Capsular contracture (CC) is a complication of breast augmentation that presents as breast induration, which eventually may become painful for the patient and cause distortion of breast shape and volume. A capsule of fibrous material forms around the implant when it is placed. This capsule is initially thin and soft, with little or no effect on the appearance of the breast; however, with time, it may undergo a progressive thickening, become harder, and shrink in such a way that it may alter the breast contours and produce a range of symptoms varying from local tenderness to severe pain.1,2 This pathologic process occurs in response to the implantation of breast prostheses and is among the most common causes of reoperation following implant placement.2,3 Previous studies have indicated that

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antibacterial lavage and/or topical antibiotics may reduce the infection rate in breast augmentation and may also reduce the occurrence of CC. In a retrospective study, Araco et al. showed that infiltrating the implant pocket with local antibiotics reduced the incidence of infections more than 4-fold compared with a nontreatment group (0.79% vs 2%, respectively); however, all patients in their study, including the nontreatment group, had their implant pockets washed with a povidone-iodine solution before implant insertion. Povidone-iodine irrigation is considered significantly more effective in preventing surgical infection compared with saline, water, or no irrigation. Indeed, povidone-iodine pocket irrigation has reduced CC in several published studies, suggesting that infection may play an important role in the pathogenesis of CC. Adams et al. used a triple-antibiotic irrigation technique in a series of 165 cosmetic augmentation patients and found a rate of grade III/IV capsular contracture of 1.8% for patients undergoing primary breast augmentation. More recently, Pfeiffer et al. suggested that the use of topical antibiotics in cosmetic breast surgery reduces infections and seroma. However, no significant difference in the development of CC was detected in their study. The aim of our comparative study was to evaluate the use of combined topical povidone-iodine administration and antibiotic irrigation in cosmetic breast augmentation.

**METHODS**

This study was approved by the institutional review board of Turku University Hospital. We retrospectively reviewed the records of 330 consecutive women (660 breasts) who underwent cosmetic breast augmentation without associated mastopexy or other concurrent procedures during 2 different periods (group A: May 2004 through January 2009, n = 165 patients and 330 breasts; group B: February 2009 through June 2010, n = 165 patients and 330 breasts) at a private plastic surgery clinic by the same senior surgeon (A.S.), who has more than 20 years of experience in breast augmentation and other plastic surgery procedures. All augmentations were performed for aesthetic reasons, and no reconstructive cases were included. Since February 2009, our operative protocol has been changed in an attempt to reduce our CC rate; therefore, patients were divided in 2 groups, reflecting the 2 different operative protocol periods.

Patient information was collected on a standardized data sheet and included baseline characteristics as well as postoperative complications. Comorbidities was also recorded and was defined as the presence of 1 or more chronic diseases (ie, high blood pressure, diabetes mellitus, hypercholesterolemia, depression). The type and size of implant were selected by the patient and surgeon during a preoperative consultation several weeks before the procedure, at which time all patients also gave informed consent. Preoperative markings were made immediately prior to the operation. All procedures were carried out under general anesthesia. An inframammary incision was used in all cases. A dual-plane implant pocket was also dissected in all cases. Dissection was atraumatic, created under direct vision while avoiding blunt instrumentation completely with electrocautery. Wounds were closed in layers with resorbable sutures and covered with Micropore medical tape (3M, St Paul, Minnesota). Implants (all form-stable, anatomically shaped, texturized silicone gel; Natrelle 410 or 510; Allergan, Irvine, California) were placed partly in the submuscular space and Redon drains (number 10) were inserted. The operating team wore powder-free gloves that were changed before each implant was handled, andmeticulous care was taken in positioning the implant.

