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ORIGINAL ARTICLE

Breast

Comparing the Clinical and Cost-Effectiveness of Abdominal-based Autogenous Tissue and Tissue-Expander Implant: A Feasibility Study

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Background: To determine the superiority of autologous abdominal tissue (AAT) or tissue-expander implant (TE/I) reconstruction, a robust comparative cohort study is required. This study sought to determine the feasibility of a future large pragmatic cohort study comparing clinical and cost-effectiveness of AAT and TE/I at 12 months postoperative.

Methods: Potential participants were screened during consultation with their surgeon. Three health-related quality-of-life scales, the Health Utility Index Mark 3, the 12-Item Short Form Health Survey, and the BREAST-Q were used preoperatively, 1, 6, and 12 months postoperatively. Direct medical costs and postoperative patient/caregiver productivity loss were collected using patient diaries. Feasibility was assessed through patient recruitment rates and compliance of patients and study staff to complete required study documentation.

Results: Sixty-three patients consented to participate, 44 completed baseline questionnaires; the feasibility objective of recruiting 80% of eligible patients was not met. A 90% completion rate for patient questionnaires was seen at 1-month follow-up and decreased up to 12 months. Quality-adjusted life years were calculated at 0.77 and 0.89 for the AAT and TE/I group, respectively. Case report form completion by study staff and patient diary completion was moderate and low, respectively. Collaborating with hospital case-costing specialists to identify direct medical costs was reliable and efficient.

Conclusions: A future large-scale study is feasible. However, due to a diminishing rate of questionnaire completion, almost twice as many patients need to be recruited than expected to have adequate power. Cost data collection from hospital sources was reliable. Case report forms need to be tailored more toward a busy hospital setting. *(Plast Reconstr Surg Glob Open 2020;8:e3179; doi: 10.1097/GOX.0000000000003179; Published online 4 November 2020.)*

INTRODUCTION

Advances in breast cancer treatment and awareness have resulted in consistent decreases in mortality rates over the last 3 decades.[1–3] With such decreases comes the concomitant increase in the frequency of breast reconstruction.[4] The Agency for Healthcare Research and Quality reported a 62% increase in breast reconstruction procedures between 2009 and 2014.[5] Among the many available reconstructive procedures are tissue-expander implant (TE/I) and autologous tissue reconstruction. Despite evidence to suggest that autologous procedures produce superior long-term satisfaction, there is increased demand for TE/I.[4] Between 2007 and 2017, there was a 10% increase in the number of TE/I procedures and an approximate 7% decrease in autologous procedures performed.[6,7] Regardless of the chosen technique, breast reconstruction should aim to meet the concerns of the patients. For most women, apprehensions about survival

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Received for publication May 13, 2020; accepted August 20, 2020.

Clinicaltrials.gov: NCT02438449.

DOI: 10.1097/GOX.0000000000003179

Disclosure: *The authors have no financial interest to declare in relation to the content of this article. This project was funded by the McMaster Surgical Associates (MSA) from McMaster University, Hamilton, Ontario, Canada.*

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is closely followed by worry over body image, self-esteem, and social life related to the mastectomy defect.[8,9]

Research suggests that patients who undergo either TE/I or autologous abdominal tissue (AAT) report overall satisfaction with their breast reconstruction. Patients receiving both procedures report improvements in psychosocial and sexual well-being with no significant differences between techniques.[10–12] Recently, low-level evidence has come forward suggesting that autogenous methods may provide better long-term satisfaction than TE/I breast reconstruction.[12] Recipients of autologous methods tend to have greater short and long-term aesthetic and general satisfaction when compared with TE/I patients.[10–13] In addition, when compared with TE/I, such evidence has reported that AAT reconstruction is safer in terms of reconstructive failure and surgical site infection.[13]

Although aesthetics and quality of life are important, the costs associated with these procedures must be considered when determining superiority of one technique over the other. Although recent comparative breast reconstruction economic evaluations have been performed, methodological weaknesses make it impossible to determine the superiority of either AAT or TE/I.[14–21] To address this knowledge gap, economic evaluations coupled to robust comparative cohort or randomized controlled trials are needed. However, due to the restrictive inclusion and exclusion criteria in multidisciplinary care, randomized controlled trials are difficult. In such a case, a cohort study is the next best option.

