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Immediate 1-stage vs. tissue expander postmastectomy implant breast reconstructions: A retrospective real-world comparison over 18 months

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Summary *Background:* Postmastectomy implant breast reconstruction is typically accomplished in a two-stage process involving a tissue expander that is later exchanged for a permanent implant. Adoption of an immediate one stage reconstruction (1-stage) approach, where feasible, has been slowed by surgeon perception that this method is less likely to achieve acceptable results.
Methods: To compare outcomes of these approaches in actual practice, we obtained commercial insurance claims on 1,316 patients throughout the United States who had immediate 1-stage or tissue expander (TE) postmastectomy implant breast reconstructions in 2008, without flaps, and compared results of these two reconstructive approaches over 18 months in terms of patient complication rates and return visits for additional procedures and/or treatment of complications.
Results: Immediate 1-stage reconstructions were identified in 95 patients (7.2 percent), mean age 49.3 years, while 1,221 (92.8 percent), mean age 49.1 years, had TE reconstructions. Data shows a modest, non-significant trend toward fewer return visits after 1-stage reconstructions vs. TE reconstructions (191 vs. 242/100 patients, respectively); RR 0.95, NS. Complications of the implant, graft or mesh were the most common complication, experienced by 28.4 percent of 1-stage and 27.4 percent of TE reconstruction patients (RR 1.03, NS). Complications involving skin or connective tissue were also common, occurring in 20.0 percent of 1-stage and 26.4 percent of TE reconstruction patients (RR 0.76, NS). The average time to expander exchange was 189 days in patients without radiation and 288 days among irradiated patients.
Conclusions: The results show that surgeons in the United States achieved substantially similar results in immediate postmastectomy implant breast reconstructions with 1-stage and TE approaches in terms of patient complications and returns for reconstruction-related services

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over 18 months. As evolving mastectomy techniques make 1-stage implant reconstructions more attractive, we hope these findings will motivate researchers to compare the approaches in more strictly controlled clinical studies.

Introduction

Breast cancer in the United States is oft-cited as the most common cancer of women, apart from skin cancers, affecting as many as one in nine American women and creating significant morbidity and mortality. Estimated annual expenditures in the United States on breast cancer care were approximately $14 billion in 2006, with an additional $12 billion cost for loss of productivity due to breast cancer deaths.[1] Approximately 207,090 new diagnoses of invasive breast cancer were expected among American women in 2010,[2] with 40—55 percent of these women currently opting for a mastectomy, although rates vary widely.

Implant-based breast reconstruction after a mastectomy is overwhelmingly a two-stage procedure in the United States.[3] In the first stage, a tissue expander is placed, and in subsequent office visits it is expanded to the target volume. In the second stage, typically as an outpatient surgery, the expander is removed and replaced with an implant (saline or silicone), and contralateral symmetry procedures are performed, such as mastopexy, reduction, or even augmentation. The time interval between the first and second stage can vary from a month if tissues heal appropriately, to over a year if adjuvant treatments such as chemotherapy and/or postmastectomy radiation are planned.

When feasible, an immediate one-stage reconstruction (1-stage) offers significant advantages — avoidance of a second operation and its attendant risks, morbidity and costs; decreased time for convalescence; and earlier restoration of body image. A single-stage procedure is felt to be more fastidious and exacting, placing greater demands on surgeon's skill and experience. Even in the hands of seasoned surgeons, some patients having single-stage reconstruction will require additional surgery stemming from dissatisfaction with the result. Yet, the similarity of the techniques involved makes for a natural transition from TE to 1-stage reconstructions, and acceptance of the latter is growing as treatment protocols evolve.

The embrace of nipple-areola complex (NAC) sparing mastectomies in the United States is creating greater opportunities for direct-to-implant 1-stage reconstruction. Furthermore, as increasing numbers of women seek genetic screening for BRCA mutations, more and more prophylactic mastectomies are being performed. NAC sparing mastectomies are especially attractive for woman seeking bilateral prophylactic mastectomies, since no cancer is present, and 1-stage reconstruction is particularly desirable in bilateral procedures, since symmetry is easier to achieve.

No large studies have been available comparing 1-stage and TE reconstructions in actual practice over the months and years post-reconstruction in which problems develop. Accordingly, we obtained commercial insurance claims data on a cohort of patients receiving immediate 1-stage or TE postmastectomy implant breast reconstructions and sought to compare the two approaches over time in terms of patient complications and return visits for planned and unplanned procedures and the treatment of complications.

