Early results of a novel technique for ring-reinforced aortic valve and root restoration†

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Abstract

OBJECTIVES: Surgery for aortic root aneurysm without valve stenosis is increasingly being transformed from the Bentall procedure to valve-sparing aortic root remodelling or reimplantation. In this report, a new repair option is explored, with full functional ‘restoration’ of the aortic root complex using a geometric annuloplasty ring, leaflet repair, and sinus/ascending aortic replacement with a Valsalva graft.

METHODS: The geometric annuloplasty ring restores elliptical annular shape and size in patients with tri-leaflet aortic insufficiency (AI). The ring mounts the three valve commissures on 10° outwardly flaring posts, and facilitates required leaflet procedures. In clinical application, the device has been effective in achieving stable AI reduction with low valve gradients. In this report, 6 patients with aortic root aneurysms and moderate/severe AI were managed with valve repair using the annuloplasty device and leaflet reconstruction, and then concomitant sinus and ascending aortic graft replacement with coronary implantation.

RESULTS: In the 6 initial root aneurysm patients, there were no in-hospital mortalities, procedural conversions, or valve-related complications. Preoperative AI grade was 2–4 and fell to 0–1 postoperatively. Post-repair mean systolic gradients ranged from 7 to 12 mmHg, and all patients had stable intermediate-term valve function.

CONCLUSIONS: Aortic root restoration using a geometric annuloplasty ring and Valsalva graft may be the most physiological method of aortic valve repair and root replacement. Even with severe leaflet derangements, valve sparing can be achieved with good competence and potentially stable long-term results. This technique could assist in extending valve sparing into most categories of aortic root disease.

CLINICAL TRIALS: Patients were managed as part of a Phase I (ClinicalTrials.gov Identifier: NCT01400841), supported by BioStable Science and Engineering (BSE), Austin, TX, USA; www.biostable-s-e.com.

Keywords: Aortic aneurysm • Valve repair • Annuloplasty ring • Aortic valve • Aortic valve repair • Ring annuloplasty • Valve sparing • Aortic root restoration

INTRODUCTION

‘... it sometimes happens that the root of the aorta is so involved in the disease process that the wall is too attenuated to be sutured to the proximal end of the aortic prosthesis. In this situation ... a Starr valve and the prostheses were inserted en bloc. The ostia of the coronary arteries were anastomosed to the side of the aortic graft.’

Mr. Hugh Bentall, 1968

In 1968, Prof. Hugh H. Bentall of the Royal Postgraduate Medical School, Hammersmith Hospital, London, first replaced the entire aortic root complex with a composite prosthetic valve—Dacron graft conduit for aortic root aneurysm [1]. The coronary arteries were implanted with an inclusion technique into the side of the Dacron graft. No question exists that this operation was a major advance, and it became the procedure of reference in subsequent years [2]. Recently, however, it has become clear that long-term complications of prosthetic aortic valves are significant [3, 4], and efforts have shifted towards sparing the native valve [5]. Towards this end, ‘remodelling’ and ‘reimplantation’ aortic root procedures have been perfected [6–8] and have achieved better late results—essentially those associated with autologous aortic valve repair [9, 10].

Although controversial, it could be debated that most current valve-sparing procedures have disadvantages. With the simpler ‘modified remodelling’ technique, aortic valve repair often is accompanied by subcommissural annuloplasty, as described by Cabrol et al. [11]. Because the entire annulus is not reinforced, recurrent annular dilatation and aortic insufficiency (AI) can occur [12, 13]. Reimplantation surrounds the entire aortic root with an external Dacron graft, minimizing late redilatation [14]. However, the reimplantation procedure is complex, requiring extensive

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dissection of the deep aortic root and geometrically complicated valve suture lines. Reimplantation also may not provide the best valve repair, since it simply constricts the valve externally in a circular fashion. The current report describes the first 6 patients managed with an alternative procedure—‘aortic root restoration’—with insertion of a geometric annuloplasty ring, leaflet reconstruction, and complete replacement of the sinuses and ascending aorta with a Valsalva graft.

