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Research Paper

Evaluation of Stability and Reliability of Motorized Unilateral External Fixator, Designed and Simulated Using Finite Element Method to Treat Bone Fractures and Bone Loss

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Abstract

Today, it is common to align broken bones using external bone fixators; ease of installation and adjustability are among the advantages of unilateral external bone fixators compared to circular and horseshoe models. The present study aimed to ensure the stability and strength of the motorized unilateral external bone fixator, equipped with four motors designed in SolidWorks software. The device was simulated and analyzed using the finite element method in Ansys software. The results were as follows: Simulation of compressive, bending, and torsional forces and reliability evaluation using the finite element method in each simulated experiment. The designed device has the necessary stability, rigidity, and desirable reliability to fix the long broken bones in place, with the possibility of displacing the bone when having a lost part. Precise bone displacement is possible since the device has four independent motorized units based on the patient's needs and the instructions of a specialist to rebuild bones.

Keywords

Unilateral External Bone Fixator, Bone Fracture, Bone Loss, Orthopedics, Finite Element Method

1. Introduction

Unilateral external bone fixators are extensively utilized in orthopedics to fix broken bones and, in some cases, to displace broken bones that contain a lost part to make up the lost bone. Therefore, a motorized unilateral external bone fixator with the necessary strength and stability is suitable for treating bone loss and fractures.

In this regard, the device must be adjusted carefully to achieve the desired result because a mistake in it may lead to many injuries, including failure in treatment and the need for re-surgery and re-installation of the device, which in turn may cause various problems, including increased costs, prolonged treatment time, infection, or loss of bone repair and recovery. By examining the history of evolution and external fixators, we can understand the importance of using unilateral external bone fixators in orthopedics. Here, the process of using and developing external fixators is discussed, and the investigations carried out on the degree of strength and stability, as well as the effect of using these fixators in the treatment of bone fractures, are briefly reviewed.

The use of external fixators has primarily caused limb reconstruction techniques to advance. Fragomen et al. [1] Stated that the external fixator, which is currently the latest resort for fixation and becoming the primary method of the treatment of various bone and soft tissue pathologies, needs to be developed and optimized. According to Paul et al. and Hernigou [2, 3], although in traumatology and orthopedics, external bone fixation is often considered a "novel" procedure, it has been used by physicians and surgeons for many centuries ago. Around 377 BC, Hippocrates made a natural early external fixator. The first models of these devices included wooden splints to treat fractures. The new and familiar concept of an external bone fixator was introduced by Jean-François Malgin, who made a device called a "metal point" in 1840. Then, in 1843, he introduced a two-fork machine called the "metal claw". Paul et al. and Hernigou [2, 3] Stated that Dr. Clayton Parkhill was one of the first to develop a true unilateral external bone fixator in 1897. According to Paul et al. [2], Lambert designed the monocortical fixator in 1911. The compressive mechanism of modern external fixators is derived from Lambert's design and ingenuity. In their study, Fleming et al. [4] Stated that the Ilizarov external fixator is used to fix bone fractures. A study performed by Goodship and Kenwright showed that induced axial micromotion at the site of fracture could accelerate the healing process. Broekhuizen [5] Stated that the Wagner device (Mathys, Bettlach, Switzerland), which is made of stainless steel, was initially designed to lengthen long bones, especially the femur. Qiao et al. [6] Developed robotic design and orientation techniques that can improve the device's accuracy. Wei et al. [7] provided digital measurement methods using Paley’s deformity measurement method addition, they proposed a deformity correction algorithm to calculate the elongations of the six rods. Corona et al. [8] worked on circular frames to improve the preoperative planning process for post-traumatic tibial deformities. Based on their research, Zhao et al. [9] Stated that by combining the advantages of series and parallel mechanisms, the production of hybrid robots can meet specific clinical needs, including joint fractures and large multi-component fractures. Matsushita et al. [10] Considered the hifixator device, an external fixator that utilizes a new sliding mechanism. This mechanism maintained its capability in 72% of the motions performed at the fracture site, even when the pins were loose, and the torque was 4 Nm. In a study, Sangkaew [11] stated that the technique has modified the distraction osteogenesis with the help of the available external fixator of AO/ASIF, which is a safe, cost-effective, and versatile tool. In the research performed by Hussain et al. [12] On increasing the lower limb length by unilateral external fixator in the field of limb-length discrepancy using the Wagner method, it was concluded that according to the criteria of application, in 89% of bony results and 97% of functional outcomes, an excellent or good degree of success was achieved. Tang et al. [13] Concluded that single-stage arthrodesis of the knee using a unilateral external fixator with cannulated screws is an effective way the treatment of end-stage tuberculosis of the knee. In the study of Basso et al. [14], It was concluded that 95.8% of patients were satisfied with the method of using unilateral external fixators in the treatment of humeral shaft fractures. The results of a study performed by Yushan et al. [15] showed that the treatment of significant tibial defects due to infection in trifocal bone transport using a unilateral rail system significantly improved postoperative function and reduced the duration of regenerate consolidation and docking union. Sen et al. [16] Examined a combined method for the treatment of distal femoral bone defects following the removal of bone infection using an external fixator with a short supracondylar nail and concluded that the combined strategy was influential in the treatment of distal femoral segmental bone defects after debridement of osteomyelitis, which had a high rate of union and acceptable complication rates. Strebe et al. [17] evaluated three strategies of double stacking, crosslinking, and diagonal pin from ultra-high molecular weight polyethylene bone models and available external fixator parts. The results showed that double stacking was the most efficient way to increase resistance against bending, especially anterior-posterior bending and axial pressure; however, it significantly increased the cost.. Ang et al. [18] Evaluated the axial and torsional stiffness of the externalized titanium locking compression plate (ET-LCP), the externalized stainless steel locking compression plate (ESS-LCP), and the unilateral external fixator (UEF) and introduced the use of LCP as an external fixator a proper alternative to the old UEF because its smaller structure is more acceptable for patients and puts no pressure on axial and torsional stiffness. Li et al. [19] used the finite element method to examine the stress and deformation of the external bone fixator system under axial, torsional, and bending load and to compare the biomechanical properties of the two fixators. One of the two fixators had a pin deviation angle, and the other did not. When the pin deviation angle changed 0-20 degrees, the growth rate of stress or deformity was prolonged, but when it exceeded 20 degrees, the slope of the growth rate increased much more; in other words, the effect of pin deviation on the stability of external bone fixator system increased. In their study, Zainudin et al. [20] Claimed that if parameters such as the biomechanical perspective are considered an external fixator, the bone will be successfully healed; pin diameter is one of these parameters. The finite element method was used to simulate the standing phase. The results demonstrated that selecting a pin with a diameter of 6.5 mm leads to the least von Mises stress on the joint surface of the pin and bone. Shi et al. [21] reported that the plate-type external fixator has higher stiffness and strength than the unilateral external fixator. The highest biomechanics belonged primarily to the classical plate-type external fixator, followed by the extended plate-type external fixator with a slight difference. The plate-type external fixator has higher stiffness and strength than the unilateral external fixator under axial compression, four-point bending, and torsion. Jean et al. [22] They have utilized the Hoffmann®3 device as a reference for comparison in the study. To determine the structural strength, six external fixators were examined in three modes - axial compression, mediolateral (ML) bending, and torsion. The results showed that the stiffness of UUEF and UBEF devices compared with the reference fixator may be helpful in fracture healing and protection. Lesniewska et al. [23] performed finite element analysis on fracture healing using a fixation device. Relevant analyzes were performed under axial and variable loaded boundary conditions. The results demonstrated that at the beginning of the fracture healing process, the stresses in the external fixator device are the highest and gradually decrease over time. In a study performed by Donaldson et al. [24], It was concluded that local bone yielding at the pin-bone interface in the external fixation method using half-pin causes the fixator to loosen. The peri-implant yielded threefold bone volume increases from young to old patients. If three half-pins are used instead of two half-pins on each side of the fracture, the yielded bone volume will be reduced by 80% in all age groups. Using titanium half-pins minimizes the importance of yielded bone by about 60-65%. Roseiro et al. [25] Developed a finite element model simplified for external fixation of the tibia bone to determine the stiffness at the fracture center. The genetic algorithm was also defined to minimize the displacement of the fracture center (objective function) by changing the position of the external fixator's mechanical parts and evaluating the load imposition types. Wang et al. [26] Stated that based on the calculated results if a solid screw is used, there is a lot of stress at the beginning of the fracture healing process, both on the screws and the femur. Still, when using a hollow screw, when an open screw is used, the stress is distributed more evenly, and in the middle of the healing process, the stress on the femur is significantly reduced. Li et al. [27] Reported that stiffness as the main criterion is measured to evaluate the mechanical stability of external fixators. The external fixator's stiffness affects the fractured bone's local biomechanical environment. They developed a theoretical model by modifying Young’s modulus of the callus using Castigliano’s theory to evaluate the compression stiffness, torsional stiffness, and bending stiffness of the fixator-bone system during the healing process. The results showed the similarity of the three methods of stiffness assessment in the fixator-bone system. Finite element simulation shows that as the healing time lengthens, the transmission of the load between the fixator and bone changes. Moreover, finite element analysis confirms the results of the theoretical model. Salunkhe et al. [28] Designed a high-power external fixator, which weighed only 1.217kg and had a suitable mechanism for the dynamic treatment of unstable fractures. Maximum displacement was determined between fractured bone fragments. The maximum removal from applying a compressive force of 2000 N was only 0.0018 mm, which is within the acceptable range.

