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# Analytical and Mechanical Study of Transtibial Osseo-Integrated Prostheses Implant

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## Abstract

In amputation surgery, osseointegration is the placement of a metal implant in the residual bone and is conducted with an external prosthesis. In this study, the prospective application of Ti–13Nb–13Zr alloy in a transtibial osseointegrated prosthesis was carefully examined. The alloy demonstrated favourable mechanical properties, such as strong mechanical strength with an average yield strength of 482 MPa, ultimate tensile strength of 551.843 MPa and modulus of elasticity of 74 GPa. In compression testing, the material showed its resilience to compressive loads, exhibiting 700 MPa yield strength and 1010 MPa compressive strength. The elastic modulus of Ti–13Nb–13Zr alloy is approximately 55–65 GPa, which is much closer to that of human bone (10–30 GPa) compared with that of Ti–6Al–4V alloy (110 GPa). This proximity reduces stress shielding, a common issue in implants that a mismatch in stiffness between the implant and bone leads to bone resorption. Analyses using the finite element method demonstrated uniform stress distribution, safety factors and minimal deformation for a range of implant sizes, guaranteeing structural integrity and functionality. The maximal von Mises stress on the tibia bone and implant did not surpass the yield tensile stress of the titanium alloy and bone, which is 470 and 175 MPa, respectively; the maximum safety factor at L=120 and D=3 and the stress levels are not expected to induce material failure. These findings bring up new possibilities for enhanced prosthetic design and use in the field of biomedical engineering by demonstrating the alloy's potential suitability for osseointegrated prosthetic applications.

***Keywords:*** *Implants; osseointegration; prosthetics; bone attachment; Ti–13Nb–13Zr alloy*

## 1. Introduction

Traditionally, prosthetic limb attachment has been accomplished by screwing the artificial limb into a socket that fits the stump. Over the years, several developments in socket technology have improved the connection between the stump and socket. Even with these advancements, this attachment method's efficacy is usually considered lacking [1–3].

In developed nations, chronic vascular disease stands as the primary reason for limb loss [4]. Nonetheless, many apparently healthy people also experience amputation because of trauma, neoplasia, infection and vascular embolism [5, 6]. The traditional method of attaching a prosthetic limb to the residual limb involves using a socket [7]. However, many socket prosthesis users report a worse quality of life [8–11] and have encountered problems such as dermatitis and infected sores. The inability of the residual limb's soft tissues to sufficiently sustain body weight leads to discomfort, degeneration and irritation of the soft tissues [12], as well as poor control over the prosthetic limb [10]. Additionally, variations in stump volume caused by swelling exert an effect on the attachment [13, 14]. For the past 20 years, an alternative technique that entails affixing the prosthetic limb directly to the femur using a percutaneous implant has been proposed. The procedure that results in long-term repair is called osteointegration [15].

The goal of prosthetic bone anchoring is to reduce or eliminate the aforementioned issues. The principles of osseointegration, which has been employed to replace artificial teeth since 1965, serve as the foundation for our innovative approach [16]. A study found that after 15 years, the mandibular bone has a 90% implant survival rate [17]. For the external prosthesis to form a solid, long-lasting link, osteointegration necessitates direct contact between the fixture and bone tissue [18]. This strategy removes range-of-motion (ROM) restrictions induced by sockets and skin conditions related to sockets, facilitates handling prostheses and improves limb control [19–21]. One possible remedy for bone-anchored prostheses would be to utilise a transcutaneous osseointegration implant [22]. Currently, this method is used for patients who have had transfemoral amputations because of trauma or malignancies, but it may also be useful for patients who have peripheral vascular disease or transtibial amputations [23–25]. The impact of osseointegration implant surgery on functional performance and the risk of adverse events, particularly in specific patient groups, is not well supported by current data. Despite the premise that bone-anchored prostheses aid in the early recovery of walking and movement, comprehensive research on the first year following therapy is lacking. Prospective trials focused on amputees of the lower extremities who were having trouble using conventional socket-suspended prostheses and were thus candidates for press-fit osseointegration implants and preplanned rehabilitation regimens [26].

