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CoolSculpting or Cryolipolysis: A Guide for Primary Care Practitioners

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A scholarly paper submitted to the faculty of
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in partial fulfillment of the requirements for the degree of
Master of Science

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ABSTRACT

CoolSculpting or Cryolipolysis: A Guide for Primary Care Practitioners

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A desire for the ideal body image has influenced development of a non-surgical body shaping procedure known as CoolSculpting, or cryolipolysis. The purpose of this clinical feature is to inform nurse practitioners regarding the risks and benefits of cryolipolysis so they can educate their patients. Cryolipolysis as a safe, effective method of reducing small areas of unwanted fat. Side effects are minimal and include pain, redness, bruising, and swelling. Results are seen within twelve weeks, but long-term effects are unknown. There are contraindications, and it is relatively expensive; however, it may be a safer option than invasive surgery.

Keywords: CoolSculpting, cryolipolysis, cryotherapy, body image, body contouring, fat, panniculitis

TABLE OF CONTENTS

Abstract.....	ii
CoolSculpting or Cryolipolysis: A Guide for Primary Care Practitioners	1
Introduction.....	1
Background.....	3
How does cryolipolysis work?	3
Is cryolipolysis effective?.....	3
Does cryolipolysis last long-term?	5
How is cryolipolysis performed?.....	6
Where is cryolipolysis performed?.....	7
How does cryolipolysis compare to other procedures?.....	7
What are the side effects of cryolipolysis?	8
What are the contraindications for cryolipolysis?	9
What are the risks of cryolipolysis?	9
How much does cryolipolysis cost?	10
Role of the nurse practitioner in regards to cryolipolysis.....	11
Conclusion.....	11
Table 1 <i>Pros and Cons of CoolSculpting or cryolipolysis</i>	12
References.....	13

CoolSculpting or Cryolipolysis: A Guide for Primary Care Practitioners

Introduction

Throughout history, society's view of the ideal body image has changed. Prior to the twentieth century, thinness was viewed as a representation of malnutrition, poverty, and disease while heavier weight was associated with health, wealth, and prosperity. Artists during the Middle Ages depicted women with a heavier build, round stomachs, and large breasts and hips. This "reproductive figure" was considered superior for its ability to carry and bare healthy children.¹ (pg. 18, para. 4)

Since the twentieth century, there has been an obsession with thinness, seemingly fueled by Hollywood and the fashion industry. In the 1920s hand drawn images of women with short hairstyles, flat chests, and shapeless figures were copied and distributed, causing women to bind their breasts, diet, and participate in extreme exercise routines to try and fit this mold. The 1940s brought a new influence from Hollywood, which emphasized curvy bodies and slim waists. Society idolized Marylyn Monroe who demonstrated these qualities as a "pin-up girl" in the Playboy centerfolds. During the 1960s to 1990s, women wanted to be very thin, as depicted by the fashion model "Twiggy" and actress Audrey Hepburn, both of whom were tall and slender with an almost emaciated look. Still influenced by Hollywood, photo-shopped images, and social media, today's women want to be slim but muscular with large breasts and bottom and a flat stomach.¹ Men, throughout time, have idolized the athletic, muscular build that is depicted in the marble sculptures of ancient days.¹ In order to obtain these ideal body shapes, men and women have turned to gym memberships, nutritional regimens, and cosmetic procedures.

To meet their ideal body goal, Americans are trending towards non-surgical cosmetic interventions, where applicable, instead of surgical interventions. In 2016, the American Society

for Aesthetic Plastic Surgery reported 627, 243 Americans had surgery (liposuction, male breast reduction, abdominoplasty) and 169,695 had a non-surgical procedure (CoolSculpting/cryolipolysis, Vaser Shape, Liposonix) to remove unwanted fat. Although more people had surgical rather than non-surgical procedures, the increase, compared to 2015, in non-surgical procedures was 5.6% and in surgical procedures was 2.7%.² Thus, non-surgical procedures are gaining in popularity. The surgical risks of infection, pain, scarring, bruising, thrombosis, and risks associated with anesthesia are deterrents to surgical procedures for many people. The growing number of men and women having non-surgical procedures indicates that people are seeking less invasive body shaping procedures. The cost difference and recovery time may also be a reason people are choosing the non-surgical approach. In 2017, the average abdominoplasty treatment was \$6,083 with two to four weeks of recovery. In contrast, the three currently available non-surgical, fat reduction procedures averaged \$1,664 with little or no downtime.²

