Transcatheter Mitral Valve Replacement With a Novel Dual Stent Bioprosthesis

Benjamin M. Moore, MBBS; H.K. Bernard Ng, MBBS; Christopher Naoum, MBBS, PhD; Lisa Simmons, MBChB, PhD; Bruce L. Cartwright, MBBS; Michael K. Wilson, MBBS; Martin K.C. Ng, MBBS, PhD

There has been great interest in transcatheter mitral valve replacement (TMVR) as a potential therapy for high-risk patients with severe mitral regurgitation, with several distinct device systems undergoing first-in-man clinical studies. The Intrepid TMVR (Medtronic Inc, Redwood City, CA), designed for transapical delivery, comprises 2 interconnected self-expanding nitinol stents: (1) an inner stent that houses a bovine pericardial tissue trileaflet valve and; (2) an outer ring that fixes to the mitral annulus by radial force in a cork-like effect (Figure 1).[1] The outer fixation ring is designed to conform to the dynamic anatomy of the mitral valve throughout the cardiac cycle, avoiding distortion of the inner stent and valve.

We report an early case of Intrepid TMVR. A 79-year-old male presented with recurrent admissions for heart failure with severe functional mitral regurgitation secondary to posterior leaflet tethering and annular dilatation in the setting of moderate to severe ischemic cardiomyopathy (LV ejection fraction 37%). His comorbidities included severe pulmonary hypertension, type 2 diabetes mellitus, chronic atrial fibrillation, and chronic kidney disease (creatinine clearance 49mL/min). He was deemed high risk for conventional mitral valve surgery on Interdisciplinary Heart Team assessment (STS mortality risk 7%) and found to be anatomically suitable for TMVR with the Intrepid device.

TMVR was performed under general anesthesia with transesophageal echocardiography (TEE) guidance. Transapical access was obtained via a mini-anterolateral thoracotomy with placement of a 33Fr apical introducer sheath. The 46 mm Intrepid valve was then deployed under rapid ventricular pacing.[2] The delivery sheath was removed with systolic blood pressure less than 100mmHg and hemostasis achieved with direct closure.[3] Unlike other TMVR systems, the Intrepid valve does not require rotational alignment nor capturing of the native mitral valve leaflets.[4] A good hemodynamic result was achieved with trivial paravalvular leak and no significant left ventricular outflow tract encroachment (Figure 2). Computed tomographic imaging was obtained on day 4 postprocedure showing the Intrepid valve in situ, not obstructing the left ventricular outflow tract (Figure 3), with 3D computed tomography and TEE reconstructions demonstrating the dynamic conformable outer stent in systole and diastole (Figure 4, Movie I in the Data Supplement).

The patient made a robust recovery. At 3 months post intervention, his functional status had significantly improved from NYHA class III to class II dyspnea, corresponding to an increase in his 6-minute walk distance from 140 m to 300 m. The patient suffered a right middle cerebral artery territory embolic infarct at 4 months in the context of warfarin cessation for a dental procedure; he subsequently made a full neurological recovery post urgent embolectomy. TEE did not show intracardiac thrombus. At 6 months he remained functionally independent, with transthoracic echocardiography (TTE) reconfirming appropriate valve function (Movie II in the Data Supplement).

The Intrepid TMVR uses a novel new design to address severe mitral regurgitation in high-risk patients.

Disclosures

None.

References

1. Investigator's Brochure, Version 2015.05.12, Intrepid TMVR System.
2. Meredith I, Bapat V, Morriss J, McLean M, Prendergast B. Intrepid transcatheter mitral valve replacement system: technical and product description. *EuroIntervention*. 2016;12(Y):Y78–Y80. doi: 10.4244/EIJV12SYA21.
3. Seco M, Martinez G, Bannon PG, Cartwright BL, Adams M, Ng M, Wilson MK, Vallely MP. Transapical aortic valve implantation—an Australian experience. *Heart Lung Circ*. 2014;23:462–468. doi: 10.1016/j.hlc.2013.10.095.
4. Cheung A, Webb J, Verheye S, Moss R, Boone R, Leipsic J, Ree R, Banai S. Short-term results of transapical transcatheter mitral valve implantation for mitral regurgitation. *J Am Coll Cardiol*. 2014;64:1814–1819. doi: 10.1016/j.jacc.2014.06.1208.

From the Royal Prince Alfred Hospital (B.M.M., H.K.B.N., L.S., B.L.C., M.K.W., M.K.C.N.) and Concord Hospital (C.N.), University of Sydney, New South Wales, Australia.

The Data Supplement is available at http://circinterventions.ahajournals.org/lookup/suppl/doi:10.1161/CIRCINTERVENTIONS.116.004841/-/DC1.

