Selection of Dermal-Parenchymal Pedicle Based on Tumor Quadrant Location in Therapeutic Mammoplasty for Early-Stage Breast Cancer: A Prospective Cohort Study of Surgical, Pathological, Patient-Reported and Early Oncological Outcomes

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ABSTRACT

Background: Therapeutic mammoplasty (TM) combines oncological resection with breast-reduction techniques, extending breast conservation to women with early-stage breast cancer and macromastia or marked ptosis. The dermal-parenchymal pedicle is chosen mainly according to tumor quadrant. We evaluated the surgical, pathological, patient-reported and early oncological outcomes of a location-guided pedicle strategy. Patient and Methods: In this single-center prospective cohort (May 2022 to May 2023; follow-up to 31 May 2025), 100 women with stage I–II invasive carcinoma or extensive DCIS underwent TM with an inferior pedicle for upper/central tumors (Group A, n = 50) or a superior/superomedial pedicle for lower-quadrant tumors (Group B, n = 50). Allocation was non-randomized and determined by tumor location. The primary endpoint was initial margin clearance on the first excision specimen. Positive margins (ink on tumor) and close margins (<1 mm invasive, <2 mm DCIS) were reported separately under one definition. Secondary endpoints were final margins, Clavien–Dindo complications, axillary outcomes, BREAST-Q (breast-conserving therapy module), Harris cosmetic rating and disease-free survival (DFS). Secondary analyses were exploratory. Results: Initial margin clearance was 94.0% (47/50; 95% CI 83.5–98.7) in Group A and 92.0% (46/50; 80.8–97.8) in Group B (overall 93.0%, 86.1–97.1; Fisher p = 1.000). Initial ink-on-tumor margins occurred in 2.0% (2/100) and close margins in 5.0% (5/100); all were re-excised, no patient required mastectomy for margins, and final positive and close margins were 0%. Sentinel node identification was 98.7% (77/78 cN0 patients), and axillary dissection was avoided in 88.5% (69/78) of cN0 patients; lymphedema occurred in 5/31 patients with ALND and 0/69 without. NAC vascular compromise was 4.0% vs 14.0% (p = 0.160). Grade IIIb re-operation for complications was 4.0% in each group (4.0% vs 8.0% when planned re-excision with NAC realignment was added; p = 0.678). BREAST-Q (n = 49 vs 48; median 28.2 months) Satisfaction with Breasts was 86.4 ± 8.2 vs 82.8 ± 9.5 (unadjusted p = 0.049; Bonferroni-adjusted p = 0.195). Harris ratings were excellent/good in 92.0% vs 88.0% (Krippendorff's alpha 0.79). At a median follow-up of 30.1 months, three ipsilateral breast tumor events (two true recurrences, one new primary) occurred at 13.8–22.1 months; 24-month DFS was 98.0% vs 96.0% (log-rank p = 0.560), with no distant metastases or

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deaths. Conclusions: Location-guided pedicle selection in TM achieved a low initial positive-margin rate, acceptable complication rates and high patient-reported satisfaction, with encouraging but short-term oncological results. Because allocation was non-randomized and confounded by tumor location, between-pedicle differences are associations, not evidence of superiority.

Keywords: Oncoplastic Breast Surgery, Therapeutic Mammoplasty, Inferior Pedicle, Superior Pedicle, Margin Status.

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1. INTRODUCTION

Neoplastic breast surgery integrates plastic-surgical principles into breast-conserving surgery (BCS) without compromising oncological safety [1, 2]. In women with moderate-to-large breasts or moderate-to-severe ptosis, conventional BCS often yields unfavorable cosmesis, including “bird-beak” deformity, nipple malposition, asymmetry and parenchymal retraction, which whole-breast radiotherapy may aggravate [2, 3]. Therapeutic mammoplasty (TM) addresses these limitations by embedding a generous wide local excision within a formal mammoplasty pattern [4, 5]. Redistribution of the residual parenchyma and repositioning of the nipple-areola complex (NAC) on a dedicated dermal-parenchymal pedicle allow wide resection while preserving breast shape and permitting symmetrization of the contralateral breast [6, 7].

Pedicle selection is governed primarily by tumor quadrant, breast volume, shape and degree of ptosis. Technical descriptions of the two pedicles [8, 9] and anatomical studies of the NAC blood supply [10] frame the rationale used here: **Inferior dermal-parenchymal pedicle (Group A):** based on the inframammary fold and central-inferior breast, preserving the inferior and lateral contributions to the subdermal and parenchymal vascular plexus (including anterior intercostal perforators of the lower interspaces); it is used for tumors of the upper outer (UOQ), upper inner (UIQ) and central/subareolar regions, where the resection removes tissue from the upper breast and leaves the lower-pole pedicle intact.

Superior / superomedial pedicle (Group B): a superior or superomedial flap nourished mainly by the internal thoracic perforators of the upper interspaces and branches of the lateral thoracic artery, as described for superomedial and vertical-pattern techniques [9, 10]; it is used for tumors of the lower outer (LOQ), lower inner (LIQ) and 6 o’clock regions, because the inferior breast can be resected widely while the NAC is carried on the upper pole. Because pedicle choice follows tumor location, the two techniques serve different anatomical zones and are not exchangeable comparators. This prospective cohort study evaluates the surgical, pathological, patient-reported and early oncological outcomes of a standardized, tumor-location-guided pedicle strategy. The primary endpoint was initial margin clearance; secondary endpoints were final margin status, complications (including NAC vascular compromise), axillary outcomes, BREAST-Q scores, cosmetic ratings and disease-free survival.

2. PATIENTS AND METHODS

This was a single-center prospective cohort study. The first patient was operated on May 2022 and the last on May 2023; follow-up continued to the predefined data cutoff of May 2025. The study was approved by the Institutional Review Board before enrolment and all patients gave written informed consent, including consent for publication of clinical photographs. The study was reported in accordance with the STROBE statement [11]; the completed checklist is provided as supplementary material. Because the investigators did not assign participants to an intervention (both pedicle techniques are established standard care and were selected by tumor location), the study was an observational cohort and was not prospectively entered in a clinical-trial registry, which is not required for observational studies under ICMJE policy; the protocol is available from the corresponding author. Inclusion criteria were: (i) core-needle-biopsy-proven invasive carcinoma of clinical stage T1–T2, N0–N1 (mobile, biopsy-proven N1), M0, or extensive ductal carcinoma in situ (DCIS), amenable to breast conservation, i.e., clinical anatomic stage I–IIB; (ii) macromastia or moderate-to-severe ptosis (Regnault grade II–III) making TM appropriate; (iii) tumor size and tumor-to-breast ratio compatible with breast conservation on imaging and multidisciplinary team (MDT) review (no fixed upper size limit; tumors up to approximately 5 cm were accepted when an acceptable cosmetic result was predicted); (iv) planned adjuvant whole-breast irradiation; and (v) written informed consent. Exclusion criteria were: active smoking, multicentric disease or widespread DCIS requiring mastectomy, prior breast or chest-wall radiotherapy, connective-tissue disease, clinical stage III–IV or inflammatory disease, pregnancy, and any contraindication to breast conservation or radiotherapy. Diabetes mellitus was not an exclusion criterion. Eligibility

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was determined on pre-operative clinical stage; no enrolled patient had four or more positive nodes (pN2) on final pathology, so all patients were also pathological stage I–II. Biopsy-proven cN1 disease was permitted because our Hospitals is a tertiary referral center that receives patients with node-positive early breast cancer; all cN1 nodes were confirmed by ultrasound-guided needle biopsy.

