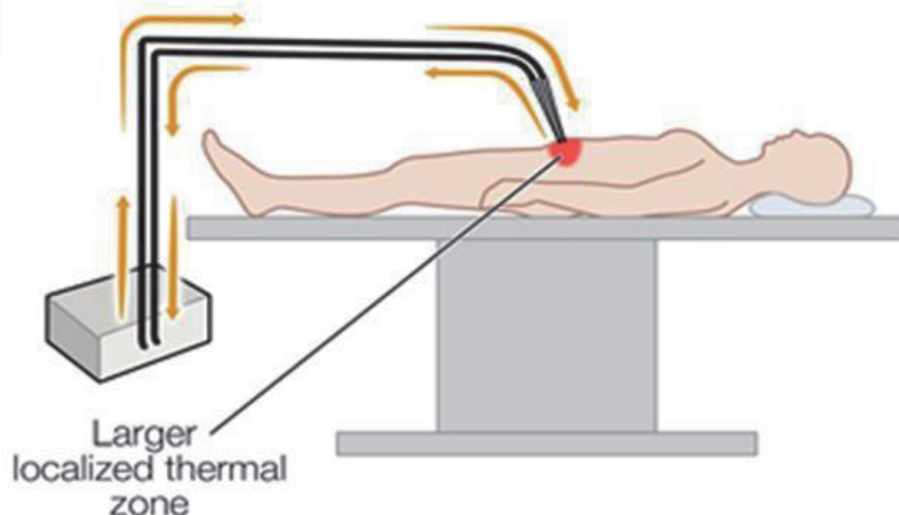


Figure 14.
Electrical current flowing through the patient and bipolar electrosurgical device.

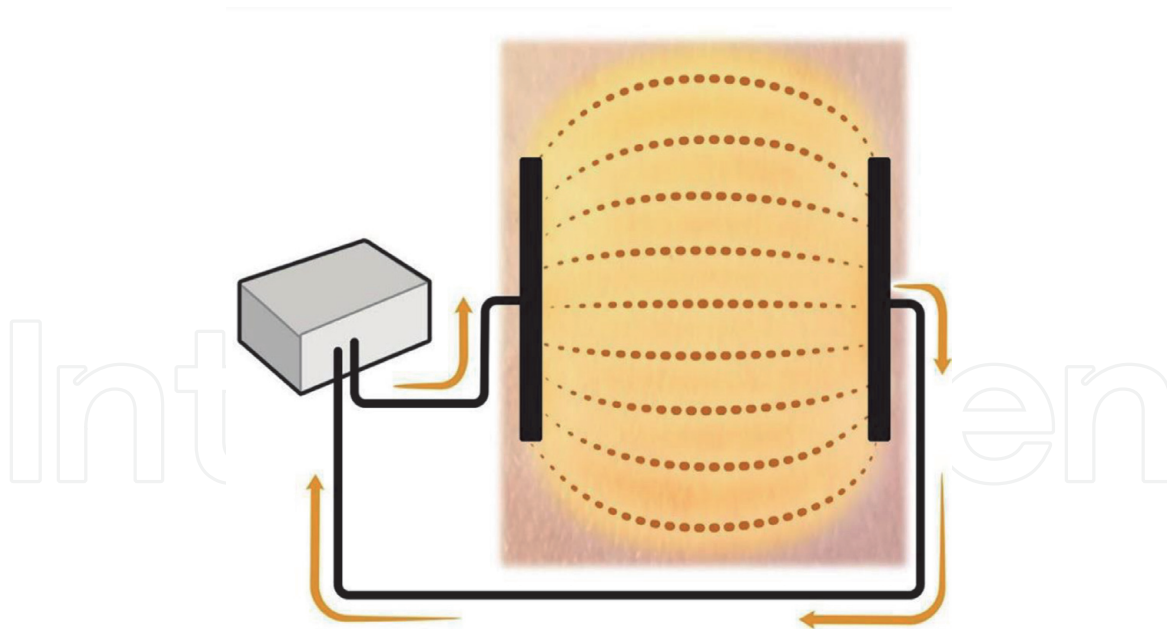


Figure 15.
Electrical current distribution for bipolar system.

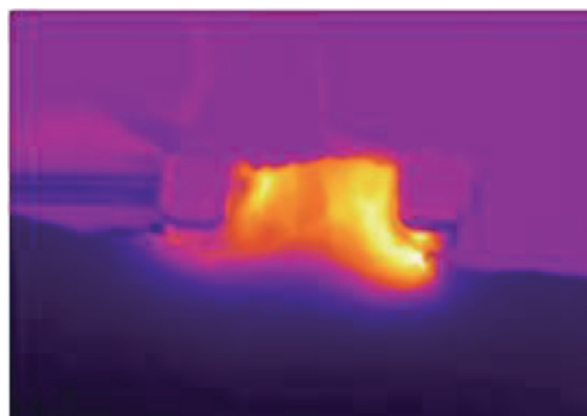


Figure 16.
Thermal image of heat distribution created in the skin folded between two parallel electrodes.

distance between the electrodes. For bipolar systems shown in **Figure 15**, most of the heat is concentrated between the electrodes.

