Outcomes of Implant Removal and Total Capsulectomy for Breast Implant Illness: A Retrospective Review of 248 Patients

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Abstract:

Background

Breast implant illness (BII) is a term coined to describe systemic symptoms that patients ascribe to their breast implants. Though the concept of implants as an underlying cause for a systemic illness remains controversial, the implant characteristics, capsular histology, and outcomes of patients who choose to undergo explanation for BII have largely been underreported.

Methods

We reviewed demographics, symptoms, outcomes, and capsular histology and cultures of all women who presented to the senior author with symptoms attributed to BII and underwent breast implant removal with total capsulectomy from August 2016-February 2020. Chi-square and logistic regression analysis were performed to evaluate association between implant type, composition, and findings of inflammation on capsule pathology.

Results

248 patients were included. 40.2% had silicone implants, 59.8% had saline implants, 84.8% had smooth implants, and 15.2% had textured implants. 23% of the capsules submitted to pathology demonstrated acute or chronic inflammation. Capsular inflammation was independently associated with silicone vs. saline (Right OR=2.18 [1.16-4.11], p=0.016, Left OR=2.35 [1.08-5.12], p=0.03) and textured vs. smooth implants (Right OR=2.18 [1.16-4.11], p=0.016, Left OR=2.25 [1.17-4.31], p=0.01). There was one pneumothorax, three hematomas requiring evacuation, and two DVTs. Among 46 patients who addressed specific symptoms during the postoperative visit, 95.7% reported a decrease in the number of symptoms after surgery.

Conclusions

In a large cohort of BII patients undergoing explantation, we found that capsular inflammation is significantly associated with silicone and textured implants. Implant removal with capsulectomy can be safely performed in patients with BII with a low complication rate and high patient satisfaction.

Introduction

Breast implant illness (BII) is a novel description for a constellation of symptoms potentially driven by a poorly characterized immune response to breast implants.[1, 2] The name for this disease process has been coined by women who believe they have become ill from their implants rather than a medical professional society. Awareness of BII is increasingly fueled by the power of social media, with one recent study reporting an online group that reached nearly 110,000 members.[3, 4] BII symptoms are frequently non-specific, vary in severity, and can affect nearly all organ systems, characteristics which have been noted to overlap with many somatization disorders.[5-7] Despite growing concern among the general public regarding BII, breast augmentation is on the rise, with nearly 330,000 procedures performed in 2018 (a 15% increase from 2014), and national data shows ongoing trends favoring implant-based breast reconstruction.[8, 9] The leading professional societies in plastic surgery have hosted several panels to discuss BII, and continue to offer forums to facilitate dialogue between patients, patient advocates, and surgeons.[10-12]

There is a paucity of knowledge about the potential pathophysiology of BII, and many prior studies of implants and systemic disease have occurred in nonsurgical fields with controversial conclusions.[2, 6, 13-18] Treatment recommendations for this patient group can vary widely, with nearly all surgeons advocating frank and even-handed discussion with patients in light of strong evidence supporting the safety of implants[14, 19], but disagreeing whether surgical treatment including explantation and capsulectomy should be offered for symptoms of uncertain etiology.[2, 4, 20] We sought to better characterize the presenting symptomatology, postoperative outcomes, patient satisfaction and capsular findings of a population of patients who self-identified as having BII and proceeded to undergo removal of their implants combined with a total excision of the associated implant capsule.

Methods

This study was conducted after receiving approval from the hospital institutional review board at Abington Hospital-Jefferson Health with a waiver of the need for individual consent (IRB#19-039). We retrospectively reviewed the medical records of all women aged 18 and older who presented to the senior author from 2016-2020 with systemic symptoms that patients ascribed to their breast implants and subsequently underwent total capsulectomy and implant removal after appropriately balanced discussion of expectations, risks, and the current scientific evidence. Cultures were routinely obtained intraoperatively from the implant pocket and all capsules were submitted for permanent pathology.

Data obtained from medical records included demographics, indication for initial placement of implants (reconstruction versus cosmetic), medical history, physical exam findings, presenting symptoms, results of any laboratory tests obtained, operative findings at time of surgery, simultaneous procedures, and postoperative follow-up. The senior author obtained cultures from all implant pockets prior to excision of the capsule. The first four post-operative visit notes were reviewed to determine each patient's level of satisfaction with the results of the procedure and specific postoperative symptoms when available, with a mean follow-up of six months.

