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Practice Trends in the Management of Asymptomatic Breast Reconstruction Patients with Textured Implants: A Survey Analysis

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Background: Despite the increasing prevalence of breast implant associated anaplastic large cell lymphoma, there remains a paucity of literature guiding management of asymptomatic patients with textured breast implants. This risk can be anxiety provoking in breast reconstruction patients given their history of cancer or increased future risk. The purpose of this study is to evaluate current practice trends when managing the concerned asymptomatic patient following textured implant-based breast reconstruction.

Methods: An electronic survey was distributed to members of the American Society of Plastic Surgeons, regarding management of asymptomatic breast reconstruction patients with textured devices. Anonymous responses were collected, and statistical analysis was performed.

Results: A total of 304 responses were received. Of respondents, 237 (92%) have managed asymptomatic patients with textured devices. Historically, the overwhelming majority (89%) used textured devices; however, only 25% report current use. Regarding management of asymptomatic breast reconstruction patients, 87% recommend conservative management, while 13% recommend surgical management. When surgery is performed, 16.3% of respondents elected for implant exchange, 33.8% recommended implant exchange with partial capsulectomy, and 49.8% elected for implant exchange with total capsulectomy. Evaluation of practice patterns based on demographics demonstrated statistically significant differences in current use of textured devices and management of acellular dermal matrix.

Conclusions: Despite decreased current use, there is a significant population of asymptomatic breast reconstruction patients with a history of textured devices concerned for risk of breast implant associated anaplastic large cell lymphoma. This survey demonstrates ongoing variability in surgeon recommendations regarding conservative and surgical management of these patients and the need for continued development of evidence-based guidelines. *(Plast Reconstr Surg Glob Open 2023; 11:e5139; doi: 10.1097/GOX.0000000000005139; Published online 17 July 2023.)*

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INTRODUCTION

Breast implant associated anaplastic large cell lymphoma (BIA-ALCL) was first described in 1997; however, it was not widely considered until 2011 when the FDA issued an "Update on the Safety of Silicone Gel-Filled Breast Implants."[1,2] Public awareness further increased with announcement of the association with textured implants and the voluntary recall of Allergan (Irvine, Calif.) BIOCELL textured breast implants in 2019.[3] Historically, the reported lifetime risk of developing BIA-ALCL ranged

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from one in 30,000 (0.0033%) to one in 2832 (0.035%) in women with textured implants.[4–7] However, recent studies demonstrate increasing incidence secondary to increased awareness, improved device database registration, and cumulative exposure time.[6] Due to many factors, the exact incidence of BIA-ALCL is difficult to determine, but most recent reports are as high as one in 2969 (0.034%) women with breast implants and one in 355 (0.3%) women with textured implants.[4,8–10] Since first described, many studies have been conducted to determine disease etiology and risk factors.[5,11] It is currently believed that a combination of factors contribute to development of BIA-ALCL, including textured implant surface, patient genetic predisposition, and possible bacterial contamination (biofilm).[1,4]

As of April 2022, the FDA and global medical device reports have recorded 1130 cases of BIA-ALCL worldwide with 59 associated deaths, which is expected to be underreported.[12] In response to the recall in 2019, the FDA issued a statement that routine removal of textured implants was not recommended in the asymptomatic patient.[3] Despite these recommendations, the risk of cancer can be anxiety provoking, particularly in the breast reconstruction population. Therefore, many asymptomatic patients present with concerns related to their risk of developing BIA-ALCL, seeking advice on screening or surgical management.

Although guidelines to manage the symptomatic patient with textured implants have been published,[5,13] a paucity of literature remains on management of the asymptomatic patient with textured implants. With various options for management of asymptomatic reconstruction patients with textured implants and the lack of available long-term data, best practice recommendations are based on expert opinion.[14]

The purpose of this study was to survey members of the American Society of Plastic Surgeons (ASPS) to investigate ongoing management trends in asymptomatic breast reconstruction patients with textured implants. Survey goals included examining current use of textured devices, details in the management of asymptomatic patients who may or may not request surgery, and management of acellular dermal matrix (ADM) when present. Lastly, we sought to evaluate the impact of surgeon demographics on practice trends.

