Surgical Treatment for Capsular Contracture: A New Paradigm and Algorithm

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Background: Capsular contracture following breast augmentation is prone to recurrence with conventional surgical therapy. Adding acellular dermal matrix improves results but significantly increases operating time and cost. This study tested a new treatment algorithm that uses acellular dermal matrix selectively to optimize success rates while minimizing its drawbacks.

Methods: All patients surgically treated by the authors for Baker grade III/IV capsular contracture between 2007 and 2018 were included in this retrospective cohort study. Data were collected on patient, breast augmentation, capsular contracture, and surgical treatment characteristics, in addition to follow-up findings. Treatment success was defined as Baker grade II or better.

Results: One hundred eighty patients underwent 217 surgical treatments for capsular contracture. Conventional treatment was used in 185 cases and acellular dermal matrix in 32. Twenty-six patients were treated for a second occurrence and four were treated for a third. The average follow-up was 2.4 years. Conventional treatment was successful in 72.5 percent of first occurrences, 62.5 percent of second occurrences, and 50.0 percent of third occurrences. Acellular dermal matrix was successful in 96.9 percent of cases. The odds of failure were increased by bilateral capsular contracture (3.9 times) and previous treatment failure (3.5 times). When acellular dermal matrix was used selectively for bilateral capsular contracture or in unilateral cases with a previous treatment failure, the overall treatment success rate improved to 85.6 percent compared with 64.2 percent when this algorithm was not followed ($p < 0.001$).

Conclusion: This study demonstrates that selective acellular dermal matrix use can increase success rate to over 85 percent in the overall treatment of capsular contracture, and to nearly 100 percent in individual cases. (*Plast. Reconstr. Surg.* 146: 516, 2020.)

Baker grade III/IV capsular contracture is a vexing complication of breast augmentation, the most frequently performed aesthetic procedure in the United States.[1] The overall incidence of capsular contracture ranges from 3 to 19 percent.[2–13] Although associated pain rarely dominates patient concerns, aesthetic morbidity that includes firmness, implant malposition, and asymmetry is a strong driver for surgical intervention. As a result, capsular contracture is the most common reason for reoperation after breast augmentation.[5,7,10]

Conventional surgical treatment of capsular contracture typically includes either anterior or total capsulectomy, implant replacement, and pocket change where applicable. Intravenous antibiotics; antibiotic pocket irrigation; and enhanced sterile precautions including glove changes, skin protection, insertion funnels, and a "no-touch" approach are important adjuncts. Although the combination of such techniques is considered the gold standard, failure rates remain as high as 54 percent.[14] More recently, acellular dermal matrix has emerged as a new therapeutic adjunct to improve results. However, it adds significant operating time and cost to the procedure.[15–19]

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Studies to date have reported the success rates of various surgical treatments for capsular contracture, but none have proposed a treatment algorithm evaluated with patient outcomes. The goal of this study was to create an algorithm that includes selective acellular dermal matrix use to optimize the overall success rate while minimizing the impact of acellular dermal matrix disadvantages. The study hypothesizes that bilateral contracture and previous surgical treatment failure are positively associated with capsular contracture treatment failure when using conventional techniques without acellular dermal matrix.

PATIENTS AND METHODS

A retrospective cohort study of breast augmentation patients surgically treated for Baker grade III/IV capsular contracture between 2007 and 2018 was conducted. Patients having undergone breast augmentation performed by the authors and subsequently developing capsular contracture, in addition to those presenting to the practice with capsular contracture following initial treatment elsewhere, were included. Collected data included patient and primary augmentation procedural characteristics, findings at surgery, surgical treatment methodology, and follow-up results (Table 1).

