

Nonsurgical Body Contouring With Focused Ultrasound

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UltraShape™ is an exciting, clinically proven, nonsurgical and noninvasive body-contouring solution for both men and women. It offers an alternative to patients seeking effective reduction of localized areas of fat deposits without surgery. The procedure uses ultrasound technology to deliver focused ultrasound waves to target and break down fat cells without any effect on surrounding tissues or organs.

Billions of dollars are spent each year on exercise programs and weight-loss products in an attempt to reduce or maintain one's body shape. There is also the surgical option of liposuction, which was the second most popular surgical procedure being performed by plastic surgeons in the United States in 2008 (American Society of Aesthetic Plastic Surgery national statistics). With a liposuction procedure there are surgical risks and downtime to consider. Patients are now seeking alternative methods for effective reduction of localized areas of fat deposits without surgery. There are several different techniques being utilized to provide nonsurgical fat disruption such as mesotherapy, cryotherapy, and focused ultrasound therapy. For the purpose of this article, focused ultrasound therapy will be the only technique discussed. UltraShape™ is an exciting, clinically proven, nonsurgical, and noninvasive body-contouring solution for both men and women.

UltraShape™ was developed in Israel and received its CE mark in June 2005. It is currently available in 57 countries around the world and

more than 200,000 patient treatments have been performed. The UltraShape™ Contour I medical device was approved by Health Canada in 2007. A third-generation device, the Contour 1, version 3, was approved by Health Canada in 2009. As of February 2010, the Contour I is not available in the United States but is awaiting Food and Drug Administration approval.

UltraShape™ was introduced into our office in October 2008 and has proven to be a major component of our nonsurgical aesthetic practice.

TECHNOLOGY

The Contour I uses ultrasound technology to deliver focused ultrasound waves to target and break down fat cells without any effect on surrounding tissues or organs. The contents of the fat cells are then processed by body's natural metabolic pathways, the same way that fat is processed when one loses weight.

There are three components to the ultrasound technology that increase the effectiveness and safety to the target cells and surrounding tissues.

Focused Beam

Focused ultrasound delivers low energy at the surface but provides a concentrated intensity of energy where the ultrasound waves converge at the focus. This focused energy allows targeting of defined tissues at a controlled depth, while leaving adjacent structures, such as skin, blood vessels, nerves, and muscles, unharmed (Figure 1).

Pulsed Energy

The ultrasound wave is delivered in pulses, which allows the generated heat to dissipate before the next pulse begins. This minimizes the temperature rise (0.5 C) within and around the targeted tissues.

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The author has no conflict of interest.

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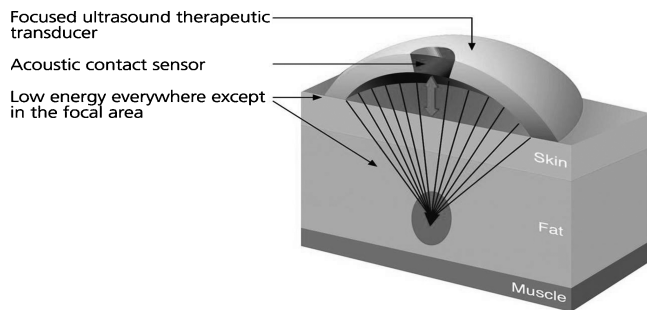


Figure 1. Focused energy.

Nonthermal Mechanical Effect

The energy delivered is transformed into mechanical stresses, which results in better control of tissue effect. The high mechanical stresses remain within the focus and exist only for the duration of energy delivery. This allows the targeting of tissues that are most susceptible to mechanical disruption, while more resistant structures remain intact.

WHAT HAPPENS TO THE FAT?

The most common concern regarding noninvasive fat reduction is what happens to the destroyed fat cells. Clinical studies have been done by Teitelbaum et al. (2007) to ensure that there are no adverse effects from the ultrasound procedure. The blood laboratory tests were done from 0 to 84 days post-treatment, and it was concluded that there were no clinically significant changes. Other tests included pulse oximetry, liver ultrasound, and two-point discrimination, which again confirmed no clinically significant changes.

