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Breast

Use of Antibiotic-impregnated Polymethylmethacrylate (PMMA) Plates for Prevention of Periprosthetic Infection in Breast Reconstruction

Thomas Johnstone, BS*
Kelsey Lipman, MD*
Nathan Makarewicz, BA*
Jennifer Shah, BA*
Elizabeth Turner, PA-C†
Victoria Posternak, MS, RN*
Daniel Chang, MD*
Brian Thornton, MD†
Rahim Nazerali, MD, MHS, FACS*

Background: Periprosthetic infections remain a major challenge for breast reconstruction. Local antibiotic delivery systems, such as antibiotic beads and spacers, have been widely used within other surgical fields, but their use within plastic surgery remains scarce. In this study, we demonstrate the use of antibiotic-impregnated polymethylmethacrylate (PMMA) plates for infection prophylaxis in tissue expander (TE)-based breast reconstruction.

Methods: A retrospective review of patients who underwent immediate breast reconstruction with prepectoral TEs over the span of 5 years performed by two surgeons was completed, revealing a total of 447 patients. Data pertaining to patient demographics, operative details, and postoperative outcomes were recorded. Fifty patients underwent TE reconstruction with the addition of a PMMA plate (Stryker, Kalamazoo, Michigan) impregnated with tobramycin and vancomycin. Antibiotic plates were removed at the time of TE-to-implant exchange. Patient-matching analysis was performed using the 397 patients without PMMA plates to generate a 50-patient nonintervention cohort for statistical analysis.

Results: The intervention cohort (n = 50) and 1:1 patient-matched nonintervention cohort (n = 50) demonstrated no statistically significant differences in patient demographics or operative characteristics other than PMMA plate placement. The rate of operative periprosthetic infection was 4% in the intervention group and 14% in the nonintervention group ($P = 0.047$). The rate of TE explantation was also reduced in the intervention group (6% versus 18%; $P = 0.036$). Follow-up averaged 9.1 and 8.9 months for the intervention and nonintervention groups, respectively ($P = 0.255$).

Conclusion: Local antibiotic delivery using antibiotic-impregnated PMMA plates can be safely and effectively used for infection prevention with TE-based breast reconstruction. *(Plast Reconstr Surg Glob Open 2023; 11:e4764; doi: 10.1097/GOX.0000000000004764; Published online 18 January 2023.)*

INTRODUCTION

Tissue expander (TE)-based breast reconstruction is the most common reconstructive technique used following mastectomy, accounting for 83,487 of 137,808 (60.5%) breast reconstruction procedures conducted in 2020 per the American Society of Plastic Surgeons Statistics Report.[1] Implant-based reconstruction is popular due to its technical feasibility, decreased operative time, and lack of required donor site compared with autologous reconstruction. Despite its advantages, TE implant-based methods have their own limitations, including capsular contracture, animation deformity, and increased risk of infection. Specifically, rates of periprosthetic infection have been reported in the literature to range widely from 1% to 35%, with most studies reporting rates from 10% to 20%.[2–13] Evidence suggests that patients are at the highest risk for infection within

*From the *Department of Surgery, Division of Plastic and Reconstructive Surgery, Stanford University, Stanford, Calif.; and †Thornton Plastic Surgery, Louisville, Ky.*

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the first 4 months postoperatively, with later presentations being less common.[5,9,10,14–16]

The conservative approach to managing periprosthetic infections traditionally involves a trial of intravenous antibiotic therapy, with failure often resulting in operative washout with device explantation. This leads to significant physical and psychological consequences for patients and increases health care spending drastically. Furthermore, patients who attempt secondary autologous reconstruction after explantation typically wait 4–6 months from the date of explant to secondary reconstruction.[8,11,17–21] Many patients who undergo TE explantation choose to forego further reconstruction altogether; percentages are estimated to be 17%–59% in the literature.[21,22] Moreover, delayed autologous reconstruction after an infection ultimately has inferior aesthetic outcomes owing to scarring, contraction, and loss of the skin envelope. More recently, various implant salvage protocols have been developed in hopes of preserving the reconstructed breast pocket but are not suitable for all scenarios.[8,16,19,21,23,24]

