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Capsular contracture — What are the risk factors? A 14 year series of 1400 consecutive augmentations☆

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Summary The modern era of breast augmentation and reconstruction began in 1963, with the introduction of silicone implants by Cronin and Gerow. To date, the demand for cosmetic augmentation continues to increase exponentially. However, whilst the surgical techniques and quality of mammary prosthesis have improved dramatically in recent years, patients are still confronted with significant potential complications. We performed a retrospective study of 1400 consecutive primary breast augmentations performed between March 1995 and March 2009 by a single surgeon. We specifically examined the incidence of capsular contracture and the possible causative factors.

Follow up ranged from 1 to 16 years. The mean age at the time of surgery was 32.8 years and fill volume was between 195 ml and 800 ml. Our capsular contracture rate was in the order of 26.9%. BMI >30, fill volumes >350 ml, smoking and alcohol consumption did not significantly increase capsular contracture rate. Implant type, pregnancy, infection and delayed haematoma significantly increased the risk of capsular contracture.

Our series has given us a unique insight into the frequency of capsular contracture and identified several risk factors. To our knowledge, this is the first report of pregnancy having a significant effect on capsular contracture. We now counsel patients thoroughly into the detrimental effects of pregnancy on the implant.

☆ This article has not been presented or submitted to any other journal.

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Introduction

The modern era of breast augmentation and reconstruction began in 1963, with the introduction of silicone implants by Cronin and Gerow. To date, the demand for cosmetic augmentation continues to increase exponentially and it is the most commonly performed cosmetic surgical procedure in the United States, with a total of 355,671 procedures in 2008.[1] However, whilst the surgical techniques and quality of mammary prosthesis have improved dramatically in recent years; patients are still confronted with significant potential complications. For more than 40 years, capsular contracture has remained the most common complication, resulting in significant economic impact. The Mentor and Allergan pre-market approval studies cited the capsular contracture rate for saline and silicone gel implants as 15%.[2,3]

Despite numerous theories and anecdotal reports, the aetiology of capsular contracture remains unresolved. With such a potential impact on patient and surgeon satisfaction, the search for the cause of capsular contracture has been relentless. Potential causes include the hypertrophic scar hypothesis, silicone gel bleed, foreign bodies, haematoma, age and infection.[4] In an attempt to shed further light on this entity, we performed a retrospective study of 1400 consecutive primary breast augmentations performed between March 1995 and March 2009 by a single surgeon (PL). We specifically examined the incidence of capsular contracture and the possible causative factors.

Methods

A retrospective case note review was conducted of all consecutive aesthetic breast augmentations performed by the senior author (PL) between March 1995 and March 2009. We specifically excluded all patients who were undergoing mastopexy augmentation, had previous augmentations with a different surgeon, or were undergoing reconstructive breast surgery. The surgery itself was performed unassisted by PL using a standard technique, which was not modified during the study period and will be described below. All dressing changes and follow up were conducted by PL. Pertinent details recorded from the patient notes were: - age at time of surgery; hand dominance; BMI; smoking status; alcohol consumption; pregnancy and breast feeding; size and type of implants; post-operative complications and their management; Bakers grade of capsular contracture[5] at all follow up appointments; any subsequent surgery. Patients were routinely called for follow up yearly for a period of 5 years. Thereafter appointments were made at the patient's request.

Technique

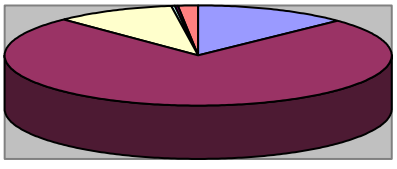
PL performed all breast augmentations using a standard technique, which did not alter for the duration of the study. Patients were advised to stop smoking pre-operatively and achieve a BMI of less than 30, although this was not enforced prior to surgery.

