Total Artificial Heart

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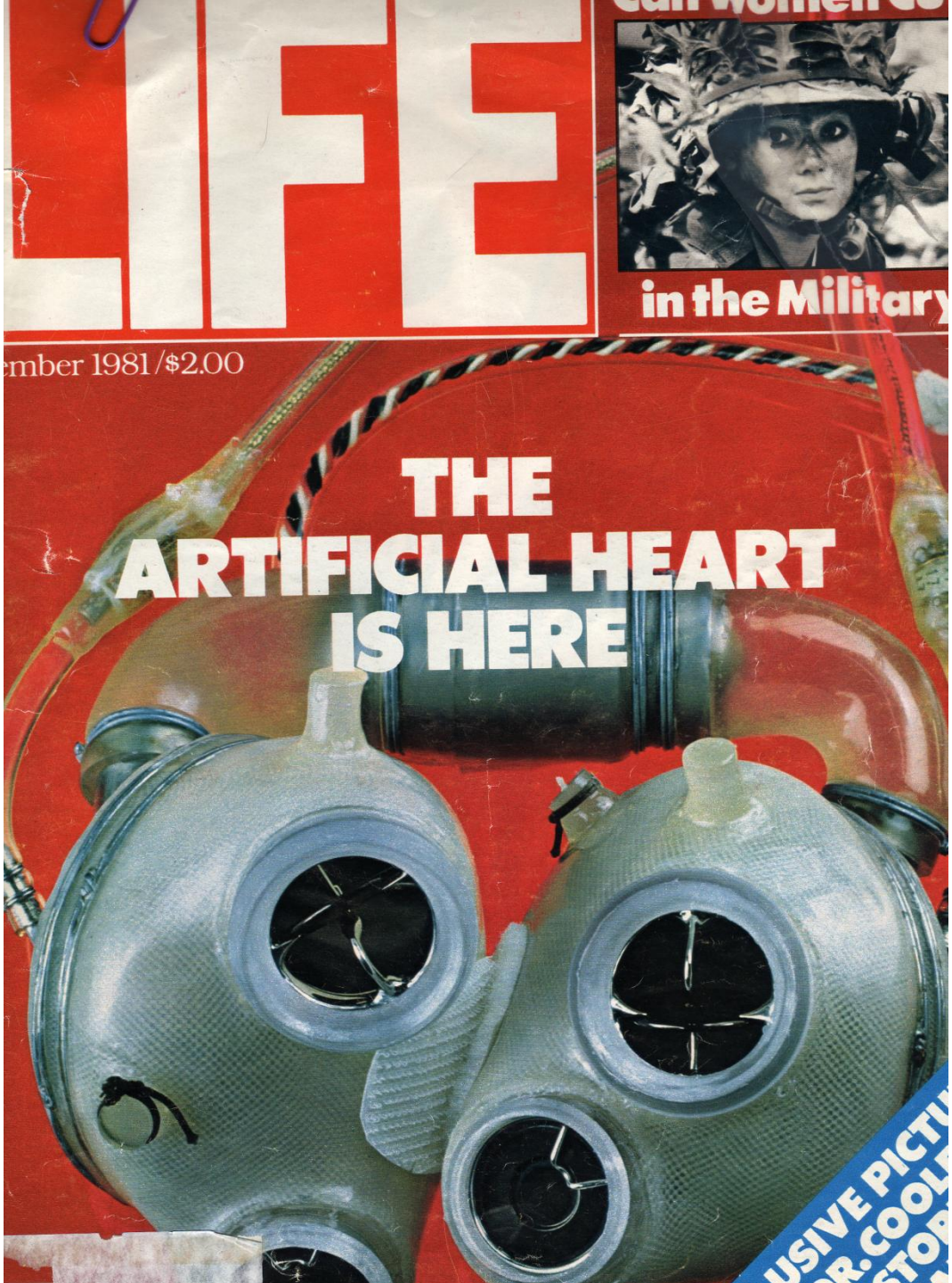
Dubrovnik, 26-29.09.2013.


LIFE
in the Military
ember 1981/$2.00
THE
ARTIFICIAL HEART
IS HERE

Becoming the Standard of Care

Bi-Ventricular Failure

- Pediatric and Adult Congenital
- Persistent Ventricular Tachycardia
- Cardiomyopathy:
  - Restrictive
  - Infiltrative
  - Hypertrophic
  - Amyloid
- Refractory Cardiogenic Shock
- Transplant Rejection
- Acquired VSD

Unique Uses

"The SynCardia TAH-t is the only……."

- FDA Approved TAH, ever.
- Device:
  -That lowers CVP to single digits, creating the potential for liver and kidney recovery.
  - For failure of the transplanted heart.
  - For massive LV infarct.
  - For Acquired VSD.
  - For ventricular rupture.
  - That diffuses mural thrombus.
  - For some congenital conditions.
  - For cardiac malignancies.
  - For severe hypertrophic cardiomyopathy.
  - For amyloid cardiomyopathy.