In group A, patients received antibiotics as a single intra-venous dose of 1.5 g of cefalothin (Cefazolin; Pfizer, New York, New York) administered perioperatively. Neither the implant devices nor the pockets were irrigated. No changes in surgical procedures or systemic antibiotics occurred during the group A trial. In group B, 750 mg of cefuroxime (Zinacef; GlaxoSmithKline, Middlesex, United Kingdom) was administered intravenously during the operation. After pocket dissec-tion, the implants and the pockets were irrigated (25 mL per breast) with 10 mL Betadine (10% povidone-iodine solution) mixed with 750 mg of cefuroxime and 80 mg of gentamicin diluted in 15 mL of 0.9% sodium chloride solution. The nurse prepared the irrigant solution during the initial part of the procedure. Implant devices were kept in their containers and bathed with the Betadine and antibiotic solution during pocket dissection. Excess irrigant was immediately suctioned out. Postoperatively, patients were instructed to take ibuprofen (600 mg, 3 times per day) as needed. Patients in group A were also given 750 mg of cephalexin (Keflexin; Orion Corporation, Espoo, Finland) orally, twice a day for 1 week, and patients in group B received 500 mg of levofloxacin (Tavanic; sanofi-aventis, Bridgewater, New Jersey) orally, once a day for 5 days. Patients were discharged within 24 hours. According to standard prophylaxis measures for deep venous thrombosis (DVT), if no previous DVT was reported, heparin was not administered, and only elastic stockings and mechanical calf compression were used until mobilization. All patients wore a well-fitted surgical or athletic brassiere for 4 weeks.

Two outpatient follow-up examinations were performed by the senior surgeon (A.S.) at 4 weeks and at 6 months postoperatively. The primary outcome was clinically evident CC, defined as grade III or grade IV by the Baker classification system (Table 1). The Baker classification system takes into account not only the appearance of the breast but also the perception of the breast by the patient and the surgeon. Clinical evaluation of CC is subjective and related to the investigator’s experience. We used a modified version of the classic Baker classification scale for each breast. Indication for corrective surgery was considered when a grade III or IV contracture was found, and only these results were considered significant for assessment. The senior surgeon graded each patient’s CC according to this system. Extra follow-up (beyond 6 months) occurred only in case of adverse events, but all patients in the present study had extra postoperative visits/consultations free of charge and a 5-year replacement warranty against rupture of the implant and for CC.
Secondary outcomes were postoperative complications, including infection, seroma requiring an extra antibiotic treatment, or surgical intervention. For these variables, time of occurrence and course of action were recorded. In this study, we did not consider other complications concerning implant malposition or asymmetry.

### Statistical Analysis

Statistical analysis was performed using SPSS statistical software (version 16.0.1; SPSS, Inc, an IBM Company, Chicago, Illinois). Descriptive statistics for quantitative continuous variables (implant size) and qualitative ordinal variables were the mean and standard deviation (SD) after confirmation of normal distribution. Normality assumptions have been demonstrated with histograms, Q-Q plots, skewness and kurtosis, Kolmogorov-Smirnov tests, and Shapiro-Wilk tests.

Homogeneity between groups was verified in continuous variables, with the t-test used for comparison of means and the χ² test for categorical variables. P < .05 was considered statistically significant. Results were expressed as mean (SD) values.

### RESULTS

The mean (SD) age of the 336 patients was 35 (8) years (range, 18-58 years), and comorbidity was present in 9.2% of cases. The combined groups had a mean (SD) follow-up evaluation of 23.12 (9.82) months (range, 12-72 months) and mean (SD) implant size of 312.47 (107.65) cc (range, 140-595 cc). Characteristics of both patients and implants are outlined by group in Table 2; the 2 groups were comparable. Drains were removed within 24 hours in all patients.

For group A (control group, n = 165), the following complications were observed at follow-up: 10 (6%) cases of CC (Baker grade III or IV), 3 (1.8%) cases of superficial wound infection, 3 (1.8%) cases of seroma, and 1 (0.6%) case of hematoma. In group B (intervention group, n = 165), only 1 (0.6%) case of high-grade CC was detected (Baker grade III), along with 2 (1.2%) cases of superficial wound infection, 2 (1.2%) cases of seroma, and 2 (1.2%) cases of hematoma. It should be noted that most CC occurrences were graded as 1 or 2 (155 cases [94.0%] in group A and 164 cases [99.4%] in group B).

All infections and seromas were treated with antibiotics, bandages, and follow-up without further complications. Hematoma and high-grade CC cases required reoperation. A significant difference was found in the frequency of CC in group A vs group B (P = .006; Table 3). However, there were no significant differences in the occurrence of infection (P = .65), seroma (P = .65), or hematoma (P = .57) (Table 3).

The mean (SD) time from primary operation to occurrence of CC was 17.3 (12.2) months in group A and 26 months in group B. No allergic reactions to the antibiotics or povidone-iodine were reported. None of the CC patients had any other postoperative complications; therefore, we did not find any correlation between postoperative complications and CC.

