Concept of an expandable cardiac valve for surgical implantation in infants and children

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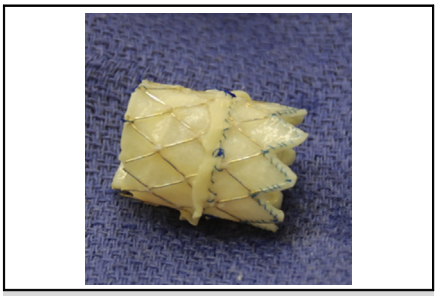
ABSTRACT

Background: Options for cardiac valve replacement in children are limited to fixed-diameter prostheses that do not accommodate for somatic growth. An externally stented bovine jugular vein graft has been modified for surgical valve replacement in pediatric patients, with the intention of subsequent valve expansion in the catheterization laboratory as the child grows.

Methods: Pediatric patients at a single institution who underwent surgical implantation of an expandable bovine jugular vein valve between 2010 and 2014 were reviewed retrospectively. Forty-two patients underwent implantation at median age of 10 months (range, 3 weeks to 5.8 years) in aortic, mitral, pulmonary, or tricuspid positions. Numerous techniques for valve modification and implantation were used.

Results: The valve was competent with low gradient acutely postoperatively in all patients. Eight patients experienced central or paravalvular deterioration, and 7 required reoperation for valve-related adverse outcomes. Twenty patients underwent at least one previous valve repair or replacement. Twenty patients underwent 32 episodes of catheter-based balloon expansion of the valve, exhibiting a significant decrease in median gradient from 12 mm Hg to 8 mm Hg ($P < .001$) with no significant increase in grade of regurgitation. At 12 months after implantation, Kaplan-Meier analysis indicated that 88% would be expected to be free from reoperation (95% confidence interval, 78%-98%). A total of 6 deaths occurred, 3 before discharge and 3 late.

Conclusions: A surgically implanted externally reinforced bovine jugular vein demonstrates acceptable short-term function and is amenable to catheter-based enlargement as the child grows. Modification of valve design and implantation techniques are necessary to reduce perivalvular complications. (J Thorac Cardiovasc Surg 2016;■:1-10)



Modified Melody valve with pericardial skirt and shortened stent.

Central Message

This novel design for an expandable valve demonstrates acceptable function and is amenable to enlargement as the child grows.

Perspective

Options for cardiac valve replacement in children are limited to fixed-diameter prostheses that do not accommodate for somatic growth. An externally stented bovine jugular vein graft has been modified for surgical valve replacement in pediatric patients, and demonstrates the ability for subsequent valve expansion in the catheterization laboratory as the child grows.

CONG

The prosthetic valves commonly used for semilunar or atrioventricular (AV) valve replacement in children function at a fixed diameter, and thus require reoperation for replacement as a child grows. For patients undergoing implantation of an allograft conduit in the right ventricular outflow tract (RVOT) position, catheter-based expansion of the valve allows for delays in surgical reoperation, but is frequently associated with the development of valvular insufficiency.[1] Whereas placement of an oversized valve at the time of original surgical replacement in anticipation of somatic growth may shorten the time to reoperation, this is not always feasible owing to space limitations.[2]

A bioprosthetic valve with an adjustable diameter that can be subsequently expanded with somatic growth is an

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Read at the 96th Annual Meeting of The American Association for Thoracic Surgery, Baltimore, Maryland, May 14-18, 2016.

Received for publication March 1, 2016; revisions received July 19, 2016; accepted for publication Aug 19, 2016.

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0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2016.08.040

Abbreviations and Acronyms

ASD = atrial septal defect
AV = atrioventricular
CI = confidence interval
ECMO = extracorporeal membrane oxygenation
ePTFE = polytetrafluoroethylene
IQR = interquartile range
LVOTO = left ventricular outflow tract obstruction
PA = pulmonary artery
RVOT = right ventricular outflow tract
SVD = structural valve deterioration

attractive alternative for surgical valve replacement in children. A valved bovine jugular vein mounted within a platinum-iridium stent (Melody valve; Medtronic, Minneapolis, Minn), approved for transcatheter implantation into the RVOT, has demonstrated acute valvular competence within a size range of 10 to 22 mm.[3,4] The Melody valve can be modified for surgical implantation into semilunar or AV valve positions. We hypothesize that surgical valve replacement with the bovine jugular vein valve at a compressed diameter is associated with acceptable short-term valve performance, and that subsequent catheter-based valve expansion after somatic growth is feasible with durable valvular function.