During the UltraShape™ procedure, the membranes of the fat cells are disrupted. The fat cell content, primarily composed of triglycerides, is dispersed into the interstitial fluid among the cells and then cleared via the lymphatic system and transported through the vascular system to the liver. The liver makes no distinction between fat coming from the UltraShape™ procedure and fat originating from consumed food. Both are processed via the body's natural mechanisms.

More specifically, fat clearance is performed by the physiological pathways—the lymphatic, venous, and immune systems. The triglycerides from the broken fat cells are released into the interstitial fluid. They are then metabolized by the lipase enzyme into glycerol and free fatty acids. Glycerol is phosphorylated and transported through the vascular system. The 3-free fatty acids are bound to each albumin molecule and transported to the liver. Fat metabolites are processed in the liver in the same manner as fat originating from digested fat. The cell

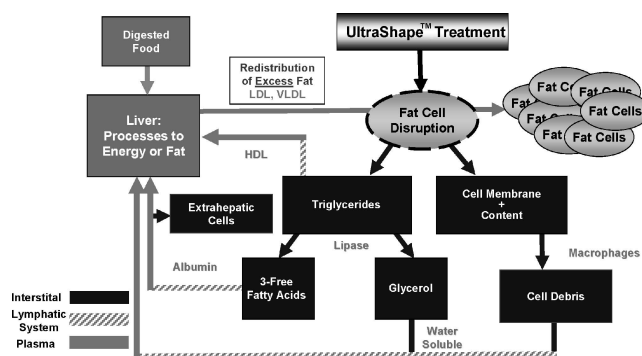


Figure 2. Natural mechanism for fat clearance. Used with permission from UltraShape™ Ltd.

debris is eliminated by phagocytosis (Figure 2; Brown S, 2005; Brown AB et al, 2009).

PATIENT SELECTION

As with any noninvasive procedure, it is important to select the right candidates and manage patient expectations carefully. The ideal candidate to undergo the UltraShape™ procedure is a motivated patient with realistic expectations, the desire to reduce localized fat deposits and body circumference, and the desire to improve body shape without surgery or downtime. As a guideline, UltraShape™ patients should have a normal to overweight body mass index (≤ 30) with localized fat deposits that are at least 1.5 cm thick. Also, just as with surgical liposuction, patients should be willing and able to maintain a healthy diet and exercise regimen to maximize the results. UltraShape™ is not a treatment for weight reduction, obesity, skin laxity, or patients with unrealistic expectations (UltraShape™ Contour I application guide, 2007).

CONTRAINDICATIONS

UltraShape™ is intended for use on patients who are in good health, aged 18 years and older, and have a subcutaneous fat thickness of at least 1.5 cm in the intended area of treatment. As with any device, there are contraindications that need to be considered when assessing a patient for an UltraShape™ procedure.

General contraindications include the following:

- Age less than 18 years
- Pregnancy, lactation, or anticipated pregnancy during the treatment
- Pacemaker, implanted cardiac defibrillator, or other electromagnetic-implanted medical device
- Metabolic disorder involving abnormal fat metabolism, including but not limited to severe hyperlipidemia or hepatosteatosis
- Hepatitis or other liver disease

- Altered states of the immune or inflammatory system
- Disorders of connective tissues
- Bleeding disorder or coagulopathy
- History of poor wound healing
- History of exposure to highly fat-soluble compounds, such as pesticides or drugs known to be stored in the liver

Treatment area contraindications include the following:

- Fat thickness less than 1.5 cm or greater than 3 cm in a “pinch test”
- Treatment area outside sites where safety has been demonstrated in the UltraShape™ clinical studies—abdomen, outer thighs, and flanks
- Open wound in the treatment area
- Abdominal hernia, rectus abdominal diastasis or known aortic aneurysm (for treatment of the abdomen)
- Any implanted foreign body underlying the intended treatment area
- Keloids, hypertrophic scars, or depressed scars in the treatment area (UltraShape™ Contour I physician guide, 2007)

THE ULTRASHAPE™ PROCEDURE

The initial consultation and assessment must be performed by a physician, but the treatment may be delegated to an aesthetician, nurse, or technician. The UltraShape™ setup has a computerized system known as the Real Time Tracking and Guidance System, which allows a technician to provide an effective treatment with minimal risks to the client. This system ensures that the treatment is performed only within the designated treatment area, each end point is treated only once, and the area is homogeneously covered to ensure smooth results.

