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Breast

Textured and Smooth Implant Use Reported in the Tracking Operations and Outcomes for Plastic Surgeons Database: Epidemiologic Implications for BIA-ALCL

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Background: Breast-implant–associated anaplastic large cell lymphoma (BIA-ALCL) is associated with prolonged exposure to textured implants. Current studies describing textured implant use are limited to single center/surgeon experiences. Using the Tracking Operations and Outcomes for Plastic Surgeons database, the study aims to characterize national trends in rates of smooth versus textured implant utilization. The hypothesis is that rates of textured implant use have decreased in the most recent time period.

Methods: Tracking Operations and Outcomes for Plastic Surgeons was queried from 2007 to 2019 for CPT codes involving breast implant use in augmentation and reconstruction. The rate of smooth and textured implant utilization was calculated for each year per procedure type. Generalized additive models with a smoothing function and Pearson chi-square tests were used to assess the trends.

Results: Textured implant use peaked in 2016, being utilized in 17.83% of cosmetic and 40.88% of reconstructive procedures. Textured implants were more commonly used for reconstructive compared with cosmetic cases for 2007–2009, 2011, and 2013–2019 ($P < 0.02$). Both cosmetic and reconstructive cases had nonlinear trends in textured implant use over the study period, with textured rates decreasing from 2017 to 2019 ($P < 0.001$). In 2019, textured implants were used in 2.15% of cosmetic and 7.58% of reconstructive cases.

Conclusions: This is the first national study describing trends in textured versus smooth breast implant use in the United States. Textured implant utilization peaked in 2016. Based on a median time horizon of 10 years before development of BIA-ALCL, the peak number of cases can be anticipated in 2026 or thereafter.
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INTRODUCTION

Understanding the relationship between Breast-Implant–Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) and breast implants has improved in recent years, as the number of cases has continued to rise. As of January of 2020, there have been approximately 733 confirmed cases of BIA-ALCL worldwide.[1] BIA-ALCL is defined as a $CD30^+$, ALK^- T-cell lymphoma that arises around breast implants.[2–10] The most common presenting symptom of BIA-ALCL is a delayed and persistent seroma around the effected implant; less commonly, patients may present with a mass.[4–6,11,12] Diagnosis is made with percutaneous aspiration of the seroma fluid or intraoperative sampling of periprosthetic fluid.[6,13] Treatment of BIA-ALCL is evolving and requires a case-based, multidisciplinary approach.[11,13] Scientific studies and case accumulation demonstrate a strong association to textured surfaced implants.[3,4,6,8–11,14,15] As information on the epidemiology and pathogenesis of the disease continues to grow, a

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multifactorial etiology of BIA-ALCL has been proposed, including method of texturing, bacterial contamination, formation of a biofilm, genetics, chronic inflammation, and exposure time.[11,12,14]

The increasing number of cases of BIA-ALCL is a significant public health concern. The American Society of Plastic Surgeons National Clearinghouse of Plastic Surgery Procedural Statistics recorded approximately 387,720 breast implant-based cosmetic and reconstructive procedures in the United States in 2019, but does not distinguish between smooth and textured implant utilization.[16] Although the lifetime prevalence of BIA-ALCL was initially estimated to be 1 in 30,000 women with a textured implant, more recent single center studies demonstrate incidence rates ranging from 1:355 to 1:559.[6,9,10] A multicenter or national examination of textured versus smooth implant use across the United States is needed to provide further epidemiologic information.

The Tracking Operations and Outcomes for Plastic Surgeons (TOPS) registry is a self-reported database started in 2002 that aggregates plastic surgery procedures with associated outcomes. Currently, the TOPS registry contains 1.4 million operations from American Society of Plastic Surgeons member surgeons across the United States in a variety of practice settings. It distinguishes between smooth and textured breast implants.[17] The purpose of the current study is to report the proportion of textured versus smooth breast implant use over time using the TOPS database to evaluate changes in practice patterns more broadly across the United States. The study hypothesis is that the proportion of textured implants use has decreased over time due to an increased understanding of the association with BIA-ALCL. The overarching goal is to better understand a time horizon during which the number of new annual cases of BIA-ALCL can be anticipated to peak.

