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ARTICLE

# Outcomes of smooth round implant-based immediate breast reconstruction: Long-term follow-up results

Soo Hyun Woo[a], In Ah Yoon[a], Eun Jeong Choi[b], Hyun Ho Han[a], Jin Sup Eom[a], Taik Jong Lee[c] and Eun Key Kim[a]

[a]Department of Plastic Surgery, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea; [b]Department of Plastic Surgery, College of Medicine, The Catholic University of Korea, Seoul, Korea; [c]Department of Plastic Surgery, Uijeongbu Eulji Medical Center, Eulji University, Gyeonggi-do, Korea

**ABSTRACT**

The issue of breast implant-associated anaplastic large cell lymphoma in 2019 has resulted in the discontinuation of textured breast implants and resumption in the use of smooth round implants. However, in the field of breast reconstruction, long-term follow-up data for direct-to-implant reconstruction using smooth round implants is insufficient. This retrospective study aimed to evaluate the long-term outcomes of breast reconstruction using smooth round implants. This study included 185 patients (208 breasts) who underwent smooth round implant-based immediate breast reconstruction between 2007 and 2018. Their demographic information and surgical and oncological data were collected. Early (within 90 days) and late (after 90 days) complications, reoperations, implant maintenance, and the survival rate were analyzed to evaluate the long-term outcomes and identify the related factors. The mean follow-up period was 112.08 months. The most common early complications were skin necrosis (9.13%) and infection (3.85%). The factors influencing the development of early complications were the mastectomy specimen weight (237.14 ± 114.84 cc and 298.04 ± 141.53 cc for no complication and any complication, respectively; $p = 0.0123$) and implant volume (222.79 ± 77.76 cc and 264.48 ± 89.03 cc for no complication and any complication, respectively; $p = 0.0082$). The most common late complication was capsular contracture (13.46%). Approximately 91.35% of the implants were maintained during the follow-up period. The factors affecting the development of early complications and implant maintenance were the mastectomy specimen weight and implant volume. This study provides information on long-term follow-up results useful in cases where only smooth round implants are available, which can then serve as a basis for future related studies.

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## Introduction

Immediate breast reconstruction following mastectomy for breast cancer can be broadly categorized into implant-based and autologous reconstructions. Implant-based reconstruction is more widely used owing to several advantages, including a relatively simpler technique, lack of donor site morbidity, and short operation time. However, foreign body reactions can cause several adverse events. Some of the major complications are capsular contracture (CC), infection, seroma, and implant rupture. Extensive research has been conducted in an attempt to reduce the incidence of these complications, and the implants used have evolved over time [1]. Since the first form of breast implant fabricated by filling a silicone shell with silicone gel was reported by Cronin and Gerow in 1962, breast implants have been enhanced and advanced over the years [1,2]. In 1992, the US Food and Drug Administration (FDA) banned third-generation silicone implants based on inadequate evidence on their safety and effectiveness, and saline implants replaced them. Silicone implants were approved for use again in 2006, and from around 2007, smooth silicone implants have become the most popular type of breast implants [3]. In 2010, textured implants were developed, and with study findings suggesting that these implants reduce the risk of CC, a major complication of implant-based reconstruction, they began to dominate the market. However, breast implant-associated anaplastic large cell lymphomas (BIA-ALCLs) that are exclusively associated with textured implants have emerged as a critical issue [4–6]. In July 2019, the US FDA requested Allergan to recall its BIOCELL-textured breast implants and immediately banned the use of textured implants. As a result, smooth round implants replaced textured implants and dominated the market.

In the history of breast implants, the dominance of smooth round implants was short lived (2007–2010). Moreover, the number of patients who underwent immediate breast reconstruction using smooth round implants in Korea was small because breast reconstruction was not covered by the national health insurance (NHI) at the time. In addition, direct-to-implant (DTI) reconstruction was rarely performed, with two-stage tissue expander reconstruction being the most popular approach [7]. Therefore, long-term data on immediate breast reconstruction using smooth round implants are scarce [8]. Furthermore, the sudden return to the use of smooth implants in 2019 in response to the unanticipated BIA-ALCL issue forced surgeons to provide explanations and recommend these implants despite its limitations and the lack of data on the long-term outcomes of DTI reconstruction with these implants [4]. In this context, as textured implants were taken off the market in 2019, the vast majority of surgeons are

CONTACT Eun Key Kim nicekek@korea.com Department of Plastic Surgery, Asan Medical Center, University of Ulsan College of Medicine, Olympic-ro 43 gil, Songpa-gu, Seoul, Korea

familiar with smooth round implants. This study aimed to provide additional information on the long-term outcomes of breast reconstruction using smooth round implants.

