

The case for polyurethane foam covered silicone gel breast implants.

Dr Daniel Fleming has Australia's largest breast augmentation practice. He has performed more than 3000 breast implant operations using smooth, textured and polyurethane foam covered implants. Here he explains why the published evidence, accumulated over 40 years, and his own experience has led him to recommend polyurethane foam covered implants to all patients seeking breast augmentation.

Introduction

The first polyurethane foam covered silicone gel breast implants were used by Ashley in 1968.¹ They have always been known to reduce contracture rates but there have been concerns about their safety, specifically about the possible degradation of the foam to 2,4 TDA, a known carcinogen in high doses in rodents. This was one of the reasons why textured implants were developed in 1984, some 16 years after foam. Interestingly if you look up the patent applications for textured implants, including Allergan's Biocell texturing, they all start by stating the patent applied for is for a process of texturing the surface of silicone implants "to simulate an open cell foam to reduce capsular contracture" or words to that effect. Texturing was therefore an attempt to reproduce the benefits of the foam. As we shall see it did not work.

The long term evidence has consistently shown that PU foam implants dramatically reduce contracture rates compared with both smooth and textured implants.^{2,3} Surgeons who use these implants have also found they reduce the incidence of displacement and rotation compared with implants with other surfaces, allowing them to use anatomical implants without the fear of early or late rotation. Evidence accumulated from more than 40 years of in vivo experience with these implants has proved conclusively that they are safe and, with the exception of a temporary rash in 1% of patients, have no greater incidence of other complications compared with smooth and textured implants.^{2,3}

Capsular contracture

How common is capsular contracture? Some surgeons do not feel capsular contracture is much of a problem anymore. You can find a published paper to support any figure you like from 1% to 50%. When I talk to surgeons having given presentations about the foam many of them tell me that they don't see much capsular contracture in their patients but, "I see a lot from other doctors". They often fail to make the connection that "other doctors" may well be seeing their contractures!

All of the evidence shows that when independent assessments of a surgeon's contracture rate are made they always are much higher than the surgeon had thought. This was brought painfully home to me when I was involved in the trial of titanium coated gel implants. Because these patients were in a trial follow up was formalised and comprehensive. My one year grade 3 and 4 rate was 7% (incidentally no different for titanium and non titanium implants). Previously I would have estimated my one year rate to be about 3 or 4 %. Other doctors in the trial had the same experience. Were we bad doctors? How come we were not replicating the very low rates sometimes published by the so called leaders in the field?

The Baker classification is universally used to report contracture rates, with only grades 3 and 4 being considered contractures. So a grade 2 does not count and a grade 3 does. Of course all grade 3 capsules were once a grade 2. It is necessarily a subjective judgement, made by the examiner in each patient, whether a capsule has reached the criteria of grade 3 and is therefore reported as a contracture, or if the patient is still a grade 2 and thus contracture free. The implications for observer bias especially when assessing one's own patients are obvious.

Scott Spear, commenting in PRS has observed:

“The information that plastic surgeons will be most interested in would be that regarding single-lumen textured and smooth silicone gel implants. The very best data regarding those devices are available from the core clinical studies that were submitted to the Food and Drug Administration over the last year as part of the Premarket Approval process by both Inamed (now Allergan) and Mentor.”⁴

Commenced in 2000, these are 10 year, prospective, multi-centred studies in the US of smooth and textured silicone gel implants. The FDA required these studies as a condition for the re-approval of gel in the US in 2006. The FDA also required that Mentor and Allergan make available to patients the results of the core studies.

Allergan's data show a re-operation rate of 30% at 7 years for 455 primary augmentation patients operated on by multiple surgeons. 40% of the re-operations were for one of two reasons – capsular contracture or displacement. The grade 3 and 4 contracture rate at 7 years was 15.5% with no difference between textured and smooth⁵. Mentor's data is published for 6 years of follow up and they have a contracture rate of 10%.⁶ Handel et al have shown using Kaplan Meier analysis that contracture rates will increase with time⁷ so Mentor's rate will be higher at 7 years. Kaplan Meier analysis is also the statistical method approved by the FDA for the core studies.

