InCore® Lapidus System Strength Profile in First Tarsometatarsal Joint Fusion, A Finite Element Comparison

John M Armacost, BS[ǂ], Gregory J Denham, BS[#]

Background

Fusion of the First Tarsometatarsal (TMT) Joint is a common definitive treatment for hallux abducto valgus. Described and refined by Albrecht[1] and Lapidus[2] to include the second metatarsal, the procedure is now more commonly performed omitting incorporation of the second metatarsal into the fusion[3]. The First TMT Fusion, often referred to as the Lapidus or Modified Lapidus procedure has been an important tool in treating hallux abducto valgus, with points of debate pertaining to the procedure generally focusing on 1) hardware type and configuration, 2) fusion site preparation method, and 3) post-operative protocol.

The purpose of this article is to assess the biomechanical attributes of a novel solid shank screw and post construct (InCore Lapidus System, Nextremity Solutions, Inc. Warsaw, IN[*]).

Types of Fixation Constructs

Though Lapidus originally fixated the fusion site with chromic catgut[2], fixation methods include k-wires, crossing screws, and various plating systems.

Crossing screw type fixation consist typically of 3.5 or 4.0mm compression style screws[4]. Typically, one screw is started at the dorsal aspect of the metatarsal and directed toward the plantar aspect of the medial cuneiform, and a second screw is placed from the dorsal aspect of the medial cuneiform and directed toward the plantar aspect of the first metatarsal, though various trajectories are used. The fusion is also sometimes expanded to incorporate screws passing into the second metatarsal and/or the intermediate cuneiform.

In recent decades, various plating systems have been proposed as potential improvements over crossing screws for fusion site stability. Variations of dorsally, medially, and plantarly placed plates, as well as the incorporation of locking, non-locking, and crossing screws, have all been proposed in the parade of plate improvements. A multitude of biomechanical and clinical studies now exist to assess the benefits associated with each type of hardware solution.

Biomechanical Comparisons

Biomechanical Bench Testing

Many studies seek to assess the loads experienced by the foot, as well the biomechanical characteristics of plating systems and crossing screws. Bending moment experienced at the TMT joint during healthy walking is cited by Dayton[5] to be 15 – 30 Nm[6,7]. Stokes[8] shows the Bending moment at the first metatarsal to be 8.0 to 13.0 Nm during normal walking, with loads being counteracted naturally by tension in the flexor tendons and tendon sheaths, though as discussed by Ray[9], the ligamentous support and articular contour are altered and mechanically compromised during arthrodesis. He went on to note that the loads maintained by two crossing screws far exceeded that seen by the forefoot while standing or ambulating in a cast, positing in his 1998 article that postoperative weight bearing through the heal might be shown to be plausible[**]. Graham[10] discussed his results which showed a medial plate construct being stronger than the original, intact foot, and surviving loads well above that previously measured to pass through the first metatarsal during walking. These studies give some sense of the magnitude of forces that can be seen through the joint and suggest what strength target might be plausible for a fixation construct.

Study Limitations Due to Bone Variability

Cottom[11] noted the shifts in values that can be experienced across studies due to bone mineral density (BMD) and specimen preparation. An important consideration in any orthopedic procedure involving hardware is the quality of bone stock at the site of placement. Several studies confirm that the bone mineral density of the specimens tested were important contributors to the initial strength at the fusion site. Hofstaetter et al[12] found a correlation between bone density and osteotomy site stiffness in hallux valgus performed on cadaver specimens utilizing a standard Ludloff procedure, indicating that bone mineral density may be a part of the algorithm in determining ideal start of early weight bearing. Klos[13] also showed a significant correlation between BMD and number of cycles to failure in a cadaver model for Lapidus fusion. Gruber[14], who was unable to show a significant difference in load to failure or stiffness between crossing screws and dorsomedial locking plate for metatarsocuneiform arthrodesis in a cadaver model, did however correlate the load to failure of both constructs to the specimen BMD.

Adding to the potential study variables is the various joint preparation methods utilized. It has been shown that joint preparation methods that preserve the subchondral plate can improve joint stability, screw purchase, and reduce metatarsal shortening[9].

Finite Element Approach

A general comparison of hardware in a cadaver model is difficult given the large standard deviation of results seen in cadaver testing. Dayton[5] performed similar comparisons in a bone analog model. Bone analog testing is a common method of comparing constructs while eliminating the variability seen in cadaver analysis. Another method of assessing biomechanical properties without the inherent variability of cadaver specimens is by use of finite element computer modeling. This type of analysis has been used extensively for musculoskeletal biomechanical analysis throughout the body, and more specifically in the foot. Budhabhatti et al[15] utilized the method to assess the ideal angles for arthrodesis of the first ray in hallux limitus. Subsequent analysis of the first ray of the foot has been performed extensively[16,17], with Wai-Chi Wong et al assessing risk of non-union of the first metatarsocuneiform arthrodesis directly using a finite element approach[18].

For the reasons noted above, a finite element computer modeling approach was chosen as a consistent and unbiased means to compare the InCore Lapidus System with a clinically relevant construct.