Penetration depth of RF for bipolar devices is a function of electrode size and the distance between them. By increasing the distance between the electrodes, the electrical current can go deeper, but divergence is also increased. In case the distance between the electrodes is much larger than the electrode size, the heating profile will be similar to two monopolar electrodes. Schematically, bipolar current distribution and measured thermal effect are presented in **Figures 5b** and **6b**, respectively.

The most uniform distribution of RF current is obtained in planar geometry when tissue is placed between two large parallel electrodes. This can be realized when negative pressure forces the tissue to fill the cavity between the parallel electrodes. Measured RF energy distribution for the cavity filled with the tissue is shown in **Figure 16**.

11. Capacitive coupling of RF energy

High frequency current is able to penetrate through the dielectric material which behaves as capacitor. This effect is used to isolate metal electrode from patient. This

method is called capacitive coupling. There are a number of devices in the medical esthetic market that use this technology for RF delivery [18, 19].

The capacitance of planar dielectric layer is described by the following equation:

$$C = \frac{\epsilon\epsilon_0 S}{L} \quad (12)$$

Where ϵ is dielectric constant of dielectric material, ϵ_0 is the vacuum permittivity, S is area of dielectric and L is thickness of the layer.

Impedance of the dielectric layer depends on frequency of current (f)

$$R = \frac{1}{2\pi f C} \quad (13)$$

For example, polyimide layer with area of 4cm^2 and thickness of 100micron has capacitance of about 106 pF and impedance of this layer is 1.5 kOhm at 1 MHz and 375 Ohm at 4 MHz.

For cylindrical geometry capacitance is represented by the following equation

$$C = \frac{2\pi\epsilon\epsilon_0 L}{\ln\left(\frac{b}{a}\right)} \quad (14)$$

Where a is inner diameter and b is outer diameter of dielectric coating.

The leakage of RF current through the dielectric coating should be taken into the account at design of electro-surgical instruments.

12. Thermal relaxation time

The temperature dissipation is characterized by thermal relaxation time (TRT) of the targeted area. For localized treatment, in order to avoid significant heat transfer, the pulse duration should be less than the TRT.

The TRT is a function of tissue thermal properties, heated volume shape and size. Soft tissue has thermal properties close to the water.

For the planar object the TRT can be estimated as [20].

$$TRT = \frac{d^2}{4a} \quad (15)$$

Where d is thickness of layer, and a is tissue diffusivity. Diffusivity is equal to tissue conductivity divided by the heat capacitance and measured in $\text{cm}^2 \text{s}^{-1}$.

For a cylindrical object, such as a blood vessel or hair, a similar equation can be used with different geometrical factors.

$$TRT = \frac{d^2}{16a} \quad (16)$$

where d is object diameter; one can see that cooling time is square function of the size.

Thermal relaxation time should be taken in to the account when thermal effect should be localized. It is critical in fractional RF technologies when thermal coagulation should by limited by small zones around the needle electrodes.

13. Tissue modification by RF energy

The thermal effect of RF on tissue is not different from laser or any other heating method. Multiple studies [21, 22] discuss the temperature effect on tissue. Since treatment effect is not only a function of temperature, but also of the period of time (when this temperature is applied), it is known that in the millisecond range the coagulation temperature is 70-90 °C, while if temperature is applied for a few seconds, the temperature of 45 °C causes irreversible damage. Hyperthermia studied intensively for treatment of cancer confirms strong dependance of tissue vitality on time that temperature is maintained [23]. RF induced hyperthermia was measured for adipocytes in a clinical study [24]. The fat cell viability was 89% after RF heating for 1 min at 45 °C while after heating during 3 min the vitality dropped down to 40% (**Table 2**).

There is extensive data on the correlation between tissue temperature, pulse duration and treatment effect. Moritz and Henriques demonstrated that the skin thermal damage threshold is a function of temperature and time [25]. Later it was demonstrated that skin damage function can be described by Arrhenius equation where pre-exponential factor is a linear function of pulse duration [22].

$$D = At \exp \left(\frac{-\Delta E}{RT} \right) \tag{17}$$

Pulse duration is one of the most critical parameters when utilizing RF energy in order to achieve a clinical response. It affects treatment results because timing influences the thermo-chemical process in tissue. The other effect of pulse duration is energy dissipation away from the treatment zone due to heat conductivity from the exposed area to the surrounding tissue.

In other words, the degree of damage is a linear function of pulse duration and an exponential factor of tissue temperature. This means that tissue temperature is more influential on the degree of damage than the pulse duration.

