Berlin Heart®

EXCOR® Adult

Successful Treatment of Biventricular Heart Failure Using the EXCOR® Adult VAD

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Gold Standard in Biventricular Circulatory Support

The EXCOR® VAD – Gold Standard in Biventricular Circulatory Support

- Severely decompensated heart failure patients with signs of significant right ventricular failure may not profit from LVAD therapy alone
- 37 % of patients in the ENDURANCE trial developed RV failure after LVAD placement[1]
- In case of significant RV failure, unexpected RVAD insertion is necessary to establish an adequate end-organ support
- Overall hospital mortality of up to 50 % was observed for unplanned RVAD implantation following LVAD placement, in contrast to 30 % in patients with planned BVAD implantation[2]
- Early planned BVAD implantations have improved outcomes, compared to delayed conversion from LVAD to BVAD[2,3]

"BVAD as a BTT results in high survival rates comparable to those observed in patients with LV failure treated with LVAD."[4]

[1] Pagani et al., HeartWare HVAD for the Treatment of Patients with Advanced Heart Failure Ineligible for Cardiac Transplantation: Results of the ENDURANCE Destination Therapy Trial, oral communication ISHLT 2015

[2] Takeda et al. Outcome of unplanned right ventricular assist device support for severe right heart failure after implantable left ventricular assist device insertion. J Heart Lung Transplant. 2014 Feb;33(2):141-8

[3] Fitzpatrick et al. Early planned institution of biventricular mechanical circulatory support results in improved outcomes compared with delayed conversion of a left ventricular assist device to a biventricular assist device. J Thorac Cardiovasc Surg 2009;137:971-7

[4] Bartfay et al., Gold standard in biventricular circulatory support – excellent results with an old school device, oral communication EUMS 2014

The EXCOR® System

- The EXCOR® system is the only VAD with different pump sizes for patients with biventricular heart failure, thus enabling an adaptation to the required cardiac output.
- An extensive portfolio of cannulae offers various options to fit individual anatomical needs.
- The blood contact surfaces of the EXCOR® blood pumps are coated with Carmeda® BioActive Surface (covalently bound heparin) to minimize thromboembolic complications. The transparent pump chambers allow easy use and inspection. The three-layer blood membrane ensures safe and long-term operation.
- The mobile driving unit Excor mobile allows a full day of mobility and enhanced quality of life for the patients.

FIGURE 1 EXCOR® Adult BVAD

Exceeding Outcomes in Patients with EXCOR® Adult Blood Pumps

Review of the EXCOR® Adult Bileaflet Valve Study

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Study background: evaluation of improved EXCOR® Adult blood pumps with Bicarbon™ bileaflet valves by Sorin with optimal hemocompatibility

Study objective: to confirm long-term clinical safety and device performance (effectiveness)

Primary end point: to evaluate survival of patients either to HTx, recovery or survival to 12 months on device

Prospective, observational, non-invasive, multicenter study conducted in the University Hospital Heidelberg (Germany), Universitätsspital Zurich (Switzerland) and the University Hospital Aachen, (Germany).

Observation period: September 2014 to March 2016, including 1-year follow-up.

with Bileaflet Valves

EXCOR® Adult blood pumps with bileaflet valves show an outstanding survial of 92 % in patients with biventricular heart failure

Patient characteristics

Variable	EXCOR® Adult BVAD patients (n=12)
Median age [years] (range)	43 (21 – 58)
Median weight [kg] (range)	77 (53 – 116)
Median size [cm] (range)	179 (163 – 196)
Median BMI [kg/m²] (range)	23 (20 – 30)
Male / female [%]	83 / 17
LVEF [%] (range)	15 (10 – 24)
CI [l/min/m²] (range)	1.7 (1.1 – 3.0)
Preoperative ECMO/IABP [%]	67
INTERMACS Level [%] 1 2 4	 50 42 8

