

## Reflections on Breast Implants and Explantation

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It is hard to know where to begin about breast implants.

I started medical school out in California at Stanford. The school was built on an old dairy farm full of rolling green hills dotted with live oaks and streets lined with palm trees, but behind this bucolic setting was a vibrant plastic surgery department. There were all sorts of new and exciting developments in plastic surgery in the 1970s. Stanford's surgeons were busy, busy, busy. They were among the first to use an operating microscope to reattach fingers that had been severed, and later to cut off a toe and move it up to the hand to fashion a thumb. And they were among the first to work on transgender reorientation surgery, where they were also cutting off parts to repurpose them!

Bell bottoms, free love and hippies of the sixties in San Francisco had also given way to a more troubled side. Before we knew about AIDs, we saw young men with strange, heretofore rare symptoms, now popping up on many young men: purple skin lesions called Kaposi Sarcoma. The AIDS virus was discovered as the cause for these strange purple spots in 1982. And we saw the first topless strip club. The Condor Club featured Carol Doda, who went from her modest 34Ds to her infamous twin peak 44 triple Ds. She achieved this dubious triumph through the miracle of silicone injections. And the advertisement went something like, "See her get bigger before your eyes." And she truly did get bustier through monthly injections of silicone directly into her breasts.

More generally, breast implants that were filled with silicone gel were introduced in 1963. Breast implants filled with salt water were introduced two years later in 1965. This was a decade before the federal Food and Drug Administration began to regulate implant devices, under the Medical Devices Act of 1976. So when I started in medicine in 1975 implants were kind of a curious and relatively new development. They seemed to offer women (or men) more options. You could enhance a bustline for purely cosmetic reasons, or use implants for breast cancer reconstruction. Breast implants seemed to fill a need, and they were quickly and eagerly accepted by both doctors and their patients.

Sales representatives for the implant manufacturers popped up in doctors' offices. Without a lot of research to back up their claims, the reps routinely bragged that the implants were so strong and sturdy that you could run a VW bug over them and they wouldn't break! The breast implants would probably "last at least 5000 years," and be like the Egyptian mummies with perfectly preserved breasts. Women could rest assured that their little breast implants would be sitting pretty, sparkling like new thousands of years in the future because they were made of inert, but common materials found in the earth's crust, silica. So the reasoning went, more like a rock. Silica does make up about 15% of the earth's crust and is found not only in quartz, but toothpaste. Like a rock, it should endure. Unfortunately estimates of how long the implants lasted have steadily decreased since their initial introduction. Projections basically went from 5000 years, to perhaps 50 years, to, oh well, maybe 15!

The manufacturers did not think deeply about potential risks or side effects, either, and there were simply no efforts for any long-term follow-up studies. Since the FDA's control over implantable medical devices came in 1976, and implants were already available, they were unfortunately "grand fathered" as safe. Any downsides and potential health risks were quietly buried in internal memos by the manufacturers. Perhaps they reasoned that the what-they-don't-know-won't-hurt-them philosophy would protect them. They buried their heads in the sand. Which is also made out of silicon dioxide.

I started practice in Denver in 1988. As a new surgeon, I don't think I was as vested in breast implants as some of my more established colleagues, so when a few women asked me to remove their breast implants along with their surrounding scar tissue, I agreed. I've always felt that it was a woman's choice to have breast implants placed, and that it should be her choice to also have them removed. I think that it is completely patronizing to say that women cannot decide when it is time to remove their breast implants. Or that this explanation decision is somehow the doctors' decision?

Early on the more established plastic surgeons reasoned that it was dangerous to have the implants removed. It required surgery! Horrors! But by that rationale no one should risk surgery to have breast implants in the first place. It was surgery! Most plastic surgeons advised women to keep their implants in, even if they were experiencing problems. Or they said to replace them with new implants. Plastic surgeons felt that the explant surgery was not only unnecessary, but also disfiguring. No woman who had implants could go back to their "au naturel" state without regret, was their reasoning.

CBS News anchor Connie Chung's powerful report in December 1990 finally highlighted the emerging problems with silicone breast implants. It was the first nationally televised report informing the public that implants were failing, and that behind the bra-line, women were having problems.

