

# A Noninvasive Mechanical Treatment to Reduce the Visible Appearance of Cellulite

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## PRACTICE POINTS

- Several cellulite treatments have shown improvement in the firmness of collagen and the dermis but not in the appearance of cellulite.
- The noninvasive mechanical treatment for women with cellulite evaluated in this study showed a strong correlation between the treatment and the reduction in the visible appearance of cellulite in this study population.

*Cellulite is a cosmetic condition of subcutaneous fat herniation through fibrous connective tissue that results in a dimpled appearance of the skin. Occurring in approximately 85% to 90% of all women worldwide, cellulite has been well studied. The result has been the development of a plethora of treatment protocols yielding little to no success. We describe a noninvasive mechanical treatment for women with cellulite, evaluating the safety and effectiveness of a technique that utilizes a unique patented device for the reduction of the visible appearance of cellulite.*

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Cellulite is a cosmetic problem, not a disease process. It affects 85% to 90% of all women worldwide and was described nearly 100 years ago.<sup>1</sup> Causes may be genetic, hormonal, or vascular in nature and may be related to the septa configuration in the subdermal tissue. Fibrosis at the dermal-subcutaneous junction as well as decreased vascular and lymphatic circulation also may be causative factors.

Cellulite has a multifactorial etiology. Khan et al<sup>2</sup> noted that there are specific classic patterns of cellulite that affect women exclusively. White women tend to have somewhat higher rates of cellulite than Asian women. The authors also stated that lifestyle factors such as high carbohydrate diets may lead to an increase in total body fat content, which enhances the appearance of cellulite.<sup>2</sup>

The subdermal anatomy affects the appearance of cellulite. Utilizing in vivo magnetic resonance imaging, Querleux et al<sup>3</sup> showed that women with visible cellulite have dermal septa that are thinner and generally more perpendicular to the skin's surface than women without cellulite. In women without cellulite, the orientation of the septa is more angled into a crisscross pattern. In women with a high percentage of perpendicular septa, the perpendicular septa allow for fat herniation with dimpling of the skin compared to the crisscross septa pattern.<sup>2</sup> Other investigators have discussed

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Dr. Roubal is president, owns patents, and has patents pending on behalf of Paul's Engineering, Inc. Drs. Busuito, Freeman, and Placzek report no conflict of interest.

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the reduction of blood flow in specific areas of the body in women, particularly in cellulite-prone areas such as the buttocks and thighs, as another causative factor.<sup>2,4,5</sup> Rossi and Vergnanini<sup>6</sup> showed that the blood flow was 35% lower in affected cellulite regions than in nonaffected regions without cellulite, which can cause congestion of blood and lymphatic flow and increased subdermal pressure, thus increasing the appearance of cellulite.

Although there is some controversy regarding the effects of weight loss on the appearance of cellulite,<sup>2,7</sup> it appears that the subdermal septa and morphology have more of an effect on the appearance of cellulite.<sup>2,3,8</sup>

Rossi and Vergnanini<sup>6</sup> proposed a 4-grade system for evaluating the appearance of cellulite (grade I, no cellulite; grade II, skin that is smooth and without any pronounced dimpling upon standing or lying down but may show some dimpling upon pinching and strong muscle contraction; grade III, cellulite is present in upright positions but not when the patient is in a supine position; grade IV, cellulite can be seen when the patient is standing and in a supine position). Both grades III and IV can be exacerbated by maximal voluntary contraction and strong pinching of the skin because these actions cause the subcutaneous fat to move toward the surface of the skin between the septa. This grading system aligns with categories I through III described by Mirrashed et al.<sup>9</sup>

There are many cellulite treatments available but few actually create a reduction in the visible appearance of cellulite. A number of these treatments were reviewed by Khan et al,<sup>10</sup> including massage; a noninvasive suction-assisted massage technique; and topical agents such as xanthine, retinols, and other botanicals.<sup>4,11-14</sup> Liposuction has not been shown to be effective in the treatment of cellulite and in fact may increase the appearance of cellulite.<sup>9,15</sup> Mesotherapy, a modality that entails injecting substances into the subcutaneous fat layer, is another treatment of cellulite. Two of the most common agents purported to dissolve fat include phosphatidylcholine and sodium deoxycholate. The efficacy and safety of mesotherapy remains controversial and unproven. A July 2008 position statement from the American Society of Plastic Surgeons stated that “low levels of validity and quality of the literature does not allow [American Society of Plastic Surgeons] to support a recommendation for the use of mesotherapy/injection lipolysis for fat reduction.”<sup>16</sup> Other modalities such as noninvasive dual-wavelength laser/suction devices; low-energy diode laser, contact cooling, suction, and massage devices; and infrared, bipolar radiofrequency, and suction with mechanical massage devices are available and show some small improvements in the visible