METHODS

Data Source

Following submission of the current study design, data from the TOPS registry were obtained from the American Society of Plastic Surgeons. The proportion of practicing US plastic surgeons currently reporting in TOPS is approximately 11%, of which 46% are solely in private practice while 9% are in academic settings. Data are case-level and includes demographic and surgical-related information.[17] Unique patients were identified using unique case identification numbers. The database was queried for cases during 2007–2019.

Study Population

TOPS was queried for Current Procedural Terminology codes involving permanent breast implant placement for either augmentation or reconstructive indications: 19325, 19340, 19342, and 19380. For implant utilization rates, cases with unknown implant texturing, cases with both smooth and textured implants present, and male cases were excluded. Due to inconsistently captured data on anatomic versus round shape for textured implants, a subgroup analysis could not be performed for this variable. Macro- versus microtexturing was determined by the implant manufacturer. Cases with implants from more than 1 manufacturer or with an unknown manufacturer were excluded from the macro- versus microtexturing analysis.

TOPS Variables

Demographic data (age, race/ethnicity, insurance type, body mass index, tobacco use, and diabetes status) were recorded and reported for unique patients. Among all included cases, subgroups were created by procedure type: cosmetic or reconstructive based on TOPS variables describing procedure classification. Cosmetic cases were defined as exclusively being cosmetic, whereas reconstructive cases were defined as being general reconstructive, cancer, or both general reconstructive and cancer cases.

Implant texturing (smooth or textured) was aggregated by case for the overall cohort and for each subgroup. Market share of textured implants was further parsed out by microtextured versus macrotexturing.

BIA-ALCL Literature Review

A literature review of BIA-ALCL publications from 2007 to 2019 was conducted on 1/18/2020 in the following bibliographic databases: Pubmed (legacy), Embase (Embase.com), and Scopus. The 4 search strategy components were related to breast/mammaplasty, prosthesis, ALCL, and strategies/practices for ALCL risk reduction, respectively. The search terms used were subject headings (MeSH, Emtree terms) and/or keywords. Boolean Operators "OR" and "AND" were used to combine the search terms and the search strategy components. Search results were limited to English.

Statistical Analysis

Over the 12-year study period, all unique patients per procedure type (cosmetic versus reconstructive) were identified, and their demographic characteristics were assessed using mean (SD) and median (interquartile range for continuous variables, and sample size (n) and percent for categorical variables). The rate of implant type (smooth versus textured) by year was assessed for all cases and by procedure type. Rates were defined as the total number of cases of a particular implant divided by total number of cases (or total number of cases by procedure) in that year, multiplied by 100. Generalized additive models describing the utilization rate by year, with a smoothing function for year, were used to assess the trends of textured implant utilization rates over time. Pearson chi-square tests were used, at each year, to assess the difference in utilization of smooth versus textured implants between cosmetic and reconstructive procedures. The market share of macro- versus microtextured implants among all textured implant cases per year was also described using n and percent. All statistical tests were two-sided, with an α of 0.05. All analyses were performed using R Statistical Software (version 3.6.3; packages: ggplot2, dplyr, mgcv).

Table 1. Cohort Sociodemographic and Clinical Characteristics

	Cosmetic Cases	Reconstructive Cases
Year	2007–2019	2007–2019
Unique patients	64,745	10,158
Age		
Mean years (SD)	34.8 (10.44)	52.8 (11.34)
Median years (IQR)	34 (27–41)	53 (45–61)
Race, n (%)		
White (Hispanic or not Hispanic)	53,346 (82.39)	8883 (87.45)
Black/African American	1444 (2.23)	431 (4.24)
Asian	1904 (2.94)	181 (1.78)
Hispanic or Latino	5354 (8.27)	372 (3.66)
American Indian/ Alaskan Native or Hawaiian/ other Pacific Islander	153 (0.24)	27 (0.27)
Mixed Race/other/ unknown	2544 (3.93)	264 (2.6)
Payment source, n (%)		
Private insurance	488 (0.75)	7595 (74.77)
Medicaid or medicare	37 (0.06)	856 (8.43)
Self-pay	60,051 (92.75)	293 (2.88)
Combination	739 (1.14)	622 (6.12)
Other/worker's compensation	1096 (1.69)	43 (0.42)
Not reported	2334 (3.6)	749 (7.37)
Body mass index		
Mean, kg/m^2 (SD)	22.31 (3.33)	26.28 (5.60)
Median, kg/m^2 (SD)	21.77 (20.12–23.84)	25.11 (22.31–29.11)
Not reported, n (%)	1953 (3.02)	1581 (15.56)
Tobacco use status, n (%)		
Non-tobacco user	49,532 (76.5)	7230 (71.18)
Former	4095 (6.32)	1286 (12.66)
Current	6819 (10.53)	629 (6.19)
Not reported	4299 (6.64)	1013 (9.97)
Diabetes status, n (%)		
Yes	355 (0.55)	329 (3.24)
No	57,791 (89.26)	8665 (85.3)
Unknown	2091 (3.23)	126 (1.24)
Not reported	4508 (6.96)	1038 (10.22)

All n are the sum of unique patients over the 12-year period. Percentages are out of the total unique patients per case type.

