Impact of progressive sinotubular junction dilatation on valve competence of the 3F Aortic and Sorin Solo stentless bioprosthetic heart valves

Michael Scharfschwerdt, Hans-H. Sievers*, Adel Hussein, Ernst G. Kraatz, Martin Misfeld

Department of Cardiac Surgery, University Clinic of Schleswig-Holstein, Campus Lübeck, Ratzeburger Allee 160, 23538 Lübeck, Germany

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Abstract

Objective: The use of stentless bioprostheses for aortic valve replacement provides excellent haemodynamics; however, these valves bear the potential risk of progressive regurgitation over time. To overcome this disadvantage, a new generation of pericardial stentless prostheses has been developed. This study aims to assess the tolerance of such bioprostheses against progressive sinotubular junction dilatation. Methods: Five specimens of both the 3F Aortic and Sorin Solo stentless bioprostheses (diameter 25 mm) were investigated in a pulsatile flow simulator incorporating a device for gradual expansion of the sinotubular junction diameter. Closing characteristics were obtained by high-speed video imaging and the corresponding regurgitations were determined by ultrasonic flow measurements. The diameters $D_R$ at which primary distinct regurgitation occurs, were correlated to the original diameters $D_A$ and expressed as percentage values. Results: The highest tolerance against sinotubular junction dilatation was found for the 3F Aortic (156/5%) compared to the Sorin Solo (145/6%, $p = 0.0127$) bioprosthesis. Visualisation of the valves revealed strong leaflet folding at labelled diameter, similar in both valve types. Conclusions: New-generation pericardial stentless bioprostheses provide favourable adaptability to sinotubular junction dilatation, more pronounced for the 3F prosthesis. Whether undue leaflet folding caused by the redundant tissue influences long-term function remains to be established.

Keywords: Heart valve bioprosthesis; Stentless

1. Introduction

The application of bioprosthetic valves for the replacement of malfunctioning aortic valves increases continuously. In Germany in 2008, a total of 12 397 prosthetic heart valves were implanted in aortic position in single-valve procedures, 78.3% of which were homografts and xenogenic bioprostheses.[1]. For homografts, there is a rising lack of availability, thus porcine and bovine bioprostheses become more and more important. Two configurations of bioprosthetic valve substitutes are common, either stented or stentless, both providing excellent haemodynamics. However, stentless valves reveal a greater potential for postoperative improvement of left ventricular function due to favourable transvalvular gradients and effective orifice area indices [2,3]. This advantage, commonly associated with the distensibility of such stentless prostheses, was impaired by cases of late aortic insufficiency in patients undergoing valve replacement following dilatation of the sinotubular junction [4,5]. Although re-operations due to severe valve insufficiency caused by isolated root dilatation were rare, mild or moderate aortic regurgitation occurred more often (10—18% of all patients within 10 years, depending on valve type and implantation procedure [4–6]) and could be correlated to greater sinotubular junction diameters in those patients [4,7].

In a previous in vitro investigation, we found a significant less tolerance towards aortic regurgitation, related to changes of aortic root dimensions, for the Toronto SPV and the Freestyle stentless bioprostheses compared with native porcine aortic valves [8]. This loss of adaptability is probably related to the glutaraldehyde fixation of the valves, which stiffen and shrink the leaflet material, reducing leaflet stretching ability and leaving insufficient coaptation reserve. Meanwhile, a new generation of pericardial stentless bioprostheses has been developed featuring redundant leaflet tissue for larger coaptation area, which may provide better adaptability to adverse changes in root dimensions. This study aimed to evaluate the 3F Aortic and Sorin Solo stentless valves regarding their tolerance against aortic regurgitation with respect to sinotubular junction dilatation.

2. Methods

2.1. Experimental setup

Tests were performed with the 3F Aortic, Model 1000 (3F Therapeutics Inc., Lake Forest, CA, USA) and the Sorin...
Freedom Solo (Sorin Biomedica Cardio, Saluggia, Italy) stentless bioprosthetic heart valves (Fig. 1). Valve size was 25 mm for both types of prostheses. Five specimens of each type were used for the study.

Measurements followed the protocol, details of which have been described previously [8]. In brief, the bioprostheses were implanted in root inclusion fashion into a 26-mm Dacron vascular graft incorporating redundant patch material, which allows for further increase of sinotubular junction diameter (Fig. 2). Dilatation of the prosthesis was performed by means of an adjustable ring-shaped device mounted outside the prosthesis at the height of the respective valve commissures, providing a 0.8-mm gradual increase of diameter from 26 mm up to 45 mm. Commissural height, defined as the distance between the base suture line and the fixation of the commissures (Fig. 3), was 20 mm for the 3F Aortic and 17 mm for the Sorin Solo valve.

