Toxic Breasts - a peek inside the breast implant industry

By Julie Chadwick, November 22, 2006

Few aspects of the human anatomy have generated more hype, insecurity and fetishization than the female breast. It has been used to sell products; been the object of fame and obsession, and the cause of wishful thinking and embarrassment. It has been pushed, lifted, separated and prodded into every shape imaginable, as dictated by the fickle face of fashion. However, nothing has been quite as dangerous as the trend towards a surgically enhanced bust.

The possibility of changing one's "God-given" lot must have seemed like a miracle to certain hopeful young women when the prospect of breast implants first loomed in the early 1900s. These first experimentations were not actually implants but injections—first with paraffin, with disastrous results, and later with the patient's own fat tissue, which was quickly reabsorbed and left scarring and unsightly lumps. Both methods were abandoned by the 1920's and by the middle of the century, the body ideal was moving away from the svelte "flat" flapper and towards the curviness of the cheesecake pin-up. With this shift came more pressure on women to conform to the ideal, and subsequently created more desire for, and interest in, surgical options.

Medical knowledge gained during World War II, coupled with technological advances with synthetics led surgeons to experiment with the insertion of spongy polyurethane derivatives with names like Surgifoam and Ivalon. These too, however, proved to be unsuccessful, as breast tissue filled in the holes and contracted around the sponge, often reducing it to a hard lump that was difficult to extricate.MORE...

Inspired by Japanese prostitutes that were injecting silicone directly into their breasts in an attempt to attract American sailors, doctors in the US began to experiment with liquid silicone.

Through the 50s and 60s, this practice became popular with topless dancers in Las Vegas and San Francisco. Its use became more widespread as, initially, it appeared to be a less-invasive procedure that any doctor could do. It is estimated that anywhere from at least 12,000 to 50,000 women received silicone injections during its period of popularity, which began to wane in the mid-60's. It wasn't long before complications associated with the injection of silicone began to set in.

Some of the noted clear-cut effects were pain, skin discoloration, edema, ulceration and necrosis, calcification, granulomas, migration of the fluid, infection, cysts, axillary adenopathy, disfigurement and loss of the breast, liver granulomas and dysfunction, acute pneumonitis or adult respiratory distress syndrome, pulmonary embolism, coma, and death.

As Frank Gerow and Thomas Cronin, two plastic surgeons from Texas, were developing the first silicone breast implant in 1961, there was already some dissent from within the ranks. On Jan. 24 of that same year, Ethel Mullison, the Staff Associate from the Dow Corning Center for Aid to Medical Research, sent a memo to Cronin. In the letter, she states that there are problems with silicone being "injected directly into the body," and that "if enclosed within a silicone bag, the fluids would tend to diffuse out through the walls of the silicone rubber and be absorbed into the tissues."

This problem came to be known as 'bleed' - the tendency of silicone to ooze out of its protective shell (also made of silicone) and behave exactly like silicone injections - with all of the attendant complications.

The first woman to receive silicone breast implants was Timmie Jean Lindsey, in 1962, and the following year Dow Corning began selling their Silastic brand of implants, without any long term testing or monitoring of their effects in humans.

By 1976, the state of Nevada felt compelled to make the practice of injecting silicone a felony. Today, it is not approved by the FDA for any cosmetic use.

As silicone made the journey from injections to implantations, many of the earlier problems and complications proved difficult to shake. Controversy over the safety of silicone dogged the breast augmentation industry every step of the way.

The awareness of potential health threats associated with breast implants rocketed its way into the public consciousness when Dow Corning was hit with multiple lawsuits in the early 90's. However, Dow had been quietly fighting complaints and court actions for a long time.

In 1976, an amendment enacted by the FDA granted the Administration new power to regulate medical devices. However, it was a little too late for implants—they had already been on the market for a number of years, and as a result had been "grandfathered" into the system.

The first court settlement was quietly awarded in 1977, to the tune of $170,000 (US). Another case against Dow Corning was subsequently won in 1984, for over $1.5 million (US), during which numerous internal company documents and memos were leaked. By 1988 the FDA jumped into action and recategorized breast implants as a high-risk product. They set a deadline for manufacturers to prove the safety of implants by July of 1991.

