
Use of Acoustic Wave Therapy (AWT) in the Treatment of Cellulite

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BACKGROUND. Cellulite is defined as skin relief alterations that give the skin an orange peel or mattress appearance. Historically, few treatments have been truly effective. Several studies have shown extracorporeal pressure waves, similar to Acoustic Wave Therapy (AWT) to be effective in the treatment of cellulite.

OBJECTIVES. To determine the effectiveness of Acoustic Wave Therapy (AWT) delivered using a ballistic pressure head (D-Actor) in improving the appearance of cellulite.

METHODS. Patients were recruited from phone calls and inquiries made at a one location medical practice office. Patients were treated for cellulite based on their regions of complaint. An area was defined as a 20x30 cm area (typically the front or back of one thigh). Each area received 6 treatments (two a week for three weeks) consisting of 1,000 vertical pulses and 1,000 horizontal pulses. Patients had photographs and circumference measurements taken before and after treatment. Weight and electrical impedance measurements were taken before and after each treatment.

RESULTS. Adequate weight and body fat data was collected on 102 patients. Thigh circumference data was collected on 72 patients. Patient satisfaction surveys have been completed by 19 patients to date. All patients contributing data had before and after photographs taken. Average weight loss was small, 0.19 lbs (0.08 kg), and fell short of statistical significance, $p=0.21$. Similarly per-

centage body fat using lower body electrical impedance was small at 0.02% a non-significant change with $p=0.45$. Thigh circumference decrease was significant at 0.45 cm, $p=0.025$. Patients rated their posterior thigh treatment at 84% extremely pleased and anterior thigh treatment at 52% extremely pleased. Sixty eight percent of responders were more confident in revealing clothing and 74% were more comfortable with their body. Only 11% (2 patients) disagreed that they were more confident in revealing clothing or in their body. Seventy three percent of responders stated the treated area was closer to the appearance they desired. Only 11% of responders (2 patients) responded that the area was not closer to the appearance they desired. Before and after photographs reveal moderate to substantial improvement in the appearance of cellulite. Continued improvement in cellulite appearance was seen for up to 4 weeks past the end of treatment (maximum duration of follow-up). No significant side effects were reported.

CONCLUSIONS. AWT delivered by a ballistic pulse method is effective for improving the appearance of cellulite in the majority of patients. The improvement is most apparent in the before and after photographs. A small decrease in thigh diameter is also seen. No significant changes in weight or body fat composition were seen. The optimum number and timing of treatments and the use of complimentary techniques requires further study.

CELLULITE is defined as changes in the surface contour of the skin that result in an orange peel or “mattress” appearance of the skin.¹ It is present in post-pubertal females of all race and ethnic types, effecting 85-98% of this population. Cellulite is not defined as a pathologic condition, but it is a substantial cosmetic concern for many adult females. It can cause significant psychological and self-worth issues, and commonly affects clothing and activity choices. Several contributory factors have been proposed for the formation of cellulite: altered connective tissue septae, vascular changes, inflammatory changes,² and protrusion of subcutaneous adipose tissue into the reticular dermis. Body mass index, thigh circumfer-

ence, and the percent of fat in the thigh correlate with the severity of cellulite. Skin compliance (elasticity) has a negative correlation.³ Biopsy studies have pointed to sclerotic fibrous tissue septae as playing the predominant role in the “mattress” appearance. Biopsy studies also confirm the importance of fat protrusion into the reticular dermis in the severity of cellulite.⁴ Research has suggested pressure or acoustic waves are effective in disrupting the sclerotic fibrous tissue septae responsible for much of the uneven appearance of cellulite.⁵ Acoustic wave therapy has also been demonstrated to increase the thickness of the reticular dermis and decrease the protrusion of fat into the reticular dermis.⁶ These studies suggest that acoustic wave therapy (AWT) is a promising new treatment for improving the appearance of cellulite. The purpose of this study was to demonstrate the effectiveness of AWT using a 20 mm ballistic head (D-Actor) in improving the appearance of cellulite.

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Methods

Patients were recruited from phone inquiries to a single location medical practice. Patients completed a questionnaire covering: demographics, medical background, and potential contraindications to therapy. Each patient signed an informed release covering the risks and benefits of the procedure. A release of information and photographs were also obtained. Patients were allowed full discrimination on the areas treated. An area was defined as a 20x30 cm area. As applied, this resulted in an area covering a posterior or anterior thigh, one buttock or arm and one half of an abdomen. Each area as defined received 2,000 AWT pulses: 1,000 in a horizontal snaking pattern and 1,000 in a vertical snaking pattern (figure 1). Each area was treated twice a week for 3 weeks, a total of 6 treatments. Weight, percentage body fat and electrical impedance were taken before and after each treatment. Percentage body fat was measured using lower body electrical impedance. Each patient had thigh circumference measurements taken before the first treatment and after the sixth treatment. Circumference measurements were standardized at specific distances below the gluteal folds: 10 cm for small patients, 12 cm for average patients and 16 cm for large patients. Patients were encouraged to return for a follow-up visit 2-3 weeks following the completion of therapy. At this visit, the patient was interviewed, follow-up photographs were taken, and patients were encouraged to complete a patient satisfaction survey (appendix 5). To date, (surveys continue to be completed) 19 surveys have been completed. Patients had photographs taken before the first treatment and before the sixth treatment. When possible, another set of photographs was taken 2-3 weeks after the last treatment. Early in the study, photographs were taken against a black backdrop.

