



Hospices Civils de Lyon



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MOMENTUM 3

« Louis Pradel » Hospital - Lyon



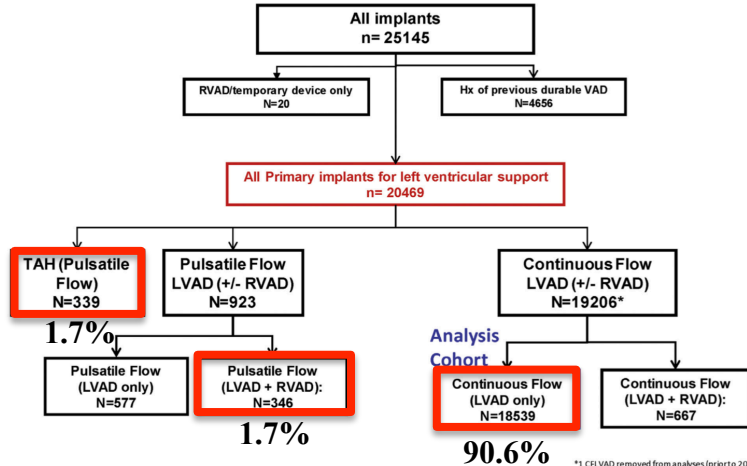
CONFLICTS OF INTEREST

No conflict of interest to disclose

INTRODUCTION

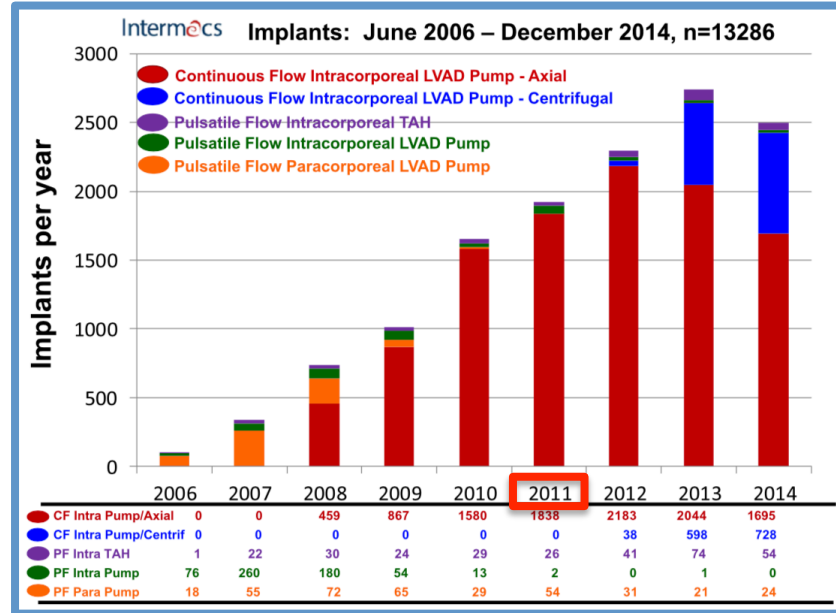
Intermedics

Implants: June 2006 – December 2017

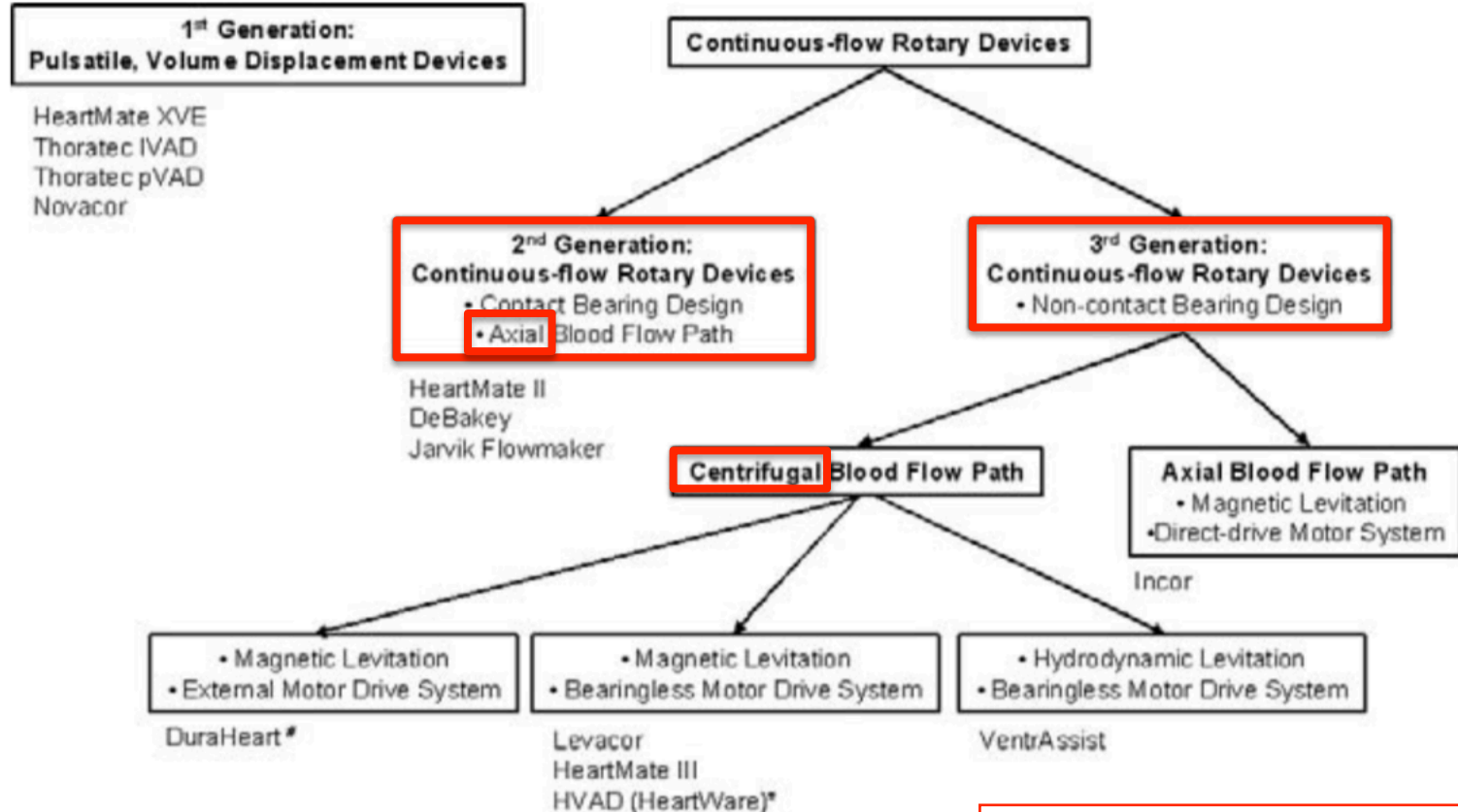


Ann Thorac Surg 2019;107:341-354

J Heart Lung Transplant 2015;34:1495-504