A metal implant is surgically inserted into the remaining bone of a severed limb on side to create bone-anchored prostheses, often referred to as osseointegrated lower limb prostheses. Afterwards, a connection is used to attach this implant to an external prosthesis via a little skin incision on the opposite side of the stump. Since May 5, 1990, when Sweden implemented the first osseointegrated femoral prosthesis, several designs have been created [27]. Six osseointegrated prosthesis designs are now available for purchase. Every design has its own signals, advantages and disadvantages [28]. The Osseointegrated Prosthesis for the Rehabilitation of Amputees (OPRA) design is the most ancient osseointegrated prosthetic design and has the longest patient follow-up data available, having been developed over three decades [29].

This study uses ANSYS Workbench 17.2 to numerically analyse the fatigue and mechanical characteristics of the suggested Ti–13Nb–13Zr alloy as an implant inserted into the tibia bone for prosthetic osseointegration to improve fit (i.e. with regard to the volume and shape of tissue stump) and gait cycle; eliminate skin irritations due to friction, sweat or heat; and enhance quality of life and ROM at sitting, standing or walking for patients. The elastic modulus of Ti–13Nb–13Zr is approximately 55–65 GPa, which is much closer to that of human bone (10–30 GPa) compared with that of Ti–6Al–4V (110 GPa). This closeness reduces stress shielding, a common issue in implants that a mismatch in stiffness between the implant and bone leads to bone resorption.

## 2. Experimental Procedures

### 2.1. Material selection for the implant

The cylindrical sections of the Ti–13Nb–13Zr alloy according to ASTM F-1713:2008 [30] were provided with dimensions (L = 400 mm and D = 13 mm), as illustrated in Fig. 1, to study tensile, compressive and fatigue properties, particularly to create standardised specimens for mechanical testing. The chemical composition of the Ti–13Nb–13Zr alloy used in the study is shown in Table 1, which offers a thorough explanation of the alloy under investigation and demonstrates its appropriateness as an implant material. The chemical analysis was carried out via X-ray fluorescence testing at the material laboratory of the Ministry of Science and Technology in Baghdad, Iraq.

**Table 1,**
**Chemical Composition (weight percent %) of Alloy.**

| Elements | wt. pct. % | Elements |
|---|---|---|
| Zr | 14.23 | Zr |
| Nb | 13.15 | Nb |
| Fe | 0.1125 | Fe |

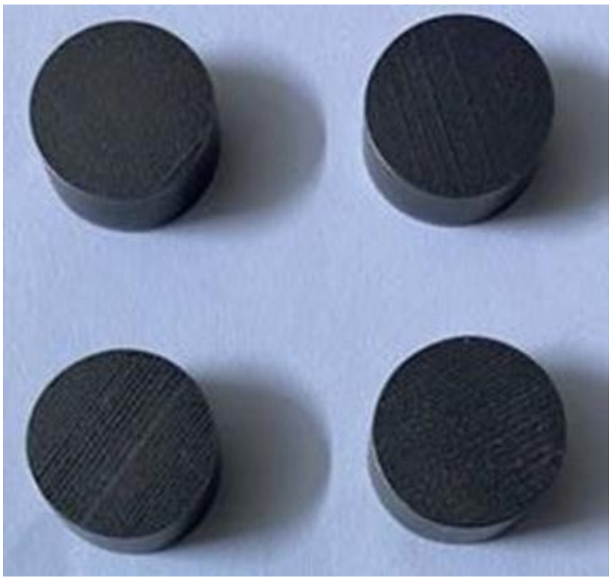

**Fig. 1. Ti-13Zr-13Nb Specimen (D=13, t=25) mm.**

## 2.2. Tensile test device

The mechanical properties and tensile strength of materials used to create titanium alloy implants are evaluated using tensile test equipment, which is crucial for determining how long a material will last and how well it can withstand stretching stresses, as depicted in Fig. 2. The ASTM E8/E8M [31] standard is primarily adopted to assess the properties of Ti–13Nb–13Zr. This standard describes how to calculate tensile properties such as elongation, area reduction, yield strength and ultimate tensile strength. These qualities are essential to comprehending how the material behaves under strain. They shed light on its mechanical capabilities, robustness and applicability for a range of uses, such as implant material in prostheses, to determine if Ti–13Nb–13Zr is a viable material for implants, as demonstrated in Fig. 3.