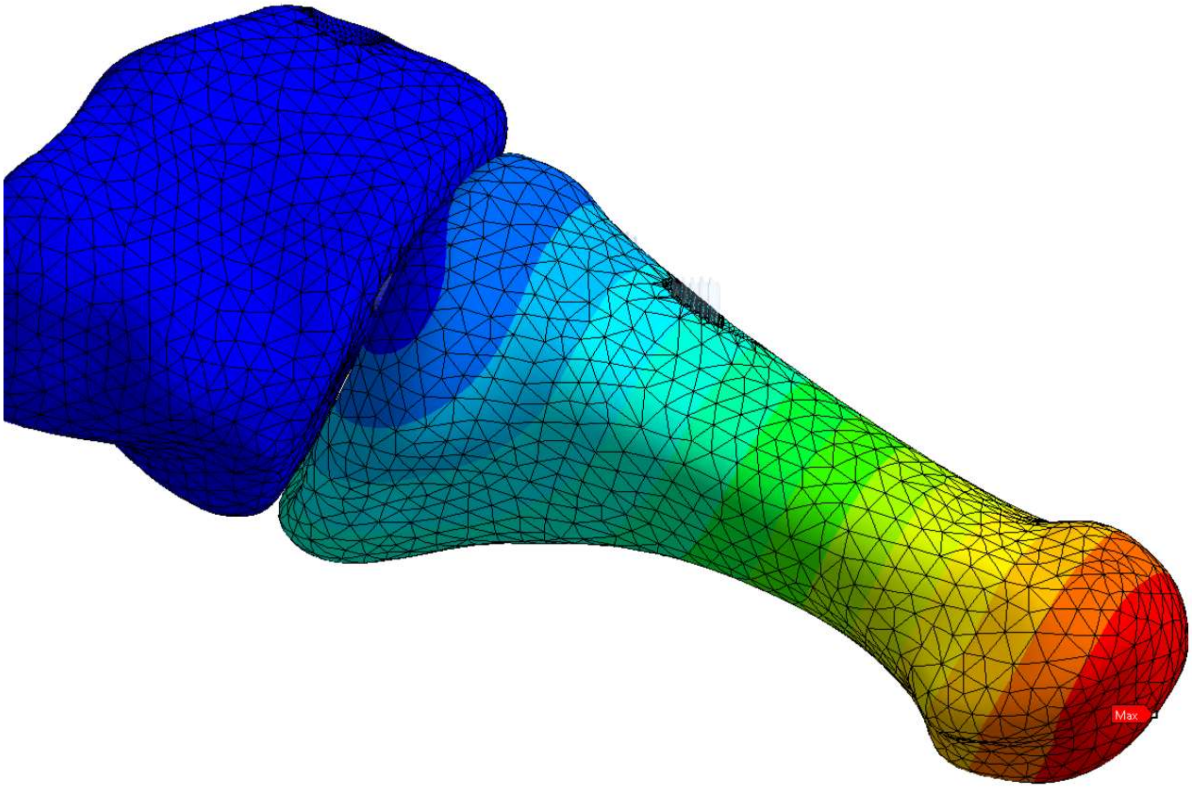

Figure 1: Example of medial cuneiform and first metatarsal with full mesh, and color indicating amount of deflection with a moment application, simulating a cantilever loading scenario.

Finite Element Analysis

Assumptions

As stated above, a finite element method of comparing hardware in TMT fusion was selected due to the inherent lack of bias with respect to variations in cadaver specimens. A chosen bone quality is used throughout the analysis, insuring a consistent plumb line for all studied constructs.

Because crossing screws are still arguably the gold standard for hardware choice in terms of literature volume, clinical success, and biomechanical benchmarking in the Lapidus procedure, they are chosen to be the benchmark against which the InCore Lapidus System is compared. In addition, endpoints for the analysis should include an assessment of the stress experienced by hardware through a typical load scenario, chosen here to be 5 Nm, as well as a quantification of plantar gapping. 5 Nm is a value on par with the magnitude of maximum loading seen at yield in some biomechanical studies[9,10]. Plantar gapping would indicate an important resultant of force application since close apposition of mating bones is necessary for bony fusion.

The computer modeling and load analysis was performed by Citadel Structural Mechanics LLC, Warsaw, IN. An entire left foot model (Zygote, American Fork, UT) near average size was chosen to place the Medial Cuneiform and First Metatarsal in space with respect to loading.

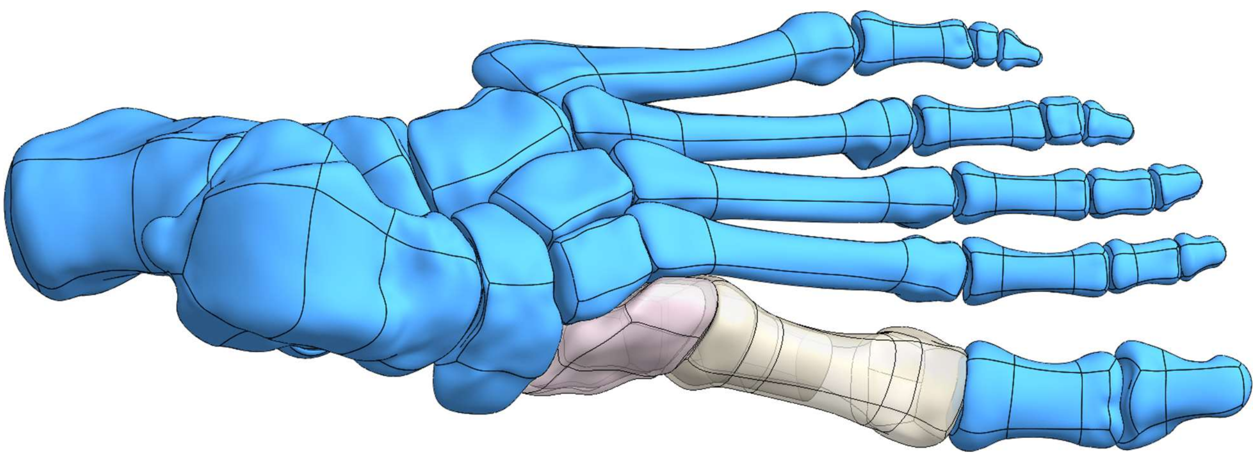

Figure 2: Bones shown in blue are provided as reference only.

The relevant bones were then isolated with hardware located mimicking positioning typically used clinically. Bones were shelled, allowing the creation of a composite model wherein the outer shell (approximately 2.75mm thick) of the bone mimics cortical bone, and the internal portion of the bone contacting hardware has physical properties closer resembling cancellous bone.

Material	Young's Modulus	Poisson's Ratio	Tensile Yield Strength	Tensile Ultimate Strength
Bone – Cortical	17 GPa	0.40	114 MPa	133 MPa
Bone – Cancellous	310 MPa	0.30	4.4 MPa	4.4 MPa
Ti_6Al_4V ELI (ASTM F136)	110.5 GPa	0.30	795 MPa	860 MPa

Figure 3: Table of material property assumptions[19,20].

