Symptom Improvement After Explantation With No Capsulectomy for Systemic Symptoms Associated With Breast Implants

Patricia McGuire, MD; Caroline Glicksman, MD, MSJ; Sarah Ferenz, BA; Melinda Haws, MD; Marisa Lawrence, MD; Summer Black, MD; and Kate Faasse, PhD

Aesthetic Surgery Journal
2024, Vol 44(8) 820–828

https://doi.org/10.1093/asj/sjae034
www.aestheticsurgeryjournal.com

OXFORD
UNIVERSITY PRESS

Abstract

Background: Systemic symptoms associated with breast implants (SSBI) is a term used to describe a group of patients who attribute a variety of symptoms to their implants. Previous studies have shown symptom improvement after implant removal in these patients irrespective of whether part or all the implant capsule has been removed.

Objectives: The aim of this study was to evaluate implant removal with no capsule removed in symptomatic and control subjects.

Methods: Eligible study subjects were sequentially enrolled at 5 investigator sites. The SSBI Cohort included patients with systemic symptoms they attributed to their implants who requested explantation. The Non-SSBI Cohort included subjects without systemic symptoms attributed to their implants who requested explantation with or without replacement. All subjects agreed to undergo explantation without removal of any capsule.

Results: Systemic symptom improvement was noted in SSBI subjects without removal of the implant capsule, comparable to the results of our previously published study. SSBI patients showed a 74% reduction in self-reported symptoms at 6 months with no capsulectomy which was not statistically different from partial or total capsulectomies ($P = .23$).

Conclusions: Explantation with or without capsulectomy provides symptom improvement in patients with systemic symptoms they associate with their implants.

Level of Evidence: 3

Editorial Decision date: February 7, 2024; online publish-ahead-of-print February 10, 2024.

Dr McGuire is a clinical instructor of surgery, Washington University, St Louis, MO, USA and is a clinical editor for *Aesthetic Surgery Journal*. Dr Glicksman is an assistant clinical professor, Hackensack Meridian School of Medicine, Neptune, NJ, USA and is a clinical editor for *Aesthetic Surgery Journal*. Ms Ferenz is an MD candidate, Chicago Medical School, North Chicago, IL, USA. Dr Haws is an assistant clinical professor, Department of Plastic Surgery, Vanderbilt University, Nashville, TN, USA. Dr Lawrence is a plastic surgeon in private practice in Atlanta, GA, USA. Dr Black is a plastic surgeon in private practice in Metairie, LA, USA. Dr Faasse is an associate professor of health psychology, University of New South Wales, Australia.

Corresponding Author:
Dr Caroline A. Glicksman, 2164 State Highway 35, Building A, Sea Girt, NJ 08750, USA.
E-mail: docglicksman@gmail.com; Instagram: @drcarolineglicksman

In recent years we have seen an increasing number of women worldwide who attribute a wide variety of systemic symptoms to their breast implants. This condition may be referred to as systemic symptoms associated with breast implants (SSBI) or breast implant illness (BII). Although it is established that there exists an association between textured breast implants and anaplastic large cell lymphoma, there is no current definitive epidemiological evidence to support a direct link between breast implants and any autoimmune disorder. SSBI has been reported with all types of implants—smooth, textured, silicone gel, and saline—and all manufacturers.

Over a hundred symptoms, in no specific configuration, have been attributed by patients to their breast implants. Most often, patients have a normal physical exam and no laboratory findings to explain their symptoms. There is no recognized diagnostic test or pathophysiological explanation for SSBI; it is currently not accepted as a medical disease. Previous studies have demonstrated that patients who self-report systemic symptoms they attribute to their implants will experience symptom improvement after implant removal.[1,2] Often these patients present to plastic surgeons requesting not only the removal of their implants, but also removal of the surrounding implant capsule. Their assertion is that any toxins and contaminants in the implant may also be present within the implant capsule, and failure to remove the capsule could preclude symptom improvement. Patients often receive additional encouragement from certain physicians and nonphysicians to have their implants removed en bloc. The only valid, scientifically proven indication for en bloc capsulectomy (removal of the implant and capsule with a surrounding margin of uninvolved tissue) is the treatment of a capsular malignancy such as breast implant–associated anaplastic large cell lymphoma (BIA-ALCL) or breast implant–associated squamous cell carcinoma (BIA-SCC).[3]

There are recognized indications for total capsulectomy including the removal of a ruptured implant to keep the gel within the capsule and the management of capsular contracture.[4,5] A relative indication for or against performing a capsulectomy is the removal or exchange of textured implants and patient or surgeon concerns for potential development of BIA-ALCL or BIA-SCC.[6] Current data does not show this is a risk-reducing procedure.[7,8] However, total capsulectomy has been shown to carry higher surgical risk, including hematoma, pneumothorax, and rib pain if the implant is in the subpectoral position, and significant contour irregularities may occur with any pocket location.[9] The surgery to remove a capsule is a more invasive procedure and takes longer, therefore exposing the patient to a longer general anesthetic. Furthermore, lengthier and more invasive procedures generally are more expensive, often placing a financial burden on patients whose implants were placed for aesthetic reasons.

