Ventricular assist device using a thoracotomy-based implant technique: Multi-Center Implantation of the HeartMate 3 in Subjects With Heart Failure Using Surgical Techniques Other Than Full Median Sternotomy (HM3 SWIFT)

Check for updates

Igor Gosev, MD,[a] Duc Thinh Pham, MD,[b] John Y. Um, MD,[c] Anelechi C. Anyanwu, MD,[d] Akinobu Itoh, MD, PhD,[e] Kunal Kotkar, MD,[f] Koji Takeda, MD,[g,h] Yoshifumi Naka, MD, PhD,[i] Matthias Peltz, MD,[j] Scott C. Silvestry, MD,[k] Gregory Couper, MD,[l] Marzia Leacche, MD,[m] Vivek Rao, MD, PhD,[n] Benjamin Sun, MD,[o] Ryan J. Tedford, MD,[p] Nahush Mokadam, MD,[q] Robert McNutt, PhD,[r] Daniel Crandall, PhD,[r] Mandeep R. Mehra, MD, MSc,[e] and Christopher T. Salerno, MD[s]

ABSTRACT

Objectives: The HeartMate 3 (Abbott) left ventricular assist device provides substantial improvement in long-term morbidity and mortality in patients with advanced heart failure. The Implantation of the HeartMate 3 in Subjects With Heart Failure Using Surgical Techniques Other Than Full Median Sternotomy study compares thoracotomy-based implantation clinical outcomes with standard median sternotomy.

Methods: We conducted a prospective, multicenter, single-arm study in patients eligible for HeartMate 3 implantation with thoracotomy-based surgical technique (bilateral thoracotomy or partial upper sternotomy with left thoracotomy). The composite primary end point was survival free of disabling stroke (modified Rankin score >3), or reoperation to remove or replace a malfunctioning device, or conversion to median sternotomy at 6-months postimplant (elective transplants were treated as a success). The primary end point (noninferiority, −15% margin) was assessed with >90% power compared with a propensity score-matched cohort (ratio 1:2) derived from the Multi-Center Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3 continued access protocol.

Results: The study enrolled 102 patients between December 2020 and July 2022 in the thoracotomy-based arm at 23 North American centers. Follow-up concluded in December 2022. In the Implantation of the HeartMate 3 in Subjects With Heart Failure Using Surgical Techniques Other Than Full Median Sternotomy study group, noninferiority criteria was met (absolute between-group difference, −1.2%; Farrington Manning lower 1-sided 95% CI, −9.3%; $P < .0025$) and event-free survival was not different (85.0% vs 86.2%; hazard ratio, 1.01; 95% CI, 0.58-2.10). Length of stay with thoracotomy-based implant was longer (median, 20 vs 17 days; $P = .03$). No differences were observed for blood product utilization, adverse events (including right heart failure), functional status, and quality of life between cohorts.

Conclusions: Thoracotomy-based implantation of the HeartMate 3 left ventricular assist device is noninferior to implantation via standard full sternotomy. This study supports thoracotomy-based implantation as an additional standard for surgical implantation of the HeartMate 3 left ventricular assist device. (J Thorac Cardiovasc Surg 2024;168:1474-84)

Pump insertion by left thoracotomy with aortic access by partial sternotomy (A) or right thoracotomy (B).
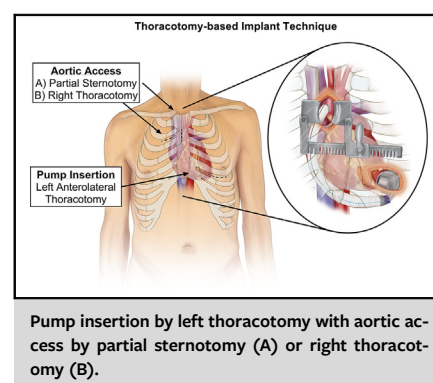
CENTRAL MESSAGE

Thoracotomy-based implantation of the HeartMate 3 LVAD is noninferior to implantation via standard full sternotomy. No major benefits or risks for the thoracotomy-based implant technique were observed.

PERSPECTIVE

This study supports thoracotomy-based implantation as an additional standard for surgical implantation of the HeartMate 3 LVAD.

ADULT

Abbreviations and Acronyms
AST = aspartate transaminase
EPPY = events per patient year
HM3 = HeartMate 3
HM3 SWIFT = Implantation of the HeartMate 3 in Subjects With Heart Failure Using Surgical Techniques Other Than Full Median Sternotomy
ICU = intensive care unit
INTERMACS = Interagency Registry for Mechanically Assisted Circulatory Support
LVAD = left ventricular assist device
MOMENTUM 3 = Multi-Center Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3
PAPi = pulmonary artery pulsatility index
PCWP = pulmonary capillary wedge pressure
PRBC = packed red blood cells
RAP = right atrial pressure

Scanning this QR code will take you to the table of contents to access supplementary information. To view the AATS Annual Meeting Webcast, see the URL next to the webcast thumbnail.

The HeartMate 3 (HM3) (Abbott) left ventricular assist device (LVAD) provides substantial improvement in short- and long-term morbidity and mortality in patients with advanced heart failure.[1,2] The Multi-Center Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3 (MOMENTUM 3) trial portfolio and postapproval registries report low rates of hemocompatibility-related outcomes and a 5-year survival exceeding 50%.[2-4]

Early during surgical implant hospitalization, patients experience the greatest risk of adverse events, including bleeding requiring blood transfusions or return to the operating room and severe right heart dysfunction, which can result in prolonged intensive care unit (ICU) and overall hospital length of stay.[5] The development of such events influences late outcomes.[6] Multiple retrospective and 1 prospective study (of a device now removed from distribution) examining the thoracotomy-based surgical technique for LVAD implantation, bilateral thoracotomy, or right thoracotomy with partial sternotomy have reported associations with improved perioperative outcomes compared with a standard median sternotomy approach, including less bleeding, decreased use of transfusions, decreased incidence of right heart failure, decreased ICU stay, and overall length of stay.[7-10]

A standard median sternotomy has historically been the standard approach for LVAD implantation in pivotal clinical trials.[11] Median sternotomy offers excellent exposure of the heart, including the great vessels and right ventricle; however, exposure of the apex of the left ventricle requires an anterior elevation of the heart. The thoracotomy-based approach (bilateral thoracotomy or partial upper sternotomy for aortic access with left thoracotomy for LVAD implant) results in a more limited exposure of the right ventricle but allows the surgeon to preserve the right heart's pericardium and maintains the heart in its anatomic position with a direct view of the left ventricular apex.[12,13] Whether these technical differences provide incremental clinical benefit in implantation of the HM3 LVAD remains uncertain. Therefore, we designed the prospective, multicenter, single-arm Implantation of the HeartMate 3 in Subjects With Heart Failure Using Surgical Techniques Other Than Full Median Sternotomy (HM3 SWIFT) study to compare clinical outcomes of the thoracotomy-based technique for implantation of the HM3 LVAD with a standard median sternotomy in propensity score–matched patients from the MOMENTUM 3 trial portfolio.

ADULT

METHODS

Study Design

In HM3 SWIFT, we sought to enroll patients for HM3 LVAD implantation and used a thoracotomy-based surgical approach with plans to compare outcomes to a propensity matched patient population from the MOMENTUM 3 continued access protocol (CAP), in which the median sternotomy approach was mandated for all patients. Details of the trial for the MOMENTUM 3 CAP, including primary results, have been previously published.[14] The HM3 SWIFT study was conducted at 23 centers in North America, data were collected at participating centers, audited by the sponsor (Abbott) and analyzed by the sponsor in partnership with the steering committee members. The HM3 SWIFT study began enrollment in December 2020 and completed 6-month follow-up in all enrolled patients in July 2022. The MOMENTUM 3 CAP began enrollment in August 2016 and completed 2-year follow up in November 2020. The authors vouch for the completeness and accuracy of the data and analyses. The protocol was approved by each participating center's institutional review board. Before participation in the HM3 SWIFT study, implanting surgeons were required to complete 3 thoracotomy-based implants. No surgical proctorship was required.

Patients with advanced-stage heart failure deemed to be candidates for implantation of a LVAD were considered for enrollment in the HM3 SWIFT study. Patients were excluded if biventricular circulatory support or concurrent procedures were planned at the time of LVAD implant, or if irreversible end organ dysfunction or active infection were present. Written informed consent was obtained from all HM3 SWIFT patients or their authorized representatives. Data on end points and adverse events were collected after implantation as they occurred and patients' regular follow-up occurred on day 1, 1 week, discharge, 3 months, and 6 months postimplant.

Surgical Methods

The standard approach to LVAD implantation as used in the MOMENTUM 3 trial requires a median sternotomy, followed by cardiopulmonary bypass to gain median access to the heart and the ascending aorta. In HM3 SWIFT, surgeons used the thoracotomy-based technique (Figure 1) involving either a bilateral thoracotomy or a partial upper sternotomy for access to the ascending aorta coupled with a left anterolateral thoracotomy incision to gain access to the apex of the left ventricle. Cardiopulmonary bypass could be initiated by directly cannulating the ascending aorta or peripherally by cannulating the common femoral artery and vein. The precise location of the thoracotomy incision was determined via an intraoperative transthoracic echocardiogram before initiating the thoracotomy-based surgery. The thoracotomy incision was typically made at the fifth or the sixth intercostal space, with potential variability depending upon the degree of cardiomegaly and the size of the chest. Following the incision, the ribs were separated, the apical sewing ring was sewed on to the apex and coring initiated. The centrifugal pump was inserted through the apical sewing ring and locked into its position. The outflow graft was frequently tunneled through the pericardium and anastomosed to the ascending aorta via a small upper right thoracotomy or a hemi-sternotomy. Depending on surgical preferences, the driveline was tunneled either to the left subcostal area or toward the right side. The pump was then turned on, de-aired, and the speed increased until the desired speed was reached to adequately support the left ventricle.

Principal End Points

The primary end point was a composite of survival at 6 months free of disabling stroke (stroke with a modified Rankin score >3), reoperation to replace the device, or conversion of the surgical approach to median sternotomy. Elective transplant within 6 months without occurrence of other components of the primary end point was considered a success. The primary end point was compared with a propensity score-matched patient population from the MOMENTUM 3 CAP trial to assess for noninferiority. Other secondary end points include length of ICU stay and hospital length of stay as well as blood product utilization during implantation, functional status, quality of life, and survival.

The rates of major adverse events such as stroke, bleeding, right heart failure, and infection were also evaluated (definitions provided in the Appendix E1). Functional status was evaluated by change in 6-minute walk test and New York Heart Association class. Quality of life was assessed with the European Quality of Life-5 Dimensions 5-level questionnaire, the Quality of Life-5 Dimensions visual analog scale, and the Kansas City Cardiomyopathy Questionnaire.

