Late Infection Following Breast Augmentation With Textured Silicone Gel–Filled Implants

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Background: Infection after insertion of a breast prosthesis is an uncommon but feared complication. Previously reported infection rates vary and include reconstructive and cosmetic patients.

Objective: We sought to define the infection rate and the presentation of postoperative infection in the patient with aesthetic breast augmentation.

Methods: A prospective analysis was undertaken of 288 patients who underwent aesthetic breast augmentation with textured silicone gel-filled implants between 1998 and 2002. Patients were monitored for clinical findings of infection, and microbiological analyses were performed for each case of infection. “Early infection” was defined as signs and symptoms of infection beginning 20 days or less post-surgery; “late infection” was defined as all cases with an onset more than 20 days post-surgery. Treatment was classified as antibiotic therapy only, conservative surgical intervention (with or without implant salvage), or implant explantation and replacement.

Results: Early infectious complications occurred in 6 of 288 women (2.08%). Late infection complications occurred in 10 of 288 women (3.47%). Late infection occurred more often and was more severe than early infection (P < .05). For the late infection group, the length of time to infection onset was between 20 and 280 days (average, 82 days). The length of time to infection was shown to be bimodal and organism-related. The group of infections caused by Enterobacter species had a significantly longer time of onset (P < .05) than the group caused by Staphylococcus aureus.

Conclusions: There is strong evidence that late infections can occur in patients who have undergone aesthetic breast augmentation using textured silicone gel-filled implants. Further studies are needed to determine whether similar late infection rates affect patients with aesthetic breast augmentation who receive saline-filled implants. (Aesthetic Surg J 2005;25:249-254.)

Breast augmentation is one of the most common procedures in plastic surgery. Approximately 334,000 augmentation mammoplasties were performed in 2004 in the United States alone. Although capsular contracture and implant malposition are the most common complications following this procedure, infection is perhaps the most feared. Moreover, some investigators who have sought to elucidate the causes of capsular contracture have related it to low-grade postoperative infection.

The incidence of infection following breast augmentation and reconstruction using implants ranges from 1% to 24%. There are several reports in the literature dealing with implant-related infection, but most of these have not clearly differentiated aesthetic breast augmentation from breast reconstruction procedures. Those investigators who tried to differentiate between aesthetic and reconstructive procedures reported an infection rate of approximately 3%-8.9 No previous study has focused solely on the infection rates following breast augmentation in the healthy cosmetic patient. The distinction is clinically significant because many reconstructive patients have risk factors for infection that may not apply to the aesthetic patient, such as radiotherapy, age, tumor stage, previous chemotherapy, and timing of reconstructive surgery. Early studies suggested that the risk of infection following subcutaneous mastectomy was 8.9%.9

Patients undergoing reconstructive surgery may be more likely to accept the risk of complications than are those undergoing aesthetic surgery and may be more accepting of antibiotic therapy, additional surgery or whatever therapy...
is proposed to address complications. Hence, infection rates and their treatment may be considered differently in these two very distinct groups of patients.

The previous studies dealing with infection rates after breast augmentation also report signs and symptoms of infection usually beginning less than 20 days after surgery. In 25 years of clinical experience, the senior author has found that, in a significant number of cases, the signs and symptoms of infection started much later and required different management than early infections. One large US Food and Drug Administration (FDA) report suggested that silicone gel–filled implants might be associated with a later onset of infection signs than saline implants. However, this report did not specify the characteristics of infection, the differences in length of time before the onset of infection, or the treatment outcome in these cases. To address questions concerning the onset and management of infection after aesthetic breast augmentation, the senior author’s experience during the past 3 years was prospectively analyzed.

**Patients and Method**

Our analysis included 288 aesthetic breast augmentation procedures performed between 1999 and 2002 at the same institution by the senior author. Patient ages ranged from 17 to 54 years, with an average age of 28 years. Only textured silicone gel–filled implants were used, placed either subglandularly or submuscularly. Implant sizes ranged from 135 cc to 350 cc and were determined preoperatively without help of a silicone size tester. Preoperative antibiotic prophylaxis with cefazolin was used in all cases. In most cases, only the surgeon handled the implant before insertion.

All the patients were followed for at least 2 years after surgery. Patients were examined for clinical findings of infection, including cellulitis, warmth, swelling with or without drainage, or systemic signs such as fever and implant exposure. For purposes of this study, “early infection” was defined as signs and symptoms of infection beginning 20 days or less postoperatively, and “late infection” was defined as all cases with later onset. Cases of infection were classified as “mild” (erythema and swelling with no purulent discharge or collection), “moderate” (cellulitis, purulent discharge or collection with or without systemic signs of infection) (Figure 1), or “severe” (implant exposure) (Figure 2). The diagnosis of infection was always made by the surgeon and was followed by routine microbiological culture of the drainage or wound before administration of antibiotics. Clinical parameters were correlated with microbiological findings. All other plastic surgery procedure infection rates in this hospital were equal to or below those reported in recent international surveys.