Part 2 of the Aesthetic Surgery Education and Research Foundation (ASERF) Biospecimen Study was a prospective, blinded study that evaluated implant capsules for heavy metals, bacterial and fungal DNA, and histological abnormalities. The data failed to demonstrate statistically significant differences between the capsules from symptomatic patients and a control group without symptoms they attributed to their implants.[10]

With 94% follow-up at 1 year, the symptomatic cohort showed at least partial symptom improvement with a 68% reduction in the number of symptoms reported. The symptom improvement was independent of whether part or all of the capsule was removed. However, all subjects in the study underwent at least a partial capsule removal because capsule specimens were required for laboratory analysis. This leaves open the question of whether symptom improvement could occur when no capsule is removed. This study evaluated the systemic symptom improvement in subjects enrolled in 2 cohorts who underwent implant removal with no capsulectomy.

METHODS

This study was designed to prospectively evaluate subjects seeking either breast implant explantation or revision surgery. Eligible study subjects were sequentially enrolled into 1 of 2 cohorts at 5 investigator sites. Subjects included genetic females with an age range of 25 to 65 years whose implants had been placed for aesthetic reasons. The SSBI Cohort included patients with self-reported systemic symptoms they attributed to their implants who requested explantation, and the Non-SSBI Cohort included patients who underwent either implant exchange or explantation without self-reported systemic symptoms that they attribute to their implants. Data collection of systemic symptoms and PROMIS-validated questionnaires were collected at baseline, and at 3 to 6 weeks, 6 months, and 1 year later. The study was previously submitted to clinicaltrials.gov (NCT04255810) and no additional funding was received for this portion of the study. The study was approved by the Northside Hospital IRB (Atlanta, GA), and was performed under the guidance of the Declaration of Helsinki. All patients signed an informed consent prior to enrollment in the study after detailed consultation including the options for the various capsulectomy types and no capsulectomy. The surgical procedure included removal or exchange of implants with no capsule removal. Capsulectomy terminology is defined as follows: (1) en bloc is the removal of the implant and a margin of normal tissue for treatment of capsular malignancy; (2) total intact capsulectomy is the complete removal of capsule and implant as a single unit; (3) total capsulectomy is the complete removal of the capsule but not necessarily in one piece; (4) partial

capsulectomy leaves some capsule behind; and (5) no capsulectomy means the capsule tissue is left intact. The investigators performed surgery as per their clinical judgment. Enrolled subjects agreed to undergo explantation of their implants, with or without replacement, and without capsulectomy. Subjects were aware that they may be excluded from the study (screen failure) if there was a medical indication for capsulectomy determined at the time of surgery. Patients were required to participate in at least 1 year of follow-up. Exclusion criteria included subjects living further than 3 hours travel from the investigator; breast reconstruction patients (increased confounders for symptoms, eg, radiotherapy, antiestrogen tamoxifen); HIV positive; presence of an abscess or infection; active malignancy anywhere in the body; or has been implanted with any silicone implant other than a breast implant (Supplemental Table 1). The first patient was enrolled in June 2022.

Patients were required to complete a baseline systemic symptoms questionnaire and then again at 3-6 weeks, 6 months, and 1 year after surgery (Supplemental Table 2). Patient surveys were deidentified by assigning a site and subject number at enrollment. Demographic data were collected, including past medical history, allergies, medications, menopausal status, the presence of dental amalgams, 22 systemic symptoms, physicians they had seen, family or personal history of autoimmune disease, significant life changes, and their primary source for medical information (physicians, FDA, social media). Implant information included the manufacturer, implant fill (silicone or saline), and the surface (texture or smooth), the year of implant placement, and any previous implants the patient may have had. Patients also filled out National Institutes of Health Patient Reported Outcome Measurement Information System (PROMIS) questionnaires. These are a standardized set of patient-reported outcome measures that cover mental, physical, and social health. PROMIS measures produce a *t*-score (mean [standard devation], 50 [10]) in a reference population (typically the US general population). The questionnaires used in this investigation included anxiety, fatigue, cognitive function, and sleep disturbance. The validated questionnaires were completed at baseline and then repeated at 3 to 6 weeks and at 6 months postoperatively. Case report forms documented patient demographics, including age, race, ethnicity, education level, marital status, medications, reproductive history, history of any tobacco or marijuana use, history of anxiety or depression, and the presence of any tattoos including their color and percentage of body surface area. Surgeon investigators then completed a comprehensive surgeon observation form on the day of surgery that documented the style of implant placed, the implant manufacturer, the implant fill and shell, the implant pocket location, and a description of the existing implant capsule. Any evidence of double capsule, deflation, or rupture was also recorded.

