UNIVERSITÀ DEGLI STUDI FIRENZE
DIEF DIPARTIMENTO DI INGEGNERIA INDUSTRIALE

ADDITIVE 4 BIOMEDICAL

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DEMONSTRATION OF USE OF A NOVEL 3D PRINTED SIMULATOR FOR MITRAL VALVE TRANSCATHETER EDGE-TO-EDGE REPAIR

Michele Bertolini, Politecnico di Milano

mecc

POLITECNICO MILANO 1863

Plesso Didattico Morgagni, Viale Morgagni, 44-48, 50134 Firenze

SC 09/A3 CoCo AM Additive Manufacturing

ASSOCIAZIONE NAZIONALE DISEGNO E METODI

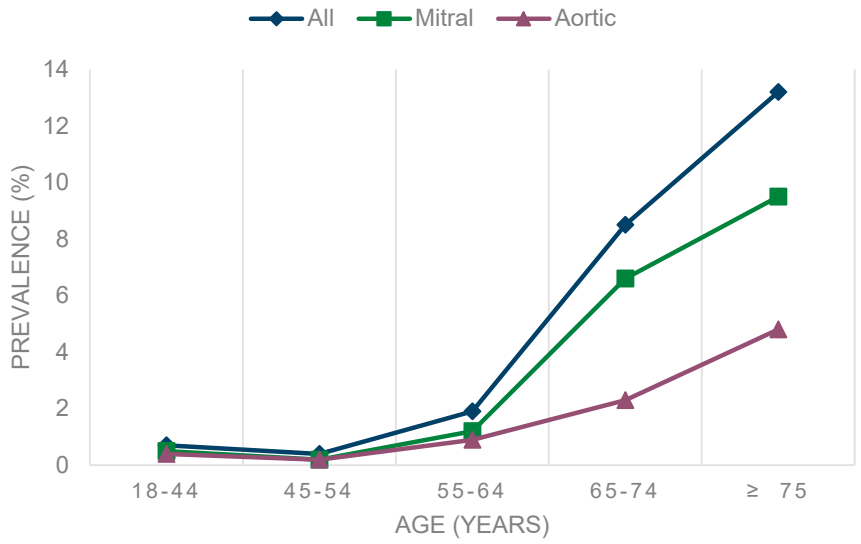
COMET

aias

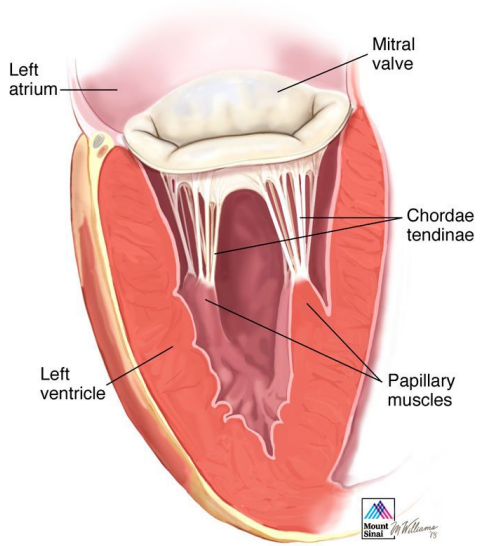
INTRODUCTION

Background:

- **2.5%** of people in developed countries have at least moderate valve disease
- Mitral Valve (MV) disorders are the most widespread (**mitral valve regurgitation**)
- Instead of open surgery, **minimally invasive** approaches are gradually taking place
- **MitraClip**™ (Abbott Laboratories) has become the most widely adopted Transcatheter Edge-to-Edge Repair (TEER) approach, with >100,000 procedures (2021)



[Geoffrey D. Huntley et al., 2019]

