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SILICONE GEL BREAST IMPLANTS: PAST, PRESENT, AND FUTURE

SILIKONSKI IMPLANTATI ZA DOJKE: PROŠLOST, SADAŠNJOST I BUDUĆNOST

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SUMMARY

The authors have provided an in-depth review of the history of saline and silicone gel-filled breast implants. In the history of medicine, no devices have been more scrutinized and thoroughly studied than breast implants. Although we as plastic surgeons recognize and appreciate the benefits that our patients derive from these devices, society as a whole continues to remain skeptical. The reasons for this are complex and multifactorial but appear to be fueled by the media, oppositional organizations, and several trial lawyers. Prior to 1990, when the silicone gel implant controversy began, there were only eight indexed publications that dealt with the issue of silicone gel breast implants. Since 1990, there have been more than 500 indexed publications dealing with silicone gel implants. At the time of the moratorium in 1992, we as plastic surgeons did not have a leg to stand on because there was a paucity of scientific evidence to support our observations that silicone breast implants were safe and effective devices.

Keywords: silicone breast implant, implant filler, surface texture

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INTRODUCTION

The female breast has long been an object of both individual and societal interest. The breast represents a woman's femininity and sensuality. One does not have to look far in the media to recognize the relative value of the breast in female perception by society. These factors represent some of the underlying motives that have made surgery of the female breast, both aesthetic and reconstructive, an area of great interest and a formidable challenge to plastic surgeons for decades. Arguably, no device or single surgical procedure has altered the landscape of breast surgery as dramatically as prosthetic breast implants. Breast implants have been in use since before the mid-1960s, yet the topic still produces heated debate and emotions. Breast implants are medical devices designed for surgical implantation to alter the size and shape of the breast in women. The principal indications are aesthetic enlargement and reconstruction of breast deformities related to cancer treatment, trauma, or congenital abnormalities. Breast implants are manufactured filled with either physiologic saline or silicone gel. Each has advantages and disadvantages, but silicone-filled devices are used most commonly and generally yield the most natural results.

Millions of women have had implantation surgery since the introduction of silicone gel-filled breast implants more than 40 years ago. It continues to be the most popular cosmetic procedure performed by plastic surgeons, with more than 300,000 performed annually.¹ In the 1990s, sharp controversy arose regarding the health safety of silicone gel-filled breast implants, and their use was restricted by the U.S. Food and Drug Administration (FDA) in 1992. Ultimately, no evidence was found to support significant safety concerns, and the devices were released again for general use in November 2006.² Nevertheless, some continue to question the safety of silicone gel breast implants, and FDA-mandated postapproval safety studies will be underway through 2018. It is possible that controversy will reemerge as data from these studies become available, and patients still need clarification of the safety issues involved.

For these reasons, it is important that plastic surgeons performing breast implant surgery understand the fundamental technology behind breast

¹ American Society of Plastic Surgeons (2009), 2008 plastic surgery procedural statistics; 2009. Available at: <http://www.plasticsurgery.org/Media/stats/2008-US-cosmetic-reconstructiveplastic-surgery-minimally-invasive-statistics.pdf>.

² U.S. Food and Drug Administration. (2009), Silicone gel-filled breast implant timeline, Available at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM064461>.

implants and be familiar with all the safety issues. Patients and others in their local communities will expect them to be experts. This paper reviews the fundamentals of silicone chemistry, the history of breast implantation surgery and regulation, and current knowledge about safety and efficacy. The purpose is to equip the practitioner to hold a well-informed opinion about silicone gel breast implants, to be able to answer common questions about the use of breast implants and to work with their patients to make sound clinical decisions about breast implantation surgery.

SILICONE

Silicone refers to a family of compounds with a molecular backbone of alternating silicon (Si) and oxygen (O) atoms. Silicon is a semimetallic element found in nature as silica (SiO₂), the most abundant substance on Earth, commonly found in nature in the sand and quartz-containing rocks. Silicon is located just below carbon on the periodic table and therefore has similar chemical behavior, most notably the ability to form long-chain molecules called polymers. The basic repeating unit (monomer) of the silicone polymer is siloxane (R₂SiO), named because it contains silicon, oxygen, and alkane (saturated hydrocarbon) side groups. The most common formulation used in medicine is poly(dimethylsiloxane) (PDMS), in which the siloxane monomer carries two methyl (—CH₃) groups.

