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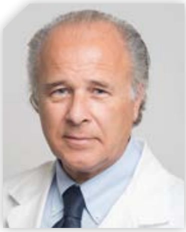

ANTONINO DI PIETRO

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SUMMARY

Background. *Cellulite is a major aesthetic concern affecting approximately 90% of post-puberal women worldwide. Numerous invasive and non-invasive treatments have been proposed, with variable efficacy. The objective of this study was to investigate the effectiveness of a new microwaves platform, ONDA Coolwaves® (DEKA, Florence, Italy), in the treatment of cellulite in the areas of the buttocks and posterior thighs.*

Material and Methods. *Patients with cellulite on the buttocks and posterior thighs were enrolled in two Italian Centers. The treatment protocol consisted of 4 sessions of ONDA Coolwaves® at intervals of 30 days. Clinical evaluations and standardized digital photographs were performed before the first treatment, at 4 and at 8 weeks after the last treatment. To assess the severity of cellulite the cellulite severity scale (CSS) was used.*

Results. *Twenty women were enrolled in this study. At baseline, 95% of the patients showed a moderate-severe CSS. A grade II-III cellulite was found in 85% of the women, while 15% showed a mild cellulite (grade I). Eight weeks after the last treatment, an overall improvement of cellulite grade was found ($p<0.05$) with 80% of the women showing a mild CSS and 20% of patients showing a moderate CSS index. Totally, 25% of the patients did not have signs of cellulite in the follow-up period, while 75% patients showed a reduction of cellulite to grade I or II.*

Conclusions. *This prospective study confirmed the efficacy of ONDA Coolwaves® (DEKA, Florence, Italy) for the treatment of cellulite on both buttocks and posterior thighs areas, with no detected side effects.*

KEYWORDS
Microwaves, cellulite.

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INTRODUCTION

Cellulite is one of the most common lipodystrophy syndromes, which affects 80-90% of post-adolescent women [1]. Firstly described in the early 20th century, it has been referred to by several synonyms, including gynoid lipodystrophy, nodular liposclerosis, edematofibrosclerotic panniculopathy, panniculosis, adiposis edematosa, dermopanniculosis deformans, and status protrusus cutis [2-4].

Clinically, cellulite shows off with a surface relief alteration resulting in depression and raised areas leading to an irregular appearance, such as dimpled, orange peel, cottage cheese, or mattress-like appearance of the area of interest, typically located over the thighs and buttocks but also on the legs, arms and abdomen [5]. Changes occurring in the course of cellulite formation regard fibrosis and sclerosis of the tissues, which may results a wavy course of the skin surface with palpable multiple nodules. Many studies confirmed that cellulite depressions are associated with a significant increase in the presence and thickness of underlying subcutaneous fibrous septa. In cases of significant advancement of changes, nodules and sclerotic lesions are accompanied by soreness, dryness and thinning of the skin covering the changed area [6-9].

Women are most commonly affected by cellulite due to the structure and anatomy of their subcutaneous septa compared to men [10]. Particularly, in women, fibrous septa are usually oriented perpendicularly to the skin surface, creating large, rectangular fat lobules. Fibrosis leads to the retraction of the septa, pulling the skin down and creating depressions or dimples. The raised areas result from projection of underlying fat lobules into the dermis. In men, the fibrous septa are organized in a crisscross pattern which create smaller subcutaneous fat lobules, reducing the risk of developing cellulite dimples [10].

The etiopathogenesis of cellulite is either multifactorial and unclear, but it is known to incorporate genetic, vascular, hormonal and environmental factors [11]. Most of the current data indicates that either endothelial dysfunction and lymphatic disorders play an important role in the etiology of this phenomenon, causing interstitial matrix alterations and structural changes in subcutaneous adipose tissue [12-15].

