


Off-pump pulmonary valve replacement with the new Shelhigh Injectable Stented Pulmonic Valve

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 Supplemental material is available online.

Significant pulmonary regurgitation (PR) is common after surgical or percutaneous treatment of pulmonary stenosis and tetralogy of Fallot (TOF) and leads to significant late morbidity and mortality.¹ Optimal timing of pulmonary valve replacement (PVR) and procedures minimizing surgical trauma are therefore important.² The new Shelhigh Injectable Stented Pulmonic Valve NR4000-PA MIS (Shelhigh Inc, Union, NJ) offers the possibility of PVR without cardiopulmonary bypass (CPB). Here we report our early experience with the first clinical use of this new device.

Patients and Methods

Patients. Four patients, median age 14.8 (11.2–40) years, received PVR with the Shelhigh Injectable Stented Pulmonic Valve. Three had PR following transannular patch or commissurotomy at previous TOF repair, and 1 after repair of congenital pulmonary stenosis. Median interval between initial repair and actual surgery was 14 (10.4–33.4) years. All patients had exercise intolerance and dyspnea on exertion; all presented with severe PR, progressive RV dilatation, impaired RV function, and 2 with impaired left ventricular function. Informed consent for compassionate use under CE regulations were obtained from all patients.

Device description and implantation technique. The Shelhigh Injectable Stented Pulmonic Valve, an evolution of the Shelhigh Pulmonic Valved No-React-treated Conduit NR4000-PA, consists of a porcine pulmonic valve mounted inside a self-expandable stent covered by No-React-treated pericardium (Figure 1, A and B), available in sizes 17 to 29 mm. Through a median sternotomy main pulmonary artery (MPA), bifurcation and right ventricular outflow tract (RVOT) were dissected free and 2 purse-string sutures were placed on the distal RVOT. For preinjection preparation, the

chosen valve was gently compressed with the supplied loop restrictor, slid into the barrel of the delivery trocar (Figure 1, C), and the introducer tip secured on the barrel (Figure 1, D). After heparinization (Liquemin, Roche Pharma Inc., Reinach, Switzerland; 70 IU/kg body weight), the delivery trocar was introduced through a small incision across the purse-string sutures and the barrel further advanced through the introducer tip into the MPA (Figure 2). Under digital control, the valve was ejected from the barrel while the delivery trocar system was slowly withdrawn. After deployment, the valve was secured with several transmural sutures placed at the proximal and distal rim of the valve. After assessment of the valve performance, the chest was closed in a routine fashion.



Dr Berdat

Results

Valve insertion, delivery, and placement were successful and hemodynamic performance was excellent in all patients (Figure E3, Table E1). Before valve insertion, 1 patient required additional reduction plasty of the severely enlarged MPA (33 mm). Early recovery was uneventful and all patients were discharged home. However, 1 patient required reoperation 2 months later due to valve migration with severe MPA obstruction and recurrent PR. This failure is explained by a dilated and conical-shaped MPA (maximal diameter 35 mm), which had not been reduced at the time of valve insertion, and insufficient transmural valve fixation. Routine echocardiographic follow-up after 4, 9, 12, and 18 (median 12.2, range 4.3–18.2) months showed good results in the remaining 3 patients with low gradients in all and moderate paravalvular PR in 1. RV function has recovered to subnormal values in all but the 1 patient with moderate PR. All patients were in New York Heart Association functional class I at the latest follow-up.

Discussion

Because patients with TOF or isolated congenital pulmonary stenosis usually need several cardiac reinterventions in the long term, minimizing procedural invasiveness and risks is mandatory. To date, surgeons reduce the impact of repetitive surgery by performing most of these procedures on a beating heart under normothermia with very low early mortality and morbidity in recent years. The new Shelhigh Injectable Stented Pulmonic Valve now offers the advantage of avoiding completely CPB use. Compared with the percutaneous approach,³ it offers several advantages. All implant sizes needed are available and the procedure is not limited by small catheters or access vessel diameters. Furthermore, No-React-treated biologic implants resist calcification and degeneration with excellent results⁴ in contrast to the percutaneously used conduit.⁵ Additionally, concomitant procedures frequently necessary on the

