

Implications of Long-term Indwelling of Tissue Expander in Breast Reconstruction: Risk of Expander Rupturing

TAKAAKI FUJII, REINA YAJIMA and HIROYUKI KUWANO

Department of General Surgical Science, Graduate School of Medicine, Gunma University, Gunma, Japan

Abstract. *Background/Aim: Breast reconstruction with a tissue expander (TE) is associated with postoperative complications, including rupturing of the TE. Any device can have a mechanical failure, and a TE may rupture over time. Although an interval of around one year from initial TE insertion to the second stage of two-stage surgery is historically considered the standard, the optimal interval has not yet been determined. Furthermore, the durability of a TE and the influence of long-term indwelling on TE rupture are uncertain. In this study, we retrospectively investigated the effects of long-term indwelling on TE durability and rupturability. Patients and Methods: We analyzed 24 patients and 25 breasts with breast cancer that had undergone breast reconstruction with an expander that was indwelling for more than a year. The resected margins were all clear, and none of the patients required postoperative radiotherapy. Results: From a total of 25 reconstructed breast mounds, the TE ruptured in 4 cases. None of the clinicopathological features, including primary tumor progression, method of operation, presence of adjuvant chemotherapy, was significantly associated with TE rupture. Rupture was observed beginning at 1.5 years after the initial TE insertion. The rupture rate was 32.6% by the third year and 55.1% by five years. There were no ruptures among cases with TE exchange within a year. Conclusion: Long-term indwelling of TE is associated with TE rupture. We recommend that the appropriate interval between the first and second stages of breast reconstructive surgery is approximately one year.*

With increasing emphasis on the cosmetic outcome of breast surgery, the role of breast reconstruction with tissue expanders (TEs) has become more important (1-5). In breast surgery, cosmetic results are often very important to patients. We have previously reported the advantages of immediate breast reconstruction using a skin flap with subcutaneous tissue (1). Our method makes it easy to cover the inferolateral region of the expander and provides a more expandable material for covering the inserted expander (1). Furthermore, there have been no major complications with our method, such as hematoma, skin necrosis, wound dehiscence, major infection, capsule contracture, expander displacement, or rupture (1). Breast reconstruction with an expander is associated with postoperative complications (6-12). Any device can have a mechanical failure, and a TE may rupture over time. The TE rupture rate has been reported to be around 1-3% (8, 9), though the rupture rate may increase the longer a TE has been in place. Although an interval about a year from initial TE insertion to the second-stage surgery is historically considered the standard, the optimal interval has not yet been determined. Recently, we experienced the rupture of a TE that had been in place for more than 2 years in patients who had received immediate breast reconstruction with a TE. The reason why some patients do not receive an exchange of TE within a year are various, including clinical, social, and individual factors. In two-stage breast reconstruction, the long interval between stages could be considered an indicator of TE rupture. However TE durability and the influence of the duration of indwelling on TE rupture is uncertain. In this study, we retrospectively investigated the effect of long-term indwelling on TE durability in breast cancer patients who had undergone breast reconstruction with a TE.

Correspondence to: Takaaki Fujii, MD, Ph.D., FACS. Department of General Surgical Science, Graduate School of Medicine, Gunma University 3-39-22 Showa-machi, Maebashi, Gunma 371-8511, Japan. Tel: +81 0272208224, Fax: +81 0272208230, e-mail: ftakaaki@gunma-u.ac.jp

Key Words: Tissue expander, breast reconstruction, rupture, long duration, complication.

Patients and Methods

Patients. This study enrolled 24 consecutive patients and 25 breasts whose TE was not exchanged within a year after the first stage of two-stage reconstruction with an expander. All patients were treated at the Department of General Surgical Science, Graduate School of Medicine, Gunma University, from 2003 to 2012. Nine patients

underwent skin-sparing or nipple-sparing mastectomy, 11 patients underwent mastectomy, and 4 patients underwent two-stage breast reconstruction with an expander after mastectomy. None of the patients had received neo-adjuvant chemotherapy or radiotherapy. Patients with incomplete clinical information were excluded. Among the 25 breasts, the TE had ruptured in 4 (16.0%) cases. All patients included in this study gave their informed consent at the time of surgery for inclusion in future analyses. Patients whose tumors were attached to skin or muscle were excluded.

