

**Objective:** The objective of this study was to examine the efficacy and safety of the latest multisource radiofrequency handpiece, specially designed for body area skin treatments. The new handpiece features six concentric electrodes, each connected to an independently controlled radiofrequency generator. **Design and**

**settings:** This was an international multicenter study across two sites. Twenty-five patients were enrolled into the study. Patients underwent at least five sessions of body skin tightening and circumference reduction. The first four sessions were held at one-week intervals and the other 1 to 4 remaining sessions, at two-week intervals.

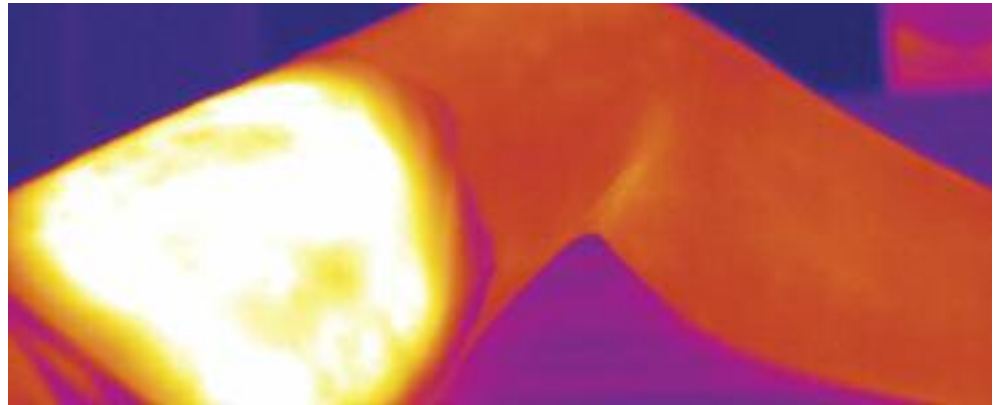
**Participants:** Twenty-five patients (23 women and 2 men). **Measurements:** Overall change was graded by the physicians using the global aesthetic improvement scale. Patients were asked to complete satisfaction questionnaires at the end of the treatment sessions. Images were taken prior to the treatments, before every treatment session, and at the follow-up visit. **Results:** No adverse events were reported as a result of the treatment. Measured body weight of the patients, as monitored during the study period, was stable ( $\pm 2$ kg). Ninety-two percent of the patients were pleased with

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# Body Contouring and Skin Tightening Using a Unique Novel Multisource Radiofrequency Energy Delivery Method

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Body skin laxity and an increase of abdominal and thigh circumference with age are a growing cosmetic concern. Skin laxity occurs at the age of 35 to 40, mostly on the inner arms and legs and in the abdominal area. The impact of these problems on patient's self-esteem may affect quality of life both psychologically and socially.<sup>1-3</sup>

Basic science shows that body skin laxity is related to loss in quantity and function of dermal collagen fibers. Histological studies of lax skin show

dermal atrophy, primarily due to loss of collagen, degradation of elastic fibers, and loss of hydration.<sup>4-6</sup>

Multiple studies have shown that raising dermal temperature to  $>46^{\circ}\text{C}$  and maintaining this temperature for at least three minutes triggers the release of heat-shock proteins (HSPs). This increase will start a healing cascade and subsequently production of new collagen and elastic fibers.<sup>7-10</sup>

Radiofrequency (RF) energy uses the tissue's resistance within the various skin layers to produce heat. In

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[Abstract continued]

the results and finished all the treatment sessions. Twenty-four patients (96%) saw an improvement in body shape. Ninety-two percent of the patients would recommend the treatment to others. Overall change graded by the physician by the global aesthetic improvement scale provided the following results: 44 percent of the patients had more than 75-percent improvement, 32 percent of the patients between 50- to 75-percent improvement, 20 percent of the patients had between 25- to 50-percent improvement and only four percent had less than 25-percent improvement.

**Conclusion:** The authors' data show that the handpiece examined provides high efficacy in skin tightening and body contouring after 5 to 8 painless treatments. Patient subjective questionnaires show very high satisfaction rates.

