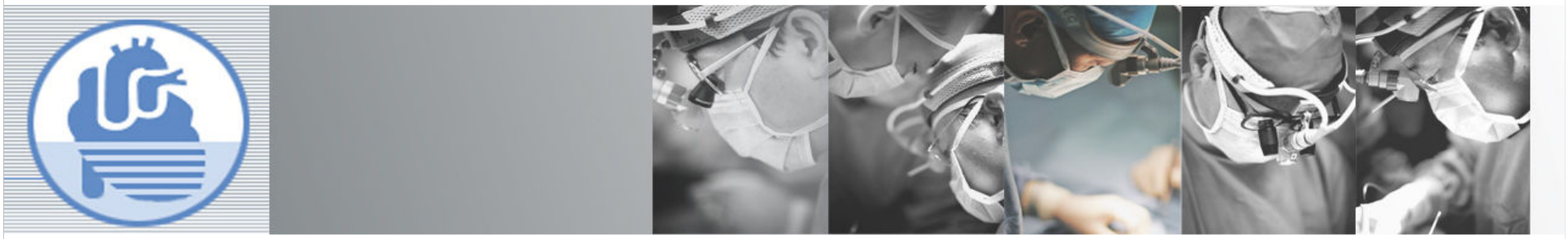
Ventricular Assist Device in Pediatric Heart Failure



양 지 혁

성균관의대 삼성서울병원

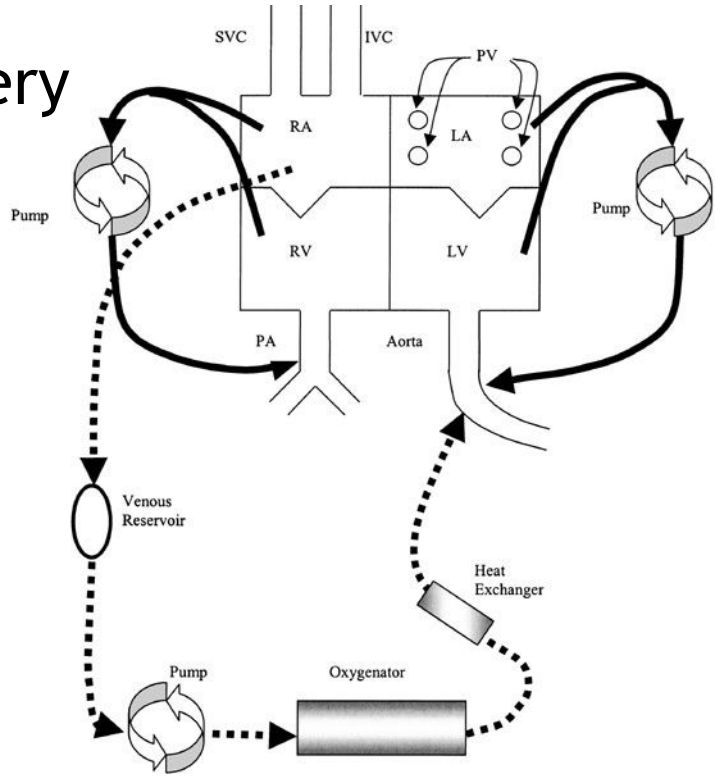
흉부외과학교실

순서

- 서론
- 왜 VAD가 필요한가?
  - 말기심부전치료의 현황
  - ECMO vs. VAD
  - 심근회복에 대한 기계순환보조의 효과
- 어떤 환자에서 VAD를 사용할 것인가?
- 어떤 VAD를 사용할 것인가?
- 결론

Introduction

- Ventricular Assist Device ; VAD
- Purpose of VAD support
  - Bridge to transplantation
  - Bridge to myocardial recovery
  - Destination therapy



Introduction

- ↑ pediatric patients with end stage heart failure
  - Progress in pharmacologic and surgical therapies
  - ↑ the number of patients surviving initial palliative procedures
  - Improvements in treatment of cardiomyopathies, myocarditis
- ↑ Number of cardiac transplantation in Korea
- Improved results after adult VAD support

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Epidemiology of Heart Failure in Adults

Prevalence 2004 Age 20+	Incidence (New Cases) Age 35+	Mortality 2004 All Ages	Hospital Discharges 2004 All Ages	Cost 2007
5,200,000 (2.5%)	550,000	57,700 *	1,099,000†	$ 33.2 billion

(AHA, Heart Disease and Stroke Statistics – 2007 Update. *Circulation* 2007)

* From 1994 to 2004, deaths from HF increased 28%. In the same time period, the death rate declined 2.0%

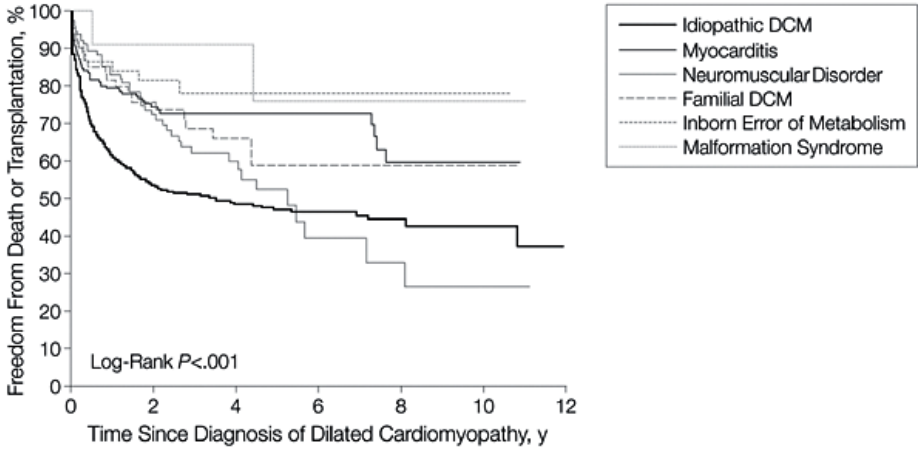
† rose from 399,000 in 1979

Incidence of End-Stage Heart Disease in Children

- Mortality after CHD operations (2003, USA)
  (AHA, Heart Disease and Stroke Statistics – 2007 Update. *Circulation* 2007)
  - 4.8% mortality in > 25,000 operations
- Incidence of DCMP in children
  (Towbin et al. JAMA 2006)
  - Age < 18 yrs
  - 0.57 / 100,000
- Incidence of primary CMP in children
  (Nugent et al. NEJM 2003)
  - age < 10 yrs in Australia
  - 1.24 / 100,000

Freedom from death or transplantation for patients with pure DCMP, by cause

- 1426 patients
- Age at Diagnosis
  - 1.5 yrs (median)
- Age at listing for transplantation
  - 4.0 yrs (median)
- Age at transplantation
  - 4.8yrs (median)
- Freedom from death or transplantation
  - 1 yr 69%
  - 2 yrs 61%
  - 5 yrs 54%
  - 10 yrs 46%

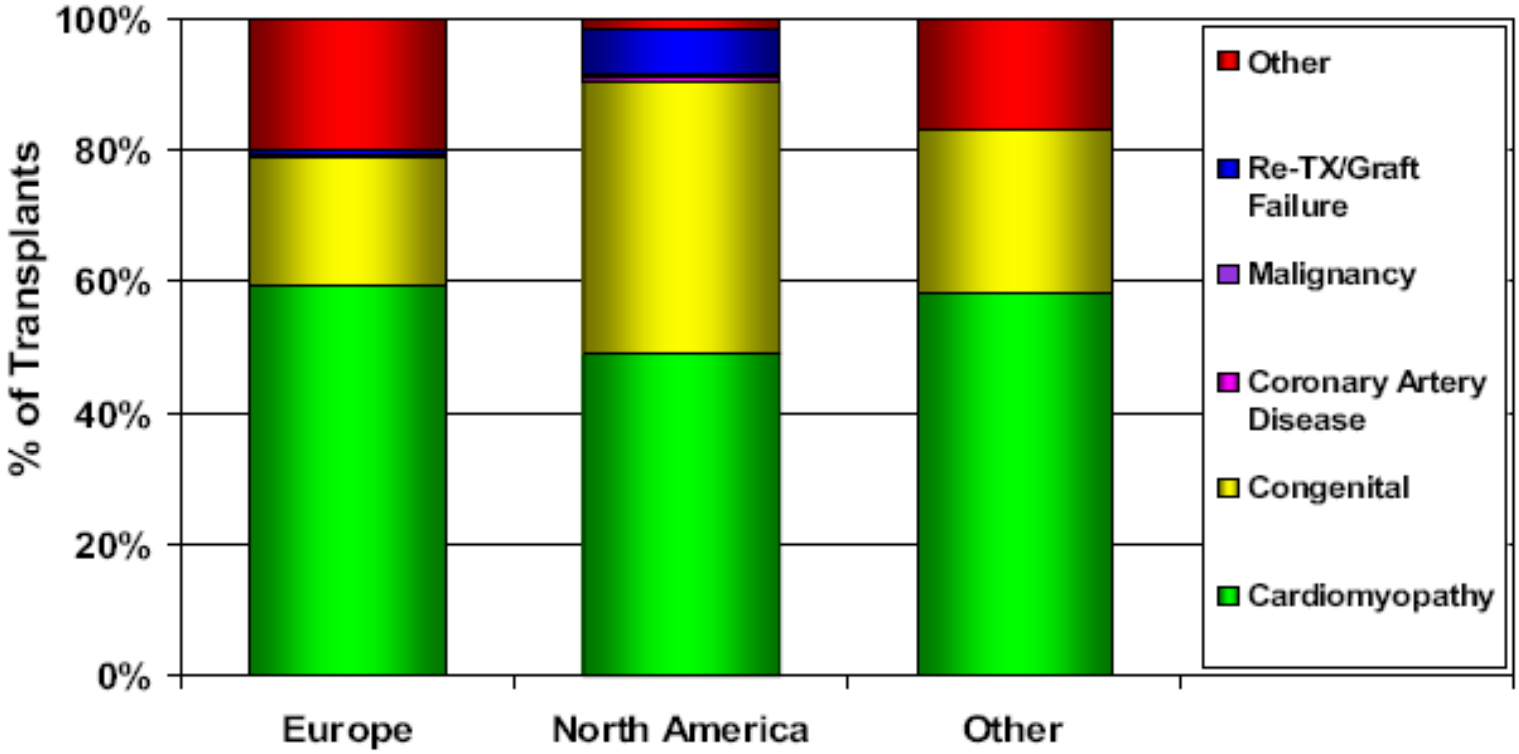


No. at Risk Cohort							
Idiopathic DCM	941	252	132	68	30	13	0
Myocarditis	222	95	55	32	12	1	0
Neuromuscular Disorder	125	56	25	8	5	1	0
Familial DCM	66	33	21	11	4	1	0
Inborn Error of Metabolism	54	27	20	8	5	1	0
Malformation Syndrome	15	6	6	2	2	1	0

(Towbin et al. JAMA 2006)

