

**Multicenter Study of MagLev Technology in Patients  
Undergoing Mechanical Circulatory Support Therapy  
with HeartMate 3 (MOMENTUM 3) –  
Long Term Outcomes**

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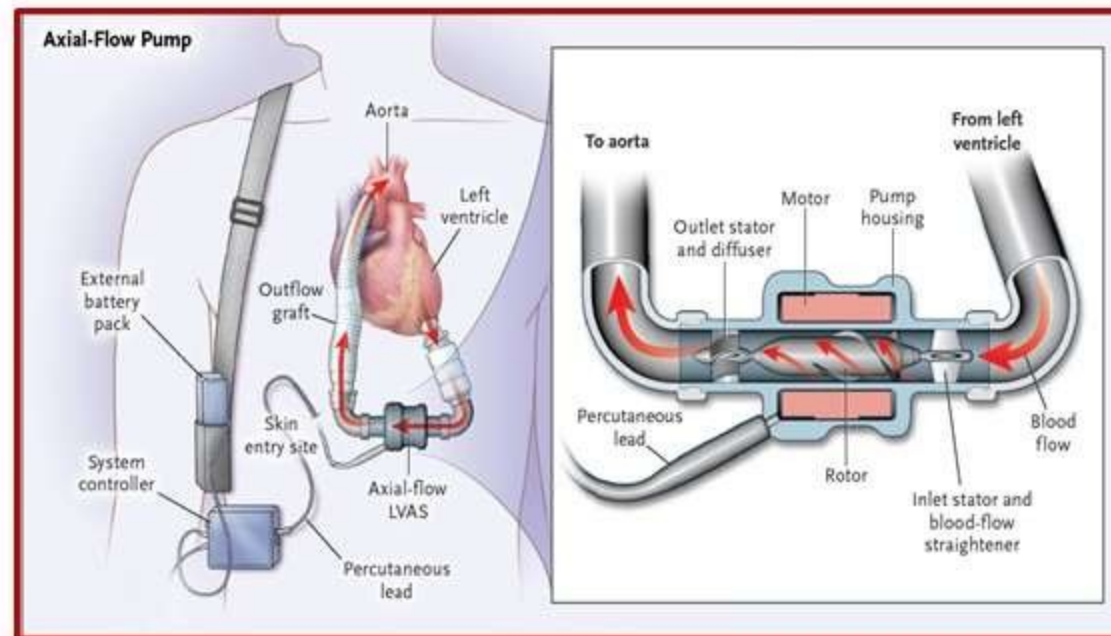
*Mandeep R. Mehra, MD, Daniel J. Goldstein, MD, Nir Uriel, MD, Joseph C. Cleveland, Jr., MD,  
National Principal Investigators, on behalf of the MOMENTUM 3 Investigators*

**MOMENTUM 3**



# Background

- Continuous-flow Left Ventricular Assist Systems (LVAS) improve survival and quality of life in patients with advanced heart failure refractory to medical therapy<sup>1</sup>



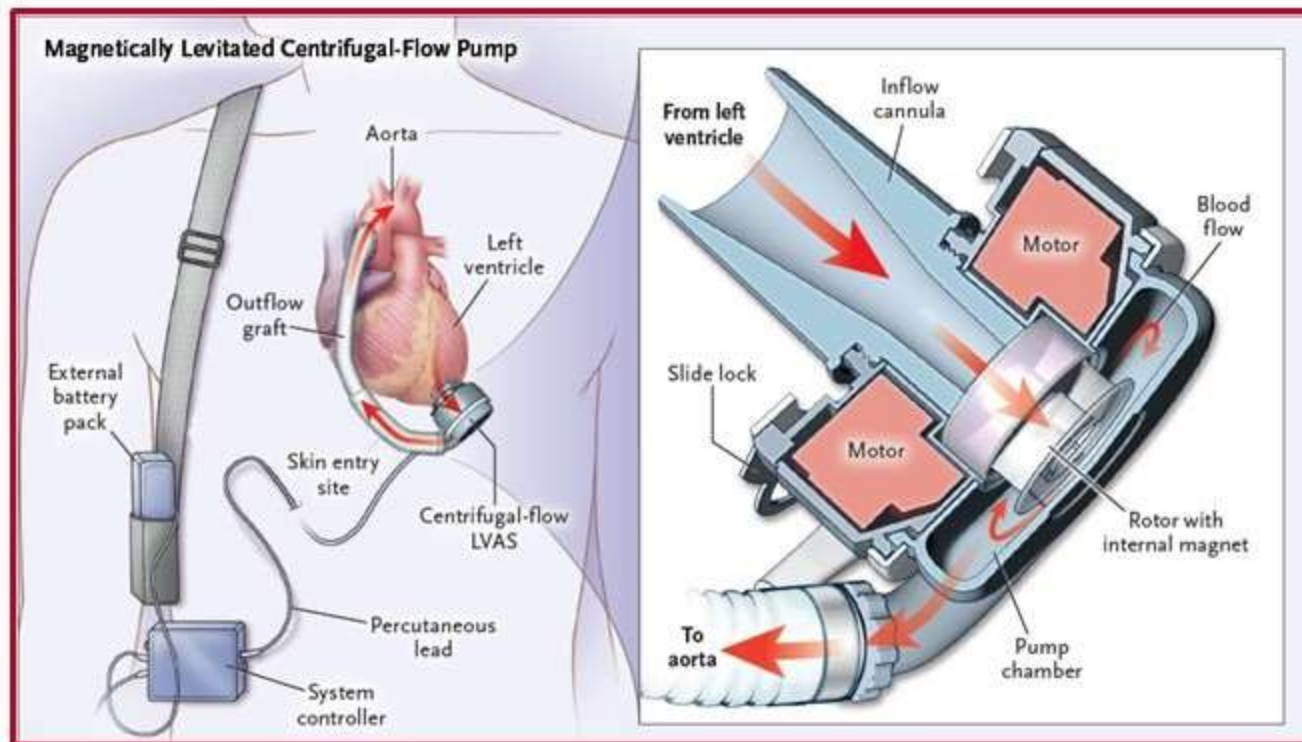
The HeartMate II LVAS is a mechanical bearing axial continuous-flow blood pump;  
An LVAS approved for *both* Bridge-To-Transplant (BTT) and Destination Therapy (DT) patients

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## Background

- **LVAS, such as the HeartMate II, are associated with significant risk of pump thrombosis requiring pump exchange, limiting long-term durability**
  
- **Other major adverse events of concern with LVAS devices include stroke, bleeding and device related infection<sup>1</sup>**

# HeartMate 3 LVAS



- **Wide** blood-flow passages to reduce shear stress
- **Frictionless** with absence of mechanical bearings
- **Intrinsic Pulse** designed to reduce stasis and avert thrombosis