Statistical Analysis

The 2 cohorts of patients were compared at baseline by means of a logistic regression analysis in which patient cohort was the dependent variable and the baseline characteristic was the explanatory variable. Age, BMI, and length of time implants were in place were also compared between the 2 cohorts using either a 2-sided 2-sample *t*-test or the Wilcoxon signed-rank test as appropriate. Symptom resolution at follow-up times of 3 to 6 weeks and 6 months were then compared within the SSBI Cohort and the Non-SSBI Cohort by method of capsulectomy (none, partial, total, en bloc). This was done with a Fischer's exact test for categoric variables and analysis of variance for percentage reduction in the number of symptoms. Statistical significance was set at $P \leq .05$.

The mean symptom counts and PROMIS mean scores at the 3 time points were calculated with linear mixed models. These models incorporated terms for cohort, participant, time, and a cohort-by-time interaction. The *F*-test then provided information regarding the variation in outcome measure that is attributed to the factors (time and cohort) relative to any variation due to randomness. If greater variation is explained by these factors rather than randomness, then the *F*-statistic is larger, resulting in a *P*-value that is significant. Cohort was used as a between-subjects fixed effect and time was used as a within-subjects fixed effect, with a random intercept for participant. Cohort-by-time interactions are most applicable to understanding the course of SSBI and are reported without main effects. Significant interactions were followed with pairwise contrasts using a Bonferroni correction and were used to assess how cohorts differed by time following significant interaction effects. PROMIS data were analyzed with IBM SPSS Statistics (v. 27). A *P*-value of $\leq .05$ was regarded as statistically significant.

RESULTS

All patients underwent removal with or without exchange to new implants with no capsule removal. One subject was removed from the study when an abnormality of the capsule encountered in surgery warranted a capsulectomy. No modification of the capsule was performed by any investigator, including cauterization or plication of the capsule and no drains were used. Through 6 months of follow-up, there were no reported clinically evident seromas or infections, and no significant contour deformities were reported. Subject follow-up was high in both cohorts: 97% (n = 37) at 3 to 6 weeks and 84% (n = 31) at 6 months in the SSBI Cohort, and 100% (n = 35) at 3 to 6 weeks and 83% (n = 30) at 6 months in the Non-SSBI Cohort. The average follow-up time was 7 months (range, 5 months-1 year) in

Table 1. Baseline Demographics of the SSBI and Non-SSBI Cohorts

	SSBI Cohort vs Non-SSBI Cohort	
Baseline characteristic	Odds ratio	*P*-value
Age (years) (continuous)	—	.7876
Marital status		
Single	0.448	.4230
Married	0.595	.4191
Divorced	2.044	.4799
BMI (kg/m^2) (continuous)	—	.9988
Education		
High school/GED	2.958	.6148
Some college/vocational school	2.829	.1374
College graduate	1.453	.4764
Postgraduate education	0.249	.0074
Tobacco history		
Never	0.946	1
Former	0.806	.7911
Current	—	.4933
Marijuana use		
Never	0.780	.7793
Former	0.731	.7318
Current	0.731	.7318
Tattoos (yes/no)	0.942	1
Menopause status		
Premenopausal	1.270	.8057
Perimenopausal	1.169	1
Postmenopausal	0.597	.5580
Medications		
Antibiotics (yes/no)	0.631	.6737
Antidepressants (yes/no)	2.954	.0942
Antianxiety medications (yes/no)	3.333	.0550
Antihypertensive medication (yes/no)	1.164	1
Aspirin/NSAID (yes/no)	0.971	1
Birth control (yes/no)	0	.4930
HRT (yes/no)	1.707	.7101
Thyroid medication (yes/no)	2.550	.2196
Other herbal-nonprescription medicines (yes/no)	1.246	1

GED, General Educational Development; HRT, hormone replacement therapy; NSAID, nonsteroidal anti-inflammatory drug; SSBI, systemic symptoms associated with breast implants.

Table 2. Source of Medical Information

	SSBI Cohort vs Non-SSBI Cohort	
Source of medical information	Odds ratio	*P*-value
BII site	—	.0113
Social media	20.209	<.0001
Plastic surgeon site	1.181	.8139
FDA site	1.382	.6210
American Society of Plastic Surgeons/The Aesthetic Society sites	0.345	.0466
CNN, *USA Today*, *Network News*	1.441	.7531

BII, breast implant illness; SSBI, systemic symptoms associated with breast implants.

the SSBI Cohort, and 7 months (range, 4 months-1 year) in the Non-SSBI Cohort.