Indications for Use of TAH

INTERMACS Level 1 - NYHA Class IV

Data as of June 10, 2013

Indications (Worldwide)	
Cardiomyopathy	73%
Other	27%

Number of Cases	
AcuteMI	95
Cardiogenic Shock	43
Rejection	40
Hypertrophic Cardiomyopathy	31
Congenital	27
LVAD Device Failure	29
Arrhythmias (inc. VT)	15
Ventricular Septal Defect (VSD)	7

Source: Internal Database, Patient Implant Forms, Total World as of 6/10/13

"Other" Indications Success

Data as of June 10, 2013

Patient Status Pre-Implant (North America)	
Pre-Implant Heart Condition	**% Transplanted or alive on device**
AcuteMI	74.5%
Cardiogenic Shock	81.8%
Rejection	59.3%
Hypertrophic Cardiomyopathy	70.0%
Congenital	73.3%
LVAD Device Failure	64.7%
Arrhythmias (inc. VT)	66.7%
Ventricular Septal Defect (VSD)	75.0%

100% of patients under the age of 21 with a congenital diagnosis have been successfully BTT or are alive on device.

Source: Internal Database, Patient Implant Forms, US and CAN as of 6/10/13

TAH

- Severe biventricular dysfunction & aortic regurgitation requiring aortic valve replacement
- Apex canulation impossible due to friable tissue
- Myocardial necrosis, expected perforation or thrombus formation in the ventricle

TAH

- Malignant heart tumor
- Therapy-resistant malignant arrhythmia
- Chronic or acute severe rejection after heart transplantation, not responding to medical treatment

US Centers

Abbott Northwestern Hospital
Advocate Christ Hospital
Allegheny General Hospital
Arkansas Children's Hospital
Aurora St. Luke's Hospital
Banner Good Samaritan
Barnes Jewish Hospital
Baylor University Medical Center
Boston Children's Hospital
Brigham & Women's Hospital
Carolinas Medical Center
Cedars-Sinai Medical Center
Children's Hospital of Philadelphia
Children's Hospital Wisconsin
The Christ Hospital Cincinnati
Cincinnati Children's
Cleveland Clinic
Froedtert Hospital
Hermann Memorial
The Hospital at the University of Pennsylvania
Indiana University/Clarion
Inova Fairfax
Integris Baptist Medical Center
Intermountain Medical Center
Lucile Packard Children's Hospital at Stanford
Massachusetts General
Mayo Clinic, Rochester
Mayo Clinic, Jacksonville
Mayo Clinic, Phoenix
Methodist DeBakey Heart & Vascular Center
Montefiore-Einstein Medical Center
Mott Children's Hospital
Mt. Sinai Medical Center
Nebraska Medical Center
New York Presbyterian /Columbia
Ochsner Medical Center
Ohio State University Medical Center
Penn State University Medical Center
Phoenix Children's Hospital
Primary Children's Hospital
Providence Sacred Heart Medical Center
Rush University Medical Center
St. Joseph's Heart & Vascular Center
St. Thomas Hospital
St. Vincent's Hospital
Sentara Heart Hospital
Seattle Children's
Seton Heart Specialty Care/Transplant
Shands Hospital University of Florida Gainesville
Sharp Memorial Hospital
Spectrum Health Grand Rapids
Stanford University
Strong Memorial
Tampa General
Temple University Hospital
Texas Children's Hospital
Texas Heart Institute
Thomas Jefferson University Hospital
University of Arizona Medical Center
University of California Los Angeles Medical Center
University of California San Diego
University of Chicago Medical Center
University of Iowa Hospitals
University of Kentucky Medical Center
University of Louisville/Jewish Hospital
University of Maryland
University of Michigan
University of Minnesota
University of North Carolina
University of Pittsburgh Medical Center
University of Southern California CV Thoracic Institute
University of Utah
University of Washington Medical Center
University of Wisconsin Hospital
Vanderbilt University Medical Center
Virginia Commonwealth University Medical Center
Yale New Haven Hospital

