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SILICONE AND SALINE IMPLANTS FREQUENTLY ASKED QUESTIONS BY SUSAN E. KOLB, M.D., F.A.C.S., A.B.I.H.M.

As Plastikos Surgery Center is the only clinic in the United States offering both surgical as well as holistic treatment of silicone and saline breast implant immune and neurological disorders, we have gathered some of the questions more frequently asked by our patients, who often come in from out of state for treatment. We hope to further educate our patients and their doctors regarding this challenging disorder.

How does silicone cause systemic illness?

When the integrity of the silicone shell breaks down, either due to a time-related lipolysis reaction of the shell or due to disruption of the shell from trauma, silicone gel can leak into and beyond the scar capsule that surrounds the implant. This is often associated with a burning discomfort and numbness down the arm and usually occurs around 8 to 10 years after implantation or within a few weeks of an accident. Macrophages will attempt to digest the silicone and may travel via the lymphatic system to the systemic circulation. Silicone-laden macrophages tend to travel to the central and peripheral nervous system and organs. Silicone and other substances can be released from the macrophages along with substances called cytokines that can lead to inflammatory states. Many of the processes outlined in the Silicone Immune Protocol (which can be found at www.plastikos.com under "Resources") help by decreasing the precursors of this inflammatory state. Silicone and other chemical breakdown products of implants probably cause a metabolic disruption of our energy systems that affects multiple organs and physiological systems, including the endocrine system. Biotoxins from mold in and around the implants and migrating silicone may also cause fibromyalgia. The science of silicone is not well understood, as it has not been extensively studied. Chemicals known to be in the gel are both neurotoxic and carcinogenic.

What are the local (chest wall) problems that are associated with implants?

Capsular contracture, which is the tightening of the scar capsule around the implant, is usually associated with subclinical infection of the scar capsule. Capsular contractures can be treated with a combination of antibiotics, massage exercises, high doses of Vitamin E, N-Acetyl Cysteine and healing techniques that help resolve the subclinical infection. This must be done early, however, because once the capsular contracture is established and the collagen cross bonded, surgical treatment consisting of removal of the capsule is usually needed.

Once the silicone begins to leak out of the shell, one can either see a new capsular contracture, if infection of the capsule occurs, or a softening of the capsule if disruption of the shell occurs without capsular contracture.

With textured shells or with polyurethane shells, we often see thick capsules that can invade local tissues including breast, muscle, and the lining of the ribs if the implants are submuscular. These capsules can be difficult to surgically excise but if left in the body can be a source of problems both local and systemic. Textured implants manufactured with the lost salt technique appear to be associated with an aggressive form of lymphoma.

Other local problems include migration of the implants, which is more likely to occur if a submammary placement (under the breast tissue, but not under the muscle) is used or if steroids are used in the implant pocket or in saline implants, which seem to migrate more easily than silicone implants. Other local problems include mastodynia, which is breast pain or discomfort and is often due to local infection or inflammation.

Are mammograms or MRIs needed prior to surgery?

I prefer to obtain a recent breast ultrasound to look at breast tissue and possible extracapsular silicone including the possibility of silicone in axillary lymph nodes. Neither mammogram nor ultrasound exams usually detect intracapsular rupture, which is the most frequent type of rupture. Leakage is not detected by any method and is best diagnosed clinically. Sometimes a breast MRI is useful as it is more likely to show rupture, but it is expensive, and I feel it usually is not necessary if features of implant failure are present unless silicone has migrated away from the implant. I would caution against a mammogram preoperatively as many implants have shell integrity problems, and the pressure from a mammogram may rupture the Silastic shell. Also, a 2007 article published in the American Journal of Roentgenology warns against using the standard radiation dose in women with breast implants, as this may lead over time to an increased risk of radiation-induced breast cancer. A mammogram or breast MRI may be done postoperatively if cancer detection is an issue, as breast ultrasounds are less effective for cancer detection.

What is “en bloc” implant resection and why is it important?