Takeaways

Question: How is the American Society of Plastic Surgeons managing asymptomatic breast reconstruction patients with textured devices?

Findings: Our survey study demonstrated that the majority of surgeon respondents recommend conservative management in asymptomatic patients, consistent with the Food and Drug Administration recommendations.

Meaning: There is a significant population of asymptomatic breast reconstruction patients with textured devices concerned for future risk of breast implant associated anaplastic large cell lymphoma. Current practice guidelines are based on expert opinion, and additional research needs to be performed to determine if implant exchange decreases risk.

METHODS

A 22-question survey investigating management patterns of asymptomatic breast reconstruction patients with a history of textured devices was created by the authors. It was generated and distributed by ASPS, on QualtricsXM survey software (SAP, Walldorf, Germany), to all 5189 active members practicing in the United States. Anonymous responses were collected from April 2021 to August 2021.

The first part of the survey, consisting of 16 questions, was targeted to determine practice scope and patterns. Two questions were "select all that apply," and an additional two questions allowed for open-ended responses. The remaining 12 questions were standard multiple choice, with only one answer accepted. Respondents were asked questions regarding use of textured devices, experience managing concerned asymptomatic patients with textured implants, details of surgical management including capsulectomy and presence of ADM, risks/complications encountered, and experience with insurance coverage for surgery. (**See figure, Supplemental Digital Content 1,** which shows the complete survey. **http://links.lww.com/PRSGO/C670**.) The second part of the survey consisted of six questions focused on respondents' demographics, including age, practice type (cosmetic versus reconstructive), practice setting, years in practice, geographic region, and gender.

Descriptive statistics were performed on the collected data and analyzed for trends. The results were reported as percentages based on the number of valid responses per question. Questions that allowed for open-ended responses were reviewed individually; trends were examined and summarized. To analyze the impact of surgeon demographics on management patterns, χ^2 and Fisher exact tests were performed to compare demographic variables to responses on select questions from part 1 of the survey. The Fisher exact test was performed as an alternative to the χ^2 test when more than 20% of the variables had an expected count of less than 5. A value of P less than 0.05 was considered statistically significant.

RESULTS

The survey was distributed to 5189 United States practicing ASPS members; 2513 (48%) did not open the email/survey communications, and 245 (5%) opted out of delivery. Of the 2431 members (47%) who opened the survey, a total of 304 responses were received, and 250 respondents completed the survey. Based on standard definitions outlined by the American Association for Public Opinion Research, the response rate, defined as the number of survey responses divided by the total number of distributed surveys, would be 6.1% (=304/(5189 – 245)). The cooperation rate (12.5%) is defined as responses divided by received surveys (304/2431); this excludes the 2513 ASPS members who did not open the email/survey communication.[15]

Of the respondents, 271 (89%) reported performing implant-based breast reconstruction in their practice. The remaining 11%, who answered "no" to question #1

Table 1. Responder Demographics

Demographics	N (%)
Practice type	
Majority cosmetic	113 (45.2%)
50/50	79 (31.6%)
Majority reconstruction	58 (23.3%)
Clinical setting	
Solo practice	95 (38%)
Plastic surgery group	46 (18.4%)
Academic	44 (17.6%)
Employed physician	65 (26%)
Years in practice	
9 years or less	60 (24%)
10–19 years	72 (28.8%)
20–24 years	41 (16.4%)
25+ years	77 (30.8%)
Surgeon age (y):	
<45	68 (27.5%)
45–54	66 (26.7%)
55–64	68 (27.5%)
65+	45 (18.2%)
Region	
East	49 (19.6%)
Midwest	49 (19.6%)
South	94 (37.8%)
West	57 (22.9%)
Gender	
Feminine	183 (73%)
Masculine	62 (24.8%)
Prefer to not respond	5 (2%)

("Do you perform implant-based breast reconstruction?"), either discontinued the survey or were excluded from statistical analysis. Demographics of respondents are outlined in Table 1.

