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ARTICLE

In search for the 'perfect' breast implant: are textured implants still indicated in today's breast augmentation practice?

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ABSTRACT

The popularity of breast augmentation procedure has driven research and debate as to whether any given implant characteristic offers a functional advantage. One such debate exists about the role of surface texturing. In the aftermath of the recent withdrawal of aggressively textured surfaces we would like to summarize the first author's experience of nearly 1500 primary aesthetic breast augmentations with different surfaces and offer our thoughts on this topic. All consecutive primary breast augmentations operated by the first author from January 2010 to June 2019 were included. All patients had silicone implants inserted *via* inframammary incision. Of all the operated cases, 1029 consecutive female patients had at least 6 months' follow-up (mean 15.1 months). Their mean age was 31.2 years, mean BMI 20.8 kg/m^2 and mean implant volume was 311 cc. 997(96.9%) patients had dual plane and 32(3.1%) had sub-glandular implant placement. In total 113 patients (11.0%) developed a complication. This represented 15.1% of those with round and 10.0% of anatomical shape (or 10.6% of textured and 14.5% of smooth surface implants). As clinicians, we like patients to receive all the advantages of an implant but not be exposed to any risks. However, in reality, such a 'perfect implant' still does not exist. New literature continues to shed light on this trade-off between an implant's perceived utility and its complications profile. We hope that the search for an alternative technology, with more beneficial surface characteristics and less drawbacks, continues.

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Breast augmentation; breast implant; textured implant; smooth implant; BIA-ALCL

Introduction

Aesthetic breast augmentation is an increasingly popular operation [1]. Historically, surgeons in the USA have preferred to use smooth implants [2–4], while European and Australian surgeons [4,5] have primarily used textured implants for aesthetic and reconstructive breast surgery [6,7]. This is at least partially related to the fact that anatomical implants were introduced in 1994, two years after the Food and Drugs Administration (FDA) moratorium in the US [7]. In Europe and Australia meanwhile, textured (including anatomical shaped) implants continued to be used.

This difference in practice is reflected in the resulting literature [2–4,6,7]. Some surgeons have used almost exclusively one or the other type [2,8], while others have advocated using a set of indications for each implant shape [5,9]. The long-term Core studies [10–12] reported their outcomes based on implant shapes, but not on surface texturing. However, we do know that all anatomical implants were textured and that round implants were a mixture of smooth and textured surfaces. In view of the recent concerns about breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL) and the consequent regulatory steps [13–15], we analyze the first author's experience of nearly 1500 breast augmentations over the last 10 years and discuss our assessment of the future direction. Given the current situation of regulation, we are not expecting to see any more Level I or II evidence, so we believe it is important to share this experience.

Materials AND methods

Demographics

All consecutive female patients who underwent primary aesthetic breast augmentation by the first author (P.M.) from January 2010 to June 2019 at our clinic, were analyzed. All patients were counselled in accordance with the Declaration of Helsinki guidelines and written informed consent was obtained preoperatively. All implants had a silicone fill and inserted through an inframammary incision. Data was collected prospectively for patient age, BMI (in kg/m^2), preoperative cup-size, number of children, existing medications, smoking status, physical characteristics of the implants, length of follow up and any complication. Patients whose follow up was less than 6 months were excluded from this review.

Surgical technique and follow up

Pre-operative assessment, indications for choosing an implant and surgical technique has been described previously [5,16]. All patients were seen at 1 week and whenever was needed during the healing phase. Follow up was arranged for 6 and 12 months after surgery. All patients received a one-year in-house insurance plan that offered free correction of problems related to the outcome.

Analysis

The data was analyzed using the 'R' open-source statistical software. Fisher's exact test was used to calculate the significance of

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Table 1. Results from different implant surfaces.

