Comments on "Determination of Low Molecular Weight Silicones in Plasma and Blood of Women after Exposure to Silicone Breast Implants by GC/MS"

SIR: The authors of this article[1] have chosen a particularly challenging problem to address: the detection and analysis of low molecular weight (LMW) cyclic silicones at trace levels, where both adventitious contamination and losses of these volatile materials are highly probable. It has been pointed out previously[2−4] that the use of silicones (including LMW cyclics) in personal care products, such as anti-perspirants, cosmetics, and lotions, as well as in plastic lubricants and GC stationary phases, may have led to erroneous reports in the literature arising from contamination. Poly(dimethylsiloxane)s (PDMS) are commonly used in laboratory equipment as lubricants, etc.

LMW cyclics can be generated by rearrangement of PDMS in the presence of certain catalysts.[5] This reaction can occur in the injection port of a gas chromatograph. When one is working near the limits of detection (LOD), it is prudent to challenge all phases of the work, including the results, with utmost care and to investigate all possible sources of error as critically as possible.

Flassbeck et al.[1] claim to have found LMW cyclic siloxanes in the plasma or blood of women who have had silicone breast implants, which in some cases were later explanted. Their data do not support this conclusion. Nor is it established that their data show a trend that implantation with silicone prostheses increases the amount of LMW cyclics in the body, as they claim. Unfortunately, many key data were not presented in their paper, so few conclusions are possible. It is clear, however, that inadvertent contamination did play a role in their results. Specific areas of difficulty are:

1. The presence of 20 ng/mL hexamethylcyclotrisiloxane (D_3) in the blood of a patient whose implants were explanted 4 years prior (Table 4) is not credible in view of the high vapor pressure and low enthalpy of vaporization for D_3.[6] Significantly, the authors were unable to recover more than 30% of D_3 in their spiked blood samples (Table 2), attesting to the difficulty of retaining this material without special precautions.

2. The erratic appearance or nonappearance of LMW cyclics in various samples, commented on by the authors themselves, is hard to rationalize. For example, *no* cyclics were detected in the whole blood of one patient who had implants for 12 years, including one ruptured implant (Table 2). Another patient with intact implants allegedly showed the presence of both D_3 and D_4 (octamethylcyclotetrasiloxane) in a blood sample.

3. Extraction efficiencies were determined using concentrations of LMW silicones well above those reportedly encountered in blood and plasma samples. Relatively small amounts of contamination at the concentration levels reported for the samples would not have been detected in the recovery studies. The recovery studies should have been carried out at the concentration levels reported for the samples.

4. No statistical data are given to permit evaluation of the reliability of either the recovery studies or the blood and plasma analyses. If the limit of detection was 2 ng/mL, how meaningful are reports of 2 or 3 ng/mL? We cannot tell.

5. There is no identification as to the source of the implants. It is probable that different manufacturers have differing amounts of LMW silicones in their gel. In contradiction to the author's claim that the gel contains 1−2%, one reliable analysis showed <0.1% cyclic siloxanes.[7]

6. Only two blood samples of control subjects were measured. This category should have been substantially expanded, especially in view of previous reports (their ref 17) that silicone could be detected in the blood of volunteers without implants.

7. Selective ion monitoring (GC/MS) was used for the analysis. Whereas this technique is useful to obtain maximum sensitivity, it can be misleading in that background and interferences can give erroneous results. Confirmation by another approach would be appropriate.

In short, if we discount the values reported that are below the limit of quantitation, half of each group did not show any silicone regardless of the time or condition of the implants. In the half that did show silicone, results are erratic and inconsistent. It is claimed that blanks were run, but no data or chromatograms are presented, and key statistical data are missing.

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(1) Flassbeck, D.; Pfleiderer, B.; Grümping, R.; Hirner, A.V. *Anal. Chem*. **2001**, *73*, 606−611.
(2) Carpenter, J. C.; Gerhards, R. In *The Handbook of Environmental Chemistry, 3.H, Organosilicon Materials*; Chandra, G., Ed.; Springer: Berlin, 1997; p 30.
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(4) Smith, A. L.; Parker, R. D. In *The Analytical Chemistry of Silicones*; Smith, A. L., Ed.; Wiley: New York, 1991; Chapter 4.
(5) Moore, J. A. In *The Analytical Chemistry of Silicones*; Smith, A. L., Ed.; Wiley: New York, 1991; Chapter 13, p 423.
(6) The vapor pressure for D_3 (M_w = 222) is roughly 10 000 times greater than that of a hydrocarbon of similar molecular weight. Heats of vaporization for the LMW cyclics are about half those of the corresponding molecular weight hydrocarbons.
(7) Private communication, Southwest Research Institute, 1993.

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