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3D Image Based Inspection and Simulation Applied to Additive Manufactured Spinal Truss Medical Implants

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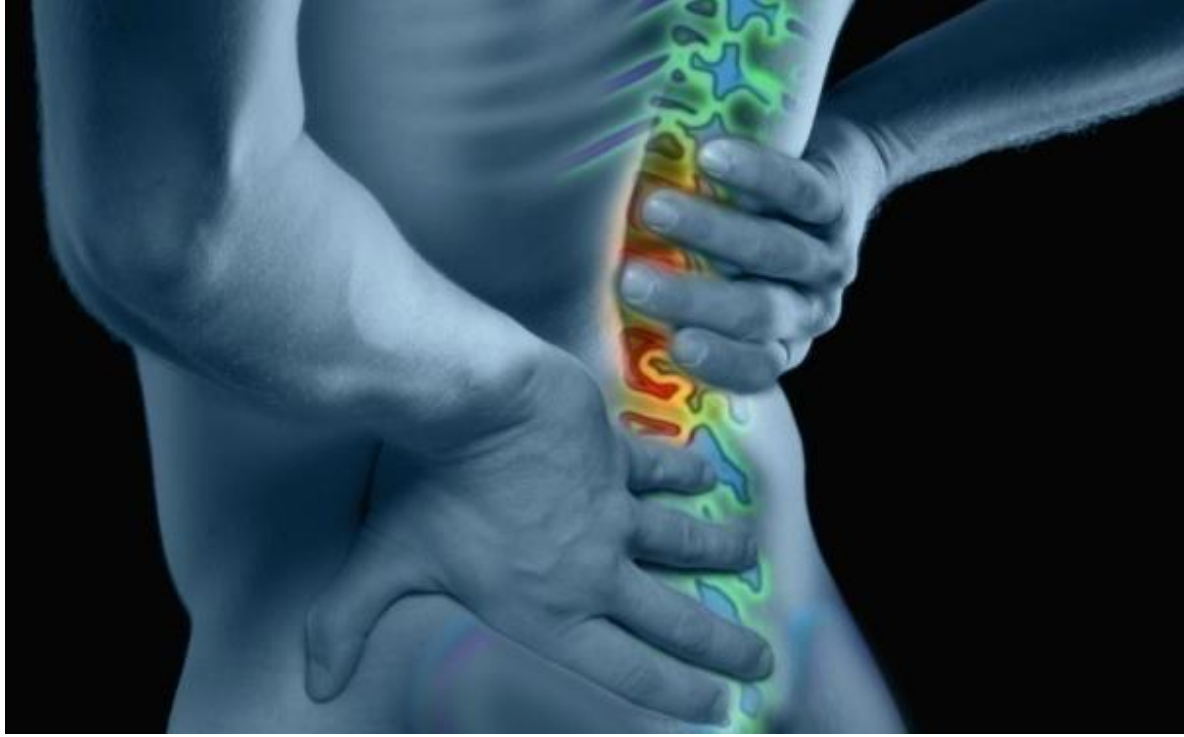
[1]Synopsys, [2]4Web Medical, [3]Nikon Metrology [4]OnScale [5]Thornton Tomasetti, [6]University of Exeter

September 2019

Background

Low-Back Pain

- 84% of adults will have low back pain at some point
- Wide variety of approaches for treatment
  - Suggests that optimal approach is unsure
- Some suffer from chronic or recurrent courses, with substantial impact on quality of life
- Number of approaches for Lumbar Interbody Fusion (LIF)
- 4Web Medical has developed a posterior spine truss system
  - First company to have FDA 510(k) Cleared Additive Manufactured (AM) device for implantation onto patients
  - Uses Titanium alloy (Ti6AL4V) manufactured using Electron Beam Melt (EBM) technology



4WEB MEDICAL

POSTERIOR SPINE TRUSS SYSTEM™

Typical AM Workflow

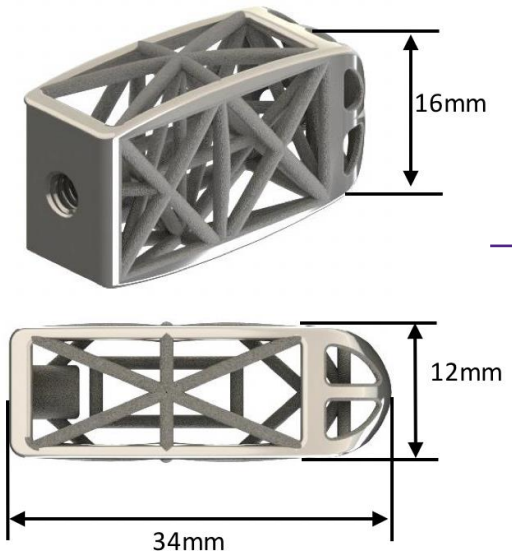
A simplified view of the design, simulation and AM workflow

CAD-Based Design

CAD-Based Simulation

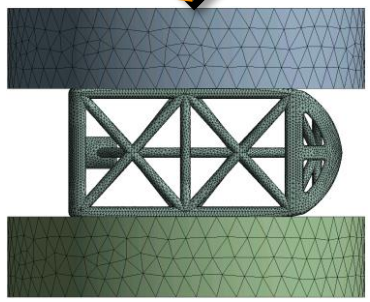
AM Build

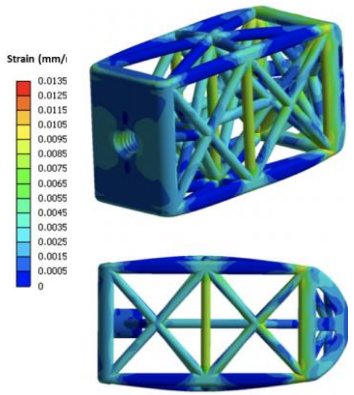
OSTS-MD0016-34



Compression

Compression -Shear



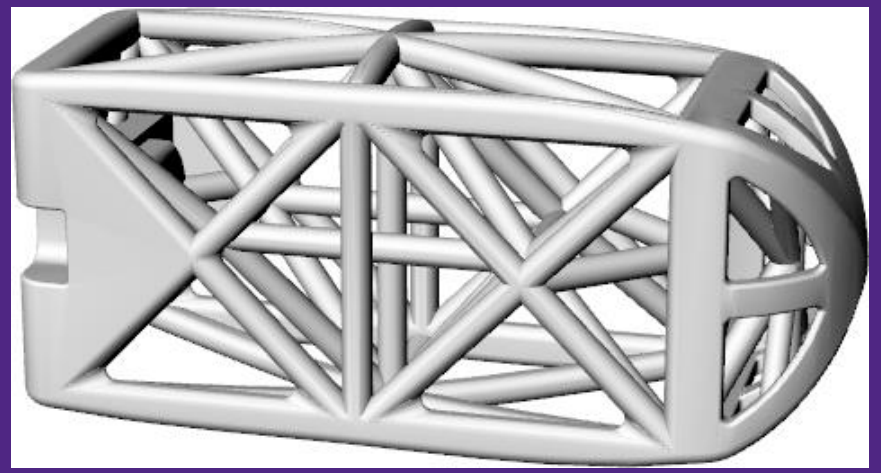


Mechanical testing per ASTM F2077-17 (Test Methods For Intervertebral Body Fusion Devices)

Quality?
Accuracy?
Performance?

BIG QUESTIONS

As-Designed



VS

As-Built

What are the differences?

How do these differences affect **performance**?

Quality Control of AM Medical Devices

SYNOPSYS® | SIMPLEWARE PRODUCT GROUP

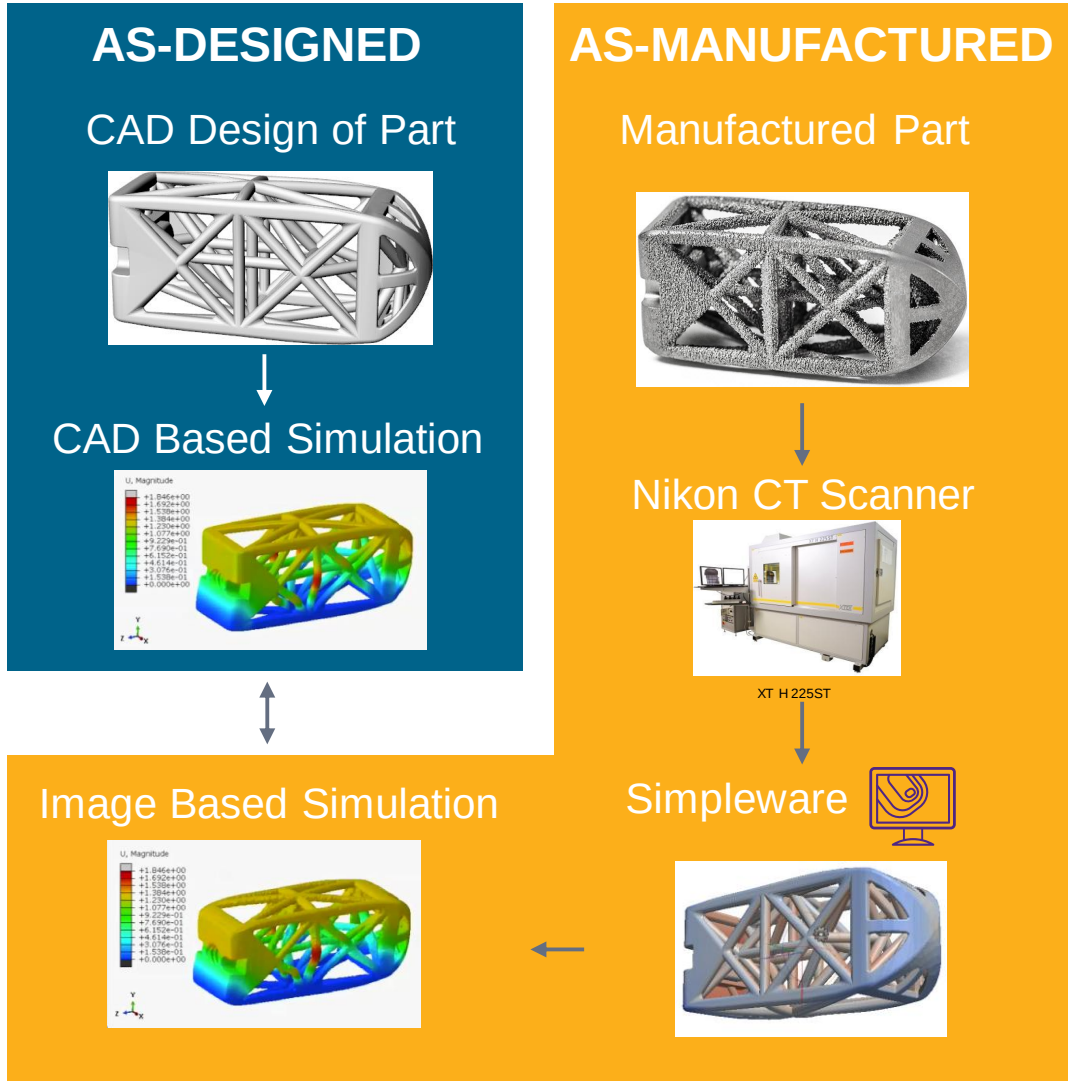
In Collaboration With:

4WEB MEDICAL

Nikon

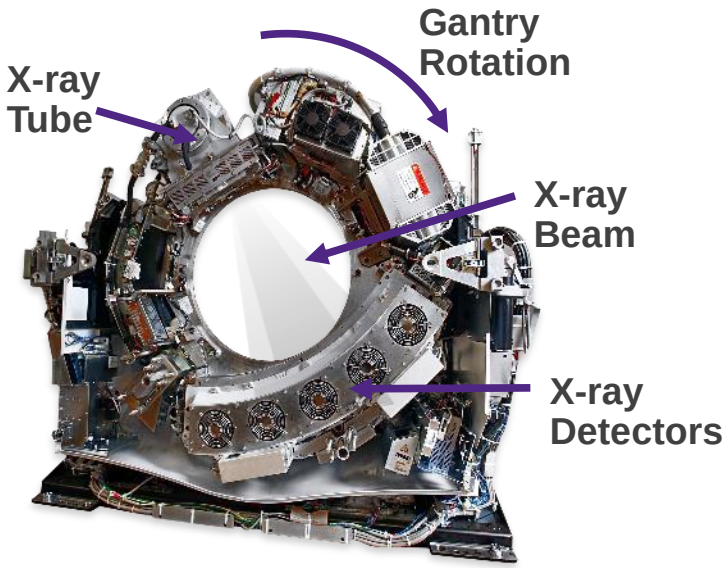
Thornton Tomasetti

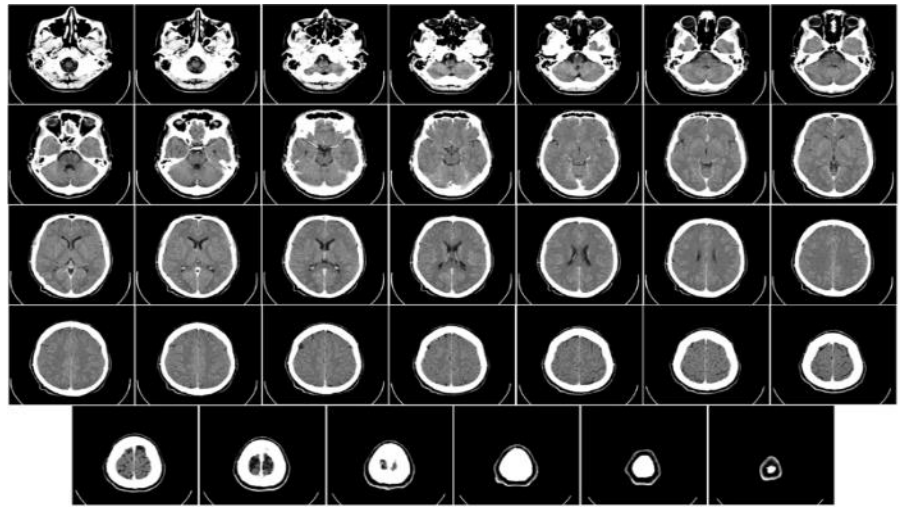
- There continues to be uncertainty in as-built vs. as-designed geometry/performance
- Need to understand how the as-manufactured part differs from as-designed
- Leveraging Computed Tomography (CT) and Image-Based Finite Element (FE) Simulation
- Goal: Understand geometric AND performance uncertainties through image-based simulation through a proof of concept workflow



What is Computed Tomography (CT)?

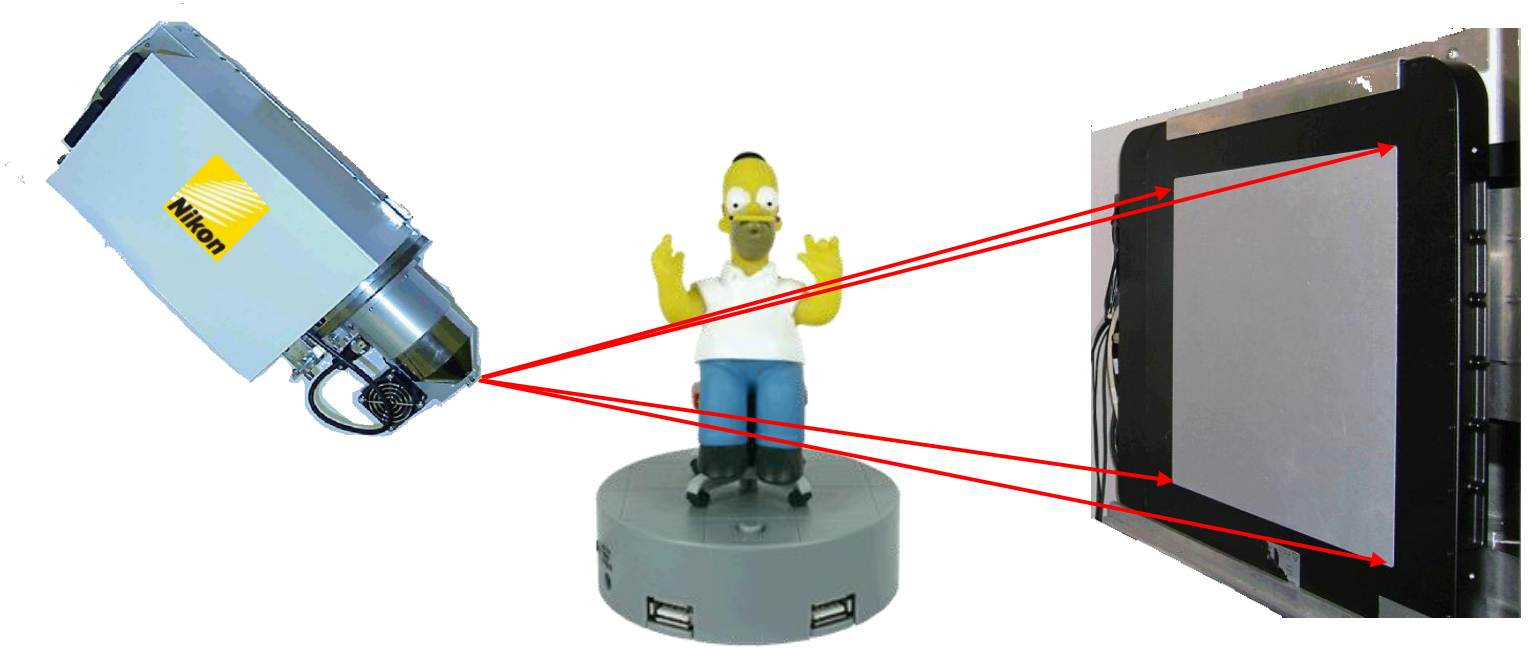
- Process of imaging an object from all directions using penetrating radiation (X-rays) and reconstructing the internal 3-D structure from the intensity values in the projected images.





What is Computed Tomography (CT)?

- Industrial CT keeps the source and detector stationary and rotate the object. Hospital patients might complain if we did this to them!



What is Computed Tomography (CT)?

- Industrial CT keeps the source and detector stationary and rotate the object. Hospital patients might complain if we did this to them!
- The scanning is normally done in a large lead-shielded cabinet:

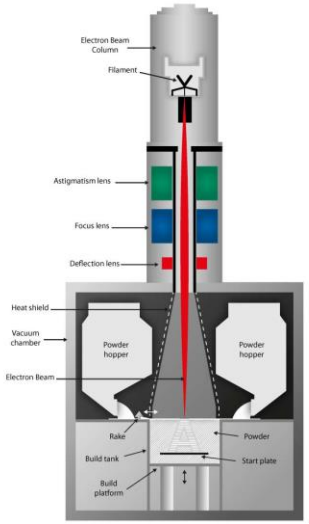
Nikon XT H 225

Nikon XT H 320/450

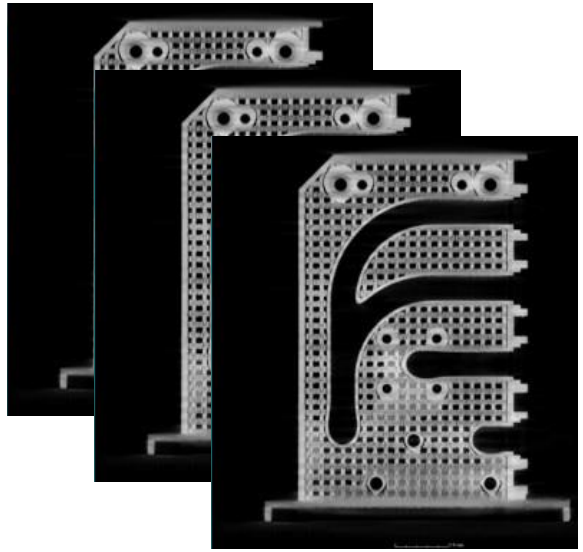
Nikon XT H 225ST

AM to CT Scan

Electron Beam Melting (EBM)

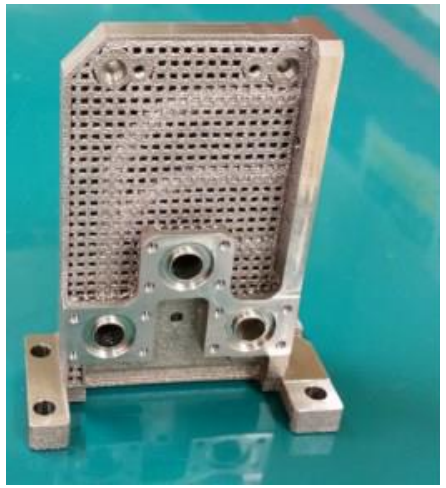


http://www.arcam.com/technology/electron-beam-melting/hardware



Exported Image Slices

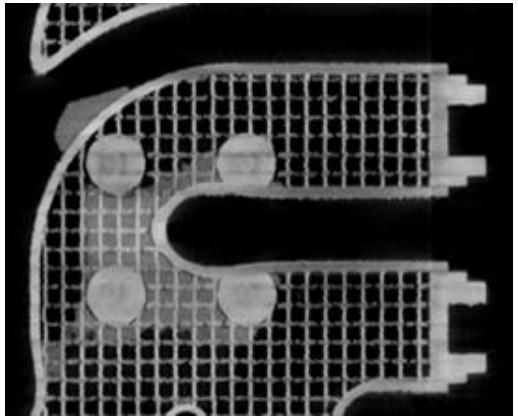
AM Titanium Alloy (Ti6Al4V) Manifold



CT Scanner

AM Problems Discovered Through CT

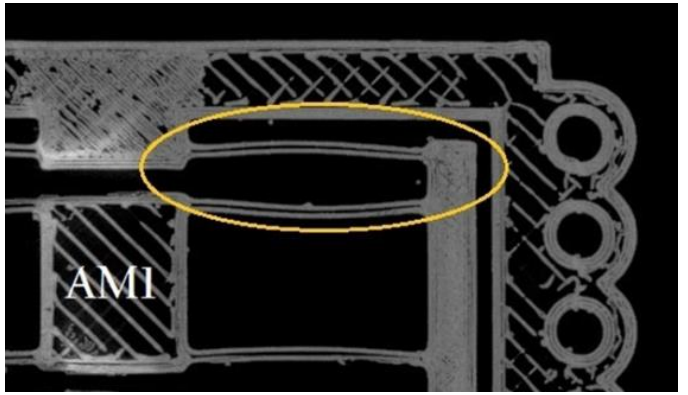
What do we look for when checking the structural integrity of AM parts?



Powder residues blocking channels

Defect (voids, pores, cracks, inclusions)

Departure from CAD model – dimensional analysis, wall thickness measurements, checking for warping.