**Fig. 2. Test machine holds the specimen under tension.**

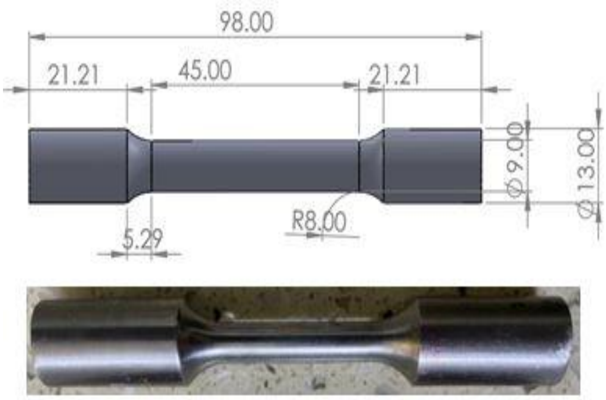


**Fig. 3. Tensile test specimen and dimension in mm for metallic material**

## 2.3. Compression test device

A compressive force is applied to a specimen between two jaws to assess its compressive strength, deformation characteristics and axial load tolerance, as shown in Fig. 4.


**Fig. 4. Compression Test Machine.**

A static compression test was performed on a Ti–13Nb–13Zr specimen in compliance with ASTM E9-09 [32] criteria. The sample in this test was continuously traversed at a speed of 2 mm/min until it cracked or broke. Three samples were subjected to this technique. Figure 5 displays the specimen's dimensions used for the compression test.

**Fig. 5. The dimension of specimen (D=13, L=25) mm**

## 2.4. Fatigue test on a rotating Ti–13Nb–13Zr alloy specimen

The typical method for performing a fatigue test on a rotating specimen composed of Ti–13Nb–13Zr alloy is to apply repeated stresses to it cyclically, as shown in Fig. 6. The fatigue life and durability of materials, especially those subjected to rotational stresses or forces, are commonly assessed through this type of test. Such assessment provides crucial information for engineering and design by illuminating the extent to which a material can withstand the stresses caused by rotational motion over time.


**Fig. 6. Rotating fatigue device.**

Swanson et al.'s study [33] provided a comprehensive dataset that was used to build the S-N curve for human bone. With this specific testing protocol, samples are subjected to alternating compressive and tensile stresses to establish a relationship between the number of cycles (N) and stress (S), with the average stress for all cycles equal to zero. The results are necessary for analysis of tibia bone with implant via ANSYS software.

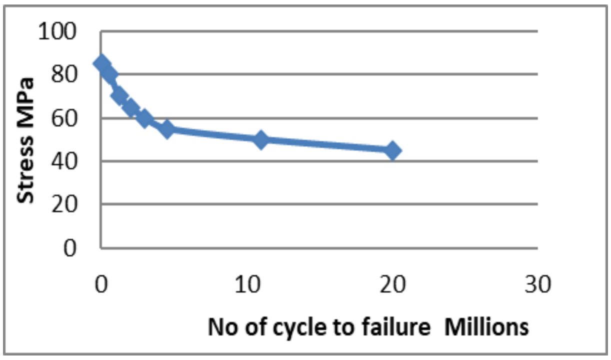


**Fig. 7. The S-N curve of Tibia bone [33]**

## 2.5. Experimental evaluation of loads

Force plates were used to assess the gait cycle of the patient shown in Fig. 8 during the test. The test aimed to assess the weights that the prosthetic limb experienced in different walking scenarios. The characteristics of the patient are as follows: 74 kg, male, 1.60 m tall, aged 30 and left amputation walking on a plate at the engineering department of prosthetics and orthotics. Ethical approval was obtained from Al-Nahrain University's College of Engineering (02/2020). This information is meant to be utilised with finite element method (FEM) software, such as ANSYS 17.2, to ascertain distribution of stress and deformation of the implant inserted into tibia bone and to comprehend how the prosthetic limb and the body interact as the patient walks.

