Modified bio-Bentall procedure: 10-year experience

Paul P. Urbanski*, Nico Heinz, Xiaochin Zhan, Husam Hijazi, Michael Zacher, Anno Diegeler

Cardiovascular Clinic Bad Neustadt, Bad Neustadt, Germany

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Abstract

Objective: Biological aortic valve conduits are rarely used because of the concern that possible structural valve deterioration would require complete conduit replacement in a technically demanding operation. The aim of the study was to evaluate the 10-year experience with complete aortic-root replacement using a modified composite graft in which biological valve prosthesis was located inside the vascular graft allowing its replacement within the tube and leaving the coronary ostia untouched. Methods: Self-assembled composite grafts as described have been used in our clinic since 1998 as the standard for patients needing a biological aortic-root replacement. Until December 2008, they were implanted in 182 consecutive patients with a mean age of 70 ± 8 years. Indications for root surgery were chronic aneurysm, porcelain aorta, acute dissection, acute endocarditis and intra-operative root injury in 168, five, three, three and three patients, respectively. All perioperative data were collected prospectively. Results: The technique performed ensured a significant valve oversizing in 30 patients with an annulus equal to or smaller than 23 mm (22.0 ± 1.3 mm) for whom the mean valve prosthesis size of 26.3 ± 2.4 mm was used. Rethoracotomy due to bleeding was necessary in eight patients (4.4%). No blood transfusion during the entire hospital stay was required for 69 patients (37.9%). The overall patient survival, including 30-day mortality of 0.5%, was 74.2% at the mean follow-up of 4 ± 2.7 years. The linearised death rate was 6.5% year−1 and was similar for that of the general age- and sex-matched control populations. Re-operation for valve deterioration occurred in one patient and was performed easily by valve replacement within the graft. Conclusions: Aortic composite graft with biological valve prosthesis located inside the tube offers the possibility of considerable valve oversizing, excellent haemostatic characteristics and simple replacement of the valve prosthesis in case of its deterioration and can therefore be recommended for younger patients.

Keywords: Ascending aorta; Aortic valve; Biological valve prosthesis; Valve composite graft

1. Introduction

The use of valved conduits consisting of a mechanical valve prosthesis and a vascular graft for the complete replacement of the aortic root, as described first by Bentall and De Bono in 1968 [1], has become a standard surgical technique. Nowadays, there are several conduits with mechanical valves available and very few with biological valves. Implantation of a conduit with a biological valve prosthesis is not very widely used because in cases of re-operation, due to a structural degeneration of the xenograft, usually the entire conduit has to be replaced [2,3]. In 1998, we introduced a self-assembled composite graft consisting of a stentless valve prosthesis incorporated into the sealed woven polyester graft (InterGard, InterVascular, La Ciotat, France) [4,5]. This device had been believed to improve haemodynamic characteristics resulting not only from the stentless valve but also additional valve oversizing and should have allowed replacement of the valve prosthesis within the vascular graft; it was therefore established as routine for biological root repair in our facility. The aim of the study was to evaluate the outcome after using the device in 182 patients during a 10-year period.

2. Patients and methods

From 1998 to the end of 2008, 182 consecutive patients for whom anticoagulation was not desirable or contraindicated and who needed complete aortic-root replacement underwent implantation of self-assembled composite grafts containing an aortic valve xenograft. The group included 119 men and 63 women with a mean age of 70 years (range, 24–85 years).

A 24-year-old female patient with Turner syndrome was the exceptional case among the otherwise elderly group. Preoperative patient characteristics are shown in detail in Table 1. Indications for root surgery were chronic aneurysm, porcelain aorta, acute dissection, acute endocarditis and intra-operative root injury in 168, five, three, three and
The assembly of the composite graft during surgery has been described previously [5, 6]. Until the end of 2005, the composite graft was accomplished during cross-clamp time. In short, for oversizing the valve, the stentless valve composite graft was accomplished during cross-clamp time. Starting in 2006, the composite graft was accomplished before clamping of the aorta by using the new technique in all patients [7]. Coronary ostia were implanted using the Kouchoukos button technique in all patients [6].

Table 1
Preoperative patient characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>No (%) or mean ± SD (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>119 (65)</td>
</tr>
<tr>
<td>Age (Y)</td>
<td>70 ± 8</td>
</tr>
<tr>
<td>NYHA functional class III/IV</td>
<td>122 (67)</td>
</tr>
<tr>
<td>Concomitant disease</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>135 (74)</td>
</tr>
<tr>
<td>Coronary heart disease a</td>
<td>31 (17)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>27 (15)</td>
</tr>
<tr>
<td>COPD</td>
<td>16 (9)</td>
</tr>
<tr>
<td>Previous neurologic events</td>
<td>17 (9)</td>
</tr>
<tr>
<td>Permanent</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Transient</td>
<td>11 (6)</td>
</tr>
<tr>
<td>Previous cardiac surgery</td>
<td>16 (9)</td>
</tr>
<tr>
<td>EuroSCORE logistic (%)</td>
<td>15.9 ± 14.3 (2.6—93.6)</td>
</tr>
</tbody>
</table>

NYHA: New York Heart Association; COPD: chronic obstructive pulmonary disease.

