A Novel Rigid Annuloplasty Ring for Aortic Valve Reconstruction: An In Vitro Investigation

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Background. Remodeling of the dilated valve annulus with a prosthetic ring for repair of valve insufficiency is a well-established concept in mitral and tricuspid valve surgery and may also be suitable for aortic valve reconstruction. A novel rigid aortic annuloplasty ring was tested in vitro.

Methods. Ten fresh porcine aortic roots were investigated in a pulsatile flow simulator before surgery (group N), after patch dilatation of the annulus (group D), and after reconstruction using a rigid annuloplasty ring (group R). The ring was designed to (1) prevent contact with the leaflets, reducing the risk of contact injury, (2) be applicable to all valve phenotypes, (3) prevent injury to the conduction bundle, and (4) be implantable from inside the aortic root (subvalvular). For each group pressure gradient, leakage volume, and coaptation height were measured.

Results. With the annuloplasty ring, regurgitation volume decreased from $-8.50 \pm 1.91$ mL (group D) to $-4.75 \pm 1.66$ mL (group R; $p < 0.0003$), not different from group N. Coaptation height of the leaflets increased from $0.62 \pm 0.08$ mm (group D) to $0.77 \pm 0.11$ mm (group R; $p < 0.005$), similar to group N. Mean pressure gradient increased from $2.98 \pm 0.38$ mm Hg (group D) to $3.72 \pm 0.40$ mm Hg (group R; $p < 0.0001$).

Conclusions. This novel aortic annuloplasty ring has the potential for supporting aortic valve reconstruction by remodeling the subvalvular area.

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Replacement of the aortic valve is the most frequently performed procedure in patients with aortic valve disease. Two types of substitutes are available, bioprostheses and mechanical valves. The advantage of bioprostheses is no need of permanent anticoagulation because of low thrombogenicity. The disadvantage is the age-dependent limited durability, so that repeated surgical procedures—especially in young patients—are required [1, 2]. Mechanical heart valves are durable; however, because they consist of thrombogenic material, life-long anticoagulation is necessary. This anticoagulation reduces the risk of thromboembolic events, but can lead to bleeding complications. Akins and colleagues [3] showed that the combined risk of thromboembolism and hemorrhage remaining after implantation of mechanical valve prostheses is about 4% per patient-year. In aortic insufficiency (AI), which may be caused by lack of leaflet coaptation owing to dilatation of the aortic root or annulus, leaflet tissue often is macroscopically unaffected, allowing aortic valve repair. Theoretically aortic valve repair warrants the advantages of autologous leaflet tissue with inherent features such as durability, resistance to infection, remodeling, physiologic movement, and no need for anticoagulation. Midterm results are promising [4, 5], but recurrence of AI is reported [6], sometimes related to progressive dilatation of the aortic annulus, underlining the importance of repairing the dilated aortic annulus. This fact was recently supported by Aicher and associates [7], who pointed out that reducing the dilated atrioventricular junction by a suture technique is effective to improve the results of aortic valve repair. There are other various techniques of aortic valve annuloplasty, for example, subvalvular plastic strips or bands, sometimes combined with leaflet correction [8–11]. Moreover, several ring prostheses have been developed [12–15].

The aim of this study was to investigate the hemodynamic and functional effects of a rigid aortic annuloplasty ring for reconstruction of AI caused by annulus dilatation.

Material and Methods

Ten porcine hearts from a local slaughterhouse were prepared immediately after slaughter. Aortic roots were carefully dissected with truncated ascending aorta 3 cm above the sinotubular junction (STJ). Left ventricular muscle and anterior mitral valve leaflet were removed and sutured to a 1.5 cm polyethylene terephthalate fiber (Dacron) graft (Hemashield Platinum; Boston Scientific Corp, Wayne, NJ) with a diameter of 26 mm in a

Dr Sievers has applied for a patent on the annuloplasty ring described in this article.