## Methods

Patients who underwent breast reconstruction using smooth round implants following mastectomy between August 30, 2007, and September 30, 2018, were included in this study. Patients who had a two-stage reconstruction involving expander/implant insertion and patients who had both autologous flap and implant-based reconstructions were excluded.

Data were collected retrospectively by reviewing medical records after obtaining approval from our Institutional Review Board (approval no. 2022-0188). Demographic data included age, body mass index (BMI), smoking history, pre-existing condition, and pregnancy history. Surgical data included the reconstruction side, mastectomy type, mastectomy specimen weight and implant volume, lymph node (LN) dissection, previous breast surgery, contralateral procedure, implant manufacturer, and acellular dermal matrix (ADM) use. Oncological data included cancer stage, preoperative or postoperative chemotherapy and radiotherapy (RT), hormone therapy, trastuzumab use, and cancer recurrence. Distant metastasis, contralateral breast metastasis, and survival were also examined.

The documentation of complications was based on all available post-operation medical records (inpatient, outpatient, and/or emergency department). Postoperative complications were categorized into early (onset at $\leq$90 days after surgery) and late (onset at >90 days). Early complications included infection, skin necrosis, seroma, hematoma, wound dehiscence, and implant exposure. Late complications included infection, seroma, implant rupture, malposition, rotation, animation deformity, CC, thinning, rippling, and asymmetry. CC was recorded according to Baker classification [9]. The final outcome was implant retention. For patients lost to follow-up at plastic surgery, data on the final outcome were collected on the basis of the medical records and imaging findings at the breast surgery department. If the implants were removed, whether they were simply explanted, replaced, or converted to autologous flaps or whether an expander was inserted was recorded.

To identify the predictors affecting early complications, late complications, and implant removal, the factors were compared after dividing them into subgroups based on the complications and implant maintenance. Continuous variables (means ± standard deviations) were compared between the two groups using two-sample *t*-tests or Wilcoxon's rank sum test. Categorical variables were analyzed using the chi-square test or Fisher's exact test. A *p*-value of <0.05 was considered statistically significant. Statistical analyses were performed using SAS v9.4 (Cary, NC, US).

## Results

A total of 185 patients (208 breasts) were included in the analysis. Table 1 shows the general demographic data of patients. The patients' mean BMI was 20.36 ± 2.38 kg/m$^2$, and the mean follow-up period was 112.08 ± 24.39 months.

The mastectomy type was nipple-sparing mastectomy (NSM) in 85.58% ($n$ = 178) and skin-sparing mastectomy (SSM) in 14.42% ($n$ = 30) of the excised breasts. The mean mastectomy specimen weight was 245.34 ± 120.21 g, and the mean implant volume was 228.49 ± 80.45 cm$^3$. Bilateral reconstruction was performed in 12.4% ($n$ = 23) of the patients, and ADM was used during reconstruction in 93.7% ($n$ = 195) of the excised breasts (Table 2). The plane of implant insertion was subpectoral in all patients, and two Jackson-Pratt drains were used and removed when the drainage was less than 30 cc per day.

Table 1. Patients' general demographic data.

| Variables | Patients ($n$ = 185) | | Breasts ($n$ = 208) | |
|---|---|---|---|---|
| Age (years) | 39.58 | 7.83 | 39.66 | 7.84 |
| Body mass index (kg/m$^2$) | 20.36 | 2.38 | 20.48 | 2.44 |
| Smoking history | 7 | 3.78 | 9 | 4.33 |
| Hypertension | 0 | 0.00 | 0 | 0.00 |
| Diabetes mellitus | 1 | 0.54 | 1 | 0.48 |
| Pregnancy history | 114 | 61.62 | 128 | 61.54 |
| ASA score of 2 | 23 | 12.43 | 28 | 13.46 |
| Mean follow-up period (mo) | 112.08 | 24.39 | 111.31 | 24.16 |

Values are presented as means ± standard deviations or numbers (%).
ASA, American Society of Anesthesiology.

