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A retrospective audit of Novagold™ 'hydrogel' breast implants☆

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Summary Novagold™ breast implants were withdrawn from use in the UK in December 2000 due to concerns about the metabolic fate of the implant filler material, the hydrogels polyvinylpyrrolidine (PVP) and guar gum. A total of 250 women in the UK had these implants, 66 of which were performed in our unit. A total of 44% of cases needed further surgery for complications. Capsular contracture requiring surgical intervention occurred in 32%. Symptomatic ruptures occurred in 10.5%. Infection was recorded in 1.5%. From comparison with published data, the incidence of capsular contracture is comparable, but the occurrence of rupture is almost twice that of saline-filled implants. It is hypothesised that an osmotic gradient occurs due to the hydrogel filler causing the implants to swell and weaken the elastomer shell. When the PVP/guar gum filler is released into the subcutis, a vigorous tissue reaction occurs causing pain and swelling. These results show that this composition of implant poses potential risks, which should be considered by manufacturers in the future. We advise removal of symptomatic implants, as rupture is likely to have occurred.

Novagold™ breast implants (Somatech Medical Ltd, UK) were introduced to the UK in 1996 as a viable alternative to silicone breast implants. It was at this time that confidence in silicone breast implants had been shaken by claims of an increased risk of malignancy, autoimmune disease and connective tissue disorders associated with silicone implants.[1] A number of alternative breast implants appeared on the market in the mid-1990s that did not contain silicone as a filler material. Two manufacturers used hydrogels as the filler material contained within a silicone elastomer shell. The Novagold implant used polyvinylpyrrolidone, a synthetic hydrogel, and guar gum, a natural hydrogel, as a filler, within a textured shell. Polyimplant Prosthesis™ (PIP; Clover Leaf Products, UK) used the natural hydrogel, hydroxypropylcellulose, as the filler. Similar implants also introduced at this time included the Trilucent™ implant (AEI Inc., USA), which had a lipid filler based on soya

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bean oil. These implants were reported to have a more natural feel, be radiolucent and were seen to be 'bio-friendly' due to their organic constituents.

All three of the aforementioned silicone implant alternatives were withdrawn in the UK between 1999 and 2000. Over 4500 women had Trilucent breast implants, 4000 had PIPs, and 250 had Novagolds implanted in England, Scotland and Wales between 1994 and 2000. Trilucent implants and PIPs had a high incidence of rupture and painful swelling of the breast.[2,3] All three implant types had undergone flawed preclinical trials and the metabolic fate of the filler materials had not been fully investigated. The Trilucent implants were advised to be explanted due to potential peroxidisation of fatty acids within the soya bean oil if released from a ruptured implant, with the subsequent production of malondialdehyde which has been shown to be genotoxic and carcinogenic in animal studies.[4] Novagolds and PIPs had no evidence of such toxicity from their fillers so the advice was to only explant if symptomatic.[3] No specific studies of Novagold implants citing any potential complications after implantation had previously been performed, but due to their similarity with PIPs, the same advice for subsequent management was given by the Medicines and Healthcare Regulatory Authority (MHRA).

Between 1997 and 2000, 104 patients in the Lancashire region had Novagold breast implants, 66 of these performed within the Department of Plastic & Reconstructive Surgery, Lancashire Teaching Hospitals NHS Trust. We present the results of an audit of Novagold breast implants.

Methods

All cases of breast augmentation using Novagold breast implants were traced from operating theatre records within the Department of Plastic & Reconstructive Surgery between the dates of 1 March 1997 and 28 February 2000. Medical case notes were retrieved and results were gathered via a retrospective case note review using an audit proforma. Information such as patient details, demographic details, operative indications, operative details, implant details and any complications were recorded. The information was then input into a Microsoft Excel spreadsheet for subsequent analysis. All cases of breast augmentation used a standard subglandular breast implant placement, whilst breast reconstruction used a latissimus dorsi pedicled musculocutaneous flap with subsequent subpectoral or subcutaneous implant placement.

Results

The time frame concerned in this audit was from March 1997 to the product withdrawal in February 2000. A total of 66 operations involving 64 patients were performed involving 103 Novagold implants. Two patients had existing Novagolds replaced with Novagolds prior to the product recall. The average age of patients was 38.7 years (range 12—73 years).

Forty-two procedures were primary implant procedures whilst the remaining 24 were revision procedures for existing breast implants. The initial indications for the 42 primary implant procedures were: bilateral breast hypoplasia in 17 cases; breast asymmetry in 14 cases; and breast reconstruction after mastectomy in 11 cases. The 24 revision procedures involved 18 cases of breast implant capsular contracture, five cases of previous implant rupture and one case of previous implant infection with delayed re-insertion of the implant (Fig. 1).

The operative procedure carried out involving the Novagold implant in the 42 primary implant procedures was unilateral breast augmentation in 23 cases and bilateral breast augmentation in 19 cases. The implant revision procedures included 13 replacements after capsulotomy, five replacements after capsulectomy and six direct replacements after previous implant rupture or infection.

Complications requiring further surgery occurred in 29 patients from the total of 66 operations, or 44% of the total case load. These complications were either capsular contracture, implant rupture, or implant infection. The complication rates were capsular contracture in 32% of cases, implant rupture in 10.5%, and infection in 1.5% (Fig. 2).

Capsular contracture requiring further surgery occurred in 21 patients (32%). Eight per cent of these occurred after primary augmentation and 24% after reconstruction or revision. Recurrent contracture, occurring in five patients, was associated with radiotherapy to the breast in 80% of cases. The average time for re-operation was 36 months (range 8—74 months) after the initial Novagold implant procedure.

Ruptured implants occurred in seven patients and these were diagnosed either clinically or on ultrasound scan. All of the patients were symptomatic with painful swollen breasts (Fig. 3). The implants were of various volumes from 160 to 270 ml. Six patients had replacement procedures while one patient had the implants removed bilaterally without subsequent replacement. Re-operation occurred on average after 42 months (range 13—86 months).

Discussion

Hydrogels are natural or synthetic polymeric macromolecules that have the ability to retain water within their structure without dissolving in solution. Polyvinylpyrrolidone (PVP or povidone) is a synthetic polymer of N-vinylpyrrolidone. It has had various medical applications since

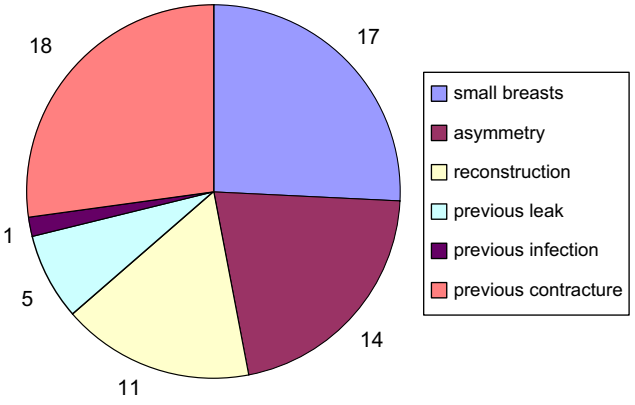

Figure 1 Indication for Novagold breast implants, $n = 66$.