CIRCUMFERENTIAL REDUCTION USING THE ENDYMED PRO RADIOFREQUENCY SYSTEM - A CONTROLLED CLINICAL STUDY WITH 12 MONTH FOLLOW-UP

Summary of the Results of a Long-Term Study

JOSEFINA ROYO de la TORRE, MD; JAVIER MORENO-MORAGA, MD; ESTEFANIA MUÑOZ; PALOMA CORNEJO NAVARRO, MD Instituto Médico Laser, Madrid, Spain.

Study published in: J Clin Aesthet Dermatol. 2011;4 (1):28–35.

INTRODUCTION

An undesired increase in abdominal circumference results typically from weight changes and/or weakening of the fibrous, connective tissue in the skin. This weakening of the fibrous tissue happens as people age, following dramatic weight loss and in women post-pregnancy. Radiofrequency has been found to be useful in the safe delivery of energy to the dermis and subcutaneous tissue, independent of skin color. The non-destructive heating of the connective tissue in the dermis and around the fat lobules in the subcutaneous tissue triggers a collagen remodeling response in which ineffective collagen fibers are replaced by younger, denser and more effective collagen. These changes in the fibrous tissue lead, in turn, to circumferential reduction. In order to neutralize the effect of weight fluctuation on the circumference measurement, we weighed the patient before and after each treatment, and at follow-up visits, and compared the circumferential measurements in the treated areas to untreated control areas.

MATERIALS AND METHODS

The study population was comprised of 33 healthy patients (all women) who were interested in circumferential reduction in the abdominal area. The mean age of the patients was 44.2±13.6 years. Patients were 25 years or older and gave their informed consent to participate in the study, and agreed to undergo a complete clinical follow up.

All of the patients received six treatment sessions; the first four treatments were performed every two weeks and the last two treatments every three weeks. At all sessions the authors recorded the following data: weight, measurement of the contour of the area to be treated at a preset height measurement, and measurement of the untreated control area. The different levels at which the abdominal circumference could be measured can lead to errors in data recording. Therefore, in each case, the authors recorded the height (distance from the floor) at which the abdominal circumference and control area were first measured to ensure that they were always taken from the same point. A photograph of the area was also taken. Patients were asked to evaluate the degree of pain according to a visual analog scale. All sessions were held and data recorded in a room with a stable temperature of 24º C.

ABSTRACT

The increase in abdominal circumference results typically from weight changes and/or weakening of the fibrous, connective tissue in the skin. Thirty three female patients, mean age 44.2±13.6, who were interested in body shaping and abdominal circumference reduction, were included in the study.

Patients were treated by the novel EndyMed PRO™ radiofrequency system that emits energy at 1MHz at 1 to 65 Watts from multiple, phase controlled RF sources. The mean reduction in the contour of the treatment area after six treatment sessions was –2.9±1.6cm, which stabilized, after 12 months, at –1.9±2.0cm. There were no significant differences in the variation of the contour of the control area (–0.5±0.6cm after 6 sessions and –0.5±0.5cm at the 12-month visit) and no significant changes in weight. Reported pain was minimal (1.1 in a scale of 1-10, with 10 being the most painful).

We conclude that the system used in this study, EndyMed PRO, is safe and effective for non-invasive, pain-free and long term circumferential reduction.

Patients returned at 6, 9, and 12 months after the sessions to record weight and to measure the contour of the treated area and of the untreated control area, both at preset heights.

The radiofrequency device used was the EndyMed PRO™, a phase-controlled, multi-source radiofrequency system that emits at 1MHz at 1 to 65 Watts. The first radiofrequency systems implementing bipolar RF have demonstrated some limited benefit due to the superficial flow of energy between the bipolar electrodes. Other RF systems that utilize monopolar RF technology use a single electrode, which allows the energy to flow uncontrolled through the body. With monopolar (or unipolar) RF the energy spreads beyond the target area, and therefore the use of this type of RF technology can be associated with pain and other local and systemic safety concerns.

EndyMed's proprietary 3DEEP® radiofrequency technology overcomes the drawbacks of other radiofrequency technologies by utilizing an array of several RF sources, controlling the flow of current between the electrodes. Since adjacent electrodes possess an identical polarity, no current is created between these electrodes on the skin's surface. The multiple electrical fields that are created repel each other, driving the energy deeper into the tissue of the dermis and hypodermis, the precise target for this type of circumferential reduction aesthetic treatment.

