Evaluation of Breast Silicone Implants

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KEYWORDS

• Silicone • Breast implant • MR imaging • Intracapsular leak • Extracapsular leak

KEY POINTS

- The linguine sign represents complete collapse of the envelope within the fibrous capsule and is the most specific sign of implant failure.
- The inverted-loop sign (also called hang-noose or keyhole sign) represents the most common form of intracapsular rupture.
- MR imaging of silicone implants requires no intravenous contrast but does require orthogonal image acquisition at sufficiently narrow sections to detect small signs of implant failure.
- MR imaging is the most sensitive imaging method to detect and evaluate breast silicone implant integrity.

The history of development and commercial use of breast silicone implants is exceptional.[1,2] Developed and tested before US Food and Drug Administration (FDA) guidelines for medical device implantation, reports of various complications were raised in the 1980s, including low birth weights of infants born to women with silicone implants and increased incidence of brain tumors and suicide rates in women with implants. The most widely publicized concern involved immunologic responses resulting in collagen vascular diseases. Given such concerns, coupled with the relatively unregulated introduction into the marketplace, the FDA, as well as Canada's HealthCanada, placed a moratorium on commercial availability of silicone breast implants in 1992. Their use was banned except under stipulated protocols limited to reconstructive purposes. Other countries expressed concern but took no regulatory action. Eleven years later, following 15 studies involving 34,000 subjects with implantation follow-up of 7 to 15 years, both countries reversed their decision and allowed implants to be reintroduced into the commercial marketplace with an agreement to provide post-market approval studies (relatively unprecedented) during the next 10 years. By this time, only two manufacturers, Mentor (Santa Barbara, CA) and what is now Allergan Medical (Santa Barbara, CA), were producing silicone implants.

There have been, and continue to be, innumerable variations on the types of silicone breast implants using silicone.[3] Different shapes, sizes, components, shell texturing, and fixation patches, as well as valves, have been developed to provide sufficient variation for women and their plastic and reconstructive surgeons to select one based on multiple factors, especially body habitus. Current FDA-approval criteria provide formidable challenges to the companies seeking to propose new devices because post-market approval studies continue to provide data. Most breast implants currently in use are single-lumen devices, with the second most common device being a silicone inner lumen and an outer saline lumen.

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Before the widespread use of silicone implants, various foreign substances were injected directly into the breast, most notably paraffin and free silicone (Fig. 1). This resulted in considerable breast hardening and pain, and these breast-injected substances were banned in many countries. Mammography is usually sufficient for demonstrating such substances, which may interfere with the primary purpose of this modality as a tool in detecting breast cancer, though MR imaging may be useful.[4] Of interest, prognostic characteristics for breast cancer of women with implants are comparable to those without implants, although sensitivity of mammography is lessened. The presence of silicone within the breast may interfere with cancer detection, but no causal relationship between silicone and breast cancer has been shown.[5,6] Ultrasound is of little value for such patients because the reverberative artifact produced by the granulomatous response of the breast to these diffuse injections obscures breast detail (Fig. 2). Even tumor-specific breast MR imaging protocols are compromised by such

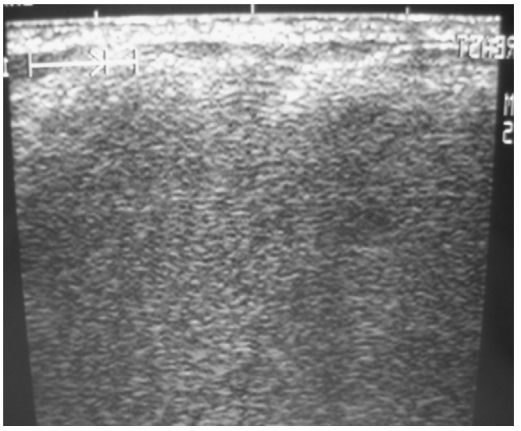

Fig. 2. Ultrasound of breast with silicone injections shows the snowstorm appearance of increased echogenicity due to interfaces with silicone injected globules, breast tissue, and associated granulomatous reactions.

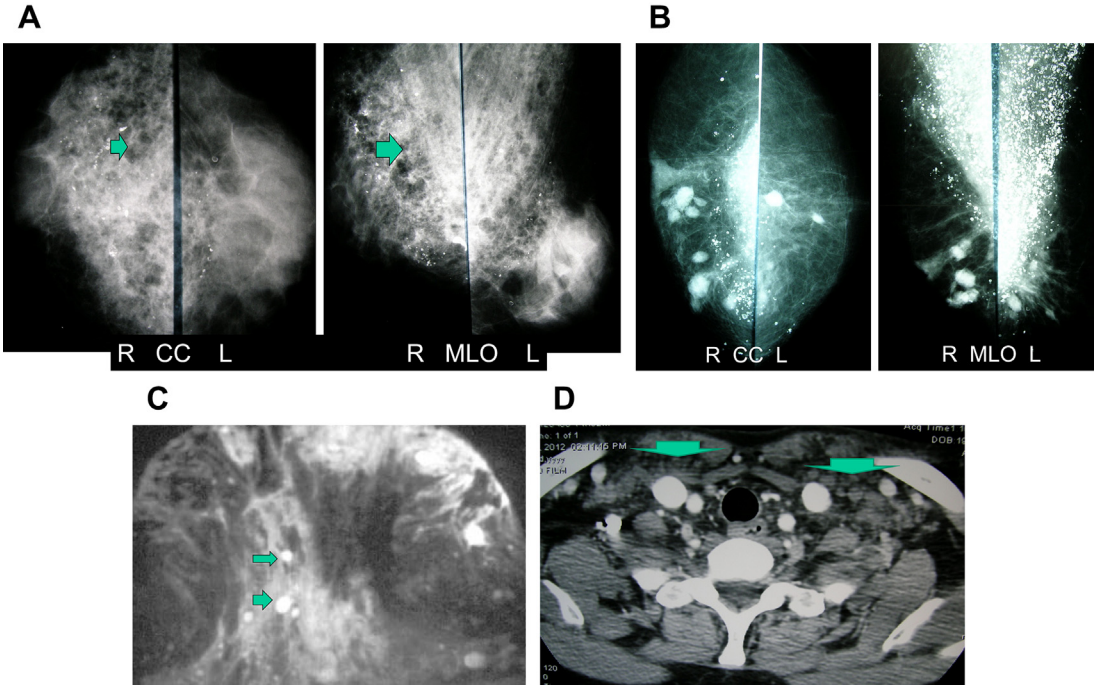

Fig. 1. Foreign materials injected into breast craniocaudal (CC) and mediolateral oblique (MLO) views. (*A*) MLO and CC mammographic views: paraffin injections. Radiolucent paraffin injected into breast causing universal distortion of architectures. *Arrow* points to injected paraffin. (*B*) MLO and CC mammographic views: silicone injections. Radiodense silicone injections form discrete silicone cysts and granulomata, often migrating toward the axillary portions of each breast. (*C*) MR imaging axial projection, 3 minutes following gadolinium injection. Extensive fibrosis in the breast following silicone injections more than 10 years ago. Silicone granulomata with chronic inflammatory response causing gadolinium accumulation at multiple sites. *Arrow* points to enhancing silicone granuloma. (*D*) CT axial scan at level of clavicles demonstrate migration of innumerable silicone globules that have incited surrounding granulomatous reaction (*arrows*).