As a result, the use of antibiotics for both TE infection prophylaxis and salvage has become a topic of great interest in the plastic surgery community. Local antibiotic delivery systems that deliver antibiotics to the site of interest have been widely used by orthopedic and vascular surgery, but applications within plastic surgery remain scarce. However, recent literature has started to expand the role of local antibiotic delivery systems in the breast reconstruction space. Applications for infection prophylaxis have thus far included gentamicin-infused collagen sponges and continuous irrigation protocols.[18,25,26] More recently, local antibiotic delivery in the context of implant salvage has also been explored: polymethylmethacrylate (PMMA) antibiotic-impregnated plates, antibiotic beads, and continuous postsalvage irrigation regimens have been reported, with each describing a degree of improvement in salvage rate.[21,23,27,28] Although these methods have improved salvage outcomes in terms of infection reduction, emphasis on prophylactic methods has the ability to reduce the patient morbidity that comes with salvage procedures and the long-term sequelae.

In this study, we aim to evaluate the safety and efficacy of implantable antibiotic-impregnated PMMA plates placed at the time of TE insertion for infection prophylaxis. In a retrospective chart review of prospectively collected data, we describe the early characteristics and outcome profiles of patients treated with this technique to guide future efforts in local antibiotic prophylaxis in TE-based breast reconstruction.

Takeaways

Question: Do antibiotic-impregnated PMMA plates provide infection prophylaxis in the setting of two-stage implant-based breast reconstruction?

Findings: A cohort of patients who received antibiotic-impregnated PMMA plates at the time of tissue expander placement had significantly lower postoperative infection and explantation rates than a propensity score matched cohort at an average of 9 months of follow-up.

Meaning: PMMA plates can be safely and efficaciously used for infection prophylaxis in tissue-expander-based breast reconstruction.

METHODS

A retrospective chart review was conducted of all TE-based breast reconstructions following mastectomy for breast cancer or prophylaxis by the senior authors (R.N. and B.T.) since May 2017. Patient demographics, operative details, complications, and postoperative course were recorded. Demographics historically related to infection risk were evaluated, including age, body mass index (BMI), comorbidities such as diabetes and hypertension, smoking status, and history of radiation or chemotherapy. Complications were either nonoperative (managed with conservative measures) or operative. Infection was defined as the presence of at least two clinical criteria (eg, warmth, pain, erythema, drainage, and fever) and leukocytosis. If patients did not improve on a trial of intravenous broad-spectrum antibiotics, they underwent washout with explantation of the expander.

All patients were instructed to use chlorhexidine wash several days before and on the morning of surgery. Patients received intraoperative intravenous antibiotics, which were redosed if the procedure duration surpassed 4 hours (cephalosporin). After completion of the mastectomy by breast surgery colleagues, all patients were reprepared with betadine, and new sterile drapes were placed. There were no changes, or systematic differences, in mastectomy-performing surgeons in the intervention and nonintervention cohorts. Before placing the TE into the prepectoral breast pocket, it is first prepared on the back table. A sheet of FlexHD (MTF Biologics, Edison, N.J.), a pliable perforated acellular dermal matrix (ADM), is trimmed around the TE. Slits are placed along the ADM, and the tabs are passed through. The ADM is secured to the tabs of the expander with 4-0 chromic suture. Antibiotic-impregnated plates did not impact ADM placement. The TE is secured with 2-0 polydioxanone (PDS) suture (Ethicon, Somerville, N.J.). Two drains are placed into the pocket and tunneled through lateral stab incisions and secured in place using 3-0 nylon. The incision is closed in layers with 3-0 Vicryl deep dermals and a 3-0 stratafix subcuticular. Prineo wound dressing (Johnson & Johnson, New Brunswick, N.J.) is applied over the incision.

