

Longitudinal evaluation of cryolipolysis efficacy: two case studies

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Summary

Cryolipolysis treatment, or cold-induced destruction of adipocytes, provides a noninvasive option for localized subcutaneous fat reduction without damaging the overlying skin or adjacent structures. This case study examines the long-term visibility of fat layer reduction subsequent to cryolipolysis treatment, through longitudinal evaluation. Two male subjects were unilaterally treated on one flank. Baseline and postprocedure photographs (at 2 or 5 years) of the treated and contralateral untreated flanks display durable results despite natural fluctuations in body weight.

Keywords: fatty tissue, cryosurgery, cosmetic procedure, cosmetic surgery, frozen fat, thermal injury

Introduction

Unwanted focal collections of subcutaneous fat negatively impact body shape and image, and as a result of new technological advances, body reshaping and fat removal cosmetic procedures have become increasingly popular. Presently, liposuction is the most common procedure for body contouring and removal of local subcutaneous fat. Due to its invasive nature there are, however, inherent surgical risks and downtime associated with recovery. The demand for noninvasive forms of body contouring has inspired numerous alternative techniques that utilize various forms of energy or cooling including radiofrequency, ultrasound, laser, and infrared light. One novel development in noninvasive body contouring is cryolipolysis or the selective destruction of adipocytes via cold exposure. This technique has been shown to provide safe and effective reduction in subcutaneous fat.

Numerous studies have shown that localized fat reduction can occur when the fat tissue is exposed to

cold under certain conditions, suggesting that fat cells may be more sensitive to cold than other tissues.^{1–5} Dermatologists have been aware of cold panniculitis with subsequent atrophy for a half century or more.^{1–4} Porcine studies investigated the utility of using controlled cooling to remove fat by localized skin cooling, by selectively inducing apoptosis of adipocytes without injury to the overlying skin or adjacent structures.^{6,7} Selective removal of fat is possible without injuring skin, because fat is less resistant to cold injury than the overlying skin.^{6–8} Histopathologic evaluation of cryolipolysis-treated fat reveals inflammation in the treated subcutaneous adipose tissue 3 days following treatment.⁸ Phagocytosis of fat by macrophages was present 14- and 30-days post-treatment. Histopathologic evidence of inflammation diminished significantly 90 days following treatment, as affected adipocytes underwent apoptosis and were digested by macrophages, resorbed, and eliminated. The serum lipid levels and liver function studies measured in both humans and animals undergoing cryolipolysis were within normal limits, as measured over a 3-month period following cryolipolysis treatment.^{11,13}

Various multicenter, prospective, nonrandomized human studies have shown that a single controlled cooling procedure produces visible subcutaneous fat

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layer reduction through selective cryolipolysis.^{9–14} Dover *et al.*¹⁰ evaluated treatment of 32 male and female subjects enrolled in a prospective study of cryolipolysis. Each participant underwent treatment of one flank at a programmed heat extraction rate, referred to as a “Cooling Intensity Factor.” This study used a CIF of 33, which corresponds to -64 mW/cm^2 , for 60 min. The contralateral flank served as an untreated control. Ultrasound measurements demonstrated an average fat layer reduction of 22.4% at 4-months post-treatment. The best individual results were observed in participants with modest and discrete fat bulges. No adverse events were reported and 94% of participants indicated that they either had no discomfort during treatment or felt a level of discomfort no greater than what they had expected. Eighty percent of the subjects reported satisfaction with their results at 6-month postprocedure.¹⁴

Results from several other studies are consistent with these findings. Riopelle *et al.*¹³ measured the flanks of five male subjects via ultrasound and reported an averaged 18.2% fat layer reduction, 6-month postcryolipolysis procedure. Similarly, Coleman *et al.*¹¹ treated the flanks of nine subjects and reported a 20.4% fat layer reduction at 2 months, and 25.5% reduction at 6-month postcryolipolysis treatment. Shek *et al.*¹² demonstrated a statistically significant fat layer reduction in 21 subjects after a single treatment.

There have been no reports to date that provide evaluation of efficacy beyond 6-month post-treatment, which may reflect the fact that this treatment is relatively new or simply that longer follow-up periods add cost and compliance issues. These case studies provide information about the long-term efficacy of cryolipolysis by visual comparison of baseline and late follow-up photos of treated and un-treated control areas in two subjects. To demonstrate the longevity of cryolipolysis for fat layer reduction, larger, prospective trials are needed which follow subjects 1–5 years after treatment.

Case report

Case 1

A 44-year-old man with persistent localized fat deposits on his flanks which were not reduced by diet or exercise was treated with two cryolipolysis treatments on one flank to ascertain how affective this treatment would be when applied to him (CoolSculpting, ZELTIQ, Inc., Pleasanton, CA, USA). The treatments were performed on the same left flank with the contralateral flank serving as an untreated control. Treatment sites were adjacent to each other on the left flank with 50% overlap between the first and second treated regions. Each treatment was 60 min in duration at a CIF of 42 (-72.9 mW/cm^2). At baseline, the participant weighed 205 pounds with a BMI of 27.0. Photographs document initial fat layer proportions and any preexisting asymmetry between sides (Fig. 1). At 2 years postprocedure, the subject weighed 215 pounds – having gained 10 pounds since baseline. Despite weight gain, the left flank continued to show substantial reduction at 2-year post-treatment, relative to the untreated flank (Fig. 1).