The core studies, “the very best data” according to Spear, reveal what happens in the medium term in the real world. With respect, none of us really know what our contracture rate is unless we involve ourselves in this kind of supervised trial. Not surprisingly Allergan is not promoting the results of its core study. Because of the FDA requirement perhaps it can be found deep in their US website.⁷ I cannot find it on their other international sites.

The results for secondary cases are of course substantially worse. Also these were all round implants. Had anatomical implants been included in the studies it is likely the re-operation rate would have been even higher because of rotation.⁸

Smooth versus textured

Why was there no difference between textured and smooth in the core study? Because most textured implants behave like smooth ones. Ask yourself of all of the textured implants you have ever removed how many had Velcro like adhesion to the capsule? Not many is the answer every surgeon I have asked has given. It could be argued this was because they are a self selecting group of patients because they needed removal for complications. If so, then the uncomplicated other side which is often removed at the same time for cosmetic reasons should have been adherent. Was it? Also consider patients who have textured implants removed solely for cosmetic reasons such as size change? Were these adherent? When visiting South

America I found most surgeons using textured implants there advise their patients to massage them in the post operative period – what does that tell you? The mantra that textured implants offer less contracture than smooth is based on the meta-analysis by Barnsley,⁹ which only showed this for sub glandular placement and not for sub muscular. Meta-analyses are of course only as good as the original papers they were analysing. The extreme subjectivity of whether a capsule is labelled a grade 2 and therefore not considered a contracture, or a grade 3 and therefore included in the contractures, is one difficulty in comparing or meta-analysing contracture studies. Add to this the fact that contractures increase over time and many studies have a follow up of only a few years, it is then not surprising there is such a diverse range of reported incidences for textured and smooth implants.

The rationale for foam covered implants

Why should the foam reduce contracture rates so much? This is revealed by histological analysis of the normal capsules associated with different implant surfaces. The collagen fibres which make up the capsule around both smooth and textured implants are aligned end on end. If a stimulus to contract occurs (whatever it may be), the fibres can shorten over one another concentrically around the implant causing a shrink wrap effect and the consequences with which we are all too familiar. PU foam implants work because the foam becomes integrated into the full thickness of the capsule. The foam is a 3D matrix or lattice and the collagen fibres wrap around the foam struts. They are no longer end on end but disjoined and cannot shorten over one another causing the concentric shrinkage. Thus contracture rates are literally decimated at least. A strong Velcro effect between the capsule and the implant invariably occurs. When removing these implants after some months there is a cleavage plane between the implant surface and the capsule. The explant is no longer covered in foam as this now resides in the capsule (Figure 1). This creates a stable marriage between the implant and the capsule. Rotation has not been described and the medium to long term downward displacement commonly seen to a greater or lesser extent with smooth and textured implants has also not been reported.

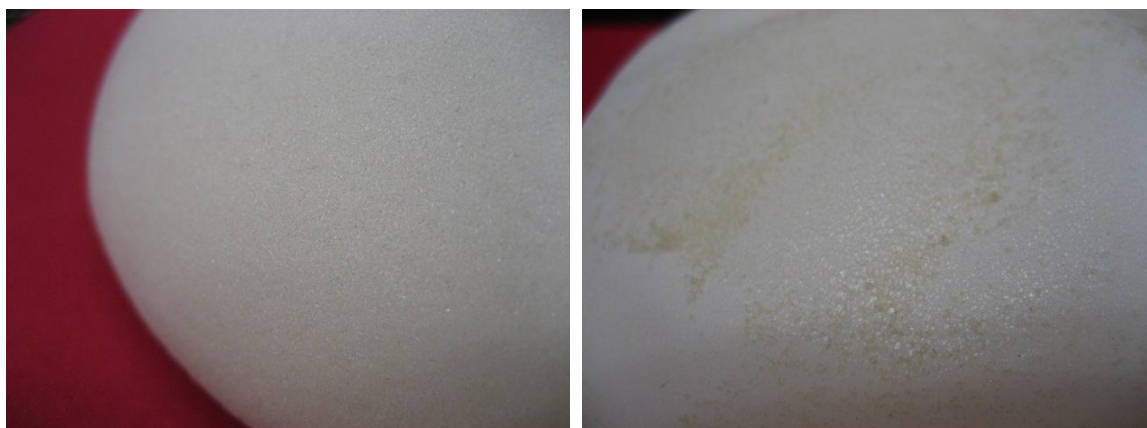


Figure 1 Comparison of unused foam implant surface and foam implant explanted after 6 month. Explantation cleaves the implant from the foam which is integrated into the capsule.

