Development & Design of Improved Commissure for Tissue-Engineered Transcatheter Heart Valves

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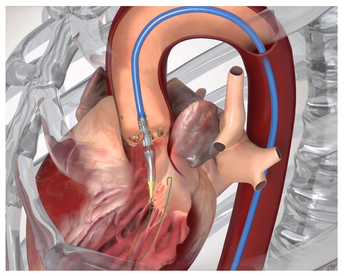
Introduction & Previous Work

Transcatheter aortic valve replacement (TAVR) is a minimally-invasive procedure in which replacement heart valves are delivered through the blood vessels, precluding the need for painful and complex open-heart surgery.

While most commercial valves today use chemically-fixed porcine tissue in the construction of the replacement valves, the Tranquillo group has been exploring the use of decellularized, engineered tissue as leaflet material. Whereas fixed porcine pericardium is mostly inert and will steadily degrade over time, the engineered tissue can be remodeled and repaired by the recipient's cells after implant. Thus, significant valve longevity improvements may be realized by incorporating engineered tissue into the TAVR design.

Working in conjunction with Dr. Lerhman's group at Mayo Clinic, early prototypes had previously been fabricated. Literature reports of high stress concentrations in the commissure regions of transcatheter valves were confirmed by significant damage to our early prototypes during testing. Further, the minimal commissure protection in our early valve designs led to unacceptable levels of paravalvular leakage (PVL) during valve closure.

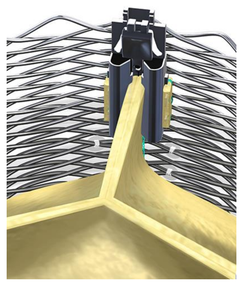
The goal of this project was to engineer a commissure design to mitigate valve failure through tissue tearing, and to improve overall valve hemodynamics. (I.e. reduction of PVL).



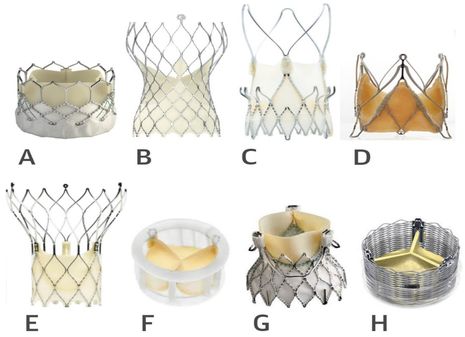
► Artist's rendering of TAVR implantation process. (Valve pictured is an Edwards Lifesciences Sapien XT).

Commercial Commissure Designs

Current commercial design of commissures generally falls into two categories: sewing-intensive or clip-retained. Neither approach is perfectly applicable to tissue engineered THEVs, due to differences in the material properties of fixed porcine pericardium vs. engineered tissue.

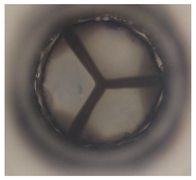


▲ Clip-retained commissure design (Boston Scientific "Lotus" valve).

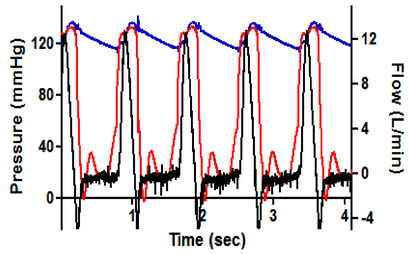


Methodology

Prototype TEHVs were tested to failure using a ViVitro Labs pulse duplicator, running custom LabView data acquisition software. Proximal & distal pressures, and flow rate were recorded for hydrodynamic assessment. Upon failure, tissue was carefully removed from the valves for visual analysis.



