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ORIGINAL ARTICLE

Evaluation of the combination of radio frequency, infrared energy and mechanical rollers with suction to improve skin surface irregularities (cellulite) in a limited treatment area

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Abstract

This IRB-approved (Institutional Review Board) study evaluated the efficacy of a device that combines radio frequency, infrared energy and mechanical rollers/suction (ELOS technology) to reduce skin surface irregularities in a limited treatment zone. Sixteen patients were enrolled and received two treatments per week for 4 consecutive weeks. Treatments were limited to a 20.53 cm × 33.02 cm area of the posterior or lateral thigh and lasted for 15 minutes. Maximum machine settings were used for all but one individual at every treatment. Evaluations consisted of a patient questionnaire and photographic assessment of skin contour by three physicians at 3 and 6 months after the last session who were blind to the treatment each patient received. Physician evaluators determined that all patients were improved at both post-treatment periods. The average improvement at 3 and 6 months was 62% and 50%, respectively. All patients felt they were improved. One patient described the treatment as painful and required reduced treatment parameters after the initial treatment. Bruising within the treatment area was observed in five patients following the initial sessions but this did not alter the treatment protocol and did not occur in subsequent treatments. One patient had a superficial skin burn due to poor electrode contact that did not require corrective treatment.

Key words: *Cellulite reduction, ELOS technology, infrared energy, radiofrequency*

Introduction

Cellulite is a condition where the skin is puckered, dimpled or quilted in appearance. It is usually found in women after puberty and most often located on the hips, thighs and buttocks. There are structural differences between men and women that may explain the high incidence of cellulite in women. In men, there is a strong network of connective tissue in the fat layer and a thicker dermis, which may block the protrusion of the superficial fat layer into the dermis (1). There are many purported etiologies of cellulite, which include tethering fibrous septae with a thinner overlying dermis; lipodystrophy; hormonal, circulatory disorders; and hereditary factors (2–5). Treatment alternatives include topical agents, massage and surgical subcision (6–10). Recent studies have evaluated the efficacy of a device that combines radio frequency (RF), infrared (IR), suction and mechanical rollers to reduce surface irregularities (11,12).

This study will evaluate the ability of such a device to improve skin irregularities while treating only isolated regions (one-quarter of the thigh) using maximal energy settings at all treatment sessions.

Methods

Sixteen patients were enrolled in this IRB-approved study. Exclusion criteria included a history of deep venous thrombosis, presence of a sun-tan, infectious skin condition, previous scarring or treatment with a laser or light-based device in the study area, history of diabetes, ingestion of sun-sensitizing or anti-coagulant medication, or pregnancy.

Patients received two treatments a week for a total of eight treatments. All treatments were performed by the primary investigator. Prior to treatment, a minimal amount of conductive fluid was applied to the skin to allow electrode conductivity while maximizing surface friction and the mechanical effect of the operator. Sessions lasted approximately 30 minutes, with each area of the thigh being treated for 15 minutes. The total area treated measured approximately 20.53 cm × 33.02 cm or less per leg. The area selected

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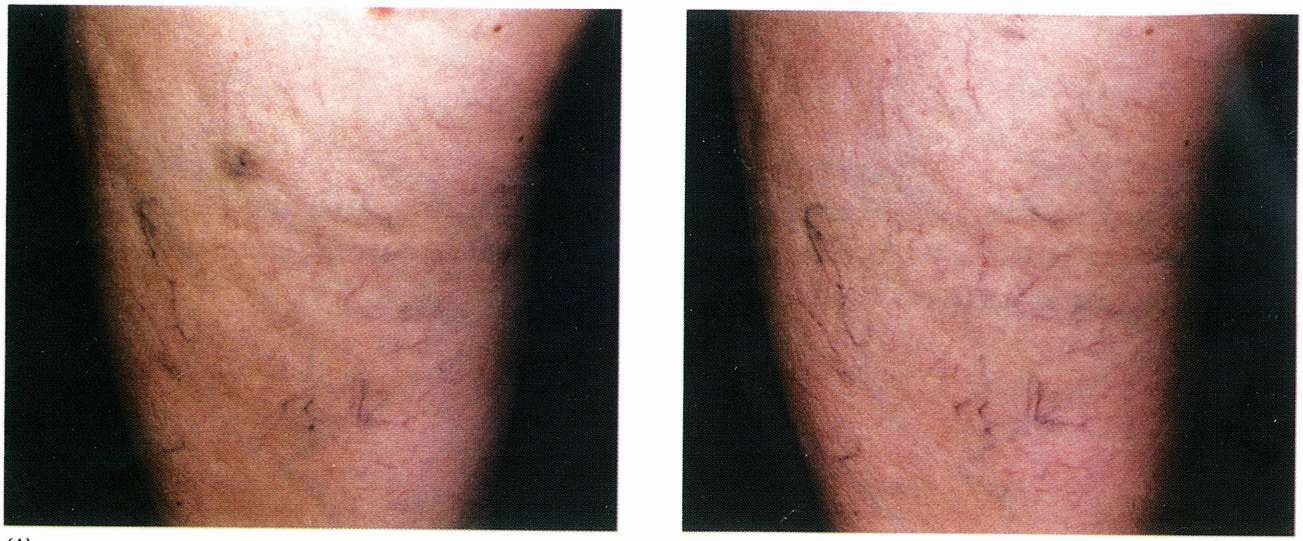


