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# Clinical Advancements and Innovative Techniques in Non-Ablative Monopolar Radiofrequency Energy for Smoothing, Tightening and Shaping the Thighs

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## I. INTRODUCTION

The number of body shaping procedures continues to increase at exponential rates year after year. A recent report by the Medical Insight Group claims that these procedures will rise 17.6% over the next 3 years to 32.5 million procedures by 2010.

Various invasive treatment options are available in the market today such as liposuction, mesotherapies and surgery. These procedures vary significantly in cost, invasiveness, recovery time, complication risks and treatment results. Many individuals refrain from undergoing these procedures and want less invasive treatment options.

Recently, a new non-invasive procedure for body shaping was introduced using a deep contouring treatment tip from Thermage. This novel, single treatment procedure incorporates technology designed to provide greater volumetric heating which causes deeper skin tightening in mildly overweight patients without surgery or injections and little to no downtime. This technology is based on monopolar capacitive radiofrequency energy (RF). It has been demonstrated that by delivering RF energy to heat the dermis and subcutaneous tissue, an immediate contraction of existing collagen fibrils is caused followed by secondary collagen synthesis and remodeling<sup>1</sup>. According to the manufacturer, the deep treatment tip has a 1/e depth<sup>2</sup> of approximately 4.3mm which is 79% deeper than its medium depth treatment tip and this enables more focused therapeutic energy to be delivered deeper into the subcutaneous tissue than other non-ablative therapies. Heating depth may vary from patient to patient due to skin thickness and impedance. In addition it has been observed that heat remains in the tissue minutes longer which may contribute to an even greater degree of collagen contraction.

This study describes the effects of monopolar capacitive RF treatment on the posterior and anterior regions of the thigh and is based on the manufacturer's recommended procedure guidelines, using the 3.0cm<sup>2</sup> DC (deep contouring) treatment tip.

## II. METHODS AND MATERIALS

### A. Patient Selection

Between October 6, 2006 and February 16, 2007, 10 patients between the ages of 35 and 59 were selected to undergo treatment with the deep treatment tip. Patients had an average BMI of 24.9 and weight of 150 lbs. Mass and laxity in the anterior and posterior thigh region was treated. The patients who were selected were also candidates for liposuction, and wanted improvement in skin laxity, cellulite and circumference reduction. Exclusion criteria for this study included: patients

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<sup>1</sup> (Zelickson, B. D., D. Kist, et al) *Arch Dermatol* 140(2): 204-9; February 2004

<sup>2</sup> The depth at which the electric field drops to 1/e (37%) of the surface field strength in a homogeneous medium

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with a body mass index greater than 27 and patients who were considered obese, had excessive skin laxity, a pacemaker or implantable defibrillator.

### **B. Patient Preparation**

Circumferential measurements around the thighs were taken. Vectors were defined and drawn on treatment areas; vector lines were determined by reviewing areas that showed signs of laxity. Circles were also drawn to identify problem areas where the patient desired smoothing of unwanted bulges or cellulite. A 3.0cm<sup>2</sup> skin marking grid paper was then applied to the treatment area with alcohol.

### **C. Treatment Protocol**

For each patient the starting setting was determined based upon their personal impedance levels and heat sensation feedback. On average, patients were treated with 900-1600 pulses of RF energy to a clinical endpoint, to ensure positive outcomes. Treatment levels ranged from 393.0 to 397.0 with the mean treatment level of 395.0. Each patient was instructed to provide heat sensation feedback in order for the treatment level to remain effective and comfortable.

The RF energy was delivered using a multiple staggered pass technique (circle then square on the treatment grid, providing a 50% overlap on each pulse). Multiple passes were used to tighten and contour the entire gridded area as well as vectors and problem areas. On average, 3-4 passes were applied over the gridded area and 4-6 passes were applied to vectors and problem areas until a visible and/or palpable clinical endpoint was achieved. Pulses were delivered distal to proximal and medial to lateral. In order to ensure full tip-to-skin contact, the treatment tip was kept perpendicular to the skin and generous amounts of coupling fluid were applied throughout the procedure. The tissue was warm to the touch but not hot before re-treating the same area again. Upon completion of the treatment each patient was given a compression garment to wear for 24 hours.

### **D. Post Treatment Follow Up**

Provided patients returned for scheduled appointments, most were seen for evaluation sessions at 3-4 month and 6 month intervals. Measurements were taken by using a standard tape measure. Patients were measured from the groin to 6 inches down the leg, both inner and outer thighs, then circumferentially. This technique was used to identify the mid-section of the upper thigh area where treatment was given in each of the patients. Post procedure and follow-ups included "after" photos following the same guidelines as the "before" photos to measure aesthetic improvements. Calculated circumference reduction from baseline was reviewed at each post treatment session. In addition, weight was taken at each session in order to monitor any fluctuations. Observed changes were thoroughly analyzed and recorded.

## **III. RESULTS**

The results of this study revealed subtle to moderate volume reduction that appeared immediately in many patients and continued to improve for up to 6 months. Many variables that contributed to the results included degree of skin laxity and solar damage, the individual's wound-healing response as well as differences in skin thickness and underlying tissue.

Overall, most patients received the benefit of increased collagen density, circumferential reduction and younger looking skin in the posterior and anterior thigh regions.

