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Silicone Immune Treatment Protocol

By

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There are two major types of breast implants to consider and each one has its own special considerations and particular areas of concern. The first is silicone gel implants which also include double-lumen implants and Becker tissue expanders which contain 50 cc's of silicone gel on the outside with the remaining saline on the inside. Double lumen implants are the opposite with silicone gel on the inside and saline and a second lumen on the outside. All of these are considered gel implants. Gel implants come both in textured and smooth with the textured surface having been developed in the early 1990's. Textured surfaces in general are felt to, in some cases, lead to less capsular contracture, but in other cases are felt to harbor infection more easily and flake off and become incorporated in the scar capsule and lymph nodes and interact with the immune system sooner than a smooth shell. Early implants made by Dow-Corning had Dacron patches on the back which may be visible on x-ray. There was also an implant called a "Natural Y" implant made by Surgitek which had a polyurethane coating around a gel implant. This polyurethane coating became incorporated within the scar capsule forming around the implant and was degraded over time. There is a question of whether one of the products of degradation called TCA might be carcinogenic. This implant is no longer on the market. McGhan, also known as Inamed and more recently known as Allergen has developed a new cohesive silicone gel implant with less risk of silicone spillage if ruptured. The FDA approved the use of silicone gel implants for both Mentor and Allergan in late 2006.

The saline implants have actually been around for many years and the earliest saline implants were very thick and sturdy. The later saline implants had leakage problems that were excessive and fell out of use with most plastic surgeons until the implant crisis occurred in the early 1990's then both Mentor and McGhan began selling more of their saline implants as gel implants were no longer available for use without the research status. Mentor had a posterior valve implant which leaked more readily and was taken off of the market. McGhan (now Allergan) and Mentor both currently have anterior valve implants that are widely used. Both also come in a textured or smooth shell with the same potential problems with the textured as listed under silicone. The recent study from Mentor shows that the 7 year deflation rate on a smooth anterior valve Mentor implant is 3.7%. There are higher deflation rates with the

textured implants and I have noticed especially after mammograms the older textured implants have appeared to be more prone to deflation.

All Silastic elastomers, which are made of silicone which hold either the gel or the saline, undergo a lipolysis reaction which occurs only in the human body and does not occur when the implant is sitting on the shelf. This lipolysis reaction makes the implant more permeable and the silicone gel starts to leak out at 8 to 10 years. I have removed multiple silicone gel implants which have very little gel in them but no rupture of the silastic shell. The silicone leaking out of an intact shell makes the patient just as ill as if the implant shell was ruptured. The gel implant that ruptured most readily was the Surgitek silicone implant according to studies but many implants are found to be ruptured at 15 to 20 years.[1] Conditions predisposing to implant rupture are:

- Closed capsulotomy by the surgeon to break up capsular contracture which is scar contracture occurring around and in a sub-clinically infected implant.
- Trauma such as automobile accidents or direct trauma during falls. and
- Mammograms.

Many patients report that the implant pops during a mammogram and they become ill two to three weeks later with symptoms of silicone toxicity. For this reason I do not recommend mammograms be done as screening tests on patients with silicone gel implants and avoided with patients with saline implants if they are over 5 years of age. Fortunately, there is a study from Taiwan showing that women with breast implants have better breast cancer detection using ultrasound than mammogram although this is an area that requires further study.[2] The role of breast MRI's in the detection of breast cancer in patients with breast implants also deserves investigation. An article in the American Journal of Roentgenology reports that women with breast implants who undergo mammography may receive an unacceptable level of radiation compared to women without breast implants that may place them at a higher rate for breast cancer.[3]

