

Cutaneous Hypersensitivity-Like Reactions Associated With Breast Implants: A Review

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BACKGROUND Breast implantation is an increasingly common procedure for both cosmesis and reconstruction. Risk of cutaneous reactions to breast implants is low and typically described in postsurgical settings. Adverse skin hypersensitivity-like reactions to implants have also been reported but are not well described.

OBJECTIVE To review the scientific literature on cutaneous hypersensitivity-like reactions to breast implants.

METHODS A systematic literature review was conducted using PubMed. Articles pertaining to breast implants and cutaneous hypersensitivity-like reactions in humans were included.

RESULTS In total, 10 studies on hypersensitivity-like reactions from breast implants were included in the review. Potential allergenic compounds in breast implants include silicone, polyurethane texturing, and acellular dermal matrix. Perivascular lymphocytic infiltrate was a common finding on histopathology. Patch testing and preoperative silicone cube implantation were used to determine sensitivity. Attempted treatments included topical and oral corticosteroids, montelukast and antibiotics. Most cases required implant removal for resolution of symptoms.

CONCLUSION Cutaneous hypersensitivity-like reactions to breast implants seem to be rare complications, sometimes necessitating implant removal. Future studies are needed to establish their incidence and etiology, and the diagnostic role of patch testing and preoperative screening.

The authors have indicated no significant interest with commercial supporters.

In 1961, Cronin and Gerow¹ created the first breast implant consisting of a silicone envelope filled with viscous silicone and reinforced by a Dacron patch. A year later, Freeman performed the first breast reconstruction using this first-generation gel implant.² Since then, breast implantation for either cosmesis or reconstruction has become a common procedure in the armamentarium of plastic surgeons. In the United States, the Women's Health and Cancer Rights Act mandates that all health insurance companies provide reimbursement for reconstruction of both breasts after mastectomy.³ Because of this mandate, postmastectomy breast reconstructions increased from 46 percent in 1998 to 63 percent in 2007.^{4,5}

Over the past 5 decades, breast implants have evolved to optimize aesthetic appearance, while reducing risks of contracture, rejection, and infection. Today, the basic structure consists of a silicone outer capsule that can be either textured or smooth, filled with an inner gel consisting of silicone or saline. In general, there are 5 ways to classify the different types of implants currently available on the US market: fill (saline vs silicone), shape (anatomic vs round), degree of silicone molecule cohesion (firm vs pliable), and outer membrane (textured vs smooth) (Figure 1).^{6,7} The currently available textured silicone implants are created by forming the texture directly into the silicone shell. In the past, textured implants were constructed using polyurethane foam but were pulled from US market in 1989 because of the breakdown of

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ISSN: 1076-0512 • Dermatol Surg 2017;0:1–7 • DOI: 10.1097/DSS.0000000000001448

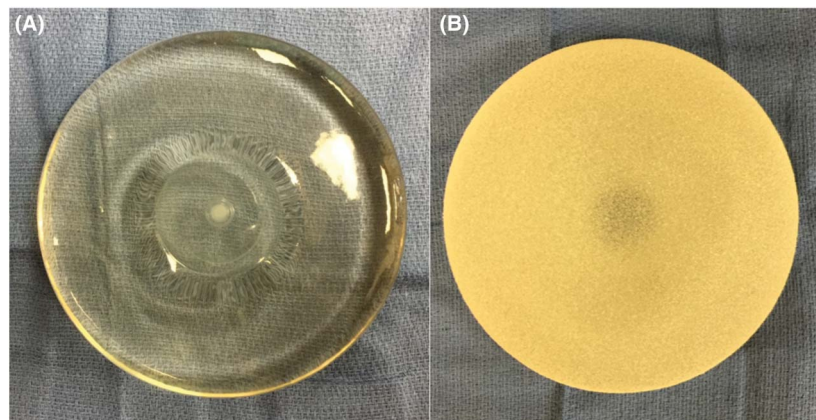


Figure 1. (A) Silicone smooth, round implant and (B) textured silicone implant.

polyurethane to 2-toluene diamine, a compound found to be carcinogenic in animals.⁸

