TRANSCATHETER AORTIC VALVE REPLACEMENT:
MEASURING PHYSIOLOGICAL COMPLIANCE AND VESSEL GEOMETRY
USING A VALVULOPLASTY BALLOON CATHETER

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Aortic Stenosis is the narrowing of the aortic valve opening:

- Mainly caused by age-related calcification (~50%¹);
- It affects 2% of people who are over 65 years of age²;
- High rate of death if untreated (~50% in the first two years¹);
- Traditionally treated with open-heart surgery²;

At least 30% of the patients cannot undergo surgery¹

Transcatheter Aortic Valve Replacement (TAVR)
A bioprosthetic valve is inserted through a catheter and implanted within the diseased native valve

¹ [Leon et al., Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery, 2010]
² [Czarny et al., Diagnosis and management of valvular aortic stenosis, 2014]
Research Background
Aortic Regurgitation is a major procedural complication associated with TAVR:

- Reported in 72.4% of the cases within GARY registry\(^1\);
- Even mild leaks are associated with higher mortalities at two years\(^2\);

**Pre-operative imaging techniques for sizing**

(2D TEE/TTE, MDCT, 3D TEE)

- Annular diameter is subject to change after valvuloplasty
- Lack of information about the mechanical properties
- Undersizing of the prosthetic valve
- Malpositioning of the prosthetic valve
- Elliptic Shape of the annulus
- Additional step in the TAVR workflow

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\(^1\) [Zahn et al., Transcatheter aortic valve implantation: first results from a multi-centre real-world registry, 2010]
\(^2\) [Kodali et al., Two-year outcomes after transcatheter or surgical aortic-valve replacement, 2012]
By using a robotic system capable of constantly monitoring the **volume** of fluid injected in a **standard BAV balloon catheter** and its **pressure**

- Is it possible to estimate the geometry of the aortic annulus?
- Is it possible to estimate the mechanical properties of the aortic annulus?
NUMERICAL SIMULATIONS

Finite Element Model of BAV Balloon Catheter and Aortic Annuli

EXPERIMENTAL VALIDATION

Experimental test rig for data collection and phantom models of Aortic Annuli

DATA FITTING

Automatic algorithm to retrieve unknown annulus diameter from P-V curves
MATERIALS AND METHODS
Finite Element Model of the BAV Balloon Catheter

Dimensions: 20x40x75 mm
Nominal diameter: 23 mm
Nominal pressure: 4 atm
Burst pressure: 6 atm

Model reconstructed from polariscopic images using Solidworks;
Variable thickness along the longitudinal axis (Extremities: 0.26mm; Cylindrical Part: 0.06mm);
Approximations were made to make the model symmetric;

Numerical Model with MSC Marc
One sixth of the balloon;
13824 elements (8-node Hexahedron);
Linear elastic isotropic material (Young Modulus E = 600 MPa, Poisson's Ratio $\nu = 0.45$);
Additional simulation to force tri-folding during the deflation process;
Boundary conditions to force radial expansion.

Dimensions:
- 20x40x75 mm
- Nominal diameter: 23 mm
- Nominal pressure: 4 atm
- Burst pressure: 6 atm
Finite Element Modeling of rigid aortic vessels

ANNULAR DIMENSION (18 mm – 23 mm)

ANNULAR SHAPE
Elliptical shape
Ellipticity: 0.82\(^1\)
Length: 2 cm

ANNULAR LENGTH (2 cm – 5 cm)

\(^1\) [Maeno et al., Transcatheter Aortic Valve Replacement With Different Valve Types in Elliptic Aortic Annuli, 2017]
Finite Element Model of BAV Balloon Catheter and Aortic Annuli

Experimental test rig for data collection and phantom models of aortic annuli

Automatic algorithm to retrieve unknown annulus diameter from P-V curves
Experimental Setup (Geometry Assessment)

INCREASING DIAMETER LENGTH: 2 cm to 5 cm

3D-PRINTED LINEAR RAIL, STEPPER MOTOR AND TERUMO SYRINGE

SILICONE-BASED COMPLIANT CYLINDERS

0-7 bar ABSOLUTE PRESSURE SENSOR

ARDUINO UNO BOARD + VELLEMAN MOTOR SHIELD

3D-PRINTED PLA HOLDERS

STEEL PLATFORM
Experimental Setup (Distensibility Assessment)
EXPERIMENTAL AND NUMERICAL RESULTS
Experimental vs Numerical Results
Experimental Results – Rigid Vessels

