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Review Article

A literature review and summary of capsular contracture: An ongoing challenge to breast surgeons and their patients

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ABSTRACT

Capsular contracture is a significant difficulty where implants are used in both breast augmentation and breast reconstruction surgery. This report reviews the published literature focusing on factors and techniques that reduce the incidence of this complication, as well as evaluating the available treatment options for patients who have developed a contracture.

A search of the MEDLINE database for clinical studies involving the understanding, diagnosis and management of capsular contracture was performed, with 106 articles deemed relevant for this review. Our search criteria included observational studies as we wish to discuss and highlight the areas of this condition that have been investigated, and unfortunately there is limited clinical evidence in regard to high quality trials in this field.

Risk factors for capsular contracture are multi-factorial, and all surgeons should aim to minimise these as much as possible both intra- and peri-operatively. However, in high risk patients it is not achievable to completely remove these elements. When capsular contracture does develop, there are currently only a limited number of surgical options including capsulotomy, capsulectomy with or without re-implantation, or reconstruction with autologous tissue. These procedures, as well as the original implant surgery, ought to be discussed with patients on an individual basis, taking into account their personal needs and expectations.

The future of this complication may lie in the development of pharmaceutical interventions, and recent studies have shown promising results. Although this field requires more research, the effectiveness of some new pharmaceutical approaches, to provide alternative non-surgical options for patients with capsular contracture, can only aid both patients and the breast surgeon.

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1. Introduction

Capsular contracture is a complication of breast augmentation which continues to reduce both surgeon and patient satisfaction with the end appearance of the breast. It has been well documented across the literature although still remains an enigma in both its formation as well as in regard to reducing its presentation.

There are numerous available systematic reviews and hundreds of studies on various topics within capsular contracture. Our objective for this paper is to review and present the current understanding of capsular contracture in breast augmentation that is available in the literature. We can find no single paper which summarises its aetiology, initial interventions to reduce its occurrence and later management.

2. Methodology

We reviewed the literature, searching the EMBASE and MEDLINE databases from inception to January 2014 with the following search term used:

capsular[All Fields] AND ("contracture"[MeSH Terms] OR "contracture"[All Fields]) AND ("breast"[MeSH Terms] OR "breast"[All Fields])

This as well as pertinent linked 'related citations' were reviewed.

We decided to include all studies, including observational reports so as to provide an understanding of current methodology and areas of interest in this condition. There is a recent systematic review by Araco et al [1] which showed little high quality studies, and we did not wish to repeat this study.

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Exclusion criteria included those with abstracts not written in English and communication letters.

Using the search terms above, 803 articles were found. These were reviewed in regard to title and abstract using a priori criteria resulting in 150 articles being reviewed in more detail. Of these, 106 were found to be relevant and are referenced below. The following aim to summarise the findings in the papers reviewed.

3. Capsular contracture – A review of the literature

3.1. Introduction

Patients who undergo breast augmentation or reconstruction with implants are largely satisfied with the resulting breast appearance [2,3].

Despite this, it is still the surgeon's duty to accurately council and educate the patient about the potential complications (both those that can occur, and those that are believed by the patient to be possible, from the surgery) [3–23] and how these may lead to an undesirable result. These complications include haematoma, scarring (both hypertrophic and keloid), infection, seroma, necrosis, breast asymmetry and most importantly, the commonest complication seen, capsular contracture [24–28].

Capsular contracture develops due to the fact that the implant is too large to be successfully phagocytised by the body, as would happen with a much smaller imbedded foreign body. Likewise, silicone is too inert to cause a toxic reaction, as it has no active bindings sites [29]. Instead, a fibrous capsule, made of myofibrils and collagen, surrounds the foreign implant. Normally it does not exceed the 1 mm [30] – 1.5 mm [31] thickness. This capsule formation is described as a part of the normal healing process, and some studies suggested it might even help to keep the implant in situ [16,32].

However, when this capsule thickens and the implants dimensions are altered, then the condition is described as capsular contracture.

At best the capsule compromises the aesthetic appearance of the breast; at worst it causes the breast to feel firm, even hard and painful [16,29].

As the capsule contracts around the implant it does so with a centripetal force, changing the natural implant shape to a sphere, a shape which has the smallest surface area to volume ratio [20]. This leads to the appearance of spherical breasts, defining capsular contracture, a finding similar to the unnatural effects of the push-up bra [20]. Likewise, the pressure on the walled-off implant causes it to feel harder to touch then when no capsule is present.

