### Cost Comparison of Immediate One-Stage And Tissue-Expander Breast Reconstructions After Mastectomy in Commercially Insured Patients

There was little difference between the options in terms of the frequency and cost of return visits. Patients receiving one-stage reconstructions returned slightly less often for breast-related services during the first 18 months after reconstruction, but the difference was not statistically significant.

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### **ABSTRACT**

Objective: Growing acceptance of nipple-sparing mastectomy and rising rates of prophylactic mastectomy due to genetic findings make immediate one-stage implant breast reconstruction an attractive option for many American women facing post-mastectomy breast reconstruction. We compared medical services utilization and cost of immediate one-stage reconstruction with that of the more common tissue-expander (TE) breast reconstruction.

**Design:** Retrospective administrative claims database analysis.

Methods: We obtained commercial insurance claims on patients in the U.S. who had undergone one-stage or TE post-mastectomy implant breast reconstructions in 2008, and we compared 18-month results in terms of the frequency and cost of return visits for additional procedures and/or for the treatment of complica-

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tions. Return visits were categorized as planned, planned with revision, or unplanned.

Results: Among 1,316 immediate implant breast reconstructions, 95 (7%) were one-stage procedures and 1,221 (93%) were TE reconstructions. The data showed a modest, nonsignificant trend toward fewer return visits after one-stage reconstruction versus TE reconstruction (191 vs. 242 visits per 100 patients, respectively; relative risk [RR]: 0.95). Patients with TE reconstructions returned more often for planned returns and planned returns with revisions. Patients with one-stage reconstructions returned more often for unplanned events. The total costs over 18 months were \$34,839 and \$39,062 for one-stage and TE reconstructions, respectively, for a difference of -\$4,223 (P = 0.38). The initial reconstruction, including the mastectomy, accounted for 64% of the 18-month costs with one-stage reconstructions and for 54% of the 18-month costs for TE reconstructions.

Conclusion: Costs and utilization trended lower over 18 months for one-stage versus TE reconstructions following post-mastectomy breast reconstructions but did not achieve statistical significance.

### INTRODUCTION

Breast cancer is one of the most common cancers of women in the U.S., affecting as many as one in nine American women. Approximately 207,090 new diagnoses of invasive breast cancer were expected among women in the U.S. in 2010 (American Cancer Society 2010), with 40% to 55% of these women currently opting for a mastectomy, although rates vary widely.

Implant-based breast reconstruction after a mastectomy is typically a two-stage procedure in the U.S. (American Society of Plastic Surgeons 2010). In the first stage, a tissue expander (TE) is placed, and in subsequent office visits saline is added until the target volume is reached. In the second stage, the expander is removed and replaced with a permanent implant (saline or silicone).

When feasible, a one-stage reconstruction may offer significant advantages, i.e., avoidance of a second operation and its attendant risks, morbidity and costs; decreased time for convalescence; and earlier restoration of body image. However, a one-stage procedure is not suitable for every patient, dependent on the quality of chest wall tissue and the size and shape of the contralateral breast. Even in the hands of seasoned surgeons, some patients having onestage reconstructions will require additional surgery stemming from patient and/or surgeon dissatisfaction with the result.

The embrace of nipple–areola complex (NAC)-sparing mastectomies in the U.S. is creating greater opportu-

nities for direct-to-implant one-stage reconstruction. Further, as increasing numbers of women seek genetic screening for *BRCA* mutations, more prophylactic mastectomies are being performed. NAC-sparing mastectomies are especially attractive for woman seeking bilateral prophylactic mastectomies since no cancer is present, and one-stage reconstruction is particularly desirable in bilateral procedures since symmetry is easier to achieve.

No large studies have compared the costs of one-stage and TE reconstructions in clinical practice over the months and years postreconstruction in which problems develop. Short-term analyses of TE reconstructions may miss the cost of the second-stage procedure (expander exchange) altogether; while the expander is sometimes exchanged for the implant within the 90-day global period for CPT 19357, many women wait weeks or months longer to finalize the reconstruction, especially if they are undergoing radiation treatment or chemotherapy. Smaller studies examining both implant and flap reconstructions have found that immediate one-stage reconstructions have lower medical costs compared with flap procedures and TE reconstructions (Damen 2011). Estimated annual expenditures in the U.S. for breast cancer care of approximately \$ 14 billion in 2006, with over \$1 billion spent on reconstructions, present an imperative to examine the clinical efficacy and costs associated with alternative approaches to breast reconstruction (National Cancer Institute 2010).