All abdominal areas were divided into 100cm² rectangles or squares, marked on the skin with surgical pencil. The average number of squares/rectangles in each treatment area was five. The squares/rectangles were drawn with a 20-percent overlap to avoid untreated areas (cold spots) and to ensure that the whole area was heated. Sufficient sweeps were made to complete the pre-therapeutic (preheating) stage in which the surface temperature must reach 40-42°C. Once the pre-therapeutic temperature was reached, each session involved 8 x 30-second sweeps, with breaks of two seconds between each sweep.

RESULTS

The mean radiofrequency power used during the treatments was 40±7 W. The mean variation in weight during treatment was –0.7±1.7 kg after six sessions and –0.6±1.7 kg at the 12-month checkup.

The mean reduction in the contour of the treatment area after the six treatment sessions was –2.9±1.6cm, which stabilized after 12 months at –1.9±2.0cm. There were no significant differences in the variation of the contour of the control area (–0.5±0.6cm after 6 sessions and –0.5±0.5cm at the 12-month visit) (see Table 1, Figure 1).

Significantly, the mean degree of pain reported by the patients was low, at 1.1 in a scale of 1-10, with 10 being the most painful.

Study Results: Circumferential Reduction Comparison: Treated and Untreated Areas, at Various Time Points

Results	After 6 sessions	6 month follow-up	9 month follow-up	12 month follow-up
Circumference reduction - Treated area (cm)	2.9±1.6	2.6±1.2	2.3±1.6	1.9±2
Circumference reduction - Control area (cm)	0.5±0.6	0.7±0.6	0.5±0.6	0.5±0.5
Visual improvement laxity - (Clinician)	3.5±1.0	2.9±0.7	3.0±0.5	3.2±0.6
Visual improvement laxity - (External evaluator)	3.2±0.8	2.6±1.3	2.7±0.5	2.9±0.8
Final weight variation (kg)	-0.7±1.7	-0.6±2.0	-0.8±2.0	-0.6±1.7
Grade of pain (scale 0–10) (Average per session)	1.3	1.2	1	1

Table 1. *Circumferential reduction in treated vs. untreated areas (cm) after 6 treatments and at follow-up visits: 6, 9 and 12 months after the end of the treatment sessions.*

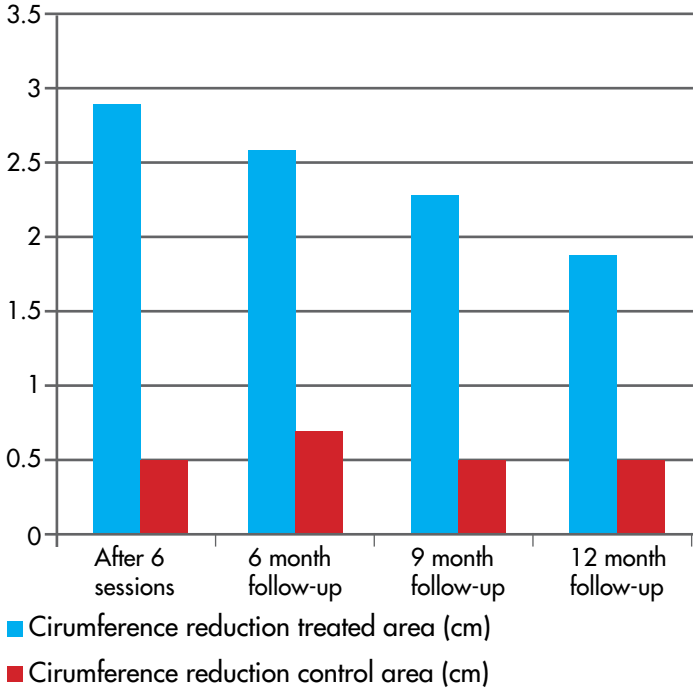

Figure 1. *Circumferential reduction in treated vs. untreated areas (cm) after 6 treatments and at follow-up visits: 6, 9 and 12 months after the end of the treatment sessions.*

Figure 2. *Before (left) and after (right) 6 treatments.*
Circumference reduction: 5.5 cm, weight change: -2.9 kg.

Figure 3. *Before (left) and after (right) 6 treatment sessions.*
Circumference reduction: 2.5 cm, weight change: -0.9 kg.

CONCLUSION

This report summarizes the effect of the EndyMed PRO™, a radiofrequency treatment system, on abdominal circumference, in a group of 33 patients. We achieved a significant circumferential reduction of 2.9 cm after the completion of 6 treatment sessions vs. a small change of 0.5 cm in the control area. This small reduction in the control area may be attributed to a minimal average weight loss of 1.3 kg. in the study group. A significant difference in circumferential reduction in the treated area vs. the controlled area was noted after 6 months (2.6 cm), after 9 months (2.3 cm) and 12 months (1.9 cm) after the completion of the treatment series proving the long term effect of the treatment.

