Original Article

An 11-year retrospective analysis of clinical outcomes after prepectoral implant-based breast reconstruction performed by a single surgeon

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Background: Prepectoral implant breast reconstruction is being offered to an increasing number of breast cancer patients because it results in less postoperative pain, faster recovery and a lower risk of animation deformity compared to subpectoral reconstruction. However, broad acceptance of this muscle-sparing procedure is still slow secondary to safety concerns, including an increased risk of capsular contracture, implant exposure, implant visibility and delayed detection of breast cancer recurrence. This study aimed to describe clinical outcomes in prepectoral breast reconstruction performed by a single surgeon over an 11-year period.

Methods: A retrospective chart review was conducted of all patients who had prepectoral or subpectoral implant breast reconstruction from 2010 to 2021. Demographic, clinical and operative data were assessed. Outcomes were determined by comparing complication rates between prepectoral and subpectoral implant reconstruction, including, capsular contracture, infection, mastectomy skin flap necrosis, implant loss, seroma, hematoma, dehiscence and local recurrence.

Results: A total of 758 prepectoral reconstructions were performed in 468 patients with a mean age of 52.5±9.9 (± SD) years and mean body mass index (BMI) of 28.8±6.1 kg/m^2. A total of 163 subpectoral implant reconstructions were performed in 100 patients with a mean age of 46.9±8.8 years and mean BMI of 25.2±5.0 kg/m^2. Complication rates in prepectoral implant reconstruction patients were low and comparable to subpectoral patients, with regard to major infection (3.4% *vs.* 1.2%), major necrosis (1.7% *vs.* 1.2%), capsular contracture (6.5% *vs.* 9.8%), implant loss (4.1% *vs.* 4.3%), seroma (0.3% *vs.* 1.2%), hematoma (0.3% *vs.* 0%), dehiscence (0.7% *vs.* 1.2%), local recurrence (1.3% *vs.* 1.2%) and total complications (22.7% *vs.* 22.1%), respectively (P≥0.1462). Postmastectomy radiation and therapeutic reconstruction were risk factors for a complication in prepectoral implant reconstruction.

Conclusions: Prepectoral implant reconstruction is associated with low complication rates comparable to subpectoral implant reconstruction. Rates of capsular contracture, implant exposure and local recurrence were not increased with prepectoral reconstruction. Prepectoral implant reconstruction should be offered to breast cancer patients in settings where there is an experienced team of oncoplastic surgeons because of its decreased invasiveness, postoperative pain and low complication rates.

Keywords: Prepectoral; implant; breast reconstruction; outcomes

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Introduction

The most common method of breast reconstruction offered to breast cancer patients following mastectomy is implant-based breast reconstruction (1). Traditionally, prosthetic breast reconstruction has been performed in the submuscular plane and has evolved over time from complete coverage of the implant with the pectoralis and serratus muscles and fascia to partial submuscular coverage with the use of acellular dermal matrix (ADM) to cover the lower pole (2-8). Prepectoral implant breast reconstruction has become an alternative reconstructive option to partial and total submuscular coverage methods and can incorporate total implant coverage with ADM, or a combination of upper pole coverage with an ADM sling and lower pole coverage with an inferior de-epithelialized dermal flap (9). The placement of an implant or tissue expander in the prepectoral space with the aid of ADM avoids elevation of the pectoralis and serratus muscles and fascia. It is a muscle-sparing procedure, resulting in less postoperative pain, faster recovery and lower risk of animation deformity compared to subpectoral reconstruction (10,11). Multiple studies have shown acceptable outcomes after prepectoral breast reconstruction compared to submuscular reconstruction (12-21).

Despite these advantages, broad acceptance of the procedure is still slow secondary to safety concerns, including a fear of increased risk of capsular contracture, implant exposure and implant visibility, as well as delayed detection of breast cancer recurrence. This study aimed to describe clinical outcomes in prepectoral breast reconstruction performed by a single surgeon over an 11-year period, and to compare outcomes after prepectoral reconstruction to outcomes after subpectoral reconstruction performed by the same surgeon during the same study period. We present the following article in accordance with the STROBE reporting checklist (available at https://abs.amegroups.com/article/view/10.21037/abs-21-78/rc).