OUS Centers

AHEPA, Thessoliniki, Greece

Akdeniz Antalya, Turkey

Allemaines Krankenhaus, Vienna

Azienda Ospedaliera di Padova

Bakoulev Moscow, Russia

CHU, Bordeaux

CHU, Tours

CHU, Rennes

CHU, Rouen

Deutsches Herzzentrum Berlin

Ege, Izmir, Turkey

Florence Nightingale, Istanbul, Turkey

Freeman, Newcastle, United Kingdom

Friedrich-Alexander University Hospital Erlangen

Gazientep University Hospital, Turkey

Groupe Hospitalier LaPitie-Salpetriere

Hannover Medical School, Germany

Herz-und Diabeteszentrum Nordrhein Westfalen

Herzzentrum Leipzig GmbH Universitaetsklinik

Herzzentrum Koln

Hopital Guillaume et Rene Laennec/Centre Hospitalier

Universitaire de Nantes

Inselspital Bern

Kerckhoff, Bad Nauheim, Germany

Kosuyolu Kalp, Istanbul, Turkey

Mondaldi Hospital, Naples

Montreal Heart Institute

National Research Cardiac Center, Astana, Kazakhstan

Nine September, Izmir, Turkey

Onassis Heart Center, Athens

Onze Lieve Vrouwz, Aalst

Ospedale Niguarda, Milan

Ospedale San Camillo, Rome

Ospedale Bambino Gesu, Vatican City

Ospedale San Gerardo di Monza, Italy

Ospedale Sant'Orsola Malpighi Bologna, Italy

Ospedali Riuniti di Bergamo, Italy

Papworth Hospital, United Kingdom

Policlinico Santa Maria alle Scotte, Siena, Italy

Rabin Medical Center, Israel

S Maria dela Misericordia, Udine, Italy

Sahlgrenska Universitetssjukhuset, Goteburg

San Raffaele, Italy

Santariskiu, Vilnius, Lithuania

St. Vincent's, Sydney, Australia

Siyami Ersek, Istanbul, Turkey

YIH, Ankara, Turkey

Universitatsklinikum, Freiburg, Germany

Universitatsklinikum, Muenster, Germany

University Clinic, Duisburg, Germany

University Hospital Dusseldorf

University Hospital Innsbruck

University Hospital Lund

University of Ankara, Turkey

University of Heidelberg Hospital

University of Kaunas, Lithuania

UMC, Ljubljana, Slovenia

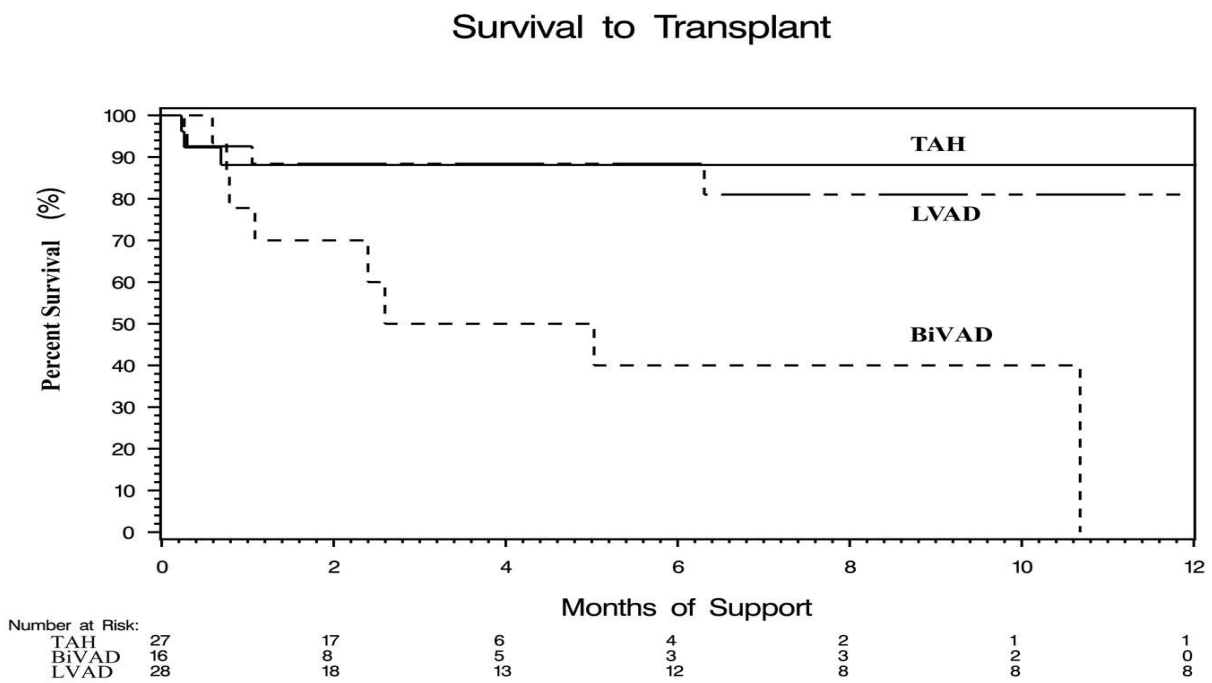
Center & Implant Growth

Year	Number of Certified Centers			Number of Implanting Centers			Number of Implants		
	US	OUS	TOTAL	US	OUS	TOTAL	US	OUS	TOTAL
2006	7	7	14	6	8	14	17	32	49
2007	12	10	22	10	8	18	26	41	67
2008	13	14	27	10	10	20	37	33	70
2009	13	15	28	8	10	18	30	33	63
2010	15	18	33	9	10	19	39	27	66
2011	24	25	49	17	14	31	44	37	81
2012	40	35	75	32	22	54	71	54	125
2013	48	39	87	31	16	47	72	34	106

Freedom Driver

is the Game Changer!

Data Rules!