The circumferential reduction was independent of minimal average weight fluctuation. There were no side effects to the treatment. Pain level was minimal at 1-1.3 on a scale of 0-10, with 10 being the most painful.

We conclude that the system used in this study, EndyMed PRO, is safe and effective for non-invasive, long term circumferential reduction.

REFERENCES

Ellman M, Vider I, Harth Y, Gottfried V, Shemer A.
Noninvasive therapy of wrinkles and lax skin using a novel multisource phase-controlled radiofrequency system.
J Cosmet Laser Ther. 2010;12:81–86.

Yoram Harth, MD and Daniel Lischinsky, BSc
A novel method for real-time skin impedance measurement during radiofrequency skin tightening treatments.
Journal of Cosmetic Dermatology, 2011, 10:24-29

Josefina Royo de la torre, MD; Javier Moreno-Moraga, MD; Estefania Muñoz; Paloma Cornejo Navarro, MD .
Multisource, phase-controlled radiofrequency for treatment of skin laxity: correlation between clinical and in-vivo confocal microscopy results and real-time thermal changes.
J Clin Aesthet Dermatol. 2011;4(1):28–35.

Sarwer DB, Magge L, Clark V.
Physical appearance and cosmetic medical treatments: physiological and sociocultural influences.
J Cosmet Dermatol. 2003;2:29–39.

Hexsel D, de Oliveira Dal'Forno T, Cignachi S.
Social impact of cellulite and its impact on quality of life. In: Goldman MP, Bacci PA, Leibaschoff G, Hexsel D, Angelini F, eds.. Cellulite: Pathophysiology and Treatment. New York: Taylor & Francis; 2006:1–5.

Uitto J. The role of elastin and collagen in cutaneous aging: intrinsic aging versus photoexposure.
J Drugs Dermatol.2008;7(2 Suppl):S12–S16.

Avram MM, Avram AS, James WD.
Subcutaneous fat in normal and diseased states: 1. Introduction.
J Am Acad Dermatol. 2005;53(84)9:663–670.

Querleux, Cornillon C, Joliven O, Bittoun DJ.
Skin research technology anatomy and physiology of subcutaneous adipose tissue by in-vivo magnetic resonance imaging and spectroscopy: relationships with sex and presence of cellulitis.
Skin Research & Technology. 2002:8:118–124.

Piérard GE, Nizet JL, Piérard-Franchimont C.
Cellulite from standing fat herniation to hypodermal stretch marks.
Am J Dermatopathol. 2000;22:34–37.

Arnoczky SP, Aksan A.
Thermal modification of connective tissue. Basic science considerations and clinical impressions.
J Am Acad Orthop Surg. 2000,8:305–313.

Dierickx C.
The role of deep heating for non-invasive skin rejuvenation.
Lasers Surg Med. 2006;38:799–807.

Sadick NS, MakinoY.
Selective electro-thermolysis in aesthetic medicine: a review.
Lasers Surg Med. 2004;34: 91–97.

Brigthtman L, Weiss E, Chapas AM, et al.
Improvement in arm and post-partum abdominal and flank subcutaneous fat deposits and kin laxity using a bipolar radiofrequency, infrared, vacuum and mechanical massage device.
Lasers Surg Med. 2009;40:791–798.

Nootheti PK, Magpantay A, Yosowitz G, Calderon S, Goldman M.
A single-center, randomized, comparative prospective clinical study to determine the efficacy of the Velasmooth System versus the Triactive System for the treatment of cellulite.
Lasers Surg Med. 2006;38(10):908–912.

Zelickson BD, Kist D, Bernstein E, et al.
Histological and ultrastructural evaluation of the effects of a radiofrequency-based non-ablative dermal remodeling device. A pilot study.
Arch Dermatol. 2004;140:204–209.

del Pino E, Rosado RH.
Effect of controlled volumetric tissue heating with radiofrequency on cellutis and the subcutaneous tissue of the buttocks and thighs.
J Drugs Dermatol. 2006;5(8):714–722.

Ellman M, Vider I, Harth Y, Gottfried V, Shemer A.
Noninvasive therapy of wrinkles and lax skin using a novel multi-source phase-controlled radiofrequency system.
J Cosmet Laser Ther. 2010;12:81–86.

Arnoczhy SP, Aksan A.
Thermal modification of connective tissues: basic science considerations and clinical implications.
J Am Acad Orthop Surg. 2000;8:305–313.