The patient group from January of 2021 to the present followed the above surgical protocol plus the additional intraoperative modification of placement of an antibiotic-impregnated PMMA plate. Patients were counseled during the surgical consent process regarding the use of antibiotic-impregnated PMMA before surgery and were offered placement of the antibiotic-impregnated PMMA disc. Antibiotic plate creation followed the described method by Albright et al.[23] Specifically, antibiotic plates were prepared on the back table consisting of one package of PMMA, which includes 1 g of tobramycin (Stryker, Kalamazoo, Mich.), an additional 1.2 g of tobramycin (X-Gen Pharmaceuticals, Big Flatts, N.Y.), and 3 g of vancomycin (Pfizer, N.Y.). Antibiotic plates cost $168.52 per patient, regardless of whether reconstruction was unilateral or bilateral. Once thoroughly mixed, the solution is split in half to provide the appropriate amount for a single plate (two plates are used in bilateral cases). Each plate is then hand-molded to approximately 6 cm in diameter, small enough to be removed from the incision at TE to implant exchange (Fig. 1). The plate is then molded to the contour of the patient's chest wall to optimize fit under the expander. The plate is slid under the prepectoral tabbed TE before the 2-0 PDS suture is tied down, securing the plate between the pectoralis major and the expander (Fig. 2). The rest of the operation is as described above. All patients in both cohorts received Keflex 500 mg four times per day for 7 days after surgery, as has been standard in our practice. Antibiotic plates are removed at the time of TE to implant exchange. PMMA plates posed no additional difficulty to remove compared with TE removal.

Patient matching and statistical tests were performed using the R Environment for Statistical Computing (Vienna, Austria), specifically the MatchIt and TableOne packages. Patients in the nonintervention and intervention groups were matched by age, BMI, diabetes status, smoking status, hypertension, chemotherapy history, radiation history, and laterality of mastectomy. Each intervention group patient was matched to one nonintervention group patient. Unpaired *t* tests were used to assess differences in the distributions of normally distributed continuous variables, while the Wilcox-Mann-Whitney test was used for nonnormally distributed continuous variables. Fisher and Barnard exact tests examined differences in categorical variables between groups. The threshold to assess significance was a *P* value of less than or equal to 0.05 in all between-group analyses.

RESULTS

Patient Characteristics

The retrospective review included 447 patients: 50 in the PMMA plate intervention group and 397 in the nonintervention group. The 397 patients without PMMA plates were eligible to be matched to the intervention cohort. After performing 1:1 matching according to age, BMI, diabetes status, smoking status, hypertension, adjuvant and neoadjuvant chemotherapy history, adjuvant and neoadjuvant radiation history, laterality of mastectomy, immediate reconstruction, and follow-up, a subset of 50 patients was identified as the nonintervention cohort to be used for statistical analysis.

The characteristics of patients in both cohorts and comparative statistics are summarized in Table 1. The average age of the intervention and nonintervention cohorts was 50 and 45.5 years, respectively ($P = 0.576$). The average BMI for both groups was also similar (26.3 in the intervention cohort versus 25.4 in the intervention cohort, $P = 0.535$). No statistically significant differences in variables used in the matching protocol were observed: rates of smoking history, type II diabetes mellitus, hypertension, unilateral and bilateral reconstructions, chemotherapy, and radiation exposure were similar across both cohorts.

Operative Characteristics

Operative characteristics are summarized in Table 2. There were no statistically significant differences observed in the number of unilateral versus bilateral reconstructions, or in the rates of nipple-sparing versus nonnipple-sparing mastectomy between groups. No difference was noted regarding the percentage of patients undergoing either axillary lymph node dissection or sentinel node biopsy between cohorts.