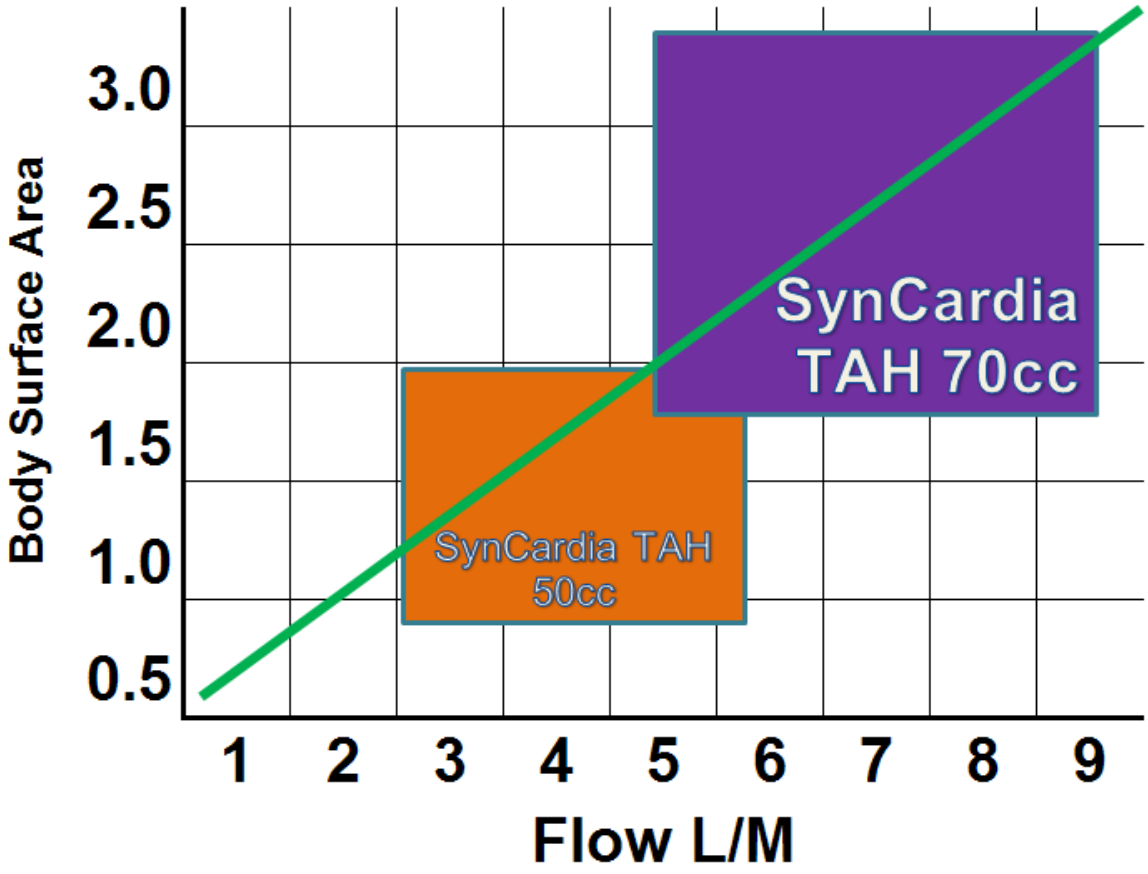
Source: "Survival to Transplant in Patients Undergoing Mechanical Circulatory Support as Bridge: Retrospective Analysis of LVAD, BiVAD and TAH Strategy." *O.E. Pajaro, A.V. Kalya, R.S. Gopalan, L.L. Staley, K.L. Diane, J.M. Spadafore, C.N. Pierce, B.N. Noble, C. Krishnaswamy, R.L. Scott, F.A. Arabia. Presented as an abstract at the International Society for Heart & Lung Transplantation (ISHLT) 32nd Annual Meeting, Concurrent Session 43: VAD Bad, April 21, 2012.*

50 cc TAH

70 cc
Needs 10 cm
T-10 → Sternum

50 cc
Needs 7 cm
T-10 → Sternum

In Process
50cc Heart



AIM

- Primary use of total artificial heart

WHY

To avoid other complications as:

- Bleeding
- Infection
- Tromboembolic events

IS IT

- Postinfarction ventricular septal defect (PI VSD)?

Strategies

Early closure

- Immediately eliminates the detrimental effect of blood shunting, but at the risk of exposing the usually hemodynamically unstable patient to the risk of surgery.
- Additionally, early operative management usually means operating in a friable myocardium.

Postponing surgical repair to a later time

- gives the theoretical advantage of myocardial recovery and scar tissue formation.
- mechanical circulatory support to impart hemodynamic stability and delay surgical treatment until such time as myocardium recovers and scar tissue forms around the defect.

Bridge to repair or BTT or bridge to bridge

- ECMO
- LVAD
- BiVAD

Posterobasal VSD – surgical repair?

Possible

- High mortality
- High morbidity


VERY HARD
00
13
21
16
23
64

Posterobasal VSD with mitral valve involvment – surgical repair?

