Enhancing Patient Outcomes in Aesthetic Breast Implant Procedures Using Proven Antimicrobial Breast Pocket Irrigations: A 20-Year Follow-up

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Abstract

Background: Capsular contracture (CC) remains the most common complication of implant-based aesthetic and reconstructive breast surgery. With subclinical infection proven to be the primary etiology, antimicrobial breast pocket irrigation has been recommended as the key step to reduce CC but has not been universally adopted.

Objectives: The purpose of this study was to review the rates of CC observed when applying proven antimicrobial breast pocket irrigations.

Methods: Data from patients undergoing cosmetic breast augmentation were recorded prospectively from 1997 to 2017. The irrigation was performed with either a Betadine-containing (50% Betadine or "Betadine triple") or a non-Betadine triple antibiotic regimen. The database was assessed to determine the type of implant used, the incidence of CC, and possible contributing factors. The degree of CC was recorded according to the Baker classification.

Results: A 20-year prospective data collection yielded 2088 patients with 4176 implants; of these patients, 826 had textured implants and 1262 had smooth implants. The incidence of Grade III/IV CC was found to be 0.57% in all patients undergoing primary breast augmentation (1.21% in textured implants and 0.16% in smooth implants).

Conclusions: This study constitutes the largest and longest review of CC in a controlled, single-surgeon setting. The incidence of CC is low and reinforces the efficacy/utility of antimicrobial breast pocket irrigation. Both the Betadine and non-Betadine antibiotic regimens were found to be effective, with the Betadine regimen being preferred. Universal adoption of Betadine-containing antimicrobial breast pocket irrigation is recommended to reduce CC and other device-associated infections.

Level of Evidence: 4

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Despite breast augmentation being one of the most commonly performed cosmetic surgery procedures, along with other popular breast implant–based aesthetic procedures including breast augmentation revision and

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augmentation mastopexy, capsular contracture (CC) remains the most common complication, with an incidence ranging from 1.7% to 19%.[1–3] Validated scientific data have confirmed the primary etiology of CC to be subclinical infection with the relative bacterial load being the key factor.[4–22] For this reason surgeons attempt to reduce bacterial load in the breast implant pocket as far as possible to minimize device-associated infection, and for many years the single most important step was believed to be the use of proper antimicrobial breast pocket irrigation.[16]

The use of Betadine (Avrio Health, New York, NY) was initially popularized and elucidated by Burkhardt et al in the 1980s.[12–15] Although surgeon awareness existed, there was lack of standardization, with a variety of unproven irrigations being used. With the aim of providing broad-spectrum antimicrobial coverage against the many different types of bacteria that have been reported to cause CC, while at the same time decreasing the concentration of Betadine which had been demonstrated to affect wound healing, the senior author described a Betadine triple (BT; 50-100 mL povidone-iodine stock solution, 1 g cefazolin, 80 mg gentamycin, 500 mL normal saline) and a 50% Betadine (povidone-iodine) regimen for breast pocket irrigation in 2000.[7]

Unfortunately, in the spring of 2000, the FDA issued a curious advisory against the use of Betadine in any contact with breast implants based on reports that it caused a higher deflation rate of saline implants. Subsequently, following further bench research, the same group described a non–Betadine-containing agent called non-Betadine triple antibiotic (NB-TAB; 50,000 U bacitracin, 1 g cefazolin, 80 mg gentamicin, 500 mL normal saline).[8] This regimen was also found to be highly effective although had slightly lower Gram-negative coverage than BT and 50% Betadine.[9]

Seventeen years later, in August 2017, the FDA finally lifted the restriction on Betadine for use with Allergan implants based on long-term data, and supplied directions for use, making Betadine once again an on-label acceptable use in breast implant pocket preparation/irrigation. What was formerly an off-label practice can now be practiced openly for bacteria/biofilm mitigation and antimicrobial prophylaxis.

Unfortunately, a recent survey also showed that despite previous publications there is still a lack of standardization when it comes to irrigation solutions.[23] The purpose of this study was to perform a 20-year analysis of the CC rates observed with the BT and NB-TAB regimens. This would constitute the largest and longest series in a controlled single-surgeon setting.

METHODS

Database

The study was performed according to the guiding principles of the Declaration of Helsinki. The study was IRB exempt under 45 CFR § 46.104(d)(4) (WCG IRB, Puyallup, WA). Clinical data from consecutive patients undergoing cosmetic breast augmentation were recorded prospectively in a digital database from January 1997 to December 2017. The data included routine parameters, namely: dates of surgery, incision site, pocket location, implant type, size, and material, irrigation solution, capsule grade, complications, reoperations, and postoperative duration. The database was assessed to determine the incidence of CC and possible contributing factors. All cases were operated by a single surgeon (W.P.A. Jr). We also continue to follow-up with all patients virtually on an annual basis and any patient who indicates any issue is flagged for in-person consultation. We also recommend an in-person visit every 5 years for an ultrasound exam. Prophylaxis with amoxicillin (1 dose) prior to dental prodecdures was recommeneded. Only in-person visits are reported in the study. The data collected were the standard data collected prospectively for all patients, and the final analysis was de-identified. Guiding principles were followed and written consent was provided, by which the patients agreed to the use and analysis of their data.

