



NMR investigation of breast implants

Analysis of the silicone structure using ^1H -NMR



Background

In 2010 the production and sale of implants of Poly Implant Prothesis (PIP) were stopped by French authorities. The National Health Service (NHS) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) revealed a much higher rate of implant ruptures related to those implants. That is why the responsible authorities of several countries advised all concerned women to remove or replace implants from PIP. The filling of an implant is usually made out of silicone rubber. Such silicone rubber is highly cross linked and remains in the implant even if it is cut into pieces. In the implants of PIP this silicone was replaced by cheap industrial silicone which is not certified for the use in medical devices. The scope was to develop a test method for the used silicone by using ^1H -NMR spectroscopy.

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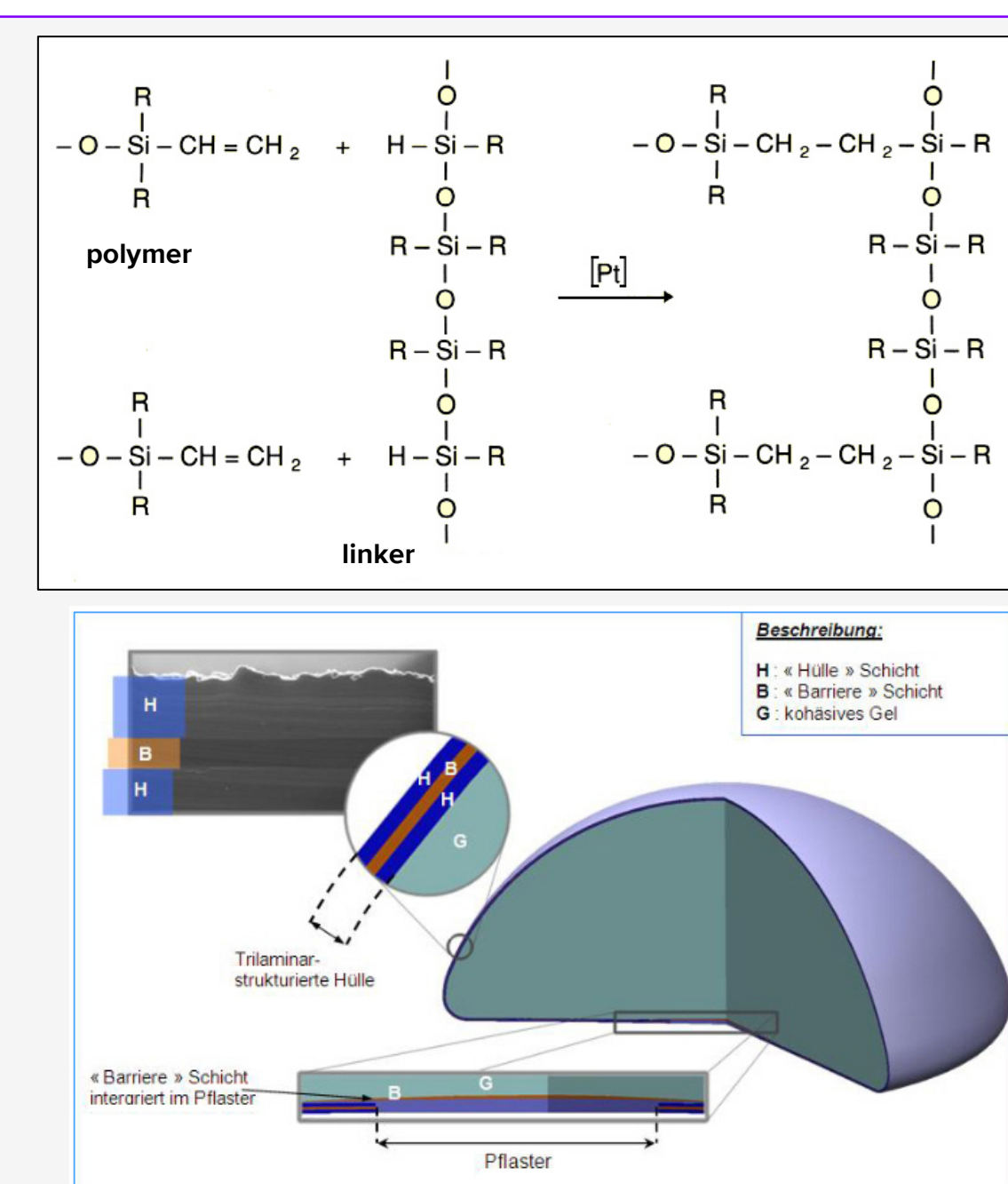
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Structure of breast implants