Demographics

There was no statistical difference between the 2 cohorts with respect to age, marital status, BMI, tobacco history, menopausal status, medication use, or the use of nonprescription herbal supplements. The age range of subjects in the SSBI Cohort was 28 to 62 years (mean, 46.3 years); the age range in the Non-SSBI Cohort was 30 to 65 years (mean, 46.9 years). There was a statistically significant difference in the education level with more subjects in the Non-SSBI Cohort obtaining postgraduate-level education (Table 1). Patients were asked at baseline what their primary source was for medical information. Social media and BII websites were the primary sources of medical information for the SSBI Cohort (Table 2).

Table 3. Implant Characteristics

		SSBI Cohort vs Non-SSBI Cohort	
Baseline characteristic	Means/percentages	Odds ratio	*P*-value
Breast implant: saline (yes/no)	SSBI Cohort = 54.1% Non-SSBI Cohort = 42.9%	1.559	.3581
Breast implant: silicone gel (yes/no)	SSBI Cohort = 45.9% Non-SSBI Cohort = 57.1%	0.642	.3581
Breast implant: smooth (yes/no)	SSBI Cohort = 97.3% Non-SSBI Cohort = 77.1%	10.372	.0125
Breast implant: textured (yes/no)	SSBI Cohort = 2.7% Non-SSBI Cohort = 22.9%	0.096	.0125
Length of time implant in place (years)	SSBI Cohort = 13.8 Non-SSBI Cohort = 14.4	1.482	.6983

SSBI, systemic symptoms associated with breast implants.

Implant Characteristics

SSBI Cohort

In the SSBI Cohort 54% of the implants were saline, 97% were smooth, 2.7% had textured implants, and 45.9% were silicone gel. Implants were in place for a range of 3 to 28 years (mean, 13.8 years).

Non-SSBI Cohort

In the Non-SSBI Cohort 43% of the implants were saline, 57% were silicone, 77.1% were smooth, and 22.9% were textured. Implants were in place for a range of 1 to 25 years (mean, 14.4 years). There was a statistical difference between the types of implant surface. The SSBI Cohort had more smooth surface implants, and the Non-SSBI Cohort had more textured surface implants. There was no significant difference between the number of years implanted between the cohorts (Table 3).

Medical History

There was a statistically elevated incidence of self-reported illness in the SSBI Cohort compared with the Non-SSBI Cohort including thyroid disease, rheumatologic or autoimmune disease, and history of anxiety and or depression. There was no statistical difference between the 2 cohorts for self-reported rheumatoid arthritis, fibromyalgia, or irritable bowel syndrome. There was no statistical difference in reported allergies to pollen, medicines, food, or mold between the cohorts (Supplemental Tables 3, 4).

Systemic Symptoms and Symptom Improvement

At baseline, 100% of the SSBI Cohort stated they experienced at least 1 physical symptom, with a mean of 12.68 symptoms. At 3 to 6 weeks, their symptoms had reduced to a mean of 4.39. Symptom reporting in the SSBI Cohort remained relatively stable at 6 months (mean, 3.30). The most common reported systemic symptoms at baseline in the SSBI Cohort were fatigue (92%), brain fog (89%), memory issues (78%), anxiety (73%), dry eyes (73%), insomnia (73%), and joint pain (70%). At baseline, 84% the Non-SSBI Cohort reported experiencing at least 1 physical symptom, with a mean of 3.11 symptoms, substantially fewer than the SSBI Cohort. Their symptom reporting remained stable across the recorded follow-up times. The most common symptoms reported by the Non-SSBI Cohort at baseline were anxiety (46%), headaches (35%), fatigue (27%), brain fog (27%), and dry eyes (19%) (Supplemental Table 5).

There was a significant cohort-by-time interaction, $F(2, 129.53) = 56.37$, $P < .001$, reflecting elevated baseline physical symptoms in the SSBI Cohort. At baseline the SSBI Cohort reported significantly more symptoms than the Non-SSBI Cohort ($P < .001$). There was a significant decrease in symptoms in the SSBI Cohort from baseline compared with the 3- to 6-week and 6-month follow-ups ($Ps < .001$). The mean number of symptoms of the SSBI Cohort did not differ significantly between the 3- to 6-week and 6-month time points ($P = .13$) (Supplemental Figure 1).

The Non-SSBI Cohort did not differ in their symptom reporting over time ($Ps > .33$). Although there was a large and statistically significant reduction in the number of symptoms reported by the SSBI Cohort from baseline to the postoperative follow-up time points, the SSBI Cohort still reported significantly more symptoms than the Non-SSBI Cohort at 3 to 6 weeks ($P = .007$). However, this difference was no longer significant at 6 months ($P = .15$) (Supplemental Table 6).

