

Silicone implants making a comeback

Years of alarm washed away by new research and a gel like Gummi Bears

By Sharon Kirkey Glenn Lowson,
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Dr. Walter Peters says women are once again requesting silicone breast implants following medical studies that found no link between the implants and serious disease. After removing 629 silicone implants from the breasts of frightened women during the past 10 years, Dr. Walter Peters is now doing something he finds "totally mind-boggling."

He is putting them back in.

Nine years after silicone breast implants were removed from the Canadian market amid panic the devices caused everything from joint pain to cancer, they appear to be making a comeback.

"You would never have believed it," says Dr. Peters, a professor of plastic surgery at the University of Toronto and an international expert on silicone breast implants.

"After all the stuff that's gone on, after having been through all this controversy and gone to court as a witness on all these cases and all this research we've done, [silicone] implants are back on the market again. It just boggles my mind to no end."

The re-emergence of silicone is being fuelled by several large studies that found no link between the implants and serious disease, and by a new generation of silicone implants that contain thicker and firmer gels than their older, more fluid cousins -- and are thus likelier to hold their shape should they rupture.

"The older silicone implants had a semi-liquid silicone in there. If you cut them, the silicone gel would sort of pour out," says Dr. Claudio De Lorenzi, a Kitchener plastic surgeon and past president of the Canadian Society of Aesthetic Plastic Surgery. "If they broke, they would be a little harder to clean out, because this gel is quite sticky -- it sticks to instruments, it sticks to gloves."

The new "cohesive" gel implants, which also have a thicker shell, look more like the inside of a Gummi Bear. "We cut one in half, and it doesn't pour out. It doesn't stick to anything," Dr. De Lorenzi says.

For now, silicone breast implants are available in Canada through special access only, meaning surgeons must apply to Health Canada for permission to use them in specific cases, a regulatory hurdle doctors say requires little more than filling out a few forms. Health Canada has received 400 requests for silicone implants since the government decided, in December, 1999, to once again make them available under special access.

"From our point of view, the weight of the scientific evidence was very strong then," says Beth

Pieterse, director of Health Canada's medical devices bureau. "There were three very significant reports -- two from the U.S., one from the United Kingdom -- that [found] there was no connection between [the implants] and some of the diseases there was uncertainty with before. So we felt we could release them."

None of the silicone implants have been licensed in Canada for general use. But some surgeons are convinced it is only a matter of time.

The truth, Dr. Peters says, is women are asking for them. "There was so much controversy, I would have thought women would be much more hesitant to get back into gel implants. But they're not," says Dr. Peters, who was the principal investigator of the first large-scale study of its kind to rule out any links between silicone and diseases of the immune system.

"A lot of the women who we took [silicone] gel implants out of, because they were scared of them, and we replaced them with saline implants, ended up having suboptimal results. Now they're coming back to get the gel ones put back in. I've got an actress from Los Angeles who's coming up here to get it done because they're more easily available here than they are in the States."

What makes silicone attractive to some women, surgeons say, is that no other filling comes as close to the look and feel of a natural breast. Saline implants -- the only type available in Canada between 1995 and 1999 -- have a different viscosity or thickness. Think of a water balloon, Dr. De Lorenzi says. "A saline implant is basically a silicone-rubber shell that's filled with salt water. It doesn't move like breast tissue. It doesn't feel the same." And it can be prone to wrinkling or folds when used in thin women who have very little breast tissue or fat tissue to begin with, giving the breast the appearance of a scallop shell.

The new cohesive gel implants, which are made by McGhan Medical Corporation -- one of the manufacturers that faced lawsuits during the earlier silicone scare -- "feel good and look good," Dr. De Lorenzi says. "These are excellent for women who are really thin who want to have a B cup or a small C. If those girls had saline implants, you would see the ripples through the skin."

Silicone implants are also "indicated," he says, for women who have experienced a significant amount of "deflation" after giving birth, which is one of the main reasons women seek breast enhancement.

