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Use of Circular Foldable Nitinol Blades for Resecting Calcified Aortic Heart Valves

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The use of percutaneous aortic valve implantation is limited, as the native calcified valve is left in situ. A new device has been developed for resecting calcified aortic valves, using collapsible nickel-titanium blades: laser-cut T-structures of Nitinol sheet-material (Ni51Ti49 at.%) have been grinded on a high-speed milling cutter to produce cutting edges which have been given the shape of half-circles afterwards. These have been connected to each other and to struts by using rivets which also serve as articulating axes for the cutting ring. The blades are folded around these axes and retreated into a tube to be inserted in the heart through the calcified valve leaflets. Once released, the cutting edges regain their ring-shape. By combining rotation of the ring with a translating movement against a second ring of slightly greater diameter on the instrument, a punching process is created which cuts the calcified valve leaflets and leaves a circular annulus, where a prosthesis can be fixed. In vitro cutting of artificially calcified valves ($n = 6$) resulted in a resection time of $t = 22 \pm 6.29$ s with a maximum turning moment of $M = 2.4 \pm 1.27$ Nm, proving the function and the feasibility of the concept.

Keywords aortic valve, biomaterials, blade design, Nitinol, percutaneous valve implantation, resection tool, superalloys

1. Introduction

The standardized surgical procedure for treating aortic stenosis is aortic valve replacement (AVR) using open heart surgery (Ref 1-3): This "Goldstandard" procedure is performed "on-pump" using extracorporeal circulation after median sternotomy. The aorta is opened and the calcified native aortic valve is resected subsequently. Afterward, the new prosthesis is implanted either by a running suture line or pledget-armed single stitches. However, this procedure is rather time-consuming (20-60 min), and may therefore lead to trauma, especially in the case of additional comorbidities (e.g., poor left ventricular function or renal insufficiency). These comorbidities are currently becoming more frequent because of the aging population and so, morbidity and mortality following this surgery will increase (Ref 4-7).

One possibility to reduce the time on cardiopulmonary bypass is the use of sutureless valves. Therefore, after resection of the native diseased calcified tissues, the prosthesis—mostly an equine or porcine pericardial valve on a metal stent structure—is placed within the aortic annulus. It is fixed either by self-expanding (Nitinol frame) or by dilatation with a balloon catheter. For additional safety, up to three stay sutures are placed. However, experience shows that there is the problem of severe aortic insufficiency and paravalvular leakage caused mainly by the irregular geometries of the native tissues wherein the prosthesis is placed (Ref 8).

Percutaneous techniques for AVR via transfemoral or transapical access have become an alternative treatment option for high risk patients during the recent years (Ref 9-12). These methods minimize concomitant trauma and can be used in beating-heart conditions: The native valve is pressed against the aortic wall via balloon valvuloplasty and represents the landing zone, where a stented biological prosthesis is implanted afterward. However, as this calcified layer may be non-circular, often paravalvular leakage and regurgitation can be observed; even distortion and geometry-change of the prosthesis and of the aortic annulus may result (Ref 8, 13, 14). These factors may limit the function and long-term durability of the implanted valve.

As a result, a fast resection of the degenerated valve leaving an exact pathologic geometry would be advantageous not only for improving catheter-based implantation (Ref 15, 16) (if done endovascularly), but also for reducing the time of extracorporeal circulation by accelerating resection and thereby enabling the use of sutureless valves in open heart surgery.

In this report, we describe a resection device developed for this purpose by Endosmart GmbH in collaboration with the West German Heart Centre, University Hospital Essen and the Department of Physical Engineering, Fachhochschule Gelsenkirchen (patents pending). Production and function of the instrument which is intended for minimal-invasive surgery,

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using collapsible Nitinol cutting edges for the resection of calcified aortic valves, are described, as well as the results of several tests which were carried out under different configurations of the device.

2. Materials and Methods

2.1 Requirements

The basic idea was to design an easy-handling instrument, which allows a quick resection of the native aortic valve (less than 30 s), thus enabling reduction of ECC (Extracorporeal Circulation) times in open heart surgery and with the potential to be used in surgery on beating heart in a future application. As the tool was intended to be inserted through the strongly calcified leaflets of a native stenotic aortic valve with an opening area of only 0.75 cm^2 to 1.0 cm^2, the maximum outer diameter of the instrument tip which crosses the valve should be less than 10 mm (30 French). Furthermore, the cutting of different diameters according to the size of the calcified valve should be possible, leaving a circular rim of 1-2 mm, which functions as a "neo-annulus" for the insertion of the prosthesis. The valve leaflets should be resected mechanically, using a blade-expansion mechanism to create a circular cutting edge of up to 27 mm diameter in the expanded configuration (Fig. 1).