**Table 1. Summary Statistics of Average Circumferential Reduction Over Time (n=10)**

Immediate Post Tx	Three-Four Months Post Tx	Six Months Post Tx
0.0-3.0 centimeters	0.5-4.0 centimeters	1.5-4.0 centimeters

**Table 2. Individual Patient Circumferential Reduction Over Time**

Patient	Immediate Post Tx	Three-Four Months Post Tx	Six Months Post Tx
KW-2	Rt. Thigh = 0.0 cm Lt. Thigh = + 1.0 cm	Rt. Thigh = - 2.5 cm Lt. Thigh = - 1.0 cm	Rt. Thigh = - 3.5 cm Lt. Thigh = - 3.0 cm
JR-1	Rt. Thigh = - 1.0 cm Lt. Thigh = - 1.0 cm	Rt. Thigh = - 4.0 cm Lt. Thigh = - 1.0 cm	N/S
TSM-2	Rt. Thigh = - 1.0 cm Lt. Thigh = 0.0 cm	Rt. Thigh = - 2.0 cm Lt. Thigh = - 3.0 cm	N/S
SAS-006**	Rt. Thigh = - 2.0 cm Lt. Thigh = - 2.0 cm	Rt. Thigh = - 4.0 cm Lt. Thigh = - 2.0 cm	Rt. Thigh = - 8.0 cm Lt. Thigh = - 5.0 cm
MLN-004	Rt. Thigh = - 1.0 cm Lt. Thigh = 0.0 cm	Rt. Thigh = - 2.0 cm Lt. Thigh = - 1.0 cm	N/S
EAR-003	Rt. Thigh = - 2.0 cm Lt. Thigh = - 2.0 cm	Rt. Thigh = - 2.0 cm Lt. Thigh = - 2.0 cm	Rt. Thigh = - 4.0 cm Lt. Thigh = - 3.0 cm
KAW-001	Rt. Thigh = - 0.5 cm Lt. Thigh = - 0.5 cm	Rt. Thigh = - 0.5 cm Lt. Thigh = - 1.0 cm	Rt. Thigh = - 1.5 cm Lt. Thigh = - 2.0 cm
JMS-005	Rt. Thigh = + 0.5 cm Lt. Thigh = 0.0 cm	Rt. Thigh = - 0.5 cm Lt. Thigh = - 0.5 cm	Rt. Thigh = - 2.5 cm Lt. Thigh = - 3.5 cm
TMS-002	Rt. Thigh = 0.0 cm Lt. Thigh = - 3.0 cm	Rt. Thigh = - 1.0 cm Lt. Thigh = - 3.0 cm	N/S
SS-2***	Rt. Thigh = 0.0 cm Lt. Thigh = 0.0 cm	Rt. Thigh = - 8.0 cm Lt. Thigh = - 9.0 cm	Rt. Thigh = - 12.0 cm Lt. Thigh = - 11.0 cm

\*\*Eliminated from 6 month evaluation due to large weight loss between 3<sup>rd</sup> and 6<sup>th</sup> month of evaluation.

\*\*\* Eliminated from 3 & 6 month evaluation due to large weight loss at 3<sup>rd</sup> and 6<sup>th</sup> month of evaluation.

N/S = No show for 6 month follow-up

All patients experienced circumferential reduction with the mean amount measuring 2.0 cm. Immediately post treatment, the average reduction in volume was 0.5 cm – 3.0 cm, at 3 months the average reduction was 0.5 cm-4.0 cm and at 6 months volume reduction averaged 1.5 cm-4.0 cm. Results appeared immediately in many patients and continued to improve for up to 6 months. All patients with the exception of two maintained a constant weight plus or minus 5 pounds. One patient lost 20 pounds during the 3<sup>rd</sup> and 6<sup>th</sup> month evaluation period, another lost 18 pounds at the 6<sup>th</sup> month evaluation period. Therefore these measurements were not included in the final evaluation results. Patients experienced little to no downtime and did not exhibit any serious adverse effects. On rare occasions, some patients experienced temporary redness which disappeared within a few minutes.

**A. Patient Photos**



**Figure 1: Patient before (left) and 3 months post treatment**

	Baseline	3 months
Right Thigh Circumference	51.0 cm	50.0 cm
Left Thigh Circumference	53.0 cm	50.0 cm
Weight	136 lb	140 lb

**B. Patient Photos**



**Figure 1: Patient before (left) and 6 months post treatment**

	Baseline	6 months
Right Thigh Circumference	56.5 cm	54.0 cm
Left Thigh Circumference	56.5 cm	53.0 cm
Weight	135 lb	130 lb

#### **IV. DISCUSSION**

The mechanism of action of RF treatment is hypothesized to be that of immediate collagen contraction, followed by secondary collagen synthesis and remodeling. Considering this, our group fostered an interest in the possible favorable effects using the deep treatment tip in the anterior and posterior thigh areas. Our patients frequently complain that the thigh areas are ones that most dissatisfies them. We conducted a clinical investigation in our own patient population for the purpose of evaluating the possible effect. Our evaluation is based on the differences in circumferential reduction and appearance of skin texture for each of the subjects treated using the treatment tip.

The data reported here supports the hypothesis that using the deep treatment tip reduces volume, improves skin texture and appearance and reduces sagging of skin in the thigh area of patients that are mildly overweight.

#### **V. CONCLUSION**

Monopolar RF energy applied to the anterior and posterior thigh to achieve tightening, contouring and reduce the appearance of cellulite has proven to be an effective and safe non-invasive treatment among patients. The procedure is well-tolerated and produces cosmetic results that are satisfying to both patients and clinicians.

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