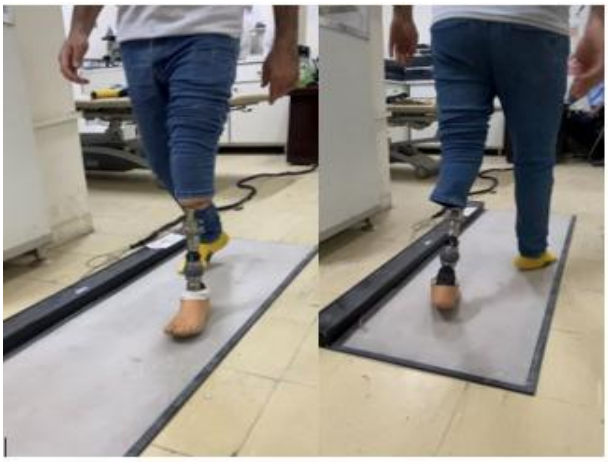

**Fig. 8. Patient wearing below knee osseointegrated prosthesis**

## 2.6. 3D Modelling and FEM model

The model used in the below-knee amputation study was created using SolidWorks, a 3D parametric modelling programme widely used in engineering and design applications. The model is shown in Fig. 9.

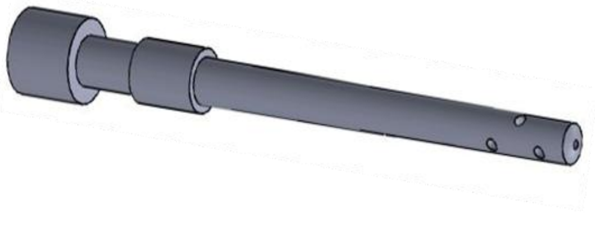

**Fig 9. The model of the prosthetic implants.**

For the implant and bone depicted in Fig. 10, the SolidWorks model enables the visualisation, analysis and customisation of the prosthetic design. This programme lets engineers and scientists precisely change the size of the implant, making sure it fits well, works with the body and is useful for patients who have had transtibial amputations. This strategy makes it possible to accurately alter and enhance the prosthetic design, improving its use and capacity to effectively meet the needs of each user.

**Fig. 10. Different length of implant with tibia bone**

This study examined the link between total deformation, safety factor and stress distribution via FEM through numerical simulations of eight bone implantation situations. The implant cavities had varying internal diameters (3, 4, 5 and 6 mm) and lengths (195 and 120 mm), as shown in Fig. 3. ANSYS Workbench, a programme created by ANSYS (in version 17.2), was utilised. The implant and tibia bone were meshed with the help of ten node tetrahedral elements (SOLID187 type, Fig. 11). These elements are commonly employed to discretise and approximate the geometry of solid structures in FEM analysis. This analysis helps simulate and comprehend behaviours of stress and deformation in prosthetic systems.

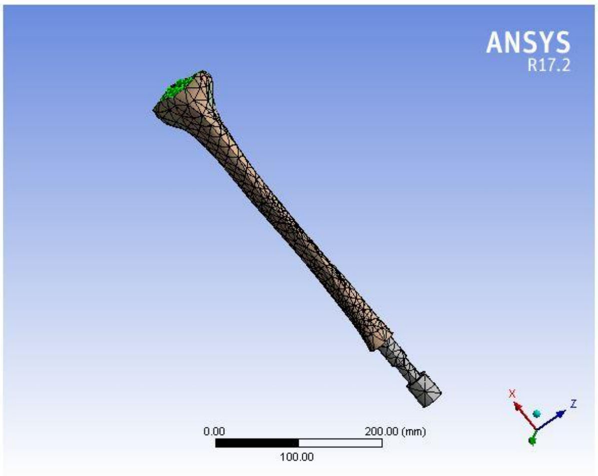


**Fig. 11. Meshed model**

For the contact interactions between the prosthesis and the bone, eight-node surface-to-surface contact elements were employed. These contact elements, specifically TARGE170 and CONTA174, facilitated the simulation of the interactions between different model components. They enabled consideration of the contact behaviours and forces involved in the mechanical interaction and load transfer between the prosthesis and the bone. With consistent support in the implant and a force exerted from the patient's weight at the proximal end of the tibia, Fig. 12 illustrates how boundary restrictions affect the model's analysis. These boundary conditions were essential for simulating and evaluating the behaviour and performance of the prosthetic system under specific loading and support scenarios.