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**Figure 1A.** Multisource RF large handpiece with six linearly arranged electrodes

order to transfer successfully the RF energy into thermal energy, one should consider the size and depth of the tissue being treated and the impedance of the skin.

In contrast to laser and intense pulsed light systems that are limited in use in patients with dark skin, RF energies are “color blind” and can be used for patients of all skin types.<sup>12</sup> The latest generation of RF is the United States Food and Drug Administration (FDA)-cleared multisource phase-controlled 3DEEP™ technology, which uses six independent phase-controlled RF generators. The multiple electrical fields created repel each other and force the energy to flow to a deeper layer of the skin. This innovative technology reduces the amount of energy flow through the skin surface allowing highly effective, painless heating of the dermis and subcutaneous tissue, eliminating the need of active epidermal cooling.<sup>15,16</sup>

To prevent overheating, the energy is emitted only if the electrodes are in full contact with the skin and the handpiece is in motion. Real-time

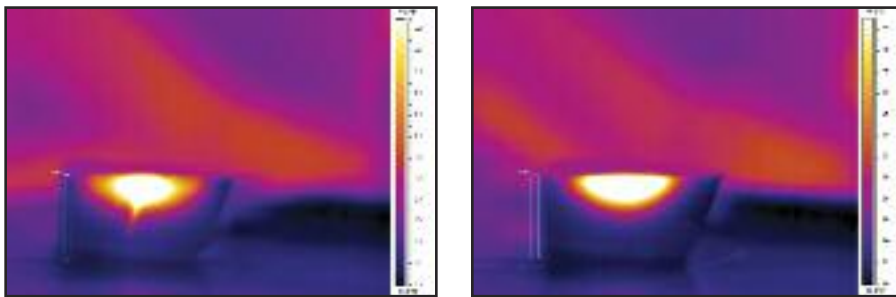
measurement of skin impedance assures the delivery of constant energy to the patient skin independent of their skin impedance.<sup>17–19</sup>

de la Torre et al<sup>20</sup> studied the use of multisource phase-controlled RF for the treatment of abdominal area lax skin. For the study, the authors used the EndyMed Pro systems with the large, linearly arranged 6 electrodes handpiece (Figure 1A). Patients were treated six times and re-examined at 6, 9, and 12 months after the end of the treatment sessions. Confocal microscopy images showed increase in epidermal thickness, changes in dermal papillae, and dermal collagen matching younger rejuvenated skin. Abdominal circumference measurements have shown an average reduction of 2.9cm after six treatments and 1.9cm 12 months after the end of the sessions.<sup>17</sup>

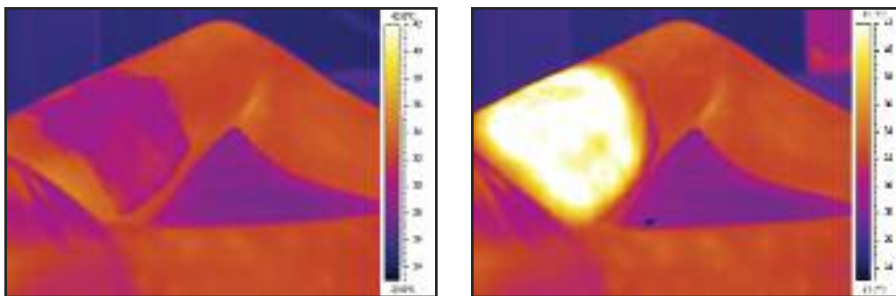
In the present clinical study, the authors used EndyMed's latest multisource RF handpiece, the Shaper, which is specially designed for body skin treatments (Figure 1B),



**Figure 1B.** In this handpiece, six concentric electrodes are controlled simultaneously by six RF sources, thus creating multiple electrical fields of energy inside the tissue.



**Figures 2A and 2B.** Thermal images (using FLIR SC 640) on agar compound simulating skin tissue resistance. (A) Large handpiece; (B) Shaper handpiece



**Figures 3A and 3B.** Thermal images (using FLIR SC640) of a treatment area on inner thighs. (A) Baseline, average temperature of 30°C, with ultrasonic gel; (B) After six passes of 30 seconds each, the average temperature is 42°C

and the EndyMed Pro system.

