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ARTICLE

Loss to follow-up after direct-to-implant breast reconstruction

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ABSTRACT

Loss to follow-up is inevitable in retrospective cohort studies, and patients are lost to follow-up after direct-to-implant reconstruction despite annual follow-up recommendation. We analyzed more than 500 patients to analyze the rate of loss to follow-up to plastic surgery and to investigate the factors affecting it. A retrospective review of patients who underwent direct-to-implant reconstruction between July 2008 and August 2016 was performed. Loss to follow-up to plastic surgery was defined as a difference of ≥24 months between the total and plastic surgery follow-up. The rate of loss to follow-up and associated factors including patients' demographics, surgery-related variables, oncological data, and early and late complications were analyzed. Of 631 patients who underwent direct-to-implant reconstruction, 551 patients continued visiting the hospital for breast cancer-related treatment. Of the 527 patients who were eligible for the study, 157 patients (29.8%) were lost to plastic surgery follow-up. Surgery-related variables, early complications, cancer stage, and adjuvant therapies were not significantly different. Younger age was significantly associated with loss to follow-up in univariate analysis. However, logistic regression revealed that a long total follow-up period, distant metastasis, and absence of late elective complications were significant factors contributing to follow-up loss. Late elective complications such as malposition, capsular contracture, and mastectomy flap thinning were more common in the follow-up group (48%) than in the loss to follow-up group (22%). Follow-up loss after direct-to-implant reconstruction was not associated with specific demographic or surgery-related variables, and postoperative courses significantly affected the loss to follow-up.

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Introduction

Implant breast reconstruction, one of the most popular breast reconstruction methods in recent years, is largely divided into two-stage reconstruction with a tissue expander and direct-to-implant reconstruction. Direct-to-implant breast reconstruction was initially less used due to concerns regarding complications such as mastectomy skin necrosis and unfavorable results. However, with advances in mastectomy techniques and the use of acellular dermal matrix, one-stage implant reconstruction has evolved to yield stable outcomes and has been used more often recently. Direct-to-implant breast reconstruction has been reported to have aesthetic outcomes and complication rates comparable to those of other techniques [1,2]. The greatest advantage of direct-to-implant reconstruction is that the period until completion of the final reconstruction is short and that reconstruction is almost complete with one operation. However, even after reconstruction is over, the patient needs continuous surveillance. This is primarily attributed to the nonpermanent nature of the prosthesis and the possibility of delayed complications or elective revisions [3–6. In addition, the association between lymphoma and implants has recently been identified, and awareness of the importance of surveillance is increasing. Therefore, annual follow-up is recommended for all patients with breast implants [7,[8]]. Unfortunately, little evidence could be found whether regular follow-up is related to earlier detection of complications or better prognosis because the characteristics as well as outcomes of those who were not followed-up are not clearly elucidated. However, the existence of these loss to follow-up group may affect the interpretation and reliability of retrospective studies which should have enrolled and analyzed theoretically all patient.

A retrospective cohort study is frequently used as a representative research methodology to analyze the outcome of surgeries. However, this study method inevitably has a certain ratio of loss to follow-up [9], and its effect on the interpretation of study results has been considered significant in the field of epidemiology [10,11] In a retrospective cohort study, those lost to follow-up may have a different outcome compared with the outcome of those who complete the study. For example, mortality was significantly higher among non-attendees after lung volume reduction surgery in a previous study, which underestimated overall mortality [12]. Longitudinal studies of osteoporosis in older individuals may underestimate bone loss because of a lack of follow-up among subjects who are too frail to return [13]. An individual who does not return after plastic surgery may have specific demographic characteristics. However, it is also possible that there are no specific problems or complaints; conversely, it is possible that the results are too unsatisfactory or the doctor-patient relationship was not sufficiently strong. In either case, bias can affect the validity of the inferences drawn from the study.

