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# Guidelines and Indications for Breast Implant Capsulectomy

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### Abstract

This article discusses indications for performing a capsulectomy in conjunction with explantation of breast implants. This issue has rarely been addressed in the literature, and there is no consensus on guidelines to assist surgeons in deciding whether a capsulectomy is warranted. The many factors that must be weighed when considering performance of a capsulectomy are outlined, and recommendations for the explantation contexts in which capsulectomy may be considered optional or should usually be performed are given. Capsulectomy may be indicated in the majority of instances when breast implants are removed or exchanged, but the potential risks of capsule removal must always be balanced against the potential benefits.

Approximately 1 million American women have breast implants, the vast majority of which are silicone gel-filled with a smooth surface. Smaller proportions are silicone gel with a textured elastomer shell or a polyurethane-coated surface, double lumen with a smooth surface, and now increasing numbers of saline-filled implants with textured or smooth elastomer shells. In 1994, more than 37,000 women with implants<sup>1</sup> underwent explantation because of concerns about the safety of silicone, implant rupture, local complications such as capsular contracture, or a desire to change breast size. Unfortunately, there is no real consensus on whether a capsulectomy should be performed in conjunction with explantation.

Regardless of whether a woman chooses to replace her implants or simply remove them, the surgeon is faced with the dilemma of whether to perform a complete or partial capsulectomy or to leave the capsule in place. There have not been any clear-cut capsulectomy guidelines from

implant manufacturers or professional societies. For example, a statement released by the American Society of Plastic and Reconstructive Surgeons<sup>2</sup> in 1995 basically outlines some of the risks and benefits of capsulectomy, but the brief discussion does not offer much decision-making help to the surgeon faced with specific explantation scenarios. Furthermore, only a few clinicians<sup>3-5</sup> have addressed the issue of capsulectomy indications or presented case reports<sup>5,6</sup> that illustrate potential problems with retained implant capsules.

Because the literature lacks specific guidelines concerning when a capsulectomy should be done, the time seems appropriate to outline the many factors that must be weighed when considering performance of a capsulectomy. The capsulectomy indications presented in this article are based on my own experience gained in doing hundreds of explantations and implant replacements. The different scenarios in which a capsulectomy should be considered are addressed to guide surgeons in their own decision-making process. Some surgeons will disagree with the recommendations offered here. Nevertheless, perhaps this article can serve as a starting point for further discussion on the subject of capsulectomy and development of guidelines that reflect consensus within the plastic surgery community.

[Table I](#) presents my general recommendations for situations in which a capsulectomy may be considered optional, depending on the type of implant being explanted (filler material and shell surface characteristics) and the type and position (subglandular or submuscular) of the replacement implant, if any. Double-lumen implants are not specifically addressed in this article. Instead, it seems reasonable to view a double-lumen implant with an intact saline shell as being most like a saline implant; if the outer saline lumen is disrupted, I treat it as comparable to a silicone gel implant. [Table II](#) summarizes those contexts in which I believe a capsulectomy should almost always be performed.



TABLE I Contexts in ... TABLE II Contexts in...

Factors that influence the decision to perform a capsulectomy are multiple and extend beyond the type and position of explanted and replacement implants. A major portion of this article addresses these many factors, including the thickness of the capsule, the presence of grade III or IV capsular contracture or silicone granulomas, capsule calcification, and removal of a ruptured silicone gel implant. The contexts in which a partial capsulectomy may be more appropriate are also discussed. When considering a capsulectomy, it is important to remember that a retained capsule may present as a palpable mass or appear as an abnormality on mammography after explantation. Because a retained capsule may require future biopsies to rule out breast carcinoma, the benefits of leaving a capsule should outweigh this potential risk.

### **Position of Existing and Replacement Implants and Extent of Capsules**

As a general rule, a capsulectomy should be performed when no implant will be reinserted after explantation or when a replacement implant will be inserted in a different tissue plane than the explanted implant. Retained capsules in a subglandular position are more likely to present as palpable masses or mammographic artifacts than submuscular capsules because there is less tissue coverage. Fortunately, removal of a capsule above the muscle is typically less complicated than with submuscular capsules, with the exception of implants placed subcutaneously.

