DOI: 10.71762/7nc5-tx24

Research Paper

Investigating the Strength and Stability of a Motorized Unilateral External Bone Fixator Device Under Bending Load in Dynamic Mode

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Received: December 16, 2025; Revised: February 1, 2026 Accepted: February 4, 2026

Abstract
Using a unilateral external bone fixator to align broken bones is now commonly used. One of the main benefits of this type of fixator is that it is easier to install and adjust than other types, such as circular or horseshoe-shaped models. The goal of this study was to make sure the single-sided motorized external bone fixation device is stable and strong. The device was designed with four motors and built using SolidWorks software. It was tested under a bending force of 150N while the motors were running. The device was also analyzed using the Finite Element Method (FEM) in ANSYS software. After testing it in the lab with the same bending force, the results showed that the device has the necessary strength, rigidity, and reliability to help stabilize broken long bones. It can also move the broken parts of the bone, especially when some of the bone is missing. The device has four separate motor units that allow precise movement of the bones based on the patient's condition and the doctor's instructions, helping the healing process.

Keywords
Unilateral External Bone Fixator, Bone Fracture, Bone Loss, Orthopedics, FEM, Orthopedic Surgery

1. Introduction
Unilateral external bone fixators are commonly used in orthopedics to hold broken bones in place and, in some situations, to shift broken bones that are missing a part to replace the lost bone. Because of this, a motorized unilateral external bone fixator that is strong and stable is a good choice for treating bone loss and fractures.

In this case, the device needs to be set up carefully to get the best outcome because an error can cause serious problems, like treatment failure, needing another surgery, and reinserting the device, which can lead to issues such as higher costs, longer recovery times, infections, or loss of bone healing and recovery. By looking at the history and development of external fixators, we can see why unilateral external bone fixators are important in orthopedics. Here, the process of using and improving external fixators is explained, and the studies done on their strength, stability, and how effective they are in treating bone breaks are briefly covered.

The use of external fixators has mainly helped improve techniques for reconstructing limbs. Fragomen et al. [1] It was mentioned that the external fixator, which is now the most recent option for fixing bones and is becoming the main approach for treating different bone and soft tissue problems, requires further development and improvement. According to Paul et al. and Hernigou [2-3], even though in fields like traumatology and orthopedics, using an external bone fixator is often seen as a new or advanced technique, doctors have actually been using it for a very long time. As far back as 377 BC, Hippocrates created an early form of an external fixator made from natural materials. In the past, these tools were often made of wood and used to help heal broken bones. Later, in 1840, a doctor named Jean-François Malgin came up with a device called the "metal point." Then, just a few years later, in 1843, he introduced another tool known as the "metal claw," which was a two-forked device. Paul et al. and Hernigou [2, 3]. Clayton Parkhill was one of the first people to create a real unilateral external bone fixator in 1897. According to Paul et al. [2], Lambert created the monocortical fixator in 1911. The way modern external fixators work by applying compression comes from Lambert's original design and clever ideas. In their study, Fleming et al. [4] mentioned that the Ilizarov external fixator is used to treat broken bones. A study by Goodship and Kenwright found that creating small movements along the broken bone can help speed up the healing process. Broekhuizen [5] mentioned that the Wagner device, made by Mathys and Bettlach in Switzerland and constructed from stainless steel, was originally created to help lengthen long bones, particularly the femur. Qiao et al. [6] created robot designs and methods for positioning that help the device work more precisely. Wei et al. [7] used digital measurement techniques based on Paley’s deformity measurement method and also suggested a deformity correction algorithm to determine the length changes of the six rods. Corona et al. [8] worked on circular frames to help plan surgeries better for tibial deformities caused by trauma. Based on their research, Zhao et al. [9] said that by mixing the good parts of series and parallel systems, hybrid robots can be made to suit particular medical needs, such as treating joint breaks and big, complex fractures. Matsushita et al. [10] The Hifixator device is an external fixator that uses a new sliding mechanism. This mechanism worked well in 72% of the movements at the broken bone site, even when the pins were not tight, and the torque was 4 Nm. In a study by Sangkaew [11], the method has changed the way distraction osteogenesis is done by using the available external fixator from AO/ASIF, and it is safe, affordable, and can be used in many different situations. In the research performed by Hussain et al. [12], using a unilateral external fixator to increase the length of the lower limb in cases of limb-length discrepancy with the Wagner method, the results showed that 89% of the bone outcomes and 97% of the functional outcomes were either excellent or good based on the criteria used. Tang et al. [13] concluded that performing a single-stage knee fusion using a unilateral external fixator with cannulated screws is an effective treatment for end-stage tuberculosis of the knee. In the study of Basso et al. [14], it was found that 95.8% of patients were happy with the approach of using unilateral external fixators for treating humeral shaft fractures. The results of a study performed by Yushan et al. [15] The study found that using a single rail system for trifocal bone transport to treat large tibial defects caused by infection greatly improved how well the patient's leg functioned after surgery and helped the bone heal faster and come together more quickly. Sen et al.