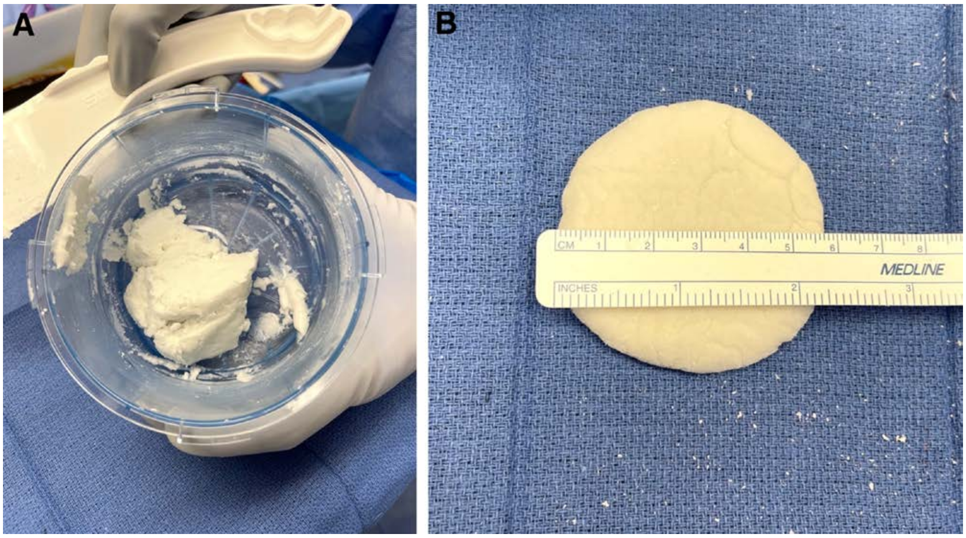

Fig. 1. Creation of antibiotic-impregnated PMMA plate. A, The PMMA base mixed with antibiotic powder and activating solution. B, The PMMA after molding into an approximately 6 cm diameter plate, small enough to be removed from the incision at TE to implant exchange.

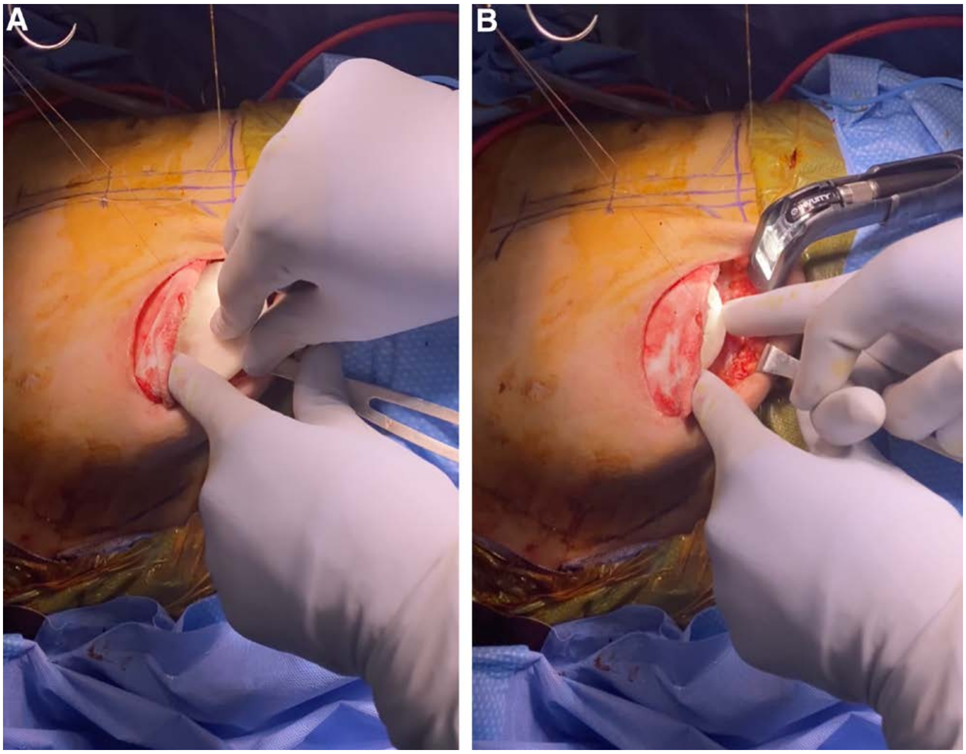

Fig. 2. Placement of PMMA plate below TE. A, The initial placement of the PMMA plate beneath the prepectoral TE. B, Ease of sliding the plate completely beneath the expander before the PDS suture is tied down.

