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Aesthetic Surgery Journal 2013 33: 835 originally published online 15 July 2013

DOI: 10.1177/1090820X13494757

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Broad Overview of a Clinical and Commercial Experience With CoolSculpting

W. Grant Stevens, MD, FACS; Laura K. Pietrzak, MSHS, PA-C;
and Michelle A. Spring, MD

Aesthetic Surgery Journal
33(6) 835–846
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DOI: 10.1177/1090820X13494757
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Abstract

Background: Cryolipolysis has been shown to be a safe and effective noninvasive procedure for the reduction of localized subcutaneous fat.

Objectives: The authors examine the safety, efficacy, and procedural growth of cryolipolysis (via the CoolSculpting device; Zeltiq, Pleasanton, California) in a single plastic surgery practice.

Methods: A retrospective chart review was conducted for 528 consecutive patients who underwent cryolipolysis treatment from January 2010 to December 2012. The number of patients, the number of treatment cycles, the average number of cycles per patient, all treatment areas, and all procedural complications were recorded and analyzed. Overall practice growth with the device was also analyzed.

Results: Over the study period, 1785 anatomic sites were treated with 2729 cycles, primarily in the lower abdomen (28%, n = 490 cycles), upper abdomen (11%, n = 189), left flank (19%, n = 333), right flank (19%, n = 333), inner thigh (6%, n = 111), outer thigh (5%, n = 87), and back (6%, n = 99). The age distribution for men and women was similar (46.6 ± 12.8 years for women and 46.5 ± 12.3 years for men; overall range, 18–79 years). Only 3 cases of mild or moderate pain/neuralgia were reported and resolved in 4 or fewer days. No adverse events were reported. Procedure volume showed consistent growth, with treatment cycles increasing by 823% by 2012.

Conclusions: Based on the results in this single plastic surgery practice, cryolipolysis is a safe and effective nonsurgical body contouring method associated with high patient satisfaction that can generate steady, significant business growth.

Level of Evidence: 4

Keywords

cryolipolysis, body sculpting, nonsurgical fat reduction, noninvasive body contouring



Accepted for publication May 3, 2013.

Previous clinical studies have shown that cryolipolysis can remove discrete, localized fat safely and effectively for the purposes of noninvasive body contouring.^{1–5} The procedure has received Food and Drug Administration (FDA) clearance for fat reduction in the flanks (2010) and abdomen (2012). In this article, we will specifically discuss cryolipolysis via the CoolSculpting device (Zeltiq, Pleasanton, California), which extracts energy via cooling to reduce the volume of subcutaneous fat. We will analyze the results from a retrospective series of patients treated in a single private practice that first added this device in December 2009. Since its introduction at our practice, demand for the procedure has grown steadily, and we

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Editor's Note: In this article, the authors discuss off-label use of the CoolSculpting cryolipolysis device (Zeltiq, Pleasanton, California).

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currently have 6 CoolSculpting systems in steady use. We undertook this study in an effort to understand the clinical and commercial impact of this procedure and device on our practice.

METHODS

A retrospective chart review was conducted for 528 consecutive patients who underwent cryolipolysis treatment (performed by L.K.P.) from January 2010 to December 2012. Data included the number of patients treated, the total number of treatment cycles, the average number of treatment cycles per patient, treatment areas, and procedural complications. Patient demographic data were analyzed for sex, age, ethnicity, and skin type. Patients' experiences with cosmetic procedures prior and subsequent to cryolipolysis were explored. Safety was evaluated according to the number of complications and adverse events (AE). Procedural growth was evaluated from year to year.

Patients typically met with a physician assistant for the initial consultation, during which areas of concern were discussed, realistic expectations for fat reduction were established, and the sites for applicator placement and the number of cycles were planned based on a whole-body assessment. The treatment areas were prioritized to establish a plan that would satisfy the patients' needs, in keeping with their budgetary restrictions.

Two cycles, spaced 8 weeks apart, were usually recommended for each treatment site. On the day of treatment, each patient met with the physician assistant or medical assistant for baseline photographs, after which the physician assistant performed the cryolipolysis treatment. Each treatment cycle was 60 minutes in duration and was delivered in a treatment room. Patients typically resumed normal activities immediately posttreatment. Posttreatment care instructions informed patients that erythema, edema, bruising, and soreness were expected and usually lasted several days. Temporary sensory changes, such as numbness, itching, and neuralgia in the treatment area were also to be expected. During follow-up visits, which were typically conducted 2 or 3 months after the initial treatment, patients met with the physician assistant or medical assistant for follow-up photographs, weight measurement, and discussion of results and patient satisfaction.

RESULTS

Patient Demographics and Aesthetic History

Of the 528 patients in this series, 76% were women ($n = 403$) and 24% were men ($n = 125$). Over the course of the study period, the male patient population grew in response to targeted advertising, ultimately comprising 24% of the overall population and 42% of the patient population from the last quarter of 2012. The overall and sex-specific age distributions are shown in Figure 1. The age distributions for women and men were similar, as the average age of

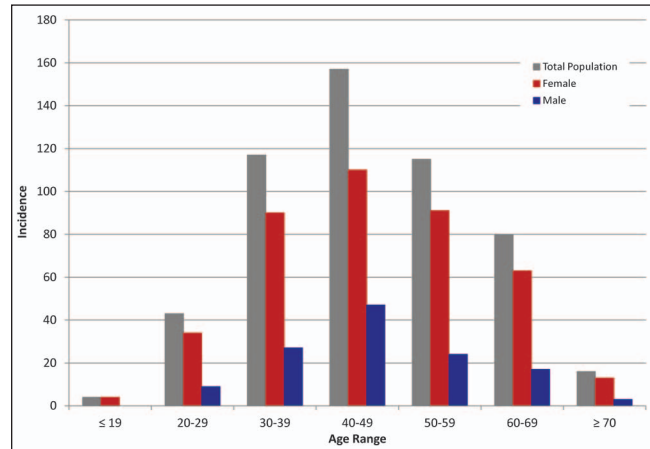


Figure 1. Age distribution. The population was 76% women and 24% men, with similar age distributions. The average age of women in our series was 46.6 ± 12.8 years, while the average age of men was 46.5 ± 12.3 years.

