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Silicone for Cosmetic Surgery

Introduction

With increased media attention on beauty and physical perfection, many women in the United States have been undergoing breast augmentations and reconstruction. Silicone implants have been fundamental to the success of many of these operations prior to the 1990s. Silicone is a gel composed of a polymer called polydimethylsiloxane.

Since the first successful silicone implantation was reported in 1950, silicone for medical applications became widely implemented in breast, buttock and facial augmentation.[1] Roughly 1.5 to 1.8 million U.S. women were reported to have obtained breast implants in 1997; 70% of the implants were for augmentation purposes and 30% were for reconstruction.[1] An estimated 10 million U.S. residents have some type of implant made in part from silicone.[1]

Although they were initially thought to cause few complications, silicone implants have drawn many health and safety controversies for some time.[1] Silicone gel-filled implants, as opposed to saline-filled implants, were removed from the market in 1992 as a result of litigation from many women claiming that the implants caused autoimmune and connective-tissue disease.[1] In 2006, the Food and Drug Administration (FDA) re-approved its manufacture, but under strict regulation. The FDA did not find any relation with the claimed diseases.[1]

Currently, silicone is not only used for silicone implants but also for other cosmetics, construction materials, automotive supplies, drugs, food, lubricants and prosthetics.[1] After 60 years, the market has accumulated more than $10 billion in world-

wide sales.[2] Because the versatility and widespread applications of silicone have drawn the attention of chemical industry, numerous chemical engineers have been active in the development of large-scale production.

Chemical Structure

Silica, a common compound in most rocks, is also known as silicon dioxide with chemical formula, SiO_2.[3] *Silicon* (no final "e") is a semi-metallic element not found in nature in its elemental form; it is best known for its use in computer chips. [3] *Silicone* (with a final "e"), on the other hand, is a "semi-inorganic" polymer with desired properties such as high resistance to temperature and high insulation and lubrication.[2]

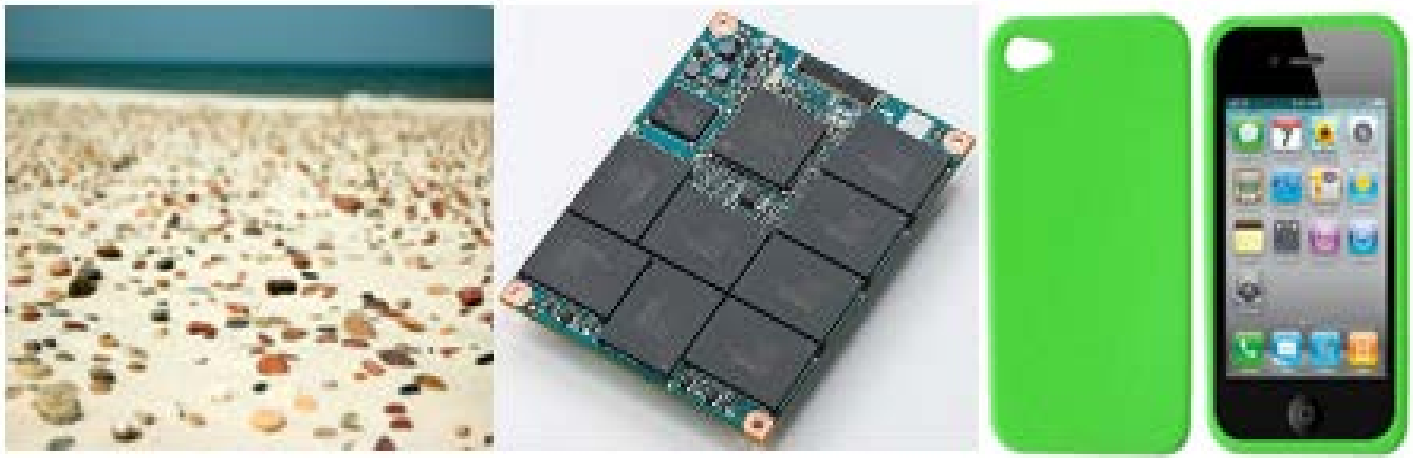

Figure 1: Beach sand contains almost pure crystalline silica[4]; silicon used to make computer chips[5]; silicone used to make an iphone case[6]

