

Breast Implant Utilization Trends in USA versus Europe and the Impact of BIA-ALCL Publications

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Background: The goals of this study were to analyze and compare breast implant preferences between US and European surgeons in terms of size, shape, and surface texturing. Furthermore, we set out to investigate the impact of BIA-ALCL scientific publications on surgeon practice patterns.

Methods: Breast implant sales data from the USA and Europe dating from June 2013 to September 2018 were provided by one of the world's leading breast implant manufactures (Mentor Worldwide LLC). Change-point analysis was used to identify when significant changes in sales trends occurred. These changes were compared with dates of government announcements and publications of landmark scientific articles regarding BIA-ALCL.

Results: Our data demonstrate that US surgeons tend to prefer larger, smooth round implants compared with European surgeons, who prefer smaller, textured round implants. Despite these differences, medium-sized implants were still the most common size used between both regions. Sales trends illustrate an increase in smooth implants and a decrease in textured implants for both regions. Significant changes in trends align with publication dates of announcements and landmark scientific articles.

Conclusions: We demonstrate definitive differences in implant preferences between the USA and Europe. We encourage physicians to continue their pursuit of publishing because it seems these publications affect medical device selection. (*Plast Reconstr Surg Glob Open* 2021;9:e3449; doi: [10.1097/GOX.0000000000003449](https://doi.org/10.1097/GOX.0000000000003449); Published online 19 March 2021.)

INTRODUCTION

The use of silicone implants in breast surgery is ubiquitous. Worldwide, breast augmentation is the most common surgical procedure performed by plastic surgeons, representing 17.6% of all plastic surgical procedures. Of the 1,862,506 breast augmentations performed worldwide in 2018, 17.3% were performed in the United States,

followed by Brazil (14.8%), Mexico (3.8%), Germany (3.5%), Italy (3.5%), Argentina (2.7%), and Colombia (2.3%).¹ Similarly, breast augmentation continues to be the most common cosmetic surgical procedure in the USA, with over 313,000 augmentations performed in 2018, a 48% increase since the year 2000.²

Moreover, for breast reconstruction, silicone implants are the most common reconstructive option. In 2018, the American Society of Plastic Surgeons (ASPS) recorded 101,657 breast reconstruction procedures, of which 78,814 utilized silicone implants; 18,441 were autologous tissue-based, and 4402 utilized saline implants.² Overall, 82% of reconstructions were implant-based compared with 18% autologous.

Anecdotal differences in implant selection have been mentioned in the literature based on geographical region. These differences pertain to implant filling material, surface texturing, size, and shape. However, limitations in the studies exist given the methodologies utilized, which have typically been survey-based studies.^{3,4} More concrete evidence of implant preferences will shed light on the practice patterns of US and European surgeons. Moreover, it remains unclear if the recently published reports on Breast

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Received for publication September 3, 2020; accepted December 28, 2020.

Presented at the American Society of Plastic Surgeons, Annual Meeting, September 23, 2019, San Diego, Calif., and at the Texas Society of Plastic Surgeons, Annual Meeting, November 1, 2019, Galveston, Tex.

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DOI: [10.1097/GOX.0000000000003449](https://doi.org/10.1097/GOX.0000000000003449)

Disclosure: Aldona Spiegel is a consultant for MTF and Mentor. All the other authors have no financial interest to declare in relation to the content of this article.

Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) in high-impact plastic surgery journals have impacted the utilization trends of breast implants in different regions of the world.

This study has 2 aims, based on the analysis of the sales data from one of the world's leading breast implant manufacturers: (1) to analyze and compare breast implant preferences in terms of implant size, shape, and surface texturing between US and European surgeons; and (2) to investigate the impact of BIA-ALCL scientific publications on surgeon practice patterns over time.

METHODS

Sales Percentage Data

One of the world's leading breast implant manufacturers (Mentor Worldwide LLC) provided global sales data for comparing implant preferences and utilization trends of surgeons in the United States, when compared with those of international surgeons. The countries included in this study were listed at the discretion of the implant manufacturer and were those for which implant sales data between June 2013 to September 2018 had been obtained and were readily available. These countries, all in Europe, included Austria, Belgium, Luxembourg, France, Germany, Italy, Norway, Portugal, Spain, Sweden, Lithuania, Switzerland, the Netherlands, Ireland, and the United Kingdom.

Utilization Trends: USA versus Europe

Utilization preferences between the USA and the European countries were analyzed in terms of implant size [small (100–295 cm³), medium (300 cm³–550 cm³), large (555 cm³–800 cm³); surface (smooth versus textured), and shape (round versus shaped)].