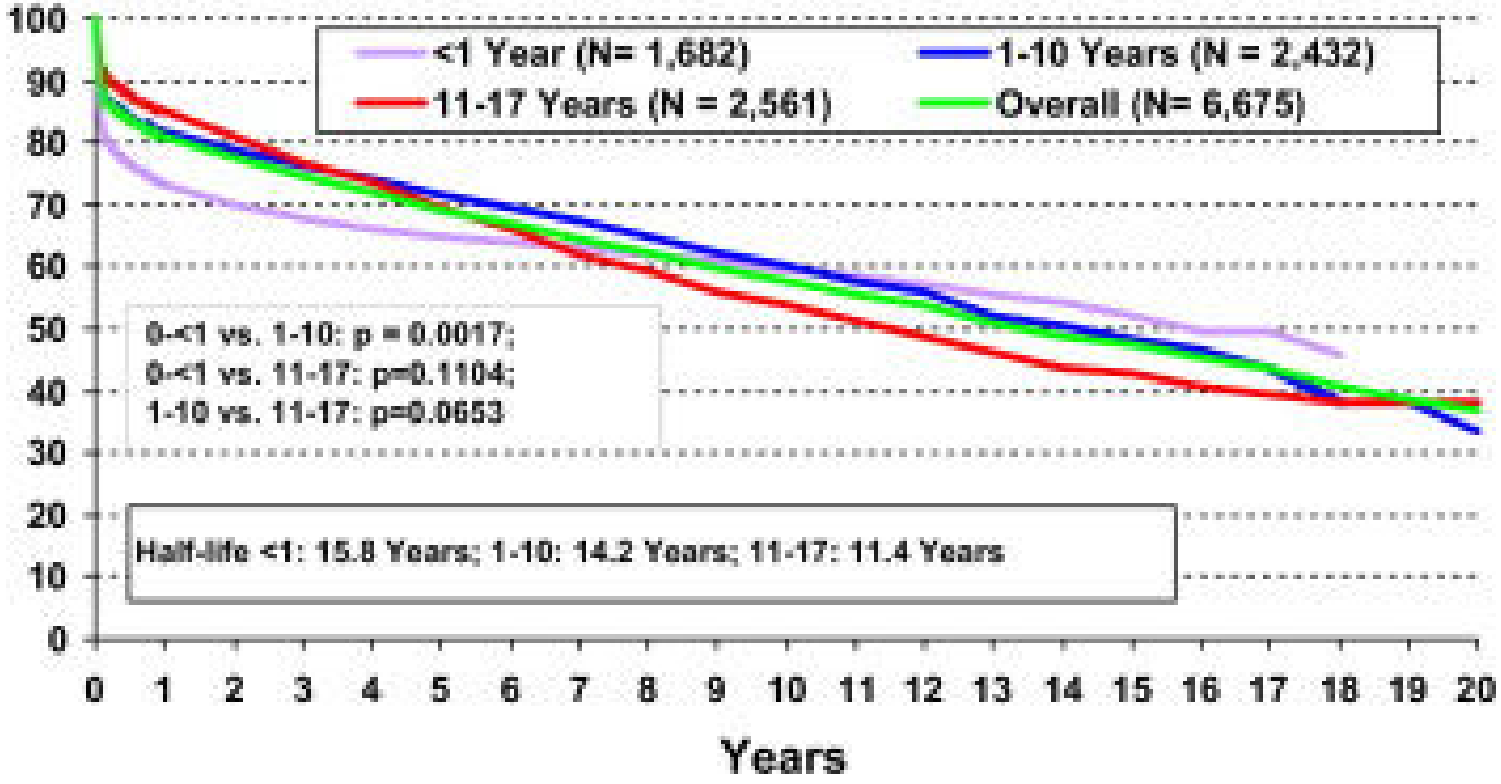
Registry of the ISHLT: 10th Official Pediatric Heart Transplantation Report 2007

- Diagnosis distribution for Pediatric Heart Transplants (2000 ~ 2006)



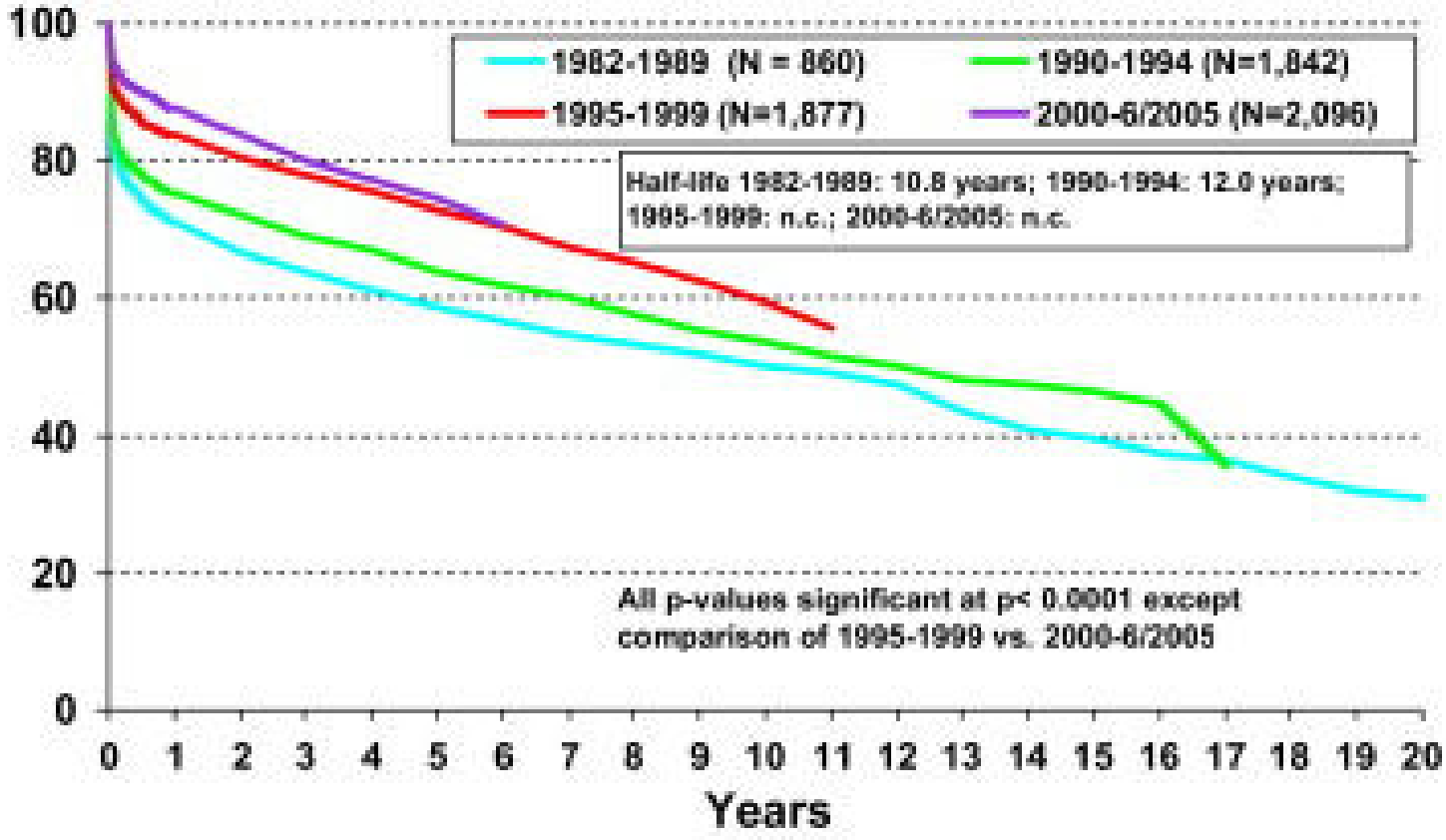
Registry of the ISHLT: 10th Official Pediatric Heart Transplantation Report 2007

- Kaplan-Meier survival stratified by age at transplant (1982 ~ 2005)



Registry of the ISHLT: 10th Official Pediatric Heart Transplantation Report 2007

- Kaplan-Meier survival stratified by era of transplant (1982 ~ 2005)

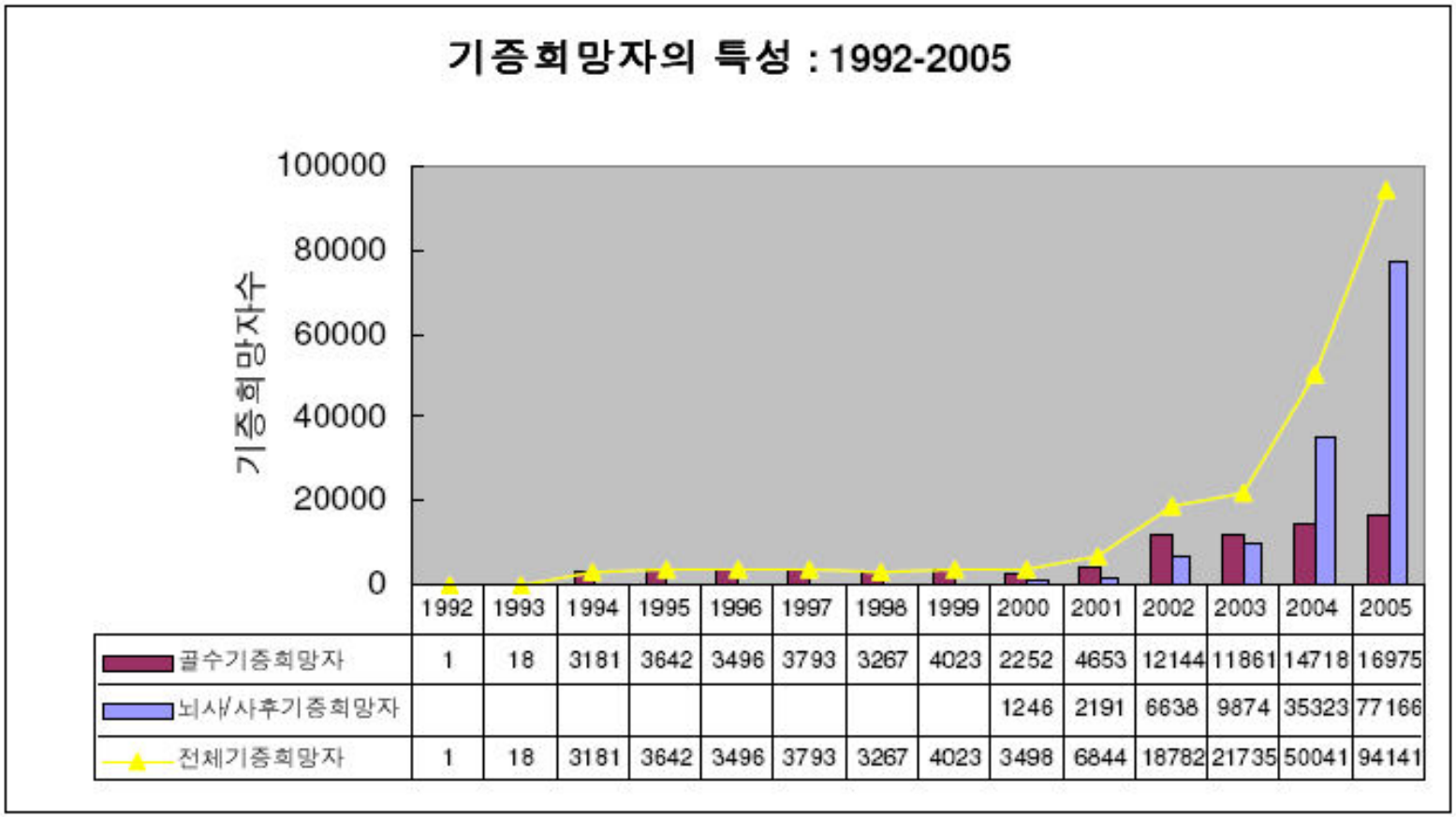


Congestive Heart Failure in Korea

- *Korean Circulation J* 2005
  - 1759 adult patients in 9 University hospitals
  - Most common etiology : IHD
- Estimated incidence of DCMP by Towbin's data
  - 450,000 birth X 0.57 = 2.6 / year
- Estimated incidence of CMP by Australian data
  - 450,000 birth x 1.24 = 5.6 / year