Silicone molecules are long polymer chains. A common form consists of a chain of smaller monomer units called dimethylsiloxane[1].[1] Typically, each dimethylsiloxane monomer contains one oxygen atom and two methyl groups[2] attached to the central silicon, as shown in Figure 2. The silicon within the monomer provides inorganic characteristics, while the methyl-group side chains provide organic characteristics.[1] The monomers react with each other, forming a long chain called polydimethylsiloxane or PDMS, commonly called silicone.[1]

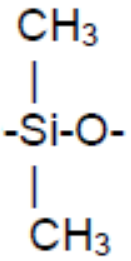

Figure 2: Dimethylsiloxane monomer[7]

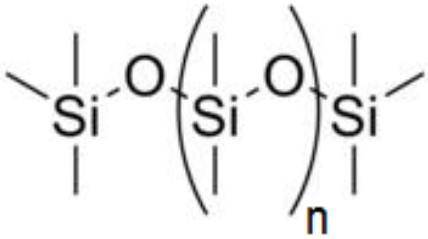

Figure 3: Polydimethylsiloxane (PDMS) [8]; The 'n' and bracket denote a repeat of 'n' monomers

[1] Not all silicone monomer units are dimethylsiloxanes; monomers can have as little as one and up to four oxygens attached to the silicon, and the combination of all types of monomers affect the polymer chain length and structure.[1] For simplicity, only "D Unit" dimethylsiloxanes are discussed here, because they are typically the most abundant polymer chain.

[2] Methyl groups (CH_3-) are three hydrogen atoms attached to a carbon atom

The characteristics of a silicone polymer depend on its chain length that can range from hundreds to thousands of dimethylsiloxane monomer units.[1] The varying lengths can cause PDMS to exist as a solid, liquid or a viscous gel.[1]

An early version of Dow Corning's[3] and other silicone implant manufacturers' breast implants, consists of a silicone-based shell, silicone gel, and additional filler made of amorphous silica.[1] The shell helps to maintain the shape of the implant, and the gel consists of a single giant chain of PDMS, comprising 20% of the implant's mass, swelled by smaller chains, comprising 80%.[1] The large chain network creates the framework for the smaller chains to pack between them, similar to a sponge absorbing water.[1]

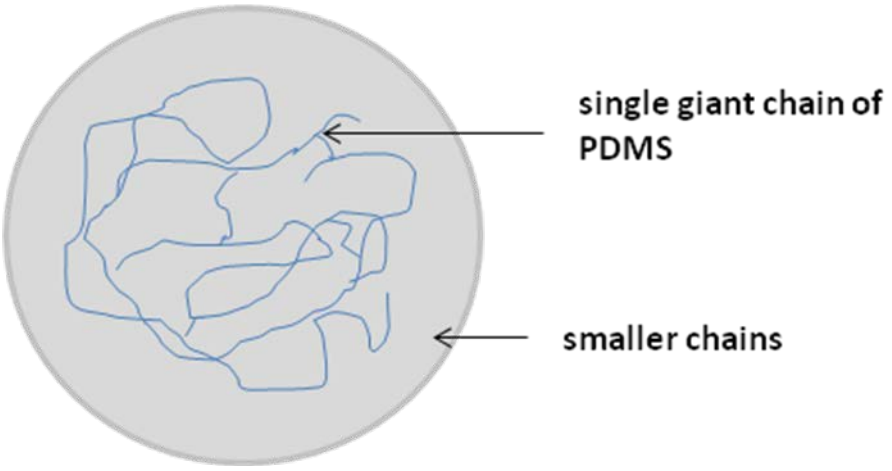

Figure 4: Silicone gel, comprising a single giant chain of PDMS, swollen by smaller chains

