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The history and development of breast implants

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ABSTRACT
This review discusses the historical development of smooth and textured silicone gel filled implants, and examines the reasoning behind product development and aspects of surgical technique from a surgeon's perspective.

KEYWORDS
Breast implants – Silicone breast implants – Breast implant history – Breast implant development

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Introduction

Breast augmentation may be unilateral, differential or bilateral and the outcome is dependent on patient expectation being realised as well as chest wall symmetry, the frame and vectors of the myoskeleton,[1] the shape and consistency of the operative breast, the position or ptosis of the breast on the chest wall, the compliance or laxity of the lipocutaneous envelope and the means whereby the volume of the breast is increased. In this paper, we discuss the historical development of smooth and textured silicone gel filled implants, and examine the reasoning behind product development and aspects of surgical technique from a surgeon's perspective.

Prior to the introduction of silicone implants by Cronin and Gerow in 1962, women sought breast augmentation through a variety of methods including injections of glycerine, autologous fat, ox cartilage, silicone oil and even snake venom, all of which carried high risk and morbidity.[2] Autologous fat injections may have a role in filling simple small area contour defects, particularly of the upper pole in marginal breast ptosis.[3,4]

The first silicone implant was a thin shelled, low viscosity, silicone filled implant, which was first reported to have been used for a woman's breast augmentation in 1964.[5] Capsular contracture can lead to further complications, one of these being rupture, with the rate of silent rupture possibly being as high as 50% at 20 years.[2]

Interestingly, in 1969, Ashley appeared to have significantly reduced the high rate of capsular contracture at that time by using anatomically shaped implants covered in polyurethane foam.[6] Despite the notable absence of data on safety up until 1992, many thousands of women opted to have silicone implants. Without these data and sufficient knowledge, in the 1980s, an increasing number of women with silicone implants experienced complications and required revision surgery involving implant exchange. As a result (and because the desire of women to have fuller shaped breasts seemingly outweighed the risks highlighted in the media), the market for implant exchange expanded greatly.

In the same era, silicone technology advanced rapidly at Dow Corning. Alastair Winn founded Applied Silicone, which remains one of the only two major global suppliers of raw silicone to manufacturers. It became evident that the original implants had no barrier shell. Consequently, low viscosity silicone migrated in some quantity into the tissues, leading to a significant granulomatous tissue response. The huge legal misconception at that time was that the lowest molecular weight silicone component of the gel was the cause of the capsular contracture and this silicone brought about an associated illness. After approximately 200,000 lawsuits, some of which were successful, Heyer-Schulte and subsequently Baxter were able to scientifically disprove the claims. However, this was too late to prevent the breakup of Dow Corning into a number of subsidiaries, all developing the technology further.[7]

Silicones are made biochemically by attaching oxygen molecules to silicon. This process involves a complex chemical reaction of toxic agents, and it is little wonder that scares of cancer and silicone related illnesses developed over the decades, persisting even up to the present day. Nevertheless, in the 1980s, the main concern was that of a silicone induced illness that resulted in a moratorium on the use of silicone filled, silicone elastomer shell implants enforced by the US Food and Drug Administration (FDA) and by Health Canada in 1992.

Silimed started producing polyurethane implants in Brazil in 1989. These implants were improved versions of the first polyurethane implants reported by Ashley and undoubtedly became the best implants owing to the low incidence of capsular contracture.[8] It has been suggested

that the reduced incidence of capsular contracture is a result of the polyurethane biointegrating, whereby the collagen fibres form on the characteristic lattice created by the polyurethane, preventing the parallel formation of collagen and therefore contraction.[9] Although similar to silicone shell implants, cancer in the form of sarcoma has been induced in rats by 2,4-diaminotoluene, a degradation product of polyurethane. However, this association has never been reported in humans.

