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Contactless Abdominal Fat Reduction With Selective RF™ Evaluated by Magnetic Resonance Imaging (MRI): Case Study

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Abstract

Background: Noninvasive body shaping methods seem to be an ascending part of the aesthetics market. As a result, the pressure to develop reliable methods for the collection and presentation of their results has also increased. The most used techniques currently include ultrasound measurements of fat thickness in the treated area, caliper measurements, bioimpedance-based scale measurements or circumferential tape measurements. Although these are the most used techniques, almost all of them have some limitations in reproducibility and/or accuracy. This study shows Magnetic Resonance Imaging (MRI) as the new method for the presentation of results in the body shaping industry.

Materials and Methods: Six subjects were treated by a contactless selective radiofrequency device (BTL Vanquish ME, BTL Industries Inc., Boston, MA). The MRI fat thickness was measured at the baseline and at 4-weeks following the treatment. In addition to MRI images and measurements, digital photographs and anthropometric evaluations such as weight, abdominal circumference, and caliper fat thickness measurements were recorded. Abdominal fat thickness measurements from the MRI were performed from the same slices determined by the same tissue artefacts.

Results: The MRI fat thickness difference between the baseline measurement and follow up visit showed an average reduction of 5.36 mm as calculated from the data of 5 subjects. One subject dropped out of study due to non-study related issues. The results were statistically significant based on the Student's T-test evaluation.

Conclusions: Magnetic resonance imaging abdominal fat thickness measurements seems to be the best method for the evaluation of fat thickness reduction after non-invasive body shaping treatments. In this study, this method shows average fat thickness reduction of 5.36 mm while the weight of the subjects didn't change significantly. A large spot size measuring 1317cm^2 (204 square inches) covers the abdomen flank to flank. The average thickness of 5.36 mm of the fat layer reduced under the applicator translates into significant cumulative circumferential reduction. The reduction was not related with dieting.

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Introduction

Body contouring is the targeted removal of a limited amount of adipose tissue to achieve a more aesthetic body shape. There is no shortage of invasive and noninvasive body contouring procedures available for individuals looking to improve their physical appearance for aesthetic or medical reasons.

Invasive surgical procedures for fat reduction are associated with risks of side effects, great discomfort, lengthy downtime and substantial financial costs. The search for safer alternatives and advancement in technology expedited the development of less-invasive and noninvasive body contouring techniques and procedures. Numerous noninvasive transcutaneous fat reduction technologies are available in the aesthetic field which include mechanical massagers, lasers, high intensity focused ultrasounds, cryolipolysis, radiofrequency (RF) or their combinations.[1-3]

Selective radiofrequency is new to cosmetic dermatology and other noninvasive aesthetic treatments such as skin tightening and fat reduction.[2]

The medical use of RF is based on an oscillating electrical current that forces collisions between charged molecules and ions, which are then transformed into heat. RF-generated tissue heating has different biological and clinical effects depending on the depth of tissue targeted and frequency used. Selective RF technology also has the ability to noninvasively and preferentially heat large volumes of subcutaneous adipose tissue. By selecting the appropriate electric field, it is possible to selectively obtain greater heating of fat. Adipose tissue contains electrical dipoles. The direction of dipoles is chaotic and polarization arranges dipoles in one direction. Dielectric polarization requires that every electrical dipole is rotated against the polarization of the electrical field. With a rapidly alternating electromagnetic field, all electrical dipoles oscillate. This oscillating movement causes the dipoles of fatty tissue to heat up, a principle mechanism of action of RF on fat.

The contactless selective radiofrequency device is designed to deliver noncontact transcutaneous selective RF and to generate heat specifically in subcutaneous adipose tissue to induce adipocyte apoptosis with only minimal effect on skin and muscle.[4] Adipose tissue and skin have different structures and different impedances: water in skin has low impedance but subcutaneous adipose tissue has high impedance and the applicator–generator circuitry is engineered to selectively deliver the energy to the adipose tissue layer. The contactless selective radiofrequency system focuses energy specifically into the adipose tissue layer, while limiting the delivery to the dermis, epidermis and muscles. A multipolar broad field applicator shapes the electro-magnetic field to optimize the penetration and maximize the treatment area. In addition, the applicator is equipped with a system that automatically tunes the tissue–applicator–generator circuitry to selectively deliver the energy to the adipose tissue layer while minimizing the risk of overheating in the skin, muscles, or internal organs.

