SYNOPSYS®

CASE STUDY

Investigating Spinal Implants

3D Image-Based Methods for Assessing Performance of Additive Manufactured Spinal Implants

“We’ve seen quite a bit of interest in assessing differences between as-designed and as-manufactured parts. It’s now possible to scan a manufactured item, create a model with Simpleware, and compare it to the original design. We simulate the behavior of the manufactured product and assess whether it will function as originally intended. If it doesn’t, engineers can make corrections to the manufacturing process or adjust the design so the final product meets all expectations.”

~Mahesh Kailasam, Advisor at Thornton Tomasetti

Thanks to: 4WEB, Nikon, Thornton Tomasetti

At a Glance

- Workflow bridges CT, image processing, and FE simulation
- Analysis of as-manufactured implants reveals deviations from as-designed part
- Simulation in SIMULIA™ Abaqus enables minimization of functional differences in parts
- Proof-of-concept closes design loop from original models to actual parts for clinical applications
- Methods effective at handling complex anatomical and CAD data

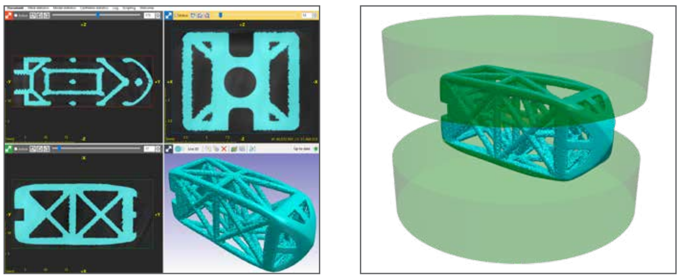
Overview

Spinal fixation is a standard of care for patients who suffer from traumatic and chronic injuries that affect mobility and cause increased pain. Additive manufacturing (AM) provides one solution for patient-specific orthopaedic devices, enabling a wider set of inputs and design choices than traditional production. However, there are still questions about workflow efficiency, quality assurance and the validation of parts.

AM particularly creates questions over accuracy, quality, strength, and part reliability, requiring comparison of original designs and as-manufactured parts. 3D imaging technologies like industrial computed tomography (CT) are useful here for allowing comparative evaluation and reverse engineering of parts as computational models to study factors such as porosity and dimensional deviations. These methods were brought together by a range of companies to use Simpleware software and other tools to analyze design deviations in a spinal implant.

3D Image Data Acquisition and Image Processing

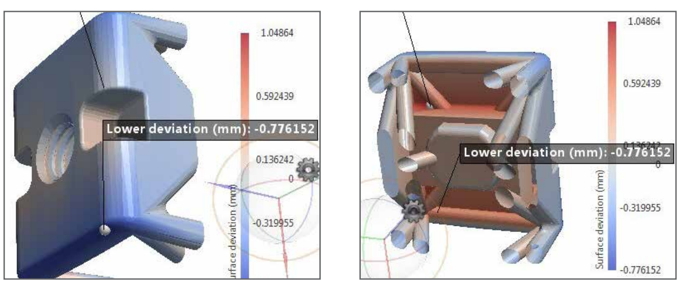
4WEB Medical have developed an FDA-cleared, proprietary Truss Implant Technology™ that leverages mechanobiologic mechanisms through a truss design, stimulating an osteogenic response to facilitate spinal fusion and improved joint stability. To do so, a spine implant was manufactured by 4WEB Medical's 3D printing technology and scanned using a Nikon XT H 225 ST CT system. The 3D voxel data was prepared in Nikon CT Pro 3D software, before being imported to Simpleware software for comprehensive image processing, segmentation, and measurements to create a high-quality model of the implant geometry.



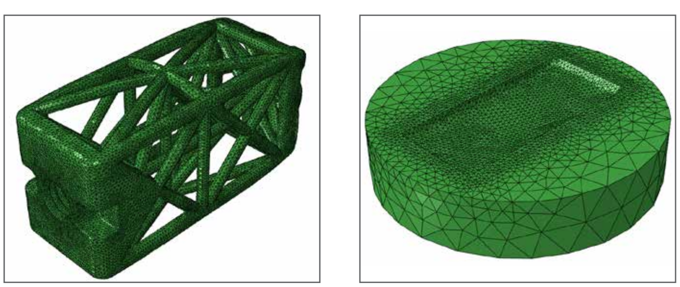
Import and segmentation of scan data in Simpleware software, and Simpleware implant model showing custom-made platens used to apply a load to the spinal implant

Surface Deviation Analysis

The original computer-aided design (CAD) model of the part was compared to the CT scan data of the actual AM truss implant using the surface deviation analysis tools available in Simpleware software.



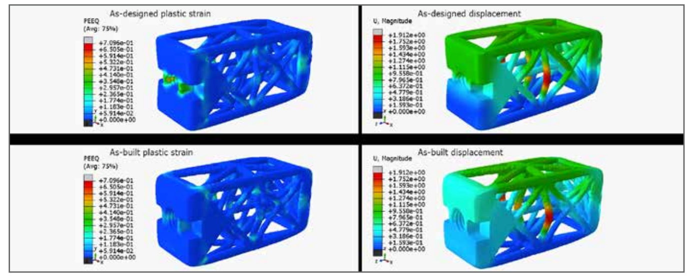
Surface deviation analysis of different sections of the implant in Simpleware software



FE mesh generation of the implant and platens in Simpleware software

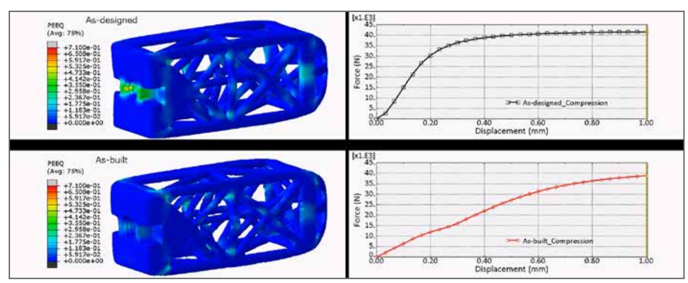
Finite Element Mesh Generation and Simulation Results

High-quality finite element (FE) meshes were generated in Simpleware software for simulation in SIMULIA™ Abaqus, enabling analysis of differences between as-designed and as-manufactured parts. In this case, Abaqus was used to compare plastic strain and displacement in both versions of the part.



Plastic strain and displacement under compression in Abaqus, comparing as-designed and as-built spine implants

Preliminary geometric comparison results showed that the as-designed and as-manufactured implants were in good agreement, with only slight deviations in overall height at the ends of the implant. Furthermore, the as-printed truss members were typically smaller in diameter than the original CAD model. When simulating plastic strain and displacement in combined compression and shear, the two versions of the implant performed comparably. Differences in results occurred with the onset of yielding, likely associated with earlier issues with struts in the manufactured implant, but still within the physiological range of a patient.



Plastic strain and force-displacement curves under compression in Abaqus, comparing as-designed and as-built spine implants

Conclusions

The workflow enabled data suitable for adjusting the AM process and potentially the original CAD designs to minimize the impact of functional differences. Future work in this area will address the range of simulations, physical test data, the effect of porosity, and differences in scan resolution. However, the current approach is suitable for linking 3D imaging, model generation, simulation, and AM, with broad applications to medical devices and other high-value parts. This type of approach may in future help with clinical decision-making and reducing the risk of defects in patient implants.

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