Primary diagnosis

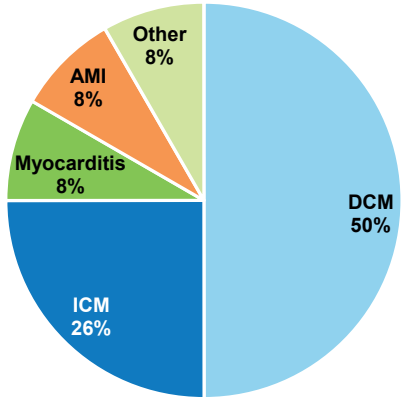


FIGURE 1 Primary diagnosis

Review of the EXCOR® Adult Bileaflet Valve Study

Outcome

The overall median support time was 248 days (57 - 365 days), with a total of 2,936 days of cardiac support.
1-year survival was 92 %, 50 % of the patients were transplanted and 42 % were still on support.
Mobilization of all 12 patients on Excor mobile with a median time of 10 days (range 4 - 40 days).

Out of Hospital treatment: 9 patients (75 %) were discharged after median time of 58 days (range 31 - 98 days), 2 patients remain hospitalized until their transplantation.

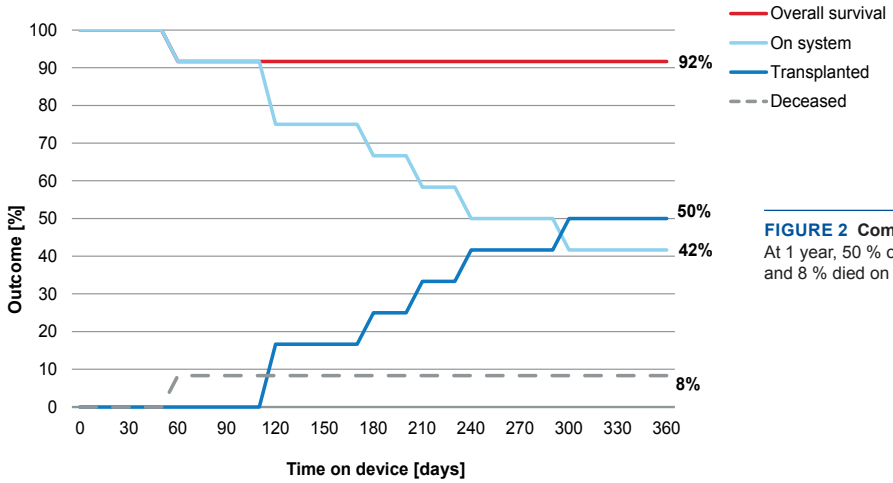


FIGURE 2 Competing outcome with 1-year survival (n=12)
At 1 year, 50 % of the patients were transplanted, 42 % were still on support and 8 % died on support. 1-year survival was 92 %.

with Bileaflet Valves

EXCOR® Adult blood pumps with bileaflet valves were proven to be reliable and effective

Outcome (n, %)	30 days	180 days	1-year
On system	12 (100 %)	8 (67 %)	5 (42 %)
Transplanted	0	3 (25 %)	6 (50 %)
Deceased	0	1 (8 %)	1 (8 %)

