ACD

Deleterious outcome of No-React–treated stentless valved conduits after aortic root replacement: Why were Warnings ignored?

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Objective: The implantation of a composite graft is the treatment of choice for patients with aortic root disease if the valve cannot be preserved and the patient is not a suitable candidate for a Ross procedure. Several years ago, the Shelhigh NR-2000C (Shelhigh, Inc, Millburn, NJ) was introduced in Europe. Being a totally biologic conduit and considering the lack of homografts, the graft seemed an ideal conduit for patients with destructive endocarditis, as well as for older patients who were not suitable candidates for oral anticoagulation.

Methods: From 2001 until 2006, the Shelhigh NR-2000C stentless valved conduit was implanted in 115 patients for various aortic root pathologies. The conduit consists of a bovine pericardial straight graft with an incorporated porcine stentless valve. Aortic root repair was performed during standard cardiopulmonary bypass and mild hypothermia in the majority of patients. Deep hypothermic circulatory arrest combined with selective antegrade cerebral perfusion was used when the repair extended into the arch.

Results: Seven patients with uncomplicated early outcome presented with unexpected sudden disastrous findings at the level of the aortic root, although 1-year follow-up computed tomographic scans were normal. Four of these patients underwent emergency operations because of desintegration of the graft, along with rupture of the aortic root. Retrospectively, the main findings were persistent fever or subfebrility over months and a halo-like enhancement on computed tomographic scans. Extensive microbiologic examinations were performed without finding a causative organism.

Conclusion: The use of the Shelhigh aortic stentless conduit can no longer be advocated, and meticulous follow-up of patients in whom this device has been implanted has to be recommended.

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The Shelhigh NR-2000C is a totally biologic stentless conduit designed for the treatment of various aortic root pathologies. After implanting 115 conduits, 7 patients presented with disastrous findings, including aortic root rupture. Meticulous follow-up of those patients who already underwent implantation of this device has to be recommended.

Thierry Carrel reports terminating a previous relationship with Shelhigh.

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The implantation of a composite graft is the treatment of choice for patients with aortic root disease when the valve cannot be repaired or reimplanted by using the David procedure and when the patient is not a suitable candidate for a pulmonary autograft procedure.[1-4] Several years ago, a new xenopericardial conduit (Shelhigh, Inc, Millburn, NJ) was introduced in Europe.[5,6] The Shelhigh conduit NR-2000C consists of a bovine pericardial straight graft with an incorporated porcine stentless valve. It is preserved in a special process, called No-React by the manufacturer, meaning it is glutaraldehyde cross-linked, detoxified, and heparin treated with the aim of less calcification and tissue deterioration in the long term.[7-9] We present here some alarming, if not deleterious, signs of conduit malfunction that required reoperation or were most probably responsible for the patient's death.

Materials and Methods

Patients

The Shelhigh stentless valved conduit was implanted in 115 patients between 2001 and March 2006 for various aortic root pathologies. The initial clinical experience was satisfactory; in

Abbreviations and Acronyms
CT = computed tomography
FDA = US Food and Drug Administration

particular, hemostatic and hemodynamic properties were encouraging. Being a totally biologic conduit and considering the lack of homografts, the Shelhigh graft seemed an ideal conduit for patients with destructive endocarditis, as well as for older patients who do not want lifelong oral anticoagulation.[10-13]

Device

The Shelhigh stentless aortic valve conduit is a totally biologic conduit available in sizes between 21 and 31 mm. Rinsing is not required. The conduit and the valve are glutaraldehyde cross-linked, detoxified, and heparin treated with No-react. This proprietary detoxification process eliminates residual glutaraldehyde and ensures stable tissue cross-linking with less calcification and tissue deterioration in the long term.[7-9] After achieving preservation, individual noncoronary porcine cusps are selected and fitted on a scallop-shaped tubular bovine pericardium. This assembly satisfies the hemodynamic requirements for flexibility and strength. The 150-mm-long pericardial cuff can be trimmed appropriately for each case and facilitates repair when complete repair of the ascending aorta is required. In vitro hemodynamics have been described as excellent, with ideal coaptation of the leaflets. Laboratory testing performed in a pulse duplicator evaluated the stentless valve in the fresh aortic root; at all flow rates, the stentless valve showed uniformly higher effective orifice areas and better hemodynamics than the similar valve with a ring. These tests confirmed that the ring transfers the stress from the commissures to the aortic valve.[14,15]

