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

J. Hardwicke*, N.R. Gaze, J.K.G. Laitung

Department of Plastic & Reconstructive Surgery, Lancashire Teaching Hospitals NHS Trust, Royal Preston Hospital, Sharoe Green Lane, Fulwood, Preston PR2 9HT, UK

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Summary Novagold™ breast implants were withdrawn from use in the UK in December 2000 due to concerns about the metabolic fate of the implant filler material, the hydrogels polyvinylpyrrolidine (PVP) and guar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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* Corresponding author. Address: Wound Biology Group, School of Dentistry, Cardiff University, Heath Park Campus, Cardiff CF14 4XY, UK.
E-mail address: joe_1976@lycos.co.uk (J. Hardwicke).

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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

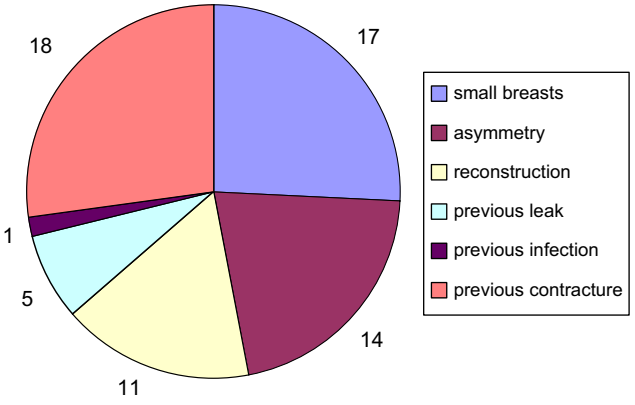

Figure 1 Indication for Novagold breast implants, $n = 66$.

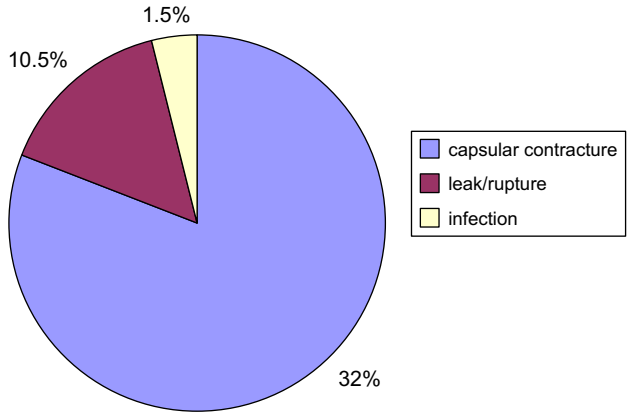

Figure 2 Complications requiring further surgery.

its introduction including as a plasma expander, biomedical coatings and carrier molecule for iodine in surgical scrub solution. It is inert and can be metabolised by the kidneys if the molecular weight is less than 40 kD. The range of PVP applications has reduced since reports in the medical literature of PVP storage disorders related to intravenous usage.[5] Accumulation of PVP within renal mitochondria, the reticuloendothelial system and cellular lysosomes can occur with larger molecules of over 100 kD molecular weight.[6]

Novagold implants also contained guar gum in the filler material. This acts as a thickening agent to allow the PVP hydrogel to attain a more natural feel. Guar gum is an extract from the seed of the leguminous shrub *Cyamopsis tetragonoloba* where it acts as a water and nutrient store, and is itself a natural hydrogel. Guar gum is made up of non-ionic, polydisperse rod-shaped polymers of 10 kD molecular weight. It is an economical thickener and stabiliser and is used in a variety of foodstuffs for this purpose. It is inert and is not absorbed from the gastrointestinal tract. It is also thixotropic — meaning that when it is agitated it becomes more liquid but when left to rest will reform back to a more thick gel-like status.

