

# Unusual Skin Reaction to Silicone Content in Breast Implants

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**We present a patient who had a long history of unsuccessful bilateral mammary operations with insertion and extraction of various implants, some of which were filled with silicone gel, others with saline. In addition to complications in the tissue surrounding the prosthesis, she had distant widespread skin lesions which, we believe, were due to leakage from the implant. A cutaneous test with material from various implants, such as the gel content and the shells, caused an unusually prolonged inflammatory response, which was difficult to classify as being either irritative or allergic. Macromorphologically and histologically, the provoked lesions resembled the previous cutaneous lesions. We believe that the patient's complications are due to an unusual host response to silicone. Key words: silicone breast implants; leakage; inflammatory response.**

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Silicone breast implants have been used for breast augmentation and reconstruction since the early 1960s. Most patients tolerate the implants, but some authors believe that there may be a relationship between connective tissue disease and silicone leaked from the prostheses (1). Prospective and retrospective epidemiological investigations have shown no differences between patients with or without implants as regards the frequency of symptoms of rheumatic disease or scleroderma (2, 3). Silicone has also been used for skin augmentation, to fill up wrinkles, lips and acne depression scars. Among such patients, migration of silicone has been described, as well as various host reactions, such as granulomatous nodular cellulitis and facial ulcerations (4–6). These case reports suggest a possible individual host reactivity to silicone. We believe that the case described here belongs to this group, since we were able to induce an unusual type of skin reaction with the silicone gel from the breast implant and the prosthetic shell.

## CASE REPORT

A 57-year-old Caucasian female, who had been pregnant 4 times, suffered from intermittent brown discharge from both breasts after her last delivery in 1968. Extensive investigations resulted in a diagnosis of benign fibroadenomatosis. Because of her persistent symptoms, a subcutaneous left mastectomy was performed in 1981, using immediate reconstruction with a mammary implant followed by a similar operation one year later on the other side. For a summary of the surgical history over the years see Table I. She also had chronic microscopic haematuria for which examinations revealed no cause.

### *Cutaneous history*

After the right musculus latissimus dorsi plasty (Table I), the patient developed a red, well-demarcated exudative lesion over the right scapula in the area around the scar that would not heal (Fig. 1). There was

no reported rupture or leakage from the implant during the operation. A biopsy showed cicatricial dermatitis with hyperplastic epidermis, intra- and extra-cellular oedema, hypogranulosis and parakeratosis. In some places spongiform pustules were seen. There was oedema in the papillae and cell infiltrates around the superficial vessels, consisting of lymphocytes, histiocytes, plasma cells and eosinophils, but no neutrophils were seen. The connective tissue was rich in fibrocytes, fibroblasts and vessels. The deeper parts of the dermis and adnexal structure were healthy.

Similar exudative cutaneous lesions developed adjacent to a scar on the right upper arm and on the lower extremities without history of trauma. Some of them enlarged more than 10 times during a 3-month period. A magnetic resonance image investigation of these areas was done and no signs of silicone deposits could be seen (7).

### *Treatment*

Various topical and systemic treatments were tried. Topically, ordinary zinc lotion was superior to steroids. Systemic administration of sulphasalazine, azathioprin, methotrexate and PUVA did not affect the condition but some relief was obtained with oral steroids.

### *Laboratory investigations*

Various blood tests were performed, all of which were within normal limits, i.e. complete blood count, liver enzymes, antinuclear antibodies, rheumatoid factor, antibodies towards basal membrane and against keratinocyte membranes. Urinalyses revealed intermittent microscopic haematuria.

## EPICUTANEOUS TESTING

The results were negative using European standard patch-test series and an extensive topical corticosteroid series (Chemotechnique Diagnostics, Malmö, Sweden). Gold sodium thiosulphate and palladium chloride induced a strong allergic reaction. Additional tests were performed (Finn Chamber technique), using material from a few prostheses: (a) the outer part of the capsule of the Heyer-Schulte<sup>®</sup> Implant; (b) the gel content of a McGhan-made prosthesis; (c) the outside capsule of the latter prosthesis; (d) the capsule of the Biocell<sup>®</sup> Implant (McGhan, Santa Barbara, CA, USA); (e) 5% sodium lauryl sulphate in water. The test material was removed after 48 h and read after another 24 h. The first 2 substances induced markedly erythematous, well-demarcated, oedematous and weeping lesions (Fig. 2). It was impossible to classify macroscopically the reaction as allergic or irritative. The histological examination showed that the epidermis was partly necrotic and contained a blister filled with amorphous substance. The granular cell layer was reduced and the stratum corneum thin and parakeratotic. Lymphocytes were scattered diffusely in the upper dermis, particularly around the vessels. The deep dermis and adnexal structures were normal. No silicone particles were seen in any of the histological specimens. Substance (c) and (d) produced no reaction and (e) had a toxic effect that faded away in a couple of weeks. The tests were read and photographed weekly for the first month and after three months and two years.