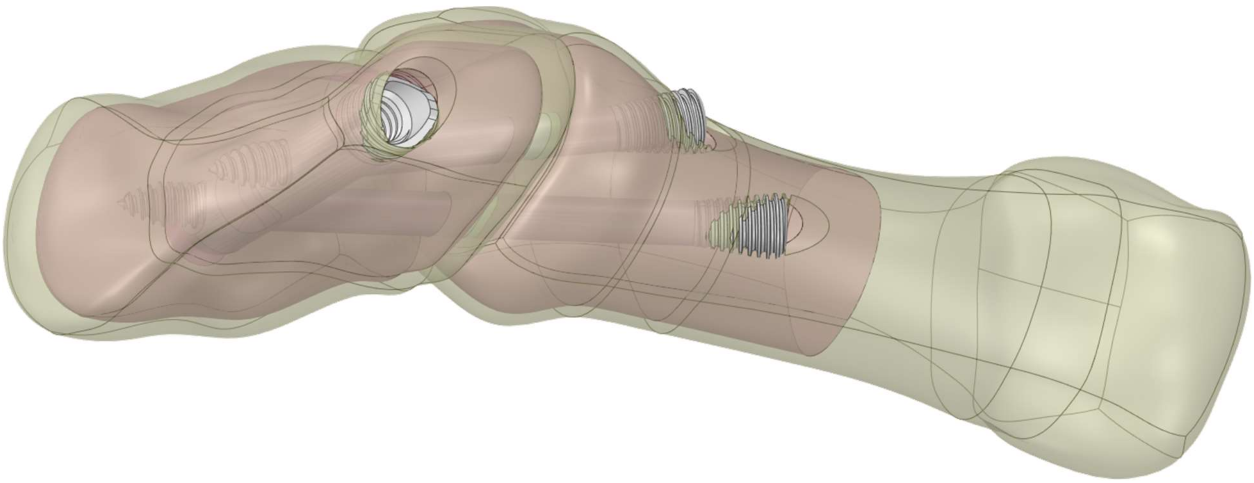

Figure 4: Medial Cuneiform isolated with InCore Lapidus placed.

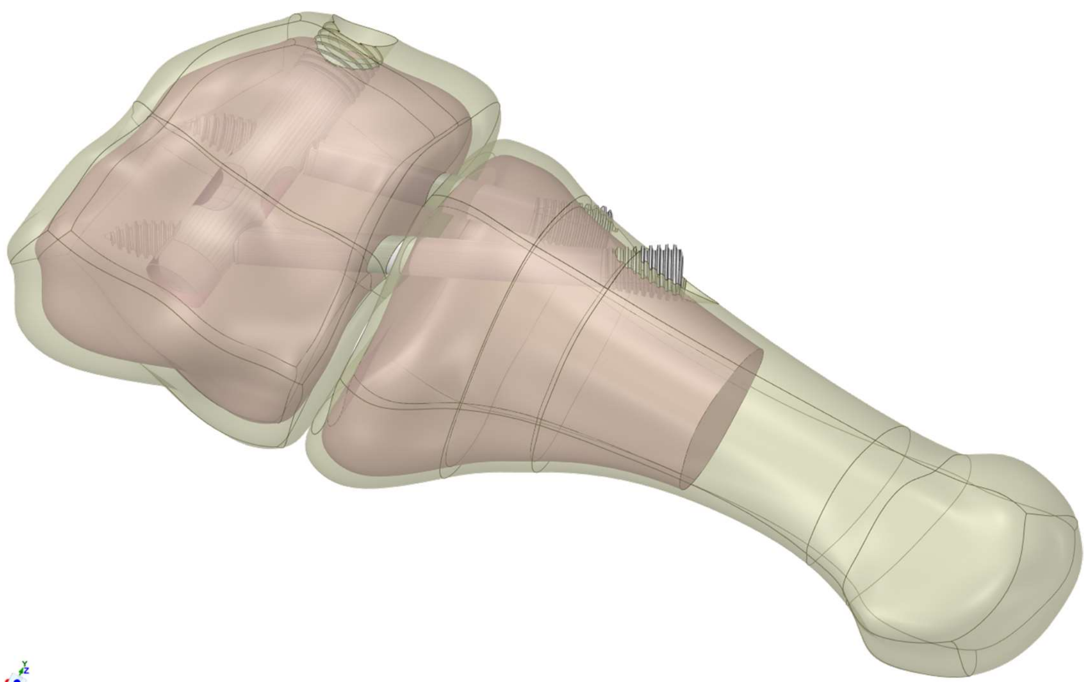

Figure 5: Medial view of construct demonstrating hybrid bone model.

Methods

A tetrahedral finite element mesh was then applied to the model, with a more refined mesh applied to the hardware as well as where the bone interfaced with the hardware, to better isolate stress conditions near boundaries.

