"Hands-Free" Noninvasive Body Contouring Devices: Review of Effectiveness and Patient Satisfaction

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ABSTRACT

The demand for body contouring is increasing rapidly and has generated the need for a variety of non-invasive body contouring devices. This review concentrates on three popular "hands-free" body contouring devices and analyzes their mechanism of action, as well as their evidence of safety and efficacy. It also addresses some issues of usability from both the operators' and patients' point of view.

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INTRODUCTION

Since both the demand for body contouring and interest in non-invasive approaches is growing so rapidly, this paper will review the literary evidence behind the devices currently available in addition to going over the methods for non-surgical body contouring. Liposuction continues to be one of the leading cosmetic surgical procedures worldwide. The International Society for Aesthetic Plastic Surgery reported that in 2014, more than 1.37 million liposuction procedures had been performed globally, making it the second most common cosmetic procedure after eyelid surgery.[1]

According to the American Society for Aesthetic Plastic Surgery, 10.9 million non-surgical procedures were performed in 2015, compared with only 1.9 million surgical procedures: almost 396,000 surgical fat reduction procedures and 2.6 million non-surgical skin-tightening procedures were performed in the United States.[2] While there are numerous noninvasive body-contouring devices currently available on the market, all of these devices deliver some form of energy that creates changes in the adipocytes.

All non-surgical procedures for body sculpting induce fat cell shrinkage, apoptosis, or necrosis. A variety of energy sources can accomplish this, including: laser light, radiofrequency, acoustic and shock waves, or cold. They differ from each other not only by their mechanism of action, but also in the response rate, side effects, level of discomfort/pain, and the number of treatments required. Although no procedure has yet been accepted as the gold standard, cryolipolysis, high-intensity ultrasound, and non-contact radiofrequency are all competing for the role of being the safest and most effective procedure.

This review will concentrate on three popular "hands-free" devices (Table 1): Coolsculpting System by Zeltiq, Vanquish by BTL Industries, and SculpSure by Cynosure – each of which employ different energy types. They have one thing in common: when positioned for treatment at a designated area, they do not require active "hands-on" participation by the operator; ie, set-up, turn-on, and monitor. The Vanquish radiofrequency device is the only one of the three that operates in non-contact mode, while the other two devices – Coolsculpting System and SculpSure – require direct contact with the skin during treatment.

The Coolsculpting System generates "destructive" energy (cold) in the handpiece and transfers it to the subcutaneous fat via direct contact with the skin. The non-contact radiofrequency, and contact laser devices, have their respective energy selectively absorbed and converted to heat within the tissues designated for destruction.

Cryolipolysis: Coolsculpting System

CoolSculpting treatment (Zeltiq Aesthetics, Pleasanton, CA) is indicated for reduction of fat in the abdomen, brassiere rolls, lumbar rolls, hip rolls/flanks, inner thigh, medial knee, peritrochanteric areas (saddlebags), arms, and ankles. This device has an applicator, which is applied to the treatment area, allowing tissue to be vacuumed up between 2 cooling panels measuring 4.5x7 cm (31.5 cm^2) each, for 30 to 60 minutes. The amount of cooling is determined by thermistors that monitor the skin temperature.[3]

The aim of cryolipolysis is to cause selective damage to the adipocytes without producing any dermal damage. The exact mechanism of the selective destruction of adipocytes by cooling is still not fully understood.

In an early animal study by Manstein et al,[4] cold exposed subcutaneous fat had a nearly 80% reduction of the superficial fat layer at varying temperatures at 3.5 months. They observed that lower temperatures (–5°- –7°C) had a higher possibility of

TABLE 1.

Energy Source for Hands-Free Devices		
Energy	**Effect**	**Device (Company)**
Cold	Cooling	Coolsculpting System (Zeltiq)
Selective Focused-Field Radiofrequency	Heating	Vanquish ME (BTL Industries, Inc)
Diode Laser	Heating	SculpSure (Cynosure)

fat damage after 28 days. The cryolipolysis was highly selective in targeting the subcutaneous fat layer without affecting the epidermis, dermis, or underlying muscular tissue. Serum lipid levels showed insignificant changes for up to 3 months post-treatment. An additional animal study by Zelickson et al[5] confirmed these earlier findings. In their study, 2 pigs underwent ultrasound assessment to measure the thickness of the fat layer, which was reduced by 33% after treatment. Pathological gross measurement of the fat-layer reduction revealed a mean decrease of 51.5%. The authors found no significant increase in serum lipid levels after treatment.