But the problems for manufacturers were just beginning. As women experienced ruptures and other health problems associated with implants it became increasingly apparent that implants did not last 5000 years or even 15. The rupture rate for some brands was approaching 50% after only 7 to 10 years.

It may be an apocryphal story, but FDA Commissioner David Kessler was supposedly amused when he was first appointed as FDA commissioner and he went to give a speech. He felt no one would want to hear a relatively low level government official and expected a small, subdued crowd. Boy, was he surprised. It was an auditorium that to him felt like the size of a football stadium, with a huge collection of screaming fans. He looked out over the vast number of people all hoping to gain FDA approval for this or that device or medication or lotion, so they could sell it to the American people. At that pivotal moment, Mr. Kessler realized that he was the only one standing for the American consumer against this massive onslaught of aggressive businessmen, giant pharmaceutical companies with their phalanx of lobbyists, earnest entrepreneurs and enthusiastic inventors, all seeking to selling snake oil or whatever. He was their only hope. It was David Kessler in 1991 who proposed the moratorium on the sale of silicone breast implants against the unanimous advice of the panel that recommended these implants be allowed to remain on the market, though with further study. It was only later that the panel recommended the moratorium on gel implants be narrowed to only allow women with breast cancer, and a few other diagnoses, to further study their safety.

It became apparent that many women were having problems with their breast implants. Lynda Roth was one of them. She had undergone breast cancer reconstruction using silicone gel implants in the 1980s but with her own investigative research decided to have them removed because of a myriad of health complaints in her own body. She felt that if she had developed so many symptoms perhaps others had as well. She reached out and discovered that she was not alone. She founded The Coalition of Silicone Survivors out of her home in Broomfield Colorado.

Lynda had no medical background but was trained as a social worker. She was a relentless organizer. Lynda Roth published her first newsletter for the Coalition of Silicone Survivors in January in 1993. It went out by mail. She had a mailing list and used postage stamps. The internet was barely getting started, and only later there was something called an ethernet cable that had to be connected in order to be online. It was slow and tedious work. She relied heavily on her fax machine. The newsletter depended on sources such as the Command Trust Network. The Command Trust Network was a national silicone implant information clearinghouse founded by Sybil Goodrich and Kathleen Anneken, RN, in California. In Missouri, Kathy Keithley-Johnston also published the Toxic Discovery newsletter. Without these underground, word-of-mouth networks, everyone just thought they were the only ones who had problems. Articles in the newsletters included everything from Raynaud syndrome to reflex sympathetic dystrophy, scleroderma, fungal infections, fibromyalgia, auto immune testing, arthritis, chronic fatigue syndrome, inflammatory bowel disease, transient ischemic attacks, and numerous other medical problems that women were experiencing.

The Toxic Discovery Network kept women informed about medical issues but also about the ongoing legal actions in different states. Lawsuits in Oregon and Texas and other states were bundled up into a class action lawsuit against Dow Corning. The plaintiffs' efforts against Dow Corning and six other manufacturers eventually led to settlements in the billions of dollars for women to have their implants removed and receive necessary medical treatment. The bases for the legal victory were internal memos and documents that revealed that Dow Corning knew about potential health risks years before. They chose to ignore them. Not to report them. Not to follow up on them. They chose the head in the silicon dioxide (sand) approach.

To reach out to women who had implants, the Command Trust Network then also had to advertise in local newspapers! Because there was no national registry of breast implants to serve as a source to identify women or men who had received implants, it was only through word of mouth, newsletters, friends telling friends, a sprinkling of articles in women's magazines, that women discovered class action proceedings. This lack of national registry is still true today and makes it difficult for outreach programs, for follow up. Or for long-term studies.

Without women such as Lynda Roth, Kathy Keithley-Johnston, and many other local, state and national leaders, women with breast implants would never have realized that other women were experiencing similar issues. The proceedings of the class action lawsuit were complicated, with endless requirements for documentation and reports. These women provided a map for women to negotiate the maze of legal proceedings.

