

Practice Parameter

Treatment Principles of Silicone Breast Implants

I. INTRODUCTION

Cosmetic breast augmentation with silicone implants has been an accepted surgical procedure in the United States for four decades. While there have been changes to the manufacturing process of silicone implants over this time frame, particularly in shell thickness and gel cohesion, few changes in the way the procedure is performed have occurred. This is due to the fact that there continues to be a high degree of patient satisfaction with the results of the procedure as it is currently being carried out. This means that the outcomes from silicone breast implant surgery have been found to be safe, effective, and improve the quality of patients' lives.

Since cosmetic breast implant surgery in general is associated with a low occurrence of surgical complications such as infection, hematoma, and wound dehiscence, these immediate problems do not diminish the effectiveness of long term breast implantation. Most immediate surgical complications are mild and do not lead to additional hospitalization.¹

There are many variables that may influence the long term result and effectiveness of cosmetic breast augmentation surgery. Some of these variables are unpredictable, such as how breast tissue will respond to the implant, how well wound healing will occur after surgery, and the normal alterations in breast shape which occur due to the aging process, weight gain or loss, or pregnancy. However, there are some infrequent sequelae (adverse side effects) such as capsular contracture, seroma, silent rupture, late infection and pain that are particularly challenging and can diminish the effectiveness of the procedure. The long-term results and management of these sequelae can cause patient dissatisfaction, possible implant removal, with or without replacement and increased costs associated with reoperations. Breast implants do not last forever and it is likely that a patient will need to have one or more reoperations over the course of a lifetime.

The primary focus of this Practice Parameter is directed toward two areas that are unique to silicone breast implant surgery. First, an overview and management of unique long term effects which may occur after the typical postoperative recovery period, or even much later, up to years after the surgery. Secondly, general long term considerations. This Practice Parameter will not address alleged connective tissue disorders or rheumatic diseases. To date, several large epidemiological studies of women with and without implants indicate there is no scientific evidence that women with silicone breast implants have an increased risk of connective tissue diseases. These diseases appear to be no more common in women with implants than those women without implants.²

II. DISCLAIMER

Practice parameters are strategies for patient management developed to assist physicians in clinical decision making. This practice parameter, based on a thorough evaluation of the scientific literature and relevant clinical experience, describes a range of generally acceptable approaches to diagnose, manage, or prevent specific diseases or conditions. This

practice parameter attempts to define principles of practice that should generally meet the needs of most patients in most circumstances.

However, this practice parameter should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all the circumstances presented by the patient, the diagnostic and treatment options available and available resources.

This practice parameter is not intended to define or serve as a standard of medical care. Standards of medical care are determined on the basis of all the facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. This practice parameter reflects the state of knowledge current at the time of publication. Given the inevitable changes in scientific information and technology, periodic review, updating and revision is anticipated.

III. BACKGROUND

Informed Consent

Preoperative education regarding risks, alternatives, consequences, and benefits is essential to ensure successful outcomes and patient satisfaction. Each patient presents with a unique situation relative to the size, shape and condition of her breasts and needs to be carefully informed of the realistic expectations which may be obtained based on her own physical presentation before surgery. Patients should be educated to the consequences of negative conditions such as capsular contracture, implant malposition, implant rupture, and the possibility of re-operation. Surgeons should discuss with their patients that at some point, critical management decisions about their implants may be needed and financial responsibility for future treatment should be discussed prior to the initial surgery.

Surgical Technique

There is a general consensus among plastic surgeons that silicone breast augmentation can be successfully performed by a variety of techniques and no one technique is best suited for all situations. When selecting the breast implant incision site the surgeon takes into consideration the patient's individual clinical characteristics, the desired aesthetic results and patient preference. Due to their pre-filled size, silicone gel-filled implants, especially textured implants, need a larger incision than inflatable saline implants. The incision size influences the insertion site options as care must be used to avoid damage to the implant at the time of insertion that may cause premature failure. Damage to an implant might occur if an implant is inserted through an incision that is too short or a subcutaneous tunnel that is too constricting.