Inflammatory factors could play a role in the fibrous septal development too [13]. Significant decreases in the subcutaneous expression of adiponectin, an adipocyte-derived hormone with anti-inflammatory, antifibrotic, and vasodilatory functions, may play a role in cellulite pathogenesis [1,16]. Changes in the subcutaneous tissue could also be worsened by age, due the an increased skin laxity [17]. Moreover, female sex hormones may play a significant role in the development of lipodystrophy. Particularly, the exacerbation and progression of cellulite seems to correlate with pregnancy-related hyperestrogenism, the use of birth control pills or hormone replacement therapy in postmenopausal women [11]. Alcohol consumption stimulates lipogenesis and causes body dehydration, resulting in the excessive and improper storage of fat [18]. Smoking significantly contributes to a greater amount of free radicals production in the body, and to contract the small blood vessels, responsible for local micro-circulatory impairments [19]. Finally, lifestyle factors such as high carbohydrate diets, and a sedentary life may lead to an increase in total body fat content, which enhances the appearance of cellulite [1].

To assess the severity of cellulite, Nürnberger and Müller [4] first proposed a clinical grading scale for cellulite, including three grades:

- 1. Grade I= the skin of the affected area is smooth while the subject is standing or lying, but the alterations to the skin surface can be seen by pinching the skin or with muscle contraction (visible changes with skin clamping or muscle contraction);
- 2. Grade II= the orange peel aspect of the skin or mattress appearance is evident when standing, without the use of any manipulation of the skin pinching or muscle contraction (visible without manipulation);
- 3. Grade III= the alterations described in grade or stage II, are present together with raised areas and nodules (visible changes associated with nodules).

Recently, Hexsel et al. [20] validated a standardized and objective method of grading cellulite, the *cellulite severity scale* (CSS). It is based on 5 key morphologic aspects of cellulite, including the 1) number of depressions; 2) depth of depressions; 3) clinical morphology; 4) extent of skin laxity, flaccidity, or sagging; and 5) Nürnberger–Müller classification grade. Each variable is graded from 0 to 3, leading to overall grades of mild (1–5), moderate (6–10), and severe (11–15).

During the years, many treatments have been proposed to improve cellulite, including topical therapy, injectables (eg, chemical septolysis with collagenase), lymphatic or vacuum-assisted massage, acoustic wave therapy, light therapy, external non-invasive lasers, and radiofrequency (RF) devices [21,22]. Unfortunately, unpredictable efficacy and the potential for only short-term improvement despite numerous treatment sessions limit their popularity.

Herein, we describe a non-invasive treatment for women with cellulite, evaluating the safety and effectiveness of a new technique that utilizes microwaves for the reduction of the visible appearance of cellulite, the ONDA Coolwaves® system (DEKA, Florence, Italy).

Materials and methods

This prospective study was performed in two Italian Centers (Istituto Dermoclinico Vita Cutis e Studio Medico Perosino Associati) from September 2018 to June 2019.

Female patients with gluteal and posterior thighs cellulite, aged > 18 years with a body mass index (BMI) <30 were enrolled.

Exclusion Criteria:

- Volunteers undergoing other cosmetic treatment in the last 6 months prior to the study;
- Pregnant or lactating patients;
- Patients having both present or past history of cardiovascular diseases, cancers, metabolic disorders, immunosuppression.

After being informed about the aim of the study, patients gave their written informed consent. Moreover, all the patients gave consent to the use of their photographs for scientific purposes. All the enrolled volunteers were properly informed about the treatment steps and procedures to be performed. The participants were not submitted to any food restriction and were asked to maintain their usual daily activities.

The treatment protocol consisted of 4 sessions of ONDA Coolwaves® (DEKA, Florence, Italy) spaced 30 days apart each other. The ONDA Coolwaves® is a microwaves platform utilizing two handpieces which allow a selective concentration of the specific microwave dielectric heating in both deep and superficial subcutaneous tissues. An effective contact cooling system is implemented to avoid rebouncing thermal damage to the superficial layers during the microwaves transmission.

