SMART HIP IMPLANT

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INTRODUCTION

When people's hip joint is worn or damaged, they can choose to replace their damaged hip with a smart hip implant, improve their mobility, and relieve pain. This report aims to design a long-lasting smart hip implant that can be checked using vibration-based non-destructive testing (NDT), a non-invasive monitoring approach.
Hence, the design criteria are as follows:

- The implant should be lightweight.
- The life expectancy is at least 15 years, equivalent to 5 million loading cycles.
- The implant should have at least five natural frequencies within the range of 100Hz and 3000Hz.
- The material should be either Titanium Alloy Ti-6AL-4V or Stainless Steel 316L.

In this report, the smart implant models are subjected to a finite element analysis using the software Ansys to estimate whether the design will meet the criteria.

METHODS

1ST CAD MODEL

The first CAD model is downloaded from Ansys Private: FEA in Healthcare Industry Analysis of a Hip Implant—Lesson 4 [1]. To simplify the analysis, the acetabular cup and inset of the Smart hip implant are ignored. The head, neck, and femoral stem are considered one body.



FIGURE 1 ANSYS CAD MODEL

MATERIALS

Given the operational conditions of the smart hip implant, which is subjected to a fluctuating load varying from 0 to 2049N, the plot line corresponding to a stress ratio of 0 is selected.

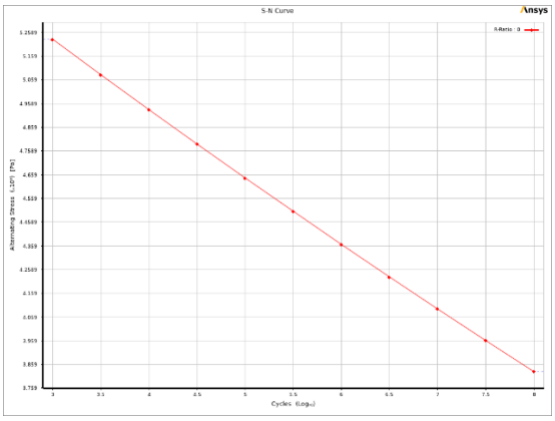


FIGURE 2 TI–6AL–4V FATIGUE PERFORMANCE (R = 0) (ANSYS)

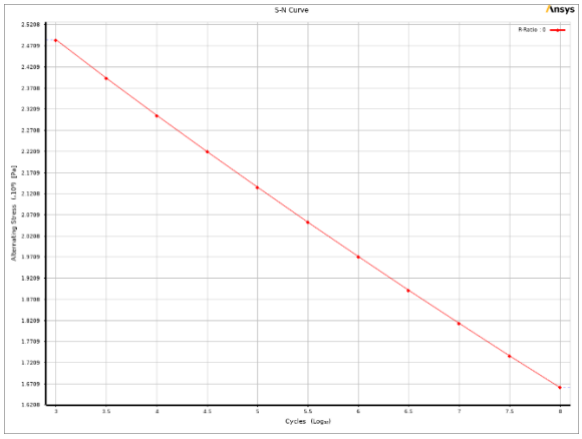


FIGURE 3 STAINLESS STEEL 316L FATIGUE PERFORMANCE (R = 0) (ANSYS)

Other related material properties (from Ansys Engineering Data) are shown in the table below:

Material	Elastic modulus (GPa) (20°C)	Ultimate tensile strength (GPa)	Yield Strength (GPa)	Poisson's ratio	Density (g/cm³)
Ti-6Al-4V	113.2	1.182	1.05	0.34	4.425
SS 316 L	195	0.521	0.229	0.30	7.969

BOUNDARY CONDITIONS

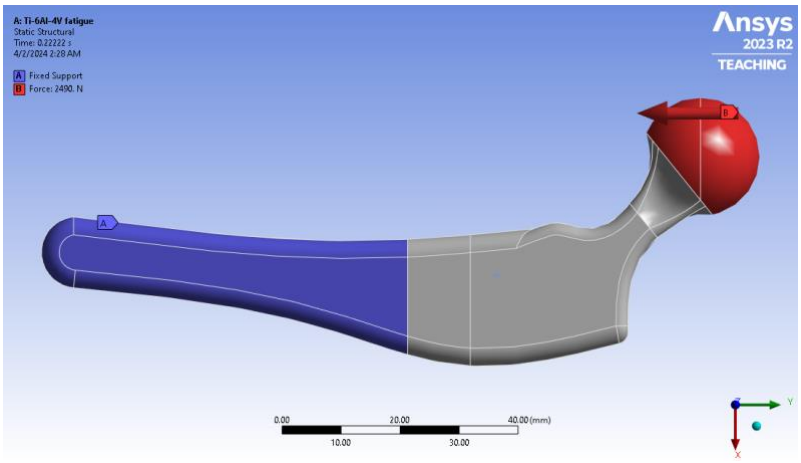


FIGURE 4 BOUNDARY CONDITION [1]

Loads: It is assumed that the implant's head is subjected to a force (vertical along the axis of the stem body) oscillating between 0 to 2490 N.