Advertisements for CoolSculpting, the most widely marketed non-invasive fat reduction procedure, pique the interest of men and women with a desire to achieve their ideal body image. They then turn to their primary care providers for advice, asking “how does it work? Does it work long-term? Where and how is it performed? How does it compare to other body sculpting procedures? Is it affordable? Is it safe? Am I a candidate?” Providers should be able to inform their clients with a basic knowledge of the procedure as well as the associated risks and benefits. The purpose of this clinical feature is to provide nurse practitioners and other care providers with current evidence regarding the risks, benefits, and realities of cryolipolysis or CoolSculpting so they can educate their patients.

Background

Historically, cryolipolysis developed after observing inflammation and atrophy of adipose tissue, or panniculitis, in the mouths of children after cold exposure from eating frozen popsicles. This same phenomenon was also observed in the thighs of women who rode horseback in cold weather. This phenomenon inspired Manstain and colleagues to further investigate the theory of adipocyte inflammation and reduction by localized cold exposure to the abdomens of pigs. They found a significant reduction in exposed adipocytes that continued 3.5 months following cold exposure. Another significant finding was the lack of damage to exposed skin and surrounding tissues. This study was the pioneer to other investigations regarding the use of localized cold to spot reduce unwanted fat.³

How does cryolipolysis work?

Cryolipolysis induces selective apoptosis to adipocytes, which are then carried away by the inflammatory process. Immediately after a treatment, there is no change to the cells and tissue, but within three days, evidence is seen of adipocyte apoptosis and initiation of an inflammatory response with an increase of inflammatory cells. The exact mechanism that sparks this apoptosis is still unknown. Fourteen days after treatment, inflammation peaks as macrophages, neutrophils, and lymphocytes surround the adipocytes. Around 30 days post-treatment, the adipocytes appear smaller and are irregularly shaped as they are taken up through phagocytosis. After 90 days, inflammation declines, and the thickness of the fat layer when observed microscopically is visibly reduced.⁴

Is cryolipolysis effective?

A few large studies have been conducted to evaluate evidence regarding the effectiveness of cryolipolysis. In 2013, Stevens and colleagues reviewed charts of 528 patients ranging from

18 to 79 years old who elected to undergo cryolipolysis. They compared the number of treatments each patient received, areas treated, and any reported complications. Each patient was photographed and then received a treatment lasting 60 minutes. Then, if indicated, a second treatment was given eight weeks later. The most common treatment sites were the lower abdomen and bilateral flanks. Only three patients reported complications of pain or neuralgia, which resolved within four days. Follow-up visits involved post-treatment photographs to compare treatment results to baseline photographs and a patient satisfaction survey. Of the 528 patients, only four were dissatisfied enough to ask for a refund. However, those four all expressed satisfaction after a free supplemental treatment.⁵ Limitations of this study include that it is a retrospective chart review and the Zeltique CoolSculpting device manufacturer provided some funding for the study. Further, results were based on patient satisfaction and did not include any actual measurements.

Another large study conducted in Europe evaluated 518 participants with healthy BMIs but localized fat deposits. Researchers examined safety, tolerance, and satisfaction after a CoolSculpting procedure. They compared the number of treatments, areas treated, and side effects immediately following treatments. Three months after treatment, participants completed a satisfaction survey, were photographed, and measured with calipers. Results indicate the majority of participants chose to treat flanks (59%) and abdomen (28%), and most underwent only one treatment. Reported short-term side effects were erythema (100%), minimal pain (96%), bruising (9.8%), severe pain with application of the device (4%), changes in sensitivity (2.9%), and vasovagal response (2.1%). All these adverse events resolved spontaneously within a few days. After three months, caliper measurements averaged 23% fat reduction in 94% of the participants. 73% were either satisfied or extremely satisfied with their results, and 82% would

recommend CoolSculpting to a friend. In photographic comparison, 85.5% of participants showed visible reduction in size of abdomen or flank but little or no visible reduction on treated thighs, knees, and buttocks. There were no reports of discoloration. Limitations of this study include that 56% of participants could not be contacted for follow-up evaluation.⁶