Accrual and quota closure. A total of 155 consecutive patients with early-stage breast cancer who were candidates for TM were screened (Figure 1). Pedicle selection was dictated by tumor quadrant (Group A, upper or central tumors; Group B, lower-quadrant tumors). Enrollment continued until the prespecified quota of 50 analyzed patients per group was reached (N = 100), after which protocol enrollment closed; subsequent patients received routine care outside the study. Fifty-five patients were excluded before allocation: 32 failed inclusion criteria, 15 required total mastectomy because of multicentricity or widespread DCIS, and 8 declined study participation.

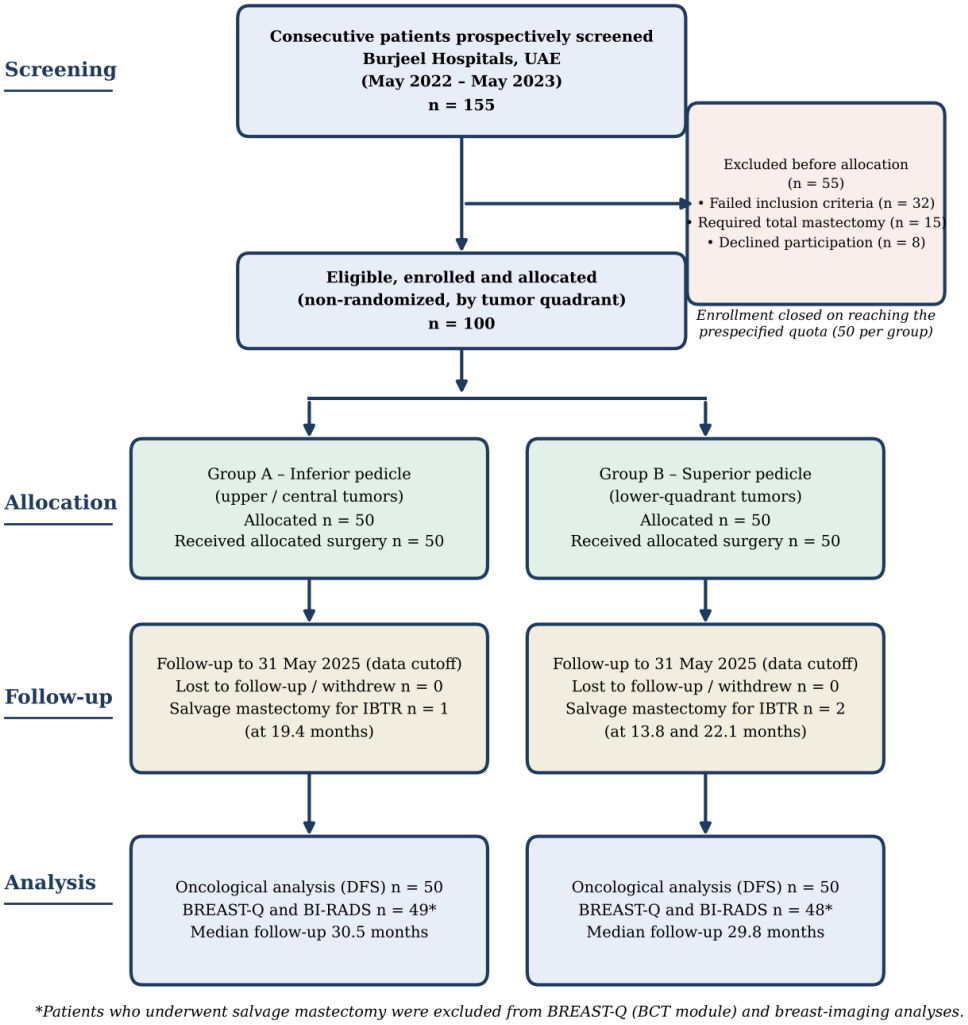


Figure 1. STROBE flow diagram of the prospective cohort. Enrollment closed when the quota of 50 patients per group was reached. Three patients (one in Group A, two in Group B) underwent salvage mastectomy for ipsilateral breast tumor events; they remained in the oncological analysis but were excluded from the BREAST-Q and breast-imaging analyses. IBTR, ipsilateral breast tumor recurrence; DFS, disease-free survival.

Preoperative work-up, pedicle selection, and surgical technique

All patients underwent bilateral digital mammography and breast ultrasound, with dynamic contrast-enhanced MRI when indicated, to define tumor extent and exclude multicentricity. Tissue diagnosis was established exclusively by image-guided 14-gauge core-needle biopsy; fine-needle aspiration cytology was not used for primary diagnosis. The pedicle was assigned before surgery by the MDT and operating surgeon: inferior pedicle for tumors in the upper quadrants and central region, and superior/superomedial pedicle for tumors in the lower quadrants and at 6 o'clock. Operations were performed by a team of three senior oncoplastic surgeons. Wise-pattern (inverted-T) skin incisions were used in 88 patients (88%) and vertical short-scar patterns in 12 (12%). The resection removed the tumor with a target macroscopic healthy margin of

1–2 cm, preserved the subcutaneous vascular plexus of the pedicle, and included deep parenchymal anchoring to limit distortion (Figures 2 and 3). The specimen was oriented with sutures and the cavity was marked with surgical clips. Contralateral symmetrization with a matching reduction using the same skin pattern was performed at the same operation in 94 patients (47 per group); in 6 patients (3 per group) it was staged after completion of radiotherapy and was finished before the 12-month cosmetic assessment. Contralateral specimens were examined histologically (see Results).

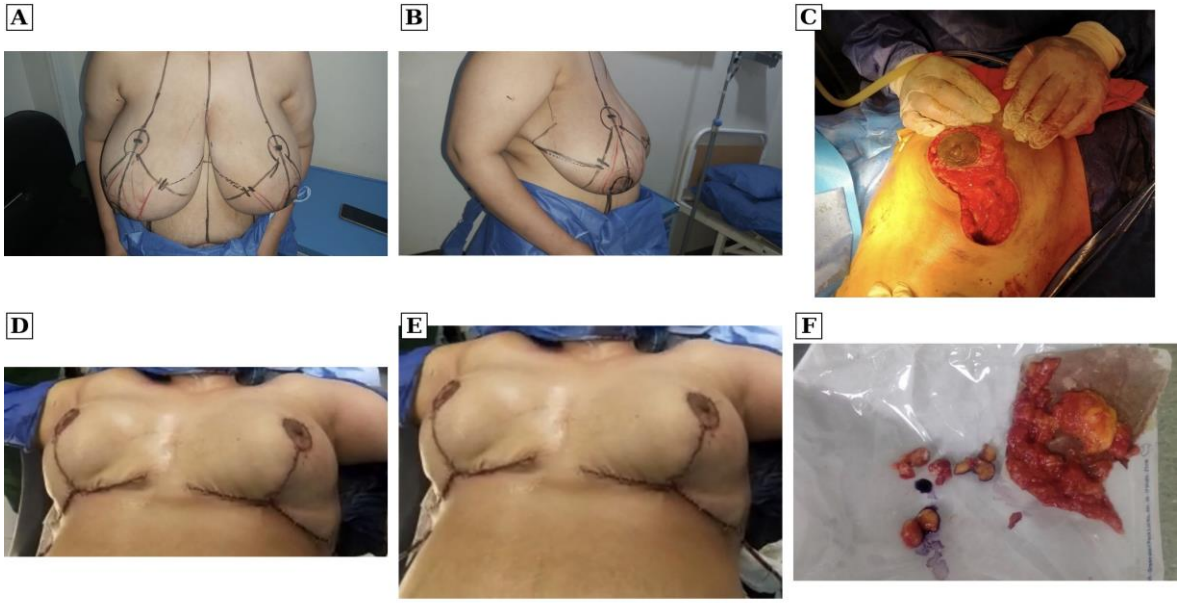


Figure 2. Representative case of Group A (inferior pedicle). (A) Preoperative frontal view with Wise-pattern markings. (B) Preoperative lateral view. (C) Intraoperative view after de-epithelialization of the inferior dermoglandular pedicle with the NAC preserved on it. (D) Immediate postoperative view on the operating table showing the inverted-T closure and repositioned NAC. (E) Additional immediate postoperative view of the closure. (F) Excised specimens: blue-dyed sentinel node and axillary nodal tissue (left); breast tissue containing the tumor with excess skin and orientation sutures (right). All panels are from the same patient; written consent for publication was obtained.

