Shur-Clens: An Agent to Remove Silicone Gel After Breast Implant Rupture

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Removal of silicone gel from surrounding tissues after implant rupture is difficult. Local inflammation, infection, and silicone granulomas warrant thorough removal of the silicone gel. Shur-Clens (20% solution of the surfactant poloxamer 188), povidone–iodine, and saline are agents that are used to aid in the removal of silicone gel from tissue. The purpose of this study was to compare the efficacy of silicone gel removal by these three agents in vitro. Shur-Clens, povidone–iodine, and saline were compared as solvents for silicone gel. Four weight increments of silicone gel (0.02 g, 0.04 g, 0.06 g, and 0.08 g) were placed on glass slides. These slides were placed in separate beakers containing 40 ml test solution. The slides were soaked for 1 minute with gentle agitation. The slides were removed, rinsed gently with de-ionized water, and placed in a vacuum desiccator to dry. The slides were weighed to determine the amount of silicone removed after soaking in the solution. Analysis of variance was used to determine the significance between the three solvents. The percentages of silicone gel removed for the four weight increments (0.02 g, 0.04 g, 0.06 g, and 0.08 g) in saline were 5.6%, 2.9%, 2.1%, and 5.8%, respectively. In povidone–iodine solution, the percentages were 18.9%, 25.4%, 28.8%, and 51.9%. In Shur-Clens, the percentages were 31.3%, 43.0%, 63.5%, and 79.9%. The greater percentage of silicone gel removed by Shur-Clens was significant compared with the other solutions ($p \leq 0.05$). Shur-Clens was shown to be a more effective solvent for removal of silicone gel in vitro. This enhanced efficacy is a result of the fact that Shur-Clens contains 20% of the surfactant poloxamer 188. The authors' clinical experience with 7 patients who underwent ruptured silicone breast implant removal demonstrated the superiority of Shur-Clens. Shur-Clens is a surfactant cleanser that is widely available, is inexpensive, and has a good safety profile. They propose the use of Shur-Clens to clean silicone gel spillage to decrease local complications resulting from residual silicone gel.

Silicone gel breast implants were introduced in 1963 and are composed of a silicone elastomer envelope filled with silicone gel.[1-3] As of 1996, an estimated one to two million women in the United States have silicone gel breast implants, 70 to 80% for cosmetic augmentation and 10 to 20% for reconstruction after mastectomy.[1-3]

The composition of silicone implants is polydimethyl siloxane, a synthetic polymer of silicon and oxygen with methyl side chains.[1] The polymer chains are lengthened to make silicone gel and are cross-linked with an addition of amorphous silica to form a rubber-like silicone elastomer.[1] Silicon constitutes 40% by weight of the silicone polymer. The silicone gel breast implant has undergone many changes since its conception, the latest being new shell formulations that minimize gel bleed and textured-surface envelopes that reduce the incidence of firmness associated with capsular contracture.[3-5]

In 1992, the Food and Drug Administration imposed a brief moratorium on the use of silicone gel implants. Silicone gel breast implants are now only available for reconstruction. Accumulated evidence from several epidemiological studies has shown that silicone gel does not cause autoimmune or rheumatic disease such as rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis, scleroderma, polymyositis, fibromyalgia, or inflammatory arthritis.[3,6,7] However, local effects secondary to silicone gel may include breast pain, breast or nipple hypesthesia, capsular contracture, infection, granuloma formation, and delayed wound healing.[1-4,8-10]

The risk for rupture of silicone breast implants increases with age of the implant.[1,2] Rupture can involve visible tears or complete disruption of the elastomer shell. In the study by Robinson and

colleagues[11] of 300 patients, the rate of overt rupture or silicone bleed was 11% at 8 years, 49% at 12 years, and 95% at 20 years after implantation. In the study by Beekman and associates[12] of 426 implants, a 50% rate of either gel bleed or rupture was found at 7 to 10 years.

After rupture, the silicone gel is usually engulfed by macrophages and is trapped in the fibrous scar capsule.[2,3,13] Silicone invokes a nonspecific foreign body response, resulting in typical macrophage invasion, giant cell formation, and eventual scarring.[3] Because silicone is hydrophobic, it is unlikely to be transported by any mechanism other than macrophage migration or local diffusion.[3] There is no evidence to suggest any systemic health hazard or physiological effect for ruptured silicone gel that is contained within the scar envelope.[3] Tissue silicon assays on women undergoing explantation found elevated silicon levels only within the implant capsule and surrounding breast tissue, and found baseline silicon levels at distant sites compared with nonaugmented cadavers.[14]