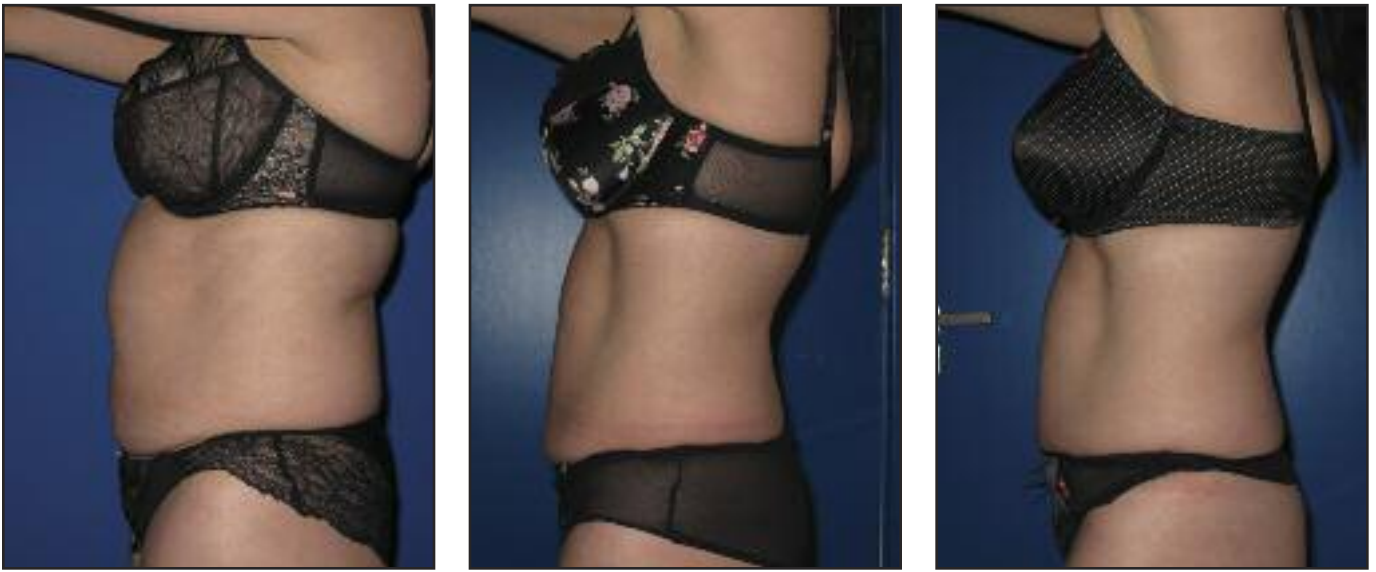
The new Shaper handpiece features six concentric electrodes, each connected to an independently controlled RF generator. The surface area of the

electrodes is 40.7cm<sup>2</sup>, allowing focused RF energy and treatments of bigger areas than the previous handpiece in which the electrodes were arranged in a linear fashion (Figures 2A and 2B).

## MATERIALS AND METHODS

The study included 25 healthy subjects (23 women and 2 men) ages 29 to 69 years (average, 51.28±10.02) who underwent body skin tightening and circumference reduction across two international sites. All subjects were treated with the Shaper handpiece (EndyMed Pro, EndyMed Medical, Caesarea, Israel). Subjects were recruited after they fulfilled all inclusion criteria, provided informed consent and committed to attend all treatments and follow-up visits. Treatment areas included abdomen (21), thighs (7), flanks (10), and arms (4). Some subjects were treated for more than one area. Degree of clinical improvement was assessed by the Global Aesthetic Improvement Scale (GAIS) and subjects' satisfaction by post-treatment questionnaires.