Methods

A retrospective chart review was performed of all patients who had prepectoral or subpectoral implant-based breast reconstruction with an inferior de-epithelialized dermal flap and ADM performed by the senior author (A.O.Y) at Mount Sinai South Nassau in Oceanside, New York and Yale New Haven Health/Bridgeport Hospital in Bridgeport, Connecticut between January 1st, 2010 and April 30th, 2021. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013), and was approved by the NYU Winthrop Institutional Review Board (IRB approval number 17411) and informed consent for this retrospective analysis was waived.

Demographic characteristics were evaluated, including age, body mass index (BMI), active smoking, history of diabetes and radiation exposure. Clinical and operative characteristics were also recorded, including laterality, prophylactic or therapeutic indication, implant volume, whether autologous fat grafting was performed as a secondary procedure, and whether the nipple-areolar complex was harvested and repositioned as a free nipple graft. Outcomes were assessed by calculating complication rates, including capsular contracture, infection, mastectomy skin flap necrosis (MSFN), implant loss, seroma, hematoma, dehiscence and local recurrence. Major complications were defined as those requiring rehospitalization or reoperation, and minor complications were managed without rehospitalization or reoperation.

All patients who had prepectoral or subpectoral implant breast reconstruction with an inferior de-epithelialized dermal flap with a Wise pattern or modified-Wise pattern mastectomy incision and ADM were included. Patients who underwent prepectoral or subpectoral implant breast reconstruction with other mastectomy incision patterns were excluded. Patients with a history of premastectomy radiation therapy who underwent prepectoral or subpectoral implant breast reconstruction were also excluded because implant breast reconstruction in this group of patients is not standard of care. The majority of patients in the study underwent Wise pattern mastectomy and were large breasted, had a certain degree of ptosis and wanted to be smaller or similar in breast size. Of these patients, those who were suitable candidates and for whom it was oncologically safe, had the nipple-areolar complex harvested as a full-thickness graft and grafted to a new location on the reconstructed breast. Patients who did not have the nipple-areolar complex harvested as a free graft had the nipple sacrificed with the Wise pattern mastectomy. A small

