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Cellulite grading scale and skinfold Changes in Response to Shock Wave versus Bipolar Radiofrequency

Maha A.Hassan

Department of physical therapy for surgery, faculty of physical therapy, Cairo University, Cairo, Egypt

Abstract : The purpose of this study was to compare between the efficacies of both the shock wave therapy versus bipolar radiofrequency on cellulite in females. **Methods of evaluation**: (Measurement of the cellulite grading scale and the thigh skin fold). Thirty female patients with cellulite grade ≥ 2 at their thighs were participated in this study. Their ages were ranged from 25 to 45 years; they were divided into two groups. Group (A) received the shock wave therapy. Group (B) received the bipolar radiofrequency; duration of treatment was 15 minutes applied 2 times per week for 4 weeks. **Results and Conclusion: -** Results showed that both shock wave therapy and bipolar radiofrequency had valuable effects on cellulite in females, but bipolar radiofrequency was more effective than the shock wave therapy as evidenced by the highly significant decrease in the cellulite grading scale and thigh skin fold.
Key words (Shock wave therapy, Bipolar radiofrequency and Cellulite).

Introduction

Cellulite is defined as changes in the surface contour of the skin that result in orange peel or "mattress" appearance of the skin. Cellulite is not defined as a pathologic condition, but is a substantial cosmetic concern for many adult females. It was described in 1920 as an unaesthetic condition by Alquier and Paviot. In the same decade, Lagueze described cellulite as a hypodermic disease characterized by an increase in fat and interstitial edema[1].

Shock waves used in ESWT are high amplitude sound waves from a transient pressure disturbance that propagate in three-dimension space with a sudden rise from ambient pressure to its maximum pressure at thewave front. The waves are transmitted to the patient through either water or a coupling gel. A shock wave is a more than 100 mPa (1000 bar) within less than 10 ns (nanoseconds), followed with a low tensile amplitude (upto 10 MPa), a short life cycle of approximately 10 μs and a broad frequency spectrum in the range of 16 to 20MHz; Shock waves differ from ultrasound waves that are typically biphasic and have a peak pressure of 0.5 bar.

In essence, the peak pressure of shock wave is approximately 1000 times that of ultrasound wave[2]. The initial therapeutic introduction of shock waves to the human body was noninvasively treat kidney stones (lithotripsy), this technology has evolved to be considered the procedure of primary choice forurolithiasis[2].

Medium-energy, high focused extracorporeal shock waves (ESW) applied locally to the skin with cellulite may be a potential noninvasive therapy approach. Recently low-energy defocused ESW treatment showed some evidence of remodeling of the collagen within the dermis, recently application of laser or radiofrequency (RF) have been shown to improve cellulite appearance[3].

Shock wave is a sonic pulse that has certain physical characteristics. There is a high peak pressure, sometimes more than 100 Mpa (500 bar). But more often approximately 50 to 80 Mpa, a fast initial rise in pressure during a period of less than 10 ns, a low tensile amplitude (up to 10 Mpa), a short life cycle of approximately 10 Ms, and abroad frequency spectrum, typically in the range of 16 Hz to 20 MHz[4].

Shock wave was applied clinically as lithotripsy to break up calcific deposits within the body. Extracorporeal shock wave therapy now has become established as the procedure of choice for most renal calculi-for the post 10 years this technology has been increasingly applied to abroad range of musculoskeletal conditions. Shock wave (SW) application is new approach for the treatment of lipidema and cellulite, it represents an easy to handle, non-invasive, side effects free, local therapy type with short application periods-the original idea was to stimulate lipid mobilization and lipolysis in edematous regions[5].

Radiofrequency (RF) energy is a type of electromagnetic wave which is exponentially attenuated during transition into the target tissue. At high frequencies of electromagnetic wave, power is transferred rapidly close to the surface, attenuating the wave as it is dispersed. At lower frequencies, in the spectrum of RF for example, because the wavelength is greater and therefore the heating cannot be localized to limited areas, the energy penetration is deeper. For this reason, the term "bulk" tissue heating is used[6].

