

E. Stretti¹, M.F. Zaccone¹, A. Zaccaria¹, F. Danielli¹, E. Gasparotti^{2,3}, B.M. Fanni^{2,3}, K. Capellini^{2,3}, S. Celi³, G. Pennati¹ and L. Petrini⁴

¹ LaBS, Department of Chemistry, Materials and Chemical Engineering, Politecnico di Milano, Milan, Italy
² BioCardioLab, Bioengineering Unit, Fondazione Toscana Gabriele Monasterio, Massa, Italy
³ Department of Information Engineering, University of Pisa, Pisa, Italy
⁴ Department of Civil and Environmental Engineering, Politecnico di Milano, Milan, Italy



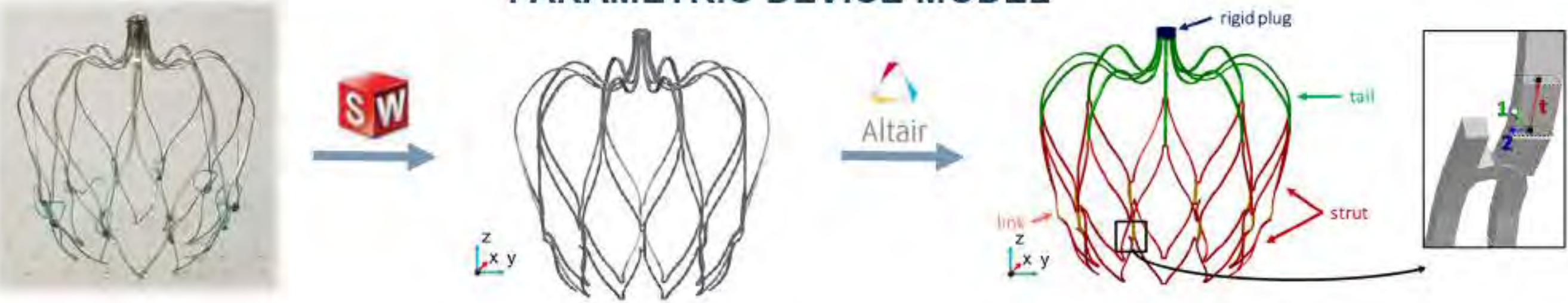
<https://www.watchman.com>

INTRODUCTION

Left atrial appendage (LAA) is the most common site of thrombus formation for patients affected by non-valvular atrial fibrillation (AF). The standard treatment for AF is the administration of oral anticoagulation (OAC), but a significant number of patients could not be started on OAC because of severe complications, such as bleeding risk. For these patients **LAA occlusion** is a winning alternative: this minimally invasive procedure consists in the release through a catheter of a stented device, which closes permanently the LAA, preventing blood clot formation and migration. The pre-operative planning is fundamental to achieve a successful device implantation, but, due to the high variability of the LAA anatomies, it can become challenging. For this reason, in-silico models simulating the Watchman implantation in the patient-specific LAA anatomy could be a helpful tool for clinicians. This work aims to build and validate a **finite element model** of the **Watchman implantation procedure**. Moreover, deployment tests in 3D-printed patient-specific geometries were performed to assess the reliability of the model.

MATERIALS AND METHODS

PARAMETRIC DEVICE MODEL



Geometry reconstruction: Starting from CT images of the real device, the 3D CAD of Watchman was realised in Solidworks..
Mesh: The mesh composed by beam elements was generated in Hypermesh. A MATLAB code was implemented to provide the correct beam orientation.

IMPLANTATION PROCEDURE

Following the clinical technique, the LAAO was simulated using the solver **Abaqus 2018**. To validate the finite element model, the procedure was performed by the clinician on the 3D printed LAA. Fluoroscopic images were taken to compare the Watchman positioning in the in-silico and in-vitro models. Finally, the simulations were replicated by substituting the material properties of the 3D printed LAA with realistic patient-specific parameters.



