Original Article

Direct comparison of CGCRYODERM and DermACELL in the same patient for outcomes in bilateral implant-based breast reconstruction: a retrospective case series

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Background: The use of acellular dermal matrix (ADM) has been popularized in implant-based breast reconstruction (IBR). However, it is still controversial if ADM-associated complication rates differ with varying types of ADM products. The aim of this study was to compare postoperative complications between CGCRYODERM and DermACELL.

Methods: A retrospective chart review was performed on 32 patients (64 breasts) who underwent bilateral prosthetic breast reconstruction between June 2015 and December 2019. All patients received two different ADMs in each breast during the surgery. Demographic variables, operative characteristics, and postoperative outcomes were compared between the cryopreserved and pre-hydrated ADM.

Results: The overall major and minor postoperative complications developed in 7 and 1 out of 32 patients, respectively. Seroma and infection were the most common complications. There were no cases that infection and/or seroma involved both breasts in one individual. No significant differences were observed in terms of seroma, infection, hematoma, mastectomy flap necrosis, or drainage period between the CGCRYODERM and DermACELL groups (P=0.5637, 0.1797, 1.0000, 0.3173, and 0.2925, respectively). There was no case of reconstruction failure leading to explantation.

Conclusions: There were no statistically significant differences in postoperative complications between the two breasts reconstructed with CGCRYODERM and DermACELL in the same patient who underwent bilateral IBR. This is the first study to compare cryopreserved and pre-hydrated ADMs. We suggest that CGCRYODERM is a suitable option with a comparable safety profile for IBR.

Keywords: Acellular dermal matrix (ADM); breast reconstruction; breast implants; CGCRYODERM; DermACELL

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Introduction

Acellular dermal matrix (ADM) is widely used in implant-based breast reconstruction (IBR). This matrix is a soft connective tissue allograft created by the decellularization process while preserving the intact extracellular skin matrix. When implanted, this structure serves as a scaffold for cell incorporation and revascularization (1). In 2005, Breuing first introduced the use of ADM in IBR for inferolateral pole coverage (2). The introduction of ADM improved aesthetic outcomes, resulting in more natural-looking breasts. In addition, it facilitates tissue expansion in two-stage breast reconstruction and offers more opportunities for immediate direct-to-implant (DTI) reconstruction (3,4). Furthermore, IBR using ADM has become a preferred procedure for patients and surgeons, as there is an increasing demand for risk-reducing mastectomy (5).

However, the use of ADM in IBR raises concerns about potential safety issues associated with postoperative complications such as seroma, infection, and explantation (6). As there are various products available in the market, surgeons need more information to reduce ADM-related complications through appropriate surgical techniques, patient selection, and product choice (7,8). ADMs vary significantly depending on the source, processing methods, level of sterility, preparation, biomechanical properties, and available sizes (9). However, it has not been established whether and why there are differences in complication rates among different ADM products (10-13).

Very recently, the U.S. FDA has provided advice on the use of certain brands of ADMs with higher risk profiles in IBR (14). To date, studies comparing the outcomes of different ADMs are relatively limited to specific products such as aseptic freeze-dried Alloderm (LifeCell Corp., Branchburg, NJ, USA), Alloderm Ready-To-Use (RTU), and sterile pre-hydrated DermACELL (LifeNet Health, Virginia Beach, VA, USA) (13,15-18). Further studies are needed to evaluate the outcomes of various types of ADMs.

CGCRYODERM (CGBio Corp., Seongnam, Korea) is an aseptically processed human ADM that was introduced in 2011 as the first using a cryopreservation technique (19). Its manufacturing method can preserve the native dermal matrix structure with adequate tensile strength and abundant growth factors for angiogenesis (20). It requires refrigeration and must be thawed for 3 min, and it has a longer shelf-life than DermACELL stored at room temperature (5 *vs.* 2 years). On the other hand, freeze-dried ADM (e.g., Alloderm) requires lengthy rehydration for approximately 30 min (21).

The objective of our study was to compare the complications between CGCRYODERM and DermACELL in the same patient who underwent bilateral IBR. To the best of our knowledge, this is the first study to compare cryopreserved and pre-hydrated ADM.

We present the following article in accordance with the STROBE reporting checklist (available at https://dx.doi.org/10.21037/gs-21-149).