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Two of the most common silicone breast implant insertion approaches include the inframammary and periareolar incisions. Both are basic, straightforward and without significant changes over the past forty years. There is debate over distant site insertion incisions such as the trans-axillary and umbilical (TUBA) methods. The trans-axillary approach is utilized by some surgeons as the insertion site for silicone implants and it has the advantage of a less visible scar. However, the trans-axillary approach is generally not used for secondary or reoperation procedures in situations where the surgeon needs more control to resolve the problem that necessitated the re-operation.³ The TUBA approach is limited to inflatable saline implants and therefore cannot be utilized for the placement of silicone breast implants.⁴

Mastopexy, or breast lift with skin reduction, has also been in wide use for decades, often in conjunction with silicone implant insertion. Other than vertical mastopexy with simultaneous implantation, there has been little in the way of new incisions or techniques. There is some debate associated with a one-stage (simultaneous) augmentation combined with a mastopexy in contrast to a two staged approach, with a mastopexy first followed by an augmentation at a later date.^{5,6} Mastopexy is designed to reposition the nipple, reshape the breast, and reduce the skin envelope, while an augmentation enlarges the volume of the breast and expands the skin envelope. Many one-stage procedures result in successful outcomes and satisfied patients, however there is an increased possibility of complications including infection, implant exposure, reoperations, loss of nipple sensation, and malposition of the nipple and/or implant.^{6,7}

Choosing an appropriate pocket location for placement of the silicone implant is an important decision. Placement choices include submuscular (under the pectoral muscle), subglandular (in front of the muscle and behind the breast tissue) or dual-plane (partially submuscular and partially submammary). Surgeons debate the benefits and drawbacks for each method mindful that providing adequate long-term soft tissue coverage over any implant is critical to minimizing long-term tissue compromise and reoperation. The pocket choice is typically determined by the patient's body type, the amount of soft tissue coverage available and the type and size of the implant.

The different pocket locations have advantages and drawbacks. The submuscular placement is widely accepted and offers the added benefit of thicker implant coverage for thin women. Studies indicate that submuscular implant placement allows for greater mammographic visualization when compared with sub-glandular placement, regardless of breast size or implant type and size.⁸ Potential drawbacks for the submuscular position include the possibility of the distortion of breast shape during pectoralis muscle contraction and a risk for implant displacement upward or other malposition. Patients who have adequate skin and breast volume may be candidates for subglandular placement which may be a less painful procedure. Patients with inadequate skin or breast volume may experience visible or palpable outer shell edges or rippling with subglandular placement.³ The risk of capsular contracture is generally higher with subglandular placement. Depending on the patient's physical condition, some surgeons prefer the dual-plane augmentation and maintain that it optimizes the benefits of each pocket location while limiting the tradeoffs of a single pocket approach.⁹ In general, regardless of the implant position, discomfort levels are the same by ten days in most patients.

IV. PERIOPERATIVE MANAGEMENT

Antibiotic Use

The intra-operative prophylactic use of antibiotics is a time honored surgical dictum and most surgeons administer antibiotics just before the time of surgery (most commonly cephalosporin type antibiotics when not contraindicated due to an allergy). Studies indicate systemic antibiotic prophylaxis at the time of breast augmentation surgery was associated with a significant reduction in the infection rate (0.42% vs. 0.87%).¹⁰

Differences of opinion exist regarding minimizing contact with the implant shell at the time of insertion and whether or not to irrigate the pocket prior to insertion with antibiotic solutions. Many surgeons advocate the use of irrigating the implants and the pocket prior to insertion with antibiotic solutions. The use of povidone-iodine (betadine) in pocket irrigation has been more controversial. In 2000 the U.S. Food and Drug Administration (FDA) announced that any contact between breast implants and betadine is contraindicated due to reports of potential weakening of silicone shell.¹¹ However, there have been recent studies that found no evidence that betadine irrigation leads to weakened implant shell integrity.^{12,13}

Postoperative prophylactic usage of antibiotics varies. Some surgeons prescribe antibiotic under the theory that their use will reduce the risk of late capsular contracture but more clinical trials are necessary before this can be recommended.¹⁰

Postoperative Care

Management of the silicone breast implant patient during the immediate post-operative recovery period varies among surgeons. Surgical compression bras are preferred by some, while others prefer breast bands to maintain implant position. Massage of the implants is advocated by some surgeons, although there is no data comparing patients who do massage in contrast to those who do not.¹⁴ When to release the patient to regular activities may vary from surgeon to surgeon. In general the immediate post operative results are dependant more on individual differences in the patient's ability to heal than on the independent variables of surgical technique or instructions for after-care.

