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Acoustic wave therapy for cellulite, body shaping and fat reduction

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ABSTRACT

Background: Cellulite is a common aesthetic condition that affects almost every woman. **Objective**: To evaluate the efficacy of acoustic wave therapy (AWT) for cellulite and body shaping. **Methods**: In this open-label, single-centre trial, 30 women presenting moderate or severe cellulite underwent 12 sessions of AWT on the gluteus and back of the thighs, over six weeks. The following assessments were performed at baseline, and up to 12 weeks after treatment: Cellulite Severity Scale (CSS), body circumference measurements, subcutaneous fat thickness by magnetic resonance imaging (MRI), quality of life related by Celluqol® and a satisfaction questionnaire. **Results**: The treatment reduced cellulite severity from baseline up to 12 weeks after the last treatment session (subjects presenting severe cellulite: 60% to 38%). The mean CSS shifted from 11.1 to 9.5 ($p < 0.001$). Hips circumferences reduced from 99.7 and 103.2 cm to 96.2 and 100.3 cm (respectively, $p < 0.001$). The average thickness of the subcutaneous fat tissue also decreased (28.3 ± 6.5 mm to 26.7 ± 6.1mm; $p < 0.001$). The treatment also improved quality of life. More than 90% of the subjects would undergo the treatment again and 89% were satisfied with the results. No serious adverse events were reported. **Conclusions**: AWT is a safe treatment to improve cellulite appearance and reduce body circumferences.

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KEYWORDS
Acoustic wave therapy; body shaping; cellulite; Cellulite Severity Scale; subcutaneous fat tissue thickness

Introduction

Cellulite is a common aesthetic condition affecting mainly women after puberty (1). The most affected areas are gluteus and thighs (2). It is clinically characterised by relief alterations of the skin surface (3,4), which include typical depressed and raised lesions, giving to the skin of the affected areas an orange peel, cottage cheese or mattress-like aspect (3,4). The depressed lesions of cellulite are the most frequent, and they present different depths and shapes.

Hexsel and cols published a study showing that cellulite depressions are significantly associated with the presence of underlying fibrous septa (5). The authors compared subcutaneous tissue in areas with and without cellulite (control areas) on the buttocks of 30 subjects using magnetic resonance imaging (MRI). Perpendicular fibrous septa were found in 96.7% of the areas with cellulite depressions. Besides this important anatomical feature, other factors can cause or aggravate cellulite. Recent evidence supports that cellulite severity increases with age (6). Skin laxity and amount of fatty tissue are also linked to cellulite onset and worsening (6,7).

Different treatments alone or in combination have been proposed to improve cellulite appearance. They range from diet and topical products to surgical procedures. Lasers, radiofrequency, infrared light, ultrasound-based devices and more recently extracorporeal shock wave therapy (ESWT) or acoustic wave therapy (AWT) (8–15) have been reported as effective methods for the reduction of cellulite.

The AWT is a non-invasive technique based on the propagation of mechanical waves into the tissues. It is suggested that this technology increases local blood circulation and cell metabolism and induces self-regenerating processes (16,17). Some authors reported AWT could also increase cell proliferation of collagen and elastin fibres (16–18), and lipolysis (18). Some studies reported the efficacy of the treatment in improvement of cellulite and body contouring after eight sessions with the equipment (14,15,19,20).

Considering the reported effects of AWT on cellulite, we conducted a study to evaluate its efficacy in women presenting moderate-to-severe cellulite. Besides, effects of AWT on other clinical aspects usually associated to cellulite were assessed.

Material and methods

Study design and subjects

This was a prospective, single-centre, open study approved by the local Ethics Committee of *Associação Hospitalar Moinhos de Vento* and conducted from 2013 to 2014. All subjects were recruited from a research centre in Porto Alegre, Brazil, and provided written informed consent before enrollment. The main inclusion criteria were female subjects aged between 20 and 60 years presenting moderate or severe cellulite degree according to the Cellulite Severity Scale (CSS) (21) (Table 1) and stable body weight. The main exclusion criteria were other treatment for cellulite less than 30 days prior to the study, excessive tanning, intense physical exercises started during the study and aesthetic surgical procedures on the treated area.

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Table 1. (a) Cellulite Severity Scale (CSS). The CSS is composed by five items graded from 0 to 3; and (b) the final score ranges from 1 to 15, resulting in cellulite classification as mild, moderate or severe.

a)

(A) Number of evident depressions	(B) Depth of depressions	(C) Morphological appearance of skin surface alterations	(D) Grade of laxity, flaccidity or sagging skin	(E) Nürnberger and Müller Scale
0 No depressions	**0** No depressions	**0** No raised areas	**0** Absent	**0** Grade zero
1 1 to 4	**1** Superficial	**1** 'Orange peel'	**1** Slight	**1** 1st grade
2 5 to 9	**2** Medium depth	**2** 'Cottage cheese'	**2** Moderate	**2** 2nd grade
3 10 or more	**3** Deep	**3** 'Mattress'	**3** Severe	**3** 3rd grade

b)

Cellulite Classification	Scoring
Mild	1 to 5
Moderate	6 to 10
Severe	11 to 15

Considering that cellulite severity tends to increase with age, half of the subjects were aged less than 40 years and the other half was over 40 years to obtain a homogeneous sample. All the subjects should follow the same procedures during the whole study.