Despite most respondents (89%) having used textured devices in the past, only 26% of respondents currently use textured devices in their reconstructive practice (Fig. 1A, B). Of the 26% who actively use textured devices, 59% report using only textured tissue expanders, 30% report using both textured tissue expanders and implants, and 11% report using only textured implants. Recorded responses for continued use of textured devices included patient desire for anatomic/textured implant (18.3%), surgeon preferences (15.5%), use of textured tissue expanders only (56%), and special situations (9.9%) (Fig. 1C).

A majority (91.5%) of surgeons have managed asymptomatic reconstructive patients with prior or current textured breast devices, whereas only 8.9% have diagnosed BIA-ALCL while managing an asymptomatic patient. When considering the management of asymptomatic patients, 87% of the respondents recommended nonsurgical management with a combination of observation, clinical screening examinations, and/or imaging. The other 13% recommended surgical management with exchange for smooth implant with or without capsulectomy (Fig. 2A). When patients request surgical management, 49.8% of respondents perform implant exchange with complete capsulectomy, 33.8% perform implant exchange with partial capsulectomy, and 16.3% perform

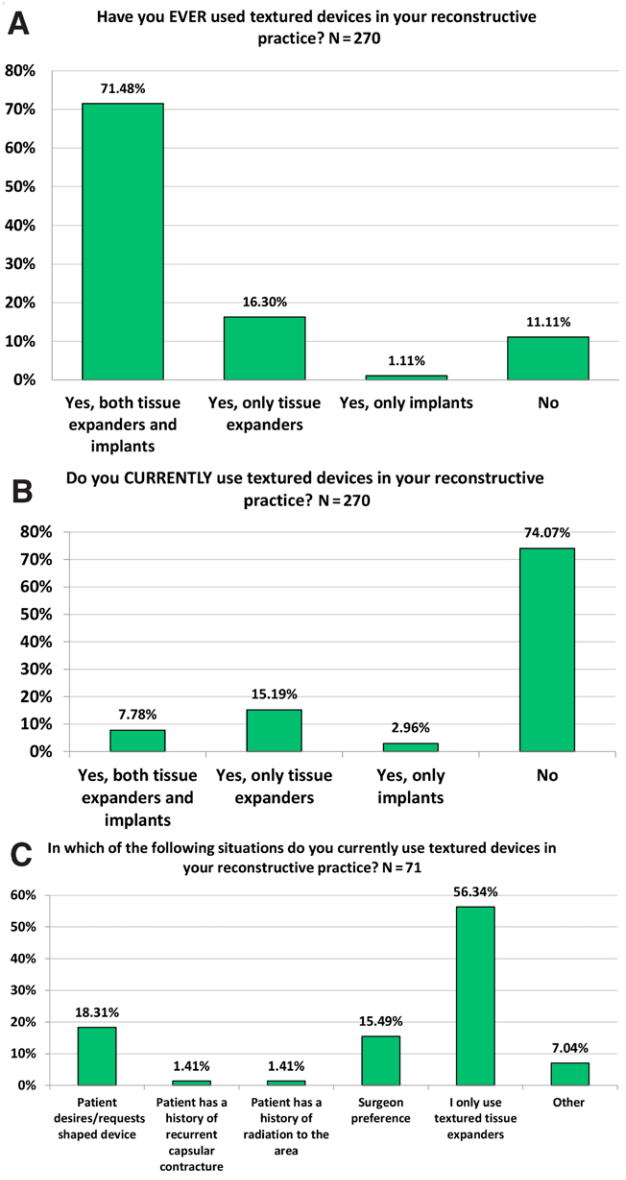

Fig. 1. Use of textured devices. A–C, Graphs showing response distributions regarding questions relating to use of textured devices.

implant exchange alone (Fig. 2B). At the time of surgery, if ADM was present in the capsule, most respondents would leave ADM if well incorporated (65.7%), if there was concern for thin skin flaps (33.1%), or if there was a history of radiation (16.0%). Only 9.7% of respondents always remove all present ADM.

