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CASE REPORT
Cosmetic

Silicone Migration from Intact Saline Breast Implants

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Summary: Breast augmentation is a widely performed surgical procedure worldwide, predominantly using silicone gel-filled implants. Concerns have primarily revolved around ruptures and the potential health risks associated with leaked silicone from silicone gel-filled implants. Cases of silicone migration from the shell of saline breast implants remain scarce. This case report introduces a unique case of a 66-year-old patient with silicone migration from intact saline breast implants. The patient presented with a range of symptoms consistent with breast implant illness. Radiological findings suggested the presence of silicone in the axillary lymph nodes, despite the integrity of the implants, thereby confirming silicone migration. Histopathological evaluation revealed a foreign body reaction and the presence of silicone in the axillary lymph nodes. Given the saline filling, the source is likely the polydimethylsiloxane shell. The rarity of documented silicone migration from intact saline breast implants, especially in patients with breast implant illness, underscores the need for more research into the health implications of leaked silicone particles from breast implants. *(Plast Reconstr Surg Glob Open 2024; 12:e5608; doi: 10.1097/GOX.0000000000005608; Published online 8 February 2024.)*

INTRODUCTION

Breast augmentation is a widely performed procedure, with over 1.6 million surgeries globally in 2021.[1] Silicone breast implants are made of a silicone outer shell composed of polydimethylsiloxane (PDMS) elastomer and filled with saline solution or silicone gel. Silicone gel-filled breast implants are generally favored for aesthetics and durability reasons, although in the United States, saline-filled implants remain a popular choice.[1] Despite their widespread use, safety concerns persist.

Complications from breast implants include local complaints such as capsular contracture, pain, and ruptures as well as systemic complaints like fatigue, arthralgia, and hair loss.[2] This constellation of symptoms is referred to as breast implant illness (BII), among other nomenclatures.[3] While the pathophysiology of BII remains to be elucidated, silicone-induced inflammation is suspected to be of significant contribution.[3] Additionally, breast implants have been association with various cancers, including lymphoma and squamous cell carcinoma.[4]

Several cohort studies found over 60% of women affected by BII to experience symptom amelioration upon removal of the implants.[5] Furthermore, a cohort study found over 70% of women with BII to experience concomitant local complications, suggesting an interplay between local and systemic symptoms.[5]

Saline implants have a higher rupture rate; however, they allow for straightforward detection and the release of harmless saline solution.[2] Conversely, silicone leakage from ruptured silicone gel-filled implants varies with potential migration to regional lymph nodes and distant organs. A silicone-specific modified oil-red-o staining, validated by energy-dispersive x-ray analysis, allows for silicone detection in tissues.[6] Due to the uncertain health effects of silicone leakage, the FDA recommends regular rupture screening and preventative replacements.[4] Silicone leakage in ruptured gel-filled implants has been widely documented; however, our understanding of this phenomenon in intact gel-filled implants is limited. The barrier shell is supposed to prevent silicone leakage. However, intact silicone gel-filled breast implants may exhibit a phenomenon known as "gel-bleed," referring to the microscopic diffusion of silicone from the gel through the shell.[4]

Patient inquiries at our clinic raised a crucial question: Could transitioning from silicone to saline implants mitigate the risks associated with silicone migration? To date, silicone particle migration from saline implant shells is rare, with just two cases of silicone pulmonary embolisms

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from ruptured saline PIP implants, which contained industrial-grade silicone.[7,8]

This case report challenges the prevailing assumption that saline implants resist silicone migration and presents evidence of silicone migration to axillary lymph nodes from intact saline implants.

CASE DESCRIPTION

A 66-year-old female patient consulted our specialized silicone-outpatient clinic at Amsterdam University Medical Center, in August 2022. She was referred by her plastic surgeon due to suspicion of BII. The patient reported a gradual onset of fatigue, arthralgia, muscle weakness, sicca complaints, and brain fog over the past approximately 10 years. Additionally, she experienced localized pain in her left breast and axillary region.

The patient had undergone breast augmentation surgery in the United States, Texas, in 2006, during which 300 mL McGhan 68 saline-filled implants were implanted as her initial set (Fig. 1). Notably, she had not undergone any subsequent revision or replacement surgeries and had no other medical devices implanted. Her medical history included mild hypertension, managed with a beta-blocker, and a history of smoking until age 41.

