

ORIGINAL RESEARCH

Ultrasound cavitation versus cryolipolysis for non-invasive body contouring

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ABSTRACT

Background/Objectives: The demand for non-surgical and non-invasive devices is continuous and increasing. Such devices have gradually gained ground in the reduction of localised fat and the improvement of body contouring. The study aimed to compare the effects of ultrasound cavitation and cryolipolysis on localised abdominal fat.

Methods: In total, 60 participants with a body mass index (BMI) over 30 kg/m², whose age ranged between 25 and 45 years, were included. The participants were randomly assigned to three groups of 20 each, using ultrasound cavitation and diet, cryolipolysis and diet, and diet only (the control group), respectively. Measures were bodyweight, BMI, waist circumference and suprailiac skinfold were measured at the beginning of the study and 2 months later.

Results: The three groups showed significant improvements in all measured variables after 2 months. There was no statistically significant difference in bodyweight or in BMI among the groups after treatment. However, the groups using ultrasound cavitation and cryolipolysis showed better post-treatment improvement than the diet-only group in waist circumference and suprailiac skinfold. There was no statistically significant difference

post-treatment between the cavitation and cryolipolysis groups in waist circumference or suprailiac skinfold.

Conclusion: Both ultrasound cavitation and cryolipolysis are safe and effective for the reduction of abdominal fat thickness and for abdominal contouring.

Key words: body contouring, cryolipolysis, fat reduction, ultrasound cavitation.

INTRODUCTION

Body contouring is a major medical aesthetic need worldwide. Individuals' desire for favourable body shape has led to the rapid growth of innovative, non-invasive, yet comfortable and safe solutions, with minimal downtime.^{1,2} Although liposuction successfully reduces fat and improves body contouring, there is still a continuous demand for non-surgical and non-invasive methods that might be as efficacious. Most patients refuse surgery and invasive procedures; instead, they select non-invasive procedures that gradually result in fat reduction and the improvement of texture and body contouring.^{2,5}

Cryolipolysis is a method of non-invasive fat reduction that significantly reduces s.c. fat without injury to adjacent tissues. It is a non-invasive, Food and Drug Administration-approved procedure that causes apoptotic fat cell death and reduces s.c. fat thickness. Reduction of s.c. fat in the flank, upper and lower limbs, and abdomen can be achieved without changes in a patient's lipid profile or liver function levels.⁴

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Abbreviations

BMI	body mass index
CIF	cooling intensity factor

For many years ultrasound has been used for fat reduction either invasively or non-invasively. Zocchi pioneered internal ultrasonic devices that have been used in liposuction to directly destroy fat cells, but there are some complications associated with it, such as burns and skin irregularities.⁵ On the other hand, non-invasive ultrasound cavitation can produce similar outcomes in fat reduction and improvement of body shape to those produced by invasive ultrasound liposuction which is relatively cheaper, low risk and more safer.^{6,7}

Ultrasound cavitation is a novel application that uses ultrasound without surgical intervention. It delivers an energy signature through the skin for adipose tissue disruption.^{7,8} Ultrasound cavitation is applied externally and transmitted through the skin to the s.c. fat for absorption. This procedure has been shown to significantly reduce the circumference of treated areas.

One of the most important aspects that distinguishes ultrasound cavitation from liposuction is the lack of drawbacks that are associated with surgical procedures. Indeed, an ideal non-invasive procedure of delivering energy to the fat would reduce periprocedural morbidity such as infection, scarring, and anaesthesia associated with surgical procedures.^{9,10}

To the best of our knowledge, there are few comparisons in the literature between ultrasound cavitation and cryolipolysis on participants with localised abdominal adiposity. The purpose of this study is to help both patients with localised abdominal obesity and clinicians, by informing patients about the best, safest, and most effective treatment for their localised abdominal obesity and enabling clinicians to find the most effective therapies for localised fat reduction.