Methods

Study population and data collection

We retrospectively reviewed all patients with unilateral or bilateral breast cancer who underwent bilateral IBR using two different ADMs (CGCRYODERM and DermACELL) at one institute between June 2015 and December 2019. The study was conducted in accordance with the Declaration of Helsinki (revised in 2013). The study was approved by the institutional review board of Seoul National University Hospital (no. 1906-125-104), and individual consent for this retrospective analysis was waived. Patient demographics, operative findings, and postoperative outcomes were collected and analyzed for association with the types of ADMs. Patient outcomes included the following: (I) seroma (subcutaneous fluid collection requiring percutaneous or operative drainage); (II) infection (the presence of a hot, red breast rash requiring additional treatment with antibiotics, surgery, or both); (III) hematoma (requiring surgical exploration); (IV) mastectomy flap necrosis (partial or full-thickness necrosis); (V) capsular contracture [Backer grade III or IV assessed by three plastic surgeons (SMJ, JHH, USJ)]; (VI) prosthesis problems (rupture, deflation, malposition, or exposure); (VII) reconstructive failure (prosthesis explantation as a result of any complication); and (VIII) duration of drainage (postoperative days until all drains were removed). Overall complication rates were analyzed using the outcomes except for duration of drainage, and major complications were separately defined as those requiring unplanned readmission and/or reoperation after discharge for any complication.

Procedures

Surgical procedures were performed by a single senior plastic surgeon (USJ) at a single institute. In immediate

reconstruction cases, experienced general surgeons performed total mastectomy (nipple-sparing mastectomy or skin-sparing mastectomy) at the same institute. After confirmation of the frozen biopsy results, reconstruction type (two-stage tissue expander (implant or DTI) was intraoperatively determined depending on the amount of breast skin excised. The prosthetic devices included in this study were of surgeon preference. The TEs used were Biocell®-textured Natrelle® 133 (Allergan, Inc., Dublin, Ireland) and Siltex®-textured MENTOR® CPX™4 (Mentor, Corp., CA, USA). All implants used were MENTOR® CPG™ (Mentor, Corp., CA, USA) and BellaGel (Hans BioMed, Daejeon, Korea). The author (USJ) used two different ADMs (CGCRYODERM and DermACELL) that were on consignment at the institute during his practice since 2015. In all cases, the ADM was placed in the subpectoral plane as an extension of the pectoralis major muscle. DermACELL is ready to use but should be rinsed briefly in warm saline prior to implantation. Conversely, CGCRYODERM was thawed in warm sterile saline for approximately 3 min. All the drains were placed inferiorly along the inframammary fold. A Jackson-Pratt drain was placed between the ADM and the mastectomy flap while one Hemovac drain was placed between the prosthesis and the ADM. Drains were maintained until the output was less than 30 mL/day for two consecutive days. All patients received a prophylactic dose of intravenous antibiotics perioperatively during admission to the hospital, and oral antibiotics were continued after discharge (usually 5 days).

Statistical analysis

All data were queried using Microsoft Excel (Microsoft Corp., Redmond, WA, USA). To evaluate the differences between two breasts from one individual, paired comparison was performed using Wilcoxon's signed rank test for continuous parameters and McNemar's test for parametric parameters. All analyses were performed with IBM SPSS Statistics version 23 (IBM Corp., Armonk, NY, USA). The statistical significance level was set at $P<0.05$.

Histologic analysis

After obtaining informed consent, histologic samples were taken from bilateral breast capsules around the ADM in one representative patient at the second stage of breast reconstruction, exchanging TE with permanent implants. Immunohistochemical staining was performed to analyze the expression of alpha-smooth muscle actin (α-SMA) in myofibroblasts and CD31 in endothelial cells. For histological examination, hematoxylin and eosin (H&E) and Masson's trichrome (MT) stains were used to assess the general (plus cellularity) and collagen structures, respectively.

Results

Between June 2015 and December 2019, 45 patients underwent bilateral IBR using CGCRYODERM and DermACELL in each breast. Among the 45, 8 patients who had previously undergone breast-conserving surgery, and 5 who underwent different reconstruction methods (one and two stage) for each breast were excluded from this study. The demographics and preoperative characteristics of the 32 patients are shown in *Table 1*. The average patient age was 43.9 years, and the mean BMI was 22.9 kg/m^2. There were no smokers or diabetic patients in our study. Ten *BRCA1/2* mutation carriers were identified. Among them, one patient was diagnosed with bilateral breast cancer, while 9, who underwent contralateral prophylactic mastectomy, were diagnosed with unilateral breast cancer. Ten of the 32 patients (31.3%) received neoadjuvant chemotherapy. Ten patients (8 of 38 breasts in the CGCRYODERM group *vs.* 6 of 38 in the DermACELL group) underwent adjuvant radiation therapy. The mean follow-up period was 925.78±393.19 days.