The current study was designed to determine the feasibility of a large pragmatic comparative cohort study. Feasibility studies ask "whether something can be done, should we proceed with it, and if so, how?".[22] The primary research question was, "for patients undergoing immediate or delayed postmastectomy breast reconstruction, is AAT-based reconstruction superior in terms of clinical- and cost-effectiveness when compared with 2-stage TE/I reconstruction at 12 months?" Feasibility was assessed through patient recruitment and compliance of patients and study staff to complete the required study documents. A 12-month time horizon was selected to capture the Health-Related Quality of Life (HRQoL) changes that occur during recovery, while still offering a realistic level of follow-up commitment for patients.

METHODS

Patient Recruitment

Although a sample size calculation is not required for a feasibility study, justification for the target sample size is needed.[23] An a priori sample size calculation was performed; a total of 40 patients, 20 in each group (AAT and TE/I), were required. Patients were recruited by 2 expert surgeons between March 2015 and April 2017. (**See appendix, Supplemental Digital Content 1**, which displays the sample size justification, **http://links.lww.com/PRSGO/B487**.) During consultations, the surgeons screened patients for eligibility (Fig. 1). Eligible patients were invited to participate in the study; those who wished to participate gave signed consent.

Primary Outcome

The primary outcome of this study was to determine the feasibility of recruiting 80% of eligible patients (ie, each surgeon can recruit approximately 4–5 patients per month).

Secondary Outcomes

Compliance with Completion of Patient Questionnaires

Patients were asked to complete 3 HRQoL questionnaires preoperatively, as well as 1, 6, and 12 months postoperatively. The term HRQoL refers to the value assigned to the duration of an individual's life, as modified by impairments, functional states, perceptions, and social opportunities that are influenced by a disease, injury, or treatment option.[24] The 3 questionnaires used were, The BREAST-Q, the Health Utility Index Mark 3 (HUI-3), and the 12-Item Short Form Health Survey (**see appendix, Supplemental Digital Content 2**, which displays the questionnaires used for this study, **http://links.lww.com/PRSGO/B488**). This study aimed to determine if a 90% completion rate at each follow-up point for each of the

Inclusion Criteria:
1) Patients 18 years of age or older;
2) Patients undergoing breast reconstruction (immediate or delayed) after mastectomy procedure on one or both breasts;
3) Eligible for two step TE/I, or one of the following AAT procedures: pedicled transverse rectus abdominis myocutaneous (TRAM), free TRAM, muscle-sparing TRAM flap, deep inferior epigastric perforator flap, superficial inferior epigastric artery flap, and Rubens flap.

Exclusion Criteria:
1) Patients who have had previous breast reconstruction surgery;
2) Patients undergoing other procedures during reconstruction surgery, other than the mastectomy itself in the case of immediate or delayed reconstruction;
3) Patients unable to complete the questionnaires due to language barriers;
4) Geographic inaccessibility or inability to adhere to study protocol requirements.

Fig. 1. Inclusion and exclusion criteria.

three questionnaires could be attained. In this, and future studies, as one or both breasts may require reconstruction, the unit of measurement is the patient and HRQoL is the clinical outcome.

At the initial consultation, 1-month, and 6-month follow-up appointments, consenting patients were given the 3 questionnaires. They were asked to complete these questionnaires and return them at their next appointment, wherein they would receive their next set of questionnaires. Patients were asked to complete baseline questionnaires 1-week before surgery. At 12-month follow-up, patients were given the option to complete the last set of questionnaires in clinic or return them using a provided stamped envelope. It was estimated that the 3 questionnaires could be completed within 30 minutes.[25,26]

Compliance with Completion of Case Report Forms

The surgeons and study support staff were expected to complete 5 case report forms (CRFs). These forms included (1) patient screening and enrollment; (2) confidential patient information; (3) demographics; (4) baseline and surgical report; and (5) study completion. The patient screening and enrollment form and the baseline surgical report form were to be completed by the surgeon. The confidential patient information, the demographics, and the study completion form were to be completed by the support staff. Here, "support staff" refers to either the research assistant or the administrative staff that were present during this study. This study aimed to determine the compliance rate of completion of these CRFs.