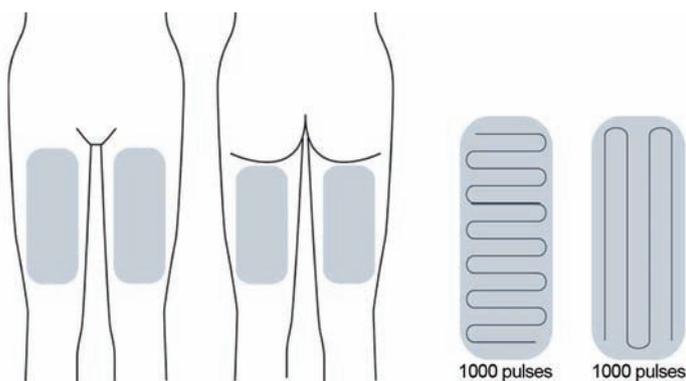


Figure 1. Illustration of the treatment pattern.

Upon its arrival, a LPG Results 6 photostation was used to help standardize the photographs.

Results

During the initial phone intake, 167 patients expressed interest and received some treatment, all were women. The average age was 42.8 years, (range 14-65 years). Of these, 102 agreed to inclusion and completed weight, percentage body fat and electrical impedance data. Complete circumference data was obtained for the right thigh on 72 and the left thigh on 75 patients (total of 147 thighs). Before and after photographs were reviewed by staff and the individual patients. However, no standardized photographic evaluation was performed. Average weight loss during the three week period was 0.19 lbs (0.08 kg). This was not statistically significant, $p=0.21$. Similarly, percentage body fat decreased by 0.02%, also not statistically significant, $p=0.45$. No additional weight loss recommendations or techniques were employed during the treatment course. Thigh circumference did decrease 0.45 cm, which was statistically significant with $p=0.025$. While this was a small decrease, any statistically significant decrease in thigh circumference over a three week period of time represents a worthwhile improvement. Responding patients rated their posterior thigh treatment at 84% on a scale of 0-100, with 0 being extremely disappointed and 100 being extremely pleased. Patients having their anterior thigh treated rated their treatment at 52% of extremely pleased using the same scale. When asked if they were more confident in revealing clothing, 68% of responders agreed that they were, while only 11% (2 patients) disagreed that they were more confident in revealing clothing. Seventy four percent of responders were more comfortable with their body. Only 11% (2 patients) disagreed that they were more confident in their body. Seventy three percent of responders stated the treated area was closer to the appearance they desired, while 11% of responders (2 patients) responded that the area was not closer to the appearance they desired. In each category, the 2 patients responding negatively are the same 2 individuals. Before and after photographs ranged from significant after initial treatment (appendix 1 and 2), to improvement noted 2 weeks after treatment (appendix 3) to mild improvement in small dimpling and texture (appendix 4). No patients saw worsening. Continued improvement was seen in each photograph taken at the 2-3 week follow-up appointment. Patients saw continued improvement throughout follow-up (maximum of

6 weeks). Response to the photographs was positive from researchers, patients and independent observers. Patients reported no significant pain or discomfort. Two patients received mild bruising. This appeared to be a calibration error on the pressure settings of one of the D-Actors. After adjustment, no further bruising was reported.

Conclusions

AWT delivered by a using ballistic head and pulsed mode (D-Actor) was effective for improving the appearance of cellulite in the majority of patients treated. The patients reported minimal side effects during and after treatment. The appearance of cellulite continued to improve throughout the 3-6 week follow-up period. The improvement is most apparent in the before and after photographs. A small decrease in thigh diameter is also seen. This is gratifying given the short duration of the treatment course (3 weeks). Additional measurement after further follow-up and possible additional treatments is warranted. Further studies should also address optimal timing and number of treatments, appropriate follow-up, timing and intensity of maintenance treatments and additional treatments to augment the response. Studies have shown combined therapy to be effective.⁷ The addition of endermology, mesotherapy and alternative AWT heads each deserve evaluation as well. No significant changes in weight or body fat composition were seen. However, the duration of the study was short (three weeks for weight and percentage body fat). Longer duration and the use of additional treatments, exercise and diet modification could enhance this result. In summary, AWT is an important new addition for improving the appearance of cellulite. The future should see its use alone and with other complementary therapies for improving the appearance of cellulite.