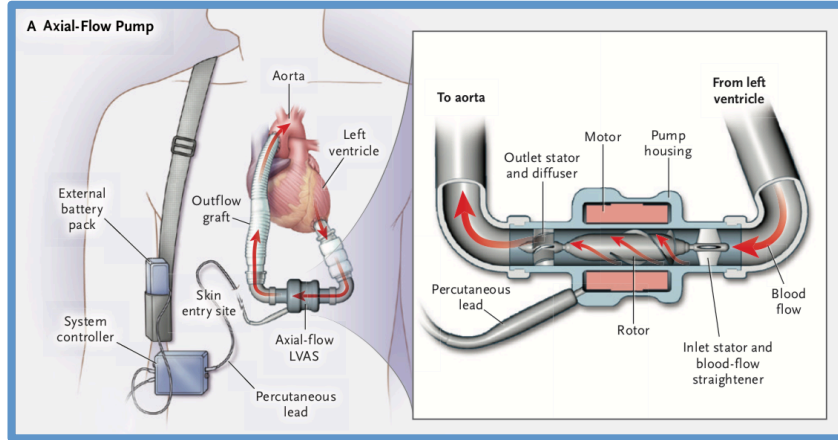


INTRODUCTION



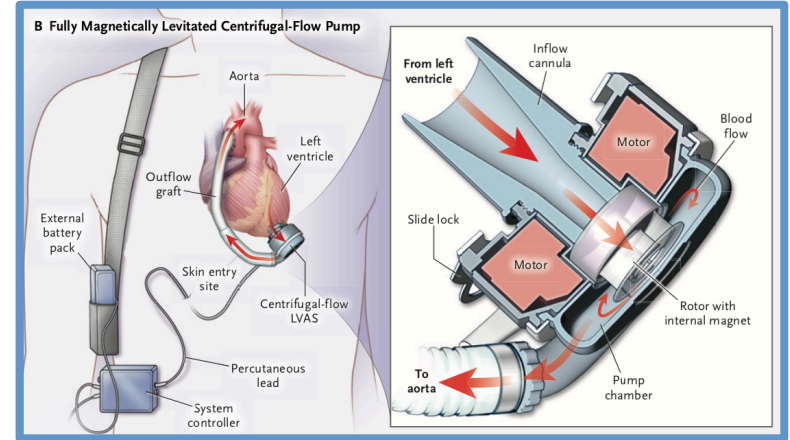
MOMENTUM 3

The Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HeartMate 3



HeartMate II

vs.



HeartMate 3

MOMENTUM 3

STUDY POPULATION

Inclusion criteria

Age ≥ 18 years

End-stage heart failure (BTT or DT strategy)
NYHA III-IV *LVEF $\leq 25\%$*

**Refractory
to OMM**

**Inotrope
Dependent**

IABP support
(at least 7 days)

