

Surgical Treatment of Capsular Contracture (CC): Literature Review and Outcomes Utilizing Implants in Revisionary Surgery

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Abstract

Background The objective of this clinical review is to provide an overview of the use of breast implants after capsular contracture (CC) surgical treatment, with a focus on type of implants used. 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 literature related to surgical treatment of capsular contracture and implant replacement. Each article was reviewed by two independent reviewers to ensure all relevant publications were identified. The literature search identified 54 applicable articles. Of these, 26 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.

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Results Only four articles report the replacement of implants after surgical treatment of capsular contracture. Six articles reported an implant exchange with only smooth silicone gel filled implants. Two reviews advice to use smooth implants in implant replacement.

Conclusion With our expertise in the field and the results of this up-to-date literature review, it can be concluded that implant exchange is recommended in case of breast revision for capsular contracture, and the use of subpectoral smooth silicone gel breast implants is a good option after surgical treatment in patients with primary or recurrence Baker III–IV.

Level of Evidence III 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 Revisionary surgery · Capsular contracture · Breast augmentation · Prosthetic breast reconstruction · Smooth silicone gel breast implants

Background

Capsular contracture is almost ubiquitously cited as the most common reason for reoperation after breast augmentation [1]. Periprosthetic capsular formation remains a highly unpredictable and unpreventable event despite the continuous evolution of prosthetic materials and surgical techniques [2]. Although its precise cause is unknown, infection, haematoma, radiation therapy, gel bleed, and foreign body reaction at the host implant site have been implicated, further suggesting that the cause is likely multifactorial [3]. Only capsular contractures rated grades 3 and 4 on the Baker classification scale require surgical treatment. Various surgical therapeutic options are offered and debated, including capsulotomy, capsulectomy, change of plane, the use of acellular dermal matrices (ADMs) and replacement with tissue flaps [1, 3, 4].

Recent trends show "capsulectomy, site change, and implant exchange" to be the gold standard treatment of clinically significant contractures [1, 4]. Although reoperation with implant exchange has a success rate of 79% and is the most definitive method for capsular contracture in non-irradiated breast reconstructions, there is still a recurrence rate of 54% [5].

When treating capsular contracture, it is essential to replace the implant in the affected breast with a new implant. This is mostly due to suspected issues with biofilms, which are extremely hard to eradicate from the silicone elastomer of the implant [5]. Although there are many theories as to the cause of capsular contracture, no study has taken into consideration the impact of the external surface of the prosthesis on recurrence rates of capsular contracture after prosthetic revision.

The purpose of this study was to perform a systematic review of the current literature to analyse the surgical treatment of capsular contracture in breast reconstruction, focusing particularly on type of implant re-implanted after the procedure. Moreover, we report our own experience to validate that reported in the literature.

Materials and Methods

A search was conducted of literature published between January 1, 1988 and September 20, 2020 using 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 keywords: "capsular contracture", "surgical treatment of capsular contracture", "recurrent capsular contracture", "revision breast surgery", "implants in revision breast surgery". Terms were expanded to include the corresponding MeSH terms, and a separate literature search was performed for each of the procedures found. A manual search of study references was also performed. There were no limitations on study design, and references were checked for duplicity and deleted accordingly.

Data Extraction and Endpoint

The study endpoint was the type of implant that was used during revision surgery and the recurrence rate of capsular contracture after revision surgery.

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 [6]. Each study was appraised by at least two reviewers (NZ and JCV), 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 (VS), and the level of evidence was later determined by consensus.

We applied the ASPS guidelines by which 8 objective questions were used to evaluate selection bias, intervention bias, and measurement bias. The maximum score that could be achieved per study was 8. To assess if confounders were adequately addressed in each paper, we also evaluated the inclusion/exclusion criteria, methods, discussion of limitations, and appropriateness of study conclusions based on the study results.

Results

The literature search yielded 1527 unique publications. After applying the selection criteria, 54 publications were reviewed, and 26 were included in this review (Table 1).

The initial consensus between the reviewers after screening the title and abstract was 98.9%. Screening of the reference lists of the included papers did not result in the inclusion of additional studies. One study was included only after essential information was acquired through correspondence with the authors [7]. Additional information was also received for two further studies reported in the literature.