STEPS

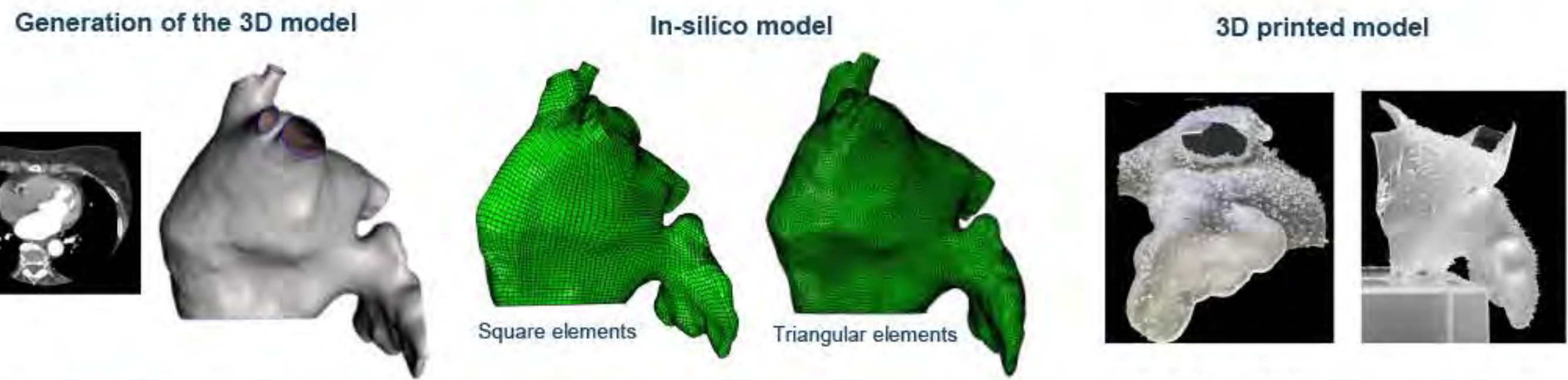
- In all the steps the LA inlets and outlet were fixed in the three directions, while rotations were allowed.
- Crimping:** crimping of the device down a catheter of 12F diameter.
- Deployment:** unsheathing of the catheter, maintaining the device fixed.
- Guidewire removal** to allow the device position adjustment.

MATERIAL PROPERTIES

- Watchman device:** the superelastic **Ni-Ti** material properties calibrated in a previous work [1] were exploited for the device.
- 3D printed LA and LAA:** linear elastic material.
- LA and LAA:** the linear elastic material properties of the patient specific atrium were idealised through CT-gated images.

Watchman		3D printed LA and LAA	
EA	60000 MPa	E	2.5 MPa
EM	25000 MPa	N	0.45
v	0.3	P	1.15e-03 g/mm ³
sL	0.04	S	1.5 mm
σLS	350 Mpa	LA and LAA	
σLE	450 Mpa	E	0.005 MPa
σUS	250 Mpa	v	0.45
σUE	150 Mpa	P	1e-03 g/mm ³
σCLS	500 MPa	s	2 mm
T0	25 °C		
δσ/δT	15 MPa/°C		

PARAMETRIC PATIENT MODEL



Starting from the patient thoracic CT images at 60% of the cardiac cycle, the 3D .stl format model of the LAA and Left Atrium (LA) was generated through 3DSlicer. Smoothing and refining of the model was obtained in Meshmixer.

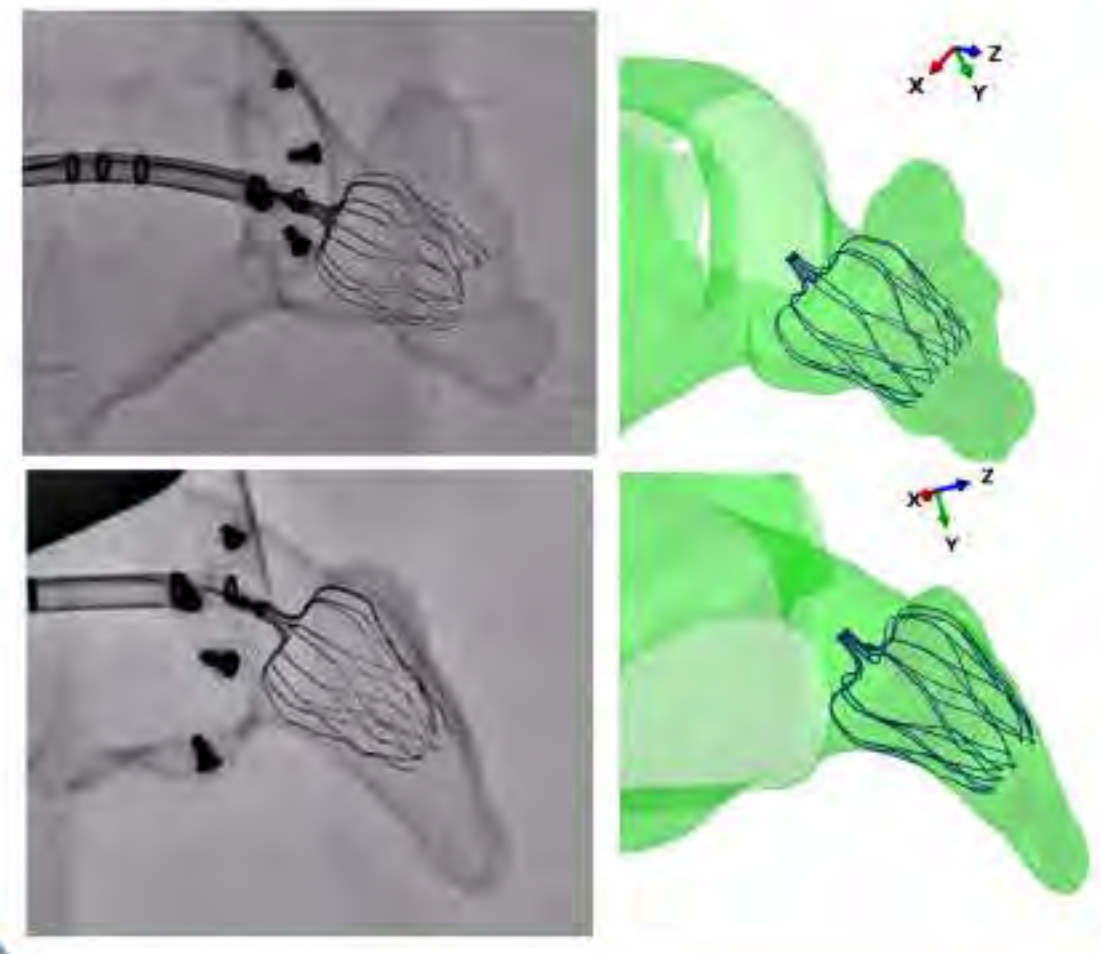
The mesh was generated in Hypermesh (triangular element) and ANSA (square element through hexablocks meshing). After a element sensitivity analysis, triangular mesh guaranteed a adequate trade off between accuracy and effort in the model realisation.