Stiffness of the External Fixation System at Axial Pressure Load and Mechanical Stability for the External Fixation Device in the Case of Anterior-Posterior Bending were analyzed, and results for displacements it obtained for selected critical places on the device and the place of fracture. By considering all data, it can be concluded that the external fixation device Orthofix has good mechanical stability for the AP bending load. Also, there is a possibility to improve the device using new advanced materials or by device redesign [29 & 30].

According to studies, designing a device to decrease errors is an efficient step in bone fracture treatments. Moreover, being motorized helps the device to function during the bone loss treatment and gives the patient a sense of comfort, which is very important. For this purpose, a motorized external unilateral fixator device was designed to be used in the treatment of fractures and bone loss. This device can effectively fix the bone in four areas. Most importantly, it can use the motors installed in each part of it (four separate units) to make the necessary displacements of parts of the bones to build bone and compensate for bone loss. The present simulation study aimed to use the finite element analysis method to evaluate the strength and reliability of a motorized unilateral external bone fixator containing four motors capable of moving separately in the vertical direction (up and down) according to the patient's requirements and the specialist's diagnosis. The device was designed in SolidWorks software and then analyzed in Ansys software using the finite element simulation method to achieve an appropriate and reliable design for utilization in medical orthopedic centers. Therefore, with the approval of stability, strength, and rigidity of the motorized unilateral external bone fixator, it will be possible to produce and use it to treat patients with long bone fractures, limb disability, short leg, lack part of the bone, and other bone (orthopedic) disorders, as well as those who tend to increase height.

2. Material

The unilateral external bone fixator equipped with four motors has medical (orthopedic) use and considering the need for long-term use of the device by the patient during treatment, it is necessary to choose a medically approved material with high thermal resistance, strength, corrosion resistance, and abrasion resistance. Therefore, we searched for medical devices and equipment materials, and stainless steel 316 was the most commonly used material. Stainless steel 316 has characteristics such as high machinability, ductility, weldability, and thermal resistance, and at the same time, it is non-magnetic. Therefore it was selected as the primary material, and the device stability and strength were analyzed by the finite element simulation method considering stainless steel as the primary material. The chemical composition, as well as mechanical and physical properties of stainless steel 316, were extracted from standard sources and are shown in Tables 1, 2, and 3, respectively.

Table 1. The percentage chemical composition of stainless steel 316

Grade		C	Mn	Si	P	S	Cr	Mo	Ni	N
316	Min	-	-	-	-	-	16.0	2.00	10.0	-
	Max	0.08	2.0	0.75	0.045	0.030	18.0	3.00	14.0	0.10
316L	Min	-	-	-	-	-	16.0	2.00	10.0	-
	Max	0.03	2.0	0.75	0.045	0.030	18.0	3.00	14.0	0.10
316H	Min	0.04	-	-	-	-	16.0	2.00	10.0	-
	Max	0.10	2.0	0.75	0.045	0.030	18.0	3.00	14.0	-

Table 2. Mechanical properties of stainless steel 316

Grade	Tensile Strength (MPa) Min	Yield Strength 0.2% Proof (MPa) Min	Elongation (% in 50mm) Min	Hardness	
				Rocwell B (HR B) Max	Brinell (HB) Max
316	515	205	40	95	217
316L	485	170	40	95	217
316H	515	205	40	95	217

Table 3. Physical properties of stainless steel 316 under annealed conditions

Grade	Density (Kg/m^2)	Elastic Modulus (GPa)	Mean Coefficient of Thermal Expansion			Thermal Conductivity		Specific Heat	Electrical Resistivity (nΩ.m)
			0-100°C (µm/m/°C)	0-130°C (µm/m/°C)	0-538°C (µm/m/°C)	at 100°C (W/m.k)	at 500°C (W/m.k)	0-100°C (J/Kg.K)	
316 & 316L/H	8000	193	15.9	16.2	17.5	16.3	21.5	500	740

3. Method

3.1. For designing the device and analysis of the device

The unilateral external bone fixator was designed in SolidWorks software and then simulated and analyzed using the finite element method in Ansys software. For this purpose, the simulations were performed for loading and applying compression, bending, and torsional forces and the results were analyzed.

