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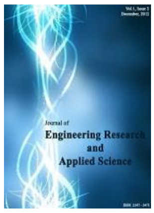

Computer Aided Automatic Fixator Design

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Abstract
A fixator is a device used in the lengthening of bone (distraction osteogenesis) and in the correction of bone deformities. It is employed for therapeutic purposes in various fields, including Orthopedic Trauma, Pediatric Orthopedics, Deformity Surgery, and other surgical specialties. In this study, the computer-aided design (CAD) and system analysis of a fixator device, manually used in the Limb Reconstruction System, for its automated operation have been conducted. The aim of this work is to theoretically achieve the bone lengthening process by employing an electric motor sensitive to a pressure sensor that controls the mechanism used in the bone lengthening process. The driving motor of the mechanism will be continuously operated by a pressure-sensitive sensor until the amount of bone lengthening reaches the targeted value. Two different materials are utilized in the study. The first involves the design of the fixator in the computer-aided design (CAD) program, while the second encompasses coding for the system to ensure the motor operates at the desired pressure level. The outputs obtained from the study are analyzed to determine whether the fixator accomplishes its task through the motor. The values observed indicate the success of the process. This newly designed fixator system, different from manually operated ones in the literature, will contribute to research in this field with its automatic usability facilitated by a pressure-sensitive sensor, providing ease of use and uniqueness.

Keywords: *Limb Lengthening, Fixator, Automatic, Limb Reconstruction System, Computer-Aided Design (CAD)*

1. Introduction
When bones break under a certain force, they require additional support during the healing process to fuse correctly and withstand new forces for protection. Throughout the healing process, support is provided through methods such as casts, braces, bandages, internal fixators, and external fixators [1]. A fixator is a system obtained by connecting a broken bone (such as in the leg or arm) to a stable support outside the bone by passing nails or wires through the bone [1-2]. Fixators encompass different classifications based on the location of support or the design of their elements. Internal fixation involves the use of plates, wires, screws, and intramedullary nails, while external fixation utilizes pin fixators with clamps and their simple derivatives, circular fixators, or specific fixators obtained by using multiple different fixator components according to need [3]. Additionally, implants such as nails or wires used in fixator systems are expected to be biocompatible, causing no toxic effects after placement in the human body, and possess sufficient strength according to the applied load on the bone. They should also be resistant to wear and tear [4].

2. Materials in Fixator Structure
In contemporary studies, there are widely used metal materials that meet the expectations. Some metals, due to their excellent mechanical properties and corrosion resistance, serve as passive substitutes for hard tissue replacement, such as bone plates and screws, spinal fixation devices, and complete hip and knee joints.

Among biocompatible materials, type 316 stainless steel has become well-known in the market. In the 1950s, the carbon content of 316 stainless steel was reduced from 0.08 to a maximum of 0.03 to enhance corrosion resistance and minimize sensitivity to chloride solutions. Hence, it is known as the 316L stainless type. Table 1 provides the compositions of stainless steel. Stainless steels, especially types 316 and 316L, are widely used for implant manufacturing. They cannot be hardened by heat treatment but can be hardened by cold working. This group of stainless steel exhibits better corrosion resistance compared to others [5].

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Table 1. Composition of 316L Stainless Steel [6].

Element	Composition (%)
Carbon	0.03 max.
Manganese	2.00 max.
Phosphorus	0.03 max.
Sulfur	0.03 max.
Silicon	0.75 max.
Chromium	17.00-20.00
Nickel	12.00-14.00
Molybdeum	2.00-4.00

Another material known for its use in fixators is Co-Cr alloys. There are essentially two types of Co-Cr alloys: castable CoCrMo alloy and generally forged (hot) CoNiCrMo alloy. Currently, these two alloys are widely used in implant manufacturing. Like other alloys, an increase in strength is accompanied by a decrease in ductility. Both cast and forged alloys exhibit excellent corrosion resistance. The modulus of elasticity of CoCr alloys remains unchanged with variations in ultimate tensile strength. The values range between 220 and 234 GPa, higher than other materials such as stainless steel [5].