Silicone gel escapes outside the capsule in 11 to 23% of cases, when the scar envelope is torn, in addition to disruption of the implant shell.[2,3,13] Silicone gel in surrounding tissue elicits inflammation and silicone granuloma formation, which represent the body's natural response to a foreign substance.[13,15] There are rare instances of silicone extending into the lymph nodes, causing silicone lymphadenopathy; into the sheath of the brachial plexus with signs of compressive neuropathy; or into the skin, resulting in induration, necrosis, and deformity.[2,3,16-18] Silicone gel, like all other implanted foreign substances, may predispose patients to local infection. Bacteria such as *Staphylococcus epidermidis*, *Propionibacterium acnes*, *Escherichia coli*, and *Clostridium perfringens* have been cultured from silicone breast implants.[4,7,9,10]

These potential complications necessitate removal of silicone gel as much as possible from surrounding tissue after breast implant rupture. Also, removing the implant and capsule together without opening the capsule is probably the best way to avoid these problems.

The purpose of this study was to compare the efficacy of silicone removal by three solvents in vitro: saline, povidone–iodine, and Shur-Clens

(Conva Tec, Princeton, NJ). All three solvents are inexpensive and widely available. Removal of silicone gel from surrounding tissues after implant rupture is difficult (Fig 1). In the operating room, saline and povidone–iodine solution are currently used to displace silicone gel from breast tissue during explantation.

Iodophor antiseptic solution contains 10% povidone–iodine, which slowly releases iodine into solution for controlled antiseptic activity. It has been used widely in the operating room for prepping skin before surgery. Povidone–iodine solution has also been used anecdotally with the insertion of new breast implants to decrease the incidence of capsular contracture.

Shur-Clens is a wound cleanser that contains only the surfactant poloxamer 188 (20% by weight). No other agents or preservatives are contained in this sterile solution. Poloxamer 188 is a pluronic polyol (Pluronic F-68) that consists of hydrophilic oxyethylene groups at both ends of a hydrophobic oxypropylene chain.[19,20] As a surfactant, the hydrophobic portion surrounds the water-insoluble substance, and the hydrophilic shell facilitates its removal.[19] Shur-Clens does not display intrinsic antibacterial activity, but does not potentiate infection because it does not inhibit tissue defenses.[19-21] It does not cause any local or systemic toxicity and is excreted rapidly from the body.[20,21] As a result of these data, the Food and Drug Administration has indicated that poloxamer 188 is safe and effective for cleansing wounds.[22]

Materials and Methods

Saline, povidone–iodine solution (Betadine Antiseptic Solution; The Purdue Frederick Company, Norwalk, CT), and Shur-Clens were compared as solvents for silicone gel, which was removed from a new silicone gel implant. A small incision was made around the injection port of a silicone gel-filled breast implant from Mentor (Santa Barbara, CA). Using a glass stirring rod, aliquots of the silicone gel were removed from the implant, spread onto a 1 × 2-cm surface of a glass microscope slide, and weighed. For each solvent, four incremental weights of silicone gel were placed on glass slides for testing (0.02 g,
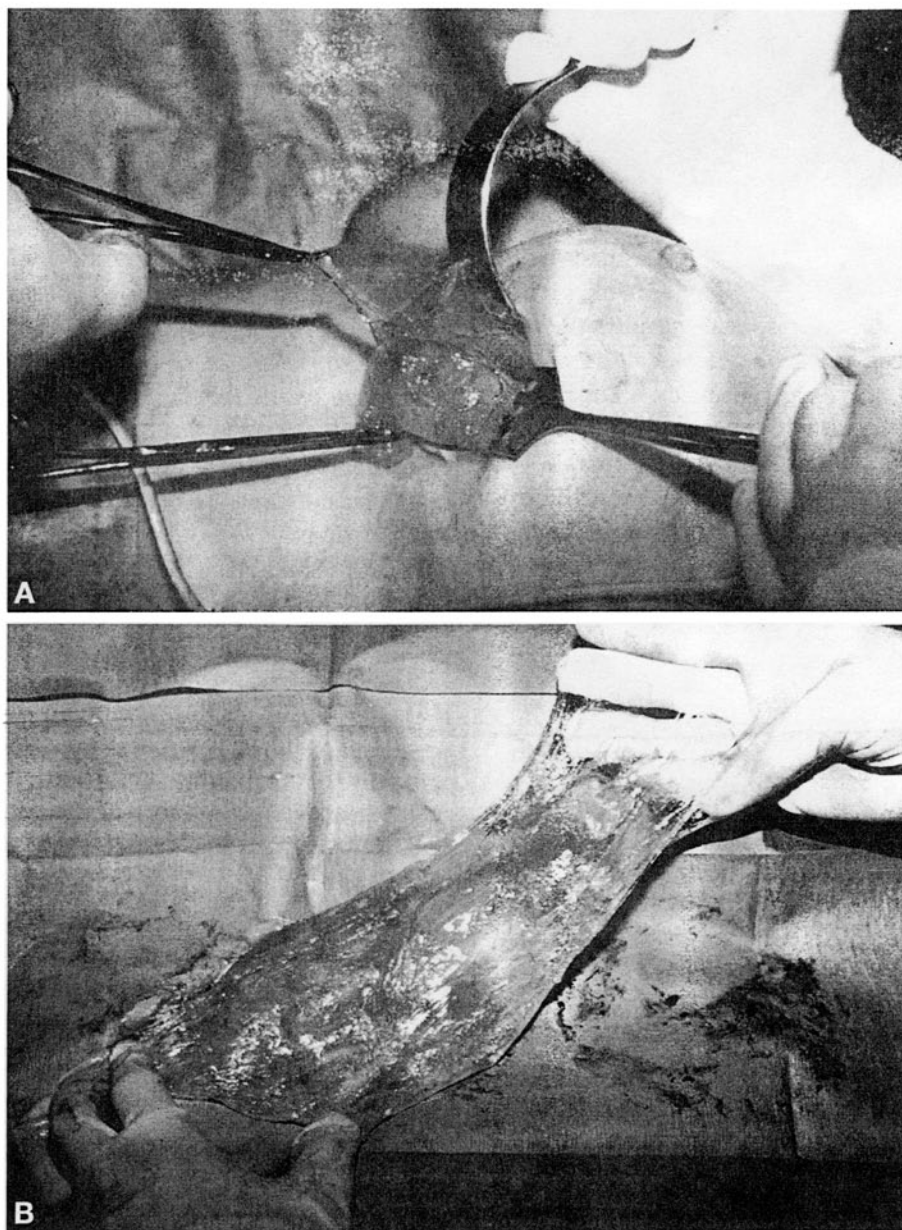
Fig 1. (A) Removal of ruptured silicone gel breast implant. (B) Demonstration of the adherent, viscous, stringy silicone gel.

