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PAPER

Design, Engineering Analysis, and Fabrication of a Prototype Electromechanical Finger Fixator Control System

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ABSTRACT

This paper investigates a new external fixator system for treating finger contractures. This innovative system is electric and user-friendly, providing precise readings of the angles of diseased finger joints. Accurate measurements of the angles of the diseased finger joints can assist therapists and patients during rehabilitation procedures. The fixator consists of ten parts assembled using polyether-ether-ketone (PEEK) for the plastic components and stainless steel for the metal components. The design model was engineered, drawn, and analyzed using SolidWorks Computer-Aided Design software. The verification process utilizes finite element analysis to demonstrate that the maximum stress was lower than the yield strength of the chosen materials. As a result, the new device design is robust and stable enough to withstand the anticipated loading conditions of human fingers. Subsequently, a prototype was fabricated using advanced additive manufacturing technology, specifically fused deposition modeling (FDM). The proposed fixator is simple to control, reliable, easy to use, and reproducible. It enables device users to exercise their finger joints throughout the day without requiring the assistance of specialists.

KEYWORDS

design medical device, finite element analysis, rehabilitation, external fixator, additive manufacturing

1 INTRODUCTION

Human hands are both communicative and vulnerable. Any limitations in motion or even a slight injury can significantly impact a person's life. Proximal interphalangeal (PIP) joint contractures in the fingers are considered the most common hand injuries and may result in a loss of hand function and subsequent disability. The severity of an injury can range from a minor sprain to a complex intra-articular fracture. Complications at the PIP joint may arise following appropriate treatment due to the complex anatomy of the joint. Classification systems for PIP joint injuries and

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complications cover various types of injuries, including collateral ligament injuries, fractures in the proximal phalanx joint, fractures at the base of the middle phalanx, redislocation, post-traumatic arthritis, chronic swelling, and permanent loss of function [1]. The PIP joint is responsible for approximately 85% of the finger's daily activity, which involves the flexion and extension motion of the entire joint [2]. Most PIP joint contractures require patient intervention during treatments and rehabilitation procedures, but they are often neglected, leading to a long-lasting deformity of the digit [3].

Previous studies have shown that externally supported static and dynamic distractors are considered effective treatment methods for PIP joint injuries, even after surgery, as a therapeutic procedure. In the 19th century, distractors were first used in the United States of America, as stated in [4]. Subsequently, researchers developed the concept and working techniques, and various external fixator designs were introduced and clinically evaluated. Fahmy (1990) developed the 'S' Quattro, a device designed to treat phalangeal fractures. It features a unique dual-spring column system that includes two modified K-wires and two serpentine springs [5]. A. Messina invented the continuous extension technique (TEC) device in 1986, and it gained popularity from 1991 to 1996. It is a sizable device capable of applying longitudinal traction to multiple fingers simultaneously [6].

In 1994, to enhance the TEC, Hodkinson developed the proximal interphalangeal skeletal traction extender (PIPSTER) fixator. It is a small and simple device that consists of two anchor points separated by a threaded nut. One fixation point is positioned horizontally across the base of the proximal phalanx, while the other is positioned across the head of the middle phalanx [7]. The "multiplanar" device was created in 1998 and was specifically designed to perform three-dimensional mandible distraction procedures [8]. Neil Ctron designed the Verona device, which corrects deformities caused by severe Dupuytren's disease in the PIP joint. It is less bulky, applies angular corrective force, and provides distraction if needed [9]. Slade developed a simple fixator in 1990 for PIP fracture dislocations using three Kirschner wires and dental rubber bands, which were utilized from 2002 to 2012. The 1.4 mm K-wires are inserted parallel to each other, perpendicular to the long axis of the finger, and then bent. Rubber bands are then applied [10]. A modified dynamic distraction external fixator (DDEF) device, which included a traction bow, 3 K-wires (1.2 mm), and rubber bands, was utilized in the treatment of 20 patients with old PIP joint fracture-dislocation from March 2005 to March 2014 [11].

A new external fixator system called the Ichi-Fixator was developed by Neo Medical in Saitama, Japan, in 2019. This procedure involves inserting 2–3 fixator pins (1.2–1.5 mm) into the phalangeal bone, depending on the type of finger phalangeal fracture. The pins are bent to a 90° angle using specialized benders until they are parallel. Both wires are then cut using a flat wire cutter and a metal clamp. The fracture is manually reduced under fluoroscopy, and the wires are secured with a screw. Finally, the pins are firmly secured using a clamp [12]. In 2020, a study in Egypt treated twenty consecutive patients who had comminuted intra-articular PIP joint fractures using a simplified method involving dynamic external fixation with a 1.2 mm K-wire. The treatment involved inserting a wire percutaneously, through the center of rotation of the head of the proximal phalanx, parallel to the joint in the coronal plane, without damaging the joint capsule. Another longer K-wire was then drilled perpendicular to the CR of the middle phalangeal head [13]. Between 2008 and 2014, 11 patients were treated consecutively for fracture-dislocation of the PIP joint using a simple two K-wires (1.4 mm) dynamic external fixator without the use of rubber bands. The procedure involves placing the first K-wire transversely through the center of the proximal phalanx and driving the second K-wire through the head of the middle phalanx [14].