In the Dover et al[6] multicenter study for treatment of the flank and back, 32 patients were treated once. At the 4 month follow up evaluation, 84% of them reported fat reduction and contour changes. In 10 patients, ultrasound measurements revealed a 22.4% reduction in the fat layer.

Coleman et al[7] conducted a study to assess clinical efficacy and sensory changes after cryolipolysis. In 10 patients a Coolsculpting System prototype device was used to treat flanks. Patients received treatment on one side and the other side was used as a control. Weekly neurological sensory testing was conducted in 9 patients with 66.7% of them exhibiting some degree of reduction in sensation after treatment. The sensation was restored in 3.6 weeks on average after the procedure, with fully restored sensation within 2 months post procedure. Six out of 9 patients also had ultrasound evaluation of fat-layer thickness showing average reduction of 20.4% and 25.5% in fat layer thickness at 2 and 6 months, respectively. Histological evaluation of biopsies from one patient showed no long-term changes to structure or functionality of either epidermal nerve fibers or nerve plexi in the dermis.

In the Klein et al[8] 40-patient multicenter study of cryolipolysis, serum lipid levels and liver enzymes were measured at day 1 and then at 1, 4, 8, and 12 weeks after treatment. The results showed no significant increase in triglyceride or lipid levels 12 weeks after cryolipolysis.

The study by Shek et al[9] evaluated the efficacy of cryolipolysis and the benefits of repeated treatment of the flanks and abdomen. In 21 patients, a single cryolipolysis session led to an average 14.67% fat layer reduction measured by calipers, with 81% of them reporting improvements in the treated area. An additional 12 patients underwent two treatments 3 months apart, with average improvements of 14.0% after the first treatment but only 7.2% improvement for the abdomen and 4.3% for the flanks after second treatment.

In a European multicenter cryolipolysis study of 518 patients by Dierickx et al,[10] most of the subjects had treatment of the flanks and abdomen. Less than 50% of the patients were seen at 3 months follow up and 73% of them reported being either extremely satisfied or satisfied. Caliper measurements showed 94% of patients had some degree of reduction in fat thickness, with an average reduction of 23%. The reported side effects were erythema (100%), clay-like skin (52%), stiff skin (48%), bruising from the vacuum hand piece (9.8%), severe pain (4%), increased sensitivity (2.5%), nodular or diffuse infiltration in the treatment area (2.5%), vasovagal reaction (2.1%), and decreased sensitivity (0.4%).

Of a retrospective series of 528 patients who underwent cryolipolysis for treatment of a variety of areas, 11 identified flanks as the most popular treatment area (38%), followed by lower abdomen (28%), and abdomen (11%). No objective measurements of fat-layer reduction were performed in that study. They reported 3 cases of mild-to-moderate pain or neuralgia that resolved within 4 days.

To summarize, the main indications for cryolipolysis have been in patients with small fat deposits on the flanks or abdomen and in the reviewed studies, the average reductions in the fat layer have ranged from 14.0% to 25.5%.[6-7,9] The reported complications had relatively few long-term ramifications. The primary reported side effects were erythema and sensory changes that had resolved reasonably quickly. No significant elevations in serum lipid levels were observed after cryolipolysis treatment.

According to one report[12] cases of severe adverse events like paradoxical adipose hyperplasia were seriously under-reported. Its consequences aren't fully understood nor appreciated. The authors observed a significant decrease in the quantity of interstitial cells, with fewer vessels in the paradoxical adipose hyperplasia tissue when compared with control tissue. Adipocytes in control tissue had round, smooth edges compared to the irregularly contoured edges in paradoxical adipose hyperplasia tissue. The authors have concluded that paradoxical adipose hyperplasia appeared to be hypocellular and hypovascular and that "cryolipolysis may cause vessel loss, which could lead to ischemia and/or hypoxia that further contributes to adipocyte death." But these findings need further investigation and confirmation.

The Coolsculpting System is well suited for treatment of smaller, defined fat accumulation areas where the benefit of shorter and fewer treatment sessions are advantageous. Using this

device to treat large areas takes away any time advantage and could also generate some disadvantages by requiring special accuracy in alignment of the hand pieces to the adjacent areas.

Selective Focused-Field Radiofrequency: Vanquish

The Vanquish™ device from BTL Industries, Inc., (Framingham, MA) uses selective focused-field radiofrequency to heat subcutaneous adipose tissue. This technology is designed to generate heat in adipose tissue, with minimal effect on skin because they have a different water content. Adipocytes and skin have different water content, and accordingly different impedance. This allows the selective radiofrequency to concentrate in lower water content, high impedance subcutaneous adipose tissue.