### DISCUSSION

We performed a comparative study to evaluate the effectiveness of combined povidone-iodine solution and antibiotic (cefuroxime and gentamicin) pocket irrigation in reducing postoperative CC in cosmetic breast augmentation.
In our study of 330 women, we used both a povidone-iodine solution and antibiotics (cefuroxime and gentamicin), achieving excellent results and minimizing the rates of infection, seroma, and CC (Table 3). Our solution combined the recommendations by Adams et al\(^9\) for antibiotics with the suggestions by Burkhardt and Eades\(^7\) and Wiener\(^8\) for povidone-iodine. However, both our antibiotics and our povidone-iodine solutions had a higher concentration than the ones reported in the studies by Adams et al\(^9,37,38\). In our solution, bacitracin was not used due to limited availability in Finland. We also used cefuroxime instead of cefazolin for the same reason. The amount of irrigant used was less than what was reported in previous literature.\(^9\) Similar techniques for reducing CC were discussed by Rohrich et al.\(^39\) In another study, Fanous et al\(^40\) theorized that their decreased CC rate was due to postoperative drains, but they used breast pocket irrigation with antimicrobial solutions as well. Recent findings from a porcine model study demonstrated protection against subclinical implant infection and CC from antibiotic-impregnated mesh placed at the time of surgical insertion.\(^41\)

We also minimized the potential for bacterial contamination by avoiding periareolar incisions, which might reduce CC risk according to previous literature,\(^12\) and we dissected the pockets using direct visualization and atraumatic technique with complete electrocautery.\(^18\) In group B (patients with irrigation), we also prescribed oral antibiotics postoperatively for 5 days,\(^9\) although there is no clear evidence about the benefits of this practice.\(^42,43\)

Our mean (SD) follow-up was 24 (13) months in group A and 22 (3) months in group B, while the mean (SD) time of CC occurrence was 17.3 (12.2) months in group A. The single case of high-grade CC in group B occurred 26 months postoperatively. Interestingly, the case of CC in the topical antibiotics group occurred approximately 4 months after a dental procedure treated without an oral antibiotic prophylaxis. A recent report recommends a follow-up period longer than 42 months and the inclusion of Baker grade II subjects in CC analyses,\(^44\) but we believe our results were not altered by our modified scale or the fact that we only analyzed patients with Baker grade III or IV CC.

The use of povidone-iodine in the irrigation solutions may cause concern. Betadine has no effect on the mechanical properties of the implant shells for irrigation of the pocket or the implant itself.\(^7,45,46\) Indeed, it may cause a fibroblast toxicity, which can be protective against CC, decreasing the chance of deformity.\(^47\) In very rare cases, povidone-iodine might cause skin-allergic hypersensitivity reactions, such as irritation or iododerma-like eruption due to the oxidative effects of iodine.\(^48\) For this reason, the surgeon should disclose the intended use of povidone-iodine to the patient, with appropriate background information about the risks. To address potential issues, the povidone-iodine irrigation may be used immediately, followed by saline irrigation, which prevents contact of the implant with povidone-iodine, thus reducing the possibility of adverse effects. Furthermore, some patients might have systemic allergies to antibiotics. In our series, there were no hypersensitivity reactions to the antibiotics. Nevertheless, breast pocket irrigation recommendations for common antibiotic allergies are proposed in the literature.\(^9\)
The results of this report must be viewed in the light of some limitations and potential biases influencing our findings. The lack of prospective, double-blind, and randomized settings are major concerns in this study. There are several important disadvantages to any retrospective case series study—the investigator is dependent on the availability and accuracy of the medical records, and the follow-up is relatively short. Some patients may not have been followed because they sought advice from another surgeon or did not consider their symptoms remarkable, but we believe that most patients were followed because all patients were asked to contact their surgeon if any trouble occurred.

Another confounding variable in the study design might be the differences in perioperative antibiotic regimens between the 2 groups. The postoperative administration of levofloxacin for 5 days vs cephalaxin for 7 days might have affected the CC rate. In addition, we did not truly evaluate the effect of Betadine on CC, as we did not compare groups that received no irrigant with those that received antibiotic irrigant plus Betadine. Larger, randomized, double-blind, controlled trials with longer follow-up and standard techniques are needed to clarify this issue.

CONCLUSIONS

Despite the potential bias and the limitations of this retrospective study, our results support the use of topical povidone-iodine combined with antibiotic irrigation to prevent CC in cosmetic breast augmentation.

Disclosures

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

Funding

The authors received no financial support for the research, authorship, and publication of this article.

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