Elevated Serum Silicon Levels in Women with Silicone Gel Breast Implants

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ABSTRACT

The metabolic fate of silicone gel leaked from an intact or ruptured prosthesis is unknown. In this study, serum was blindly assayed by inductively coupled plasma atomic emission spectroscopy (ICP-AES) for elemental silicon in 72 women with silicone gel breast implants and 55 control women (mean age 48 yr, both groups). Blood was drawn and processed using silicon-free materials. The mean silicon level in controls was 0.13 ± 0.07 mg/L (range 0.06-0.35 mg/L), whereas in implant patients, the mean was significantly higher at 0.28 ± 0.22 mg/L (range 0.06-0.87 mg/L) (P < 0.01, Student’s t-test with correction for unequal variances). Using the mean of the control group + 2 SD as a cutoff for normal range (0.27 mg/L), 25/72 (34.7%) implant patients exceeded this value, compared with 2/55 (3.6%) controls. There was no significant correlation between past rupture of one or both implants, current rupture at the time of the blood draw, or the number of years with implants and silicon levels. The results suggest that serum silicon levels are elevated in many women with silicone gel breast implants. The chemical species involved and kinetics of this elevation remain to be determined.

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INTRODUCTION

Biomedical applications of silicones have been numerous (1). Silicones are generally very well tolerated by the body, but occasional adverse reactions to the foreign material have been noted, for example, as complications of joint replacement or ventriculoperitoneal shunts (2,3). Currently, there are concerns that long-term exposure to components of silicone gel-filled breast implants may be associated with autoimmune or inflammatory diseases (4). Polydimethylsiloxane (PDMS) polymers, which form the silicone gel in breast implants, are manufactured from elemental silicon. The silicone rubber implant shell is also made of PDMS with fumed, amorphous silica added as a strengthening filler (5). It has been shown that the gel can bleed through the implant shell over time (6). In addition, there is potential for mechanical breakdown and degradation of the implant shell owing to hydrolysis, mechanical forces, and perhaps effects of oxidative attack from the body’s inflammatory cells (7). Silicon is a major component of breast implants, accounting for 35–40% of the implant by weight (8). If implant components are degraded with time and gain access to the circulation after leakage or rupture, circulating silicon might be elevated in the blood or serum of such women as soluble silicic acid, or even as hydrophobic silicone fragments in association with lipids or carried in peripheral blood cells. A recent study involving several women has shown silicon-containing material that was presumed to have migrated from their silicone gel implants to sites of connective tissue disease (9). In the current study, we examined the sera of women with and without implants, hypothesizing that the silicone gel implants would serve as an endogenous source of ongoing elevation of serum silicon levels, especially in those women who had ruptures at the time of the blood draw or a history of past rupture.

METHODS

Subjects

Women with silicone gel breast implants were recruited by a press release announcing the study. Some women were referred for the study after undergoing ultrasound or mammography locally. Control women were recruited to match the ages of the subjects. Informed consent was obtained from all volunteers. Women were excluded if they had only one implant, dual lumen or saline implants, or polyurethane coating, because it was unknown how these variables might affect serum silicon levels. Women were also excluded if their implants had been removed prior to