Textured implants, even when they do adhere, can only at best affect the capsule/implant interface as the texturing remains on the surface of the implant. This is insufficient to alter the full thickness of the capsular architecture and therefore to

reduce contracture rates. The images below taken from Handel's paper² show the histologies of smooth, textured and foam capsules and should clarify the above.

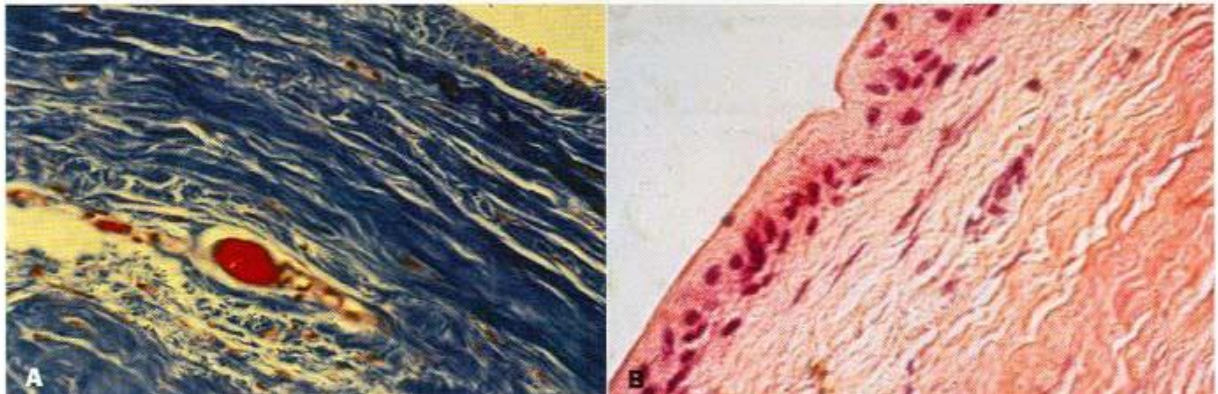


Figure 2. Smooth surfaced implant capsule with collagen stained blue on the left and textured surface capsule with collagen stained pink on the right. Note the end on end alignment of collagen fibres.

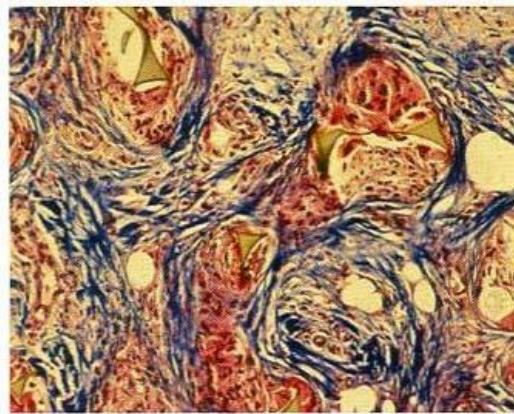
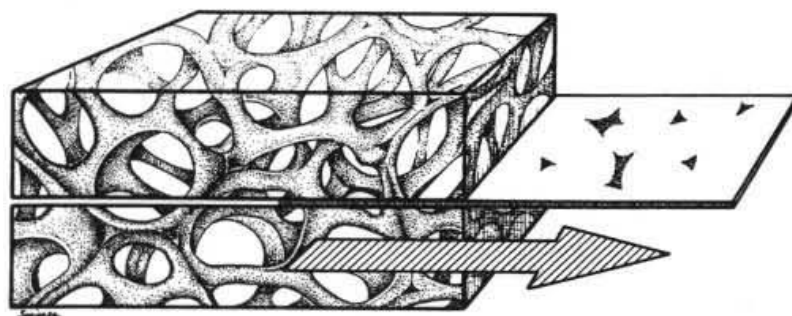


Figure 3. Polyurethane foam covered implant capsule with collagen stained blue. Note interlacing and consequent disjoining of collagen fibres around the foam matrix which shows as the triangular structures as illustrated below in Figure 4 (from Sinclair¹⁰).



