

# Computationally Designed 3D-Printed Segmental Defect Implant Optimized for Mechanobiologic Performance in Long Bone: Pre-Clinical Assessment in a Sheep Model

Ali Kiapour<sup>1</sup>, Mitchell Greenberg<sup>2</sup>, Santiago Lozano-Calderon<sup>1</sup>, Thomas P. Schaer<sup>3</sup>

<sup>1</sup>Massachusetts General Hospital, Harvard Medical School, Boston, MA; <sup>2</sup>Geneva Foundation, Tacoma, WI;

<sup>3</sup>Department of Clinical Studies New Bolton Center, University of Pennsylvania, School of Veterinary Medicine, Philadelphia, PA  
[akiapour@mgh.harvard.edu](mailto:akiapour@mgh.harvard.edu)

**Disclosures:** Ali Kiapour (N); Mitchell Greenberg(N); Santiago C. Lozano (N); Thomas P. Schaer(1-PSI, 1.3B,4,5-ReGelTec, 3B-Peptilogics, 3B,4,5-Acutive Technologies, 3C-PAX Therapeutics, 3C-OrimTech, 3C,5-SINTX Technologies, 3C-OsteoCentric Technologies, 3B,6-Elute, 5-DePuy Synthes, 5-Alcyone Therapeutics, 5-Camber Spine, 5-Stryker, 5-4WEB, 5-Aravis, 5-Waypoint Orthopedics, 6-Heraeus, 6-Apyx, 6-Altus Spine, 5,6-Vet-Len).

**INTRODUCTION:** While intramedullary nailing fixation is the preferred treatment for femoral shaft fractures, a nonunion can still develop [1]. Aseptic nonunion is a serious complication that may arise following the treatment of long bone fractures with intramedullary nailing, with an incidence rate of up to 12.5% in the femur and tibia [2]. Stress and load shielding due to the use of solid nails and high-stiffness fixation constructs can contribute to nonfusion due to bone loss. Studies have shown that mechanical stiffness and properties of the fixation implants can affect the osteointegration and fusion rates [3]. This work demonstrates the biomechanical assessment of computationally optimized implants to be used in animal study for clinical assessment of the fusion.

**METHODS: Development of Implant Prototypes:** The Computed tomography (CT) images of the left hindleg of skeletally mature sheep, weighing 65kg, were obtained and used for the computational design of the partial tibia implants. The CT was imported into Mimics Innovation Suite (Materialise Inc.) for anatomical segmentation and creation of 3D models (Figure. 1). The anatomical model of the sheep's left hind leg was then imported into nTop (nTop Inc.) for implant design and computational optimization. A bone defect volume (implant space) with a height of 3cm, spanning around the mid-length of the bone, was separated to use for the creation of the lattice implant. Using the trajectory of the intramedullary canal, an 8.5mm nail that went 15mm beyond the endplates (cranial and caudal ends) of the implant volume was designed. Three implant designs, including a hollow lattice with solid through the nail (WN), surface lattice with solid pegs (WP-D1), and volume infill lattice with solid pegs (WP-D2), were created. **Biomechanical Analysis:** The 3D models of the three implant designs and the anatomy were imported into Synopsys Simplware's software for mesh generation and finite element (FE) pre-processing work. The constructs were meshed using tetrahedral volumetric mesh, and the tibial bone was segmented to create a 1mm cortical shell and infill cancellous bone layers. The FE model components were brought into Abacus (Simila Inc.) for material properties assignment (Titanium for implant and bone properties, [4]) and simulation of physiological loads. Each implant design-bone assembly construct was subjected to two loading conditions, including pure compressive load (1800 N max) and pure torsion (10 Nm mas), and the stress, strain, and construct stiffness were calculated and compared among the cases.

**RESULTS:** The Peg design implants had 33% (D1) and 15% (D2) total graft volumes compared to traditional nail constructs, respectively (Figure 2). The surface lattice Peg (D1) and the volume lattice Peg (D2) designs had compression stiffness of almost 89% and 32% less than the solid nail construct, respectively. In torsion, both pPeg designs had similar torsional stiffness with a reduction in stiffness of 26% (D1) and 24% (D2) compared to the solid nail constructs (Figure 2). Assessment of the stress distribution on all three constructs showed that the solid nail (WN) construct has the lowest stress under the compressive load, while the Peg designs had higher, more uniformly distributed stresses under the load. The peak stress in all of the constructs was below the yield limit of the material. Comparison of the microstrain distribution across the lattice showed that the solid nail design experienced near to zero strain (bone loss region per Wolff's diagram) whereas the two pPeg designs were able to produce relatively uniform strain values in the middle and close to the upper band of (D2) adapted bone remodeling state.