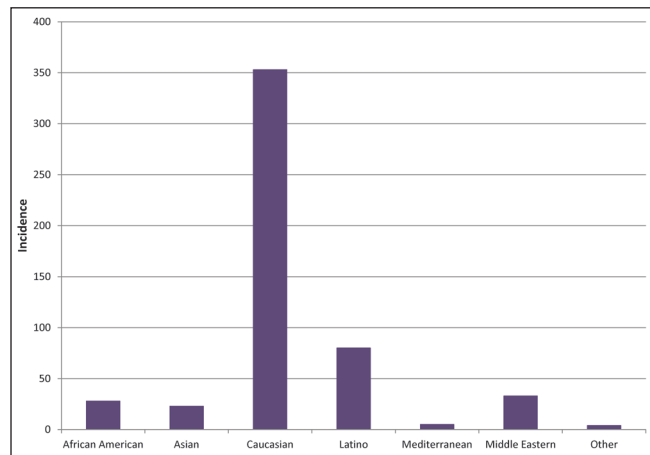


Figure 2. Ethnicity distribution. The ethnic distribution of patients in this series was 67% Caucasian, 15% Latino, 6% Middle Eastern, 5% African American, 4% Asian, 1% Mediterranean, and 1% other.

female patients was 46.6 ± 12.8 years and the average age of male patients was 46.5 ± 12.3 years. The overall patient age range was 18 to 79 years.

The ethnic distribution of the patient population is shown in Figure 2. Our patients were primarily Caucasian (67%), followed by Latino (15%), Middle Eastern (6%), African American (5%), Asian (4%), Mediterranean (1%), and other (1%). We consider these demographics representative of the overall population in our practice location (Marina del Rey, California)⁶ and of the socio-economics that drive elective cosmetic procedures. Corresponding to the ethnic distribution, the Fitzpatrick skin type (FST) distribution in our patient population is shown in Figure 3. The majority of patients were FST 2

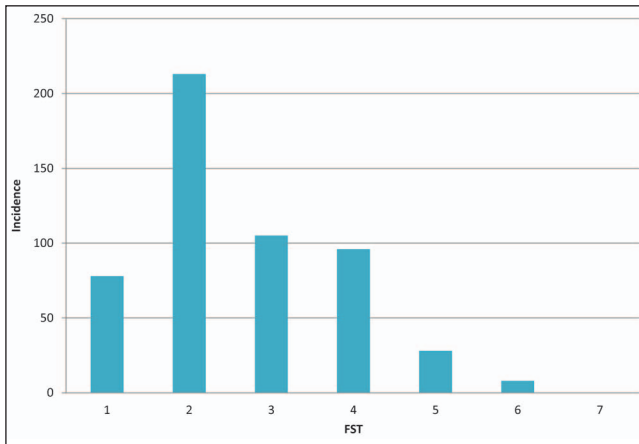


Figure 3. Fitzpatrick skin type (FST). The majority of the 528 patients in this series were FST 2 (40%), followed by FST 3 (20%), FST 4 (18%), FST 1 (15%), FST 5 (6%), and FST 6 (1%).

(40%), followed by FST 3 (20%), FST 4 (18%), FST 1 (15%), FST 5 (6%), and FST 6 (1%).

Of the 528 patients treated with cryolipolysis, 66% (n = 348) were patients new to the practice who presented specifically for CoolSculpting. Of these new patients, most were aesthetic neophytes, as 62% (n = 215) had not previously undergone any type of cosmetic procedure. Ninety-five percent of these new patients (n = 332) had never received injectable treatments, 89% (n = 309) had never undergone liposuction, and 66% (n = 228) had not had previous plastic surgery. Of the new patients who presented for cryolipolysis, 40% (n = 139 of 348) became established patients in the practice and later underwent additional procedures, including surgical procedures, nonsurgical injectable treatment, skin care, laser hair removal, and resurfacing procedures. Prior and subsequent aesthetic procedure histories for the new patients who came to the practice seeking CoolSculpting are shown in Table 1.

Clinical Outcomes

Clinical use patterns for the CoolSculpting device were analyzed by identifying the sites treated at each clinic visit

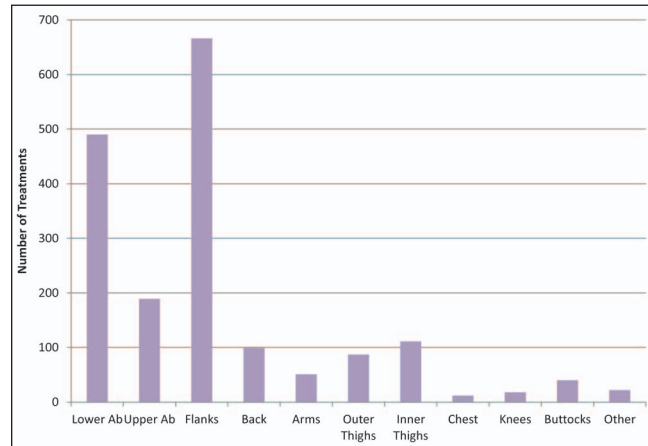


Figure 4. Treatments per site. A total of 1785 treatments were delivered to the lower abdomen (28%, n = 490), upper abdomen (11%, n = 189), flanks (38%, n = 666), inner thighs (6%, n = 111), outer thighs (5%, n = 87), and back (6%, n = 99).

and the number of treatment cycles delivered. The treatments delivered based on anatomic site are shown in Figure 4. Over the study period, 1785 anatomic sites were treated with 2729 cycles. (Multiple cycles were often delivered to the same treatment site.) Treatments were delivered primarily to the lower abdomen (28%, n = 490), upper abdomen (11%, n = 189), left flank (19%, n = 333), right flank (19%, n = 333), inner thigh (6%, n = 111), outer thigh (5%, n = 87), and back (6%, n = 99). Again, the CoolSculpting device received FDA clearance for fat reduction for the flanks in 2010 and for the abdomen in 2012. Treatment in any other area constitutes an off-label use. Table 2 shows the average number of cycles delivered for each treatment area. The areas that required the highest number of cycles were the back and the inner and outer thighs, with more than 2 cycles on average, while the flanks required the lowest average number of cycles, at 1.06 per flank.

The treatments delivered to different anatomic sites were also analyzed by sex. The number and percentage of women and men who received treatment at each site are shown in Table 3. Men almost exclusively received treatment to the lower abdomen and flanks, with a small

Table 1. Incidence of Prior and Subsequent Procedures for Patients New to the Practice (n = 348 of 528)

Prior Aesthetic Procedures				Subsequent Aesthetic Procedures			
Plastic Surgery	Liposuction	Injectables	Other Procedures	Plastic Surgery	Liposuction	Injectables	Other Procedures
34%	11%	5%	16%	2%	1%	16%	23%
n = 120	n = 39	n = 16	n = 56	n = 8	n = 3	n = 57	n = 80

Table 2. Average Number of Treatment Cycles by Anatomic Site

Treatment Site	Average Cycles
Lower abdomen	1.61
Upper abdomen	1.53
Flanks	1.06
Back	2.26
Arms	2.00
Thighs (outer)	2.18
Thighs (inner)	2.23
Chest	2.00
Knees	2.00
Buttocks	1.98
Other	1.95

Table 3. Number and Percentage of Treatments by Anatomic Site and Patient Sex

Anatomic Site	No. of Treatments		% of Sex Population	
	Female	Male	Female	Male
Lower abdomen	353	137	26	35
Upper abdomen	168	21	12	5
Flanks	447	217	32	55
Back	95	4	7	1
Arms	51	0	4	0
Thighs (outer)	84	0	6	0
Thighs (inner)	108	2	8	1
Chest	0	12	0	3
Knees	18	0	1	0
Buttocks	37	1	3	0
Other	21	0	2	0

percentage undergoing treatment in the upper abdomen and chest regions. Women, in comparison, received treatment over a much wider range of areas, including the lower and upper abdomen, the flanks, the inner and outer thighs, the arms, and the back. Sex distribution results are shown in Figure 5. The treatment sites were also analyzed by patient age range. Table 4 shows the percentage of patients in each age range who received treatment to

various sites. The lower abdomen and flanks were the most popular treatment sites for all age ranges; these data are shown in Figure 6.