Lastly, titanium alloys are the most commonly used materials. Attempts to use titanium for implant production date back to the late 1930s. Titanium has been found to be well-tolerated in cat femurs, similar to stainless steel and CoCrMo. The lightweight nature of titanium (4.5 g/cm3, refer to Table 2) and its excellent mechanicochemical properties make it a standout choice for implant applications [5].

Table 2. Specific Gravities of Some Metallic Implant Alloys [7].

Alloys	Density (g/cm3)
Ti and its alloys	4.5
316 Stainless steel	7.9
CoCrMo	8.3
CoNiCrMo	9.2
NiTi	6.7

In the production of implants, a commonly used titanium alloy is Ti6Al4V. The main alloying elements of this alloy are aluminum (5.5-6.5%) and vanadium (3.5-4.5%). Ti6Al4V alloy exhibits a fatigue strength approximately equal to that of CoCr alloy (550 MPa) after rotary bending fatigue tests [8].

Titanium alloys can be strengthened and their mechanical properties can be altered through controlled composition and thermomechanical processing techniques. The strength of the material varies from a much lower value than that of 316 stainless steel or CoCr alloys to approximately equal to annealed 316 stainless steel of cast CoCrMo alloy. However, titanium has poor shear strength, making it less desirable for bone screws, plates, and similar applications. It also tends to exhibit galling or seizing tendencies when in sliding contact with itself or another metal [5].

In this study, considering the information obtained from literature research, the preference has been given to the use of titanium material. In future work, the aim is to experiment with different composite materials.

2.1 Types of Fixators

Fixators vary based on their application areas and designs. They are categorized as internal and external fixators based on their application areas. External fixators are further grouped based on the number of planes and the design of their basic elements.

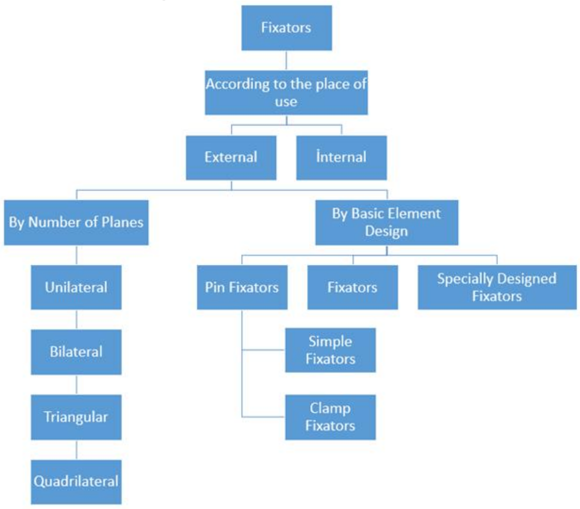

Figure 1. Fixator groups [9].

2.1.1 Internal Fixators

Internal fixation procedures are typically conducted through an open operation using screws, plates, and wires. The treatment process is carried out with these elements without causing harm to the fracture biology [10].

Figure 2. Example plate and screw for fracture fixation [11].

2.1.2. External Fixators

External fixator can be defined as a comprehensive system that addresses the stability loss of the skeleton by creating a frame connecting the fixatives implanted into the bone to a rod or a group of rods from the outside [12]. External fixators are a frequently used method for stabilizing bone fractures. This method, especially employed in the treatment of tibia and femur fractures, was developed by Gavril Ilizarov in the 1950s. The systems used in these methods are referred to as the Ilizarov method. The Ilizarov method is applied in fracture fixation, limb lengthening surgeries, and the correction of deformed bones. Such fixators consist of tensioned wires, parallel rings, and threaded rods [13].

