

Enhancing Patient Outcomes in Aesthetic and Reconstructive Breast Surgery Using Triple Antibiotic Breast Irrigation: Six-Year Prospective Clinical Study

William P. Adams, Jr., M.D.

Jose L. Rios, M.D.

Sharon J. Smith, R.N.

Dallas, Texas

Background: Capsular contracture remains one of the most commonly reported complications in aesthetic and reconstructive breast patients. Previous in vitro studies from the authors' laboratory have recommended a new triple antibiotic povidone-iodine irrigation (2000) and subsequently a triple antibiotic non-povidone-iodine-containing irrigant (2001) to optimize broad-spectrum coverage of various bacteria implicated in capsular contracture; however, the clinical efficacy of these in vitro studies remains unproven. The purpose of this study was to determine the clinical efficacy for the previously reported triple antibiotic breast irrigation. The cost-effectiveness of universal application of irrigation solutions in breast prosthesis surgery was analyzed as well.

Methods: Patients undergoing aesthetic and reconstructive breast implant procedures were treated with a standardized operative technique, including the use of triple antibiotic breast irrigation by a single surgeon. Capsular contracture was assessed using a simplified Baker scale and graded by two independent caregivers to maximize objectivity and consistency. Additional complications were also recorded, including reoperation. Patient charges for antibiotic irrigation and reoperation for contracture were determined and compared.

Results: A total of 335 patients operated on since 1997 were evaluated prospectively. They ranged in age from 18 to 86 years, and the mean follow-up was 14 months (range, 6 to 75 months). The rate of grade III/IV capsular contracture in the study groups was 1.8 percent for patients undergoing primary breast augmentation. Patients undergoing augmentation-mastopexy had a grade III/IV contracture rate of 0 percent. Breast reconstruction patients had a 9.5 percent rate of grade III/IV contracture.

Conclusions: Triple antibiotic breast irrigation is clinically associated with a low incidence of capsular contracture compared with other published reports, and its clinical efficacy supports previously published in vitro studies. Application of triple antibiotic irrigation is recommended for all aesthetic and reconstructive breast procedures and is cost effective. (*Plast. Reconstr. Surg.* 117: 30, 2006.)

Despite 40 years of problems, capsular contracture remains a significant complication in aesthetic and cosmetic breast surgery. The incidence of contracture has been

reported to be as high as 50 percent in some series,¹ and despite suggestions by some surgeons that contracture is no longer a problem, it is still a significant issue for aesthetic and reconstructive breast patients. The best and most controlled available data come from the implant manufacturers' premarket approval prospective trials, with rates of 9 percent for primary augmentation and up to 30 percent for breast reconstruction patients in the Mentor Corp. saline trial (2001), 9 percent for augmentation and 25 percent for reconstruction patients in the Inamed Corp. saline trial (2001), and 8 to 9 per-

From the Department of Plastic Surgery, Parkland Health and Hospital System, and the Department of Plastic and Reconstructive Surgery, University of Texas Southwestern Medical Center.

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cent for the augmentation subgroup in Inamed's and Mentor's silicone gel implant premarket approval trial (2003 and 2005).²⁻⁴

Although the underlying etiology of capsular contracture has yet to be fully elucidated, there is a well-established correlation between capsular contracture and bacterial infection.⁵⁻¹⁰ The use of breast pocket irrigation with povidone-iodine as a means of preventing subclinical implant pocket infection, and subsequent capsular contracture, was championed by Burkhardt and colleagues^{11,12} and widely practiced by plastic surgeons for many years. Without any additional scientific data, many surgeons also opted to use various other antibiotic-containing solutions, such as double antibiotic solution (polymyxin B/gentamicin) for breast pocket irrigation.

A wide variety of organisms have been implicated in the development of capsular contracture.^{5,13} Adams et al.¹⁴ provided recommendations for optimal broad-spectrum antibacterial coverage of the organisms most likely to cause implant contracture and infections. A critical analysis of a variety of solutions revealed the ideal coverage was provided by a combination of povidone-iodine, gentamicin, and cefazolin. Despite the complete absence of any evidence that extraluminal povidone-iodine contributes to implant shell failure, the U.S. Food and Drug Administration prohibited the contact of povidone-iodine with breast implant prostheses.^{15,16} Subsequent *in vitro* investigations at our institution¹⁵ yielded an alternative solution of bacitracin, gentamicin, and cephalexin that provided antibacterial coverage comparable to that of the initial povidone-iodine-containing solutions.¹⁴ Despite the promising *in vitro* results, the efficacy of this triple antibiotic solution in the clinical setting had not been established.

