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Extracorporeal Shock Wave Therapy in the Treatment of Cellulite: A Prospective Randomized Controlled Trial

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Abstract: The aim of the study was to demonstrate the efficacy and safety of extracorporeal shock wave therapy in cellulite treatment. Twenty five women suffered from bilateral thigh cellulite graded as Stage 2 or 3 on Nurnberger-Muller Scale, were enrolled in this study. The means of age, weight, height and BMI were 35.8±9.63 years, 77.36±8.76 Kg, 164.76±4.14 cm and 28.40, respectively. They were treated by extracorporeal shock wave therapy with the energy flow density of 0.02 mJ/mm², 4000 shots at 16 Hz and 120 mJ for one thigh and the other thigh left for comparison. They received 8 sessions for 4 weeks. Nurnberger-Muller Scale for cellulite, thigh circumferential measurement of the thigh and self-assessment of satisfaction using visual analogue scale have been collected pre-treatment, post-treatment and follow-up (4 weeks after treatment). There were statistically highly significant differences in the 3 outcome measures of the treated side ($p<0.05$) compared with untreated side ($p>0.05$). The improvement of cellulite continued for 4 weeks after finishing the treatment.Extracorporeal shock wave therapy was safe and effective for improving the appearance of thigh cellulite after 4 weeks of treatment and the beneficial effects persisted for 4 weeks later as it seems to have long-term benefits.

Key words: Extracorporeal Shock Wave · Cellulite

INTRODUCTION

Cellulite is the most common lipodystrophic disease and is found in 85% of post-adolescent female of all ethnics and rarely seen in males [1]. Cellulite is not considered a disease but rather a purely cosmetic problem and has no association with morbidity and mortality and therefore, it cannot truly be described as a pathological condition [2].

Cellulite is a topographical alteration which characterized by "orange peel" syndrome, cottage cheese skin or synonymously [3, 4]. Cellulite can be found in any area of the body that contains subcutaneous adipose tissue. The more vulnerable areas are the upper outer thighs, the back of thighs and buttocks. Cellulite can also be present on the breasts, the lower part of the abdomen, the upper arms and the nape of the neck. Obesity is not essential for the presence of cellulite [5].

The pathophysiology of cellulite includes alterations of the adipose tissue and microcirculation causing fibro-sclerosis in the connective tissue. It is a non-inflammatory, degenerative condition, producing changes of the hypodermis [6]. The negatively affected microcirculation may also cause intracellular edema and decreased lymphatic drainage. It can be also classified as fibrotic, edematous, adipose, or combinatory [7]. Cellulite is characterized by alterations of the skin surface which include depressions and raised areas. Flaccidity, looseness, or slack of the skin further exacerbates relief alterations in the most of subjects [8].

Treatment modalities can be divided into four main categories: (1) Reduction of aggravating factors, which include stress, weight gain, sedentary lifestyle and hormonal contraceptives. Therefore, diet and exercise should be encouraged as an initial step in the treatment of cellulite [9, 10]; (2) Physical and mechanical methods,

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such as massage suction techniques, skin kneading, or liposuction [11] and phosphatidylcholine injections [12]; (3) Pharmacological agents include xanthines, retinoids, lactic acid and herbals [13], (4) Laser or radiofrequency increasing blood and lymphatic circulation [14]. However, there is no method of treatment of cellulite that is completely effective [15].

Extracorporeal shock wave therapy (ESWT) generated shock waves in which mechanical energy is transformed from electrical energy by the piezo-effect were first used for treating kidney and urethral stones in1970s [16]. Since the late 1980s, ESWT have been used in treatment of various diseases of the musculoskeletal system, such as plantar fasciitis [17], Achilles tendinopathy, medial tibial stress syndrome, greater trochanteric pain syndrome, tennis elbow, golfer's elbow and calcifying tendonitis of the elbow and shoulder [18]. Recently, ESWT was used in treatment of erectile dysfunction, chronic pelvic pain and Peyronie's disease [19]. Non-randomized clinical data suggest that ESWT applied as acoustic wave therapy is effective in terms of improved skin elasticity and revitalizing dermis in cellulite [20]. The purpose of this study was to demonstrate the efficacy and safety of extracorporeal shock wave therapy in the treatment of cellulite.