Later, silicone implants were modified to prevent ruptures and leakage of silicone gel fluid.[1] Dow Corning and other manufacturers have made implants with shells that are not made of silicone or with additional layers of shells to prevent leakage.[1] Currently there is no such thing as a "standard" silicone breast implant.[1] More than 240 kinds of

[3] In 1962, Dow Corning was the first and largest former manufacturer of silicone gel breast implants. Dow Corning filed for bankruptcy in 1995, emerging from bankruptcy protection in 2004.[9] [10]

U.S.-made silicone breast implants exist, having different compositions of silicone in the fluid and shell.[1]

Brief History

The first discovery of silicone was in the early 1900's from research by an English organic chemist, Frederick Kipping.[11] Around this time, chemists began making new chemical compounds with silicon bound to carbon, that would not react with water.[11] Kipping combined two known compounds, silicon tetrachloride with a Grignard reagent, $MgBr(C_2H_5)$, and performed a series of reactions to form new compounds that would react with water.[11] When treating one of these compounds with water, he obtained silicone, which he originally thought was an unimportant messy material.[11]

Prior to the discovery of silicone, cosmetic breast surgery in the late 1800s was performed using either autogenous tissue, alloplastic[4] implants, or injections.[1] Autogenous-tissue use was a practice in which fat from part of a healthy breast, lipoma from the hip, or a muscle flap was transferred to the breast, but was unsuccessful due to long-term shrinkage of the dermis-fat graft.[1] Many forms of alloplastic implants existed which included the use of glass balls, ground rubber, and polymer sponges.[1] These methods were also unsuccessful because they led to hard, unnatural-looking breasts and other complications.[2]

In 1950, a successful (urethral) silicone implantation was reported. Silicone was used for shunts, joints, tracheotomy tubes, artificial lenses for the eye, artificial heart valves, and facial implants for birth defects.[1] In 1962, Dow Corning Corporation made

[4] nonbiological material such as metal, ceramic, and plastic

the first silicone gel implants for Dr. Thomas Cronin whose research on implantations in dogs showed no signs of toxicity or other complications.[1] A competitive alternative, saline-filled gels, was also released in the market around the same time. These gels had unsatisfactory properties such as high deflation rates[5], leaky valves, a weight up to 8% heavier than that of a comparable-volume gel implant, thin consistency, which was water-like rather than tissue-like, and wrinkling that is visible through the skin.[1] By the early 1970s the Dow-Corning-Cronin-Dacron patched implants had gained popularity of 88% of all implantations.[1]

Safety Concerns

In the past decade, the major concern with the use of silicone breast implants was whether its rupture and subsequent leak of the silicone gel were associated with connective tissue, rheumatic, neurological diseases or cancer.[12] "In 1992, the FDA banned most uses of silicone-gel filled implants because the manufacturers had not proved their safety". [13] In 1993, the FDA had also required saline-implant manufacturers to prove the safety of saline-filled implants.[13] Manufacturers were able to continue saline implant production after demonstrating that rupture in saline implants would simply cause the harmless saltwater solution to spill out into the surrounding tissue.[13] By 1997, the federal Department of Health and Human Services had selected the Institute of Medicine (IOM) to evaluate a number of studies regarding the safety of silicone implants.[13]