The hydrosilation reaction is catalyzed by small amounts of platinum. Small amounts of residual platinum may be detected in the final product.³ Some forms of platinum have immunogenic potential, and the possibility of this as a source of adverse reactions to silicone gel breast implants has been suggested. However, no clinical report has positively related the trace platinum found in breast implants to human disease, and the type and quantity of platinum used in manufacturing provide no biologically plausible rationale for health problems from this cause.^{4,5} Silicone-based medical devices have been in use since the late 1950s.⁶

In plastic surgery, silicone devices have been used in a wide variety of clinical applications. Silicone implants are used to augment the craniofacial

³ Maharaj SV. (2007), Exposure dose and significance of platinum and platinum salts in breast implants. *Arch Environ Occup Health*; 62(3), 139–146.

⁴ Wixtrom RN. (2007), Silicone breast implants and platinum. *Plast Reconstr Surg*; 120(7 suppl 1), 118S–122S.

⁵ Bondurant S, Ernster V, Herdman R, eds. (2000), Silicone breast implants and cancer. In: *Safety of Silicone Breast Implants*. Washington, DC: National Academy Press, 233–241.

⁶ Costantino PD. (1994), Synthetic biomaterials for soft-tissue augmentation and replacement in the head and neck. *Otolaryngol Clin N Am*; 27(1), 223–262.

skeleton and reconstruct the orbital floor. They are used in hand surgery for joint reconstruction, flexor tendon replacement, and bone block spacers. Little controversy has surrounded the use of silicone for these applications. The application that has generated the most controversy is breast implantation surgery.

It is important to keep in mind that the majority of silicone gel is silicone oil within the confines set by the PDMS gel matrix. The ratio of silicone liquid to gel is controlled by manufacturers to control the viscosity of the gel. Elastomers of silicone have high degrees of cross-linking and almost no PDMS oil. Breast implant shells, both silicone and saline filled, consist of a vulcanized silicone elastomer that is reinforced with silica for increased strength.⁷ In an effort to reduce gel bleed from silicone-filled devices, phenyl or trifluoropropyl groups are bonded to the shell to decrease the shell permeability to PDMS oil.^{8,9} These “low-bleed” implant shells with “barrier coating” are characteristic of the current third-, fourth-, and fifth-generation implants.

HISTORY OF MANUFACTURING AND MATERIALS

Prior to the development of prosthetic breast implants, numerous materials were put on trial for the purpose of augmenting the female breast. Until the 1950s, materials included autogenous fat and dermal grafts, fat injections, paraffin injections, and insertion of glass balls, ivory, rubber, and Terylene wool.^{10,11} These materials frequently led to infection, tissue necrosis, and firmness of the breast. The autogenous materials were uniformly troubled by resorption. The 1950s and 1960s saw the use of many other products.

The development of the silicone gel prosthesis in 1962 marked an important new era in breast surgery. Since Cronin and Gerow first reported its use, few other materials have been used for breast augmentation. This is partly due to the success of silicone devices and also the subsequent FDA

⁷ Brody GS.(1997), On the safety of breast implants. *Plast Reconstr Surg*, 100, 1314

⁸ Barker DE, Retsky MI, Schultz SL.(1981), The new low bleed mammary prosthesis: an experimental study in mice. *Aesthetic Plast Surg*,5, 85.

⁹ Caffee HH.(1986), The influence of silicone bleed on capsular contracture. *Ann Plast Surg*, 17, 284.

¹⁰ Bondurant S, Ernster V, Herdman R, eds. (2000), *Safety of Silicone Breast Implants*. Washington, DC: National Academy Press.

¹¹ Young VL, Watson ME. (2001), Breast implant research: where we have been, where we are, where we need to go. *Clin Plast Surg*, 28(3), 451.

regulation of medical devices that started shortly after the development of silicone gel devices.¹²

Currently available breast implants are made of a silicone elastomer shell filled with either physiologic saline solution or silicone gel. Each has advantages and disadvantages. Saline filled devices can be adjusted to optimum size at the time of implantation, but they can be unnaturally firm, form visible wrinkles on the breast surface, and move less naturally with changes in body position. Silicone gel-filled implants overcome these disadvantages because they simulate the density of natural human tissue. They are particularly useful when there is a small amount of overlying soft tissue as in the augmentation of very small breasts or breast reconstruction.