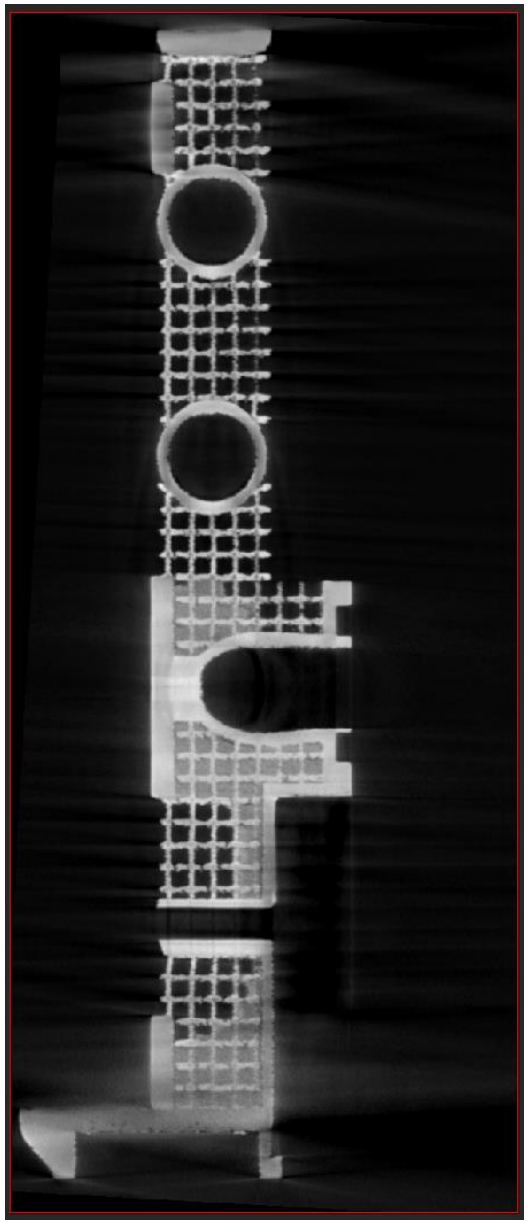


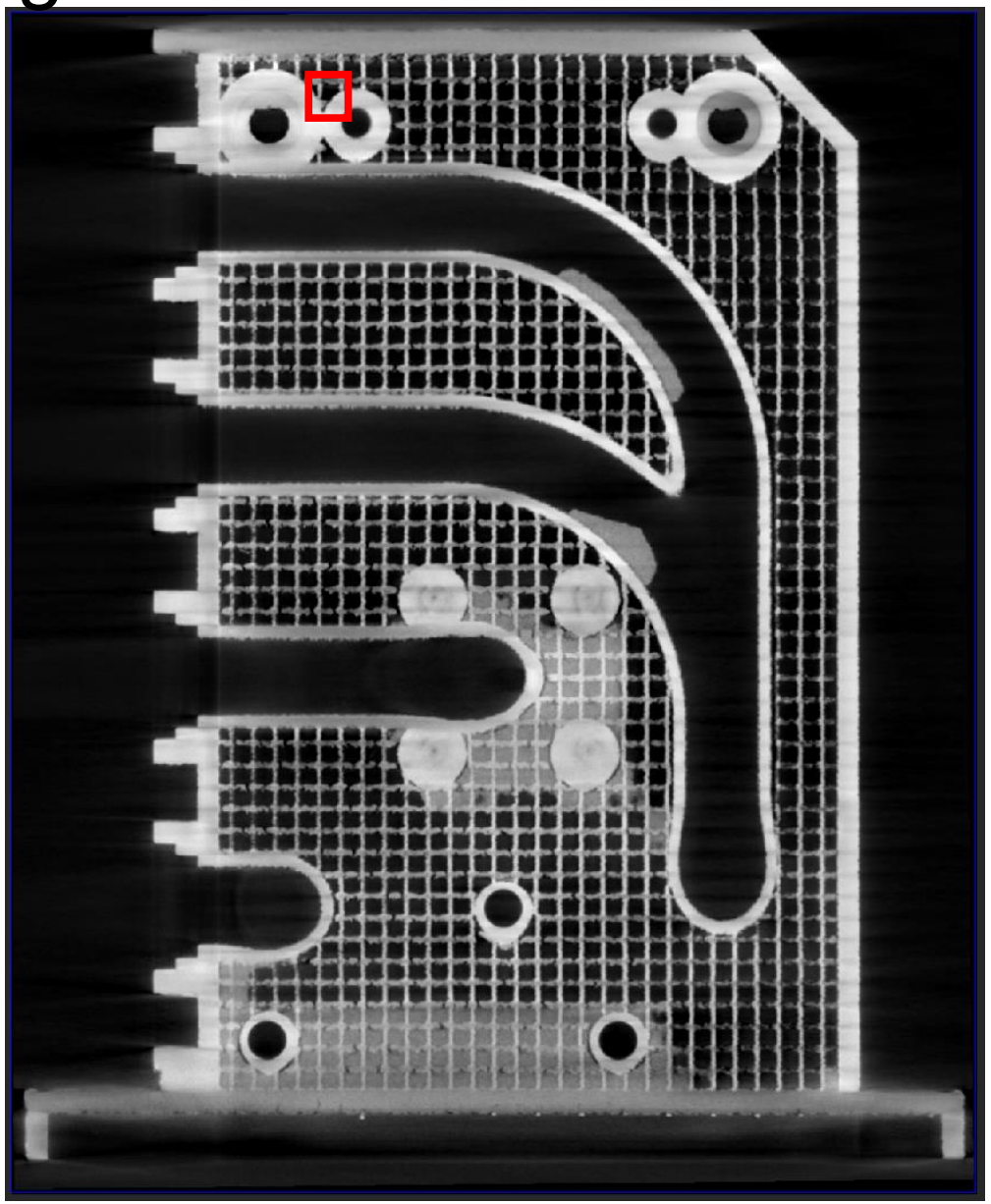
Allow you to examine geometric differences from design

BUT WHAT ABOUT PERFORMANCE DIFFERENCES FROM DESIGN?