		Textured implants ($n = 919$)	Smooth implants ($n = 110$)	p-Value
Patent characteristics				
	Mean age	31.3 years (18–60 years)	30.9 years (19–62 years)	.69
	Children	1.1 (0–6)	0.9 (0–6)	.12
	BMI	20.8 (15.6– 30.8)	20.2 (16.9–26.7)	.15
Cupsize	A	444 (48.3%)	80 (72.7%)	<.001
	B	420 (45.7%)	22 (20.0%)	<.001
	C	55 (6.0%)	8 (7.3%)	.62
	Follow up	16.0 months (6–116 months)	8.1 months (6–24 months)	<.001
Implant shape				
	Anatomical	837 (91.1%)	–	n/a
	Round	82 (8.9%)	110 (100.0%)	<.001
Same implants on both sides				.11
	Symmetrical	837 (91.1%)	94 (85.5%)	
	Not symmetrical	82 (8.9%)	16 (14.5%)	
Implant placement				
	Dual plane 1	1 (0.1%)	0 (0%)	n/a
	Dual plane 2	506 (55.1%)	80 (72.7%)	<.001
	Dual plane 3	390 (42.4%)	20 (18.2%)	<.001
	Subglandular	22 (2.4%)	10 (9.1%)	.02
Complications				.26
	Yes	97 (10.6%)	16 (14.5%)	
	No	822 (89.4%)	94 (85.5%)	
Type of complication				
	Rotation	29 (3.2%)	n/a	n/a
	Implant failure	3 (0.3%)	0 (0%)	n/a
	Double bubble	5 (0.5%)	1 (0.9%)	n/a
	Bottoming out	16 (1.7%)	11 (10.0%)	<.001
	Capsular contracure	32 (3.5%)	1 (0.9%)	n/a
	Seroma	11 (1.2%)	0 (0%)	n/a
	Hematoma	7 (0.7%)	3 (2.7%)	<.001
Reoperation				
	Due to complication	82 (8.9%)	8 (7.3%)	.54
	Patient choice (in absence of complication)	37 (4.0%)	2 (1.8%)	.13
	Total	119 (12.9%)	11 (10.0%)	.20

binary outcome variables and student's t-test for continuous variables. p-Value of less than .05 was considered significant.

Results

One thousand four hundred and thirty-four female patients underwent primary aesthetic breast augmentation with the first author from April 2009 to June 2019. Of these, 1029 patients had at least 6 months follow up, whose data was used for further analysis. There were no oncologic patients.

Demographics

Mean age of the patients at surgery was 31.2 years (range, 18 to 62 years). The mean patient height was 167.4 cm (range, 140 to 188 cm) and their mean BMI was 20.8 kg/m^2 (range, 15.6 to 30.8 kg/m^2). The mean number of children at the index operation was 1.07 (range, 0 to 6). 524 patients (50.9%) considered themselves to have 'A' cup-size, 442 (43.0%) a 'B' and 63 (6.1%) a 'C' cup-size. 120 patients (11.7%) were using (at least one) medication for an existing medical condition while 225 (21.9%) were only taking the contraceptive pill. 113 patients (11.0%) admitted to smoking an average of 8.8 cigarettes per day (range, 1 to 20 cigarettes/day). Mean follow up was 15.1 months (range 6 to 116 months) after surgery.

Operations performed

All operations were performed in general anesthesia *via* an inframammary incision. Thirty- two patients (3.1%) received the implants in the sub-glandular pocket while the rest of them (997 patients, 96.9%) had dual plane placement. In total 2058 implants were used with a mean implant volume of 316 cc (range, 140 to 615 cc). 1820 (88.4%) implants were macrotextured, 18 (0.9%) were microtextured and 220 (10.7%) smooth as per ISO (International Organisation for Standardization) [17] classification, respectively manufactured by Allergan (Irvine, CA), Mentor (Santa Barbara, CA) and Motiva (Establishment Labs, Costa Rica). 384 implants (in 192 patients, 18.7%) were round in shape with mean volume of 340 cc (range, 205 to 560 cc) while 1674 implants (in 837 patients, 81.3%) were anatomical shaped with a mean volume of 311 cc (range, 140 to 615 cc). Tables 1 and 2 give the breakdown of characteristics for different shape and surface implants. Figures 1 and 2 show long-term results from different implant types.

Complications

In total, 113 patients (11.0%) developed a complication postoperatively (Table 1). These represented 15.1% ($n = 29$) of patients with round implants and 10.0% ($n = 84$) of those with anatomical implants (not statistically significant, p-value = .07). Among all patients, in 27 cases (2.6%) the implants 'bottomed out' at a mean 10.7 months after augmentation (range, 5 to 39 months). Six patients (0.6%) developed a 'double bubble' deformity at a mean 14.0 months of follow up (range, 6 to 58 months). 33 patients (3.2%) developed capsular contracture (CC) at an average 35.6 months (range, 3 to 112 months). Ten patients (1.0%) developed postoperative hematomas that were managed surgically. There were 12 (1.2%) small volume uncomplicated seromas that

Table 2. Results by implant shape.