The following are the necessary conditions, simulations, and boundary conditions used in the finite element method.

The Schanz holder of the device is designed in a standard way so that it is possible to use the standard threaded schanzes (threaded pins) commonly used in orthopedics. The fixator consists of four threaded pin holders (Schanz holder), each of which can move on the main shaft independently from the motor. First, a 3D model of the bone fixator was designed using the SolidWorks software. Also, the CT scan image of a bone fractured into four pieces, part of which was lost, was prepared and converted using the Mimics software into a 3D model to be used in SolidWorks software. Using the schanzes installed in the Schanz holder of the device, the segmented parts of the fractured bone were fixed next to each other. Figure 1 shows the 3D view of the device with schanzes and the bone. (The process of attaching the device to the bone by schanzes and placement of the fractured bone segments was carried out according to the studies, some of which have been presented in the last part of this study). Table 4 shows the mechanical properties of stainless steel 316 and bone for achieving the specific force application process to perform the device simulations. The schanzes used in this study were 5×200 mm standard solid threaded schanzes (threaded pins). The 3D file of SolidWorks with step. The extension was inserted into the Ansys Workbench and meshed using the different available elements (Figure 2). After studying the mesh convergence obtained by increasing the density of elements in sensitive places of the system, the number of elements and nodes was set at 364770 and 639921, respectively, for simulation and analysis by the finite element method.

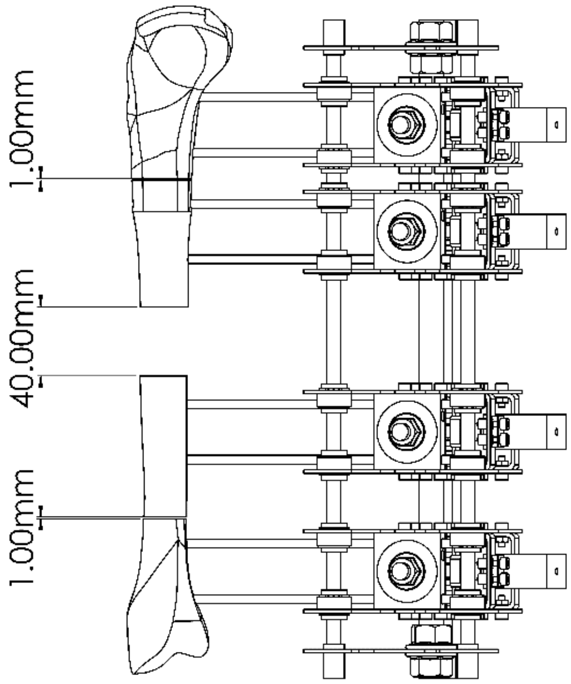

Figure 1. The motorized unilateral bone fixator was designed in SolidWorks software along with schanzes and how to attach threaded schanzes to the fractured bone containing lost parts

Table 4. Mechanical properties of stainless steel 316 used in the device [19, 25]

Materials	Young's modulus (GPa)	Poisson's ratio	Yield strength (MPa)
Stainless steel	193	0.31	205
Bone	17	0.3	300

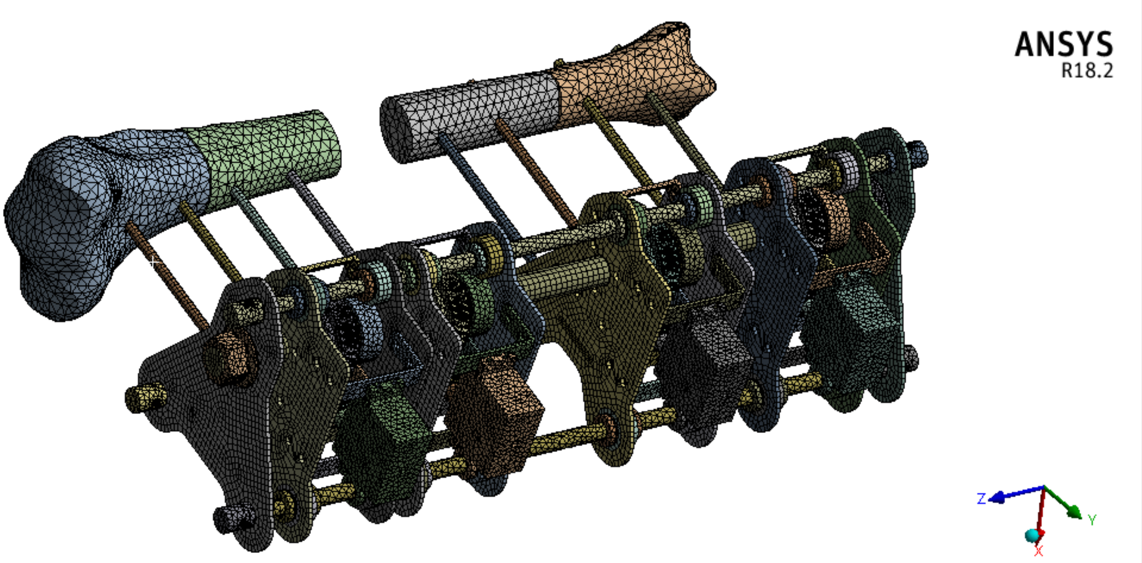

Figure 2. Final meshing for modeling a motorized unilateral bone fixator

3.2. Conditions of simulation and analysis using finite element method

In this model, the bone density, the mean Young modulus, and Poisson's ratio were considered 1800 kg/m^3, 18 GPa, and 0.2, respectively. The contact surface of the schanzes with the bone was assumed to be fixed, explaining that none of the surfaces had a degree of freedom relative to each other. The material of different parts of the device was stainless steel 316, which has a Young modulus and Poisson's ratio of 193 GPa and 0.3, respectively. Except for moving contact surfaces between the parts that have a degree of freedom from each other, the contact between other parts was bonded or fixed. In this simulation, it was assumed that the standard threaded pins (schanzes) inside the bone have no movement at all, the schanz holders move on the central axis, and the guide rods move in the form of a cylindrical joint to be able to move along their axis if needed.