METHODS

Participants with a body mass index (BMI) greater than 30 kg/m², aged between 25 and 45-years old, and with localised abdominal fat participated in this randomised controlled trial.

This study included only 60 participants out of the 108 volunteers who expressed a desire to undergo elective body sculpting and met the selection criteria. Every patient was given a primary examination to obtain a complete picture of their health status, to identify any contraindications, and to determine if the patient could participate in the study.

The following participants were excluded from the study: those who suffered from abdominal hernias, severe diabetes or autoimmune diseases; patients with osteoporosis, phlebitis and thrombophlebitis; patients with metallic sections, articular prosthesis, intrauterine devices or a pacemaker; pregnant women; patients with a reduced nervous sensibility or with neurological pathologies; patients with obliterating arteriopathies and patients with important inflammatory processes or neoplastic diseases. Throughout the study, participants were asked to avoid products that might change the appearance of the skin, such as retinoids and vitamin creams. Additionally, topical steroids were not used on the treatment site for 8 weeks before the treatment

and throughout the study to avoid the effect of topical steroids on the inflammatory responses to cryolipolysis after the treatment and to assess if there were any complications during and after the application of cryolipolysis or ultrasound cavitation. Furthermore, none of the participants underwent other slimming or aesthetical procedures (such as endermology, mesotherapy and radiofrequency) during the study. All participants signed an informed consent form prior to the study.

The participants were classified randomly into cavitation, cryolipolysis and control groups with equal numbers of 20 patients per group. A regular diet was used for all groups. The diet prescribed for the three groups was a balanced hypocaloric diet that provided 1500 to 1800 kcal daily, according to the requirement of each participant. The diet varied according to each participant's age and eating habits. The diet was low in fat (20 to 25%), high in complex carbohydrates (50 to 60%), and sufficient in protein (25 to 30%).¹¹ No vitamins or other nutritional supplements were prescribed.

Skinfold measurements

A caliper was used to measure suprailiac skinfold thickness where s.c. fat was pulled away from the muscle with the caliper tongs situated at their ends. For men, the direction of fold pulling was vertical and was taken 2 cm to the side of the umbilicus; and for women, the skinfold was pulled diagonally and was taken above the iliac crest along the anterior axillary line. The suprailiac skinfold thicknesses was measured pre- and post-treatment to determine progress.

Cryolipolysis

The apparatus used for this study (Zeltiq Aesthetics, Pleasanton, CA, USA) contains a thermoelectric cooling element. This device comprises a control console with a treatment applicator appended with a link. This device allowed for the use of variable, preset plate temperatures during treatments. The cold temperature was kept at a consistent level by means of temperature sensors imbedded in the treatment plates. Each participant was treated on the abdominal area with a thermal coupling gel placed on the abdomen, and the applicator was then applied. Abdominal tissue was drawn into the cup-shaped applicator with a moderate vacuum to ideally and optimally situate the tissue between two cooling panels. This allowed for more effective cooling of the tissue.

A cooling intensity factor (CIF) was then chosen by the clinician. The CIF is an index value representing the rate of heat flux into or out of the tissue opposite the cooling device. Treatment with the Zeltiq non-invasive cooling device was conducted at CIF 42 for 30 minutes. The energy extraction rate, or cooling, was controlled by sensors that monitored the heat flux out of the treated areas and was regulated by thermoelectric cooling cells. Following completion of the treatment, the system automatically stopped the exposure to cold and the clinician released the vacuum.

Each participant underwent a cryolipolysis session on the same abdominal area every 2 weeks for 2 months. Clinical viability was determined before, during and after the 2-month treatment, using bodyweight, BMI, waist circumference and suprailiac skinfold measurements.