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We analyzed the outcome of more than 500 patients who underwent direct-to-implant reconstruction immediately after skin-sparing or nipple-areolar skin-sparing mastectomy with a long-term follow-up. The primary aim of this study was to analyze the rate of loss to follow-up to plastic surgery and to investigate the factors affecting it, and the purpose of this study was twofold. First, we aimed to investigate whether specific predictable variables such as demographic, surgery-related, or oncologic factors affect patients' follow up. Second, we also tried to examine the relationships between the outcomes of the reconstruction and follow-up, therefore to consider the implication of loss to follow-up on the interpretation of the outcome analysis.

Methods

Between July 2008 and August 2016, 631 patients underwent direct-to-implant breast reconstruction using silicone implants. A retrospective review of the medical records was performed for all patients who visited the outpatient clinic of Asan Medical Center for follow-up of breast cancer between August 2018 and July 2019. Patients whose death was confirmed during the follow-up period were excluded from the study. This study was approved by the institutional review board of the hospital (Approval No. 2018-0540).

Loss to follow-up to plastic surgery was defined as a difference of 24 months or more between the last outpatient visit to the hospital and the last outpatient visit to the plastic surgery department. Patients' demographic variables, surgical-related variables, oncological data, and outcomes including early and late complications were investigated. The rate of loss to follow-up and the factors affecting it were analyzed.

Early complications were defined as complications occurring within 90 days of surgery, including infection, seroma, hematoma, skin necrosis/delayed wound healing, and wound dehiscence/implant exposure. Skin necrosis/delayed wound healing represented those without implant exposure, and wound dehiscence/implant exposure represented those with actual implant exposure. Early reoperations included incision and drainage, hematoma evacuation, debridement, and wound repair. Patients who removed or exchanged the initial implant within 90 days were excluded from the study.

Late complications were defined as complications that occurred more than 90 days after surgery, which were divided into mandatory complications and elective complications. Late mandatory complications included late infection, late seroma, and rupture, which necessitated medical or surgical treatment. Late elective complications included implant rotation, malposition, capsular contracture (≥grade 3), persistent pain, and problems related to mastectomy flap thinning such as rippling, implant visibility, or palpability. For the evaluation of late complications, patients' medical records and available photographs were reviewed. If a patient had multiple complications, each complication was independently counted. The rates of overall (early or late) complications, overall mandatory complications, and overall elective complications were determined based on the number of patients. To determine the final status (maintenance or loss) of the implant, medical records from all departments and the patient's clinical photographs and radiologic images were used.

The total follow-up period was defined as the difference between the last visit to the hospital and the surgery date, and the plastic surgery follow-up period was defined as the difference between the last visit to the plastic surgery outpatient clinic and the surgery date.

Independent t-test was performed for continuous variables, and chi-square analysis and Fisher's exact test were performed for categorical variables. Logistic regression analysis was also performed. All statistical analyses were performed using SPSS 25.0 (IBM Corp., Armonk, NY, USA). Values of $p < 0.05$ were considered significant.

Results

Of 631 patients who underwent direct-to-implant breast reconstruction between July 2008 and August 2016, 551 patients visited the outpatient clinic for breast cancer-related treatment between August 2018 and July 2019. A total of 24 patients were excluded from the study because of the removal or exchange of the initial implant within 90 days, and 527 patients were included in the final study population. Of these patients, 370 patients visited the plastic surgery clinic within 24 months from the last outpatient visit (follow-up), and 157 patients were lost to follow-up to plastic surgery (loss to follow-up).

The patients' demographic variables and surgery information are summarized in Table 1. The mean age of the patients was 42.7 years old in the follow-up group and 40.4 years old in the loss to follow-up group, with statistically significant differences in univariate analysis ($p = 0.002$). The mean body mass index (BMI) of the follow-up group and loss to follow-up group was 21.50 kg/m^2 and 21.17 kg/m^2, respectively ($p = 0.204$). Variables related to surgery such as unilateral or bilateral reconstruction, contralateral cosmetic procedure, mastectomy technique, and size of the implant showed no significant differences between the two groups (Table 1).

The patients' oncological data are summarized in Table 2. There were no significant differences in breast cancer stage,

Table 1. Patient demographic variables and surgery information.