Treatment protocol

The AWT was performed with both C-Actor® and D-Actor® handpieces of Cellactor SC1 (Storz Medical AG, Switzerland) on the gluteus and back of the thighs. The C-ACTOR® handpiece is a high intensity electromagnetic system generating acoustic planar waves, whereas D-ACTOR® handpiece is a vibrating massage system operated by compressed air generating "slow impact" acoustic radial waves (22). Ultrasound gel was always applied to the skin, during the treatments with both handpieces to avoid energy loss. All the treatment sessions were applied by the same trained professional.

Each treatment session consisted of 1000 pulses of the C-Actor® handpiece (0.56 to 1.02 mJ/mm^2) plus 4000 pulses of the D-Actor® handpiece (2.6 and 4.6 mJ/mm^2), as recommended by the manufacturer. The handpieces were moved with slight pressure in skin following the direction towards the lymph nodes. All the treatment sessions were applied by the same trained professional.

The subjects underwent two sessions per week, over six weeks. The minimum interval between the sessions was 48 hours.

Assessments

Subjects attended five evaluation visits: at baseline (T_0), after six treatment sessions, up to three days after the complete treatment (12 sessions) (T_1), 4 and 12 weeks after complete treatment (T_2 and T_3). At baseline, physical and clinical assessments, inclusion and exclusion criteria verification, cellulite severity scoring, measurements of hips and thighs circumference, subcutaneous adipose tissue thickness, skin elasticity, length of dermal-hypodermal junction, and assessments of quality of life and satisfaction were performed. After six treatment sessions, only adverse events and cellulite grading were checked. At all post-treatment visits, all the efficacy measurements were taken and adverse events were recorded. All the assessments for each subject were performed by the same dermatologist.

Cellulite severity

The primary endpoint was the cellulite severity assessed by the CSS (Table 1). The CSS is a validated and comprehensive scale for the standardised assessment of cellulite and the different features of this condition (21). The number and depth of depressions, the morphological appearance of alterations in the skin surface and degree of laxity are considered together with Nürnberger–Müller previous cellulite scale. The scores of each item range from 0 to 3, and the sum of these values gives the final classification, which may be mild (1 to 5), moderate (6 to 10) or severe (11 to 15).

Hips and thighs circumference measurements

Two circumference measurements were taken on the hips, at 10 and 15 cm below the iliac crest. Likewise, two circumference measurements were obtained from each thigh, at 5 and 10 cm below the gluteus fold. The iliac crest and gluteus fold were used as anatomical markers to obtain standardized measurements, and reduce possible biases.

Subcutaneous adipose tissue thickness

Magnetic resonance images of the upper thighs were obtained before treatment and 12 weeks after last treatment session. Besides showing the hypodermis architecture, it provides an objective measure of the subcutaneous adipose tissue thickness.

Before each examination, an oily capsule was placed at the middle point of the posterior thigh, 5 cm below the gluteus fold, to mark the area to be assessed. The examinations were made with 1.5 Tesla closed Bore Scanner (Magnetom Essenza, Siemens, Erlangen, Germany) with dedicated flexible coils, and images were T1-weighted (339 ms/12 ms, time repetition/time echo). Anatomical structures were defined as references in the baseline images, to obtain the same image slice in the follow-up examination.

The thickness of subcutaneous adipose tissue before and after treatment was measured with Syngo software (Siemens, Erlangen, Germany) in millimetres (mm). Two measures were taken in each MRI, and the average of both was considered for the evaluations. An independent radiologist performed the magnetic resonance evaluations before and after treatment.

Skin elasticity

The skin elasticity was assessed with Cutometer® MPA 580 (Courage-Khazaka, Germany), and the R5 parameter (net elasticity) was defined as outcome. The R5 results vary between 0 and 1, and the closer the value is to 1, the more elastic the skin. Before each measurement, the probe was positioned over the skin at the marked point and then the measurement was started, according to the device settings previously established. Measurements were taken at the middle point of the posterior thigh, 5 cm below the gluteus fold (treated area), and in the inner part of the forearm, at the middle point between the wrist and the elbow (control area).

Table 2. Celluqol® questionnaire scoring and interpretation.

