ORIGINAL ARTICLE

Clinical Effects of Noninvasive Ultrasound Therapy for Circumferential Reduction

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Introduction: *Conventional body contouring techniques such as liposuction, although now far less invasive, still require extended periods of recuperation and the use of compression garments. Several noninvasive techniques for soft tissue, adipose, and dermal treatment have been reported in the literature as also producing circumferential measurement reductions in patients. These results can now be correlated to evidence-based scientific methodology versus anecdotal reports.*

Materials and Methods: *Patients were treated using the VASER Shape (Sound Surgical Technologies, Louisville, Colo) as part of routine practice. Circumferential measurements were made before and after treatments.*

Results: *Two hundred and four patients were treated in 741 treatment sessions at 12 centers in the United States beginning in June 2010. When measured immediately after treatment, the patients experienced a 0.8-in circumferential reduction in the abdomen and a 0.5-in reduction on the thighs. Circumferential reduction continued over the course of treatments, resulting in reductions of more than 2-in and 1-in, respectively, in the abdomen and thighs. In no cases were any analgesics or anesthesia provided to patients before or during treatment. In general, the patients reported that the treatment was pleasant and felt warm but not uncomfortable. After treatment, patients were able to continue with their normal daily routines. Patients reacted positively to the procedure and the immediacy of results, and many reported that their clothes fit better when they dressed after treatment. In addition to circumferential measurement changes, patients also reported the sensation of feeling tighter in the treated area and that the treated areas had smoother skin.*

Conclusions: *The VASER Shape system presents a novel approach to achieving immediate circumferential measurement reduction noninvasively with no patient downtime.*

According to the cosmetic surgery procedure statistics report from the American Society for Aesthetic Plastic Surgery, more than 299 000 liposuction procedures were performed in the United States in 2010, making liposuction one of the top aesthetic surgery procedures performed domestically, second only to breast augmentation surgery.[1] This figure is dwarfed by the 60% of men and 51% of women in the United States who are overweight or obese.[2] Although modern liposuction technology permits office-based procedures under local anesthetic and/or conscious sedation, there are still significant risks associated with any surgical procedure and anesthesia.[3–6] In addition, surgical liposuction requires significant downtime and the wearing of restrictive garments for long periods after the procedure.[7]

In recent years, increasing attention has been paid to noninvasive treatments for skin laxity and subcutaneous fat. This research has resulted in devices that use various energy modalities, such as ultrasound, radiofrequency, and thermal (hot and cold), all of which attempt to provide effective treatment with minimal downtime and reduced postprocedure discomfort.[8–13]

These technologies have shown modest circumferential reduction results in the medium term, but have not

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reduced patient discomfort and adverse sequelae to an acceptable level in all cases.

We describe here a retrospective observational study at twelve participating centers, following patients treated with the VASER Shape system (Sound Surgical Technologies, Louisville, Colo). The device uses ultrasound delivered through an ergonomic dual-transducer handpiece to effect circumferential change in patients.

Patients and Methods

Patient Population

Observational data were collected from patients requesting treatment using the VASER Shape system across 12 centers after the system was introduced in the United States (May 2010).

VASER Shape

The VASER Shape device is a computerized system that uses ultrasound waves and massage therapy to treat a variety of conditions of the human body.

The system uses a dual-transducer head that emits a double beam of overlapping ultrasonic energy at a frequency of 1 MHz. The ultrasound beams overlap and treat fatty tissue between 1 cm and 5 cm below the surface of the skin. These beams may also be modulated at frequencies between 20 kHz and 60 kHz. The VASER Shape system uses ultrasound energy to affect tissue in a noninvasive manner. Ultrasound energy passes through the skin on the way to the underlying tissue layers.

The ultrasonic handpiece delivers energy, like a continuous massage, and results in acoustic thermal and acoustic mechanical effects. These mechanisms couple the ultrasonic energy into the adipocytes, compressing and expanding the cells. Through this process, lipid within the cells is released into the interstitial fluid. The operator applies the handpiece with a continual motion, gently following the patient's body contour, which improves patient interaction and acts in concert with the lymphatic system.

The VASER Shape device also includes a separate vacuum handpiece that provides a lymphatic massage. This handpiece provides gentle, rhythmic, programmable suction using a patented elastomeric membrane that enables the opening of the lymphatic system at the beginning of the treatment and the lymphatic drainage massage at the end of the treatment.

Patient Preparation and Treatment

Before treatment, the region of interest was circumferentially measured and photographed at different circumferential positions.

