Consulting Report (v3)

Development of a 2D FE Model to Predict Peak Stress Location in the Human Femur during Level Gait

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Executive Summary

High Altitude Analytics has successfully developed an analytical tool that can be deployed by Zimmer Biomet to help diagnose and treat patients at risk of femur microfractures with Zimmer Biomet's newly developed bone morphogenic protein injection. In the specific femur studied in this comparison the key metric determined by Zimmer Biomet was the peak von Mises stress. High Altitude Analytics has shown that this newly developed FEA tool can precisely and accurately model peak von Mises stress in a human femur like that of SIMULIA's Abaqus cost prohibitive software. This tool developed by High Altitude Analytics can be deployed into field clinics so that Zimmer Biomet can cost effectively and quickly diagnose and treat patients with Zimmer Biomet's new morphogenic protein that will result in reducing patient's risk of femoral fracture.

Introduction

Per the request of Zimmer Biomet, High Altitude Analytics has developed, validated, and verified a computational modeling tool capable of predicting the magnitude and location of peak von Mises stress in the human femur bone. This modeling tool has been developed to aid Zimmer Biomet in deploying their new bone morphogenic protein that can be injected to the surface of a bone where it will stimulate new bone formation and strengthen tissues that could be at risk of being damaged. Through various clinical studies Zimmer Biomet has determined that peak von Mises stress between 52-55 MPa has been linked to a 17% increased risk of microfracture during repetitive loading. It has also been determined that above 55 MPa the risk of microfracture jumps to 42% above the normal risk level. This modeling tool that High Altitude Analytics has developed will be used in determining patients at risk of fracture and to aid in the injection location of the morphogenic protein. High Altitude Analytics has provided this report to discuss the development and the results for the client and the US FDA to demonstrate the validity of the computational tool that was developed.

Methods

To generate the most accurate computational tool for Zimmer Biomet, High Altitude Analytics has utilized SIMULIA Abaqus 2019 for validation and verification purposes to compare to an accurate 2D FEA computational tool. Mathwork's Matlab 2020 was used to produce the computational tool for Zimmer Biomet. This model provided by Abaqus was spot checked at various elements and compared to the 2D FEA Matlab code and the results were determined to have a high level of accuracy. For example, peak von Mises stress in both the Abaqus and Matlab code were found to be the same value at the same node, as well as the maximum displacement.

The geometry of the femur bone has been provided by a patient specific X-ray similar to Figure 1. The material of the human femur bone that was used to generate this report was linear elastic and isotropic. The femur bone had a modulus of elasticity of 20,000 MPa and a Poisson's ratio of 0.35 in plane strain conditions. The bottom of the bone (nodes 68 – 112) were fixed, representing the femur's mating to the knee joint. The applied static compressive load to the femur bone was - 20 Newtons in the X direction and - 50 Newtons in the Y direction which is representative of a peak load in a level gait. This load was applied to node 186 indicated in Figure 2. The mesh of the femur bone was generated with over 1300 Linear Strain Triangle elements and can be seen in Figure 2 below. These elements are 2nd order and have 6 nodes and two degrees of freedom.

Figure 1. X-Ray of Human Femur Bone provided by Smith & Nephew, Inc. Image displays X-Ray of a human's left femur bone.

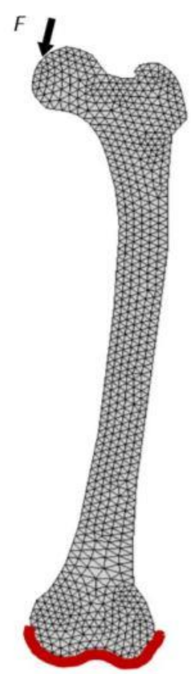

Figure 2. Mesh of Human Femur Bone provided by Colorado School of Mines' FEGN525 Course. Image displays a force being applied in the X and Y directions as well as over 1300 LST elements.

Furthermore, we are assuming a converged mesh for peak von Mises stress which helps further validate the model provided by High Altitude Analytics. To highlight a comparison that was made between Abaqus and Matlab please refer to Figure 3 and Figure 4 below, where one can see that the SIMULIA Abaqus Model – Figure 3 has a peak von Mises Stress at the same exact node as the Matlab generated model – Figure 4.

