A Predictive Model for Determining Permanent Implant Size During 2-Stage Implant Breast Reconstruction

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Background: Two-stage tissue expander (TE)/permanent implant (PI) breast reconstruction remains the most commonly performed technique in breast reconstruction. Predictions for the PI size preoperatively impact on the number and range of implants made available at TE exchange. This study aims to identify critical preoperative variables and create a predictive model for PI size.

Methods: Patients who underwent 2-stage implant breast reconstruction from 2011 to 2017 were included in the study. Linear and multivariate regression analyses were used to identify significant preoperative variables for PI volume.

Results: During the study period, 826 patients underwent 2-stage TE/PI breast reconstruction. Complete records were available for 226 breasts. Initial TE fill ranged from 0% to 102% with a mean final fill of 100.6% of TE volume. The majority of PIs were smooth round (98.2%), silicone (90%) implants. In a multivariate analysis, significant variables for predicting PI size were TE final fill volume ($P < 0.0001$), TE size ($P = 0.03$), and a history of preoperative radiation ($P = 0.001$). Relationships between these 3 variables were utilized to form a predictive model with a regression coefficient of $R^2 = 0.914$.

Conclusions: Significant variables for predicting PI volume were TE final fill volume, TE size, and a history of preoperative radiation. The ability to more accurately predict the PI volume can improve surgical planning, reduce consignment inventory, and simplify operating room workflow.

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techniques are utilized for breast reduction. Developing a predictive model for PI size during TE exchange can simplify workflow and reduce the overall costs of breast reconstruction. This study retrospectively reviewed our experience at a large academic center with 2-stage implant breast reconstruction to identify the significant preoperative reconstructive variables when determining PI size.

**PATIENTS AND METHODS**

All patients who underwent mastectomy and 2-stage TE/PI breast reconstruction at Yale New Haven Hospital from 2011 to 2017 were included in the study. Medical records were reviewed retrospectively with approval from the institutional review board. Patients with incomplete medical records were excluded from the study. Patient demographics, medical history, surgical history, history of radiotherapy, operative details, and reconstructive outcomes were recorded.

After the mastectomy was performed by the breast surgeon, a TE was placed in a partial or complete submuscular plane.

TE size and profile were chosen based on preoperative base diameter measurement and final mastectomy weight. A TE size that matched the mastectomy weight was usually utilized unless there was an alternative patient preference. Postoperative drains were placed in all cases and maintained until 24-hour drain outputs were appropriately low. Patients returned for routine saline TE fills. Final TE fill volume and the size, type, and profile of the PI were a result of discussions between the patient and plastic surgeon.

Patient characteristics were compared with descriptive statistics. Linear regression and multivariate analyses between final TE fill volume and PI size were performed while correcting for body mass index (BMI), breast cup size, surgeon, type of mastectomy, mastectomy weight, TE size, TE projection, presence of acellular dermal matrix (ADM), preoperative radiation, postoperative radiation, implant projection, and PI fill material.

Statistical significance was defined as \( P < 0.05 \). Significant and near-significant values were used to create a predictive equation for PI size. SPSS statistical software (IBM Corporation; Armonk, New York) was utilized for all statistical analyses.

**RESULTS**

**Patients and Demographics**

Eight-hundred twenty-six patients underwent 2-stage implant breast reconstruction from 2011 to 2017. Complete records were available for 140 patients for a total of 226 breasts. Patients’ mean age was 54 (range, 25–81) with a mean BMI of 27 (range, 16–44).

A total of 3.9% of breasts had a history of irradiation before mastectomy, whereas 8.8% of breasts received radiation therapy following mastectomy and before TE exchange. The majority of mastectomies were skin sparing (81.7%) with a smaller proportion of nipple-sparing mastectomies (11.6%) (Table 1).

The majority of TEs were Mentor CPX4 (99.5%) and medium projection (80.1%) ranging in size from 225 to 850 cc (Fig. 1). Initial fill in the operating room at the time of TE placement ranged from 0 to 600 cc or 0–102% of the TE volume. Mean time between TE placement and exchange was 188 days (range, 43–1,028 days). Mean final fill volume percentage was 100.6% (range, 46–155%) of TE volume. The majority of PIs placed were high (63%) or moderate plus (26%) profile, smooth round (98%), silicone (90%) implants. Mean PI size was 505 cc with a range from 180 to 960 cc.