MATERIALS AND METHODS

Study Design: The study was designed as a prospective, randomized, controlled study with pre-treatment, post-treatment and follow up (Four weeks after completion of treatment) evaluation to assess the efficacy of ESWT by comparison the treated side versus untreated side. This study was carried out over the period from October 2013 to June 2014 at the outpatient physical therapy clinic, Applied Medical Sciences College, Prince Sattam bin Abdulaziz University (Formerly Salman bin Abdulaziz University), Saudi Arabia.

Subjects: Twenty five healthy female subjects expressed a wish for to enhance the appearance of their cellulite with the following inclusion criteria: age between 20 and 50 years, moderate bilateral thigh and buttock cellulite graded as Stage 2 or 3 on the Nurnberger-Muller Scale, no hormonal treatment within last the 6 months, commitment to the study and ability to follow the study procedures. Exclusion criteria were: prior surgery in the treated area (especially liposuction), medical and/or cosmetic treatment of cellulite existing or within the last 3 months, infection and/or tumor disease within the treated side, acute inflammation of the treated area, anticoagulation therapy and/or hemorrhagic disorders, pregnancy, significant weight changes (caused by disease or diet), modified hormonal treatment, drugs (eg, corticosteroids, non-steroidal anti-inflammatories), vascular abnormalities and previous treatment with ESWT.

All subjects participated in the study were informed about the nature of the study and gave their informed Institutional Ethical Committee Clearance and wrote informed consent to participate in it. Each subject was informed about the study design (One side treated, the other side left for comparison) as a unilateral treatment on a randomly selected side (right or left).

Procedures

Outcome Measures: There were 3 outcome measures Nurnberger-Muller Scale for cellulite, thigh circumferential measurement of treated thigh and self-assessment of satisfaction using visual analogue scale (VAS). The three outcome measures were collected pre-treatment, post-treatment (following the last session) and follow up (4 weeks after the last session).

Nurnberger-Muller Scale for Cellulite: Is a simple grading-score of cellulite by inspection. It is a widely used tool for measuring cellulite. The 4-graded scales according to Nurnberger-Muller are:

Stage 0: Smooth surface of skin while lying down and standing - Wrinkles upon pinch-test.

Stage 1: Smooth surface of skin while lying down and standing – Dimpling appears upon pinch-test or muscle contraction.

Stage 2: Dimpling appears spontaneously while standing but not while lying down.

Stage 3: Dimpling appears spontaneously while standing and lying down.

The Nurnberger-Muller Scale can be used to evaluate changes in cellulite severity following treatment intervention [21].

Thigh Circumferential Measurement: Was done using tape measure and was always taken at a constant distance from a specific anatomical landmark which was a distance of 10 cm below the greater trochanter for the thigh [22]. Each subject stood erect with her weight evenly distributed on both feet with legs slightly a parted during measurement.

Visual Analogue Scale (VAS): Self-assessment of the success and satisfaction on a visual analogue scale 0-10 (0 = no change, 10 = fully satisfied) [23].

Treatment Procedures

Treated Side: Was the study side which consisted of 25 right or left thigh with cellulite graded as Stage 2 or 3 on the Nurnberger-Muller Scale who were treated by high energy extracorporeal shock wave therapy (ESWT) from Zimmer MedizinSysteme (*ZWave*® device, Germany) with the energy flow density per shot set at 0.02 mJ/mm^2. Subjects received 8 sessions of ESWT (2 sessions per week) for 4 weeks. Subjects were positioned on a treatment table and the areas of the posterior thigh and the buttock areas were exposed. The medial and lateral lines of the thigh served as borders of the treatment area which extended superiorly until the buttock crease and inferiorly 5 cm above the popliteal crease. After application of coupling gel, 4000 shots were applied homogeneously at 16 Hz and 120 mJ. Movement of the ESWT probe was from distal to proximal on treated side with slight pressure in skin contact towards the lymph nodes and backwards without any pressure, with a centripetal direction of treatment. No anesthesia was needed as the procedure was almost painless. Subjects only felt a vibrating sensation. Subjects were carefully observed at the end of each session to evaluate any side-effects such as pain, swelling or irritation. A redness of the skin on the treated area is typically observed for 1 - 2 hours after the session as a normal effect.