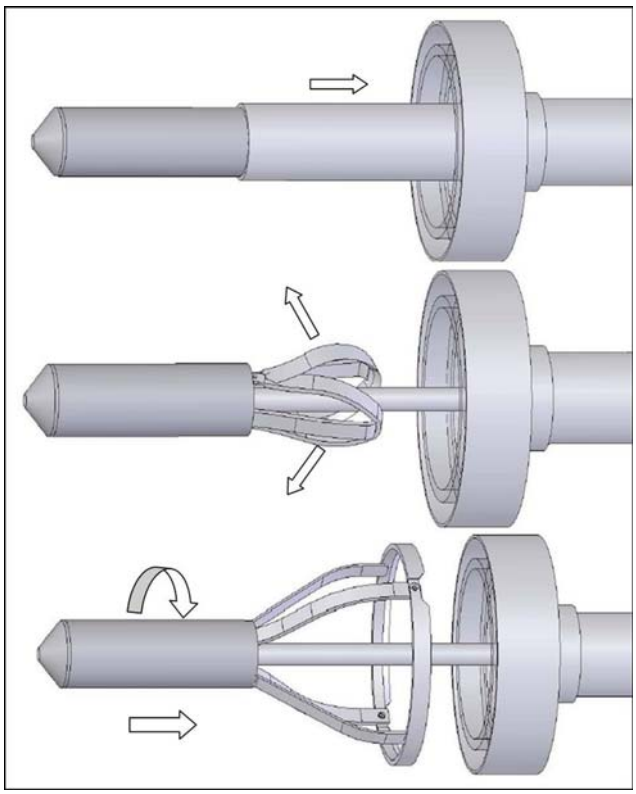

Fig. 1 Concept of resection

2.2 Cutting Edges

The shape of the circular cutting edges should ensure great stability and hardness to allow the creation of precise geometries during the cutting process. On the other hand, they should be collapsible into an insertion tube with an outer diameter of less than 10 mm. Thus, high flexibility was required. In view of the required properties, Nitinol has become the material of choice because of its superelastic behavior: The material can undergo extreme elastic deformation (up to 8%) while it regains its predefined shape when it is released and unloaded.

The blades were made from Nitinol (Ni51Ti49 at.%) sheet (thickness 0.35 mm), cut with a Nd:YAG-laser into T-structures, and shaped by heating at 530 °C while fixed on a 3D-structure. The resulting shapes were precise semi-circles with defined radius, created by flexing the T cross member. The T long member was bent as well to serve as support and connection to the instrument via the cross-structure at the 'foot' end. Furthermore, supporting struts were laser-cut and shaped, possessing a cross-shaped 'foot' end, too. In order to create the blade circle/cutting ring, two T-structures were connected to each other and to two of the additional struts by special rivets, which are perpendicular to the circle axis and are serving as articulating joints for the cutting edges. The different assembling steps are displayed in Fig. 2.

2.3 Sharpening

Before shaping, the blades underwent multi-stage grinding on a high-speed milling cutter (Aciera F1, SA Muller Machines Brügg, Switzerland, 10.000 rpm) using cera-gloss (Cera Gloss diamond, Edenta AG, AU/SG, Switzerland). After dressing of the rims (SRD Finisher 200, Service Precision Grinding Inc., Port Byron, NY, USA, 260 rpm), the T-structures were fixed in a custom-made holder, enabling a precise infeed and feed motion during grinding. The parameters of the three different steps of finish-milling are shown in Table 1 (Ref 17).