Most surgeons surveyed (71.6%) consider patients to be at risk of developing BIA-ALCL after exchange of a textured tissue expander for a smooth implant. An estimated 70.7% of surveyed surgeons would inform patients of the textured device history. When asked about leaving ADM in a pocket from a prior textured device, 39.9% of respondents had no concerns that it would increase risk of BIA-ALCL, whereas 60.1% had concerns about increased future risk. Most concerned surgeons (35.3%) removed

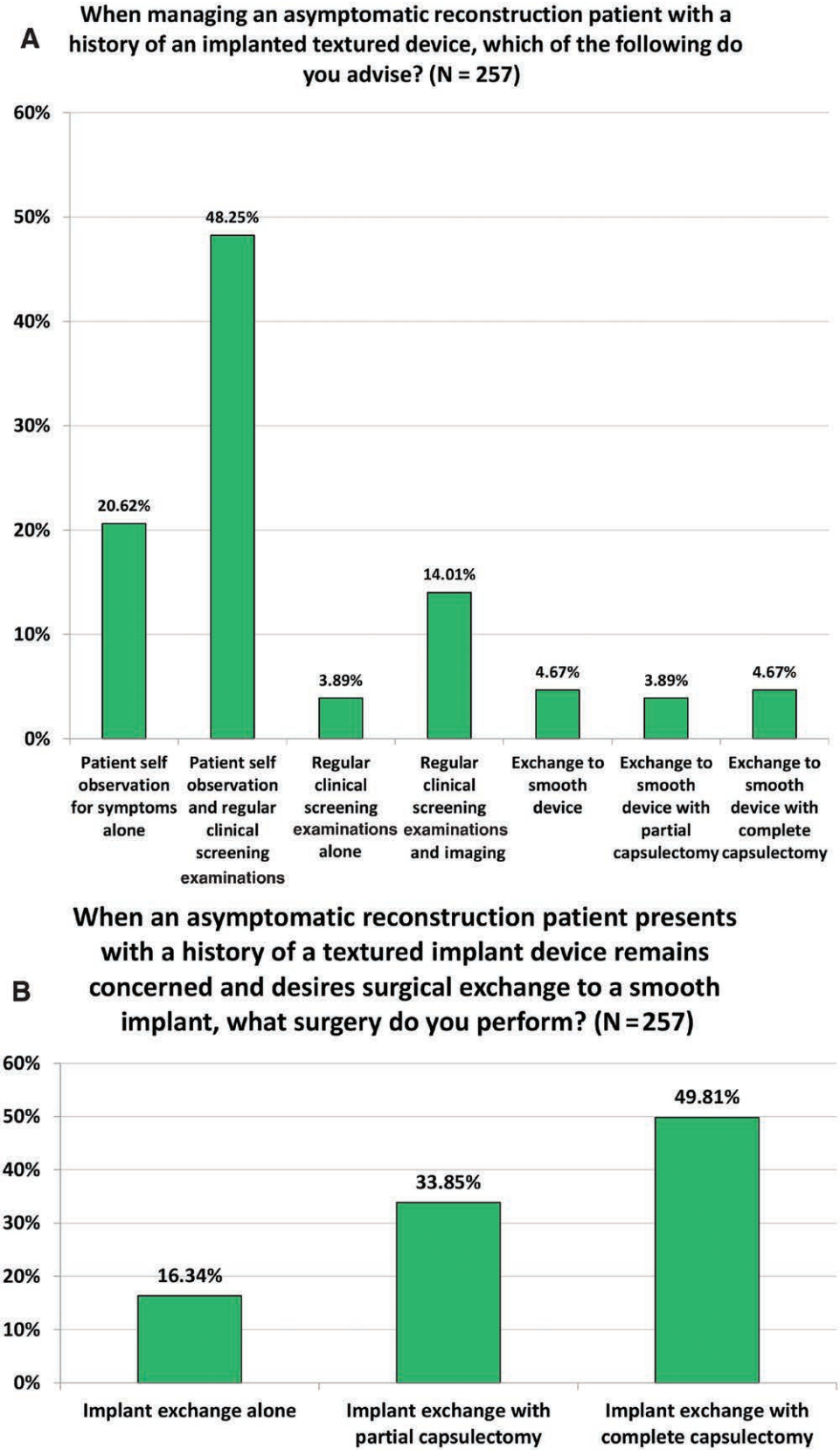

Fig. 2. Management of asymptomatic patients. A, B, Graphs showing response distribution to management of asymptomatic breast reconstruction patient with a history of textured implant with conservative and surgical management (n = 257).