In addition to analyzing the correlations between patient demographics and treatment sites, we examined system use frequency in the practice. The commercially available applicators used in the study period were the CoolCurve (eZ App 6.2), CoolCore (eZ App 6.3), and CoolMax (eZ App 8.0). Figure 7 shows the rates of applicator use at various sites, with the CoolCore applicator involved in 79% of all treatments. The CoolCore applicator was used across all treatment sites, while the CoolMax was primarily applied to the lower abdomen and was used nearly as often as the CoolCore at this particular treatment site, and the CoolCurve was used for flank treatment but only for a small fraction of treatments relative to the CoolCore.

Patient Safety and Efficacy Data

Patient charts were mined for reported complications. Typical side effects of cryolipolysis procedures reported in clinical studies include erythema, edema, bruising, and transient neuralgia.^{1,3} These were typically reported to resolve spontaneously within 2 weeks posttreatment. Subjectively, we can say that side effects observed in our practice were consistent with those reported in the literature, but they were generally not recorded in the patient charts. Only 3 cases of side effects were noted in the patient charts, and all 3 were reports of mild to moderate pain or neuralgia, which resolved in 4 or fewer days. No adverse events were reported.

While patient surveys were not conducted for this study, we believe that follow-up visits with the physician assistant allowed patients to express concerns and dissatisfaction. Two patients requested refunds and 4 patients who were initially dissatisfied with their fat reduction received follow-up cryolipolysis treatments without charge and were subsequently satisfied with their results. We believe this represents a high level of patient satisfaction.

Clinical results for treatment of various regions are shown in Figures 8 through 16.

Commercial Experience

Only 1 CoolSculpting system was available in our practice from December 2009 (when it was purchased) through July 2011. The demand for cryolipolysis continued to grow over the course of the study period, and systems were added to meet demand, as depicted in Table 5. Two systems were used from August through December 2011, 3 systems from January through October 2012, and 4 systems since November 2012. In 2010, when only the initial system was in use, there was an average of 3.98 cycles

Table 4. Percentage of Treatments by Anatomic Site and Patient Age

Treatment Sites	Age Ranges						
	≤19	20-29	30-39	40-49	50-59	60-69	≥70
Lower abdomen	22	36	31	30	26	22	17
Upper abdomen	4	16	9	8	12	12	13
Flanks	44	22	39	38	35	40	50
Back	11	4	2	4	10	6	7
Arms	7	3	3	3	3	3	0
Thighs (outer)	4	3	6	5	4	6	4
Thighs (inner)	4	9	7	7	7	4	3
Chest	0	2	0	0	1	0	3
Knees	4	1	1	1	1	2	0
Buttocks	0	3	2	3	2	1	3
Other	0	0	1	1	0	4	1

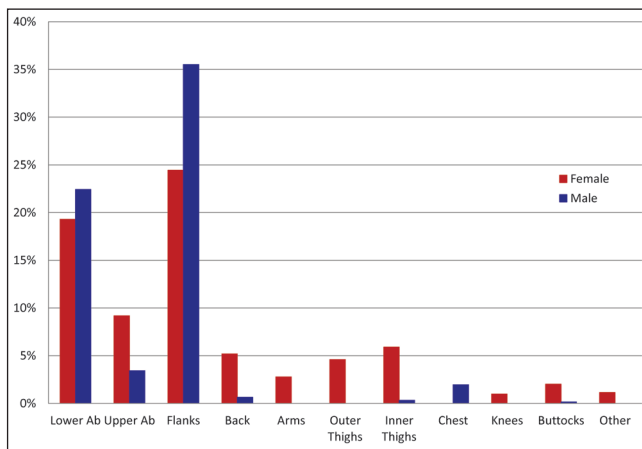


Figure 5. Treatment sites by patient sex, showing the percentage of men and women who received treatment in each anatomic location. Men received treatment to the lower abdomen and flanks almost exclusively. Women received treatment over a much wider range of areas.

delivered weekly. As cryolipolysis gained popularity in 2011 and became accepted as a safe and reliable nonsurgical body-contouring procedure,^{3,4,7} demand increased to an average system use of 12.2 cycles per week until a second system was installed in August 2011. After a third system was purchased, demand continued to increase, and the 3 systems averaged 12.6 cycles per week. The study period ended before meaningful data could be gathered

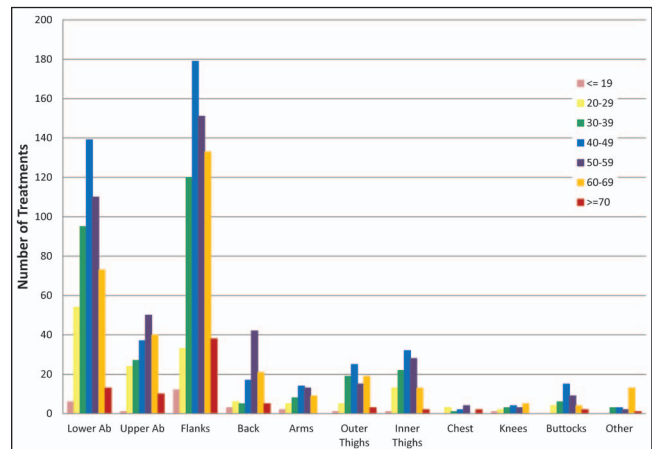


Figure 6. Treatment sites by age.

about an average per-week cycle rate for all 4 systems. As an aside, after the study period covered in this article, 2 additional systems were added to this practice. Compared with the 201 treatment cycles delivered in 2010, the total cycles delivered increased by 233% in 2011 and 823% in 2012 (n = 671 and n = 1857, respectively).