2.4 Resection Technique

For resection, a rotating punching technique was chosen. Therefore, two cutting rings are needed with a slight gap

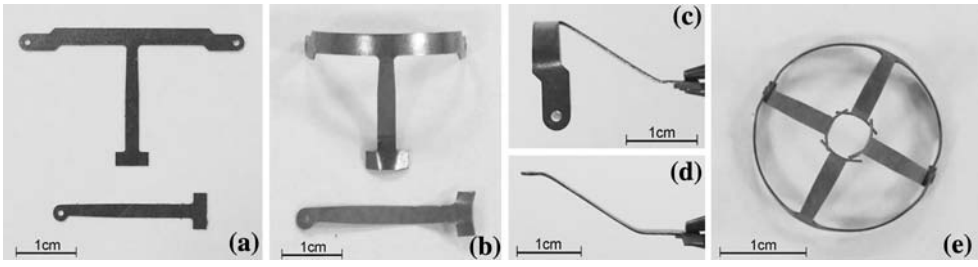

Fig. 2 Assembly of Nitinol cutting ring: (a) laser-cut blade and supporting strut; (b-d) blade and strut after shaping; (e) assembled cutting ring

(in this case 0.15 mm) between the outer surface of the inner ring and the inner surface of the outer ring. The blades of the two rings face each other with the material to be cut placed in-between. While one ring stays fixed, the other one approaches with a combination of translation and rotation movements until the final punching, when the mobile ring penetrates the fixed one.

2.5 Resection Tool

The resection tool used in this study was a prototype for open heart surgery, possessing one foldable and expandable blade, which has to pass the calcified valve, and a stable non-foldable ring structure as its counter part. Assembling of the prototype is shown in Fig. 3 and 4. The foldable Nitinol blade (outer diameter $d = 16.0$ mm, sheet thickness 0.35 mm) is mounted on the distal end of the instrument (A), with its cutting edge pointing at the main body. The "feet" of the blades are fixed on the distal sheath whose chamfered cap facilitates the instrument insertion through the center of the valve leaflets and protects the activating mechanism of the blades. Inside the distal sheath, the supporting struts are fixed on the body which can be moved along the longitudinal axis. The distal body (A) is connected to the main body via a tube, which transmits the turning and translation motion and also houses the activating struts of the cutting edge. Opposite to the collapsible blade, a massive, non-foldable ring, made of stainless steel (inner diameter 16.3 mm, outer diameter 18 mm, height 9 mm) acts as the counter-blade. This ring is chamfered on its outer rim for insertion in the aorta, but only burred at the inner rim to facilitate the punching process. This ring is connected to the "activating body" via a shaft of acrylic plastic (B), which by being translucent, enables visibility during resection. The activating body (C) houses two mechanisms: By operating lever (1), a contact protecting sheath (outer diameter 9 mm) in the acrylic shaft can be translated along the longitudinal axis to enclose/release the collapsed cutting edges; lever (2) is used to push the supporting struts in proximal direction and to expand the cutting ring to its circular shape. The body (D) of the mechanism houses an epicyclic gear (planetary gear 30/1, Faulhaber GmbH, Schönaich, Germany, 3.71:1), which increases the turning speed of the blade, and a screw thread (lead length 0.35 mm), which in turn transforms the turning motion of the handle (E) into a combination of translation and rotation movements. Handling is facilitated by using a ratchet.

Table 1 Parameters for finish-milling

Setting	Pre-grinding	Fine-milling #1	Fine-milling #2
Infeed, mm	0.1	0.04	0.01
Feed motion, mm/s	2.0	2.0	2.0
Rotation speed, rpm	10.000	10.000	10.000
Grinding tool	Cera Gloss HP green	Cera Gloss HP yellow	Cera Gloss HP yellow

2.6 Resection Process

The collapsible blades are folded, and the proximal contact protecting sheath is pushed over them until it makes contact with the distal insertion cap. From the aortic side, the so closed distal head is advanced through the center of the aortic valve until the massive counter ring touches the valve. The protective sheath is pulled back and the cutting edges are expanded. By turning the handle, the distal member (A) with the blade is moved toward the counter ring, thus punching out the tissues entrapped in-between. When the valve leaflets are cut, the instrument as a whole is pulled back out of the created "neo-annulus".

2.7 Test Specimens

Commercially available ingredients were mixed in order to replace native contents of calcifications (Table 2) and obtain material with comparable properties to native calcifications. Collagen was mixed with water (1:7) and after dissolution, 0.5 g hydroxyl-apatite and 3.5 g calcium carbonate were added. The mixture was dried for 48 h at room temperature and then fragmented to form particles. Moderately calcified valves were simulated by gluing (Loctite 4011, Zyanakrylat, Henkel®, Germany) one calcified fragment on each of the three leaflets of the commercially available (worn out/expired) stented aortic valve bioprostheses with geometries similar to native valves. After removing parts of the rigid stent structure, the prostheses were fixed in a steel tube to allow for stable conditions during resection (Fig. 5, 6).