Commonly accepted principles of caring for any patient with a peri-operative emergency such as bleeding, nausea and vomiting or a wound infection are typically no different with breast implants than any other surgical procedure. Evacuation of a post-operative hematoma is a well accepted treatment but fortunately is rarely necessary. While studies vary, one recent study indicated that a hematoma occurred in 2.3 percent of implantations and occurred on average on the fifth post-operative day.¹ In general though, the surgical principles to stop bleeding, manage post operative hemodynamic volume changes, nausea and vomiting and treat infections with drainage and antibiotics, are true of all surgical disciplines and their basic application to silicone implants has very little in the way of unique elements or drawbacks.

V. MANAGEMENT OF UNIQUE LONG TERM EFFECTS OF SILICONE IMPLANTS

In contrast to the general agreement associated with immediate postoperative care, there is a variation of opinions among plastic surgeons regarding care of the assortment of other conditions unique to silicone implants. These include pain, late infections, seroma, silent rupture and capsular contracture. Many of these conditions can present physical

barriers to accurate assessment by manual examination. Even radiological testing can occasionally be inaccurate. These situations require skillful assessment and adept surgical management as surgeons must strike a balance between the patient's history and symptoms, which may be vague, misleading and are often accompanied by limited physical findings. To help surgeons with their management and decision making process unique to silicone breast implants, a series of paradigms are outlined below.

Pain

The new onset of breast pain, not associated with the immediate post-operative period, can be problematic. In one study comparing long term symptoms in women following breast implant surgery and reduction mammoplasty surgery, the implant patients were three times more likely to report pain than the reduction mammoplasty patients.¹⁵ Late onset pain can be attributed to a variety of causes, some of which are well understood, while others are more puzzling. Possible causes of late onset pain include rupture, infection and calcification around the implant. Capsule formation, especially under the muscle, may result in nerve compression and pain. However, late onset breast pain is most commonly associated with pain from capsular contracture.¹⁶ The occurrence of atypical pain months or even years after insertion of an implant should not be dismissed and requires an accurate analysis of the possible causes and associated diagnoses.

Unilateral and bilateral pain occurring at the time of the menstrual cycle may change after breast implantation. By elucidating the timing of the onset and dissipation, this type of pain is usually not difficult to assess and manage by history, physical examination, medication and reassurance.

Some patients experience unilateral, positional pain. Usually neurogenic in origin, this type of pain dissipates over time and can occur as scar tissue forms along the capsule interface with the branches of the inter-costal nerves. Symptom presentation may often be vague and confusing, and accompanied by non-specific physical findings. Palpable neuromas are extremely rare. More often there is localization of the pain by manual examination but without textural or structural changes in the soft tissue. Since pain may also be a symptom of capsule thickening or implant rupture, a series of calculated steps should be undertaken in the work up of these symptoms. These patients should undergo serial examination and if the pain remains constant and unchanged in nature, a mammogram, ultrasound or MRI examination may be necessary to determine the status of the implant and source of the pain.

In light of non-specific or even normal physical findings with negative radiological testing for rupture, symptomatic treatment should be undertaken. Anti-neuritic medications such as Neurontin may reduce symptoms if used at appropriate levels. Anti-inflammatories may also be useful. Treatment may take place over a few days or many months until the pain subsides. Re-examination and retesting at intervals is needed to reassure both the patient and the surgeon that the implant has not ruptured or has been the subject of false negative testing. False negative MRI examination is uncommon but should be considered in all patients with persistent unexplained pain. Ultimately, exploration of the implant to ensure its status may be necessary in rare instances. Capsulorrhaphy, capsulectomy, or capsulotomy may be appropriate to reposition the implant to relieve capsular contracture, but may not relieve true neurogenic pain.

Late Infection

Late breast implant infections can occur at any time from a month to many years after the implant surgery. In a survey of 10,941 patients who underwent breast augmentation, 0.8 percent of the patients experienced late infections.¹⁰ The pathogenesis of a late infection of the breast occurring one or more months after insertion of a breast implant is mostly anecdotal, however some studies indicate that late infections may result from secondary bacteremia or an invasive procedure in a location other than the breast. The site of implantation may act as a trap for bacteria, particularly when bloodstream infection occurs. Some authors recommend that invasive dental or surgical procedures performed under septic conditions be accompanied by antibiotic prophylaxis although there is no scientific evidence at the present time to support such a recommendation.¹⁰ Individuals with breast implants seeking to undergo body piercing procedures to the breast region must consider the possibility that an infection could develop anytime following this procedure. Individuals who currently wear body piercing jewelry in the breast region are advised that a breast infection could also develop from this activity.