Antibiotic Irrigation

The antimicrobial breast pocket irrigations used were based on previous in vitro studies. Prior to 2000 it was BT and after the FDA notice in 2000 it included NB-TAB, BT, or 50% Betadine (the preferred breast pocket irrigant used with signed off-label consent).

Surgical Technique

The steps of our 14-point plan were followed in all cases.[16] Perioperative intravenous antibiotics were administered to all patients. Implants were chosen based on tissue-based planning principles. Talc-free gloves were used and pockets were developed precisely with prospective hemostasis under direct vision. Pockets were irrigated with sequential evacuation of 150 mL of saline, followed by 75 mL of the irrigation solution, followed by a final 75 mL of the irrigation solution without active evacuation. The skin surrounding the incision was also cleansed with the same solution or a chlorhexidine sponge stick. Implants were inserted without the use of any sleeves. Deep closure was done with a watertight 3-0 Vicryl or polydioxanone suture (Ethicon Inc., Raritan, NJ) in the superficial fascia. Skin was closed with deep subdermal sutures followed by a subcuticular closure. Band-aid gel strips or steri-strips were placed.

All patients were given a well-fitted surgical brassiere for 6 weeks, but not required to wear it for the first 3 days unless an anatomic implant was used. Patients were evaluated postoperatively at 1 to 2 days, 1 week, 3 months, and 12 months, and yearly thereafter. The degree of CC was

Table 1. Capsular Contracture Summary Data

	Total	Textured	Smooth
Patients	2088	826	1262
Implants	4176	1652	2524
Capsular contracture	12	10	2
Capsular contracture rate	0.57%	1.21% ($P < 0.02$)	0.16% ($P < 0.02$)

recorded according to the Baker classification at the follow-up visits.

RESULTS

A 20-year prospective data collection from 1997 to 2017 yielded 2088 patients with 4176 implants; 826 patients had textured implants and 1262 patients had smooth implants. The patients were followed annually. Their average age was 35 years (range, 17-84 years). The 826 (45%) patients with textured implants were part of an FDA clinical trial. Mean overall follow-up was 6 years (range, 1-20 years).

Capsular Contracture

Out of the 2088 patients, 12 developed Grade III/IV CC. Minimum follow-up for any capsule assessment in the study was 1 year, with the mean overall follow-up being 6 years. The rate of Grade III/IV CC was found to be 0.57% in all patients undergoing primary breast augmentation (Table 1). There were no new CCs after 10 years observed in the study.

Irrigation Solution

There was no significant difference in contracture rates or any other parameter when comparing Betadine-containing (BT or 50% Betadine) and NB-TAB regimens.

Implant Type

Out of the 826 patients with textured implants, 10 (1.21%) had CC. Out of the 1262 patients with smooth implants, 2 (0.16%) had CC.

DISCUSSION

Capsular contracture remains the most common complication in aesthetic and reconstructive breast surgery.[4,11] The Baker classification grades CC into the following types: I, natural breast—implant not discernible; II, soft breast—implant palpable; III, firm breast—distorted shape; and IV, firm breast—shape distortion and pain. Grades III and IV will typically be reoperated. The cause of CC has generally been deemed as multifactorial although we submit that this is not supported by good data. The etiology with the strongest evidence base is clearly the subclinical infection hypothesis popularized by Burkhardt and supported by many publications.[4,5,7–9,11–16,19–21,24–38] It is well-known that CC is a polymicrobial issue, and the end result of a net sum of potentiators and suppressors. One of the most important suppressors is proper antimicrobial breast pocket irrigation, and this has been supported by over 31 studies in peer-reviewed publications.[39]

Boyd Burkhardt first described the use of Betadine for CC prevention in the 1980s.[12–15] Many scientists in the wound-healing field have denounced the use of Betadine due to its negative effects on wound healing.[40] Furthermore, in the 1990s most plastic surgeons used different types of antiseptic and antibiotic antimicrobial breast pocket irrigations, none of which (except for 50% Betadine) had been scientifically evaluated, creating a lack of evidence-based practice with this procedure. This led to original studies to scientifically evaluate the common antimicrobial breast pocket irrigations and to make clinical recommendations not only on specific antimicrobial breast pocket irrigations but also on the standardization of breast implant pocket preparation.[7] Ultimately, the BT preparation, which allowed for a lower overall concentration of Betadine, or 50% Betadine was recommended for the best broad-spectrum coverage of all common bacteria that were tested.