Untreated Side: Was the control side which consisted of the contralateral side (right side or left side) of the same 25 subjects. This side was left without treatment for comparison with the treated side.

Statistical Analysis: Mann-Whitney U test was used to assess the difference in the Nurnberger-Muller Scale for cellulite (Non-parametric variable) between both sides (Pre-treatment, post-treatment and follow-up time) and Friedman test was used to assess these parameters within each side, while Dunn's Multiple Comparisons test was used to determine the significant difference between measurements time of evaluation (Pre-treatment and post-treatment, pre-treatment and follow-up time, post-treatment and follow-up time). One way repeated measures of ANOVA using Greenhouse-Geisser test was used to assess the difference within each side in circumferential measurement and VAS, while Least Significant Difference (LSD) test was used to determine the significant difference between measurements time of evaluation (Pre-treatment and post-treatment, pre-treatment and follow-up time, post-treatment and follow-up time). Un-paired t-test was used for thigh circumferential measurements and VAS (Parametric variables) between both sides. Descriptive statistics (Mean and standard deviation) were computed for all data. Data were coded and entered to a statistical package of social science (SPSS, version 20). All p-values less than 0.05 were believed to be statistically significant.

RESULTS

The means of age, weight, height and BMI were 35.8±9.63 years, 77.36±8.76 Kg, 164.76±4.14 cm and 28.40, respectively.

Frequency and percentage of subjects in Nurnberger-Muller Scale for cellulite of treated side and untreated side are summarized in Table (1). There was a statistically highly significant difference within the treated side ($P<0.001$). Dunn's Multiple Comparisons test revealed that a high improvement in cellulite from pre-treatment, post-treatment and follow-up time with $p<0.01$ between pre-treatment & post-treatment, $p<0.001$ pre-treatment & follow-up which means a highly significant difference. There was a significant difference $p<0.05$ in post-treatment & follow-up time which revealed that the improvement of cellulite continued for 4 weeks after finishing the treatment. In the untreated side, there was a statistically non-significant difference within the untreated side ($P>0.999$). Comparison revealed that there were non-significant differences pre-treatment ($p>0.999$), but there was an extremely significant difference between both sides in post-treatment and follow up time ($P<0.001$).

The mean changes in thigh circumferential measurement and VAS of treated side and untreated side are summarized in Table (2). There was a statistically significant difference within the treated side in thigh circumferential measurements ($F= 18.768$, $P<0.05$). Pairwise comparison test using LSD test revealed that a high improvement in cellulite from pre-treatment, post-treatment and follow-up time (53.68±4.48, 50.33±3.08 and 48.10±2.51, respectively) with $p<0.05$ between pre-treatment & post-treatment, pre-treatment & follow-up and post-treatment & follow-up time which revealed that the improvement of cellulite continued for 4 weeks after

Table 1: Frequency and percentage of subjects in Nurnberger-Muller Scale of cellulite pre-treatment, post-treatment and follow-up time between both sides

	Time of evaluation											
	Pre-treatment				Post-treatment				Follow-up			
	Treated		Untreated		Treated		Untreated		Treated		Untreated	
Nurnberger-Muller Scale of cellulite	F	%	F	%	F	%	F	%	F	%	F	%
Grade 0	0	0	0	0	3	12%	0	0	15	60%	0	0
Grade 1	0	0	0	0	8	32%	0	0	7	28%	0	0
Grade 2	12	48%	12	48%	11	44%	12	48%	0	0	12	48%
Grade 3	13	52%	13	52%	3	12%	13	52%	3	12%	13	52%