Points	Interpretation
From 8 to 16	Cellulite does not affect patient's quality of life.
From 16 to 24	Cellulite slightly affects patient's quality of life.
From 24 to 32	Cellulite considerably affects patient's quality of life.
From 32 to 40	Cellulite intensely affects patient's quality of life.

Length of dermal–hypodermal junction

An indication of the severity of adipose protruding into the dermis may be obtained by the length of dermal–hypodermal junction. In cellulite, it is increased because more adipose tissue protrudes into the dermis (23). Assessments were conducted with a high-frequency ultrasound (Dermascan C®, Cortex Technology, Denmark) at the middle point of the posterior thigh, 5 cm below the gluteus fold (treated area), and in the inner part of the forearm, at the middle point between the wrist and the elbow (control area).

Quality of life and satisfaction

The purpose of the Celluqol® questionnaire (24) is to evaluate the quality of life in women with cellulite. It accounts for how much cellulite affects patient life style. The following items are considered: clothing, diet, recreation and physical activities, relationship with the partner, feelings and changes in daily habits. Each item is graded from 1 (not at all affected by having cellulite) to 5 (affected all the time by having cellulite). The final score of Celluqol® results from the sum of the points of each question and ranges from 8 to 40 (Table 2). Subjects answered the Celluqol® at baseline visit and at all post-treatment visits.

Patient satisfaction with treatment was assessed with a questionnaire, answered at all post-treatment visits. Subjects reported whether they were satisfied with the treatment and if they would like to undergo the treatment again. They were also requested to state the perceived improvement in cellulite appearance: a lot improved, improved, a little improved, no difference, a little worse, worse and a lot worse.

Statistical analysis

Baseline analyses considered the intention-to-treat population, and the treatment outcomes were assessed considering the per protocol population. Descriptive analyses were used for demographic data. Categorical variables are presented in percentages. Quantitative and continuous variables were presented as mean ± standard deviation.

Results in the follow-up visits were compared to baseline using Student *t*-test for paired samples for continuous variables. Differences between groups were compared using Student *t*-test for independent samples.

Results

Thirty-eight women were screened for this study after providing written consent, and thirty started the treatment. Twenty-five completed the study: 11 were under 40 years and 14 were over 40 years. The reasons that led to the discontinuation were lose of interest in the study and unavailability to continue the treatment and/or to attend to follow-up visits.

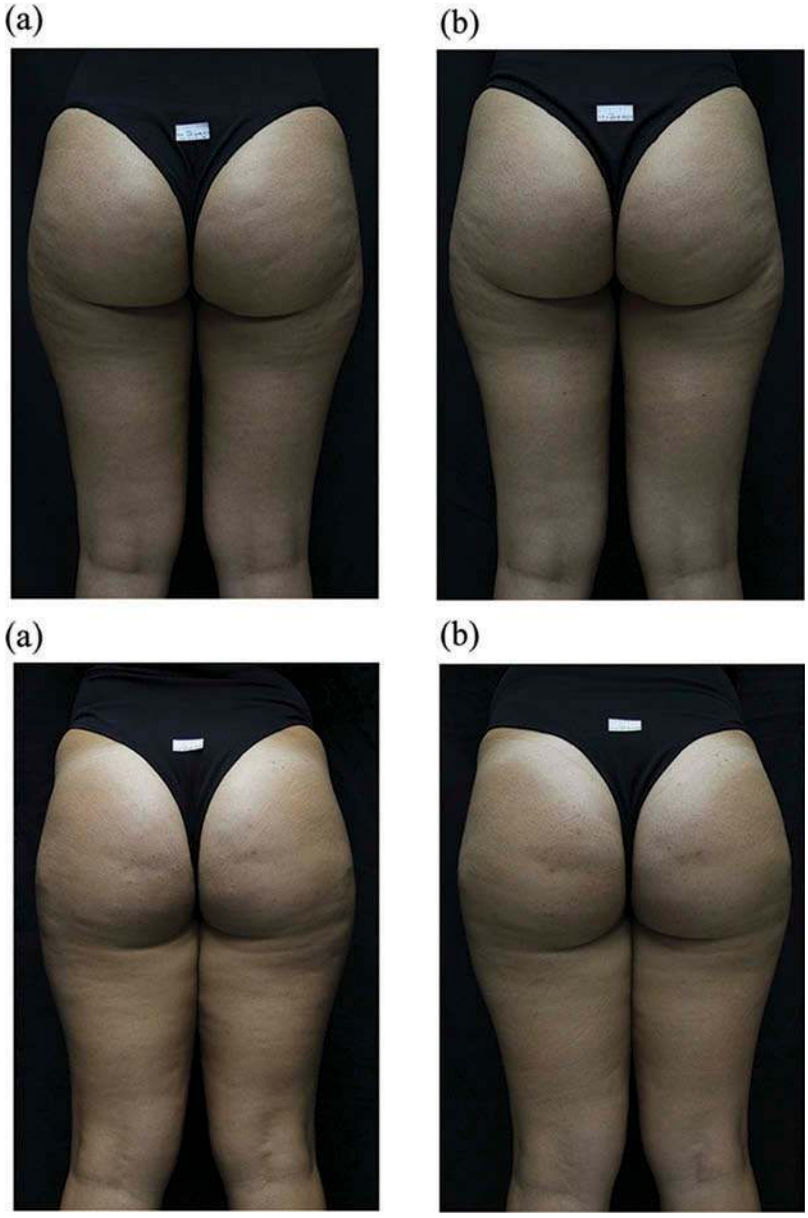
The mean age of the whole sample was 41.5 ± 11.5 years and average of the body mass index (BMI) was 24.3 ± 2.5 kg/m^2. Most of the subjects had Fitzpatrick skin phototype III (46.7%), were taking hormonal contraceptives (70%) and had no pregnancy history (66.7%).