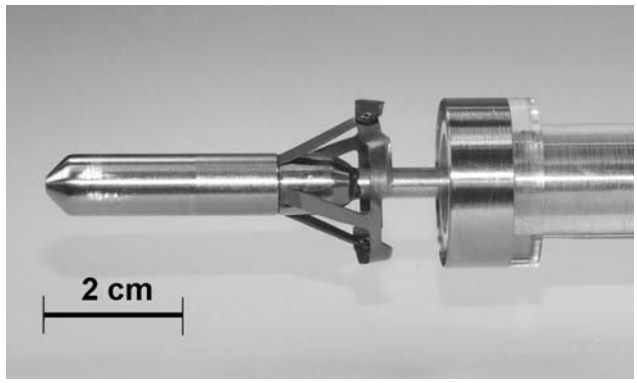

Fig. 4 Zoom on distal end of resection tool for open heart surgery

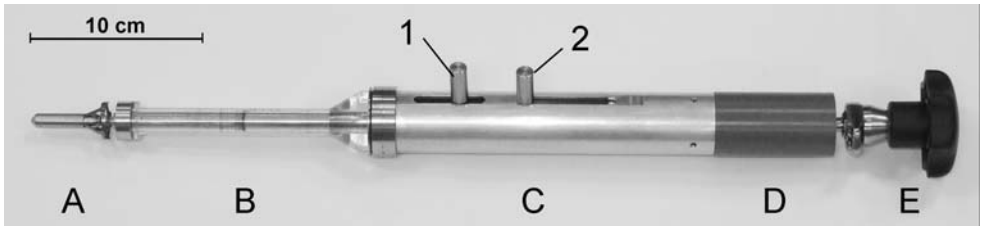

Fig. 3 Resection tool for open heart surgery

Table 2 Components of calcifications

Component		Equivalent
Calcium	Calciumcarbonate	"Weinkalk," Art.Nr.: 35500, Schlag GmbH®, Aalen, Germany
Collagen	Bone-glue	Perlform, MH + P®, Berlin, Germany
Hydroxylapatite	Hydroxylapatite	"Ostim" < 250 µm, Ch: 7A001, AAP Biomaterialien®, Dieburg, Germany

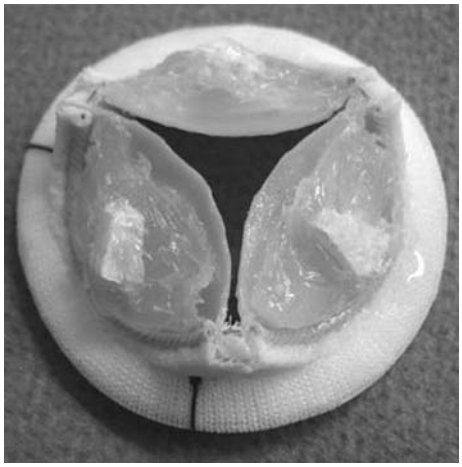

Fig. 5 Test specimen: Artificial particles glued on a bioprosthesis to simulate a moderately calcified aortic valve

Fig. 6 Test specimen fixed in stainless steel tube

2.8 Measurements

This study was carried out to obtain: (1) The overall function and handling of the instrument, (2) the time needed for resection, and (3) an idea of the turning moments during resection. Turning moments were recorded by inserting a torque sensor (DR-2477, Lorenz Messtechnik GmbH, Altdorf, Germany) between the handle and the main body of the instrument and processing the information using a digital connector (CB-68LP, National Instruments, Austin, Texas) and a PCA-card (PCI-MIO-16E-4, National Instruments, Austin, Texas). The measurements were saved and evaluated after the experiments using LabVIEW (version 6.1, National Instruments, Austin, Texas) for numerical and graphical analyses. Resection time and the maximum turning moment during this testing period were registered.