The purpose of this study was to evaluate the incidence of capsular contracture in the practice of one surgeon (Adams) using the triple antibiotic solution recommended by the *in vitro* studies. We also performed a cost analysis of the universal application of pocket irrigation in patients undergoing breast implant placement.

PATIENTS AND METHODS

Database

Data from patients undergoing breast augmentation from 1997 to 2004 were prospectively recorded in a database. These data included dates of surgery, incision location, pocket location, type

of breast pocket irrigation, implant type, implant filler material, implant texture, implant shape, capsule grade, secondary operations, preoperative and postoperative measurements, and complications. The database was assessed to determine the incidence of capsular contracture and possible contributing factors.

Antibiotic Irrigation

The antibiotic irrigation regimen was based on our previous *in vitro* studies.^{14,15} Before the U.S. Food and Drug Administration decree (in 2000), the irrigation solution consisted of 50 ml of povidone-iodine, 1 g of cefazolin, 80 mg of gentamicin, and 500 ml of normal saline. After the year 2000, the solution consisted of 50,000 U of bacitracin, 1 g of cefazolin, 80 mg of gentamicin, and 500 ml of normal saline.

Surgical Technique and Postoperative Care

Preoperative intravenous antibiotics were administered to all patients (cefazolin or vancomycin/gentamicin for penicillin-allergic patients).

Implant size and type and incisional approach were chosen based on individual patient breast dimensional analysis,¹⁷ soft-tissue characteristics, and patient preferences. Talc-free gloves were used at all times during the procedures. Pockets were developed precisely under direct vision with no blunt dissection, with particular attention paid to hemostasis, as described by Tebbets.¹⁸ Pockets were irrigated with 120 to 150 ml of normal saline followed by 120 ml of the triple antibiotic solution without active evacuation of the irrigation. The skin surrounding the incisions was cleansed with the triple antibiotic solution. Prostheses (saline or silicone gel) were kept in their containers and bathed in the triple antibiotic solution during pocket dissection. A new pair of talc-free gloves was donned before implant insertion and preparation. Implants were inserted with minimal skin contact; insertion sleeves were not used. Filling of the saline implants was performed with sterile injectable saline via a closed system. Subsequent digital implant manipulation or skin/parenchymal redraping maneuvers were performed after the surgeon's gloved fingers were dipped in the triple antibiotic solution. Incisions were closed with interrupted or running 3-0 Vicryl or Prolene in the superficial fascia. Skin was closed with deep subdermal sutures, followed by a subcuticular closure. Steri-Strips

(3M, St. Paul, Minn.) were placed and maintained for 6 weeks.

Antibiotics were continued for 5 days postoperatively. All patients wore a well-fitted surgical brassiere, or athletic brassiere, for 6 weeks. Pain control was accomplished with rofecoxib or ibuprofen, and hydrocodone/acetaminophen if needed. Implant displacement exercises were prescribed only for those patients in whom smooth round implants were placed. The exercises involved medial and superior displacement of the implant 10 times, three times per day for 1 month and once daily thereafter.

Postoperative Evaluation

Patients were evaluated postoperatively at 5 days, 2 weeks, 6 weeks, 3 months, 6 months, and 12 months, and yearly thereafter. Examinations were performed by two individual health providers. Any patient with grading discrepancies between the examiners was re-assessed by both providers, and a final determination of grading was made jointly. The degree of capsular contracture was recorded according to a simplified Baker classification. Baker I/II was characterized by a soft breast with no distortion of breast shape. Baker III/IV was characterized by a firm breast and/or obvious distortion of the breast on visual inspection, with or without pain.

Cost Analysis

The charges for the components of the triple antibiotic solution at our institution were obtained from Pharmacy Services (Zale Lipshy University Hospital, Dallas, Texas) and other community surgical facilities. Operating room, anesthesia, and surgeon fees were also obtained for patients undergoing bilateral implant exchange procedures. A comparison was performed of the potential cost differences in breast prosthesis placement with

and without universal application of the antibacterial irrigation protocol.

