



# Acute Immunologic Reaction to Silicone Breast Implant after Mastectomy and Immediate Reconstruction: A Case Report and Review of the Literature

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#### ABSTRACT

**Background:** Since the introduction of silicon-based medical devices into clinical practice, several reports appeared in the medical literature regarding their adverse effects. However, there are few reports of immunologic reactions to these implants.

**Case presentation:** A case of systemic reaction to a breast implant inserted for immediate breast reconstruction in a breast cancer patient is presented. The patient developed fever and skin rash two months after the surgery. Investigations disclosed no infectious origin for the fever, though an immediate response to steroid therapy was observed.

**Conclusion:** Immunologic reaction should be considered in case of systemic signs and symptoms after silicone breast implant placement as a rare complication.

#### Introduction

Silicone became commercially available since 1943<sup>1</sup> as a polymer of dimethylsiloxan with molecular structure consisting of long chains of alternating silicon and oxygen atoms. Depending on the length of polymer chain and crosslinking, silicone can take fluid, gel or solid forms.<sup>2</sup> Silicones are widely used in manufacturing medical devices

Address for correspondence: Dr Ali Aminian, M.D. Address: Bariatric & Metabolic Institute, Cleveland Clinic, 9500 Euclid Avenue, Desk M61, Cleveland, OH 44195, USA Phone: 001 216 445.5098 Fax: 001 216 445 1586 Email: aminiaa@ccf.org including cerebrospinal fluid shunts, intravenous tubing, drug delivery systems, cardiac valves, arthroplasty prostheses, breast implants, intraocular lens implants and cochlear implants.<sup>2, 3</sup> Since the introduction of silicone based medical devices into clinical practice, several reports appeared in the medical literature regarding their adverse effects such as systemic and local allergic reactions.<sup>3-6</sup>

In this case report, the immunologic reaction to a breast silicone implant is presented in a breast cancer patient who underwent mastectomy and immediate breast reconstruction with a silicone implant.

#### **Case Presentation**

A 51-year-old post-menopausal woman was referred to our breast clinic for evaluation of an



Figure 1. Before the breast conserving surgery (first operation)



**Figure 2.** Skin rash on the chest and abdomen after the second operation.

abnormal finding in screening mammography. She had a positive family history of invasive ductal carcinoma of the breast in her 54-year-old sister. She had three full-term pregnancies and 29 months of lactation in total. The history was negative for oral contraceptive pills (OCP) use or post-menopausal hormone replacement therapy (HRT). She had undergone breast biopsy 4 years ago, with the pathology report of fibrocystic changes and sclerosing adenosis. There was no personal or family history for ovarian and colon cancer.

Physical examination revealed nodularity in the site of previous surgery. On mammography, an irregular density with suspicious microcalcifications was detected in the lower inner quadrant (LIQ) of the right breast (BIRADS category IV). Ultrasonography showed a parenchymal distortion measuring  $16 \times 8 \times 6$ mm compatible with the mammographic findings. Stereotactic core needle biopsy was performed and the pathology report revealed invasive lobular carcinoma (ILC). MRI did not reveal any concomitant lesions in ipsilateral and contralateral breasts.

The patient underwent breast conservation surgery with superior pedicle reduction mammoplasty technique after wire localization of the lesion. The tumor was removed with wide margins and sent to the pathology laboratory. In order to reshape the breast, the lower outer quadrant (LOQ) of the same breast was resected symmetrically and was sent for the pathological evaluation separately. At the end of intervention, sentinel lymph node dissection was performed. It was decided to postpone the symmetrization of the contralateral breast.

Sentinel lymph nodes were free of tumor on frozen section and on permanent pathology reports. A 22 mm ILC was detected in the LIQ of the breast with clear resection margins. The pathologist found a 7 mm focus of ILC in the second part of the specimen (from the LOQ) at the resection margin which was not detectable in preoperative MRI.

Considering the multi-centric disease in the breast, simple mastectomy and immediate breast reconstruction with silicone gel breast implant (CEREFORM 515 cc anatomic ATH prosthesis) was performed (Figure 1). No complications occurred in the postoperative period.

Three weeks later, chemotherapy with Adriamycin and Cyclophosphamide was administered. After the third session of chemotherapy, the patient developed fever, skin rash and pain at the surgical site.

At the time of re-admission to the hospital, the patient had a fever of 39°C. Physical examination showed no abnormalities except for skin rash on the anterior surface of chest and abdomen (Figure 2). Laboratory investigations were performed to rule out deep vein thrombosis, urinary tract infection, thrombophlebitis and other rare conditions such as tuberculosis, brucellosis and hepatitis. Assess-ments showed no specific positive findings in favor of infection, except small fluid collection which was observed in breast ultrasound in the medial and lateral part of the implant.

Despite negative findings of the investigations, empiric antibiotic therapy with Imipenem, Vancomycin, Amikacin and Amphotericin B was initiated. After 5 days of antibiotic therapy, the patient was still febrile and thus antibiotics were discontinued.