MISSION IMPOSSIBLE

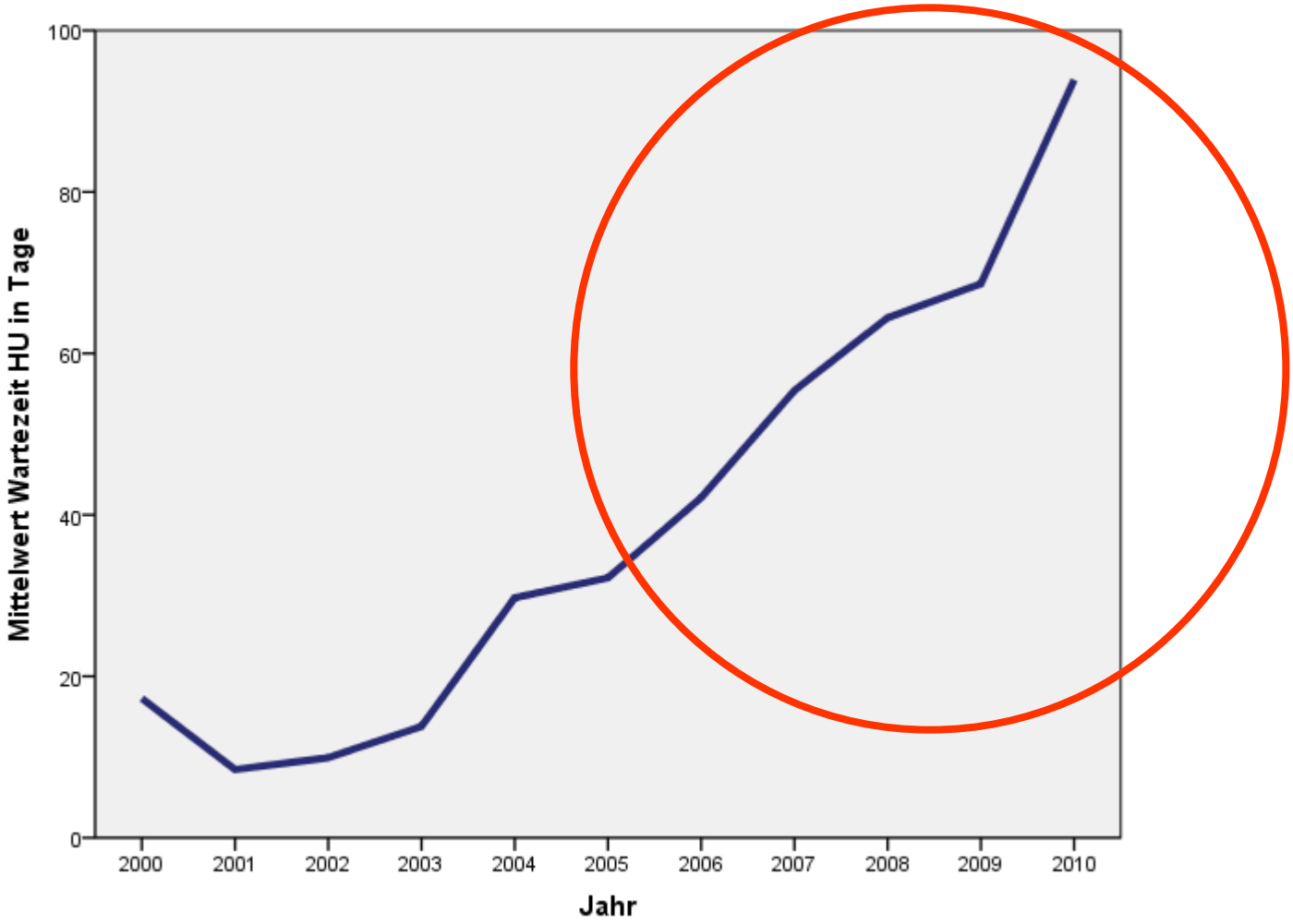
Bridge to transplantation

- ECMO
- LVAD
- BiVAD

BTT

- Waiting time for Tx
- Eurotransplant – UNOS
- HU listing - 20 days to 120 days

Median waiting time for HU



- Add some new complications

BTT
or bridge to bridge

- ECMO
- LVAD
- BiVAD

- Add some new complications

CASE

Use of a totally artificial heart for a complex postinfarction ventricular septal defect.

Knezevic I, Jelenc M, Danojevic N, Racic M, Poglajen G, Ksela J, Androcec V, Mesar T, Mikuz U, Vrtovec B. Heart Surg Forum. 2013 Jun;16(3).

- October 2011, a 60 year-old man
- history of tobacco abuse
- episode of chest pain,
- dyspnea and exercise intolerance of one week duration.
- ECG - subacute inferior wall myocardial infarction, troponin and LDH levels were 35,8 µg/l and 3.7 µkat/l, respectively.