Implants can be placed either above the muscle which is called submammary or below the muscle which is called submuscular. The submuscular position can either be just below the pectoralis but not above the serratus or total submuscular coverage which is below the pectoral and serratus muscles. Approaches for putting the implants in include submammary which is the most common approach used, periareolar which is less commonly used due to increased rate of capsular contracture as well as loss of nipple sensation and loss of ability to breast feed, and finally axillary and umbilical approaches both of which are less desirable because of contamination issues through these areas especially with fungus as well as difficulty in adequately releasing part of the insertion of the pectoralis muscle if needed through these approaches. Implants with capsules can only be explanted through the submammary and periareolar approaches and only if the periareolar incision is long enough. Normally a submammary approach is better especially with silicone. It is important to try to remove the silicone implants en bloc or with the capsule intact around the implant in order to avoid silicone spillage

which can occur if the capsule is opened during surgery before removal from the chest wall. This is not always possible especially in the submuscular position when the capsule is very adherent to the ribs and the implant becomes exposed during this dissection. Saline implants can be removed through a periareolar incision with fewer problems as long as the implant is not ruptured. Occasionally it is necessary to make an incision in the axilla to remove the axillary and high infraclavicular capsule which cannot be reached from the submammary position especially if the patient has a long chest wall. Many plastic surgeons and general surgeons doing explantation do not take proper care and remove large amounts of muscle and/or breast tissue with the capsule which is easy to do if you are not familiar with the anatomy and there by create indentations and other breast deformities. If implants are over 300 to 350 cc's, often a donut and/or internal mastopexy is necessary to remove extra skin so that wrinkling does not occur. If the nipple areolar complexes are low, an asymmetrical donut mastopexy can be performed to raise the nipple and remove the excess skin. If the patient has severe ptosis, for example grade III ptosis, with the nipples are pointing to the ground, it is necessary to perform a more extensive mastopexy such as in an internal, a lollypop, or even an anchor pattern mastopexy in some cases. I prefer <u>not</u> to routinely perform the anchor pattern mastopexy unless they have already have had that done in the past because of the potential loss of blood supply of the nipple areolar complex which can result in loss of the nipple areolar complex, partial or complete. If an anchor pattern mastopexy is done, it is best to avoid extensive undermining and perform a dermal lift.

So when patients come to you with silicone implants in, there needs to be a determination whether the patient requires removal of the implants. The guidelines that I use include presence of the silicone symptoms which are outlined in the medical symptom questionnaire and the age of the implant. There is literature recommending that any silicone gel implant over 8 years of age be removed because of the effect of this lipolysis reaction. I do not necessarily recommend removal of silicone implants in asymptomatic patients that are less than 8 years old. I do try to educate the patients, however, on early symptoms of silicone leakage which includes burning discomfort of the chest wall sometimes associated with paresthesias of the arm on that side and the immune symptoms which most often are sinusitis, periodontal disease and frequent viral infections which fail to clear up in a timely manner. If the patient is already explanted, they need to be examined carefully for enlarged lymph nodes in the lower axilla. These lymph nodes are usually approximately 1-2 cm in diameter and contain pathology consistent with silicone induced histiocytosis upon biopsy. Often lymphatic channels in the lower axilla also filled with silicone. If needed, ultrasound of the axilla as well as the breast can be obtained and sometimes intra-breast tissue lymph nodes as well as these lower axillary lymph nodes are found to be enlarged. Other areas of silicone accumulation can be picked up on ultrasound, mammogram and MRI and are usually associated with tender areas. It is important to understand, however, that we often find a silicone accumulation in the breast with negative tests including ultrasound, mammogram and breast MRI. And these tests can only find retained silicone when the volume of silicone is of a certain amount and require an experienced ultrasoundographer. It is very important to remove any silicone collections in the chest wall, axilla or other locations. Patients who have had closed capsulotomies often have silicone even in their upper abdominal areas and up the axilla to the