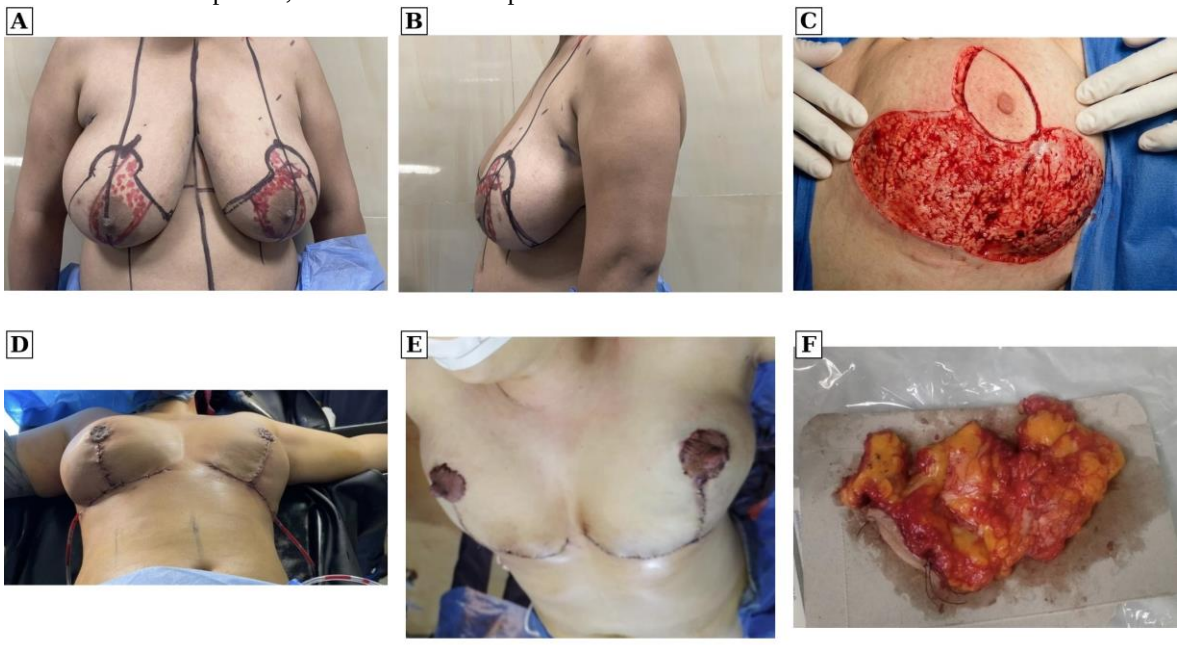


Figure 3. Representative case of Group B (superior pedicle). (A) Preoperative frontal view with markings; the red stippled area indicates the planned de-epithelialization zone, and the NAC is carried on the superior pedicle. (B) Preoperative lateral view. (C) Intraoperative view after de-epithelialization, with the NAC preserved on the superior dermoglandular pedicle. (D) Immediate postoperative view of the inverted-T closure with drains and the elevated NAC. (E) Additional immediate postoperative view of the closure. (F) Excised breast tissue containing the tumor with excess skin. All panels are from the same patient; written consent for publication was obtained.

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Margin definitions and re-excision policy

A single set of margin definitions was applied to the first excision specimen and to the final status after any re-excision. Margins were assessed on final paraffin sections of inked, serially sliced specimens. **Positive margin:** ink on tumor (invasive carcinoma or DCIS). **Close margin:** no ink on tumor, but a tumor-to-ink distance of less than 1 mm for invasive carcinoma or less than 2 mm for DCIS. **Clear margin:** at least 1 mm for invasive carcinoma and at least 2 mm for DCIS. Positive and close margins are reported separately throughout. The positive-margin definition corresponds to the SSO–ASTRO consensus for invasive carcinoma ("no ink on tumor") [12]; the 2 mm threshold for DCIS follows the corresponding DCIS guideline [13]. Re-excision policy was stricter than the consensus guideline. Intraoperative frozen-section examination was performed routinely, and any positive or close margin prompted immediate re-excision of the involved margin. Patients whose final paraffin pathology showed a positive or close margin not detected by frozen section underwent planned formal re-excision. This stricter threshold was adopted because re-excision after pedicle transposition and parenchymal reshaping is technically harder, tumor-bed orientation is altered, and it was considered preferable to resolve close margins before radiotherapy. Under a consensus-based 0 mm policy, only ink-on-tumor margins would have required re-excision; the effect of this policy is shown in the Results. Initial margin clearance (primary endpoint) was defined as a clear margin on the final pathology of the first excision specimen before any re-excision, and final margin status as the status after all re-excisions.

Axillary management and lymphedema assessment

Axillary management followed a uniform prospective algorithm. Clinically node-negative (cN0) patients underwent sentinel lymph node biopsy (SLNB) with a dual tracer (technetium-99m radiocolloid plus patent blue or indocyanine green), and the identification rate was recorded. All sentinel nodes underwent intraoperative frozen-section examination. Sentinel-node macrometastasis (>2 mm) led to completion axillary lymph node dissection (ALND, levels I–II) at the same operation. Sentinel-node micrometastasis (pN1mi, 0.2–2 mm) was managed according to MDT consensus without completion ALND and with regional nodal irradiation (RNI) [14, 15]. Failed sentinel-node identification led to ALND. Patients with biopsy-proven cN1 disease underwent upfront ALND. Isolated tumor cells were not encountered. Arm lymphedema was assessed at baseline and at 3, 6, 12 and 24 months by sequential bilateral arm circumference measurements at four landmarks (metacarpophalangeal joints, wrist, and 10 cm below and above the lateral epicondyle) and was defined as an inter-arm difference of more than 2 cm at any landmark. This definition is pragmatic and non-standardized; volume-based or symptom-based criteria could give different incidence rates. Lymphedema is reported by axillary procedure (SLNB alone versus ALND).

Adjuvant therapy

MDT protocols dictated adjuvant treatment. Whole-breast irradiation (40.05 Gy in 15 fractions, or 50 Gy in 25 fractions with a boost) was planned for all patients. RNI was given to all node-positive patients (pN1mi and pN1) per MDT consensus. Chemotherapy comprised AC-T (8 cycles over 16–20 weeks) or TC (4 cycles over 9–12 weeks) and started after wound healing; trastuzumab was given to all HER2-positive patients, and endocrine therapy to all hormone-receptor-positive patients. We recorded every patient whose chemotherapy start was delayed beyond 30 days and the reason for the delay.

Patient-reported outcomes, cosmetic evaluation and surveillance

BREAST-Q. Patient-reported outcomes were collected with the BREAST-Q postoperative module for breast-conserving therapy (BCT) [16], which suits oncoplastic breast conservation with radiotherapy. The four prespecified domains were Satisfaction with Breasts, Psychosocial Well-Being, Sexual Well-Being and Physical Well-Being (Chest); Adverse Effects of Radiation was analyzed as an exploratory scale. The information, surgeon, medical-team and office-staff scales were not analyzed because they do not relate to pedicle choice. The postoperative BCT module is not tied to a fixed time point; it was administered in clinic at the last scheduled study visit with PRO collection before the data cutoff, with a minimum interval of 24 months from surgery so that late radiotherapy-related tissue changes would have stabilized. Raw scores were Rasch-transformed to 0–100 (higher is better). The instrument was used under license from its developers (Memorial Sloan Kettering Cancer Center and the University of British Columbia), in the validated English or Arabic version according to patient preference. A pre-operative baseline questionnaire was not collected, so the scores describe post-treatment status and not change from baseline. Questionnaires were self-completed on a tablet in clinic before consultation and checked for completeness by a research nurse who was not part of the surgical team. Patients who had undergone salvage mastectomy were excluded from the BCT analysis because the module is not valid after mastectomy.