Figure 3. Triangular External Fixator [14]

2.2. Ilizarov Method

The Ilizarov method was developed by Russian orthopedist Gavriil Abramovich Ilizarov in 1951. Since its emergence in the mid-20th century, the Ilizarov method has significantly advanced, becoming an applicable technique for bone lengthening, correction of severe deformities, and defect management. As indicated by reported studies, it continues to be one of the most widely used tools for bone reconstruction. Treating patients using distraction osteogenesis for bone lengthening, defect management, and deformity correction remains among the crucial procedures associated with the Ilizarov method.

Figure 4. Pin External Fixator [15].

The Ilizarov method, which stands as a significant contribution to the field of orthopedics, continues to be one of the most important developments in bone reconstruction [16-17]. Since its emergence in the mid-20th century, it has progressed significantly, evolving into an applicable technique for bone lengthening, correction of severe deformities, and defect management. The Ilizarov apparatus, widely used for a variety of orthopedic diseases and injuries, constitutes a system of techniques for bone fixation, distraction, compression, and transplantation. Ilizarov apparatus components include rings, spokes, and Kirschner wires.

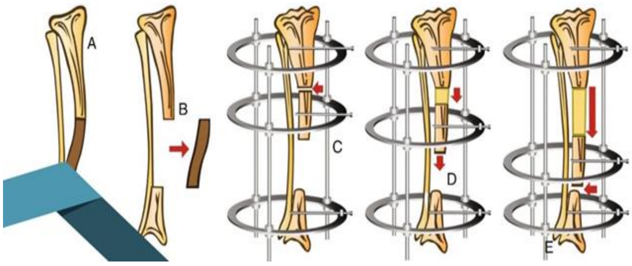

Figure 5. Schematic explanation of the Ilizarov method [18].

2.3. Place of Fixator in Bone Lengthening

Distraction osteogenesis (DO) has been successfully employed in the last half-century for bone lengthening. In 1905, Professor Codivilla initiated research on bone elongation for the treatment of deformities and malunions. Since then, although the most effective techniques for the DO process have not always been well-known, the field has made numerous advancements in various ways [20]. Critical to successful DO is the optimal distraction rate and rhythm, and ideal stability, with external fixation proving to be a reliable tool. The technique known as the "classic method" or the "Ilizarov method" has become a criterion for stability, with external fixation alone used to achieve stability. Ilizarov, pioneering many advancements in this field, initiated experiments with external fixators in the 1950s [21-22].

Figure 6. The Ilizarov System [19].

From the past to the present, the Ilizarov method has shown excellent results. However, recent innovations in external fixation have sparked research into techniques that can minimize the need for external fixation during surgical procedures. Known disadvantages of external fixators include issues such as pin tract infections, skin irritation, soft tissue tethering, and joint stiffness. Integrated fixation techniques that combine internal and external stabilization, such as Lengthening Over a Nail (LON), Lengthening and Then Nailing (LATN), lengthening followed by plating, and bone transport over a nail, are employed to minimize the duration of external fixation. Based on these increasing advancements, there has been a growing trend towards performing bone lengthening or fixation procedures with a fully implantable device in recent times [23].

2.3.1. Limb Reconstruction System (LRS)

Limb reconstruction is a subspecialty within orthopedic surgery, utilizing reconstruction techniques in the treatment of limb lengthening and deformity correction. Reconstruction techniques are employed to replace missing bone and lengthen or correct deformed bone segments. Treatment is often required due to complications arising after injuries, including the correction of limb deformities and limb lengthening.

Figure 7. Bone length elongation [24].

Limb reconstruction surgery fundamentally involves restructuring a bone or joint using an external fixator or frame. An external fixator is attached to the bone using screws and wires [25].

The LRS (Limb Reconstruction System) is a unilateral rail system consisting of Schanz pins, rail bars, and sliding clamps. By adjusting the rail system, the limb can be lengthened or straightened, joint deformities can be corrected, and missing, infected, or abnormally formed bone can be replaced. Specifically designed to allow early weight-bearing due to rigid fixation of fractured segments, the LRS system enables surgeons to perform simple and effective surgeries by facilitating early loading and reducing the economic burden.