	Total ($n = 527$)	Follow-up ($n = 370$, 70.2%)	Loss to follow-up ($n = 157$, 29.8%)	p value
Age	42.02 ± 8.02 (21–67)	42.71 ± 8.16 (21–67)	40.40 ± 7.48 (28–63)	0.002*
BMI (kg/m^2)	21.40 ± 2.77 (15.1–34.3)	21.50 ± 2.63 (15.7–32.1)	21.17 ± 3.09 (15.1–34.3)	0.204
Bilateral reconstruction**	43 (8.2%)	27 (7.3%)	16 (10.2%)	0.267
Contralateral procedure	22 (4.2%)	13 (3.5%)	9 (5.7%)	0.244
Nipple-areolar sparing mastectomy***	424 (80.5%)	295 (79.7%)	129 (82.2%)	0.519
Implant size (cc)	241.74 ± 83.57 (115–525)	243.96 ± 84.40 (115–525)	236.50 ± 81.62 (115–460)	0.350

BMI: Body mass index, *Statistically significant, **vs. unilateral reconstruction, ***vs. skin sparing mastectomy.

Table 2. Oncological data.

	Total ($n = 527$)	Follow-up ($n = 370$)	Loss to follow-up ($n = 157$)	p value
Stage				
prophylactic	22 (4.2%)	17 (4.6%)	5 (3.2%)	0.432
in situ	96 (18.2%)	65 (17.6%)	31 (19.7%)	
1	177 (33.6%)	122 (33.0%)	55 (35.0%)	
2	191 (36.2%)	141 (38.1%)	50 (31.8%)	
3	41 (7.8%)	25 (6.8%)	16 (10.2%)	
Preoperative radiation	23 (4.4%)	19 (5.1%)	4 (2.5%)	0.245
Postoperative radiation	48 (9.1%)	32 (8.6%)	16 (10.2%)	0.574
Preoperative chemotherapy	118 (22.4%)	82 (22.2%)	36 (22.9%)	0.847
Postoperative chemotherapy	160 (30.4%)	108 (29.2%)	52 (33.1%)	0.369
Postoperative hormone therapy	350 (66.4%)	248 (67.0%)	102 (65.0%)	0.647
Postoperative Herceptin therapy	82 (15.6%)	65 (17.6%)	17 (10.8%)	0.051

Table 3. Oncological events during the follow-up period.

	Total ($n = 527$)	Follow-up ($n = 370$)	Loss to follow-up ($n = 157$)	p value
Locoregional recurrences	60 (11.4%)	40 (10.8%)	20 (12.7%)	0.524
Local recurrence	45 (8.5%)	31 (8.4%)	14 (8.9%)	0.840
Lymph node recurrence	17 (3.2%)	10 (2.7%)	7 (4.5%)	0.297
Distant metastasis	35 (6.6%)	14 (3.8%)	21 (13.4%)	<0.0001*

*Statistically significant.

Table 4. Early complications and reoperations.

	Total ($n = 527$)	Follow-up ($n = 370$)	Loss to follow-up ($n = 157$)	p value
Overall early complications	56 (10.6%)	38 (10.3%)	18 (11.5%)	0.684
Infection	5 (0.9%)	3 (0.8%)	2 (1.3%)	0.637
Seroma	11 (2.1%)	9 (2.4%)	2 (1.3%)	0.519
Hematoma	13 (2.5%)	11 (3.0%)	2 (1.3%)	0.362
Skin necrosis/delayed wound healing	37 (7.0%)	24 (6.5%)	13 (8.3%)	0.461
Dehiscence/implant exposure	12 (2.3%)	9 (2.4%)	3 (1.9%)	1.000
Early reoperation	24 (4.6%)	19 (5.1%)	5 (3.2%)	0.326

preoperative and postoperative radiation, chemotherapy, hormone therapy, and Herceptin therapy.

Oncological events during the follow-up period are summarized in Table 3. There were no significant differences in local or lymph node recurrences. Distant metastasis occurred in 6.6% of patients. The loss to follow-up group showed a significantly higher incidence of distant metastasis (13.4%) compared with the incidence of the follow-up group (3.8%, $p < 0.00001$).