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continuous suture technique with monofilament 4-0 Prolene (Ethicon, Norderstedt, Germany). This was necessary for mounting the root in the test circuit, leaving approximately 1 cm of tissue between the Dacron tube and the aortic annulus. Coronary arteries were ligated, and the preparation was placed in a pulsatile flow simulator (Fig 1). Leakage and closing volumes, mean and peak pressure gradients, and leaflet coaptation height were measured in the native valves (group N), then the aortic annulus was dilated by enlarging the area below each commissure using a 1 cm × 1 cm large, rhombus-shaped piece of aortic wall tissue (Fig 2). The measurements were repeated after reconstruction of the valve using the annuloplasty ring (group R).

Techniques of Measurements
The pulsatile flow simulator provides near physiologic conditions at 64 beats/min and a stroke volume of 60 mL [16]. The systemic pressure was 125/80 mm Hg, and physiologic saline solution was used for the testing fluid. These measurements in each group were made in ten different aortic valves (A1 to A10). Pressure gradients were measured with pressure sensors (Envac Ceracore M capacitive pressure transducers, Endress + Hauser, Maulburg, Germany) 65 mm below and 40 mm above the aortic valve, and regurgitant volumes were measured with an ultrasonic measuring device (HT207 ultrasonic flowmeter, Transonic Systems Inc, Ithaca, NY). A transesophageal echocardiography probe was used to measure leaflet coaptation. Valve motions were documented with a Motionscope HR-1000 high-speed camera (Redlake Imaging Corp, Morgan Hill, CA) above the aortic valve.

Rigid Prosthetic Ring Device
The rigid prosthetic ring device had an outer diameter of 21 mm and an inner diameter of 19.5 mm and consisted of a closed, rigid metal ring that was covered with a woven Dacron layer (Fig 3). This size was chosen in relation to the internal anatomic diameter of the native root. In particular, the metal part of the ring device is not embedded uniformly into the Dacron layer: the upper portion of the ring consisted only of a soft Dacron layer for stitching, aiming to prevent leaflet contact after suturing. The advantages of this rigid novel aortic annuloplasty prosthetic ring (Genese BioMedical, Inc, Denver, CO) are the following: (1) the suture ring prevents contact to the leaflets to avoid any leaflet contact injury, (2) there is no dependence on valve geometry, such that it can be used in bicuspid as well as in tricuspid valves, (3) it protects the area of the conduction bundle to prevent injury to the conduction system, (4) internal application facilitates implantation, and (5) rigidity assures a definite shape.

The triangle elevation (conduction triangle) was placed at the area of the underleaflet triangle between the right and noncoronary sinus, intending to prevent injury to the conduction bundle (Fig 4). Suturing was accomplished after regular aortotomy through the aortic valve. The sutures (2-0 polyfilament) were placed from inside the left ventricular outflow tract to the outside of the root after dissection of this area. In the clinical setting, it is intended that the root will be dissected from outside the noncoronary sinus in both directions toward the coronary ostia. In this area the ring can be fixed with stitches from inside to outside of the root. In the opposite area it is intended that the ring will be fixed by stitches placed...
from inside the outflow tract into the sinus of the left and right coronary leaflets.

**Statistical Analysis**

Statistical analysis was performed by analysis of variance. Data were expressed as mean ± standard deviation. All analyses were accomplished with R version 2.14.1 (R Development Core Team Vienna, Austria [17]). Differences between groups with a probability value of less than 0.05 were considered significant.

**Results**

Results of hemodynamic measurements are shown in Table 1. Patch dilatation decreased leaflet coaptation height, but hemodynamics remained unchanged. Regurgitant volume decreased after ring repair, and leaflet coaptation height increased at the cost of an increase in pressure gradient.