In 2017 and 2018, a modified Suzuki technique was introduced to manage unstable PIP joint fracture, dislocations, and pilon injuries. The initial alteration was prompted by a study conducted at Al-Razi Hospital in Kuwait between March 2006 and October 2013. The technique involved the use of a simple K-wire device and plastic cable ties to maintain a stable distraction of the K-wire frame [15]. In 2018, the study included 36 patients who were treated for finger injuries. The modified Suzuki technique involves creating a loop at the ends of the axial traction instead of using a hook to prevent slippage. Cerclage wires were used instead of rubber bands to ensure more reliable traction and reduce the incidence of breakage. The distal traction K-wire was also bent around the axial traction K-wire [16].

The pin and rubber traction system are commonly used to treat PIP joint fractures and dislocations. An alternative fixator that utilizes a plastic syringe instead of rubber bands to maintain the distraction force was presented in 2020 [17]. The newly developed fixator, called the "P-frame," was utilized with 40 patients who had PIP joint fracture dislocations and were treated between November 2017 and November 2019. The device consisted of K-wires (1.5 mm), mini rods, and mini-screws [18]. In 2021, a concise overview of the history of hand surgery in Thailand was published, showcasing the most recent advancements. Sittichoke Anantaseri developed the "A-knife" for trigger finger surgery; Sunthorn Wongsiri created the Minisure blade and retractor for carpal tunnel release; and Sunyarn Niempoog devised the true interlocking metacarpal nail [19]. A case study conducted in India from January 2021 to May 2022 utilized a distinctive static external fixator comprising a uniplanar or biplanar 2 ml syringe needle cap and 0.8 mm small Kirschner wires. This fixator was optimal for stabilizing the joint around the fractured area [20]. Joshi's external stabilization system (JESS) conducted a prospective cohort study using an external fixator on 30 patients with hand fractures between November 2018 and October 2020 [21].

The external fixator bracket is a specially designed device that is low-profile to accommodate use with fingers. Its distinctive features allow it to operate in both dynamic and static states [22]. Recently, the serial casting orthoses method, using thermoplastic materials, has shown effective results in treating flexion contractures of the PIP joint [23].

The compass hinge (Smith and Nephew, Memphis, TN, USA) [24] [25], Minirail Fixator System (Orthofix Medical Inc., Lewisville, TX, USA) [26] [27], and DigiFix® external fixator (Gexfix SA, CH-1227 Carouge, Switzerland) [28] are distinctive design elements of unilateral external finger fixators. They were designed to attach to the phalanges of the fingers using stainless steel wires and contain two separate arcuate elements: distal and proximal. They differ from other fixators in that they allow both active and passive ranges of motion. The primary components of these three devices are made of polymers.

The plastic parts of the compass hinge device were fabricated from polyetherimide (PEI), and the motion was manually controlled by a worm gear mechanism. The most common complication associated with the use of this device was mechanical failure, which required design improvement [29] [30] [31] [32] [33]. The plastic parts of the Minirail fixator are made from black carbon fiber material, which is often unsuitable for use by patients. The Minirail device features a hex pivot lock that operates in both active and passive motion. The fixator is commonly used to treat intra-articular fractures of the digits [34] [35]. The single-use articulated dynamic external fixator (DigiFix®) body is made from an advanced polymer material called polyphenylsulfone (PPSU) and is black. A pivot lock mechanism is utilized for both dynamic and static modes. Unstable metaphyseal fractures, infrapatellar fat pad (IFP) missing articular fragment (MF) articular fractures, and open fractures of phalanges are examples of indications for Digifix [28]. Mechanisms for active and passive movements enable the precise positioning of the required angle on all devices. This research introduces a new operational system for accurately controlling PIP joint motion, as recommended for each contraction, which is not available in other finger fixators. The concept of an electromechanical control system was derived from the operational principles of a digital protractor ruler [36]. The design specifications for the proposed device are inspired by the advantages of other fixators: it should be small to attach to central digits easily, easy to operate for users, light weight, reliable, and capable of permitting both active and passive movements.

2 MATERIALS AND METHODS

The study was conducted in two main stages to develop the final prototype of the proposed fixator device. The design strategy was developed first, followed by the prototype manufacturing. Figure 1 summarizes all the steps involved in the current device design process.

In the initial stage, a geometric model of each fixator component was created using Computer Aided Design (CAD) software, SolidWorks 2019® Premium 2019 × 64 (Dassault Systèmes SolidWorks Corporation in Waltham, USA). After that, the SolidWorks 2019® simulation package, a set of structural analysis tools, was used. It employs finite element analysis to predict how a device will behave physically by testing the CAD models. The new device parts require materials with appropriate mechanical properties to withstand the natural movement of human fingers. To achieve this, biocompatible PEEK (VICTREX®) has been proposed as the primary polymer for the device. Furthermore, it has been recommended to use stainless steel 316L for the metal screws that will assemble the various components of the device.