On the morning of surgery the patient is instructed to wash with 2% chlorhexidine. Intravenous Gentamycin or Cephalexin is given on induction. A 5 cm inframammary incision is used gain access to the subglandular pocket. The pectoralis fascia is raised using monopolar diathermy on a coagulation setting. This permits bloodless sub-fascial plane elevation. Dissection is strictly limited to the lateral border of pectoralis major to avoid potential haematoma formation or nerve damage. Having secured haemostasis, the implant is washed in saline and Cephradine or Gentamycin solution. It is then placed under the pre-pectoral fascia and the incision is closed in layers with vicryl sutures. Drains are not routinely used and patients are discharged the following day.

Results

Over the 14 year study period, 1400 patients underwent primary breast augmentations performed by the senior author. The mean age at the time of surgery was 32.8 years (range = 17—66 years) Patient BMI ranged from 15 to 38, with a mean of 21.2 and 39% of patients admitted to being smokers. Length of follow up was from 1 year to 16 years, with a mode of 6 years.

The implants used during the study period included GFX-EHP (Nagor Ltd, Isle of Man, UK) (1052 patients) Eurosilicone (Eurosilicone SAS, Apt Cedex, France) (178 patients), McGhan style 410 (Inamed Aesthetics, Wokingham, UK) (139 patients), Siltex (Mentor Medical Systems LTD, Newbury, UK) (23 patients), Silimed (Eurosurgical Ltd, Surrey, UK) (4 patients), Misti Gold (Bioplasty Inc, Minneapolis, USA) (4 patients). This data is illustrated in Figure 1. Fill volume ranged from 195 ml to 800 ml (mode 295 ml). 16.6% (232 patients) required asymmetrical augmentations with a mean difference in fill volume of 5 ml—295 ml (mode of 20 ml). Patients were more likely to require a larger implant on the right side (63.6% of asymmetrical



Implant Type	Number of patients
Eurosilicone	178 (12.71%)
GFX	1052 (75.14%)
Mcgghan	139 (9.93%)
MistiGold	4(0.29%)
Silimed	4(0.29%)
Silitex	23(1.64%)

Figure 1 Pie chart illustrating relative proportions of each implant type.

Reasons for Revision

Reasons for Revision	Number (%age)
CapsularContracture	23 (13.52)
Palpable Edge implant/fold	2 (1.17)
Cysts	5 (2.94)
Wants to be Smaller	9 (5.29)
Wants to be Larger	63 (37.06)
Pregnancy	17 (10)
Hypertrophic Scar	10 (5.88)
Infection	2 (1.18)
Lumps	2 (1.18)
Inverted nipple	1 (0.59)
Mastopexy	2 (1.18)
Capsulectomy	6 (3.53)
Shape	4 (2.35)
Rippling	2 (1.18)
Wrinkling	1 (0.59)
Psychiatric Disorder	1 (0.59)
Tenderness	3 (1.76)
Implant Rotation	1 (0.59)
Pectoral Movement of implant	2 (1.18)
Haematoma	3 (1.76)
Seroma	1 (0.59)
Incidental cancer	1 (0.59)
Implant no longer wanted	9 (5.30)
Total	170

Figure 2 Table illustrating reasons for implant revision.

augmentations). 170 patients had revision procedures and the reasons can be seen in Figure 2. The majority were because the patient wanted to be larger (37.06%). Nine patients wished removal of implants completely and only 9 patients wanted to be smaller.

26.9% of patients developed capsular contracture (grade 2, 3 or 4) in one or both breasts A total of 110 patients (7.9%) needed a capsulectomy.

For the patients who had hand dominance recorded, there is no significant difference between the rates of capsular contracture in left and right handed people with relation to the ipsilateral breast ($p = 0.202$). Subgroup analysis showed that there is no significant association between BMI over 30 or excess alcohol consumption (>14 u per week) and capsular contracture ($p = 0.834$, 0.413 respectively). There was also no significant association between capsular contracture and smoking ($p = 0.472$) or fill volumes greater than 350 ml (left breast $p = 0.752$ and right breast $p = 0.190$). It was noticed that postoperative pregnancy was related to capsular contracture. The incidence in patients who became pregnant in the post operative period was 43.6%, compared to 23.9% in those who did not become pregnant ($p = 0.008$). The results of capsular contracture for all patient factors can be seen in Figure 3a.