Another possible route of breast implant infection is the human breast itself, as it is not a sterile anatomic structure. Breast ducts are known to harbor bacteriological flora similar to that of the skin which can provide a passage from the skin surface to deep within the breast tissue.¹⁰ Seemingly insignificant trauma to the breast may spread an innocuous contagium into the less vascularized peri-capsular scar where the body's ability to mount an anti-pathogen response is physically affected by the reduction in blood flow within the capsular tissues.

A dull ache in the parenchyma of the breast may be the only presenting symptom followed by malaise and a low grade fever days later. Elevations of the white count may be low and non-specific at this point. Unfortunately, confusion about the signs and symptoms of late breast implant infection can lead to delay in the diagnosis and proper management. It is critical that the initial treatment is directed at an accurate diagnosis of the primary underlying problem.

In the past, the treatment for periprosthetic infection typically involved removing the breast implant, treating the infection and replacing the implant at a later date. Surgeons no longer assume the implant must be removed and instead determine the appropriate treatment based on the severity of the infection. In many cases the infection will resolve with antibiotic treatment and implant removal is not always required.¹⁷ When to remove an implant in the light of a low grade infection is controversial. Most surgeons advocate removal as a last resort. However, in clinical situations with severe infectious conditions and in the absence of an identified source of infection, removal of the implants should be strongly considered.¹⁰

In cases where infection is suspected and the patient presents with erythema and/or a fever of 101° or greater, empiric antibiotics should be prescribed. If the symptoms resolve in two weeks, no further treatment may be needed. If symptoms persist, the next step is to explore the implant and irrigate the pocket. Any exudate should be cultured and culture specific antibiotics prescribed.¹⁸ Draining the pocket without removal of the implant(s) is an alternative. Transcutaneous placement of a drain must be carefully considered due to the risk of implant puncture and subsequent shell failure. If at any time signs or symptoms of sepsis (fever > 102°, chills or rash) occur during the treatment period, the patient should be hospitalized. Blood cultures should be obtained and intravenous antibiotics started. An infectious disease consult may be requested.¹⁸

The management of a severe infection usually involves removal of the implant along with post surgical drainage and a 10 to 14 day course of antibiotics, usually intravenously.¹⁰ There are differences of opinion regarding the optimal length of time between implant removal and re-insertion. Factors such as the causative organism(s), the appropriateness of and duration of antimicrobial therapy, fluid formation, condition of the patient's tissue and patient's preferences all influence the timing for implant replacement.

If the patient and physician choose to replace the implant, a new implant should be inserted once the breast and the pocket have been sterilized by antibiotics and the passage of time. The FDA designates breast implants as single use devices which should not be sterilized and reinserted.¹⁹ The removal of one or both implants at the time of treatment and replacement at a later time is a matter of debate but should also be considered in the surgeons' discussion of the alternatives with the patient. There is often great reluctance to this alternative because of added expense and the psychological impact on the patient. But it must be considered as one of the alternative treatment choices at any point during the management of a breast implant infection.

Seroma

Rare fluid collections within the capsule can occur but the origin of the fluid is unknown. Significant collections can expand the size of the breast and be the first presenting sign of a seroma. If the breast is enlarged and intracapsular fluid is present, an ultrasound assisted aspiration with culture and sensitivity should be performed and antibiotics ordered.¹⁸ Reports of fluid microbiology usually reveal sterile fluid similar to serum with high white counts; only rarely do cultures of these seromas grow bacteria, fungus or mycobacteria. If the symptoms resolve in two weeks and the culture is negative, no further treatment may be needed. However, sporadic case reports reveal a high frequency of recurrence. If the fluid returns, intra-operative drainage is the rule with or without removal of the implant. Drains placed at the time of surgical exploration are useful but can lead to further scarring. In recurrent seromas, removal of the implant should be considered but seroma formation after implant removal has been known to persist and long term drainage may be needed. The exact pathogenesis is not known.