A recent study conducted in France used a newer device (Cristal Cryolipolysis). 147 patients underwent 60 minutes of cold exposure to either flank, abdomen, thigh, back, or buttocks, followed by five minutes of massage to the treated area. Reported side effects include severe pain (0.6%), vasovagal response (2%), numbness (0.6%), bruising (1.3%), erythema/blistering (0.6%), and painful induration at site of treatment (2.7%). All adverse events resolved independently, and there was no report of paradoxical adipose hyperplasia, a reaction in which tissue at the treatment site enlarges rather than reduces. The mean circumference loss for all treatment sites was 2.8 cm ($p < 0.05$). Of the 147 participants treated, 75.5% were satisfied with their results, and 80.6% expressed interest in receiving a second treatment.⁷

These three studies all indicate high participant satisfaction, measurable results, and a few temporary adverse effects that resolved without intervention. There are some limitations to consider. It is difficult to standardize measurement techniques due to variables, such as pressure applied to the calipers or ultrasound probe when measuring tissue thickness. However, the large sample size in these studies helps support the results despite these limitations.

Does cryolipolysis last long-term?

Cryolipolysis was first approved by the FDA in 2010, so it is still quite new. Thus, little research has been conducted on the long-term effectiveness. One study, completed in 2016, evaluated the effectiveness of cryolipolysis in two male participants over a period of six and nine years. The first participant, a 44-year-old male at the time of treatment, received two 60-minutes

cycles to his left flank. The right side remained untreated as a control comparison. Photographs of his flanks were taken at baseline, two months, two years, and six years. Compared to baseline, this man gained 10 pounds at two years and 5.2 pounds at six years. The second participant, a 45-year-old male at time of treatment, received one 60-minute treatment to his right flank. The left remained untreated as a control. Photographs of his flanks were taken at baseline, three months, five years, and nine years. Weight from baseline fluctuated from a 10-pound decrease at five years to a 0.2-pound decrease at nine years. At the conclusion of the study, physicians certified in either dermatology or plastic surgery blindly evaluated the progressive photographs of both participants. They were able to distinguish the baseline from post treatment photographs 100% of the time by comparing flank size.⁸

Although the sample size of this study is small and limited to only male participants who had only one area treated, it indicates that there is potential for long term effectiveness of cryolipolysis despite weight changes. As the popularity of CoolSculpting increases, more studies are needed evaluating the long-term results of various treatment sites on a variety of people.

How is cryolipolysis performed?

After an initial consultation with a trained provider, cryolipolysis is done using a vacuum cupped applicator attached to the treatment site. An aesthetician or healthcare provider applies a gel layer to the skin before placing the applicator. This ensures equal thermal contact between the machine and the tissue being treated. The tissue is cooled to a temperature just above freezing and is maintained at that temperature for 40 to 60 minutes. During this time, no intervention is needed. When the treatment is almost over, the machine notifies the operator to remove the applicator. The site is then massaged for a brief time (about five minutes), and the client is sent home. Depending on the treatment site, a second treatment may be done about eight

weeks after the first. Results are often seen within about three weeks and peak by about 12 weeks.⁴

Where is cryolipolysis performed?

CoolSculpting is performed at a variety of locations, including medical spas, plastic surgeons' offices, dermatology clinics, family practice clinics, and beauty salons. The procedure is done by someone trained to use the machine, which includes medical assistants, aestheticians, nurses, physicians' assistants, nurse practitioners, and physicians. It should always be done under the supervision of a board certified licensed provider who has undergone the recommended training in order to consult, advise, perform the procedure, and follow-up. ZELTIQ Aesthetics offers a three-day training to individuals who operate their machines.⁹ Consumers should be wary of providers who lack proper certification.

