Cryolipolysis for Noninvasive Contouring of the Periumbilical Abdomen With a Nonvacuum Conformable-Surface Applicator

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BACKGROUND Although most cryolipolysis treatments are performed with vacuum applicators, some patients may have areas of fibrous, nonpinchable fat or find vacuum suction to be uncomfortable.

OBJECTIVE This study evaluates a nonvacuum conformable-surface applicator for cryolipolysis of the periumbilical abdomen.

METHODS/MATERIALS Twenty subjects with periumbilical subcutaneous fat were treated with a nonvacuum cryolipolysis applicator in this prospective, single-center, open-label clinical trial. Each subject underwent a single treatment cycle with an optional second treatment 10 weeks later. Efficacy was evaluated by blinded review of digital photographs. Subject satisfaction was assessed at 10-week follow-up.

RESULTS Twenty subjects completed one treatment, of which 6 underwent the optional retreatment. Independent review demonstrated 77% correct identification of baseline photographs after one treatment, which improved to 100% after a second treatment. Patient questionnaires after one treatment revealed 50% satisfaction, with 60% willing to recommend the procedure and 60% reporting visible fat reduction. After second treatment, however, 100% were satisfied, 83% were willing to recommend, and 100% reported visible fat reduction.

CONCLUSION Cryolipolysis with a nonvacuum conformable-surface applicator is safe, effective, and well tolerated for noninvasive reduction of fibrous periumbilical abdominal fat. Efficacy and subject satisfaction is significantly greater with 2 treatments than with a single session.

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A variety of noninvasive fat reduction modalities are currently available, including radiofrequency energy, high-intensity focused ultrasound, near-infrared laser, low-level light treatment, nonthermal ultrasound, and cryolipolysis.[1,2] Cryolipolysis, the application of controlled cooling to noninvasively damage subcutaneous adipocytes, is based on the greater susceptibility of lipid-rich adipocytes to cold injury compared with surrounding water-rich cells.[3–5] Cryolipolysis has been shown to treat the flanks,[6–10] abdomen,[9,11,12] inner thighs,[13–15] outer thighs,[16] submental area,[17,18] arms,[14,19] and chest[20,21] with an excellent safety profile.[22–26]

Cryolipolysis is commonly performed using vacuum applicators, which pull tissue into cooled cups or between cooled parallel plates through suction. Some patients, however, find the vacuum suction uncomfortable. Areas of fibrous subcutaneous fat, such as the periumbilical abdomen, back, and outer thighs, also cannot be easily pinched and pulled into cryolipolysis applicators. A nonvacuum conformable-surface applicator has consequently been shown to safely reduce fat in the lateral thighs with high subject satisfaction scores.[16] This study evaluated the use of this same type of cryolipolysis applicator in patients with unwanted subcutaneous fat deposits of the

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periumbilical abdomen who were not candidates for traditional vacuum cryolipolysis applicator treatment.

Materials and Methods

This was a prospective, single-center, open-label, interventional cohort study. The protocol was approved by an independent review board (IntegReview, Austin, TX). Eligible subjects were male or female, between 18 and 65 years of age, with clearly visible subcutaneous fat of the periumbilical abdomen. Exclusion criteria included prominent visceral abdominal fat; a history of a previous fat reduction procedure in or near the treatment area; a known history of cryoglobulinemia, cold urticaria, cold agglutinin disease, Reynaud disease, or paroxysmal cold hemoglobinuria; a history of a bleeding disorder; current medications that may increase the risk of bruising; and the presence of an active implanted device such as a pacemaker, defibrillator, or drug delivery system in or near the treatment area. For the duration of the study, subjects were instructed to avoid implementing major changes to their diet or exercise routine, to maintain their weight within ±5% of baseline measurement.

After screening, subjects received a single cryolipolysis cooling cycle (−13°C, 75 minutes) to the periumbilical abdomen with the nonvacuum applicator (CoolSmooth PRO) of a commercially available cryolipolysis device (CoolSculpting System, ZELTIQ Aesthetics, Pleasanton, CA) at commercial treatment parameters. The targeted treatment area was marked with a black permanent marker immediately before treatment with the subjects standing. With subjects then lying supine (180°) on a treatment table, a protective gel pad was first draped over the periumbilical area, followed by placement of the cryolipolysis applicator, which was secured with Velcro straps for the entirety of treatment. At the conclusion of the treatment cycle, the cryolipolysis applicator was immediately removed, and a 2-minute manual massage of the treated areas was performed. Subjects were able to resume normal activities immediately after treatment. All treatments were paid for by subjects at a discounted (30%) rate.