By the time the deadline arrived, another settlement was awarded —the largest yet—of $5.4 million. By September of that same year, the evidence that was submitted to the FDA was determined insufficient to judge whether breast implants were safe or unsafe, and they were required to submit further data. Three months later another case against Dow Corning was won, with $7.3 million awarded. Another 137 lawsuits were pending. In 1992, the FDA clamped down and severely limit the use of silicone breast implants.

By 1995, Dow Corning was facing some 20,000 lawsuits and a global settlement suit in which about 440,000 women had registered. Dow filed for bankruptcy.

The court heard plaintiffs' testify that their ruptured and leaking implants were causing them a range of health problems including joint pain, headaches, autoimmune diseases, connective tissue diseases, arthritic-like conditions, chronic fatigue, muscle pain, and dizziness.

The verdict seemed to be that there were grave problems with the use of silicone from the beginning, and that it's containment within a silicone bag did little to limit it's adverse effects within the body. This was the conclusion of not only the growing numbers of "implant survivors" but that of a growing body of experts as well.

Dr. Pierre Blais was the former Senior Scientific Advisor for Canada's now-defunct Department of Health and Welfare for fourteen years. He now runs Innoval Consultants, a firm engaged in the design, testing and failure analysis of high risk medical systems.

In his line of work he has examined over 7,000 cases of explantation, from which they have recovered over 9,000 different implants. Blais says they've seen "every single type that has ever been used worldwide. Some are as old as the 1950's."

"[They're] mostly of US manufacturing origin because they dominate the field." Blais continues: "what we're seeing is an unprecedented degree of poor quality. It doesn't matter where you get them from, it doesn't matter when they were put in, what we see consistently across all years and all types is very poor quality, frequent manufacturing defects, and in almost all cases, major problems that arose as a result of the implant. At the very least, a poor appearance; at the very worst, death."

"We have a very substantial number of these implants which were removed at death. We call that necropsy."

In October of this year, Health Canada made a strange move - the decision to lift the restrictions on silicone implants that have been in place for over fifteen years, specifically for two corporations - Inamed and Mentor. What has changed between the early 90's—when the ban was put into effect—and now?

Health Canada's Dr. Supriya Sharma told CTV Newsnet on Oct. 20 of this year that there have been many changes since the early 90's in terms of how silicone implants are manufactured.

"It's an illusion," stresses Blais. "Basically, the technology's exactly the same, the materials are still the same [...] the same people who were around in the 60's, 70's and 80's making breast implants are still around. Only the names of the companies have changed as a result of multiple acquisitions,

bankruptcies, problems, movement of the company abroad and so on."

Sharma went on to say that Health Canada believed that because the gel inside and the layers on the outside of silicone breast implants is now thicker, it is a safer product than it was in the 90's. Blais disagrees.

"It's a total misconception," explains Blais. First of all, "there is no such thing as 'silicone' in the singular. It's thousands of different compounds, mixed very much like rubbers. [...] There is enormous variations between silicones. It's no more descriptive a term [to say silicone] than it is to say, 'rubber'.

"In the case of breast implants, even the process to make breast implants does not ensure uniformity from implant to implant of the same batch, and we have instances where the silicones are from the same implant and yet have different properties from point to point. It's extremely variable."

This makes it very difficult to determine the safety of silicone implants and how they behave in a woman's body, says Blais. Even if there had been long-term testing or studies done in the 60s before silicone breast implants went on the market, Blais says that "the studies would apply specifically, only, to the batch of product that has been studied. It would not apply to anything before, and most probably nothing after."

How is it, then, that Health Canada managed to approve silicone implants with confidence?

They cite reviews from the UK and the US that conclude there is "no evidence of a causal relationship between silicone gel-filled implants and a number of auto-immune diseases or other systemic illnesses." They also cite a Canadian study that "showed that women undergoing cosmetic breast augmentation do not appear to be at an increased long-term risk of developing cancer," and a publication published in an American journal that showed that "women undergoing cosmetic breast augmentation do not appear to be at an increased long-term risk of developing cancer."

They also established an Expert Advisory Panel to advise Health Canada in their decision.