Clinical evaluations were performed before the first treatment (at baseline), at 4 and at 8 weeks after the last treatment. Cellulite grade was determined by clinical inspection of the patient's skin. To assess cellulitis severity, the CSS was used. The treated areas were inspected and constantly monitored during all the sessions. Standardized digital photographs with a digital camera (Reflex Nikon D800) were also performed at baseline, at 4 and at 8 weeks after the last treatment.

Patients comfort and satisfaction were evaluated using a five-point Likert scale questionnaire (0 = worse; 1 = little satisfaction or not satisfied; 2 = fairly satisfied; 3 = satisfied; and 4 = very satisfied).

All the clinical and antrophometric data, including age and BMI of the patients were recorded and put into a database. The Wilcoxon signed rank test was used for statistical analysis, with an alpha level of 5% ($p < 0.05$) being considered significant. Data were represented as means ± standard deviation (SD).

Results

➜ Demographic data

A total of 20 women took part in the study and completed all the study visits. Mean age (± SD) at baseline was 37.0 ± 12.1 years (range, 19–56 years) and mean was BMI 21.7 ± 2.2 kg/m2 (range, 19–28 kg/m2).

➜ Cellulite Severity Scale

At baseline, the mean CSS (± SD) was 9.2 ± 2.3. 75% out of the 20 patients (n=15) showed a moderate CSS, followed by 20% of women with a severe CSS (n=4) and only 5% (n=1) patients with a mild CSS (**Figure 1**). According to Nürnberger and Müller classification, 65% (n=13) of the women rated as grade II and 20% (n=4) as grade III cellulite; 15% of the women (n=3) showed a grade I cellulite (**Figure 2**). Moderate-severe skin depressions as well as medium-severe depth depressions were present in 75% (n=15) out of the 20 patients. Concerning skin laxity, 65% (n=13) of the women showed slight laxity, while 35% (n=5) presented a moderate form.

At follow-up, 8 weeks after the last treatment, all the parameters analyzed according to CSS, were improved ($p<0.05$). Mean CSS was 4.2 ± 1.9. Totally, 80% (n=16) of the women showed a mild CSS while 20% (n=4) of the patients presented a mo-

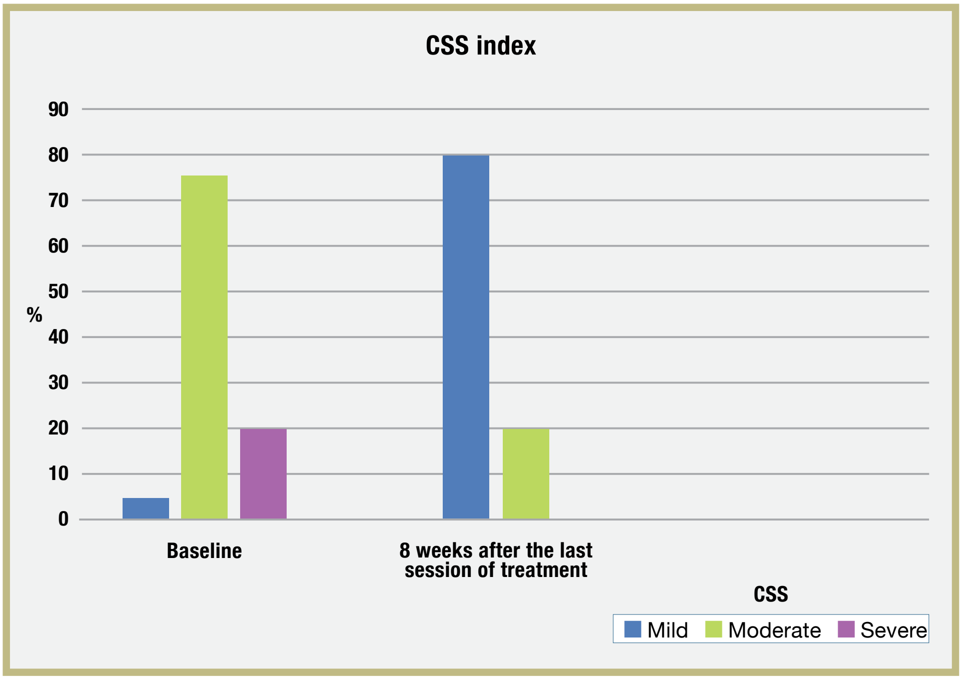

Figure 1. *Cellulite severity scale (CSS) at baseline and 8 weeks after the last session of ONDA Coolwaves® (DEKA, Florence, Italy).*

