Al-Khwarizmi Engineering Journal
ISSN (printed): 1818 – 1171, ISSN (online): 2312 – 0789
Vol. 20, No. 2, June, (2024), P P. 14- 25

Al-Khwarizmi Engineering Journal

Finite Element Analysis of New Designed Intercalary Prosthesis Implant (Ulna Bone)

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(Received 3 September 2023; Accepted 28 January 2024; Published 1 June 2024)

https://doi.org/10.22153/kej.2024.01.001

Abstract

Implantation via an intercalary prosthetic method is a reliable solution for reconstructing a long defect in bones that has been damaged by severe disease or accidents. In the current study, using data from computed tomography (CT) scans, a novel costumed intercalary prosthesis design has been created. To achieve this purpose, the CT scan data of a patient in (DICOM) file format was converted into computer-aided design models and saved in stereolithography (STL) format using the 3D slicer (5.0.3) software. The STL files were loaded into Meshmixer software to design the models of the intercalary prosthesis. Finite element analysis (FEA) was applied to validate the strength of the prosthesis with impact, tensile testing, and torsional testing. According to the results of the impact tests, the highest recorded deformation was 8.8485e-002 m in the area where the implant body interfaces with the bone intramedullary canal, due to the high-stress (Von Mises Stress) value of 3.78 E9 PA. In the torsional loaded the highest deformation recorded was 1.3871e-008 m when the Von Mises stress reached 49006 PA, and with the application of the tensile test the largest deformation measured as 1.0458e-006 m at maximum Von Mises stress seen was recorded as 6.6012e+006 PA which caused that. A solid rod of Ti6Al4V alloy was selected. Finally, the analysis proved that the implant had enhanced mechanical properties. Based on the findings, it can be inferred that the prosthesis was successfully implanted, and a satisfactory result was obtained by using this design method.

***Keywords**: Intercalary prosthetic; Computed tomography (CT); DICOM file; Stereolithography (STL); Finite element analysis (FEA).*

1. Introduction

In fractures of the adult diaphyseal forearm, exact anatomical repair is necessary to achieve bone union and good functional results. Consequently, surgical intervention is required for the majority of adult diaphyseal forearm fractures. [1]. Forearm fractures can be successfully treated with open reduction and plating osteosynthesis, a method that has been used for a long time and has shown great results in terms of functional outcomes. [2]. Intercalary prosthesis implantation and other forms of elastic-stable intramedullary fixation have made it feasible to stabilize unstable fractures with less invasive procedures, which in turn has reduced discomfort, improved limb function, and improved patients' quality of life when dealing with humeral diaphyseal bone metastases. [3-4]. When treated with open reduction and plating, comminuted or segmental forearm fractures have an increased risk of infection and non-union. Because intramedullary fixation has numerous advantages over plate fixation—such as fewer periosteal stripping, retention of the fracture hematoma, and the biomechanical benefits of a central load-bearing implant—it is used for adult forearm fractures. [5-7]. In the same concept, the missing bones that resulted from the removal of tumors are treated by using a custom design of the intercalary prosthesis [8]. This technique assists in preserving the remaining osseous part and functional reconstruction after tumor resection using a personal osteotomy guide plate and prosthesis based on 3D printing technology [9]. Intercalary prostheses are a growing possibility for diaphysis segmental defect reconstruction due to the development of cementation and ingrowth fixation procedures [10]. The most popular treatment for treating imminent and pathologic bone fractures is intramedullary nail fixation. However, this procedure is known to cause long-term discomfort, weakness, and limited mobility [11]. Biomechanical principles state that periosteal bone heals with callus when a load-sharing implant, like an intramedullary nail, causes a specific amount of strain. While this theory works for various types of long-bone fractures, it is most useful when dealing with comminuted fractures [12]. A finite element model was developed to simulate traffic collision scenarios involving adult bone fractures. The primary objective of this model was to evaluate the extent of injuries received in different parts of the skeleton [13-14]. In order to learn more about the bones' mechanical strength and how loads are distributed, many researchers have used finite element (FE) analysis on human forearm fractures [15]. By analyzing X-ray images for geometric and material properties, patient-specific finite element models can be constructed. Due to its efficiency in collecting data on both static and dynamic reactions, finite element analysis (FE) has found widespread application in implant biomechanics research. [16]. This work aims to study a new customized intercalary prosthesis implant for forearm bone and segmental defect reconstruction. In order to develop the current intercalary prosthesis, the data has been carefully derived from the patient's computed tomography (CT). Consequently, the finite element method (FEM) has been established to numerically evaluate the model's dependability for intercalary prosthetics.

