The Breast Implant Journey:

Where are we? How did we get here?

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Breast augmentation surgery changes the shape and or size of the female breast. It is a relatively straightforward, minimally invasive procedure, which can be done by a board-certified plastic surgeon for cosmetic purposes, or in conjunction with or following breast cancer procedures to restore the shape and size of the breast. The first mammary prostheses were implanted in 1962. Although well-received and very popular, it has not been without controversy. Implant have been linked to silicone leakage, cancer, and immune diseases. There have been cases with huge awards, company bankruptcy, product bans, and product reissue. This article will offer the legal nurse consultant insight into the history of breast implants and breast implant litigation, as well as illustrating the application of legal principles such as mass tort law and Daubert's principle in these cases.

INTRODUCTION

Breast augmentation surgery changes the shape and or size of the female breast. It is a relatively straightforward, minimally invasive procedure, done either in the hospital setting or an outpatient facility by a board-certified plastic surgeon. Women undergo breast surgery either for cosmetic or reconstructive reasons (after mastectomy). Drs. Cronin and Gerow of Houston, Texas, designed the first prosthesis in conjunction with Dow Corning. It was implanted in 1962. The new implants were well received by the plastic surgery community and the general population for reconstruction following mastectomy, as well as cosmetic breast enlargement. However,

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since then, there has been much controversy regarding their safety. They have been linked to silicone leakage, cancer, and immune diseases. Despite this, in 2018, there were 329,614 breast augmentations performed, according to the American Society for Aesthetic Plastic Surgery (ASAPS) (ASAPS, 2018).

SILICONE

Silicone was discovered in the early 1900s by a British chemist, Fredericks S. Kippling, as a result of combining silicon and ketone. A US scientist, J. Franklin Hyde, the first organic chemist at Corning Glass, picked up Mr. Kippling's work in the 1930s. In 1943, Dow Chemical and Corning Glass merged to form Dow Corning Corporation to research and make products for the American public. Products made included home insulation and furniture polish.

These products involved direct skin contact or inhalation exposure to silicone components, so there were concerns about safety. V.K. Ross and associates published a study in 1948 that demonstrated the products were well tolerated after subcutaneous or intraperitoneal ingestion (Fisher 2015). Dow Corning then began to focus on the medical applications of silicone Dow Corning. In 1959 the Center for Aid to Medical Research was established to assist in the discovery of new applications for silicone. Within three years, products were developed that included silicone tubings, intravascular catheters, and lubrication for syringes and needles. Requests outpaced supply (Fischer 2015). As a result, in 1962, Dow Corning formed its Medical Products Division.

DEVELOPMENT

In the 1950s, breasts were augmented using sponges made of plastic polymers. Over time they hardened, but few women had them removed. Dr. Thomas Cronin, Baylor University, began to explore other options. He joined with his Dr. Frank Gerow and began to design a new mammary device made of gel and fixed in place with a dacron patch. They implanted the first Dow Corning breast implants for augmentation in March 1962 (Fischer 2015). They presented at The International Congress of Plastic Surgeons in Washington DC, and at the April 1963 Plastic Surgeons meeting in Mexico City and were exceptionally well received. Dow Corning readied the implants for commercial distribution. Dr. Cronin wrote instructions for the surgeons and included them with the implants, which became the first product information sheet (Fisher 2015). He updated these product information sheets continually, based on his experiences and feedback from other surgeons.

Cronin listed three categories of risk for breast implant surgery:

- Those associated with any surgical procedure such as pain, bleeding, postoperative infection, and permanent scar.
- Increased risk of infection due to the implantation of foreign material.
- Those specific to a silicone breast implant such as dissatisfaction, asymmetry, diminished nipple sensation, and a fibrotic reaction on the surface of the implant.

During the 1970s, the demand for breast implant surgery grew. The device was continually improved, and soon they were also used for breast reconstruction, following mastectomy. Some women complained of unnaturally firm breasts after surgery, which was called capsular contraction. This was thought to be gel leakage, called "gel bleed" (Fischer 2015). Softer saline implants subsequently came on the market.

THE ROLE OF THE FEDERAL DRUG ADMINISTRATION

The Federal Drug Administration began in 1862 and was part of the Department of Agriculture. In 1901 it became the Bureau of Chemistry, and in 1927 it was the United States Food, Drug, and Insecticide Administration. In 1930, the name was shortened to the U.S. Food and Drug Administration (FDA), which is how we refer to it today.

The FDA's mission is to "protect and advance public health by helping to speed innovations that provide our nation with safe and effective medical products and that keep our food safe and reduce harm from all regulated tobacco products (FDA website, FDA History)."