It is well known that sustained hyperthermia at 42 °C for tens of minutes causes death of most sensitive cells such as in the brain [26]. In laser medicine the pulse duration in the millisecond range causes tissue to burn at a temperature above 60-70 °C.

Dehydration and carbonization of the ablated treated tissue may cause the accumulation of a non-conductive tissue layer on the electrode surface. This tissue is sometimes called eschar and if it accumulates on the surface of the treatment electrode, it may affect significantly the energy delivery to the electrode and hence

Temperature	Tissue effect
37-44 °C	Acceleration of metabolism and other natural processes.
45-50 °C	Conformational changes, hyperthermia (cell death)
50-80 °C	Coagulation of soft tissue
50-80 °C	Collagen contraction
90-100 °C	Formation of extracellular vacuoles, evaporation of liquids
>100 °C	Thermal ablation, carbonization

Table 2.
Tissue thermal effect.

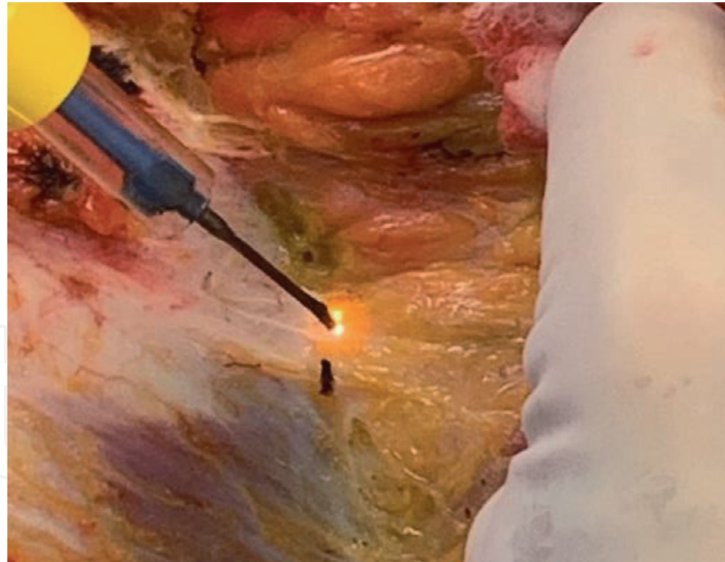


Figure 17.
Cutting Bovie electrocautery, with an eschar built upon the fine needle tip.

the treatment zone or even damage the hand piece. Carbonization or Eschar reduces or totally blocks the working area of electrodes and affects treatment efficiency, reducing the electrical current flow to the tissue (**Figure 17**).

Usually, the surgeon must clean an electro-surgical instrument periodically during the treatment to remove any eschar from the treatment electrode. Alternatively, companies, like InMode created a technological solution avoiding this problem. In InMode devices, impedance monitoring measures the increase resistance to flow (increased impedance) caused by eschar on one of the electrodes and cuts off the RF energy and flow of RF current briefly, minimizing the risk of the eschar built up at all.

The most important tissue modification induced by RF heating is a contraction of collagenous tissue. This effect is known for decades and is used intensively in orthopedy [27, 28] and ophthalmology [29].

Skin contraction was a primary focus for the first RF devices in esthetic medicine [9, 15, 17, 19]. Only in the last decade there is the understanding that the skin appearance is more affected by collagen in the reticular dermis and fibro septal network (FSN) binding skin with superficial fascia and muscles. A study published in 2011 [30] showed that skin has very dense collagenous tissue and shrinkage of collagen fibers is limited, while connective tissue in the subdermal space may contract above 30% during a few seconds of heating. The threshold temperature for collagen contraction was measured in the range of 60-70 °C.

In the experiments in our facility, the contraction of FSN was quantified on ex-vivo post abdominoplasty human tissue. The area was marked proximal to the RFAL cannula tip and monitored during RF energy application. The resulting measurements are presented in **Figure 18**.

One can see that thermal exposure of subcutaneous tissue with RF energy during three seconds resulted in area contraction by 42%.

14. Radiofrequency assisted lipolysis (RFAL)

RFAL technology was developed by InMode Ltd. to improve treatment results during liposuction procedure. The thermal contraction of collagen in dermis and subdermal FSN allows treatment of patients with saggy skin and patients for whom previously excessive skin was a main concern [31].

