Title:

Replacement of the Ascending Aorta, Aortic Root and Valve with a Novel Stentless Valved-Conduit

Running Head:

Replacement of Ascending Aorta and Valve

Authors:

Kelvin K.W. Lau MRCS DPhil

Krystyna Bochenek-Klimczyk MD

Manuel Galiñanes MD, PhD, FRCS

Andrzej W. Sosnowski FRCS

Institution and Affiliations:

Cardiac Surgery Unit, Cardiovascular Sciences Department, Glenfield Hospital, University of Leicester, Groby Road, Leicester, LE3 9QP UK (all authors)

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Corresponding author:

Manuel Galiñanes, Cardiac Surgery Unit, Cardiovascular Sciences Department, Glenfield Hospital, University of Leicester, Groby Road, Leicester, LE3 9QP, United Kingdom

Tel: +44 116 2563032

Fax +44 116 2502449

e-mail: mg50@le.ac.uk

Abstract:*Purpose*

Biological valved-conduit grafts avoid the need for anticoagulation, and can exploit the excellent hemodynamic performance of stentless valves. Incorporation of sinuses of Valsalva into the neo-aortic root can improve the function of the stentless valves.

Description

Here we present a novel prefabricated stentless valved-conduit incorporating sinuses of Valsalva and describe the technique of implantation. The BioValsalva™ valved-conduit incorporates a stentless porcine aortic valve (Vascutek Elan™) suspended within a triple-layered vascular conduit (Triplex™, Vascutek, Renfrewshire, Scotland) constructed with sinuses of Valsalva.

Evaluation

The BioValsalva™ valve-conduit was used in twelve patients with aortic regurgitation due to annulo-aortic ectasia unsuitable for aortic valve repair and concomitant ascending aorta aneurysm with no mortality and excellent functional result.

Conclusion

The prefabricated, composite stentless-valved-conduit, which material is hemostatic and reduces bleeding, is easy to implant with short ischemic time, and lends itself well to a variety of insertion techniques.

Introduction:

The replacement of the aortic root, ascending aorta and aortic valve with a valved-conduit is a well-established procedure for the treatment of ascending aorta aneurysms and aortic dissection. However, this operation is still associated with high perioperative mortality and morbidity. The nature of the prosthetic material used may play a role in these complications. Knitted vascular conduits did not have favourable handling properties and hemostasis was suboptimal, contributing to mediastinal bleeding, a life-threatening complication. To overcome this problem, woven prostheses with zero-porosity were developed. The use of a xenograft root, which if necessary could be extended distally with a vascular graft, has also been proposed (1). However, the xenograft aortic wall is prone to calcification. If reoperation were required, then replacement of the entire xenograft root would be necessary, compounding the risk of surgery (2). The use of a mechanical valve in a composite graft requires long-term anticoagulation and is a disadvantage especially in elderly patients, in patients unsuitable for anticoagulation, and in patients with extended aortic pathologies, such as aortic dissection and thoracoabdominal aortic aneurysms.

Composite valved-conduits using mechanical and bioprosthetic prostheses have traditionally been designed as straight tubes without incorporating the sinuses of Valsalva. The physiological importance of the sinuses is beginning to be recognised. Vortices which form at this site improve blood flow to the coronary arteries and promote earlier and more gradual valve leaflet closure, thus reducing stress of the leaflet coaptation (3). Furthermore, in the absence of the sinuses, there is a theoretical risk of collision of the valve leaflets with the vascular graft resulting in abrasive wear. Therefore, the ideal composite valved-conduit used for replacement of the aortic

valve, aortic root and ascending aorta should possess the following characteristics: (i) sinuses mimicking the anatomy of the aortic root, (ii) a synthetic conduit material which should be both hemostatic and easy to handle, whilst resistant to calcification and deterioration with time, and (iii) a valve which does not require anticoagulation, has good hemodynamics and is durable. Here we report on a new bioprosthetic valved-conduit BioValsalva™ (Vascutek Terumo, UK) which consists of a stentless bioprosthesis, the Elan valve that has been shown to afford excellent hemodynamics with performance (4), within a polyester and polytetrafluoroethylene (PTFE) triple-layered conduit which is hemostatic, has favourable handling properties and incorporates sinuses of Valsalva (Figure 1).

Technology

The BioValsalva™ prosthesis consists of a stentless porcine valve (Vascutek Elan™) pre-implanted within a longitudinally-corrugated Triplex™ vascular graft incorporating sinuses of Valsalva. The selected porcine valves were predilated and preserved with low-pressure fixation in 0.5% buffered glutaraldehyde. They did not receive anti-mineralisation treatment. Only two sizes of the prosthesis were used (26 and 28mm for the conduit and 25 and 27mm respectively for the valve). The diameters of the sinus of Valsalva for these conduits are 32mm and 35mm respectively. As discussed below, different implantation techniques can be used to accommodate one of these two prostheses sizes into a wide range of aortic anatomy.

Surgical technique

The operation was performed through a median sternotomy. Transesophageal echocardiogram (TOE) was performed in all patients prior to and following separation from CPB.

