Calibrated cusp sizers to facilitate aortic valve repair: development and clinical application

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Abstract

Based on the natural mathematical relationships between the components of the human tri-leaflet aortic valve, new calibrated cusp sizers were developed in order to facilitate aortic valve assessment in the operating room and enhance the chance for a perfect restoration of aortic valve competence. These sizers were used clinically to guide the implementation of established aortic valve repair techniques in 10 consecutive patients with severe aortic valve regurgitation. Valve repair was successful in all cases, and at a median follow-up was 5.5 months, aortic valve function remained stable, with aortic regurgitation $\leq 1+$ in every patient and no significant gradient across the aortic valves. This preliminary clinical experience indicates that the calibrated cusp sizers can provide reliable insight into the mechanism of aortic valve insufficiency, and can guide aortic valve repair techniques successfully. We hope that the simplicity and reproducibility of this method would assist in its dissemination and further increase the percentage of aortic valves that are repaired when compared with current practice.

Keywords: Surgical equipment • Aortic valve • Surgery • Repair • Cardiac surgery

INTRODUCTION

Notwithstanding the satisfactory outcome of aortic valve and root reconstruction techniques that have been advocated by dedicated surgeons [1, 2], there still persists a general reluctance to perform these procedures, which are often regarded as an esoteric ‘art form’ that is difficult to learn or perform. One major limitation to the wider application of these techniques has been the difficulty in recognizing the exact alterations responsible for valve regurgitation [3] and re-establishing the natural correlation between the dimensions of all valve components.

The aim of the present project was to develop a standardized device for aortic valve assessment in the operating room. We used the normal mathematical relationships between the components of the human tri-leaflet aortic valve to construct a set of calibrated cusp sizers, which were then evaluated clinically for their capability to facilitate intra-operative decision-making and enhance the chance for a perfect restoration of aortic valve competence.

MATERIALS AND METHODS

Principles and design

Based on previous geometric descriptions of normal anatomy, an aortic root model was constructed as a cylindrical unit, with its height equivalent to 70% of its diameter, and a diameter of the circle formed by the bases which equals that formed by the commissures [4, 5].

Aortic cusp design was constructed according to the following considerations: (i) the valve model consisted of three identical cusps; (ii) valve cusps were in the closed position, forming inter-cusp coaptation zones; (iii) the inter-leaflet triangles were eliminated, and the height of the coaptation zone at the commissures was set at 50% of the height of the root [4]; (iv) the length of cusp attachment line to its supporting sinus was set at 200% of the diameter of the root [1, 6]; (v) the angle of the free edge of the cusp to the plane through the commissures was set at 32°; and (vi) the angle of the inferior surface of the cusp to the plane through the bases was set at 22° [4, 5].

Based on these parameters, computer-assisted design software [Autodesk Mechanical Desktop 2009, Autodesk, Inc., USA] was used to construct the theoretical three-dimensional model of the aortic root (Fig. 1). Next, the three-dimensional geometry of a single aortic cusp in the closed position was replicated across a range of proposed aortic root diameters (at odd numbers from 19 to 31 mm). Representations of these aortic cusps were manufactured in a steel-leaflet form (Fig. 2, Supplementary Video 1), and appropriate handles were added to the design. The necessary root diameter (in millimetres) that correlates with the dimensions of each individual cusp size was marked at the handle (Fig. 3).

Patients

Between January and September 2011, 10 consecutive patients (7 males, mean age 43 ± 15 years) underwent aortic valve repair
using the above described sizers. Preoperative trans-thoracic echocardiography confirmed that the aortic valve was tricuspid in every case, with the presence of isolated severe (≥3+) aortic valve regurgitation. Each patient signed an informed consent form, and the study protocol was approved by the local medical research committee.

Operative technique

After median sternotomy, cardiopulmonary bypass was established and the heart was arrested with standard cardioplegic techniques. A transverse aortotomy was performed a few millimetres above the sino-tubular junction, and the Spring retractor (Geister® Medizintechnik GmbH, Tuttlingen, Germany) was introduced to expose the aortic valve.