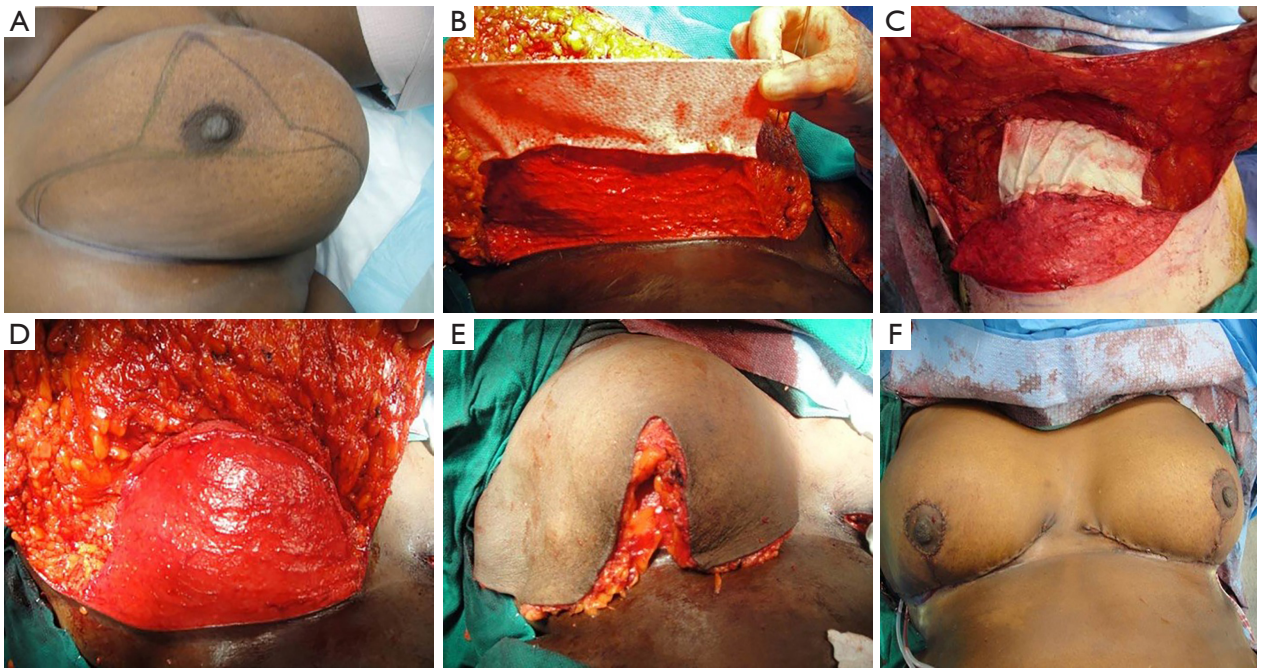

Figure 1 Prepectoral breast reconstruction technique. (A) Wise pattern mastectomy and inferior dermal flap harvest design; (B) a de-epithelialized dermal flap is fashioned from inferior breast skin and sewn to acellular dermal matrix (ADM); (C) to create the implant pocket, the ADM and de-epithelialized dermal flap are sutured to chest wall; (D) the implant is placed in the implant pocket, covered with de-epithelialized dermal flap inferiorly and ADM superiorly; (E) the mastectomy flaps are draped over implant; (F) in suitable patients, the flap is inset with a free nipple graft. Permission for reuse from *Ann Surg Oncol* 2018;25(10):2899-2908.

number of patients in the study who did not have ptosis underwent nipple-sparing mastectomy with the nipple-areolar complex left intact and implant reconstruction. Postoperatively, patients were seen in clinic weekly or bi-weekly, or until it was confirmed that complete wound healing had occurred without complications.

Materials

Smooth round silicone gel implants or expandable saline implants (Mentor Worldwide LLC, Irvine, CA, USA) and porcine-derived Strattice® acellular dermal matrix (Allergan Inc, Irvine, CA, USA) were used in all reconstructions.

Prepectoral implant breast reconstruction technique

As most patients had some degree of ptosis, a Wise or modified-Wise pattern mastectomy incision with an inferior de-epithelialized dermal flap was used (*Figure 1A-1F*). To create the implant pocket, a piece of ADM was sewn to the medial point of the mastectomy pocket, the superior point of the pectoralis muscle and the superior point of the inferior de-epithelialized dermal flap. The implant was covered with ADM superiorly and the de-epithelialized dermal flap inferiorly and was sutured down to the chest wall, serratus fascia and inferior de-epithelialized dermal flap, closing the implant pocket. One closed suction drain was placed in the mastectomy pocket and was removed after 2 weeks in non-radiated breasts and after 3 to 4 weeks in radiated breasts. Patients for whom it was oncologically safe, had the nipple-areolar complex harvested as a full-thickness free nipple graft and wrapped in saline-moistened gauze. After mastectomy and implant reconstruction was performed, the skin overlying the ideal nipple location on the breast mound was de-epithelialized and the free graft was sutured in place (*Figures 2,3*). The vast majority of reconstructions were performed in a single-stage direct-to-implant approach. Patients who had a deficit of skin and who wished to accomplish a significant increase in breast size were accommodated with a two-stage expander-to-implant reconstruction. In this study, autologous fat grafting was an integral component of breast reconstruction as a way

Figure 2 Left, postoperative photograph of a 65-year-old patient 5 years after bilateral prepectoral implant reconstruction with free nipple graft. Right, postoperative photograph of a 45-year-old patient 2 years after left unilateral prepectoral implant reconstruction with free nipple graft.

Figure 3 Postoperative photographs of a 64-year-old patient 2 years after bilateral prepectoral implant reconstruction with free nipple graft.

to improve contour deformities and customize the upper and medial pole.

Subpectoral implant reconstruction was performed in a similar manner using a Wise or modified-Wise mastectomy incision. An inferior de-epithelialized dermal flap was fashioned from excess lower-pole breast tissue. The pectoralis major muscle was elevated off the chest wall. The superior aspect of the de-epithelialized dermal flap was sewn to the inferior aspect of the elevated pectoralis major muscle to create the implant pocket, and a lateral piece of ADM was sewn to the inferior de-epithelialized dermal flap, the pectoralis major muscle and the lateral chest wall fascia. After the implant was placed in the mastectomy implant pocket, the implant pocket was closed by placing lateral sutures in the ADM.

Statistical analysis

Continuous variables were described as the mean ± SD and compared using a two-tailed *t*-test. Categorical variables were described as percentages. To determine associations between categorical variables and complication rates, a two-tailed Fisher's exact test was used. P values less than 0.05 were considered significant.

