

Open Capsulotomy: An Effective but Overlooked Treatment for Capsular Contracture after Breast Augmentation

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Background: The prevailing theory for capsular contracture after breast augmentation is a subclinical capsular infection. A capsulectomy, site change, and implant replacement are recommended. An open capsulotomy leaves the capsule in the patient. Theoretically, such a procedure would be ineffective because it does not remove the infected tissue. Recurrences occurred frequently in women treated in the 1970s when leaky silicone gel implants were in use. Open capsulotomy has not been studied in women implanted with third-generation devices.

Methods: Seventy-five consecutive women with Baker III/IV capsular contractures after breast augmentation treated with open capsulotomies between 1996 and 2016 were retrospectively evaluated. The original implants were usually saline-filled (72.2%). Replacements were all smooth and round, and 92.6% were also saline-filled.

Results: Seventeen women (22.7%) developed a recurrent capsular contracture. Two patients (2.7%) experienced a second recurrence. Patients with ruptured silicone gel implants ($n = 13$) had a significantly greater risk of recurrence ($P = 0.01$). There was no significant difference in recurrence rates comparing patients whose intact implants were reinserted (12.5%) with women whose intact implants were replaced (18.2%). Povidone–iodine irrigation did not affect the recurrence rate. Capsular contracture was corrected with 1 procedure in 77.3% of patients and 2 procedures in 97.3% of patients.

Conclusions: Open capsulotomy is a safe and effective treatment that avoids the additional morbidity and cost of a capsulectomy. The findings challenge the infected biofilm theory of capsular contracture. Open capsulotomy deserves reconsideration by plastic surgeons. (*Plast Reconstr Surg Glob Open* 2016;4:e1096; doi: 10.1097/GOX.0000000000001096; Published online 4 October 2016.)

The prevailing explanation for capsular contracture is chronic inflammation caused by a bacterial biofilm.^{1–9} The “gold standard” treatment calls for a capsulectomy, along with a site change and implant exchange.^{2,7,9} However, Wan and Rohrich,⁷ in a recent systematic review, found little supportive evidence for this recommendation. Recurrence rates after surgical treatment are sparsely reported.⁵

Capsulectomies require greater dissection than open capsulotomies, increasing the level of difficulty, operating time, and patient discomfort.^{5,8} There is additional bleeding and an increased risk of pneumothorax after total capsulectomy.^{1,5,8} To avoid morbidity, a lesser procedure is preferred. However, open capsulotomies are typically regarded as inadequate, and more disposed to recurrence of a capsular contracture.⁷ This opinion is based on studies published in the 1970s and 1980s^{10–15} evaluating women treated with leaky second-generation silicone gel implants. Although open capsulotomies were commonly performed in the 1980s,¹⁶ this procedure was largely replaced by capsulectomy¹⁷ after investigators implicated bacterial biofilms as a cause of capsular contractures.^{18,19}

Clinical experience with earlier generation implants should not be relied upon when evaluating third-

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generation devices.^{6,20} This study was undertaken to determine the efficacy of open capsulotomy alone as a treatment for capsular contracture in breast augmentation patients treated with modern, third-generation breast implants, including saline implants, that were not evaluated in early studies.^{10–15} This is an important clinical question because saline implants were used almost exclusively in the United States from 1992 to 2006 during the silicone gel moratorium, and continue to be a popular choice among patients,⁵ representing approximately 30% of breast augmentation patients in the United States today (Mentor Worldwide LLC, Personal communication, May 2016).

PATIENTS AND METHODS

A retrospective chart review was conducted from 1996 to 2016. All women who underwent an open capsulotomy by the author were included. All patients had Baker III/IV contractures. Only cosmetic breast augmentation and augmentation/mastopexy patients were included. Three patients with extensive capsular calcification, treated with capsulectomies, were excluded. Breast reconstruction patients were also excluded. This study was determined to be exempt from institutional review board oversight by Chesapeake Institutional Review Board Services.

Surgery

All patients underwent outpatient surgery using total intravenous anesthesia (Fig. 1). Patients received cefazolin 1 g IV before surgery and 3 doses of cephalexin 500 mg orally twice daily postoperatively. An inframammary approach, usually along the original scar, was used exclusively. This approach optimizes exposure. The existing capsule was circumferentially incised either partially or totally (Fig. 2). In patients with existing subpectoral pockets, the original (expanded) pockets were reused, with no attempt to dissect a new tissue plane. When the original implants were subglandular, a new submuscular pocket was developed whenever possible,^{5,7} with no attempt to remove or suture the original capsule. New subpectoral pockets were created using sharp dissection to release the inferior pectoralis origin, and blunt dissection of the pocket.

