Use of patient specific 3D printed vascular models for software validation and image guided treatment simulation (AAPM 2018)

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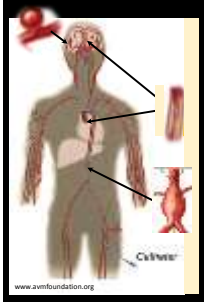
Outline

- Context
  - Research needs for vascular 3D printed phantoms
- Phantom Manufacturing
  - Computer model development
  - Manufacturing:
    - Vascular Model
    - Cardiac Models
  - Post-print model preparation
- Phantom testing and treatment planning:
  - Clinical software validation
  - Endovascular intervention simulation
  - Treatment Planning

Outline

- Context
  - Research needs for vascular 3D printed phantoms

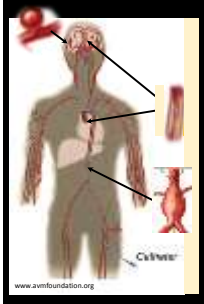
Introduction:
Need for Accurate Patient-Specific Vascular Phantoms



Endovascular interventions:

- Involve x-ray imaging of vasculature and catheter or device manipulation
- Devices are actuated distally using catheters, balloon, guidewires etc.
- Require placement of small devices such as stents, coils, valves, embolic materials etc.

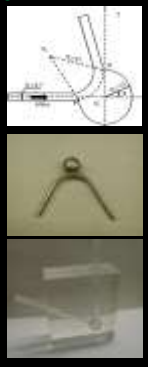
Introduction:
Need for Accurate Patient-Specific Vascular Phantoms



All elements involved: devices, imaging software and interventionalist require rigorous testing, validation and training.

Before 3D printing:
Idealized Models

1. Cad Design
2. Idealized low melting metal mold manufacturing
3. Silicone casting



Lieber et. al (2004)

Before 3D Printing: Patient Specific Aneurysm Phantom Manufacturing

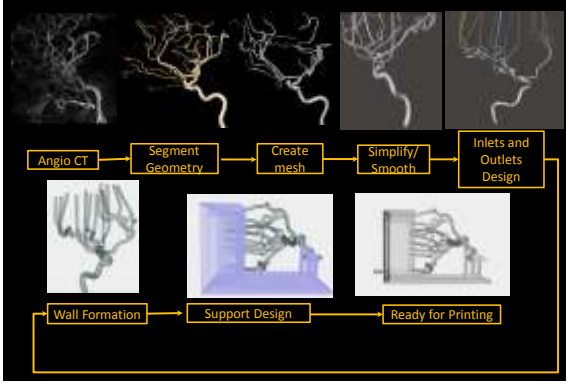
1. 3D data generation and CAD Design
2. Wax model rapid-prototyping
3. Silicone casting

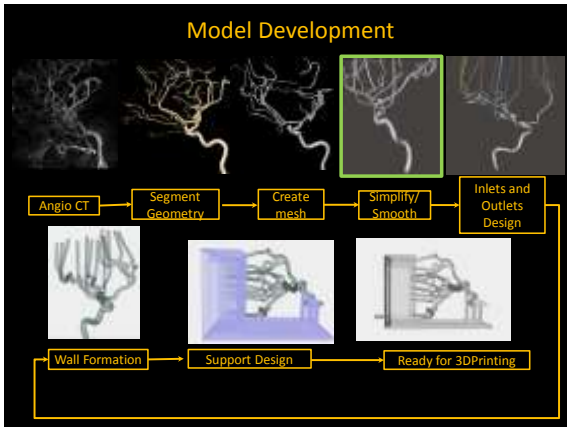
Rudin et. al (2006)