**Reconstructive Outcomes**

Mastectomy specimen weights were compared with preoperative self-reported breast cup size, TE size, and PI size. PI sizes were significantly different between patients with A cup versus B cup breasts (\( P < 0.0001 \)) and B cup versus C cup breasts (\( P = 0.034 \)), but differences were not significant between patients with breasts larger than C cup (Table 2).
Similarly, the weight of the mastectomy specimen increased as self-reported breast cup size increased. There was a significant difference in mastectomy specimen weights between cup sizes A and B ($P < 0.001$), B and C ($P = 0.011$), and D and DD ($P = 0.042$; Table 3).

When ADM was used, patients had larger initial TE fill volume ($P < 0.0001$), final TE fill volume ($P = 0.012$), and PI size ($P = 0.015$; Table 4). Time between TE placement and TE exchange was not significantly different with ADM ($P = 0.494$). Higher intraoperative initial TE fill from use of ADM did not have a statistically significant impact on postoperative complications such as mastectomy flap necrosis, infection, or implant explantation.

The linear regression between mastectomy weight and TE final fill volume and PI size had correlation coefficients of 0.43 and 0.40, respectively (Fig. 2).

Difference in volume between the PI and final TE fill volume was calculated for each breast (Fig. 3). With respect to PI and TE volumes, 73.2% of breasts had greater PI volume than TE final fill volume, whereas 8.3% had matching PI volume to TE final fill volumes, and 18.4% of breasts had a smaller PI than TE final fill volume. TEs were grouped into categorical variables for final TE fill volume ranges, and mean PI volumes were compared within each TE size grouping yielding no overlapping 95% confidence intervals between any group.

A multivariate analysis was used to evaluate the relationship between TE final fill volume and PI size. Variables were evaluated both independently and simultaneously (Table 5). Significant variables included TE final fill volume ($P < 0.0001$), TE size ($P = 0.003$), history of preoperative radiation ($P = 0.001$), and breast cup size ($P = 0.031$). On simultaneous multivariate analysis, modified radical mastectomy also achieved significance ($P = 0.034$).

A predictive equation for PI size during TE exchange was calculated using final TE fill volume, TE size, and whether the patient had a history of preoperative breast radiation with an $R^2$ of 0.914:

$$PI = 71.7 + 0.8(TE\ Final\ Fill) + 0.1(TE\ Size) - 50.2(XRT)$$

TE size and TE final fill volume are reported in milliliters and preoperative radiation is represented as a binary value (1 = yes, 0 = no; Table 6). Although a modified radical mastectomy was statistically significant, its regression coefficient of 1 lacked clinical significance to justify inclusion in the formula. Preoperative breast cup size was only significant between A to B and B to C cup breasts and, therefore, excluded from the formula. TE and PI projection were not statistically significant, $P = 0.074$ and $P = 0.163$, respectively.

**DISCUSSION**

We retrospectively reviewed our multi-year institutional experience with 2-stage implant breast reconstruction. Multivariate regression analysis compared the significant variables for PI size during TE exchange. A predictive equation for PI size incorporating TE size, TE final fill volume, and history of radiation therapy was developed with a regression coefficient of 0.914. Although many centers have implants on consignment, the full range of implant

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### Table 2. Breast Cup Size and PI Size

| Breast Cup Size | Mean Implant Size (cc) | Breast Cup Comparison | $P$  |
|-----------------|------------------------|-----------------------|------|
| A               | 295.3 ± 66.6           | A versus B            | < 0.0001 |
| B               | 472.9 ± 126.4          | B versus C            | 0.0340 |
| C               | 549.7 ± 159            | C versus D            | 0.1590 |
| D               | 620.7 ± 164.9          | D versus DD           | 0.6860 |
| DD              | 645 ± 105.2            |                       |      |

All data reported as mean ± SD. Bold signifies a statistically significant $p$-value ($p<0.05$).