Cosmetic evaluation. Cosmetic outcome was rated at 12 months with the four-category Harris scale (excellent, good, fair, poor) from standardized frontal and oblique photographs by an independent panel of three evaluators who did not take part in any of the operations (two consultant oncoplastic surgeons and one consultant plastic surgeon from other institutions). Photographs were de-identified, cropped to remove identifying features and markings, and presented in random order. Both techniques leave an inverted-T or vertical scar, so the pedicle cannot be deduced from the scar pattern; blinding was nevertheless tested by asking each rater to guess the pedicle type for every case. The panel rating was the majority rating

of the three evaluators. Because the Harris scale is ordinal, agreement was quantified with Krippendorff's alpha for ordinal data [17] and with the mean pairwise quadratic-weighted kappa; the intraclass correlation coefficient (two-way random, absolute agreement, single measures) is given as a supplementary index.

Surveillance. Patients had clinical examination every 3 months for 2 years, then every 6 months, with mammography and ultrasound every 6 months for 2 years and annually thereafter. The BI-RADS category of the last surveillance imaging was recorded in patients with a conserved breast. Ipsilateral breast tumor recurrence (IBTR) was classified as a true recurrence (same quadrant or within 3 cm of the tumor bed, with the same histology and receptor profile) or a new primary tumor (different quadrant, distant from the bed, or different histology or receptor profile).

Statistical analysis

Analyses used IBM SPSS Statistics 28.0 and R 4.3.2. Continuous data were checked with the Shapiro–Wilk test and are presented as mean ± SD or median (IQR); groups were compared with the Welch t-test or Mann–Whitney U test. Categorical variables were compared with the chi-square or Fisher exact test. Exact (Clopper–Pearson) 95% confidence intervals are given for proportions, and risk differences use the Newcombe hybrid-score interval. No inferential tests were applied to baseline characteristics. DFS was defined as the time from surgery to IBTR (including a new ipsilateral primary), regional or distant recurrence, contralateral breast cancer, second primary cancer or death; patients without an event were censored at last follow-up. DFS was estimated by the Kaplan–Meier method and compared with the log-rank test.

Endpoints and sample size. The single primary endpoint was initial margin clearance, reported with 95% confidence intervals and compared between groups with Fisher's exact test. Secondary endpoints were final margin status, complications, axillary outcomes, the four BREAST-Q domains, cosmetic rating and DFS; all are exploratory. No a priori sample-size calculation was performed; 50 patients per group was a protocol-defined quota. For the primary endpoint, a sample of 100 patients gives a 95% confidence interval about ±6 percentage points around an expected clearance of 93%, and 50 per group gives about ±9 points per group. With 50 per group, power is 80% to detect a difference in initial clearance only as large as 95% versus 75%. For the BREAST-Q domains (n = 49 and 48), power is 80% to detect a standardized difference of about 0.57 SD (roughly 5 points for an SD of about 9). The study was not powered for rare events such as NAC necrosis. **Multiplicity:** p-values are unadjusted except for the four prespecified BREAST-Q domains, for which Bonferroni-adjusted p-values and Benjamini–Hochberg q-values are also reported. A two-sided $p < 0.05$ defined nominal significance. **Sensitivity analysis:** the Clavien–Dindo IIIb re-operation rate was also calculated counting planned re-excision with NAC realignment as a complication-related re-operation, and counting every return to theatre for any reason. There were no missing data and no loss to follow-up.

3. RESULTS

Study population and follow-up

One hundred patients (Group A n = 50; Group B n = 50) were enrolled and analyzed, and none was lost to follow-up. Median follow-up at the 31 May 2025 cutoff was 30.1 months overall (IQR 28.1–31.9; range 24.3–36.3), 30.5 months (28.5–32.1) in Group A and 29.8 months (27.9–31.5) in Group B (Mann–Whitney p = 0.243). Baseline and tumor characteristics are shown in Table 1. Twenty-two patients (22%) had biopsy-proven cN1 disease (10 in Group A, 12 in Group B). Contralateral specimens were benign in 98 patients and showed atypical ductal hyperplasia in 2; no occult malignancy was found.

Table 1. Baseline demographic, clinical and tumor characteristics

Characteristic	Group A: Inferior pedicle (n = 50)	Group B: Superior pedicle (n = 50)
Age, years (mean ± SD)	51.4 ± 6.8	52.1 ± 7.2
Body mass index, kg/m² (mean ± SD)	28.6 ± 3.4	29.1 ± 3.8
Type 2 diabetes mellitus	6 (12.0%)	7 (14.0%)
Regnault ptosis grade II / III	22 (44.0%) / 28 (56.0%)	24 (48.0%) / 26 (52.0%)
Tumor location (defines group)		
UOQ / UIQ / central	24 / 14 / 12	—
LOQ / LIQ / 6 o'clock	—	26 / 16 / 8
Clinical nodal status: cN0 / cN1 (biopsy-proven)	40 (80.0%) / 10 (20.0%)	38 (76.0%) / 12 (24.0%)
Histology: IDC / ILC / DCIS	42 / 6 / 2	41 / 7 / 2
Histological grade 1 / 2 / 3	8 / 32 / 10	7 / 31 / 12
ER and/or PR positive	41 (82.0%)	40 (80.0%)
HER2 positive (3+ or FISH+)	8 (16.0%)	9 (18.0%)
Ki-67 > 20%	21 (42.0%)	23 (46.0%)

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Characteristic	Group A: Inferior pedicle (n = 50)	Group B: Superior pedicle (n = 50)
Pathological tumor size, cm, median (IQR) [range]	1.7 (1.3–2.6) [0.5–4.8]	1.6 (1.3–2.5) [0.6–4.7]
pT category: pTis / pT1 / pT2	2 / 32 / 16	2 / 33 / 15
pN category: pN0 / pN1mi / pN1 (1–3 nodes)	34 / 2 / 14	32 / 2 / 16

Values are n (%) unless stated. No inferential tests were applied to baseline characteristics. Tumor location determines group by design. UOQ/UIQ, upper outer/inner quadrant; LOQ/LIQ, lower outer/inner quadrant; IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; DCIS, ductal carcinoma in situ. No patient had pN2 disease.

Margin outcomes and re-excision

Table 2 shows operative, margin and axillary data. On final pathology of the first excision specimen, 93 of 100 patients (93.0%; 95% CI 86.1–97.1) had a clear margin: 47/50 (94.0%; 83.5–98.7) in Group A and 46/50 (92.0%; 80.8–97.8) in Group B (risk difference 2.0 percentage points, 95% CI −9.3 to 13.5; Fisher p = 1.000). Margins were positive (ink on tumor) in 2 patients (2.0%; 95% CI 0.2–7.0; one per group) and close in 5 (5.0%; 1.6–11.3; 2 in Group A and 3 in Group B). Of the 5 close margins, 3 were invasive (<1 mm) and 2 were DCIS (<2 mm).

All 7 patients with a non-clear margin were re-excised: 4 intraoperatively after a positive or close frozen-section margin (both positive margins and 2 close margins; 2 per group) and 3 after final pathology (close margins; 1 in Group A and 2 in Group B). Frozen section therefore identified 4 of 7 non-clear margins (57.1%). Under a 0 mm consensus policy, only the 2 ink-on-tumor margins would have required re-excision (2.0%), so the stricter institutional threshold raised the re-excision rate from 2.0% to 7.0%. No patient needed conversion to mastectomy for margins. After re-excision, final margins were clear in all 100 patients, with 0 positive and 0 close margins (Clopper–Pearson 95% CI for 50/50: 92.9–100.0 per group; 100/100: 96.4–100.0). Because re-excision was applied to every non-clear margin, this final clearance rate is largely a consequence of policy and is not comparable with the initial clearance rate.