RESULTS

A total of 335 patients underwent procedures involving placement of a breast prosthesis. Two hundred forty-eight patients underwent breast augmentation. Twenty-four patients had an implant placed during augmentation-mastopexy procedures. The remaining 63 patients had an implant placed as part of the reconstruction after ablative surgery for breast cancer. Patients with less than 6 months of postoperative follow-up were excluded, as were 14 patients who were lost to follow-up, resulting in 165 augmentation patients, 22 augmentation-mastopexy patients, and 63 reconstruction patients for full evaluation. Of the 14 patients not seen for follow-up, 12 were contacted by telephone, and none of these patients complained of firm breasts (this is for verification only; this group was not included in the analysis).

Mean patient age was 35 years (range, 18 to 63 years) in the augmentation group; 37.5 years (range, 25 to 48 years) in the augmentation-mastopexy group, and 52.2 years (range, 34 to 86 years) in the reconstruction group. The mean follow-up was 14 months (range, 6 to 75 months). The demographics of implant type and pocket plane are reported in Table 1.

The rate of grade III/IV capsular contracture (Table 2) in our study groups was 1.8 percent (three of 172) for patients undergoing primary breast augmentation. Patients undergoing augmentation-mastopexy had a grade III/IV contracture rate of 0 percent. Breast reconstruction patients had a 9.5 percent (six of 57) rate of grade III/IV contracture.

The overall reoperation rates (all causes) were 2.8 percent for augmentation, 16 percent for augmentation-mastopexy, and 10.5 percent for recon-

Table 1. Implant Demographics and Pocket Plane

Implant Type	Augmentation (n = 165 patients and 330 implants)	Augmentation-Mastopexy (n = 22 patients and 44 implants)	Reconstruction (n = 63 patients and 99 implants)
Saline	252 (76%)	38 (86%)	15 (15%)
Smooth	196 (78%)	32 (84%)	8 (53%)
Textured	56 (22%)	6 (16%)	7 (47%)
Silicone gel	78 (24%)	6 (14%)	84 (85%)
Smooth	0	0	44 (52%)
Textured	78 (100%)	6 (100%)	40 (48%)
Pocket plane			
Dual plane 1	137 (83%)	7 (32%)	
Dual plane 2	22 (13%)	7 (32%)	
Dual plane 3	4 (2.4%)	8 (36%)	
Retropectoral	1 (0.6%)	—	
Subglandular	1 (0.6%)	—	

struction (Tables 3 and 4). No augmentation patient developed an infection. One patient each in both the augmentation-mastopexy and reconstruction subgroups developed an infection.

DISCUSSION

Breast augmentation is one of the most popular cosmetic procedures performed by plastic surgeons. According to the statistics from the American Society of Plastic Surgeons,¹⁹ 236,888 breast augmentations were performed in 2002. In addition, more than 74,000 breast reconstruction procedures involving the placement of a breast prosthesis were performed in the same year. The reported rates of capsular contracture have been highly variable.¹⁹⁻²¹ The best data available from implant manufacturers' saline prospective trials were 9 percent after augmentation and 27 percent after breast reconstruction.^{2,3} Thus, estimates of the number of women experiencing grade III/IV capsular contracture yearly may range from 22,000 to 44,000.

The cause of capsular contracture has been debated for many years, and no theory has been universally accepted. The precise mechanisms involved have yet to be elucidated, but a correlation with bacterial infection has been established in multiple reports.⁵⁻¹⁰ Whether or not the presence of bacteria is responsible for a subclinical infection, or results in the initiation of an inflammatory cascade with a final common pathway leading to contracture, the potential role of micro-organisms is impossible to deny.

The effectiveness of antibacterial irrigation solutions has been reported for many years in the specialties of orthopedics, ophthalmology, obstetrics and gynecology, and general surgery.²²⁻²⁶ Use of an antibacterial irrigation solution during placement of breast prostheses is logical given current data on the infectious theory of capsular contracture; however, it continues to be disputed whether antibiotic irrigation exerts its effect through local decreases in bacterial counts or through its systemic absorption, although local effects seem most logical.

Table 2. Capsular Contracture Rate by Procedure

Procedure	Capsular Contracture Rate (%)
Breast augmentation (<i>n</i> = 165)	1.8 (three of 165 patients)
Augmentation-mastopexy (<i>n</i> = 22)	0 (zero of 20 patients)
Breast reconstruction (<i>n</i> = 63)	9.5 (six of 63 patients)

One must also understand that a wide variety of organisms (other than *Staphylococcus epidermidis*) have been cultured from the pockets of patients with capsular contracture. Thus, an "optimal" irrigation solution for use in breast implant surgery must provide broad-spectrum coverage of all these organisms. In 1997, we developed a special interest in this area, since the specific type of breast pocket irrigation used by many surgeons was anecdotal, with a variety of different solutions used. We decided to apply the scientific method to provide better practice guidelines for surgeons using breast implants.

