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유방보존술 후 생분해성 스페이서를 이용한 용적 유지와 영상 추적 안전성에 대한 임상적 분석

(Radiologic Safety and Volume Preservation of a 3D-Printed Bioresorbable Spacer in Breast-Conserving Surgery: A Retrospective Analysis of 53 Patients)

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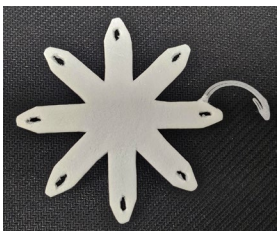
Purpose: Breast-conserving surgery (BCS) is an established oncologic treatment for early-stage breast cancer; however, postoperative volume deficiency and contour deformity remain common concerns. Existing reconstructive options, including local flaps, fat grafting, and acellular dermal matrix (ADM), may increase surgical complexity or interfere with postoperative imaging surveillance. TissueDerm is a novel three-dimensional (3D) printed bioresorbable polycaprolactone spacer designed to preserve lumpectomy cavity volume while allowing host tissue integration. This study aimed to evaluate the clinical safety and radiologic surveillance compatibility of the TissueDerm BCS spacer.

Methods: A retrospective review was conducted of 53 consecutive female patients who underwent BCS with TissueDerm spacer implantation between July 2024 and May 2025.Postoperative complications, adjuvant treatment timelines, and oncologic outcomes were assessed. Radiologic evaluation was performed using routine postoperative breast imaging at approximately 6 months, including MRI, CT, mammography, and ultrasonography. MRI findings were independently reviewed by two breast radiologists with emphasis on Breast Imaging Reporting and Data System categorization and the presence of spacer-related artifacts or abnormal findings.

Results:
The mean age was 48.6 years, and the mean tumor size was 17.3 mm. The mean operative time was 116 min, and drains were used in 6 patients (11.3%). No intraoperative complications were recorded. No major postoperative complications occurred. No seroma, infection, wound dehiscence, hematoma, fat necrosis, or foreign body reaction was documented.

MRI follow-up was available in all 53 patients. No spacer-related artifact limited interpretation. BI-RADS categories were 1-2 in 43 patients (81.1%), 3 in 9 (17.0%), and 4 in 1 patient (1.9%); the higher-category finding was investigated and confirmed benign. During a median clinical follow-up of 12 months, no local recurrence or distant metastasis was observed.

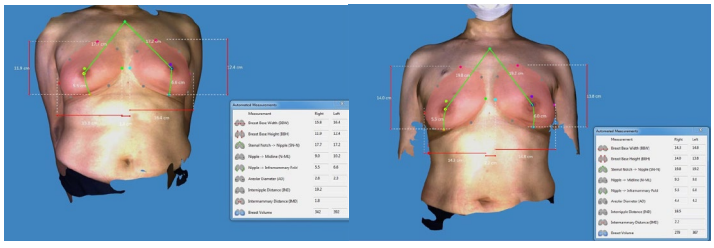
Figure 1. TissueDerm BCS spacer, a bioresorbable collagen-based mesh.



Spacer component before assembly

Assembled spacer

Figure 2. Representative clinical case demonstrating volume preservation Preoperative (left) & Postoperative (right) image demonstrating preservation of breast contour (right).



Three-dimensional (3D) surface images

Figure 3. MRI findings after partial mastectomy with spacer

MRI performed at 6 months postoperatively demonstrates stable dome-shaped tissue formation at the surgical site following placement of the TissueDerm BCS spacer. No imaging artifacts interfering with oncologic surveillance were identified.

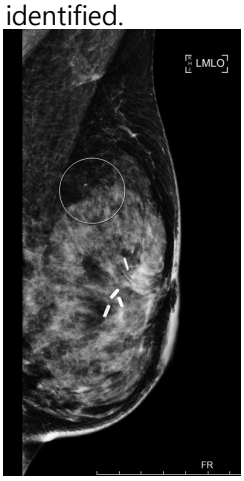


Figure 4. Postoperative mammographic findings following TissueDerm BCS spacer

Mammography performed after placement of the TissueDerm BCS spacer demonstrates preservation of breast contour without evidence of collapse. Symmetry between both breasts is maintained. No fluid collection or inflammatory changes are observed.

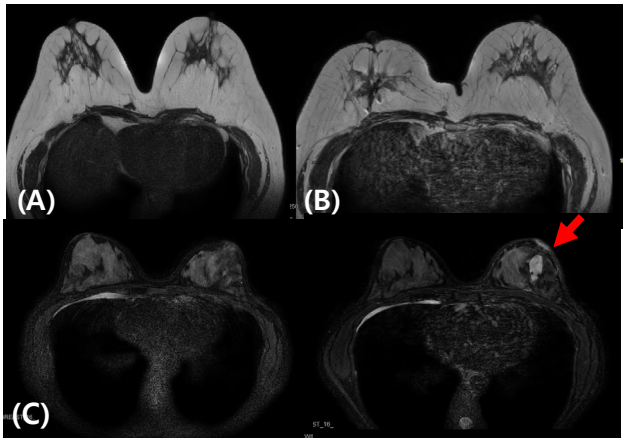


Figure 5. Comparison of postoperative breast contour with and without spacer placement.
(A) Preoperative MRI without spacer placement.
(B) Postoperative MRI showing contour deformity without spacer placement.
(C) Preoperative MRI with TissueDerm spacer placement.
(D) Postoperative MRI showing preserved breast contour with spacer placement.

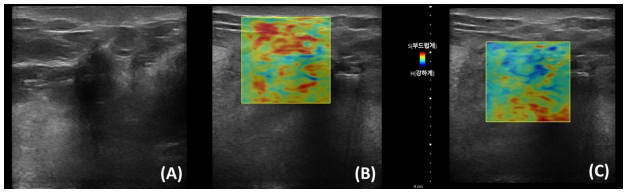


Figure 6. Elastographic evaluation of tissue characteristics following TissueDerm BCS spacer placement

(A) Conventional ultrasonography of the surgical site following spacer placement. (B) Elastography of the spacer-inserted region after radiotherapy, demonstrating relatively soft and compliant tissue characteristics. (C) Elastography of a control site without spacer placement.

Table 1. Radiologic outcomes on postoperative MRI

Variable	Value
Total patients with MRI at 6 months	53
Spacer-related artifact interfering surveillance	0
BI-RADS 1-2	43 (81.1%)
BI-RADS 3	9 (17.0%)
BI-RADS 4	1 (1.9%)
Higher-category finding confirmed benign	1
Local recurrence during follow-up	0

Conclusion:

The TissueDerm BCS spacer demonstrated favorable postoperative safety, with no major complications or delays in adjuvant therapy. In addition, it showed effective space maintenance and supported autologous tissue regeneration, thereby contributing to preservation of breast contour after breast-conserving surgery. Radiologic evaluation across serial MRI, CT, ultrasonography, and mammography confirmed stable imaging characteristics and radiologic transparency without compromising diagnostic quality or oncologic surveillance. Collectively, these findings suggest that the 3D-printed bioresorbable TissueDerm BCS spacer is a safe and imaging-compatible option for volume preservation in breast-conserving surgery.