Fixed Support: It is assumed that the implant's stem is fixed from its tail to approximately halfway through its length.

FATIGUE SIMULATIONS

The equivalent stress is integrated within the static structural analysis in the Ansys simulation environment. Then, the life result under the fatigue analysis module is configured to accommodate the simulation specifics. The Tresca criterion is used due to its conservative approach to failure analysis and relevance for ductile materials like Ti-6Al-4V and SS 316l. The simulation accounts for a zero-based loading condition, mirroring the model's exposure to a fluctuating force with a magnitude ranging from zero to 2490N. In alignment with the flexibility of the employed materials, the Gerber mean stress correction methodology is implemented for the fatigue assessment.

Loading	
Type	Zero-Based
Scale Factor	1.
Definition	
Display Time	End Time
Options	
Analysis Type	Stress Life
Mean Stress Theory	Gerber
Stress Component	Max Shear
Results Input (Beta)	Stress
Life Units	
Units Name	cycles
1 cycle is equal to	1. cycles

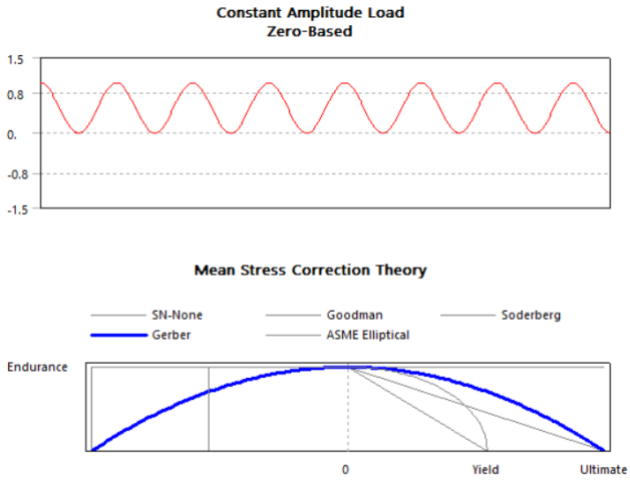


FIGURE 5 FITIGUE SIMULATIONS SETTING

FREQUENCY SIMULATIONS

This study employs a modal analysis framework, with adjustments made to capture the hip implant's initial ten natural frequencies. This allows for extracting the first five natural frequencies while providing insight into the model's vibration tendencies. The pre-stress settings are integrated with the established boundary conditions under the static structural system, ensuring consistency with the fixed support.

RESULTS

MESH REFINEMENT STUDY RESULTS

The convergence study is conducted on the whole model to save computing speed and storage while maintaining accurate results:

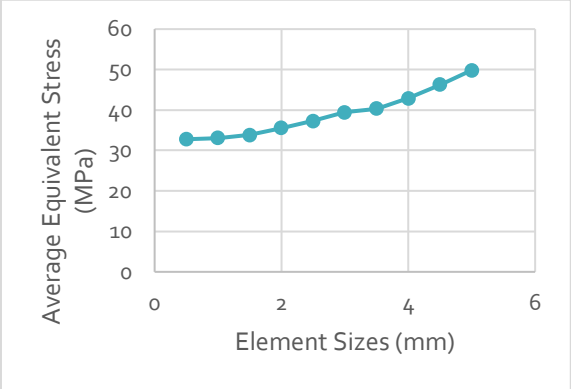


FIGURE 6 AVERAGE EQUIVALENT STRESS V.S. ELEMENT SIZES

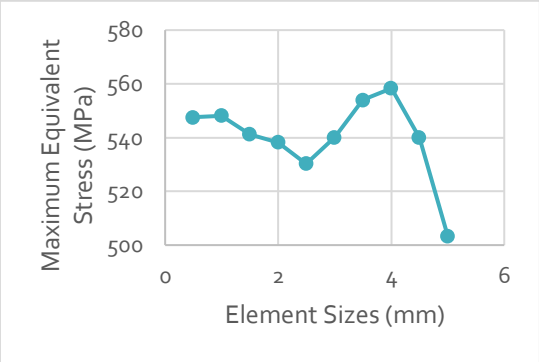


FIGURE 7 MAXIMUM EQUIVALENT STRESS V.S. ELEMENT SIZES

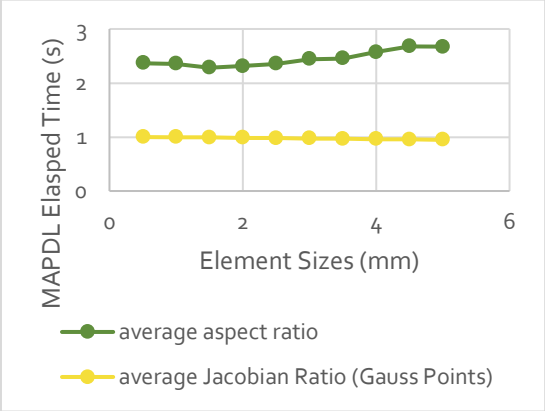


FIGURE 8 MESH QUALITY PLOT

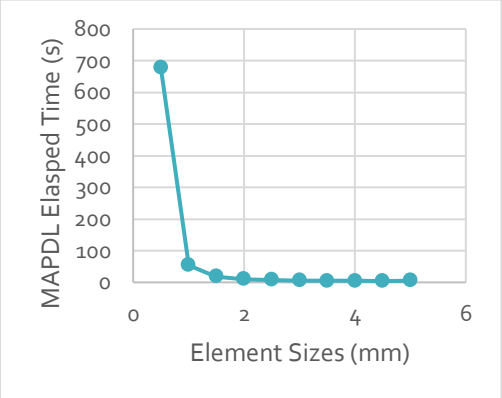
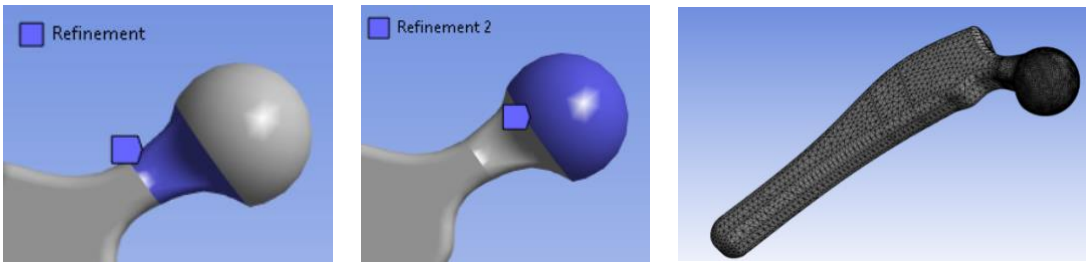


FIGURE 9 ELAPSED TIME V.S. ELEMENT SIZE

Based on the stress plots, the mesh size of 1 mm is the most effective after some initial variation, especially at 2 - 4 mm. The Jacobian ratio is near ideal for all sizes, indicating adequate mesh quality. The aspect ratio remains stable at 2.3 for mesh sizes between 0 and 2 mm, within an acceptable range. For optimal balance between accuracy and efficiency, a 1 mm mesh size is used as computation time significantly increases for smaller mesh sizes. This results in 15710 elements being generated, with an average aspect ratio of 2.356 and an average Jacobian ratio of 0.969.



Upon analysing equivalent stress, it becomes apparent that there is a concentration of stress around the implant's neck, with the force affecting the entire implant's head. Therefore, local refinement is necessary in these areas, which reduces the average aspect ratio to 2.1157.

SANITY CHECKS

The Finite Element Analysis (FEA) was conducted on a titanium alloy version of the initial CAD model to verify the accuracy of the FEA setup. The analysis yielded a maximum deformation of 0.496 mm in the model, which is within an acceptable range, indicating the design's structural integrity under the applied loading conditions. Visual inspection of the simulation animation revealed no significant mesh irregularities or connectivity issues, affirming the mesh quality. The observed deformation pattern closely adheres to the predefined boundary conditions: the model's bottom half remained fixed, and the top half demonstrated downward deformation. This behaviour aligns with a hip implant's expected performance under real-life conditions. High-stress areas were concentrated around the implant's neck, attributed to its slender and angled design. This stress distribution is realistic and aligns with expectations for such geometric features.

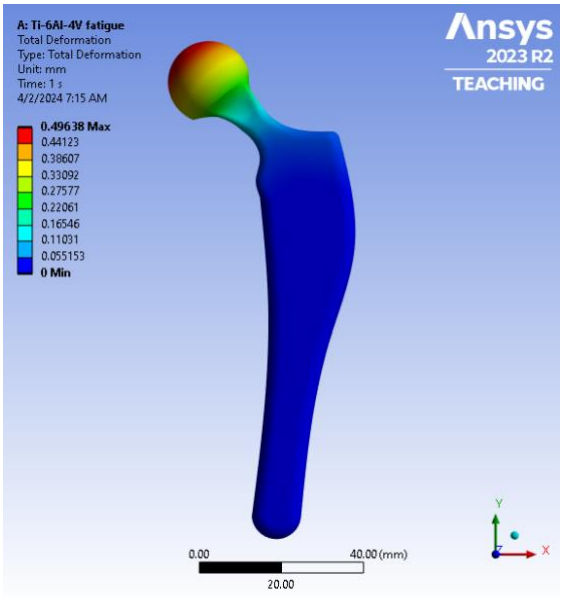


FIGURE 10 TOTAL DEFORMATION PLOT (A TITANIUM ALLOY VERSION OF THE INITIAL CAD MODEL)