**DISCUSSION:** The study demonstrates that computationally optimized 3D-printed long bone fixation implants can be programmed to improve the mechanobiology performance of the constructs under physiological loads, leading to a faster and more efficient fusion rate. Such optimization can be done in a way that preserves the construct's mechanical strength and integrity within thresholds of the *in vivo* load.

**SIGNIFICANCE:** 3D-printed lattice constructs for long bone fixations can be designed using principles of mechanistic theorem to optimize the micro-strain generated at the bone-implant interface based on an improved bone cell differentiation process and faster fusion rate. The through lattice constructs can prevent bone loss due to the load shield effect, which is common in solid through nail constructs. A faster fusion rate can lower complication rates such as nonunion or pseudarthrosis, which is common in long bone fixation procedures. The findings of this study need to be further investigated in clinical settings.

**REFERENCES:** [1] Wu et al., *Medicine* 2019; [2] Garnavos et al., *Injury* 2017; [3] Kiapour et al., *Spine*, 2022; [4] Kiapour et al., *J Neurosurg Spine*, 2021.

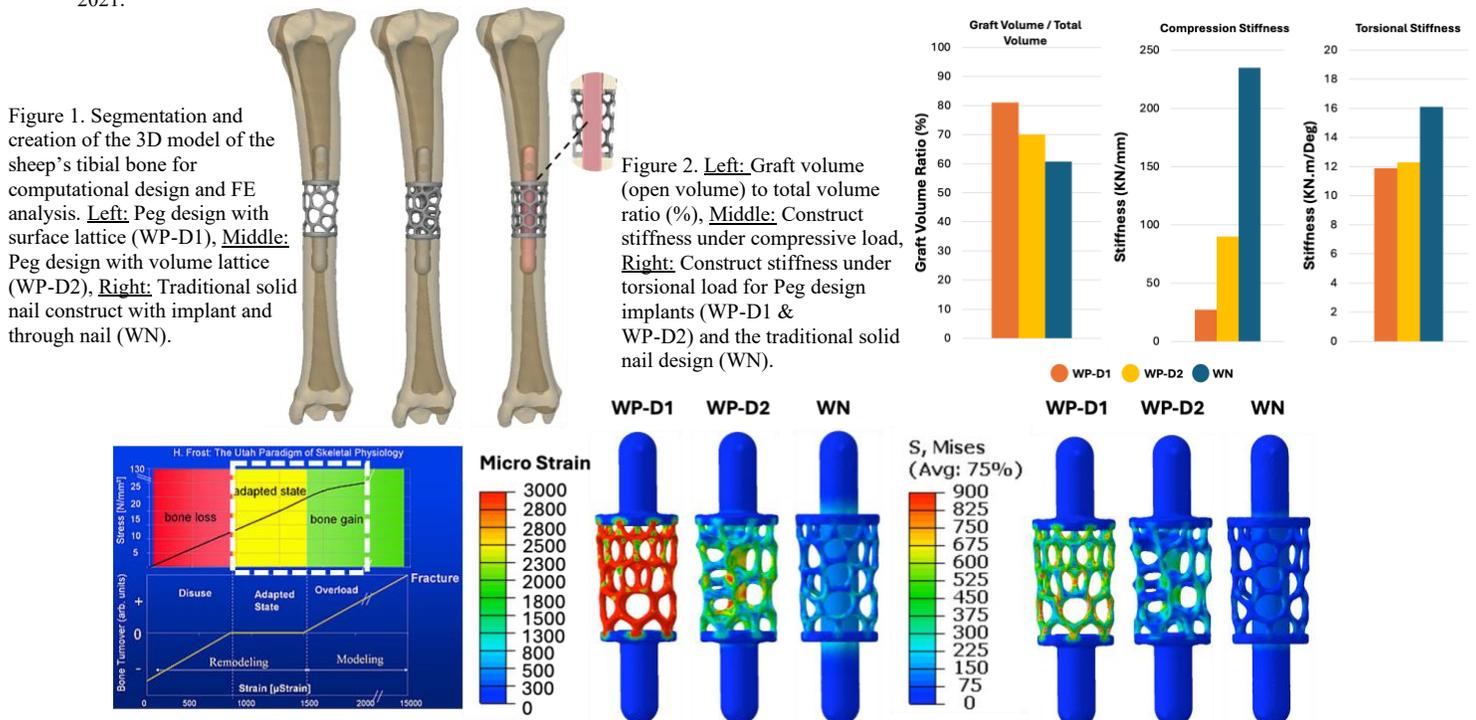


Figure 3. **Left:** Mechanostat, modeling- and remodeling microstrain thresholds (Wolff's law), **Middle:** Microstrain distribution on Peg and Nail implant constructs under full compressive load. **Peak von Mises stress** under compressive load for three designs.