Aesth Plast Surg (2019) 43:1454–1466
https://doi.org/10.1007/s00266-019-01464-9

ORIGINAL ARTICLE BREAST SURGERY

Smooth Prosthesis: Our Experience and Current State of Art in the Use of Smooth Sub-muscular Silicone Gel Breast Implants

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Received: 18 March 2019 / Accepted: 16 July 2019 / Published online: 24 July 2019

Abstract

Background The objective of this clinical review is to provide an overview of the use of silicone gel-filled breast implants placed in the sub-muscular position, with a focus on complication rates reported for both smooth and textured implants. Furthermore, our experience in this field is also reviewed.

Methods MEDLINE, EMBASE, Web of Science, Scopus, the Cochrane Central and Google Scholar databases were reviewed to identify the literature related to smooth breast implants. Each article was reviewed by two independent reviewers to ensure all relevant publications were identified. The literature search identified 98 applicable articles. Of these, just a few articles were found to have a therapeutic level of evidence. The reference lists in each relevant paper were screened manually to include relevant papers not found through the initial search.

Results Eight articles report the risk of capsular contracture when the breast implants were placed in the sub-muscular position. Six of these articles report a similar rate of capsular contracture in smooth and textured implants. Local complications such as wrinkling, late seroma and double capsules were found to be associated with the use of textured breast implants (4 articles). All articles concerning BIA-ALCL reported a total absence occurring in smooth breast implants. All cases have been associated with textured mammary prostheses.

Conclusion With our expertise in the field and the results of this up-to-date literature review, it can be concluded that there are no significant advantages of using one type of implant surface over the other when placed in the sub-pectoral position.

Level of Evidence V This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Smooth sub-muscular silicone gel breast implants · Breast augmentation · Prosthetic breast reconstruction · Capsular contracture · BIA-ALCL

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Background

Globally breast augmentation is the most commonly performed surgical procedure in aesthetic plastic surgery. In addition, implant-based breast reconstruction is ranked the most popular technique performed in post-mastectomy patients [1-6].

According to the American Society of Plastic Surgeons, approximately 400,000 women in the USA undergo cosmetic or reconstructive breast augmentations annually [7]. In 2017, the total amount of aesthetic breast augmentation surgeries performed in the USA was 333,392, an increase in comparison with figures reported in 2016 (312,774).

There are a variety of breast implant types available including round and shaped; saline and silicone; smooth, textured and polyurethane-coated implants.

Smooth and textured mammary implants remain the most commonly used prostheses for breast augmentation. Despite polyurethane covered implants revealing good aesthetic results, they tend to be the least preferred therapeutic option for many surgeons [1-8].

The current breakdown of breast implant usage in the USA is approximately 87% smooth and 13% textured, whereas device preferences differ substantially outside the USA, with 90% usage of textured implants in Europe and Australia [9-12].

Despite the continuous evolution of mammary implants and the advancements in surgical techniques, peri-prosthetic capsular formation remains a highly unpredictable and unpreventable complication often leading to the re-intervention in the medium-to-long-term interval [4, 13-16].

It is believed that textured breast implants have a lower risk rate of capsular contracture; hence, many surgeons prefer to use these implants over smooth implants. However, it is interesting to note that the incidence of capsular fibrosis varies significantly in the current literature, with many papers citing comparable contracture rates with smooth and textured implants [17-19].

Disadvantages of textured implants include the occurrence of contour irregularities such as wrinkling and palpable edges and the theoretical increased risk of bacterial adherence due to the greater surface area.

Overall, many randomized controlled trials have shown conflicting results when comparing textured with smooth implants. Earlier studies report a clear advantage with the use of textured implants [20-25], whereas later studies found no significant improvements in terms of reduction of capsule formation [19, 26]. Therefore, it is unclear whether texturing reduces the incidence or merely delays the onset of capsular contracture.

The literature review also highlighted that many surgeons have reverted back to using smooth implants following an increased awareness of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), which has been gaining interest and importance in recent years.

The purpose of this study was to perform a systematic review of the current literature to analyze the use of smooth and textured mammary implants and their associated complications. Moreover, we report our own experience to validate that reported in the literature.