First, aortic valve morphology was systematically evaluated: cusps (for integrity and mobility); commissures (for splaying and attachment) and root (for shape and diameter). Next, the calibrated cusp sizers were used to assess the geometry of each aortic cusp as follows: the sizer was placed so that the deeper curve rested on cusp attachment line, and was pushed against the concavity of the cusp (Fig. 4). The sizer that corresponded with the inter-commissural distance, inner surface area and free-edge length of the cusp was selected, and the matching root diameter was noted. An aortic cusp was considered to be prolapsed if its free-edge was found to be stretched out in comparison to the free-edge of the sizer that corresponded with the inter-commissural distance, and was considered to be contracted if its free-edge was found to be shortened compared to the free-edge of the selected sizer. If valve cusps were un-diseased (neither prolapsed nor contracted) but unequal in size, we averaged the root diameters indicated by the three cusps. On the other hand, if one or more of the cusps were either prolapsed or contracted, we averaged the root diameters indicated by the un-diseased cusps.

The aortic valve repair technique consisted of three components. First, aorto-ventricular junction correction was performed by sub-commissural annuloplasty with buttressed horizontal mattress sutures placed at the lower limits of coaptation zones, as indicated by the chosen cusp sizer. Secondly, sino-tubular junction correction was performed by passing a purse-string of 4-0 Prolene suture around the junction, and

Figure 1: Theoretical three-dimensional model of the aortic root and aortic valve: (a) inter-commissural distance; (b) root height; (c) commissural coaptation height; (d) root diameter; (g) central coaptation height; (h) cusp free edge length; and (j) inferior surface length.

Figure 2: The steel-leaflet form of the cusp sizer: oblique-view, anterior view and side-view (from top).
tying it over a Hegar dilator of the pre-determined ‘matching’ root diameter. Thirdly, the geometry of each aortic cusp was re-assessed, and cusp correction was performed when necessary. Cusp prolapse was corrected by free-edge plication at the raphe with a 5-0 Prolene suture, while free-edge shortening was corrected by cusp augmentation with a pericardial patch, using the selected cusp sizer as a template in either case.

An aortic valve re-implantation procedure was decided on if the aortic root was significantly dilated (sino-tubular diameter >33 mm). Measurements of cusp geometry with the calibrated cusp sizers were the sole criterion to determine the sizes of the Valsalva graft that were used, as well as the appropriate heights of the commissures. In addition, the calibrated cusp sizers were used to evaluate and correct any residual or induced cusp prolapse following valve re-implantation.

Operative results were evaluated immediately by intra-operative transoesophageal echocardiography. An acceptable repair was defined as aortic regurgitation ≤1+ with a mean gradient <15 mmHg. Any post-repair eccentric jet or aortic regurgitation >1+ was immediately addressed with additional repair manoeuvres; no patient left the operating room with aortic regurgitation >1+.

In the hospital, all patients received prophylactic subcutaneous low-molecular weight heparin, and anti-platelet agents were administered at discharge and for 6 weeks postoperatively. Warfarin was prescribed for patients who had undergone concomitant repair or replacement procedures on other heart valves.

Transthoracic echocardiography was performed prior to hospital discharge, and at 3 and 6 months. A follow-up form was filled in for each patient, and morbidity and mortality data were recorded as recommended by the European Association for Cardiothoracic Surgery, American Association for Thoracic Surgery and the Society of Thoracic Surgeons.

RESULTS
Operative profile

The pathophysiology of aortic valve regurgitation was degenerative in two patients and annulo-aortic ectasia in eight patients. Valve repair was successful in all cases, and no procedure was converted to prosthetic valve replacement. Procedures performed were six aortic annuloplasty procedures (correction of aorto-ventricular junction and sino-tubular junction) without cusp correction, two aortic annuloplasty procedures with cusp free-edge plication and two aortic valve re-implantation (David-III) procedures. Concomitant cardiac procedures included six mitral valve repairs, one mitral valve replacement, four tricuspid valve repairs and one coronary artery bypass grafting operation. The mean aortic cross-clamp time was 42 ± 15 min, and the mean cardiopulmonary bypass time was 63 ± 21 min. All patients underwent intra-operative transoesophageal echocardiographic controls.

Clinical outcomes

There were no in-hospital deaths. Follow-up was complete for all patients. Median follow-up was 5.5 months, with a maximum follow-up of 9.5 months. There were no mortalities, and no re-operations were necessary. Eight patients were in New York Heart Association functional class I and two patients were in...
functional class II. Three patients were receiving oral anticoagulants due to atrial fibrillation (two patients) or concomitant replacement procedures on other heart valves (one patient). No episode of haemorrhage or aortic endocarditides was observed.