The integrity of the Expert Advisory Panel was called into question in early Nov. of 2005. The Canadian Medical Association Journal (CMAJ) reported that Nanaimo/Cowichan MP Jean Crowder was calling for the removal of three of the panel members because all three had either worked for, or accepted money from Inamed and Mentor. These were the very companies who's breast implant license applications, and safety and efficacy data, were under review.

Two panel members—Dr. Harold Brandon from Washington University and Dr. Michael Brook from McMaster University—had accepted money from Inamed to make presentations on behalf of the company at FDA hearings five months before being appointed to the Health Canada Expert Advisory Panel.

"It was shameful and outrageous," says Dr. Diana Zuckerman, president of the National Center for Policy Research for Women & Families, "but at least in the US it was clear that they were paid consultants, there to make a presentation on behalf of the company about how great the product is. In Canada, that wasn't the case."

Panel member Dr. Mitchell Brown of Sunnybrook & Women's College Health Sciences Centre was busy being paid to promote the (as-yet-unapproved) implants at his clinic and writing in a medical journal about "when silicone gel implants are reintroduced" a full year before they were officially given the green light by Health Canada (emphasis added).

"It distresses me greatly that Health Canada has decided to lift the ban on silicone gel implants," says Patty Faussett, who received implants in 1997 and had them out the following year after experiencing Multiple Sclerosis-type symptoms. "We've been shouting and waving our arms for years trying to get [experts'] attention about these very real dangers to so many women, but they have chosen to disregard the many reports of women harmed, in favor of profits for the corporations. "

Fausset says that before she had the implants, she wasn't sick in over ten years. After having them

out, she got tests back from a rheumatologist that told her that she had an elevated rheumatoid factor (80% of people with rheumatoid arthritis have this, and it is also linked with autoimmune diseases), a lowered C3 Complement and macrocytosis (the enlargement of red blood cells that is linked to liver disease, bacterial overgrowth and parasitic infestation, among other things).

And here's the catch—Patty Faussett's implants were saline. Canada is only now lifting its ban on silicone implants—however, saline-filled implants have been on the market since the 60's. Although saline is generally regarded as a safe alternative to silicone, Blais insists this is not the case.

"The main problem with saline," asserts Blais, "is that the companies who make them do not make the port—the valve, as it is called—secure. The result is that during the lifetime of the implant, the patient's body fluids percolate or leak back into the implant, and this stuff rots 'in situ'. In other words, blood, proteins and tissue which somehow finds its way into the implant becomes entrapped within the implant and sooner or later bacteria and fungi goes in too, and it uses the patient's fluids and protiens as food. And it then grows."

Blais says the valves used in today's saline implants are the same valves used on saline implants in 1976, and in 80% of saline implants, the valves come from the same manufacturer.

Another problem that arises with saline implants is that the silicone bag around the saline is porous, and becomes more and more porous over time—notably so, according to Blais, after a period of about five years.

"As more and more fluid from the patient becomes pumped into the [implant], the water part of this fluid leaks out through the bag, making the inside more and more concentrated with decaying tissue. It acts as a concentration machine where the inside is the nest for ongoing—what we call in our trade—colonization."

Following Blais down the rabbit hole of this grotesque underground world of butchered beauty, I wondered aloud what that would look like. He was only too happy to oblige with a description, remarking that the saline implants that were sent to him were "always like that."

"Even for the implants where the effect is not so 'gross', in other words, you don't see a huge amount of foreign stuff stuck inside—like a bad aquarium? You find that when you look at the fluid closely. The particles and the inoculae—the 'seeds', so to speak, of the bacteria—are already there after a year. The amount increases with time.

"Occasionally, very rarely, we will get one that is not badly colonized after five or six years but more than 80% of them have such a level of contamination on the inside that you can see it by looking at the implant at a distance of one meter. In some cases the implants are totally black."

So is there no way to make both silicone and saline implants high quality, safe products? Can't technology save us in our quest for the perfect pair of breasts? Blais, who has been in the business of failed implants, among other things, for over a quarter of a century, doesn't mince his words.

"A breast implant—or for that matter, most implants—don't just sit there. They cause the tissue around them to reshape, to re-form in a different way. In other words, the implant does not accommodate to the patient, the patient accommodates to the implant.

