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contents

Cryolipolysis treatment of subcutaneous fat reduction in lower face and neck : A short-term Clinical study

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Abstruct

A variety of interventions to reduce subcutaneous fat in lower face and neck have been reported. However, conservative treatments are only temporarily effective and surgical procedures have associated downtimes and complications that may be unacceptable for the treatment of a benign condition. While Cryolipolysis seems to be promising in body fat reduction, cheek or lower face treatment with cryolipolysis has not been reported. We report a new technique to resolve these problems.

In a one-year period, twentyseven patients underwent this procedure for fat reduction in lower face. We used the CLATUU Alpha (Classys inc., Seoul, Korea) which is a cryolipolysis system for cheek and submental areas. A small-volume cup applicator was used to administer two cryolipolysis treatments, delivered in 40-minute treatment cycles. Two treatments with an interval of four weeks were performed.

Twenty-one patients were followed over 8 weeks postoperatively. All of them were satisfied with the results in terms of effectiveness and minimal postoperative limitation. Postoperative pain was mild. Ecchymosis and numbness usually resolved within a week. Facial nerve injury was not observed. No recurrence, hematoma, infections, skin necrosis, or hypertrophy occurred.

Introduction

Attempts to reduce facial adiposity by diet or exercise alone are often unsuccessful. Over the years, a variety of surgical and non-surgical medical interventions have been used to remove subcutaneous fat in the lower cheek and chin.

Cryolipolysis, the application of controlled cooling to non-invasively damage subcutaneous adipocytes, is based upon the greater susceptibility of lipid rich adipocytes to cold injury compared to surrounding water rich cells. Cryolipolysis has been shown to safely and effectively reduce subcutaneous fat on the body.

To reduce subcutaneous fat in lower face and neck, two types of novel small-volume vacuum cup applicators were developed and clinically investigated. The goal of our study was to examine the safety and efficacy of cryolipolysis for non-invasive fat reduction and tightening of lower cheek and submental area.

Materials and Methods

In a 1-year period, 27 female patients (age range, 23 to 64 years; mean age, 39.2 years) underwent this procedure for reduction of localized adiposity in the lower cheek and submental neck areas. Patients were selected with the criteria listed in Table 1.The procedures were performed by the first author (K.I.) at the clinic on an outpatient basis with local anesthesia cream. All subjects gave informed consent for the clinic Institutional Review Board-approved protocol, which was based on the Declaration of Helsinki.

The primary objective of this study is to evaluate the safety of lower cheek and submental fat reduction with the novel cryolipolysis equipment (CLATUU-alpha System, Classys Inc., Korea). Safety is defined as incidence of device- and/or procedure-related adverse events.

Two types of small-volume cup applicators were used to administer two cryolipolysis treatments, delivered in 80-minute treatment cycles (temperature -9°C, duration 40 minutes for both cheeks and 40 minutes for neck). Flat cups were applied for cheeks, and a contoured applicator was used for neck (Figure 1). Two treatments with an interval of 4 weeks were performed.

A protective gel pad was applied to the skin. The flat cup small volume applicators were positioned in the bilateral lower cheeks, and vacuum suction was initiated (Figure 2). Next, the contoured cup was positioned in

the center neck submental area, and suction was started. Positioning of vacuum cup must avoid lower bony contour (i.e., border of mandibular bone) to prevent marginal mandibular nerve injury. The vacuum adhered the applicator to the treatment area and special cushions provided additional support throughout the each 40 minutes treatment. Patients were instructed to remain relaxed and still throughout the treatment. At the end of procedure, the area was manually massaged for a few minutes allowing the tissue to regain its original shape.

The secondary objective endpoints included assessment of neck fat layer thickness. All patients were also evaluated before and after 8-week post last treatment by digital photography, subject satisfaction surveys, and 2-dimensional ultrasound imaging.

Ultrasound images were acquired at baseline and 8 weeks post-final treatment visits with the subject lying in a supine position. A 7-MHz resolution linear transducer was used to acquire ultrasound images of the submental treatment site (Viamo, Toshiba, Japan). The transducer was positioned medially in the sagittal plane. Ultrasound images were processed to measure anatomical features in the pre and post-treatment images and the neck fat layer reduction was calculated.

Table 1

Patient exclusion criteria

1. Weight change exceeding 10 pounds during the course of the study.
2. Machine treatment with cavitation ultrasound, high-intensity focused ultrasound, radiofrequency or laser procedures in the area.
3. Botulinum toxin injections and fat-melting injection within the area.
4. History of fat reduction surgery procedure in the area.
5. Current dental infection.
6. Known history of cryoglobulinemia, cold urticaria, or paroxysmal cold hemoglobinuria.
7. Known history of Raynaud's disease, or any known condition with a response to cold exposure that limits blood flow to the skin.
8. Impaired skin sensation or thermal sensitivity in the area.
9. Open or infected wounds in the area.
10. Currently taking or has taken diet pills or weight control supplements within the past month.
11. Any dermatological conditions, such as scars in the location of the treatment area that may interfere with the treatment or evaluation.
12. Active implanted device such as a pacemaker, defibrillator, or drug delivery system.
13. Pregnancy or intending to become pregnant in the next 5 months.
14. Lactating or has been lactating in the past 6 months.

Results

Twenty-one patients were followed over 8 weeks after the last session. All of them were satisfied with their results in terms of effectiveness and minimal postoperative limitation to their social activities. Results are summarized in Table 2.

Lower cheek and submental fat elimination assessed with digital photograph was graded as either good, fair, or poor. A good result indicates that both patient and physician found apparent reduction and tightening of the area. Fair was defined as a minor change noticed by physician but unnoticeable for patient.

A poor result required that the patient and clinician were not aware of any changes.

Figures 3- 4 show representative subjects at baseline and at 8 weeks after second treatment. Visible reduction in lower cheeks and submental fullness is demonstrated from the pre and post-treatment photographs.

Ultrasound images were analyzed to calculate neck fat layer reduction. The measurement showed a mean reduction of 1.85 mm, with a range from no increase to a reduction of 3.0 mm.

All subjects were evaluated for side effects at the treatment sites and assessed for side effects including erythema, edema, bruising, numbness, and tingling at the treatment site. In addition, any other side effects were also assessed and recorded. No hematoma, infections, skin necrosis, or hypertrophic scar occurred.

The adverse effects of the procedure were typically mild and resolved without intervention by the final 8-week

follow-up visit. Numerical rating scale (NRS) of patient satisfaction (from zero to ten) was recorded at second and final visit. The mean score at 4 weeks after one session was 4.2, and increased to 6.8 at 8 weeks after two sessions.

Table 2

Postoperative evaluation of 21 patients

Variable	number
Fat elimination	
Good	11/21
Fair	7/21
Poor	3/21
Reduced thickness of fat	
>3.0mm	0/21
3.0mm	4/21
2.0mm	12/21
1.0mm	3/21
No change	2/21
Complications	
Bruising	2/21
Erythema	18/21
Edema	16/21
Hematoma	0/21
Hyperpigmentation	2/21
Infection	0/21
Facial nerve injury	0/21
Neck movement limitation	0/21
Numbness	17/21
Paradoxical adipose hypertrophy	0/21
Scar formation	0/21
Skin Necrosis	0/21
Tingling	5/21
NRS patient satisfaction score	
Timing of measurement	mean
4 weeks after one session	4.2/10
8 weeks after two sessions	6.8/10

Discussion

A variety of interventions to reduce subcutaneous fat in lower face and neck have been reported. The fat volume and position of the face and neck changes as it ages. Increases in fat in the lower cheek and neck compartment play a crucial role in the perception of aged looking [1-2].

Fat reduction of lower face and neck has been primarily limited to surgical liposuction. While liposuction may provide the most apparent result, many patients are reluctant because of the downtimes and risks.

However, conservative treatments are only temporarily effective and surgical procedures have downtimes and complications that may be unacceptable for the treatment of a benign condition.

Non-surgical fat reduction methods have been developed and are gaining popularity. Injectable fat loss methods have been researched for over a decade. But the study involved up to six treatment visits with up to 50 injections per visit in the clinical trials [3-5]. The trend in cosmetic medicine is non-invasiveness, but effectiveness and durability are also required.

Cryolipolysis, the application of controlled cooling to non-surgically damage subcutaneous fat, is based upon the greater susceptibility of lipid rich adipocytes to cold injury compared to surrounding water rich cells. Cryolipolysis has been shown to safely and effectively reduce subcutaneous fat on the body such as treatment of the flanks, abdomen, and thighs [6-8].

We report a new technique to resolve these problems in the management of subcutaneous fat in lower face and neck. The method we reported is facial application of the cryolipolisis system used for body liposculpture, which is a relatively new technique and still under development. Flat and contoured types of small volume vacuum applicators were evaluated for cryolipolysis treatment of lower cheek and neck.

There was no incidence of serious complications. Common side effects such as erythema and numbness were mild and self-resolving. Cryolipolysis was demonstrated to be safe and effective for subcutaneous fat reduction of lower cheek and neck.

Efficacy of treatment was assessed by clinical photographs and ultrasound imaging. For the photographs, subjects were photographed capturing front, side profile, and 45° oblique images. Photos were taken at pre-treatment, 4 weeks post-treatment, and 8-weeks post-final treatment follow-up visits. A limitation of the study is that the face and neck fat reduction wasn't quantified using a standardized scale, thus providing an assessment of the relative clinical improvement. This study was designed similarly to previous studies which evaluated efficacy by review of clinical photographs, ultrasound measurement of fat layer reduction, and patient surveys [9-11]. Mean fat layer reduction was measured by ultrasound to be 1.8 mm. This result is lower compared to other cryolipolysis studies for thighs [9,11], however, the fat layer reduction was appreciable for a small volume treatment of the chin area.

While cryolipolisis is promising, it is not appropriate for all patients seeking neck and facial rejuvenation by reducing submental fat. For patients with excessive skin and muscle laxity, surgical procedures will still be necessary to improve the contour [12]. But for many patients wishing to reduce facial fat, cryolipolysis with a small volume applicator provides a safe and effective treatment option.

Cryolipolysis seems to be superior in downtimes and postoperative immobilization, however, surgeons must remember that direct cooling application to cheek subcutaneous layer has a certain risk of facial nerve complications. The marginal mandibular nerve of the facial nerve is frequently injured during corrective and cosmetic surgery. Positioning of vacuum cup must avoid lower bony contour (i.e., border of mandibular bone) to prevent marginal mandibular nerve injury. Marginal mandibular brunch runs superficially near mouth. Controlled positioning of applicators, and even distribution of cooling energy and vacuum fixation are fundamental for safe practice.

To date, there is only one report of marginal mandibular nerve injury following submental cryolipolysis over one hundred patient procedure reviews [13-15]. Submental and cheek cryolipolysis require in-depth knowledge of this nerve and safe positioning of applicators, cooling level, vacuum power, and patient selection. Every facial procedure needs facial nerve anatomy for prevention of nerve injury. So this procedure should be done by plastic surgeons experienced in facial liposuction and surgery.

Longevity of effectiveness was unknown because this was a short-term study. Some fat tissues may recover from temporal damage, and work again after a year or longer. Future studies should aim to optimize customization by selecting the appropriate applicator to maximize tissue draw for the facial area and treatment characteristics while obtaining long-term follow-up data. The efficacy of this technique in areas that have been treated previously with liposuction remains to be studied. We need more data to present this issue.

Conclusion

As demonstrated by 21 patients followed in the study, lower cheek and submental fat can be reduced safely and effectively with a small volume cryolipolysis applicators.

While the outcomes are mild, this technique is suited for the patients who desire local reduction at modestly sized facial fat without surgery. As shown by patients, cryolipolysis produced visible tightening effect in the lower face and neck contour, and generated high patient satisfaction.

Although the specific mechanism has not been completely elucidated, cryolipolysis in the lower cheek and submental area appears to be effective and safe in the short term, with a limited side effect profile.

Moreover, it appeared to be clear that cryolipolisis facial treatment has various potential for plastic surgery for

maxillofacial contouring and rejuvenation of the aging face. Further studies are required for basic research and long-term analyses. With adequate selection of applicators and patients, cryolipolisis treatment can be a new option for fat reduction of lower face and neck.

FIGURES

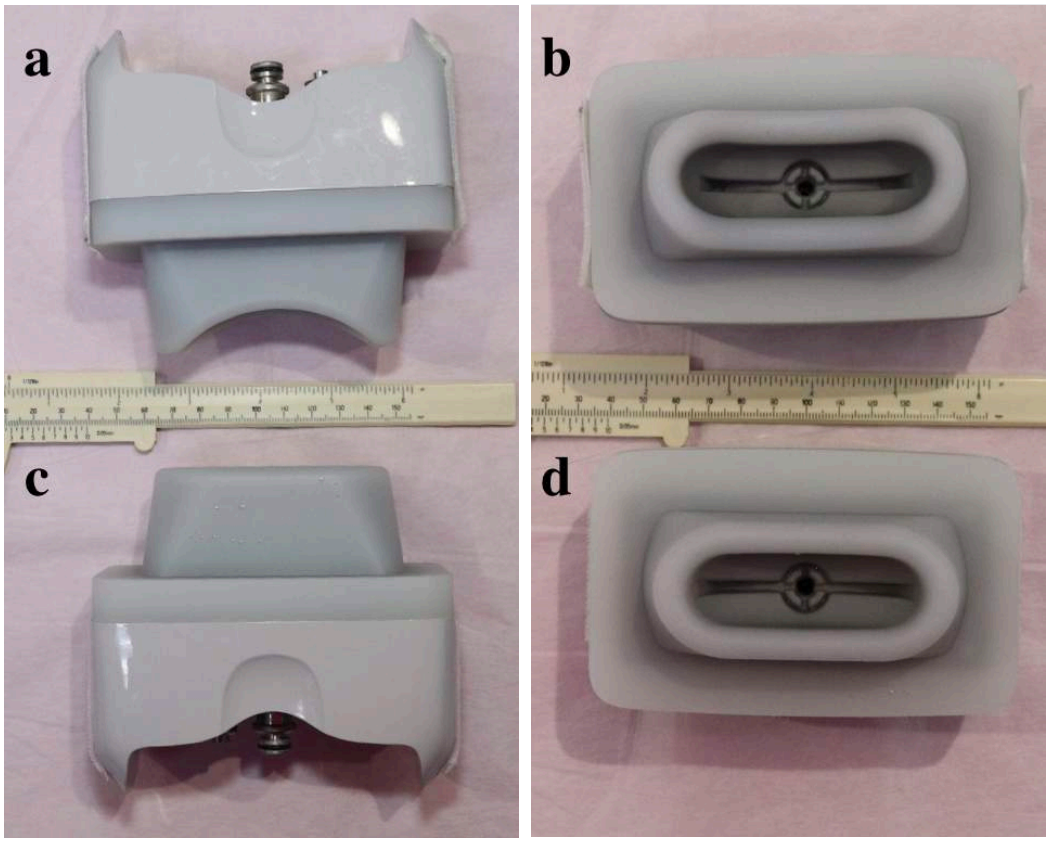

Figure 1. Small volume applicator for neck (a) side view and (b) top view showing contoured cooling surface. Small volume applicator for lower cheek (c) side view and (d) top view showing flat cooling surface.

