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Bleeding – an outdated phenomenon

by Dr. Oliver Bögershausen

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Bleeding – an outdated phenomenon

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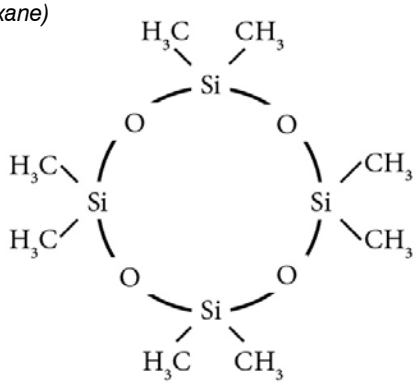
Widespread in medical literature is the term „bleeding“. It describes the diffusion of low molecular weight components from the silicone gel filling of an implant through the shell into the environment of the implant.
This „bleeding“ is a phenomenon that goes back to the design of the first implant generations. It does no longer play a role for modern implants made by reputable manufacturers. This is due to two factors:

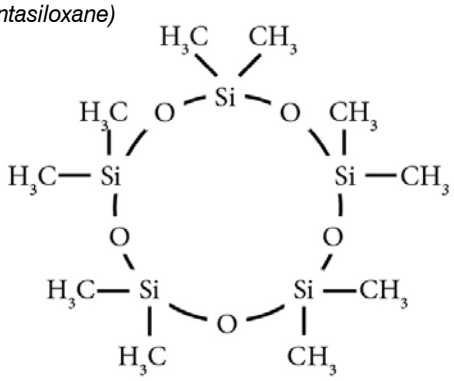
1. The silicone gel filling

Starting point for any „bleeding“ is the silicone filling of the implant. Modern implants are filled with silicone gel. A gel is basically a system of a solid and a liquid phase. The solid phase forms a sponge-like three-dimensional grid, the grid pores are filled with a liquid.
Gels differ in their ability to hold the liquid phase. The aim is to lock the liquid phase permanently in the three-dimensional grid. Figuratively speaking, the liquid phase shall not run like water from a wet sponge. This is meant by the term „cohesiveness“ (cohesiveness has nothing to do with the firmness of a gel). These characteristics are featured by the gels used for breast implants at least since the early 1990s.
However, even a cohesive gel may tend to show „bleeding“. If the liquid phase contains very small (low molecular weight) components they may move relatively freely in the three-dimensional grid of the solid phase. Thus, they may also diffuse through the grid of the silicone elastomer (see below) of the implant shell and be released into the environment of the implant. The smallest silicone molecules are the so-called cyclic D4 (octamethylcyclotetrasiloxane) and D5 (decamethylcyclopentasiloxane) molecules.

Cyclic D4 silicone molecule (octamethylcyclotetrasiloxane)



Cyclic D5 silicone molecule (decamethylcyclopentasiloxane)

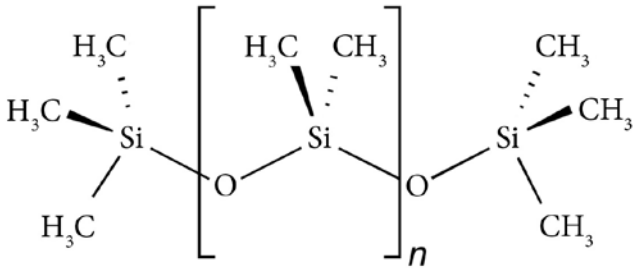


These molecules are so small that they may relatively easily diffuse through a shell without a barrier layer if the corresponding „driving force“ is available. Since D4 is the starting point for the synthesis of silicone, D4 is always contained in the silicone raw material. D4 consists of 4 and D5 of 5 siloxane units.
The actual molecules of a silicone gel consist of more than 100 siloxane units. These molecules are too large to diffuse through the shell. In the earlier silicone gels, the percentage of D4 and D5 was several 100 ppm. Therefore, strategies had to be developed to prevent these low molecular weight components from being released into the surrounding tissue through the shell. One strategy was the development of the barrier layer (see below), another was a purifying process that removed these low molecular weight components from the silicone gel. Applied Silicone Corporation and NuSil Silicone Technology, the two suppliers of the raw silicone used by all reputable manufacturers for the production of breast implants, today provide silicone gels that contain less than 10 ppm of D4 and D5 molecules. This corresponds to less than 3 µl in a 300 g implant.
Another effect that is neglected in the discussion of „bleeding“ is the aqueous environment of an implant, which is thus hydrophilic. Since silioxanes are hydrophobic, there exists no „driving force“ inducing them to diffuse out of the gel into the surrounding tissue. Thus, the situation of an implant in the body cannot be compared with the situation of an implant, for example, in a plastic bag – plastic is hydrophobic.