2. Design and Selection of Implant for Patient Forearm

The individual, a female aged 50, sustained closed fractures of the ulna and radius subsequent to a motor vehicle collision in January 2021. Upon injury, the patient was immediately admitted to a local hospital, and surgeries were performed to fix the fractures. The present case currently requires a new surgery with the design and manufacture of a new intercalary prosthesis implant due to the fractures being classified as complicated as a result of the extensive fragmentation observed in the damaged bones as shown in Fig 1.

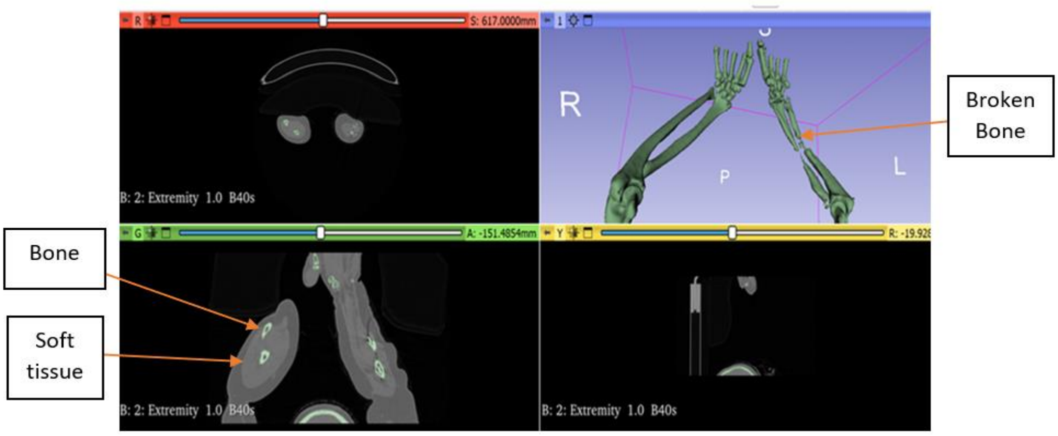


Fig. 1. CT for the ulna and radius.

Therefore, a titanium alloy medical implant was purposefully developed to replace the affected portions of both the ulna and radius bones, employing a uniform design for both skeletal structures.

The present study provides a comprehensive understanding of the design process involved in the development of a medical implant specifically designed for the Ulna bone. The severity of the forearm damage was determined by a CT scan. In order to create a 3D digital model of the implant, CT scan data was collected and transmitted to E3D 64v in DICOM format. The stage of analysis of the design of the pulverized part began as soon as the CT format was converted to the STL extension using a 3D Slicer (5.0.3). This was done in an attempt to find the best design for a particular circumstance. The STL file was initially imported into Mashmixer software (3.5.474). Taking advantage of human symmetry, we were able to accurately measure the broken part of the healthy bone on the opposite side and create a medical implant with identical proportions. Using the mirror and the symmetry command, we were able to flip the healthy component of the mirror image and subtract the broken piece from the whole as shown in Fig 2.

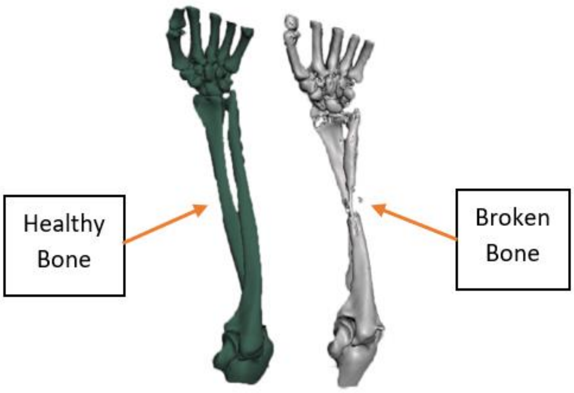


Fig. 2. Symmetry of forearm bone.

Upon calculating the suitable sizes for the implants, the SolidWorks software version 2021.2 has been utilized. The application was employed for the purpose of design, specifically for the initiation of the Ulna bone segment design, as outlined in the subsequent description.

