

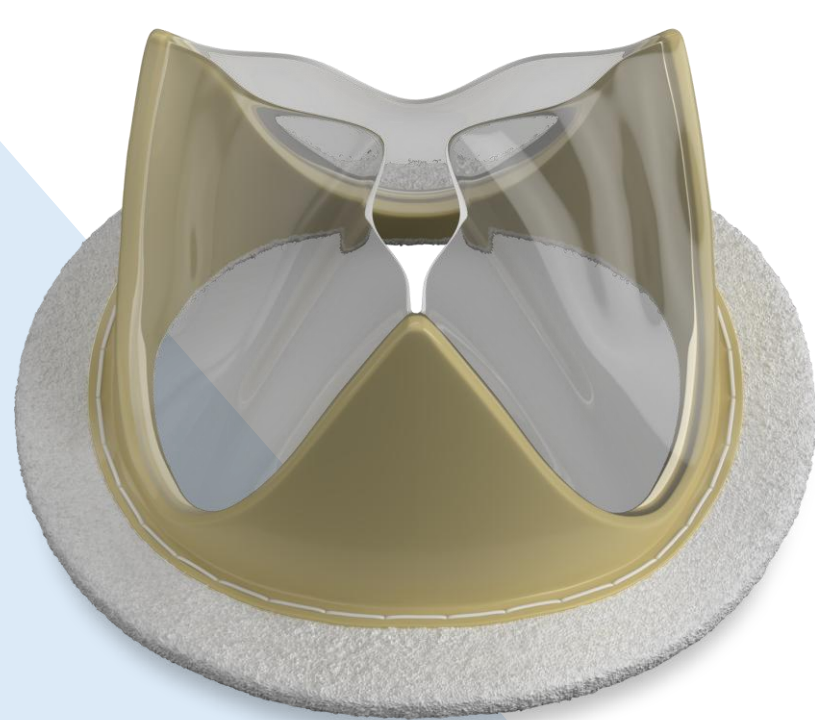
Development and Evaluation of Custom Instruments for Robotically-Assisted Mitral Valve Replacement

J. Ryan Stanfield^{1,2}, J. Michael Smith³, Robert L. Smith⁴, Isaac George⁵, Andy C. Kiser⁶

1.University of Utah, Salt Lake City, USA, 2.Foldax, Inc., Salt Lake City, USA, 3.The Christ Hospital, Cincinnati, USA, 4.Baylor Scott & White Health, Plano, USA, 5.Columbia University Medical Center, New York, USA, 6.St. Clair Hospital, Pittsburgh, USA

BACKGROUND

Mitral valve replacement (MVR) presents unique challenges in handling and implanting valves when done so with minimally-invasive surgery (MIS). Some materials used in prosthetic heart valves can be subject to external manipulation, inadvertent handling, or interaction with sharp objects during MIS procedures that **could compromise the integrity and function of the device** long-term. We have designed specialized instruments and protective covers to enable safe, reproducible implantation through a minimally invasive approach.



METHODS

Using surgeon input, a **two-piece protective cover** was developed **to shield valve leaflets on both atrial and ventricular** sides during robotic manipulation. Key features include

- atraumatic edges
- a rigid internal body to prevent frame deformation
- multiple threaded holes for handle attachment
- geometry optimized for robotic grasping
- a lanyard hole for suture retention to prevent component loss.

