UNIVERSITÀ DEGLI STUDI FIRENZE
DIEF DIPARTIMENTO DI INGEGNERIA INDUSTRIALE

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INTERVENTIONAL CARDIOLOGY: SIMULATION OF LAAO PROCEDURE

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ADDITIVE 4 BIOMEDICAL

SC 09/A3 CoCo AM Additive Manufacturing

ASSOCIAZIONE NAZIONALE DISEGNO E METODI

COMET

aias

INTRODUCTION

- Activity carried out within **CUSTOM3D** – Customized 3D in Medicine
- Study 3D printing applications in the clinical care.
- Develop best practices for personalized medicine approaches applying 3D technologies.

CUSTOM3D

aouc

Azienda Ospedaliero Universitaria Careggi

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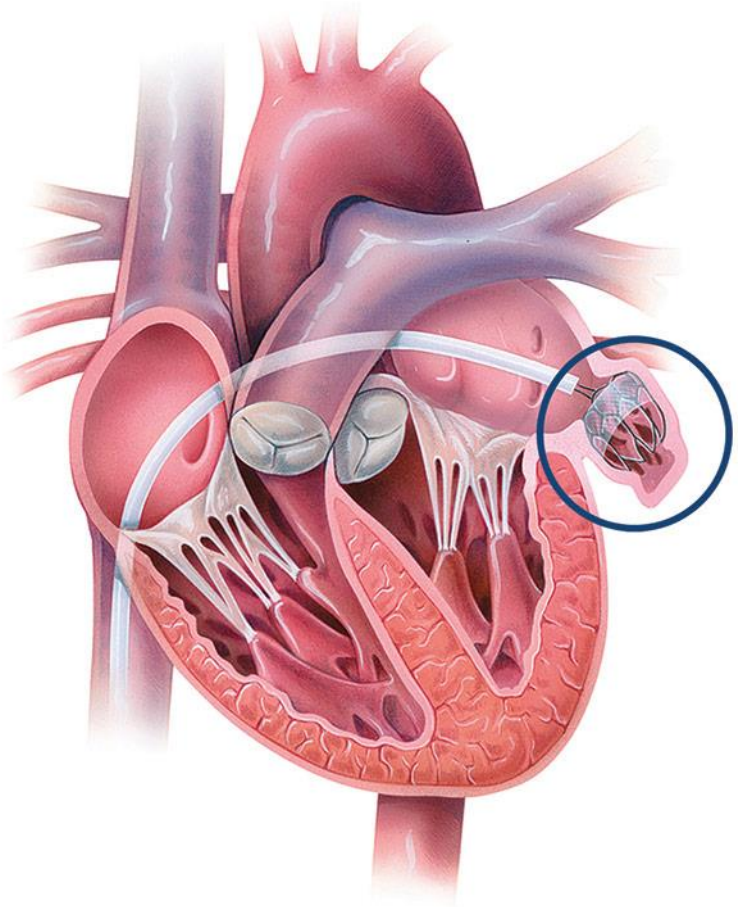
TEAM INNOVAZIONE PROCESSO E PRODOTTO

- This specific activity was carried out in collaboration with the «Interventistica Cardiologica Strutturale» group of AOU Careggi, lead by Prof. Carlo Di Mario