In the present study, commercial insurance claims data were obtained on a cohort of patients receiving immediate one-stage or TE post-mastectomy implant breast reconstructions. We sought to compare the two approaches over 18 months in terms of the total cost, the frequency

of return visits, and the nature and treatment costs of procedure-related complications.

#### **METHODS**

This study used 2008-2009 insurance claims obtained from the Thomson Reuters MarketScan Commercial Claims and Encounters Database, which is derived predominantly from large self-insured employers and features a mix of plan types: preferred provider organizations, point-of- service plans, and health maintenance organizations, along with some indemnity coverage. The data set obtained included only those plans that require the use of standardized Current Procedural Terminology (CPT) in reporting for billing and collections purposes. The source met Health Insurance Portability and Accountability Act of 1996 (HIPAA) criteria for a limited-use dataset, so no institutional review board (IRB) approval was required.

In this data set, we identified patients who had an implant breast reconstruction procedure — designated as the "index event" — performed during the same visit as mastectomy from Jan. 1 to June 30, 2008. Mastectomy was identified by CPT codes 19180, 19182, 19200, 19220, 19240, or 19301 to 19307 (per 2008 usage). Breast reconstruction post-mastectomy was defined by CPT codes 19340, 19342, or 19357. In addition, patients were required to have a minimum of 12 months of continuous enrollment following the index event.

Patients were excluded from the study if their initial reconstruction included a flap or other autologous breast reconstruction procedure, defined by CPT codes 19361, 19364, 19366, 19367 to 19369, or 15734, unless CPT or Healthcare Common Procedure Coding System (HCPCS) codes documented the use of an allograft or a xenograft during the same procedure. This exception was made

because of a pattern of miscoding in the claims data.

Table 1 lists the CPT code definitions for mastectomy and breast reconstruction procedures.

In addition, patients were excluded for pre-existing breast implant complications; for unrelated surgery concurrent with initial reconstruction; for death during the 18-month postindex period; or for TE reconstruction in which the TE exchange procedure could not be identified from available claims (including up to 2 years of data). No deaths appeared to be related to complications stemming from either type of reconstruction.

For patients who met the qualifying criteria, the initial breast reconstruction was classified as one-stage if it included CPT 19340 or 19342 but not 19357, and if subsequent claims did not include 11970, or manual review indicated that the TE was implanted in a revision. Initial reconstruction was considered a TE reconstruction if it included CPT code 19357, or if a reconstruction coded with 19340 or 19342 was followed by CPT 11970 without an intervening cause. Insufficient data were available to distinguish reliably between unilateral and bilateral reconstructions.

Each patient's health insurance claims for an 18-month post-index period (study period) were reviewed to identify services related to the breast reconstruction using diagnosis and procedure codes. Contemporaneous claims were organized into inpatient and outpatient episodes of care so that diagnosis and procedure codes from all providers involved could be used to clarify the nature of each event.

For episodes involving hospital or facility care (except home health and ambulance services), the episode included all services from any provider with service dates between the beginning and ending dates of the facility claim. All other episodes were single-

day events and included all services with the same date. If the service date of breast reconstruction surgery occurred within 5 days of another episode involving the same procedure code, the latter was assumed to be a misdated late bill and was considered to be part of the earlier episode.

All episodes of care involving breast reconstructive procedures or complications subsequent to the hospital stay for the initial mastectomy and reconstruction were evaluated as post-index events. Post-index events were classified into three groups, based on the extent to which the patient was returning to the hospital for a planned service (nipple reconstruction, identified by CPT 19350, and/or the initial TE exchange):

• Planned return — Expander exchange or nipple reconstruction without medical complication

- or revision, capsule revision/ removal, or any autologous procedure
- Planned return with revision Capsule revision/removal, other revision, or any autologous procedure done in conjunction with a planned service; no medical complication
- Unplanned return Any postindex event involving a medical complication, or a return visit with any other breast reconstruction procedure code that did not include nipple reconstruction or the expander exchange

Medical complications were identified by ICD-9 diagnosis codes and were grouped into categories for reporting purposes. A medical complication was included if it occurred within category-specific time limits following the initial breast reconstruction or any subsequent related procedure, and was excluded if intervening claims revealed another surgery that might have caused the complication. Complications of the implant, graft, mesh, or tissue or artificial skin graft were included without time limits. Other complications were evaluated within time limits. as follows:

- Infection, breast necrosis, or complications of the skin or connective tissue: six months.
- Procedural complications subject to a 90-day global period for reimbursement: 90 days
- Other procedural complications: 30 days
- Hematoma or seroma: 30 days

Cost was evaluated from a healthplan perspective as the total allowed cost (i.e., the amount eligible for payment under the medical plan's terms after applying rules, such as discounts, but before applying coordination of benefits, copayments, and deductibles) (Thomson Reuters 2010),

# TABLE 1 CPT codes for mastectomy, repair, and/or reconstruction procedures

Code	Description		
Mastecto	omy codes		
19180	Mastectomy, simple, complete*		
19182	Mastectomy, subcutaneous*		
19200	Mastectomy, modified radical*		
19220	Mastectomy, modified radical (urban type)*		
19240	Mastectomy, modified radical, excluding pectoralis major*		
19301	Mastectomy, partial		
19302	Mastectomy, partial with axillary lymphadenectomy		
19303	Mastectomy, simple, complete		
19304	Mastectomy, subcutaneous		
19305	Mastectomy, modified radical		
19306	Mastectomy, modified radical (urban type)		
19307	Mastectomy, modified radical		
Implant l	oreast reconstruction codes		
19340	Immediate breast prosthesis		
19342	Delayed breast prosthesis		
19357	Breast reconstruction with tissue expander		
Flap reco	onstruction codes (excluded)		
19361	Breast reconstruction, latissimus dorsi flap		
19364	Breast reconstruction, free flap		
19366	Breast reconstruction, other technique		
19367	Breast reconstruction, TRAM flap		
19368	Breast reconstruction, TRAM flap		
19369	Breast reconstruction, TRAM flap		
15734	Myocutaneous muscle flap (excluded unless coded in conjunction with allograft or xenograft )		
*These co	des were no longer in effect as of 2007 but were considered valid indicator		

<sup>\*</sup>These codes were no longer in effect as of 2007 but were considered valid indicators of mastectomy for the purposes of this study.

TRAM = Transverse rectus abdominis myocutaneous

segregated into facility and professional services on a line-item basis.

Fifty-six events in 49 patients were excluded from cost-per-event calculations because of invalid reimbursement data (i.e., non-positive allowed cost in total or for facility services, if involved; index event with no data on facility allowed cost; or net payment exceeding allowed cost by more than 10% of allowed cost). The 49 patients were excluded from the analysis of overall cost per patient; however, all patients and events were included in event-rate calculations.

Patients were considered to have received radiation treatment if a review of all available coded claims (including up to 2 years of data) found any procedure codes for radiation therapy services or diagnosis codes for a radiotherapy encounter, convalescence, or follow-up, or a history of irradiation. Patients who received a consultation with a radiation oncologist that did not result in treatment were not classified as having received radiation treatment.

For the cost comparisons, two sided t-tests of differences in means were used to evaluate the statistical significance of observed differences, with 95% confidence intervals (CIs). For differences in return rates, Fisher's exact test was used, which is a useful test when sample sizes are small and/or unbalanced, as in this

study. Statistical analyses were performed using STATA software (College Station, Tex.), version 10.

# RESULTS Study population

The study population for this analysis included 1,316 women with an average age of 49.1 years (range, 22 to 65 years). One-stage reconstructions were identified in 95 patients (7%), whereas 1,221 (93%) had TE reconstructions; 18% of the study population received radiation, and this was similar across one-stage or TE reconstructions.

The distribution of type of breast reconstructions varied by geography,

with fewer immediate one-stage reconstructions performed in the North, Central, and Southern states and more performed in Western states. Table 2 summarizes demographic and geographic information for the two study arms.

#### Utilization

Return rates for each category of patients were compared, covering the 18-month study period subsequent to the index event. Patients undergoing TE reconstructions returned more often for planned services and for treatment during which planned services were performed along with breast-revision procedures.