Transthoracic echocardiography was performed prior to discharge, and was repeated at 3 and 6 months. The aortic valve repair operations resulted in a significant reduction in the diameters of the aorto-ventricular junction (−12%) and the sino-tubular junction (−13%), which remained stable during follow-up, with no significant gradient across the aortic valves (13 ± 4 mmHg). Aortic cusp coaptation heights measured 5 ± 1 mm, and valve cusps met at the middle distance (effective leaflet height 9 ± 2 mm) between the nadir of their insertion and the sino-tubular junction. Aortic valve function remained stable in all patients, with zero aortic regurgitation in six patients (including four patients who underwent isolated annuloplasty procedures, one patient who underwent aortic annuloplasty with cusp correction and one patient who underwent valve re-implantation procedure) and trace aortic regurgitation in four patients.

**DISCUSSION**

Restoring aortic valve competence demands correcting aortic root dilatation and reproducing matching cusp geometry [7, 8]. Formerly, surgeons had to make these crucial adjustments based solely on ‘eye-balling’ and their expertise [9]. More recently, however, a number of devices with diverse designs were developed to facilitate intra-operative decision-making through measuring inter-commissural distances [10], leaflet heights [11] or aortic cusp dimensions [3]. The calibrated cusp sizers, presented here, were designed to assist in investigating the mechanisms of valve regurgitation systematically, and to guide selecting the appropriate technique to valve repair; a methodology that is comparable to that attributed for the success and wide adoption of mitral valve repair procedures.

The design of the calibrated cusp sizers was based on previous morphological studies and geometric models of the natural adult human aortic root [4-6]. In this model, the diameter of the circle formed by the bases was considered to be equal to that formed by the commissures. This is justified by the fact that valve commissures are attached a millimetre or so below the sino-tubular junction where the diameter of the root approximates that of the aorto-ventricular junction [1]. Moreover, several studies have shown that the ratio of these two diameters remains close to 1.0 (1.2 ± 0.1) throughout the cardiac cycle at normal aortic pressures, and that their optimal ratio in reconstructed aortic root is ≈ 1:1 [4, 5].

Since few aortic valves have cusps of equal size, it was often necessary to average the diameters indicated by the three cusps when using these sizers which consider identical sizes for all three cusps. We deem this simplified approach to be safe, as some mismatch can be accommodated by the redundant coaptation surface of the cusps, and since various dimensions may change by several millimetres before an aortic valve becomes incompetent [12]. In fact, our model demonstrates that the free edge would have to stretch by more than 20% of its expected length for the cusp to prolapse below the coaptation zone.

Our preliminary experience demonstrated the usefulness of these sizers; identifying the exact alterations in cusp geometry (prolapse or contraction) and root morphology (annulo-aortic ectasia) was straightforward, and intra-operative decision-making and surgical correction (site of sub-commisural annuloplasty sutures, reaching matching root diameter, correct free-edge plication for cusp prolapse and selecting appropriate size of Valsalva graft in re-implantation procedures) were uncomplicated. In one case, cusp sizers identified the need for aorto-ventricular junction correction that was not recognized by eye-balling. Overall, we were able to preserve and restore valve competence in all patients in this series, and appropriate coaptation heights and effective leaflet heights were consistently maintained [2, 12].

The major limitations of this report are that only few patients were studied and that the follow-up time is limited. Nevertheless, the effectiveness of the techniques that we employed is well established [1, 2, 12, 13], hence we are encouraged to believe that our satisfactory early results will be followed by similarly gratifying outcome on the long term. It is also possible to use the calibrated cusp sizers to facilitate aortic valve repair with alternative techniques such as aortic valve re-modelling, internal or external prosthetic ring annuloplasty [8, 14], and pericardial patch repair for extensive cusp pathologies [15].

Overall, we believe that the calibrated cusp sizers can provide reliable insight into the mechanism of aortic valve insufficiency, and can guide aortic valve repair techniques successfully. We hope that the simplicity and reproducibility of this method would assist in its dissemination and further increase the percentage of aortic valves that are repaired when compared with current practice.

**SUPPLEMENTARY MATERIAL**

Supplementary material is available at ICVTS online.

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Conflict of interest: M.B.I. discloses that he has a financial relationship with Geister Medizintechnik GmbH.

REFERENCES