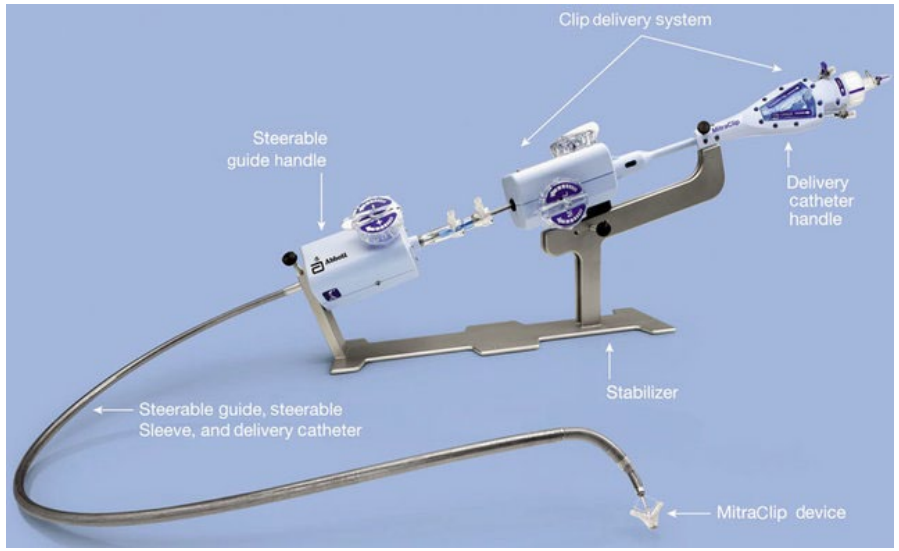


https://www.mitralvalverepair.org/

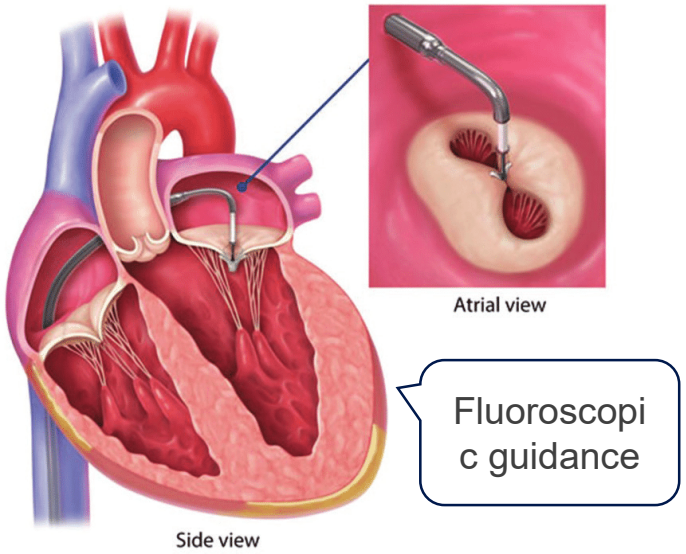
INTRODUCTION

The **MitraClip** is a cobalt-chromium catheter delivered device, which utilises two grippers to grasp and **coapt** the MV leaflets

Procedure: very challenging (**steep learning curve**) → Need for proper **training** → **Simulators** (SBT) **BUT** Important limitations of today's simulators