chest wall including the brachial plexus and MRI's have been useful to test and locate these areas. In the case of ruptured implants, the body will gather up the silicone over several years and form a silicone granuloma which is tender, firm, and distinct from surrounding tissue. These can be localized on physical examination, mammogram, ultrasound, and MRI (the MRI is especially useful if you are looking in the abdomen and up into the axilla). These areas should be removed surgically if present. If the patient has already been explanted and has deformities such as indentations, excess waviness and rippling of the skin, nipple inversion, nipple drooping, and breast ptosis, these can be improved with the various mastopexy techniques discussed above. In most cases, however, and in some cases of severe deformity, we first attempt to correct the chest wall muscle deformity by internal chest wall muscle surgery but if the deformity is too great the patient may actually have to have breast reconstruction including a latissimus dorsi flap or sometimes a TRAM flap. If the patient has a negative silicone T cell sensitivity test and is willing to take the risk of future immune and autoimmune problems with the Silastic shell of the smooth saline implant, I have corrected deformities with reimplantation using smooth saline implants if the chest wall deformities are severe and especially if insurance coverage is not available for the other reconstruction techniques as all of these non-implant techniques are very expensive. Future techniques including stem cell, hyuronic acid and fat transfers may be developed.

If a patient is having chest wall pain, this is a symptom of either infection or inflammation from retained silicone in most cases. The other cause of pain is fibrocystic disease which I have seen in a large number of cases especially over areas of retained silicone and/or recurrent capsules. When I culture the areas of fibrocystic disease they are positive for bacteria in many cases. This mastodynia appears to respond to antibiotics as well as anti-fungal agents, however, when the medicines are stopped the pain often returns. In some cases, in those patients not responsive to the holistic protocol for fibrocystic disease, with massive amounts of silicone and fibrocystic disease in the breast, I have had to do subcutaneous mastectomies to control the disease. Usually, however, we try to limit the surgery to partial mastectomies just removing the fibrocystic disease tissue as well as the areas of retained silicone. In patients with severe ruptures, I have had to go back five and six times to do this separated by a period of one to three years between each surgery. Fortunately, the body tends to gather up the silicone over time as tender silicone granulomas which can be removed with surgery.

In this section of the protocol we will outline the various mechanisms by which silicone and saline breast implants cause disease as well as the different systems affected. The main difference between silicone and saline implants is that the gel in the silicone implants can migrate long distances either directly or more commonly inside macrophages. The silicone is toxic to the macrophages; therefore the macrophages break open, releasing cytokines in areas distant from the chest wall creating a pain condition and inflammation. Saline implants also can cause microscopic silicone to be introduced into the body via the macrophage system especially if the coating is textured. But to give you an example of the degree, a smooth saline implant has only one part of silicone in the capsule compared to one hundred parts in the capsule of the silicone gel implant.[4] Therefore, there is much more leakage out of the shell into the capsule

and thus into the body from silicone gel implants than from saline implants. The silicone gel implants especially in the 1970's (between 1970 and 1985 specifically) had a great deal of gel bleed and the implants developed in 1985 (called low bleed) had less gel bleed but still eventually bled gel after the lipolysis reaction occurred 8 to 10 years after implantation. Silicone spreads widely throughout the body and has a predilection for the neurological system including the CNS. Silicate crystals have been biopsied from the sural nerve in patients with ruptured implants and many patients have lung biopsies positive for silicone. It is felt to go to all major organs including the reproductive organs and the liver. Silicone is found in far areas from the chest wall including underneath the skin and it is sometimes biopsied as a nodule. Many patients have rashes with a sand like material coming out of them which can get infected. They often improve on antibacterial and antifungal creams and/or medicines. If one side of the chest wall is cleaned up with removal of the silicone, the lesions on that corresponding arm decrease. One of my patients had silicone come out of her chin as it migrated up the neck in a retrograde manner in the lymphatic system. Biopsy of the chin lesion showed foreign body granulomatous reaction consistent with silicone. The pathologist was sure that I was biopsing an area from her chin implant but the patient had no chin implant and had only ruptured breast implants. When capsular cultures are performed, approximately half of my silicone gel explants have infection ranging in a wide variety of gram positive and gram negative organisms including staphococcus, pseudomonas, Enterococcus, and a multitude of other organisms. In a high percentage of the saline patients, especially textured saline, capsular cultures are positive as well. We have been successful in isolating fungal elements inside the saline implants in patients ill from biotoxin illness. These are also sent to Dr. Pierre Blais, (Innoval, Ltd) in Canada and he reports different types of fungi inside the implants seen on microscopy including aspergillus. Many patients will not recover without treatment with anti-fungal agents. Patients who go to plastic surgeons who do not treat with anti-fungals often have an exacerbation of their symptoms due to surgical stress combined with peri-operative antibiotics and become very ill for several months after surgery with systemic candidiasis symptoms and bio-toxin symptoms including severe fatigue, myalgias, mental clouding and increased digestive symptoms which are worsened with the ingestion of sugar and carbohydrates. Many of my patients also complain of shortness of breath which resolves on anti-fungal treatment. This may actually be an allergic reaction to pulmonary candidiasis or a bio-toxin symptom from mold. The bacterial infection needs to be treated in these patients around the time of surgery if we have positive capsular cultures which can be used for culture specific antibiotic treatment. Cultures are not always positive so I usually begin the patients on Cipro or Zithromycin in the peri-operative period usually based on the amount of mastodynia or breast tenderness. If they have a great deal of mastodynia, I will begin them on antibiotics prior to surgery along with an anti-fungal agent such as Diflucan if liver function tests are normal. The antibiotic often will usually improve the mastodynia which probably in most cases will reoccur after the patient is done with the medication if the implants are not subsequently removed. I believe that the pain is mostly due to infection but also can be due to inflammation from the cytokine release caused by the silicone in the macrophage. There is a medical report of a 11 patients with atypical chest pain with negative cardiac workups which were probably felt to be due to local inflammatory conditions and neuroma formation of the chest wall due to ruptured and/or leaking breast implants.[5] Migration of the silicone was discussed in the first portion