This effect was demonstrated and substantiated by pathologic and histologic findings in the in vivo porcine model.[5] The pathological examination clearly demonstrated the fat layer reduction in the treated area and microscopic photographs of histology and TUNEL staining for apoptosis showed that the reduction was caused by the apoptotic phenomenon. Histologic evaluation revealed that the epidermis, dermis, and hair follicles were unaffected by the treatment, while adipocytes were significantly affected. Thermocouples used to monitor irradiated tissue temperature during the procedure showed that the adipose tissue was gradually heated up to the temperature of ~45–46° C, while the skin temperature reached only 42° C. These findings confirmed that non-contact selective RF was safe and effective for subcutaneous fat reduction in this porcine animal model. Laboratory, histological, or gross pathological analyses did not indicate any safety risks or side effects. It opened a way to contact-free selective RF use for the reduction of human adipose tissue in clinical practices. A human study has also confirmed the results of the animal study in terms of temperature elevation in the irradiated adipose tissue, and TUNEL staining for increase in apoptotic index in adipocytes 1 hour after a 45-min, non-contact selective RF treatment.[6] There are other reports and studies that further demonstrate the safety and effectiveness of contactless selective RF treatment for abdominal fat reduction.[7-8]

Noninvasive body shaping methods may face several issues associated with the accuracy and repeatability of the measured results. Currently employed measurement methods involve caliper, ultrasound and circumferential measurements. They are low cost, fast and easy to use, however the precision of measurement is limited. There are more accurate and reproducible measurement techniques such as magnetic resonance imaging and CT scans, but these methods involve visits to a specialized facility, incurring additional costs, and in the case of CT, exposes subjects to radiation.

FIGURE 1. Sample of digital photographs for subject 1. (A) Subject 1, baseline image. (B) Subject 1, follow-up image.

(A)

(B)

It has been demonstrated that MRI is a safe and accurate method to evaluate volumetric changes in fat reduction. One transverse slice at the level between L2-L3 gives a high and consistent predictive value for abdominal fat.[9-11] For abdominal scanning with focus on subcutaneous fat tissue, a dual-echo MRI technique is most suitable. Its main advantages are fast acquisition with minimal signal reduction, the ability to examine the entire abdomen in a single breath-hold and a complete elimination of patient respiratory motion or slice misregistration artefacts.[12]

In the present noninvasive body shaping study, the MRI-based assessment of subcutaneous fat reduction is employed and it

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compared with traditional techniques of caliper and circumference measurements.

METHODS AND MEASUREMENTS

The study enrolled six participants (2 females and 4 males) who met the following inclusion criteria: age (22-60 years), BMI (25-30 kg/m^2) and caliper fat thickness (~40 mm). All subjects provided informed written consent prior to participation in any study-related activities. They underwent the standard therapy protocol of four 45 min, once-a-week treatment sessions by a contactless radiofrequency device (BTL Vanquish ME, BTL Industries Inc., Boston, MA) cleared for abdominal circumferential reduction. The following anthropometric measurements were performed and recorded prior to each treatment session as part of the patient record card: weight, caliper and circumference measurements. Digital photographs were taken at the baseline, after the 4th treatment session, and at the follow-up visit. See Figure 1.

There were 2 MRI sessions, the first MRI scanning was done before the start of the treatment cycle and the second at the 4-weeks post-treatment follow-up visit. The abdominal area was scanned in several equidistant slices. The MRI scans were mostly obtained in dual-echo regime and exported in DICOM format for further analyses.

Slices taken at before and at the 4-week post-treatment were compared based on the homologous position of the umbilicus and anatomical artefacts such as blood vessels or random structures in the subcutaneous fat. Thickness of the subcutaneous fat tissue was measured in the area around the umbilicus and related to the visible artefacts in the fat tissue. Two measurements of the fat tissue layer were taken from each patient.

RESULTS

Five out of six subjects completed the study as defined by the protocol. One subject dropped out of the study due to non-study related issues. The average age of the subjects was 35.8 years.

According to follow-up data available all subjects significantly reduced their subcutaneous fat thickness in the abdominal area as measured from the MRI scan. Average reduction was 5.36 mm (SD ± 1.49). See Figure 2. The Student's T-test has found statistically significant with $p = 1.94 \cdot 10^{-6}$ as summarized in Table 1.