Dilute povidone–iodine solution was used before 2000. Only saline solution was used for irrigation subsequently because of (probably unwarranted²¹) concerns regarding the effect of antibiotics on implants. The beginning of the study coincided with the author’s transition from textured to exclusively smooth, round implants, based on a questionable clinical benefit and possibly more leaks and wrinkles using textured devices.^{22,23} Drains, nipple shields, implant funnels, and acellular dermal matrix were not

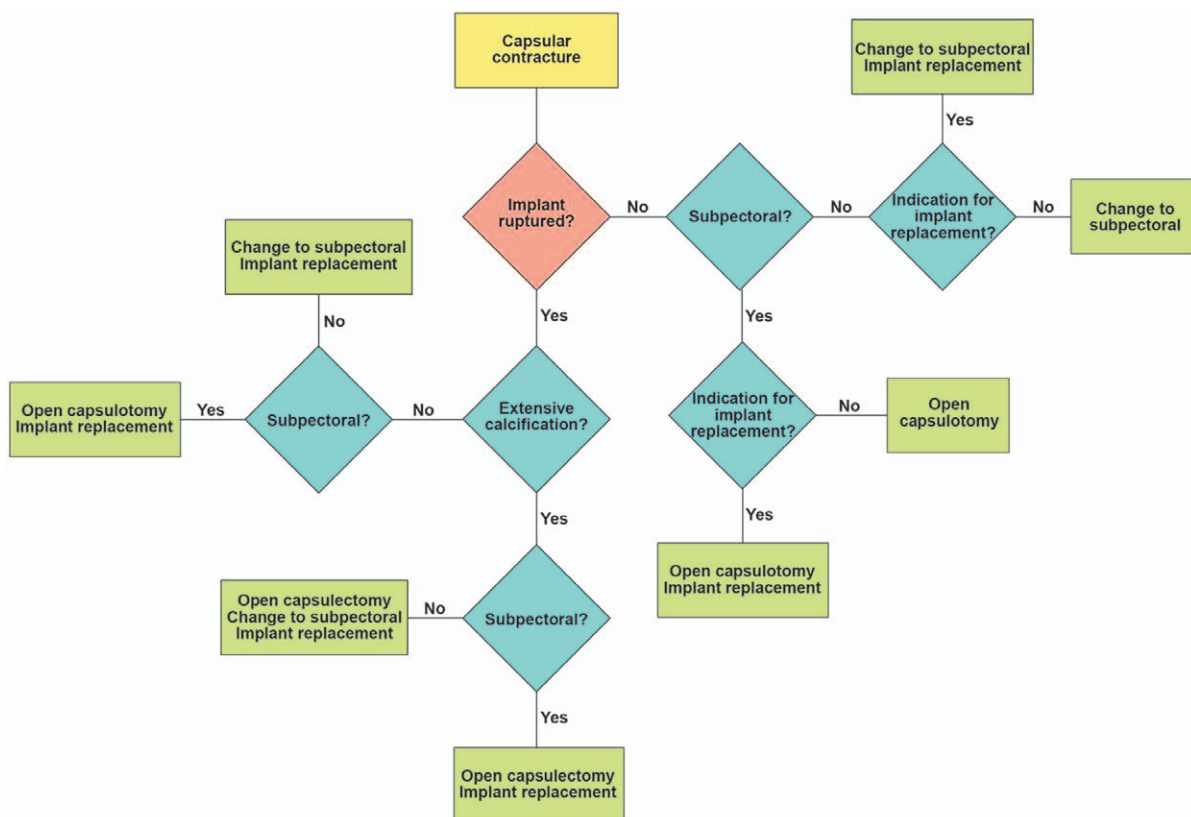


Fig. 1. Treatment algorithm. Indications for implant replacement, apart from rupture, are subjective and include old implants (usually >10 y), size change, preference for a saline-filled or smooth implant, a deflation on the contralateral side, and warranty renewal. Implant manufacturers now provide free replacement implants for variable periods (3–10 y) after implantation.