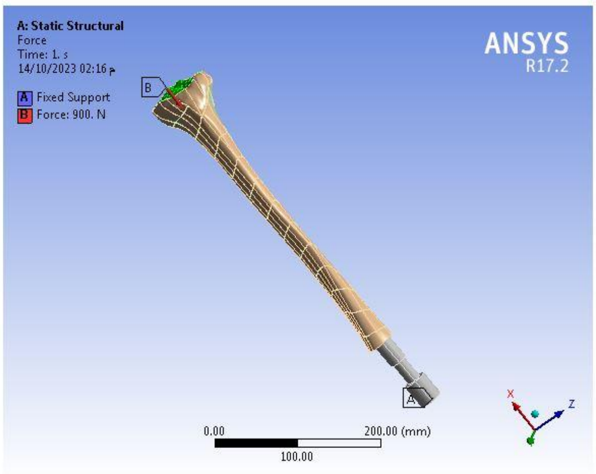


**Fig. 12. Boundary condition of model**

## 3. Results and Discussion

### 3.1. Tensile property results for metallic material

The mechanical properties determined in this study exhibit a characteristic curve that is typical, especially at the point at which 0.2% plastic deformation occurs. In accordance with ASTM standard requirements, the evaluated Ti–13Nb–13Zr alloy samples were subjected to static tensile testing. The findings indicate that the average yield strength is 482 MPa, ultimate tensile strength is 551.843 MPa and modulus of elasticity is 74 GPa, in comparison with those obtained by Lee and Bansal [34, 35]. Table 2 and Fig. 13 summarises these results and compares them with the ASTM F1713 standards and the supplier's certificate. The feasibility of the material for biomedical engineering prosthetic applications must be evaluated through these comparisons. Whether a material satisfies the mechanical requirements for use in biological prostheses can be determined by comparing it with standards and specifications. For the alloy in this study, it has low elastic modulus of approximately 55–65 GPa, which is much closer to that of human bone (10–30 GPa) compared with that of Ti–6Al–4V (110 GPa). This proximity reduces stress shielding, a common issue in implants that a mismatch in stiffness between the implant and bone induces bone resorption.

**Table 2,**
**Mechanical properties of Ti-13Nb-13Zr alloy.**

| Sample | $\sigma_y$ (MPa) | $\sigma_{ult}$ (MPa) | E GPa) |
|---|---|---|---|
| 1 | 470.562 | 556.5 | 74 |
| 2 | 504.103 | 544.735 | 75 |
| 3 | 472.235 | 554.4 | 73 |
| ASTM F1713[30] | 465 | 670 | 75 |

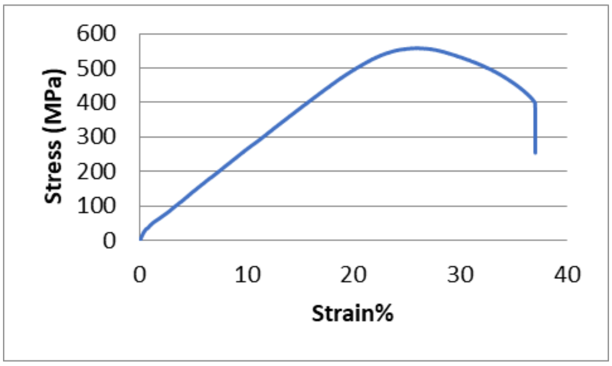


**Fig. 13. Average stress-strain curve for implant.**

## 3.2. Compression property results

The compression yield strength and compressive strength results are 713 and 470 MPa, respectively. The standard compression stress–strain curves in Fig. 14 and Table 3 illustrate the Ti–13Nb–13Zr alloy's remarkable ductility and robust strength. These characteristics are crucial for biomedical applications, especially for prosthetic components, which need materials that can support large weights without sacrificing their structural integrity. The Ti–13Nb–13Zr compression test is crucial for understanding the material's response to compressive pressures during weight-bearing tasks, essential for osseointegrated prosthetic components. It confirms the material's resistance to mechanical pressures, enhancing the efficacy, safety and compatibility of prosthetic implants with bone.

