Transcatheter aortic valve replacement: transapical resection of the aortic valve in vivo

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Received 13 November 2011; received in revised form 29 February 2012; accepted 12 March 2012

Abstract
The resection of pulmonary valves has already been demonstrated in an experimental beating-heart model. The aim of this study was to analyse the transapical laser-assisted resection of aortic valves in an in vivo porcine model in a non-beating heart. The resection was performed in a porcine model (n = 10) using a Thulium:YAG laser. After establishing a standard extracorporeal circulatory support, the aortic valve isolation chamber (AVIC) system was inserted transapically. The resection of the aortic leaflets was carried out step-by-step in the arrested heart. The AVIC and occlusion of coronary ostia [6]. Additionally, the occurrence of emboli may result in neurological disorders including strokes [7]. A pre-treatment of the annulus by removing the diseased valve before implantation will prevent the above-mentioned complications. After successful isolation and resection of the pulmonary valve in a beating-heart porcine model [8], the aim of this study was to analyse the transapical isolation of the left ventricular outflow tract (LVOT) in a cardioplegic heart with consecutive laser-assisted resection of the native aortic valve under full extracorporeal circulatory support.

INTRODUCTION
The era of catheter-based implantations of stent-mounted valves began in the early 1990s, with experimental investigations by the two pioneers Henning Rud Andersen and Dusan Pavcnik. It is currently a challenging method to treat diseased heart valves.

Despite encouraging results [1, 2], the following problems have been reported after valved stent implantation into highly calcified aortic valves: paravalvular leakages [3, 4], mitral regurgitation [5] and occlusion of coronary ostia [6]. Additionally, the occurrence of emboli may result in neurological disorders including strokes [7]. A pre-treatment of the annulus by removing the diseased valve before implantation will prevent the above-mentioned complications. After successful isolation and resection of the pulmonary valve in a beating-heart porcine model [8], the aim of this study was to analyse the transapical isolation of the left ventricular outflow tract (LVOT) in a cardioplegic heart with consecutive laser-assisted resection of the native aortic valve under full extracorporeal circulatory support.

MATERIALS AND METHODS
The aortic valve isolation chamber
The transapical aortic valve isolation chamber (AVIC) system was developed to separate the aortic valve from the circulatory system [8]. The AVIC with a length of 160 mm and a diameter of 30 F, generates an isolated operating room around the aortic valve to ensure that no debris escapes during the resection procedure. The AVIC consists of a trocar with the subvalvular balloon (diameter 40 mm), a rotatable instrument inlay and the supravalvular balloon (Fig. 1a and b). To isolate the aortic valve, the supravalvular balloon was inflated in the ascending aorta and the ventricular balloon in a subvalvular position. Due to the fact that both coronary ostia were not shielded with special catheters, a cardioplegic solution was administered directly into the AVIC. After a stable chamber was generated, the blood in the AVIC was flushed-out with a saline solution. The use of a two-stage right atrial cannula for partial venous cannulation results in a small but steady amount of blood flow through the lungs into the left heart. Therefore, in 3/10 cases, an additional pulmonary artery vent catheter was established to reduce the pulmonary blood flow. The pressures of the AVIC balloons were controlled on-line to detect and compensate any pressure decrease caused by a leakage with a subsequent unstable chamber function. To ensure a clear view during the resection process, an irrigation flow (permanent or flush) was established using an adaptable saline solution drip-infusion.

The resection device
The aortic valves were resected by a continuous wave Thulium: YAG laser system with 20 W power-rating (Tm:YAG: 2.01 μm, ITL...
Lasergeräte SN: #00272001, 380/400 V 16 A, Lübeck, Germany). The laser fibre (Ø 365 µm, CeramOptec GmbH, Bonn, Germany) was controlled by a newly designed pseudoelastic microactuator system Institute for Microtechnology, which was integrated into the rotatable instrument inlay (Fig. 1c). The forceps catheter (Ø 1.3 mm) was manually controlled. The visualization (Polydiagnost, Pfaffenhofen, Germany, Ø 0.7 mm) was realized via the transapical AVIC system.