Methods

Using 2008—2009 claims data from United States commercial insurers obtained from Thomson-Reuters™ MarketScan®, we identified patients who had an implant breast reconstruction procedure performed during the same visit as mastectomy from January 1, — June 30, 2008; designated as the 'Index Event.'

Mastectomy was identified as Current Procedural Terminology (CPT®) code 19180, 19182, 19200, 19220, 19240, 19301, 19302, 19303, 19304, 19305, 19306, or 19307 (used in 2007 and 2008 calendar years). Breast reconstruction was defined by CPT® codes 19340, 19342, or 19357. Additionally, patients were required to have a minimum of 12 months of continuous insurance coverage following the Index Event. Table 1 refers to CPT® code definitions for mastectomy and breast reconstruction procedures.

Patients were excluded if their initial reconstruction included a flap or other autologous breast reconstruction procedure, defined by CPT® codes 19361 (latissimus dorsi flap), 19364 (Free flap), 19366 (other reconstruction), or 19367, 19368, or 19369 (transverse rectus abdominis myocutaneous flap). Patients whose initial reconstruction included CPT® code 15734 (myocutaneous muscle flap) were excluded unless other codes confirmed allograft or xenograft use during the same procedure. Additionally, patients were excluded for pre-existing breast implant complications; unrelated surgery concurrent with initial reconstruction; death during the 18-month post-Index period; TE reconstruction in which the tissue expander exchange procedure could not be identified from available coded claims (including up to two years of data).

The initial breast reconstruction was classified as immediate 1-stage if it included CPT® 19340 or 19342 but not 19357, and subsequent claims did not include 11970 (tissue expander exchange), unless the tissue expander was implanted in a revision. TE reconstructions were identified by CPT® code 19357, or a breast reconstruction coded with 19340 or 19342 that was followed by 11970 without an intervening cause. Insufficient data was available to differentiate unilateral and bilateral reconstructions.

Because of variations in coding practices, the exchange event in TE reconstructions was identified hierarchically so that the strongest available definition was used, and the

Table 1 CPT® Codes for mastectomy, repair and/or reconstruction procedures.

Code	Description
Mastectomy codes	
19180	Mastectomy, simple, complete[a]
19182	Mastectomy, subcutaneous[a]
19200	Mastectomy, modified radical[a]
19220	Mastectomy, modified radical (urban type)[a]
19240	Mastectomy, modified radical, excluding pectoralis major[a]
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 breast reconstruction codes	
19340	Immediate breast prosthesis
19342	Delayed breast prosthesis
19357	Breast reconstruction with tissue expander
Flap reconstruction 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)

[a] These codes were in no longer in effect as of 2007, but were considered valid indicators of mastectomy for the purposes of this study.

earliest date meeting that definition if more than one such event occurred.

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 could be used to clarify the nature of event. For episodes involving hospital or facility care (excepting home health and ambulance services), the episode included all claims with service dates between the beginning and ending dates of the facility claim. All other episodes were single-day events that included all services on that day. If a breast reconstruction surgery code was repeated within five days, the latter was assumed to be a misdated bill, not a new procedure.

Each episode of care involving breast reconstructive procedures or complications subsequent to the hospital stay for the initial mastectomy and reconstruction was evaluated as a post-index event and classified into one of three groups, as shown in Table 2.

Medical complications were identified by diagnosis code and grouped into categories for reporting purposes. A medical complication was included if it occurred within category-specific time frames following the initial breast reconstruction or any subsequent related procedure, and excluded if analysis of services between the breast procedure and the complication revealed a potential alternative cause for the complication. Complications of the implant, graft, mesh, or tissue or artificial skin graft were included without time limit. 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, hematoma or seroma, 30 days. Definitions of categories by ICD-9 diagnosis code are shown in Table 3.

Patients were considered as having received radiation if a review of all available coded claims (including up to two years of data) found any procedure codes for radiation therapy services or diagnosis codes for radiotherapy encounter, convalescence or follow-up, or a history of irradiation.