BIA-ALCL–Related Publications

The following scientific publications in high-impact surgery journals, national podium presentations, and press-related updates from government agencies around the world were selected:

- U.S. Food and Drug Administration, January 2016. Anaplastic Large Cell Lymphoma (ALCL)
 - Noted possible association between breast implants and the development of BIA-ALCL. Estimated a total of 100–250 cases of ALCL in women with breast implants worldwide.⁵ Increased from 60 cases previously estimated in 2011.⁶
- French Agency for the Safety of Medicine and Health Products, June 2016, Breast-Implant-Associated Anaplastic Large-Cell Lymphoma (BIA-ALCL): Information Update about Ongoing Investigations.
 - Noted an over-representation of textured implants manufactured by Allergan in the 29 reported cases of BIA-ALCL. Established a clear link between ALCL and breast implants.⁷
- ASPS, Plastic Surgery the Meeting, Podium Presentation, September 2016, Doren E., Miranda RN, Selber JC, et al. “United States Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma.”
 - In the USA, 49 cases were reported in the cosmetic population, 44 in the reconstructive population, and 7 unknown. Lifetime prevalence—33 per million with textured implants.⁸
- ASPS, Plastic Surgery the Meeting, Podium Presentation, September 2016, Knight R., Loch-Wilkinson A-M, Wessels W, et al. “Epidemiology and Risk Factors for Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) in Australia & New Zealand.”
 - Reviewed 35 cases representing over 15% of known cases in the world. More than 60% of BIA-ALCL cases were attributed to a specific texturing technique.⁹
- Australian Government, Department of Therapeutic Goods Administration, Dec 2016. Breast Implants: Expert advisory panel advice on association with anaplastic large cell lymphoma
 - Confirmed 46 cases of BIA-ALCL in Australia, including 3 deaths. No cases were identified in patients with smooth implants only. A possible cure was suggested through removal of the implant with complete capsulectomy.¹⁰
- U.S. Food and Drug Administration, March 2017. Breast Implant Associated Anaplastic Large Cell Lymphoma
 - Total of 359 medical device reports of BIA-ALCL worldwide, including 9 deaths. Most of the surface materials were noted to be textured implants (203 of 231). Recommended health-care providers formally educate patients on the disease.¹¹
- *Plastic & Reconstructive Surgery*, May 2017. Srinivasa D.R., Kaura A., et al. Global adverse event reports of breast implant-associated ALCL: An international review of 40 government authority databases
 - Underscored the tracking of BIA-ALCL cases around the globe to determine its worldwide incidence and prevalence. Analyzed federal data-banks from 37 countries—70% of the devices reported were manufactured by Allergan; 8.7% by Mentor.¹²
- *Plastic & Reconstructive Surgery*, May 2017. Doren E.L., Selber J.C., et al. U.S. epidemiology of breast implant-associated anaplastic large cell lymphoma.
 - First U.S. epidemiology report of BIA-ALCL. Estimated an incidence rate of 2.03 per 1,000,000 persons for BIA-ALCL versus 3 per 100,000,000 for breast ALCL. No cases were reported with smooth only implants. Set forth recommendations to include ALCL risks in the consenting process of breast implants.¹³
- *European Journal of Surgical Oncology*, August 2017. Johnson L., o'Donaghue JM, McLean N, et al. Breast implant associated anaplastic large cell lymphoma: The U.K. experience. Recommendations on its management and implications for informed consent.
 - Highlighted that the risk of ALCL was not discussed with patients during the consenting process in the UK concluded that the surgeon must inform the patient of the known risks associated with the textured implant.¹⁴

- *Plastic & Reconstructive Surgery*, October 2017. Loch-Wilkinson A-M, Beath KJ, Knight RJW, et al. Breast implant-associated anaplastic large cell lymphoma in Australia and New Zealand: High-surface-area textured implants are associated with increased risk.
 - Demonstrated that high-surface-area textured implants were associated with an increased risk of developing BIA-ALCL¹⁵

Change-Point and Statistical Analysis

Change-point analyses were conducted on implant sales trends over time, and a correlation was performed analyzing periods when significant changes in trends were detected, and dates when selected scientific and government manuscripts were published. The Shapiro-Wilk test and histograms were used to test for normality. The Mann-Whitney test was conducted to compare implant sales data between the USA and Europe in terms of implant size, surface texture, and shape. Change-point analyses were performed to determine significant variations on implant sales trends over time in the USA and Europe. Significance level was defined at a $P < 0.05$. IBM SPSS software (IBM SPSS Statistics for Windows, version 25.0. Armonk, N.Y.: IBM Corp.) and Change-Point Analyzer software (Taylor Enterprises, version 2.3) were used to conduct these analyses.

RESULTS

From 2013 to 2018, monthly reports on implants sales in the USA and Europe were provided.

Implant Size by Categories: USA versus Europe (Fig. 1)

Small implants (100–295 cm³) composed the smallest percentage of US implant sales at 12.8% compared with a more substantial 29.1% of European sales ($P < 0.0001$). Medium-sized implants (300–550 cm³) consisted of the majority of sales for both regions: 69.3%—US sales, and 67.7%—European sales ($P < 0.0001$). Large implants (555–800 cm³) made up a greater portion of the US sales compared with European: 17.8% for the USA, and only 3.3% for Europe ($P < 0.0001$).

Textured and Smooth Implants: USA versus Europe

The US market is represented mostly by smooth implants (87.5% versus 5.1%, $P < 0.0001$), whereas the European market is mostly represented by textured implants (94.8% versus 12.5%) (Fig. 2). Interestingly, in Europe, 56% of the implants sold during this period of time were textured/round, and only 39% where textured/shaped. The remaining 5% were smooth/round implants (Fig. 3).

On the other hand, in the USA, the majority of implants sold were round/smooth (88%), followed by shaped/textured (7%) and round/textured (5%) (Fig. 3).

