testicular prosthesis: a cause for chronic fatigue? *BJU Int* 2000;**86**(9):1090.

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Histological appearances of Trilucent™ breast implant capsules

There have been several papers published on Trilucent implants, discussing patient satisfaction, inflammatory response, explantation and chemical analysis of the triglyceride filter, following recall of Trilucent implants by the Medical Devices Agency (MDA) in 1999.[1] A small number of these studies have examined the histological appearances of the explanted capsules.[2–5] We have examined 58 Trilucent Breast Implant capsules both macroscopically and microscopically. The capsules were removed from 34 women following recall by the MDA. To the best of our knowledge there were no complications associated with the implants.

Thirty-three of the 58 cases when examined macroscopically had numerous small yellow nodules on the capsule surface. These yellow nodules were presumed to be lipid. There was no evidence of acute inflammation or calcification. In 44 cases there was a variable foreign body response together with chronic inflammation and refractile nonpolarising material within the capsules, assumed to be oil that had leaked from the implant (Fig. 1). All of the 33 cases that had yellow nodules macroscopically, histologically showed refractile material in the capsule together with a foreign body response. Synovial metaplasia was identified in 14 cases, eight of which were associated with villous hyperplasia but not with a foreign body response or refractile material (Fig. 2). All cases with villous hyperplasia showed no evidence of foreign body response or leakage of oil.

Original animal studies on the cellular reactions to oil-based implants found no foreign body reaction to the oils and the capsules were thin and soft on examination.[6] Recent published reports,[2–5] in contrast to the original animal studies, describe an inflammatory foreign body response to the implants

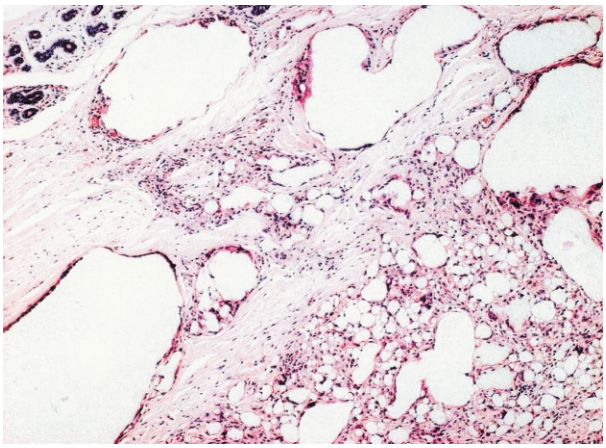

Fig. 1 Florid inflammation with multinucleated foreign body giant cells surrounding refractile material (seen as empty spaces of variable size).

with the presence of lipid deposition in the capsular tissue. The majority of the reports describe four consistent features: intense inflammation with foreign body reaction, refractile material within the substance of the capsule, synovial metaplasia and villous hyperplasia. Of the 58 capsules we examined not all showed these four features in combination. When villous hypertrophy and synovial metaplasia occurred together there was no associated foreign body response or refractile material (oil). Flat synovial metaplasia was noted in seven biopsies, four of which showed no evidence of foreign body reaction or refractile material, but in the remaining three mild to moderate foreign body reaction and refractile material was present.

In summary, it appears that without leakage of the oil the response is synovial metaplasia with villous hypertrophy but following leakage of the oil a foreign body reaction of variable severity occurs. Leakage of oil was evident in 44 of 58 cases and as

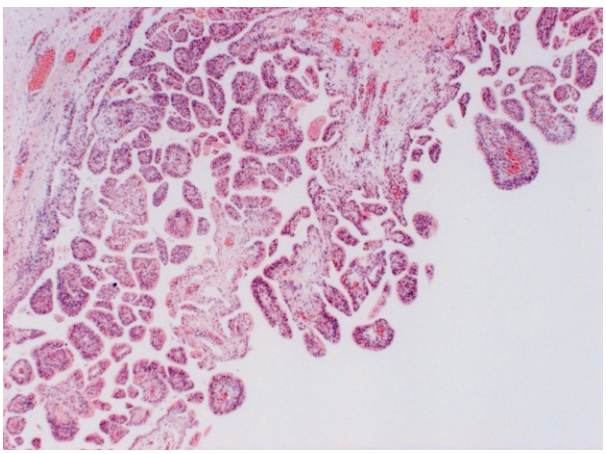

Fig. 2 Synovial metaplasia with florid villous hyperplasia.

the genotoxicity of this material is uncertain,[7] we feel the recommendations regarding explantation are justified.

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