There is a significant difference between the rates of capsular contracture across the different groups of implant types ($p < 0.001$). After adjusting for multiple comparisons, a pairwise analysis found a significant difference in the capsular contracture rates between Eurosilicone (12.8%) and GFX (26.6%), with $p < 0.001$ (Figure 3b).

Early post operative complications included infection (6 patients), haematoma (8 patients) and diathermy or lighted retractor burns (2 patients). There were 6 cases of periprosthetic infection and 5 necessitated implant removal. Procedural specimens showed no growth in 2 patients, pseudomonas in 2 patients, mixed organisms in the fifth patient and the remaining patient had purulent fluid with acute inflammatory changes but no specific organism confirmed by culture. Interestingly both patients growing pseudomonas had used a spray tan prior to surgery and this may have been a contributing factor. One of the patients developed spontaneous swelling 5 years after her original augmentation which was treated by aspiration of fluid in the clinic and oral antibiotics alone. Three of the six patients went on to develop capsular contracture.

Eleven haematomas occurred from within 24 h of surgery to 5 years postoperatively. The majority (63.6%) was in the first 24 h and therefore a direct result of surgery. Of the remaining, 3 patients developed spontaneous swelling and one was a result of direct trauma. All bar one were managed with return to theatre and haematoma evacuation. The other patient declined surgery and it settled spontaneously. Her haematoma was a result of being elbowed by her daughter several months following her augmentation. None of the haematomas developing within 24 h of surgery had capsular contracture. All the haematomas treated between 5 days and 5 years from surgery went on to develop capsular contracture.

Discussion

The literature is saturated with information regarding complications of breast augmentation, but most series have many variables including surgical technique, operating surgeon and short follow up with different clinicians. Our study is a 14 year series of augmentations performed and followed up by one surgeon, who performs a standard technique which has not altered over the study period. There are, however, several important disadvantages of any retrospective case series study; the investigator is dependent on the availability and accuracy of the medical record and the series is by necessity non-randomised. In this study, we attempted to reduce the inaccuracies by including consecutive patients and using an independent researcher to examine the notes. We acknowledge that complications may still be underreported. Patients may seek advice from another surgeon or not consider their symptoms worthwhile. However, given that follow up is

a

	Capsular Contracture Grade 2 or above		P value
	Yes	No	
Left handed	9 (47.4%)	10 (52.6%)	Fisher's Exact Test P= 0.202
Right handed	62 (31.6%)	134 (68.4%)	
BMI > 30	21.0 (19.8 -22.3)**	21.1 (19.9 – 22.7)**	Mann-Whitney p= 0.834
Alcohol Consumption >14u/week	4 (0 – 10) **	4 (0 – 10) **	Mann- Whitney P=0.413
Smoker	132 (25.4%)	388 (74.6%)	Fisher's Exact Test p = 0.472
Non Smoker	193 (23.6%)	624 (76.4%)	
Pregnancy	14 (43.6%)	22 (56.4%)	Fisher's Exact Test p= 0.008*
No pregnancy	325 (23.9%)	1035 (76.1%)	
Eurosilicone	23 (12.8%)	157 (87.2%)	Fisher's Exact Test p= <0.001*
GFX	279 (26.6%)	770 (73.4%)	
McGhan	31 (22.6%)	106 (77.4%)	
Other implant	9 (28.1%)	23 (71.9%)	
Implant volume >350ml left breast	63 (20.3%)	248 (79.7%)	Fisher's Exact Test p= 0.752
Implant volume <350ml left breast	231 (21.3%)	852 (78.7%)	Fisher's Exact Test p= 0.752
Implant volume >350ml right breast	61 (18.7%)	265 (81.3%)	Fisher's Exact Test p= 0.190
Implant volume <350ml right breast	238 (22.3%)	830 (77.7%)	Fisher's Exact Test p= 0.190