On physical examination, mild capsular contracture was noted in the right breast, without palpable axillary lymphadenopathy on either side. Comprehensive laboratory analysis excluded differential diagnoses such as autoimmune disorders. An ultrasound examination confirmed implant and capsule integrity but suggested the presence of silicone deposits in the axillary lymph nodes. Magnetic resonance imaging confirmed the implants' integrity (Fig. 2).

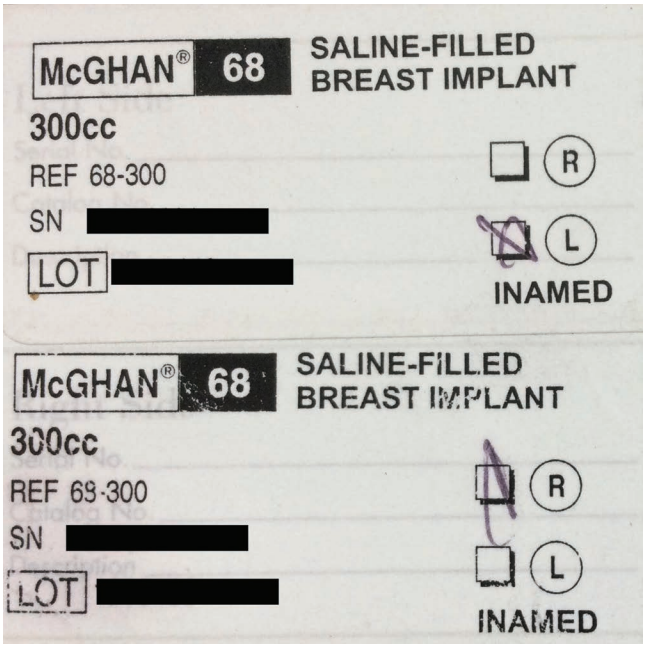

Fig. 1. A photograph of the patient's implant ID card detailing model and serial number.

Takeaways

Question: Does silicone leakage and foreign body reaction occur in patients with intact saline breast implants?

Findings: This case report presents the first documentation of silicone migration from the shell of intact saline implants to axillary lymph nodes, causing a foreign body reaction in a patient with breast implant illness.

Meaning: The findings indicate that intact saline implants are not immune to silicone leakage and foreign body reactions, highlighting the need for further research.

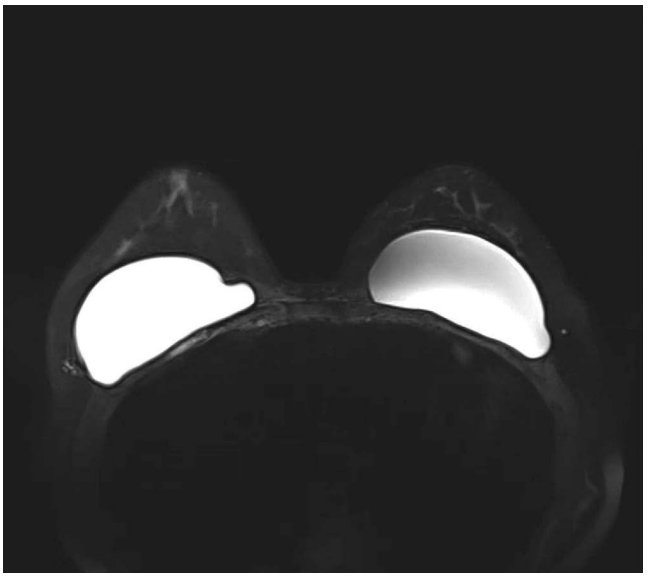

Fig. 2. Axial T2-weighted magnetic resonance imaging displaying intact saline implants.

To further investigate silicone migration and the associated immune response, an axillary lymph node needle biopsy was conducted. Histological analysis demonstrated optically empty vacuoles accompanied by histiocytic reactions, signifying a foreign body reaction to silicone. Macrophages within the lymphoid tissue exhibited granular brown/black pigment in their cytoplasm. Some also displayed fine droplet vacuolated cytoplasm that appeared as glassy, nonbirefringent material under microscopic examination (Fig. 3). Silicone particles were confirmed via silicone-specific modified oil-red-o (MORO) staining (Fig. 4).