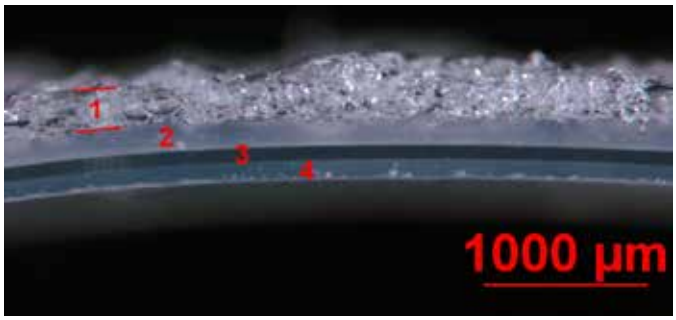
2. The barrier layer

In the mid-1980s, the so-called „barrier layer“ was integrated in the shell structure. For a better understanding, following a brief explanation of the basic shell manufacturing process for mammary implants.
All manufacturers construct their breast implant shells in layers. To this effect, a positive mold is repeatedly coated with silicone dispersions. This is achieved either by dipping the mold in silicone dispersion or by pouring the silicone over the mold. Silicone dispersions are fluids of relatively high viscosity and consist of a suitable dispersion medium, usually xylene, and silicone molecules. (Dispersion = heterogeneous mixture of two or more substances which do not dissolve into each other)
After each coating process, the dispersion medium is evaporated and a new layer applied. Once the manufacturing of the shell is finished, which means that the desired shell thickness has been attained, the applied silicone is vulcanized. This process cross-links the entire silicone into a single giant molecule (silicone elastomer). This cross-linking makes the number of layers cast to build up the shell completely irrelevant.
All shells of modern implants are equipped with a so-called barrier layer. This layer is meant to minimize the diffusion of low molecular weight components from the silicone filling (see above) into the surrounding tissue. This is the reason why these shells are built of two different „types of silicone“. To obtain the necessary stability, pure polydimethylsiloxane (PDMS) is used, where the two free valences of the silicon are occupied by methyl groups.

Polydimethylsiloxane (PDMS)



For the barrier layer, silicones are used where a certain amount of the methylene groups will be replaced by either phenyl or trifluoropropyl. Due to the different electronegativity of these molecules, they create an effective diffusion barrier for pure PDMS molecules.
Since these barrier silicones have a different light refraction, the barrier layer is clearly visible in light microscopic images (see top right), the darker layer marked with the number 3). Among others, it is this optical effect that prompted the term multi-layer envelope. As may be seen in the image, three areas can be distinguished in the shell apart from the roughened surface (1). (2) and (4) are areas of PDMS, (3) is the barrier area. In this context, the term „area“ is selected on purpose, because each of these areas may again consist of several layers of identical silicone (see above). Of how many layers an area consists, depends on the intrinsic production process of the respective manufacturer.



