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EDITORIAL COMMENT

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ADULT CARDIAC

Another report on unfavourable long-term outcome following implantation of the Shelhigh No-React™ valved tube 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 haemodynamic performance than 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 was considered an additional advantage.

In this issue of the journal, the group from Zürich's University Hospital reports additional unfavourable mid- to long-term results following implantation of the 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 haemodynamics 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 dilatation, acute type A aortic dissection or aortic valve endocarditis with destruction of the aortic root) or the implantation technique (interrupted versus continuous sutures). A review of the literature revealed that other institutions had observed similar singular cases [6].

The present analysis by the Zürich group confirms our observations and reports similar mid- to long-term adverse outcome with a relatively high rate of premature deaths, 'an abnormalous 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 who died because of what the authors called unoperable intraoperative status. A similar case report was published by Tjan *et al.* [6] from Münster, where the only solution to the uncontrollable intraoperative situation was the removal of the whole heart and the construction of a biventricular assist device as a bridge to transplantation. We have fortunately never encountered 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 reoperate.

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 on a series of 51 consecutive patients who received the Shelhigh conduit, with a reoperation rate of 13% (7/51) [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 1 year after implantation. The intraoperative findings were very similar to 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 it 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 unknown reasons and the overall rate of reoperation of 8.6% (25 patients) was worrying. We found similar causes leading to reoperation: 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 Zürich group are even worse than those of ours with a reoperation rate close to 20% and a surprisingly high rate of unexplained deaths. For all centres 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.

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