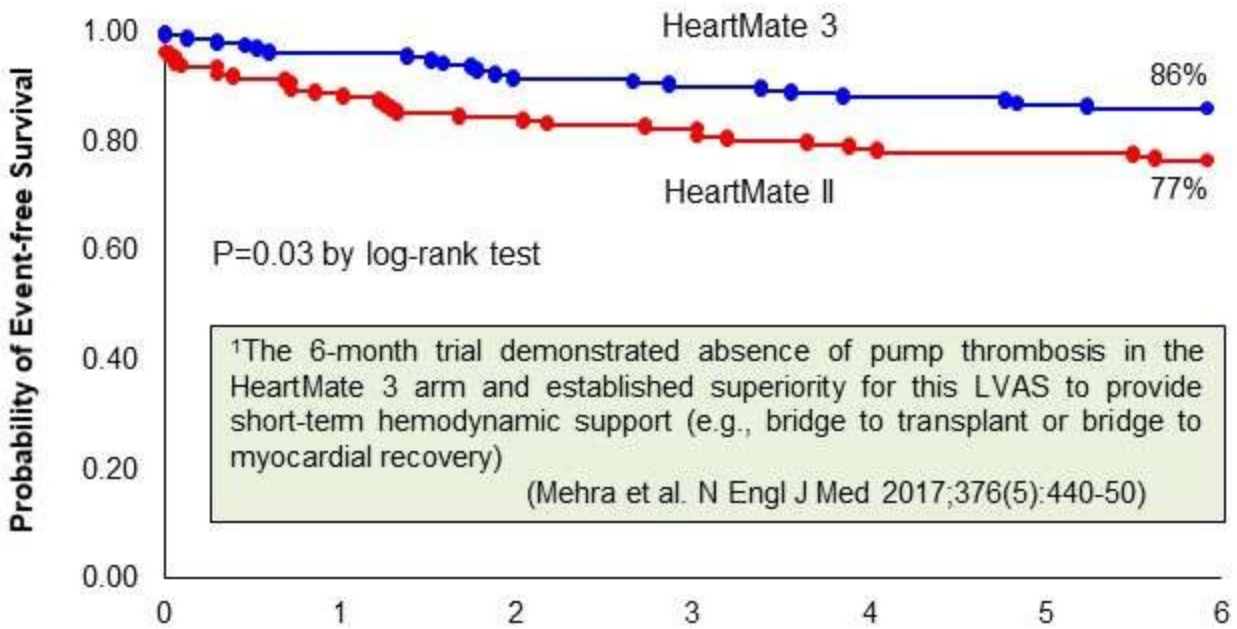
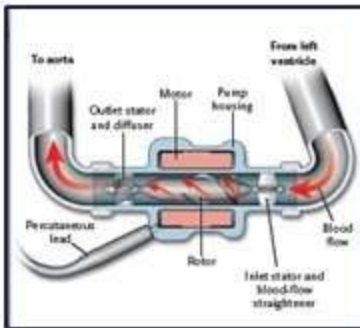
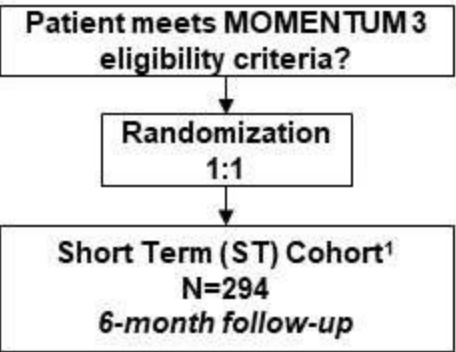
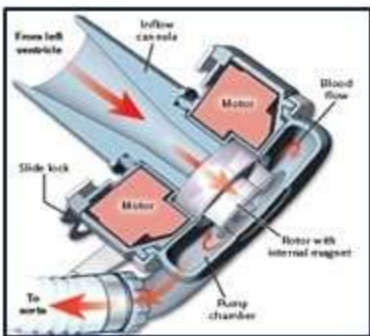
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## MOMENTUM 3 Target Population

- **Patients with advanced heart failure and severe limitations (NYHA III B or IV), refractory to guideline-mandated medical management and deemed as necessary candidates for left ventricular assist device implantation, irrespective of the intended goal of pump support (BTT or DT)**
- **Key exclusion criteria** included planned biventricular support, irreversible end-organ dysfunction, or active infection

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# Study Design

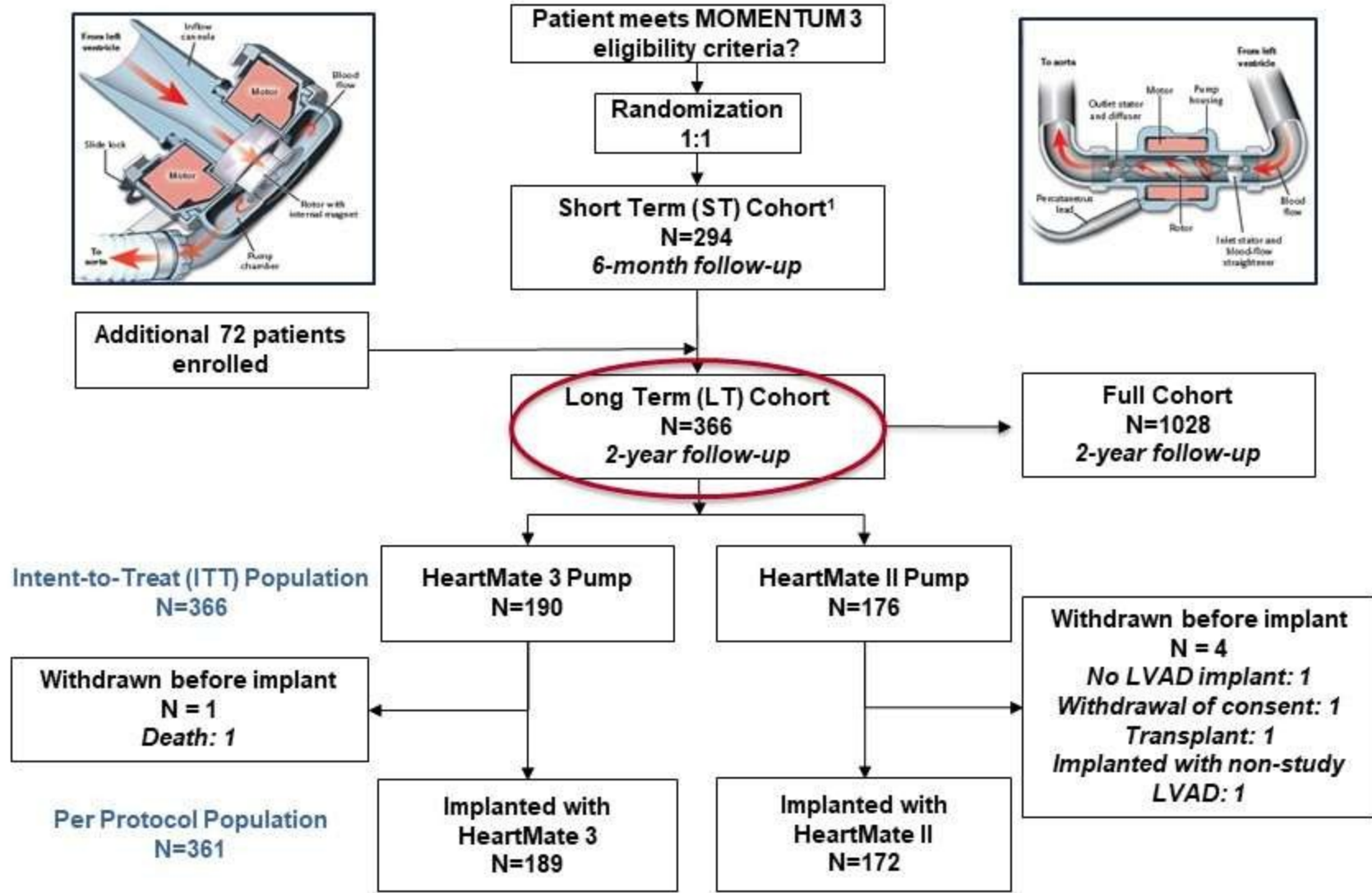


<sup>1</sup>The 6-month trial demonstrated absence of pump thrombosis in the HeartMate 3 arm and established superiority for this LVAS to provide short-term hemodynamic support (e.g., bridge to transplant or bridge to myocardial recovery)  
(Mehra et al. N Engl J Med 2017;376(5):440-50)