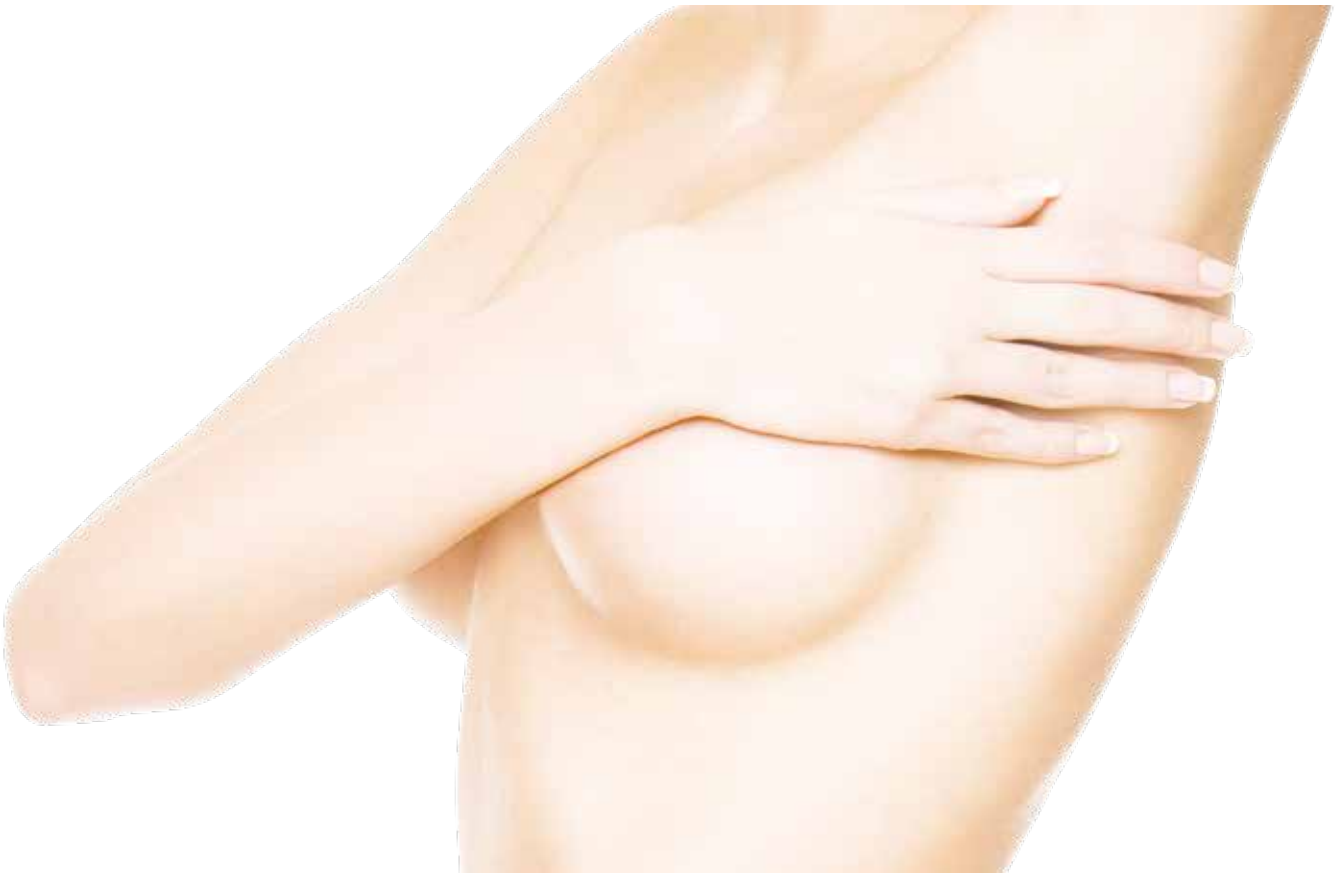
Cross-section through a textured shell: 1 = roughened surface, 2 and 4 = PDMS areas, 3 = barrier area (barrier layer)

The important factor is that the number of layers definitely says nothing about the quality of a shell. Rather, stability and uniformity of the shell thickness are the quality criteria that are essential.

There are a few general rules regarding the process:
- The lower the silicone content in the dispersion, the less viscose it is.
- The lower the silicone content in the dispersion, the thinner is the layer that can be achieved with a coating procedure.
- The thinner the layer obtainable per silicone coating, the more often silicone must be applied to achieve the desired layer thickness.
- The more often silicone is applied, the greater the risk of failures in the shell.
- With low-viscosity silicone dispersions, a more uniform shell structure may be obtained (within certain limits). (From the quality point of view, this rule is contrary to the one before.).
- The barrier area reduces the stability of the shell. Therefore, it is desirable for stability reasons to design the barrier area as thin as possible. However, to maximize the barrier effect, the area must be constructed as strong as possible. These two requirements are contradictory too.

A typical smooth-walled shell consists of three areas (2, 3, and 4). Of how many layers a shell consists, depends on the manufacturing process and is no feature giving any evidence regarding the quality. But since the marketing departments of the implant manufacturers need something they can talk about, at times the number of layers is brought to the fore as a quality criterion: “Our shell is composed of 6, 7, 8 (or more) layers.“ Only to give some number at this point – and at the same time clearly pointing out that it is not a number that stands in any way in relation to the quality of the shells – it may be said that a smooth-walled POLYTECH shell consists of 5 layers.

Both procedures – first, the introduction of the barrier region, and second, the immense purification of the raw silicone for the gel – have led to the fact that bleeding has become a matter of low importance with modern implants.



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