The details extracted from the database were age, histological type, primary tumor size, lymphatic or vascular invasion, estrogen (ER) and progesterone (PgR) expression status, the human epidermal growth factor receptor 2 (HER2) score of the primary tumor, and axillary lymph node status. ER and PgR status was assessed by ALLRED scores, and an ALLRED score of 3 or higher was considered as ER- and PgR-positive (13).

Surgical procedure. In cases receiving nipple-sparing mastectomy, with the patients under general anesthesia in a supine position, both arms were abducted to 90° and a 6-7 cm incision was made along the mid-axillary line (1). This incision prevents direct contact between the expander and the incision. A skin- or nipple-sparing mastectomy and total mastectomy were performed to remove the breast tissue under direct vision. After completion of mastectomy, dissection between the pectoralis major and pectoralis minor was performed. Then, the inferomedial attachments of the pectoralis major were detached as much as possible in order to secure enough space and to prevent superior displacement of TE. The expander was inserted into the space between the major and minor pectoral muscles, a partial subpectoral position for just superior pole coverage. Skin with subcutaneous tissue was used to cover the inferolateral portion of the expander for soft-tissue support in the inferior pole. One suction drain was placed onto the pectoralis major.

Sentinel lymph node biopsy was performed with the radio-guided method. In cases that are node-positive, level I axillary clearance is routinely performed.

Statistical analysis. The 25 cases were divided into two groups: those with TE rupture and those without. We conducted a univariate statistical analysis using Fisher's exact test or the χ^2 test with Yates's correction. To compare the two groups, we used Student's *t*-test. Differences were considered statistically significant when $p < 0.05$. The cumulative risk of TE rupture was calculated using the Kaplan-Meier method.

Results

We analyzed the cases of 24 patients and 25 breasts with breast cancer that had undergone two-stage breast reconstruction with an expander that was indwelling for over one year. The resected margins were all clear, and none of the patients required postoperative radiotherapy. From a total of 25 reconstructed breast mounds, the TE ruptured in 4 cases (16%). The cases were divided into a rupture group and a non-rupture group. Table I shows the patients' characteristics and summarizes the results of the univariate analysis conducted to determine the relationship between the clinicopathologic variables and TE rupture. As can be seen,

Table I. Clinicopathological variables associated with TE rupture.

	Present (n=4)	Absent (n=21)	p-Value
Duration of TE indwelling (y)	3.1±1.4	2.7±2.6	0.599
Age (y.o.)	47.1±11.3	48.4±8.9	0.607
Operation (n)			0.701
NSM mastectomy	2	7	
after mastectomy	1	10	
Histology (n)			0.664
IDC	3	15	
DCIS	1	3	
others	0	3	
Tumor size of invasion (mm)	17.3±12.5	18.4±13.6	0.966
Lymph node metastasis (n)	0	3	0.578
Luminal type (n)	4	18	0.578
HER2 (n)	1	1	0.300
Nuclear grade 3	2	6	0.382
Lymphovascular invasion (n)	1	9	0.468
Adjuvant chemotherapy (n)	1	1	0.300

Values are expressed as mean±SD. IDC, Invasive ductal carcinoma; DCIS, ductal carcinoma in situ; TE, tissue expander; NSM, nipple-sparing mastectomy; NG, nuclear grade.

none of the clinicopathological features, including primary tumor progression, method of operation, and presence of adjuvant chemotherapy, was significantly associated with TE rupture. However, there were no ruptures in cases where the TE was exchanged within a year (1), and the risk of a rupture in cases with long-term indwelling of TE varied over the follow-up period. Figure 1 shows the time to TE rupture by the Kaplan-Meier curves. TE rupture was observed beginning at 1.5 years after the initial insertion. The rupture rate was 32.6% by the third year, and 55.1% by five years. There were no other major complications, such as hematoma, skin necrosis, wound dehiscence, major infection, capsule contracture, or expander displacement.

