Development of a Novel Adapter to Enable Less-Invasive Left Ventricular Assist Device Implantation via the Left Ventricular Apex

David Schibilsky,* Johannes Scheumann,* Philipp Julian Koester,* Halil Demir,* Manuel Rausch,† Paul Puiu,* Christoph Benk,* Sven Maier,* Simon Neudorf,* Patric Diel,* Sebastian Grundmann,‡ Klaus Kaier,§ Friedhelm Beyersdorf,* and Wolfgang Bothe*

The first prototype of an adapter to enable left ventricular assist device (LVAD) implantation solely *via* the left ventricular (LV) apex and without requiring cardiopulmonary bypass (CPB) was tested in healthy and acutely failing pig hearts. The adapter consists of a fixation, blood guiding, and connecting module fitting to a HeartMate 3 (HM3; Abbott, Chicago, IL) pump. Implantation was performed *via* a left thoracotomy in five pigs (96 ± 18 kg). Invasive blood pressure was measured before (CTRL), 30 minutes after HM3 initiation (HM3_CTRL), during acute heart failure (HF) induced by rapid pacing (CTRL_HF), and 5 minutes after initiating HM3 support (HM3_HF). To further estimate the LVAD performance, blood pressure amplitudes were calculated in the healthy heart without (CTRL) and with HM3 support (HM3_CTRL) as: systolic–diastolic blood pressure. Our adapter implantation and connection to the HM3 pump succeeded in all animals. Compared to the normal beating healthy heart, blood pressure amplitudes were significantly smaller during HM3 support (CTRL: 41 ± 5 mm Hg *vs.* HM3_CTRL: 20 ± 4 mm Hg; $p < 0.05$). Under HF conditions, mean blood pressure returned to normal values after pump initiation (CTRL_HF: 29 ± 6 mm Hg, HM3_HF: 83 ± 24 mm Hg). The adapter prototype allowed safe, straightforward, and less-invasive LVAD implantation solely *via* the LV apex without using CPB and support of the LV during acute HF in the pig heart.

From the *Department of Cardiovascular Surgery, University-Heart Center, University Medical Center Freiburg, Faculty of Medicine, University of Freiburg, Freiburg, Germany; †Aerospace Engineering & Engineering Mechanics, The University of Texas at Austin, Austin, Texas; ‡Department of Cardiology and Angiology, Heart Center Freiburg—Bad Krozingen, Faculty of Medicine, University of Freiburg, Freiburg, Germany; and §Institute of Medical Biometry and Medical Informatics, University Medical Center Freiburg, Faculty of Medicine, University of Freiburg, Freiburg, Germany.

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David Schibilsky, Johannes Scheumann, and Halil Demir contributed equally.

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Correspondence: Wolfgang Bothe, Department of Cardiovascular Surgery, Heart Center Freiburg-Bad Krozingen, Hugstetter Str. 55, 79100 Freiburg, Germany. Email: wolfgang.bothe@universitaets-herzzentrum.de.

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The continuous development of left ventricular assist devices (LVADs) designed for left ventricular (LV) long-term support (LVAD) has resulted in a significantly better patient outcomes.[1] Although LVAD implantation has become clinical routine, there is still a high number of complications during and after the surgical procedure.[2,3] LVAD implantation usually requires applying cardiopulmonary bypass (CPB) and sternotomy.[4] Furthermore, outflow graft placement requires access to the ascending aorta, which necessitates a partial sternotomy or thoracotomy also in "less-invasive" LVAD implantations.[5] This factor leads to relevant tissue adhesions, thereby significantly increasing the complexity of redo surgeries, as in the case of heart transplantation.

We designed an adapter that is inserted solely *via* the LV apex, redirecting the blood flow in conventional LVAD pumps. The inflow is placed in the LV and the outflow *via* the aortic valve in the ascending aorta. The goal of this adapter is to enable single-access, less-invasive LVAD implantation without requiring CPB, while providing the reliability of the latest LVAD pump designs. The aim of this study was to test our adapter's feasibility in combination with a conventional LVAD pump in healthy and acutely failing pig hearts.