The early days of the FDA was a time of many new medical advancements. Most, such as cardiac defibrillators and implantable pacemakers, were legitimate, but there were fraudulent inventions, such as the cure for sterility via electrical coils *(For many fraudulent devices, see also JLNC Spring 2018, Walker J, FDA history, medical devices, and searching the medical device database…Ed. note)* A citizens' advisory committee was appointed to examine the claims of all medical devices. As

a result, the Medical Device Amendments Act was passed in 1976. This act ensured the review and reclassification of every medical device that was currently in use. Advisory committees, such as The General and Plastics Surgery Devices Panel devised three classifications of devices:

- Class I: Devices used external to the body, such as surgical instruments and wound dressings that require limited control.
- Class II: Devices, such as sutures, with a function that requires performance standards.
- Class III: Devices with potential for hazard, including all intended for surgical implantation. New products always required premarket approval (PMA), and as a result of this classification, some established products, despite their long record in the marketplace, needed premarket approval. (Fisher 2015)

Initially, breast implants were considered Class II due to their longstanding use and low complication rate. However, in 1982, the FDA conducted a full review of all models of silicone gel devices and announced breast implants were now assigned to class III. However, it wasn't until 1988 that the FDA required manufacturers to file a premarket approval application (PMA).

In November 1991, the FDA continued conducting more hearings to ensure the implant manufacturers provided the required documentation for product safety; they concluded the manufacturing data were not convincing. On January 6, 1992, the FDA issued a product recall; plastic surgeons and manufacturers expressed their unhappiness and disagreement. More hearings and discussion followed, and in April 1992, the moratorium was lifted, but with severe restrictions: only saline implants and mastectomy patients were included. To receive implants, breast augmentation patients had to agree to be part of a research study. It took six more years for the final approval of saline implants. Approval for silicone implants came in 2006 with the added requirement for extensive post-approval studies, due to limited data on long term outcomes.

LITIGATION ERA

The first lawsuit, *Corley v. Dow Corning* https://www.leagle.com/decision/1978710570sw2d1401671, changed the litigation landscape. Norma Corley suffered from breast infections that she claimed were caused by her implants. Until this case, Dow Corning had never lost a lawsuit, and they refused to settle. She was awarded $170,000. This case was noteworthy as it was to become the first case in a mass tort action against Dow Corning.

In the second case, *Maria Stern v. Dow Corning,* 1982, Ms. Stern alleged that she sustained a ruptured breast implant. Maria Stern also had chronic fatigue and joint pains, which she attributed to silicone spreading throughout her body. She had no medical facts or diagnosis to back up her theory. She also claimed she underwent the procedure without proper informed consent. She was the first woman to allege that her implants caused systemic autoimmune disease.

During the discovery phase, a law clerk found documents that showed Dow Corning withheld evidence regarding the potential hazards of silicone (Connelly, p 40) The materials included letters from plastic surgeons concerning implant rupture and reactions to the silicone. He also found a pamphlet that Dow Corning gave to patients about their surgery, "Facts you should know about your new look" (Connelly, p 41). However, it included no information about implant rupture or capsular contraction; or that potential silicone leakage could cause enlarged lymph nodes, scar formation, or inflammation. This lack of information substantiated her claim of lack of informed consent. Stern's legal team found a physician to back up her medical claims without scientific proof or medical diagnosis. She was awarded $211,000 for pain and suffering, and $1.5 million in punitive damages.

Perhaps most controversial during this time was Connie Chung's 20/20 TV broadcast in December 1990 about the safety of silicone implants. She focused on the danger of breast implants and, at the end of the segment, showed pictures of disfigured women. The result of this broadcast and ensuing publicity was nationwide patient panic.

The third case, *Hopkins vs. Dow Corning,* was in 1991 (http://www.casetext.com/case/hopkins-v-dow-corning-corp) Mary Ann Hopkins received breast implants for reconstruction following bilateral mastectomies. She began to suffer from chronic fatigue and was diagnosed with mixed connective tissue disorder. Using the same documents as the Stern case, the suit contended that the disease was caused by gel leakage. Again, there was no evidence linking the disease to the implants. Dow Corning stood by their package inserts. She was awarded $840,000 for pain and suffering, and $6.5 Million in punitive damages.

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ing; a month later, there were 3,558 (Fischer, p198). Dow Corning feared mass tort litigation under the federal rules of civil procedure, revision 1938, Rule 23 (Legal Information, n.d.). This rule allowed the consolidation of closely related cases, which are then registered by the judge as a class. A lead counsel and one plaintiff is appointed who represents the entire class of litigants. The outcome of the trial applies to every member of the class (Fischer 2015). The breast implant class was registered for discovery purposes only. In this way, the potential for large plaintiff verdicts was protected.

Pamela Johnson v. Bristol-Myers Squibb in 1992 was notable for being the first suit after the moratorium. It was settled for $5 million compensatory awards and $20 million punitive damages. Two Dow Corning victories followed after the expert witnesses were discredited.