10

All image roads lead to a grid…





All image roads lead to a grid…

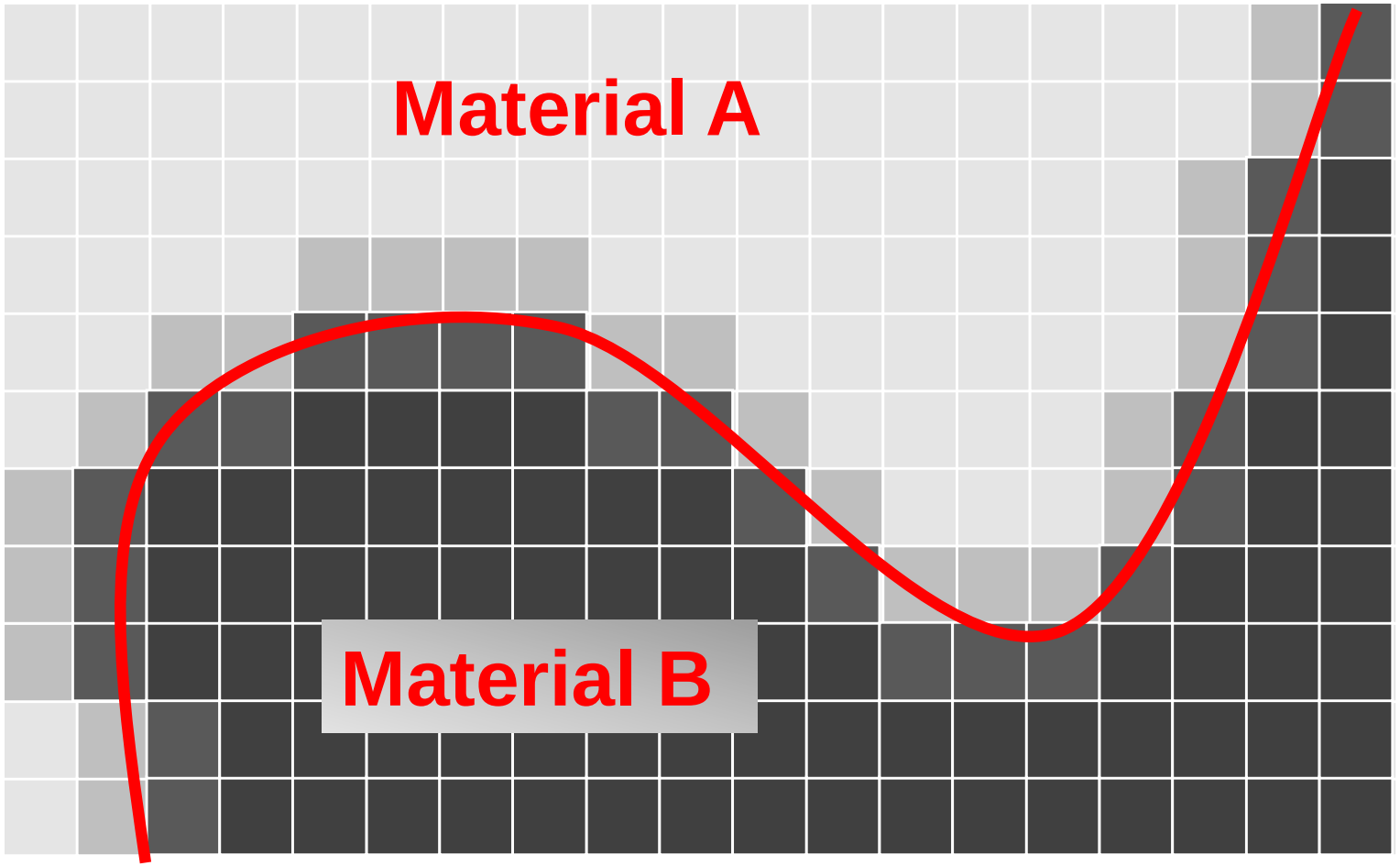


Image-based meshing workflow in Simpleware

1. Import volume image data

Image-based meshing workflow in Simpleware

2. Voxel Grid Formed

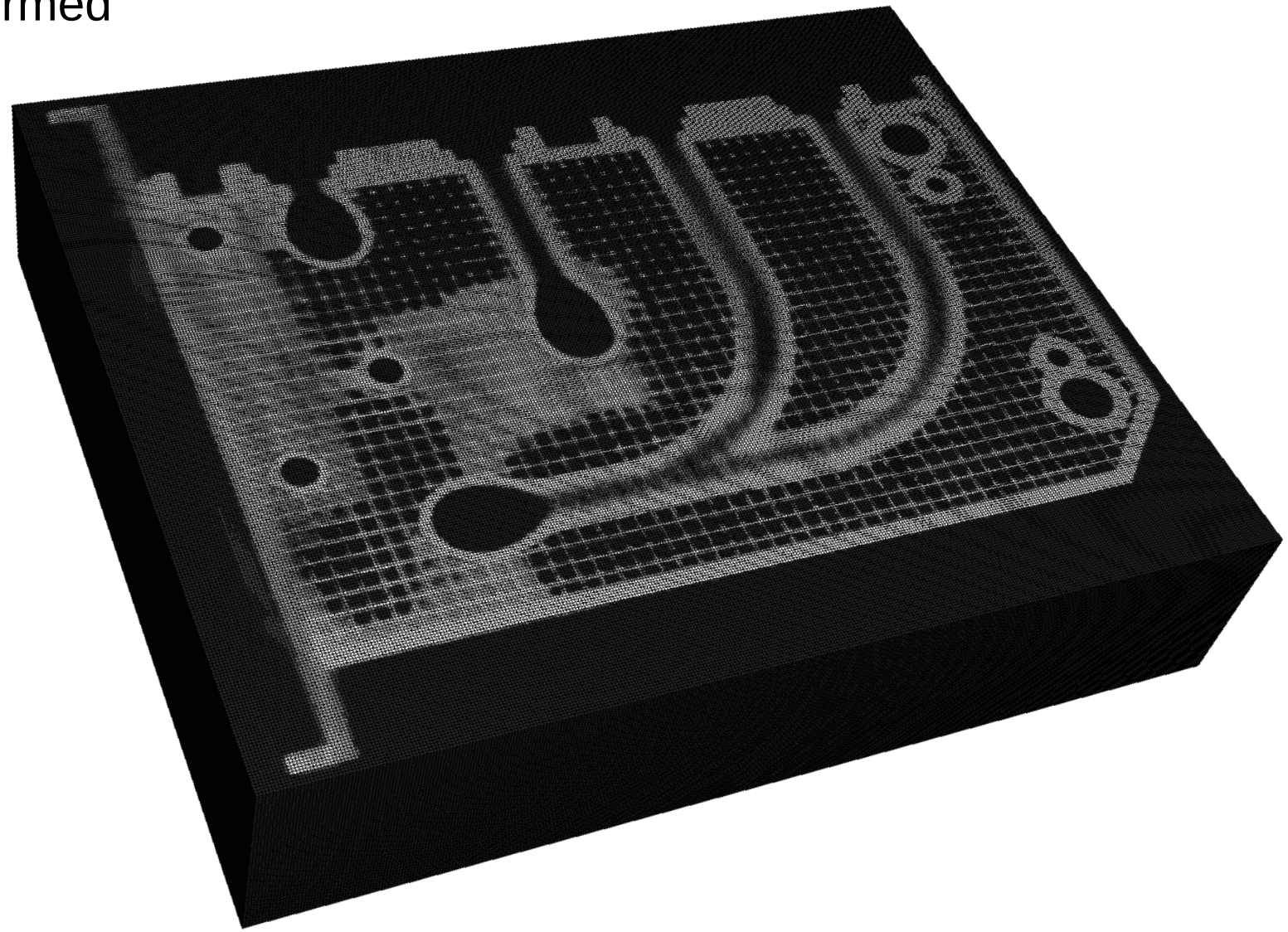


Image-based meshing workflow in Simpleware

3. Segmentation of regions of interest

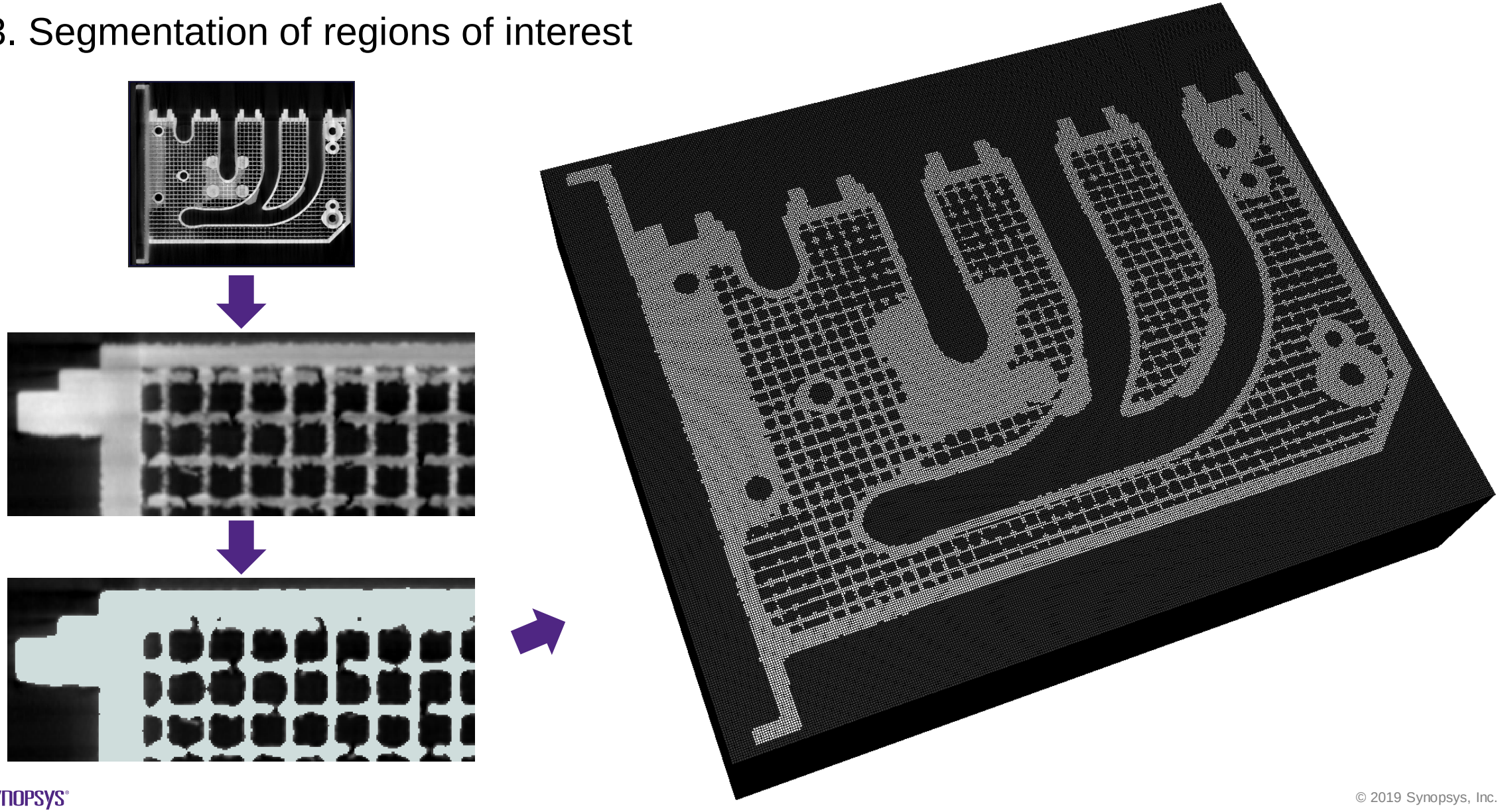


Image-based meshing workflow in Simpleware

4. Extract Segmented Voxels

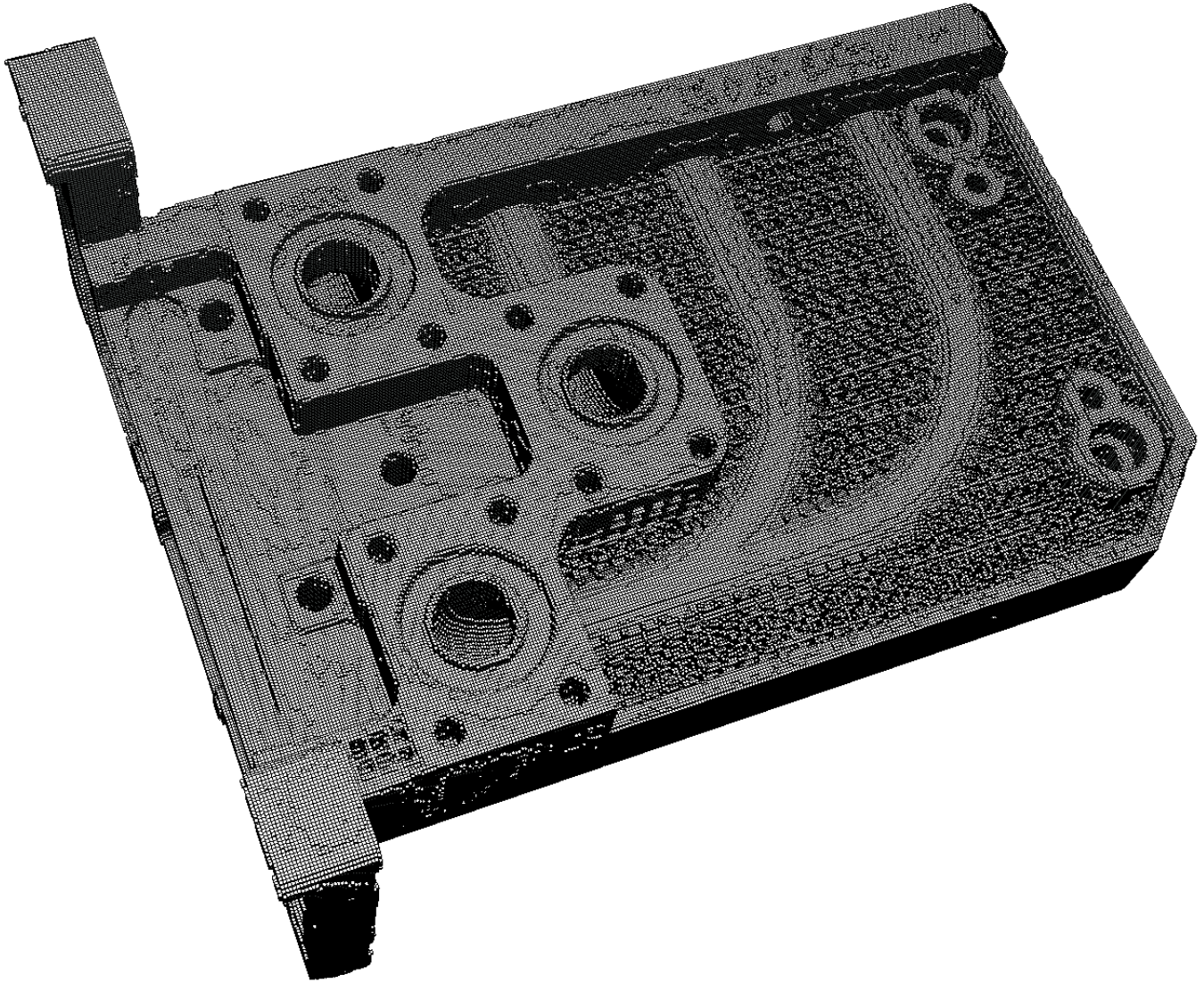
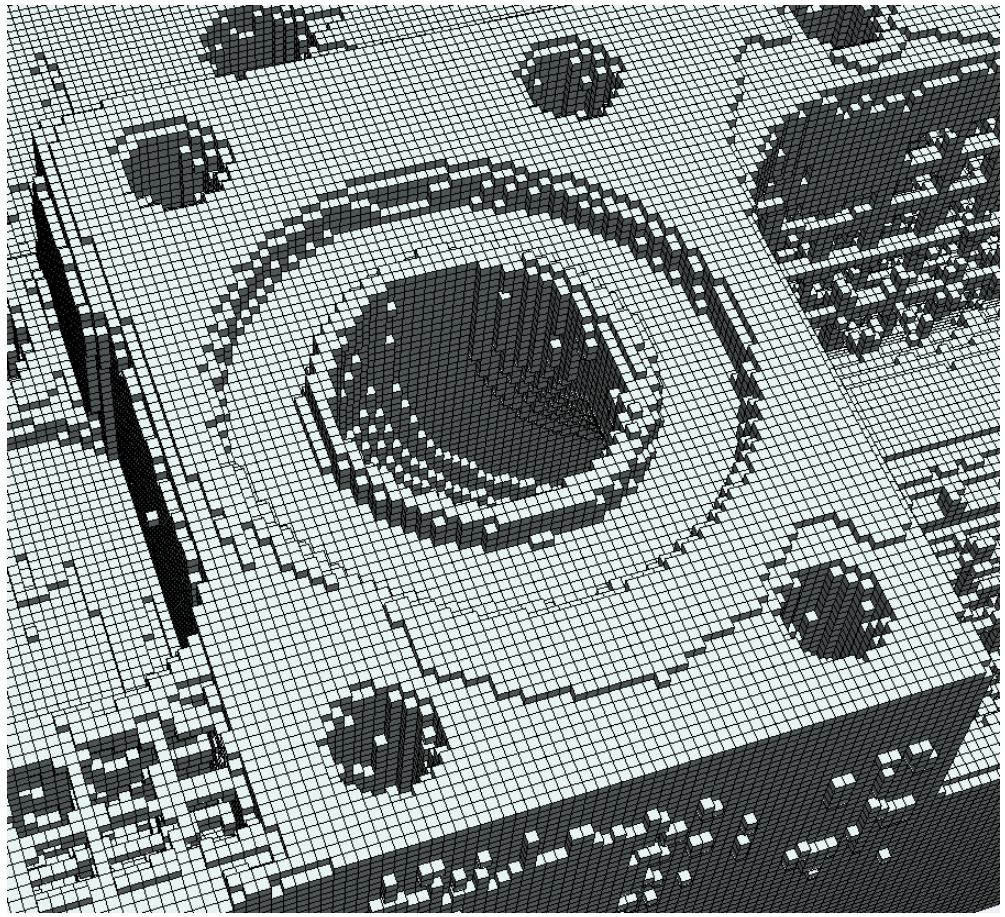