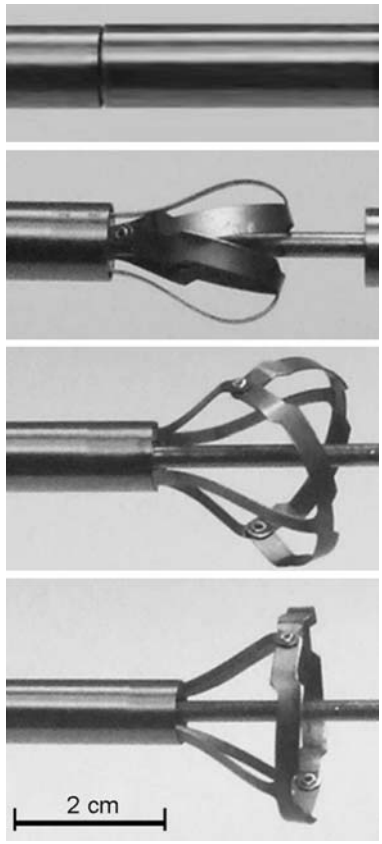

Fig. 7 Expansion of the Nitinol cutting blades

3. Results

Six artificially calcified aortic bioprostheses were used for the resection procedure with the prototype for open access. The cutting of the leaflets was successful in all the specimens without any complication during resection. The resection tool was easy to handle, even when elevated forces had to be applied; the expansion of the cutting ring worked well (Fig. 7).

Resection time was 22 ± 6.29 s (Mean $\pm$ SD); maximum turning moment of the instrument was 2.4 ± 1.27 Nm (Mean $\pm$ SD). The surface of the specimens was quite smooth after resection (Fig. 8). The results are listed in Table 3.

4. Discussion

The major findings of this study include (1) the function of the resection tool prototype using Nitinol blades was confirmed and (2) the realization of an aortic valve resection in less than 30 s using this tool seems to be possible regarding the results obtained for the resection of stented valves fixed in a steel tube.

Sutureless valves are rather a new application in the field of aortic valve replacement, but they will certainly become more

important and more widely available when the problems of insufficiency and paravalvular leakage of the prostheses are solved. In our opinion, it is therefore necessary to create a defined circular geometry in the native tissue before inserting a new valve. As of date, to our knowledge no instrument exists for this purpose. Resection methods which can be found in several patents, especially on endovascular resection of aortic valves (e.g., Ref 18, 19), are neither feasible nor clinically reasonable. Most of the concepts cannot produce a geometrically circular cut—being one of the main requirements—as they only "chip off" small parts of the leaflets with each cutting movement of the device. Other methods—mostly non-mechanical techniques such as laser or water jet cutting—are very difficult to handle and time-consuming, and thus do not allow a very fast resection. Therefore, we decided to develop an instrument which cuts the native valve by a rotational punching process between two circular cutting edges.

The configuration of this prototype is a further development of a previous study, in which we investigated grinding possibilities, stability, and fundamental design of the cutting edges (Ref 17). The use of flat cutting edges (instead of waved ones or saw-tooth blades) and the rotating punching process showed the best results. The sheet thickness of 0.35 mm for the Nitinol blades was chosen as tests revealed that it offers the best combination of shape stability and flexibility: Using thinner sheets facilitates the folding of the cutting edges and their insertion into the protecting sheaths. On the other hand, stability gets poor with turning moments ranging from 2.5 to 3.0 Nm as they were obtained in this study, thus causing elastic deformation during cutting. Contrarily, the use of thicker sheets decreases flexibility, i.e., the blades can be folded only with difficulty, causing deformation and ultimately leading to non-circular/oval cutting rings in the expanded state. Further experiments will show whether the right parameters were chosen or whether the alloy grade or the thermo-mechanical treatment needs to be changed.

In this study, the shaping of the cutting edges was performed on a complex 3D structure, using 25 min of heat treatment at 530 °C in normal atmosphere, followed by quenching in water. The temperature of 530 °C was chosen as a compromise, as we were not able to create a non-oxidising environment in our furnace. On the one hand, lower temperatures would have increased the heating time while not totally preventing the creation of an oxide layer. On the other hand, higher temperatures would have reduced time, however, resulting in a much thicker oxide layer on the blades. The rather long time span was determined by tests: We increased heating times at fixed temperature until the sheet material did not bend back elastically when the loading was removed. In future studies, the effect of the temperature curve of the blades during the nominal 25 min of heating should be dealt with to learn more about its influence on the thermodynamic, micro-structural, and mechanical properties and about its effects on stability and elasticity of the blades.