Table 1. Patient Demographics

Patient Demographics	Intervention Group	Nonintervention Group	*P*
Total no. patients	50	50	
Median age (y, IQR)	50.00 (43.5–57.0)	45.50 (42.0–58.8)	0.576
Median BMI (kg/m^2, IQR)	26.37 (23.4–30.0)	25.42 (21.7–30.9)	0.535
Comorbidities (% of cohort)			
Type II diabetes mellitus	3 (6.0)	4 (8.0)	>0.9
Hypertension	11 (22.0)	12 (24.0)	>0.9
Current smokers	6 (12.0)	11 (22.0)	0.287
Patients with prior irradiation of the breast (% of cohort)	4 (8.0)	4 (8.0)	>0.9
Patients with neoadjuvant chemotherapy (% of cohort)	13 (26.0)	10 (20.0)	0.635

Demographics of the intervention and nonintervention cohorts.
IQR, interquartile range.

Table 2. Operative Characteristics

Operative Characteristics	Intervention Group	Nonintervention Group	*P*
Laterality of reconstruction (% of cohort)			
Unilateral	19 (38.0)	11 (22.0)	.126
Bilateral	31 (62.0)	39 (78.0)	.126
Mastectomy type (% of cohort)			
Nipple-sparing	30 (60.0)	35 (70.0)	0.402
Nonnipple-sparing	20 (40.0)	15 (30.0)	0.402
Accompany lymph node procedure (% of cohort)			
Axillary lymph node dissection	6 (12.0)	2 (4.0)	0.269
Sentinel lymph node biopsy	34 (68.0)	33 (66.0)	>0.9

Operative characteristics of the intervention and nonintervention cohorts.

Postoperative Care and Complications

Postoperative details and complications with comparative statistics are highlighted in Table 3. No statistical differences were observed in the rates at which patients in both cohorts received adjuvant radiation or chemotherapy. No difference was observed in time to drain removal or time to TE-to-implant exchange. The average final fill volume was similar across groups.

There were no statistically significant differences in nonoperative wound dehiscence, nipple necrosis, mastectomy skin necrosis, or infection. There were no differences regarding operative hematoma, wound dehiscence,

Table 3. Postoperative and Complication Data

Postoperative and Complication Data	Intervention Cohort	Nonintervention Cohort	*P*
No. patients receiving adjuvant chemotherapy (% of cohort)	9 (18.0)	8 (16.0)	>0.9
No. patients receiving adjuvant radiation (% of cohort)	13 (26.0)	6 (12.0)	0.126
Final TE fill volume (mL, IQR)	495.0 (400.0–538.8)	480.0 (360.0–540.0)	0.381
Time to TE exchange (d, IQR)	138 (127.25–165)	153 (121–171)	>0.9
Time to drain removal (d, IQR)	15 (13–15)	15 (13–20)	0.101
Complications, nonoperative management (% of cohort)			
Wound dehiscence	2 (4.0)	0 (0.0)	0.495
Nipple necrosis	1 (2.0)	3 (6.0)	0.617
Mastectomy skin necrosis	0 (0.0)	1 (2.0)	>0.9
Infection	0 (0.0)	1 (2.0)	>0.9
Complications, operative management (% of cohort)			
Hematoma	1 (2.0)	0 (0.0)	>0.9
Wound dehiscence	2 (4.0)	3 (6.0)	>0.9
Mastectomy skin necrosis	4 (8.0)	5 (10.0)	>0.9
Infection	2 (4.0)	7 (14.0)	**0.047**
No. TE explantations (% of cohort)	3 (6.0)	9 (18.0)	**0.036**
Median follow-up (d, IQR)	273 (232.8–335.0)	266 (181.3–327.8)	0.255