Materials and Methods

These animal experiments were approved by our local ethics committee (Freiburg, Germany, approval number G-19/103) and conducted following the rules and regulations of the German animal protection law and animal care guidelines of the European Community (2010/63/EU). Five pigs (96 ± 18 kg) underwent total intravenous anesthesia (TIVA) as previously described.[6]

Adapter Principles

The adapter is displayed in Figure 1 and consists of a fixation, blood guiding, and connecting module. The fixation module is surgically attached to the LV apex. The blood guiding module redirects the blood flow in a conventional LVAD pump. The blood guiding module is introduced along a guidewire (which is placed *via* the center of the fixation module into the aorta) and placed with the outflow in the ascending aorta and the inflow in the LV cavity. The connecting module, which is attached to the blood guiding module, is potentially suitable for any LVAD. In these experiments, the connecting module was designed to accommodate a HeartMate 3 (HM3) pump (Abbott, Chicago, IL).

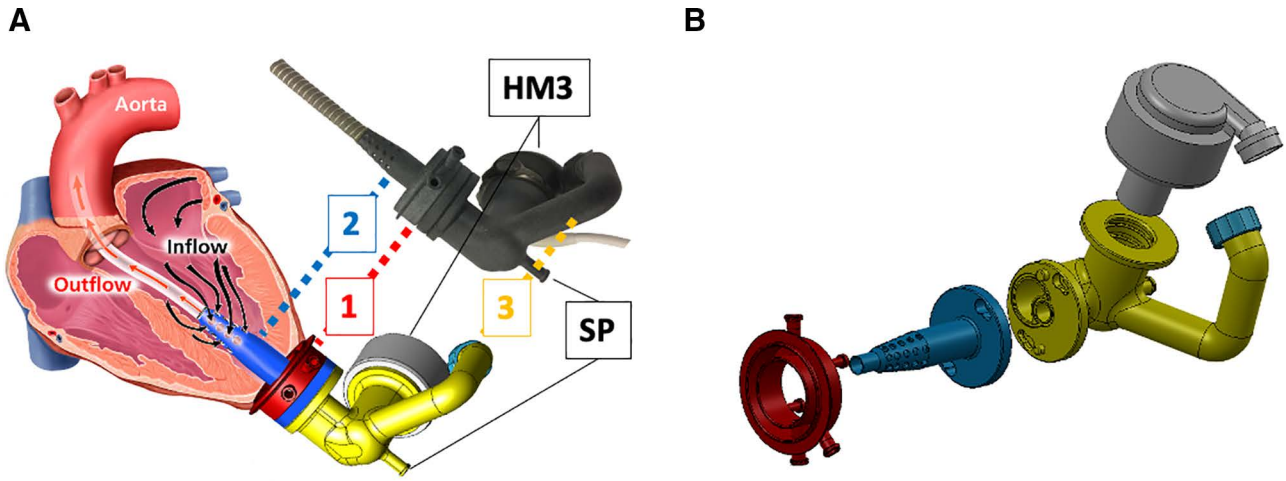

Figure 1. A: This adapter consists of a fixation (number 1), blood guiding (number 2), and connecting (number 3) module connected to a HM3 (Abbott, Chicago, IL). A vascular prosthesis was used as outflow and stiffened with a balloon catheter introduced *via* the SP. **B**: Exploded assembly view of the used prototype illustrating the connections of the adapter itself and of the adapter to the LVAD and to the apical ring using self-made locking mechanisms. HM3, HeartMate 3; LVAD, left ventricular assist device; SP, Seldinger port.

Surgical Technique

The LV apex was punctured through a left thoracotomy and a guidewire was placed in the aorta. The Teflon felt on the fixation module was attached to the LV apex with a 4-0 Prolene suture (Figure 2A). After administering heparin intravenous (IV) (300 I.E./kg), the blood guiding and connecting module (attached to a HM3 pump) were introduced over the guidewire (Figure 2B), attached to the fixation module, and the system was de-aired (Figure 2C).