Recording of Resource Use and Costing Estimation

This study assessed the feasibility of collecting information on resource utilization and costing data. Such information would allow performance of a cost-effectiveness analysis of the 2 surgical interventions from the perspective of the third-party payer and the society. Direct costs to the healthcare system included surgeon and anesthesiologist fees, costs of the operating room, patient hospitalization, and outpatient clinic costs. Productivity loss, which relates to the time lost from work or activities of daily living (eg, volunteering) for both the patient and their caregiver, was considered to determine the cost to society. Ultimately, a monetary value can be assigned to the time lost from both work or activities of daily living, using the human capital method.[27]

Compliance in Completion of Patient Diary

Patient diaries were used to collect information on frequency of appointments and productivity loss by both the patient and their caregiver. Patients were asked to start recording such information immediately following the completion of the original surgery and continue until 12 months post-surgery. We aimed to determine the completion rate of these patient diaries at each follow-up time point.

Statistical Analysis

The analysis was performed over several stages to meet the goals for this feasibility study. First, descriptive analysis of patient characteristics, age at surgery, body mass index (BMI) at surgery, and type of surgery (unilateral versus bilateral) stratified by surgery technique (AAT versus TE/I) was undertaken. Next, compliance/completion rates by surgery technique were computed for each of the 3 HRQoL questionnaires. Descriptive analyses were performed for the summary scores of each of the questionnaires separately, by surgery technique and across time points. Analyses was performed as per the individual questionnaire manuals. Effect sizes[28] (Cohen's *d*) were computed for the changes in scores from baseline to 12 months for each of the domains and scales of the HRQoL questionnaires by surgery type. No scores or subdomains were weighted. The effect sizes are to be used in a future large definitive study comparing the effectiveness of these procedures. Completion rates were computed for the 5 CRFs used in the study. Next, descriptive analyses of the length of surgery and length of hospital stay by surgery type were performed. Finally, we examined completion rates of patient diaries across time points and by surgery technique. All analyses were performed in SPSS version 25.[29]

The performance of a cost-effectiveness analysis requires integration of the costs and effectiveness of the competing interventions. The effectiveness in this study is measured with quality-adjusted life years (QALYs). The calculation for QALYs uses the "Multiattribute Utility Function" from the HUI-3 questionnaire. In the current study, the time horizon was 1 year; this was taken into consideration during calculation. The following formula was used to calculate the QALY of each patient, and the QALYs were then averaged for both AAT and TE/I: QALY = (baseline score + 6-month score) × 6/12 × 1/12 + (12-month score + 6-month score) × 6/12 × 1/2.

Ethics Approval and Study Registration

This study was approved by the Hamilton Integrated Research Ethics Board, Project Number: 148. This study was registered on clinicaltrials.gov, NCT02438449.

RESULTS

Patient Selection and Recruitment

Figure 2 outlines patient recruitment and retention. The first feasibility outcome of this study was to obtain a recruitment rate of 80%. Of the 74 eligible patients, 63 consented to participate (80.8%). However, as only 44 of these patients completed baseline questionnaires, the actual recruitment rate was 59%. A major issue in recruitment was identified; half of the screened patients did not meet the inclusion criteria.

Patient Characteristics

Table 1 summarizes the patient characteristics of all 44 patients who completed the baseline demographic information. A significant difference in BMI between groups was detected; BMI in the AAT group was 4.7 points higher. This is understandable, as the selection of cases was not randomized. Patients with a larger BMI may have self-selected or been advised by their surgeon to AAT reconstruction.