appearance of cellulite, but no rating scales were used in any of these studies.<sup>17,18</sup> DiBernardo<sup>19</sup> utilized a 1440-nm pulsed laser to treat cellulite. It is an invasive treatment that works by breaking down some of the connective tissue septa responsible for the majority and greater severity of the dermal dimpling seen in cellulite, increasing the thickness of the dermis as well as its elasticity, reducing subcutaneous fat, and improving circulation and reducing general lymphatic congestion.<sup>19</sup> The system showed promise but was an invasive treatment, and one session could cost \$5000 to \$7000 for bilateral areas and another \$2500 for each additional area.<sup>20</sup> Burns<sup>21</sup> expressed that the short-term results showed promise in reducing the appearance of cellulite. Noninvasive ultrasound<sup>22,23</sup> as well as extracorporeal shock wave therapy<sup>24,25</sup> also has shown some improvement in the firmness of collagen but generally not in the appearance of cellulite.

We sought to evaluate the efficacy and safety of a noninvasive mechanical treatment of cellulite.

### Methods

This study was conducted in accordance with the guidelines set forth by the US Department of Health and Human Services' Policy for Protection of Human Research Subjects and the World Medical Association's Declaration of Helsinki. Participants were recruited through local area medical facilities in southeastern Michigan. Written informed consent was obtained from all participants prior to beginning the study.

Patients with grades II to IV cellulite, according to the Rossi and Vergnanini<sup>6</sup> grading system, were allowed to participate. All participants in the study were asked not to make lifestyle changes (eg, exercise habits, diet) or use any other treatments for cellulite that might be available to them during the study period. Exclusion criteria included history of deep vein thrombosis, cancer diagnosed within the last year, pregnancy, hemophilia, severe lymphedema, presence of a pacemaker, epilepsy, seizure disorder, or current use of anticoagulants. History of partial or total joint replacements, acute hernia, nonunited fractures, advanced arthritis, or detached retina also excluded participation in the study.

Participants completed an 8-week, twice-weekly treatment protocol with a noninvasive mechanical device performed in clinic. The device consisted of a 10.16-cm belt with a layer of nonslip material wrapped around the belt. The belt was attached to a mechanical oscillator. We adjusted the stroke length to approximately 2 cm and moved the dermis at that length at approximately 1000 strokes per minute.

Each participant was treated for a total treatment time of 18 to 24 minutes. The total treatment area

included the top of the iliac crest to just above the top of the popliteal space. The width of the belt (10.16 cm) was equal to 1 individual treatment area. Each individual treatment area was treated for 2 minutes. First the buttocks and bilateral thighs were treated, followed by the right lateral thigh and the left lateral thigh. The belt was moved progressively down the total treatment area until all individual treatment areas were addressed. The average participant had 3 to 4 bilateral thigh and buttocks treatment areas and 3 to 4 lateral thigh treatment areas on both the left and right sides of the body.

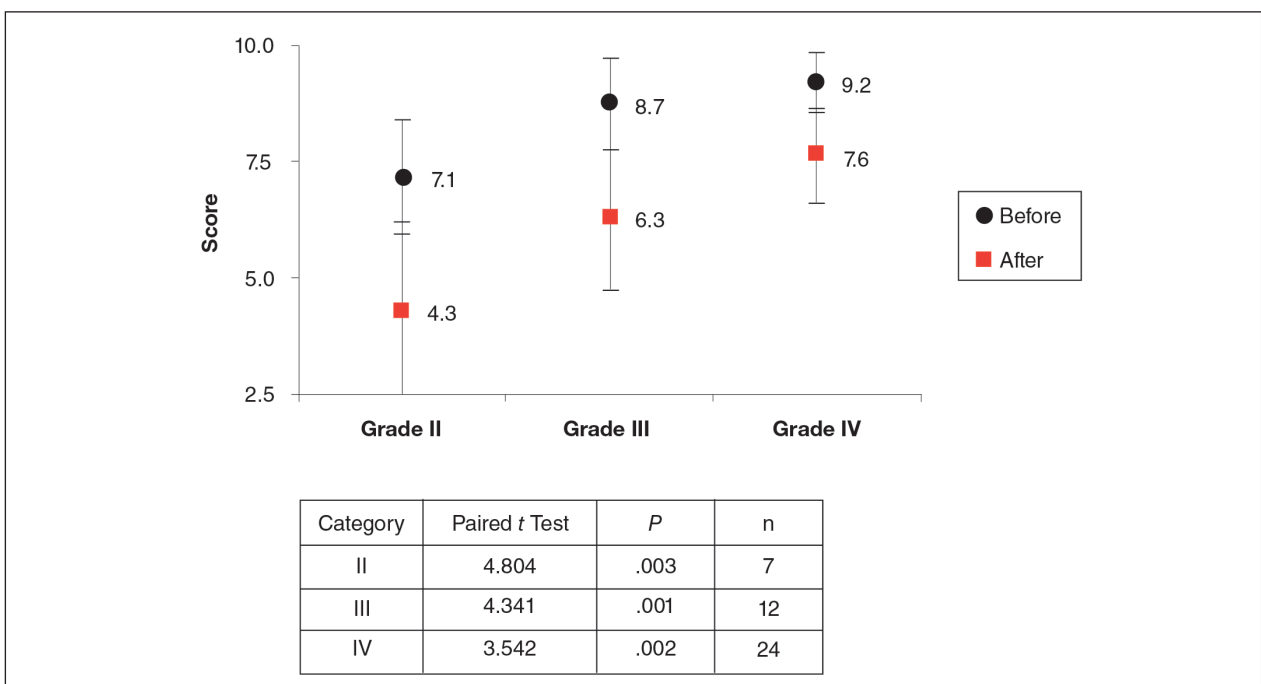
Digital photographs were taken with standardized lighting for all participants. Photographs were taken before the first treatment on the lateral and posterior aspects of the participant and were taken again at the end of the treatment program immediately before the last treatment. Participants were asked to contract the gluteal musculature for all photographs.

