A novel device for endovascular native aortic valve resection for transapical transcatheter aortic valve implantation

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INTRODUCTION

Cardiac surgery is increasingly performed on elderly patients with increasing comorbidities including impaired ventricular function, coronary disease, peripheral vascular disease and renal insufficiency. The factors of these comorbidities have been described as independent factors for mortality in the elderly population [1]. Open heart surgery using cardiopulmonary bypass to replace the aortic valve is associated with a higher morbidity and mortality in the elderly population [2, 3].

Transapical transcatheter aortic valve implantation (TAVI) is an approach to minimize morbidity and mortality in selected high-risk patients [4, 5]. With this technique, the calcified native valve remains in situ and has to be squeezed between the transcatheter valve and the aortic wall. This may lead to several complications. Implantation of the valve into a non-circular calcified annulus with a risk of severe paravalvular leak [6], risk of coronary ostia occlusion [7] and embolization of debris [8, 9] increase the mitral insufficiency [10] and prosthesis patient mismatch [11]. For these reasons, resection of the native valve before TAVI may be advantageous. Several resection methods have been published, using waterjet [12], laser cut [13, 14] or foldable cutting edges [15]. In this study, we describe a novel resection device designed for use in the setting of transapical access.

MATERIALS AND METHODS

Study design

The device trials were performed in human cadavers undergoing necropsy analysis. Inclusion criteria were the presence of aortic valve stenosis and leaflet calcification observed after aortic transaction at the level of the ascending aorta. From June 2009 to January 2011, 15 suitable cases were selected. The outcomes for the study were resectability and the measurement of forces needed for the cut.

The heart was explanted with a segment of the ascending aorta. The instrument was inserted through the apex, and the resection was performed under visual inspection (Fig. 1). Once completed, the resected area was measured directly by inserting a surgical probe.

Finally, the force needed to cut the valve was quantified. Force results were reported in Newton (N). The resected leaflets were mounted on a circular platform. The platform was clamped on a 6 degrees-of-freedom force sensor [Assurance Technologies Inc. Model: FT3025, 15/50 (force, ±15 lb; torque, ±50 lb)]. The three reaction forces and the three reaction torques needed to perforate the leaflet and to cut the leaflet were measured by the sensors. Four experiments were performed using a perforation blade and 10 experiments were performed using a cutting blade (Fig. 2). A post-treatment then computed the longitudinal force...
(leaflet perforation force) and the transversal force (leaflet cutting force).

RESULTS

The resection was successfully completed in 14 out of 115 (93%) cases. All the resected leaflets and debris have been captured successfully in 15 out of 15 (100%) cases. One case with a bicuspid valve had a prominent calcification of his median raphe. The resection tool could only perform a partial resection.

The mean annulus diameter of aortic specimens measured by probe insertion was 24.2 ± 1.9 mm. The mean resected area diameter measured by probe insertion was 20.0 mm. This is perfectly correlated to our instrument blade size of 20 mm (Fig 3). The surrounding myocardial tissue examination did not reveal any injury to the anatomical structures. Analysis of the resected leaflets provided a mean leaflet thickness of 0.5 ± 0.1 mm and a mean calcifications thickness of 4.1 ± 0.5 mm. The mean leaflet resection force was 7.1 ± 3.7 N (min = 2.0 N and max = 11.5 N). The mean leaflet perforation force was 7.3 ± 7.2 N (min = 1.0 N and max = 16.3 N). The mean duration of the resection was 45 ± 30 s.

DISCUSSION

This study confirms that transapical aortic valve resection is feasible in human heart. The analysis of the strength of calcified leaflets provides novel information about the force required to cut a native human calcified valve. To the best of our knowledge, such data have never been published in the medical literature. Wendt et al. [15] report the maximum force needed to resect artificially calcified bioprosthesis but not human native valve. In this study, 3.0 ± 0.6 N was required for moderate calcification and 3.5 ± 0.6 N for severe calcification. This is somewhat lower than the current finding of 11.5 ± 3.7 N. Possible explanations include the fact that human native valves may be stronger than the commercially available bioprosthesis. A second explanation could be that natural calcification over the course of many years could lead to stronger calcification than artificial calcification process performed within a few weeks. The force measured on the bench model gives an initial idea of the perforating and cutting forces required, but more sophisticated measurements should be conducted for different types of motion. In fact, it appears that the motion made by the surgeons (e.g. up and down motion) may have an influence on the resection force. It is also important to estimate in advance the limit of calcification that the tool can handle.