Pediatric Heart Transplantation in Korea

- Annual Report 2005 (KONOS)



	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
골수기증희망자	1	18	3181	3642	3496	3793	3267	4023	2252	4653	12144	11861	14718	16975
뇌사/사후기증희망자									1246	2191	6638	9874	35323	77166
전체기증희망자	1	18	3181	3642	3496	3793	3267	4023	3498	6844	18782	21735	50041	94141

Pediatric Heart Transplantation in Korea

표 3-2-15. 뇌사 기증자로부터 심장을 이식받은 자의 생존율 - 연령별

Table 3-2-15. Cadaveric Heart Transplants - Age at Time of Transplant

이식받을때의연령별 Age(Years) at Time of Transplant	계 Total	3개월 3 Month Survival		1년 1 Year Survival		2년 1 Year Survival		1년 3 Year Survival	
		%	표준오차 Std.Err.	%	표준오차 Std.Err.	%	표준오차 Std.Err.	%	표준오차 Std.Err.
전체 Total	115	95.65	0.0190	88.99	0.0301	85.06	0.0363	85.06	0.0363
1-5	1	100.00	0.0000	100.00	0.0000	100.00	0.0000	100.00	0.0000
6-10	2	100.00	0.0000	100.00	0.0000	100.00	0.0000	100.00	0.0000
11-17	12	100.00	0.0000	90.91	0.0867	75.76	0.1560	75.76	0.1560
18-34	17	94.12	0.0571	87.84	0.0807	87.84	0.0807	87.84	0.0807
35-49	40	95.00	0.0345	86.76	0.0553	86.76	0.0553	86.76	0.0553
50-64	38	97.37	0.0260	91.55	0.0468	87.57	0.0593	87.57	0.0593
65+	5	80.00	0.1789	80.00	0.1789	53.33	0.2483	53.33	0.2483

Pediatric Heart Transplantation in Korea

표 4-5-2. 심장을 이식받기 위해 등록한 자의 특성-연령별(1):1995-2005

Table 4-5-2. Heart Registrations Characteristics - Age(1) : 1995 to 2005

(단위: 명)

구분 Classi-fication	<1		1-5		6-10		11-17		18-34	
	등록자 Patients	사망자 Deaths	등록자 Patients	사망자 Deaths	등록자 Patients	사망자 Deaths	등록자 Patients	사망자 Deaths	등록자 Patients	사망자 Deaths
계 Total	5	1	20	3	21	10	45	23	78	19
1995									1	
1996										
1997									1	
1998							2	1	3	1
1999							4	3	14	6
2000	1		5	1	7	4	8	4	16	4
2001	1		3	1	3	2	10	6	8	2
2002	1		2		5	4	6	5	5	2
2003			2	1			7	2	9	2
2004	2	1	5		4		3	1	10	2
2005			3		2		5	1	11	

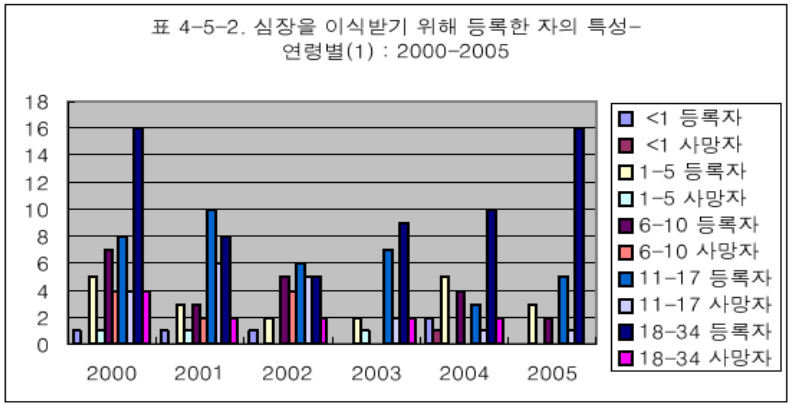
표2-6-2. 뇌사기증자로부터 이식받은 심장의 특성-연령별 : 2000-2005

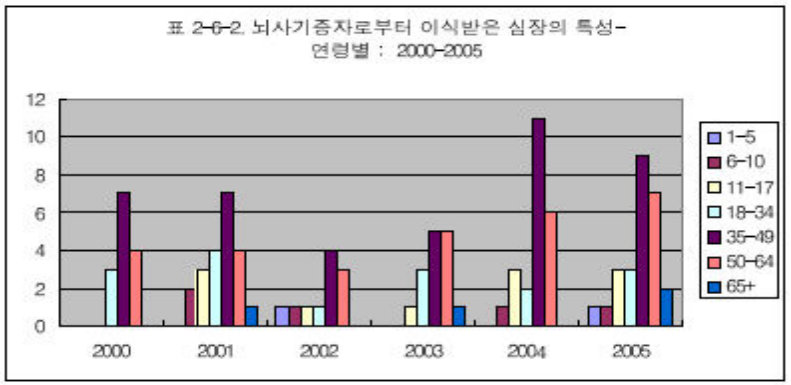
Table 2-6-2. Cadaveric Heart Recipients - Age : 2000 to 2005

(단위: 건)

구분 Classi-fication	<1	1-5	6-10	11-17	18-34	35-49	50-64	65+	계 Total
2000					3	7	4		14
2001			2	3	4	7	4	1	21
2002		1	1	1	1	4	3		11
2003				1	3	5	5	1	15
2004			1	3	2	11	6		23
2005		1	1	3	3	9	7	2	26
1						2			2
2									
3		1			1		1		3
4						1	2		3
5				1	1				2
6			1			2	1		4
7				1		1			2
8						1		2	3
9							1		1
10							2		2
11						1			1
12				1	1	1			3

주1) 구분은 전체 기증자의 적출일 기준이고, 2000-2005년, 2005년의 월별자료임.





Pediatric Heart Transplantation in Korea

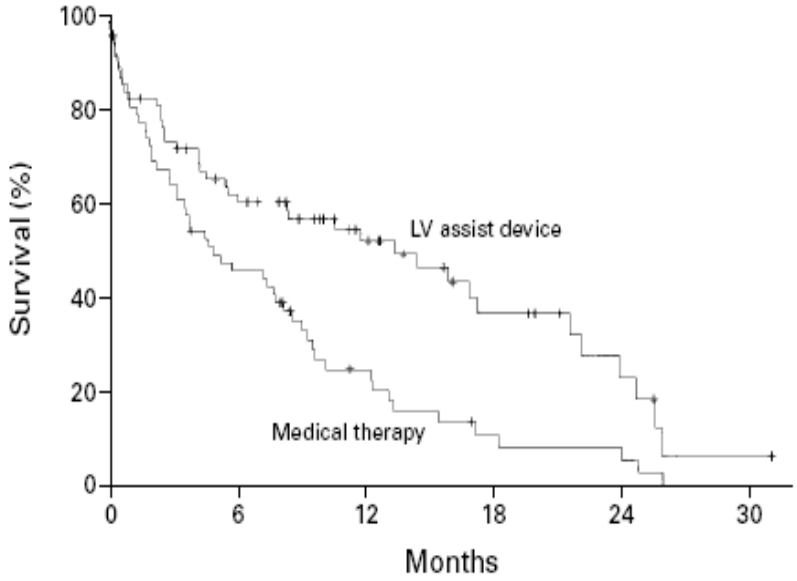
연령군	≦ 17 yrs	> 17 yrs
심장이식 등록자	91	78
대기 중 사망자	37 (41%)	19 (24%)
이식받은 자	18	92

- 10세 이하 이식대기자 : 46명
- 10세 이하 기증자 : 3명

Prevalence 2004 Age 20+	Incidence (New Cases) Age 35+	Mortality 2004 All Ages	Hospital Discharges 2004 All Ages	Cost 2007
5,200,000	550,000	57,700 *	1,099,000†	$ 33.2 billion

REMATCH Study (Rose et al. NEJM 2001)

- Randomized Evaluation of Mechanical Assistance for Treatment of Congestive Heart Failure
- 129 patients with end-stage heart failure who were ineligible for cardiac transplantation
- Reduction of 48% in the risk of death
- Significantly improved QOL at 1 yr



No. at Risk						
LV assist device	68	38	22	11	5	1
Medical therapy	61	27	11	4	3	0

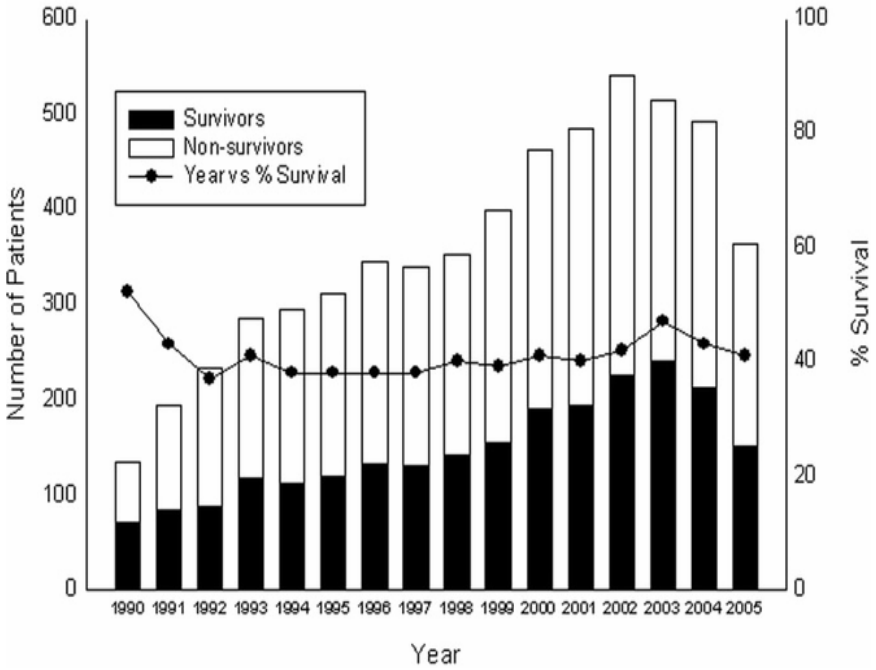
ECMO in Children

- **Total Numbers of ECLS Cases Reported by the ELSO Registry International Summary, July 2004**

	Total Cases	Survive to Discharge or Transfer	
		Number	%
Neonatal			
Respiratory	19,061	14,681	77
Cardiac	2,215	841	38
ECPR	151	65	43
Pediatric			
Respiratory	2,762	1,536	56
Cardiac	2,936	1,256	43
ECPR	282	111	39
Adult			
Respiratory	972	515	53
Cardiac	474	156	33
ECPR	132	50	38
Total	28,985	19,211	66

ECLS, extracorporeal life support.