Table 2. Patients' surgical information.

| Variable | Implants | |
|---|---|---|
| Reconstruction side | | |
| Right | 111 | 53.37 |
| Left | 97 | 46.63 |
| Mastectomy type | | |
| Nipple-sparing | 178 | 85.58 |
| Skin-sparing | 30 | 14.42 |
| Mastectomy weight (g) | 245.34 | 120.21 |
| Implant volume (cm$^3$) | 228.49 | 80.45 |
| Lymph node dissection | | |
| None | 78 | 37.50 |
| Sentinel node | 95 | 45.67 |
| Axillary node | 35 | 16.83 |
| Previous breast surgery | | |
| None | 172 | 83.09 |
| Augmentation | 9 | 4.35 |
| Benign mass excision | 6 | 2.90 |
| Breast-conserving surgery | 20 | 9.66 |
| Bilateral reconstruction | 46 | 22.12 |
| Contralateral procedure | | |
| Augmentation | 4 | 1.92 |
| Reduction | 1 | 0.48 |
| Mastopexy | 1 | 0.48 |
| Implant manufacturer | | |
| Allergan | 14 | 6.73 |
| Mentor | 194 | 93.27 |
| Use of acellular dermal matrix | 195 | 93.75 |
| Revisional surgery | 14 | 6.73 |

Values are presented as means ± standard deviations or numbers (%).

Neoadjuvant and adjuvant chemotherapies were performed in 10.58% and 39.42% of the patients and preoperative and postoperative RTs in 3.85% and 6.73% of the patients, respectively. Postoperatively, 9.13% ($n$ = 19) of the patients had a local recurrence, while 5.29% ($n$ = 11) had an LN recurrence. Of the 185 patients, 10 died during follow-up, and the cause of death was distant metastasis in all of them. The survival rate was 94.59% ($n$ = 175) (Table 3).

Regarding complications, 13.46% ($n$ = 28) of the patients developed early complications, and the most common early complication was mastectomy skin necrosis (9.13%, $n$ = 19), followed by infection (3.85%, $n$ = 8), implant exposure (3.85%, $n$ = 8), wound dehiscence (3.37%, $n$ = 7). 29.33% ($n$ = 61) of the patients developed late complications, and the most common late complication was grade 3 or higher CC (13.46%, $n$ = 28), followed by rippling (7.21%, $n$ = 15), asymmetry (6.73%, $n$ = 14), malposition (4.33%, $n$ = 9). Regarding the final outcome, 91.35% ($n$ = 190) of the patients had their breast implants retained (Table 4).

The incidence of early complications was significantly higher with a heavier mastectomy specimen (237.14 g vs. 298.04 g,

Table 3. Patients' oncological information and survival status.

| Variable | No. implants | % |
|---|---|---|
| Perioperative | | |
| Stage | | |
| 0 (prophylactic mastectomy) | 1 | 0.48 |
| In situ | 39 | 18.75 |
| 1 | 87 | 41.83 |
| 2 | 65 | 31.25 |
| 3 | 15 | 7.21 |
| 4 | 1 | 0.48 |
| Neoadjuvant chemotherapy | 22 | 10.58 |
| Adjuvant chemotherapy | 82 | 39.42 |
| Hormone therapy | 134 | 64.42 |
| Trastuzumab use | 20 | 9.62 |
| Preoperative radiotherapy | 8 | 3.85 |
| Postoperative radiotherapy | 14 | 6.73 |
| Follow-up | | |
| Local recurrence | 19 | 9.13 |
| Regional (lymph node) recurrence | 11 | 5.29 |
| No. of surgery for recurrence | | |
| 0 | 182 | 87.50 |
| 1 | 25 | 12.02 |
| More than 2 | 1 | 0.48 |
| Implant removal owing to recurrence | 1 | 0.48 |
| Distant metastasis | 12 | 5.77 |
| Contralateral breast metastasis | 7 | 3.37 |
| Survival status | Patients ($n = 185$) | % |
| Alive | 175 | 94.59 |
| Dead | 10 | 5.41 |

Values are presented as numbers (%).