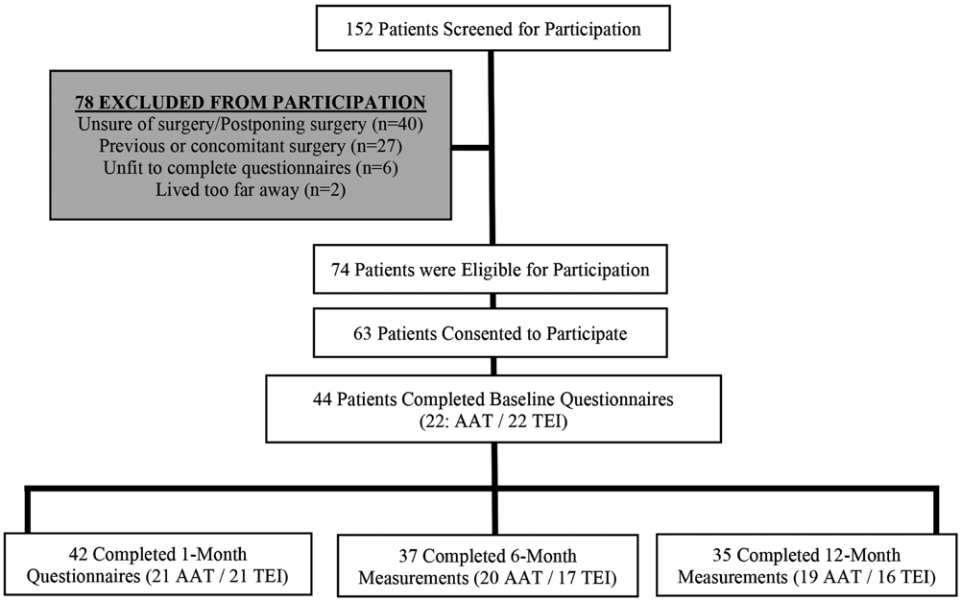

Fig. 2. Patient recruitment and retention data. n, number of patients.

Health-related Quality-of-life Measures

The feasibility outcome of achieving 90% completion rate for all questionnaires across all time points was not achieved. This objective was met, collectively, at 1 month and for the BREAST-Q in AAT patients at 6 months. Completion rates decreased as the study progressed with the lowest rates of completion found at 12 months (Table 2). A questionnaire was considered complete if it was handed in with at least 85% of the questions completed. Skipped questions were rare in all questionnaires across all time points. The odd missed question in the 12-Item Short Form Health Survey or HUI-3 seems to be due to random chance. In the BREAST-Q, questions on body confidence/comfort and sexuality were the most frequently skipped or marked as "NA" This was especially prominent during months 1 and 6.

Tables 3–5 summarize average scores of the HRQoL questionnaires. No significant differences in HRQoL measures were found between groups at 12 months. Significant differences were found within groups when comparing baseline with 12-month responses. In TE/I patients, cognition and multiattribute scores in the HUI-3 and satisfaction with breasts and psychosocial well-being in the BREAST-Q significantly increased. Conversely, a significant decrease in physical well-being (abdomen) was seen from baseline to 12 months in AAT patients. The minimal clinically important difference for HUI is 0.03[24] and 4 for the BREAST-Q.[30] As such, all changes seen from baseline to 12 months in both groups are clinically important.

Quality-adjusted Life Years

Using the results from the HUI-3, the effectiveness of the 2 approaches is as follows: QALYs were calculated at 0.77 years for AAT patients and 0.89 years for TE/I patients.

The calculation of the effect sizes, specifically from the BREAST-Q, addresses another feasibility outcome. Overall, the effect sizes for all 3 questionnaires were very small or minimal, with none exceeding 0.2 (Table 6).

Compliance of Case Report Form Completion

Completion rates for the CRFs used in this study are shown in Table 7. Only the CRFs of those patients remaining at 12 months were considered. The most commonly completed CRF was the demographics form; the study completion form had the lowest completion rate.

Direct Medical Resource Utilization

Table 8 summarizes the average length of surgery and hospital stay for AAT and TE/I patients.

Table 1. Patient Characteristics

	AAT, n (%)		TE/I, n (%)		Total, n (%)	
Unilateral	9 (40.9)		5 (22.7)		14 (31.8)	
Bilateral	13 (59.1)		17 (77.3)		31 (70.5)	
	22 (50.0)		22 (50.0)		44 (100.0)	
	n	$\bar{x}$ (SD)	n	$\bar{x}$ (SD)	n	$\bar{x}$ (SD)
Age at surgery	22	50.3 (7.8)	22	49.7 (10.0)	44	50.0 (8.9)
BMI at surgery*	22	29.1 (6.9)	22	24.4 (4.2)	44	26.6 (6.0)

*Significant difference between AAT and TE/I patients, $P < 0.05$.
n, number of patients who completed section of questionnaire; $\bar{x}$, mean.