MOMENTUM 3

STUDY POPULATION

Exclusion criteria

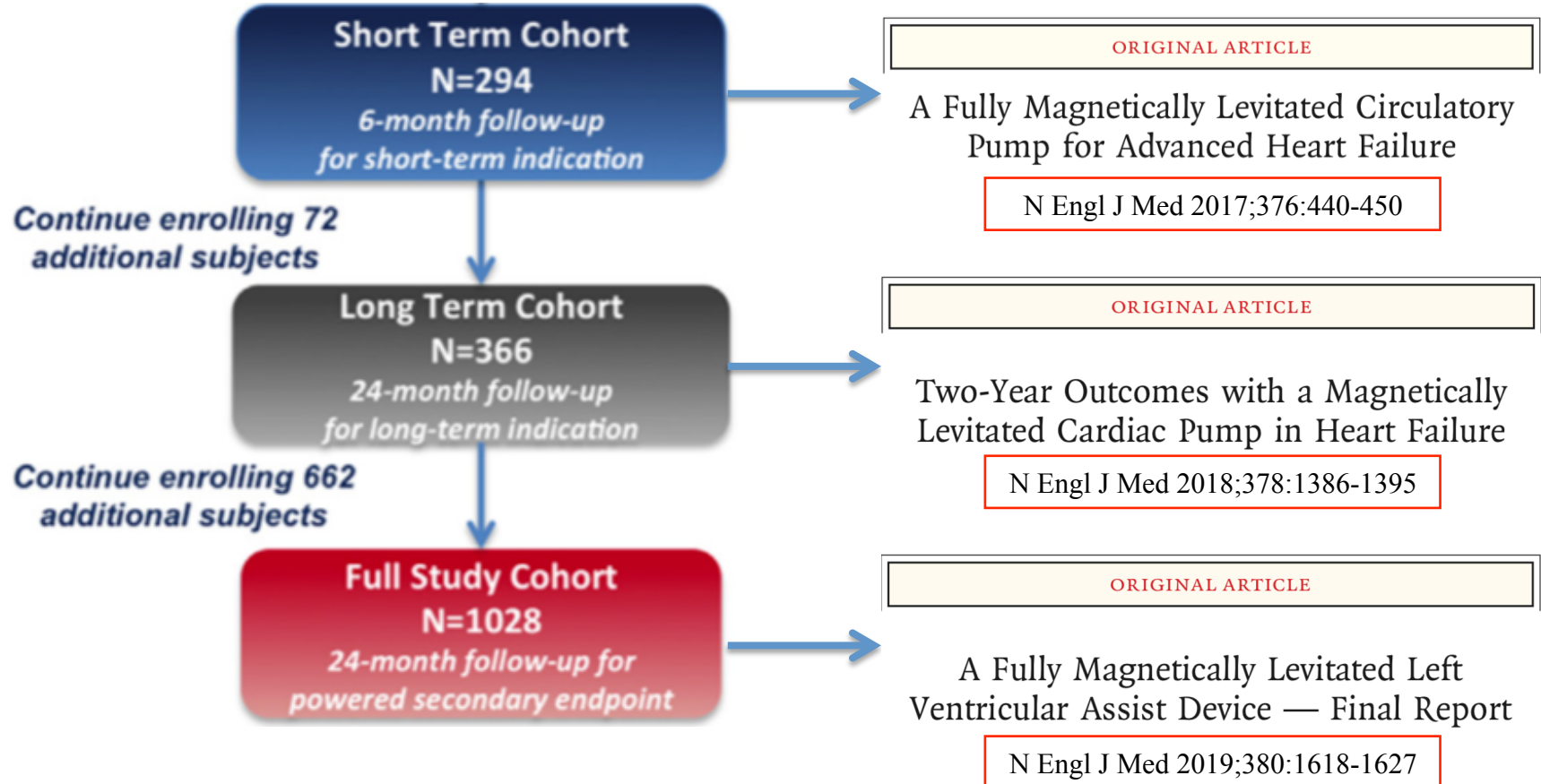
- 1) Etiology of heart failure due to or associated with uncorrected thyroid disease, obstructive cardiomyopathy, pericardial disease, amyloidosis, or other non-ischemic etiologies
- 2) Technical obstacles which would preclude successful LVAD implantation
- 3) Existence of ongoing mechanical circulatory support (MCS) other than IABP
- 4) Positive pregnancy test
- 5) Presence of mechanical circulatory support at the time of LVAD implantation
- 6) Current or previous deep vein thromboses, pulmonary embolism, or the need for chronic renal replacement therapy
- 7) Current or previous aortic aneurysm, aortic dissection, or the need for chronic renal replacement therapy
- 8) Psychiatric disease/disorder or non-compliance with the study protocol
- 9) History of confirmed, uncontrolled hypertension at enrollment
- 10) Presence of an active, uncontrolled infection at enrollment
- 11) Intolerance to anticoagulation or bleeding risk that the investigator will require
- 12) Presence of any one of the following risk factors for indications of severe end organ dysfunction or failure:
 - a) An international normalized ratio (INR) ≥ 2.0 not due to anticoagulation therapy
 - b) Total bilirubin $> 43 \mu\text{mol/L}$ (2.5 mg/dl), shock liver, or biopsy proven liver cirrhosis
 - c) History of severe chronic obstructive pulmonary disease (COPD) defined as the ratio of forced expiratory volume in one second to forced vital capacity (FEV_1/FVC) < 0.7 , and $\text{FEV}_1 < 50\%$ predicted
 - d) Fixed pulmonary hypertension with a most recent pulmonary vascular resistance (PVR) ≥ 8 Wood units that is unresponsive to pharmacologic intervention

3) Existence of ongoing mechanical circulatory support (MCS) other than IABP

- 8) Psychiatric disease/disorder or non-compliance with the study protocol
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 - d) Fixed pulmonary hypertension with a most recent pulmonary vascular resistance (PVR) ≥ 8 Wood units that is unresponsive to pharmacologic intervention
- 13) Patient has moderate to severe aortic insufficiency without plans for correction during pump implant
- 14) Pre albumin $< 150 \text{ mg/L}$ (15mg/dL) or Albumin $< 30\text{g/L}$ (3 g/dL) (if only one available); pre albumin $< 150 \text{ mg/L}$ (15mg/dL) and Albumin $< 30\text{g/L}$ (3 g/dL) (if both available)
- 15) Planned Bi-VAD support prior to enrollment
- 16) Patient has known hypo- or hyper coagulable state such as disseminated intravascular coagulation and heparin induced thrombocytopenia (HIT)
- 17) Participation in any other clinical investigation that is likely to confound study results or affect the study
- 18) Any condition other than heart failure that could limit survival to less than 24 months

