Commentary on: The Modern Polyurethane-Coated Implant in Breast Augmentation: Long-Term Clinical Experience

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As in all studies with such small numbers of cases, especially when they are uncontrolled, retrospective, or contain different cohorts of patients, there is very little statistical significance within the article by Pompei et al. This is particularly true when the observed capsular contracture rate is found to be only approximately 1% at 14 years and the reoperation rate is approximately 3% over the same time.1 Obviously, this is indicative of the authors’ experience and still compares favorably with the 2011 extended FDA study data derived from thousands of women, with follow-up of approximately 60% over 10 years from McGhan, who reported a 19.1% capsular contracture rate and roughly a 30% reoperation rate for all reasons, including lifestyle change over 10 years.2 There is certainly no evidence from this small series, spread over 12 years with what appears to be a minimum of 4 years follow-up, that capsular contracture rates are even less than those of the first-generation implants, as these authors claim. There is actually very little difference in the pore size or thickness of the polyurethane that is used when the authors claim a new “5 layers of polyurethane,” and this statement needs a reference. The main differences between the original implants and the so-called modern polyurethane breast implants is the sterilizing method and the discontinuing of the use of the glue adhesive to bond the polyurethane to the underlying silicone elastomer to replace it with a vulcanized bonding. The latter is an attempt to reduce the incidence of delamination of the polyurethane layer from the elastomer, although this still occurs. This is more likely to occur where there are infoldings of the pseudosynovial layer in layer 1 of the integrating capsule.3 The oft-quoted large single series of patients with polyurethane implant cosmetic augmentations, published by Vázquez in 2007,4 reported a capsular contracture rate of only 1% over 18 years. More recently, Castel et al in 20155 quoted a 0.1% capsular contracture rate over 30 years from using the first generation of polyurethane implants, which is remarkable. However, other United States-based surgeons have presented similar supportive data over the past 30 years, including well-known authors such as Hester, Tebbetts, and Maxwell.6 This paper has quite a few basic flaws, confounders, and errors, but the general findings follow the same trend as in other publications from authors worldwide7-8, which show that polyurethane implants are the gold standard against which conventional silicone implants have to be measured over the long term. With the emergence of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) associated with all implants, but especially those with an outer texture derived from salt extraction technology, surgeons are obligated to select the best products with the fewest complications and to choose the correct plane for implant placement.9 I disagree that surgeons are motivated to put in implants with the best record of success. If that were the case, then polyurethanes would be used exclusively. There are likely other motives involved, including the corporate policy of the facility where the procedure is carried out, financial costs, sales misinformation, surgeons’ awareness, and implant availability.

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In this retrospective study, I was disappointed to see so few cases included over 12 years, the lack of controls, the low number of primary cosmetic augmentation cases with the majority of implants being inserted at the time of mastopexy, and the flat pattern of the graph after 3 years with a complication rate of 2.3% up to 15 years. Evidence is emerging of complications that appear later, when the polyurethane has finally disappeared after 20 years.3 The follow-up assessments were presumably performed by rotating junior staff with an unknown amount of experience over a long period of time rather than being performed by the implanting surgeon, because the follow-up and fall-out rates are not cited, and round implants were inserted only until anatomical implants were introduced by Polytech, which were therefore used preferentially in this study.

Based on the data collected, it seems that the complication rate was higher with anatomical polyurethane implants rather than round implants, but I have actually found that the conical polyurethane implant introduced by Silimed in 2009 has many other advantages over the anatomically shaped implants, including better contour, better takeoff, and better projection, and with less axillary fullness if larger implants are used.10 I also rarely use the subpectoral plane and instead have faith that any upper pole firmness will soften over approximately 1 year. Ashley11 himself designed the first polyurethane implant as a teardrop shape, and in his original paper, he had an understanding of the problems that we are still discussing today. In fact, Polytech and Silimed only parted ways in the mid-2000s after forming Polytech Silimed to gain a CE Mark and capture the European market. The main implants were actually Silimed implants and were originally made in Brazil (Silimed, Rio de Janeiro, Brazil) and supported by many of the great plastic surgeons, including Pitanguy himself12, until the two companies parted ways. The Polytech and Silimed implants are now different in that the polyurethane implant is heat sterilized by Polytech, whereas they are ethylene oxide gas sterilized with Silimed. This difference may have relevance to the few unexplained ruptures that these authors noted. I also have access to a patient with Polytech implants that shattered only a few years after they were implanted (Figure 1). Having experience using Silimed implants since 2005 in private practice and within the Aesthetic Surgery Training Programme that I run at Anglia Ruskin University, I have not yet seen a rupture, nor a Baker 3 or 4 capsular contracture, with any Silimed implants, and I see my patients myself annually.

I find it difficult to understand why abnormal muscle contraction was so rarely noted in this series, considering that approximately 25% of cases complain of this finding normally. I also cannot understand why the likely main reason for late reoperation described in the text, which is sliding ptosis, was not explained. This happens when loose breast parenchyma slides over adherent submuscular or submammary implants, which by definition must include polyurethane. In addition, if the capsular contracture rate is so low, then why are these authors favoring use of the submuscular plane? I do not agree with their philosophy for using drains, the use of bipolar cautery when they use monopolar for bloodless dissection, their thoughts on biodisintegration of polyurethane, their assumption that silicone bleeds if there is delamination of the polyurethane, or their antimicrobial regime, and there is no mention of using the silicone sleeve for no-touch insertion of the implants to avoid biofilm. It should be remembered that Mentor implants have a texture that is created by the negative imprint of polyurethane, and Mentor implants do not leak after the polyurethane is removed. The decision to use polyurethane implants should depend on the confidence of the implanting surgeon to use a safe implant. However, the surgeon should not be constrained by the regulatory powers of national bodies or institutions, thus the surgeon should not have any difficulty with fully informed consent and should also be vulnerable to legal issues themselves.

Despite my hopefully constructive criticism of this article, the authors’ argument for the preferential use of polyurethane implants over silicone implants in primary breast augmentation to avoid capsular contracture remains unequivocal. However, this situation is far from ideal, and if implantable materials remain the future for breast augmentation and reconstructive breast surgery, then alternatives to silicone and polyurethane need of discovered and developed.

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REFERENCES