The VASER Shape treatment begins with a short massage to the lymphatic system to facilitate drainage during and after the ultrasonic procedure. The procedure generally includes the terminal, axial, inguinal, and popliteal lymph nodes. This part of the procedure may be performed manually or by using the Zonal Massage handpiece.

The VASER Shape ultrasonic treatment may be conducted in one of three ways: using automatic preprogrammed settings or one of two user-defined modes of continuous and modulated.

In the automatic mode, the VASER Shape is programmed by entering the area being treated and the type of treatment. The technician then follows the instructions based on preset programs from the machine during treatment. In the continuous mode, the ultrasonic energy is delivered at constant amplitude. The user can program the power delivered. In this mode, most of the ultrasonic energy is delivered superficially and primarily affects the upper layers of tissue. In modulated mode, the ultrasonic energy is modulated at a programmable frequency between 20 kHz and 60 kHz. The modulation of the ultrasonic energy varies the intended treatment depth.

After the ultrasound treatment, the Zonal massage handpiece is used to facilitate lymphatic drainage of the area treated. The gentle suction of the Zonal handpiece massages the treated tissues, promoting the movement of interstitial and other fluids toward the lymph nodes. The Zonal handpiece is moved across the treated area toward the lymph nodes, draining the treatment area. Each area is treated in this manner for approximately 3 to 6 minutes.

After completion of the lymphatic drainage, the region of interest was usually remeasured circumferentially and rephotographed. The patients were then allowed to proceed with their regular schedule with no required recovery period. The time required for measurement, treatment, and remeasurement was typically 1 hour.

Follow-up

Patients underwent subsequent treatment sessions according to patient and office schedules, generally on a weekly basis. Between ultrasonic treatments, patients either returned to the center for a lymphatic drainage session or were instructed on how to perform a lymphatic drainage massage at home.

Statistical Measures

Circumferential measurements from the areas of the body reported were analyzed separately and combined

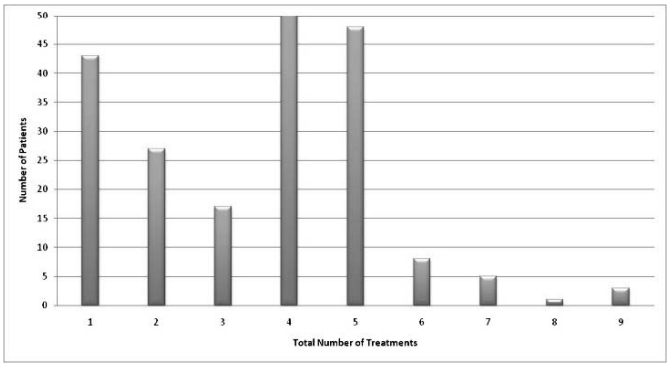

Figure 1. *Number of treatments per patient.*

where paired data were available. All tests applied were two-tailed, with a value of $P \leq .05$ considered statistically significant. Paired *t*-tests were performed for normal data, and the Wilcoxon signed-rank test was used for non-normal data.

Results

Patients and Visits

Two hundred and four patients were treated in 741 treatment sessions at 12 centers in the United States beginning in June 2010. The mean number of treatments per patient was 3.5 (median = 4; range = 1–9) (Figure 1). Most patients underwent between 1 and 5 treatments, and only 4.4% of patients completed 6 or more treatments.

The median number of days between visits was 7 (mean = 7.0; range = 1–70 days). Figure 2 shows the number of days between each patient visit.

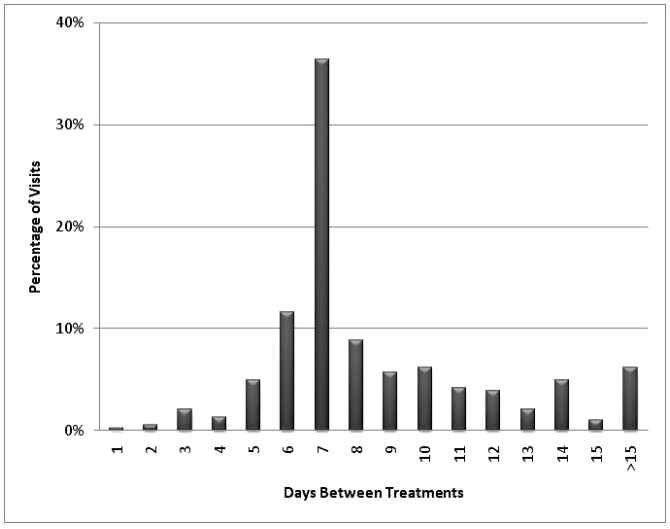

Figure 2. *Number of days between treatments.*

Table 1. Body Areas Treated at First Visit*

Body Area Treated	No.	%
Arms	24	3.0
Upper torso	43	5.3
Lower torso	387	47.7
Pelvis	92	11.3
Upper leg	261	32.2
Lower leg	4	0.5

*More than one area may have been treated in the first visit, and multiple modalities may have been applied to each area during the visit.