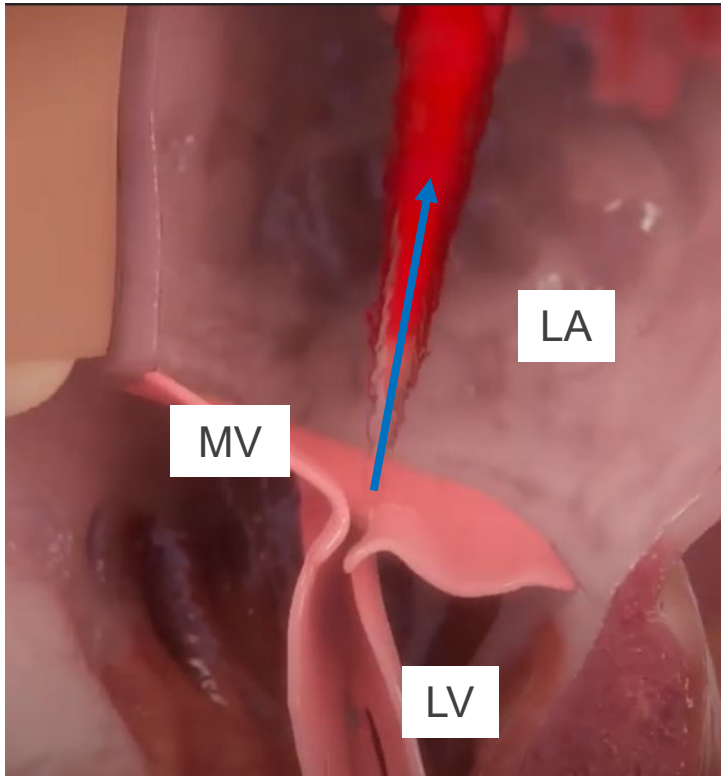


https://www.abbott.com/

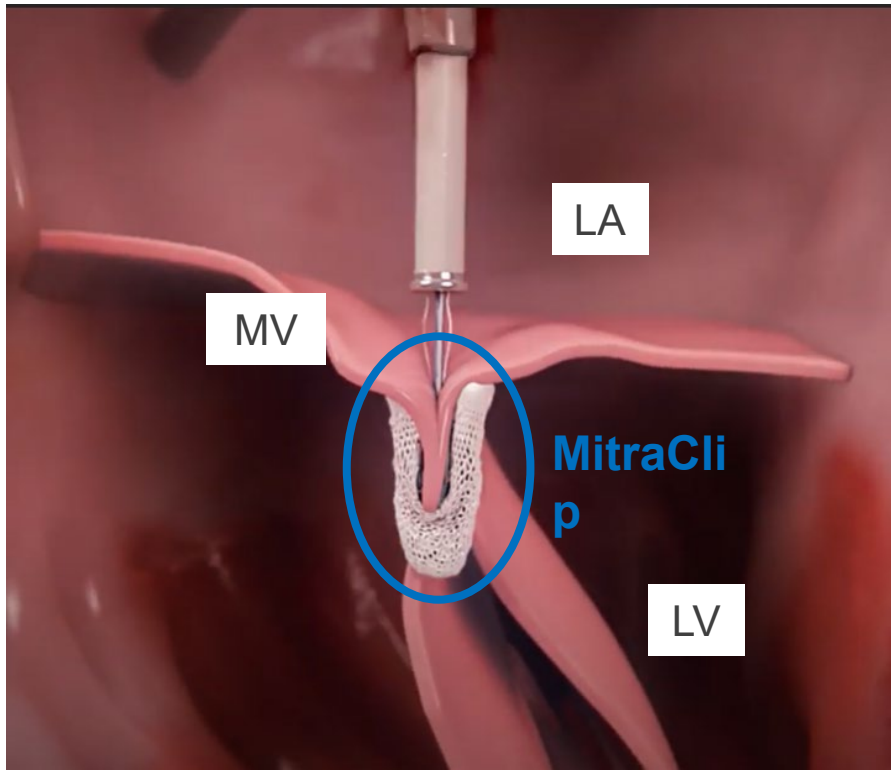


https://www.intechopen.com/books/5815

INTRODUCTION



Before (regurgitant valve)

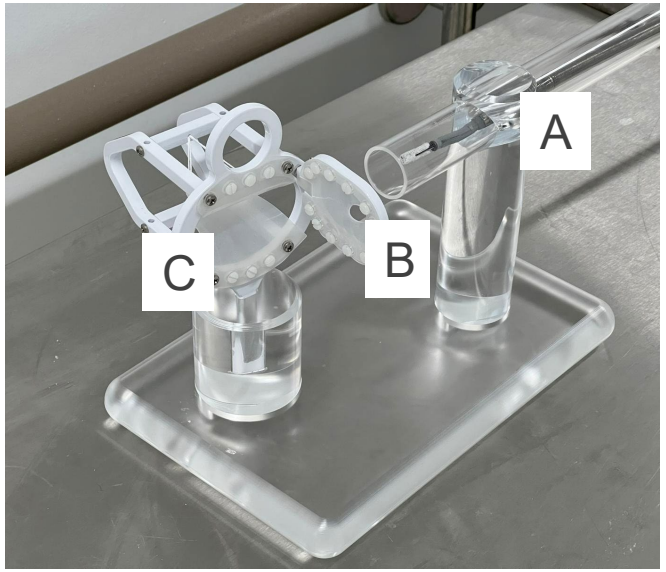


After MitraClip implantation

https://www.abbott.com/

STATE-OF-THE-ART

The state-of-the-art training for MitraClip by Abbott is here reported:



A: Inferior Vena Cava (IVC)
B: Transeptal puncture
C: Annulus with leaflets

Limitations:

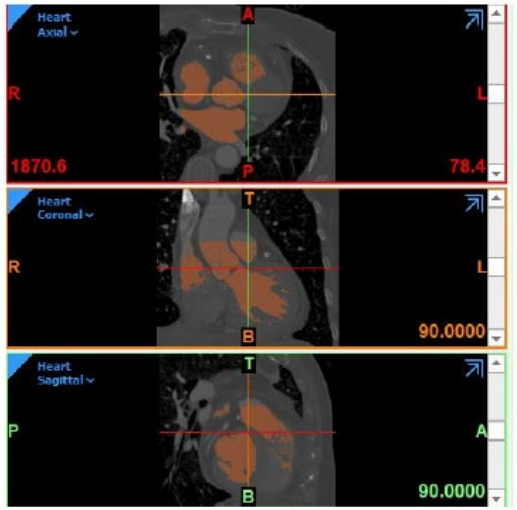
- Lack of physical borders
- Materials do not represent human tissue
- Unrealistic procedural scenario

Objective:

- ✓ Anatomical realism
- ✓ Accurate mechanical behaviour
- ✓ Include the challenges of the procedure