T-tests were used for statistical tests of means; for proportions, Fisher's Exact Test was used; a useful test when sample sizes are small and/or unbalanced as in this study. Statistical analyses were performed using STATA software (College Station, TX), version 10. Any assumptions regarding inclusion/exclusion criteria, coding and billing, identification of complications, etc, were made *a priori* to the data analysis to prevent bias.

Results

Study population

The study population for this analysis included 1,316 females, average age 49.1 years (range 22—65 years); 17.8 percent of the study population received radiation. Immediate 1-stage reconstructions were identified in 95 patients

Table 2 Definitions of post-index event categories.

Post-Index Event Category	Definition	Exclusions
Planned return	Nipple reconstruction (CPT® 19350) or, in TE reconstructions, the initial expander exchange	Medical complication or revision, capsule revision/removal or any autologous procedure
Planned return with revision	Planned procedure (above) with a revision, capsule revision/removal, or any autologous procedure	Medical complication
Unplanned return	Medical complication, or any other breast reconstruction procedure code that did not include a planned service	

Table 3 Summary population information.

	Reconstruction type		
	1-stage reconstruction	TE reconstruction	Total
# of patients	95	1,221	1,316
Average Age	49.3 years	49.1 years	49.1 years
Percent patients receiving radiation	18.9%	17.7%	17.8%
Mean Days to TEX[a]		206.5 days	

[a] Tissue expander exchange (TEX) for a permanent implant.

(7.2 percent), while 1,221 (92.8 percent) had TE reconstructions. Table 3 summarizes demographic information for the two study arms.

The average number of days from initial reconstruction to TEX was 206.5 days (range 20—677 days; inter-quartile range 126—257 days). The average number of days to TEX was 288 days among patients who received radiation therapy at some point and 189 days among patients with no radiation treatment. Figure 1 shows the cumulative percentage over time of patients whose TEs had been exchanged for a permanent implant, for patients with and without exposure to radiation.

Prophylactic removal of one or both breasts was identified in 24/95 (25 percent) patients having 1-stage reconstructions and 237/1221 (19 percent) of those having TE reconstructions. Genetic risk was documented by diagnosis code in 20 percent of the patients with prophylactic mastectomies, nearly always in conjunction with family and/or personal history.

Patient returns for services subsequent to index event

Total returns

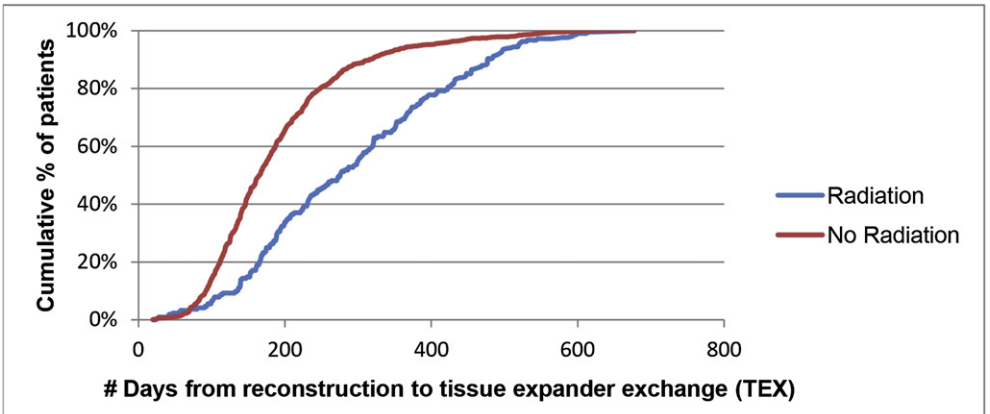
The total number of return visits for breast-reconstruction related services during the 18-month study period were compared, by type of reconstruction. Patients receiving 1-stage breast reconstructions returned slightly less often (191 times/100 patients) than patients receiving TE reconstructions (242 times/100 patients), but the difference was not statistically significant; RR: 0.95, NS.

Planned and unplanned returns

As noted in Table 2, 1-stage reconstructions have only one reason for a Planned Return (nipple reconstruction, where needed), while expander reconstructions have two reasons (nipple reconstruction and TEX). Accordingly, patients undergoing 1-stage reconstructions returned less often for Planned Services than did patients undergoing TE reconstructions; return rates were 17 per 100 vs. 61 per 100 respectively; RR: 35 percent, $P < 0.05$. Nipple reconstruction (with or without unplanned services) was documented in 23 (24.2 percent) patients with 1-stage reconstructions and 594 (48.6 percent) patients with TE reconstructions.