Table 4. Impact of Method of Explantation (No Capsulectomy, Partial Capsulectomy, Total Capsulectomy, or Total Intact) on the Resolution of Symptoms at 3 to 6 Weeks and at 6 Months

SSBI Cohort						
Dependent variable	Time point	No capsulectomy (n = 37)	Partial capsulectomy (n = 8)	Total capsulectomy (n = 27)	Intact total (n = 15)	*P*-value
Percentage reduction in number of symptoms	3-6 weeks	68.0 [21.3]	64.9 [42.8]	49.9 [42.1]	54.5 [35.7]	.2301
	6 months	72.8 [25.6]	79.3 [15.5]	64.1 [32.4]	63.6 [30.9]	.6450
50% or more reduction in symptom number	3-6 weeks	29 (85.3)	8 (80.0)	14 (53.8)	8 (61.5)	**.0426**
	6 months	26 (86.7)	9 (90.0)	19 (73.1)	9 (69.2)	.3965
80% or more reduction in symptom number	3-6 weeks	10 (29.4)	5 (50.0)	8 (30.8)	4 (30.8)	.6813
	6 months	15 (50.0)	4 (40.0)	12 (46.2)	7 (53.8)	.9406
Non-SSBI Cohort						
Dependent variable	Time point	No capsulectomy (n = 38)	Partial capsulectomy (n = 25)	Total capsulectomy (n = 19)	Intact total (n = 6)	*P*-value
Percent reduction in number of symptoms	3-6 weeks	−3.4 [155.4]	43.0 [101.8]	−5.5 [121.8]	19.8 [51.9]	0.2084
	6 months	−13.6 [165.7]	37.3 [89.0]	35.0 [56.9]	14.8 [60.0]	0.6987
50% or more reduction in symptom number	3-6 weeks	15 (50.0)	11 (73.3)	5 (33.3)	1 (20.0)	0.0952
	6 months	14 (56.0)	9 (60.0)	6 (46.2)	1 (20.0)	0.4796
80% or more reduction in symptom number	3-6 weeks	11 (36.7)	7 (46.7)	3 (20.0)	1 (20.0)	0.4381
	6 months	11 (44.4)	8 (53.3)	3 (23.1)	1 (20.0)	0.3543

Values are mean [standard deviation] or n (%). SSBI Cohort, patients seeking explantation because they believe their implants are responsible for their symptoms; Non-SSBI Cohort, patients requesting implant exchange or explantation without self-reported breast implant illness. Data for partial, total, and intact total capsulectomy were obtained from Part 1 of the Aesthetic Surgery Education and Research Foundation Biospecimen Study with updated data as available by continued follow-up. The odds ratios and *P*-values are from a logistic regression analysis with group as the dependent variable and the baseline characteristic as the explanatory variable. The *P*-value is for a 2-sided test of the null hypothesis that the true odds ratio equals 1.

Systemic Symptom Improvement by Capsulectomy Type

A limitation of Part 1 of the ASERF Biospecimen Study was that all subjects underwent at least a partial capsulectomy to obtain the necessary biospecimens for various analytical tests.[11,2] No capsule tissue was removed in this study at the time of implant removal or implant removal and replacement in either cohort. A cohort analysis was performed comparing the systemic symptom improvement by capsulectomy type—total intact (en bloc), total precise, partial, and no capsulectomy. At 6 months, 94% of the SSBI no-capsulectomy subjects had at least partial reduction from the number of symptoms reported at baseline, and a 74% reduction in the average number of symptoms reported. There was no statistical difference in symptom improvement, or in the longevity of symptom improvement based on the type of capsulectomy performed, including no capsulectomy at 6 months (Table 4).

Patient Reported Outcome Measurement Information System (PROMIS) Data

At baseline, subjects in the SSBI Cohort reported significantly higher levels of anxiety, sleep disturbance, and fatigue, as well as significantly lower cognitive function than the Non-SSBI Cohort. Following explantation, the SSBI Cohort reported numerically similar anxiety scores to the Non-SSBI Cohort (control), but still reported numerically greater sleep disturbance and fatigue scores, and lower cognitive function scores than the Non-SSBI

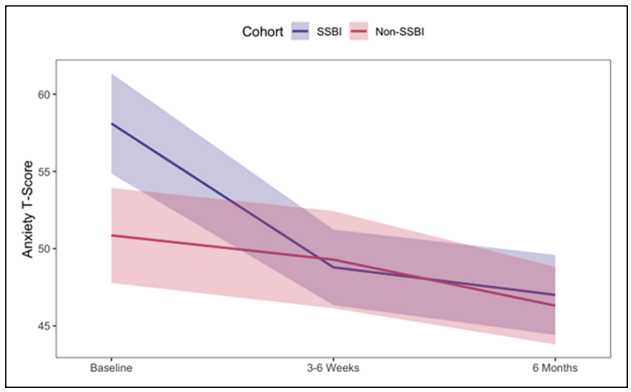

Figure 1. Patient Reported Outcome Measurement Information System anxiety *t*-score. SSBI, systemic symptoms associated with breast implants.

