



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 scarring¹. 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 session². 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 chest³. 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

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that could be safely pulled into the applicator. Each treatment session had a duration of 60 minutes. The self-reported patient satisfaction score was assessed 3 months 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 treatment 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 recommended 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 received more than two sessions on the lower abdomen, and one of four patients received four cycles of treatment

Table 1. Circumference evaluation and satisfaction score according to the treatment sites

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

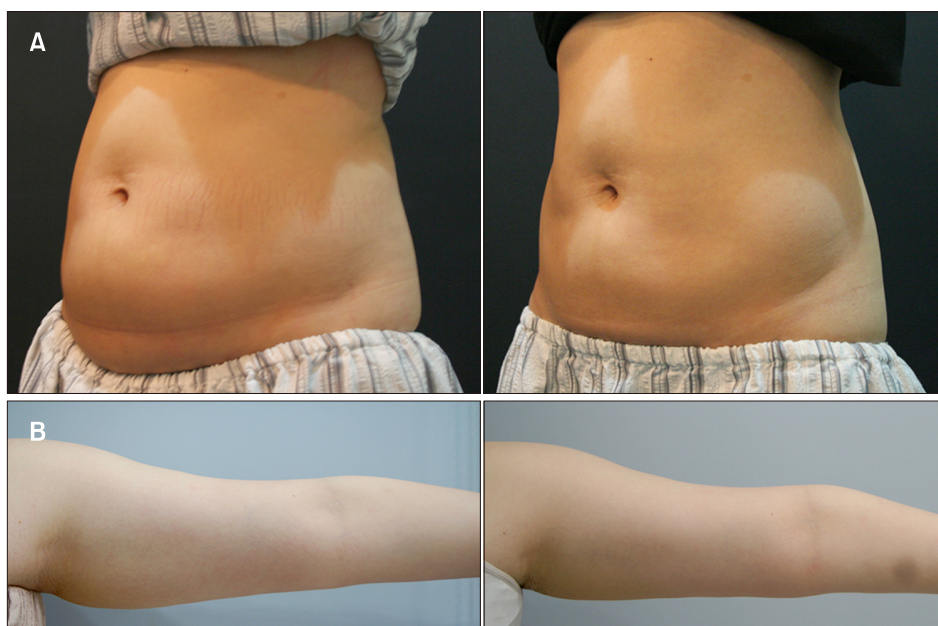


Fig. 1. (A) Baseline and 12 week post-treatment photos for a 39-year-old female. Patient received two sessions of cryolipolysis treatment to her lower abdomen and both flank areas. Weight change was +3 kg from baseline. (B) Baseline and 12 week post-treatment photos for a 20-year-old female. Patient 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 cm and -0.69 cm, respectively (Table 1). The average change of body weight at 3 months was -0.15 kg. Among the 41 patients, only 3 patients lost weight (-1 , -2 , -3 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 cells⁴. 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 adipocytes⁵. The susceptibility of adipocytes to cold is greater than that of other cells, leading to selective adipocyte destruction⁶. The surrounding inflammatory cells, especially macrophages, subsequently engulf and digest the adipocytes⁶. After 4 weeks of treatment, these inflammatory cell infiltrations become reduced and the volume of adipose tissue decreases⁷. Two to four months after treatment, the inflammatory response further decreases, and the volume of adipose tissue decreases⁷. The well-known adverse effects of cryolipolysis are discomfort (96%), pain (55%), and bruising (9.5% ~ 50%)². 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 nerves⁵.

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.

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