In the second stage, a sturdy and efficient prototype of the main device structure was created using fused deposition modeling, an additive manufacturing technology. The fabrication material used was thermoplastic ABS. This helped to confirm the accuracy of the dimensions, features, and manual assembly process of the new design components.

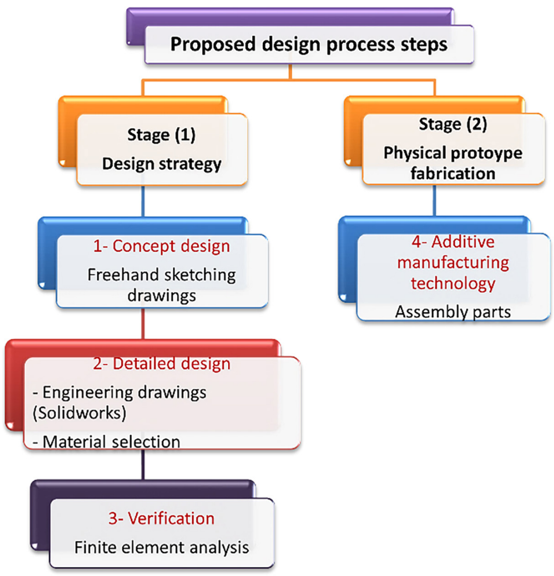


Fig. 1. The design process summary steps for the proposed device

2.1 Stage (1): Design strategy

This stage was divided into two steps. The first step was the concept design, which involved creating initial drawings using freehand sketching for both the mechanical movement and the electronic components of the proposed fixator. Second, we contacted an electronics company specializing in small projects (Makers Electronics, Alexandria, Egypt) to assess the feasibility of processing and implementing the initial idea. According to the available resources in Egypt, imports were restricted as a result of the current global financial crisis.

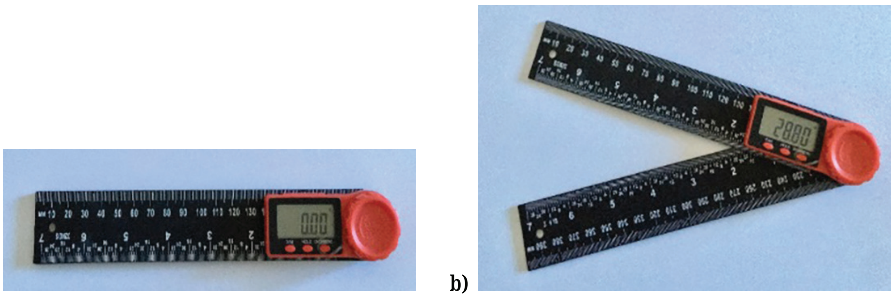
Step two involved the detailed design, which encompassed the final design features of the proposed fixator device. The engineering drawings with accurate dimensions were created using SolidWorks CAD software 2019 and used to manufacture the corresponding mechanical parts. The consultant at the electronic store presented the most cost-effective design for the electronic parts to fulfill the required function of the device.

A) Concept design

To create the mechanical parts of the new device, a brief study of the anatomical details of the PIP joint was conducted. Furthermore, the registered patents and commercial joint fixators were analyzed to integrate new design approaches reported since 1986. Three US patents (9155561, 4604997, and 5100403) were reviewed to generate ideas for mechanical mechanisms that would enable the proposed device to achieve the required dynamic movements of the finger joints [26] [37] [38]. The distractor described in US Patent 0097944 A1 aids in understanding the procedure for treating joint contractures and other orthopedic conditions. In addition, the clamping blocks' development feature is used to support the inserted K-wires [39].

US Patent 5376091 was issued in 1994, and the Smith and Nephew company detailed the operational mechanisms and surgical technique for using the compass hinge device. This helped improve the understanding of the working principle of the PIP joint fixator and the required biomaterials. This understanding was crucial in developing the design of the new device components [24] [25]. In 2016, a new design called the protractor hinge device was introduced as a potential solution to address the limitations of the Compass hinge distractor. The new model was validated as the first fixator to combine polymer and metal-assembled material parts [40]. The orthopedic companies Orthofix and Gexfix presented their products, which played a significant role in the creation of the proposed design. The new design parts include movement mechanisms (open-lock control mechanism), their sizes, and instructions for attaching the device to the diseased human finger [27] [28].