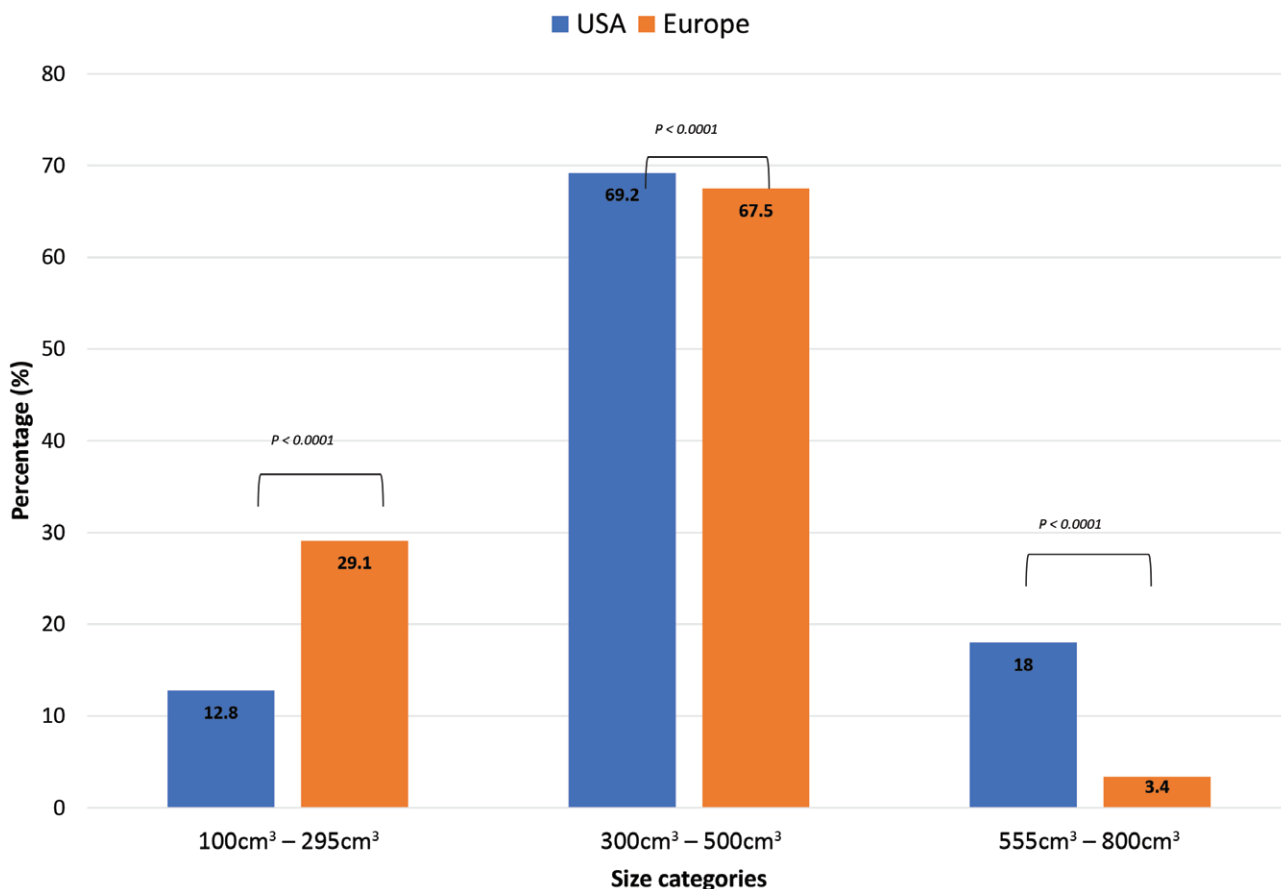


Fig. 1. Implant size utilization by region.

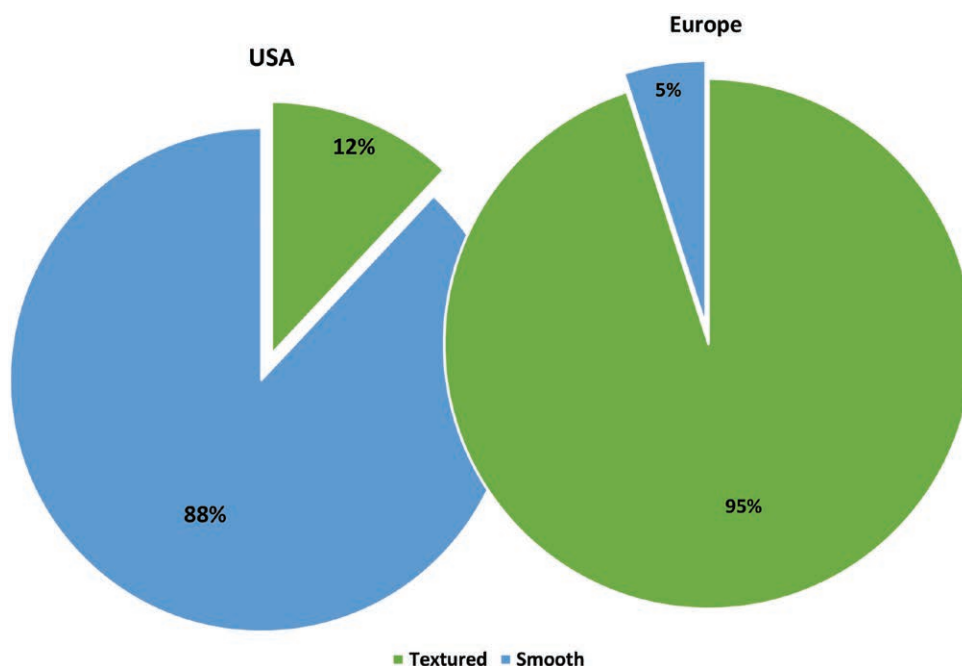


Fig. 2. Implant surface texture utilization by region.

