In vitro comparison of three techniques for ventriculo-aortic junction annuloplasty†

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Abstract

OBJECTIVES: In aortic valve repair, reduction and stabilization of the ventriculo-aortic junction (V AJ) is generally recommended. In this in vitro study, we compare three techniques of annuloplasty: the subcommissural annuloplasty (SCA), the internal ring (IR) and the external ring (ER) annuloplasty.

METHODS: Ten fresh porcine aortic valve preparations were tested in a pulsatile mock loop. Each sample was tested untreated (baseline: B). The annuloplasty techniques were then performed successively in each sample. Each technique was tested, then removed and the following technique performed. SCA was applied at 50% of interleaflet triangle height; the ER and IR were applied with a moderate reduction (15–20%) of the V AJ. Hydrodynamic, video and echographic parameters were collected. Flow rate and arterial pressure were maintained consistently between groups.

RESULTS: Effective orifice area decreased significantly with each annuloplasty technique compared with baseline (P < 0.001). Mean transvalvular pressure drop was significantly higher in the ER and IR vs SCA (P = 0.007). Annuloplasty reduced valve opening and closing time in comparison to baseline. Echocardiography confirmed that the V AJ experienced a greater reduction with the ER and IR vs SCA. A narrowing of the lower third of the sinuses of Valsalva was observed after the ER, and subvalvular narrowing was observed after the IR. Valve coaptation increased with all annuloplasty techniques.

CONCLUSIONS: The three annuloplasty techniques examined demonstrated differential effects on aortic valve function and root morphology. The ER and IR have greater potential to reduce V AJ diameter in comparison to SCA. The IR induced a subvalvular remodelling of the V AJ, whereas the ER induced a paravalvular remodelling.

Keywords: Aortic valve regurgitation • Aortic valve repair • Annuloplasty

INTRODUCTION

Aortic valve repair is currently considered as an alternative to valve replacement in the treatment of pure aortic regurgitation (AR) [1, 2]. In patients with chronic AR, the degree of ventriculo-aortic junction (V AJ) and sino-tubular junction (STJ) dilatation has been correlated with the severity of AR by preventing adequate cusp coaptation [3]. As such, remodelling of V AJ and STJ represents an important target for restoration of valve competence [2]. This concept is supported by several authors who showed that the absence of V AJ annuloplasty increases the risk of recurrent AR especially in patients with annuloartic ectasia [4–7].

Annulus reduction using a suture surrounding the base of the aorta to treat AR was first described by Taylor et al. in 1958 [8]. Since then, several techniques were developed using similar concepts. Duran [9] and Cosgrove et al. [10] developed each an annuloplasty based on compression stitches located at a different level of the annulus. Subcommissural annuloplasty (SCA), consisting of a constriction of the interleaflet triangle [11], gained popularity because of its simplicity and reproducibility. More recently, several techniques using external or internal subvalvular rings or strips have been described but their clinical use remains limited [12–17]. Although the above techniques have been shown to reduce AR, data

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regarding their effect on valve function and root morphology are still insufficient.

The objective of this study was to compare in vitro three different techniques of VAJ annuloplasty: the SCA, external ring (ER) and internal ring (IR) annuloplasty. For each, we sought to quantify parameters of valve function and root morphology.

MATERIALS AND METHODS

FoRcardioLab pulsatile mock loop

The mock loop (Fig. 1) consisted of a computer-controlled hydraulic piston pump designed to simulate left ventricular ejection and to test the aortic root functional unit (ARFU) [18]. To analyse the ARFU function, the loop was equipped with pressure transducers, flow meter probe and high-speed digital camera positioned above the valve. Echographic analysis was performed using a transthoracic probe immersed in the atrial bath surrounding the ARFU sample.

Sample preparation and surgical treatments

Using fresh swine hearts, ARFUs were harvested by experienced surgeons. The ARFU samples included ~1.5 cm of left ventricular outflow tract. The outflow tract was made cylindrical by closing the mitral valve commissures with a running suture to the adjacent muscular septum. The ascending aorta was transected 0.5 cm above the STJ. The aortic root was dissected deep into the VAJ freely, and coronary ostia were ligated. Circular Dacron meshes were sutured to the inflow and outflow of the ARFU sample to fix it in the housing section of the mock loop (Fig. 2a and b). Only samples with physiologic anatomies were considered, and 10 samples were included in the study.