Standard CPB was established between the right atrium and aortic arch with moderate hypothermia (28°C), or deep hypothermia (17°C) if circulatory arrest was required. A modified Bentall technique with complete resection of the ascending aorta and aortic valve, and reimplantation of the coronary buttons was used in all patients.

The sewing ring of the BioValsalva™ composite conduit was anastomosed to the aortic annulus using a variety of techniques depending on the aortic anatomy. When the tissue was healthy, continuous and semi-continuous sutures were used, with or without pledget reinforcement. When the tissue quality was poor and the annulus calcified, interrupted mattress sutures were used. Interrupted mattress sutures were also used when a small aortic annulus was encountered, allowing the implantation of a larger root into the supraannular position; whilst everted mattress sutures reinforced with continuous sutures were used when there was a large annulus, to allow a smaller root to be implanted in the intraannular position.

The vascular graft was fenestrated with a punch (5.6 mm) and the coronary buttons were anastomosed to the BioValsalva™ graft using 5/0 Surgipro™ (Syneture, USA). Following completion of the coronary anastomoses, the tube graft was cut to length and an end-to-end anastomosis to the distal ascending aorta was fashioned using a continuous 3/0 Prolene™ (Ethicon, USA) suture reinforced with Teflon felt and tissue glue (Glubran™, GEM, Viareggio, Italy).

Patients with aneurysms extending distally underwent further ascending aorta and arch replacement with a 28mm Dacron conduit. The distal anastomosis was performed under circulatory arrest with a tube-graft inversion technique as described previously (5).

Clinical Experience

Between December 2006 and June 2007, 12 BioValsalva™ prostheses were implanted electively in 12 patients (9 males, 3 females) with annuloaortic ectasia and aortic regurgitation resulting from degenerative valve disease unsuitable for repair. The procedure was thoroughly explained and informed consent was obtained for all patients in accordance with the General Medical Council (UK) guidelines. The regional ethics committee has confirmed that ethical approval is not required under the NHS research governance guidelines. The mean CPB time was 145 ± 28 minutes, and the mean aortic cross-clamp time was 95 ± 21 minutes mean $\pm$ standard error of the mean). Deep hypothermic circulatory arrest (20-22 minutes) was used in three cases for distal ascending aorta and arch replacement with a 28mm Dacron conduit. There were no in-hospital deaths or reoperations for bleeding or tamponade.

All patients underwent post-operative CT of aorta and echocardiography prior to discharge. Figure 2 is a representative axial CT section and Figure 3 shows the valved-conduit in a CT reconstruction. These confirm the presence of three distinct sinuses of Valsalva. The mean peak-gradient of the aortic valve prostheses was 18 ± 6 mmHg. The mean effective orifice area (EOA) $\pm$ standard error of the mean was 2.2 ± 0.3 and $2.4 \pm 0.4 \text{ cm}^2$ for the 25 and 27mm prostheses, respectively. In all cases the

valve prostheses were functioning well with no evidence of regurgitation. Hematoma was noticed around the ascending aorta in 4 patients. In addition, one patient underwent MRI of the aorta. This latter investigation could not demonstrate obvious dynamic movements of the sinuses of Valsalva during the cardiac cycle, however this important issue should be addressed in future studies in a larger group of patients.

Comments:

We have shown here that the BioValsalva™ prosthesis, a novel valved-conduit, can be safely used with short aortic cross-clamp times and good hemostatic properties. We have also shown that the prosthesis is versatile, allowing the use of a variety of surgical techniques to accommodate specific anatomical findings. The availability of such a valve-conduit may have important implications for improving the surgical outcome of the correction of the aortic valve, aortic root and ascending aorta pathology.

The Bentall procedure is the gold standard for repair of ascending aortic aneurysms and aortic regurgitation. Universal use of mechanical valves is limited by their need for anticoagulation and suboptimal hemodynamics. With improved durability of bioprosthetic valves coupled with their excellent hemodynamic profile, several groups have modified the Bentall procedure to incorporate stentless aortic valves (1, 6, 7). These were constructed intraoperatively following sizing of the annulus. Intraoperative construction requires an extended cross-clamp time. In addition, imperfectly placed sutures can result in distortion of the valve which might only be identified by TOE upon discontinuation of CPB (8). The new prefabricated BioValsalva™ valved-conduit eliminates the ischemic time required for the

construction of the valved-conduit construction during surgery and the risk of valve malfunction. Our results show a mean ischemic time of 95 minutes, which compares favourably to other series of Bentall operations (8).

Composite grafts constructed from the first-generation Toronto SPV valve within a Dacron[™] tube have been shown to have good hemodynamic performance accompanied by good medium-term clinical outcomes (3, 7). The BioValsalva[™] prosthesis utilises an Elan[™] stentless aortic valve that has also been shown to possess excellent hemodynamic performance and clinical results (4, 9).