Previous studies have reported that the PIP joint functions as a small hinge in the human digit. Consequently, the new device components should be compatible with that application. The electronic components were designed using reverse engineering through the disassembly of a digital protractor ruler [36]. The operating system of this protractor functions on the same concept as two hinges (or ruler links) moving in relation to each other to measure the angle between them. This was exactly what the new fixator required to measure and digitally control the movement between the middle phalanx and proximal phalanx of the finger. Figure 2 depicts a digital protractor ruler positioned at a zero angle and in a random working position.



a) b)

Fig. 2. Digital protractor ruler a) zero angle position; and b) random working position

The red section of the digital ruler, as depicted in Figure 3, corresponds to the unlocked state with a liquid crystal display (LCD) monitor. This design was replicated and implemented on a smaller scale for our prototype, resulting in a device that can be easily attached to fingers.

Fig. 3. Open lock with a liquid crystal display (LCD) monitor part

A preliminary concept design, sketched freehand and consisting of nine main parts, is depicted in Figure 4. These components include the proximal hinge, distal hinge, pivot lock attached to the LCD monitor, two lower slotted clamping blocks, and four connecting screws.

The distal device hinge is considered the primary framework for the proposed model and is designed to house the proximal device hinge part. The two lower slotted clamping blocks are assembled with two device hinges using four M2 connection hexagonal head standard screws. This design helps to secure the Kirschner wires (K-wires), which support the fixator in the phalanges of the human fingers. The axis of the proposed device is aligned with the axis of the PIP joint, facilitated by the hole guide part. The new fixator is attached to the patient's injured digits on either hand and in a single position, with the proximal device hinge component supported in the proximal phalanx and the distal device hinge part in the middle phalanx.

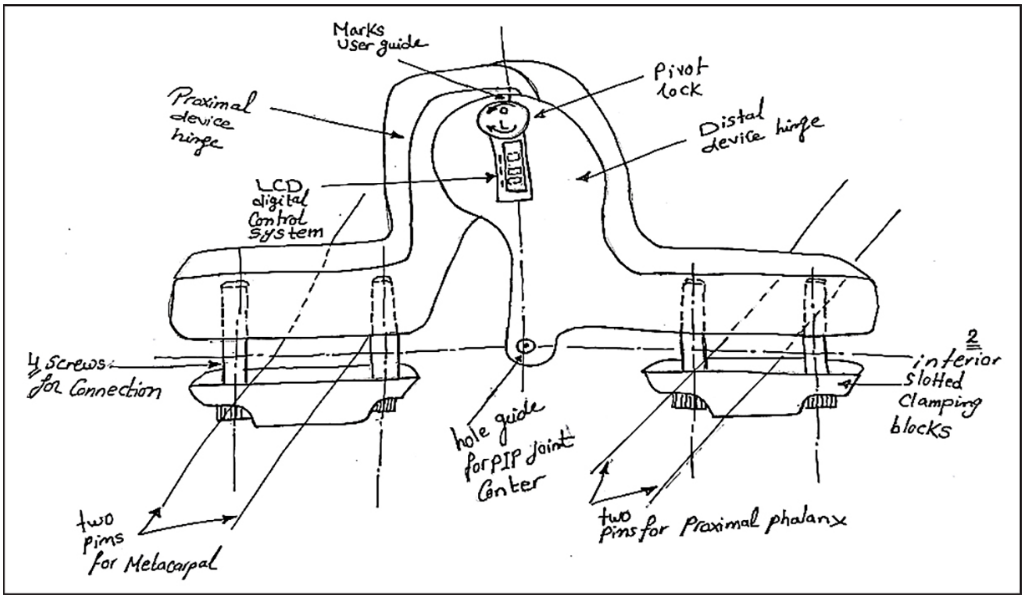


Fig. 4. The first concept design of the proposed fixator

During the detailed design phase, disassembly was carried out on the control digit unit, which includes the pivot lock and LCD digital control system. This step identified the necessary components essential for constructing the final design model. The five primary components within the digital control unit are the microcontroller, 5-bit LCD screen, inductive position encoder, switches, and 3V battery.

The Maker Electronic Company acknowledged that it was not feasible to produce a printed circuit board (PCB) smaller than the Chinese digital protractor ruler PCB, as depicted in Figure 5, or even of the same size. This was due to the absence of manufacturing machines with high working resolution in Egypt. They suggested two solutions. The initial plan was to send the newly designed PCB for manufacturing, but this proved to be excessively costly and difficult to implement due to the Egyptian government's prohibition on imports during the financial crisis. The second solution was to make a slight change to the design by retaining the concept of a digital control system and using components that are available or manufactured locally.