Table 2. Completion Rates of Questionnaires at Each Time Point by Group

	1 Month		6 Months		12 Months	
Questionnaire	AAT	TE/I	AAT	TE/I	AAT	TE/I
SF-12v2	100%	100%	86%	77%	86%	82%
HUI-3	95%	95%	86%	82%	82%	77%
BREAST-Q	95%	95%	91%	77%	86%	73%

SF-12v2, The 12-item Short Form Health Survey.

Table 3. SF-12v2 Results across Time Points by Surgery Type

		Baseline		1 Month		6 Months		12 Month	
Subdomain	**Group**	**n**	**$\bar{x}$ (SD)**	**n**	**$\bar{x}$ (SD)**	**n**	**$\bar{x}$ (SD)**	**n**	**$\bar{x}$ (SD)**
Transformed physical composite score	AAT	21	49.3 (10.2)	21	25.1 (9.5)	19	48.2 (8.6)	18	51.3 (6.7)
	TE/I	21	52.2 (11.9)	21	41.0 (10.2)	16	52.1 (8.1)	19	51.6 (6.6)
Transformed mental composite score	AAT	21	48.7 (12.2)	21	45.4 (14.0)	19	48.2 (11.3)	18	49.6 (11.9)
	TE/I	21	50.4 (9.4)	21	51.9 (8.4)	16	54.8 (8.3)	18	54.1 (9.3)
Physical functioning	AAT	22	71.6 (36.4)	22	27.3 (29.8)	19	68.4 (27.4)	19	80.3 (21.4)
	TE/I	22	84.1 (27.3)	22	54.6 (24.0)	16	82.8 (27.0)	18	81.9 (22.4)
Social functioning	AAT	22	83.0 (28.2)	22	61.4 (24.1)	19	80.3 (22.9)	19	82.9 (23.7)
	TE/I	22	87.5 (18.5)	22	818 (22.1)	18	87.5 (19.6)	18	86.1 (27.4)
Role functioning—physical	AAT	22	75.0 (33.9)	22	30.1 (26.1)	19	74.3 (23.4)	19	80.9 (21.4)
	TE/I	21	76.8 (31.5)	21	51.9 (27.2)	18	75.7 (31.6)	18	81.3 (25.1)
Role functioning—emotional	AAT	22	78.4 (29.9)	21	60.7 (33.8)	19	80.3 (22.2)	19	81.6 (24.8)
	TE/I	22	80.7 (24.3)	22	75.0 (26.2)	18	92.4 (16.1)	18	89.6 (22.8)
Mental health	AAT	22	69.3 (24.6)	22	58.0 (24.6)	19	65.8 (23.1)	19	71.7 (21.2)
	TE/I	22	71.6 (17.8)	22	72.6 (17.5)	18	77.1 (16.2)	18	76.0 (19.6)
Bodily pain	AAT	22	81.8 (30.1)	22	48.9 (22.5)	19	76.3 (21.2)	19	81.6 (20.1)
	TE/I	22	86.4 (27.5)	22	58.0 (33.1)	18	84.7 (24.5)	18	87.5 (21.4)
General health	AAT	21	80.2 (18.1)	22	72.3 (17.9)	19	77.4 (14.4)	18	80.0 (15.7)
	TE/I	22	83.0 (15.8)	22	77.3 (14.0)	17	90.0 (13.3)	18	90.3 (10.6)
Vitality	AAT	22	56.8 (28.0)	22	36.4 (26.4)	19	48.7 (24.3)	19	56.6 (28.7)
	TE/I	22	63.6 (24.1)	22	52.3 (24.3)	18	65.3 (24.5)	18	68.1 (18.8)

n, number of patients who completed section of questionnaire; $\bar{x}$, mean.

