Silicone Gel Breast Implants at 50: The State of the Science

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Relatively few medical devices continue to remain in existence for 50 years. The history of the breast implant, from its conceptual origin by Drs Cronin and Gerow as a medical device that would enhance breast size to a saline-filled model introduced in France in 1964 to the latest-generation devices, remains intriguing. It is astounding that, since 1991, 4.15 million women in the United States have undergone breast augmentation, more than the entire population of Connecticut (3.6 million). This device has even survived attempts to completely remove it from the marketplace. In writing this editorial, I intentionally decided not to chronicle each milestone of the silicone breast implant but to touch on areas of interest and lessons learned that will be of benefit as we move forward into the newest era of highly differentiated, anatomically shaped, form-stable devices and what lies beyond. Breast augmentation, 50 years after its introduction, is a highly refined procedure that uses newer devices, made with better technology and a better understanding of how to minimize the risk of adverse events associated with this procedure.

POLITICS OF SILICONE BREAST IMPLANTS

The year 1992 brought the start of both evidence- and quality-based movements within plastic surgery. It became incumbent upon plastic surgeons to get serious about data and clinical research if we wanted silicone breast implants back on the market after the Food and Drug Administration (FDA) moratorium. A lot of research was needed to demonstrate that these devices were safe and that they added to the quality of patients’ lives. It took years to generate high-quality data that would convince the FDA to approve gel-filled breast implants.

2006 was an important year because of the reintroduction of silicone gel-filled implants to the US market, following a 14-year moratorium. Plastic surgeons advocating for their patients, based on science, safety, and choice, won the day at the FDA hearings. As co-chair of the Joint American Society of Plastic Surgeons (ASPS)-American Society for Aesthetic Plastic Surgery (ASAPS) Breast Implant Task Force, I recall that it looked extremely bleak on the day of the hearing. We had collected only a handful of our patients to testify favorably about breast implants, and there were literally legions of naysayers, claiming every imaginable affliction from silicone. This was a time for us, as plastic surgeons, to depend on the preponderance of scientific evidence that demonstrated safety and patient benefit. This ultimately convinced the FDA to return these devices to the marketplace.

In retrospect, the moratorium existed largely because of the political influence of the naysayer organizations claiming that breast implants were harmful and a shameful lack of scientific evidence that proved that they were safe. Since that time, there has been a significant amount of scientific activity directed at answering challenging questions regarding the effects of device rupture, the relationship of augmentation procedures to autoimmune disorders, and patient satisfaction after breast augmentation.

In looking back, I find that there was a silver lining to the whole matter, which was the fact that the ultimate value of scientific evidence trumped “junk science” and contrary opinion. We learned a great deal about how to improve the quality and safety of breast implant outcomes in the years of quantitative research required to return the gel-filled devices to the marketplace in 2006.

The lessons learned have been overall beneficial for plastic surgeons in the years since. We should never forget the importance of data and scientific evidence, along with patient advocacy, when it comes to the politics of medical devices. This further emphasizes the value of data collection via patient registries and ongoing investigational activities. No longer can plastic surgeons be end users of a device; rather, we need to collect data as clinician-scientists on a daily basis.

THE ANAPLASTIC LARGE CELL LYMPHOMA MATTER OF 2010

The anaplastic large cell lymphoma (ALCL) matter of 2010 highlighted an extremely rare cancer associated...
with breast implants. Anaplastic large cell lymphoma had been recognized for some time as a result of case reports throughout the world. The variability of its expression—from reported fatalities to individuals cured by capsulectomy—remains intriguing. This disorder has been reported in all categories of breast implants and is not limited to a single brand or type. Anaplastic large cell lymphoma is an area that needs continued study to determine exactly what type of lymphoproliferative disorder it comprises. Research into the immunology of capsular layers and surface texturing would expand our understanding of the host response to all types of implanted devices.

The response of organized plastic surgery and the device manufacturers was admirable; they worked to develop an understanding of the dimensions of ALCL and a reasonable process for managing late-term periprosthetic fluid accumulation. Although this condition is extremely rare, the “weight” given to this topic in terms of the response became the first step to understanding it better. Patients with breast implants can feel reassured that the incidence of ALCL is remote, similar to the risk of being struck by lightning, but continued vigilance even for rare events makes sense. The concept of a registry for patients with implants and unusual occurrences such as ALCL also makes sense. A central data repository offers certain advantages when case reports of seemingly rare events occur. Plastic surgery organizations must partner with device manufacturers to develop registries that provide postapproval studies and surveillance for late-term adverse events.

**REGULATORY AGENCY ACTIONS, 2012**

In 2012, FDA approval was given for round and anatomically stable implants from a third manufacturer (Sientra, Santa Barbara, California). Approval is anticipated shortly for the form-stable, highly cohesive implants from 2 other manufacturers (CPG, Mentor, LLC, Santa Barbara, California; 410, Allergan, Inc, Irvine, California). Whether you are a proponent of round or anatomically shaped, form-stable devices, there has been a change in the marketplace and an opportunity for plastic surgeons to improve outcomes for our patients with the latest generation of devices, according to peer-reviewed scientific articles in the *Aesthetic Surgery Journal* and others. These devices represent an opportunity for surgeons to produce better long-term outcomes with lower incidences of adverse events, typical of the studies published for round, smooth implants.