While there has never been any publication showing an increased risk of breast cancer in women with any implant (whether silicone or polyurethane), statisticians (using meta-analysis from dubiously validated publications) can unwittingly and seriously misinterpret data to suggest otherwise. If statistical data are to be believed, the evidence points to the contrary in that the incidence of breast cancer is lower in women with implants.[8,10–14]

Even now, there are still lobby groups concerned about the possible association between silicone implants and silicone induced illness. Despite this, a duopoly of manufacturers survived, McGhan and Mentor, who later became known as Allergan and Ethicon respectively. Both companies supplied higher molecular weight cohesive silicone implants, with an integral barrier layer, to the rest of the world while the moratorium was in place. During this period, women in the US and Canada opted mostly for saline breast implants that are silicone elastomer shells filled with saline at the time of insertion. These implants gained further popularity following the forced withdrawal of the enthusiastically introduced hydrogel and soya oil filled implants, which carried the selling point of being able to screen through them on mammography.[15,16]

Moving a little further into the 21st century, after 2006 the manufacturers submitted study data to the FDA. Even though the collected data were incomplete, this resulted in silicone gel filled implants being reintroduced in the US.[17,18]

Interestingly, Allergan anatomical implants have been available in the UK since the 1990s but in the US, only since 2012. Issues with these silicone implants (eg patient disappointment regarding the lack of upper pole projection, edgy feel, double capsule formation, rotation, partial adherence and upper pole folds) are all well known. They were popular in Europe until losing their CE mark in 2019.[19] Similarly, in 2016, Silimed lost its CE mark in Europe for the production and distribution of its silicone implants following a surface particle scare.

Returning to capsular contracture and its influence on the development of silicone implants, there appears to have been a reliance on data of dubious accuracy, which potentially and inadvertently may have led to the enthusiastic but inappropriate development of textured silicone implants. Textured implants were originally introduced in an attempt to reduce capsular contracture rates, based on the known fact that polyurethane does significantly reduce the incidence of capsular contracture. However, they missed the fact that the polyurethane was biointegrating and it was the neogenerating layer that was preventing the contracture, not the surface texture. The underlying silicone implant essentially has a Mentor texture, which is known for its non-adherence.[8]

In a bid to try and replicate the lowered risk of capsular contracture but without using polyurethane itself, McGhan chose to create a rougher outer silicone shell texturing, based on impregnating, through extracting salt crystals into the outer layer during manufacture. In contrast, Mentor produced a textured implant using the negative imprint of a removed polyurethane foam layer on the outer layer of its silicone shell. The resultant textures are what we can describe as coarse or fine respectively, the former being supposed to adhere to tissues and the latter not.[20,21] In reality, the coarse textured McGhan implant can never completely adhere because there is a smooth patch on the posterior surface.

Presentations at meetings during the 1990s were often about textured implants and propensity to reduced capsular contracture rates. Despite this, the actual supportive data were scarce. The development of coarse textured silicone implants has possibly led to the increasing global incidence of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).

BIA-ALCL is now known to be more commonly associated with coarser textured implants, particularly implants textured using salt extraction technology.[22] Nevertheless, polyurethane has also been implicated in BIA-ALCL in Australia and New Zealand, and is well referenced in Australia's Therapeutic Goods Administration notifications although their hypothesis related to larger pore size with polyurethane implants is likely to be incorrect because the polyurethane layer has all but smoothed off and biointegrated by five years.[8] Mentor implants, on the other hand, have less association with BIA-ALCL development, according to published data.[20] In fact, Mentor implants have a similar texturing to the microtexture surface that would possibly result from delamination of the polyurethane implant that is banned in many countries.[23]

The persistent roughness on a mobile McGhan implant appears to be at least partially incriminated in the late development of BIA-ALCL, presenting as sudden swelling of the breast with separation of implant and capsule, and seroma formation, probably resulting through inflammatory mediators. There are also biofilm theorists that may have evidence to support a microbial induced inflammatory aetiology for this rare condition.

