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

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Summary—Polyurethane-covered breast implants have been recommended by some authors for aesthetic and reconstructive procedures, since with these implants the incidence of capsular contracture is insignificant and risks of implant displacement or exposure are reduced. Reports on the use of these implants focus merely on aesthetic aspects, and risks associated with disintegration and incorporation of the polyurethane-coating are often overlooked. The authors have observed several complications associated with the use of these prostheses; two cases of long-lasting complication are described, which are ascribed to difficult removal of infected fragments of the coat and to delayed foreign body reaction to polyurethane. The authors believe that the hazards associated with these implants outweigh their advantages for primary use, but suggest their use for secondary procedures in patients who have had recurrent problems with smooth implants.

Since Ashley's first report (1970) on the use of polyurethane-coated breast implants, this kind of prosthesis has become widely used. Several relevant articles report a virtual non-existence of capsular contracture with the use of different polyurethane-coated implants placed in the submuscular or subcutaneous plane for aesthetic and reconstructive purposes. Pennisi (1984) reports only one case of capsular contracture in a series of 111 subcutaneously placed implants; he uses a custom made implant manufactured by Heyer-Schulte which is covered by a thin large pore layer of polyurethane sponge. Such a low incidence of contracture in 44 patients of this series who had subcutaneously placed implants following subcutaneous mastectomy is of particular interest since Slade (1984) reports a 100% incidence of capsular contracture following subcutaneous insertion of smooth surface implants in subcutaneous mastectomy patients. Eyssen et al. (1984) report no occurrence of capsular contracture in 92 patients who underwent breast reconstruction with submuscular placement of Natural-Y prostheses.

Herman (1984) noted no capsular contracture in 84 patients following subglabular augmentation mammoplasty using the Même prostheses.

Lack of capsular contracture seems to be due to tissue growth into the coating, peripheral degradation, liberation and phagocytosis of polyurethane fragments resulting in individual microencapsulation and multi-directional contractile forces which tend to neutralise one another (Lilla and Vistnes, 1976; Brand, 1984).

In our experience such response to polyurethane is also effective both in reducing risks of extrusion since a highly vascular non-contracting capsule develops, and in minimising chances of implant displacement because of adhesion to surrounding tissues.

The reports on complications associated with the use of polyurethane-coated breast implants mainly focus on aesthetic evaluations: wrinkling over the superior pole of the breast and a visible or palpable peripheral ridge have been described (Guthrie, 1984). As noted by Marion (1984), international literature is surprisingly lacking in reports of major complications associated with the incorporation of the covering in the surrounding tissue and with foreign body reaction to polyurethane fibres. Pollock (1984) reports a long standing infection, and Capozzi and Pennisi (1981) report a case of persistent infection and a case of clear fluid collection around the prosthesis, with tenderness and fever, which was interpreted as a reaction to polyurethane.

Materials and methods

We have used 70 polyurethane-covered breast implants for breast reconstruction in 54 patients with radical mastectomy (9), modified radical mastectomy (24), subcutaneous mastectomy (20) and
Poland’s syndrome (1). All implants were placed in totally submuscular pockets.

Complications

Seven cases of complications, related to the particular kind of prosthesis, were observed. Four patients presented with an itching rash of the anterior chest; three of them healed with topical and/or systemic therapy but in one of them (Case 2) the rash did not subside and the patient developed persistent pain and temperature; the implants were removed in the tenth postoperative week. No sign of periprosthetic infection was observed and culture of periprosthetic fluid showed no growth. Two cases of persistent clear fluid drainage from the submuscular pocket through the subcutaneous mastectomy incision were observed; in one of these patients drainage did not subside until the implant was replaced with a smooth surfaced one. One patient developed periprosthetic infection at the third postoperative week; cultures showed *Staphylococcus epidermidis*. Antibiotic treatment was unsuccessful and the implant was eventually removed. Purulent drainage persisted for 5 weeks.

We have also observed three cases of complications in patients who had undergone breast reconstruction using polyurethane-covered implants following subcutaneous mastectomy at other hospitals. Two of them had clear fluid drainage which in one patient failed to heal with conservative treatment. The subcutaneously placed implant was then removed and replaced with a submuscular double-lumen prosthesis.

Two cases of long-lasting complications which have required secondary procedures are described below.