4. Results and discussion

4.1. The first stage

To examine the device stability using the finite element method, the force applied was simulated in the Ansys software so that the force was applied in the axial direction of the bone while the other end of the bone was fixed. The boundary conditions considered for this simulation were that one end of the bone was assumed to be fixed (F), and a force equivalent to 150N was applied to the other end (Figure 3) [10, 17, 19, 21]. After simulation and force application, three displacement and deformation contours, as well as Von mises stress and safety factor, were obtained as data required for device analysis.

The maximum displacement in the bone and its schanzes (Figure 4) was about 1.71 mm, which was in the direction of applying force and the bone axis. Also, the maximum Von mises stress was 204.15 Mpa (Figure 5). The safety factor of the system was 1.014 (Figure 6), indicating that the maximum force allowed to apply to the system is approximately 150 N, and applying more force will cause the schanzes to fail.

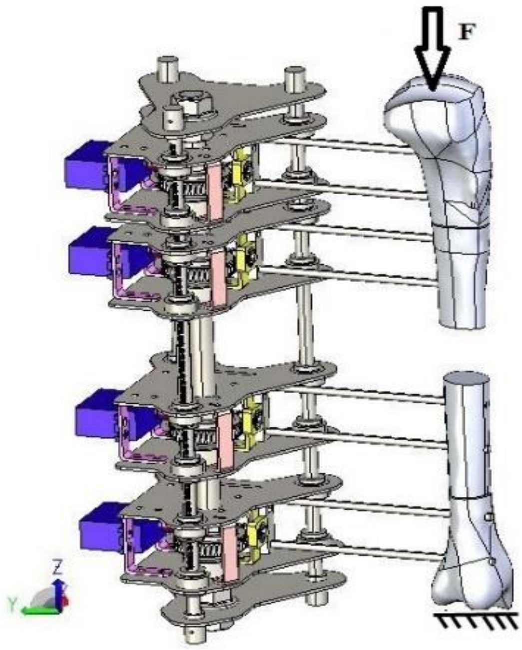

Figure 3. Fixed site of the fractured bone, for simulation and analysis of the motorized unilateral external fixator with four independent motorized units using finite element method and the site of applying 150N force to the fractured bone and the direction of applying force

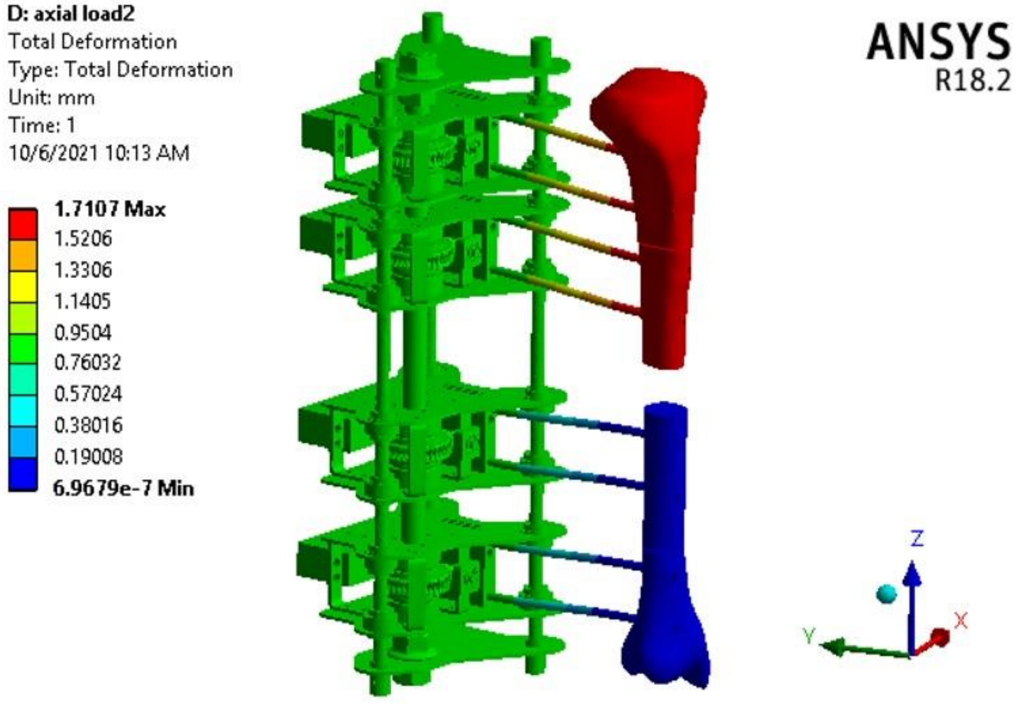

Figure 4. Distribution of displacement and deformation in all parts of the system due to the application of 150N force along the axis of the fractured bone