There was no special treatment of the Nitinol structures before aging, but dressing of the rims and sharpening of the cutting edges. We performed sharpening before heat treatment mainly for production reasons. Flat sheeting was much easier to fix and to grind on a high-speed milling cutter than complex structures. Thus, the sharpening procedure could be optimized and nearly standardized, resulting in reproducible good sharpness of cutting edges, comparable to razor blades (Fig. 9) (Ref 17). Heat treatment following this process created a thin oxide layer on the blades which reduced the initial sharpness, but as the cutting edges still passed the sharpness test according to DIN 58298, we decided to use them for this study. For future studies, we will have to think about possibilities to remove the oxide layer and to restore the initial state, for example, using electro-polishing. We also thought about DLC (Diamond-like carbon) coating to improve the durability of the cutting edges, but due to the high stresses induced by the folding of the blades during application (radius of up to 14 mm got reduced to radius of about 3 mm), there was the risk of damage to and detachment of the thin layer; therefore, this method was not used.

Fig. 8 Cutting result of moderately calcified bioprosthesis: Zoom (×20) on artificial calcification

Table 3 Resection results

	I	II	III	IV	V	VI	Mean	SD
Resection time, s	32	26	18	23	18	15	**22**	**6.29**
Maximum turning moment, Nm	4.6	3	1.9	2.4	1.2	1.3	**2.4**	**1.27**

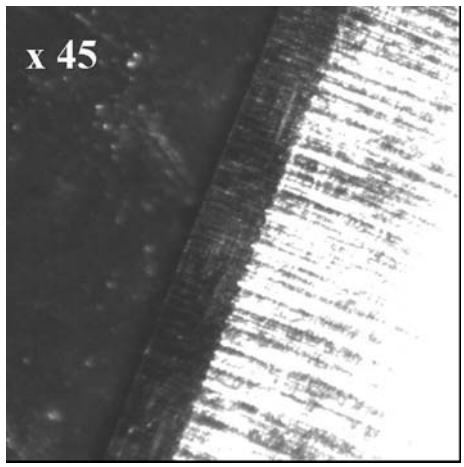

Fig. 9 Microscopic view (×45) of a sharpened blade after multi-stage grinding

As this study is meant to be a first step in testing the instrument, the test-setup was important for analyzing the results. Therefore, we chose to use commercially available worn-out or expired stented valves, for example, the ''Edwards 25 mm Aorta S.A.V. 2650''-bioprosthesis (Edwards Lifesciences, Irwine, CA) or the ''Medtronic 25 mm Aorta Mosaic Ultra 25-A 305''-bioprosthesis (Medtronic Inc., Minneapolis, MN). All the specimens had in common, that the valve consisted of natural tissue, being attached to a stented frame in a semilunar fashion similar to geometries of native valves. As the rigidity of the stent was not comparable to native tissues, it would have prevented taking the desired blade diameter. Therefore, the upper tips of the semilunar structures were cut before we added the particles for simulating calcifications. Finally, the suture cuff of each valve was fixed in a steel tube to guarantee stable conditions during resection. For comparable results, the instrument was attached to a holding fixture, thus eliminating differences due to the instrument's angle to the valve or due to a positioning out of the valve's center.

Another important point to note relates to choosing the right size for the cutting edges. Before normal surgery, the diameter of the diseased valve can be measured using TEE guidance (transoesophageal echocardiography), CT (computer tomography), or MRT (magnetic resonance tomography). The nominal diameter of the blade set is chosen to be smaller to generate a circular rim of 1-2 mm, which will act as ''neo-annulus'' for the prostheses. As we wanted to cut prostheses of 25 mm diameter, we had to subtract additional 5 mm for the supporting stent frame and suture cuff, thus performing resection with a nominal blade diameter of 16 mm.

All these abovementioned points have to be considered when analyzing the results.

Operating the instrument was easy. There was neither a problem to insert the instrument head through the leaflets of the prostheses nor to open the foldable blades which regained their circular shape and enabled it to perform the cutting process. Furthermore, the rotational punching was easy to perform as a ratchet was included in the handle. On the other hand, quite relevant forces had to be applied on the handle because of the elevated turning moments ranging from 1.2 to 4.6 Nm. Without the use of the holding fixture for the instrument, stable cutting and accurate positioning of the instrument would have been very difficult. It is not really clear, why torques had to be that high, especially as cutting seemed quite uniform. Regarding the turning moments, a much more discontinuous movement would have been expected. Presuming that the forces are not only produced by the cutting itself and that the contact-free torque sensor is no source for torques, we concluded that at least one of the components between blades and handle had to be responsible. With an efficiency of 88%, the transmission gear contributed to the increase of forces, but probably the main cause was the thread that was used for the transformation of the turning motion into a combination of translation and rotation. In order to investigate the influence of the thread, this part of the instrument should be redesigned to separate these two movements.