Implantation after subcutaneous mastectomy or breast reconstruction in a subcutaneous plane

after mastectomy usually produces capsules that are very close to the skin. Inadvertent injury to or devascularization of the skin may occur when removing these capsules, and I recommend leaving them in place when they are adherent to the skin. Alternatively, a partial capsulectomy can be performed to remove only the posterior portion of the capsule. If the perceived reason for removal of a subcutaneous capsule appears to override the risk of skin injury, the capsulectomy must be performed with great care.

Capsulectomy in the submuscular space is often more difficult because of muscle movement during removal of the capsule from the deep surface of the pectoralis major muscle and adherence of the capsule to the chest wall. Aggressive attempts to totally excise such a capsule may injure the muscle or result in a pneumothorax. Thus, a partial capsulectomy of only those submuscular capsule portions that can be safely removed with relative ease may be more appropriate. Thin, flimsy capsules are particularly difficult to remove from the intercostal spaces. Consequently, thin capsules without calcification in the submuscular plane usually do not need to be removed, and they will likely be resorbed. An exception to this is the presence of a ruptured silicone gel-filled implant; maximal removal of the gel can be very difficult without a capsulectomy.

Sometimes a portion of a capsule, usually one in a submuscular position, will extend into the axilla; this scenario most often occurs in the context of extracapsular rupture of a silicone gel implant. The superior portion of capsules that extend into the axilla may be near the axillary contents, and attempted removal of this capsule piece risks damage to major structures. For example, pulling inferiorly with instruments may displace the brachial plexus or axillary vessels into the operative field where they can be injured. Controlling bleeding or repairing nerves or vessels damaged by such a maneuver requires additional incisions and time. Risking this type of injury-and the associated complications-is not warranted for complete removal of a capsule. However, if it is deemed necessary to remove this portion of a capsule because of a palpable mass or a patient's insistence, a separate axillary incision should be made to gain adequate exposure and minimize risk to the axillary structures. In my experience, this technique is rarely required, and a prudent way to deal with a rupture that has forced gel into the axilla is to wipe away any free gel with sponges, excise all the capsule that can be safely removed, and leave the axillary portion of the capsule in place. The capsular remnants will often resorb over time. If resorption does not occur, the portion of a capsule left in the axilla typically does not interfere with mammography.

The overriding guideline for deciding whether a capsulectomy should be performed in conjunction with explantation-particularly when the implant has been in a submuscular or subcutaneous position-is that the potential benefit must exceed the risk. When removal risks a serious complication, leave the capsule (or the portion that would be problematic to remove) behind. A partial capsulectomy is often better than no capsulectomy, especially in those cases when removal of the posterior aspect of a capsule or a portion in the axilla cannot be accomplished without jeopardizing the surrounding structures.

### **Implant Filler Material**

There are no filler-related indications for performing a capsulectomy when saline-filled implants are explanted aside from the other factors discussed elsewhere. The same is true for double-lumen implants in which the outer saline-filled shell is intact. Capsulectomy is generally considered to be more important in patients with silicone gel implants. Researchers have detected either silicone<sup>7,8</sup> or silicon<sup>9,10</sup> in the capsules of gel-filled implants. Performing a

capsulectomy is thought to remove the gel more completely as well as eliminate the potential for radiopaque, residual silicone to interfere with mammography.

### **Ruptured Silicone Gel Implants**

Rupture of a silicone gel implant in the subglandular space typically is better confined than a rupture in the submuscular space, where extrusion of gel toward the axilla is relatively common, especially if the rupture is extracapsular. Regardless of the implant's position, total capsulectomy facilitates gel removal when silicone gel implants are ruptured or leaking. However, it is important for surgeons and patients to understand that capsulectomy does not guarantee a total removal of all silicone. Some gel released through bleed or rupture may be trapped in tissue outside the capsule, often in minuscule amounts that cannot be readily visualized or palpated. Because silicone gel cannot be dissolved or washed away with any solution that is safe to use in the human body, complete gel removal through irrigation is impossible. In addition, it is difficult to wipe away-or sponge up-all silicone gel from an extracapsular rupture; thus the surgeon can mechanically remove only as much gel as is visible and practical. Despite these cautions, capsulectomy in conjunction with explantation of a ruptured silicone gel implant seems warranted in all cases unless other factors outweigh the benefit of removing as much gel as possible.