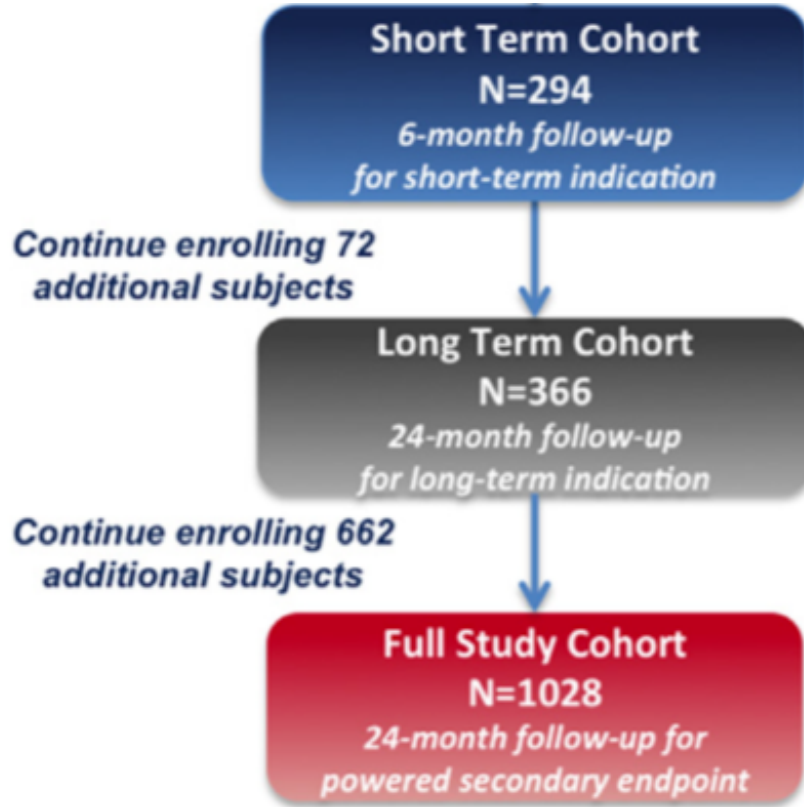
MOMENTUM 3

STUDY DESIGN



MOMENTUM 3

STUDY DESIGN



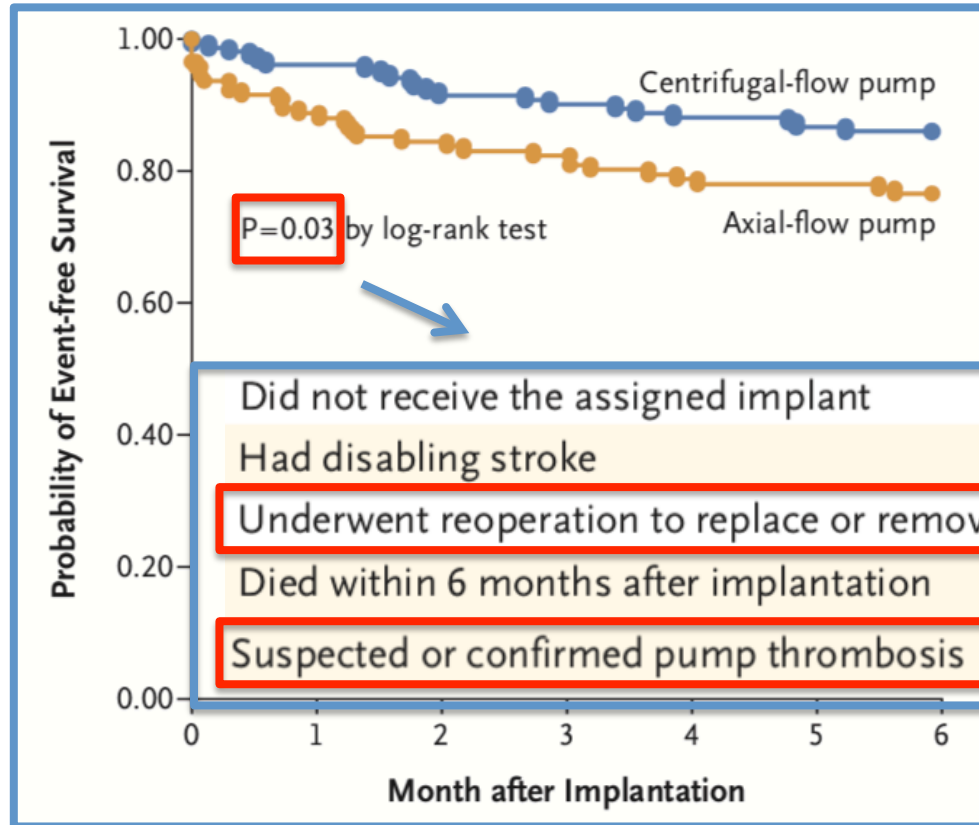
PRIMARY ENDPOINT

Composite of survival free of disabling stroke (with disabling stroke indicated by a modified Rankin score >3; scores range from 0 to 6, with higher scores indicating more severe disability) or survival free of reoperation to replace or remove the device (for reasons other than recovery)

MOMENTUM 3 - SHORT TERM COHORT

Characteristic	Centrifugal-Flow Pump Group (N=152)	Axial-Flow Pump Group (N=142)
Age — yr		
Mean	60.3±12.3	58.9±12.0
Intended goal of pump support — no. (%)		
Bridge to transplantation	41 (27.0)	37 (26.1)
Bridge to candidacy for transplantation	27 (17.8)	27 (19.0)
Destination therapy	84 (55.3)	78 (54.9)
INTERMACS profile — no. (%)‡		
1	1 (0.7)	4 (2.8)
2	50 (32.9)	44 (31.0)
3	76 (50.0)	69 (48.6)
4	22 (14.5)	23 (16.2)
5	2 (1.3)	2 (1.4)
6 or 7	0	0
Not provided	1 (0.7)	0