Statistical analysis was performed using SAS® 9.4 (SAS Institute, Cary, NC). Chi-squared analysis was utilized for independent variables, and logistic regression analysis was used to evaluate implant characteristics associated with findings of inflammation on pathology, which was defined as calcification or microcalcifications, histiocytic reaction or abundance of histiocytes, macrophages, or giant cells, presence of sclerosis, lymphoid or lymphocytic

infiltration, or the term inflammation otherwise contained in the final pathology report with reference of the capsule.

Results

A total of 248 patients underwent bilateral implant removal and with total capsulectomy with the senior author from August 2016 to February 2020. 93% had implants placed for cosmetic purposes. The average patient age was 44 years (Range: 22-72 years) and average BMI was 24. On physical exam, 130 patients (55%) exhibited Baker II and 95 patients (39%) exhibited Baker III/IV capsular contracture at initial presentation. Patient characteristics are summarized in **Table 1**.

The most common symptoms mentioned at time of initial evaluation included generalized pain, fatigue, cognitive "fogginess," migraines, headaches, anxiety, arthritis, vision changes, dyspnea, hair loss, weight gain, back pain, rashes, back pain, generalized gastrointestinal issues, and depression. The number of complaints did not vary significantly between types of implants. Symptoms are summarized in **Figure 1**.

Simultaneous procedures at time of implant removal and total capsulectomy included mastopexy in fifty-three patients (21%), scar revision in twelve patients (4.9%), breast reconstruction in five patients (2.0%), and abdominoplasty in one patient (0.4%). One patient additionally had implant replacement of silicone with saline implants based on request (0.4%). There were six major complications which consisted of one pneumothorax that required hospital admission for observation, three breast hematomas that required evacuation in the OR, and two deep vein thromboses which were managed with anticoagulation. Minor complications consisted of five delayed seromas and three liquified hematomas which were treated by aspiration. Three

patients who underwent simultaneous mastopexies had a suture infection which was treated with antibiotics.

Ninety-eight patients (40.2%) had silicone implants, and 146 (59.8%) had saline implants. 207 patients (85%) had smooth implants, and thirty-seven (15%) had textured implants. Specific implant characteristics by type are summarized in **Figure 2**.

All capsules were submitted to permanent pathology, and 111 (23%) of the capsules were found to have evidence of acute or chronic inflammation. One capsule did have atypical lymphocytic infiltration but was CD30 negative in testing for anaplastic large cell lymphoma (ALCL). Bacterial colonization was noted in fourteen patients, eight (3.28%) right breast pockets, and nine (3.69%) left breast pockets. The most common organisms from cultures included several strains of staphylococcus as shown in **Table 2**. One patient had cultures positive for Candida albicans from both breast pockets and underwent a two-week course of fluconazole after consultation with an infectious disease specialist and had an otherwise uneventful postoperative course. Twelve patients had capsular findings of “refractile/non-polarizable foreign material or silicone”. Of these patients, three had bilateral implant rupture, four had one ruptured and one unruptured implant, and five had no evidence of rupture (**Table 3)**. Four of these patients had saline implants and eight had silicone implants.

Capsular inflammation was significantly associated with silicone implants vs. saline implants (right silicone 31.3% vs. right saline 16.4%, p=0.007; left silicone 29.9% vs. left saline 15.1%, p=0.005). Additionally, inflammation was significantly associated with textured implants vs. smooth implants (right textured 38.9% versus right smooth 19.9%, p=0.01; left textured 37.8% versus left smooth 18.5%, p=0.008). **Figure 3** shows rates of inflammation by implant type.

On logistic regression modeling, capsular inflammation was independently associated with silicone vs. saline (OR=2.18 [1.16-4.11], p=0.016 right capsule, OR=2.25 [1.17-4.31], p=0.015 left capsule) and textured vs. smooth implants (OR=2.26 [1.04-4.9], p=0.040 right capsule, OR=2.35 [1.08-5.12], p=0.031 left capsule). Textured and silicone characteristics independently increased inflammation when present together to approximately 51% but had an additive rather than synergistic effect on increasing inflammation.

The average number of follow-up visits was 3.9±2.1, with a duration of 1.8 to 6 months. Post-operative visit notes addressed specific symptoms in 46 patients, and of these, 44 (96%) reported a decrease in the number of symptoms after surgery. 92% of patients reported being overall satisfied with the results of the surgery.

