

UniForm™ – Radiofrequency and Massage in Treatment of Cellulite

Michael Scheflan, MD, Plastic Surgeon - Atidim Medical Center, Tel Aviv, Israel

ABSTRACT

Background and Aims: Recent developments have made it possible to use radiofrequency for non-ablative aesthetic and dermatologic applications in the treatment of cellulite. The present study was designed to evaluate a novel concept in the treatment of localized cellulite using two integrated technologies - UniPolar RF (thermal) and rotational massager (mechanical) module.

Subjects and Methods: Eight patients (age 29-62; mean 41.25) with moderate degree of cellulite (mean 2.62; range[0-4]) and body mass index (BMI) between 19-30 participated in a randomized, split-design study. Treatment was done on the unilateral thigh with the contralateral thigh serving as an internal control (no treatment). Six treatments were performed at 2-week intervals with the UniForm module (Accent^{XL} system, Alma Lasers Ltd. Caesarea, Israel). Follow-up visit was done 1 month after the last treatment. Vectra 3-D photography system (Canfield, USA) was used to capture before and after photos. Clinical improvement was assessed on the basis of changes in anatomical circumferences measurements and cellulite grading scale by a physician blinded to the study.

Results: All patients but one have shown improvement in thigh circumference and in the appearance of cellulite in the treated side. No similar changes were apparent in thigh circumference or in the appearance of cellulite in the untreated/contralateral side. The global mean overall improvement of the anterior thigh was 43.52% and of the posterior thigh was 48.42%, for a mean improvement of 45.89%. The global group mean improvement was 42.5%. The mean cellulite grade improved on average 1.12 cellulite grade. No significant adverse effects were observed during and between treatments.

Conclusion: The UniForm module is an effective modality for temporary reduction in the appearance of cellulite and skin laxity.

INTRODUCTION

There are numerous therapies that have been advertised and employed to 'treat' cellulite. Current cellulite treatment modalities are designed to target the skin surface, connective tissue, adipose tissue, and/or circulation of the cellulite prone/affected areas. Treatment modalities can be divided into four main categories: attenuation of aggravating factors, physical and mechanical methods, pharmacological agents and laser. Existing non-invasive and minimally-invasive technologies for improving the appearance of skin and sub-cutaneous fat appearance, such as deep body massage, radiofrequency (RF), and light-based treatments, have gained popularity recently due to their minimal downtime, relative safety, and cosmetic benefit in temporary reduction in the appearance of cellulite. More recently, RF technology has been reconfigured for non-ablative use in the aesthetic arena. Among the earlier professional cellulite reduction treatments is deep tissue massage to break up fat deposits. Professional massage has been historically proven effective in improving circulation and stimulating the release of harmful toxins in the skin, however, this procedure is tedious, heavily dependent upon the skill of the practitioner and therefore not amendable to widespread use in medical aesthetic practices. While deep tissue massage was formerly performed by aestheticians,

massage therapists and other non-physicians, the application of regulated medical equipment to the treatment has resulted in a growing number of aesthetic physicians entering the field. Therefore, the improvement in the appearance of cellulite and the removal of unwanted body fat by using a non-invasive technique is desirable to patients and physicians.

TECHNOLOGY

The UniForm is FDA cleared for temporary reduction in the appearance of cellulite. The module is part of the Accent^{XL} system (Alma Lasers Ltd. Caesarea, Israel) and incorporates both a UniPolar* RF energy applicator for deep tissue heating and a mechanical massager applicator for manipulation of the skin and enhancement of lymphatic drainage. The UniPolar applicator provides topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as: relief of pain, relief of muscle spasms, and increase in local circulation and temporary reduction in the appearance of cellulite.

The Accent^{XL} UniForm comprises a concave metal tip for RF application and a ring of balls arrayed around the tip for rotational massage (Figure 1-A) housed in a handpiece (Figure 1-B).

