


# The Learning Curve of Reverse-Sequence Endoscopic Nipple-Sparing Mastectomy with Immediate Prepectoral Implant Reconstruction: CUSUM Analysis

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**Background:** The reverse-sequence endoscopic nipple-sparing mastectomy with immediate prepectoral implant reconstruction (RSEM-IPI) has been described as a safe and feasible procedure for early-stage breast cancer. The aim of this study was to evaluate the learning curve for RSEM-IPI.

**Methods:** Between January 2023 and February 2024, we collected data on 104 consecutive patients who underwent RSEM-IPI at our hospital (53 for group 1 and 51 for group 2). The surgeons in group 1 completed the endoscopic training and assistance, whereas the surgeons in group 2 did not. The learning curve was analyzed using the cumulative sum (CUSUM) method to assess changes in the operative times across the case sequence.

**Results:** Among the 281 patients who received breast reconstruction surgeries, a total of 104 consecutive data were recorded and eligible. Both groups had higher rates of postoperative complications including bleeding, nipple-areolar complex (NAC) ischemia, skin ischemia, infection and longer drainage duration during the phrase 1 compared to the phrase 2. Notably, in terms of the most severe postoperative complications, implant expose and loss, both groups exhibited higher rates during the phrase 1. Breast-Q scores for group 1 in phases 1 and 2 were 66 and 84, respectively, while for group 2, they were 67 and 80. As compared with surgeons in group 2, well-trained surgeons in group 1 were more accessible for stable learning curve with fewer training patients (18 patients) and relatively lower rate of postoperative complications ( $p > 0.05$ ).

**Conclusion:** The estimated learning curve for RSEM-IPI was achieved after 18 cases in the well-trained surgeon group. The endoscopic training and assistance were critical to master the breast endoscopic surgeries for breast surgeons.

**Keywords:** breast cancer reconstruction, learning curve, reverse-sequence, endoscopic mastectomy

## Introduction

Breast cancer has become the second most common malignant tumor in humans.<sup>1,2</sup> The incidence of breast cancer continues to rise globally and in China.<sup>1,2</sup> With the advancement of research, the 5-year survival rate for breast cancer patients has increased by nearly 10% over the past decade.<sup>2,3</sup> Among these treatments, surgery remains a crucial method for curing early-stage breast cancer patients.<sup>4,5</sup> Over the past century, surgical techniques for breast cancer have undergone revolutionary changes, becoming more precise, minimally invasive, and less damaging.<sup>5,6</sup>

Early-stage breast cancer patients may not be suitable for breast-conserving surgery and may face the dilemma of mastectomy. The choice of breast reconstruction surgery poses a challenge for all breast surgeons. Autologous reconstruction is time-consuming, labor-intensive associated with significant trauma and long-time recovery. Although its acceptance has increased in recent years, its clinical application remains limited due to the complexity of the procedure.<sup>7</sup> Prosthetic reconstruction is currently the mainstream choice, as it is relatively simple to perform, which has fewer complications and is widely accepted by clinicians.<sup>8,9</sup> Prepectoral implant reconstruction is more widely used in clinical practice due to its

superior cosmetic outcomes.<sup>8</sup> Professor Zhenggui Du from West China Hospital of Sichuan University has modified the endoscopic mastectomy + immediate prosthetic implantation technique by a reverse-sequence method for breast removal.<sup>8</sup> This technique, known as the reverse-sequence endoscopic nipple-sparing mastectomy with immediate prepectoral implant reconstruction (RSEM-IPI), has gained widespread acceptance due to its scarless approach on the breast.

Breast endoscopic surgery has been developed over a decade, but RSEM-IPI procedure has recently been promoted in China.<sup>8,10</sup> Our research team has been actively engaged in related explorations and has accumulated a certain level of technical expertise. We aimed to construct the learning curve of RSEM-IPI by analyzing previous data, thereby assisting more breast surgeons in achieving rapid growth, mastering this technique swiftly, reducing postoperative complications, and comparing the advantages and disadvantages of RSEM-IPI with other breast surgical treatments.