Early complications occurred in 10.6% of patients, and 4.6% of patients required reoperation. The most common complications were skin necrosis and delayed wound healing. There were no significant differences between the follow-up group and loss to follow-up group patients (Table 4). However, there were significant differences in overall late complications between the two groups (49.5% in the follow-up group vs. 22.3% in the loss to follow-up group, $p < 0.0001$). Among the types of late complications, mandatory complications requiring medical or surgical treatment showed no differences between the two groups. Late elective complications such as malposition, rotation, significant capsular contracture, persistent pain, and mastectomy flap thinning (diagnosed based on physical examination or complaints) showed significant differences (both overall and individual items) (Table 5). There were no significant differences in the proportion of patients who maintained the initial implant between the two groups (93.8% in the follow-up group vs. 95.5% in the loss to follow-up group, $p = 0.426$).

Table 5. Late complications.

	Total ($n = 527$)	Follow-up ($n = 370$)	Loss to follow-up ($n = 157$)	p value
Overall late complications	218 (41.4%)	183 (49.5%)	35 (22.3%)	<0.0001*
Mandatory complications**	12 (2.3%)	10 (2.7%)	2 (1.3%)	0.524
Late infection	7 (1.3%)	6 (1.6%)	1 (0.6%)	0.680
Late seroma	4 (0.8%)	4 (1.1%)	0 (0.0%)	0.323
Implant rupture	4 (0.8%)	3 (0.8%)	1 (0.6%)	1.000
Elective complications***	212 (40.2%)	177 (47.8%)	35 (22.3%)	<0.0001*
Malposition	55 (10.4%)	46 (12.4%)	9 (5.7%)	0.021*
Rotation	60 (11.4%)	56 (15.1%)	4 (2.5%)	<0.0001*
Capsular contracture (≥grade 3)	65 (12.3%)	54 (14.6%)	11 (7.0%)	0.015*
Persistent pain	29 (5.5%)	26 (7.0%)	3 (1.9%)	0.020*
Mastectomy flap thinning	63 (12.0%)	50 (13.5%)	13 (8.3%)	0.09
Final implant maintenance	497 (94.3%)	347 (93.8%)	150 (95.5%)	0.426

*Statistically significant, **Including late infection, late seroma, and implant rupture, ***Including malposition, rotation, capsular contracture (≥grade 3), persistent pain, and mastectomy flap thinning.

Logistic regression analysis identified a long total follow-up period ($p < 0.00001$), distant metastasis ($p < 0.0001$), and absence of late elective complications ($p < 0.0001$) as significant predictors for loss to follow-up. Other variables such as age ($p = 0.497$), locoregional recurrence ($p = 0.287$), and absence of overall late complications ($p = 0.051$) or late mandatory complications ($p = 0.153$) were not significant predictors of loss to follow-up.

The average total follow-up period was 54.54 months, and the plastic surgery follow-up period was 35.90 months (49.95 months and 42.72 months, respectively, in the follow-up group and 65.38 months and 19.82 months, respectively, in the loss to follow-up group). In the loss to follow-up group, the total follow-up period was significantly longer, and the plastic surgery follow-up period was significantly shorter ($p < 0.0001$, Table 6, Figure 1).

In the loss to follow-up group, 14.6% of patients stopped visiting the plastic surgery department within 3 months, and approximately 43.9% of patients were lost to follow-up within 12 months. In addition, around 73.9% of patients in the loss to follow-up group were lost to follow-up within 24 months (Table 7, Figure 2).

Table 6. Total and plastic surgery follow-up period.

	Total ($n = 527$)	Follow-up ($n = 370$)	Loss to follow-up ($n = 157$)	p value
Total follow-up (months)	54.54 ± 19.98 (26–133)	49.95 ± 16.08 (26–133)	65.38 ± 23.80 (32–132)	<0.0001*
Plastic surgery follow-up (months)	35.90 ± 20.48 (0–133)	42.72 ± 17.27 (10–133)	19.82 ± 18.40 (0–86)	<0.0001*
Difference**	18.65 ± 21.87 (−9 to 132)	7.23 ± 7.60 (−9 to 24)	45.55 ± 20.94 (24–132)	<0.0001*

*Statistically significant, **Difference between total follow-up and plastic surgery follow-up.