A meta-analysis was not executed as the heterogeneous data could not be combined numerically to produce meaningful results; a narrative systemic review was performed instead.

Two studies did not perform implant exchange in their management of capsular contracture but instead replaced the original implants in the same pocket after treatment. They reported a capsular contracture recurrence rates of 0 [8] and 10% [9]. Other two studies replaced the original implant in some, but not all, patients, and reported a capsular contracture recurrence rate of 0 [36] and 23% [37].

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Author	Year	Primary vs recurrent CC	Type of intervention	Implant exchange?	Type of implant	CC Recurrence rate* (FU)
Baran et al. [16], Turkey	2001	N.R	Open capsulotomy, leave the capsule tissue intact and to prepare a new pocket above or beneath the muscle	Yes	Textured silicone gel-filled implants	12 % (average, 1 year)
Caffee [15], USA	2002	Recurrent CC	Capsulectomy (partial/total) with implants placed in subpectoral plane and steroid infiltration	Yes	Textured saline implants	9% (range, 8 months -10 years)
Castello et al. [22], Italy	2011	Primary and recurrent CCs	Open capsulotomy and creation of a neoprecapsular- subpectoral pocket	Yes	Textured gel and polyurethane anatomical or round	0 % (average, 24.1 months)
Cheng et al. [3], USA	2013	Primary and recurrent CCs	Total capsulectomy, implant insertion with complete ADM coverage and fibrin sealant	Yes	Textured saline implants	0 % (average, 9 months)
Collis et al. [17], England	2000	Primary and recurrent CCs	Anterior capsulectomy	Yes	- Textured silicone gel-filled implants	39 % for the textured silicone gel
					- Polyurethane-coated mammary prosthesis	implants
					discussion of the manufacture of the second se	(average, 7 years)
			Total capsulectomy	Yes	- Anatomical textured silicone gel-filled implants	11 % using textured silicone gel 10% using polyurethane-coated
					- Polyurethane-coated	implants
					mammary prosmesis	(average, 2.5 years)
Costagliola et al. [20], France	2013	Primary and recurrent CCs	Capsulectomy (partial/total) with implant replacement and local corticosteroid therapy (catheter left in place)	Yes	Smooth or textured saline; smooth or textured cohesive gel	0% (range: 2-10 years)
Embrey et al. [30],	1999	N.R	Capsulectomy (partial/total)	Yes	N.R	17 %
USA			Open capsulotomy			20 %
Hester et al. [13], USA	2012	Primary and recurrent CC	Anterior capsulectomy and relocating the implant to a partially subpectoral/partially subglandular, or dual-plane, position with ADM	Yes	Smooth silicone gel-filled implants	3.75 % (average, 1.3 years)
Henriksen et al. [43], Denmark	2012	Primary and recurrent CCs	Capsulectomy (partial/total)	Yes	N.R	53% (average, 4 years)
Hoffman [18], USA	1989	Primary and recurrent CCs	Open capsulotomy	Yes	Polyurethane-coated mammary prosthesis	0 % (maximum, 3 years)
Hung [9], Taiwan	2020	Primary CC	Anterior capsulectomy (90%) and total capsulectomy (10%)	No	Round smooth and textured silicone gel-filled implants	10% (average, 11.5 months)
Johnson et al. [7], USA	2018	Recurrent CC	Partial capsulectomy and segmental interpositional graft placement of ADM	Yes	N.R	14.3 % (average, 52.8 months)
Lee et al. [23], South Korea	2011	Primary CC	Open capsulotomy and subpectoral, precapsular implant repositioning technique and oral leukotriene antagonists	Yes	Smooth or textured saline; smooth or textured cohesive gel	4 % (median: 26 months)
Lesavoy et al. [11], USA	2010	Primary and recurrent CCs	Modified capsulectomy (maintenance of the posterior aspect of the capsule and the anterior capsule on the undersurface of the pectoralis major) and site change from subpectoral to new subglandular pocket	Yes	Smooth round silicone gel implants	0 % (average, 20.2 months)

Table 1 Results on the use of breast prostheses after surgical treatment of capsular contracture (III-IV Baker)—literature review

