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A comparative study of postoperative prophylactic antibiotics in breast augmentation primary versus delayed: Retrospective review

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Abstract
Background: The use of postoperative prophylactic antibiotics following augmentation mammoplasty remains a controversial topic, with many surgeons opting for extended prophylaxis.
Objectives: The authors evaluate the role of postoperative prophylactic antibiotics in both primary and secondary cosmetic breast augmentation.
Methods: A five-year retrospective chart review was performed on all patients undergoing cosmetic breast augmentation at a single institution from January 2005 to December 2009. The four attending physicians in this study utilized similar perioperative protocol and implant materials. Patients were divided into two cohorts: those who had received three days of postoperative antibiotics (primarily cephalosporin's) and those who had not. End points of particular interest included infection, capsular contracture (CC), and local wound complications. The mean follow-up time was 3.8 years.
Results: A total of 605 implants were included over the five-year study period. The overall infection rate was 0.66%. For primary augmentation, 493 implants were studied, with 52% of those patients having received postoperative antibiotics. There was no statistically significant reduction in infection, CC, or total complication rate for those receiving postoperative antibiotics. Similarly, 112 implants were studied for secondary augmentation, and again, postoperative antibiotics were not associated with a reduction in complications.
Conclusions: The data suggest that there was no reduction in the overall rate of total complications, infection, or CC with postoperative prophylactic antibiotics for either primary or secondary cosmetic breast augmentation. This study provides Level 3 evidence in support of discontinuing prophylactic postoperative antibiotics following cosmetic breast augmentation.

Keywords: Capsular contracture, infection, postoperative antibiotics, primary or secondary or revision breast augmentation (BA), prophylactic antibiotics

Introduction
Capsular contracture, infection, postoperative antibiotics, primary or secondary or revision breast augmentation (BA), prophylactic antibiotics
The role of postoperative prophylactic antibiotics following aesthetic surgery remains uncertain. Despite controversy surrounding the utility of extended prophylaxis, this practice has become commonplace for many surgeons. Krizek *et al.* first and most notably established trends in antibiotic administration. In 1975, Krizek assessed surgeons' prophylactic antibiotic prescription habits, and a 1985 follow-up survey demonstrated a marked increase in the prevalence of antibiotic administra-tion [1, 2]. Further surveying of practice patterns has suggested that the upward trend in antibiotic administration frequency has continued into the current century [3]. Within the framework of evidence-based medicine (EBM), this upward trend in prophylaxis prescription remains inexplicable given the lack of data to support it. In fact, 64% of plastic surgeons cited personal experience as the determining factor in their decision to administer antibiotics, thus making anecdotal evidence the primary determinant of antibiotic usage within the plastic surgery community [4]. Given the tenuous grounds for formulating prophylactic antibiotic regimens, it should come as no surprise that the debate about best practices with regard to prophylactic postoperative antibiotics has continued among plastic surgeons. Despite being classified as a clean procedure, cosmetic augmentation mammoplasty has been met with perhaps the greatest controversy over antibiotic usage due to the involvement of a foreign body—the prosthetic implant [5] A 2002 survey by Perrotti *et al.* [6] suggested that 70% of surgeons utilized postoperative antibiotic prophylaxis for cosmetic breast augmentation. Minimal evidence has been published that would supplant such a majority consensus.
One could contend that the lack of evidence is due to the inherent difficulties in studying the efficacy of prophylactic antibiotics in cosmetic breast augmentation. This is primarily because rates of infection for this procedure are comparatively low. Most recently, a series of over 1700 cosmetic implants demonstrated zero infections, and a database analysis of over 36,000 augmentations revealed an infection rate of 0.21% [7, 8]. Most literature is in agreement that rates of infection are generally less than 1% for primary cosmetic breast augmentation [9, 10]. To study events that are so infrequent, large series are necessary. However, large series often require multicenter study protocol designs, and these lack many of the internal controls required for the delicate study of infection rate. Furthermore, this topic is difficult to study because most series examining rates of infection lack a subset of patients who have not received postoperative antibiotics, thereby

eliminating a potential control group. This is a testament to most plastic surgeons' understandable reluctance to place their patients at a perceived—albeit unproven—increased risk by not providing postoperative antibiotics [11]. The purpose of this study is to evaluate the role of postoperative prophylactic antibiotics in both primary and secondary cosmetic breast augmentation.