In order to identify the effect exerted by each procedure individually, each sample was first tested under basal conditions.

Figure 1: Schematic diagram of the mock loop (left panel) and a picture of the experimental setup (right panel): a: computer-controlled hydraulic piston pump; b: test section for ARFU sample housing; c: adjustable dynamic afterload for the simulation of the systemic input impedance; d: atrial bath connected to the ventricle chamber; e: with one-way service valve placed; p1, p2, Part: pressure transducers placed immediately upstream and downstream of the ARFU sample and at the inlet of the hydraulic afterload to record the arterial pressure simulated in the in vitro model; Q: flow meter probe; V: high-speed digital camera for image recordings of the valve from the aortic view.

Figure 2: The ARFU fixed in the housing section (a). View of the ARFU outflow; aortic valve can be seen inside the ARFU (b). ARFU with subcommissural annuloplasty stitches at the three commissures (c). ARFU with the ER (d). ARFU with the IR (e).
(B), prior to any surgical procedure. Then, without removing preparation from the housing section of the mock loop, a set of surgical treatments were applied in sequence, and tests performed after each one. First, an SCA was applied at the 50% height of each commissure as performed in routine clinical practice (Fig. 2c). After testing, SCA stitches were removed from the sample, and an ER was applied. The ER and IR were performed using a Simplici-T® band (Medtronic, Inc., Minneapolis, MN, USA). The choice of a flexible and relatively elastic material was made in accordance with the type of material proposed in most of the relevant literature [12–15]. The ER consisted of a circumferential band implanted around the lowest portion of the aortic root with six felt reinforced sutures passed from the inside 1–2 mm below the cusp insertion (Fig. 2d). After testing the sample again, the ER was removed and an IR was applied. The IR consisted in a circumferential band implanted 1–2 mm below cusps insertion, following the same line than the proximal suture in the reimplantation technique for valve sparing root replacement (Fig. 2f) [19]. The IR was fixed using 9–10 ‘U’ stitches tied externally at the base of the aortic root (Fig. 2e). Between each treatment, the ARFU sample integrity was carefully inspected to rule out macroscopic deterioration that could influence the results of testing.

The circumferences (C) of the ER and IR were evaluated as follows with the objective to obtain mild-to-moderate VAJ constriction:

\[
C_{ER} (\text{mm}) = (\phi_{pre} + 4) \pi,
\]

where \(\phi_{pre}\) is the diameter of the native ARFU at the level of the VAJ, the addendum 4 mm took into account the thickness of the sample’s wall.

A similar approach was adopted for IR implantation:

\[
C_{IR} (\text{mm}) = \phi_{pre} \pi
\]

without adding 4 mm as the ring was implanted inside the ARFU.

**Experimental protocol**

Tests were conducted in the mock loop simulating physiologic conditions: 70 bpm, with a mean flow rate ranging 4.6–4.7 L/min and a mean simulated arterial pressure ranging 96–99 mmHg. No statistical difference was found in the imposed working conditions between tests (P < 0.172).

The flow rate, the ARFU’s upstream and downstream pressures, and the pressure in the afterload were acquired at a sampling rate of 200 Hz via an A/D acquisition board (USB 6210, National Instruments, Austin, TX, USA). Hydrodynamic events and digital videos records at 1000 fps were synchronized using the internal triggering TTL function of the camera (Miro2, Vision Research, Wayne, NJ, USA).

Post-processing of the raw hydrodynamic data and the high-speed digital recordings was performed to calculate the following quantities:

- The mean systolic pressure drop (\(\Delta p_m\), mmHg) across the ARFU, as the difference between pressures measured in \(p_1\) and \(p_2\) (Fig. 1) averaged over the systolic interval.
- The maximum systolic pressure drop (\(\Delta p_m\), mmHg).
- The effective orifice area (EOA, cm²) evaluated with the following formula [20]:

\[
EOA (\text{cm}^2) = \frac{Q_{rms}}{k \sqrt{\Delta p_m}},
\]

where \(Q_{rms}\) (L/min) is the root mean square systolic flow rate, \(\Delta p_m\) (mmHg) the mean systolic pressure drop across the sample and \(k\) a conversion factor (\(k = 3.1\) to yield the EOA in cm²).
- Valve leakage was estimated by extracting the telediastolic backflow from the measured flow-rate tracings and by integrating the telediastolic backflow over the diastolic interval to obtain the valve leakage volume [18].
- The opening and closing times (OT and CT, respectively) of the sample’s leaflet were evaluated with a visual inspection of the high-speed video recordings performed independently by two engineers.