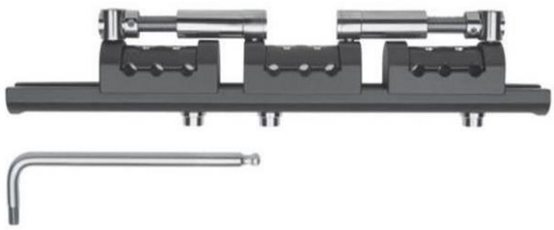

Figure 8. Limb Reconstruction System [26].

Pal and colleagues [29] conducted a study comparing the outcomes of compound tibial shaft fractures treated with Ilizarov ring fixators and limb reconstruction system fixators. The study included individuals with tibial shaft fractures, consisting of 26 males and 6 females, with an average age of 40. They followed the cases for an average of 6 months, ranging from 3 to 24 months, from September 2012 to October 2014. They found that among cases treated with the rail fixator, 68.75% showed excellent, 18.75% showed good, and 12.50% showed fair radiological results. In contrast, among cases treated with the ring fixator, 56.25% showed excellent, 18.75% showed good, 12.50% showed fair, and 12.50% showed poor radiological outcomes.

Figure 9. LRS system Fixation in the femoral bone. [27]

Figure 10. LRS system Fixation in the human body [28].

In their study, Patil and colleagues [30] investigated the definitive treatment of open tibia fractures using the Limb Reconstruction System (LRS). They conducted a study treating 54 cases with an average age of 42±5 over a 26-month period using LRS. According to the ASAMI (Association for the Study and Application of the Method of Ilizarov) score, they found that the bone outcomes were excellent in 36 cases, good in 14 cases, fair in 2 cases, and poor in 2 cases out of the 54 patients. Regarding functional outcomes, they reported excellent results in 43 cases, good in 7 cases, and fair in 4 cases. They described postoperative patient satisfaction as excellent because the fixation allowed immediate weight-bearing. The average length of hospital stay was 7 days, and they determined a 40% reduction in the economic burden compared to multi-stage surgery.

This study differs from other studies in terms of advantages by making modifications to the design of the selected Limb Reconstruction System (LRS) fixator. The operation of this fixator involves manually rotating the pins four times a day. However, the aim of the upcoming study is to automate the manual system using motors and sensors. Through this research, the goal is to make the use of the fixator system more comfortable for individuals experiencing bone problems or discomfort with their aesthetic appearance and for physicians monitoring the patient's condition. The objective is to enable early discharge of the patient and provide greater comfort in the use of the fixator system.

3. Material and Method

3.1. Automated System Fixator Computer Aided Design

The operation of the system will consist of five main components. These components are: Fixed Rail, Clamp (central, flat), Clamp Screw, Motor, and Screws.

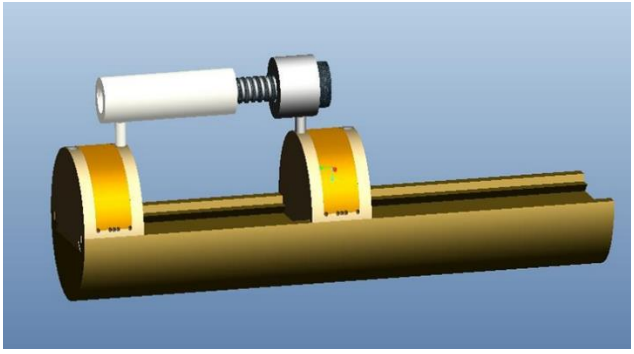

Figure 11. Three Dimensional View of the Fixator System

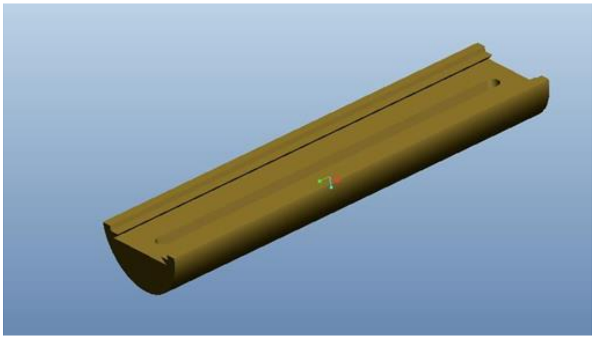

Figure 12. Three-dimensional design of the rail system.