Results

Over the 11-year study period, 758 prepectoral implant breast reconstructions were performed in 468 patients with an average follow-up of 24 months, a mean age of 52.5±9.9 (± SD) years and mean body mass index (BMI) of 28.8±6.1 kg/m^2 (*Table 1*). Twenty-seven patients (5.8%)

were active smokers, 24 patients (5.1%) were diabetic and 107 breasts (14.1%) received postmastectomy radiation therapy. The majority of reconstructions were bilateral (62.0%) and therapeutic (54.5%) and 98.3% were single-stage direct-to-implant. Mean implant volume was 356.0±123.8 cc, 41.3% had autologous fat grafting for contour deformities as a secondary procedure and 52.6% had a nipple-areolar complex free graft.

During the same study period, 163 subpectoral implant breast reconstructions were performed by the same surgeon in 100 patients with a mean follow-up of 32 months, a mean age of 46.9±8.8 years and a mean BMI of 25.2±5.0 kg/m^2. Five patients (5.0%) were active smokers, 3 patients (3.0%) were diabetic and 23 breasts (14.1%) received postmastectomy radiation therapy. Similar to the prepectoral cohort, the majority of reconstructions were bilateral (63.0%) and therapeutic (62.6%) and 72.4% were single-stage direct-to-implant. Mean implant volume was 366.1±136.8 cc, 77.9% had autologous fat grafting as a secondary procedure and 33.1% had a nipple-areolar complex free graft.

Demographic and clinical characteristics were similar between prepectoral and subpectoral implant reconstruction patients; however, prepectoral reconstruction patients were older (52.5±9.9 *vs.* 46.9±8.8 years; P=0.0001), had a higher BMI (28.8±6.1 *vs.* 25.2±5.0 kg/m^2; P=0.0001), a shorter follow-up period (23.6±24.0 *vs.* 31.9±22.4 months; P=0.0016), a larger percentage of free nipple grafts (52.6% *vs.* 33.1%), a smaller percentage of autologous fat grafting (41.6% *vs.* 77.9%) and a larger percentage of single-stage reconstructions (98.3% *vs.* 72.4%), respectively (P=0.0001). The higher BMI in prepectoral reconstruction patients can be attributed to the need for more upper-pole soft-tissue coverage required to perform this technique compared to subpectoral implant reconstruction. The shorter follow-up period in prepectoral reconstruction patients can be attributed to the fact that this technique was adopted and incorporated into the reconstructive armamentarium of the senior author later in her career.

Complication rates were low after prepectoral implant reconstruction, with capsular contracture (6.5%), implant loss (4.1%), major infection and minor mastectomy skin flap necrosis (3.4%) being the most common. Complication rates after prepectoral implant reconstruction were comparable to those after subpectoral implant reconstruction, with regard to major infection (3.4% *vs.* 1.2%), minor infection (0.9% *vs.* 0.6%), seroma (0.3% *vs.* 1.2%), hematoma (0.3% *vs.* 0%), dehiscence (0.7% *vs.* 1.2%), major mastectomy skin flap necrosis (1.7% *vs.* 1.2%), minor mastectomy skin flap necrosis (3.4% *vs.* 1.2%), capsular contracture (6.5% *vs.* 9.8%), implant loss (4.1% *vs.* 4.3%), local recurrence (1.3% *vs.* 1.2%), local recurrence in therapeutic reconstructions (2.4% *vs.* 1.9%), total complications (22.7% *vs.* 22.1%) and breasts with one or more complication (14.8% *vs.* 16.6%), respectively (P≥0.1462). It is important to note that in many cases multiple complications occurred in the same breast, as poor mastectomy skin flap quality often leads to necrosis, infection, seroma and implant loss.

To determine risk factors for complications after prepectoral implant reconstruction, demographic, clinical and operative characteristics were compared between patients with one or more major or minor complications to patients without a complication (*Table 2*). Demographic, clinical and operative characteristics were similar in patients with a complication to patients without a complication; however, patients with a complication had a higher rate of receiving postmastectomy radiation therapy (28.0% *vs.* 11.6%; P=0.0001), a higher rate of therapeutic reconstruction (64.4% *vs.* 52.6%; P=0.0206) and a longer follow-up period (35.5±29.0 *vs.* 22.3±22.8 months; P=0.0001). Age, BMI, active smoking, diabetes, bilateral reconstruction, single-stage reconstruction, implant volume and autologous fat grafting were not significantly associated with a complication after prepectoral implant reconstruction.