TABLE 2
Summary of population information

	Reconstruction type				
	One-stage	TE	Total		
Number (%) of patients	95 (7)	1,221 (93)	1,316 (100)		
Average age, years	49.3	49.1	49.1		
Percent patients receiving radiation	19	18	18		
Mean days to tissue-expander exchange		206.5			
Geographic region*					
Northeast	16 (17%)	200 (16%)	216 (16%)		
North Central	21 (22%)	340 (28%)	361 (28%)		
South	40 (42%)	528 (43%)	568 (43%)		
West	18 (19%)	149 (12%)	167 (13%)		
* Excludes four TE reconstructions in which geographic region could not be identified.					

### Average return rates per patient for hospital care or complications\*

	Reconstruction type				
Episode category	One-stage (n = 95)	TE (n = 1,221)	Relative risk	<i>P</i> value†	95% CI
Planned	0.17	0.61	0.34	0.0000	0.217, 0.559
Planned with revision	0.06	0.52	0.15	0.0000	0.069, 0.338
Unplanned	1.67	1.28	1.65	0.0000	1.553, 1.765
Total returns	1.91	2.42	0.92	0.07	0.849, 1.01

<sup>\*</sup> Comparison of average return rates following an immediate one-stage or TE non-flap post-mastectomy breast reconstruction in patients with at least 12 months of continuous enrollment post-index.

<sup>†</sup> Two-sided Fisher's exact test

CI = confidence interval; TE = tissue expander

Patients undergoing one-stage reconstructions returned more often for unplanned services but had a lower overall return rate.

Table 3 summarizes the return rates for each study arm.

## Costs associated with breast reconstruction

Total cost per patient: Eighteenmonth costs — including the initial reconstruction and all follow-on return visits, facility, and professional services combined — averaged \$34,839 for patients undergoing one-stage reconstructions compared with \$39,062 for patients undergoing TE reconstructions, for a difference of \$4,223 (P = 0.38). The initial reconstruction, including the mastectomy, accounted for 64% of 18-month costs with one-stage reconstructions and for 54% of 18-month costs with TE reconstructions.

The distribution of costs per patient for 1,297 patients who had no events excluded for invalid data was consistent with differences in the rate and nature of return visits (Figure 1).

Cost per event (index events): The cost per event for the initial reconstruction averaged \$6,269 and \$16,244 for professional and facility costs, respectively, for immediate one-stage reconstructions compared with \$7,932 and \$13,227, respectively, for TE exchange reconstructions (Figure 2). The difference in professional costs was \$1,663 (P = 0.0008), and the difference in facility costs was \$3,017 (P = 0.12).

Costs for return visits: The mean per-event cost associated with planned returns was lower for both professional and facility costs for patients with one-stage reconstructions (\$1,888 and \$2,471, respectively) compared with TE reconstructions (\$2,723 and \$5,113, respectively) (Figure 3). The difference in professional costs was \$835 (P = 0.02), and the difference in facility costs was \$2,642 (P = 0.000).

The professional and facility mean costs associated with a planned return with revision was also lower for patients with immediate onestage reconstructions compared with patients undergoing TE reconstructions, but the difference was non-significant. The professional and facility costs per event averaged \$3,940 and \$6,393, respectively, for one-stage reconstructions versus \$4,744 and \$7,002, respectively, for TE reconstructions. The difference in professional costs was \$804 (P = 0.49), and the difference in facility costs was \$609 (P = 0.71).

Conversely, the mean cost for an unplanned visit was higher (but not significantly so) for patients who underwent one-stage reconstructions compared with those who received TE reconstructions.

The professional and facility costs per unplanned return visit averaged \$2,668 and \$6,089, respectively, for one-stage reconstructions compared with \$2,218 and \$4,904, respectively, for TE reconstructions. The difference in professional costs was \$450 (P = 0.34), and the difference in facility costs was \$1,185 (P = 0.28).

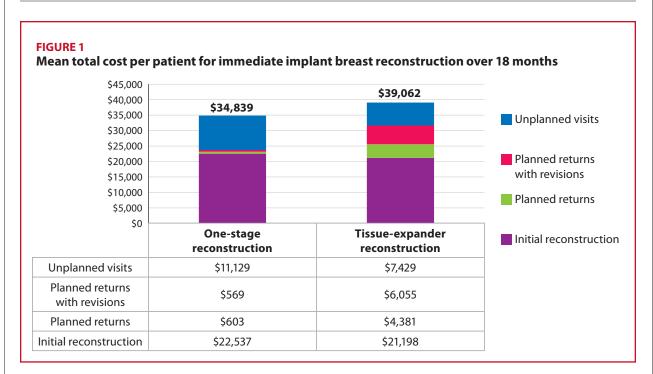
Return visits because of a complication accounted for 87% of unplanned returns following onestage reconstruction and for 84% of unplanned returns following TE reconstruction (Table 4). Complications were most commonly associated with the implant, graft, or mesh (40% of unplanned visits following one-stage reconstruction and 32% of unplanned visits following TE reconstruction). Return visits for an unplanned procedure without a complication accounted for 13% of unplanned returns following onestage reconstruction and for 16% of unplanned returns following TE reconstruction (Table 4).