### Table 3. Breast Cup Size and Mastectomy Weight

| Breast Cup Size | Mean Mastectomy Weight (g) | Breast Cup Comparison | $P$  |
|-----------------|----------------------------|-----------------------|------|
| A               | 172.3 ± 87.76              | A versus B            | < 0.0001 |
| B               | 409.9 ± 171                | B versus C            | 0.0110 |
| C               | 571.6 ± 304.3              | C versus D            | 0.5760 |
| D               | 622.7 ± 220.8              | D versus DD           | 0.0420 |
| DD              | 819.0 ± 223.5              |                       |      |

All data reported as mean ± SD.
Table 4. The Effect of ADM on TE Fill, Duration of Expansion, and PI Size

| Implant and Patient Characteristics | ADM Range | No ADM Range | P   |
|------------------------------------|-----------|--------------|-----|
| TE initial fill (cc)               | 231.4 ± 157.3, 0–600 | 118.4 ± 118.4, 0–600 | < 0.0001 |
| TE initial fill (%)                | 44.5 ± 24.1, 0–103 | 25.4 ± 23.5, 0–86 | < 0.0001 |
| TE final fill (cc)                 | 505.1 ± 174.9, 200–810 | 445.9 ± 179.3, 150–900 | 0.0119 |
| TE final fill (%)                  | 102.1 ± 19.1, 46–156 | 98.6 ± 20.4, 49–138 | 0.1917 |
| Expansion duration (d)             | 171.3 ± 135.8, 68–647 | 182.7 ± 113.1, 43–531 | 0.4940 |
| PI volume (cc)                     | 534.1 ± 166.3, 200–800 | 480.1 ± 166.3, 180–960 | 0.0145 |
| Mean BMI                           | 27.5 ± 6.6, 16–44 | 26.5 ± 5.8, 18–41 | 0.2965 |

All data reported as mean ± SD.

Fig. 2. A, Linear regression model between the mastectomy specimen weight (g) and associated TE final fill volume (cc) ($r^2 = 0.43$). B, Linear regression model comparing mastectomy specimen weight (g) to PI size (cc) ($r^2 = 0.40$).

Fig. 3. Differential between PI volume and final TE fill volume derived by subtracting the PI size (cc) from the TE final fill volume (cc).
sizes and quantities are not always available. Other institutions order implants per case, returning unused implants and generating significant back end workflow with regard to purchase orders.

Implant sizers and PIs of varying volume are ordered for each TE exchange. With growing experience, surgeons’ ability to predict final PI size improves. Developing a predictive model for PI sizing enables improved estimation of the final PI size.

The 3 significant variables for predicting final PI size were TE final fill volume, TE size, and history of preoperative radiation. Although TE fill volume and size are correlated, including both in the final formula yielded a higher overall regression coefficient. Preoperative radiation was associated with a 50 cc decrease in PI size regardless of TE fill volume. As expected, a history of preoperative radiation resulted in lower final implant volumes likely related to reduced soft-tissue compliance. The high complication risk associated with implant reconstruction in the setting of irradiated breasts has been well documented, but to our knowledge, no studies exist evaluating the impact of radiation on final PI size.5

The introduction of ADM in breast implant reconstruction represented a major and controversial development in breast reconstruction.10 Our study demonstrates that ADM use increases initial and final TE fill volume and PI size. Although ADM use may theoretically reduce the total number of fills required by increasing intraoperative fill volumes, it did not impact on time between TE placement and exchange as likely surgical timing was independent of completion of TE expansion alone.3,11,12

The relationships between self-reported bra cup size, mastectomy weight, and implant size were insightful findings. PI size increased with self-reported breast cup size, but above a C cup there was no statistically significant difference. The largest silicone and saline implants in the United States are 800 cc and 960 cc, respectively. At the larger end of breast sizes, there may not be adequately sized breast implants to replace mastectomy volumes. Furthermore, multiple studies have documented incorrect bra sizing in up to 70% of women and bra cup size variability by style, fabric, padding, and elastics.13,14 In contrast, the relationship between increasing bra cup size and mastectomy weights was more consistent at higher bra cup sizes. The relationships between bra size, mastectomy weight, and implant size are intuitive to plastic surgeons performing reconstruction. However, quantifying the relationship offers objective confirmation. Notably, the plastic surgeon did not impact on the predictive equation for PI volume. Implant projection and mastectomy type did not have a clinically significant impact on final PI size either. Limitations to the study include its retrospective nature. The majority of the mastectomies were skin-sparing with predominantly smooth, round silicone implants used. Generalizability of results would be limited to smooth, round silicone implants, and the CPX4 Mentor TEs or their equivalent for Allergan and Sientra. Patient-reported outcomes to assess patient satisfaction using this formula were not available and are planned in an upcoming study.