Methods

A five-year retrospective chart review was performed on all patients who underwent cosmetic augmentation mammoplasty between January 2012 and December 2017 at Civil Hospital, BJ Medical College, Ahmedabad. Hospital records provided intraoperative procedural notes, immediate post-operative care information, and details of outpatient anti-biotic prescription regimens upon discharge. In addition to inpatient records, office notes provided postoperative follow-up care information, including details about complications and further patient management. Data for office documentation were obtained and recorded following routine outpatient physical examination. Pre- and perioperative data collection included patient age, smoking status, body mass index (BMI), comorbidities, drains, and implant type (saline or silicone gel). Postoperative end points of particular interest were infection and capsular contracture (CC); however, other documented postoperative complications were recorded from office data as well. CC was defined as Grade 3 or 4, per guidelines of the Baker grading system [12, 13]. Infections were defined by a positive bacterial culture. In cases where an aseptic culture was not feasible, clinical indicators of infection were also utilized, such as pain, erythema, fever, leukocytosis, and/or other local inflammatory response symptomatology.

Perioperative Protocol

All surgeons in the study utilized a similar perioperative protocol. One gram of cefazolin was given to all patients 60 minutes prior to skin incision; if patients were allergic to penicillin, clindamycin was administered. (All patients received a single dose of preoperative antibiotics, although it could be argued that the few patients above 80 kg should have received a second dose.) Intraoperative, all patients received antibiotic irrigation to both the implant and breast pocket [14, 15]. The antibiotic utilized for irrigation was strictly bacitracin. Implants placed in this series, both saline and silicone gel, were all smooth-walled implants from the same manufacturer (Mentor Corp., Santa Barbara, California). Prior to handling the implant, surgeons placed their gloved hands in bacitracin solution. It should be noted that none of the surgeons in this study employed certain intraoperative precautions that have been advocated by others, including "no-touch" techniques, nipple shields, or a change of gloves for implant placement. Additionally, there were no drains placed in this study.

Study Design

Prior to designing this study, it was well known to the authors that, of the four surgeons participating in the study, Surgeon A rarely prescribed postoperative antibiotics, whereas Surgeons B, C, and D routinely prescribed antibiotics for three days postoperatively. Surgeon A performed approximately half of all breast augmentations in the practice.

Rates of complications were compared between the cohort of patients who had not received postoperative antibiotics and the cohort who had received three days of postoperative antibiotics. Fisher's exact test was performed for categorical variables, and the Mann-Whitney U-test was performed for nonparametric continuous variables. Parametric continuous variables were analyzed via t-test. All tests were two-sided, and statistical significance was set at a *P* value of <.05. Inferential statistical analysis was performed with SPSS for Windows Version 18.0. Analysis of statistical power was performed with PS Power and Sample Size Calculations Version 3.0.

Table 1: Demographic and intraoperative comparison of the primary augmentation cohort receiving antibiotics versus the cohort that did not receive antibiotics (n = 257)

	No Postoperative Antibiotics	**Postoperative Antibiotics**	***P* Value**
No. patients	130	127	
Demographics			
Age, y	36.8	37.3	.58
Length of follow-up,	3.7	4.2	.001
Body mass index	21.9	21.8	.63
Smoking	28 (21.8)	29 (23.6)	.74
Comorbidities	6 (5.0)	5 (3.9)	.68
Prior breast surgery	7 (5.4)	22 (17.3)	.005
Intraoperative			
Implant type			.25
Saline	63 (48.0)	77 (60.6)	
Silicone	55 (42.0)	50 (39.4)	
Incision			
Per areolar	14 (11.0)	77 (60.6)	<.001
Inframammary	103 (79.0)	48 (38.4)	
Plane of dissection			.53
Sub glandular	6 (5.0)	4 (3.0)	
Dual-plane	113 (87.0)	123 (97.0)	
Mastopexy	17 (13.1)	40 (31.5)	.001

Table 2: Rates of complications for the primary augmentation group of patients who were given postoperative antibiotics versus patients who did not receive postoperative antibiotics (n = 493)