Figure 2. The small volume applicators for lower cheeks were placed and secured by vacuum suction and cushions.

Figure 3. Baseline (a, b) and 8 week after 2 sessions of treatment (c, d) photos for a 23 year-old female.

Figure 4. Baseline (a, b) and 8 week after 2 sessions of treatment (c, d) photos for a 27 year-old female.

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CLATUU Alpha Body Contouring: Effective Treatment for Thighs and Double Chin

Subtitle: CLATUU Alpha Helping Medical Practitioners Provide Comfortable Treatments

Dr. Ki-Bum Kim (Chief of Dermatology, Misogain Clinic in Gimpo)

Introduction of CLATUU Alpha and Its Features

Concept

These days, it seems that a marketing strategy with the right product concept is significant. The CLATUU Alpha is a good example of this. There are numerous types of treatments for the double chin and thighs. However, instead of emphasizing the utilized technology, CLATUU Alpha treatment chooses to emphasize specific types of treatment applicators such as Wing V (for double chin treatment) and Alpha Queen (thigh treatment), which are very helpful when marketing. This is especially true as a large number of consumers (patients) have already shown a lot of interest in the Ultraformer III lifting concept from CLASSYS. Although it is paramount to quickly analyze and accept marketing trends in aesthetic medicine, when it comes to considering medical devices as a medical practitioner, treatment efficacy and its safety should be thoroughly considered. But I have strong confidence in the medical devices from CLASSYS after using the original CLATUU 360 so I did not need to hesitate when considering the purchase of this medical device, CLATUU Alpha.

Efficacy

Recently, the most popular treatment for double chin is injection treatment and a large number of treatments have been performed up to now. However, there are still many patients with a needle phobia and with that particular treatment, multiple injections are needed, which is a burden on the patients. In this sense, it is good to see that there is a non-invasive but effective double chin treatment. Compared to other parts of the body, the double chin area has a relatively small amount of adipose tissue. Despite the apoptosis treatment mechanism, actual results from the treatment can start to appear after a week post treatment and continue for about a month. Whenever the patients visit for their follow-up appointment, they are able to see results of the treatment and they have heard a positive comment from others about the results. So I can say this device can be quite successful.

It is difficult to remove thigh fat effectively and find suitable thigh treatments due to the characteristics of adipose tissue in the thigh area. Although RF (radiofrequency) treatment is usually performed for this, it is a time-consuming and labor-intensive treatment. The thigh treatment called Alpha Queen is easy to do, as after attaching the applicator to the treatment areas, the auto recognition system recognizes the applied applicator and proceeds with the treatment automatically with set parameter. All the physician needs to do is to complete the treatment by turning off the device.

Instead of using the cup-type applicator, I used to apply the other company's flat-type plate applicator to deliver cooling energy to the thighs. Personally this type of treatment seemed to be inconvenient for me. While analyzing the advantages and disadvantages of the other company's cryolipolysis devices, I observed that the larger size applicators for thigh treatments from CLATUU Alpha are very ergonomic and conscientious of women's thigh shape in Asia. Also this applicator can be applied on the abdomen areas which is another benefit. The thigh applicators are designed to treat the thigh areas but I did apply this on the abdomen areas following the analysis of the mechanism of cryolipolysis. To my delight, the result from the abdomen treatment was quite successful which made me more encouraged to make the decision to purchase this device.

WING V

FLAT V

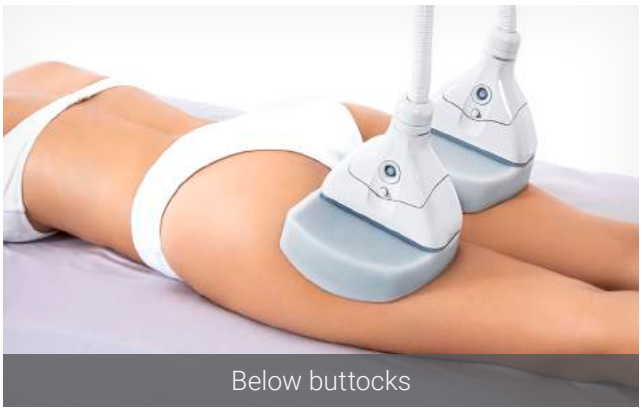
Why CLATUU Alpha?

There are three main types of treatments in dermatology: pigmentation-based, skin elasticity and obesity treatments. Pigmentation and skin elasticity treatment are normally treated with laser or ultrasound-based medical devices. Medical practitioners' labor and his or her treatment experience are the key factors for treatment effectivity. The optimal result is achieved with the combination of the main medical devices and other combined treatments based on the patient's indications.

In the case of obesity treatments, it takes a relatively long time compared with pigmentation or elasticity treatment, and the effect of the obesity treatment is gradually noticed. Therefore, from the doctor's perspective, I tend to be more hesitant and tentative when purchasing those types of medical devices.

This device allows the physicians to proceed with comfortable treatments with better results, which is the most appealing aspect. The CLATUU Alpha is a hands-free device. Once the physician attaches the applicator to the intended treatment areas, there is nothing to do for the physician. It is very convenient, as the physician only needs to complete the treatment after pre-setting the time. In the meantime, the physician is able to continue to treat other patients.

Front thighs



Below buttocks

Lateral thighs

Inner thighs

ARC-T

Precautions

When the physician understands the basis of cryolipolysis, there are no special precautions to note. It may be a bit uncomfortable due to the gel from gel pad, but an experienced staff can handle this efficiently. The most common issues from cryolipolysis treatment generally result from inappropriate use of the gel pads. However, the physician can proceed with the treatment without those concerns, as the device is designed to prevent those issues. Also, if there are unexpected side effects, CLASSYS will respond to deal with those issues. Therefore, the physicians are treating the patient without much concern.

In the case of patients with too small amounts of adipose tissue, it is hard to suction the tissue into the applicator. So the treatment is not recommended for those patients, as the patient is not suitable for the treatment.

Suction 3 | Cooling 5 | Duration 40min

Before Treatment | 7 weeks Post Treatment

Suction 3 | Cooling 5 | Duration 40min

Before Treatment | 8 weeks Post Treatment

Suction 3 | Cooling 5 | Duration 40min

Before Treatment | 4 weeks Post Treatment

Suction 3 | Cooling 5 | Duration 40min

Before Treatment | 5 weeks Post Treatment

Suction 3 | Cooling 5 | Duration 40min

Before Treatment | 6 weeks Post Treatment

Suction 3 | Cooling 5 | Duration 40min

Before Treatment | 12 weeks Post Treatment

Suction 3 | Cooling 5 | Duration 40min

Before Treatment | 4 weeks Post Treatment

Suction 3 | Cooling 5 | Duration 40min

Before Treatment | 8 weeks Post Treatment

Wing Max (Arc-A): Time-saving and relatively effortless treatment with better clinical outcomes for lower abdomen

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The body contouring market has been growing rapidly around the world in line with increasing number of obese population. According to the global body contouring market outlook for 2016 to 2024, the body contouring market size is set to reach USD 1.2 billion by 2024, at a CAGR of 7.1% over that range. In the recent years, non-surgical procedures have gained popularity as consumers look for less painful, more cost-effective and safer alternatives to get their desired body shape. Non-invasive methods have been performed a lot recently and one of the most popular methods is cryolipolysis. This modality is basically a procedure based on the principle that fat is vulnerable to cooling energy. When exposed to cooling energy, fatty tissues start to disintegrate which induces the programmed death of fatty tissues which is called apoptosis. The accurate application of cooling activates apoptosis of the fatty tissues, which induces an inflammatory response and the surrounding macrophages then digest the cell debris. This scientific evidence is the basis upon which the cryolipolysis treatment was developed.

Cryolipolysis procedures have proven to be safe and effective procedure for body contouring and have been in place for approximately 10 years. Numerous clinical articles and studies have demonstrated the effectiveness and safety of the clinical outcomes post cryolipolysis treatments. As shown in statistical data, more consumers prefer to choose non-invasive body contouring treatment due to the fact that it requires no anesthesia, consumers feel less pain, and they can return to their daily routines immediately post treatment. In particular, cryolipolysis procedures are convenient for the physicians as well as the patient. If physicians have in-depth anatomical knowledge and the underlying mechanisms of cryolipolysis, it will be very easy for them to proceed the treatment, regardless of their experience.

I recently began using the Clatuu Alpha (known as Clatuu in Russia) while using the Clatuu 360. The Clatuu Alpha (CLASSYS, South Korea) has seven applicators specially for the body contouring procedures in a variety of areas including double chin, bra fat, flanks, upper and lower abdominal fat, above the knee and thighs fat. Each applicator is designed to be specific to a variety of sites, and among them, the large abdominal applicator, called Wing Max (also known as Arc-A in Russia) seems to be quite innovative in terms of its capability of suctioning and covering a large amount of subcutaneous fatty tissues. Figure 1 shows the Arc-A applicator applied to lower abdomen and hand-piece is supported firmly by a cushion. Figure 2 shows the treatment areas after removing the hand-piece, indicating a large area of the lower abdomen were well suctioned. Figure

3 shows a result of Arc-A treatment on lower abdominal areas and as clearly shown below, without any weight loss, reduction in fat bulging on lower abdomen (marked in red) was quite noticeable.

Figure. 1. During Treatment: Specially designed cushion supporting the Arc-A (Wing Max)

Figure. 2. After removing the applicator

Figure 3.

In clinical studies, cryolipolysis was proven to reduce subcutaneous fat layers at the treatment site by up to 25% after just one treatment. Figure. 4 shows 5 weeks' follow-ups photos after one Arc-A (also known as Wing Max) treatment. Table. 1 shows body circumferences at navel level, 5 centimeters above and below the navel and patient's weight after one treatment session of the treatment. It is noticeable that 2 centimeters reduction of waist circumferences at navel level was recorded while the patient had weight gain from 66.3 kg to 66.8 kg (+0.5kg) 5 weeks- following the procedure. This results are quite impressive and the patient was satisfied with this.

Figure 5 also shows the results after two Arc-A treatments on the upper and lower abdomen. The waist circumference size reduced from 114 cm (before treatment) to 106.5 cm (-7.5cm) 4 weeks post treatment without any significant weight change. Although the patient had a slight weight gain from 90.4kg to 90.6 kg, waist circumference reduction was 7.5 cm. At week 9, the patient had weight gain from 90.4 kg to 91.5 kg but as shown below in figure. 5, the fat reduction effect on the abdomen remained steady, indicating cryolipolysis is effective for localized fat reduction.

Figure. 6 shows lateral and frontal photos and its measurements after 9 weeks post treatment. In this case, the patient experienced weight loss as well as waist circumference reduction effect. The best results were recorded at week 9 with -3.5 centimeters waist circumference reduction and – 1.5 kg weight loss. As shown below in figure. 6, cryolipolysis results are long-lasting, as adipocytes are actually destroyed and gradually removed from the body's lymphatic system.

Figure 4.

Before Treatment | 5 weeks Post Treatment

Table 1.

Circumference Measurement	Before Treatment (10/30)	2 weeks post treatment (11/13)	3 weeks post treatment (11/20)	5 weeks post treatment (12/03)
5cm above navel	77.5cm	76cm (-1.5cm)	76.5cm (-1cm)	75cm (-2.5cm)
navel	88cm	87cm (-1cm)	86cm (-2cm)	86cm (-2cm)
5cm below navel	97cm	95.5cm (-1.5cm)	95cm (-2cm)	96cm (-1cm)
Weighs (kg)	66.3kg	65kg	67kg	66.8kg

Figure 5.

Before Treatment | 9 weeks Post Treatment

Table 2.

Circumference Measurement	Before Treatment (10/25)	1 weeks post treatment (11/6)	4 weeks post treatment (11/29)	9 weeks post treatment (01/03)
6cm above navel	102.5cm	102cm (-0.5cm)	96.5cm (-6cm)	101.5cm (-1cm)
navel	114cm	110cm (-4cm)	106.5cm (-7.5cm)	111cm (-3cm)
6cm below navel	121cm	119.5cm (-1.5cm)	116cm (-5cm)	117cm (-4cm)
Weighs (kg)		90.4kg	90.6kg	91.5kg

Figure 6.

Before Treatment | 9 weeks Post Treatment

Table 3.

Circumference Measurement	Before Treatment	1 weeks post treatment (11/7)	4 weeks post treatment (11/27)	9 weeks post treatment (01/07)
navel	93.5cm	94cm (-0cm)	91.5m (-2cm)	90cm (-3.5cm)
5cm below navel	101cm	100.5cm (-0.5cm)	100cm (-1cm)	100cm (-1cm)
Weighs (kg)	71.6kg	71.6kg	71.9kg	70.1kg

Most cryolipolysis devices have similar applicator sizes and shapes. However, the Arc-A (Wing Max) applicator is nearly twice the size of the Wing applicator. In fact, when this applicator is applied on the treated areas, the area covered is twice that of Wing applicator. Many patients were concerned about the pain and discomfort during the procedure because of the noticeably larger applicator size. However, the level of pain during this procedure is quite bearable and similar to other Clatuu Alpha procedures. There is no pain aside from the cooling and tugging sensation on the treatment areas at the beginning of the treatment. Then treated areas become numb after about 10 minutes, so pain also dissipates accordingly. Generally, side effects are quite minor including redness and tenderness. Most minor side effects disappear within a few days to weeks after the procedure.

The Clatuu Alpha has dual hand-pieces which means multiple areas can be treated simultaneously. A large number of adipocytes in the lower abdomen can be effectively suctioned using one hand-piece, so another hand-piece can be utilized for the treatment of the double chin or the upper abdomen. Figure. 7 indicates how 2 different areas are treated simultaneously. It is time-saving and relatively effortless treatment with better clinical outcomes. In addition, compared to the labor-intensive procedure like radiofrequency or high intensity focused ultrasound, the treatment allows physicians to have relative freedom during the treatment duration once the applicator is applied on the treatment areas and treatment begins. This is a huge advantage especially for the physicians in busy and hectic clinics.

Figure 7. Double chin and lower abdomen treatment with Arc-A (Wing Max) and Wing Mini

In the body contouring market, a majority of customers wish to reduce abdominal fat, especially fat in the lower abdomen. According to statistics from the North American Journal of Medical Science, the most commonly desired areas for body contouring is the abdomen. In many cases, more than 66 % of body contouring areas is the abdomen especially in the lower abdomen. The accumulation of abdominal subcutaneous fat often occurs as a result of childbirth or lifestyles such as drinking alcohol, having a sedentary lifestyle or overeating. In particular, due to a large number of fatty tissues accumulation in the lower abdominal region, a general type of applicator may not be suitable for the treatment of this area for some patients. To address that matter, the Arc-A (also known as Wing Max) applicator has been introduced and is an innovative applicator that can solve these problems. Patients are able to notice their treatment results in as little as 4 weeks post treatment and the frozen fatty tissues continue to leave outside of the body through the lymphatic system for 2 to 3 months.