Case 2

A 45-year-old man was seen for persistent localized fat deposits on his flanks that were not reduced by diet or exercise, and opted to receive a single cryolipolysis treatment to determine if, and how well, this treatment worked for him (CoolSculpting). The treatment was performed on the right flank with the contralateral flank serving as an untreated control. His right flank was treated with the cryolipolysis device at a CIF of 34 (-65.2 mW/cm^2) for 60 min. At baseline, the participant weighed 190 pounds with a BMI of 23.7. Photographs were taken to document initial fat bulge proportions and any preexisting asymmetry between

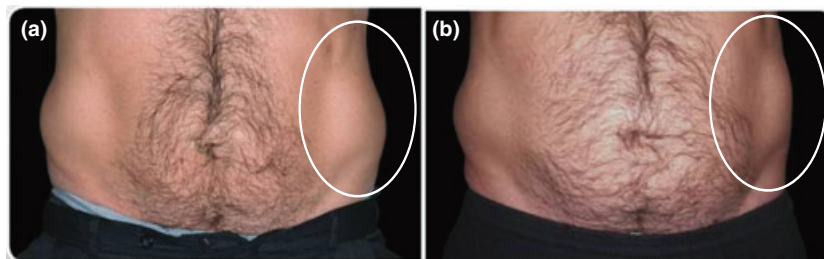


Figure 1 Pre- and post-treatment images showing fat layer reduction on the patient's left (treated) flank at 2-year post-treatment. (a) The image was taken prior to the procedure, and (b) the image was taken 2 years after the procedure.

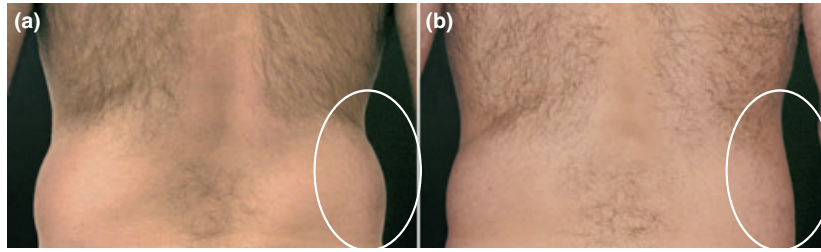


Figure 2 Pre- and post-treatment images showing fat layer reduction on the patient's right (treated) flank 5 years following treatment. (a) The image was taken prior to the procedure, and (b) the image was taken 5 years after the procedure.

sides (Fig. 2). At 5-year postprocedure, the participant had lost 10 pounds in overall body weight. Despite weight loss, the 5-years post-treatment photographs demonstrate a persisting and notable reduction in the right (treated) flank as compared to the left (untreated control) flank (Fig. 2).

Comment

While clinical studies indicate cryolipolysis treatment results in an average of approximately 20% fat layer reduction,^{9–13} the durability of these results had not previously been evaluated. These case studies support the finding that fat reduction via cryolipolysis is durable at 2- 5-years post-treatment in this very small sample size, even in the presence of fluctuations in body weight. The limited data from these case studies suggest that there is no deposition of new adipose tissue reversing the effects of the cryolipolysis procedure over time in these subjects. Asymmetries between the treated and contralateral untreated areas observed at earlier post-treatment time points are preserved at later time points.

Historical data demonstrate that cryolipolysis treatment induces adipocyte apoptosis followed by a natural clearing process lasting up to 4 months.^{6–14} It should be noted that neither subject's progression was documented through this period, making it unclear whether maximum efficacy was sustained. Future long-term, prospective studies of cryolipolysis with an untreated control site will further elucidate the durability of outcomes in a broader population. The obvious difficulty in performing these studies is the willingness of subjects to forgo treatment on the control site for an extended period of time. This would most certainly be a major limiting factor of long-term, unilateral treatment studies.

Cryolipolysis is a safe and effective procedure for fat layer reduction in isolated pockets of excess adipose tissue. The cases presented here demonstrate quite dramatically the effectiveness and longevity of cryolipoly-

sis treatment in two individuals. Having an untreated control site is key for controlling for factors like exercise and diet, because both sides would be subjected to the same influences. Having a bilaterally controlled study is an absolutely essential feature when evaluating treatments for fat layer reduction, because fluctuations in diet, exercise and lean body mass have a very large effect on subcutaneous fat. Future studies in select populations willing to maintain treatment to a single side could quantify the longevity of cryolipolysis treatments, although compliance would be a very large issue with such an investigation.

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