

## Stent-based, off-pump creation of an apico-aortic conduit

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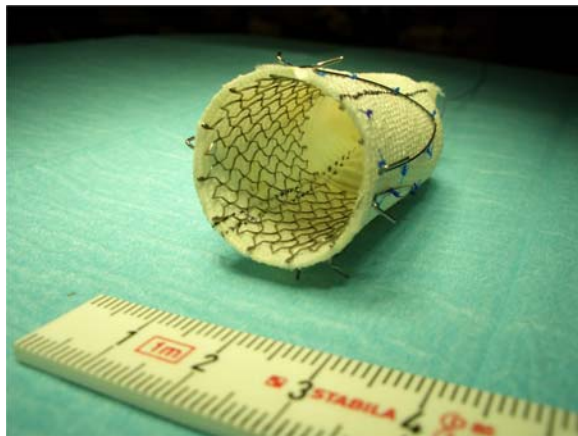
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## 1. ABSTRACT

An apico-aortic conduit (AAC) is an alternative therapy in patients with aortic valve stenosis and severe concomitant disease. We investigated whether it is feasible to create an apico-aortic conduit off-pump with a newly developed, stent-based coring- and cannulation-device in the animal model. A new self-expandable, stent equipped and hooked prosthesis and a sheath enabling both airtight removal of tissue and introduction of the prosthesis were designed and experimentally investigated in six pigs. Hemodynamic- and echocardiographic investigations were performed without and with aortic stenosis. In three animals MRI was performed. There was no significant blood loss, no relevant contamination with air and no hemodynamic depression during the whole procedure. It was possible to yield the entire cardiac output through the conduit after creating a high grade aortic stenosis. Autopsy revealed an excellent anchorage of the prosthesis. Neither relevant intracavitary injury nor thrombotic formation was seen. This study proves the feasibility of a stent-based, off-pump creation of an AAC. The principle of this approach might be used for other purposes.

## 2. INTRODUCTION

Since Hufnagel's first correction of aortic regurgitation in 1952 (1), an operative aortic valve replacement evolved into an operative therapy with excellent results (2,3,4). However, some patients with aortic valve disease are not candidates for classic aortic valve surgery for example due to extensive adhesions after previous surgery or a porcelain aorta. In these cases creation of a valved conduit from the left ventricular apex to the descending aorta (Apico-Aortic Conduit, AAC) is an established alternative to treat severe aortic stenosis (5,6). Also the mitral valve has already been treated in this way (7). A major disadvantage of this method is the need for extracorporeal circulation (ECC) with all its consequences in most cases because a big punched hole has to be made into the hearts apex. A method to simplify the connection between the apex and a vascular prosthesis without the need for ECC would be very attractive in order to minimize the overall trauma of this operation. Therefore we developed a new stent-based prosthesis (Apical prosthesis) in conjunction with a combination of sheath and coring device (Coring sheath). Both the technical feasibility and the functionality of a completely off-pump created AAC were investigated in the animal model.



**Figure 1.** Photograph of an early apical prosthesis.



**Figure 2.** Photograph of the coring sheath.

### 3. MATERIALS AND METHODS

#### 3.1. Apical Prosthesis

To achieve a sutureless and blood-tight positioning in the apex we aimed for a prosthesis realizing the following requirements: possibility to introduce via the Coring sheath what means compressible with strong selfexpansion after release, stability towards pressing out by selfanchoring and additionally low thrombogenicity inside. Following some preliminary investigations, we decided for a commercially available vascular prosthesis (20 mm Hemashield Platinum, Boston Scientific, USA) as basis. A commercially available selfexpanding Nitinol stent (22 mm Sinus XL, Optimed, Germany) was sutured (Prolene 5.0, Ethicon, Johnson & Johnson Intl; USA) inside the vascular prosthesis. Afterwards four v-formed pieces of elastic wire (V2a steel of 0.5 mm diameter) were placed on the outside of the prosthesis. The ends of the wire were bent up resulting in eight hooks at the outside (Figure 1).