The incidence of capsular contracture is difficult to pinpoint. The use of new techniques has meant that some surgeons achieve consistently low contracture rates [20].

Certain factors such as the indication for surgery will increase one's risk, and the incidence in these patient groups will naturally be higher [27].

Capsular contracture is commonly graded using the Baker Classification [6,33]. This has been revised to take into account those patients who have had prosthetic breast reconstruction, rather than solely patients with firm breasts after augmentation mammaplasty, as the original classification described. Typically patients graded Class III or IV will require intervention.

Although a range from zero to 50% has been noted [34], a more realistic incidence for capsular contracture, would be between 8% and 15% [35].

There is some discrepancy as to agreement over when capsular contracture is likely to develop and present. Some studies have noted its appearance as early as two years after surgery [3], while others have documented development at five years [34]. Studies suggesting presentation within a year support the subclinical infection pathway described below, as well as the relationship to surgical technique, drain placement and other short-term complications [3].

Presentations later than this are possibly caused by a secondary infection from systemic bacteraemia, elastomer degradation or filler bleeds [27], or the chronic effect of the implant on surrounding tissues [3].

4. Capsular contracture: Diagnosis and classification

4.1. Diagnosis

4.1.1. Clinical

Capsular contracture may initially present with mild breast induration. With progressive increase of capsule thickness, the breast becomes firmer. It may progress and eventually shrink the breast in such a way that it totally distorts the breast shape. It may result in a range of symptoms, varying from local tenderness to severe pain [1].

4.1.2. Radiological

Mammography. Mammography is ideal for breast parenchymal evaluation and obvious extracapsular silicone implant rupture. It fails, however, to consistently detect intracapsular implant rupture [36,37].

Mammography can be useful in evaluating the breast with minimal to moderate capsular contracture. With severe capsular contracture, mammography has a very limited use in assessing the breast [38].

Ultrasound scan [39–45]. The diagnostic accuracy of ultrasound in the hands of a skilled radiologist has a very high sensitivity [39–42]. However, due to the steep learning curve, the absence of a panoramic view and the high operator dependence, there is much debate about the usefulness of this investigative tool.

Magnetic Resonance Imaging. Numerous studies have shown that MRI is the most reliable test [37,46–48], and it has been proven to also be the most accurate, as well as being non-operator dependant [49–51].

MRI has therefore been crowned the 'gold standard' [52] for imaging implants. In the USA, the Food and Drug Administration guidelines recommend MRI-implant evaluation at 3 years after breast augmentation and every 2 years thereafter [53].

4.2. Classification of capsular contracture

As above, Bakers classification is commonly used as the standard for commenting on the amount of breast contracture evident. The basis of this classification is around patient perceived firmness or pain in the breast, the clinically palpable implant and the implants visibility. Grade IV is universally deemed an indication for removal of the implant, although earlier classes should be reviewed on a patient by patient basis. The original classification described by Baker in 1978 [33], aimed at the augmented breast, was expanded to include reconstructed breasts in 1995 by Spear, with the division of I into IA and IB [6]. IA still described an augmented or reconstructed breast which appeared absolutely natural, but IB described a palpable implant on examination. These descriptions are summarized in Table 1. Gylbert made further comments on the palpable deformity in 1989 [54], and multiple other descriptions have been attempted over the years [55], although the Baker classification remains to both be popular and the most practical method of assessing breast firmness [6].

Table 1
Baker Classification of breast contracture [6,33].

Baker Class	Breast firmness/pain	Implant	Implant visibility
IA	Soft	Non palpable	Non visible
IB	Soft	Palpable	Non visible
II	Minimal	Palpable	Non visible
III	Moderate	Easily palpable	Distortion visible
IV	Severe	Hard, tender, cold	Distortion may be marked

5. Capsular contracture: Possible aetiological background theories and reducing their impact

The aetiology of capsular contracture is not fully understood, and probably multifactorial.

Many theories have been suggested including that an inflammatory process secondary to a subclinical infection, particularly in the asymptomatic patient, leads to scar formation. Another thought is that it is of an immunological nature [27].

This second theory arose from studies that illustrated elevation of serum fibrosis indices and other humoral factors, which directly correlate to the degree of contracture [10,56].

Other theories that have been suggested and explored include the haematoma formation, foreign body reaction and myofibroblast activation theories [5,44,57].

It has been suggested that implants with a textured surface have been shown to reduce or delay the rates of capsular contracture formation [2,58–63] and shown to be conclusive certainly for subglandular breast augmentation in the meta-analysis by Wong et al [26]. This study however stated that further investigation might be needed to see if this is maintained long-term, and to exclude only a delay in the capsular contracture.