Table 2: Thigh circumferential measurement and VAS pre-treatment, post-treatment and follow-up time between both sides

	Scores					
	Thigh circumferential measurement			VAS		
	Mean ± SD			Mean ± SD		
Time of evaluation	Treated	Untreated	p-value	Treated	Untreated	p-value
Pre-treatment	53.68±4.48	53.68±4.60	0.867	2.28±2.39	2.16±1.93	0.846
Post-treatment	50.33±3.08	53.67±4.61	0.004	5.48±2.02	2.88±2.68	0.001
Follow-up	48.10±2.51	53.14±4.29	0.001	6.80±1.80	3.04±2.75	0.001
p-value	0.001	0.327		0.001	0.192	

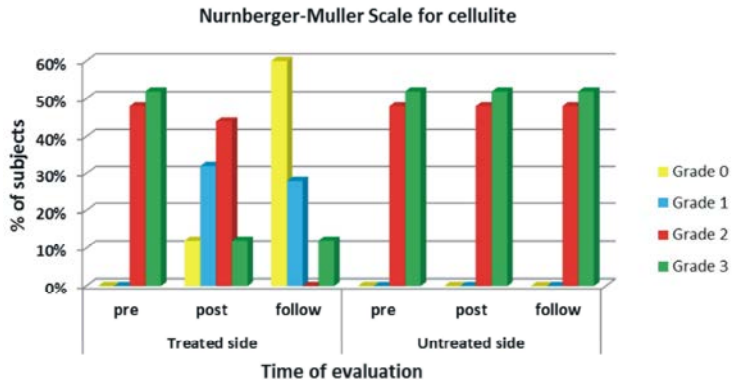

Fig. 1: Percentage of subjects in Nurnberger-Muller Scale of cellulite pre-treatment, post-treatment and follow-up time in both sides

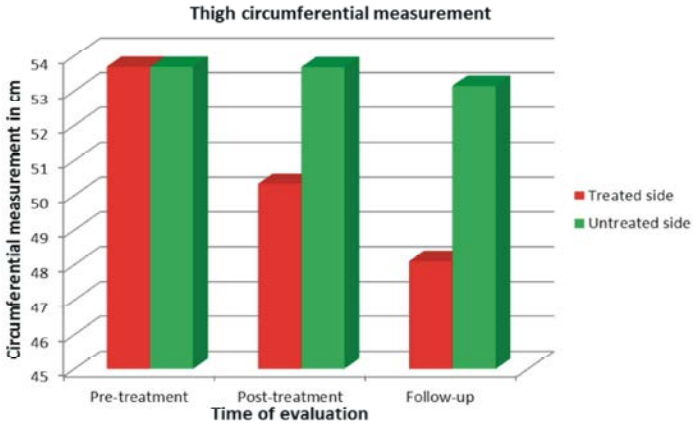

Fig. 2: Thigh circumferential measurement in cm pre-treatment, post-treatment and follow-up time in both sides

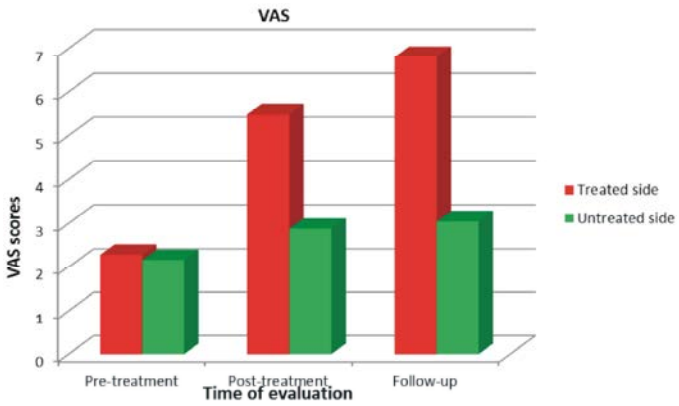

Fig. 3: VAS pre-treatment, post-treatment and follow-up time in both sides

finishing the treatment. In the untreated side, there was a statistically non-significant difference within the untreated side (P>0.05). Comparison revealed that there were non-significant differences pre-treatment (p>0.05), but there was a significant difference between post-treatment and follow up time (P<0.05) between both sides.