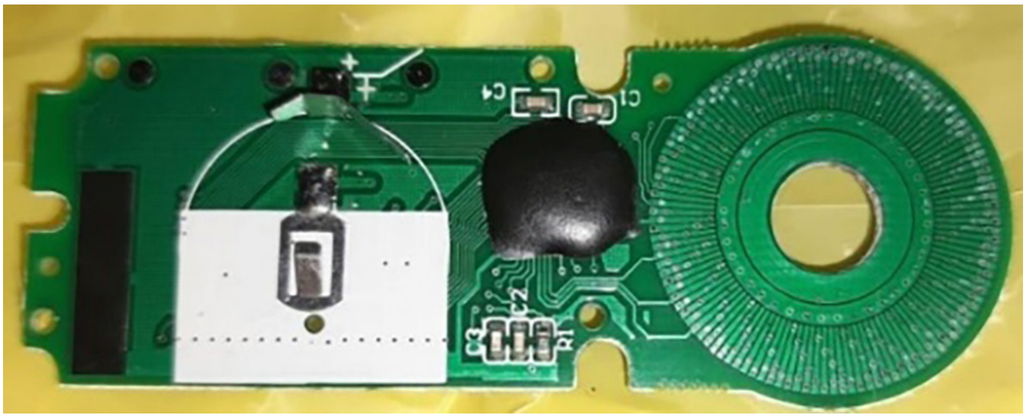


Fig. 5. The Chinese digital protractor ruler PCB

A new design was presented to the Maker Electronic Company team for approval before implementation. Due to the large size of electronic components, patients with PIP joint issues can wear the components on their wrists in the form of smartwatches. Furthermore, it was strongly recommended that all the components be isolated to ensure waterproof functionality. The team of electronic engineers presented a practical design for an electronic control component and provided the authors with a brief block diagram of the working steps, as shown in Figure 6. We followed this progress by modifying the freehand sketch concept design and preparing another one to approve both the mechanical and electrical aspects, as illustrated in Figure 7.

B) Detailed design

Engineering solid model: A CAD geometrical model was created for each mechanical movement part of the approved concept design using SolidWorks 2019® Premium 2019 × 64 (Dassault Systèmes SolidWorks Corporation, Waltham, USA). The overall dimensions of the proposed device are based on anthropometric data for the 50th percentile of the human hand (designed for the average) [41] [42]. Figure 8 displays the engineering drawings with the primary dimensions (width × height × thickness) for a medium-sized device (52.33 × 41.75 × 8.00) in millimeters. Figure 9 depicts the three-dimensional assembly view of the engineering drawing for the new device model, including the names of its parts.

