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ORIGINAL CONTRIBUTION

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Clinical evaluation of simultaneously applied monopolar radiofrequency and targeted pressure energy as a new method for noninvasive treatment of cellulite in postpubertal women

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Summary

Introduction: This study investigates noninvasive cellulite treatments based on simultaneous application of monopolar radiofrequency (RF) and targeted pressure energy to evaluate efficacy and safety and to see whether simultaneous application has any benefits in noninvasive cellulite treatments.

Methods: Thirty women with cellulite (fibrous/adipose/aqueous types) received 4 gluteofemoral treatments (~24 minutes; ~1000 cm^2) using a simultaneous application of RF and targeted pressure energy. Clinical improvement was assessed using a pentile grading scale and satisfaction questionnaires. Hip/thigh circumference was measured. Ultrasonography and thermography observed changes in dermal/subcutaneous tissue composition and in gluteofemoral thermal profile. Evaluation at 3 months posttreatment was compared against the baseline.

Results: The clinical improvement averaged 2.17 $\pm$ 0.95 (54% improvement). Cellulite was reduced in 93% of cases, while 73% of patients showed good/very good/excellent improvement, with most significant improvement seen in patients with moderately severe cellulite. Hips and thigh circumference decreased on average by 2.31 cm and 2.13 cm, respectively ($P < .001$). Patient satisfaction was very high, averaging 4.47 $\pm$ 0.57 points (1-5 scale). Ultrasonography revealed smoothing and thickening (+0.28 $\pm$ 0.15 mm) of the dermis and an average reduction of 1.96 $\pm$ 1.60 mm in fat thickness ($P < .05$). Subjects with significant cellulite reduction had a more homogenous thermal profile at follow-up as a result of therapy-induced diminution of topographic skin defects. No adverse events were recorded.

Conclusion: The application is effective and safe for treating cellulite. The level of clinical improvement after 4 sessions is comparable to results reported after 6-20 sessions in studies on stand-alone RF/laser/targeted pressure energy devices. The technology is promising and deserves further attention and research.

KEYWORDS
cellulite, noninvasive, radiofrequency, targeted pressure energy

1 | INTRODUCTION

Gynoid lipodystrophy is a skin condition affecting predominantly postpubertal women (prevalence is around 85%-98%).[1-4] It causes topographic changes to the skins surface as a result of alternations in dermal and subcutaneous tissues, leading to "orange peel" like skin.[3,5,6] These gender-specific cutaneous alterations are caused by connective tissue fibrosis where the perpendicular orientation of the fibrous septa in women and its shortening allow fat cells to protrude into the dermis and cause dimpling,[1,5] which further increases with decreased skin elasticity[7] and thickness, as well as with impaired microcirculation and blood flow.[3,6]

A consecutive application of different treatment modalities is a frequent approach to improve clinical efficacy when treating cellulite noninvasively, such as the application of diathermy immediately followed by a targeted pressure energy.[8] Noninvasive radiofrequency (RF) devices are effective for induction of neocollagenesis and neoelastogenesis through heating of the dermis and subcutaneous tissue.[7,9] RF has also been reported to increase local blood flow[10] and to affect subcutaneous adipocytes, inducing their apoptosis.[11] All this leads to overall tightening and reshaping of the treated area.[12] The application of intense mechanical waves of short duration (μs) and intensities of around 10 MPA improves blood and lymphatic microcirculations,[13,14] causes neovascularization, promotes lipolysis, and increases collagen fiber density, as well as improves skin elasticity[1,12] and activates fat-splitting enzymes.[14,15] Previous literature confirms the efficacy of RF and targeted pressure energy[3,12,16] for cellulite reduction, yet the efficacy of their simultaneous application has not been described yet. This study evaluates this treatment approach and aims to investigate any incremental benefits to practitioners or to the concept of noninvasive cellulite treatments in general when the two energies are applied simultaneously.

2 | METHODS

We treated 30 women (avg. 34 years, BMI 25.9 kg/m^2) who exhibited gluteofemoral cellulite using a system which combines the emission of monopolar RF and targeted pressure energy in a single applicator (BTL UNISON, BTL Industries, Boston, MA). Subjects received 4 weekly treatments (~24 minutes each, ~1000 cm^2 on gluteofemoral region). Conductive cream was applied to the skin, and the applicator was moved across the treated region. Skin temperatures of 40-45°C were reached within 90 seconds of the treatment. The mechanical component stimulated the tissue, inducing sensations similar to an intensive massage.