Table 4. HUI-3 Results across Time Points by Surgery Type

		Baseline		1 Month		6 Months		12 Month	
Subdomain	**Group**	**n**	**$\bar{x}$ (SD)**	**n**	**$\bar{x}$ (SD)**	**n**	**$\bar{x}$ (SD)**	**n**	**$\bar{x}$ (SD)**
Multiattribute score	AAT	22	0.76 (0.27)	20	0.60 (0.25)	18	0.77 (0.15)	16	0.84 (0.13)
	TE/I	21	0.84 (0.15)	21	0.70 (0.24)	18	0.85 (0.13)	16	0.92 (0.08)*
Vision	AAT	22	0.96 (0.02)	21	0.95 (0.09)	20	0.94 (0.09)	17	0.96 (0.02)
	TE/I	22	0.97 (0.02)	21	0.97 (0.02)	18	0.96 (0.03)	16	0.97 (0.03)
Hearing	AAT	22	0.99 (0.03)	20	0.99 (0.03)	18	0.99 (0.03)	17	0.99 (0.03)
	TE/I	21	1.0 (0.0)	21	1.0 (0.0)	18	1.0 (0.0)	17	1.0 (0.0)
Speech	AAT	22	1.0 (0.0)	21	0.99 (0.04)	19	1.0 (0.0)	18	0.99 (0.04)
	TE/I	21	1.0 (0.0)	21	1.0 (0.0)	18	1.0 (0.0)	17	1.0 (0.0)
Cognition	AAT	22	0.92 (0.16)	21	0.89 (0.17)	20	0.94 (0.16)	18	0.95 (0.10)
	TE/I	23	0.92 (0.12)	21	0.95 (0.08)	18	0.95 (0.10)	17	1.0 (0.02)*
Ambulation	AAT	22	0.96 (0.07)	21	0.83 (0.21)	20	0.97 (0.07)	18	0.97 (0.07)
	TE/I	23	0.99 (0.05)	21	0.97 (0.07)	18	0.98 (0.05)	17	1.0 (0.0)
Dexterity	AAT	22	0.99 (0.04)	21	0.97 (0.12)	20	0.99 (0.04)	18	0.99 (0.03)
	TE/I	23	0.98 (0.06)	21	0.91 (0.23)	18	1.0 (0.0)	17	1.0 (0.0)
Emotional	AAT	22	0.89 (0.19)	21	0.81 (0.23)	20	0.94 (0.08)	18	0.96 (0.07)
	TE/I	23	0.95 (0.09)	21	0.94 (0.1)	18	0.98 (0.04)	17	0.97 (0.07)
Pain	AAT	22	0.87 (0.24)	21	0.76 (0.19)	20	0.88 (0.09)	18	0.92 (0.08)
	TE/I	23	0.93 (0.12)	21	0.72 (0.23)	18	0.89 (0.13)	17	0.95 (0.08)

n, number of patients who completed section of questionnaire; $\bar{x}$, mean.
*Significant within-group difference from baseline ($P < 0.05$).

Table 5. BREAST-Q Results across Time Points by Surgery

		Baseline		1 Month		6 Months		12 Month	
Subdomain	**Group**	**n**	**$\bar{x}$ (SD)**	**n**	**$\bar{x}$ (SD)**	**n**	**$\bar{x}$ (SD)**	**n**	**$\bar{x}$ (SD)**
Satisfaction with breasts	AAT	22	52.3 (17.4)	21	57.0 (18.3)	20	54.2 (18.3)	19	58.0 (23.6)
	TE/I	22	53.2 (281)	21	42.9 (15.3)	17	52.9 (19.1)	16	72.7 (17.8)*
Psychosocial well-being	AAT	22	59.8 (20.4)	21	60.6 (19.6)	20	65.1 (20.4)	19	68.5 (22.1)*
	TE/I	22	62.7 (21.8)	21	52.7 (14.1)	17	70.4 (21.7)	16	78.9 (22.6)
Physical well-being (chest)	AAT	22	74.3 (20.3)	21	61.7 (14.9)	20	70.2 (15.5)	19	73.0 (14.5)
	TE/I	22	73.2 (15.6)	21	59.8 (13.8)	17	73.3 (16.5)	16	73.1 (15.1)
Physical well-being (abdomen)	AAT	22	79.8 (24.7)	21	48.8 (16.6)	20	61.8 (16.9)	19	66.1 (24.3)†
	TE/I	NA							
Sexual well-being	AAT	22	44.6 (22.2)	21	44.3 (28.3)	20	47.7 (24.6)	19	52.4 (26.6)
	TE/I	21	62.7 (192)	20	35.3 (22.8)	17	59.1 (29.6)	16	54.4 (30.4)
Satisfaction with outcome	AAT	—	—	21	66.3 (22.3)	19	58.3 (20.8)	19	64.5 (25.0)
	TE/I	—	—	20	67.7 (18.4)	17	79.2 (20.3)	16	82.6 (21.7)
Satisfaction with surgeon	AAT	—	—	21	93.1 (12.9)	20	89.8 (18.6)	19	89.6 (15.2)
	TE/I	—	—	20	89.8 (17.6)	17	95.9 (8.2)	16	95.2 (10.4)