American plastic surgeons will need to develop an understanding of device texture, more sophisticated planning, and precise surgical technique, compared to their current knowledge of round, smooth devices. The other foremost factor is improving our management of the patient expectations that drive reoperation rates for size change. When patients are held completely accountable for the clinical decisions made before surgery regarding size, reoperation for incorrect size becomes a nonissue. I have had no reoperations for size change in 11.5 years with the anatomically shaped, form-stable study breast augmentation cohorts. The combination of all of these factors equates to a high degree of patient satisfaction and superior long-term outcomes.

The message here is that form-stable, anatomically shaped implants cannot be placed according to a round, smooth implant mind-set. This device is not a good fit for all patients seeking breast augmentation or reconstruction. Surgeons who have had the opportunity to use these devices will be the first to say that not every patient is a good candidate, especially those with loose breast tissue envelopes, for whom round, smooth gel implants may be better suited.

There is a learning curve and an experiential knowledge requirement before proficiency is achieved. This is hardly different than in aviation when aircrews receive a new aircraft with different performance characteristics. Even a senior pilot would not expect to fly a new Boeing 787 or Airbus A-380 without being trained and rated. The evolution of the process for the use of breast implants also mirrors movements in aviation and manufacturing, where dramatically improved outcomes are associated with process engineering and planning systems. The days are long gone of both “seat-of-their-pants” aviators and the “artistic” plastic surgeon’s approach to breast augmentation, due to excessive variation in results.
IMPROVING AUGMENTATION OUTCOMES

Even after performing breast augmentations for more than 35 years, I do not view this as a simple operation, nor do I think that the questions surrounding this device have all been answered. I do know that the quality of my outcomes with breast implants dramatically improved about 13 years ago, when, as an investigator on the Core Gel Study (which included the Inamed [now Allergan] 410 and Mentor CPG implants), I started collecting data and analyzing my outcomes. The lessons that I learned in these studies demonstrated that the process of breast augmentation would fit into a standardized planning and quality program similar to the Toyota Production System.13,16 The results of this outcomes analysis/improvement process in my own clinic have been very gratifying in terms of yielding low reoperation rates and extremely high patient satisfaction. Reoperation must be minimized because any reoperation implies that there was a problem with the outcome. The data from long-term follow-up has been extremely useful in validating the importance of multidimensional planning, accurate management of patient expectations, and precise surgical technique.

In my opinion, these anatomically shaped, form-stable devices provide plastic surgeons and their patients with a unique option. The published literature on shaped devices demonstrates better outcomes, lower reoperation rates, and superior patient satisfaction. From my perspective as an approved clinical investigator for 11.5 years, I see an opportunity to create a new marketplace with innovation, value, and differentiated outcomes with the form-stable devices that did not exist previously. Currently, there is an intensely competitive marketplace in which most surgeons use undifferentiated, round devices. If a plastic surgeon chooses to become proficient with anatomically shaped, form-stable devices, there is a distinct opportunity for him or her to grow rapidly in the new marketplace I mentioned previously, because the market typically favors “first movers.”17 However, all surgeons should keep in mind, again, that proficiency with anatomically shaped devices takes some time and requires attention to detail in all parts of the process so as to produce great long-term outcomes, lower rate of adverse events, and higher patient satisfaction.

NONIMPLANT BREAST AUGMENTATION

Breast enlargement with nonimplant technologies, whether with autologous stem cells or synthetic injectables, is in its infancy. Some of the work published thus far shows promise, but nothing reaches the current level of positive outcomes that we can produce with breast implants. The path toward widespread use of synthetic fillers for breast augmentation is littered with serious adverse events, even when the material is claimed to be “biocompatible.” Furthermore, not every patient seeking breast size enhancement has sufficient stem cell donor sites to permit serial harvest and transfer. Stem cells may ultimately show promise, yet the ability of this technology to produce safe, effective, and satisfying long-term outcomes still has to be proven with Level 1 scientific evidence, not “hucksterism.”

As of August 2012, the FDA has repeatedly sought to blur the line between manufacturing medical products and practicing medicine whenever new techniques emerge. In this particular situation, the removal of stem cells from a patient’s body and subsequent reinjection into the same patient is viewed as a drug by the FDA.18,19 The standard for regulation is not whether the agency feels that a technique is novel but whether it meets the definition of being a medical product. Scientific evidence will be needed here to deal with a stodgy, overreaching regulatory agency.

CONCLUSIONS

It is far too early to write an obituary on the silicone breast implant, just like it would be too early to write one on aircraft designed 50 years ago that still provide safe service to millions of passengers. The interesting issue here is what we have discovered through 50 years of use and what we still have to learn. Many areas need additional study, including the immunology of implanted biomaterials, new polymers to replace silicone elastomers and gel, and optimal management of patient expectations regarding size outcomes in breast augmentation.

Fifty years ago, 2 geniuses invented the breast implant. It remains a great inheritance for future generations of plastic surgeons willing to nurture it and improve the outcomes that it produces for our patients. We must actively demonstrate good stewardship of these beneficial devices and maintain and improve them in a hostile regulatory environment. Plastic surgeons can no longer be merely end users of devices but must transition into clinician-scientists who utilize planning processes and make data-driven decisions that improve the quality of our outcomes with all categories of breast implants.

Disclosures

Dr Jewell is an approved clinical investigator for Allergan, Mentor, Medicis, Solta, and Excallard-Pfizer and a consultant for Allergan, Medicis, Solta, Sound Surgical, Excallard-Pfizer, and AorTech. Dr Jewell has formerly published peer-reviewed scientific manuscripts and book chapters on breast implant surgery and quality improvement/process engineering applied to breast augmentation.

REFERENCES