Standardized photographs taken at the baseline and 3 months posttreatments were given to masked clinical specialists to grade the level of clinical improvement on a 0- to 4-point pentile arbitrary scale. Circumferential hip and thigh measurements were taken. Subjects' weight was monitored. Subjective satisfaction was assessed by a 5-point Likert scale questionnaire. Diagnostic ultrasound scans and skin surface thermal photographs were taken on five randomly selected patients as a secondary evaluation. The ultrasonography (Mindray M7 UZV 4D, 10 MHz linear transducer) of spots strongly affected by cellulite was used to examine the dermis/subcutaneous tissue composition before and 3 months after treatments. The infrared thermography was used to examine the gluteofemoral temperature profile before and 3 months after treatments. The data were statistically evaluated using a paired two-tailed Student's t test and a one-tailed Wilcoxon signed-rank test (α set at 5% for both).

3 | RESULTS

Cellulite was significantly improved with the combined RF and targeted pressure energy protocol. The clinical improvement score averaged 2.17 ± 0.95, corresponding to moderate or 54% ± 24% improvement 3 months posttreatment. In 93% (n = 28) of cases, a visible reduction in cellulite was noted, while 73% (n = 22) of patients showed "good" or above average improvement (Table 1). Most significant improvement was seen in patients with moderately severe cellulite. The density and depth of dimples were reduced significantly in patients who were graded as "excellent improvement." In the follow-up, the circumference decreased compared to the baseline on average by 2.31 cm on the hips and by 2.13 cm on each thigh ($P < .001$).

The average weight has not changed significantly (−0.43 kg). All patients had strong postprocedure erythema which resolved within 60 minutes; no adverse events were reported.

Subjective satisfaction averaged 4.47 ± 0.57 points, while 97% (n = 29) reported they were satisfied or very satisfied with treatment results. Ultrasonography revealed smoothing and thickening of the dermis (avg. +0.28 mm or 14%) and a reduced subcutaneous fat layer (avg. −1.96 mm or −9%) coupled with diminution of the fat protrusion effect. Both changes were statistically significant ($P < .05$) (Table 2). Infrared thermography showed improved thermal profile homogeneity 3 months posttreatments in 2 patients who were graded as having "very good improvement" on the clinical improvement scale. The baseline images showed more irregularities corresponding to topographic skin defects which were reduced with the improved skin texture after treatments. The remaining 3 patients did not show any significant changes (See Figures 1-3).

4 | DISCUSSION

This study shows significant improvement of cellulite after 4 simultaneous RF and targeted pressure energy treatments.

TABLE 1 Evaluation of clinical improvement

Scale	Patients (#)	Patients (%)
0%-20% (no improvement)	2	6.7
21-40% (mild improvement)	6	20.0
41%-60% (good improvement)	11	36.7
61%-80% (very good improvement)	7	23.3
81%-100% (excellent improvement)	4	13.3

TABLE 2 Circumferential measurements and ultrasonography results

Measurement	Baseline	Follow-up	Difference	*P*-value
Hip circumference (cm; n = 30)	105.3 ± 8.4	103.0 ± 8.6	−2.3 ± 1.6	<.001
Thigh circumference (cm; n = 30)	63.9 ± 6.9	61.8 ± 6.9	−2.1 ± 1.7	<.001
Thickness of dermis (mm; n = 5)	2.0 ± 0.2	2.3 ± 0.2	0.3 ± 0.1	<.05
Thickness of subcutaneous tissue (mm; n = 5)	21.5 ± 3.7	19.5 ± 4.7	−2.0 ± 1.6	<.05

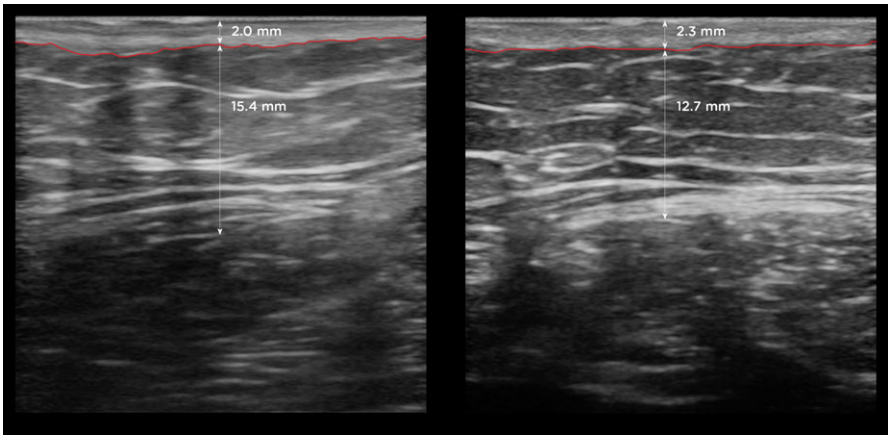

FIGURE 1 Ultrasonography showing changes in dermal and subdermal tissues before (left) and 3 months posttreatment (right)