### **Silicone Granulomas**

A capsulectomy is almost always indicated when silicone granulomas, often associated with extracapsular implant ruptures, are present adjacent to a capsule. Although there is no evidence that granulomas produce a systemic problem, their excision will achieve more complete removal of silicone gel. More importantly, granulomas can become a diagnostic dilemma by presenting as a palpable mass or radiopacity on mammography after explantation. For this reason, they should always be removed. A capsulectomy facilitates removal of silicone granulomas by permitting more thorough visual and manual inspection of the breast tissue to make sure all granulomas are identified.

Large granulomas are usually easy to locate by inspection and palpation. However, very small ones (<5 mm in diameter) can be overlooked but may later become evident on a mammogram or MRI. The best way to search for small granulomas is by careful palpation and meticulous examination of the breast tissue, pectoralis major muscle, chest wall, and axilla. Granulomas are usually hard and can be discriminated from normal breast tissue and muscle. An intact implant does not exclude the possibility that granulomas are present, especially if they were not detected when a previous ruptured implant was removed.

### **Capsule Thickness**

In my experience, I have observed that some capsules are resorbed after explantation; however, I have been unable to determine the exact factors that can be used uniformly to predict capsule resorption. This process seems to occur more often when a capsule is thin or with implants placed in the submuscular plane. Because thin, flimsy capsules are difficult to remove and will probably be resorbed, they may be left in place. In contrast, thick, fibrous, avascular capsules are unlikely to resorb and may produce palpable breast masses and/or mammographic artifacts. For these reasons, complete capsulectomy of thickened capsules should be performed at the time of explantation. If a complete capsulectomy is too risky, then a partial capsulectomy is warranted.

## **The Presence of Capsular Contracture**

Any capsule with a Baker grade III or IV contracture should be removed, regardless of whether the implant will be replaced. No matter its position, a contracted capsule that is left in place can produce breast deformity and a palpable mass, as well as interfere with mammography. In addition, established grade III or IV capsules may be colonized by bacteria. Their removal decreases the bacterial load and also may diminish the likelihood of developing a subsequent capsular contracture when implants are replaced.

## **Surface Characteristics of an Implant**

Implants with smooth elastomer shells typically produce relatively uniform capsules with a smooth surface, and the decision to remove these capsules during implant exchange is not directly related to the surface characteristics of the elastomer. Instead, other factors-such as the severity of capsular contracture, the capsule thickness, and the filler material and position of the existing and replacement implants-are usually more important than the smooth shell (see [Table II](#)). However, if an implant with a smooth surface is to be replaced by one with a textured surface, a capsulectomy should usually be performed to allow the shell texturing to interact with a fresh tissue surface, which may be important in minimizing capsular contracture.

When explanting implants with textured shells, the texturing is an important variable in the decision-making process. A capsulectomy often may be considered optional if a replacement implant will be placed in the same position as the removed textured implant. However, I recommend a capsulectomy when textured silicone gel implants are replaced with saline (textured or smooth) to remove any gel that may be in the capsular tissue.

It is important to note that both saline and silicone gel textured implants can induce synovial metaplasia,<sup>[11-15](#)</sup> and this fact alone may be a strong indication for performing a capsulectomy when removing a textured implant. Synovial metaplasia is benign, but it can produce a viscous fluid in the intracapsular space, which may result in seroma formation. Capsulectomy also may be indicated for textured implants because particulation or fragmentation of the textured elastomer shell has been found in implant capsules,<sup>[12](#)</sup> although this finding is not known to cause any adverse health effects. The chances of fragmentation are presumably greater when there is tissue ingrowth into the texturing, but it probably occurs with most textured implants to some extent. Silicone gel from breast implants and particulate silicone from joint prostheses also have been reported to migrate to lymph nodes,<sup>[16-21](#)</sup> and it seems theoretically possible that particulate elastomer may also do this, although I have been unable to find documentation of the phenomenon.

Capsules surrounding polyurethane-covered implants are usually thick and often have an inflamed appearance. Thus, it seems doubtful a capsule containing polyurethane will completely resorb or, if so, how long the process may take. In addition, the polyurethane is often delaminated from the silicone shell of these implants and remains within the capsular tissue. Capsules surrounding polyurethane-covered implants, therefore, should always be removed, even though there is no consensus that polyurethane has negative health consequences.