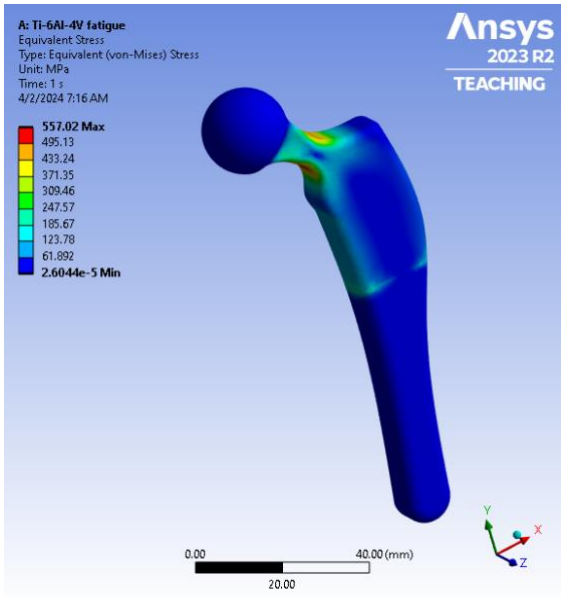


FIGURE 11 EQUIVALENT STRESS PLOT (A TITANIUM ALLOY VERSION OF THE INITIAL CAD MODEL)

FIRST ITERATION OF CAD MODEL ANALYSIS

The fatigue and frequency simulations are conducted on Titanium Ti-6Al-4V and Stainless Steel 316 L.

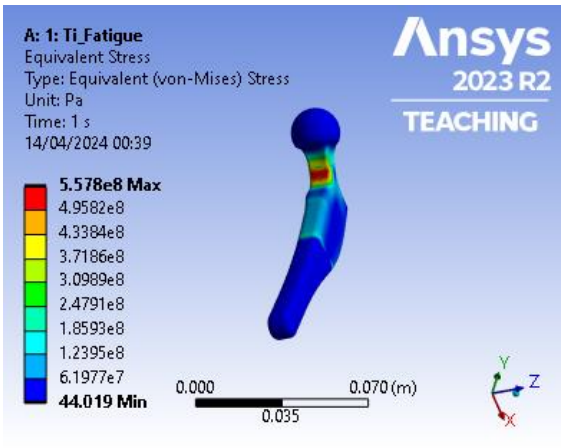
TITANIUM ALLOY SMART HIP IMPLANT

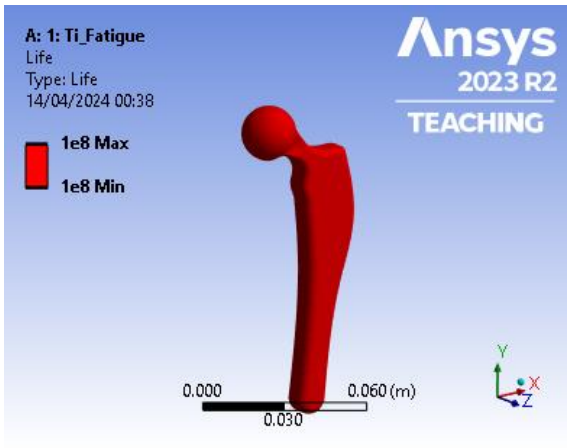
STATIC STRUCTURAL ANALYSIS

The highest value of stress experienced by the model is 0.558 GPa, under the yield strength of the Titanium alloy 1.05 GPa, indicating no static structural failure.

FATIGUE ANALYSIS

The Ansys Fatigue analysis indicates that the entire structure withstands 100 million life cycles, with a maximum shear stress of 165.32 MPa, leading to an alternating stress of 82.66 MPa. Reviewing the S-N curve, the lowest alternating stress for 100 million cycles is 382.9 MPa. If Ansys provides a complete S-N curve for Ti-6Al-4V, the structure is predicted to have infinite life cycles, satisfying the design criteria. However, if the curve is incomplete, the life expectancy still exceeds 100 million cycles. This confirms that the design meets the necessary standards.





VIBRATION ANALYSIS

Only two of the model's first five natural frequencies are within the target range (100 Hz to 3000 Hz).