Materials and Methods

A search was conducted of the literature published between January 1, 1991, and December 20, 2018, using the EMBASE, MEDLINE (PubMed), Web of Science, Scopus, the Cochrane Central and Google Scholar databases. The search studied articles published in the English language only. Databases were searched using variations of the following key words: "smooth prosthesis," "breast augmentation," "prosthetic breast reconstruction," "smooth breast implants," "BIA-ALCL," "smooth subglandular silicone gel breast implants," "smooth submuscular silicone gel breast implants" and "capsular contracture." Terms were expanded to include the corresponding MeSH terms, and a separate literature search was performed for each of the procedures found. In addition, a manual search of study references was performed to ensure completeness. No limitations were placed on the study design. References were checked for duplicity and deleted accordingly.

Data Extraction and Endpoints

The primary endpoint investigated was the rate of capsular contracture observed with both smooth and textured breast implants. Secondary endpoints analyzed included histological features of capsules, double capsules, wrinkling, late seroma, and BIA-ALCL and patient satisfaction.

Critical Appraisal of the Literature

A quality score was calculated for each article using a checklist from the American Society of Plastic Surgeons (ASPS) guidelines for therapeutic studies [27]. Each study was appraised by at least two reviewers (NZ and FG), and rating decisions were based on the consensus of the reviewing authors. If a discrepancy occurred between the reviewers, the literature was appraised by a third reviewer (MR), and the level of evidence was determined by consensus.

The ASPS guidelines evaluate selection bias, intervention bias and measurement bias with 8 objective questions. The maximum score that could be obtained per study was 8. The assessment of whether confounders were adequately addressed in each paper included an evaluation of the inclusion/exclusion criteria, methods, discussion of limitations and appropriateness of study conclusions based on the study results.

Results

The literature search yielded 3985 unique publications. After applying the selection criteria, 98 publications were reviewed and 58 were included in this review (Table 1).

The initial consensus between the reviewers after screening the title and abstract was 99.6%. Screening of the reference lists of the included papers did not result in the inclusion of additional studies. Two studies were included only after essential information was acquired through correspondence with the authors [23, 28]. Additional information was also received for three further studies reported in the literature.

Capsular Contracture

Twenty-five studies discussing capsular contracture associated with the use of smooth implants were identified, eight of which were literature reviews.

Ten of these studies evaluated the degree of capsular contracture when the implants were placed in the subglandular position, while three reviewed the rate of capsular contracture in the sub-muscular location. Five papers identified the risk rates in both sub-muscular and subglandular positions, and seven studies did not specify the placement of the implant.

In the studies investigating the sub-glandular location, 11 papers reported a minor rate of capsular contracture in textured implants, whereas 4 articles presented a comparable rate of contracture between textured and smooth implants.

Regarding the studies concerning implants positioned under the pectoralis major muscle [8], six reported a comparable rate of contracture between smooth and textured implants. Two reviews [11, 29] from this collection considered both the sub-glandular and sub-muscular placements.

In relation to the seven studies not reporting implant placement, five report a decrease in the rate of capsular contracture when using textured implants, while two studies report a comparable rate of contracture between smooth and textured implants.

Histological Features of Capsules

Five studies were identified to document the histological features of the peri-prosthetic capsule. The results of all five studies differed; hence, a single conclusion could not be drawn. One study reported no difference in the capsular features with the use of differently coated implants [30], one reported a decrease in the capsular thickness with smooth implants [31], and another associates a thicker capsule with textured implants [32].

BIA-ALCL and Other Local Complications

Two studies and two literature reviews were identified to report an absence or rarity of anaplastic large cell lymphoma (ALCL) associated with the use of smooth breast implants. An association was confirmed between the development of BIA-ALCL and the use of textured mammary implants.

Four reviews document the incidence of double capsules, wrinkling and late seroma. All reported the incidence of each complication to be associated with the use of textured devices.

Our Experience

One hundred and forty-six patients (254 implants) underwent breast surgery between June 2016 and January 2018 across two sites. One hundred percent of the patients at the first site and 75% of patients at the second site underwent breast augmentation for aesthetic indications. At the second site, 20 patients underwent breast reconstruction. Fourteen of these patients underwent unilateral reconstruction, while 6 patients received bilateral nipple-areolar complex (NAC)-sparing mastectomies using a radial lateral access. Patients' demographics are reported in Table 2.