In addition to treating more patients by incorporating additional systems to meet demand, our approach evolved as patients sought treatment for multiple areas and returned for repeat treatments. The 3.45 average treatment cycles delivered per patient in 2010 increased steadily to

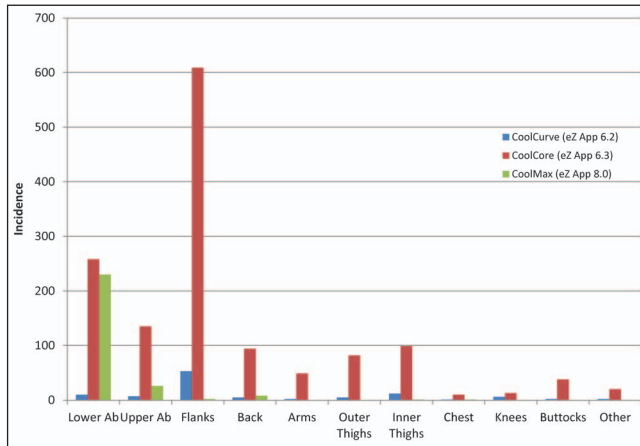


Figure 7. Applicator use per site. The CoolCore applicator was used most frequently in all treatment areas. The CoolCurve applicator was primarily used for the lower abdomen area. The CoolMax applicator was used primarily in the flanks, but it was used infrequently relative to the use of the CoolCore applicator.

4.43 in 2011 and 5.22 in 2012—an increase of over 50% in 2 years. Also, the percentage of patients who received more than 4 treatment cycles increased from 22% in 2010 to 29% in 2011 and 38% in 2012. Furthermore, in an effort to improve efficiency and reduce patients' time commitment, we implemented a procedure that used 2 systems to treat multiple sites simultaneously, such as the left and right flanks, reducing the time required to deliver treatments in half.

DISCUSSION

This study represents the largest and most comprehensive review of cryolipolysis patient data to date. While these study results are limited by the retrospective nature of the review, we hope they will provide significant value to the existing aesthetic surgery knowledge base because of the study's size and unique scope. The largest extant article on cryolipolysis is a lipid serum level and liver function safety study with 40 patients,⁷ whereas this study presents the first broad overview of clinical and commercial experience in a significantly larger population ($n = 528$ patients). Demographic data, treatment data (eg, treatment sites, applicator use, number of cycles per site), and business growth (eg, annual cycles delivered, average cycles per patient per year, male patient population growth) have not previously been quantified. This article also presents information about the low incidence of adverse events and the relatively few cases of dissatisfaction. Since cryolipolysis was introduced in our clinical practice, there has been steady, significant business growth, with a greater than 8-fold increase in treatment cycles over the study period. The procedure requires little clinician time, aside from setup and removal of the applicator, so multiple patients can be treated simultaneously if multiple CoolSculpting systems are available in the practice. We have employed cryolipolysis on patients with previous, poorly executed liposuction to contour and correct regions that are not uniform. With careful treatment planning, proper applicator placement, and multiple treatment cycles, cryolipolysis can produce results comparable to those of liposuction, which we believe is shown in our clinical examples (Figures 8-16).

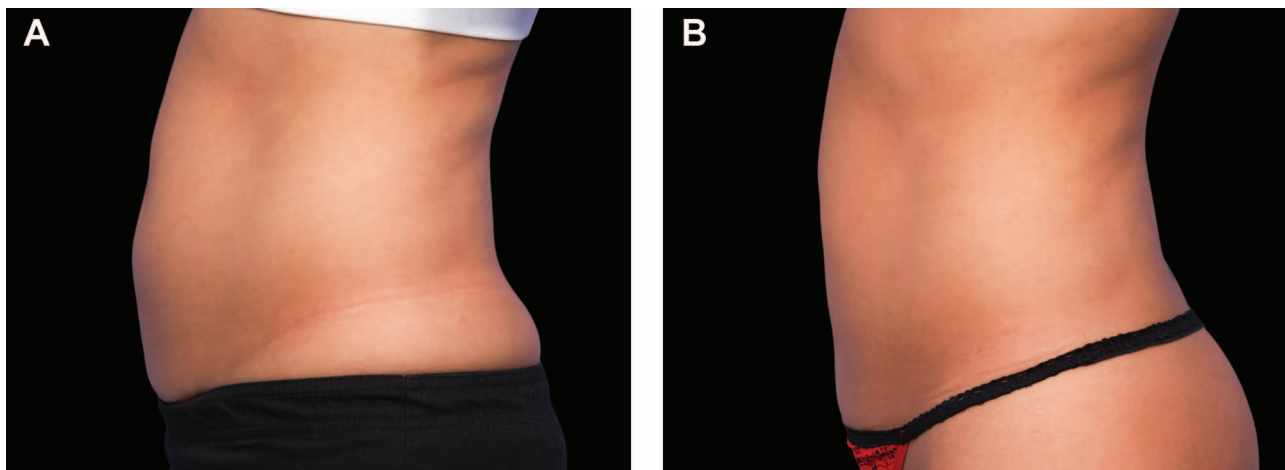


Figure 8. (A) This 27-year-old woman was active and healthy before treatment but was concerned about fat in her lower abdomen. (B) Three months after cryolipolysis of the lower abdomen, the patient is shown with a weight change of +1 lb. over baseline.

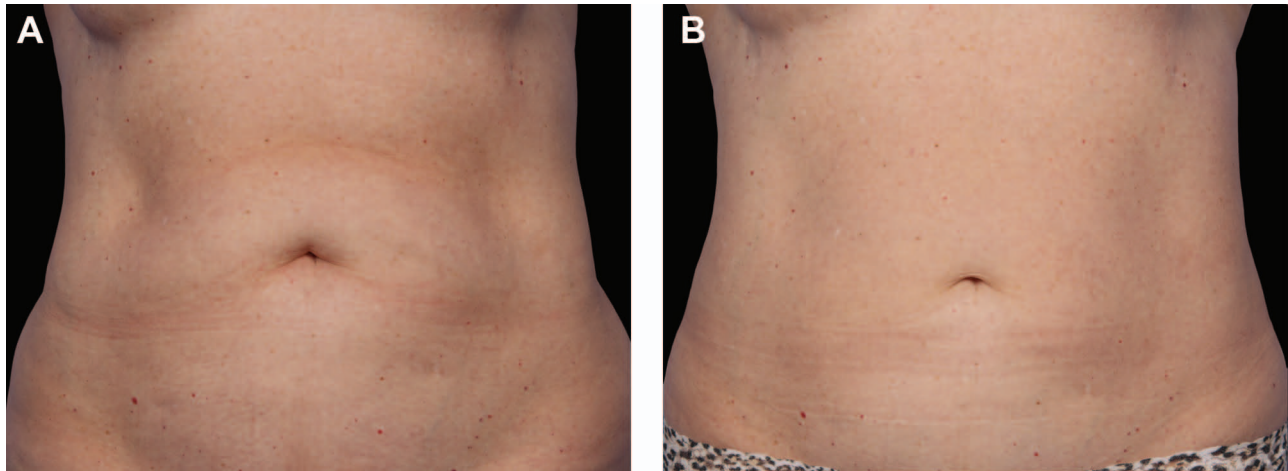


Figure 9. (A) This 59-year-old woman presented with concern about excess fat in her abdomen and flanks (often referred to as a “muffin top”). (B) Three months after 2 treatments, with each treatment consisting of 1 cycle to the upper, middle, and lower abdomen, plus left and right flanks, the patient is shown with a weight change -4 lbs. under baseline.