METHODS AND RESULTS

The design of the HAART ring (‘Hemispherical’ Aortic Annuloplasty Reconstructive Technology; BioStable Science and Engineering, Inc., Austin, TX, USA; US Patent Number 8,163,011 B2) was developed from anatomic studies of human cadaver valves, as well as CT angiography of normal human valvular geometry [15, 16]. The ring is based on the concept that the permanent restoration of normal annular circumference and elliptical shape will facilitate the quality of valve repair in tri-leaflet aortic valves, both acutely and long term. The device has been evaluated in animals and patients with excellent results [17, 18]. The three-dimensional rings are computer-milled from one-piece Titanium blocks and covered with a thin layer of Dacron cloth to promote rapid endothelialization. Base geometry of the ring is elliptical with a 2:3 minor-to-major diameter ratio and three equidistant subcommissural posts that flare 10° outward [19]. The trial protocols for these human studies were approved by the German Competent Authority and the Ethics Committee of Munich, Germany. Selection criteria were mandated by the regulatory body, and each patient provided written informed consent [18].

The 6 patients in this report were operated on for aortic root replacement at the Deutsches Herz Zentrum München between August 2012 and March 2013. Preoperative patient characteristics are given in Table 1. Three patients were female and 3 male, and all had root aneurysms approximating or exceeding 45 mm in sinus diameter. All had moderate or severe AI and some degree of concomitant heart failure. Operations were performed with median sternotomy, standard cardiopulmonary bypass, and cold blood cardioplegia. Aortic valves were approached through complete transverse aortotomies, 1.5 cm above the right coronary artery and commissural tops (Fig. 1A). Traction sutures were placed above each commissure for exposure. After performing an accurate valve analysis to identify leaflet pathology, leaflet free-edge lengths were sized with special ball sizers (Fig. 1B) such that twice the leaflet free-edge length equaled the required ring circumference, as previously validated [17–19]. All patients had annular dilatation with significant leaflet prolapse in 5 (Tables 1 and 2). One patient had perforation of the non-coronary leaflet. All patients had leaflets that were symmetrical to within one ring size. If a one-size discrepancy did exist, the smaller value was chosen for the annuloplasty device. This protocol indicated a 25 HAART ring in 1 patient, 23 rings in 4 and

### Table 1: Preoperative patient characteristics

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Age (years)</th>
<th>Gender</th>
<th>NYHA CHF class</th>
<th>LVEF</th>
<th>LV EDD (mm)</th>
<th>LVEDD (mm)</th>
<th>Sinus/AA diameter (mm)</th>
<th>Annular diameter (mm)</th>
<th>AI grade</th>
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<tbody>
<tr>
<td>1</td>
<td>55</td>
<td>M</td>
<td>2</td>
<td>0.40</td>
<td>64</td>
<td>51</td>
<td>47/48</td>
<td>27</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>73</td>
<td>F</td>
<td>2</td>
<td>0.60</td>
<td>59</td>
<td>29</td>
<td>44/54</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>51</td>
<td>F</td>
<td>3</td>
<td>0.47</td>
<td>61</td>
<td>57</td>
<td>47/38</td>
<td>32</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>74</td>
<td>M</td>
<td>3</td>
<td>0.60</td>
<td>73</td>
<td>49</td>
<td>42/48</td>
<td>26</td>
<td>4</td>
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<tr>
<td>5</td>
<td>72</td>
<td>F</td>
<td>3</td>
<td>0.40</td>
<td>76</td>
<td>58</td>
<td>42/53</td>
<td>24</td>
<td>4</td>
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<tr>
<td>6</td>
<td>64</td>
<td>M</td>
<td>3</td>
<td>0.32</td>
<td>73</td>
<td>57</td>
<td>48/57</td>
<td>28</td>
<td>2</td>
</tr>
</tbody>
</table>

NYHA: New York Heart Association; LVEF: left ventricular ejection fraction; LV EDD: left ventricular end-diastolic diameter; LV EDD: left ventricular end-systolic diameter; AA: ascending aorta; AI grade aortic insufficiency grade (0 = none/trace, 1 = mild, 2 = moderate, 3 = moderately severe, 4 = severe).
a 21 ring in 1. In all patients, ring annuloplasty was performed as the initial part of the procedure.