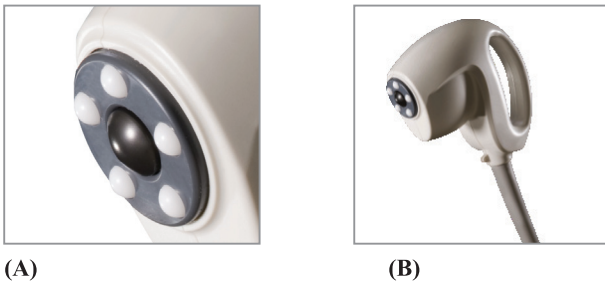


Figure 1. RF tip + Massage ring (A), UniForm handpiece (B)

The UniForm module thus incorporates two separate technologies that can be operated in two distinct modes: Mode I employs the massage alone for mechanical manipulation of the skin. The massage ring holds 5 freerolling balls and rotates at a speed of 150 turns/minute (Figure 2-A). Mode II combines the massage ring and the UniPolar RF tip for mechanical + thermal effects (Figure 2-B). The RF emissions result in a gradual increase in subcutaneous tissue temperature. In parallel, the rotational massage enhances micro-circulation and facilitates drainage of trapped intercellular fluid to the lymphatic system and breakdown of adhesions. The UniForm module is kept in constant motion across the skin during treatment.

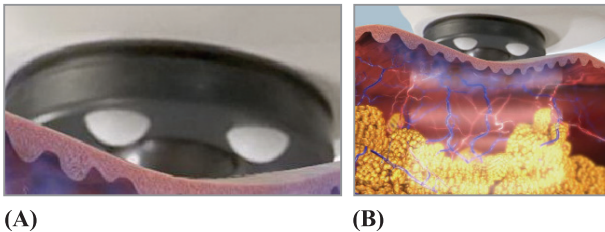


Figure 2. Mode I: Massage ring only (A), Mode II: RF tip + massage ring (B)

MATERIAL & METHODS

Eight women patients aged 29 - 62 (average 41.25 year -old) and skin phototypes II to IV. Patient average body weight and body mass index (BMI) at baseline was 65.12 kg and 23.76 kg/m², respectively.

Grade	Skin Appearance
0	Smooth, no dimpling
1	Few small, shallow, visible dimples on thighs
2	Moderate number of visible dimples (some large) on thighs
3	Numerous visible dimples (many large) on most of thigh area
4	Resembles cottage cheese

Table 1. Scale for grading cellulite in skin

Individual cellulite degree was established for each patient according to a visual grading scale (Table 1). All patients presented cellulite located in various body areas; the thigh areas were selected for treatment. Three patients exhibited grade 2 cellulite and five patients exhibited grade 3 cellulite. Four patients were treated on their left thigh and four patients were treated on the right thigh. None of the patients had undergone any previous treatments for cellulite. All the patients were informed of the purpose of the study and signed a consent form. Circumference measurements were taken before each treatment session and 4 weeks post last treatment. Circumference measurements were taken using a professional measuring tape (Gulick II, USA).

Before and after measurements were made at 5 cm below the mid thigh (lower thigh) and at 5 cm above the mid thigh (upper thigh). The same vertical distance from the floor was maintained for each before and after measurement. Cellulite appearance was estimated subjectively by before and after photography. Global improvement was assessed by a blinded physician to the treated area according to the following scale: 0%-20%; 21%-40%; 41%-60%; 61%-80%; and 81%-100%.

The Accent^{XL} system with the UniForm module was used for the treatment protocol. The treatment started with emission of RF (incorporated with the massager) for deep tissue heating. Once the skin temperature increased, the therapeutic phase was recorded till the recommended energy was invested per treatment area. Mild pressure was put on the handpiece at the time of treatment while it traced path. A total energy of 60kJ was invested at each treatment area of 15 x 30 cm (lateral, frontal, inner, posterior). The energy levels (145-178W) were adjusted depending on the subject's sensitivity, skin response and fat layer thickness. The temperature was monitored by laser thermometer and a total energy counter was displayed on the system. At least one minute was needed to reach 40°C. The treated area was monitored for redness and increase in external skin temperature. The end criterion was reaching the recommended total energy (kJ) and maintaining skin temperature of 40-43°C. During the treatment, heat sensation was felt by the patient and erythema was noticeable. Treatment session lasted approximately 30-45 min (for one thigh). No posttreatment care was needed. Patients were instructed to drink plentiful water (2 liters a day).