Our equation for determining PI size has a high predictive value. With better presurgical implant planning, there is an opportunity to reduce the range of PIs required for each TE exchange. Application of the formula has the opportunity to simplify workflow, decrease implant storage space in the operating room, and simplify purchase orders and indirect costs of breast reconstruction. Future research directions include a prospective trial utilizing the predictive formula combined with a financial analysis to determine direct and indirect cost savings.

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REFERENCES
1. 2016 Plastic surgery statistics report. Available at: https://www.plasticsurgery.org/news/plastic-surgery-statistics. Accessed July 1, 2017.
2. Albornoz CR, Bach PB, Mehrara BJ, et al. A paradigm shift in U.S. breast reconstruction: increasing implant rates. Plast Reconstr Surg. 2013;131:15–23.
3. Qureshi AA, Broderick K, Funk S, et al. Direct hospital cost of outcome pathways in implant-based reconstruction with acellular dermal matrices. Plast Reconstr Surg Glob Open. 2016;4:e831.
4. Radovan C. Breast reconstruction after mastectomy using the temporary expander. Plast Reconstr Surg. 1982;69:195–208.
5. Fitzpatrick AM, Gao LI, Smith BL, et al. Cost and outcome analysis of breast reconstruction paradigm shift. Ann Plast Surg. 2014;73:141–149.
6. Qiao Q, Zhou G, Ling Y. Breast volume measurement in young Chinese women and clinical applications. Aesthetic Plast Surg. 1997;21:362–368.
7. Longo B, Farcomeni A, Ferri G, et al. The BREAST-V: a unifying predictive formula for volume assessment in small, medium, and large breasts. Plast Reconstr Surg. 2013;132:1e–7e.

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Table 5. Independent Regression Model for Predicting PI Size

| Implant and Patient Characteristics | P       |
|-----------------------------------|---------|
| PI size                           | N       |
| TE final fill                     | < 0.0001|
| TE size                           | 0.0030  |
| TE projection                     | 0.4620  |
| Mastectomy weight                 | 0.2030  |
| BMI                               | 0.8220  |
| Surgeon                           | 0.1930  |
| Implant projection                | 0.1650  |
| Saline                            | 0.5700  |
| Nipple sparing                    | 0.7630  |
| Modified radical                  | 0.8070  |
| Preoperative radiation            | 0.0010  |
| Postoperative radiation           | 0.6330  |
| Alloderm                          | 0.8300  |
| Cup size                          | 0.0250  |

Table 6. A Predictive Equation for Preoperatively Estimating PI Size

R2 = 0.914
PI = 71.7 + 0.8 (TE final fill) + 0.1 (TE size) – 50.2 (XRT)

TE final fill: volume (cc); TE size: volume (cc); Rx Pre: 1 = yes, 0 = no. XRT = history of pre-operative radiation.
8. Tebbetts JB, Adams WP. Five critical decisions in breast augmentation using five measurements in 5 minutes: the high five decision support process. *Plast Reconstr Surg.* 2006;118:35S–45S.

9. Fischer LH, Nguyen D. Double-chamber tissue expanders optimize lower pole expansion in immediate breast reconstruction requiring adjuvant radiation therapy. *Ann Plast Surg.* 2016;76:S171–S174.

10. Breuing KH, Colwell AS. Immediate breast tissue expander-implant reconstruction with inferolateral AlloDerm hammock and postoperative radiation: a preliminary report. *Eplasty.* 2009;9:e16.

11. Sbitany H, Serletti JM. Acellular dermis-assisted prosthetic breast reconstruction: a systematic and critical review of efficacy and associated morbidity. *Plast Reconstr Surg.* 2011;128:1162–1169.

12. Pannucci CJ, Antony AK, Wilkins EG. The impact of acellular dermal matrix on tissue expander/implant loss in breast reconstruction: an analysis of the tracking outcomes and operations in plastic surgery database. *Plast Reconstr Surg.* 2013;132:1–10.

13. Pechter EA. A new method for determining bra size and predicting postaugmentation breast size. *Plast Reconstr Surg.* 1998;102:1259–1265.

14. Bengtson BP, Glicksman CA. The standardization of bra cup measurements: redefining bra sizing language. *Clin Plast Surg.* 2015;42:405–411.