**Table 3,**
**Compression and Yield Strength results.**

| Sample No. | $\sigma_{ult}$ (MPa) | $\sigma_y$ (MPa) |
|---|---|---|
| 1 | 714 | 470 |
| 2 | 716 | 472 |
| 3 | 708 | 469 |
| **Average** | **712.6667** | **470.3333** |
| Taekyung Lee [34] | 720 | 475 |

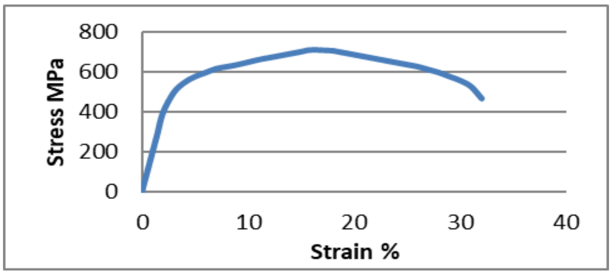


**Fig. 14. Stress-strain curve under compression.**

## 3.3. Fatigue property results for metallic material

The tensions used in the fatigue testing ranged from 600 MPa to 250 MPa, and the test was conducted at room temperature. Figure 15 shows the S–N curves obtained during the testing. The sample exhibited superior fatigue qualities in all tested scenarios, as shown by the tensile test results, corroborating the findings. A progressive degradation of the material's fatigue resistance was indicated by the Ti–13Nb–13Zr samples' fatigue strength, which slowly declined as the number of failure cycles rose. This design is close to that in reference [36] and is crucial for evaluating the longevity and long-term usefulness of prosthetic components made of this material. Understanding the material's behaviour under cyclic loading and its capacity to withstand fatigue over time is essential for ensuring the continued functioning of prosthetic implants in real-world, long-term applications.

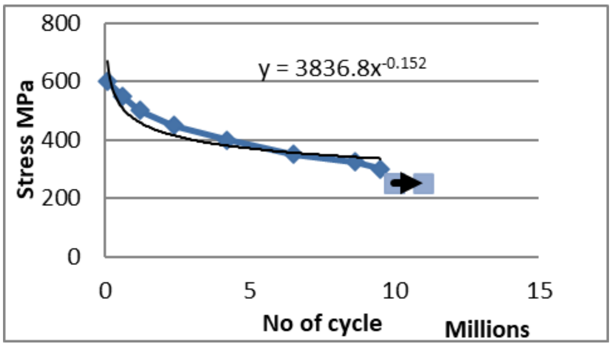


**Fig. 15. S-N curve for metallic material.**

## 3.4. Gait cycle analysis (force plate) results

The peak ground reaction forces at heel contact and toe-off are significant factors to consider. Recognising any significant variations in the right and left legs' characteristics is also important. Clinicians and researchers can assess the loading conditions on the implant's abutment and the functionality and stability of the implant during gait by examining the peak values of forces and moments during heel contact and toe-off. Figure 16 shows the force–time curve, from which the maximum force is 600 N.

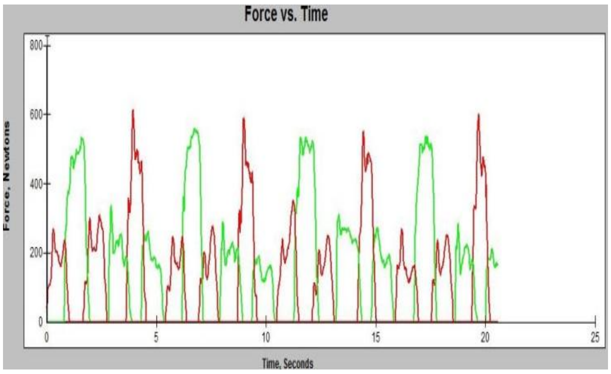


**Fig. 16. Ground reaction force vs. time for patient when walking on force plate.**

## 3.5. FEM analysis results

As presented in Figs. 17–19, the FEM evaluations performed on prosthetic tibia implants with varying inner diameters and lengths reveal comparable stress distributions, total deformations and safety factors when the tibia bone and implant are fused. Table 4 displays the results of the numerical analysis for each of the eight situations.