Statistical Analysis

SWIFT was powered to assess whether the implantation of the HM3 LVAD with the thoracotomy-based surgical technique was noninferior to a propensity score-matched patient population from the MOMENTUM 3 CAP trial, which mandated a median sternotomy-based surgical technique. A total of 100 HM3 SWIFT patients allowed for at least 90% power with 1-sided 5% significance to test for noninferiority. To establish the comparator groups, propensity scores were calculated for each HM3 SWIFT and MOMENTUM 3 CAP patient, via logistic regression, and were then matched at a ratio of 2 MOMENTUM 3 CAP to each HM3 SWIFT patient. The baseline covariates used to propensity match HM3 SWIFT patients to MOMENTUM 3 CAP patients included age, sex, race, body mass index, Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile, intended goal for use (bridge to transplant, bridge to candidacy, or destination therapy), diabetes, history of hypertension, estimated glomerular filtration rate, right atrial pressure to pulmonary capillary wedge pressure ratio (RAP/PCWP), total bilirubin value, blood urea nitrogen level, aspartate transaminase (AST) level, alanine transaminase level, hemoglobin level, PCWP, RAP, pulmonary artery pulsatility index (PAPi), and concomitant procedures. To ensure the inclusion of all potential subjects in the propensity match, multiple imputation was employed to impute missing values for baseline covariates that were used in the generation of the propensity scores. Missing baseline covariates for SWIFT subjects included AST, diabetes, RAP/PCWP, the most prevalent being PCWP and diabetes, having 4 out of 102 (4%) and 3 out of 102 (3%) missing, respectively. Missing baseline covariates for CAP subjects included alanine transaminase level, AST level, total bilirubin value, PCWP, RAP, PAPi, and INTERMACS, the most prevalent being PAPi and RAP, having 65 out of 1680 (3.9%) and 44 out of 1680 (2.6%) missing, respectively. An optimal matching algorithm without replacement (2 sternotomy patients were matched to at most 1 thoracotomy patient) was employed. The range of propensity scores considered for matching was restricted to the range of the test subjects, extended by 0.25 times the pooled SD of the logit of the propensity scores, and a caliper of 0.2 was imposed. Exact matching on sex and the occurrence of a concurrent procedure was initially attempted; however, sex was removed from the exact restriction to facilitate a successful match.

Noninferiority of the thoracotomy-based surgical technique could be established if the lower, 1-sided 95% confidence boundary of the difference between the thoracotomy-based (HM3 SWIFT) and propensity-score matched sternotomy based (MOMENTUM 3 CAP) groups in the percentage of primary end point success at 6 months was numerically greater than minus 15 percentage points, calculated by the Farrington-Manning Risk-difference approach. Overall difference and 95% CI using the Newcombe score method for the components of the primary end point are shown, and event-free survival estimates are calculated by the Kaplan-Meier method. Patients who are withdrawn without a prior primary end point event are excluded from this binary primary end point calculation but included in all other analyses.

The length of stay secondary end point was analyzed with Wilcoxon signed-rank test. Poisson regression was used to compare the rates of major adverse events between the 2 groups as numbers of events per patient-year.
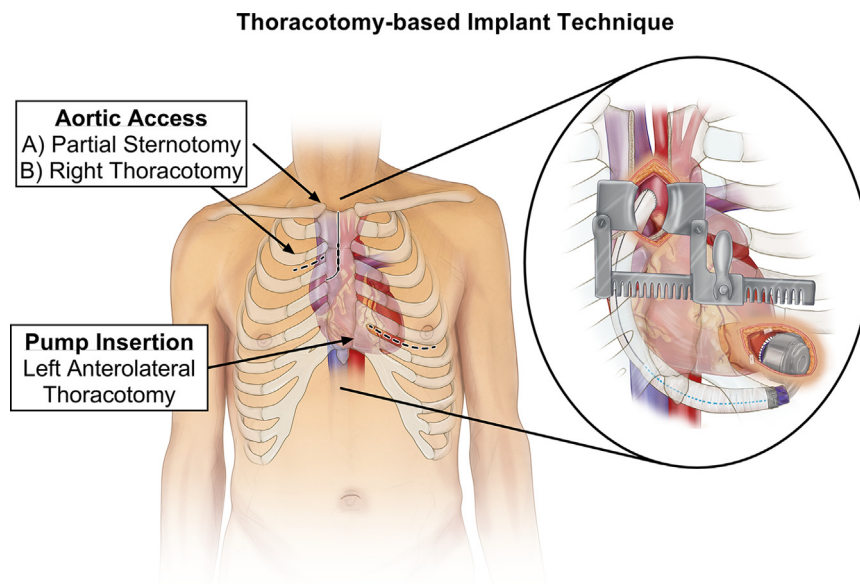
Thoracotomy-based Implant Technique

FIGURE 1. Pump insertion by left thoracotomy with aortic access by partial sternotomy (A) or right thoracotomy (B).

The rate difference was described with corresponding 95% CI using the Clopper Pearson exact method. Overall survival and freedom from any disabling stroke were analyzed by the Kaplan-Meier method, with hazard ratios (HRs) calculated from Cox proportional hazard models. Longitudinal changes in functional status and quality of life were analyzed by linear mixed-effects modeling. Finally, frequency distributions were used to investigate whether patients at sites that enrolled more patients (>5 patients/site) experienced shorter length of stay and shorter length of bypass time to determine if a learning curve may impacted these outcomes. Statistical analyses, including the matching algorithm, were performed with the use of SAS software, version 9.4 (SAS Institute).

RESULTS

Propensity Matching Outcomes

From December 2020 through January 2022, a total of 102 patients were implanted with the HM3 by the thoracotomy-based technique and were matched to 204 sternotomy-based implanted patients from the MOMENTUM 3 CAP Study (Figure E1). Variables identified for propensity matching of thoracotomy-based and sternotomy-based patients are shown pre-match in Table E1 and after thoracotomy-based patients were propensity matched with a 1:2 ratio to sternotomy-based patients from the MOMENTUM 3 CAP trial, are shown in Table E2. Figure 2 shows the post-match alignment. The matching process identified 204 sternotomy-based patients that were similar, within standardized difference <0.1, except for history of hypertension, which showed a standardized difference 0.11. Post-match standardized difference calculations did not include pre-match, multiply imputed baseline covariate values. There were no statistical differences in variables used for propensity matching after matching was performed.

Patient Details Between Groups

Key baseline characteristics after propensity matching are shown in Table 1, which are indicative of an advanced heart failure patient population. Patients were mostly men (81.4% thoracotomy-based and 83.8% sternotomy-based), White (68.6% thoracotomy-based and 72.1% sternotomy-based), implanted with destination therapy intent (60.8% thoracotomy-based and 60.3% sternotomy-based) and INTERMACS Profile 1 or 2 (31.4% thoracotomy-based and 32.4% sternotomy-based) or Profile 3 (49.0% thoracotomy-based and 47.1% sternotomy-based).

Primary End Point

In the analysis of the primary end point, 85.2% of thoracotomy-based patients met the criteria compared with 86.1% of sternotomy-based patients (Table 2). The noninferiority criterion (absolute between-group difference, −1.2%; Farrington Manning lower 1-sided 95% CI, −9.3%; $P < .0025$) was met (Figure 3, A). Details of the primary end point components according to the first treatment-failure event that occurred are shown in Table 2. There were more elective transplants among MOMENTUM 3 CAP patients. No differences were observed in actuarial freedom from the primary end point (HR, 1.1; 95% CI, 0.6-2.1) (Figure 3, B). When evaluating all events, there were no differences between the 2 groups in overall survival (HR, 0.9; 95% CI, 0.5-1.9; $P = .85$) (Figure 4, A), cause-specific mortality rates (Table E3), or freedom from disabling stroke (HR, 1.0; 95% CI, 0.6-4.1; $P = .97$) (Figure 4, B).

TABLE 1. Baseline characteristics of the thoracotomy-based and matched sternotomy-based cohorts

Characteristic	Thoracotomy-based (n = 102)	Sternotomy-based (n = 204)
Age (y)	59.1 ± 13.4 (n = 102/102)	58.4 ± 12.4 (n = 204/204)
Male sex	81.4 (n = 83/102)	83.8 (n = 171/204)
Race*		
Asian	2.0 (n = 2/102)	0.0 (n = 0/204)
Black or African American	24.5 (n = 25/102)	24.5 (n = 50/204)
Native Hawaiian or Pacific Islander	0.0 (n = 0/102)	0.5 (n = 1/204)
White	68.6 (n = 70/102)	72.1 (n = 147/204)
Other	1.0 (n = 1/102)	2.9 (n = 6/204)
Hispanic or Latino ethnicity	10.3 (n = 10/97)	4.9 (n = 10/204)
Body mass index	29.05 ± 6.97 (n = 102/102)	28.82 ± 6.47 (n = 204/204)
Destination therapy	60.8 (n = 62/102)	60.3 (n = 123/204)
INTERMACS profile		
1 or 2	31.4 (n = 32/102)	32.4 (66/204)
3	49.0 (n = 50/102)	47.1 (n = 96/204)
≥4	19.6 (n = 20/102)	20.6 (n = 42/204)
History of CABG or valve repair/replacement	27.5 (n = 28/102)	28.4 (n = 58/204)
NYHA functional class		
IIIB	23.5 (n = 24/102)	8.4 (n = 17/203)
IV	76.5 (n = 78/102)	91.6 (n = 186/203)
Creatinine (mg/dL)	1.4 ± 0.5 (n = 102/102)	1.4 ± 0.4 (n = 204/204)
BUN (mg/dL)	29.1 ± 13.5 (n = 102/102)	28.4 ± 14.6 (n = 204/204)
ALT (U/L)	41.9 ± 97.2 (n = 102/102)	43.4 ± 57.9 (n = 203/204)
AST (U/L)	34.5 ± 43.7 (n = 101/102)	38.7 ± 55.2 (n = 203/204)
Total bilirubin (mg/dL)	0.9 ± 0.5 (n = 102/102)	1.0 ± 0.6 (n = 203/204)
LDH (U/L)	301.9 ± 130.2 (n = 96/102)	267.9 ± 106.4 (n = 193/204)
LVEF (%)	17.6 ± 5.1 (n = 101/102)	17.0 ± 5.0 (n = 203/204)
LVEDD/LVIDD (mm)	69.5 ± 9.0 (n = 79/102)	68.6 ± 10.5 (n = 178/204)
RAP (mm Hg)	11.3 ± 6.8 (n = 99/102)	11.0 ± 6.9 (n = 204/204)
PVR (Wood units)	3.1 ± 1.7 (n = 93/102)	3.1 ± 1.6 (n = 202/204)
PCWP (mm Hg)	23.5 ± 9.9 (n = 98/102)	23.2 ± 9.5 (n = 202/204)
Cardiac output (L/min)	4.0 ± 1.1 (n = 100/102)	4.0 ± 1.2 (n = 204/204)
Cardiac index (L/min/m^2)	2.0 ± 0.5 (n = 100/102)	2.0 ± 0.6 (n = 204/204)
MAP (mm Hg)	82.8 ± 11.1 (n = 102/102)	81.5 ± 12.2 (n = 202/204)

Values are presented as mean ± SD or %. *INTERMACS*, Interagency Registry for Mechanically Assisted Circulatory Support; *CABG*, coronary artery bypass graft; *NYHA*, New York Heart Association; *BUN*, blood urea nitrogen; *ALT*, alanine transaminase; *AST*, aspartate transaminase; *LDH*, lactate dehydrogenase; *LVEF*, left ventricular ejection fraction; *LVEDD*, left ventricular end-diastolic diameter; *LVIDD*, left ventricular internal diameter end diastole; *RAP*, right atrial pressure; *PVR*, pulmonary vascular resistance; *PCWP*, pulmonary capillary wedge pressure; *MAP*, mean arterial pressure. *Race or ethnicity was self-reported.

