

MEDCAC Public Hearing

Sean Pinney, MD
Associate Professor of Medicine
Mount Sinai Medical Center

On behalf of
Heart Failure Society of America

Heart Failure Society of America

- > 1300 Members (multidisciplinary including MDs, PhDs, nurses and PharmDs)
- Mission is to enhance the quality and duration of life for HF patients
- Research, education & prevention

HFSA Position Statements

1. We support the NCD and do not endorse any change in the current patient selection criteria which derive from prospective, randomized trials.^{1,2}

1. Rose EA et al. NEJM 2001;345:1435.
2. Slaughter MS et al. NEJM 2009;361:2241.

HFSA Position Statements

2. We recognize the need for further well-controlled clinical trials including examination of “less-sick” patients. We do not endorse expansion of destination therapy into this population in the absence of randomized clinical trials.

HFSA Position Statements

3. Recommendations regarding VAD surgeon and center qualifications should be informed by specific volume-outcomes analyses, and the recommendations of professional societies (eg STS, ABTS).

DT Evidence Base

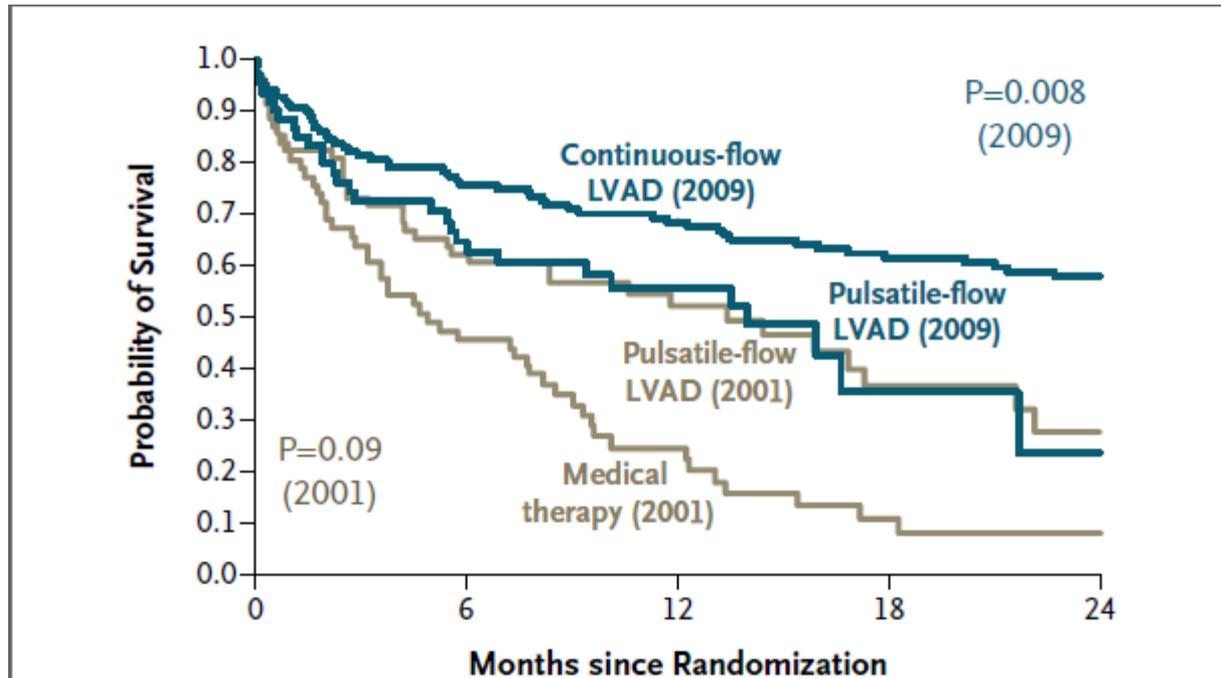
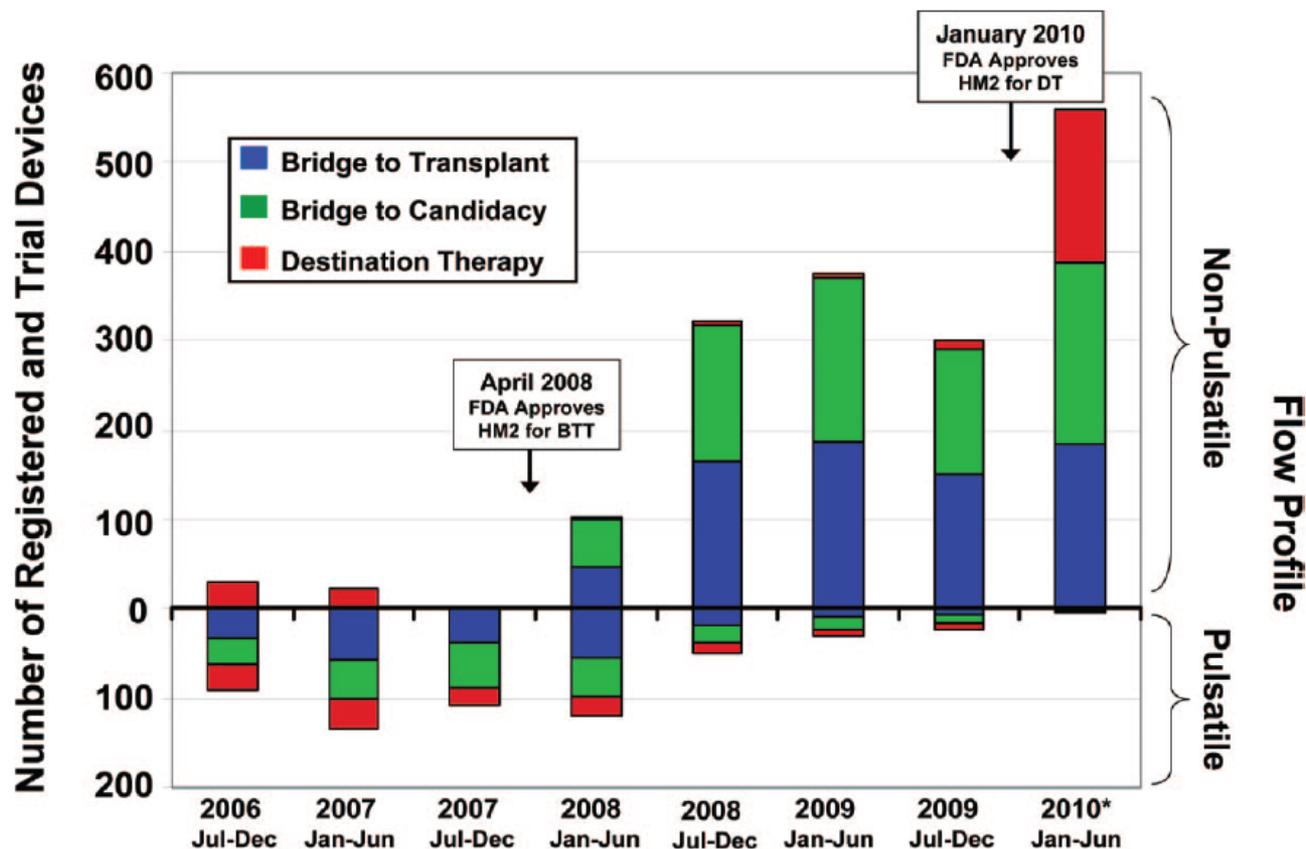


Figure 1. Survival Rates in Two Trials of Left Ventricular Assist Devices (LVADs) as Destination Therapy.