Treatment strategies were as follows:

1. Antibiotic therapy only.
2. Conservative surgery with implant salvage (including wound debridement, saline lavage, curettage, capsulectomy, implant position change and insertion of a new implant at the time of the surgical intervention) plus antibiotic therapy.
3. Antibiotic therapy plus explantation of the device and delayed (4 to 6 months) insertion of a new implant.

The choice of treatment was based on the classification of the infection as early or late and as mild, moderate, or severe.

**Results**

Early infectious complications occurred in 6 of the 288 women (2.08%) and were associated with 6 of the 560 implants (1.07%) (Table 1). In 4 of these cases
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(67%), the infection was classified as mild. In the other 2 cases the infection was moderate. In both moderate cases, cellulitis was present, with swelling and serous discharge. No body core temperature higher than 38°C (100.4°F) or leucocytosis (blood cell count greater than 10,000/mm³) was documented. The length of time to infection onset was between 8 and 20 days (average, 14 days). All the cases were treated with empiric antibiotic therapy and responded with resolution of the clinical infection within 4 to 8 days. None of the early infectious complications required surgical therapy, although late scar touch-up was performed in 2 patients.

Late infectious complications occurred in 10 of 288 women (3.47%) and was associated with 10 of 560 implants (1.78%). Infection was classified as mild in 2 of these cases (20%), moderate in 4 cases (40%), and severe in 4 cases (40%) (Table 2). In patients with mild infections, erythema and swelling were present with no purulent discharge. In those with moderate infections, cellulitis was present with swelling—with serous discharge in 2 cases, and with purulent discharge in the other 2 cases. In the 4 patients with severe infections, purulent discharge was present, with implant exposure. No body core temperature higher than 38°C (100°F) or leucocytosis (blood cell count higher than 10,000/mm³) was documented, even in the severe cases. The length of time to infection onset was between 20 and 180 days (average 82 days) (Figure 3). Cultured bacteria included Staphylococcus aureus coagulase in 5 patients (50%) and Enterobacter species in 5 patients (50%). Infection onset was bimodal and organism-related. The average length of time to infection onset for infections caused by Enterobacter species was 105 days, which was significantly longer (P < 0.05) than the average 31 days to onset of infection for the S aureus infections.

All patients with late infection complications initially received antibiotic therapy, which resulted in a partial down-staging of the signs and symptoms of infection but failed to achieve a complete response. Consequently, surgical intervention was required in all these cases. Patients with mild or moderate infections (60%) received conservative surgical treatment with implant salvage (including wound debridement, saline lavage, capsulectomy, implant position change and insertion of a new implant at the time of the surgical intervention), plus antibiotic therapy. Patients with severe infections underwent implant explantation plus antibiotic therapy, followed by insertion of a new implant after 4 to 6 months. The salvage rate after late infection was 60%, compared with a 100% salvage rate after early infection. All cases treated were infection-

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<th>Table 2. Classification of late infection cases</th>
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Figure 2. A, B, A 25-year-old woman with severe infection (implant exposure) 72 days after implantation.
free after 4 months’ follow-up and had good aesthetic results despite the severity of infection.

Discussion

Breast augmentation with implants is one of the most popular aesthetic surgical procedures. Silicone gel-filled implants were introduced by Cronin and Gerow in 1962. Currently, they are the most commonly used implants worldwide (particularly in Brazil and Europe), although their use in the United States is restricted according to FDA guidelines.

Several complications have been associated with augmentation mammoplasty, of which infection is perhaps the most dreaded. Pajkos and colleagues reported that the presence of coagulase-negative staphylococci was significantly associated with capsular contracture following breast augmentation. Although other investigators did not confirm this association, a low-grade infection continues to be a possible pathogenesis for fibrous capsular contracture after augmentation mammoplasty. In our study, capsular contracture did not develop in any of the patients with infection through the end of follow-up.

Infection rates after augmentation mammoplasty have been reported to range between 1% and 24%. Almost all the series with reported infection rates included a heterogeneous group of aesthetic and reconstructive patients. In our study, the incidence of early infection following aesthetic augmentation mammoplasty with textured silicone gel-filled implants was 2.08%. This rate is in line with the US Centers for Disease Control National Nosocomial Infection Surveillance (NNIS) report’s assertion that clean surgery can be expected to have an infection rate of approximately 1.5%. The use of a foreign device, such as a silicone implant, may increase this rate.