Table 1 continued	q					
Author	Year	Primary vs recurrent CC	Type of intervention	Implant exchange?	Type of implant	CC Recurrence rate* (FU)
Maxwell et al. [21], USA	2009	Primary and recurrent CCs	Anterior capsulectomy or open capsulotomy with creation of a neopectoral pocket and placement of a new implant into developed neopectoral pocket.	Yes	36% silicone gel-filled implants (smooth and textured)	0% (average, 26.2 months)
			In some patients had concurrent placement of ADM		64% form stable, highly cohesive silicone gel-filled implants	
Melmed [19], USA	1990	N.R	Open capsulotomy	Yes	Polyurethane-coated mammary prosthesis	13 % (minimum, 14 months)
Pozner et al. [56], USA	2013	N.R	Open capsulectomy (partial/ssstotal) and relocating the implant to a partially subpectoral/partially subglandular, or dual- plane, position with ADM	N.R	N.R	2.8 % (average, 17 months)
Sigalove et al. [10], USA	2019	Primary and recurrent CCs	Open capsulotomy, site change from subpectoral (dual plane) to prepectoral, and implant replacement	Yes	Smooth round silicone implants	0 % (average, 18.9 months)
Spear et al. [57], USA	2003	Primary and recurrent CC	Total capsulectomy and relocating the implant to a partially subpectoral/partially subglandular, or dual-plane, position	Yes	60% saline implants (smooth and textured)	0 % (average, 11.5 months)
					40% silicone gel implants (smooth and textured)	
Spear et al. [36],	2013	Primary and recurrent CC	Total capsulectomy (37 %).	87% Yes	Silicone and saline smooth	0 % (average, 1.5 years)
P C D			Anterior capsulectomy (19 %) and relocating the implant to a partially subpectoral/partially subglandular position with ADM.		round implants	
			Dual-plane conversion (5%)			
Swanson [37], USA	2016	Primary and recurrent CCs	Open capsulotomy and relocating the implant into the pocket.	Yes (36%)	Smooth or textured saline; Smooth or textured cohesive gel	22.7 % (average, 4 years)
Wagner et al. [12], USA	2019	Primary and recurrent CCs	Implant exchange, capsulectomy, and possible exchange of site (ICES)	Yes	Smooth round gel-filled implants	15.8 % (average, 56 months)
			ADM placement in the reconstructive position, implant exchange, capsulectomy, and possible exchange of site (SPICES)			2.7 % (average, 56 months)
Xue et al. [8], China	2011	Primary CC	Open capsulotomy, insertion of a prosthesis anterior to the original capsule (deep to the pectoralis muscle without its removal from the cavity) and preservation of the contracted capsule	No	Smooth round silicone implants 0% (average, 29 months)	0% (average, 29 months)
Zingaretti et al. [14], Italy	2016	Primary and recurrent CCs	Open capsulotomy and creation of a neoprecapsular- subpectoral pocket	Yes	Anatomic textured silicone implants	9% (average, 29.3 months)

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Author	Year	Year Primary vs recurrent CC	Type of intervention	Implant exchange?	Type of implant	CC Recurrence rate* (FU)
Review Florin et al. [24], USA Wan et al. [1], USA	2018 2016	There were no obvious trends recurrence rates of capsular	in recurrence rate of contracture with textured, saline, or silicone replacement implants. However, smooth implants were associated with overall contracture	replacement impl	ants. However, smooth implants v	vere associated with overall I
CC: capsular contracture N.R: not reported FU: follow-up ADM: acellular dermal matrix *Capsular contracture recurren	acture rmal m ure recu	CC: capsular contracture N.R: not reported FU: follow-up ADM: acellular dermal matrix *Capsular contracture recurrence rate (Baker grade III or IV)				

Twelve studies described implant exchange after revision surgery for managing capsular contracture. Variable capsular contracture recurrence rates were observed when implant exchange was performed with different types of implant. For example, 5 studies performed an implant replacement with only smooth silicone prosthesis and reported widely variable capsular contracture recurrence rates of 0 to 15.8% [8, 10–13], while 3 studies, which used only textured silicone prosthesis, reported a capsular contracture of 9 to 50% [14–17].

One study performed an implant replacement with only textured saline prosthesis and reported a capsular contracture rate of 0% [3]. Two studies performed an implant replacement with only Polyurethane-coated mammary prosthesis and reported a capsular contracture rate of 0 [18] and 13% [19].

