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[Preclinical Testing of Heart Valves](#)

Application of a Staged Validation Approach to Patient-Specific Tissue Restoration Pulmonary Heart Valve FSI Simulations: From Material Testing to Post-Op and Long Term Modeling

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Abstract

RVOT reconstruction is commonly performed in pediatric cardiac surgery to address structural malformations. Current valved autografts and allografts suffer from limited durability, growth potential, and frequent reinterventions, prompting the need for improved solutions. One candidate is the fully synthetic, bioabsorbable Xeltis Pulmonary Valve Conduit (XPV), made of supramolecular UPy.

XPV has shown promise in enabling Endogenous Tissue Restoration (ETR) in RVOT reconstruction, supported by animal studies and small clinical trials. Optimizing such in-situ regenerative valves using computer modeling and simulation (CM&S) presents a set of challenges as the reality presents a coupled ETR and Fluid-Structure Interaction (FSI) problem.

We present a validated simulation framework mimicking RVOT reconstruction. Patient-specific multiphysics models incorporate FSI behavior of the valve conduit and pulmonary arteries, where all components deform under fluid load. This enables realistic quantification of structural and fluid stresses to inform ETR modeling and predict long-term patient-specific responses. 3 device models and 13 patient models were developed and validated in parallel. Mimicking the surgery, the valve conduit was implanted into each host model for postoperative predictions. A multi-layer validation strategy was applied at each integration level: material, structural, FSI and ETR modeling.

Our results show that such extremely complex models can be reliably constructed by adapting current VVUQ standards and that model uncertainty does not propagate linearly across complexity layers. These models and virtual environments can serve as *in silico* benches for device evaluation, virtual cohorts to optimize animal trials, and tools to predict failure modes.

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