[16] studied a combined approach for treating bone defects in the lower part of the thigh after removing an infection in the bone. This method used an external fixator along with a short nail above the knee joint. The study found that this combined treatment was effective for bone defects in the lower part of the thigh after cleaning up the infection. The treated bones healed well, and the number of complications was manageable. Strebe et al. [17] tested three methods: double stacking, crosslinking, and diagonal pinning using ultra-high molecular weight polyethylene bone models and existing external fixator parts. The findings indicated that double stacking was the best method for improving resistance to bending, especially in the front-to-back direction and under axial pressure. However, this method also led to a much higher cost. Ang et al. [18] checked the stiffness along the length and twisting of the externalized titanium locking compression plate (ET-LCP), the externalized stainless steel locking compression plate (ESS-LCP), and the unilateral external fixator (UEF). Found that LCP can be used as an external fixator, which is a better choice than the old UEF. This is because LCP has a smaller design, which is more comfortable for patients, and it doesn’t affect the stiffness in the same way as UEF. Li et al. [19] The FEM was used to look at how stress and bending of the external bone fixator system changed when it was under different kinds of force, like pushing straight, twisting, and bending. It also compared how well two different fixators worked. One fixator had a pin angle, and the other did not. When the pin angle was between 0 and 20 degrees, the speed at which stress or damage built up was slower. But once the angle went over 20 degrees, the speed at which stress or damage increased became much faster. This means that the pin angle has a bigger effect on how stable the external bone fixator system is when it's more than 20 degrees. In their study, Zainudin et al. [20] said that if you take into account things like the biomechanical view, using an external fixator can help the bone heal well. One of these important factors is the size of the pin. They used a computer model called FEM to study the standing position. The findings showed that using a pin that is 6.5 mm in size causes the least stress on the joint area between the pin and the bone. Shi et al. [21] found that the plate-type external fixator is stiffer and stronger than the unilateral external fixator. The best biomechanical performance was seen in the classical plate-type external fixator, and the extended plate-type external fixator came next, with a small difference between them. The plate-type external fixator performed better than the unilateral type in axial compression, four-point bending, and torsion tests. Jean et al. [22] used the Hoffmann®3 device as a reference for comparison. To check the structural strength, six external fixators were tested in three different ways: axial compression, mediolateral (ML) bending, and torsion. The findings suggested that the stiffness of the UUEF (unilateral uniplanar external fixator) and UBEF (unilateral biplanar external fixator) compared to the reference fixator could be beneficial for fracture healing and protection. Lesniewska et al. [23] conducted a finite element analysis on fracture healing with the use of a fixation device. Appropriate analyses were carried out under axial and varying load conditions. The findings showed that during the early stages of the healing process, the stresses in the external fixator are at their peak and tend to decrease as time progresses. In a study performed by Donaldson et al. [24], it was found that the fixator becomes loose because the bone near the pin breaks down at the point where the pin meets the bone in the external fixator that uses half-pins. The amount of bone that breaks down around the implant increases three times from young patients to older patients. If three half-pins are used instead of two on each side of the broken bone, the amount of bone that breaks down will be reduced by 80% in all age groups. Using titanium half-pins helps reduce the effect of broken-down bone by