#### 3.2. Coring sheath

This device was easily built from a brass tube of 19 mm outer diameter. The proximal end was sharpened to act as a punch. At the distal part an integrated silicone tube could be used as sheath when clamped. In the distal end of

the brass tube different silicone sealings could be positioned (Figure 2).

#### 3.3. Conduit prosthesis

Two 20 mm vascular prosthesis (Hemashield Platinum, Boston Scientific, USA) were sutured to the ends of a stentless aortic valve (Edwards Prima 21 mm, Edwards Lifesciences, USA) resulting in a valved conduit.

#### 3.4. Animal model

Six female pigs of 70 kg bodyweight were used for the animal investigations. The animal research protocol was approved by the local authorities (50.203.2-AC 14 51/05). The experimental animals received humane care in compliance with the "Principles of Laboratory Animal Care" formulated by the National Society for Medical Research and the "Guide for the Care and Use of Laboratory Animals" prepared by the Institute of Laboratory Animal Research and published by the National Institutes of Health (NIH Publication No. 86-23, revised 1985). After premedication general anesthesia was induced. Routine monitoring and catheterization for cardiothoracic surgery was installed followed by baseline measurement of hemodynamics. Heparin was used in a dose of 3 mg/kg, protamine in an equivalent dose. All animals were sacrificed humanly after completion of the investigation. A detailed post mortem examination was performed in all animals.

#### 3.5. Operative procedure

After median sternotomy and opening of the pericardium an additional small left-sided lateral thoracotomy was performed in the fourth intercostal space. The descending aorta was prepared a few centimeters distal the arch. After partial clamping an end-to-side anastomosis to the conduit prosthesis was performed by hand with a running suture (Prolene 4.0, Ethicon, Johnson & Johnson Intl; USA). After deairing, the conduit prosthesis was clamped and passed into the opened pericardium. The following procedures were all performed beating-heart via the sternotomy.

#### 3.6. Cardiac intervention

Besides to surgical judgment the use of epicardial ultrasound was used to determine the best position and direction to place the apical prosthesis. A puncture of the apex served to insert a stiff wire in Seldingers technique into the left ventricle. Over this wire the coring sheath, with a robust spherical balloon catheter (Retrograde Cardioplegia Catheter 14 Fr. Edwards Lifesciences, USA) inside, was attached to the left ventricular apex. The end of the coring sheath was sealed. The balloon catheter was introduced into the left ventricle and filled with saline. Under cautious pressure and rotation against the balloon catheter the coring sheath now cutted into the apex. After complete perforation of the myocardium the coring sheath was held in place and not further advanced. Now it was possible to retrieve the punched cylinder of myocardium into the distal part of the coring sheath. By clamping the silicone tube in the middle of the coring sheath it was possible to replace the balloon catheter (with loaded myocardium) by the crimped apical

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prosthesis. The latter was crimped in a polyethylene tube exactly fitting the inside of the coring sheath. At the end of this tube a pushing mechanism was put in a seal. Declamping of the coring sheath was followed by advancing the tube with the apical prosthesis 1.5 centimeters out of the sheath into the left ventricle. Under echocardiographic control first the inner tube was pulled back allowing the proximal end of the apical prosthesis to expand. Then the expanded apical prosthesis was pulled back as far as the hooks reached the myocardium. As a last step the coring sheath was removed resulting in a completely released apical prosthesis, which was tied up. The ends of both prosthesis were deaired and joined resulting in the completed AAC. Coagulation was reconstituted with protamine.