* P is statistically significant

** Data displayed as Median (Quartiles)

b

Pairwise Comparisons - Capsular Contracture Rates				
	Eurosilicone	GFX	Mcgghan	Other
Eurosilicone	-	<0.001*	0.024	0.033
GFX	<0.001*	-	0.353	0.840
Mcgghan	0.024	0.353	-	0.497
Other	0.033	0.840	0.497	-

Fisher's Exact Test p-values for comparisons of pairs of implant types

*Significant after Bonferroni Correction at p=0.008

Figure 3 a. Table showing capsular contracture rate in relation to different patient factors. b. Table showing pairwise comparisons of capsular contracture rate for each implant type.

without charge and there is no surgical fee for revisions, we think these cases will be in the minority.

As expected, the most common surgical complication of textured silicone implants was capsular contracture, with an overall incidence in the order of 27%. Review of the notes allows us to search for possible causative factors which were highlighted by the literature and anecdotally noted by the senior author.

Formation of a fibrous tissue capsule around an implant is a normal physiological response to a foreign body. However, when a capsule forms around the implant it may contract and lead to serious problems such as tenderness, pain and distortion of the breast. Unfortunately, this is a relatively common and yet unpredictable complication. The evaluation of capsular contracture is fraught with difficulty and related to the experience and sensitivity of the assessor, as well as the amount and consistency of overlying breast tissue. Our overall capsular contracture rate was 26.9%. We analyzed Baker's grade[5] for each breast and found that most patients had a grade 1 or 2 capsule. In total 110, (7.9%) patients required surgical intervention, leaving 267 patients with grade 2 or 3 capsule choosing no surgical intervention.

There are numerous theories regarding the aetiology of capsular contracture. Polymicrobial infection has long been implicated as a causative factor.[6] Bacteria, including staphylococcus epidermidis, have been cultured with significant frequency from implant capsules.[7–11] In our study, 6 patients developed evidence of peri-prosthetic infection with evidence of warmth, erythema, swelling, tenderness and pyrexia. No specific organism was identified in four out of the six patients. Interestingly this subgroup of patients had a 50% capsular contracture rate in the infected breast. The two patients who developed pseudomonas infections had used spray fake tan prior to surgery. It is postulated that the spray tan bottles may be colonized with pseudomonas which contaminates the implant intra-operatively. The senior author now advises patients not to use spray tans pre-operatively and to wash in 2% chlorhexideine on the day of surgery[8,12]Haematoma has often been cited as a causative factor. Fibrin triggers fibroblast activation and proliferation, which results in excess extracellular deposition of collagen.[13] In a manner similar to hypertrophic scar formation, this is thought to cause thick capsules which can contract. Not only would this explain early onset capsular contracture, but micro-tears due to wear or trauma can cause bleeding and delayed capsular contracture. In cases of capsular contracture, the senior surgeon often noted that a portion of the capsule (normally that over the back plate) was adherent to the implant itself and the remainder of the capsule was firmly attached to the surrounding tissue. Thus it is possible that this differential movement of the capsule permits tearing of the capsule with bleeding and haematoma formation. This eventually culminates in capsular contracture. In keeping with this, many implants removed from breasts with capsular contracture have a yellowish staining of the shell which is thought to be due to contact with haemoglobin (Figure 4). Furthermore, it was anecdotally noted that Eurosilicone implants, which we felt to be inferior in texturing to Nagor implants, resulted in less capsular contracture than the Nagor implants. We postulated that the weaker texturing on the shell grips the implant less tightly and is therefore less likely to tear the peri-prosthetic capsule and cause bleeding and subsequent haematoma formation. In our series it became evident that a treated haematoma within 24 h of surgery did not result in capsular contracture, but delayed presentation or spontaneous haematomas occurring 5 days or more postoperatively all resulted in capsular contracture.