Treatment Areas

During the first treatment, most of the body areas treated involved the lower torso (48%), upper legs (32%), and pelvic area (11%), as shown in Table 1. Other areas treated included the arms; upper torso areas (eg, bra-roll and buffalo hump); and lower legs, including the ankles.

Treatment Modalities

Treating technicians were given the flexibility to tailor the number and type of ultrasonic modalities used in each treatment. Table 2 shows how the different modalities—automatic, continuous, and modulated—were used. In most treatments, physicians preferred the ability to fully control the duration, depth, and type of ultrasound delivered by using the modulated mode.

The modulation frequency changes the depth at which the ultrasonic energy is most effective. Technicians chose lower modulation settings to treat thicker areas, such as the lower torso, and higher settings for thinner areas, such as the arms, as shown in Table 3.

Circumferential Changes at First Treatment

Patients were remeasured immediately and circumferential changes were noted immediately after the treatment. Figure 3 shows the circumferential changes

Table 2. Treatment Modality by Area*

Area	Automatic	Continuous	Modulated
Arms	0	55	88
Upper torso	2	21	69
Lower torso	23	306	952
Pelvis	0	34	231
Upper leg	59	189	673
Lower leg	0	9	10
Total	84	614	2023

*Multiple modalities may have been used in 1 treatment.

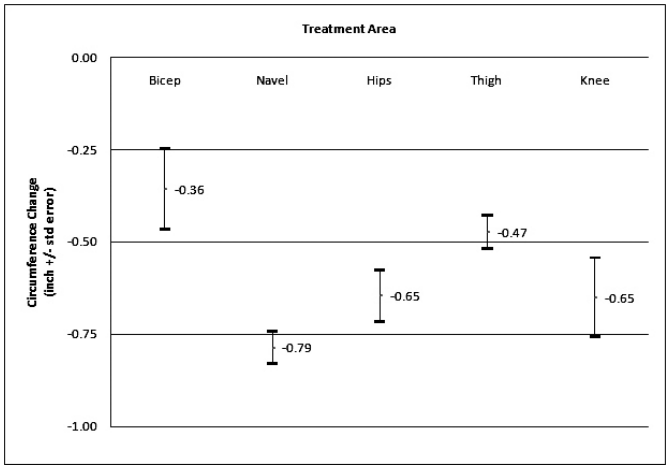

Figure 3. *Circumferential changes after first treatment.*

between the measurements before and after the first treatment.

Analysis using a paired two-tailed *t* test showed that treatment with the VASER Shape resulted in a significant ($P < .001$) decrease in circumference across all body areas. The greatest changes were recorded at the levels of the navel and the hips, where patients experienced reductions of 0.78 in ($P < .001$) and 0.65 in ($P = .004$), respectively (Table 4). In some cases, an increased circumference was measured immediately after treatment. There were no reports of associated edema with these cases, however, and the measurement technique or placement may have been in error.

Circumferential Changes Over Time

The circumferential measurements continued at each visit. Table 4 shows the mean circumferential change at each visit averaged over the number of treatments (overall torso measurements were taken at the navel). These results mirror those experienced at the initial treatment. Overall, patients experienced continued reduction throughout treatments, with a mean circumferential change of more than 0.6 in at the navel and more than 0.5 in at the hips per treatment visit. Figure 4 shows that the circumferential change achieved during the first treatment continued in the intervening period to the second treatment. Where all 3 data points were reported (before treatment, after treatment 1, and before treatment 2), the largest change between visits was observed at the hips, with approximately 0.4 in lost ($P = .02$, paired two-tailed *t* test).

Examining the changes experienced over time in the 3 most treated areas, lower torso, hips, thigh, as measured at the levels of the navel, the widest part of the hips, and the widest part of the thigh, we found a trend toward continued reduction in size throughout the first 5 treatments (Figure 5). Measurements showed a large decrease at the first treatment followed by a plateau through treatment 3 and more reduction at treatments 4 and 5. Analysis using two-tailed t tests showed that changes remained statistically significant ($P < .05$) in all 3 of these areas through the third visit and in the thighs ($P < .001$) through the fifth visit.

