

# The Development of Silicone Breast Implants for Use in Breast Augmentation Surgeries in the United States

In the 1960s, two plastic surgeons from the United States, Thomas Dillon Cronin and Frank Judson Gerow, collaborated with the Dow Corning Corporation, which specialized in silicone products, to create the first silicone breast implant. Surgeons used the implant, named the Cronin-Gerow implant, to improve the look of a woman's breasts, by correcting for asymmetry, augmenting the size, or creating a more uplifted profile. Surgeons began widely using the breast implant almost immediately after it reached the US market in 1964, and breast augmentation quickly became one of the most popular cosmetic surgeries in the country. The creation of a silicone breast implant not only established a new branch of cosmetic surgery, but it also enabled women with breast cancer to receive reconstructions to improve their aesthetic appearance after cancer treatment and removal of the cancerous breast tissues.

Prior to the creation of silicone breast implants, women had used a variety of materials in the attempt to augment their breasts. In the early twentieth century, surgeons implanted objects into women's breasts such as glass balls, ivory, ground rubber, ox cartilage, sponges, and tapes to enhance the look of the breasts. Women also injected their breasts with materials such as milk, silicone, and paraffin, a petroleum product. Globally, after World War II, around 1945, prostitutes in Japan began injecting their breasts with industrial-grade liquid silicone to better suit the tastes of American soldiers who still occupied the country. Although successful initially in altering the shape of the breast, the silicone often caused the flesh of the breast to rot and grow tumors. Physicians referred to that condition as silicone rot. Most of surgeons' early efforts at augmenting breasts had unsafe side effects for their patients, ranging from mild infections to severe organ damage. Surgeons continued attempting to augment women's breasts into the second half of the 1960s, when Cronin and Gerow began working on the silicone breast implant.

Cronin learned of silicone gel in 1961 when he attended a plastic surgery conference in New Orleans, Louisiana. It was there he learned of the Dow Corning Corporation. Cronin learned that the company had created a product that had varying viscosities, did not react with the body, and could be used as an implantable prosthesis, or artificial body part. Thomas Biggs, one of Cronin's former surgical residents at Baylor University in Waco, Texas, recalled in an interview that, around the same time as the conference, Cronin's colleague, Gerow, visited a blood bank and saw that instead of glass bottles, blood was being stored in plastic bags. After handling one of the blood bags, Gerow noticed that the sensation strongly resembled a woman's breast. Gerow communicated his idea of an implant as a bag filled with malleable material to Cronin, who then took the concept to physician Silas Braley, then head of Dow Corning's medical research division.

Cronin and Gerow then collaborated with Dow Corning to create the Cronin-Gerow implant, which was a silicone rubber envelope, shaped like a teardrop, and filled with viscous silicone gel. When designing the implant, the creators placed a polyester patch on the backside of the implant for better adherence to a woman's chest cavity. In early 1962, Cronin and Gerow developed a biscuit sized prototype for the implant and tested it on a dog named Esmeralda. Surgical resident Biggs watched over the dog during recovery. He stated that the implant had no adverse effects and would have stayed in the dog longer than a few weeks had she not started chewing at her stitches.

After determining that their implant was safe for a dog, Cronin and Gerow proceeded to look for women to try out the implant. While most products implanted in the human body in the US require approval from the Food and Drug Administration, or the FDA, Cronin and Gerow's breast implant did not require similar approval because it was not classified as a medical device, allowing Cronin

and Gerow to test it directly on human patients. Their first round of patients included twelve women. In 1962, they found their first patient, named Timmie Jean Lindsey, in Houston, Texas. She agreed to receive the surgery with the stipulation that the doctors would also pin back her ears.

After completing the study with the initial twelve women, Cronin and Gerow presented their findings in a 1963 paper titled, "Augmentation Mammoplasty: A New "Natural Feel" Prosthesis." They introduced a natural-feeling implant to the International Society of Plastic Surgeons in Washington D.C. in 1963. Biggs, Cronin's resident, recalled that the room was full of people. The creation of the silicone breast implant came at a time in the US when popular culture had many references to large breasts. In the 1950s, Playboy magazine and Barbie had just launched, and the busty silhouettes of Marilyn Monroe and Jane Russell were displayed in media as ideal women, presenting curvier figures and augmented breasts as desirable traits.

With the backing of the Dow Corning Corporation, Cronin filed a patent for the implant in August 1963, and on 27 December 1966, the device's patent was granted and filed as a surgically implantable human breast prosthesis. In 1964, Dow Corning started marketing the invention to the public. Biggs said that the implants could not be manufactured quickly enough due to high demand. By the early 1970s, the Cronin-Gerow implant accounted for nearly eighty-eight percent of all implants sold. Breast augmentation also became a popular surgery, generating over 500 million US dollars in revenue by 1992 in the United States alone, with around two million women having undergone the surgery up to that year.