The patient also told us that 2 weeks after the test she developed fever and the lesions on her back became worse (Fig. 1). An infection on the test site was treated with antibiotics. Subsequently, the two positive, initially separate, test lesions became larger and confluent. After 2 months, the lesion measured 8 × 15 cm, and its macromorphological appearance was the same as that of the other lesions on her back and the rest of her body. The histology was similar to the lesions

Table I. *The various surgical procedures performed and mammary implants used over the years*

Year	Site	Implant	Implant content	Manufacturer	Indication Operation Symptoms
1981	Left breast	Heyer-Schulte <sup>®</sup> Insertion	Saline	Mentor Inc H/S, Santa Barbara, Ca, USA	Fibroadenomatosis mastectomy, 2 months post op., infection
1982	Right breast	Heyer-Schulte <sup>®</sup> Insertion	Saline	See above	Fibroadenomatosis mastectomy
1983	Left breast	Heyer-Schulte <sup>®</sup> Extraction and insertion	Double lumen: Outer saline, inner silicone gel	See above	Cleavage of fibrous capsule of the prosthetic cavity
April 1984	Right/Left breasts	Style80 <sup>®</sup> Replacement	Silicone gel	McGhan Medical Corporation, Santa Barbara, Ca, USA	Enlargement and reduction of each implant cavity
November 1994	Right breast	Style80 <sup>®</sup> Insertion	Silicone gel	See above	Reduction of implant cavity and reconstruction of areola mammariae
May 1985	Left breast	Style40 <sup>®</sup> Extraction	Silicone gel	Surgical Products Division/3M, St Pauls, MN, USA	Rupture of implant, seepage of gel
October 1995	Left breast	Style40 <sup>®</sup> Insertion	Silicone gel	McGhan Medical Corporation, Santa Barbara, CA, USA	
January 1986	Left breast	Style40 <sup>®</sup> Extraction	Silicone gel	See above	Infection
May 1986	Right breast	Style40 <sup>®</sup> Replacement	Silicone gel	See above	Cleavage of the fibrous capsule of the prosthetic cavity
1988–91	Abdomen				3 operations: Plasty of fundus ventriculi and removal of adhesences
June 1991	Left breast	Extraction			Persistent local pain. Recon- struction with musculus latissimus dorsi plasty. Post-operative infection
November 1991	Right breast	Extraction			Local pain and arthralgia Silicone leakage. Musculus latissimus dorsi plasty
February 1992	Left breast	Siltex <sup>®</sup> Insertion	Saline	Mentor Inc H/S (See above)	Failure of musculus latissimus dorsi plasty
July 1992	Left breast	Siltex <sup>®</sup> Replacement	Saline	See above	Pain and change of position of implant
1993	Right breast Upper arm				Removal of basal cell carcinoma

shown in Fig. 1. She was unwilling to have any more skin tests with various concentrations of pure silicone and other implants. Two years later, the lesion on the test site was still present, but it had decreased in size and measured 5 × 5 cm. The other cutaneous lesions showed no

change. Three patients who had vague symptoms, which they ascribed to the gel-containing mammary implants, were negative, using the same epicutaneous test procedure. For ethical reasons, no tests were performed on healthy subjects.



Fig. 1. The patient's back on her first visit to the dermatology clinic.

#### COMMENT

The patient has a more than 10-year history of complications following various gel-containing breast implants. The present discussion deals with the question whether, due to leakage, silicone could cause the severe dermatitis, or whether the complications were associated with the various implants tried. We believe that the reaction was due to leakage, since the skin reactions to the test with the implants used (gel content and shell) were initially mild and limited to the two patch-test areas. The skin lesions then enlarged and became confluent. The severity increased during the first 3 months and gradually regressed to less than 40% of the largest area after 2 years. Regarding the macro- and micromorphology the provoked lesions and those on other parts of the skin surface were similar. It was noteworthy that both the shell of the first saline-filled implant (Heyer-Schulte<sup>®</sup>) and the gel content of the mammary implant used for testing (McGhan) induced the unusual skin reaction. However, the shell of the latter prosthesis caused no skin

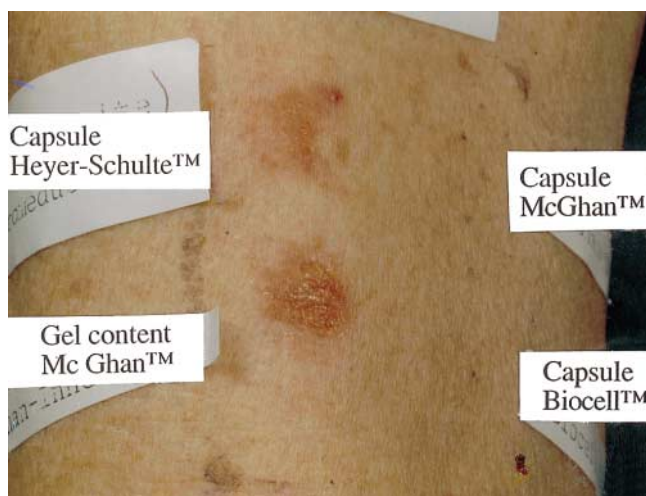


Fig. 2. Test site after 72 h.

reaction. The cutaneous reaction was probably caused by a common antigen, i.e. the silicone present in the gel and the shell. We do not believe that any contamination of the shell had occurred. Fumed silica (silicon dioxide) can be used to synthesize the elastomeric shell in both gel-filled and saline-filled breast implants (2). We consider that all the failures in the patients' implants may have been due to host reaction to components of the prosthesis, from the envelope or the gel content. Unfortunately, she was unwilling to undergo any other tests, so we cannot definitely state that the offending compound in the gel is silicone. Nevertheless, cutaneous provocation demonstrated an extraordinary cutaneous response to components of the breast prosthesis.

Since increased amounts of silicone have been reported in the tissue around breast implants, in the axillary nodes and the liver of a few patients, we know that silicone particles can migrate (6–9). The lesions of the patient described here were distant from the initial source. They were still present 2 years after the gel-filled breast prosthesis was removed. The occurrence of lesions outside the thoracic area suggests that internal migration of silicone could be responsible for the skin lesions that developed later. The fever and activation of the dorsal skin lesion following patch testing indicate a systemic effect.

This patient may exemplify of a type of contact reactivity to the gel content in mammary implants and the reactivity pattern described is probably due to silicone. Furthermore, we believe that the series of complications related to the breast implants may be due to a specific individual reaction pattern to silicone.

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