It sounds quaint now to remember that we held conferences, literally "meet and greets," where women could share their stories. Lynda Roth again was a relentless organizer. She cajoled me into attending a few conferences with her not only in Colorado but also California and Oregon and even Australia. In Australia women who had never heard of Connie Chung or the Connie Chung disease nevertheless had a cornucopia of symptoms similar to their American counterparts. At these meetings Dr. Pierre Blais presented his findings on implants. He had done extensive research on silicone and saline implants. And I presented my beliefs that it is important to remove the scar tissue or capsules that surround the implants. The scar tissue surrounding the implants is filled with foamy macrophages, basically a white blood cell that is designed to phagocytize foreign body materials such as silicone particles. I felt that these tissues should be removed as they contained tiny fragments of the silicone shell. Many surgeons in those days thought that these capsules would just be absorbed by your body if left in place, but they were wrong.

Dr. Blais of course presented his research to the FDA. Frank Vasey's book *The Silicone Breast Implant Controversy* (1993) was widely distributed. He was a rheumatologist in South Florida who noticed many women with similar complaints in his practice and wrote a book documenting their stories and his findings. Patti Scher and Marian Koch's book, *Breast Implants, the Untold Truth: a Complete Handbook*, was also shared. Without Amazon or online reviews or Facebook, it was slow going.

So it was in the early '90s that I first met women who had problems with breast implants. After listening, I agreed to re-operate on them years after they had had their implants removed, and found their capsules, still in place. That scar tissue is now well known not to dissolve, but must be surgically excised. I must again admit to a very negative reaction by my fellow plastic surgeons, many of whom even today still do not accept that there could be any reason for women to have their implants removed – ever. Perhaps these are the same plastic surgeons who still feel women with breast implants always wish their implants were bigger. But I felt, just as with penicillin, a drug that has saved millions of lives, and that heralded in the age of antibiotics, some people do not do well with it. (My father was one who reacted to that drug. He developed a severe anaphylactic allergy to penicillin after being on it for over year following the retained surgical sponge after an appendectomy. He remained deathly allergic to it.) Other allergies, like with poison ivy, similarly develop through repeated exposures, as the immune system reacts. Likewise I believe some women's bodies develop negative reactions or allergies to implants. I believe it because I have seen so much of it. I don't have large significant epidemiological studies but many, many women whom I have seen complain of very similarly weird and not at all well categorized health issues that developed after implantation. After the implants are removed many women, but not all, feel better. Some feel better immediately, some feel gradually better over the ensuing year, some have an up and down course, and some little change at all. But I would say that ALL are immensely relieved to be done with the ANXIETY of not knowing if it is their implants that are making them ill. Immense relief.

As every woman is unique, so is every implant. Each implant, each batch of gel, each bag of IV saline is unique. Every woman's experience is unique. Some women after implantation never have a problem, even living with ruptured gel implants for years. Some women start quickly onto that downhill path of not feeling well. Every woman is unique.

We live in a society that preys on unhappiness. It is called consumerism. If we were all for just one moment happy with how we looked, or what we had, our world would stop. We would stop buying. Instead, we live in a world where we could be happier – if we just had the right sweater, the cutest shoes, just take this pill, get this latte or – you know you want it – the perfect breasts.

This is my 30<sup>th</sup> year of practice. I have been so lucky to meet so many women, Lynda Roth among them, but also so many patients who have provided me with much positive feedback and affection. I am forever grateful. And just as every patient has her own story, I have seen many women who have just loved their look with breast implants and never had a single problem from day one. Not even a cold. Their implants go in. They look great. They feel comfortable. They forget they even have them. Why some women react negatively remains a puzzle. Is it a virus? Is it something in that particular batch of silicone? That particular bag of saline? Something in the initial surgery, or something that they were exposed to later, and the implants act as a trigger?

The manufacturers are trying harder. The standards for manufacturing have risen dramatically over the last 30 years. Remember the old polyurethane coated implants, Meme – French for “same self?” They

were advertised as the most natural feeling of all implants, and their initial capsular contracture rate studies showed impressive results. What happened? They were pulled from the market overnight. The supplier of the polyurethane foam had no idea the foam was being used in the implant; they thought it was part of the packing material. They were generally suppliers of polyurethane foam for car seats and other parts, and when they realized their foam was being used in people, they stopped supplying it. This would not happen today. Every manufacturing step is monitored. And every implant is still made by hand. The shell is made on a mandral/mold by either spraying or dipping, but they are removed by hand, and the backing glued in place, by hand, the fill ports fitted in place by hand, the gel filled by hand. The employees do try to maintain high standards of quality.