[5] term used to describe a ruptured saline implant that has collapsed

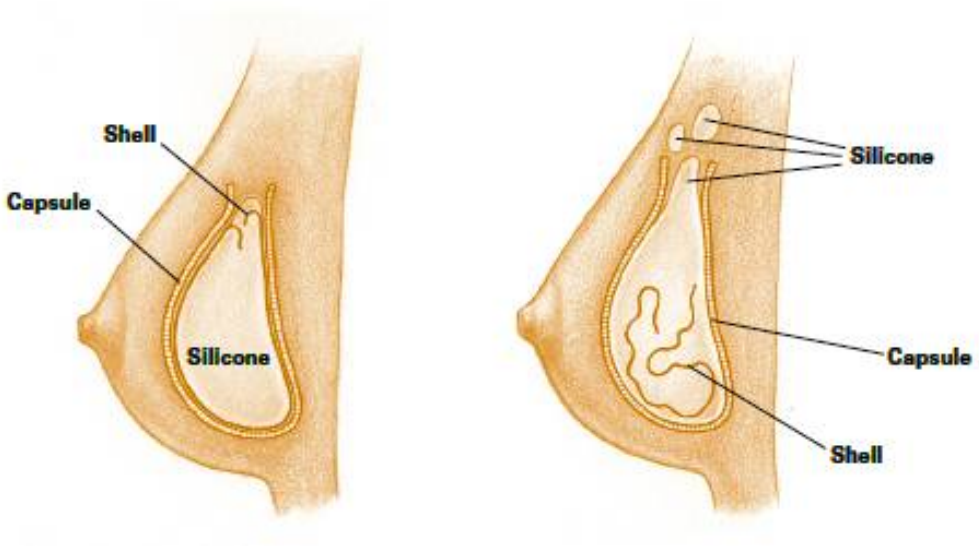

Figure 5: Ruptured silicone breast implant[13]

Following several years of study, the IOM determined that silicone-gel filled breast implants do not cause tumors, autoimmune disease, adverse effects on breast-fed infants, harm to a developing fetus, and weakening of the immune system.[1] IOM stated that the risk of tumors, autoimmune disease, and any adverse effects would be unchanged by the use of silicone implants.[13] The IOM called attention to problems regarding the need to replace implants, local complications, and the need for additional surgery.[13] Local complications included discomfort, rupture and deflation, severe contracture of fibrous tissue around the implant, infections, hematoma (a pooling of clotted blood), pain, and implant displacements.[13] By 2006, the FDA reapproved the manufacture of silicone breast implants to companies that complied with FDA's Good Manufacturing Practices, after concluding that silicone implants had no relation to major diseases.[12]

Research

Following their release in the market in the 1960's, extensive research was done on silicone and saline-filled implants. Until 2008, five generations of silicone implants have emerged.[14] The first generation silicone implants dating from 1963 to 1972, were heavy and had tough shells.[13] Their rupture frequencies were low because of the tough shell but complications from capsular contractor, the buildup of fibrous tissue around the implant, were common. [13] By 1972, manufacturers had made modifications, creating a second generation of implants that had thinner shells and more flexibility.[13] However, these implants had 50 to 95% rupture frequencies after 12 or more years.[13] By the mid 1980s manufacturers developed a third generation of silicone implants with an added barrier coating or modified layer that helped to lower rupture rates.[13]. These implants have a 10% rupture frequency in 5 years.[13] Due to lawsuits in the U.S. that caused many companies to go out of business or declare bankruptcy, the third generation implants have been removed from the American market.[15] Implant manufacturers have continued to develop fourth-generation silicone implants that contain more viscous gel and reduce leakage.[14] Manufacturers have also developed a fifth generation of silicone implants that can allow the construction of anatomically shaped implants.[14]

Saline-filled implants have also been extensively modified since first released in the late 1960s by Heyer Schulte Corporation.[13] "Early saline implants were fragile and heavy, with audible "sloshing", and there was a very high deflation rate up to 76%".[13] The modern generation of saline implants has much lower rates of deflation and contains a more viscous fluid to prevent sloshing.[13]

Although there have been many studies on the safety of silicone-filled breast implants, there has been little study on the effects of saline-filled implants because saline is harmless.[13] Due to the growing popularity of saline implants, it is likely that further studies will be made on their long-term safety.

