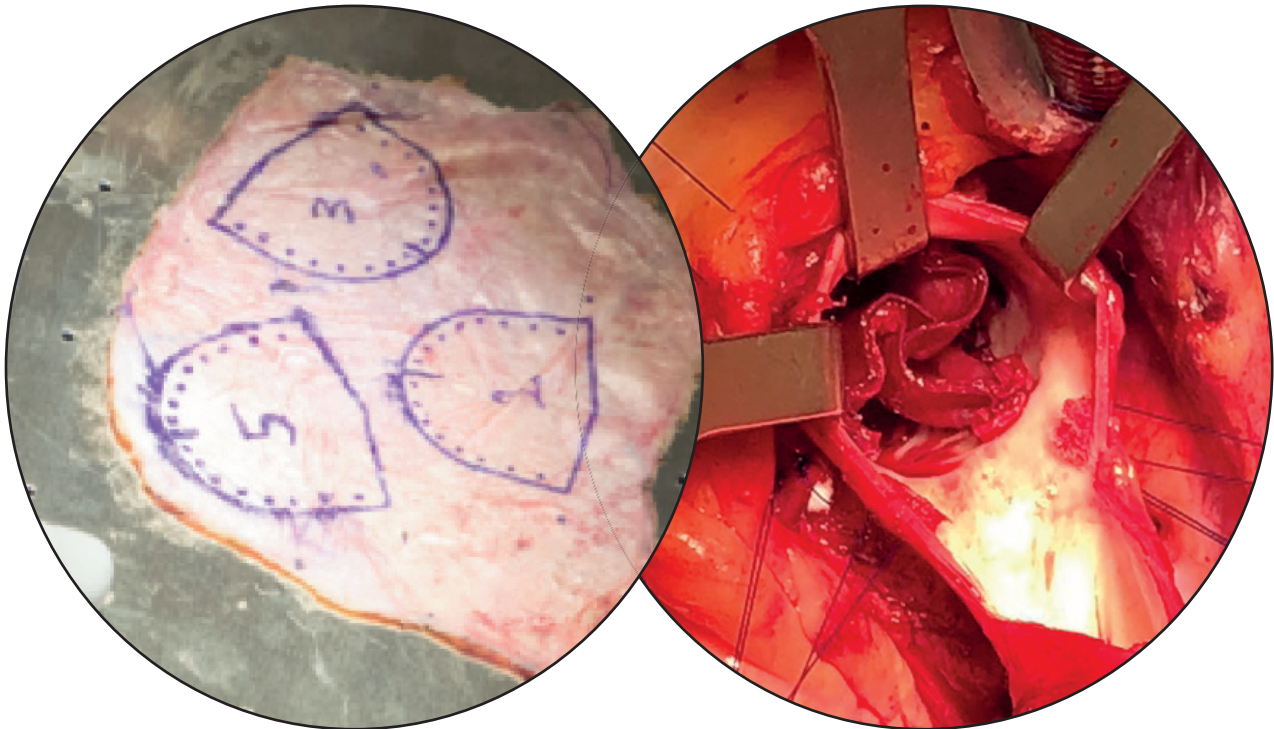




# Three-Leaflet Aortic Valve Reconstruction Utilizing the Ozaki Procedure in Patients with Congenital Aortic Valve Disease *(ages 8 months to 25 years)*



## AVNeo™ Presentation

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**Christopher W Baird, MD**

Associate Professor, Harvard Medical School  
Director, Congenital Heart Valve Center  
Boston Children's Hospital

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**Brenda Sefton**, Mariana Chavez, Gerald Marx, Pedro J. del Nido, Christopher W. Baird  
Boston Children's Hospital, Boston, MA

**Objective:** The Ozaki procedure with complete cusp replacement for aortic valve disease has excellent long-term results in adults. To date, limited results of the Ozaki procedure in pediatric patients have been reported. Thus, we report our early outcomes of the Ozaki procedure for congenital aortic and truncal valve disease in children and young adults.

**Methods:** Between March 2015 and September 2018, a retrospective analysis was performed on 50 patients with congenital aortic valve disease undergoing 3-leaflet aortic valve reconstruction utilizing the Ozaki sizers and templates at a single institution. Outcome measures included mortality, surgical or catheter-based re-interventions and echocardiographic measurements

**Results:** The median age at surgery was 11 y (8m-25y) with a median weight of 39.85 kg (5.2-121.7kg). Twenty patients had aortic regurgitation (AR), 6 had aortic stenosis (AS) and 24 patients had AS/AR. Two patients had quadricuspid truncal valve, 21 had tricuspid, 20 had bicuspid and 7 had unicuspid aortic valves. Thirty patients had prior aortic valve repairs and 4 had prior aortic valve replacements. Pre-operative echocardiography revealed the average annular diameter was  $2.0 \pm 0.51$  cm and peak gradient for AS and AS/AR patients was  $61.41 \pm 22.92$  mmHg. Autologous pericardium, Photofix® and CardioCel® bovine pericardium were used in 20, 28, and 2 patients, respectively. Eight patients required aortic annular enlargement, 14 sinus enlargement and 5 sinus reduction. Additional concomitant procedures were required in 43 patients, including biventricular repair, mitral valvuloplasty, ascending aortoplasty, aortic root reduction, sub-aortic membrane resection and pulmonary artery plasty. Median ICU and hospital LOS was 1.87 and 5.44 days, respectively. There were no hospital mortalities or early conversions to valve replacement. At discharge, 96% (48 of 50) patients had mild or less regurgitation and mean peak gradient was  $17.10 \pm 9.67$  mmHg. At median follow-up of 1yr (range, 30d-2.7y), 92% (34 of 37) patients had less than moderate regurgitation and 97% (36 of 37) patients had mild or less stenosis. Two patients underwent aortic valve re-operation at median of 1.5yrs; one patient had single leaflet restriction relieved at time of biventricular repair and one had endocarditis, severe AS and underwent replacement.

**Conclusions:** Three-leaflet aortic valve leaflet reconstruction utilizing the Ozaki procedure has excellent early results and could be considered in very young pediatric patients in whom size precludes conventional prosthetic valve replacement.

Longer term follow-up is necessary to determine the optimal patch material, valve function and durability.

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