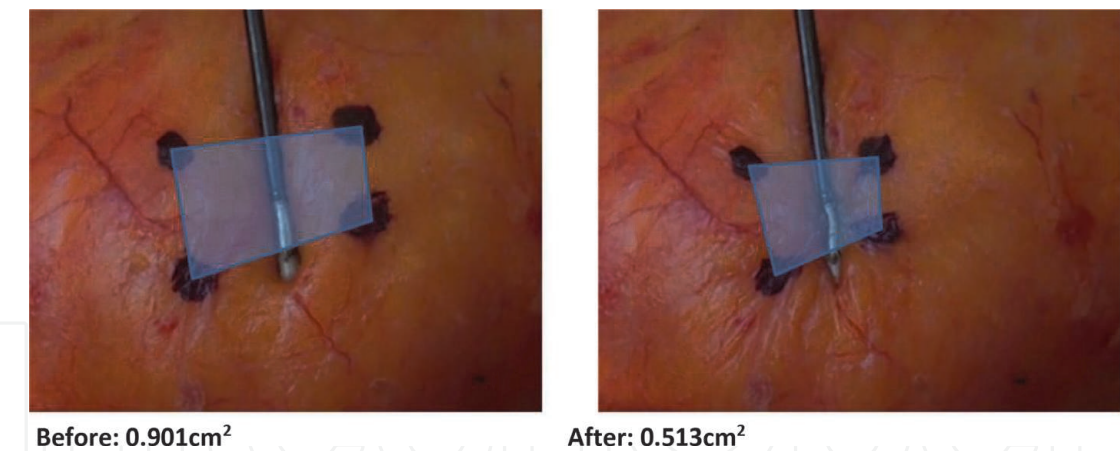


Figure 18.
Subcutaneous fat before and after application of RF energy.

The uniqueness of RFAL technology is that it does not fall under any standard device definitions. It combines features of monopolar and bipolar technologies, minimally-invasive and non-invasive technologies, creating very specific energy profile treating simultaneously subcutaneous fat, connective tissue forming FSN and dermis. Each of these tissue components requires different thermal exposure. Adipose tissue should be destroyed, FSN should be remodeled without denaturation of collagen while skin should be exposed to sub-necrotic heat to modify it without superficial burn [31–33].

The RFAL device geometry is shown in **Figure 19**. The RF current flows back and forth from the internal electrode (cannula tip), where the thermal effect is coagulative, to a larger, external electrode. The external electrode moves along the skin surface, in tandem with the internal electrode and creates a gentle, non-ablative bulk heating effect on the dermis. Ratio between size of internal and external electrode is selected to limit skin heating at sub-necrotic heating while temperature in the fat should reach 50-70 °C.

Moving the hand piece back and forth through the intended treatment area, uniform coagulation of adipose and vascular tissue is achieved. While the external electrode is always moved over the skin surface, the internal electrode should pass through the deep, intermediate and/or superficial fat layers to treat the adipose

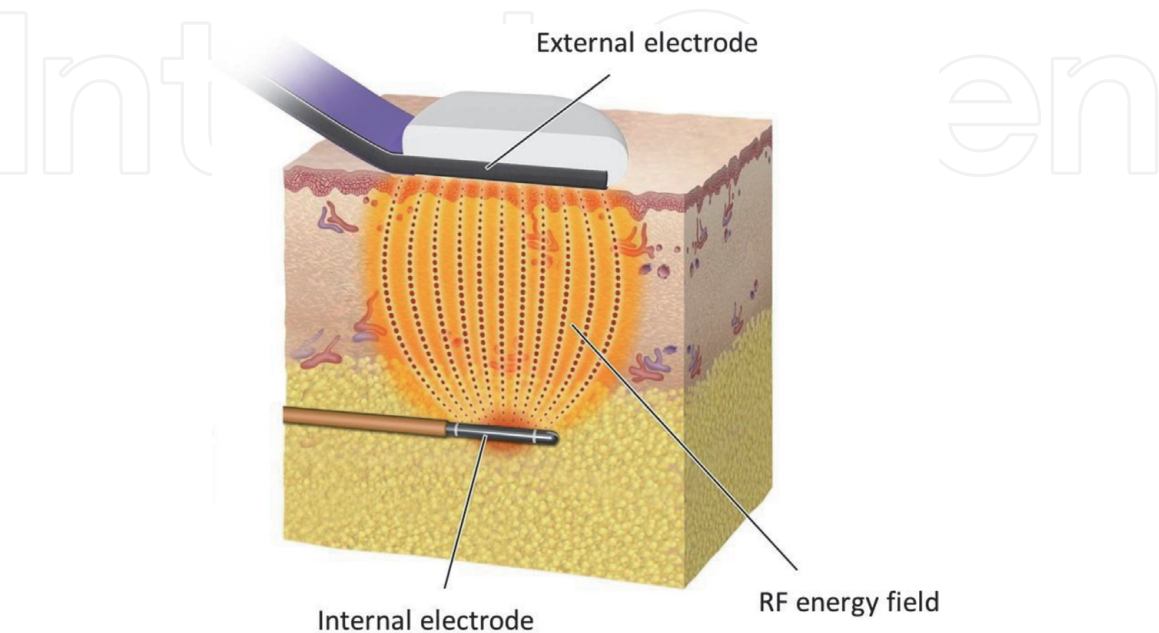


Figure 19.
Schematic depiction of RFAL treatment geometry.

tissue up to the depth of 5 cm. The Lipo-coagulation, results in liquefaction of the adipose tissue, hemostasis and stimulated contraction of adjacent vertical, oblique and horizontal fibers of the FSN, that connects the overlying soft tissue to the underlying muscle.

