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The use of SERI™ Surgical Scaffolds in direct-to-implant reconstruction after skin-sparing mastectomy: A retrospective study on surgical outcomes and a systematic review of current literature

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Summary *Introduction:* Little is reported on surgical outcomes of SERI Surgical Scaffold, a bioresorbable silk-derived surgical scaffold, developed to provide soft-tissue support and repair, in implant/expander breast reconstruction.
Methods: A retrospective chart study was conducted of all patients who underwent direct-to-implant reconstruction with a SERI surgical scaffold after skin-sparing mastectomy, recording surgical characteristics, perioperative complications and reoperations. A systematic literature review was conducted focusing on preclinical and clinical studies reporting on use of SERI in breast surgery.
Results: A total of 16 patients (22 breasts) were identified (mean age at surgery was 47 ± 6.8 years, mean BMI 23.1 ± 3.1 kg/m^2, mean ablation weight 530 ± 221 g, median clinical follow-up time 27 months (range 25–37)). There were no intraoperative complications. Postoperative bleeding, that required reoperation occurred in one (5%) breast, postoperative seroma in 10 (45%) and surgical site infection in 2 (9%). Scaffold-related complications occurred in 3 (14%) breasts, comprising lack of scaffold integration in all, resulting in skin ulceration in 2 and the scaffold lying free in the breast pocket surrounded with seroma in one. Nine articles were selected and reviewed from the 170 identified.

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Discussion: The role of silk-derived scaffolds in breast reconstruction is yet to be determined. Though first reports have shown promising results, our and others results suggest that scaffold-related complications, such as lack of scaffold integration, may occur more frequently than previously described. Further research is necessary to determine possible (dis)advantages of the scaffold in specific patient groups.

Introduction

Mastectomy is performed prophylactically and in women with breast cancer who cannot be treated with breast conserving surgery. The loss of a breast has a negative effect on the quality of life in patients and reconstructive surgery is frequently performed.[1–4] Surgical breast reconstruction can be performed with implants/tissue expanders or with autologous tissue. Implant/expander-based reconstruction is frequently performed for primary reconstruction of the non-irradiated breast. The role of acellular dermal matrices (ADMs) and other meshes in implant/expander breast reconstruction is growing. While most recent studies focus on reconstructive surgery with ADMs, little is reported on other products.[5] The SERI Surgical Scaffold is a bioresorbable silk-derived surgical scaffold, developed to provide soft-tissue support and repair. Little is reported on the use and surgical outcomes of SERI Surgical Scaffold in implant/expander breast reconstruction. Initially, positive surgical outcomes were reported.[6,7] However, in recent case series and case reports, objections were raised against the use of the SERI Surgical Scaffold in breast reconstruction surgery.[8,9] In this study, a retrospective review on surgical outcomes of the use of SERI Surgical Scaffold in direct-to-implant breast reconstruction after skin-sparing mastectomy was presented and a systematic review of current literature was performed.

Methods

Retrospective case series

A retrospective chart review was conducted on all patients who underwent direct-to-implant reconstruction with a SERI surgical scaffold after skin-sparing mastectomy at Tergooi Hospital, Hilversum, The Netherlands. All patients were retrospectively identified from the hospital registry. A retrospective chart study was conducted, recording patient demographics (age at reconstruction, somatic comorbidity, history of chemotherapy, history of radiotherapy, indication for surgery, body mass index (BMI), history of smoking), surgical characteristics (surgery duration, type and size of prostheses implanted), hospitalization duration, intra- and postoperative complications and reoperations.

Literature review

Studies were identified which focused on all preclinical and clinical uses of the SERI Surgical Scaffold. A systematic literature review was conducted in the PubMed, Embase and Cochrane Library databases using the following search string: *('SERI®' OR 'SERI™' OR 'SERI' OR 'silk') AND ('breast' OR 'breasts' OR 'breast reconstruction' OR 'mammoplasty')*. Titles and abstracts were independently screened by two reviewers (Franke and van der Sluis). Subsequently, the full text articles were screened. References from the remaining articles were checked for eligibility. Disagreement regarding exclusion or inclusion of papers was resolved by discussion between the reviewers.

Postoperative protocol

Intravenous flucloxacillin is used as prophylactic antibiotic regime and continued orally for 5 days after surgery. Two surgical drains are placed and removed when production of fluid is less than 20 ml/24 hours with a limit of 2 weeks. No supportive garment or bra is used after surgery.

Ethical statement

Formal and documented ethical approval was obtained (Commissie Toetsing Studieprotocollen, reference number 17.022). The study adhered to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines and conformed to the World Medical Association Declaration of Helsinki. Consent was obtained from all photographed patients for use of the photographic material.

Results

Retrospective study on surgical outcomes

An overview of patient demographics and surgical outcomes is presented in Table 1. A total of 16 patients were identified. Ten underwent unilateral and six underwent bilateral breast reconstruction. All procedures were performed by the same plastic surgeon. Skin-sparing mastectomy was prophylactic in 14 breasts and because of malignancy in eight. Mean age at surgery was 47 ± 6.8 years, mean BMI 23.1 ± 3.1 kg/m^2, mean ablation weight 530 ± 221 gram, median clinical follow-up time 27 months (range 25–37). The median hospitalization duration was three days (range 3–5). There were no intraoperative complications. Postoperative bleeding, that required reoperation occurred in 1 (5%) breast, postoperative seroma in 10 (45%) and surgical site infection in 2 (9%). Scaffold-related complications occurred in 3 (14%) breasts. In all 3 cases, lack of scaffold integration occurred, resulting in skin ulceration with the scaffold exposed in 2 (Figure 1) and the scaffold lying free in the breast pocket surrounded with seroma in 1 (Figure 2).