We measured arterial blood pressure and LV end-diastolic diameters (LVEDDs) before (CTRL) and 30 minutes after HM3 initiation (HM3_CTRL) in the healthy hearts. Then, HM3 flow was stopped, and after inducing heart failure (HF), we acquired another dataset (CTRL_HF). Acute HF was induced *via* rapid pacing (heart rate >180/min) to achieve a mean systolic blood pressure< 40 mm Hg. Data was assessed five minutes after initiating HM3 support (HM3_HF). As one animal developed refractory ventricular fibrillation, the device was implanted and tested under HF conditions only.

To further estimate the LVAD performance, blood pressure amplitudes were calculated in the healthy heart without (CTRL) and with HM3 support (HM3_CTRL) as: systolic–diastolic blood pressure.

LV end-diastolic diameters with and without HM3 support were compared to the respective control group. All data normality distribution was compared using a paired t-test (SigmaPlot Version 12.5; Systat Software, San Jose, CA).

Results

The implantation procedure and connection to the HM3 pump succeeded in all animals. Mean time from skin incision to HM3 initiation was 86 ± 21 minutes. Blood loss was <300 ml in all animals. Figure 3C displays the indicated HM3 flow rates. After HM3 initiation in the healthy heart (HM3_CTRL) and in the HF state (HM3_HF), the indicated HM3 flow rates amounted to 5.2 ± 1.4 L/min and 5.8 ± 1.4 L/min, respectively. Figure 3, A and B show arterial blood pressures and LVEDDs, respectively. LVEDDs were lower with HM3 support (HM3_CTRL) than in the healthy hearts' control state (CTRL). Under HF conditions (CTRL_HF), HM3 initiation (HM3_HF) restored mean arterial blood pressure and was associated with a decrease in LVEDD. Compared to the normal beating healthy heart, blood pressure amplitudes were significantly smaller during HM3 support (CTRL: 41 ± 5 mm Hg *vs.* HM3_CTRL: 20 ± 4 mm Hg; $p < 0.05$). We observed no relevant aortic insufficiency at any time. HM3 pump flows were stable during control and heart failure conditions (Figure 3C).

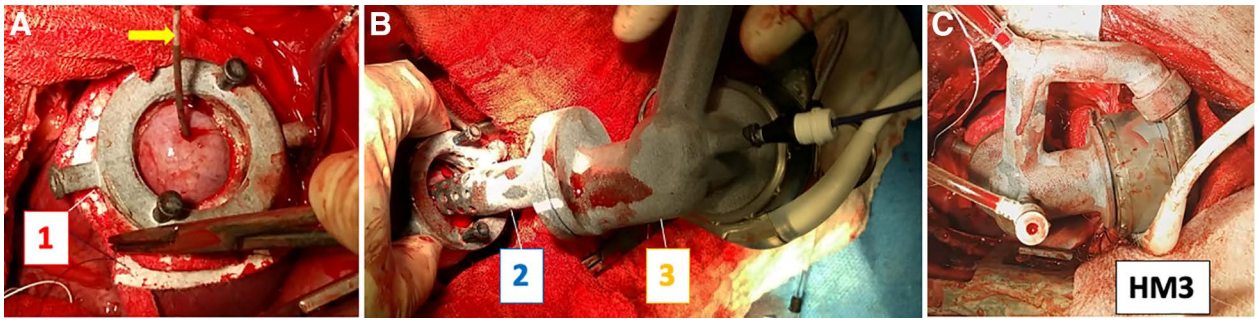

Figure 2. The LV apex was punctured, a stiff guidewire placed in the aorta, and the fixation module (number 1) was attached (**A**). The blood guiding module (number 2) (that was *via* the connecting module [number 3] connected to a HM3 pump) was introduced along the guidewire (**B**) and attached to the fixation module. The balloon was retracted and the system de-aired (**C**). HM3, HeartMate 3; LV, left ventricle.