Once a client has been assessed by the physician and it is determined that he or she is a good candidate, consent, photos, weight, and circumferential measurements are done and documented. Standardized measurements are essential to be able to evaluate the results once the treatment sessions are complete. It is beneficial to use a medical height-measuring device that measures from a fixed point to the widest point within the treatment area. The treatment area outline may change in consecutive treatments but the height will always stay constant.

Positioning the patient is the next challenge. To ensure optimal delivery of the ultrasound energy to the fat layer, the transducer must be placed flat and within full contact during the procedure. The treatment area is “gathered” and surgical tape is applied around the edges to keep the fat in a central area. Pillows and bolsters are necessary to aid in positioning.

Once the patient is positioned, drapes are applied around the treatment area, making sure they are at least 5 cm from the line marking of the treatment area. This ensures that when positioning the transducer at the edges of the treatment area, the transducer will not be placed on the drapes and full contact is maintained.

Next, the colored markers are placed around the treatment area on the stationary towels. The Tracking system’s camera and software automatically detects the marked treatment area. The transducer is placed in the center of the treatment area so that it can be “acquired” by the tracking system and the software maps the treatment plan.

Once the software has acquired all the parameters for the treatment area, it displays the treatment nodes and indicates the first node to be treated with a yellow dot.

As each node is treated, it turns from yellow to red, with the software automatically tracking the treatment in real time. The technician has the option to skip nodes if these are located near boney prominences and scars.

Once the treatment is complete and the oil is wiped off the patient’s skin, special care must be taken with the transducer. The transducer contains ceramic and may be cleaned only with 70% alcohol. The use of soaps, wipes, or cleaners could damage the black membrane, which may result in an adverse event for the patient (Figure 3) (UltraShape™ Contour I user manual, 2007).

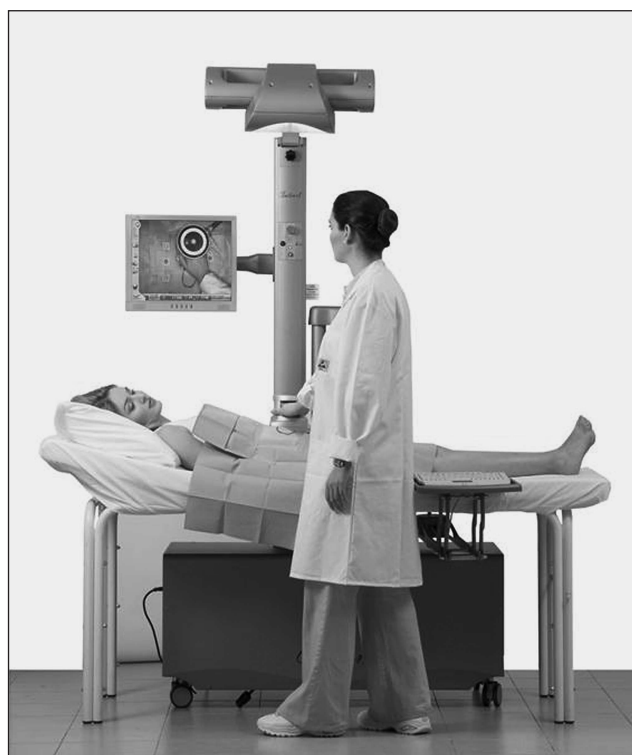


Figure 3. UltraShape™ tracking system.

BOX 1. UltraShape™ (FAQs)

During the UltraShape™ procedure, the membranes of the fat cells are disrupted. The fat cell content, primarily composed of triglycerides, is dispersed into the fluid between the cells and then transported through the vascular and lymphatic systems to the liver. The liver makes no distinction between fat coming from the UltraShape™ procedure and fat originating from consumed food. Both are processed via the body's natural mechanisms.