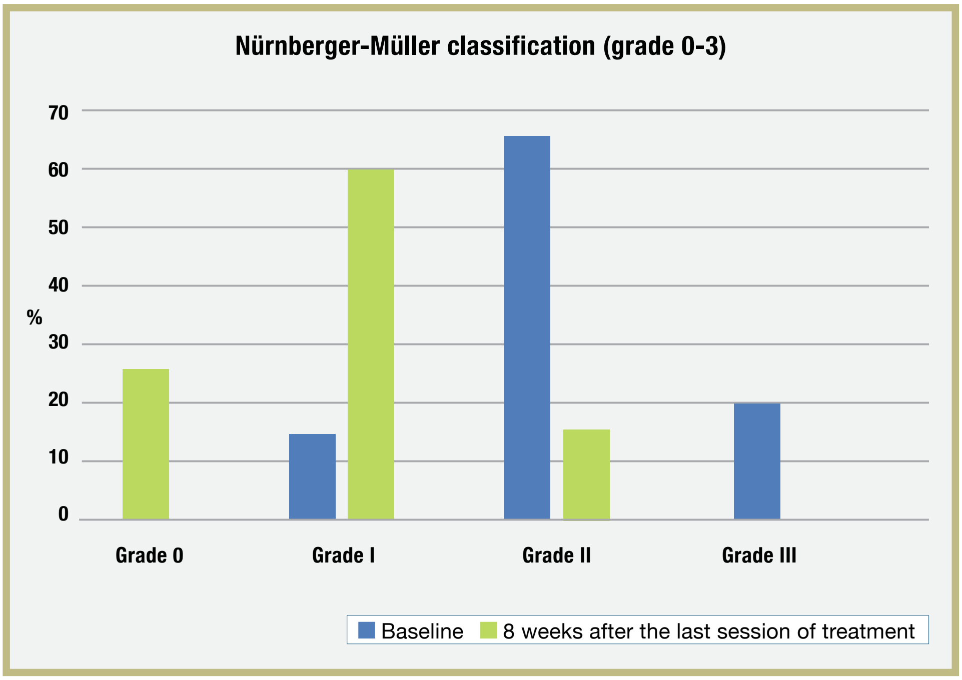

Figure 2. *Nürnberger–Müller classification (grade 0-3) at baseline and 8 weeks after the last session of ONDA Coolwaves® (DEKA, Florence, Italy).*

derate CSS index (**Figure 1**). None of the women showed severe CSS. An overall improvement of cellulite grade, according to Nürnberger and Müller classification, was shown ($p<0.05$) with 25% (n=5) of the patients with no signs of cellulite, while 60% (n=12) out of the 20 patients showed a grade I cellulitis and 15% (n=3) a grade II cellulite (**Figure 2**).

Only 10% of the patients (n=2) showed moderate depressions, while 65% (n=13) and 15% (n=5) patients showed mild or did not show depressions, respectively. Moreover, 20% (n=4) out of 20 patients presented severe depth depressions, while 65% women (n=13) showed medium depth depressions. Skin laxity was absent in 65% (n=13) of patients and mild (n=7) in 35% of women.

Among volunteers, no significant statistical BMI variation was found.

➜ Side effects

None of the volunteers reported either pain or other side effects such as post-operative ecchymosis, oedema, blistering, hardness, neurovascular and local tissue injury (e.g. temporary loss of cutaneous sensory), swelling or nodules during either the treatment nor in the follow-up period.