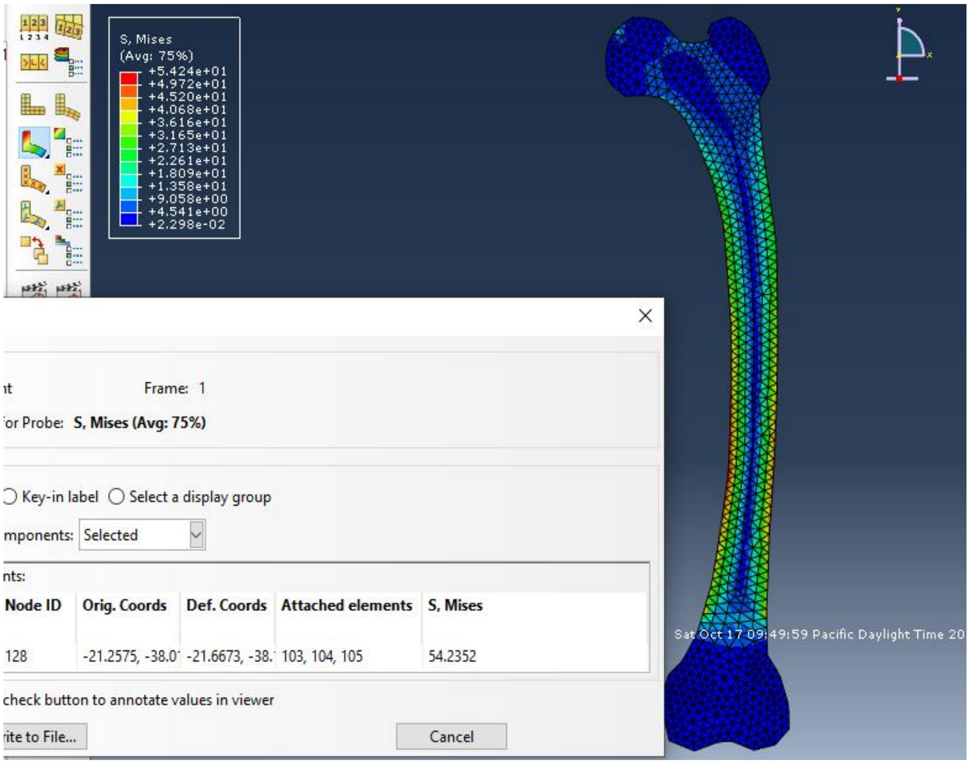

Figure 3. SIMULIA Abaqus FEA Model. Image displays peak von Mises Stress at Node 128.

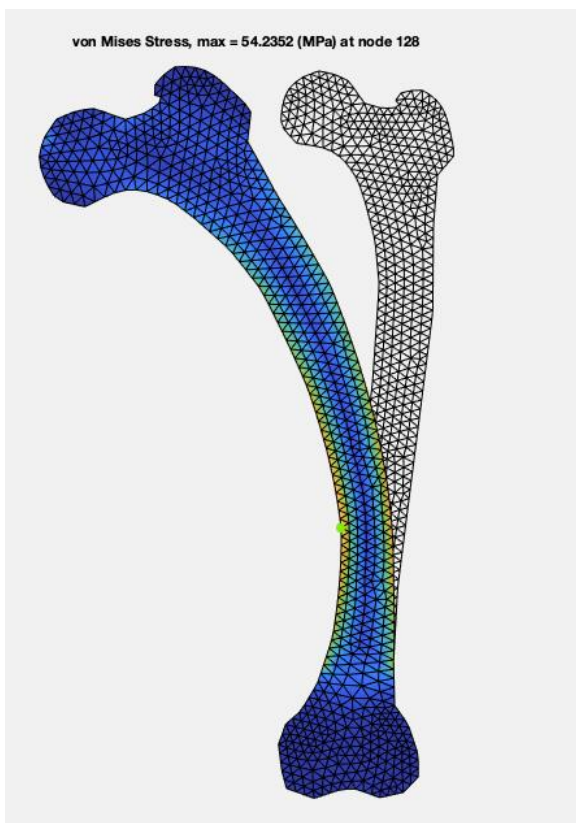

Figure 4. Matlab Generated FEA Model. Image displays peak von Mises Stress at Node 128.

The following equations were implemented into Matlab to model the results presented in this report which made use of the principle of virtual work as discussed in *"Concepts and Applications of Finite Element Analysis"* (Cook et Al). Where Table 1 below represents the variables and the meanings of those variables.

$$\int [\delta\varepsilon]^T \, [\sigma] \, dV = \int [\delta u]^T \, [F] \, dV + \int [\delta u]^T \, [\phi] \, dS \quad (1)$$

$$\{u\} = [N]\{d\} \quad (2)$$

$$\{\varepsilon\} = [B]\{d\} \quad (3)$$

$$[\delta u]^T = [\delta d]^T \, [N]^T \; and \; [\delta\varepsilon]^T = [\delta d]^T \, [B]^T \quad (4)$$

$$[k]\{d\} = r_e \quad (5)$$

$$[k] = \int [B]^T [E][B] \, dV \quad (6)$$

$$\{r_e\} = \int [N]^T [F] \, dV + \int [N]^T [\phi] \, dS + \int [B]^T [E]\{\varepsilon_0\} dV - \int [B]^T \{\sigma_0\} \, dV \quad (7)$$

$$\sigma_{vM} = \sqrt{\sigma_x{}^2 + \sigma_y{}^2 + \sigma_z{}^2 - \sigma_x\sigma_y - \sigma_y\sigma_z - \sigma_z\sigma_x + 3\tau_{xy}^2} \quad (8)$$