Table 4. Early/late complications and final outcomes.

| Variable | No. implants | % |
|---|---|---|
| Early complications | | |
| Any complications within postoperative 90 days | 28 | 13.46 |
| Infection | 8 | 3.85 |
| Skin necrosis | 19 | 9.13 |
| Seroma | 5 | 2.40 |
| Hematoma | 2 | 0.96 |
| Dehiscence | 7 | 3.37 |
| Implant exposure | 8 | 3.85 |
| Late complications | | |
| Any complications after postoperative 90 days | 61 | 29.33 |
| Infection | 0 | 0.00 |
| Seroma | 1 | 0.48 |
| Rupture | 4 | 1.92 |
| Malposition | 9 | 4.33 |
| Rotation | 3 | 1.44 |
| Animation deformity | 6 | 2.88 |
| Capsular contracture (grade 3 or higher) | 28 | 13.46 |
| Pain | 0 | 0.00 |
| Thinning | 6 | 2.88 |
| Rippling | 15 | 7.21 |
| Asymmetry | 14 | 6.73 |
| Final outcome | | |
| Maintenance | 190 | 91.35 |
| Explantation | 2 | 0.96 |
| Exchange to new implants | 15 | 7.21 |
| Autologous conversion | 1 | 0.48 |

Values are presented as numbers (%).

$p = 0.0123$) and larger implant volume (222.79 $cm^3$ vs. 266.48 $cm^3$, $p = 0.0082$). There were no significant differences in the remaining variables, including RT, between the two subgroups (Table 5). None of our study parameters were significantly associated with the risk of late complications (Table 6).

The implant removal group was older (43.17 years vs. 39.33 years, $p = 0.047$) and had a significantly heavier mastectomy specimen (301.61 g vs. 240.01 g, $p = 0.0374$) and larger implant volume (267.65 $cm^3$ vs. 224.99 $cm^3$, $p = 0.0359$) than the implant retention group. The proportion of patients who developed an early complication (61.11% vs. 8.95%, $p < 0.0001$) or late complication (61.11% vs. 26.32%, $p = 0.0019$) were also significantly higher in the implant removal group. Local recurrence and LN recurrence were not directly associated with implant removal (Table 7).

## Discussion

Although several results of the use of smooth round implants in augmentation mammaplasty for aesthetic enhancement have been reported [8,9], long-term follow-up data of patients who underwent breast reconstruction using smooth round implants is lacking. As smooth round implants are the only option currently available, valid long-term follow-up data is required, which calls for a reference (baseline) study on previous patients. According to Frey et al., who analyzed the outcomes of 1028 cases of immediate breast reconstruction following NSM, 51.8% ($n = 533$) of patients had tissue expander-based reconstruction, while 22.6% ($n = 232$) had DTI reconstruction [10]. They did not distinguish between smooth and textured implants; however, 78.1% of the implants used for DTI reconstruction were smooth implants. Although one study analyzed patients with a high proportion of smooth implants, two-stage reconstruction—as opposed to DTI reconstruction—was the trend at the time. Thus, our study is significant for providing long-term follow-up data on patients who underwent a single type of surgery (DTI reconstruction) only using smooth implants, with only a few patients excluded from the study.

The most common complications in the current study were skin necrosis followed by infection, which seemed to be hardly associated with the type of implant. In the study by Frey et al., the most common complication of DTI reconstruction was mastectomy flap necrosis (19.4%), followed by partial and complete nipple necroses (12.7%) and infection (4.7%) [10]. The incidence of infection is similar to that in our study (3.85%), while the incidence of skin necrosis is quite different (9.13%). This discrepancy may be attributable to the differences in the patient populations. Frey et al. analyzed a predominantly Caucasian population with a mean BMI of 23.32 $kg/m^2$, among whom 32.8% had a smoking history and a mean implant volume of 373.64 cc. In contrast, our study population was predominantly Korean with a relatively slim body habitus and low BMI (20.36 kg/m2). We speculate that the low rate of smoking history (3.78%) and smaller implant volume (228.49 cc) contributed to the lower incidence of skin necrosis.