No. at Risk	Months after Implantation						
	0	1	2	3	4	5	6
HeartMate 3	152	146	138	135	130	128	127
HeartMate II	142	125	119	116	110	106	103



# Study Design



# Study Aim and Primary Endpoint

## Study Aim

- **The long-term (2-year) study** is designed to ascertain success to optimally support patients who wait for extended periods for heart transplantation or are ineligible for heart transplantation (e.g., destination therapy)

## Primary Endpoint

- **Survival at 2 years free of disabling stroke (>3 mRS) or reoperation to replace or remove a malfunctioning device**

# Baseline Characteristics - 1

Characteristic	HeartMate 3 (n=190)	HeartMate II (n=176)
Age - years		
Mean	61 ± 12	59 ± 12
Median (range)	65 (19-81)	61 (24-84)
Male sex - no. (%)	150 (78.9)	143 (81.2)
Race or ethnic group - no. (%)		
White	127 (66.8)	131 (74.4)
Black or African American	52 (27.4)	32 (18.2)
Other*	11 (5.8)	13 (7.4)
Body surface area - m <sup>2</sup>	2.1 ± 0.3	2.1 ± 0.3
Ischemic cause of heart failure - no. (%)	80 (42.1)	88 (50.0)
History of atrial fibrillation - no. (%)	81 (42.6)	83 (47.2)
History of stroke - no. (%)	16 (8.4)	20 (11.4)
Previous cardiac surgical procedure - no. (%)		
Coronary-artery bypass	44 (23.2)	41 (23.3)
History of valve replacement or repair	18 (9.5)	7 (4.0)
Concomitant medication or intervention - no (%)		
Intravenous inotropic agents	167 (87.9)	152 (86.4)
Diuretic	166 (87.4)	165 (93.8)
ACE inhibitor or Angiotensin II-receptor antagonist	58 (30.5)	66 (37.5)
Beta-blocker	111 (58.4)	98 (55.7)
CRT/CRT-D	75 (39.5)	62 (35.2)
ICD/CRT-D	122 (64.2)	123 (69.9)
IABP	25 (13.2)	26 (14.8)

\* Significant differences between groups for history of valve replacement or repair (P=0.04) and diuretic use (P=0.05).

\* Native Hawaiian or Pacific Islanders, and other. CRT(-D) denotes cardiac resynchronization therapy with or without defibrillator; ICD, implantable cardioverter-defibrillator; IABP, intraaortic balloon pump.

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## Baseline Characteristics - 2

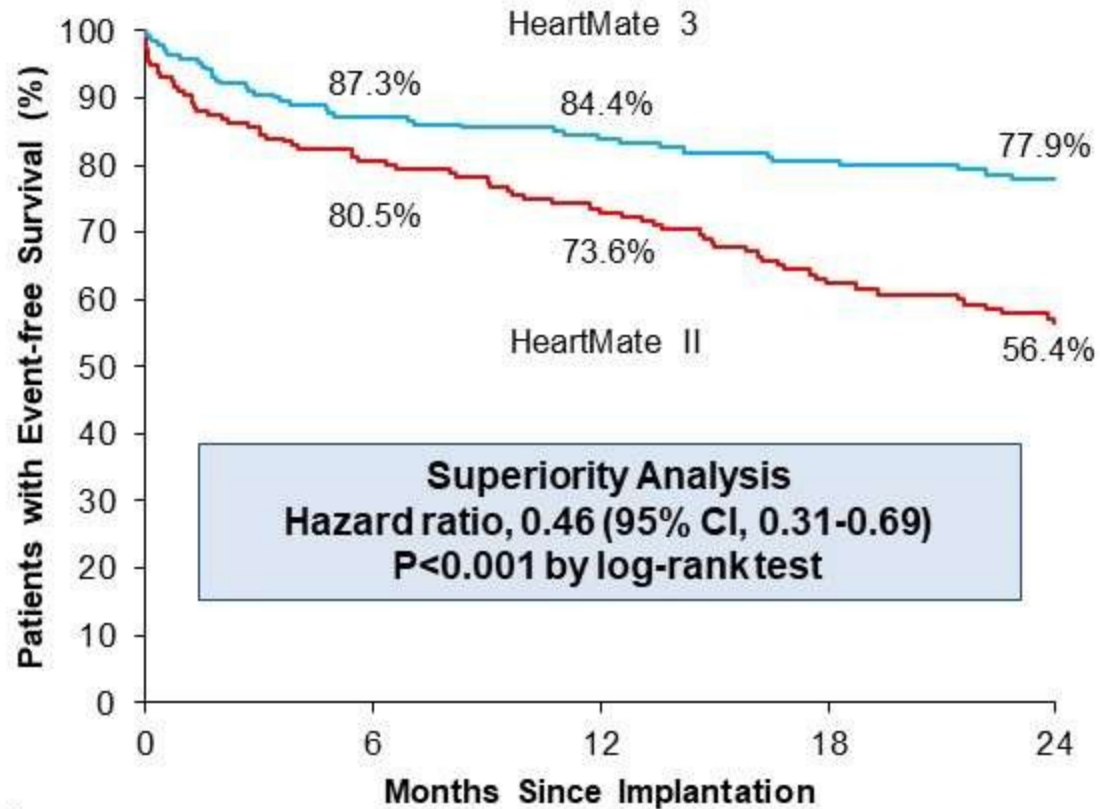
Characteristic	HeartMate 3 (n=190)	HeartMate II (n=176)
Left ventricular ejection fraction - %	17.2 ± 4.9	17.4 ± 5.0
Arterial blood pressure - mmHg		
Systolic	110.2 ± 15.6	106.3 ± 12.9
Diastolic	67.0 ± 10.8	65.4 ± 10.4
Mean arterial pressure - mmHg	79.5 ± 10.1	78.4 ± 9.8
PCWP - mmHg	23.9 ± 8.6	22.2 ± 9.2
Cardiac index - liters/min/m <sup>2</sup> of body-surface area	2.0 ± 0.5	2.0 ± 0.7
PVR - Wood units	3.2 ± 1.7	3.0 ± 1.6
Right atrial pressure - mmHg	11.0 ± 6.5	10.5 ± 6.7
Serum sodium - mmol/liter	135.5 ± 3.8	135.2 ± 4.1
Serum creatinine - mg/dl	1.4 ± 0.4	1.4 ± 0.4
<b>INTERMACS profile – no (%)</b>		
1	1 (0.5)	4 (2.3)
2	61 (32.1)	51 (29.0)
3	101 (53.2)	91 (51.7)
4	24 (12.6)	28 (15.9)
5-7 or not provided	3 (1.6)*	2 (1.1)
<b>Intended goal of pump support – no (%)</b>		
Bridge to transplantation (BTT)	49 (25.8)	42 (23.9)
Bridge to candidacy for transplantation	30 (15.8)	28 (15.9)
Destination therapy (DT)	111 (58.4)	106 (60.2)

before assessment was performed. There were only significant differences between groups for systolic blood pressure (P=0.01).  
 PCWP, pulmonary-capillary wedge pressure; PVR, pulmonary vascular resistance; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support.