Silent Rupture

Unexplained or spontaneous implant rupture can occur, even in patients without rupture risk factors such as trauma or surgical and diagnostic procedures involving the breast or chest. Because silent ruptures can go unnoticed by both patients and physicians, the frequency is unknown. However, in a recent Danish study using magnetic resonance imaging (MRI), Holmich reported a silicone breast implant rupture incidence rate of approximately two implant ruptures per 100 implant years, with an estimated 5-year survival probability of 98 percent and 10-year survival of 83 – 85 percent.²⁰

In rare instances, free silicone from ruptured implants has been known to extend to contiguous body regions which make interpretation of local symptoms more difficult. Most commonly the leaked silicone remains in the intracapsular space, which explains why the physical findings associated with a rupture may be absent and often unnoticed by the patient.²¹ Subtle changes to the breast may occur and may be the only presenting symptoms. These findings may include: slight changes in the position of the implant or shape of the breast, vague discomfort, and changes in the texture, softness or firmness of the implant. Some breast capsules relax after rupture while more often the capsule may thicken in response to the rupture. Palpable

shell failures may be difficult to ascertain even in well experienced examiner's hands. Lymphadenopathy is not often associated with silent rupture.

When signs of rupture occur, MRI examination or ultrasonography and mammography may be used to confirm the diagnosis. Studies indicate MRI is generally the accepted state-of-the-art technique for evaluation of implant integrity.²² Some surgeons recommend first screening with ultrasonography in combination with mammography as radiologists indicate the combined approach is 80-90 percent accurate in diagnosing implant rupture and also less expensive than an MRI.²³ If a diagnosis cannot be obtained utilizing physical examination or ultrasonography and mammography results, an MRI should be ordered.

There is a general consensus that symptomatic and/or extracapsular implant rupture warrants explantation with or without implant replacement. Explantation is recommended when the signs of silicone migration such as pain, lumps, granulomas, and increasing fibrosis are present.²¹ This is particularly true in light of a recent study which reported women with extracapsular ruptures were six times more likely to experience capsular contracture than women who had intact implants.²⁴

However, the plan of treatment for asymptomatic implant ruptures is more controversial. A recent study by Holmich studied asymptomatic ruptured silicone implants patients over two years and suggested that in most instances, implant rupture was harmless and did not produce significant clinical symptoms or activate the humoral immune system. There was a small risk of progression of silicone gel migration because free silicone was kept in place by the surrounding fibrous capsule.²¹ This suggests that asymptomatic women could be followed with regular clinical examinations, including evaluation of specific signs of silicone migration.

The physician who has detected a silent rupture must provide the patient with complete information on the pros and cons of explantation with or without replantation versus a watch and see approach. This includes the risks of possible silicone migration weighed against the risks associated with explantation surgery. If explantation surgery is chosen the patient may choose to replace one or both implants with saline or silicone implant(s).

Whether to remove the capsule at the time of replacement is dependant on the amount of thickening, calcification and silicone leakage found, the surgeon's judgment and the patient's desires. Some advocate changing the pocket in regards to sub-muscular or sub-glandular implant position, i.e. moving the implant to the opposite position from the one originally chosen for implant location.

Patients may be advised to undergo MRI examination in the future to verify the condition of the breast implants inside their body. There is no consensus on routine silent rupture screening for silicone breast implant patients. Some advocate that all asymptomatic patients routinely undergo a screening MRI at 10 years and every 5 years thereafter. At this point there is no science to support the health benefits of screening all asymptomatic patients nor has a cost to health benefit analysis been performed.

Capsular Contracture

Capsular contracture is the most frequent condition that leads to re-operation after breast implant surgery.¹ The specific rate of capsular contracture is unknown as study rates vary greatly depending on the type, texture, placement and age of the implant. Infection, hematoma, silicone bleed and individual predisposition to hypertrophic scarring are thought to be factors associated with capsular contracture formation.¹⁰

For over thirty years there has been wide spread acceptance of the Baker system, a four tier scale that grades capsule thickening or contracture. Grade I has been accepted to be the softest result without palpable thickening. Grade II results have a more palpable implant, a little firmness, but no visible changes in the appearance of the results. Grade III represents greater implant palpability and firmness but also visible distortion in the position of the implant, as well as the possibility of some level of pain. Grade IV typically represents severe distortion or malposition as well as hardening that is symptomatic.

Large variations in the timing and methods of treating capsular contracture exist. Patients may accept Grade II contractures, especially if they are bilateral. Few patients, however, feel comfortable with untreated unilateral Grade III or IV conditions. In the past, manual rupture of the capsule, or closed capsulotomy, was a relatively common procedure, however the practice is expressly discouraged by the manufacturers and contraindicated by the FDA as it can cause implant rupture or deflation.¹¹ Capsular contracture treatment options available include:²⁵

- No clinical treatment and continue to accept the symptoms.
- Remove existing implants, do not replace implants, do not remove capsules.
- Remove existing implants, do not replace implants, perform capsulectomy.
- Remove existing implants, release capsule (capsulotomy), replace with new implants.
- Remove existing implants, perform open capsulectomy, replace implant with new implants.