LAAO Procedure

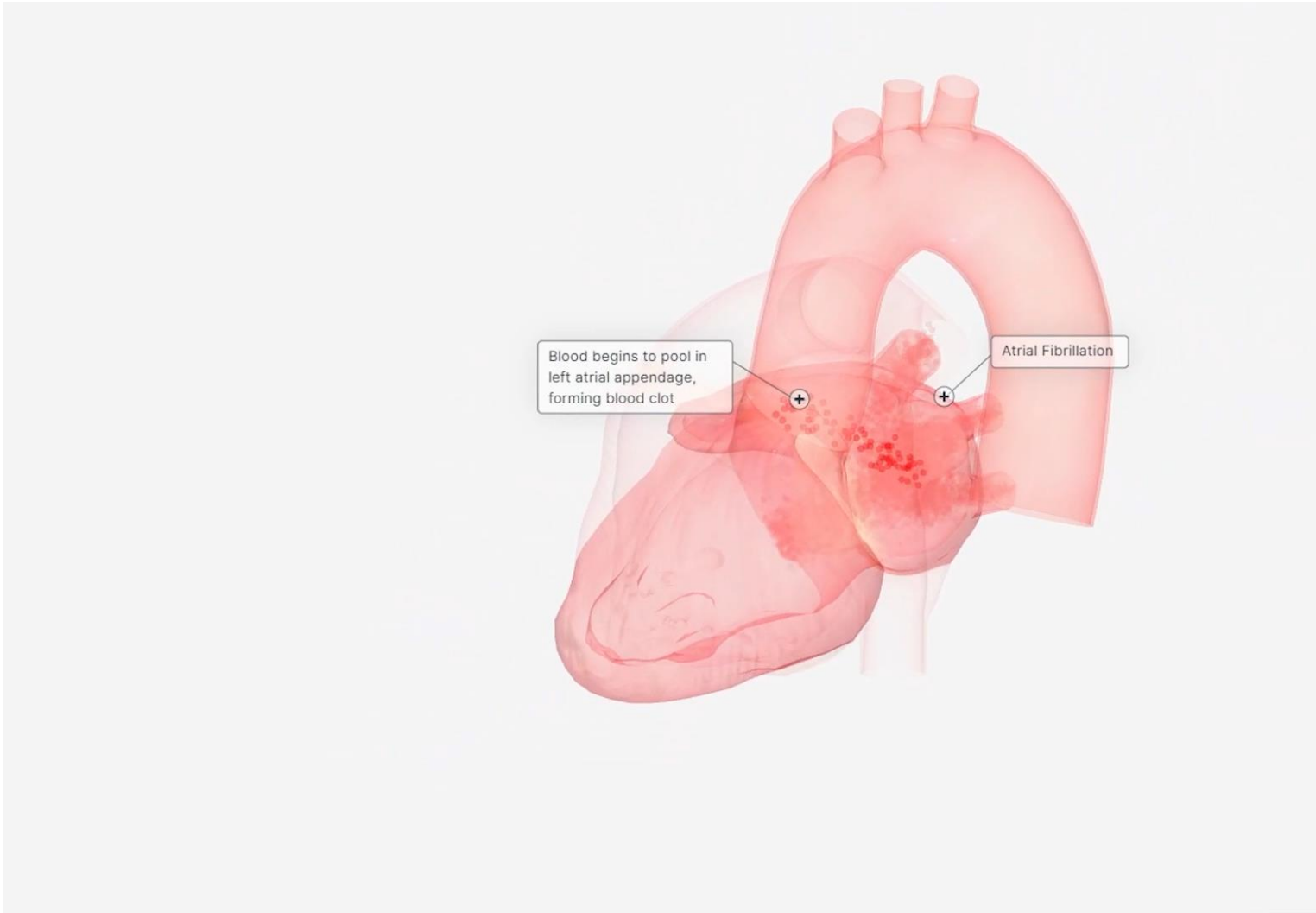


GOAL: improve the preparation of the cardiac surgeon performing a LAAO surgical procedure by using patient-specific 3D printed anatomical replicas

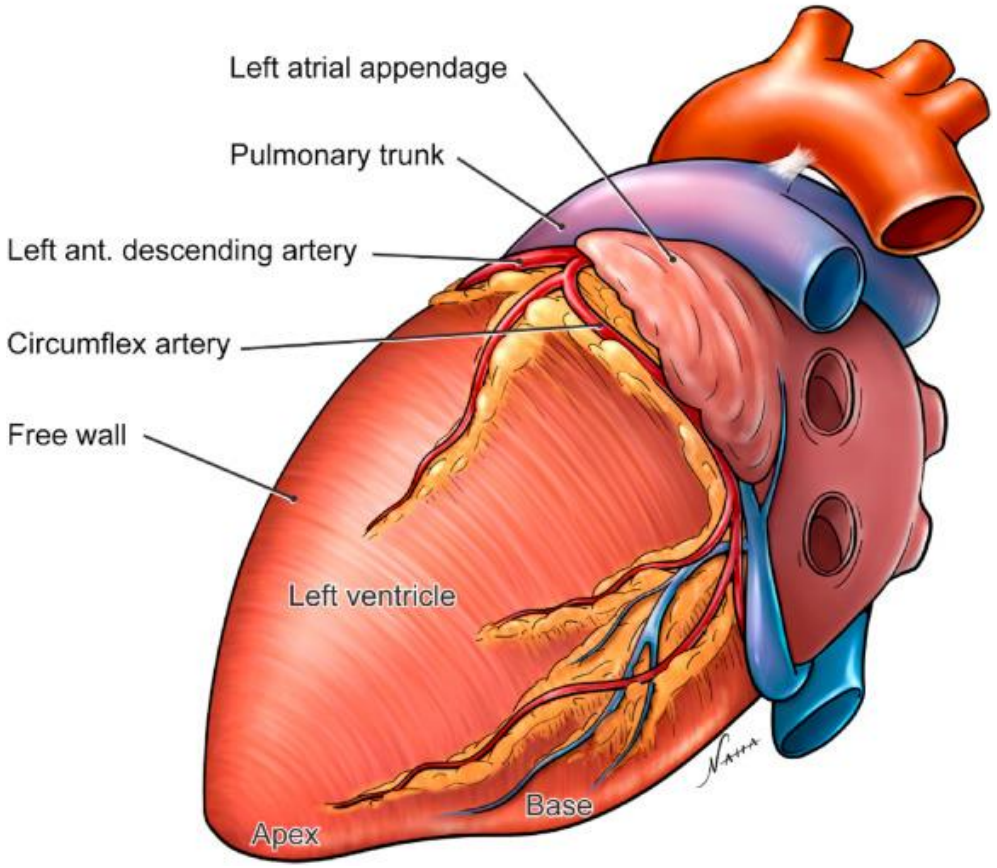
- LAAO: Left Atrial Appendage Occlusion
- Procedure carried out to minimize risks associated with clot formations in hearts
- LAAO is a procedure that places a device that acts as a barrier to prevent blood clots in the left atrial appendage

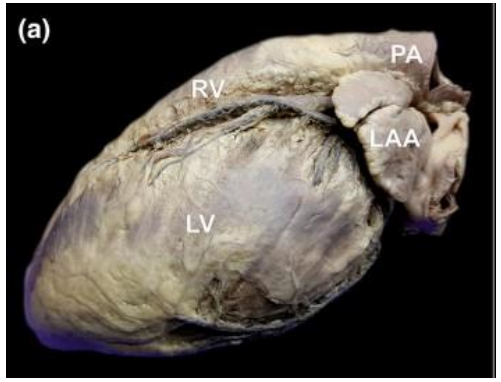
CLOT FORMATION

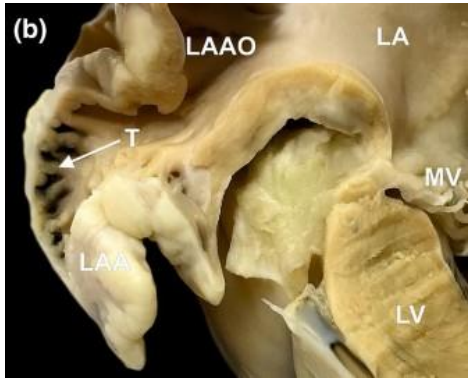
- Atrial fibrillation causes an irregular contraction
- Blood flow is irregular
- Blood pools in the LAA area