Hospitalization and Index Procedure Details

There were no differences in ICU length of stay between the 2 groups (mean, 12.6 ± 3.0 days thoracotomy-based vs 11.3 ± 1.5 days sternotomy-based; $P = .84$); however, in patients discharged, the length of index implant hospitalization was longer in thoracotomy-based patients (median, 20 days; Quartile 1, Quartile 3, 15, 29) thoracotomy-based vs median, 17 (Quartile 1, Quartile 3, 13, 25) sternotomy-based; $P = .03$ (Table 3). The total implant and cardiopulmonary bypass time was longer in the thoracotomy-based

implant compared with the sternotomy-based implant (both $P < .0001$) as shown in Table 4. Blood transfusions, whole blood, and packed red blood cells units were not different between the groups (Table 4). Furthermore, the rate of use of other blood products was similar (Table 4) and the overall amount of other blood products used was similar, except for cryoprecipitates, which when used, required fewer units in thoracotomy-based patients (2.4 U thoracotomy-based vs 7.1 U sternotomy-based; $P = .0009$) (Table E4).

ADULT

TABLE 2. Components of the primary end point

Primary end point outcomes	Thoracotomy-based (n = 102)	Sternotomy-based (n = 204)	Difference (95% CI)*
Primary end point success	85.0 (n = 85/100)	86.2 (n = 175/203)	−1.2 (−9.3 to 6.7)
Success			
Alive and event-free	85.0 (n = 85/100)	80.8 (n = 164/203)	4.21 (−5.4 to 12.5)
Elective transplant	0.0 (n = 0/100)	5.4 (n = 11/203)	−5.4 (−9.4 to −1.0)
Failure (first event)			
Death	11.0 (n = 11/100)	10.3 (n = 21/203)	0.66 (−6.2 to 9.0)
Debilitating stroke (MRS >3)	3.0 (n = 3/100)	3.0 (n = 6/203)	0.04 (−3.8 to 5.7)
Transplant due to device malfunction	0.0 (n = 0/100)	0.5 (1/203)	−0.49 (−2.7 to 3.2)
Conversion to sternotomy	1.0 (n = 1/100)	NA	NA

Values are presented as %. *MRS*, Modified Rankin score; *NA*, not available. *The CI, calculated by Newcombe score method as 95% CI, except for primary end point success difference, which is calculated by Farrington-Manning as 2-sided 90% CI.

Major Adverse Events

Comparisons of major adverse event rates between thoracotomy-based and the matched sternotomy-based cohort, including hemocompatibility-related events adverse events (stroke and bleeding), are shown in Table 5. The overall rate of right heart failure was not different in between the two cohorts (0.52 events per patient year [EPPY] thoracotomy-based vs 0.68 sternotomy-based; $P = .26$). However, right ventricular assist device use was higher in thoracotomy-based cohort (0.33 EPPY thoracotomy-based vs 0.12 sternotomy-based; $P = .02$). There was no difference in stroke of any subtype and severity (0.19 EPPY thoracotomy-based vs 0.18 sternotomy-based; $P = .92$).

Functional Status and Quality of Life

There were sustained improvements from baseline in the 6-minute walk test, New York Heart Association functional class, Kansas City cardiomyopathy questionnaire overall summary score, and EuroQOL-5 dimension-5 level visual analog scale in both groups (Figure E2). There were no
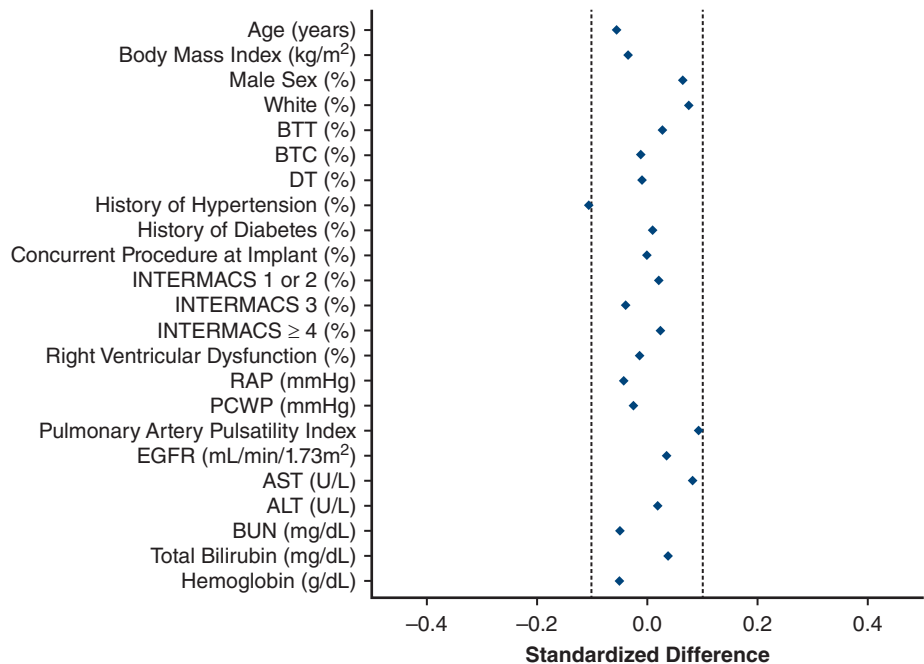
FIGURE 2. Standardized differences after matching. The standardized differences between the thoracotomy-based population and the matched sternotomy-based cohort were similar, within standardized difference <0.1, except for history of hypertension, which showed a standardized difference = 0.106. *BTT*, Bridge-to-transplant; *BTC*, bridge-to-candidacy (for transplant); *DT*, destination therapy; *INTERMACS*, Interagency Registry for Mechanically Assisted Circulatory Support; *RAP*, right atrial pressure; *PCWP*, pulmonary capillary wedge pressure; *eGFR*, estimated glomerular filtration rate; *ALT*, alanine transaminase; *AST*, aspartate transaminase; *BUN*, blood urea nitrogen.

A

B

A

B

FIGURE 3. Primary end point analysis. A, The noninferiority criterion (absolute between-group difference, 1.2 percentage points; Farrington Manning CI, −5.3 to 7.7%) was met for the primary end point. The primary composite end point (survival at 6 months free of disabling stroke (modified Rankin score >3), or reoperation to remove or replace a malfunctioning device, or conversion to open sternotomy; elective transplant within 6 months without other components of the primary end point was considered a success) was not significantly different between the thoracotomy-based patients and matched sternotomy-based patients. The evaluable population for the binary end point was 100 thoracotomy-based patients, and 200 sternotomy-based patients. Two thoracotomy-based patients were withdrawn before 6 months without a primary end point event and could not be included in the binar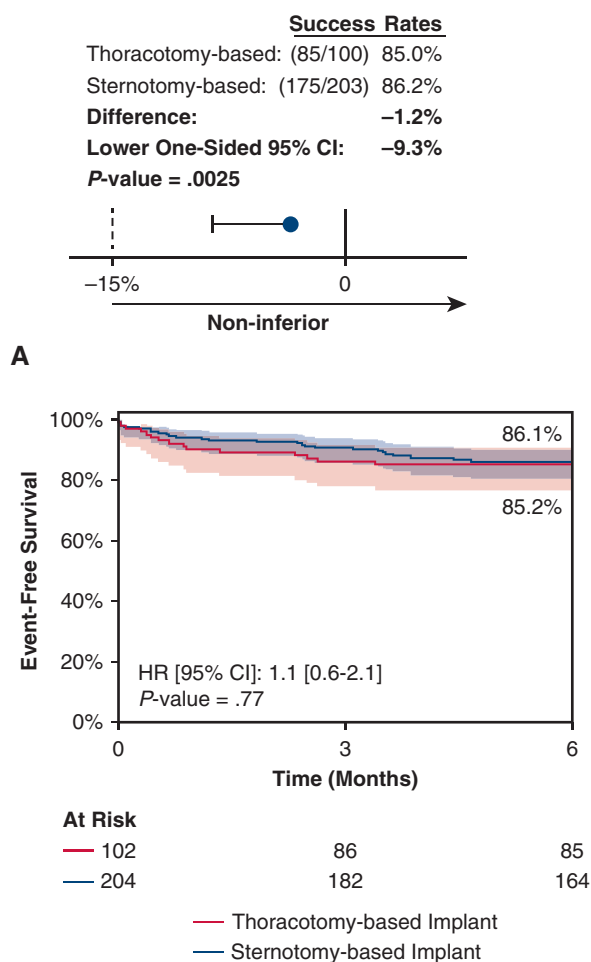y end point. B, The Kaplan-Meier survival free from primary end point event was not different between the thoracotomy-based patients and matched sternotomy-based patients. Shading shows 95% CI. *HR*, Hazard ratio.

FIGURE 4. Kaplan-Meier survival and freedom from disabling stroke. No differences were noted between the 2 groups in overall survival (A) or freedom from disabling stroke (B). Shading shows 95% CI. *HR*, Hazard ratio.

differences in functional-status test results or quality of life measures between the treatment groups.

Subgroup Analyses

For the prespecified subgroups of age, sex, race, or ethnic group, intended goal of pump support (bridge to transplantation or destination therapy), or INTERMACS profile, no interaction between the individual prespecified subgroups and implant method was observed regarding the primary end point. Additional details are provided in Table E5. Within the thoracotomy-based technique, aortic access was obtained by right thoracotomy in 41 out of 102 (40%) of patients, the remaining patients had partial sternotomy that included both type-J in 47 out of 102 (46%) and type T in 13 out of 102 (13%). In 1 subject with a partial sternotomy, the type of hemi-sternotomy was not recorded. Aortic access performed via small right

TABLE 3. Length of stay in discharged patients

Characteristic	Thoracotomy-based	Sternotomy-based	P value
Intensive care unit (d)	7 (5, 15) (n = 90)	8 (5, 13) (n = 188)	.84
Index hospitalization (d)	20 (15, 29) (n = 91)	17 (13, 25) (n = 189)	.03

Values are presented as median (quartile 1, quartile 3).

thoracotomy or partial upper sternotomy in the thoracotomy-based implant surgical technique did not result in differences in primary end point success, survival, or freedom from disabling stroke (Table E6). Finally, sites that enrolled more patients (>5 patients/site) in the study did not demonstrate experienced shorter length of stay and shorter length of bypass time (Figure E3).

DISCUSSION

The principal finding of the HM3 SWIFT study is that the thoracotomy-based surgical technique is noninferior when compared with a traditional median sternotomy-based implant of the HM3 LVAD. We could not find any major benefits or risks for the thoracotomy-based implant technique in adverse events, health care resource use parameters (length of hospital stay or use of blood products), or in functional capacity, quality of life, or survival among the surgical implant techniques.

