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Capsular Contracture in Breast Augmentation: Medical Management and Indications for Capsulectomy

Whitney Florin, MD, DDS[1] and Jacob Haiavy, MD, DDS, FACS[1]

Abstract

This article reviews the literature on the etiology and management of capsular contracture, focusing on indications for capsulectomy along with explantation of breast implants. This article outlines the clinical factors which should be considered when managing capsular contracture. This article offers the most comprehensive review to date of surgical and nonsurgical management of capsular contracture. The goal of treatment is to prevent recurrence of capsular contracture, minimize risk to the patient, and obtain esthetic results. Capsulectomy is indicated in the majority of cases when breast implants are being removed or replaced in the setting of contracture. However, the surgeon must consider the risks and benefits of capsulectomy.

Keywords

breast augmentation, general cosmetic surgery

Introduction

Background

Breast augmentation is one of the most popular cosmetic surgeries performed worldwide. In fact, breast augmentation was among the top 2 most commonly performed surgeries in the United States in 2016.[1,2] The number of breast augmentations has grown 4% from 2015, with over 300,000 procedures performed in 2016.[1] Notably, removal of breast implants saw a 13% increase compared with 2015, with over 43,000 cases performed in 2016.[2] In 2016, Americans spent more than 15 billion dollars on surgical and nonsurgical cosmetic procedures, with a 1.5 billion dollar increase in expenditures over the past year. Surgical procedures account for 56% of the total expenditures.[2]

Capsular contracture is a troublesome complication of breast implants which may require revision surgery. Capsular contracture initially presents with firmness of the breast and can progress to pain and distortion of the breast shape and volume. When an implant is placed, a fibrous capsule forms around it. In a normal breast, the capsule is thin and soft, with no effect on the appearance of the breast. In a contracted breast, the capsule becomes thick and hard, and shrinks in a way which alters the contour of the breast and the position of the implant.[3,4] Contracture is thought to be due to a chronic inflammatory process in the implant pocket, which converts a normal foreign body response to a pathologic response. The process is not completely understood but seems to be affected by bacterial contamination or biofilm, blood, silicone gel leakage, and tissue trauma.[4-6]

The Baker classification describes 4 grades of capsular contracture (Table 1), with grade I being a normal, soft breast; grade II being a minimally firm breast; grade III being a moderately firm breast with some visible deformity; and grade IV being a painful, hard, and obviously distorted breast[4,7] (Figure 1). Typically grade III and grade IV capsular contracture require surgical management.[3,4,8,9]

Reported rates of capsular contracture vary widely from 1% to 30% of patients who receive implants.[3,4,9,10] The strongest data come from premarket approval studies. The rates of capsular contracture in these studies range from 2% to 15% after primary breast augmentation, and from 5% to 22% after revision breast augmentation with a 3- to 7-year follow-up.[11-22] Capsular contracture is often cited as one of the most common reasons for reoperation after breast augmentation.[4]

Araco et al[3] found that approximately 92% of contractures occur within the first 12 months of surgery. Others report that contracture typically develops within the first few

[1]Inland Cosmetic Surgery, Rancho Cucamonga, CA, USA

Corresponding Author:
Whitney Florin, Associate, Inland Cosmetic Surgery, 8680 Monroe Court, Rancho Cucamonga, CA 91730, USA.
Email: drwhitneyflorin@gmail.com

Table 1. Baker Classification of Capsular Contracture.

Grade	Description
I	Normal breast
II	Minimally firm breast
III	Moderately firm breast with some visible deformity
IV	Painful, hard, and obviously distorted breast

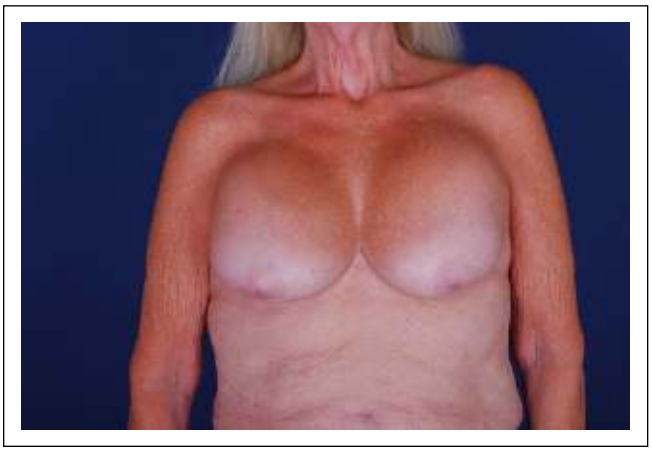

Figure 1. An example of bilateral grade IV capsular contracture with obviously distorted breasts which were hard and painful.

months after implantation; however, signs of contracture may present over 5 years after breast augmentation.[23] Some factors increase the likelihood of contracture, including the indication for surgery (reconstruction vs cosmetic), type of implant used (smooth vs textured, saline vs silicone), and implant pocket (subglandular vs submuscular).[3]

Reconstruction Versus Cosmetic Augmentation

Capsular contracture occurs more often in cases of breast reconstruction versus cosmetic breast augmentation.[3,4,24,25] Pre- or postoperative exposure to chemotherapy[24] and/or radiation therapy[3,26,27] can increase the risk of contracture in reconstruction patients. These treatments impair the immunologic response of the tissue and enhance the fibrosis of tissue that normally forms around a foreign body. However, the extent to which chemotherapy and radiotherapy contribute to capsular contracture is not fully understood.[3]

In 2009, Araco et al[3] published a systematic review of the current literature on capsular contracture. Six studies which investigated the relationship between adjuvant chemotherapy and breast reconstruction were reviewed.[28-33] Interestingly, only 1 out of the 6 studies showed a statistically significant increase in the occurrence of wound complications in patients receiving adjuvant chemotherapy.[31] It is notable that there are no studies on the long-term side effects of chemotherapy on tissue or the rates of capsular contracture.[3]