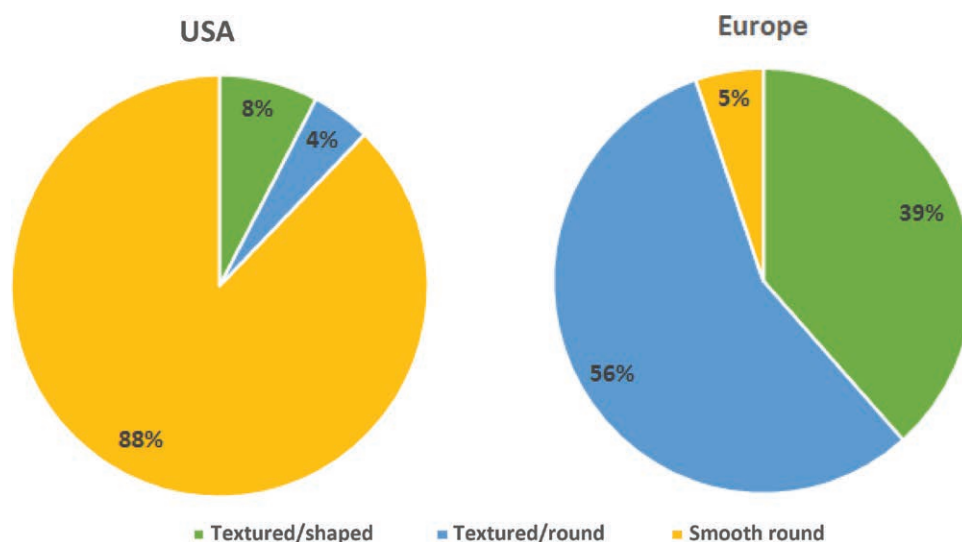


Fig. 3. Implant surface texture and shape utilization by region.

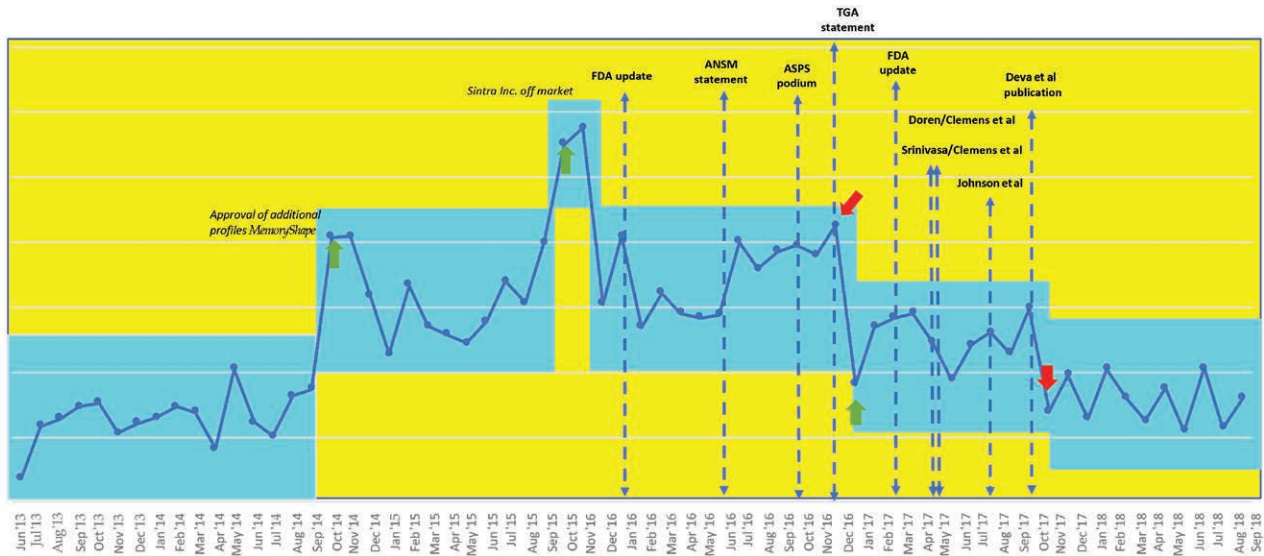
Impact of BIA-ALCL Scientific Publications on Implant Sales Textured Implants

USA: During the study period, 5 significant changes in sales trends were noted (green and red arrows on the graph line, Fig. 4). The first was a significant uptrend in textured implant sales occurring in October 2014 (95% CI [Oct. '14, Oct. '14]), which correlates with the approval of additional profiles of shaped textured implants by the company. The second uptrend occurred 1 year later in October (95% CI [Oct. '15, Oct. '15]), correlating with the time Sientra Inc. implants were recalled.