Visual assessment of potential treatment area adverse events, such as erythema, blanching, bruising/purpura, edema/swelling, or sensory abnormalities (numbness, tingling, or itching), was evaluated immediately after treatment and at 10-week follow-up by the investigator. These were graded on a 4-point scale, with 0 = absent, 1 = mild (slight, barely perceptible), 2 = moderate (distinct presence), and 3 = severe (marked, intense). Subjects rated procedural pain and discomfort immediately after treatment on a 5-point scale, with 0 = very comfortable, 1 = somewhat comfortable, 2 = neither comfortable nor uncomfortable, 3 = somewhat uncomfortable, and 4 = very uncomfortable. At the 10-week follow-up visit, subjects completed a written questionnaire to assess satisfaction with results and were given the option of undergoing a second treatment to the periumbilical abdomen.

At baseline and follow-up visits, photographs were acquired using standardized digital photography (DSLR camera with 16- to 50-mm lens at f/6.3, 1/320 seconds exposure, and automatic ISO) with external (3,000 K) 45° soft lighting in a dedicated room to ensure consistency. Study subjects were photographed standing with their arms crossed and raised at shoulder level and their feet separated at a fixed distance using a foot-positioning guide. Front, 45°, and 90° views were obtained for each subject. Photographs from 10-week post-treatment visits were compared with baseline photographs by 3 blinded, independent physicians. Pre-treatment and post-treatment photograph pairs were randomized for each subject, and the reviewers were asked to determine which image was the pre-treatment image.

Results

Twenty patients were enrolled. Demographic data are shown in Table 1; mean age was 42.8 years; and mean BMI was 23.2. All subjects completed a single treatment cycle with 10-week follow-up. Subsequently, 6 patients underwent the optional second treatment. All 20 subjects, 17 females and 3 males, also remained within the allowed ±5% weight change limit at the first treatment follow-up visit. After the second treatment visit, 1 subject gained 6.0 lbs (+5.4% change relative to baseline) and was excluded from efficacy analysis. Independent review of photographs was

TABLE 1. Subject Demographic Data

Characteristics (n = *20*)	*Mean*	*SD*	*Median*	*Range*
Age (yr)	42.8	10.6	44.9	22.3–63.1
Weight (lbs)	143.4	32.1	133.4	112.0–245.0
BMI	23.2	2.5	22.3	20.8–29.2

Fitzpatrick Skin Type					
I	*II*	*III*	*IV*	*V*	*VI*
1	13	5	1	0	0

Sex		*Ethnicity*				
Male	*Female*	*African American*	*Asian*	*Caucasian*	*Hispanic*	*Other*
3	17	0	1	19	0	0

BMI, body mass index.

thereby performed on 20 subjects after the first treatment and 5 subjects after the second treatment.

Representative pre-treatment and post-treatment photographs are shown in Figures 1–4, demonstrating significant reductions in periumbilical subcutaneous fat after cryolipolysis. Figure 1 shows a subject that underwent 2 sessions of cryolipolysis, whereas Figures 2–4 show subjects that underwent a single treatment. Independent review of randomized before-and-after photographs revealed a correct identification rate of 77% (46 of 60) after the first treatment, which improved to 100% (15 of 15) after the second treatment.

From the 10-week follow-up questionnaire after the first treatment, 50% of subjects were satisfied with the treatment, 60% were willing to recommend the cryolipolysis procedure, and 60% noticed visible abdominal fat reduction. After the second treatment, however, 100% of subjects reported satisfaction with treatment, 83% were willing to recommend the cryolipolysis procedure, and 100% noticed visible fat reduction.

The mean pain score obtained immediately after treatment was 2.1, indicating the procedure was generally considered to be neither comfortable nor uncomfortable. Mean adverse event scores assessed by the investigator immediately after treatment were 1.8 for erythema (moderate), 0.3 for edema (absent), and 1.2 for sensory changes (mild). No subject was found to have bruising or blanching. Moreover, all site reaction scores were 0 at the 10-week follow-up visit. There were no serious or unanticipated device- or procedure-related adverse events during the course of the study.

Discussion

Cryolipolysis for the noninvasive reduction of periumbilical fat has been traditionally performed using vacuum applicators. However, certain patients may find vacuum suction to be intolerable, may have insufficient fat to fill a traditional vacuum applicator, or may possess more fibrous fat that is difficult to pull into a vacuum applicator. This study evaluated a nonvacuum conformable-surface cryolipolysis applicator for the treatment of modest or fibrous (i.e., poorly suctionable) periumbilical abdominal fat. The applicator was found to be highly tolerable and demonstrated an excellent safety profile, with transient moderate erythema and mild sensory changes (particularly numbness) that completely resolved by 10-week follow-up. Given that the nonvacuum applicator lies flat on the target tissue and does not pull tissue between 2 cooling plates such as vacuum applicators, treatment time is extended to ensure

