Response to “Cryolipolysis: The Importance of Scientific Evaluation of a New Technique”

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With great interest, I read Dr Swanson’s Letter to the Editor. While I appreciate his efforts to stress the importance of scientific evaluation, I was surprised about the number of incorrect points he made in his commentary.

The author took umbrage to my clinical and commercial overview of cryolipolysis being the second most viewed article published in the Aesthetic Surgery Journal (ASJ). What he failed to point out is that the third most viewed publication in the esteemed ASJ is another cryolipolysis article. Clearly, the aesthetic surgery community is interested in cryolipolysis for non-surgical body contouring.

And while safety, efficacy, and tolerability are of primary concern, plastic surgeons are also interested in growing their practices. My overview article did not purport to be a comprehensive investigation of a new technology. As stated in the title, it was a clinical and commercial overview, a retrospective study of the first 528 patients treated at a private practice. The article shed light on the patient population for a non-surgical body-contouring procedure and how it could help grow a plastic surgery practice. While it seems to offend the author’s sensibilities to quantify cross-selling, there are many ASJ readers interested in non-surgical and eager to learn that 66% of the cryolipolysis patients were new to the practice, 62% were aesthetic neophytes, and 40% of the new “Freeze the Fat” patients have stayed with our practice and over the last two years, have enjoyed many other services and goods. I look forward to quantifying the secondary and tertiary revenue stream in the next year.

The author points out that redness, bruising, and temporary numbness are common, and that nodules can occur after cryolipolysis. These are known side effects and patients are counseled appropriately. There aren’t claims that the procedure is completely painless and has no side effects. The author finds it hard to believe that we reported no adverse events and only four initially-dissatisfied patients that were subsequently re-treated and satisfied. These are the data that were found after mining 528 consecutive patient charts. There was no effort on the part of the authors to underreport cryolipolysis complications or overstate treatment efficacy. All patients were evaluated by numerous physicians and physician assistants at the practice. There were no serious adverse events in the first three years. There were some cases of temporary neuralgia or paresthesia, but these self-resolved and weren’t considered serious adverse events.

And it is incorrect to state that a “claim of skin tightening based on two patients who also lost weight is tenuous.” There was no claim of skin tightening. It was a letter to the editor sharing observations of skin tightening, intended to foster discussion based on anecdotal reports of skin tightening from peers and subjective observations of skin.

Subjects repeatedly voiced their satisfaction with the noninvasive nature and minimal downtime of the procedure. Cryolipolysis is not intended to replace liposuction. My liposuction procedural volume hasn’t changed; I’ve just grown my non-surgical practice significantly with cryolipolysis.

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tightly from the clinicians and patients in my practice. The article stated “we wanted to publish these observations to raise awareness of an unexpected effect of cryolipolysis that merits discussion and further exploration” and that a “clinical research study is currently underway to explore cryolipolysis-induced skin-tightening hypotheses, to obtain quantitative objective measurements of skin tightening, and to establish the mechanism of action.”

In the paragraph discussing “spot freezing,” there are numerous incorrect statements. The author asks how one could truly “sculpt” body areas when the tissues swell following cryolipolysis. The patients are counseled on what to expect from the cryolipolysis procedure and understand that treatment effects will be visible in typically 2-3 months. This is why the report of <5% improvement at 6 weeks is not relevant. Sasaki et al reported global aesthetic improvement scores 6 months after cryolipolysis, noting significant improvement for the abdomen, hip, and bra roll treatments. The author reports that Dierickx et al found little or no treatment benefit for thighs, buttocks, and knees. At that point, the contoured vacuum applicators were designed to treat abdomens and flanks. There is now a flat vacuum applicator for the inner thighs, a surface non-vacuum applicator for the outer thighs, and a prototype small-volume applicator which might be appropriate for knees. And while the author quoted my article, saying “cryolipolysis results are comparable to those of liposuction,” he omitted the full statement saying that “with careful treatment planning, proper applicator placement, and multiple treatment cycles, cryolipolysis can produce results comparable to those of liposuction.” The patients are counseled on realistic expectations for fat reduction, patient assessments prepare them for the number of treatment cycles they will need to achieve the desired outcome, and the decision is left to the patients with no effort to sell them on either cryolipolysis or liposuction.

Almost all people have fat that they wish to lose. Very few actually want to undergo elective surgery. The majority don’t want liposuction because of anesthesia, downtime, risk of infection, pain, surgical revisions, scars, and bleeding. For some, there is stigma associated with aesthetic surgery. As a surgeon, the author appears so biased in favor of surgery that he doesn’t appear to understand the actual wishes of the general population. I am listening to the patients and providing services that appropriately address their needs, both surgical and non-surgical.

Finally, the author implies cryolipolysis lacks scientific evaluation, that “scrutiny should include patient-reported outcome studies, magnetic resonance imaging of the fat layer, and photographic measurements by investigators who do not have a financial conflict.” Magnetic resonance imaging (MRI) is not the only reliable method of measuring soft tissues and he incorrectly quotes Garibyan et al as stating MRI is the most reliable method for imaging the fat layer. Ultrasound, often used in body contouring studies, is an accepted, validated method of fat layer measurement. The clinical photographs from cryolipolysis studies are always assessed by blinded, independent physician reviewers, not the investigators in the studies. My financial disclosures are always clearly stated in publications and presentations. I collaborate with nearly 20 companies, including competitors to the CoolSculpting system, as an advisory board member, consultant, investigator, or speaker. To imply my observations on cryolipolysis are untrue and that my integrity is compromised by financial involvement is grossly unjust.

I’ve investigated in 11 non-surgical devices and speak out on the technologies with proven safety and efficacy. As the author stated, some systems lack scientific evidence of safety and efficacy. But cryolipolysis is a non-surgical body contouring system with over $80 million spent over 10 years in research and clinical studies prior to commercial launch and 5 years of commercial experience. I have written on the dangers of cryolipolysis counterfeit devices and will soon be publishing a clinical study on a cryolipolysis surface applicator for lateral thigh fat reduction. I have studies underway to examine optimized treatment parameters and new applicator prototypes. I’m committed to evidence-based medicine and will continue investigating new technologies and publishing and speaking out on behalf of medical systems with proven safety, efficacy, tolerability, and patient satisfaction.

**Disclosures**

Dr Stevens is an investigator and speaker for Sientra (Santa Barbara, CA) and Silimed (Santa Barbara, CA); an investigator for Mentor Contour Profile Gel (Santa Barbara, CA) and Cohera Medical, Inc; a medical luminary and speaker for Solta Medical (Hayward, CA) and Zeltiq (Pleasanton, CA); a medical luminary for Cutera (Brisbane, CA), Merz (Greensboro, NC), Exilis (Framingham, MA), and Syneron-Candela (Irvine, CA); a speaker for Allergan Academy (Irvine, CA) and Cynosure (Westford, MA); and a consultant for TauTona (Menlo Park, CA).

**REFERENCES**

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