A critical in vitro analysis of the antimicrobial effectiveness of a variety of irrigation solutions was reported by our group in 2000¹⁴ and again in 2001¹⁵ (after the U.S. Food and Drug Administration's ban on povidone-iodine use during placement of breast prostheses). The results of these studies were interesting and informative, but the correlation of the in vitro methodology to the clinical realm was purely speculative.

The current study was performed to evaluate the actual clinical efficacy of the optimal irrigation solutions as determined by our previous in vitro analyses. The capsular contracture rates are favorable in comparison to the most recent premarket approval data available from the two breast implant manufacturers.²⁻⁴ We chose the premarket approval data as an appropriate means for comparison since these data are well-controlled and the most currently available from multiple plastic surgeons across the country with a specific interest in breast surgery.

In this study, the incidence of contracture in the augmentation group was reduced four- to five-fold, and three-fold in the reconstruction group.

Table 3. Reoperation by Procedure

Reason for Reoperation	No. of Cases
Augmentation group (<i>n</i> = 248 cases total)	
Size exchange	1 (0.4%)
Early deflation (iatrogenic)	2 (0.8%)
Saline to gel conversion	2 (0.8%)
Exploration for possible malposition	1 (0.4%)
Capsular contracture	1 (0.4%)
Total	2.8%
Augmentation-mastopexy group (<i>n</i> = 24)	
Delayed wound healing/ infection	1 (4%)
Revision for asymmetry/aesthetic concern	3 (12%)
Total	16%
Reconstruction (<i>n</i> = 63 cases)	
Capsular contracture*	2 (3%)
Deflation/rupture	2 (3%)
Asymmetry	2 (3%)
Total	10%

*One patient had infection and capsular contracture.

Table 4. Recommended Breast Irrigation Solutions for Allergies

Allergen	Recommended Irrigation Solution
Cephalosporin or penicillin	250 cc of povidone-iodine solution,* 80 mg of gentamicin, and 250 cc of 0.9% normal saline
Bacitracin	50 cc of povidone-iodine solution,* 1 g of cefazolin, 80 mg of gentamicin, and 500 cc of normal saline
Gentamicin/aminoglycoside	250 cc of povidone-iodine and 250 cc of normal saline
Iodine	50,000 U of bacitracin, 1 g of cefazolin, 80 mg of gentamicin, and 500 cc of normal saline

*When using povidone-iodine solution, disclose use to patient or rinse the povidone-iodine clear with saline for 5 minutes before putting the implant in contact with the pocket.

These results are significantly lower than many previously reported rates, and the details of the surgical technique have been provided for reproducibility. Our findings indicate that very low rates of capsular contracture are achievable despite the findings of the recent prospective trials, and that the triple antibiotic irrigation is effective in vivo, supporting our previous in vitro studies.

Implant texture made no significant difference and showed no significant benefit in capsular contracture in this study. The indication for use of a textured implant in this trial was use of a shaped device (saline or gel). In the augmentation subgroup, all capsular contractures occurred with smooth saline implants (but the total number of contractures was very low and 78 percent of the augmentation implants were smooth). In the reconstruction group, contracture occurred in three of six patients with smooth implants and three of six with textured implants.

We also analyzed the cost-effectiveness of the universal application of triple antibiotic breast pocket irrigation during breast implant procedures. The average costs of triple antibiotic solution range from \$2 to \$154. As all components are generic, the lower values are more realistic. A total solution cost of \$5 for the combination solution was used in the comparison. The total cost of reoperation for capsular contracture at our institution ranged from \$7217 to \$7667. Treatment of 100 primary augmentation patients with irrigation solution costs \$500. Another \$14,434 can be estimated for reoperations at a 2 percent contracture rate, for a total of \$14,934. Assuming a contracture rate consistent with the most recent available data (9 percent), \$64,953 would be spent on reoperations. The savings would measure over \$50,000. It is important to note, however, that this figure does not include revenues lost from time off work, the morbidity of another operation, and the possibility of recurrent contracture. If these measures are taken into account, the "savings" would be much

greater than we have calculated. Additional important operating room management issues include mixing of the solution by the operating room nurses before the procedure. We have found that this eliminates oversights and overcomplications encountered when this step is left to the discretion of the pharmacy.