$\{\delta\varepsilon\}$	Vector of strains
$\{\delta u\}$	Virtual displacement
[F]	Body forces in volume V
[ϕ]	Surface tractions on surface S
{d}	Nodal displacement degree of freedom
[B]	Strain-displacement matrix
[E]	Plane Stress matrix
[k]	Element Stiffness matrix
$\{r_e\}$	Consistent Nodal Loads
σ_{vM}	von Mises Stress

Table 1. Variables involved in the equations for the Matlab Computational Model provided by *"Concepts and Applications of Finite Element Analysis"* (Cook 2002).

Results

The results generated from Abaqus and Matlab showed a high degree of precision and accuracy in regard to each other. Outlined in Table 2 below the results can be compared with the Abaqus and Matlab models. The mesh has been assumed to be converged. The results displayed in both Abaqus and Matlab show the same number of triangular LST elements totaling 1339 elements that have two degrees of freedom and 6 nodes per element. The forces that are applied at F_x and F_y would vary based on patient specific data regarding their level gait. In addition, the modeled geometry of the femur would vary depending on the genetics of the patient. As a reminder the computational tool that was developed is to insure that peak von Mises stress is similar in both the Abaqus and Matlab models.

Table 2. Comparison of FEA results utilizing Abaqus and Matlab.

	Abaqus	Matlab
Maximum von Mises Stress	54.235 MPa at Node 128	54.235 MPa at Node 128
Maximum Displacement Magnitude	7.424 mm at Node 186	7.424 mm at Node 186

Discussion

Zimmer Biomet has contracted High Altitude Analytics to develop a computational modeling tool to assess patients on a case by case basis which can perform a risk assessment of the patient's femur bone. This risk assessment is used to gauge the patient's suitability of Zimmer Biomet's new bone morphogenic protein that can be injected to stimulate new bone formation to strengthen bone tissue at risk of damage. Based on clinical studies it has been determined that a patient with a level gait that experiences peak von Mises stress in the range between 52-55 MPa is at a 17% increased risk of a microfracture. When the patient's level gait experiences peak von Mises stress above 55 MPa their fracture risk increased 42% above normal levels. What was determined in this specific model was that the patient whose femur was meshed would be at a 17% increased risk level for microfracture and would make for a good candidate for the new bone morphogenic protein. This is because for this specific analysis the patient had a peak von Mises stress of 54.235 MPa. High Altitude Analytics would preferably like to gather a larger sample size of femur bones to ensure that the results generated by the Matlab code are both precise and accurate on a multiple patient study. With that being said, it is within High Altitude Analytics best judgement, with the information supplied, that this computational tool has been successfully developed for Zimmer Biomet to deploy into the field clinics in order to aid patients at risk of fractures in their femur. Also, High Altitude Analytics has consulted "Behaviour of Human Femur Bone Under Bending and Impact Loads" (Arun et Al) for basic dimensions of the femur to see if basic beam theory calculations are accurate and to determine if they are within reason for purposes of this study, bearing in mind that Zimmer Biomet's injection can only help a patients ability to reduce fracture and assuming the side effects of the injection are non-existent which is outside of High Altitude Analytics scope.

The comparison with the results from SIMULIA Abaqus and the 2D FEA code generated with Matlab are precise. The results were nearly identical which accomplished the business objective of Zimmer Biomet contracting High Altitude Analysis to design this computational tool to be deployed in clinics without the high cost of an Abaqus license. The solution time for the computational tool ran in a reasonable amount of time which would allow for a patient to be considered as a candidate for this treatment and treated with the new morphogenic protein injection within one visit.

In conclusion, High Altitude Analytics has determined that the computational tool developed for Zimmer Biomet will be effective in diagnosing patients at risk of microfractures in their femurs. This will allow Zimmer Biomet to deploy this tool at field clinics cost effectively and give patients a diagnosis and injection within the same day if the clinics can process X-rays and the geometry within the visit. High Altitude Analytics would also like to note the need for a larger sample size if the injection was to have any adverse effects in order to verify the Abaqus and Matlab results across a number of different femur sizes and human load factors during their level gait.

References

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Credits

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