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# Primary End Point Analysis (ITT)

Survival at 2 years free of disabling stroke (>3 mRS) or reoperation to replace or remove a malfunctioning device



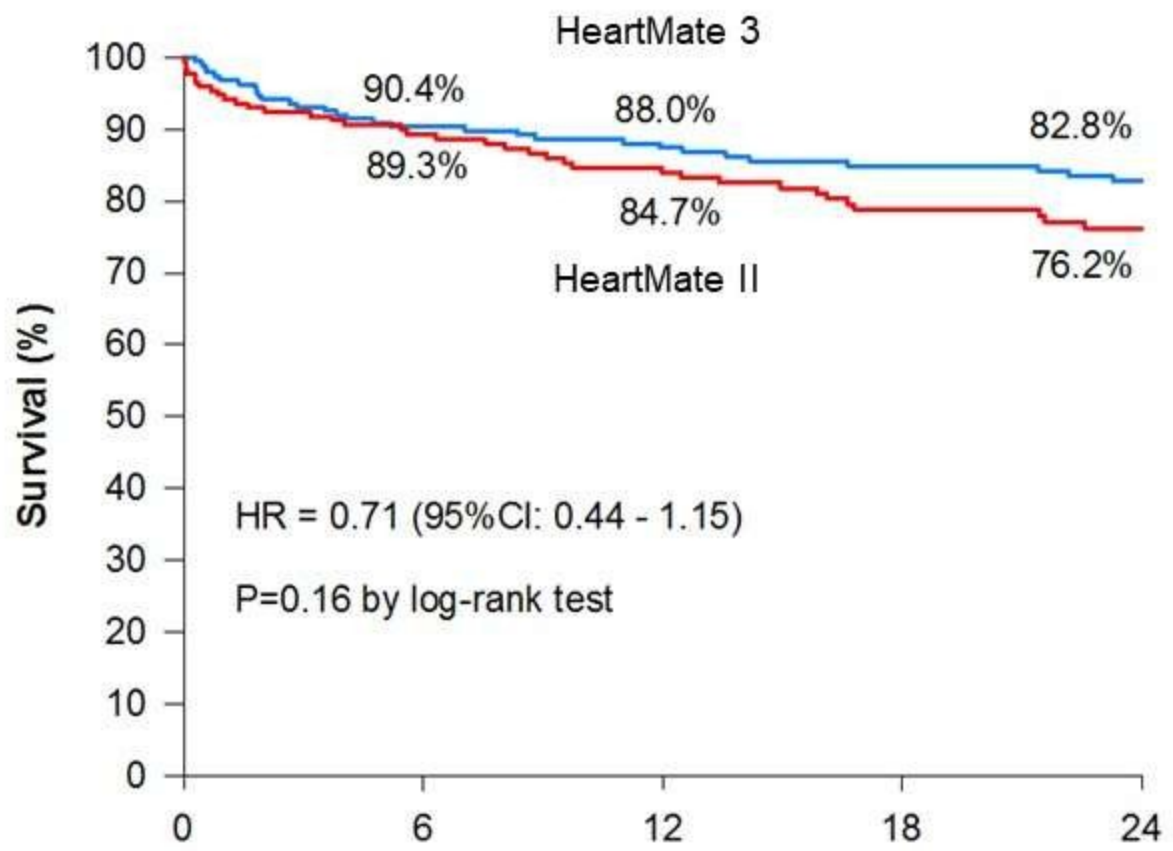
No. at Risk		0	6	12	18	24
HeartMate 3	190	161	141	122	111	
HeartMate II	176	134	114	90	75	



ified Rankin Score; CI, confidence interval

# Primary Endpoint Component 1

## Overall Survival



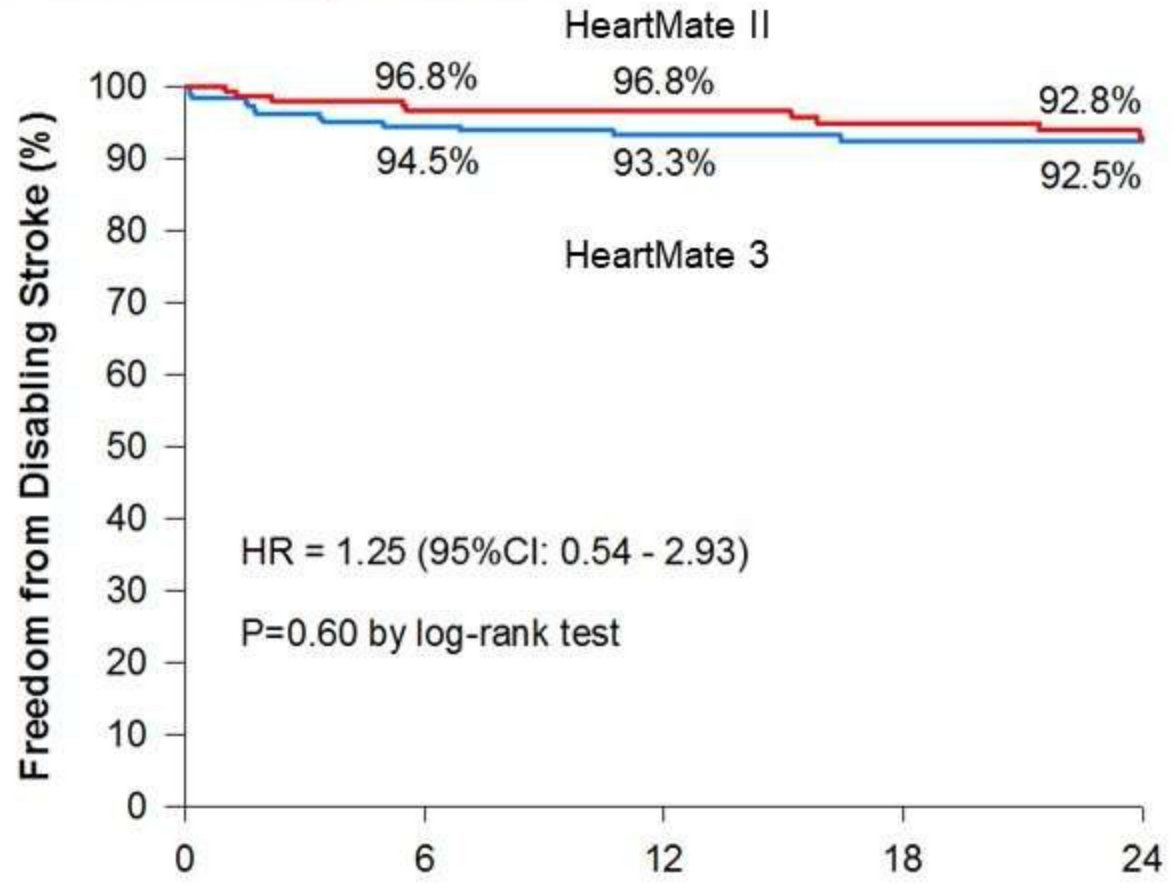
No. at Risk		Months After Implant				
	0	6	12	18	24	
HeartMate 3	189	165	146	127	117	
HeartMate II	172	141	121	98	86	