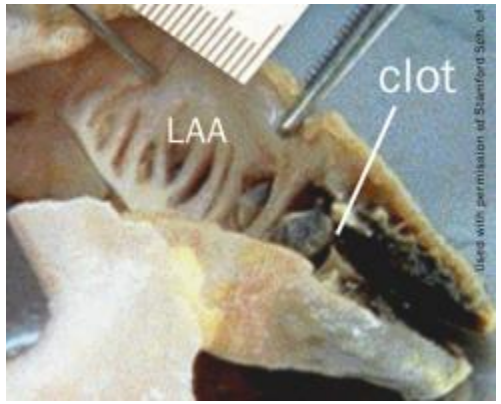


LAA – CLOT GENERATION









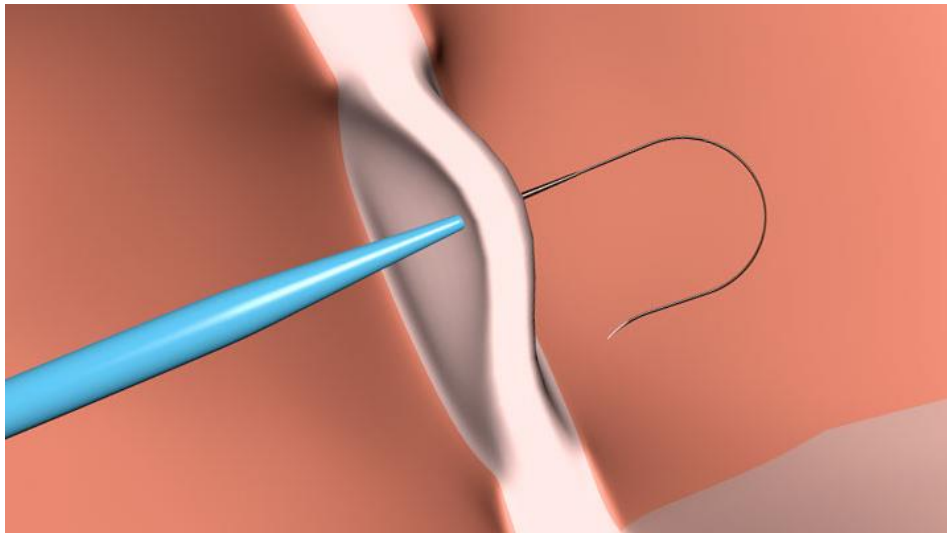
- Complex internal shape
- Pectinati muscles

LAAO PROCEDURE: STEPS

- Procedure is carried out thanks to a delivery catherer
- Access from the Inferior Vena Cava (IVC) in the femoral vein
- Navigation to the Right Atrium (RA), access from IVC
- From RA to LA thanks to a **Trans-Septal Puncture**
  - The puncture is performed in the Fossa Ovalis (FO)
- Arrival in the Left Atrium LA
- Cathether moves towards LAA
- Occluding device is **positioned in the LAA**
- Occluding device is detached from catherer
- Catherer is retrieved
- Occluding device is integrated by the heart tissue