The demographic data are presented by age in Table 3. There were no significant differences in BMI, body circumference, Fitzpatrick skin phototype, and smoking habits between patients under 40 years old and over 40 years old, at baseline. There was a trend of more severe cellulite in older patients, and skin laxity presented significant differences between patients under 40 years old and over 40 years old.

Table 3. Demographic data.

	Subjects under 40 y.o. N = 15	Subjects over 40 y.o. N = 15	P value
Mean age (years; mean±SD)	31.3 ± 4.3	51.6 ± 6.1	<0.001**
BMI (Kg/m^2; mean±SD)	23.7 ± 2.6	24.8 ± 2.5	0.23**
Fitzpatrick skin phototype n (%)			
II	4 (26.7)	2 (13.3)	0.45*
III	7 (46.7)	7 (46.7)	
IV	3 (20)	6 (40)	
V	1 (6.7)	0 (0)	
Smoking habits n (%)	0 (0)	1 (6.7)	0.31*
Contraceptive methods n (%)*			
Hormonal	15 (100)	6 (40)	0.01*
Partner with vasectomy	0 (0)	1 (6.7)	
Surgically sterile	0 (0)	2 (13.3)	
Not applicable (menopause)	0 (0)	6 (40)	
Pregnancy history n (%)			
0	12 (80)	8 (53.3)	0.58**
1	1 (6.7)	4 (26.7)	
2	1 (6.7)	3 (20)	
4	1 (6.7)	0 (0)	
CSS n (%)			
Moderate	17 (57)	9 (30)	0.07*
Severe	13 (43)	21 (70)	
Skin laxity (mean±SD)			
R5 parameter thigh	0.89 ± 0.16	0.73 ± 0.13	0.04**
R5 parameter forearm	0.84 ± 0.13	0.65 ± 0.14	0.04**

y.o.: years-old; * Chi-square test; ** Student t-test for independent samples.

