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ORIGINAL ARTICLE

Sonication of Removed Breast Implants for Improved Detection of Subclinical Infection

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Abstract
Background Capsular fibrosis is a severe complication after breast implantation with an uncertain etiology. Microbial colonization of the prosthesis is hypothesized as a possible reason for the low-grade infection and subsequent capsular fibrosis. Current diagnostic tests consist of intraoperative swabs and tissue biopsies. Sonication of removed implants may improve the diagnosis of implant infection by detachment of biofilms from the implant surface.
Methods Breast implants removed from patients with Baker grades 3 and 4 capsular contracture were analyzed by sonication, and the resulting sonication fluid was quantitatively cultured.
Results This study investigated 22 breast implants (6 implants with Baker 3 and 16 implants with Baker 4 capsular fibrosis) from 13 patients. The mean age of the patients was 49 years (range, 31–76 years). The mean implant indwelling time was 10.4 years (range, 3 months to 30 years). Of the 22 implants, 12 were used for breast reconstruction and 10 for aesthetic procedures. The implants were located subglandularly ($n = 12$), submuscularly ($n = 6$), and subcutaneously ($n = 4$). Coagulase-negative staphylococci, *Propionibacterium acnes,* or both were detected in the sonication fluid cultures of nine implants (41%), eight of which grew significant numbers of microorganisms (>100 colonies/ml of sonication fluid).
Conclusions Sonication detected bacteria in 41% of removed breast implants. The identified bacteria belonged to normal skin flora. Further investigation is needed to determine any causal relation between biofilms and capsular fibrosis.

Keywords Biofilm · Breast implant · Capsular fibrosis · Contracture · Sonication · Subclinical infection

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Periprosthetic capsular contracture is a severe complication experienced by 30% of patients after breast prosthesis implantation [5–7]. The etiology of capsular contracture remains unclear. Implant filling, placement of the prosthesis, surface texture, and low-grade prosthesis infection are hypothesized as influencing the formation of capsular fibrosis and subsequent contracture [4].

We specifically investigated microbial colonization of the implant as the possible cause for a persistent chronic low-grade infection and subsequent formation of capsular fibrosis, as previously suggested by other investigators [7–9, 11]. This hypothesis is supported by the fact that unilateral contractures may occur after bilateral augmentation surgery with identical implants, making systemic (host-related) and implant-specific causes less likely.

Several studies aimed to detect adherent bacteria growing in biofilms on breast implants, but no conclusive data were published. Most of these studies used conventional swabs, biopsies of the periprosthetic fibrotic capsule, or both, and judged the results to be positive if at least one of several samples yielded bacterial growth [2, 12]. This microbiologic method, however, lacks sensitivity and specificity, as demonstrated in other surgical specialties such as orthopedic surgery [3]. Conventional swabs can be false-negative in about 30% of cases with prosthetic joint infection, making this method unreliable for detecting implant-associated infection.

Sonication of removed implants is a new diagnostic method shown by our group to improve the diagnosis of prosthetic joint infection significantly by detachment of microbial biofilms from the hip and knee prosthetic surface [14]. Furthermore, sonication of parts of breast implants and capsule biopsies performed by Pajkos et al. [9] yielded positive cultures for 38.5% of implants and 89.5% of capsules involving severely contracted breasts. We hypothesized that sonication of whole-breast implants with an optimized sonication method can improve the detection of microbial colonization of removed breast implants and generate new insights into the pathogenesis of capsular contracture.

Patients and Methods

Study Population

The study was conducted at the University Hospital Basel, Switzerland, an 800-bed primary and tertiary health care center. This hospital is the major provider of acute medical care for about 300,000 inhabitants. The study enrolled patients undergoing breast implant removal for Baker 3 and 4 capsular contracture in the Department of Plastic, Reconstructive, and Aesthetic Surgery at the University Hospital Basel, Switzerland between March 2007 and February 2008. Patients were excluded if obvious contamination occurred in the operating room.

Collection of Breast Implants

Whole-breast implants were aseptically removed from the patient, and each was placed in a separate sterile polyethylene container (Lock & Lock, HPL 933; Vetrag AG, Stäfa, Switzerland). The reason for implant removal, the implant type and placement, and the indwelling time of the implant were recorded by the surgeon. The surgeon assessed breast firmness using the Baker manual scaling method [13].