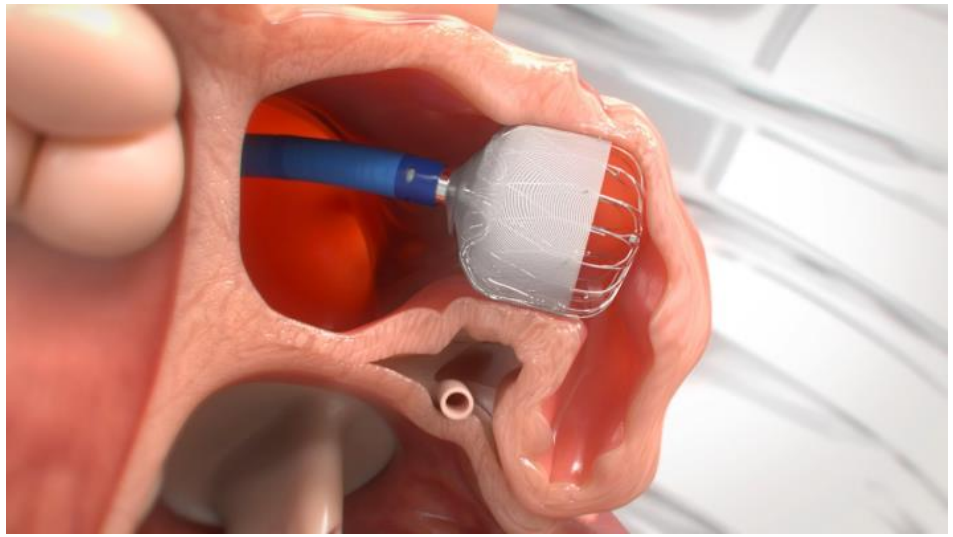
DIFFICULT STEPS

- Trans-Septal Puncture and path to LAA



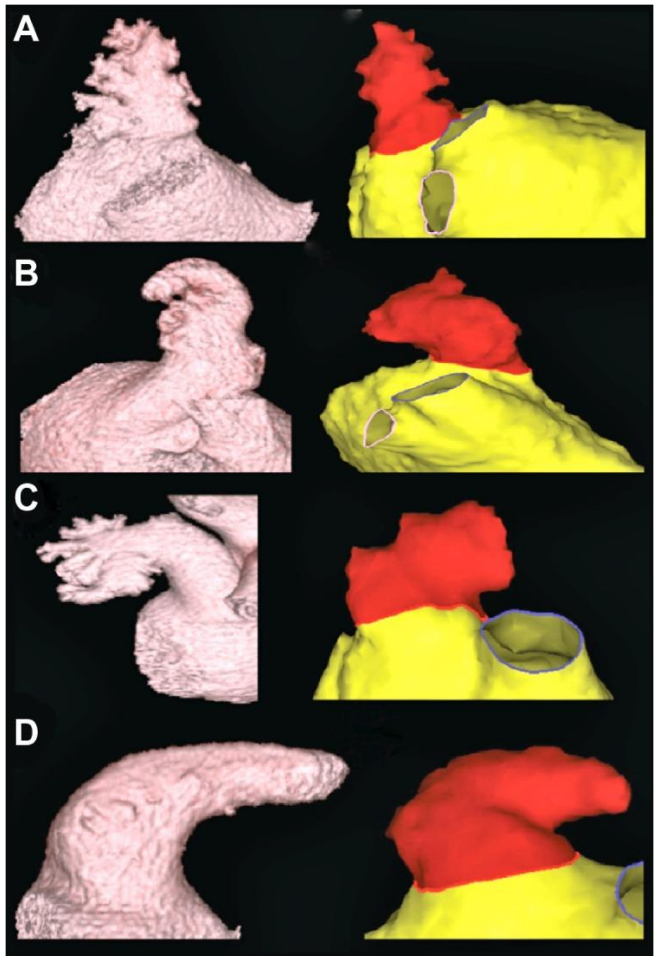
- Specific puncture point determines how the surgeon will be able to guide the cathether in the LA
- LAA position in the LA depends on specific patient's anatomy
- LAAO is a procedure controlled by the surgeon at the groin, requires great deal of manual dexterity

- Positioning of the device

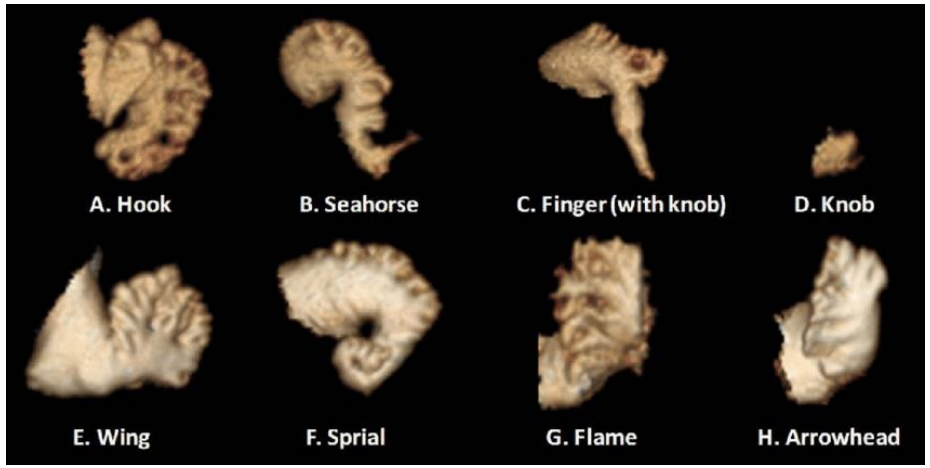


- LAA **shape** is highly variable (internal shape is irregular)
- LAA **size** is highly variable
- **Choice** of the correct device
- Ideal position of the occluding device is hard to identify
- LAAO is a procedure controlled by the surgeon at the groin, requires great deal of manual dexterity

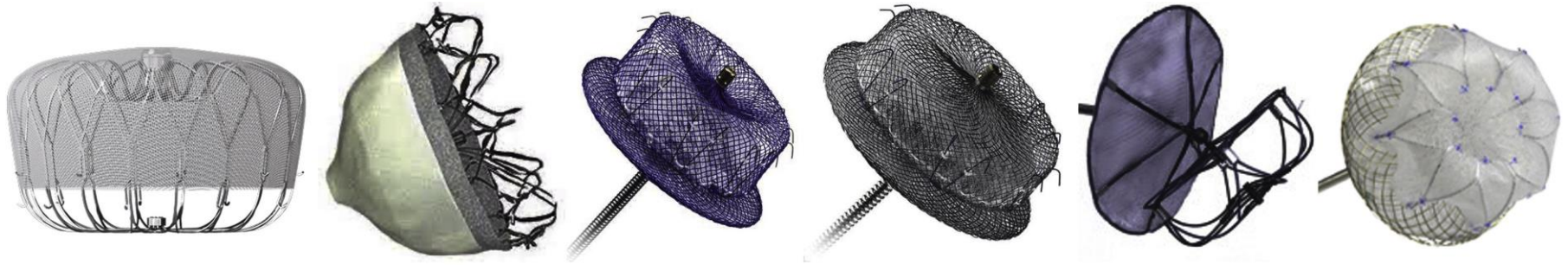
LAA ANATOMY



- 4 main categories: (A) cactus, (B) windsock, (C) cauliflower, and (D) chicken wing.
- Several examples of more complicated anatomies
- Size varies depending on patient's anatomy
- Tissue elasticity depends on pathological conditions



OCCLUDING DEVICES



WATCHMAN FLX *Boston Scientific* | **WaveCrest** *Biosense Webster* | **Amulet** *Abbott Vascular* | **AMPLATZER** *Abbott Vascular* | **Ultraseal LAA Occluder** *Cardia* | **LAmbre** *Lifetech*