Silicone is widely accepted to be a physiologically inert and biologically compatible compound. Once a point of debate in the medical community, claims regarding an association between silicone breast implants and long-term auto-immune/rheumatologic sequelae have been disproved by the scientific literature.^{9–12} Polydimethylsiloxane (PDMS) is the most common form of silicone, and is the material used in both the silicone envelope and silicone gel contained in breast implants.⁹ The behavior of silicone compounds is largely related to the degree of cross-linking. Although PDMS with a decreased degree of cross-linking has been used to yield a more natural looking breast, it may result in increased risk of PDMS molecules seeping through the implant encasing.⁹

To provide structural integrity and improved tissue ingrowth, more than 56% of breast reconstructions are now performed using acellular dermal matrix (ADM).^{4,13} Acellular dermal matrix is a form of biologic mesh, created through a process of tissue decellularization with an intact extracellular matrix, serving as a scaffold for vascularization.^{4,13} Acellular dermal matrix is primarily used as an inferior-lateral sling to help increase breast projection, avoid tissue droop, decrease capsular contracture rate, and improve implant coverage.^{4,14}

In general, cutaneous risks with breast implants seem to be low, with the most common complications being seroma, hematoma, pain, infection, or wound dehiscence.⁴ However, several reports have documented

the presence of cutaneous hypersensitivity-like reactions to breast implants, despite the biological compatibility and presumed inertness of their compounds. We review the literature pertaining to cutaneous hypersensitivity as a complication of breast implantation and the compounds implicated in those reactions.

Methods

A literature search on PubMed was conducted using the terms “breast implant” and “hypersensitivity” or “rash” with no set date range, which resulted in 67 articles. Only articles with information directly pertaining to humans were included. Publications were excluded if they were not published in English language, involved nonhuman models, or if the skin lesions were due to infection, dehiscence, seroma, or hematoma. Any publications referencing association between silicone and autoimmunity were excluded because the scientific literature has largely debunked any such claims. The initial 67 articles were reviewed by the first author (J.G.L.), and if the article was deemed relevant after title and abstract review, the entire article was further examined to ensure eligibility. Ultimately, 57 articles were eliminated using this filtering method, and in total, 10 studies with an aggregate of 14 patients were included in the review.

Results

Patient Presentation

Of the 10 studies included, 8 were case reports and 2 were case series. In total, 14 patients are analyzed in these studies.^{15–24} Table 1 outlines the type of implant, clinical

presentation, time course, treatment, and outcomes of each case. Most patients presented with skin findings of erythematous pruritic papules, patches, and/or pustules overlying the skin of the implanted breast with varying involvement of other body sites (Figure 2). The time course of cutaneous manifestations ranged from immediate to 43 months post-op, with majority of patients presenting within the first 5 months (12/14). One patient did not report mammary skin lesions but instead presented with a reaction of the cervix after implant rupture from a mammogram.¹⁶ Six of the 14 patients manifested systemic symptoms including fever ($n = 3$), arthritis ($n = 1$), seroma ($n = 1$), and breast edema ($n = 2$). One of these patients progressed to anasarca and arthritis, ultimately requiring inpatient hospitalization.¹⁸

Six patients had smooth silicone breast implants and 4 patients had textured implants (1 non-polyurethane-textured saline, 1 polyurethane-textured silicone, and 2 non-polyurethane-textured silicone). Of note, 3 of the reported patients were found to have ruptured implants (Kirwan, Dargan, and Koh): 1 with smooth silicone and 2 with non-polyurethane-textured silicone.^{16,21,24} Finally, Ganske and colleagues presented a case series of 4 patients who developed erythematous reactions overlying the region where ADM was placed, also known as “Red Breast Syndrome,” which is a noninfectious self-limited erythema.^{23,25,26}

Diagnostic Work-Up

Most diagnoses were based on the clinical presentation and history of recent breast implantation. Five cases reported results from skin biopsies, lymph nodes, and implant capsules, largely demonstrating lymphocytic cellular reactions.^{17–19,21,23} Finally, 4 of the studies used patch testing as part of the work-up. Two cases performed modified patch testing with non-polyurethane-textured silicone implants and found patients to be sensitive to the textured outer silicone surface and not the smooth inner layer.^{17,21}