➜ Patient Satisfaction Index

Seventeen out of the tewnty patients reported a significant improvement of cellulite.

On a scale of 0-4, the patients agreed (3.8) that they were satisfied with the results of the treatment. Three patients reported a mild satisfaction index because cellulite was improved but not completely disappeared. Patients also found an improvement in skin laxity.

Discussion

Cellulite is a condition that affects psychological aspect in majority of women. Many therapeutic options have been

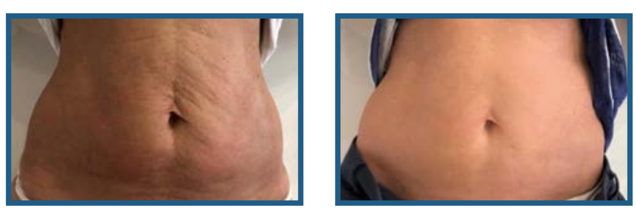

Figure 3.
Abdomen cellulite of a 42 female patient before (a) and after (b) 1 month of treatment with ONDA Coolwaves® (clinical photography).

Figure 4.
Buttocks and tights cellulite of a 38 female patient before (a) and after (b) 4 months of treatments with ONDA Coolwaves® (clinical photography).

developed to overcome this condition, including topical treatments, non-invasive energy-based devices, and minimally invasive interventions [1,5,12,13,22,23,24].

RF techniques are one of the most commonly treatment for cellulite. Many companies propose RF systems (100 kHz–40 MHz) as valid and reliable alternatives to other technologies aimed at reaching the same clinical results [25]. RF is an electromagnetic energy that works by heating the tissues. When applied to tissues, RF generates oscillating magnetic fields that move electrically charged particles, producing heat in the tissues, and the amount of heat produced depends on the resistance (bio-impedance) of the target tissue [26-28]. The heat that is delivered to the subcutaneous layer is presumably absorbed by adipocytes till, to supposedly induce the breaking down of fat cells through the membrane's lysis [29,30]. Subsequently, a wound-healing process such as collagen neo-synthesis would therefore improve various tissue characteristics [30,31]. By elevating the tissue temperature at the target area, some collagen denaturation, remodelling and new collagen generation are stimulated. According to the literature, RF also favours a decrease in thickness and fat accumulation in adipocytes, consequently reducing venous and lymphatic fluid retention caused by hypodermal tissue compressing vessels and nerve endings [32].

RF generates heat in different tissues by transforming energy through three basic mechanisms from electromagnetic field. These mechanisms include (i) orientation of electric dipoles that already exists in the atoms and molecules in the tissue; (ii) polarization of atoms and molecules to produce dipole moments; and (iii) displacement of conduction electrons and ions in the tissue [33].

RF devices deliver thermal energy via electrode. Electro-thermal energy production with this modality could be monopolar (single electrode with return electrode), unipolar (single electrode with no return), bipolar (2 electrodes), or multipolar (3 or more electrodes) [24,34]. Recently, contactless RF devices have also been developed.35-36 RF has been used alone or in combination with other treatments, such as infrared light and mechanical manipulation [24,37,38].

Current studies focusing on RF in the treatment of cellulite were reported in **Table 1** [27-29, 39-54]. Among the RF devices, combination therapy is the most investigated technique, with ten published scientific papers. Six randomized controlled trials (RCTs) were also available.

In a recent review by Vale et al., [26] authors reported all the current literature on RF in the treatment of cellulite. Generally, authors showed the efficacy of high-energy RF and RF combination therapy for treating cellulite; however, authors underlined that the methodological quality of these studies was low and that statistical analyses was not performed in all the studies. Moreover, not all the studies used a standardized method to objectively evaluate the results of the treatment, thus making difficult to confirm their results.