Of the studies that performed implant exchange, capsular contracture recurrence rates were reported to be 0 [20], 13 [19], and 26% [17].

Studies that also performed site change with implant exchange reported somewhat lower capsular contracture recurrence rates of 0 [11, 21, 22], 4 [23], and 12% [16].

Two reviews reported that smooth implants were associated with overall lower recurrence rates (0%) of capsular contracture [1, 24].

Our Experience

In the current retrospective study, a total of 37 patients underwent an operative revision surgery in two centres due to capsular contracture Baker grade \geq III between January 2017 and August 2019. Patients who were surgically treated for implant rupture, infection, or displacement were not included in the present study.

Eighty-six percent of the patients at the first site (n = 19) and 27% of patients (n = 4) at the second site underwent breast revision for capsular contracture (Baker type III–IV) after aesthetic indications (Fig. 1a–d). A total of 14 patients who underwent reconstructive surgery (nipple sparing mastectomy) were resubmitted to revision surgery after capsular contracture (Fig. 2a–d). One patient included in the study had previously undergone radiotherapy; 7 patients underwent chemotherapy (Table 2).

The average elapsed time from the first breast implantation surgery to breast prosthesis revision was 46 months for Centre 1 and 34 months for Centre 2. Eighty-seven percent of the patients at the first site and 67 % of the patients at the second site underwent prosthetic revision surgery for a primary capsular contracture. Furthermore, a total of eight patients (22%) underwent breast revision for a recurrent capsular contracture (Table 3). Of the patients' who underwent operative revision surgery due to capsular

lower

Fig. 1 Preoperative view **a**, **c** and 30 months after the secondary breast reconstruction **b**, **d** with the use of a new subpectoral smooth implant after total capsulectomy in a 38-year-old woman with significant bilateral capsular contracture after bilateral breast augmentation



contracture, 87% had previously had a textured silicone gel breast implant. (Table 4). Furthermore, 54% of the implants were initially placed in the submuscular position (Table 4).

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 centres for all patients. All patients received perioperative antibiotic prophylaxis (cephazolin 2 g, intravenous injection, 30 min before the beginning of surgery).

The skin incision was performed on the scar of previous incision in all patients: the inframammary incision was utilized for all patients who underwent revision surgery after cosmetic indications whereas a lateral incision was used for those patients who underwent surgery after reconstructive purposes.

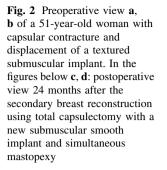
Surgeons preferred to remove the implant and capsule together, without opening the capsule.

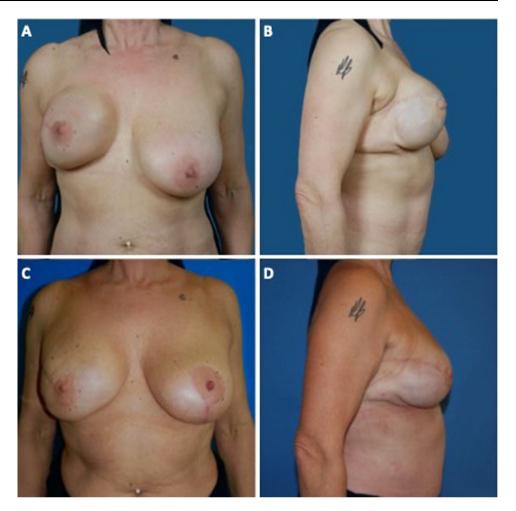
After the total capsulectomy, the implant was placed in the submuscular plane in all patients, therefore the new implant was located in a different plane in respect to the preceding implant site in those who previously had the implant in the subglandular plane. All patients received Nagor Impleo breast implants (Soft Cohesive Gel-Filled Smooth, Moderate/High Range Implants—Dublin, Ireland).

Overall, the postoperative complications experienced across both centres included 3 hematomas, 2 post-operative seromas (occurred just weeks post-surgery), 1 wound dehiscence, and 3 implant displacements (Table 5). The average follow-up period was 29.4 months (Centre 1) and 26.3 months (Centre 2), with a follow-up range of 12–44 months.