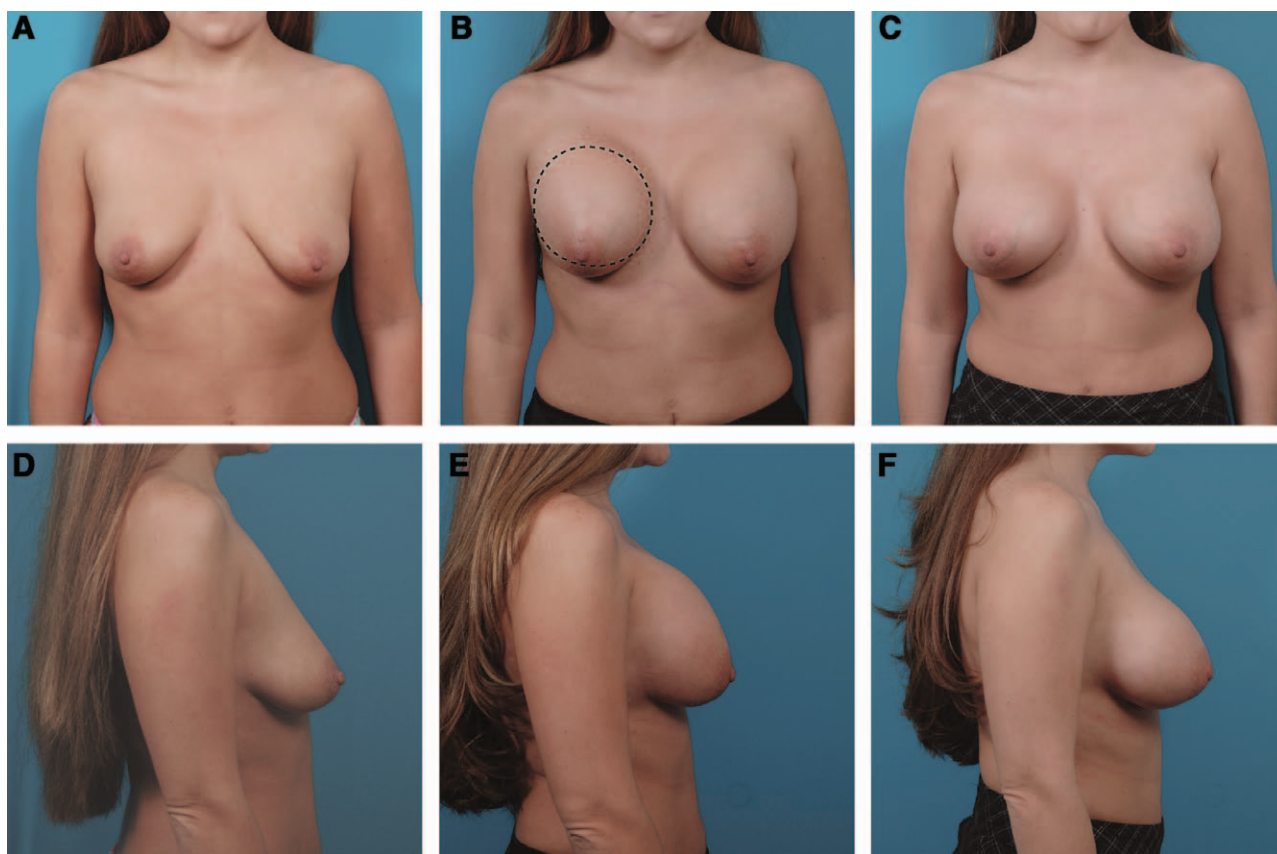


Fig. 2. This 29-year-old woman developed a Baker III capsular contracture after her breast augmentation using Mentor smooth, round, Moderate Plus profile saline-filled implants inflated to 420 cc. She is seen before (A, D) and 1 month after her breast augmentation (B, E). Two months after her breast augmentation, she underwent a right open capsulotomy with reinsertion of the same implant in the same subpectoral pocket. The hatched line indicates the capsulotomy incision. She is seen 1 month after the capsulotomy (C, F). She had no recurrence.

used. Patients were instructed to wear a bra day and night for at least 2 weeks, not to massage their breasts, and to avoid vigorous physical activity for 1 month.

Statistical Analysis

A chi-square test was used to compare categorical data. The cumulative incidence of capsular contractures per patient was estimated using Kaplan–Meier analysis, calculated from the date of implant insertion to the date of the reported complication. A value of $P < 0.05$ was considered significant.