The next significant change in trend was a marked downtrend in December 2016 (95% CI [Dec. '16, Dec.

'16]) (red arrow, Fig. 4). This change was immediately preceded by the TGA statement of 2016; however, several other government agency statements and national podium presentations took place in that year. The 2016 FDA statement, the ANSM statement, and the 2 aforementioned ASPS podium presentations occurred in the months leading up to the significant downtrend of December 2016.

A statistically significant uptick was noted shortly after in January 2017 (95% CI [Sep. '16, Feb. '17]); however, overall sales trends for textured implants were maintained at a lesser volume until yet again a significant downtrend occurred in November 2017 (95% CI [Sep. '17, Jan.'18]).



USA - Textured

Month when a change in trend occurred	95% Confidence interval	Confidence level
October 2014	(Oct. '14, Oct. '14)	100%
October 2015	(Oct. '15, Oct. '15)	99%
December 2016	(Dec. '16, Dec. '16)	98%
January 2017	(Sep. '16, Feb. '17)	100%
November 2017	(Sep. '17, Jan. '18)	100%

Fig. 4. CPA trend of textured implant sales in the USA and corresponding scientific publications. Green and red arrows indicate statistically significant positive and negative change points in implant sales trend, respectively.

This overall change in trend was immediately preceded by the Deva et al publication. In the months leading up to this change in trend, 3 other notable articles by Doren et al, Srinivasa et al, and Johnson et al were published in high-impact journals, and the FDA 2017 update was released (Fig. 4).

Europe: During the same study period, only 2 significant changes in trend were noted. The first, an uptrend in textured sales, occurred in July 2015 (95% CI [Feb. '15, Oct. '15]). The second, a negative change in trend, did not occur until August 2017 (95% CI [Jul. '17, Dec. '17]), immediately following 1 notable publication by Johnson et al in the *European Journal of Surgical Oncology* (Fig. 5). Trends were seemingly unaffected during the time period of notable safety agency announcements, scientific publications and US podium presentations; however, an overall decrease in textured implant utilization was noted during the timeframe of the study.

Smooth Implants

USA: Smooth implants followed a distinct pattern during the study period. Six statistically significant changes in trend were noted. Two downtrends and 2 uptrends occurred between October 2014 and December 2015, leading to a decrease in smooth implant sales volume during the time period when additional MemoryShape profiles were approved and when Sientra Inc. was pulled from the market (Fig. 6). However, the uptrend in December 2015 (97% [Nov. '15, Jan '16]) is estimated to fall within

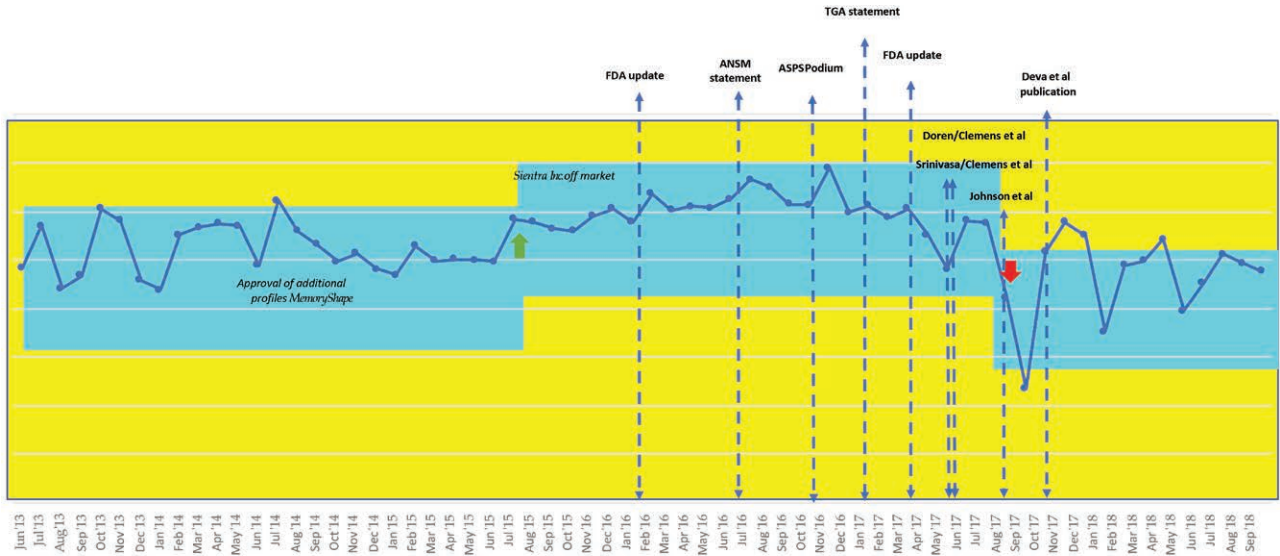
the vicinity of the 2016 FDA update. The next statistically significant uptrend in smooth sales occurred in January 2017 (95% CI [Sep. '16, Feb. '17]) immediately following the 2016 TGA statement. This was preceded in the prior months by the ASPS podium presentations (Fig. 6). The final significant uptrend occurred in November 2017 (95% CI [Sep. '17, Jan. '18]), ensuing the publication of the 4 previously mentioned scientific articles (Fig. 6).