The implant procedures were performed by two surgeons (P.V. at the first site and P.C.P at the second site). The same procedure was followed in both centers for all patients.

The inframammary incision was utilized for all patients who underwent implantation for cosmetic indications, whereas a lateral incision was used for those patients who underwent surgery for reconstructive purposes.

All patients received Nagor Impleo breast implants (Soft Cohesive Gel-Filled Smooth, Moderate/ High Range Implants—Dublin, Ireland), placed via partial sub-muscular augmentation mammoplasty (dual-plane type I).

Overall, the postoperative complications experienced across both centers included 5 hematomas, 2 postoperative seromas (occurred just weeks postsurgery), 1 implant rupture, 1 case of post-mastectomy prosthetic infection, 5 implant displacements and 1 case of wrinkling. The implant rupture resulted in implant replacement 13 months after initial implantation, while the prosthetic infection resulted in implant removal just 21 days postsurgery.

The average follow-up period was 18.1 months (Center 1) and 19.8 months (Center 2), with a follow-up range of 12–30 months.

Table 1 Results of smooth prosthesis implantation—literature review

Outcome	Author	Year	Implants used	Placement	Main results
Capsular contracture	Coleman et al. [83], England	1991	Siltex textured silicone implant (Mentor) Siltex smooth silicone implant (Mentor)	Sub-glandular	Silicone breast implant surface texturing has been shown to reduce the short-term incidence of adverse capsular contracture in sub-glandular augmentation mammaplasty
	Hakelius et al. [41], Sweden	1992	Smooth silicone intrashiel style 40 McGhan Textured Biocell implant	Sub-glandular	At the end of the follow-up period, after 1 year, the breasts augmented with textured implants had a lower tendency to develop contracting capsules than the breasts augmented with smooth implants
	Pollock [84], USA	1993	N.R	Sub-glandular	Textured surface silicone implants are shown statistically to reduce capsular contracture to 4 percent, compared with a 21 percent incidence with smooth surface silicone implants
	Burkhardt et al. [24], USA	1994	Mentor Smooth Saline Implant (Mentor 1600 series Siltex device) Mentor Textured Implant (Mentor 2600 series Siltex device)	Sub-glandular	Compared with smooth implant, textured surfaced implant significantly reduced adverse contractures
	May Jr. et al. [30], USA	1994	N.R	N.R	In this clinical study, we could not confirm the suggestion that textured silicone expanders produce less capsular contracture
	Burkhardt et al. [25], USA	1995	McGhan series 68 smooth saline implant McGhan 168 textured implants	Sub-glandular	Compared with smooth implant, textured surfaced implant significantly reduced adverse contractures
	Handel et al. [17], USA	1995	N.R	Sub-glandular Sub-muscular	Smooth and textured silicone implants had contracture rates similar to each other
	Asplund et al. [28], England	1996	Third generation silicone, Dow Corning Silastic II HP/ Dow Corning Silastic MSI HP	Sub-muscular	There was a small but inconclusive difference in capsular contracture rate that favored the placement of textured rather than smooth implants in the sub-muscular pocket
	Hammerstad et al. [85], Norway	1996	N.R	N.R	Implant texturization reduces the incidence of capsular contracture
	Tarpila et al. [26], Sweden	1997	Textured Saline prosthesis (Biocell, style 168) Smooth Saline prosthesis (McGhan)	Sub-glandular	The incidence of contracture did not differ between textured and smooth prostheses
	Malata et al. [22], England	1997	Siltex textured silicone implant (Mentor) Siltex smooth silicone implant (Mentor)	Sub-glandular	Silicone breast implant surface texturing has been shown to reduce the short-term incidence of adverse capsular contracture in sub-glandular augmentation mammaplasty
	Collis et al. [23], England	2000	Siltex textured silicone implant (Mentor) Siltex smooth silicone implant (Mentor) Nagotex smooth silicone implant (Nagor) Polyurethane silicone implant (Mème Polytech)	Sub-muscular Sub-glandular	Sub-pectoral placement has a marked effect reducing capsular contracture rates respect sub-glandular placement and appears to be independent of surface texturing. The large difference in contracture rates between textured and smooth implants in the sub-glandular position appears to be lost in sub-pectoral placement, with both implant types resulting in low contracture rates
	Fagrell et al. [19], Sweden	2001	Fine textured saline implant (Siltex, style 2800) Smooth saline implant (Mentor style 1800)	Sub-glandular	This study showed no significant difference of contracture with smooth versus fine textured implants