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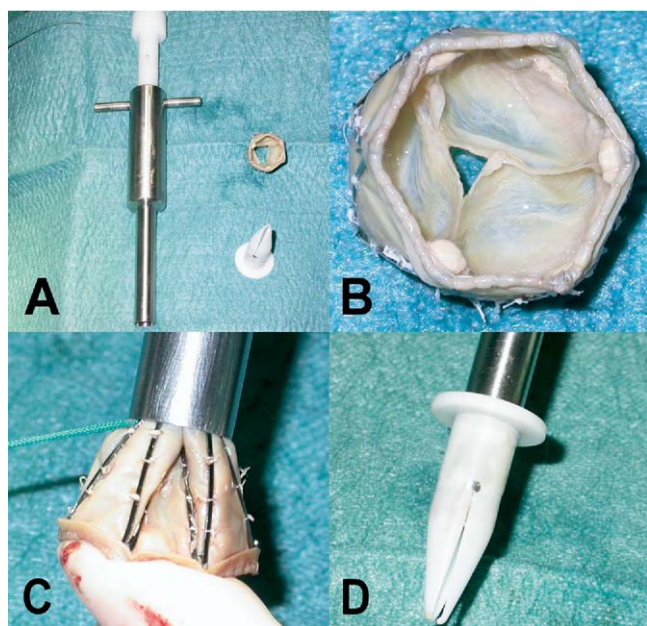


Figure 1. A, The Shelhigh Injectible Stented Pulmonic Valve device system. B, Detailed view of the Stented Pulmonic Valve. C, The valve is gently compressed and slid into the barrel of the delivery trocar. D, Barrel with loaded valve and mounted insertion tip.

RVOT or the pulmonary artery can be performed simultaneously. Preoperatively, RVOT and pulmonary artery morphology has to be studied carefully by transthoracic echocardiography and magnetic resonance imaging to determine prosthetic valve size and decide on additional procedures. Our early experience shows that reduction plasty of an enlarged MPA of >28 mm and semicircular fixation of the implant are mandatory to ensure a stable position and prevent paravalvular regurgitation. Device handling and valve implantation, however, have proven easy and straightforward. The follow-up will provide the necessary information on mid- to long-term performance of the Shelhigh Injectible Stented Pulmonic Valve.

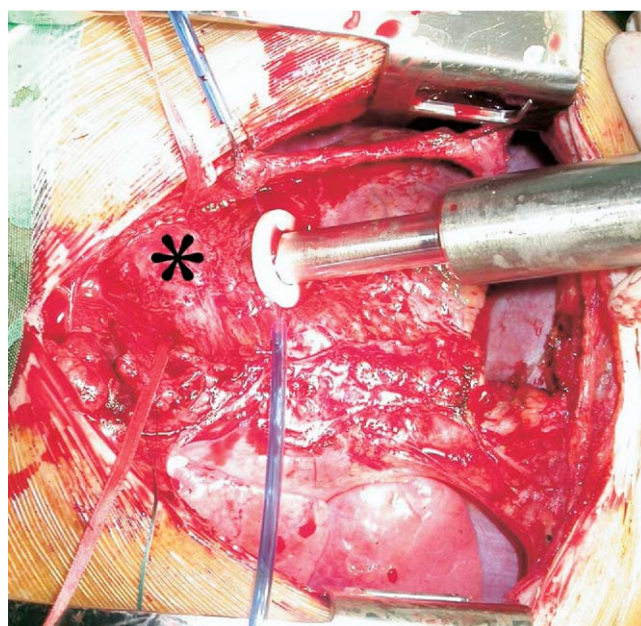


Figure 2. Surgical view showing insertion of the delivery trocar system across the RVOT into the main pulmonary artery (*asterisk*) before ejection of the valve.

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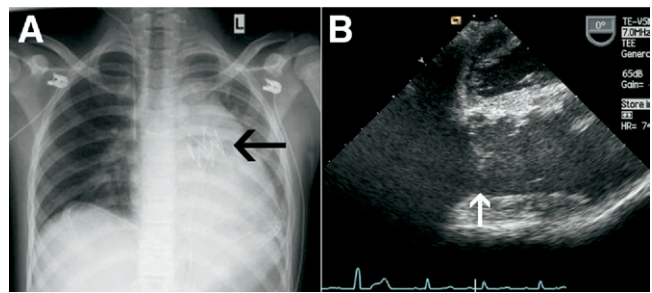


Figure E1. A, Postoperative chest radiograph showing the stented valve in correct position (*arrow*). B, Postoperative transthoracic echocardiography showing excellent valve function (*arrow*) without regurgitation or gradient.

TABLE E1. Valve hemodynamics and perioperative data

Patient	Valve size (mm)	Operation time (min)	Peak gradient*	Pulmonary regurgitation*	LOS
1	23	160	4.7	None	8
2	25	150	7.5	Trace	7
3	29	170	11	None	7
4	23	280	5	None	8

*Echocardiographic and invasive measurements. LOS, length of hospital stay in days.