0.04 g, 0.06 g, and 0.08 g). Eighteen slides were prepared for each weight increment. The weights were determined not to be too small to cover the entire surface area of the glass slide nor too large to be affected by the cohesive forces in silicone gel. Forty milliliters of each solvent (normal saline, povidone–iodine solution, or Shur-Clens) were poured into separate 100-ml beakers to cover the entire surface area of silicone gel on each glass slide. Three 150-ml beakers, each

containing 80 ml deionized water, were also obtained to rinse the solvent off each glass slide before drying.

The procedure repeated for each of the 18 glass slides covered with a known weight of silicone gel was: Each glass slide was soaked individually in 40 ml solvent for 1 minute to approximate the time used to wash silicone gel from a breast pocket in the operating room. While still in the solvent, the silicone-covered surface of the glass

Efficacy of Removing Various Amounts of Silicone Gel From Glass Slides

Initial Amount of Silicone, g	Removal Efficacy, %		
	Saline	Povidone–Iodine[a]	Shur-Clens[b]
0.02	5.6 ± 2.5	18.9 ± 7.3	31.3 ± 13.2
0.04	2.9 ± 1.5	25.4 ± 11.0	43.0 ± 15.5
0.06	2.1 ± 0.7	28.8 ± 12.5	63.5 ± 15.2
0.08	5.8 ± 6.9	51.9 ± 16.8	79.9 ± 6.0

[a]Significantly ($p \leq 0.05$) greater removal of silicone gel compared with saline.
[b]Significantly ($p \leq 0.05$) greater removal of silicone gel compared with both saline and povidone–iodine.

slide was scrubbed with the tip of a glass stirring rod at a 60-deg angle for 20 seconds to mimic the scrub time in the operating room.

Then, the glass slide was removed from the solvent beaker and was swirled gently back and forth in 80 ml de-ionized water for 30 seconds to rinse off the solvent and to prevent further interaction between the solvent and the silicone gel. After the glass slide was removed from the rinse beaker, excess water in areas not contacting the silicone gel was blotted with a paper towel. Next, the glass slide was placed in a vacuum desiccator for 15 hours to allow complete drying. A control slide with a drop of water was also placed in the vacuum desiccator to confirm complete dryness of the glass slides.

After complete drying, the postsolvent weight was recorded. Calculations were used to determine the amount and percent of silicone gel removed after soaking in the different solvents for each initial silicone gel weight. Six repetitions of this experiment were performed for each weight increment and solvent. The results were averaged and reported as the mean ± one standard deviation. Analysis of variance and Duncan multiple-range post hoc tests were used to determine the significance between the three solvents.