The rings were sutured beneath the leaflets and commissures, and directly into the annuli, using nine transannular horizontal mattress sutures of 4-0 Prolene™ (Ethicon, Inc., Somerville, NJ, USA) — one in each post and two in the body of each sinus—supported with small supra-annular Dacron pledgets (Fig. 1C) [18]. Ring implantation time ranged from 27 to 19 min (Table 2), and has fallen routinely below 20 min with experience [21]. Then, leaflet prolapse was corrected using central plication sutures of 7-0 Gore-Tex in 5 of 6 patients to equalize leaflet length and effective height to >8 mm (Table 2). An adequate effective height was required before aortic closure. In Patient 1, a perforated non-coronary leaflet also was repaired with a patch of glutaraldehyde-fixed autologous pericardium. Good leaflet apposition and an effective height of >8 mm were obtained routinely (Fig. 1D).

The aneurysmal sinuses were excised, usually after ring placement and leaflet repair, preserving both coronary origins as buttons. The aortic root was mobilized minimally. Graft size was determined as 5–7 mm larger than the annuloplasty ring, also taking into account the size of the distal aorta. In 5 of 6 patients, a 28 mm Gelweave Valsalva™ Graft (Vascutek®, Terumo Cardiovascular Systems, Scotland, UK) was employed for sinus and ascending aortic replacement (creating three equally spaced broad sinus scallops), and a 30 mm graft was used once. Each scallop was sutured from the nadir of the sinus (Fig. 1E) to the top of the commissures using a 4-0 Prolene™ suture (Ethicon, Inc., Somerville, NJ, USA), essentially eliminating aortic tissue. At several points along each suture line, a bite of the ring pledget was taken to reinforce the reconstruction and connect the graft to the ring. The suture lines were kept very tight, and tested with a fine nerve hook if necessary. Of course, the long suture lines were created very precisely to avoid bleeding, and in the last 3 patients, autologous pericardial strips were added for reinforcement. Then, the coronary buttons were implanted into the sides of the graft, and the distal anastomosis was constructed using standard techniques.

A view of the completed procedure is shown in Fig. 1F, and video frames of three of the valves before and after repair are illustrated in Fig. 2. After bypass, residual valve leak was trivial to mild (Fig. 3). Potential complications of ring implantation, such as injury to the aortic valve cusps, anterior mitral leaflet or A-V node, were not observed, and all patients recovered uneventfully. All patients were treated with only aspirin 100 mg/day for 6 months and are being followed clinically with periodic transthoracic echocardiograms. The 1–6 month latest postoperative data are given in Table 2, documenting continued excellent aortic valve function. No change in clinical or echocardiographic status and no

| Table 2: Operative and postoperative information |
|-------------------------------|-----------------|-----------------|-------------|
| **Operative data** | **Latest (1–6 months) follow-up data** |
| Patient | Ring size (mm) | Ring implant time (min) | Leaflet prolapse plication | Graft size (mm) | NYHA CHF class | AI grade (0–4) | AV mean gradient (mmHg) | Valve area (cm²) | LVEF | LVEDD (mm) | LVESD (mm) |
| 1 | 23 | 27 | LC NC patch | 28 | 1 | 1 | 10 | 2.6 | 0.43 | 56 | 36 |
| 2 | 21 | 24 | — | 28 | 1 | 1 | 14 | 2.3 | 0.60 | 44 | 29 |
| 3 | 23 | 26 | RC, NC | 30 | 1 | 1 | 7 | 2.8 | 0.54 | 55 | 39 |
| 4 | 25 | 20 | RC | 30 | 1 | 1 | 9 | 2.6 | 0.50 | 66 | 45 |
| 5 | 23 | 19 | RC | 28 | 1 | 1 | 12 | 2.7 | 0.40 | 64 | 52 |
| 6 | 23 | 19 | RC | 28 | 1 | 0 | 12 | 2.7 | 0.65 | 46 | 32 |

NYHA: New York Heart Association; AV: aortic valve; AI grade: aortic insufficiency grade (0 = none/trace, 1 = mild, 2 = moderate, 3 = moderately severe, 4 = severe); LVEF: left ventricular ejection fraction; LVEDD: left ventricular end-diastolic diameter; LVESD: left ventricular end-systolic diameter; LC: left coronary leaflet, NC: non-coronary leaflet; RC: right coronary leaflet.