Correspondence to Martin K.C. Ng, MBBS, PhD, Department of Cardiology, Royal Prince Alfred Hospital, Missenden Rd, Camperdown, New South Wales 2050, Australia. E-mail mkcng@med.usyd.edu.au

(*Circ Cardiovasc Interv*. 2017;10:e004841. DOI: 10.1161/CIRCINTERVENTIONS.116.004841.)

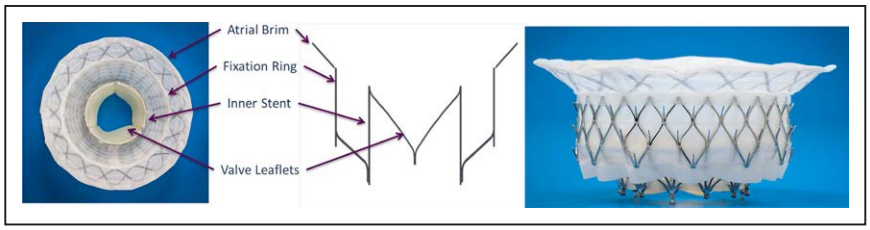

Figure 1. The Intrepid transcatheter mitral valve replacement with en face and side on views showing atrial brim, fixation ring, inner stent and valve leaflets.[1] Reproduced from Medtronic. Copyright © 2017, Medtronic.

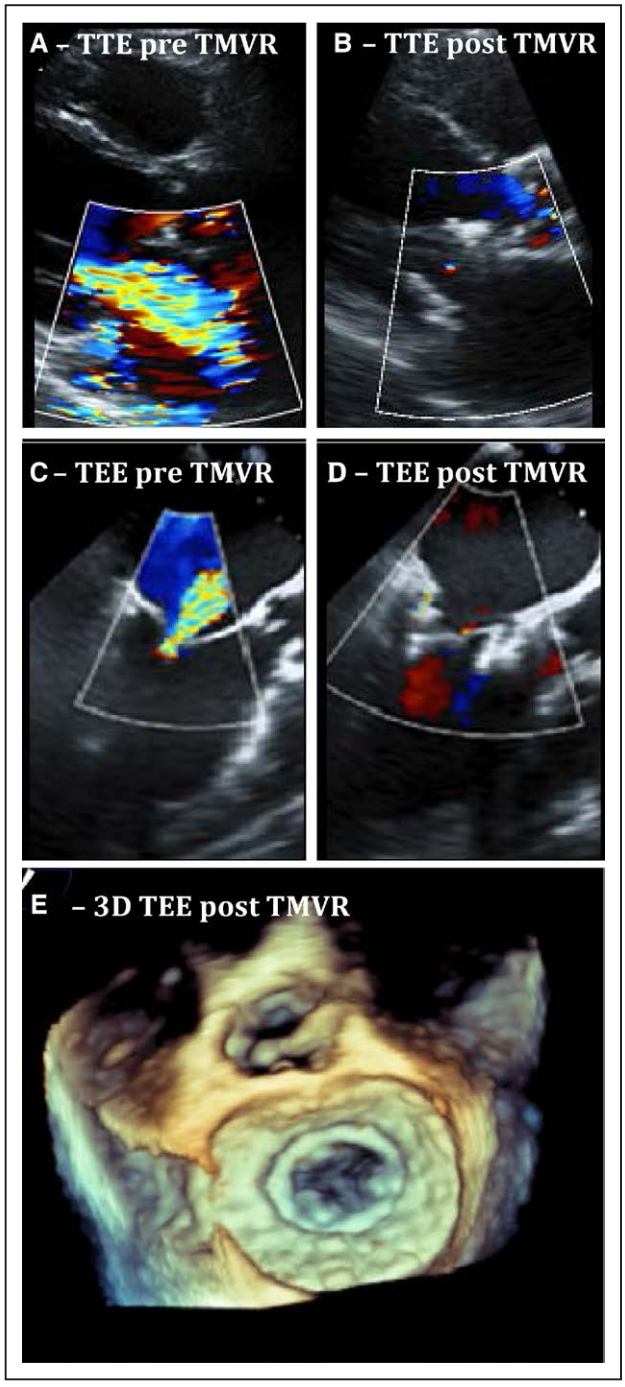

Figure 2. Mitral regurgitation on transthoracic echocardiography (TTE) pre–transcatheter mitral valve replacement (TMVR; **A**) and post-TMVR (**B**); mitral regurgitation on TEE pre-TMVR (**C**) and post-TMVR (**D**). En face 3D TEE view of TMVR in situ is shown in (**E**). Severe mitral regurgitation is demonstrated pre-TMVR placement with only trivial regurgitation post-TMVR.