The operative characteristics were summarized in *Table 2*. Thirty-one of 32 patients (81.6%) were reconstructed immediately following bilateral mastectomies, and one underwent bilateral delayed reconstruction with TE following modified radical mastectomy. Sixteen of the 32 breasts (50%) were reconstructed with TE (*Figure 1*), and the remaining underwent DTI (*Figure 2*). The overall mean mastectomy specimen weight was 360±195 g. The two groups were comparable in terms of reconstruction method, axillary surgery, size and type of tissue expanders or implants, as well as preoperative characteristics. The mean ADM surface area and mean mastectomy weight showed statistically significant differences in operative characteristics between the CGCRYODERM and DermACELL groups ($P<0.0001$, $P=0.0121$, respectively).

The overall complications in the CGCRYODERM and DermACELL groups were 12.50% and 15.63%, respectively (*Table 3*). Major complications requiring readmission and/or reoperation after discharge were not significantly different between the CGCRYODERM and

Table 1 Overall patient demographics

Characteristic	Values
Number of patients	N=32
Age, years (mean ± SD)	44.25±8.21
body mass index, kg/m^2 (mean ± SD)	22.87±3.63
Smoking status, n (%)	
None	32 (100.00)
Smokers	0 (0.00)
Comorbidities, n (%)	
Diabetes	0 (0.00)
Hypertension	2 (6.25)
Previous breast surgeries, n (%)	
Augmentation mammoplasty	3 (9.38)
Laterality, n (%)	
Unilateral breast cancer	11 (34.38)
Bilateral breast cancer	21 (65.63)
Diagnosis, n (%)	
Stage 0	7 (21.88)
Stage I	4 (12.50)
Stage II	15 (46.88)
Stage III	6 (18.75)
BRCA 1/2 mutations, n (%)	
Noncarriers	22 (68.75)
Carriers	10 (31.25)
Chemotherapy, n (%)	
None	14 (43.75)
Neoadjuvant	10 (31.25)
Adjuvant	10 (31.25)
Radiation therapy, n (%)	
None	22 (68.75)
Adjuvant	10 (31.25)
Hormone therapy, n (%)	
None	15 (46.88)
Adjuvant	17 (53.13)
Follow up period, d (mean ± SD)	925.78±393.19

DermACELL groups (12.50% *vs.* 12.50%, P=1.0000). All complications occurred within 90 days postoperatively, and it was found that seroma and infection were the most common complications (4 of 32 patients). There were no cases that infection and/or seroma involved both breasts in one individual. Only one patient in the DermACELL group underwent implant change in the non-irradiated breast during adjuvant radiation therapy 87 days after surgery. On the other hand, the other patients were treated with intravenous antibiotics and debridement. There were no cases of Baker grade III or IV capsular contracture, any prosthesis problems, or reconstruction failures that led to explantation in our study.

Additionally, there were no significant differences in the drain duration between the CGCRYODERM and DermACELL groups (*Table 4*).

For histologic analysis, fibrovascular ingrowth (indicating integration within the host tissue at the time of biopsy) and chronic inflammation were observed in both ADMs. There were slightly more spindle cells considered as myofibroblasts in the DermACELL sample than in the CGCRYODERM sample (Figure S1).

Discussion

This retrospective study demonstrated that there were no significant differences in postoperative complications between the two different human ADMs (CGCRYODERM *vs.* DermACELL) in bilateral IBR. ADM-related complications are associated with several patient factors which include age, body mass index, smoking status, presence of diabetes, and breast size (6). In addition, reported complication rates vary widely because of different surgical techniques and postoperative management in different centers and different definitions of complications (22). In this study, all reconstructive surgeries were performed by an experienced surgeon. Factors affecting complication risks were reduced by comparing two different ADMs concurrently implanted in the same patient.