Radiation therapy is another important factor to consider in patients undergoing reconstructive surgery. Radiation is known to increase the incidence of capsular contracture, implant rupture, hematoma, and infection.[3] The rate of capsular contracture was higher in the irradiated group in 13 articles which were reviewed in Araco et al.[3] However, most studies are retrospective and include patients who received radiation therapy at variable clinical time points (before, during, or after reconstruction). These studies do not control for concomitant chemotherapy, implant position, or implant type. Moreover, these studies do not include all types of contracture, but rather only Baker grade III or IV contractures. This variability may explain the wide range of reported capsular contracture in the irradiated groups (32%-73%) compared with the nonirradiated groups (0%-40%). Despite the variation, all studies show the significant risk of capsular contracture in the setting of radiation therapy.[3]

Prevention of Capsular Contracture

Measures to prevent capsular contracture are well described in the literature. These include preoperative intravenous antibiotics, sterile and atraumatic techniques (including Keller funnel for silicone implants), careful hemostasis, and triple antibiotic irrigation of the implant pocket.[4,34,35] Textured implants[4,36-38] and a submuscular pocket[4,39,40] had classically been associated with decreased incidence of capsular contracture following primary breast augmentation.

However, once capsular contracture has occurred, literature on surgical management is less clear. Management of capsular contracture has evolved from closed capsulotomy to open capsulotomy and/or capsulectomy with implant exchange. The indications for partial versus complete capsulectomy have not been well established. There is also a variety of medical management available. This article offers the most comprehensive review to date of surgical and nonsurgical management of capsular contracture. The objective of this article is to provide information on the etiology of capsular contracture and a thorough discussion of treatment options for contracture.

Methods

A computerized search was performed on PubMed in August 2017 to identify relevant articles on capsular contracture. The search start date was January 1, 1970, and the end date was the present date. Earlier literature was reviewed, which consisted mainly of discussion articles. The most recent systematic reviews on capsular contracture were reviewed and summarized in this article. The earliest article was dated 1972 and the most recent article was dated 2016. In total, 99 articles were selected for review.

Table 2. Indications for Partial or Total Capsulectomy in Conjunction With Implant Removal.

No replacement of an explanted implant or tissue expander
Exchange of an existing implant in one tissue plane for a new implant in a different tissue plane
Capsular contracture (Baker grades III and IV)
Calcified or thick, fibrous capsule
Removal of a ruptured implant, especially one filled with silicone gel
Removal of silicone granulomas
Exchange of an implant for one with a larger volume
Replacement of a smooth implant with a textured implant (regardless of filler material in existing or new implant)

Management of Capsular Contracture

Current Approach

Management has evolved from closed and open capsulotomies in the 1970s to 1980s,[41,42] to capsulectomy, site change and implant exchange in the 1990s.[43-46]

Today, capsulectomy, site change and implant exchange is considered the gold standard treatment of clinically significant capsular contracture.[5,47,48] This is based on high recurrence rates after capsulotomy alone, the theory of biofilm calling for complete removal of the prosthesis and all bacteria-harboring capsule,[34,49] and limiting periprosthetic scar and inflammation by changing the pocket.[4] However, the actual clinical evidence behind this treatment plan is not entirely clear.

Moreover, the indications for partial versus complete capsulectomy are elusive. The surgeon is therefore left with the decision of whether to perform a partial or complete capsulectomy, open capsulotomy, or to leave the capsule in place. Despite the impressive number of breast surgeries performed in the United States, there have not been clear guidelines from implant manufacturers or professional societies regarding capsulectomies.

A statement released by the American Society of Plastic and Reconstructive Surgeons in 1995 outlines the risks and benefits of capsulectomy but for many surgeons, this was not comprehensive enough.[45] Up until an article by Young in 1998,[45] there were only a few articles discussing capsulectomy[47,50,51] and case reports discussing the problems associated with retained implant capsules.[51,52] Since then, there have been several systematic reviews of management of capsular contracture.[3,4]

A systematic review of 24 observational articles published by Wan and Rohrich[4] in 2016 found that there is no definitive evidence that capsulectomy is more effective than capsulotomy in preventing recurrence of capsular contracture.[4] However, the data are limited in that many studies did not specify the extent of capsulectomy performed. Therefore, it remains unclear if the extent of capsulectomy affects recurrence rate of capsular contracture.[4] Data by Collis and Sharpe[44] show lower recurrence rate of capsular contracture for total versus anterior capsulectomy in subglandular contracture. However, after controlling for implant type, the significance of this finding is unclear.[4] Costagliola et al[53] found no difference in recurrence of capsular contracture whether total or anterior capsulectomy was performed. However, total capsulectomy was performed for all subglandular contractures, and anterior capsulectomy was performed for all submuscular contractures. Therefore, the significance of these data is unclear as well.[4]

General Indications for Capsulectomy

Given that there is inadequate evidence to suggest that total capsulectomy is superior to anterior capsulectomy in the treatment of contracture, we allow the clinical scenario to guide our management of the capsule. Above all, the benefit of capsulectomy must outweigh the risk to the patient. The factors that affect the decision to remove a capsule extend beyond the type of implant, implant pocket, and quality of the capsule (Table 2).