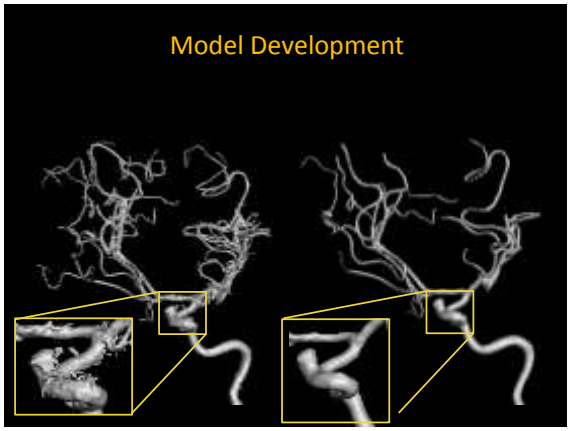
Outline

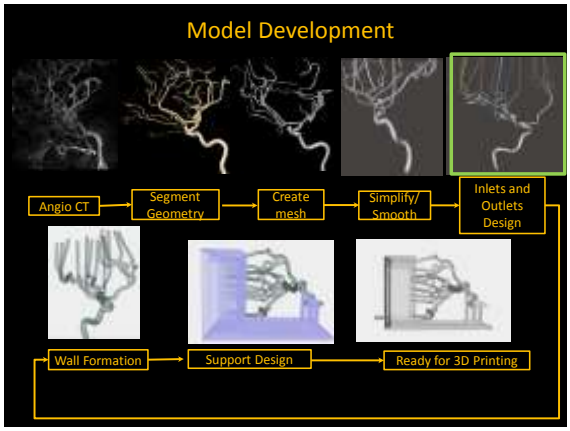
- Phantom Manufacturing
  - Computer model development
  - Manufacturing:
    - Vascular Model
    - Cardiac Models
  - Post-print model preparation

Model Development




Model Development
Angio CT
Segment Geometry
Create mesh
Simplify/ Smooth
Inlets and Outlets Design
Wall Formation
Support Design
Ready for 3DPrinting


Model Development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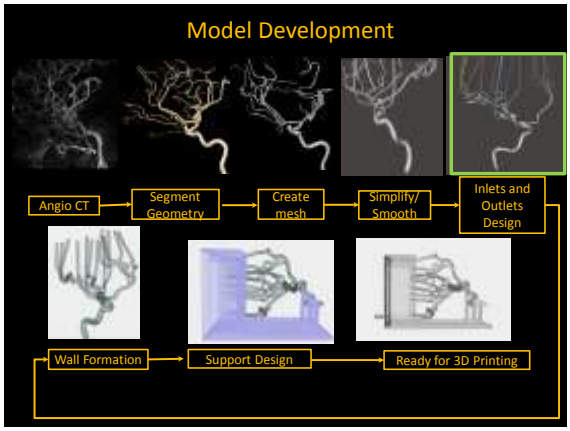
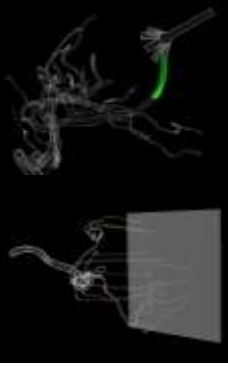
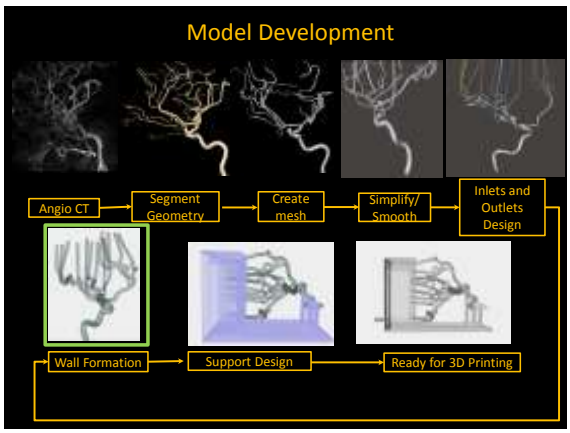


Inlets and Outlets Design



- Steps to add/extend vascular structures
  - Import CAD designed structure
  - Connect tube between distal artery and CAD structure, using Spline Interpolation
  - Perform Boolean union between the three structures.