This study did not reveal any predictive risk factors for complications associated with ADM-assisted IBR. However, we noted that four patients who developed major infection (one in the CGCRYODERM group and three in the DermACELL group) had several common aspects. All *BRCA* mutation carriers were diagnosed with unilateral breast cancer. Infection requiring intravenous antibiotics occurred in the contralateral breasts within 90 days after risk-reducing nipple-sparing mastectomy (NSM) and immediate DTI reconstruction. Among four

Table 2 Operative findings by type of acellular dermal matrix

	CGCRYODERM (n=32)	DermACELL (n=32)	P value
Mastectomy indication, n (%)			0.1317
Malignancy	29 (90.63)	24 (75.00)	
Contralateral risk-reducing surgery	3 (9.38)	8 (25.00)	
Type of mastectomy, n (%)			0.8013
Skin-sparing mastectomy	15 (46.88)	14 (43.75)	
Nipple-sparing mastectomy	16 (50.00)	17 (53.13)	
Modified-radical mastectomy	1 (3.13)	1 (3.13)	
Axillary surgery, n (%)			0.6547
Sentinel lymph node biopsy	21 (65.63)	19 (59.38)	
Axillary lymph node dissection	11 (34.38)	13 (40.63)	
Number of lymph nodes examined (mean ± SD)	6.42±5.82	3.77±5.06	0.0770
Timing of reconstruction, n (%)			–
Immediate	31 (96.8)	31 (3.13)	
Delayed	1 (3.13)	1 (3.13)	
Type of reconstruction, n (%)			–
Two-stage TE/implant	16 (50.00)	16 (50.00)	
Siltex® textured	13 (40.63)	13 (40.63)	
Biocell® textured	3 (9.38)	3 (9.38)	
Direct-to-implant (DTI)	16 (50.00)	16 (50.00)	
Anatomical textured	15 (46.88)	15 (46.88)	
Smooth round	1 (3.13)	1 (3.13)	
ADM surface area, cm^2 (mean ± SD)	90.97±11.37	105.75±21.38	<0.0001*
Mastectomy weight, g (mean ± SD)	372.73±212.33	347.79±177.60	0.0121*
Permanent implant volume, cc (mean ± SD)	359.00±78.25	351.00±85.14	0.1680
TE volume, cc (mean ± SD)	403.13±76.31	400.00±81.65	1.0000
Initial TE fill (%) (mean ± SD)	39.98±21.71	41.06±22.36	0.3750
Expander-to-implant time, d (mean ± SD)	288.93±122.55	288.93±122.55	–

*, P value <0.05.

patients, three who concurrently developed major seroma (one in the CGCRYODERM group and two in the DermACELL group) received neoadjuvant chemotherapy. In addition, complications developed in non-irradiated breasts before and during radiation therapy.

It is still controversial whether some ADMs are associated with a higher risk of complications than others. Previous studies have shown relatively lower complication rates of sterile pre-hydrated ADMs compared with other aseptic or/and freeze-dried ones (17,23,24). Conversely, there is increasing evidence that no statistically significant differences were observed between sterile versus aseptic ADMs in drain duration and complications after IBR (16,18,25,26). In this study, the results indicate that CGCRYODERM has a safety profile comparable with that of DermACELL. Moreover, the diversity of available sizes