	No Postoperative	Postoperative	
	Antibiotics, No. (%)	Antibiotics, No. (%)	*P* Value
No. Implants	236	257	
Infection	3 (1.3)	0	.11
Capsular ntracture	2 (0.8)	3 (1.0)	1
Total omplications	7 (3.0)	6 (2.0)	.8

Results

Primary Breast Augmentation

In the primary breast augmentation group, there were 511 implants placed in 257 patients. Three patients with congenital breast hypoplasia received only a unilateral implant. One hundred twenty-seven patients were administered three days of extended postoperative antibiotic prophylaxis, and 130 patients did not receive postoperative antibiotics. The number of patients for each respective antibiotic regimen was as follows: cephalexin, 111; clindamycin, 10; ciprofloxacin, three; and azithromycin, three. The mean age of the patients at the time of operation was 37 years, and the mean BMI was 21.9. Average overall length of follow-up for the primary augmentation group was 3.9 years.

Table 1 provides a demographic and intraoperative comparison between the postoperative antibiotics group versus those who did not receive antibiotics. There was approximately six more months of follow-up for patients who were administered postoperative antibiotics. Additionally, patients with a prior history of breast surgery (breast biopsy, previous cosmetic surgery, or lumpectomy) were more likely to be given postoperative antibiotics following augmentation. More patients who underwent con-current mastopexy and periareolar incision received postoperative antibiotics than any other primary augmentation group.

Analysis of postoperative complications was calculated per individual implant, as opposed to per patient. Postoperative complications included seroma, hematoma, infection, or CC (Grade 3 or higher). Eighteen implants were excluded from analysis due to inadequate follow-up documentation. In total, there were 13 implant complications in 11 separate patients (out of 493 implants). There were five instances of CC, three infections, four hematomas, and one seroma (Table 2). A detailed description of the infected patients is provided in Table 3. In comparing the antibiotics group to the antibiotic-free group, there was no statistically significant difference in the rate of infection, CC, or overall complications.

Secondary Breast Augmentation

In the secondary breast augmentation group, there were 112 implants placed in 54 patients. Fourteen patients only had one implant placed during secondary augmentation, and seven patients had more than one revision breast augmentation during the study period. The number of patients for each respective antibiotic regimen was as follows: cephalexin, 25; clindamycin, three; ciprofloxacin, three; and trimethoprim/sulfamethoxazole, one. Average age at the time of operation was 47 years, and average BMI was 22.4. Average overall length of follow-up was 3.5 years.

Table 4 provides a demographic and intraoperative comparison between the postoperative antibiotics group versus those who did not receive antibiotics. Patients who underwent capsulotomy at the time of secondary breast augmentation were more likely to be administered postoperative antibiotics.

In total, there were six implant complications out of 112 implants. There was one instance of CC, one infection, and four hematomas. Table 5 includes details of the one

Table 3: Culture and Clinical Indicators of Infection (n = four)]

Patient no	Setting	Weeks Postoperative	Temperature (>101.1°F)	White Blood Cells (×1000/ mm^3)	Cellulitis	Pain	Swelling	Culture	Implant Removal	Management/Notes
1	Primary	1	No	—	Yes	Yes	Yes	No culture	No	The patient was man-aged conservatively with an additional three days of cepha- lexin.
2	Primary	2	Yes	19.3	Yes	Yes	Yes	No growth	No	The patient was admitted and given intravenous vanco- mycin, discharged on PO linezolid.
3	Primary	2	No	—	No	No	Yes	*Enterobacter cloacae* and methicillin-suscep-tible *Staphylo-coccus aureus*	No	Extended course (two weeks) of cipro floxacin
4	Secondary	13	Yes	—	Yes	Yes	Yes	*Pseudomonas aeruginosa*	Yes	The infection occurred shortly after an invasive dental procedure. This Was managed with implant removal and extended oral course of ciprofloxacin.

Infection in the secondary augmentation cohort. The use of postoperative antibiotics was not associated with a statistically significant difference in the rate of infection, CC, or overall complications (Table 5).