Despite multiple RF devices that attempt to treat cellulite, no procedures have been proven to be successful in the long term [32]. As the demand for non-invasive and long-lasting treatments to reduce cellulite has been growing up, new medical devices have been developed accordingly. Recently, a new microwave technology has been setup [33]. Microwaves are part of the RF spectrum; they are electromagnetic waves with a frequency range between 1 and 300 GHz [55]. In a previous study by Bonan et al., [56] ONDA Coolwaves®, (DEKA, Florence, Italy) a new microwave device, has been successfully used for the treatment of localized subcutaneous adiposities. The ONDA system handpieces generate waves at 2.45 GHz which interact with biological molecules and generates localized, controlled heat absorbed by selected biological targets, such as fat, through a biophysical process called "dielectric heating". Authors hypothesized that microwaves could act directly on the adipose tissue, sparing the dermo-epidermal layers, promoting adipocyte cells heating, and, consequently, leading to macrophage-mediated adipocytes lysis. Interestingly, authors found an improvement in the patients' skin tone and texture. Authors hypothesize that this improvement could be the result of the action of microwaves on collagen septa. Controlled hyperthermia could cause solubilisation of the deeper collagen fibers and activate fibroblasts, remodelling collagen fibers. On these basis, we aimed at evaluating if microwaves could also improve cellulite. The objective of our study was to verify the effectiveness and safety of ONDA Coolwaves® in the treatment of cellulite and its long-term efficacy.

To assess the severity of cellulite in a standardized and objective way, the CSS was used. We found a significant improvement of cellulite with a significant reduction of number and depth of depressions in all the patients. The mean total CSS score improved from moderate-to-severe at baseline to mild 8 weeks after the protocol treatment with ONDA Coolwaves®.

No side effects were reported, neither after the single sessions of treatment, nor in the follow-up period, making the treatment safe and well tolerated by all the patients. Our results also showed a long-term efficacy of the treatment, since benefits were kept up to 8 weeks after the last session of treatment (totally 6 months). Interestingly, during the treatment period, there were no significant changes in the BMI, confirming previous data [56].

One of the limits of our study could be the small number of enrolled patients. Therefore, further studies with a larger number of patients will be needed to more fully characterize the clinical potential of microwaves and their mechanism of action.

Conclusions

This prospective study confirmed that ONDA Coolwaves® (DEKA, Florence, Italy) treatment is a safe and effective treatment for cellulite of the buttocks and posterior thighs. Moreover, the evaluation of parameters through the CSS before and 8 weeks after the last treatment, proved a long-lasting effect of ONDA Coolwaves®.

Conflict of interest: none
Financial disclosure: none

Table 1. *Overview of studies evaluating the efficacy of radiofrequency in cellulite.*

References	Year	Design	Teraphy	N° patients	Statistical analysis
Sadick NS	2004	OS	Unipolar RF	35	no
Alster TS	2005	OS	Combination	20	no
Emilia del Pino M	2006	OS	Combination	26	no
Kulick M	2006	OS	Combination	16	no
Wanitphakdeedecha R	2006	OS	Combination	12	no
Nootheti PK	2006	RCT	Combination	20	yes
Sadick N	2007	OS	Combination	16	no
Alexiades-Armenakas M	2008	RCT	Unipolar RF	10	yes
Goldberg DJ	2008	OS	Unipolar RF	30	no
Romero C	2008	RCT	Combination	10	yes
Van der Lugt C	2009	OS	Bipolar RF	50	no
Manuskiatti W	2009	OS	Low-level RF	37	yes
Kaplan H	2009	OS	Low-level RF	12	no
Boisnic S	2010	RCT	Low-level RF	24	yes
Levenberg A	2010	OS	Low-level RF	37	yes
Hexsel DM	2011	OS	Combination	11	yes
Mlosek RK	2012	RCT	Low-level RF	45	yes
McDaniel D	2015	OS	High-level RF	30	yes
Hayre N	2016	RCT	High-level RF	36	yes
Suh DH	2017	OS	High-level RF	12	no
Wanitphakdeedecha R	2017	OS	Combination	25	yes
Firtz K	2018	OS	Combination	30	yes

OS= observational study, RCT= randomized controlled study, RF= radiofrequency.

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