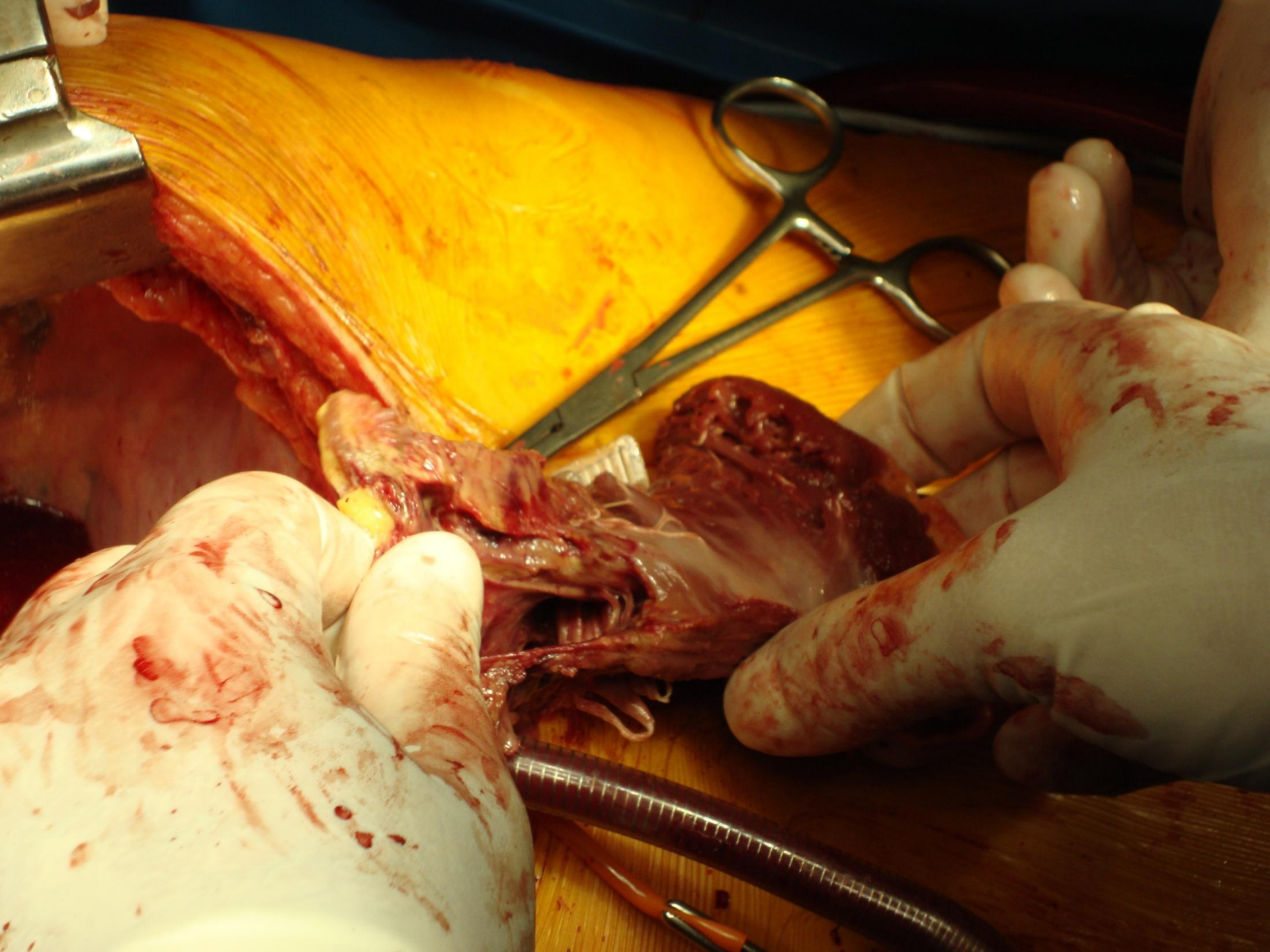
- Emergently taken to the cardiac catheterization laboratory, where complete occlusion of the distal third of the right coronary artery was found.
- Percutaneous coronary intervention was performed, with two bare-metal stents inserted and a left ventriculography showed a VSD.

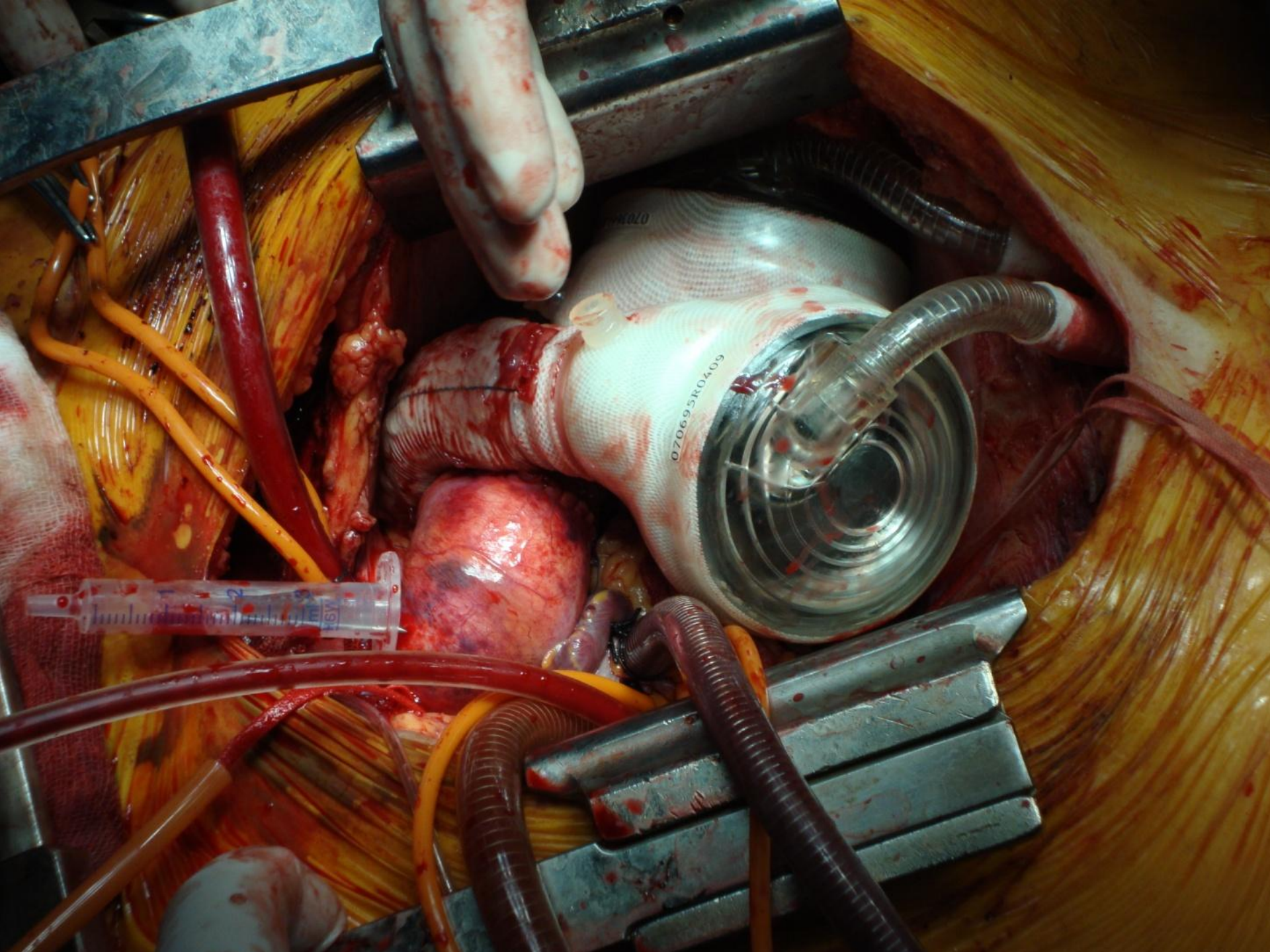
- hemodynamically unstable with a blood pressure of 84/71 mm Hg and moderately tachycardic.
- intra-aortic balloon pump
- transthoracic echocardiography immediately post insertion showed a large VSD in the posterior part of the interventricular septum with an estimated size of approximately 1.5 cm and the pulmonary-to-systemic flow (Q_p/Q_s) was 2.1.
- Systolic function was mildly depressed with an estimated ejection fraction of 50%.