Following the FDA's label change against the use of Betadine in conjunction with breast implants, a non–Betadine-containing alternative was investigated, resulting in NB-TAB in 2001.[8] A subsequent clinical study in 2006 of both BT and NB-TAB demonstrated a 5 times lower CC rate compared with FDA clinical trials in aesthetic surgery and 9 times lower in reconstructive cases.[9] Other investigators have looked at these same proven antimicrobial breast pocket irrigations and have demonstrated a 10-fold lower CC rate.[11,35]

In 2017 the FDA lifted its restriction for Betadine, and it was once again available for use as an on-label practice. During the years of the Betadine restriction we continued to use primarily BT as our antimicrobial breast pocket irrigation of choice and off-label consent was routinely executed.

Our series is the largest by a single surgeon, with 4176 implants and 2088 patients followed over 20 years. We report an overall CC incidence of 0.57%, which is among the lowest in any series. Furthermore, the majority of CCs occur within 2 years and therefore the mean follow-up is quite long-term.[4,31,41–44] Prior to much of the science on CC there was a general position that CC increased over time; however, we have not found this consistent with our 25-year

experience and this study does not support that notion. We submit that those anecdotal observations never used the more modern higher-level proven techniques, and we have not seen that trend in this study.

This low incidence is attributed not only to standardized use of the proven antimicrobial breast pocket irrigations, but also to a standardized process for breast implant pocket preparation. We originally described these practices in the sentinel publication in 2000 and reinforced them in the clinical follow-up in 2006, and finally recodified the practices as a 14-point plan in 2013.[7,9,16]

The current recommendations for a systematic standardized breast implant pocket preparation are listed below. It should be noted that doing these the same way, every time, for every case is the key to this process-oriented approach.

1. Use intravenous antibiotic prophylaxis at the time of induction.
2. Avoid periareolar incisions.
3. Use nipple shields.
4. Perform careful atraumatic dissection.
5. Perform careful hemostasis.
6. Avoid dissection into the breast parenchyma.
7. Use a dual-plane pocket.
8. Perform breast pocket irrigation with proven antimicrobial solution.
9. Minimize skin implant contamination.
10. Minimize the time of implant opening, repositioning, and replacement
11. Change surgical gloves prior to handling the implant, and use clean or new instruments.
12. Avoid using a drainage tube.
13. Use a layered closure.
14. Use antibiotic prophylaxis to cover subsequent procedures that breach skin or mucosa.

Although all steps are recommended, they are guidelines, and clearly the relative importance of each step is different. We submit that antimicrobial breast pocket irrigation is the most important step for adequate breast implant pocket preparation. Although there is no way to absolutely prove this position, this specific step actively reduces the bacterial load when done properly vs the other steps that passively minimize the load.

In terms of minimizing skin contamination, we have never utilized a sleeve or funnel in our procedures as our observation is that many surgeons reuse these from one side to the other, which increases the bacterial load, and there is a distinct lack of data regarding potential subclinical damage to the elastomer of the implant with these devices. There are many acceptable methods to reduce skin-implant contamination, and our choice is to reprep the skin in this series with the antimicrobial breast pocket irrigation. Currently, based on a recent study that has reconfirmed that chlorhexidine-containing preparations are preferred and optimal, producing instantaneous eradication of all skin flora upon application, we have switched to reprepping the skin around the incision with a chlorhexidine prep stick.[45] Of course, the prep strength of chlorhexidine is only suitable for external skin treatment in combination with proper recommended internal antimicrobial Betadine-containing irrigation.

The other comment regarding the 14-point plan is that it was originally published for aesthetic breast implant–based procedures; however, the concepts have remained consistent since our sentinel publication in 2000, and this plan may be applied to other procedures, including breast reconstruction or breast augmentation revision, although certain elements—such as avoiding the use of a drain—may not be possible. Based on discussion with surgeons and observation, we would recommend not missing the forest for the trees when thinking about the concept of minimizing the bacterial load during any breast implant procedure to reduce device-associated infection.

Comparison of Betadine vs Non-Betadine

There was no difference in any parameter between the 2 regimens; however, in the light of recent revelations that breast implant–associated anaplastic large cell lymphoma (BIA-ALCL) is caused by chronic inflammation by a Gram-negative microbiome, we prefer the use of BT over NB-TAB as it has stronger Gram-negative coverage,. It should be noted that NB-TAB does indeed have activity against Gram negatives but requires a longer contact time.[45] Also relevant to this conversation is that in the winter of 2020, in the United States, bacitracin was removed from the market as its only remaining indication was for pediatric pneumonia and many other superior agents are now available. Thus, based on all of our studies, irrigating with BT or 50% Betadine is our recommendation.[7–9,16] There were no cases of BIA-ALCL in this series.