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Appendix 1



BEFORE - May 5, 2006



AFTER - May 25, 2006

Appendix 2

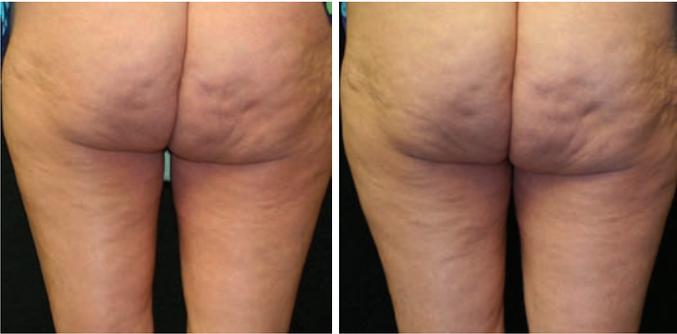


BEFORE - May 11, 2006



AFTER 6th treatment - May 26, 2006

Appendix 3



BEFORE - April 20, 2006 AFTER - May 10, 2006



3 weeks post-treatment - June 1, 2006

Appendix 4



BEFORE - April 24, 2006 AFTER - May 10, 2006

Appendix 5

1. Name: _____ Gender: Female Male Age: _____

2. How did you hear about our cellulite service?

3. How far did you have to travel to reach our office?

4. What areas were treated? (please check all that apply)

- a. Posterior Thigh
- b. Anterior Thigh
- c. Buttocks
- d. Abdomen
- e. Arms
- f. Other (please specify) _____

5. How long has it been since your first treatment? (please check which best represents you)

- a. less than 3 weeks b. 3-4 weeks
- c. 5-6 weeks d. 7-8 weeks
- e. 9-10 weeks f. 11 weeks or more

6. How long has it been since your last treatment?

- a. 1 week of less b. 2-3 weeks
- c. 4-5 weeks d. 6-7 weeks
- e. 8-9 weeks f. 10 weeks or more

7. What was the severity of your cellulite prior to treatments?

- a. No Cellulite
- b. Slight dimpling
- c. Dimpling & skin depressions
- d. Dimpling & severe depressions

8. State the degree to which you agree or disagree with the following statements.

(circle only one response for each statement)

1= strongly agree, 2= agree, 3= somewhat agree, 4= neither agree or disagree, 5= somewhat disagree, 6= disagree, 7= strongly disagree

strongly agree agree somewhat agree neutral somewhat disagree disagree strongly disagree

a. During my original consultation, I had all the time I needed to ask questions. 1234.....567

b. My consultants explained the treatment procedures clearly and completely. 1234.....567

- c. My consultant communicated to me realistic expectations. 1234.....567
- d. My operator(s) were always polite and respectful. 1234.....567
- e. My operator(s) were skilled in making the treatment comfortable. 1234.....567
- f. My operator(s) were consistent from treatment to treatment. 1234.....567
- g. I am now more confident with my body because of the cellulite treatment. 1234.....567
- h. My treated area(s) are now closer to the physical appearance goals I desire. 1234.....567
- i. I feel more confident wearing shorts or other revealing attire since my treatments. 1234.....567

9. On a scale from 0 to 100 (0 being extremely disappointed and 100 being extremely pleased) please evaluate your satisfaction level with the appearance improvement of your treated areas. (please fill in for all areas treated)

- a. Posterior Thigh _____
- b. Anterior Thigh _____
- c. Buttocks _____
- d. Abdomen _____
- e. Arms _____
- f. Other _____
- please specify _____

10. On a scale from 0 to 100 (0 being extremely disappointed and 100 being extremely pleased) please evaluate your overall experience from the moment you walked in the lobby to checkout.

11. I began to see improvement to your treated area(s) after my? Please circle one.

- a. 1st treatment b. 2nd treatment c. 3rd treatment d. 4th treatment
- e. 5th treatment f. 6th treatment g. 1-3 weeks after treatment
- h. 4-6 weeks after treatment i. more than 6 weeks after treatment j. I have not seen improvement

12. What was the severity of your cellulite after your treatments?

- a. No Cellulite
- b. Slight dimpling
- c. Dimpling & skin depressions
- d. Dimpling & severe depressions

13. Please share with us any comments you might have expressing your level of satisfaction/dissatisfaction with the results of your treatment?

14. Please let us know any additional suggestions you might have for us to improve upon our service?

15. Would you recommend the cellulite treatment to a friend? a. yes b. no c. not sure

16. Please state the degree to which you are interested in the following services?

(1=highly interested, 2= interested, 3= neutral, 4=disinterested, 5= highly disinterested)

	highly interested	interested	neutral	disinterested	highly disinterested
a. Botox	1.....	2.....	3.....	4.....	5.....
b. Restylane	1.....	2.....	3.....	4.....	5.....
c. Laser hair removal	1.....	2.....	3.....	4.....	5.....
d. Photo-facial	1.....	2.....	3.....	4.....	5.....
e. Microdermabrasion	1.....	2.....	3.....	4.....	5.....
f. Collagen remodeling (wrinkle treatment)	1.....	2.....	3.....	4.....	5.....
g. Cosmeceuticals and other topical skin treatments	1.....	2.....	3.....	4.....	5.....
h. Spider and Varicose vein reduction	1.....	2.....	3.....	4.....	5.....