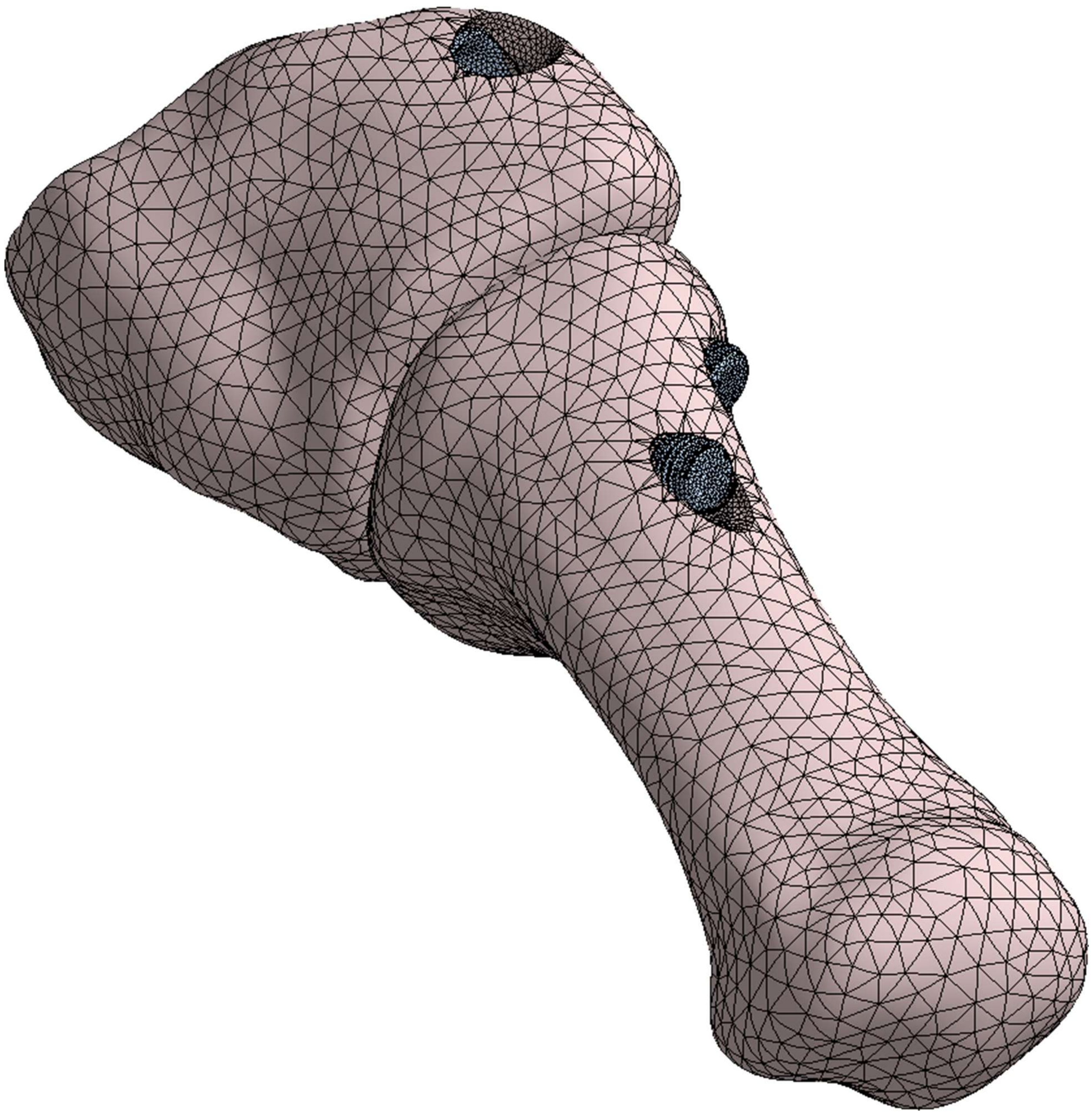

Figure 6: Fully meshed assembly with InCore Lapidus placed.

The load condition that was applied was chosen to mimic biomechanical studies wherein the tarsal bones were potted and a load was applied directly to the distal head of the first metatarsal. The pure moment load chosen generated the same loading effects at the TMT joint that a load at the metatarsal head does, without generating load vectors perpendicular to the joint line.

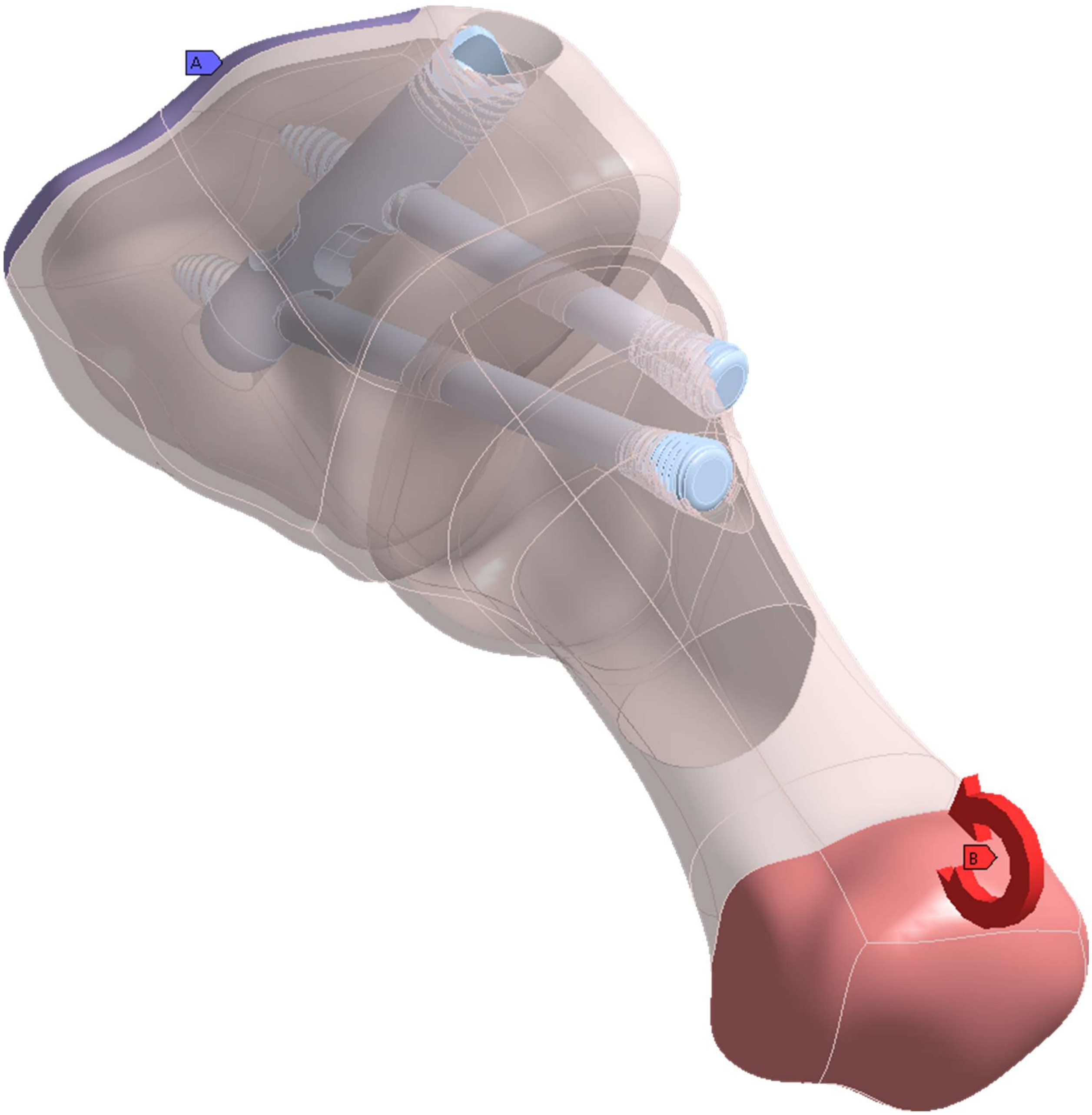

Figure 7: Load condition of the assembly mimicking a cantilever condition.

Results

A 5 Nm moment load was first applied to the construct to determine stresses within the implant. The maximum stresses (487 MPa for upper screw) appeared at the joint line, with both screws sharing similar stresses far below the tensile yield strength of the titanium alloy (860 Mpa). The same loading condition for the Two Crossing Screws construct predicted stresses of 971Mpa, more than the tensile yield strength of the titanium alloy.

