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ABSTRACT

Background: Gynoid lipodystrophy, or cellulite is superficial pockets of trapped fat causing the uneven dimpling of skin commonly in women. It has a cosmetic concern and may induce negative psycho-social side-effects. Extracorporeal Shockwave Therapy (ESWT) is effective in treating this condition, but need further high quality studies. Aim of this study was to investigate the effects of ESWT on skinfold and severity of cellulite. **Methods**: This randomized controlled study included fifty healthy female subjects ranging from 18–55 years of age who express a desire to improve the appearance of their cellulite. They were divided randomly into two equal groups. Group (A) received Low Level Laser Therapy. Group (B) received Low Level Laser Therapy and focused Extracorporeal Shockwave Therapy. Treatment lasted 6 weeks (2 sessions/week). Patients were assessed by skin fold caliper to measure skin fold in mm and Hexsel cellulite severity scale. **Results**: Skin fold thickness and Hexsel cellulite severity were significantly improved post-treatment in both groups (P<0.001), but the group who had ESWT had significantly more improvements (p<0.001). **Conclusion**: Extracorporeal Shockwave Therapy is effective in improving cosmetic appearance of women suffered from cellulite.

Keywords: Cellulite, Gynoid lipodystrophy, severity, skin fold, shockwave.

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INTRODUCTION

Gynoid lipodystrophy, or cellulite, refers to superficial pockets of trapped fat which causes the skin to have an uneven dimpling or "orange peel" appearance (1). It is an interstitial edema associated with an increase in fat content (2). It occurs in 90% of post-adolescent women (1), especially on the thighs and buttocks. This is because the subcutaneous connective tissue septa are thin, at right angle to the surface causing large fat-cell chambers that herniate into the corium forming papillae adiposae. Then fibrosis of the collagen septa occurs and leads to their shortening and ultimately their retraction, which causes the protrusions and depressions that characterize cellulite (2,3). Cellulite remains an issue of cosmetic concern and may induce negative psychosocial side-effects in those suffering its consequences on their appearance (4).

The cause of cellulite appears to be multifactorial and not universally agreed upon. The causes are hypothesized to be deterioration of dermal vasculature causing edema and tissue hypoxia with thickening and sclerosis of the fibrous septa (5) and chronic inflammatory processes with diffuse infiltration of macrophages and lymphocytes into the fibrous septa (6), alterations in the intercellular matrix and structural anatomy of subcutaneous tissue (7). Environmental, genetic and hormonal factors and bad lifestyle affect cellulite Alcohol stimulates occurrence. lipogenesis, dehydration, and impaired storage of fat (8). Obesity increases risk for the development and progression of cellulite (9). Patients with cellulite have increased concentrations of serum malondialdehyde (MDA) and plasma protein carbonyls resulting from oxidative stress (4).

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Hexsel scale assesses skin texture, such as the number and depth of depressions, classification of the morphological appearance of the skin, degrees of flaccidity, and cellulite severity (0-3). The evaluator performs the sum of the score of each item and classifies the cellulite between light degree (1-5 points), moderate (6-10 points), and severe (11-15 points) (**10,11**).

Interventions compose topical medications, avoiding bad lifestyle, subcision, extracorporeal shock wave therapy (ESWT), radiofrequency, laser and light devices, dermal fillers, ultrasound, and carboxytherapy, among others (**12,13**).

ESWT is a large amplitude positive pressure pulse that transfer electrical energy into mechanical one (14). It positively affects biological tissue (11), through decreasing oxidative stress substances and increasing lipid peroxidation products (15). So, it prevents sclerosis, smoothens the skin (15), improves skin elasticity (16), improves mobility, pain and skin and body contour, decreases body circumference (17), improves neocollagenesis, microcirculation, lymphatic drainage, cell matrix mobilization via mechanotransduction, mechanical disruption of localized adiposities via cavitation (4,11,18), restructures of skin and subcutaneous tissue, remodel collagen, thus clinically improving the aspects of cellulite and localized fat (4,11). Improvements with ESWT are independent from patient's individual cellulite grade at baseline, BMI, weight, height, or age (19).

ESWT represents an easy to handle, noninvasive, side effect free, local therapy type with short application periods in treating cellulite (4). However, further research is needed to prove their effects and to treat this condition, given its multifactorial nature. So, this study aimed to investigate the effects of ESWT on cellulite.