Table 3. Modulation Frequency by Area*

Area	N/R†	20	25	30	35	40	45	50	55	60
Arms	1	11	6	18	26	12	6	2	2	4
Upper torso	0	27	2	11	3	18	0	1	0	7
Lower torso	6	365	94	242	55	121	9	37	4	19
Hips	0	94	56	32	12	33	0	0	0	4
Thigh	12	250	114	125	53	89	4	4	3	19
Knee	0	8	0	0	0	2	0	0	0	0
Total	19	755	272	428	149	275	19	44	9	53

*Multiple modalities may have been used in 1 treatment.
†N/R indicates not reported.

Table 4. Mean (± SD) Circumferential Change (in inches) During Treatments by Body Area

Area	Initial Treatment	All Treatments
Bicep	–0.36 ± 0.11	–0.28 ± 0.04
	$P = .014$	
Navel	–0.78 ± 0.06	–0.63 ± 0.04
	$P < .001$	
Hips	–0.65 ± 0.09	–0.52 ± 0.05
	$P = .004$	
Thigh	–0.49 ± 0.05	–0.35 ± 0.03
	$P < .001$	
Knee	–0.61 ± 0.15	–0.33 ± 0.08
	$P < .001$	

Table 5. Mean (± SD) Circumferential Change (in inches) Over 5 Treatments by Body Area

Area	Change Over 5 Treatments
Bicep	–0.56 ± 0.21
	$P = .13$
Navel	–2.12 ± 0.40
	$P = .131$
Hips	–1.81 ± 0.69
	$P = .131$
Thigh	–1.0 ± 0.13
	$P < .001$
Knee	–1.23 ± 0.50
	$P = .763$

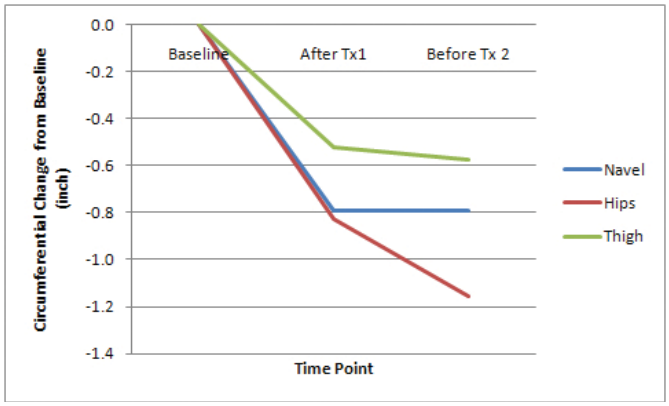

Figure 4. *Cumulative circumferential change between treatments 1 and 2. Tx indicates treatment.*

According to one-sided *t* tests, the change in circumference remained significant through the fifth visit for thighs.

After 5 completed treatments, patients experienced, on average, a circumferential reduction of 2.1 in at the level of the navel and 1.8 in at the hips (Table 5).

Figure 6 and Figure 7 show examples of patient results immediately after 1 treatment and after 2 treatments, respectively. In Figure 6 the patient's abdomen was treated. Figure 7 shows a profile view of a different patient's abdomen after 2 treatments. Not only has the abdomen been reduced in size but the stretch-marks on the abdomen are narrower and less visible.

Treatment Tolerance

In general, the patients reported that the treatment was pleasant and felt warm but not uncomfortable. In cases where the patient perceived that the treatment was too warm, the technician allowed the skin

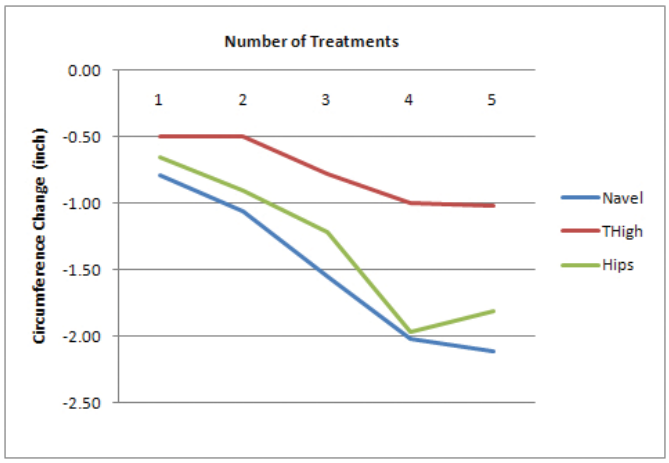

Figure 5. *Cumulative circumferential change over treatments 1 to 5.*

Figure 6. *Before (left) and after (right) photographs of patient's abdomen following the first treatment.*

temperature to cool before recommencing treatment or changed the rate of movement of the ultrasound handpiece on the skin to reduce the temperature increase in an area. After treatment, patients were able to continue with their normal daily routines.

