



Fig. 3. Baseline and posttreatment photographs of study subject STE-002 with cryolipolysis treatment to the left lateral thigh.

In his comments about the ultrasound fat layer reduction, Dr. Swanson says “a p value of $7.68E-8$ is confusing; p values are expected to lie between 0.0 and 1.0.” This is simply scientific notation, Dr. Swanson. A p value of 0.0000000768 certainly lies between 0.0 and 1.0 and for clarity, should be denoted in scientific notation as $7.68E-8$. Although Dr. Swanson asserts that the 2.6-mm mean reduction in fat thickness is within the range of measurement error, this is untrue. As shown by the t test comparing ultrasound measurements on the untreated control and the treated thighs, the fat layer reduction was significant.

Dr. Swanson has an interesting point in discussing conflict of interest between plastic surgeons and device manufacturers, but his assertions of impropriety for the cryolipolysis lateral thigh study are unfounded. The equipment, compensation, and study support are clearly described in the article. I carefully listed my disclosures to ZELTIQ and the numerous other companies with which I collaborate. I remain objective and unbiased as I continue to evaluate nonsurgical procedures, including cryolipolysis, and advancements in surgical techniques.

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DISCLOSURE

Dr. Stevens is a clinical professor of surgery at the University of Southern California Keck School of Medicine, Division of Plastic Surgery, the director of the Aesthetics Division of the USC Division of Plastic Surgery, the director of the Marina del Rey-USC Aesthetic Surgery Fellowship, and the director of Marina Plastic Surgery. He has been a paid consultant for Zeltiq as well as a shareholder. There has been no outside funding of this response.

REFERENCES

1. Swanson E. Cryolipolysis: A question of scientific and photographic integrity. *Plast Reconstr Surg*. 2015;136:862e–864e.
2. Stevens WG, Bachelor EP. Cryolipolysis conformable-surface applicator for nonsurgical fat reduction in lateral thighs. *Aesthet Surg J*. 2015;35:66–71.
3. Swanson E. Cryolipolysis: The importance of scientific evaluation of a new technique. *Aesthet Surg J*. 2015;35:NP116–NP119.
4. Stevens WG. Response to “Cryolipolysis: The importance of scientific evaluation of a new technique”. *Aesthet Surg J*. 2015;35:NP120–NP122.
5. The Stevens Institute. Available at: <http://www.freeze-thefat.com/before-after-photos-los-angeles/coolsculpting/3006/>. Accessed August 30, 2015.
6. ZELTIQ. CoolSculpting Web site. Available at: <http://www.coolsculpting.com/forphysicians/results/>. Accessed August 30, 2015.
7. Stevens WG. Does cryolipolysis lead to skin tightening? A first report of cryodermadstringo. *Aesthet Surg J*. 2014;34:NP32–NP34.
8. Kaminer MS, Coleman WP III, Weiss RA, Robinson DM, Coleman WP IV, Hornfeldt C. Multicenter pivotal study of vacuum-assisted precise tissue release for the treatment of cellulite. *Dermatol Surg*. 2015;41:336–347.

The Effect of Abdominoplasty and Outcome of Rectus Fascia Plication on Health-Related Quality of Life in Post-Bariatric Surgery Patients

Sir:

We read with great interest the article by Staalesen et al. entitled “The Effect of Abdominoplasty and Outcome of Rectus Fascia Plication on Health-Related Quality of Life in Post-Bariatric Surgery Patients” published in the December of 2015 issue of *Plastic and Reconstructive Surgery*.¹ We would like to bring to your attention some methodologic pitfalls presented in this study that should be taken into account when analyzing its results.