3.2. Fixator Rail

The rail system is a robust structure that employs a precise screw assembly mechanism to ensure the controlled positioning of clamps along the axis of the rail. The rail system is a small platform with sliding-element linear bearings. The guide screw used in the system is provided with various tips and shaft end configurations, allowing compatibility with almost any type of rotary power source.

3.3. Clamps

The clamps are designed to enable controlled sliding along the axis of the fixing system's rail.

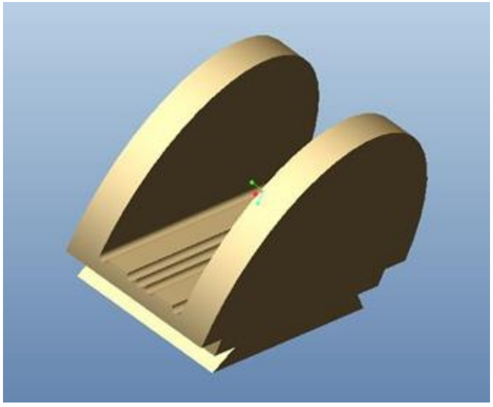

Figure 13. Clamp Three-dimensional view

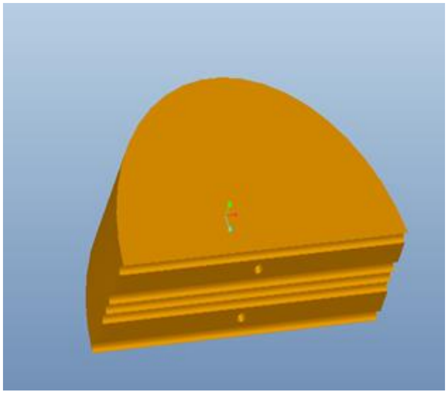

Figure 14. Clamp Clamp inner part view

3.3.1 Clamp Screw

The clamp screw ensures that the clamps are fixed to the rail system. Its dimensions vary according to the length of the rail system.

3.4. Engine

The motor will be selected to meet the sliding feature between the rail and the clamps.

3.5. Pins

Pins are used to fix the fixator to the femur or tibia bone. Dimensions vary according to the fixator.

3.6. Working Principle

The assembly of all parts designed in the Computer-Aided Design (CAD) program was also carried out in this program. Initially, ensuring the rigidity of the fixing rail was prioritized because other components would be assembled onto the rail system, making its stability crucial for the overall system. Subsequently, clamp components were added, and necessary design changes and features were selected to enable the movement on the rail. Once the clamp components were in place, the motor was fixed to facilitate automatic extension. After completing the assembly without any issues, motor tests were conducted in the program to assess the mechanical functionality of the system.

4. Conclusion

In this project supported by TUBİTAK 2209-A University Students Research Projects Support Program, the Fixator system was assessed by developing a product with the selected materials. In the simulation environment, the tests for the motor, sensor, and LCD screen have been conducted and they have been taken as output. In addition, a code of the working system has been written for the engine to work at the desired time and at the desired value. Based on the obtained outputs, the motor operated as intended according to the programmed code. An extension plan of 0.25mm and 1mm was executed four times a day. When a distance of 3 cm is set to the distance sensor, the outputs obtained from the simulation are as shown in Figure 15, 16, 17.