2.1. Surgical technique

The mean gradient across the aortic valve prostheses upon before 2000. Since 2000, we have completely abandoned using any tissue glue in aortic surgery. Although, tissue glue was used in only one patient operated otherwise indicated. Overall survival was estimated by the Kaplan–Meier method. The life-table curves were used for graphical comparison between the study population and an age- and sex-matched German population.

2.2. Statistical analysis

The statistical analysis was performed with the SPSS software (SPSS Inc., Chicago, IL, USA). Values in the tables and text are expressed as mean ± standard deviation unless otherwise indicated. Written documents including echocardiographic images were requested from physicians and reviewed. All data were analysed according to reporting guidelines [8, 9].

3. Results

3.1. Operative data

The mean gradient across the aortic valve prostheses before hospital discharge was 9.5 ± 3.2 mmHg. In all cases the valve prostheses were competent without signs of insufficiency. At the time of the follow-up, the mean

Table 2
Operative data.

<table>
<thead>
<tr>
<th>Variables</th>
<th>No (%) or mean ± SD (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial arch replacement</td>
<td>66 (36)</td>
</tr>
<tr>
<td>Total/subtotal arch replacement</td>
<td>10 (6)</td>
</tr>
<tr>
<td>CABG a</td>
<td>31 (17)</td>
</tr>
<tr>
<td>Mitral valve repair</td>
<td>10 (6)</td>
</tr>
<tr>
<td>Mitral valve replacement</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Others</td>
<td>6 (3)</td>
</tr>
<tr>
<td>CPB duration (min)</td>
<td>160 ± 40</td>
</tr>
<tr>
<td>Aortic cross-clamp time (min)b</td>
<td>106 ± 27</td>
</tr>
<tr>
<td>Circulatory arrest time (min)</td>
<td>14 ± 8 (5—44)</td>
</tr>
</tbody>
</table>

a CABG: coronary artery bypass grafting.
b Including circulatory arrest.

aortic annulus in the same manner as described above [6].

Operative data including the extent of surgery are shown in Table 2.

All perio-operative data were collected prospectively. For follow-up, patients and their physicians were contacted. Written documents including echocardiographic images were requested from physicians and reviewed. All data were analysed according to reporting guidelines [8, 9].
transvalvular gradient was 10.0 ± 7.7 mmHg with a slight aortic regurgitation in seven cases.

### 3.3. Survival

Clinical follow-up data were available for all patients. The mean follow-up was 48 ± 32 months (range, 3–125 months) totalling 728 patient-years. One death occurred during the 30-day postoperative period (0.5%) and was caused by sepsis due to jejunum ischaemia after complete ascending aorta and aortic arch replacement because of a porcelain aorta. At autopsy, a severe stenosis of the upper mesenteric artery was revealed.

There were 46 late deaths including four deaths which occurred in-hospital or during the 90 postoperative days after surgery. Thirty deaths, including 19 with a sudden or unknown cause, were considered to be valve related and five cardiac related. Causes of late death are listed in Table 3. The linearised death rate was 6.4% year⁻¹ and the actuarial survival, including 30-day mortality, was at 5 and 8 years, 74.3% and 57.6%, respectively. For a descriptive comparison of survival between the study population and an age- and sex-matched German population, the life-table curves were used (Fig. 1). The curves were similar with a slight increase in mortality in the study population; however, one should bear in mind that this cohort consisted completely of patients with cardiovascular diseases, which are the most frequent cause of death in the human population.

### 3.4. Re-operation

Four patients required aortic re-operation during the entire follow-up period. Two patients required early revision due to mediastinitis that was treated by transposition of the omentum flap into the mediastinum, which led to long-term healing in one of them. One patient underwent replacement of the whole composite graft because of endocarditis and another patient underwent aortic valve re-placement because of xenograft degeneration 3 and 7 years after the primary aortic-root replacement, respectively.

#### 3.5. Structural valve deterioration

Structural valve deterioration requiring surgery was noted in only one patient, who was the youngest female patient of the series, 7 years after the primary surgery and shortly after successful pregnancy.

#### 3.6. Endocarditis

Endocarditis was noted in a total of three patients. One of them was treated conservatively resulting in a favourable long-term outcome without any recurrent endocarditis during his 10-year follow-up period. Another patient underwent successful re-replacement of the aortic root with a mechanical valve composite graft without recurrent endocarditis during the following 3 years. The last patient was not referred to surgery and died from multi-organ failure.