In order to remove the silicone implants without spilling silicone gel into the chest cavity, we try to remove the scar capsule around the implant without disrupting the capsule. It is not always possible to remove the scar capsule intact, especially if the capsule is thin and the Silastic shell is disrupted. Detoxification methods are very important before and after surgery, as even with “en bloc” techniques silicone is released into the system and can cause a “flu-like” illness if not properly managed.

What is the recommended detoxification program before and after surgery?

After taking a history and physical to determine the patient’s problems, we recommend an individualized treatment program. Many patients benefit from a yeast program, as systemic candidiasis is very common, and it is important to address this prior to surgery as yeast symptoms can be exacerbated from antibiotics and surgical stress. Most patients benefit from a diet that decreases the inflammatory precursors in the diet and that decreases sugar and carbohydrates that allow yeast to grow.

Inositol is used to help the body eliminate silicone breakdown products. Please see the articles on Inositol on the website at www.plastikos.com.

The immune system problems seen in silicone patients should be treated prior to surgery in order to avoid postoperative complications. The use of immune supplements such as EpiCor, transfer factors, thymic factors, and mushroom extracts to increase natural killer cells, and beta 1,3 Glucan to increase macrophages is outlined in the protocol and in the information on Transfer Factor Plus on the website at www.plastikos.com. Many of the bacterial, viral, and fungal infections cannot be effectively treated unless the immune system disorders are addressed.

In general, before surgery we recommend EpiCor, Agaricus Bio, and Transfer Factor Plus for the immune system, Inositol, Siliconex and Brainpower for detoxification, CORvalenM, Malic Acid (Magnesium Malate) for magnesium supplementation, milk thistle (Super Thistle X or Silymarin) for liver detoxification, Probiotic (Probiotic Pearls or Ortho Biotic) to prevent harmful bacteria and/or yeast overgrowth after surgery in the gastrointestinal tract. We recommend supplements for biotoxin detoxification, chemical detoxification, and silicone detoxifications that are tailored to the individual patient. Additional information on toxicity may be needed in order to tailor this program to the individual patient. Many of us have heavy metal toxicity and other problems, along with silicone toxicity. That is why I was led to get my boards in holistic medicine in order to understand this aspect of the healing program. Patients ask me how long they should stay on the Silicone Immune Protocol. The answer is not known, but I believe it has to do with the amount of silicone and chemical leakage into the body and whether the implants are replaced with saline and of course the state of the immune system. Patients should usually stay on the protocol 6 – 12 months postoperatively and preoperatively if possible. Many times the protocol is tailored to the individuals’ total toxic load and their response to the treatment protocol.

Is it necessary to remove lymph nodes containing silicone?

Silicone naturally is taken up by the lymphatic system and travels into the axillary lymph node system and often can be detected on ultrasound exams. I have seen many patients on the detoxification program have silicone move through the lymphatic system, and I feel that unless the lymph node is abnormal (i.e., tender and/or enlarged) removal is probably not necessary and may be detrimental in that scarring from surgery can disrupt the fine lymphatic channels that drain the breasts. Enlarged, firm or tender axillary lymph nodes should be removed if possible. Patients with textured silicone and saline implants have an increased risk of a malignant lymphoma probably due to the chemicals used during manufacturing, so removal of enlarged abnormal axillary lymph

nodes will probably decrease this risk. Removal of several lymph nodes in the lower axilla is not associated with increased risk of lymphedema of the arms.

What problems do saline implants cause?

Saline implants have local complications of capsular contractures, infection, inflammatory reactions to textured surfaces, deflation, and in the case of textured more than smooth saline implants, migration of silicone from the shell into the capsule and lymphatics with possible immune reaction and possible increased risk of lymphoma.