These findings collectively implicate silicone migration from the saline implants' PDMS shell and suggest an inflammatory response induced by foreign material. Given the high suspicion of BII, the patient is awaiting implant removal.

DISCUSSION

This case report marks the first documented evidence of silicone migration from an intact PDMS elastomer shell in saline implants to an axillary lymph node, eliciting a foreign body reaction. Prior research suggested the potential

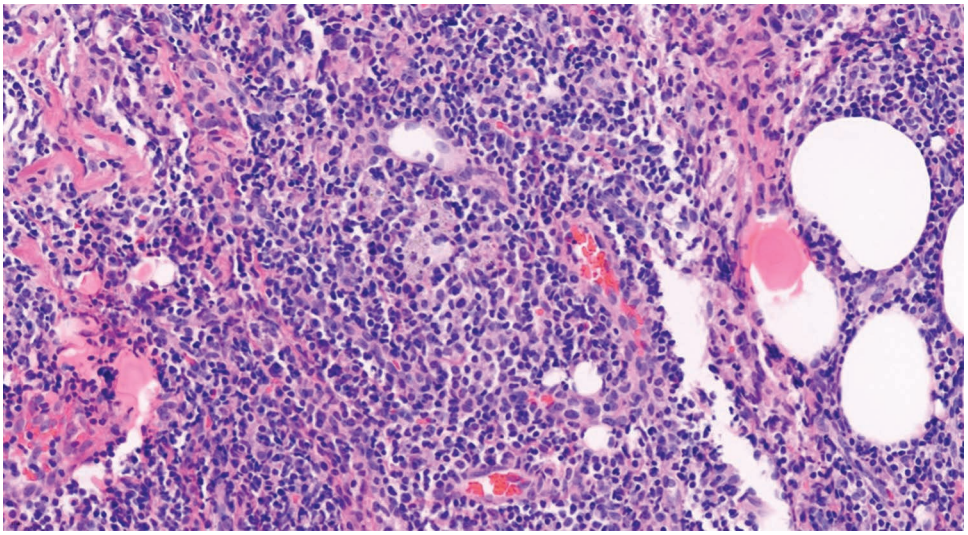

Fig. 3. Histopathology of an axillary lymph node biopsy showing fibrolipomatous tissue, lymphoid structures, and macrophages with brown/black pigment. (H&E, 600×).

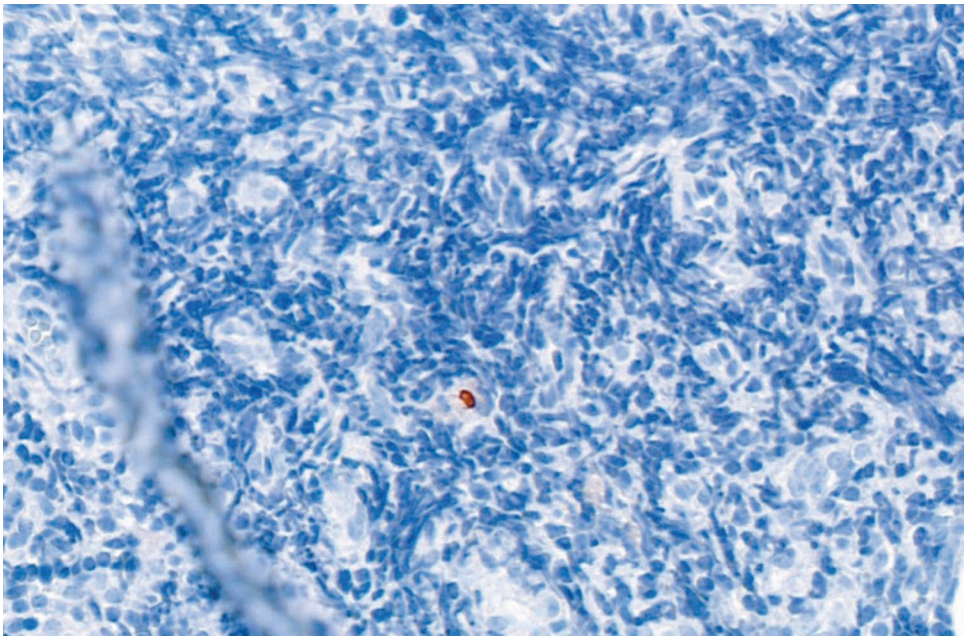

Fig. 4. Histopathology using MORO staining, showing focal red staining within a macrophage in the axillary lymph node. (MORO, 600×).