A bipolar configuration carries energy via two negative (cathode) and positive (anode) electrodes but with a fixed distance, while both electrodes are in contact to the skin. This way the RF's electrical current propagation is limited by the area between electrodes. The calculation of assessed penetration depth of RF energy in a bipolar system is half the distance between the electrodes. For example, in a bipolar system with a 4-mm distance between two electrodes, the theoretical depth is approximately 2 mm [7].

There is little evidence to support dramatic cellulite reduction with the combination of diet and regular exercises. Diet and exercise cannot change the histological structure of the perpendicular bands connecting the skin to the underlying fascia and thus cannot eliminate cellulite in its entirety[8]. So the need to this study developed to provide a guideline about the effects of shock wave therapy and bipolar radiofrequency therapy on cellulite in females.

30 females with cellulite grade ≥ 2 at their thighs were participated in the study. They were randomly divided into 2 groups: Group A (shock wave group): This group was composed of 15 females and received shock wave therapy. Group B (bipolar radiofrequency group): This group was composed of 15 females and received bipolar radiofrequency therapy.

Those who were not diagnosed before were excluded from the study the ethical committee of physical therapy college of Cairo university approved the study.

Materials and Methods

Thirty female patients with cellulite grade ≥ 2 at their thighs were participated in this study. Their ages ranges from 25 to 45 years. They were selected from the outpatient clinic of the plastic surgery department at el Kasr el Aini Hospitals.

Patients were randomly divided into two equal groups in number, each group was consisted of 15 patients.

Group A (shock wave group): This group was composed of 15 females; their ages ranged from 25 to 50 and received shock wave therapy 2 times per week for 4 weeks.

Group B (bipolar radiofrequency group): This group was composed of 15 females; their ages were ranged from 25 to 50 and received bipolar radiofrequency therapy 2 times per week for 4 weeks.

The patients who were excluded from the study included the following: Pregnant, breast feeding, Diseases of the skin, Thrombosis or post-thrombosis syndrome, Known malginoma or chemotherapy, Anti-coagulation therapy, Cortisone- therapy, Known metabolic disorders (ie, diabetes mellitus hyper-cholesterinemia etc.), Inflammation within treatment area, Other simultaneous treatment of cellulite, Morbid obesity (BMI>40).

Evaluation Procedures:

1-Measurement of cellulite grading scale (table1): This method of measurement was conducted by asking the patient to stand and then lying supine. The therapist observed the surface of the thigh skin, if there was mattress phenomenon; it was grade 3 of cellulite. Two measurements were taken before treatment and at end of treatment [1].

2-Measurement of skin fold: Patients were instructed in comfortable standing position, therapist chosen the site of the skin and pinch it by fingers. Then grasping skin and adipose tissue (but not the muscle). The skin caliper was applied at the level of cellulite tissue and therapist's fingers at right angle with the skin surface. The measurement in (cm) was determined after waiting 2 seconds with the caliper still engaged, then released. This procedure was repeated two times (pre and post values) [9].

Table (1) Cellulite Grading scale (Adapted from Hexsel et al., 2005)

Grade	
0	▪ Smooth surface of skin while lying down and standing. ▪ Wrinkles upon pinch-test
1	▪ Smooth surface of skin while lying down and standing. ▪ Mattress phenomenon upon pinch-test
2	▪ Smooth surface of skin while lying down ▪ Mattress-phenomenon spontaneously while standing
3	▪ Mattress- phenomenon spontaneously while standing and lying down

Treatment procedures:

- Before treatment, all patients received full explanation to the purpose of the treatment, the therapeutic and physiological benefits of this method of treatment.
- Before starting the treatment, all measurements of each patient were taken for a comparison.
- Each patient was placed into comfortable position that allows the vision of the treated area.
- Other parts of the body which won't be treated were covered and the treated area was cleaned by alcohol.

