The Efficacy and Safety of Cryolipolysis for Subcutaneous Fat Reduction

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Dear Editor:

Liposuction remains the gold standard method for fat reduction; however, it is accompanied by severe adverse effects, including infection, prolonged recovery time, hematoma, and scarring. Moreover, liposuction has a risk of fatal complications related to anesthesia. Noninvasive techniques of fat reduction have been developed for and preferred by patients who are seeking safer alternatives to surgery. Cryolipolysis is one of the most frequently performed noninvasive techniques of fat reduction. Low-level laser therapy, cryolipolysis, radiofrequency (RF), and high-intensity focused ultrasound (HIFU) are the four most common energy devices for fat reduction. Among several other devices for fat reduction, cryolipolysis and HIFU were the only devices that have accomplished significant reductions with a single treatment session. Cryolipolysis received Food and Drug Administration clearance for fat reduction in the flanks in 2010, abdomen in 2012, and thigh in 2014. However, the procedure has also been used for off-label treatments of the arms, thighs, knees, back, and chest. Although numerous clinical studies have been conducted in the United States, only a limited number of patients have been treated and studied in other countries. In this study, we investigated the tolerance, safety, and patient satisfaction of cryolipolysis in Korea. This article reports the results of a retrospective series of patients treated at multiple private practices in Korea. This study was approved by the Institutional Review Board of Asan Medical Center (no. 2016-0669). We received the patient’s consent form about publishing all photographic materials. The patients received cryolipolysis treatments (CoolSculpting; ZELTIQ Aesthetics, Pleasanton, CA, USA) between May 2014 and December 2015. Trained clinicians collected patient data on age, sex, and medical history. The chart review was conducted at 673 cryolipolysis treatment sites in 281 patients. Of the 281 patients, 41 were available for evaluation. The treatment efficacy was assessed according to circumference measurements before treatment and at the 1-month and 3-month follow-up. When patients have repeated treatment sessions, we measured the circumference after the last treatment. As the results can be affected by body weight, circumference measurements were also performed before treatment and at the follow-up visits. The abdominal circumference was measured at the level of umbilicus and the circumference of treatment sites other than abdomen was measured at the center of sites pulled into the applicator. For accuracy, the circumference of all treatment sites was measured at the same point before and after procedures. The treatment sites included any roll of fat.
that could be safely pulled into the applicator. Each treat-
miment session had a duration of 60 minutes. The self-re-
ported patient satisfaction score was assessed 3 months af-
after the last treatment with measurement of the results, and
was evaluated by using a four-point scale as follows: ‘3’
(>75% improvement), ‘2’ (51%~75% improvement), ‘1’
(25%~50% improvement), ‘0’ (<25% improvement). Safety was evaluated according to the number of adverse
events.

The cryolipolysis procedure was performed at 97 treat-
mament sites in 41 patients. The average patient age was 44
years, and the overall age range was 21~69 years. Treatments were delivered primarily to the lower abdo-
men (26.8%, n=26), lower flank (18.5%, n=18), arm
(17.5%, n=17), inner thigh (10.3%, n=10), banana line
(9.2%, n=9), upper abdomen (7.2%, n=7), lateral thigh
(4.1%, n=4), upper back (2%, n=2), axilla, lower back
(1%, n=1), upper flank (1%, n=1), and anterior thigh
(1%, n=1). A single session of treatment was usually rec-
ommended for each treatment site, and ten patients
(24.3%) received more than two treatment sessions for the
same site. The areas that required more than two sessions
were the lower abdomen, lower flank, arm, lateral thigh,
inner thigh, banana line, and upper back. Four patients re-
cieved more than two sessions on the lower abdomen,
and one of four patients received four cycles of treatment

| Treatment site    | Circumference measurements, Average change from baseline to 1-month follow up (cm) | Circumference measurements, Average change from baseline to 3-month follow up (cm) | Average change of body weight (kg) | Satisfaction score |
|-------------------|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------------------|-------------------|
| Axilla            | 0.00                                                                                 | 0.00                                                                             | 0.00                              | 1.00              |
| Arm               | −0.09                                                                                | −0.56                                                                            | −0.12                             | 2.06              |
| Upper back        | −1.00                                                                                | −1.00                                                                            | −3.00                             | 2.00              |
| Lower back        | 0.00                                                                                 | −0.75                                                                            | 0.00                              | 2.00              |
| Upper abdomen     | −0.29                                                                                | −0.71                                                                            | −0.14                             | 1.29              |
| Lower abdomen     | −0.33                                                                                | −0.92                                                                            | −0.04                             | 1.88              |
| Upper flank       | −1.00                                                                                | −1.00                                                                            | −2.00                             | 1.00              |
| Lower flank       | −0.31                                                                                | −0.69                                                                            | −0.17                             | 1.89              |
| Banana line       | −0.07                                                                                | −0.37                                                                            | −0.33                             | 2.00              |
| Anterior thigh    | 0.00                                                                                 | −0.50                                                                            | 0.00                              | 3.00              |
| Lateral thigh     | −0.50                                                                                | −1.13                                                                            | 0.00                              | 2.50              |
| Inner thigh       | −0.40                                                                                | −0.68                                                                            | 0.00                              | 2.00              |
| Average           | −0.33                                                                                | −0.69                                                                            | −0.48                             | 1.88              |