ECMO in Children



ECLS for Cardiac Failure (July 2004)

	Total Runs	No. Survived	% Survived
0–30 days			
Congenital Defect	2,006	719	36
Cardiac Arrest	24	5	21
Cardiogenic	22	11	50
Shock			
Cardiomyopathy	72	48	67
Myocarditis	27	11	41
Other	168	74	44
31 days and <1 year			
Congenital Defect	1,318	548	42
Cardiac Arrest	25	6	24
Cardiogenic	11	4	36
Shock			
Cardiomyopathy	61	28	46
Myocarditis	33	18	55
Other	155	65	42
1 year and <16 years			
Congenital Defect	740	297	40
Cardiac Arrest	49	19	39
Cardiogenic	34	11	32
Shock			
Cardiomyopathy	200	108	54
Myocarditis	96	60	63
Other	260	113	43
≥16 years			
Congenital Defect	42	12	29
Cardiac Arrest	43	9	21
Cardiogenic	74	34	46
Shock			
Cardiomyopathy	73	25	34
Myocarditis	14	9	64
Other	297	92	31

Effects of Mechanical Cardiac Support

- Unloading of ventricle → decreased wall stress
- Improvements in myocardial remodeling

  (Young. *Ann Thorac Surg* 2001; Duncan. *Ann Thorac Surg* 2002)
- Regression of myocardial cellular hypertrophy, especially in length

  (Zafeiridis et al. *Circulation* 1998)
- Reversal of disruption of the dystrophin complex

  (Vatta et al. *Lancet* 2002)
- ↓ β-receptor Ab

  (Loebe et al. *Eur J Cardiothorac Surg* 1997)
- ↑ responsiveness to β-adrenergic stimulation

  (Burkhoff et al. *Prog Cardiovasc Dis* 2000)
- ↓ renin, angiotension-II, epinephrine, norepinephrine, arginine vasopressin

  (Young. *Ann Thorac Surg* 2001)
- LVAD can decrease PAP, and improve septal configuration & RV fx

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Indications for Mechanical Support

- Myocardial dysfunction after cardiac surgical procedures
- End-stage heart failure from chronic cardiomyopathies or congenital heart defects
- Acute myocarditis
- Myocardial infarction/coronary ischemia
- Post-transplant cardiac failure

(Chang et al. *Pediatr Cardiol* 2005)

Considerations before Implantation

- Rule out residua in postoperative patients
  - AV valve regurgitation or stenosis
  - Outflow tract lesions
  - Residual shunts
  - Coronary ischemia from ostial stenosis or external compression/kinking secondary to outflow tract reconstruction

(Chang et al. *Pediatr Cardiol* 2005)

Contraindications

- Advanced multiorgan failure
- Severe coagulopathy
- Severe CNS damage
- Extreme prematurity (<1.5kg)
- Eisenmenger syndrome
- Certain chromosomal abnormalities
- Uncontrolled infection
- Significant aortic insufficiency

(Chang et al. *Pediatr Cardiol* 2005)

Indications for Heart Transplantation

(ACC/AHA 2005 guideline adult heart failure. *JACC* 2005)

Absolute indications in appropriate patients

For hemodynamic compromise due to HF

Refractory cardiogenic shock

Documented dependence on IV inotropic support to maintain adequate organ perfusion

Peak VO2 < 10 mL/kg/min with achievement of anaerobic metabolism

Severe symptoms of ischemia that consistently limit routine activity and are not amenable to coronary artery bypass surgery or percutaneous coronary intervention

Recurrent symptomatic ventricular arrhythmias refractory to all therapeutic modalities

Relative indications

Peak VO2 11 to 14 mL/kg/min (or 55% of predicted) and major limitation of the patient's daily activities

Recurrent unstable ischemia not amenable to other intervention

Recurrent instability of fluid balance/renal function not due to patient noncompliance with medical regimen

Insufficient indications

Low left ventricular ejection fraction

History of functional class III or IV symptoms of HF

Peak VO2 > 15 mL/kg/min (and greater than 55% of predicted) without other indications

REMATCH study inclusion criteria

- the presence of symptoms of NYHA class IV heart failure for at least 90 days despite attempted therapy with ACE inhibitors, diuretics, and digoxin
- LVEF $\leq$ 25 %
- peak oxygen consumption $\leq$ 12 mL/kg/min
- continued need for IV inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion

Heart Failure Staging in Children

- ISHLT:Practice Guidelines for Management of Heart Failure in Children. (Rosenthal et al. *J Heart Lung Transplant* 2004)

Stage	Interpretation	Clinical Examples
A	At risk for developing heart failure	Congenital heart defects
		Family history of cardiomyopathy
		Anthracycline exposure
B	Abnormal cardiac structure and/or function	Univentricular hearts
	No symptoms of heart failure	Asymptomatic cardiomyopathy
		Repaired congenital heart disease
C	Abnormal cardiac structure and/or function	Repaired and unrepaired congenital heart defects
	Past or present symptoms of heart failure	Cardiomyopathies
D	Abnormal cardiac structure and/or function	Same as stage C
	Continuous infusion of intravenous inotropes or prostaglandin E_1 to maintain patency of a ductus arteriosus	
	Mechanical ventilatory and/or mechanical circulatory support	

Indications for Heart Transplantation in Cardiomyopathies and CHD

- Class I
  - stage D heart failure associated with systemic ventricular dysfunction in pediatric patients with cardiomyopathies or previous repaired or palliated congenital heart disease (Level of Evidence B).
  - stage C heart failure
    - associated with severe limitation of exercise and activity. If measurable, such patients would have a peak maximum oxygen consumption 50% predicted for age and sex (Level of Evidence C).
    - associated with significant growth failure attributable to the heart disease (Level of Evidence B).
    - associated with near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator (Level of Evidence C).
    - in pediatric restrictive cardiomyopathy disease associated with reactive pulmonary hypertension (Level of Evidence C).

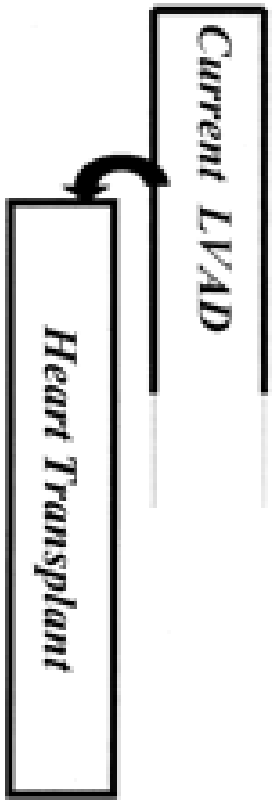
Indications for Heart Transplantation in Cardiomyopathies and CHD

- Class I
  - In the presence of other indications for heart transplantation, heart transplantation is feasible in patients with pediatric heart disease and an elevated pulmonary vascular resistance index 6 Woods units/m^2 and/or a transpulmonary pressure gradient 15 mm Hg if administration of inotropic support or pulmonary vasodilators can decrease pulmonary vascular resistance to 6 Woods units/m^2 or the transpulmonary gradient to 15 mm Hg (Level of Evidence B).

(Canter et al. *Circulation* 2007)

Strategy for Heart Failure Populations

Potential Populations for Support	Estimated 50% Mortality
• Acute cardiogenic shock	Imminent
• Chronic CHF into low output state with organ dysfunction	1 month, without reversible factors
• CHF Class IV inotrope-dependent	3-6 months
• CHF IV ACEI-intolerant due to symptomatic hypotension or progressive renal dysfunction	About 6 months
• Class IV on ACEI therapy Plus additional risk factors, e.g. – Cachexia – Peak oxygen uptake < 10 ml/kg/min – Hyponatremia – Progressive renal dysfunction	? 6-12 months
• CHF IV on oral therapy including ACEI	± 12 months
• Class IV stabilized to Class III	> 24 months



(Stevenson et al. *Circulation* 2003)

Therapeutic Recommendations for Mechanical Support in Children with HF

ISHLT:Practice Guidelines for Management of Heart Failure in Children. (Rosenthal et al. *J Heart Lung Transplant* 2004)

- Institution of mechanical cardiac support should be considered
  - in patients without structural CHD, who manifest acute low cardiac output or who have intractable arrhythmias during a presumably temporary condition that is refractory to medical therapy (HF Stage D) such as myocarditis, septic shock, or acute rejection following cardiac transplantation. (Level of Evidence C; Strength of Recommendation I)
  - in patients with or without structural congenital heart disease, who have acute decompensation of end-stage HF, primarily as a bridge to cardiac transplantation (HF Stage D). (Level of Evidence B; Strength of Recommendation I)

Therapeutic Recommendations for Mechanical Support in Children with HF

- Institution of mechanical cardiac support may be considered
  - in patients who have experienced cardiac arrest, hypoxia with pulmonary hypertension, or severe ventricular dysfunction with low cardiac output after surgery for congenital heart disease, including “rescue” of patients who fail to wean from cardiopulmonary bypass or who have myocarditis (HF Stage D). However, the outcomes in this group are less satisfactory than for other indications for mechanical support. (Level of Evidence B; Strength of Recommendation IIa)

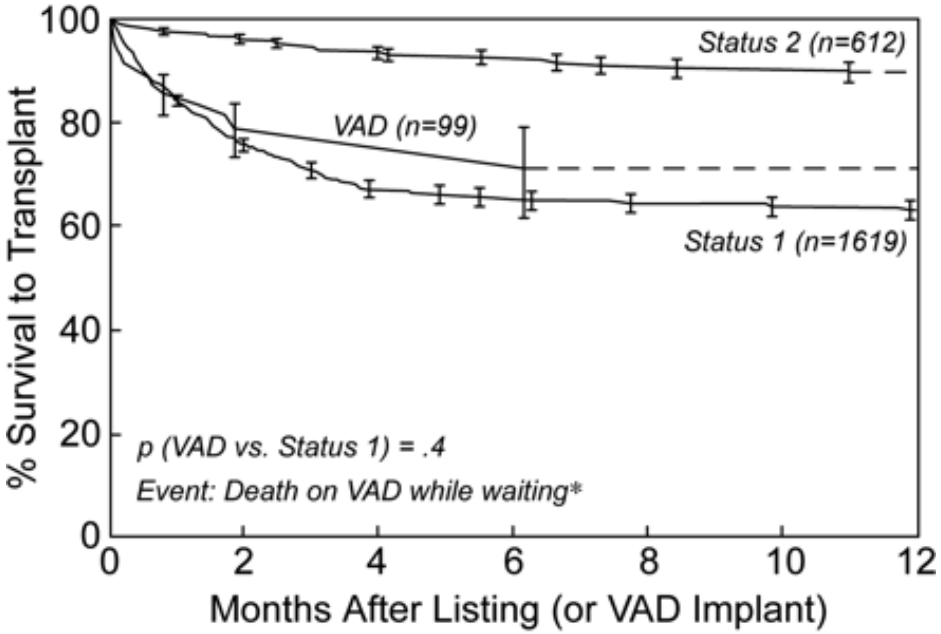
Therapeutic Recommendations for Mechanical Support in Children with HF

- Mechanical cardiac support is not indicated
  - in those cases in which there is evidence of a severe and irreversible defect (e.g. catastrophic intracranial hemorrhage, or advanced multisystem organ failure). However, in practice, the determination of the severity and/or irreversibility of the associated condition may be difficult to determine, so the decision concerning eligibility for mechanical support is a difficult clinical judgment. (Level of Evidence C; Strength of Recommendation IIb)

Survival to Transplantation of Patients Bridged with VAD Support

(Blume et al. *Circulation* 2006)

- Multi-institutional study
- 2375 children listed for transplantation
- 77 of 99 pts supported with VAD survived to TPL
- 5 pts weaned from support and recovered
- 17 pts died on support
- Since 2000, 86% survived to transplantation



*Censored at transplant.