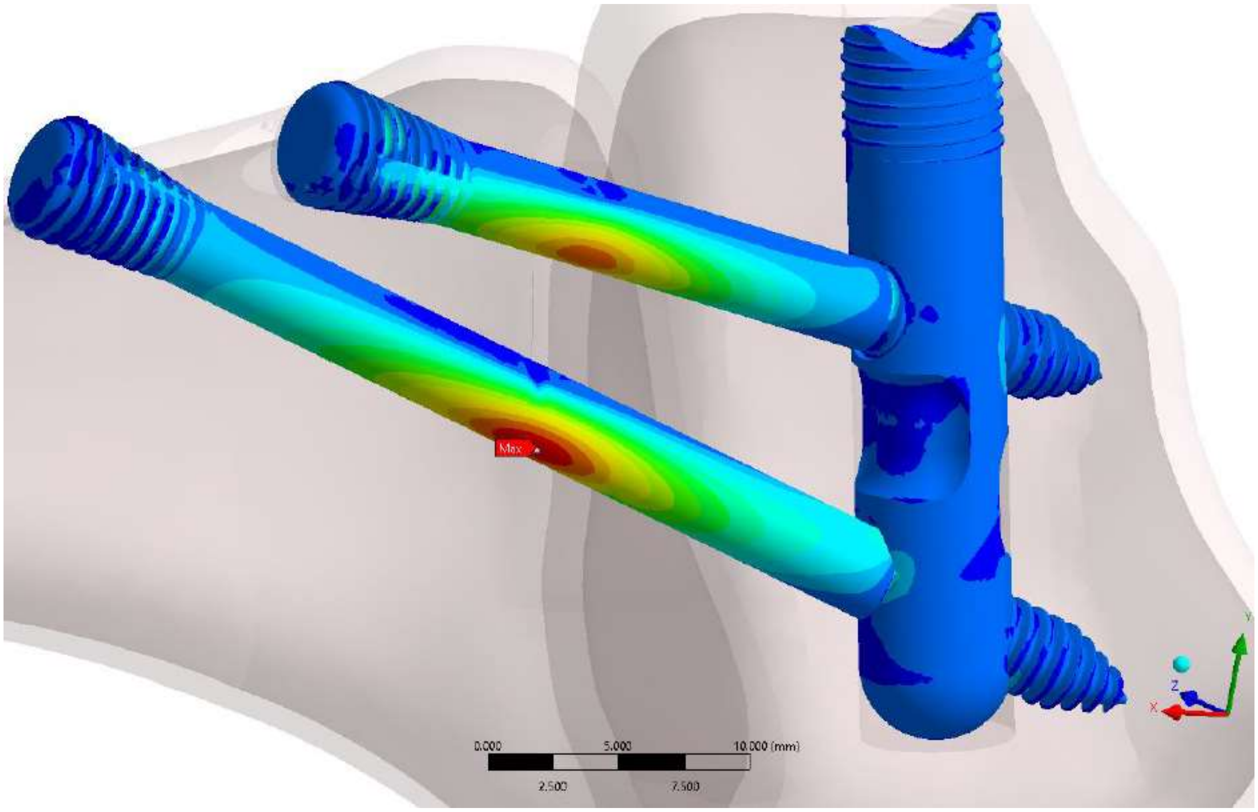

Figure 8: Graphic displaying Maximum Principal Stresses.

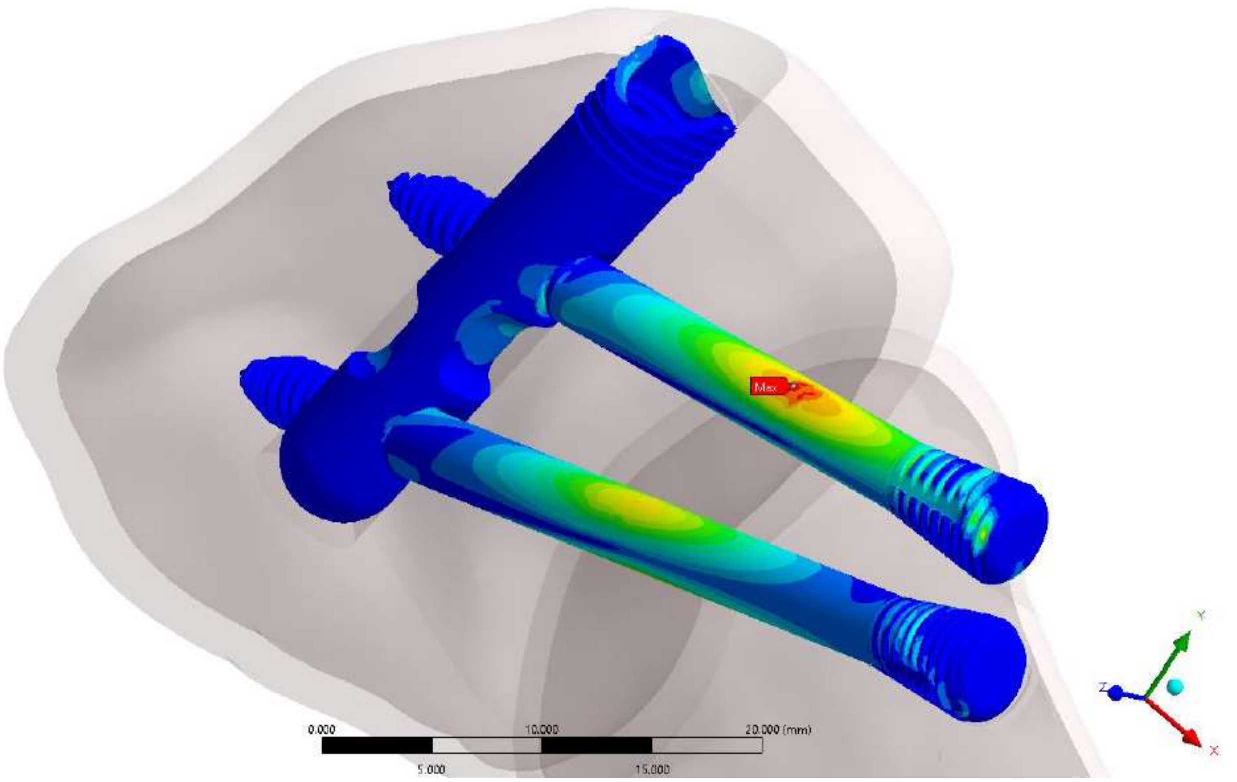

Figure 9: Graphic displaying von Mises Stresses within the construct.