about 60 to 65%. Roseiro et al. [25] created a simple version of the Finite Element Method to study how well an external fixator works on a broken tibia bone. This helps find out how stiff the broken area is. Also, a genetic algorithm was set up to reduce how much the broken part moves. It does this by adjusting where the parts of the external fixator are placed and by testing different ways the body's weight and forces are applied. Wang et al. [26] found that if a solid screw is used, there is a lot of stress early on during the bone healing process, both on the screws and the femur. However, when a hollow screw is used, the stress is spread more evenly, and in the middle of the healing process, the stress on the femur goes down a lot. Li et al. [27] said that stiffness is the main thing used to check how stable an external fixator is. The stiffness of the fixator affects the way the broken bone moves and works. They made a model based on Young's modulus of the callus, using Castigliano's theory, to check how stiff the fixator and bone system is when healing. Their results showed that all three ways of checking stiffness give similar results. The finite element method showed that as healing goes on, how the fixator and bone share the force changes. Also, the finite element method supported the findings from the theory. Salunkhe et al. [28] designed a high-power external fixator that weighed just 1.217 kilograms and had a good system for treating unstable fractures dynamically. The biggest movement between the broken bone pieces was measured. When a compressive force of 2000N was applied, the maximum movement was only 0.0018 millimeters, which is within the acceptable limit. The stiffness of the external fixation system under axial pressure and its mechanical stability when facing anterior-posterior bending were studied. The results looked at how much the device moved at key points, including the fracture site. Based on all the information, it was found that the Orthofix external fixation device has strong mechanical stability when dealing with anterior-posterior bending loads. It is also possible to make the device better by using new advanced materials or by redesigning the device. [29, 30]. Albushtra et al. [31] using a unilateral external fixator as the main and final treatment is a good, easy, and effective choice for TDF, with a high chance of success even in places where resources are limited. Abd Aziz et al. [32] using unilateral fixation can work well for small fractures, but it might be a problem if the fracture gap is larger. Çöpoğlu et al. [33], one of the biggest issues when using an external fixator in a clinic is when the pin comes loose from the bone. This can cause an infection around the pin or make the bone breakage less stable. Using a Micro-Motion Damping Pin might help reduce this problem. External fixation is a method of stabilizing fractures that employs pins that are connected to the bone at one end, travel through the surrounding soft tissues, and are fixed to a rigid external metal or composite frame [34]. Bing Wui Ng et al. [35] study was conducted on two clinical cases treated with a novel concept of cross self-locking rods external fixation construct, were being described, coupled with a biomechanical analysis of its stability in comparison with other constructs by using a finite element study.

Studies show that creating a device to reduce mistakes is a good way to improve bone fracture treatment. Also, having a motorized device helps it work better during bone loss treatment and makes the patient feel more comfortable, which is really important. For this reason, a motorized external unilateral fixator was made to help treat fractures and bone loss. This device can hold the bone in four different areas. Most importantly, it uses motors in each of its four separate parts to move certain parts of the bone as needed to help grow new bone and make up for lost bone.

The goal of this study is to test the strength and stability of a motorized unilateral external bone fixation device using both computer simulations and real experiments. The device has four motors that can move up and down, and it is made separately so it can be controlled based on the patient's condition and the doctor's recommendation. The device was created using SolidWorks software and then tested under bending with a method called FEM in ANSYS software. The aim was to find a safe and effective design for use in medical orthopedic centers. After making and putting together the parts, the device was tested in a standard lab setting to check how it handles bending. Since the device was found to be stable, strong, and rigid under bending, it can now be produced in large numbers and used to help patients with different bone-related issues. These include people with long bone fractures, limb defects, short legs, those who want to increase their height, and individuals missing part of a bone, among other orthopedic conditions.

2. Material

The unilateral external bone fixator equipped with four motors has medical (orthopedic) use, and given the patient's need for long-term use of the device 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 FEM, considering stainless steel as the primary material. The chemical composition, as well as the 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	
				Rockwell 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 design of the unilateral external bone fixator was created using Solid Works. Then, the design was moved to ANSYS software for simulation and analysis using the finite element method (FEM). The required simulations were carried out to apply loading and bending force. After that, the device was made for testing, along with clamps and a tube that was used in place of a bone. The tube had similar specifications to the tibia bone and was fixed next to the other tube using the clamps. The setup was then subjected to a bending load under real conditions in a standard lab environment based on the designed test. The results from the software simulation were compared with the results from the actual experiment, and both were examined and analyzed. The following section discusses the software simulation and the experimental method, along with the necessary conditions. It also presents the boundary conditions used in the FEM and in the experimental method. The device's schanz holder is designed in a standard way to allow the use of standard threaded schanz (threaded pins) commonly used in orthopedics .