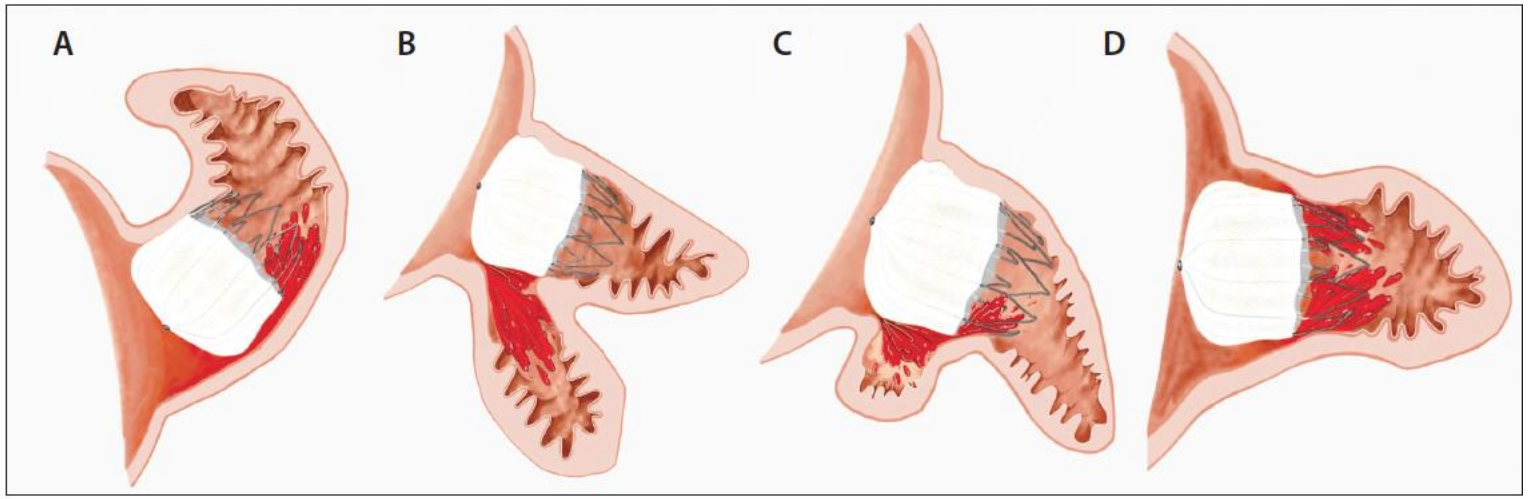
Left Atrial Appendage Occlusion: Current Stroke Prevention Strategies and a Shift Toward Data-Driven, Patient-Specific Approaches; Mendez, Keegan et al.; Journal of the Society for Cardiovascular Angiography & Interventions, Volume 1, Issue 5, 100405

Diameter (mm)	16	18	20	22	25	28	31	34
Maximum Landing Zone Width (mm)	11-13	13-15	15-17	17-19	19-22	22-25	25-28	28-31
Minimum LAA Depth (mm)	≥10	≥10	≥10	≥10	≥12	≥12	≥12	≥12
Lobe Length (mm)	7.5	7.5	7.5	7.5	10	10	10	10
Disc Diameter (mm)	22	24	26	28	32	35	38	41

Left Atrial Appendage Occlusion/Exclusion: Procedural Image Guidance with Transesophageal Echocardiography; Vainrib, Alan F. et al.; Journal of the American Society of Echocardiography, Volume 31, Issue 4, 454 - 474