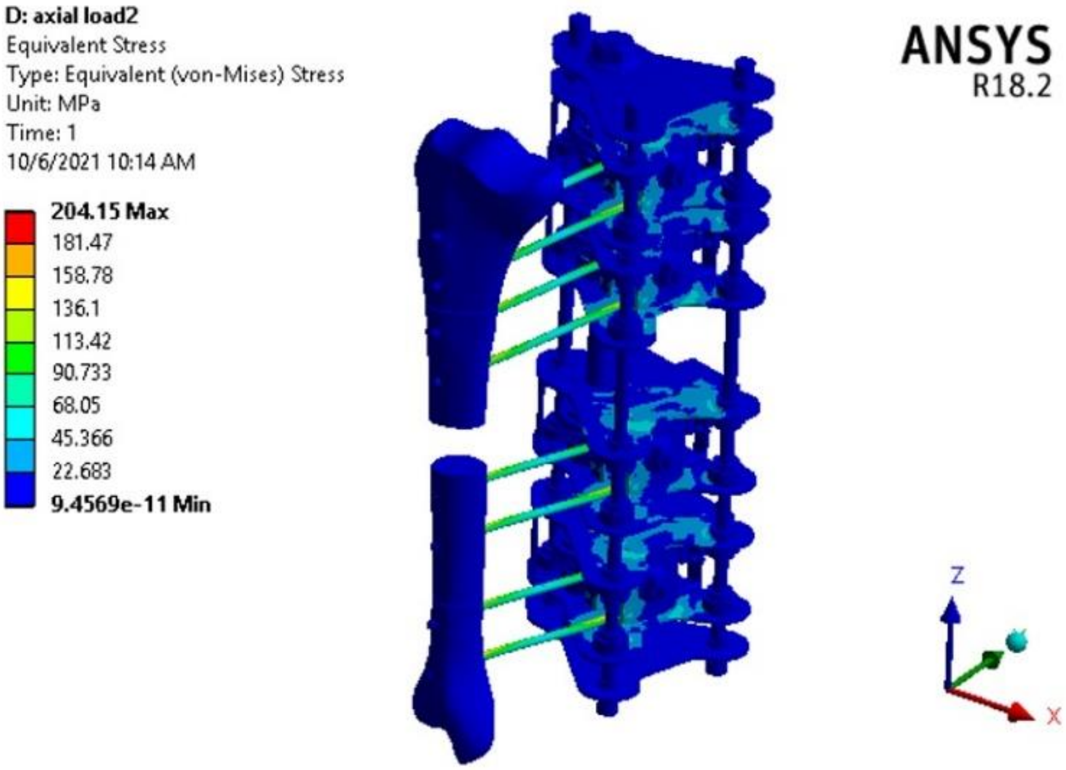

Figure 5. Distribution of Von mises stresses in all parts of the system due to the application of 150N force along the axis of the fractured bone

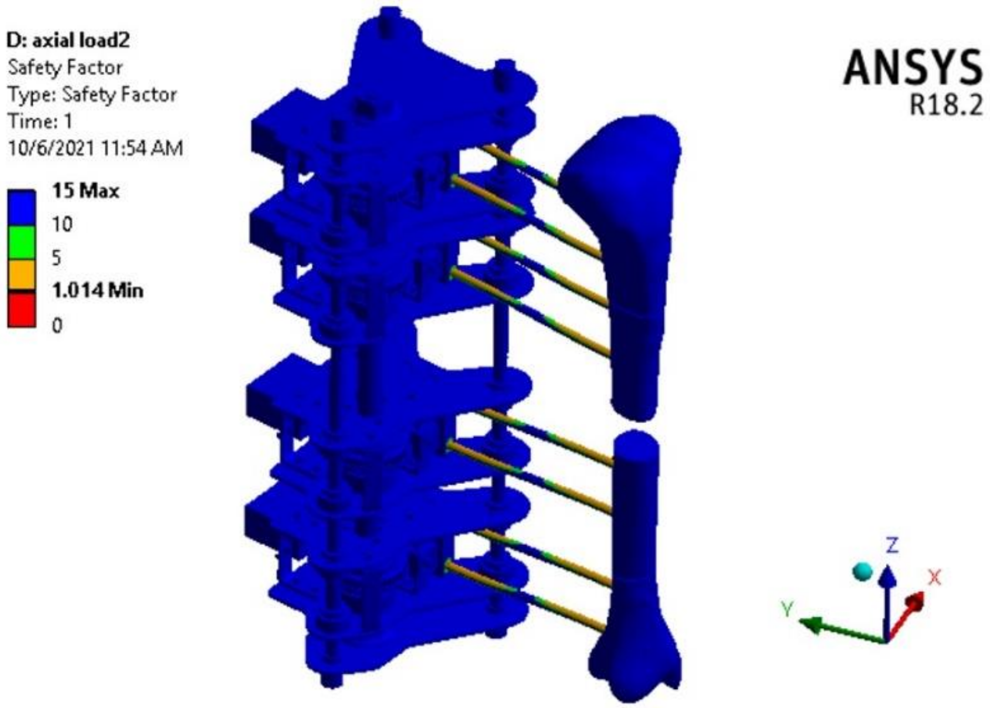

Figure 6. Distribution of safety factors in all parts of the system due to the application of 150N force along the axis of the fractured bone

According to the Von mises stress obtained from this simulation and also considering the yield stress of 205 MPa of stainless steel 316, the maximum allowable values of axial force and the safety factor were 150N and 1, respectively. Any increase in force will change the form of schanzes and break them. Table 5 shows the data obtained from the deformation, and the amount of Von mises stress obtained for the three forces up to the force that causes the schanzes to break.

Table 5. Data obtained from the application of force in the simulation of compressive force

Force (N)	Max def (mm)	Stress (MPa)
50	0.57	82
100	1.14	164
150	1.7107	204.15

Simulation of the compressive force showed that the device has good stability, and only the schanzes failed that were used as standard. Thus, the maximum compressive force of 150N was approved. Due to the Von mises stress contour and the safety factor obtained in the bone fixator structure, the device has significant stability against the applied force regardless of the schanzes. By applying this force value, the system stability will not change at all, so the strength and rigidity of the device have acceptable values.

4.2. The second stage

Torsion was simulated in Ansys software using the finite element method to ensure the strength and rigidity of the device. Figures 7 show the boundary conditions of the torsional force applied and the fixed site (bone) in the simulation, respectively. In this simulation, the maximum allowable torque was about 8 Nm [10, 17, 19, 21].

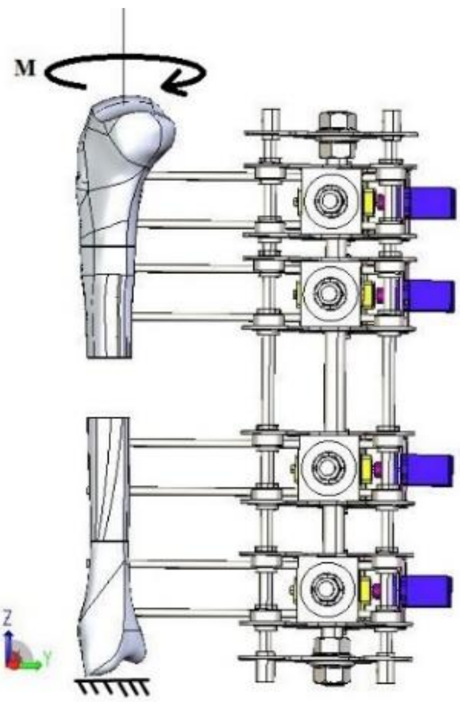

Figure 7. The site of applying the 8Nm (M) torque to one end of the fractured bone and its direction and Fixed bone end site in torsional simulation