Thoracotomy-based implantation of LVADs via bilateral thoracotomy or left thoracotomy with partial upper sternotomy increased in popularity after the introduction of a hydrodynamically levitated centrifugal LVAD, the HeartWare HVAD (Medtronic) in 2008. A Prospective, Single-Arm, Multi-Center Study in Collaboration With INTERMACS to Evaluate the Thoracotomy Implant Technique of the HeartWare HVAD System in Patients With Advanced Heart Failure, the first prospective trial using this technique

in the now discontinued LVAD, showed improved outcomes with the thoracotomy-based approach that included a decreased length of stay and an increase in 6-month survival compared with performance goals derived from prior studies with the device.[10] After the MOMENTUM 3 trial demonstrated improved event-free survival and decreased adverse events with the HM3 LVAD compared with the HeartMate II pump, multiple single and multicenter retrospective studies assessed potential benefits of the thoracotomy-based surgical technique with HM3 device. These studies suggested an association of the thoracotomy-based technique with decreased need for blood transfusions, decreased incidence of right heart failure, improved mobility, shorter intubation time, reduced ICU and overall length of stay, and improved survival. Additionally, advantages for such alternative techniques have been suggested in selected subgroups of patients with a prior sternotomy, patients on extracorporeal membrane oxygenation, and obese patients.[15-17] These may be important because the presence of a prior sternotomy has been shown to represent increased risk for mortality after LVAD implantation.[18] Most studies of alternative surgical approaches are limited to single centers or are retrospective, often confounded by selection bias and largely confined to centers with highly experienced surgical teams. Therefore, a prospective, multicenter study was necessary to evaluate the feasibility, safety, and outcomes to establish the

TABLE 4. Implant procedure details

Characteristic	Thoracotomy-based (n = 102)	Sternotomy-based (n = 204)	P value
Total implant time (min)	395.8 ± 129.5 (n = 102/102)	284.3 ± 110.9 (n = 204/204)	<.0001
Total time on CPB (min)	122.6 ± 64.8 (n = 100/102)	83.5 ± 39.8 (n = 203/204)	<.0001
Received blood products	82.4 (n = 84/102)	79.9 (n = 163/204)	.61
Whole blood	1.0 (n = 1/102)	2.0 (n = 4/204)	.67*
Packed red blood cells	44.1 (n = 45/102)	34.8 (n = 71/204)	.11
Fresh frozen plasma	32.4 (n = 33/102)	37.3 (n = 76/204)	.40
Platelets	43.1 (n = 44/102)	40.2 (n = 82/204)	.62
Cryoprecipitate	25.5 (n = 26/102)	27.0 (n = 55/204)	.78
Cell saver	56.9 (n = 58/102)	54.4 (n = 111/204)	.68
Concurrent procedures	12.7 (n = 13/102)	12.7 (n = 26/204)	.27
CABG/valve	4.9 (n = 5/102)	8.3 (n = 17/204)	.22

Values are presented as mean ± SD or %. *CPB*, Cardiopulmonary bypass; *CABG*, coronary artery bypass graft. *Fisher exact test.

TABLE 5. Adverse events

Adverse event type	Thoracotomy-based			Sternotomy-based			P value*
	n (%)	Events	EPPY	n (%)	Events	EPPY	
Stroke	6 (5.9)	8	0.19	14 (6.9)	16	0.18	.92
Hemorrhagic stroke	2 (2.0)	2	0.05	7 (3.4)	7	0.08	.52
Ischemic stroke	5 (4.9)	6	0.14	9 (4.4)	9	0.10	.53
Other neurological event	12 (11.8)	14	0.33	17 (8.3)	19	0.21	.22
Bleeding	39 (38.2)	54	1.26	75 (36.8)	117	1.31	.83
0-7 d postimplant	12 (11.8)	12	0.28	32 (15.7)	33	0.37	.42
>7 d postimplant	30 (29.4)	42	0.98	54 (26.5)	84	0.94	.81
Bleeding requiring surgery within 14 d	9 (8.8)	9	0.21	23 (11.3)	23	0.26	.61
Bleeding requiring surgery within 30 d	11 (10.8)	11	0.26	24 (11.8)	25	0.28	.82
Arterial non-CNS thromboembolism	4 (3.9)	4	0.09	2 (1.0)	2	0.02	.10
Major infection	39 (38.2)	61	1.43	78 (38.2)	113	1.27	.44
Localized	24 (23.5)	32	0.75	55 (27.0)	71	0.79	.78
Sepsis	14 (13.7)	17	0.40	19 (9.3)	25	0.28	.26
Driveline	9 (8.8)	11	0.26	17 (8.3)	17	0.19	.43
Right heart failure	22 (21.6)	22	0.52	58 (28.4)	61	0.68	.26
RVAD	14 (13.7)	14	0.33	11 (5.4)	11	0.12	.02
>14 consecutive days on inotropes	10 (9.8)	10	0.23	22 (10.8)	22	0.25	.90
Ventricular arrhythmia	14 (13.7)	17	0.40	33 (16.2)	36	0.40	.97
Renal dysfunction	15 (14.7)	15	0.35	20 (9.8)	22	0.25	.29
Respiratory dysfunction	18 (17.6)	20	0.47	37 (18.1)	45	0.50	.79

EPPY, Events per patient year; CNS, central nervous system; RVAD, right ventricular assist device. *Calculated using Poisson regression.

thoracotomy-based implant technique as an additional standard surgical technique for HM3 LVAD implantation.

The HM3 SWIFT study outcomes suggest that the thoracotomy-based technique is feasible (only 1 patient required conversion to a median sternotomy) and safe because outcomes suggest similar adverse outcomes at 6-months when compared with a standard sternotomy-based surgical approach. Although the HM3 SWIFT study does not suggest any absolute contraindications to the use of the thoracotomy-based approach, implanting surgeons should plan their case based on their experience and comfort level with a given approach (either thoracotomy-based or sternotomy-based) according to the complexity of the case, including any concomitant procedures. Although surgeons were required to have performed at least 3 alternative technique HM3 LVAD implants before enrollment in the study, no structured training or other required experience in less invasive techniques was instituted, therefore allowing us to interpret the findings of HM3 SWIFT in a broader scalable manner for more routine consideration. Despite diversity in surgical experience among the 23 centers, outcomes and adverse events were comparable to the median sternotomy approach.

We could not confirm previous reports that suggested advantage of the alternative implant technique approach. It may reflect no difference between techniques, patient characteristics, or be a result of the short duration of observation, although prior observations suggested advantages limited to early outcomes. We did note that use of right ventricular assist device was greater among the thoracotomy-based population (although this did not increase overall right heart failure rates and did not influence late outcomes). This may reflect practice changes between the timing of HM3 SWIFT and MOMENTUM 3 studies. The MOMENTUM 3 study showed a rise in the use of right ventricular assist device between its pivotal trial and its postapproval-phase experience.[1,14] Whether this reflects more wider selection of patients with significant right heart failure or a greater propensity for prophylactic use of right ventricular assist device during implant is unknown and could explain the observed differences. Additionally, increasing experience, including better understanding of the hemodynamics of the failing right ventricle combined with improved ease of implantation, and consequent earlier use, of percutaneous right ventricular assist device, may account for the observed differences.

Another factor of importance is that this study was conducted during the COVID-19 pandemic, which may have influenced the patients screened and enrolled for LVAD implants. During the COVID-19 pandemic, the patients receiving LVADs may have been sicker because the pandemic limited access to care for many patients and

may have resulted in patients with nutritional gaps or frailty, 2 aspects not easily amenable to structured evaluation within this study.[19-21] Such causes for confounding may not be easily apparent and cannot always be corrected by a propensity score assessment. Influences to the timing of outpatient and inpatient evaluation combined with fear of the pandemic may have delayed the timing of heart failure patients' presentation for advanced therapies. Furthermore, within hospitals, staffing shortages and decreased availability of hospital beds may have delayed discharge from the ICU and especially from the hospital for patients requiring discharge to other facilities. Therefore, if some benefits could have existed, these may have been negatively influenced by pandemic-related effects that are not subject to quantitation easily. These details may also explain our finding that thoracotomy patients experienced longer lengths of stay for their index hospitalization despite no overt differences in adverse effects and no change in duration of ICU length of stay. The hypothesis that these effects are likely due to extrinsic factors rather than the surgical procedure is supported by a learning curve analysis, which did not show a decrease in length of stay or bypass time at sites with higher enrollment.

Study Limitations

Other than limitations already expressed (era differences and pandemic influence) we should recognize that the nonrandomized study design increases risk of unrecognized confounders that could be unaccounted for in the propensity score matching. During the HM3 SWIFT study, new allocation systems that changed the practice for bridging to transplant with LVADs occurred, diverting relatively sicker and mostly destination therapy patients toward primary LVAD implantation.[22] These challenges would have primarily obscured any benefits associated with the thoracotomy-based implant technique but likely do not influence the interpretation of noninferiority in our study. Lastly, variation by site and specific surgeon have the potential to greatly influence both length of stay and bypass time. However, this study aimed to show broad applicability of the thoracotomy-based surgical approach, and as such leveraged a relatively large number of sites, which leaves us unable to discriminate such an influence.

CONCLUSIONS

The prospective, multicenter HM3 SWIFT study conducted across North America demonstrated noninferiority of the thoracotomy-based surgical approach (bilateral thoracotomy or left thoracotomy with partial upper sternotomy) when compared with a standard median sternotomy for implantation of the HM3 LVAD. No major risks or benefits for the thoracotomy-based implant technique were observed in adverse events, health care resource use (length of stay), functional capacity, quality of life, or 6-month survival.

Webcast

You can watch a Webcast of this AATS meeting presentation by going to: https://www.aats.org/resources/lb1-implant-of-the-heart-mate-3-left-ventricular-assist-device-using-techniques-other-than-full-median-sternotomy-primary-findings-of-the-multi-center-heart-mate-3-swift-clinical-trial.
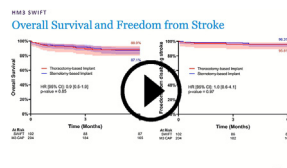
Conflict of Interest Statement

Dr Gosev reports consulting for Abbott. Dr Pham reports consulting for Abbott, Abiomed, and Medtronic. Dr Itoh reports speaker honoraria from Abbott and Abiomed. Dr Kotkar is a speaker (nonfinancial) for Abiomed and 3M. Dr Naka reports consulting for Abbott, Biomet-Zimmer, Cryolife, and receiving speaker's fees for Nipro Co. Dr Peltz reports research support from Bridge to Life Ltd and Paragonix Inc. Dr Silvestry reports consulting for Abbott, Abiomed, Medtronic, and data and safety monitoring board participation for Carmat. Dr Leacche reports consulting for Abbott and advisory board participation for Abiomed. Dr Rao reports consulting for Abbott, Medtronic, and Gore. Dr Sun reports consulting for Abbott. Dr Tedford reports consulting for Abbott, Medtronic, Aria CV Inc, Alleviant, Acorai, Acceleron, Cytokinetics, Itamar, Edwards LifeSciences, Eidos Therapeutics, Lexicon Pharmaceuticals, Gradient, and United Therapeutics. He is the national co-principal investigator for the RIGHT-FLOW clinical trial (Edwards), serves on steering committees for Merck, and a research advisory board for Abiomed. He also does hemodynamic core lab work for Merck. Dr Mokadam reports consulting for Abbott, Medtronic, SynCardia, Carmat, and Xylocor. Drs McNutt and Crandall are employees of Abbott. Dr Mehra reports payment made to institution from Abbott for consulting; consulting fees from Mesoblast, Janssen, Moderna, and Paragonix, and Baim Institute for clinical research; he is an advisory board member for Transmedics, NuPulseCV, Leviticus, and FineHeart. Dr Salerno reports consulting for Abbott. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling manuscripts for which they may have a conflict of interest. The editors and reviewers of this article reported no conflicts of interest.