Image-based meshing workflow in Simpleware

4. Extract Segmented Voxels



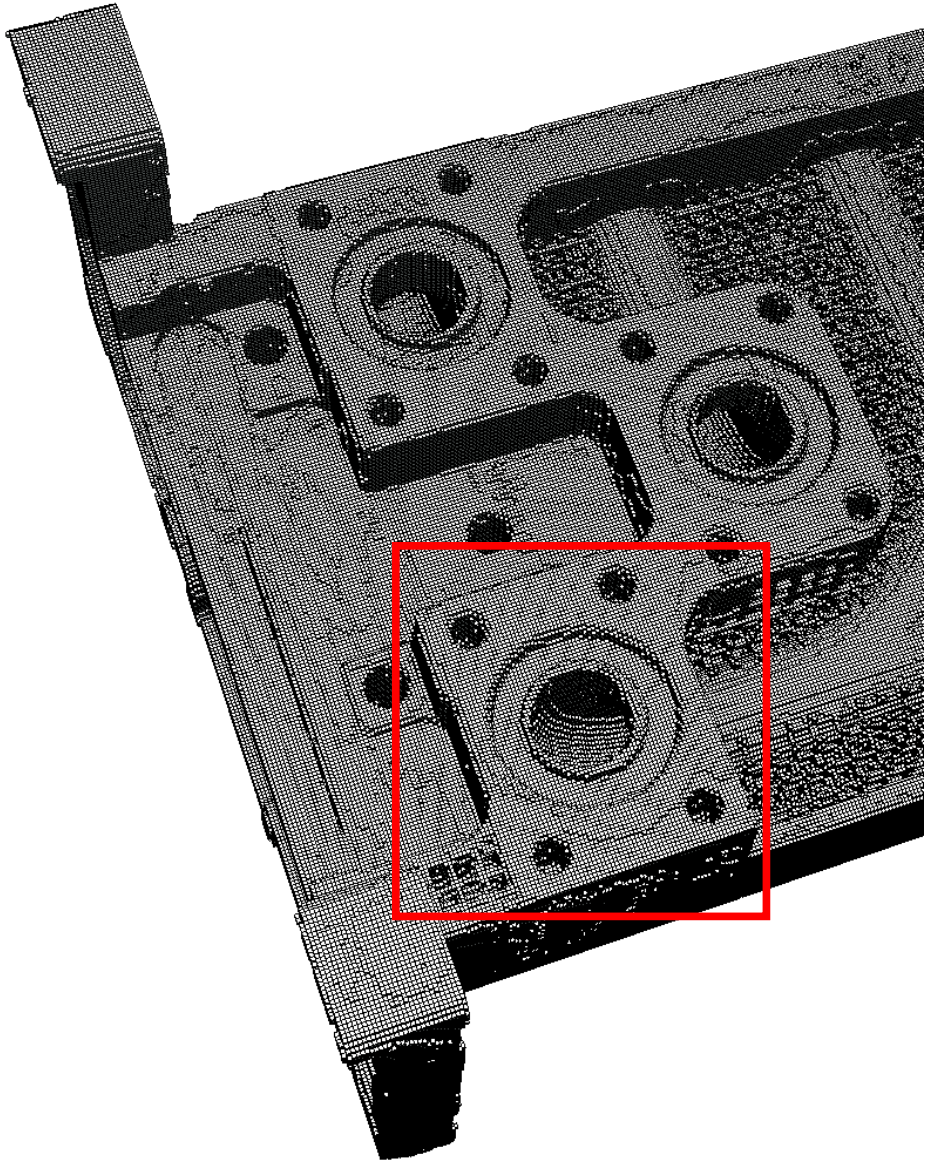
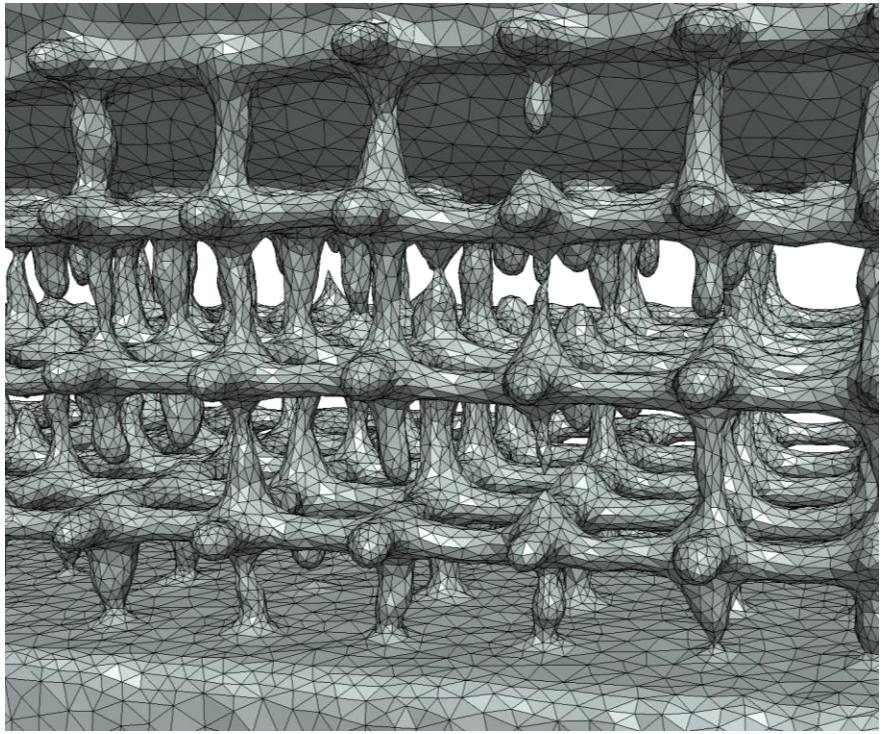


Image-based meshing workflow in Simpleware

5. Create surface mesh (STL)



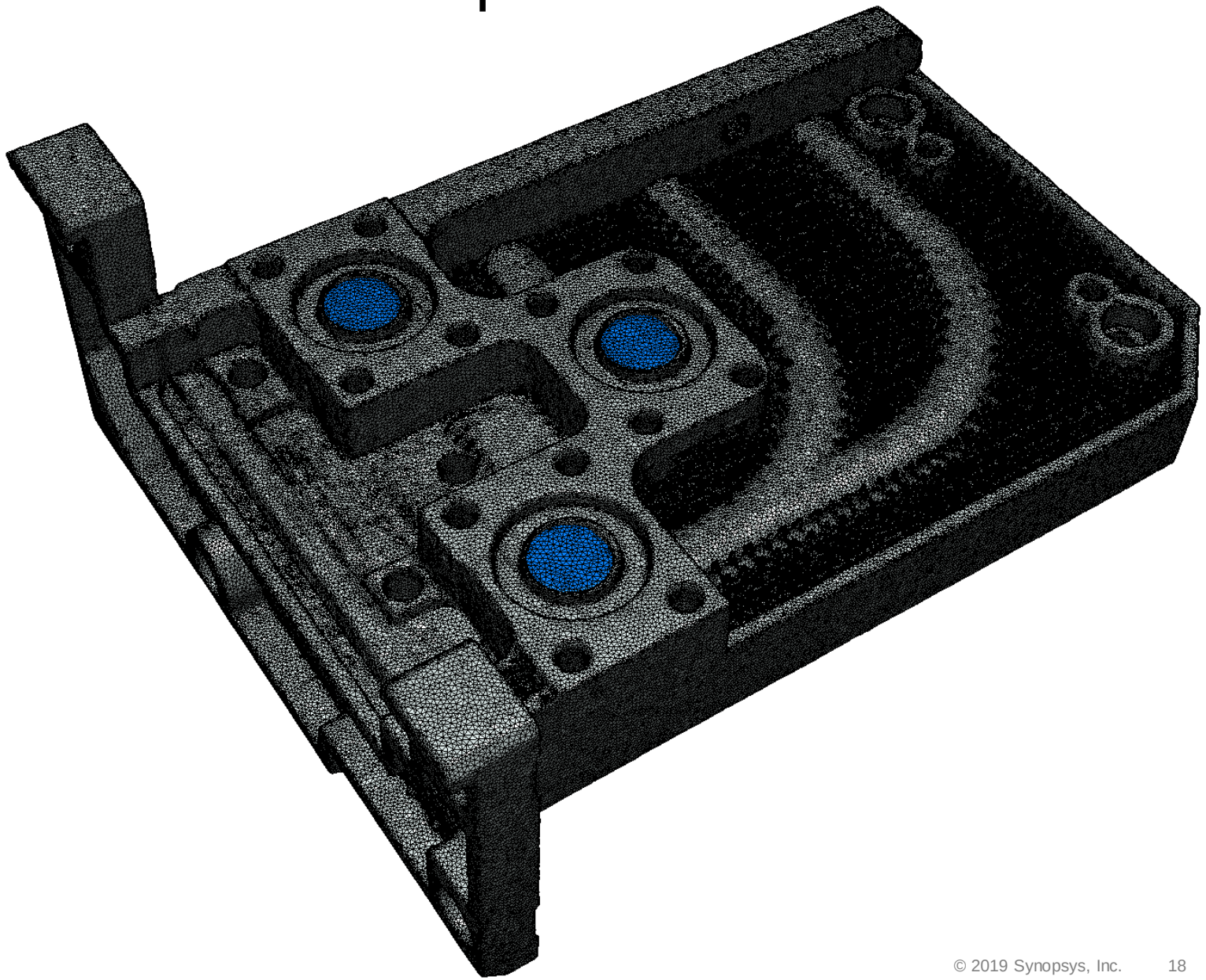
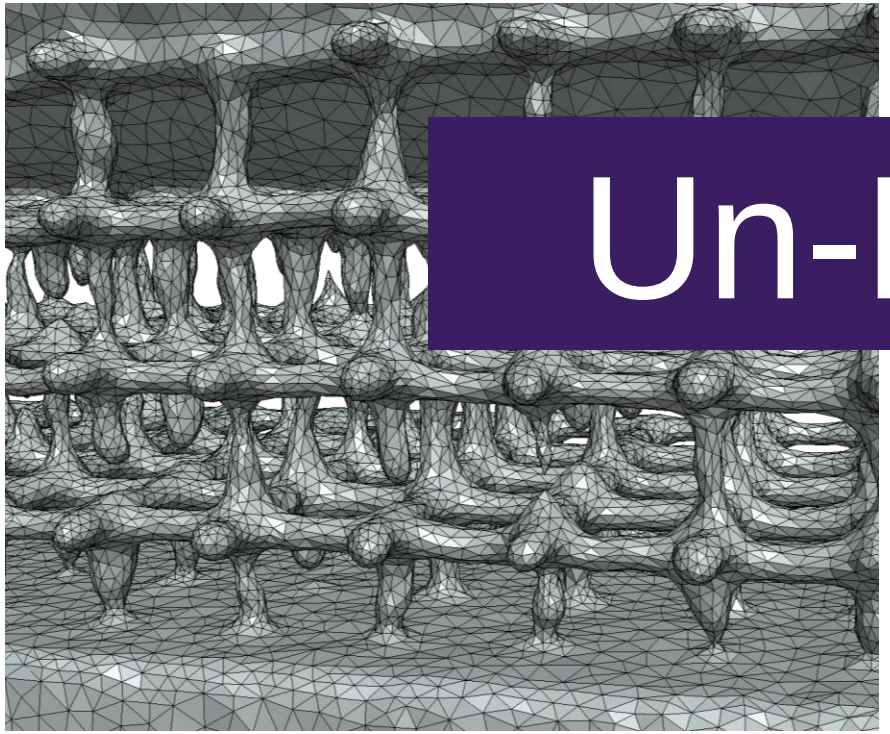


Image-based meshing workflow in Simpleware

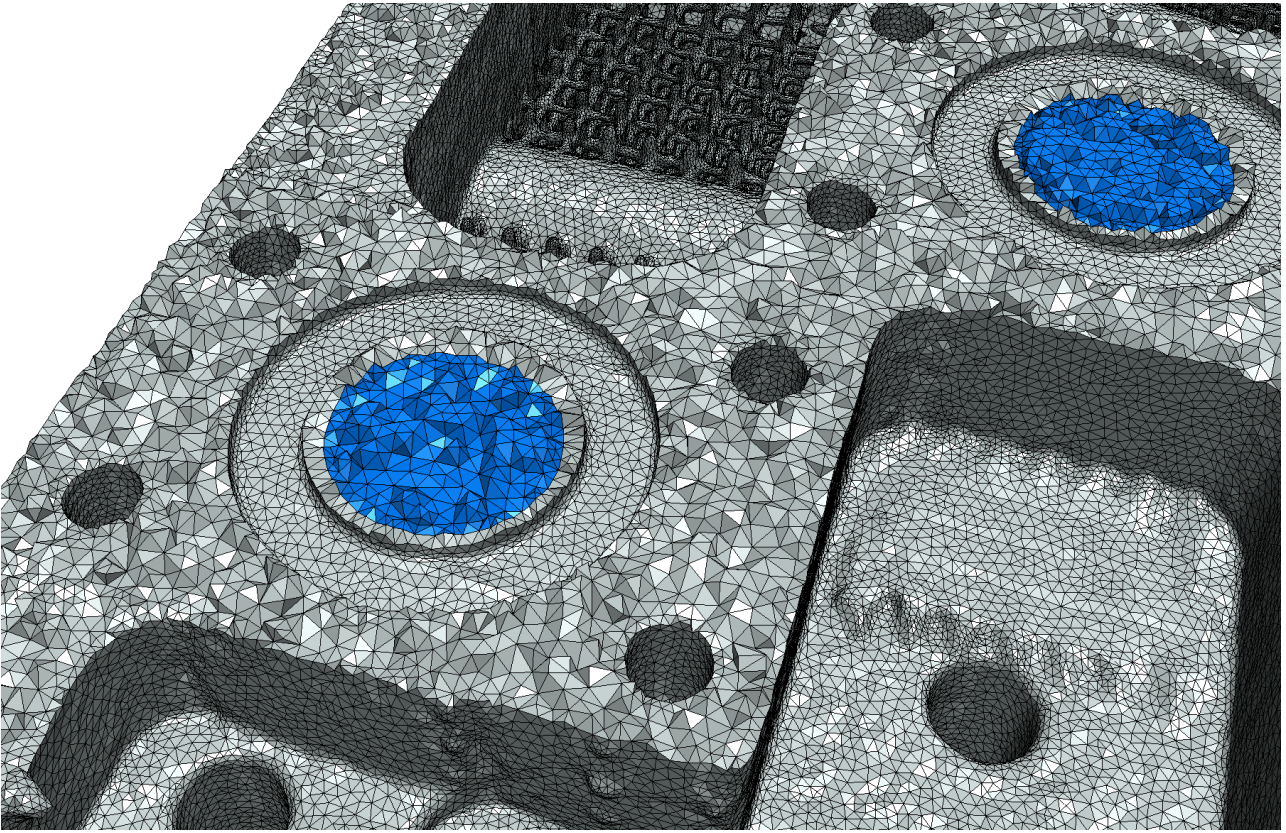
5. Create surface mesh (STL)