Europe: During the study period, 2 significant changes occurred over time. The first change was a statistically significant downtrend in sales that occurred in July 2015 (95% CI [Feb. '15, Oct. '15]). The second change in trend did not occur until August 2017 (95% CI [Jul. '17, Dec. '17]). Following the publication by Johnson et al in the *European Journal of Surgical Oncology*, a significant uptrend was noted in smooth implant sales in Europe demonstrating and an overall increase in utilization in the timeframe of our study (Fig. 7).

DISCUSSION

Regional Implant Preferences

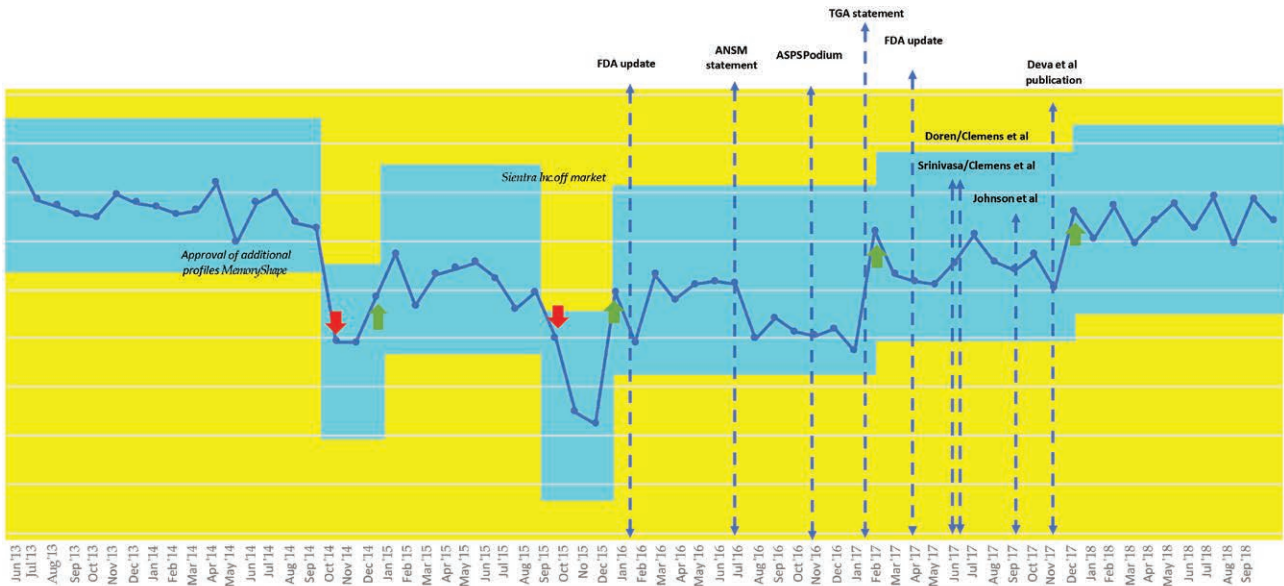
To our knowledge, this is the first study analyzing sales data to gain insight into breast implant utilization trends in 2 different regions of the world. Additionally, this is the first approach to understanding the impact of scientific and safety agency publications regarding BIA-ALCL on implant sales trends in the USA and Europe.



Europe: Textured

Month when a change in trend occurred	95% Confidence interval	Confidence level
July 2015	(Feb. '15, Oct. '15)	100%
August 2017	(Jul. '17, Dec. '17)	100%

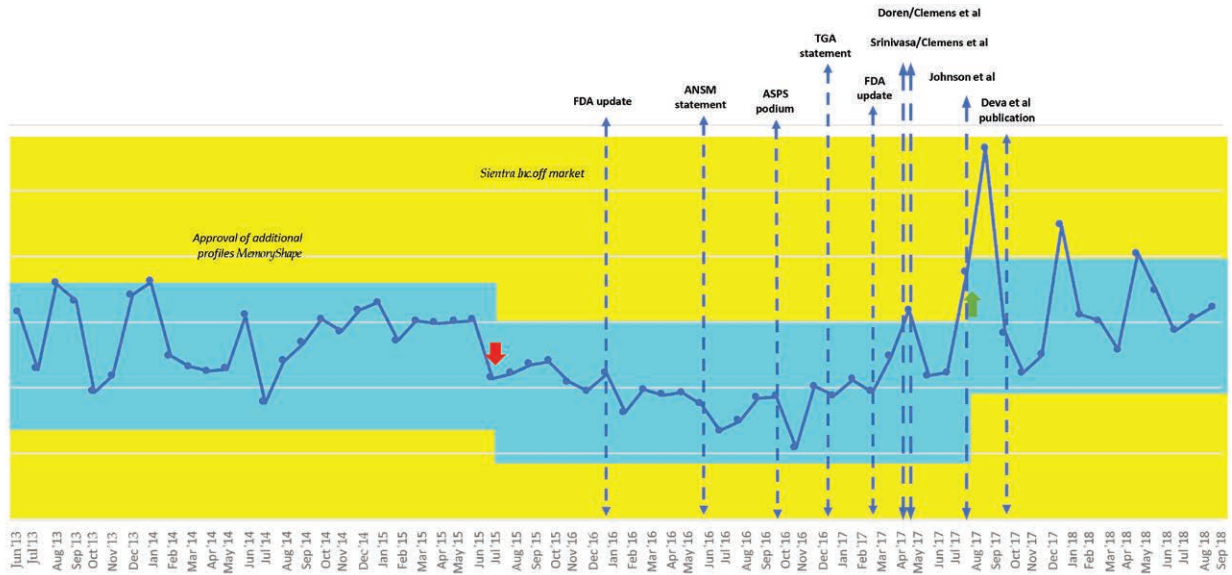
Fig. 5. CPA trend of textured implant sales in Europe and corresponding scientific publications. Green and red arrows indicate statistically significant positive and negative change points in implant sales trend, respectively.