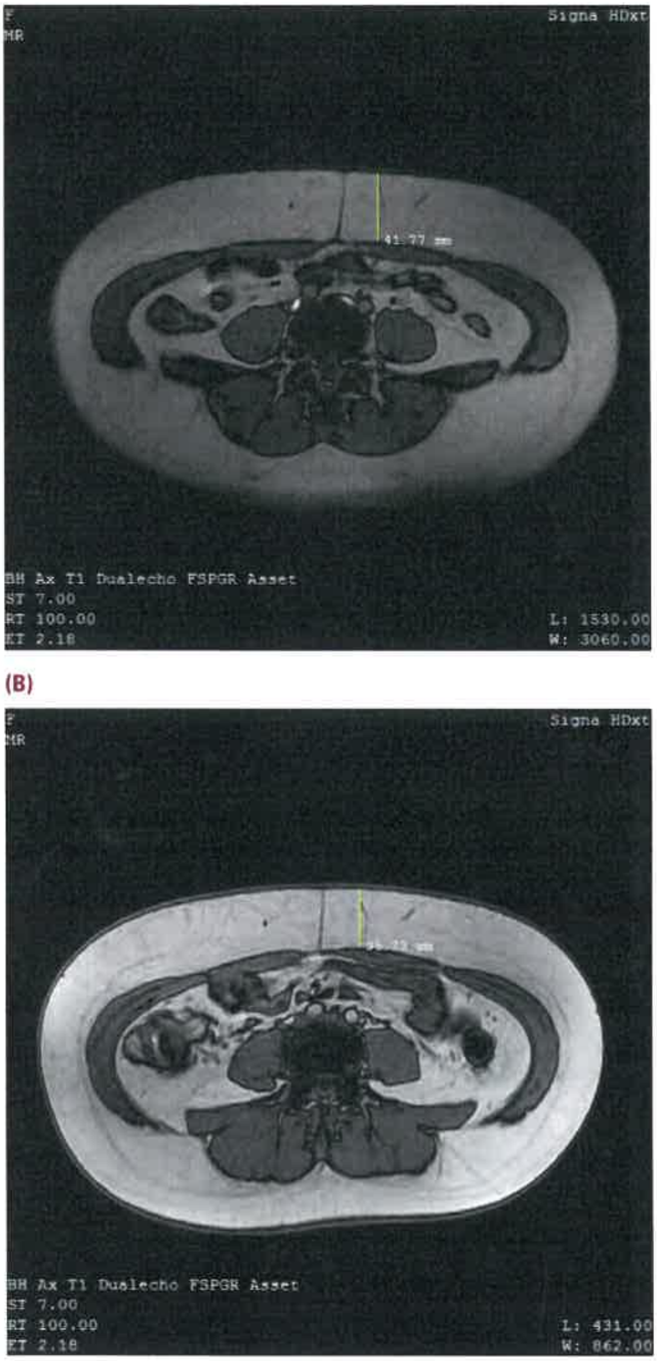
DISCUSSION

MRI imaging is widely used to assess, evaluate and quantify intraabdominal and subcutaneous fat deposits in obesity and diabetes.[13-15] Its use in cosmetic dermatology and aesthetic body contouring is much less frequent.[16]

FIGURE 2. Baseline and follow-up visit MRI images for subject 1. (A) Subject 1, baseline image. (B) Subject 1, follow-up image.

(A)

(B)



Success of various noninvasive technologies for body sculpting and subcutaneous fat reduction is marred by lack of standard, reliable, reproducible evaluation methods. Most frequently employed anthropometric measurements by themselves are prone

TABLE 1.

MRI Fat Thickness Measurements (mm)	
Subject	Difference (Baseline vs 4-wk F/U)
1	-6.04
	-7.04
2	-3.71
	-3.33
3	-4.93
	-5.40
4	-5.16
	-4.20
5	-8.61
	-5.14
Average Change	-5.36
SD	±1.49
P(<=t) two-tail	1.94·10-6

Anthropometric secondary measurements (weight, caliper, and circumferential measurements) were recorded at all sessions and the average values are summarized in Tables 2-4.

TABLE 2.

Weight Measurement (kg)	
	(Mean ± SD)
Baseline	87.94±27.45
4-wk F/U	87.7±27.35
Difference	0.24±0.66

TABLE 3.

Circumference Measurement (cm)			
	Abdomen (Mean ± SD)		
	Upper	Middle	Lower
Baseline	101.6±14.28	106.0±14.7	105.5±13.44
4-wk F/U	96.6±14.00	100.3±14.55	100.6±13.08
Difference	-5.0±2.45	-5.7±3.46	-4.9±2.58

TABLE 4.

Caliper Measurement 9 (mm)		
	Abdomen (Mean ± SD)	
	LEFT	RIGHT
Baseline	36.92±7.98	37.48±8.47
4-wk F/U	33.16±8.96	32.64±9.48
Difference	-3.76±2.42	-4.84±2.25

to influence by the subject, operator, device and technique employed. CT and MRI techniques seem to be the least influenced by these factors but remain costly and time consuming.

To the best of our knowledge, this is the first study of a non-invasive, noncontact body shaping technique that utilized an MRI to evaluate and measure abdominal fat reduction for aesthetic purposes and compare these findings with the standard anthropometric measurements. The comparison of the anthropometric data with the MRI-based measurements shows a high degree of correlation between the observed abdominal fat thickness reduction evaluated by MRI, reduction in the abdominal circumference and pinch caliper measurements.

CONCLUSION

Subjects with more significant circumferential and caliper reduction also showed greater reduction in fat layer thickness. Average change in subjects' weight was imperceptible suggesting that the results were related to the treatment, not diet nor exercise. Results were proven to be statistically significant. A large spot size measuring 1317cm^2 (204 square inches) covers the abdomen flank to flank. The average thickness of 5.36 mm of the fat layer reduced under the applicator translates into significant cumulative circumferential reduction. The obtained results prove the efficacy of a contactless radiofrequency device. MRI is literally the most transparent method for the verification of non-invasive body shaping therapy results.

DISCLOSURES

Dr. Downie is a Clinical Investigator and speaker for BTL. She did not receive compensation for this article. Dr. Kaspar is a Clinical Investigator. He did not receive compensation for this article.

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