*Significant within-group difference from baseline ($P < 0.05$).
†Significant within-group difference from baseline ($P < 0.01$).
n, number of patients who completed section of questionnaire; $\bar{x}$, mean.

Table 6. Calculated Effect Sizes for HRQoL Questionnaires

Questionnaire	Effect Size
SF-12v2	
Physical component score	0.018
Mental component score	0.116
HUI-3	0.090
BREAST-Q	
Satisfaction with breasts	0.021
Psychosocial well-being	0.000
Physical well-being (chest)	0.000
Sexual well-being	0.035
Satisfaction with outcome	0.076

SF-12v2, The 12-Item Short Form Health Survey.

Table 7. Completion Rate of CRFs

Case Report Form	n	Percentage Out of 35 Patients
Screening and enrollment	20	57.1%
Confidential patient information	22	62.9%
Demographics	34	97%
Baseline and surgical report form	20	57.1%
Study completion form	1	2.8%

n, number of CRFs completed.

Table 8. Average Length of Surgery and Hospital Stay

	AAT		TE/I	
	n	$\bar{x}$ (minutes)	n	$\bar{x}$ (minutes)
Length of initial surgery				
Unilateral	9	353	5	97
Bilateral	10	483	11	102
Length of exchange surgery				
Unilateral	—	—	4	71
Bilateral	—	—	10	111
	n	$\bar{x}$ (days)	n	$\bar{x}$ (days)
Length of hospital stay	18	5.44	2*	1.3

n, number of patients; $\bar{x}$, mean.
*Two of the TE/I patients were required to stay overnight during the course of their 2-stage procedure. Note: length of hospital stay was only available for 18 of the 19 AAT patients.

Patient Diary and Patient-reported Out-of-pocket Expenses

Compliance with completion of patient diaries was inconsistent both within and across time points. Table 9 summarizes the sections of the diaries that were complete for each time point for both groups. Patients were not consistent in handing in diaries at each time point. Only 1 patient from the AAT and 2 patients from the TE/I handed in diaries at all 3 time points. Patients were also not consistent in completing all sections of the patient diaries. Patient compliance was highest at 1 month.

DISCUSSION

The objective of this study was to determine the feasibility of a large cohort study comparing the cost and clinical effectiveness of AAT and TE/I breast reconstruction techniques. Despite the initial high interest by patients to participate in the study, the goal of an 80% recruitment rate was not met; the recruitment rate was calculated at 59%. This low recruitment rate will have implications for a definitive study. Future studies would need to recruit almost twice as many patients as expected. This low recruitment rate will increase the time needed to complete a definitive study, resulting in greater research costs. This issue could be mitigated by inviting additional surgeons to participate in the future definitive study.

Regarding the issue of baseline noncompliance, the authors believe that, despite being reminded that participation was voluntary, some patients may have consented due to a feeling of "obligation" to participate in the study. Many patients seemed eager to help with breast cancer research; however, their continued participation seemed to wane as time went by. Following consent, patients may have changed their mind and did not complete questionnaires. It may be beneficial to have the study introduced to patients when they are first contacted to book their consultation appointment. This would allow more time for patients to decide if they truly wanted to participate in the study.