How does cryolipolysis compare to other procedures?

There are risks associated with undergoing a major surgical procedure: pain, infection, scarring, deep vein thrombosis, pulmonary embolism, prolonged recovery time, and anesthesia associated complications. Surgical procedures can also be very expensive when combined with hospital and anesthesia bills. The risks and expense of surgery is likely to dissuade many candidates from undergoing elective body shaping procedures, especially since less risky non-surgical options are now available. Cryolipolysis may be the answer for people who have small amounts of unwanted fatty tissue in localized areas. It causes minimal pain, carries no infection risk, requires little to no down-time, and it can be done in an office or clinical setting without anesthesia, which cuts down on the cost. Another benefit to cryolipolysis is that it does not affect systemic lipid levels or liver enzymes, which would allow patients with conflicting co-morbidities (see below), who would not be surgical candidates, to participate.¹⁰

How does cryolipolysis compare to other non-surgical fat reduction procedures? In an eight-week randomized control trial comparing cryolipolysis to diet and laser lipolysis therapy (an FDA approved method of removing unwanted fatty tissue), cryolipolysis was found to have the greatest fat layer reduction using caliper skin fold measurements on obese adolescents.¹¹ Kennedy and colleagues compared four non-surgical treatments: cryolipolysis, low-level-laser-therapy, radio-frequency, and high-intensity focused ultrasound as well as a few additional techniques, such as mechanical massage, shockwave therapy, acoustic wave therapy, and topical creams. The researchers found the initial four treatments to all be effective but noted that the greatest reduction occurred when cryolipolysis was combined with shockwave therapy (a technique used to reduce cellulite).¹²

What are the side effects of cryolipolysis?

The process of freezing localized adipocytes in order to induce apoptosis and removal by the inflammatory response has some imperfections. As observed in the European study done in 2013, 100% of patients reported erythema at the site, and 96% reported minimal pain. There are also reports of bruising, numbness, blistering, severe pain, and syncope. These adverse reactions are reported to be short-lived, resolving within a few days.⁶

Numbness following cryolipolysis may have implications for future treatment of chronic pain. Some researchers suggest using cryolipolysis to treat Notalgia Paresthetica, a neuro-sensory condition of the upper back, which is manifested by hyper-pigmentation, pruritus, burning, a tingling sensation, and pain. Cohen suggested that because cryolipolysis occasionally causes numbness at the treatment site for up to one month, it may be causing damage to the lipid-rich myelinated dermal nerves in the area, and therefore relieving symptoms.¹³

What are the contraindications for cryolipolysis?

While the option of cryolipolysis is available to more people than an invasive surgical procedure would be, there are still a few conditions that would prevent an individual from being a candidate. Because the elimination of adipocytes is done by the immune system, anyone who is immunocompromised would not be a candidate. It should not be used as a treatment for obesity as it only removes localized fat deposits. Circulatory contraindications include: Raynaud's disease, use of blood thinners, hypo-coagulability, and Cryoglobulinemia (a disorder with increased risk for blockages in the vasculature when exposed to cold). Certain skin conditions that would be a contraindication are: eczema, psoriasis, dermatitis, hives, scar tissue, recent injury, and cellulitis. Individuals who are pregnant or breast feeding, suffer from chronic pain or severe anxiety, or who have a hernia or implanted device near the treatment site should also reconsider the option of cryolipolysis.¹⁴

What are the risks of cryolipolysis?