Sonication of Breast Implants

In the microbiologic laboratory, 100 ml of sterile Ringer's solution was added to each container holding the breast implant, which was processed within 6 h of removal (Fig. 1). The container was vortexed for 30 s, then sonicated for 1 min at a frequency of 40 ± 2 kHz and a power density of 0.22 ± 0.04 W/cm^2, as determined by a calibrated hydrophone (Type 8103; Brüel and Kjær, Naerum, Denmark).

For sonication, an ultrasound bath (BactoSonic; Bandelin GmbH, Berlin, Germany) was used. The resulting sonication fluid was plated in aliquots of 0.1 ml onto aerobic and anaerobic sheep blood agar plates, incubated at 37°C for 7 days, and inspected daily for bacterial growth. Microorganisms were enumerated and classified using routine microbiologic techniques. Positive sonication was considered if 10 colony-forming units (CFU)/ml or more of sonication fluid were detected.

Negative Control Implants

Three sterilized breast implants were included in the sonication process as negative control implants. These were placed on the table with the surgical instruments in the regular operating room. They subsequently were placed in sterile polyethylene containers, then processed as described earlier for implants collected from patients.

Results

Patient Characteristics

During the study period, 22 breast implants from 13 patients were investigated (Table 1). At the time of implant removal, the mean patient age was 49 years (range, 31–76 years). For

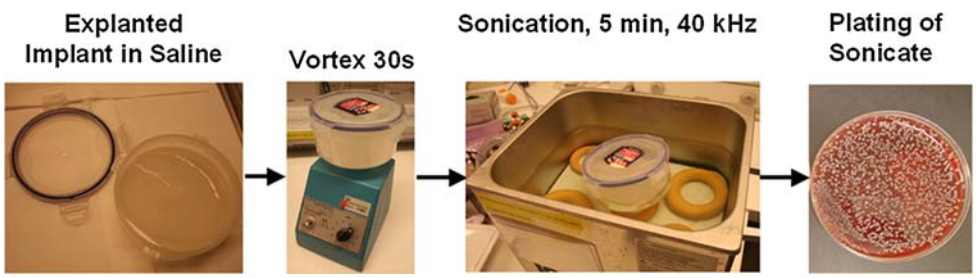

Fig. 1 Sonication procedure. Aseptically removed breast implants were placed in sterile containers, then vortexed and sonicated in Ringer's solution

Table 1 Patient characteristics

Characteristic	Total ($n = 22$)
Age (years): mean (range)	49 (31–76)
Implant indwelling time (years): mean (range)	10.4 (0.25–30)
Preexisting breast disease: *n* (%)	
Breast hypoplasia (aesthetic procedure)	12 (55)
Breast cancer (reconstructive procedure)	10 (45)
Capsular contracture: *n* (%)	
Baker 3	6 (27)
Baker 4	16 (73)

4 implants (18%), previous implant replacement surgeries had been performed before the current surgical procedure due to capsular contracture, whereas for 18 implants (82%), the current surgery was the first procedure after primary breast implantation. The mean implant indwelling time was 10.4 years (range, 3 months to 30 years). Of the 22 implants, 12 (55%) were used for breast reconstruction and 10 (45%) for aesthetic procedures. At explantation, the diagnosis was Baker 3 capsular contracture for 6 implants (27%) and Baker 4 contracture for 16 implants (73%).

Implant Characteristics

In terms of placement, 12 implants were positioned subglandularly, 6 submuscularly (partially), and 4 subcutaneously (all reconstructions only) (Table 2). The surface structure was textured for 16 implants (73%) and smooth for 6 implants (27%). Of the 22 implants, 20 contained silicone gel (high cohesive), and 2 contained silicone fluid (low cohesive). The mean volume of the breast implants was 230 ml (range, 130–750 ml).

Table 2 Implant characteristics and relative sonication results

Characteristic	Total ($n = 22$) *n* (%)	Positive sonication results ($n = 9$) *n* (%)
Location of implant		
Subglandular	12 (55)	5/12 (42)
Subpectoral	6 (27)	3/6 (50)
Subcutanous (reconstructive)	4 (18)	1/4 (25)
Surface of implant		
Textured	16 (73)	7/16 (44)
Smooth	6 (27)	2/6 (33)
Type of implant		
Silicone gel (high cohesive)	20 (91)	9/20 (45)
Silicone liquid (low cohesive)	2 (9)	0/2 (0)
Volume of implant (ml)		
<250	13 (59)	6/13 (46)
≥250	5 (23)	3/5 (60)
Ruptured	4 (18)	0/4 (0)

Microbiology

Nine (41%) of the implants showed significant numbers of bacteria growing in sonication fluid cultures (>10 CFU/ml of sonication fluid). Coagulase-negative staphylococci were identified on three implants, *Propionibacterium acnes* on two implants, and both organisms (coagulase-negative staphylococci and *Propionibacterium acnes*) on four implants. On 8 (89%) of 9 implants with a positive sonication culture, high numbers of microorganisms (>100 CFU/ml of sonication fluid) were detected, indicating a multiple-layer biofilm on the prosthesis surface.