Operative Technique

Surgical treatment for capsular contracture in this study consisted of using the original incision site, either anterior or total capsulectomy, subglandular to subpectoral pocket plane conversion whenever the former was encountered, and change to smooth implants when the originals were textured. Capsulotomy alone, as an alternative to capsulectomy, was never used. Conversion to a subpectoral plane from a subglandular position was always done because of acknowledged advantages in terms of aesthetics, breast imaging, and influence on capsular contracture prevention. The tradeoff for a rare instance of significant animation deformity was deemed acceptable. Changes in implant volume, either up or down, were also accommodated when the patient requested. Round implants were always selected as replacements based on Level I evidence demonstrating no aesthetic superiority using anatomical implants.[20] Smooth implants were always chosen as replacement implants given that all implants were subpectoral, a scenario where textured implants offer little advantage.[21–25] The implant filler type was changed in 18.4 percent, and 87.5 percent of these were a saline to silicone conversion, because of patient preference. Concurrent mastopexy based on anatomical circumstances was added in only 3.7 percent.

Acellular dermal matrix was used selectively as an adjunct toward the end of the series when this technology was adopted by the practice. Indications included previous failed surgical treatment for capsular contracture and for bilateral cases (Figs. 1 and 2). Acellular dermal matrix was placed through either a preexisting periareolar or inframammary incision following capsulectomy. It was not necessary to make incisions any longer than the original. Typically, two large pieces (9 × 18.5 cm) of Strattice Contour 2 (Allergan, Inc., Irvine, Calif.) were on hand for each breast, although three pieces total could often be used for both sides. Factors that influenced how much material was needed included the degree of pectoralis muscle/breast overlap, the thickness of the breast tissue, and implant size. Coverage extended from the pectoralis border to the inframammary crease, spanning the full width of the implant pocket. Less extensive coverage was not considered, given the premise that acellular dermal matrix acts as an interface between the implant and breast tissue to prevent capsular contracture. Acellular dermal matrix use in this study was for the singular purpose of preventing capsular contracture. It was not used for concurrent reasons such as adding soft-tissue thickness, buttressing a capsulorrhaphy, or preventing lower pole stretch.

The Strattice pieces were shaped and trimmed using the breast with a sizer inside as a template. Darts were cut into the pieces as necessary to create a three-dimensional contour. The pieces were sutured to the muscle, to each other, and anchored at the inframammary crease. They were pie-crusted before insertion and a single drain was

Table 1. Data Categories Examined

Category	Items Examined
Patient	Age; smoking history
Primary breast augmentation	Incision location; implant (volume, filler type, shape, surface type); pocket plane; concurrent mastopexy
Capsular contracture	Baker grade; laterality (right, left, bilateral); onset after augmentation (in months); implant status (intact, ruptured, deflated); prior pharmacologic treatment
Surgical treatment	Capsulectomy type; pocket plane change; implant changes (volume, filler, shape, surface); ADM use; postoperative pharmacologic treatment
Follow-up	Baker grade (physical examination, phone); interval from surgery (in months)

ADM, acellular dermal matrix.