Survival at 18-months

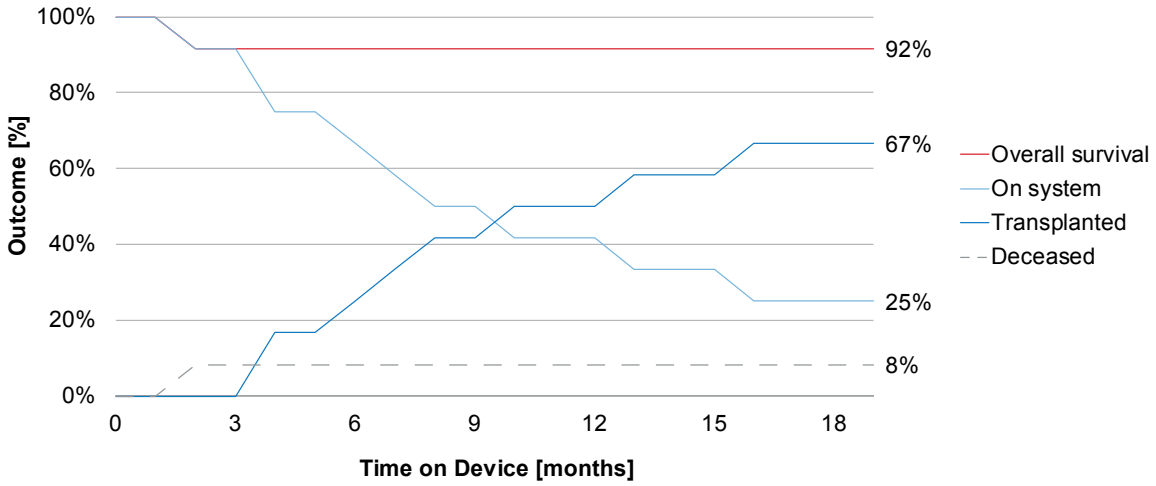


FIGURE 3 Survival at 18-months (n=12)
At 18 months, 67 % of the patients were transplanted, 25 % were still on support and 8 % died on support. 18-months survival was 92 %.

Excellent Results in Treating Biventricular Failure Using EXCOR®

Review of the Swedish Experience

S.-E. Bartfay, H. Lidén, M. Holmberg, K. Karason, J. Gäbel, B. Redfors and G. Dellgren (Sahlgrenska Universitetssjukhuset, Gothenburg, Sweden)

During the observation period (February 2010 to February 2014), 19 patients were supported with EXCOR® Adult BVAD.

Patient characteristics

Variable	EXCOR® Adult BVAD patients (n=19)
Median age [years] (range)	35 (20 – 61)
Median weight [kg] (range)	77 (52 – 100)
Median size [cm] (range)	175 (144 – 192)
Median BSA [m²] (range)	2.0 (1.5 – 2.6)
Male / female [%]	53 / 47
Preoperative ECMO/IABP [%]	63
INTERMACS Level [%] 1 2 ≥3 n.s.	 21 53 5 21

Primary diagnosis

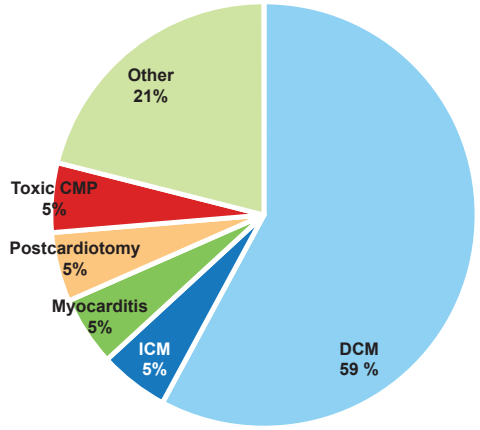


FIGURE 4 Primary diagnosis

Adult BVAD

Outstanding survival of 95 % was demonstrated in patients with bi-ventricular heart failure supported with EXCOR® Adult.

Outcome

The overall median support time was 150 days (19 - 380 days), with a total of 2,898 days of cardiac support.

Overall survival was 95 %, 90 % of the patients were transplanted and 5 % were weaned.
1-year survival was 95 %, 85 % of the patients were transplanted, 5 % were weaned and 5 % were still on support.

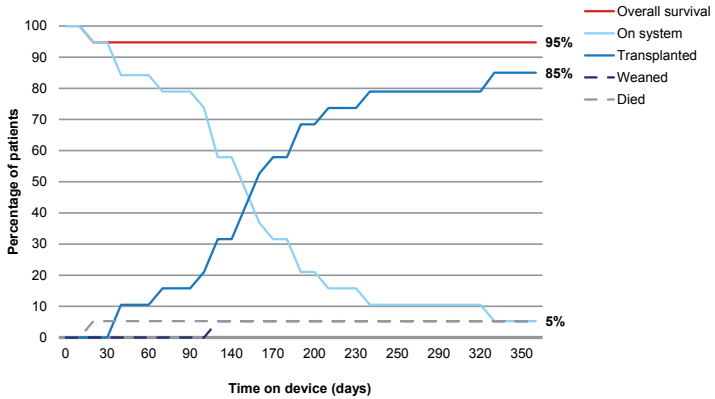


FIGURE 5 Competing outcome with 1-year survival (n=19)
At 1 year, 85 % of the patients were transplanted, 5 % had been weaned and 5 % were still on support. 1-year survival was 95 %.

