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THE SILICONE BREAST IMPLANT CONTROVERSY

by

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There has been a great deal of controversy regarding the safety of silicone breast implants. For the women who have implants, conflicting media reports can be a source of considerable stress. As a plastic surgeon performing breast surgery for over twenty years and a woman who has had silicone gel breast implants from 1985 to 1997, I hope to help inform women regarding this topic.

There are still many unanswered questions regarding the safety of silicone breast implants. Studies are ongoing, but results may not be available for several years. Education may help relieve some of the anxieties until results become available.

Silicone implants are silicone shells filled with either saline (salt water) or silicone gel, or a combination of the two. Some silicone gel implants are coated with a polyurethane material and are called Natural-Y implants.

Silicone breast implant complications can be divided into two categories: local chest wall complications and more generalized "systemic" problems. Local complications include capsular contracture, or the tightening of scar capsule around the implant, malposition and rupture and/or leakage of the implant.

Capsular contractures can cause local discomfort and upward displacement of the implant. Capsular contractures are believed to be the result of a low-grade infection around the implant. The low-grade infection causes tightening of the normal scar around the implant and as the implant is squeezed, it appears more firm. Capsular contractures are more common when the implants are placed behind the breast tissue and in front of the chest wall muscles. This is felt to be due to the contamination of the implant from breast ducts, which normally contain some bacteria. If the implants are placed behind the chest wall muscles and the surgeon avoids cutting through the breast tissue, the incidence of capsular contractures is reduced. Irrigation of the surgical area with antibiotics has also been shown to reduce the risk of capsular contracture.

Malposition of the implant is usually due to capsular contracture. When the scar tissue tightens, the implant tends to ride up on the chest wall. Malposition can also be due to steroids placed in the pocket or inside the saline implant during surgery. Steroids can thin tissue, leading to a gradual downward migration of the implant.

Rupture of the implant occurs when the silicone shell has a hole or tear, which allows the migration of the contents outside the shell. Saline is reabsorbed without difficulty but silicone gel is not as easily disposed of by the body. In most cases, the scar capsule around the implant contains the majority of the silicone gel. Leakage occurs when silicone "bleeds" through the silicone shell. The idea that microscopic silicone has spread throughout the body has been a source of concern for many women with ruptured and/or leaking implants. For women who have migration of larger amounts of silicone gel outside of the scar capsule, the surgical removal of this material is more difficult. Again, however, the body tends to isolate the offending material with scar and other tissue designed to contain foreign material within the body.

Fortunately, the majorities of ruptures of silicone gel implants occurs inside and are grossly contained by the scar capsule. Surgical removal of the scar capsule and ruptured implant is much easier if the silicone has not migrated into tissues outside of the scar capsule. It is important that the explanting surgeon use a technique that minimizes the risk of *free* silicone coming into contact with tissues and that all of the scar capsule be removed, as it contains silicone particles in the majority of cases.

Pathological examination of the scar capsules surrounding the silicone gel implants often show macrophages filled with vacuolated or foamy material. The macrophages are the body's scavenger cells, which attempt to ingest any material that the body regards as foreign. Most silicone gel implants, especially those manufactured prior to 1985, were known to have small amounts of silicone gel "bleed" or leakage through this silicone shell. The breast implant manufacturers were aware of these phenomena and, in the early

1980's, Dow Corning developed a "low bleed" gel implant, which had a different silicone shell that was less likely to have silicone gel bleed. We assume that the silicone gel bleed occurs to some extent in all silicone gel implants and this accounts for the foamy material found in the macrophages in the scar capsule. Even in patients with unruptured implants, we assume that some silicone gel travels beyond the shell of the implant.

The early silicone gel implants developed by Cronin had fairly thick silicone shells. These had a tendency to form capsular contractures and often had calcium deposits within the scar capsules. The tendency for implants to rupture increased when companies developed a thinner, more pliable silicone shell. The thinner shell, developed in 1969, was widely used until the development of the low bleed implant in 1984. Further improvements in the silicone shell occurred in 1990, when a textured silicone shell was developed which was not only more resilient but was felt to reduce the incidence of capsular contracture.

Currently, plastic surgeons are able to choose between two types of saline implants. The smooth wall saline filled implants are felt to have fewer problems with wrinkling, and the textured saline filled implants are felt to have a lower incidence of capsular contracture. Because the saline implants are a different (lighter) density than silicone gel implants, they tend to feel "sloshy" or less natural than silicone gel implants, especially if the woman has very little breast tissue to cover the implants. For this reason, we usually recommend that saline implants be placed beneath the chest wall muscles, as the muscle allows for additional coverage over the implant, so that wrinkles and irregularities are less noticeable. Placement under the muscle also reduces the risk of capsular contracture. For women who already have systemic symptoms, we recommend the use of smooth saline implants, as textured implants are felt to have more risk of having silicone material separate from the implant. It is important that symptomatic women realize that the Silastic envelope of the saline implant is a silicone polymer that may break down in the body into silica, thus possibly also eliciting an immune response. Also, there may be an association of textured implants manufactured with the lost salt technique with a malignant non-Hodgkin's lymphoma.

In 1984, silicone gel implants coated with polyurethane were developed. This implant was called "Natural-Y" and was felt to produce a more natural feeling breast due to tissue ingrowth into the polyurethane material. There was a more pronounced foreign body reaction in the scar tissue around this implant and a higher incidence of problems with infection than with standard silicone gel implants. This implant was useful in that some patients who developed capsular contractures around regular silicone gel implants would not form contractures around this implant. The problem that has never been resolved is the potential of biological activity of some of the breakdown products of polyurethane. Some patients also experienced localized allergic reactions of the material. Polyurethane coated implants tend to be more difficult to remove, as the tissue ingrowth is more advanced. We always attempt to remove the entire scar capsule around this implant, as the polyurethane foam is incorporated into the scar tissue. Natural-Y implants are no longer available for implantation.