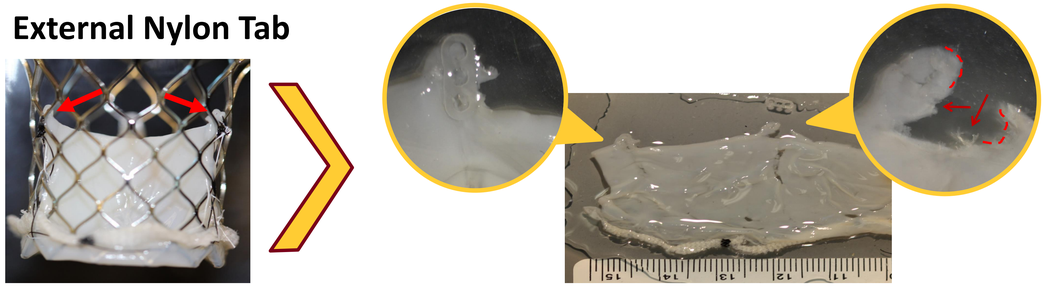
◄ End-on views of a prototype valve in the ViVitro tester. Note the excellent coaptation in the left image, which corresponded to very low levels of PVL.



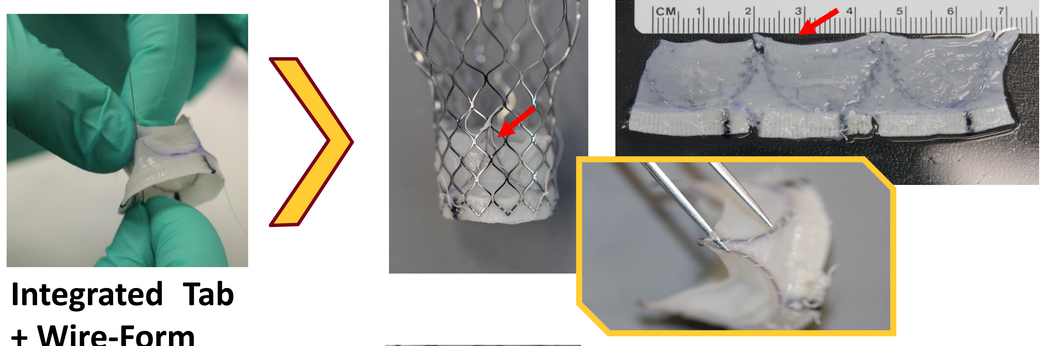
▲ Representative hemodynamic data collected from the first prototype tissue valve constructed during this project. (External nylon tab version).

Prototypes and Testing Outcomes

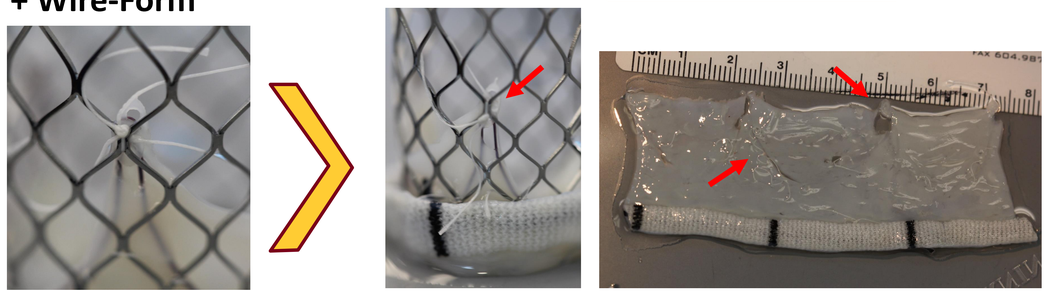
External Nylon Tab



Nitinol Wire-Form

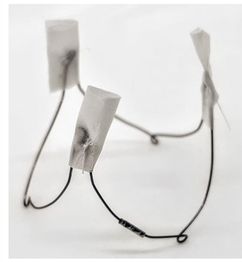


Integrated Tab + Wire-Form



Future Research

Future prototypes are planned, with two designs in the early stages of fabrication. These new valves will include polymer mesh padding of commissures, and/or a clip system. (Inset is a Boston Scientific Lotus valve, from which design inspiration was drawn).



Conclusions

- Tabs, wire-form alone insufficient to protect commissure region
- Combined protection scheme more promising
- Improvements in engineered tissue suture retention necessary for optimal valve fabrication

References

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