

Rupture of a Hydrogel-Filled Breast Implant

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In the early 1960s, Cronin and Gerow began to use a silicone bag filled with silicone gel for breast augmentation. Since then, researchers have been looking for different filler materials.

An ideal prosthesis does not induce any tissue reaction, is stable, gives the breast a natural appearance, and is radiolucent during mammography. In case of rupture of the envelope, the filler material should be biocompatible, nontoxic, noncarcinogenic, nonteratogenic, and easy to remove during operation. The advantage of using a silicone gel is the natural feeling of the implant and the chemical stability of the gel.¹

Because of the radiodensity of silicone gel, there are difficulties in interpreting mammograms in women with silicone gel-filled implants, thus rendering them less reliable.^{2,3} Therefore, materials that were more radiolucent were tested.^{4,5} In 1992, U.S. the Food and Drug Administration restricted the use of silicone gel-filled breast implants in the United States because they feared silicone-associated diseases.

Carboxyl methyl cellulose is a hydrogel used in the Monobloc breast implant (Laboratoires Arion, Lyon, France). As the manufacturer claims, the prosthesis feels natural, is nonallergenic, and induces less capsular contraction. The filler material is biodegradable and radiolucent.⁶ As a result, this filler material can be attractive in countries where the use of silicone-filled breast implants is limited by strict regulations. For patients with a higher risk of breast cancer, a more radiolucent breast implant is necessary for better interpretation of mammograms. Also, for patients anxious about carrying silicone material in their body, the hydrogel-filled breast implant can be an attractive alternative.

CASE REPORT

We present a case of a 30-year-old patient with a unilateral increase in volume of one breast. She underwent bilateral breast augmentation 2 years previously. Monobloc, hydrogel-filled textured shell implants were placed in the subglandular position. On her left side, a 240-ml prosthesis was placed, and on her right side, a 260-ml prosthesis was placed. The operative procedure was performed without any complications. One year after operation, our patient suffered from stomach ache and gripe. She visited her physician for several months. Objective signs or symptoms were absent. Laboratory blood results were normal at that time. In the next period, she noticed that her breast size was not constant. She claimed that her left breast had shrunk once in a while.

Two years postoperatively, she reported for her yearly checkup. She mentioned that her left breast had lost volume in the last 2 weeks and the right breast size was not changed. At the same time, she had noticed a sensitive swelling in her right axilla. There were no other complaints.

On examination, it seemed that the left breast was of normal size, whereas the right breast had increased in volume (Fig. 1). The left breast was not red or painful. In her right axilla, a round and painful tumor, with a diameter of 1 cm, was noticed. Both breasts felt smooth (Baker I). Her body temperature was normal.

Laboratory blood results on liver, kidney, inflammation, and coagulation parameters were all normal. Because to us it seemed clear that the right prosthesis was leaking, we advised our patient to have it replaced. She elected to undergo explantation of both implants and have them replaced with silicone gel-filled prostheses with the same (larger) volume as her right breast.

Two days later, she was operated on. On opening the implant cavity of the right breast, we found a seroma-like substance, with a clear, yellowish aspect. The right prosthesis was ruptured on the edge (Figs. 2 and 3). Inspection of the cavities showed no difference in capsule formation between both sides. After rinsing both cavities thoroughly with a povidone-iodine solution, augmentation was performed with two textured silicone gel-filled prostheses. Culture swabs taken during operation revealed no infection. There were no complications after operation (1-year follow-up). The painful tumor in her right axilla disappeared in 2 weeks.

DISCUSSION

Hydrogel-filled breast implants have been used in The Netherlands since 1995. More

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FIG. 1. The right breast is swollen and contains a ruptured hydrogel-filled implant.



FIG. 2. Point of scissors shows the defect in the ruptured prosthesis.



FIG. 3. Yellowish (ruptured) right breast prosthesis.

than 3300 have been implanted until now. Exact data on failure of these implants are not available at this moment.

Hydrogel breast implants consist of a silicone elastomer shell containing hydrogel filler. Hydrogels are polymeric materials that have the ability to swell in water without dissolving and retain water within their structures.⁷ This explains the swelling of the breast containing the leaking implant. Swelling of the lymph node, as presented in this case, is possibly caused by staining of carboxyl methyl cellulose in the lymph node and its hydrophilic characteristic. Another hypothesis is that swelling is caused by an inflammatory reaction.

The possible cause of rupture can be repetitive stress at the site of the envelope, causing

weakening and fracture of the fold.⁸ This is also why the Food and Drug Administration has set a “fatigue testing protocol” to be predictive of clinical failure for breast implants.⁹

Exact data on the behavior of these prostheses in vivo have not been published yet. Both in France and in England, hydrogel-filled breast implants were withdrawn from the market as a precautionary measure, because there is not enough information on the behavior of this filler material in the human body.^{10,11}

Capsular formation around an implant can be a desirable tissue reaction. In the event that a filler material is able to initiate an unwanted tissue reaction, for example, the formation of siliconoma, the capsule can form a “natural” barrier between the leaking material and surrounding tissue. In this case, there was no sign of a capsule.

SUMMARY

New filler materials for breast prostheses are introduced to meet patients’ satisfaction and safety requirements. These new materials should be tested according to a standardized test protocol. Even then, it still might be possible that unknown reactions to the filler material or envelope appear only after years of use.

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