In the early nineties, Hakelius and Ohlsen also confirmed that textured implants reduced the development of capsular contracture [64].

Much more recently, in 2006, Barnsley et al. published a meta-analysis highlighting that textured implants reduced the risk five-fold [63]. However, some papers report no advantage [65,66].

When analysing the relationship between silicone and capsular contracture, several studies have been undertaken, with varying results. One study showed no difference between silicone and saline implants in an experiment involving rabbits models [67], while others have demonstrated a definitive association between silicone and capsule formation when compared [68–70].

In the late 1970s, Cairns and de Villiers [71] identified capsular contracture in 90.7% of the implanted silicone prosthetics in their cohort, after a 4 year period. They described them resulting in a contracture, classed as a Baker grade of III, which is similar to findings since reported by Reiffel et al. [72] and Gylbert et al [73].

Gasperoni et al. [74] found a capsular contracture rate of 3.3% when polyurethane-coated implants were utilized and only a few of the contractures were found to be clinically significant. The theories proposed, regarding why polyurethane-covered implants may prevent or prolong the onset of capsular contracture, include: first, collagen fibrils are arranged randomly into 'sponge' spaces, rather than parallel [60]; and second, punctures to the implant are less likely to result in a rupture, leading to silicone leak from the implant [75].

It has also been suggested that as the polyurethrane degrades through phagocytosis that there is no alignment of scar (capsular) tissue.

Placement of the implant may be either subglandular or submuscular [28]. Literature tends to favour the submuscular and subfascial placement for reducing the incidence of capsular contracture [65]. Hendricks reported no Baker III or IV with submuscular placement [76]. With subfascial placement Ventura and Marcello [77] found only 2% of patients were graded Baker II. Finally, Gutowski et al. published data reporting that the subglandular position increased risk eight-fold for developing capsular contracture [78]. This said, some have found no significant association [79].

When placed under the muscle, the clinical detection of capsular contracture is thought to be less, and the overlying muscles (pectoralis major, external oblique, rectus sheath and serratus anterior muscle fascia) act as a barrier to the glandular tissue [76]. The muscle boundary also 'massages' the implant when the muscles contract, favouring anatomical and physiological organisation of the capsule collagen fibres. However, submuscular placement is not preferable for patients who participate actively in sports [28].

The breast ducts connect the deep tissue with the skin surface so it is not surprising that the breasts contain bacteria commonly seen in the natural skin flora. Placing the implant into the submuscular limits the direct contact with the glandular tissue and thus minimises bacterial contamination [80].

Bacterial infection is thought to play a part in the development of capsular contracture. Contamination with Staphylococcus epidermidis with miniature implants using sixteen rabbits showed that contaminated implants had uniformly firmer consistency. Histology showed fibrous capsules with abundant collagen formation and that they were two to three times thicker than the (saline) control [81].

Although S. epidermidis is well documented, a variety of organisms have been isolated as causative [82,83] and a broad spectrum antibiotic approach should be initially implemented. Rates of capsular contracture have been reduced with the use of a triple antibiotic breast irrigation technique (often cefazolin, gentamycin and bacitracin). This has been recommended to improve clinical outcome and for its cost-effectiveness by several papers [27,34].

The longer the implant has been in place, the higher the risk of developing a contracture, with a direct correlation assumed to exist [61]. Araco et al. support Handel's hypothesis of capsular contracture as a chronic and progressive complication [34]. In a study evaluating treatment options, the 'watch and wait approach' showed that the capsular contracture worsened [16]. Other studies have proven that increased implant duration has shown capsules to be significantly thicker [30].

Numerous intra-operative techniques have been described to reduce contracture rates. Antibacterial breast pocket irrigation, intra-operative 10% povidone–iodine washes [84,85], thorough haemostasis, talc-free gloves when handling the implant and peri-operative antibiotics have been suggested as being important in optimising outcomes of breast augmentation [26].

Lower rates of capsular contracture are favoured by an inframammary incision (0.59%) rather than the peri-areolar incision (9.5%). The likely reason for this is again the bacterial contamination pathway, with the assumption of taking a deeper route through the breast tissue and bypassing the ducts near the nipple-areola complex that harbour higher quantities of bacteria by their nature of being closest to the skin surface [86].