Position of Existing and Replacement Implants

A capsulectomy should be performed when no implant will be replacing the explanted implant, or when the replacement implant will be placed in a different tissue plane (ie, changing from subglandular to submuscular position, or submuscular to subglandular pocket). Retained capsules in a subglandular position are more likely to present as palpable masses or artifacts on mammography, which may lead to an unnecessary biopsy to rule out malignancy. Therefore, capsules in the subglandular position should be removed assuming this can be done with minimal risk to the patient. However, implants which have been placed after subcutaneous mastectomy or breast reconstruction often lead to capsules which are quite close to the skin. Injury to the skin or devascularization can occur when attempting to remove these capsules. Therefore, capsules which are adherent to the skin should be left in place to minimize risk of skin injury. In these cases, partial capsulectomy to the posterior portion of the capsule can be performed.[4,45]

Capsulectomy in the submuscular space provides its own set of concerns. It can be difficult to remove the capsule from the deep surface of the pectoralis major muscle due to contraction of the muscle. There can be injury to the muscle leading to excessive bleeding which can be difficult to control. Moreover, the capsule is often adherent to the chest wall. When the capsule is normal (thin and flimsy), it can be particularly difficult to remove from the chest wall. Aggressive attempts at a total capsulectomy can lead to pneumothorax. Therefore, capsules in the submuscular plane which are not thickened or calcified do not necessarily need to be removed. Thin capsules will likely be resorbed spontaneously and will likely not cause palpable masses or interfere with mammography.[4,45]

Another difficult scenario is when the capsule extends into the axilla. This tends to occur with older silicone implants in a submuscular position with extracapsular rupture. When attempting capsulectomy, pulling inferiorly on the capsule with instruments can bring the axillary contents into the operative field, putting them at risk of injury. Attempt to remove the capsule which is in the axilla risks injury to the brachial plexus or axillary vessels. Controlling bleeding or repairing damaged nerves would likely require an additional axillary incision, as well as increased operative time. In most situations, it is not advisable to aggressively remove capsule which extends into the axilla. If it is considered necessary to remove this portion of the capsule (ie, due to patient's insistence or a palpable mass), it is prudent to create a separate axillary incision to gain exposure to the site and minimize injury to surrounding structures.[45]

Implant Filler Material

There are no indications for capsulectomy which are specific to saline implants, whereas capsulectomy is considered more important for silicone implants. Research has found silicone in the capsules of silicone implants.[23,54-56] Capsulectomy is thought to remove potential for residual, radiopaque silicone to interfere with mammography.[45]

Most cosmetic surgeons will agree that ruptured silicone implants can lead to difficulty in the operating room. Ruptured implants in the subglandular space tend to be more confined than ruptured implants in the submuscular space, which can extend into the axilla, especially if the rupture is extracapsular. Total capsulectomy can facilitate removal of silicone material when the implant is ruptured. Capsulectomy, however, does not guarantee removal of all silicone material. Some gel may be present in tissue beyond the capsule and may not be visible or palpable. Moreover, silicone cannot be dissolved so it is not possible to completely remove all gel even with copious irrigation. It is also difficult to completely wipe away silicone in an extracapsular rupture. The surgeon can only remove as much as gel as possible, without causing unnecessary harm to the patient. In cases of ruptured silicone implants, capsulectomy is warranted unless other factors outweigh the benefits of capsulectomy.[4,45]

Silicone Granulomas

Silicone can induce the formation of foreign body granulomas.[45,57] When silicone granulomas are present, capsulectomy is usually indicated. While there is no clear evidence that granulomas cause a systemic response, excision of granulomas will lead to more complete removal of silicone. Granulomas can also present as a palpable mass or a radiopacity on mammography. Therefore, when granulomas are accessible to the surgeon, they should be removed. A capsulectomy facilitates removal of granulomas as they are typically adjacent to the capsule in an extracapsular rupture. Removing the capsule also permits greater exposure to identify granulomas. Large granulomas are typically easy to find with inspection and palpation. Small granulomas (<5 mm) can be missed in surgery but later become evident on mammography or magnetic resonance imaging (MRI). Careful examination and palpation of breast tissue, pectoralis major muscle, chest wall, and axilla can lead to identification of small granulomas, which are typically harder than the surrounding tissue. An intact implant does not rule out silicone granulomas, as they may have been missed when a previous ruptured implant was removed.[45]

Capsule Thickness and Presence of Capsular Contracture

It is not entirely clear which capsules will resorb on their own. However, it seems that thin capsules in the submuscular plane tend to resorb. Therefore, thin, flimsy capsules can be left in place because they are difficult to remove and most likely will be resorbed. Thick, fibrous capsules, on the other hand, are unlikely to be resorbed and may lead to palpable masses and/or abnormalities noted on mammography. Therefore, thick capsules should be removed at the time of explantation of the implant. If complete capsulectomy is considered too risky, then partial capsulectomy should be performed.[4,45]

Some authors have suggested that any capsule with a Baker grade III or IV capsular contracture should be removed, regardless of whether the implant will be replaced.[23,45] A severely contracted capsule which is left in place can produce a breast deformity and palpable mass. There are concerns that this residual capsule can also interfere with mammography. Grade III or IV capsules may also be colonized by bacteria. Removal of the capsules can decrease the bacterial load and lower the risk of developing a subsequent capsular contracture if the implants are replaced.[23,45] However, it is important to always consider the risks of total capsulectomy, including damage to surrounding structures. The surgeon must use clinical judgment to decide the extent of capsulectomy to be performed, even in the setting of capsular contracture.

Calcification of the Implant Capsule

Calcification of the implant capsule can occur as well.[45,57-62] Destouet et al[57] reported calcification in up to 30% of women who had breast implants for 10 years or longer. The cause of calcification of the capsule is unknown. Siggelkow et al[60] reported on 53 capsules around silicone breast implants from 43 patients (23 smooth and 30 textured devices). A higher Baker score was found with increasing patient age, implant duration, and thickness of capsule. Calcification was associated with duration of implant and age of patient. Focal calcification was noted mostly on the inner side of the breast capsule. In this study, calcification was only found around

smooth implants in the subglandular site following cosmetic augmentation.