MOMENTUM 3 - SHORT TERM COHORT

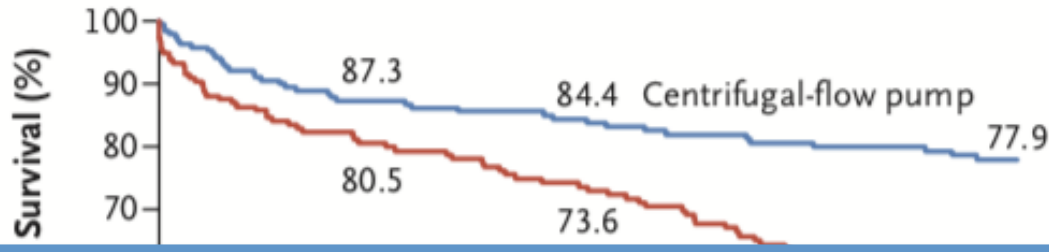


Intention-to-Treat Population

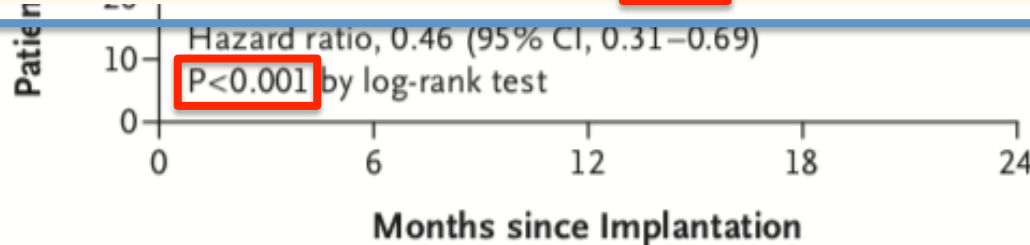
	HM3	HM II	<i>p</i>
Did not receive the assigned implant	1	4	0.15
Had disabling stroke	6	4	0.59
Underwent reoperation to replace or remove pump†	1	11	0.002
Died within 6 months after implantation	13	14	0.70
Suspected or confirmed pump thrombosis	0	14	<0.001

MOMENTUM 3 - LONG TERM COHORT

Intention-to-Treat Population

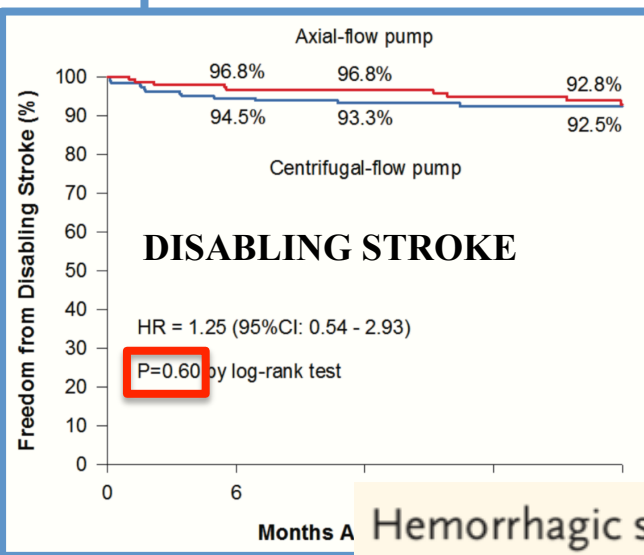
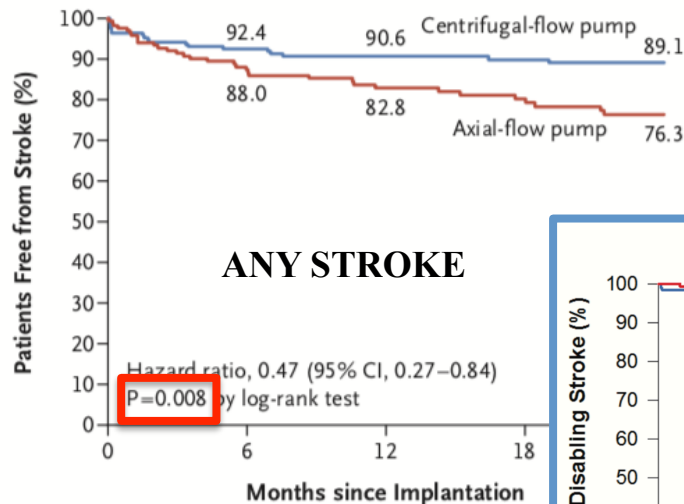


Event	Centrifugal-Flow Pump Group (N=189)		Axial-Flow Pump Group (N=172)		Hazard Ratio (95% CI)	P Value†
	no. of patients with event (%)	no. of events	no. of patients with event (%)	no. of events		
Suspected or confirmed pump thrombosis	2 (1.1)	2	27 (15.7)	33	0.06 (0.01–0.26)	<0.001



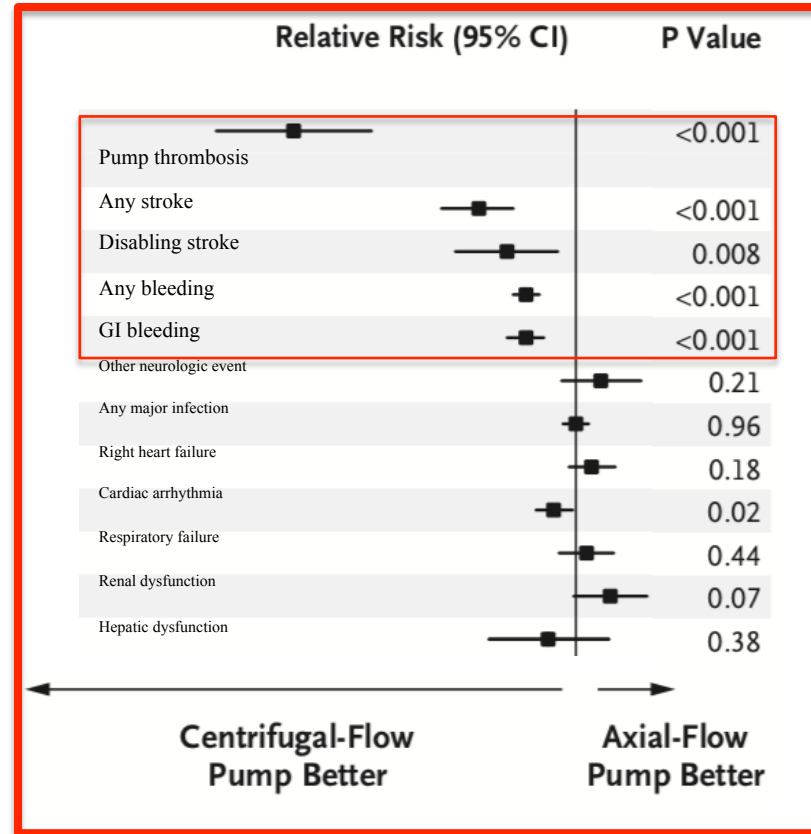
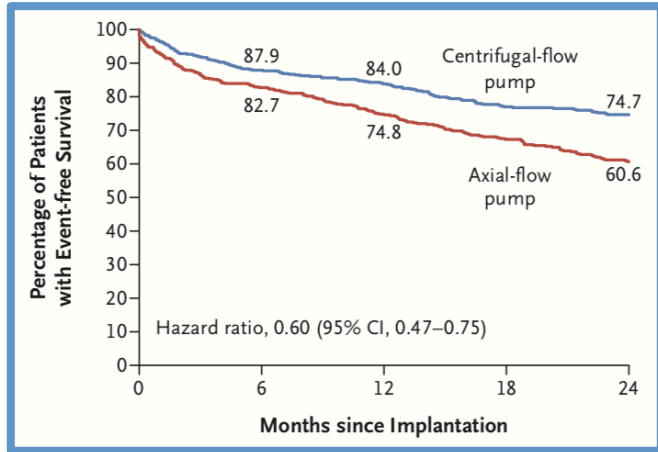
MOMENTUM 3 - LONG TERM COHORT