There are numerous medical devices available in the field of aesthetic medicine, and it is paramount for physicians to be informed about each device and its modalities correctly as well as safety and efficacy to provide optimal treatment options for all customers.

CLATUU Alpha Rapidly Freezes Fat : Crystalizing fatty tissues in less time to re-contour various body areas

Dr. Villy Rodopoulou, MD | Greece

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Engineered to be physician- and patient-friendly, CLATUU Alpha, a recent offering from Classys, Inc. (Seoul, South Korea), harnesses the concept of cold panniculitis to achieve excellent results in less time, as well as the ability to re-contour more body areas than ever before. Treatment cost is also greatly reduced due to the dramatically lower expense of associated consumables.

As plastic surgeon Villy Rodopoulou, M.D., of the KOSMESIS Aesthetic Plastic Surgery Center (Athens, Greece) explained it, "Body contouring is extremely popular all over the world and cold-based treatment is one of the best ways to achieve results non-invasively, as long as patients have manageable localized unwanted fatty deposits. However, there have always been limitations. Treatment sessions are long and expensive, and until recently you could only treat certain body areas."

According to Dr. Rodopoulou, CLATUU Alpha's patented 360° Surround Cooling Cup technology provides approximately 20% better suction and achieves 18% better coverage than the previous version by cooling more internal fatty tissue to temperatures as low as other devices.

"By using this three-dimensional (3D) cooling cup rather than the usual two-plated/sided applicator, we get a deeper and more uniform 3D cooling effect, crystallizing fatty tissue without damaging skin. Improved suction allows us to reach lower temperatures safely, which gives us a better tissue response," said Dr. Rodopoulou. The duration of treatment totals about 45 minutes per session (covering two areas) rather than the 50 to 70 minutes seen with competing devices.

Experts discuss advanced energy-based face-lifting solutions

The device also features an expandable range of interchangeable cup sizes and shapes, allowing physicians to treat more body areas effectively. Cup offerings include Flat (abdomen, arms, inner thighs, anterior thighs, pubis, buffalo hump), Flat Mini (submentum and lateral neck, axila, knees), Wing (abdomen, flanks, gynecomastia in men and love handles), Wing Plus (abdomen, bra line, love handles, flanks and below the buttocks), and Wing Mini (submentum, axilla, knees).

"We can treat almost from head to toe, at least to above the knees," Dr. Rodopoulou stated. "Even difficult, but popular treatment areas, such as around the knees, can be reduced using CLATUU Alpha, and it is very easy to change cups."

A novel but obvious innovation is CLATUU Alpha's dual cup configuration; each cup is independently adjustable and can attach to the body at any angle thanks to the device's flexible arms. In addition to treating more rapidly per applicator, the ability to use two cups simultaneously from a single platform further speeds the treatment.

"Obviously, bilateral treatment will provide a better overall result faster, but any aesthetic device is costly, so being able to do this with a single device, as with CLATUU Alpha, provides us this functionality without having to purchase two machines," Dr. Rodopoulou stated.

In Dr. Rodopoulou's opinion, the cost of treatment is an especially attractive benefit for those residing in places such as Greece where the economy has been slow to rebound from a strong recession.

“With CLATUU Alpha the cost of consumables is very reasonable, so we are not forced to pass this cost on to the patient,” she said. “Here in Greece, and in the rest of the world, low cost makes this modality more accessible because more people can afford it, thus demand is driven by affordability as well as the safety, comfort and efficacy of treatment.”

Female patient brfore and three months after treatment of double chin and lateral neck redution with CLATUU Alpha
Photos courtesy of Villy Rodopoulou, M.D., E.B.O.P.R.A.S.

Body Contouring: Improved body contour by Combination - treatments

Dr. Gerd Gauglitz, MD | Germany

Body contouring has become a trend. In this way, more and more Germans want their thick lining with different processes of the body of optimizing the silhouette. Non-invasive treatments combination of radiofrequency and cryolipolysis promise good results reported by PD Dr. Gerd Gauglitz, Munich, during an event in the framework of this year's dermatology practice in Frankenthal.

Fig. 1: PD Dr. MD. Gerd Gauglitz (Munich), lecturer during the event in Frankenthal.

Body contouring is a scarce commodity - the area is a growing market with growth rates of up to 15%, said PD Dr. Gerd Gauglitz, Department of Dermatology and Allergology, Ludwig-Maximilians-University of Munich. Procedures for body contouring were now in greater demand in Germany. While the method is highly advertised with colorful images of slim candidates (which usually require no shaping), he sees patients in daily practice.

Different constellations: With skin laxity and well-defined fat deposits, those with good skin quality, but clearly overweight, as good as people with bad skin and overweight both quality and those with good skin quality and distributed fat deposits. The subcutaneous fat tissue or perspiration (superficial subcutaneous adipose tissue) can be used both by invasive processes (Liposuction, abdominoplasty, etc.). – With all known risks and side effects - as well as non-invasive, Gauglitz reminded.

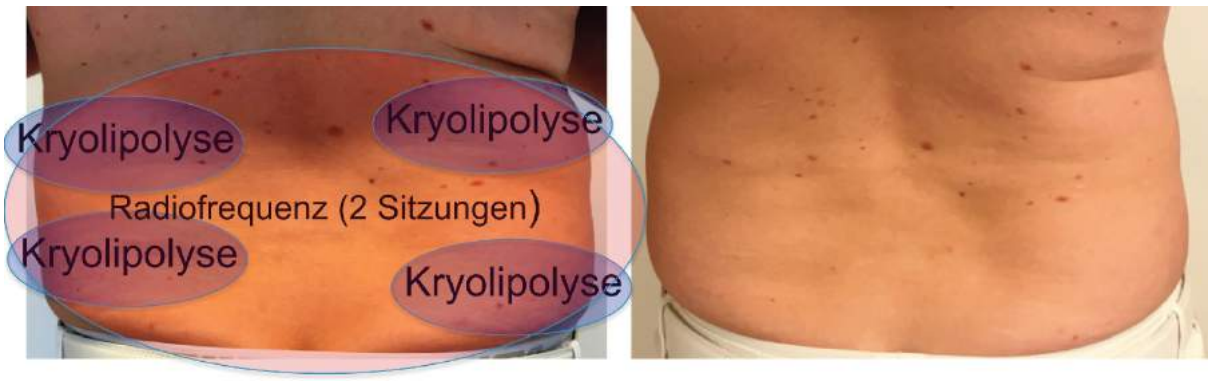

Fig. 2a-b: Appearance (L.) and 2 months after (R.) Cryolipolysis (two areas per side) as well as double Radiofrequency treatment (Pulse width 160, Frequency 0.78, 42 Grad).

In the context of the non-invasive Body contouring, it is possible to make the SAT by means of several mechanisms: by destroying the adipocytes (apoptosis, necrosis) - This is irreversible - or by extracting the fat content of the cell (Mechanical pressure, meso treatment), this effect is reversible. The destruction of the cells can be generated, mechanically, or thermally and often causes a long-lasting or permanent effect, only one treatment is needed. However, no immediate results are visible in most cases and some procedures can be painful. In contrast, the extraction of the cell contents by mechanical pressure or the introduction of physiological signals trajectories results in a rapid effect, however, which is not permanent, so most treatments are usually required, explained by Gauglitz.

The reduction in the volume range of the current approach is wide: in addition to cryolipolysis and radiofrequency, ultrasound, shock waves, lipolysis and lasers are also used. The documentation of the picture was very demanding especially to consider before / after images of the body and place high demands on the skills and equipment, Gauglitz gave advice to colleagues: "If you want body contouring treatment, you must either invest in vintage cameras called Body Stations, to 30,000 Euro cost, or they deal with methods that really work. "He has been referred to a recently published work (Z. Alizadeh et al. Int J Endocrinology Metab.2016 OCT; 14 (4): e36727), which original publications contour the three main methods of the body: Cryolipolysis, radiofrequency and HIFU (High intensity focus ultrasound). In these methods, significant effects were observed(Reduction in circumference 2-4 cm).

Cryolipolysis for local Fatty deposits

The Cryolipolysis is based on the fact that the adipocytes are significantly more sensitive than other serine cells. In animal models, low temperatures (-3, -5, and-7 degrees) appear to be associated with better response Gauglitz reported. "You can reduce up to 35 percent of subcutaneous adipose tissue with a session," he said. The method is a good response (> 70%) and can be performed effectively as a delegating performance independently of the practitioner. Gauglitz and his team used the device Clatuu ™ Company CLASSYS Inc, which are currently working on a study. The unit has several cooling levels, which can be varies to 9 degrees, it builds a strong vacuum (Stage 1-4: 50 kpa) and works very well, he reported. This has to be considered in patient selection, so not "too good to get results".

The cryolipolysis is generally more suited for localized fatty deposits, so you cannot work on the surface, so no holistic improvements can be achieved with the corresponding findings. It will reach to reduce fat, but no significant improvement in the Skin Laxity and the results only after two to three Months. For these reasons, describing the reward of the combination with other procedures, Gauglitz's experiences:

"We can learn from other body areas-so we have better outcomes In the last few years, it has seen that it is useful in the facial area to combine several methods to achieve the holistic results that the patient expected. "Therefore, he recommended combining cryolipolysis with a subsequent radiofrequency treatment.

Fig. 3a-b: Fat reduction and improvement of skin quality by combination of cryolipolysis and radiofrequency action. Appearance (L.) or after (R.) of the combination treatment.

Protocol treatment:

20.05.16 Cryolipolysis Hip: Perimeter hip 90 cm

27.05.16 Cryolipolysis upper and lower abdomen: Extensive upper abdomen 75 cm, lower abdomen 90 cm

29/08/16 interim result: Extensive upper abdomen 69 cm, Hip/ lower abdomen 84 cm

17:10:16 every week 7 week 7 x radio frequencies with DMA on the abdomen

15:12:16 End result: abdominal circumference above 66 cm, Hip / lower abdomen 79 cm

Radiofrequency skin tightening

Radiofrequency treatment produces heat in various tissues by converting electromagnetic energy. In the subcutaneous fat layer of the heat development accelerates the fat metabolism and release of the liquid fat from the cells in the extracellular matrix. A large number of studies have already been carried out on the effectiveness of the process of reducing fat, the tissue (Cellulite) and the rejuvenation of the skin, according to Gauglitz.

There are large differences between the different devices, and a wide variety of protocols. The method has to be executed multiple times and becomes a handler-dependent; he described the limits of the procedure. As a plus he booked that radiofrequency therapy proved good response rates (71-97%) and high patient satisfaction. The method can also be used on a flat surface and quickly visible effects - such as an improved Skin Laxity - are generated - to achieve your holistic results. Further benefits of the Gauglitz. are "Nice common-Result of the economic effects of the combination of the cryolipolysis radiofrequency technology because it offers the device Pollogen Legend™ from Lumenis," says Gauglitz. This way you may not only remove localized fatty deposits -. Silhouette will change significantly.

Gauglitz is presently known as a veterinarian in a special way of working with the cryogenic cryptolysis in the radiofrequency area: The cryolipolysis of the door was found on the hemispheres on the bovine binder, and the radiofrequency was found on the radio.

Although this "impressive results", according Gauglitz certainly could not be reached with each foot-ten differences there are quite different, he said. "The combination of the methods is advantageous in many cases, addition of fat reduction by Cryolipolysis with radiofrequency adjustment on skin and generally a much more homogeneous result which receive-the other hand, the positive effect the patient can immediately see".

[Source: Lecture from PD Dr. Gerd Gauglitz "Body contouring – For the Dermatological Conference Praxis 2017, March 17, 2017, Frankenthal]

Reducing Knowledge Barriers on Facial & Body Contouring

Dr. Villy Rodopoulou, MD | Greece

CLASSYS CLATUU Alpha

Plastic and aesthetic surgeon, surgeon Dr Villy Rodopoulou graduated from the Medical School of the University of Athens in 1992. She completed her training in General Surgery at the 1st University Department of Surgery of the University of Athens. Then, as a scholar, she specialized in Reconstructive and Aesthetic Surgery at Cook County Hospital and the University of Illinois Medical Center in Chicago. She completed her training at the State General Hospital of Athens. She got the title of the Plastic Surgeon in 2001 and she was also certified by the European Board of Plastic Reconstructive and Aesthetic Surgery. A key certificate, since a limited number of European doctors hold it.

Villy Rodopoulou has also been working in London since 2002 as a Cosmetic Plastic Surgeon. Her job objectives are on facial surgery (invasive and noninvasive procedures), breast, and laser techniques. She is acquainted with all the new generation non-invasive technologies for face rejuvenation and laser hair removal, such as Intense Pulsed Light (IPL), Soprano ICE Laser Alexandrite and Radio-Frequency (RF). It is noteworthy that she owns an extensive experience in the application of cryolipolysis, having developed a personal technique, 3D Cryolipolysis, which she has presented at the most well respected scientific international conferences of her specialty.

Double chin and inner thighs before (left) and after (right). Dr. Villy Rodopoulou explained that the procedure using CLATUU Alpha not only yields less downtime, but is also less likely to cause side effects, and is more convenient for both practitioners and patients.

Moreover, her studies has been published in every scientific journal of her specialty, as well as in the Year Book of Surgery (the latter was done upon request). She has given more than 80 scientific conference presentations and is constantly being informed about her scientific field, taking part in international seminars and graduate programmes.

Villy Rodopoulou is a member of Athens Medical Association, the British Medical Council, the Greek and the International Society of Plastic, Reconstructive and Aesthetic Surgery (IPRAS), the International Society of Aesthetic Plastic Surgery (ISAPS), the American Society of Plastic Surgeons, the Greek Society of Melanoma and the Greek Breast Surgery Association. Dr Villy Rodopoulou has been invited as injections' instructor (Anti-Wrinkle And Muscle Relaxant Injections/Hyaluronic acid) at the Hellenic Plastic Surgery Congress and many others.

An opportunity to choose aesthetic medicine as a practice?

Aesthetic plastic surgeons, like myself, are highly qualified and trained to execute aesthetic procedures of all kind. The field of aesthetic medicine is a rapidly growing part of an aesthetic plastic surgeon practice, offering lots of non-invasive opportunities and surgeons of course are better at performing them more adequately. Our extensive knowledge of anatomy and skin biology is helping to improve appearance of skin, shape up the body, and treat certain aesthetic disorders. It requires delicate handling and the thought of 'creation' is highly intriguing.

What is your relationship with CLASSYS?

I was quite happy with the results since I first started using CLATUU in 2015. The big volume of patients and sessions I performed applying my personalized technique, using the term: 3D-Cryolipolysis and led to remarkable results which I started presenting in well-respected international meetings like IMCAS, ISAPS etc. Therefore, the company approached me and requested me to become their KOL (key opinion leader) for popular field of cryolipolysis and I gladly accepted their invitation.

Explain why you chose CLATUU Alpha.

Liposuction still remains the gold standard surgical option to remove unwanted fat. However, we are in the era of minimally invasive medical aesthetic procedures and while one could argue that only surgery guarantees a drastic change, it is accompanied by multiple adverse effects and increased cost. Therefore, this field is gaining popularity not only because of low downtime but also because there is lower stigma and barrier to entry. In 2019 non-invasive treatments can be quick lunchtime procedures with quite effective and long-term results. Thus, it is definitely a value for money choice for both patients and doctors.