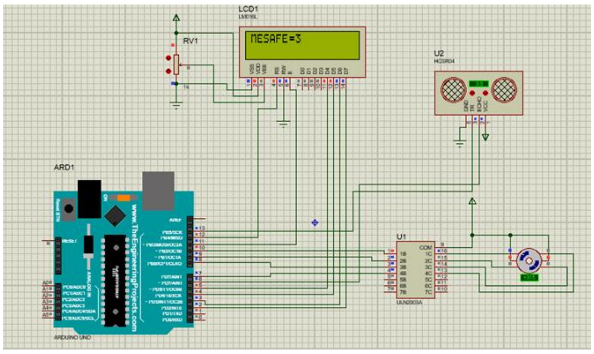

Figure 15. Outputs of materials from simulation. The whole system

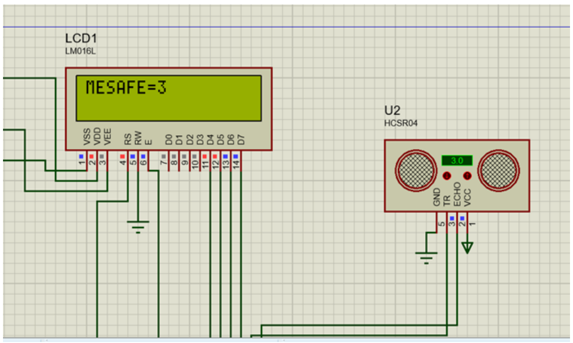

Figure 16. Outputs of materials from simulation. LCD screen output and distance sensor.

As a result of combining the products, the fixator with the automatic system shown in Figure 18 was created. With the arduino code written, the bone lengthening process was carried out to 0.25mm four times a day.

In order to test the code uploaded to the Proteus system on the product, the code was transferred to the Arduino Uno card through the Arduino Ide program. As seen in Figure 19, the outputs obtained were the same as the outputs obtained from the simulation. In the current system, the cards are fed with an external 9V source. If necessary, the volt value can be increased. The arduino card works with the current coming from the power supply and the code loaded on the card enters the function. The motor rotates at the desired value and distance based on the written commands. These parameters can be changed on the code. It also provides the right to revise where necessary. With the engine running, the distance sensor detects the movement and transfers the current information to the LCD screen.

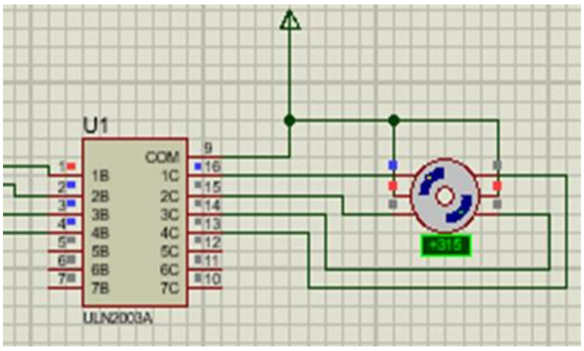

Figure 17. Outputs of materials from simulation. the value obtained from the engine.

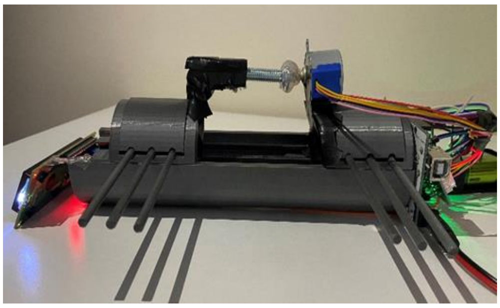
Figure 18. Fixator product with automatic system

Figure 19. Elongation output obtained

In the light of the outputs obtained from these trials, the operations planned to be carried out automatically were carried out. This project is a study carried out in order to ensure the comfort of the patient and the physician. Time efficiency was provided for the physician, the possibility of early discharge for the patient and waiting for the physician was eliminated, the fixation system used for physicians following the patient's condition was provided to be more comfortable, and in addition to all these, the system was performed automatically, not manually, as desired.

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