Application of Shock wave therapy:

- Shock wave equipment (developed by STORZ medical AG) with D-Actor applicator (radial waves) and energy levels (0.1-12) with mean energy level 5 This level corresponds to an energy flux density of 0.13-0.6 mJ/mm2.
- Each treatment region covered an area about 20x30 cm (Typically front or back of one thigh) which was scanned with 2000 shots using D-actor applicator in both horizontal (1000 shots) and vertical (1000 shots) directions for 15 minutes.
- The treatment was applied 2 times per week for 4 weeks.
- After the end of treatment program, all measurements of each patient were taken for a comparison.

Application of Bipolar Radiofrequency therapy:

- The device was switched on, (Power-shape) main power (1 MHz, auto selectable), and the temperature measurement (38° - 41°C).
- The treated area was lubricated with paraffin oil
- The duration was set at fifteen minute.
- The temperature was modified according to the sensation of the patient.
- Press on start button.
- Move the electrode above the treated area.
- Switch off the device.
- Clean the electrode.
- The treatment was applied 2 times per week for 4 weeks.
- After the end of treatment program, all measurements of each patient were taken for a comparison.

Statistical procedures:

In this study, the descriptive statistics (mean, standard deviation, standard error, minimum, maximum values, were calculated for all patients in the groups of the study. Comparison was made by independent T. test to compare the pre-treatment and post-treatment variables between the two groups of the study for the thigh skin fold. Paired t-test was used to compare the before and after treatment results in the same group for the thigh skin fold. Comparison before and after the treatment within the same group was done by **Wilcoxon signed-ranks test** for the cellulite grading scale. **Mann-Whitney test** was used to compare the results from each group for the cellulite grading scale to see if they differ significantly. A value of $P < 0.05$ was considered statistically significant [10].

Results:

Table (2): The statistical analysis of AGE mean difference, t. and probability values and the level of significance in the 2 groups; between group (B) and group (A)

AGE statistical analysis

	Group (B)	Group (A)
Mean of AGE in years	37.0667	37.0000
± standard deviation	7.3724	7.2899
Standard error	1.9035	1.8822
Mean difference	0.066667	
t. value	0.03	
p. value	0.978	
Level of significance	Non significant	

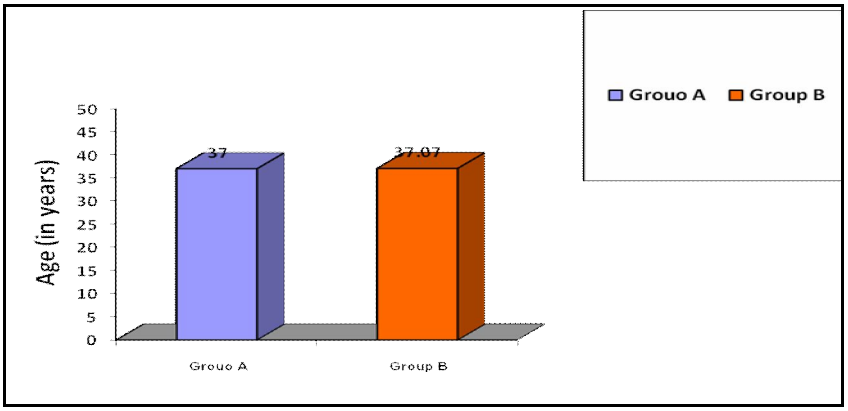

Figure (1): Bars representing the mean values of the AGE in years and shows non-significant differences between the two study groups.

Results of the Cellulite grading scale (CGS) per degrees in the first study group (shock wave therapy group).

Table (3): Distribution of CGS per degrees in the first study group (shock wave therapy group) measured pre- and post-assessment.