What was your first impression with CLATUU Alpha

As a plastic surgeon I come across with multiple different non-invasive technologies, all promising outstanding results. Because of this fast growing emerging market, I am always aware of counterfeit medical devices. My intention is not only achieving great outcomes but also ensuring patients' safety. As soon as I started using CLATUU, I was impressed by device performance and effectiveness as well as patient tolerance. That is the reason when the new model came in the market, CLATUU alpha, I immediately obtained it as a second CLATUU machine in my practice so that I can offer my patients multiple areas per session and thus, minimizing their treatment time. I am happy to be able to offer them a full body sculpting non-invasively using 3D Cryolipolysis in just one day!

What features does CLATUU Alpha offer?

Before I take on board any new device, I read thoroughly multiple scientific articles and take into consideration every different scientific opinion. The moment I decide that this new technology is safe and efficient I think of patient tolerance as well. Therefore, I test them on myself first. Also, I consider both time spent at our private practice and cost. Non-invasive treatments are supposed to be safer and ''financially friendlier'', compared to surgery. Nowadays, many patients seek minimally invasive and affordable ways to get rid of stubborn fat. Double chin, inner and outer thighs, arms and love handles are only some of 3D cryolipolysis applicable examples. CLATUU introduces a new patented 360° surround cooling technology that secures even cooling and a nicely reduced, smoothed out result with maximum comfort during treatment. CLATUU literally met my demanding expectations; after trying at least three of its competitive devices in order to decide. Quite important is also the extra benefit of minimal consumables of CLATUU.

How would you explain the demand for CLATUU Alpha and procedures?

Most of our patients are highly satisfied with 3D cryolipolysis treatment. In 1 hour, we can treat 4 different areas using 2 CLATUU devices and 4 handpieces. This way we minimize the time they spent at our private practice and our patients can quickly, with no downtime return to their everyday routine and also, we have a short patient turnover in the practice. So, we can treat more patients in one day compared to other devices, not to mention the minimal consumables and the easy exchange of handpieces. Very often patients combine their 3D cryolipolysis session with other aesthetic treatments we offer such as injectables, microdermabrasion, mesotherapy and skin treatments performed during the 3D cryolipolysis treatment cycle. At initial patientdoctor consultation therapeutic goals are determined and therapeutic plan is designed. This helps not only our patients to have realistic expectations but also us to perfectly meet them. Adverse effects are tolerable and include mild pain during usually the first 5 minutes, mild numbness, tingling and mild bruising in some cases. All of these resolve within hours or a few days without intervention. After 2months, we re-examine the treated areas and decide whether or not a second cryolipolysis cycle is needed.

Most common area of interest is the abdomen either upper or lower or both and the love handles. Possible reason for that is because it is a common area of fat accumulation both in men and women and in general the torsal area, therefore we call the improvement of this area non-invasive torsoplasty. 9. Medical procedures include non-invasive body sculpting, even for difficult body areas and face contouring. Specifically, for face contouring we often aim to reduce submental fat or as commonly known double-chin as well as the lateral neck area. For that purpose, we document precise measurements using skinfold caliper. Photographs for before and after evaluation are also collected using standardized cameras.

Many procedures can be combined with cryolipolysis. We often use LPG endermologie that stimulates the skin and fatty tissue to soften up the fat cells bands and make them less fibrous. At the same time, this stimulation helps to release fat and to activate blood and lymphatic circulation, therefore, we achieve cellulitis improvement. An unexpected benefit of 3D cryolipolysis, is skin tightening and it is almost regularly observed. Thus, we have also paired it with a radiofrequency device in order to maximize that bonus effect. Both combinations are efficient and safe, as long as carried out separately to cryolipolysis, preferably after a few days. However, 3D cryolipolysis alone can have a significant result and combinations are based upon initial consultation. Each patient has diverse needs and financial capacity.

Classys' key opinion leader (KOL) Villy Rodopoulou.

Most important thing when using CLATUU as per our experience, is setting realistic goals. Patients will notice fat reduction approximately within 3 months and maintaining a stable weight is of high importance in order to objectively evaluate the results. Thus, patience is needed. ''Instant effect'' results are not an option with 3D cryolipolysis.

In our private practice we have treated more than 40 patients in this area so far as it is a quite new technique and the results are extremely satisfying not only from a clinician aspect but also from written patient evaluations and we currently have under submission of the relevant scientific paper. Submental fat can be

difficult to deal with and other non-invasive methods such as injection lipolysis require multiple visits and frequently lead to bruising and significant swelling for several days. While CLATUU alpha offers a pain-free, one or sometimes two cycles of 1-hour treatment option with no downtime. Patients gain back their facial contouring and subsequently their confidence. It seems that a youthful, fresh face has a direct psychological impact and we are grateful for generating beautiful faces and happy patients at the same time.

Most users are very happy with the results of Clatuu and the 3D cryolipolysis treatment is quite popular among specialists. 15. There was a big audience, actually much more than our expectations, and they were quite impressed, given the big volume of patients and the remarkable results that we presented following 3D cryolipolysis. Quite effective. Therefore, I am quite happy with the outcome of our cooperation.

Dr. Villy Rodopoulou attended the 3-day Aesthetic & Anti-Aging Medicine World Congress (AMWC) Monaco from April 4-6, 2009, and shared her clinical data with attendees while introducing the CLATUU ALPHA procedure.

How do you communicate with CLASSYS?

Mostly by e-mail. I was happy to share my technique and tips in multiple instances. Doctors, dermatologists or plastic surgeons should be open-minded and at the same alert when it comes to new devices or techniques. Safety and effectiveness always should come first when treating a patient.

Cryolipolysis for Non-invasive Body Contouring: Safety and Efficacy

Dr. Adrian Lim, Dermatologist, Sydney Australia

Introduction

The rise of body sculpting procedures has highlighted the increasing demand from everyday patients seeking effective technology for fat reduction concerns.

A number of non-surgical modalities have been introduced for the non-invasive reduction of adipose tissues, including cryolipolysis, radiofrequency, low-level laser, and high-intensity focused ultrasound (HIFU).

All non-surgical procedures for body contouring either induce fat cell necrosis or apoptosis of the targeted adipocytes to remove unwanted adipose tissues. Whereas apoptosis is a form of cell death that is generally caused by normal, healthy processes in the body, necrosis is cell death that is caused by external factors or disease, such as trauma or infection. Apoptosis, which can also occur as a defense mechanism during healing processes, is almost always normal and beneficial to an organism, while necrosis is always abnormal and harmful.

Cryolipolysis and Apoptosis (Brand Names include: Clatuu Alpha, Coolsculpting, Cooltech)

The principle behind cryolipolysis rests on the premise that adipose cells are more susceptible to cooling than other types of skin cells. The application of cold temperatures triggers apoptosis of adipose tissues. Apoptosis induces adipose cell death without disturbing the membrane of adipose tissues. As a result, this triggers an inflammatory response and leads to slow digestion of adipocytes by surrounding macrophages. The lymphatic system gradually removes the debris of those for the duration of one to three months. At this time, the patient starts to notice the treatment result from treatment.

Cryolipolysis was originally approved by the US Food and Drug Administration in 2010. This came about by accident in 1970 following a scientific study that found children who sucked on frozen popsicles experienced fat shrinkage in their cheeks, forming dimples. Doctors and researchers capitalized on this discovery and

created a machine that reduced fat by freezing it. The cooling method was modified using a device that suctioned up body fat tissue and exposed it to a very low temperature to freeze the fat cells without affecting connecting tissue including the skin (protected by a gel pad).

CLATUU Alpha

CLATUU Alpha (CLASSYS, South Korea) is one of the leading cryolipolysis medical devices and is now commonly used to treat fat in the double chin, flanks, thighs, abdomen, bra fat and back areas and underneath the buttocks with seven applicators and well-controlled cooling technology combined with effective and controlled suction. Recently, Clatuu Alpha introduced innovative types of applicators which apply on double chin and thighs areas. Those applicators are surprisingly well designed to fit with body's anatomical features on intended target areas to achieve optimal results. Clatuu Alpha encompasses dual applicators. which allow us to treat two areas at once along utilizing the world's first patented 360° cooling applicators the most technologically advanced cryolipolysis technology available today for effective fat reduction treatment.

Safety of CLATUU Alpha

Clatuu Alpha has been studied in both vivo and vitro clinical trials in many clinical studies and proves to be safe for all skin types, with no reported pigmentary changes, and is safe for repeated application. Millions of treatments have performed worldwide with no major health risk factors related to the treatment have been reported and there was no reduction in liver function or lipid levels, indicating that Clatuu Alpha treatment is safe. Improved technology allows stable cooling temperature so that it can provide enhanced treatment results in a shorter period of time compared with other conventional methods. On average, 20-30% of permanent fat cell death in treated areas are noted according to vitro and vivo experiment.

Although Clatuu Alpha effectively reduces subcutaneous fat layers, lifestyle and other factors may also play a significant role to achieve optimum results. A person who continues with a poor diet and maintains a sedentary lifestyle while undergoing Clatuu Alpha can expect less fat reduction. Therefore, it is paramount that the patient is encouraged to maintain a healthy lifestyle post-treatment in order to look and feel their best.

Fat freezing results: before & after images (Photos by Body Catalyst)

Area treated: Inner Thighs

Number of treatments: 2 sessions

Area treated: Love Handles

Number of treatments: 1 session

Area treated: Love Handles

Number of treatments: 2 sessions

Area treated: Love Handles

Number of treatments: 1 session

Area treated: Lower Abdomen & Love Handles

Number of treatments: 2 sessions

Area treated: Upper & Lower Abdomen

Number of treatments: 2 sessions

Overview of Modern Non-invasive Methods of Correction of Local Fat Deposits for Use in the Field of Aesthetic Medicine

KARAMYSHEVA
Anastasia Alexandrovna / Physiotherapist

Introduction

Every year, the number of overweight and obese people is constantly increasing around the world, and according to WHO experts, the "obesity epidemic", is becoming an increasingly acute medical and social problem that threatens not only the health of society as a whole, but also the economy of different countries.

In Russia, the problem of combating overweight is no less acute than it is around the world. According to domestic researchers, the prevalence of overweight among the adult population of Russia in recent years has been 60% for men and 59.2% for women. Moreover, the frequency of obesity in adults is 21.9 and 29.7% among the male and female population, respectively.

Due to the prevalence of obesity among the population, interest in various body shaping methods is currently on the rise. An increase in body weight of 20% or more from standard values and excessive adipose tissues lead to a violation of the aesthetic perception of the human body. This limits the physical activity of patients, negatively affects the quality of life and in some cases leads to the loss of professional fitness.

It has been proven that the number of fat cells remains constant in adulthood and that fat mass in adults is primarily determined by changes in lipid accumulation in existing adipocytes. Weight loss does not reduce the number of adipocytes, but only changes their size. Similarly, a significant weight gain leads to an increase in body fat, which is due to an increase in the volume of adipocytes, and not their number.

Body Correction Techniques

Most people struggle with body size fluctuations in their lifetime. The most commonly used methods are regular exercise and weight control programs. However, all these measures provide only temporary changes in the volume of fat cells and are not always successful. To achieve a lasting result of reduction in fat mass in a certain part of the body, it is necessary to reduce the number of adipocytes.

Invasive Methods

Over the past decade, the market of aesthetic medicine has constantly shifted from invasive procedures to non-invasive treatments. According to ASAPS statistics, in 2016 non-invasive cosmetic procedures grew twice as fast as surgical procedures. In 2017, it was recorded that more than 300,000 liposuction procedures were performed per year and was the most common surgical cosmetic procedure after breast augmentation. Due to the high risk of complications (for example, infection, scarring or hematoma) following surgical procedures, the demand for non-invasive procedures for removing adipose tissues in different areas has gained popularity.

Non-invasive Methods

Unlike invasive treatments, non-invasive body contouring procedures used to produce modest results. However, with the development of advanced technology in recent years in the field of aesthetic medicine, improved results can be achieved with non-invasive body contouring treatments. The longevity of the results of non-invasive treatments are well established in a number of clinical articles. To date, the leading technologies

for non-invasive body contouring widely used to reduce subcutaneous fat, are:

• Cryolipolysis

• High Intensity Focused Ultrasound (HIFU).

All these technologies are aimed at temporary or permanent reduction in the volume of adipose tissues. The mechanisms of action of these methods are different. They range from coagulation necrosis (HIFU) to the programmed death of fat cells (Apoptosis) caused by local panniculitis (cryolipolysis). At the same time, specialists in aesthetic medicine have the opportunity to combine these technologies to achieve optimal results for body contouring.

Cryolipolysis

In the 70s, researchers found that adipose tissue is susceptible to cold exposure. From this moment, research began on cryolipolysis to exploit this technology to reduce fat mass. The method was first discovered by a group of scientists at Harvard University under the direction of Professor Dieter Manstein. In 2009, for the first time, the first cryolipolysis device was introduced to the world. Cryolipolysis is a widely used method for body contouring treatments around the world.

Underlying Principle

In response to tissue exposed to cooling energy, an inflammatory reaction occurs in the area of treatment, followed by phagocytosis of the debris of adipocytes and a gradual decrease in the thickness of the fat layer. Histological studies immediately after the procedure have showed no noticeable changes in the tissues. After 3 days, the number of macrophages, neutrophils, lymphocytes and monocytes in the affected area increases. By the 7-14th days, the inflammatory process becomes more noticeable and reaches its peak by the end of the first month (then the first results of the treatment become visually noticeable). Then the intensity of inflammation decreases, the thickness of the interlobular septa in the subcutaneous fat increases. It is assumed that the latter is the result of selective death of adipocytes, a decrease in the thickness of adipose tissue, and thus increase the proportion of collagen in the hypodermis. The process is completed after about 90 days and by this time the results of cryolipolysis become maximized.

DEVICES

CLASSYS produces devices for aesthetic medicine.

Today, the CLATUU(Classys, South Korea) device has recently gained popularity among the many different cryolipolysis devices. This device delivers cooling energy via parallel cooling plates and utilizes 360° surrounding cooling technology within the applicator cup, which makes the cryolipolysis procedure 18.1% more efficient than other devices.

Thanks to the 360° surrounding cooling technology, the results after a single treatment are markedly improved after two months. The ability to treat with two applicators in one procedure makes body contouring treatments twice as effective as previous versions of cryolipolysis devices.

Cryolipolysis does not lead to changes in serum lipids and does not affect liver function, indicating CLATUU is a safe and effective procedure to reduce localized body fat with a high level of patient satisfaction.

Photos before and 3 months after the CLATUU Alpha procedure

Photos before and 3 months after the CLATUU Alpha procedure

Photos before and 2 months after the CLATUU Alpha procedure

Photos before and 2 months after the CLATUU Alpha procedure

High Intensity Focused Ultrasound (HIFU)

This modality has been used clinically for pathological conditions in various organs for more than 50 years (for cancer treatment). The predictable effects of HIFU have become a promising tool for treating various diseases. The current therapeutic possibilities of HIFU in human medicine include the treatment of cancer and solid tumors, leiomyomas (also known as fibroids) and atrial fibrillation.