Patient Reactions

Patients reacted positively to the procedure and the immediacy of results, and many reported that they noticed their clothes fitting better when they dressed after treatment.

In addition to circumferential measurement changes, patients also reported the sensation of feeling tighter in the treated area and that the treated areas had smoother skin.

Safety

There have been no adverse events reported in this patient population. There have been no burns, edema, or other severe conditions. Immediately after treatment,

Figure 7. *Before (left) and after (right) photographs of patient's abdomen following the second treatment.*

Table 6. Comparison of Noninvasive Results

Technology	No. of Treatments	Abdomen (cm)	Thigh (cm)
VASER Shape	5	5.38 ± 1.01	2.59 ± 0.33
Radiofrequency[8]	8–9	5.17 ± 1.04	3.50 ± 2.16
Focused ultrasound[13]	3	4.15 ± 2.30	4.60 ± 2.12

patients did experience some reddening or erythema; however, this generally resolved within hours of the treatment with no need for medical intervention.

Discussion

The VASER Shape system is designed to deliver ultrasonic energy at varying depths. In this series we realized reductions of 2.1 in in the abdomen and 1.0 in in the thighs over 5 treatments, and reductions of 0.8 in and 0.5 in, respectively, were achieved at the first treatment. These results were achieved with no adverse events and no patient discomfort.

The ultrasonic handpiece is simple to use and allows the technician to adjust for patient comfort and anatomy during the treatment. The handpiece is completely under the control of the user and requires no additional equipment or setup. In contrast, other devices using ultrasound require precise tracking systems[13,14] to achieve final results (Table 6). This ease of use allows for a wide range of users to incorporate the VASER Shape into their practice with minimal training required.

In general, there is a paucity of peer-reviewed, published data on noninvasive body contouring techniques. A search of the recent published literature revealed only 2 reports, one for radio frequency treatment and the other for focused ultrasound where a similar follow-up period occurred and circumferential measurements were obtained at comparable locations. Table 6 shows comparative midterm results with different modalities of noninvasive therapies. The results attained with the VASER Shape are comparable to those attained with other types of treatment.

In addition to changes observed over the course of several sessions, VASER Shape treatments showed reduction of 0.5 in to 0.75 in immediately after application. This is in contrast to slow reduction over a period of months with modalities such as cryolipolysis.[10]

One controlled study was performed by Jewell et al[15] using a high-intensity focused ultrasound. The investigators performed 1 treatment and then followed up with subjects at 12 weeks, measuring circumferential change as the endpoint. The abdominal circumferential reductions after 1 treatment were 0.9/1.8 cm at 4 weeks, 2.3/2.6 cm at 8 weeks, and 2.1/2.5 cm at 12 weeks for 47 J/cm^2 and 59 J/cm^2, respectively. In comparison, use of the VASER Shape resulted in a 2.0 cm abdominal reduction immediately after the first treatment. This reduction increased to 5.4 cm immediately after the fifth treatment, which was approximately 4 weeks after the first treatment. The Jewell results for 1 treatment are similar to those obtained with the VASER Shape; however, 7.6% (9/118) of the subjects in the Jewell study reported severe procedural pain, and 22.2% required analgesia before, during, or after the procedure. The VASER Shape resulted in no reports of severe pain, demonstrating a similar circumferential reduction without significant patient discomfort.

The ultrasound energy of the VASER Shape was very well tolerated and offered a high degree of clinical safety. No significant adverse events, such as burning, seroma, or hematoma, were reported. The lack of these types of events demonstrates that the heat generated by the VASER Shape system does not harm the patient and that the ultrasonic energy does not damage or rupture blood vessels under the skin. In no instances was it necessary to treat patients with heavy sedation or narcotics during the sessions, which is in contrast to the need for these medications with modalities such as focused ultrasound.

No disturbances or disruptions of sensation were reported in patients treated with the device. This is in contrast to sensation disruptions lasting up to 6 weeks with cold-based therapies.[11]

We conclude that the VASER Shape system has shown immediate circumferential reduction in a wide range of patients. Although it does not provide the dramatic reduction seen with liposuction, the device may be considered for patients who have local areas to be treated or who do not wish to have invasive procedures performed. The circumferential reductions observed with the VASER Shape are similar to those for other noninvasive modalities, but it offers a superior ease of use, a low incidence of adverse events and a high degree of patient comfort.

Conclusion

The VASER Shape system presents a novel approach to achieve immediate anatomical circumferential reduction in a noninvasive way and with no patient downtime or discomfort. Future clinical and preclinical

studies will provide greater insight into the mechanism of action of this new technique and will provide better guidance on patient selection and treatment parameters.

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