A Novel System for Enhanced Annulus Access and Visualization During Minimally-Invasive Aortic Valve Replacement

Thomas Poschner[1], Paul Werner[1], Christoph Gross[1], Andrea Gaster[2], Anna Bartunek[2], Sabine Scherzer[1], Günther Laufer[1], Jude S. Sauer[3], Martin Andreas[1]
[1]Department of Cardiac Surgery, Medical University of Vienna, Austria, [2]Division of Cardiothoracic and Vascular Anesthesia and Intensive Care Medicine, Medical University of Vienna, Austria
[3]LSI SOLUTIONS®, Victor, NY, USA

MEDICAL UNIVERSITY OF VIENNA

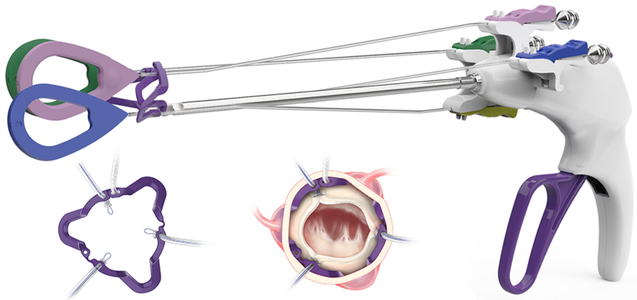


Fig 1: Novel ARR system

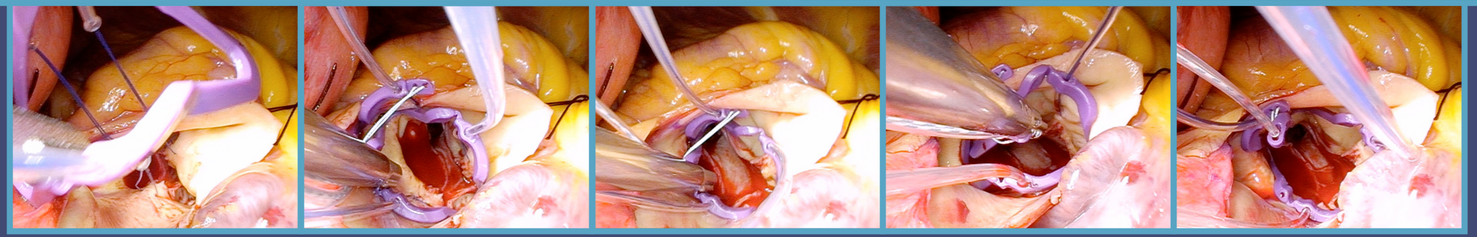
OBJECTIVE

Minimally invasive valve replacement is increasingly performed worldwide in an effort to improve patient comfort and reduce morbidity. However, limited working space and visualization often increase technical complexity and surgical times. We evaluate a novel system to improve aortic annular orientation, stability, and visualization during minimally invasive surgical aortic valve replacement (SAVR).

METHODS

The Aortic Root Retraction System (ARR; LSI SOLUTIONS®, Victor, NY, USA) consists of a collapsed retractor preloaded onto a delivery device. The flexible retractor is a plastic frame with 3 sinus arches that is deployed by expansion and suture fixation and suspended in the aortic root below the sino-tubular junction. Three sizes of ARR retractors are available. The ARR frame is removed from the surgical site just prior to parachuting down the prosthetic valve. A pilot trial was initiated for safety evaluation in 20 SAVR patients regarding ARR use with automated suturing devices.

Disclosures:
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2A: Guide *2B: Insert* *2C: Present* *2D: Partial deployment* *2E: Full deployment*

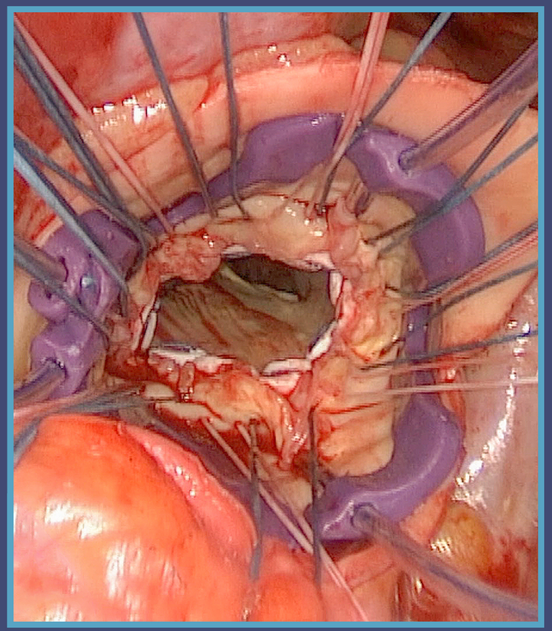


Fig 3: ARR in clinical use

RESULTS

Thus far, 3 patients (71.3±2.9 years, one female, 27.2±2.4 BMI kg/m2, EuroSCORE II 1.54±1.30%) have undergone SAVR via either anterior right thoracotomy (ART, n=2) or upper hemisternotomy (UHS, n=1) using the ARR system. Mean aortic cross-clamp and cardiopulmonary bypass time for ART were 80±13 min and 98±21 min, respectively, and 58 min and 65 min, respectively, for UHS. ARR placement was successful in all patients, requiring a mean of 03:32±00:24 min. Placement of the ARR system facilitated aortic root stabilization and orientation for improved intraoperative annulus visualization and suturing. No device-related adverse events have occurred. The automated RAM® Device (LSI SOLUTIONS®, Victor, NY, USA) was used to place the pledgeted annular sutures with an average time of 01:18±00:18 min for each suture. The SEW-EASY® Device was used to pass the annular sutures through the prosthetic sewing cuff; the average time for each cuff suture was 00:20±00:04 min. The average time to suture and secure the prosthetic aortic valve in each patient was 32:17±9:16 min. No patients required permanent pacemaker implantation or developed paravalvular leakage. All clinical outcomes were considered satisfactory; 30 day survival was 100%.

CONCLUSIONS

The ARR system represents a novel and effective approach to enhance visualization exposure and annular stability in minimally invasive SAVR. Device handling requires a short learning curve and appears intuitive and straightforward. The ARR system represents a promising tool for minimally invasive valve replacement.