Outcome per diagnosis

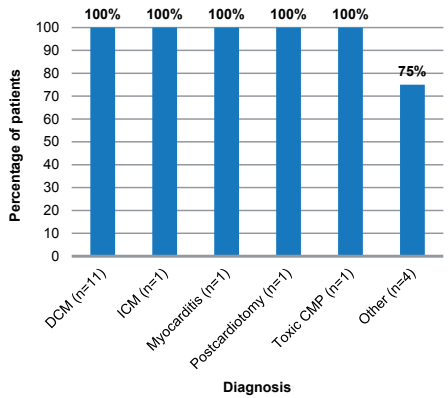


FIGURE 6 Outcome per diagnosis (n=19)
All patients diagnosed with DCM, ICM, myocarditis, postcardiotomy and toxic CMP survived until transplantation or recovery.

Review of the Swiss Experience

V. Falk and M. Wilhelm (Universitätsspital Zürich, Zurich, Switzerland)

During the observation period (September 2004 to November 2013), 36 patients were supported with EXCOR® Adult BVAD.

Patient characteristics

Variable	EXCOR® Adult BVAD patients (n=36)
Median age [years] (range)	48 (19 – 62)
Median weight [kg] (range)	76 (45 – 130)
Median size [cm] (range)	177 (158 – 196)
LVEF [%] (range)	17 (8 – 45)
CI [l/min/m²] (range)	1.9 (1.2 – 2.7)
Preoperative ECMO/IABP [%]	36

Primary diagnosis

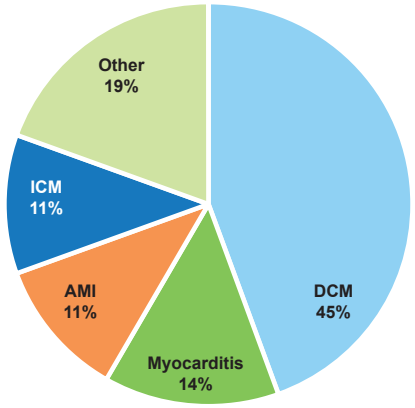


FIGURE 7 Primary diagnosis

EXCOR® Adult BVAD

1-year survival of 78 % was demonstrated in patients with biventricular failure supported with EXCOR® Adult.

Outcome

The overall median support time was 195 days (4 - 907 days), with a total of 8,967 days of cardiac support.

Overall survival was 69 %, 66 % of the patients were transplanted and 3 % were still on support.
1-year survival was 78 %, 56 % of the patients were transplanted and 22 % were still on support.

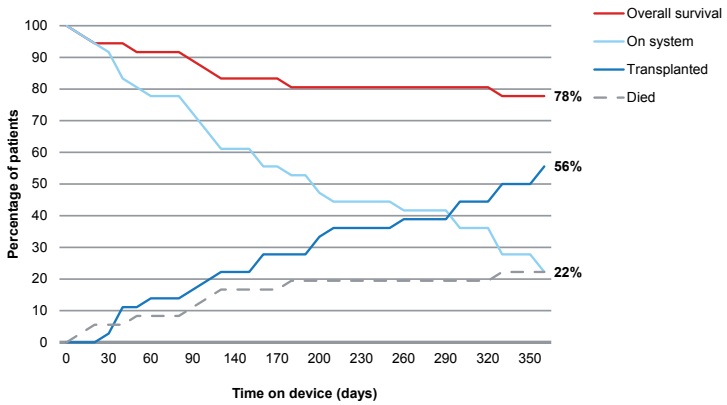


FIGURE 8 Competing outcome with 1-year survival (n=36)
At 1 year, 56 % of the patients were transplanted, 22 % were still on support and 22 % died on support. 1-year survival was 78 %.