Treatment and Outcomes

Overall, 9 of the 14 patients underwent implant removal, resulting in significant or complete symptom relief. Of these patients, 2 had textured silicone implants, 1 textured saline, 5 smooth silicone, and 1

ADM/tissue expander combination. Various treatments attempted before implant removal included topical and systemic corticosteroids, topical zinc, PUVA, and systemic medications including sulfasalazine, azathioprine, and methotrexate.¹⁹ Sabbagh and Ganske also trialed oral antibiotics (erythromycin with bactroban and cefadroxil, respectively) without improvement in cutaneous findings.^{17,23}

MacDougal¹⁵ reported the only patient whose symptoms were relieved with topical steroid therapy. All other patients eventually required implant removal.¹⁹

Oral medications were used with some success in 4 patients. Oral corticosteroids led to successful resolution in 2 patients, one with reaction to ADM and the other to smooth silicone. Another patient responded to a course of levofloxacin and a 1-month course of montelukast.¹⁸ There was also a case where complete resolution of symptoms was achieved with initiation of adjuvant chemotherapy for breast cancer.²³ Notably, Marcusson and Bjarnason¹⁹ were the only group that attempted treatment with PUVA, but this was unsuccessful and the patient ultimately had implant removal.

Discussion

The literature pertaining to cutaneous hypersensitivity-like reactions and breast implantation is limited to case reports and series, and therefore, the precise incidence is unknown. Although the paucity of data is likely a reflection of the rarity of this complication, there is also a possibility that hypersensitivity to breast implants is underreported in the literature. However, it is also important to note that because of the lack of data and histopathologic confirmation, causation between hypersensitivity reactions and breast implantation cannot be assumed.

Of the patients discussed in this review, 6 developed cutaneous complications with smooth silicone implants, 2 with textured silicone, 1 with textured saline, 1 with polyurethane textured silicone, and 4 with ADM. Three of the implants were found to be ruptured, and 11 were intact. Given the small sample size, it is not possible to draw conclusions about the

TABLE 1. Patient Presentation, Time Course, and Treatment

Study	Type of Implant	n	Reaction	Time Course	Treatment/Outcome
MacDougal ¹⁵	Textured (PU)	1	Pruritic erythematous patches over the lower lateral quadrant of each breast	1–2 wk	Resolved with topical steroids
Kirwan ¹⁶	Smooth silicone; ruptured	2	Painful erythematous eruption of the cervix	2 m	Implants removed, and replaced with autologous reconstruction with complete symptom resolution
	Smooth silicone		Tender erythematous papules/plaques over bilateral breasts extending to axillae with edema	5 mo	Complete resolution with removal of bilateral implants
Sabbagh and colleagues ¹⁷	Textured Saline	1	Painful pruritic papules/pustules on chest, arms, neck, face, and scalp	5 mo	No relief with oral steroids or antibiotics (erythromycin and bactroban). Complete resolution with implant removal and replacement with smooth saline implant.
Genovese ¹⁸	Smooth silicone	1	Erythematous, pruritic maculopapular eruption under left breast spreading to torso and extremities. Systemic symptoms included arthritis, anasarca, leukocytosis, elevated LFTs, and fever, requiring inpatient admission.	3 wk	Resolution with oral corticosteroid course
Marcusson and Bjarnason ¹⁹	Smooth silicone	1	Erythematous exudative plaque overlying nonhealing incision from the right latissimus dorsioplasty, used for coverage left breast implant. Exudative lesions also noted on the right upper arm and lower extremities that continued to enlarge over a 3-mo period.	Immediately post-op	Minimal relief with topical zinc and oral steroids. No relief with systemic sulfasalazine, azathioprine, methotrexate, or PUVA. Improvement with removal of implants. At 2-yr follow-up, plaque had decreased in size.
Cantisani and colleagues ²⁰	Smooth silicone	1	Erythematous painful papules/blisters on the right breast and myalgia.	Days	Complete resolution with implant removal
Dargan and colleagues ²¹	Textured silicone	1	Tender erythematous breast edema, serous discharge from surgical site, fever, and leukocytosis. Patient with notable history of urticaria and contact dermatitis to adhesives.	3 wk	Complete resolution with implant removal
Mallon and colleagues ²²	Smooth silicone; ruptured	1	Erythematous eruption on bilateral breasts and left anterior trunk. Bilateral implant rupture was noted on MRI and ultrasound.	43 mo	Complete resolution with implant removal
Ganske and colleagues ²³	ADM	4	Erythematous plaque over reconstructed breast, associated with nightly fevers and eosinophilia	9 mo	Initial resolution with course of cefadroxil. Symptoms recurred and were subsequently treated with methylprednisolone course with improvement. Nevertheless, patient elected for implant removal.
			Bilateral erythema overlying both breasts reconstructed with ADM mesh	1 mo	Improvement with methylprednisolone course. Erythema recurred 1 mo later, and resolved with 2nd methylprednisolone course.
			Erythema overlying lower mastectomy flap	2 wk	Complete resolution with levofloxacin and 1-mo course of montelukast.
			Erythema over the inferolateral pole of reconstructed breast	1 mo	No improvement with antibiotics (Augmentin, 5-wk course, IV Unasyn, 10-d course of IV ciprofloxacin, Vancomycin, oral ciprofloxacin). Complete resolution with initiation of adjuvant chemotherapy.
Koh and colleagues ²⁴	Textured silicone; ruptured	1	Maculopapular eruption overlying the reconstructed breast associated with seroma, swelling and implant rupture	3 wk	No relief with topical or oral steroids. Complete resolution with left ruptured implant removal.