Ultrasound cavitation

A Proslimelt device (Promoltalia, Naples, Italy) was used for ultrasound cavitation. This device emits low-frequency ultrasound pulsed waves ranging from 30 to 70 kHz through a transducer of 45 mm diameter at a power of 3 watts/cm². The treatment was conducted by putting the patient in a comfortable supine lying position and setting the transducer on an abdominal region that was already secured with conduction gel. The same abdominal area was treated for one 30-minute session every 2 weeks for 2 months. Additionally, bodyweight, BMI, waist circumference and suprailiac skinfold measurements were taken before, during and after the 2-month treatment.

Statistical analysis

A statistical power analysis suggested that sample sizes above 15 participants per group were required to achieve more than 80% power. Data were first analysed using the Kolmogorov–Smirnov test to recognise a normal distribution. The differences between the pre- and post-treatment measurements were analysed using the paired Student's *t*-test. The differences between the three groups were analysed using a one-way ANOVA followed by the least significant difference post hoc test. The level of significance for all tests was set at 0.05. Statistical tests were performed using SPSS vers. 17 (Chicago, IL, USA).

Table 1 Characteristics of participants

Characteristics	Group A	Group B	Group C
Age (year)	34.1 ± 4.95	35.5 ± 5.33	35.75 ± 5.27
Weight (kg)	88.7 ± 7.97	89.55 ± 10.56	89.48 ± 9.49
Height (cm)	164.65 ± 7.74	166.0 ± 9.11	165.2 ± 7.59
BMI (kg/m ²)	32.67 ± 0.91	32.4 ± 1.0	32.7 ± 0.87

Table 2 Bodyweight, BMI, waist circumference, suprailiac skinfold pre- and post-treatment in each group

Variables		Group A (mean ± SD)	Significance (<i>P</i> value)	Group B (mean ± SD)	Significance (<i>P</i> value)	Group C (mean ± SD)	Significant (<i>P</i> value)
Bodyweight	Pre	88.7 ± 7.97	0.0001*	89.55 ± 10.56	0.0001*	89.48 ± 9.49	0.0001*
	Post	82.79 ± 7.85		84.35 ± 10.4		84.8 ± 9.59	
Body mass index	Pre	32.67 ± 0.91	0.0001*	32.4 ± 1.0	0.0001*	32.7 ± 0.87	0.0001*
	Post	30.48 ± 0.95		30.5 ± 0.89		30.97 ± 0.95	
Waist circumference	Pre	105.65 ± 5.91	0.0001*	104.3 ± 5.51	0.0001*	105.55 ± 4.95	0.0001*
	Post	96.35 ± 5.75		97.55 ± 4.9		102.55 ± 4.72	
Suprailiac Skinfold	Pre	30.34 ± 2.28	0.0001*	30.44 ± 2.9	0.0001*	30.16 ± 3.18	0.0001*
	Post	24.49 ± 2.46		25.14 ± 2.79		27.69 ± 2.73	

Data are presented as the mean ± standard deviation; **P* < 0.05 (significant).

RESULTS

Participants

There were 20 participants in each of groups A (five male and 15 female), B (six male and 14 female) and C (5 male and 15 female), respectively. Their characteristics are shown in Table 1.

Effect of ultrasound cavitation and diet (group A)

There was a significant decrease of 6.66% in bodyweight post-ultrasound cavitation and diet (pre: 88.7 ± 7.97; post: 82.79 ± 7.85; *P* < 0.0001). The BMI showed a significant reduction of 6.67% (pre: 32.67 ± 0.91; post: 30.48 ± 0.95; *P* < 0.0001). In addition, there was a significant reduction in waist circumference of 7.04% (pre: 105.65 ± 5.91; post: 96.35 ± 5.75; *P* < 0.0001). Finally, the suprailiac skinfold was significantly reduced by 19.28% (pre: 30.34 ± 2.28; post: 24.49 ± 2.46; *P* < 0.0001), as shown in Table 2.