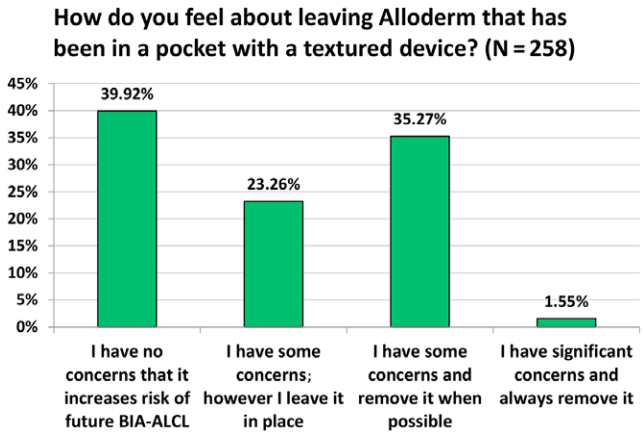

Fig. 3. A graph showing response distribution of survey question 10: How do you feel about leaving ADM (Alloderm) that has been in a pocket with a textured device? (n = 258).

ADM when possible. In total, 23.3% opted to leave the ADM in place despite having some concerns, and 1.6% always remove the ADM in this scenario (Fig. 3).

Operative complications were reported by 46% of surgeons who have operated on asymptomatic patients, including surgical site infection, wound healing problems, implant loss, hematoma, and seroma. When evaluating experience with insurance coverage for surgery of an asymptomatic patient with textured devices, the responses were split with 49.4% of the respondents having experienced issues with insurance coverage, whereas 50.6% of respondents reported no issues with coverage.

Around 18% of respondents have managed a case of BIA-ALCL. Sixty-five percent of surgeons who reported that they have managed a BIA-ALCL diagnosis state that it has not impacted their overall management of these patients. The remaining 35% report that their practice was impacted, and reported changes include increased awareness of symptoms, increased willingness to perform implant exchange in asymptomatic patients, and discontinued use of textured devices.

Analysis of practice patterns based on surgeon demographics demonstrated no statistical difference between different clinical settings (ie, academic, hospital employed, or solo practice) on management strategies recommended to asymptomatic patients. (**See table, Supplemental Digital Content 2,** which shows the statistical analysis of survey questions. **http://links.lww.com/PRSGO/C671**.) There were statistically significant differences in current use of textured devices for breast reconstruction across several demographics ($P < 0.05$). Current use of textured devices was less common in primarily reconstructive practices, surgeons with fewer years in practice (<9 years in practice, 91.7%), younger surgeons' age (<54 years, 84%), and practice primarily in the east (**Supplemental Digital Content 2, http://links.lww.com/PRSGO/C671**). In patients with a history of radiation, female surgeons ($P = 0.01$) and West Coast surgeons ($P = 0.04$) were more likely to leave ADM in place. There were no statistically significant differences in practice patterns for any of the demographic variables with regard to advice for asymptomatic patients, surgery performed for asymptomatic patients, removal of ADM when well incorporated in the capsule or with concern of thin mastectomy skin flaps.

Nonresponder analysis demonstrated comparable demographics of ASPS members, nonresponders, and survey responders. (**See table, Supplemental Digital Content 3**, which shows detailed nonresponder analysis. **http://links.lww.com/PRSGO/C672**.)

DISCUSSION

BIA-ALCL is an uncommon T-cell lymphoma identified in patients with breast implants with a textured surface. As of April 2022, of all 1130 confirmed cases of BIA-ALCL, 71% were associated with a textured device, 26% did not specify device surfaces, and 3% were associated with smooth devices. In the 3% (37 cases) associated with smooth implants, 18 patients had unknown history of prior implants, eight had a history of textured implants, 10 had a history of prior implants with unknown texture, and one had a history of only smooth implants.[12,16] However, in this patient with smooth implants, history of other implants remains unclear and thus, BIA-ALCL risk remains primarily associated with textured implants.[12]

Despite this association, 25.9% of survey respondents continue to use textured devices in practice (Fig. 1). Of these surgeons, 58.6% use only textured tissue expanders. Although minimal, the FDA has confirmed at least eight cases of BIA-ALCL in patients with textured tissue expanders that were subsequently exchanged for smooth permanent implants[12,17,18] Additionally, 71.6% of survey respondents consider this a risk factor for future development of BIA-ALCL. The majority (70.7%) of surgeons surveyed discuss this risk with patients. Based on these findings, we believe all patients with current or a prior textured implants should be made aware of the theoretical risk of developing BIA-ALCL and monitor for potential symptoms.