Safety

Are polyurethane foam covered implants safe? Unequivocally yes. They have been used in hundreds of thousands of women for up to 4 decades. The Handel 2006 data^{2,7} and Vazquez and Pellon's 18 year experience³ show that other complications occur, at worst, at the same rate as for other implant surfaces. The temporary rash in 1% of patients is the only exception to this. Handel was using an older incarnation of foam implants from Surgitek, a division of Bristol Myers. Vazquez and Pellon were using Silimed implants which is what we have available today. Their results in a large number of patients closely followed for 15 years, all in front of the muscle, show a contracture rate of 1%. The attachment of the foam to the Surgitek implant surface was less reliable than Silimed's vulcanisation process and this may explain why Vazquez and Pellon got even better results than Handel.

The foam does biodegrade very slowly over many years.¹⁰ Concerns arose when two case reports were published by Chan et al^{11,12} showing measurable levels of 2,4 TDA in the urine of two patients who had PU foam implants. Importantly it was not found in their blood. The Health Board of Canada commissioned research by an Expert Panel on the Safety of Polyurethane-covered Breast Implants.¹³ The panel could find no evidence of a significant risk but called for further investigation. This was done by Hester et al¹⁴ under FDA supervision. In summary, the reason no free 2,4 TDA was found in the patients' blood was that it was never in the blood. Chan's method of preparing the urine samples prior to detecting TDA is relevant. The urine was treated with 6 times normal hydrochloric acid and then boiled for 1 hour at 105° C. The elevated urinary TDA subsequently detected was present as an artefact caused by in vitro acid hydrolysis. This had cleaved 2,4 TDA off from the harmless oligomers that are produced as part of the slow metabolism of PU foam by inflammatory cell esterases. This has been the conclusion of other investigators as well.¹⁵

It is also important to realise that 2,4 TDA has never been shown to be carcinogenic in humans at any concentration and two occupational studies of workers exposed to it over long periods did not show any increase in cancers of any type.^{16,17}

Also 2,4 TDA was detected intermittently in the urine of control subjects with no implants. Hester et al concluded the miniscule amounts of free 2,4 TDA found in the non hydrolysed urine of implanted patients posed no significant risk, a conclusion shared by the Health Board of Canada and Australia's Therapeutic Goods Administration. Even if it was assumed that 2,4 TDA was equally carcinogenic in humans as it is in rodents, the levels found in the urine would equate to a lifetime risk of developing breast cancer increased by less than 1 in a million. A risk defined by the WHO as unmeasurable.

It is pertinent to compare this theoretical risk with the known real risk of death from a general anaesthetic given to a healthy patient undergoing a capsulectomy which she would not have needed if had she had foam implants – about 1 in 80,000. It should also be mentioned polyurethane foam itself has no association with an increased risk of cancer in any species and is used in other human prosthetic devices, such as pacemakers and prosthetic heart valves.

Disadvantages - myths and reality

In addition to the misperceptions concerning safety, other myths about these implants abound such as you can't remove them once they are in, they are too difficult to put in or you need a bigger incision. These are simply not true and Silimed has been provided with operative videos by the author which prove this.

What are the real disadvantages? The temporary rash over the breasts occurs in about 1% of patients in the second post operative week and lasts for one to two weeks. It is itchy and the patient is well so it is easily diagnosed and distinguished from infection. It is treated symptomatically with anti histamines or topical steroids, has no long term effects and does not recur. Removal of foam implants, although much less likely than with other implants, is sometimes, but not always slightly more difficult than with non foam implants. It is however perfectly possible. If all of the prosthetic material needs to be removed then a capsulectomy will be required if the implants have been in for more than 3 weeks as the foam will have started to integrate into the capsule. In cases of infection this is not always necessary as removal of the prosthesis alone and appropriate antibiotic treatment is usually enough to allow successful re-implantation after 3 months. Late infection with atypical mycobacteria however would require total capsulectomy.