Calcified capsules make the breast very hard, abnormally round, and cause discomfort. Mammographers typically do not have difficulty distinguishing between calcifications in a capsule and microcalcifications associated with carcinoma. However, a calcified capsule can obscure areas of breast tissue. Therefore, every attempt should be made to completely remove calcified capsules. Typically these capsules are easy to remove, even when they are in the submuscular plane, because there is a distinct tissue plane.[45]

Smooth Shell Versus Textured Shell of Explanted Implant

Considerations for capsulectomy depend on whether the implant being explanted has a smooth or textured shell and the type of implant being used to replace it. Implants with a smooth elastomer shell tend to cause a relatively uniform and smooth capsule. The decision to remove this capsule depends on the factors discussed previously, ie, positioning of the existing and replacement implant, filler material, capsule thickness, and severity of capsular contracture. Also, if an implant with a smooth surface is to be replaced with an implant with a textured surface, a capsulectomy should be performed to allow the textured shell to interact with a fresh tissue surface. This may decrease the risk of capsular contracture in the future.[45]

When removing textured implants, the capsule can be left intact if a replacement implant is placed in the same position. However, if a textured silicone implant is removed, it is reasonable to perform a capsulectomy to remove any gel which may be present in the capsule.[45]

Both saline and silicone gel textured implants can lead to synovial-like metaplasia.[23,45,60] Synovial-like metaplasia is benign but it can lead to dense hyaline collagenous fibrosis after implant duration of more than 2 years. Synovial-like metaplasia is more prominent in pockets surrounding textured implants which have been in place for a longer amount of time.[60] This may also lead to fluid formation in the intracapsular space which can result in seroma formation. Therefore, it may be wise to perform a capsulectomy when removing textured implants to decrease the risk of synovial metaplasia and seroma.[45]

Change in Volume of the Implant

When an existing implant is being replaced with a larger implant, a capsulotomy or capsulectomy should be performed. If the capsule is a grade I or grade II and normal in appearance, open capsulotomy can be performed. It is obvious that using a larger implant will require some change to enlarge the implant pocket. Some surgeons do prefer to do a complete capsulectomy to have a fresh tissue surface against the new implant. When an existing implant is being replaced with a smaller implant, a capsulectomy may not be necessary, but can be performed, depending on the factors discussed in this article.[45]

Considerations for Implant Replacement

Implant exchange is associated with lower recurrence rates of capsular contracture (0%-26%) versus with no implant exchange (0%-54%).[4] This is particularly notable when the replacement implant is placed in the same plane. Replacing old implants in the same pocket is misguided as it is associated with the highest risk of recurrence of contracture.

There were no obvious trends in recurrence rate of contracture with textured, saline, or silicone replacement implants. However, smooth implants were associated with overall lower recurrence rates of capsular contracture. This is in contrast with the established clinical association of higher rates of capsular contracture with smooth implants versus textured implants. However, that association was based exclusively on primary breast augmentation data and may not apply to revision surgery.[4]

Selection of the replacement implant should ultimately be based on the patient's tissue characteristics. Textured implants have a higher risk of rippling and palpability compared with smooth implants, especially in the subglandular plane. Saline implants also have a higher risk of rippling compared with silicone implants. Therefore, it is reasonable to use smooth gel implants to minimize rippling and palpability in the patient with thin overlying breast tissue.[4]

Acellular dermal matrix is associated with a lower recurrence rate of capsular contracture (0%-7%) compared with recurrence rate with reaugmentation without acellular dermal matrix (5%-19%). However, these studies are limited by their short follow-up periods (average, 1.4-3.6 years).[4]

Perioperative Considerations

Operative Time and Technique

Capsulectomy adds approximately an hour to the operative time, which means increased cost to the patient. Moreover, adequate exposure for capsulectomy may require a larger incision than if implantation alone was being performed. Some surgeons prefer to remove the implant and capsule together, without entering the implant capsule. The thought is that this technique results in a more complete removal of silicone gel, especially in the case of a ruptured silicone implant. Some surgeons also find this method to be easier. However, this technique requires a larger incision, and there is not clear evidence that the benefits of this method outweigh the morbidity.[45]

Moreover, the capsule may still be entered despite the best efforts of the surgeon. Thus, ruptured silicone material enters the extracapsular space and must be manually

Figure 2. An example of ruptured silicone implants and fragments of the capsules which were removed bilaterally.

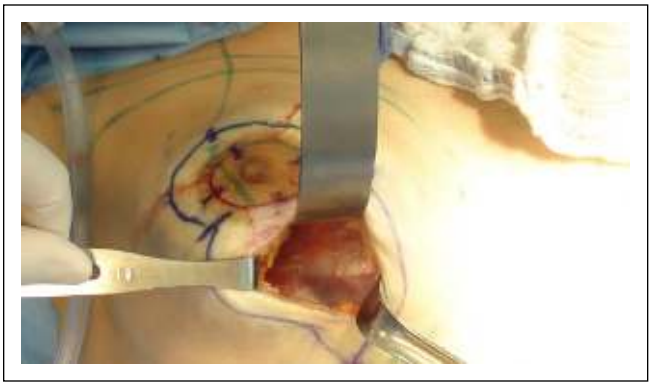

Figure 3. An example of thin, normal appearing capsule which was adherent to the chest wall and left in place to prevent damage to surrounding structures.

removed. The authors of this article begin the dissection around the capsule and implant, especially in the case of a known ruptured silicone implant. As much dissection as can safely be performed is carried out. Sometimes the entire implant and capsule can be removed without entering the implant capsule. Other times the capsule is entered and ruptured silicone material extravasates. At this point, the capsule is removed in pieces along with the implant and implant material (Figure 2). In the case of submuscular pockets, entering the implant capsule and removing the implant prior to capsule dissection may sometimes facilitate greater exposure (Figure 3).

Preoperative Discussion and Informed Consent

Typically an inframammary or periareolar incision is best for implant explantation and capsulectomy. For small areola (<4-5 cm in diameter), an inframammary incision is advised. For extension into the axilla, an additional axillary incision may be needed for better accessibility. Preoperatively, the surgeon should have an open discussion with the patient regarding the need for new, larger, or multiple incisions. The benefits of capsulectomy versus the risks and additional expense must be discussed with the patient. Patients undergoing removal of implants for severe capsular contraction should be explained that capsulectomy is recommended to eliminate a possible palpable and visible mass, mammographic artifact, possible bacterial colonization, and risk of a poor aesthetic result.[45] This discussion must include an explanation that if the capsule is adherent to the chest wall (in a submuscular plane) or to the skin (in a subglandular plane), a partial capsulectomy will be performed to minimize risk to the patient.