Outcome per diagnosis

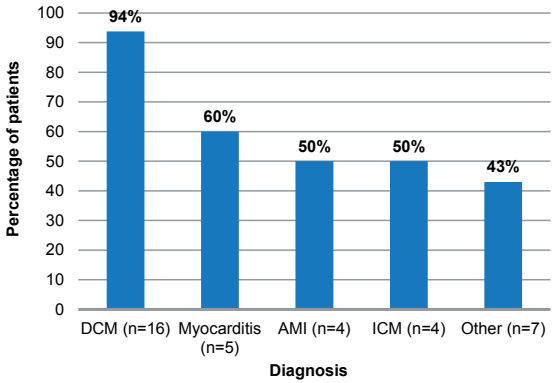


FIGURE 9 Outcome per diagnosis (n=36)
94 % of the patients with DCM survived until transplantation. 60 %, 50 % and 50 % of the patients with myocarditis, acute myocardial infarction and ischemic CMP were successfully supported with EXCOR® BVAD until transplantation, respectively.

Successful Long-term Support until Transplantation of Biventricular

Review of the Greek Experience

P. Sfirakis and L. Louca (Onassis Cardiac Surgery Centre, Athens, Greece)

During the observation period (June 2004 to July 2013), 53 patients were supported with EXCOR® Adult BVAD.*

Patient characteristics

Variable	EXCOR® Adult BVAD patients (n= 53)
Median age [years] (range)	46 (19 – 59)
Median weight [kg] (range)	74 (45 - 112)
Median size [cm] (range)	175 (154 - 190)
Median BMI [kg/m²] (range)	25 (14 - 35)
Male / female [%]	81 / 19
LVEF [%] (range)	15 (10 - 35)
CI [l/min/m²] (range)	1.1 (1.0 - 2.6)
Preoperative ECMO/IABP [%]	55
INTERMACS Level [%] 1 2	 60 40

Primary diagnosis

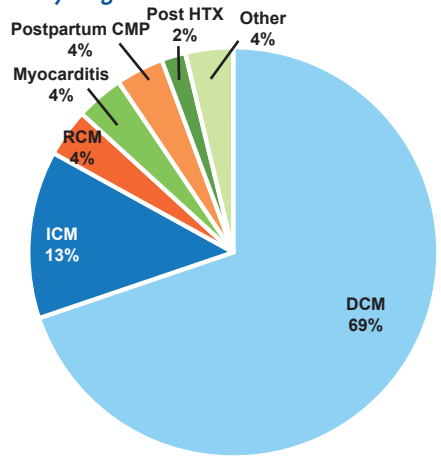


FIGURE 10 Primary diagnosis

*Patients switched from implantable LVAD to EXCOR® BVAD were excluded.

Failure Patients with EXCOR® Adult BVAD

1-year survival was 83 % in patients with biventricular failure supported with EXCOR® Adult. Successful long-term support of up to 4 years until transplantation was demonstrated.

Outcome

The overall median support time was 448 days (3 - 1,434 days), with a total of 27,487 days of cardiac support.

Overall survival was 68 %, 60 % of the patients were transplanted and 8 % were still on support.
1-year survival was 83 %, whereof 21 % of the patients were transplanted and 62 % were still on support.

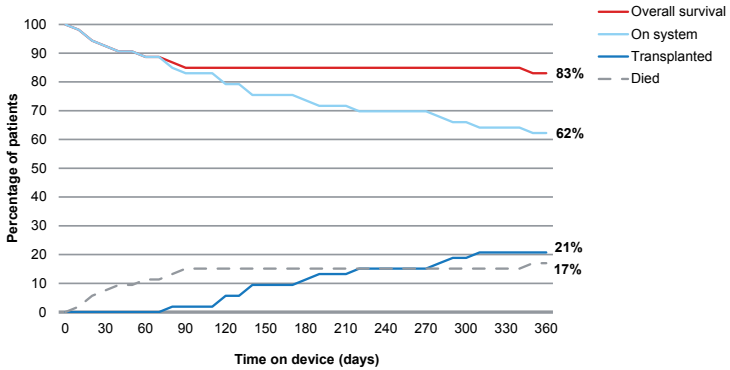


FIGURE 11 Competing outcome with 1-year survival (n=53)
At 1 year, 21 % of the patients were transplanted, 62 % were still on support and 17 % died on support. 1-year survival was 83 %.