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Types of VAD

Centrifugal pumps (Bio-pump, Medtronic)

Pulsatile pumps

Thoratec VAD (Thoratec Corp, Pleasanton, CA)

Berlin Heart EXCOR VAD (Mediport Kardiotechnik, Berlin, Germany)

Medos-HIA system (MEDOS-Helmholtz Institute, Aachen, Germany)

Abiomed BVS-5000 (Abiomed, Danvers, MA)

HeartMate VAD (Thoratec)

Novacor VAD (World Heart Corp, Oakland, CA)

Pierce-Donachy Pediatric System (11 cc)

Hemopump (DLP Corp, Grand Rapids, MI)

Toyobo-Zeon Pump (Japan)

Axial Flow Pumps

MicroMed DeBakey VAD Child device (MicroMed Technology, Inc, Houston, TX)

Jarvik-2000 Heart (intracardiac)

Thoratec HeartMate II

Berlin Heart INCOR I

SUN Medical Technology Research Corporation IVAP VAD (intracardiac; Pittsburgh, PA)

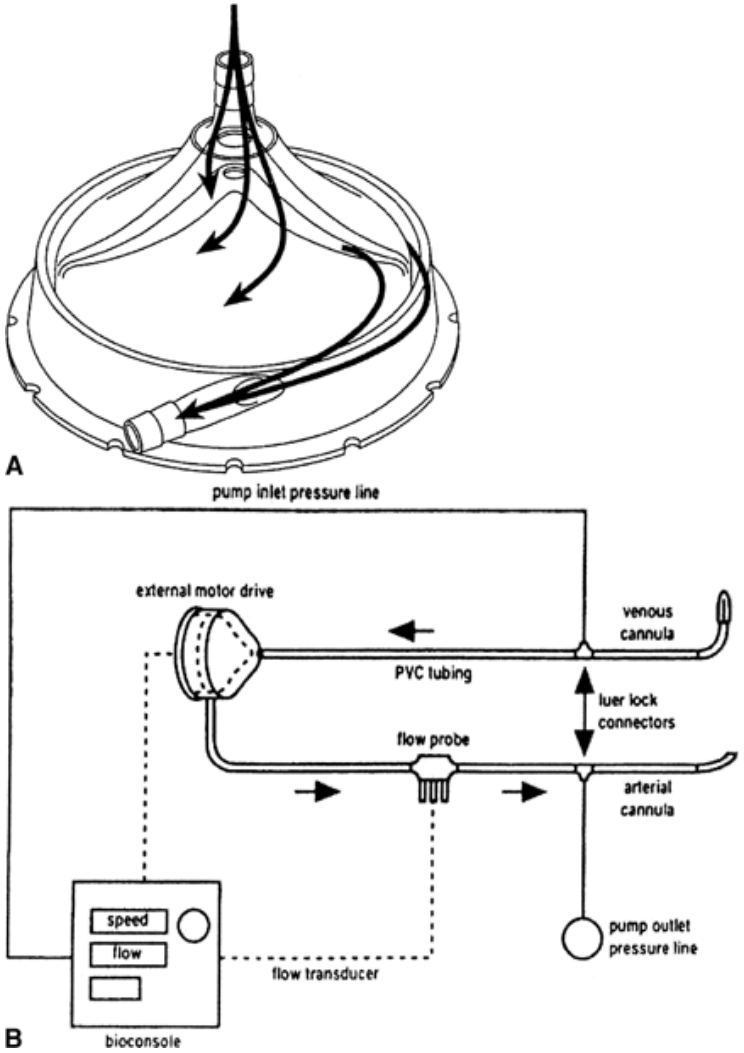
Impella system (intracardiac; Aachen, Germany)

Valvo pump (intracardiac; Japan)

INTEC axial flow pump (intracardiac; Valhalla, NY)

PediPump (intracardiac >15 kg or extracardiac but intracorporeal <15 kg; The Cleveland Clinic Foundation, Cleveland, OH, and Foster-Miller Technologies, Albany, NY)

Centrifugal pump



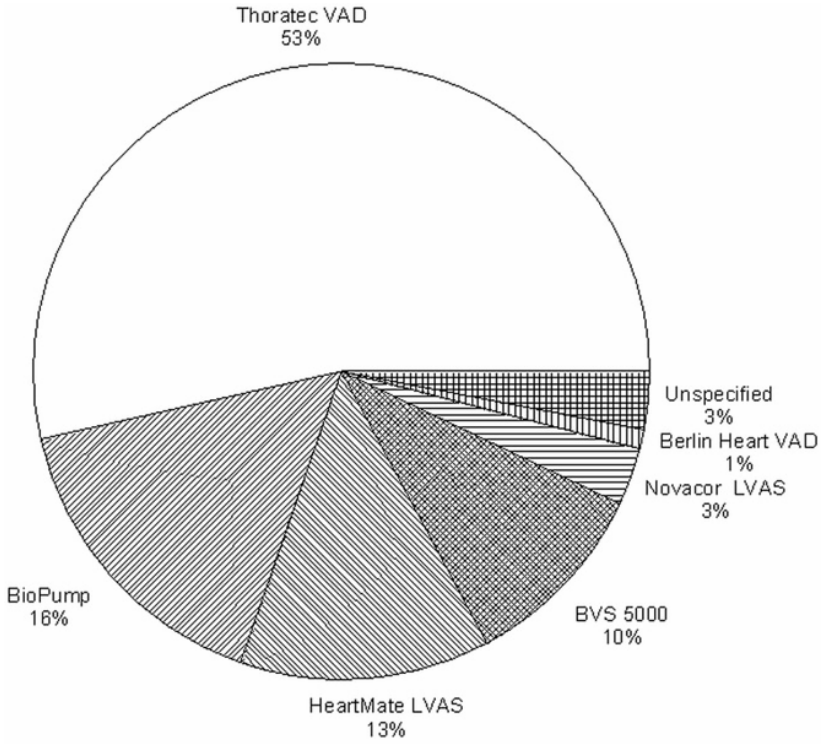
- one of the best options for short-term support in acute situations
- avoid excessive negative inlet pressure or low left atrial pressure as this can entrain air in the circuit.
- Patients are unable to ambulate and require sedation and ventilation.
- Centrifugal devices require significant anticoagulation.
  - aPTT : 60 ~ 80 sec
  - ACT : 140 ~ 180 sec

Centrifugal pump

- (Karl et al. *Semin Thorac Cardiovasc Surg Pediatr Card Surg Ann* 2006)
- Postop. Support of 116 children (1989~2005)
- Median age : 3.0 months (2 days ~ 19 yrs)
- Median Bwt. : 4.6kg (1.9 ~ 70kg)
- Median support time : 75 hrs
- The probability of weaning : 66%
- The probability of hospital discharge : 43%
- Complications
  - Re-exploration for bleeding : 19 pts
  - Sepsis : 3 pts
  - neurologic deficits : 3 survivors
  - No permanent renal sequelae
  - mechanical circuit complication: 12 pts

Clinical Use of VAD in Children

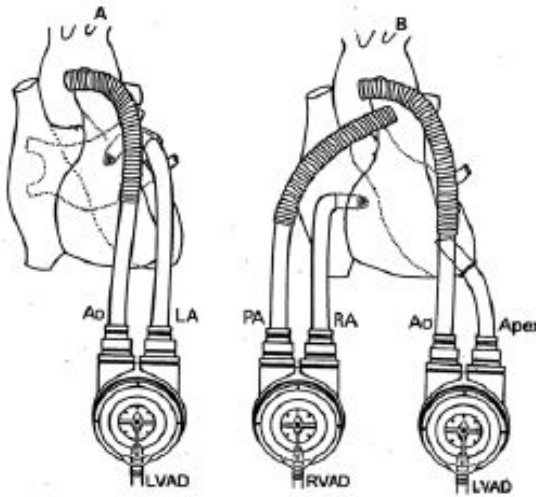
(Blume et al. Outcomes of Children Bridged to Heart Transplantation with Ventricular Assist Devices: A Multi-institutional Study. *Circulation* 2006)



	Age, y			
Device Type	0–5	5–10	10–15	>15
Long term				
Thoratec VAD (Thoratec Corp, Pleasanton, Calif)	0	5	31	17
Heartmate LVAS (Thoratec Corp, Pleasanton, Calif)	0	0	8	8
Novacor LVAS (WorldHeart Inc, Oakland, Calif)	0	0	2	1
EXCOR Pediatric (Berlin Heart AG, Berlin, Germany)	1	0	0	0
Short term				
BVS 5000 (Abiomed Inc, Danvers, Mass)	0	1	6	3
Bio-Pump (Medtronic, Minneapolis, Minn)	9	2	5	0

Device unspecified. n=3.

Pulsatile pump - Thoratec

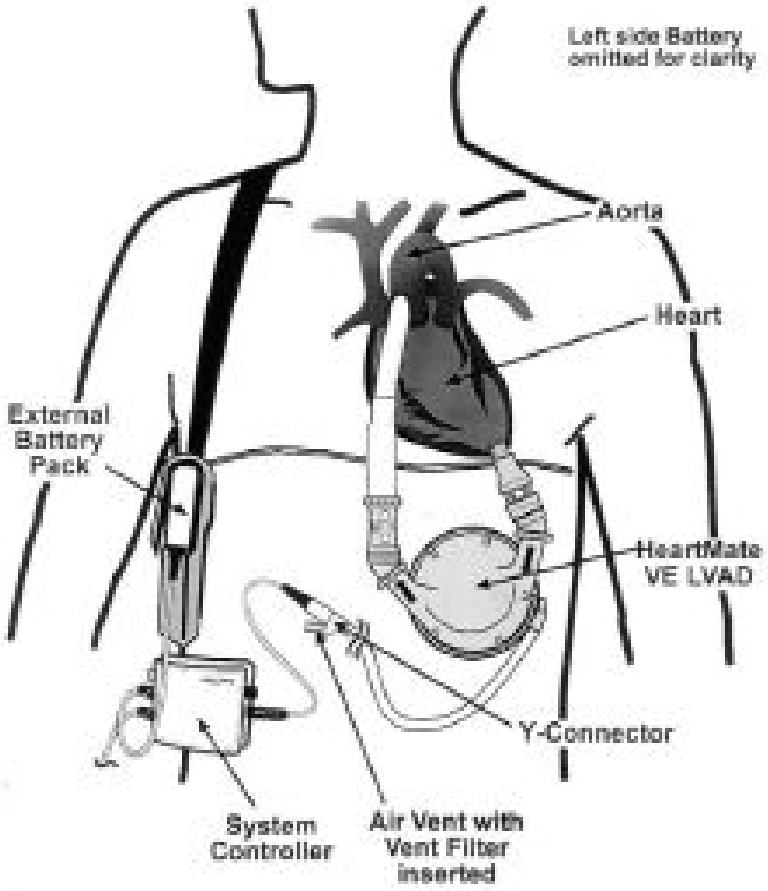


- Thoratec VAD (Thoratec Corp. Pleasanton, CA)
  - pneumatically driven
  - a blood sac (65 cc)
  - Björk-Shiley valves
  - maximal output of 7 L/min
  - limited by its size because it is limited to patients with a BSA > 0.7 ~ 0.8m^2
- Only FDA-approved longterm Bi-VAD