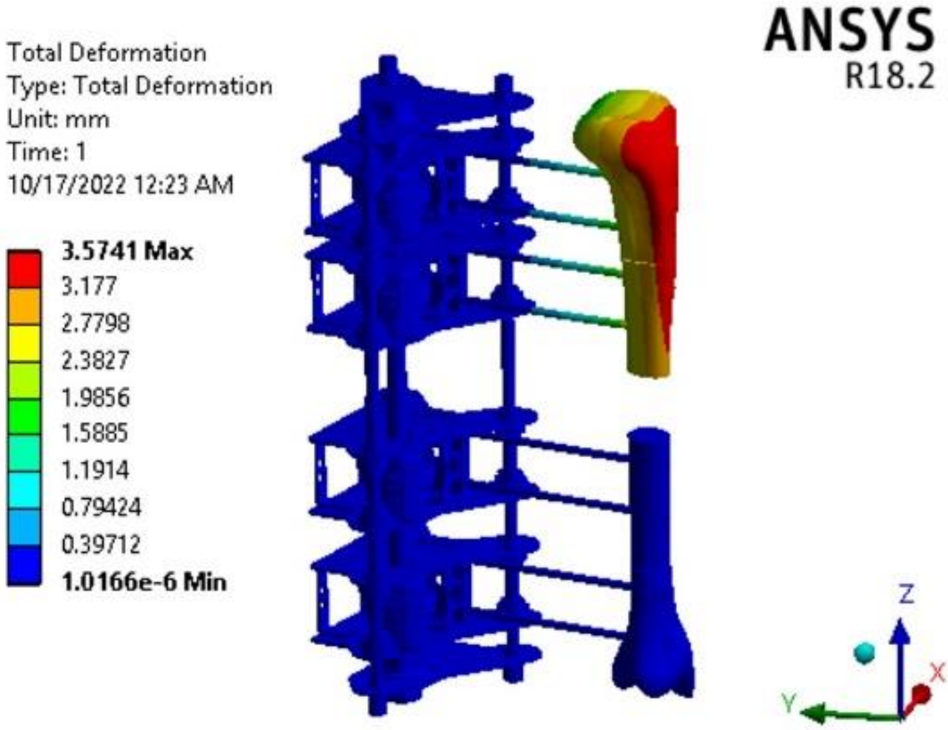

Figure 8. Displacement and deformation of all parts of the system due to the application of 8Nm torque along the axis of the fractured bone

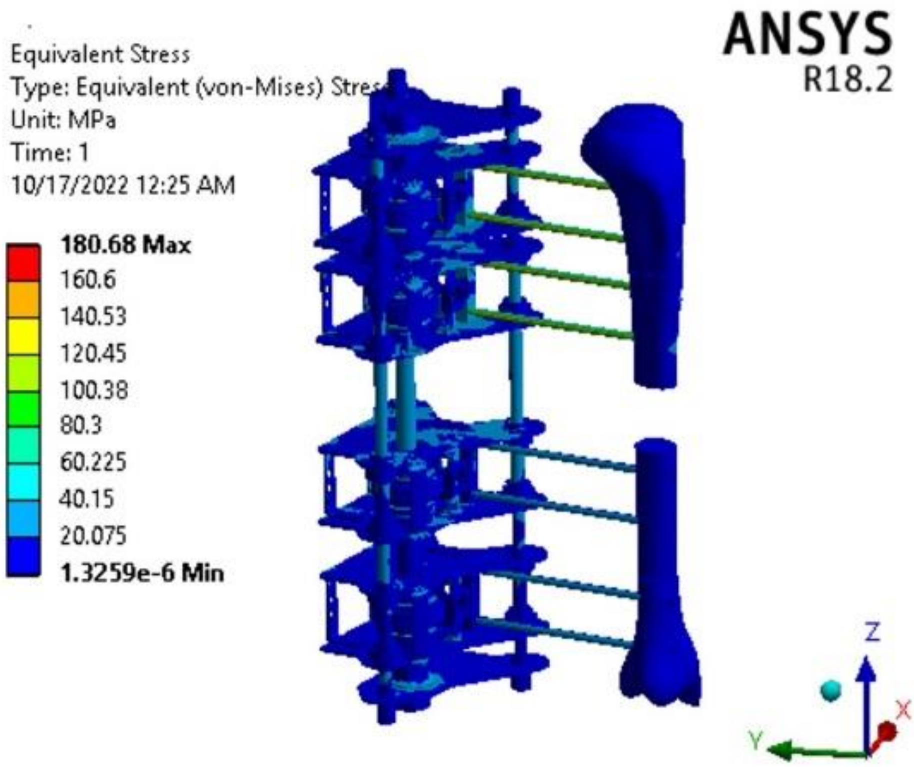

Figure 9. Distribution of Von mises stress in all parts of the system due to the application of 8Nm torque along the axis of the fractured bone

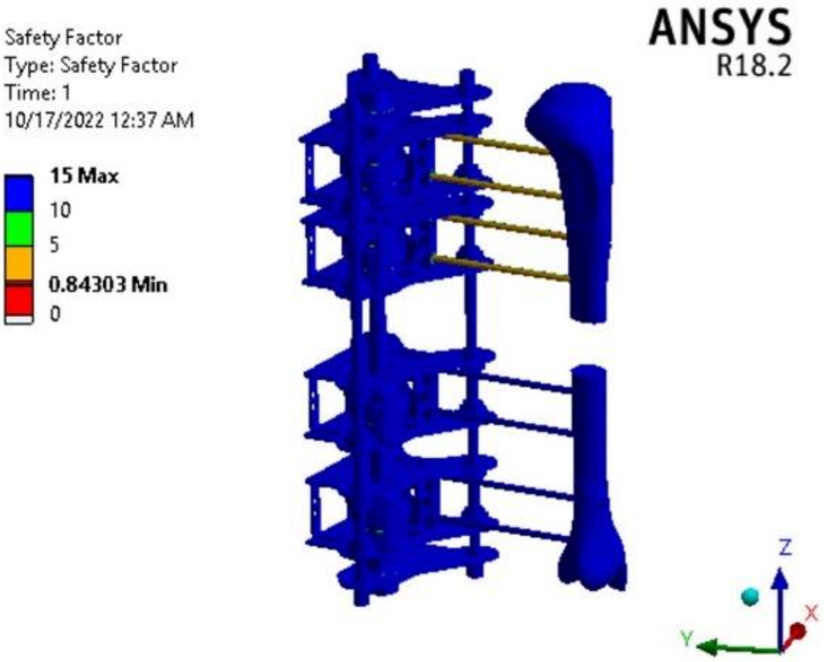

Figure 10. Site of the minimum safety factor in all parts of the system due to the application of 8Nm torque, along the axis of the fractured bone