- patient required norepinephrine pressor support.
- Subsequent cardiac echocardiography studies revealed **progression of the VSD size**. On the third day, the diameter of the VSD had already increased to **3 cm** and a pulmonary-to-systemic flow (Q_p/Qs) of 3.1 was measured.
- interventricular rupture was **extending up to the mitral valve annulus**, causing mitral regurgitation.

- Due to the extensive and complex tear in septal myocardium that included the mitral valve apparatus, it was concluded that operative closure of the VSD was technically not feasible and the patient was presented as a candidate for total artificial heart (CardioWest, Syncardia, Inc.).

- The patient was taken to the OR on the fourth day post-admission

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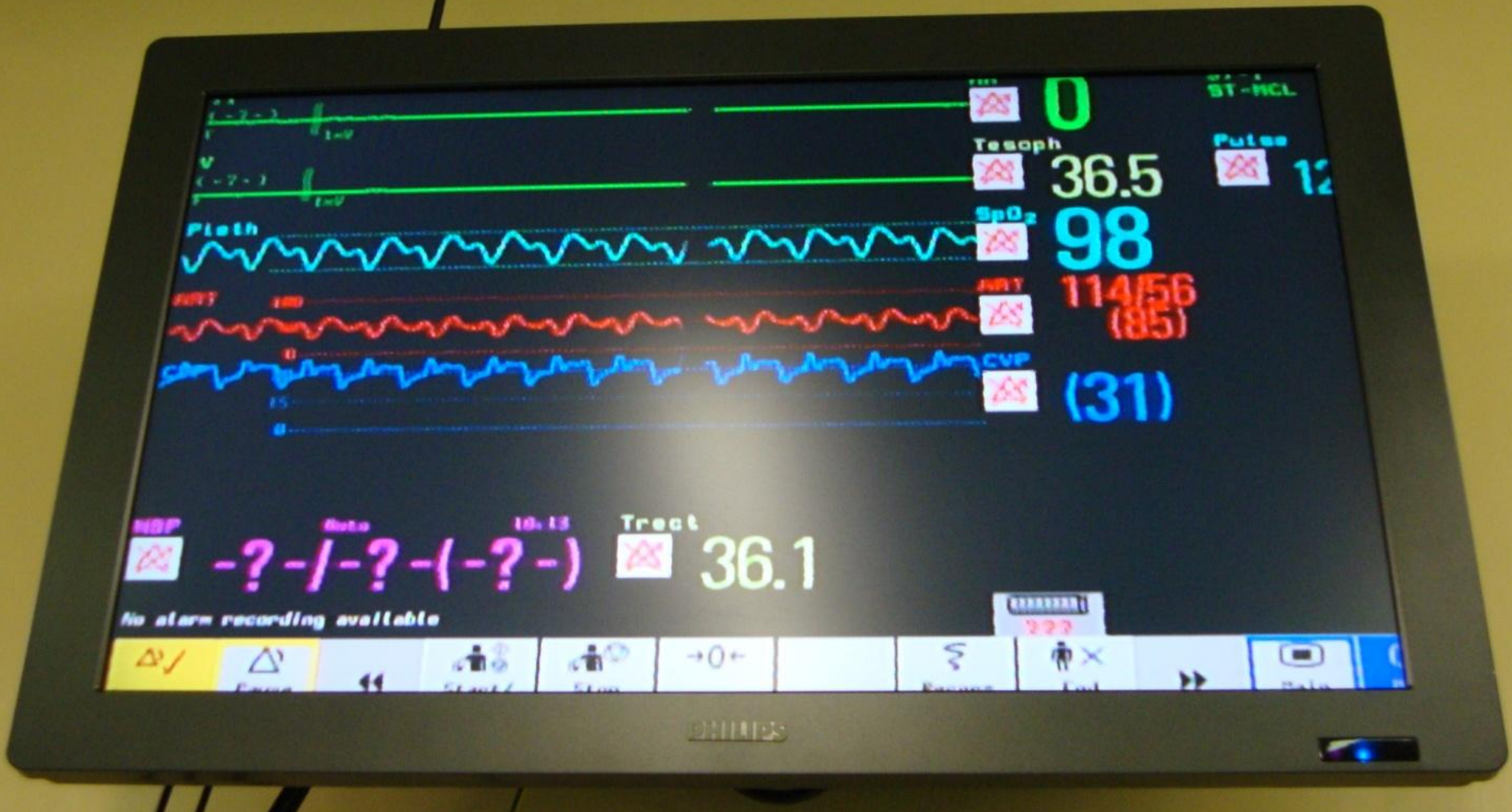