RESULTS

Seventy-five women with Baker III/IV contractures (Fig. 3) underwent open capsulotomies (Table 1). In 68 patients (90.7%), the existing implants were subpectoral. Among the 7 patients with subglandular implants, 6 were changed to a subpectoral pocket. The mean time lapse between implantation and diagnosis of a capsular contracture was 4.0 years. The mean interval between the first open capsulotomy and diagnosis of a recurrent contracture was 8.4 months.

Seventeen patients (22.7%) returned with a recurrence (Fig. 4). Fifteen women were re-treated; 2 women elected

not to have additional surgery. Two patients (2.7%) returned with a third capsular contracture; neither patient elected to have it treated. In 12 women (including 3 bilateral contractures, only 1 of which recurred on both sides), the recurrence was on the same side, and in 5 patients the recurrence was on the contralateral side. Thirteen patients were found to have ruptured silicone gel implants or silicone bleed at surgery; 9 of these patients had recurrences (69.2%). Replacement of a leaking silicone gel implant significantly increased the risk of a recurrent contracture ($P = 0.01$) compared with intact implant replacement. There was no significant difference comparing recurrence rates in patients with implants that were reinserted (6/48 patients, 12.5%) versus intact implants that were replaced (2/11 patients, 18.2%).

Indications for implant replacement (frequently more than 1) included: old implants, usually >10 years ($n = 15$), larger size ($n = 13$), preference for saline ($n = 8$), a deflation on the contralateral side ($n = 4$), suspected implant rupture ($n = 2$), and smaller size ($n = 1$).

Twenty-six women who received povidone–iodine irrigation during surgery (before 2000) had a similar ($P > 0.05$) recurrence rate (19.2%) to patients treated subsequently with saline irrigation (17.2%).

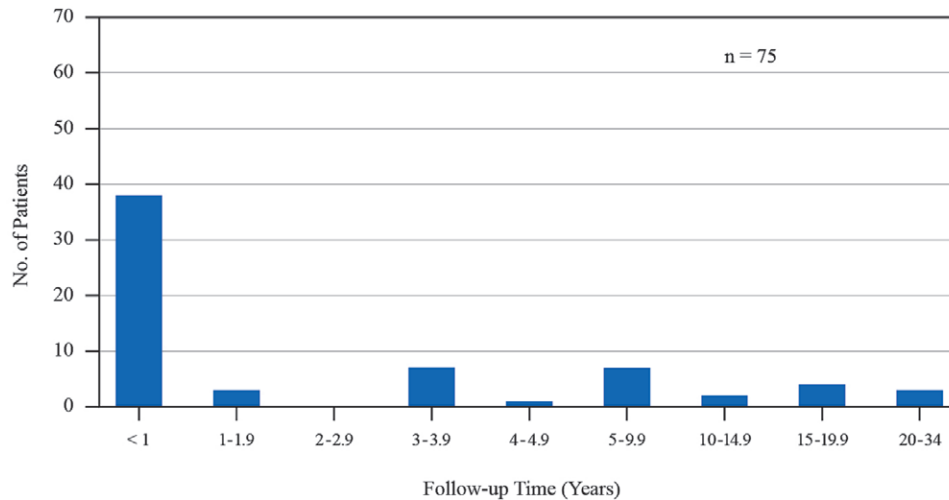


Fig. 3. Time interval between the original breast augmentation and diagnosis of capsular contracture in 75 consecutive women treated with open capsulotomy during 1996 to 2016.

Complications are listed in Table 2. The most common complication was a recurrent capsular contracture (22.7%). Although not part of the study group, the 3 women treated with capsulectomies (heavily calcified capsules) during the study period did not experience recurrences.

Implants manufactured by Mentor Corporation (Santa Barbara, Calif.) were used predominantly by the author from 1996 to 2009. Allergan (Irvine, Calif.) implants were inserted primarily from 2010 to 2016. Consequently, most women received Mentor implants (Table 1). The group sizes were insufficient for comparison of capsular contracture rates by manufacturer.