References

1. Mehra MR, Naka Y, Uriel N, Goldstein DJ, Cleveland JC Jr, Colombo PC, et al. A fully magnetically levitated circulatory pump for advanced heart failure. *N Engl J Med*. 2017;376:440-50.
2. Mehra MR, Goldstein DJ, Cleveland JC, Cowger JA, Hall S, Salerno CT, et al. Five-year outcomes in patients with fully magnetically levitated vs axial-flow left ventricular assist devices in the MOMENTUM 3 randomized trial. *JAMA*. 2022;328:1233-42.
3. Yuzefpolskaya M, Schroeder SE, Houston BA, Robinson MR, Gosev I, Reyentovich A, et al. The Society of Thoracic Surgeons Intermacs 2022 Annual Report: focus on the 2018 heart transplant allocation system. *Ann Thorac Surg*. 2023;115:311-27.
4. Zimpfer D, Gustafsson F, Potapov E, Pya Y, Schmitto J, Berchtold-Herz M, et al. Two-year outcome after implantation of a full magnetically levitated left ventricular assist device: results from the ELEVATE Registry. *Eur Heart J*. 2020;41: 3801-9.
5. Uriel N, Colombo PC, Cleveland JC, Long JW, Salerno C, Goldstein DJ, et al. Hemocompatibility-related outcomes in the MOMENTUM 3 trial at 6 months: a randomized controlled study of a fully magnetically levitated pump in advanced heart failure. *Circulation*. 2017;135:2003-12.
6. Nayak A, Hall SA, Uriel N, Goldstein DJ, Cleveland JC, Cowger JA, et al. Predictors of 5-year survival with a fully magnetically levitated LVAD in the MOMENTUM 3 trial. *J Am Coll Cardiol*. 2023;82:771-81.
7. Gosev I, Wood K, Ayers B, Barrus B, Knight P, Alexis JD, et al. Implantation of a fully magnetically levitated left ventricular assist device using a sternal-sparing surgical technique. *J Heart Lung Transplant*. 2020;39:37-44.
8. McGee E Jr, Danter M, Strueber M, Mahr C, Mokadam NA, Wieselthaler G, et al. Evaluation of a lateral thoracotomy implant approach for a centrifugal-flow left ventricular assist device: the LATERAL clinical trial. *J Heart Lung Transplant*. 2019;38:344-51.
9. Riebandt J, Schloglhofer T, Moayedifar R, Wiedemann D, Wittmann F, Angleitner P, et al. Less invasive left ventricular assist device implantation is safe and reduces intraoperative blood product use: a propensity score analysis VAD implantation techniques and blood product use. *ASAIO J*. 2021;67:47-52.
10. Saeed D, Muslem R, Rasheed M, Caliskan K, Kalampokas N, Sipahi F, et al. Less invasive surgical implant strategy and right heart failure after LVAD implantation. *J Heart Lung Transplant*. 2021;40:289-97.
11. Liotta D, Hall CW, Maness JH, Debakey ME. The implantable intrathoracic circulatory pump: surgical technique. *Cardiovasc Res Cent Bull*. 1964;3:54-61.
12. Hanke JS, Dogan G, Shrestha M, Haverich A, Schmitto JD. Innovations in implantation techniques of ventricular assist devices. *J Thorac Cardiovasc Surg Open*. 2021;8:28-32.
13. Hanke JS, Rojas SV, Avsar M, Haverich A, Schmitto JD. Minimally-invasive LVAD implantation: state of the art. *Curr Cardiol Rev*. 2015;11:246-51.
14. Mehra MR, Cleveland JC Jr, Uriel N, Cowger JA, Hall S, Horstmanshof D, et al. Primary results of long-term outcomes in the MOMENTUM 3 pivotal trial and continued access protocol study phase: a study of 2200 HeartMate 3 left ventricular assist device implants. *Eur J Heart Fail*. 2021;23:1392-400.
15. Ayers B, Sagebin F, Wood K, Barrus B, Thomas S, Storozynsky E, et al. Complete sternal-sparing approach improves outcomes for left ventricular assist device implantation in patients with history of prior sternotomy. *Innovations (Phila)*. 2020;15:51-6.
16. Bjelic M, Ayers B, Paic F, Bernstein W, Barrus B, Chase K, et al. Study results suggest less invasive HeartMate 3 implantation is a safe and effective approach for obese patients. *J Heart Lung Transplant*. 2021;40:990-7.
17. Potapov E, Loforte A, Pappalardo F, Morshuis M, Schibilsky D, Zimpfer D, et al. Impact of a surgical approach for implantation of durable left ventricular assist devices in patients on extracorporeal life support. *J Card Surg*. 2021;36: 1344-51.
18. Mehra MR, Nayak A, Morris AA, Lanfear DE, Nemeh H, Desai S, et al. Prediction of survival after implantation of a fully magnetically levitated left ventricular assist device. *JACC Heart Fail*. 2022;10:948-59.
19. Einstein AJ, Shaw LJ, Hirschfeld C, Williams MC, Villines TC, Better N, et al. International impact of COVID-19 on the diagnosis of heart disease. *J Am Coll Cardiol*. 2021;77:173-85.
20. Garcia S, Stanberry L, Schmidt C, Sharkey S, Megaly M, Albaghdadi MS, et al. Impact of COVID-19 pandemic on STEMI care: an expanded analysis from the United States. *Catheter Cardiovasc Interv*. 2021;98:217-22.
21. Hirschfeld CB, Shaw LJ, Williams MC, Lahey R, Villines TC, Dorbala S, et al. Impact of COVID-19 on cardiovascular testing in the United States versus the rest of the world. *JACC Cardiovasc Imaging*. 2021;14:1787-99.
22. Cogswell R, John R, Estep JD, Duval S, Tedford RJ, Pagani FD, et al. An early investigation of outcomes with the new 2018 donor heart allocation system in the United States. *J Heart Lung Transplant*. 2020;39:1-4.

Key Words: HeartMate 3, LVAD, thoracotomy, minimally invasive, outcomes

ADULT

APPENDIX E1. ADVERSE EVENT DEFINITIONS

Bleeding

An episode of suspected internal or external bleeding that results in 1 or more of the following:

a. Death,
b. Reoperation,
c. Hospitalization, and/or
d. Transfusion of red blood cells as follows:

*If transfusion is selected, then apply the following rules:

During first 7 days postimplant:

- ≥50 kg: ≥4 U packed red blood cells within any 24-hour period during first 7 days postimplant.
- <50 kg: ≥20 cc/kg packed red blood cells within any 24-hour period during the first 7 days postimplant.

After 7 days postimplant:*

- Any transfusion of packed red blood cells after 7 days following implant with the investigator recording the number of units given. (Record number of units given per 24-hour period.)

Note: Hemorrhagic stroke is considered a neurological event and not as a separate bleeding event.

*Any transfusion ≥2 U packed red blood cells after 7 days following implant will be considered a serious bleed.

Cardiac Arrhythmias

Any documented arrhythmia that results in clinical compromise (eg, diminished ventricular assist device flow, oliguria, presyncope, or syncope) that requires hospitalization or occurs during a hospital stay. Cardiac arrhythmias are classified as 1 of 2 types:

1. Sustained ventricular arrhythmia requiring defibrillation or cardioversion.
2. Sustained supraventricular arrhythmia requiring drug treatment or cardioversion.

Pericardial Fluid Collection

Accumulation of fluid or clot in the pericardial space that requires surgical intervention or percutaneous catheter drainage. This event will be subdivided into those with clinical signs of tamponade (eg, increased central venous pressure and decreased cardiac/ventricular assist device output) and those without signs of tamponade.

Device Thrombosis

Suspected device thrombosis is an event in which the pump or its conduits contain a thrombus that results in or could potentially induce circulatory failure. Suspected device thrombus is an event in which clinical or mechanical circulatory support device parameters suggest thrombus on the blood contacting components of the pump, cannulae, or grafts. Signs and symptoms should include at least 2 of the 3 following criteria:

a. Presence of hemolysis,
b. Worsening heart failure or inability to decompress the left ventricle,
c. Abnormal pump parameters.

Suspected device thrombus should be accompanied by 1 or more of the following events or interventions:

i. Treatment with intravenous anticoagulation (eg, heparin), intravenous thrombolytics (eg, tissue plaminogen activator), or intravenous antiplatelet therapy (eg, eptifibatide and tirofiban).
ii. Pump replacement.
iii. Pump explantation.
iv. Urgent transplantation (United Network for Organ Sharing status 1A).
v. Stroke.
vi. Arterial non–central nervous system thromboembolism.
vii. Death.

Confirmed device thrombus is an event in which thrombus is confirmed by the sponsor returned product analysis to be found within the blood contacting surfaces of device inflow cannula or outflow conduit or grafts. This can also be reported via direct visual inspection or by incontrovertible contrast radiographic evidence or by the absence of an appropriate Doppler flow signal that results in or could potentially induce circulatory failure or result in thromboembolism.

Hemolysis*

A plasma-free hemoglobin value >40 mg/dL, concomitant with a rise in serum lactate dehydrogenase >3 times the upper limit of normal, in association with clinical signs associated with hemolysis (eg, anemia, low hematocrit, hyperbilirubinemia, and hemoglobinuria) occurring after the first 72 hours postimplant.

*Hemolysis in the presence of worsening heart failure or inability to decompress the left ventricle or abnormal pump parameters should be reported as suspected device thrombosis, not as hemolysis.

Hepatic Dysfunction

An increase in any 2 of the following hepatic laboratory values (total bilirubin, aspartate aminotransferase/aspartate transaminase, and alanine aminotransferase/alanine transaminase) to a level >3 times the upper limit of normal for the hospital, beyond 14 days postimplant (or if hepatic dysfunction is the primary cause of death).

Hypertension

Blood pressure elevation of a mean arterial pressure >110 mm Hg, despite antihypertension therapy.

Major Infection

A clinical infection accompanied by pain, fever, drainage, and/or leukocytosis that is treated by antimicrobial agents (nonprophylactic). A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures. The general categories of infection are listed below:

Localized nondevice infection. Infection localized to any organ system or region (eg, mediastinitis) without evidence of systemic involvement (see Sepsis definition), ascertained by standard clinical methods and either associated with evidence of bacterial, viral, fungal, or protozoal infection, and/or requiring empirical treatment.

Percutaneous site and/or pocket infection. A positive culture from the skin and/or tissue surrounding the drive line or from the tissue surrounding the external housing of a pump implanted within the body, coupled with the need to treat with antimicrobial therapy, when there is clinical evidence of infection such as pain, fever, drainage, or leukocytosis.

Internal pump component, inflow or outflow tract infection. Infection of blood-contacting surfaces of the left ventricular assist device documented by positive site culture.

Sepsis. Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension.

Myocardial Infarction

Two categories of myocardial infarction will be identified:

Perioperative myocardial infarction. The clinical suspicion of myocardial infarction together with creatine kinase, myocardial band (CK-MB) or troponin >10 times the local hospital upper limits of normal, found within 7 days following ventricular assist device implant together with electrocardiogram findings consistent with acute myocardial infarction. (This definition uses the higher suggested limit for serum markers due to apical coring at the time of ventricular assist device placement and does not use wall motion changes because the apical sewing ring inherently creates new wall motion abnormalities.)

Nonperioperative myocardial infarction. The presence at >7 days postimplant of 2 of the following 3 criteria:

a. Chest pain that is characteristic of myocardial ischemia,
b. Electrocardiogram with a pattern or changes consistent with a myocardial infarction, and
c. Troponin or creatine kinase (measured by standard clinical pathology/laboratory medicine methods) greater than the normal range for the local hospital with positive myocardial band fraction ($\geq 3\%$ total creatine kinase).