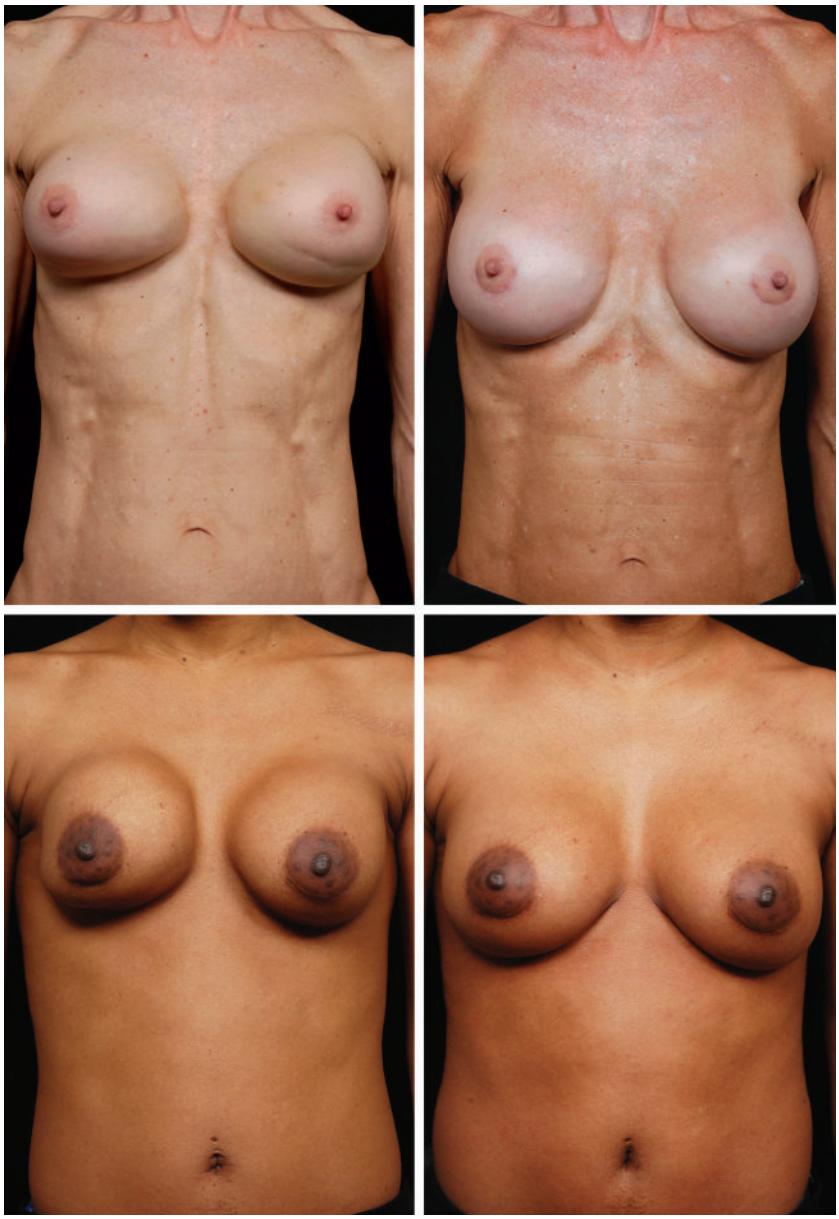

Fig. 1. Bilateral capsular contracture patients treated with capsulectomy and acellular dermal matrix. The patient with subpectoral silicone implants and second occurrence of bilateral capsular contracture following conventional treatment in the pre -acellular dermal matrix era (*above, left*). The patient shown following treatment with acellular dermal matrix at 12 months. Baker grade II bilaterally (*above, right*). Smoker, with silicone subpectoral implants and first-time bilateral capsular contracture (*below, left*). Postoperative views at 46 months; the patient was still a smoker. Baker grade II bilaterally (*below, right*).

placed after insertion. The implants were then placed with the aid of an insertion funnel and the access opening left in the Strattice construct for this purpose then closed in the case of periareolar access. [**See Video 1 (online)**, which demonstrates the periareolar approach to acellular dermal matrix implant pocket lining technique. **See Video 2 (online)**, which demonstrates the inframammary approach to acellular dermal matrix implant pocket lining technique.]

All patients had drains placed for 1 week postoperatively. None of the acellular dermal matrix patients were placed on medical prophylaxis against capsular contracture, whereas