## Materials and Methods

### Patients and Groups

We retrospectively analyzed all patients with early-stage breast cancer in the comprehensive breast care center, the second affiliated hospital of Xi'an jiaotong university. Between January 2023 and February 2024, 104 patients with early-stage breast cancer performed the reverse-sequence endoscopic nipple-sparing mastectomy with immediate prepectoral implant reconstruction, who were divided into two groups, group 1 and group 2. Group 1 was Yang Zhao and Shuai Lin's group, including 53 patients, as well as group 2 was other surgeons' group, including 51 patients. The surgeons and assistants in group 1 completed 3-month endoscopic training of breast cancer surgery and 6-month laparoscopic assistance in our hospital and West China hospital. On the other hand, the surgeons and assistants in group 2 were not assigned to complete the endoscopic training and laparoscopic assistance. All patients signed the operation consents. Besides, all surgeons and assistants in each group had completed more than 300 traditional operations of breast cancer. The therapeutic strategies of patients with breast cancer were drawn up according the national comprehensive cancer network (NCCN) guideline for breast cancer (<https://www.nccn.org/>).

### Clinical Parameters and Files

One hundred and four patients with early-stage breast cancer in group 1 and group 2 were eligible for our study. All clinical parameters of 104 breast cancer patients were recorded in our center. The clinical parameters included age, gender, T status, lymph node status, hormone receptor status, Her-2 status, neoadjuvant/adjuvant chemotherapy and radiotherapy. As we did the learning curve analysis, the post- and intra-operative parameters including bleeding volume, drainage duration, nipple-areolar/skin ischemia, infection, implant expose and implant loss were involved in our study. In addition, Breast-Q questionnaire was completed to acquire the cosmetic Q score<sup>11,12</sup> at the postoperative 3 month. We characterized the operation time as the single parameter to establish learning curve. According to learning curve, different phases were divided for learning RSEM-IPI. Operative time was characterized as the timing of RSEM and implant placement.

### Inclusion and Exclusion Criteria

Inclusion and exclusion criteria were made up according to the guideline of breast cancer reconstruction of China.<sup>13</sup> Inclusion criteria: 1. Female; 2. Invasive breast cancer or breast carcinoma in situ; 3. Contraindications or refusal of breast-conserving surgeries; 4. Thickness of subcutaneous tissue was acceptable for RSEM-IPI, sub-areolar biopsy confirmed as tumor-free and negative; 5. Signed consent form; 6. Clinicopathological data were available; 7. Breast ptosis grade 1–2.<sup>14</sup> The indications of RSEM-IPI were referred to Zhenggui Du's paper.<sup>8</sup>

Exclusion criteria: 1. Metastatic breast cancer; 2. No accomplishment of R0 resection, skin invasion or satellite nodules; 3. Severe underlying diseases or severe cardiopulmonary dysfunction leading to the inability to tolerate general anesthesia; 4. Clinicopathological data was missed or unavailable; 5. Breast ptosis grade 3.<sup>14</sup>

### Operative Team and Technique

The surgeons and assistants in group 1 and group 2 cooperated together for 1 year or longer. The breast surgery nurses team had been built for 2 years, who were able to understand the concept of breast reconstruction and do a favor to finish the reconstruction surgery. The operations were performed according to the guideline of Zhenggui Du's team.<sup>8,10</sup> In brief, the

incision of axillary fossa skin was designed and applied, 4–5 cm, to sentinel lymph node biopsy or axillary lymph node dissection, where the disposable surgitactor for breast cancer was fixed on the incision. The flow rate and pressure were facilitated as 15 L/min and 12 mmHg, respectively. Then, the mammary gland was freed by retromammary space between mammary gland and pectoralis major, and subcutaneous tissue between skin and mammary gland. The implant (Mentor, USA) was put into the prepectoral space, and the Fowler's or semi-upright position was intra-operatively used for the cosmetic outcome of implant. The operation times were recorded (min). The implants in this study were provided from Mentor 311 and 321 series. TiLoop mesh (PFM, Germany) was selectively used for patients with prebreast cancer receiving postoperative radiation.

## Postoperative Follow-up and Oncological Outcomes

Patients were scheduled for follow-up visits every 3 months for the first 2 years, then every 6 months for a further 3 years, and every year thereafter. Patients were requested to complete the self-administered Breast-Q questionnaires at 3 months after surgery to acquire the satisfaction degree for the cosmetic outcome of implant-based reconstruction.