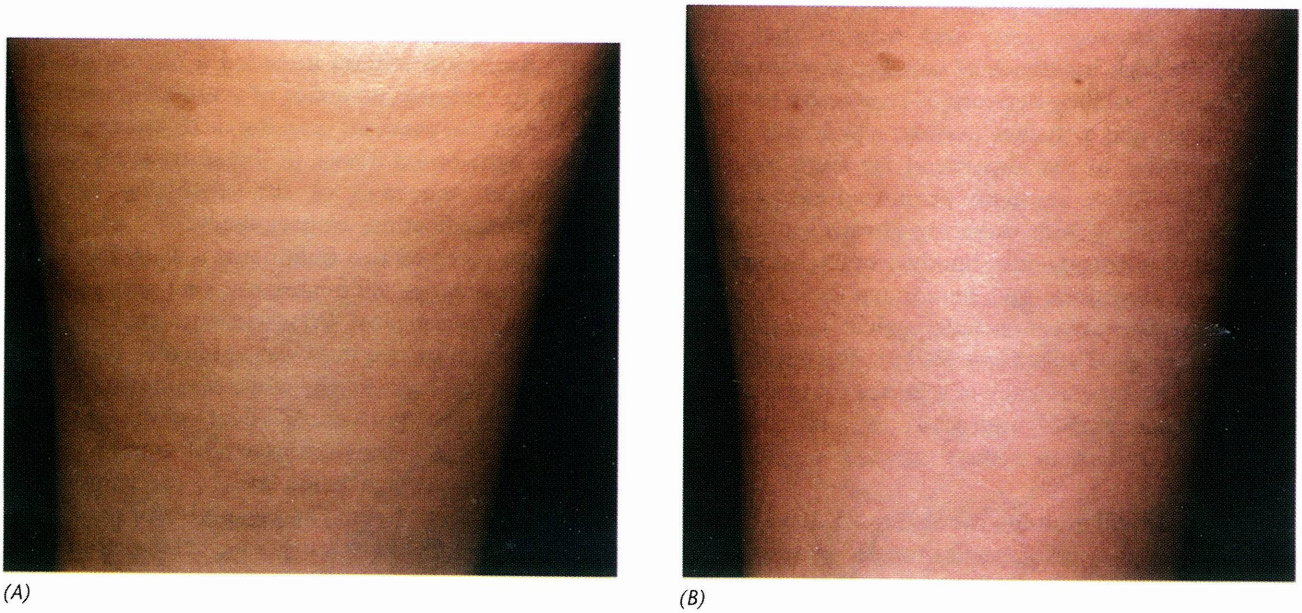
(A) (B)

Figure 1. (A) This 57-year-old woman had moderate irregularities of her left, lateral thigh. She had bruising that dissipated by the time she received her first treatment. Unlike the other study patients, she had a relatively large number of superficial vessels in the treatment area. (B) Six months after her last treatment, she was evaluated as having a 25% improvement. There did not appear to be an increase in the number of visible blood vessels after her eight treatments.

for treatment contained the most skin surface irregularities and was either the lateral or posterior thigh.