Results

Saline solution was fairly ineffective in removing silicone gel from glass slides. Regardless of the amount of silicone gel present, saline was only able to remove 2 to 6% of the material (Table). Use of povidone iodine solution resulted in a significant ($p \leq 0.05$) increase in silicone gel removal. As the amount of silicone gel present increased, the mean percentage of silicone gel

removed increased. The efficacy of povidone–iodine in removing 0.02 g silicone gel was 19% and increased to 52% with 0.08 g of silicone gel. Shur-Clens was significantly ($p \leq 0.05$) more effective in removing silicone gel than povidone–iodine. With 0.02 g silicone gel, Shur-Clens removed 31% of the material, and this efficacy increased to 80% with a challenge of 0.08 g silicone gel. The relative performance of the three solvents becomes apparent when results are presented as a graph (Fig 2).

Discussion

Shur-Clens was shown to be a more effective solvent for removal of silicone gel in vitro than either saline or povidone–iodine solution. This efficacy is a result of the fact that Shur-Clens is an aqueous solution of the surfactant poloxamer 188 (20% by weight). Surfactants are surface-active agents that reduce surface tension markedly.[19] The hydrophobic portion faces the hydrophobic silicone gel while the hydrophilic shell is exposed on the outer surface.[19] The presence of a hydrophilic shell makes the silicone gel water soluble and facilitates its removal. However, we need to acknowledge that removing silicone gel from a glass slide is much easier than removing it from tissues, and this would need further elucidation with animal studies.

Shur-Clens does not display intrinsic antibacterial activity, but its surfactant action minimizes damage to host tissue defenses and thus does not potentiate infection.[19–21] Shur-Clens does not interfere with local wound healing nor does it exhibit systemic toxicity.[21] Poloxamer 188 (the only agent in Shur-Clens) has a long history of
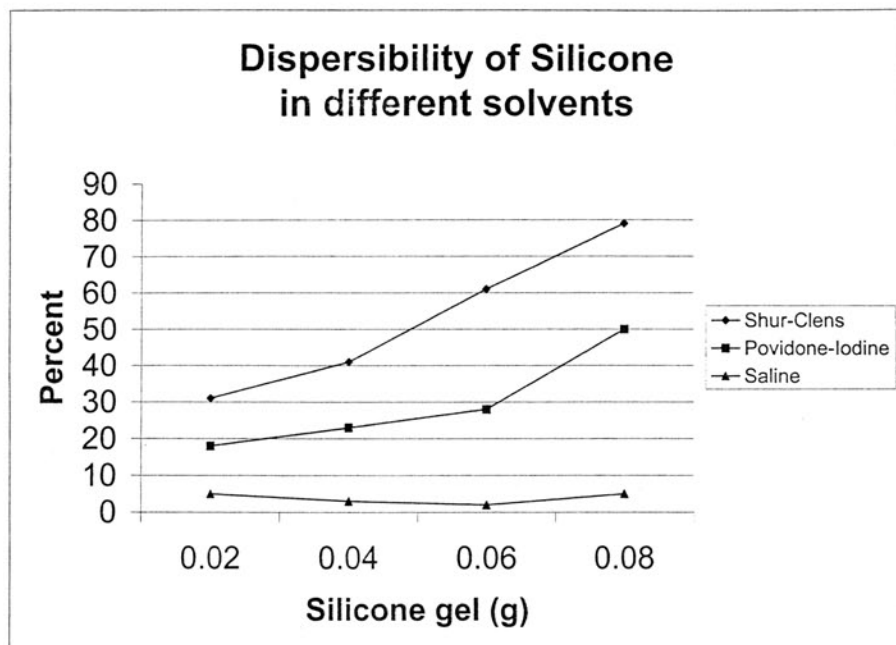
Fig 2. Dispersiveness of silicone in different solvents.

biocompatible medical use. Long-term toxicity studies in animals and humans reveal it to be safe even for intravenous use.[21] As early as 1965, poloxamer 188 was used as the emulsifying agent for intravenous nutrition.[23] After the Food and Drug Administration was established, poloxamer 188 was approved for use in humans. Subsequently, an intravenous solution of poloxamer 188 (RheothRx; Glaxo Wellcome, Reasearch Triangle Park, NC) was approved by the Food and Drug Administration as an antithrombotic agent[24] and for the relief of episodic pain for patients with sickle cell disease.[25] Currently, poloxamer 188 (RheothRx) is undergoing extensive multicenter trials to document its benefit in the acute treatment of myocardial infraction.[26]

Our clinical experience with 7 patients who underwent ruptured silicone breast implant removal suggests the superiority of Shur-Clens over saline or povidone–iodine solution. In our limited experience, removal of silicone gel from breast pockets is easier and more thorough with Shur-Clens compared with saline or povidone–iodine solution—the solvents typically used to remove silicone gel. We propose the use of Shur-Clens to clean silicone gel spillage to decrease local complications resulting from residual silicone gel.

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