USA: Smooth

Month when a change in trend occurred	95% Confidence interval	Confidence level
October 2014	(Oct. '14, Oct. '14)	94%
December 2014	(Dec. '14, Feb. '15)	91%
September 2015	(Sep. '15, Oct. '15)	99%
December 2015	(Nov. '16, Jan. '17)	97%
January 2017	(Sep. '16, Feb. '17)	100%
November 2017	(Sep. '17, Jan '18)	100%

Fig. 6. CPA trend of smooth implant sales in the USA and corresponding scientific publications. Green and red arrows indicate statistically significant positive and negative change points in implant sales trend, respectively.



Europe: Smooth

Month when a change in trend occurred	95% Confidence interval	Confidence level
July 2015	(Feb. '15, Oct. '15)	100%
August 2017	(Jul. '17, Dec. '17)	100%

Fig. 7. CPA trend of smooth implant sales in Europe and corresponding scientific publications. Green and red arrows indicate statistically significant positive and negative change points in implant sales trend, respectively.

Our results have shown that US surgeons tend to prefer larger, smooth implants, compared with European surgeons who tend to prefer smaller, textured breast implants. Although many factors may contribute to this trend, a likely explanation may stem from the fact that US patients have a higher average body mass index than their European counterparts.¹⁶ Overall however, medium-sized implants (300–550 cm³) were still the most commonly used size by surgeons in both regions. Interestingly, in Europe, most of the textured implants were textured/round, a combination rarely used by US surgeons.

Our results align with previously published surveys discussing trends in breast augmentation procedures. In 2016, Hidalgo et al found that 44% of US surgeons utilized mostly smooth and sometimes textured implants, and 44% utilized strictly smooth implants. The most common size range was 300–350 cm³ (42%) followed by sizes >350 cm³ (36%).³ In 2017, Heidekrueger et al conducted an international study comparing the US data provided by Hidalgo et al with the trends in breast augmentation in Latin America, Europe, Asia, and Oceania. An estimated 89.4% of the European surgeons mostly or only used textured implants, whereas 10.6% mostly or only used smooth implants. In comparing the 2 surveys, 84.6% of US surgeons used smooth implants, 10% used textured, and 5.4% used equally smooth and textured breast implants. Moreover, in the USA and Oceania, over two-thirds of surgeons usually used implant sizes greater than 300 cm³ (in the USA, 36% of respondents used implant sizes > 350 cm³), whereas in Europe and Asia, surgeons mostly used implants < 300 cm³.⁴

Although these 2 studies were well conducted, they have an important limitation: survey response rate. In Hidalgo et al’s US survey, the response rate was 21.5%. In the international analysis conducted by Heidekrueger et al, the response rate ranged from 0.6% to 30.5%, and only 11 European countries were included.⁴ In contrast, our analysis includes sales data from 15 European countries, including all the sales information available during a 5-year period. Our sales data incorporate both aesthetic and reconstructive populations in both the USA and Europe. This may inevitably skew preferences toward larger implant sizes compared with the previous studies, given the reconstructive populations need for relatively larger implant sizes post-mastectomy.

Scientific Publications, Government Agency Announcements, and National Presentations

Change-point analysis (CPA) was performed to assess the impact of national agency announcements, scientific publications, and presentations on sales trends. This is a powerful tool that can be used to conduct analysis on chronological data to identify whether a statistically significant change in trend has occurred and precisely when that change most likely occurred. It can detect subtle changes not apparent to the naked eye or to other data analytic methodologies. Moreover, CPA provides confidence levels for each change detected and confidence intervals associated with the timing of each change.¹⁷

Throughout our 5-year study period, we observed an overall decrease in the sales of textured breast implants and an overall increase in the sales of smooth implants

in both the USA and Europe. These particular trends became apparent at a time when government agency announcements, national podium presentations, and scientific publications in high-impact scientific journals discussing the epidemiology and pathogenesis of BIA-ALCL began to surface with increasing frequency.