Table 2. Operative characteristics, margin outcomes and axillary management

Variable	Group A: Inferior (n = 50)	Group B: Superior (n = 50)	p-value
Operative characteristics			
Skin pattern: Wise (inverted-T) / vertical	43 (86.0%) / 7 (14.0%)	45 (90.0%) / 5 (10.0%)	0.766
Resection weight, g (mean ± SD)	495.0 ± 110.5	472.3 ± 105.0	0.297
Contralateral symmetrization: simultaneous / staged	47 / 3	47 / 3	1.000
Margin status on first excision specimen (final pathology)			
Clear (≥1 mm invasive; ≥2 mm DCIS)	47 (94.0%; 83.5–98.7)	46 (92.0%; 80.8–97.8)	1.000
Close (no ink; <1 mm invasive, <2 mm DCIS)	2 (4.0%)	3 (6.0%)	1.000
Positive (ink on tumor)	1 (2.0%)	1 (2.0%)	1.000
Re-excision and final margin status			
Any re-excision (intraoperative / post-operative)	3 (6.0%) (2 / 1)	4 (8.0%) (2 / 2)	1.000
Conversion to mastectomy for margins	0	0	—
Final positive margin / final close margin	0 / 0	0 / 0	—
Final clear margins, n (95% CI)	50 (100.0%; 92.9–100.0)	50 (100.0%; 92.9–100.0)	—
Axillary management			
cN0 patients, n	40	38	
SLNB identification rate (cN0)	40/40 (100.0%)	37/38 (97.4%)	0.487
SLNB alone, no ALND (cN0 patients)	36 (90.0% of cN0)	33 (86.8% of cN0)	0.734
of which pN0 / pN1mi (RNI, no ALND)	34 / 2	31 / 2	
SLNB + completion ALND (sentinel macrometastasis)	4	4	
Failed SLNB → ALND (pN0)	0	1	
Upfront ALND (biopsy-proven cN1)	10	12	
Any ALND, all patients	14 (28.0%)	17 (34.0%)	0.666

Margin definitions are given in Section 2.3. Overall initial clearance was 93/100 (93.0%; 95% CI 86.1–97.1), initial positive margins 2/100 (2.0%; 0.2–7.0), initial close margins 5/100 (5.0%; 1.6–11.3). Risk difference in initial clearance (A − B) 2.0 percentage points (95% CI −9.3 to 13.5). Overall SLNB identification 77/78 (98.7%; 93.1–100.0); ALND avoided in

69/78 cN0 patients (88.5%; 79.2–94.6). p-values are Fisher's exact tests except resection weight (Welch t-test).

Axillary outcomes

Out of 78 cN0 patients, 77 had a sentinel node identified (98.7%; 95% CI 93.1–100.0); mapping failed in one Group B patient, who underwent ALND (pN0). Sentinel nodes were negative in 65 patients, showed micrometastasis in 4 and macrometastasis in 8. The 8 patients with macrometastasis underwent completion ALND. The 4 patients with micrometastasis did not undergo ALND and received RNI. All 22 cN1 patients had biopsy-proven nodal disease and were pN+ by definition. Overall, ALND was avoided in 69 of 78 cN0 patients (88.5%; 79.2–94.6). Among all 100 patients, 69 (69%) did not undergo ALND and 31 (31%) did (22 upfront for cN1, 8 completion, 1 after failed mapping). No regional recurrence occurred, but the study was not designed to establish the oncological safety of ALND omission, and the 4 patients managed without ALND after micrometastasis are too few to support a safety conclusion. The 34 pathologically node-positive patients (4 pN1mi, 30 pN1; no pN2) all received RNI: 4 patients (11.8%) had pN1mi, 21 (61.8%) had one or two positive nodes and 9 (26.5%) had three positive nodes.

Complications

Complications are graded in Table 3 according to the Clavien–Dindo classification [18]. NAC vascular compromise occurred in 2 patients (4.0%) in Group A and 7 (14.0%) in Group B (Fisher p = 0.160). Partial NAC necrosis occurred only in Group B (0.0% vs 6.0%; p = 0.242; 1 Grade I and 2 Grade II, all managed conservatively), and no total NAC necrosis occurred. T-junction dehiscence was frequent in both groups (18.0% vs 22.0%), mainly Grade I (13 of 20 episodes). Four patients (4.0%) required re-operation for a complication under general anesthesia (Grade IIIb): in Group A, one acute expanding hematoma evacuated within 12 hours and one localized parenchymal necrosis requiring debridement and delayed closure; in Group B, two large subcutaneous hematomas with pedicle tension requiring operative drainage (2/50 vs 2/50; p = 1.000). Three further patients had planned oncologic re-excision after final pathology under general anesthesia: one in Group A and two in Group B, the latter combined with operative NAC realignment because re-excision of the cavity edge displaced the nipple. These were planned consequences of the margin policy and not treatments of a postoperative complication, so they were excluded from the primary Grade IIIb analysis. Because NAC realignment under anesthesia could be viewed as a Grade IIIb event, two sensitivity analyses were done (Table 3): counting the two NAC realignments as Grade IIIb gave 2/50 (4.0%) in Group A versus 4/50 (8.0%) in Group B (p = 0.678), and counting every return to theatre for any reason gave 3/50 (6.0%) versus 4/50 (8.0%) (p = 1.000). The conclusion that re-operation rates did not differ is unchanged, although the confidence intervals are wide. Arm lymphedema occurred in 5 patients (2 in Group A, 3 in Group B), all of whom had undergone ALND followed by RNI. The incidence was 5/31 (16.1%; 95% CI 5.5–33.7) after ALND (2/14 [14.3%; 1.8–42.8] in Group A and 3/17 [17.6%; 3.8–43.4] in Group B) and 0/69 (0%; 0–5.2) after SLNB alone (Fisher p = 0.002). Overall rates were therefore 4.0% and 6.0%, but they depend mostly on the axillary procedure and not on the pedicle.

Table 3. Postoperative complications graded by the Clavien–Dindo classification

Complication	Highest grade	Group A (n = 50)	Group B (n = 50)	Fisher p
NAC vascular compromise (overall)	I–II	2 (4.0%)	7 (14.0%)	0.160
Transient ischemia / epidermolysis	I	2 (4.0%)	4 (8.0%)	0.678
Partial NAC necrosis	I–II	0 (0.0%)	3 (6.0%)	0.242
Total NAC necrosis	IIIb	0 (0.0%)	0 (0.0%)	1.000
T-junction wound dehiscence	I–II	9 (18.0%)	11 (22.0%)	0.803
Symptomatic fat necrosis	I–IIIa	7 (14.0%)	5 (10.0%)	0.760
Axillary seroma requiring needle aspiration	I	5 (10.0%)	6 (12.0%)	1.000
Arm lymphedema (> 2 cm)	II	2 (4.0%)	3 (6.0%)	1.000
after ALND	II	2/14 (14.3%)	3/17 (17.6%)	1.000
after SLNB alone	—	0/36 (0.0%)	0/33 (0.0%)	—
Primary: re-operation for a complication under general anesthesia	IIIb	2 (4.0%)	2 (4.0%)	1.000
Sensitivity 1: primary + planned re-excision with NAC realignment	IIIb	2 (4.0%)	4 (8.0%)	0.678
Sensitivity 2: any return to theatre (including planned re-excision)	IIIb	3 (6.0%)	4 (8.0%)	1.000

Every event is graded by the highest Clavien–Dindo grade reached. Dehiscence: 13 of 20 episodes Grade I (dressings only; 6 in Group A, 7 in Group B) and 7 Grade II (antibiotics). Fat necrosis: 4 of 12 events needed percutaneous aspiration or excision under local anesthesia (Grade IIIa; 2 per group). Seroma aspiration was done in clinic without anesthesia or imaging guidance. Lymphedema had no Grade III events; conservative management (compression, physiotherapy).