Skin or connective-tissue problems were more common with TE reconstructions, accounting for 30% of unplanned returns in that group compared with 11% of unplanned returns in the group receiving onestage reconstructions, which possibly reflected stricter patient-selection

TABLE 4
Complications driving unplanned returns\*

Complication category	One-stage reconstructions	TE reconstructions
Complication of implant, graft, or mesh	40%	32%
Complication of tissue/artificial skin graft	4%	2%
Hematoma	2%	2%
Infection	19%	16%
Necrosis, breast	1%	2%
Procedural complications with 90-day global period	2%	2%
Procedural complications — other	18%	5%
Seroma	8%	5%
Skin/connective tissue	11%	30%
Procedure without complication diagnosis	13%	16%

<sup>\*</sup> Unplanned return visits in which the complication diagnosis was involved, by percentage Note: The sums total greater than 100% as some visits involved more than one category of complication.



criteria for one-stage reconstruction. For unplanned returns involving skin and connective-tissue problems, manual therapy (CPT 97140) and therapeutic exercise (CPT 97110) were the most common services provided to patients who had received TE reconstruction. The diagnosis most commonly identified in these visits was ICD-9 709.2 (scar/fibrosis, skin). Manual therapy and therapeutic exercise were not provided to patients who had undergone one-stage reconstruction.

Procedural complications not subject to a 90-day global period were

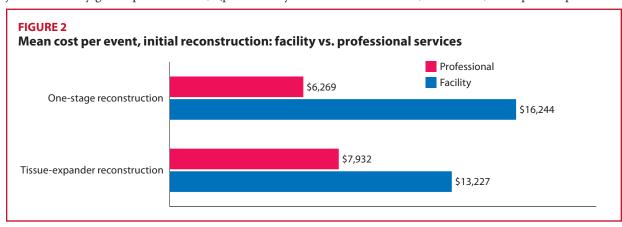
present in 18% of the unplanned returns in one-stage reconstructions; 90% of these visits involved a non-healing surgical wound (ICD-9 998.83), and 14% involved disruption of the external operation wound (ICD-9 998.32) (Table 4). Among TE reconstructions, procedural complications not subject to a 90-day global period were present in 5% of the unplanned return visits; 36% of these visits involved a non-healing surgical wound, while 61% involved disruption of the external operation wound.

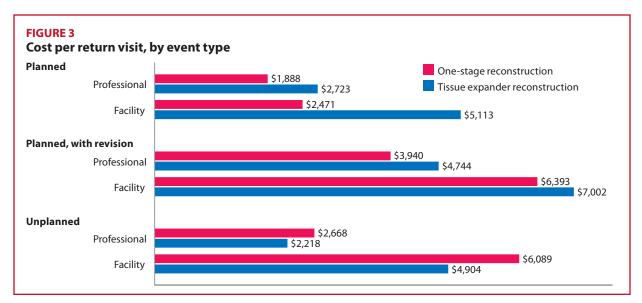
Other procedural complications (present only in TE reconstruction

patients) included hemorrhage and disruption of the internal operation wound (14% and 11% of unplanned returns, respectively) (Table 4).

Much of the cost of unplanned return events was generated by a small proportion of patients, particularly those with one-stage reconstructions. The top 10% of patients in terms of cost for unplanned returns accounted for nearly half (49%) of the costs of unplanned returns following one-stage reconstructions and for 31% of these costs following TE reconstructions.

Overall, the top 5% of patients in





terms of the total allowed cost accounted for 18% of all events and for 27% of all costs among patients who received one-stage reconstructions, compared with 7% of all events and 14% of all costs among those who underwent TE reconstructions.