Completion of postoperative questionnaires was more consistent; however, the goal of 90% completion rate at all follow-up periods was also not met. Breast reconstruction patients are an incredibly vulnerable population; they are potentially dealing with a cancer diagnosis, an upcoming surgery, and a long recovery. For this reason, it is not surprising that patients most often listed stress and forgetfulness as reasons for not completing baseline and follow-up questionnaires. Future investigators should consider these real-life challenges in their research. To enhance completion rates during follow-up, future investigators should consider having questionnaires completed in the clinic. This suggestion, however, is dependent on available clinic space and the patient's schedule. In the current study, this option was not always feasible due to additional appointments, family obligations, or concerns about parking fees. Additionally, if funding allows, incentives such as a draw for gift-cards upon study completion could be integrated into the study protocol.

In addition to stress and forgetfulness, it is important to note that many patients mentioned confusion around certain questions or that they felt some questions were not applicable to them. As mentioned previously, these questions were often related to comfort/confidence with the body. Interestingly, the authors found that the number of omitted questions decreased as the patients' recovery

Table 9. Completion Rates of Patient Diaries at Each Time Point

	1 Month		6 Months		12 Months	
	AAT	TE/I	AAT	TE/I	AAT	TE/I
Diary Section	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Productivity loss	9 (43%)	3 (33%)	5 (25%)	3 (18%)	5 (26%)	4 (25%)
Patient-borne expenses	11 (52%)	8 (38%)	6 (30%)	4 (24%)	8 (42%)	4 (25%)
Appointments	11 (52%)	3 (33%)	3 (15%)	3 (18%)	3 (16%)	2 (13%)

n, number of patients who completed section; %, percentage of total patients within surgical group.

progressed from 1 to 12 months. Although the questions were applicable, they may have been avoided depending on how the patients were feeling about themselves early in recovery. To prevent patients from bypassing relevant questions, future studies could utilize data collection software, which reminds patients to complete questionnaires and "forces" answers. Investigators must, however, consider the cost and potential patient discomfort with such technology.

Completion of the patient diaries was suboptimal. This unmasked several issues that require explanation/interpretation. The authors speculate that the completion of the patient diary may have been too onerous for this patient population. It was observed that patients often would not return diaries at each time point but would wait until they were full. Diaries were often not dated very well, making it difficult to determine when appointments or medically necessary purchases were made. Furthermore, blank spaces could have been incorrectly interpreted as incomplete when, in reality, patients had no data to enter. The authors suggest including options such as "I have no expenses to report" within the diary to decrease the frequency of "blank responses". Future investigators could also utilize data collection software for patient diaries, while considering the above-mentioned limitations of cost and patient comfort.

The completion rate of study CRFs revealed some challenges. The screening and enrollment form was not realistic, specifically, in a busy hospital clinic. Such an environment does not offer the privilege of time and space. As these clinics often experience a high volume of patients in a short period of time, the authors suggest the use of a "screening log" in a password-protected electronic document. This method would allow quick data entry at the time of the patient consultation and would reduce paperwork. The baseline surgical report form, which was to be completed by the surgeon at the time of surgery, was also impractical. Ensuring the form was available to the surgeon required extra organization on behalf of already busy administrative assistants. Furthermore, at our institution, surgeries can occur at 1 of the 2 McMaster-associated hospitals, making this coordination between surgeon and assistant even more difficult. The authors suggest that a more realistic approach would be to have a research personnel complete this form after the surgery using operative records.

In addition to the above-mentioned suggestions, the authors recommend the following 6 methodological considerations for a future definitive study: (1) Consider the rate of attrition and the very small effect size calculated from the BREAST-Q. Both attrition and effect size will impact the required sample size[28]; (2) Consider the use of health records, as they may be more reliable when compared with patient diaries. This information should also be used to double check the patient diary entries; (3) Consider the use of hospital experts such as case-costing specialists. These individuals can be incredibly useful, especially when data collected through other means, such as patient diaries, may be less reliable. Similar to health records, these data can not only provide information, but also act as a method of quality control; (4) Consider the significant difference in BMI between AAT and TE/I patients; a subgroup analysis by BMI may be warranted; (5) Although not considered in our study, future data collection should capture adjuvant therapies, as these can drastically influence conclusions; and (6) Comparisons between immediate and delayed reconstructive patients should be made to determine any detrimental effects on quality of life due to mastectomy.

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