Table 1 continued

Outcome	Author	Year	Implants used	Placement	Main results
	Handel et al. [1], USA	2006	N.R	N.R	Smooth and textured implants had similar contracture rates
	Blount et al. [62], USA	2013	N.R	Sub-muscular	We did not find a significant association between capsular contracture rate and shell type
	Spear et al. [61], USA	2014	Natrelle, Allergan (Smooth styles 40 and 45) Natrelle, Allergan (Biocell textured styles 110 and 120)	Sub-glandular	Augmentation capsular contracture rates were overall relatively comparable between texture and smooth
	Diaz [63], USA	2017	Natrelle, Allergan (Smooth styles) Natrelle, Allergan (Biocell textured styles 110 and 120)	Sub-muscular	There were no significant differences in complications based on implant surface texture. Implant surface texture may not play an important role in preventing capsular contracture or other complications as once thought, especially if a meticulous surgical technique is used
Review	Wong et al. [86], Singapore	2006	N.R	Sub-glandular	Implant texturization reduces the incidence of early capsular contracture in sub-glandular breast augmentation
	Barnsley et al. [29], England	2006	Mentor (Siltex) Inamed Corp. (Biocell)	Sub-muscular Sub-glandular	Textured surface breast implants are superior over smooth surface breast implants in decreasing the proportion of patients who develop capsular contracture Sub-muscular placement was the only subgroup in which significance was not achieved
	Namnoum et al. [87], USA	2013	Natrelle, Allergan (Smooth styles) Natrelle, Allergan (Biocell textured styles)	Sub-muscular Sub-glandular	Risk of capsular contracture was significantly reduced with textured surface versus smooth implants
	Liu et al. [88], China	2015	N.R	N.R	Smooth implants were more likely to be associated with capsular contracture than textured implants
	Quinn et al. [89], Australia	2016	N.R	N.R	Textured implants have a lower risk of capsular contracture than smooth implants
	Cifuentes et al. [90], Spain	2017	N.R	N.R	The use of textured breast implants probably decreases the risk of capsular contracture
	Calobrace et al. [77], USA	2018	Siltex textured silicone implant (Mentor) Siltex smooth silicone implant (Mentor) Textured Saline prosthesis (Biocell, style 168) Sientra HSC+	N.R	Smooth implants presented a higher rate of capsular contracture, especially when placed above muscle
	Calobrace et al. [11], USA	2018	Sientra HSC+	Sub-muscular Sub-glandular	Texture implants and sub-muscular placement can significantly reduce the incidence of capsular contracture
BIA-ALCL	Cifuentes et al. [90], Spain	2017	N.R	N.R	Textured breast implants might be associated with an increased risk of anaplastic large cell lymphoma
	Keith et al. [91], USA	2017	Polyurethane implant	Sub-glandular	More cases have been reported with textured versus smooth implants