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Lymphedema by procedure: ALND (upfront or completion) 5/31 vs SLNB alone 0/69 (p = 0.002).

Adjuvant therapy

All 100 patients received whole-breast irradiation and RNI was given to all 34 node-positive patients (16 [32.0%] in Group A, 18 [36.0%] in Group B; Table 4). Adjuvant chemotherapy was given to 45 patients (22 [44.0%] and 23 [46.0%]) and began at a mean of 24.5 ± 4.2 days after surgery overall (24.1 ± 4.0 days in Group A, 24.9 ± 4.4 days in Group B; p = 0.528). Chemotherapy began later than 30 days in 5 of 45 patients (11.1%; 2 in Group A and 3 in Group B), with a maximum of 38 days; the causes were T-junction dehiscence (3), hematoma evacuation (1) and partial NAC necrosis (1). No patient started chemotherapy later than 42 days. Radiotherapy in the 55 patients without chemotherapy started at a mean of 37.8 ± 5.9 days (Group A) and 38.5 ± 6.3 days (Group B), and in no patient later than 56 days. In patients receiving chemotherapy, the interval from surgery to radiotherapy was 24.2 ± 3.1 and 24.6 ± 3.4 weeks.

Table 4. Adjuvant therapy and timelines

Parameter	Group A (n = 50)	Group B (n = 50)	p-value
Whole-breast radiotherapy	50 (100.0%)	50 (100.0%)	1.000
Regional nodal irradiation (all pN+: pN1mi and pN1)	16 (32.0%)	18 (36.0%)	0.833
Radiotherapy start, no chemotherapy, days	37.8 ± 5.9	38.5 ± 6.3	0.668
Surgery to radiotherapy start, after chemotherapy, weeks	24.2 ± 3.1	24.6 ± 3.4	0.675
Adjuvant chemotherapy	22 (44.0%)	23 (46.0%)	1.000
AC-T (8 cycles)	15 (30.0%)	16 (32.0%)	1.000
TC (4 cycles)	7 (14.0%)	7 (14.0%)	1.000
Chemotherapy start after surgery, days	24.1 ± 4.0	24.9 ± 4.4	0.528
Chemotherapy start later than 30 days	2/22 (9.1%)	3/23 (13.0%)	1.000
Trastuzumab (all HER2-positive patients)	8 (16.0%)	9 (18.0%)	1.000
Endocrine therapy (all ER/PR-positive patients)	41 (82.0%)	40 (80.0%)	1.000

RNI recipients (n = 34): pN1mi 4, one or two positive nodes 21, three positive nodes 9; none had four or more positive nodes. Chemotherapy: AC-T, doxorubicin–cyclophosphamide followed by a taxane; TC, docetaxel–cyclophosphamide.

BREAST-Q and cosmetic outcomes

BREAST-Q BCT questionnaires were completed by all eligible patients: 49 in Group A and 48 in Group B, after exclusion of the 3 patients with salvage mastectomy (response 97/97; no missing items). Median time from surgery to completion was 28.2 months overall (IQR 25.8–30.6; range 24.0–35.8), 28.5 (26.2–31.0) in Group A and 27.8 (25.5–30.2) in Group B. The complete response reflects in-clinic administration to patients under active follow-up and should be interpreted with possible social-desirability bias in mind. Satisfaction with Breasts was nominally higher in Group A (86.4 ± 8.2 vs 82.8 ± 9.5; unadjusted p = 0.049; Bonferroni-adjusted p = 0.195; Benjamini–Hochberg q = 0.161), a difference of 3.6 points (about 0.4 SD) that is smaller than most published minimal important difference estimates for BREAST-Q scales [19] and did not persist after multiplicity correction. The other domains were not significantly different (Table 5). Harris-scale cosmetic results were excellent or good in 46 patients (92.0%) in Group A and 44 (88.0%) in Group B (p = 0.741); all 100 patients were rated at 12 months, before the earliest recurrence (13.8 months). Inter-rater reliability of the three-person panel was substantial: Krippendorff's alpha (ordinal) was 0.79 (95% bootstrap CI 0.71–0.86), the mean pairwise quadratic-weighted kappa was 0.82 (range 0.79–0.85), and the ICC was 0.85 (95% CI 0.79–0.90). Raters guessed the pedicle type correctly in 161 of 300 judgments (53.7%), which does not differ from chance (p = 0.23), supporting effective blinding. Surveillance imaging in patients with a conserved breast was BI-RADS 1–2 in 47 of 49 (95.9%) in Group A and 44 of 48 (91.7%) in Group B (p = 0.436); the remainder were BI-RADS 3 (2 and 4 patients, respectively; probable benign fat necrosis).

Table 5. Patient-reported, cosmetic and imaging outcomes

Outcome	Group A	Group B	p-value	Bonferroni p / BH q
BREAST-Q BCT module (Rasch-transformed 0–100)	**n = 49**	**n = 48**		
Satisfaction with Breasts	86.4 ± 8.2	82.8 ± 9.5	0.049	0.195 / 0.161

Outcome	Group A	Group B	p-value	Bonferroni p / BH q
Psychosocial Well-Being	88.2 ± 7.6	85.6 ± 8.9	0.126	0.502 / 0.167
Sexual Well-Being	78.5 ± 11.2	76.1 ± 12.0	0.311	1.000 / 0.311
Physical Well-Being (Chest)	85.7 ± 9.4	82.1 ± 10.6	0.080	0.321 / 0.161
Adverse Effects of Radiation (exploratory)	84.0 ± 10.1	82.5 ± 10.9	0.484	—
Cosmetic and imaging outcomes	**Group A**	**Group B**		
Harris scale excellent / good at 12 months (n = 50 per group)	46 (92.0%)	44 (88.0%)	0.741	—
BI-RADS 1–2 at last surveillance imaging (n = 49 / 48)	47 (95.9%)	44 (91.7%)	0.436	—
Inter-rater reliability of the Harris panel (both groups combined)	Krippendorff's alpha 0.79 (0.71–0.86); weighted kappa 0.82 (0.79–0.85); ICC 0.85 (0.79–0.90)			

BREAST-Q values are mean ± SD compared with the Welch t-test; adjustment applies to the four prespecified domains only. The reliability row is not a between-group comparison. Group A n = 49 and Group B n = 48 exclude patients with salvage mastectomy. BCT, breast-conserving therapy; BH, Benjamini–Hochberg.

Oncological outcomes

Three ipsilateral breast tumor events occurred (Table 6): one in Group A (2.0%) and two in Group B (4.0%) (Fisher p = 1.000), at 13.8, 19.4 and 22.1 months after surgery (median 19.4 months), all before 24 months and all treated with salvage total mastectomy. Two were true recurrences (2.0% overall) and one was a new primary (1.0%). The two true recurrences arose at the margin of the tumor bed in patients with aggressive biology (grade 3, hormone-receptor-negative); one of them (B-1) had a close margin at the first excision that was re-excised intraoperatively with a final clear margin, and neither was adjacent to the transposed pedicle. The new primary arose in the upper inner quadrant of the parenchyma of the superior pedicle, 6.5 cm from the index cavity. No regional recurrence, distant metastasis or death occurred. Kaplan–Meier 24-month DFS was 98.0% in Group A and 96.0% in Group B (log-rank p = 0.560; Figure 4). Because all three events occurred before 24 months, these estimates are not affected by censoring, but the analysis rests on three events and is not informative about late recurrence, particularly in the 80–82% of patients with hormone-receptor-positive disease.