6. Capsular contracture: Conservative and surgical management

6.1. Medical

Pirfenidone (PFD) has anti-inflammatory and antifibrotic characteristics. In a study in 2006 [87], the administration of PFD immediately after mammary implantation in a series of 10 rats, and continued for eight weeks reduced inflammation, contracture and capsule thickness when compared to the control. The total content of collagen in the PFD group was 50% less than the control. Despite a small sample, the results were encouraging to suggest a larger, human study should be undertaken.

Leukotriene receptor antagonists (LTRA) may present a new non-surgical approach for the management of capsular contracture [88–92].

Zafirlukast (Accolate) has been used in the prevention and long term treatment of asthma. It is well tolerated although reported side effects include headache and nausea.

It was initially believed that this anti-inflammatory agent could perhaps be used in the treatment of capsular contracture after a patient presented with Baker grade III, two months after a primary breast augmentation. A dramatic improvement was seen using this treatment, and at three months the patient was re-classified as Baker grade I.

The anti-inflammatory properties target cellular-mediated proliferation without the unwanted effect of a generalised immunosuppression. A statistically significant difference of capsular contracture rate (4% down to 1%) was noted when Zafirlukast was introduced. It appears to be most effective in the early stages (less than six months) and prophylactically in high risk patients.

The longevity of these impressive results once patients are off, the therapy is yet to be established.

Montelukast has also been found to be effective, but not to the same extent [88].

In one study, using 40 rat models, the collagen fibres and fibroblast layer were reduced in the Zafirlukast-treated group compared to the control. The study confirmed effectiveness in preventing fibrosis and in reducing the extent of collagen reaction when a capsule has been formed [89].

A prospective study of 120 females (216 prostheses) showed that Zafirlukast may be effective in reducing pain and breast capsule distortion in long standing contracture for over a year [90].

However despite this promising evidence, hepatic failure is a rare but very serious associated complication. Liver function tests may be appropriate in patients treated with Zafirlukast [91,92]. Mainly for this reason, Zafirlukast is at present not indicated for breast implant surgery, until the full extent of the side effects and effectiveness are understood. Randomised clinical trials are currently underway [28].

Many papers [93–95] have suggested the use of triamcinolone injections. A recent study in Italy, published in 2011, demonstrated that ultrasound guided injection of 40 mg of triamcinolone acetonide, in the peri-implant area of breasts affected by Baker grade IV capsular contracture, is effective in reducing capsular thickness and patients' discomfort even in the patient who has undergone adjuvant chemo-radiation therapy for breast cancer [96].

Ultrasound guided injection allows safe delivery of steroids into the small space around the implant after breast augmentation or reconstruction [96].

6.2. Manipulation

Closed capsulotomy describes a technique where the breast is firmly grasped and manually compressed to rupture the underlying periprosthetic scar tissue [28]. This procedure has initially a good outcome (100% 'better' or 'same'), however these effects are short-lived, meaning the procedure has to be repeated numerous times (58% of breasts had the procedure more than once) [16].

The complications associated with closed capsulotomies (haematoma, shell rupture with Silicone leak, implant pseudoherniation) are not acceptable by today's standards, and this procedure is not advised in light of this and the limited short-term benefits.

6.3. Ultrasound [97–99]

A study conducted in 2002, in Spain, which looked at the use of external ultrasound to both treat and prevent the formation of capsular contracture, showed promising results [98]. J. Planas, the leading clinician, claimed success rates of up to 97% in improving the clinical findings, 'by at least one Baker degree'. To achieve this, anything between 2 to 16 sessions, of ultrasound application were needed, and the best results were seen with subglandular implants.

6.4. Surgery

Capsular contracture is seen less often when the procedure is primary augmentation [61]. The risk increases if the surgery is a revisional intervention; even more so in breast reconstruction [3].

With breast reconstruction patients, they may have pre- and post-operative exposure to chemotherapy and or radiotherapy. These adjuvant therapies are known to increase the rates of subclinical infection and subsequently enhance the natural fibrosis of tissues [39]. Patients who will, or have post mastectomy radiation have optimised results with a delayed autologous tissue reconstruction after therapy [100].

Surgical approaches (capsulotomy or capsulectomy) are often reserved for patients scoring Baker III or IV [1].

Open capsulotomy describes a surgical approach with usually circumferential and longitudinal cuts made into the fibrous capsule to end the distortion of the implant. The capsule is not removed, but the breasts are softened. This is the preferred, less extensive technique for submuscular cases [1,28].

In submuscular patients, the posterior wall of the capsule lies directly on the ribs and attaches to the intercostals muscles. Capsulotomy therefore reduces the risks of the more complicated capsulectomy which includes haematoma and pneumothorax [101,102].