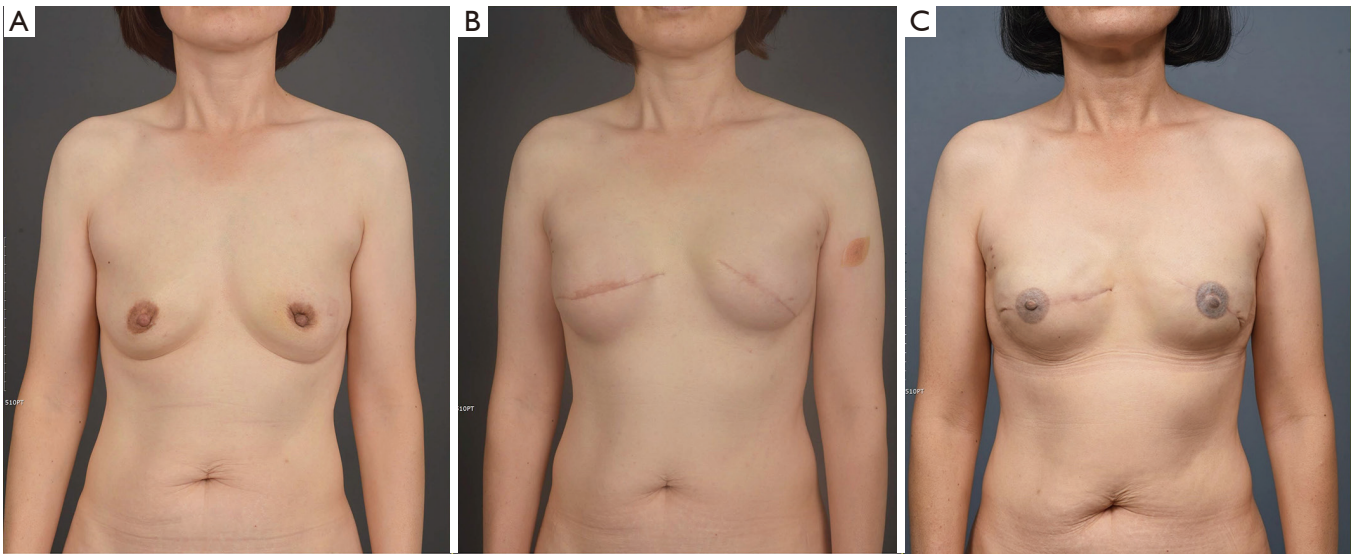

Figure 1 A 51-year-old female patient was diagnosed with bilateral breast cancer (right stage II, left stage 0). The patient underwent immediate two-stage tissue expander/implant reconstruction (right CGCRYODERM 5×16 cm^2, left DermACELL 5×16 cm^2) after bilateral skin-sparing mastectomies (right 268.5 g, left 236 g) with sentinel lymph node biopsy. She received adjuvant chemotherapy without complications. (A) Initial photograph, (B) intermediate photograph 7 months after tissue expander insertion (textured tissue expanders Allergan N-67-133FX11 350 cc each), and (C) postoperative photograph 2 years after the second surgery (textured anatomical implants Mentor CPG321 235cc each).

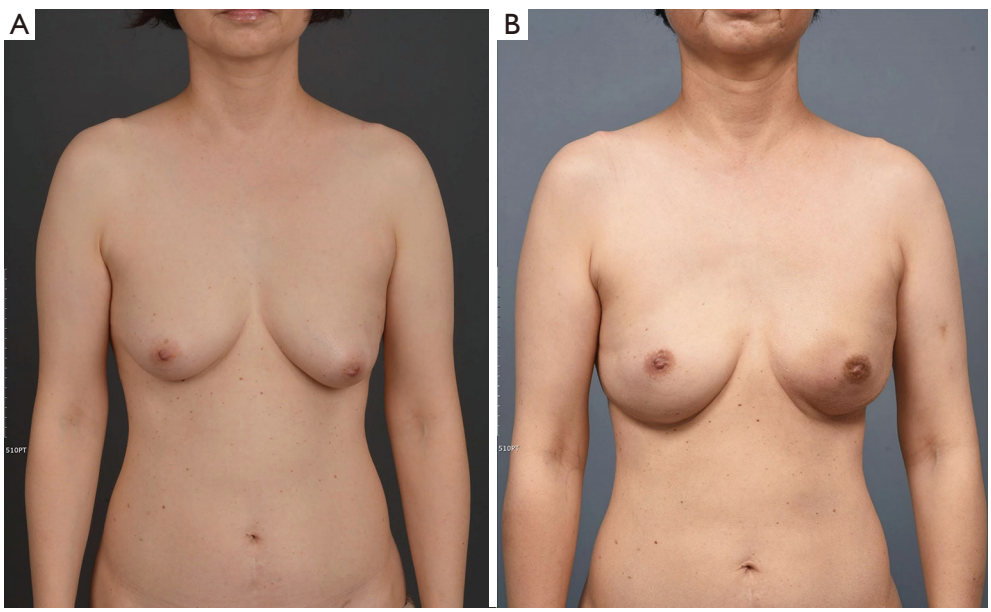

Figure 2 A 51-year-old female patient with *BRCA1* mutation. She was diagnosed with left breast cancer (stage II). The patient underwent immediate direct-to-implant reconstruction (right DermACELL 8×16 cm^2, left CGCRYODERM 7×15 cm^2; textured anatomical breast implants BellaGel BATM-L; right 195 cc, left 215 cc) after bilateral nipple-sparing mastectomies through lateral inframammary fold (right 166 g, left 195.5 g) with sentinel lymph node biopsy. She received adjuvant chemotherapy and radiation therapy without complications. (A) Initial photograph, and (B) postoperative photograph 1.5 years after reconstruction.