To get the best connection to the bone and figure out the right piece's direction, an octagonal shape element is first constructed to be the most appropriate for facilitating osseointegration with a 14-mm diameter is first constructed. Then, a 12-mm-diameter cylinder was made on the octagonal face to act as the implant body's support, and the sector with the best mechanical properties was identified as the implant sector (Fillet). The implementation of fillets serves to disperse stress across a wider surface area, hence enhancing the durability and load-bearing capacity of the components, as shown in Fig 3.

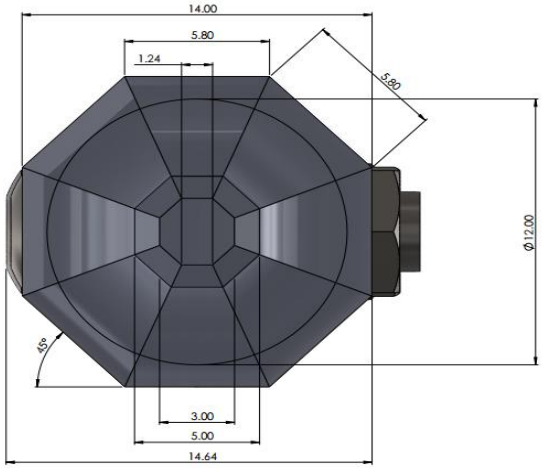


Fig. 3. Octagonal element and cylinder shaft.

shapes an octagonal one will provide optimal contact with the surrounding bone while still allowing for bone growth and blood to flow to the area for osseointegration. An incision on the front of the implant reveals the connection to another implant, as shown in Fig 4.

Fig. 4. Bone intramedullary canal shaft and the location of contact with the complementary implant Structure.

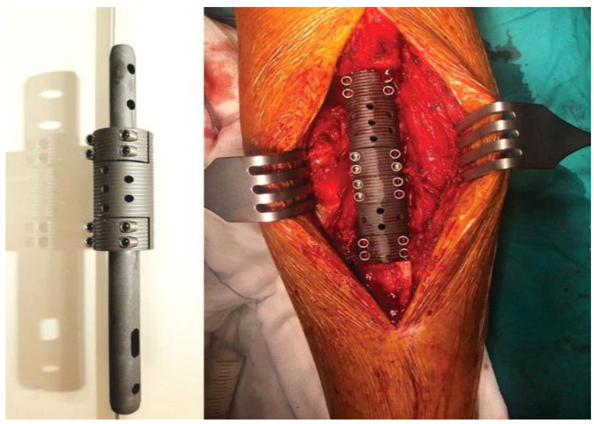


Fig. 5. Osseointegration between the bone and the proposed implant [17].

Then, an implant with an upward projection was designed to facilitate its integration with the other component, thereby ensuring stability and protrusion and emergence. Upon completion of the protrusion, attention was redirected to the screw-insertion holes, which serve to secure the two implant components together. Pre-drilling and tapering were performed on the implant to facilitate the insertion of M 3.6 screws, as shown in Fig 6.

Fig 6. Cylinder shaft implant and its holes screw.

Three holes with a difference of 90 degrees were placed at the bottom of the implant to share it with the bone and for the bone itself to be built on it for a complete interlock after the bone has preventing displacement. Likewise, the height of the negative projection on the opposite side was determined using the same measurements for the completely healed. Three holes were placed in two different surfaces of the trunk for complete connection later between the bone and the implant, 45-degree angle stem feathering aids implant entry during the surgical process, as shown in Fig 7.

Fig. 7. Fixing screws of bone marrow shaft.

The initial component of the implant was successfully constructed, while the subsequent component exhibited symmetry and required few alterations to its connections. The implant was manufactured using the SolidWorks software package. The measurements used in this work are illustrated in Fig 8.