MATERIALS AND METHODS Study Design

This study was a randomized controlled study. The patients (n=50) were divided randomly into two equal groups. Group (A) received Low Level Laser Therapy. Group (B) received Low Level Laser Therapy and focused Extracorporeal Shockwave Therapy.

Study setting

This study was conducted at the outpatient clinic, Shebin El-Kom teaching Hospital.

Ethical approval

This study was done in accordance with standards of the research ethical committee. It also followed the principles of Helsinki Declaration of the 1975, as revised in 1983. All patients participated had the objective and details of the study been explained, then signed the informed consent.

Patients

Fifty females whose age ranged from 18–55 years and diagnosed with or complained from cellulite shared in the study. Women who were pregnant or had local diseases of the skin were excluded.

Procedures

1. Measurement procedures:

Outcomes were measured pre-and post- 6 weeks of the treatment.

1.1. Skin fold caliper to measure skin fold in mm:

Participants were standing comfortably. Researcher (first author) grasped skin and adipose tissue at the level of cellulite. Then, he applied the skin caliper to the grasped tissues at right angle. Two readings for the skin fold (in mm) were taken and averaged (20).

1.2. Hexsel cellulite severity scale:

It objectively measured the 5 clinical morphologic features of cellulite, each graded from 1 to 3 (zero for absence of the feature or normal skin); (A) Depressions count (inspected visually): 1 = 1-4depressions, 2 = 5-9 depressions, and $3 = \ge 10$ depressions, (B) Depressions depth (inspected visually): 1 = Superficial, 2 = Medium depth, and 3 = Deep, (C) Morphological appearance: 1 = 'Orange peel' appearance, 2 = 'Cottage cheese' appearance, and 3 = 'Mattress' appearance, (D) Degree of draping (skin flaccidity, sagging or laxity): 1 =Slight, 2 =Moderate, and 3 =Severe, and (E) Cellulite grading scale: 1= Mattress phenomenon upon pinch-test, 2= Mattressphenomenon spontaneously while standing, and 3= Mattress- phenomenon spontaneously while standing and lying down. Based on the final numeric score, cellulite was further classified as mild (1-5), moderate (6-10), or severe (11-15) (21).

2. Therapeutic Procedures:

2.1. Application of Low Level Laser therapy: The patients were placed in comfortable position that allows the vision of the treated area only and instructed to wear goggles. The therapy consisted of Low Level laser sessions for 30 minutes, 2 times/ week for 6 weeks. Maximum average power 1 Watts, Wave length: 904 nm, Energy density: 3.6 J/cm² (22).

3. Application of Shock wave therapy:

Shock wave equipment was used (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 scanned with 2000 shots in both horizontal (1000 shots) and vertical (1000 shots) directions for 15 minutes. The treatment was applied 2 times per week for 6 weeks (7).

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STATISTICAL ANALYSIS

Statistical package for social sciences (SPSS) version 24 was used for all analysis. Descriptive statistics (means and standard deviations) was presented for all variables. Analytical statistics were done using paired t-test for within-group comparisons and unpaired t-test and analysis of covariance (ANCOVA) for between group comparisons, pre- and post-treatment, respectively. Significance level was set at 0.05.

RESULTS

Baseline characteristics:

Baseline characteristics of all patients in both groups were presented in Table (1). Groups were not differed significantly at baseline, i.e. homogenous groups (p>0.05).

٠ Within-groups comparisons:

Mean (SD) of skin fold (mm) pre- and posttreatment were 38.3 (5.92) and 35.36 (5.24), respectively in group A, and were 33.92 (7.22) mm and 27.04 (5.78) mm, respectively in group B. There were significant improvements in skin fold posttreatment in the two groups (p < 0.001). As shown in Table (2).

Mean (SD) of Hexsel scale pre- and post-treatment were 9.12 (2.19) and 7.32 (2.39) points, respectively in group A. While, they were 5.56 (2.89) and 2.72 (1.7) points, respectively in group B. There were significant improvements in Hexsel scale posttreatment in the two groups (p < 0.001). As shown in Table (2).

Between-groups comparisons:

There were significant differences in skinfold between groups at pre-treatment (p=0.02). So, ANCOVA were used to detect differences between groups post-treatment with pretreatment scores as a covariate. There were significant differences between groups A and B, in favor of group B (P<0.001). As well, there were significant differences in Hexsel scale between groups A and B (p<0.001), in favor of group B. As shown in Table (2).