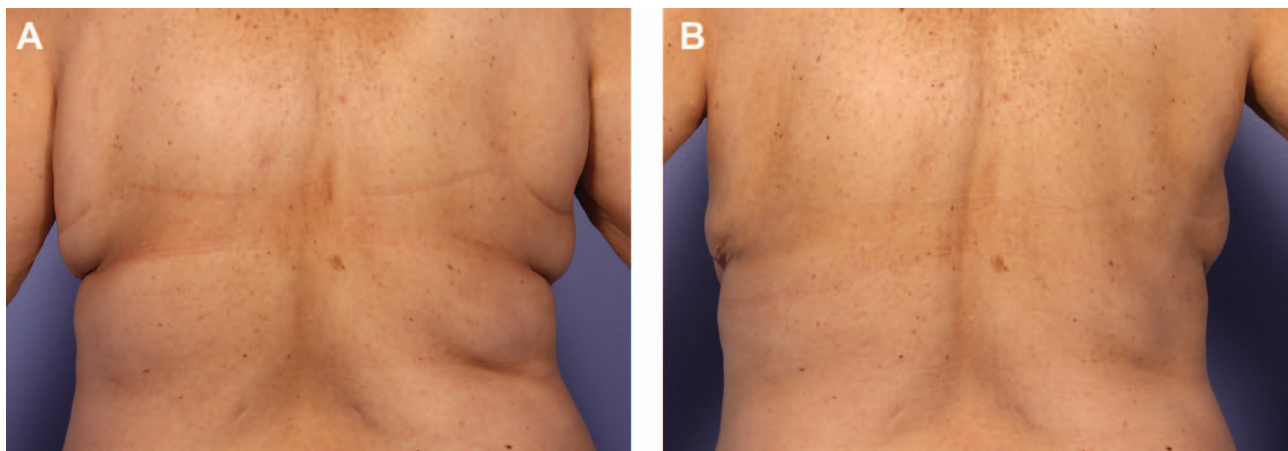


Figure 10. (A) This 58-year-old woman was unhappy about her “bra rolls.” (B) Three months after cryolipolysis treatment to the upper back, the patient is shown with no weight change since baseline.

Overall, the CoolSculpting system has been highly profitable. Net revenue—considering the cost of the system, consumables, cycle cards, and marketing—is approximately 60% of gross revenue. Marketing was carried out systematically, beginning with internal marketing to the established patient base, followed by creation of a micro-website and then a mobile website. In the second year of using cryolipolysis, we initiated a billboard campaign, followed by advertisements on sports radio stations. The marketing budget comprised approximately 20% of gross revenue. We recovered the capital investment made in CoolSculpting within an estimated 7 months for the first system purchased, 2 months for the second and third systems, and 1 month for the fourth system. These

calculations are based on an average \$750 cycle charge to the patient and the annual cycle described previously in this article.

Our retrospective chart review showed that 66% of the cryolipolysis patients were new patients who came to the practice specifically for CoolSculpting, so this provided us an opportunity to cross-sell dermal fillers, neuromodulator injections, aesthetic facials, laser hair removal, and skin resurfacing treatments, as well as surgical procedures. Of the new patients who presented for CoolSculpting, 40% became established customers who received additional cosmetic treatments. Although 95% of the new patients did not have prior experience with injectables, the most popular follow-ups for these



Figure 11. (A, C) This 39-year-old woman presented for treatment of inner thigh fat. (B, D) Two months after cryolipolysis, the patient is shown with no weight change since baseline.