Figure 20 shows thermal profile created by RFAL cannula inside porcine tissue.

The temperature around the internal electrode is 70 °C. The volume exposed to high temperature around the cannula. The tissue between internal and external electrode is exposed to directional RF flowing between the electrodes.

Computer simulation shows similar thermal profile (**Figure 21**) to the measured thermography.

One of the advantages of RF energy is that it is can be delivered into the body though the very tiny sub-millimeter cannula. That allows to minimize incision and mechanical trauma at treatment of such delicate zones as face and neck [33]. Large size cannula results in higher non-uniformity and especially for subcutaneous fat.

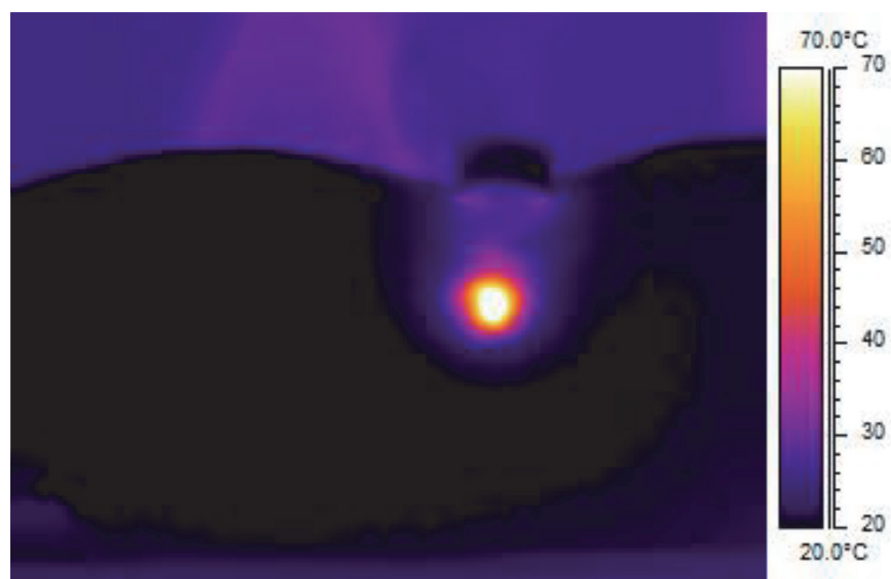


Figure 20.
Thermal profile in the tissue created by RFAL device.

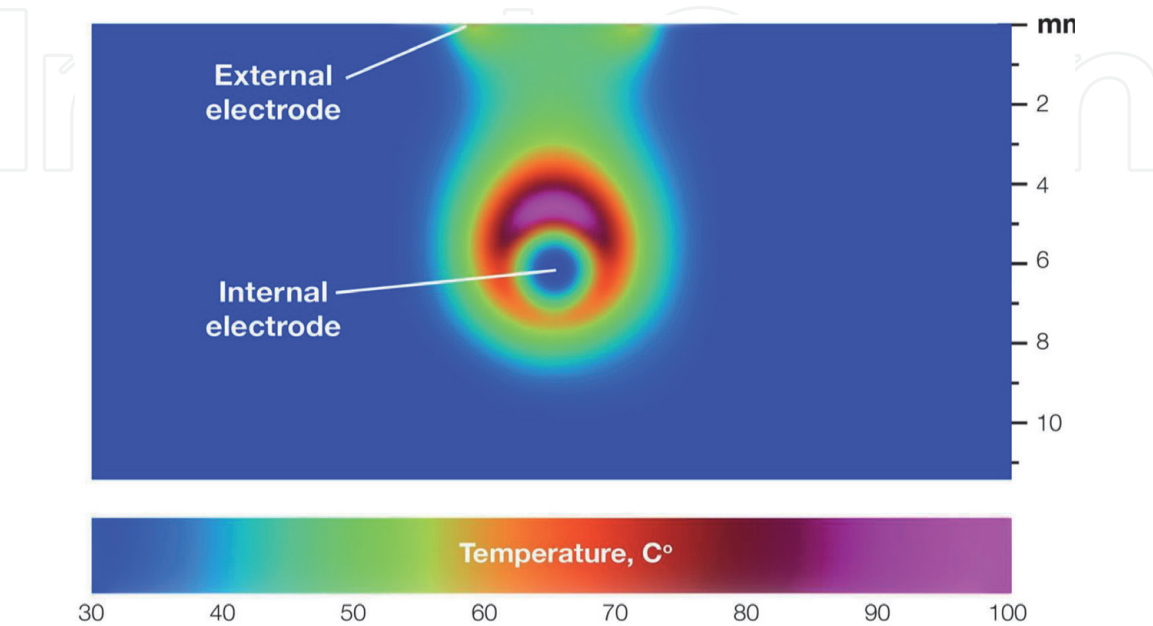


Figure 21.
Computer simulation of temperature field created by RFAL device.