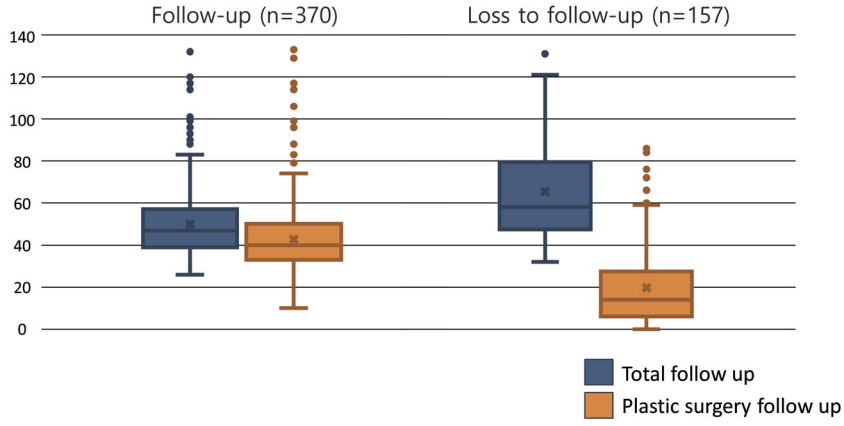

Figure 1. Box-and-whisker plots of the total and plastic surgery follow-up period in the two groups. The average total follow-up and the plastic surgery follow-up period was 49.95 months and 42.72 months, respectively, in the follow-up group (left) and 65.38 months and 19.82 months, respectively, in the loss to follow-up group (right). In the loss to follow-up group, the total follow-up period was significantly longer, and the plastic surgery follow-up period was significantly shorter ($p < 0.0001$).

Table 7. Plastic surgery follow-up period in the loss to follow-up group.

Period (months)	0–1	1–3	3–6	6–12	12–24	24–36	36–48	>48
Patient number	19	4	20	26	47	18	8	15
Cumulative number	19 (12.1%)	23 (14.6%)	43 (27.4%)	69 (43.9%)	116 (73.9%)	134 (85.4%)	142 (90.4%)	157 (100%)

Discussion

Between July 2008 and August 2016, 551 (83.7%) of 631 patients who underwent direct-to-implant reconstruction visited our hospital for breast cancer-related treatment or follow-up. Of these patients, 24 patients removed the implant within 90 days, and 527 patients were eligible for the study. A total of 157 (29.8%) patients did not visit the plastic surgery department for more than 2 years, representing our 'loss to follow-up' group. Considering that we recommended annual follow-up for all patients with implant-based reconstruction, this number was higher than expected.

The longer the total follow-up period, the higher the incidence of loss to follow-up. It is possible that the determination to visit the plastic surgery clinic is reduced over a long follow-up period. However, the awareness of plastic surgeons and patients about the follow-up of the implant may have become greater recently. Among patients in the loss to follow-up group, around 3/4 of them stopped visiting the plastic surgery department within 2 years. Considering that many patients who received breast cancer treatment in our hospital continued visiting the hospital for at least 5 years, the importance of continued implant surveillance may have been insufficiently emphasized or underestimated.

Contrary to our assumptions, preoperative demographic variables, surgery-related variables, breast cancer treatment, or prognosis did not affect loss to follow-up in most cases. Age showed a significant effect in univariate analysis; a younger age was associated with a greater loss to follow-up. However, this was not significant in logistic regression analysis. With an increase in direct-to-implant reconstruction over time, indications have been expanding regarding age, breast size, and ptosis [2]. Therefore, in the interpretation of the relationship between age and loss to follow-up, the total follow-up period should be considered as a confounding factor. Local and lymph node recurrence did not increase loss to follow-up; however, distant metastasis significantly increased follow-up loss. Locoregional recurrence is mainly treated in oncologic surgery and radiation oncology departments. Recurrence surgery is sometimes associated with plastic surgery. In cases of distant metastasis, the main department of care is transferred from breast surgery to oncology, and the patient is often enrolled in clinical trial treatment including targeted therapy. The oncologist's and patient's perception of the severity of the disease would be a factor that distracts their attention from the breast implant.