RESULTS

Over the 12-year study period, a total of 80,826 cases were included in the final analysis, with 64,745 unique female patients constituting a total of 66,690 cosmetic cases, and 10,158 unique female patients constituting a total of 13,579 reconstructive cases. In contrast to cosmetic patients, reconstruction patients tended to be older, to have greater body mass index, and were more likely to have diabetes. Most of the cosmetic cases (92.75%) were self-pay in contrast to just 2.88% of reconstructions. These trends, in addition to the distribution of race between reconstruction and cosmetic indications, can be seen in Table 1.

Trends in Overall, Cosmetic, and Reconstructive Cases

The total number of cases recorded per year in TOPS ranged from 1958 to 10,058 cases (Fig. 1A). The lowest proportion of textured implant use was reported in 2007, at 3.37% of included cases. Thereafter, textured implant use gradually increased to its greatest proportion in 2016 at 22.89% of cases. Starting in 2017, textured implant utilization rates began to decrease, with use in 3.61% (n = 112) of cases in 2019. This nonlinear trend in textured implant utilization rates was significant over the 12-year study period ($P = 0.001$; Fig. 1B).

For cosmetic indications, the total number of cases ranged from 1656 to 8502 cases over the study period. Textured implants were used in 2.90% of included cases in 2007 and gradually increased to a peak rate of 17.83% in 2016. Starting in 2017, textured implant use began to decrease, reaching a nadir of 2.15% in 2019. Overall, textured implant utilization for cosmetic cases demonstrated a significant nonlinear trend ($P = 0.0003$; Fig. 2).

For reconstructive cases, the total number of included cases per year ranged from 302 to 1673 cases. From 2007 to 2012, the annual textured implant utilization was <10%. A gradual increase in utilization started in 2013, reaching a peak usage of 40.88% in 2016. Thereafter textured implant use decreased each year to a rate of 7.58% in 2019. This nonlinear trend in reconstructive, textured implant utilization rates was significant over the study period ($P = 0.0008$; Fig. 3).

Trends in Cosmetic versus Reconstruction Cases

Overall, textured implants were utilized in a significantly greater proportion of reconstructive cases compared with cosmetic cases for 2007–2009, 2011, and 2013–2019 ($P < 0.02$ for each year). There were no significant differences in texture implant utilization rates between cosmetic and reconstructive cases during 2010 and 2012.

Trends of Macro- versus Microtextured Implants

Over the study period, the total number of textured implant cases meeting the inclusion criteria for manufacturer-specific texturing information ranged from 60 to 1003, in 2007–2015 (Fig. 4). Use of macrotextured implants ranged from 28.02% to 66.59% per year. There was no clear trend in rates of macro- versus microtextured implants over the study period.

DISCUSSION

Given the strong association between textured implant surface and BIA-ALCL, the trends and future incidence of BIA-ALCL should be examined in relation to the use of textured implants.[5,6,8,18] The TOPS registry was specifically queried, as it captures information on implant texture and includes both cosmetic and reconstructive cases. The study findings show that the proportion of textured implant use for all indications was relatively stable (range: 3.37%–6.02%) from 2007 to 2012, but increased steadily thereafter, peaking at 22.89% in 2016 (Fig. 1). The rise in textured implants corresponds with the FDA approval of anatomic textured silicone implants for Sientra in 2012 and for Allergan and Mentor in 2013. Starting in 2017, there was a rapid decline in textured implants, likely related to an increasing awareness of BIA-ALCL and increasing incidence rates reported in the literature. Interestingly, the drop in textured implant utilization reported in TOPS by US plastic surgeons temporally preceded other significant