Per-Protocol Population



	HM3	HM II	<i>p</i>
Hemorrhagic stroke	8 (4.2)	16 (9.3)	0.06
Ischemic stroke	12 (6.3)	23 (13.4)	0.03

MOMENTUM 3 - FULL STUDY COHORT

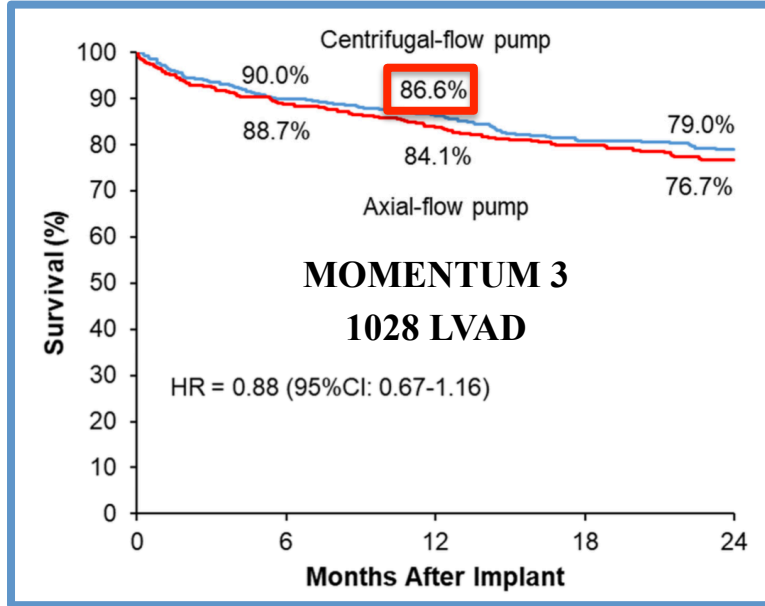


DISCUSSION

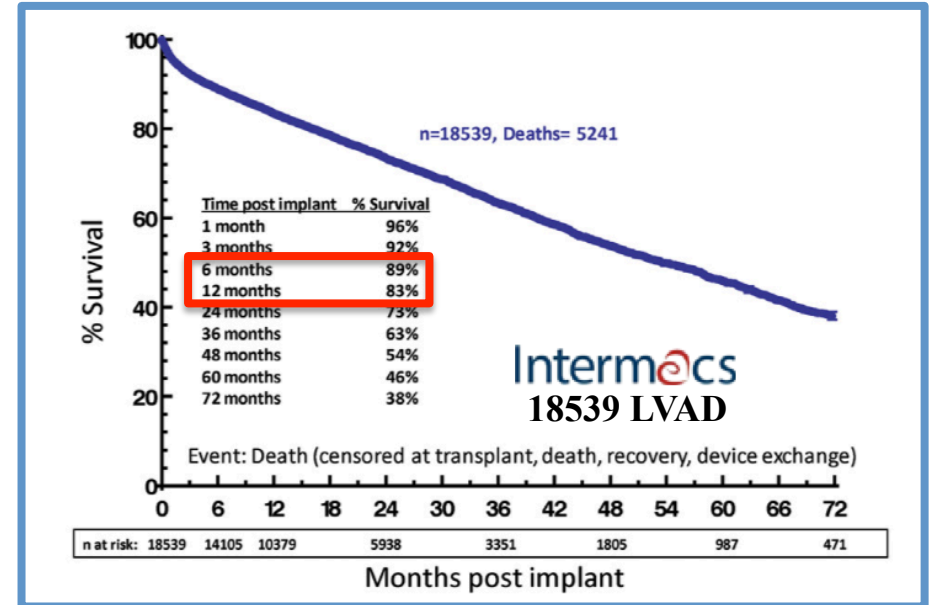
MOMENTUM 3 **vs.** **REAL LIFE DATA**

DISCUSSION

OVERALL SURVIVAL



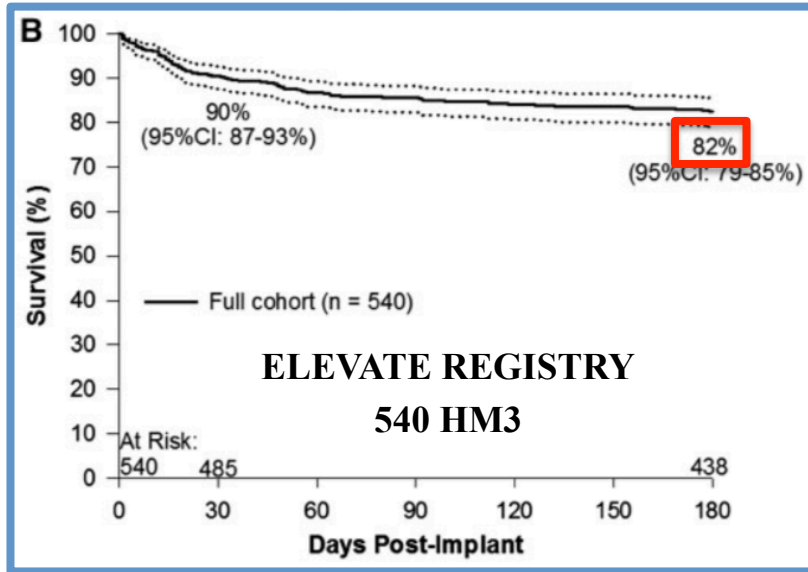
N Engl J Med 2019;380:1618-1627



Ann Thorac Surg 2019;107:341-354

DISCUSSION

OVERALL SURVIVAL



Eur Heart J 2018;39:3454-3460

