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Letters to the Editor

Long-lasting complications with the use of polyurethane-covered breast implants

Sir

I feel that the article (*British Journal of Plastic Surgery*, 1986, **39**, 549) merits further discussion.

The authors quote seven cases with long-lasting complications, yet three of these consisted of an erythematous rash that cleared with topical or systemic therapy (they failed to state what this therapy was). They then go on to discuss two cases in detail.

Case 1 refers to a bilateral insertion of prostheses in the presence of "conspicuous haematoma". Areolar necrosis resulted and infection occurred, resulting in removal of the prosthesis on the left side. On the right side a capsule developed.

One cannot but question the surgical judgement to go ahead and insert a prosthesis in the presence of "conspicuous haematoma" and not expect complications. For 20 years now, it has been well documented in the literature that haematoma is one of the conditions that inevitably leads to capsular contracture, especially in the presence of smooth-walled implants. To expect different in the presence of a polyurethane-covered implant is naïve. To risk putting in polyurethane implants in the presence of a haematoma seems doomed from the start.

In Case 2, the surgical technique is allegedly to have placed the implant in a sub-muscular pocket and yet polyurethane was found in the subcutaneous tissues. With complete coverage of the pectoralis-serratus anterior muscle, how can this possibly occur?

Readers should be cautioned to accept these reports as typical of the results that are normally associated with good surgical judgement and technique. Undoubtedly, infections and reactions do occur with the use of polyurethane implants. However, there seem to be circumstances here that contraindicate insertion in the one instance and question technique in the second case.

Yours faithfully

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Sir

I believe that the *warning* expressed by Berrino *et al.* is erroneous and misleading for the following reasons:

1. The article does not clearly mention what implants were used. Were they Ashley-Natural-Y, Heyer-Schulte or Cox-Uphoff, or were they one of the new types—Même, Vogue or Optimam—which are entirely different from the others?
2. Schatten (1984), in his large series, reported (as did Berrino *et al.*) several cases of reversible erythematous rash but no rash appeared if the implants were not soaked in penicillin or bacitracin. There is no scientific evidence that the rash is caused by the polyurethane itself. Does a rash qualify as a complication?

   Schatten now has 9 years of experience and in his series of 356 implants of the new types only 3 complications occurred.

   Herman's second report (Herman, 1985) includes 290 operations (probably more than 500 implants). Dolsky (1985) reports about 400 implants of the Même type. Argenta *et al.* (1985) report their experience with PU implants in congenital malformations. Shapiro (1986) has suggested a technique that reduces the problem of infection.

   All these references deserve study before one takes the warning of Berrino into serious consideration.
3. Berrino *et al.* report "seven cases of complications, related to the particular kind of prosthesis". If we consider that reversible rashes do not represent complications, we are left with a 5.7% complication rate. At least two of them (and one of his other case reports) could have happened with *any* implant. His "revision rate" was 4.3%.

   Do these numbers justify a warning about the risks associated with the PU covering? A recent study by Brody (1986) includes 3501 implants of all types. The revision rate was 25% and the incidence of complications was 16.2% (capsular contracture not included).
4. Berrino *et al.* had some difficulties in removing all the PU fragments. In my opinion it is essential to do a capsulectomy—to remove the entire implant with the capsule attached to it. This is admittedly more difficult and more traumatic than removing a smooth implant but it can be performed almost by blunt dissection under local anaesthesia. The capsulectomy is, of course, much more difficult if the implant is placed deep to the muscle as in Berrino's series.
5. A survey—preliminary report: I have recently finished a survey among 19 users of Optimam and Même implants in Norway and Sweden. This study includes 897 implants and approximately 4000 "implant years". The revision rate was less than 4% and the incidence of late infection was less than 1%.

   One must have reservations about the validity of reports based on surveys, but this study confirms the favourable observations made by some of the authors mentioned above.
6. Personal experience—preliminary report: Since April 1984 I have used 105 of the new PU implants for augmentation and congenital breast deformities.