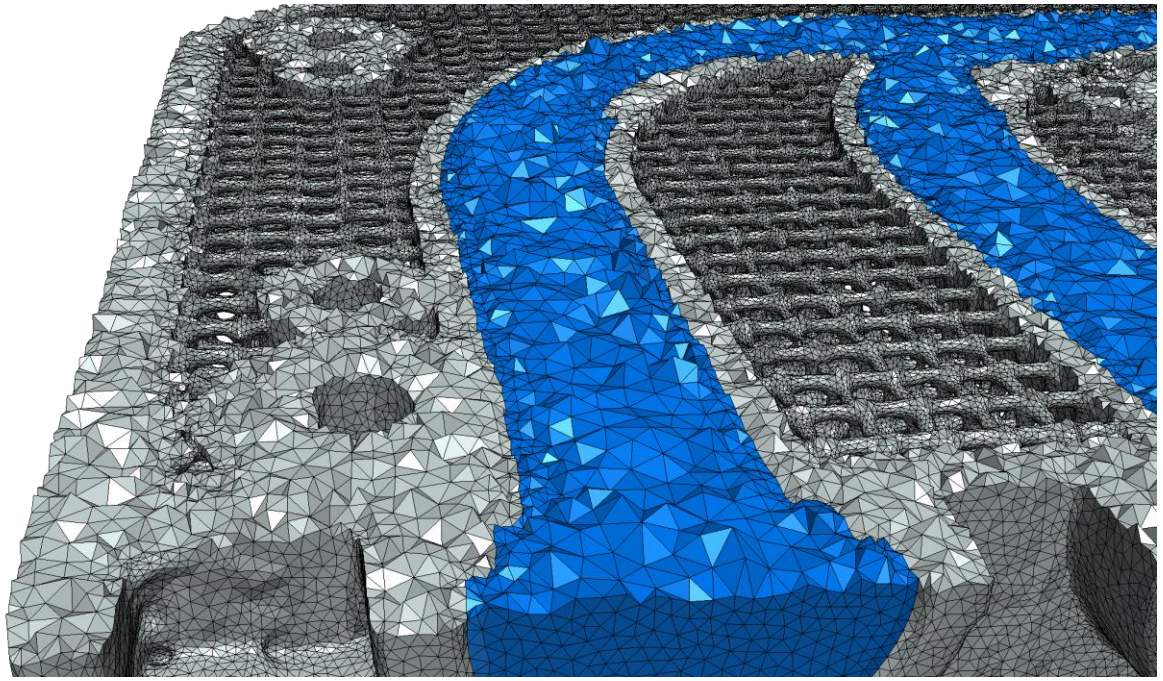


Un-Meshable??

Image-based meshing workflow in Simpleware

6. Create volumetric FE/CFD mesh

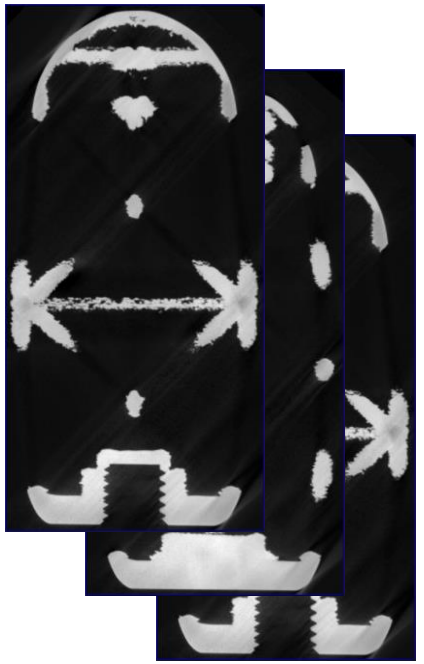




4Web AM part CT Scan

4WEB Truss Implant
AM Titanium Alloy
(Ti6Al4V)

CT Scanner
(Nikon XTH 225 ST)



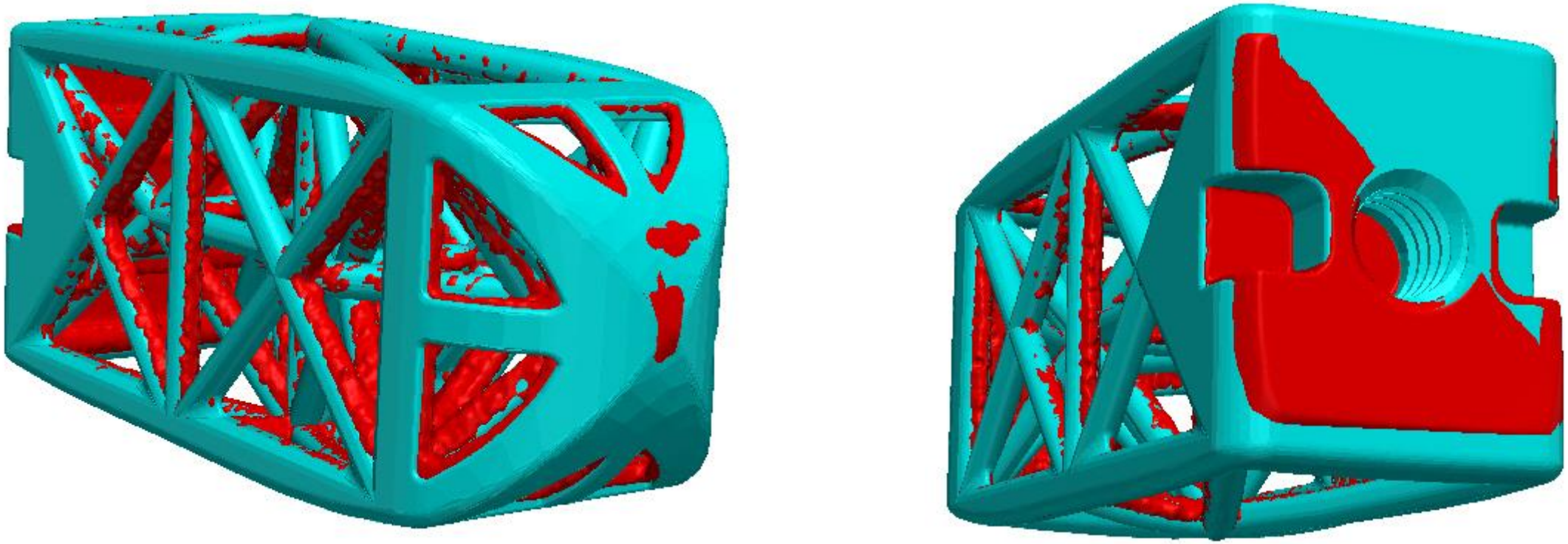
Exported Image Slices
(18μm cubic resolution)

FE model Reconstruction from Image Data

Simpleware Software (Synopsys Inc., Mountain View, CA) – Image Processing & Meshing

Surface Deviations

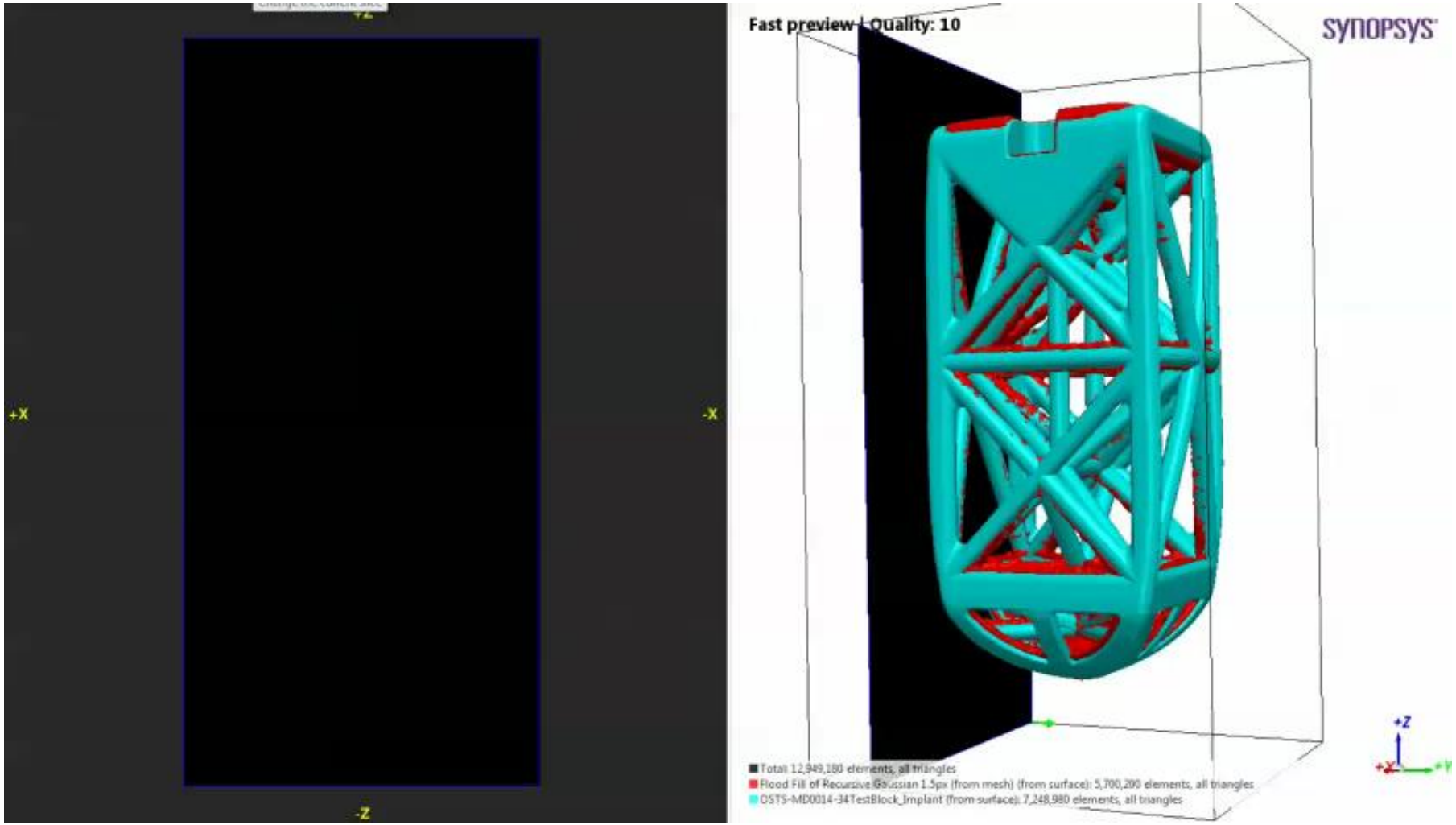
Comparing as-manufactured reconstruction to as-designed CAD



- As-designed (CAD model)
- As-fabricated (CT scan)