After 14 days of unresolved fever in spite of extensive investigations and empiric treatments, the site of surgery was explored in order to examine for surgical site infection around the implant and surrounding tissues. The skin was erythematous; however, the implant was normal without any leakage or purulent collections, except for 15 cc of clear serous fluid which was aspirated and sent for smear and culture. The smear showed no microorganisms or white blood cells (WBC) and the

culture was negative after 72 hours. Thus, the implant was not removed.

After ruling out the infectious causes, immunologic reaction to silicone implant was suggested as the potential etiology of fever. Accordingly, corticosteroid therapy with Dexamethasone 8 mg q12 h was initiated. After the first dose of dexamethasone, the patient became afebrile and other symptoms subsided. The patient was discharged from the hospital with a low dose of oral corticosteroid (Prednisolone 5mg q12h) and received the remaining chemotherapy courses without any complications. Prednisolone was discontinued gradually after 2 months. During 12 months of follow up, the patient reported no abnormalities at the surgical site.

### Discussion

Breast implants are one of the most widely used silicon-based medical devices. Silicone gel-filled breast implants have been studied rigorously for their safety and adverse outcomes.

Since the introduction of silicone gel-filled breast implants, numerous reports suggested the association of silicone gel-filled breast implants and autoimmune phenomena.<sup>7-11</sup>

McLaughlin addressed specific safety issues regarding silicone gel-filled breast implants in a review article.<sup>12</sup> He summarized the epidemiologic evidence on the topics related to breast implant safety issues including connective tissue disease, suicide, neurologic disease, implant rupture, and local perioperative complications and additional surgery. He concluded that the epidemiologic evidence does not support a causal association between breast implants and breast or any other type of cancer, definite or atypical connective tissue disease, or neurologic disease and it does not hamper the diagnosis of breast cancer.

Although the association of breast implants and connective tissue diseases has not been proved, there are several reports related to the local and systemic adverse effects of silicone implants.

Genovese presented a patient who developed fever, skin rash and arthritis after her breast implants were replaced due to capsular contracture. The patient developed maculopapular skin rash 3 weeks after the procedure. The rash started at inframammary fold and spread to her torso and extremities. Three months later, she developed arthritis and intermittent high grade fever. Extensive diagnostic evaluations for infectious diseases were negative. Autoimmune work-ups for rheumatologic diseases were negative excep for an elevated erythrocyte sedimentation rate (ESR). She gradually developed cough and shortness of breath, altered mental status, anemia and low-grad e disseminated intravascular coagulation (DIC) and generalized edema. The symptoms improved with the initiation of steroid therapy. In an extensive and detailed discussion, the authors concluded that her symptoms only could be explained with Adult-Onset Still's disease.<sup>13</sup>

Sabbagh reported a case of idiosyncratic allergic reaction to a textured saline implant. The patient developed painful, pruritic lesions of the scalp, chest, and arms 5 months after implantation of Siltex Becker tissue expander mammary prostheses. Biopsy of the lesions revealed perivascular lymphohistiocytic infiltrate. An allergic reaction to Becker implants was considered as the cause of the lesions and patch testing with representative material provided by the manufacturer was performed. It revealed reaction to the textured shell patch as the cause of the lesions. All lesions disappeared after removal of the implants. In their review of the literature, they suggested that this case was different from other reported cases, as the patient had an acute idiosyncratic allergic reaction which was not previously reported.<sup>14</sup>

Dargan reported a case of type IV hypersensitivity reaction to silicone breast implant.<sup>15</sup> In this case report, three weeks after insertion of a silicone breast implant, the patient presented with pain and swelling at the surgical site, serous discharge from the wound, low grade pyrexia and flue like symptoms. The implant was removed and the systemic symptoms subsided rapidly. Biopsy of the capsule revealed a delayed hypersensitivity reaction.

Other studies have considered silicone breast implants as a probable cause of immunological response with resultant systemic features. In the published case report by Blasiak *et al* a patient with breast implants presented with fever and skin rash. All the investigations for an infectious cause of the fever were negative. Finally, the potential relationship between her symptoms and silicone implant were considered and the patient was treated by corticosteroids and implant removal.<sup>16</sup>

Silva *et al* compared inflammatory reactants before and after implantation of breast silicone prosthesis. The results indicated that C-reactive protein (CRP) increases after implantation of silicone prosthesis. This result indicates the probability of inflammatory reactions related to the silicone breast prosthesis.<sup>17</sup>

In our setting, patch testing was not available. However, due to detection of no infectious causes and a dramatic response to corticosteroid administration, we suggested that the patient developed an immunologic reaction to the implant. To conclude, immunologic reaction should be considered in case of systemic signs and symptoms after silicone breast implant insertion as a rare cause.



The authors declare no conflict of interest.

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