		Round implants ($n = 192$)	Anatomical implants ($n = 837$)	p-Value
Patent characteristics				
	Mean age	29.1 years (19–62 years)	31.7 years (18–60 years)	<.01
	Children	0.7 (0–2)	1.2 (0–6)	<.01
	BMI	20.2 (16.0–28.1)	20.9 (15.6– 30.8)	.15
Cupsize	A	123 (63.9%)	401 (48.0%)	<.01
	B	55 (28.8%)	387 (46.2%)	<.01
	C	14 (7.3%)	49 (5.8%)	.48
	Mean follow up	13.1 months (6–91 months)	15.6 months (6–116 months)	.04
Implant shape				
	Textured	82 (42.7%)	837 (100.0%)	<.01
	Smooth	110 (57.3%)	–	n/a
Same implants on both sides				.34
	Symmetrical	170 (88.5%)	761 (90.9%)	
	Not symmetrical	22 (11.5%)	76 (9.1%)	
Implant placement				
	Dual plane 1	0 (0%)	1 (0.1%)	n/a
	Dual plane 2	134 (69.6%)	452 (54.1%)	<.01
	Dual plane 3	45 (23.6%)	365 (43.5%)	<.01
	Subglandular	13 (6.8%)	19 (2.3%)	.02
Complications				.07
	Yes	29 (15.1%)	84 (10.0%)	
	No	163 (84.9%)	753 (90.0%)	
Type of complication				
	Rotation	n/a	29 (3.4%)	n/a
	Implant failure	1 (0.5%)	2 (0.23%)	.61
	Double bubble	2 (1.0%)	4 (0.5%)	.47
	Bottoming out	16 (8.4%)	11 (1.3%)	<.001
	Capsular contracure	4 (2.1%)	29 (3.5%)	.26
	Seroma	3 (1.6%)	9 (1.1%)	.61
	Hematoma	4 (2.1%)	6 (0.7%)	.20
Reoperation				
	Due to complication	18 (9.4%)	72 (8.6%)	.74
	Patient choice (in absence of complication)	7 (3.7%)	32 (3.8%)	.91
	Total	25 (13.0%)	104 (12.4%)	.82

were aspirated with ultrasound guidance and managed according to existing protocol. In 29 patients (3.4% of) the anatomical implants mal-rotated at a mean 13.4 months after surgery (range 3 to 48 months). Tables 1 and 2 give the breakdown of complications for implant with respect to their shapes and surfaces.

In total, 90 patients (8.7%) had a re-operation (mean age 29.9 years, range 18–50 years) for a complication (with mean follow up 34.1 months, range 6–116 months). Another 39 patients (3.8%) chose to have further surgery (mean age 30.5 years, range 18–47 years) in the absence of a complications (with mean follow up 32.4 months, range 7–96 months). Of the these 36 chose to have a larger implant and three chose to remove their implants.

Discussion

Due to historical reasons, there has been a geographic difference in the types of implant surfaces used. In the United States, approximately 13% of breast implants used have textured surfaces, compared to 90% in Europe and Australia [6,7]. Textured implants were introduced with the aim of decreasing capsular contracture [18–20] and implant malposition/rotation [18,20]. It was believed that an irregular surface will allow ingrowth of fibroblasts to prevent mal-positioning, as well as discourage a net vector of contraction, in order to prevent capsular contracture (CC) [18–20]. Surface roughness, that was earlier considered a binary dichotomy, has been described in the recent literature as consisting of many 'grades'. However, there is no consensus on its terminology, so that ISO [17] refers to three subtypes (Macrotexture, Microtexture, Smooth) whereas many authors classify it in to four types [21–24]. Broadly speaking, polyurethane surfaces have the 'most aggressive texturing' (i.e. highest surface area) followed by respectively Biocell™, Siltex™ and 'smooth' surfaces [21–23].