And if the shell should rupture, the sticky gel would not be released into the breast tissue, "because it's all really thick gel. It just stays there. It's like the old, first-generation [silicone] implant," Dr. Peters says.

The enthusiasm is a seismic shift from the mood just a decade ago, when reports began to surface linking implants with such systemic autoimmune problems as rheumatoid arthritis, lupus and scleroderma.

In July, 1991, six months after a national U.S. television news program aired a special report about the dangers of silicone breast implants, an Alabama jury awarded US\$5.4-million to a woman who had traces of silicone in her lymphatic system. By December of that year, more than 100 individual lawsuits had been filed against Dow Corning, the leading manufacturer of

silicone-gel implants, while a special panel struck by the U.S. Food and Drug Administration began reviewing the safety data -- only to find manufacturers had failed to provide sufficient evidence the devices were safe.

In January, 1992, the FDA ordered doctors to stop using silicone-gel implants until studies on their safety could be completed. The same year, manufacturers pulled their implants off the Canadian market. (The implants were still available, however, through special access between 1992 and 1995, before they were removed from the market entirely.)

The moves provoked a flurry of liability action in Canada and the United States. In 1995, U.S. breast implant maker Bristol-Myers Squibb reached a \$28-million out-of-court settlement in a class-action suit involving women in Ontario and Quebec; a global class-action settlement, affecting all manufacturers of breast implants, resulted in a settlement of US\$4.2-billion in 1994.

The settlements were driven by the "rupture phenomenon," Dr. Peters says. "Many of the implant companies had sent letters out with the implants to patients saying, 'Rest assured, these things will last your lifetime,'" says Dr. Peters, who has been involved as an expert witness for manufacturers and plastic surgeons in about 25 liability cases. "In fact, some of the companies actually had done their own work and found out they were not lasting, they were losing strength and rupturing over time. They had not been totally upfront." But the manufacturers were never willing to accept their products caused serious health problems. "And now we have all this new evidence accumulated that there doesn't seem to be any causation issue," Dr. Peter says.

Last year, in what is considered a watershed report, a panel of experts convened by the U.S. Institute of Medicine concluded that while silicone implants frequently rupture and leak, potentially causing pain, disfigurement and repeat surgery, women with gel implants were no likelier than other women to develop serious autoimmune disorders.

Other studies -- including a large study in the United Kingdom, the Harvard Nurses Epidemiological Study in 1995 and a study by Mayo Clinic investigators in 1994 -- found no evidence linking silicone implants with connective tissue diseases and other problems.

The cumulative message was the same, Dr. De Lorenzi says: "The health issues were not the issues of brain cancer or problems like that. They were the issues we always talked about -- capsular contracture [where scar tissue forms around the implant, causing the breast to harden], [the fact] implants will eventually break, all those sorts of things. But people didn't get autoimmune disease, they didn't get arthritis, they didn't get the other things that attorneys were claiming."

Still, thousands of women rushed to get their implants out "because they assumed they had a problem, or else why would [governments] have banned them," Dr. Peters says.

"And then as we took out a lot of the implants, it turned out they had ruptured with a pretty high frequency, and that added more fuel to the flame. But there were no immune changes in the body. We've looked at the antibodies, we've looked at several hundred patients. Ruptured implants do not cause a woman's immune system to get hyperactive."

Still, not everyone is buying into silicone's sudden redemption.

For one thing, while a recent study by the U.S National Cancer Institute found women who had silicone breast implants were less likely to die from cancer, immune disorders and other diseases than women in the general population, they were two to three times likelier to die from brain cancer -- and nearly twice as likely to die from suicide, pneumonia and emphysema. There was also an increased risk of respiratory-tract cancer.

In a news release, the researchers speculated the higher risks for brain and respiratory cancer may be the result of "chance findings" or "factors common to women who choose to have implants," such as smoking, and not exposure to silicone. Still, even the scientists involved acknowledge "there have been suggestions that implants may have an effect on neurologic pathways," though the evidence has been conflicting.