Discussion

The association of breast implants with autoimmune or systemic symptoms is an ongoing, heavily debated topic. Despite early reports of patients with silicone implants developing an immunoadjuvant disease[21-23], large retrospective studies comparing incidence of autoimmune diseases in women with silicone implants found no association, a finding confirmed by a special committee of the Institute of Medicine in 1999.[19, 24-27] This ultimately resulted in lifting the FDA moratorium on silicone implants but has by no means put an end to the controversy surrounding implant-related systemic illness. In recent years, an increasingly large number of women with prominent social media presence are seeking implant removal for a constellation of non-specific systemic symptoms referred to as BII. A recent review by Magnussen et al suggests that efforts at scientific investigation of an underlying pathophysiology for these symptoms has unfortunately been hampered by misrepresentation in the media and an

excessive focus on litigation.[2] The pathogenesis of an immunoadjuvant disease process associated with breast implants has been contested in the literature for decades, with several rheumatology studies stipulating a direct effect of silicone in biochemically altering metabolic or cellular processes [13, 22, 28, 29], while others argue that the constellation of somatic symptoms ascribed to implants may be the result of disrupted pain processing pathways leading to psychological distress in a manner similar to disorders like fibromyalgia.[5, 30] The relation of either these hypotheses to breast-implant illness remains unclear at the present time, however an important question to address is whether implant removal and excision of the associated capsule as many BII patients specifically request is associated with consistent symptom improvement and postoperative satisfaction. To this end, we sought to characterize the presenting symptoms, demographics, outcomes, and implant and capsular findings of a large cohort of BII patients who presented to the senior author and ultimately elected to undergo implant removal with total capsulectomy.

In our cohort of patients, we found several interesting characteristics among the majority of women who underwent explantation. Preoperatively, the most common presenting symptoms were non-specific somatic complaints such as generalized pain (163 patients, 67%) and fatigue (133 patients, 55%). We found that in forty-six patients who had postoperative follow-up addressing specific symptoms, forty-four patients (96%) reported overall improvement. A review by De Boer et al of twenty-three case series and reports from 1960-2016 evaluating outcomes of implant explantation in patients with silicone implants found that 75% of patients appeared to improve symptomatically, although this could not be linked to any specific change in autoantibody, inflammatory, or other serum markers.[30] Importantly, De Boer and colleagues observed that symptomatic improvement occurred in patients who had systemic complaints that

did not meet criteria for a known autoimmune disease. A higher number of musculoskeletal complaints was shown to correlate with higher likelihood of improvement in a study by Rohrich et al of thirty-eight patients with silicone implants undergoing explantation.[31] In the largest retrospective study of explantation in BII patients to date, Wee et al found sustained improvement in several common symptom domains from thirty days postoperatively in 752 patients.[32] In contrast, two prior studies have failed to show any significant improvement in patients who underwent explantation for systemic symptoms.[20, 33] Slavin et al studied forty-six women who presented for implant removal, eight of whom complained of systemic symptoms, and found that although there was an initial period of improvement of symptoms, only one of eight patients had sustained improvement after 2.5 year follow up.[33] The study was limited by the relatively small number of patients with symptoms that fit the pattern of BII, with the majority of patients requesting explantation either from fear of harmful consequences or aesthetic reasons. 74% of the patients from this study did undergo a capsulectomy with implant removal, and the authors found an overall low complication rate (4.3% wound infection), with the majority of patients satisfied with the result of the combined procedure. Godfrey et al evaluated postoperative outcomes in thirty-seven women who underwent explantation followed by autologous breast reconstruction.[20] Importantly, only ten patients in the study had isolated systemic symptoms such as fatigue, myalgias, arthralgia, paresthesia, or sicca symptoms, whereas the others reported local symptoms or anxiety about the implants as the primary motivation for explantation. An initial improvement in 89.2% of the patients was followed by relapse, with only 32.4% demonstrating improvement in their systemic symptoms at six month follow up. Our patient cohort differed from these earlier studies, as we aimed to study the effect of explantation in patients who were predominantly limited by their systemic symptoms. In the

majority of previous explantation studies that included patients who attribute systemic symptoms to their implants, definite conclusions have been limited by small number of patients, the subjective nature of symptoms, difficulty in distinguishing patients limited by predominantly local symptoms from those with systematic complaints or anxiety about their implants, referral bias, short period of follow-up, or explantation for old generation implants that had a high rate of rupture or leakage. [20, 31, 34-38] Additionally, these studies focused on patients with silicone implants in light of the FDA moratorium, although one large retrospective controlled study found a similar incidence of reported symptoms in patients with saline implants.[39]