of this article and needs to be surgically handled when appropriate. Migration throughout the rest of the body, however, needs to be handled with a detoxification program. Other than Dr. Douglas Shanklin's studies of the use of Inositol with urinary excretion of silicate, we have very little information on how effective our detox programs are other than patient reports of clinical improvement. There are a large number of chemicals besides silicone in the implants that require detoxification and therefore detoxification methods that increase intracellular levels of glutathione are important in the detoxification program. Some implants also contain platinum as a catalyst. Platinum after rupture of the implants becomes very toxic causing a clinical syndrome of new onset adult asthma which can be improved with Zantac, multiple lipomas and neurological disease. There is a platinum detox protocol which is available and platinum, if suspected, can be measured on hair analysis as a screening test and/or in a urinary platinum test. There are multiple other methods to detect platinum but I have found the hair analysis to be one of the most reliable. Platinum has since been replaced by tin as a catalyst and we see in our saline patients tin levels rising over time and then decreasing if a detoxification program for tin and other metals is implemented. The other question of mechanism of disease has to do with the adjuvant disease caused by silicone. Silicone is a known adjuvant which means that it stimulates the immune system to respond as do other adjuvants like squalene which was the adjuvant most likely used in the Anthrax vaccine. Typically, adjuvants are used in vaccines to increase the immune response to the antigen in the vaccine which otherwise might not be strong enough to elicit an immune response that would be protective. It is interesting that Dow Corning claimed that silicone was inert as it was a known adjuvant long before the claims that it was inert were stated in the Dow Corning literature. The degree to which individuals react to silicone may be related to HLA types. Dr. Leroy Young studied groups of people and found that certain HLA types are more susceptible to silicone auto-immune disease than others.[6] So, to recap, silicone disease may include several components including infection, silicone migration, reactions to chemicals in the implants other than silicone and, of course, silicone and the potential for silicone to act as an adjuvant. I believe that silicone toxicity is mediated a great deal by cytokine formation and that is why Plaquenil which is an interleukin-2 blocker is effective in many women with silicone toxicity. Specifically, the protocols are designed to decrease arachidonic acid and other cytokines in order to help control the pain condition. I find it interesting that my patients with silicone injections, which probably have the largest amount of free silicone in their bodies, subsequently report that diet is the most important factor in controlling their pain. If they do not avoid dietary factors that increase arachidonic acid and cytokines, they have much more pain.