## Cumulative Sum (CUSUM) Analysis and Fitting Curve Equation

CUSUM analysis was a statistical technique applied to surgical procedures for the quantitative estimation of learning curve, which was the running total of differences between the individual data points and the average of all data points. In the present study, we referred to the RSEM-IPI operative time as the parameter for CUSUM. Cases were arranged chronologically from the earliest case to the latest case. CUSUM was defined using the following equation:  $CUSUM_n = \text{Operation time}_n - \text{Operation time}_{\text{average}} + CUSUM_{n-1}$ .<sup>15,16</sup> According to the CUSUM process, the learning curve can be represented intuitively while detecting consistent changes in the operative time. The fitting curve equations of group 1 and group 2 were established in the software of Excel.

## Statistical Analysis

All statistical analyses were performed using the Statistical Package for Social Sciences, version 25.0 (SPSS, Chicago, USA). Continuous variables are expressed as means or medians and were compared using ANOVA and t tests, according to the normality of data and the homogeneity of variance test. Categorical variables are expressed as proportions and were compared using the Chi-square and Fisher's exact tests. In this study, the learning curve was analyzed using the CUSUM methods. Two-sided *P* values < 0.05 were considered as significant.

## Results

### Study Flow Chart and Patients' Characteristics

As shown in [Figure 1](#), the flow chart of this study was constructed. We retrospectively analyzed all patients with breast cancer performing immediate breast reconstruction in the comprehensive breast care center of the second affiliated hospital of Xi'an jiaotong university from January 2023 to February 2024. One hundred and four patients with early-stage breast cancer were eligible for our study (RSEM-IPI), who were divided into two groups, group 1 (Yang Zhao and Shuai Lin' group for 53) and group 2 (Weili Min's group for 51). The clinicopathological characters of the patients in group 1 and group 2 were shown in [Table S1](#). Accordingly, the similar distribution of the different clinicopathological parameters were observed between group 1 and group 2.

### Surgical Technique and Process of RSEM-IPI

All surgeons in group 1 and group 2 had the ability to perform a variety of breast cancer surgeries, including mastectomy, breast-conserving surgery, sentinel lymph node biopsy and axillary lymph node dissection. The surgeons in group 1 were assigned to achieve the endoscopic training and assistance ([Figure 2](#)), but the surgeons in group 2 not.

The operative procedures and notions were referred to Zhenggui Du's instructions.<sup>8,10</sup> During the RSEM-IPI, we fixed and located trocars in the axillary incision ([Figure 3A](#)). We initially freed the mammary gland in the retromammary space. Then, the mammary gland was completely removed through the subcutaneous tissue layer ([Figure 3B and C](#)). RSEM-IPI was able to provide an opportunity to create the aesthetic outcome with the non-wounded breast skin.