Discussion

Broad acceptance of prepectoral implant-based breast reconstruction as an alternative to submuscular implant reconstruction after mastectomy has been slow secondary to a fear of increased risk of capsular contracture, implant exposure and implant visibility, as well as delayed detection of breast cancer recurrence. The results of this large cohort study of 758 prepectoral implant-based reconstructions in 468 patients performed by single surgeon over an 11-year period show that this muscle-sparing technique of direct-to-implant reconstruction can be performed safely with low complication rates, comparable to those associated with subpectoral implant reconstruction. Rates of capsular contracture, implant exposure and local recurrence were not increased in this study during the senior author's 11-year experience performing prepectoral implant breast reconstruction. Furthermore, postmastectomy radiation therapy and therapeutic reconstruction were risk factors for a major or minor complication after prepectoral implant

Table 1 Demographic, clinical and outcome characteristics in prepectoral versus subpectoral implant-based breast reconstruction

Characteristics	Prepectoral total	Subpectoral total	P value
No. of patients	468	100	
No. of breasts	758	163	
Follow-up‡ (months)	23.6±24.0	31.9±22.4	0.0016*
Demographic			
Age‡ (years)	52.5±9.9	46.9±8.8	0.0001*
BMI‡ (kg/m^2)	28.8±6.1	25.2±5.0	0.0001*
Smokers	5.8 [27]	5.0 [5]	1.0000
Diabetes	5.1 [24]	3.0 [3]	0.4487
Postmastectomy radiation	14.1 [107]	14.1 [23]	1.0000
Clinical			
Unilateral	38.0 [178]	37.0 [37]	0.9097
Bilateral	62.0 [290]	63.0 [63]	
Prophylactic	45.5 [345]	37.4 [61]	0.0677
Therapeutic	54.5 [413]	62.6 [102]	
Single-stage	98.3 [745]	72.4 [118]	0.0001*
Two-stage	1.7 [13]	27.6 [45]	
Implant volume (cc)	356.0±123.8	366.1±136.8	0.3541
Autologous fat grafting	41.3 [313]	77.9 [127]	0.0001*
Free nipple graft	52.6 [399]	33.1 [54]	0.0001*
Complications			
Infection (major)	3.4 [26]	1.2 [2]	0.2056
Infection (minor)	0.9 [7]	0.6 [1]	1.0000
Seroma	0.3 [2]	1.2 [2]	0.1462
Hematoma	0.3 [2]	0	1.0000
Dehiscence	0.7 [5]	1.2 [2]	0.3593
Necrosis (major)	1.7 [13]	1.2 [2]	1.0000
Necrosis (minor)	3.4 [26]	1.2 [2]	0.2056
Capsular contracture	6.5 [50]	9.8 [16]	0.1786
Implant loss	4.1 [31]	4.3 [7]	0.8305
Local recurrence total	1.3 [10]	1.2 [2]	1.0000
Local recurrence therapeutic	2.4 [10]	1.9 [2]	1.0000
Complications total	22.7 [172]	22.1 [36]	0.9180
≥1 complication	14.8 [113]	16.6 [27]	0.4689

‡, continuous variables reported as the mean ± SD. Categorical variables reported as percentages with the number comprising the percentages in brackets. *, the difference is statistically significant. Adapted from *Ann Surg Oncol* 2018;25(10):2899-2908. BMI, body mass index; SD, standard deviation.

Table 2 Demographic, clinical and operative characteristics associated with at least one major or minor complication in prepectoral implant-based breast reconstruction

Characteristics	≥1 complication	No complication	P value
No. of patients	104	424	
No. of breasts	118	640	
Follow-up‡ (months)	35.5±29.0	22.3±22.8	0.0001*
Demographic			
Age‡ (years)	51.6±9.3	52.4±9.9	0.4553
BMI‡ (kg/m^2)	29.5±6.9	28.7±5.8	0.2260
Smokers	8.6 [9]	5.4 [23]	0.2494
Diabetes	8.6 [9]	3.8 [16]	0.0659
Postmastectomy radiation	28.0 [33]	11.6 [74]	0.0001*
Operative and clinical			
Unilateral	30.8 [32]	34.4 [146]	0.5629
Bilateral	69.2 [72]	65.6 [278]	0.5629
Prophylactic	35.6 [42]	47.3 [303]	0.0206*
Therapeutic	64.4 [76]	52.6 [337]	0.0206*
Single-stage	97.4 [115]	98.4 [630]	0.4381
Two-stage	2.5 [3]	1.6 [10]	0.4381
Implant volume (cc)	370.7±129.1	353.3±122.7	0.1608
Autologous fat grafting	43.2 [51]	40.9 [262]	0.6843