#### 3.7. Thrombo-embolic events

The linearised risk of thrombo-embolic events was 2.1% year⁻¹. These events occurred in 15 patients including 12 major strokes (four of them lethal) and three transient ischaemic attacks. Seven of the patients suffered from atrial fibrillation, and four of them were on anticoagulation therapy with warfarin.

#### 3.8. Haemorrhage

Seven patients suffered significant haemorrhage, which led to the 1.0% linearised risk of bleeding. Four of them were being treated with warfarin for indications unrelated to the biological valve replacement (atrial fibrillation), and all these four patients died from the haemorrhage. This results in a 2.1% year⁻¹ linearised risk of lethal bleeding among a total of 47 patients, in whom warfarin had been given. The three remaining haemorrhages occurred in patients who had undergone long-term aspirin therapy and included two gastrointestinal bleedings and one lethal cerebral bleeding. The linearised risk of lethal bleeding in the entire population was 0.7%.

### 4. Discussion

Biological valve prostheses have rarely been used for assembling valved conduits because of the concern that the possible structural valve deterioration would require complete conduit replacement in a technically demanding operation [3]. Nevertheless, the increasing age of patients undergoing aortic valve surgery in the past decades has resulted in a clear trend of using biological substitutes for aortic valve and aortic-root replacement [10]. Many young patients needing aortic-root replacement do not want any

<table>
<thead>
<tr>
<th>Cause</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemorrhage</td>
<td>5 (2.7)</td>
</tr>
<tr>
<td>Stroke</td>
<td>4 (2.2)</td>
</tr>
<tr>
<td>Mediastinitis</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Sudden/unknown</td>
<td>19 (10)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>4 (2.2)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Non-cardiac/non-valve-related</td>
<td>11 (6)</td>
</tr>
</tbody>
</table>

Table 3 Late mortality (n = 46).

Fig. 1. Life-table curves demonstrating survival after aortic-root replacement with biological valve composite graft versus aged- and sex-matched German population.
limitation of their quality of life and also request biological alternatives to avoid the necessity of life-long anticoagulation therapy. In addition, considering the life activities of the young, it is rational to use aortic valve prostheses with nearly physiological orifice areas; and therefore, a pulmonary autograft or homograft is thought to be very suitable. However, owing to their limited availability and applicability, both devices cannot be considered widespread alternatives for biological root replacement [11,12]. Moreover, the re-operations after these procedures, an option that surgeons should always bear in mind, belong to the category of high-risk surgery [12—14]. The same pertains to porcine root xenografts, which are, in fact, commercially available without limitation but also demand challenging replacement of the whole aortic conduit in cases of late valve prosthesis degeneration [14]. There is also a reasonable concern about the suture line between the biograft and vascular tube extension for distal ascending replacement because different complications, reaching from early rupture to late false aneurysm formation, have already been described [15,16].

The most important advantages of moving the valve prosthesis from the end to the inside of a vascular tube are the ability to considerably oversize the valve and simplification of its replacement if necessary. In this technique, the aortic annulus does not determine the size of valve prosthesis; and therefore, a noticeable oversizing of the valve and increase of the aortic orifice area can be achieved, regardless of whether a mechanical or biological valve prosthesis is used [17—19]. In addition, a degenerated biological valve prosthesis can be replaced within the vascular graft rather than replacing the complete conduit.

Recently, our technique has found an increased following by several groups who use the self-assembled biological composite grafts consisting of different valve and vascular prostheses for the same reasons as mentioned above [20]. Even though the use of stented prostheses is easier because only one suture line is necessary for fixation, the sewing rim of stented prostheses impedes use of the whole space inside the tube (Fig. 2). Considering that stentless valves offer improved haemodynamic characteristics and the whole space of the graft can be used, we have established our self-assembled composite graft with stentless valve prosthesis as routine. In such composite grafts, no space between the valve and the tube remains unused, and therefore, an optimal haemodynamic effect can be achieved.

We were also able to prove the feasibility of valve re-placement within the vascular graft; however, during the period of the study, only one such case of valve prosthesis replacement was performed. Recently, we were confronted with another two cases of valve deterioration after more than 10 years. In all cases, the valve prostheses were replaced within the vascular graft leaving the conduit in place in the manner as reported in detail elsewhere [21].

This surgical option can hardly be expected after implantation of the stentless root prosthesis with graft extension, as first described by Westaby et al. in 1998, in which the valve prosthesis is anastomosed directly to the aortic annulus [22]. This technique can lead to calcification of the anastomosis or even the aortic wall of the entire xenograft necessitating a challenging re-replacement [23,24]. Even though some authors speculate that only cusp resection and valve re-placement could be performed inside the bio-root, such a re-operation has not been reported to date. Moreover, it seems to be questionable if the inevitable valve undersizing within the xenograft would allow implantation of the prosthesis with a sufficient size. On the contrary, our supra-annular implantation technique allows use of vascular tubes with relatively large calibres (91% of patients received tubes equal to or larger than 26 mm), which ensures the possibility of valve re-placement with a prosthesis of sufficient size.