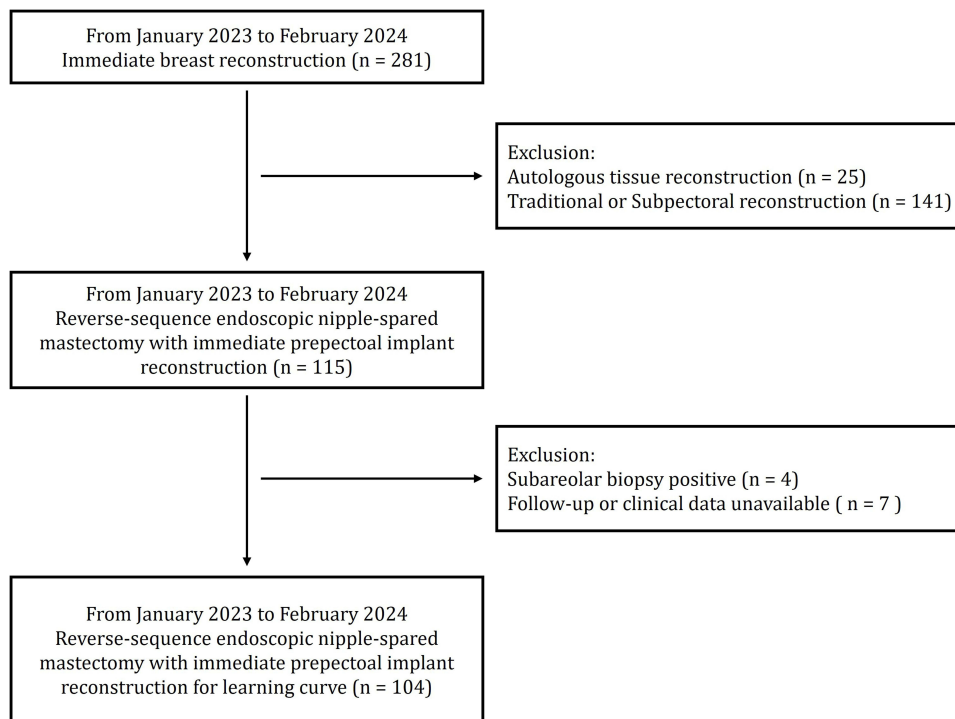


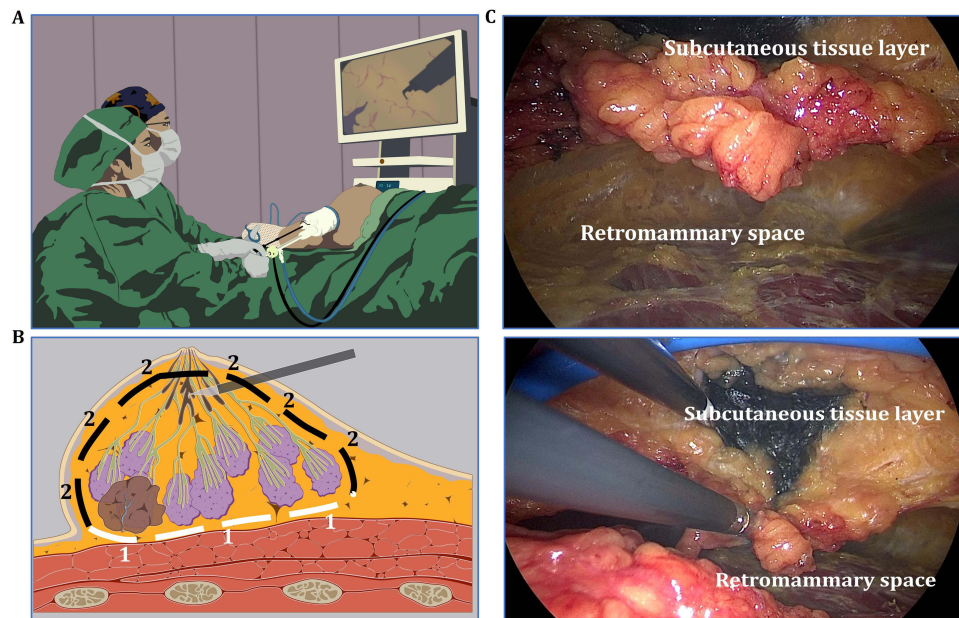
Figure 1 Flow chart of study for learning curve analysis.



Figure 2 Endoscopic training.