The size and shape of the implant itself may affect capsular contracture. Implants greater than 350 ml are said to be associated with higher capsular contracture incidence, although this may be a reflection of the increased risk of haematoma or infection.[14] We found no association between the size of the implant and the risk of capsular contracture.

Many authors have claimed an immunological basis to the formation of capsular contracture. It has been reported that late capsular contracture can occur following a severe cold or other viral illness. Unfortunately reporting is often limited by deficiencies inpatient recall. In patients who definitely report a viral illness, activated CD4+ cells have been seen around the vessels in the inner layer of the capsule. It is postulated that there is antigen mimicry between the viral antigens and the silicone particles in the outer capsule.[15–17] To our knowledge, we are the first to identify post-operative pregnancy as a significant risk factor for the development of

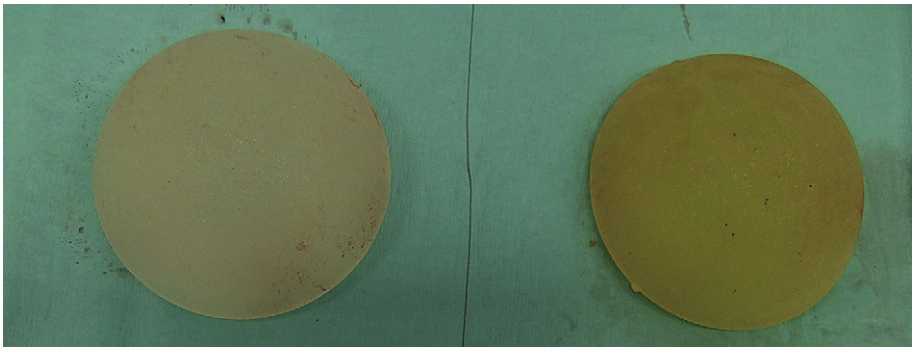


Figure 4 Photograph illustrating discoloured implant seen at the time of capsulectomy. Implant on the right of the photograph was removed from the breast with grade 3 capsular contracture 3 years after augmentation. There was old haematoma found within the capsule. Implant on the left side was from the breast with grade 1 capsular contracture.

capsular contracture. The exact mechanism for this is as yet unclear. The increase in breast vascularity may result in increased haematoma formation or perhaps there is an immunological basis to this phenomenon. We would recommend that further research be conducted in this area. Patients should be warned that augmentation is best delayed until family plans have been addressed.

Treatment of established capsular contracture is also a matter of debate, but the majority of surgeons perform open capsulectomy removing the entire capsule and implant. In this series, all capsular contractures were treated with full capsulectomy and replacement of the implant. Despite this, there will always be a subgroup of patients who have recurrent capsular contracture, often in both breasts and can be considered to be "capsular cripples". With the recent resurgence of polyurethane implants, the senior author is now using polyurethane as his primary breast implant and we await with interest the long term capsular contracture data.

Conclusion

Our series of 1400 consecutive breast augmentations has given us an insight into the frequency of surgical complications and the range of fill volumes required for this population. By far the most significant and troublesome complication is capsular contracture, which occurred with a frequency of 26.9% in our series. At the cellular level, capsular contracture is thought to be due to any factor producing peri-prosthetic inflammation, with resultant collagen deposition and contracture. Unfortunately the wealth of literature on the topic seems to be contradictory. What we do know, is that whilst many agents have been implicated, capsular contracture is most likely to be a multi-factorial problem. It is the net sum of the potentiators and suppressors that ultimately result in the pathologic state of capsular contracture. We have demonstrated that capsular contracture can be precipitated by delayed haematoma formation, peri-prosthetic infection and pregnancy. It appears to be unrelated to smoking, alcohol consumption, implant size, BMI or handedness. Whilst every attempt is made to prevent infection and bleeding, we now counsel patients thoroughly into the detrimental effects of pregnancy on the implant.

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Ethical approval

Not required.

Conflicts of interest

None declared.

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