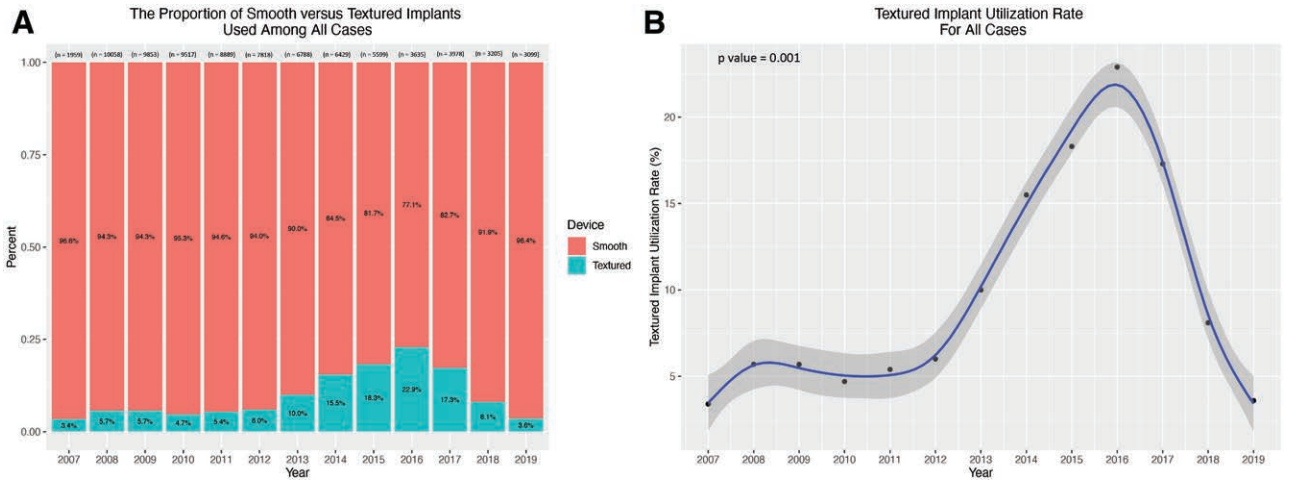

Fig. 1. Overall proportion of smooth versus textured implants used among all cases with overall textured implant utilization rate modeled over time. A, The proportion of implants for all cases in TOPS with total number of procedures per year (n). B, Textured implant utilization rate (blue curve) with standard errors (gray-shaded area) using a generalized additive model, with $P = 0.001$ indicating a significant, nonlinear trend between the rate of textured devices utilized and year. The utilization rate of textured implants increased to peak around 2016. The rate of utilization decreased during 2016–2019.