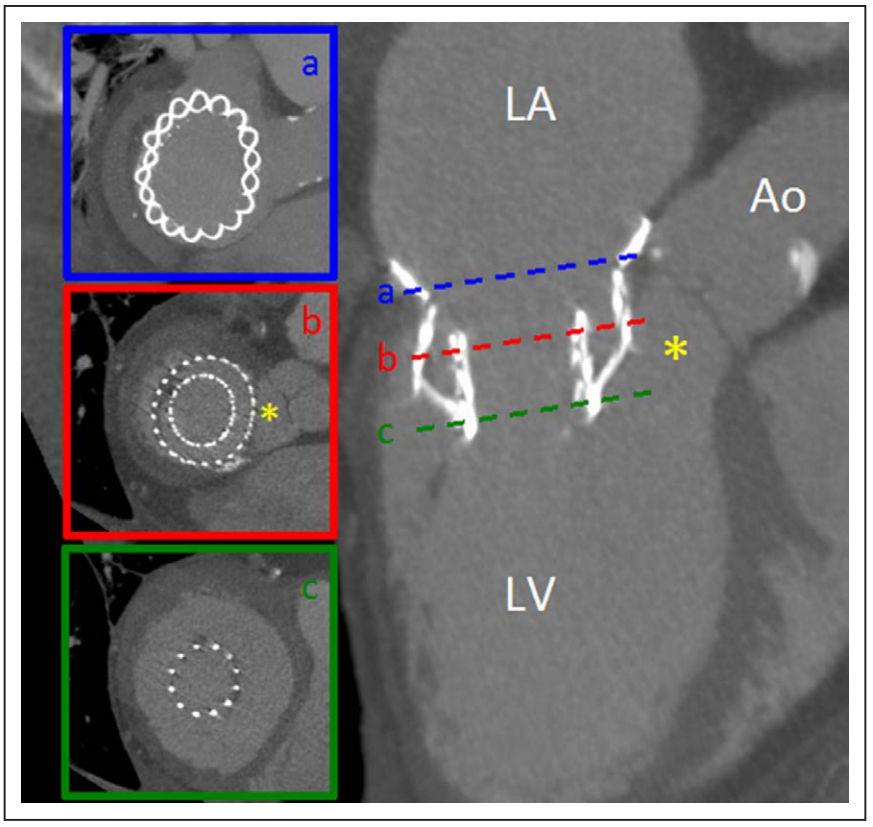

Figure 3. Computed tomographic imaging of the Intrepid transcatheter mitral valve replacement in situ with long axis demonstrating a widely patent left ventricular outflow tract* and multiple short-axis views: atrial brim (**a**), mid prosthesis through fixation ring and inner stent (**b**), and ventricular section of inner stent (**c**).

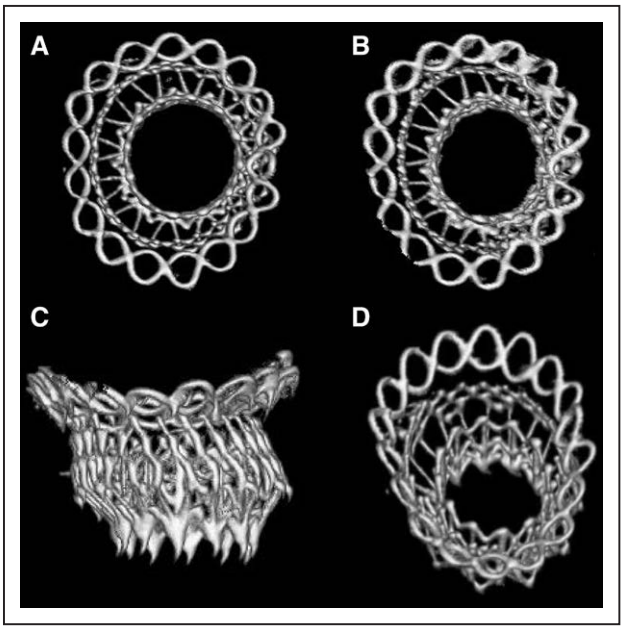

Figure 4. Three-dimensional (3D) computed tomography reconstruction of the Intrepid valve in situ. En face view in diastole (**A**) and systole (**B**); oblique view (**C**) and septal-lateral view (**D**).

Transcatheter Mitral Valve Replacement With a Novel Dual Stent Bioprosthesis

Benjamin M. Moore, H.K. Bernard Ng, Christopher Naoum, Lisa Simmons, Bruce L. Cartwright, Michael K. Wilson and Martin K.C. Ng

Circ Cardiovasc Interv. 2017;10:
doi: 10.1161/CIRCINTERVENTIONS.116.004841
Circulation: Cardiovascular Interventions is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 1941-7640. Online ISSN: 1941-7632