But leaving aside the issue of whether silicone causes systemic disease, "we know that the gel implants have been associated with a variety of local complications," says Vancouver lawyer David Klein, who is involved in a class-action lawsuit against breast-implant manufacturers that involves about 2,000 Canadian women.

The complications, he says, include rupture, capsular contractures, scarring and inflammation.

"The silicone implants were on the market for about 30 years and went through a host of combinations and changes with respect to the shells, their thickness, the viscosity of the gel inside," Mr. Klein says. But they all suffered from "gel bleed," he says. "It didn't matter what mixture the manufacturers put inside, it didn't matter how thick the shells were made. They all leaked silicone. "It surprises me that after the history of disease and local complication problems silicone gel implants had, that cosmetic surgeons would even consider putting them back in again," Mr. Klein says. "This is a cosmetic product. It's not a life-saving product. "In Washington, D.C., the National Center for Policy Research for Women and Families says studies such as the National Cancer Institute report raise more alarming questions than they answer. "These articles are a wake-up call for the almost 300,000 women and teenagers who plan to get breast implants this year," the group's head, Diane Zuckerman, told MSNBC this week in an online report dubbed "The Return of Silicone Valley." Experts such as Dr. Peters would argue with such critics about many things, but not the numbers. Breast Augmentation is more popular than ever.

Whether silicone ever again becomes the implant of choice for Canadian women seeking breast enhancement remains to be seen. Ninety-five per cent of all breast implants used between 1963 and 1992 were silicone-gel implants. "I don't know if [silicone] will ever come back to that kind of popularity," Dr. Peters says. "But it's certainly coming back."

Date: Thursday, June 21, 2001
Silicone Implants making a comeback

To Whom It May Concern:

I am writing in response to Sharon Kirkey's article of June 16, 2001 entitled "Silicone implants making a comeback".

As a co-founder and spokesperson for Breast Implant Line of Canada (a support group for people with breast implants or for those considering having the surgery), I take umbrage at this most unfair portrayal of such a contentious issue that affects so many women, their partners, children and employers.

Since we began in 1992, I have taken more than 10,000 calls from women whose health has been adversely affected by these faulty medical devices.

The statement by Dr. Walter Peters that he is now doing something that he finds "totally mind-boggling" is, in itself totally mind boggling.

What does he mean? Is he surprised that marketing efforts by unscrupulous manufacturers are luring unsuspecting and naive young women into his office?

Or is his mind boggled by the fact that he continues to implant women with devices that have never been proven safe?

The article says: "The re-emergence of silicone is being fuelled by several large studies that found no link between the implants and serious disease..." My queries to this statement are:

- * who funded these studies?
- * are these "studies" recent studies or are they quoting from a compilation of studies which were undertaken many years ago?
- * are brain cancer and respiratory-tract cancer not considered serious diseases? (please refer to the reporter's quotes from the US National Cancer Institute's study)
- * If connective tissue diseases, scleroderma, lupus, etc. are not caused by silicone gel breast implants then why did implant manufacturers place implant recipients in a grid based on such diseases and then disburse payments to them?

I find it curious that these "newer" implants are considered safe and will mimic the consistency of the first round of silicone gel breast implants.

Where is the proof of safety? Or will those women being implanted be studied for a decade or two only to find the results of what horrible health conditions they may encounter?

In 1972, I was a recipient of one of the earliest silicone gel breast implants. Within five years, I began having health problems not normally seen in a woman in her mid to late 20's. I have since been diagnosed with numerous conditions some of which include: arthralgias, myalgias, alopecia, fibromyalgia, osteoporosis and osteoarthritis.

I present with symptoms of rheumatoid arthritis and lupus. I had a spinal fusion and a hysterectomy. I was recently diagnosed with diabetes. It may be true that many people have some of these conditions. How many people have all of these conditions? I contend that those who have diagnoses similar to mine have them because of the one factor we have in common - silicone gel breast implants.

It is incumbent upon the National Post to report in a fair and factual way. How many Canadian

women did Ms. Kirkey interview for this article?

I, for one, am available to discuss this matter.

S. Joyce Attis

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