This should be accompanied by a new regional left ventricle or right ventricle wall motion abnormality on a myocardial imaging study.

Neurologic Dysfunction

Any new, temporary, or permanent, focal, or global neurological deficit, ascertained by a standard neurological history and examination administered by a neurologist or other qualified physician and documented with appropriate diagnostic tests and consultation note; or an abnormality identified by surveillance neuroimaging. The examining physician will classify the event as defined below:

a. Transient ischemic attack,* defined as an acute transient neurological deficit conforming anatomically to arterial distribution cerebral ischemia that resolves in <24 hours and is associated with no infarction on brain imaging (head x-ray computed tomography performed >24 hours after symptom onset; or magnetic resonance imaging).
b. Ischemic stroke*: A new acute neurologic deficit of any duration associated with acute infarction on imaging corresponding anatomically to the clinical deficit, or a clinically covert ischemic stroke seen by surveillance imaging, without clinical findings of stroke or at the time of event recognition.
c. Hemorrhagic stroke*: A new acute neurologic deficit attributable to intracranial hemorrhage, or a clinically covert intracranial hemorrhage seen by surveillance imaging, without clinical findings of intracranial hemorrhage at the time of event recognition.
d. Encephalopathy: Acute new encephalopathy† due to hypoxic-ischemic injury, or other causes, manifest as clinically evident signs or symptoms, or subclinical electrographic seizures found by complete neurological diagnostic evaluation to be attributable to acute global or focal hypoxic, or ischemic brain injury not meeting 1 of ischemic stroke or intracranial hemorrhage events as defined above.
e. Seizure of any kind.
f. Other neurological event (non-central nervous system event): Examples include neuromuscular dysfunction or critical care neuropathy.

*Modified Rankin Score will be used to classify the severity of all strokes.

†Acute encephalopathy is a sign or symptom of some underlying cerebral disorder, and is manifest as depressed consciousness with or without any associated new global or multifocal neurologic deficits in cranial nerve, motor, sensory, reflexes, and cerebellar function.

Psychiatric Episode

Disturbance in thinking, emotion or behavior that causes substantial impairment in functioning or marked subjective distress requiring intervention. Intervention is the addition of new psychiatric medication or hospitalization. Suicide is included in this definition.

Renal Dysfunction

Two categories of renal dysfunction will be identified:

Acute renal dysfunction. Abnormal kidney function requiring dialysis (including hemofiltration) in subjects who did not require this procedure before implant, or a rise in serum creatinine >3 times baseline or >5 mg/dL sustained for more than 48 hours.

Chronic renal dysfunction. An increase in serum creatinine ≥2 mg/dL above baseline, or requirement for hemodialysis sustained for at least 90 days.

Respiratory Failure

Impairment of respiratory function requiring reintubation, tracheostomy or (the inability to discontinue ventilatory support within 6 days (144 hours) post–ventricular assist device implant. This excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.

Right Heart Failure

Symptoms and signs of persistent right ventricular dysfunction requiring right ventricular assist device implantation or requiring inhaled nitric oxide or inotropic therapy for a duration of more than 14 days at any time after left ventricular assist device implantation. To compare with prior studies, this study will begin collecting details of events involving nitric oxide or inotropic therapy for a duration of more than 7 days, whereas reportable right heart failure will begin at 14 days of therapy.

To further stratify right heart failure events, the following criteria will be used to identify a sub-category of persistent, clinically significant right heart failure events:

- Death due to right heart failure or
- Right ventricular assist device or
- Hospitalization with primary diagnosis of decompensated right heart failure with evidence of right heart support or
- Postdischarge inotropes or
- >30 consecutive days on inotropes

Arterial Noncentral Nervous System Thromboembolism

An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by 1 or more of the following:

1. Standard clinical and laboratory testing
2. Operative findings
3. Autopsy findings

This definition excludes neurological events.

Venous Thromboembolism Event

Evidence of venous thromboembolic event (eg, deep vein thrombosis or pulmonary embolism) by standard clinical and laboratory testing.

Wound Dehiscence

Disruption of the exposed surfaces of a surgical incision, excluding infectious etiology, and requiring surgical repair.

Other

An event that causes clinically relevant changes in the subject's health (eg, cancer).

ELIGIBILITY CRITERIA FOR MULTI-CENTER STUDY OF MagLev TECHNOLOGY IN PATIENTS UNDERGOING MECHANICAL CIRCULATORY SUPPORT THERAPY WITH HeartMate 3 CONTINUED ACCESS PROTOCOL

Inclusion Criteria

1. Subject or legal representative has signed informed consent form.
2. Age ≥18 years.
3. Body surface area ≥1.2 m^2.
4. New York Heart Association functional class III with dyspnea upon mild physical activity or New York Heart Association functional class IV.
5. Left ventricular ejection fraction ≤25%.
6. a. Inotrope dependent

   OR

   b. Cardiac index <2.2 L/min/m^2, while not on inotropes and subjects must also meet 1 of the following:

   - On optimal medical management, based on current heart failure practice guidelines for at least 45 out of the past 60 days and are failing to respond.
   - Advanced heart failure for at least 14 days AND dependent on intra-aortic balloon pump for at least 7 days.
7. Women of childbearing age must agree to use adequate contraception

Exclusion Criteria

1. Etiology of heart failure due to or associated with uncorrected thyroid disease, obstructive cardiomyopathy, pericardial disease, amyloidosis, or restrictive cardiomyopathy.

2. Technical obstacles that pose an inordinately high surgical risk in the judgment of the investigator.

3. Existence of ongoing mechanical circulatory support other than intra-aortic balloon pump.

4. Positive pregnancy test if of childbearing potential.

5. Presence of mechanical aortic cardiac valve that will not be either converted to a bioprosthesis or oversewn at the time of left ventricular assist device implant.

6. History of any organ transplant.

7. Platelet count <100,000 × 103/L (<100,000/mL).

8. Psychiatric disease/disorder, irreversible cognitive dysfunction, or psychosocial issues that are likely to impair compliance with the study protocol and left ventricular assist system management.

9. History of confirmed, untreated abdominal aortic aneurysm >5 cm in diameter within 6 months of enrollment.

10. Presence of an active, uncontrolled infection.

11. Intolerance to anticoagulant or antiplatelet therapies or any other peri/postoperative therapy that the investigator will require based upon the patients' health status.

12. Presence of any 1 of the following risk factors for indications of severe end organ dysfunction or failure:

    a. An international normalized ratio ≥2.0 not due to anticoagulation therapy,

    b. Total bilirubin >43 μmol/L (2.5 mg/dL), shock liver, or biopsy proven liver cirrhosis,

    c. History of severe chronic obstructive pulmonary disease defined by forced expiratory volume in 1 second/forced vital capacity <0.7, and forced expiratory volume in 1 second <50% predicted,

    d. Fixed pulmonary hypertension with a most recent pulmonary vascular resistance ≥8 Wood units that is unresponsive to pharmacologic intervention,

    e. History of stroke within 90 days before enrollment, or a history of cerebrovascular disease with significant (>80%) uncorrected carotid artery stenosis,

    f. Serum creatinine ≥221 μmol/L (2.5 mg/dL) or the need for chronic renal replacement therapy, or

    g. Significant peripheral vascular disease accompanied by rest pain or extremity ulceration.

13. Patient has moderate to severe aortic insufficiency without plans for correction during pump implant.

14. Prealbumin <150 mg/L (15 mg/dL) or albumin <30g/L (3 g/dL) (if only 1 available); prealbumin <150 mg/L (15 mg/dL) and albumin <30g/L (3 g/dL) (if both available).

15. Planned bi-ventricular assist device support before enrollment.

16. Patient has known hypo- or hypercoagulable states such as disseminated intravascular coagulation and heparin-induced thrombocytopenia.

17. Participation in any other clinical investigation that is likely to confound study results or influence the study.

18. Any condition other than heart failure that could limit survival to <24 months.

19. Patients actively listed for heart transplant (this exclusion applies only after commercial approval of the HeartMate3 for short-term use).

ELIGIBILITY CRITERIA FOR IMPLANTATION OF THE HeartMate 3 IN SUBJECTS WITH HEART FAILURE USING SURGICAL TECHNIQUES OTHER THAN FULL MEDIAN STERNOTOMY

Inclusion Criteria

1. Subject or legal representative has provided written informed consent by signing the study informed consent form.

2. Subject must be aged 18 years or older at the time of informed consent.

3. Subject is receiving the HeartMate3 as his or her first left ventricular assist device.

4. Body surface area ≥1.2 m^2.

5. Subject is New York Heart Association functional class III with dyspnea upon mild physical activity or New York Heart Association functional class IV.

6. Left ventricular ejection fraction ≤25%.

7. Subject is:

    a. Inotrope dependent
    OR

    b. Has a cardiac index <2.2 L/min/m^2 while not on inotropes and meets 1 of the following criteria:

       • On optimal medical management, based on current heart failure practice guidelines for at least 45 out of the past 60 days and is failing to respond to therapy.

       • Advanced heart failure for at least 14 days AND dependent on intra-aortic balloon pump for at least 7 days.

8. Women of childbearing age must agree to use adequate contraception

Exclusion Criteria

1. Subject has a planned concomitant procedure at time of implant (eg, valve repair, coronary artery bypass graft, or atrial septal defect repair.

2. Subject has greater than mild aortic insufficiency.

3. Physiologically significant (ie, requires intervention) atrial septal defect.

4. Subject has severe right heart failure.

5. Subject has planned biventricular assist device support before enrollment.

6. Presence of mechanical aortic valve.

7. Subject has ongoing mechanical circulatory support at the time of left ventricular assist device surgery other than intra-aortic balloon pump.

8. Subject has a history of any organ transplant.
9. Positive pregnancy test.
10. Etiology of heart failure due to or associated with uncorrected thyroid disease, obstructive cardiomyopathy, pericardial disease, amyloidosis, or restrictive cardiomyopathy.
11. Technical obstacles that pose an inordinately high surgical risk, in the judgment of the investigator.
12. Platelet count <100,000 × 103/L (<100,000/mL).
13. Psychiatric disease/disorder, irreversible cognitive dysfunction, or psychosocial issues that are likely to impair compliance with the study protocol and left ventricular assist system management.
14. History of confirmed, untreated abdominal aortic aneurysm >5 cm in diameter within 6 months of enrollment.
15. Presence of an active, uncontrolled infection.
16. Intolerance to anticoagulant or antiplatelet therapies or any other peri-/postoperative therapy the investigator will require based upon the subjects' health status.
17. Presence of any 1 of the following risk factors for indications of severe end organ dysfunction or failure:

    a. An international normalized ratio ≥2.0 not due to anticoagulation therapy.
    b. Total bilirubin >43 μmol/L (2.5 mg/dL) or biopsy-proven liver cirrhosis.
    c. History of severe chronic obstructive pulmonary disease defined by forced expiratory volume in 1 second/forced vita capacity <0.7, and forced expiratory volume <50% predicted.
    d. Fixed pulmonary hypertension with most recent pulmonary vascular resistance ≥8 Wood units that is unresponsive to pharmacologic intervention.
    e. History of stroke within 90 days before enrollment, or a history of cerebrovascular disease with significant (>80%) uncorrected carotid stenosis.
    f. Serum creatinine ≥221 μmol/L (2.5 mg/dL) or the need for chronic renal replacement therapy.
    g. Significant peripheral vascular disease accompanied by rest pain or extremity ulceration.
18. Prealbumin <150 mg/L (15 mg/dL) or albumin <30 g/L (3g/dL) (if only 1 available); prealbumin <150 mg/L (15 mg/dL) and albumin <30 g/L (3 g/dL) (if both available).
19. Subject has known hypo- or hypercoagulable states such as disseminated intravascular coagulation and heparin-induced thrombocytopenia.
20. Participation in any other clinical investigation that is likely to confound study results or influence the study.