Methods

We have reviewed the evidence suggesting that texturing has benefit in preventing capsular contracture. A literature search identified ten papers that compared capsular contracture rates in smooth and textured implants.[24–33] Only seven publications were felt suitable for inclusion in this review (Appendix 1 – available online).[24,26–31] All studies used either the Baker scale or the Breast Augmentation Classification (BAC) to grade the severity of capsular contracture. Four of the seven studies also gathered data

using applanation tonometry. When using the Baker/BAC scoring systems, a statistically significant difference between the use of smooth or textured implants and the incidence or severity of capsular contracture was found in only two of the studies.[24,26] Equally, when using tonometric measurements, there was a statistically significant difference in just two studies.[28,30]

Findings

The few publications that may have influenced what essentially remains a subjective binary choice between smooth and textured silicone shell implants have been critically examined. Any benefit to the use of textured implants over smooth implants regarding capsular contracture was found to be questionable. The analysis provided in Appendix 1 was felt to be required as perhaps the interpretation of these data has in the past inadvertently supported the development, manufacture, distribution and surgical use of coarse textured implants that now appear to be more associated with BIA-ALCL. This in itself appears to be a sound reason to encourage the use of smooth shell cohesive gel implants for breast augmentation.

The main limitation of all of these studies was the reliance on the Baker scale, which is an inherently subjective form of assessment for determining the severity of capsular contracture. This subjectivity is amplified in most studies as there was often more than one observer carried out the patient assessments and sometimes even the authors themselves. As a result, no matter what the data showed, a degree of bias was involved in scoring and cannot be eliminated. Future studies should have a single independent external assessor to review all pre and postoperative patients and data.

Errors in the Baker scoring system include subjectivity because both visual and touch aspects of this type of assessment can be affected by the patient-to-patient variance in soft tissue quantity covering the implants, the pocket placement of implants and the positioning of the patient.[20,21] There is currently no alternative method of assessment in sight, however, that would deliver both objective and quantitative accuracy.

One study that is not included in the analysis in Appendix 1 (because it was neither randomised, nor did it give any evidence towards whether smooth or textured implants increase the rate of capsular contracture) was that by Poeppl *et al* in 2007.[32] They presented serological analysis via enzyme linked immunosorbent assay showing a statistical significance for the difference between serum hyaluronan levels of 25ng/ml ±11.7ng/ml in their control group and 26ng/ml ±14ng/ml in patients with capsular contracture. Although they did not find any statistically significant difference between capsular contracture around smooth implants and that around textured implants, their physiological assessment alludes to the possibility that a physiological change related to the severity of capsular contracture could be established and measured in the future.

Assessment forms aside, other obvious limitations included the low number of patients in each study, the small fraction of these patients who completed the follow-up periods and the short timeframe over which follow-up review was conducted. Unfortunately, these three limitations together actually make doing a study like this extremely difficult as fewer patients tend to turn up for follow-up visits the more time passes. In addition, some studies did not help the cause given that they performed follow-up at different times for patients and then calculated an 'average' follow-up time. Even the often quoted capsular contracture rates in Sharpe's papers at one and three years cannot be accurate or objective,[24,25] a clear example of why these studies needed to be scrutinised.

What also commonly varies between studies (and is underestimated) is the improved surgical technique, especially regarding pocket dissection, as well as haemostasis, implant fit, and antiseptic techniques to reduce biofilm and haematoma.[22,34] The original breast implants were inserted into subglandular pockets in a somewhat traumatic manner. Instead of a measured pocket, using a minimum 5cm incision, surgeons generally used smaller incisions, just adequate to insert an index finger or Hegar dilator to create a submammary blind pocket. In addition to large implants going into small pockets, there was significant soft tissue trauma and a high risk of haematoma. Drains were the norm. It is therefore not surprising that the capsular contracture rate was so high, particularly with the higher gel bleed, thin shell implants.

In order to counter this, surgeons were advised to make submuscular pockets in the 1990s; in so doing, they were able to hide the upper pole of the implant and could also create a wider pocket with less tissue damage. Some argued, however, that the rupture rate was higher.[35] The majority of implants in the FDA extended implant studies were placed behind the pectoralis major. The transaxillary approach was championed by Tebbetts[36] and then others described their preferred dual plane approach (by dividing the lower, mid or high pectoralis according to ptosis presentation) or the split muscle approach.[19]

All techniques have created different problems, including the risk of late sliding ptosis (eg in heavier breasted women who subsequently have children).[5] These problems happen less frequently with subfascial pockets provided that the surgeon only inserts implants of a diameter that can be covered by the native breast tissue, to avoid a palpable upper pole edge.