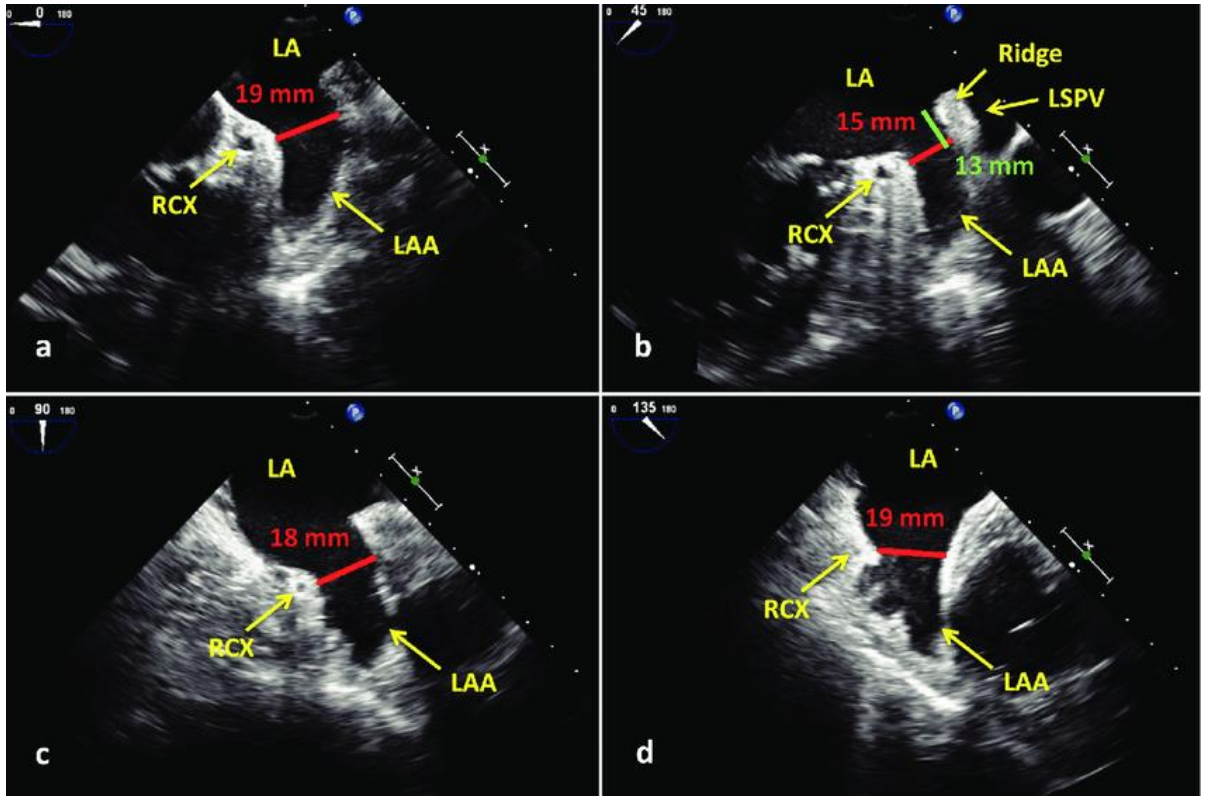
Approximate cost: 6000€

POSITIONING OF THE DEVICE

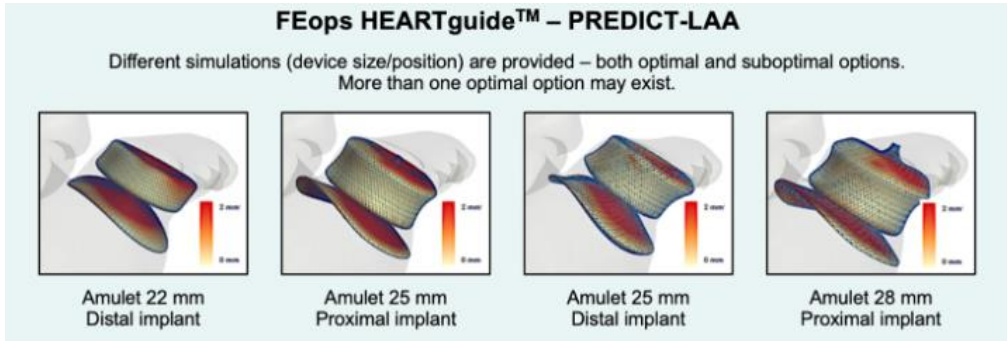


- Cardiac surgeon studies the LAA anatomy during the preparation phase:
  - CT, Ecography (US)
- Decides on
  - Occluding device type
  - Size
  - Positioning of the device with respect to the LAA

EXISTING SOLUTIONS: PREPARATION



Schmidt-Salzmann M, Meincke F, Kreidel F, Spangenberg T, Ghanem A, Kuck KH, Bergmann MW. Improved Algorithm for Ostium Size Assessment in Watchman Left Atrial Appendage Occlusion Using Three-Dimensional Echocardiography. J Invasive Cardiol. 2017 Jul;29(7):232-238. PMID: 28667807.



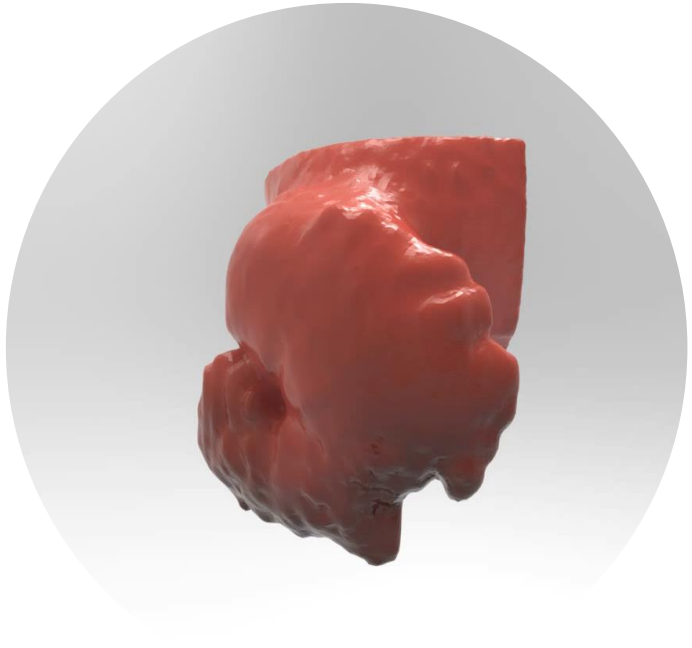
FEops: FEM tool to predict placement and fitting of occluding devices

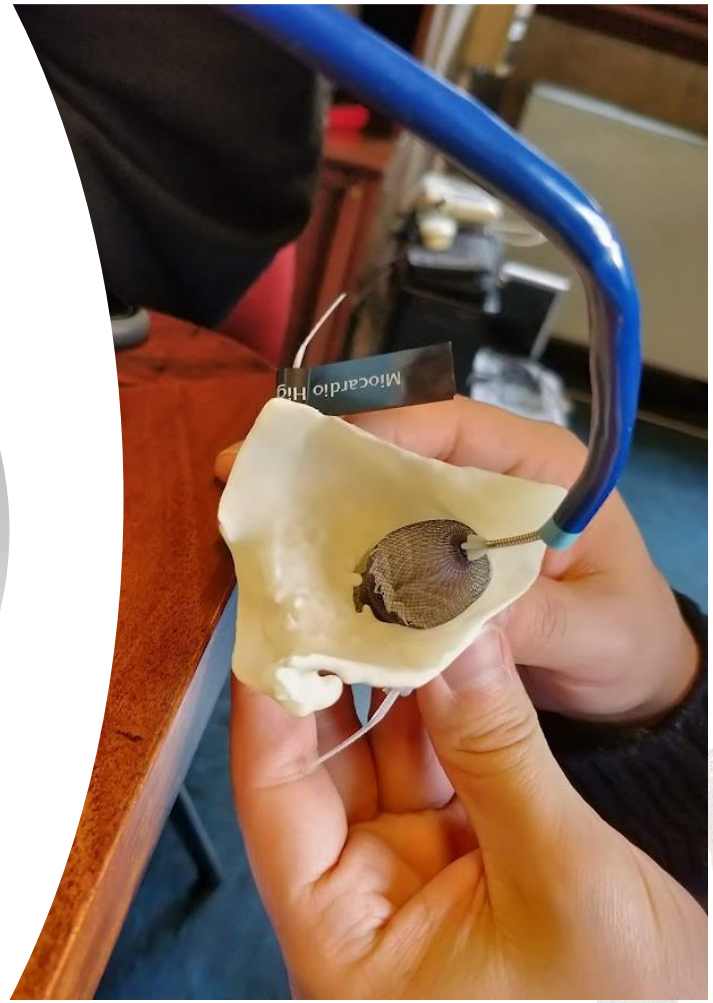
EXISTING SOLUTIONS: DURING THE INTERVENTION

- ECO data
- 2D X-Ray angiography

WHAT WE PROPOSE?