Saline implants have similar problems but less migratory problems because the gel, of course, is not in the implant. As mentioned above, infection appears to be a large problem with the saline implant population that becomes ill. This infection can be around the implant which is often exacerbated by the patient's breast feeding with the implant in the submammary position or it can be within the implant where bacteria and/or fungi are found in the implant with a valve leak. Dr. Pierre Blais has described defective valves in many saline implants and the contamination within the implant which may have occurred at the time of surgery or after surgery which then allows the contaminated fluid to come in contact with the body. I have seen many instances where the patient does not become

ill until the implant begins to leak. And if the implant is not removed in a timely manner the patient becomes progressively more and more ill. Interestingly, the symptoms occurring in patient with a left sided deflation would often remain on the left side of the body including the neurological symptoms. Thus the importance of using a closed saline system where saline is not taken off the back table to fill the implant becomes obvious as well as trying to decrease any skin contamination by using a sleeve in the case of a small opening and also the importance of avoiding bringing the implant in contact with breast tissue. It is known that breast ducts contain bacteria and are not sterile. Therefore, total submuscular coverage through a submammary incision achieves this goal better than the other approaches. Thus, we also see why axillary and umbilical approaches are less desirable. Saline implant patients also have chemical exposures especially tin toxicity. I have noted that many patients who have high mercury levels do not respond well to saline implants perhaps because of the additive effect of tin and mercury toxicity to the nervous system. Again, especially in the case of textured saline implants where silicone does flake off and get incorporated into the capsule, lymph nodes, and further out into the immune system via macrophages, silicone adjuvant disease may play a role in the illness caused by textured saline implants.

In the next section we will examine immune, auto-immune, neurological, endocrine, and metabolic problems in the breast implant population and the treatment of these problems.

I. IMMUNE ISSUES

When implants begin to leak either silicone gel or saline, often the first symptom is signs of immune system failure especially involving the cellular immune system. The majority of patients will develop signs of systemic candidiasis including muscle aches, fatigue and mental clouding as well as the other symptoms listed above. Bacterial problems such as periodontal disease, sinusitis, bladder infections, bronchitis, H-Pylori infection, and other bacterial infections can become more prominent and more difficult to control. Implant patients have a variety of viral infections including Coxsackie, Epstein-Barr, Herpes, HHV6 as well as inability to clear quickly normal flu and cold viruses. Mold growing in or around breast implants with leaky valves may produce a bio-toxin that leads to immune dysfunction as white blood cells lose regulation of cytokine response. Therefore, attention to the immune system through immune supplements which increase both humeral and cellular immunity are an important part of the protocol. The immune symptoms usually appear before the auto-immune symptoms.

II. AUTOIMMUNE ISSUES

Autoimmune symptoms and signs include Raynaud's syndrome, positive ANA's, elevated sed rates (ESR) and positive rheumatoid factors. In patients with silicone deposits within muscles we see high CPK levels and in some patients we see elevated thyroglobulin antibodies and thyroid Peroxidase antibodies. We also see anti-cardiolipin antibodies in some patients as well as a variety of other antibodies which are positive in Scleroderma and lupus. As far as the auto-immune disease caused by silicone, I do not believe that this is either lupus or rheumatoid arthritis. I have seen some patients who appear to have Scleroderma but they are often treated effectively with long courses of either Cipro or Minocin combined with a holistic protocol with resolution of their symptoms. I also

do not believe that the majority of patients come to me with a diagnosis of multiple sclerosis actually have multiple sclerosis. Very few of my patients with multiple sclerosis have any bladder or bowel problems or optic nerve problems. In a similar note, the patients with a diagnosis of lupus have no renal or CNS involvement which is very common in lupus. I believe these patients have atypical connective tissue disease, and atypical neurological disease caused by the silicone adjuvant mechanism or bio-toxin disease from mold bio-toxins. Overall, the majority of patients with auto-immune disease have clearing of the auto-immune disease with removal of the silicone followed by detoxification and immune support.