Analyzing the Consolidated Standards of Reporting Trials flowchart presented in Figure 1 of the article, we can find two important incongruities. First, randomization is a core principle for statistical inference, and in their study, 94 patients were distributed randomly into two groups: the plicated group, which included 38 patients; and the nonplicated group, which was composed of 56 patients. The difference between the samples was 1.48; in other words, the nonplicated group had 48 percent more patients than the plicated group. Randomization is expected to produce equal-size groups, and a randomization process showing a 48 percent sample size variation is inadmissible. Restricted randomization techniques, such as blocking, stratification, and minimization, could be used to achieve balance between group sizes.² Unfortunately, none of these techniques was used in the study; in addition, they do not mention which randomization method was performed in their study.

Second, among the 56 patients in the nonplicated group, three did not undergo the allocated surgery, and one was not operated on. Of the 52 remaining patients, 11 were lost to follow-up (i.e., a rate of 21.2 percent). Of the 38 patients in the plicated group, three did not undergo the allocated surgery. Of the 35 patients who were operated on, three were lost to follow-up (i.e., a rate of 8.6 percent). A more than two-fold value in loss to follow-up between groups is likely to bias final study results if reasons for unavailability of patient data are associated with the outcome of interest.³

Analyzing Table 1, we can see a clear difference between the groups in terms of the amount of abdominal excess skin. In the plicated group, the mean was 5.38; in the nonplicated group, the mean was 4.10, with a value of $p = 0.0041$ (i.e., in the plicated group, a mean 31.22 percent more abdominal excess skin compared with the other group was observed). This important difference may influence the results obtained and creates only nebulous support for the study conclusions.

Knowing these pitfalls, their findings may magnify their personal opinion rather than the strength of evidence obtained in their results. It is important to elucidate it because most patients presenting for body contouring after massive weight loss have high-grade abdominal deformities with multiple rolls. Change in body mass index is positively correlated with deformity grade, and more aggressive contouring procedures may be required to correct the resultant abdominal deformity.⁴

Their study also detected a decrease in the general health dimension of the Short-Form survey in the nonplicated group at follow-up, whereas no significant difference was found in the plicated group compared with preoperative scores. Knowing this, and analyzing the data in Tables 3 and 4, we can produce a dangerous assertion not included in their article: abdominoplasty following bariatric surgery does not improve, and may decrease, quality of life. This statement is dangerous because post-bariatric surgery body contouring treatment is often regarded as cosmetic and therefore of

low priority, which means funding is either unavailable or subject to various criteria.⁵

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DISCLOSURE

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REFERENCES

1. Staalesen T, Olsén MF, Elander A. The effect of abdominoplasty and outcome of rectus fascia plication on health-related quality of life in post-bariatric surgery patients. *Plast Reconstr Surg*. 2015;136:750e–761e.
2. Saint-Mont U. Randomization does not help much, comparability does. *PLoS One* 2015;10:e0132102.
3. AKI EA, Briel M, You JJ, et al. LOST to follow-up Information in Trials (LOST-IT): A protocol on the potential impact. *Trials* 2009;10:40.
4. Zammerilla LL, Zou RH, Dong ZM, Winger DG, Rubin JP, Gusenoff JA. Classifying severity of abdominal contour deformities after weight loss to aid in patient counseling: A review of 1006 cases. *Plast Reconstr Surg*. 2014;134:888e–894e.
5. Valente DS, Padoin AV. Post-bariatric surgery body contouring treatment in the public health system: Cost study and perception by patients. *Plast Reconstr Surg*. 2015;135:785e–786e.

Closed Incision Negative-Pressure Therapy Is Associated with Decreased Surgical-Site Infections: A Meta-Analysis

Sir:

The article entitled “Closed Incision Negative-Pressure Therapy Is Associated with Decreased Surgical-Site Infections: A Meta-Analysis” by Semsarzadeh et al.¹ (*Plast Reconstr Surg*. 2015;136:592–602) was enlightening and of particular interest to our practice. There have been previous contradictory findings regarding incisional wound vacuum-assisted closure and wound infection.² The meta-analysis affirmed a significant decrease in the rate of surgical-site infections with the application of incisional wound vacuum-assisted closure, but excluded pediatric patients from the study.

We would like to share our experience with incisional wound vacuum-assisted closure therapy. Based