Table 3 Postoperative outcomes comparing CGCRYODERM versus DermACELL

	CGCRYODERM (n=32)	DermACELL (n=32)	P value
Overall complication, n (%), [events]	4 (12.50) [5]	5 (15.63) [8]	0.7055
Major* complication, n (%), [events]	4 (12.50) [5]	4 (12.50) [7]	1.0000
Seroma, n (%)	1 (3.13)	2 (6.25)	0.5637
Major*, n (%)	1 (3.13)	2 (6.25)	0.5637
Infection, n (%)	1 (3.13)	4 (12.50)	0.1797
Major*, n (%)	1 (3.13)	3 (9.38)	0.3173
Hematoma, n (%)	1 (3.13)	1 (3.13)	1.0000
Major*, n (%)	1 (3.13)	1 (3.13)	1.0000
Mastectomy flap necrosis, n (%)	2 (6.25)	1 (3.13)	0.3173
Major*, n (%)	2 (6.25)	1 (3.13)	0.3173
Reconstructive failure, n (%)	0 (0.00)	0 (0.00)	–

*, requiring unplanned readmission and/or reoperation after discharge for any complication.

Table 4 Duration of drainage comparing CGCRYODERM versus DermACELL

Mean duration of drainage ± SD (d)	CGCRYODERM	DermACELL	P value
Subcutaneous (SubQ)	6.44±4.16	6.34±2.75	0.8672
Submuscular (SubM)	12.50±3.55	12.28±4.27	0.2925

may avoid an unnecessarily large surface area associated with additional complications and price (Figure S2).

Different processing, preparation, and sterilization methods of ADMs may impact the histological architecture and subsequent incorporation (27,28). DermACELL is terminally irradiated at a low dose at ultralow temperatures to achieve a sterility assurance level (SAL) of 10^{-6} (lower compared with other products with SAL of 10^{-3}). In contrast, CGCRYODERM focused on minimal manipulation to preserve the integrity of the dermal layer structure after a series of decellularization and decontamination. The freezing process, which can irreversibly destroy the matrix structure by ice crystallization, and the drying process, which can further alter the collagen structure by removing bound water surrounding biomolecules, were eliminated (19,21). Theoretically, the more preserved dermal structure of CGCRYODERM may be associated with less inflammatory response (29). Although the histological examination was performed in a single case, the result showed more decreased number of myofibroblasts in the CGCRYODEROM capsule. It is reported that decreased presence of myofibroblasts is related to reduced capsular contracture rates with addition of ADM in IBR (27,30,31).

This study had several limitations. First, this retrospective study was performed at a single academic center. Second, the small sample size was insufficient to draw conclusions with high statistical power. Third, there were differences in risk factors between the two breasts in the same patient. Moreover, the laterality of cancer affects the size of the excised breast skin, reconstruction method (one *vs.* two stages), amount of axillary lymph node dissection, and postoperative radiation. An appropriately powered randomized controlled trial (RCT) is needed to investigate these results further, as in previous RCTs comparing biological and synthetic meshes in the same patient (32-34). Lastly, this study was limited to one representative case for histologic analysis of ADM capsules. Further studies are needed to reveal any significant differences through histological evaluation and the correlation with clinical outcomes.

In conclusion, there was no evidence of inferiority between seroma, infection, hematoma, or mastectomy flap necrosis in CGCRYODERM compared with DermACELL in the same patient who underwent bilateral IBR. Given our

results, the authors suggest that CGCRYODERM can be used interchangeably with DermACELL in ADM-assisted IBR.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (revised in 2013). The study was approved by the institutional review board of Seoul National University Hospital (no. 1906-125-104), and individual consent for this retrospective analysis was waived.