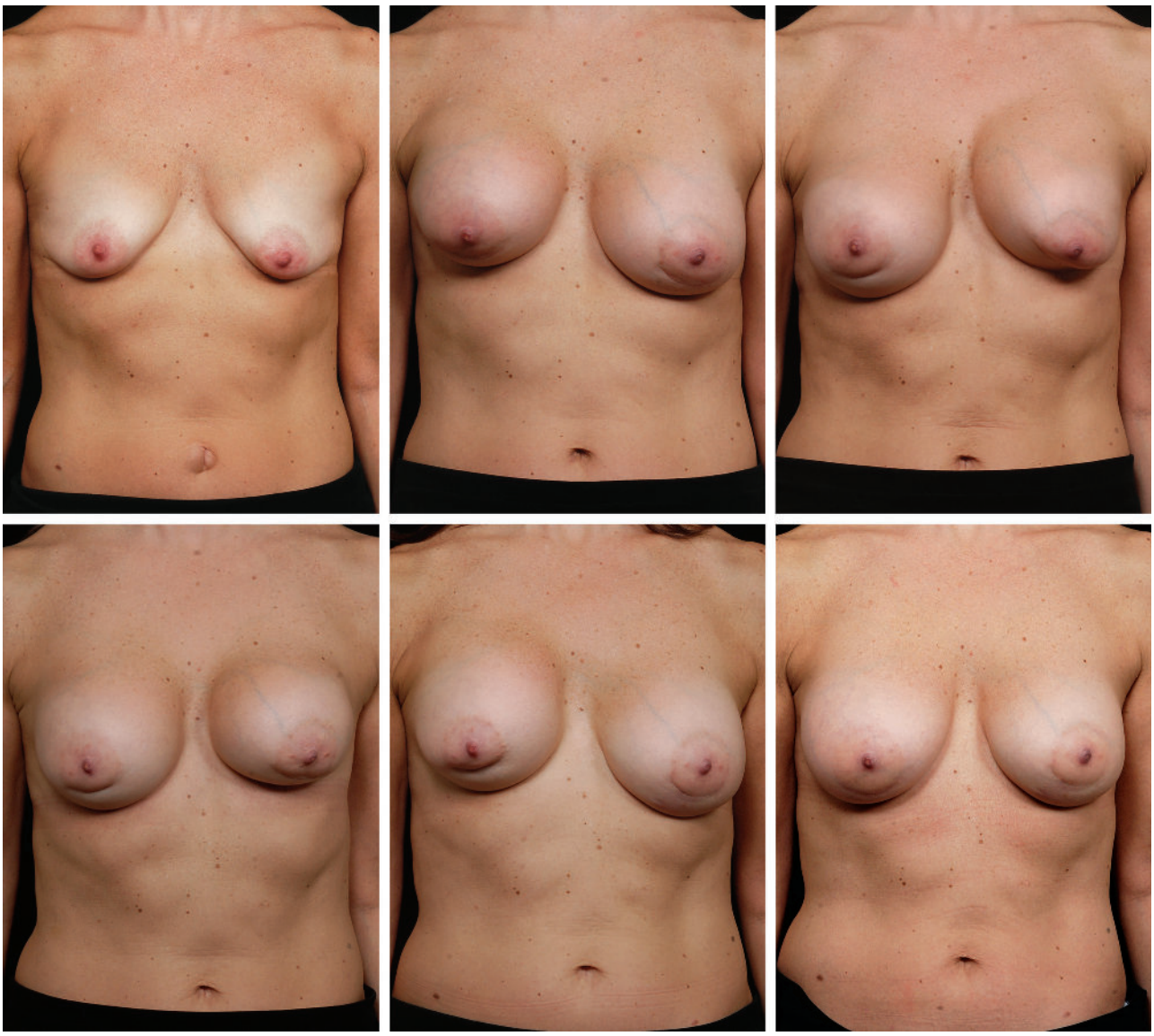

Fig. 2. Refractory alternating unilateral capsular contractures spanning the pre–acellular dermal matrix and acellular dermal matrix eras. Preoperative view for a periareolar approach to subpectoral augmentation with silicone implants in 2013 (*above*, *left*). Right capsular contracture before treatment with conventional method in 2014 (*above*, *center*). Left capsular contracture before treatment with conventional method in 2015 (*above*, *right*). Recurrent left capsular contracture before treatment with acellular dermal matrix in 2016 (*below*, *left*). Recurrent right capsular contracture before treatment with acellular dermal matrix in 2017 (*below*, *center*). Stable result at 1 year. Baker grade II bilaterally (*below*, *right*).

conventionally treated patients were sometimes placed on Singulair (Merck, Kenilworth, N.J.), 10 mg once per day for 6 weeks. Implant massage was not used in any patient postoperatively.

Patient Follow-Up Methodology

Treatment success was defined as Baker grade II or better as assessed by either the most recent chart note, phone call inquiry, or in-office examination. When reachable, patients were interviewed by phone and a brief questionnaire was completed (Fig. 3). They were then requested to return for in-office examination to corroborate Baker classification assessment by phone. Those returning for in-office examination helped validate the accuracy of the telephone interview method for patients who could only be reached by phone and did not return for in-office examination.