After the removal of saline implants, the capsule has been shown to contract and reduce, folding over the first couple of months and virtually disappearing after a year. Capsulotomy may be the preferred treatment for patients with saline implants [1].

Complete capsulectomy removes the anterior and posterior scar tissue. If no implants are to be re-inserted in the space, it is left to heal. Capsulectomy has increased risks when involving submuscular implants, on account of the capsule resting on the intercostal muscles. This is based on the theory of a biofilm, and so, removal of all bacteria harbouring capsule and prosthesis is needed [103,104].

Evidence suggests that calcium can accumulate in a capsule left behind and interfere with routine screening mammograms. Capsules from silicone implants have also been shown to produce further contractures even long after the implants have been removed. Since the capsule is removed with this procedure these complications are avoided in capsulectomy [1].

Implant removal alone may solve the problem but may not however give an acceptable cosmetic result to the patient if there is a lot of skin excess or great amount of ptosis in the empty breasts. In this situation, a mastopexy may address this. Alternatively re-implantation can be considered, as can reconstruction with autologous tissue, with both options discussed below.

Re-augmentation into a different plane is preferred as reoccurrence risk is very high for reinsertion into the same position [1].

If the original implant is in the subglandular plane, then re-implantation is preferred submuscularly. This position also facilitates mammographic investigation, ensures adequate tissue coverage, and avoidance of contact between the new implants and the inflamed glandular tissue [1,28].

If the first placement of implants was submuscularly, capsulotomy is indicated and the implant may be replaced in this position. In a lot of cases, there is not enough tissue to cover the implant, and rippling risk is high [28]. However, one study suggests an alternative. On 36 patients with subpectoral implants requesting re-augmentation the implant (s) were removed, modified capsulectomy performed, the pectoralis major muscle re-suspended to the chest

wall. They then underwent re-implantation in the subglandular position for re-augmentation. This has been successfully performed on patients with capsular contracture [105].

The individual needs of the patient need to be met. Strictly speaking, the only way of treating the capsular contracture and preventing re-occurrence is to remove the implant, without implant replacement [28].

Some patients who have had repeated capsulectomies and implant exchanges have found pleasing results at 5 years according to Gurunluoglu et al. when autologous tissue is used to reconstruct the breast [106]. Here, a total of 14 flaps were created to maintain breast volume and aesthetic appearance where new implants were not desired.

These included TRAM flaps, DIEP flaps and SIEA flaps. This method of reconstruction produced satisfactory results and is an option worth considering in the patient who gains no improvement from the more simple surgical techniques.

6.5. Conclusion

It should be noted that there is little in the way of controlled trials in regard to the prevention and/or management in capsular contracture. Capsular contracture has complicated breast augmentation from day one, and studies that describe their experience in this field are often diverse and multifactorial, making it difficult to suitably compare or analyse specific treatments. It is for this reason that a true systematic review is often limited in its conclusions, and hence our decision to present a description of current theories and techniques rather than a 'cure' for this complication.

Capsular contracture can be a very distressing complication of breast augmentation with prosthetic implants leaving a patient with spherical, hard, painful breasts. Modern techniques have dramatically reduced the incidence and prevention is always better than cure, and these are shown in Table 2.

Although rates of capsular contracture have dropped considerably over the recent decades, the management options for patients who are in higher risk groups are important. The patient always has the option of 'do nothing'; however, this is unfavourable, patients typically find no relief or that their condition worsens [5].

This is important, as at present, there are limited surgical options for patients with capsular contracture. It may be cured by removal of the implants; this however, is unlikely to leave satisfactory aesthetic result with an empty ptotic breast.

Reconstruction is possible with autologous tissue in patients willing to have further extensive surgery. However patients wanting replacement with implants are less likely to have such pleasing results with re-implantation (especially into the same plane) with a high risk of reoccurrence. More research needs to be done to look at the long-term effects of Pirfenidone and Leukotriene receptor antagonists to see if these are safe and effective pharmaceutical treatments.

Table 2
Steps to prevent capsular contracture in breast augmentation remembering this is a natural process where a foreign body reaction becomes a pathological contracture.

Sterility and haemostasis	No touch technique of implant Use of antibiotics (triple irrigation) Meticulous haemostasis
Approach	Atraumatic (to breast/pocket and implant) Inframammary approach
Submuscular plane	Or use of ADM Obliteration of dead space
Implant	Polyurethrane coated Textured

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