Animals

‘German Landrace’ pigs (60 ± 5 kg) received humane care, as approved by the Centre for Experimental Animal Research at Kiel University (V312-72241.121-6(63-5/06) 2 July 2006) and in compliance with the ‘Guide for the Care and Use of Laboratory Animals’ prepared by the Institute of Laboratory Animal Resources, National Research Council and published by the National Academy Press, revised 1996.

The resection

The animals were pre-medicated and anesthetized as reported elsewhere [9]. After a median sternotomy, cardiopulmonary bypass was established in a standard fashion.

A double purse-string, pericardial patch armed monofil suture (3-0) was placed before the apex had been opened. Then the AVIC was inserted (Fig. 2a). After inflation of the supravalvular balloon, cardioplegia was administered via the AVIC. The AVIC inlay and the microactuator with a laser were piloted by a cardiac surgeon (Figs 2b and c and 3a and b). The forceps catheter, the visualization endoscope, the chamber perfusion and the pressures monitoring of AVIC balloons and chamber were controlled by assistants.

The direction of the cut was virtually pre-tested before the actual laser resection with a target power level of 20 W was started. The resection process was exclusively video controlled and digitally recorded. The leaflets were excised 2–3 mm from the annulus (Fig. 3c and d). The fragments of the resected leaflets were removed via the AVIC.

Parameters

The AVIC deployment time, AVIC sealing and visualization, resection time, any lesions in the surrounding tissue (within 40 mm of the annulus and the endomyocardium) and the tractability of all instruments were analysed. The stability of the AVIC-system, and any complications during the resection process were protocoll. The macropathology of the specimens was also analysed. Data were expressed as mean ± standard deviation.

RESULTS

Aortic valve isolation chamber deployment

The transapical deployment of the AVIC was easy to perform. The time from skin incision to the AVIC deployment took 85 ± 15.7 min. In all cases, the cardioplegic solution was...
administered directly into the AVIC after insufflation of the anterior balloon, and the heart stopped immediately.

**Aortic valve isolation chamber sealing and following visualization**

The sealing of the valve was established in 5.8 ± 1.5 min and was successful in 9/10. In 1/10, no sufficient sealing could be observed. Additionally, in 3/10, a pulmonary artery vent was necessary. After the AVIC became stable, the endoscope offered a clear view of the valve, the annulus and the ascending aorta (Table 1).

**Resection time and accuracy**

The resection took, on average, 7.4 ± 2.7 min per leaflet and was completed in 7/10. In 2/10, the resection was interrupted due to a dysfunction of the AVIC and the instruments, and in 1/10, the laser source failed. The tractability of the laser fibre with the shape memory alloy was sufficient (Table 1). In combination with the rotatable inlay, the accuracy of the forceps catheter improved, too.

**Gross anatomy**

The gross anatomy showed only superficial lesions on the endomycardium and the papillary muscles. The mitral valve remained unaffected. After the procedure, no damage to the ascending aorta, such as intimal lesion or haematoma, could be observed.

**Stability of the aortic valve isolation chamber system**

The following AVIC-related problems occurred, such as dismantling of bonding surfaces (0/10), twisting of tubes (0/10) and leakages of subvalvular balloons (2/10), but no intracardiac loss of components was observed. The connection catheter to the supravalvular balloons revealed laser-related damage in 2/10.

**DISCUSSION**

**Aortic valve isolation chamber technology**

The sealing method of the AVIC is one of the important aspects of intracardiac microsurgery technology. Due to the different structures that make up the LVOT, such as the myocardium, the anterior mitral leaflet, and the aortic annulus, the subvalvular sealing device must be highly adaptable. In this study, a polyethylene balloon with a maximum volume of 60 ml was used to seal the LVOT. During the inflation process, the polyethylene surface aligned to the LVOT. As shown in the results, the sealing was sufficient in 9/10. In one case, no isolation of the LVOT was established. Detailed post-experimental inspection of this hearts' LVOT showed a prominent myocardium in the LVOT.