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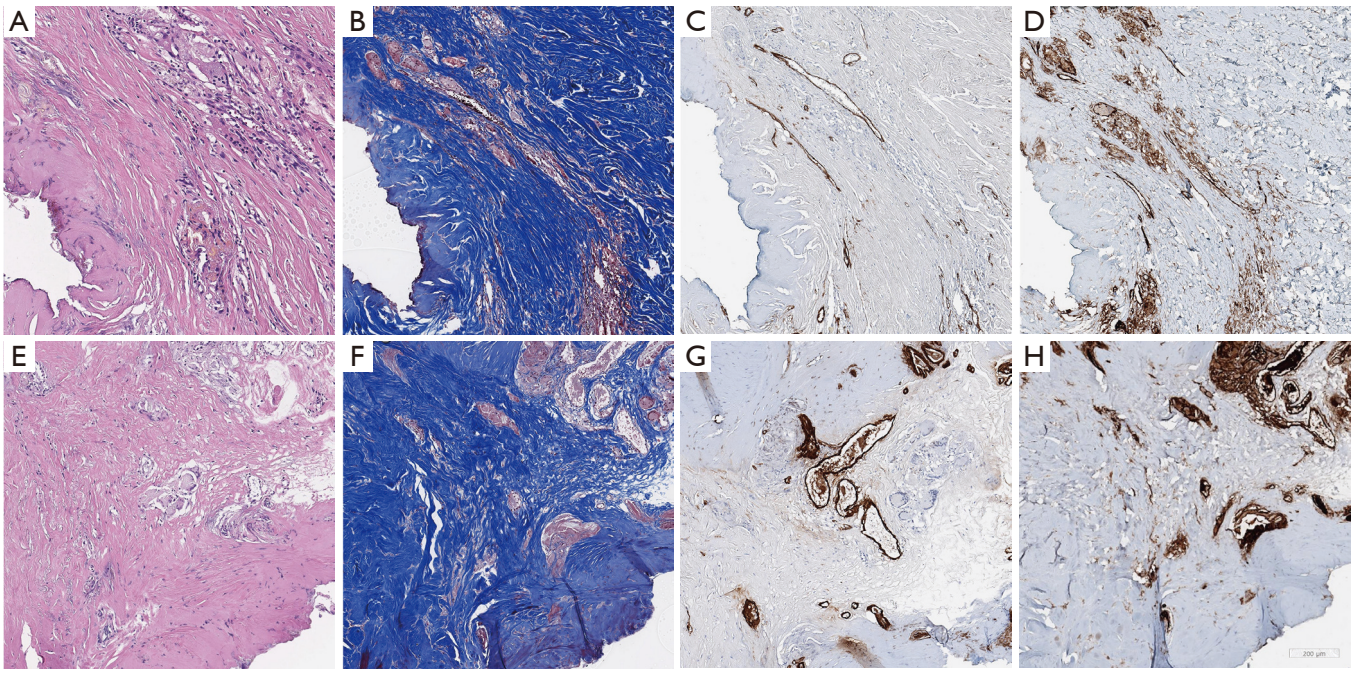

Figure S1 Representative histology images showing the breast capsules around the acellular dermal matrix 8 months after placement. A 39-year-old woman was diagnosed with bilateral breast cancer (right stage II, left stage 0). The patient underwent bilateral two-stage tissue expander/implant reconstruction (textured anatomical implants BellaGel BATM-M; right 340 cc, left 310 cc) after bilateral skin-sparing mastectomies (right 238.5 g, left 243 g) with right axillary lymph node dissection and left sentinel lymph node biopsy. The patient received adjuvant hormone therapy without chemotherapy or radiation therapy. (A,B,C,D) CGCRYODERM 6 × 14 in the right breast versus (E,F,G,H) DermACELL 5 × 14 in the left breast. (A,E) Hematoxylin and eosin (H&E) staining, (B,F) Masson's trichrome (MT) staining, (C,G) immunohistochemistry (IHC) for alpha-smooth muscle actin (α-SMA), and (D,H) IHC for CD31 (magnification ×5, scale bar 200 μm).

Sizes of ADM (surface area, cm^2), n (%)	CGCRYODERM (n=32)	DermACELL (n=32)
4x16 cm (64 cm^2)	N/A	1 (3.13)
5x14 cm (70 cm^2)	3 (9.38)	N/A
5x15 cm (75 cm^2)	3 (9.38)	N/A
5x16 cm (80 cm^2)	1 (3.13)	5 (15.63)
6x12 cm (72 cm^2)	N/A	1 (3.13)
6x14 cm (84 cm^2)	3 (9.38)	N/A
6x15 cm (90 cm^2)	3 (9.38)	N/A
6x16 cm (96 cm^2)	15 (46.88)	11 (34.38)
7x15 cm (105 cm^2)	2 (6.25)	N/A
7x16 cm (112 cm^2)	2 (6.25)	N/A
8x16 cm (128 cm^2)	N/A	14 (43.75)

Figure S2 Sizes of CGCRYODERM versus DermACELL used in this study.

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