

INTRODUCTION

October 2016,

Medical Reporter – please correct your article. We are irate on the discrepancies in your article written about breast implants. Please see Dr. Patten's corrections:

Please review the regulatory history of breast implants on the FDA website and print a correction to your article. In April 1992 FDA concluded the product manufacturers did not provide sufficient evidence of safety or effectiveness. Consequently, FDA removed silicone breast implants from the market except for reconstruction and revision. The removal was not voluntary as you said, but ordered. It was not until 2006 that a silicone implant was first allowed back on the market for cosmetic augmentation. Thus, except for some strictly controlled studies, the silicone implant was, because of safety concerns, held off the market for 14 years. The newer implants maybe safer because they leak less, rupture less, and sometimes self-seal. FDA says as of August 2016 the follow-up data on the newer implants is so poor conclusions are not justified.

It would be helpful to the women contemplating implants for you to mention the present FDA safety concerns which include rupture, spill, pain, serious

infection, capsular contraction, disfigurement, asymmetry, ptosis, scarring, redo operation, anaplastic large cell lymphoma, and change in nipple sensation.

The implant placed under the pectoralis muscle caused loss of T4, the nerve to the nipple resulting in anesthetic nipples. Furthermore, when T4 tried to grow back it encountered the physical barrier of the implant. The nerve then jumbles on itself and forms a neuroma. Compression of the breast causes the neuroma to discharge and the patient feels a sudden severe electric pain in the chest which has simulated heart attack. Several cases are reported in the literature of emergency medicine. In my practice there were several women who would not let their lovers touch their breasts because of the lightning pains.

At present, with the newer silicone implants, the 10 year removal rate for revision patients is 32.4%. The ten year removal rate for primary reconstruction after mastectomy is even higher at 53.6% and the ten year removal rate for primary cosmetic augmentation is 20.8%. Thus, a person getting an implant, even with the newer implants, will likely get a host of local complications and need further surgery. Our own observed rate of redo operation in our patient population of women who presented with implant problems was on the average one redo operation every three years.

While you are at rewrite, you might consider discussing the results of the court cases against the implant companies.

Their product and their malfeasance cost them 6.2 billion dollars.

On September 2nd, 1994, *The Wall Street Journal* published the news of the final settlement approved by U.S. District Judge Sam C. Pointer, Jr. in Birmingham, Alabama. Judge Pointer said the global agreement was generally “reasonable, fair, and adequate.” He cleared the way for women to file claims against the settlement fund. Nearly all major suppliers, manufacturers, and distributors of breast implants are party to the agreement. The leading corporate participants are Dow Corning Corporation, a joint venture of Dow Chemical and Corning, Inc., Bristol-Myers Squibb, Baxter International, Minnesota Mining & Manufacturing, and Union Carbide.

Women were to be, and are being, compensated for ruptured implants, spilled silicone, and a host of autoimmune diseases. You can read about the compensation plans on the internet by dialing the subject into Professor Google.

The implant companies were found liable, not on the basis of my research and that of my research fellow Britta Ostermeyer, MD, but on the basis of

their own research as revealed in company documents.

The Wall Street Journal article explains how much of the evidence came from company documents (147 pages reviewed by Thomas Burton, Staff Reporter of *The Wall Street Journal*) that showed that as far back as 1975 the company knew about the immune effects of low molecular weight silicones. Much of the original work had been done on dogs at Dow Corning. When the experiments came out the wrong way, i.e. showing complications, scientists signed a secrecy agreement. And a lot of experiments in dogs did turn out the wrong way: That is, the experiments showed the silicone induced autoimmunity. Furthermore, the company applied for and received a U.S. Patent for the use of silicone to augment the antibody responses of vaccines. Thus, Dow was caught in a contradiction. On the one hand, they argued that the silicone had no effect on the immune system and yet, on the other hand, they argued in their patent that it did. Logically you can't have it both ways. Either the dimethylsiloxane stimulated the immune system or it didn't.

The other contradiction that hurt their case was the package insert itself. The package insert came with the implants. The insert said "if a woman had an autoimmune disease or if an autoimmune disease was suspected, then that woman should not be implanted.

If a woman develops an autoimmune disease after implantation, then the implant should be removed along with the surrounding capsule and such patient should not be reimplanted.”

Thus, the manufacturer is caught. If they didn't think the implant influenced autoimmune disease, why include in the package insert the advice that it could? Logically, you can't have it both ways. Either you believe your implant can influence the immune system or you don't believe it can. If you believe it can, then you put that statement in your package insert as a warning.

In court, it looked like they knew in certain women the implant could cause autoimmune disease and they had put a warning in the package insert to notify physicians of that fact. Furthermore, the package insert even told the doctors what to do in the event that an implanted woman developed an autoimmune disease: Explant the implant and the surrounding capsule (to remove the leaked silicone) and do not implant that woman again. In these days of precision medicine, it is a pretty good bet that some women are genetically predisposed to develop immune problems after implant. It would be nice to know who these women are so the complication can be avoided.