HR, hazard ratio; CI, confidence interval

# Primary Endpoint Component 2

## *Freedom from Disabling Stroke*



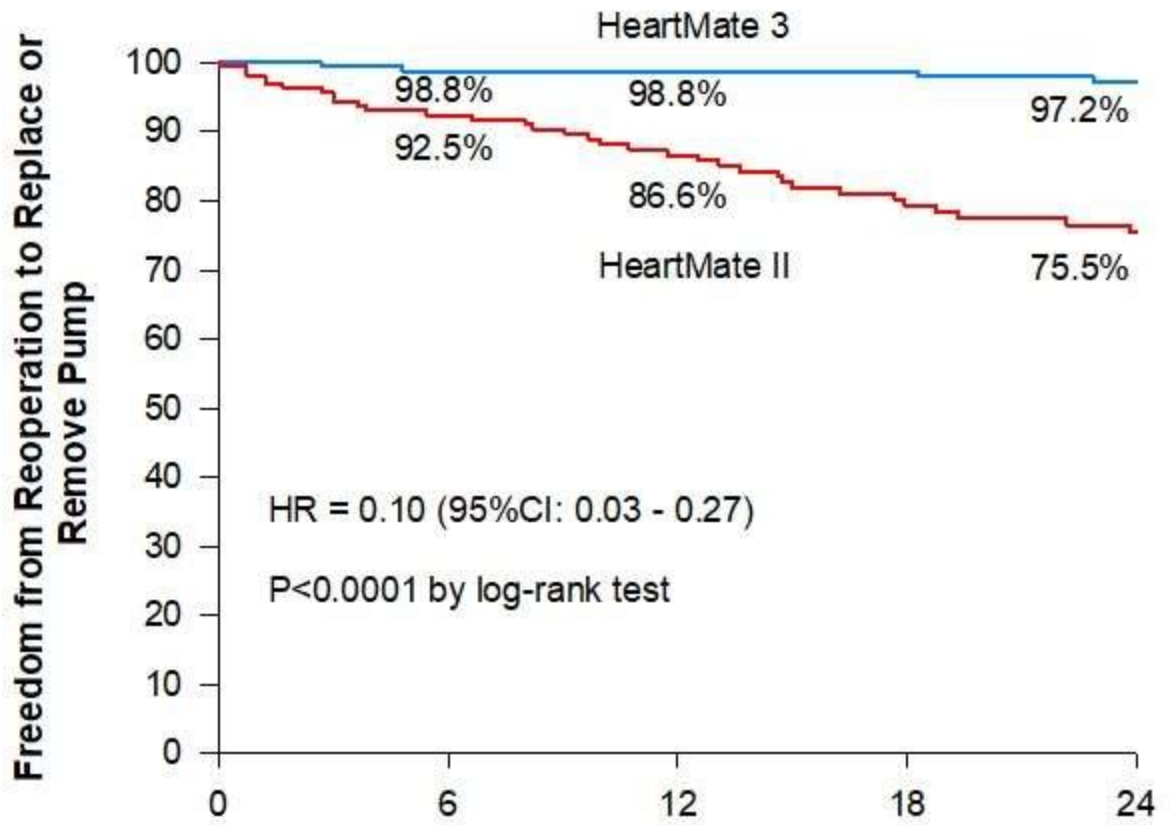
No. at Risk	0	6	12	18	24
HeartMate 3	189	162	142	123	114
HeartMate II	172	139	121	97	84



ratio; CI, confidence interval

# Primary Endpoint Component 3

## *Freedom from Reoperation to Replace or Remove Pump*



No. at Risk	0	6	12	18	24
HeartMate 3	189	164	145	126	114
HeartMate II	172	135	114	90	76

- There was a **ten-fold** difference in the reoperation rate between HeartMate II and HeartMate 3
- HeartMate 3 reoperations were due to infection (1), electrical fault (1), and outflow-graft twist (1)
- **2/3<sup>rd</sup>** of HeartMate II reoperations were due to “pump thrombosis or severe hemolysis”



ratio, CI, confidence interval

# Key Adverse Events

## *Pump Thrombosis, Neurological Events, Bleeding*

	HeartMate 3 (n=189)		HeartMate II (n=172)		HR (95% CI)	P Value*
	n (%)	no. of Events	n (%)	no. of Events		
Suspected or confirmed pump thrombosis	2 (1.1)	2	27 (15.7)	33	0.06 (0.01-0.26)	<0.001
Resulting in reoperation	0 (0)	0	21 (12.2)	25	NA	<0.001
Any stroke	19 (10.1)	22	33 (19.2)	43	0.47 (0.27-0.84)	0.02
Ischemic stroke	12 (6.3)	14	23 (13.4)	26	0.44 (0.22-0.88)	0.03
Hemorrhagic stroke	8 (4.2)	8	16 (9.3)	17	0.42 (0.18-0.98)	0.06
Other neurologic event <sup>†</sup>	22 (11.6)	25	15 (8.7)	16	1.27 (0.66-2.45)	0.39
Bleeding	81 (42.9)	187	90 (52.3)	206	0.71 (0.53-0.96)	0.07
Bleeding that led to surgery	23 (12.2)	29	30 (17.4)	34	0.66 (0.38-1.13)	0.18
Gastrointestinal bleeding	51 (27.0)	107	47 (27.3)	100	0.92 (0.62-1.37)	1.00