US Implant Sales

Two statistically significant down-trending change points were noted in the US textured sales data (red arrows, Fig. 4). The first, in December 2016, following 3 national safety agency announcements—the FDA, the ANSM, and the TGA—and the 2 ASPs podium presentations.^{8,9} Temporally, the TGA announcement closely precedes this change in trend; however, just 2 months prior, surgeons from all over the world congregated at the 2016 ASPs Plastic Surgery Meeting (PSTM), in Los Angeles, Calif. Today, PSTM is the largest gathering of plastic surgeons worldwide. In total, 75 different countries are represented, yet 74% of the 3565 attendees are plastic surgeons who reside in the USA.¹⁸ Podium presentations at national meetings offer an opportunity to bring issues such as BIA-ALCL into the spotlight and unequivocally influence surgeon practice preference. It is understandable that a small lapse of time would exist before an inciting event's ripple could impact a manufacturer's sales data.

The second significant downtrend for US textured implants occurred in November 2017 (red arrow, Fig. 4). In the 8 months preceding this change, the 2017 FDA announcement and the 4 aforementioned scientific articles regarding BIA-ALCL were published. Deva et al's publication in *Plastic & Reconstructive Surgery (PRs)* most closely precedes the change point; it showed a direct correlation between BIA-ALCL risk and increased surface area of textured implants and seemingly compelled many of its surgeon readers to immediately modify their practice. We acknowledge that the change in implant trends could have stemmed from the cumulative effects of all publications mentioned within the timeframe. In 2016, PRs articles were cited over 34,000 times, demonstrating the power and outreach of scientific publications.¹⁹

Eight months prior, the FDA had also recommended that surgeons begin educating their patients about the disease process. Doren et al, shortly after recommending surgeons, discuss the risk of ALCL with patients during the consenting process.

Hence, smooth implants now offered surgeons and patients a less-dubious preoperative discussion, and their utilization began to rise. Positively significant change points noted on January 2017 and November of 2017 (green arrows, Fig. 6) confirm that US smooth implant sales exhibited inversely proportional trends when compared with US textured implant sales, which were on the decline (red arrows, Fig. 4).

European Implant Sales

Textured implants, being the preferred implant of the region, exhibited greater resistance to significant change in trends throughout the timeframe of our study. This can be attributed to many underlying factors, one being the strong underlying surgeon preference toward textured implants

in Europe. The first significant change was an increase in sales around July 2015 (green arrow, Fig. 5). This may be attributed to the manufacturer's production of additional MemoryShape profiles, providing surgeons with more versatile textured options to fit their patients' needs. Additionally, the removal of Sientra Inc.'s implants from the market in October 2016 was followed by a period of sustained growth in textured implant sales. It is not until August 2017, after all aforementioned regulatory updates (including 1 in France), 2 podium presentations and 3 major scientific publications that a statistically significant decrease in textured sales and an overall decrease in textured implant sales volume was appreciated (red arrow, Fig. 5). Interestingly, this decrease ensued following the Johnson et al publication in the *European Journal of Surgical Oncology*—a regional journal, with an impact factor rivals that of *PRs Journal*.^{19,20} Johnson et al concluded that it is indeed the surgeon's duty to inform the patient of the known risks associated with the textured implant. This again speaks to the power of major publications, and their ability to elicit abrupt changes in practice behavior. Furthermore, literature in local/regional journals seems to have a significant impact on utilization trends of manufactured medical products in that community.

The fact that the change in trends for implant sales was less pronounced in Europe may also be attributed to the notion that information stemming from presentations and journals based in the United States takes longer to percolate overseas. ASPs's PSTM is a highly influential conference, and despite its international participation, today, the only European country listed as one of the top 10 countries in attendance is the United Kingdom, making up 3.4% of international attendees, and less than 0.9% of all attendees.¹⁹ Furthermore, our data take into account 1 implant manufacturer—the risk of BIA-ALCL associated with the textured implants of our sponsor company was significantly lower than other textured implants on the market, perhaps masking an actual greater decrease in all textured breast implant utilization in the 2 regions. The trends noted in our study are based off of one global implant manufacturer. We understand this is indeed a limitation and that sampling one company's data do not provide an exact picture of overall implant trends in the world. Our collaborator, however, is one of the largest and most popular implant manufacturers on the planet. Thus, we feel the data do provide noteworthy insight.

Similar to US implant sales, smooth implant sales in Europe were inversely proportional to textured sales. Smooth implant sales experienced an overall increase in sales volume and had a statistically significant downtrend in sales in July 2015 (red arrow, Fig. 7) and a significant uptrend following Johnson et al's publication in August 2017 (green arrow, Fig. 7)—the same dates in which textured implant noted an uptrend and a downtrend in sales, respectively (green arrow, red arrow, Fig. 5).

CONCLUSIONS

It is apparent that regional differences in breast implant preferences exist with regard to size, texture, and shape. Although medium-sized implants were the most common size utilized by surgeons in both regions, our

study showed that European surgeons favored smaller, round, textured implants when compared with US surgeons, who favored larger, smooth implants. Furthermore, the publication dates of scientific material regarding BIA-ALCL coincides with a decline in textured implant sales and an increase in smooth implant sales in both Europe and the United States. Although there are many factors at play, it appears that publications in local high-impact journals and national podium presentations may have a more significant and instantaneous effect on regional surgeon practice behavior and medical device selection than do national safety agency announcements. This finding validates the importance of peer-reviewed scientific publications and their impact on plastic surgery practice.

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