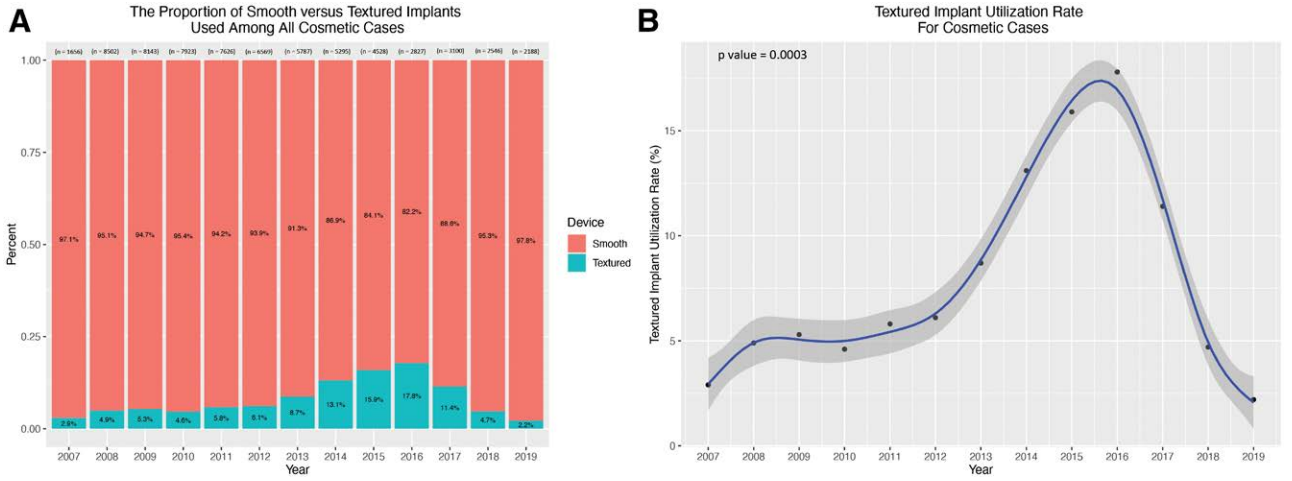

Fig. 2. Overall proportion of smooth versus textured implants used among all cosmetic cases, with cosmetic textured implant utilization rate modeled over time. A, The proportion of implants for all cosmetic cases in TOPS with total number of cosmetic procedures per year (n). B, Textured implant utilization rate (blue curve) with standard errors (gray-shaded area) using a generalized additive model, with $P = 0.0003$ indicating a significant, nonlinear trend between the rate of textured devices utilized in cosmetic procedures and year. The utilization rate of textured implants increased to peak around 2016. The rate of utilization decreased during 2016–2019.

events surrounding their use. It was not until December of 2018 and July 2019 that Allergan voluntarily recalled its textured implants and tissue expanders in Europe and the United States, respectively. Moreover, the Food and Drug Administration did not hold its General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee until March of 2019, which addressed a number of topics surrounding breast implants.[19] The reduction in textured implant use, in advance of any regulatory intervention or market withdrawal, suggests a proactive and patient-safety–centered approach by US plastic surgeons based on the growing scientific evidence. Moreover, surgeons are strongly encouraged to disclose the relationship between textured implants and BIA-ALCL to all patients in the preoperative setting, with heavy emphasis on shared decision-making when considering textured implant placement.[6,20]

The current data demonstrate a peak in textured implant usage in 2016. It is currently understood that the mean and median interval from textured implant placement to BIA-ALCL diagnosis should be approximately 10.7 ± 4.6 and 10.4 years, respectively; however, because its pathogenesis is based on exposure time to texturing, disease development is left skewed.[3,6,10,11] Considering these epidemiologic factors and in light of the current study findings, the time horizon for peak BIA-ALCL cases in the United States can be anticipated to be 2026 or thereafter. As such, plastic surgeons will need to remain vigilant in counseling, diagnosing, and treating patients with BIA-ALCL for the foreseeable future.

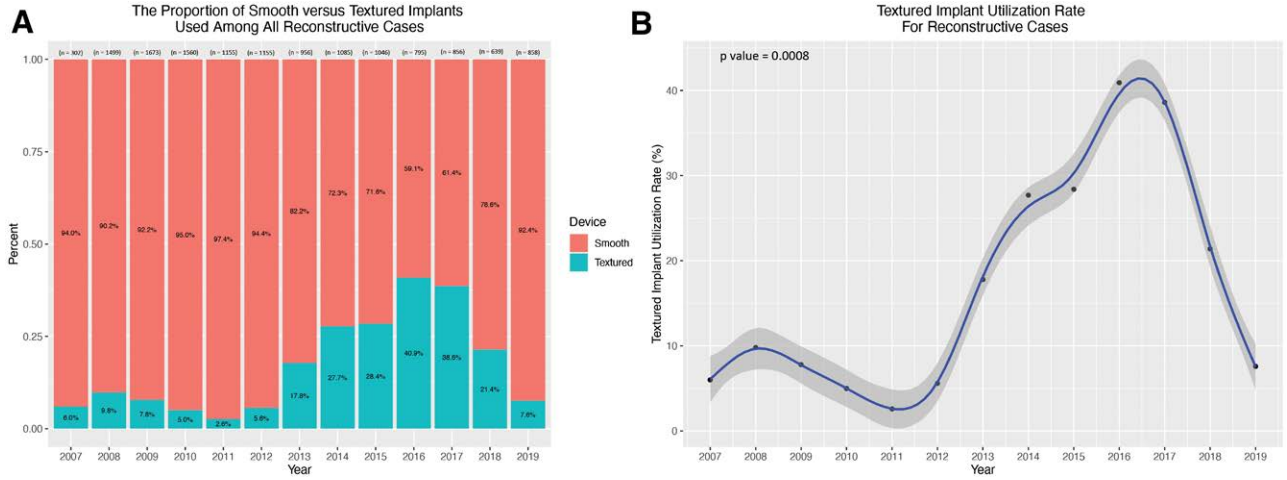

Fig. 3. Overall proportion of smooth versus textured implants used among all reconstructive cases, with reconstructive textured implant utilization rate modeled over time. A, The proportion of implants for all reconstructive cases in TOPS with total number of reconstructive procedures per year (n). B, Textured implant utilization rate (blue curve) with standard errors (gray-shaded area) using a generalized additive model, with $P = 0.001$ indicating a significant, nonlinear trend between the rate of textured devices utilized in reconstructive procedures and year. The utilization rate of textured implants increased and then decreased to a low around 2011. Following 2011, the rate increased to peak around 2016. The rate of utilization decreased during 2016–2019.