There are advantages and trade offs to all of the capsular contraction treatment options listed above and at this point there is no one accepted standard. The treatment choice must be tailored to the patient's needs and wishes as no one option is best suited for all patients. Recurrent capsular formation can lead to discussions about removal without replacement, an option that should always be considered but may not be readily accepted by the patient, especially when there has been long term placement of the original implants.

At this point there is no one accepted standard that will prevent a recurrence of capsular contracture. However, some surgeons report excellent results when they change the pocket from a submammary or a submuscular location to a dual-plane pocket.²⁶ Other suggestions include replacing implants with a different texture surface than the originals,²⁵ and taking steps to prevent possible predisposing causes such as infection and hematoma development.

VI. GENERAL LONG TERM CONSIDERATIONS

Breast Cancer Screening

Current medical information does not demonstrate an increased risk of breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes.¹⁶ It is recommended that all women perform periodic self-examination of their breasts, have mammography according to American Cancer Society guidelines, and to seek professional care should a breast lump be detected.

Breast implants may make mammography more difficult and may obscure the detection of breast cancer. Any breast implant can impair the detection

of breast cancer, regardless of the type of implant or where it is placed in relation to the breast. Implant rupture can occur from breast compression during mammography and patients should be advised to inform the mammography technologist of the presence of breast implants so that appropriate mammogram studies may be obtained. Patients with capsular contracture may find mammogram techniques painful and the difficulty of breast imaging may increase with the extent of contracture. Because more x-ray views are necessary with specialized mammography techniques, women with breast implants will receive more radiation than women without implants who receive a normal exam. However, the benefit of the mammogram in finding cancer outweighs the risk of additional x-rays. Many patients undergo a pre-operative mammogram and another one after implantation to establish a baseline view of their breast tissue.

Breast augmentation procedures, such as the periareolar incision that involve cutting through breast tissue can potentially interfere with sentinel lymph node mapping procedures. If this is a concern, individuals considering breast augmentation by these approaches may elect to consider another surgical approach such as inframammary or standard periareolar.

Ultrasound, specialized mammography and MRI studies may be of benefit to evaluate breast lumps and the condition of the implant(s). If a breast biopsy is ordered, care must be exercised to avoid damaging the breast implant.

Breast Feeding

While women have successfully breast-fed their children after breast augmentation, some may experience problems. The IOM report said that women with either silicone gel-filled or saline-filled breast implants showed lactation insufficiency ranging from 28-64%. The periareolar approach was the factor most associated with lactation insufficiency. The IOM report said that there is convincing evidence that infants breast-fed by mothers with breast implants receive no higher elemental silicone intake from breast milk than infants breast-fed by mothers without breast implants.¹¹

Routine Post-augmentation Long-term Follow-up

There have been no published studies regarding the effectiveness of routine follow-up of the asymptomatic breast augmentation patient. However, it is recommended that the surgeon maintain routine follow-up with all patients at three to five year intervals post-operatively. This would include a directed history and physical examination to monitor outcome, quality, patient satisfaction and to screen for implant related problems including silent rupture. MRI examination of asymptomatic patients 10-years after implantation should be considered to screen for silent rupture and at subsequent five year intervals. Patients should be encouraged to notify the surgeon's office of any address changes and to return sooner for reevaluation if they notice any new changes in their breasts.

VII. CONCLUSIONS

Difficult decisions when dealing with these rare conditions are faced by both surgeons and implant patients from time to time. Many of these occurrences are seen later, sometimes even years after implant placement. These rare events tend to be unique to each patient both in terms of onset, and treatment response. Options exist, including temporary or permanent removal of implants that must be emphasized when dealing with these patients.

Established surgical principles should be applied in all cases such as physical examination and radiological testing, sometimes serially, in order

to increase the accuracy of diagnosis, and when making patient management decisions.

The decision to return to the operating room should also follow general guidelines applicable to all surgeons, including drainage cultures, and antibiotics when dealing with seroma or infection. Capsule removal with or without implant replacement is a time honored principle of plastic surgery as well, unique to breast implants.

The goal of this practice parameter is to foster the safety, efficacy and patient satisfaction of breast augmentation for all patients.

VI. REFERENCES

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