The results of the analysis of the application of torsional force to the fractured bone, including the three contours of displacement, deformation, as well as Von mises tension and safety factor, are as follows: The maximum displacement of the bone and consequently the schanzes holder in the direction perpendicular to the bone axis was about 3.57 mm (Figure 8). The maximum Von mises stress was 180.68 MPa (Figure 9). The safety factor of the system was 0.843 (Figure 10), indicating that the maximum torque allowed to apply to the system is approximately 8 Nm, and using more torque will cause the schanzes to fail. Table 6 shows the deformation results and the Von mises stress value obtained from the simulation for 3 forces (up to the force leading to system failure). This means that applying a torque of about 8 Nm, causes the schanzes to fail.

Table 6. Results of applying the torque force leading to deformation and the value of Von mises stress caused by applying the three torsional forces (from the low values to the value that leads to system failure)

Torque (N.m)	Max def (mm)	Stress (MPa)
2	0.92	49
6	2.7	149
8	3.5741	180.68

Therefore, in this simulation, it is observed that the schanzes have been deformed, but the device still retains its rigidity. However, since the schanzes limit the torque tolerance on the fractured bone, the torque cannot be increased in torsional simulation. Considering the Von mises stress contour and the degree of safety factor obtained in the bone fixator without considering the schanzes, the device has significant stability against the torques applied in the simulation, and application of this amount of torque (8 Nm) causes no change in the device stability. This indicates the device's degree of strength and rigidity against the application of torsional force.

4.3. In the third stage, the bending simulation was performed by applying a force of 150N from four points (Figure 11) and then analyzed using the finite element method, considering the boundary conditions (e.g., applying force from four points to assess the device strength and stability).

In this case, the gaps between the upper and lower pieces of the bone were not considered, and the two-piece bone was regarded as one piece. This experiment was carried out to show changes in the length of the moment arm on the bone. Figure 11 shows the simulation's force sites (F) and offers the hypothetical sites used to keep the device fixed during the simulation.

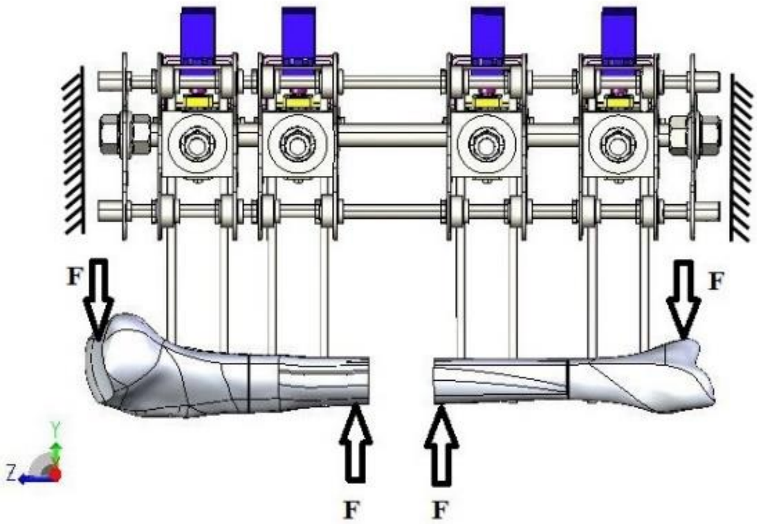

Figure 11. The site of the application of 4 forces to the two ends of the broken bone and their direction and Fixed surfaces of the device in the bending test simulation

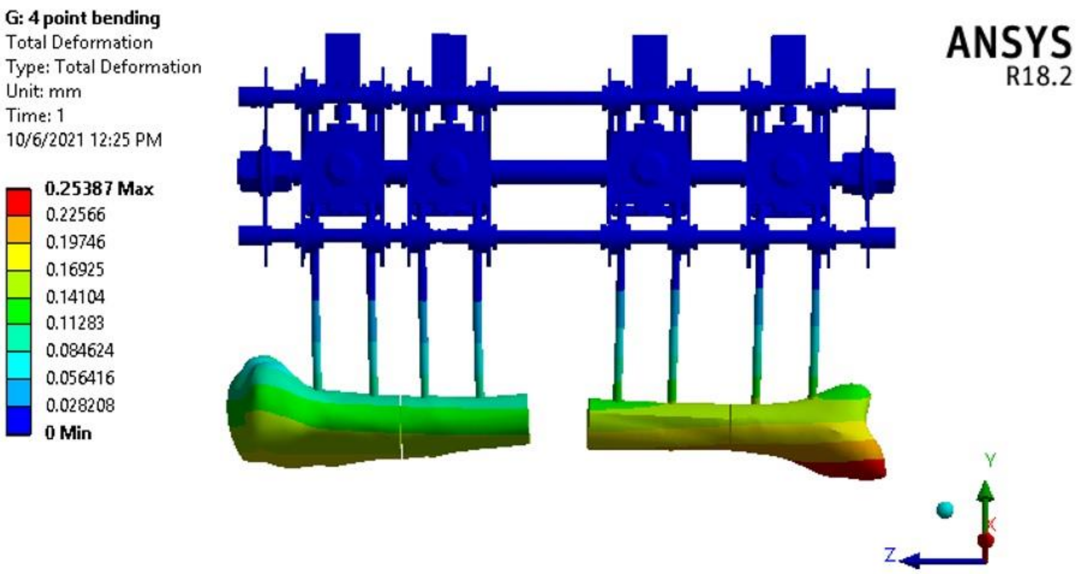

Figure 12. Displacement and deformation distribution in all parts of the system were caused by applying a force of 150N in the direction perpendicular to the axis of the fractured bone at four points