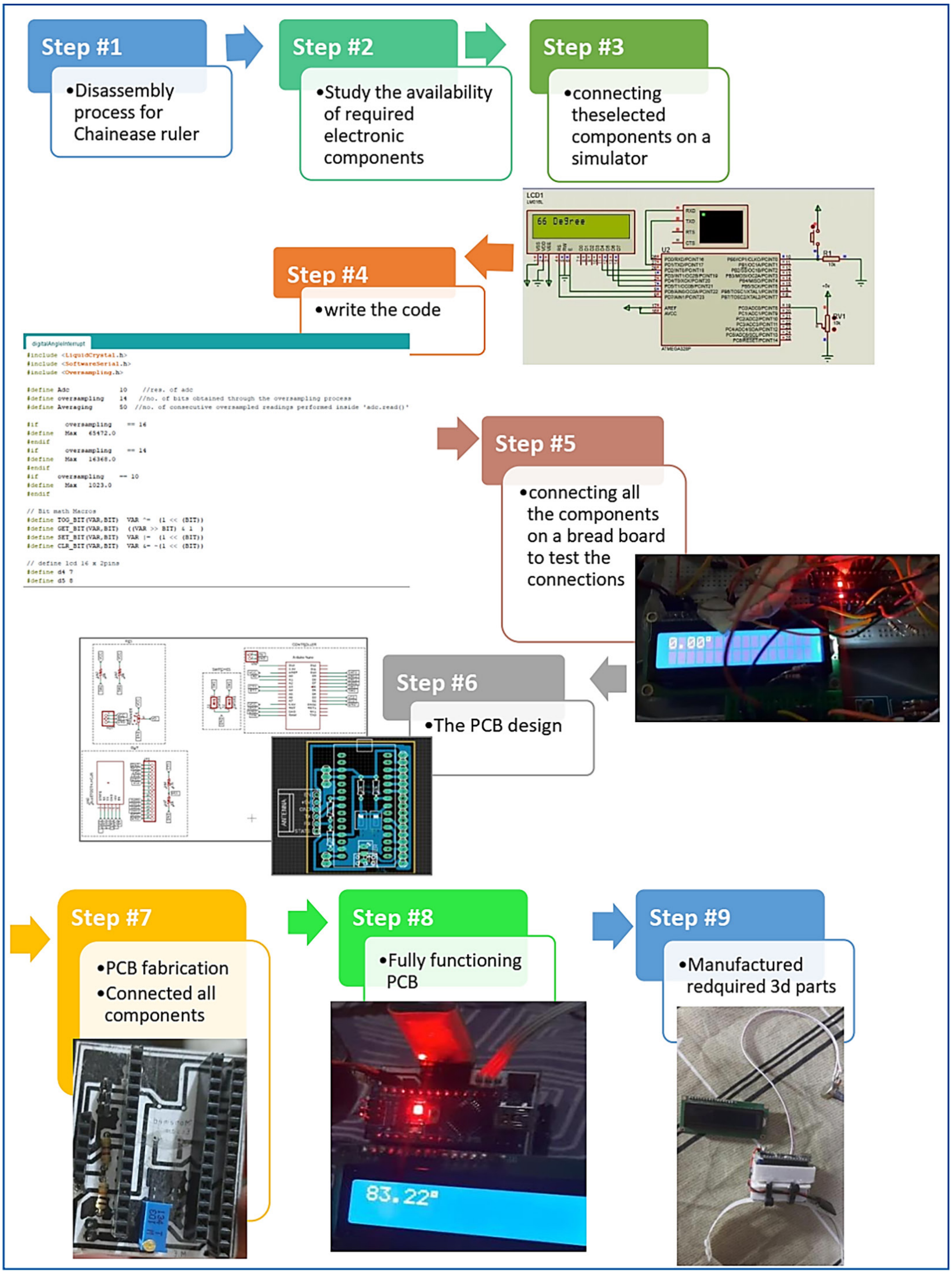


Fig. 6. The Maker Electronic Company's proposed design for electronics control parts

