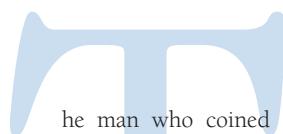


W. Grant Stevens, MD, FACS, on Cohesive Gel Breast Implants

“Gummy bear” implants are state-of-the-art and seemingly on the verge of wide acceptance in the United States



The man who coined the term “gummy bear gel implants” spoke with PSP about his hopes for the future of breast augmentation.

W. Grant Stevens, MD, FACS, is the Medical Director of Marina Plastic Surgery Associates in Marina del Rey, Calif. In practice for 23 years, he is past chairman of the department of surgery of Marina del Rey Hospital and associate clinical professor at the University of Southern California, as well as the director of the Cosmetic Surgery Fellowship. He has performed more than 10,000 breast augmentations.

The gummy bear implant goes by different monikers. Also known as the Mentor CPG, Sientra Cohesive Gel Implant, Inamed Style 410 Implant, and Type 5 form-stable cohesive gel implant.

These implants were invented in the early 1990s and has gained a reputation for being a longer-lasting implant that maintains a predictable shape.

The gel is more cohesive or firm and more solid than other silicone gel implants. Silimed or the US Sientra is the only company to offer a round cohesive gel or gummy bear implant.

The cohesive breast implant's unique teardrop shape anatomically mirrors the patient's breasts, which project more at the bottom than at the top. As the implant is thinner at the top, it will more naturally blend into the upper chest.

The largest growth has been in women who want their breasts lifted as well as enlarged at the same time.

PSP: What is your opinion of the new silicone breast implants, and how do they differ from the old type that was banned?

Stevens: The new silicone breast implants are the form-stable, highly cohesive gel breast implants. These are the state-of-the-art implants which have been available to me for now over 6 years. I've implanted well over a thousand of them, and I'm extremely happy with them. I have documented a lower capsular contracture rate, a lower instance of implant fold,

and an improved appearance of the breasts. In addition to that, they offer the peace of mind to the surgeon and the patient in the

unlikely event that the implant failed, the implant material would remain intact and well confined within the pocket.

PSP: Does the procedure for breast augmentation vary depending on the client, or is it more standardized?

Stevens: The procedure of breast augmentation is highly patient-specific. Cookie-cut surgery on breast implants results in unsightly, distorted, unattractive breasts. There are many different techniques in breast-augmentation surgery, and they are patient-specific. Each woman has their own anatomical variation and her own needs that are specific to her. The implants need to be tailored to the patient as well as the surgical technique.

PSP: What are the most common questions or concerns that patients have when they come in for an initial consultation, and how do you manage their fears?

Stevens: My patients have a number of

By Shelli Merrill





Figure 1. A 49-year-old female had a mastopexy and augmentation with Mentor CPG implants -- that is, submuscular placement -- and went from a 36C to 36D.

questions when they meet with me regarding breast augmentation surgery. Clearly, they want to not only look good, but to feel good; and they are concerned about their underlying health. The most important thing that I'm concerned about is their health and safety.

[I'm convinced that] cohesive gel breast implants...offer the highest degree of safety for the patient. In addition to that, my patients and [I] are concerned about complications of breast surgery, including capsular contracture or hardening of the breasts. I'm happy to report that that's very low, less than 3%. They're also concerned about the need for further surgery, rippling, distortion, rotation, and so forth.

PSP: Do you see an increase in a certain type of woman as far as age, ethnicity, or career type?

Stevens: There's always been a baseline interest in breast augmentation. However, I'm seeing an increasing number of Baby Boomer patients who have had previous implants [and] want to remove their saline or their older gels and switch. I've also seen a number of women who have had their children already, and they wish to have simultaneous augmentation or enlargement of the breast with breast-lift procedures.

The largest growth I'm seeing in my breast-augmentation practice has been in women who wish to have their breasts lifted as well as enlarged at the same time.

With regard to criticism about the gummy bear implants, there is a misconception among plastic surgeons and some patients that the form-stable cohesive gel

breast implants cannot be put in through a periareolar or nipple incision. I have placed more than a thousand of these implants, [with] the majority of these, in fact, through a nipple incision or periareolar incision.

PSP: How is breast augmentation presently changing in regard to materials and tools used for the procedure?

Stevens: The biggest change that I see in breast augmentation and breast implants are the introduction of highly cohesive, form-stable, silicone gel breast implants, oftentimes referred to as gummy bear breast implants. We have gone through many stages of silicone gel over the last 4 years now, and over the last 10 years or so we have had form-stable cohesive gel breast implants internationally. However, in the United States they've been available only on a limited basis. The world has embraced the cohesive gel form-stable breast implants; however, the FDA has yet to approve them for widespread use.

There are a limited number of surgeons in the United States who have been conducting ongoing studies on these implants. Based on what I know, the cohesive gel breast implants appear to have a lower complication rate, in particular lower capsular contracture rate. They have fewer problems with wrinkling or folding.