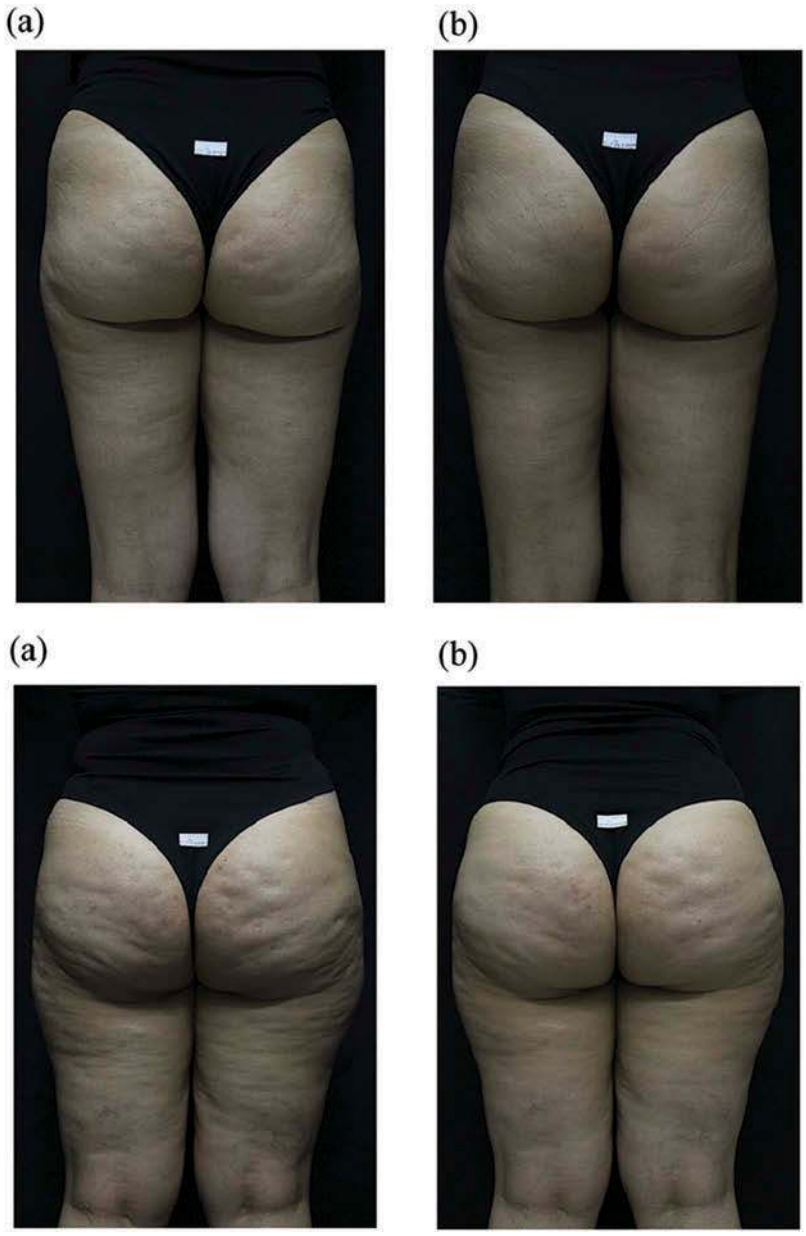


Figures 1 and 2. Cellulite appearance of two subjects under 40 years before treatment (a) and 12 weeks after 12 AWT sessions (b). The subjects presented positive results, with improvement in cellulite appearance and body contouring.

The BMI at each follow-up visit did not differ significantly from baseline (p = 0.56).

In general, the treatment reduced the cellulite severity of the overall sample and is clearly visible in some subjects up to 12 weeks after treatment (Figures 1–4). No subjects presented mild cellulite severity at baseline, but 8% reached mild severity after treatment (T_1) and after treatment (T_1) and up to four weeks after treatment (T_2). Of note, the percentage of subjects with moderate severity increased from 40% at baseline to 62% 4 weeks after treatment (T_2), whereas the percentage of subjects with severe cellulite decreased from 60% at baseline to 30% 4 weeks after treatment (T_2) (Figure 5). Twelve weeks after the last treatment session (T_3), no subjects presented mild cellulite severity, 62% had moderate, and 38% severe cellulite (Figure 5). Moreover, when considering the total CSS grading, a statistically significant reduction is observed from baseline to follow-up visits ($p < 0.001$, analysis of variance for repeated measures). The mean CSS grading of the whole sample reduced from 11.1 at baseline to 9.5 twelve weeks after treatment (T3) (Figure 6). When considering age groups under and over 40 years-old separately, a statistically significant reduction is observed for both (p < 0.001, ANOVA for repeated measures).

The effects of the treatment in body circumference for the whole sample considered together are described in Table 4. Significant reduction in hip perimeter was observed after treatment for the whole sample in both measurement points. On the other hand, thigh perimeters reduced only at the measurement point 5 cm below the gluteus fold (p = 0.009). The mean baseline value was 54.2 cm, and reduced to 53.6 cm 12 weeks after treatment (T_3).



Figures 3 and 4. Cellulite appearance of two subjects over 40 years before treatment (a) and 12 weeks after 12 AWT sessions (b). The subjects presented positive results, with improvement in cellulite appearance and body contouring.

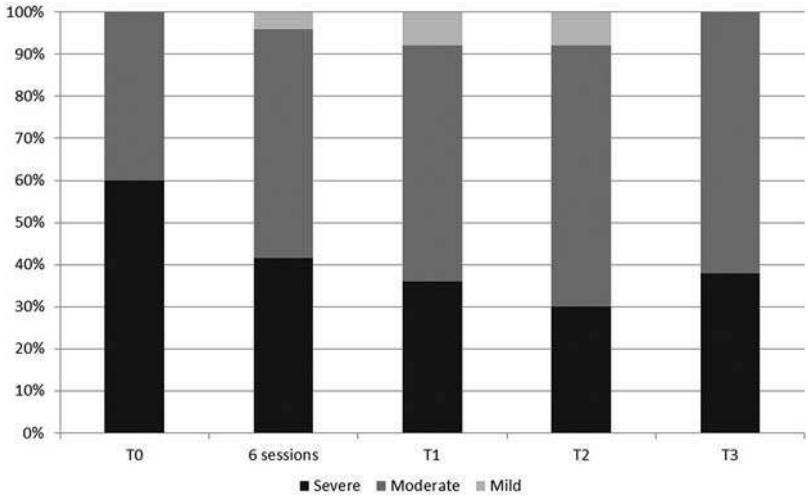


Figure 5. Percentage of severe, moderate and mild cellulite among the whole sample at baseline and at each evaluation visit.