We also developed

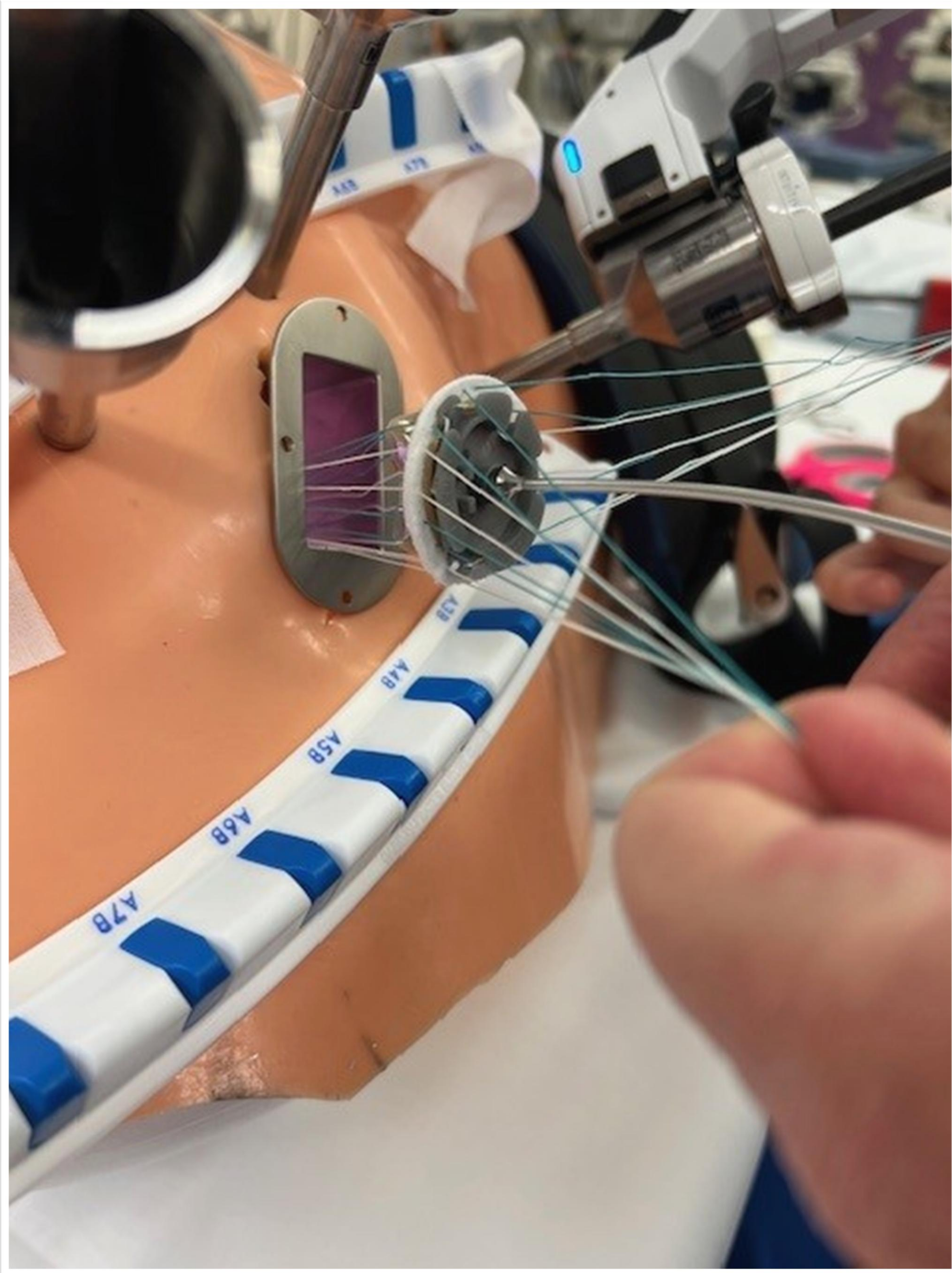
- Custom access ports for compatibility with robotic instruments
- a simulated mini-thoracotomy model specifically for the da Vinci robotic platform.

Two independent operators implanted the polymeric leaflet valve using this novel simulation platform, assessing ergonomics, safety, and procedural efficiency..



RESULTS

Both operators successfully completed simulated valve implantation without leaflet or annular injury. The protective cover maintained structural integrity and facilitated secure handling throughout the robotic procedure. Surgeons reported **improved confidence in leaflet protection, enhanced visualization, and reliable device control.** The specialized instruments and mitral valve simulator enabled a reproducible training experience without device related complications.



CONCLUSIONS

Custom-designed protective covers and robotic ports **improved the feasibility and safety of robotically-assisted MVR** with polymeric leaflet valves in this in vitro setting. These innovations address potential barriers to adoption of robotic valve surgery and may shorten the learning curve for complex minimally invasive procedures. Future work will focus on refining designs for clinical application and evaluating performance in vivo.

