ESCVS article - Experimental

Cutting precision in a novel aortic valve resection tool. Research in progress

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Abstract

Background: We recently demonstrated the first in-vitro cutting results of a minimal-invasive aortic valve resection tool. The current study was designed to assess the cutting accuracy of this new device improved by the implementation of a linear motor-based propulsion unit. Methods: Native aortic valves of isolated swine hearts (valve diameter 17.8 ± 0.9 mm, mean ± S.D.) were artificially stenosed and calcified (n = 7). Subsequently, valves were resected by the use of a new aortic valve resection tool. The cutting process was performed by fitting the instrument with foldable Nitinol cutting blades (diameter 15 mm) and two software-operated linear motors combined with separated manual rotation. Aortic valve area was measured pre- and postprocedure by software-guided binary area calculation. Aortic valve residue has been determined and the grade of accuracy has been assessed via calculating the average midpoint of the neoannulus. Furthermore, radial deviation of concentricity was calculated and cutting time was measured. Results: Aortic valve resection was successful in all cases and nearly all leaflets (2.5 ± 0.4) with a weight of 0.22 ± 0.12 g were cut. Aortic valve area increased significantly (0.3 ± 0.1 cm² vs. 1.1 ± 0.2 cm², P < 0.001) with a mean cutting time of 49.7 ± 15.0 s. Mean lateral leaflet rim within the annulus was 3.2 ± 3.2 mm. Cutting precision revealed a median deviation of the cutting ring from the desired position of 1.3 ± 0.6 mm (y-axis) and 1.4 ± 0.5 mm (x-axis). Median center deviation of the cutting ring was 2.6 ± 0.8 mm. Conclusions: The present study clearly confirmed ability of an accelerated cutting of stenotic aortic valve by the aortic valve resection tool. Nearly all leaflets were cut and a small rim was left within the annulus, hence providing an ideal ‘landing zone’ for the new prosthesis. Nevertheless, the aortic valve resection tool should be enhanced by adding a centering mechanism, thus achieving a more precise cutting process in order to avoid secondary damage.

Keywords: Aortic stenosis; Aortic valve resection; Resection tool; Sutureless valve implantation; Cutting performance; Minimal-invasive

1. Introduction

Degenerative and calcified aortic stenosis (AS) is the most frequent form of adult heart valve disease with an increased prevalence in the elderly and the prognosis is poor once symptoms occur [1]. At present surgical aortic valve replacement (AVR) by the use of extracorporeal circulation is the golden standard which is commonly performed with optimal results [2]. However, valve excision and thorough debridement of the annulus may be rather time consuming especially in the case of severe calcification followed by encircling the annulus with sutures for valve fixation. Therefore, owing to an aging and multimorbid patient population, contemporary patients will benefit from reduced ischemic and procedure time [3]. Thus, the accelerated resection of the stenotic native aortic valve would be favorable prior to the implantation of the new prosthetic aortic valve. For this purpose, the West German Heart Center Essen in collaboration with Endosmart GmbH and the Department of Physical Engineering, Fachhochschule Gelsenkirchen, developed an innovative prototype of a novel aortic valve resection tool based on foldable nickel-titanium (NiTi) blades (European and US patent pending) which offers the possibility of an accelerated valve resection [4, 5].

The aim of the present study was, therefore, to determine the cutting accuracy and precision of this new aortic valve resection tool in an in-vitro study.

2. Material and methods

2.1. Study design

Resection of artificially stenosed aortic valves was performed in ex-vivo porcine hearts (n = 7). All studies were performed with the prototype of our minimal-invasive aor-
tic valve resection tool equipped with rotating and foldable Nitinol cutting edges (further details will be listed below). In contrast to our previous studies an implemented linear motor drive system enabled precise translation.

During each experiment the following data were obtained:

- Aortic valve diameter (mm)
- Aortic valve area, pre- and post-resection (cm²)
- Resecting time (s)
- Number of resected leaflets
- Maximum aortic valve residue per valve leaflet (mm)
- Distance from aortic valve rim to the aortic wall at nine defined measuring points (mm)

Aortic valve diameter, aortic valve residue and the distance from the valve rim to the aortic wall was measured by an analog slide gauge with a resolution of 0.05 mm (Promat RN 11, Max Schön AG, Lübeck, Germany). Aortic valve area was calculated by image processing and analysis software (ImageJ, U.S. National Institutes of Health, Bethesda, Maryland, USA). Calculation was based on a digitally recorded photography of the aortic valve (including a metric reference scale) prior to and after the resection process. The relevant section was enlarged and the aortic valve area was digitally inked (Adobe Photoshop Elements, Adobe Systems, San Jose, California, USA). Additional shading and filling of the relevant parts improved contrast. Afterwards, a binarization was performed and by the use of the reference scale, the aortic valve area was automatically calculated. The process of aortic valve area calculation is illustrated in Fig. 1.