   Although observation time is short, I find it relevant to mention my experiences so far. Revisions have been performed on five breasts; two because of dissatisfaction with the size (same patient), one due to

foreign body granuloma, one due to haematoma (and ruptured implant) and the last due to malposition. All were replaced with the same type of implant.

At one year follow-up, all breasts have remained soft (Baker I). No infection or rash has been registered.

Berrino, whatever PU implant he used, apparently did not see any contractures. He emphasises that malposition and extrusion are unlikely to happen with PU implants. These qualities are important. On the other hand, these implants are more difficult to implant and to remove and have a late infection rate higher than that of smooth implants. The foreign body reaction is significant and will occasionally lead to implant removal. Rare complications that we never (?) see with other implants can occur.

Do the benefits of the PU prosthesis outweigh its drawbacks? Only the experienced user can answer this. However, there is no scientific evidence that PU implants represent a hazard.

Berrino *et al.* have presented their valuable experience to use in an honest way but their study does not form the basis of a warning.

Yours faithfully

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Reply from Dr Berrino

Sir

Dr Melmed's and Dr Dillerud's letters on our article need to be discussed separately. With regard to Dr Melmed's letter, the following points require to be clarified further:

1. In Case 1 the prostheses were not placed "in the presence of a conspicuous haematoma" as Dr Melmed claims. The experienced general surgeon who performed the operation states that the haematoma and subsequent cutaneous problems developed as unexpected complications in the postoperative period. It is probable that if smooth prostheses had been inserted, the patient would have recovered uneventfully following implant removal, and secondary submuscular reconstruction could have been satisfactorily carried out at a later date. Instead, multiple fragments of infected polyurethane remained incorporated in the surrounding tissues, requiring excision of portions of the underlying fascia and muscle, thus strongly jeopardising subsequent reconstruction. Even if one can disagree with the initial decision to place the implants subcutaneously, the long-lasting complications observed in this case were directly related to the polyurethane cover of the prosthesis rather than to "questionable surgical judgements" since they could not have occurred with smooth implants.
2. As we have previously reported (*Tumori*, 1984, **70**, 451: *Plastic and Reconstructive Surgery*, 1985, **76**, 639; *Scandinavian Journal of Plastic and Reconstructive Surgery*, 1986, **20**, 89; *Aesthetic Plastic Surgery*, 1986, **10**, 237) and also stated in this paper, we always place breast implants in totally submuscular pockets: in Case 2 the prostheses were placed in subpectoral/subserratus muscular pockets. Fluid collection drained through the muscular coverage to the skin. We did not describe polyurethane fragments in the subcutaneous tissue, as Dr Melmed claims. Guthrie (1984) observed similar soupy fluid collections around polyurethane prostheses, while no description of such occurrence exists with the use of smooth implants. This delayed complication was therefore due to a reaction to polyurethane in the absence of infection rather than to a "questionable surgical technique", as Dr Melmed asserts.

Dr Dillerud's letter requires individual point-by-point discussion:

1. Meme and Optimam prostheses have been mainly utilised, depending on the surgical problem and on their availability at the Centres where the operations were carried out. Natural Y Optimam prostheses had been utilised in Cases 1 and 2.
2. No antibiotic solution was used for soaking but nevertheless an itching rash appeared in some patients; this was also experienced by other authors (Eyssen *et al.*, 1984; Guthrie, 1984). An itching rash requires specific treatment and therefore is to be considered a complication; moreover, the appearance of a rash as an early reaction is to be noted since it could precede a delayed reaction as observed in Case 2 and also reported by Guthrie in various patients. Jabaley and Das (1986) also described a rash as an early complication in a patient who developed late breast pain and tenderness requiring implant removal. We think that this observation deserves some consideration although it needs to be investigated further. Some well known series with low rates of complications