ASSIST-ICD REGISTRY

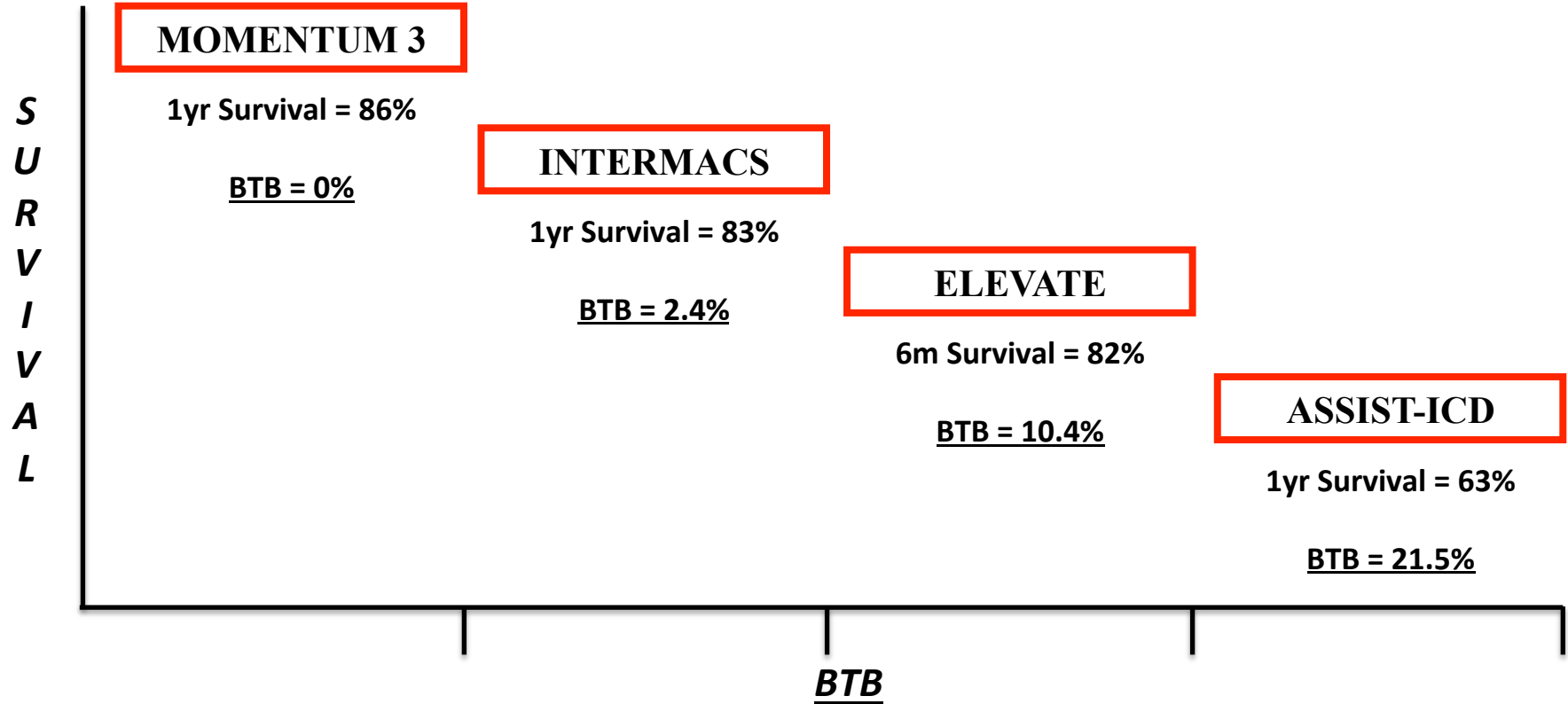
671 LVAD

1yr Survival = 63.2%

Eur J Cardiothorac Surg
Paper under review

DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY



DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY

The Use of Extracorporeal Life Support in Adult Patients With Primary Cardiac Failure as a Bridge to Implantable Left Ventricular Assist Device

Ann Thorac Surg 2001;71:S77-S81

Outcome Evaluation of the Bridge to Bridge Concept in Patients With Cardiogenic Shock