Effect of cryolipolysis and diet (group B)

There was a significant decrease of 5.8% in bodyweight post cryolipolysis and diet (pre: 89.55 ± 10.56; post: 84.35 ± 10.4; *P* < 0.0001). The BMI showed a significant 5.85% reduction (pre: 32.4 ± 1.0; post: 30.5 ± 0.89; *P* < 0.0001). Furthermore, waist circumference was significantly reduced by 6.47% (pre: 104.3 ± 5.51; post: 97.55 ± 4.9; *P* < 0.0001). Finally, the suprailiac skinfold was significantly reduced by 17.41% (pre: 30.44 ± 2.9; post: 25.14 ± 2.79; *P* < 0.0001) as shown in Table 2.

Effect of diet (group C)

There was a 5.25% significant decrease in bodyweight post diet (pre: 89.48 ± 9.49; post: 84.8 ± 9.59; *P* < 0.0001). The BMI showed a significant reduction by 5.29% (pre: 32.7 ± 0.87; post: 30.97 ± 0.95; *P* < 0.0001). In addition, waist circumference showed a significant reduction of 3.03% (pre: 105.55 ± 4.95; post: 102.55 ± 4.72; *P* < 0.0001). Finally, suprailiac skinfold was significantly reduced by 8.18% (pre: 30.16 ± 3.18; post: 27.69 ± 2.73; *P* < 0.0001), as shown in Table 2.

Table 3 Comparison between the three groups in bodyweight, body mass index, waist circumference, suprailiac skinfold pre-treatment

Variables	Group A	Group B	Group C	P value
Bodyweight	88.7 ± 7.97	89.55 ± 10.56	89.48 ± 9.49	0.95
Body mass index	32.67 ± 0.91	32.4 ± 1.0	32.7 ± 0.87	0.55
Waist circumference	105.65 ± 5.91	104.5 ± 5.51	105.55 ± 4.95	0.54
Suprailiac skinfold	50.54 ± 2.28	50.44 ± 2.9	50.16 ± 5.18	0.94

Data are presented as the mean ± standard deviation; * $P < 0.05$ (significant).

Table 4 Comparison between the three groups in bodyweight, waist circumference, suprailiac skinfold post-treatment

Variables	Group A	Group B	Group C	P value
Bodyweight	82.79 ± 7.85	84.35 ± 10.4	84.8 ± 9.59	0.77
Body mass index	30.48 ± 0.93	30.5 ± 0.89	30.97 ± 0.95	0.18
Waist circumference	96.35 ± 5.75	97.55 ± 4.9	102.55 ± 4.72	0.001
Suprailiac skinfold	24.49 ± 2.46	25.14 ± 2.79	27.2	0.001

Data are presented as the mean ± standard deviation; * $P < 0.05$ (significant).

Comparison of the three groups pre-treatment

At baseline (pre-treatment), all parameters were similar among the examined groups, as revealed by the ANOVA test (Table 3).

Comparison of the three groups post-treatment

Post-treatment, there was no significant difference between the three groups in bodyweight ($P = 0.77$), and BMI ($P = 0.18$); while there was a significant difference among the three groups in waist circumference ($P = 0.001$) and suprailiac skinfold ($P = 0.001$), as revealed by ANOVA test (Table 4).

For waist circumference, there was no significant difference between group A and group B ($P = 0.46$), as revealed by a post hoc test. There was a better reduction in waist circumference in both groups A and B than in group C ($P = 0.001$) and ($P = 0.005$), respectively.

Concerning the suprailiac skinfold, there was no difference between groups A and B post-treatment ($P = 0.44$). Both groups A and B showed a better reduction in the suprailiac skinfold than group C ($P = 0.0001$) and ($P = 0.004$), respectively, as revealed by a post hoc test.

Safety of cryolipolysis and ultrasound cavitation

Most participants in the ultrasound cavitation and cryolipolysis groups did not report any complications such as pain or haematoma during or after treatment, as shown in Table 5. Some patients reported mild discomfort and numbness during application, which resolved after the session, and these participants did not complain at every session. Side-effects from ultrasound were minor, and only one participant reported the appearance of blisters on the abdominal region after ultrasound that disappeared within 48 h and only two participants with cryolipolysis reported bruising.