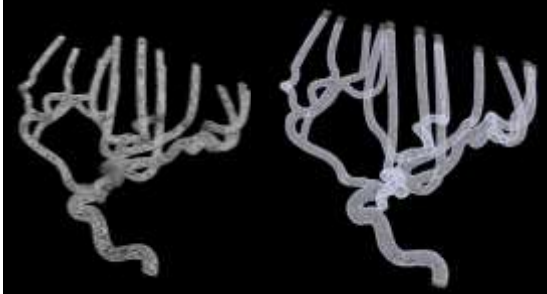
Wall Formation

- Lumen Extrusion (Wall thickness 1-2 mm).
- Reinforced Bends

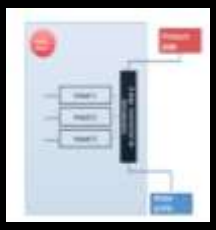
Wall Formation

- Lumen Extrusion
- Wall thickness 1-2 mm.
- Reinforced Bends

Inner Lattice structure



Experimental Setup



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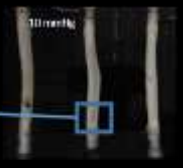
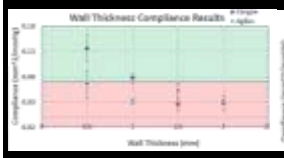
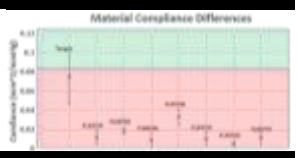
Arterial Wall Mechanics

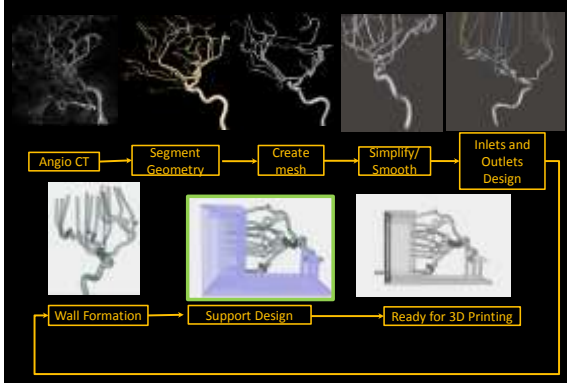


Arterial Wall Mechanics

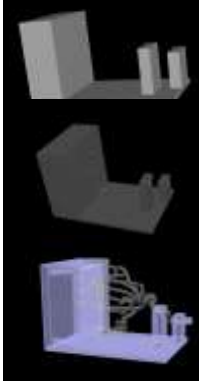




Model Development

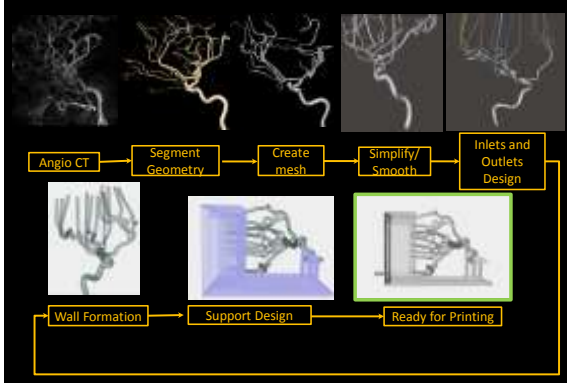


Support Design

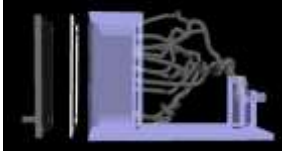


- Steps to add structures
  - Import CAD designed structure
  - Subtract model outer shell from the CAD structure
  - Add model and trim inlets and outlets

