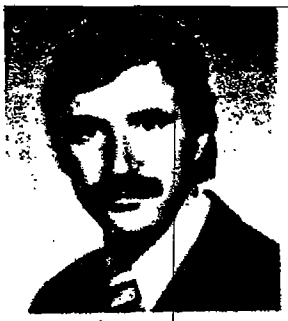

Augmentation Mammaplasty Associated with a Severe Systemic Illness

Barry F. Uretsky, M.D.,
J. James O'Brien, M.D.,
Eugene H. Courtiss, M.D.,
and Martin D. Becker, M.D.

A case report of a systemic, near-fatal illness possibly related to augmentation mammaplasty with silicone gel prostheses is presented. Twenty-four hours after the augmentation procedure, the patient, a 32-year-old woman, developed a high fever followed by diffuse arthritis, renal failure, and bilateral pulmonary infiltrates. Shortly after removal of the prostheses, the patient's condition improved dramatically. Samples from blood, urine, sputum, and breast pockets collected at the time of prosthesis removal demonstrated silicone polymers. Evidence is presented that indicates the illness was not of infectious origin.

From the Departments of Medicine and Surgery, Norwood Hospital, Norwood, and the Department of Surgery, Newton-Wellesley Hospital, Newton Lower Falls, MA.

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Address reprint requests to Dr. Uretsky, Department of Cardiology, Presbyterian-University Hospital, Pittsburgh, PA 15217.

It is estimated that over half a million augmentation mammaplasties using silicone gel implants have been performed since 1959, with no documented adverse systemic reactions to the implant material during this period. We present a case, however, of a near-fatal illness that we believe may be related to the implantation of silicone gel mammary prostheses.

A 32-year-old woman in good health underwent an uneventful bilateral augmentation mammaplasty* under local anesthesia in an office surgical unit. Twenty-four similar procedures have been performed to date under identical conditions without complications. The prostheses were steam sterilized according to the manufacturer's instructions. The day following surgery the patient developed a fever of 40° C, rigors, and drenching sweats. On examination, there was no apparent explanation for her fever, which persisted during the course of the illness. The patient was hospitalized three days after undergoing mammaplasty. On the fourth postoperative day she complained of dysesthesia in the distal extremities, but no objective sensory deficit could be detected. Symmetrical joint swelling (proximal interphalangeal joints of both hands, knees, and ankles) occurred on the eighth day of her illness. On the tenth postoperative day, diffuse peritoneal signs developed. Intravenous ampicillin and clindamycin were started. Laparotomy revealed only a small amount of viscous fluid and moderate enlargement of both kidneys. At the time of surgery, the patient's blood urea nitrogen was 62 mg per deciliter and her creatinine, 2.0 mg per deciliter. On the following day, respiratory insufficiency with bilateral lower lobe infiltrates developed. Arterial blood gases showed a pH of 7.40, pCO_2 of 22 mm Hg, and bicarbonate 15 mg per deciliter. No predominant organism was seen on Gram stain of sputum. During the eleven days following implantation, her hematocrit fell from 36% to 26% and her platelet count fell from 133,000 per cm^2 to 44,000 per cm^2. There was no evidence of bleeding, hemolysis, or intravascular coagulation. The left breast incision showed no signs of inflammation on repeated breast examinations. The edges of the right incision were somewhat erythematous, but without tenderness,

*Heyer-Schulte 240 ml low-profile gel implants, model No. 2100.

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warmth, or pain on palpation. At the time of laparotomy, surface swabs of both healing breast wounds revealed moderate growth of coagulase positive *Staphylococcus aureus*. Two days after laparotomy, clindamycin and ampicillin were discontinued. Oxacillin was begun and continued until the patient's discharge. Six preantibiotic blood cultures drawn over the first twenty-four hours after admission and urine cultures (day 1), spinal fluid (day 4), and peritoneal fluid (day 5) were sterile. Sputum culture (day 7) showed a very light growth of *Klebsiella*.

The following studies were normal: antinuclear antibody titers, lupus cell preparation, latex fixation, serology, cryoglobin titer, heterophil screen, Coombs' test, serum protein electrophoresis, complement levels (total, C_3, C_4), prothrombin time, partial thromboplastin time, thrombin time, alkaline phosphatase, lactic dehydrogenase, bilirubin, uric acid, glucose, cholesterol, calcium, total protein, electrolytes, urinalysis, cerebrospinal fluid protein and sugar, haptoglobin, thyroxin, and electrocardiogram. Fibrinogen level was 540 mg per deciliter (normal 200 to 400 mg per deciliter); fibrin split products were greater than 10 μg per milliliter and less than 40 μg per milliliter, and sedimentation rate was 120 mm per hour. Urine collected over a twelve-hour period showed no evidence of fat.

Clinical deterioration (increasing respiratory embarrassment, decreasing renal function, and delirium) ensued. The breast implants were removed intact on the eleventh day and were normal in appearance. Approximately 25 ml of thin, slightly sanguineous, opalescent fluid was removed from each breast pocket. A moderate growth of coagulase positive *S. aureus* was cultured from each sample.