In women with no body fat and especially in athletic women, the results are poor whichever plane is used but as long as low profile, appropriate diameter implants are used in a pocket larger than the implant, then a mobile, smooth shell implant will give as good a result as any other but without the risks of submuscular placement (in particular, the abnormal appearance when actively using

the pectoralis major muscle). In the unlikely event of BIA-ALCL developing, it is less likely that a complete *en bloc* capsulectomy will be possible if the implants are in the submuscular plane and even if it is possible, there will be a major disruption or deformity of the pectoralis major itself.[20,37]

With some regulators in support, various authors championed the use of triple antibiotic therapy instead of betadine to reduce what was already an enviably low capsular contracture rate.[34,38,39] While this was a noble concept from a surgical point of view, it was a microbiological disaster with some feeling that it contributed to antibiotic resistance and the emergence of atypical flora, which may to a certain extent be associated with BIA-ALCL.[26] It appears that these organisms are often killed by iodine but are resistant to powerful antibiotics.

The error here was that the FDA accepted dubious data on implant safety, namely that betadine could cause separation of the valve from a saline expander.[38–40] There was little else that surgeons could use as an antiseptic other than a now controversial triple antibiotic prophylaxis regime because chlorhexidine has a possibly underreported association with intraoperative anaphylaxis and hypochlorite has no FDA approval either.[41] Burkhardt and Eades' findings looked at the beneficial influence of betadine on capsular contracture rates, albeit with numerous limitations.[27]

The two papers from Sharpe *et al* in 1991 and 1997 describe a small cohort of the same patients, followed for one year and then three years.[24,25] These publications helped to promote the use of textured implants globally. They attempted to show that textured implants have a reduced risk of capsular contracture compared with smooth implants. These data should, however, have been treated with more caution.

Modern scientists have been aware for years of the limited scrutiny afforded to publications from that era. In particular, it should be noted that the comparison was between a thin shelled, smooth silicone implant and a soft gel, first generation, textured silicone implant, in a single surgeon's private practice, using a traumatic method to create a pocket and inserting a textured implant without mentioning the possibility of introducing bacterial biofilm.[24,25] That was the technique of the day. There was no mention of pocket size in relation to implant diameter and no clinical photographs. Furthermore, a very subjective and inconsistent measurement tool was used to assess the outcomes. Statistical methodology was also questionable and there was no necessity to declare conflict of interest at that time.

When the data required by the FDA on the extended performance of silicone gel filled implants were published by Allergan in 2014, it was determined that in this much larger series, there was no evidence that shell texturing reduced the risk of capsular contracture, especially if insertion was into submuscular pockets.[17] These data were interpreted before clinicians understood the possible significance of biofilm.

The reality remains that there has never been a validated, independent and appropriately controlled study comparing capsular contracture rates when using different implants, let alone a prospective study simply comparing smooth and textured implants. Nevertheless, each manufacturer has claims on capsular contracture rates for their implants but much like the publications analysed in Appendix 1, McGhan and Mentor produced non-comparative and incomplete follow-up data. Consequently, there is probably little difference between the available implants in terms of capsular contracture rates, particularly given that the silicone is identically sourced from either of the two US producers of medical grade silicone.

Further studies need to be performed and scrutinised in order to reliably draw valid conclusions as to whether texturing of silicone implants does affect the rate of capsular contracture or whether it in fact gives results that are no different from those of smooth implants. In order to do this, the flaws in the studies that have been evaluated in this paper must be recognised.

Conclusions

Considering the high incidence of capsular contracture in thousands of women following breast augmentation, it is in the surgical community's best interests to discover ways of reducing the risk. So far, the data regarding the effect of texturing silicone shell implants on the rate of capsular contracture in comparison with smooth shell implants show no significance and are largely unreliable. This perhaps explains the current consensus in patient safety and reducing the risk of BIA-ALCL for being in favour of smooth shell implants.

It has also become clear that overall data regarding breast implantation and postoperative complications have not previously been scrutinised in depth. While the aetiology of capsular contracture is unclear, such scrutiny should be directed towards not only implant texturing but also other potential influences on the rate of capsular contracture, including the associated problems with the use of betadine and the controversy over implant pocket selection. For now, however, the debate over the use of textured or smooth shell silicone implants for breast augmentation remains unsolved.

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