III. NEUROLOGICAL PROBLEMS

Neurological problems occur from several mechanisms which may be different in silicone versus saline patients. In silicone patients we see actual migration of the silicone perhaps via the macrophages or directly in some cases along the myelin sheaths up the arm into the axilla along the brachial plexus and down the arm. Many patients have abnormal nerve conduction tests and palpable tenderness along the brachial plexus and nerves of the upper arm. With silicone implants, the silicone migrates into the myelin sheath and auto-immune reaction can occur which can then affect the nerves. If only one side is ruptured and/or leaking it is not uncommon to have one sided neurological symptoms. Typically the upper extremities are affected first. Sensory is affected prior to motor and lower extremities are affected later. There is also a B12 deficiency commonly seen which may exacerbate the neurological disease. Many patients with intestinal candidiasis do not properly absorb B12. Therefore, either sublingual or injectable B12 is necessary. Dr. David Perlmutter, a holistic neurologist, has noted along with other doctors, that large doses of B12 (i.e. B12 3000 micrograms IM q week x 12 weeks) is effective in helping the neurological disease associated with silicone. Many silicone patients come in wheelchairs, unable to walk prior to surgery, are able to walk after appropriate surgical and medical treatment of this disease. It was noted in Canada where the general surgeons were doing the explants but not taking out the capsules and leaving a great deal of ruptured material in the women, that many more women became disabled in wheelchairs than in the US where plastic surgeons generally perform the procedure. Thus, it appears that if explantation is not properly performed, the patient can become very ill. The other supplement that may be important in treating neurological diseases is large doses of alpha Lipoic Acid, (i.e. 1,000 to 2,000 mgs. a day) which helps detoxification of neuro-toxic chemicals by increasing levels of intracellular glutathione.

Bio-toxins from mold in and around the breast implants are neurotoxins which can cause the following if the breast implant is infected:

- numbness
- weakness
- fasciculations or muscle twitching
- blurred vision
- headaches

- abnormal brain MRI's
- mental clouding
- cardiac arrhythmias
- seizures

IV. ENDOCRINE PROBLEMS

Endocrine symptoms occur because of silicone, chemical or bio-toxin activity which acts as an endocrine disruptor. Many women with silicone breast implants have low alpha MSH levels which cause problems with the hypothalamus (see the bio-toxin pathology diagram at www.chronicneurotoxins.com. Silicone is also estrogenic in nature, therefore, women with ruptured and/or leaking silicone gel implants can have increased problems with fibrocystic disease, ovarian cysts and uterine fibroids. It is interesting to note that silicone, because of its cytokine production and pressure from the implant within the breast, actually decreases the risk of breast cancer. The endocrine system which is affected as well, includes a decrease in ADH which presents as nocturnal enuresis which may contribute to the sleep deprivation in the women. If a woman is getting up more than 2 times during the night to urinate, it would be helpful to prescribe Desmopressin nasal spray 0.2 cc. intranasally before bed. Many patients also have sub-clinical hypothyroidism which can be evaluated with use of basal metabolic temperature and the free T4. If the free T4 is in the lower range of 0.8 to 1.0 associated with a basal metabolic temperature below 97, small amounts of Armour Thyroid in the 30 to 90 mg. range and/or appropriate T4 and T3 combinations can greatly improve the fatigue, weight gain, constipation, dry skin, and hair loss. The hair loss is particularly concerning to these women. Many women also have a selenium deficiency where by T4 to T3 conversion is decreased therefore selenium replacement at 200 mcg. a day may be necessary. The third part of the endocrine system which may be disrupted is the adrenal system. Many patients have adrenal insufficiency which can be diagnosed by shining a light on the pupil. If the pupil fails to maintain its constriction but instead waivers back and forth, this indicates adrenal insufficiency. Adrenal stress indices can be measured. If the patient does have cortisol deficiencies, Cortef or other corticosteroids can be prescribed until the condition is corrected via surgery and the detoxification program. Supplements such as Adrenal Stress End, DHEA, and other adrenal support supplements are useful. Some women also have reduced sex hormones which can lead to irregular or altered menses and premature menopause.