Only a few long-term risks are associated with cryolipolysis. The most commonly reported one is a phenomenon called Paradoxical Adipose Hyperplasia (PAH), which is a well demarcated area of tissue enlargement at the site of treatment following cryolipolysis. It is rare, occurring at a rate of 0.0051%¹⁵; however, this may have been underreported. One clinic in Miami reported a 0.78% occurrence rate in 510 patients treated. This clinic observed that PAH occurred more often in Hispanic males treating the lower abdomen with a single applicator. There may be a genetic predisposition for developing PAH as it occurred in twins treated at different clinics.¹⁶ When PAH is suspected, no further cryolipolysis treatments should be performed, and the patient should be treated with surgical liposuction to remove the enlarged adipocytes.¹⁷

A second long-term risk of cryolipolysis is frostbite at the treatment site. One case describes a 35-year-old female who underwent a single 60-minute treatment on her flanks in an uncertified beauty salon. She reported pain with rewarming and blisters at the site a few hours after the treatment. This subsequently resulted in necrotic tissue requiring six weeks of careful treatment and observation by a plastic surgeon. This case emphasizes the importance of choosing a certified provider with positive reported outcomes.¹⁸ A second case occurred with a 55-year-old old female who attempted a do-it-yourself cryolipolysis treatment at home using dry ice. This resulted in full and partial thickness burns to 4% total body surface area on her abdomen, which required skin grafting. Providers should be aware that there are online sources describing how to perform cryolipolysis at home. These attempts should be discouraged due to the inability to monitor and maintain a constant treatment temperature without the use of a certified cryolipolysis device.¹⁹

How much does cryolipolysis cost?

As mentioned previously, when comparing non-surgical to surgical fat reduction procedures, cryolipolysis is less expensive due to its non-invasive nature, and it can be done in an out-patient setting without anesthesia or other modalities. However, this does not mean that it is inexpensive. In 2017, the average cost of a non-surgical fat reducing procedure (CoolSculpting, Vasershape, Liposonix) was \$1,664. Often a patient undergoes two or even three treatments of cryolipolysis, which would double or triple that expense per treatment site. While less expensive than a surgical procedure, cryolipolysis is the third most expensive non-surgical cosmetic procedure in the United States.²

A large portion of the payment for a CoolSculpting procedure covers overhead costs. The provider who purchases a machine must also purchase cards that allow the machine to run. One

card allows 16-24 cycles. Without a card, the machine will not work, enabling ZELTIQ (the manufacturer of the machines) to continue earning revenue on machines after they are sold.²⁰

Role of the nurse practitioner in regards to cryolipolysis

A nurse practitioner may play a few different roles in the process of cryolipolysis, such as teaching, screening, consulting, or performing the actual procedure. The information in this article is intended for nurse practitioners, or other healthcare providers, with patients who request information about cryolipolysis and have questions regarding its physiology, efficacy, long-term benefits, how and where it is performed, how it compares to other procedures, the risks and benefits, whether they are a candidate, and if it is affordable. Table 1 provides guidance in teaching patients about cryolipolysis treatment.

Conclusion

As society today is drawn towards an ideal body shape, nurse practitioners and other healthcare providers need to be aware of the options that are available to their patients and be able to educate them with unbiased information. Cryolipolysis appears to be a safe, effective, non-surgical procedure that allows limited removal of adipocytes from troublesome areas. There are many factors to consider regarding each individual's health, but with the information in this clinical paper, a nurse practitioner or other healthcare provider is better equipped in guiding a patient who is considering cryolipolysis as a body shaping option.

Table 1
Pros and Cons of CoolSculpting or cryolipolysis

Pros	Cons
Works well for small stubborn areas that are difficult to reduce through diet and exercise.	Not for large area reduction and not a weight loss solution
Results appears to maintain over several years, despite mild weight gain	Results take up to 3 months for completion
May be done as an outpatient in a certified clinic, spa or beauty salon.	May require multiple treatments
Side effects are temporary, usually resolving within 3 days.	Side effects include immediate <ul style="list-style-type: none"> • pain • erythema • bruising • numbness
Long-term risks are rare and can be prevented under most circumstances.	Long term risks include <ul style="list-style-type: none"> • Paradoxical Adipose Hyperplasia • Frostbite
Less expensive than surgical cosmetic procedures	3 rd most expensive non-surgical cosmetic procedure in the United States (\$1,664 average cost of treatment in 2017)
Fewer contraindications than for surgical procedures	Contraindications exist

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