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ORIGINAL ARTICLE

Safety of the use of an absorbable implant in breast-conserving surgery followed by radiotherapy: preplanned interim results from a prospective study

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Abstract

Oncoplastic techniques aim to optimize cosmetic and oncologic results after BCS. Absorbable scaffolds may aid volume replacement while preserving radiotherapy (RT) planning and follow-up imaging, though clinical evidence remains limited. This interim analysis of a prospective, multicenter, single-arm trial (Tens-BBC/003/2021; NCT05941299) included 25 patients with 6 month follow-up after BCS and whole-breast RT. Outcomes were adverse events (AEs), device usability, pain (VAS), satisfaction, quality of life (BREAST-Q©), cosmetic and imaging results, and RT tolerance. Mean age was 53.6 years, BMI 24.8 kg/m^2. Tumors were mainly in the upper-outer quadrant (52%); T1c in 56%, T1b in 20%, T2 in 24%. Histology was invasive ductal carcinoma in 72%, nodal status cN0 in 96%. Mean surgery time was 74.7 min; drains were used in 76%. REGENERA™ type A (70 mL) was implanted in 84%, type B (100 mL) in 16%. No major complications occurred. Of 94 AEs within 90 days, all were mild/moderate and unrelated to the device; four later AEs (in one patient) were possibly implant-related. Investigator satisfaction (VAS) improved from 8.4 at implantation to 9.2 at 6 months; usability targets were exceeded. Pain decreased from 2.3 to 1.56. BREAST-Q© showed higher breast satisfaction (+8.9, $p=0.041$), reduced distress (–10.3, $p=0.006$), and a modest decline in physical well-being (–11.6, $p=0.012$). All patients completed RT; acute toxicity occurred in 44%, all grade 1–2. Cosmetic outcomes were good to excellent in 88%. Radiological integration was satisfactory, with no significant interference in MRI. REGENERA™ is safe, feasible, and biocompatible for volume replacement in BCS. It provides high satisfaction and favorable cosmetic results without compromising RT or follow-up imaging. Early results support its integration into oncoplastic practice, though long-term evaluation is required.

Keywords Breast-conserving surgery · Absorbable scaffold · Polyurethane · REGENERA™ · Breast cancer · Oncoplastic · Interim analysis

Background

Breast-conserving surgery (BCS) is the gold standard for early-stage breast cancer, offering oncologic outcomes comparable to mastectomy while preserving breast architecture [1]. However, cosmetic results depend on tumor size, breast volume, and location, with high tumor-to-breast ratios or inner/central lesions posing higher risks of deformity if not reconstructed [2]. Oncoplastic breast surgery (OBS) addresses these issues through volume displacement (local glandular rearrangement) or volume replacement (by importing the patient's own tissue, to the breast defect), the latter indicated in small breasts or after large resections [3]. Traditional replacement relies on autologous tissue (LICAP, AICAP, MICAP flaps), fat grafting, or microsurgery [4, 5], but these entail donor-site morbidity, longer operative times, and technical demands.

Extended author information available on the last page of the article

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