For the echographic analysis, the following parameters were recorded using long- and short-axis views: VAJ diameter (valve open and valve closed), aortic root diameter (valve open and valve closed), coaptation length (length of the cusp contact), the
maximum valve opening area (by planimetry) and the maximal diameter of the ER and IR.

Statistical analysis

Data are presented as mean ± standard deviation when normally distributed or median (interquartile range) for non-parametric data. Determinations were based on five consecutive simulated cardiac cycles. When comparing treatments applied in sequence to each sample, in the case of evidence of normality, statistical analysis was performed with a one-way repeated-measures ANOVA test. When normality was not verified, a Friedman repeated-measures analysis of variance on ranks was performed. A post-hoc Tukey test was performed to evaluate differences between groups. *P*-values <0.05 were considered statistically significant.

RESULTS

Pooled hydrodynamic results

The main hydrodynamic quantities and indexes, based on the pooled data of the 10 samples, are summarized in Table 1. Sample diameters always decreased in the treated conditions compared with B, with a minimum decrease of 12% (SCA vs B), and a maximum decrease of 19% (IR vs B).

Both Δpmean and Δpmax increase with treatment when compared with B: the maximum variation was between the ER and B (177 and 28% increase in Δpmean and Δpmax, respectively), whereas the minimum variation was between SCA and B (61 and 9% increase in Δpmean and Δpmax, respectively). The EOA also decreased with treatments when compared with the B (minimum variation: SCA vs B, 32%; maximum variation: ER vs B, 41%).

Hydrodynamic quantities were found to be significantly different when comparing each surgical treatment with the B configuration, with the exceptions of Δpmean and Δpmax between SCA and B (Table 1). In addition, no significant differences were found in any of the obtained pooled results when comparing the ER with IR.

The mean valve leakage volumes were similar between B and the different surgical treatments.

Single-sample hydrodynamic results

In Fig. 4, the Δpmean and EOAs measured for all tested samples are plotted for all the treatments applied. Experimental values recorded for non-treated samples showed the lowest pressure drop. An intermediate increase in the pressure drop was observed in the majority of the samples when tested with the SCA. Additional increases in the pressure drop were observed in the majority of the samples when tested with the ER. Finally, no consistent pattern was observed between the ER and IR, with some IR values being higher and others being lower. The EOAs in all tested samples followed a similar but inverse relationship between B, SCA, ER and IR.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Qmean (L/min)</th>
<th>paur (mmHg)</th>
<th>p (mm)</th>
<th>Δpmean (mmHg)</th>
<th>Δpmax (mmHg)</th>
<th>EOA (cm²)</th>
<th>VLV (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>4.7 ± 0.2</td>
<td>96.3 ± 3.2</td>
<td>21.9 ± 1.4</td>
<td>3.1 ± 1.2</td>
<td>24.3 ± 3.3</td>
<td>3.9 ± 0.7</td>
<td>3.0 ± 1.6</td>
</tr>
<tr>
<td>SCA</td>
<td>4.7 ± 0.3</td>
<td>97.2 ± 2.2</td>
<td>19.3 ± 1.1</td>
<td>5.0 ± 1.4</td>
<td>26.5 ± 3.2</td>
<td>3.0 ± 0.4</td>
<td>2.9 ± 2.3</td>
</tr>
<tr>
<td>ER</td>
<td>4.6 ± 0.2</td>
<td>98.7 ± 3.3</td>
<td>18.1 ± 1.4</td>
<td>8.6 ± 2.7</td>
<td>31.3 ± 4.1</td>
<td>3.8 ± 2.1</td>
<td>3.8 ± 2.3</td>
</tr>
<tr>
<td>IR</td>
<td>4.6 ± 0.3</td>
<td>99.4 ± 4.2</td>
<td>17.8 ± 1.2</td>
<td>17.9 ± 3.2</td>
<td>30.8 ± 4.4</td>
<td>4.0 ± 2.7</td>
<td>4.0 ± 3.0</td>
</tr>
</tbody>
</table>