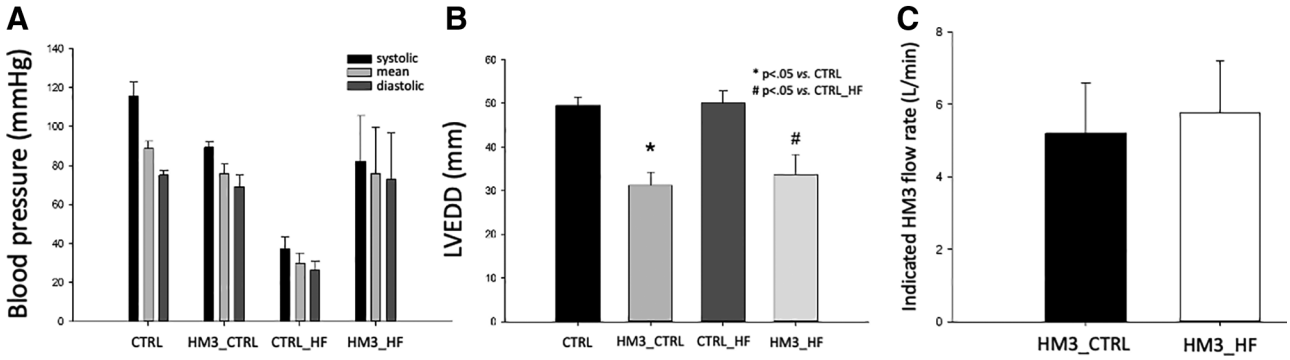

Figure 3. Hemodynamic measurements and indicated HM3 flow rates: Arterial blood pressure (**A**) and LVEDDs (**B**) in the healthy heart (CTRL) and during HM3 support (HM3_CTRL) as well as during acute HF conditions without (CTRL_HF) and during HM3 support (HM3_HF), indicated HM3 flow rates (**C**) during HM3 support in the healthy heart (HM3_CTRL) and acute HF conditions (HM3_HF, see Methods). HF, heart failure; HM3, HeartMate 3; LVEDD, LV end-diastolic diameter.

Discussion

This study's principal findings are that: 1) the novel adapter enables safe, less-invasive HM3 implantation without CPB and 2) the measured parameters suggest effective HM3 support in both the healthy and acutely failing pig heart.

LVADs are usually implanted *via* a full sternotomy using CPB.[4] Our adapter was designed to enable a ventricular assist device (VAD) to be implanted solely *via* the LV apex. Slaughter *et al.*[7] followed a similar strategy: they developed a fully implantable pump located in the LV cavity. Although this pump's development began around 15 years ago, the device is still not available on the market, possibly due to difficulties in obtaining approval for a new pump design. To avoid having to engage in the complex development of a new pump technique, it was our goal to design an adapter enabling surgeons to use commercially available and clinically approved pumps. Similar to the aforementioned device, the outflow cannula lies across the aortic valve. As we expected from the work by Slaughter *et al.*[7] and our experiences with transvascularly implanted Impella devices (Abiomed, Denvers, MA), we detected no aortic valve insufficiency after device implantation.[8] Furthermore, recent experience in bridging a patient with restrictive cardiomyopathy to cardiac transplantation using Impella 5.0/5.5 devices for more than 200 days strengthened this assumption. The explanted heart of this patient showed no structural alteration or thrombus formation at the level of the aortic valve or within other adjunct cardiac structures.

After conventional LVAD implantation, geometric changes (including twists) in the outflow graft have been reported.[9] Thanks to our adapter's design, such complications are unlikely. Compared to conventional LVAD implantation, single-access surgery could reduce operation time, blood loss, and the risk of infection compared to a conventional or even to current concepts of less invasive LVAD implantation by limiting the surgery to a single access limiting surgical access to a single incision at the apex also has the potential to accelerate postoperative recovery and reduce adhesions.

Limitations

Several limitations must be considered. We carried out no analysis of potential embolisms, and our design was not optimized in terms of the blood flow pattern. Computational simulations will be necessary to optimize this design in the future. Furthermore, the current design is bulky and large, which may need modification to facilitate placement in human anatomy. Therefore, currently, we are working on the development of new design prototypes, which will undergo extensive 4D flow simulation models before further longer-term animal experiments are justified. The long-term mechanical passage of the aortic valve comprises possible thromboembolic problems and affection of aortic valve function and structure.

In conclusion, this novel adapter makes a straightforward, safe, and less-invasive LVAD implantation possible without CPB. Preliminary data suggest effective LV support during acute HF in the pig heart. Further device optimization and testing are needed before our device can be introduced onto the market and in clinical practice.

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