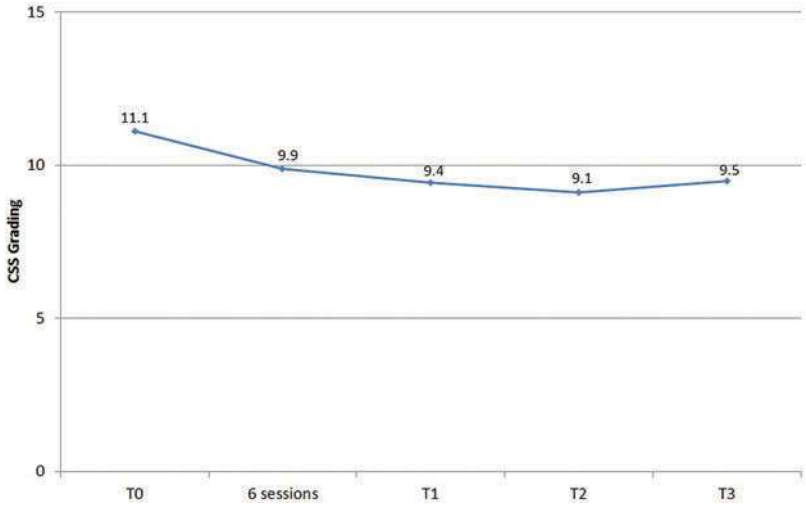


Figure 6. Mean of Cellulite Severity Scale total scores during the study period.

Table 4. Circumference of hips and thighs in the whole sample (mean values in cm).

	T_0	T_1	T_2	T_3	*P* value*
Hips 10 cm below the iliac crest	99.7 ± 6.1	97.9 ± 6.1	96.7 ± 6.6	96.2 ± 6.6	<0.001†
Hips 15 cm below the iliac crest	103.2 ± 5.9	101.4 ± 6.1	100.8 ± 5.8	100.3 ± 6.3	<0.001†
Thighs 5 cm below the gluteus fold	54.2 ± 3.7	53.6 ± 3.5	53.9 ± 3.4	53.6 ± 3.5	0.009†
Thighs 10 cm below the gluteus fold	49.6 ± 3.2	49.2 ± 3.0	49.8 ± 3.3	49.4 ± 3.4	0.017§

*ANOVA for repeated measures.
†The significant difference refers to the observed reduction of circumference.
§The significant difference refers to the observed increase of circumference.

When splitting the results by age group, the results showed hips circumference significantly reduced in the gluteal area in older and younger subjects (Figure 7), and on thighs circumferences in the younger group at the measurement point 5cm below the gluteus fold (Figure 8).

The magnetic resonance images indicated a significant reduction in the subcutaneous fat thickness, as illustrated in Figure 9. The average thickness of the measured points decreased from 28.3 ± 6.5 mm at baseline to 26.7 ± 6.1 mm at the last follow-up visit ($p < 0.001$). Younger subjects presented a significant reduction from baseline to the last follow-up visit (31.4 ± 4.1 mm to 29.0 ± 4.0 mm; $p = 0{,}002$), whereas it was not observed for the older group (25.8 ± 7.0 mm to 24.9 ± 7 mm; $p > 0.05$).

No significant improvements in skin elasticity and in the dermal–hypodermal junction length were observed in the treated areas in the whole sample. These results were observed also when split by age groups.

At baseline, 80% of the subjects scored between 24 and 32 in the Celluqol® questionnaire, which means cellulite considerably affects quality of life (Table 2). This percentage reduced to 48% right after the last treatment session (T_1) and to 46% 12 weeks after the last treatment session (T_3). The percentage of subjects who scored between 16 and 24 increased from 13% at baseline to 33% right after the last treatment session (T_1), and to 42% 12 weeks after the last treatment session (T_3). And, no patients scored between 8 and 16 at baseline. Right after the last treatment session (T_1), 7% of the patients scored between 8 and 16, percentage that increased to 11% four weeks after treatment (T_2), and remained in 4%, 12 weeks after treatment (T_3).

Eighty-one percent of the subjects reported that cellulite had improved right after the last session and 76% kept the same opinion 12 weeks after the last treatment session. More than 90% of the subjects reported that they would undergo the treatment again and 89% were satisfied with the results after treatment.

No serious adverse events were reported. Only three subjects reported having adverse events during the study, being all mild and none related to the treatment.

Discussion

AWT has been initially used to treat health conditions such as kidney stones (25,26) and injuries in the musculoskeletal system and soft tissue (27–29). The positive effects empirically observed on skin and subcutaneous tissue after these treatments led to the development of the technology to be applied for cosmetic purposes also. Prior research with AWT has shown improvements in appearance of cellulite (14–17,20) skin elasticity (18), and body contouring (19,22).