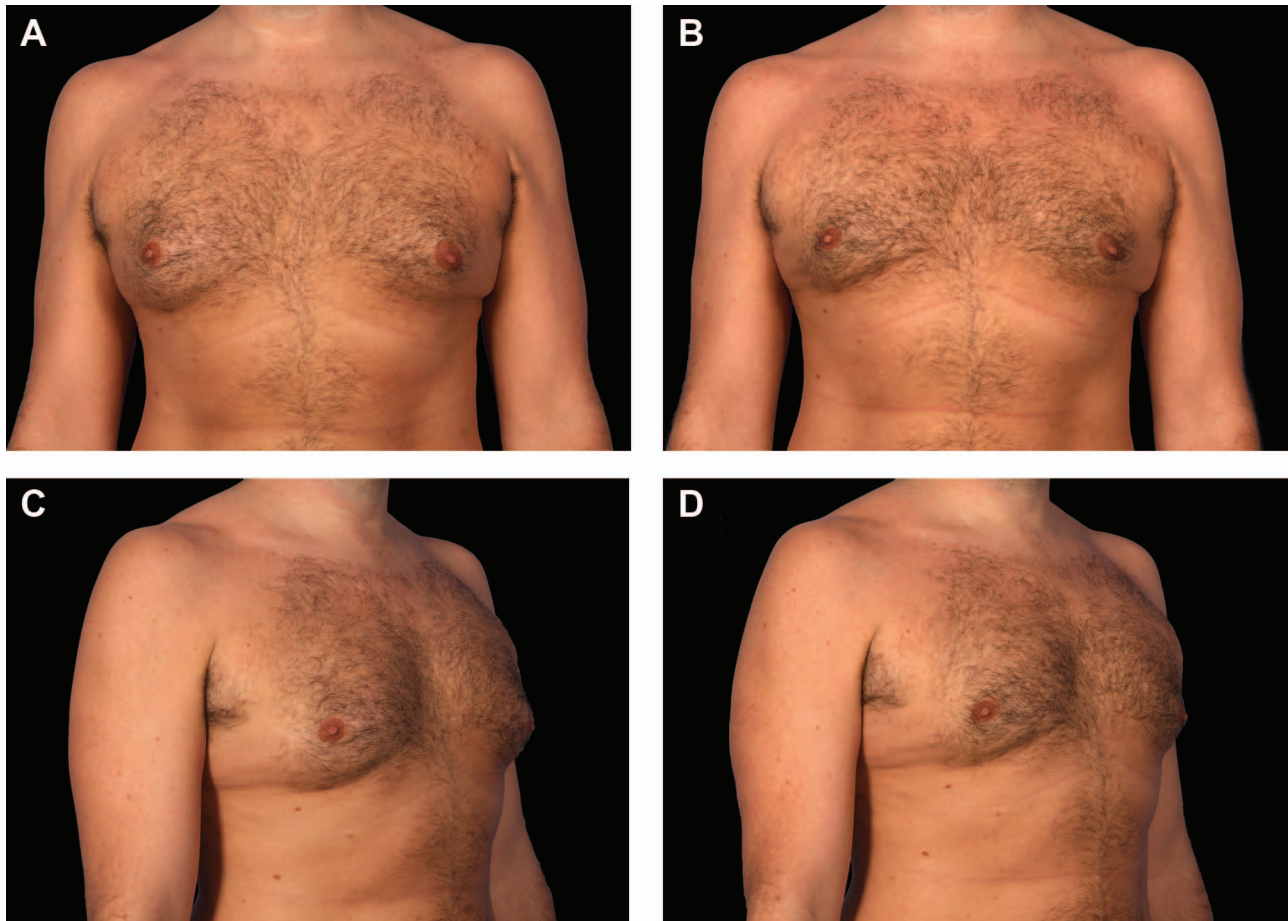


Figure 12. (A, C) This 37-year-old man presented for nonsurgical treatment of gynecomastia. (B, D) Two months after a single treatment cycle to each side of the chest, the patient is shown with no weight change since baseline.

patients were injectable facial procedures such as neuromodulators and dermal fillers. Therefore, we believe CoolSculpting provides an excellent business opportunity to introduce neophyte aesthetic patients to new procedures for the face.

In addition to reaching aesthetic neophytes, cryolipolysis has provided a unique growth opportunity with men. Targeted marketing was used to raise awareness of cryolipolysis among men. As shown in Figure 17, the male patient population responded dramatically to an advertising campaign that was initiated in June 2012 on a popular sports radio network. By the end of 2012, the percentage of male cryolipolysis patients at this practice was 42% ($n = 54$ in the fourth quarter of 2012).

CONCLUSIONS

In this retrospective patient chart review of cryolipolysis treatment in a single plastic surgery practice, data showed no adverse events and only a few side effects, which were

mild and temporary. We believe our clinical results show high efficacy as well. Cryolipolysis appealed to both women and men, and targeted marketing campaigns were effective at increasing the proportion of men who sought treatment. Aesthetic neophytes were also likely to present to our clinic seeking this type of treatment. Over the course of the study period, the total number of treatment cycles increased by more than 800%. Therefore, we believe cryolipolysis with the CoolSculpting device to be a safe and effective nonsurgical body-contouring technique that can generate steady, significant business growth.

Acknowledgments

The authors thank Melissa Silva, Fabio DeNegri, and Tami Ellis Greiner for assistance with chart review and data entry.

Disclosures

Dr Stevens is an investigator for Sientra and Silimed (Santa Barbara, California), Cohera Medical (Pittsburgh,

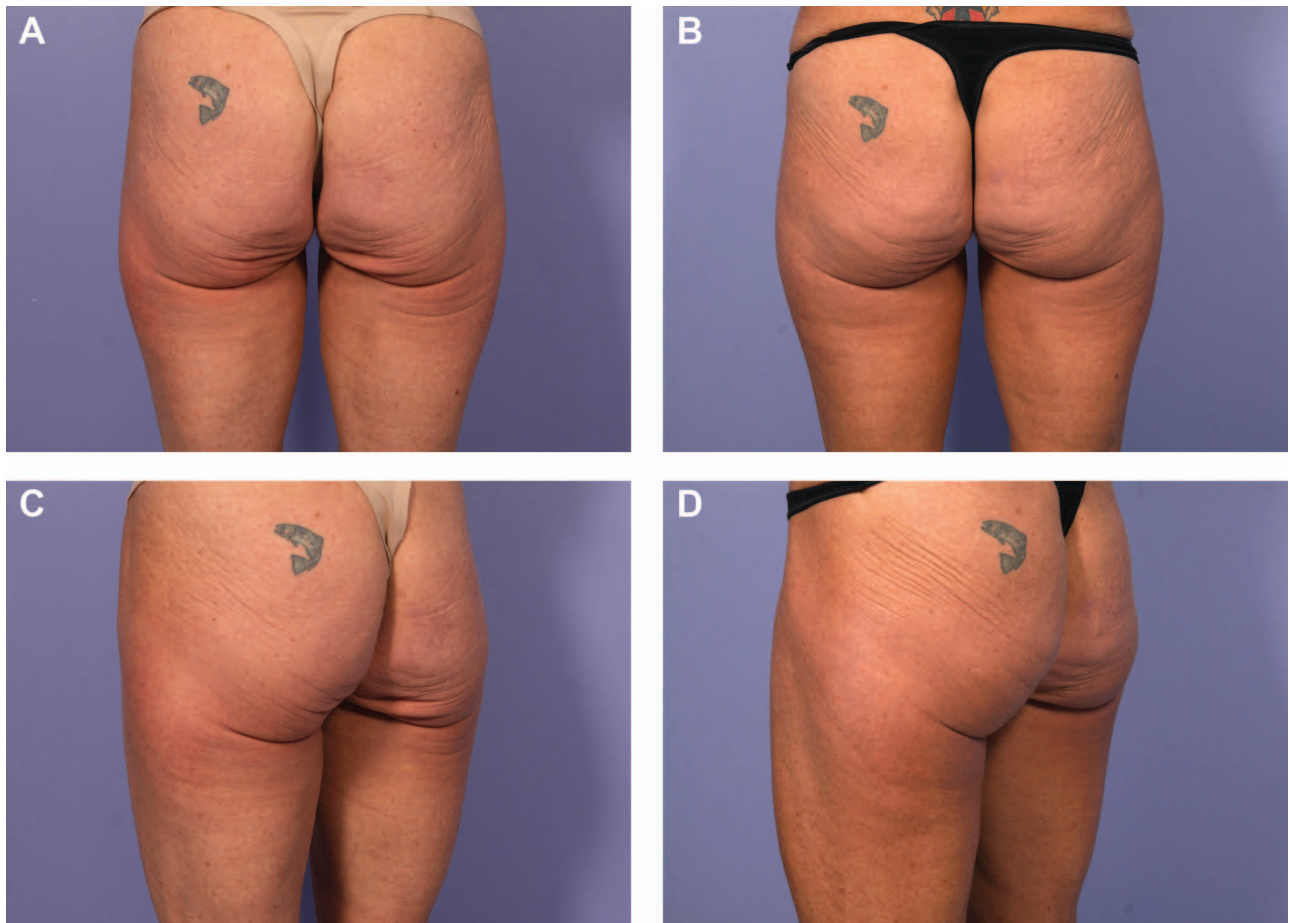


Figure 13. (A, C) This 57-year-old woman presented for treatment of “banana rolls” under her buttocks. (B, D) Five months after 2 cryolipolysis cycles on each side, the patient is shown with a weight change of +4 lbs. over baseline.