There is a LOT more information we need to know. Women who choose implants must be informed of potential risks to their body and their health. Implants are a rarely a one and done but a lifetime commitment to care and maintenance.

Lynda Roth died in 2010 after a long battle with metastatic breast cancer. She lived to see the defeat of Dow Corning and the legal victory for thousands of woman. She lived also to see the return of gel implants, and followed that news wryly. Upon her death, she asked for donations to go to the Haitian Relief Fund. Helping others is always what it is all about.

#### EXPLANT SURGERY

The surgery to remove the implants is very similar to that of placing the implants, but more time-consuming. Again, I feel it is important to remove all the scar tissue that surrounds the implant. And I am passionate about that. That scar tissue is really as thin as an eggshell or the inside membrane of an egg shell. You can actually see through it. It is a thin fibrous capsule that surrounds the implants. It is your body's first line of defense against foreign material. The scar tissue can sometimes peel off like an egg shell and come out all in one piece but other times it is too thin or too stuck and must be peeled off in tiny pieces.

Once the scar tissue is removed the pocket where the implants rested is thoroughly irrigated, rinsed out, scrubbed out, washed out and then finally a drain placed to remove any further particles that could remain. This allows the tissue to start fresh and to begin to heal. The entire process usually takes about two hours, though it can take much longer.

Removing the scar tissue along with the implant is known as en bloc. I have a video of a saline implant that has been removed en bloc.

#### PATHOLOGY

The implant capsules are routinely sent to pathology. The pathologist determines which other studies should be performed, and if additional testing is required, it will be done. While there are numerous potential tests, I send a list to the pathologist, who then decides what is appropriate. This avoids unnecessary and costly extras. Afterwards the implants are usually returned to the patient.

#### WHAT ABOUT ENLARGED LYMPH NODES?

I do not recommend lymph node removal. Lymph nodes are your body's natural defense. They are doing their job capturing gel or whatever. Removing them can be harmful to the lymphatic drainage system.

## RECOVERY

During the surgery, I use a long acting local anesthetic called EXPAREL®. It is injected while you are asleep. It reduces post-operative pain just like the numbing medicine the dentist uses to numb your mouth but it lasts for 96 hours. There is still some discomfort that requires the use of post-operative opioids. We have also been suggesting the use of topical CBD oil rather than opioids to reduce pain. It is important to rest. Keep your arms by your sides. Walking and moving around is encouraged. Do not lie in bed. Someone must be with you for the first 24 hours after surgery. Or an overnight stay at the hospital can be arranged.

I always use drains. Once the implants and capsules are out, and numbing medicine is injected, I rinse out the area. I scrub it out. Rinse it out again. The drains help drain out all this fluid and typically remain in place for 48 hours. They are removed in the office, usually 2 days after surgery, by the PA or nurse. Then you may shower, wash your hair, but no Zumba or Pilates classes for a few weeks or until all the pain and bruising are gone. You can gradually increase your arm movements over the following few weeks.

## RISK

Risks of explantation surgery are the surgery itself. There are the risks from anesthesia, even though the lightest anesthesia possible is used, from bleeding and even a risk of pneumothorax. Sometimes when trying to remove a stubborn bit of capsule from the ribs, I can create an opening down to the lung space. This is repaired during the surgery. I have not seen any long term sequelae, because it is repaired once it occurs. In general, after the first week most women can return to a desk job. For more vigorous work, it may take 3 weeks or more. If you have big beach vacation with surfing lessons, give yourself 2 months or more.

## POST OPERATIVE APPEARANCE

Many women are very anxious about their appearance after explantation. In general women with implants that were placed underneath the muscle have less to fear about their postoperative appearance after removal. The muscle and breast tissue are still stuck together. Once that implant is removed, the muscle heaves a big sigh of relief and pulls itself back into place. It's a muscle. As the muscle pulls itself back up it also pulls the breast tissue that is attached to it back into place. Most women look about the same as they did before they had implants but older. Time and gravity march on!

It is a different story for women with implants that were placed just up underneath the skin and breast tissue. The skin and breast tissue themselves can be very attenuated after years of dealing with an implant, especially if the implant has become very hard. It's as if a heavy bowling ball has been placed on a pillow. Once you remove the bowling ball, the pillow is left with an indentation where the ball was, leaving the breast shaped more like a volcano than a mountain peak. The skin may not have the strength or elasticity to pull itself back together; the breast tissue can be permanently atrophied by the compression.