The fixing device has four threaded pinholders, called schanz holders. Each holder can move separately along the main axis thanks to a motor. First, a 3D model of the bone fixing device was created using SolidWorks software. Also, a CT scan image of a bone that broke into four parts, with some parts missing, was prepared and converted into a 3D model using Mimics software. This model was then used in SolidWorks. Using the Schanzes, which are threaded pins, installed in the schanz holders of the device, the broken parts of the bone were fixed together. Figure 1 shows the 3D view of the device with the Schanzes and the bone. (The process of attaching the device to the bone with Schanzes and positioning the broken bone segments was done as described in the studies, some of which are mentioned at the end of this study.) Table 4 shows the mechanical properties of stainless steel 316 and bone to help with the force application process needed for the device simulations. The Schanzes used in this study were standard solid threaded pins, 5 mm in diameter and 200 mm in length. The SolidWorks 3D file with a .step extension was imported into ANSYS Workbench and meshed using different available elements (Figure 2). After looking at the mesh convergence by increasing the element density in the most sensitive areas of the system, the number of elements and nodes were set to 364,770 and 639,921, respectively, for simulation and analysis using the finite element method (FEM).

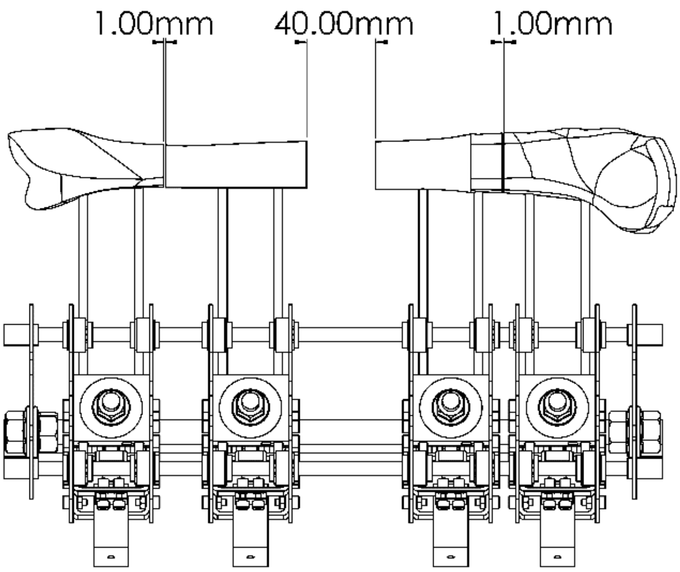

Figure 1. The motorized unilateral bone fixator designed in SolidWorks software along with Schanzes and how to attach threaded Schanzes to the fractured bone containing lost parts