Cohort. Cognitive function reported by the SSBI Cohort remained significantly lower than the Non-SSBI Cohort at both 3 to 6 weeks and 6 months.

Anxiety

Subjects in the SSBI Cohort had a baseline mean anxiety *t*-score of 58.11. At 3 to 6 weeks their anxiety had decreased to a mean score of 48.79. Anxiety in the SSBI Cohort remained fairly stable at 6 months (mean, 47.00). At baseline, the Non-SSBI Cohort (mean, 50.87) reported lower anxiety than the SSBI Cohort, and their reported anxiety remained stable across all follow-up times (Supplemental Table 6).

There was a significant cohort-by-time interaction, $F(2, 131.77) = 7.64$, $P = .001$, indicating increased baseline anxiety in the SSBI Cohort. At baseline the SSBI Cohort reported significantly elevated anxiety compared with the Non-SSBI Cohort ($P = .001$). The SSBI Cohort reported a significant reduction in anxiety from baseline compared with the 3- to 6-week and 6-month follow-ups (Ps $< .001$). The mean anxiety did not significantly differ across the postoperative follow-up times ($P = .88$). There were no significant differences between the cohorts at the postoperative follow-up times (ps $> .82$). The Non-SSBI Cohort's reported anxiety did not change between baseline and 3 to 6 weeks ($P = .91$) or between 3 to 6 weeks and 6 months ($P = .40$) but significantly decreased from baseline to 6 months ($P = .046$) (Figure 1).

Cognitive Function

The SSBI Cohort had a baseline mean cognitive function *t*-score of 40.33. At 3 to 6 weeks this mean score had increased to 49.86. Cognitive function in the SSBI Cohort remained fairly stable at 6 months (mean, 51.63). At baseline the Non-SSBI Cohort (mean, 53.02) reported higher cognitive function scores compared with the SSBI Cohort, and their cognitive function scores remained relatively stable across the follow-up time points.

There was a significant cohort-by-time interaction, $F(2, 133.74) = 7.71$, $P = .001$, reflecting lower cognitive function in the SSBI Cohort at baseline. The SSBI Cohort reported a baseline cognitive function that was significantly lower than that of the Non-SSBI Cohort ($P < .001$). The SSBI Cohort then reported significant improvement in cognitive function from baseline to the 3- to 6-week and 6-month follow-ups (Ps $< .001$). Their mean cognitive function scores did not differ significantly across the postoperative follow-up times ($P = .94$). The SSBI Cohort's cognitive function scores remained numerically and significantly lower than those of the Non-SSBI Cohort at both follow-up times (Ps $< .05$). The cognitive function score of the Non-SSBI Cohort did not differ significantly over time (Ps $> .36$) (Supplemental Figure 2).

Fatigue

The most significant change in PROMIS scores in this investigation was in fatigue. The SSBI Cohort had a baseline mean fatigue *t*-score of 65.07. At 3 to 6 weeks their fatigue scores had decreased to a mean of 48.71 and remained lower and rather stable at 6 months (mean, 49.36). At baseline the Non-SSBI Cohort (mean, 48.61) reported lower levels of fatigue, and their reported fatigue remained stable across the follow-up time points (Supplemental Table 6).

There was a significant cohort-by-time interaction, $F(2, 129.29) = 23.83$, $P < .001$, indicating heightened fatigue in the SSBI Cohort at baseline. The SSBI Cohort reported significantly elevated fatigue compared with the Non-SSBI Cohort ($P < .001$) at baseline. The SSBI Cohort reported a significant decrease in fatigue from baseline to 3 to 6 weeks and then at 6 months follow-up (Ps $< .001$). Their mean fatigue scores did not differ significantly across the 2 postoperative follow-up times (Ps $> .99$). There were no significant differences between the 2 cohorts at the postoperative follow-up times (Ps $> .06$). The Non-SSBI Cohort's reported fatigue did not change over time (Ps $> .16$) (Supplemental Figure 3).

Sleep Disturbance

The SSBI Cohort had a baseline mean sleep disturbance *t*-score of 59.45. At 3 to 6 weeks their sleep disturbance scores had decreased to a mean of 47.47 and remained fairly stable at 6 months (mean, 48.12). At baseline the Non-SSBI Cohort (mean, 49.95) reported lower sleep disturbance compared with the SSBI Cohort, and their reported sleep disturbance decreased across the follow-up times (Supplemental Table 6).