In this study, we investigated the effects of a combined treatment with C-Actor® and D-Actor® handpieces of Cellactor SC1 (Storz Medical AG, Switzerland) on the improvement of cellulite, using the most recent and validated scale (21) to determine the cellulite severity. The CSS differentiates from other evaluations because it includes the main anatomical features contributing to the appearance and worsening of cellulite. Results showed that 12 treatment sessions of AWT improved cellulite grading when

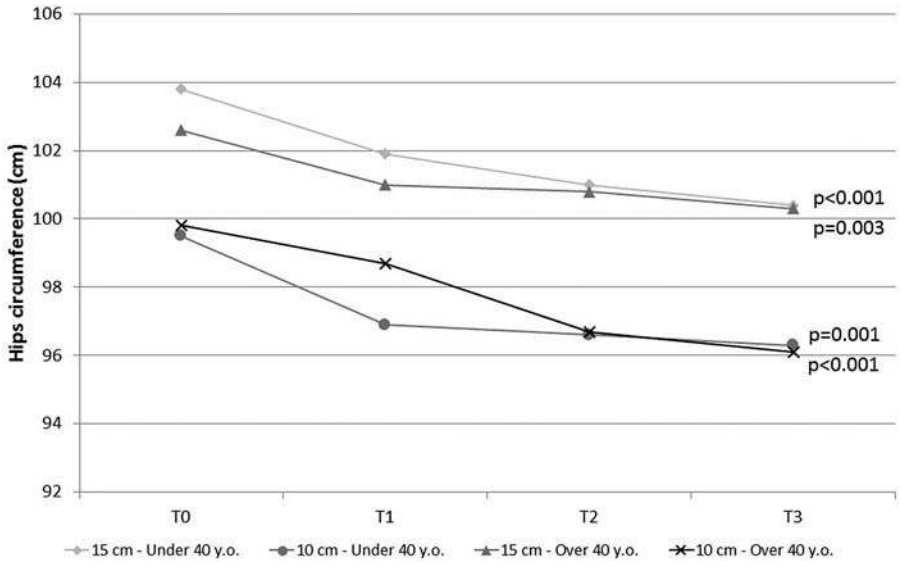


Figure 7. Hip circumference at the measurement points 15 cm and 10 cm below the iliac crest before and after treatment for subjects under and over 40 years.

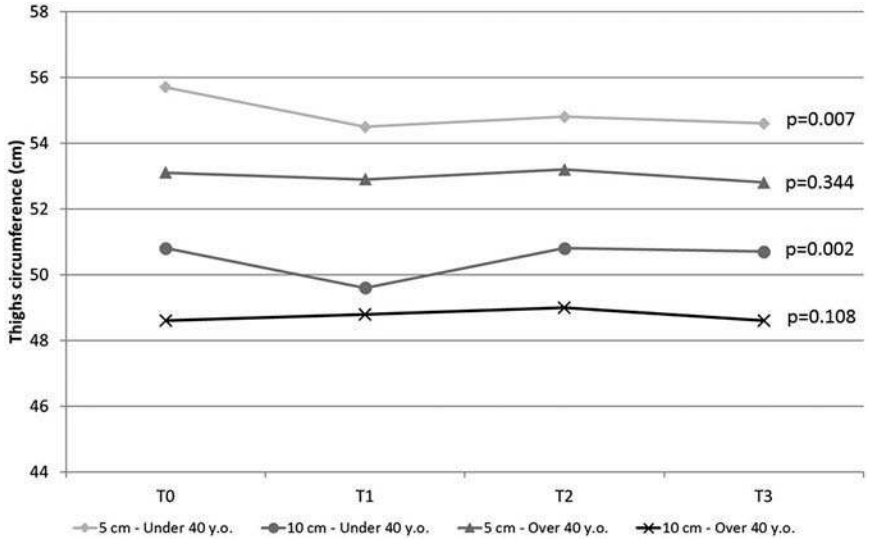


Figure 8. Thighs circumference at the measurement points 5 cm and 10 cm below gluteus fold before and after treatment for subjects under and over 40 years.