Most patients request a capsulectomy once they understand the risks and benefits. This is particularly true with women who are having silicone implants removed because of the perceived risk of silicone material. Patients should be informed that the current scientific evidence does not support a risk of retained silicone gel material in the implant pocket. It is also important to clarify that removal of silicone material or the implant capsule may not improve systemic symptoms that some patients attribute to the presence of breast implants. When a patient does request a capsulectomy, it should be performed assuming it does not pose significant risk to the patient.[45]

Open Capsulotomy

Open capsulotomy is reasonable in certain situations, such as modification of the capsule for a larger implant, correction of a malpositioned implant, modification of the shape of the breast, and conversion of a tissue expander to a permanent implant.[4,45] This is assuming the breast is soft and the capsule is thin and normal in appearance. In the case of a malpositioned implant in which the implant is intact, the same implant can be reinserted after capsulotomy and pocket modification. However, the implant manufacturers state that implants are for single use only, which precludes implant reuse after capsulectomy or capsulotomy. The surgeon should be aware of these recommendations and be prepared to defend the decision to reuse an implant.[45]

Delayed Capsulectomy

Delayed capsulectomy may be required for retained capsules that produce an unaesthetic result, palpable mass, mammographic abnormality, source of fluid accumulation or infection. A surgeon will ideally avoid the need for a delayed capsulectomy by performing a capsulectomy at the time of implant removal or replacement. However, the patient may have had the implant removed by another surgeon and then presents later with the need for capsulectomy. This most commonly occurs in the patient with capsular contracture who did not have capsulectomy at the time of the initial surgery. In this case, delayed capsulectomy should be performed.[45]

Contraindications to Capsulectomy

Below is a summary of situations in which total capsulectomy should be avoided to prevent unnecessary harm to the patient.

1. A thin and flimsy capsule can be difficult to remove and capsulectomy can cause damage to surrounding tissue.
2. In a submuscular implant when the posterior capsule is tightly adherent to the ribs and intercostal muscles causing a risk of chest wall perforation and pneumothorax, a partial capsulectomy should be performed.
3. The risk of capsulectomy of subglandular implants in a thin patient usually outweighs the benefit. Removing a subglandular capsule can injure the skin by compromising blood supply or cause a perforation through the skin. A partial capsulectomy of the posterior portion of the capsule can be performed.
4. Patients with very thin overlying breast tissue who are replacing a saline-filled implant may benefit from the tissue padding of the capsule. In situations in which the breast is soft and the capsule is normal appearing, the capsule can be left in place to decrease risk of rippling of the implant.
5. In the case of a malpositioned implant, such as one that is laterally or inferiorly displaced without capsular contracture, a normal appearing capsule can be used for capsulorrhaphy.

Special Considerations

Carcinoma in the Capsule or Adjacent to the Capsule

There has been a long history of speculation about the safety of breast augmentation, specifically regarding increased risk of carcinoma and/or autoimmune disorders with silicone. The National Institutes of Health found no associations between breast implants and cancer, autoimmune disorder, neurologic disorder, or other systemic diseases.[63] Moreover, the risk of breast cancer is not higher for silicone implants compared with saline-filled implants.[63,64]

However, there have been a few reports of carcinoma which seemed to arise from the breast implant capsule.[65-67] Paletta et al[65] reported a squamous cell carcinoma which apparently arose from the implant capsule 15 years after breast augmentation. Kitchen et al[66] reported an implant capsule lined by benign squamous epithelium and another case of squamous cell carcinoma in the implant capsule. It is reasonable to assume that squamous cell carcinoma is preceded by benign squamous epithelium. However, prior to this report, there were no cases of epithelialization of breast implant capsules. The origin of the epithelial cells in the breast implant capsule is unclear. The usual histological findings in the breast implant capsule have been well documented. Host tissue reactions around the implant include formation of a fibrous capsule, foreign body giant cell reaction, and infiltration of chronic inflammatory cells.[3,4,58,59,66] In addition, calcification of the fibrous capsule has been reported.[45,58,59]

There are several possibilities as to the origin of the epithelial cells in the capsule. One is that microscopic skin fragments could be implanted in the incision at the time of implant placement. These epithelial fragments could subsequently form an epithelial lining. Another theory is that dermal adnexal structures could proliferate into an epithelial lining. However, the most plausible theory is that ductal epithelium undergoes squamous metaplasia. Ducts are invariably transected during placement of an implant. It is recognized that endoderm-derived epithelium in the bronchus, thyroid, urethra, and prostate can undergo squamous metaplasia in the setting of chronic irritation. Therefore, it is possible that epithelium from transected ducts proliferated within the implant capsule and became metaplastic in response to chronic irritation from the breast implant.[65,66]

When carcinoma is present in or adjacent to the implant capsule, it is recommended to remove the implant, the capsule in its entirety, and any abnormal surrounding tissue to submit as a pathology specimen.[45,67]

Anaplastic Large Cell Lymphoma

There has also been concern over the association of breast implants and anaplastic large cell lymphoma (ALCL).[68,69] In 1995, a case series of 3 women with breast implants and cutaneous T-cell lymphoma was reported.[70] Since then, there are 63 documented cases of primary breast implant-associated ALCL.[68] While breast cancer is the most frequent cancer affecting women, primary lymphoma of the breast is exceedingly rare, accounting for only 0.04% to 0.5% of malignant breast tumors, 1% to 2% of extranodal lymphomas, and less than 1% of all non-Hodgkin lymphomas.[71] In 2011, the U.S. Food and Drug Administration (FDA) released an alert that women with breast implants have an increased, although very low, risk of developing breast implant-associated ALCL.[72] Since that report, the FDA added that ALCL occurs more frequently with textured implants compared with smooth surface implants. This form of ALCL appears to have a more benign course than systemic ALCL. Treatment of ALCL is removal of the implant and complete capsulectomy, along with oncologic consultation to investigate other sites of disease.[69] Most patients with breast-confined disease achieve complete remission after surgical management. Women with more extensive disease benefit may also benefit from chemotherapy.[68,69] While ALCL is extremely rare, clinicians must be vigilant. Patients with late-onset seroma, sudden breast swelling, and/or pain should be suspected of having ALCL and be worked up appropriately.[68]