In 1972, implant manufacturers introduced the second generation of breast implants to the market. The first implants were overly firm, so manufacturers made the new implants with thinner shells and low cohesion silicone. Those changes improved the shape, feel, and appearance of silicone breast implants. However, the implants were also less durable and sometimes ruptured, causing gel leakage and capsular contracture, or a hardening of the scar tissue around a woman's implant. In 1972, William Pangman, one of the inventors at the implant manufacturer, Mentor, created a foam-coated implant to reduce incidences of capsular contracture by causing an inflammatory reaction that prevented the formation of scar tissue capsule around the implant. Complications associated with those types of implants appeared later in class action lawsuits in the 1990s.

The next development was in 1985, when Hilton Becker, a plastic surgeon in Boca Raton, Florida, invented the double lumen implant, which was a saline implant encased within a silicone implant. The benefit of the two-layer device was to have both the aesthetic of the silicone implant, while also being able to postoperatively adjust the volume of the saline implant by adding or removing saline from the inner shell with a filling tube. However, the more complex construction of double lumen implants caused higher failure rates than the traditionally-designed implants. Because of that, physicians later stopped using double lumen implants in augmentation surgeries. However, due to their expandable nature, the double lumen implants found success in reconstruction surgery in cases where women had their breasts surgically removed due to cancer.

In the 1980s, implant companies created the next generation of implants which had rubber-coated shells that prevented rupture and thicker filler gels that were more cohesive. Rupture rates decreased among women, but the new implants were firmer and required more breast tissue to cover them for a natural look and feel. American culture was also experiencing a shift towards more athletic figures, which resulted in a return to more natural implant shapes during the time, with implants made to be more teardrop-shaped as opposed to perfect semicircles. The implants also featured a new textured surface to the breast implant. The textured implants prevented rotation of the prosthesis in the implant pocket due to added friction but were more expensive than the older, smoother option, which was more likely to lead to capsular contracture, or the hardening of scar tissue surrounding the implant. Insurance companies in the United States generally did not cover breast augmentations as they were considered elective procedures. However, in certain cases, such as reconstruction after breasts were removed due to cancer, insurance policies had exceptions and would cover some or all of the surgical costs. In response to rising safety concerns from women with implants, in 1988, the FDA changed the silicone implant's classification from Class II, to Class III, meaning that the devices needed approval from the FDA that they were medically safe before companies sold them to consumers.

Implant-producing companies released the subsequent generation of implants in the early 1990s, which are still used as of 2019. Implant manufacturers began making implants with highly cohesive gel, more similar to solid than liquid, with a consistency that manufacturers related to that of a gummy bear. Doctors preferred the higher cohesiveness of the gel implants because they had a natural, but firm feel, and ensured that the silicone would not leak or spread in the body extensively if the implant ruptured. The studies, "Experience with Anatomical Soft Cohesive Silicone Gel Prosthesis in Cosmetic and Reconstructive Breast Implant Surgery," published in 2004, and, "Cohesive Silicone Gel Breast Implants in Aesthetic and Reconstructive Breast Surgery," published in 2005, reported low rates of capsular contracture and shell rupture, and higher rates of improved medical-safety and technical success than that of early-generation breast implants.

In the 1990s, thousands of women who had previously undergone breast augmentation with silicone implants began experiencing adverse effects and sued the Dow Corning Corporation and other implant manufacturers in a series of class action lawsuits. By the end of 1993, over 12,000 women had filed claims. The women argued that the implants had caused a variety of complications including implant rupture and diseases of the immune system such as arthritis and lupus, which cause inflammation in different parts of the body. Dow Corning stated that while rupture and surgical complications were possible, silicone itself did not cause disease. In January of 1992, the FDA called a temporary ban on the supply and use of silicone implants, stating that implant companies never supplied sufficient evidence proving the safety of the implants, and that the devices needed to be reviewed. In April of that same year, the FDA lifted the ban, but only allowed the use of silicone implants in cases of reconstruction. Dow Corning, the world's largest implant manufacturer at the time, controlling thirty five percent of the market, withdrew from the implant industry on 19 March 1992. Dow Corning and other implant companies reached a 4.25 billion US dollar settlement with the claimants in 1994, but Dow Corning later also filed for bankruptcy in 1995 due to the number of lawsuits the company was facing.

Since the creation of the silicone breast implant, the number of women undergoing breast augmentation has increased from 101,176 women annually in 1997 to over 300,000 women annually in 2017, and is projected to continue increasing. Studies of women with augmented breasts have generally shown that after surgery, women have reported that they have an improved quality of life, that they feel more feminine, and that they experience greater motivation for daily activities. The option of having breast reconstruction also helps women recovering from breast cancer surgeries regain positive body image and decrease depression rates. With the rise in women with augmented breasts also came an alleged ailment called Breast Implant Illness, where women believe the implants are causing autoimmune and connective tissue disorders. While some studies have been conducted regarding the connection between breast augmentation and autoimmune diseases, no conclusive results have been found as of 2019.

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