## **Calcification of a Capsule**

Calcification of a capsule occurs in about 30 percent of women who have breast implants for 10 years or longer, although the cause of such calcification is unclear.<sup>22</sup> A recent study found that the calcium deposited in implant capsules is calcium pyrophosphate.<sup>23</sup> Distinguishing between capsule calcification and microcalcifications associated with carcinoma of the breast is rarely a problem for mammographers, but a calcified capsule can obscure areas of breast tissue.

Calcified capsules are very hard (Baker grade IV+) and make the breast abnormally round, aesthetically unappealing, and uncomfortable. Women with calcified capsules often seek explantation for relief of their severely contracted capsules and to improve the quality of their mammograms. A calcified capsule should always be excised, especially because failure to perform a capsulectomy will result in a palpable mass and an abnormal mammogram, and the capsule will never completely resorb. Calcified capsules are usually easy to remove, even when they are in a submuscular position, because there is a distinct plane separating the capsule from the surrounding tissue.

### **Change of Volume When an Implant Is Exchanged**

Whenever an existing implant is removed and replaced with one of a larger size, I prefer to perform a capsulectomy. However, when the breast is soft, with a grade I or II capsule, many surgeons do only an open capsulotomy. I see nothing wrong with such a decision, but personally, I prefer to start with a fresh tissue surface. It should be intuitively obvious that replacing a smaller implant with a larger one requires some surgical action to enlarge the space. Forcing an implant with a larger volume into a smaller existing capsule will exert pressure on, and possibly damage, the new implant. If an implant is exchanged for one of a smaller volume, a capsulectomy may be optional, depending on other factors discussed in this article.

### **Infection**

A significant portion of capsules are culture positive for microorganisms, most frequently *Staphylococcus epidermidis*, and this condition has been associated with contraction of implant capsules.<sup>24-26</sup> Such bacterial colonization is typically discovered incidentally, during a routine explantation. It is doubtful that a culture-positive capsule could lead to an acute suppurative infection, which is a rare but recognized complication of breast implants. These infections are usually manifest by pain, fever, swelling, and erythema. Once diagnosed, removal of the infected capsule is always warranted. Surgeons should be aware that inflammation secondary to an infection surrounding an implant may result in increased bleeding during capsulectomy.

Failure to perform a capsulectomy when an infection is present can result in a persistent dead space colonized by bacteria, and antibiotics may not be sufficient to eliminate the infection. Explantation plus capsulectomy allows the normal healing process to proceed and speeds resolution of the infection and softening of the tissues; the time until subsequent surgery can be performed to correct any residual deformity is thereby shortened. Although drains are usually not required after a capsulectomy unless there is persistent bleeding after efforts to achieve hemostasis, constant vacuum drains should be used routinely after capsulectomy in the presence of infection.

### **Carcinoma in or Adjacent to a Capsule**

Carcinoma occurring in or adjacent to a breast implant capsule represents a rare but

problematic situation. The behavior of these lesions is incompletely understood. Until our knowledge improves, the safe approach is to remove both the implant and the capsule and include the capsule in the pathology specimen. In this context, performing a mastectomy rather than a lumpectomy is probably the wiser course of treatment.

### **Additional Operative Time, Expense, and Incisions**

A capsulectomy usually adds approximately 1 hour to the operative time of an explantation. The added time means the cost of the explantation will be higher. To gain adequate access to a capsule for removal, a larger incision may be needed than for explantation alone. Some surgeons prefer to remove the implant and capsule together, without opening the capsule. They believe this is easier and also results in more complete removal of silicone gel, particularly if a gel-filled implant has ruptured. This method of capsulectomy almost always requires a substantially longer or additional incision, and I do not believe there is scientific proof of its benefit to warrant the added morbidity and disfigurement that can result. This approach has the added disadvantage of increasing the risks of damaging the implant with an instrument, which may confuse the integrity classification of the explanted device. Even if a surgeon does not remove a capsule and implant simultaneously, an inframammary incision slightly longer than one used for implantation is probably safer for capsulectomy. An inframammary incision is typically preferred when implantation was done through a transaxillary or a periareolar approach, especially in patients with small areolas (<4 to 5 cm in diameter). Submuscular capsules, in particular, are more difficult to expose and remove through periareolar incisions.