Infection

Many capsules are culture positive for microorganisms, such as *Staphylococcus epidermidis*, which is associated with capsular contracture.[23,34,73-76] Colonization of bacteria is usually an incidental finding, found during removal of implants.[45] However, Pajkos et al[34] reported a *S. epidermidis* biofilm in a patient with recurrent capsular contracture. The thought is that once a biofilm forms on the outer surface of the implant surface, it can be a source of chronic inflammation and irritation which can lead to capsular contracture. The theory of subclinical infection may contribute to why implants placed above the muscle have higher contraction rates than submuscular implant. Implants above the muscle are in close proximity to the breast ducts which carry bacteria more than 90% of the time.[23,77]

An acute suppurative infection, on the other hand, is an uncommon complication of breast implants. An acute infection is manifested by pain, swelling, erythema, and fever. Once an infection is diagnosed, explantation with complete removal of the capsule is always indicated. This will speed the resolution of the infection and allow the normal healing process to proceed. It is advised to place a drain when a capsulectomy is performed in the setting of an infection. Failure to remove the capsule when an infection is present will lead to a dead space colonized by bacteria which antibiotics may not be able to sufficiently penetrate. This will lead to delayed healing and increased time before the implant can be replaced.[45,49,75,76]

There are simple preventive measures that have been found to decrease bacterial load, such as a preoperative dose of intravenous antibiotics, irrigation of the implant pocket with antimicrobials before placement of the implant, and minimizing contact between the implant and the surrounding skin and breast tissue.[34] In a 6-year prospective clinical study, Adams et al[35] demonstrated that "triple antibiotic irrigation" decreased the incidence of capsular contracture and infection. The solution consists of 50,000 units of bacitracin, 1 gram of cefazolin, and 80 mg of gentamicin in 500 mL of normal saline. An alternative to triple antibiotic irrigation is povidone-iodine irrigation. A systematic review by Yalanis et al[78] carried out a meta-analysis of 4 studies comparing povidone-iodine irrigation to saline irrigation. This review found that povidone-iodine irrigation decreased Baker III/IV capsular contracture (2.7% vs 8.9%, $P < .00001$) and was not associated with increased rate of implant rupture compared with saline irrigation.

Medical Management of Capsular Contracture

Breast Exercises

To prevent and treat early capsular contracture, many surgeons encourage postoperative breast exercises.[79-81] These exercises are designed to keep the implant pocket and capsule larger than the implant. The authors of this article advocate breast exercises starting on postoperative day 1. The exercises include pushing the implants up, down, and together. Each exercise should be held for 30 to 60 seconds and should be done at least 4 times per day for the first 3 months. At this point, patients are instructed to continue the exercises 2 times per day for life.

Vitamin E

Baker first published the effectiveness of vitamin E in reducing the incidence of capsular contracture.[82] Vitamin E, also known as alpha-tocopherol, is an anti-inflammatory and a lysosomal stabilizer. It is a biological antioxidant that protects cells from the effects of free radicals and stabilizes their membranes. In terms of wound healing, vitamin E decreases fibroblast and collagen formation.

Baker placed his patients on 1000 IU of vitamin E 2 times daily starting 1 week before surgery and continued for 2 years after surgery. If capsular contracture developed, the dose was increased to 1000 IU 4 times daily. If no contracture developed, the dose was reduced to 1000 IU once daily. Baker reported a decreased rate of capsular contracture in the group that took vitamin E. However, the incidence of severe capsular contracture (Baker IV) remained the same in the 2 groups. He reported no increased risk of bleeding in those who took vitamin E. He recommends the synthetic form of vitamin E to avoid nausea or skin eruptions in patients with oily skin which can be seen with the natural form of vitamin E.[82] Although high dose vitamin E is still used by some practitioners, it did not gain widespread use due to concerns about patient compliance, various reports on efficacy, and possible side effects, such as dermatitis.

Zafirlukast (Accolate)

Because capsular contracture is thought to be an accelerated or prolonged inflammatory response, it seems logical to turn to immune modulators to treat capsular contracture. One such drug is zafirlukast (Accolate) which is a leukotriene receptor antagonist (LTRA). In 1996, zafirlukast was FDA approved for preventative and long-term treatment of asthma.[80] Zafirlukast inhibits the eosinophilic influx and contractile activity of smooth muscle in all 3 leukotrienes (LTC_4, LTD_4, LTE_4) in both humans and laboratory animals. This, in turn, decreases bronchial hyperresponsiveness to prevent an asthma attack. This drug is used to prevent asthma symptoms, rather than treat an asthma attack.

Schlesinger et al[80] reported a series of 5 cases of patients who developed capsular contracture after breast augmentation or reconstruction. These patients were given zafirlukast 20 mg by mouth, twice daily for 3 months. They noted that many of their patients dramatically improved with zafirlukast and were able to avoid surgery. They found that the rate of capsular contracture decreased from 4% to 1% once they

initiated treatment with zafirlukast in their patients with capsular contracture.[81]

The macrophage is an important intermediary between the inflammatory phase and scar formation.[83] The macrophage-mediated release of fibroblast-activating cytokines, transforming growth factor beta, platelet-derived factor, and interleukins leads to collagen production, organization, and extracellular matrix degradation. Mast cell response is characterized by histamine-like activity which can lead to more collagen formation in scars. LTRAs directly inhibit this response and can therefore reduce the severity of capsular contracture.[80]

Prevention and early intervention of capsular contracture is important. Schlesinger et al[80] recommend the use of zafirlukast in capsular contracture of less than 6 months or in those who are at high risk of developing contracture, such as a patient with a hematoma, infection, or a history of capsular contracture or hypertrophic scarring.