LAA and half LA were printed using the Formlabs Form2 SLA 3D printer. The material used for the 3D printed geometry is Elastic50A with a printing resolution of 0.1mm

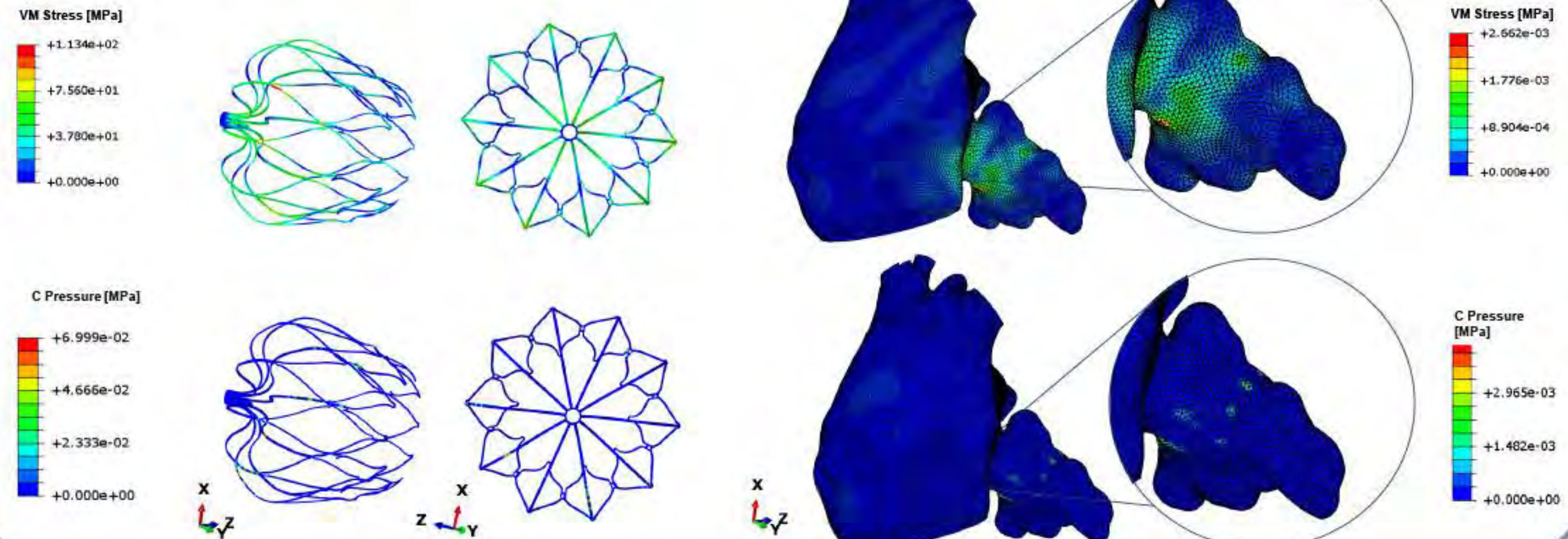
RESULTS



VALIDATION OF THE MODEL: SIMULATION WITH RESIN MATERIAL PROPERTIES



SIMULATION WITH LAA MATERIAL PROPERTIES



CONCLUSIONS

- Up to now**
- The finite element model of LAA was developed
 - The deployment was simulated in one Left Atrial Appendage using different positions and depths
 - Validation of the implant procedure simulation throughout the comparison between the 3D-printed experimental tests' results and the in-silico model's results
 - Implant outcome prediction in patient-specific geometry imposing realistic material properties



- Next steps**
- Evaluate the stability, anchoring and correct sizing of the device for different deployment positions and depths
 - Introduction of a curved catheter
 - Replicate the study on more patient-specific LAAs
- Limitations:**
- The wall atrium pressurization is not considered in this study
 - Static boundary conditions were used