Another report on unfavourable long-term outcome following implantation of the Shelhigh No-React™ tube valved graft

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Totally biological valved conduits like the Shelhigh No-React™ implant were expected to offer several advantages for patients requiring aortic root replacement in whom a tissue valve would be the preferential option. The stentless design of the valve promised a better hemodynamic performance following implantation of a stented valve. Furthermore traditionally glutaraldehyde-preserved biological valves tended to calcify, especially in younger patients, whereas the novel No-React™ detoxification process promised to ensure stable tissue cross-linking, resulting in less calcification and tissue deterioration. This was demonstrated in the animal model (1). Finally, availability of the conduit from the bench in the most commonly used sizes as opposed to self-constructed valved tubes and homografts is considered as additional advantage.

In this paper, the group of Zürich's University Hospital reports additional conflicting mid- to long-term results following implantation of the former Shelhigh conduit in aortic root ± ascending aortic position (2). Their initial experience, like ours and that of other groups, was satisfying regarding the implantability of the graft, the postoperative hemodynamics and the short-term clinical results (3,4). More than 15 years ago, we optimistically implanted this graft when a tissue valve was found to be the best solution for patients requiring aortic root replacement. Years ago, we were the first group to describe some negative experience with the Shelhigh conduit since several patients presented with sudden disintegration of the graft, leading to unexpected severe complications that required most difficult redo-operations (5). Unfortunately, we were not able to find which patients may be at increased risk for such complications: no statistical significant relationship was found regarding the timing of the operation (planned versus emergency) nor regarding the underlying pathology (aortic root dilation, acute type A aortic dissection or aortic valve endocarditis with destruction of the aortic root) or the implantation technique (interrupted versus continuous sutures). Review of the literature revealed that other institutions have observed similar singular cases.

The present analysis by the Zürich's group confirms our observations and reports similar mid- to long-term adverse outcome with a relatively high rate of premature death, "a very high rate of reoperations due to endocarditis, aorto-ventricular disconnection and structural valve failure" (2). The authors concluded that this may be potentially connected to the nature of the conduit. In fact looking at the details of this small series, there are several patients that died because of what the authors called unoperable intraoperative status. A similar case report was published by Tjan et al. from Münster, where the only solution to the uncontrollable intraoperative situation, was the removal of the whole heart and the construction of a bi-ventricular assist device as a bridge to transplantation (6). We have fortunately never encoutered an unoperable intraoperative situs although the amount of destruction of the aortic root was surprising and technically extremely challenging in all cases we had to re-operate.

In that sense, these observations are in line with other reports: the summarized experience of Calderon presented at the meeting of the Society of Heart Valves Diseases a series of 51 consecutive patients who received the Shelhigh conduit, with a reoperation rate of 13% (7/51) after Shelhigh conduit implants (7). All patients of this series demonstrated a similar finding to that described by the Zürich group, with a disintegration of the proximal anastomosis at the level of the aortic annulus within one year after implantation. The intraoperative findings were very similar with pseudo-aneurysmal formation and sterile abscess formation. Another group in the Netherlands published a similar experience in 2011 (8).

Extensive work from a Munich group has independently focused on the No-React® patch from the same provider and used for pericardial closure in 127 patients. Also in this location, a high incidence of sterile abscess formation was found. Bacterial growth was never found and the underlying mechanism of abscess formation was suspected to be a xenogenic complement mediated graft rejection (9).

To share our experience, we exchanged intensively with the dutch group and presented our common results at the 2015 EACTS meeting (10). The series included 291 consecutive patients with a mean age of 69 years. During a mean follow-up of 70.3 ± 53.1 months, 29 patients (11.1%) died from unkown reasons and the overall rate of re-operation of 8.6% (25 patients) was worrisome. We found similar causes leading to re-operation: infection of the conduit (n=9), aorto-ventricular disconnection (n=4), pseudo-aneurysm formation (n=4) and structural valve degeneration (n=8).
The results presented by the Zurich group are even worse than ours with a re-operation rate close to 20% and a surprisingly high rate of unexplained deaths. For all centers that have implanted the Shelhigh conduit, we strongly recommend long-term follow-up, especially in asymptomatic patients, since unexpected findings may be observed independently of structural valve degeneration.

References

1. Albolhoda A, Sumei Y, Oyarzun J, McCormick J, Bogden J, Gabbay S. Calcification of bovine pericardium glutaraldehyde versus No-React® biomodification. Ann Thorac Surg 1996;62:169-74.
2. Sahin A, Müggler O, Sromicki J, Caliskan EI, Reser D, Emmert MY, Alkadhi H, Maisano F, Falk V, Holubec T. Long-term follow-up after aortic root replacement with the Shelhigh® biological valved-conduit: a word of caution! Eur J Cardiothorac Surg 2016 in press.
3. Carrel TP, Berdat P, Englberger L, Eckstein F, Immer F, et al. Aortic root replacement with a new stentless aortic valve xenograft conduit: preliminary hemodynamic and clinical results. J Heart Valve Dis 2003;12:752–757.
4. Wendt D, Raweh A, Knipp S, El Gabry M, Eißmann M, Dohle DS, Tsagakis K, Thielmann M, Jakob H, Benedik J. Comparison of mid-term haemodynamic performance between the BioValsalva snd the BioIntegral valved conduits after aortic root replacement. Interact Cardiovasc Thorac Surg. 2016 Apr 4. pii: ivw066. [Epub ahead of print].
5. Carrel TP, Schoenhoff FS, Schmidli J, Stalder M, Eckstein FS, et al. Deleterious outcome of No-React-treated stentless valved conduits after aortic root replacement: why were warnings ignored? J Thorac Cardiovasc Surg 2008;136:52–57.
6. Tjan TDT, Klotz S, Schmid C, Scheld HH. Creation of a self-made total artificial heart using combined components of available ventricular assist devices. Thorac Cardiovasc Surg 2008;56:51–53.
7. Calderon E, Spina A, Camurri N, Bellieni L, Bentini C, et al. *Early failure of Shelhigh bioconduit in aortic position: an underestimated drawback.* Fifth Biennal Meeting of the Society of Heart Valve Disease, 2009.
8. Kaya A, Heijmen RH, Kelder JC, Schepens MA, Morshuis WJ. Stentless biological valved coduit for aortic root replacement: initial experience with the Shelhigh BioConduit model NR-2000C. J Thorac Cardiovasc Surg 2011;141:1157-62.
9. Elmer, C. Experimental work-up of the bovine NO-REACTpericardial patch used in cardiac surgery in conjunction with late complications after its application. Doctoral Thesis 2007, Institute of Surgical Research, Ludwigs-Maximilians-Universität-München, Germany.
10. Reineke DC, Kaya A, Heinisch PP, Oezdemir B, Winkler B, Huber C, Heijmen RH, Morshuis W, Carrel TP, Englberger L. Long-term follow-up after implantation of the **Shelhigh**® No-React® complete biological aortic valved conduit†. Eur J Cardiothorac Surg. 2015 Dec 30. pii: ezv452. [Epub ahead of print].