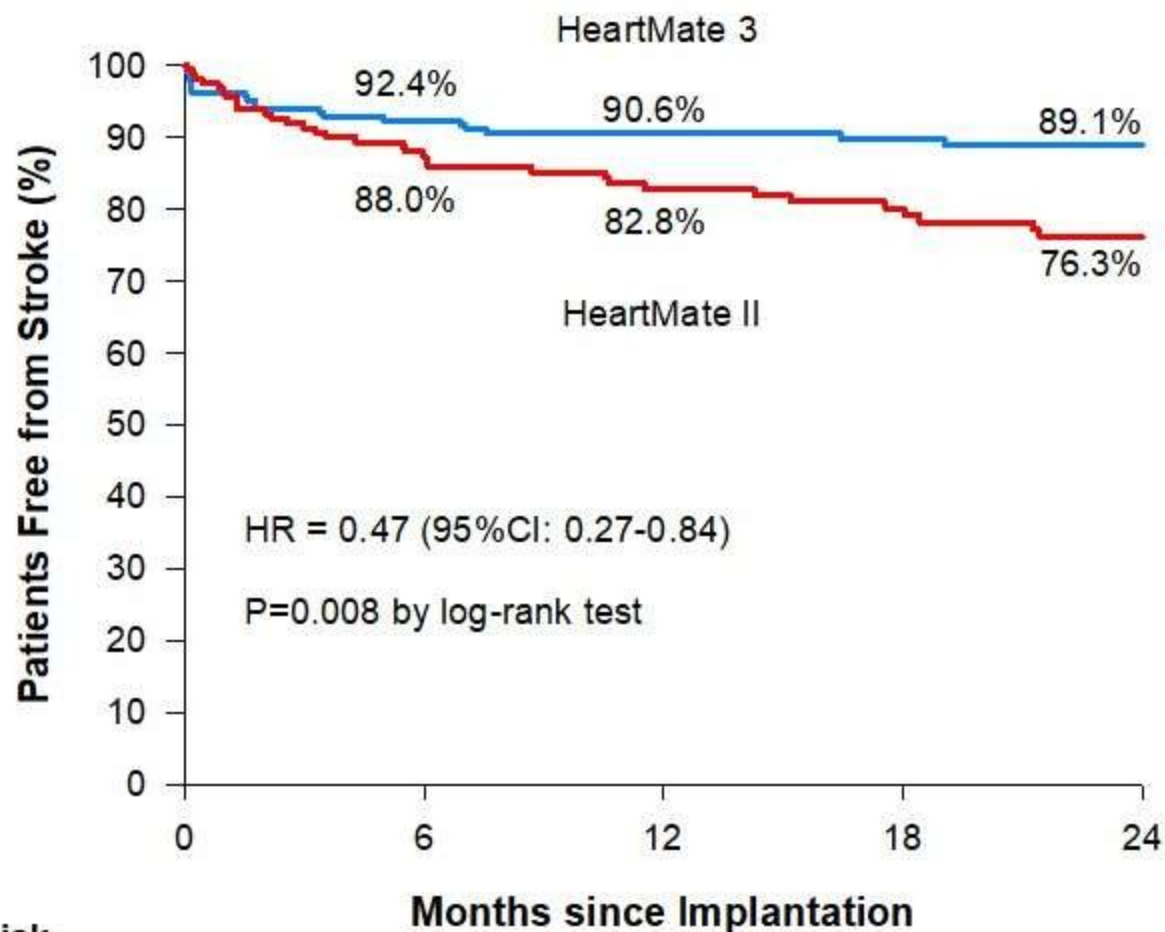
HR, hazard ratio; CI, confidence interval

\*P values were calculated with the use of Fisher's exact test. <sup>†</sup>Includes transient ischemic attacks and neurologic events other than stroke



# Key Adverse Events

## Stroke

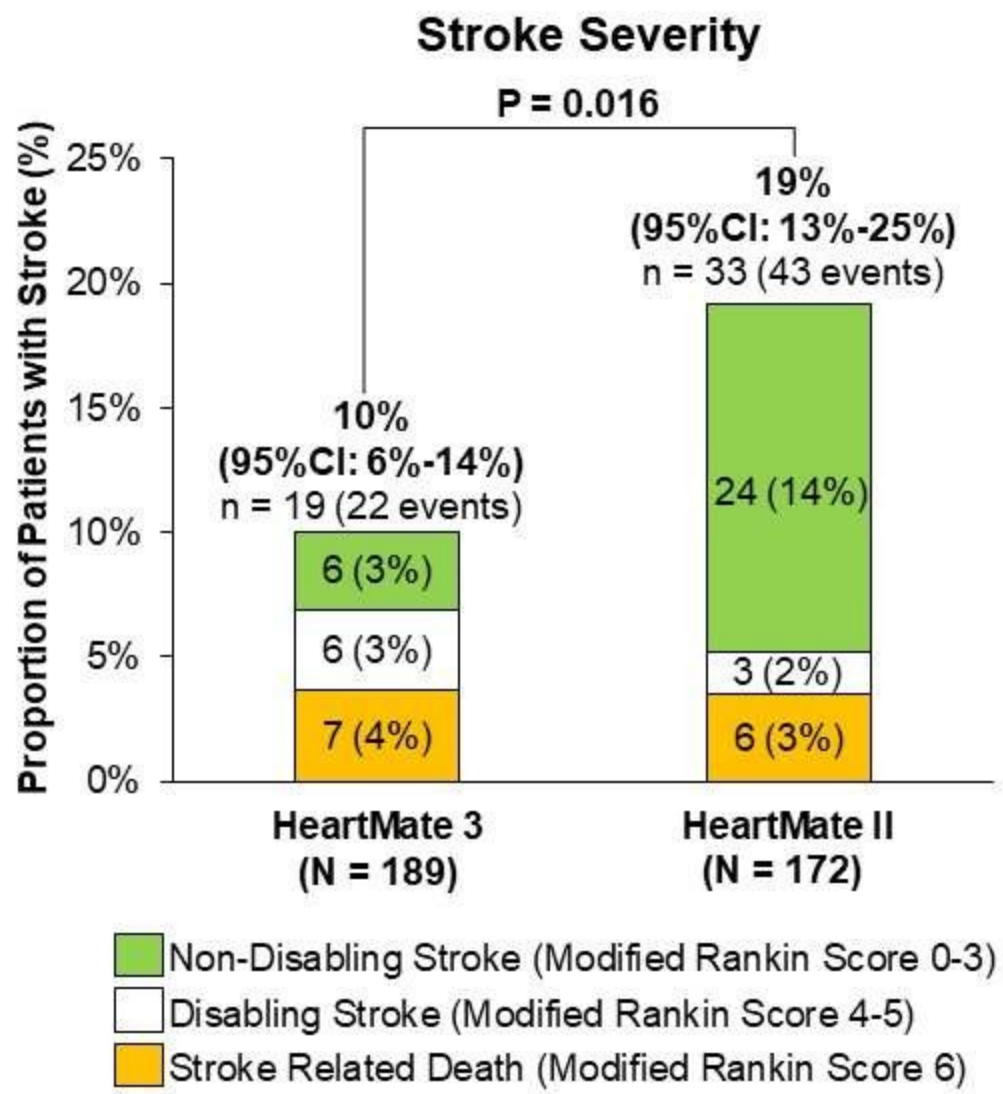


No. at Risk		Months since Implantation				
		0	6	12	18	24
HeartMate 3	189	159	138	120	111	
HeartMate II	172	127	104	85	73	

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# Key Adverse Events

## Stroke



...subjects and 9 HeartMate II subjects had >1 stroke. The score for the most severe stroke is shown. 1.6% of HeartMate 3 subjects (n = 3) and 5.2% of ... subjects (n = 9) had a modified Rankin score of 0 at 60 days post-stroke. CI denotes confidence interval.