Discussion

Surgery is still important as a primary treatment for breast cancer. Immediate breast reconstruction with a tissue expander has become an increasingly popular procedure (1, 3-6). However, this procedure is associated with postoperative complications (6-12). The most frequent complications are capsular contracture and wound infection (10), but TE rupture is also an important complication that underscores the need to exchange a TE within a certain period of time. The rupture rate has been reported to be around 1-3% (8, 9), but rupture may become increasingly likely the longer it remains in place. Although an interval of one year from initial TE insertion in two-stage surgery is

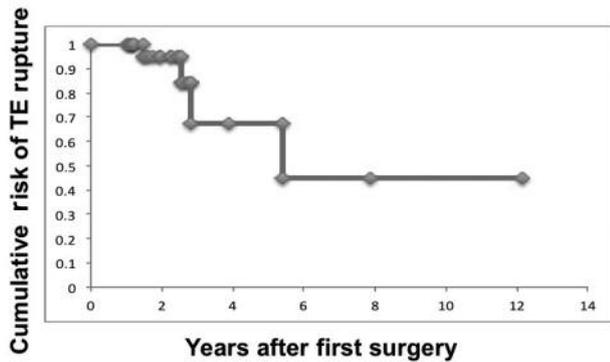


Figure 1. Time to tissue expander rupture by the Kaplan-Meier curves among breast cancer patients with an expander showed a 32.6% rupture rate by the third year, and 55.1% by five years. The median follow-up duration was 2.3 years.

historically considered the standard for TE, the optimal interval between TE exchange is still unclear. Our previous study (1) revealed no major complications, including TE rupture. This absence of ruptures is attributable to the short duration of expander indwelling; all cases underwent the second stage of reconstruction within a year, with the average duration of expander indwelling being 0.56 ± 0.21 years in that series. Because there were no ruptures with TEs replaced within a year, the operative procedure is not to be associated with TE rupture. Furthermore, in the current study, none of the clinicopathological features, including primary tumor progression, method of operation, or presence of adjuvant chemotherapy, was significantly associated with TE rupture. In our rupture cases, there is no definite cause of rupture, including an object bumping against TE. From these findings, it may be of utmost importance to consider the duration of TE indwelling as a risk factor for TE rupture.

Magnetic resonance imaging (MRI) is another factor to consider in cases of long-term indwelling (14-16). Breast TEs are constructed from silicone elastomer and consist of an expansion envelope with a textured surface and a ferromagnetic component of the integrated injection site. The electromagnetic field of the MRI can interfere with biomedical devices, resulting in potential hazards, compromising of the diagnosis, or the creation of artifacts. The presence of artifacts is almost unavoidable. Furthermore, MRI scans could cause TE infusion port dislodgment and heating in the region of the TE (14-16). Thus, when a TE is indwelling, MRI scans should not be performed in patients who need to be evaluated for concurrent diseases. From this viewpoint also, long-term indwelling of TE should be avoided.

This preliminary study has potential limitations, the major one being that the number of cases was relatively small. In addition, we used retrospective methods of data collection.

Additional research on a large number of cases is needed to evaluate the clinical effectiveness of long-term TE indwelling. However, this fundamental proposition cannot be studied in randomized controlled trials. To the best of our knowledge, this is the first report describing the durability of TE and long-term indwelling as a risk factor in TE rupture, which is considered ultimately important clinically.

In conclusion, we have demonstrated that long-term indwelling of TE is associated with TE rupture. As TE rupture was observed beginning at 1.5 years after TE insertion, we recommend that the second stage of breast reconstructive surgery occur within about a year after the first.

Conflicts of Interest

The Authors declare that they have no competing financial interests.

Acknowledgements

The Authors would like to thank Saitoh Y, Yano T, Matsui Y, Ito K and Sato A for their secretarial assistance. Supported by Grants-in-Aid from the Japanese Ministry of Education, Culture, Sports, Science and Technology.