Infection

In summary of Table 2 and Table 5, the rate of infection was similar regardless of Postoperative antibiotic prophylaxis for both the primary (*P* =.11) and secondary (*P* =.46) augmentation groups. In combining the primary and secondary augmentation groups (605 total implants), the infection rate was 0.3% for those who received postoperative antibiotics versus 1% for those who did not (*P* =.36).

Discussion

Capsular Contracture

The first end point of interest regarding postoperative antibiotics was CC. In accordance with persuasive evidence in the literature, it remains a long and widely held belief that capsular fibrosis is associated with low-grade subclinical infection [16, 17]. Among other studies, a 2007 series by Schreml *et al.* [18]. Demonstrated that a positive bacterial culture swab was identified in 66.7% of Baker Grade 3 and 4 contractures, but no positive bacterial cultures were isolated upon culturing implants of Baker Grade 1 and 2 contractures.

More specifically, biofilms have been described as the causative infectious process involved with CC. Biofilms are oftentimes undetected by bacterial swab and thus have likely been a historically-overlooked bacterial phenomenon causing implant complications. Drawing from sonication and broth culture techniques described by Pajkos *et al.* [19] studies from Rieger *et al*. [20] and del Pozo and Patel [21] have utilized these more sensitive techniques to isolate coagulase-negative staphylococci, *Propionibacterium acnes*, and *Corynebacterium* species biofilms from implants that demonstrated CC (as opposed to *Staphylococcus aureus*, which is the single organism most strongly implicated in fulminant periprosthetic infection that requires immediate implant removal) [22, 23] Most recently, Tamboto *et al.* [24] further demonstrated, in an animal model, that *Staphylococcus epidermidis* introduction into the implant pocket can lead to biofilm formation and subsequent capsular fibrosis.

Thus, a strong link between underlying bacterial etiology and high-grade CC has been demonstrated previously in the literature. In terms of prevention, a prospective study by Adams *et al*. [15] suggested that perioperative triple antibiotic irrigation is an effective means of reducing CC in cosmetic augmentation. Although our own perioperative protocol is not without issue for some specifically the decision to use bacitracin as opposed to Betadine [14] or triple antibiotic irrigation [15] it was consistent across all patients and therefore should not contribute to bias in analyzing the efficacy of postoperative antibiotics. Unlike intraoperative irrigation, no evidence has been presented to suggest that postoperative antibiotics confer added protection against biofilm-related CC. In a retrospective clinical study, the capacity to evaluate the effect of postoperative antibiotics and biofilm formation is very limited for several reasons. First, contracture is time-dependent. Patients would need to return to the clinic at equivalent time periods postoperatively, so that antibiotic cohorts could then be compared at each time point. Furthermore, a micrograph or other, more sensitive quantitative method of detection would be potentially necessary as well. Also, evidence has come forth to suggest that certain antibiotics, such as aminoglycosides and fluoroquinolones, are more effective against these often resistant biofilms [25, 26]; there-fore, multiple antibiotic types and lengths of administration would need to be considered. A small percentage of patients in our study were administered ciprofloxacin (fluoroquinolone) and azithromycin (macrolide). Admittedly, this was reflective of a less-than-prudent choice for gram-positive prophylactic coverage rather than an attempt to prevent biofilm formation. (Ciprofloxacin is more appropriate as a penicillin alternative in cases of abdominal or head/neck surgery, whereas azithromycin is typically less than ideal for prophylaxis in general.)

In a broad sense, our clinical data suggest that three days of postoperative antibiotics (primarily cephalosporins) are not effective in reducing the rate of CC. However, retrospective study designs are unfortunately limited in their ability to pass more definitive judgment on the ability of postoperative antibiotics to influence CC. Such conclusions would require a well-controlled prospective trial comparing multiple antibiotic regimens.