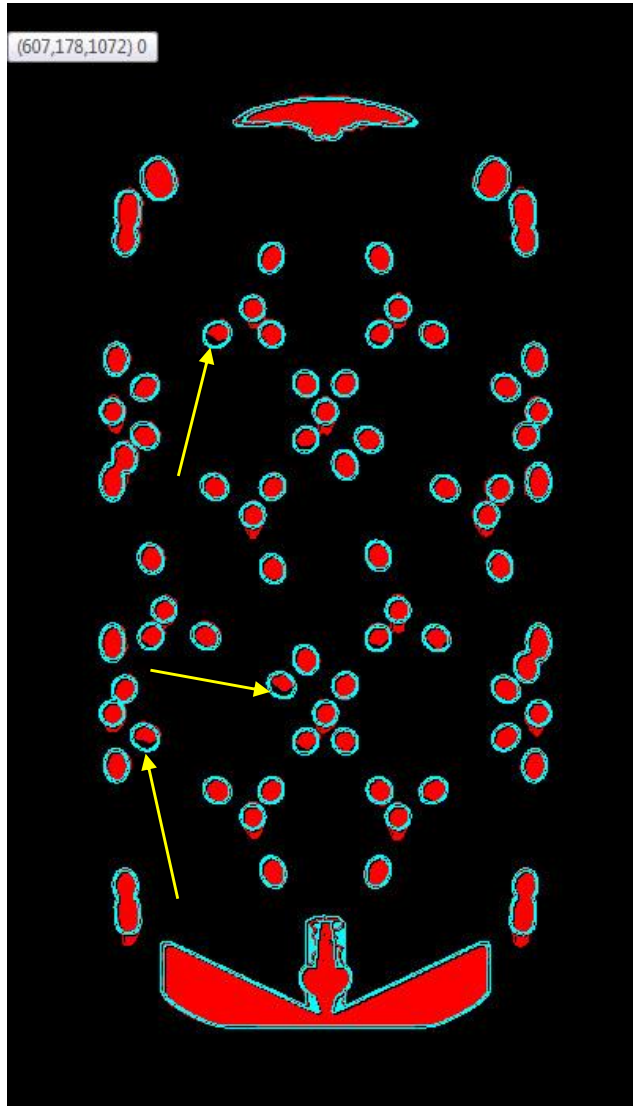
Surface Deviations

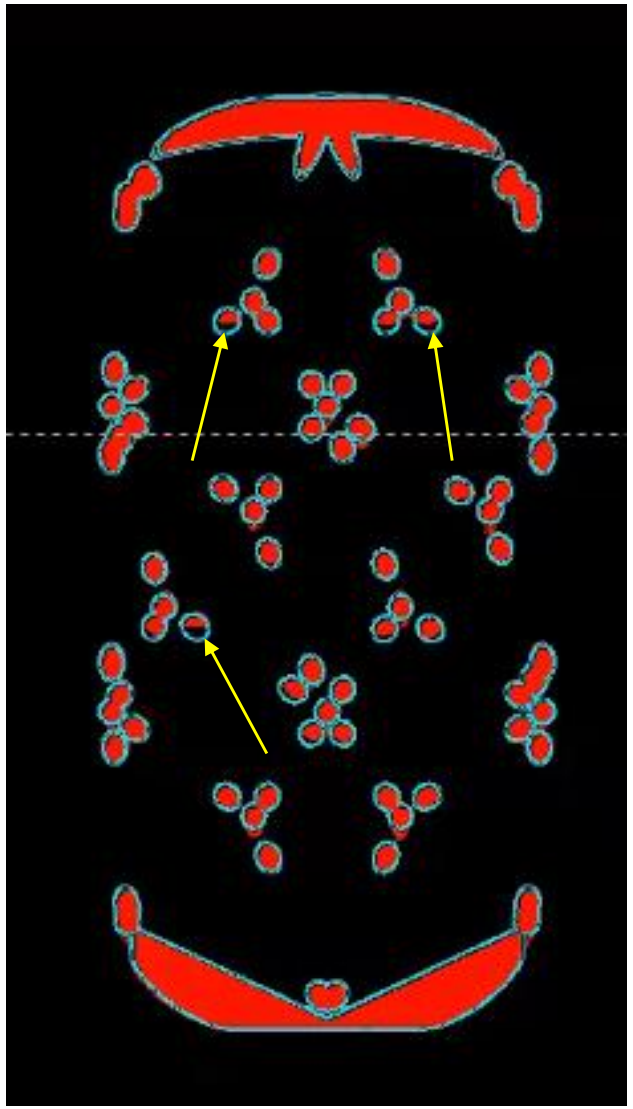
Comparing as-manufactured reconstruction to as-designed CAD



Surface Deviations

Comparing as-manufactured reconstruction to as-designed CAD

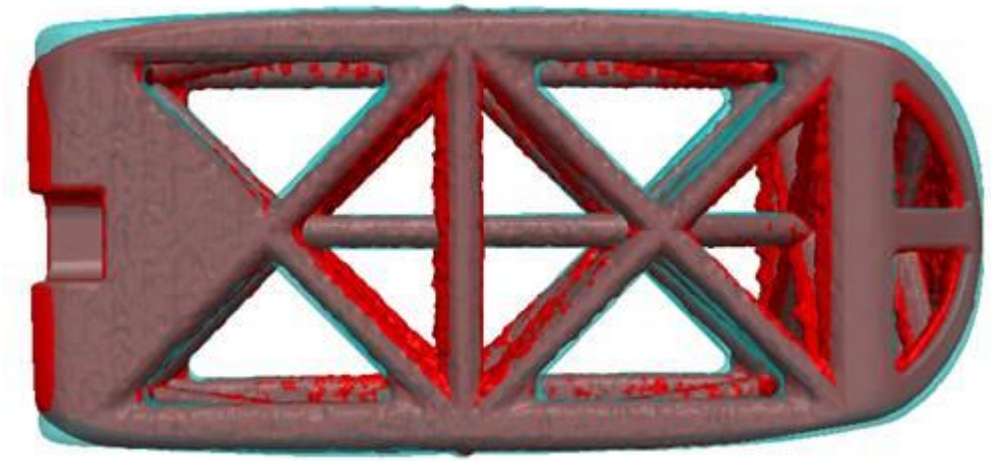




Surface Deviations

Comparing as-manufactured reconstruction to as-designed CAD

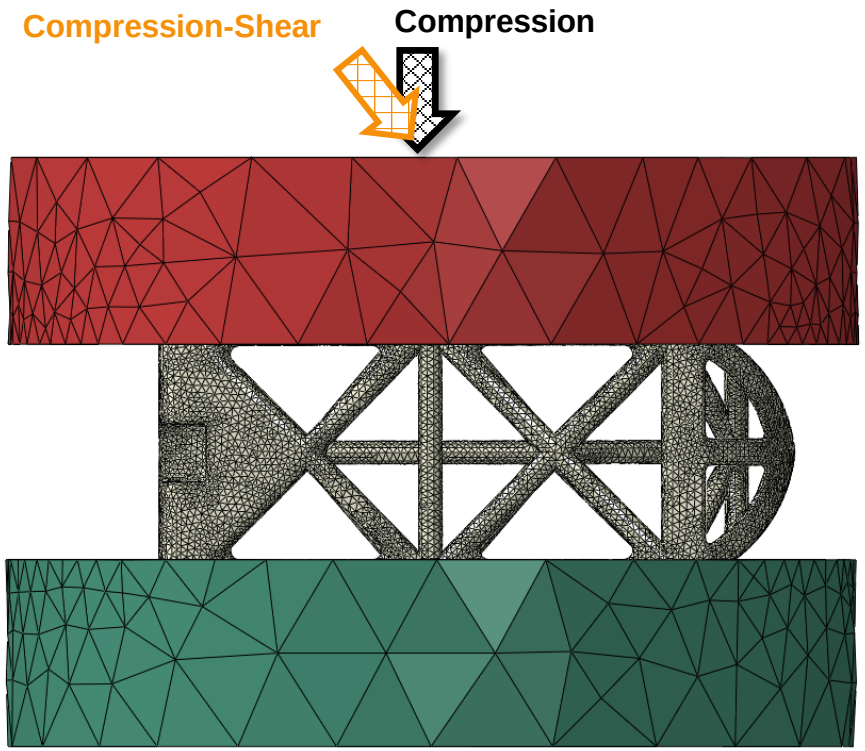
- Preliminary geometric comparison results showed good agreement overall
- Slight deviations in overall height at the ends of the implant.
- As-printed truss members are typically somewhat smaller in diameter than the CAD model of the intended design with some struts having larger deviations than others

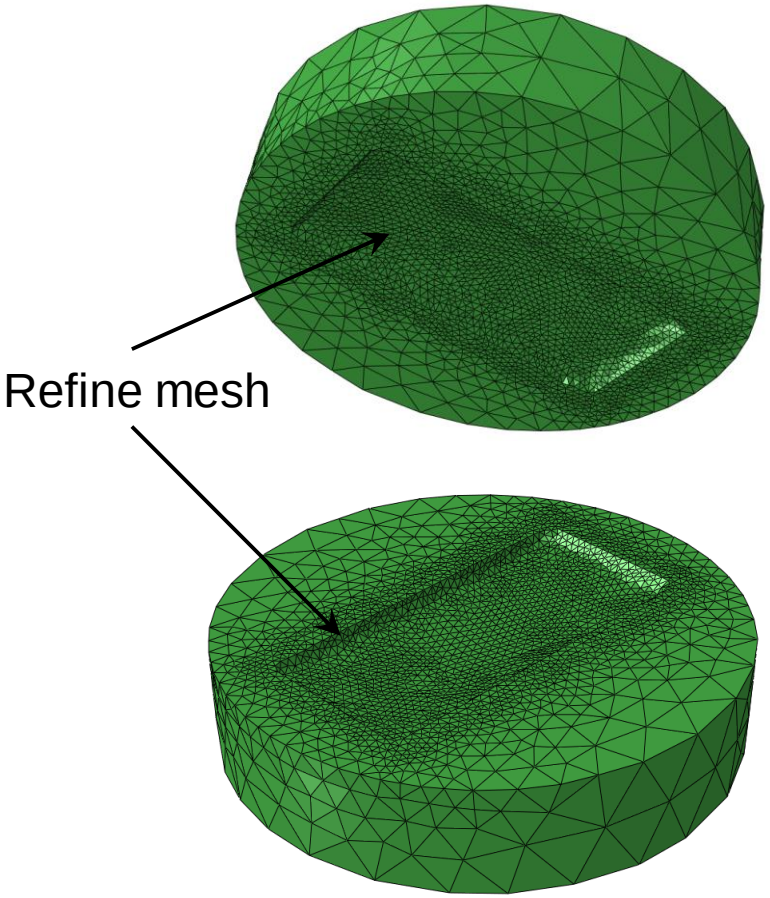


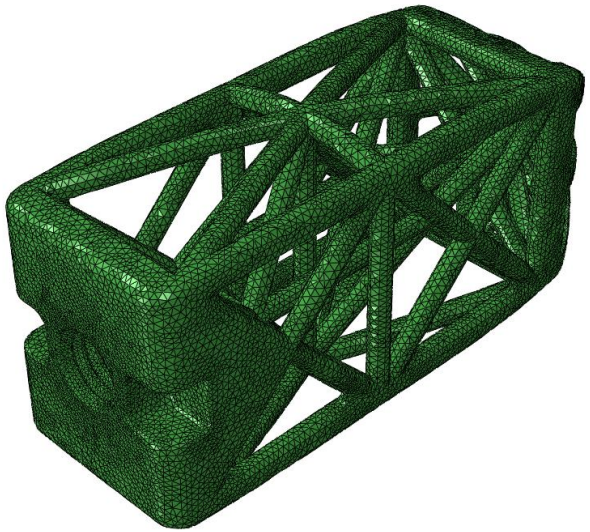
- As-designed (CAD model)
- As-fabricated (micro CT scan)

FE Model and Analysis

Repeating CAD based model Boundary Conditions on Image Based Model



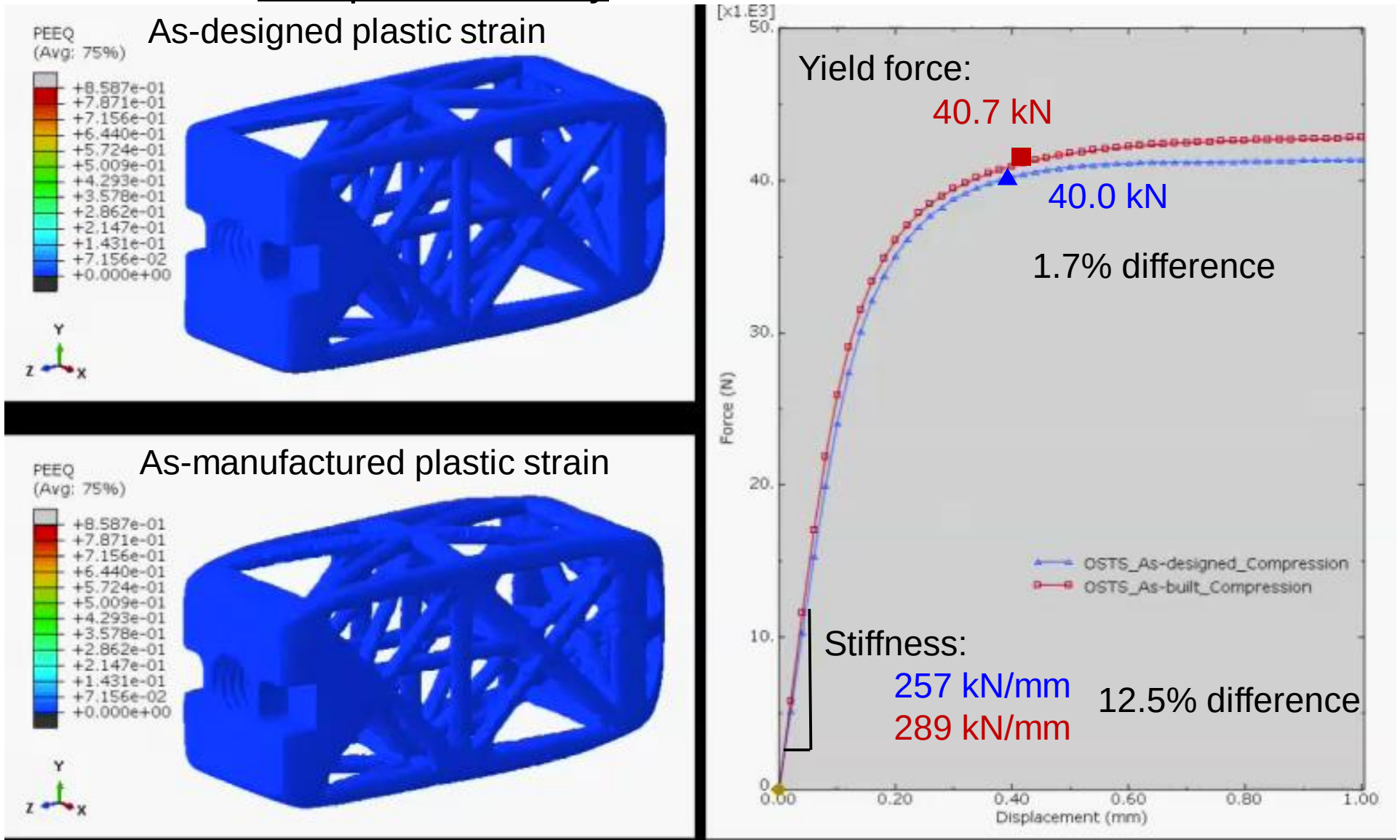




Implant: 381,576 C3D4 elements
Top platen: 32,782 C3D4 elements
Bottom platen: 29,209 C3D4 elements
Solved in Abaqus (Dassault Systemes, Johnston, RI)