One warning note: an initial incision around the lower part of the nipple does tend to be stuck after explantation, whether the implants were placed submuscular or subglandular. The incision to remove the implants is usually three inches or longer and placed in the bra line (inframammary fold.)

If a lift is used, then the incision is the incision of a lift. A lift is not usually required unless:

1. You can hold a pencil underneath your breast (and walk around);
2. The nipples are pointed downwards; or

3. When looking straight in the mirror, no skin is showing beneath the nipple/ areola and the bottom of the breast. (No fair raising up your arms. Arms should be at your sides. )

A lift adds more time to the surgery, and more time for recovery. After explantation alone, women usually recover over the course of weeks, but with a lift the recovery can be measured in months. There are more restrictions during recovery with women who have a lift. We ask you keep your elbows at your sides and resist (!) unloading the dishwasher for a few weeks. Relax. Walk. Get outdoors. But do not vacuum or do laundry.

#### FAT TRANSFERS

I have been doing fat transfers for over 20 years. Initially I used them to help volumize the area under the lower eyelids and the cheeks. I was using a teaspoon at a time. Now I have also used fat transfers with breast surgeries for a long time. The fat is harvested from some other part of your body using a special cannula. Once the fat is harvested it is processed very carefully via gravity or the PureGraft System. This results in fat cell seeds. They are then planted in little teeny rows of fat, like piping on a wedding cake, inside the breast tissue. I use a one cc syringe and one mm needle so each fat cell can be close to blood vessels, increasing the chances of survival. These relatively new techniques have allowed me to go from transferring a few teaspoons of fat to a cupful of fat at a time. In general though I prefer to limit the amount of fat transferred at once to 240 to 300cc (or about eight to twelve ounces) of fat per breast per time. This is about the size of package of cream cheese. I consider fat grafting as “frosting.” It is not like an implant; it is not as sturdy or firm as an implant. Fat is much softer and more subtle. The fat is not pumped in like insulation foam or whip cream inside a Twinkie. It is laid down in teeny rows. This means it will not tend to migrate, but should stay put.

Radiographs or mammograms will see the fat, but it looks like fat. Sometimes tiny fat cysts may develop but they are distinguished as fatty cysts.

Fat contains more stem cells pound per pound than bone marrow. Fat is an all-natural product. And while fat cells may change with you, the fat that is transferred is donor dominant. This means that the fat always acts like the fat where it was taken from, not like where it was transferred to. So if the fat is taken from your thighs, and that is the fat that is always the first to gain, and the last to lose, then this fat once transplanted into the breast will always act like thigh fat. If you lose weight, the fat cells themselves will shrink, but remain in place. If you gain weight, the fat cells in your breasts will get bigger like your thighs used to.

Fat grafting does create a whole new area of soreness from wherever I take the fat from. It creates more areas for your body to heal. Fat grafting is not for everyone. It can be done at a later stage though, after explantation, when your body may be in a healthier state.

#### WHAT ABOUT INSURANCE?

I have discovered how insurance companies plan to reduce health care costs. They have created so much process that doctors and all the people that work in the doctors' offices will spend all of their time doing paperwork, completing PBA's (prior benefit authorization forms), calling to see where exactly the forms should be sent because each policy has a different address (United Health Care literally has dozens of addresses to process their forms), and therefore doctors and their staff have no time to actually do surgery, or answer the phone or to talk to and see patients.

We can provide ICD codes and CPT codes, but in the end it is your insurance company. We have developed separate insurance guidelines for explanation surgeries. Note that even when insurance

companies cover the costs of removal they likely do not cover the more complicated en bloc capsulectomy. We know that any reimbursement can help!

Linda Huang is a board certified plastic surgeon in Denver Colorado. She received a B.A. from Yale and her M.D. from Stanford, and completed post-graduate training in general and plastic surgery at Georgetown and Duke respectively. She has been in private practice in Denver since 1988. She is married and has three grown children and a new granddaughter. Dr. Huang can be reached at 1601 E. 19<sup>th</sup> Ave., Suite 3150, Denver CO 80207, 303-831-8400, and at [lindahuangmd.com](http://lindahuangmd.com).