Statistical Analysis

The data were summarized as counts, percentages, means ± SD, medians and interquartile

Telephone follow-up questions.

1. Have you had further breast surgery since your last procedure with us? Yes No
   Approximately when? _____
   What was the purpose? _____
   Which side, or both? _____
   What was done? _____

2. How would you describe your breast(s) today?
   Very hard and round, feels tight or uncomfortable _____ (IV)
   Somewhat hard and round, looks higher _____ (III)
   More firm than natural, yet soft _____ (II)
   Very soft and natural, feels normal _____ (I)

3. How does this compare to just before your last surgery with us?
   Much better now
   About the same as before surgery
   Worse than before surgery

Fig. 3. Telephone follow-up questions. Question 2 addresses the Baker classification.

range, and odds ratios. Continuous variables were compared using two-sample t tests when parametric assumptions were satisfied, and Wilcoxon rank sum tests otherwise. Chi-square and Fisher's exact tests were used to compare categorical variables and for contingency table analysis. Cohen's kappa (κ) was calculated to determine Baker grade agreement between in-office examinations and phone assessments of capsular contracture.[26] Logistic generalized linear mixed modeling with random effects was performed to evaluate treatment success of anterior versus total capsulectomy; association of treatment failure with previous treatment failure, bilateral capsular contracture, and implant rupture; and efficacy of the proposed treatment algorithm.

The level of statistical significance for hypothesis testing was set at $\alpha = 0.05$. Statistical analyses were performed using SAS version 9.4 (SAS Institute, Inc., Cary, N.C.).

RESULTS

The study included 180 patients who developed capsular contracture after primary breast augmentation, which was performed by a surgeon other than the senior author (D.A.H.) in 59.1 percent of cases. Overall, patient age averaged 46.5 ± 10.2 years, 7.2 percent of patients were smokers, and 18.5 percent had taken medical prophylaxis against capsular contracture postoperatively, with the latter not proving effective. These variables were all not significantly different between conventional and acellular dermal matrix treatment groups. The median duration between breast augmentation and onset of capsular contracture was 7 months (interquartile range, 3 to 24 months).

These 180 patients underwent a total of 217 operations (Table 2). One hundred eighty-five cases involved conventional treatment as described, and acellular dermal matrix was used as an adjunct in 32. Most patients had breast augmentations using smooth, round, silicone implants placed in the subpectoral plane through a periareolar incision.

Capsular contracture was unilateral in 50.2 percent of cases and bilateral in 49.8 percent. Baker classification was grade III in 72.8 percent and grade IV in 27.2 percent. Silicone implant rupture was identified in 12.0 percent of cases. Treatment type depended on whether capsular contracture was unilateral or bilateral, but not on Baker grade or implant rupture. Within the whole group, 13.4 percent of cases were reoperations after a previous treatment failure, and more of these tended to be next treated with conventional techniques rather than with acellular dermal matrix because of the emergence of that option much later in the series ($p < 0.001$).

Conventional treatment was successful in 72.5 percent of first occurrences, 62.5 percent of second occurrences, and 50.0 percent of third occurrences of capsular contracture (Table 3). Acellular dermal matrix was used in 32 patients and was successful in 96.9 percent of cases. The

Table 2. Preoperative Characteristics between Conventional and Acellular Dermal Matrix Treatment Groups

Characteristic	Conventional Treatment	ADM	*p*
No.	185	32	
Breast implant			
Mean volume, cc	261.0 ± 74.1	267.9 ± 66.7	0.633
Surface, %			
Smooth	77.7	78.1	
Textured	22.3	21.9	0.959
Shape, %			
Round	94.0	100	
Anatomical	6.0	0	0.376
Filler, %			
Silicone	60.0	81.2	
Saline	40.0	18.8	0.021
Pocket, %			
Subpectoral	75.7	93.8	
Subglandular	24.3	6.2	0.020
Incision, %			
Periareolar	56.0	65.6	
Inframammary	33.2	28.1	
Axillary	10.3	6.3	
Umbilical	0.5	0	0.704
Complication, %			
Implant rupture	10.3	21.9	0.062
Capsular contracture			
Laterality			
Unilateral	53.5	31.3	
Bilateral	46.5	68.7	0.020
Baker grade			
III	72.4	75.0	
IV	27.6	25.0	0.763
Previous treatment failure	9.7	34.4	<0.001

one acellular dermal matrix failure occurred in a patient with stable stage IV lung cancer receiving multiple rounds of targeted therapy with different agents. It was not necessary to remove the acellular dermal matrix in this patient.