In our practice, the response rate to zafirlukast was 50% resolution of significant capsular contracture (Baker III-IV) with prevention of surgery. It is important to keep in mind that a reported side effect of zafirlukast is liver toxicity. Therefore, patients should have a baseline liver enzyme panel drawn prior to starting this medication and patients should have their liver function monitored while on the medication. This should be clearly discussed with patients prior to starting zafirlukast. As other medications and natural supplements with similar anti-inflammatory effects and fewer adverse effects have become known, the authors have reduced the use of this medication.

Montelukast (Singulair)

Montelukast (Singulair) is another LTRA that is approved for the treatment of asthma. Montelukast inhibits leukotriene D_4 and is prescribed as a single 10 mg dose. Schlesinger et al[80] reported an improvement in patients with severe capsular contracture who were given montelukast, but felt that zafirlukast had a better response rate. This difference in response is likely because zafirlukast blocks all 3 leukotriene receptors, whereas montelukast blocks only 1. Unlike zafirlukast, montelukast does not have the risk of liver toxicity. The most common side effects of montelukast are headache, influenza-like symptoms, abdominal pain, dyspepsia, and cough.

Huang and Handle[84] published a retrospective study of 19 patients with capsular contracture treated with montelukast. They found that 37% of their patients completely improved, 26% improved, 16% had no change, and 11% worsened. They noted that patients with mild capsular contracture (Baker II) had a greater likelihood of improving with montelukast than patients with severe capsular contracture (Baker III-IV).

Milk Thistle (Silymarin)

Milk thistle (*Silybum marianum*) is a natural herb that has antioxidant and anti-inflammatory effects. Milk thistle is the most well-researched plant in the treatment of liver disease. The active complex of milk thistle is a lipophilic extract from the seeds of the plant and is composed of 3 isomer flavonolignans (silybin, silydianin, and silychristin) collectively known as silymarin. Silybin is the component with the greatest degree of biological activity and makes up 50% to 70% of silymarin. Silymarin is found in the entire plant but is most concentrated in the fruit and seeds. Silymarin acts as an antioxidant by reducing free radical production and lipid peroxidation. It also has antifibrotic activity and inhibits the binding of toxins to the hepatocyte cell membrane receptors.[85]

Studies also suggest that silymarin protects against genomic injury, increases hepatocyte protein synthesis, decreases the activity of tumor promoters, stabilizes mast cells, chelates iron, and slows calcium metabolism.[86] The antioxidant properties of milk thistle are similar to vitamin E, vitamin C, and bioflavonoids, in that they all act by reducing oxidative damage.

The senior author first learned of the effects of milk thistle at a live breast surgery course, where another surgeon was using it for early capsular contracture. Milk thistle is an appealing choice as it has a low incidence of side effects and is liver protective. The most common side effects of milk thistle are gastrointestinal upset and loose stools. Milk thistle comes in variable doses, ranging from 70 to 2000 mg. The senior author initially treated patients with 200 mg twice daily and saw a low rate of improvement of capsular contracture. With higher doses, he found increased efficacy. The authors now recommend 1000 mg twice daily in patients who develop capsular contracture. We have noted that milk thistle is most effective when started as soon as clinical signs of contracture develop. We therefore educate our patients about the signs of capsular contracture at our initial consultation. We advise that patients begin therapy as soon as hardness of the breast is noted.

External Ultrasound

External ultrasound has been suggested as a possible treatment for capsular contracture since the late 1970s. Initially, there were case reports of encapsulated breasts softening after ultrasound treatment alone. Later, there were reports of even better results when combining ultrasound with closed capsulotomy for the treatment of capsular contracture.[87]

In 1997, Planas et al[88] reported a series of 24 patients with 34 encapsulations treated with external ultrasound after closed capsulotomy. The ultrasonic device used was based on a 2-MHz generator with timing adjustable power emission connected to 8 transducers designed for breast anatomy. They reported 82% of the patients achieved significant improvement of capsular contracture with stability for a minimum of 12 months.

In 2002, Planas[89] reported his recommendations for prophylactic use of external ultrasound for the treatment of capsular contracture. He theorized that early application of

ultrasound facilitates healing, decreases edema and inflammation, thereby decreasing the likelihood that capsular contracture will develop. The mechanical effects of ultrasound produce micromassages that improve lymphatic drainage and diminish edema. The biochemical effects increase vascular proliferation, tissue oxygenation, and fibrinolysis. These effects, in turn, decrease inflammation.

His protocol of ultrasound therapy is as follows: Session 1 is 7 days after surgery, session 2 is 15 days after surgery, and session 3 is 21 days after surgery. His preliminary results 18 months after implementing this protocol show faster reduction of edema, faster absorption of small bruises and less postoperative swelling. Most impressive though is none of the patients on this protocol have developed capsular contracture.[89]

We have not used ultrasound therapy for prevention of capsular contracture, but we use it once capsular contracture has developed. In our experience, all patients who begin ultrasound therapy do report softening of their breasts, but they seem to have rebound tightening once they stop treatment. We have not seen complete resolution of severe encapsulation with ultrasound therapy alone. Therefore, we combine ultrasound with other modalities.