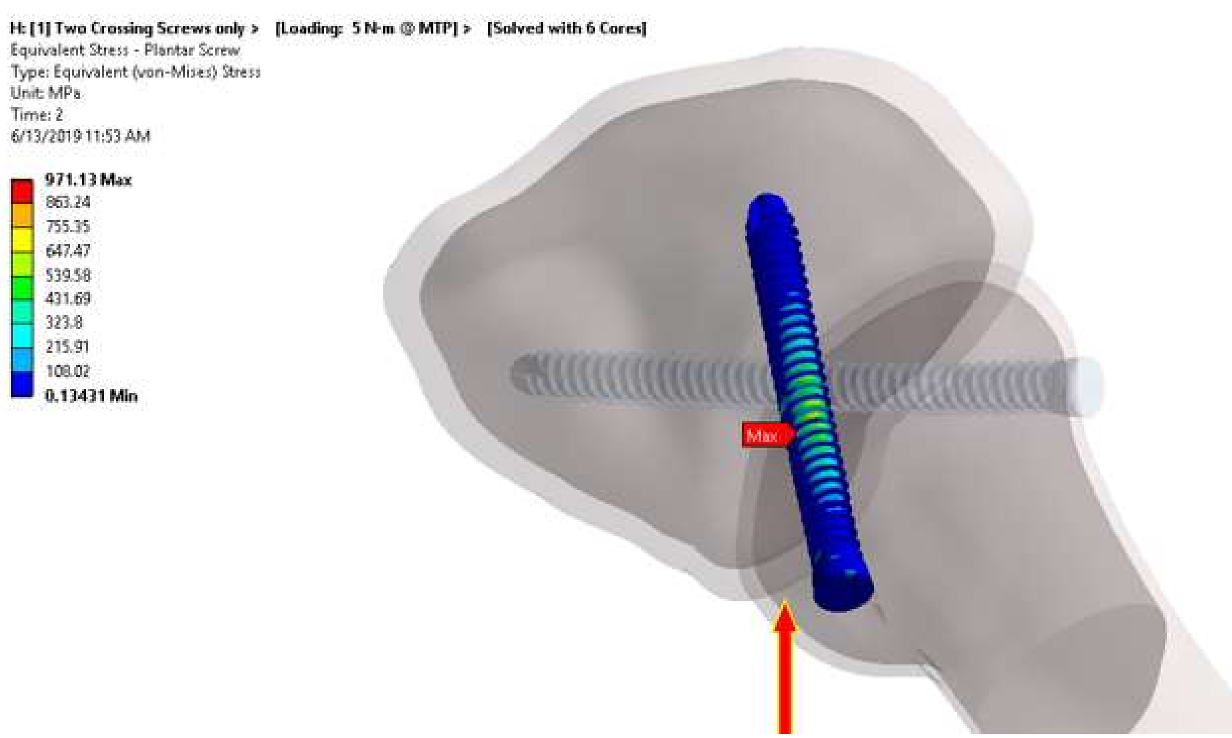

Figure 10: Peek stress experienced by the threaded crossing screw was located at the joint line as well.

In addition, the amount of movement measured in terms of plantar gapping of the fusion site was recorded. This was determined by locating two points on the plantar aspect of each bone and measuring the change in distance between the loaded and unloaded condition. At 5 Nm, the InCore Lapidus System showed a plantar gap of 0.83 mm, while crossing screws demonstrated plantar gapping of 0.99 mm.

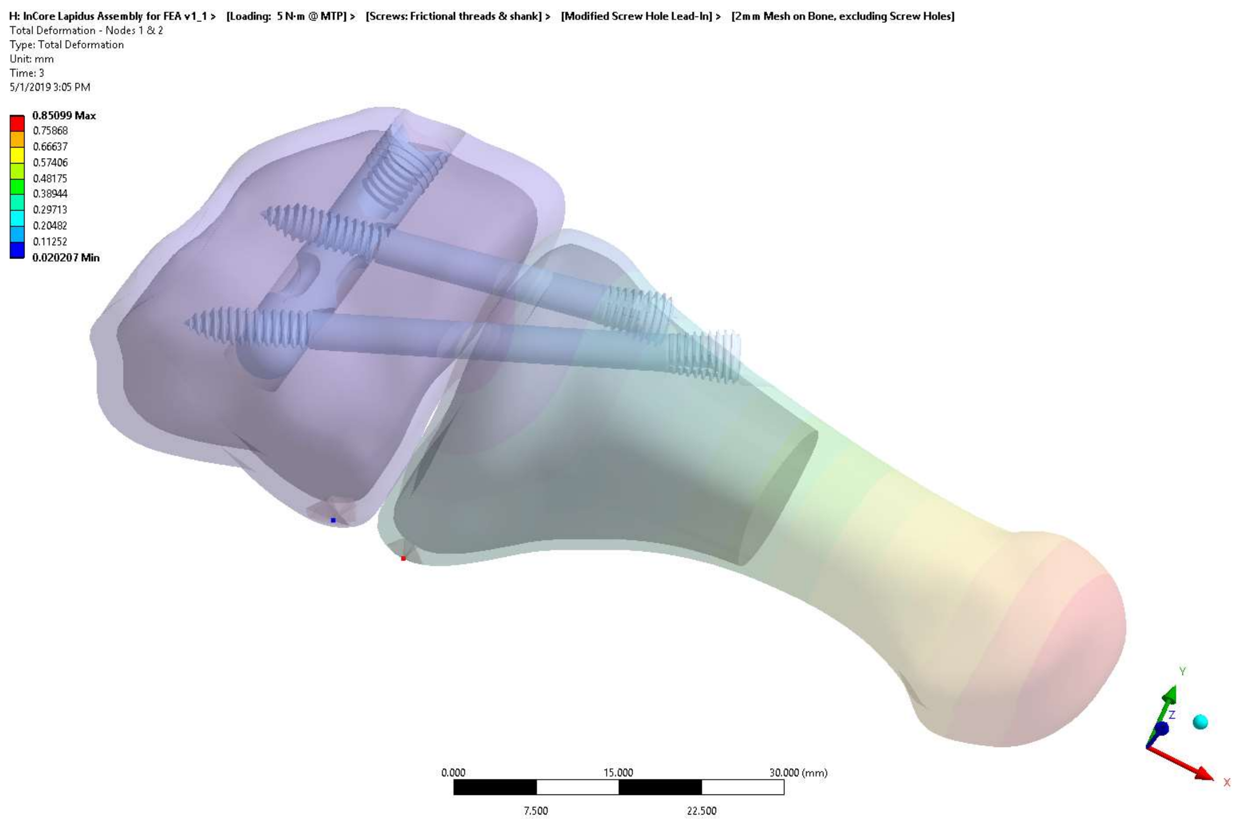

Figure 11: InCore Lapidus in "Undeformed View" i.e. shows the physical appearance of the bones before the load is applied, but still shows the deformation contour map results on the bones.