Breast implant volume change occurred in 29.0 percent of surgical treatments, surface change in 19.4 percent, filler change in 18.4 percent, and pocket change in 20.3 percent. Surgical treatment included anterior capsulectomy in 50.3 percent of cases and total capsulectomy in 49.7 percent. The odds of treatment success were not higher with total compared to anterior capsulectomy (OR, 0.6; $p = 0.249$).

The average follow-up time was 13 months (range, 1 month to 18.5 years) for conventional treatment and 15 months (range, 1 month to 4.3 years) for treatment with acellular dermal matrix, and the difference between groups was not statistically significant ($p = 0.728$). Eighty-nine of the 180 patients who underwent surgical treatment completed a phone assessment of capsular contracture extending the average follow-up period in the conventional treatment group to 2.6 years and to 2.4 years overall. Among these patients, 20 returned for an in-office examination, and Baker grade agreement between phone and in-office assessments was $\kappa = 0.69$, corresponding to a "substantial" agreement ($p = 0.001$).[27] Moreover, 65 of the 89 patients provided a Baker grade over the phone similar enough to their Baker grade at the last office examination that it did not change treatment outcome.

On regression analysis, bilateral capsular contracture and previous treatment failure were found to have large odds ratios significantly associated with conventional treatment failure (Table 4). Simple regression revealed that the odds of conventional treatment failure were increased by bilateral capsular contracture (3.9 times) and previous treatment failure (3.5 times), but not by implant rupture (1.2 times). Subsequently, multiple regression showed that bilateral capsular contracture and previous treatment failure maintained odds ratios greater than 2. Previous treatment failure was statistically significant in the simple regression model ($p = 0.032$) and bilateral capsular contracture was statistically significant in the multiple regression model ($p = 0.029$) (Table 4).

A contingency table analysis of conventional treatment failure by bilateral capsular contracture and previous treatment failure was then performed (Table 5). Among unilateral cases treated with capsulectomy alone, the failure rate was significantly higher for those with a previous treatment failure (50.0 percent) than for those without (17.7 percent) ($p = 0.007$). However, the failure

Table 3. Success Rate of Conventional versus Acellular Dermal Matrix Treatment Based on Capsular Contracture Occurrence

	First Occurrence	Second Occurrence	Third Occurrence	Overall
No.	187	26	4	
Conventional treatment, %	72.5	62.5	50.0	71.4
Anterior capsulectomy	67.4	71.4	0	67.7
Total capsulectomy	77.8	55.6	50.0	75.0
ADM, %	95.0	100	100	96.9

ADM, acellular dermal matrix.

Table 4. Regression Analysis of Conventional Treatment Failure

Predictor	OR	95% CI	*p*
Simple regression			
Bilateral capsular contracture	3.9	0.6–23.3	0.139
Previous treatment failure	3.5	1.1–10.8	0.032
Implant rupture	1.2	0.4–3.7	0.740
Multiple regression			
Bilateral capsular contracture	2.3	1.1–4.6	0.029
Previous treatment failure	2.6	0.8–7.8	0.093

Table 5. Contingency Table Analysis of Conventional Treatment Failure

Previous Treatment Failure	Failure Rate (%)	*p*
Unilateral		
No	17.7	0.007
Yes	50.0	
Bilateral		
No	36.6	0.638
Yes	25.0	

rate did not depend on whether there was a previous treatment failure for bilateral cases.