Two board-certified plastic surgeons were asked to rate the before/after photographs in a blinded manner. They graded each photograph on a rating scale of 0 to 10 (0=no cellulite; 10=worst possible cellulite). These data were analyzed using a Wilcoxon signed rank test. These data were compared to the participants self-evaluation of the appearance of cellulite in the photographs from the initial and final treatments using a rating scale of 0 to 10 (0=no cellulite; 10=worst possible cellulite).

The circumference of the widest part of the gluteal area was measured before and after treatment ( $\pm 0.5$  cm). The data were analyzed using a paired *t* test.

## Results

The study included 43 participants (age range, 21–67 years; mean age, 37.6 years; weight range, 51–97 kg; mean weight, 64.95 kg) who resided in the Midwestern United States, were interested in reducing their cellulite, and were willing to commit to treatment 2 times weekly for the duration of the 8-week study. Fourteen percent (6/43) of participants were smokers. Participant self-assessments were divided into 3 categories based on the Rossi and Vergnanini<sup>6</sup> grading system: category II, *n*=7; category III, *n*=12; and category IV, *n*=24. Although all the categories in our analysis showed statistically significant improvements, we found that there was more improvement in category II participants versus category III, and then again more improvement in category III versus category IV. The data for each treatment were analyzed separately using a paired *t* test, as we were not interested in comparing categories, only the effect of the treatment. We were testing to see if the difference was greater than 0, and the paired *t* values were statistically significant in all cases (category II, *P*=.003; category III, *P*=.001; category IV, *P*=.002)(Figure 1).



**Figure 1.** Mean participant self-assessment of cellulite before and after treatment (0=no cellulite; 10=worst possible cellulite).

Using a correlation analysis, we found that age, body weight, or body mass index were not significantly correlated with the difference between the before and after physician rating. The difference between before and after treatment also was independent of whether or not the participant exercised or had an adverse reaction to the belt. Adverse reactions to the belt were characterized by redness and/or minor raising of the skin immediately following the treatment. These reactions all dissipated within 12 hours. It also appeared that the rating scales correlated well with the participants self-perception of their cellulite and the improvements seen in the photographs (Figures 2 and 3).

The mean circumference of the widest part of the gluteal area before treatment was 100.2 cm and the standard deviation was 8.14 cm. The mean circumference after treatment was 98.3 cm and the standard