‡, continuous variables reported as the mean ± SD. Categorical variables reported as percentages with the number comprising the percentages in brackets. *, the difference is statistically significant. BMI, body mass index; SD, standard deviation.

reconstruction. Another important outcome of this study is that it demonstrates that larger breasted women with ptosis who are not ideal candidates for nipple-sparing mastectomy can safely undergo immediate prepectoral implant reconstruction using a Wise pattern mastectomy incision with the nipple-areolar complex harvested and repositioned in an ideal location as a free graft.

In a large 12-year study of 1,522 two-stage expander-to-implant subpectoral reconstructions in 1,221 patients, Cordeiro and McCarthy reported outcomes comparable to that of our study. The authors reported an overall early total complication rate of 5.8%, with the most common complication being infection (2.5%), followed by native skin flap necrosis (2.0%), hematoma (0.4%), seroma (0.2%) and delayed wound healing (0.4%) (2). In a follow-up study, the authors reported long-term complications in a subgroup of 410 reconstructions in 315 patients with a minimum of 1 year of follow-up (22). The rates of severe Grade III and IV capsular contracture in the group as a whole was 18.1%, which included patients who received pre- and postmastectomy radiation and was 10.3% in non-radiated patients. These rates of capsular contracture were higher than that reported in our study (6.5%) which included Baker's Grade II through IV capsular contracture.

The results of this large study also compare favorably with other published studies on clinical outcomes after prepectoral implant breast reconstruction. In a study comparing prepectoral breast reconstruction in 51 patients (84 breasts) to subpectoral breast reconstruction in 115 patients (186 breasts), Sbitany *et al.* showed the overall total complication rate was 17.9% in the prepectoral group and was comparable to that of the subpectoral group (18.8%) (16). In the prepectoral group the most common complications were minor infection (4.8%), seroma (3.6%), major infection and hematoma (2.4%) and major mastectomy skin flap necrosis and implant

loss (1.2%). In the subpectoral group, the most common complications were minor infection (9.1%), seroma (6.5%), major infection (5.9%), implant loss and major mastectomy skin flap necrosis (4.3%) and hematoma (1.1%). In this study, complications in both prepectoral and subpectoral patients compared favorably with that of our study. Nealon *et al.* reported an overall complication of 14.0% in 183 prepectoral direct-to-implant reconstructions (114 patients), with capsular contracture comprising 1.8%, major MSFN 4.4%, seroma 8.8%, hematoma 5.3% and implant loss 3.5% (23). In this study, 6.1% of prepectoral reconstructions received premastectomy radiation therapy and 24.6% received postmastectomy radiation therapy. Interestingly, rates of capsular contracture (1.8% *vs.* 6.5%) and implant loss (3.5% *vs.* 4.1%) in this study were lower than that reported in our study, while rates of major MSFN (4.4% *vs.* 1.7%), seroma (8.8% *vs.* 0.3%) and hematoma (5.3% *vs.* 0.3%) were higher.

The non-randomized, retrospective design are limitations of this study because of the potential for selection bias. However, the significance of this study lies in that it demonstrates that prepectoral breast reconstruction can be performed safely and effectively with complication rates comparable to that of submuscular reconstructive methods. In settings where there is an experienced team of oncoplastic surgeons, prepectoral breast reconstruction should be offered to breast cancer patients after mastectomy because of low complication rates, reduced invasiveness of the procedure, postoperative pain and faster recovery.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://abs.amegroups.com/article/view/10.21037/abs-21-78/rc

Data Sharing Statement: Available at https://abs.amegroups.com/article/view/10.21037/abs-21-78/dss

Peer Review File: Available at https://abs.amegroups.com/article/view/10.21037/abs-21-78/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://abs.amegroups.com/article/view/10.21037/abs-21-78/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the NYU Winthrop Institutional Review Board (IRB approval number 17411) and informed consent for this retrospective analysis was waived.

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