The most evident findings were issues occurring in the later stages. We categorized late complications into mandatory and elective complications. The development of late mandatory complications did not affect loss to follow-up. This is probably because they were rare but noticeable complications that require medical or surgical treatment, and most of them occurred within

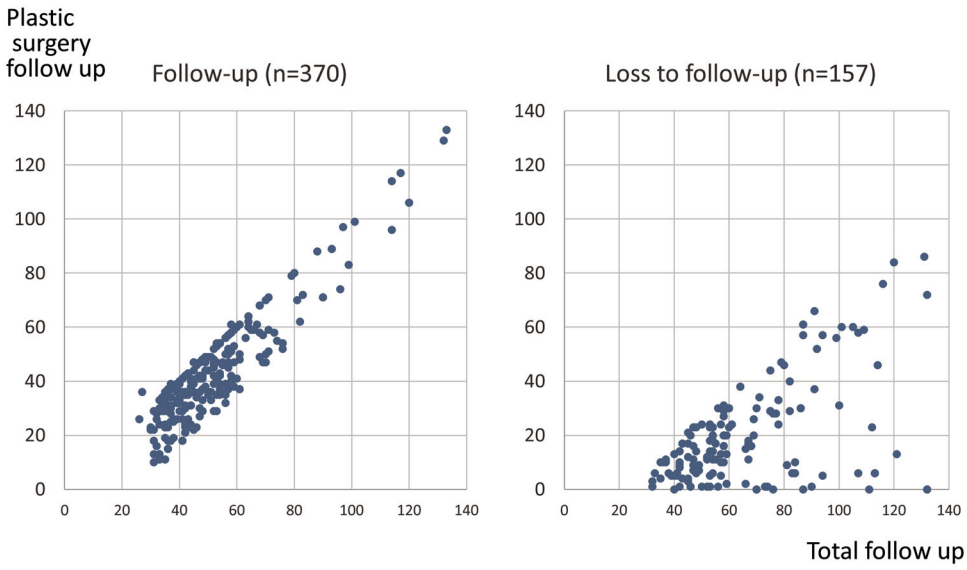

Figure 2. Scatter plots of the total and plastic surgery follow-up period in the two groups. The average difference in the total and plastic surgery follow-up period was 7.23 months in the follow-up group (left) and 45.55 months in the loss to follow-up group (right), which was significant ($p < 0.0001$). Approximately 73.9% of patients in the loss to follow-up group were lost to follow-up within 24 months.

1–2 years [14]. Elective complications diagnosed based on the doctor's observation or patient's appeal are not regarded as complications in all studies [15,16]. However, they are factors that can greatly influence the satisfaction and well-being of patients. Recent outcome studies have highlighted the importance of patient-reported outcomes (including studies using BREAST-Q), and this information should be provided to patients in preoperative consultation [17,18]. Overall late elective complications occurred in around 40% of patients in total, with 48% of patients in the follow-up group and 22% of patients in the loss to follow-up group. This may appear high but is comparable to the findings of previous studies [19,20].

Late elective complications were significantly more common in the follow-up group. This can be interpreted in several ways. Complications that appeared at a relatively late period might have been diagnosed and recorded more often in the follow-up group, and it would not have been recorded in the loss to follow-up group despite their occurrence. On the other hand, patients who were aware of elective complications might have visited the plastic surgery clinic as follow-up group. Patients might also have been dissatisfied with the results and received a replacement or revision surgery at another hospital. Theoretically, the number of elective complications can be calculated as $177 + 157 \times (177/370)$ and arithmetically between $177 + 35$ and $177 + 157$. Besides, which would be the most appropriate denominator for this retrospective cohort study – 631, 551, or 527? The selection of variables could either overestimate or underestimate the results.