Pulsatile pump - Thoratec

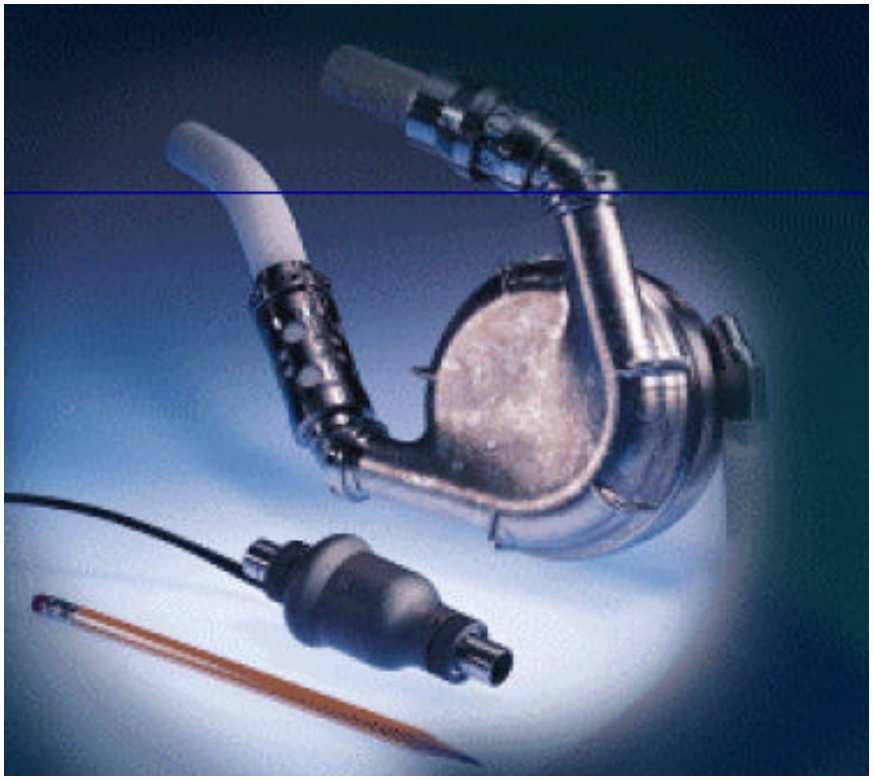
- (Hill. *Semin Thorac Cardiovasc Surg Pediatr Card Surg Ann* 2006)
- 209 patients
  - Mean age : 14.5 years (5 ~ 18 years)
  - Mean BWt. : 57 kg (17 ~ 118 kg)
  - Mean duration of VAD support : 44 days (0 ~ 434 days)
- Survival to transplantation or recovery : 68.4%
  - cardiomyopathy 74.1 %, acute myocarditis 86.0%, CHD 27.3%
- Overall survival rate in smaller children (BSA <1.3 m2) : 51.7%(n=31)
- Thromboembolisms and neurologic hemorrhagic events
  - thrombus formation because of a reduced blood flow
  - systolic hypertension from a large stroke volume for the relatively oversized device
  - Ventricular cannulation for inflow
  - Fixed rate mode 80-90 stroke/min with partial stroke volume and high drive pressure

Pulsatile pump – HeartMate



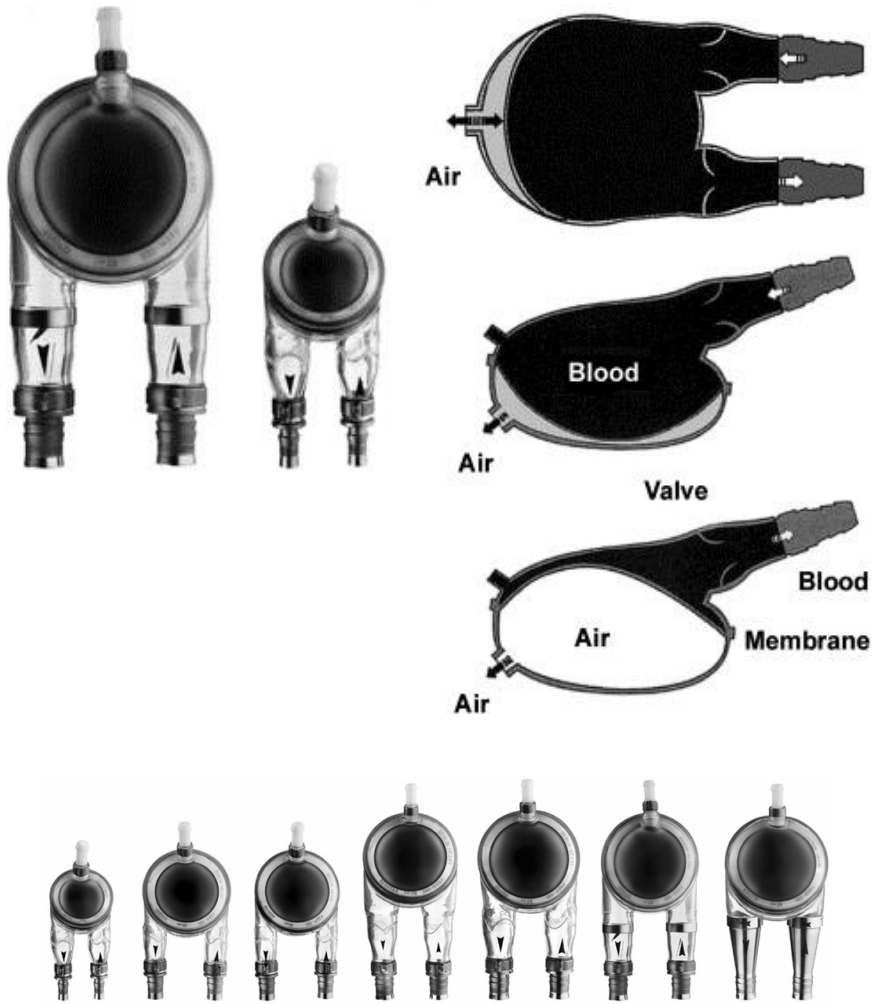
- implantable, long-term, univentricular cardiac assist device
  - Flattened titanium cylinder
  - Polyurethane diaphragm
  - LV apex cannulation
- Less need for anticoagulation
- the first FDA approved device as a bridge-to-transplant
- pneumatically driven (implantable pneumatic [IP]) and electrically powered (vented electric [VE])

Pulsatile pump – HeartMate



- very low thromboembolic rate (5%) without anti-coagulation
- Limitations
  - Flows of 3.0 liters/min may predispose to clot formation inside the pump
  - BSA > 1.5m2
  - Right heart failure

Pulsatile pump – Berlin Heart

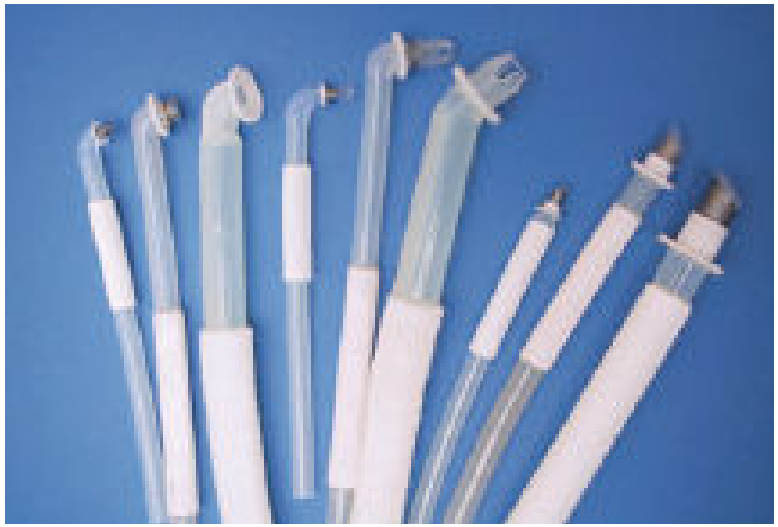


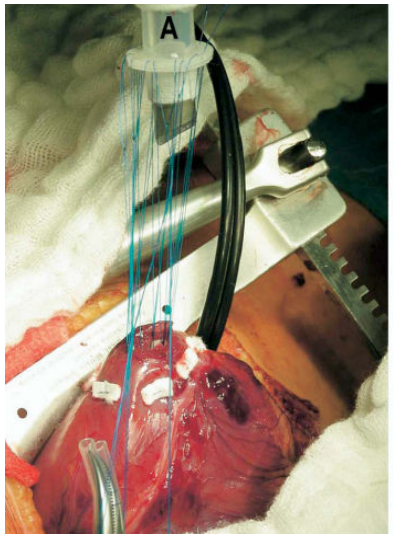
- Composition
  - translucent, semirigid housing of polyurethane
  - a blood chamber and an air chamber divided by flexible diaphragm
  - Trifleaflet polyurethane valves
- has been used in Europe in pediatric patients since 1992
- available in a range of sizes with pump volumes of 10 to 80 cc for use in infants through adults
- can be used down to a BSA of 0.2 m^2

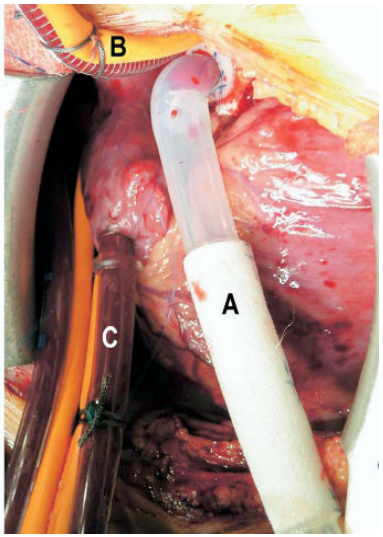
Pulsatile pump – Berlin Heart

- currently not approved by the US Food and Drug Administration, but can be obtained with emergency exemptions
- (Hetzer et al. *Semin Thorac Cardiovasc Surg Pediatr Card Surg Ann* 2006)
  - 68 children
  - Mean age 7.6 yrs (2 days ~ 17 yrs)
  - Mean VAD support 35 days (0~420 days)
  - 62% survived to transplantation or after weaning