Period of treatment	Degrees	Number	Percent
CGS pre-assessment	2	3	20
	3	12	80
CGS post-assessment	1	2	13.3
	2	12	80.0
	3	1	6.7

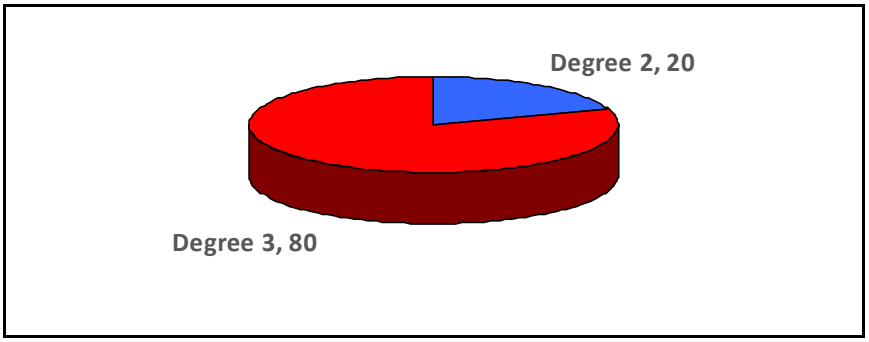

Figure (2): Percentage of CGS per degrees measured pre-assessment in the first study group (shock wave therapy group).

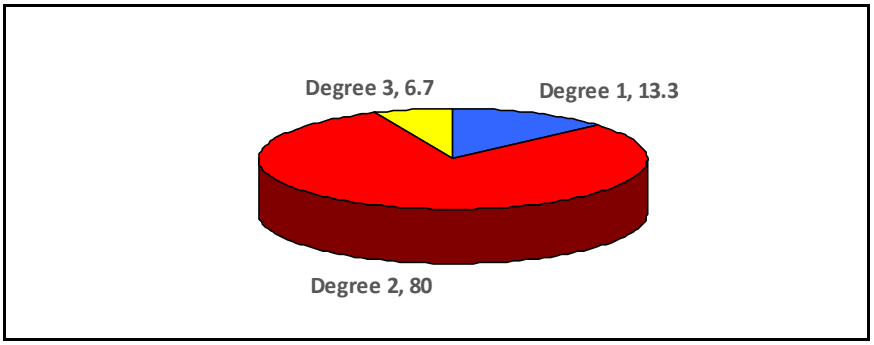

Figure (3): Percentage of CGS per degrees measured post-assessment in the first study group (shock wave therapy group).

Results of the CGS per degrees in the second study group (bipolar radiofrequency group).

Table (4): Distribution of CGS per degrees in the second study group (bipolar radiofrequency group) measured pre- and post-assessment.

Period of treatment	Degrees	Number	Percent
CGS pre-assessment	2	2	13.3
	3	13	86.7
CGS post-assessment	0	4	26.7
	1	10	66.7
	2	1	6.7

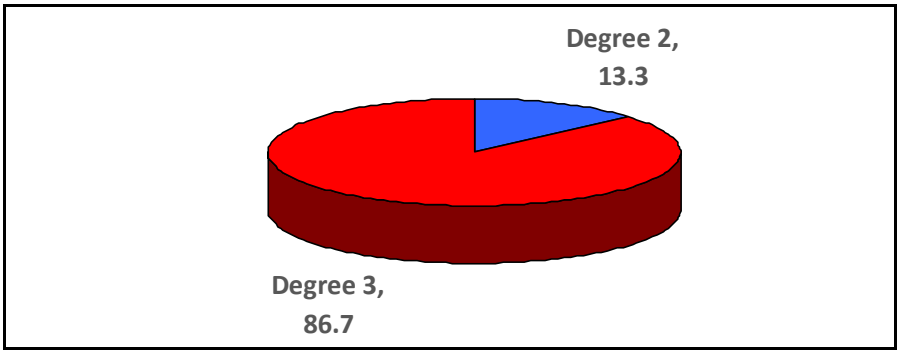

Figure (4): Percentage of CGS per degrees measured pre-assessment in the second study group (bipolar radiofrequency group).

