

Antisilicone antibodies are biologically unlikely

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Received: 17 April 2008 / Accepted: 21 April 2008 / Published online: 7 June 2008
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Dear Editor,

In the recent publication “The association between silicone implants and both antibodies and autoimmune diseases” [1], the investigators evaluated the sera and capsular tissue from patients undergoing reconstructive procedures for burn scars. Fifteen patients with burn scar contractures were implanted with silicone tissue expanders, while 15 burn patients were not. The investigators reported elevations in serum immunoglobulin (Ig) E and the presence of antisilicone antibodies in the capsular tissue for the silicone-implanted group. Given the historical interest in this topic and the existing consensus that there is no antisilicone immune response, a closer examination of this study is warranted.

Tissue expanders typically use the same silicone elastomer as silicone breast implants, which have been extensively studied and scrutinized as a result of the breast implant debate. Three independent review panels have carefully assessed the specific issue of silicone immunogenicity. All three groups concluded that there is no convincing evidence to support an association of silicone

breast implants with immune-related human health conditions [2–4]. One report also pointed out that the enzyme-linked immunosorbent assay (ELISA) methodology used to measure antisilicone antibodies is flawed, and the existence of antisilicone antibodies is biologically unlikely [2].

If antisilicone antibodies do not exist, is there a plausible explanation for their observations? A number of studies have demonstrated that proteins, including antibody proteins, will bind nonspecifically to silicone. In the case of Goldblum et al. who first reported on the existence of an antisilicone antibody [5], further research by Goldblum and others determined that these observations were not due to a specific antisilicone antibody but to different circulating levels of albumin [6, 7]. As albumin and IgG can compete for nonspecific adsorption onto silicone substrates, low levels of albumin in their “positive” patient sera allowed for more nonspecific adsorption of the IgG fraction. Theoretical calculations [8] and experimental ELISA-based data [9] confirm the high affinity of human IgGs for silicone surfaces.

The elevations in serum IgE also have biologically plausible explanations. A selective increase in serum IgE has been observed following surgical procedures, and the magnitude of increase appears to correlate with the surgical injury intensity [10]. Unfortunately, the investigators failed to account for the additional tissue expander implant procedure in this present study. Alternatively, ethylene oxide (ETO) gas is used to sterilize a variety of silicone medical devices, and residual ETO can react with endogenous proteins to create neo-antigens. In several patients who have experienced silicone shunt malfunctions, there was no evidence of an infection, but the patients presented with elevated eosinophil counts and serum IgE antibodies specifically directed toward ETO protein conjugates [11].

We believe the authors were too quick to reach their conclusions, unaware of other more likely mechanisms and

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the extensive literature rebutting the hypothesis of a specific immune response to silicone.

Conflict of interest All three authors are employed by Dow Corning, a supplier of silicone and silicon based materials.

References

1. Bekerecioglu M et al (2008) The association between silicone implants and both antibodies and autoimmune diseases. *Clin Rheumatol* 27:147–150
2. Bondurant S et al (2000) Committee on the safety of silicone breast implants, division of health promotion and disease prevention, institute of medicine. safety of silicone breast implants. National Academy, Washington, DC
3. Diamond BA et al (1998) Rule 706 National Science Panel Report, United States District Court, Northern District of Alabama, Southern Division, In re: Silicone Gel Breast Implant Products Liability Litigation (MDL 926)
4. Sturrock RD (1998) Silicone Gel Breast Implants: The Report of the Independent Review Group. UK Department of Health, Medicines and Healthcare products Regulatory Agency, London. July 1998. Accessible at <http://www.mhra.gov.uk/home/groups/dts-bi/documents/websiteresources/con2032510.pdf>
5. Goldblum RM et al (1992) Antibodies to silicone elastomers and reactions to ventriculoperitoneal shunts. *Lancet* 340:510–513
6. Goldblum RM et al (1998) Modulation of IgG binding to silicone by human serum albumin. *FASEB J* 12(Pt II):5967
7. White KL, Klykken PC (1998) The non-specific binding of immunoglobulins to silicone implant materials: The lack of a detectable silicone specific antibody. *Immunol Invest* 27:221–235
8. van Oss CJ, Naim JO (1995) A specific immunoglobulin binding to hydrophobic surfaces. *Curr Topic Microbiol Immunol* 210:85–91
9. Butler JE et al (1995) The adsorption of proteins on a polydimethylsiloxane elastomer (PEP) and their antigenic behavior. *Curr Topic Microbiol Immunol* 210:75–84
10. Navarro-Zorraquino M et al (2001) Determination of the immunoglobulin E postoperative variation as a measure of surgical injury. *World J Surg* 25:585–591
11. Pittman T et al (1994) The role of ethylene oxide in sterile shunt malfunctions. *Br J Neurosurg* 8:41–45