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

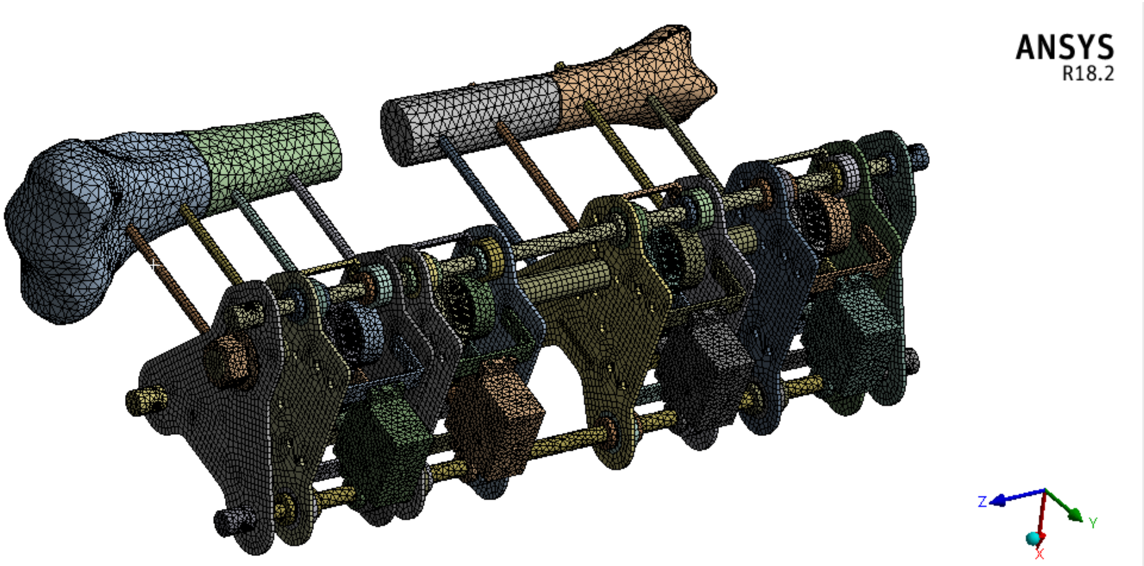

Figure 2. Final meshing for modeling a motorized unilateral bone fixator

3.2 Conditions of simulation and analysis using FEM

In this model, the bone density, the average Young's modulus, and Poisson's ratio were set to 1800kg/m³, 18GPa, and 0.2, respectively. The surfaces where the Schanzes touch the bone were fixed, meaning none of the surfaces could move or change position relative to each other. The device parts were made of stainless steel 316, which has a Young's modulus of 193GPa and a Poisson's ratio of 0.3. Except for the moving parts that can move relative to each other, all other contacts were either bonded or fixed. In this simulation, it was assumed that the standard threaded pins (Schanzes) inside the bone do not move at all, the schanzholders move along the central axis, and the guide rods move like a cylinder, allowing them to slide along their axis if needed.

3.3 Conditions considered for Experimental method

To perform tests that mimic real-life conditions, a polypropylene pipe with an outside diameter of 40mm, an inside diameter of 26.6mm, a thickness of 6.7mm, and a length of 400mm was used. This pipe replaced the tibia bone, as its dimensions closely match those of a real tibia. The pipe was cut into four sections. Each section was held in place using standard stainless steel threaded clamps, which had a diameter of 5mm and a length of 200mm. The setup, including the clamps and the pipe, was then secured in a bending testing device as per the test plan. Once the motors were turned on, the bone fragments started moving. At the same time, a bending force of 150N was applied. However, during the experiment, a force higher than 150N was accidentally applied. All tests were carried out under standard lab conditions, which included a temperature of 25 degrees Celsius and a humidity level of 25%.

4. Results and discussion

4.1 In the first stage

To check how stable the device is, we used the FEM method in ANSYS software. In this simulation, a force was applied in the same direction as the bone's axis, while the other end of the bone was fixed. The setup included fixing one end of the bone and applying a force of 150N to the other end, as shown in Figure 3 [10, 17, 19, 21]. At the same time, the two middle motors of the device moved 0.25mm in one second. After running the simulation and applying the force, we got data including three displacement and deformation patterns, as well as Von Mises stress and safety factor values, which were needed for analyzing the device.

The maximum displacement in the bone and its Schanzes, as shown in Figure 4, was about 1.60mm. This movement happened in the same direction as the force being applied and along the bone's main line. The highest Von Mises stress measured was 324.96MPa, as shown in Figure 5. The safety factor of the system was 15, as shown in Figure 6, which means the system can handle up to about 150N of force. However, within the area of the Schanzes, the confidence coefficient was about 5, meaning the system can still handle up to around 150N of force. If more force is applied, the Schanzes may break.

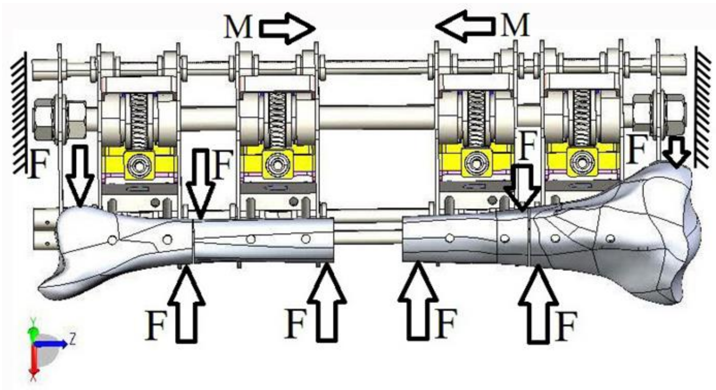

Figure 3. Boundary conditions for the simulation of bending force in dynamic mode