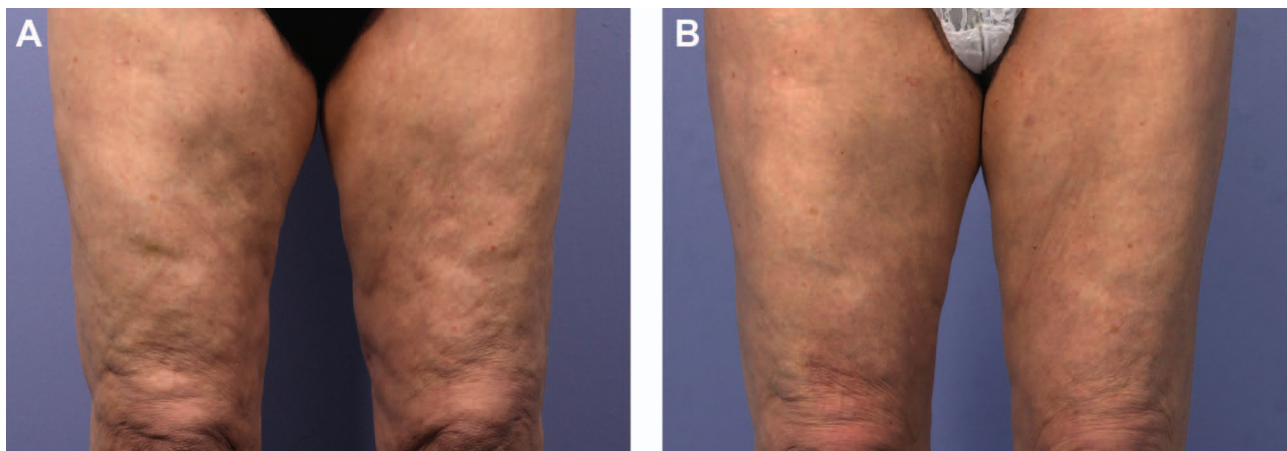


Figure 14. (A) This 66-year-old woman presented for treatment of her legs. (B) Four months after cryolipolysis treatment to her medial and lateral thighs, the patient is shown with no weight change since baseline.

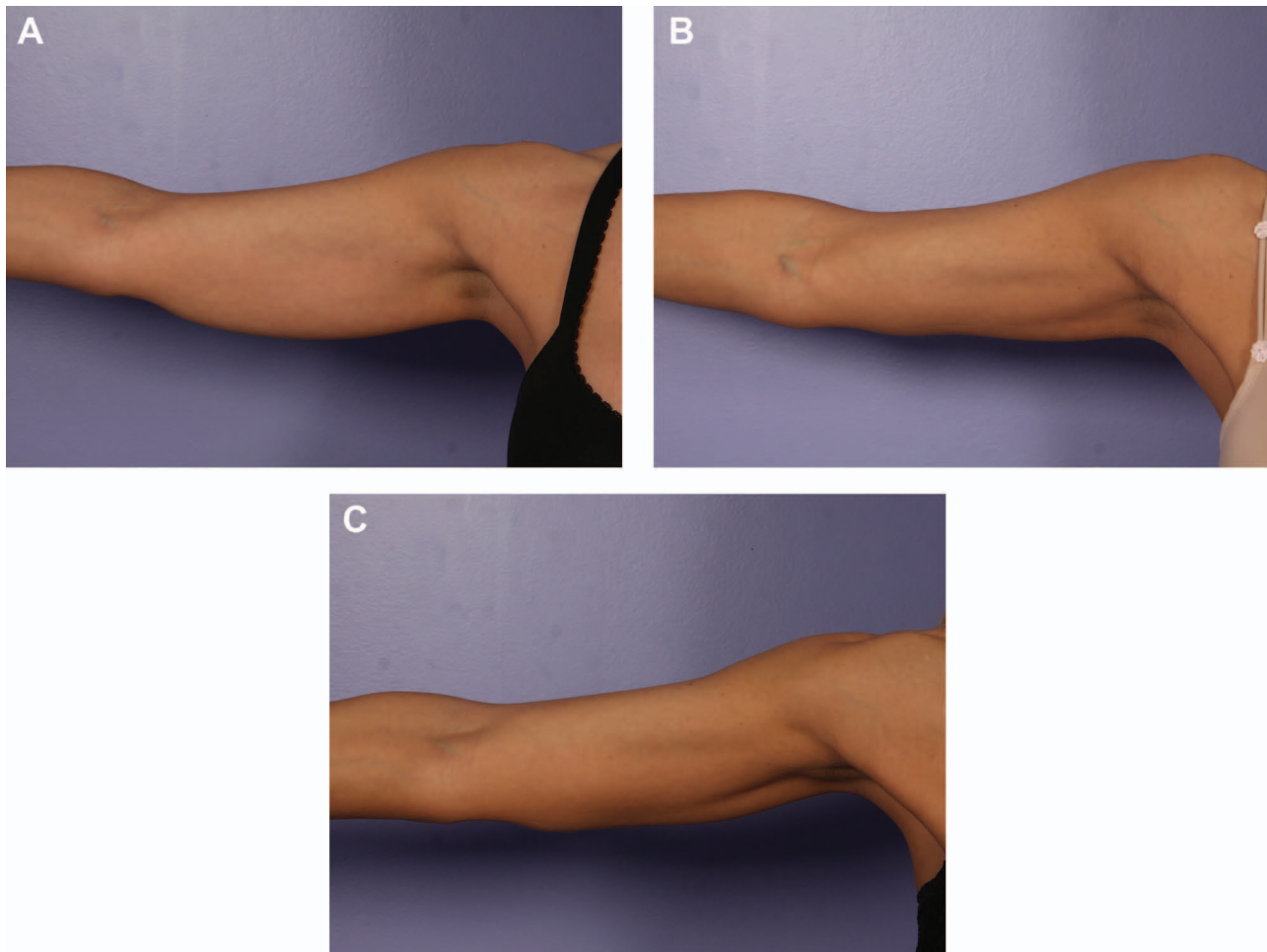


Figure 15. (A) This 48-year-old woman presented for treatment of her upper arms. (B) Two months after 1 treatment cycle and (C) 4 months after the first treatment, by which time she had undergone 1 additional cycle at the 2-month visit, the patient is shown with a weight change of -4 lbs. under baseline.

Table 5. Weekly Cycles Delivered by Number of Systems Available in the Practice.