The manufacturing process of breast implants, as of all medical devices, is a tightly regulated process that must meet rigid quality assurance criteria. Surprisingly, the majority of breast implant shells are produced individually through a handmade process. Shells are produced through repeated dipping of mandrels into liquid silicone dispersion that is then cured with heat or humidity. After the silicone shell is cured, it may be removed from the mandrel, inspected for irregularities, and measured to ensure precise compliance with thickness standards. Shells are filled with their appropriate silicone gel and sealed with a patch bonded to the surface. Saline-filled devices have a valve incorporated into the shell to allow the filling of the device *in vivo*.

IMPLANT GENERATIONS

When the generation scheme was first proposed, there were essentially three generations of breast implants corresponding to products developed in the 1960s (first generation), 1970s (second generation), and 1980s (third generation). First-generation devices are represented by the original silicone gel implant developed by Cronin and Gerow. This device, the Silastic o, was manufactured by Dow Corning from approximately 1964 to 1968. The Silastic o possessed a thick elastomer shell with seams and a viscous silicone gel. Dow Corning made several modifications to the original device, including changes in the elastomer, creating a seamless shell, and later made the shell much thinner. First-generation devices overall were characterized by thick shells, a thick viscous gel, and Dacron patches, and were produced

¹² Cronin TD, Gerow FJ. (1963), Augmentation mammoplasty: a new "natural feel" prosthesis. In: Transactions of the Third International Congress of Plastic Surgery. Amsterdam, Netherlands, 41.

until the late 1970s. The most commonly reported complication of these devices was a capsular contracture.

Second-generation devices were modified in an attempt to improve the rate of capsular contracture. These devices were designed with a much thinner shell (0.13 mm versus 0.25 mm average thickness) and a less viscous gel, and the Dacron patches were removed.¹¹ The first second-generation device was Dow Corning's Silastic I. It was introduced in 1972, and the manufacturing of the Silastic I overlapped with the production of Silastic 0. Silastic I was produced until 1986. It did not provide any appreciable reduction in the incidence of capsular contracture and reportedly had a higher incidence of rupture that was attributed to the strength of its shell.¹¹

Gel bleed is the diffusion of non-cross-linked silicone oil from the gel across the elastomer shell into the surrounding environment. Although the significance of this phenomenon remains unclear, it stimulated manufacturing changes that are characteristic of third-generation devices. Thicker, reinforced barrier shells characterize third-generation devices.

The thickness and strength improvements were developed out of concern for shell failure with second-generation devices. Shell strength was improved by reinforcing the elastomer composition with silica.⁷ Creating a barrier to gel diffusion with phenyl or trifluoropropyl groups bonded to the shell surface reduced diffusion of non-cross-linked silicone.^{8,9} These properties are retained in current manufacturing processes. It is important to keep in mind that gel bleed is a function of diffusion of silicone oil across the elastomer. The gel bleed does not change based on the viscosity (degree of cohesion of the gel filler).

Saline-filled breast implants were first manufactured in France in 1964, introduced by Arian with the goal of being surgically placed via smaller incisions. These devices had a high failure rate and were discontinued in the early 1970s.¹¹ HeyerSchulte was the first U.S. manufacturer of saline-filled devices. The original devices consisted of thin shells created through a high-temperature vulcanization (HTV). These devices were prone to spontaneous deflation.¹¹ Modifications in shell manufacturing have allowed high success rates that characterize modern saline-filled devices. The current devices are manufactured with thicker, room temperature-vulcanized (RTV) shells.

IMPLANT FILLER

Modifications in the characteristics of the implant filler have also occurred. The most obvious is the change to saline-filled devices during the “implant crisis.” However, significant modifications have occurred in the silicone gel characteristics. The modifications in silicone gel technology are significant enough that many consider the modern era gels to be the fourth implant generation. Since 1992, due to increased demands to improve manufacturing processes, silicone gel implants have been improved devices with slightly thicker shells and more cohesive gel filler than third-generation devices.

Because breast implants are filled with medical-grade silicone, changes in silicone gel chemistry have centered on the cohesive quality of the gel. All silicone gels are cohesive, but the degree of cohesiveness has clinical importance. The degree of cohesiveness is a reflection of the elastic memory or shape retention of the gel. Cohesiveness is produced by the chemical cross-linking of the silicone gel molecules. The degree of cohesiveness imparts important characteristics to the structure and feel of the implant. Second-generation implants produced before 1985 contained minimally cohesive gels. Third- and fourth-generation devices evolved to contain increasingly cohesive gels after 1985, and in 1993, form-stable cohesive gel implants were introduced.