There was a statistically significant difference within the treated side in VAS (F= 31.485, P<0.05). Pairwise comparison test using LSD test revealed highly satisfaction of treatment from pre-treatment, post-treatment and follow-up time (2.28±2.39, 5.48±2.02 and 6.80±1.80, respectively) with p<0.05 between pre-treatment & post-treatment, pre-treatment & follow-up and post-treatment & follow-up time which revealed that the satisfaction of treatment continued for 4 weeks after finishing the treatment. In the untreated side, there was a statistically non-significant difference within sides (P>0.05). Comparison revealed that there were non-significant differences pre-treatment (p>0.05), but there was a significant difference between post-treatment and follow up time (P<0.05) between both sides. Figure (1) shows the percentage of subjects in Nurnberger-Muller Scale of cellulite pre-treatment, post-treatment and follow-up time in both sides. Figure (2) shows the mean values difference of the thigh circumferential measurements in cm pre-treatment, post-treatment and follow-up time in both sides. Figure (3) shows the mean values difference of VAS pre-treatment, post-treatment and follow-up time in both sides.

DISCUSSION

The results of this study suggested that ESWT is effective in treating cellulite through improvement of clinical picture in Nurnberger-Muller Scale for cellulite as the results of the treated side tended toward normality compared with the untreated side. This effect can be reinforced by the reduction in thigh circumferential measurement (10 cm below the greater trochanter of the thigh) as well as by the satisfaction of the subjects by VAS. The data also showed that improvement from ESWT became more effective after 4 weeks from finishing the treatment. Also, it may be possible that successful cellulite treatment will result from high energy ESWT with the energy flow density per shot set at 0.02 mJ/mm^2.

In recent years, ESWT has become the best studied therapy option for cellulite. This is most likely due the fact that ESWT is noninvasive, does not require drugs and can be easily completed within few minutes per treatment session without any side effects.

The first underlying mechanisms of the evident improvements of thigh cellulite after treatment with ESWT come from its mechanical response. In terms of the mechanical perspective, it might hypothesize that the ESWT has interrupted either the fat components or the septae or both, which might lead to softening of the stricken skin. Magnetic resonance imaging (MRI) has shown that fibrous septa are visualized in 97% of the area with cellulite depressions, which are noticeably thickened in cellulite stricken areas. Shock wave energy might have impaired the fibrous septae and thus the stricken skin became softer [24].

The second potential underlying mechanism of ESWT is reduction of lymphedema. Lately, a significant decreasing of lymphedema was reported clinically following 4 sessions of ESWT in women with secondary lymphedema after breast cancer treatment [25]. In animal trials ESWT and the vascular endothelial growth factor (VEGF-C) hydrogel appear to influence a synergistic effect in promoting lymphangiogenesis [26]. On the other side, ESWT might affect mesenchymal stem cells.

There is developing experimental results proposing that SWT activation pathways in adipose-derived stem cells [27]. Clinically, sick skin appears to be normal after SW treatment such as progressive systemic sclerosis with regulation of endothelial progenitor cells and circulating endothelial cells [28].

The results of the current study are generally in line with earlier reports of positive outcome treatment of cellulite with ESWT in the previous studies.

In an early pilot study by Braun *et al.* [29], 20 women with "severe cellulite measured with a pinch test" were treated using the electromagnetic SW device. Each woman received 6 treatment sessions with 2,400 impulses per session on the left leg. Under the authors' subjective impressions of the treated leg and photographic analysis, a significant improvement in skin surface appeared for more than 70% of the subjects. However, treatment success was not described according to changes in cellulite grades [29].