Surface characteristics

For the same implant shell type, increasing the surface roughness increases its surface area which in turn impacts host tissue response [21,22,25]. Biomechanical studies have shown higher fibroblast adhesion [25,26] with textured surfaces. Clinical 'core' studies [10–12] suggest that textured anatomical devices from the *same* manufacturer lead to less capsular contracture with respect to their round implants [10–12,27] (which are made of an unknown mix of smooth and textured surfaces). Additionally, textured surfaces from *different* manufacturers have different rates of capsular contracture and implant malposition/rotation [10–12,27]. However, there does not appear to be a linear relationship between the degree of surface roughness and clinical effect. On one hand, Biocell™ surface has a higher incidence of double capsules, possibly from mechanical shearing [28] of the excessively textured surface. On the other hand, the corresponding anatomical implants have a relatively higher risk of capsular contracture (9.2% at 10 years) [27] and a higher risk of malposition than from a less aggressively textured Siltex™ surface (3.4% at 9 years) [27]. However, this is still better than round implants from respective manufacturer (19.1% at 10 years with Allergan and 12.1% at 9 years with Mentor's combined smooth and textured surface) [27]. That is at odds with the thinking [20] that mirror image texturing of Biocell™ may be better at preventing micro-movements than Siltex. In our series (Table 1), the textured implants (with a mean follow up of 16.1 months) had a 3.5% risk of CC and 1.8% risk of bottoming out. The smooth implants had a slightly lower

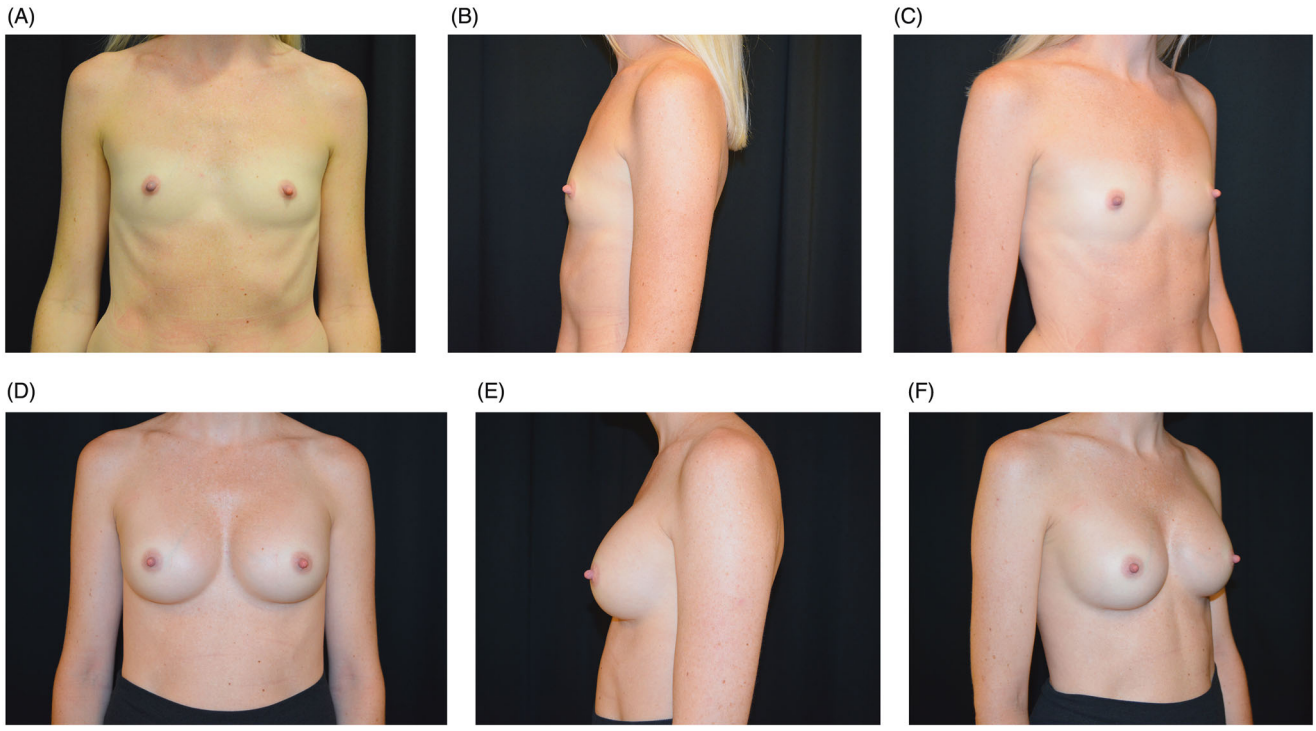

Figure 1. (A, B, C) This 34-year-old woman presented for breast augmentation. Her desire was to have a moderate enlargement with natural and proportionate look. A 295 cc anatomical implant was used on both sides, with a dual-plane technique *via* a submammary incision. (D, E, F) Appearance after 4 years shows nice and natural shape of the breasts with conservation of the body proportions.