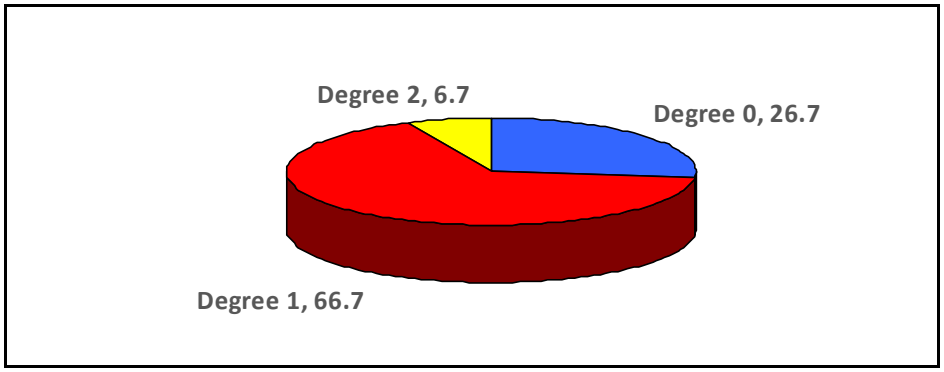

Figure (5): Percentage of CGS per degrees measured post-assessment in the second study group (bipolar radiofrequency group).

Table (5): Comparison between degrees of CGS in the two studied groups measured pre- and post-assessment.

	Pre- assessment	Post-assessment
Z value	-0.482	-4.244
P value	0.630	0.001
Level of significance	Significant	Significant

Z value= random variable in a standard form.

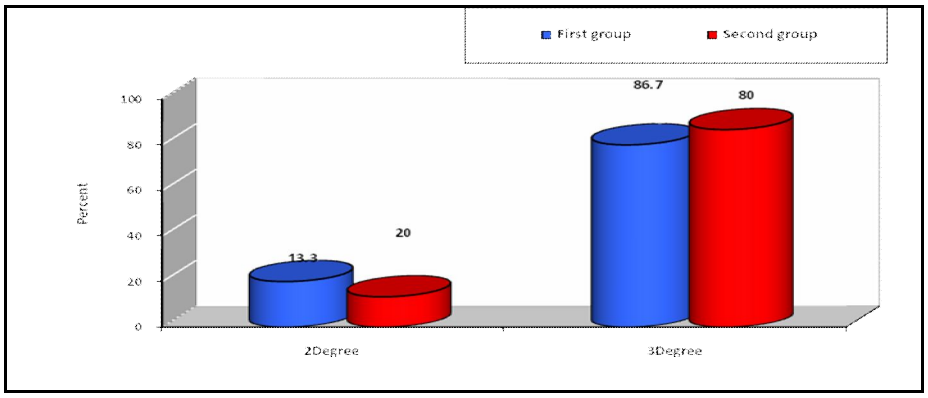

Figure (6): Comparison between degrees of CGS in the two studied groups measured pre-assessment.

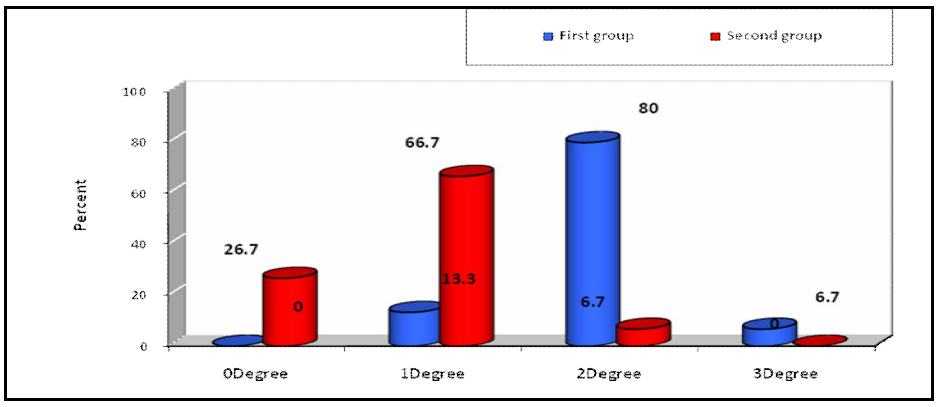

Figure (7): Comparison between degrees of CGS in the two studied groups measured post-assessment.

