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

Kota Ichikawa, M.D.[1 2], Muneo Miyasaka, M.D.[1 2], and Akihisa Yamazaki, M.D.[2]

[1] Department of Plastic Surgery, Tokai University School of Medicine, Japan

[2] Atsugi Beauty Clinic, Japan

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

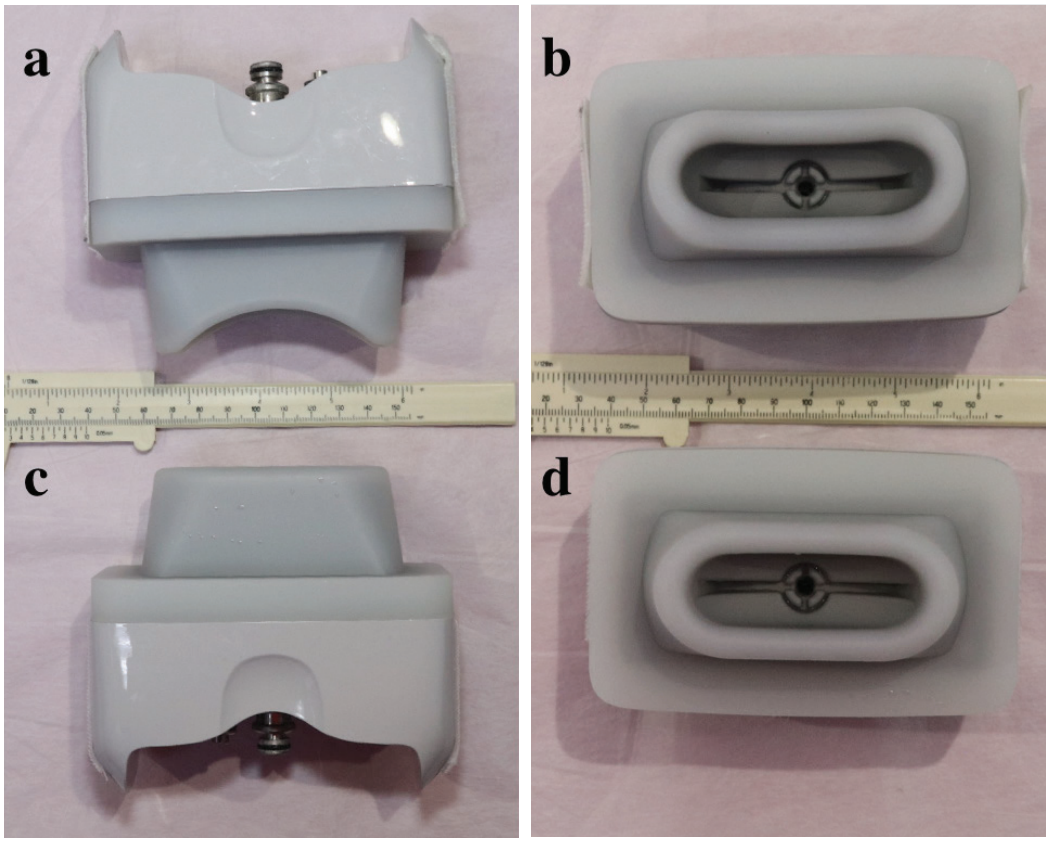

Figure 1. Small volume applicator for neck (a) side view and (b) top view showing contoured cooling surface. Small volume applicator for lower cheek (c) side view and (d) top view showing flat cooling surface.

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.

References

1 Patel, BC (2006) Aesthetic surgery of the aging neck: Options and techniques. Orbit 25(4): 327– 356.

2 Hatef, DA, Koshy, JC, Sandoval, SE, Echo, AP, Izaddoost, SA, Hollier, LH (2009) The submental fat compartment of the neck. Semin Plast Surg 23(4): 288– 291.

3 Rzany, B, Griffiths, T, Walker, P, Lippert, S, McDiarmid, J, Havlickova, B (2014) Reduction of unwanted submental fat with ATX-101 (deoxycholic acid), an adipocytolytic injectable treatment: Results from a phase III, randomized, Placebo controlled study. Br J Dermatol 170(2): 445– 453.

4 Ascher, B, Hoffmann, K, Walker, P, Lippert, S, Wollina, U, Havlickova, B (2014) Efficacy, patient-reported outcomes and safety profile of ATX-101 (deoxycholic acid), an injectable drug for the reduction of unwanted submental fat: Results from a phase III, randomized, placebo-controlled study. J Eur Acad Dermatol Venereol 28(12): 1707– 1715.

5 McDiarmid, J, Ruiz, JB, Lee, D, Lippert, S, Hartisch, C, Havlickova, B (2014) Results from a pooled analysis of two European, randomized, placebo-controlled, phase 3 studies of ATX-101 for the pharmacologic reduction of excess submental fat. Aesthetic Plast Surg 38(5): 849– 860.

6 Zelickson, B, Egbert, BM, Preciado, J, Allison, J, Springer, K, Rhoades, RW, Manstein, D (2009) Cryolipolysis for non invasive fat cell destruction: Initial results from a pig model. Dermatol Surg 35: 1462– 1470.

7 Avram, MM, Harry, RS (2009) Cryolipolysis for subcutaneous fat layer reduction. Lasers Surg Med 41(10): 703– 708.

8 Manstein, D, Laubach, H, Watanabe, K, Farinelli, W, Zurakowski, D, Anderson, RR (2009) Selective cryolysis: A novel method of non invasive fat removal. Lasers Surg Med 40: 595– 604.

9 Zelickson, BD, Burns, AJ, Kilmer, SL. Cryolipolysis for safe and effective inner thigh fat reduction (2015) Lasers Surg Med 47(2): 120– 127.

10 Munavalli, GS, Panchaprateep, R (2015) Cryolipolysis for targeted fat reduction and improved appearance of the enlarged male breast. Dermatol Surg 41(9): 1043– 1051.

11 Stevens, WG, Bachelor, EP (2015) Cryolipolysis conformable surface applicator for non-surgical fat reduction in lateral thighs. Aesthet Surg J 35(1): 66– 71.

12 Schlessinger, J, Weiss, SR, Jewell, M, Narurkar, V, Weinkle, S, Gold, MH, Bazerkanian, E (2013) Perceptions and practices in submental fat treatment: A survey of physicians and patients. Skinmed 11(1): 27– 31.

13 Lee NY, Ibrahim O, Arndt KA, Dover JS (2018) Marginal Mandibular Injury After Treatment with Cryolipolysis. Dermatol Surg 44(10):1353-1355

14 Lipner SR (2018) Cryolipolysis for the treatment of submental fat: Review of the literature. J Cosmet Dermatol. 17(2):145-151

15 Touré G, Tran de Fremicourt MK, Randriamanantena T, Vlavonou S, Priano V, Vacher C (2019) Vascular and Nerve Relations of the Marginal Mandibular Nerve of the Face: Anatomy and Clinical Relevance. Plast Reconstr Surg 143(3):888-899