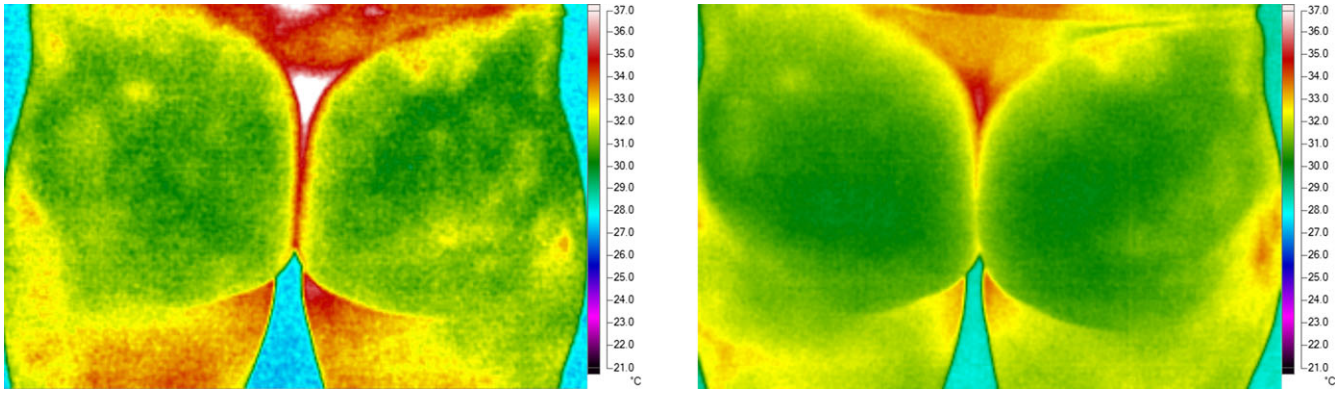

FIGURE 2 Thermography showing changes in the thermal profile before and 3 months posttreatment

FIGURE 3 Example of patient photographs before (left) and 3 months posttreatment (right). The patient was graded as having "mild improvement"

Standard deviation of observed circumferential changes can be explained by diverse anthropometric values of the subjects (BMI range 20-36 kg/m^2). Levels of subjective patient satisfaction exceeded the results from masked clinical evaluation which suggests patients could recognize changes difficult to identify by the naked eye, such as increased skin elasticity, texture, and a sense of improved blood perfusion. A reduction in the causes of cellulite was further evidenced by ultrasonography. Comparison of thermal images suggests that skin temperature profile inhomogeneity is a function of cellulite severity, but further research is necessary to validate such hypothesis.

Goldberg et al[17] and Wanitphakdeedecha et al[18] applied six RF-based treatments and showed moderate reduction in cellulite, with 10% of nonresponding and 8% of dissatisfied patients, respectively. Other studies on noninvasive RF or laser treatments included 6-20 treatment sessions (Harth et al,[19] Lach et al,[20] Mlosek[21] et al, Manuskiatti[22] et al, Wanitphakdeedecha et al[23]). Targeted pressure energy studies for cellulite reduction included 6 sessions (Knobloch

et al,[16] Christ et al[15]), 8 sessions (Schlaudraff et al[24] Steinert et al[25] Nassar et al[26]), or 12 sessions (Hexsel et al[27]). Suction-based evidence then speaks about a minimum of 15 treatments (Kutlubay et al[28] Gülec[29]). All studies report mild-to-moderate improvements.

The results presented herein show significant reduction in cellulite 3 months after 4 treatments. This suggests that the simultaneous emission of two energies effectively treats cellulite in shorter treatment times compared to stand-alone or consecutive application of RF, laser, or targeted pressure energy. We hypothesize the energies applied together may induce different (enhanced) physiological reactions in the treated tissue compared to their stand-alone application; this, however, needs to be verified by further research.

DISCLOSURES

The authors have no commercial interest in BTL and received no compensation for this study. Klaus Fritz, Carmen Salavastru, and Magdalina Gyurova have no relevant conflict to declare.

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