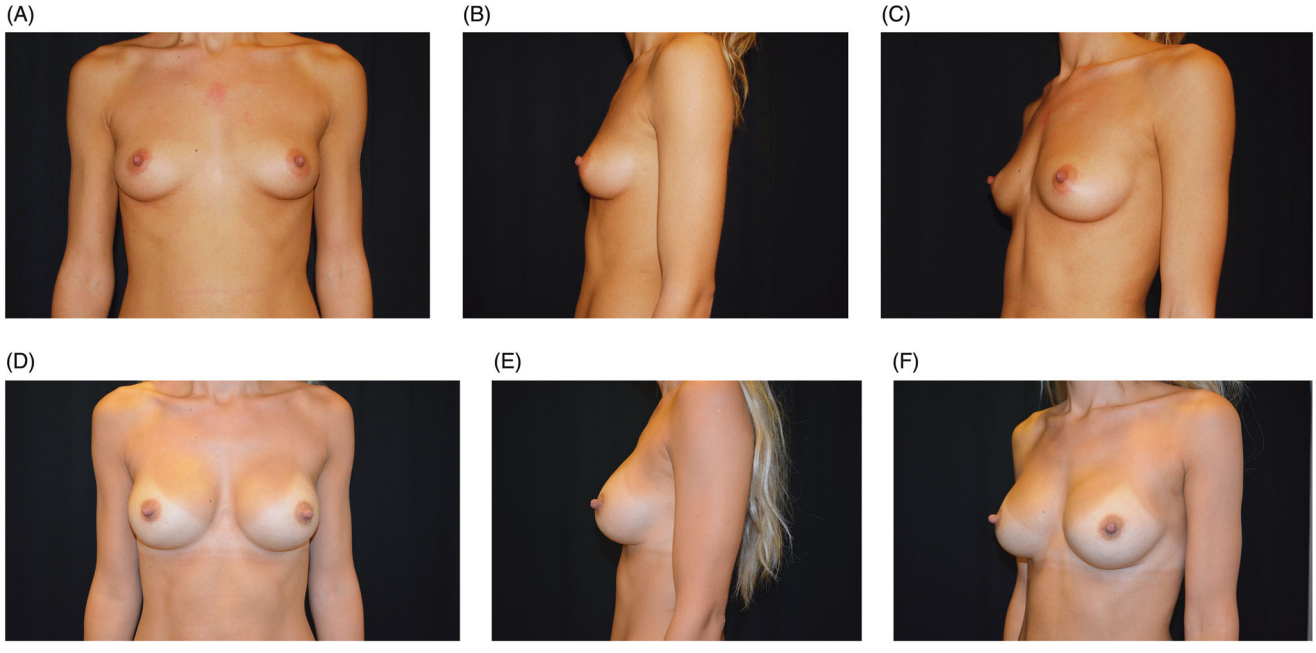

Figure 2. (A, B, C) This 25-year-old woman presented for breast augmentation. Her desire was to have a fairly big enlargement with a full augmented look. A 340 cc round implant was used on both sides, with a dual-plane technique *via* a submammary incision. (D, E, F) Appearance at 8 years postoperatively shows good upper pole fullness and nice shape of the breasts.

(0.8%) risk of CC but a much higher (9.3%) risk of bottoming out (even with at a significantly shorter mean follow up, of 8.0 months). The increased bottoming out may be due to a relatively larger volume of the round implants, as compared to anatomical implants of similar base (Figure 3) [9,29]. We anticipate that a longer follow up will further clarify this difference in risk.