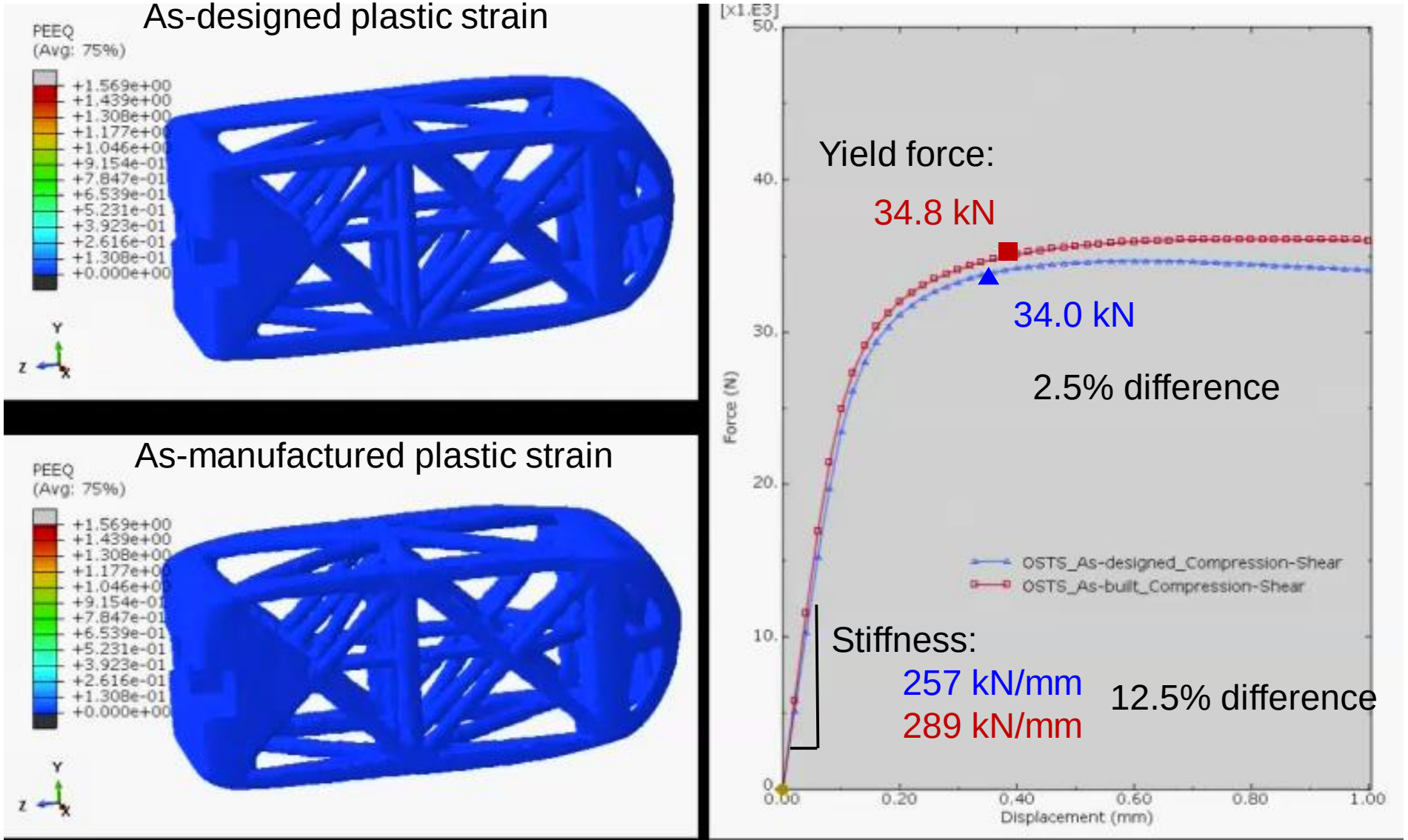
FE Model and Analysis

Analysis Results – Compression Only



FE Model and Analysis

Analysis Results – Compression and Shear



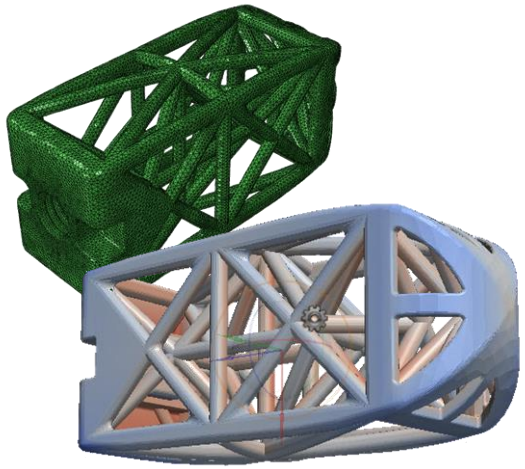
FE Model and Analysis

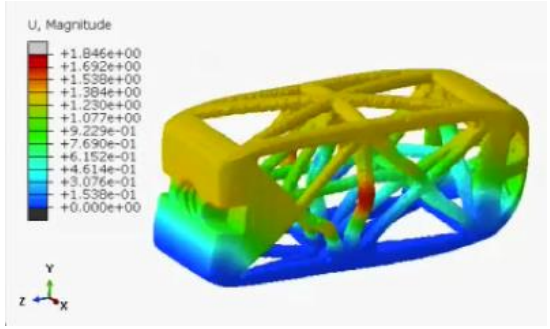
Repeating CAD based model Boundary Conditions on Image Based Model

- The as-manufactued and as-designed implants perform comparably in pure compression and combined compression and shear.
- As-manufactured stiffness and strength is slightly higher than predicted by the as-designed model. These slightly higher values are likely due to its being slightly shorter at the ends.
- As expected, the inclusion of shear reduces the yield force. The reduction is about 15%.
- Yield values occur well above the level of physiological loading
- Vertical stiffness are the same as the compression-only load case.

Discussion and Conclusion

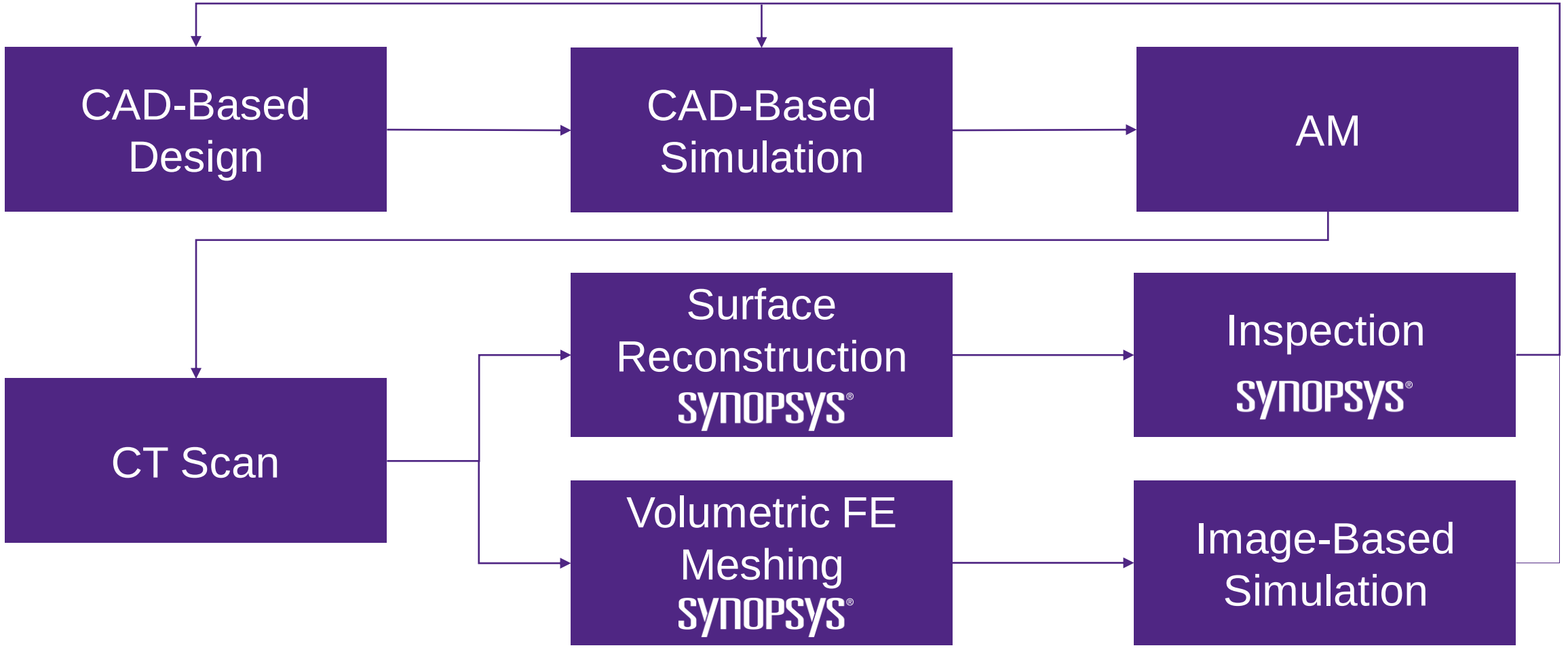
- There is a need for quantification of **geometric** and **performance** uncertainty
- Demonstrated a Proof of Concept Workflow that:
  - Can capture **geometric** uncertainty via CT scanning and reconstruction
  - Can bridge the gap from CT imaging to FE simulation while capturing the complexity of real-world geometries to help understand **performance** uncertainty





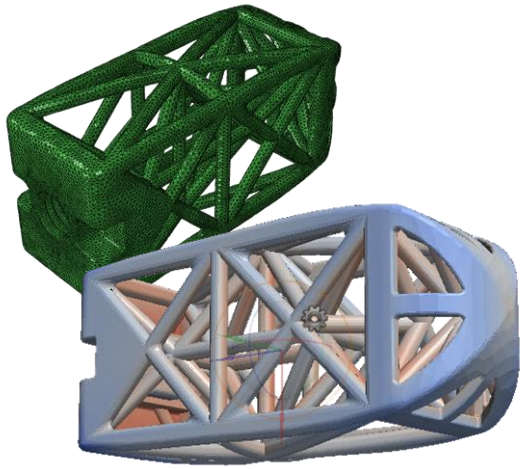
Closing the Loop

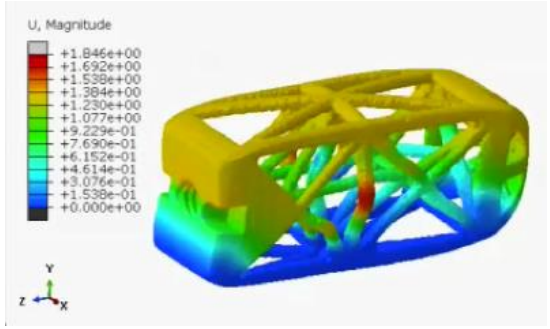
A proposed workflow for closing the loop on AM design and manufacturing



Conclusion

- Future Work
  - Refine the simulation approach
  - Increase the number of scanned samples
  - Incorporate physical test data that will enable model validation.
  - Incorporate the effects of porosity (Scan resolution dependent)





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Thank You