- 3D Printed replica of the LAA anatomy of the patient
- Flexible material, mimicking properties of interest of the heart tissue
- Help the surgeon build a 3D image of the LAA shape in order to better react according to the information





ADDITIVE 4 BIOMEDICAL

MATERIALS AND TECHNOLOGIES: PRELIMINARY STUDY

- Stratasys J750 digital anatomy
- Material: 5 materials taken from the «Structural Heart» Stratasys Library (Myocardium, Vessell Wall)

- Formlab 3B
- Material: Elastic 50 A

PRELIMINARY TESTS

- Material transparency ✓
- Flexibility ✓
- Costs ✓

→Formlabs 3B

METHOD

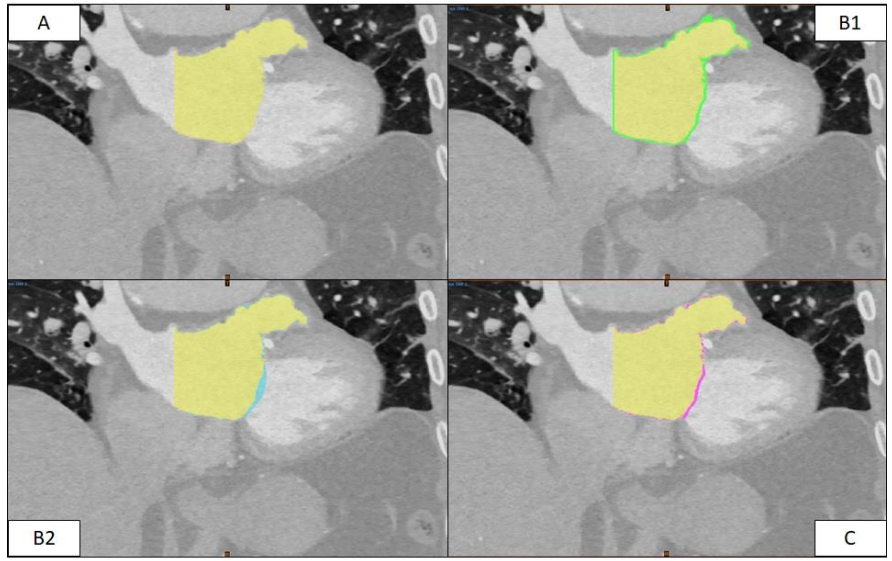
- Methodology tested on 10 cases – preliminary study
- LAAO operations performed in AOU Careggi

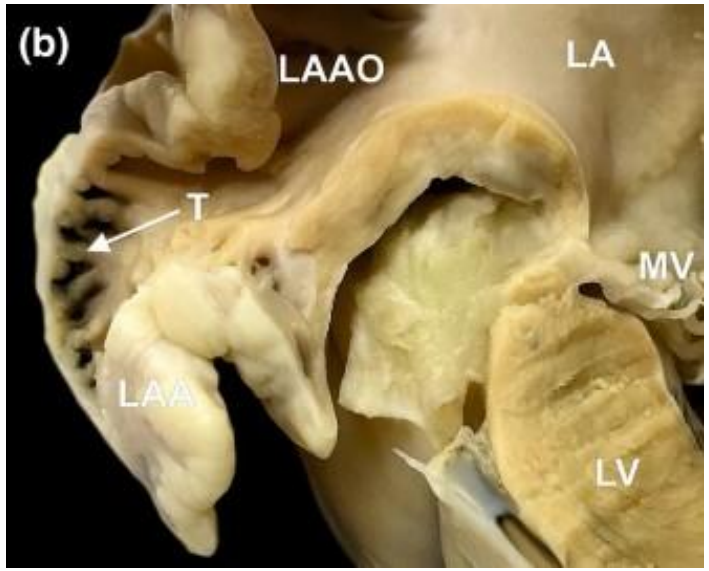
Azienda Ospedaliero Universitaria Careggi

CT Data	Segmentation	Modeling	Printing	Occluding device test
• Cardiac CT, contrasted	• Mimics Materialise 21	• Geomagic Design X	• Formlabs 3B	• AOU Careggi

SEGMENTATION

- Development of a **fast**, **reliable** and **repeatable** procedure
- Structure of interest: LAA (internal and external surface)
  - **Small HU difference**
- Fastest approach: offset of internal surface (yellow mask)

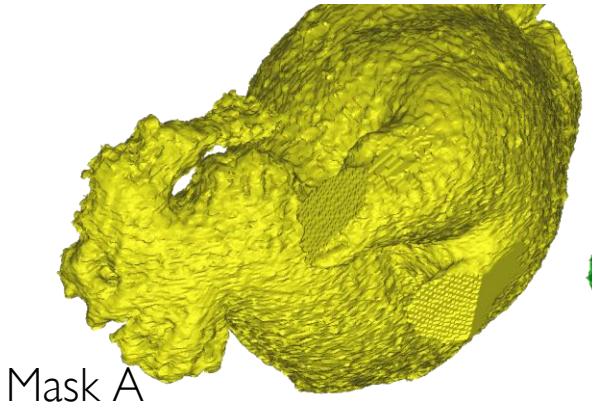




SEGMENTATION

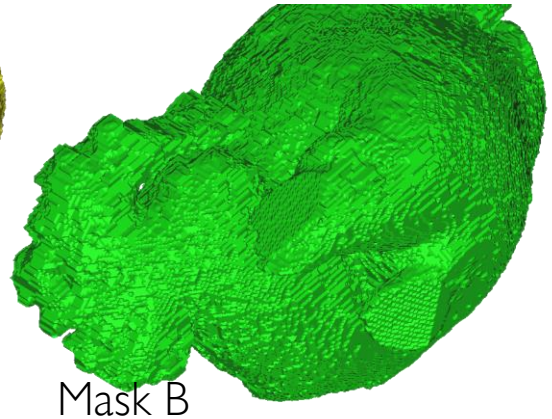
- Alternative procedure based on a «filter» mask (mask B)