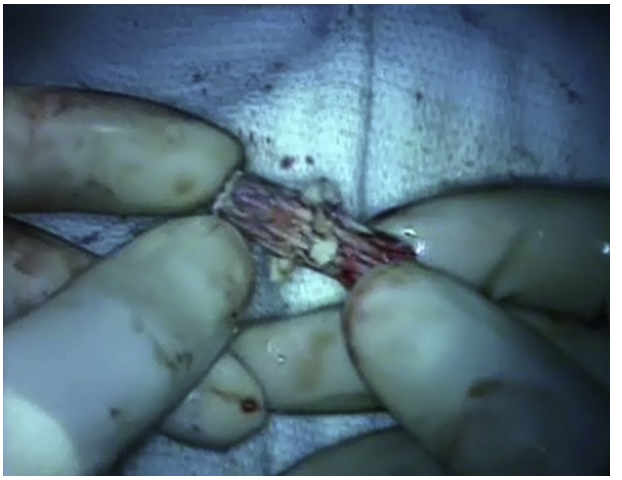
METHODS

All patients at Boston Children's Hospital who underwent surgical implantation of the Melody valve at a compressed diameter (<18 mm) with the intent of subsequent catheter-based expansion between May 2010 and November 2014 were identified, and a retrospective review of medical records was performed after approval by the Boston Children's Hospital Institutional Review Board. Insertion of the Melody valve in the mitral, tricuspid, and aortic positions was done under off-label use designation. Candidates for surgical Melody insertion typically included infants and young children deemed too small for implantation of a traditional mechanical or bioprosthetic valve (annulus size <16 mm). For patients requiring RVOT reconstruction, surgical Melody implantation served as an alternative to implantation of a homograft or xenograft valve for patients in whom long-term valve competence was deemed essential (eg, those at risk for pulmonary hypertension and right ventricular dysfunction).

Operative Procedure

Although the surgical technique differed according to position of implantation, the guiding principle was similar–implantation that would enable subsequent transcatheter balloon expansion as the child grows. To accomplish this goal, methods of fixation were designed to allow subsequent transcatheter expansion in a controlled fashion. Procedural details, including valve modification and insertion techniques, were obtained from operative reports, and complications related to surgical implantation were recorded.

For AV valve replacement, the technique for implantation has been described previously (Video 1).[3-5] The valve preparation and implantation technique was similar for the aortic position. A circumferential skirt of bovine pericardium was sewn externally to the stent at its midsection to facilitate fixation to the valve annulus. For selected patients who underwent stent and graft wall resection, the skirt was attached to the stent below the level of the graft resection. The circumferential skirt was sutured to the annulus with either interrupted or continuous sutures.



VIDEO 1. Insertion of the Melody valve into the mitral position with a subsequent saline test and balloon dilation. Video available at http://www.jtcvs.org.

The device was oriented to maintain alignment of resected graft segments with coronary ostia before suture implantation. After annular fixation, balloon dilation of the valve was performed. The balloon size was 1 mm greater than the AP mitral annular measurement obtained by preoperative transthoracic or transesophageal echocardiography, as confirmed intraoperatively by ensuring passage of a similar-sized Hegar dilator through the annulus.

Implantation into the pulmonary position was performed by orthotopic replacement of the main pulmonary artery (PA) as a conduit, implantation within a polytetrafluoroethylene (ePTFE) tube graft, or implantation within a native PA after longitudinal pulmonary arteriotomy. To facilitate a distal anastomosis of the conduit to the branch PA, the valve was modified by suture addition of a sleeve of ePTFE or bovine pericardium to the distal end of the stent. Once the distal anastomosis was complete, the proximal anastomosis to the right ventriculotomy site was performed by direct suture of the stent to the RV muscle posteriorly, and the addition of an ePTFE or bovine pericardial hood anteriorly. Before completion of the proximal hood, the valve was expanded to the appropriate size. For the RVOT position, the balloon diameter was selected as $z = 0$.

Postoperative management included aspirin for antiplatelet therapy indefinitely. Testing with Verify Now was performed to ensure adequate dosing and therapeutic effect. Echocardiography was performed before discharge and at routine 2- to 4-month intervals to evaluate the progression of transvalvular gradient and regurgitation.

Catheter-Based Valve Expansion

A patient was deemed a candidate for re-expansion if the gradient across the prosthesis as measured by pulse wave Doppler increased with somatic growth. Although no predefined threshold values for gradient triggered re-intervention, a precipitously rising gradient and absolute value > 10 mm Hg for a mitral or tricuspid valve and 40 mm Hg for an RVOT or aortic valve position were considered indications.

At catheterization, femoral venous access was used to approach the valve. For mitral dilation, the left atrium was accessed through either a previously placed atrial septal defect (ASD) or transseptal puncture. The balloon size used for expansion was recorded and compared with the original balloon size used at implantation. Gradient across the prosthesis and regurgitation grade were recorded immediately before and after catheter-based expansion.