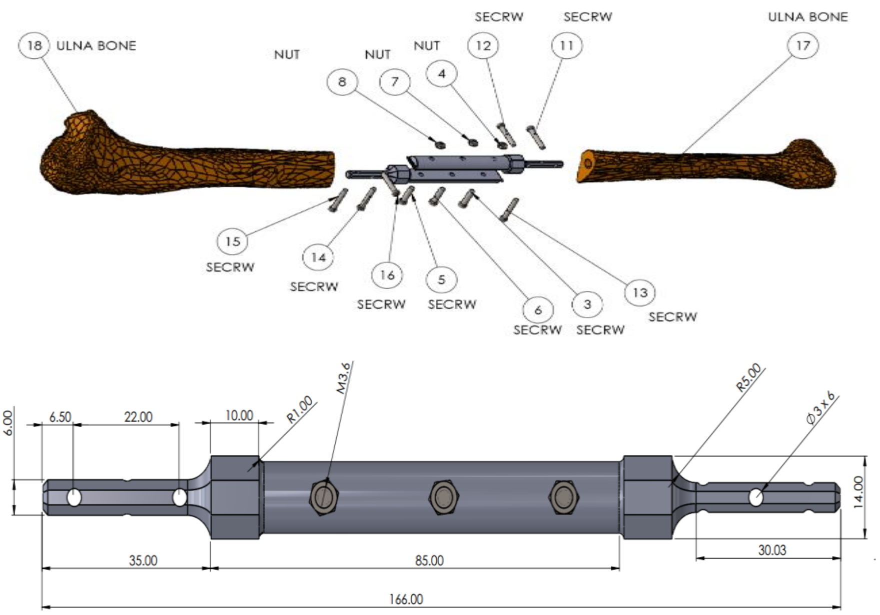


Fig. 8. Assembly of the implant.

3. Intercalary Prosthesis Implant Material

The material used in this study is Titanium alloy (Ti6Al4V), Table 1 shows the material's chemical composition. Ti alloy is a biomaterial of exceptional quality that finds extensive application in the biomedical field, specifically in the fabrication of orthopedic implants, Cranial implants, dental implants, Ti mesh, and artificial joints all contain Ti alloys [18]. Ti alloys generally comprise the principal constituent Ti, as well as possible additional elements including vanadium, niobium, aluminum, and zirconium. By utilizing Ti as its primary constituent, the material attains exceptional biocompatibility and lightweight characteristics, there by mitigating the potential for rejection reactions. The incorporation of elements such as aluminum and vanadium into a material can augment its strength and resistance to corrosion, thus enhancing its stability during implantation. Niobium incorporation has the potential to enhance biocompatibility and mitigate tissue reactions [19]. For numerous years, metal implants have been employed in the medical field to secure prosthetics or substitute absent organs or tissue [20]. Ti-6Al-4V implants have the potential to become the most effective method for regenerating significant bone defects, according to many results [21]. At the present time, total hip replacement stands as one of the most frequently conducted surgical procedures [22]. An approximated 15–20 years is the average lifespan of hip replacements or 75% by way of estimation. [23]. Ti alloys are extensively employed in the fabrication of implants owing to their favorable mechanical properties and biocompatibility [24].

Table 1,
Chemical Composition of Titanium alloy (Ti6Al4V).

Element	**AL**	**V**	**Fe**	**Mo**	**Si**	**Cu**	**W**	**Nb**	**Ni**	**Sn**	**Mn**	**Ti**
Composition (%Wt.)	6.37	4.33	0.03	0.01	0.01	0.01	<0.01	0.008	<0.005	<0.005	<0.004	Balanced

4. Finite Element Analysis for Implant

The research methodology employed for the implementation of split prostheses for ulna replacement focused on conducting a comprehensive analysis with the assistance of appropriate design software. All samples were loaded with different types of load Impact, torsion, and tension on various fixation areas. In each case, to find out the weaknesses of the implant model and the maximum stresses that lead to the failure of the model.

First, a three-dimensional model of the implant was created for the FE analysis of the intercalary prosthesis implant. The model employed was rebuilt using data from CT (DICOM) images and represented a replacement for the ulna shaft from the forearm bone. It was afterward imported into (ANSYS 2020/R1), Fig 9 summarizes the methodology of finite element analysis as a flowchart, and the medical model underwent three tests include:

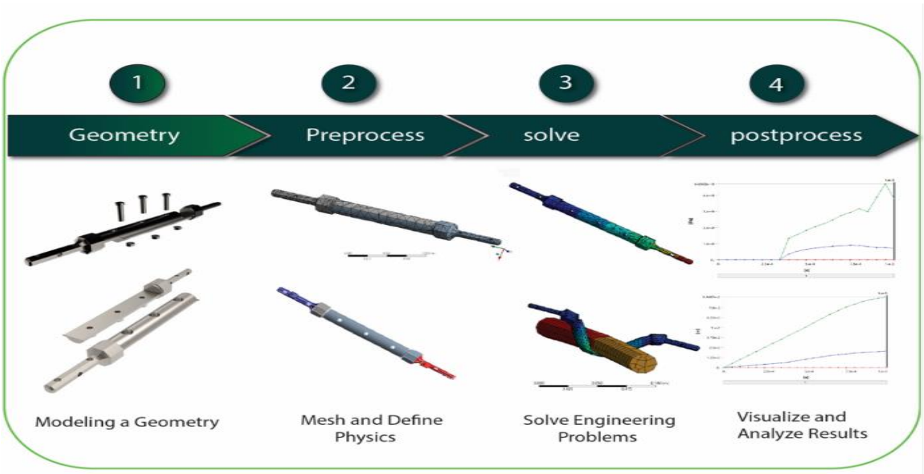


Fig. 9. Methodology of finite element analysis.

4.1 Impact test

High-load-rate medical implant fracture characteristics can be determined using impact testing, an analysis method developed for this purpose. The finite element method (FEM) simulated the implant's dynamic effect.

The implant passed its impact test, which involved an impact with a 0.96 kg item at 100 m/s on the x-axis. the stress distribution and von Mises stress have been recognized as vital elements in finite element analysis. Meshing is an important step for finite element analysis of the implant model. Smaller elements were used on the model's proximities and curvatures with the help of a model wizard in (ANSYS 2020/R1) to create an optimal mesh. The number of Triangle Surface Mesh components used in the implant model is 13146, and the number of nodes is 3664, as can be seen in Fig 10.

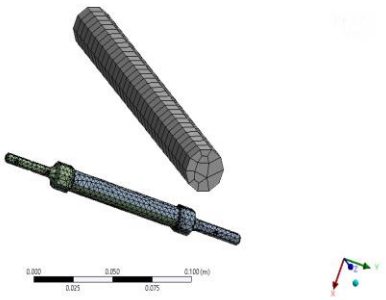


Fig 10. Mesh generation of impact test.

4.2 Torsional test

Torsion is a widely employed testing technique utilized for the evaluation of the torsional yield strength and deformation of customized implant bone specimens under standardized conditions. The concept of elements and nodes refers to a fundamental constituent or component of a system, that has the number of Triangle Surface Mesh elements used for the implant model as 2433, while the number of nodes is 5238, as shown in Fig 11.

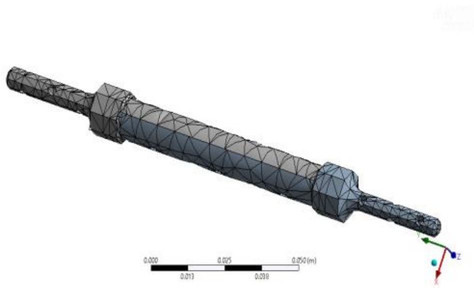


Fig. 11. Mesh generation of the torsional test.

4.3 Tensile test

FEA was conducted in order to get insight into the distribution of stress under a tensile load. The stress distribution resulting from the preload application of a 50 Newton in the Y-axis is determined using the model developed by the FEM, as shown in Fig 12, The triangle Surface Mesh elements utilized for the implant model amount to 2433, while the number of nodes totals 5238.

Fig 12. Shows the axial load and fixed support.

5. Result and Discussion

Three groups were set up for finite element analysis testing: impact test, torsional tests, and tensile tests. Von Mises stress and deformation were observed as the main factors in FEA. To observe the Von Mises stress nephogram and deformation, data were collected from the ANSYS General Postproc. The unit of stress was Pa, and the values presented in this study were under an impact load of 0.96kg at 100m/s, torsional load 1.e-003 N.m, and tensile load 50 N. To check the implantation of an intercalated prosthesis, the boundary conditions were applied to the finite element analysis; one end of the implant was fixed in the fixture and the other lateral limb was loaded with hypothetical values of impact load, tensile strength, and torque. In this aspect, the results showed that the ulnar finite element model is able to accurately predict its biomechanical properties, The Von Mises Stress of impact load valued was 3.78 E9 PA, as Fig 13, and the highest recorded deformation was 8.8485e-002 m, as Fig 14, Caused by an impact of the body moving at high speed in a direction perpendicular to the intercalary prosthesis implant. To find out the weaknesses of the implant model and the critical stress that lead to its failure.