DISCUSSION

Existing Studies Comparing Open Capsulotomy and Capsulectomy

A recent systematic review⁷ compared the rate of recurrent capsular contracture after open capsulotomies (0%–54%) with capsulectomies (0%–53%), finding them similar. All except one study of open capsulotomies meeting the authors'⁷ inclusion criteria were published between 1972 and 1987.^{10–15} Moufarrege et al¹⁵ reported a 54% failure rate after open capsulotomies. Little and Baker¹² reported 6 recurrences among 18 open capsulotomies (33%). Higgs et al¹¹ reported a 34% capsular contracture rate, and 46% of contractures were bilateral. In all 3 studies, second-generation devices had been implanted between 1973 and 1978 and many of the women had undergone closed capsulotomies. By contrast, Freeman's¹⁰ 1972 study reported only 2 recurrences after 35 capsulotomies (5.7%) in patients treated with more durable first-generation devices. The most recent study of open capsulotomy, published in 1999, also evaluated patients treated predominantly (70%) with second-generation devices; no recurrence rates were provided.²⁴

In the only head-to-head comparison in women treated with the same (albeit, second generation) implants, Higgs et al¹¹ reported a 34% recurrence rate after capsu-

lectomy ($n = 29$) and a very similar 31% recurrence rate after open capsulotomy ($n = 26$). Other studies of capsulectomy, all published after 2000,^{3,17,25,26} evaluated women with third-generation implants. Costagliola et al²⁵ reported no recurrences after capsulectomies, but these patients were treated with steroids. Caffee²⁶ reported a recurrence rate of 30.7% after capsulectomy and subpectoral placement of new textured saline implants. Collis and Sharpe¹⁷ reported an 11% recurrence rate after total capsulectomy and a 50% recurrence rate after a partial “anterior disc” capsulectomy, although the follow-up time was shorter for patients treated with total capsulectomy. In 2012, Hester et al³ reported a 53.4% recurrence rate after traditional capsulectomy.

From 1963 to 1992, over 95% of all breast implants were silicone gel implants; only 5% were saline-filled.²⁷ First-generation implants had a thick gel and a thick elastomeric shell.^{4,27} Second-generation implants, implanted in the 1970s, had much thinner envelopes.^{4,27} Peters et al²⁷ reported a 95% failure rate for second-generation implants 12 years after implantation. Silicone leakage into the tissues is known to increase the inflammatory response and increase the risk of contracture.^{28,29} In response to this problem, in the early 1980s breast implant companies started manufacturing third-generation implants that contained an additional barrier layer.^{4,27}

Improved implant design compromises any comparison of open capsulotomies performed decades ago with capsulectomies performed more recently,⁷ hence the need for evaluation of open capsulotomy in women treated with third-generation devices. A prospective cohort study comparing capsulotomy and capsulectomy would be ideal, but impractical in view of the requirement for equipoise.

Etiology of Capsular Contracture

Infection as a factor predisposing to capsular contracture is supported by numerous microbiological studies that have cultured organisms from the capsule.^{18,19,30,31} Many investigators advocate an infectious etiology.^{2,4,6,19,32–36}

Table 1. Patient Data for 75 Patients Treated with Open Capsulotomy

	Original Surgery (%)	First Capsulotomy (%)	Second Capsulotomy (%)
No. patients	75	75	15
Age at surgery (y)			
Mean	36.3	41.7	46.0
Range	18.0–62.0	18.6–71.0	21.9–69.2
Body mass index (kg/m ²)			
Mean	21.4	22.3	24.5
Range	15.4–26.3	16.7–27.8	19.8–25.8
Implants*			
Saline	52 (72.2)	25 (92.6)	4 (100.0)
Silicone gel	20 (27.8)	2 (0.7)	0
Surgeon			
Swanson	51 (68.0)	75 (100.0)	15 (100.0)
Other surgeon	24 (32.0)	0	0
Right implant volume (cc)			
Mean	379	392	340
Range	175–800	160–800	280–420
Left implant volume (cc)			
Mean	382	397	330
Range	100–800	180–800	270–420
Capsular contracture			
Right	—	39 (52.0)	6 (40.0)
Left	—	24 (32.0)	8 (53.3)
Bilateral	—	12 (16.0)	1 (6.7)
Time between surgery and diagnosis of capsular contracture (y)			
Mean	—	4.0	0.7
Range	—	0.02–34.0	0.04–2.8
Capsulotomy			
Unilateral	—	63 (84.0)	14 (93.3)
Bilateral	—	12 (16.0)	1 (6.7)
Implant replacement			
No implant replacement	—	48 (64.0)	11 (73.3)
Unilateral implant replacement	—	2 (2.7)	2 (13.3)
Bilateral implant replacement	—	25 (33.3)	2 (13.3)
Manufacturer†			
Mentor	33 (44.0)	14 (51.9)	2 (50.0)
Allergan (includes McGhan and Inamed)	16 (21.3)	13 (48.1)	1 (25.0)
Dow Corning	5 (6.7)	0	0
Sientra	1 (1.3)	0	0
Surgitek	1 (1.3)	0	0
Hutchison	1 (1.3)	0	0
Unknown	18 (24.0)	0	1 (25.0)
Mastopexies performed‡			
Yes	14 (19.2)	11 (14.7)	0
No	59 (80.8)	64 (85.3)	15 (100.0)
Site change			
Already subpectoral	—	68 (90.7)	15 (100.0)
Changed from subglandular to subpectoral	—	6 (8.0)	0
Stayed subglandular	—	1 (1.3)	0