Machine settings were constant for all patients: RF (1 MHz – 20 W), IR light (700–1500 nm – 12.5 W) and suction (750 mmHg negative pressure/ 250 ms on – 150 ms off). For the first 5–7 minutes of treatment, the applicator was moved slowly with light pressure against the skin and a 75% overlap of the antecedent, treated area. Once the skin became warm to touch, the applicator was advanced with firm pressure against the skin and only a 25% or less overlap. In addition, as the suction elevated the skin, the handpiece was pulled gently to stretch the skin before moving to the next site. The pull was not sufficient to break the suction seal of the treatment head interface with the skin and potentially cause an arch burn due to the loss of electrode contact. Owing to the curvature of the thigh, the treatment head was rotated wherever necessary to provide optimal contact between the applicator and skin. Following treatment, patients wore compressive stockings for 48 hours except to cleanse. Acetaminophen was recommended for any post-treatment discomfort. Leg circumference was not measured as only a portion of the thigh was treated.

Photographs of the treated areas were obtained before the initial treatment and then at 3 and 6 months after the last session. Pictures were reviewed



(A) (B)

Figure 2. (A) Pretreatment, posterior right thigh view of a 34-year-old woman. She was felt to have minimal pretreatment irregularities. (B) Six months after her last session, she was felt to have a 75% improvement.