Table 1 continued

Outcome	Author	Year	Implants used	Placement	Main results
Review	Clemens et al. [92], USA	2017	N.R	N.R	There are no known pure smooth implant cases; furthermore, BIA-ALCL has been reported in association with all major forms of implant texturing techniques from current implant manufacturers
	Calobrace et al. [77], USA	2018	Siltex textured silicone implant (Mentor) Siltex smooth silicone implant (Mentor) Textured Saline prosthesis Allergan (Biocell, style 168) Sientra HSC +	N.R	Very rare incidence of BIA-ALCL correlates with smooth implants
Other complication with prosthesis Review	Hall-Findlay et al. [78], Canada	2011	CML Microcell textured highly cohesive implants (CUI) CMH Microcell textured highly cohesive implants (CUI) Biocell textured surface silicone gel implants (Allergan 115,120) Smooth-walled responsive gel implants (Allergan 15, 20) Smooth-walled silicone gel cohesive I implants (Mentor)	Sub-glandular Sub-muscular	Double capsules and late seromas were not seen in smooth saline or smooth silicone gel breast implants but only in aggressively textured implants. The phenomenon of late seromas and double capsules has only been seen by the author in the Biocell textured surface implants—both the round and shaped implants and in all three (sub-glandular, sub-fascial, and sub-pectoral) pocket locations
	Park et al. [75], Korea	2013	Allergan textured implant (Style 110, 115,120, 153, 410) Allergan smooth saline implant Mentor textured implant Polytech textured implant Unknown origin textured implant	N.R	In 82% late seroma was found in patients with Biocell textured implants, suggesting that late seroma formation is strongly associated with the mechanical features of certain breast implants
	O'Shaughnessy [76], USA	2015	N.R	N.R	Long-term outcome studies show higher propensity of visible rippling and wrinkling with textured devices Double capsule formation has been seen most commonly around textured devices
	Calobrace et al. [77], USA	2018	Siltex textured silicone implant (Mentor) Siltex smooth silicone implant (Mentor) Textured Saline prosthesis (Biocell, style 168) Sientra HSC+	N.R	Smooth prostheses present a greater mobility and often drift to the sides Wrinkling, late seromas, and double capsules have been seen in varying degrees based on texture types
Histological features of capsules	May Jr. et al. [30], USA	1994	N.R	N.R	The capsular collagen typing and fibroblast-populated collagen lattice studies demonstrated no difference between smooth and textured capsules
	Wyatt et al. [93], USA	1998	N.R	N.R	Synovial-like metaplasia, villous hyperplasia and foreign material were more often observed in the textured group. Differences in the density of collagenous capsules were not significant, and collagen fibers oriented parallel to the implant surface were more often observed in the smooth group after 5 years

Table 1 continued

Outcome	Author	Year	Implants used	Placement	Main results
	Minami et al. [31], Brazil	2006	N.R	N.R	The greater incidence of capsular contracture in smooth implants was correlated with the progressive increase in total capsule thickness, due to a higher concentration of collagenous fibers, when compared with textured implants
	Fischer et al. [32], USA	2015	Polytxt, Polytech Polysmoooth, Polytech	N.R	Fibrotic capsules were significantly thicker in the textured implant group with respect to the smooth implant group Capsule thickness decreased significantly Over the study period in both smooth and textured implant groups
	Atlan et al. [94], France	2018	Allergan Smooth Allergan Biocell Motiva SilkSurface Motiva VelvetSurface Polytech MESMOsensitive Mentor Siltex Allergan Microcell Sientra True Texture Eurosilicone Cristalline Nagor Nagotex Polytech Polytxt Polytech Microthane	N.R	With increasing surface texture complexity, there was increased capsule disorganization, tissue ingrowth and tissue adherence
Patient satisfaction: Aesthetic results	Tarpila et al. [37], Sweden	1997	Textured Saline prosthesis (Biocell, style 168) Smooth Saline prosthesis (McGhan)	Sub-glandular	The patients' views on the results did not differ between textured and smooth prostheses
	Fagrell et al. [19], Sweden	2001	Fine textured saline implant (Siltex, style 2800) Smooth saline implant (Mentor style 1800)	Sub-glandular	The majority of the patients preferred the smooth implants
	Handel et al. [1], USA	2006	N.R	N.R	Smooth implants received higher satisfaction scores than textured and polyurethane foam-covered devices

N.R not reported

Discussion

In November 2018, Biocell breast implants, made by industry giant Allergan, were at the center of the biggest controversy in plastic surgery. Consequently, they have come under great scrutiny among a growing number of plastic surgeons who are documenting a high incidence of health problems.

On December 18, 2018, GMED made the informed decision not to renew the CE mark for Allergan's textured mammary implants. Hence, the French Competent Authority, ANSM, requested Allergan to remove all of their Biocell and Microcell textured breast implants from the market [33]. Allergan's smooth implants are their only breast implants which remain CE marked and available throughout Europe. This decision has reopened the debate on whether smooth or textured implants are superior, based on their reported complication rates.