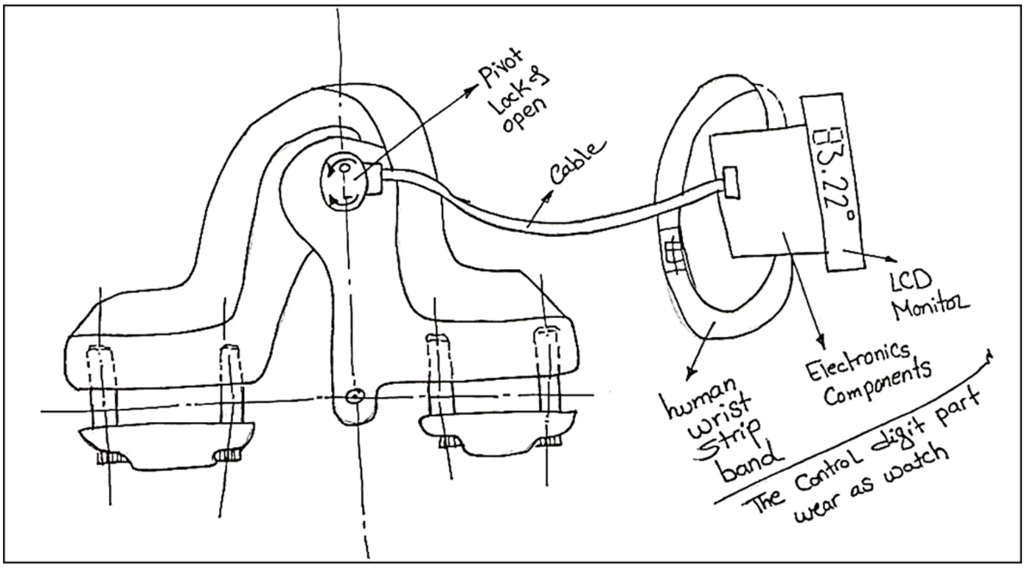


Fig. 7. The modified concept design for proposed device

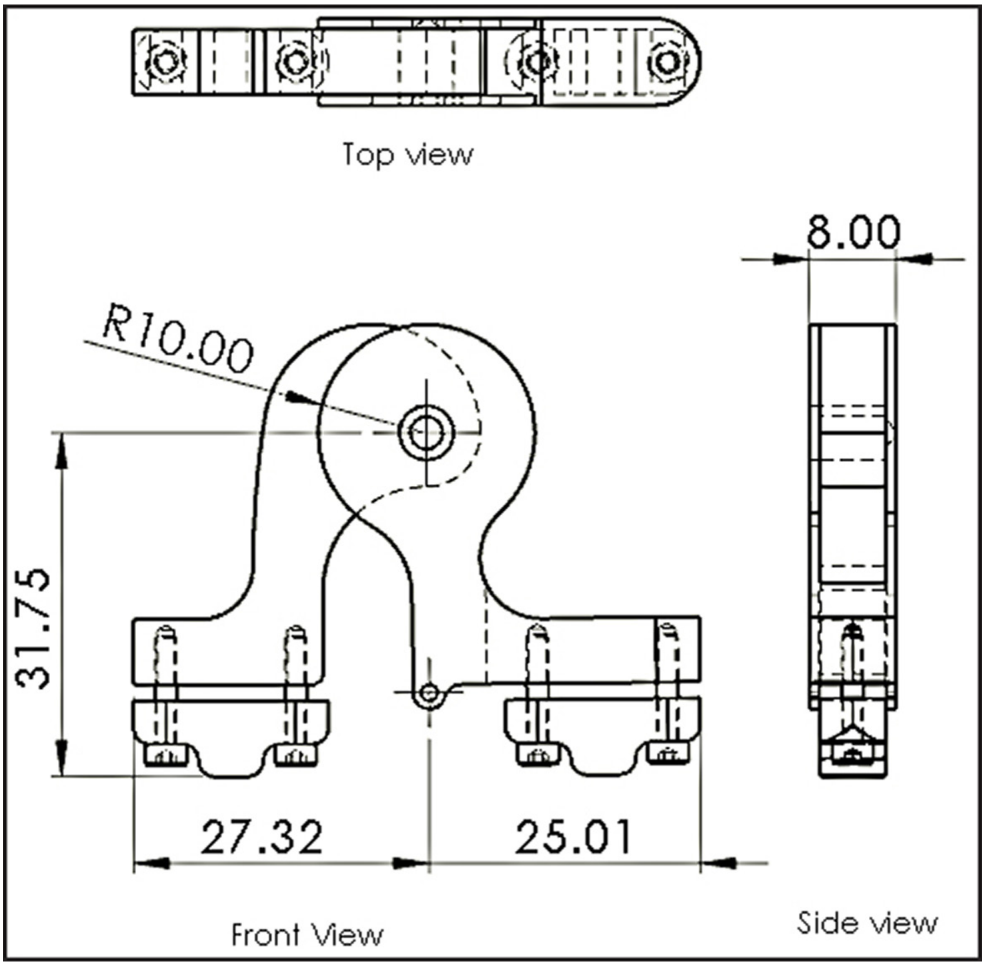


Fig. 8. New device's engineering drawings with overall dimensions in millimeters

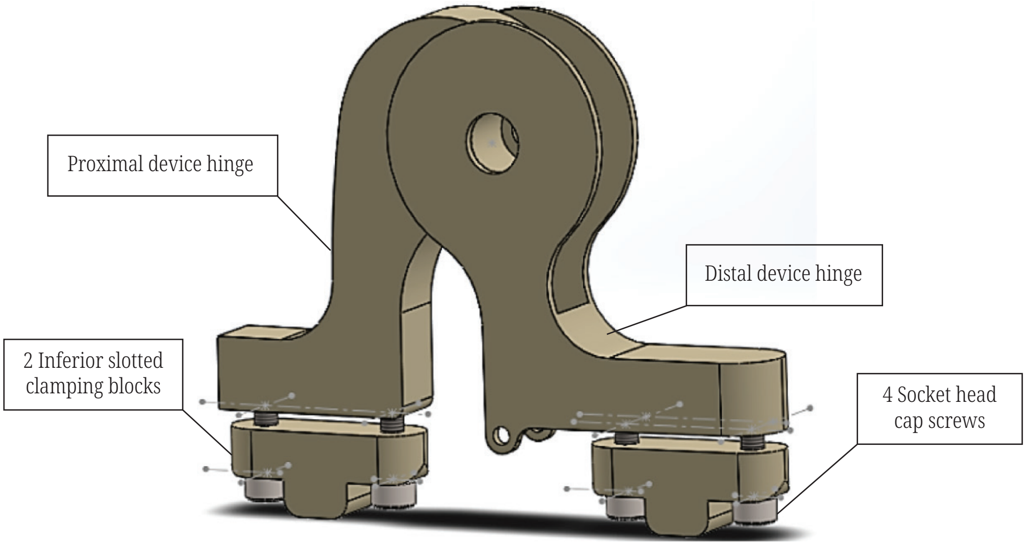


Fig. 9. The 3-dimensional assembly view of the new device model

Material selection suggestion: The materials for the new device parts should possess appropriate mechanical properties to withstand the natural movements associated with the daily activities of human fingers. According to previous studies, the human finger makes approximately one million movements per year [43]. A biocompatible PEEK was suggested for the polymer components of a new device, including the proximal and distal device hinges and the inferior slotted clamping blocks. Furthermore, PEEK exhibits good mechanical, thermal, and chemical properties. It is non-toxic, radiolucent, easy to fabricate, and a non-resorbable polymer. According to the VICTREX® material guide sheet, PEEK has a young's modulus of 3.6 GPa and a yield strength of 110 MPa [44]. Stainless steel 316L was suggested for the metal parts (4 hex head screws), which have a Young's modulus of 193 GPa and a yield strength of 205 MPa [45].

C) Design verification

Finite element analysis: A finite element analysis was conducted on the mechanical movement components to verify the properties of our design. Finite element analysis enables the assessment of deformation in the loaded model structure before an expensive prototype is manufactured. SolidWorks Simulation (SolidWorks 2019, Dassault Systèmes SolidWorks Corporation, Waltham, USA) was used for the analysis. The solid model included the lock pivot, the proximal device hinge component, and the distal device hinge component, all assembled with the inferior slotted clamping blocks.

The model was meshed using a standard solid mesh type with high mesh quality. It consisted of a total of 111306 nodes, an element size of 0.87783 mm, and a total of 70163 tetrahedral elements. This number was determined through automated mesh convergence testing. Constraints were applied to the model. The guide hole for the PIP joint center was constrained to allow rotation, while the proximal and distal device hinges were fixed in the pivot lock hole. The force of 210 N was applied vertically downward to the model through the inferior slotted clamping block part at the distal hinge side. Additionally, the applied force was directed perpendicular to the middle phalanx of the finger to simulate the force that a human would likely apply to the device.