Results

Eight patients completed the treatment protocol. All subjects were treated for cellulite in the thigh areas. Circumference reduction was observed in all remaining patients but one patient. Similarly, improvement in the appearance of cellulite was observed in all but one patient. Treatments were well endured with minimal to no discomfort. Table 2. depicts mean group circumference reduction one month after the last treatment for upper and lower thighs, respectively.

	Before	After	Change
Upper thigh	56.4±1.1	53.8±1.9	-2.5±0.3
Lower thigh	51.6±1.6	49.8±1.8	-1.8±0.2

Table 2. Thigh circumference change one month after 6 treatments (Values are mean ± standard deviation expressed in centimeters)

Patient cellulite grades before (blue bars) and one month after (red bars) six UniForm module treatments is depicted in Figure 3. The mean cellulite grade improved on average by 1.12.

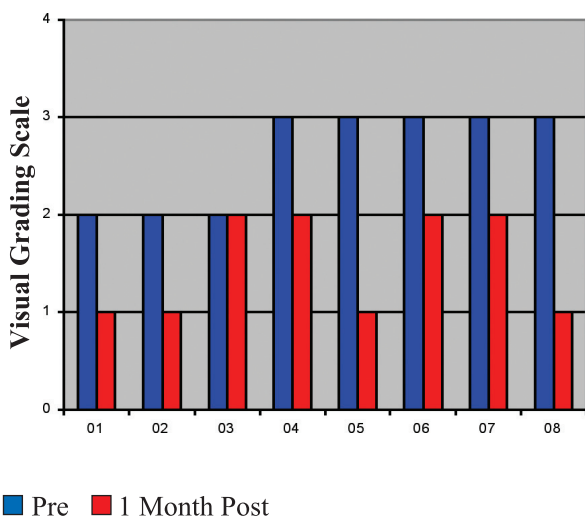


Figure 3. Cellulite visual grading scale before and one month after six UniForm treatments

The global mean overall improvement of the anterior thigh was 43.52% and of the posterior thigh was 48.42%, for a mean improvement of 45.89% (Figure 4). The global group mean improvement in the treated area was 42.5%. No significant adverse effects were observed or reported by the patients during or between treatments.

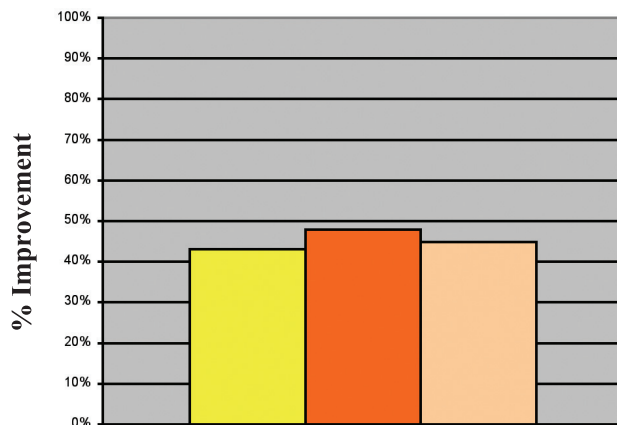


Figure 4. Improvement (%) in the anterior (yellow), posterior (orange) and overall appearance of cellulite (pink) as judged by an expert before and one month after six UniForm treatments