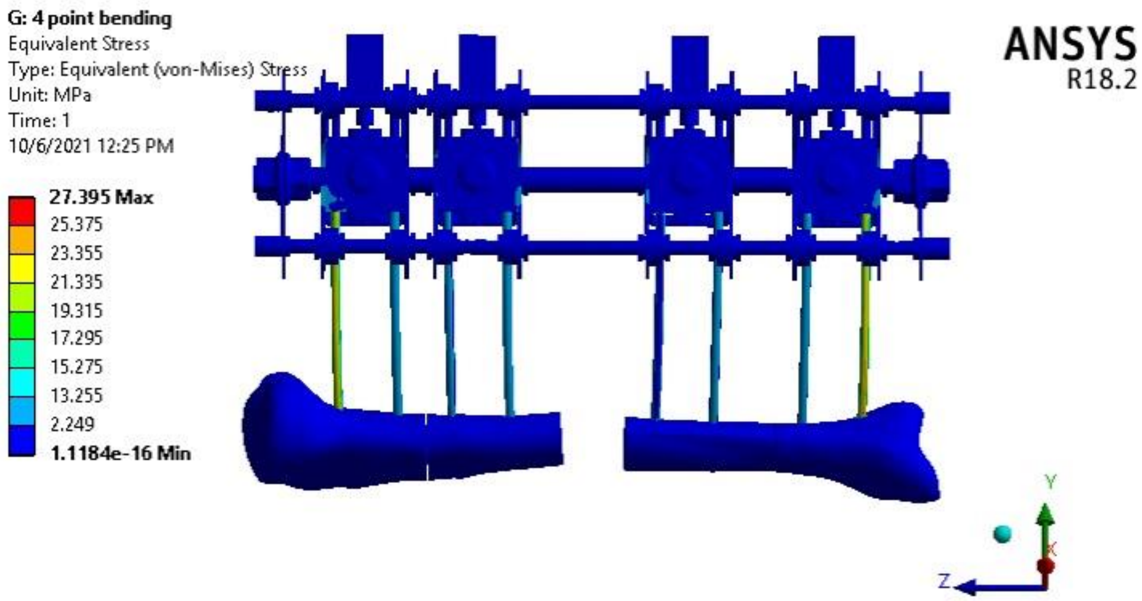

Figure 13. Von mises stress distribution in all parts of the system was caused by applying a force of 150N on the fractured bone axis at four points

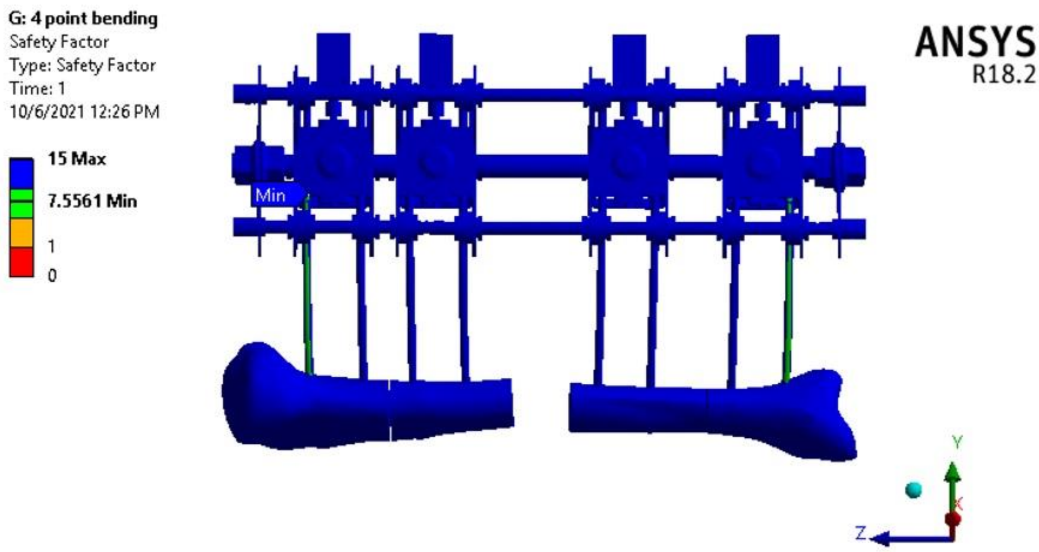

Figure 14. The safety factor in all parts of the system caused by applying a force of 150N perpendicular to the axis of the fractured bone at four points

Bending with a force of 150N was simulated using the finite element method [10, 17, 19, 21]. The maximum bone displacement observed was about 0.25 mm (Figure 12), and the maximum Von mises stress was 27.395 MPa (Figure 13). Figure 14 shows the factor of safety contour, which represents the stability of the whole system. The minimum value of the safety factor was 7.5, meaning that the system has the necessary strength and resistance under a force of 150N and with the applied boundary conditions.

The results of the bending force simulation proved that the application of 150N force causes the deformity of schanzes. Table 7 shows the results of static analysis of the force applied to the fractured bone during the bending simulation and its sites.

Table 7. Results of the force applied in bending simulation (4 points)

Force (N)	Max def (mm)	Stress (MPa)
150	0.25387	27.395
525	1.8	208

The simulation of the four-point bending test using the finite element method proved that the application of 150N force causes the deformity (failure) of schanzes. Considering the Von mises stress contour and the degree of safety factor obtained in the external bone fixator, regardless of the schanzes, the device showed significant stability against the forces applied in the simulation. Therefore, it can be stated that by using a force of 150N, the device maintains its stability, indicating its strength and rigidity. Therefore, the fixing structure in the present study corresponds to the structure presented by Alamdin et al. [31].

In the present study, compressive, torsional, and 4-point bending forces were simulated based on finite element analysis, and the results showed that the motorized unilateral external bone fixator, designed to fix fractured bones and displace from four areas of long fractured bones, has the necessary stability and safety and even if the applied force exceeds the force, which leads to deformation and fracture of the schanzes, the device still maintains its rigidity and stability [32].

5. Conclusion

In the present study, the motorized unilateral external bone fixator was designed and simulated by SolidWorks software. Its strength and rigidity against bending, torsion, and compression forces were analyzed via simulation with Ansys software using the finite element method. The results indicated that the device has the necessary and desirable stability and rigidity. Considering the obtained reliability coefficient of each experiment simulated by the finite element method, which was within the acceptable range (50-150N for compressive forces, 2-8Nm for torsional forces, and 150-525N for 4-point bending forces), the device has been confirmed in terms of reliability. Therefore, it is a reliable and stable tool used in orthopedic surgeries to keep long fractured bones fixed. Moreover, due to having four independent motorized units, this device can displace long fractured bones containing a lost part for osteogenesis and making up the lost bone.

6. References

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