*In 3 patients, the original implant type (saline vs silicone gel) was unknown.

†Indicates manufacturer of original implants (when known) in the first column, manufacturer of replacement implants used at the time of the first open capsulotomy in the second column (when implants were replaced), and manufacturer of replacement implants used at the time of a second capsulotomy in the third column (when implants were replaced).

‡In 2 patients, the record did not indicate whether mastopexies had been performed at the time of the original breast augmentation.

and recommend numerous steps to optimize sterility at the time of implant insertion. Reaching beyond a correlation, some researchers now claim that bacterial biofilm infections *cause* capsular contracture.^{34–36} Tamboto et al³⁴ investigated capsular contracture using a porcine model, injecting *Staphylococcus epidermidis* around miniature silicone gel implants. Capsular contractures developed in 28 of 36 inoculated pockets (78%), but also occurred in 7 of 15 uninoculated pockets (47%).

There are problems with the theory of a purely infectious etiology. Positive and negative bacterial cultures from implants and capsules may be obtained from women with and without capsular contractures.^{30,31,37–40} Jacombs et al³³ detected 20-fold (72-fold in vitro) more bacteria attached to textured implants than smooth implants in

their porcine model, and more growth of biofilm, despite similar capsular contracture rates. Capsular contractures can occur years after implantation and the cumulative risk increases over time (Fig. 3),^{1,2,23} which would not be expected if the cause were a bacterial infection acquired at surgery. Capsular contractures occur more frequently after breast reconstruction using implants.^{1,2,23,41} The source of bacteria in postmastectomy patients is unclear. Curiously, a histological study⁴² found that mast cells, the predominant inflammatory cell in hypertrophic scars, disappear as the capsular contracture becomes more severe. Poppler et al,⁴³ using specialized cultures and scanning electron microscopy in women undergoing expander/implant exchange, were unable to find a correlation between biofilm formation and capsular contracture. These investigators⁴³

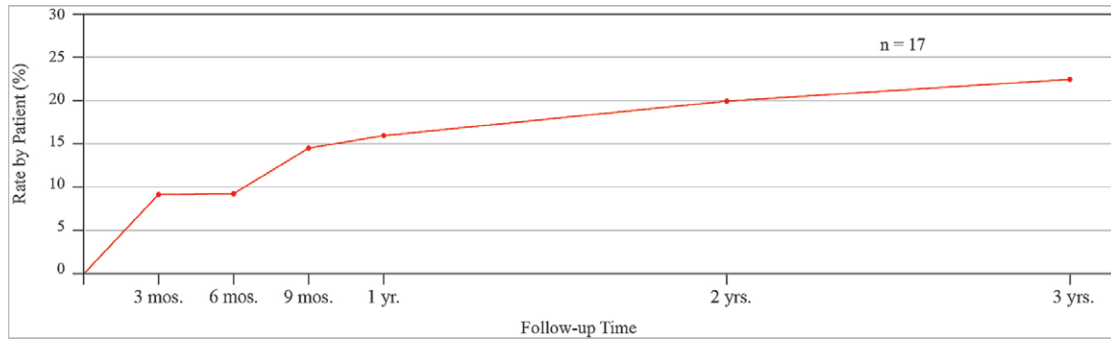


Fig. 4. Kaplan–Meier analysis: Cumulative incidence of recurrent capsular contracture in 17 consecutive women after open capsulotomy.