Model Development



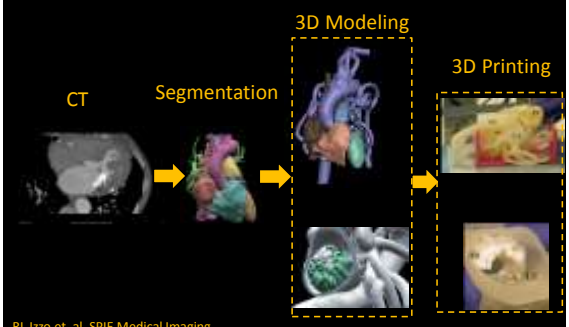
Ready for Printing*



- Steps to prepare for 3D printing
  - Add final structures
    - Chamber door
    - Rubber Seal
  - Select printing materials

Kelsey N. Sommer et. al. Design optimization for accurate flow simulations in 3D printed vascular phantoms derived from computed tomography angiography. Part of SPIE Medical Imaging 2017

Mitral Valve Cardiac Model for treatment planning*



RL Izzo et. al. SPIE Medical Imaging,

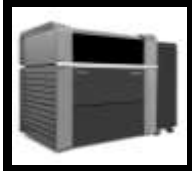
Manufacturing: 3D Printing

- Objet PolyJet 3D printer, Model260 V (Objet-Stratasys, Inc. Eden Prairie, MN)
- Printing area: 255 × 252 × 200 mm.
- Resolution for rigid materials:
  - Z-axis: ultrafine 16 micron layers,
  - X-Y plane:
    - 20-85 µm materials for features <50 mm; and up to 200 µm for full model size.
- Resolution for soft materials:
  - Z-axis 32 µm
  - XY plane 200 µm in-plane accuracy.

Manufacturing: 3D Printing

- Objet PolyJet 3D printer, Connex 3 (Objet-Stratasys, Inc. Eden Prairie, MN)
- Printing area: 340 × 340 × 200 mm .
- Resolution for rigid materials:
  - Z-axis: ultrafine 16 micron layers,
  - X-Y plane:
    - 20-85 µm materials for features <50 mm; and up to 200 µm for full model size.
- Digital model materials:
  - Hundreds of composite materials can be manufactured on the fly.

Manufacturing: 3D Printing



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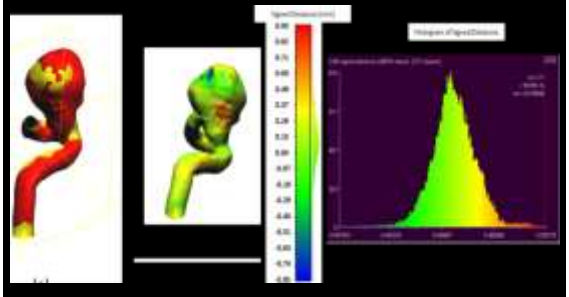
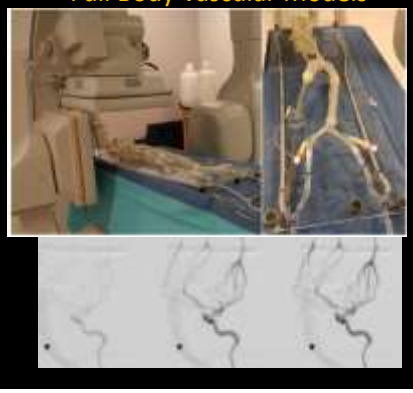
Accuracy of the 3D printing



CloudCompare, "3D point cloud and mesh processing software Open Source Project," http://www.danielgm.net/cc/

Full Body Vascular Models



Manufacturing: Phantoms

Complex Phantom
Manufacturing time $9^{1/2}$ hours

Simple Phantoms
Manufacturing time less than 20 minutes

Manufacturing
Support Cleaning

Manual Support removal can take between 2-4 hours

Support removal automation

- Use of agitation cycles
- Ultrasonic bath
- Specialized detergents
- Controlled Heating Cycles

Ultrasonic Bath (PostProcess Technologies)

Ultrasonic Cleaning Cycle

Initial

3 hours in ultrasonic Bath

One hour manual cleaning

Manual labor reduced by 50%-60%, however still substantial

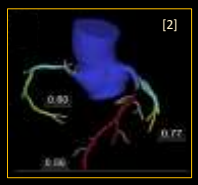
Outline

- Phantom testing and treatment planning:
  - Clinical software validation
  - Endovascular intervention simulation and device testing
  - Treatment Planning