Han et al. compared the outcomes of DTI and two-stage reconstructions using textured anatomical implants and reported an incidence of 20.6% for seroma, 10.3% for skin necrosis, 9.4% for CC, and 9.0% for infection [7]. With the exception of a higher incidence of CC in our study (13.46%), the incidence of other major complications (e.g. skin necrosis, infection, and seroma) was actually lower with smooth implants than with textured implants. We speculate that the discrepancy is due to strict patient selection criteria applied at the earlier time of DTI reconstructions.

In our study, only a heavier mastectomy specimen and larger implant volume were significantly associated with early complications (Table 5). Although some studies linked preoperative RT to the risk of complications [11], the association was not significant in our study. This may be attributed to the fact that in the past, patients who had undergone preoperative RT or are anticipated to require postoperative RT were recommended to undergo autologous reconstruction should they need DTI reconstruction. BMI has also been associated with early complications; however, this association was not observed in our study, as most of our patients were Asians, particularly Koreans, with a low mean BMI.

**Table 5.** Subgroup comparison: early complications (within postoperative 90 days).

| Variable | No complication ($n = 180$) | | Any complication ($n = 28$) | | $p$ |
|---|---|---|---|---|---|
| Age (years) | 39.32 | 7.64 | 41.86 | 8.82 | 0.1115 |
| Body mass index (kg/m$^2$) | 20.39 | 2.42 | 21.03 | 2.53 | 0.2022 |
| Pregnancy history | 110 | 61.61 | 18 | 64.29 | 0.7481 |
| Neoadjuvant chemotherapy | 22 | 12.00 | 0 | 0.00 | 0.0499* |
| Preoperative radiotherapy | 7 | 3.89 | 1 | 3.57 | 1.0000 |
| Hormone therapy | 116 | 64.44 | 18 | 64.29 | 0.9870 |
| Trastuzumab therapy | 18 | 10.00 | 2 | 7.14 | 1.0000 |
| Previous surgery | 31 | 17.22 | 5 | 17.86 | 1.0000 |
| Stage 2 or 3 | 66 | 36.67 | 14 | 50.00 | 0.1773 |
| Skin-sparing mastectomy | 27 | 15.00 | 3 | 10.71 | 0.7736 |
| Any lymph node dissection | 29 | 16.11 | 6 | 21.43 | 0.5860 |
| Implant manufacturer: Allergan | 169 | 93.89 | 25 | 89.29 | 0.4097 |
| Mastectomy specimen weight (g) | 237.14 | 114.84 | 298.04 | 141.53 | 0.0123* |
| Implant volume (cm$^3$) | 222.79 | 77.76 | 266.48 | 89.03 | 0.0082* |

Values are presented as means ± standard deviations or numbers (%).
*$p < 0.05$.

**Table 6.** Subgroup comparison: late complications (after postoperative 90 days).

| Variable | No complication ($n = 147$) | | Any complication ($n = 61$) | | $p$ |
|---|---|---|---|---|---|
| Age (years) | 39.16 | 7.94 | 40.89 | 7.51 | 0.1480 |
| Body mass index (kg/m$^2$) | 20.46 | 2.44 | 20.52 | 2.46 | 0.8650 |
| Pregnancy history | 88 | 59.86 | 40 | 65.57 | 0.4409 |
| Neoadjuvant chemotherapy | 14 | 9.52 | 8 | 13.11 | 0.4433 |
| Adjuvant chemotherapy | 58 | 39.46 | 24 | 39.34 | 0.9880 |
| Preoperative radiotherapy | 6 | 4.08 | 2 | 3.28 | 1.0000 |
| Postoperative radiotherapy | 9 | 6.12 | 5 | 8.20 | 0.5573 |
| Hormone therapy | 91 | 61.90 | 43 | 70.49 | 0.2389 |
| Trastuzumab therapy | 12 | 8.16 | 8 | 13.11 | 0.2701 |
| Previous surgery | 24 | 16.33 | 12 | 19.67 | 0.5615 |
| Stage 2 or 3 | 52 | 35.37 | 28 | 45.90 | 0.1554 |
| Skin-sparing mastectomy | 21 | 14.29 | 9 | 14.75 | 0.9302 |
| Any lymph node dissection | 22 | 14.97 | 13 | 21.31 | 0.2654 |
| Implant manufacturer: Allergan | 140 | 95.24 | 54 | 88.52 | 0.1238 |
| Mastectomy specimen weight (g) | 236.73 | 114.82 | 266.10 | 130.97 | 0.1088 |
| Implant volume (cm$^3$) | 222.58 | 79.87 | 242.64 | 80.72 | 0.1021 |
| Early complications (within postoperative 90 days) | 17 | 11.56 | 11 | 18.03 | 0.2134 |
| Local recurrence | 12 | 8.16 | 7 | 11.48 | 0.4503 |
| Regional (lymph node) recurrence | 7 | 4.76 | 4 | 6.56 | 0.7343 |