Figure 2: Operative views of the first 3 patients before and after aortic root restoration. Dilated and pathological annuli are evident before repair with central leaflet incompetence. For Patient 1, the blue arrow points to a hole in the non-coronary leaflet, which was closed with an autologous pericardial patch. In Patient 3, yellow arrows show right- and non-coronary leaflet prolapse, which was corrected with central leaflet plication. See text for other details.
DISCUSSION

Hugh H. Bentall made a significant contribution in 1968 by describing composite replacement of the aortic root using a prosthetic valved conduit, the Bentall procedure [1]. However, root surgery currently is transitioning to valve sparing [22], and early data suggest improvements in outcomes [9, 10, 22]. Effective methods of valve-sparing aortic root replacement are now being refined [23, 24], and because over half of root aneurysms have significant AI, aortic valve reconstruction is frequently required. Full annuloplasty rings have been more stable than suture annuloplasty for other cardiac valves, and the addition of aortic ring annuloplasty to valve remodelling could improve the consistency and stability of repair. Additionally, subcommissural annuloplasty, external rings [20] or circular sutures [25] are geometrically non-specific and do not consider the elliptical shape of the normal annulus. The design of the HAART ring takes these factors into account and reconstructs the complete three-dimensional annulus to normal 2:3 elliptical geometry with 10° outwardly flaring commissures. Thus, aortic ring annuloplasty restores physiological root geometry and, like full annuloplasty rings in other valves, could minimize late repair failures.

Root reimplantation surrounds the entire aortic root with a Dacron graft that prevents further root dilatation, and long-term results have been quite stable [8, 14]. However, the procedure requires deep dissection of the aortic root and a complex geometric valve reimplantation within the graft. Reimplantation may not be a very good valve repair, and in some settings, has performed less well in patients with severe valve derangements, perhaps being most applicable to those with relatively normal valve cusps. Also, the repair result is evident only at the end of the procedure, and in up to 5% of cases, the repair can fail, requiring conversion to a Bentall operation. Finally, the circular geometry of the Dacron graft may not provide the best annuloplasty for leaflet coaptation, particularly under pathological conditions. A comparison of current valve-sparing and root replacement techniques is given in Table 3.

In ‘root restoration’, an aortic annuloplasty ring is placed as the initial part of the procedure. With a reduction in annular circumference and recovery of ellipticality, the annular component of mal-coaptation is corrected, and the required leaflet procedures then can be performed precisely (Fig. 2). Excellent leaflet vertical coaptation height and valve competence can be achieved (Figs 2 and 3), with mean systolic valve gradients approximating 10 mmHg [21]. Precise graft sizing is another advantage, and in all patients, grafts 5–7 mm larger than the ring were used, mimicking normal anatomy [16]. Despite this promising first-in-man experience, however, longer follow-up and a larger sample size will be necessary for full evaluation, including possible formal statistical comparisons with the other procedures.

<table>
<thead>
<tr>
<th>Table 3: Comparison of current root replacement techniques</th>
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<tbody>
<tr>
<td>Reimplantation (David⁴)</td>
</tr>
<tr>
<td>Annulus stabilized</td>
</tr>
<tr>
<td>Annular geometry respected</td>
</tr>
<tr>
<td>Sinuses reconstructed</td>
</tr>
<tr>
<td>Normal Coronary flow Dynamics</td>
</tr>
<tr>
<td>Predictable annulus reduction</td>
</tr>
<tr>
<td>No root Mobilization Required</td>
</tr>
</tbody>
</table>

Technical characteristics of current aortic root replacement procedures, and comparison with aortic root ‘restoration’.
In conclusion, a novel three-dimensional aortic annuloplasty ring underwent initial trials in humans with aortic root aneurysms and significant AI, and together with Valsalva graft replacement of the sinuses and ascending aorta, the procedure was termed ‘aortic root restoration’. Repair efficacy seemed to be facilitated, and early results were excellent. This approach holds significant promise for increasing the applicability and stability of autologous aortic valve reconstruction in patients with aortic root disease.

**Funding**

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**Conflict of interest:** Domenico Mazzitelli and Philip Crooke are consultants for BioStable Science and Engineering, and J. Scott Rankin is Chief Medical Officer.

**REFERENCES**