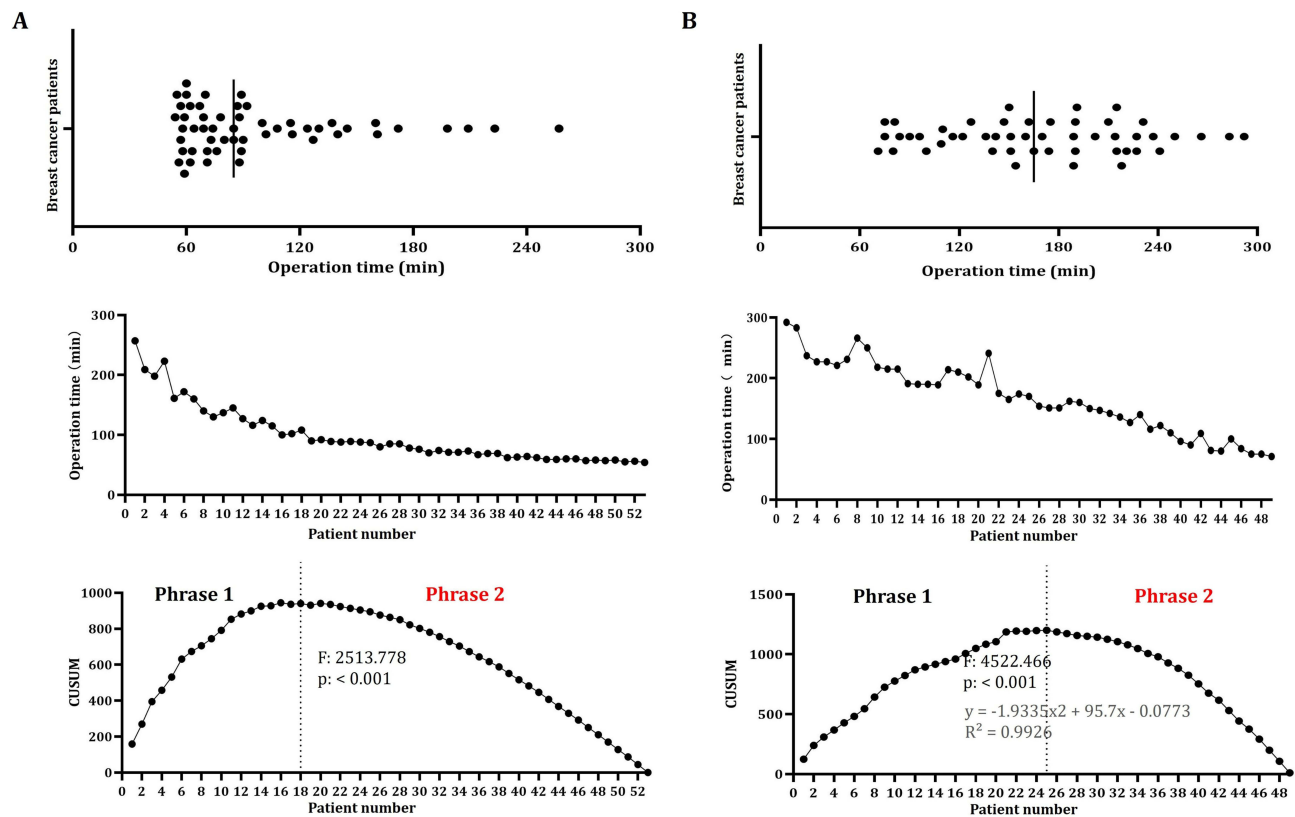
### Learning Curve Analysis of RSEM-IPI

All 104 eligible patients with early-stage breast cancer underwent RSEM-IPI in the group 1 and group 2, and the consecutive data were recorded. In the cohort of group 2, 2 patients did not complete RSEM-IPI, while performed the traditional mastectomy with the immediate implant reconstruction. We defined the operative time as the single variable for CUSUM



**Figure 3** RSEM-IPI. **(A)** Surgical techniques of RSEM-IPI. **(B)** Schematic diagram of RSEM-IPI. The dashed lines delineated the extent of the resected breast tissue. “1” indicates the white dashed boundary at the base of the gland, while “2” denotes the black dashed boundary on the epidermal side of the gland. **(C)** Subcutaneous tissue layer and retromammary space showed during surgery.

analysis. The operative time from the patients from group 1 and group 2 are shown in **Figure 4A** and **B**. According to the operative time from group 1 and group 2, we established the learning curves for group 1 and group 2, by which the curve fitting equations for group 1 and group 2 were conceived for group 1:  $y = -1.1112x^2 + 50.454x + 332.4$  and group 2:  $y = -1.9335x^2 +$



**Figure 4** Learning curves of RSEM-IPI in group 1 **(A)** and group 2 **(B)** according the operative time.

95.7x - 0.0773. We divided the learning curves of group 1 and group 2 into two phrases, phrase 1 (learning phrase) and phrase 2 (mastering phrase) (Figure 4A and B). According to the learning curve of group 1, case 1–18 represented phrase 1, as well as case 19–53 indicated phrase 2. In the group 2, case 1–25 represented phrase 1, while case 26–49 indicated phrase 2. Hence, surgeons in the group 2 needed more cases to access phrase 2. It indicated that endoscopic training and assistance was dominant to promote surgeons' ability to complete RSEM-IPI.