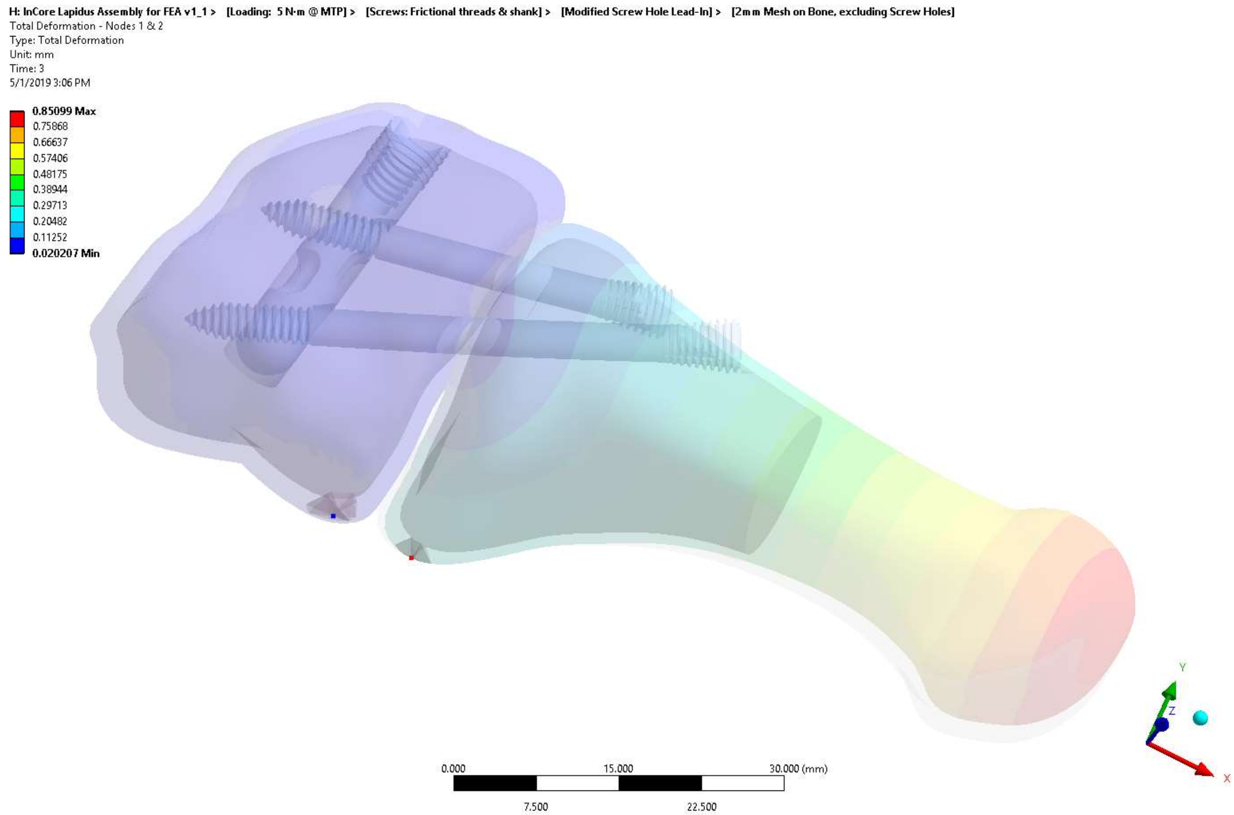

Figure 12: InCore Lapidus in "Deformed View" i.e. shows the physical appearance of the bones after the load is applied as well as the deformation contour map results on the bones.

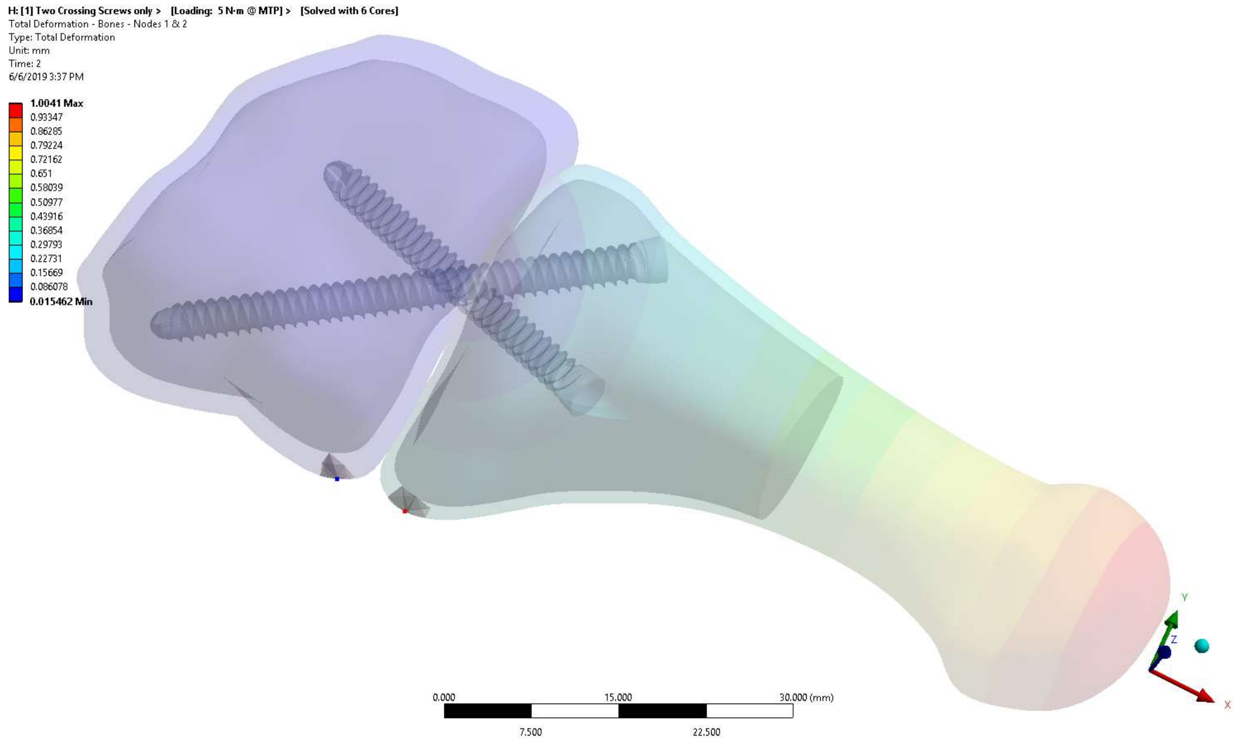

Figure 13: 2 Crossing Screws in "Undeformed View" i.e. shows the physical appearance of the bones before the load is applied as well as the deformation contour map results on the bones.