### 3.7. Further Investigations

15 minutes after completion of the interventional procedure further investigations were carried out to further characterize the AAC. To simulate aortic stenosis the ascending aorta was snared (Mersilene Tape 4mm, Ethicon, Johnson & Johnson Intl; USA) as required to generate a high grade stenosis. Measurements were performed both in a state of normal left ventricular outflow and simulated (supracoronary) aortic stenosis. Each state was investigated with a clamped AAC and open AAC. The following measurements were performed: hemodynamics inclusively right heart catheter (all Datex Ohmeda, GE Healthcare, USA), flow measurement (22 mm; Medi-Stim ASA, Norway). Transesophageal- as well as epicardial echocardiography (Vivid 5, GE, USA). In three of the six animals the chest was closed and an MRI (Philips Achieva: 1.5 Tesla, Philips, Netherlands) performed. After 90 minutes of postoperative observation and investigation the animals were euthanized. For post mortem examination the heart with the complete thoracic aorta was carefully excised. After careful washing with saline, the heart and prosthesis were studied to identify injury or clot formation.

## 4. RESULTS

### 4.1. Animals

All six animals survived the intervention procedure and the 90 minutes of post-interventional observation period. Ventricular fibrillation occurred once when the metal of the coring Sheath touched the septum. After one defibrillation the intervention could be completed. Single, neither sustained nor hemodynamically relevant, rhythm disturbances occurred during the whole intervention. The overall blood loss was negligible. The animals stayed cardiopulmonary surprisingly stable until euthanasia.

### 4.2. Coring sheath

The device worked very well in the intended purpose and was easy to operate. By the use of the balloon catheter removal of a piece of myocardium (18 mm in diameter) was possible without relevant blood loss both in the coring sheath itself or alongside. Furthermore the catheter served as a counterpart during the coring so that no relevant compression of the heart was necessary. The positive left ventricular pressure resulted in nearly no air

bubbles being washed away during coring. Nevertheless two persons were needed to operate the device.

### 4.3. Apical prosthesis

In the here chosen proportions the nitinol stent combined with the metal attachments developed a quite strong selfexpansion force serving for a tight (air and blood) adaption to the myocardial wall. Nevertheless no tearing of the myocardium occurred. The eight hooks provided a strong anchoring against pressing the prosthesis out of the left ventricle (longitudinal stability). The stent equipped part of the prosthesis took part in the movement pattern of the apex, the rotation movement was then slowly absorbed by the free textile part of the prosthesis. When measured by puncture there was no relevant pressure gradient from the left ventricle to downstream the prosthesis.

### 4.4. Cardiac intervention

The whole off-pump implantation procedure of our new apical prosthesis was guided by epicardial ultrasound. Hereby essential information could be obtained like for example the exact direction of the intervention in order to avoid injury to the septum or papillary muscles. Another relevant information was the exact visualization of hooks and the status of the stent deployment for exact positioning and course of the intervention. In the last few animals the whole intervention at the apex took about 15 minutes. Although a purse-string suture was prepared around the apex for safety reasons (unexpected bleeding) it was needed only one time in the second animal, when a cant of the coring sheath happened. After tying the suture the bleeding stopped. No relevant luxation of the heart was necessary to perform the procedure. The pressure necessary for coring was established between the balloon catheter and the coring sheath. Hereby it was not necessary to compress the heart, what could otherwise lead to hemodynamic depression. Nevertheless two persons were needed to perform the intervention: one person emphasizing in holding and moving the device, another person to operate the coring sheath.

### 4.5. Further investigations/measurements

After finishing the complete AAC (Figure 3) its functionality was assessed. Hemodynamic assessment in combination with the flow- measurement could demonstrate that the AAC was able to overtake the full function of the normal left ventricular outflow tract (LVOT). Without a stenosis the spontaneous flow in the AAC was 2.4 (+/- 0,4) liters per minute. There was no relevant change in overall-hemodynamics when a high grade aortic stenosis was induced and the AAC was open (Table 1).