During the next six days, the pulmonary infiltrates and joint swelling resolved, renal function normalized, the platelet count rose to 380,000 per cm^3, and the hematocrit increased to 30%. The patient was discharged on the sixth day following removal of her breast implants. Some drainage from the right breast incision persisted. Culture grew *Klebsiella*, which was treated with cephalexin and irrigation. Healing was complete at seven weeks. Hypesthesia of the distal third of the left second and third fingers gradually cleared over a three-month period.

Methods

At the time of prosthesis removal, samples of urine, sputum, and breast fluid were collected and stored in silicone-free containers. Blood samples were collected in silicone-lined test tubes. Samples of blood as well as drainage from the patient's right breast wound were obtained three weeks after discharge from the hospital. A control blood sample was obtained at the same time from a healthy volunteer, and each was divided and stored in both siliconized and nonsiliconized containers. Extraction and qualitative analysis for silicone were performed employing mass spectrophotometry.*

Results

Silicone polymers were found in all of the samples obtained at the time of prosthesis removal, including fluid from both breast pockets, blood, urine, and sputum. Breast drainage and blood samples stored in a nonsiliconized tube obtained from the patient three weeks following hospital discharge failed to demonstrate silicone.

Blood collected simultaneously from a siliconized tube did show traces of silicone, however. A control blood sample, collected in both siliconized and nonsiliconized tubes, showed no trace of silicone when examined by the same methods. Analysis for complement-fixing antibodies against silicone were negative.†

Discussion

Several features militate against staphylococcal sepsis as the cause of the patient's illness. The breast incisions and pockets showed little evidence of infection although *S. aureus* was grown from them. The left healing wound appeared entirely normal. The wound edges on the right were slightly erythematous, but not warm, edematous, or tender on palpation. Six blood cultures, drawn over a twenty-four-hour period of clinical toxicity and fever, were negative. This finding by itself makes staphylococcal sepsis, particularly from endocarditis, unlikely [6]. Diffuse arthritis in the absence of frank joint infection is not a usual feature of diffuse

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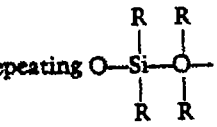
*Analysis performed by Skinner and Sherman, Inc, Waltham, MA.

†Analysis performed by Dr. Sidney Cooperband, Director, Cancer Research Center, Boston University School of Medicine, Boston, MA.

staphylococcal disease [8]. Multiple sputum Gram stains and cultures performed when bilateral pulmonary infiltrates were present did not reveal the presence of *S. aureus*. Finally, in conjunction with the above findings, the patient appeared to be deteriorating while on an appropriate intravenous antibiotic (oxacillin) for more than seventy-two hours. Furthermore, she improved dramatically within twenty-four hours after the breast prostheses were removed.

Silicone (dimethylpolysiloxane, i.e., polymers of



repeating O—Si—O—Si units) is used extensively in such varied medical products as ventricular shunts, joint prostheses, test tube lining, syringes, and needles, as well as breast implants.

The wide application of silicone stems from its chemical stability in biological systems. Little or no change in physical properties as a function of temperature, low surface tension, or aging, combined with minimal tissue reaction and lack of immunogenicity, explains the popularity of this substance for medical purposes.

The only reported tissue reaction to silicone breast implants with which we are familiar is the formation of a localized periprosthetic fibrous capsule [3]. In addition, silicone granuloma formation following capsular rupture in vivo has been reported [4]. Illicit silicone injections, in which the purity of the substance is unknown, have been associated with hepatic granulomas and an acute febrile systemic illness which on occasion has been fatal [5]. Animal studies utilizing subcutaneously injected medical-grade silicone have not included descriptions of a systemic illness [1, 7]. These studies have shown, however, that after local injections of silicone, the substance can be recovered in various organs including the kidney, spleen, liver, adrenal glands, ovaries, lymph nodes, and pancreas [1, 7].

We believe that the most likely source of silicone in the samples from our patient was the gel implants. The possibility of contamination of the samples as a result of exposure to silicone in the collecting tubes must be considered. However, since none of the blood obtained in the siliconized tube of a control patient revealed the presence of silicone, and since none of the materials used in the collection of urine, sputum, or breast fluid contained silicone, we consider the possibility remote that our results were due solely to sample contamination.

The presence of silicone in the samples does not necessarily indicate a causal relationship between the recovered material and the patient's illness. In fact, in view of the known "bleed" phenomenon associated with gel-type prostheses [2], it would seem reasonable that silicone might be recovered from the fluid in the breast pockets. No published data exist to quantitate the magnitude of bleed. Also, if bloodborne dissemination does occur, there is no evidence that it is associated with deleterious effects in humans.

In spite of these reservations, our patient's clinical course, particularly the dramatic onset of her illness shortly after the prostheses were implanted and prompt resolution after their removal, suggests the possibility of silicone as a factor in the pathogenesis of this problem. It is unclear why this apparently healthy woman developed a severe systemic illness under the circumstances described. Until further data relating to the magnitude of silicone bleed and the biological effects of its dissemination become available, we suggest that in any postimplantation patient with an unknown febrile illness, the possibility of a relation to implant surgery be considered.

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