Based on these findings, a surgical treatment algorithm for capsular contracture was created (Fig. 4). This algorithm was then evaluated using the 217-case patient cohort. Interestingly, the algorithm was found to have been followed 51.2 percent of the time for surgical treatment of capsular contracture during the over 10-year study period (Table 6). Analysis showed that when acellular dermal matrix was used selectively for cases of bilateral capsular contracture or unilateral cases with a previous treatment failure, the overall treatment success rate was improved to 85.6 percent compared with 64.2 percent when this algorithm was not followed ($p < 0.001$).

Table 6. Success Rate of Capsular Contracture Treatment Based on Algorithm

Algorithm Followed	Success Rate (%)	*p*
No	64.2	<0.001
Yes	85.6	

DISCUSSION

Capsular contracture is a distressing development for both patients and surgeons alike. It creates a pall over the patient's decision to have surgery in the first place, with its attendant expense and time away from normal life. Fortunately, most patients can adapt to the situation and move forward without long-term regret if the problem can be solved in one step. Recurrent

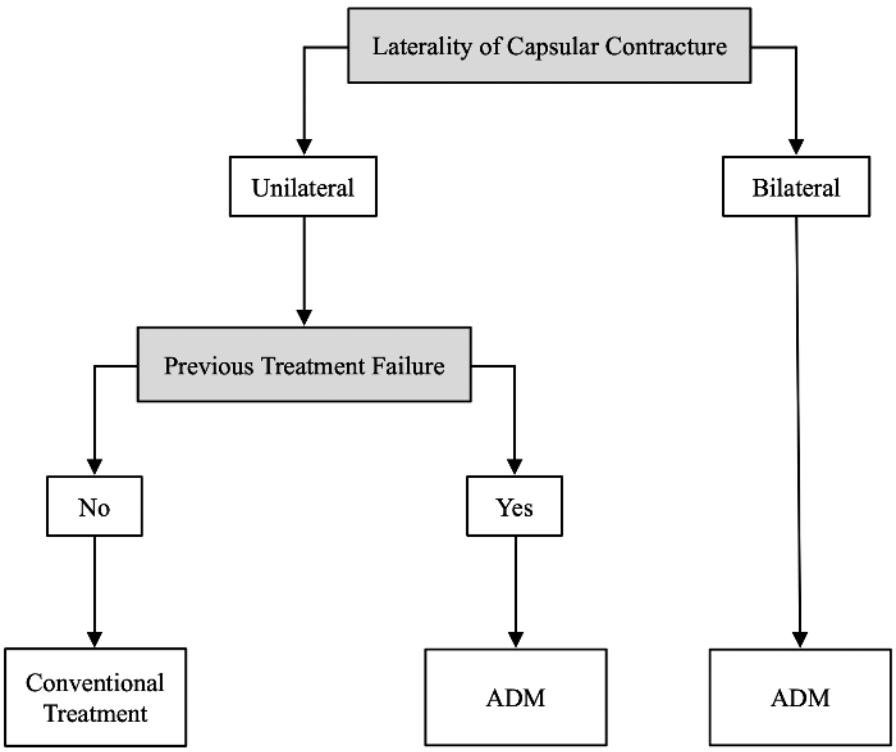

Fig. 4. Proposed treatment algorithm for Baker grade III/IV capsular contracture. *ADM*, acellular dermal matrix.

capsular contracture leads to frustration, however, particularly when another effort using the same remedy portends an increased likelihood of repeated failure.

With a nearly 100 percent success rate, treatment that includes acellular dermal matrix to completely line the nonmuscular portion of the anterior implant pocket has been shown in this study and in previous reports to be a far more reliable option in situations prone to failure.[15–19] The two main disadvantages of acellular dermal matrix use in the treatment of capsular contracture are increased operating room time—approximately 1 hour per breast—and the great expense of the material itself. Although human acellular dermal matrix is used freely for breast reconstruction and other purposes in a hospital setting, the cost is prohibitive for the self-pay patient, which was the case for all of the acellular dermal matrix patients in this study (Table 7). Porcine-derived acellular dermal matrix is more affordable, although it is still very expensive. Fortunately, it has proven to be highly effective as a substitute in this study.