Geographic differences contributed to a higher cost per patient for the initial reconstruction in the one-stage group. As shown in Figure 4, the average allowed cost (i.e., facility

and professional costs combined) for the initial one-stage reconstruction was similar in all regions of the U.S. except the West. In western states — which had 19% of the one-stage reconstructions but only 12% of the TE reconstructions — the average cost of an initial reconstruction was \$9,497 higher for one-stage reconstructions than for TE reconstructions (\$30,677 vs. \$21,180, respectively).

### FIGURE 4 Average allowed cost for initial breast reconstruction, by geographic region \$35,000 One-stage reconstruction Tissue expander reconstruction \$30,000 \$25,000 \$20,000 \$15,000 \$10,000 \$5,000 Northeast North central South West Region

# Effect of radiation on post-index event rates

As noted previously, the statistical evidence was insufficient to suggest an effect of radiation on return rates in either study arm.

#### DISCUSSION

In this review of clinical activity (as defined by medical claims) following initial breast reconstruction, little difference was observed between immediate one-stage reconstructions and TE reconstructions.

During the first 18 months after reconstruction, patients receiving one-stage reconstructions returned slightly less often for breast-related services, but the difference was not statistically significant. Moreover, in a comparison of defined procedure-related complications, there was little difference in outcomes between the two surgical approaches.

An analysis of post-index event costs reported elsewhere (Singh 2012) showed a consistent trend toward lower costs associated with immediate one-stage reconstructions, although the differences rarely achieved significance.

Overall, one-stage reconstructions averaged approximately \$4,200 less for professional and facility costs over

18 months compared with TE reconstructions. In fact, across the categories of services we examined, only one — unplanned services — had higher mean professional and facility costs for one-stage reconstructions. This is not surprising, considering that the costs of breast-revision procedures contributed exclusively to unplanned services for one-stage reconstruction procedures, but could be included under another category of returns planned returns with revisions — for the TE reconstruction group. However, the treatment of complications was the primary driver of unplanned returns in both groups.

Mean facility costs for index events (initial reconstructions) were also \$3,017 higher for one-stage reconstructions, but the difference did not reach statistical significance. It is possible that the higher facility cost for index events was related to the use of biologic graft material, which is often employed in one-stage reconstructions. In addition, the permanent implant is included in the initial cost of reconstructions for one-stage patients but is a subsequent event for TE reconstructions.

Unplanned return visits added \$3,700 more to the mean total perpatient cost for immediate one-stage reconstructions compared with TE reconstructions. These costs were not evenly distributed within the populations. More than half (53%) of patients undergoing one-stage reconstructions and 45% percent of patients receiving TE reconstructions experienced no unplanned return visits. This finding suggests that further study of cost differences between one-stage and TE reconstructions is warranted, as surgeons in the U.S. gain more experience in performing one-stage reconstructions and in selecting appropriate patients for the procedure. A recent study conducted in the Netherlands — where one-stage reconstructions are more

common than TE reconstructions — found significantly lower costs over an average follow-up period of more than 5 years with one-stage reconstruction compared with TE or two kinds of flap reconstructions (Damen 2011).

Our study data confirm the importance of longer time frames when evaluating and comparing cost and utilization in post-mastectomy breast reconstructions. The average number of days from the initial reconstruction to the TE exchange was more than 6 months. Analyses that looked at data solely within six months or less following the initial procedure would miss the return visit for the TE exchange, which includes a permanent silicone or saline implant in many patients, and this could skew comparative cost equations if it is not included.

### STUDY LIMITATIONS

Studies using administrative databases have inherent limitations compared with prospective clinical studies based on the primary collection of clinical data. With administrative data, an analysis is limited to services reported by diagnosis and procedure codes, which lack the precision of medical-chart data and can be manipulated to maximize reimbursement.

In this study, the lack of data to make a reliable distinction between bilateral and unilateral procedures prevented us from offering statistics or subgroup analyses on this basis. Both the costs and the incidence of per-patient complications are likely to be higher in bilateral reconstructions.

In addition, the retrospective nature of our analysis makes it difficult to directly control for other factors that may have influenced outcomes.

### CONCLUSION

In this study, cost and utilization

during an 18-month period following postmastectomy, non-flap implant breast reconstructions trended lower for immediate one-stage versus TE reconstructions, but did not achieve statistical significance. Downstream costs were substantial with both approaches. Further analysis of this comparison is warranted as more strictly controlled clinical studies become available, and as surgeons in the U.S. gain more experience with the one-stage approach.

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