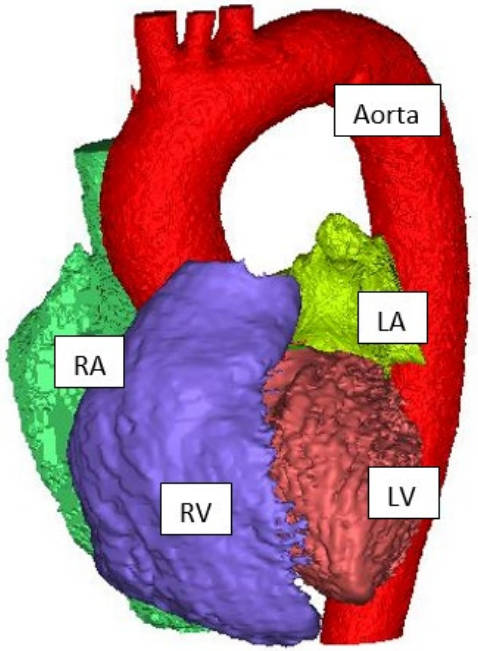
MATERIALS AND METHODS

I. Anatomy-based design:



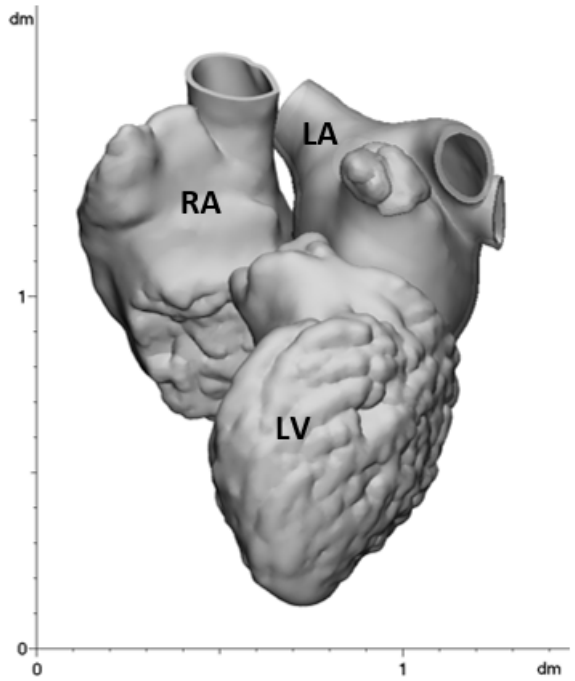
Starting point: medical **CT scan**

Segmentation



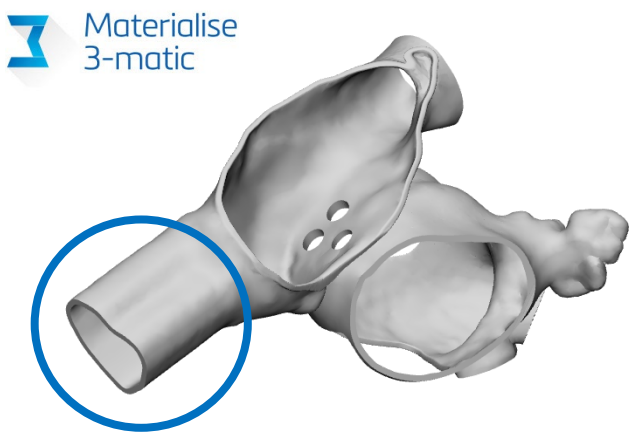
Preliminary **masks** (independent masks)

Post-processing

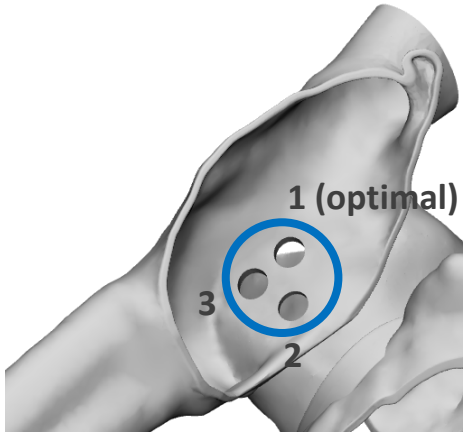


Hollow model, keeping **atria** and **LV** (STL)