Mode	Frequency (HZ)
1.	1704.2
2.	2572.2
3.	6167.6
4.	7861.7
5.	8448.3

TABLE 1 NATURAL FREQUENCIES OF THE INITIAL TITANIUM ALLOY MODEL ITERATION

STAINLESS STEEL HIP IMPLANT

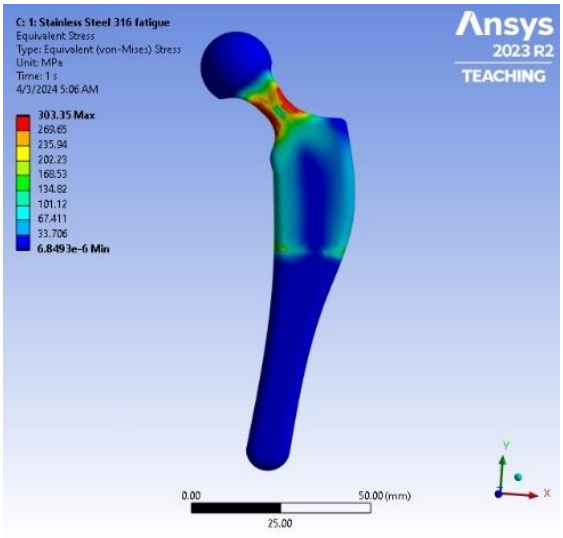
STATIC STRUCTURAL ANALYSIS

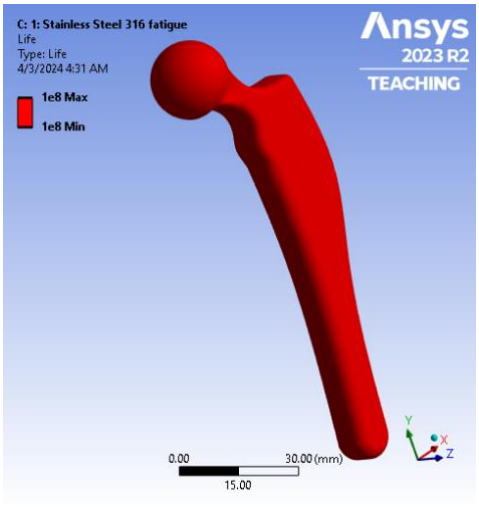
The model's highest stress value is 557. MPa, below the ultimate tensile strength (521 MPa) but above the yield strength (229 MPa). This indicates that while the material has not reached its ultimate failure point, it has surpassed the yield threshold, suggesting the onset of permanent deformation and a potential risk of static structural failure under these conditions.

FATIGUE ANALYSIS

The fatigue analysis of the Stainless Steel 316L model indicates a life expectancy of 100 million loading cycles, with the alternating stress falling below the minimum stress threshold documented in the Ansys Engineering Data S-N curve. Consequently, the model surpasses the design criteria of 5 million loading cycles.

However, the permanent deformation detected during the static structural analysis raises concerns about the suitability of this material and model combination for a hip implant application. This observation suggests that while the fatigue life criteria are met, the material's performance under actual operating conditions may not be adequate, necessitating further evaluation or reconsideration of material selection.





VIBRATION ANALYSIS

Only two of the model's first five natural frequencies are within the range (100 to 3000 Hz).

Mode	Frequency (HZ)
1.	1688.4
2.	2536.
3.	6139.5
4.	7746.7
5.	8434.1

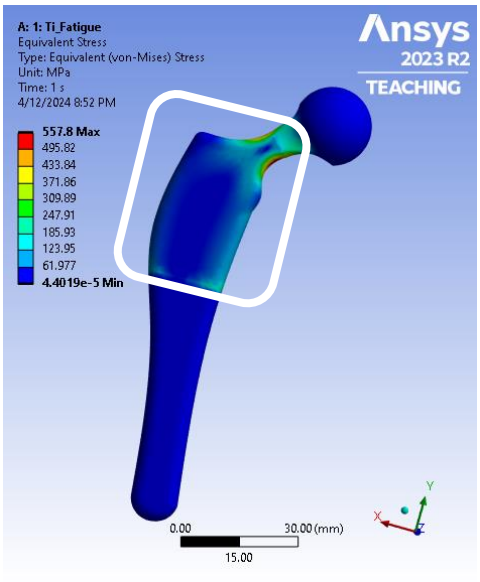
TABLE 2 NATURAL FREQUENCIES OF THE INITIAL STAINLESS STEEL MODEL ITERATION

CAD MODEL REFINEMENT FOR INCREASED NATURAL FREQUENCIES

Natural frequency occurs when a system tends to oscillate without any external force or damping applied to it. It is related to the system's mass, stiffness, damping condition, and boundary conditions:

$$\omega = \sqrt{\frac{k}{m}}$$

Changing the model's geometry can alter its mass distribution and stiffness, thereby changing its natural frequencies. Hence, a second CAD model is designed to increase the number of natural frequencies within the range.



The dynamic response of the hip implant is unaffected by the mass of its fixed section, rendering any modifications unnecessary. It is worth noting that reshaping the head component may lead to discomfort and implant failure, and as such, it is not a viable option for model refinement. The model refinement will concentrate on the neck and upper half of the femoral stem.

The current natural frequencies are higher than the target range, and one way to achieve the goal is to decrease the model's stiffness without compromising too much weight. The blue section of the model indicates that it did not undergo much stress, so this part can be removed to reduce stiffness.

Analysing the first five natural frequencies of vibration movements (shown in green and yellow notation), the following part of the model (shown in orange notation) is trying to cut off to increase body flexibility.