The fifth-generation implants are form-stable cohesive gel implants (e.g., Inamed 410 and Mentor CPG). These are shaped silicone gel devices with enhanced cohesion that offer improved breast shaping and results. These implants are currently undergoing clinical trials in the United States. Silicone gel and saline are the only materials presently available for use as filling material for breast implants in the United States. Soy-filled implants (Trilucent) were marketed for a short time period in Europe but were voluntarily pulled from the market in 2000 by the manufacturer.^{13,14} Trilucent implants contained Trilipid 6, a medical-grade triglyceride fat extracted from soybean oil. This material was studied in animals and not shown to be a safety concern. Approximately 5,000 European women and 50 U.S. women received the implants as part of European and U.S. clinical trials. In the United States, the devices had limited availability through an investigation device exemption. The devices were taken out of clinical use due to the development of

¹³ Barnett MP. (1997), Triglyceride-filled breast implants. *Plast Reconstr Surg*, 99, 2105.

¹⁴ Rizkalla M, Duncan C, Mathews RN. (2001), Trilucent breast implants: a 3-year series. *Br J Plast Surg*, 54, 125.

inflammatory reactions resulting from the leakage of the oil into the surrounding tissues.^{15,16} The reactions resolved with the removal of the devices and did not present long-term health concerns. There are presently no other alternative fillers available through a clinical trial.

SURFACE TEXTURE

Surface texturing of silicone implants was first performed in the late 1960s, with the goal of preventing capsular contracture.¹¹ Polyurethane-coated implants were introduced at this time but not popularized until the 1980s. Polyurethane devices were demonstrated to significantly lower the incidence of contracture, but two main concerns led to their discontinuation. Polyurethane was shown to undergo a degradation process in vivo that produced toluene diamine.^{17,18}

Currently, two different textured silicone elastomer shells are available from Mentor Corporation and Inamed. Mentor was the first to receive FDA approval for its textured shell. The Siltex pattern is created as a negative contact imprint of a texturing foam. This produces many fine nodules on the surface of the shell in a regular distribution. The size of these nodules ranges from 40 to 100 μ m in height and from 70 to 150 μ m in width.¹⁹ Inamed's Biocell surface is produced through a lost salt technique. The implant shell is coated with finely graded salt under light pressure. The salt crystals are subsequently lost through the manufacturing process, leaving many fine depressions on the surface of the shell. These pores range from 600 to 800 μ m in diameter and from 150 to 200 μ m in height.¹⁹

In regard to silicone gel implants, both surface textures have been shown to have benefits in improving the rate of capsular contracture, but this effect has not been realized in association with saline-filled devices, and therefore a universal benefit has not been demonstrated.¹¹ The texturing also provides adhesiveness of the implant to the surrounding tissue. This is an extremely

¹⁵ Choudhary S, Cadier MAM, Cottrell BJ. (2000), Local tissue reactions to oil-based breast implant bleed. *Br J Plast Surg*, 53, 317.

¹⁶ Papanastasiou S, Odili J, Newman P, et al. (2000), Are triglyceride breast implants really biocompatible? *Ann Plast Surg*, 45, 172.

¹⁷ Young, V.L. (2001), 451. Sinclair TM, Kerrigan CL, Buntic R. (1993) Biodegradation of the polyurethane foam covering of breast implants. *Plast Reconstr Surg*, 92, 1003.

¹⁸ Benoit FM. (1993), Degradation of polyurethane foams used in the Meme breast implant. *J Biomed Mater Res*, 27, 1341.

¹⁹ Danino AM, Basmacioglu P, Saito S, et al. (2001), Comparison of the capsular response to the Biocell RTV and Mentor 1600 Siltex breast implant surface texturing: a scanning electron microscopic study. *Plast Reconstr Surg*, 108(7), 2047.

important consideration with shaped devices to prevent rotation and for certain considerations in breast reconstruction. Increased fold flaw failure^{11,20} is a theoretical concern with a nonmobile device. When a device is not allowed to rotate, the natural folds in the elastomer shell do not cycle, and fatigue of the fold and subsequent failure may occur; however, this has not been demonstrated scientifically.