Also cogent is the known shortage of bacitracin and the reluctance of surgeons to use povidone-iodine-containing irrigation solutions due to U.S. Food and Drug Administration restrictions. We do not disagree with many who find it illogical that the Food and Drug Administration has not reconsidered its strange decision to restrict povidone-iodine usage when there have now been multiple studies that have not found any detrimental implant effect of extraluminal povidone-iodine.^{15,16,27,28} Despite the bureaucracy of this process, keep in mind that the off-label use of povidone-iodine-containing breast irrigation is still permissible at the discretion of the operating surgeon. In this situation, the surgeon can disclose the intention to use povidone-iodine to the patient with appropriate background information, and we have found patients to be not only accepting but grateful that their physician is acting in their best interest. Alternatively, the povidone-iodine irrigation may be used if after a 5-minute contact time it is followed by a saline irrigation, which prevents contact of the implant with povidone-iodine (this must be dictated in the operative note). Either practice is sound and permitted.

In addition, some patients have systemic allergies to antibiotics. Our breast pocket irrigation recommendations for common antibiotic allergies are summarized in Table 4.

It is important to note that most capsular contractures present within 1 year of the procedure; thus, the mean follow-up of our series (14 months) is adequate. In fact, all contractures in every subgroup in this study occurred within 1 year from operation and all were clinically detectable within

6 months postoperatively. Thus, the majority of patients do form contractures within a year of operation, and we believe this is secondary to a subclinical bacterial contamination of the periprosthetic pocket. More perplexing are contractures that form years after implantation. Potential causes for late contracture include secondary infection from systemic bacteremia and chronic capsular maturation changes mediated by elastomer degradation or filler bleed.

The lack of a prospective, double-blind, randomized trial design is a weakness of our report. Acknowledging this fact, we are unsure whether the aforementioned type of trial is ethical in the current era. Given the available data on the association between contracture and the presence of bacteria, the significant morbidity and costs associated with capsular contracture and its treatment, and the minimal risks associated with antibiotic irrigation, randomization of patients to a non-treatment group (saline only) would be ethically unsound at best. Furthermore, we believe the etiology of capsular contracture is multifactorial, and there is no way to completely isolate an experience with triple antibiotic without other confounding variables, such as tissue trauma and bleeding, both of which may also increase the possibility for contracture. Our recommended surgical technique minimizes both tissue trauma and bleeding, and these ultimate study limitations warrant acknowledgment. Nevertheless, we would conclude that triple antibiotic breast irrigation (povidone-iodine/cefazolin/gentamicin or bacitracin/cefazolin/gentamicin) has proven efficacy in both vitro and in vivo clinical studies. Its use clinically with our recommended technique yields capsular contracture rates four to five times lower than other available prospective premarket approval data.

Our technique for the placement of breast prostheses has been standardized, and our recommendations for surgeons include the following:

- atraumatic pocket dissection under direct vision, avoiding blunt instrumentation;
- soaking of implants in irrigation solution during pocket dissection;
- irrigation of pocket with 120 to 150 ml of irrigation solution without any active evacuation;
- cleansing of skin surrounding the incisions with irrigation solution;
- glove change before implant handling;
- aseptic implant insertion; and
- minimal implant manipulation after insertion (gloves should be washed with antibiotic solution if further implant handling is required)

New methods for the delivery of drugs, such as antibiotics, are being investigated. In a recent publication, Darouiche et al.²⁹ reported the use of saline-filled implants impregnated with minocycline/rifampin in a rabbit model. The sustained delivery of these drugs resulted in a significant decrease in the rates of contracture in their model. It is foreseeable that implants may be manufactured with antibiotics impregnated within their shell, for optimal control of the bacteria most often associated with capsular contracture; however, enhanced implant technology will not replace meticulous technique and use of antimicrobial irrigation to minimize implant pocket contamination.

As we attempt to advance the science of aesthetic and reconstructive breast surgery, we have found the use of triple antibiotic irrigation integral in reducing the incidence of complications associated with these procedures and enhancing the patient's experience.

William P. Adams, Jr., M.D.

2801 Lemmon Avenue West, Suite 300
Dallas, Texas 75204
dr@dr-adams.com

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