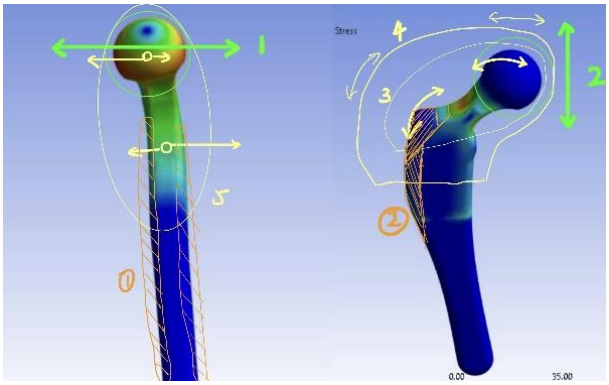


FIGURE 12 FIRST FIVE NATURAL FREQUENCIES VIBRATION MOVEMENT ANALYSIS

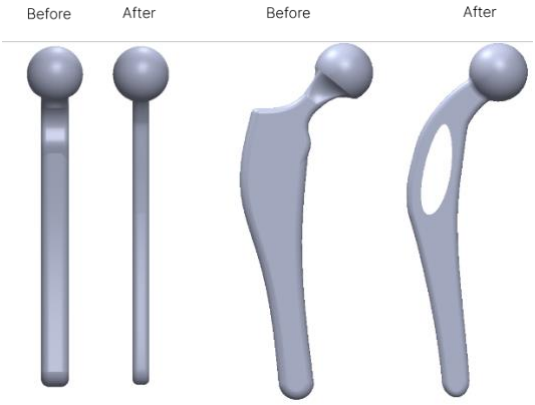


FIGURE 13 CAD MODEL BEFORE & AFTER COMPARISON

SECOND ITERATION OF CAD MODEL ANALYSIS

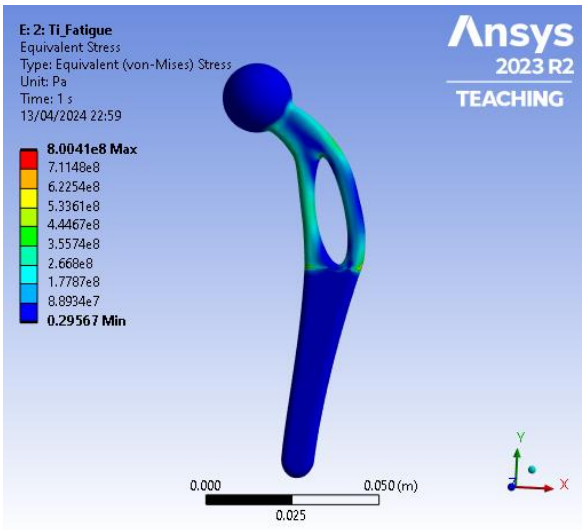
TITANIUM ALLOY SMART HIP IMPLANT

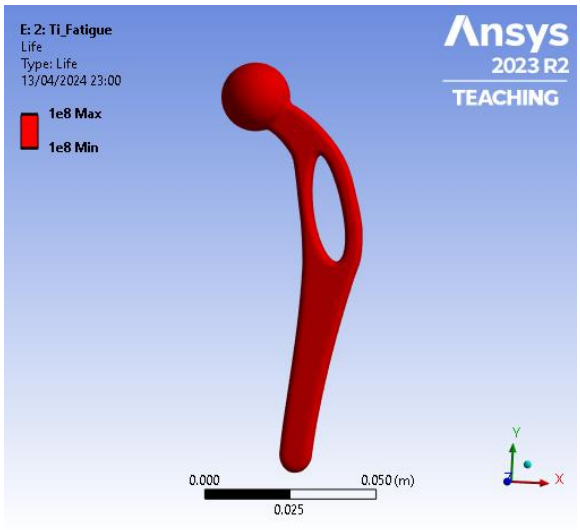
STATIC STRUCTURAL ANALYSIS

The analysis shows a maximum equivalent stress of 0.800 GPa on the structure, below the Ti-6Al-4V alloy's yield strength of 1.05 GPa. This confirms the structure's capability to withstand the applied load without yielding.

FATIGUE ANALYSIS

Consistent with the original CAD model analysis, the updated version demonstrates a life expectancy exceeding 100 million cycles. This performance aligns with the established design criteria, affirming the model's suitability for its intended application.





VIBRATION ANALYSIS

Following the first iteration, the overall natural frequencies of the model have decreased. This adjustment has resulted in one additional natural frequency falling within the 100-3000 Hz target range. Despite this improvement, the model now possesses three natural frequencies within the specified range, which still needs to meet the criterion of having five natural frequencies. Further modifications may be necessary to achieve the desired performance criteria.