Angehrn *et al*. [30] treated 21 subjects with cellulite using defocused ESWT. Treatment consisted of 12 sessions at intervals of 3–4 days, with 4,000 impulses to thigh per treatment session, with energy of 0.018 mJ/mm^2. Results were subjective opinion of improvement and collagenometry measurements. At the end of treatment, 17 subjects (81%) subjectively were improved. They concluded that low-energy defocused ESWT might improve cellulite by reducing the collagen within the dermis.

In a case study by Garcia [31], 52-year-old woman were treated by ESWT, with the energy flow density per shot set at 0.02 mJ/mm^2. The treatment was applied to the right lateral thigh, one time per week for 10 weeks. A 3700 shots where applied homogeneously at 16 Hz and 120 mJ. The control area was the left thigh. Diagnostic high-resolution ultrasound, thermography and photography were performed pre and post treatment. It was concluded that ESWT was an interesting non-invasive therapy for cellulite, not only by reinforcing the skin's scaffolding fabric, but also by remodeling the subcutaneous fat tissue.

In a double-blind, randomized controlled trial, Knobloch *et al*. [23], 53 females were treated by ESWT; 6 treatment sessions for 2 weeks, with 2,000 impulses at 4 Hz and an energy flux density of 0.35 mJ/mm^2 and sham ESWT with the same protocol as the active ESWT but with an energy flux density of 0.01 mJ/mm^2. In addition, specific gluteal strength training was performed by all women. ESWT reduced the mean of the photo-numeric Cellulite Severity Scale (CSS) from 10.9±3.8 to 8.3±4.1 at 12 weeks after the last treatment, whereas sham-ESWT did not (CSS from 10.0±3.8 to 10.1±3.8). They reported that the combination of ESWT and gluteal strength training were superior to gluteal strength training [23].

In another study by Schlaudraff *et al.* [32], 14 Caucasian females with cellulite (Grade mean 2.5±0.09) were treated by ESWT unilaterally 2 times per week for 4 weeks (Total 8 sessions) with 15,000 impulses per session applied at 15 Hz. The mean cellulite grade improved from 2.5±0.09 to 1.57±0.18 after the last treatment session and 1.68±0.16 at follow-up. No patient's condition aggravated, the treatment was well tolerated and no unwanted side effects were observed. They concluded that ESWT was a safe and effective treatment option for cellulite [32].

In the present study, it is the first time to treat cellulite with ESWT as a non-invasive method of treatment in Arabian countries; it was a prospective, randomized, controlled study with pre-treatment, post-treatment and follow-up (Four weeks after completion of treatment) evaluation. Three outcome measures were used to confirm the results, one measure was objective (thigh circumferential measurement) and 2 measures were subjective (Nurnberger-Muller Scale for cellulite for the practitioner and self-assessment of satisfaction using VAS for the subjects). It was so difficult to take photographic analysis from Nurnberger-Muller Scale for cellulite because of traditional cultures of Arabian countries restrict photographing of females, so that clinical observations of the scale were only recorded. After the follow-up time, subjects advised to complete treatment with ESWT to untreated side to achieve symmetry on both thighs.

In the present study thigh cellulite improved after treatment by ESWT only for 1 month of treatment (8 sessions -2 per week) without any side effects according to several potential mechanisms have been proposed in the literature, including enhanced microcirculation, apoptosis of fat tissue and enhanced lymph circulation. One month after finishing treatment, results showed that there were significant differences between post-treatment and follow-up time of evaluation (4 weeks later) in favor of follow-up time as the improvement in the 3 outcome measures were more than post-treatment improvement, which means that treatment of cellulite with ESWT has long lasting benefits as improvement continued after finishing the treatment.

CONCLUSION

Extracorporeal shock wave therapy with the energy flow density of 0.02 mJ/mm² was safe and effective for improving the appearance of thigh cellulite after 4 weeks of treatment and the beneficial effects of ESWT on cellulite persisted for 4 weeks later as it seems to have a long-term benefits.

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