Fig. 1. (A) Baseline and 12 week post-treatment photos for a 39-year-
old female. Patient received two sessions of cryolipolysis treatment
to her lower abdomen and both flank areas. Weight change was +3 kg from baseline. (B) Baseline and 12 week post-treatment photos for a 20-year-old female. Patient received two sessions of cryolipolysis treatment to her arms. There was no weight change.
on the lower abdomen. The average change from baseline to the 1-month and 3-month follow-up was $-0.33\,\text{cm}$ and $-0.69\,\text{cm}$, respectively (Table 1). The average change of body weight at 3 months was $-0.15\,\text{kg}$. Among the 41 patients, only 3 patients lost weight ($-1, -2, -3\,\text{kg}$).

Fig. 1 shows the clinical photographs of patients. Of the 41 patients, 8 (19.5%) reported pain in the treated area that required analgesics after treatment. None of the patients reported pain at 2 weeks after treatment. Two patients (4.8%) reported numbness, and one patient (2.4%) reported a tingling sensation in the treated site, which subsided spontaneously at 3 days after treatment without further intervention. There were no other adverse effects including scarring, bleeding, hyperpigmentation, or hypopigmentation. The average satisfaction score was 1.88 of 3. Patients who were treated in the anterolateral thigh reported the highest satisfaction score (2.5–3).

In general, noninvasive modalities for fat reduction deliver energy with adipocytes as the target. Heat is the most important stimulus generated by laser, RF, and ultrasound. The energy sources of laser, RF, and ultrasound are finally transformed into the heat, and this thermal energy destroys fat cells. On the other hand, the mechanism of cryolipolysis is completely different from that of other modalities. Cryolipolysis uses ‘cold’ exposure or thermal energy reduction to destroy fat cells. The exposure to low temperature induces apoptosis of adipocytes. The susceptibility of adipocytes to cold is greater than that of other cells, leading to selective adipocyte destruction. The surrounding inflammatory cells, especially macrophages, subsequently engulf and digest the adipocytes. After 4 weeks of treatment, these inflammatory cell infiltrations become reduced and the volume of adipose tissue decreases. Two to four months after treatment, the inflammatory response further decreases, and the volume of adipose tissue decreases. The well-known adverse effects of cryolipolysis are discomfort (96%), pain (55%), and bruising (9.5%–50%). A significant risk of transient sensory nerve dysesthesia, which resolved during 2–3 months, has been reported, and the histopathologic evaluations showed no significant changes in peripheral nerves.

In our study, we treated 281 patients, and no patient reported a significant adverse effect including persistent erythema, blistering, or skin necrosis (data not shown). Although there were reports of numbness (4.8%) and tingling sensation (2.4%) in the treated site, these conditions subsided spontaneously. The cryolipolysis procedure achieves selective reduction in superficial fat without causing injury to the epidermis or dermis. The main advantage of cryolipolysis is a low profile of adverse effects. Taking the findings together, although the outcomes of cryolipolysis are rather modest, this technology is well suited to patients who desire safe and noninvasive fat reduction.

**CONFLICTS OF INTEREST**

The authors have nothing to disclose.

**REFERENCES**

1. Mordon S, Plot E. Laser lipolysis versus traditional liposuction for fat removal. Expert Rev Med Devices 2009;6:677-688.
2. Kennedy J, Verne S, Griffith R, Falto-Aizpurua L, Nouri K. Non-invasive subcutaneous fat reduction: a review. J Eur Acad Dermatol Venereol 2015;9:1679-1688.
3. Stevens WG, Pietrzak LK, Spring MA. Broad overview of a clinical and commercial experience with CoolSculpting. Aesthet Surg J 2013;33:835-846.
4. Mulholland RS, Paul MD, Chalfoun C. Noninvasive body contouring with radiofrequency, ultrasound, cryolipolysis, and low-level laser therapy. Clin Plast Surg 2011;38:503-520.
5. Coleman SR, Sachdeva K, Egbert BM, Preciado J, Allison J. Clinical efficacy of noninvasive cryolipolysis and its effects on peripheral nerves. Aesthetic Plast Surg 2009;33:482-488.
6. Zelickson B, Egbert BM, Preciado J, Allison J, Springer K, Rhoades RW, et al. Cryolipolysis for noninvasive fat cell destruction: initial results from a pig model. Dermatol Surg 2009;35:1462-1470.
7. Avram MM, Harry RS. Cryolipolysis for subcutaneous fat layer reduction. Lasers Surg Med 2009;41:703-708.