Implant shape

Surface texturing allowed the development of anatomical implants with the aim of mimicking the 'tear drop' shape of an aesthetic natural breast. As to whether an implant shape confers an aesthetic advantage has also been hotly contested. Some

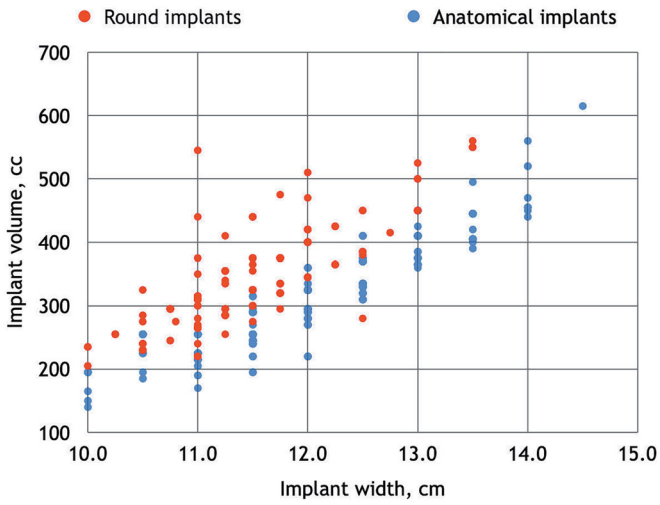

Figure 3. Relationship between implants of different shapes and their volume.

authors have argued (after excluding certain breast types) that the difference in implant shape is irrelevant since the final outcome is equivalent and indistinguishable [2,30]. However, the conditions excluded in these studies are in fact those situations where there is a strong indication for the use of anatomical implants. In our experience, in a breast with a short constricted lower pole, an anatomical low height implant will respect the existing glandular border whereas a round implant may have a higher risk for a double-bubble deformity [5,9]. Similarly, patients with significant breast asymmetry or chest wall deformity can also benefit from anatomical implants as each of their dimensions (height, width and projection) can be adjusted individually to clinical need [5,9,16]. For this reason, we do believe that indications for use of an implant shape in *every* single patient, is a much more relevant topic for discussion rather than debating aesthetic outcome of these shapes in *selected* subgroups.

In case of patients who may achieve similar aesthetic result from either shape, choosing one or the other implant shape has a much less impact on the final outcome. However, the difference in final outcome between round and anatomical implants is more obvious in patients with poor soft tissue envelope or those who receive large volume devices (particularly if they have a high cohesive gel, full/extra-full projection or are placed in a sub-glandular pocket) [16]. Indications for the use of anatomical and round implants have been described previously [5] and will therefore not be replicated here. So, while we are not claiming that anatomical implants are somehow inherently 'superior' or 'better' than round ones, we do think that they still serve an important function in breast surgery, especially in certain subgroups of patients.

Another concern commonly expressed about anatomical implants is related to their malposition by rotation. However, this discussion seems to take place without reference to the other form of implant malposition i. e. bottoming out. The Core studies [10–12] showed that the *total* risk of implant malposition was less in (textured) anatomical implants as compared to round implants from the same manufacturer (that were a mix of both surfaces) [27]. This may be due to increased adherence of the textured surface [26], or due to the relative lighter weight of the anatomical implants [9] when compared to round implants of the same base (Figure 1). In our series, 4.8% patients with anatomical implants had a malposition (3.4% implant malrotation and 1.4% bottoming out), as compared to 8.4% (malposition from bottoming out) in round implants. We think that while texturing aims to decrease the risk of rotation of anatomically shaped implants, it needs to be accompanied with a precise technique for best effect. A learning curve is therefore to be expected before achieving a low complication rate with textured anatomical implants [9,17].

In recent past, there has been a rapid accumulation of literature about BIA-ALCL. Currently the most discussed 'trade off' with texturing is its association with BIA-ALCL. Some of the recent estimates for the risk are 1 in 2832 for polyurethane surface [31], 1 in 3817 for Biocell [31] and 1:60,631 for Siltex-textured surfaces [31]. This risk has been deemed high enough to lead to withdrawal of aggressively textures implants from the market [13–15] and to issue comprehensive guidelines for management of symptomatic patients [32]. Nonetheless, at present time, the risk is not considered high enough to warrant prophylactic explantation in asymptomatic individuals [14,15,33–37]. There is evidence that surgeons are changing their preferences about which implant surfaces to use newer surfaces [38]. However, it would be premature to make a head-to-head comparison between older and newer implant surfaces until there is an equivalent amount of follow up data for the latter. As evidence for ALCL has become available, it has been incorporated into our clinical practice. The risk of developing BIA-ALCL is 1:3817 (as quoted in the manuscript) and occurs at an average of 8–10 years. With a total of 1820 macro-textured implants used in this group, there is <0.5 chance of having one in this group. There has been no BIA-ALCL case in this group of patients.