As mentioned above, anastomosing between the annulus and a vascular graft allows general use of a tube with a diameter that differs significantly from the patient’s annulus diameter. Thus, the tube diameter, rather than the annulus diameter, determines the size of the valve prosthesis to be implanted. In this way, it is possible to implant stentless valves in patients with annular ectasia and an annulus diameter larger than 30 mm or to oversize a small annulus with considerably bigger valve prosthesis. A further advantage of leaving the margin of the tube for anastomosing with the aortic annulus is excellent haemostatic characteristics of the suture line between the coated polyester and aortic tissue, even in case of annulus alteration, as in endocarditis or re-do surgery.

Even if the mean follow-up duration of the group described is shorter than after using the St. Jude Toronto prosthesis for valve replacement in the native aorta, our data confirm that the durability of this porcine valve is not adversely impacted by placement in the straight vascular tube and is at least as good as in a native aorta [25].

In conclusion, an aortic composite graft with biological stentless valve prosthesis located inside the tube offers the possibility of considerable valve oversizing, excellent haemostatic characteristics and simple replacement of the valve prosthesis, if necessary, and can therefore be recommended for younger patients.

Acknowledgements

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References


Appendix A. Conference discussion

Dr L. Lange (Munich, Germany): I think your results are excellent. You show a very nice way of your own composite graft, especially at a time when commercially available grafts all have their disadvantages still. You have excellent operative mortality of 0.5%, 30 days, this is very, very good, and also your long-term mortality is very good. So actually from what you just presented to us there is nothing to criticise. I just would caution on two things, actually.

The first is you emphasise very much that you can oversize. Now, you know the left ventricular outflow tract, of course, is limited by the smallest diameter, and the smallest diameter is the aortic valve ring or the subvalvular area. Now, if you have a 23 or 21 ring and you put in a 26 or 27 prosthesis, you still have the limitation of the aortic valve ring, and since you do not present any echo data and not any gradients, I would not stress too much the fact that you are able to oversize. The other thing is that I also would not stress too much, you say you only had one incidence of structural valve degeneration. Again, if you do not do a continuous echocardiographic survey after the operation, it is hard to tell whether you have structural valve degeneration or not. So maybe you can comment on those two things.

Dr Urbanski: The orifice area of the valve used you in the supra-annular position is bigger than when you put the valve into the annulus. Of course, it is some limitation of the size of the annulus. But you can utilise the complete orifice area of the native aortic valve. Due to the sewing rim of the prosthesis the orifice area in the intra-annular position is smaller than in supra-annular. In this technique you can use the stentless valve also for every pathology. Even in a patient with an annulus of 30 mm you can use a stentless valve which normally is not possible, because the biggest stentless valve is 29 mm. You cannot sew a stentless prosthesis to an annulus of 30 mm directly because the valve becomes insufficient. In this way you can use the composite graft with a stentless prosthesis even in patients with annular ectasia.

And the second question was about degeneration, echocardiographic examination, yes?

Dr Lange: The incidence of structural valve degeneration.

Dr Urbanski: For the purpose of the follow-up we asked every patient and every physician, home physician, cardiologist, to send us the echocardiographic examinations, and none of the patients, with the exception of these three patients who were already operated on (two of them even after the study), showed any degenerative changes on the valve.

Dr J. Ennker (Lahr, Germany): I have one question. We do not see the advantage of sewing a stented valve into a prosthesis. We have been employing, for example, the Freestyle valve in several hundred patients with aortic-root pathology and we used it as a full root and there was no need to implant this valve into an additional prosthesis. We will use the prosthesis in a supra-annular fashion above the Freestyle, and that is fine, and we also can treat pathologies of 30 and 31 mm without creating insufficiency. Could you comment on that?

Dr Urbanski: Of course, you can use the root technique with extension of the Dacron tube for ascending replacement, even arch replacement. I think the advantage of our technique is that you can use a stentless valve in every patient, as I said, in patients with a bigger annulus and in patients with a small annulus. The second advantage I think is that you avoid a calcification of the aortic wall, and the re-operation is simpler than after using a complete bio-root, because you don’t have calcification of the root. It is not only theoretical, but we were able to demonstrate in three cases that the re-operation was really very easy, and we could implant a sufficient valve prosthesis into the tube. I am wondering if after using the bio-root you can excise only the cusps and put a sufficient big prosthesis into the bio-root. I am not sure.

Dr Ennker: That depends on your coronary button. If it is large enough, it is not a problem. But this is also a fine solution.