Because of this process you are advised that following the treatment you need to maintain a negative calorie intake for the first 4 days. For the following 2 weeks, it is important to be conscious of the fat content in your diet. This will ensure that fat energy released as a result of the UltraShape™ treatment is utilized by the body and is not stored as fat in other areas of your body.

After your UltraShape™ treatment you can immediately resume your daily activities. You must be aware that the treatment is not “magic” and you should maintain a healthy lifestyle (diet and exercise) to preserve the effect.

WHAT FOODS ARE HIGH IN FAT?

- Dairy foods (whole milk, ice cream, and creams);
- Fatty red meats;
- Butter is not only high in fat, but saturated fat as well;
- Oils are fat, although some may have lower saturated fat;
- Egg yolks, which are particularly high in cholesterol;
- Cheese (sorry, there are some that are better than others though); and
- Processed meats (sausage, salami, hot dogs, and bologna).

WHAT ARE SOME FOODS THAT ARE LOW IN FAT AND BETTER TO EAT?

- Fruits
- Vegetables
- Fish and shellfish
- Cereals, rice
- Pasta
- Nuts and seeds
- Vegetable oils are preferable to butter (see below).

SOME SPECIFICS OF “HOW TO DO IT”

- Eat more vegetables, fruits, and grains.
- You do not have to stop eating foods you enjoy that are high in fat; just cut down on the amount of their servings. Use bigger quantities of low-fat foods to accompany them.
- Instead of a steak that covers the whole plate, get a cut that you really like of modest size. Four ounces of beef is recommended—that is a steak about the size of a deck of cards.
- Eat one egg instead of two.
- Eat fatty foods less often. You do not have to quit your favorite foods completely.
- Trim the visible fat. Remove all of the skin from poultry.
- Limit organ meats (liver, kidney).
- Use lunch meats sparingly (salami, bologna, and sausage).
- Make egg dishes with egg whites rather than egg yolks.
- Drink skim or 1% milk (if you drink milk).
- Watch the cheese (sorry!). Look for low-fat varieties, especially for cooking.
- Do not add fat as you cook.
- Instead of frying—use these techniques (and use a rack to allow the fat to drain if possible):
 - Roasting (on a rack if possible so fat drains away)
 - Grilling
 - Baking
- Do not settle for dull. A little imagination can go a long way in keeping foods interesting:
 - Try new spices
 - Get a good low-fat cookbook with a number of recipes and alternatives. Invest a little time in planning some good alternatives
- Cut down on added fats, such as salad dressing and butter. Try and use those that are low in saturated fats, and in moderation!
 - **Avoid** (These contain about 40% saturated fat)
 - Butter
 - Lard
 - Palm oil, coconut oil
 - **Use** (These contain about 20% saturated fat)
 - Olive oil
 - A vegetable oil spray to brown or saute food
 - Canola, safflower, sunflower, peanut, and corn oil
- Read the labels. Unfortunately, you really have to pay attention to some foods that say “Healthy” or “No cholesterol.” They may still contain large amounts of fat and saturated fat!
- Use prudence when dining out.

TABLE 1 Treatment Areas

Abdomen	37
Bilateral flanks	33
Bilateral lateral thighs	16
Unilateral flank	2
Unilateral lateral thigh	3

POSTTREATMENT EXPECTATIONS

The triglycerides are cleared gradually over the first week when most circumferential reduction takes place, and the clearance of the cell debris occurs through the wound-healing process over the first 3–4 weeks.

Because of this clearance process, a patient's commitment to maintaining his or her weight with a low-fat diet and increased exercise will enhance the results of the UltraShape™ treatment. This will ensure that fat energy released as a result of the UltraShape(treatment is utilized by the body and is not stored as fat in other areas of the body.

After the UltraShape™ treatment, patients can immediately resume daily activities. It must be emphasized that the treatment is not “magic” and that a healthy lifestyle (diet and exercise) must be maintained to preserve the effect (Box 1).