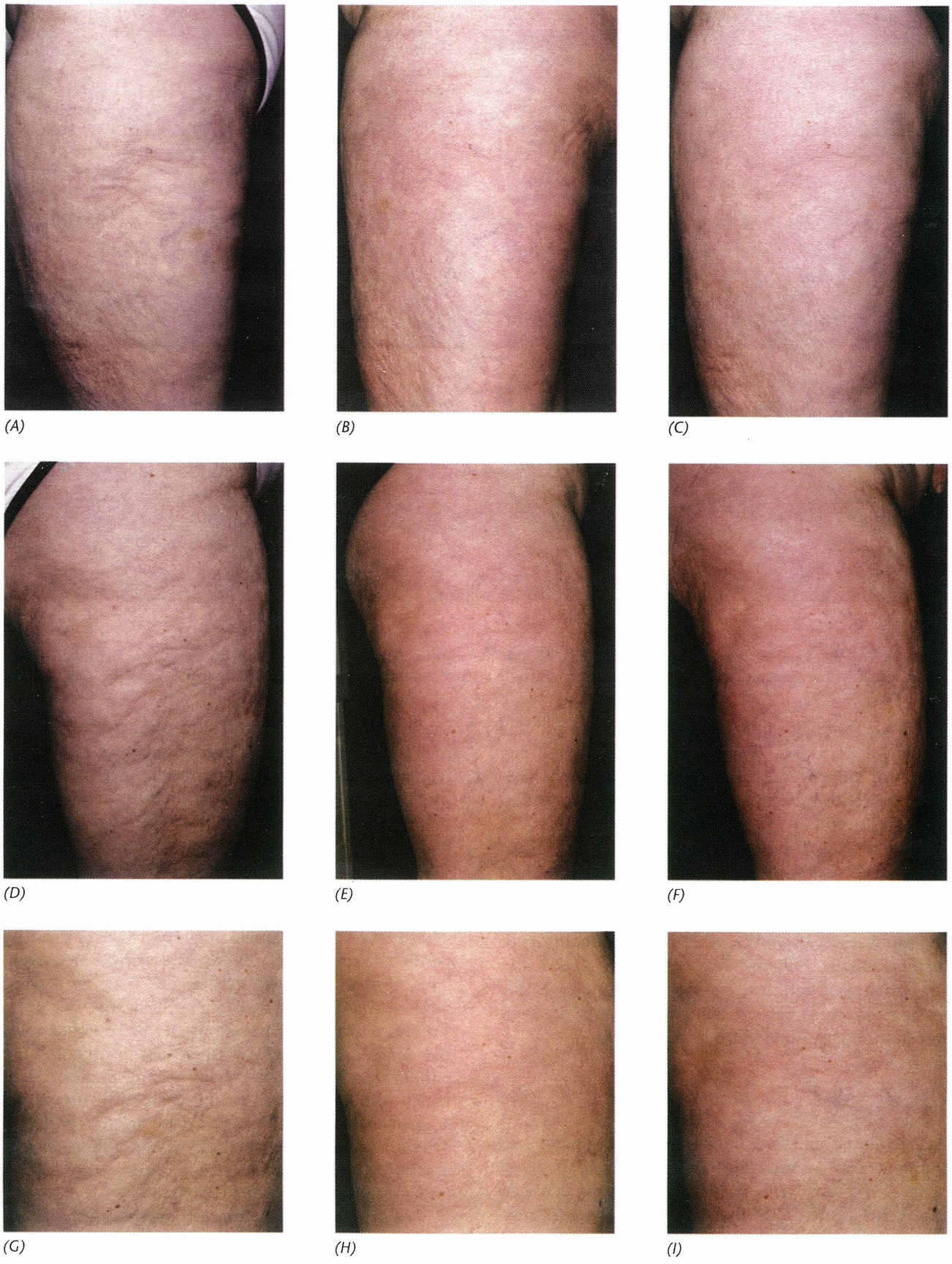


Figure 3. (A) Pretreatment, left lateral thigh view of a 58-year-old woman demonstrates marked skin irregularities. (B) Three months after treatment. (C) Six months after treatment. (D) Pretreatment, right lateral thigh. (E) Three months after treatment. (F) Six months after treatment. (G) Pretreatment, close-up view, right lateral thigh. (H) Three months after treatment. (I) Six months after treatment.

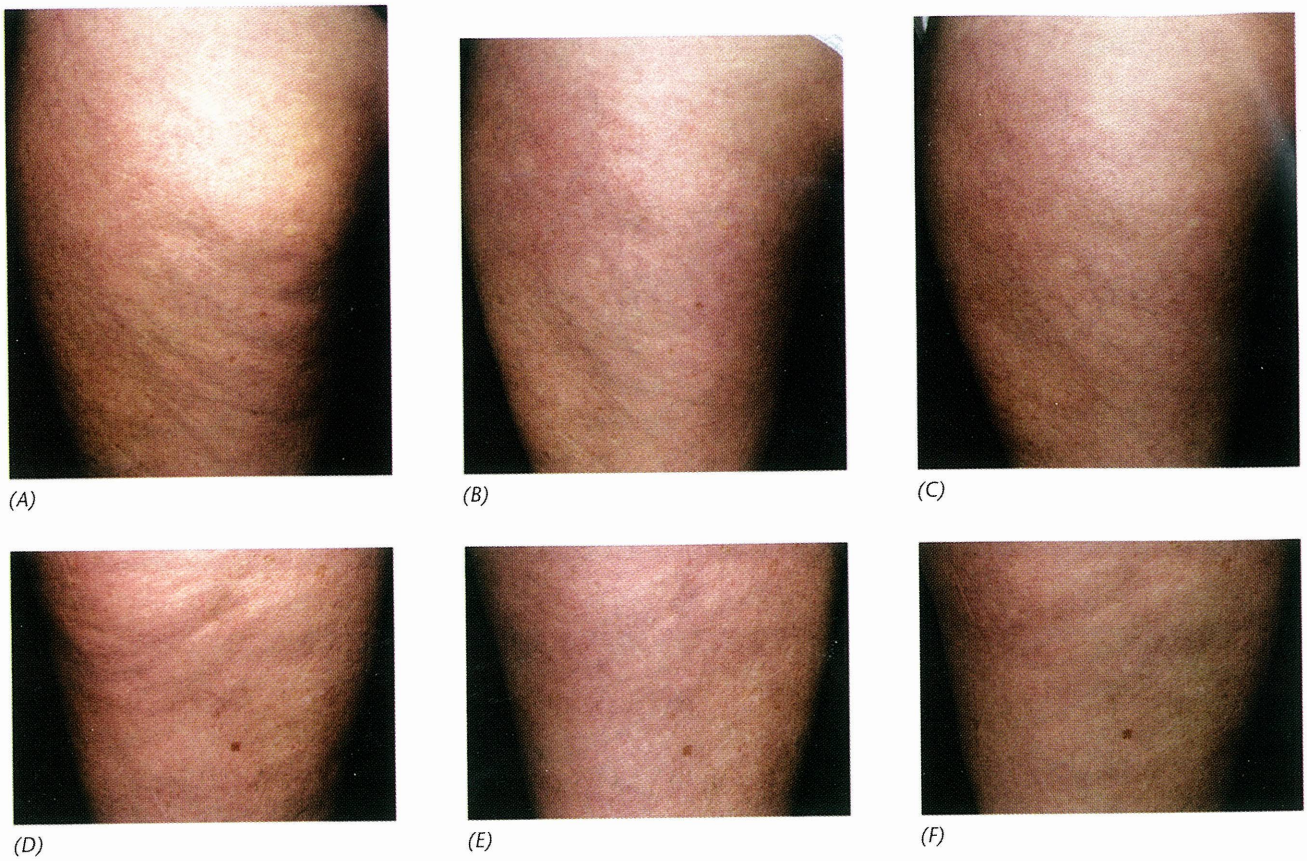


Figure 4. (A) Pretreatment, left lateral thigh view of a 60-year-old woman. (B) Three months after treatment. (C) Six months after treatment. (D) Pretreatment, close-up view, right lateral thigh. (E) Three months after treatment. (F) Six months after treatment.

by three physicians, who were unaware of the treatment provided. They were asked to rank any observed improvement in the post-treatment pictures as follows: 0=no change, 1=25% smoother, 2=50% smoother, 3=75% smoother and 4=100% smoother (no residual irregularities). The three physician scores were then averaged for each patient at 3 and 6 months after the last treatment.