**2.2. Cutting precision**

Cutting precision was defined as the deviation of the midpoint of the neo-annulus (center deviation) and the deviation of the whole neo-annulus from the calculated central position. After the cutting process, the rim dimensions were obtained at nine defined and fixed measuring points (Fig. 2). Afterwards, the Cartesian coordinates of these measuring points and the designated positions, depending on determined aortic valve and cutting ring diameter (15 mm) were calculated. In order to calculate the cutting accuracy, the midpoint of the cutting ring (15 mm) was calculated and was compared for each experiment with the new created midpoint after the resection procedure. The Pythagorean theorem calculated the Cartesian coordinates of the created midpoint after the resection. By the use of a linear system of equations, in each case, three arbitrary real positions (out of the nine measuring points) computed the midpoint of the neo-annulus. The arithmetic mean of 15 calculated midpoints defined the created midpoint of the neo-annulus. The distance between the midpoint of the neo-annulus and the desired midpoint defined the median center deviation and was additionally calculated in x- and y-direction. Furthermore, the median deviation of the cutting ring from the desired position was calculated. This deviation was calculated by subtracting the real positions of the annulus from the desired positions within the Cartesian coordinates graph and was calculated for x- and y-deviation.

**2.3. Aortic valve resection tool**

Aortic valve resection was performed by using the aortic valve resection tool as previously described by our group [5]. The prototype of this innovative, easy-handling and short-time-procedure device is illustrated in Fig. 3. Due to anatomical reasons (in contrast to our previous studies) the current experiments were performed with 15 mm diameter cutting edges. Opposed to our preliminary tests, the resection tool was equipped with a linear motor drive.
system. This technical innovation offers on the one hand the decoupling of the two motions and on the other hand, the translation could be easily changed by digitally adjusting form feed of both linear motors.

2.4. Linear motors and motion controller

The implementation of two synchronal linear motors (LM 1247 ‘Quickshaft’, Dr Fritz Faulhaber GmbH & Co KG, Schönaich, Germany) decoupled feed motion and manual rotation during the cutting procedure. The linear motors allowed precise heading with automated linear form feed (0.175 mm/step) by a computer-controlled, customized sequence program. Maximum and nominal force of each motor was 9.3 N and 3.1 N, respectively. A ring connected both motors with the manual driven rotation part of the instrument, decoupling automated heading from manual rotation (Fig. 3 F/G). Motion control units operated (Motion Controller MCLM 3003/06 C, Dr Fritz Faulhaber GmbH & Co KG, Schönaich, Germany) and the Motion Manager® software package offered user-defined heading of both linear motors (version 3.0, Dr Fritz Faulhaber GmbH & Co KG, Schönaich, Germany).

2.5. Test specimens: swine hearts

Seven porcine hearts, one day after explantation (stored at 5 °C), taken from five-month-old swine were prepared for aortic valve resection. After removing of blood residue, the aorta was cut one centimeter above the aortic valve. The left ventricle was opened 40 mm below the aortic valve enabling unlimited view during the cutting process.

The aortic valve was artificially stenosed by fusing the three unrestricted leaflets (Prolene 6-0, Ethicon, Norderstedt, Germany) and additionally, the aortic valve was freeze-dried by a cooling spray prior to the resection process (75 Super, Kontakt Chemie, CRC Industries Deutschland GmbH, Iffezheim, Germany). Both methods simulate aortic valve ‘calcification’. A ‘stenosed’ valve is illustrated in Fig. 1a.

2.6. Statistics

Continuous and normally distributed data were reported as mean ± standard deviation (S.D.). A Student t-test was used for paired data testing. A P < 0.05 was considered to indicate statistical significance. All statistical analyses were performed using the Sigma-Stat® software package, version 2.0 (Systat Software Inc, San Jose, CA, USA).

3. Results

3.1. Test setup

Seven artificial stenosed porcine aortic valves with a diameter of 17.8 ± 0.91 mm were used for the resection procedures. All valves were cut and no signs of complications occurred during the resection. A total of 2.5 ± 0.4 leaflets were resected, leaving a flat and smooth surface within the annulus.

Neither the resection tool nor the linear motor drive system showed any signs of malfunction during the experiments. A resection result is illustrated in Fig. 4. Results are listed in Table 1.

3.2. Resection time

Resection time was 49.7 ± 15.0 s (range 26–64 s). Results are listed in Table 1.