Table 4: Demographic and intraoperative comparison of the secondary augmentation cohort receiving antibiotics versus the cohort that did not receive antibiotics (n = 64)

	No Postoperative Antibiotics	**Postoperative Antibiotics**	***P* Value**
No. patients	34	30	
Demographics			
Age, y	46	48	.67
Length of follow-up, y	3.5	3.7	.6
Body mass index	22	23	.36
Smoking	5 (15.0)	2 (6.7)	.74
Comorbidities	1 (2.9)	1 (3.3)	.92
Prior breast surgery	6 (17.6)	6 (20.0)	.81
Intraoperative			
Implant type			.72
Saline	11 (32.0)	11 (37.0)	
Silicone	23 (68.0)	19 (63.0)	
Incision			.26
Periareolar	6 (18.0)	9 (30.0)	
Inframammary	28 (82.0)	20 (70.0)	
Plane of dissection			.93

Subglandular	1 (3.0)	1 (3.0)	
Dual-plane	33 (97.0)	29 (97.0)	
Mastopexy	9 (26.5)	3 (10.0)	.09
Capsulectomy	14 (23.0)	18 (35.0)	.2
Capsulotomy	3 (5.0)	18 (35.0)	.001

Table 5: Rates of complications for the secondary augmentation group of patients given postoperative antibiotics versus those who did not receive postoperative antibiotics (n = 112)

	No Postoperative Antibiotics, No. (%)	**Postoperative Antibiotics, No. (%)**	***P* Value**
No. implants	60	52	
Infection	0	1 (2.0)	.46
Capsular ontracture	0	1 (2.0)	.46
Total complications	3 (5.0)	3 (6.0)	1

Infection

Although retrospective studies may be limited for the analysis of CC, it is more reasonable to gather meaningful, Level 3 evidence on the ability of postoperative antibiotics to influence the rate of infection. Including both primary and secondary augmentations in this series (605 implants), the total rate of infection was 0.66%. In our study design, we chose to stratify primary and secondary augmentation complication rates, before additionally performing a brief analysis that combines both groups. This decision was largely based on a study of augmentation/mastopexy from Spear *et al.*, [27]. Who noted the complication rate for primary augmentation to be 1.7% versus 21.6% for the secondary augmentation group. Given the significant variation in those numbers, we felt it was best to stratify the data.

Interestingly, one of the infections in our series occurred in the secondary augmentation cohort three months post-operatively and immediately followed an invasive dental procedure (Table 3). Although the culture of *Pseudomonas* makes the diagnosis of hematogenous spread quite improbable, bacterial seeding has drawn speculation for a number of years in the literature [28, 29] Hematogenous spread as the etiology of late infection and contracture is possible yet difficult to prove, particularly since the literature is relegated to case reports. Antibiotic prophylaxis prior to semi invasive procedures for those with implants is another controversial area that lacks evidence-based data, but that topic is beyond the scope of this article.

In comparing the primary augmentation group that received antibiotics and the group that did not receive antibiotics, there was a selection bias toward potentially higher-risk patients receiving postoperative prophylaxis. These patients had a statistically significant increased rate of periareolar incisions, prior breast surgery, and concur-rent mastopexies. This bias largely represents one surgeon's preference for using a periareolar incision and concurrent mastopexy; that surgeon also happened to routinely utilize antibiotics. To some degree, it may also represent surgeons' anecdotally guided administration of antibiotics for patients with these potential risk factors. Past literature has suggested risk factors that include but are not limited to corticosteroids, hematomas, preceding lactation, vigorous exercise/massage, and postsurgical trauma [9, 30]. Perhaps future studies will utilize potential risk factors as a guide for when extended prophylaxis is war-ranted. These previously reported factors might be potential confounding elements in our study, along with surgeon experience. Surgeon A, who never prescribed antibiotics, was the most senior surgeon and had the highest volume of augmentations. Assuming this translated to increased technical ability, the intersurgeon variability may have caused bias in our study as well.

It could be argued that the fact that the antibiotic group achieved a lower rate of infection (albeit not to a statistically-significant degree) despite including higher risk patients and less experienced surgeons is a demonstration of antibiotic efficacy. Our results, however—which we argue provide evidence against the need for postoperative prophylaxis—are in accordance with the few other studies that have been published in the literature on this matter. A 1991 study by Leroy and Given [31] found that perioperative antibiotic prophylaxis (both intravenous preoperative and at least 24 hours oral postoperative) provided no reduction in rates of infection. Recently, Khan [22] examined the rate of postoperative infection in 1628 primary augmentations, comparing three cohorts of different prophylactic antibiotic regimens: (1) parenteral preoperative antibiotics alone, (2) parenteral preoperative antibiotics plus 24 hours of postoperative oral antibiotics, and (3) parenteral preoperative antibiotics plus five days of postoperative oral antibiotics. Khan noted that the lowest rates of infection were achieved in the group receiving only preoperative antibiotics.