Table 2. Complications*

	First Capsulotomy (%)	Second Capsulotomy (%)
No. patients	75	15
Complications		
No	51 (68.0)	10 (66.7)
Yes	24 (32.0)	5 (33.3)
Recurrent capsular contracture	17 (22.7)	2 (13.3)
Implant deflation	3 (4.0)	2 (13.3)
Delayed healing†	2 (2.7)	0
Hematoma	2 (2.7)	0
Allergic rash	2 (2.7)	0
Cellulitis	1 (1.3)	0
Seroma	1 (1.3)	1 (6.7)
Partial wound dehiscence†	1 (1.3)	0
Partial areola necrosis†	1 (1.3)	0

*Five patients had more than 1 complication. Therefore, the total number of complications exceeds the number of patients who had complications.

†Patients treated with simultaneous mastopexies.

theorize that stressful stimuli might lead independently to inflammation and a biofilm. Paradoxically, antimicrobial therapy may even induce biofilm formation to confer resistance.^{44,45}

The limitations of an infectious etiology are evident in the clinical findings of this study. An open capsulotomy leaves all of the capsule (and biofilm) in the patient, virtually guaranteeing treatment failure. Yet, this simple maneuver is 77.3% effective after 1 release and 97.3% effective after 2 capsulotomies. The success rate is even higher in patients with intact implants, in whom free silicone gel is not a factor; 86.4% had no recurrence. Moreover, there was no change in the recurrence rate after povidone–iodine irrigation was replaced with saline irrigation.

Another theory for capsular contracture is based on the mechanical action of myofibroblasts^{1,7,9,43,46,47} and abnormal collagen deposition.^{9,42,43} A capsulotomy breaks this mechanical force.⁷ It is possible, although unproven, that nonpathogenic bacteria may be protective against pathogens³⁸ (similar to the flora of the digestive tract) and attempts to alter the microbial environment with antibiotics may be counterproductive. Triple antibiotic irrigation is recommended.^{6,48} However, recent studies have found no benefit in capsular contracture rates comparing triple antibiotic with saline irrigation.^{49,50} Other studies challenge the efficacy of perioperative systemic antibiotics.^{51,52}

For the period 2002 to 2012, the author’s capsular contracture rate after primary breast augmentation was 6%,⁵³ similar to other series,^{3,54} and to manufacturer core study data (8.1%–18.9%),^{20,41,55–57} which are regarded as most robust.^{5,7} It is not clear that conforming to numerous technical recommendations^{4,35} (apart from the usual sterile technique) makes a difference in the capsular contracture rate.³

Site Change

Some investigators recommend a subglandular/subpectoral site change, or a neopocket.^{58–60} In their comparison of capsulectomy and site change versus open capsulotomy and no site change, Wan and Rohrich⁷ find evidence to support a site change. However, as with the comparison of capsulectomy and capsulotomy, the difference in implant shell integrity is a confounding factor. An open capsulotomy in women treated in the 1970s with second-generation implants^{11,12,15} is more likely to fail in the presence of ruptured implants and silicone bleed.

An open capsulotomy limits the wound area and theoretically minimizes inflammation and fibroblast activity by preserving the existing capsule. The subpectoral location seems to be at a lower risk for capsular contracture,^{1,5,6,16,56} a finding often attributed to more separation from non-sterile breast tissue,^{1,6,18,19} although there is still plenty of contact. The number of patients undergoing a site change in this study (n = 6) was too small to make any conclusions regarding effect on capsular contracture rate. Regardless of capsular contracture risk, replacing a subglandular implant in the submuscular plane provides additional tissue cover and optimizes upper pole aesthetics.^{5,7}

Implant Replacement

In this study, the subgroup of patients whose ruptured or leaking silicone gel implants were replaced had a significantly ($P = 0.01$) higher risk of recurrence than patients whose intact implants were replaced, underscoring the increased risk associated with silicone gel leakage.

Perhaps counterintuitively, patients whose implants were not replaced were at no greater risk of recurrence than women whose intact implants were replaced. This finding contrasts with a recent core study of Sientra (Santa Barbara, Calif.) breast implants, which found a reduced recurrence risk in women whose implants were replaced.⁵⁷

This finding was based on the analysis of a subgroup of 68 patients (of 150) whose contractures responded to treatment.⁵⁷ The investigators noted that 3 study sites had a much higher rate of capsular contracture than the others.⁵⁷ Confounding variables must be considered.