Postoperative and complication data of the intervention and nonintervention cohorts.
IQR, interquartile range.

or mastectomy skin necrosis. However, the PMMA cohort demonstrated a statistically significant reduction in the incidence of operative infection (4% versus 14%; P = 0.047). In addition, the PMMA group demonstrated a decreased rate of TE explantation (6% versus 18%; P = 0.036). Average follow-up was 9.1 and 8.9 months for the intervention and nonintervention groups, respectively (P = 0.255).

No signs of impaired TE function or integrity were presented as a result of PMMA plate addition. Similarly, there were no signs of adverse reactions or changes in macroscopic tissue in patients with PMMA plate placement.

DISCUSSION

TE implant-based breast reconstruction remains the most commonly used technique for breast reconstruction worldwide, with approximately 80% of patients choosing this method.[29,30] However, implanting a foreign body in the breast pocket inevitably carries a higher risk of infection compared with autologous reconstruction. The severity of periprosthetic infections can vary widely from localized erythema that improves with antibiotics to systemic illness requiring operative intervention and explantation of the device. Operative intervention and TE removal result in high morbidity for patients, both physically and psychologically. It also takes a tremendous toll on health care spending and often leads to future operations and hospitalizations. As a result, there has been an increased emphasis on preventing infection and enhancing salvage protocols in recent years.

Local antibiotic delivery systems, rather than high doses of systemic antibiotics, have been used in other surgical fields, such as orthopedic surgery, but their introduction into the plastic surgery community is recent.[31,32] Lapid[18] first introduced gentamicin-infused collagen sponges for the treatment of periprosthetic breast implant infection in a case series published in 2011. Since then, antibiotic delivery vehicles have also included absorbable antibiotic beads, continuous irrigation systems, and antibiotic-impregnated PMMA plates.[23,26–28] Although the study volume is scarce, applications have been shown to be effective in both the infection prophylaxis and salvage setting.[18,21,23,26–28,33]

In the periprosthetic infection prophylaxis literature, Kenna et al[33] described the use of antibiotic beads, while Hunsicker et al[26] and Tutela et al[25] used continuous irrigation systems. Using biodegradable antibiotic beads with vancomycin and gentamicin and a TE in the submuscular pocket, Kenna et al[33] demonstrated a decreased infection rate from 11.9% in the control cohort to 1.5% (P = 0.024). Hunsicker et al[26] performed 96 hours of continuous irrigation of the breast pocket with antibiotic solution (1 g vancomycin, 80 mg gentamicin, and 50,000 UI bacitracin per L) compared with infusion of local anesthetic and demonstrated a reduced infection rate in the intervention group (2.9% versus 20.0%; P = 0.037). Similarly, Tutela et al[25] performed continuous irrigation of the breast pocket with antibiotic solution (80 mg gentamicin, 1 g cefazolin, and 50,000 UI bacitracin) for 24 hours postoperatively and demonstrated a lower incidence of premature explantation (2.9% versus 20.0%; P = 0.037) and a tendency for reduced infection rate (5.8% versus 22.2%; P = 0.06) in the irrigation cohort. In our study, we also demonstrated significant reductions in both the infection rate (0% versus 11%; P = 0.035) and rate of TE explantation (2% versus 15%; P = 0.031), further supporting the efficacy of local delivery systems for infection prophylaxis. Additionally, both reconstructive surgeons in this study experienced a similar reduction in infection rate in the intervention group, which is promising evidence for the generalizability of this technique.