Clinical Software Validation: Fractional Flow Reserve

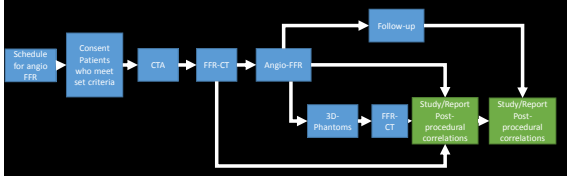
Fractional Flow Reserve:

- One standard diagnosis method is Fractional Flow Reserve (FFR)
- Minimally invasive procedure with associated risks
- Use CT angiography images and computational fluid dynamic methods to estimate FFR



[1] Cury RC, *et al*, "Coronary Artery Disease - Reporting and Data System (CAD-RADS): An Expert Consensus Document of SCCT, ACR and NASCI: Endorsed by the ACC" JACC Cardiovasc Imaging. 2016 Sep;9(9):1099-113. doi: 10.1016/j.jcmg.2016.05.005.
[2] Chinnaiyan, et al. Rationale, design and goals of the HeartFlow assessing diagnostic value of non-invasive FFRCT in Coronary Care (ADVANCE) registry. J Cardiovasc Comput Tomogr 2017;11(1):62-7

CT-FFR Software Validation: Study Design

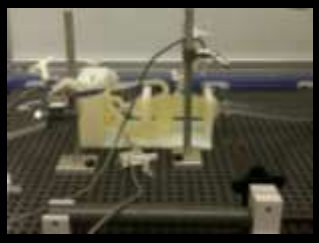


Kelsey N. Sommer et. al. SPIE Medical Imaging 2018

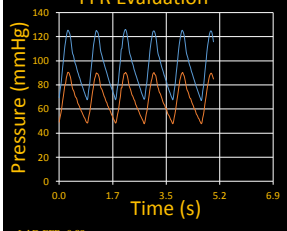
CT-FFR Software Validation: Phantom manufacturing