Values are presented as means ± standard deviations or numbers (%).

**Table 7.** Subgroup comparison: final outcomes.

| Variable | Implant removal ($n = 18$) | | Implant retention ($n = 190$) | | $p$ |
|---|---|---|---|---|---|
| Age (years) | 43.17 | 8.14 | 39.33 | 7.75 | 0.0470* |
| Body mass index (kg/m$^2$) | 20.27 | 2.33 | 20.5 | 2.46 | 0.7115 |
| Pregnancy history | 12 | 66.67 | 116 | 61.05 | 0.6398 |
| Hormone therapy | 13 | 72.22 | 121 | 63.68 | 0.4696 |
| Trastuzumab therapy | 1 | 5.56 | 19 | 10.00 | 1.0000 |
| Previous surgery | 3 | 16.67 | 33 | 17.37 | 1.0000 |
| Stage 2 or 3 | 8 | 44.44 | 72 | 37.89 | 0.5851 |
| Skin-sparing mastectomy | 5 | 27.78 | 25 | 13.16 | 0.1494 |
| Any lymph node dissection | 2 | 11.11 | 33 | 17.37 | 0.7436 |
| Implant manufacturer: Allergan | 15 | 83.33 | 179 | 94.21 | 0.1081 |
| Mastectomy specimen weight (g) | 301.61 | 157.50 | 240.01 | 115.17 | 0.0374* |
| Implant volume (cm$^3$) | 267.65 | 95.67 | 224.99 | 78.29 | 0.0359* |
| Early complications (within postoperative 90 days) | 11 | 61.11 | 17 | 8.95 | <0.0001* |
| Late complications (after postoperative 90 days) | 11 | 61.11 | 50 | 26.32 | 0.0019* |
| Local recurrence | 2 | 11.11 | 17 | 8.95 | 0.6723 |
| Regional (lymph node) recurrence | 1 | 5.56 | 10 | 5.26 | 1.0000 |

Values are presented as means ± standard deviations or numbers (%).
*$p < 0.05$.

In our study, none of the parameters were significantly associated with late complications (Table 6). Cancer recurrence and early complications were also not associated with late complications.

In terms of the final outcomes, 91.35% of the patients ($n = 190$) retained their initial implants during the follow-up period (Table 4). As collated in Table 7, a heavy mastectomy specimen and large implant volume were also significant risk factors of implant removal. Moreover, patients with early or late complications were significantly more likely to have their implant removed than those without. The patients who had their implants removed were older (43.17 years) than those who retained their implants (39.33 years). However, local or LN recurrence was not

associated with implant removal. Implant retention was not dependent on cancer recurrence but on complications, mastectomy specimen weight, and implant volume.

We analyzed the reasons for implant removal in the 18 (8.65%) patients who had their implants removed or exchanged. Two patients had their implants removed owing to infection. In 16 (7.69%) of the patients who had their existing implant replaced with a new one or autologous tissue, the reasons for the exchange were CC ($n = 4$), infection ($n = 3$), implant rupture ($n = 3$), implant exposure ($n = 3$), animation deformity ($n = 2$), and cancer recurrence ($n = 1$). In summary, elective complications such as CC and animation comprised 33.3% of all causes of implant failure, and implant rupture occurred in 1.4% of all reconstructions. Compared to the smooth implant retention rate of 82% in Vorstenbosch's study [12], the rate of implant retention in our study (91.35%) was higher than expected. As our study population comprised patients with cancer who frequented hospitals, it is possible that they might have not wanted to have their implants replaced unless absolutely necessary owing to the fatigue from frequent hospital visits and reoperations. Considering that the patients' cosmetic demands are increasing with socioeconomic changes as well as better cancer survival, exchange owing to elective/cosmetic reasons would grow in more recent studies.