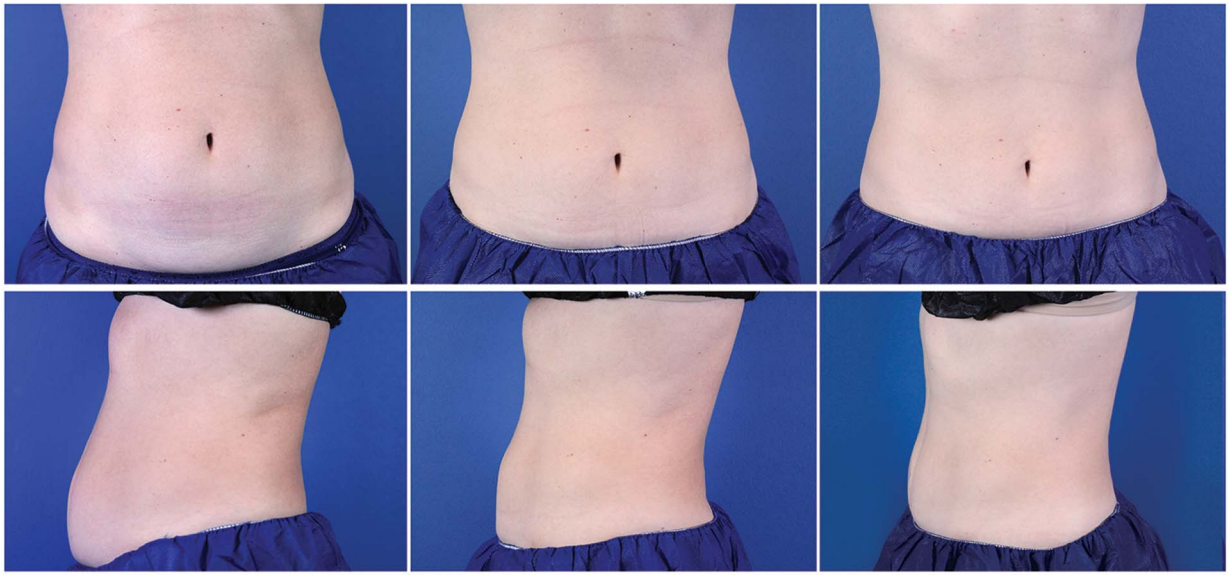

Figure 1. Baseline (left), 10 weeks after treatment #1 (middle), and 10 weeks after treatment #2 (right) photographs for a 45-year-old female subject, front (top) and 90° (bottom) views. One cryolipolysis cycle per treatment visit. Final weight change +4.2 lbs (+3.1%) from baseline.

sufficient cooling time (75 minutes vs 35–60 minutes, respectively). However, the longer duration of treatment was well tolerated.[16]

Although improvement was noted after a single treatment, the study data showed that additional treatment significantly increases the efficacy and patient satisfaction of the cryolipolysis procedure. Blinded evaluation of clinical photographs found 77% correct identification after a single treatment, increasing to 100% correct identification after 2 treatments. Subject satisfaction scores mirrored these findings. Although the number of subjects that underwent the optional second treatment is relatively small ($n = 6$), the effect of 1 and 2 treatments for these subjects followed the same trend. After the first

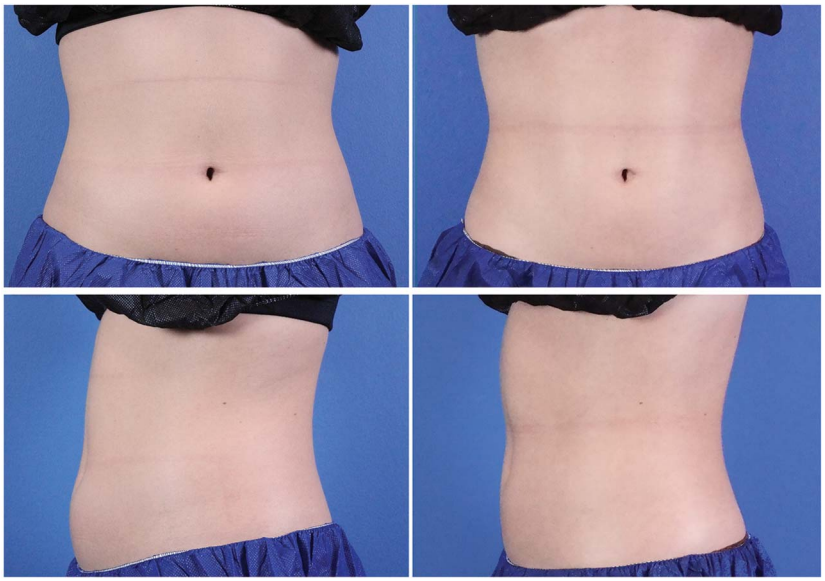

Figure 2. Baseline (left) and 10 weeks after 1 treatment cycle (right) photographs for a 22-year-old female subject, front (top) and 90° (bottom) views. Final weight change −1.9 lbs (−1.5%) from baseline.