Table 6. Characteristics of patients with ipsilateral breast tumor events

Feature	A-1 (Group A, inferior)	B-1 (Group B, superior)	B-2 (Group B, superior)
Age at surgery (years)	49	56	61
Index tumor	UOQ left; IDC, grade 3, 2.6 cm (pT2)	LOQ right (5 o'clock); IDC, grade 3, 3.1 cm (pT2)	LIQ left (7 o'clock); ILC, grade 2, 1.7 cm (pT1c)
Receptors	ER−/PR−/HER2−	ER−/PR−/HER2+	ER+/PR+/HER2−
Nodal status / axilla	cN1, pN1 (2 nodes); upfront ALND	cN1, pN1 (3 nodes); upfront ALND	cN0, pN0; SLNB alone
First-excision margin	Clear (closest 4 mm)	Close (invasive, 0.6 mm); intraoperative re-excision	Clear (closest 3 mm)
Final margin	Clear	Clear (closest 5 mm)	Clear
Adjuvant treatment	AC-T; WBI 50 Gy + boost; RNI	AC-T + trastuzumab; WBI 50 Gy + boost; RNI	WBI 40.05 Gy; endocrine therapy
Time to IBTR (months)	19.4	13.8	22.1

Feature	A-1 (Group A, inferior)	B-1 (Group B, superior)	B-2 (Group B, superior)
Detection	Clinical visit, then imaging (BI-RADS 5)	Patient-detected palpable lump	Surveillance mammography and ultrasound (BI-RADS 5)
Site relative to index bed and pedicle	UOQ, 1.5 cm from the cavity edge, in residual upper-outer parenchyma; remote from the inferior pedicle	Lower-outer, 0.8 cm from the cavity beside the inverted-T limb; outside the superior pedicle	Upper inner quadrant, 6.5 cm from the cavity, within the superior-pedicle parenchyma
Recurrent tumor	IDC, grade 3, 1.4 cm, triple-negative	IDC, grade 3, 1.1 cm, HER2-positive	IDC, grade 2, 1.2 cm, ER+/HER2−
Classification	True recurrence	True recurrence	New primary (different quadrant, histology and receptor profile)
Salvage treatment	Total mastectomy 5 weeks after diagnosis	Total mastectomy 4 weeks after diagnosis	Total mastectomy 6 weeks after diagnosis; endocrine therapy continued
Status at cutoff	Alive, no evidence of disease (follow-up 31.2 months)	Alive, no evidence of disease (follow-up 29.9 months)	Alive, no evidence of disease (follow-up 30.4 months)

UOQ, upper outer quadrant; LOQ, lower outer quadrant; LIQ, lower inner quadrant; WBI, whole-breast irradiation; RNI, regional nodal irradiation; IBTR, ipsilateral breast tumor recurrence. The cavity was marked with surgical clips. Follow-up is the time from the index operation to the data cutoff.

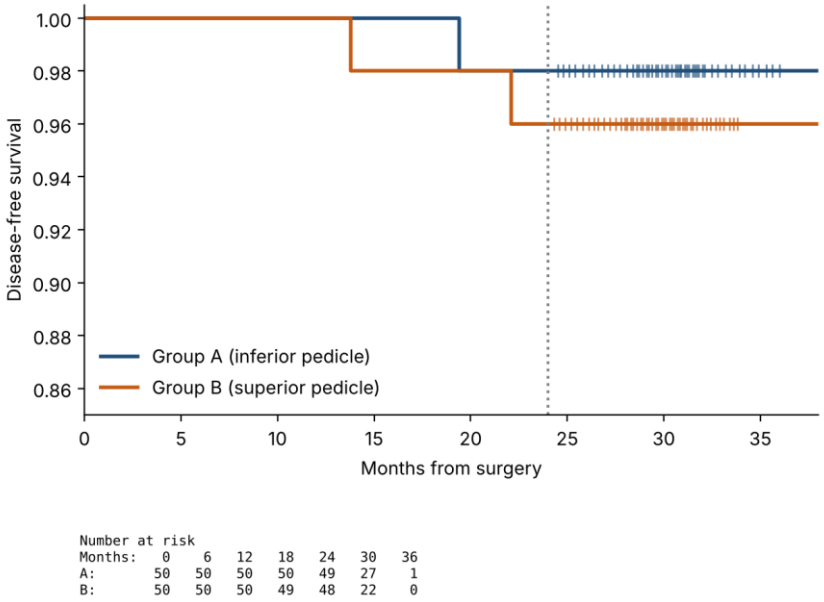


Figure 4. Kaplan–Meier estimates of disease-free survival by group. Events (ipsilateral breast tumor events) occurred at 13.8, 19.4 and 22.1 months; tick marks denote censored patients. Dotted line, 24 months. Log-rank p = 0.560. The numbers at risk are shown below the plot.

4. DISCUSSION

In this prospective cohort of 100 women, location-guided pedicle selection in TM gave a low initial positive-margin rate (2.0%), a final clear-margin status in all patients, acceptable complication rates, high BREAST-Q scores and encouraging early oncological results. Allocation followed tumor location, so all between-group comparisons are exploratory.

Margins and axillary management

Negative margins are an important determinant of local control in breast-conserving therapy [20]. By using one definition throughout, we separate true positive margins (2.0%) from close margins (5.0%) and show that the headline initial clearance

of 93.0% is mainly driven by a stricter re-excision threshold than the consensus guideline recommends [12, 13]. Under the guideline, only 2.0% of patients would have needed re-excision. For context, around one in five women having standard BCS in England needed re-operation for involved margins [21], and a systematic review of oncoplastic BCS reported positive margins in about 10.8% [2]. Differences in margin definitions and populations preclude a direct comparison. Frozen section detected only 4 of 7 non-clear margins, so routine frozen section should not be taken as a substitute for final pathology. Sentinel-node biopsy was feasible with a 98.7% identification rate, and ALND was avoided in 88.5% of cN0 patients. We emphasize that this figure describes how many cN0 patients did not need dissection under the protocol and not the oncological safety of omission: the protocol still mandated completion ALND for macrometastases, which is more conservative than ACOSOG Z0011 [22] and the more recent SENOMAC trial [23], and the number of patients managed without ALND after nodal micrometastasis is small [14]. Lymphedema was confined to ALND patients (16.1% vs 0%), which agrees with the known morbidity of axillary dissection followed by nodal irradiation [15] and implies that the overall rates of 4.0% and 6.0% reflect axillary treatment and not the pedicle. The cN1 proportion (22%) reflects tertiary referral and is higher than in screening-detected early breast cancer.

Adjuvant therapy

A historical concern about TM is that extensive dissection might increase wound complications and delay adjuvant treatment [24]. In this cohort, chemotherapy began at a mean of 24.5 days, and in 5 of 45 patients (11.1%) it began after more than 30 days because of wound complications, with a maximum of 38 days. Delay beyond about 90 days has been associated with worse survival [25], a threshold that was not approached. Because the cohort lacks a comparison group without TM, we cannot say that TM does not delay adjuvant therapy relative to standard BCS, only that delays were modest in this series. This is notable given the 18–22% rate of T-junction dehiscence, which should be anticipated in counseling and wound care.