Before

Mode	Frequency (HZ)
1.	1704.2
2.	2572.2
3.	6167.6
4.	7861.7
5.	8448.3

After

Mode	Frequency (HZ)
1.	602.16
2.	1779.9
3.	2975.6
4.	4632.1
5.	5700.6

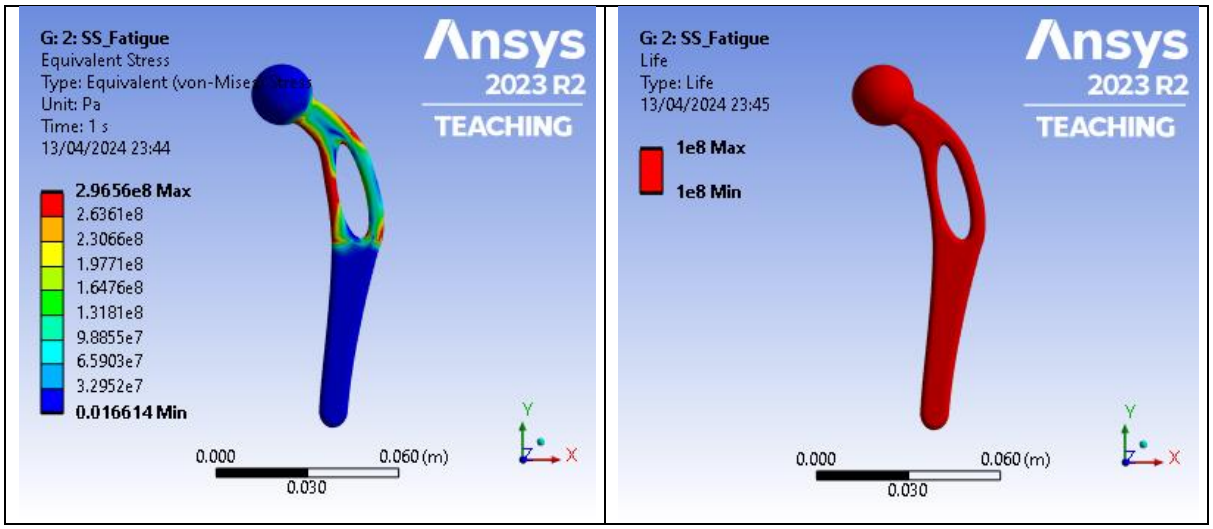
STAINLESS STEEL HIP IMPLANT

STATIC STRUCTURAL ANALYSIS

The analysis reveals that the maximum equivalent stress on the model's yield stress is 0.296 GPa, which exceeds the yield stress of 0.229 GPa. As a result, static failure due to plastic deformation is anticipated to occur in the model.

FATIGUE ANALYSIS

The model experiences a maximum shear stress of 165.32 MPa, resulting in an alternating stress of 82.66 MPa. This is below the lowest recorded alternating stress of 166.2 MPa (corresponding to 100 million life cycles) on the Ti-6Al-4V S-N curve from Ansys Engineering Data. Consequently, the model's life expectancy exceeds 100 million loading cycles, surpassing the design criteria.



VIBRATION ANALYSIS

As shown in the table below, the model after the iteration has one more natural frequency within the target range, approaching the design criteria.

Before

Mode	Frequency (HZ)
1.	1688.4
2.	2536.
3.	6139.5
4.	7746.7
5.	8434.1

After

Mode	Frequency (HZ)
1.	621.57
2.	1743.7
3.	2940.3
4.	4553.8
5.	5631.

DISCUSSION

ACCURACY

This study used finite element analysis to evaluate a smart hip implant's performance under static and dynamic loading conditions. The analysis included comprehensive convergence studies on mesh size, partial area mesh refinement, and sanity checks to validate the computational models. These studies were instrumental in accurately predicting the stress distribution, fatigue life, and vibration characteristics of the smart hip implant made from Titanium Alloy Ti-6AL-4V and Stainless Steel 316L.

LIMITATIONS

Despite the high accuracy of the models in simulating several key performance metrics, there are several limitations inherent to the methodologies and assumptions used:

Material Behaviour: Materials produced using different manufacturing methods will have different microstructural and anisotropic properties, especially in the human body environment. Material engineering data from Ansys may not adequately represent these other conditions. For example, the following graph [2] shows different S-N curves for stainless steel 316 L under different manufacturing treatments.