Similarly, patients undergoing 1-stage breast reconstructions returned less often for visits involving a revision in conjunction with a planned service. Planned Returns with Revision occurred at a rate of six per 100 patients following 1-stage reconstruction, compared with 52 returns per 100 patients following TE reconstruction; RR: 15.4 percent, $P < 0.05$.

The most common CPT code for the "revision" element of planned returns with revision was 19380 (revision) among patients receiving 1-stage reconstructions, and 19370



Radiation Exposure	Number of Days to Tissue Expander Exchange in patients with immediate post-mastectomy tissue expander breast reconstructions				
	Mean	Minimum	Maximum	StDev	N
Radiation	288.2	26	677	136.93	216
No Radiation	189.0	20	616	99.58	1005

Figure 1 Graphic showing the cumulative percent of patients in whom the tissue expander exchange (TEX) has been completed over time, by radiation status, with accompanying statistics.

(capsulotomy) for the TE patients, involved in 67 percent and 43 percent of the return visits in this category, respectively.

Conversely, patients receiving 1-stage reconstructions returned more often for services categorized as Unplanned, returning at a rate of 167 per 100 patients, vs. 128 Unplanned Returns per 100 patients following TE reconstruction; RR: 1.66, $p < 0.05$. Details on the complications contributing to Unplanned Returns are shown in Table 4.

The percentage of patients experiencing one or more Unplanned Returns was actually lower among patients having 1-stage reconstructions (45 of 95, 47.3 percent) than in patients with TE reconstructions (677 of 1221, 55.4 percent).

The *rate* of Unplanned Returns is higher for this group, however, because a greater number of patients in the 1-stage group had a large number of returns. Four or more unplanned returns were experienced by 13 percent of 1-stage reconstruction patients and 9 percent of patients having TE reconstructions, as shown in Figure 2. The maximum number of unplanned returns per patient was 24 following 1-stage and 31 following TE reconstruction. Among patients having one or more unplanned return visits, patients with 1-stage reconstructions had a mean of 3.5 unplanned returns (median, 2), while patients with TE reconstructions had a mean of 2.3 unplanned returns (median, 1).

Return visits for the treatment of complications of earlier procedures, but without any major breast reconstruction procedures reported, accounted for 62 percent of the Unplanned Returns (103.2 per 100 patients) among patients having 1-stage reconstructions and 45 percent of unplanned returns (58 per 100 patients) among patients with TE reconstructions.

In an effort to better understand the cumulative impact of patient returns for unplanned services, the results of the two latter categories were combined — Planned with Revisions and Unplanned returns. The combined rate of return for Unplanned events and Planned Returns with Revisions was 180 per 100 patients undergoing TE reconstructions vs.174 per 100 patients undergoing 1-stage reconstructions; RR: 1.22 percent, $P < 0.05$.

Analysis of radiation impact on post-index event rates

To understand whether radiation therapy had any impact on the results of the analysis of return events, the previous analysis was re-run stratifying by radiation status. No differences achieved significance.

Post-index complications

In addition to return rates for services, the incidence of medical complications were examined after the Index Event. Table 5 summarizes the results. There were no statistically significant differences in the reported

Table 4 Unplanned return visits — percentage and rate of unplanned return visits in which a particular category of complication, or none, was involved.

Complication category	Percent of Unplanned Returns		Returns per 100 patients		Definition
	1-stage reconstructions	TE reconstructions	1-stage reconstructions	TE reconstructions	ICD-9 diagnosis codes
Complication of the implant, graft or mesh	40%	32%	66.3	41.6	909.3, 996.54, 996.59, 996.60, 996.69, 996.70, 996.79
Complication of tissue/ artificial skin graft	4%	2%	6.3	3.0	996.52, 996.55
Hematoma	2%	2%	3.2	2.0	998.12
Infection	19%	16%	31.6	20.8	041.11, 041.19, 041.7, 041.85, 682.2, 682.9, 686.9, 998.51, 998.59
Necrosis, breast	1%	2%	1.1	2.5	611.3
Procedural Complications with a 90-day global period	2%	2%	3.2	2.2	998.89, 998.9, 999.9
Procedural Complications - other	18%	5%	29.5	6.8	459.0, 998.11, 998.3, 998.31, 998.32, 998.83, E87.88
Seroma	8%	5%	13.7	6.0	998.13
Skin/connective tissue	11%	30%	18.9	38.1	701.4, 709.2, 709.3, 709.8
Procedure without complication diagnosis	13%	16%	22.1	20.2	

Note: Totals sum > 100 percent because some visits involved more than one complication category.