The implant shell is made of a silicone elastomer. It is also coated with an additional barrier layer designed to prevent the diffusion of silicone into the body. This barrier layer is located within the shell between two layers of the silicone elastomer.

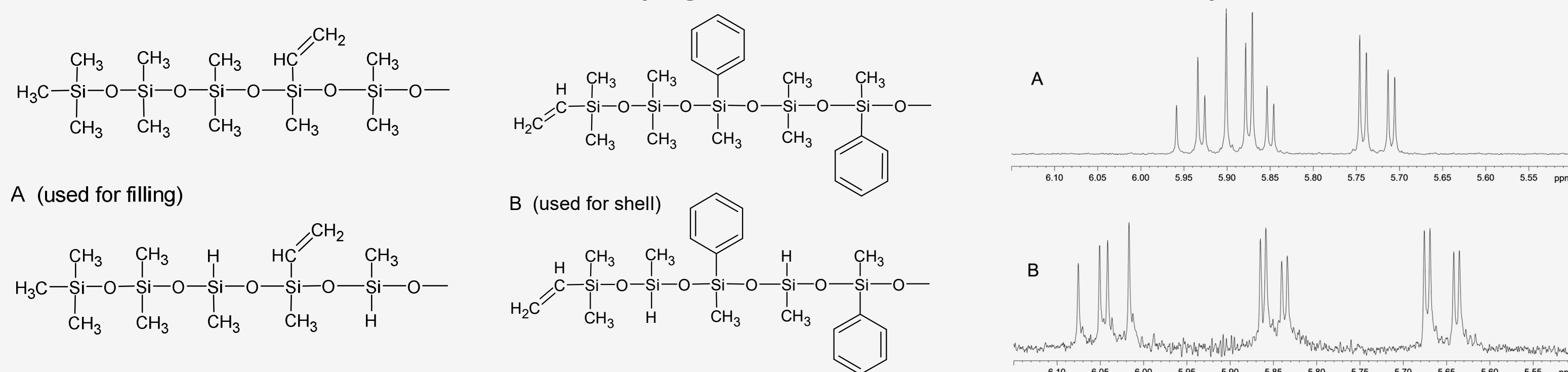
In the first generations of implants, the surface of the implants was smooth. However, studies have shown that the risk of capsular fibrosis is significantly reduced by a textured surface. Both variants are state-of-the-art and are used in today's breast implants.

The implant filling consists of a sodium chloride solution or a silicone gel. The silicone gel is a cross-linked polydimethylsiloxane. This cross-linking results in a slightly firmer and more dimensionally stable implant. It also allows the production of various implant shapes, which is not possible with a sodium chloride filling. So-called anatomical implants differ not only in shape (round, oval) but also in the orientation of the profile (curvature).