3.3. Cutting precision

The mean lateral leaflet rim after resection was 3.2 ± 3.2 mm. Aortic valve area increased from 0.29 ± 0.1 cm² to 1.1 ± 0.2 cm² (P < 0.001). The mean center deviation of the

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**Table 1**

<table>
<thead>
<tr>
<th>Cutting results</th>
<th>Porcine aortic valve (n=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median aortic valve diameter</td>
<td>17.8 ± 0.91</td>
</tr>
<tr>
<td>Resected leaflets</td>
<td></td>
</tr>
<tr>
<td>Mean ± S.D., mm</td>
<td>2.5 ± 0.4</td>
</tr>
<tr>
<td>Resection time</td>
<td></td>
</tr>
<tr>
<td>Minimum, s</td>
<td>26</td>
</tr>
<tr>
<td>Maximum, s</td>
<td>64</td>
</tr>
<tr>
<td>Mean ± S.D., s</td>
<td>49.7 ± 15.0</td>
</tr>
<tr>
<td>Lateral leaflet rim, mm</td>
<td></td>
</tr>
<tr>
<td>Mean ± S.D., mm</td>
<td>3.2 ± 3.2</td>
</tr>
<tr>
<td>Aortic valve area</td>
<td></td>
</tr>
<tr>
<td>Before resection, cm²</td>
<td>0.29 ± 0.1</td>
</tr>
<tr>
<td>After resection, cm²</td>
<td>1.1 ± 0.2</td>
</tr>
<tr>
<td>Center deviation</td>
<td></td>
</tr>
<tr>
<td>Median center deviation, mm</td>
<td>2.6 ± 0.8</td>
</tr>
<tr>
<td>x-axis, mm</td>
<td>2.1 ± 0.9</td>
</tr>
<tr>
<td>y-axis, mm</td>
<td>1.2 ± 1.2</td>
</tr>
<tr>
<td>Cutting ring deviation</td>
<td></td>
</tr>
<tr>
<td>x-axis, mm</td>
<td>1.4 ± 0.5</td>
</tr>
<tr>
<td>y-axis, mm</td>
<td>1.3 ± 0.6</td>
</tr>
</tbody>
</table>
isolated AVR has been reported to be 1.0% for patients overall risk profile. However, age is not a contraindication referred for surgery present gradual increases in age and as there is no effective medical therapy patients presenting with symptomatic aortic valve stenosis by the use of an integrated linear motor drive system. was acceptable and once symptoms occur of symptoms since morbidity and mortality will increase more, AVR should be performed promptly after the onset reduction of comorbidities. The present work aimed to these advantages of the present philosophy. The aortic annulus can be measured by TEE guidance prior to extracorporeal circulation and a corresponding cutting blade can be predetermined and fixed within the instrument’s tip. Additionally, an appropriate sutureless or balloon-expandable aortic valve prosthesis can be rinsed and prepared in advance, thus decreasing ischemic time as well. Not only the implantation of biological, sutureless aortic valve prostheses will be possible, but also the implantation of a mechanical, sutureless aortic valve will be feasible [18]. A small circular remnant of 1–2 mm within the aortic annulus should be left, which acts as the ‘neo-annulus’. This ‘neo-annulus’ plays an essential role as a kind of ‘landing zone’ for the implantation of the new prosthesis. In the present study, the mean lateral leaflet rim was 3.2 ± 3.2 mm allowing to anchor the new prosthesis. The new prosthesis should be equipped with a ‘c-shaped’ annulus, covering the ‘neo-annulus’ from below and above, preventing paravalvular leakage by this method. In this entire context, the cutting precision of this new aortic valve resection device is of utmost importance. The precise alignment, fixation and stabilization before and during the whole cutting process must be guaranteed and evaluated since secondary injury of the aortic wall, the ventricular septum or the mitral valve leaflets may occur. Within the present study a median deviation of the cutting ring from the desired position was moderate (1.4 ± 0.5 mm on the y-axis and 1.3 ± 0.6 mm on the x-axis). But keeping in mind, that the new created ideal ‘neo-annulus’ should only be 1–2 mm in width, this accuracy seems to be imprecise, particularly when considering the median center deviation of 2.6 ± 0.8 mm. In the present study, the imprecise centring may be due to porcine anatomical reason as the non-coronary cusp of the trileaflet aortic valve appeared to be partly fused with the porcine ventricular
situs after resection is essential. As well, the secure pro-
circulation, flushing of the outflow tract and the whole
incorporation of filter systems or integration of a suction
must be removed by additional safety features like the
process is crucial. During valve resection, created debris
in the current instrument to achieve an optimal position in
order to prevent secondary damage.

Furthermore, the particle generation during the resection
process is crucial. During valve resection, created debris
cannot be removed by additional safety features like the
incorporation of filter systems or integration of a suction
process is crucial. During valve resection, created debris
in the current instrument to achieve an optimal position in
order to prevent secondary damage. Anyway, this concept
can result in accelerated conventional AVR, making,
therefore, classic surgery again more attractive.

4.1. Limitations

Within the present study, aortic valve resection was based
on porcine swine hearts prepared for aortic valve resection.
Therefore, this model does not simulate ‘real-life’ human
conditions due to different valve anatomy, as the native
non-coronary porcine cusp is fused with the septum of the
ventricle. Moreover, our design of valve calcification by
sutting and freezing the native porcine aortic valve cusps
is still lacking. Future studies should be performed in more
realistic models, like human cadaver experiments before
considering the first clinical application.

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