The Vanquish system is equipped with two types of applicators: the EX applicator to treat mid-section (abdomen and flanks) and the AB applicator for treatment of thighs and saddlebags. These are selective RF contactless applicators, placed approximately 1 cm above the skin, shaping the energy field to optimize the penetration and maximize the treatment area. It automatically tunes the tissue-applicator-generator circuitry to selectively deliver the energy to tissue layers with the specific impedance of adipose tissue, while minimizing the risk of overheating the skin, muscles, or internal organs.

Using this technology in a porcine model, Weiss et al[13] confirmed that this device was effective in fat layer reduction, while it remained safe for the epidermis, dermis, and adnexal structures. Four 30-min treatments in Vietnamese pigs produced a 70% reduction of the abdominal fat layer. Ultrasound showed a reduction of fat layer from 7.6 to 2.9 mm. Histologic evaluation revealed that epidermis, dermis, and adnexal structures such as hair follicles were unaffected by the treatment, while adipocytes were significantly affected.

Fajkosova et al[14] conducted a prospective case series of 40 patients to evaluate the Vanquish device. Patients underwent weekly 30-minute treatment sessions over a 4-week period. Measurements were taken 1 month after the final treatment session. The 35 patients who completed the study had an average circumferential reduction of 4.93 cm in the abdominal zone and expressed a high degree of satisfaction with the treatment procedure and its results. Only three patients failed to show any significant reduction, but they were noted to be the thinnest patient in the study. A body mass index/circumferential reduction correlation graph revealed better results in subjects with higher body mass indices. No significant adverse events related to the treatment were noted, other than transient erythema.[14]

Dr. Key in his small study[15] used a high-resolution temperature camera to show that during Vanquish treatment the peak areas of heating corresponded anatomically to the patients' areas of greatest fat excess. This observation was further collaborated by the work of Ellis,[16] in which the thermal gradient, between the skin surface and fat tissue, proved that the thermal focal point was in the fat tissue, at about 1 cm below the skin surface and induced apoptosis there.

McDaniel et al[17] studied 2 subjects, who underwent abdominal skin biopsies at the baseline, and then again after one 45-min treatment at the maximum power setting of 200 W. The skin temperature was monitored with an infrared camera throughout the procedure. Thermocouple measurements were made at depths of 1 and 2 cm. The TUNNEL assay employed to assess apoptotic activity after high frequency focused field RF treatment, demonstrated a nearly 500% increase in the apoptotic index. This was due to an increase in deep tissue temperature to 450 C, with skin surface temperature remaining at <400 C.

The Moradi et al[18] study evaluated the safety and effectiveness of the of multiple Vanquish treatments in 24 subjects by monitoring circumferential reduction and lipid serum values. They observed that a regimen of 4 weekly, 45-min treatment sessions was safe and effective and produced statistically significant waist circumference reduction (average 4.22 cm, $P<0.001$) at the 3-month follow-up, with only minor fluctuation in lipid serum values in 2 out of 4 tested subjects.

In Downie et al,[19] a 5-subject study, statistically significant waist circumferential reduction was observed, that corresponded to greater reduction in fat layer thickness, assessed by MRI (average 5.36 mm).

The subjects in Moradi et al[18] and Downie et al[19] studies had BMI readings of up to 30 kg/m2.

The most frequently reported side effects were erythema and tenderness that had resolved quickly. The few reported adverse events were limited to occasional skin blistering related to superficial sweat accumulation, small area panniculitis which is usually associated with localized volumes of fibrose-encapsulated fat, and localized burns likely associated with undiagnosed cysts or other fluid containing subcutaneous formations.

Reviewed studies consistently demonstrated a high degree of patient satisfaction with the treatment. Objective evaluations demonstrate statistically significant waist circumference and fat layer thickness reduction assessed by caliper measurements, ultrasound and MRI evaluations.

Vanquish appears to be particularly preferential for treatment of large body area in patients with high BMI, ie, ≥25. In a single application, it can easily cover the abdomen and flanks bringing it close to competing with liposuction for patients not willing to undergo an invasive surgical procedure. To maximize the benefits of the treatment, it is recommended utilizing up to

TABLE 2.