DISCUSSION

Our clinical study showed that both ultrasound cavitation and cryolipolysis systems are safe and effective for body

Table 5 Percentage of participants who reported complications during and after treatment

Variables	Group A		Group B	
	No.	%	No.	%
No complications	19	95	18	90
Complications	1	5	2	10

contouring and for decreasing abdominal adiposity. Both significantly reduced excess s.c. adipose tissue from the abdomen, as reflected by the decrease in participants' waist circumference and skinfold measurements. There was no significant difference between the two techniques with regard to the reduction of fat thickness. This reduction in fat thickness could not be attributed to the loss of bodyweight because the participants in both groups had a significant decrease in waist circumference and skinfold estimates compared to the participants in the control group. Additionally, there was no significant distinction between the participants of the three groups in weight loss towards the end of the treatment.

In the present study the utilisation of cavitation for 2 months reduced the abdominal circumference by approximately 7.3 cm and reduced the skinfold by approximately 5.58 mm. The utilisation of cryolipolysis after 2 months reduced the abdominal circumference by approximately 6.75 cm and reduced the skinfold by approximately 5.5 mm. The use of diet only for 2 months reduced abdominal circumference by approximately 3.2 cm and reduced the skinfold by nearly 2.47 mm.

To the best of our knowledge, no previous studies have compared ultrasound cavitation and cryolipolysis in participants with localised abdominal adiposity. Rather, the previous studies investigated the effect of either ultrasound cavitation only or cryolipolysis only, without comparing techniques.

Regarding the effect of ultrasound cavitation, the results of the present study agree those of with Savoia and colleagues, who reported that cavitation is safe and effective

for body contouring through reduction of s.c. fat thickness within the treated area.⁹ Savoia and colleagues recorded a reduction in waist circumference by approximately 6.2 cm after treatment for 2 months. Additionally, Fatemi reported a reduction of 4–5 cm in waist circumference after cavitation by the reduction of fat deposits.¹² Fatemi and Kane recorded a decrease in waist circumference by an average of 4.6 cm when using ultrasound cavitation on s.c. adipose tissue.¹⁵ Additionally, Saedi and Kaminer observed a reduction in abdominal circumference approximately 2 cm after using a single treatment of ultrasound cavitation.¹⁴

Furthermore, the results of the current study support the results of Ascher, who claimed that ultrasound cavitation is a compelling non-invasive technique for fat reduction and body contouring, which was demonstrated by a decrease of 3.58 cm in waist circumference after treatment.¹⁵ Moreover, Teitelbaum and colleagues found an average reduction in waist circumference of 2 cm after a single treatment of cavitation¹⁶ and Moreno-Moraga and colleagues reported an average of 3.95 cm waist circumference reduction after ultrasound cavitation.¹⁷ Also, Shek and colleagues reported a 2.1 cm reduction in waist circumference in Chinese after 12 weeks of treatment by high intensity focused ultrasound.¹⁸ Moreover, Tonucci and colleagues reported reduction of 1.5, 2.1, and 1.9 cm in the waist, abdominal and umbilical circumferences, respectively, after five sessions of low-frequency, low-intensity ultrasonic.¹⁹ On the other hand, Shek and colleagues claimed that focused ultrasound is not effective for non-invasive body contouring among southern Asians.²⁰ The difference in results may be attributed to the variations of body size between southern Asians and our participants, in whom the targeted surface area is larger than that of the southern Asians that produced more fat reduction.