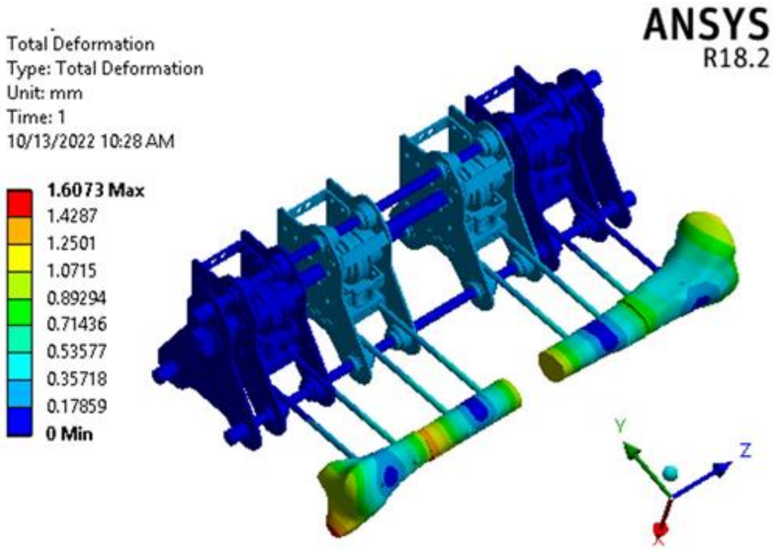

Figure 4. Deflection distribution contour of 150N bending force

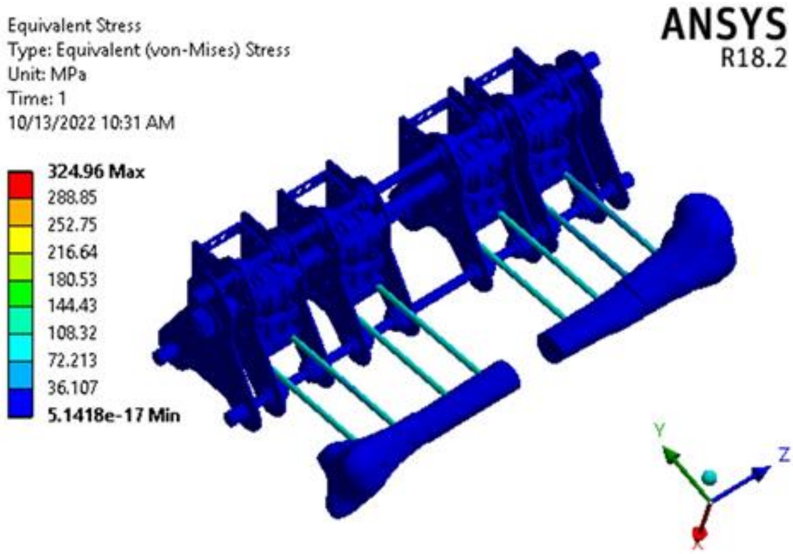

Figure 5. Von-Mises stress distribution contour applying a bending force of 150N

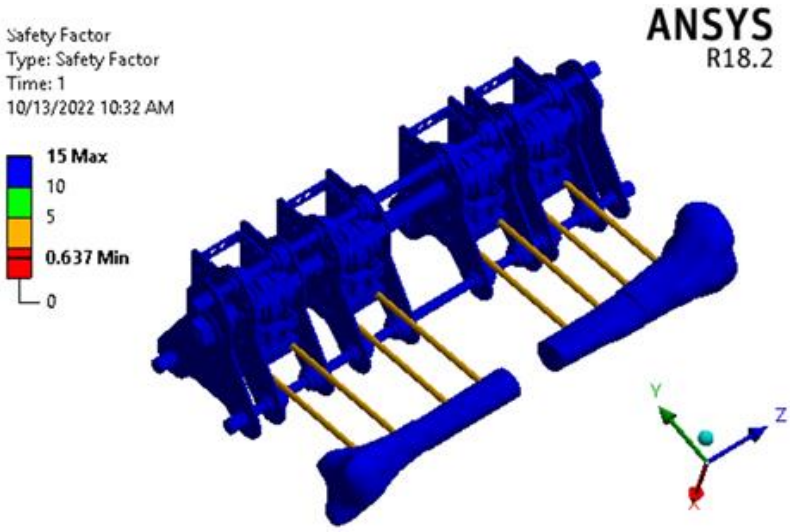

Figure 6. Distribution of the safety factor for applying a bending e force of 150N

Based on the Von Mises stress results from the simulations and taking into account the yield stress of 205MPa for stainless steel 316, the highest force that can be safely applied along the axis is 150N. The safety factor in this case is exactly one. This means that if any more force is applied, the structure may start to deform and eventually break.

The data obtained from the deformation and Von Mises stress for the application of two forces are given in Table 5; a force of 150N is the force that leads to failure in the shanzes piece.