Silicone Breast-Implant Market

In 2008, the silicone market for medical devices was $875 million in the US.[16] Silicone implants comprised 24% of the market, valued at $210 million.[16]

In 2007, the global breast-implants market, including silicone gel and saline-filled implants, was $430 million and is expected to reach $1,280 million by 2014.[17] Of the $430 million, the silicone breast implants market was $300 million and is expected to reach $950 million by 2014.[17] In contrast, the global saline-filled implant market was $160 million and is expected to reach $420 million by 2014.[17]

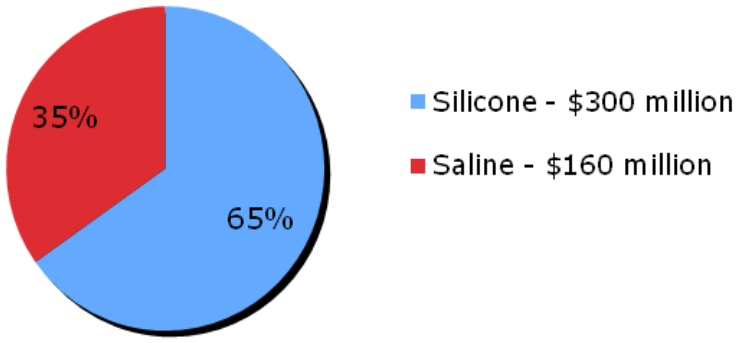

Figure 6: Global Breast-Implant Market in 2007

In the US, the silicone gel and saline-filled implants market was $110 million and $50 million. They are expected to reach $310 and $110 million in 2014.[17]

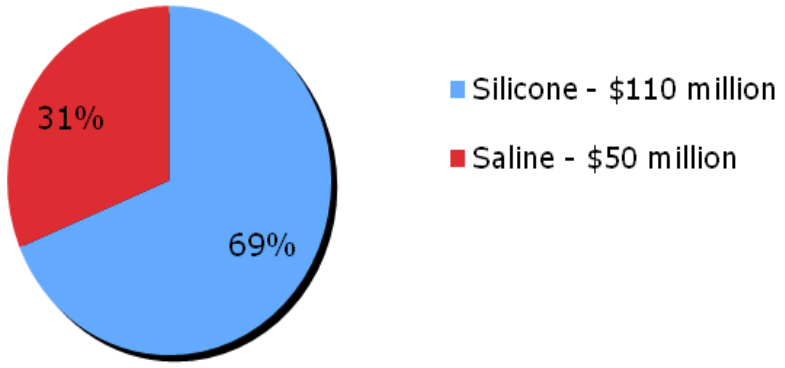

Figure 7: US Breast-Implant Market in 2007

The primary drivers for the market demand are due to the improvements made in the newer generation of breast implants that prevent ruptures and allow for greater variety in shape and size.[17] Currently, the largest producers of silicone breast implants are Allergan Inc, Medicor, Mentor Corporation, and Sientra.[17] Breast augmentation costs from Allergan Inc. amount to roughly $5,000 to $6,000 per patient.[18]

Conclusion

The discovery and development of silicone have been fundamental to the growth of a multi-billion-dollar industry. In the past few decades, there have been some safety concerns with the use of silicone breast implant, causing manufacturing companies to discontinue production in the US. However, years of research by the Institute of

Medicine have shown that its use does not lead to major diseases, allowing for a few companies such as Allergan Inc, Medicor Corptation, and Sientra to continue its manufacture. Due to the re-emergence of silicone breast implants in the US, silicone breast implant augmentations have been gaining more popularity because of increasing public awareness.[19] Currently, there is ongoing research toward developing new models of silicone breast implants with lower rupture rates. Also there are ongoing studies of local complications and the affects of saline implants. With the current generation of both types of implants, women who choose to have either silicone or saline implants may need a second operation for implant replacement after several years because of leakage.