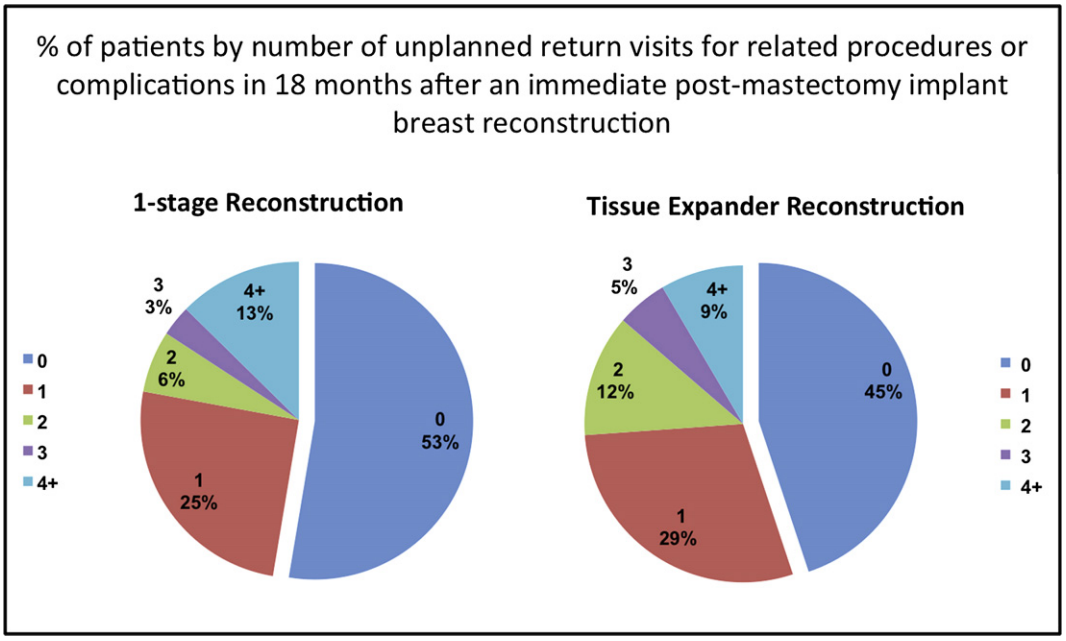


Figure 2 Number of Unplanned Returns per patient: percent distribution by type of reconstruction.

incidence of complications between 1-stage reconstructions and TE reconstructions in any of the categories of complications.

As noted in the methods section, each category of complication was examined within a specific date parameter from the Index Event. If a patient developed an infection requiring six return visits for treatment, this would be appear as one complication in Table 5 and six Unplanned Returns in Table 4.

Discussion

In this review of clinical activity as defined by medical claims subsequent to initial breast reconstruction, little appreciable difference was observed between 1-stage reconstructions and TE reconstructions. Overall, during the first 18 months post reconstruction, patients receiving 1-stage reconstructions returned slightly less often for breast-related services. Although the trend was not large enough to reach statistical significance, it is consistent with findings of a recent Dutch study, which found lower costs with single-stage breast reconstructions than with other approaches, including TE reconstruction.[4] In a comparison of defined procedure-related complications, our study again found little difference between the two approaches.

One-stage implant reconstruction is not an appropriate option for all patients, but the criteria for it are expanding. Larger volume implants are tolerated if the soft-tissues are not devascularized. Older patient ages are permissible, and the maximum age (64 vs. 65) was not materially different between the two approaches in this study. Concomitant

Table 5 Percentage of patients experiencing complications of initial breast reconstruction or subsequent related procedures.