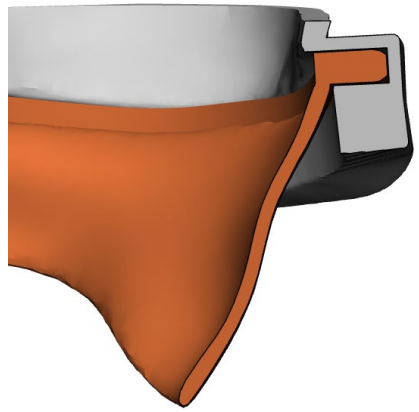
MATERIALS AND METHODS



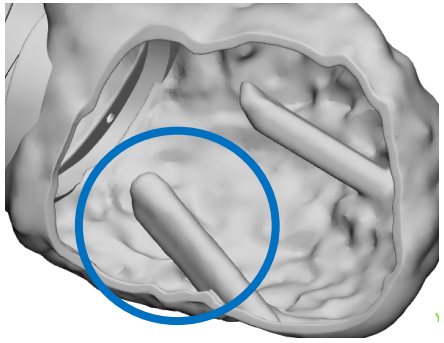
1. **IVC** extrusion



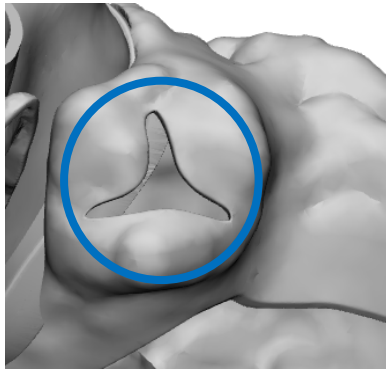
2. Holes for **transseptal puncture**



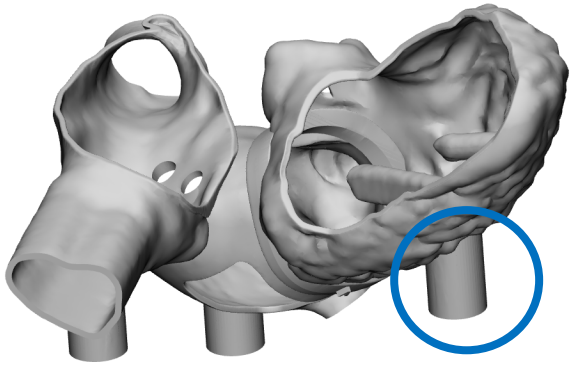
3. **Exchangeable** MV solution



4. **Papillary muscles** extrusion



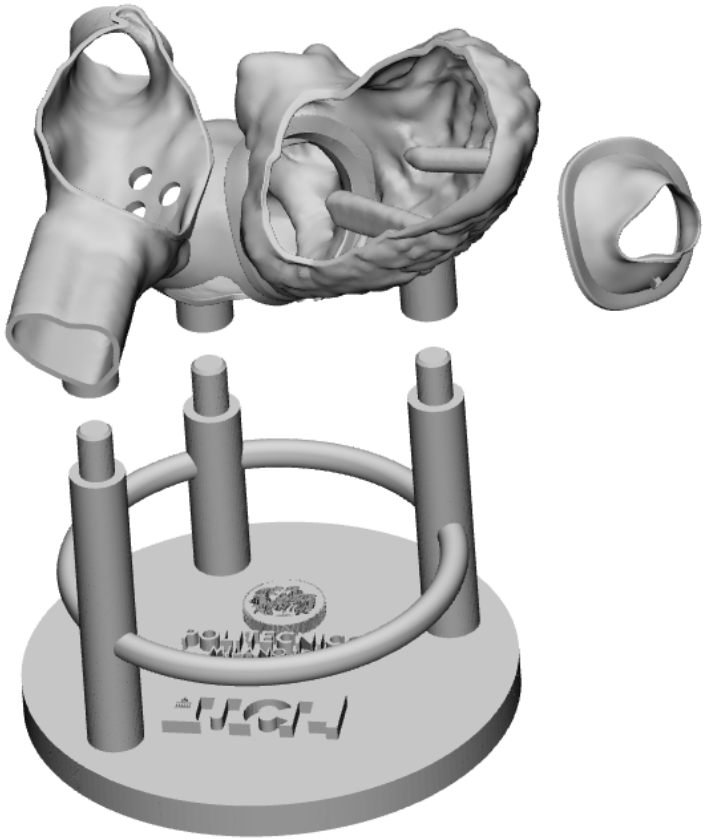
5. **Aortic valve** commissures



6. Openings and **fixation** system

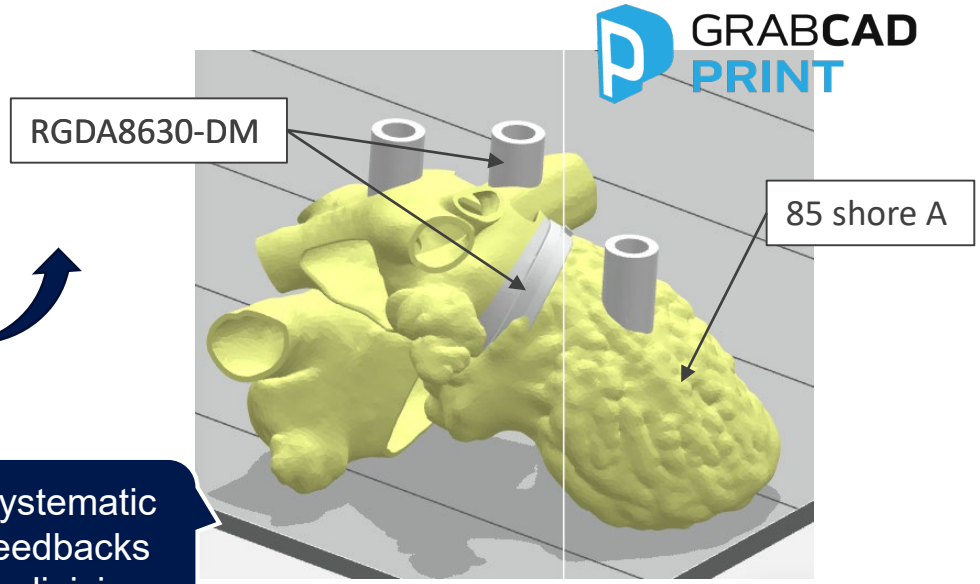
MATERIALS AND METHODS

II. 3D printing preparation:



Differentiated printing technologies:

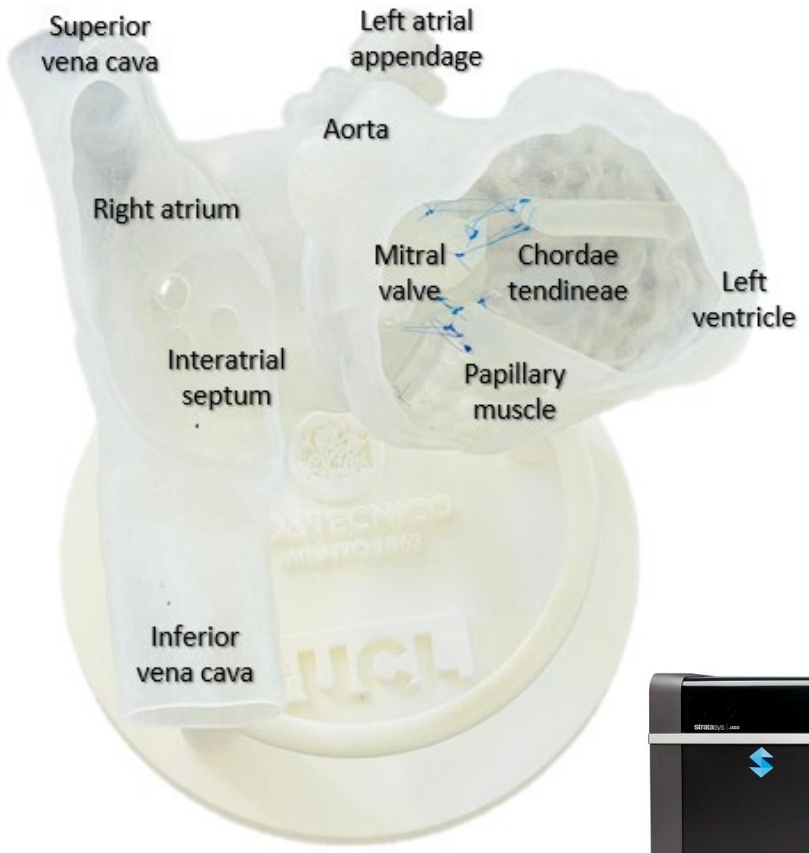
1. Polyjet (blends VeroClear + Agilus30): anatomy
2. SLS (PA2200): basement



Systematic feedbacks by clinicians

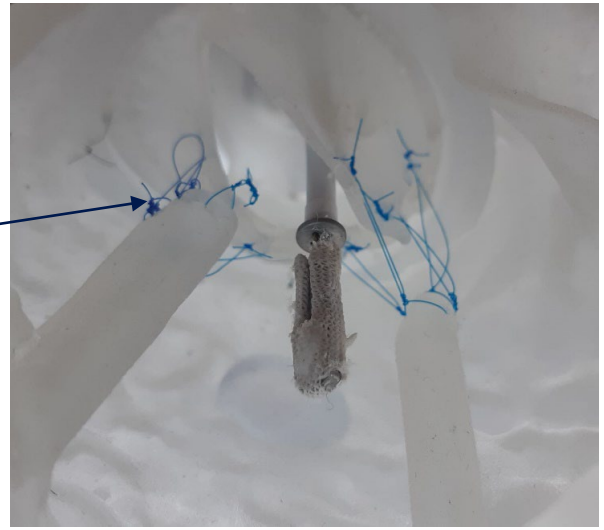
RESULTS

III. Printing



- Satisfactory **haptic** sensation for the material and finishing
- Easy and safe **matching** between model and basement and between model and MV
- **Stitching** performed without difficulties
- Translucency

Chordae tendineae (PP)