Comparative Summary of "Hands-Free" Body Sculpting Devices			
	Coolsculpting System	BTL Vanquish ME	SculpSure
Treatment Time (min)	30-60	45	25
Number of Treatments	1-3*	≤ 4	1-3*
Spot Size	63 cm2 (2 – 4.5x7cm)	EX-2100 cm^2 AB-1317 cm^2	96 cm2 (4 – 4x6cm)
Speed coverage (cm^2/min) per single session	1.1-2.1 cm^2/min	EX - 46.7 cm^2/min AB - 29.3 cm^2/min	3.8 cm^2/min
Speed coverage (cm^2/min) per treatment regimen	0.5-1.1 cm^2/min	EX – 11.7 cm^2/min AB – 7.3 cm^2/min	3.8 cm^2/min
Body Areas	Abdomen, brassiere rolls, lumbar rolls, hip rolls/flanks, inner thigh, medial knee, saddlebags, arms, ankles	Abdomen, flanks, thighs, saddlebags	Abdomen, flanks
Patients' Satisfaction	73% [10]	87% - 92%	91% - 98% [20-22]
Fat Layer thickness reduction	14.0-25.5% [6-10]	5.36mm [19]	11.50%
Circumferential Reduction(cm)	No data	4.22cm [18] 4.93cm [14]	No data
Consumables / Running Costs	Yes	None	Yes

*Unpublished current user report

four 45-min procedures. For example, the Vanquish EX applicator has a speed coverage of 46.7 cm^2/min and even with 4 treatments it is still 3 to 5 times faster than its competitors – Coolsculpting (2.1 cm^2/min) and SculpSure (3.8 cm^2/min) – for treatment of large areas (Table 2).

Diode Laser Energy - SculpSure

The SculpSure device from Cynosure (Westford, MA), is designed to deliver a single noninvasive treatment of 1,060-nm diode laser energy for reduction of abdominal and flank fat. In addition to the diode lasers, it has 4 (4x6 cm each) flat non-suction cooling applicators (Advanced Contact Cooling™ technology) to preserve the dermis from overheating. The objective of the treatment is to generate heat within the adipose tissue layer and elevate its temperature to 42 - 47 C.

Two studies by Katz and Doherty[20] enrolled 76 subjects which were divided into 2 groups. 34 subjects were assigned for the abdominal treatment and 42 for the flank treatment. In the flank group the investigators treated only one flank of each subject and used the other as control. The single 24-min treatment session used laser irradiance ranging in 0.9-1.4 W/cm^2. The flank treated areas ranged between 48 and 144 cm^2 and the abdominal areas were in the range of 192-288 cm^2.

The primary endpoint in both studies was an investigator blinded review of photographs, which were taken before treatment and again 12 weeks after the procedure. Reviewers identified correctly, an average of 95% of "before" photographs of the abdomen and 90.3% of those of the flank.

The secondary endpoint was a change in the thickness of the adipose layer at 12 weeks post procedure, as measured by ultrasound. The average reduction was 3.1±1.7 mm for the abdomen and 2.6 for the flank (P<0.001 for both). In the abdominal group, 85% of subjects said they were "extremely satisfied" or "satisfied" with the results, while 6% were "slightly satisfied." In the flank group, 86% of subjects were "satisfied" or "extremely satisfied" and 10% were "slightly satisfied."

Mean pain scores were 3.7 out of 10 for the abdominal group and 4.0 out of 10 for the flank group. The most common side effect was mild to moderate tenderness which lasted for up to 2 weeks after treatment. The other side effects included: localized firmness, edema, and ecchymosis. There were no reports of severe adverse events.

These studies demonstrated statistically significant, visibly discernible reduction in adipose tissue in the abdomen and flanks[20-23] but didn't address circumferential reduction, thus making it difficult to adequately compare them with previously reviewed noninvasive body contouring findings.

DISCUSSION

All three "hands-free" body sculpting devices appear to show a high degree of efficacy and patient satisfaction, based on the

reviewed series of case studies. There were no clinical trials comparing the effectiveness of one technology over the other in controlled independent investigations. Most of the reviewed studies were sponsored by the manufacturers of these devices, thus leaving room for bias in the analyses. Many of these studies failed to account for patient weight and lifestyle. This can seriously contribute to variations in measurements and affect outcomes. Also, there is no uniformity or defined standard in measurement techniques. The studies of two of the three reviewed devices – Coolsculpting and SculpSure– only evaluated reduction in fat layer thickness, while the third device – Vanquish ME by BTL – had some studies that not only looked at the reduction of fat layer thickness but overall circumferential reduction as well. Further studies are needed to evaluate and compare these popular devices in order to identify both technology and techniques beneficial to patient outcomes.

DISCLOSURES

Dr. Chilukuri is a speaker/consultant for the following companies: Alastin, Allergan Aesthetics, BTL Industries, Cynosure Lasers, Eclipse Micropen, Emvera Lasers, Galderma Aesthetics, PCA Skin, Skin Medica, Suneva Asthetics, and Theravent Lasers. Dr. Mueller has no conflicts of interest to decalre.

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