In a recent beating-heart study, the ventricular sealing of the right ventricular outflow tract was successful with this one-balloon technique [8]. However, the ventricular sealing with a single balloon in the aortic position is not as optimal as it seems—the occurrence of LVOT variation requires a more complex sealing. Therefore, an already postulated sealing concept should be used in future studies: adjustable balloons, stabilized in the LVOT by vacuum system. Additionally, the supravalvular sealing with the single balloon does not protect the coronaries. An aortic root isolation system, which ensures coronary perfusion, is under construction.

**Aortic valve resection in vivo**

The results of this study show that a transapical intracardiac resection of native aortic leaflets is technically possible.

In these experiments, a newly designed rotatable inlay and a shape memory alloy-based microactuator for the laser fibre guidance were used. Both offer significantly improved handling and avoid uncontrolled movements.

Nevertheless, the resection time is still high, but no severe lesions have been observed in the surrounding tissue. Compared with the retrograde resection of aortic valves using a two-step approach over the descending aorta and the carotid artery [10], this approach was performed with nearly direct access and allowed additional extracorporeal circulation.

In the opinion of physicians, the concept of clinical aortic valve resection has questionable promise. This questionable promise became more questionable with regard to the published results of transcatheter aortic valve implantation (TAVI), which have been steadily improving during the last years [11]. However, there are still unsolved problems. The paravalvular leakage, the deformation of the valved stent and neurological complications are present in all study cohorts. Moreover, everyone can see that this technology is intended to be offered to younger patients—and partly already is. This will be of questionable acceptance, especially with the current system and its technical problems [12]. Therefore, we believe that the technology must become safer, with the current developments in new implantation technologies, e.g. JenaValve, Perceval, DirectFlow, etc.

In the last years, other groups have presented their catheter-based resection concepts for the aortic valve—but without any shielding [13, 14].

We are not sure if this concept is the right one to solve all problems, but it is a beginning, and we have been continuously moving forward for 9 years. This experimental work should be considered preliminary and should be further built upon in the future.

**LIMITATIONS AND FUTURE PROSPECTS**

The use of extracorporeal circulation is no step forward to a less-invasive approach. Here, however, the extra corporeal circulation (ECC) offered the possibility of studying the aortic valve resection process and its side-effects on the surrounding tissue in a living non-beating heart. The goal of TAVI is that no ECC should be necessary—so if resection technology gains more interest, ECC should be avoided during aortic valve resection, too. Due to the experimental nature of this work, the present system was not created to be used clinically. In this study, the
coronary arteries are not sealed. A new aortic root-sealing device is under construction that allows coronary perfusion during supravalvular isolation. Furthermore, an in vivo model with calcified aortic leaflets will be created to evaluate the in vivo resection of highly calcified heart valves. Then, the resection has to be done with a Q-switched 2 μm laser radiation (personal communication). The removal of this bulky debris was already performed in an in vitro study using high-speed shavers from the orthopaedic department. These devices crushed the calcified debris and special irrigation and suction catheters removed the calcium from the chamber [10].

CONCLUSION

This study demonstrates a successfully performed transapical isolation and resection of native porcine aortic valves under ECC support in a non-beating-heart model. Despite the remarkable efforts that have been made in the field of TAVI, the pre-treatment of the highly calcified aortic annulus seems reasonable as a basic part of transcatheter intracardiac technologies in the future.

ACKNOWLEDGEMENT

The authors would like to thank Stephanus Buttgenbach, head of the Institute for Microtechnology in Braunschweig, Germany. Special thanks to Ionna Lozonschi and Lasse Bombien.

FUNDING

This work is supported by the Christian Albrechts-University of Kiel, Kiel, Germany (Junior Research Grant).

Conflict of interest: none declared.

REFERENCES


Table 1: Data of AVIC deployments and resection procedures

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min: minutes; AVIC: aortic valve isolation chamber, sealing attempts to achieve a stable isolation chamber.