Selection bias due to loss to follow-up is inevitable in most cohort studies, and its effect has been investigated in the field of epidemiology. Dettori suggested that a follow-up loss of less than 5% leads to little bias, whereas a loss of more than 20% poses a serious threat to validity; however, generally, the recommended follow-up threshold is around 60–80% [11,21]. Missing data were categorized into missing completely at random (MCAR; the probability that a subject remains in the study does not depend on the exposure, confounders, or outcome) or missing at random (MAR; the probability of a subject remaining in the study depends on the exposure or confounders but not outcome), and missing not at random (MNAR; the probability of being lost to follow-up depends on the outcomes to be measured and cannot be completely explained by the covariates) mechanisms. Kristman et al. found no notable bias when loss to follow-up was related to MCAR or MAR mechanisms. However, they found seriously biased estimates with even low levels of loss to follow-up when observations were lost to follow-up based on the MNAR mechanism [21]. Little's test of MCAR is known to be useful for testing the missing mechanism [22]. Our results appeared to be related to the MNAR mechanism.

This mechanism would be particularly significant in plastic surgery studies, which rarely involve mortality or morbidity. In order to enhance the level of evidence in retrospective studies, the exact definition of the study population, follow-up, and patient enrollment criteria would be critical. This should also be considered in the interpretation of meta-analyses or systematic reviews. In particular, in a retrospective study using a questionnaire, the questionnaire response might contribute to selection bias (similar to elective outpatient visits) even if the validity of the questionnaire itself has been well proven. Indeed, the response rate to a survey greatly decreased as the follow-up period increased [4]. Several epidemiological methodologies and assessments have investigated this issue [23–27].

There are several limitations in our study. First, the duration of the total follow-up period may have an effect on the occurrence of late complications. However, it was found that the loss to follow-up group had a longer follow-up period and less late complications. Moreover, in regression analysis, the relationship between the follow-up period and overall late complications or late elective complications was not statistically significant ($p = 0.097$ and $p = 0.067$, respectively). We arbitrarily defined 'loss to follow-up' as a difference of more than 24 months between the total and plastic surgery follow-up. We set the difference as two-fold of the recommended follow-up interval because the primary objective of this study was to analyze the elective follow-up loss or voluntary dropout from regular plastic surgery follow-up. Finally, patient selection criteria, surgical techniques, choice of the implant, and doctors' and patients' awareness could have gradually changed over time due to the long study period, and this may have also acted as a bias. We limited the study period to before August 2019 assuming that implant awareness and surveillance would be

greater after that when certain types of textured implants were recalled at the request of F.D.A.

According to our results, almost 1/3 of the patients failed to keep regular follow-up after direct-to-implant breast reconstruction which is significant to consider. Loss to follow-up was significantly affected by late oncologic courses such as metastasis. The necessity of continuing implant surveillance should be educated to such patient as well as other relevant departments. Regarding the relationship between the late elective complications and loss to follow-up, a dilogical interpretation was possible. Firstly, development of such complications would have induced further follow-up and management, or reversely loss to follow-up might have acted as a causative factor that prevented the detection of such complications and subsequently led to underestimate the incidence of late elective complications.

Conclusions

In summary, around 30% of patients with breast reconstruction were lost to follow-up to plastic surgery after direct-to-implant breast reconstruction. Loss to follow-up was increased as the total follow-up period after surgery was increased. Patients' demographic variables, surgery-related variables, early complications, breast cancer stage, adjuvant therapy, and locoregional recurrence did not affect follow-up loss. Distant metastasis significantly increased plastic surgery follow-up loss. There were no significant differences between follow-up and loss to follow-up patients in late mandatory complications such as delayed infection, seroma, and implant rupture occurring after more than 90 days. However, late elective complications such as malposition, rotation, capsular contracture, pain, and mastectomy flap thinning were significantly more common in the follow-up group, reaching 48% compared with 22% in the loss to follow-up group. Follow-up loss after direct-to-implant reconstruction was not dependent on specific demographic or surgery-related variables, and postoperative courses significantly affected the loss to follow-up. As we have shown, loss to follow-up is affected by postoperative courses. Retrospective studies are thus inevitably prone to misinterpretation of the outcomes, and which should be considered in designing and analyzing process.

Disclosure statement

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

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