Kelsey N. Sommer et. al. SPIE Medical Imaging 2018

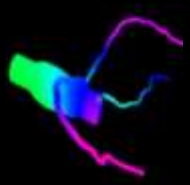
CT-FFR Bench-top validation



FFR Evaluation

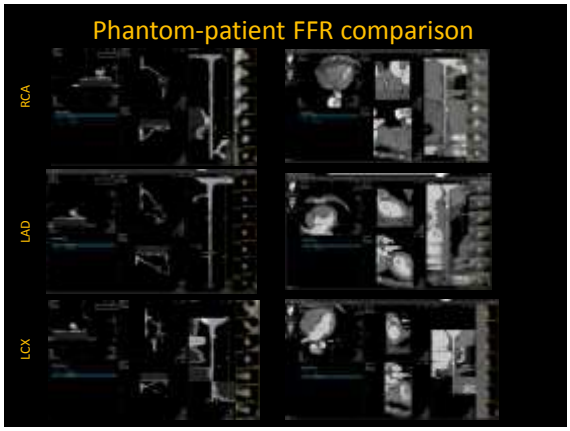


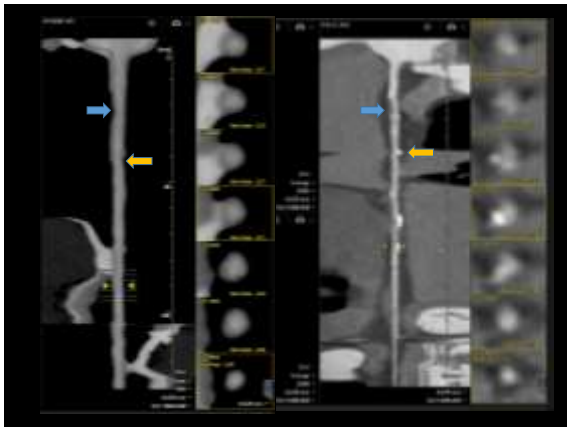
LAD FFR: 0.82

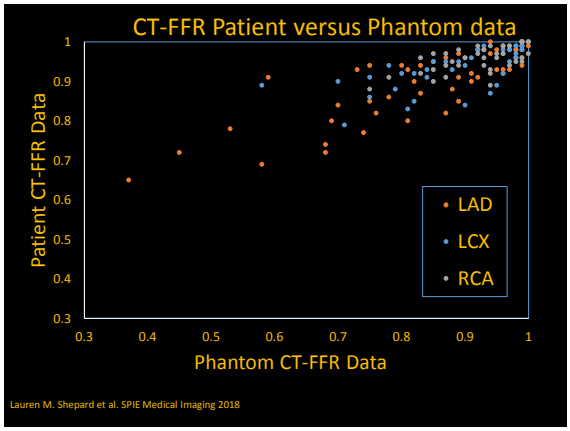


Pressure Mapping

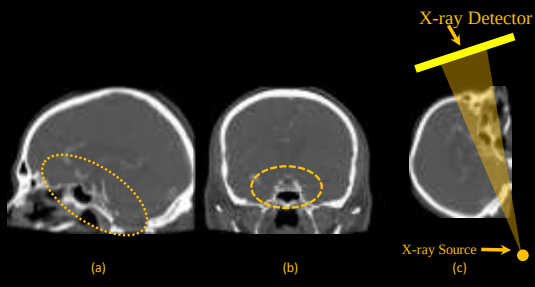
CT-Experimental Setup


Phantom-patient FFR comparison
RCA
LAD
LCX

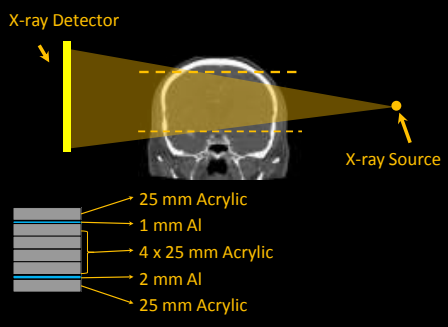



CT-FFR Patient versus Phantom data
Patient CT-FFR Data
Phantom CT-FFR Data
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
LAD
LCX
RCA
Lauren M. Shepard et al. SPIE Medical Imaging 2018

Interventions in the Circle Of Willis

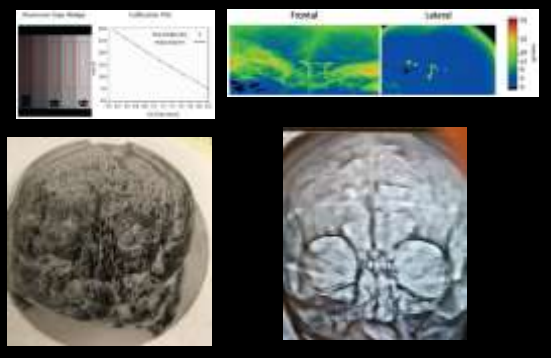


AAPM lateral head equivalent phantom*

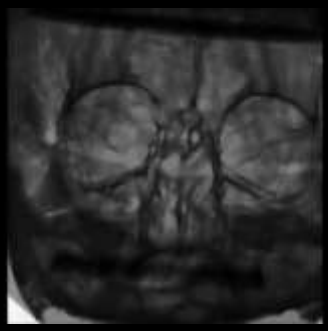


* AAPM Report No. 31, Report of task group 8, diagnostic x-ray imaging committee, standardized methods for measuring diagnostic x-ray exposures,

Anatomical noise overlay (UB-CAT Vader Systems)



DA and DSA



Phantom Testing: Procedure Simulation

- Various clots made from rabbit blood with different lengths were created
- Clots were deployed in the Middle Cerebral artery region

Medscape:
Trevo Pro Retriever (Stryker Neurovascular)