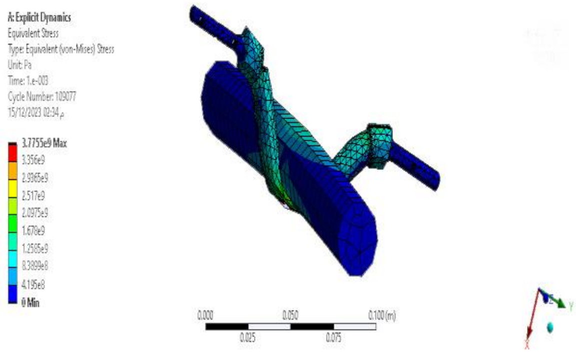


Fig. 13. Von Mises Stress during an impact test.

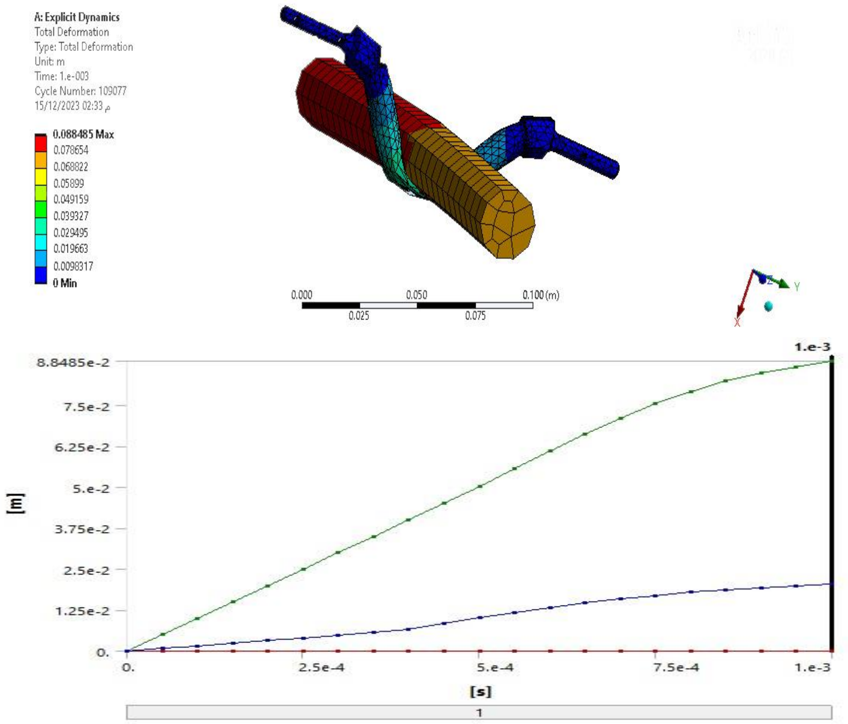


Fig. 14. Total deformation and its diagram for impact test.

And during the application of a torsional load, the location where the implant body made contact with the bone intramedullary canal coincided with the position at which the Von Mises stress reached 49006 Pa, Fig (15). This analysis also revealed that the highest deformation recorded was 1.3871e-008 m, Fig (16).

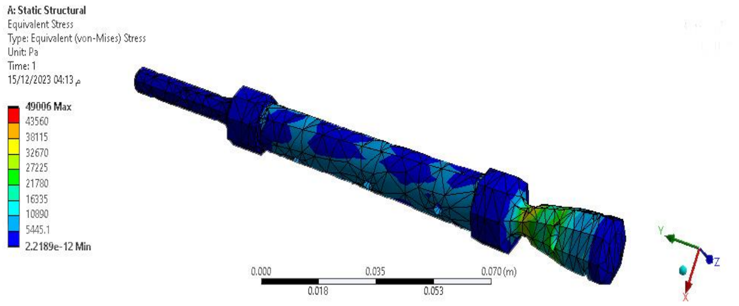


Fig 15. Von-Mises stress during a torsional test.