The burden of capsular contracture treatment is increased significantly for the patient when conventional treatment without acellular dermal matrix fails, from both psychic and cost perspectives. The algorithm proposed here minimizes both by including acellular dermal matrix as a treatment adjunct at the earliest moment that offsets its disadvantages. In so doing, it avoids the even more prohibitive cost of an acellular dermal matrix procedure added on top of that associated with a preceding conventional treatment failure. Equally important, it reliably reduces to a minimum the total number of operations a patient must undergo to be contracture free.

The findings of this study support the clinical assumption that a patient with first-time unilateral contracture demonstrating normal healing on the opposite side is a good candidate for a conventional treatment approach without acellular dermal matrix. Unilateral presentation suggests a random occurrence unrelated to individual healing biology. A bilateral contracture, however, argues for a systemic-based cause, at least in part. This may account for the higher incidence of recurrence in bilateral cases treated by conventional therapy without acellular dermal matrix. This theory, although unproven, lines up with the algorithm recommendations drawn from data analysis.

Acellular dermal matrix use for capsular contracture can be performed through either a preexisting periareolar or inframammary incision made to the same length as the original, and not longer. Although not technically complex, it does entail a choreographed sequencing of steps to proceed efficiently (Videos 1 and 2). Nevertheless, it can routinely take more than 2 hours to treat one breast. Completing one side at a time, in its entirety, is recommended practice to reduce open wound duration and thereby mitigate infection risk in bilateral cases.

Of lesser import, the data indicated a slight advantage with total capsulectomy compared to anterior capsulectomy for first-time capsular contracture when using conventional treatment methods without acellular dermal matrix. Although previously demonstrated,[28] this slight difference does not argue for routine use of total capsulectomy given the associated increased operating time, risk of pneumothorax, and increased serous fluid production. A difference between capsulectomy types could not be demonstrated with acellular dermal matrix use because of only having one treatment failure in this group. Although implant rupture has been linked to development of capsular contracture, it was not found to be significantly associated with conventional treatment failure in this study.

Limitations of this study included its retrospective nature, limited acellular dermal matrix use restricted to the latter part of the series, and follow-up methodology imperfections. However, the retrospective nature proved valuable in that it provided a historical control to demonstrate a difference between treatment first without, and then with acellular dermal matrix after it became an available adjunct. This also led to a wide spectrum of patients being treated with conventional techniques, which together with the use of consecutive sampling, contributed to minimizing selection bias. Although the data support the conclusions drawn, this study represents a single-surgeon experience. As such, the study design reflects technique preferences that include subpectoral

Table 7. Acellular Dermal Matrix Cost Considerations

Product	Source	Dimensions (cm)	Unit Cost	Units Per Breast
AlloDerm*	Human	10 × 20	$8189	2
Strattice	Porcine	9 × 18	$2730	2

*LifeCell Corp., Branchburg, N.J.

implant placement, the use of smooth implants, and creating a complete acellular dermal matrix interface between the breast tissue and implant.

The subset of patients in this study receiving acellular dermal matrix is too small to prove by itself that the nearly 100 percent success rate demonstrated applies universally. However, there are three previous publications that verify complete success in a collective series of over 150 patients followed for a minimum of 1 year in one of the studies and for a median of 3.6 years in another.[15–17]

Follow-up limitations were mitigated by the demonstration of a substantial Baker grade agreement between phone and in-office assessments. This more than doubled the average follow-up interval beyond office examination alone. Office examinations were much more difficult to obtain compared to telephone interviews, consistent with the nature of the patient base, its geographic mobility, and the general limitations of clinical compared to laboratory studies.

CONCLUSIONS

This study provides strong evidence that selective acellular dermal matrix use with capsulectomy can increase the overall success rate in the surgical treatment of capsular contracture to 85.6 percent compared to 64.2 percent with conventional surgical treatment alone. Furthermore, an acellular dermal matrix individual case success rate of 96.9 percent demonstrated in a small subset of the series holds promise and urges additional corroborative study. The proposed algorithm of selective acellular dermal matrix use for all cases of bilateral capsular contracture and in unilateral cases with previous treatment failure is recommended for the surgical treatment of Baker grade III/IV capsular contracture in the breast augmentation patient.

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