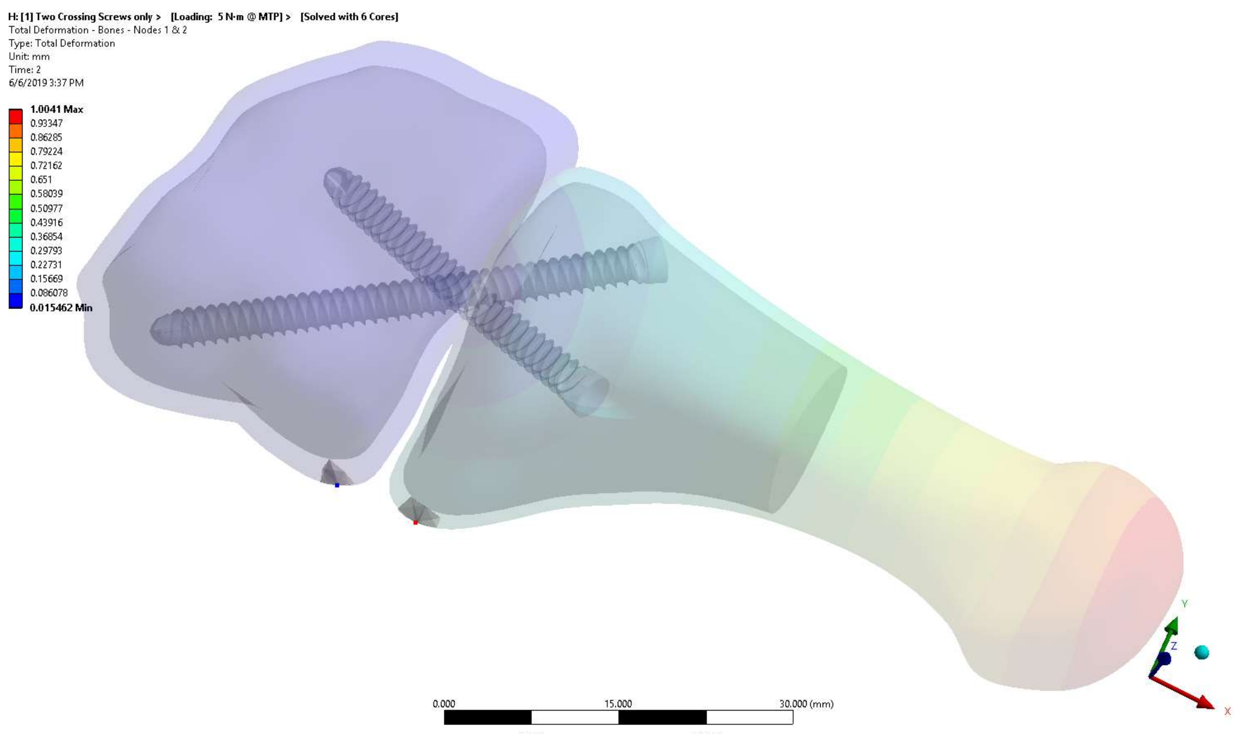

Figure 14: 2 Crossing Screws in "Deformed View" i.e. shows the physical appearance of the bones after the load is applied as well as the deformation contour map results on the bones.

Discussion

As can be seen in the computer analysis, the InCore Lapidus System compares favorably to crossing screws in terms of stress and strain within the system. The primary factors driving the measured advantage of the InCore system appear to be due to the Solid shank portion of the screw across the highly loaded joint space, as well as the anchoring of the distal tip of the screw into a shared solid post. This high joint line stress is supported by Ray[13], who tested 3.5mm crossing screws in a cadaveric model, finding that screws extending from the first metatarsal into the medial cuneiform were notably deformed in all cases at the joint. The moment of inertia calculation of a circular cross section scene in a screw, and thus the stresses observed, is a function of the square of the screw's diameter. Since a threaded screw would be calculated from its minor diameter, one would expect a fully threaded 3.5mm screw, having a minor diameter of 2.4mm, would be approximately half as strong and stiff as a solid shank screw of 3.5mm. The geometric advantage of the InCore Lapidus System is illustrated by the very clear 50% reduction in maximum hardware stress measured compared to a threaded screw.

It is noteworthy that the highest stresses in both types of fixation was seen at the joint line. The analysis maintained a cortical shell for both bones at the joint line. It has been shown that maintaining cortical bone across the fusion site correlates with improved construct mechanical properties[13]. Common methods of joint preparation may be used with either method. The InCore Lapidus System also includes a built-in system to distract the joint for visualization and joint preparation.

The load scenario chosen in this analysis resulted in stresses in the screw exceeding the yield strength of titanium, and thus leading to an expected failure of the crossing screw system. Since hardware failure is not typically seen clinically, other variables must be assessed. Potential explanations for this outcome include 1) the load chosen for this analysis exceeds that typically seen in the early weeks after surgery, 2) Ligamentous support can add a significant amount of stability not accounted for in our analysis, or 3) the inputs and boundary conditions of the analysis are not perfectly identical to typical physical parameters.

Limitations to the analysis are inherent to the computational nature of the study. While this type of analysis can be powerful in ensuring a direct comparison while keeping all relevant variables constant, the absolute value of the outputs can sometimes diverge from values measured biomechanically. Limitations due to assumptions such as bone quality and hardware placement are two of the largest variables in applying the results of the study. Human bone can vary considerably in density and quality, and there are many different starting points and trajectories for placing screws in bone. While not all variables can be accommodated, the analysis on the chosen average bone and screw placement remains a valuable point of reference in assessing the system.

Conclusion

The InCore Lapidus System compares favorably with respect to biomechanical strength and stiffness to benchmark devices currently available for the procedure.

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[I] John M Armacost is a paid consultant of Nextremity Solutions, Inc.
[II] Gregory J Denham is an employee of Nextremity Solutions, Inc.

[*] The InCore Lapidus System is distributed by Zimmer Biomet, Warsaw, IN.

[**] The InCore Lapidus System has not been tested to withstand the forces needed for partial or full weight bearing or excessive activity until healing has occurred.

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