Discussion

It is difficult to determine a single cause of capsular contracture as it is likely due to a multifactorial process involving chronic inflammation within the periprosthetic





pocket and near the developing capsule. Adams described capsule contracture formation as a balance between potentiates of inflammation (bacteria, tissue trauma, blood) and suppressors of inflammation (antibiotic irrigations, sound surgical technique, implant type, massage, vitamins), and proposed that the net sum of these factors ultimately result in the pathologic state of capsular contracture [25].

The characteristics of the implant is thought to influence the development of capsular contracture, however, studies to determine whether certain implant surface texture reduces the risk of capsular contracture in breast augmentation have yielded mixed results. Indeed, as seen in this study, the incidence of capsular contracture recurrence in current literature varies significantly. To date, the choice of surface type relies mainly on the personal preference of the surgeon rather than on the incidence of capsular contracture recurrence rate.

No obvious trends in recurrence rate of contracture have been shown with textured, saline, or silicone replacement implants, yet it was noted that smooth implants were associated with an overall lower recurrence rates of capsular contracture [1, 24]. We show here that although recurrent capsular contracture is a predominant complication after breast reconstruction, and indeed is very much discussed in the field, there is little published data on the subject.

Recently, sonication of medical devices has been introduced as a valid tool to detect biofilms on various implant surfaces. Different research groups have cultured the sonication fluid and have identified microorganisms on breast implants, establishing significant correlation to bacterial presence and rate of capsular contracture [27]. The detection and identification of microorganism on breast implants and explanted from breasts with capsular contracture have substantiated the hypothesis of an infectious aetiology of capsular contracture. As reported by Walker et al, more bacteria were detected on pathologic implants than uncomplicated ones, suggesting bacterial abundance impacts the development of complications [28]. The strong link was further supported by Tamboto et al, who has demonstrated a causal link between subclinical infection, biofilm formation, and capsular contracture in a porcine model [29].

Table 2 Demographic data of patients' who underwent an operative revision surgery due to capsular contracture Baker grade \geq III between January 2017 and August 2019

	Centre 1	Centre 2	Total
No. of patients	22	15	37
Mean patient age at breast augmentation (range, years)	46,5 y (27–66)	52,3 y (33–68)	49,4
Purpose of implantation			
Reconstructive	3 (14 %)	11 (73 %)	14 (38%)
Aesthetic	19 (86 %)	4 (27 %)	23 (62%)
Smoking			
Yes	9 (41 %)	4 (27 %)	13 (35%)
No	13 (59 %)	11 (73 %)	24 (65%)
Drugs			
Yes	9 (41 %)	10 (67 %)	19 (51%)
No	13 (59 %)	5 (33 %)	18 (49%)
Previous history of adjuvant therapy			
Chemotherapy	2 (9%)	5 (33 %)	7 (19%)
Radiotherapy	1 (4 %)	0	1 (2.7%)

Table 3 Preoperative information of patients from both centres

	Centre 1 $(n = 22)$	Centre 2 ($n = 15$)	Total $(n = 37)$
Time elapsed from implant placement to revision surgery (range, months)	46,3 (6–183)	34,4 (11–108)	40,4
Previous history of CC			
Primary CC	19 (87 %)	10 (67 %)	29 (78%)
Recurrent CC	3 (13 %)	5 (33 %)	8 (22%)
Side of contracture			
Right	2 (9 %)	5 (33 %)	7 (19%)
Left	2 (9 %)	4 (27 %)	6 (16%)
Bilateral	18 (82 %)	6 (40 %)	24 (65%)

 Table 4
 Intraoperative data analysis of the 61 breasts operated on in both centres

Total No. of breasts operated	61
Initial implant position	
Submuscular	33 (54%)
Subglandular	28 (46%)
Initial implant types	
Textured silicone gel breast implants	53 (87%)
Smooth silicone gel breast implants	8 (13%)
Mean implant volume (range, cc)	
Center 1	285,1 cc (175-505)
Center 2	267,2 cc (150-550)

The interface between the device implant surface texture and the body tissue has a dramatic influence on outcome [30]. It has been shown in a porcine model that there are 20-fold more bacteria and more growth of biofilm attached