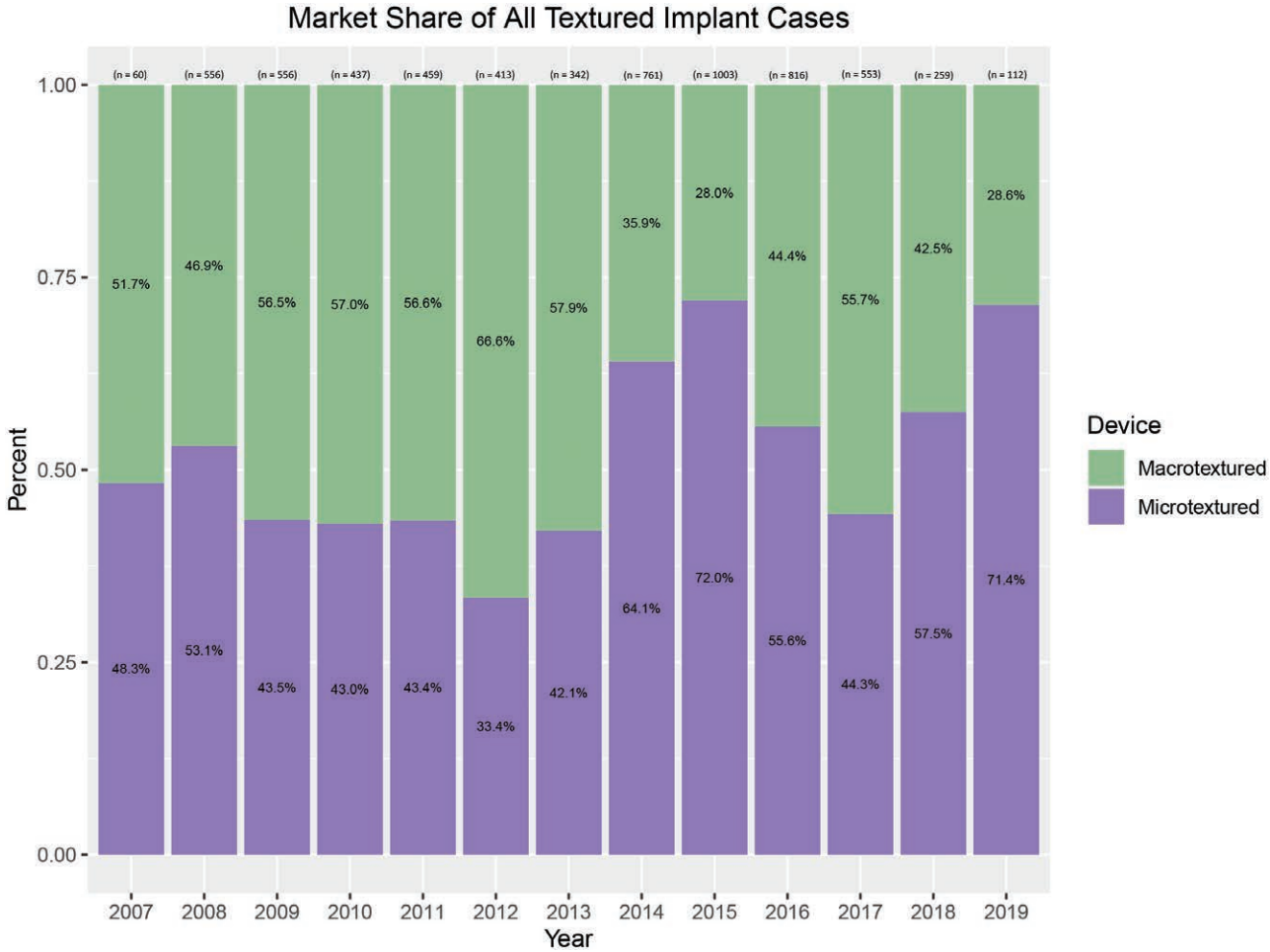

Fig. 4. Market share of all textured implant cases: macro versus microtextured.