Ultrasonic waves create compression cycles that exert positive pressure, and expansion cycles that exert negative pressure. This pushing and pulling effect can prompt the cracking of fat cells. Ultrasonic energy into the deeper fat layers can prompt cavities in the fat and theoretically decrease the overall thickness of the adipose layer. The mechanical acoustic effects of ultrasound cavitation caused selective fat cell disruption without injury to skin, vessels, nerves or connective tissue.^{2,17,21}

After disturbance of the fat cells, the substances, principally triglycerides, are scattered into interstitial space and afterwards transported through the vascular lymphatic framework to the liver. These triglycerides are hypothetically retained gradually and after that are metabolised by endogenous lipases to glycerol and free unsaturated fats. The unsaturated fats are transported to the liver where they are handled like the other unsaturated fats. Unmetabolised triglycerides are combined with transporter proteins or lipoprotein complexes, ending up as part of the aggregate lipoprotein pool. To date, there have been no changes in serum lipid profiles observed in ultrasound cavitation investigations.²

Concerning the impact of cryolipolysis, the results of this study backed the findings of Ferraro and colleagues, who stated that cryolipolysis is a powerful, and well-endured

non-invasive methodology for body contouring and the reduction of fat thickness.²² The authors recorded a decrease in the abdominal circumference by 6.86 cm. Moreover, Shek and colleagues recorded a 4.9 mm decrease in fat thickness measured by a caliper following 2 months of treatment by cryolipolysis in the abdominal region.²⁵ Likewise, Macedo and colleagues claimed that cryolipolysis is beneficial in the treatment of overabundant fat tissue in the flanks or abdomen area as a consequence of fat modulation.⁴ Additionally Dierickx and colleagues²⁴ and Sasaki and colleagues²⁵ proved that cryolipolysis is a safe, comfortable, and effective method for s.c. fat reduction.

Cryolipolysis decreases the circumference in treated regions by reducing fat thickness. Cryolipolysis-induced fat layer attrition results from the fatal apoptotic injury of adipocytes when exposed to cold temperatures. Previous studies have shown that cooling non-invasively induces adipocyte death that leads to a lessening in fat layer thickness.^{26–29} The loss of adipose tissue volume occurs gradually over time as the adipocytes are removed through an inflammatory clearing process that peaks within 2–3 months after exposure to cold.^{29–31}

Inflammatory mediators trigger phagocytosis,²² which accounts for the removal of adipocytes and the loss of fat tissue.^{25,30} Over time, this leads to a slow removal of destroyed adipocytes, with no consequent effect on lipid levels in the bloodstream and liver. Furthermore, previous studies^{22,29} showed no changes in liver function markers, suggesting that fat discharged from treated regions was cleared by the natural fat metabolism pathways.

In our study, both ultrasound cavitation and cryolipolysis were characterised by fewer post-treatment drawbacks. Both were well tolerated, with most patients reporting minimal or no discomfort during and after therapy. In addition, neither procedure constrained any activities; all participants were able to return to their normal activities at the end of every session.

Our study provides a comparison between ultrasound cavitation and cryolipolysis to determine the most effective non-invasive procedure that can be used to reduce fat thickness and improve body contours in the abdominal region. Both procedures were shown to be safe and were effective at reducing abdominal adiposity. No difference was observed between the two techniques. One possible limitation of the current study is the lack of a laboratory investigation of lipid profiles or liver enzymes, which may be needed to complete the comparison between ultrasound and cryolipolysis regarding their safety. Another possible limitation is that more accurate measurements specific for measuring abdominal s.c. tissues thickness were not used, such as ultrasonography.

Further studies are required to compare between other non-invasive procedures for localised fat reduction to determine the best methodology with the use of lipid profile or liver enzymes investigations. Additionally, these treatment modalities can be further compared without the participants participating in a weight loss programme (diet) to figure out whether the fat thickness is lessened by the same degree as with dieting.

CONCLUSION

Ultrasound cavitation and cryolipolysis are effective, safe, and well tolerated non-invasive procedures for the reduction of fat thickness in the abdominal region. Both techniques produced nearly equal reduction in waist circumference and skinfolds, and both can be used for body contouring.

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