 Table 5 Postoperative complications noted amongst patients across both centres

	<i>n</i> = 37	%
Complications		
Hematoma	3	8.2%
Implant disclocation	3	8.2%
Seroma (within 12 months)	2	5.4%
Wound dehiscence	1	2.7%
Implant infection	0	0%
Implant Rupture	0	0%
Wrinkling	0	0%
BIA-ALCL	0	0%
Late Seroma (after 12 months)	0	0%
Recurrent Contracture (grade III-IV)	0	0%
All Complications	9	24%
Follow-up period		
Center 1	29,4 months (12-44)	
Center 2	26,3 months	s (12–36)

to textured implants than smooth implants, despite similar capsular contracture rates [31]. Implants with textured surfaces harbour greater biofilm loads than those with smooth surfaces [32]. Other studies have shown that highly textured implant surfaces induce higher levels of proinflammatory gene expression and cytokine production than smoother surfaces [33, 34], which could lead to increased fibrosis.

It is believed that breast prosthesis contamination primarily occurs through contact with the skin microbiota during placement as coagulase negative Staphylococci, known skin colonizers, have been detected in both pathologic and benign implants. However, even if skin contact can be minimized, breast implants are still susceptible to being contaminated with coagulase negative Staphylococci, among other Gram positive bacteria, that reside in the breast parenchyma [28]. Therefore, a major driving factor for the occurrence of capsular contracture, and even its recurrence, is the presence of bacteria on the implant or inside the implant pocket [20, 35].

In some cases of a capsular contracture, if the former implant is fully intact, it is reinserted after capsulotomy and pocket modification [8, 9, 36, 37]. Yet, our review showed lower capsular contracture recurrence rates in studies that performed implant exchange versus those that did not. This trend was most obvious when implant exchange was performed in the same plane. Placing the same implants in the same pocket is the most ill-advised combination and is associated with the highest capsular contracture recurrence rates. Indeed, implant manufacturers state that implants are for single use only, and this includes implant reuse after capsulectomy or capsulotomy. Therefore, it is advisable to use a new implant in the affected breast when treating the capsular contracture, and surgeons should be aware of these recommendations and be prepared to defend their decision to reuse an implant [24].

Total capsulectomy with removal of the entire affected capsule and implant is the gold standard for surgical treatment of capsular contracture [21, 25]. Many authors have advocated the use of capsulectomy on the basis of the fact that this technique prevents calcium deposition. Indeed, Hardt et al. [38] reported that retained implant capsules may result in a speculated mass suspicious for carcinoma, dense calcifications that obscure neighbouring breast tissue on imaging, or a cystic mass due to persistent serous effusion, hematoma, or encapsulated silicone-filled cysts. Additionally, Copeland et al reported that capsules that formed around textured implants typically had silicone fragments, findings which were not present in capsules associated with smooth implants [39].

Another reason why total capsulectomy is the gold standard is because recurrence rates following total capsulectomy is lower than that following partial capsulectomy. However, as recurrence is still present after capsulectomy, it is important to investigate how to further decrease this incidence rate. As capsulotomy and partial capsulectomy do not change the state of the tissues surrounding the implant, the remaining capsule can act as an instigator for the development of another capsular contracture. Indeed, the persistence of capsules has the ability to produce contractures long after silicone implants have been removed [40]. Even if the anterior capsule is excised and the posterior surface of the capsule remains, the newly inserted implant will be in direct contact with the posterior wall of the capsule which is problematic tissue thereby enabling capsular contracture to occur.

In addition to replacing the implant, the site of implantation should also be considered. For example, if the implant was originally in the subglandular position, the subpectoral or dual-plane position should be considered during re-implantation. There is general agreement that the incidence of severe capsular contracture is reduced when either smooth or textured prostheses are placed subpectorally [1, 14, 41, 42].

There are probably a number of explanations for the reduced occurrence of capsular contractures following submuscular placement compared with the subglandular position. Generally speaking, the risk of capsular contracture decreases when there is more tissue that covers the implants and minimizes the implants contact with glandular tissues. The pectoralis major, external oblique, rectus sheath, and serratus anterior muscle fascia help separate the implant from the breast tissue which may delay the clinical detection of contractures. It is also believed that capsules under the muscles receive a spontaneous and continuous "massaging" effect, consequently favouring an anatomical and physiologic organization of the collagen fibres within the capsule [41].