The main objective of this study was to review the capsular contracture rates with smooth and textured mammary implants. Capsule formation is a normal tissue

Table 2 Patient demographic data

Hospital	Center 1	Center 2
No. of patients	66	80
Mean patient age at breast augmentation (range, years)	40.1 y (22–67)	36.8 y (18–64)
Total no. of breasts operated	132	122
Smoking		
Yes	25 (38%)	27 (34%)
No	41 (62%)	53 (66%)
Drugs		
Yes	23 (35%)	37 (46%)
No	43 (65%)	43 (54%)
Purpose of implantation (n)		
Reconstructive	0	20 (25%)
Aesthetic	66	60 (75%)
Intraoperative information		
Side of implant		
Right	0	23 (29%)
Left	0	18 (22%)
Bilateral	66	39 (49%)
Mean implant volume (range, cc)	316.4 cc (180–460)	232.3 cc (150–360)
Postoperative information		
Complications		
Hematoma	4	1
Seroma (within 12 months)	0	2
Implant infection	0	1
Implant rupture	0	1
Implant dislocation	2	3
Wrinkling	0	1
BIA-ALCL	0	0
Late seroma (after 12 months)	0	0
Capsular contracture (grades III–IV)	3 (2.3%)	3 (2.4%)
Length to follow-up (range, months)	18.1 months (13–26)	19.8 months (12–32)

response but can become problematic when the capsule contracts around the implant, making the breast hard and deformed [34]. It is believed that collagen fiber alignment plays a key role in the development of capsular contracture and that disruption of such fiber alignment may lead to a reductions in the incidence and severity of capsular contracture [35]. The surface texture of the breast implant can impact capsule formation, specifically the organization of the capsule's collagen fibers and adherence of the tissue to the device [36-38]. A smooth silicone implant leads to the formation of a non-adherent, dense capsule with highly aligned and organized collagen fibers [39, 40]. Deeper and more complex textures promote increased tissue ingrowth [31, 39]. As a result, the force required to break the interface between the capsule and implant is greater than with smoother surface textures, which may reduce the risk of device rotation [41, 42]. Greater tissue ingrowth has also been correlated with reduced synovial-like metaplasia in human breast capsules due to the reduction in movement between the implant and surrounding stroma [43].

Histological differences in the capsules around the different implant surfaces (smooth and textured) were identified. However, Vieira et al. concluded that the results of numerous experimental approaches have shown variations in capsule thickness with different intensities of fibrosis and inflammation in peri-prosthetic tissue of both textured and smooth silicone implants [44].

Contradictory experimental findings may, in part, be due to characteristics of implant manufacturer, consistency of the silicone gel and/or the shape of the implants themselves [44].

There are a variety of factors which have been identified as responsible for the formation of capsular contraction such as, but not limited to, intra-capsular silicone bleeding, bacterial biofilm on the smooth implant [45], peri-areolar, trans-glandular surgical approach [46], sub-glandular

implant placement, the use of sterilizable prosthetic sizers and a "superficial" surgical conduct.

Although the advantages of using textured mammary implants when using the sub-glandular location are clear, the debate remains open as to whether smooth or textured implants are superior when placed in the sub-muscular position.

It is a widely held belief that the incidence of capsular contracture following augmentation mammoplasty is reduced when the implants are placed sub-muscularly [18, 47-54]. It remains unknown if texturing plays a role in reducing capsular contracture when implants are placed in this plane since the incidence tends to be significantly lower in the sub-muscular position. In cases where the sub-muscular position is used, the choice of implant is left to the surgeon to decide based on his or her preference.

Different theories have been formulated in an attempt to explain the pathogenesis of capsular contraction. Previous clinical and preclinical studies have suggested the development of capsular contracture is caused by subclinical infections. This theory is largely accepted with bacterial biofilm on the surface of the implant being the main contributor to capsule formation. Reiger et al. [55] confirmed the direct proportion between the degree of capsular contracture and the density of bacteria found via sonification and culture.