Table 1: Measured fluid dynamic quantities are reported with valve diameters

Pooled data of 10 samples.
The imposed working conditions are reported in italics. B: basal; SCA: subcommissural annuloplasty; ER: external ring; IR: internal ring. Qmean: imposed flow rate; paur: simulated arterial blood pressure; p: sample diameter; Δpmean: mean systolic pressure drop across the sample; Δpmax: maximum systolic pressure drop across the sample; EOA: effective orifice area; VLV: valve leakage volume.
Table 2: Leaflet opening and closing times

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>SCA</th>
<th>ER</th>
<th>IR</th>
<th>P-value of the difference between treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>OT, ms</td>
<td>35 (28–40)</td>
<td>25 (17–28)</td>
<td>21 (16–25)</td>
<td>31 (25–37)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>CT, ms</td>
<td>67 (57–79)</td>
<td>57 (53–61)</td>
<td>51 (48–58)</td>
<td>52 (43–62)</td>
<td>ns</td>
</tr>
</tbody>
</table>

Pooled data of 10 samples. OT: opening time; CT: closing time; B: basal; SCA: subcommissural annuloplasty; ER: external ring; IR: internal ring.

Table 3: Echographic measures

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>SCA</th>
<th>ER</th>
<th>IR</th>
<th>P-value of the difference between treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valve opening area (cm²)</td>
<td>48 ± 8</td>
<td>34 ± 6</td>
<td>28 ± 5</td>
<td>36 ± 4</td>
<td>0.001</td>
</tr>
<tr>
<td>Ring Φ (mm)</td>
<td>na</td>
<td>na</td>
<td>29 ± 2</td>
<td>22 ± 2</td>
<td>ns</td>
</tr>
</tbody>
</table>

Pooled data of 10 samples. B: basal; SCA: subcommissural annuloplasty; ER: external ring; IR: internal ring.

**Leaflet opening and closing times**

Table 2 reports pooled experimental results for the opening times (OT) and closing times (CT) evaluated over the 10 tested samples. OTs showed a decreasing trend passing from B configuration to SCA to ER (P < 0.05). In contrast, the IR and B configurations had comparable OTs (P = ns). When comparing treatments as pairs, differences were statistically significant except for SCA vs ER. The CTs were also reduced by all the treatments. When compared with B, these differences were statistically significant in the ER and IR but not in SCA.

**Pooled echocardiographic measures**

In long-axis views, VAJ diameter decreased with all treatments, with a maximum decrease in the ER treatment (5% decrease in SCA vs B, 14% in ER vs B and 9% in IR vs B) (Table 3, Fig. 5). Over the pump cycle, VAJ diameter increased from diastol (valve closed) to systol (valve open), especially in B and SCA (23% increase in B, 19% in SCA, 5% in ER and 10% in IR). The aortic root diameter decreased with SCA and ER but not with IR. With respect to root and VAJ morphology (Fig. 5b–d), SCA did not induced significant change, ER induced a narrowing of the lower third of the Valsalva sinuses and IR induced subvalvular narrowing. Valve coaptation increased with all treatments when compared with B, with a maximum increase in the ER and IR (20% increase in SCA vs B, 30% in ER vs B and 30% in IR vs B).

In short-axis views, valve opening area decreased in all treatments when compared with basal configuration, with a maximum decrease in the ER (29% decrease in SCA vs B, 42% in ER vs B and 25% in IR vs B).

**DISCUSSION**

In this in vitro study, we show that subcommissural, ER and IR annuloplasty exert differential effects on aortic valve function and root morphology. The ER and IR showed a greater potential of VAJ reduction than the SCA. As a consequence, these techniques result in a higher pressure drop and smaller EOA. Working on normal aortic root samples, an increase in transvalvular pressure drop was expected with the reduction in the VAJ. However, despite the mild-to-moderate VAJ reduction induced with the ER and IR, the pressure drop remained in the range of clinically acceptable values. Comparing the ER and IR, pressure drop and EOA showed no consistent pattern. This likely reflects relative unpredictability of the remodelling effect despite sizing based on the native ARFU sample dimension. This unpredictability in the remodelling can be explained by the flexible and elastic characteristics of the simplici-T band and variations in the aortic wall thickness.