RESULTS

Our clinical results include our first 70 patients. Seventeen had one procedure, 23 had two treatments, and 30 had three treatments (Table 1). To this date, we have treated more than 130 patients.

Of these 70 patients, there were 91 areas treated with an average of 1.3 areas per patient (Table 2).

Outcomes were evaluated through clinical photography and weight and circumferential measurements from a defined point on the floor. The average weight loss was 2.31 lb, and the average centimeter loss was 2.5 cm per treatment area.

Complications were noted as no contour abnormalities, no systemic problems, and one patient

TABLE 2 Treatment Time Per Area

	Abdomen (min)	Flanks (min)	Lateral Thighs (min)
Photos, measurements, and markings	30	30	30
Taping, draping	15	30	30
Treatment	67	56	59
Total	112	116	119



Figure 4. UltraShape™ pretreatment photo (Photo courtesy Dr. Mitchell Brown).

with allergic reaction to tape. Several patients had local burning sensation during treatment, with one patient requesting to have the treatment discontinued. Upgrading the system hardware to Version 2, keeping the oil cool in the fridge, and using a random pattern for tracking system seems to have rectified this issue (Figures 4 and 5).

TECHNOLOGY UPDATE

In December 2009, Health Canada approved the use of the Contour 1, Version 3, device. It is a multi-application platform integrating nonthermal selective focused ultrasound (Vertical Dynamic Focus™) with bipolar radio frequency with integrated vacuum (RFVac™). The benefit is the pretreatment of the fat with RFVac™ so that fat cell disruption from the focused ultrasound is enhanced. The RFVac™ is then applied posttreatment to increase circulation



Figure 5. UltraShape™ posttreatment photo. Results after three treatments on bilateral thigh and abdomen—lost 3.5 cm of fat from abdomen and 2.5 cm of fat from thighs, 5.8 lb weight loss. (Photo courtesy Dr. Mitchell Brown).



Figure 6. New Contour 1, Version 3, System.

for faster fat clearance and tissue tightening. To this date, we have not used this new technology on our office, but we look forward to incorporating it into our existing UltraShape™ treatment (Figure 6).

CONCLUSION

The use of a nonsurgical body-fat reduction procedure provides several benefits to the patient. The procedure requires no downtime, requires no anesthesia, and is a safe procedure with minimal discomfort.

For the physician, it provides an alternative to those patients who are not surgical candidates or who do not wish to have surgery. The procedure can be delegated to a technician who can take advantage of the time commitment and use this as a cross-marketing opportunity.

As with any nonsurgical treatment, the results can be variable; therefore, proper patient selection, education about expectation, and follow-up are essential.

REFERENCES

- American Society of Aesthetic Plastic Surgery. (2008). *Cosmetic surgery national data bank*. Retrieved January 2010, from www.surgery.org/media/statistics
- American Society of Plastic Surgeons. *2000/2007/2008 National plastic surgery statistics*. Retrieved January 2010 from www.plasticsurgery.org/media/stats/2008-cosmetic-reconstructive-plastic-surgery-minimally-invasive-statistics.pdf
- Brown, S. (2005). *What happens to the fat after treatment with the ultrashape™ device*. Yokneam, Israel: Ultrashape Ltd.
- Brown, A. B., Greenbaum, L., Shtukmaster, S., Zadok, Y., Ben-Ezra, S., & Kushkuley, L. (2009). Characterization of nonthermal focused ultrasound for noninvasive selective fat cell disruption (lysis): Technical and preclinical assessment. *Plastic and Reconstructive Surgery*, *124*, 92–101.
- Teitelbaum, S. A., Burns, J. L., Kubota, J., Matsuda, H., Otto, M. J., Shirakabe, Y., et al. (2007). Noninvasive body contouring by focused ultrasound: Safety and efficacy of the Contour 1 device in a multicenter, controlled, clinical study. *Plastic and Reconstructive Surgery*, *120*, 779–789.
- UltraShape™ Contour 1 application guide* (March 2007).
- UltraShape™ Contour 1 physician guide* (March 2007).
- UltraShape™ Contour 1 user manual* (March 2007).
- UltraShape™. www.ultrashape.com