Table (1): Baseline characteristics of patients in both group

Baseline characteristics	Group A	Group B	P-value		
Age (years), mean (SD)	39.9 (±10.1)	38.1 (±10.9)	0.5		
Sex, females (count, %)	25 (100%)	25 (100%)	1.0		

SD: standard deviation

Outcomes	Group A Mean (SD)	Group B Mean (SD)	P-Value
Skin fold			
Pre	38.3 (5.92)	33.92 (7.22)	0.02^{*}
Post	35.36 (5.24)	27.04 (5.78)	< 0.001*
P-Value	< 0.001*	< 0.001*	
Hexsel scale			
Pre	9.12 (2.19)	5.56 (2.89)	< 0.001*
Post	7.32 (2.39)	2.72 (1.7)	< 0.001*
P-Value	< 0.001*	< 0.001*	

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P: probability value; (*): significant at P<0.05

DISCUSSION

Aim of this study was to investigate the effects of ESWT on cellulite. It was observed that regardless of the treatment area, there was significant reduction in skinfold and the severity of cellulite posttreatment and in favour of the group who had ESWT.

Extracorporeal shock wave therapy (ESWT) improves cellulite by its electrical energy that create mechanical disruption of targeted tissues without cytolysis, resulting in extracellular healing responses that create tissue regeneration changes such as collagen remodelling and improvement of local blood circulation from neovascularization. It also induces neoelastin formation and skin laxity improvement (11, 23). As well, ESWT may act by decreasing oxidative stress (levels of Plasma Malondialdehyde) and increasing lipid peroxidation products (15). In addition to that, Knobloch and Kraemer (16) reported that ESWT is beneficial in improving skin elasticity and revitalizing dermis in cellulite.

Extracorporeal shock wave therapy acts on the biological tissue by means of mechanoreduction; that is, it exerts a mechanical stress on the skin which is converted in response at the tissue cellular level, stimulating the fibroblasts. The cells notice the changes in their environment in the extracellular matrix and convert the mechanical information in stimuli for the production of cellular growth factor, neocollagenesis, and neoelastogenesis. Other results of the action of ESWT on biological tissue suggest that ESWT may induce lipolysis and/or apoptosis of the adipose cell (17). ESWT produces two types of cavitation: stable, where these microbubbles are formed and do not undergo implosion; and unstable, where microbubbles implosion occurs. Each cavitation type has an intensity of physiological action. The stable cavitation can stimulate the lipolysis process, while the unstable cavitation can cause cell death (24,25).

Shockwave energy might have weakened the fibrous septae that always present in cellulite depressions and thus, smoothened the afflicted skin. As well, it may reduce the associated lymphedema by promoting lymph transport (16,26). Also, it may have regenerative effect by acting on stem cells (27). Findings of the present study are supported by Angehrn et al. (4) who evaluated the effect of ESWT in the treatment of cellulite in the lateral region of thighs, in 21 women and found improvement of cellulite. As well, Knobloch et al., (27) reported that combination of focused ESWT and gluteal strength training was superior to gluteal strength training alone in terms of the cellulite severity scale (CSS). The significant mean improvement was 24% in the intervention group in contrast to the control group, a clinically meaningful difference. However, in our study the improvement in the ESWT group was 21-51% (vs. 7-19% in control group).

The current study supports the notion that stated ESWT improves severity of cellulite and morphological aspects of the skin (15). Furthermore, Schlaudraff et al., (19) examined the effect of radial extracorporeal shock waves on cellulite in fourteen caucasian females and found that the mean cellulite grade improved after the treatment supporting the results of our study.

Hexsel et al., (10) evaluated the efficacy of shockwave therapy on 30 women presenting moderate or severe cellulite. The patients underwent 12 sessions of ESWT on the gluteus and back of the thighs, over six weeks. They found that the treatment reduced cellulite severity. The mean cellulite severity scale shifted from 11.1 to 9.5. This means a 14% improvement, but in the present study, percentage of change was 51%. This may be explained by difference in severity at baseline between both studies (11.1 in Hexsel study vs. 5.6 in our study).

In Conclusion, extracorporeal shockwave therapy is effective in improving cosmetic appearance of women suffered from cellulite.

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