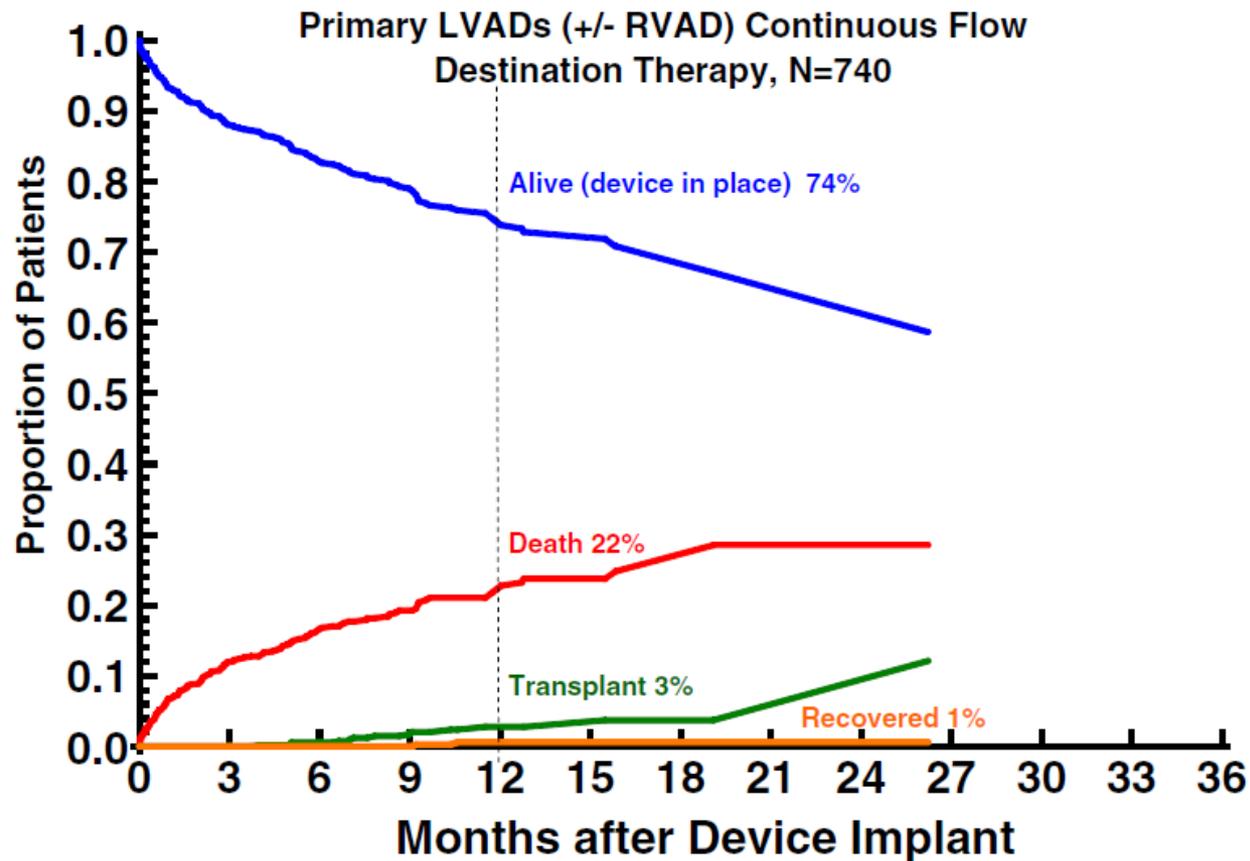
The curves labeled 2009 are those reported by Slaughter and colleagues in this issue of the *Journal*²; those labeled 2001 were reported for the REMATCH trial.¹