This study represents an important initial step to develop an adequate instrument to perform the resection of a native human calcified valve by an endovascular approach. The idea of native valve resection before TAVI was initially introduced by Quaden in 2005 [15]. This device involved a waterjet scalpel and a
A number of developments must still occur prior to using the device on live patients. First of all, the transapical tool should be smaller than 20 mm in diameter. For this reason, our team is developing a new prototype of expandable blade in order to reduce the access size through the apex. The tool also needs to be more flexible in order to penetrate with an adequate angle in the aortic valve. Eventually, we envision a multi-functional wire-mounted system to resect the native valve and deploy the new valve simultaneously.

One of the arguments of people who are against the resection of the native valve prior to TAVI is that the endovalue remains in place because of its fixation into the native leaflets. Their hypothesis is that if one resects the native leaflet, there is no way to stabilize the endovalue into the aortic annulus. The advantage of this resection device is the fact that the size of the resection blade is 20 mm and there is still a calcified ring of a few millimeters left in place to fix the stented valve properly. Most of the endovales rely on radial forces for anchoring. We believe that a partial resection, as we propose with our 20 mm blade, would provide a good anchoring calcified ring left in place. The anchoring force of the endovalue into the native valve and then into the calcified ring left after resections need to be measured on a bench. This experiment is ongoing in our department and our data will be published in the near future.

We believe that this novel device will be very useful in decreasing the amount of calcium before the implantation of the endovalue by the transapical approach. This will lead to a decrease in the rate of paravalvular leak, AV block, coronary occlusion even in the rate of late cerebral embolization.

There are two main questions left before clinical use. The first one is the risk of embolization of leaflet debris during the resection and the second is the acute aortic regurgitation induced by the resection. These two questions need to be addressed on a dynamic model. We work on an animal model but many practical problems still remain unsolved.

Directions for future study will include the trial of this instrument during conventional aortic surgery. Under aortic cross-clamping for the replacement of aortic valve, the instrument will be inserted in a retrograde fashion through the aortotomy to resect the native valve prior to the replacement of the aortic valve.

**CONCLUSIONS**

This cadaver experiment demonstrates that transapical aortic valve resection requires a maximal cutting force of 11.5 N and can be performed in <60 s. The creation of a clean circular annulus prior to TAVI may provide many advantages such as the decrease in paravalvular leak, decrease in the rate of AV block and decreased risk of coronary ostia occlusion.

**Conflict of interest:** none declared.

**REFERENCES**


**eComment. Transcatheter aortic valve implantation: need for continuing experimental research**

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We read the article by Astari et al. [1] with great interest. Although transcatheter aortic valve implantation (TAVI) has been established in clinical practice with acceptable results, it is highly desirable that basic research in this field is going on with unrestricted commitment. We still believe that this technique is far from ideal...
as mentioned seven years ago [2]. In our opinion, native aortic valve resection prior to TAVI is the only way to reach sustainable good results comparable to the results of conventional aortic valve replacement. Paravalvular leak, atrio-ventricular block, coronary occlusion and dislocation of the valve prosthesis are problems that could be solved with a reduction of calcified structures.

In our initial studies on endovascular resection of calcified aortic valves we used water and laser energy [3,4]. Astarci et al. had the idea to develop a mechanical resection tool using a simple stainless-steel circular blade [1]. Creating a large (20 mm diameter) orifice and leaving an anchoring calcified ring in the aortic root is an appealing novel method. Notionally, the compromise between a secure valved stent fixation and an optimal orifice area can be achieved with this puncture method. Furthermore, an optimal alignment of the valved stent to the surrounding structures appears to be possible due to the congruent ringlike geometry of both.

Nevertheless, the device presented is in a very early stage of development. We are looking forward to following the evolution of this device and the results of future studies that were signaled by the authors [1].

Conflict of Interest: None declared

References