A frank discussion about new, larger, or multiple incisions should be part of the preoperative patient education and informed consent. Similarly, the additional expense versus the benefits of capsulectomy should be explained to patients before surgery. Insurance carriers that pay for removal of a ruptured implant tend to approve coverage of a capsulectomy, as well. Patients undergoing explantation because of severe capsular contracture should be told that a capsulectomy is needed to reduce the risk of a poor aesthetic result and eliminate a probable palpable mass, possible bacterial colonization, and mammographic artifacts. Most patients are willing to incur the additional costs to achieve a better appearance and reduce the chances that a breast biopsy may be required at a later time.

### **Patient Request for Capsulectomy**

When a patient is informed about what a capsulectomy entails and the risks and benefits of the procedure for her particular explantation context, the majority will request that a capsulectomy be performed. This finding is especially true of women who are having silicone gel implants removed because they are concerned about what they perceive to be potential health risks of these devices. Patients should be told that current scientific evidence does not support a systemic health risk related to retained silicone gel, and removal of silicone or an implant capsule is unlikely to eliminate systemic symptoms some patients may attribute to breast implants. Instead, a capsulectomy is directed at solving local problems. The wishes of a patient requesting capsulectomy should be respected and carried out unless there is some compelling reason not to do so, such as encountering a situation in which the risks outweigh the patient's request.

### **Delayed Capsulectomy**

Delayed capsulectomy subsequent to explantation is sometimes required for retained capsules that produce a poor aesthetic result or present as a palpable mass, mammographic abnormality,

or source of persistent fluid accumulation or infection. Ideally, surgeons should avoid the need for delayed capsulectomy by performing the procedure when indicated at the time of explantation. However, it is not uncommon to encounter a patient who previously underwent explantation by another surgeon and later presents with a need for a delayed capsulectomy. This most often occurs in the context of a patient who had severe capsular contracture but the capsule was not removed at the time of explantation and/or implant exchange. In such cases, a delayed capsulectomy should be performed.

### **Open Capsulotomy**

Open capsulotomy, or scoring, of a capsule without its removal has been used to treat capsular contracture. However, the recurrence rate of another contracture has been high, and I do not believe open capsulotomy is adequate treatment for capsular contracture. This opinion can be justified by the fact that capsules often contain bacteria, established capsules are usually avascular, and a retained capsule prevents the textured surface of a new implant from interacting with healthy, well-vascularized tissue. Instead of performing an open capsulotomy, the existing implant should be removed and a capsulectomy performed.

Situations wherein open capsulotomy is reasonable include correction of a malpositioned implant (when the breast is soft but the implant is misplaced because of a technical error in formation of the pocket), needed modification to the shape of the breast mound, and conversion of a tissue expander to a permanent implant. In the case of implant malposition and shape modification, the same implant is sometimes reinserted if it is intact. Because the package inserts that come with implants state they are for single use only, this warning technically precludes implant reuse after capsulectomy or open capsulotomy. The surgeon must be aware of the manufacturer's recommendation and be prepared to defend any reuse of an implant.

### **Contraindications to Capsulectomy**

There are relatively few contraindications to capsulectomy aside from the contexts listed below:

1. A very thin and flimsy capsule is usually best left alone, especially because its removal can be difficult and can potentially lead to damage of surrounding tissue.
2. Removal of a subcutaneous implant capsule must be carefully considered due to the potential for injuring the skin. In the context of subcutaneous implants, the risks will usually outweigh potential benefits. A partial capsulectomy of the posterior portion of the capsule may be a good compromise in this circumstance.
3. Patients who need tissue padding to cover a replacement saline-filled implant may benefit from a retained capsule, which can make saline implant wrinkling less noticeable. This is especially true if there are no strong indications for performing a capsulectomy, such as the presence of a calcified or severely contracted capsule that would leave a palpable mass.
4. Capsular flaps are sometimes needed to modify a malpositioned implant or improve the aesthetic result after implant exchange. As examples, flaps might be useful when raising an inframammary crease that is too low, defining the midline in synmastia, or narrowing an implant pocket that extends too far laterally.

### **Summary**



Based on my explantation experience, I believe that capsulectomy is indicated in the majority of instances when breast implants are removed or exchanged. Nonetheless, surgeons must always remember that a capsule is not a malignancy and its removal must not be at the price of a significant complication such as injury to major nerves or vessels, pneumothorax, laceration, or devascularized skin. Because there are no known systemic benefits from capsulectomy, the local consequences of capsule removal must always be balanced against the potential benefits.

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