Each subject underwent a series of visits including a screening visit, treatment visits, and a follow-up visit. Treatment protocol included 5 to 8 sessions. All patients were photographed prior to the treatments, before every treatment session, and at the follow-up visit. The photographs were taken using standard distance and lightening. Ultrasound gel was applied to the treatment area and followed by pre-heating of two passes (1 pass=30 sec). Surface temperature was measured by infrared thermometer and when the optimal temperature of 40 to 42°C was reached, an additional 10 therapeutic passes were performed (Figure 3). Maintaining surface temperature of 40 to 42°C during all sessions was



**Figures 4A–4C.** Shaper treatment on the abdomen of a 44-year old woman. (A) Baseline; (B) After eight treatment sessions; (C) After three months follow-up. Photos courtesy of Dr. Sam Robson, Aberdeen, UK.

the indication for effective treatment. Immediately after the treatment, the treated area was visually assessed for skin response such as erythema and edema.

Patients were asked to complete satisfaction questionnaires at the end of the treatment sessions. Overall change was graded on a scale of 0 to 4, where 0=no improvement, 1=mild (less than 25%) change, 2=moderate (between 25 and 50%) change, 3=significant (between 50 and 75%) change, and 4=extensive (more than 75%) change. Safety of the treatment was monitored by patient subjective grading of pain during every treatment.

## RESULTS

Ninety-two percent of the patients were pleased with the results after completing all of the treatment sessions, and 92 percent of the patients would recommend the treatment to others.

Twenty-two patients saw significant improvement in body shape, two saw only mild improvement, and only one patient did not see any change (Figures 4–7).

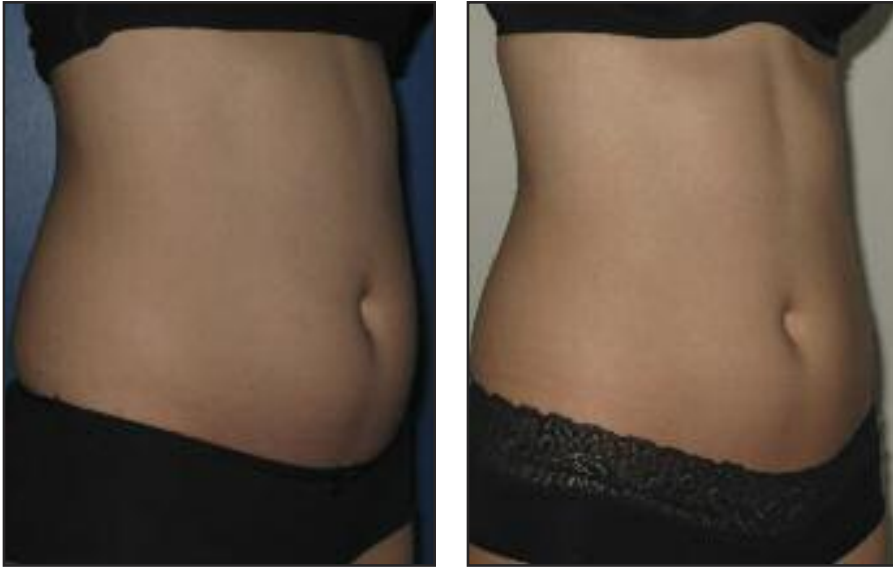
To measure objective improvement, the authors used the five-grade GAIS, where 0=no improvement, 1=improvement of <25 percent, 2=improvement of 26 to 50 percent, 3=improvement of 51 to 75 percent, and 4=improvement of >75 percent. The mean GAIS improvement was found to be  $2.36 \pm 0.84$  (*t*-test, statistically significant  $p < 0.001$ ). Overall change graded by the physicians according to the GAIS provided the following results: 44 percent of the patients had more than 75-percent improvement, 32 percent of the patients between 51- to 75-percent improvement, 20 percent of the patients had between 26- to 50-percent

improvement, and only four percent had less than 25-percent improvement (Figure 8).

None of the patients experienced discomfort during the treatment, and no adverse events occurred during the treatments.