Documented Reasons for Screen Failure (Note: It Is Not Known if Screen Failure Patients Received an Left Ventricular Assist Device as Part of Their Care)

1. Multiple reasons (n = 65)
2. Planned concomitant procedure (n = 23)
3. Refused to sign consent (n = 10)
4. Severe end organ dysfunction or failure (n = 20)
5. Patient currently on left ventricular assist device support (n = 11)
6. Ongoing mechanical circulatory support other than intra-aortic balloon pump at the time of left ventricular assist device implant (n = 18)
7. Planned Biventricular support (n = 2)
8. Technical obstacles posing high surgical risk (n = 23)
9. Mechanical aortic valve (n = 1)
10. Greater than mild aortic insufficiency (n = 1)
11. Small body surface area (n = 1)
12. Subject did not meet heart failure severity criteria (n = 11)
13. Low albumin/prealbumin (n = 9)
14. Hyper/hypocoagulable disorder (n = 8)
15. Severe right heart failure (n = 5)
16. Etiology of heart failure (n = 3)
17. Uncontrolled infection (n = 2)
18. Low platelet count (n = 1)
19. Left ventricular ejection fraction >25% (n = 1)
20. Intolerance to anticoagulant or other therapy (n = 1)
21. Psychosocial issues (n = 1)
22. Subject not of legal age at the time of consent (n = 1)
23. Participation in other clinical investigation (n = 14)
24. Unknown (n = 13)
25. Grand total (n = 245)

ADULT
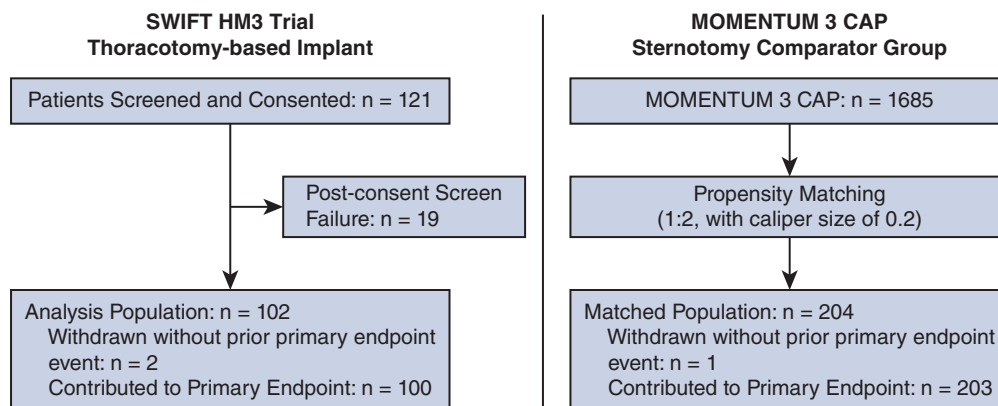
FIGURE E1. Consort diagrams. The Implantation of the HeartMate 3 in Subjects With Heart Failure Using Surgical Techniques Other Than Full Median Sternotomy (*HM3 SWIFT*) study consented 121 thoracotomy-based patients, of whom 102 were enrolled in the analysis population of the study. The 1685 sternotomy-based patients enrolled in the Multi-Center Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Continued Access Protocol (*MOMENTUM 3 CAP*) were available for propensity matching at a 2:1 ratio resulting in 204 matched sternotomy-based patients.
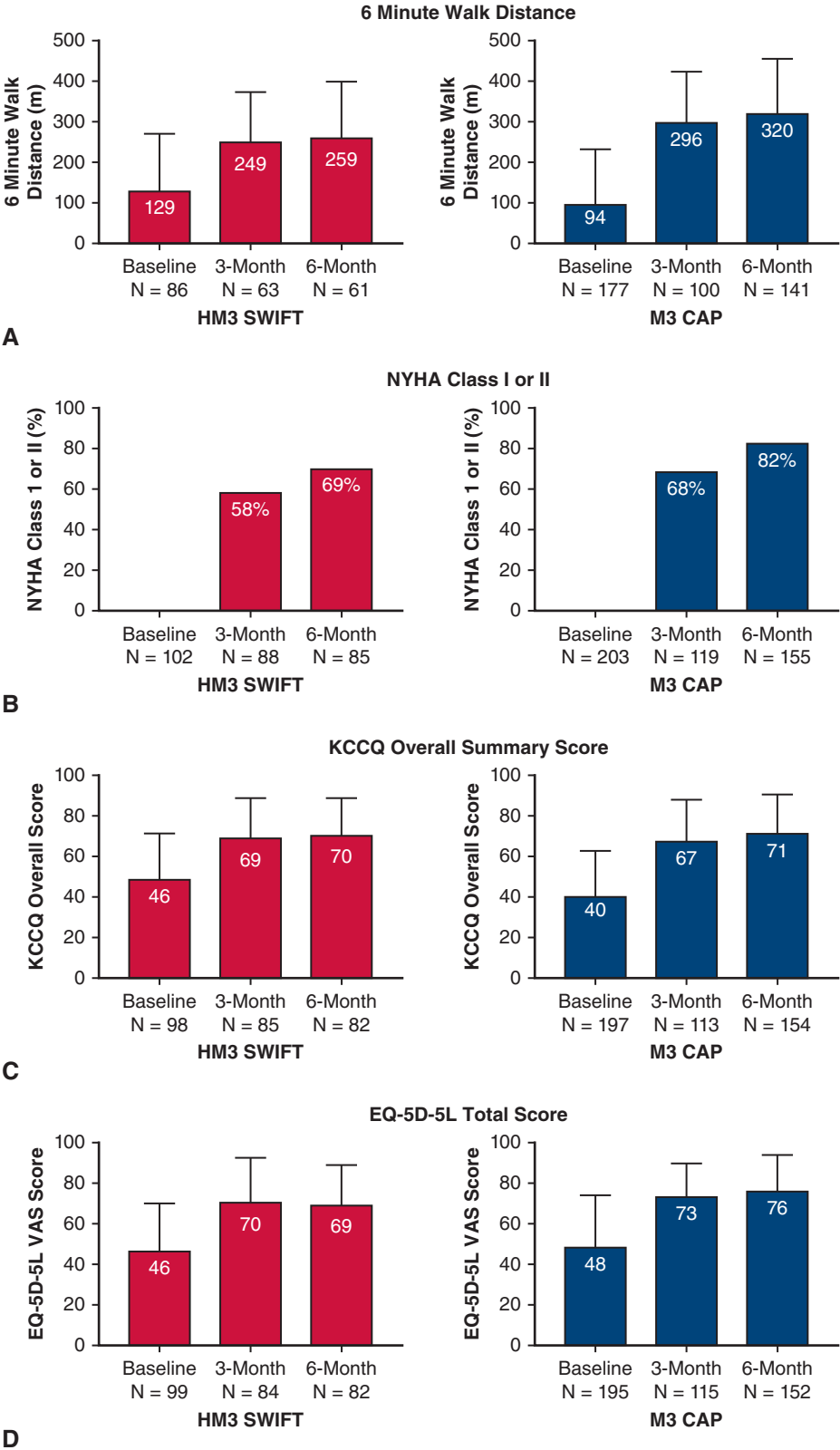
FIGURE E2. Functional capacity and quality of life. For both groups, there were sustained improvements from baseline in the 6-minute walk test (A), New York Heart Association (*NYHA*) functional class (B), Kansas City cardiomyopathy questionnaire (*KCCQ*) overall summary score (C), and EuroQOL-5 dimension–5 level visual analog scale (*EQ-5D-5L VAS*) (D). There were no clinically meaningful differences in functional status test results or quality of life measures between the treatment groups. *HM3 SWIFT*, HeartMate 3 in Subjects With Heart Failure Using Surgical Techniques Other Than Full Median Sternotomy; *HR*, hazard ratio; *M3 CAP*, Multi-Center Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3 Continued Access Protocol.

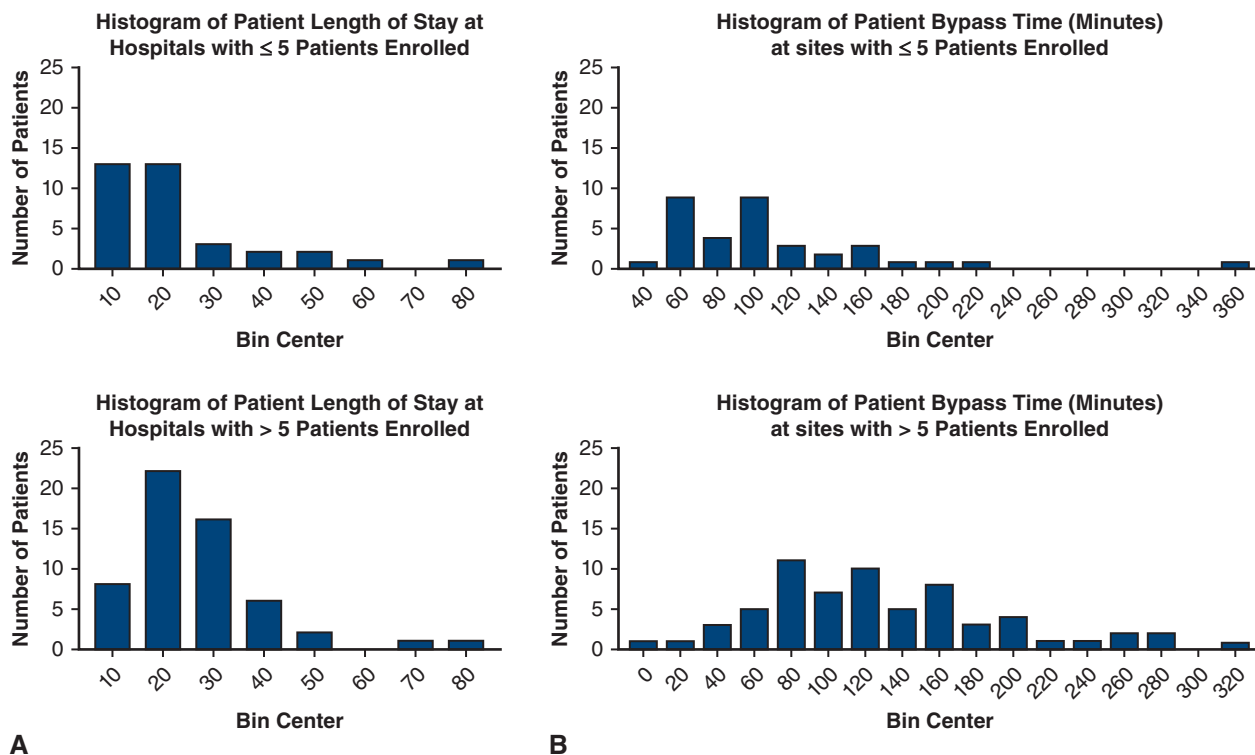**FIGURE E3.** Learning Curve at sites with higher enrollment (>5 patients per site). The distribution of length of stay (A) and bypass time (B) for patients at sites with higher enrollment was not decreased (shifted left) compared with sites with fewer patients enrolled.