Although the use of antibiotic-impregnated PMMA plates has been used in the salvage setting, this study demonstrates its first application for periprosthetic infection prophylaxis. Albright et al[23] introduced the use of antibiotic-impregnated PMMA plates and beads for TE salvage in a series of 14 patients in 2016. All implant pockets in the series were cleared of clinically relevant bacteria; one patient developed a recurrent infection requiring explantation. Antibiotic elution profiles were studied using vancomycin levels from closed suction drains and demonstrated significantly higher concentrations of antibiotics compared with systemic doses even up to the

3-week postoperative time point. In a follow-up study by Xue et al[21] involving 45 cases of salvage with the placement of PMMA plates, the primary infection clearance rate was 82.2% (n = 37). Compared with their traditional explantation group, a significantly higher percentage of salvage patients completed reconstruction (84.4% versus 35.3%; $P < 0.001$). These studies demonstrating the safety and efficacy of antibiotic-impregnated PMMA in the salvage setting prompted our application for infection prophylaxis. While effective in the salvage setting, the use of antibiotic-impregnated PMMA is ideal for the prophylaxis setting to avoid the morbidity of infection altogether. Similarly, it avoids the risk of pressure necrosis associated with the use of cement antibiotic beads. In addition, given that all patients in our study were planned for two-stage TE-implant reconstruction, PMMA plates could easily be removed at the time of implant exchange without requiring the addition of more procedures for removal.

Among the various antibiotic delivery vehicles proposed in the literature, no single modality is without its disadvantages. For PMMA specifically, given the firmness of the cement (in comparison to alternatives like antibiotic sponges), we queried whether or not patients would notice the plate during the expansion process. In our cohort, no patients complained of chest wall tenderness related to the plate and ultimately achieved similar final fill volumes compared with the nonintervention cohort. An additional consideration using PMMA is the exothermic reaction generated during the polymerization process. This limits the antibiotics used with this vehicle to heat-stable compounds, such as vancomycin, tobramycin, and gentamicin.[23] Although the systemic doses of antibiotics achieved with local antibiotic delivery systems are greatly reduced, potentially reducing the side effects associated with systemic antibiotic administration, there have also been case reports in the orthopedic literature regarding rare side effects, including delayed-type hypersensitivity and nephrotoxicity.[34,35] Future studies will help determine the risk of these complications and should characterize the side effect profile of antibiotic-impregnated PMMA plates relative to systemic antibiotic administration.

One notable limitation of our study is that antibiotic levels in the periprosthetic breast pocket were not measured systematically. This prevents any analysis of antibiotic output over time, a metric that would have been useful for quantifying the activity of the antibiotic-impregnated discs. However, our study protocol is similar to the protocol described by Xue et al[21] and Albright et al,[23] which demonstrated adequate antibiotic output in the salvage setting. A somewhat smaller limitation is the lack of long-term follow-up, which would help to determine whether antibiotic-impregnated PMMA influences the incidence of capsular contracture or reoperation rates. In addition, a cost-benefit analysis may be helpful in the future to determine whether the use of antibiotic PMMA plates is advisable for all patients for prophylaxis versus use in selected patients who are at high risk for developing an infection. Finally, this study lacks systematic collection of patient-reported outcomes. While no intervention cohort patients reported pain of note, a future study could record validated patient-reported outcome measures regarding discomfort throughout the reconstructive process, as well as happiness with the overall reconstructive result.

CONCLUSIONS

Local antibiotic delivery using antibiotic-impregnated PMMA plates can be safely and effectively used for infection prevention with TE-based breast reconstruction. Although antibiotic-impregnated PMMA plates have been previously shown to be beneficial in the salvage setting, this study represents the first application for infection prophylaxis. In this cohort, antibiotic plate placement resulted in a reduction in the incidence of periprosthetic infection and decreased rates of TE explantation. Future studies with long-term data are necessary to further characterize risks of capsular contracture, reoperation, and patient-reported outcomes.

Rahim Nazerali, MD, MHS, FACS
Stanford University Medical Center
770 Welch Road, Suite 400
Palo Alto, CA 94304
E-mail: rahimn@stanford.edu

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