There was a significant cohort-by-time interaction, $F(2, 132.62) = 6.19$, $P = .003$, indicating greater baseline sleep

disturbance in the SSBI Cohort. The SSBI Cohort reported significantly elevated sleep disturbance at baseline compared with the Non-SSBI Cohort ($P < .001$). The SSBI Cohort reported a significant decrease in sleep disturbance from baseline to 3 to 6 weeks and 6 months (Ps $< .001$). Their mean sleep disturbance scores did not significantly differ between the 2 postoperative follow-up times ($P > .99$). There were no significant differences between the 2 cohorts at either of the postoperative follow-up times (Ps $> .16$). Compared with their baseline scores, the Non-SSBI Cohort reported numerically but not significantly reduced sleep disturbance at 3 to 6 weeks ($P = .062$) and significantly reduced sleep disturbance at 6 months ($P = .024$). Their scores at the 2 postsurgical time points were not significantly different ($P > .99$) (Supplemental Figure 4).

DISCUSSION

Capsulectomy procedures differ depending on the indications for the surgical procedure and may include a patient's request. In BII social media groups, total capsulectomy, frequently interchanged with the term "en bloc," is cited as essential for symptom improvement. Previous published studies indicate symptom improvement with implant removal and total capsulectomy, partial capsulectomy, and no capsulectomy.[1]

Standardized capsulectomy terminology is outlined in the Methods section. The absolute indication for an en bloc capsulectomy is removal of an implant and capsule with a margin of uninvolved tissue for treatment of capsular malignancy. A total intact capsulectomy refers to removal of an implant and capsule as one unit. This is most often indicated with ruptured older-generation implants to minimize contact between gel and the breast tissue. A total capsulectomy is removal of the entire capsule but not necessarily as a single unit and not necessarily in one piece. If any capsule is left behind, the procedure is a partial capsulectomy. In this study, no capsule tissue was removed in either cohort. Indications for an "implantectomy" were described over 30 years ago by Scott Spear.[12] Relative indications for capsulectomy include capsular contracture, removal of a ruptured gel implant, the presence of a textured implant, and patient request. Although there is not sufficient evidence that capsulectomy is a risk-reducing procedure for BIA-ALCL or BIA-SCC, capsule removal, either partial or total, may be considered to obtain tissue for histology and to allay patient and physician concerns.[13]

Patients with systemic symptoms they attribute to their implants often request capsulectomy. Although current evidence has shown that symptom improvement occurs with total, partial, and no capsulectomy, there should be an individualized discussion with patients taking into consideration the potential risks and benefits. The advantage of not removing a capsule is that the procedure is less invasive, requires less operative and anesthesia time, carries lower risks, and may be less expensive. However, there are potential consequences to leaving behind a thickened or calcified capsule, including deformities of the breast, pain, seroma, and interference with routine breast imaging. Patients with anxiety may also express concerns related to future potential capsular malignancy.[14] Social media groups warn of the possibility of persistent symptoms caused by "retained capsule" and patients need to gauge their potential for concern if not all of their symptoms resolve. Although there is published evidence that capsules may reduce in size or dissolve with time, the fate of capsules and potential issues are variable and unpredictable, and the potential consequences need to be discussed with patients.[15]

BII social media groups and an increasing number of physician websites discuss the need for a "proper explant" and "en bloc" capsulectomy for appropriate treatment. There are surgeons who use these terms to market their practice and assert special qualifications as an "explant expert in en bloc capsulectomy." Although studies show reliable symptom improvement after implant removal, there are no published data that demonstrate, in the absence of other surgical indications, a total capsulectomy is necessary for symptom improvement. In a previously published paper reporting on Part 1 of the ASERF Biospecimen Study, systemic symptom improvement was independent of whether part or all of the capsule was removed. A limitation of that study was that at least some capsule was removed in all subjects as part of the biospecimen analysis.[2] This "no capsulectomy" study demonstrates that symptom improvement is statistically indistinguishable when no capsule tissue is removed. The strengths of this study are the prospective design and robust follow-up. A limitation of this study is the use of a historic control, although the subjects were age matched, and the same protocol and evaluation tools were used. These findings encourage surgeons to provide patients with all of their options including total, partial, and no capsulectomy as part of the informed consent process. The findings also help to create appropriate standardized terminology for capsulectomy in our literature as well as in discussions with patients and regulatory bodies.

CONCLUSIONS

Patients who attribute their systemic symptoms to their breast implants demonstrate significant symptom improvement with implant removal without capsulectomy. This option should be included in any discussion with a patient who elects to remove their breast implants when there is

no other surgical indication for capsulectomy. Further studies are indicated to delve into the potential etiologies of the self-reported symptoms and subsequent symptom resolution in these patients.