TABLE E1. Characteristics used for matching before matching

Characteristic	Thoracotomy-based (n = 102)	Entire MOMENTUM 3 potential comparator cohort (n = 1680)	Standardized difference	P value
Age (y)	59.1 ± 13.4 (n = 102/102)	60.0 ± 12.2 (n = 1680/1680)	0.068	.52
Body mass index	29.05 ± 6.97 (n = 102/102)	29.15 ± 6.72 (n = 1680/1680)	0.014	.90
Male sex	81.4 (n = 83/102)	79.6 (n = 1337/1680)	−0.045	.66
White race	68.6 (n = 70/102)	67.4 (n = 1131/1678)	−0.026	.80
Intended use				
BTT	13.7 (n = 14/102)	10.3 (n = 173/1680)	−0.106	.27
BTC	25.5 (n = 26/102)	13.9 (n = 233/1680)	−0.295	.001
DT	60.8 (n = 62/102)	75.8 (n = 1274/1680)	0.328	.0007
History of hypertension	64.0 (n = 64/100)	68.8 (n = 1155/1680)	0.101	.32
History of diabetes	50.0 (n = 51/102)	41.0 (n = 689/1680)	−0.181	.07
Concurrent procedure at implant	12.7 (n = 13/102)	37.9 (n = 637/1680)	0.605	<.0001
INTERMACS profile				
1 or 2	31.4 (n = 32/102)	35.0 (n = 583/1665)	0.077	.45
3	49.0 (n = 50/102)	50.6 (n = 842/1665)	0.031	.76
≥4	19.6 (n = 20/102)	14.4 (n = 240/1665)	−0.139	.15
Right ventricular dysfunction	26.8 (n = 26/97)	21.7 (n = 352/1623)	−0.120	.24
RAP (mm Hg)	11.32 ± 6.80 (n = 99/102)	11.09 ± 8.25 (n = 1636/1680)	−0.030	.75
PCWP (mm Hg)	23.46 ± 9.89 (n = 98/102)	23.36 ± 8.94 (n = 1649/1680)	−0.011	.92
Pulmonary artery pulsatility index	3.37 ± 3.61 (n = 97/102)	3.82 ± 4.37 (n = 1615/1680)	0.112	.24
eGFR (mL/min/1.73 m^2)	59.76 ± 24.40 (n = 102/102)	58.83 ± 22.81 (n = 1680/1680)	−0.039	.71
ALT (U/L)	41.92 ± 97.21 (n = 102/102)	42.67 ± 83.30 (n = 1678/1680)	0.008	.94
AST (U/L)	34.51 ± 43.71 (n = 101/102)	39.51 ± 240.27 (n = 1677/1680)	0.029	.49
BUN (mg/dL)	29.12 ± 13.46 (n = 102/102)	29.33 ± 15.32 (n = 1680/1680)	0.015	.88
Total bilirubin (mg/dL)	0.94 ± 0.52 (n = 102/102)	1.04 ± 0.55 (n = 1679/1680)	0.181	.07
Hemoglobin (g/dL)	11.68 ± 2.07 (n = 102/102)	11.80 ± 1.97 (n = 1680/1680)	0.063	.55

Values are presented as mean ± SD or %. *MOMENTUM 3*, Multi-Center Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support; *BTT*, bridge-to-transplant; *BTC*, bridge-to-candidacy (for transplant); *DT*, destination therapy; *INTERMACS*, Interagency Registry for Mechanically Assisted Circulatory Support; *RAP*, right atrial pressure; *PCWP*, pulmonary capillary wedge pressure; *eGFR*, estimated glomerular filtration rate; *ALT*, alanine transaminase; *AST*, aspartate transaminase; *BUN*, blood urea nitrogen.

ADULT

ADULT

TABLE E2. Characteristics used for matching after matching

Characteristic	Thoracotomy-based (n = 102)	Sternotomy-based (n = 204)	Standardized difference	P value
Age (y)	59.1 ± 13.4 (n = 102/102)	58.4 ± 12.4 (n = 204/204)	−0.055	.66
Body mass index	29.05 ± 6.97 (n = 102/102)	28.82 ± 6.47 (n = 204/204)	−0.034	.78
Male sex	81.4 (n = 83/102)	83.8 (n = 171/204)	0.065	.59
White race	68.6 (n = 70/102)	72.1 (n = 147/204)	0.075	.53
Intended use				
BTT	13.7 (n = 14/102)	14.7 (n = 30/204)	0.028	.82
BTC	25.5 (n = 26/102)	25.0 (n = 51/204)	−0.011	.93
DT	60.8 (n = 62/102)	60.3 (n = 123/204)	−0.010	.93
History of hypertension	64.0 (n = 64/100)	58.8 (n = 120/204)	−0.106	.39
History of diabetes	50.0 (n = 51/102)	50.5 (n = 103/204)	0.010	.94
Concurrent procedure at implant	12.7 (n = 13/102)	12.7 (n = 26/204)	0.000	1.00
INTERMACS profile				
1 or 2	31.4 (n = 32/102)	32.4 (n = 66/204)	0.021	.86
3	49.0 (n = 50/102)	47.1 (n = 96/204)	−0.039	.75
≥4	19.6 (n = 20/102)	20.6 (n = 42/204)	0.024	.84
Right ventricular dysfunction	26.8 (n = 26/97)	26.2 (n = 53/202)	−0.013	.92
RAP (mm Hg)	11.32 ± 6.80 (n = 99/102)	11.03 ± 6.95 (n = 204/204)	−0.042	.73
PCWP (mm Hg)	23.5 ± 9.9 (n = 98/102)	23.2 ± 9.5 (n = 202/204)	−0.025	.84
Pulmonary artery pulsatility index	3.37 ± 3.61 (n = 97/102)	3.74 ± 4.25 (n = 200/204)	0.093	.44
eGFR (mL/min/1.73 m^2)	59.76 ± 24.40 (n = 102/102)	60.65 ± 25.82 (n = 204/204)	0.035	.77
ALT (U/L)	41.9 ± 97.2 (n = 102/102)	43.4 ± 57.9 (n = 203/204)	0.019	.89
AST (U/L)	34.5 ± 43.7 (n = 101/102)	38.7 ± 55.2 (n = 203/204)	0.083	.48
BUN (mg/dL)	29.1 ± 13.5 (n = 102/102)	28.4 ± 14.6 (n = 204/204)	−0.049	.68
Total bilirubin (mg/dL)	0.94 ± 0.52 (n = 102/102)	0.96 ± 0.56 (n = 203/204)	0.038	.75
Hemoglobin (g/dL)	11.68 ± 2.07 (n = 102/102)	11.57 ± 2.02 (n = 204/204)	−0.050	.68

Values are presented as mean ± SD or %. *BTT*, bridge-to-transplant; *BTC*, bridge-to-candidacy (for transplant); *DT*, destination therapy; *INTERMACS*, Interagency Registry for Mechanically Assisted Circulatory Support; *RAP*, right atrial pressure; *PCWP*, pulmonary capillary wedge pressure; *eGFR*, estimated glomerular filtration rate; *ALT*, alanine transaminase; *AST*, aspartate transaminase; *BUN*, blood urea nitrogen.

TABLE E3. Cause-specific mortality rates

	Thoracotomy-based (n = 102)	Sternotomy-based (n = 204)	Difference (95% CI*)
Brain related	2.0 (n = 2/102)	2.9 (n = 6/204)	−0.98 (−4.60 to 4.18)
Stroke	1.0 (n = 1/102)	2.5 (n = 5/204)	−1.47 (−4.73 to 3.11)
Cardiovascular related	5.9 (n = 6/102)	7.8 (n = 16/204)	−1.96 (−7.47 to 5.05)
Infection related	1.0 (n = 1/102)	1.0 (n = 2/204)	0.00 (−2.65 to 4.42)
Respiratory related	1.0 (n = 1/102)	0.5 (n = 1/204)	0.49 (−1.88 to 4.87)
Other reasons	2.0 (n = 2/102)	0.5 (n = 1/204)	1.47 (−1.18 to 6.40)

Values are presented as %. *Clopper Pearson exact CI.

TABLE E4. Amount used in patients requiring blood products

Characteristic	Thoracotomy-based (n = 102)	Sternotomy-based (n = 204)	P value
Blood transfusions			
Whole blood (U)	1.0 ± NA (n = 1/102)	1.6 ± 0.9 (n = 5/204)	.30
Packed red blood cells (U)	3.5 ± 2.7 (n = 45/102)	3.5 ± 3.1 (n = 71/204)	.96
Other blood products			
Fresh frozen plasma (U)	3.30 ± 2.16 (n = 33/102)	3.93 ± 2.72 (n = 76/204)	.25
Platelets (U)	2.45 ± 1.62 (n = 44/102)	3.01 ± 2.84 (n = 82/204)	.54
Cryoprecipitate (U)	2.4 ± 3.1 (n = 27/102)	7.1 ± 8.0 (n = 55/204)	.0009
Cell saver (cc)	542.4 ± 427.7 (n = 58/102)	620.5 ± 375.4 (n = 111/204)	.12

Values are presented as mean ± SD. *NA*, Not applicable.

ADULT

TABLE E5. Impact of subgroups on the composite primary end point

Subgroups	Thoracotomy-based vs sternotomy-based	Interaction P value[*]
Age (y)		
<65 (n = 183)	1.05 (0.43-2.58)	.6116
≥65 (n = 120)	0.74 (0.26-2.10)	
Sex		
Female (n = 52)	0.95 (0.20-4.52)	.9486
Male (n = 251)	0.90 (0.42-1.91)	
Race		
Non-Caucasian (n = 87)	1.56 (0.38-6.35)	.3724
Caucasian (n = 216)	0.75 (0.34-1.63)	
Intended use		
BTT/BTC (n = 120)	1.07 (0.34-3.32)	.7213
DT (n = 183)	0.83 (0.35-1.93)	
INTERMACS profile		
≤3 (n = 242)	0.96 (0.45-2.04)	.7457
>3 (n = 61)	0.72 (0.15-3.38)	

Values are presented as odds ratio (95% CI). *BTT*, bridge-to-transplant; *BTC*, bridge-to-candidacy (for transplant); *DT*, destination therapy; *INTERMACS*, Interagency Registry for Mechanically Assisted Circulatory Support. *Logistic regression interaction model.

TABLE E6. Impact of the type of aortic access used within the thoracotomy-based implant technique on key outcomes

Event	Partial sternotomy (n = 61)	Mini thoracotomy (n = 41)	Hazard ratio (95% CI)	P value
Primary end point success (%)	83.5 ± 4.8	87.8 ± 5.1	1.34 (0.46-3.93)	.59
Survival (%)	84.9 ± 4.6	92.7 ± 4.1	2.08 (0.56-7.68)	.27
Freedom from disabling stroke (%)	98.1 ± 1.9	94.9 ± 3.5	0.34 (0.03-3.75)	.38

Values are presented as mean ± SD unless otherwise noted.

ADULT