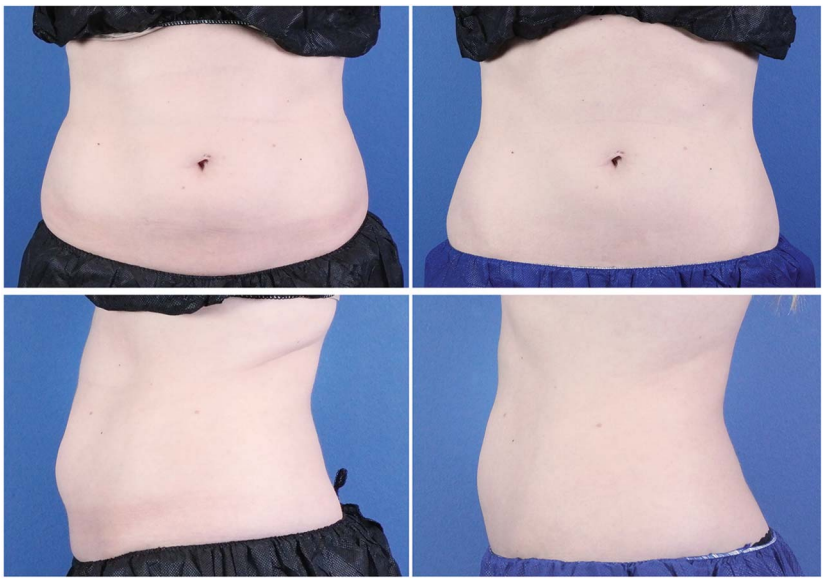

Figure 3. Baseline (left) and 10 weeks after 1 treatment cycle (right) photographs for a 30-year-old female subject, front (top) and 90° (bottom) views. Final weight change +1.5 lbs (+0.9%) from baseline.

treatment, 67% were satisfied, 83% would recommend to a friend, and 67% reported visible fat reduction; after the second, subject responses were 100%, 83%, and 100%, respectively. For the independent photograph review of the $n = 5$ subjects that remained within the ±5% weight change limit and underwent 1 and 2 treatment visits, the correct identification rate was 100% after both treatment visits.

Although the overall study data for all available subjects suggest that efficacy and patient satisfaction increase with additional cryolipolysis treatments, the sample sizes are relatively small, and the study may be underpowered. Nevertheless, a study of 10 subjects by Shed at al[9] did demonstrate that a second abdominal treatment (3 months apart) led to further improvement in abdominal contour based on caliper measurements.

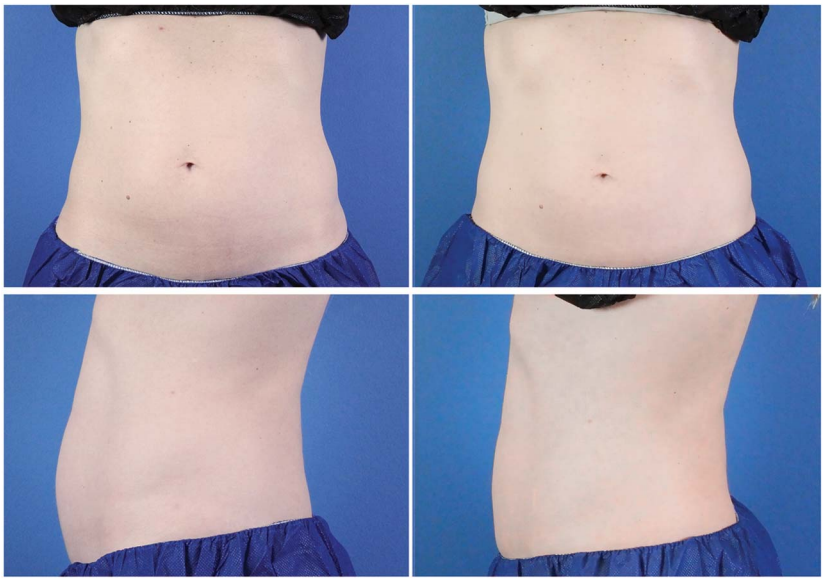

Figure 4. Baseline (left) and 10 weeks after 1 treatment cycle (right) photographs for a 46-year-old female subject, front (top) and 90° (bottom) views. Final weight change +0.2 lbs (+0.2%) from baseline.

This study demonstrates that abdominal fat can be safely and effectively treated with a nonvacuum surface cryolipolysis applicator, leading to high subject satisfaction after 1 to 2 treatment sessions. The lack of comparison with a vacuum applicator, another limitation of this clinical trial, presents an opportunity for future study and may provide valuable information regarding optimal technique for treatment of periumbilical fat.

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