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3D image-based methods for investigating additive manufactured spinal implants

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Abstract: Spinal fixation is a standard of care for patients who suffer from traumatic and chronic injuries that affect mobility and cause increased pain. New additive manufacturing (AM) technologies typically use mechanobiologic approaches that encourage fusion in the spine and increased healing for patients. A workflow has been developed to compare the differences between as-designed and as-manufactured parts that utilize 3D CT scanning, image processing software, and simulation of performance to understand the effect of deviations on devices. This preliminary workflow has been tested with a spine truss implant part and through direct comparison between simulations of as-designed versus as-manufactured geometries.

I. Introduction

Spinal fixation is used to help patients with traumatic and chronic injuries that affect mobility and increase pain in the back, neck, and limbs. Additive manufacturing (AM) is becoming a more common way of creating patient-specific orthopedic devices, including for spinal fixation. These parts can be manufactured using a wider set of inputs than traditional tooling, allowing close control over design specifications for patients. However, there are some challenges associated with this method, for which the workflow in this paper seeks to address.

I.I. Additive manufacturing challenges

AM technologies—or 3D printing, as they are popularly known—show promise to transform traditional production manufacturing because they can produce highly complex geometries and customized parts directly from the part design model without dedicated tooling. However, open questions remain in terms of accuracy, quality, strength, and reliability of AM parts. A common approach for manufacturers is to evaluate and compare the differences between original designs and the as-manufactured parts to understand how deviations affect real-life performance.

3D imaging techniques, like industrial computed tomography (CT), are useful resources to perform comparative evaluations and enable inspection and reverse engineering of AM parts [1,2]. CT scans allow for quantification of porosity, crack/defect size, and dimensional deviations in geometry against nominal designs. This method can be applied to medical AM parts and can be expanded for evaluating and considering functional performance of actual AM engineering applications.

Physics-based Finite Element (FE) simulation techniques are also being incorporated into the design process to help improve the quality of the AM design, reduce weight and ensure a high probability of successful builds [3]. Despite these efforts, however, there is still uncertainty in the differences between as-designed versus as-built AM parts, which leads manufacturers to ask the following question: "What are the differences between my design and the part that is actually manufactured and how will these differences affect performance in *reality*?". Therefore, the authors of this paper created and executed a proof-of-concept workflow for a direct comparison between Finite Element (FE) simulations of as-designed versus as-manufactured geometries via CT scanning.

II. Materials and methods

4WEB Medical has developed a proprietary Truss Implant Technology™ that leverages mechanobiologic mechanisms through a truss design [4]. This method stimulates an osteogenic response to facilitate bone-implant integration for development of spinal fusion, and to improve joint stability during the patient's healing (or fusion) process. The U.S. Food & Drug Administration (FDA) approved this technology, whilst AM truss implants have been popular and clinically significant.

A posterior spine truss implant manufactured by 4WEB Medical's 3D printed technology was scanned with a Nikon XTH 225 ST CT system (Settings in Table 1).

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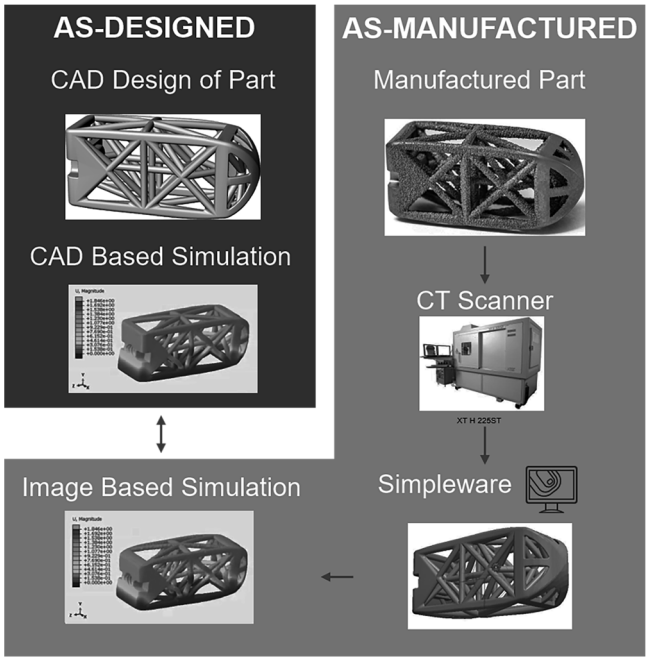

Figure 1: Example of the workflow used to compare simulations with the as-designed and as-manufactured data of an AM part

3D voxel data was reconstructed with Nikon CT Pro 3D software, and then imported into Synopsys Simpleware software (Synopsys, Inc., Mountain View, CA) for carrying out image processing, segmentation, measurements, CAD deviation comparison, and generation of Finite Element (FE) models for simulation. When generating the models in Simpleware software, the adaptive mesh refinement algorithms in the FE module were used to automatically preserve small features in the segmentation, whilst generating an efficient mesh size for simulation. Several mesh densities were generated to confirm convergence of the simulation results.

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 from Simpleware software.

FE simulations in Abaqus software (Dassault Systemes Simulia, Johnston, PI) then enabled a full understanding of the differences between as-designed and as-manufactured parts. Abaqus was used to compare as-designed versus as-manufactured plastic strain and displacement on the implant.

III. Results and discussion

Preliminary geometric comparison results showed that overall, the as-designed and as-manufactured implants were in good agreement with slight deviations in overall height at the ends of the implant. Also, the 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. The as-manufactured and as-designed implants performed comparably when examining simulations of plastic strain and displacement in combined compression and shear. Results diverge somewhat with the onset of yielding, likely the result of an earlier onset of yielding and buckling of some struts in the manufactured implant. However, these values are well above any physiological range that would be experienced by a patient. From these results, the AM process and potentially the original design can be adjusted to minimize the impact of functional differences.

IV. Conclusions

Although this paper focuses on a proof-of-concept workflow, there is ongoing work to refine the simulation approach, increase the number of scanned samples and incorporate physical test data that will enable validation of our models. Also, the effects of porosity were not directly examined in the current study but will be incorporated into the workflow as it is further developed and refined. Naturally, the capability of defect detection by X-ray CT depends very much on the part's size, complexity, and material, but in principle, high scanning metrological resolutions in the order of 10 or 5 µm are possible.

The current approach will fully close the design loop from original models through to the actual part intended for use in clinical applications. The potential for linking 3D imaging, model generation, simulation, and AM also has broad applications to other medical device designs such as hip, knee and craniofacial implants, to name a few. The workflow presented here was completed with standard processes for CT scanning, image processing, model generation and solving. However, whether this approach is scalable to in-line manufacturing analysis or will remain a pure R&D activity depends on many factors including the context of use of the models, the complexity of the analysis and the level of risk any defects may have on a patient. The benefits of this approach are to quantify fitness for purpose of AM parts by not only including geometric uncertainty, but performance uncertainty as well through CT image-based FE simulation.

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Table 1: Experimental CT Scanner settings. SOD = source-to-object distance, SDD = source-to-detector distance, Vx = Voxel size, V = tube voltage, I = tube current, Fs = Focal spot size, It = integration time, G = Gain.

Machine model	SOD (mm)	SOD (mm)	Vx (µm)	V (kV)	I (µA)	Fs (µm)	It (ms)	G --	Pre-filter (mm)
Nikon XTH 225 ST	84.5	913.7	18.5	155	65	10	250	30x	Al 2.0