References

- 1 Fujii T, Yajima R, Tatsuki H, Morita H, Suto T, Tsutsumi S and Kuwano H: Immediate tissue-expander breast reconstruction using a skin flap with thick subcutaneous tissue: a preliminary study on selective patients. *Am Surg* 81: 363-365, 2015.
- 2 Yamaguchi S, Asao T, Uchida N, Yanagita Y, Saito K, Yamaki S and Kuwano H: Endoscopy-assisted subcutaneous mastectomy and immediate breast reconstruction for breast cancer: advantage of the posterior approach. *Int Surg* 93: 99-102, 2008.
- 3 Fujii T, Yamaguchi S, Yajima R, Tsutsumi S, Asao T and Kuwano H: Accurate assessment of breast volume by computed tomography using three-dimensional imaging device. *Am Surg* 78: 933-935, 2012.
- 4 Ross GL: One stage breast reconstruction following prophylactic mastectomy for ptotic breasts: The inferior dermal flap and implant. *J Plast Reconstr Aesthet Surg* 65: 1204-1208, 2012.
- 5 Cicchetti S, Leone MS, Franchelli S and Santi PL: One-stage breast reconstruction using McGhan Sytle 150 biodimensional expanders: a review of 107 implants with six years experience. *J Plast Reconstr Aesthet Surg* 59: 1037-1042, 2006.
- 6 Colwell AS, Tessler O, Lin AM, Liao E, Winograd J, Cetrulo CL, Tang R, Smith BL and Austen WG Jr.: Breast reconstruction following nipple-sparing mastectomy: predictors of complications, reconstruction outcomes, and 5-years trends. *Plast Reconstr Surg* 133: 496-506, 2014.
- 7 Gabriel SE, Woods JE, O'Fallon WM, Beard CM, Kurland LT and Melton LJ 3rd: Complications leading to surgery after breast implantation. *N Engl J Med* 336: 677-682, 1997.
- 8 Yan C, Fischer JP, Wes AM, Basta MN, Rohrbach JI, Kovach SJ, Serletti JM and Wu LC: The cost of major complications associated with immediate two-stage expander/implant-based breast reconstruction. *J Past Surg Hand Surg* 49: 166-171, 2015.

- 9 Strock LL: Two-stage expander implant reconstruction: recent experience. *Plast Reconstr Surg* 124: 1249-1236, 2009.
- 10 Peled AW, Stover AC, Foster RD, McGrath MH and Hwang ES: Long-term reconstructive outcomes after expander-implant breast reconstruction with serious infectious or wound-healing complications. *Ann Plast Surg* 68: 369-373, 2012.
- 11 Pinsolle V, Grinfeder C, Mathoulin-Pelissier S and Faucher A: Complications analysis of 266 immediate breast reconstructions. *J Plast Reconstr Aesthet Surg* 59: 1017-1024, 2006.
- 12 Davilla AA, Mioton LM, Chow G, Wang E, Merkow RP, Bilimoria KY, Fine N, and Kim JY: Immediate two-stage tissue expander breast reconstruction compared with one-stage permanent implant breast reconstruction: a multi-institutional comparison of short-term complications. *J Plast Surg Hand Surg* 47: 344-349, 2013.
- 13 Allred DC, Harvey JM, Berardo M and Clark GM. Prognostic and predictive factors in breast cancer by immunohistochemical analysis. *Mod Pathol* 11: 155-168, 1998.
- 14 Nava MB, Bertoldi S, Forti M, Catanuto G, Vergnaghi D, Altomare L, Tanzi MC and Fare S: Effect of the magnetic resonance field on breast tissue expanders. *Aesthetic Plast Surg* 36: 901-907, 2012.
- 15 Duffy FJ Jr. and May JW Jr: Tissue expanders and magnetic resonance imaging: the "hot" breast implant. *Ann Plast Surg* 35: 647-649, 1995.
- 16 Zegzula HD and Lee WP: Infusion port dislodgement of bilateral breast tissue expanders after MRI. *Ann Plast Surg* 46: 46-48, 2001.

Received June 14, 2016

Revised July 6, 2016

Accepted July 8, 2016