We are seeing a different type of immune disorder in patients, mostly with saline implants that have more features of a biotoxicity than seen in the silicone gel patients. Some patients ask if they can replace their silicone implants with saline implants. I would advise this not to be done if the patient is very ill from immune, autoimmune, or neurological illness. I advise patients that even smooth saline implants can cause a continued immune reaction as shown by research published by Dr. Douglas Shanklin, et al. as well as problems with biotoxicity from mold. I do believe that some patients do tolerate smooth saline implants if they are able to stay on the Silicone Immune Protocol and I have many patients who are much healthier after removal of leaking or ruptured silicone implants who have been reimplanted with smooth saline implants. Some of our patients would never allow their silicone implants to be removed if saline replacement was not possible. We have much to learn about the effects of saline implants.

What deformity results from explantation and what are my options?

The deformity that may result from explantation is variable and involves several factors, including the size of the natural breast, the size of the implant, the number of previous implant procedures, the placement above or below the chest wall muscles, the type of implant, the integrity of the implant, and if capsular contracture or migration of the implant has occurred. Of course the most profound deformities occur with removal of implants after mastectomies with implant breast reconstruction, but other reconstructive options such as TRAM flaps or other flap breast reconstruction are possible and will usually be covered by insurance. My experience is that more extensive deformities may occur in patients with multiple procedures where the majority of the breast tissue consists of scar tissue, patients with severe capsular contractions causing distortion of the skin envelope, and badly ruptured silicone implants with silicone infiltrating breast tissue and local muscles. The most difficult explants are around textured and polyurethane implants as these are often vascular capsules and also in patients with virtually no capsule and extensive migration of silicone in all directions. Those patients who have failed to make capsules are also more likely to have systemic illness.

For patients without change in position of their nipple areola complexes (either too high or too low) and in patients that have normal skin elasticity and implants that are not too large, explantation only is preferred, as the skin envelope will retract over several months and allow more natural breasts to form over time. At first the breast may be flat and wide, but often within three months the breast reshapes into a more natural form.

For patients with nipple areolar displacement, poor skin elasticity (i.e., stretch marks), larger implants, severe capsular contractures and multiple surgeries, often a mastopexy is needed. We prefer an internal mastopexy, which decreases the diameter of the breast and increases breast projection, with or without a donut mastopexy, where only the top layer of dermis is removed in order to reposition the nipple areolar complex and remove excess skin. The scar that results is at the border of the nipple areolar complex and is usually well hidden, but complications of hypertrophic or thick and raised scars can occur due to bacterial or mold contamination. We change instruments and gloves between the explant and the mastopexy, as the scar capsule often grows out pathogenic bacteria. Other problems include later distortion of the nipple areolar complex, usually due to forces that are unequal that stretch the nipple areolar complex to an unattractive or asymmetrical shape over time. Revision surgery is possible for both of these problems. Nipple sensation is usually not affected by the donut mastopexy as only the top layer of skin is removed. Nipple sensation could be affected by removal of the scar capsule if the sensory nerve is adherent to the capsule and is injured during the explant. This nerve is small and is usually not apparent during the surgery.

For patients with a larger amount of skin removed with mastopexy, closure with a lollipop or anchor pattern is recommended. A full mastopexy or extensive mobilization of the breast flaps with a lollipop pattern is not recommended on most patients with explantation, as tissue loss is more likely to occur due to loss of tissue blood supply.

Mastopexies are usually not covered by insurance companies, and TRAM flaps and other breast reconstructions are usually not covered by insurance unless the patient has had prior mastectomies. Occasionally a cosmetic patient with a severe deformity from explantation can receive insurance benefits for a flap breast reconstruction. Reimplantation is usually not covered unless the original surgery was covered by insurance.

Fat injections into patients with breast tissue are generally not recommended unless they are contained to the subcutaneous plane as later complications of calcifications and fat necrosis are common and can interfere with current methods of breast cancer detection. Stem cell harvests to the breast are currently not FDA approved.

Will my insurance cover my explantation costs?