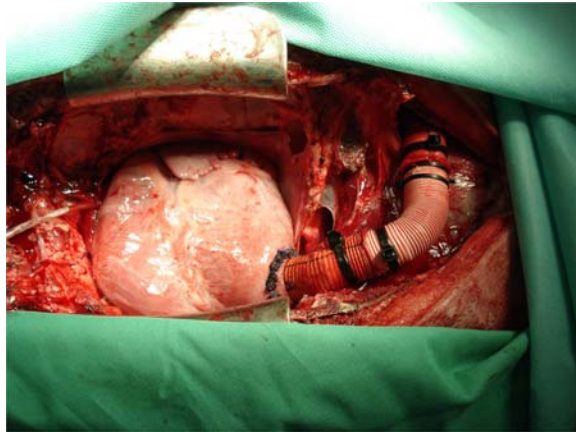
### 4.6. MRI

These investigations were performed in two conditions: one without aortic stenosis and one with a completely tied ascending aorta. These two conditions could easily be established in the closed chest by the previously installed banding of the ascending aorta. MRI imaging could demonstrate an equal perfusion through the ascending aorta and the AAC in the state of an

**Table 1.** Basic hemodynamic data for functional assessment of the AAC

Measured Parameter	No Stenosis/AAC closed	No Stenosis/ AAC open	Stenosis/AAC closed	Stenosis/AAC open
Cardiac Output [l/min]	5.5 (+/- 0.4)	5.4 (+/- 0.5)	4.9 (+/- 0.6)	5.7 (+/- 0.4)
AAC Flow [l/min]	0.0	2.4 (+/- 0.4)	0.0	5.6 (+/- 0.6)
MAP [mm HG]	65 (+/- 8.1)	64 (+/- 7.3)	54 (+/- 4.3)	68 (+/- 6.8)

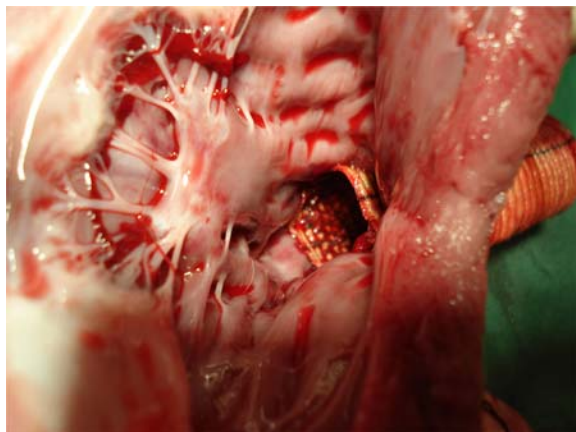
Results are presented as Mean +/- SD



**Figure 3.** Photograph of a completed AAC reaching out of the apex. Black cable straps on the vascular prosthesis facilitated assembly of all parts.



**Figure 4.** MRI showing the status of perfusion with an AAC: Left side with unobstructed aorta, right side with a completely interrupted ascending aorta (arrow).



**Figure 5.** Photograph from the inside of the heart at autopsy. The apical prosthesis is seen from the inside. There is no relevant trauma or thrombus.

unobstructed aorta whereas the complete perfusion of the aorta inclusively the supraortic branches was maintained through the AAC in a completely interrupted ascending aorta (Figure 4).

#### 4.7. Postmortem examination

Autopsy revealed a correct (intended) overall position of the apical prosthesis without signs of canting, resulting in an additional apical outflow with a diameter between 19 and 21 mm.. There was no relevant trauma to valve related structures (Figure 5). The endo- and myocardium was only slightly injured in the direct proximity of the prosthesis anchoring hooks. The whole anchoring of the prosthesis in the heart seemed not to have moved in the apex over time. No relevant thrombus was found inside the entire prosthesis. Both the biological valve part and the anastomosis to the descending aorta were unremarkable in all cases. When the apical prosthesis was removed by compression a smooth transmural cut coring of the apex could be seen. In contrast a removal of the open apical prosthesis out of the heart was only possible under very high traction leading to a tearing of the apical myocardium.