Breast implants are widely used, the cosmetic industry is growing, and there are valuable lessons to learn from countries that have experienced their own regulatory crises. Here are absolutely vital lessons to learn from governments, regulators, and the professions in Europe.²¹

PIP implant has a rupture rate disproportionately higher than equivalent devices and reawakens the debate for a more robust implant registry than a system of voluntary reporting.²²

Recent implant crises have highlighted the need for robust registries. It is important to foster international collaboration from the outset to avoid duplication of efforts and enable the development of effective international early warning systems.²³

Breast augmentation remains one of the most common aesthetic procedures performed worldwide. Silicone implants have undergone an evolution with the availability of both fourth- and fifth-generation devices. Clinicians should strive to provide ongoing data and sound science to continue to improve clinical outcomes in the future.²⁴

Most of the current generation devices have been extensively studied, and are deemed safe and efficacious with reasonable aesthetic outcomes and acceptable morbidity. Nevertheless, the shape, feel, safety, and longevity of these devices remain important areas of continuing research. Healthcare providers should be encouraged to provide ongoing robust scientific data

²⁰ Brandon HJ, Young VL, Jerina KL, et al. (2001), Scanning electron microscopy characterization of surgical instrument damage to breast implants. *Plast Reconstr Surg*;108(1):52.

²¹ Silicone breast implants: lessons from the USA(2012), *The Lancet*, Editorial, Vol 379, issue 9811, P93.

²² Berry MG, et al. (2012), The PIP mammary prosthesis: a product recall study. *J Plast Reconstr Aesthet Surg*. 2 Vol 65, Issue 6, 697–704.

²³ Cooter RD, et al. (2015), International importance of robust breast device registries. *Plast Reconstr Surg*;135(2):337-8.

²⁴ Maxwell G., A. Gabriel, *The Evolution of Breast Implants*. *Plastic and Reconstructive Surgery*. 134(1S):12S–17S, July 2014.

along with new ideas for improvement of the existing devices to enhance results and provide the best possible outcome for the patients.²⁵

In summary, there have been five generations of breast implants since their inception in the early 1960s. These generations are based on characteristics of the shell, characteristics of the filler, shape, and surface configuration. The clinical behavior of a given implant may be based on its respective generation.

CONCLUSION

Breast implant technology has advanced significantly since the mid-1960s. Introduced by Cronin and Gerow in 1962, silicone gel breast implants redefined the modern era of breast augmentation. It is important to keep in mind that those current implants, both silicone, and saline, are significantly better devices than earlier-generation devices. Future advances in implant technology are inevitable. Ongoing trials in the United States include form-stable cohesive gel implants, which comprise the next (fifth) generation of silicone gel implants. Long-term results from Europe and Brazil (Inamed 410 and Mentor CPG) are unparalleled, and early investigation device exemption results in U.S. clinical trials are promising. There is no doubt that implant technology will allow surgeons to use proper patient analysis and technique superior results in the future. The scientific evidence that we have today clearly supports the fact that silicone gel-filled breast implants are safe and effective. These scientific studies are reproducible, and there is no reason to suspect that future studies will not come to the same conclusions.

²⁵ C. Kaoutzianis; J. Winocour; J. Unger; A. Gabriel; P. Maxwell;(2019), The Evolution of Breast Implants, *Seminars in Plastic Surgery*, 33(4), 217–223.

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SAŽETAK

Autori daju širok pregled povijesti silikonskih implantata za dojke punjenih fiziološkom otpinom i silikonskim gelom. U povijesti medicine niti jedna vrsta implantata nije bila toliko pomno i temeljito proučavana kao implantati za dojke. Iako plastični kirurzi prepoznaju i cijene koristi koje pacijentice imaju od ovih vrsta implantata, društvo u cijelosti ne prestaje biti skeptično. Razlozi za to su kompleksni i multifaktorijski, ali čini se da su uveličavani od medija, nekih organizacija, pa čak i lobija odvjetnika. Do 1990., kada su započele polemike oko silikonskih implantata za dojke, tek se osam članaka u indeksiranim časopisima bavilo tom temom, a 1990. do danas objavljeno ih je više od 500. U vrijeme moratorija 1992. plastični kirurzi nisu imali čvrstog uporišta zbog nedostatka znanstvenih dokaza koji bi podržavali stajalište da su silikonski implantati za dojke sigurni i djelotvorni.

Ključne riječi: silikonski implantati za dojku, punila za implantat, tekstura površine