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

Force (N)	Max deflection (mm)		Stress (MPa)	
	Schanzes	Device	Schanzes	Device
150	1.60	No change	324.96	72.213

Simulating the application of a bending force, it shows that the device remains stable. Only the schemas that are standard and commonly used fail. Therefore, applying a maximum bending force of 150N is approved. Based on the Von Mises stress contour and the safety factor from the bone fixation device without considering the Schanzers, the device shows strong stability against the applied forces. Using this amount of force does not affect the system's stability in any way. So, the device's strength and rigidity are good and acceptable.

4.2 In the second stage

The bending test was done in a lab to make sure the device had the right strength and stiffness. The setup for the test is shown in Figure 3, which explains how the bending force was applied and where the fixed part (bone) was located. During the test, a force of 150N was used, although a slightly higher force was accidentally applied. A displacement of 0.25 mm was also applied under standard lab conditions, which means the temperature was 25°C and the humidity was 25% [10, 17, 19, 21]. After each test, the device was placed on a smooth stone, and its condition was checked. In every case, the structure of the device remained the same.

Figure 10. Bending force applied on four pieces of bone fixed in dynamic mode

After applying a bending force in dynamic mode to the four-part bone that was fixed with standard Schanzes attached to the schanze holder of the fixing device (to make sure the results were correct and accurate, the test was done three times and the results were very similar each time), the results from this test, shown in Table 6, showed that when a force of 89.34N was applied, the bone moved 0.90mm, and when a force of 173.63N was applied, the movement was 1.76 mm. This amount of movement only happened in the Schanzes and the bone (bone replacement tube), and the device stayed the same.

So, based on the bending test done in a dynamic way, the force used was higher than the expected force (150N), but the results still came out well. This means that the bone doesn't change much and stays stable. The motorized bone fixation device that was designed and made has good stability, strength, and rigidity.

The data obtained from the deformation due to the application of three bending forces are given in Table 6.

Table 6. The data obtained from the test of bending force applied on the four-piece bone in dynamic mode

Force (N)	Force (Kg)	Max deflection (mm)	
		Shanzes	Device
89.34	0.90	0.90	No change
173.63	17.70	1.76	No change

By comparing the results from the FEM simulation and the experimental method, where a bending force of 150N was applied to the quadrilateral bone in a dynamic state, it was found that the shape changes from the simulation and the experiment were very similar. In the experiments, the force applied was slightly different depending on the type of device used. The dynamic state of the bone was determined using the Schanz standard, which was connected to the schanz holders of the device and kept fixed. According to Table 7, the results from the FEM simulation for a 150N bending load and the experimental results are considered the same when the small differences are ignored.

Table 7. Comparison of simulation and experimental results of applying bending force on the four-piece bone in dynamic mode

Check method	Force (N)	Max deflection (mm)		Stress (MPa)	
		Shanzes	Device	Shanzes	Device
Simulation	150	1.60	No change	324.96	72.213
Experimental	89.34	0.90	No change	-------	-------
Experimental	173.63	1.76	No change	-------	-------

Therefore, because the results from the simulation method and the experimental method are very close, with only a small difference that doesn't affect the outcome, the changes made based on observations and tests were only within the standard Schanzes range, and the device's structure remained the same.

After reviewing and studying the research and its results, it was concluded that the designed device, a unilateral motorized external bone fixator, which is used to fix broken bones and move the four areas of broken long bones, is stable and safe.

Even if the applied force goes beyond what the Schanzes can handle, causing deformation or fracture, the device still keeps its rigidity and stability. Therefore, the fixing structure in the present study corresponds to the structure presented by Elamdin et al. [36].

Therefore, the bone fixation device has good stability even when considering the Schanzes. Applying a bending force of 150N does not affect the system's stability in any way. This means the device's stability, strength, and rigidity are good and acceptable. Since the Schanzes cannot handle this much force, there is no need to apply more force to test the device's strength [37, 38, 39].

5. Conclusion

In this study, simulation results were created using ANSYS software with the help of the finite element method, and experimental tests were done on a unilateral motorized bone external fixation device. The device was designed using SolidWorks software, and it was both simulated and built in a dynamic mode. The results show that the device has good stability, strength, and rigidity when facing bending forces. Also, considering the safety factor found in the simulation using FEM, it is within an acceptable range. Because of this, the device is considered reliable. Therefore, the device is a safe, stable, and strong tool that can be used in orthopedics to help stabilize broken long bones. Plus, since the device has four separate motorized units, it can be used to move broken long bones when part of the bone is missing, helping with bone growth and replacing the missing bone part.

6. References

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