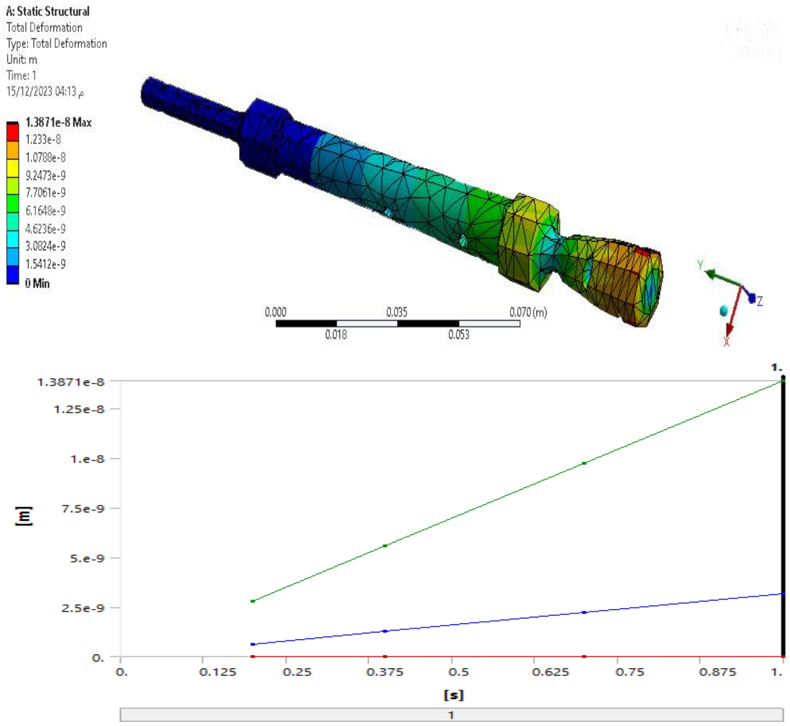


Fig 16. Total deformation and its diagram for a torsional test.

In the tensile test, the maximum stress seen was recorded as 6.6012e+006 Pa, Fig (17), while the corresponding largest deformation was measured at 1.0458e-006 m, Fig (18). All the numerical results of the tests were summarized in Table 2.

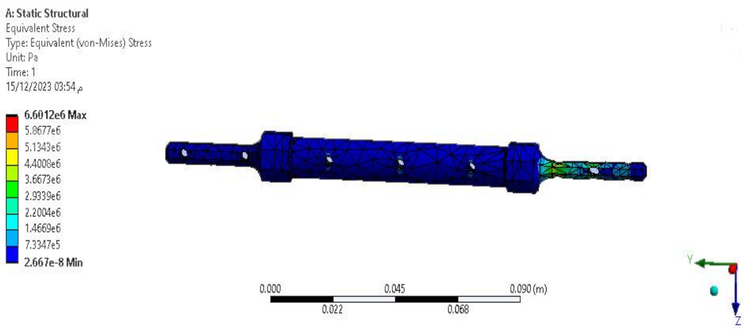
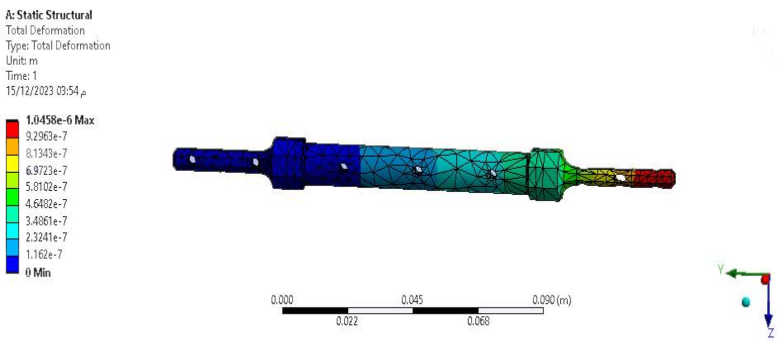


Fig. 17. Von-Mises stress during a tensile test.



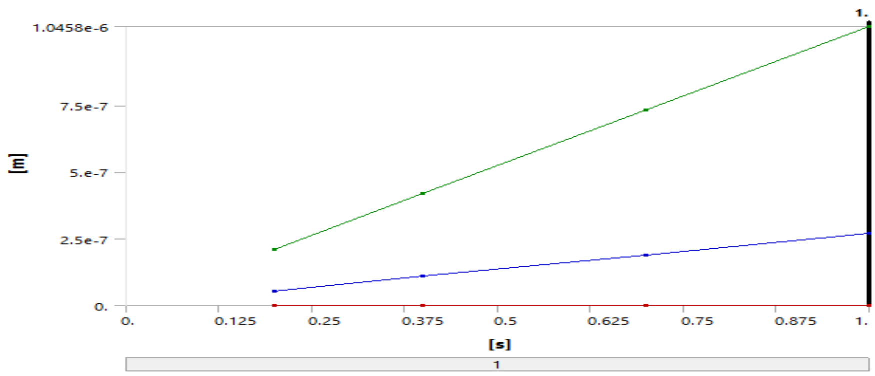


Fig. 18. Total deformation and its diagram for a tensile test.