Insurance will usually cover the cost of explantation if certain clinical criteria are met but not reimplantation or mastopexy. These include implant rupture, chest wall pain, severe capsular contracture, infection and in some cases, evidence of systemic disease. However, some insurances have in their contract that complications of cosmetic surgery are not covered. In these cases there is little recourse other than to change insurances, if possible, prior to a doctor's visit for an implant related problem. Once you have seen the doctor, the condition is preexisting so it may be excluded from future insurance coverage for a specified time period.

Breast reconstructive patients have more accessible insurance coverage for explantation and either reconstruction with saline implants or flap breast reconstruction as long as they have insurance.

Many surgeons do not know the clinical criteria that insurance companies have for explantation and assume that unless the original surgery was for reconstruction, other surgery is not covered by insurance. I was an insurance reviewer for several large insurance companies so I understand how the approval system works. I also know the outcome of several lawsuits brought against major insurance companies that denied explantation so that referencing these to medical reviewers is helpful, as legal precedence is usually not challenged. For patients without insurance we recommend they obtain insurance if possible prior to surgery that does not exclude complications of cosmetic surgery. If this is not possible, then either disability (i.e., Medicare) or Medicaid options are explained or financing programs are offered.

We would caution patients against spending large amounts of resources for detoxification programs prior to explantation. In our experience some individuals have exhausted their financial resources prior to being explanted only to have these methods fail due to the presence of ruptured or leaking implants. Removal of the implant and scar capsule is critical for recovery. Detoxification of the remainder left in the body can usually be done with oral methods rather than more expensive IV methods unless a problem with gut absorption exists.

Who should perform my explantation?

Often women return to their implanting surgeons if they suspect they are having an implant problem. Many surgeons and other doctors, such as rheumatologists, firmly believe that there is no association between systemic disease and implant failure. I would advise that you not choose an explanting surgeon with these beliefs. Explantation is often a tedious and time consuming process with a risk of chest wall deformity and/or leakage of the silicone into the systemic system with possible consequences of an exacerbation of systemic disease. Surgeons who do not understand the science of silicone or the immune system may not take precautions against systemic leakage. Surgeons who have not performed more than 50 explantations may not have the surgical skill required in this often-difficult procedure. Choosing a surgeon with sufficient explant experience and one that is also familiar with the processes to obtain insurance coverage is important. At Plastikos we offer the advantage of understanding about detoxification and immune modulation before and after surgery, as I am a founding Diplomat of the American Board of Integrative Holistic Medicine. I have also had the opportunity to experience first hand some of the problems, including immune and neurological, with which silicone is associated. I was the plastic surgeon at Senator Barbara Boxer and Representative Green's press conference when they introduced the bill to study silicone into Congress. Unlike many plastic surgeons, I studied the science of silicone as well as conditions such as platinum toxicity which was used in some implants as a catalyst and has been found in high levels in some silicone patients. If your doctor continues to insist that silicone does not cause systemic problems, refer him or her to the article in the Journal of Rheumatology, 2001: 28 : 996 - 1003 entitled "Silicone Gel Breast Implant Rupture, Extracapsular Silicone and Health Status In a Population of Women" and to the journal entitled International Journal of Occupational Medicine and Toxicity: Special Issue in Silicone Toxicity, Vol. 4 : 1, January though March 1995, published by Princeton Scientific Publishing Company, Inc.,

Princeton, NJ. There is also scientific information on implants at Dr. Diane Zuckerman's website, www.breastimplantinfo.org for information regarding government studies on implants. For a comprehensive review of the relevant literature, see *The Naked Truth About Breast Implants* by Susan Kolb, M.D., F.A.C.S., A.B.I.H.M.

If you have any other questions regarding silicone and/or saline implants and explantation and detoxification, please call Dr. Susan Kolb at 770-457-4677 or e-mail her at drkolb@mindspring.com.

The following statements and/or supplements have not been evaluated by the FDA. The FDA suggests that you consult with a health care professional before using any dietary supplement. This product is not intended to diagnose, treat, cure or prevent any disease

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