Case reports

*Case 1*

In January 1984, a woman of 51 presented at our Institute 6 months following bilateral subcutaneous mastectomy and simultaneous reconstruction performed by a general surgeon in another hospital.
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She had had Natural-Y prostheses placed in the subcutaneous plane; conspicuous haematoma had occurred which, in the operator’s opinion, had caused necrosis of the nipple-areolar complex of the left breast. A peri-prosthetic infection had developed and the left implant had to be removed 2 weeks following surgery. The areolar necrosis had failed to heal and purulent drainage had persisted since then.

On the right side a very tight capsular contracture had developed (Fig. 1).

Under general anaesthesia, the right implant was removed; on the left side multiple fragments of polyurethane incorporated in the pectoralis major aponeurosis were excised.

The right wound healed uneventfully but purulent drainage continued on the left side: culture showed Staphylococcus aureus.

Three months later the patient was again taken to the operating theatre and a more radical surgical toilet of the left wound carried out. This led to an almost complete sacrifice of the underlying pectoralis major muscle. Since the patient strongly wanted breast reconstruction a latissimus dorsi muscular flap was transposed and a double lumen prosthesis was placed in the submuscular plane.

On the right side a double lumen implant was placed in a subpectoral/subserratus muscular pocket.

The patient healed well but 4 months later presented purulent drainage from the left wound: this was apparently coming from the subcutaneous tissue and no involvement of the submuscular pocket could be demonstrated. In spite of medical treatment drainage still persists sporadically but the patient refuses further surgery.

Case 2
A woman of 45 had bilateral subcutaneous mastectomies for fibrocystic disease at our Institute in September 1983 and immediate reconstruction was carried out using Natural-Y prostheses in the subpectoral/subserratus plane. The patient healed uneventfully with a good cosmetic result. Three weeks after surgery she showed an itching rash over the whole anterior chest which disappeared in 1 week with topical treatment. Thirteen months later the patient presented with bilateral erythematous soft lumps in the outer part of the submammary creases; at these sites the edges of the implants could be easily palpated under a very thin layer of skin. Surgical drainage was carried out and Fig. 2 shows the appearance after this procedure. A very dense brownish fluid

Fig. 2

Figure 2—Case 2. Patient following surgical drainage of peri-prosthetic collection.
containing small yellowish particles was evacuated. Cultures from this fluid showed no growth but histological evaluation of the particles showed foreign body giant cells, granulation tissue and alloplastic fibres (Fig. 3).

Under local anaesthesia the implants were removed and only a very thin layer of polyurethane was found adherent to the silicone shell. Drainage continued for two months without positive cultures.

When drainage ceased, under general anaesthesia double lumen prostheses were placed bilaterally in the submuscular plane and a reverse abdominoplasty was carried out in order to obtain a thicker coverage of the implants. The patient healed uneventfully and showed no significant problem at 6 months follow-up.

Discussion
The cases we have reported offer a warning about the risks associated with the polyurethane coating of breast implants.

Placement of a breast implant is always an elective procedure and therefore the surgeon’s major concern should be to achieve the best aesthetic result with minimal chances of serious or long-lasting complications.

If for any reason a smooth surfaced prosthesis has to be removed, this is a very quick and simple operation but it is a tedious procedure which usually requires general anaesthesia when a polyurethane-covered prosthesis has been in place for more than 1 week. Moreover, when disintegration of the coating has occurred, effective removal of all fragments of polyurethane is difficult and may lead to the sacrifice of large amounts of muscular, subcutaneous or glandular tissue, as demonstrated by Case 1. Even following scrupulous and radical surgical toilet, minor fragments of the coating may be left behind and may sustain chronic infection.

The foreign body reaction observed in Case 2 is similar to those observed by other authors (Capozzi and Pennisi, 1981; Guthrie, 1984) and demonstrates that delayed reaction to polyurethane can be clinically significant. Since polyurethane fibres are removed by phagocytes, they can probably be carried to distant lymphatic sites. At the

Figure 3—Case 2. Histological appearance of one of the particles floating in the periprosthetic fluid; granulation tissue with giant cells and foreign body images are shown (25 × ).
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Present time we do not know the long-term reaction in such sites in patients who have presented significant local foreign body reaction.

In our opinion these hazards make this kind of implant unsuitable as a first choice for breast reconstruction or augmentation. Nevertheless, we believe that polyurethane-coated prostheses can be useful for secondary procedures in patients who have had previous unsuccessful placement of smooth implants.

References


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