Patients were asked to evaluate their results using the same scale, as well as describe any discomfort or adverse effects. Patient body weight was recorded at the initial visit and at the evaluation periods. Study subjects were to refrain from any change in their normal daily routines during the study.

Results

All patients enrolled completed the study. All patients were women and the average age was 49 years old (range 19–60 years). One patient had received liposuction to the study area 10 years prior.

Following treatment, there was a period of temporary erythema that resolved within 4 hours. All patients described the discomfort as being greatest during the first two to three sessions and then, despite no change in the device settings, felt that there was much less or no discomfort during the remainder of their sessions. All patients described the initial level of discomfort as minimal, except for one patient, who had a large number of superficial telangiectasias in the treatment area (Figure 1). She was the only person who described the treatment as painful but did not request additional analgesic medication other than the recommended acetaminophen before or after her sessions. She also received a reduction in the RF and IR energy settings for all treatments after her initial session. There were five patients that experienced bruising within the treatment area, which resolved in 1 week. This bruising occurred after the first or second session for these patients and did not occur in subsequent treatment sessions despite no change in the machine settings or treatment protocol. One patient received a superficial second-degree burn, which did not require any corrective measures. There was no significant change in the patients' weight at the two evaluation periods. The patient assessment of improvement was an average of 75% at 3 months and 50% at 6 months.

The average improvement determined by physicians at 3 months was 2.5 (greater than 50% improvement) and 1.9 (approximately 50% better) at 6 months. All patients were rated as having a 25% or greater improvement at both evaluation periods. The most difficult pictures to evaluate were those from patients with comparatively few pretreatment skin surface irregularities (Figure 2).