Supplemental Material

This article contains supplemental material located online at www.aestheticsurgeryjournal.com.

Disclosures

Dr Glicksman is a clinical investigator and the medical director for Motiva US Breast Implant Clinical Trial (Establishment Labs, Alejuela, Costa Rica) and is the medical director of Becton Dickinson GalaFlex Clinical Trial (Franklin Lakes, NJ). Dr McGuire is a clinical investigator for Establishment Labs. Dr Haws is an advisory board member for Sientra Strategic (Santa Barbara, CA) and RealSelf Business (Seattle, WA) and is an investor in Strathspey Crown (Newport Beach, CA). Dr Faasse participated in an Allergan (Irvine, CA) and AbbVie (North Chicago, IL) advisory board. The remaining authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

Funding

The authors received no financial support for the research, authorship, and publication of this article.

REFERENCES

1. Bird GR, Niessen FB. The effect of explantation on systemic disease symptoms and quality of life in patients with breast implant illness: a prospective cohort study. *Sci Rep*. 2022;12(1):21073. doi: 10.1038/s41598-022-25300-4
2. Glicksman C, McGuire P, Kadin M, et al. Impact of capsulectomy type on post-explantation systemic symptom improvement: findings from the ASERF systemic symptoms in women- biospecimen analysis study: part 1. *Aesthet Surg J*. 2022;42(7):809-819. doi: 10.1093/asj/sjab417
3. Longo B, Di Napoli A, Curigliano G, et al. Clinical recommendations for diagnosis and treatment according to current updated knowledge on BIA-ALCL. *Breast*. 2022;66: 332-341. doi: 10.1016/j.breast.2022.11.009
4. Wagner DS, Mirhaidari S. Capsulectomy, implant exchange, and placement of acellular dermal matrix is effective in treating capsular contracture in breast augmentation patients. *Aesthet Surg J*. 2021;41(3):304-312. doi: 10.1093/asj/sjz358
5. Adams WP. Capsular contracture: what is it? What causes it? *How can it be prevented and managed? Clin Plast Surg*. 2009;36(1):119-126, vii. doi: 10.1016/j.cps.2008.08.007
6. McGuire PA, Deva AK, Glicksman CA, Adams WP, Haws MJ. Management of asymptomatic patients with textured surface breast implants. *Aesthet Surg J Open Forum*. 2019;1(3):ojz025. doi: 10.1093/asjof/ojz025
7. Nahabedian MY. The capsule question: how much should be removed with explantation of a textured device? *Plast Reconstr Surg*. 2021;147(5S):44S-50S. doi: 10.1097/PRS.0000000000008045
8. Tanna N, Calobrace BM, Clemens MW, et al. Not all breast explants are equal: contemporary strategies in breast explantation surgery. *Plast Reconstr Surg*. 2021;147(4): 808-818. doi: 10.1097/PRS.0000000000007784
9. Afshari A, Nguyen L, Glassman GE, Perdikis G, Grotting JC, Higdon KK. Incidence and preoperative risk factors for major complications after capsulectomy: analysis of 3048 patients. *Aesthet Surg J*. 2022;42(6):603-612. doi: 10.1093/asj/sjac004
10. Wixtrom R, Glicksman C, Kadin M, et al. Heavy metals in breast implant capsules and breast tissue: findings from the systemic symptoms in women-biospecimen analysis study: part 2. *Aesthet Surg J*. 2022;42(9):1067-1076. doi: 10.1093/asj/sjac106
11. McGuire P, Glicksman C, Wixtrom R, et al. Microbes, histology, blood analysis, enterotoxins, and cytokines: findings from the ASERF systemic symptoms in women-biospecimen analysis study: part 3. *Aesthet Surg J*. 2023;43(2):230-244. doi: 10.1093/asj/sjac225
12. Spear SL. Capsulotomy, capsulectomy, and implantectomy. *Plast Reconstr Surg*. 1993;92(2):323-324. doi: 10.1097/00006534-199308000-00018
13. Asaad M, Offodile AC, Santanelli Di Pompeo F, et al. Management of symptomatic patients with textured implants. *Plast Reconstr Surg*. 2021; 147(5S):58S-68S. doi: 10.1097/PRS.0000000000008047
14. Young VL. Guidelines and indications for breast implant capsulectomy. *Plast Reconstr Surg*. 1998;102(3):884-891. discussion 892-4. doi: 10.1097/00006534-199809010-00043
15. Friedman HI, Friedman AC, Carson K. The fate of the fibrous capsule after saline implant removal. *Ann Plast Surg*. 2001; 46(3):215-221. doi: 10.1097/00000637-200103000-00002