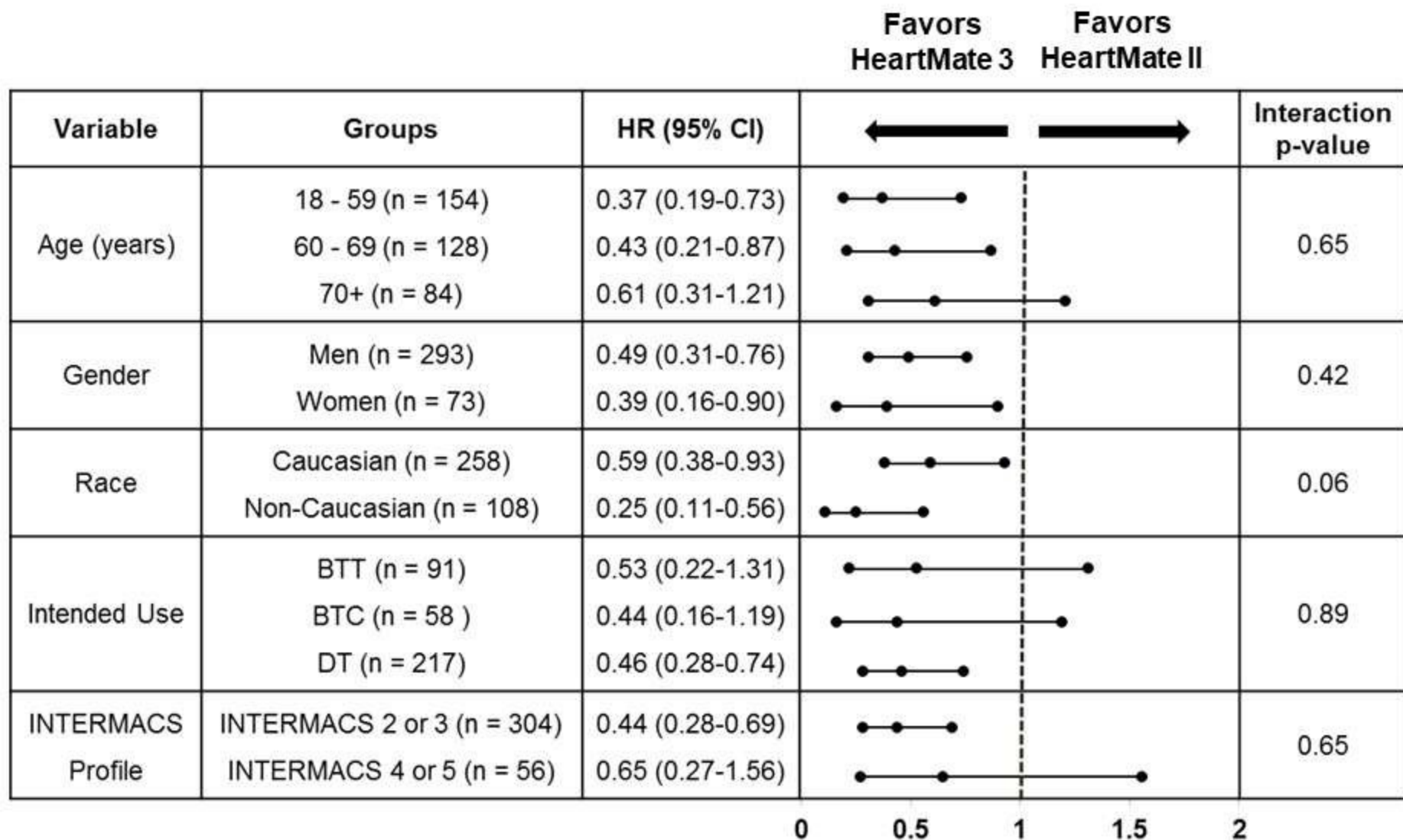


# Other Adverse Events

	HeartMate 3 (n=189)		HeartMate II (n=172)		HR (95% CI)	P Value
	n (%)	no. of Events	n (%)	no. of Events		
Sepsis	26 (13.8)	37	24 (14.0)	28	0.95 (0.55-1.66)	1.00
LVAS drive-line infection	45 (23.8)	68	34 (19.8)	59	1.15 (0.73-1.79)	0.37
Local non-LVAS infection	70 (37.0)	108	60 (34.9)	114	1.00 (0.71-1.42)	0.74
Right heart failure	60 (31.7)	73	48 (27.9)	53	1.12 (0.77-1.64)	0.49
Managed with RVAS	6 (3.2)	6	8 (4.7)	8	0.67 (0.23-1.94)	0.59
Cardiac arrhythmia	71 (37.6)	108	70 (40.7)	105	0.88 (0.63-1.23)	0.59
Ventricular	45 (23.8)	67	39 (22.7)	64	1.04 (0.67-1.59)	0.80
Supraventricular	33 (17.5)	40	36 (20.9)	37	0.79 (0.49-1.26)	0.42
Respiratory failure	45 (23.8)	61	39 (22.7)	46	1.04 (0.68-1.59)	0.80
Renal Dysfunction	25 (13.2)	29	18 (10.5)	18	1.23 (0.67-2.25)	0.52
Hepatic dysfunction	8 (4.2)	8	7 (4.1)	7	0.98 (0.36-2.71)	1.00

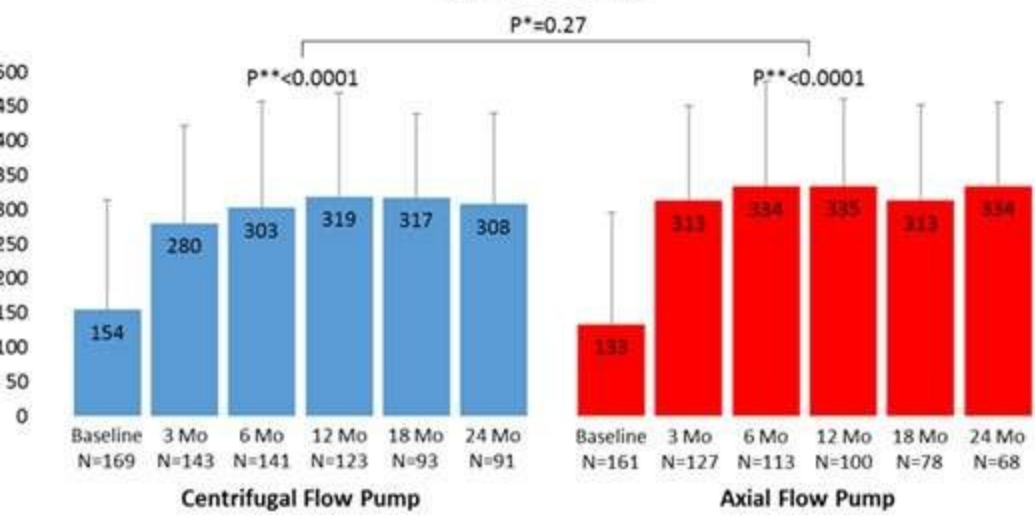
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# Subgroup Analyses of the Primary Endpoint (ITT)