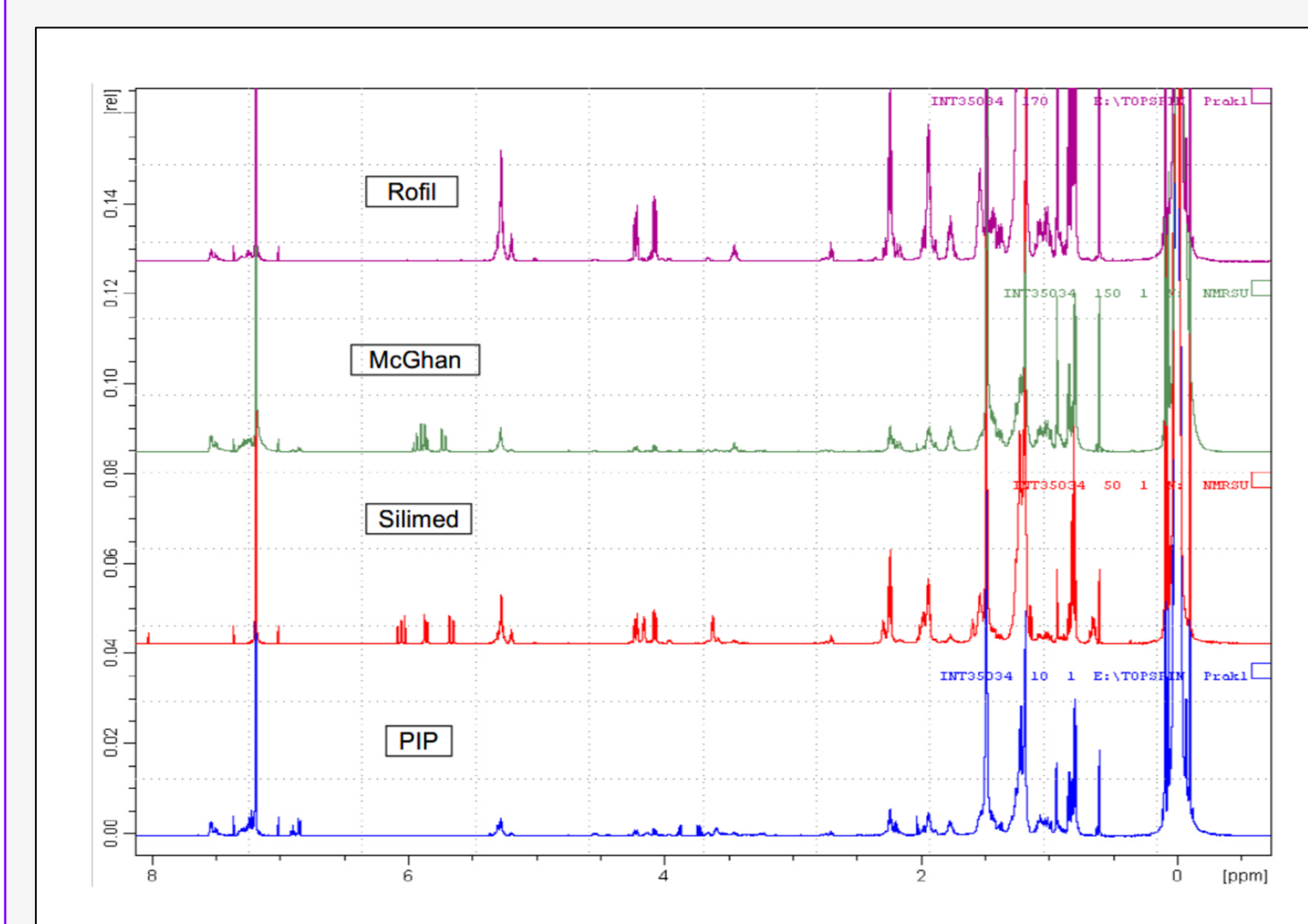
Silicone gel

The cross-linking silicone gel is a two-component oil that cross-links upon heating. Proton NMR can be used to distinguish certain structural features of the silicone. For example, it is possible to determine the position of the vinyl group that cross-links with Si-H. The coupling pattern can be used to determine whether the vinyl group is located within the polymer chain or at its end.