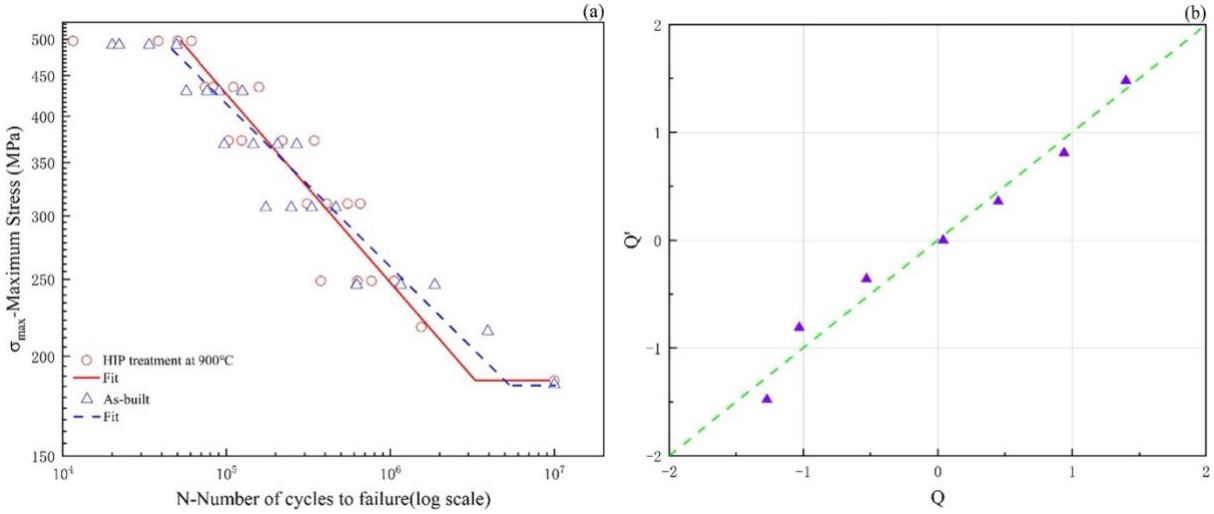


FIGURE 14 316L FATIGUE ANALYSIS (R = 0): (A) S-N CURVE (HIP MEANS HOT-ISOSTATIC-PRESSING); (B) Q-Q' GRAPH. [3]

Simplifications in Model Geometry: The omission of specific implant components, like the implant's cup in the FEA analysis, could lead to oversimplified stress distributions and natural frequency calculations. This simplification overlooks the potential interactions between the components under actual physiological conditions.

Boundary Conditions and Loading: The assumption of fixed supports and specific load applications only partially mimics the physiological conditions under which variable and multidirectional forces act on an implant. The graph below [3] demonstrates that various activities generate contact forces with different magnitudes and directions. This could lead to discrepancies between predicted and actual performance.

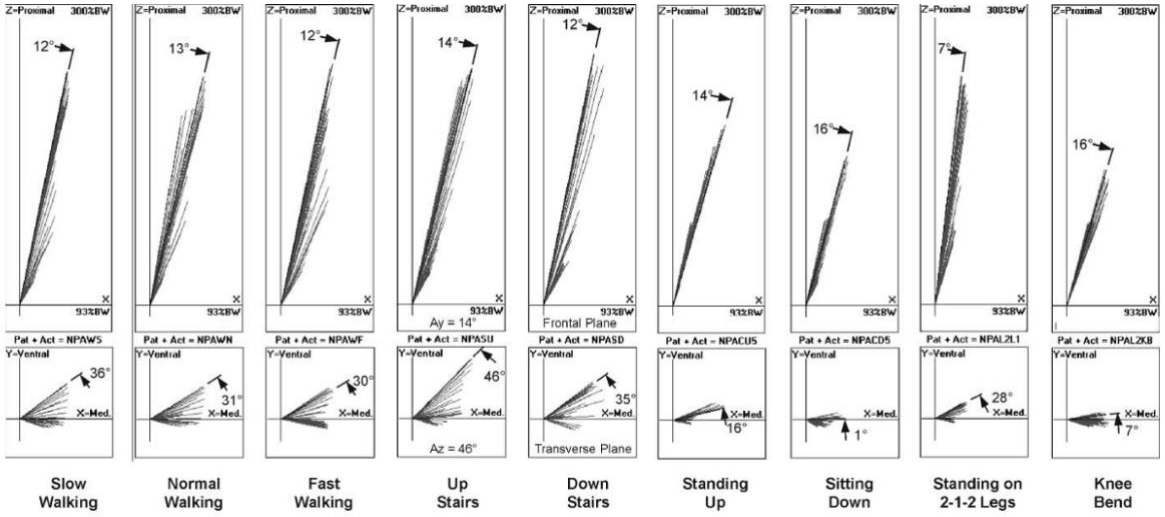


Fig. 8. Contact force vector F of typical patient NPA during nine activities. The z-scales go up to 300% BW. *Upper diagrams*: Force vector F and direction A_y of F in the frontal plane. *Lower diagrams*: Force vector F and direction A_z of F in the transverse plane.

FIGURE 15 DIRECTION OF CONTACT FORCE ON FEMORAL BONE DURING NINE ACTIVITIES [2]

CONCLUSION

Further iterations and refinements, particularly in addressing the limitations noted, are essential for optimising the design and functionality of the implants and meeting the design criteria. Given that Ti-6Al-4V has higher tensile strength and biocompatibility, it's a more promising material for future smart hip implant development.

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[1] "Analysis of a Hip Implant — Lesson 4," Ansys, [Online]. Available: https://courses.ansys.com/index.php/courses/structures-in-healthcare/lessons/analysis-of-a-hip-implant-lesson-4/.

[2] Fanyu Zeng, Yongtai Yang, Guian Qian, "Fatigue properties and S-N curve estimating of 316L stainless steel prepared by SLM," *International Journal of Fatigue,* vol. 162, 09. 2022.

[3] Bergmann, G., Deuretzbacher, G., Heller, M., Graichen, F., Rohlmann, A., Strauss, J. and Duda, G.N., "Hip contact forces and gait patterns from routine activities," *Journal of Biomechanics,* vol. 34, no. 7, pp. 859-871, 2001.