ST-HCL
Tesoph
36.5
Pulse
Pleth
SpO2
98
114/56
(85)
CVP
(31)
Treat
36.1
-?-/-?-(-?-)
No alarm recording available
PHILIPS

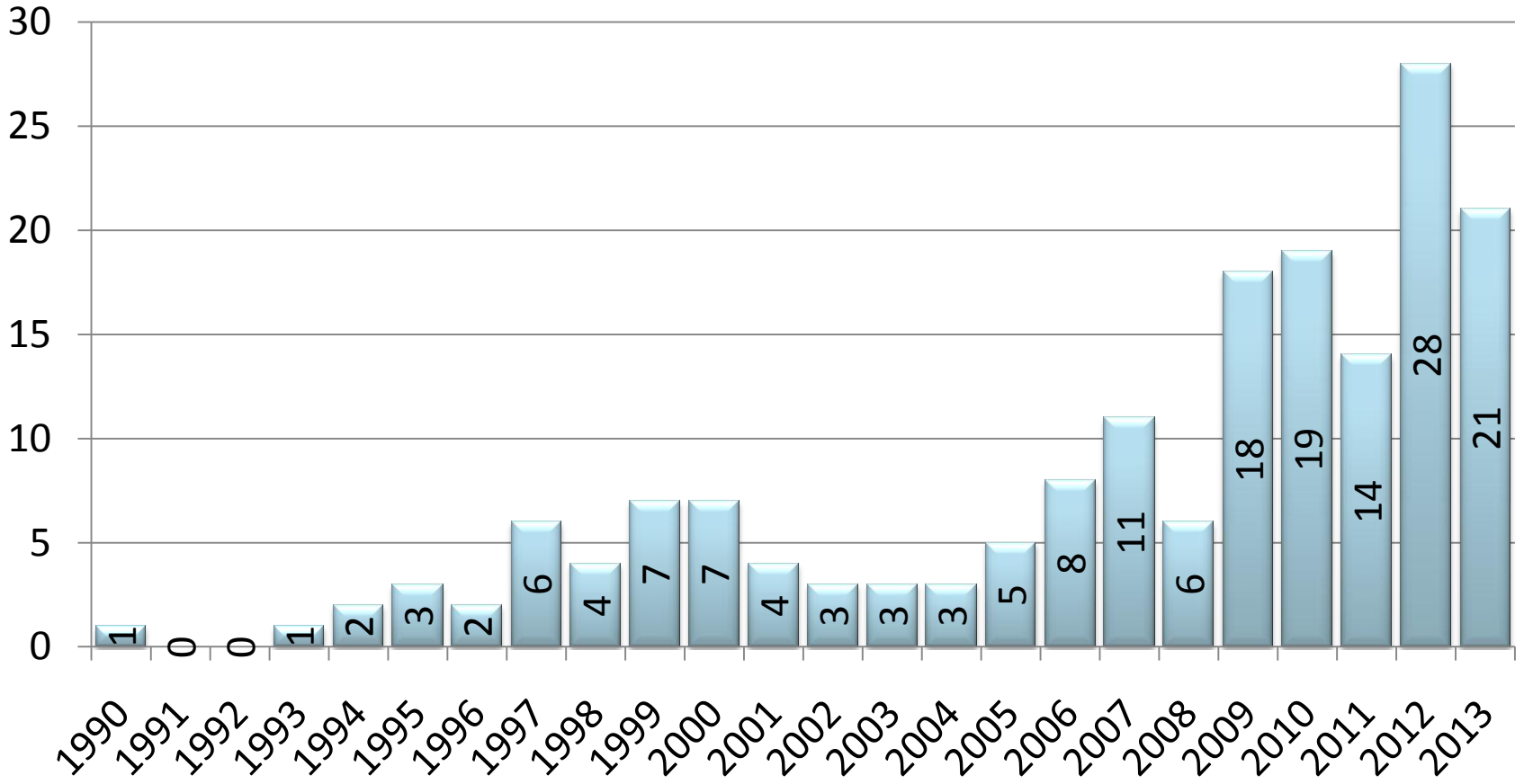
- He was discharged on the Freedom portable driver on ***day 51*** and was on the transplantation list awaiting cardiac transplantation.
- He was discharged home on ***day 63*** completely independent to perform daily activities.

- Patient was transplanted on ***day 256***.

TAH Syncardia; 3 pts, 3 BTT

- 1. male 60 yrs 256 days
- 2. male 52 yrs 22 days
- 3. male 65 yrs 75 days

Heart transplants in Slovenia



- Primary use of the total artificial heart represents a new option in those patients that were classically considered poor candidates for surgery and were consequently managed medically with very high mortality