For haemodynamic measurements, the composite grafts were mounted inside a pulsatile flow simulator providing physiological flow conditions [9] and run at a heart rate of 64 cycles per minute with a stroke volume of 60 ml for a systemic pressure of 125/80 mmHg. The test fluid consisted of physiological saline solution.

2.2. Data acquisition and analysis

Valve-closing motions were recorded with a Motionscope HR-1000 high-speed camera (Redlake Imaging Corp., Morgan Hill, CA, USA) positioned right above the valve at a rate of 500 frames per second. Simultaneously, flow through the valve was measured with a TS410 ultrasonic flow-meter (Transonic Systems Inc., Ithaca, NY, USA) mounted upstream the valve. For each valve investigated, the consecutive video sequences were carefully evaluated to detect the diameter at which the first distinct loss of central coaptation of the leaflets was observed (Fig. 4, middle). The tolerance against root

Fig. 1. Photographs of the investigated 3F Aortic (left) and Sorin Solo (right) stentless bioprosthetic valves.

Fig. 2. Schematic drawing of the composite graft incorporating folded extension patches in the sinus regions and a device for gradually increasing the sinotubular junction diameter. In brief, if the hose clip is widened (circular arrow) by turning the screw, the commissures are moving apart (outward arrows) while unfolding the extension patches. hc — hose clip; fep — folded extension patches; com — valve commissures.

Fig. 3. Schematic illustration of measured and calculated valve dimensions used in this study. $D_A$ — annulus diameter (corresponds to the labelled valve size); $D_R$ — valve diameter at which first distinct regurgitation was observed during root dilatation; $H_C$ — commissural height; $da$ — angle of commissural deviation; $hr$ — reduction of valve height provoked by the angular deviation of the commissures.

Fig. 4. Top views of the 3F Aortic (top row) and Sorin Solo (bottom row) stentless bioprostheses in diastolic state at different sinotubular junction diameters: size-to-size implantation (left), first distinct loss of central coaptation of the leaflets was observed (Fig. 4, middle). The tolerance against root
dilatation was presented as the total percentage of these diameters referenced to the primary valve diameter $D_a$. In addition, a leakage—diameter relationship was determined by calculating the means of the leakage volumes for each step of diameter. Changes in valve geometry provoked by the increase of sinotubular junction diameter were calculated for the detected diameters $D_a$, in particular, the angle of commissural deviation and the related decrease in valve height (see Fig. 3). Statistical analysis was performed by comparison of the means using the Students $t$-test for independent samples.

3. Results

The absolute and relative sinotubular junction diameters, which led to primary regurgitation in the investigated valves, are shown in Table 1. Briefly, the highest tolerance against aortic regurgitation was found for the 3F Aortic compared with the Sorin Solo bioprosthesis ($p = 0.0127$). After onset of regurgitation, further increase in diameter resulted in a proliferation of valve incompetence, with a similar course in both valve types (Fig. 5).

Visualisation of the valves showed a strong folding of the leaflets at base diameter in both valve types (Fig. 4). Loss of coaptation started centrally and became triangular with increasing diameter of sinotubular junction. The shape of maximum central opening was the same in both valve types. In two cases, the Sorin Solo valves did not close during diastole if a maximum limit (42 mm) was exceeded.

Table 1

<table>
<thead>
<tr>
<th></th>
<th>3F</th>
<th>Solo</th>
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<td>$D_a$ (mm)</td>
<td>$39.16 \pm 1.27$</td>
<td>$36.28 \pm 1.57$</td>
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<tr>
<td>$D_a/D_a$ (%)</td>
<td>$156.6 \pm 5.1$</td>
<td>$145.1 \pm 6.3$</td>
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The analysis of valve geometry showed similar values of angular deviation of the commissures at the diameters of first distinct regurgitation in both valve types ($20.7 \pm 1.9^\circ$ for the 3F Aortic and $19.4 \pm 2.8^\circ$ for the Sorin Solo bioprosthesis). Therefore, valve height decreased by about 6% in both valves.

4. Discussion

This study serves to characterise the behaviour of pericardial stentless bioprostheses in terms of progressive dilatation of the sinotubular junction in an in vitro setup.