#### 5. DISCUSSION

An aortic valve stenosis is the most common valve disease in the elderly in western countries and prevalence is still increasing. There is no doubt about the need for alternative therapies avoiding major cardiac surgery with sternotomy, cardiopulmonary bypass and cardioplegia in this patient population (8). Although the new technologies for interventional valve treatment are promising some critical points are remaining with this kind of therapy (9). Since decades the implantation of a valved conduit is known in the surgical community to be an alternative option in otherwise “inoperable” patients as for example in a porcelain aorta. Paraanatomic valved (with biological- and mechanical valves) conduits have been described to treat aortic- but also mitral valve disease (5,7,10). In the recent time only a few investigations were published, dealing with this operation (11,12). However, this kind of operation did not find really widespread use probably because of major trauma, the necessity for ECC and the technical challenge of this operation. Moreover the connection between the moving myocardium and the conduit demonstrated troublesome both intraoperatively and in the long run. Aim of our investigations was to minimize the extent and invasiveness of this operation especially to avoid the necessity for ECC and to make this operation simpler. The most critical point is the connection of the hearts apex with a big vascular prosthesis. Hence we aimed for a new technique to remove a piece of myocardium by a gate and to connect the myocardium from the inside with a vascular prosthesis by stent technology.

**Coring sheath:** Although of a very simple design, our coring sheath for the first time combines the properties of a sheath and a coring device. Hereby it is possible (to our knowledge the first description of such a technique) to core a larger piece of tissue out of a hollow-body filled with blood and remove it. This is possible without a

significant blood loss and thereby makes the application of ECC unnecessary. The coring sheath seals against blood loss by tight suiting of the myocardium against the coring blade. Although we used a purse-string suture for security reasons in the first animals it was abandoned in the further animals because it was unnecessary. By the integrated sheath it was easily possible to remove the tissue step by step without blood loss. Nevertheless this sheath would also allow to perform other interventions inside the heart which require large diameters.

**Apical prosthesis:** Our “home-made” prosthesis for the apex has its main advantage in a fixation from the inside of the heart. After expansion of the prosthesis inside the sheath it is (theoretically reversible) fixed against pressing out of the heart by the hooks. Removal of the sheath then activates the second property of the prosthesis what is sealing along the cored myocardium by radial expansion. Virtually no suture fixation of the prosthesis is necessary to hold the prosthesis in place and to seal it against blood loss. Whereas the closed prosthesis is exposed to an outwards the heart directed force no relevant force remains with complete run off through the prosthesis. Because in our apical prosthesis rigid parts are only inside the heart and a little bit beyond the apex all movements of the heart are absorbed by the vascular prosthesis. This seems to be a another relevant advantage over commercially available apical connectors which are of a large size and feature a rigid angle not allowing a rotation.

**Overall Intervention Procedure:** After a learning curve to operate our devices in the living animal it became apparent that the time to create an apical connection is very short if compared with a conventional operative technique. Although in our animals in this investigation we performed a full sternotomy to expose the hearts apex, we recognized that for insertion of our apical prosthesis only a limited surgical access seems really necessary because relevant luxation or fixation of the whole heart is not necessary. Thus in one additional animal we performed an apical connection via only a very limited lateral access to the heart and could thereby confirm our assumption.

**Limitations:** Our work investigated the principal feasibility to create an AAC without ECC in the acute animal setting. Although the major goals of this study were realized there is no answer regarding the long time effects. The “home-made” preliminary design of our devices lead to only minor technical problems like not completely adjusted proportions and length. A more professional design can easily overcome these problems and allow positive long time results.

**Conclusion:** In this study we could demonstrate the principal feasibility and excellent functionality of a stent-based, sutureless, off-pump creation of an AAC. After technical refinements and long term experiments a really minimally invasive creation of an AAC should be possible as an alternative in aortic valve therapy. The principle of this new approach might be used for other purposes like mitral valve interventions or cannulation for assist devices.

## 6. ACKNOWLEDGMENT

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**Abbreviations:** AAC: Apico-aortic conduit; ECC: Extracorporeal circulation; MRI: Magnetic resonance imaging; LVOT: Left ventricular outflow tract; l/min: liters per minute; mm Hg: Millimeters of mercury; SD: Standard deviation

**Key Words:** Aortic stenosis, Apico-Aortic conduit, Valved conduit, Off-pump; Stent, Sheath

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