Comparison between means of the first pre-treatment records of TSF in the two groups: As observed in table (6): there was non-significant difference in the first pre treatment records of TSF, between the second study and the first study groups (P > 0.05).**Comparison between the means of the second records of**

TSF in the two groups: As shown in table (7): There was a significant a highly decrease in the second records of TSF, between the second study and the first study groups ($P < 0.05$).

Table (6): The means, standard deviation, t. and probability values and the level of significance of the first pre- treatment records of the TSF in cm of the two groups

	group (2) (Bipolar radiofrequency)	**group (1) (Shock wave therapy)**
Mean in cm	8.6533	8.6467
± standard deviation	0.1922	0.1922
Standard error	0.0496	0.0496
t. value	0.09	
p. value	0.926	
Level of significance	Non- Significant	

Table (7): The means, standard deviation, t. and probability values and the level of significance of the second records of the TSF in cm of the two groups

	group (2) (Bipolar radiofrequency)	**group (1) (Shock wave therapy)**
Mean in cm	4.780	5.6933
± standard deviation	0.577	0.1944
Standard error	0.149	0.0502
t. value	-5.81	
p. value	0.0001	
Level of significance	Highly Significant decrease	

Discussion

Cellulite is a disease or normal expression of secondary sexual development, the term cellulite "refers to the popular description of the uneven, bumpy," orange peel or "cottage cheese" appearance of the thighs, buttocks, and breasts of postpubertal women. Known medical facts regarding cellulite are as follows. Cellulite rarely appears in males. Cellulite does not appear in prepubertal females. Cellulite varies in degree from mild to severe and basic cellulite is not particularly related to obesity but excess weight accentuates the condition. Cellulite reflects a variety of conditions described in the medical literature as adiposis edematosa, dermopanniculosis deformans, status protrusus cutis, and several others.' Thus, there are several conditions that give rise to skin with the "cellulite" appearance. This illustrates that the basic definitions concerning cellulite need clarification[11].

The etiology of cellulite can be evaluated by following structural changes in the dermis and subcutaneous fat in effected and noneffected regions. The changes in dermal structure in cellulite-affected areas are quite apparent. There are projections of subcutaneous fat into the reticular and papillary dermis. These projections are readily observed via ultrasound as low density regions among the denser dermal tissues.' An increase in dermal glycosaminoglycans has been reported in cellulite affected areas. This suggests greater water binding in these regions and manifests as low density (dark regions) in ultrasound images[12,13].

Extracorporeal shock wave therapy (ESWT) Shock waves appear in the atmosphere when explosive events such as lightning strikes occur. These are audibly perceived as loud “bangs”. They transmit energy from the place of generation to distant areas which may cause window panes to shatter. Shock waves are presented by a single, mainly positive pressure pulse of large amplitude that is followed by comparatively small tensile wave components[14]. When using shock waves for therapy, effects that make the pressure pulse even steeper

due to nonlinearities in the propagation medium as well as phenomena such as refraction and diffraction at acoustic interfaces have to be taken into consideration[8,15]**.**

Besides mechanical effects such as fragmentation of brittle material on acoustic interfaces (i.e., glass/air or kidney stone/surrounding tissue), cavitation bubbles are generated in the propagation medium (i.e., water or elastic body tissue), which in turn causes needle-like punctures (i.e., leading to stimulating effects such as the generation of action potentials of nerve cells). High-energy extracorporeal generated shock waves in which mechanical energy is transformed from electrical energy by the piezo-effect were first used therapeutically for kidney stone fragmentation[16,17]**.**