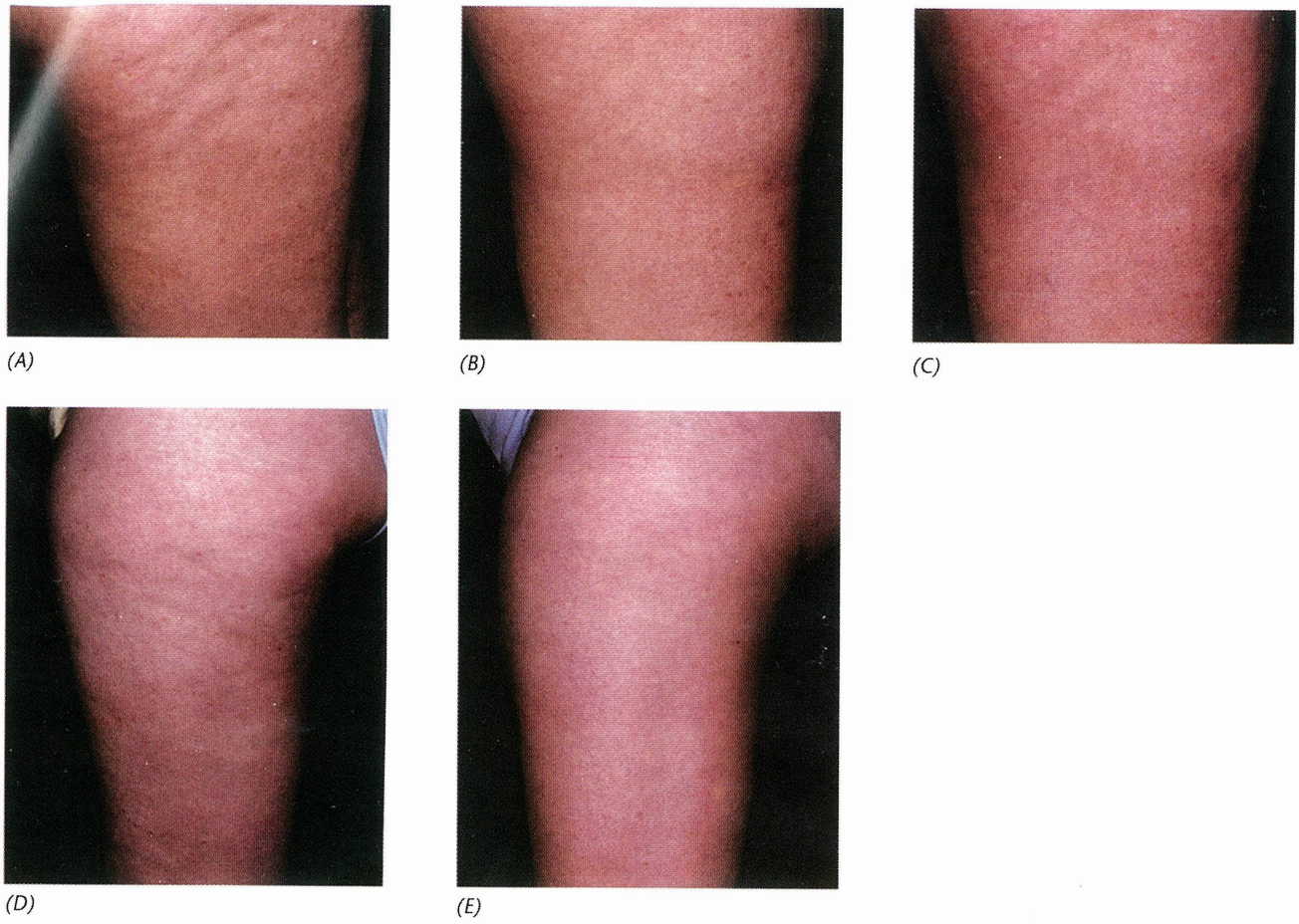


Figure 5. (A) Pretreatment, right lateral thigh view of a 56-year-old woman. (B) Three months after treatment. (C) Six months after treatment. (D) Pretreatment, left lateral thigh. (E) Six months after treatment.

The most dramatic improvement was observed in the 58-year-old patient who had significant irregularities following liposuction 10 years prior to this study (Figure 3). Her average improvement was rated 75% at both 3 and 6 months after her last treatment. Improvement was also observed in the eldest patient enrolled in the study (60 years old) (Figure 4). The majority of the patients had irregularities similar to the patient in Figure 5 at their pretreatment visit.

Discussion

This technology provided consistent improvement in all patients that lasted 6 months after their last treatment following regional therapy. Patient satisfaction was high at both follow-up periods. There was a reduction in efficacy between the 3- and 6-month evaluation points but a significant improvement remained.

The exact mechanism of action of this technology has not been clearly defined. The results of this study differ from other studies using this device and may be related to treatment parameters (all but one patient received maximal RF, IR and suction settings) and/or treatment technique. Device settings may play a role. Previous studies with this technology started with lower machine settings. In this study, the patient that required a reduction in the RF and IR settings because of pain had the lowest level of improvement. The mechanical effort of the person performing the treatment also seems to play an important role. From my personal observation, patients not enrolled in this study, who were treated by other staff in my office, did not experience the same level of improvement after eight treatments. Their vigor in massaging the tissue was felt to be less than mine. This implies that part of the clinical improvement may be related to the effect on deeper structures, such as the subcutaneous fat and fibrous septae. Combined with the study by Sadick and Mulholland (12), who noted no structural changes within the dermis of the treated skin using this device, this may provide evidence for subcutaneous, rather than dermal, effect needed to improve cellulite. Another factor may be the actual treatment time spent on each area. In this study, the treatment area was limited to 20.53 cm × 33.02 cm or less. Other articles reporting on this technology did not state the actual treatment area. The treatment zone in this investigation may have been smaller and received more 'passes/treatment time', which may have contributed to the increased efficacy at 6 months.

An interesting observation was the verbalized discomfort during the initial treatments that was not expressed in subsequent sessions despite no change in the treatment parameters. While anxiety may play a role in the articulated initial discomfort, there may be other physiologic factors that contribute to this finding. Similarly, bruising after treatment was also limited to the initial sessions, even though the treatment technique, machine settings and the person performing the treatments were the same for all sessions. This finding has been consistent with subsequent non-study patients.

The most dramatic improvement occurred in the patient who had received previous liposuction. Such treatment alters the subcutaneous anatomy, circulation and lymphatic flow and produces scar tissue that compartmentalizes the irregularities. However, despite the aberrant anatomy, the localized effect of this technology was able to provide significant improvement.

Acknowledgements

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