Outcome per diagnosis

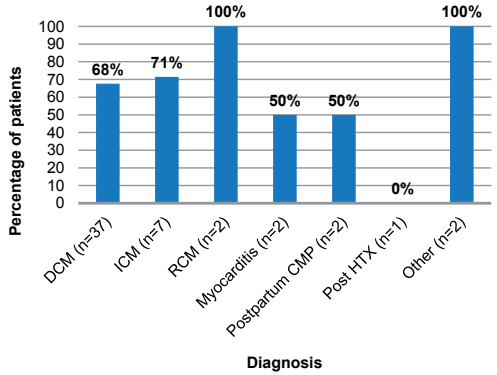


FIGURE 12 Outcome per diagnosis (n=53)
68 % and 71 % of the patients with DCM and ICM were successfully supported with EXCOR® BVAD until transplantation, respectively. No patient initially diagnosed with graft failure survived, while 100 %, 50 % and 50 % of patients with RCM, myocarditis and postpartum CMP, respectively, survived until transplantation.

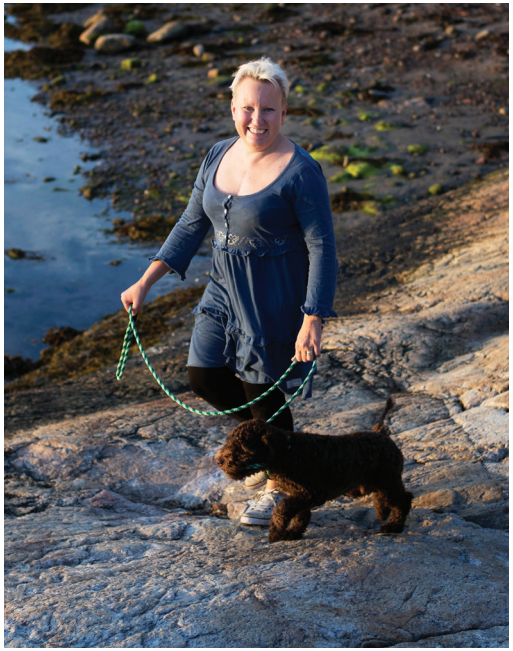
EXCOR® Adult BVAD Patient Story

"I'm getting stronger every day with my Berlin Heart pump" *Jenny K.*

Jenny K. was diagnosed with idiopathic dilated cardiomyopathy. Among other medical measures she underwent surgery to repair her mitral valve, which eventually allowed her to go back home for a period of time. However, when Jenny returned to the hospital in 2013, she was in critical condition.

A thoracic surgery was necessary and Jenny received a Berlin Heart EXCOR®. Since then the device has supported both of her ventricles and Jenny could return home to her husband and two children.

While Jenny was on the system she resumed most of her usual activities and went to the hospital once a week for routine check-ups. The Swede found friends on Facebook who have also had a Berlin Heart system. While she was on the waiting list for a heart transplant, Jenny said: "I'm getting stronger every day with my Berlin Heart pump and I try to stay fit and build up my body again to prepare for the big surgery."



After almost six months on EXCOR® System she received a donor heart in May 2014. Shortly after the transplant Jenny already felt great and reported that her new heart is very strong.

Jenny K.
System: EXCOR® Adult
Implantation age: 41 years
Indication: Idiopathic cardiomyopathy
Therapy: Bridge to transplantation
Successful transplantation after 5.5 months

Berlin Heart®

- **Single-center experiences using EXCOR® as BVAD system demonstrate excellent outcome in severely diseased heart failure patients.**
- **1-year survival was 78 % to 95 %.**
- **Successful long-term support of up to 4 years until transplantation was demonstrated.**

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