They found that the rate of capsular contracture (Baker grades III and IV) was 84% with smooth implants and 83% with textured, therefore concluding that there is no significant difference in capsular contracture formation observed between the two implant surface types [56]. Ninety percent of the prostheses with biofilm formation were identified, and it was found that an equal amount of bacteria was present on the capsules of both smooth and textured prostheses. It is interesting to note that 20 times more bacteria was identified on the surface of the textured implants in comparison with that found on the surface of smooth implants.

In vitro studies have demonstrated the influence of the topography of textured implants in the development and maintenance of a greater bacterial concentration in the peri-prosthetic biofilm when compared with the smooth topography [57, 58]. In vivo studies have shown that once the bacterial biofilm has formed on the implant surface, smooth and textured implants are both equally predisposed to capsular formation [57, 58].

The evaluation of capsular contracture has important implications for industry and research. In an attempt to prevent the development of capsular contracture and to discover more advanced materials in the design of breast implants, ensuring they have a better resistance to bacterial colonization, there has been research conducted on the interaction of the implant with microorganisms and on the interaction between the prosthetic surface and the human body, especially between myofibroblasts and the surface of the prosthesis.

To date, the production of a material that interferes with the formation of capsular contracture is an unsolved challenge due to the need of specific physical characteristics of the biomaterial and the continuous variations in the resistance profile of the microbial populations.

As well as studying new materials with these innovative characteristics, various trials have been initiated to "treat" the surface of the implants already in use in order to limit bacterial adhesion and the formation of a biofilm, including the use of anti-adhesive substances, antibiotics and antiseptics. The motive behind the use of this technique is to alter some characteristics of the implant's surface, such as its topography, its electrical charges and its hydrophobicity.

As a result, we observe the biological advantage of textured implants with better tissue adherence and a potentially lower tendency of capsular contracture development when the implant is placed in the sub-glandular position with the opposing disadvantage of acknowledging that textured implants are by their nature, predisposed to a higher colonization of bacteria.

Upon review of various studies in the literature, a comparable rate of capsular contracture with the use of smooth and textured implants placed under the pectoralis major muscle was observed (see Table 1) [17, 23, 28, 29, 59-63].

In addition, the analysis of articles concerning BIA-ALCL, wrinkling, double capsules, late seroma and patient satisfaction rates enabled us to identify and define the advantages and disadvantages of using both smooth and textured mammary implants.

Breast implant-associated ALCL (BIA-ALCL) is a rare form of lymphoma found in women with breast implants with no significant difference in its onset between patients with saline or silicone implants. Differences in the onset emerged with a small but increased risk in women developing BIA-ALCL with the use of textured implants.

Countries that have provided statistics on confirmed BIA-ALCL cases, such as the USA, France and Australia, have reported that macro-textured implants are featured in the majority of reported cases [10, 64-67].

The current lifetime risk of BIA-ALCL is estimated to be 1:3817–1:30,000 in women with textured implants based upon the current confirmed cases and textured implant sales data over the past two decades. Since the initial case report in 1996, ASPS now recognizes approximately 257 cases in the USA and a total of 656 worldwide [68-71]. Although it is a rare disease, there is a heightened awareness and concern regarding the correlation of

textured implants with the increased risk of developing BIA-ALCL.

Theories regarding the pathogenesis of BIA-ALCL hypothesize that implants with a greater surface area allow a greater bacterial load, thus a greater risk of stimulation and/ or transformation of lymphocytes [10, 72-74].

Other authors have theorized that the immune system might respond to a component of textured surfaces and that a rough surface could be irritating or abrasive, therefore increasing the risk of an inflammatory response [74].

An interesting review of multi-center, retrospective studies confirms that late seroma (occurring 12+ months after implantation) is a rare occurrence ($\leq 1\%$). The majority of cases of late seroma reported in the literature used Biocell textured prostheses (Allergan, Irvine, Calif.). Implant placement and implant fill were not found to affect the incidence of late seroma [75-78]. This suggests that late seroma formation is strongly associated with the mechanical features of certain breast implants.