## Postoperative Outcomes and Complications in the Different Learning Phrases

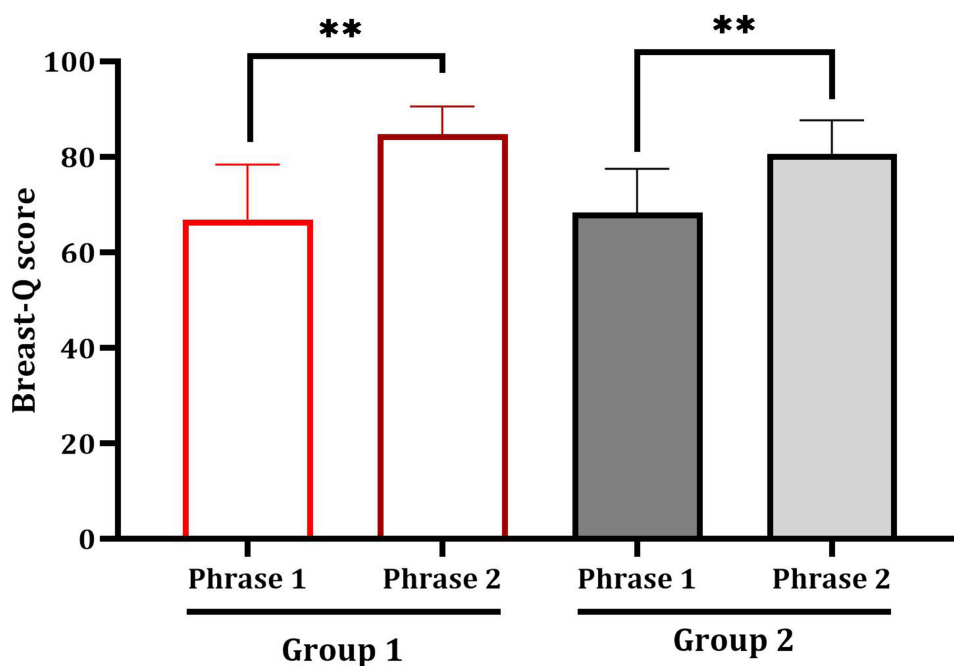
Through comparison, we found that both groups had higher rates of postoperative complications including bleeding, nipple-areolar complex (NAC) ischemia, skin ischemia, infection, drainage duration during the phrase 1 compared to the phrase 2 (Table S2). Notably, in terms of the most severe postoperative complications, implant expose and loss, both groups exhibited higher rates during the phrase 1 (Table S2). It indicated that the proficiency could only be achieved through the accumulation of case experience during the learning process. Intriguingly, we observed that during the phrase 1, the postoperative complication rate in group 1 was lower than that in group 2, further emphasizing the necessity of comprehensive training and laparoscopic-assisted practice, whereas our data showed no significant differences between the both groups. It might be due to the relatively small number of cases included. We planned to further expand our sample size for analysis.

## Aesthetic Outcomes After RSEM-IPI

The evaluation of the cosmetic outcomes of RSEM-PI was a crucial component of the overall surgical assessment. We employed the Chinese version of the Breast-Q scale to assess the cosmetic effects in surgical patients. Preliminary observations revealed that, despite the use of Tiloop mesh, the impact of radiotherapy on cosmetic outcomes remained destructive (Figure 5A and B). To illustrate the cosmetic finale of the surgery and to exclude the influence of radiotherapy, we chose to



**Figure 5** Aesthetic outcomes for patients (patient 1 (A) and patient 2 (B)) receiving RSEM-IPI after radiation. The arrow-pointed region served as the comparative area for evaluating the effects of radiotherapy versus non-radiotherapy on breast aesthetic outcomes.



**Figure 6** Breast-Q scores for phrases 1 and 2 in the groups 1 and 2. \*\* $p < 0.01$ .

apply the Breast-Q scale at the post-surgery 3 months before the initiation of radiotherapy. We utilized the Breast-Q template specifically designed for breast reconstruction, focusing on breast satisfaction after surgery. According to our observations, the cosmetic scores in both groups during Phase 1 were significantly lower than those in Phase 2 ( $P < 0.001$ , Figure 6). The average Breast-Q scores for group 1 in phases 1 and 2 were 66 and 84, respectively. While for group 2, they were 67 and 80 (Figure 6). These findings further validated the rationality of our learning curve.