15. Micro needling RF

Another RF based technology enhancing liposuction results is micro needling RF. The fractional coagulation of subcutaneous tissue helps tight the skin and reduce skin sagginess after liposuction [34].

Fractional skin treatment was introduced in esthetic medicine about two decades ago and has become one of the most popular modalities for the improvement of skin quality. This procedure is based on the coagulation of multiple small spots with a size of 100 microns to 0.5 millimeter. This allows the procedure to be very tolerable and with relatively short down-time. Focused laser beams or needle sized RF electrodes are used for ablation of micro-spots resulting in high efficiency and consistency of the treatment, with low risk of side effects and fast skin healing.

In contrast to lasers where the thermal effect is limited by the ablation crater, the RF energy flows through the whole dermis, adding volumetric heating to fractional treatment. This volumetric bulk heating adds a skin tightening effect to the more superficial improvement generated by tissue ablation.

RF fractional technologies are differentiated by needle length and size. The flat electrodes provide a more superficial effect improving texture and fine lines [34, 35] while longer needles penetrate deeper, providing deeper dermis remodeling and causing substantial skin tightening [36].

The needles can penetrate to the different depths allowing epidermal ablation and deep subdermal treatment. Recently the FDA cleared Morpheus8 device of InMode Ltd. for treatment up to depth of 7 mm.

Figure 22 shows Morpheus8 tip schematically with needles extended to the subdermal fat.

Needles coated with polymer and releasing RF energy only at the needle end provide better protection of epidermis and provide lower down time.

A microscope image of a coated needle is shown in **Figure 23**. The gold plated needle has diameter of 0.3 mm and coated with polymer of 20 microns thickness.

There are several different configurations of RF electrodes for micro-needling devices. The most common configuration is by applying RF energy between adjacent rows of needle electrodes. This method creates a coagulation zone in vicinity of the needle end.

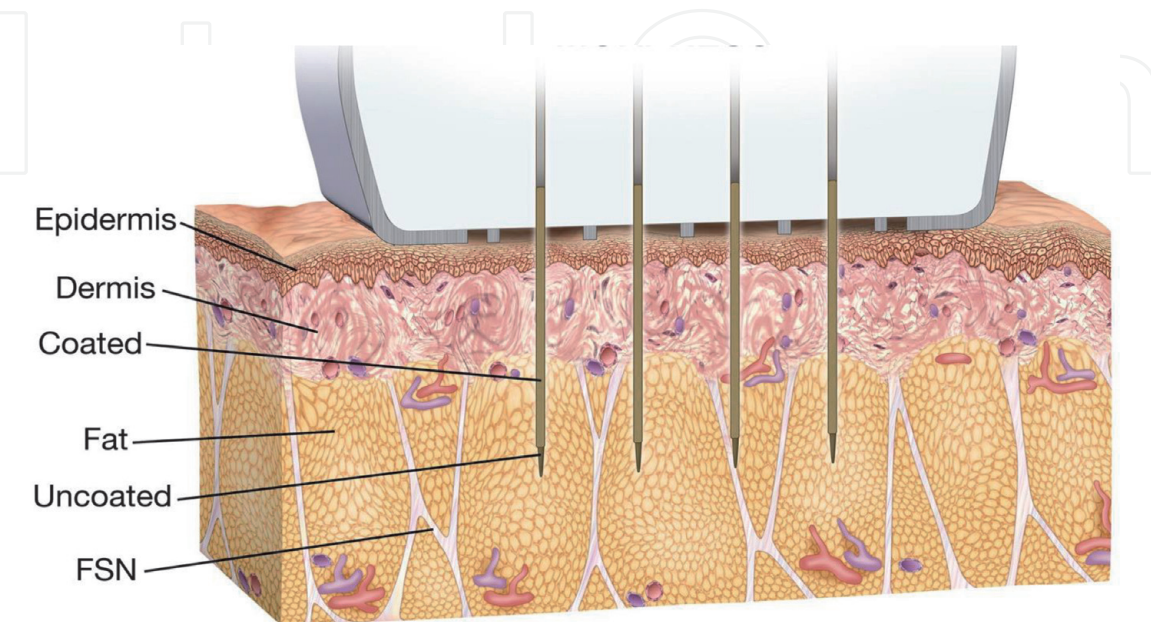


Figure 22.
Schematic illustration of Morpheus8 tip with needles penetrating into the sub-dermal space.