In the field of aesthetic medicine, HIFU is utilized to remove fat cells for body contours and treat collagen-rich layers for facial rejuvenation. Uneven skin tone is another cosmetic problem in middle-aged women. HIFU energy accurately removes the targeted adipose tissue without affecting surrounding tissue or causing incidental damage above or below the focused energy zone.

Operating Principle

Focused ultrasound causes a rapid increase in temperature in a focal region where tissue temperature reaches 70 ° C (133 ° F) in one to two seconds. This leads to almost instantaneous coagulation necrosis and cell death in the target tissue, while the surrounding areas remain intact. Thus, HIFU is effectively used to remove adipose tissue with a high degree of accuracy.

High Intensity Focused Ultrasound (HIFU) with the **Ultraformer (Classys, South Korea)** is one non-invasive method that provides safe and effective reduction of adipose tissue and an improvement in skin elasticity and tightening. For Ultraformer III body contouring treatments, cartridges reaching depths of 6, 9 and 13 mm are used and cartridges operating at a depth of 1.5, 2mm, 3mm and 4.5mm are also used to tighten the skin. This allows medical practitioners to achieve maximized results for the correction of body contours.

Photos before the procedure with the Ultraformer

Conclusions

Note that modern medical equipment used in clinics of aesthetic medicine allows medical practitioners to create individual and customized body contouring programs. The possibility of combining the non-surgical methods for correction of body contours described above allows patients to achieve the maximum reduction in the volume of subcutaneous fat and satisfy the needs of clinic clients.

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Specific Indications for Clatuu: Combinations of HIFU and Cryolipolysis for the Body

Gerd G Gauglitz, Meet the Expert Classys, Monaco, April 2019

Body Contouring

A growing number of obese people along with the heightened importance put on aesthetics and appearances, represent the key factors driving the body contouring market.

In order to respond to this demand, various types of non-invasive body contouring modalities have been developed and are available for reduction in the volume of subcutaneous adipose tissue or cellulite. Those modalities include cryolipolysis, radiofrequency, low-level laser therapy, and high-intensity focused ultrasound. Those procedures have different mechanisms for stimulating either apoptosis or necrosis of adipose tissue.

Nowadays, altering the shape of an area of the body for aesthetic purposes by targeting the fat tissue is widely available worldwide.

Global Trend

According to the CAGR statistics, the global body contouring market reached a value of US $6.1 Billion in 2018. The market is expected to reach a value of US $9.1 Billion by 2024, growing at a CAGR of 6.8% during 2019-2024, thus indicating that the body contouring market continues to grow rapidly.

Also, body shaping and skin tightening is globally the largest segment in the aesthetic market, which means combination treatments with those two modalities will be on the rise in the field of aesthetic medicine in near future.

Common Body Concerns

The most common concerns of body contouring among patients are divided into four categories: mixture of skin laxity and well-defined fat deposits, good skin quality but overweight, bad skin quality and excess weight, and good skin quality and non defined fat deposits. To tackle these combined issues, cryolipolysis as well as HIFU (high intensity focused ultrasound) treatments can be utilized to remove unwanted fat tissues and improve skin laxity. The efficacy and safety of those modalities has been well studied in numerous clinical journals and articles.

How Can We Reduce Superficial Subcutaneous Adipose Tissue (SAT)

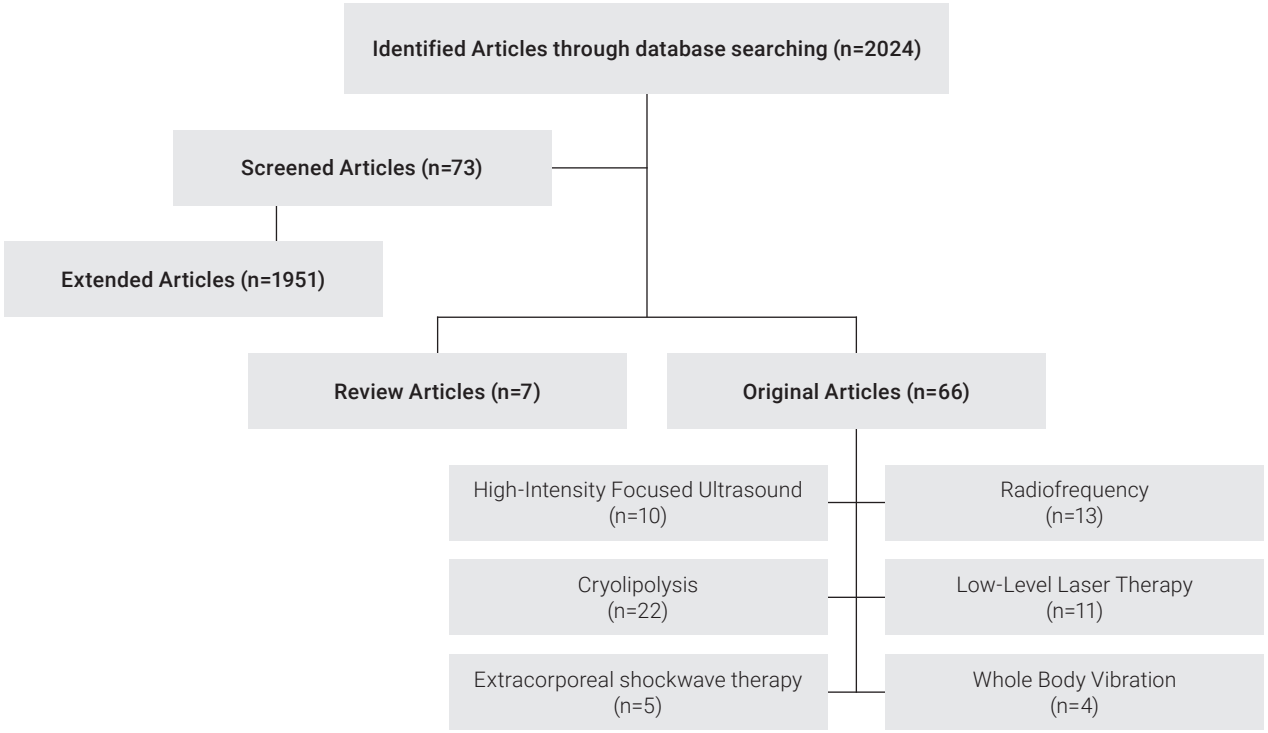
Superficial subcutaneous adipose tissue or SAT can be reduced either invasively – e.g. liposuction, abdominoplasty or non- invasively –e.g. HIFU, Cryolipolysis, LLLT, RF.

Also the biological mechanism to eliminate SAT is achieved by 2 means: Destruction of the adipocytes: apoptosis, necrosis (Irreversible) and Extracting the fat content from the cells such as mechanical pressure or mesotherapy (Reversible)

Currently, various modalities have been widely utilized for reduction of adipocytes. Specifically, HIFU and Cryolipolysis treatments induce cell death by means of mechanisms of either necrosis or apoptosis which indicates those can lead to long and lasting effects without invasive procedures, while treatments with mechanical pressure only results in immediate but short-term effects post treatment.

Variety of Technologies Available are Well Described Below.

Table 1. Various modalities for Body Contour								
	Method	**Area**	**Treatment number**	**Duration**	**Mechanism of action**	**Results**	**Pain**	**Downtime**
Volume Reduction	**Cryolipolysis**	Medium size fat pocket	1-2 times	60~90 minutes	Cell Apoptosis (non-invasive)	2~3 month post treatment	Virtually painless	No downtime
	Radiofre-quency	Small to medium fat pocket	3-8 times	60~90 minutes	Cell Apoptosis (non-invasive)	6-8 weeks post treatment	Painless to moderate pain	No downtime
	HIFU	Medium size fat pocket	1-2 times	30~60 minutes	Cell Necrosis (non-invasive)	2-4 weeks post treatment	Painless to moderate pain	No downtime
	Low Frequency Ultrasound	Small to medium fat pocket	3-8 times	60~90 minutes	Mechanical rup-ture of adipocytes (non-invasive)	6-8 weeks post treatment	Virtually painless	No downtime
	Shockwave	Small to medium fat pocket	6-10 times	60~90 minutes	Stimulation of adipocytes metabolism (non-invasive)	6-8 weeks post treatment	Virtually painless	No downtime
	Injection lipolysis	Small fat pocket	1-4 times	15~30 minutes	Biochemically induced cell ne-crosis (minimally invasive)	4-6 weeks post treatment	Mild pain but often sever swelling	Swelling or bruising may occur
	Liposuction	Any kind of fat pocket	1 times	90~120 minutes	Cell aspiration through suction cannula	Immediate effects	Post-opera-tive pain and discomfort	3 to 7 days of downtime
Volume Addition	**HA Filler**	Small to me-dium tissue defects	1 treatment or more	15~30 minutes	Tissue bulking (minimally inva-sive)	Immediate effects	Possibly painful	No downtime
	Autologous Fat Transfer (fat Grafting)	Small to me-dium tissue defects	1 treatment or more	15~30 minutes	Tissue bulking (minimally inva-sive)	Immediate effects	Possibly painful	downtime



Images Derived from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5236497/

Cryolipolysis

Jalian et al. demonstrated sensitivity of adipocytes to low temperatures in comparison with other water-rich cells in 1902. During the period between 1940 and 1970, case reports showed gradual fat reduction in the lower cheeks of children who sucked on a popsicle and the effect was known as “popsicle panniculitis”. Cryolipolysis is based on the increased sensitivity of adipocytes to low temperatures compared to other water containing cells. To reduce SAT, low temperatures is proven to be associated with better responses in vivo and vitro animal experiments.

A reduction of SAT of approximately 33% was shown after one session without side effects in animal models. More than 70% of participated patients responded to cryolipolysis. Those figures are quite impressive results. This treatment is also totally independant of the physician’s skills which indicates treatment experience of medical practitioners is not that significant part for optimal treatment result.

The efficacy of the treatment on reducing fat layers without any physical damage to surrounding cells has been clinically proven in several studies. The patient satisfaction rates were high after the session without severe adverse effects.

Summary

Cryolipolysis is suitable for localized fat reduction, according to the indication and needs of patients. Problems in different tissues are effectively treated with combination treatments in order to maximise the optimal results, as well as patients‘ satisfaction post treatment.

Also, it is important to note that educating the patients about possible treatment outcomes and expecting time of noticing the maximized treatment results is significant. Objective improvements are difficult to present in a single picture so ensure to take multiple angled photos in the exact same environment (such as place, lighting, camera).

This combined treatment leads to immediate and long-lasting results of reduction in fat tissue safely and more effectively. Great patient satisfaction with combination treatments with Ultraformer III and Clatuu are well established in several studies.

Cryolipolysis with a Double-applicator 3-Dimensional Cooling Cup Device

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Introduction

There is a strong consumer demand for non-invasive body contouring through localised fat reduction. Lasers, radiofrequency, acoustic wave and focused ultrasound are currently available options for this purpose. Since 2005, suction-assisted cryolipolysis (fat freezing) has become one of the most popular techniques for body contouring with many studies supporting its safety, efficacy and reliability. As a result, consumers and practitioners globally have embraced this method of focal body contouring. In late 2015, the Australian Therapeutic Goods Administration (TGA) approved a new cryolipolysis device with two applicators with 3-dimentional surround cooling cup (CLATUU) for body contouring.

The primary objective of this study is to assess efficacy and safety of localised fat reduction with CLATUU. The secondary objective is to compare and evaluate the different body contour measuring techniques – standardised photography, calliper measurement, circumference tape measurement, ultrasound measurement and patient self-assessment – in their validity and reliability in monitoring patient progress following cryolipolysis.

Methods

8 consecutive treatment-eligible patients were enrolled into the cryolipolysis study for prospective evaluation over a 4-month follow-up period. Patients with localised fat accumulation on the trunk and proximal limbs were included in the study. Patients with global obesity, cold intolerance such as Raynaud's, and connective tissue diseases such as morphea or lupus panniculitis, and patients with previous invasive (liposuction) or non-invasive methods of localised fat reduction procedures were excluded from the study. Patients were requested to maintain a constant weight over the study period (keeping within 3kg of baseline weight) and to maintain their current level of physical activity.

The target sites were patient initiated to reflect real-life clinical setting and the location recorded with X and Y axis using the umbilicus as the fixed reference point. All trial patients had the option of treating either single-site or 2-sites simultaneously (e.g. lateral abdomen and one inner thigh). Baseline assessment involved 6-view body photography (anterior, posterior, right anterolateral, left posterolateral, right lateral, left lateral), weight, circumference tape measurements, calliper measurements and M-mode ultrasound measure of adipose tissue thickness (mean of 12 different measurements points taken within the treatment area). All trial patients were followed-up at 2 months and 4 months for similar measurements. In 2 patients with symmetrical bilateral fat accumulation, the contralateral site served as internal control. The trial patients had the option of treating 2–sites at the one time e.g. lateral abdomen and inner thigh. Trial patients were also offered the option of a repeat treatment to the same area with a minimum interval of 2 months between treatments. The clinical measurements were undertaken by the same nurse practitioner and the ultrasound measurements were performed by the same sonographer (Toshiba)

All trial patients were treated with a standard protocol at the nominated 'problem' site(s).

The treatment protocol involved initial prior application of a matrix gel pad followed by application of either a

flat or wing (curved) suction cup depending on the body location and contour. The parameters were suction (step 4), cooling (step 4) and duration of one hour. Two months after the final treatment, patients were surveyed about their experience and satisfaction of the procedure, including self-rating of perceived degree of fat reduction post treatment.

At the end of the study, two blinded dermatologists rated the baseline, 2-months and 4-months photographs for all the trial patients according to a 4-point scale: no change (0%), mild reduction (< 25%), moderate reduction (25-50%) and marked reduction (>50%).

Results

The subject demographics were: 6 females and 2 males, age range: 36 – 60 years old (mean: 46.8 years old). One subject was excluded from the study because of an unrelated traumatic injury to the shoulder requiring surgery. Of the 7 subjects, a total of 13 sites were treated: 3 subjects requested treatment at 2 body sites, 2 subjects had 1 site treated, and 1 subject had 4 sites treated. The lateral abdomen was the most commonly nominated site (figure 1). The specified measurements were done at baseline, 2-months and 4-months post-treatment (table 1).

