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Fatigue Analysis of Prosthetic Osseointegration with a Novel Protection System

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ABSTRACT

Recent advancements in Osseointegration technology offer a promising alternative to traditional prosthetic limbs, leading to improved comfort and functionality for amputees. However, the primary concern lies in the risk of catastrophic failure and falling due to fractures within the Osseointegration system. To address this challenge, a protective system has been designed. The new design includes an internally rod part with a notch at the bottom to ensure failure at that point, made of ductile cast iron. A cover made of Ti6Al4V alloy is placed to ensure fracture isolation within the protection nail during sudden loading, preventing unexpected falls. After conducting tensile tests for the mentioned alloys and materials, and then relying on the ground reaction force in the numerical analysis using Solid Works software, Finite Element Analysis (FEA) simulations confirmed the effectiveness of this design, with the expected fracture point occurring in the protection nail after exceeding 54973 walking cycles, surpassing the expected maintenance lifespan of the prosthetic limb. This design represents a significant step forward in enhancing the safety and reliability of integrated prosthetic limbs, ultimately leading to improved mobility and peace of mind for amputees.

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1. Introduction

The loss of a limb is the most terrible physical and physiological catastrophe that a person may experience which occurrence of disease, war, and accidents or part of treatment for cancer. Diabetes and peripheral vascular diseases rank as the number one cause of amputation [1].

As a result of the amputation, prosthetic limbs were designed Which consists of prosthetic socket which is the primary and critical interface between the amputee's residual limb and the rest of the prosthesis [2], one of the main challenges for lower limb amputees is mobility. Losing a limb can have a tremendous effect on an individual's quality of life and therefore a good, comfortable fit is required to ensure a positive outcome is reached in an amputee's rehabilitation [3]. The socket has to be efficiently fitted, have adequate load transmission, and it needs to ensure stability and control. Many patients with amputations stop wearing their prosthesis and a major cause is socket-related problems [2].

There is none traditional method and advanced used for amputees called the Osseo integrated method, Osseo integrated is fitting metal implant directly in to the residual bone of an amputee and connecting an external prosthesis to it, this process enables the bone structure and external prosthesis to be connected. Based on a microscopic examination of a titanium implant inserted into the host bone, it appeared that newly formed bone adhered itself to the metal surface. Many of the problems with traditional prosthetic sockets, like poor fit and suspension, skin disintegration, and pain, are eliminated by these bone-anchored implants that pierce the skin and soft tissues. Osseo integrated implants have the potential to enhance amputees' ability to use prostheses and reduce pain and function [4].

the Advantages of Osseo integrated, the amputee can 'feel' what kind of surface they are walking on. This reduces fall risk, the prosthesis can be worn for several hours, and in

most cases all day long compared to a socket which causes sweating, allergies and bacterial growth. [5], Donning and doffing the prosthesis is fast and easy

D. Reetz et al. [4] in 2020, in the research project carried out Bone-anchored prostheses have been utilized as an alternate approach to prosthetic sockets for nearly three decades. This method directly connects the artificial limb to the femoral residuum using an Osseointegration implant.

In the research project carried out in 2020 by Jason Shih Hoellwarth et al. [6], Osseo integrated prostheses offer a rehabilitation alternative for those who have undergone amputation, there are numerous Osseo integrated implant designs, surgical procedures, and rehabilitation protocols, each with their own advantages and disadvantages.

Liang Zhou et al. [7] 2021, reported Titanium (Ti) and its alloys are widely used in biomedical engineering to develop various devices and components, particularly those intended for hard tissue replacements. Additionally, the surface characteristics of titanium implants play an essential part in facilitating the quick and stable integration of bone tissue, known as Osseo integrated.

Farhad Ghadami et al. in 2022 [8], This study looked at how Osseo integrated and bonding strength at the bone-implant interface were affected by hydroxyapatite (HA) and hydroxyapatite/titanium (HA/Ti) coatings. alonger-term study may reveal a higher bone production level during the Osseo integrated process, namely between the implant and the bone around it.