DT Evidence Base

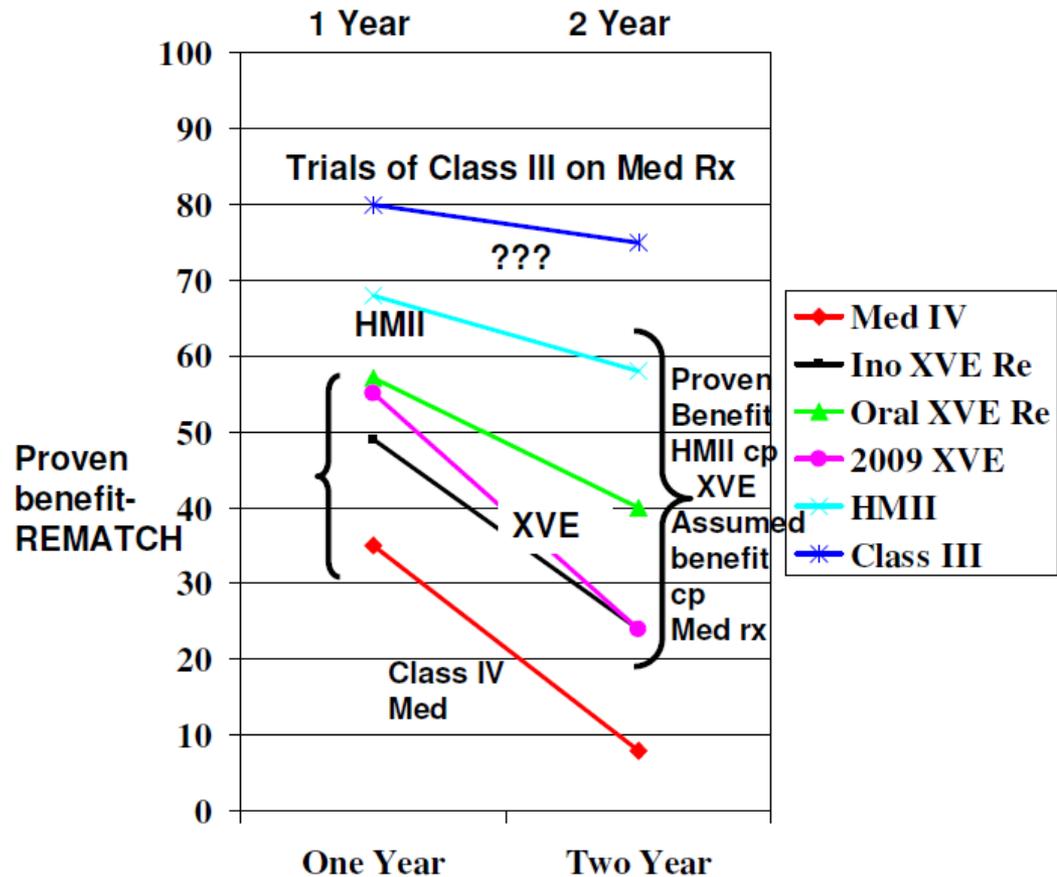


* Only 451 patients underwent DT in first 5 years after REMATCH; DT accounted for only 17% of devices implanted – Lietz K. *Circ Heart Fail* 2009;2:3-10.

DT Evidence Base



Knowledge gaps



Knowledge gaps

TABLE 2

Primary LVAD

* = includes unlikely to transplant

PROFILE-LEVEL	BTT	DT	INTERMACS CLINICAL PROFILES Official Shorthand	NYHA CLASS	Modifier option
INTERMACS LEVEL 1	357	23 (46)*	“Crash and burn”	IV	
INTERMACS LEVEL 2	612	47 (75)*	“Sliding fast” on ino	IV	
INTERMACS LEVEL 3	226	22 (31)*	Stable but Ino-Dependent Can be hosp or home	IV (if no ino)	CURRENT APPROVAL
INTERMACS LEVEL 4	150	14 (19)*	Resting symptoms on oral therapy at home.	ambu IV	+FF frequent flyer A for arrhythmia
INTERMACS LEVEL 5	27	1 (1)*	“Housebound”, Comfortable at rest, symptoms with minimum activity ADL	ambu IV	+ FF A
INTERMACS LEVEL 6	22	2 (3)*	“Walking wounded”-ADL possible but meaningful activity limited	“IIIB”	+FF A
INTERMACS LEVEL 7			Advanced Class III	III	A only

