Oil-based breast implants (Trilucent implants) have recently been withdrawn in the UK by the Department of Health (Circular CEM/CMO/99/1). This was prompted by some reports of local inflammation in a small number of women with Trilucent implants. No objective data was presented with the reason for the withdrawal being given as 'not enough was known about the long term safety and the breakdown of soybean oil in the filler and its possible effects on the body'.

To date only one clinical report of an adverse effect has been published1 and a literature search failed to reveal any objective features of a case of bleed or rupture of an oil-based implant in a clinical setting. We present two cases of Trilucent breast implant bleeds along with the gross and microscopic picture of the implant and its capsule.

Case reports

Case 1

A 62-year-old woman was referred for left breast reconstruction. She had undergone a wide excision of T2N0 breast cancer in the left breast followed by radiotherapy and tamoxifen. She had been recurrence free for 4 years prior to her referral. She underwent reconstruction with a tissue expander inserted in the subpectoral plane. This was serially inflated to 375 ml over a period of 6 months to provide a reasonable match to the size of her normal breast. As the patient was very concerned about the safety of silicone-filled breast implants, the tissue expander was replaced with a 330 ml Trilucent implant at her request. The initial result was satisfactory but after about 18 months she started complaining of pain and hardness in the reconstructed breast. A Baker grade IV capsule was noted and 30 months after implant insertion the implant was removed and a TRAM flap reconstruction was performed.

At operation the Trilucent implant, although intact, had a very bizarre appearance. It had a variegated colour with shades of yellow and brown, and was studded with whitish yellow nodules (Fig. 1). The shell of the implant was extremely friable and despite careful handling ruptured on removal. A very dense adherent capsule surrounded the implant, the anterior portion of which was removed. The whole cavity had a rancid smell.

On histological examination, the capsule consisted of thick collagen layer with the inner zone being very cellular (Fig. 2A). This inner zone contained a variety of inflammatory cells, predominantly macrophages, as well as multinucleated giant cells consistent with a foreign body reaction (Fig. 2B). Multiple lipid droplets were also observed within this inner zone.

Case 2

A 35-year-old woman had undergone a bilateral breast augmentation 30 months previously with Trilucent breast implants being inserted into subglandular pockets. Two weeks postoperatively a haematoma on the right side had been evacuated. At 30 months post-implantation the patient started to complain of pain and lumpiness in both breasts, worse on the right. Baker grade II capsules were noted with the implants being readily palpable. A change of implants and capsulectomies were performed. An identical macroscopic appearance to Case 1 was noted in both breasts with similar histological findings.

Discussion

Trilucent breast implants are filled with soybean oil and were named so, as the filler is a triglyceride mixture and the implant is radiolucent. When introduced in late 1994 in the USA and 1995 in the UK, they were hailed as a major advance in the field of breast implants. They were vigorously promoted as a safer and better alternative to silicone- and saline-filled implants.

Animal studies were conducted in rabbits looking at various aspects of oil-based implant bleed and rupture over a period of 5–6 months.2 The studies concluded that although there was a bleed of oil across the silicone elastomer shell, this was easily absorbed and metabolised by the surrounding tissues. Capsules were found to be thin and soft. The histology showed an acellular capsule with no foreign-body reaction or inflammation.

Despite concerns raised by some regarding the metabolism of the oil filler in the body on bleed or rupture of these implants,3,4 they were declared safe and were vigorously promoted.2,5 No objective clinical

SUMMARY. We present two cases (three implants) of symptomatic local tissue reactions to Trilucent breast implant bleeds. The implant shells had changed their colour and texture. Capsule histology showed foreign body reaction and inflammatory changes. These findings question the safety of these implants. © 2000 The British Association of Plastic Surgeons

Keywords: breast augmentation, soya oil, Trilucent, inflammation.
findings associated with the bleed or rupture of Trilucent implants have been published to date.

The cases that are presented confirm the known bleed of Trilucent implants.\(^2\) In marked contrast to the original suggestion that this caused no local tissue effects, our cases reveal a very significant inflammatory and foreign-body response. This reaction may account for the symptoms in our two cases and also of the patients described in the health service circular. Also of note is the presence of multiple lipid deposits indicating that this oil is not readily absorbed. Of concern is the potential for breakdown of this lipid, which is suggested in our cases not only by the presence of a rancid smell but also by the multiple yellow nodules (confirmed as lipid on histology). There are no long-term studies that focus on this area. Lastly, the silicone elastomer appears to have undergone a significant change, possibly as a result of lipid infiltration. This renders rupture much more likely. It is known that some silicone elastomer formulations can absorb lipids resulting in swelling and a decrease in their tensile strength.\(^5\)

References


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