materialise mimics



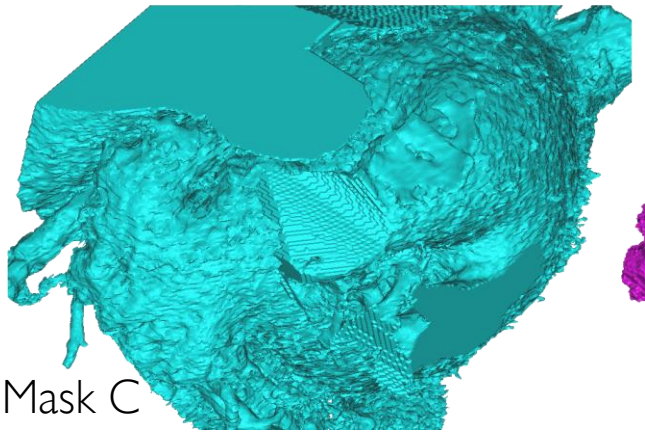
Mask A

Original segmentation mask



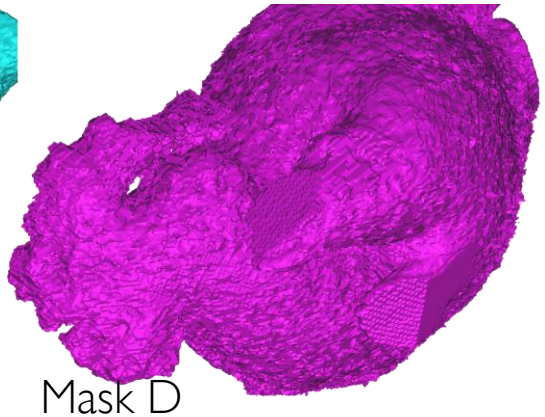
Mask B

Obtained offsetting mask A



Mask C

Rough mask obtained with a lower threshold value



Mask D

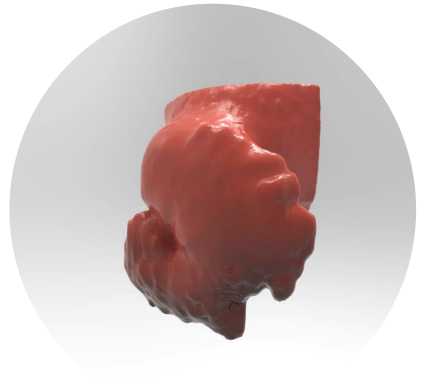
Final mask

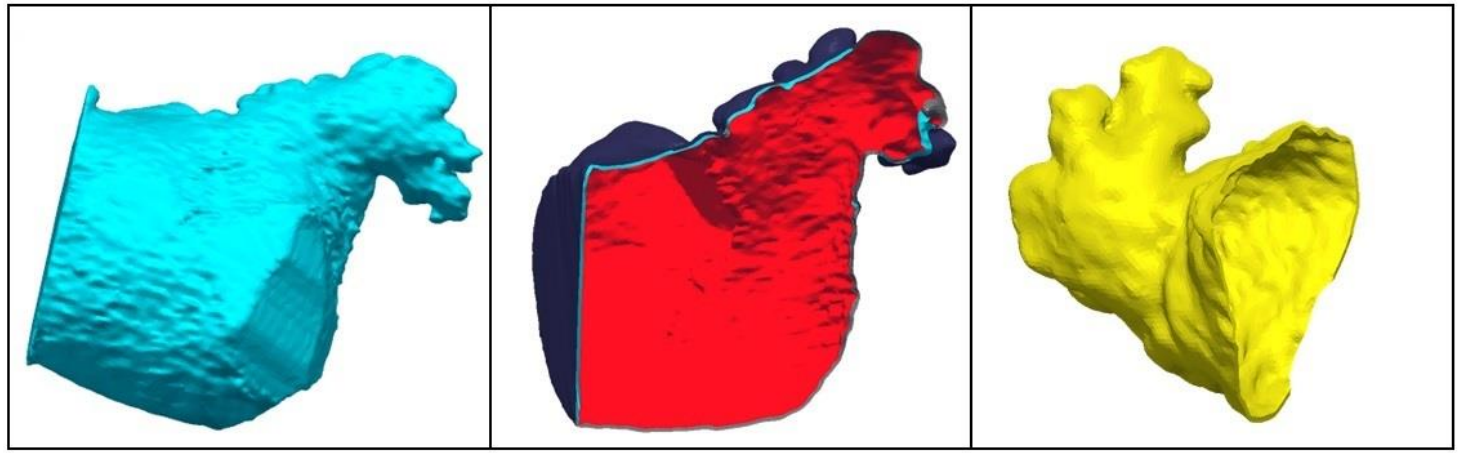
Boolean inters

MODELLING

Dx Geomagic® Design X™

- Mesh polishing operations: tunnels, free edges elimination and cuspid smoothing.
- Mask D → offset of 0.75mm
  - tradeoff value: haptic response vs printability issues for thin shell structures in flexible material (e.g.: print collapse due to its own weight, lacerations).
- Boolean subtraction between Mask D and A





PRINTING

- Print setup in PreForm
- Manual generation of supports, supervised by PreForm semi-automatic checks for unsupported areas
- Postprocessing as advised by manufacturer