In evaluating the histopathology of capsules removed from our patient cohort, we found that inflammation was present in 23% of capsules on permanent pathology and was more significantly associated with silicone and textured implants. Previous reports evaluating inflammation associated with silicone implants have found that silicone which enters the periprothestic space can induce chronic inflammation by uptake into macrophages, subsequently triggering cytokine production and fibroblast activity.[40] The phenomenon of "silicone bleed" has previously been described, wherein small amounts of silicone are found in the capsule outside an otherwise intact implant shell.[41, 42] Indeed, in our study we found evidence of refractile non-polarizable foreign material consistent with silicone in twelve patients, five of whom had no evidence of implant rupture and three patients who had a unilateral implant rupture but with histological findings of silicone in both capsules (**Table 3)**. Moreover, four of these twelve patients had saline implants. This finding supports the hypothesis that small amounts of silicone are able to enter the capsule by either leakage from the implant or degradation of the capsule, a finding which corroborates histological capsular findings from older generations of implants. In an earlier study of fifty-five patients with intact silicone implants from 1982-1986, Thomsen et al

found a positive correlation between the presence of inflammatory cells and median concentration of silicone contained within the capsule. Additionally, his group observed lymphocytes and macrophages containing droplets of non-refractile material on cross section of the biopsy specimen, suggesting silicone uptake and that an independent inflammatory process was occurring aside from a simple foreign body reaction to the silicone prosthesis.[43] A histological study by Peters et al examining 404 implant capsules from 1981-1996 noted that calcification appeared to be associated with implant shell thickness, duration after placement, and integrity of the shell. The same study interestingly found that while silicone implants were associated with several forms of calcification such as aggregate crystallization and true bone formation, saline implants were only found to have calcium adherent to the elastomer shell. In the background of these findings, it is plausible that capsular calcification represents an amplified inflammatory response more commonly associated with silicone bleed from silicone implants rather than the elastomer shell of saline implants. As silicone particles from both the filler of the implant and the elastomer shell appear to stimulate calcification, we speculate that textured implants may be associated with more inflammation due to a thicker shell or increased degree of surface area exposed to the host tissue, contributing to a higher immune response. Wee and colleagues found that patients with capsular contracture had a significantly greater self-reported improvement in symptoms after explantation.[32] Though this could partially attest to the mechanical nature of some symptoms such as chest wall restriction, the association with improvement in more nebulous symptoms such as fatigue and cognitive problems could also suggest a shared inflammatory pathogenesis between capsular contractures and BII. In another study, Peters et al evaluated the implants and capsules of 100 women who underwent explantation of silicone implants between 1992-1995, 83 of whom had systemic symptoms

without documented rheumatic or autoimmune disease.[36] They found that 42% of the capsules were colonized with bacteria and 25% were heavily calcified suggesting chronic inflammation. Similar to our study, they observed a high incidence of capsular contracture (61% Grade III/IV) among their population. Although we observed a similar rate of inflammatory capsular changes in our cohort, relatively few patients had any bacterial colonization based on our culture results (17 pockets, 3.5%). Though no conclusive evidence for adding a capsulectomy to the explant procedure is available, a prior small retrospective controlled study by Kappel et al found a more pronounced improvement in systemic symptoms when capsulectomy was added to the implant removal procedure.[45]

Our study is limited by its retrospective nature and lack of standard documentation, without which we were unable to evaluate changes in specific symptoms after explantation or correlate capsular findings on pathology with symptom severity preoperatively. Like prior studies of explantation as a treatment for patients presenting with systemic symptoms, our study is additionally challenged by the subjective bias of defining BII symptoms, lack of a control group, and selection bias as patients were predominantly self-referred to our office for explantation. Follow-up duration was also a mean of 6 months, which limits our ability to predict long-term symptom resolution or recurrence.

Nonetheless, we found that evidence of acute on chronic inflammation was significantly more common in silicone compared to saline and textured compared to smooth implants. This interesting finding potentially suggests an association between a specific implant composition and development of symptoms described as BII. We also found that implant removal with capsulectomy had a low complication rate, and that the majority of patients expressed satisfaction with their postoperative outcomes as well as improvement in their overall symptoms

during the follow-up period, suggesting that the procedure is potentially an effective treatment option for a subset of BII patients. Building on the results of our retrospective study, we are currently conducting a prospective study focusing on standardized comparison of preoperative symptoms and postoperative improvement in order to determine which patients would most likely benefit from implant removal and capsulectomy.