## Discussion

The treatment modalities for breast cancer are constantly evolving, with drugs being updated and treatment models innovated.<sup>4,8,17</sup> However, it is undeniable that surgery remains a method for curing early-stage breast cancer.<sup>18,19</sup> Surgical approaches for breast cancer are also continuously changing, with breast-conserving surgery and sentinel lymph node biopsy as representative examples. These surgical methods have become more refined and diverse, placing higher demands on breast surgeons. The breast is a symbolic organ for women, and breast surgery, to varying degrees, affects women's psychological and physiological health.<sup>3,11</sup> In clinical practices of breast surgeons, there is indeed a subset of early-stage breast cancer patients who cannot undergo breast-conserving surgery and face the dilemma of mastectomy. Breast reconstruction is an inevitable choice for these patients. The first choice is whether to perform immediate reconstruction or delayed reconstruction. Based on current clinical data, immediate reconstruction should be the preferred option due to fewer complications, lower costs, and better cosmetic outcomes.<sup>20</sup> On the other hand, the debate between autologous reconstruction and implant-based reconstruction persists.<sup>7,21</sup> Autologous reconstruction is more surgically challenging, costly, and has a slower recovery, but it offers better long-term results and is less affected by radiotherapy. In contrast, implant-based reconstruction is more affected by radiotherapy and has slightly inferior long-term results compared to autologous reconstruction, but it is less surgically challenging, less costly, and has a prompt recovery. Implant-based reconstruction remains mainstream in breast cancer reconstruction surgery. Implant-based immediate reconstruction was more commonly performed subpectoral, but the subpectoral space is artificially created and restricted, and the implant is significantly affected by the pectoralis major muscle leading to pronounced capsular contracture after radiotherapy.<sup>22,23</sup> Therefore, prepectoral implant-based immediate surgery recently has begun to emerge as the mainstream.

The placement of the implant in the prepectoral space avoids limiting impaired muscle function, muscle spasms, postoperative pain, and the dreaded animation deformity.<sup>24</sup> Additional surgery is needed to modify the animation deformity

but converting the submuscular or dual plane implant to prepectoral reconstruction. Endoscopic breast cancer surgery has been widely reported by Jiang Jun's team who have made outstanding contributions in this field.<sup>25</sup> Through the lipolysis method, axillary lymph node dissection can be successfully performed. However, mastectomy remains challenging. The team led by Zhenggui Du from West China Hospital proposed the reverse sequence method for breast cancer resection combined with immediate prosthetic implantation.<sup>8</sup> The RSEM-IPI surgery was used in clinical practice for about a decade, and the application of laparoscopy in breast reconstruction was limited by a lack of experience. Prepectoral surgery, where the prosthesis is covered by the skin, increases the risk of failure, but the risk could be mitigated by improving surgical techniques. The learning curve is a prerequisite for mastering any new surgical procedure and represents the inevitable process through which the surgeon progresses from inexperience to proficiency. The learning curve was constructed using the CUSUM method, and our study selected operative time as the single variate to build the learning curve. Based on our team's observations, 18 cases of RSEM-IPI surgery were generally sufficient to meet the learning process of surgeons, enabling them to master this technique proficiently. By comparing the surgeons in group 2, we found that the thorough laparoscopic training and preparatory work are essential prerequisites for performing RSEM-IPI surgery, effectively reducing postoperative complications, particularly for implant expose or loss. Our results also reaffirmed the reality of the learning curve, where the incidence of complications was higher during the learning phase. Specifically, the complication rates in both groups during the learning phase (Phrase 1) were higher than those in the proficient phase (Phrase 2).

For breast reconstruction surgery, aesthetic satisfaction is of paramount importance. The Breast-Q scale is the most widely used aesthetic satisfaction scale among breast plastic surgeons worldwide.<sup>26,27</sup> In our study, we employed the aesthetic satisfaction scale of the breast reconstruction module to evaluate postoperative aesthetic satisfaction. Our team also incorporated breast aesthetics as a crucial component in assessing the learning curve. We observed that during the phrase 1, the breast aesthetic scores were significantly lower than those in the phrase 2, indicating that surgical outcomes can be improved through learning. Our findings suggested that with sufficient practice, this surgical technique could be mastered and effectively applied in clinical settings, providing valuable insights and assistance for surgeons aspiring to perform this procedure. However, the limited number of cases in this study might have influenced the results. We expected to observe our findings in studies with larger sample sizes and longer follow-up period.

## Conclusion

RSEM-IPI surgery has been increasingly accepted by more breast surgeons. Our research findings will encourage more breast surgeons to standardize their learning and practice of RSEM-IPI, thereby making RSEI-IPI surgery more standardized.

## Data Sharing Statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author upon reasonable request.

## Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki. The procedures of this study were approved by the ethics committee of the second affiliated hospital of Xi'an jiaotong university (2024YS096). We obtained consent from the participants to access their medical records.

## Consent for Publication

All authors consent for publication. Consent forms have been signed.

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## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

The authors report no conflicts of interest in this work.

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