Some authors stated that Extracorporeal shock wave therapy (ESWT) is now well established and is used more than 90% worldwide, as the principal method for treating kidney and urethral stones. Extracorporeal generated shock waves are a means of bringing therapeutically effective energies to locally limited places in the body in a non-invasive way. The fact that shock waves selectively effect acoustical interfaces (connecting two media, each with a different density, e.g., oil/water or stone/tissue) and pass through homogenous elastic tissue without damage to the most part is medically important. The damage outside of the treatment zone is almost completely avoided due to the possibility of concentrating energy through focusing[5,18]**.**

Some authors documented that Cellulite (gynoid lipodystrophy)**,** the anesthetically disturbing (according to modern taste) dimpling of the skin commonly occurs on the thighs and buttocks affecting most post-adolescent woman of all races. Incipient cellulite is recognized by an "orange peel" aspect while full blown cellulite is characterized by a dimpled skin surface. Cellulite is uncommon in men, the majority of those affected also suffer androgen-deficiency disorders such as Klinefelter's-syndrome, hypo-gonadism or cirrhosis. While not potentially hazardous to health (Smith 2002) and even considered normal based upon its frequency of occurrence, cellulite remains nonetheless, an issue of cosmetic concern and may induce negative psycho-social side-effects in those suffering its consequences on their appearance[6,19].

Others documented that medium-energy; high focused extracorporeal shock waves (ESW) applied locally to the skin with cellulite may be a potential noninvasive therapy approach. Recently low-energy defocused ESW treatment showed some evidence of remodeling of the collagen within the dermis. Shock wave treatments are to be distinguished from high intensity ultrasound used in liposculpturing[2,20].

A cellulite clinical grading system has now been identified with grades varying between I and IV. Grades III and IV are the more typical presentations whereby skin dimpling is obvious in the standing position. A variety of methods have been proposed to treat cellulite. Most produce either no results or shortlived improvement. Recent studies have documented the efficacy of both (1) a low-energy diode laser with associated contact cooling, suction and massage and (2) an infrared light/bipolar radiofrequency (RF) device combined with mechanical manipulation[5].

Both systems involve biweekly treatments for 6 to 16 weeks. Results from both treatments appear to be similar. The application of heat or thermal injury to skin resulting in shrinkage of redundant or lax connective tissues by collagen denaturation was first observed with ablative laser resurfacing. Since then, skin tightening and the treatment of cellulite specifically have been explored with non-ablative technologies. The most-studied category of devices in this arena is radiofrequency (RF) devices, which encompass that part of the electromagnetic spectrum with frequencies ranging from 3 kHz to 300 MHz[22,21]**.**

The delivery of RF is termed monopolar when the energy is applied as current between a single electrode tip and a grounding plate. When the energy is applied between two points on the tip of a probe, the electrode is considered bipolar. A newer application of RF involves the emission of electromagnetic radiation (EMR) rather than current. When RF is delivered as EMR, the delivery is called unipolar and no grounding pad is necessary[5,23].

Electrical current propagation is limited to the area of skin between the electrodes and the depth of penetration is approximately half the distance between them. Temperature elevation is induced in a well-defined volume of tissue. If, in addition to RF energy, intense infrared light (IR) is used, an increased thermal effect in the target biological tissue can be obtained in overweight persons; there is a redistribution of fat in specific patterns. One aesthetic problem for most obese individuals, who achieve modest or even significant degrees of weight loss due to a diet control program combined with physical exercise, is the inability to

eliminate the accumulated fat at some specific anatomical sites, such as the abdomen, buttocks and thighs. These localized areas of fat accumulation cannot be solved by regular dietary control alone but require an additional body sculpting[24].