The survival rate during a mean follow-up period of 112.08 months was 94.59% (Table 3). It is slightly higher than that (93.3%) reported by Siotos et al. on patients who underwent mastectomy with breast reconstruction [13], and this is slightly lower than the overall survival rate (97.8%) in the study by Hammer et al. on oncologic safety in 138 patients who underwent immediate breast reconstruction [14]. However, in Hammer's study, the median follow-up period was 49.3 months, which was shorter than in our study. These findings show that the rate is not markedly different from those in previous studies on similar populations.

Many plastic surgeons consider CC to be the most concerning aspect of the use of smooth implants. Although Bellaire et al. reported that there are no significant differences in the rate of major complications, including CC, between DTI reconstructions using textured implants and smooth implants [15], many researchers accept that smooth implants are associated with a higher incidence of CC [5,16]. In our study, 13.46% of the patients had grade 3 or higher CC; this complication accounted for nearly half of all late complications and had the highest incidence even when both early and late complications were included. The incidence of CC was actually high despite reconstruction using ADM in 93.75% of the patients. Hence, this should be considered and explained to patients when using smooth implants.

This study has a few strengths. First, DTI reconstruction is the current trend in implant-based reconstructions; however, two-stage reconstruction was the standard approach prior to the introduction of textured implants. As a result, the long-term outcomes of DTI reconstruction using smooth round implants have not been well discussed [7]. We were able to collect adequate data pertinent to the latest trend because our center began performing DTI reconstruction earlier than did other facilities. Second, while early complications are unlikely to be underestimated on the basis of the follow-up period, late complications are generally vulnerable to a slight underestimation owing to follow-up losses of patients with complications [17]. However, many of our patients who were lost to follow-up at plastic surgery were still complying with their follow-up schedules at the breast surgery department. Thus, we were able to examine these patients' final outcomes (implant retention) based on the imaging findings obtained at the breast surgery department. In other words, our final data on implant retention and rupture are relatively accurate although we could not rule out those who underwent revisionary surgeries at other medical facilities. Third, we performed a long-term follow-up of nearly 10 years with a mean duration of 112.08 months.

This study also has a few limitations. First, among 208 breasts were analyzed, 97.1% ($n = 202$) of the data was obtained from 2007 to 2014. During this period, the indications for DTI reconstruction were stricter than those currently used. Two-stage reconstruction or autologous reconstruction was selected over DTI reconstruction for patients anticipated to undergo postoperative RT, patients with a high BMI, and smokers. Thus, with a broader scope of patients currently undergoing DTI, the incidence of complications would be higher than that in our study. Second, easily resolved minor complications, such as delayed wound healing, partial-thickness minor skin necrosis, and small wound dehiscence, might have been omitted in patients' medical records. These minor complications might have been underestimated owing to the nature of a retrospective chart review. Third, patients have greater aesthetic demands in recent years. As such, there may be more requests for an implant replacement owing to dissatisfaction with the shape or size of implants or deformity caused by CC. In addition, the launching of the Korean National Health Insurance Service coverage of breast reconstruction since April 2015 may have lowered the barrier to implant replacement. Thus, the rate of implant removal or exchange observed in this study might have been underestimated compared with that in recent years. Finally, we did not analyze patient reported outcome measures (PROM) or BREAST-Q results which would have provided a reasonable assumption about the practical incidence of future elective revisionary surgeries.

Our study presents long-term baseline data in a group of selected patients for future studies that would attempt to analyze the outcomes of DTI reconstruction using a smooth round implant. In summary, approximately 91.35% of the implants were maintained during the follow-up period when elective complications such as CC and animation comprised 33.3% of all causes of implant failure, and implant rupture occurred in 1.4% of all reconstructions. Trends of early complications were comparable to previous studies, while significant capsular contracture occurred in 13.46% of our study populations. Providing patients with a detailed explanation of the potential risk of CC as a late complication, obtaining informed consent, and engaging in practices to prevent it would enable a safer and effective breast reconstruction amid smooth round implants being the only available option.

## Disclosure statement

No potential conflict of interest was reported by the author(s).

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