Several measures have been advocated as a means of reducing the rate of infection in mammoplasty procedures, including changing into previously unused gloves to handle the device and postoperative antibiotic therapy, but none has been shown to decrease infection rates. Antibiotic irrigation was not used during this study. No previous study has shown that antibiotic irrigation reduces the infection rate following breast augmentation. Clinical experience seems to indicate that universal measures, such as minimal handling of tissues to avoid ischemia and trauma and administration of prophylactic antibiotics, are still the mainstays of infection prophylaxis.

The main goal of this study was to determine the incidence of late infection following augmentation mammoplasty. The 20-day cut-off point was used to define late infection because the hospital protocol asks patients to return for evaluation at 1 week, 20 days, and 3 months after the procedure. The study showed that late infection occurred in 3.47% of patients, a significantly higher incidence than early infection. Late infection also was found to be more severe in its presentation than early infection. It was more difficult to treat and was only partially responsive to antibiotic-only therapy.

Late-infection cultured bacteria included Enterobacter species and S aureus. Enterobacter is a gram-negative rod. Enterobacter species, particularly E cloacae and E aerogenes, are important nosocomial pathogens that are responsible for a variety of infections. The source of infection may be endogenous (via colonization of the skin, gastrointestinal tract, or urinary tract) or exogenous (resulting from the ubiquitous nature of these bacteria). Enterobacter species were also among the most frequent pathogens for surgical-site infections, as reported in the NNIS report covering October 1986 to April 1997. These pathogens can cause disease in virtually any body compartment. Use of foreign devices, such as intravenous
catheters, has been associated with Enterobacter species infections. Similarly, presence of a breast implant could be the predisposing factor for infection in our cases.

Infections that occur after the early postoperative period are caused by microbes that gain entry via routes other than those introduced during surgery or by microbes with low virulence. Other routes of microbial entry have been studied and are mainly nosocomial. In cases of augmentation using saline implants (not used in this study), the saline instillation and diffusion through the implant shell may also be causative and have been previously studied.12-14 Nosocomial introduction can result from transient bacteremia caused by infection in any region of the body, including the skin, genitourinary and gastrointestinal areas, or airways. Whether the late infections observed in our study were secondary to microbe seed by such transient bacteremia is not clear. However, such infection is likely to occur. Consequently, knowledge of any infection previous to surgery, such as urinary tract infection or gastroenteritis, could be useful in choosing the most appropriate empiric antibiotic. Dental procedures can also cause bacteremia and breast implant infection.15 In our patients, there were no symptomatic infections in any region of the body or dental procedures undertaken between the operative day and the day of onset of late infection.

Another cause of late infection could be low-virulence pathogens that were present at the time of operation but took a long time to demonstrate signs and symptoms. The microbes that cause this kind of low-virulence infection are typically from the Mycobacterium species. Clegg et al16 first described cases of late infection caused by M fortuitum, but these pathogens usually do not cause symptoms until at least a year after surgery. Many others have confirmed these findings.16-19 In our study, no mycobacteria were found. The pathogens found in our study do not exhibit this kind of behavior. Staphylococci classically behave aggressively and produce exuberant symptoms of infection. Yi and Khoo20 associated staphylococcal infection with a poorer implant salvage rate. In our late infection group, the Enterobacter species infection demonstrated a significantly greater time to onset than staphylococci, which is consistent with the more aggressive profile of S aureus. It is not clear if this pattern of late infection is more common in patients who received silicone gel–filled implants compared with those who received saline-filled implants, as suggested by the FDA report.4 Other factors, such as a delayed wound healing, might also affect the incidence of infection.

Another important finding of this study was the need for surgery as the definitive treatment for all cases of late infectious complications. Despite the use of antibiograms, only a partial response was seen to empiric antibiotic therapy. All cases of late infection required surgical intervention to drain bacteria, necrotic tissues, and toxins; this treatment created an open wound that could be closed with remarkably little scarring. It was not clear why these late infections were more difficult to treat, although a high salvage rate was achieved in both groups.20,21 Patients received oral antibiotics at the onset of infection and were switched to intravenous (IV) antibiotics if no response was observed. None of the early infection cases required IV antibiotic treatment. The severe late infection cases required both IV antibiotics and surgery. The choice of the antibiotic was guided by the antibiogram and the local bacterial flora.

Conclusion
A group of patients developed infection characterized by late onset of signs and symptoms following aesthetic breast augmentation using textured silicone gel–filled implants. The incidence of late-onset infection was higher than the incidence of early infection. Surgical intervention was required more often to treat late infection than early infection, although good cosmetic results and high implant-salvage rates were obtained for both groups of patients. Further studies are needed to confirm whether similar infection rates occur in cosmetic breast augmentation procedures using saline-filled implants.

References


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