Surgical Technique

Aortic root repair is performed during standard cardiopulmonary bypass and mild hypothermia in the majority of patients. Deep hypothermic circulatory arrest combined with selective antegrade cerebral perfusion is used when the repair extends into the aortic arch. The diseased aortic root and ascending aorta are completely removed, and the coronary ostia are excised with a small rim of surrounding aortic tissue. After sizing the aortic anulus with Shelhigh sizers, a valved conduit 1 or 2 sizes larger is implanted. The proximal annulus anastomosis is performed by using either continuous 4-0 polypropylene sutures or interrupted mattress 2-0 Ethibond sutures (Ethicon, Somerville, NJ). The coronary ostia are reimplanted into the conduit by using the button technique with 5-0 or 6-0 running monofilament sutures. Finally, the distal anastomosis is performed with 4-0 running polypropylene sutures (Figures 1 and 2).

Results

Postoperative Course

Unfortunately, there has been increasing concern about deleterious midterm outcomes in several patients in our single-center experience. We present 7 patients with uncomplicated early outcomes after aortic root replacement: 4 of them presented with unexpected sudden disastrous findings at the level of the aortic root, although the 1-year follow-up computed tomographic (CT) scans were normal. These 4 patients underwent conduit exchange because of desintegration of either proximal or coronary anastomoses. The main findings were persistent fever or subfebrile condition for months and a halo-like enhancement around the conduit on CT scans.

Because we first suspected severe infective endocarditis of the graft extensive testing and evaluation of the graft material and patient's blood was performed. Considering the utterly strange intraoperative findings and the nature of the graft, we even considered bovine microorganisms, without finding a causative organism. None of these patients underwent primary implantation of the graft because of native valve endocarditis.

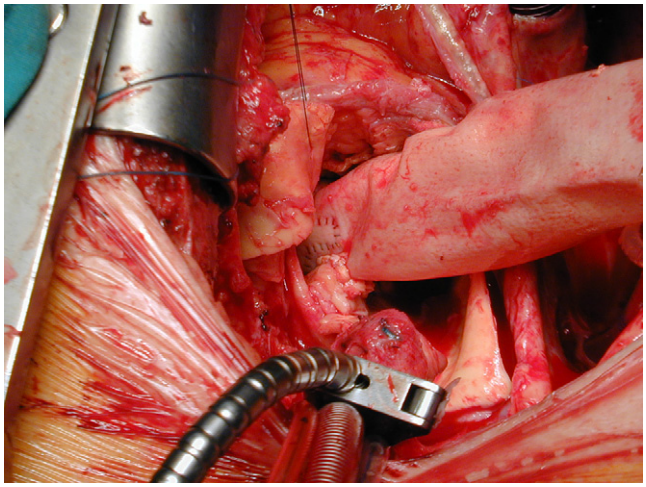

Figure 1. Implantation sequence of the Shelhigh conduit in a complex redo case. Left coronary is re-implanted (With permission of J Heart Valve Dis).

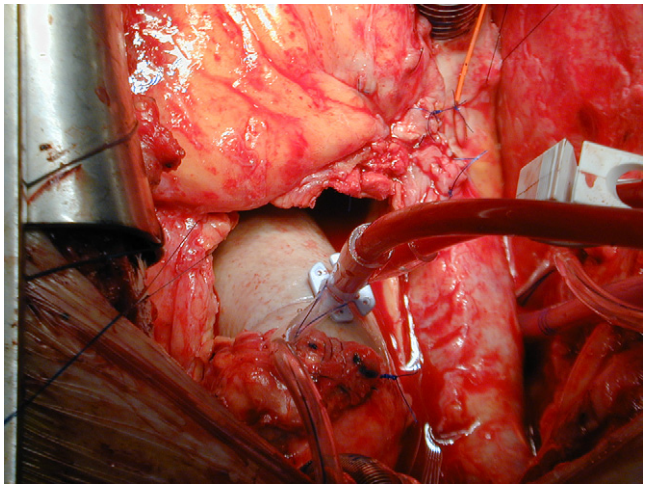

Figure 2. Final view of the Shelhigh conduit in a complex redo case, following distal anastomosis (With permission of J Heart Valve Dis).