Figure 23.
Coated needle.

The alternative technology is used in the InMode Morpheus8 device where RF energy is applied between the needle and an external electrode applied to the skin surface. Each needle has a strong thermal effect near the needle end and gradient of bulk heating toward the external electrode, similar to RFAL technology. Each needle generates small bulk heating but superposition of the heat from multiple needles results in essential thermal effect. Morpheus8 device automatically treats tissue in multiple layers delivering RF energy sequentially during needle retraction. This burst mode creates three-dimensional matrix of coagulation zones and strong bulk heating. Schematically the burst mode treatment is shown in **Figure 24**.

Micro needling technology was developed for treatment of facial wrinkles but further development of the technology has extended its use to treat the body as well.

The micro needling technology supplements both regular liposuction and energy-based minimally invasive technologies and addresses the first few millimeters of body coagulating adipose tissue and tightening FSN.

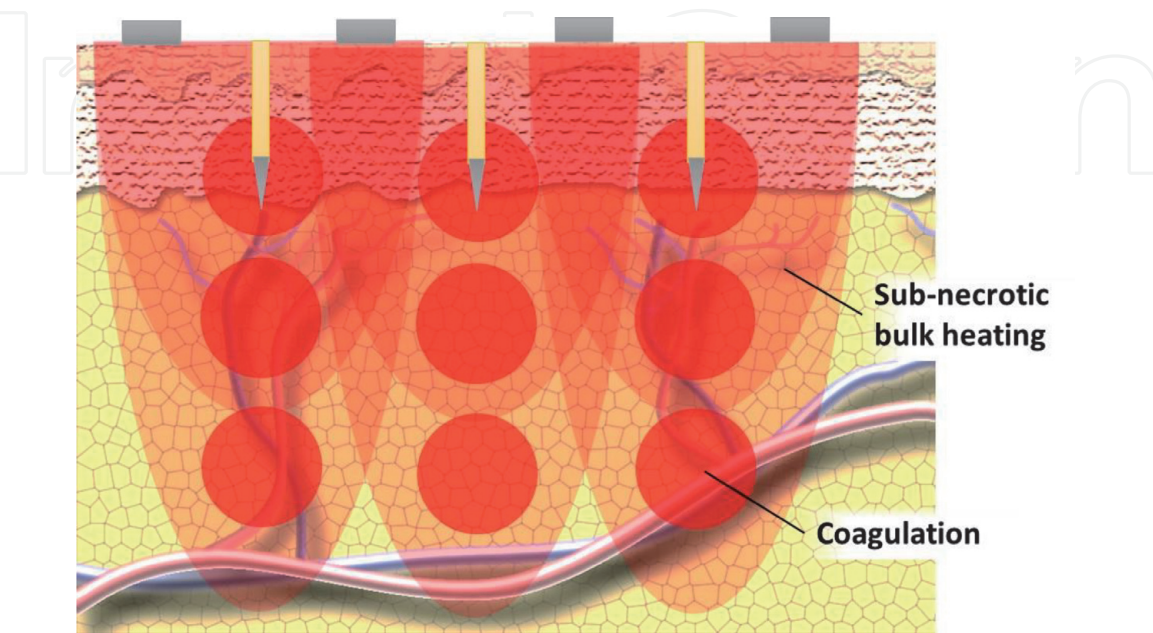


Figure 24.
Schematic illustration of burst mode treatment using Morpheus8 device.

16. Treatment control

One of the risks of any thermal treatment (laser, ultrasound, plasma or RF) is the possibility of a thermal skin injury. Thermal treatment in subcutaneous or subdermal layers may create full thickness skin burn. Therefore, monitoring of delivered energy, predictability of energy distribution and accurate measurement of tissue parameters during the treatment has crucial importance for the energy-based devices.

16.1 Tissue temperature measurements

Non uniform treatment or over-heating the treatment area may result in the risk of unwanted thermal damage to the skin during the treatment. To avoid or minimize this risk of a skin burn, real time thermal measurements are necessary. There are two basic methods of skin temperature measurements:

- Infrared (IR) thermometers measuring IR radiation of heated object.
- Contact measurements using a thermocouple, thermistor or thermo-transistors.

Advantages of IR thermometers is the speed of measurements and that they do not need to be built into the device thus are independent of the treatment. The obvious weakness of this method is collecting IR radiation from relatively large area which depends on distance from the measured area. You are also relying on a third party that is not linked in time of space to the thermal treatment being performed. Most importantly, you are not measuring the internal thermal profile.

A typical IR thermometer measures area which depends on distance between skin and thermometer and it varies from 1cm^2 to a few square inches at large distance from the patient. It allows you to monitor average skin temperature in treatment area but does not protect from appearance of small hot spots that lead to the full thickness skin burns.