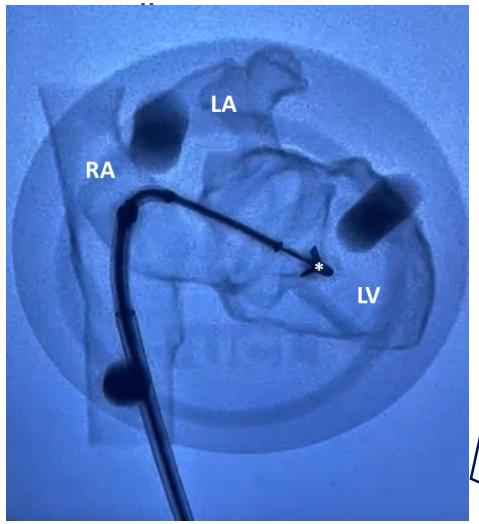
RESULTS

IV.
Testing:

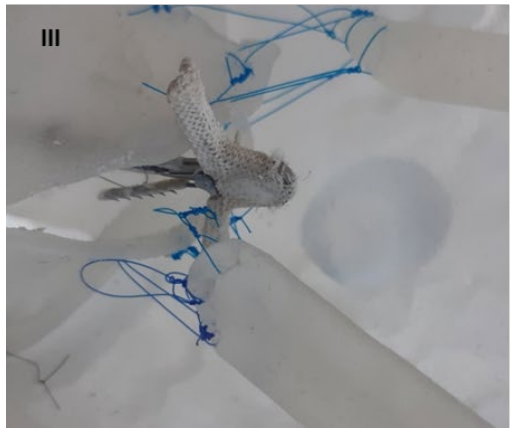
- St. Bartholomew's Hospital (London)
- Expert surgeon (> 100 cases in TEER)

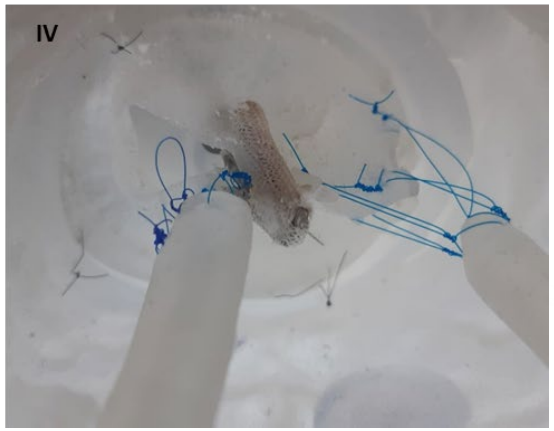
Steps of the procedure:

I. Preparation
II. Guide insertion
III. Positioning of the



Model visible under fluoroscopic imaging!





Barts Health NHS
NHS Trust

RESULTS

V. Feedbacks collection:

Quantitative questionnaires for operator's confidence

	Not confident				Highly Confident
Before this training, how confident are you with this procedure?	1	2	3	4	5

	Never before	A few times under supervision	Less than 1 year	1-5 years	More than 5 years
How long have you been carrying out this procedure for?	1	2	3	4	5

Post-Training

Please circle and rate for how accurate the following are compared to carrying out the procedure on a patient:

	Not Accurate				Highly Accurate
Carrying out the procedure on the model compared to in the catheterisation lab?	1	2	3	4	5
The height and angle of insertion above the mitral valve	1	2	3	4	5
The advancement of the catheter into the RA via the IVC	1	2	3	4	5

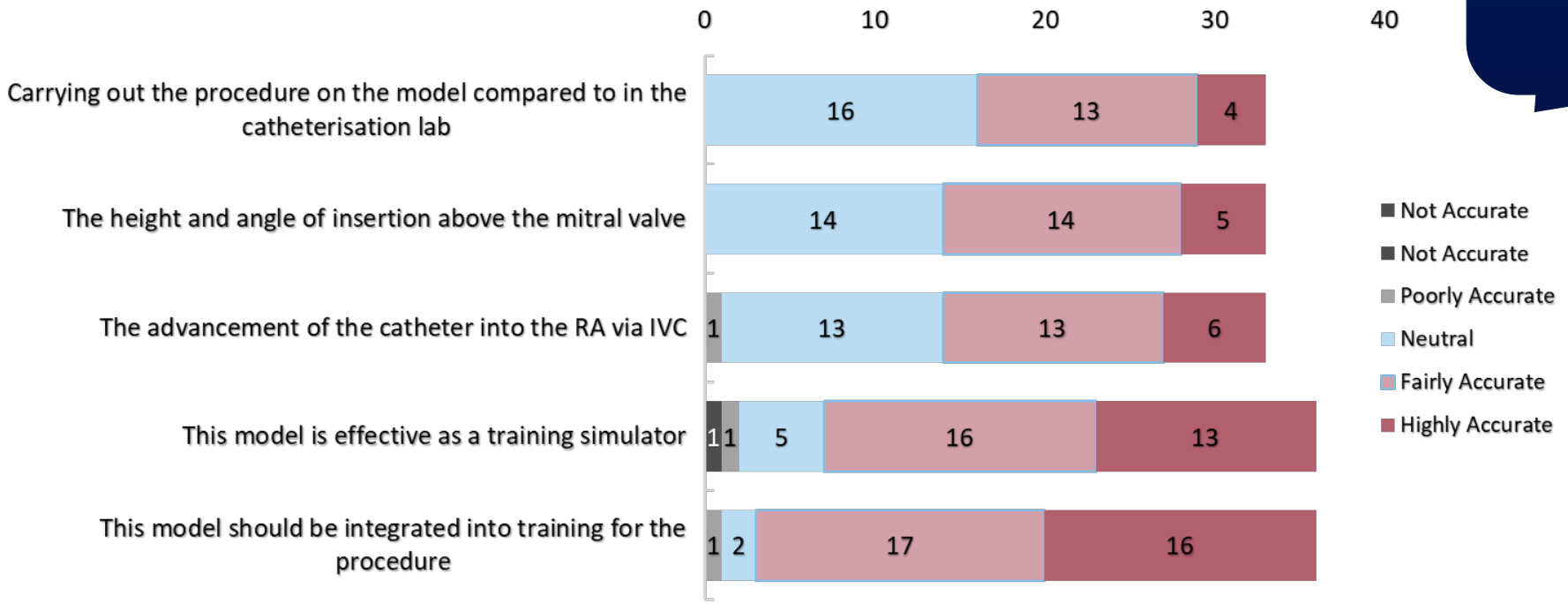
Please circle and rate for how confident you are for the following skills:

	Not confident				Highly confident
Transeptal crossing	1	2	3	4	5
Steering clip in LA	1	2	3	4	5
Positioning trajectory of clip	1	2	3	4	5
Recognising area of interest on Mitral Valve	1	2	3	4	5
Assessing position of clip above valve	1	2	3	4	5
Assessing orientation of clip above valve	1	2	3	4	5
Grasping leaflets	1	2	3	4	5
Closing a clip	1	2	3	4	5
Re-opening clip and repositioning	1	2	3	4	5
Removal of clip delivery system	1	2	3	4	5

RESULTS

Feedbacks collection results:

Post-training rating comparing 3D model to carrying out the procedure in patients



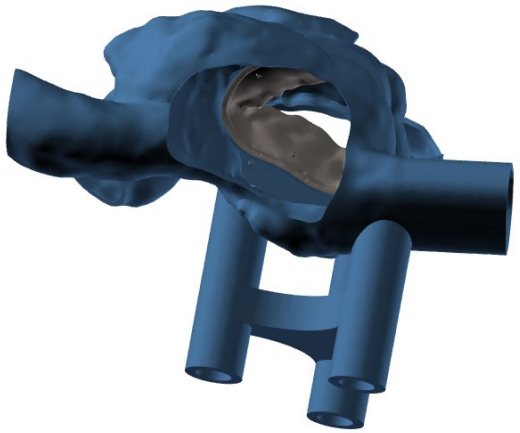
Participants:

- Different levels of **expertise**
- Different professional **qualifications** (clinician, nurse, student)

ADDITIVE 4 BIOMEDICAL

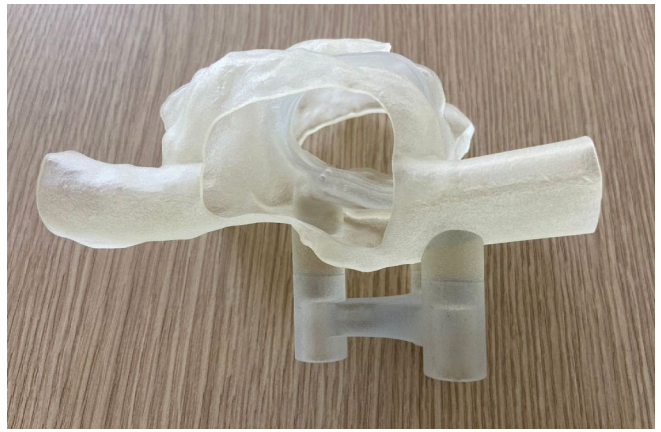
Discussion

- Preliminary users' feedbacks are promising
- Strenghts include **anatomical accuracy**, **modularity of the system**, **mechanical performance** and **translucency**
- The simulator was evaluated as highly realistic **representation of the procedural circumstances**
- The 3D printed model is an effective training simulator in increasing operator confidence



Developments:

- Feedbacks collection in a more systematic way
- Higher number of feedbacks to get statistical relevance **compared with state-of-the-art training**
- Assessment of the effect of proposed system on **improving clinical outcomes**
- Movable leaflets
- Extension to new types of transcatheter intervention (e.g. TTVR)



Thanks for the kind attention!

Reference: Bertolini, M.; Mullen, M.; Belitsis, G.; Babu, A.; Colombo, G.; Cook, A.; Mullen, A.; Capelli, C. Demonstration of Use of a Novel 3D Printed Simulator for Mitral Valve Transcatheter Edge-to-Edge Repair (TEER). Materials 2022, 15, 4284. https://doi.org/10.3390/ma15124284

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