Phantom Testing : Procedure Simulation

Pre-Procedure DSA

Procedural Roadmap

Intra-Procedure DSA

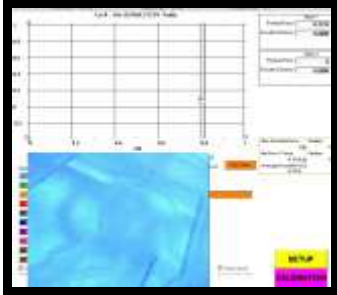
Post-Procedure DSA

Thrombectomy evaluation in 3D printed phantoms

Stent retriever thrombectomy with the Cover accessory device versus proximal protection with a balloon guide catheter: in vitro stroke model comparison

Comparison of Modern Stroke Thrombectomy Approaches Using an In Vitro Cerebrovascular Occlusion Model

Device Testing



Example of Coil Deposition in a basilar Aneurysm:

- Motorized actuation
- Automatic force registration
- Automatic catheter motion encoding
- Video recording

Treatment planning*

Grafts/ Stent Bodies

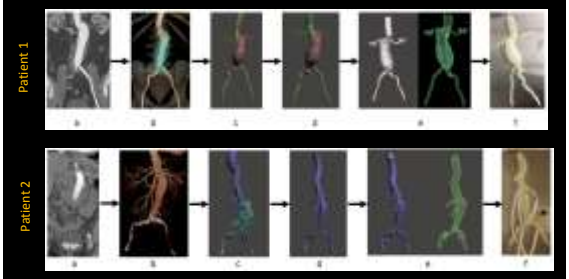
Patient Specific Zenith® Fenestrated AAA Endovascular Graft (Cook Medical) –

Distal Bifurcated Body Graft (Spiral Z)

Contralateral/ Ipsilateral Iliac Leg Graft (Ipsa Spiral Z limb)

Karen M. Meess et. al. 3D printed abdominal aortic aneurysm phantom for image guided surgical planning with a patient specific fenestrated endovascular graft system. Part of SPIE Medical Imaging 2017

AAA Phantom Fabrication Process



(a) Patient Diagnostic CT-A; (b) 3D Reconstruction; (c) Segmented Anatomy conversion to STL Meshes; (d) Design Simplification; (e) Final Phantom Design STL; (f) 3D Printed AAA Phantom

AAA Phantom Fabrication Process

Image → 3D Printed Model Process

Surgical Planning

Phantom vs. Patient Procedure Fluoroscopy

Phantom Patient

Proximal Body CODA Balloon Inflation to ensure graft seal, preventing endoleak

Phantom Patient

Distal Body CODA Balloon Inflation to ensure gate access prior to ipsilateral leg graft deployment

Treatment simulation using patient-specific 3D printed models for High- Risk Surgery patients

Patient	Vascular disease (literature case reports)	Immediate post procedure outcome	One year Follow-up
Female (62 yo)	MCA aneurysm	No complications	Alive/ no complications
Male (72 yo)	Giant Vertibro-Basilar Aneurysm	Died 48 hours post procedure	Died (Respiratory Arrest)
Male (65 yo)	Fusiform basilar aneurysm	No Complications	Alive/ no complications
Female (65 yo)	Mitral Valve replacement[2]	No Complications	Died 1 month post procedure
Female (70 yo)	Mitral Valve replacement	No Complications	Died 4 months post procedure
Male (70 yo)	Pulmonic Valve replacement	No Complications	Alive/ no complications
Male (65 yo)	EVAR (Chronic Thrombosed AAA)	No Complications	Alive/ no complications at 9 months
Male (80)	EVAR (Fenestrated Endovascular repair)	No Complications	Alive/ no complications at 6 months
Male* (80)	EVAR	No Complications	Alive/ no complications
Female* (73 yo)	EVAR[3]	No Complications	Alive/ no complications
Female* (79 yo)	EVAR[4]	No Complications	Alive/ no complications

Conclusions

- 3D printing allows development of some of the most complex vascular geometries
- 3D printed models could allow faster:
  - Device development.
  - Better tools for software validation.
  - Treatment planning and training.

Thank you