In the study conducted by Brecca M.M. Gaffney et al. in2022[9] This study was the initial endeavor to illustrate the impact of Osseo integrated prostheses on both static and dynamic balance. In the context of utilizing a trans femoral Osseo integrated prosthesis.

Figure (1) Osseointegration prosthetic components

In the study conducted by Khalid Alluhydan et al. in 2023[20], The present literature analysis has comprehensively examined diverse facets pertaining to the design of prosthetic lower limbs for individuals with amputations. Continuous improvement and innovation are necessary to improve user satisfaction, mobility, and quality of life.

2. Methodology

The chemical analysis of and ductile cast iron and Ti6Al4V alloy was examined. The results are presented in Tables 1.

Also, the experimental investigation on the mechanical properties of Ti6Al4V and ductile cast iron, samples were meticulously prepared according to ASTM standards for tensile testing. For Ti6Al4V, specimens were machined from a bulk material into standard.

Similarly, ductile cast iron samples were prepared by cutting them from a larger casting using a CNC machine.

After the samples were prepared, they were loaded into the tensile testing machine according to ASTM E8/E8M-13a. The testing machine applied a steadily increasing tensile load to the samples until they fractured. During the test, the machine recorded the applied load and the corresponding elongation of the sample, allowing for the construction of stress-strain curves as shown in figure 1. Ground reaction force (GRF) testing with Tekscan's force plate technology is a crucial tool for biomechanical analysis. It offers precise measurements of how an individual's body interacts with the ground during activities like walking. For a person of 171 cm height, 67 kg weight, and 37 years old, GRF testing provides

insights into weight distribution, movement patterns, and potential injury risks. This data aids in developing personalized rehabilitation or training programs to optimize performance and prevent injuries. Tekscan's technology allows for real-time feedback, enabling dynamic adjustments during testing to enhance movement efficiency and overall musculoskeletal health as shown in figure 2. The Osseo integrated limb and the innovative protective device are exposed to a variable load due to the effect of the ground reaction force, and this can be observed during the complete walking cycle, where the fatigue is of the repeated load type. The GRF force, which was practically measured by the force plate, is taken advantage of, as well as other information that was obtained. It is obtained practically from a tensile test, and all this information is entered into the solid work program in order to know the weakest area in the Osseo integrated limb system, and that (weakest) area must be the protection structure, taking into account that its lifespan is good, but less than that of the fusion system. During the program, the minimum life span is determined, in this study, the number of nodes reached 7109, and the type of element used is tetrahedral elements. A numerical analysis was conducted using the Solidwork program to evaluate the safety and performance of the innovative prosthetic protection component. In turn, the analysis simulated the real-world conditions that the component goes through during the various stages of the gait cycle, where a model was created. A detailed 3D rendering of the entire component including the prosthesis and the protection component of the solidwork. Using manufacturing data, the system was then physically fixed to the top of the pin to mimic its attachment to the Osseo integrated implant in the bone as shown in figure (3).