## DISCUSSION AND CONCLUSION

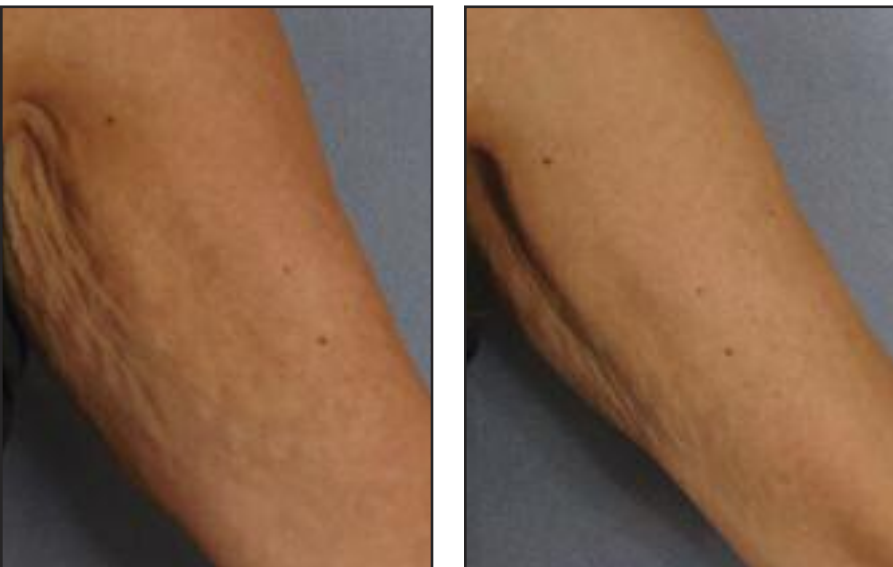
The demand for nonablative skin tightening for body contouring and skin tightening is increasing. First-generation technologies were frequently associated with pain (monopolar) or low efficacy (bipolar/multipolar). In this study, the authors use a new generation of RF—multisource RF technology—in a new configuration utilizing six circular electrodes, each connected to an independent RF generator. The unique ability of this technology to independently control the polarity of each electrode allows focused deep heat with decreased epidermal heating.



**Figures 5A and 5B.** Shaper treatment on the abdomen of a 29-year-old woman. (A) Baseline; (B) After eight treatment sessions. Courtesy of Dr. Sam Robson, Aberdeen, UK.



**Figures 6A and 6B.** Shaper on the abdomen of a 50-year-old woman. (A) Baseline; (B) After eight treatment sessions. Courtesy of Dr. Isabelle Rousseaux, France.



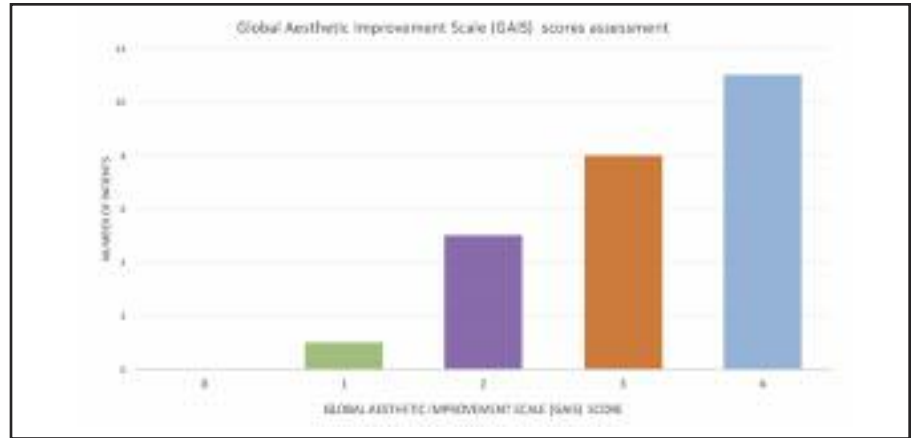
**Figures 7A and 7B.** Shaper on the arms of a 53-year-old woman. (A) Baseline; (B) After eight treatment sessions. Courtesy of Dr. Isabelle Rousseaux, France.

The authors' data show that the Shaper Handpiece achieves very high efficacy in body contouring and skin tightening in 5 to 8 painless treatments. Subjective questionnaire shows very high patient satisfaction with the treatments.

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**Figure 8.** Physician assessment—degree of improvement

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