Clinical Significance

The distinction between statistical significance and clinical significance is critical. In comparing the rate of infection in the primary augmentation group, the difference was not statistically significant (*P* =.11). In a post hoc analysis, the power was 0.239 (assuming adequate statistical power is 0.80). Therefore, there is a reasonable probability of Type II error with our study design.

Although this study lacks statistical power, we feel that results remain clinically significant. These results suggest that the routine use of postoperative antibiotics provides no real benefit to the patient. We are able to draw this conclusion for two major reasons. First, this series is yet another testament to the fact that cosmetic augmentation (both primary and secondary) can be executed with a low risk of infection in the absence of postoperative antibiotics. Both groups achieved infection rates that were well within, if not better, than previously established rates of infection. In addition to the low rate of infection, many implant infections can be successfully managed with conservative treatment, and implant removal is often unnecessary. Safety without extended prophylaxis was demonstrated decades ago, in two series with infection rates of 0.7% and 2.2% without antibiotic prophylaxis [23, 31]. Most recently, in a larger series of 1720 implants inserted without postoperative anti-biotic prophylaxis, a single surgeon reported a 0% rate of infection, which further supports the

safety of these procedures even without prophylaxis [7]. Second, the use of extended postoperative prophylaxis following cosmetic breast augmentation has not been supported by evidence in the literature. As this antibiotic administration is a therapy administered not without inherent risk, the onus should lie on those administering the therapy in order to justify the efficacy of it. No such evidence has been presented to date. With the addition of our study, there is further Level 3 evidence contradicting the Level 5–supported decision to administer antibiotics.

Risk to Benefit Ratio

It is plausible that many surgeons deviate from EBM with regard to this matter in an effort to practice defensive medicine in today's medico legal climate. In examining the risk-to-benefit ratio, we feel that patients are unnecessarily placed at increased risk with postoperative prophylaxis. There are serious, albeit rare, poor out-comes associated with the liberal administration of antibiotics. Perhaps most life threatening is pseudomembranous colitis associated with *Clostridium difficile*. Cephalosporins are thought to be one of the routine antibiotic classes with the greatest potential to induce *C difficile* colitis, and unfortunately, cephalosporins are also one of the most widely prescribed antibiotics for prophylaxis. There are, however, much more pragmatic or commonplace appeals for ceasing postoperative prophylaxis. Less threatening risks include benign gastrointestinal upset, yeast infections, and allergic reactions that can be eliminated by discontinuing postoperative antibiotic administration. In addition to avoiding those undesirable outcomes, increased patient satisfaction is further cultivated by the decreased cost and easier postoperative regimen associated with discontinuing prophylaxis.

Finally, the issue of resistance must be respected within any proper discussion of antibiotic usage. Methicillin-resistant *Staphylococcus aureus* (MRSA) is perhaps the most well-known byproduct of this phenomenon. The use of antibiotics has been associated with patients demonstrating MRSA colonization and therefore could potentially lead to MRSA infections. Antibiotic resistance is an ongoing challenge to future physicians treating patients, particularly those not undergoing elective procedures, thus making the cavalier distribution of antibiotics deleterious to both the plastic surgery patient as well as the greater population. Given that there is inherent risk to antibiotic administration and no apparent benefit, the risk-to-benefit ratio stresses the clinical significance of our findings.

Conclusions

Our data suggest that three days of routine postoperative prophylactic antibiotics provide no reduction in infection, capsular contracture, or total rates of complication for either primary or secondary cosmetic breast augmentation. Because of the retrospective nature of this study, we recommend continued examination of this matter, especially with regard to postoperative prophylaxis and biofilm-related capsular contracture. There is a paucity of data on this matter, and this study serves as part of the introduction of Level 3 evidence for surgeons to consider discontinuing the administration of prophylactic postoperative antibiotics following cosmetic breast augmentation.

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