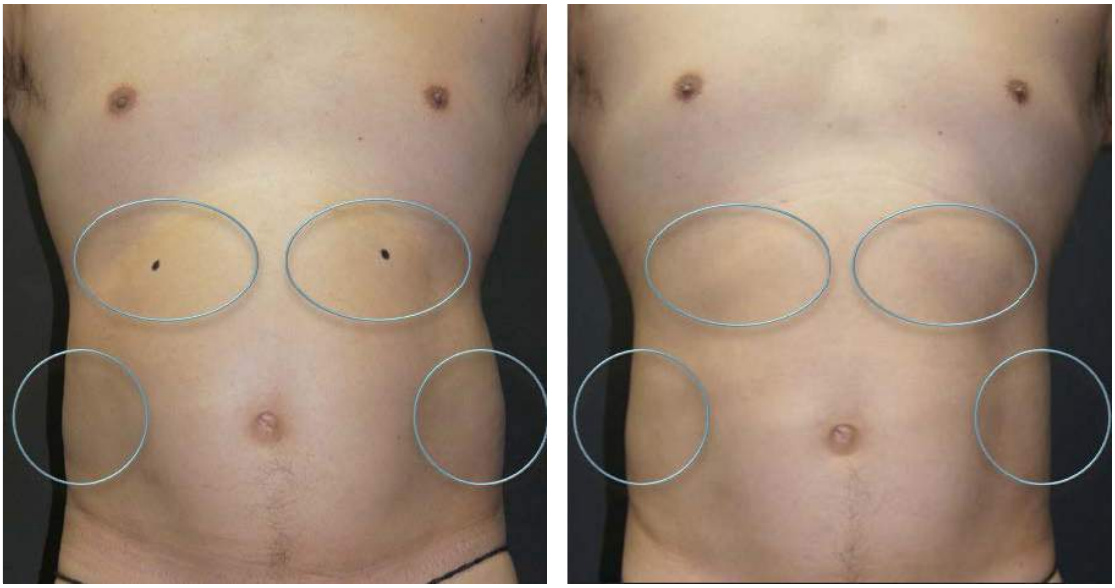


Figure 1. Left lateral abdominal before (upper left image) and 4-months after 1 treatment session (upper right image). Right lateral abdomen is the control side (untreated). Upper abdomen: right (4-months post first treatment) and left (2-months post second treatment).

The most consistent record of body contouring change was photographic assessment and ultrasonic fat measurements, where the mean global ultrasonic fat reduction across all subjects was -19.44% (control: +0.62%) (table 1). Fat reduction across the 3 treatment groups (control, single treatment, double treatment) appear to correlate with the ultrasound measurements of +0.62%, -16.43% and -19.44% respectively. The calliper and circumference measurements correlated poorly with the clinical changes, with mean global reduction of -5.54% and -0.31% respectively for the enrolled subjects. Independent blinded physician (dermatologists) assessment of localised fat reduction was -30.0% after 1 treatment and -39.5% after 2 treatments, based on a mean 4-point rating scale (table 1). There was close concordance between the blinded dermatologists global score: 1.45 and 1.36 (mean 1.41), representing a mean global reduction of -35.2% on the 4-point rating scale (control: -12.5%).

Treatment Site	Treatment Schedule	Weight Change (kg)	Diameter Change (cm)	Caliper Change (cm)	Ultrasound change (cm)	D1 Photo rating	D2 Photo rating	D1, D2 mean	Patient self-rating
R lateral abdo	Untreated	-1.8 (-2.12.%)	0 (0%)	-3.8 (-9.79%)	-0.2 (-1.46%)	0	1	0.5	P (no change)
R lat abdo	Untreated	-0.7 (-1.25%)	-2.0 (-2.44%)	-0.9 (-2.56%)	+0.7 (+2.71%)	0	1	0.5	1 (<25%)
					Untreated mean +0.6 %			Mean: 0.5 (12.5%)	Mean: 0.5 (12.5%)
L lat abdo	2mp1	-0.7 (-1.25%)	-2.0 (-1.21 %)	-5.2 (-17.23 %)	-1.6 (-6.62%)	1	2	1.5	2 (25-50%)
L inner thigh	2mp1	+2.0 (+2.87%)	+0.5 (+0.83%)	+0.5 (+ 3.84%)	-3.7 (-20.23%)	1	2	1.5	1(<25%)
L midback	2mp1	+1.4 (1.21%)	0 (0%)	-0.8 (-2.34%)	-2.2 (-10.78%)	2	2	2	2 (25-50%)
R lower lat oblique abdo	2mp1	+0.2 (0.29%)	-3.0 (-2.83%)	-4.5 (-13.52%)	-10.5 (-26.89%)	0	1	0.5	0 (no change)
R upper ant abdo	4mp1	-1.8 (-2.08%)	+5.0 (+5.43%)	-1.4 (-4,18%)	-1.0 (-7.70%)	1	0	0.5	1(<25%)
L lateral abdo	4mp1	-1.8 (-2.08%)	0 (0%)	-1.7 (-4.56 %)	-3.9 (-26.41 %)	2	2	2	1(<25%)
					1 session mean: -16.4%			Mean 1.2(30.0%)	Mean: 1.2 (30.0%)
L upper ant abdo	2mp2	-1.8 (-2.08%)	+ 5.0 (+5.43%)	-0.9 (-2.56%)	-2.3 (-16.28%)	1	0	0.5	2 (25-50%)
R inner thigh	2mp2	+2.0 (+2.87%)	-0.5 (-0.82%)	-1.0 (-7.58%)	-3.7 (-24.67%)	2	2	2	2 (25-50%)
Upper ant abdo	2mp2	+2.6 (+4.2%)	-3.0 (-3.37%)	-3.6 (-12.67%)	-8.2 (-25.03%)	2	2	2	1(<25%)
R midback	2mp2	+1.4 (1.21%)	0 (0%)	0 (0%)	-5.0 (-22.73%)	2	1	1.5	2 (25-50%)
Lower abdo	2mp2	-0.9 (-1.22%)	0 (0%)	0 (0%)	-11.8 (-26.63%)	2	1	1.5	2 (25-50%)
					2 session means: -23.1%			Mean: 1.58 (39.5%)	Mean: 1.33 (33.3%)
Mean (treated areas)		< 3kg	-0.31%	-5.54 %	-19.44 %	1.45	1.36	35.2%	36.4 %

D1: Blinded dermatologist 1.

D2: Blinded dermatologist 2

Rating: 0 (no change), 1 (mild <25%), 2 (moderate 25-50%), 3 (marked >50%)

Table 1: Summary of fat measurements and patient and physician ratings.

	Strongly disagree (-2)	Disagree (-1)	Uncertain (0)	Agree (1)	Strongly Agree (2)	Mean Score (-2 to 2)	Median Score
Q 1. I am satisfied with the outcome of the procedure							
	1 respondent	0 respondent	1 respondent	1 respondent	4 respondents	1.0	Strongly agree
Q 2. I fond the procedure comfortable							
	1 respondent	1 respondent	1 respondent	3 respondent	1 respondent	0.3	Agree
Q 3. I would consider having the procedure again in the future							
	1 respondent	0 respondent	0 respondent	2 respondent	4 respondent	1.1	Strongly agree
Q 4. I would recommend this procedure to a friend							
	0 respondent	0 respondent	1 respondent	2 respondent	4 respondent	1.4	Strongly agree
Q 5. I find the duration of treatment							
	'much longer than expected' 0 respondent	'longer than expected' 0 respondent	'about right' 6 respondents	'shorter than expected' 1 respondent	'much shorter than expected' 0 respondent	0.14	About right

Table 2: Patient satisfaction survey

The patient satisfaction survey at 2-months post-treatment revealed 71.4% (5 out of 7 patients) either 'agreed' or 'strongly agreed' that the outcome was satisfactory (table 2).

Five patients elected to have a repeat treatment on the same area 2 months after the initial treatment. Of the 2 dissatisfied patents, one felt that there was 'no change' post-procedure but revised her self-assessment to 'marked reduction' upon reviewing the before-after photos (figure 2). The overall patient self-assessment showed concordance with blinded physician assessment: -36.4% and -35.2% respectively on the 4-point rating scale (Rating: 0 [no change], 1 [mild <25%], 2 [moderate 25-50%], 3 [marked >50%]).

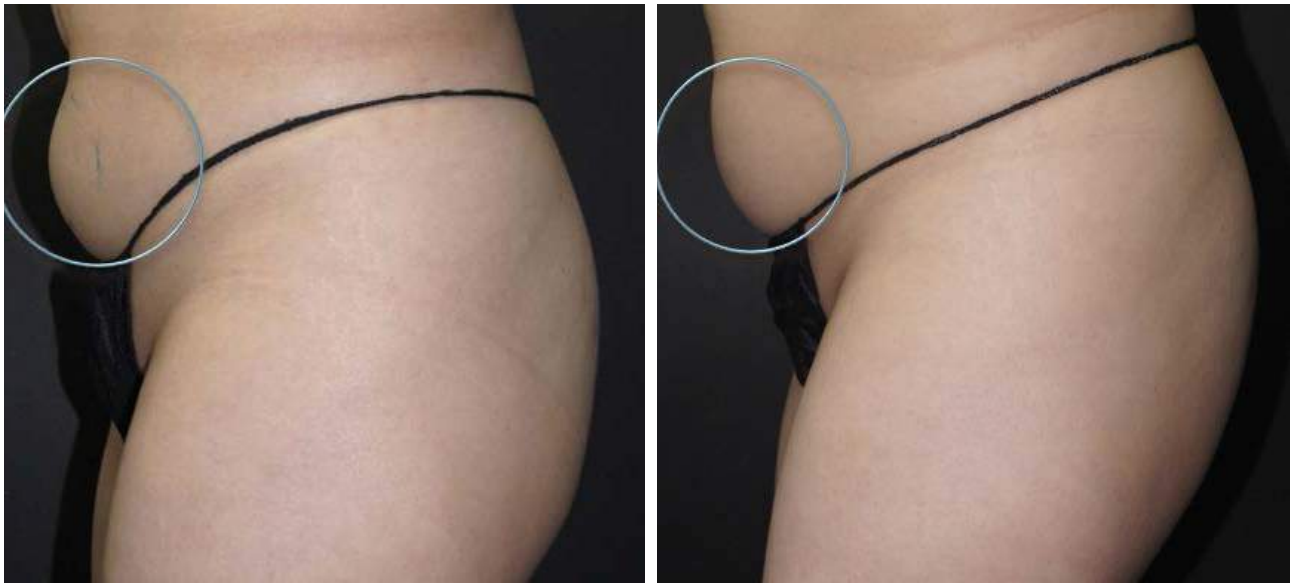


Figure 2. Lower abdomen before (left image) and 2-months after the 2 treatment sessions (right image).

Discussion

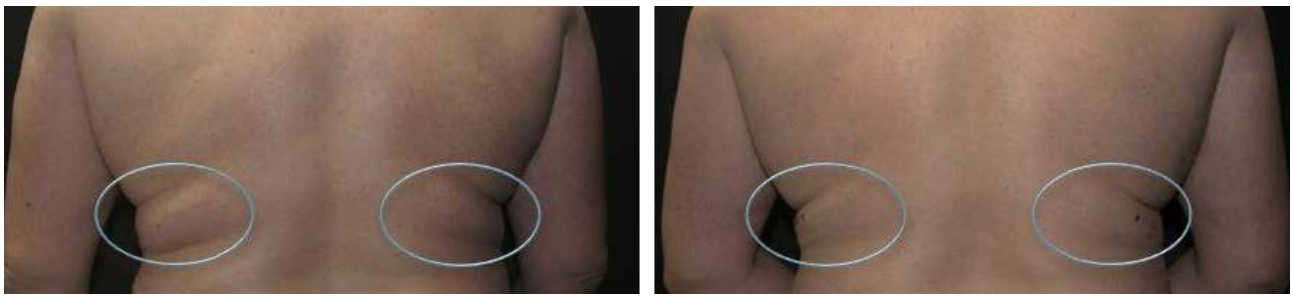
In the last few years there has been a marked increase in interest and uptake of cryolipolysis for localised fat reduction. One study showed an 823% increase in cryolipolysis procedures over a 3-year period: 201 patients treated in the first year, 671 patients in the second year and 1857 patients in the third year, highlighting the business case for offering the service.[1] Other non-surgical options for localised fat reduction include high intensity focused ultrasound, unipolar radiofrequency, acoustic wave therapy and laser therapy, but these do not compare as favourably as cryolipolysis in terms of efficacy, safety and tolerability.[2]

In one study with 42 patients, 79% noticed fat reduction on themselves at 2-4 months.[3] Another study with 50 patients, 89% showed a noticeable improvement on photography with a similar proportion (80%) being happy with the results at 6 months.[4,5] Most studies indicate a fat reduction of approximately 20 - 25% - either on calliper or ultrasonic measurements - 3 to 6 months after a single treatment session.[6,7] Two treatments appear to result in greater fat reduction than a single treatment session: 28.5% versus 19.7%.[8]

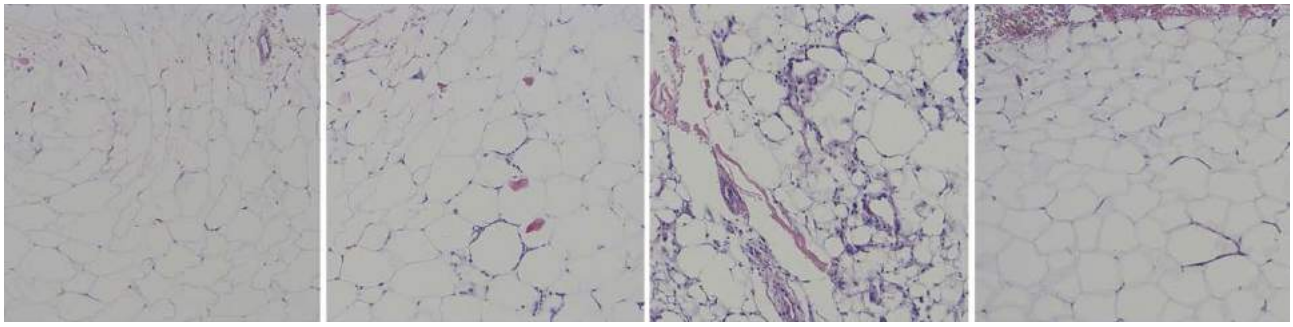
Boey et al demonstrated a 44% increase in fat loss with 2 minutes of massaging immediately post cryolipolysis, and this manoeuvre has become standard practice in most centres.[9] Carruthers et al speculated on possible skin tightening effects post cryolipolysis based on a series of 14 patients.[10]

The safety of cryolipolysis has been well established. Cryolipolysis is not associated with any alterations in serum lipids and liver function.[11] Dysaesthesia (numbness) has been reported to occur in up to 73% of patients lasting 3 weeks although 18% of cases may persist up to 3 months.[12] The dysaesthesia is self-limiting and peripheral nerve biopsy and confocal microscopy did not show any alteration in the neural network.[13] There was a single reported case of paradoxical fat hypertrophy that started at 3 months and stabilised at 5 months and the incidence of this event has been estimated to be 1: 20,000.[14]

Our study showed no adverse effects associated with CLATUU cryolipolysis. Our subjects experienced an initial 'suction' discomfort lasting 5-10 minutes followed by cold-induced numbness for the rest of the procedure. The most common post-treatment effect was numbness lasting from 1 to 3 weeks. One patient with atopic dermatitis experienced mild itching over the treated site for a few days post-cryolipolysis.