The learning curve for using these implants is not difficult as long as you know that these implants stay where they are put. They do not "settle" into the pocket. If they are too high the day after surgery they will remain so. Because smooth and textured implants often do "settle", subconsciously we may tend to put them in slightly high to allow for this. When surgeons start using the foam if they are not made aware of this they may place the implants too high. However, if you know about it and sit the patient up before closing it should not be a problem. In fact I would argue that this is an advantage since it affords control and predictability of implant position to the surgeon.

Use in revisional procedures

The predictability of placement can be helpful when treating displacements and symmastia as the implant does not exert the same pressure post operatively on any areas of the pocket which may have been closed with sutures. Rotation of anatomical polyurethane foam covered implants has not been described in secondary cases.

If a patient has a grade 3 or 4 capsule then the gold standard treatment is the creation of a virgin tissue to implant interface and the use of polyurethane foam implants. This is either achieved by making a new pocket or a plane change depending on the specific circumstances of the patient. Such treatment will reduce her risk of recurrent contracture to 2% even though she has already had a contracture. If a capsulotomy only is performed and a new tissue to implant interface not created, the foam is unable to exert the same effect on the existing capsule and recurrence is increased to 50%. These figures come from Hester, Tebbetts and Maxwell.¹⁸ This paper was never published, I am informed, because they thought there was no point as foam is unavailable in the US.

Personal experience and conclusions

I have used these implants for more than 5 years in both primary and secondary patients. In the last 18 months I have used them in more than 500 patients and now use them exclusively. They are not a panacea but I have yet to see my first capsular contracture. I have had one unilateral downward displacement which occurred the day after the surgery presumably due to over dissection of the pocket on my part combined with suture breakage. I have not seen the insidious slight downward displacement over time which detracts from the final long term results with non foam implants. Other complications have occurred with the same incidence as with other implants. In short, my results have simply mirrored the results of surgeons overseas who have used these implants for longer than me. Whereas previously I was loathe to use anatomical implants unless they were really necessary because of the risk of rotation, now the majority of implants I use are anatomical. The ability to control three dimensions with an anatomical implant rather than only two with a round, allows me to get better results in many patients.

All elements of the operative plan are critical to optimising outcomes for breast augmentation patients. The choice of implant surface is one very important part of the plan which is entirely controllable and has predictable consequences. Handel's finding that "Curves from Kaplan-Meier survival analyses reveal that contracture is a progressive phenomenon, and the longer any group of patients is followed, the greater the cumulative risk of developing contracture" is central to an understanding of the importance of this.

In Handel's own words, "This contradicts the widely held belief that if patients remain contracture-free for a year or two they probably will not develop significant contracture."¹⁹ This finding may also have some relevance in understanding the cause of capsular contracture. If the risk of contracture persists for many years after implantation (as it appears to), it seems less likely that it is related to acute events such as bacterial contamination, surgical technique, drains, antibiotics, or other ancillary measures that have a short-term impact and more likely related to some chronic effect of implants on adjacent tissue."⁷

The evidence clearly shows you can modify this chronic effect and dramatically reduce the risk of the commonest complication and the commonest reason for reoperation by choosing one implant surface (with a 40 year proven safety record) over another. The evidence also suggests it is highly likely you can substantially reduce displacement, the second commonest complication and reason for reoperation as well. It is difficult therefore to justify not using such an implant or not telling patients about it. Certainly when patients are given the evidence to consider they virtually all choose foam. It is probably only a matter of time before the lawyers realise this and a patient with contracture will sue on the basis that she was not offered an implant which was available and, had she been informed about it, she would have chosen it and very likely not needed further surgery for contracture.

If any one of us were a patient considering breast augmentation would we want to know about this option? How will you respond to the next contracture or bottomed out patient who asks you "why didn't you tell me about the foam implants?"

In August 2009, Dr Leroy Young gave a presentation about polyurethane foam covered implants at the American Society of Plastic Surgeons annual breast meeting in Santa Fe. There were a number of surgeons present who had used the devices

when they were available in the US and, unanimously, they said were the best implants they ever used.²⁰

I have been fortunate to have given talks on these implants around the world. I always ask the audience if there any surgeons present who have used these implants for any length of time who have subsequently reverted to smooth or textured implants. I have not found one yet.

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