The only other study to examine textured implant use beyond a single surgeon or center experience used The American Board of Plastic Surgery Maintenance of Certification Tracer Database.[15] Tandon et al queried this dataset for cosmetic breast augmentation procedures, demonstrating an increase in use of textured implants from 2.3% to 13.0%, between 2011 and 2015.[15] Overall, the upward trend in rates of textured implant use were highly comparable to the current study (5.84%–15.92%) for the same time period (Fig. 2); however, the more recent years captured with TOPS demonstrate reversal of this trend. Further, the TOPS dataset enabled a more comprehensive examination of all implant patients: both cosmetic and reconstructive.

The TOPS registry enabled a comparison between trends in textured implant use separately for cosmetic and reconstructive patient populations. The use of textured implants remained consistently lower in cosmetic than in reconstructive cases, throughout the study period (Fig. 2 and 3). In 2016, textured implant utilization reached a peak at 17.83% for cosmetic cases compared with at 40.88% in reconstructive cases. In contrast to augmentation procedures, breast reconstruction is more dependent on the shape of an implant to contribute to the overall breast mound contour. The greater proportion of textured implants in reconstructive cases is potentially due to the use of anatomically shaped implants, although this hypothesis could not be specifically tested with the data captured in TOPS. Interestingly, evaluation of cosmetic augmentations using the Maintenance of Certification Tracer Database showed no relationship between the increase in textured implant use and specifically anatomic-shaped implants, suggesting other indications such as to reduce capsular contracture.[15] Awareness of the differential in textured implant utilization for these patient sub-groups provides important information to plastic surgeons, especially those who perform reconstructive breast surgery.

Macrotextured implants are considered high-surface-area implants compared with the microtextured variants. The significance of distinguishing between macro- and microtextured implants is that higher-surface-area implants are associated with greater rates of BIA-ALCL.[8,14,21] Loch-Wilkinson et al estimated a 14.11 times higher risk of BIA-ALCL for macrotextured implants compared with microtextured.[14] The current study findings show no clear trend in the use of macro- versus microtextured implants (Fig. 4), although there is short-term upward trend in microtextured implants from 2017 to 2019. The TOPS data show that one of the highest annual rates of microtextured implant use was in 2019, the same year that the FDA requested a Class I recall by the manufacturer of the macrotextured implant associated with the majority of BIA-ALCL cases.[22] Currently, 2 other implant manufacturers continue to sell microtextured implants. Although rates of BIA-ALCL differ between manufacturers, a study from 2017 looking at international databases showed that every implant manufacturer has had at least 1 documented case of BIA-ALCL.[23] Future trends in the use of microtextured implants in the United States are unclear, but it is noteworthy that for reconstructive indications, 7.58% of cases still used a textured implant in 2019.

The literature on BIA-ALCL is evolving in both the basic science and clinical areas. Investigations into the pathogenesis of BIA-ALCL suggest that patient genetics, chronic gram-negative infection, formation of a biofilm, and chronic inflammation may each play a role in the development of the disease; however, the most critical factor from a clinical perspective is the textured surface of the implant combined with the risk of prolonged exposure time.[11,12,14] The accumulation of scientific literature, in addition to clinician experience, has likely contributed to the decline in textured implant use witnessed over the most recent period.

The current study is the largest and most lengthy evaluation of plastic surgeon practice patterns of textured versus smooth implant utilization in the United States. Despite the strengths of this study, there are some limitations. TOPS data are a self-reported sample of operations performed by the US plastic surgeons, most of whom are in private practice settings. As such, the true rates of textured implant use, or incidence, cannot be measured. For this reason, the analysis focused on the proportion of smooth versus textured implant use over time. Completion of all sections of the case report form is not required; therefore, evaluation could not be done on anatomic versus round textured implants. Lastly, findings from TOPS may not be generalizable to all practicing plastic surgeons.

CONCLUSIONS

US plastic surgeons' use of textured breast implants was greatest in 2016, as reported in the TOPS database. The time horizon for peak BIA-ALCL cases in the United States can be anticipated to be 2026 or thereafter. It is unclear if this trajectory can or will be shifted by elective removal of textured implants in some patients. The future of microtextured implants is uncertain, but will involve informed consent, careful follow-up, and benefit from registry use.

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