References

[1] S. Bondurant, V. Ernster, R. Herdman (2000). *Safety of Silicone Breast Implants*. National Academy Press. p. 1-77.
[2] S. J. Clarson, J. J. Fitzgerald, M.J. Owen, S. D. Smith, M. E. Van Dyke (2007). *Science and Technology of Silicones and Silicone-Modified Materials*. Oxford University Press. p. 2-7.
[3] M. Fumento (1996). *Silicone Breast Implants: Why has Science Been Ignored?* American Council on Science and Health p. 1-5.
[4] Retrieved March 13, 2011, from http://www.essence-of-mineral-makeup.com/silica.html
[5] Retrieved March 13, 2011, from http://www.fastcompany.com/blog/kit-eaton/technomix/western-digital-spends-65-million-get-ssd-market-last
[6] Retrieved March 13, 2011, from http://www.discoveryelectronics.co.uk/index.php?main_page=product_info&cPath=239_246&products_id=1239
[7] A. J. O'Lenick, Jr. (1999) Basic Silicone Chemistry – A Review. *Silicone Spectator January 2009*. Retrieved from http://www.siliconespectator.com/articles/Silicone_Spectator_January_2009.pdf
[8] Retrieved March 20, 2011 from http://www.fluorous.com/journal/?p=86
[9] B. J. Feder. (May 16, 1995) Dow Corning in Bankruptcy Over Lawsuits. *The New York Times*. Retrieved April 2, 2011 from http://www.nytimes.com/1995/05/16/business/dow-corning-in-bankruptcy-over-lawsuits.html
[10] (June 1, 2004) Dow Corning emerges from bankruptcy. *USA Today*. Retrieved April 2, 2011 from http://www.usatoday.com/money/industries/manufacturing/2004-06-01-dow-corning_x.htm
[11] Heat and Chemical Resistant Silicone Rubber Silicones 2. Organic Silicon Chemistry. *Chem Cases.* Retrieved April 2, 2011 from http://www.chemcases.com/silicon/sil2cone.htm
[12] (November 17, 2006) FDA Approves Silicone Gel-Filled Breast Implants After In-Depth Evaluation Agency Requiring 10 Years of Patiend Follow-Up. *U.S. Food and Drug Administration.* Retrieved April 10, 2011 from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108790.htm
[13] S. Bondurant, V. L. Ernster, M. Grigg, R. Herdman (2000). *Information for Women about the Safety of Silicone Breast Implants.* National Academy Press. p. 2-30.
[14] M.E. Freeman, A. J. L. Gear, C. McWhorter, S. J. Pacella, W. G. Stevens, D. A. Stoker, M. J. Tenebaum. (November, 2008) Clinical Experience With a Fourth-Generation Textured Silicone Gel Breast Implant: A Review of 1012 Mentor MemoryGel Breast Implants. *Cirugia Plastica Marina.* Retrieved April 24, 2011 from http://cirugiaplasticamarina.com/pub-memorygel.pdf
[15] (November 2007) 7 Litigation involving pharmaceutical, medical device, and vaccine manufacturers. *RDS Business Suite.* Retrieved April 24, 2011 from http://rdsinc.com
[16] (July, 2009) World Silicone Market. *Acmite Market Intelligence.* Retrieved April 27, 2011 from http://www.acmite.com/market-reports/chemicals/world-silicone-market.html

[17] (September 9, 2009) Pastic surgery biomaterials. *RDS Business Suite.* Retrieved April 27, 2011 from http://rdsinc.com
[18] Breast Augmentation Costs. *NAFICY Plastic Surgery & Rejuvenation Center*. Retrieved April 27, 2011 from http://www.breastaugmentation-seattle.com/html/more_info_surgery_cost.php
[19] (January 11, 2011) Three Years After Returning to Market Silicone Implants Are Preferred. *Plastic Surgeons News*. Retrieved April 27, 2011 from http://www.plasticsurgeonsnews.com/2011/01/three-years-after-returning-to-market-silicone-implants-are-preferred/