Discussion

This study proved that UniForm module with combined UniPolar RF and massage technology demonstrated beneficial effects on the appearance of cellulite, as well as circumference reduction of the thigh area. This is the first reported study on a UniPolar RF module that incorporates noninvasive massage therapy. The mechanism by which the UniPolar RF component improves the appearance of cellulite may be due to collagen contracture (tightening) and neocollagenesis at the subcuticular junction and possibly due to lipolysis, and to increase in the rate of fat metabolism, increase in local circulation and lymphatic drainage of adipose tissue and volumetric contraction of the connective tissue of the subcutaneous layer. Mechanical massaging enhances microcirculation and facilitates drainage of trapped intercellular fluid to the lymphatic system. The UniForm massage component may act by forming a callus of thicker, more hydrated subcutaneous tissue that has a smoother contour due to fewer local depressions. The efficacy and safety of the Accent^{XL} for the treatment of cellulite using UniPolar technology has been reported recently. In a randomized, blinded, split-design study, Aelxiades-Armenaka et al. studies 10 individuals (aged 32–57 years) with a clinically observable excess of subcutaneous fat and cellulite (minimum grade 2 out of 4) on the thighs received up to six unilateral treatments at 2-week intervals with the Accent UniPolar RF technology.

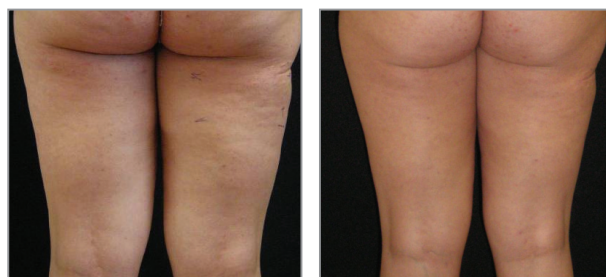
The untreated side of the thigh served as an internal control. Results were evaluated using study participant questionnaires and by two blinded evaluators using photographs and the author's cellulite grading scale at each treatment visit and at 1- month and 3-month followup visits after the final treatment. All participants responded to treatment. The blinded evaluations of

photographs using the cellulite grading scale demonstrated improvement in dimple density (11.25% mean improvement), dimple distribution (10.75% mean improvement) and dimple depth (2.5% mean improvement). The treatment was painless and side effects included minimal to moderate erythema which resolved within 1 to 3 hours. No crusting, scarring or dyspigmentation was observed. Similarly, Goldberg and colleagues showed clinical improvement in the cellulite of the upper thigh in 27 of 30 subjects treated every other week for 12 weeks with the UniPolar. Improvement persisted for 6 month in nearly all subjects. Similar to this study, results were supported by measured reductions in thigh circumferences, comparison of pre and posttreatment photographs, and histological evidence of dermal fibrosis in the upper dermis. MRI images documented the absence of disturbances in lipid metabolism. Comparison of our results with those obtained by other devices is difficult because of differences in anatomical sites treated, number of subjects, methodology of treatment, and how results were evaluated.

In summary, the combined RF and massage technology of the UniForm has been shown to be a safe and effective modality for temporary reduction in the appearance of cellulite and skin laxity.

REFERENCES

1. Alexiades-Armenakas M, Dover JS, Arndt KA. UniPolar radiofrequency treatment to improve the appearance of cellulite J Cosmet Laser Ther. 2008 Sep;10(3):148-53.
2. Goldberg David J, MD, Faxeli Amin, MD and Berlin Alexander L, MD Clinical, Laboratory and MRI analysis of Cellulite Treatment with a UniPolar Radiofrequency Device. Dermatologic Surgery 2008; 34(2):204-9.
3. Alexiades-Armenakas M. Laser and light-based treatment of cellulite. J Drugs Dermatol. 2007; 6(1):83-4.



(A)

(B)

30 year-old; cellulite grade 2; Before (a) and 1 month After (b) 6 treatments. Right-side posterior thigh treated



(A)

(B)

36 year-old; cellulite grade 3; Before (a) and 1 month After (b) 6 treatments. Left-side lateral thigh treated



(A)

(B)

41 year-old; cellulite grade 3; Before (a) and 1 month After (b) 6 treatments. Left-side thigh treated

Alma Lasers™
Wellbeing Through Technology

US Headquarters
Half Day Road
Suite 100
Buffalo Grove, IL 60089
Tel: +1-224 377-2000
Fax: +1-224 377-2050
contact@almalasers.com

International Headquarters
Halamish St.
Caesarea Industrial Park
Caesarea, 38900 Israel
Tel +972-4-627-5357
Fax +972-4-627-5368
info@almalasers.com

www.almalasers.com