**Comment**

This study shows that reconstruction of aortic valve insufficiency caused by annulus dilatation may be supported by implantation of an annuloplasty ring. The first attempts of aortic valve reconstruction by tightening the aortic base were described by Taylor and coworkers [10] in 1958 using a silk suture. Other techniques include
annuloplasty by subcommissural sutures constricting the interleaflet triangle [11], plication of the aortic sinus [18], or subcommissural U stitches [19]. In recent years, various methods of annuloplasty with use of sutures and prosthetic strips for external or intraannular application have been presented [7–9, 13, 20]. Investigations by our group with an external and an internal flexible annuloplasty ring showed effective reconstruction, with favorable results for the flexible internal ring device with a flat wire frame and a thin Dacron layer [15]. The ring used in the present work is a rigid modification of this internal ring. The intention is to create more durable conditions and to counteract deformations of the flexible ring by a deformed annulus. Furthermore, the shape of the reconstructed aortic annulus is predictable on the basis of a rigid metal frame.

Regurgitant volume increased after patch enlargement of the annulus, but this was not significant. This is most likely attributable to the high flexibility and extensibility of the juvenile porcine leaflet tissue. With the applied patch technique, the annulus was dilated up to 30%; a healthy aortic valve appears to be able to compensate for extensions of this dimension. In comparison, dilatation of the STJ in native aortic valves was tolerated up to 70% without any insufficiency [21]. By implantation of the ring, a significantly decreased regurgitation volume (group D) compared with dilated valves was possible, reaching the values of the native valve (group N). This shows that reconstruction by a ring device is feasible, and correction can be performed, achieving native aortic root conditions. Peak pressure gradients and mean pressure gradients of native and patch-dilated aortic roots were not significantly different. However, we observed a statistically significant increase in pressure gradients in the reconstructed valves. This increase in the mean pressure gradient was not established in the previously mentioned flexible internal ring device [15]. The reason for the increase of the pressure gradient is most likely owing to the reduction of the outflow tract diameter by the annuloplasty ring. Clinically, this phenomenon may be of little relevance, as the average pressure gradient in the ring setup of 3.72 ± 0.40 mm Hg does not actually create a stenosis. Even in well-established aortic valve-sparing techniques such as the David procedure, an increased pressure gradient and smaller aortic root dimensions are well known [22].

An important aspect is the coaptation height of the valve leaflets. In most cases of AI, a loss of coaptation of the leaflets is responsible for valve insufficiency [6]. The annuloplasty ring was able to regain normal coaptation height, underlining the importance of a defined geometry of the annulus corresponding to the size of the leaflets.

Rankin and colleagues [14] designed a three-dimensional reconstruction ring with promising results. The whole aortic valve has to be adapted to the device, including the commissural struts. The annuloplasty ring of this study can be implanted safely below the aortic valve and does not affect the individual asymmetry of the aortic root and aortic valve. Furthermore, the ring was designed with a smooth rigid material (Dacron tube). This may lead to impaired hemodynamics, as the physiologic interaction between valve movement and cardiac muscle contraction is absent. Furthermore, only low regurgitant volumes were achievable in the disease model (group D), although the annulus diameter was enlarged by roughly 30%. This reflects the pliability of the normal leaflet tissue. In the clinical setting, the normal pliability is often reduced so that an annulus dilatation of 30% would produce greater insufficiency and likely a more pronounced effect with the prosthetic annuloplasty ring. Moreover, this is only an acute model, and annulus stabilization should be evaluated in chronic experiments. No blood was used as test solution. The altered viscosity of the test solution influences the transvalvular pressure gradient, and possibly also the leaflet movements. However, these limitations concern all groups equally. Thus, the effect may be negligible.

It is imaginable that the reduction of regurgitant volume versus the slightly increased pressure gradient after ring annuloplasty may lead to a preserved energy balance.
for the left ventricle, which remains to be calculated in a more sophisticated setup.

In summary, the effects of the rigid aortic annuloplasty ring are promising for supporting aortic valve reconstruction.

References