ADM, acellular dermal matrix; LFT, liver function tests (aminotransferase, alanine aminotransferase, alkaline phosphatase, and gamma glutamyltransferase); n, number of patients; NED, no evidence of disease; PU, polyurethane-coated implants.



Figure 2. Fifty-eight-year-old woman with a complaint of chronic pruritus and erythema on the breast related to her saline implants. (A) Frontal view and (B) lateral view.

causal relationship between the types of implants at this time.

Red breast syndrome as described in a case series by Ganske and colleagues continues to be a poorly understood phenomenon associated with ADM.^{23,26} The pathophysiology is not well described in the literature, and it is unclear if the cutaneous reactions are due to a true hypersensitivity reaction. However, it is interesting to note that other groups have demonstrated similar reactions to ADM in other areas of surgery.^{23,25,27} For example, Vedak and colleagues describe a case of a patient who received ADM mesh for a nonhealing abdominal wound that continued to worsen. Subsequent patch testing revealed a severe reaction to the ADM mesh at 48 hours.²⁷

Another cutaneous reaction associated with breast implantation is sarcoidosis of the breast. Although no causal relationship has been found between silicone implants and cutaneous sarcoidosis, there are a few case studies reporting this rare phenomenon. For example, Sun and colleagues described a patient who presented 8 months after bilateral postmastectomy implantation with multiple hyperpigmented maculopapules involving the skin flaps and no systemic symptoms. Biopsy demonstrated noncaseating granulomas. The same patient then presented several months later with hilar lymphadenopathy consistent with a typical sarcoidosis presentation.²⁸

A few studies have been conducted in an attempt to elucidate mechanisms of hypersensitivity to implants. Copeland and colleagues analyzed previously removed breast implants from 191 patients. They identified silicone granulomas through light micros-

copy in most capsules surrounding textured silicone implants but not in capsules surrounding smooth silicone, leading to the hypothesis that silicone granules arising from textured surfaces may play a role in patients' adverse reactions to breast implants.²⁹ Narini and colleagues investigated cell-mediated immune responses to silicone gel in ewes. In their experiment, the animal groups were injected either with silicone from implants, a positive control with Freund's Complete Adjuvant, or a negative control with saline. When all ewes were subsequently tested with intradermal injections of silicone gel, a positive tuberculin response was documented in those previously injected with silicone. No significant response was seen in animals primed with saline, leading to the hypothesis that silicone might play a role delayed Type-4 hypersensitivity reactions.^{30–32}