In another case, Judge Robert Jones applied a new principle, "Daubert," which was a result of Daubert v Merrill Pharmaceuticals 1993. (Fischer 2015) It stipulated the judge was responsible for deciding the admissibility of expert scientific testimony. (Dickinson 2020). These victories changed the course of litigation. Previously, lawyers were after the most significant settlements possible. Now they reversed course. They realized this process could lead to company bankruptcy.

In 1993, a global settlement was reached by implant manufacturers Dow Corning, Bristol Meyers Squibb, and Baxter Healthcare. They jointly set aside $4.75 billion to settle claims over the next 30 years. Dow Corning was responsible for $2 million. (Fischer 2015) There were 480,000 claimants. A judge determined the settlement underfunded by at least 3 billion dollars. Dow Corning was unable to meet these demands, and on May 16, 1995, they filed for bankruptcy. (New York Times, Feder)

During the 1990s, evidence mounted that silicone was not the cause of any disease. The New England Journal of Medicine, the American College of Rheumatology, the American Academy of Neurology all supported this conclusion. The Journal of The National Cancer Institute concluded that breast implants did not cause breast cancer. The Institute of Medicine issued a report in June 1999 which declared implants did not cause immune disease. (Scheiter,2010) Litigation slowed down. Significant awards were few and far between.

BREAST IMPLANT-ASSOCIATED – ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL)

In spite of all the litigation, settlements, implant moratorium, product research, and assurances that silicone was not the cause of any disease, there are still women who complain of immunological illness related to breast implants. This phenomenon is referred to as Breast Implant Illness. Anaplastic large cell lymphoma (ALCL) has also been linked to textured breast implants and is called breast implant-associated anaplastic large cell lymphoma. (BIA-ALCL) The World Health Organization designated it as a T cell, Non-Hodgkin's lymphoma (FDA Questions and Answers) During the normal healing process, a capsule forms around the implant. However, some patients develop ALCL in and around the tissue capsule, approximately 7-10 years after surgery. Symptoms include breast tenderness, pain, skin rash over the breast area, and a fluid collection around the breast.

Diagnosis is made by physical examination and direct tissue pathology examination and immunological tissue fluid assay. The fluid is tested for CD30 immune staining. CD30IHC

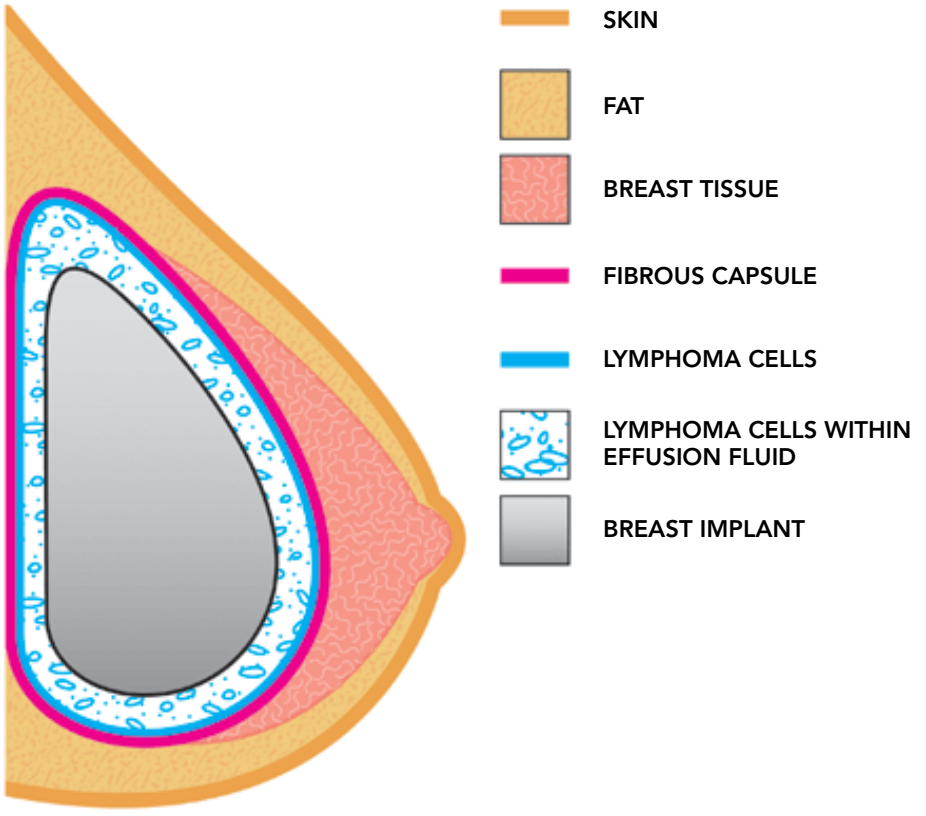

Figure 1. BIA-ALCL. https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl

Anaplastic large cell lymphoma is called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

testing is required to confirm or rule out BIA-ALCL (ASPS, BIA-ALCL, 2019). If caught in the early stages, BIL-ALCL can be treated successfully with surgery to remove the implant and capsule. If not found in the early stages, it spreads throughout the body. In these cases, chemotherapy and radiation may be necessary. If left untreated, it can be fatal. The risk of developing BIL-ALCL is 1:2,207, and 1:86,029 for women with textured implants (ASPS, BIA-ALCL, 2019).