Bleeding is a significant morbidity associated with the Bentall procedure, and can result in the need for reoperation in over 10% in some series. Earlier ascending aorta replacements were complicated by bleeding from needle holes and anastomotic lines. The BioValsalva[™] prosthesis contains a Triplex[™] vascular graft, with an inner woven polyester layer and an outer PTFE layer. The superior hemostatic properties of this conduit can be seen where the valved-conduit was anastomosed to a distal conduit in repairs involving the aortic arch: notably, there was bleeding from the Dacron graft suture holes and not in the valved-conduit. In our series, there were no reoperations and little mediastinal drainage. An added benefit with this vascular graft material is the ease of fenestration with an aortic punch, avoiding the imprecise perforation with electrocautery. Nevertheless, care must be taken to ensure that the valve leaflets are not damaged by the punch because surface tension can draw the leaflets onto the conduit wall.

Unlike mechanical valves, optimal functioning of biological valves is affected by the anatomy of the aortic root. The sinuses of Valsalva in particular, may play a role in

enhancing durability of the valves. The presence of the sinuses theoretically reduces the impact of the valve leaflets on the conduit during valve opening, and on each other during valve closure, and may improve blood flow in the coronary arteries (3).

Another major advantage of the BioValsalva™ valved-conduit is the relative ease for explantation if a reoperation is needed as the valve is not incorporated into the suture line of the prosthesis to the aortic annulus. Early bioprosthetic valved-conduits were sutured in such a way that both the valve and the vascular graft were incorporated into the anastomosis (6) and in this case full explantation of the valved-conduit is necessary when valve replacement is required. Compared to homograft and xenograft roots, the polyester vascular prosthesis is relatively resistant to calcification and dilation, and would not require replacement. Therefore reoperation could be achieved through entering the graft and excising the stentless valve. A new stentless or stented valve could then be reimplanted into a suitable position.

In conclusion, the BioValsalva™ bioprosthetic valved-conduit belongs to a new generation of prefabricated bioprosthetic valved-conduits with excellent hemodynamic profiles and hemostatic properties incorporating sinuses of Valsalva. Our series showed that this versatile valved-conduit could be implanted easily and safely using a wide range of techniques, for the replacement of the aortic valve, aortic root and ascending aorta, with good short term clinical outcomes.

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Disclosure and Freedom of Investigation:

BioValsalva™ valved-conduits were supplied at full cost to our department. The authors had full control in the patient selection, operative technique, study design, data analysis and preparation of the article. As mentioned in the acknowledgments, financial support was obtained for the publication of color figures from Vascutek, Ltd.

References:

- 1 Byrne JG, Mihaljevic T, Lipson WE, Smith B, Fox JA, Aranki SF. Composite stentless valve with graft extension for combined replacement of the aortic valve, root and ascending aorta. *Eur J Cardiothorac Surg* 2001;20:252-6
- 2 Dossche KM, Schepens MA, Morshuis WJ, de la Riviere AB, Knaepen PJ, Vermeulen FE. A 23-year experience with composite valve graft replacement of the aortic root. *Ann Thorac Surg* 1999;67:1070-7.
- 3 de Paulis R, Tomai F, Bertoldo F et al. Coronary flow characteristics after a Bentall procedure with or without sinuses of Valsalva. *Eur J Cardiothorac Surg* 2004;26:66-72
- 4 Flynn M, Iaccovoni A, Pathi V, Butler J, Macarthur KJ, Berg GA. The aortic Elan stentless aortic valve: excellent hemodynamics and ease of implantation. *Semin Thorac Cardiovasc Surg* 2001;13:48-54.
- 5 Alexiou C, Sosnowski AW. Tube-graft inversion for the construction of an "open" distal anastomosis during ascending aortic replacement: a new technique. *Ann Thorac Surg* 2007;83:326-8
- 6 Urbanski PP. New vascular graft for assembling the stentless valve composite graft. *Ann Thorac Surg* 2007;84:1771-3.

- 7 de Paulis R, Nardi P, De Matteis GM, Polisca P, Chiariello L. Bentall procedure with a stentless valve and a new aortic root prosthesis. *Ann Thorac Surg* 2001;71:1375-6
- 8 Urbanski PP, Diegeler A, Siebel A, Zacher M, Hacker RW. Valved stentless composite graft: clinical outcomes and hemodynamic characteristics. *Ann Thorac Surg* 2003;75:467-71
- 9 Akar AR, Szafrank A, Alexiou C, et al. Use of stentless xenografts in the aortic position: determinants of early and late outcome. *Ann Thorac Surg* 2002;74:1450-7
- 10 Galla JD, Lansman SL, Spielvogel D et al. Bioprosthetic valved conduit aortic root reconstruction: the Mount Sinai experience. *Ann Thorac Surg* 2002;74:S1769-72

Legends

Figure 1: BioValsalva™ valved-conduit

Figure 2: CT aorta after implantation of the BioValsalva™ valved-conduit demonstrating the origin of the coronary arteries (arrows) and the three sinuses of Valsalva (*) following implantation.

Figure 3: CT reconstruction of the aorta following implantation of the BioValsalva™ valved-conduit.