Regarding allergies, we have not treated any patient with a true allergy to Betadine in 20 years. There has been discussion whether patients who have issues with shellfish or iodine would have a problem, but we have not found this be the case and we continue to use Betadine-containing breast pocket variations in patients with allergy to shellfish or iodine. We also preoperatively identify these patients and topically test patients in the office with Betadine to confirm.

Smooth vs Textured

Although the CC rate in this study is low, we found it interesting that there was a statistically significant higher rate of CC in textured implants vs smooth. It was our impression over the years that we experienced no difference between

smooth and textured implants, but the data gave the definitive answer. Similar findings have been reported by Lista et al.[46] For many years textured implants have been inextricably linked to 2 primary urban legends:

1. Textured implants are associated with a lower CC rate; however, critical examination of the scientific data does not support this notion. Furthermore, it is difficult to explain why a textured device would have a lower CC rate given its increased surface area and affinity for bacteria, which are the primary cause for the problem. Additionally, problems with older techniques, study designs, and conclusions make the claim speculative and likely not true based on our data.
2. Textured devices were preferred because they gave a "Velcro association" that resulted in a better long-term stability of the result. The problem with this it was typically not true for aesthetic surgery textured implant cases, and although this occurred with expanders which were the original devices for which texture was popularized, this "Velcro effect" very seldomly occurred in aesthetic implant procedures.

Our conclusions from these data, coupled with the present study, is that textured devices can clearly achieve low contracture rates with the proper techniques. The techniques in the patients in these studies were standardized throughout for the over 4000 implants used. Due to the increased surface area of texture, there are more bacteria, and with the proper techniques this created a controlled increase in capsular thickness and strength. A modulated CC, if you will, and not a "Velcro effect." For the same reasons, observations by surgeons regarding the longevity/stability of textured implant results would be better explained in these terms. A similarly low rate of BIA-ALCL was observed in this study as in other publications reporting the same technique, and we firmly contend that these same techniques reduce other device-associated infection based on peer-reviewed published data and real-world data.[47]

Current Practices

Despite the senior author's previous papers, a recent survey in 2017 showed that most surgeons (60%) do not use proven antimicrobial breast pocket irrigations. Another issue we have sometimes faced is ancillary staff not mixing solutions according to the protocol, resulting in a possible decrease in antimicrobial activity. We have found direct education of the operating room staff to be the answer to this problem and recommend that the antimicrobial irrigation is prepared by the circulating nurse freshly for each patient. We also recommend the surgeon actively helps nurses to make this preparation until they are comfortable and understand why it is important for the solution to be prepared the same way every time.

Other alternatives that have been suggested for breast pocket irrigation include dilute hypochlorous acid and dilute chlorhexidene. Multiple studies have demonstrated that none of these alternative agents test/work as well as Betadine-containing irrigations.[45,48] These other agents are approved as "mechanical wound irrigations" like saline, and the agent is in the solution at a very dilute level to prevent bacterial growth in the bottle, hence their weakness in efficacy if even slightly diluted. Furthermore, neither of these options are approved breast pocket irrigation agents (off-label) and there are no long-term data for them comparable to the 20-plus years of Betadine, BT and NB-TAB.

Twenty-one other studies have supported the use of Betadine/antibiotic breast pocket irrigations. There are far more positive data on this subject than on most other plastic surgery practices. We present and summarize these data as follows:

- Three randomized clinical trials and 4 retrospective comparative studies.[11,13–15,20,35,49] All of these support antimicrobial breast pocket irrigation.
- Two meta-analyses.[50,51] Both of these support antimicrobial breast pocket irrigation.
- Four clinical case series.[9,52–54] All of these support antimicrobial breast pocket irrigation.
- Eight basic science studies or extensive reviews.[7,8,21,55–59] All of these support antimicrobial breast pocket irrigation.

Additionally, 9 more studies in other surgical disciplines (including 7 of Level 1/2) have concluded improved surgical outcomes with local antimicrobial irrigations.[60–69] Lastly, there is no known resistance to Betadine, and urban legends claiming that it is non-sterile or that it needs to dry in order to work are unfounded and simply disproven by real-world data.

A potential limitation of this study is that we do not have 100% follow-up. However, we do have a typical cosmetic breast patient distribution and patient follow-up behavior in that the majority of patients who do not follow up do not have problems, whereas patients who have problems tend to return to their surgeon of record.

CONCLUSIONS

We conclude, based on our 20-year long-term data in this study, that proven antimicrobial breast pocket irrigations coupled with proper technique resulted in very low long-term CC rates in aesthetic surgery patients. Our recommendations are to use either BT or 50% Betadine irrigations and to implement our 14-point plan to minimize device-associated infection in aesthetic breast implant procedures.

Disclosures

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