Breast implants companies were an easy target for plaintiff lawyers. They kept good records and had

both liquid and real property assets. The incidence of malfeasance was probably no more than that of any other comparable institutions in America. The sexual abuse scandal in the Catholic Church was a great tragedy and a largely self-inflicted wound. But Philip Jenkins points out in his study *Pedophiles and Priests* the actual incidence of sexual abuse in the Catholic Church and its school system is no higher than in other institutions. In fact, it is less than what exists in the New York City school system. This is not offered in any way as a defense. That such abuse should have existed at all is unforgivable. But this prompts the next question: Why was the Catholic Church scandal the one that got so much attention from the media, public officials,, and lawyers. Answer: The Church, like the implant companies, kept good records and had liquid and real property assets. They were an easy target and did not enjoy the special legal protections of the New York City School System. Plaintiff attorneys are well aware of this and being practical litigators, took take aim at the easy targets.

The real offense, of both the church and the implant companies, was the cover up. Once the problems with implants surfaced, the companies should have addressed them directly and not tried to cover up. Once the priest problem surfaced, prelates should have addressed the problem directly and not tried to cover up. It is for the cover up that penance is

required and is being paid. Unfortunately, some of the people paying are completely innocent. Lloyd's of London insured most of the implants.

In your rewrite please consider the following testimonies.

Pamela Burrell was Dr. Thomas Cronin's nurse and one of the first to get an implant and one of the first to get a serious autoimmune disease after implant. That disease remitted when the implant was removed. Pamela says, in a letter to me dated April 4, 2016, that Britta and I saved her life. We believe her.

Hollywood stars have had problems with breast implants and have not been afraid to tell the public. Testimonies are selective and subjective and therefore unscientific, but they do tell of interesting personal experiences and outlooks. All names and facts are used with permission.

Pamela Anderson Lee.

According to Dr. Richard Ellenbogen, a Beverly Hills plastic surgeon, "Pamela Anderson had huge implants and huge implants have a much higher complication rate. Pam felt uncomfortable with her large breasts and had them replaced by smaller implants. At surgery one of the large implants was found ruptured with silicone spilled into tissue. When the large implants were removed her breasts became saggy, deflated breasts requiring uplift procedures

and replacement implants. Thus, Pam went from 36DD to 36C.”

Mary Tyler Moore

Mary experienced months of pain when her implants hardened following a 1991 procedure. Dr. Ellenbogen said, “In 95 percent of cases where women have their implants removed, it’s due to the hardness phenomenon. The body reacts to the implant causing scar tissue to form around it. To a woman this feels like a knife in the chest.” Mary was forced to undergo a second operation to replace the implants with new ones. She said, “If I’d known this was going to happen to me, I’d never have had the implants in the first place.”

Jenny Jones

Jenny wanted a fuller figure – and instead wound up with “11 years of hell.” Silicone implants the talk show hostess got in 1981 hardened and five operations later, they still weren’t right. So, in 1992, she had the implants removed. Her experience, which left her with breasts that are numb and asymmetrical, convinced her to start a foundation that urges woman with implant problems to seek medical help. She said, “I don’t have cleavage, but I am better off without them.” Jenny went from 36C to AA. Jenny is famous for holding up her implant on her show while explaining that she thought they caused those “11 years of hell.”

Cher

Cher survived several procedures. “”My breast operations were a nightmare. They were really botched in everyway.”

Stevie Nicks

Stevie says she’s “living proof” that breast implants are not safe. In 1994, the Fleetwood Mac songbird became weak. She suspected the implants she got in 1976, and had them taken out. “It turned out they were totally broken,” said Stevie. She kept the removed implants in her freezer “to remind me of the agony.”

Sally Kirkland

Sally, the star of EDTv had to endure nine corrective surgeries following the rupture of her silicone implants in the late 1980s. “My body became a battle zone of scar tissue from all the operations. And I was fighting the toxic die-off as the silicone moved through my body, poisoning healthy tissue. Sally’s replacement saline implants fared no better and they were removed in August 1998.

Mary McDonough

The child star on “The Waltons” developed lupus after receiving breast implants in 1984. She finally had them removed in 1994. She said, “not only had they ruptured but the polyurethane foam around them had melted and seeped into my system. So everything had to be scraped out.”

That's enough sad stories about implants gone awry. I have hundreds of other sad stories. Don't get me started. In writing about these problems I realized that the patients I talked about here with implant problems were women. Implants caused similar problems in men. One patient, the President of a South American country, had trouble with his butt implants. Another New York City cop had trouble with his muscle implants. A well-known TV personality seemed to develop an autoimmune disease and a local reaction to his cheek implants. Another man had problems with his testicular implants and so forth. My point is that men were also affected and that implant problems are not exclusive to women.

Most of the patients with implant problems were referred to me by my friend and mentor, and fellow faculty member Frank Gerow, the pioneer of implant surgery. He was concerned about what was happening and he was concerned about the more than 15,000 malpractice suits filed against him. Frank was an excellent caring skilled physician and I am deeply grateful for the honest and intelligent way he helped me help the patients with implant problems. R.I.P.

By the way, most patients I saw in consultation loved their implants early on. But as time went by and the complications accumulated, the patients became less and less happy. The women who loved

implants the most were prostitutes, exotic dancers, and escort service workers. They told me that after implant their tips increased ten fold. That is not ten percent. That is 1000 percent. Big tits = big tips.

The Jenner implant, the thickest in the industry, probably saved an exotic dancer's life. An 86 year old man fell in love with her. She rejected him and he shot her with a 25 caliber Beretta. The bullet bounced off the Jenner proving the Jenner implant was bullet-proof. Jenner was a friend of mine and an excellent surgeon. He showed me his implant. The elastomer shell was so thick I had no trouble concluding it was bullet proof. It also never leaked or ruptured, a quality not present in most of the other implants of that by gone era.

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