"Firstly, the implant becomes surrounded by a tissue layer which gradually increases in thickness with time. Think of it as a tissue envelope, containing an implant. The space around the implant that is still within the capsule is usually a liquid. This liquid is stagnant. It's like a marsh. There is no automatic cleansing of this fluid by body processes.

"So, the liquid being stagnant in turn causes the death of the surrounding tissue. So as a result, the capsule becomes thicker and thicker. With time, there is less and less cleansing, and after about ten years, processes that are never found in living organisms without implants takes place.

"For example, large quantities of very hard, glass-like calcific deposits form, and in large amounts. I've seen implants removed after twenty years where the surrounding tissue was like a mass of leather with the inside part consisting of [something like] crushed lightbulbs.

“This is not an exception. The near-totality of implants that were put in between 1962 to about 1980 that are now being removed come out in this condition. It’s not just a statistical risk. It’s a…” Blais pauses, searching for the word, “ …guarantee. And the guarantee is that it’s the result of the way we are built.”

“Now, it doesn’t stop there.” My head is reeling, and I consider asking him to slow down, but Blais is just getting warmed up. “A breast implant sits at the crossroads of a lot of machinery. The chest is not just a bag of tissue in which you can put anything. When you put an implant into a place like this, you force it between muscles, you have it sit on top of arteries, veins, lymphatic tissue and what-have-you.

“So as a result, all of these other bits of machinery that we call our anatomy are changed. For example, blood flow into the chest is drastically reduced. Part of this blood is part-and-parcel of our coronary system. Basically the mammary artery, which is often very close to these implants, is affected to the point that it seizes to function and it calcifies. And that’s again, an expected [result].

“With time, the implants exert a sustained pressure. […] As a result of this sustained pressure, the ribcage gradually collapses and indents. We have patients where X-rays show incurvation or collapse of individual ribs that sit underneath the implant. And on and on it goes. It’s not rocket science, it’s just the way we are made.”

With that final nail banged in the coffin, I turn to the question of how did we, as women, as a society, get to this point? In all this obsession over the appearance of our breasts—how big, how pert, how they spill over, their upward (or downward) tilt—I feel like something has been lost. We have forgotten what the biological function of breasts was in the first place. Faussett brought it home for me.

“There is no doubt that the female breast has been considered one of a woman’s most alluring features. I don’t think that will ever change,” she muses, “but the difference is that in societies [in the] past, the female breast was the source of nourishment that meant life or death for an infant. The very survival of humankind depended upon the functioning human breast. In modern times, this is no longer the case. Yes, breasts are still nourishment for infants worldwide, but in our culture, we’ve made it optional to the health of the infant. Formula abounds for the woman who does not want to use her breasts as they were intended to be used. Couple the rise of the Playboy empire with the advent of easily-obtainable infant formulas, and, the breast has become more glamourous and sexy than ever before.”

And of course, this glamour has a downside. “Breast implants are deceptive. They give women hope that they, too, can have glamourous, sexy breasts. Unfortunately, that is not always the case,” says Faussett. “Hard breasts are not sexy. Obviously fake breasts are not sexy. Numb breasts greatly reduce sexual pleasure. And if you happen to be one who suffers from immune system dysfunction as a result of exposure to breast implants, you can pretty much forget about sex, as the last thing you will ever feel is sexy. Instead, you will feel like you are an eighty year old woman in a much younger body as you fight to function normally. It is definitely not sexy.”

However, Faussett asserts, “there is a dark side, and there is the lighter side, which I think I’ve found when I realized that my experience brought me closer to living a life that is purposeful, joyful and satisfying, and without all the baggage of insecurity about my body that I had. […] I realized my inward beauty more than ever, regardless—or in spite of—my suffering.”

Addendum: *as of Nov 17, the US FDA has decided it, too will be lifting the ban on silicone breast implants (but not silicone testicular implants, because of “inadequate testing”). For more information, visit the implant awareness website I am setting up at It will include audio of the full interview with Dr. Pierre Blais, as well as links to Dr. Diana Zuckerman’s, Patty Faussett’s, Kathy Nye’s and many other survivors’ and experts’ sites, and much more.*

http://www.implanttruth.jshood.com/article.html