In the video analysis, all treatments demonstrated reduction of the opening and closing times in comparison to native valve. Similar observation has already been reported by Leyh et al. [21] after valve-sparing root replacement procedures and by Scharfswerdt et al. [17] after ring annuloplasty. Reduction of root compliance and alteration of fluid dynamics inside the root...
explain modifications of valve motion but their clinical implications are still unknown.

The echographic findings correlate with hydrodynamic and video parameters. The VAJ was more reduced in the ER and IR with a relative loss of distensibility in systole. The IR showed subvalvular remodelling of the VAJ, whereas the ER showed paravalvular remodelling of the VAJ. This particular aspect observed with the ER can be accentuated in porcine valve in comparison to human valve. Effectively, pig heart has a relatively larger muscular septum on which the right coronary cusp is inserted. However, the differences observed in morphological aspect of VAJ remodelling are also explained by the topographic relationship of the annuloplasty techniques with the VAJ itself. The SCA is localized above the VAJ, which corresponds to the basal portion of the interleaflet triangle. The ER is placed just above the VAJ as it is fixed externally on the aortic side of the VAJ. The IR is located just below the VAJ as the ring is placed following the ventricular side of cusp insertion (Fig. 3).

The SCA is a simple and reliable technique. However, patients with annulus dilatation generally present with tissue fragility and the absence of circumferential support of the annulus may permit continued dilation over time. We have recently reported recurrent AR due to VAJ re-dilatation in patients undergoing bicuspid aortic valve repair including an SCA [7, 20]. The SCA bring two or three localized annulus plications; the unsupported portions of the VAJ between the stitches and even below the stitches can be affected by further stretching leading to global VAJ re-dilatation.

The ER and IR are more complex to perform than SCA, but they have the potential for better stabilization over time by the circumferential support of the annulus. In this study, we show that the ER and IR have a relatively similar impact on valve function; however, the ER remodels the aortic annulus more distally than the IR. In another in vivo study comparing the ER and IR, Scharfschwerdt et al. [17] have shown a greater potential for the IR to reduce AR in artificially dilated aortic root. The remodelling of the basal portion of the annulus brought by the IR can explain these results. However, the mid-term clinical trials on the ER developed by Lansac et al. [14] have shown encouraging results regarding the ability of the ER to correct AR.

The intravascular location of the IR raises the risk of thromboembolism and subvalvular stenosis. However, the limited clinical data available on the aortic IR do not report such ring-related events or complications after short- to mid-term follow-up [12, 13]. Moreover, according to the experience with the mitral annuloplasty ring and the stented aortic bioprosthesis, it is reasonable to expect low risk of thromboembolism with the IR [22–24].

In this study, we have used flexible rings similar to most described techniques [12–15]. In the internal position, both flexible or (semi-)rigid rings have been described [12, 13, 16, 17]. The rigid ring has the advantage to provide a predetermined internal diameter but they are less adaptable to individual anatomic variations of the aortic valve, especially if they are constructed with a crown-shaped three-dimensional design [16]. The flexible ring has the advantage to be adaptable to each individual anatomy but final internal diameter can be less predictable due to the compression effect by the fixation stitches.

**Study limitations**

The aortic valve model used in this study present two notable limitations. One is the anatomical differences between pig and human valves and the second is the absence of VAJ dilatation. Effectively, the effects of annuloplasty techniques on pathological valves with VAJ dilatation may be different than these observed in this study. Valve opening and closing time data as well as echographic measures could have been affected by operator-induced bias as they were based on visual estimation. To overcome these issues, the provided measures represent mean values of
independent observations of two operators. Finally, development and standardization of aortic rings need further investigation with respect to technical aspects like ring profile, rigidity and sizing, and on the long-term impact of the ring on valve function.

CONCLUSIONS

In this in vitro study, we show that subcommissural, ER and IR annuloplasty exert differential effects on aortic valve function and root morphology. The ER and IR annuloplasty carry a higher potential to reduce the V A J diameter in comparison to SCA. The IR induced a subvalvular remodelling of the V AJ, whereas the ER induced a paravalvular remodelling.