FREE INFLATION PHASE

PRESSURISATION PHASE

![Graph showing pressure vs volume for rigid vessels during experimental results.](image)
Circular Rigid Vessels – Annular Diameter

ANNULAR DIMENSION EFFECT
P-V curves are shifted towards the right

INCREASING DIAMETER
Circular Rigid Vessels – Annular Length

**ANNULAR LENGTH EFFECT**

A shorter annulus:

a) Slightly reduces the slope of all the p-V curves during the pressurisation phase;

b) Shifts the p-V curves associated with diameters < non-tensioned diameter of the balloon to the right;
Elliptical Rigid vessels – Annular Shape

The ellipticity of the annulus shifts the p-V curves to the right and modifies the slope during the pressurisation phase in a non-trivial way;
Experimental Results – Circular Compliant Vessels

FREE INFLATION PHASE  DISTENSIBILITY PHASE  PRESSURISATION PHASE

<table>
<thead>
<tr>
<th>Ø18 [mm]</th>
<th>Ø19 [mm]</th>
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<tbody>
<tr>
<td>Expected Distensibility [mmHg(^{-1})]</td>
<td>0.00124</td>
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<tr>
<td>Computed Distensibility [mmHg(^{-1})]</td>
<td>0.00121</td>
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<tr>
<td>Error</td>
<td>2%</td>
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</table>
NUMERICAL SIMULATIONS

Finite Element Model of BAV Balloon Catheter and Aortic Annuli

EXPERIMENTAL VALIDATION

Experimental test rig for data collection and phantom models of aortic annuli

DATA FITTING

Automatic algorithm to retrieve unknown annulus diameter from P-V curves
The graph can be divided into two regions:

1. **Annular Diameter (AD) \( \leq 20\text{mm}; \)**
2. **Annular Diameter (AD) \( > 20\text{mm}; \)**

- Curves in region 1 show a trend similar to
  \[
  f(x) = \ln(1 + e^x)
  \]

- \[
  \frac{df(x)}{dx} = g(x) = \frac{e^x}{e^x + 1}
  \] is the sigmoid function
A parametric version of $f(x)$ was used to fit data associated with an annular length 5cm:

$$f_p(x) = a \ln(1 + e^{b(x-c)}) + 1$$

The green lines on the graph represent the $c$ values associated with each curve.

<table>
<thead>
<tr>
<th>Ø [mm]</th>
<th>a</th>
<th>b</th>
<th>c</th>
<th>R2</th>
<th>RMSE</th>
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<tbody>
<tr>
<td>18</td>
<td>1.482</td>
<td>3.571</td>
<td>12.92</td>
<td>0.9994</td>
<td>0.0217</td>
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<td>18.5</td>
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<td>4.297</td>
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<td>19</td>
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<td>0.0609</td>
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<td>19.5</td>
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<td>0.0725</td>
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<td>20</td>
<td>0.00814</td>
<td>568.3</td>
<td>15.36</td>
<td>1.0000</td>
<td>0.0018</td>
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</table>
Fitting P-V curves (AD ≤ 20 mm)

- The coefficient c represents the position of the center of the knee of the function $f(x) = \ln(1 + e^x)$ (or the maximum of $\frac{d^2f(x)}{dx^2}$);

\[ f(x) = \ln(1 + e^x) \]

The coefficient c shows a direct correlation with the diameter and it could be used as a feature F1 to assess the size in the case of fixed annular length;
Fitting P-V curves (AD ≥ 20 mm)

INFLECTION POINTS:
BAV balloon catheter touched vessel wall
CONCLUSIONS AND SUGGESTIONS FOR FUTURE WORK
Conclusions

- The BAV Balloon Catheter allows to retrieve **ANNULAR DIAMETER**
- The device is sensitive to **ANNULAR LENGTH**
- Measuring the pressure and the volume inside the balloon cavity allows to assess the **DISTENSIBILITY OF SILICONE BASED ANNULI** with a compliance similar to the physiological one

- The actual device doesn’t allow to retrieve **ANNULAR SHAPE**, being not able to discriminate between circular and elliptical vessels
MAIN LIMITATIONS

• Numerical model: material non-linearities
• Vessel stenosis
• In vivo conditions have been only partially replicated

SUGGESTIONS FOR FUTURE WORK

• Balloon material: hyperelastic behaviour
• Vessel walls and stenosis should be modeled using different materials
• Circulatory system and the blood flow might be included; validation on ex vivo animal specimen, eventually followed by in vivo trials
Thank you!