When analyzing practice patterns based on surgeon demographics, textured implants were less likely to be used in reconstructive practices by younger surgeons and those with fewer years in practice (**Supplemental Digital Content 2, http://links.lww.com/PRSGO/C671**). Possible explanations for this include the desire to avoid additional cancer risk in the breast reconstruction population and surgeon comfort using smooth implants for breast reconstruction in those who completed residency training more recently, in the era of increased awareness of BIA-ALCL.

With increasing incidence of BIA-ALCL, leading organizations, including the National Cancer Comprehensive Network and the Third World Consensus Conference, have appropriately raised awareness and provided guidelines for the diagnosis and treatment of BIA-ALCL in symptomatic patients.[19–24] However, the management for asymptomatic patients with textured devices remains unclear and is based primarily on expert opinions, such as those published by McGuire et al.[14] Frojo et al recently conducted a study that surveyed The Aesthetic Society to investigate practice trends for management of

asymptomatic cosmetic patients with textured implants, which demonstrated significant heterogeneity in nonoperative and operative management.[25] Similarly, our study evaluates current practice management trends, although focusing on the breast reconstruction population, who often have higher operative risk due to factors such as thin mastectomy flap coverage of implants, previous irradiation, and presence of ADM in the pocket. Additionally, this population demonstrates higher anxiety levels due to prior cancer diagnosis.

The current FDA recommendations for asymptomatic patients with textured implants is patient education and annual screening. The FDA does not recommend prophylactic removal of textured implants.[16,21] Our results demonstrate that most surgeons' practice patterns align with the FDA's recommendations, as 87% of respondents advise nonsurgical management with observation, regular clinical screening, and/or imaging. A systematic review of surgical management in textured implant patients postulates that the evidence for risk reduction with surgical management is still hypothetical and based on the concept that the textured surface is an important causal component in the development of BIA-ALCL.[18] However, with increasing cases of BIA-ALCL developing after smooth implant exchange, patients should be cautioned that replacement of textured implants may not eliminate BIA-ALCL risk. There are no studies that have sought to determine survival probability due to risk reduction with implant exchange or removal, and thus, the importance of pursuing surgical intervention for these patients is not yet known.[12,18] Additionally, nearly 50% of surgeons surveyed reported experiencing one or more complications during surgical management of asymptomatic patients, which should be considered when pursuing surgical options.

Alarmingly, BIA-ALCL was discovered in asymptomatic patients with textured implants by 8.9% of surgeons surveyed. Given that BIA-ALCL seems to be a delayed phenomenon and is usually associated with prolonged presence of a textured implant, the impact of surgical implant exchange with or without capsulectomy as a protective strategy has yet to be determined. Therefore, in patients who are well informed of the risks of surgery and the potential benefits of anxiety reduction and unknown long-term risk reduction, surgical management may be a reasonable option.

Approximately 50% of surgeons reported difficulties obtaining insurance coverage for elective implant exchange in breast reconstruction patients with textured implants. This is especially concerning as most surgeons would offer surgery to patients who requested implant removal/exchange. Without insurance coverage, patient choices are limited, and the risk of a textured implant contributing to possible BIA-ALCL are deflected to the patient (and by proxy their surgeon). This brings to light the importance of continued research on BIA-ALCL in patients with textured devices and the possible effect of implant exchange on future disease development. Efforts to ensure insurance coverage of both surgical and conservative management options remains an important part of the continuing care for these patients.

