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Influence of dressing application time after breast augmentation on cutaneous colonization: A randomized clinical trial

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Summary Concepts regarding the best way to treat a surgical wound vary, in literature, ranging from no dressing use to dressing maintenance for 24 to 48 hours or until suture removal. This study aimed to evaluate the influence of the length of dressing maintenance after breast augmentation with implants on cutaneous colonization and surgical site infection. This is a two-arm, parallel group, randomized clinical trial. Eighty patients who were candidates for augmentation mammoplasty with silicone implants were randomly allocated to two groups, in which the dressing was removed on postoperative day 1 (group A, n = 40) or postoperative day 6 (group B, n = 40). Cutaneous colonization was examined by culturing samples collected before and after dressing removal. The criteria defined by the Centers for Disease Control and Prevention were used to assess surgical site infection. No significant difference regarding cutaneous

The study protocol has been published (Mendes DA, et al. Application time for postoperative wound dressing following breast augmentation with implants: study protocol for a randomized controlled trial. Trials. 2015;16:19).
Preliminary results have been presented, as a poster, at the 53rd Brazilian Society of Plastic Surgery's Annual Congress, in Fortaleza – CE, Brazil, on November 2016.
The study has been presented, as a poster, at the Women's Health 2017: The 25rd Annual Congress, on April 2017, in Washington, DC, USA (DOI: 10.1089/jwh.2017.29011.abstracts).

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colonization was observed between groups before dressing application. On postoperative day 6, significantly more bacterial growth was observed in group A ($p = 0.01$). No surgical site infection occurred. We concluded that maintaining the dressing for 6 days led to a lower cutaneous colonization but did not influence surgical site infection rates.

Introduction

The use of silicone implants to increase breast volume is a standard procedure.[1] In 2016, a total of 1,449,337 of these procedures were performed worldwide.[2] Positive psychosocial effects such as improvement in the patient's self-perception, quality of life, and self-esteem are anticipated after successful silicone breast implant surgery.[3–7] On the other hand, surgical site infection (SSI) is a major cause of postoperative morbidity associated with this surgery, which has legal, medical, psychological, and economic implications because it usually entails the loss of the implant. Implant removal is a traumatic event that, in practical terms, means the loss of the breast.[8]

The reported risk of SSI after breast augmentation with silicone implants ranges from 0.1% to 2.5%.[1,8–13] This risk should not be neglected and should be explained clearly to the patient during preoperative consultations. The origins of such infections are difficult to determine, but the main sources are the implant, contaminated surgical material or surgical environment, the patient's skin, the mammary ducts, and seeding of the implant by remote infection.[1,14]

The best way to control SSI is to prevent it. Prevention involves the minimization of all possible risk factors. Despite the importance of surgical wound care routines for the prevention of infection, the literature on this topic remains scant.[15,16] Recent reviews describe the available evidence for different risk factors for SSI after breast implant placement, but they do not mention studies of postoperative surgical wound care.[17–19]

Guidelines from the Centers for Disease Control and Prevention (CDC) state that the wound should remain covered with a sterile dressing for 24 to 48 hours.[20] Decisions about subsequent care should be made on a case-by-case basis. No protocol for home care has been established; each surgeon establishes his or her own postoperative routine.[20] The CDC guidelines, updated in 2017, also do not include specific recommendations on the ideal dressing application time.[21] In the context of reduction mammoplasty, maintenance of the dressing for 6 days has been found to reduce colonization of the surgical wound by coagulase-negative staphylococci.[22] The literature contains no similar information about colonization after breast augmentation.

Objective

This study was designed to assess the influence of dressing application time after augmentation mammoplasty with silicone implants on cutaneous colonization (primary aim) and SSI rate (secondary aim).

Methods

The authors adhered to CONSORT (Consolidated Standards of Reporting Trials) guidelines to report this randomized clinical trial. The trial was approved by the Ethics Committees of the Universidade Federal de São Paulo (protocol 593378-0) and of the Universidade do Vale do Sapucaí (protocol 113612). The study was registered at ClinicalTrials.gov – Protocol Registration System (protocol NCT01553604), and the study protocol was published.[23]

To calculate the required sample size, we used the two-tailed Student t test. The results indicated that 40 patients per group were needed, with a significance level of 5% and a power of 90%, considering a standard deviation of 137.8 colony-forming units (CFU) per plate and a significant difference of 100 CFU/plate, on the basis of a previous study.[22]

During private consultations, three senior plastic surgeons with more than 15 years of professional experience selected 80 patients with hypomastia as candidates for augmentation mammoplasty with silicone implant placement through the inframammary fold, between 18 and 60 years of age. Patients who participated in the study read, agreed to, and signed an informed consent form. We did not include patients with comorbidities or conditions that constituted counter-indications for surgery, such as body mass index (BMI) > 30 kg/m,[2] history of breast cancer or previous breast surgery, and requirement for combined breast surgery (e.g., mastopexy with implant placement). Patients who removed the dressing or whose dressing got wet during the follow-up period were excluded.

Randomization and allocation concealment

Patients were assigned randomly to group A ($n = 40$), in which the dressing was removed 1 day postoperatively, or to group B ($n = 40$), in which the dressing was removed 6 days postoperatively. All patients were directed to avoid getting the dressing wet when bathing.

For group assignment, a random sequence was generated using the BioEstat 5.0 program (Instituto de Desenvolvimento Sustentável Mamirauá, Belém, PA, Brazil). The blinding of allocation was guaranteed by using consecutively numbered opaque sealed envelopes containing assignments. At the time of discharge, the attending surgeon opened the envelope and the patient was assigned to one of the groups.

Preoperative evaluation

Blood was collected from all patients for determination of the hemogram, coagulogram, creatinine level, and fasting