Conclusion

Our data support that in a subset of patients presenting with BII symptoms, there is an underlying inflammatory response associated with the implant capsule, a response which appears to be more common in silicone vs saline and textured vs smooth implants. This response may be associated with symptoms of BII. More research is necessary to further elucidate the underlying process fueling BII, however in this study we have demonstrated that implant removal with total capsulectomy can be safely performed in the BII population with minimal complications and high patient satisfaction.

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Figure Legends:

Figure 1. Most common complaints reported by patients on initial evaluation

Figure 2.
A: Removed implant characteristics in terms of make and model
B: Removed implant characteristics in terms of texturing and fill

Figure 3.
A: Rates of inflammation in terms of implant fill
B: Rates of inflammation in terms of implant texturing

Figure 4.
Logistic regression modeling for odds ratios with regards to texturing and implant fill

Table 1: Patient Characteristics	
Average age at presentation (years)	44
Average age at placement of breast implants (years)	31
Average BMI	24
Reason for implant placement	
Cosmetic	226 (93%)
Reconstructive	18 (7%)
Current Smoker	19 (8.4%)
Diabetes	7 (2.8%)
Grade of Capsular Contracture	
I	11 (4.7%)
II	122 (52%)
III	60 (25%)
IV	43 (18%)
Autoimmune Diagnosis	
Arthritis	67 (27%)
Chronic Inflammatory Response Syndrome (CIRS)	3 (1.2%)
Lupus	10 (3%)
Sjogren's Syndrome	3 (1.2%)
Raynaud's Sydrome	10 (4%)
Graves Disease	2 (0.8%)
Hashimoto's Thyroiditis	20 (8.1%)
Scleroderma	1 (0.4%)
Multiple Sclerosis	1 (0.4%)
Ulcerative Colitis	1 (0.4%)
Crohn's Disease	1 (0.4%)

History of Breast Cancer	10 (4%)
History of Other Cancer	17 (6.9%)
Anxiety	79 (32%)
History of Panic Attacks	10 (4%)
Depression	38 (15%)
Suicidal Ideation	1 (0.4%)
Fibromyalgia	17 (6.9%)
Irritable Bowel Syndrome	23 (9.3%)
Mild Anemia (Hemoglobin 11-11.9 g/dL)	2 (0.8%)
Moderate Anemia (Hemoglobin 8.0-10.9 g/dL)	2 (0.8%)
Leukopenia (WBC<4.5 x 10^9/L)	7 (3%)
Elevated alkaline phosphatase (>130 U/L)	3 (1.2%)

Table 2: Operative Details	
Incision Type	
Previous Mastectomy	15 (6%)
Inframammary	173 (70%)
Mastopexy	57 (23%)
Periareolar	3 (1.2%)
Additional Procedures Performed	
Mastopexy	53 (21%)
Scar Revision	12 (4.8%)
Total Capsule Excision	
Right	244 (98.3%)
Left	245 (98.7%)
Capsule Removed Intact	
Right	27 (10.8%)
Left	28 (11.2%)

Table 2: Classification of Culture Results	

Organism	Number of Positive Cultures
1) Staphylococcus epidermidis	2
2) Staphylococcus capitis	3
3) Staphylococcus lugdunensis	1
4) Unspecified-Coagulase (-) Staphylococcus	2
5) Unspecified- Gram (+) Cocci	1
6) Unspecified- Bacillus sp.	2
7) Unspecified- Propionibacterium sp.	1
8) Unspecified- Few Mixed Skin Flora	1
9) Cutibacterium acnes	1
10) Candida albicans	2
11) Unspecified- Gram (+) Rods	1

Table 3: Patients with Pathology Findings of Non-Polarizable Refractile Material or Silicone				
Laterality of Capsular Pathology	**Laterality of Implant Rupture**	**Implant Make**	**Implant Model**	**Implant Composition**

Right	Bilateral	Allergen	Saline	Textured
Right	Right	Allergen	Silicone	Smooth
Right	N/A	Allergen	Saline	Textured
Bilateral	Right	N/A	Silicone	Smooth
Bilateral	N/A	Mentor	Saline	Smooth
Bilateral	N/A	Allergen	Saline	Smooth
Bilateral	N/A	Allergen	Silicone	Textured
Bilateral	Bilateral	N/A	Silicone	Textured
Bilateral	Bilateral	N/A	Silicone	Textured
Bilateral	Left	N/A	Silicone	Textured
Bilateral	Left	N/A	Silicone	Textured
Bilateral	N/A	Mentor	Silicone	Textured