In this study, resection of all the three valve leaflets could be completed within a time range of 15 to 32 s, validating our concept of a fast resection using a simple mechanical procedure. Other concepts which are described in the literature required much more time: from 2.3 ± 0.3 min to 12.2 ± 0.8 min per leaflet using a water stream scalpel (Ref 15), and to 15.5 ± 3 min per leaflet using a YAG laser (Ref 16). Thus, an explicit acceleration of the procedure was obtained when cutting the moderately calcified valves with our new device. Further tests will show whether these results remain the same for organic tissues which are more calcified.

It is also important to perform additional tests to identify the risks of using the resection tool in its real working environment, when cutting conditions are not as optimized as in this study. As 40 mm of the distal end of the instrument is pushed through the valve inside the left ventricle, there is the risk of the blades damaging ventricular structures during operation. Before experimenting it on living patients, surgeons have to be sure that neither an unintended lesion is created in the organic tissues, such as the ventricular wall or the mitral valve annulus, nor parts of the instrument stick to ventricular structures as the mitral cordae. Risk is reduced by the concept of not excising the valve and all the calcified tissues completely, but of leaving a rim of 1-2 mm, serving as ''neo-annulus''. Thus, a certain distance between rotating blades and ventricular tissues is already installed. Nonetheless, it would be appropriate to control the cutting procedure by endoscopic means, at least to enable a right positioning. There is less risk of damages to aortic structures, such as the coronary ostia, as the outer edge of the counter ring can be chamfered, and a rotating movement is absent.

During our tests, we observed the creation of fragments and debris. The resected valve leaflets, as well as small- and middle-sized particles generated by the cutting process were either enclosed in the counter ring or fell through the struts of the foldable blade to where there would be the left ventricle. The protection against potential embolism caused by these particles will be of utmost importance during surgery to prevent obstruction of the coronary arteries or stroke. Therefore, first of all, a filter structure should be incorporated in the instrument, being placed between the struts of the distal cutting ring, and thereby collecting most of the particles which are not already enclosed within the proximal counter ring. In addition, in the open heart situation, there is the possibility to block the coronary ostia (e.g., with probes) and to use a suction device for aspiration of particles which escape from the blades and fall into the ventricle.

Further important questions to be noted are the influence of working environment on the results and the limitations of this study. We are aware of the complexity of cardiac anatomy, and that we created optimized conditions for our tests. Replacing the steel frame by the native, non-circular aortic root could pose a problem, but possibly the circular counter ring, being nearly as big as the native valve, will spread the aorta to circular shape. Further studies will have to show, whether this is sufficient for stabilization of the instrument or other means have to be designed and integrated. In addition, cadaver studies would be necessary to investigate the influence of comorbidities or congenital defects on the function of the resection tool, as well as to cut native diseased aortic valves with blade diameters ranging from 21 to 27 mm. Regarding the Nitinol cutting edges, this would allow us to learn about forces, turning moments, and abrasion of the blades. As a result, optimizing of geometry and sizes of the blades will be possible, for example, using the Finite Element Method (FEM), especially for the dimensioning of blades with a diameter greater than 21 mm, as with increasing diameter, achieving stability during collapsing/expanding becomes more difficult. In addition, as changing of blades is rather time-consuming for the prototype of this study (approx. 5 min), a new design should allow changing of blades

more easily and quickly even during surgery, in the event of their malfunction.

However, in conclusion, the first results with this prototype show that a rapid resection of an aortic valve seems to be possible. If the use of this device can be combined with the use of a sutureless valve, then a duration for cardiopulmonary bypass below 10 min should become possible, meaning a reduction of 50-80%. Thus, morbidity and mortality rates of AVR could be reduced, and therefore this novel method of an accelerated aortic valve resection in combination with the insertion of a sutureless aortic valve will probably make conventional surgery more attractive. Further, it would be the first step toward the use of these techniques (resection and sutureless valve) in surgery on beating heart. Performing the AVR within 1 min after resection of the pathology with much better results than till now (e.g., without regurgitation) seems possible owing to the precisely shaped annulus remaining *in situ*. Further optimization of the instrument is necessary, as well as *in vitro* tests, cadaver studies, and perhaps animal trials, to continue this "development" and to use this minimally invasive instrument during open heart surgery.

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