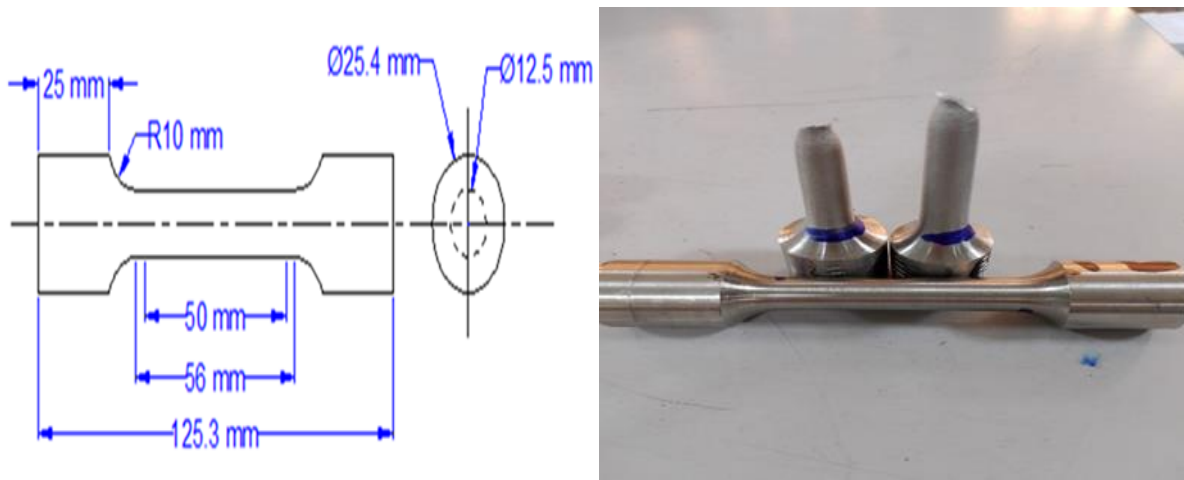


Figure 1. The sample of the tensile test



Figure 2. Ground reaction force with force plate

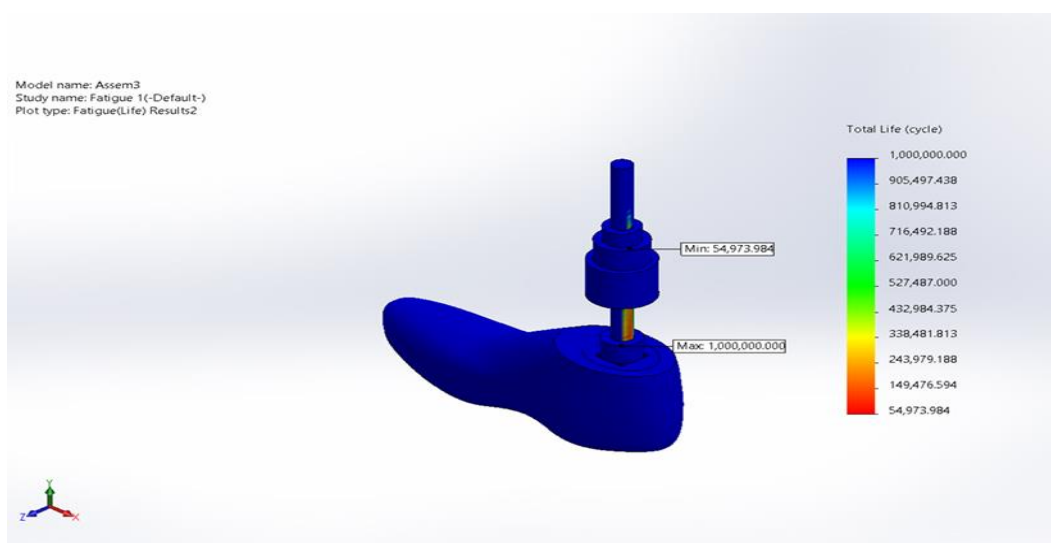


Figure 3. minimum age for fatigue failure.

Table 1: Chemical composition of Ductile cast iron and Ti-6Al-4V alloys.

Fe%	Mn%	P%	Si%	S%	Mg%	C%	Ductile cast iron
Balance	0.27	0.008	2.65	0.007	0.045	3.37	EXPERIMENTAL
Balance	0.2-0.3	0.01 max	2.3-4	0.02 max	0.02-0.05	3.2-4	STANDARD
							Ti-6Al-4V
Ti%	Al%	V%					Ti-6Al-4V
88	5.6	4.3					EXPERIMENTAL
90	6	4					STANDARD

3. Results and discussion

The tensile test results reveal significant differences between ductile cast iron and Ti-6Al-4V alloy. For ductile cast iron, the ultimate strength is 537 MPa, with a yield strength of 374 MPa and a modulus of elasticity of 178 GPa. In contrast, Ti-6Al-4V alloy exhibits notably higher mechanical properties, with an ultimate strength of 873 MPa, a yield strength of 768 MPa, and a modulus of elasticity of 118 GPa, as shown in Figure 5.