Negative Controls

None of the three sterile implants investigated by sonication showed any growth in the sonication fluid culture.

Conjoint Analysis of Implant Characteristics and Microbiology

The colonization rates for implant surfaces with regard to location of the implant (subglandular, submuscular, subcutaneous placement), implant surface (smooth vs textured), type of implant (liquid [low cohesive] vs gel [high cohesive] silicone), and implant volume (≥250 vs <250 ml) are shown in Table 2. No significant differences in colonization rates with biofilms were detected among the aforementioned groups.

Discussion

Clinically manifested postoperative infection after breast implant placement is rare [1]. However, considering the hypothesis that subclinical infection plays a role in the development of capsular fibrosis, the incidence of bacterial colonization on breast implants may be much higher [7, 9, 10].

The bacteria identified in our study consisted exclusively of skin flora. This finding has been confirmed by others [9, 12]. Previous studies had failed to detect bacteria consistently using swabs and tissue biopsies. The cultures tested positive in 30% to 67% of cases [12]. It is difficult to interpret the results of these studies because a single swab or biopsy was considered positive, which may have represented contamination [2, 12].

Pajkos et al. [9] have described the use of a sonication method to detect biofilms on parts of breast implants and on fibrotic capsule biopsies. This method yielded positive culture results for 24 (50%) of 48 cases including Baker 1 and 2 contractures. In the analysis of Pajkos' subgroups (Baker 3 and 4 capsular contractures), the cultures of capsule samples tested positive in 89% of cases, whereas the implant pieces tested positive in 38.5% of cases.

The better sensitivity of sonication in detecting subclinical infection and biofilms on orthopedic implants compared with standard swabs and biopsies has been confirmed by our group [14]. Because of the high sensitivity, we aimed to apply the sonication method only to implants causing Baker 3 and 4 capsular contracture because these contractures yielded the highest numbers of positive cultures in studies using conventional microbiology [2, 12].

We found that 41% of implants showed significant numbers of bacteria on the prosthesis surface. These results in our series may seem inferior to the findings of Pajkos et al. [9] and those of other studies yielding up to 67% of colonized implants in patients with Baker 3 and 4 capsular contractures. However, these results often were determined from only one positive swab or biopsy, which may represent contamination, especially when bacteria from the skin flora are involved. Therefore, in orthopedic surgery, at least two tissue specimens must test positive before the results are considered positive for low-virulent organisms. The same holds true for blood cultures [3].

In addition, our sonication method allows quantification of recovered bacteria in the sonication fluid, which can distinguish between contamination during prosthesis removal and biofilm infection of breast implants. Pajkos et al. [9] quantified bacteria in seven samples from three patients. In these seven samples, the numbers of bacterial counts were highly variable. Therefore, in our opinion, an accurate distinction between infection, typically comprising a multilayer of biofilm, and a contamination, typically involving low numbers of bacteria belonging to skin flora, is possible only by quantifying the numbers of removed bacteria after sonication. Our approach intended to avoid sampling errors that may occur when portions of the implant are sonicated instead of the whole implant.

Our study had some limitations, including a lack of sonication of capsules (parts or complete), which may detect bacteria in the culture for patients with Baker 3 and 4 capsular contractures. The sensitivity of the sonication method could have been gained if whole capsules had been sonicated. However, extirpation of whole capsules often may not be feasible or desired from a surgical perspective. In most cases, whole capsules were not available to us. Sensitivity would be improved further if sonication for breast implants were individually optimized because the acoustic parameters may not be transferable directly from mechanical orthopedic implants to breast implants due to differences in material, surface structure, and density.

Conclusion

Sonication of whole implants may be a useful addition to the armamentarium of procedures used to detect microorganisms on breast implants. In our series, bacteria were detected in 41% of removed breast implants. The identified bacteria belonged to normal skin flora, which colonized the implant either during implantation or later by lymphogenous or hematogenous spread or by lactiferous duct contamination. Further investigation is needed to determine the causal relation between biofilms and capsular fibrosis.

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