Table 2,
Summary of Numerical Result of Test

Type of Test	Max. Stress (Pa)	Deformation (m)
Impact Test	3.78e9	8.8485e-2
Torsional Test	49006	1.3871e-8
Tensile Test	6.6012e6	1.0458e-6

The treatment outcomes in the upper limb are still being impacted by mechanical difficulties, including aseptic loosening and structural failure [25,26]. Six patients were studied by Ahlmann and Menendez; three had tibial prostheses, two had femoral prostheses, and one had a humeral prosthesis. Only the humeral prosthesis required revision at 14 months due to aseptic loosening; increased rotational loads in the upper extremity were thought to contribute to a higher rate of failure. Higher rotational forces in addition to a shorter length of segment attachment and a smaller diameter for cement interdigitation compared to the femur were blamed for the eventual structural failure [27,28]. The utilization of finite element analysis in the field of biomedicine has demonstrated its efficacy through its inter-verification and inter-complementarity with classical biomechanics [29,30]. Finite element analysis is superior to previous experimental approaches because it causes no harm to specimens while accurately simulating the stress distribution in living tissue. On the other hand, finite element models are reusable, and their analysis is rapid and economical.

6. Conclusion

Recent research supports the use of prostheses as part of a comprehensive treatment plan to restore bone function following injury. As a more effective biological treatment option, split prostheses are more popular. Therefore, this study presents an innovative ulnar defect reconstruction method using an intercalary diaphyseal prosthesis. The ulna is modeled using finite elements. The results of the finite element analysis reinforce the hypothesized assumption that the innovative prosthesis can provide stronger initial stability under impact, torsional, and tension forces which are typically applied by forearm movements, where the max equivalent Von Mises stresses are 3.78 E9 Pa,49006 Pa, and 6.6012e+006 Pa respectively. And so a new method has been developed for treating forearm fractures. Compared to biological treatments, the implants have superior mechanical properties that allow them to withstand extremely high stresses until failure, making them an excellent choice for use in bone replacement surgeries.

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تحليل العناصر المحدودة للزرع الاصطناعي المقسم المصمم حديثا (عظم الزند)

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الخلاصة

يعد الزرع على طريقة الأطراف الاصطناعية الداخلية حلا موثوقا لإعادة بناء عيوب العظام الطويلة التي تضررت بسبب المرض الشديد أو الحوادث. في هذه الدراسة الحالية ، يتم تطوير تصميم اصطناعي مقسم جديد من بيانات التصوير المقطعي المحوسب(CT-scan) . ولتحقيق هذا الغرض ، تم تحويل بيانات الأشعة المقطعية CT للمريض بتنسيق ملف (DICOM) الى نماذج التصميم بمساعدة الكمبيوتر وحفظها في شكل ستيريوليثوغرافي (STL) باستخدام برنامج D slicer3(5.0.3) تم تحميل ملفات STL في برنامج Meshmixer لتصميم نماذج من الأطراف الاصطناعية. تم تطبيق تحليل العناصر المحدودة (FEA) للتحقق من صحة قوة الطرف الاصطناعي مع اختبار الصدمة ، واختبار الشد ، واختبار الالتواء. ووفقا لنتائج اختبارات الصدمة كان أعلى تشوه مسجل e-002 8.8485 م في المنطقة التي يتداخل فيها جسم الزرع مع القناة داخل النخاع العظمي ، بسبب الضغط العالي (إجهاد فون ميزس) بقيمة 3.78 e9 باسكال. وفي ،اختبار الالتواء كان أعلى تشوه مسجل هو 1.3871 e-008 م عندما وصل إجهاد فون ميزس إلى 49006 باسكال ومع تطبيق اختبار الشد ، تم قياس أكبر تشوه على أنه 0061.0458-e م عند أقصى إجهاد فون ميزس تم تسجيله على أنه6.6012 e006 باسكال مع تسبب ذلك. تم اختيار عمود صلب من سبيكة Ti6Al4V وأخيرا ، أثبتت التحليلات أن الغرسة قد عززت الخواص الميكانيكية. وبناء على هذه النتائج ، يمكن الاستنتاج أن الزرعة للطرف الاصطناعي لاقت نجاحا ، وتم الحصول على نتيجة مرضية باستخدام طريقة التصميم هذه.