Complication	1-stage reconstruction		TE reconstruction		Percent Difference	RR
	Percent	*N*	Percent	*N*		
Complications of implant/ graft/mesh	28.4%	27	27.4%	335	1.0%	1.03[a]
Complications of tissue/ artificial skin graft	2.1%	2	0.7%	8	1.4%	2.85[a]
Hematoma	6.3%	6	2.9%	36	3.4%	2.14[a]
Infection	9.5%	9	12.4%	152	-2.9%	0.76[a]
Necrosis, Breast	1.1%	1	3.3%	40	-2.2%	0.32[a]
Procedure complications, 90 day global period	3.2%	3	2.2%	27	1.0%	1.42[a]
Procedure complications, other	7.4%	7	6.2%	76	1.2%	1.18[a]
Seroma	6.3%	6	4.5%	55	1.8%	1.4[a]
Skin/connective tissue	20.0%	19	26.4%	322	-6.4%	0.76[a]

RR Relative risk with 1-stage reconstruction vs. TE reconstruction.
[a] non-significant.

mastopexy, which facilitates symmetry, was performed with 7 percent of the 1-stage reconstructions and with 1 percent of initial TE placements in this study.

Furthermore, the preservation of the entire skin envelope in NAC-sparing mastectomies makes direct-to-implant 1-stage reconstruction an attractive option for more patients. While there is no consensus, commonly discussed criteria for NAC are small tumor less than 3 cm in size, peripherally situated tumor greater than 2 cm away from the NAC, uni-focal disease confirmed on pre-operative MRI, and no lymph node involvement.[5,6] The frequency of NAC-sparing mastectomy could not be assessed with this data set, but we found nipple reconstruction documented in half as many patients with 1-stage reconstructions (24.2 percent vs. 48.6 percent).

Studies using insurance claims offer the opportunity to assess results as innovations are adopted into actual practice. This study confirms that in 2008, the 1-stage breast reconstruction approach was identifiably present in mainstream surgical practice in the United States, although not common, even though contemporaneous summaries of reconstructive choices did not necessarily even mention the option.[7] Data gathered from actual surgeons performing breast reconstruction as a cross-section of the United States showed progress and innovation being adopted into practice, and keeping pace with pioneering reports of 1-stage techniques.

These data also indicate that as U.S. surgeons, who are likely to have much more experience with TE reconstructions, tried the 1-stage approach, the results they achieved with it were quite similar to their results using the more familiar approach. Although more patients with 1-stage reconstructions avoided Unplanned Returns (53 percent vs. 45 percent), a higher percentage of patients undergoing 1-stage reconstruction (13 percent vs. 9 percent) encountered enough difficulties to require four or more Unplanned returns for post-reconstruction care, consistent with the assessment of Damen, et. al. (2011) that careful patient selection remains an important factor in single-stage breast reconstruction.[4]

Study limitations

Studies using administrative databases have inherent limitations because 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 addition, the retrospective nature of analysis makes it difficult to directly control for other factors that may influence outcomes.

In this study, coding anomalies were noted in the use of primary breast reconstruction codes to report obvious post-reconstruction revisions. Study patients were excluded in instances in which the expander exchange procedure could not be identified, resulting in the likely exclusion of two types of patients: those whose reconstructive course was so smooth that the expander exchange was accomplished within 90 days and without a hospital visit (no separate reimbursement), and those whose expander reconstructions failed altogether or could not be completed within 18—24 months. In addition, some identified complications, particularly those regarding skin and connective tissue, may have include scarring and other problems related to the mastectomy that cannot be distinguished from complications of the reconstruction in coded data.

However, administrative data offers a means to preliminarily assess alternative surgical approaches in much larger patient populations and compare alternative surgical approaches performed contemporaneously in multiple centers and geographic regions, especially when statistically conservative assumptions are made to mitigate the risk of bias.

For this study, patients meeting the selection criteria were analyzed from a source that includes roughly 15 percent of adults in the United States under age 65 with commercial health insurance. At the same time, a study that is so broadly representative of actual practice necessarily reflects a position earlier on the learning curve experienced with any new technology or surgical technique than is reflected in clinical studies by surgeons who have been perfecting the approach for years.

Conclusion

In this study, the evidence suggests the clinical outcomes associated with two different approaches to implant breast reconstruction, as measured by the frequency of return visits for additional procedures and treatment of complications, are substantially similar. It is anticipated these findings will stimulate direct comparative analyses with special attention to appropriate patient selection.

Conflict of interest

NS, NLR and SEF are consultants to LifeCell Corporation

LifeCell Corporation provided support for this study and was involved in the decision to submit the manuscript for publication.

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