

## An Experimental Analysis of Silicone Leakage

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### Abstract

We analyzed whether gel bleed, the leakage of silicone gel from breast implants, occurs in the human body. We simulated the phenomenon with olive oil. Silicone breast implants were submerged in olive oil, and the concentration of silicone polymers in the olive oil was measured periodically with nuclear magnetic resonance spectroscopy. We found no increase in the silicone concentration. However, clinical conditions might not be adequately simulated because of the shortness of the experimental period and the lack of external stress. However, when clinical experiences and our data are considered, we think that silicone implant durability is an important factor to prevent leakage or gel bleeding.

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**Key words:** bleeding, leakage, mammary prostheses, implants, silicone

### Introduction

Leakage of silicone gel (polydimethylsiloxane [PDMS]) from implants has received widespread attention as a possible cause of autoimmune disease, arthritis, and neurologic problems. For this reason, we measured the leakage of PDMS from new breast implants under simulated physiologic conditions.

### Material and Methods

We selected olive oil (Extra Virgin Olive Oil<sup>®</sup>, Bosco, Italy) as a solution, glass jars as the containers, and 5 types of implant (Cristalline Paragel Cohesive<sup>®</sup> implants with very cohesive gel,

Eurosilicone, France; Inflable<sup>®</sup> saline filled implants with a smooth surface, Eurosilicone, France; Standard Gel<sup>®</sup> silicone gel-filled implants with a smooth surface, Eurosilicone, France; Paragel<sup>®</sup> silicone gel-filled implants with a smooth surface, Eurosilicone, France; Cristalline Paragel<sup>®</sup> silicone gel-filled implants with a textured surface, Eurosilicone, France). All implants were of similar size. Implants were placed into jars that had been cleaned with organic solvent and rinsed in deionized water to ensure the absence of any silicone. We confirmed the absence of silicone contaminants in the experimental apparatus and the solution. Implants were submerged to simulate clinical conditions. The volume of fluid was the same in each jar and was sufficient to ensure that an implant was completely

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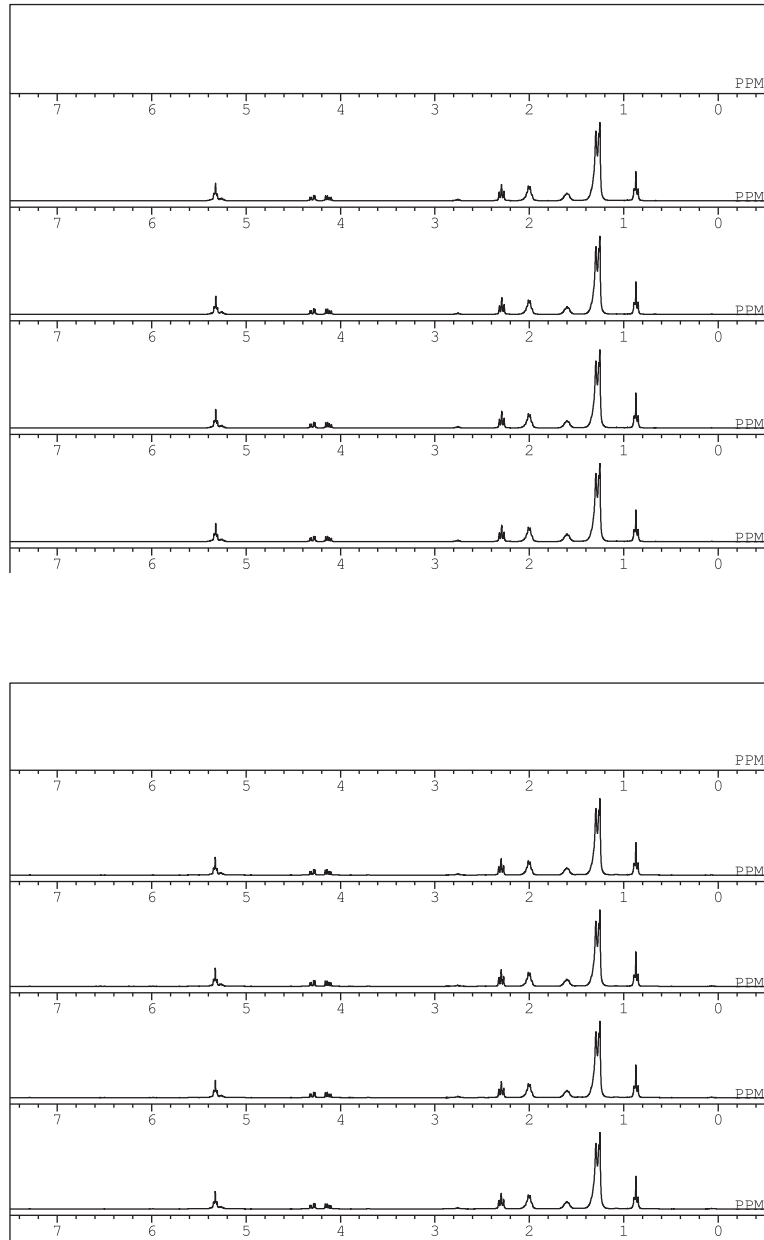


Fig. 1

Upper figure shows 1day

As follows from the top

Crystalline Paragel Cohesive®: implants with very cohesive gel

Inflable®: Saline filling smooth surface

Standard Gel®: Silicone gel filled smooth surface

Paragel®: Silicone gel filled smooth surface

Crystalline Paragel®: Silicone gel filled textured surface.