Although researchers have been unable to explain the link between breast implants and ALCL adequately, the FDA continues to study it. In March 2019, a conference was held to explore renewed safety concerns. (Grady, 2019). In July 2019, the FDA became aware of five hundred seventy-three cases worldwide of BIA-ALCL, 481 of which were related to Allergan implants. There were thirteen fatal cases, twelve of which were Allergan implants. Further research identified a sixfold higher risk of BIA-ALCL with the Allergan Biocell implant with a textured outer shell. The FDA issued a recall for Allergan Biocell textured breast implants and tissue expanders (FDA Safety Communication July 2019).

NEW DEVELOPMENTS

In the U.S., a nationwide lawsuit against Allergan was filed in August 2019. Lawsuits have also been filed in Canada and Korea. As of this writing (November 2019), the Allergan textured breast implant is still off the market.

The FDA is coordinating two breast implant registries to learn more about how implants perform and interact in the body. Breast implants are packaged with paperwork that is filled out at the time of surgery to facilitate device registration and follow up. Confirmed cases of BIA-ALCL can be reported to the FDA via the Profile Registry by the physician. This registry is a joint effort of the FDA and ASPS/PSF. (ASPS-BIA-ALCL, 2019).

On October 7, 2019, The American Society for Aesthetic Surgery, with support from Allergan, announced the development of a patient app (to be available in 2020) to facilitate the communication between patient, surgeon, manufacturer, and FDA by enabling messaging between physician and patient, giving procedure information, surveys for data collection, post-procedure outcome, and safety alerts.

The Medical Device Safety Act 2019 H.R. 2669 has been re-introduced with the hope of restoring an injured consumer's right to sue regarding Class III medical devices. Currently, device manufacturers are shielded from liability, because in *Riegel v Medtronic, Inc.*, 2008, the Supreme Court ruled that the federal preemption clause of the Food, Drug, and Cosmetic act limits state lawsuits in states against medical devices approved under the FDA's PMA process for Class III devices. The passage of the 2019 revised bill is important for consumers by ensuring manufacturers will maintain the safety of their products even after the final approval process.

SUMMARY /INDICATIONS FOR THE LNC

Breast augmentation and breast reconstruction following mastectomy are viable surgical options for any women who are dissatisfied with the size and or shape of their breasts or who have undergone cancer or other disfiguring surgery or injury. Today, although the risk is small, scientific evidence is available to support claims of illness after breast implant surgery.

Legal nurse consultants with their unique medical/legal skill set, can help a patient if she has a problem with her breast implant, seek referral for legal guidance, or simply want more information about BIA/ALCL.

Review the record carefully for informed consent, a vital and critical part of the surgical process. In both The American

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Medical Association (AMA) and the American Nurses Association (ANA) support the promotion of patient rights and self- determination (Dickensen, 2020). In both *Stern* (1982) and *Hopkins* (1991), lack of informed surgical consent affected case outcome. A frank discussion and documentation of inherent risks, benefits, and alternatives, should have been a part of the preoperative exam and interview.

Look for completed patient registry paperwork in the chart. www.thepsf.org/NBIR. All breast implants are packaged with registry forms to be filled out by the OR circulating nurse. Patients also receive an implant identification card.

If the patient has health concerns, all medical encounters, preoperative and postoperative, must be documented. *Stern* (1982) and *Hopkins* (1991) were notable because neither had medical proof or diagnosis to back up their claims.

Ask the patient if she had CD30 medical staining testing to rule out BIA-ALCL, and be sure that all testing and results are part of the chart. Confirmed cases of BIA-ALCL should be reported to the FDA via the patient profile registry. www.thepsf.org/profile

Breast implant litigation over the years involved important principles, Daubert, mass tort law, and informed consent. Although it is beyond the scope of this article to fully describe these, the LNC should have a good working knowledge about them.

BIA-ALCL can be a life-threatening disease if not diagnosed appropriately and timely. Anyone with questions about her implant and the risk of BIA-ALCL should contact her plastic surgeon, the American Society for Aesthetic Plastic Surgery (ASAPS), or American Society of Plastic Surgeons (ASPS) for more information.

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