The majority of the controversy regarding silicone gel implants centers around the relationship of these implants to systemic or more generalized disease. Having seen over 1,000 patients in the last twenty years with systemic symptoms and silicone breast implants, I have been impressed with the similarity of the symptoms of these patients to other patients I have treated with chronic infections, such as systemic Candidiasis or yeast infections. There seems to be a spectrum of severity, ranging from the patient who had mild chronic fatigue, occasional joint and muscle aches, and normal lab tests (i.e., ESR and ANA), to a more debilitating illness, such as fibromyalgia with abnormal ESR's. The more severely ill patients have frank rheumatological-like illness, similar to SLE (Lupus), scleroderma, and rheumatoid arthritis, with evidence of multi-system involvement.

The finding of frequently positive cultures of the scar capsules upon explantation has led some plastic surgeons to speculate that a low grade chronic infection around a silicone gel implant may lead to a chronic illness in which the immune system is unable to eradicate the infection or dispose of the foreign body. The interesting question then raised is whether this, in some individuals, can progress to immunological disorders, similar to lupus or scleroderma. The presence of silicone gel outside the implants, as occurs in rupture or silicone gel bleed, may increase the potential for infection in the scar capsule. If this is the mechanism of disease, then removal of the scar capsule and implants as well as antibiotic irrigation of the pocket and possible systemic antibiotics would seem reasonable. The placement of another foreign body within the same area would not be advisable, although it may be feasible to place a saline implant in another area, such as behind the chest wall muscles. The role of chemicals besides silicone as well as bio-toxins associated with the infections has yet to be scientifically explained.

If, on the other hand, the silicone itself is somehow the main offender, the advisability of replacing the implant with a silicone shell, filled with saline, must be questioned. Can the body react to the silicone shell or is only the silicone gel associated with an immune system reaction? Silica has been reported in lymph nodes in saline implant patients who have never had silicone gel implants. Several studies to date have not shown an increased incidence of traditional rheumatological disorders in groups of patients with silicone gel breast implants; however, these studies do not appear to be looking for the atypical symptoms commonly seen in silicone patients. It appears that silicone is associated with more of a metabolic disorder in conjunction with an immune

hypersensitivity than a traditional inflammatory autoimmune disease. Despite the lack of evidence of widespread development of frank rheumatological disease in large groups of breast implant patients, we are seeing symptoms of a progressive chronic disease in patients with silicone gel implants that appears to correlate with the amount of gel leakage. We are also seeing improvement of symptoms after removal of the scar capsule and implants. Patients often report return of their normal energy levels, sometimes within several weeks following surgery. Some patients only experience a partial improvement, but most patients treated to date have not had a progression of their symptoms unless large amounts of silicone gel still remain in the patient.

Currently, there is a heated debate as to the safety of silicone gel implants. I believe that since we are seeing such a high ruptured rate as silicone gel implants age, especially in the implants placed during the 70's and early 80's, we need to address the question of whether silicone gel implants should be removed based solely on the high incidence of rupture and/or leakage. Unfortunately, no currently available test, including mammography, breast ultrasound, or breast MRI, can always diagnose rupture of the silicone gel implant within the capsule. There seems to be a high incidence of the onset of burning pain along with upper extremity numbness associated with implant rupture, even when these studies are negative.

I would advise any woman with silicone gel breast implants that experiences a sudden change in shape and/or contour of her breast, or develops burning pain or numbness and tingling in the arm, be evaluated by a plastic surgeon for the possibility of implant rupture. If the patient has generalized symptoms, such as chronic fatigue and muscle and joint aches, especially if these symptoms are progressive, she should consider removal of the scar capsule and implant, even if the studies do not show a ruptured implant. If the symptoms are severe, I would not advise replacement of the implants with saline implants, as I have found recovery to be often delayed if the saline implants are replaced at the time of implant removal. For many women, the prospect of losing their breast fullness is not acceptable, so reimplantation with smooth saline implants at the time of implant and scar capsule removal may be worth the risk of a more prolonged recovery.

In addition to removal of the scar capsule and implant, both local and systemic treatments with antibiotics and antifungals help treat any sub-clinical infection in the area of the breast implant. Systemic fungal infections are treated if present, and we advocate therapies that stimulate recovery of the immune system. We advise patients on the use of Inositol to aide the body in the mobilization of silicate.

We provide a holistic approach to women with breast implant problems, including comprehensive patient education, a supportive and caring environment, and therapies to help the immune system recover. This, together with the appropriate surgical treatment, will hopefully provide a conducive environment for healing to occur.

Suggested Reading

The Naked Truth About Breast Implants: From Harm to Healing by Susan E. Kolb, M.D., F.A.C.S., A.B.I.H.M.

Visit www.TheNakedTruthAboutBreastImplants.com to read about Dr. Kolb's personal experiences and extensive knowledge of the potential dangers associated with silicone and saline breast implants.

Goddess Shift: Women Leading for a Change by Stephanie Marohn

Visit www.TheNakedTruthAboutBreastImplants.com/goddess to read about the anthology of over 40 women leaders in diverse fields of human endeavor where Dr. Kolb is a contributing author.

Optimism! Cultivating the Magic Quality that Can Extend Your Lifespan, Boost Your Energy, and Make You Happy Now by Stephanie Marohn. Visit www.TheNakedTruthAboutBreastImplants.com/optimism to read about world-famous leaders from every sphere of human endeavor revealing the secrets that kept them going during the tough times where Dr. Kolb is a contributing author.