DT Facility criteria

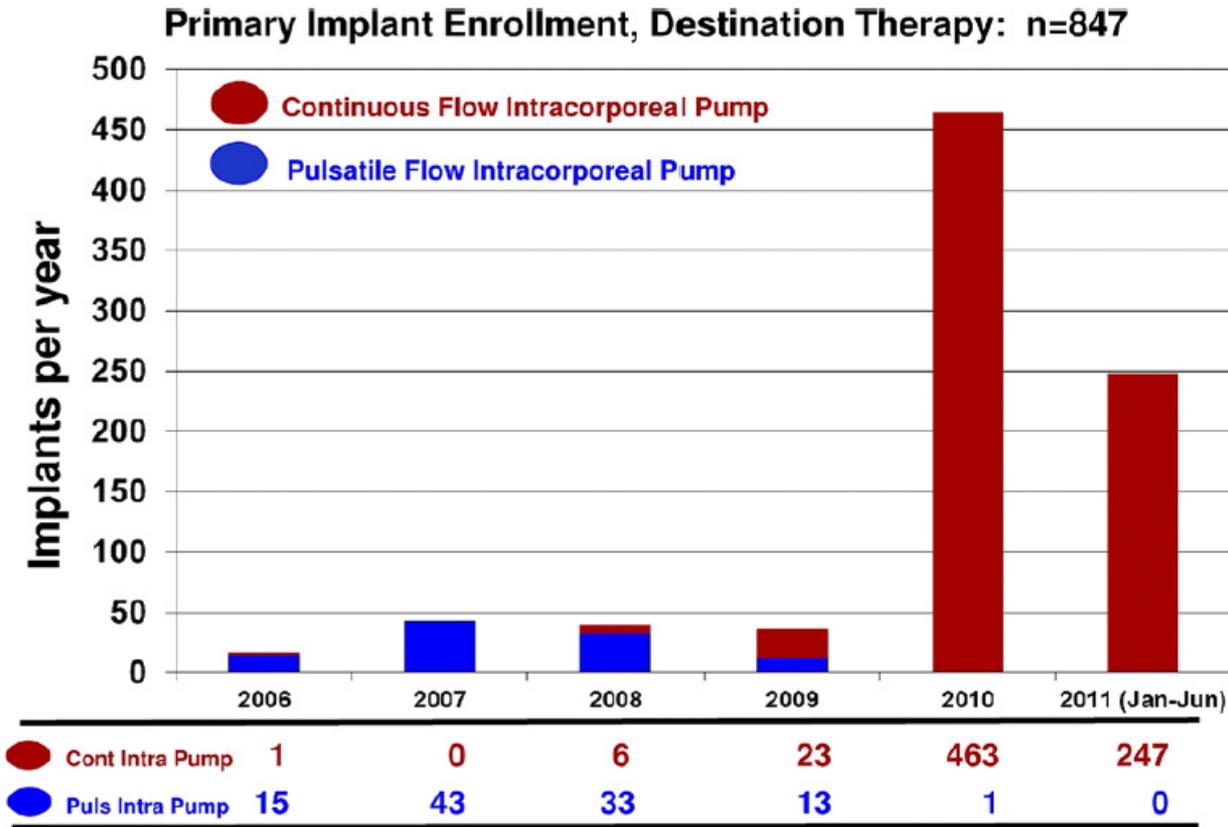
- One member with experience implanting at least 10 VADs in previous 36 months
- Report to INTERMACS
- Credentialed by the Joint Commission
- Patient informed consent materials & process

DT Facility criteria—knowledge gaps

- Center volume-outcome relationships uncertain
- Pathway for foreign trained surgeons unclear
- No pathway for VAD training certification
- Being addressed by STS and ABTS

Thank you.

DT Evidence Base



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