In many public health-matters it is not straight forward to define what constitutes an 'acceptable risk', especially when we know that even elective surgery, including aesthetic procedures, carry a non-zero risk of serious injury or even mortality [39]. Familusi *et al.* [40] identified 0.2% (i.e. 1 in 500) rate of 30-day mortality in 3637 patients undergoing abdominoplasty between 2007 and 2012 from the American College of Surgeons National Surgical Quality Improvement database. Saad *et al.* [41] found 0.07% (i.e. 1 in 1428) rate of 30-day mortality after outpatient cosmetic surgery from 2005 to 2010 in a California state database. However, there have been no calls to e.g. stop performing abdominoplasties or outpatient cosmetic surgery in California. We appreciate that 'acceptable risk' in a given medical or surgical scenario is dependent on many factors. Most of BIA-ALCL cases were linked to the Biocell surface [14] and their removal means that that the risk associated to these devices is gone for good. The micro-textured implants currently still available in the market carry a much lower risk of BIA-ALCL. Removal of *all* anatomical textured implants may therefore indeed remove the currently known associated risks completely, but we would also lose all their benefits and cost-effectiveness [42] as well, leaving limited options for the surgeon and the patient. We do think that any one implant shape should not be made to fit every patient indiscriminately and that each procedure should be individualized, taking into account patient's anatomy, implant characteristics and making the patient part of the decision-making process.

One limitation of our data set is the relatively short follow up and the disproportionate number of anatomical implants (especially in the initial phase). While longer follow up is ideal and has been reported in some industry funded papers, it is unusual in a private aesthetic practice where most patients, especially the asymptomatic ones, have no incentive to return. All patients received an in-house insurance that offered free correction of problems related to the outcome, so anyone with a complication were in fact more likely to return for follow up. We have been using proportionally more round implants recently in our cohort of patients, which provides a useful comparison. Another

potential clinical limitation may be that this review represents the authors' clinical practice and was not designed as a head-to-head comparison between anatomical and round or between smooth versus textured implants. It is for this reason that it provides a level IV evidence (and not any higher). We have used Core studies for much of the discussion as these are widely known large data sources of outcomes for various implant types. Our results are, however, from a single surgeon's experience and therefore minimize variation in selection criteria and operating technique.

In an ideal world, it would be possible to keep the positive value and benefits of surface texturing and of the anatomical implants, with an 'acceptable' level of known complications. We are also aware that 'acceptable level of risk' is somewhat subjective, dependent on who is asked for an opinion. What complicates this matter is that breast augmentation is a high-profile scenario that catches the public imagination easily and has already been an issue of discord in the past. In addition to the (actual and potential) patients and clinicians, other stake holders need to be considered as well. These include the manufacturers, the 'injury claim' lawyers and the media [43,44], each with their own set of priorities. In the current situation where the interests of lawyers, lobbying firms and media converge in one direction and that of the manufacturers in another, it is imperative for the surgeon to act as the patients' advocate and provide accurate information for a balanced decision making. This will help counsel patients, inform public and form the basis of evidence-based management.

Conclusion

There are various grades of texturing, each with a different biological reactivity. The introduction of surface texturing of breast implants was intended to improve adherence, decrease mal-positioning and afford favorable capsular contracture rates. While initial studies supported these uses, more recent data show the association of double capsules, late seromas and BIA-ALCL in proportion to the degree of texturing. As a result, aggressively textured implants have been withdrawn to remove any further exposure and international research collaboration has contributed to management guidelines for patients.

We want patients to benefit from all the advantages of a given implant and ideally have no risk. However, in reality, we have a situation where a certain number of patients may still benefit from texturing. This is best addressed on the basis of available evidence and with patient education to discuss all risks and options. We appreciate that dealing with breast implant is a complex situation where manufacturers, press, lawyers and public imagination cross paths, as much as the surgeon and the patient. We urge the need to find new surfaces or techniques to regain the benefits or offset the risks. The 'perfect breast implant' is unfortunately yet to come.

Disclosure statement

Dr. Montemurro has been a consultant to Allergan, Inc. (Irvine, CA). Per Hedén has had consultancy agreements with Allergan, Mentor, Establishment Labs, G&G Medical and GC Aesthetics, is a shareholder in Polytech and Establishment Labs, and has a Development Contract with Allergan. Dr Cheema reports nothing to disclose.

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