Pulsatile pump – Berlin Heart

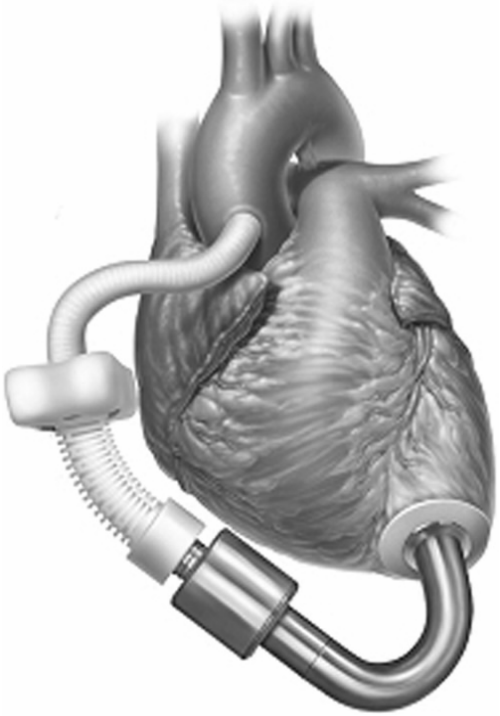


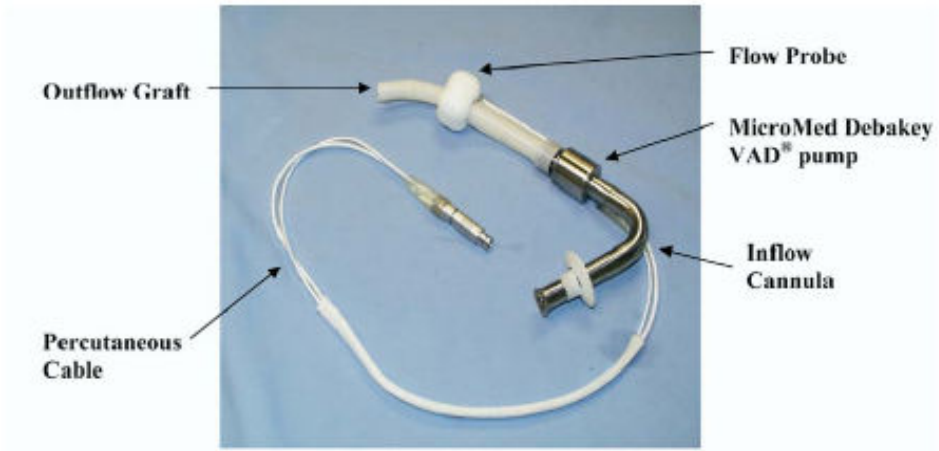


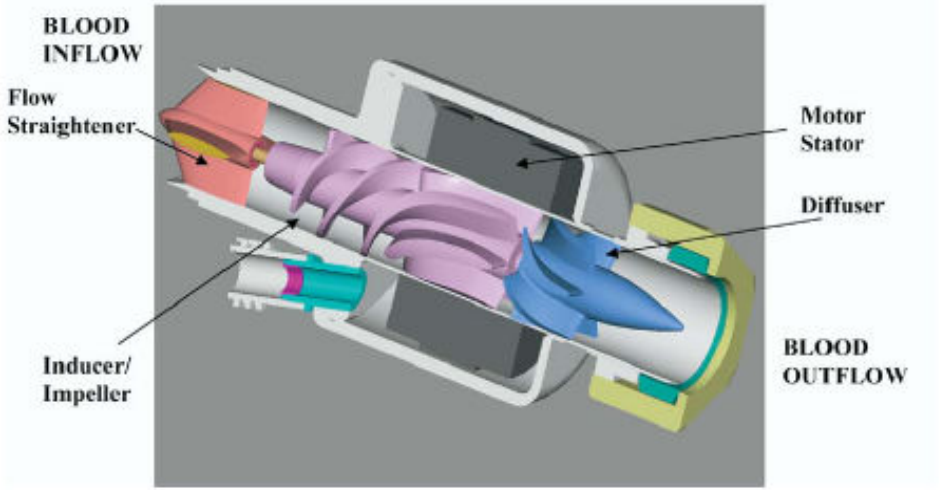


- No clinically significant hemolysis
- 4 patients suffered cerebral thromboembolism without apparent neurologic impairment.
- 15 Re-exploration for bleeding
- Survival in infants was similar to that of older children after 1999

Axial Flow Pump – Micromed DeBakey

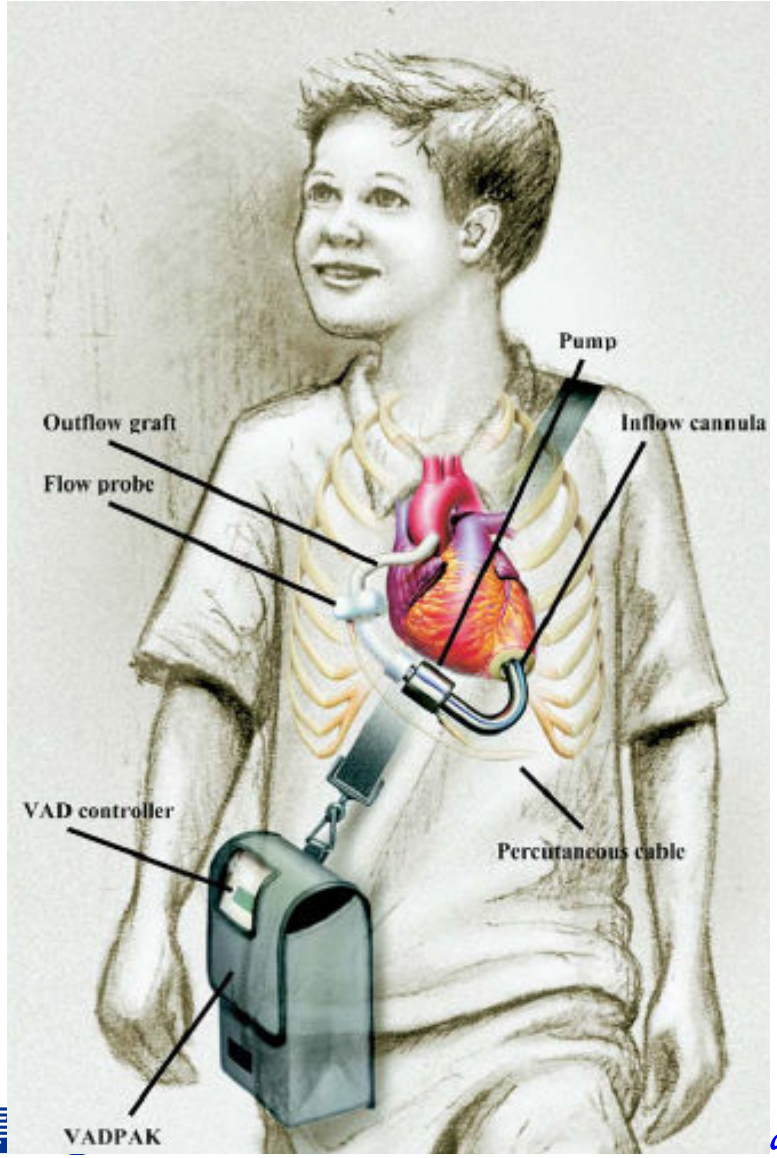






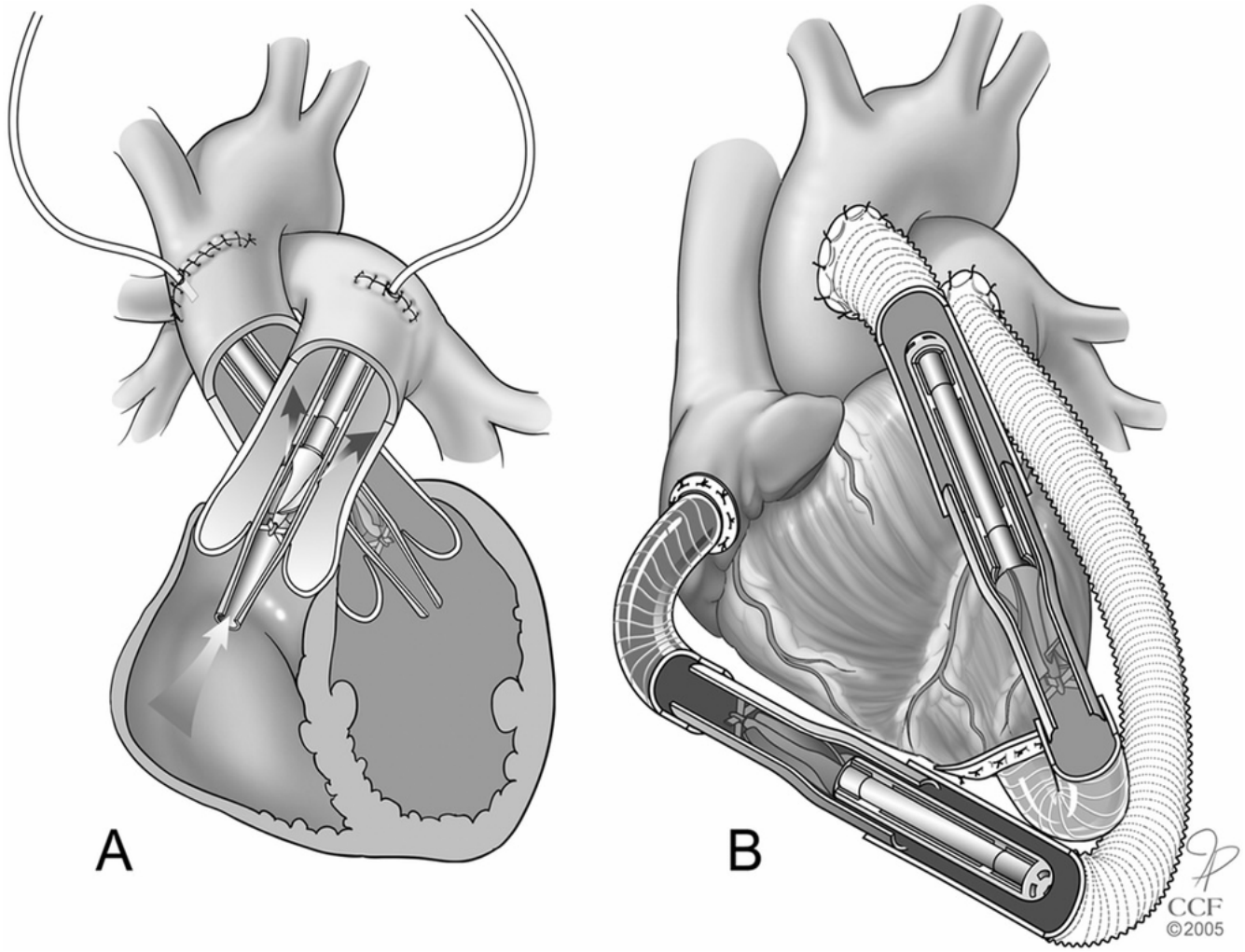
- a magnetic housing and impeller that can provide up to 10 L/min of flow
- continual flow without stasis

MicroMed DeBakey VAD Child device (MicroMed Technology, Inc, Houston, TX)

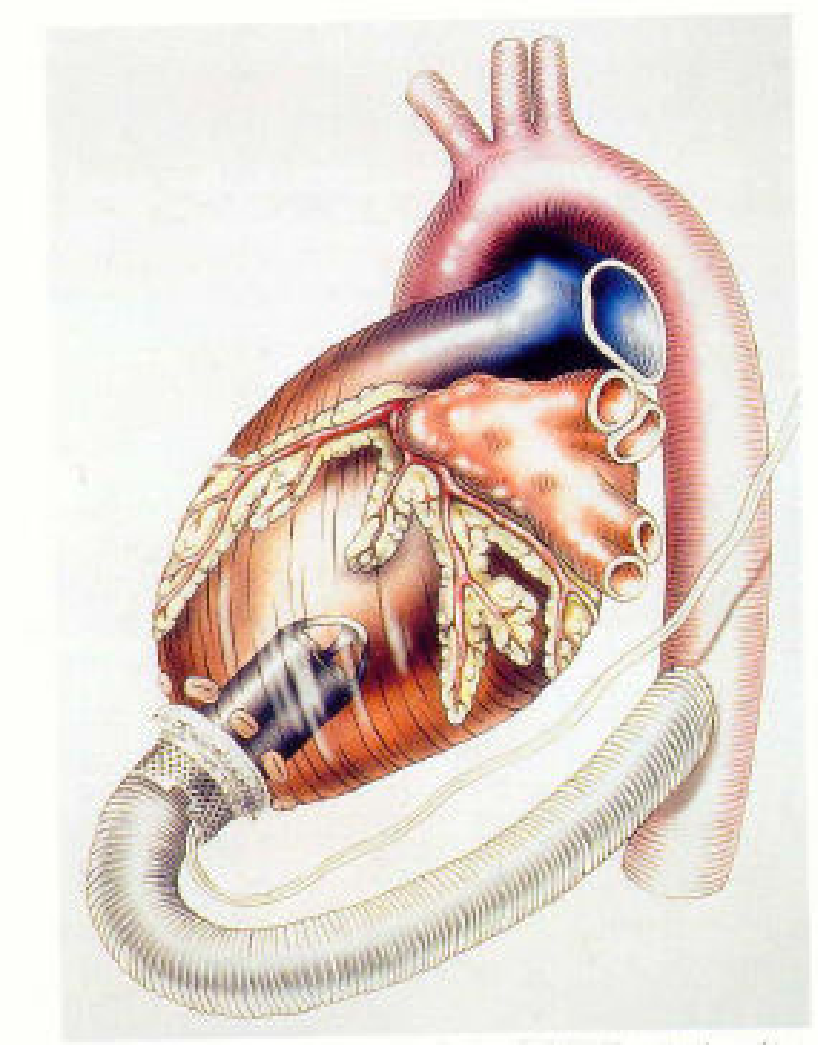


- 5 ~ 16 years of age
- 0.7 < BSA < 1.5 m2 (HDE approval February 2004)
- first implanted at Texas Children's Hospital (Houston, TX) in 2004.
- (Fraser et al. *Semin Thorac Cardiovasc Surg Pediatr Card Surg Ann* 2006)
  - 6 children
    - Mean age 11.3 yrs
  - Mean support 39 days
  - 50% survival to transplantation
- 55% survival in > 150 patients in adults (Goldstein *Circulation* 2003)