Long-term outcome studies show a higher propensity of visible rippling, wrinkling and deformity with textured devices, especially when placed in the sub-glandular position [76-78]. Furthermore, double capsule formation has been seen most commonly around textured devices [76-78]. As a result, the corresponding patient satisfaction is more favorable with smooth implants in all of the three reviews considered [1, 19, 37].

Our Experience and Rationale in the Use of Smooth Surface Implants

In our experience, the follow-up interval is not long enough to draw significant conclusions due to the relatively recent entry of these implants in Italy (September 2015) [79]; however, our results concerning capsular contracture and other local complications are very promising.

The most frequent complication identified was implant misplacement. This occurred once laterally and four times inferiorly. This complication was more common with smooth implants when using the dual-plane technique [80].

The second site had an increased incidence of complications due to having a greater number of reconstructive patients (25%).

Two cases of seroma were identified in patients who were smokers. Despite the literature suggesting there is an increased risk of experiencing complications in smokers [81], our population of patients showed only a significant difference in the complication rates between smokers and non-smokers in the incidence rate of postoperative seroma.

The average follow-up period was 18 months for the first center and 19.8 months for the second center. Two patients presented with capsular contracture Baker grade III and one with Baker grade II; these patients also presented with postsurgery bleeding with hematoma and ecchymosis of the lower mammary quadrants.

Our experience allows us to appreciate both the advantages and limitations of using smooth implants compared to textured ones, when placed under the pectoralis major muscle.

Smooth implants can be easily inserted through smaller incisions and are often more forgiving than their textured counterparts. They settle over time and show a greater softness to touch and a reduced frequency of rippling. Furthermore, the newer generation of cohesive smooth round implants is attributed to a lower incidence of wrinkling due to optimal fill. Finally, the cost of smooth implants is typically 30% less than textured implants.

As presented by Hidalgo et al. [82], there seems to be no substantial difference between round and anatomical implants when implanted under the pectoralis major muscle for cosmetic purposes.

In reconstructive patients, round smooth implants may be used in bilateral mastectomy and implant-based reconstruction, reducing the risks associated with the procedure. The aesthetic result, though, is not always adequate in unilateral reconstruction. When performing a unilateral reconstruction with no contralateral symmetrization, anatomical textured implants seem to have better results and appear to be the preferred choice in order to obtain a more natural shape of the breast. This is particularly true when reconstructing large breasts (> 250 cc) and breasts positioned wide and low. However, the authors believe that when patients require smaller implants (< 250 cc) and have their prostheses positioned under the pectoralis major muscle, there is no noticeable difference in the upper pole, from both frontal and lateral views using the two different kinds of implants.

The limitations of smooth silicone implants include, but are not limited to, higher rates of capsular contracture when placed above the muscle and a greater mobility leading to an increased risk of implant misplacement. The implant may move to the side of the breast pocket ("lateral slip") and settle to the bottom of the pocket which can stretch the lower pole over time.

Smooth Prosthesis: Current Perspective and Future Challenges

This clinical review analyzes the complication rates associated with smooth and textured mammary implants reported in the scientific literature. It is highlighted that there are many limitations associated with macro-textured and micro-textured mammary implants, such as the development of BIA-ALCL—a serious complication associated with aggressively textured implants. Since no cases have been linked directly with smooth implants, only

it has ultimately led to a resurgence in the use of smooth breast prostheses.

Therefore, the question we ask due to this increase in the use of smooth prostheses is: "Is the future a return to the past?".

Given our experience and the up-to-date clinical evidence, the use of textured implants placed under the pectoralis major muscle does not show advantages when compared to smooth implants with the same placement. However, a central role in determining the tolerance to the implant and therefore the absence of complications is given to the interface between the surface of the implant and the receiver's tissue.

We therefore hope that further research will confirm the superior breast implant surface. This will ultimately increase the quality of all aesthetic outcomes and increase the safety and performance of these devices by reducing the risk of complications in both the short and long terms.

Compliance with Ethical Standards

Conflict of interest All authors certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationship, allilations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript. The authors declare that they have no conflicts of interest to disclose.

Ethical Approval Our institutional ethics committee approved the study design.

Informed Consent Written informed consent was obtained from each patient prior to the study.

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