V. METABOLIC PROBLEMS

The metabolic problems of silicone include disruption of a portion of the Kreb's cycle. This may account for some of the fatigue via mitochondrial disruption. It is interesting to note that the hyperbaric oxygen is very successful in helping the fatigue associated with silicone immune dysfunction. We have a great deal to learn about the metabolic effects of silicone. Dr. Arthur Brawer has written an informative paper in this area where he also discusses the effects of silicone at the cellular level.[8]

In summary, the most important treatment plan for these patients is removal of the silicone and/or saline implants along with any remaining silicone which has migrated throughout the chest wall and axilla that can be surgically removed. The second most important treatment program is the treatment of the candidiasis and other fungal infections that might be present within the saline implants and can certainly affect the silicone patients as well. This is started usually with Diflucan 200 mgs. po q day x 30 days if liver functions are normal. Other anti-fungals that can be used are Nizoral 200 mg. orally twice a day, Sporanox 200 mg. orally once a day and Vorconizole 200 mg. orally twice a day. It is important to maintain the patient on alpha Lipoic Acid and Milk Thistle (Super Thistle X) during this time for liver protection. If the patient has GI symptoms and/or oral thrush, Nystatin Oral Solution 5 cc's po tid is also useful. Beware of the 'Herkimer Reaction' if too many agents are used at once. After this more natural agents are used such as oil of oregano (ADP), or Pleo-Alb which is a homeopathic rectal suppository may be used. There are a variety of other yeast herbal treatments and of course the importance of probiotics cannot be over emphasized. Patients are begun on Probiotic Pearls or Orthobiotics and are moved up to Primal Defense or other appropriate probiotics depending upon the degree of gut flora disruption. In some patients it is very important to treat viral disease, such as shingles and herpes with traditional medicines such as Valtrex although Monolaurin has been very helpful to treat the underlying viral infections present in most of these patients. There are other anti-virals supplements which are available. Bacterial infections are generally treated with antibiotics. It is important to always maintain the patient on an anti-fungal while on antibiotics. I have had remarkable response to patient's pain condition just by treating with anti-fungal agents alone. In addition, patients who have traveled outside the United States or have been exposed to parasites in uncooked foods may have parasites that present in atypical manner because of their depressed immune system. Supplements to aide in increasing levels of natural killer T cells include EpiCor and Transfer Factor Plus.

The other treatment areas involve treatments of specific symptoms such as migraines, fibromyalgia, adrenal insufficiency, all of which are outlined in the Silicone Immune Protocol. Detoxification methods, of course, include multiple modalities to increase intracellular levels of glutathione in order to process the multiple chemicals also present in the implants. This would include alpha Lipoic Acid, NAC, Recancostat, Immuno Cal (ImuPlus), IV glutathione, and coffee enemas. MSM also helps with detoxification pathways and other detoxification methods include modified fasting which should only be attempted in the patient after removal of the implant. Modified fasting works very well for pain conditions as it decreases circulating levels of immune complexes. It is also important to treat leaky gut syndrome which may be the source of the circulating immune complexes with appropriate detoxification programs such as Metagenics Ultra Clear Sustain and replacement with probiotics. Additional therapies such as ionic and electrolysis foot baths and magnetic clay baths which clinically have been shown to help increase detoxification through the skin may also be useful.

If a patient experiences a relapse it is important to evaluate the symptoms carefully, do appropriate testing and re-institute treatment programs. It is not uncommon to have to treat these patients with several courses of antibiotics combined with anti-fungal therapy. If

a patient is on antibiotics for a different condition it is not uncommon to have to treat with anti-fungals for a long period of time. Please be aware that patients develop resistance to anti-fungals and alternative anti-fungal treatment may be necessary.

In general, patients undergoing the surgical and medical treatment for silicone immune toxicity have improved with the treatment. Many patients have regained their health entirely and the patients that continue to have problems are the ones in which the silicone has been leaking and/or ruptured for the longest period of time prior to the removal of the implants. A scientific paper published in the PPRS journal states that women who have had ruptured implants for over 13 years tend to not improve.[9] However, in our hands, they do improve probably due to the medical detoxification and holistic therapies provided that address medical issues in may different systems. A holistic approach works best as silicone and saline breast implant disease is truly a holistic illness.

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.

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