Time Period	Weeks	Systems Installed	Cycles Delivered	Weekly Cycles/System
January 2010–December 2010	52	1	207	3.9
January 2011–July 2011	30	1	367	12.2
August 2011–December 2011	21	2	302	7.2
January 2012–October 2012	43	3	1628	12.6
November 2012–December 2012	5	4	216	10.8

Pennsylvania), and Mentor (Santa Barbara, California); a medical luminary for BTL (Framingham, Massachusetts),

Merz (Greensboro, North Carolina), and Syneron-Candela (Irvine, California); a speaker for Allergan Academy (Irvine, California) and Cynosure (Westford, Massachusetts); a consultant for TauTona (Menlo Park, California); and a medical luminary and speaker for Cutera (Brisbane, California), Solta Medical (Hayward, California), and Zeltiq (Pleasanton, California). Dr Spring is an investigator for Cohera Medical (Pittsburgh, Pennsylvania). Ms Pietrzak has no corporate disclosures.

Funding

Zeltiq, the manufacturer of the device discussed in this article, provided a small stipend to cover the administrative cost of patient chart review but did not approve the manuscript or fund medical writing and editing. All devices were purchased from the manufacturer at market cost and the manufacturer provided no further funding. Patients paid for their procedures and were not reimbursed by the sponsor or the investigator.

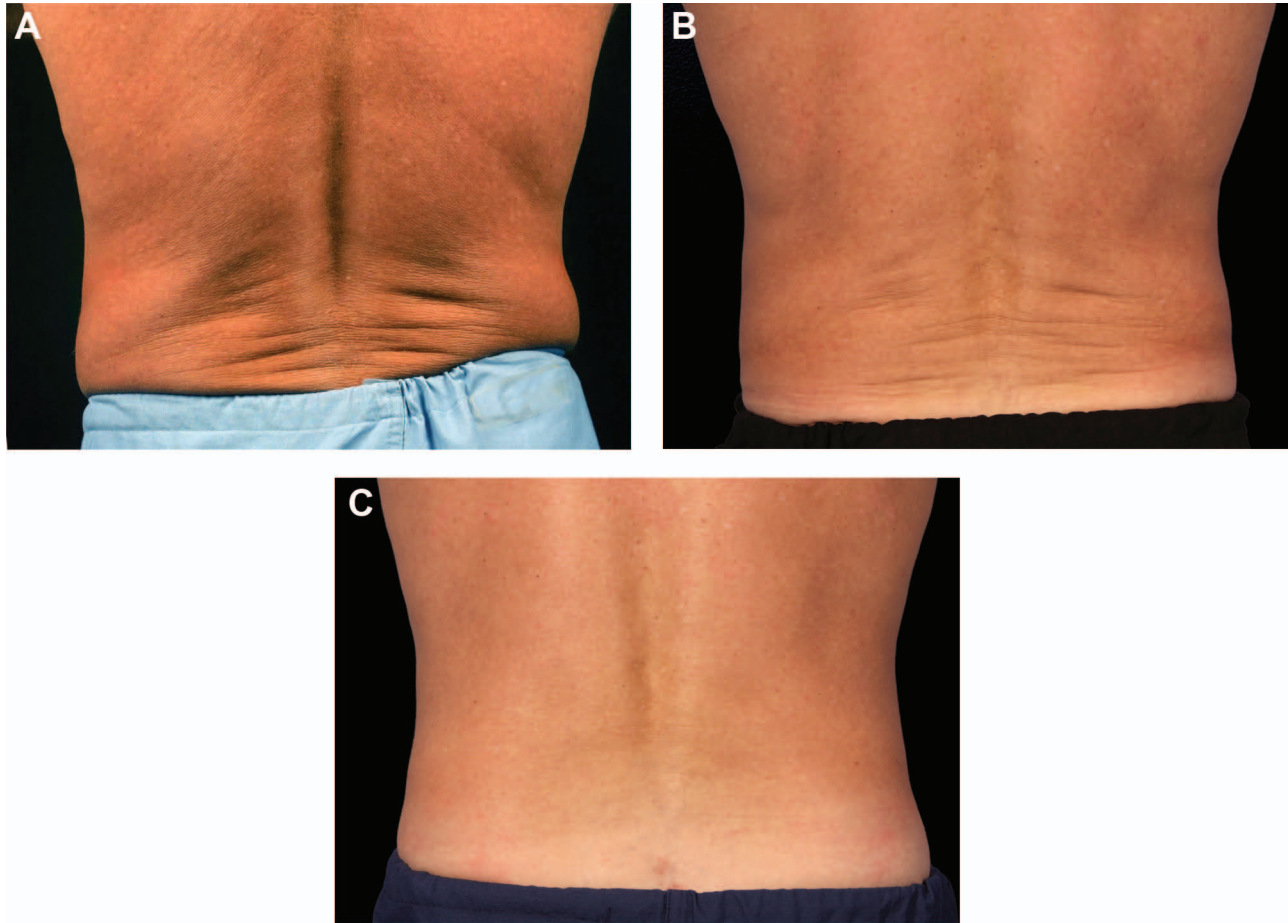


Figure 16. (A) This 58-year-old man was fit overall but displeased about fat in his flanks. (B) One year after first treatment and (C) 1 year after second treatment, the patient is shown with no weight change since baseline.

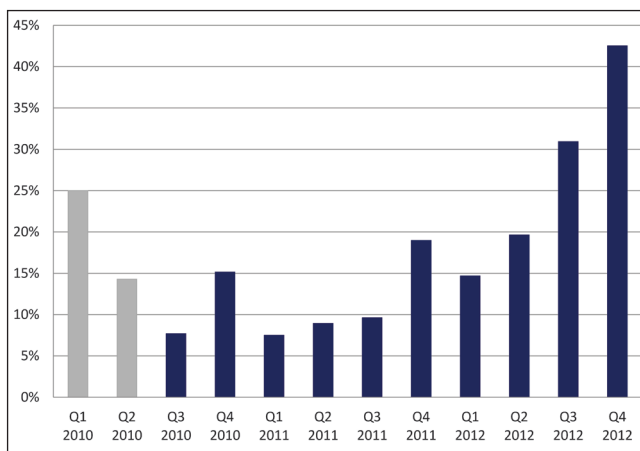


Figure 17. Growth of the male patient population. The percentage of male cryolipolysis patients grew in response to a targeted marketing campaign initiated in June 2012. By the fourth quarter of 2012, males comprised 42% of cryolipolysis patients at our practice. The bar graph was modified for the first and second quarters of 2010 because there was only 1 male patient for each of the first 2 quarters of 2010, and the small cryolipolysis patient population ($n = 4$ and $n = 7$, respectively) led to skewed results.

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