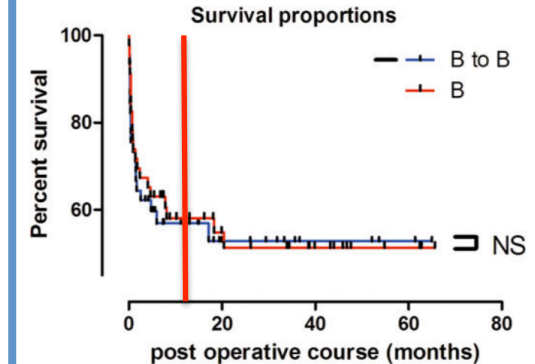
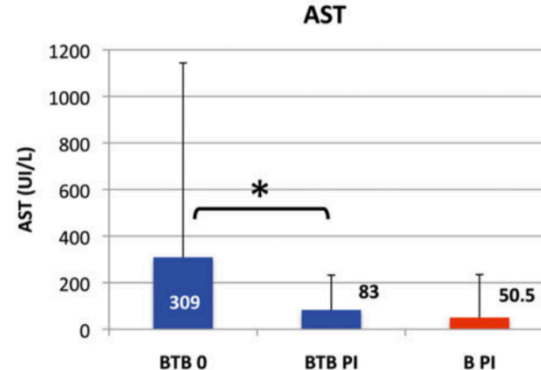
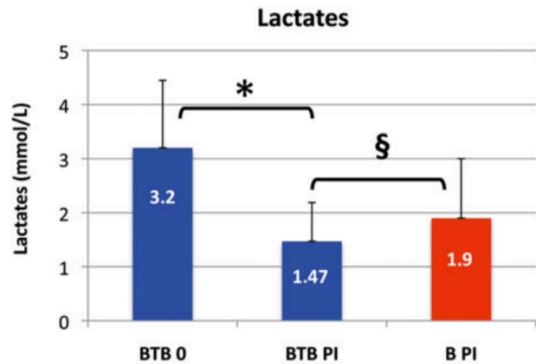
Ann Thorac Surg 2006;82:28-33

DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY

Extracorporeal life support as a bridge to bridge: a strategy to optimize ventricular assist device results

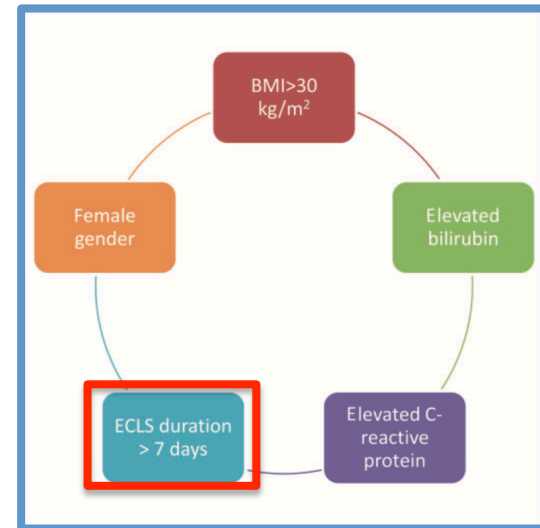
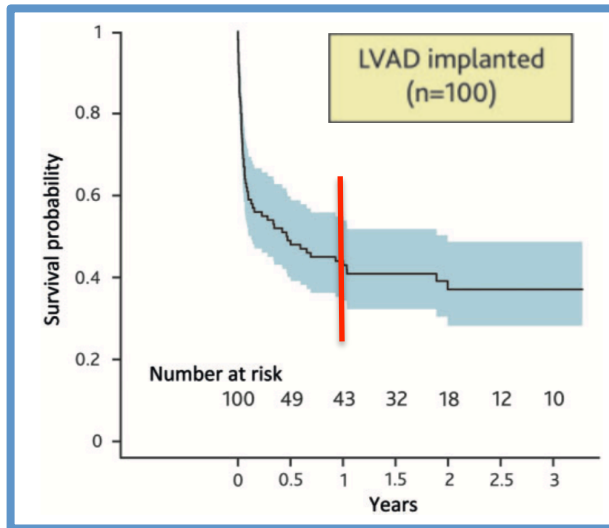
Guillaume Lebreton^{a,*}, Matteo Pozzi^{a,b}, Ciro Mastroianni^a, Philippe Léger^a, Alain Pavie^a and Pascal Leprince^a



DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY

Predictors of mid-term outcomes in patients undergoing implantation of a ventricular assist device directly after extracorporeal life support



DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY

LVAD AFTER
ECLS
CALCULATOR

Utilitaires

OUVRIIR

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STIFTUNG DES BÜRGERLICHEN RECHTS

DISCLAIMER

The ECLS after ECLS calculator is provided free of charge for the use of cardiac surgeons as an aid to decision-making in clinical situations in the treatment of patients with heart failure. All risks and benefits should be carefully considered for each individual patient, taking into account all available data and treatment options.

The German Heart Center Berlin and its employees assume no responsibility for errors or omissions in the content or for any malfunctions of the app. The German Heart Center Berlin and its employees shall in no way be liable for any direct, indirect, consequential or incidental damages arising out of or in connection with the use of this app.

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Estimation of 1-year survival after LVAD implantation directly after ECLS
Last available values measured on ECLS

Gender ☒ f ☐ m

BMI > 30 kg/cm² ☐ yes ☒ no

ECLS > 7 days ☐ yes ☒ no

Bilirubin (mg/dl)

CRP (mg/dl)

Show result

Explanation of the abbreviations
Make sure to use the right units!

About the app

RESULT

Estimated 1-year survival after LVAD implantation directly after ECLS based on entered values is

73%

Revalidation



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Estimation of 1-year survival after
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Last available values measured on ECLS

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Bilirubin (mg/dl)

CRP (mg/dl)

Show result

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 About the app

DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY

Lyon Experience

01/01/2010 – 17/10/2019

101 long-term MCS

LVAD
n = 78

BiVAD n = 20
TAH n = 3

No BTB
n = 62

BTB
n = 16

1m Survival

80.6%

$p=0.125$

62.5%

1yr Survival

62.9%

$p=0.108$

38.4%

CONCLUSIONS

- *Les résultats de l'étude MOMENTUM 3 sont très encourageants et résumés par une meilleure hémocompatibilité de l'HeartMate 3*
- *L'étude MOMENTUM 3 concerne une population plutôt sélectionnée de patients insuffisants cardiaques*
- *La comparaison de ces résultats avec notre activité clinique quotidienne nécessite une certaine prudence*