The thermistors or thermocouples are extremely miniature and can be embedded into the electro-surgical instrument. Limitation of such contact measurements is response time which depends on heat transfer from the tissue to the sensor. However, special design allows to reduce response time to sub-second range.

Ideally, the user should know the temperature inside the body where energy is utilized for the fat coagulation and FSN tightening, and temperature on the skin surface above the treatment zone to ensure skin safety.

In addition, during the procedure sophisticated mechanisms monitor the tissue temperature together with its dynamic characteristics as the speed of temperature rise, allowing precautional measures before the critical temperature is reached.

Temperature monitoring for EBD is important not only for safety but also for treatment efficacy. Collagen contraction occurs in relatively narrow range of temperatures from $50\text{ }^{\circ}\text{C}$ to $80\text{ }^{\circ}\text{C}$ and overheating may result in denaturation of collagenous tissue and uncontrolled scar formation.

RFAL technology has maximum thermal safety measurements including:

- Skin temperature monitoring;
- Fat temperature monitoring;
- Temperature surge protection catching fast temperature changes.

16.2 Monitoring of delivered energy

Most types of energy cannot be monitored directly but rather electrical supply to the energy source is monitored. RF energy has unique properties resulting from continuity Eq. (4) allowing to measure RF voltage and RF current flowing through the tissue and get in real time all information about energy deposition in the tissue. Measurement of electrical RF parameters is not difficult engineering project and it can be performed every micro-second that allows to control the RF energy delivery even for very short pulses.

Measurements of RF current (I) and RF voltage (V) allows to calculate RF power (P) and RF impedance (R) using Ohm's law

$$R = \frac{V}{I} \quad (18)$$

and Joule's law

$$P = V I \quad (19)$$

The RF energy can be calculated as integral of RF power measurement over the time:

$$E = \int_0^t P dt \quad (20)$$

RFAL and Morpheus8 technologies of InMode Ltd. utilize all these measurements to control the treatment safety and efficacy.

16.3 Impedance sensing and control of RF output

Measurements of tissue impedance should be considered separately because of importance of this parameter for different aspects of treatment. The most obvious use of the impedance measurements is indication of contact between electrodes and treated tissue. Contact measurements are important to avoid poor coupling of the RF device with patient and avoid arcing. Contact monitoring has become a common feature for most RF-based devices.

Referring to **Figure 9** one can see that coagulation, dehydration of tissue and eschar formation result in impedance increase. Monitoring of tissue impedance can be used to limit heating process and avoid undesired treatment effect.

Another use of impedance monitoring is to control the lower limit, which may indicate that the distance is too small between electrodes. In RFAL technology it is used to reduce the risk of the cannula coming too close to the skin surface.

16.4 Safety features of the RF devices

All above mentioned measurements of RF parameters worth nothing if its not used for enhanced treatment safety helping physician to optimize the procedure.

The BodyTite device from InMode Ltd. uses RFAL technology, combines the maximal number of safety features, and should be used as the gold standard for safety features for RF devices.

Performing liposuction, the physician should be concentrated on safe manipulation with the minimally invasive accessory. Safety features related to the thermal component of the treatment should be implemented in automatic or in a very intuitive way not disturbing physician attention.

The skin impedance for each patient is different and may vary for the different treatment zones, amount of tumescent applied or treatment depth. RF energy is adjusted by the device automatically to provide the required optimal energy to the patient.

Tissue impedance is monitored constantly by the BodyTite and the device automatically cuts RF energy if some of the limits are exceeded.

The user may set desired temperature cut-off limits for skin and internal electrode. The device applies full power when the temperature is significantly below the threshold and starts to reduce power automatically as treatment approaches the required target temperature. This scheme allows to avoid thermal overshooting and maintains desired heat profile. RF energy delivery is accompanied by an audible signal which speeds up as the cut-off temperature is approached, similar to modern car approaching wall while parking. RF power is switched on and off automatically to maintain the desired temperature as the user scans the treatment area with the cannula.

If the cannula accidentally comes too close to the dermis, the tissue volume between the electrodes is reduced and the applied RF power heats the tissue extremely fast. To address this issue, a temperature surge protection is implemented in BodyTite device. When the temperature sensor measures a temperature increase as too fast, the device automatically shuts RF energy and produces an audible sound to attract the physician's attention.

17. Summary

RF based medical devices are a common tool for plastic surgeons, used during most surgical procedures. RFAL and RF fractional technologies have become important modalities for about 20% of plastic surgeons, for enhancing liposuction results or by its own for patients for whom reduction of adipose compound is not a main esthetic goal. Over the last 100 years extensive knowledge has been acquired about RF technology and RF-tissue interaction. The information in this chapter can help a potential buyer of new equipment make a rational choice, based on goals of treatment and physics of the RF device in question. Even more importantly, expanding the physician's understanding of his or her devices already in use can maximize treatment outcomes and minimize unwanted side effects and complications.

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