These results highlight the superior mechanical performance of Ti-6Al-4V alloy compared to ductile cast iron. In this section, it is explained the results of research and at the same time is given the comprehensive discussion. Results can be presented in figures, graphs,

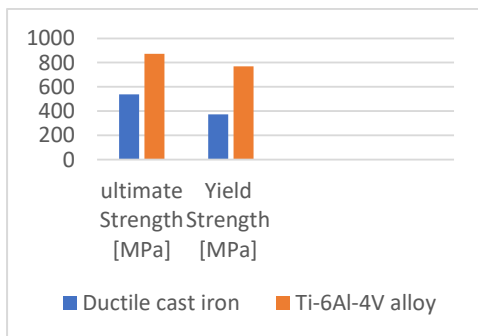


Figure 4. Tensile test results

When the ground reaction force test was performed, showed that in heel strick region When the initial peak force is reached as the entire foot contacts the ground, the vertical GRF rises. After this first peak in, the normal

force decreases according to the mid-stance phase, Since the opposite foot is in the mid-swing phase during this period, the standing leg supports the entire body weight. The leg and foot provide a strong foundation for body movement as shown in figure (5).

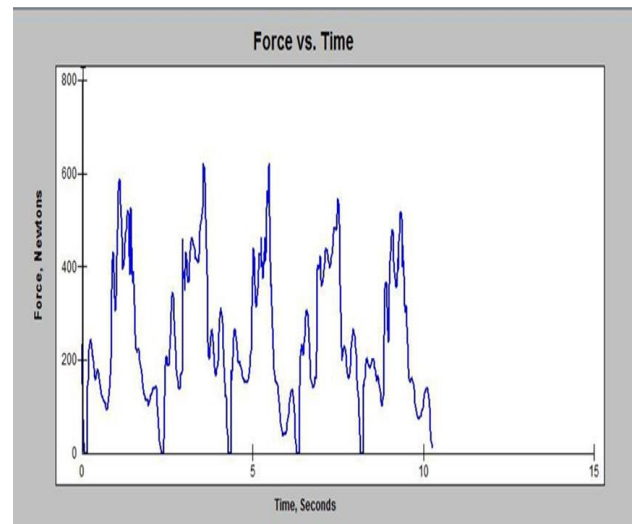


Figure 5. Ground reaction force of the study.

The GRF begins to rise again when the heel lifts off the ground. The second double support is associated with the second rising top of the GRF. Finally, the GRF pattern begins to decline toward zero, as shown in graph

From the GRF strength that was measured practically using the force plate, as well as other information obtained practically from the tensile test, all of this information was entered into the solidwork program. The weakest area in the Osseo integrated limb system was identified, which is the protective

structure, and through the program the minimum age was determined. hypothetical, the expected fracture point of the protection pin was observed to occur after exceeding 54,973 gait cycles, which exceeds The expected maintenance life of the prosthetic limb as shown in figure 6.

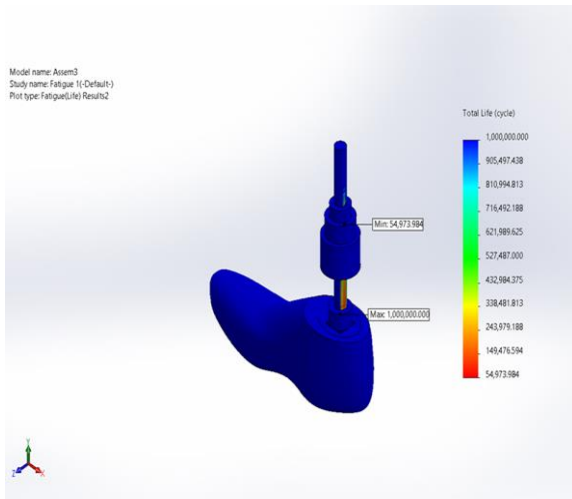


Figure 6. minimum age for fatigue failure.

4. Conclusions

- 1.The aim of the study is to protect the bone fusion system from fracture, which can cause significant damage.
- 2.The fracture must be in the innovative protective part and does not cause damage to the implant system inside the bone.
- 3.The lifespan of fatigue failure was good and less than that of the Osseo integrated system.

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