One of the patients in the studies had a positive reaction to platinum chloride.²⁰ Platinum is used as a catalyst in the cross-linking of silicone polymers in the manufacturing of breast implant outer membranes.⁹ Although studies have shown that platinum levels are significantly higher in women with breast implants compared with those without, there is no strong evidence linking platinum to cutaneous hypersensitivity after breast implantation.³³ What clinical relevance, if any, these trace amounts of platinum have, remains to be determined.⁹

Patch testing has been shown to be useful in determining sensitivity to breast implant material in 4 studies. Vedak and colleagues demonstrated that patch testing to ADM is useful in diagnosing hypersensitivity to ADM utilized during abdominal surgery.^{23,25,27} We recommend that patch testing be

considered in the work-up of patients with suspected hypersensitivity to breast implants.

Effective treatment of cutaneous complications to breast implants varied. Our review indicates that most patients (9 of 14) required complete implant removal. The others improved with topical corticosteroids ($n = 1$), oral corticosteroids ($n = 2$), antibiotics and montelukast ($n = 1$), and initiation of adjuvant chemotherapy ($n = 1$). In general, detailed treatment plans were not well described in the reviewed cases. Ideally, starting with topical steroids and progressing to systemic medications may be prudent, with breast implant removal as the last resort.

Given the high percentage of patients who required implant removal, an interesting question that arises is whether or not preimplantation screening should be performed in individuals at high risk for cutaneous reactions. However, there are currently no guidelines to establish which patients, if any, should be considered “high risk.” Cantisani and colleagues presented a patient with an established latex allergy who was exposed to latex during the surgery and subsequently developed a hypersensitivity to the breast implant. Patch testing demonstrated reactivity to thiuram mix, platinum chloride, and several other compounds. Ultimately, the patient required implant removal for resolution of symptoms.²⁰ Their case suggests that patients with a history of previous hypersensitivity may be at an increased risk of developing hypersensitivity to other allergens in the perioperative period.²⁰

In terms of preoperative interventions, only 1 study was found discussing the utility of screening before breast implantation. Atabey and Baruteçu studied 2 patients: the first had previous silicone breast implant extrusion and the second had no previous breast implant surgery with no known history of hypersensitivity. Both patients underwent implantation of a 2-mm³ silicone cube within the axilla and were observed for 48 hours and again for 3 weeks.³⁴ The first patient developed erythema of the skin overlying the silicone cube within 18 hours and did not undergo breast implantation. Contrastingly, the second patient did not develop any cutaneous symptoms and proceeded with surgery without any complications.³⁴ No studies to date have used preoperative patch testing

for components of breast implants. As the phenomenon of hypersensitivity to breast implantation is better described, the utility and cost-effectiveness of these studies will certainly be interesting.

Finally, although hypersensitivity should be on the differential for any patient with acute or chronic skin changes after breast implant, it is critical to consider and rule out a cutaneous manifestation of a malignancy.^{35,36} Cutaneous metastases from breast cancer commonly present as nodules, ulcers, or erythematous patches/plaques.³⁶ Inflammatory breast cancer can present with erythematous skin changes, edema, warmth, and dimpling. Finally, late onset seroma, recurrent seroma, or capsular contracture raises concern for anaplastic large cell lymphoma (ALCL). Weathers and colleagues describe a patient with textured silicone implants who presented with extracapsular implant rupture and cytology of periprosthetic fluid consistent with ALCL. While other cases have been published describing patients with textured implants and ALCL, causation between the breast implant and increased risk of ALCL cannot be proven.³⁵

Conclusion

Cutaneous hypersensitivity-like reaction requiring implant removal is a rare but important complication of breast implantation. Future studies are needed to determine the incidence and etiology of these reactions. Preoperative patch testing and silicone cube implantation in patients with known hypersensitivity to silicone or other compounds may prove useful; however, further investigations are needed before they can be recommended. Finally, as manufacturers continue to develop newer models of breast implants, it will be important to monitor patients for cutaneous reactions and uncover the true incidence of this rare complication.

Acknowledgments The authors greatly appreciate Nathan Molina, MD for his assistance in compiling the photographs of the various types of breast implants used in Figure 1.

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