Baseline 1-week 1-month 2-months



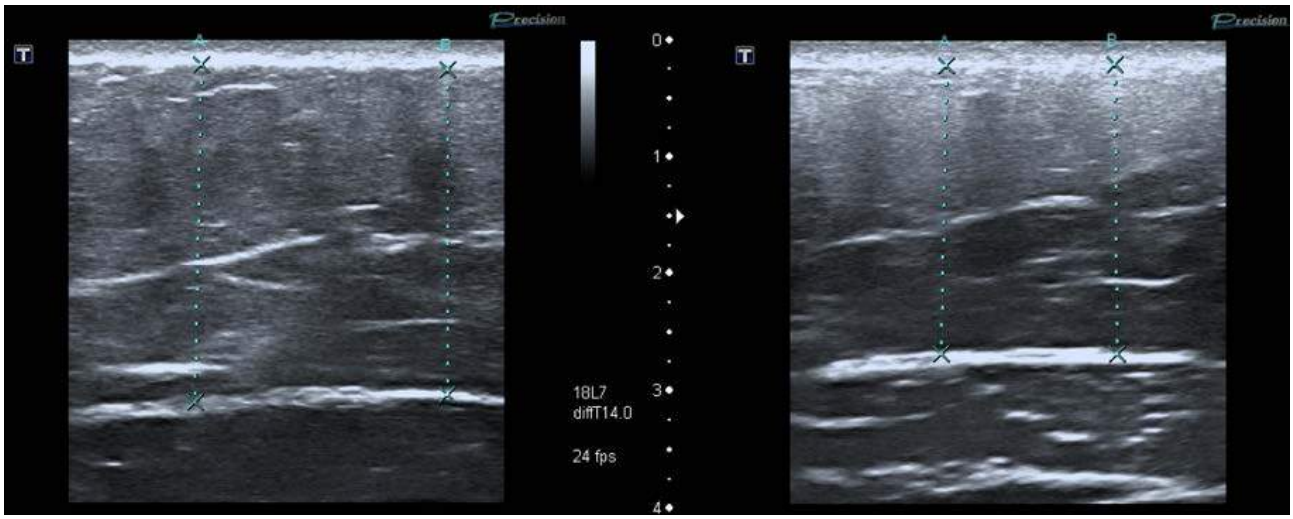


Figure 3. a, b, c. Bilateral upper postero-lateral flanks before (left top image) and after (right top image) cryolipolysis. Right flank: 2-months after 2 treatment sessions and left flank: 2-months after 1 treatment session (right top image). Histology at baseline, 1 week, 1-month and 2-months post-treatment (middle image, left to right). Post-treatment inflammatory cellular infiltrate is visible at 1-week, prominently visible at 1-month, and normalises at 2-months. Corresponding ultrasound measurements of left flank 2-months after 1 treatment session demonstrating a reduction in fat thickness (bottom image)

One patient had serial skin biopsies at baseline, 1-week, 1-month and 2-months post cryolipolysis revealing an inflammatory response that was mild at 1 week, marked at 1 month and fully resolved at 2 months (figure 3a, b) with corresponding ultrasound measurement images of the left upper posterior-lateral flank (figure 3c). Patients will typically notice localised fat loss over the treated area at 2 months, but as early as 1-month post procedure. Our pilot study on various methods of tracking fat reduction favours standardised photography and ultrasound over callipers and circumferential tape measure.

Circumferential tape measurement of abdominal girth is unlikely to be reliable given the limited target area in the context of the much larger truncal girth, which expands and contracts with the breathing cycle. We were unable to demonstrate consistency with calliper measurements of skin fold thickness, which can be pinch- and pressure- sensitive and prone to early user-error. Photography performs well on reliability, familiarity and accessibility, and furthermore, allows meaningful before-after comparison for patients. The anterior (front-on) and side (lateral) profile views are particularly useful to demonstrate contour changes. Oblique views may not

highlight contour changes adequately and this was highlighted by one patient who was uncertain about the outcome and remained unconvinced on review of post-treatment oblique photos despite a 26.9% fat thickness reduction on ultrasound (figure 4). This case illustrates how improper patient selection (high body mass index) and site selection (non-obvious fat bulge) can lead to patient dissatisfaction.

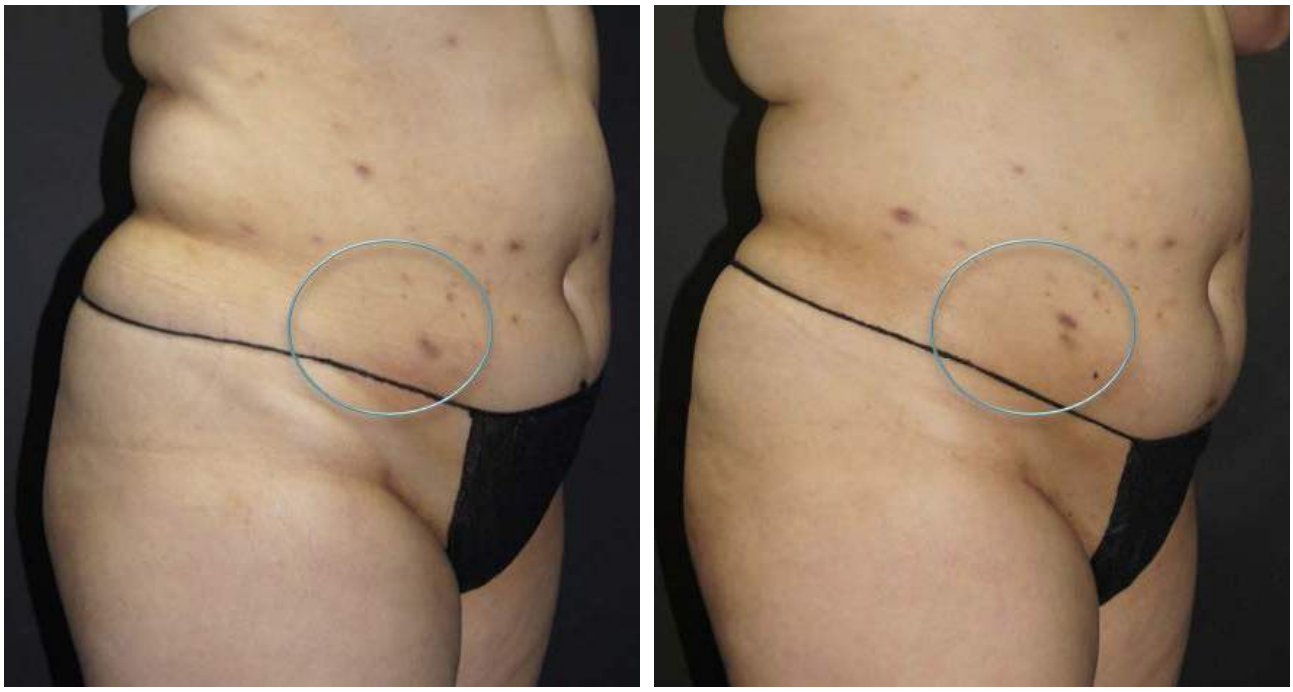


Figure 4. Right lower lateral oblique abdomen before (left image) and 2-months after 1 treatment session (right image).

Ultrasonic measurement of fat loss is essentially a research tool with significant accessibility and technical issues for most clinicians. Fat thickness measurement with the ultrasound probe is susceptible to probe-pressure and patient-posture variations (lying/ sitting/ standing) and these are likely explanations for the apparent underestimate of the global fat reduction (19.44%) relative to photographic assessment. Photographic representation of body contour can also be influenced by several factors including camera angle, lighting, patient stance, posture and breathing cycle. Nevertheless, standardised photography remains a valuable tool for monitoring post-cryolipolysis progress and provided one subject with valuable photo-documentation of visible fat reduction (figure 2).

The limitations of this study are a relatively small sample size, a predominance of torso (abdominal) treatment sites and potential investigator bias from using an industrysponsored device (Cryomed Australia).

Conclusion

Cryolipolysis with CLATUU is a safe effective procedure for localised fat reduction with a high patient satisfaction rate. Standardised photography is recommended as an effective monitoring tool and documentation of post-cryolipolysis progress.

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WILEY DERMATOLOGIC THERAPY

THERAPEUT IC HOT LINE : SHORT PAPERS

High-Intensity Focused Ultrasound Treatment after Cryolipolysis may be Used to Reduce Pain : Two case report

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Abstract

In recent years, interest in body sculpting has increased and various technologies have been used and developed. In the present study, we assessed the efficacy and safety of combination treatment using high-intensity focused ultrasound (HIFU) and cryolipolysis. The findings show that not only HIFU but also combination treatments are safe and well-tolerated options for the treatment of central abdominal subcutaneous adipose tissue (SAT). Interestingly, the pain associated with HIFU when it was performed after cryolipolysis was significantly reduced.

KEYWORDS

body sculpting, cryolipolysis, high-intensity focused ultrasound

1 | INTRODUCTION

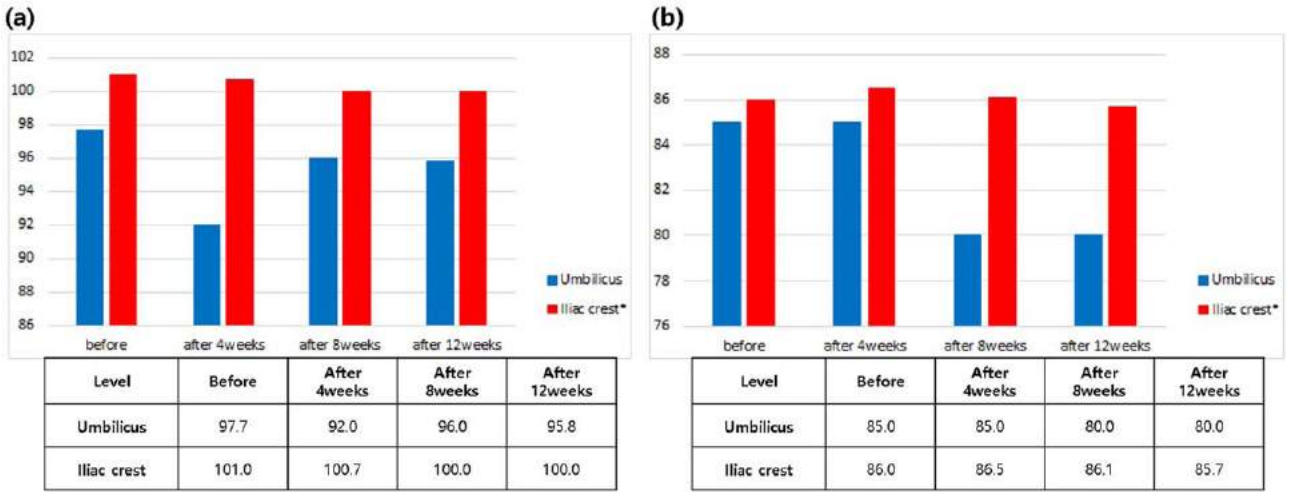
Body sculpting has become more popular and various technologies have been used and developed. These technologies include lowlevel laser therapy (LLLT), cryolipolysis, radio frequency (RF) and high-intensity focused ultrasound (HIFU). Each technique has varying results in terms of efficacy and patient satisfaction (Kennedy, Verne, Griffith, Falto-Aizpurua, & Nouri, 2015). Of these, patient satisfaction is the lowest for HIFU, which may be due to pain during the procedure (Kennedy et al., 2015). Cryolipolysis has the effect of lowering skin temperature and the feeling of temporary numbness (Nelson, asserman, & Avram, 2009). It will help to ease the pain sensations. We thought that combination treatments with two noninvasive body contouring devices would be expected to complement each other and have a synergistic effect. In the present case study, we assessed the efficacy and safety of combination treatments with HIFU and cryolipolysis.

2 | CASE REPORT

2.1 | Case 1

A 46-year-old female wanted to correct the contour of her flank. At baseline, she weighed 74.9 kg with a BMI of 27.25. The patient opted to have the left side of her abdomen treated with only an HIFU device (SCIZER, CLASSYS INC., Seoul, Korea). The contralateral side was treated first with cryolipolysis (CLATUU, CLASSYS INC., Seoul, Korea) and then HIFU (SCIZER). On her left flank, the HIFU device (SCIZER) parameters were set at a total energy dose of 120 J/cm2 at a focal depth of 1.3 cm. On her right flank, cryolipolysis treatment was

delivered first at commercial parameters (maintenance of -9°C for 40 minutes) and then the HIFU device was applied. The treatment applicators were positioned at the focal area of adiposity on her periumbilical abdomen. Waist circumference was measured at the level of the umbilicus and the superior border of the iliac crest. The results showed a waist circumference reduction of 1.9 cm from baseline at 12-week follow-up (Figure 1a). Immediately after treatment, no pain was reported on the combination treatment side, but for HIFU only treatment, the visual analogue score (VAS) was 4 (Figure 2a). Adverse events, such as erythema and bruising, were mild and spontaneously resolved within 1–2 days.



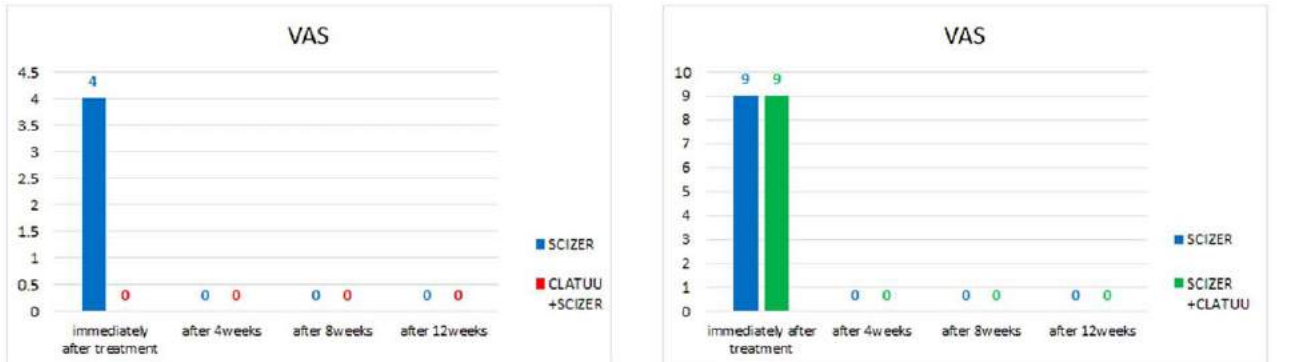
Level	Before	After 4weeks	After 8weeks	After 12weeks
Umbilicus	97.7	92.0	96.0	95.8
Iliac crest	101.0	100.7	100.0	100.0

Level	Before	After 4weeks	After 8weeks	After 12weeks
Umbilicus	85.0	85.0	80.0	80.0
Iliac crest	86.0	86.5	86.1	85.7

FIGURE 1 Measurement of waist circumference in (a) case 1 and (b) case 2

2.2 | Case 2

A 45-year-old female complained of subcutaneous fat in her flanks and wanted to remove the excessive fat. At baseline, she weighed 56.9 kg with a BMI of 20.5. The left side of the patient's abdomen was treated with only HIFU (SCIZER) using three passes to deliver a total energy dose of 120 J/cm2 at a focal depth of 1.3 cm. Her right side was treated with a single cycle of cryolipolysis using commercial parameters (maintenance of -9°C for 40 minutes) after the same HIFU procedure used on the left side. To evaluate treatment efficacy, waist circumference and subcutaneous fat thickness were measured. Waist circumference was reduced by 5 cm at the umbilical level (Figure 1b). As measured by fat CT, fat thickness decreased by 1.05 cm on both sides, and the reduction of subcutaneous adipose tissue (SAT) area was 7.3% (Figure 3). Although both sides of the abdomen received different treatment types, VAS scores were 9 on both sides (Figure 2b). The patient had no weight change. Other side effects, such as erythema and swelling, were resolved without sequelae.