Although implant exchange is generally recommended,^{2,4,6,7,9,57} the recipient site is not sterile.^{1,6,38,61} A new implant is likely to be quickly colonized by the bacteria already present in adjacent breast tissue.³⁸ Nevertheless, other indications for replacement include the following: a size change, warranty renewal, or to replace textured implants with smooth devices. Implant manufacturers have recently started providing free replacement implants for patients developing capsular contractures within 3 to 10 years of implantation.^{62–64}

Smooth versus Textured Implants

Textured implants were designed to minimize the rate of capsular contracture, but there may be no advantage over smooth implants when the implant is placed submuscularly.^{4,65,66} Shaped implants have not been shown to be superior to round implants in breast augmentation.^{5,8} Textured implants are at greater risk for rippling and deflation than smooth implants.^{7,23} Recently, textured implants have been implicated in late seromas, double capsules,⁶⁷ and anaplastic large-cell lymphoma.⁶⁸ Smooth implants are now favored by the majority of surveyed plastic surgeons.⁸ Smooth implants may reduce the recurrence rate when used as replacement implants.⁷ A recent core study with a 10-year follow-up identified the lowest capsular contracture rate in patients treated with smooth subpectoral implants inserted through an inframammary incision.⁵⁶

Capsulectomy versus Capsulotomy

A capsulectomy involves much more dissection than a capsulotomy.⁶⁹ There is less remaining tissue to provide implant cover and a greater potential for nerve injury.⁷⁰ A drain may be needed.⁵ It can be technically difficult, and dangerous, to remove capsular tissue from the axilla and the chest wall.^{1,60,69} Accordingly, an anterior capsulectomy may be recommended,⁶⁹ although this recommendation begs the question, is a capsulectomy really necessary if part of the capsule is left in the patient?

A unilateral open capsulotomy typically requires 20 to 30 minutes. Capsulectomy adds about 1 hour of operating time.⁶⁹ Because there is minimal submuscular dissection (unless a new subpectoral pocket is created), there is little discomfort. Patients return to their usual activities within a few days. Even in the event of a recurrence, the patient has experienced minimal cost and morbidity. The recurrence rate of 22.7% overall after open capsulotomy (and 13.6% for patients with intact implants) compares favorably with recurrence rates reported after capsulectomy (25%–53.4%).^{3,57}

In the case of thin, noncalcified capsules, there seems to be no harm in leaving the capsule in the patient.⁷¹ The capsule around saline implants is usually absorbed.⁷² The low seroma rate (1.3%) indicates that leaving the capsule in situ rarely leads to fluid accumulation. A capsulectomy, either partial or full, may be reserved for thick, calcified

capsules.⁷ Removal of all calcification is unnecessary.⁷¹ Capsular calcifications are not usually a source of confusion for radiologists.⁶⁹ Acellular dermal matrix is thought to reduce capsular contracture by serving as a barrier and reducing inflammation and scarring.⁷³ This objective is also accomplished with a capsulotomy.

Treatment Recommendations

Recent recommendations to avoid recurrence include capsulectomy, site change, new implants, bloodless dissection, antibiotic irrigation, glove change, covering the incision site with an adhesive barrier, form-stable implants, a sleeve or funnel, nipple shields, and acellular dermal matrix.^{2,4–6,35} In 1981, Brody and Latts⁷⁴ lamented the lack of controlled studies leading to a “shotgun approach using every means ever reported,” commenting that “the enthusiastic espousal of circumstantial evidence becomes dogma.” In the years since, investigators have frequently noted the lack of scientific data^{7,75,76} and the shortcomings of treatment dictated by clinical impressions alone.⁷⁵

In 2012, Hester et al³ commented that breast-pocket irrigation, site changes, and submuscular or dual plane implant placement had minimal identifiable effect on the rate of capsular contracture. Despite capsulectomy, site change when appropriate, and implant replacement, these experienced surgeons reported a recurrence rate of 53.4%, prompting them to start incorporating acellular dermal matrix.

A recent survey⁸ and review articles^{4,5,8} do not include open capsulotomy as a treatment option. Twenty percent of plastic surgeons use silicone gel implants exclusively.⁸ Although silicone gel implants are thought to have a more ideal feel characteristic,⁵ this difference may be negligible, particularly when the implant is placed submuscularly. The appearance of saline-filled implants is the same.⁵ Implant deflation is easier to detect, and treatment of a capsular contracture is likely to be uncomplicated and successful. Saline implants are less expensive than silicone gel implants and patient satisfaction is extremely high with both devices.^{16,77,78}

CONCLUSIONS

Capsular contracture after a breast augmentation may be safely and effectively treated with an open capsulotomy, reducing patient morbidity and cost associated with alternative treatments.

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