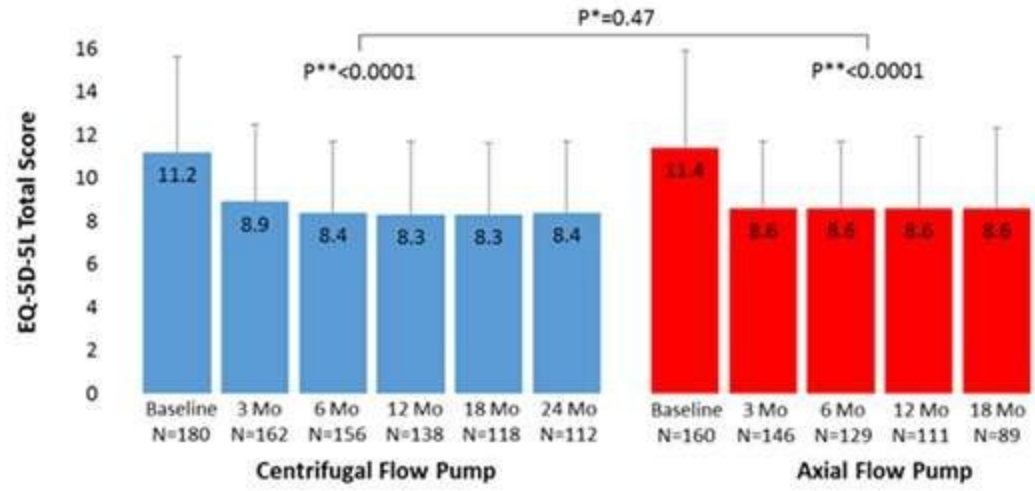


# Functional Status and Quality of Life

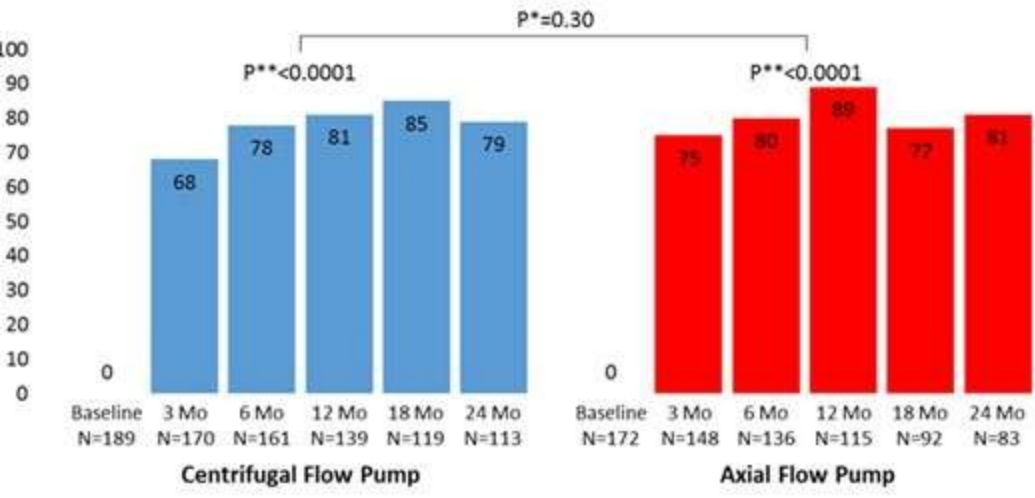
6MWT Over Time



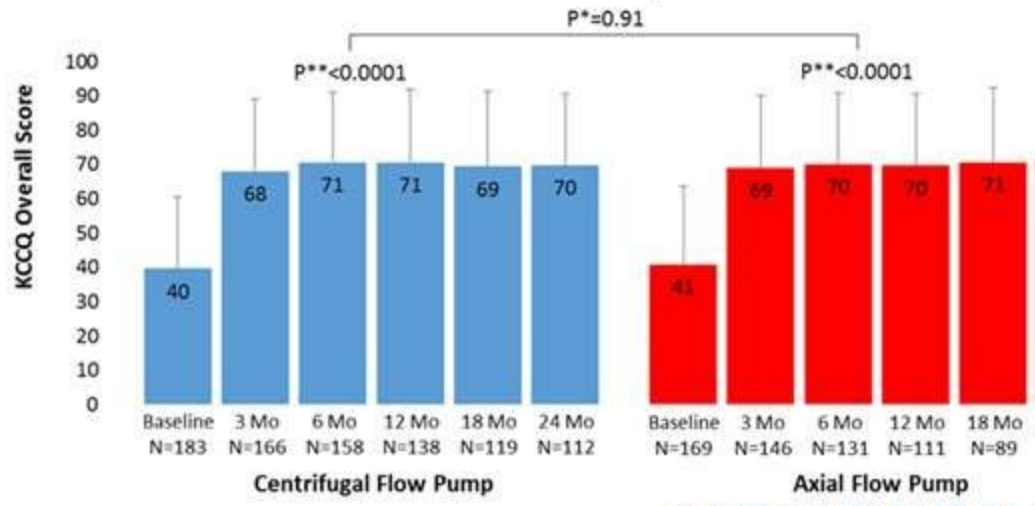
EQ-5D-5L Total Score Over Time



NYHA Class I or II Over Time



KCCQ Overall Summary Score Over Time



green treatment arms over time  
 treatment over time



# Conclusions

- The HeartMate 3 LVAS is **clinically superior** when compared to the HeartMate II axial-flow pump, at 2-years
- These benefits were primarily driven by a **lower reoperation rate** in the HeartMate 3 arm
  - largely due to excess device malfunctions resulting from **pump thrombosis** in the HeartMate II LVAS
- Importantly, we observed a markedly **lower rate of stroke** with the HeartMate 3 LVAS

# Summary

The two-year **MOMENTUM 3** trial pre-specified primary **analysis** demonstrates durability of the HeartMate 3 LVAS to optimally support patients who wait for extended periods for heart transplantation or are ineligible for heart transplantation (destination therapy)



The NEW ENGLAND  
JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Two-Year Outcomes of a Magnetically Levitated Cardiac Pump in Heart Failure

M.R. Mehra, D.J. Goldstein, N. Uriel, J.C. Cleveland, Jr., M. Yuzefpolskaya, C. Salerno, M.N. Walsh, C.A. Milano, C.B. Patel, G.A. Ewald, A. Itoh, D. Dean, A. Krishnamoorthy, W.G. Cotts, A.J. Tatroles, U.P. Jorde, B.A. Bruckner, J.D. Estep, V. Jeevanandam, G. Sayer, D. Horstmanshof, J.W. Long, S. Gulati, E.R. Skipper, J.B. O'Connell, G. Heatley, P. Sood, and Y. Naka, for the MOMENTUM 3 Investigators\*

**We THANK all the patients, our investigators,  
clinical nurse coordinators, and allied health  
personnel for their dedication to the conduct of  
the MOMENTUM 3 trial**

eridge Dr., Pleasanton, CA 94588 USA, Tel: 1 925 847 8600  
ular.Abbott/HeartMate3

**Warning:** Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, risks, potential adverse events and directions for use.

**HeartMate 3™ LVAS Indications:** The HeartMate 3™ Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in adult and pediatric patients with advanced refractory left ventricular failure and with an appropriate body surface area.

**HeartMate 3™ LVAS Contraindications:** The HeartMate 3 Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are contraindicated to, anticoagulation therapy.

**HeartMate 3™ LVAS Adverse Events:** Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are: death, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, and pump thrombosis (not associated with suspected device thrombosis) or pump thrombosis.

HeartMate is a trademark of the Abbott group of companies.

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