Stentless bioprosthetic heart valve substitutes have proven to be superior to stented bioprostheses with reference to pressure gradients and effective orifice area [2,3], which was commonly related to the greater flexibility of such unframed valves. This flexible structure enables the stentless bioprosthetic valve to follow the cyclic dimensional changes of the recipient’s aortic root, providing a maximum degree of valve opening during systole and reducing leaflet stress. However, in case of later pathological aortic root dilatation, the stentless valve would also be pulled apart, resulting in aortic insufficiency if size increase exceeds certain limits. In a previous investigation of porcine stentless valves, we have demonstrated that an increase of sinotubular junction diameter of more than 32% and 43%, respectively, for the Toronto SPV and Medtronic Freestyle stentless valves resulted in a distinct loss of leaflet coaptation, thus promoting aortic regurgitation [8]. Similar results have been reported by David et al. in a clinical echocardiographic study [4].

To overcome this disadvantage of stentless bioprosthetic valves, one might assume that additional leaflet material will increase the area of leaflet coaptation and thus enlarge the range of valve adaptability to adverse changes in root dimensions. In a study by Jin and Westaby, a slight oversizing of the valves resulted in a better valve competence and also haemodynamic efficiency compared to size-for-size implanted prostheses [10].

In the meantime, a new generation of pericardial stentless bioprostheses has been developed featuring this kind of redundant leaflet tissue for larger coaptation area. Two types of bioprosthesis were investigated in this study: the 3F Aortic valve consisted of tube-like pericardial tissue and was fixed with a circular suture at the base and three single sutures to fix the commissures onto the aortic wall; the Sorin Solo valve was crown-shaped and fixed directly to the aortic root wall with a single running suture line (Fig. 1). Both valves incorporated leaflet areas obviously greater than comparable stentless bioprostheses or the native aortic valve. As an expected consequence, at base diameter (the labelled size), both investigated valves showed folded S-shaped leaflet edges (Fig. 4, left) during testing, indicating a great amount of redundant tissue. With progressive stepwise dilatation at sinotubular-junction level, the free edges of the leaflets stretched wider and a central opening appeared, causing valve regurgitation (Fig. 4, middle). Further dilatation resulted in a triangle-shaped appearance of central valve opening (Fig. 4, right) and valve incompetence increased, with a similar course in both valve types, but different in

![Fig. 5. Relationship between sinotubular junction dimensions and valve competence for 25 mm sized 3F Aortic and Sorin Solo stentless valves during progressive dilatation of the sinotubular junction. Leakage volumes are given in negative values, to accentuate (undue) regurgitation.](https://academic.oup.com/ejcts/article-abstract/37/3/631/434042/73631434424?redirectedFrom=publication)
diameter (Fig. 5). For the 3F Aortic valve regurgitation started at approximately 156% of the labelled valve size, by contrast, for the Sorin Solo valve onset of regurgitation was visible at 145%. The later finding was also confirmed by a study of Weltert et al. [11]. A comparison with our former results from native valves and porcine stentless valve prostheses [8] revealed a slightly less dilatation adaptability of both investigated pericardial valve types with respect to the native aortic valve, but better performance compared with former porcine stentless bioprosthetic valves, which was especially true for the 3F Aortic prosthesis.

To prevent aortic insufficiency following valve replacement with stentless bioprostheses, it is also possible to support the sinotubular junction by, for example, Teflon felt strips or fibre reinforcement. However, such restriction of the sinotubular junction will possibly impact on valve dynamics and thus degrade the advantages of the stentless valves. In particular, with respect to the encouraging above results, a support of the sinotubular junction should rather be done in individual cases.

Some limitations of the setup have to be taken into account. The geometry of our model was strictly symmetrical and does not completely reflect the anatomical situation in vivo, especially different shapes of postoperative sinotubular junction dilatation or in case of bicuspid aortic valve replacement, which may differently influence the valves performance. So the presented results may just provide a preliminary insight into the capacities of modern stentless bioprostheses. Further clinical studies will be needed to clarify these aspects and also long-term behaviours of the investigated valves, which are still pending.

In conclusion, the increased tolerance of pericardial valves to sinotubular dilatation compared with first-generation stentless valves may have a potential advantage with regard to long-term valve performance. On the other hand, durability of these valves may be affected by the redundant leaflet tissue, which probably increase leaflet stress and may cause variations of leaflet degeneration over time [12].

Further clinical investigations will be needed to clarify these potential advantages and disadvantages.

References