Lower figure shows 1year

Same order in upper figure

In these figures, there were no peak line of silicone (refer to upper figure of Fig. 2)

submersed but not in contact with the surrounding surface of the jar. All jars were kept at a constant temperature of 37°C. Two milliliters of the solution in each jar was extracted periodically. All silicone

compounds in the solutions were analyzed with nuclear magnetic resonance (NMR) spectroscopy (JNM-LA300WB, JEOL Tokyo Japan)<sup>1</sup>.

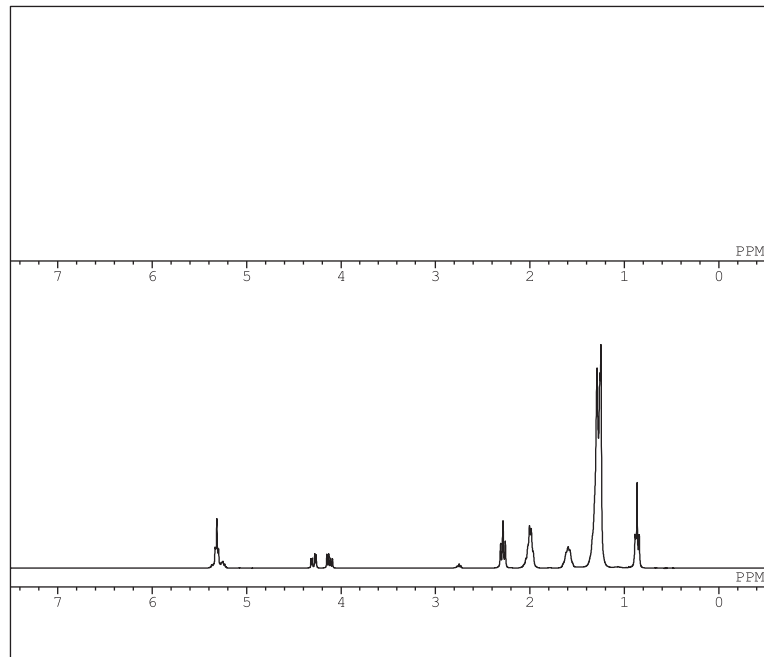


Fig. 2

Upper figure/control: silicone gel (PDMS)

Peak line shows silicone.

Lower figure/solvent: olive oil

## Results

We examined each solution every day for 1 week, every month for 3 months, at 6 months, and at 1 year. There was no increase in silicone concentration in the solution (**Fig. 1, 2**).

## Discussion

The common observation of PDMS on the surface of inserted intact implants represents gel leakage, sometimes also called gel bleed, through the intact silicone elastomer shell<sup>2</sup>. The observed PDMS was assumed to melt from the shell or diffuse through the shell<sup>3,4</sup>. Several experiments have confirmed this phenomenon. At first, the experiments involved silicone bags placed on cardboard<sup>5</sup> or in a desiccator<sup>6</sup>. These studies reported silicone leakage, but they did not simulate the environment of the implant in the human breast. Therefore, a simulated body fluid (SBF) was used in later reports<sup>7</sup>. This fluid was used to examine the mechanical properties of orthopedic biomaterials<sup>8</sup>. The purpose of these experiments was to examine the reaction of a chemical element (such

as Na and Ca,) in a SBF on the biomaterials. We also performed preliminary short-term experiments with a SBF. (This short-term experiment confirmed the presence of some crystals and Si in the solution). Silicone-gel breast implants are inserted in the subglandular or submuscular space at the breast. In these spaces, the implant is not surrounded by inorganic matter, such as a SBF, but by some type of organic matter, such as a fatty tissue.

Therefore, we concluded that that the conditions of the preliminary experiment did not accurately simulate the clinical environment of the implant. Furthermore, because PDMS is a highly hydrophobic polymer, reproducing leakage in such hydrophilic experiments is difficult and this might have been the cause of crystals appearing in the preliminary experiment. Moreover, Si has been detected in a Si-free experiment using an SBF<sup>9</sup>. For these reasons, we did not select an SBF as the solution.

Instead, we selected oil as the hydrophobic solution and organic matter for simulating the physiological conditions around the implant. Furthermore, olive oil does not easily oxidize.

For the meaningful measurement of silicone

leakage, it was reported that the following conditions must be satisfied: 1) closely reproduce the in vivo environment of the implant in vitro, 2) establish a baseline by starting with an implant surface that is free from silicone bleeding, 3) efficiently collect silicone bleed at serial time intervals over several months, and 4) quantitatively measure the silicone collected with a high degree of sensitivity, accuracy, and reproducibility<sup>7</sup>.

Our method satisfies all these conditions and provides a nondestructive technique to measure gel leakage from an implant under near-physiologic conditions of body temperature and surrounding fat.

In this experiment, we did not clarify the phenomenon of gel leakage. One possible cause is that the experiment was performed under conditions with no external factors, such as pressure.

Moreover, a report on explanted implants showed that their tensile and tear strengths were lower than those of unimplanted prostheses and were generally well below reported manufacturers' values<sup>10</sup>. Some clinical reports suggest that implants may be expected to bleed or ruptured after 10 years or more<sup>11-14</sup>. So, the shortness of our experimental period is the other possible cause.

Considering clinical experiences and our data, we believe that the durability of the silicone bag is an important factor for preventing leakage or bleeding of silicone gel. To examine the durability of the silicone bag, long-term experiments and experiments with external stress are needed.

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