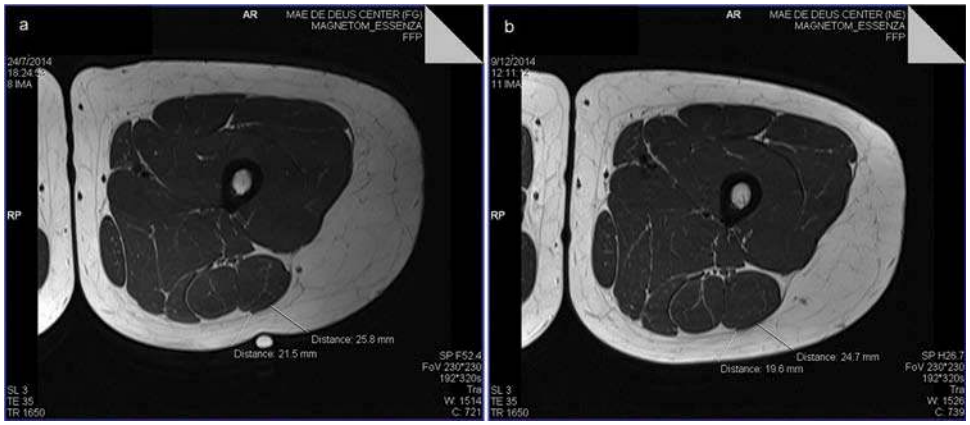


Figure 9. Subcutaneous fat tissue thickness of a 32-year-old subject at baseline (a) and 12 weeks after treatment (b). The thickness of the subcutaneous fat tissue reduced from 21.5 mm to 19.6 mm at the first measurement point and from 25.8 mm to 24.7 mm at the second measurement point.

considering the whole sample and also when considering both age groups separately. Moreover, significant effects were seen after six treatment sessions. Knobloch et al. (13) reported significant results after six sessions of ESWT on posterior thighs and hips. However, in our study, the subjects were assessed by the same dermatologist while standing in the same position with relaxed muscles, whereas Knobloch et al. performed the CSS assessment through photographs. The mean CSS grading reduction from 11.1 to 9.5 indicates numerically, the clinical and aesthetical improvement in cellulite appearance. Considering the CSS grading, it is a shift from severe to moderate. However, it is important to notice that it is a shift from the low end of severe to the high end of moderate severity. The improvement in the cellulite severity presented the same pattern when comparing the different age groups.

The secondary endpoints included the evaluation of the device effect on body circumference, subcutaneous fat thickness, skin laxity, dermal–hypodermal junction length, patient quality of life and satisfaction. AWT is known to improve body contouring (22). In the present study, the effects of the treatment in body circumference were more pronounced in the gluteal area. We found significant reduction on the hips circumferences up to 12 weeks after treatment. The thighs circumference presented reduction up to 12 weeks only on the measurement point 5 cm below the gluteus fold, and when split by groups, only for younger subjects. Other studies also had circumference as an endpoint and presented varied results (13,19,22). Adatto et al. (22) and Nassar et al. (19), who used similar treatment protocol, found significant reduction on thighs circumference after eight treatment sessions.

In this study, the significant reduction in fat tissue thickness assessed by magnetic resonance corroborates the improvement seen in thighs circumference. This effect over the fat tissue thickness provide further evidences to support the hypothesis that AWT improves cellulite through lypolisis. Nassar et al. (19) also found a decrease in fat tissue thickness in the area treated with AWT. However, their protocol included eight sessions, and evaluations were performed with ultrasound images, whereas in this study, MRI was used. Magnetic resonance images have been previously used to identify the skin structures associated with cellulite (5,6,23,30).

No significant improvement in skin elasticity and in the dermal–hypodermal junction length was observed with the methods used. Nevertheless, Christ et al. (18) observed a significant improvement in skin laxity using a different device.

As already noted by Hexsel and colleagues in a previous research (6), older patients presented more severe cellulite. In the present study, the sample presented this trend. These data together with Cutometer® results, which showed significantly more skin laxity in older patients, support the idea that laxity plays an important role in cellulite and should be treated with different technologies. Besides, BMI did not differ significantly between age groups.

This is the first study to report data on quality of life after treatment with AWT for cellulite. Improvements in quality of life after treatments for cellulite should be considered of great value as most of the patients affected by cellulite report distressing feelings and situations due to cellulite (31). Quality of life of most of the subjects was affected due to the presence of cellulite at baseline. Twelve weeks after treatment, the percentage of subjects who still felt considerable effects in quality of life reduced to 46%, and half of the subjects presented no or little negative effects in their quality of life. Patient satisfaction with the treatment was very high, as previously reported for AWT for body contouring (22).

The results of the present study refer to improvements in body shaping in hips and thigh areas in women. The effects of this technology on other body areas and in men could be further studied. A limitation of this study is that the comparisons between groups may not have enough power and are thus considered exploratory.

Conclusions

Shockwave-based devices have been shown to be a safe alternative to reduce body circumferences and improve body shape and cellulite appearance. In the present study, the most remarkable results observed were body circumferences reduction corroborated by the MRI findings, which objectively showed a reduction of subcutaneous adipose tissue thickness on the treated areas. Cellulite improvement was also evident and clinically significant for a considerable percentage of subjects. These outcomes led to high patient satisfaction and a considerable improvement in quality of life.

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Strattner has provided the equipment for the conduction of the present trial.

Declaration of interest

Dr. Hexsel has received the equipment for the conduction of the present trial. The other authors have no conflict of interest to disclose.

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