NAC perfusion, patient-reported outcomes, and the role of tumor location

NAC vascular compromise was numerically lower in Group A (4.0% vs 14.0%; $p = 0.160$), with partial necrosis only in Group B (6.0%). The inferior pedicle retains a broad base and the lower-interspace perforators [8, 10], whereas superior pedicles may be vulnerable to kinking or venous congestion when a long pedicle is folded in large or markedly ptotic breasts [9]; this mechanism is plausible but was not measured, and pedicle length (for example, sternal notch-to-nipple distance) was not recorded. The difference was not statistically significant and the study was not powered for it, so it should not be taken as evidence that either pedicle is safer. Similarly, the nominally higher Satisfaction with Breasts in Group A (86.4 vs 82.8; $p = 0.049$) did not survive Bonferroni adjustment ($p = 0.195$) and is smaller than usual minimal important difference estimates [19]. It may reflect tumor location and the amount of tissue rearranged in the lower pole as much as pedicle type. The inferior pedicle was not risk-free: two Group A patients needed Grade IIIb re-operation (hematoma; parenchymal necrosis), and symptomatic fat necrosis was numerically more frequent in Group A (14.0% vs 10.0%). Re-operation rates were similar (4.0% vs 4.0%), and in both sensitivity analyses the conclusion was unchanged (4.0% vs 8.0%, $p = 0.678$; 6.0% vs 8.0%, $p = 1.000$). The planned re-excisions with NAC realignment are the main source of disagreement between the two analyses; we think they are better regarded as planned oncologic procedures, but both views are presented so that readers can choose.

Ipsilateral breast tumor events

Three ipsilateral events occurred, all within 24 months. The two true recurrences arose in patients with grade 3, hormone-receptor-negative tumors and lay at the edge of the tumor bed outside the transposed pedicle, a pattern consistent with biology and with the limits of local control rather than with a pedicle-specific effect; neither patient had a final positive margin. The new primary arose in a different quadrant and had a different histology, a finding that should be distinguished from true recurrence when local control after TM is assessed. Previous oncoplastic series report five-year local recurrence of around 9% after extensive resections [26]; with a median follow-up of 30 months and only three events, our results cannot be compared with five- or ten-year rates.

Comparison with published series

Table 7 summarizes selected published oncoplastic and therapeutic-mammoplasty series for context. These series differ in design, margin definition, patient population and outcome instruments; the comparison is descriptive only, and cosmetic or satisfaction ratings are not interchangeable with BREAST-Q domain scores.

Table 7. Contextual comparison with published oncoplastic and therapeutic-mammoplasty series

Study	Sample	Design / technique	Key reported outcomes
Present study	100 (prospective)	Inferior vs superior pedicle, location-guided	Initial clearance 93.0% (positive margins 2.0%, close 5.0%); final clear 100%; NAC compromise 4.0% vs 14.0%; BREAST-Q Satisfaction with Breasts 86.4 vs 82.8; 24-month DFS 98.0% vs 96.0%
De La Cruz et al. 2016 [2]	6,011 (55 studies)	Systematic review, oncoplastic BCS	Pooled positive margins about 10.8% (about 89.2% clear)
Grubnik et al. 2013 [4]	251 (retrospective)	Therapeutic mammaplasty	Acceptable aesthetic result 96% (photographic panel); return to theatre 2%; recurrence 4% at mean follow-up of 50 months
Clough et al. 2003 [26]	101 (prospective)	Oncoplastic resection for large tumors	Local recurrence about 9% at 5 years; good or excellent cosmesis about 82%
McCulley and Macmillan 2005 [5]	50 (consecutive)	Therapeutic mammaplasty	Early series showing feasibility of wide excision in large breasts; margin involvement and re-excision reported as the main oncological concern
Mandrekas et al. 1996 [27]	371	Inferior pedicle reduction mammaplasty (non-oncological)	Reference for NAC and wound complications of the inferior pedicle in large breasts; NAC loss uncommon
Kelsall et al. 2017 [28]	Case-matched cohorts	Oncoplastic BCS vs mastectomy and reconstruction	Patient-reported BREAST-Q outcomes were at least comparable after oncoplastic BCS
Rose et al. 2020 [29]	Population-based cohort	Oncoplastic vs conventional BCS	Patient-reported satisfaction after oncoplastic surgery was equivalent or better than conventional BCS

Comparator figures are approximate and were taken from the original reports or their abstracts; they are given for context only. The present-study final clear-margin rate follows re-excision of every non-clear margin and should not be compared with initial clearance in other series.

Strengths and limitations

Strengths include the prospective design, standardized single-institution surgical and MDT management, complete follow-up, a single margin definition with separate reporting of positive and close margins, graded complications with sensitivity analyses, use of a validated patient-reported instrument, and an independent cosmetic panel with a documented blinding check.

Confounding by tumor location. Because pedicle choice was determined by tumor quadrant, group differences may reflect tumor site and breast anatomy and not the pedicle itself. Table 1 shows balanced tumor size, grade, receptors and stage, but location is perfectly collinear with group, and unmeasured factors cannot be excluded. Upper- and lower-quadrant tumors differ in their relation to the skin, the inframammary fold and the NAC and in the geometry of the cavity, and pedicle length and tension were not measured. The groups are therefore not exchangeable, and no causal inference about superiority of either pedicle is possible; larger studies adjusting for tumor location, breast size, ptosis and pedicle length are needed.

Other limitations are the non-randomized allocation, quota-based closure without a formal sample-size calculation (so the study is underpowered for the secondary comparisons and for rare events), the single-center setting and the modest sample. Quota closure may have introduced selection bias by excluding otherwise eligible patients. Numerous secondary comparisons were made without multiplicity adjustment, apart from the BREAST-Q domains, so the single nominally significant result ($p = 0.049$) is hypothesis-generating. No baseline BREAST-Q was collected, so scores cannot be interpreted as change, and the postoperative questionnaire was completed at variable times (24.0–35.8 months). The complete questionnaire response may reflect in-clinic administration and social-desirability effects. The Harris panel judged photographs and, although raters guessed the pedicle at chance level, residual unblinding cannot be excluded because scars are visible. The lymphedema definition (>2 cm) is non-standardized. The cohort was selected for macromastia or ptosis, which limits generalization to women with smaller breasts, and the 22% cN1 proportion reflects a tertiary referral population. Finally, median follow-up of 30.1 months suffices for surgical and early postoperative

endpoints but is short for oncological conclusions, particularly in hormone-receptor-positive disease; the DFS estimates rest on three events and longer surveillance is required.

5. CONCLUSION

A tumor-location-guided dermal-parenchymal pedicle strategy for therapeutic mammoplasty achieved an initial positive-margin rate of 2.0% and an initial clearance of 93.0% under a strict re-excision policy, with final clear margins in all patients, low and similar rates of Grade IIIb re-operation (4.0% vs 4.0%; 4.0% vs 8.0% when planned re-excision with NAC realignment is included), timely adjuvant therapy, high BREAST-Q scores and 24-month disease-free survival of 98.0% and 96.0% based on three early events. The inferior pedicle group had numerically lower NAC vascular compromise (4.0% vs 14.0%; $p = 0.160$) and nominally higher Satisfaction with Breasts (3.6 points; unadjusted $p = 0.049$; Bonferroni $p = 0.195$), differences that are not statistically robust and may reflect tumor location. As allocation was non-randomized and dictated by tumor quadrant, the findings are associations, and larger comparative studies with longer follow-up are required.

DECLARATIONS

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and applicable institutional and regulatory requirements. The study protocol was reviewed and approved by the Institutional Review Board of Burjeel Hospitals, UAE (approval No. BURJ/RERC/2022/37).

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Informed Consent Statement: Written informed consent was obtained from all participants before enrolment and randomization, after the study objectives, procedures, potential risks, and the use of their clinical data and photographs for research and publication had been explained. The study was approved by the Institutional Review Board and was conducted in accordance with the Declaration of Helsinki.

Data Availability Statement: The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to applicable institutional, ethical, and patient-confidentiality requirements.

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Author Contributions: AL, SM: manuscript preparation, protocol, data collection and management, manuscript editing. AM, ER, MH: Data acquisition, data analysis and management, manuscript editing. MU, TA, MA: Manuscript editing, project development, data analysis, and project development. All the authors have read and approved the manuscript.

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