For asymptomatic patients who remain concerned and request surgical intervention, 49.8% of respondents recommended implant exchange with complete capsulectomy, 33.8% elected to perform implant exchange with partial capsulectomy, and 16.3% recommended implant exchange alone (Fig. 2B). Although the majority perform complete or partial capsulectomy with implant exchange, there remains no literature supporting risk reduction of BIA-ALCL with capsulectomy in the absence of malignancy or capsular contracture.[9] Although the evidence supports a capsular origin of BIA-ALCL, the increased risks of complete capsulectomy, including trauma to the skin flaps, bleeding, and pneumothorax, limits consistent safe application. Therefore, it is recommended that surgeons have a detailed conversation about the risks of surgical complications and benefits before proceeding with elective surgery for the asymptomatic patient, emphasizing the inconclusive evidence to support prophylactic implant exchange with or without capsulectomy as a risk-reduction procedure.[2,6,26] Park et al emphasized four main themes during counseling that providers should focus on, which include weighing risks of BIA-ALCL, perceiving individual patients' psychosocial contexts, guiding by discussing benefits and risks of prophylactic treatment, and providing support through one-on-one consultation to strengthen the physician–patient relationship.[27]

Finally, the use of ADM in breast implant reconstruction has increased significantly with the rising popularity of prepectoral implant-based breast reconstruction.[28] To date, there have been no reports of BIA-ALCL associated with ADM, and there is a complete absence of literature regarding management of ADM previously exposed to textured implants. However, our study demonstrated that 60.1% of respondents had concerns about leaving ADM in a pocket that previously contained a textured device. Despite this, most respondents would leave ADM in place if it was well incorporated, or if patients had risk factors such as history of prior radiation or thin flaps. Interestingly, several publications promote the use of ADM following removal of textured implants with or without capsulectomy to control implant position.[28] Given the potential morbidity of removing ADM from thin mastectomy flap reconstructions with no current data to support benefit of this practice, it may be reasonable to consider leaving well incorporated ADM at this time especially in high-risk patients. With increasing popularity of prepectoral implant reconstruction and use of ADM, future studies will be important to elucidate any risk or protective effect of ADM presence on the development of BIA-ALCL.

The limitations of this study include those inherent to all large-scale surveys, including representation of a population in a single point in time, recall bias, and subjectivity to interpretation of questions. Additionally, the length of the survey may have led to survey fatigue leading to a higher chance of survey incompletion. As detailed in the results section, the response rate for our survey was lower than anticipated, at 6.1%, with a cooperation/participation rate of 12.5%. This difference is likely multifactorial and including distribution to all active ASPS members lowering the response rate. Due to the nature of survey distribution, we know that almost 50% (2513 members) did not open the email and, therefore, we cannot confirm

receipt of the survey invitation. Whether this is due to spam filters, undeliverable email address, full inbox, or other technical issues, this cohort should be removed from the calculation when evaluating responder rate, thus increasing our "effective" response rate to 12.5%.

Although a low response rate, a nonresponder analysis was performed by ASPS, which demonstrated that demographics between all ASPS members, survey nonresponders, and survey responders were comparable, including practice type, practice demographic, age, gender, and number of years as an ASPS member (**Supplemental Digital Content 3, http://links.lww.com/PRSGO/C672**). Of note, many ASPS-sponsored surveys sample only a portion of the society's membership; however, our survey was delivered repeatedly to the entire membership, ensuring adequate sampling of the population, and adding to the survey methodology quality and validity. Regardless, the inherent nature of survey studies and the low response rate, despite the favorable nonresponder analysis, is not ideal and, therefore, may not fully reflect the general population.

CONCLUSIONS

Best management of the asymptomatic breast reconstruction patient with textured implants concerning the risk of future BIA-ALCL remains ambiguous. Given the lack of evidence-based guidelines, this study can be utilized in the interim as a resource for plastic surgeons to understand current management trends. Future studies are needed as more data emerge, to determine the efficacy of conservative versus surgical strategies to optimize outcomes for these patients. In the interim, detailed discussion of risks and benefits of conservative versus surgical management should be undertaken when advising a concerned patient.

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DISCLOSURES

Dr. Lund is a shareholder of Revance, Engage technology, and Brijett. All the other authors have no financial interest to declare in relation to the content of this article.

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