Side	Treatment	immediately after treatment	after 4weeks	after 8weeks	after 12weeks
Left	SCIZER	4	0	0	0
Right	CLATUU +SCIZER	0	0	0	0

Side	Treatment	immediately after treatment	after 4weeks	after 8weeks	after 12weeks
Left	SCIZER	9	0	0	0
Right	SCIZER +CLATUU	9	0	0	0

FIGURE 2 VAS scores for pain in (a) case 1 and (b) case 2

3 | DISCUSSION

The mechanism of HIFU in body contouring suggests that adipose tissue is destroyed by thermal and mechanical effects producing adipocyte membrane disruption and coagulative necrosis (Haar & Coussios, 2007). Cryolipolysis technique showed cutaneous cooling-induced adipocyte apoptosis, triggering a selective delayed lobular panniculitis following reduction in subcutaneous fat in a model (Manstein et al., 2008). According to a number of studies for the present procedure, waist circumference and fat thickness by caliper were significantly reduced in treated areas. A study by Fatemi and Kane illustrated that HIFU treatment reduced waist circumference by a mean of 4.7 cm (Fatemi & Kane, 2010). Sasaki et al. also demonstrated a mean reduction in caliper measurements of 1 cm after a single cryolipolysis session (Sasaki, Abelev, & Tevez-Ortiz, 2014). In the present study, as both sides of the abdomen were treated differently, waist circumference, fat thickness and SAT area of fat CT were reduced, but there was no difference in fat thickness between treatment methods.

One study described synergistic effects for combined treatment with cryolipolysis and extracorporeal shock wave in 50 subjects (Ferraro et al., 2012). Mean reduction in abdominal circumference and thickness of 3.02 and 4.45 cm was achieved, respectively. In addition, extracorporeal shock followed by cryolipolysis diminished the pain associated with the procedure. The present study was the first attempt at combining cryolipolysis and HIFU.

To evaluate subcutaneous fat reduction efficacy, ultrasound, fat CT, and waist circumference were used in the present study. The results for fat thickness using ultrasound (data are not shown) were varying. Even though ultrasonography has been utilized extensively in previous studies, measurements need to be performed by well-trained clinicians, as fat thickness is influenced by various conditions. The result of fat CT at the umbilical level showed a reduction in fat thickness and SAT. Ultrasound assessment was regarded as an inexpensive and convenient method than fat CT. However, ultrasound might be inaccurate in obese person due to the presence of a septa (Black, Vora, Hayward, & Marks, 1988). With respect to waist circumference, the two cases reported showed differences between umbilical and iliac crest levels. Waist circumference change measured in the umbilical level is better reflected than that measured in iliac crest levels.

Subcutaneous fat thickness	Left (SCIZER)	14.06	13.01
	Right (SCIZER +CLATUU)	14.06	13.01
Abdominal SAT area		124.5	115.4

FIGURE 3 Subcutaneous adipose tissue (SAT) area and fat thickness by Fat CT in case 2

One literature reported that the umbilicus level in fat CT and waist circumference may provide the most useful measures of procedure efficacy, because this area contains the largest amount of fat in the body (Borkan et al.,

1982). Therefore, we consider that the objective tool of choice would be fat CT when measuring subcutaneous fat thickness. These findings show that combination treatment with HIFU and cryolipolysis is safe and well-tolerated options for the treatment of central abdominal SAT. Especially, the interesting result is that after cryolipolysis, the pain during HIFU treatment was decreased. Also the authors believe that this combination of noninvasive body contouring could be more synergistic than each device used alone.

CONFLICTS OF INTEREST

None declared.

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Non-Invasive Methods to Optimize the Figure: Market Overview: Body-forming Treatments

The demand from patients to enhance their body image is huge with having a clear tendency to favor minimal to non-invasive procedures. Several innovative, non-invasive procedures have been developed in the last few years. They are different from others in that they can deliver significant outcomes while practicing high safety standards during procedures.

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A variety of treatments serve as an alternative to the aesthetic-plastic surgery and that not only with comparable results, but also with lesser risks and side- effects as compared to the invasive methods. The focus is on enhancing the body image and optimizing the silhouette. The subcutaneous fatty tissue can be reduced, the slaggy tissue is made firm and certain methods also improve the skin tone. The treatments do not serve the purpose of weight reduction. On the contrary, a BMI of over 30 does not actually constitute a contraindication. The result is thus not reflected accordingly by fewer kilos on the weighing scale, but through size- and volume reduction and tightening of the body areas treated.

Fatty tissue

Fatty tissue comprises approx. one-third of adipocytes, which store energy in excessive energy supply (Lipogenesis) or release it, in case of missing energy supply (Lipolysis). Further components of the fatty tissue are small vessels, nerve tissue, macrophages, fibroblasts and preadipocytes in different stages of their development1. Adipocytes can be differentiated in two types: small with a diameter of approx. 50–60µm and large with a diameter of more than 100µm. Each region of the body is characterized by a separate mix of small and large and of hyper plastic and hypertrophic adipocytes.

PHOTO: Ventral area after the Cryolipolysis treatment

PHOTO: Cryolipolysis treatment: Immediately after the treatment with Clatuu, still with Gel- protection cloth.

The average life of adipocytes is ten years. Approx. 10% die each year2.

There are two types of fatty tissues: Subcutaneous and visceral fat. Lipid mobilization in the visceral adipocytes is achieved faster through diet or training than in the subcutaneous ones3, unfortunately, though the subcutaneous fat is perceived as aesthetically unpleasing.

The specification depending upon the part of the body has to do with the stronger or weaker lipolysis stimulation and different structures of the fat tissue, that is the relation of hyperplasia and hypertrophy4.

Many persons affected, who perceive undesired fat deposits as aesthetically unpleasing, are highly skeptical of a surgical intervention such as liposuction or an abdominoplasty and prefer non- or minimal-invasive procedure to the classical surgery.

The fear of a surgical intervention in general, the risk of anesthesia, the subsequent risk of scarring and the risk of uneven results, which may frequently develop later due to the damage to lymph vessels, influence the decision of the patients.

Methods

It is possible to reduce the subcutaneous fat tissue by means of different methods with the non-invasive Body contouring. Adipocytes can be destroyed thermally or mechanically. Long-term or even permanent results can be achieved. The spectrum of the current approaches for volume reduction is broad: apart from cryolipolysis and radiofrequency, there are ultrasound, shock waves, laser- and injection lipolysis also available. We would like to present all the methods in the following and compare them in the best possible manner.

Cryolipolysis (Devices e.g. CLATUU®)

Cryolipolysis is based on the fact that adipocytes are clearly more sensitive to cold than water containing cells. Almost the entire cell body of the fat cells is filled with large fat droplets. The fat droplets crystallize when cooled to below 4 degrees with subsequent damage to the cell membranes and apoptosis of adipocytes – that is to a death cell5, 6.

The challenge lies in performing the cooling exactly within this therapeutic window period, without damaging the skin thermally. Ischemia after cooling the fat tissue (when cooling, the shunts between the arteries and veins open) are jointly responsible for the apoptosis. The Ischemia-Reperfusion injury shows the mechanism, that triggers activation of the apoptosis-processes with the release of reactive oxygen and increase in the calcium level. This mechanism additionally leads to cell damage of the adipocytes in the form of intracellular edema, reduction of Na-K-ATPase-activity with reduced adenosine triphosphate, lactase-boost and distribution of free mitochondrial radicals from the damaged adipocytes7.

Even vegetative influences must be observed in cryolipolysis: activating the sympathetic nervous system, results in distribution of noradrenaline with the activation of β-adrenergic receptors with consecutive activation of genes controlling thermogenesis and energy consumption8.

Activation of β-adrenergic receptors leads to thermogenesis in the brown fat tissue with simultaneous increased degradation of the white fat tissue through hydrolysis of intracellular triglyceride, oxidation of fatty acids and activation of UCP1 (uncoupling protein 1)9.

The inflammatory cells migrate to the treatment area after three to seven days through apoptosis-signals. Infiltration through macrophages is observed after 14 days. The concerned adipocytes are incorporated through the macrophages and transported to the liver via the lymphatic system, where metabolization takes place. This fat reduction develops slowly within two to three months10.

Performing the treatment with CLATUU®

(Classys, South Korea)

Anesthesia is not required for the treatment and has no downtime as a consequence. It is particularly suitable for patients, who have gained lot of weight in short time or suffer from persistent local fat pads. A good general condition is required.

The treatment area is marked and covered with a gel cloth, to protect the skin during cooling. Different applicators are used depending upon the area of application (abdomen, flank, hip, inner thigh, upper arms, fat deposits on the back). The treatment area is brought into the applicator (Vacuum) and cooled for 40 to 60 minutes in a controlled manner. The place is massaged vigorously immediately thereafter for five to eight minutes, which is extremely important for the successful treatment and reduces the thaw pain. The success of the treatment, as per the studies, could be increased by more than 50% with forced massage11.

All the usual activities in terms of work and leisure can be resumed immediately after the treatment. The maximum result can be expected after 90 days, even if the first effects become visible after four to six weeks itself. Two to three treatments at an interval of two to three months are recommended. Calorie reduced diet and physical activity should be observed in this period.

Side (adverse) effects and contraindications

Cryolipolysis is an efficient method to reduce local subcutaneous fat deposits with concurrent skin tightening effect. It has agreeably low risk, but certainly not without risks.

Cold and vacuum in the first minutes of the treatment is unpleasant for patients, before the cold anesthesia sets in. The short-term pain when the treatment area returns to normal body temperature during and after cryolipolysis can be described as extremely uncomfortable, but no more adverse or life-threatening effects.

All other side effects are short term and reversible. Reddening of the treated skin zone, swelling, sensitivity disorders of the treatment zone and myalgia complaints, comparable to an aching muscle, are reported sometimes. Hyper-pigmentations of the treatment zone normally receding on their own, or paradoxically obese hyperplasia are seldom. The rate of adverse reaction is overall low with less than 1%, 12still the patient should be aware that Cryolipolysis is not a harmless cosmetic treatment.

Profound tissue changes are related, in the sense of cell membrane changes, cell death of subcutaneous fat cells and inflammatory consequences, linked with stimulation of fibroblasts and if required immune modulating processes. Undesired immune processes can be triggered, for instance in the sense of Panniculitis. Besides, the cold induced reflex blood flow alterations in the sense of Prinzmetal-Angina, and the triggering of hypertonic crisis in spite of carefully examining the exclusion criteria of patients have to be observed13.

Hernia, particularly belly button hernia, rectus diastasis, diseases with changed inflammatory reaction of the body like M. Crohn, colitis ulcerosa, lupus erythematosus and other collagenosis must be ruled out. Other contraindications are: Cryoglobulinemia, cold urticaria, cutaneous and systemic collagenosis, neuropathic and sensitive skin disorders, coagulation disorders, anticoagulant therapy, dermatosis with Koebner phenomenon, pregnancy and lactation period and pacemaker implantation13.

Patients with multiple sclerosis, cancer diseases, immune-modulating therapies, fibromyalgia or diseases of the rheumatic type are dissuaded until studies on larger group of patients of treatments are available.

Caution in mental illnesses would be wise, especially in Borderline-Personalities, schizoaffective psychosis etc. All internal risk factors must be weighed carefully, and all adverse effects should be elaborated in the explanatory discussion and documented.

Cryolipolysis is a method of selection for patients desirous of a quick, intensive reduction of subcutaneous fat tissue. Up to 25% of the treated subcutaneous fat tissue of the treatment area can be removed in one session. Patient satisfaction in this treatment is over 70%14. Other innovative devices have interesting treatment options for patients, for whom cryolipolysis-treatment have been contraindicated or is unsuccessful.

Highly intensive focused Ultrasound (HIFU) (Devices: e.g. Scizer®, Classys, South Korea)

HIFU is a non-invasive method for tissue heating and ablation. As far as fat reduction is concerned, high energetic ultrasound waves with high intensity are distributed over the skin and then focused sharply on the subcutaneous fat tissue. The energy is low enough on the skin surface to protect the skin.

On the other hand, high intensity ultrasound energy waves can reach depths as far below to the subcutaneous fat region, causing fat tissue to undergo a natural process of coagulative necrosis. This fat ablation can be achieved with two mechanisms: Hyperthermia and cavitation.

Cavitation

HIFU triggers molecular vibration of the affected adipocytes and the subsequent rapid heating to the temperatures higher than the upper limit of the Protein-Denaturation (60 – 65°C). This results in coagular necrosis19.

Mechanical ultrasound waves pass through the adipocytes and bring about a change of increased and reduced pressure circles leading to a vesicular separation of Gas and Solution. When the bubbles implode, the energy output triggers further mechanical damages of the focused adipocytes. Chemotactic-factors are released by the destroyed fat cells and bring about mild inflammation. Macrophages and phagocytes are stimulated and remove extracellular lipids and the cellular remains,19, 20so that the subcutaneous fat is reduced, without damaging the surrounding tissue. The prerequisite for the treatment is a BMI of less than 30 and a fat layer of at least 2.5cm.

Performance with the Scizer Device

Thanks to the integrated cooling, local anesthesia is not required. Ultrasound energy of 2MHz is applied at a depth of 9mm or 13mm and heats up the fat cells to 65°C. The treatment lasts for 15-20 minutes depending upon the patient and the treatment area. An average reduction of the abdominal perimeter between 2.5 and 8cm is achieved. The first results are visible immediately after the first treatment itself they improve gradually over a period of four to twelve weeks. Two to three treatments at the interval of two to three months are recommended. A healthy and calorie-reducing diet should be observed in the treatment period.

Risks and side (adverse) effects

The treatment in general is safe and painless. Pain, rashes, slight uneasiness, swellings, feeling of deafness or ecchymosis may occur temporarily. Metal plates or piercings in the body area should be removed, acute thrombosis, blood coagulation disorders and acute inflammations in the treatment area must be observed.

Closing remarks

A healthy lifestyle is essential for Body forming. All methods work adjuvant towards weight reduction, but they are not suited for obesity. The most important measures are a balanced nutrition and sufficient physical activity. The building of the musculature is in most cases crucial for a successful result, since it increases the basal metabolic rate and the natural Lipolysis (muscle pump). Sufficient fluid intake is also important for the desired breakdown processes. The mentioned non-invasive treatments are safe if the contraindications are compiled and carefully implemented. Particularly promising is the well-thought-out combination of the methods. Often, the best results are achieved, if three or four methods are combined for a patient, depending upon the area and tissue consistency.

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