**Table 4,**
**The analysis of prosthetic tibias with various inner diameters and lengths**

| Dimension (mm) | Von-Mises stress (MPa) | Safety Factor | Total deformation (mm) |
|---|---|---|---|
| L=120 D=3 | 46.648 | 7.0542 | 2.911 |
| L=195 D=3 | 76.186 | 5.147 | 3.392 |
| L=120 D=4 | 43.465 | 6.818 | 2.830 |
| L=195 D=4 | 60.233 | 5.126 | 3.317 |
| L=120 D=5 | 41.736 | 6.461 | 2.786 |
| L=195 D=5 | 50.980 | 4.760 | 3.738 |
| L=120 D=6 | 39.651 | 4.473 | 2.845 |
| L=195 D=6 | 48.534 | 3.479 | 3.658 |

The abutment, which is usually the prosthesis component under the highest stress, demonstrated successful safety factors in all eight cases involving below-knee amputation implants, for which tibia implants were studied. The highest von Mises stress values were recorded at L=195 mm. The von Mises stress was maximal on the tibia bone, and the implant did not surpass the ultimate tensile stress of the titanium alloy, suggesting that these stress levels are not expected to cause material failure. Given that the prosthetic implant's maximal von Mises stress is lower than the titanium alloy's ultimate tensile stress, there is minimal risk of an abutment failing in this situation. These pressures do not cause the implant to break or sustain structural damage, allowing it to keep working. Stress levels and the material's resistance to deformation should be taken into account during implant design and analysis. Through ensuring that stress levels stay below the ultimate tensile stress, the implant's integrity and functionality are preserved.

The purpose of this study's assessment of a patient who had below-knee osseointegration was to measure limb stresses experimentally during critical walking periods. Then, through FEM studies, the behaviour of eight transtibial osseointegrated prosthetic cases was evaluated to assess probable implant or bone failures. The results of total deformation and fatigue factor of safety for the tibia with implant in this study agree with those from references [37–40].

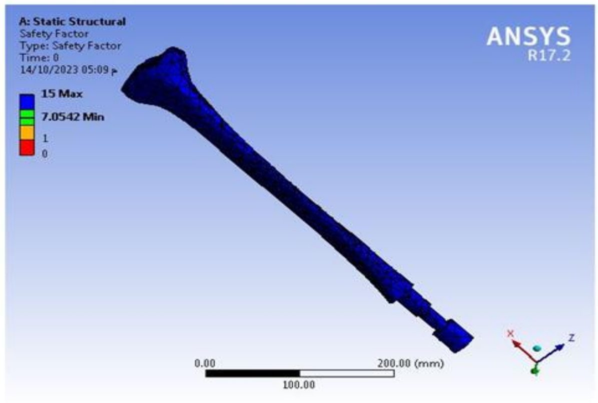


**Fig. 17. Fatigue factor of safety.**

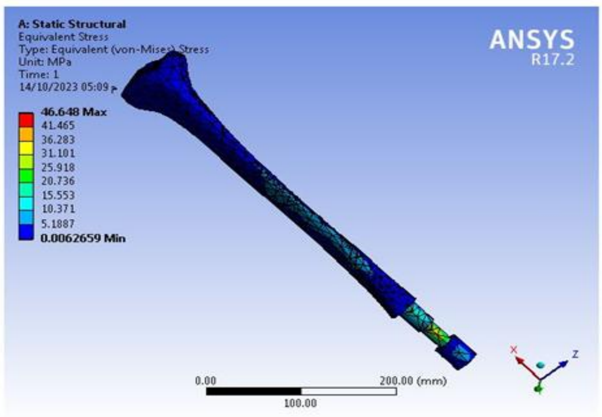


**Fig. 18. Total deformation**

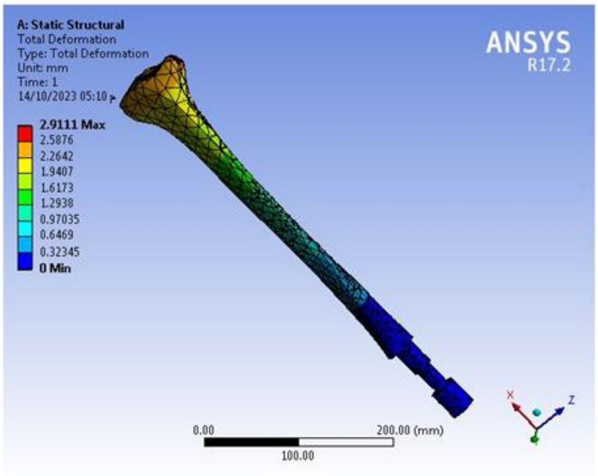


**Fig. 19. Equivalent stress (von Mises)**

## 4. Conclusions

Material Strength: The ASTM-certified Ti–13Nb–13Zr alloy demonstrated a strong mechanical strength, highlighting its potential for use in prosthetic applications.