It is important to note that the human breast is not a sterile anatomical structure. The endogenous flora derived from the nipple ducts are the same as those found in the normal skin. Indeed, bacteria common on the skin, such as coagulase-negative staphylococci, diphtheroids, lactobacilli, *Bacillus* species, β -hemolytic streptococci, anaerobic microorganisms, and *Propionibacterium acnes* have also been isolated from within these ducts. Since the multiple ducts of the nipple form passages from the skin surface to the deeper tissues of the breast, implants placed on top of the muscle are in direct contact with breast ducts,

yet implants placed below the muscle are more protected from contamination.

Our Experience and Rationale in the Use of Smooth Surface Implants for CC Treatment

The reporting of our experience has the limitation that the follow-up interval was not long enough to draw significant conclusions as these implants have only recently arrived to Italy (September 2015). However, although the follow-up period was short, our observations concerning recurring capsular contracture rate and other local complications are promising.

We noted that the most common complication identified was implant misplacement; this occurred once laterally and two times inferiorly. Additionally, implant misplacement was more common when using the dual-plane technique and with smooth implants after breast reconstruction. Patients at the first site had an increased incidence of hematoma due to having a greater number of submuscular initial implant position (50%).

Two cases of seroma (one in both centres) were identified in patients who were smokers. Despite the literature suggesting that there is an increased risk of experiencing complications in smokers [43], 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. There was no incidence of animation deformity or pain in our patients.

The average follow-up period was 29 months for the first centre and 26 months for the second centre. During that time no patients presented recurrent capsular contracture (Baker grade III and IV).

Textured implants were designed to minimize the rate of capsular contracture, but there may not be an advantage over smooth implants when the implant is placed submuscularly [2, 44–46]. Textured implants are at greater risk for rippling and deflation than smooth implants [1, 47], they have been implicated in late seromas, double capsules [48–50], and anaplastic large-cell lymphoma [51, 52]. In fact, the only known risk factor for BIA-ALCL is the presence or history of textured implants, and this problem was unknown before textured implants were introduced [52]. In his FDA presentation, Clemens reaffirmed the remarkable fact that there has been no case published of BIA-ALCL occurring in a woman implanted only with smooth implants, whose implant history is fully documented [50]. However, there has been a recent report of a case of BIA-ALCL in a patient with smooth implant and no known history of textured implant [53].

Smooth implants are now favoured by the majority of plastic surgeons in the USA with approximately 87%

preferring smooth and 13% textured [54]. Device preferences differ substantially in Europe and Australia, with 90% of surgeons favouring textured implants [2]. However, use of smooth implants may reduce the recurrence rate of capsular contracture when used as replacement implants [1, 24]. Smooth implants show a greater softness to the touch, and 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.

With our expertise in the field [2] and the results of this up-to-date literature review, it can be concluded that the use of a new subpectoral smooth implant is a good option in the treatment of recurrent CC. When re-implantation with a second implant is considered, it is very important to take into account the recent recommendations to decrease recurrence rate. These recommendations include total capsulectomy, implant placed in the submuscular plane, new implants, bloodless dissection, antibiotic irrigation, glove change, covering the incision site with an adhesive barrier, form-stable implants, a sleeve or funnel, nipple shields, and acellular dermal matrix [25, 45, 55, 56].

Limitations of the Study

This study has three main limitations. The first limitation is the small number of participants. Due to the small sample size, no statistical analysis was performed. The second limitation was the retrospective nature of the study which can introduce data collection bias. Finally, this study is limited by its quantity of long-term follow-up data. Larger series with longer follow-up are needed to validate the use of subpectoral smooth implant in the treatment of recurrent capsular contracture.

Our primary goal for the study was to create a descriptive cohort for baseline statistics but we are currently enrolling more patients who are to be prospectively followed.

Conclusion

When re-implantation is considered in a patient with recurrent CC, it is advisable to use a new implant after total capsulectomy is performed. Although the literature does not provide a univocal indication on the type of prosthesis to be used after a prosthetic revision for CC, the use of smooth implant is indicated when the prosthetic revision technique involves site change with subpectoral placement of prostheses. Long-term follow-up is needed to assess durability of outcomes.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflicts of interest to disclose.

Human and Animal Rights or 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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