for silicone leakage directly from the PDMS elastomer shell using spectroscopic analysis.[8,9] Silicone leakage may occur due to shell degradation cause by mechanical forces and interactions with the body. Although the basic design of saline implants has been maintained, specific information about changes in manufacturing processes is not readily available.

Historically, health implications have been predominantly associated with the phenomenon of silicone migration from ruptured gel-filled implants. However, the findings presented in this case report extend the scope of this discourse, indicating that silicone particles from intact saline implants can also provoke inflammatory reactions within lymphatic tissue.

Contrary to the presumed inertness of silicone, leaked particles from implants can spread within the body, triggering inflammatory responses such as granuloma formation, and lymphadenopathy mimicking malignancies on positron emission tomography imaging.[6,9,10] These clinical observations underscore the need to investigate the systemic health complaints reported by patients with various types of breast implants.

Clinical guidelines for silicone lymphadenopathy are lacking. Observation is favored over surgical intervention due to associated risks. In the event of symptoms, imaging and histopathological evaluations should be performed to rule out lymphoma.

Given the differences in silicone content in saline and silicone gel-filled implants, a pressing need emerges to investigate the link between the extent of silicone leakage and health effects, potentially extending to the genesis of BII. A prior cohort study suggested a dose-response relationship, wherein exposure to silicone gel-filled implants for over a decade reduced the likelihood of symptomatic relief after implant removal.[5] However, BII has also been documented in women with saline implants, and our findings may offer an explanation to their symptoms.[2] The generalizability of this case report's findings is inherently limited, emphasizing the need for additional research and validation to elucidate the health consequences of silicone migration.

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DISCLOSURES

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REFERENCES

1. ISAPS. ISAPS international survey on aesthetic/cosmetic procedures performed in 2021. Available at https://www.isaps.org/media/vdpdanke/isaps-global-survey_2021.pdf. Published 2021. Accessed August 20, 2023.
2. FDA. Risks and complications of breast implants. Available at https://www.fda.gov/medical-devices/breast-implants/risks-and-complications-breast-implants. Published 2023. Accessed August 8, 2023.
3. Cohen Tervaert JW, Mohazab N, Redmond D, et al. Breast implant illness: scientific evidence of its existence. *Expert Rev Clin Immunol.* 2022;18:15–29.
4. FDA. FDA update on the safety of silicone gel-filled breast implants. Available at https://www.fda.gov/medical-devices/breast-implants/update-safety-silicone-gel-filled-breast-implants-2011-executive-summary. Published 2011. Accessed August 20, 2023.
5. Spit KA, Scharff M, de Blok CJ, et al. Patient-reported systemic symptoms in women with silicone breast implants: a descriptive cohort study. *BMJ Open* 2022;12:e057159.
6. Dijkman H, Slaats I, Bult P. Assessment of silicone particle migration among women undergoing removal or revision of silicone breast implants in the Netherlands. *JAMA Netw Open.* 2021;4:e2125381.
7. Gopinath PP, Ali A, Van Tornout F, et al. Chronic silicone embolism syndrome due to PIP breast implant leakage—a new entity? *Histopathology.* 2015;66:904–906.
8. Arora A, Inaty H, Mukhopadhyay S, et al. chronic pulmonary silicone embolism related to saline breast implants. *Ann Am Thorac Soc.* 2016;13:139–141.
9. Todorov TI, de Bakker E, Smith D, et al. A case of silicone and sarcoid granulomas in a patient with "highly cohesive" silicone breast implants: a histopathologic and laser Raman microprobe analysis. *Int J Environ Res Public Health.* 2021;18:4526.
10. Bauer PR, Krajicek BJ, Daniels CE, et al. Silicone breast implant-induced lymphadenopathy: 18 Cases. *Respiratory Medicine CME.* 2011;4:126–130.