They are cohesive or form-stable and

not liquid. Therefore, in the unlikely event something was to happen to the shell, the implant would remain intact and not move from the pocket.

For many years, I would explain to the patient what form-stable gel was all about. I would describe [it] as Jell-O in your refrigerator, because that's what it looked like to me. You could cut these breast implants in half with a knife, and it's just like cutting refrigerated Jell-O.

The day that I looked to my left and saw a child eating gummy bear candy while I was speaking to a woman in terms of Jell-O, I stopped and I said, "They're like those gummy bear candies."

If you cut a traditional breast implant in half, a Type 3 gel, the gel will run. Not so with the gummy bear implants. Though gummy bear breast implants will stay solid like gummy bear candy, they do not feel as firm as the candy.

PSP: The FDA has yet to approve Type 5 form-stable cohesive gel.

Stevens: The Type 4 cohesive gel breast implants are widely available in the United States today, and that includes the Allergan implants as well as the MemoryGel Mentor Implants. They are approved and widely available.

The Type 5 form-stable cohesive gel implants are available on a limited basis

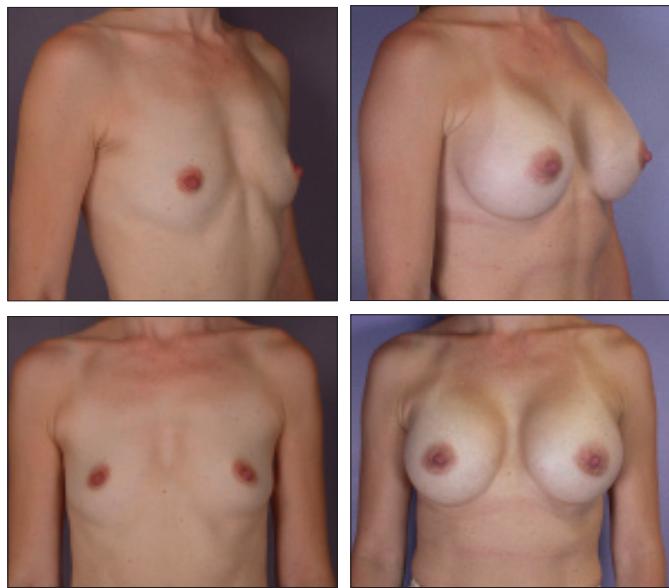


Figure 2. A 38-year-old female who has Silimed 485 cc cohesive gel implants, submuscular placement, and periareolar incision; and went from a size 32AA to 34C.

in the United States. However, they are widely available internationally. Once the FDA approves that Type 5 form-stable gel, we will have access to not only the shaped implants—sometimes referred to as teardrop implants—but also the round

implants that Sientra has available.

The Mentor CPG (Contour Profile Gel) form-stable implant is an example of a gummy bear breast implant shaped in a teardrop fashion. These implants are very helpful in women who are undergoing mastopexies or breast lifts, as well as primary augmentations. Other examples of shaped, tear drop, form-stable implants include the Sientra Enhance or the Allergan 410.

PSP: You have recently reviewed and submitted a paper on your experiences

with the Type 5 gummy bear implant.¹

Stevens: My largest series includes approximately a thousand of the form-stable cohesive gel Sientra implants, which are now being reviewed by the FDA. They are not only shaped but they're also rounded. The advantage of the round implant is that we can use it even in patients who have had previous augmentation.

One of the disadvantages of the shaped implant is that if they were to turn that, the ideal shape would be less than ideal because with the turning of the implant or

the rotating of the implant, there's a distortion of the shape of the breast.

There are a lot of women who have had previous implantation with saline breast implants, and they're unhappy with their salines or previous older gel implants. They want to either remove the older gel implants or change the size of their implants. The round cohesive gel or form-stable implants from Sientra offer distinct advantages over the shaped implants.

The Sientra cohesive gel implant is a round implant, and it is the only form-stable round implant presently being considered by the FDA for introduction to the United States.

The shaped form-stable gummy bear implants, such as the 410 and the CPG, are not ideal implants for women who have had previous breast surgery and have already pockets for those previous implants. Those women have pockets which are generally too large to safely accommodate the shaped form-stable implants. However, the Sientra form-stable silicone gel breast implants, which are round, can be safely placed in these patients.

Women who had previous breast surgery will be helped immeasurably once cohesive gel form-stable breast implants become widely available.

I'm confident that these implants will be approved by the FDA. I have done just under a thousand of them, and these are some of the happiest patients that I have in my practice.

PSP: Have you used saline implants in your breast-augmentation practice?

Stevens: I've put in thousands of saline breast implants, but I am not a fan of saline breast implants. The saline breast implants have distinct disadvantages, [which] include rippling, the feel of a water balloon in a woman's chest, and a very high instance of deflation. I've published three papers on saline breast implant deflations which are extremely disturbing.²⁻⁵ ⁿ

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References for this article can be found at www.plasticsurgerypractice.com

See See also "What Was Your Toughest Case?" by Amy Di Leo in the August 2008 issue of PSP.



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