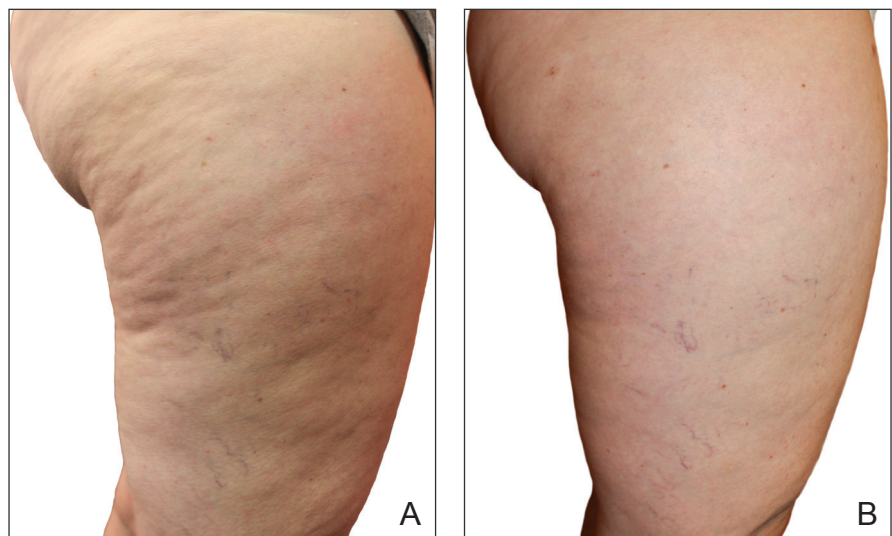
deviation was 8.02 ( $t=-2.81$ ;  $P<.05$ ). Many of the women commented that they felt more “toned,” which probably accounted for the slight difference in circumference rather than weight loss.

Of the 2 blinded board-certified plastic surgeons, one physician rated all participants in category III as significantly improved ( $P<.05$ ) and rated the other categories as marginally insignificantly improved; the second physician rated all categories as marginally insignificantly improved.

### Comment

Although there are a large number of treatment protocols that have been introduced and studied for the reduction of the appearance of cellulite,<sup>4,9,11-18</sup> many have not shown promising long-term results. Some treatments have shown improvement in the firmness of collagen and the dermis but not in the

**Figure 2.** The right lateral thigh and buttocks of a 41-year-old woman (weight, 75.5 kg; body mass index, 25.7; cellulite category IV) before (A) and after treatment (B)(cellulite category III).



**Figure 3.** Bilateral thighs and buttocks of a 27-year-old woman (weight, 72.6 kg; body mass index, 23.3; cellulite category IV) before (A) and after treatment (B) (cellulite category III).



appearance of cellulite.<sup>22-25</sup> One of the only treatments that has shown some promise is an expensive invasive treatment.<sup>20</sup>

The system used in this study was shown to be safe in all study participants. No significant adverse reactions were noted, and each participant successfully completed the protocol. Figures 2 and 3 show the strong correlation between the treatment and the reduction in the visible appearance of cellulite in this study population, which was supported by statistical analysis, particularly the participant self-reported ratings. The participants and the blinded physicians were not in agreement on the improvement of cellulite. Although the participants knew the changes that occurred to their bodies, the physicians only had photographs from which to make their decisions. The participants clearly observed noticeable differences to their bodies, while the physicians either saw no change or some improvement.

The physicians were asked to evaluate only the cellulite, but the process we employed changed more than the cellulite. The first step in the process was a toning of the legs and buttocks, which was readily observable by the patients but was outside the scope of the physicians' assessment. After the body toning, the cellulite began to improve. It is possible that the participants were responding to the entire process, which clearly was positive, while the physicians were responding only to the cellulite end point.

Our treatment regimen accomplished reduction of the visible appearance of cellulite by breaking down connective tissue septa as well as increasing the thickness of the dermis and its elasticity. It also helped reduce subcutaneous fat, improve circulation, and reduce general lymphatic congestion. The parallel motions of the unit could be adjusted, but we kept them at a mid-level range of motion. The motion at this frequency would have a tendency to not only heat the epidermis and dermal layer that we were attempting to affect but would also help accomplish breaking down the septa and improving the elasticity of the dermis. Also, the rapid motion over a period of time of pulling the dermis parallel to the subdermal tissue and fascia most likely helped improve the circulation and lymphatic flow in treated areas as well as possibly broke down the subcutaneous fat. All of these factors appear to have led to an improvement in the appearance of cellulite in our study participants.

A maintenance-type program, if continued, would likely demonstrate improved results by further breaking down the septa and improving the other factors that reduce the appearance of cellulite. We believe that the participants would

eventually be able to discontinue the use of the unit or reduce its use substantially once the desired results were obtained.

When utilizing the device, the participants were in a standing posture and leaning into the belt with a moderate force, which seemed to secondarily improve the tone of the gluteal and thigh musculature that was being treated. It may be that the oscillatory motion and the standing posture caused the muscles to isometrically co-contract, adding a secondary exerciselike effect.<sup>26-29</sup>

Proving our suggested mechanisms of action would require tissue biopsies and/or magnetic resonance imaging studies that were beyond the scope of this study. However, regardless of the mechanism of action, we do believe that this treatment has been shown to be effective, convenient, and most importantly safe.

## Conclusion

The unique device that was utilized in our study is a safe and cost-effective method of reducing the appearance of cellulite for home use and would allow for a noninvasive, low-risk procedure.

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