Radio frequency (RF) is electromagnetic radiation in the frequency range of 3-300GHz. The primary effects of RF energy on living tissue are considered to be thermal. The goal of the new devices based on these frequency ranges is to heat specific layers of the skin. The directed use of RF can induce dermal heating and cause collagen degeneration. Wound healing mechanisms promote the remodeling of collagen and wound contraction, which ultimately clinically enhances the appearance of mild to moderate skin laxity[26,25].

Radio frequency energy has become increasingly popular for medical applications that involve tissue heating in the fields of general surgery, cardiology, neurology, orthopedics and dermatology. It has been used for more than a century for a variety of medical applications, including tissue electrodesiccation and electrocoagulation, joint capsular tightening, corneal curvature alteration, incompetent saphenous venous closure, aberrant cardiac electroconductive ablation and prostate and liver neoplasm eradication, the ability of RF energy to deliver heat to dermal structures results in nonsurgical lifting and tightening of tissue without the disruption of epidermal integrity[22,11].

Radiofrequency current is formed when charged particles flow through a closed circuit. As the energy meets resistance in the tissue, heat is produced. The amount of heat will vary depending on the amount of current, the resistance levels in the targeted tissue and the characteristics of the electrodes. Human tissues, including the skin, are rich in electrolytes and an array of compounds that allow current conductance with varying degrees of impedance and resulting heat formation. The amount of RF energy applied can be configured to target specific tissues. In addition, the water content of skin varies between different areas of the body with time of the day, environmental humidity, internal hydration and the use of topical moisturizing agents[19]**.**

Based on this principle, treatments are designed to cause the shrinkage of dermal collagen using heat generated by a radiofrequency current. In addition, the treatment promotes the formation of new collagen via the natural wound healing response of the skin and a direct effect on the dermal cellular matrix. The extent of collagen shrinkage, fibroblast activation, fibroplasia and overall collagenesis in the different skin layers is based on a complex multivariate mechanism, which depends on the temperature distribution and timing. This enables shrinkage at a certain depth, followed by collagenesis at a different, preferably more superficial, layer. Mechanical stress, (e.g., vacuum) has been reported to stimulate fibroblasts, leading to collagenesis. Notably, both heat exposure and application of vacuum to the skin are also known to increase blood perfusion in the affected area, supporting the fibroblast activity and the overall rejuvenation process[27]**.**

The nonablative RF devices deliver RF energy to the skin with concomitant contact cooling and are approved for the noninvasive treatment of facial rhytides by the US Food and Drug Administration. This system uses a high-frequency generator that produces a 330-W, 6-MHz monopolar current signal. A disposable membrane tip encompassing a treatment area of either 1.0 or 1.5cm^2 is used with a disposable adhesive return pad that serves as the grounding point. The depth of heating is dependent upon the size and geometry of the treatment tip being used. A conductive coupling fluid is used during the treatment to enhance the thermal and electrical contact between the treatment tip and the skin[28].

This patented capacitive membrane tip allows for delivery of deep volumes of sustained, uniform and intense heat to tissue depths of 3-6mm. The treatment tip creates an electrical field within the tissue by alternating its charge from positive to negative 6 million times per second with electrons and ions simultaneously attracted and repelled from the surface. According to Ohm's law, it is the resistance of the tissue to the movement of these ions that generates heat[30,29]**.**

Nonablative skin rejuvenation with RF-based systems produces skin tightening through controlled dermal collagen contraction and neocollagenesis without integumental injury. This nonsurgical approach to rhytide reduction thereby avoids many of the inherent risks associated with surgical rhytidectomy. Experience with nonablative lasers and light sources have proven that tissue enhancement is possible with controlled dermal wounding without epidermal disruption. Radiofrequency devices are able to achieve greater depths of thermal injury with tissue penetration to the level of the dermis and subcutaneous layer without producing

thermal burns. Tissue tightening and reduction of prominent nasolabial folds or jowling are produced as a result of this[22]**.**

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