Low-Level Light Therapy

For nearly 40 years, the benefits of low-level laser therapy (LLLT) have been known, including the reduction of pain, inflammation, and edema; improvement of healing of wounds, deeper tissue, and nerves; and the prevention of tissue damage. Animal studies as well as randomized clinical trials have shown the biostimulatory effects of noncoherent light.[90,91] LLLT is practiced as part of physical therapy in many parts of the word. The question is no longer whether light has biological effects, but rather how energy from therapeutic lasers and light emitting diodes (LEDs) work at the cellular level and what are the optimal parameters for different uses of these light sources.[90]

Mitochondria are a likely site for the initial effects of light, leading to increased ATP production, modulation of reactive oxygen species, and induction of transcription factors.[92-95] These effects lead to increased cell proliferation and migration, modulation of the levels of cytokines, growth factors and inflammatory mediators, and increased tissue oxygenation. Clinically, these cellular changes lead to increased healing of chronic wounds, improvement of sports injuries, and pain reduction in arthritis and neuropathies.

There are multiple parameters that promote the biological responses described. However the most critical are the wavelength, energy density, and duration of treatment. The wavelength must match the absorbance of the desired photo-accepting molecule. The depth of penetration is determined by the wavelength. The energy density should be high enough to elicit the desired effect without causing unwanted tissue injury. Wavelengths between 600 and 700 nm are ideal for superficial tissue, whereas wavelengths between 780 and 950 nm are idea for deeper tissue, due to the longer penetration distance of tissue. Treatments delivered multiple times per week over several weeks result in greater efficacy.[92-95]

In 1995, Johnson et al[96] conducted a study in which 33 patients with grade III and IV capsular contracture underwent laser treatment once per week for 6 weeks. Patients received a 10 minute treatment with a LTU-904 laser. Capsular contracture improved and surgery, was avoided in 31 of the 33 patients (93.9%). They also administered patient surveys to the 31 patients who improved. They noted that the laser improved the firmness of the breast in 10% to 95% of the patients (average, 43.6%) and improved the comfort in 10% to 95% of the patients (average, 48.2%).

Jackson et al[97] performed a randomized, double-blind study to determine the effectiveness of LLLT in decreasing postoperative pain following breast augmentation. Using LLLT both pre- and postoperatively, they found a significant reduction in postoperative pain as well as the amount of pain medication needed at 1 day and 1 week following breast augmentation.

Omar et al[98] conducted a systematic review of 8 studies to assess the effectiveness of LLLT in the management of breast cancer–related lymphedema. They found moderate to strong evidence that LLLT reduces lymphedema and improves shoulder mobility.

Furthermore, Freitas et al[99] investigated the efficacy of LLLT over a 5-week period on scar tissue in 9 volunteers and found a positive effect on the macroscopic appearance of the treated scars and a decrease in scar thickness.

In light of the evidence of the role of LLLT in decreasing inflammation and improving capsular contracture, the senior author began using LLLT on his patients with capsular contracture. The device currently used in our practice is Celluma (Biophotas Inc, Anaheim, CA). Celluma is a safe, affordable, and easy to use, flexible LED array. Celluma has been FDA approved for arthritis, muscle spasm, muscle and joint pain, diminished local circulation, and inflammatory acne vulgaris. Celluma has 345 LEDs that emit energy at blue (465 nm), red (640 nm) and near infrared (880 nm) wavelengths with frequencies of 80 Hz, 680 Hz, and 800 Hz, respectively, for 30 minutes per treatment session. The device comes programmed with multiple operating modes for each clinical application. The clinical advantages of this device are the ease of adaptation to fit the contours of the body and the long duration of treatment. Both factors allow for optimal energy absorption.

Conservative Treatment Protocol

In our practice, at the earliest sign of capsular contracture, we start our conservative treatment protocol. Our patients are educated about the risk of capsular contracture at the initial consultation. We stress the importance of starting conservative therapy as soon as possible. We explain that the earlier

treatments are started, the more likely they are to be successful in treating contracture and avoiding the need for surgery.

Because the etiology of capsular contracture is multifactorial and related to inflammatory changes, our conservative protocol combines multiple modalities as follows:

1. Milk thistle 1000 mg twice daily for 3 to 6 months
2. Low-level light therapy with Celluma once or twice per week for 6 to 12 weeks
3. Ultrasound treatments once or twice per week for 6 to 12 weeks

In addition, all breast augmentation patients are taught breast exercises beginning on postoperative day 1 and patients are instructed to continue these exercises for life. The authors estimate that about 80% of our patients improve with this protocol and thereby avoid the need for surgical intervention. We further postulate that if this protocol was started immediately after surgery, we could reduce the incidence of capsular contracture. To validate this hypothesis, there should be a randomized study to assess the incidence of capsular contracture in patients who undergo this protocol versus those who only perform breast exercises.

Summary

The treatment of capsular contracture is most certainly multifactorial and includes both surgical and nonsurgical options. The ultimate goal is to prevent capsular contracture, minimize risk to the patient, and obtain esthetic results. Capsulectomy is indicated in the majority of cases when breast implants are being removed or replaced in the setting of capsular contracture. However, the surgeon must always weigh risks and benefits of capsulectomy. The removal of a capsule should not warrant significant risk to the patient, such as pneumothorax, devascularized skin, or injury to nerves or vessels. It is unclear if a total capsulectomy is advantageous over a partial capsulectomy in preventing recurrence of contracture. Therefore, it is up to the surgeon to use clinical judgment to guide management of the implant capsule.

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Author Biographies

Whitney Florin is an associate at Inland Cosmetic Surgery in Rancho Cucamonga, CA. She specializes in breast, face, and body cosmetic surgery, as well as nonsurgical facial rejuvenation. She has contributed to several journals and books on cosmetic surgery and nonsurgical esthetic facial procedures.

Jacob Haiavy is the medical director of Inland Cosmetic Surgery and has served as faculty for cosmetic breast, body, and facial rejuvenation courses and has written several journal articles on cosmetic surgery for leading publications. He is also a fellowship director of an AACS-approved full body and facial cosmetic surgery fellowship in Rancho Cucamonga, CA. He is an immediate past president of the American Board of Cosmetic Surgery and also past president of the California Academy of Cosmetic Surgery.