Axial Flow Pump - Pedipump



Axial Flow Pump – Jarvik 2000



FDA approved VADs

Device	Duration	Type of support	Device cost	Hospital discharge
Abiomed BVS 5000	Short	Uni-, biventricular	$140,000 startup, $12,400 per pump, $64,500 console	No
Thoratec LVAD	Short/long	Uni-, biventricular	$46,765 per pump,* $1,500 per cannula, $60,000 console, $150,000 startup	No
Novacor LVAD	Long	Univentricular	Implant kit (pump/cannulae) $74,500, $55,000 console, $196,000 startup (plus 2 implant kits)	Yes
Thoratec IP HeartMate	Long	Univentricular	$45,000 (pump)	No
Thoratec VE HeartMate	Long	Univentricular	$64,000 (pump), $278,450 startup	Yes

NHLBI Pediatric Circulatory Support Program (2004)

- PediPump (Cleveland Clinic Foundation)
- PediaFlow VAD (University of Pittsburgh)
- Pediatric Cardiac Assist System/pCAS (Ension, Inc, Harmar, PA)
- Pediatric Jarvik 2000 (Jarvik Heart, Inc, New York, NY)
- Pediatric VAD/PVAD (Pennsylvania State University)

Conditions for use of the Micromed DeBakey VAD Child under HDE status

Requirement
Patients must be listed for cardiac transplantation
Patients age, 5 to 16 years of age
Patient BSA, 0.7 to 1.5m2
Patients should be in NYHA class IV heart failure that is refractory to medical therapy
Device use is limited to temporary left ventricular mechanical circulatory support as a bridge to cardiac transplantation

Summary

- ECMO

Advantages	*Disadvantages*
▪ Versatile ▪ Track record ▪ Peripheral/percutaneous cannulation ▪ Can be used in patients of any size ▪ Biventricular support	▪ Short-term use only ▪ Complex circuit ▪ Complications • Bleeding • Thromboembolic ▪ Extracorporeal ▪ No ambulation / rehabilitation potential during support

Summary

- Bio-Pump

Advantages	*Disadvantages*
■ Track record ■ Can be used in patients of any size ■ LVAD, RVAD, BVAD	■ Short-term support only ■ Complications • Bleeding • Thromboembolic ■ Extracorporeal ■ No ambulation / rehabilitation potential during support

Summary

- Adult Device

Advantages	*Disadvantages*
■ Chronic support ■ Usually paracorporeal ■ Allows ambulation/rehabilitation during support ■ Excellent performance ■ LVAD, RVAD, BVAD	■ Use limited to older children ■ Decreased washout in smallest patients leads to high incidence of thromboembolic complications

Summary

- Berlin Heart VAD

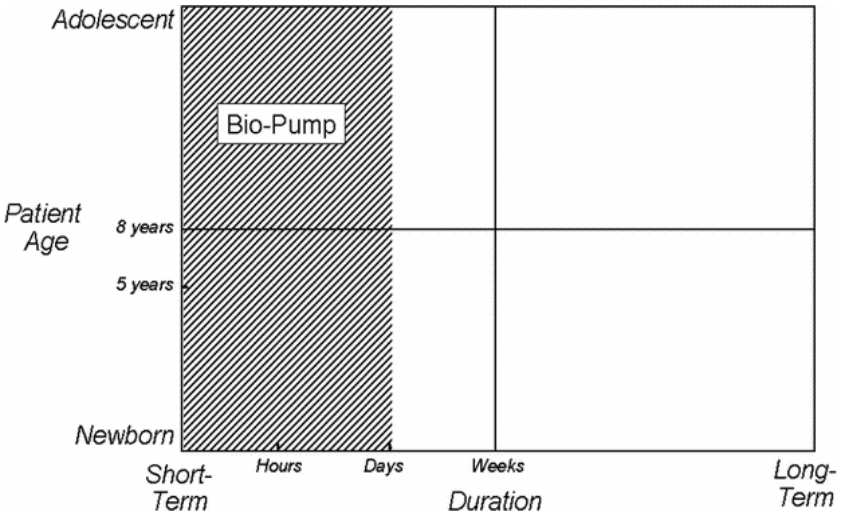
Advantages	*Disadvantages*
■ Can be used in patients of any size ■ Paracorporeal ■ Allows ambulation/rehabilitation during support ■ Excellent performance ■ Chronic support ■ LVAD, RVAD, BVAD	■ Available on emergency basis only in US centers

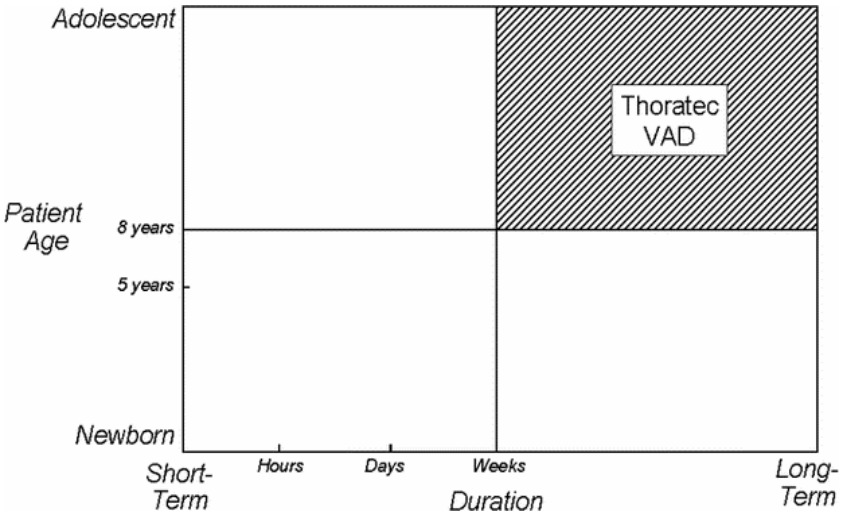
Summary

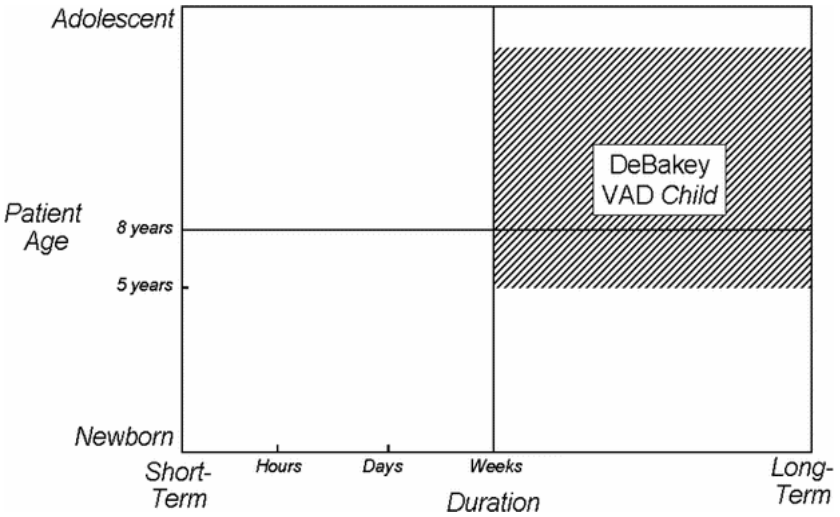
- DeBakey VAD Child

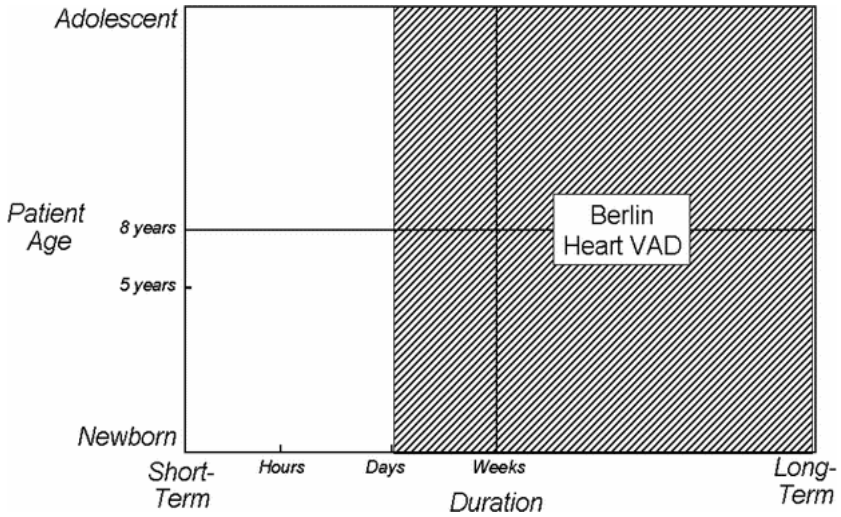
Advantages	*Disadvantages*
■ Implantable	■ Limited age range (5 to 16 years)
■ Allows ambulation/rehabilitation during support	■ Implantation difficult in samllest patients
■ Excellent performance	■ LVAD only
■ Chronic support	■ Limited indications
■ LVAD, RVAD, BVAD	

Summary


Adolescent
Bio-Pump
Patient Age
8 years
5 years
Newborn
Short-Term
Hours
Days
Weeks
Duration
Long-Term


Adolescent
Thoratec VAD
Patient Age
8 years
5 years
Newborn
Short-Term
Hours
Days
Weeks
Duration
Long-Term


Adolescent
DeBakey VAD Child
Patient Age
8 years
5 years
Newborn
Short-Term
Hours
Days
Weeks
Duration
Long-Term


Adolescent
Berlin Heart VAD
Patient Age
8 years
5 years
Newborn
Short-Term
Hours
Days
Weeks
Duration
Long-Term

Conclusion

78세 환자에 심장이식 성공

삼성서울병원

78세 심부전 환자에게 심장을 이식하는 수술이 성공을 거뒀다.

삼성서울병원 심장혈관센터 박표원·전문의 교수팀은 지난달 9일 심부전증을 앓고 있는 조 모씨(전북 김제)에게 뇌사자 심장을 이식하는 수술을 해 현재 정상으로 회복중이라고 5일 밝혔다.

이번에 심장이식을 받은 조씨는 99년 협심증 진단을 받고 약물치료를 해왔으나 올해 5월부터 하루 7~8회의 잦은 통증으로 병원을 찾았고 원인불명의 심부전으로 진단받았다.

그 동안 국내에서는 70세 이상 환자의 심장 이식이 한 차례 더 있었으나 수술에 성공하기는 이번이 처음이다. 삼성서울병원의 심장이식수술자의 평균연령은 43세에 불과하다.

박표원 교수는 "신체적·정신적으로 건강하다면 고령은 심장수술에 더 이상 큰 장애가 아니다"며 "앞으로 고령 환자에 대한 고난도 수술이 더욱 증가할 것"이라고 전망했다.

김원목기자