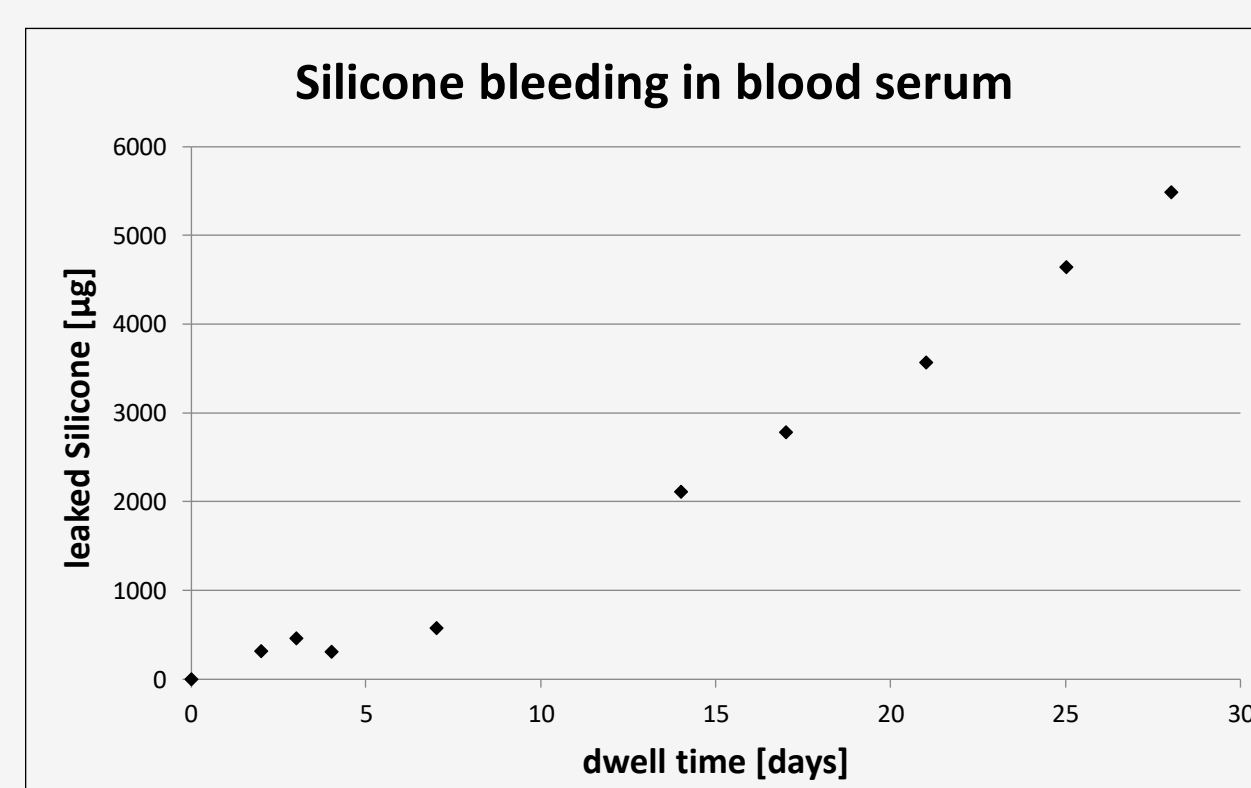
Structural comparison

Several explanted breast implants were analyzed and compared regarding their silicone structure. The analyzed implants were produced by Rofil, McGhan, Silimed and PIP. The implants of McGhan and Silimed both contained silicone with vinyl groups. The other two only contained silicone oil which was not cross-linked. The filling also showed the low viscosity of an oil due to the missing cross-linking.



Silicone bleeding

A further test was performed regarding the bleeding of an unused implant. Therefore, it was placed in blood serum (porcine) at 37°C for approx. one month. Over the time the total silicone content in the blood was determined and it showed that there is a bleeding of silicone into the surrounding. The results even indicate a potential opening effect resulting in an increased bleeding over time. However, the period under review was too short to draw a clear conclusion on this matter.



Take-Home Message

^1H -NMR spectroscopy enables detailed structural characterization of silicones, including end groups, functional groups, and average chain length determination. The method provides chemically specific information which allows reliable classification of silicone breast implants and differentiation between materials from various manufacturers based on their molecular composition. The NMR spectroscopy has once again proven to be a reliable and versatile tool for product and quality control as shown here for silicones and implant analysis.