Conflict of interest: none declared.

REFERENCES


APPENDIX. CONFERENCE DISCUSSION

Dr H.-J. Schäfers (Hamburg/Saar, Germany): The authors address the important component of the basal aortic ring, which is necessary for stable valve repair. I disagree in minor details: for instance, the subcommissural annuloplasty was not first proposed by Cosgrove but rather by Cabrol in 1966. Going into the published literature, you will find additional evidence for your hypothesis, which you have not quoted at this time.

Nevertheless, it is an interesting paper and an important subject. There are two limitations of the model. The specific anatomy of the pig heart, which has a long muscular extension of septal muscle into the right sinus, makes placement of any ring very difficult and puts it in a non-anatomic position, which you have also shown. In addition, you start off with a heart that does not have an annular dilatation but has a normal annular size. What conclusion can you draw from the presented data which technique, the internal or the external ring, you are using them are not aimed at reducing the annulus, but have a different concept, and the future will tell us which is the best and for which indication.

Dr K. Khargi (The Hague, The Netherlands): The subcommissural stitches as you are using them are not aimed at reducing the annulus, but have a different function, namely to enhance valve coaptation. So my first point is, is it correct to include this technique as a remodelling procedure for the annulus? Secondly, if you look at durability without any distension, it remains unclear from the presented data which technique, the internal or the external ring, produces the best stability without distension over the period of time? I could not figure this out from your data. Could you elaborate on that?


**Aortic annuloplasty: a new aspect of aortic valve repair**

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In the past 15 years, aortic valve repair has evolved from an occasional procedure to a reproducible treatment option for many patients with aortic valve regurgitation. With increasing experience, the principles of cusp and root repair have become more refined. In addition, specific problems have crystallized that require special solutions in order to make reconstruction of the aortic valve a reproducible and standardized operation. De Kerchove et al. [1] present an experimental study on one such detail, i.e. aortic annuloplasty.

The diameter of the aortoventricular junction has previously been assumed to be important in valve-preserving root replacement. Recent evidence has pointed out that aortoventricular dilatation is indeed a predictor for long-term aortic valve failure, not only in valve-preserving aortic replacement [2, 3] but also in isolated aortic valve repair [4]. In analogy to the principles of mitral repair it thus seems plausible to introduce a standardized annuloplasty concept into aortic valve repair. Stabilization of this anatomic structure by applying aortic valve reimplantation within a vascular graft has not uniformly resulted in adequate valve stability [3]. This aggressive form of root replacement also appears unjustified in the absence of root dilatation.

Different concepts of an annuloplasty approach have been proposed, i.e. external ring, internal ring or suture annuloplasty. At this time, there is no evidence of the superiority of one technique or implant over another. The use of a circular suture annuloplasty was reported by Taylor in 1958 [5]. The proposal of a subcommissural plication stitch was published by Cabrol et al. [6]. In a recent clinical report the use of these sutures was associated with increased risk of reoperation [4].

Few annuloplasty devices have been used clinically in the past 10 years. The biggest clinical experience has been obtained by Lansac et al. [2] with an expandible external device. The authors were able to document freedom from adverse events due to the device for up to two years and reproducible results of aortic valve repair despite a high number of centres involved. Hahm [7] reported on a partial external annuloplasty, but the effect of the technique was not well documented and it was mostly used in conjunction with pericardial cusp replacement. Fattouch [8] presented data on a combined internal and external annuloplasty, from the mixed clinical experience the effect of the devise is difficult to extract. Similarly, Izumoto [9] described the use of an internal annuloplasty without specifying results and providing a control group. At this time, experimental evidence is available only for other annuloplasty devices.

Thus, there is growing interest in an annuloplasty for the aortic valve and the increasing impression that it will be beneficial for aortic valve repair. At the same time, there is uncertainty as to the best mode of application of such a device (external vs. internal) and the best type of material (expandible, flexible or rigid). For clinical decisions, haemodynamic function, stability and biocompatibility will be essential. The device will have to effectively stabilize the aortoventricular junction at the desired diameter. It should not have acute or long-term interference with the conduction system and cusp mobility and structure.