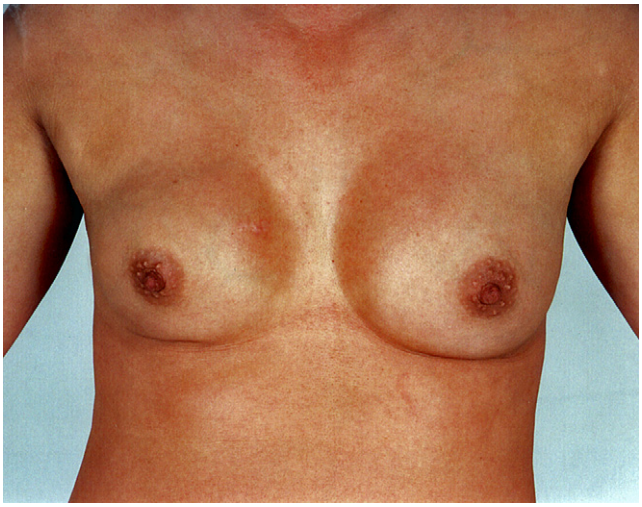

Figure 3 Left-sided implant rupture with swelling of the breast.

The Novagold hydrogel breast implants, from the results of this audit, appear to have a higher than expected incidence of implant rupture. Textured saline implants have a reported incidence of capsular contracture of 15—34% of cases in a similar time frame to this audit and a rupture incidence of 6%.[7,8] Textured silicone implants have a reported incidence of capsular contracture of between 11 and 34%[8,9] after 3 years but have a lower symptomatic implant rupture, with bleeding of the filler material, due to the cohesive silicone gels now used by most manufacturers.[10] The findings of this audit show that Novagold breast implants had a capsular contracture incidence similar to that of textured saline implants. The incidence of rupture in the Novagold implants was nearly 100% greater than the equivalent saline implant. The occurrence of rupture is similar to that of the Polyimplant Prosthesis hydrogel implant of 11.4% after 3 years.[11] Incidence of infection associated with Novagolds was comparable to other implant types at 1.5%.

The main finding of this audit was that in all cases of implant rupture there was an associated painful swelling of the breast with a large amount of fluid collecting within the breast implant envelope (Fig. 4). The fluid was sterile and acellular but accumulated in large volumes disproportionate to the size of the breast implant involved. These findings are similar to those that occurred with Polyimplant Prostheses, Trilucent implants and, historically, MISTIGold implants,[12] leading to the overall product withdrawal.

Although both constituents of the Novagold implant filler, PVP and guar gum, have been shown to be inert and non-toxic when applied topically or ingested, it appears that in the subcutaneous situation, they provoke a vigorous tissue reaction causing the production of large volumes of inflammatory exudates. The combination of acute

Figure 4 Sterile acellular inflammatory exudate caused by a 240 ml Novagold implant.

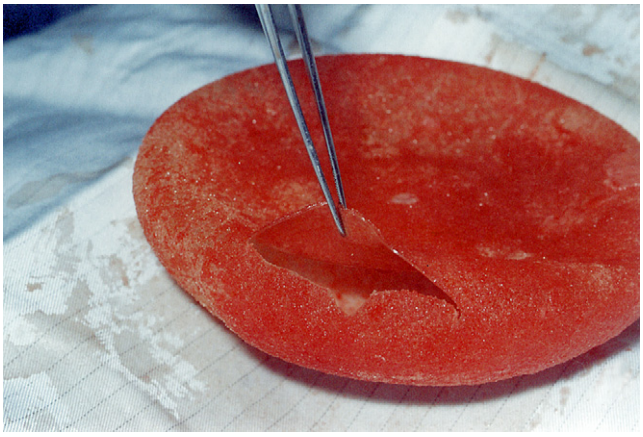

Figure 5 Area of weakness in the implant shell leading to rupture.

inflammation and stretching of the breast implant capsule leads to the ubiquitous painful swelling of the affected breast. This may mimic an infection, but as we have shown, it is a sterile inflammatory condition that nevertheless requires explantation of the ruptured implant.

We also hypothesise that due to the high oncotic pressure of the PVP hydrogel, an osmotic gradient may be produced across the implant shell leading to initial swelling of the implant which may have exposed any weakness within the shell leading to rupture (Fig. 5). When the filler bleeds into the local subcutis the described tissue reaction then occurs.

In summary, the results of this audit show that the Novagold implants have a higher risk of implant rupture compared to silicone or saline implants. Importantly, no life-threatening complications were recorded. It was wise for the product to be withdrawn in light of the complications. Our advice is to only remove the implants if symptomatic and, if swollen and painful, it is highly likely that the implant has ruptured. Asymptomatic implants can be safely left in situ if they are encountered in surgical practice, as the biological properties of the implant do not appear to affect the patient unless the filler has leaked from the implant.

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