Elastic Modulus: The elastic modulus of Ti–13Nb–13Zr is approximately 55–65 GPa, which is much closer to that of human bone (10–30 GPa) compared with that of Ti–6Al–4V (110 GPa). This closeness reduces stress shielding, a common issue in implants that a mismatch in stiffness between the implant and bone leads to bone resorption.

FEM Analysis: Consistent stress distribution, safety factors and deformation were found using the FEM over a range of implant sizes, guaranteeing dependability under various design conditions. Because the maximal von Mises stress on the tibia bone and implant did not surpass the yield tensile stress of the titanium alloy and bone, which is 470 and 175 MPa, respectively, the maximum safety factor at L=120 and D=3 and the stress levels are not expected to induce material failure.

Implant Integrity: The tibia implant's abutment showed minimal failure risk, given that its stress level stayed below the alloy's ultimate tensile stress, guaranteeing structural soundness and functioning.

## Competing of Interest

There is no conflict of interest for authorship, research and/or publication.

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# الخصائص الميكانيكية وتحليل زرع الأطراف الصناعية المتكاملة عظامياً عبر عظمة الساق

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**المستخلص**

التكامل العظمي عبارة عن وضع غرسة معدنية في العظم المتبقي خلال الجراحة ويُستخدم مع طرف اصطناعي خارجي. دُرست بعناية إمكانية استخدام سبيكة Ti-13Nb-13Zr في الأطراف الاصطناعية المدمجة عظميًا عبر الظنبوب. أظهرت السبيكة خصائص ميكانيكية ممتازة، مثل قوة ميكانيكية عالية بمتوسط مقاومة خضوع يبلغ ٤٨٢ ميجا باسكال، وقوة شد قصوى تبلغ ٥٥١,٨٤٣ ميجا باسكال، ومعامل مرونة يبلغ ٧٤ جيجا باسكال. ومن خلال اختبار الضغط، أظهرت المادة أيضًا مرونتها في تحمل الأحمال الانضغاطية، حيث أظهرت مقاومة خضوع تبلغ ٧٠٠ ميجا باسكال وقوة ضغط تبلغ ١٠١٠ ميجا باسكال. يتراوح معامل المرونة المنخفض لسبائك Ti-13Nb-13Zr بين ٥٥ و٦٥ جيجا باسكال تقريبًا، وهو أقرب بكثير إلى عظام الإنسان (١٠-٣٠ جيجا باسكال) مقارنةً بسبائك Ti-6Al-4V (١١٠ جيجا باسكال). هذا يُقلل من حجب الإجهاد، وهي مشكلة شائعة في الغرسات، حيث يؤدي عدم تطابق صلابة الغرسة مع العظم إلى ارتشاف العظم. أظهرت التحليلات باستخدام طريقة العناصر المحدودة (FEM) توزيعًا موحدًا للإجهاد، وعوامل أمان، وتشوهات طفيفة لمجموعة من أحجام الغرسات، مما يضمن سلامة الهيكل ووظائفه. لم يتجاوز أقصى إجهاد فون ميزس على عظم الظنبوب والغرسة إجهاد الشد الناتج عن الخضوع لسبائك التيتانيوم والعظم، والذي يبلغ ٤٧٠ ميجا باسكال و١٧٥ ميجا باسكال على التوالي، وهو أقصى عامل أمان عند3=L=120 D ، ومن غير المتوقع أن تُسبب مستويات الإجهاد فشل المادة. تُتيح هذه النتائج إمكانيات جديدة لتصميم الأطراف الاصطناعية واستخدامها بشكل أفضل في مجال الهندسة الطبية الحيوية من خلال إثبات ملاءمة السبائك المحتملة لتطبيقات الأطراف الاصطناعية المُدمجة في العظم.