The magnitude of this force was selected based on previous studies of hand biomechanics. The healthy human hand can exert forces ranging from 10 N to 210 N using the little and middle digits. Furthermore, the selected magnitude refers to the maximum finger grip force exerted by the human middle digit in a vertical downward direction [46] [47].

Three different angles of the extension-flexion injured finger's PIP joint were investigated. Position (1): full finger extension, 0 degrees (middle phalanx at the same level of extension as the proximal phalanx). That position is considered to exert an extreme bending load on the fingers during forceful gripping activities. Position (2): finger flexion toward the hand palm by 25°. Position (3): finger flexion, middle phalanx with a 70° inclination angle to the proximal phalanx. Figure 10 depicts the total constraints and meshed finite element model of the pivot lock position at three different positions.

Solution and results: The maximum normal stress theory was chosen to analyze the stresses in the PEEK material device hinge member, considering the brittle nature of the material [48–50]. The simulation analysis software package yielded results indicating that the stress patterns were similar for the three positions studied. In all cases, the maximum stress value was located along the two inferior slotted clamping blocks.

The maximum stress values were 19.78, 16.17, and 18.76 MPa, respectively, for the three position models studied. All of these values were below the yield strength of the selected PEEK material. The numerical solution model indicated that study position 1 recorded the highest risk case with the highest maximum stress value. Figure 11 illustrates the stress distribution patterns in the three positions.

D) Risk analysis of the proposed design

Risk analysis should be conducted for individual components as well as the assembly device. Sterilization, packaging, and labeling are essential tasks, but they were not considered in the present study, which focused solely on the design process.

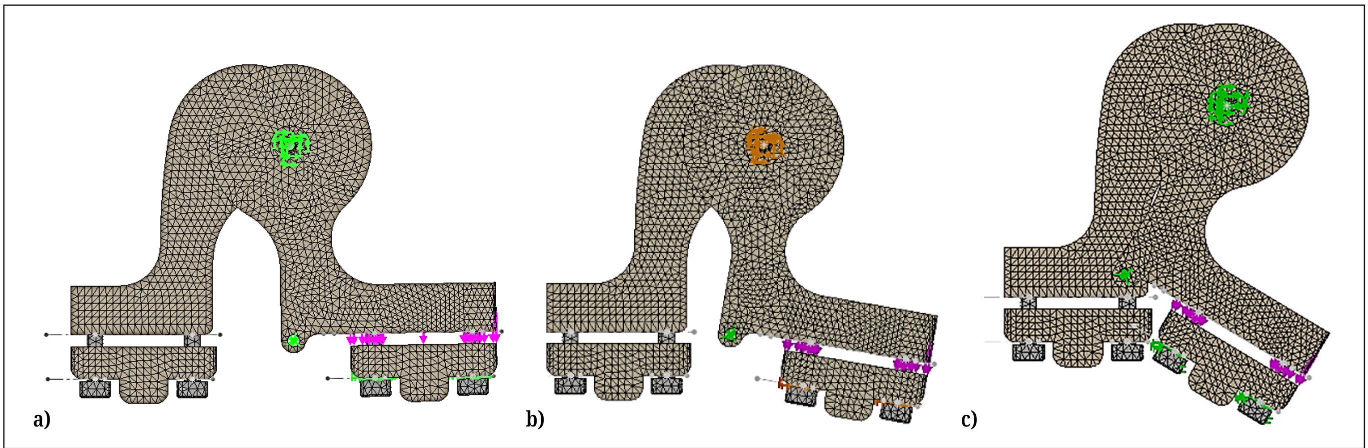


Fig. 10. Meshed finite element model with the load 210 N and constrains applied at a) full extent finger position; b) finger flexion by 25°; and c) finger flexion with 70°

2.2 Stage (2) Prototype manufacturing technique

A) Rapid prototype model

A sturdy, rapid prototype model of the main device body was created using additive manufacturing because of its ability to produce a structure with complex geometries. The physical model shown in Figure 12 was manufactured using a 3DP-12-4E UP mini 2 three-dimensional printer (Tiretime, Beijing, China) with a build volume of 120 mm × 120 mm × 120 mm at a nozzle temperature of 276 °C. The infill material used is 80% with a layer thickness of 0.15 mm, ensuring fine quality. The manufacturing material used was thermoplastic ABS with a filament diameter of 1.75 mm in the Production Engineering Department at the Faculty of Engineering, Alexandria University, Egypt. The printer was configured to optimize production time while achieving an appropriate surface finish for the product. This prototype was created to verify the dimensions of each component, the assembly process, the mechanical working mechanism, the medical functionality, accessibility, and final shape approval.

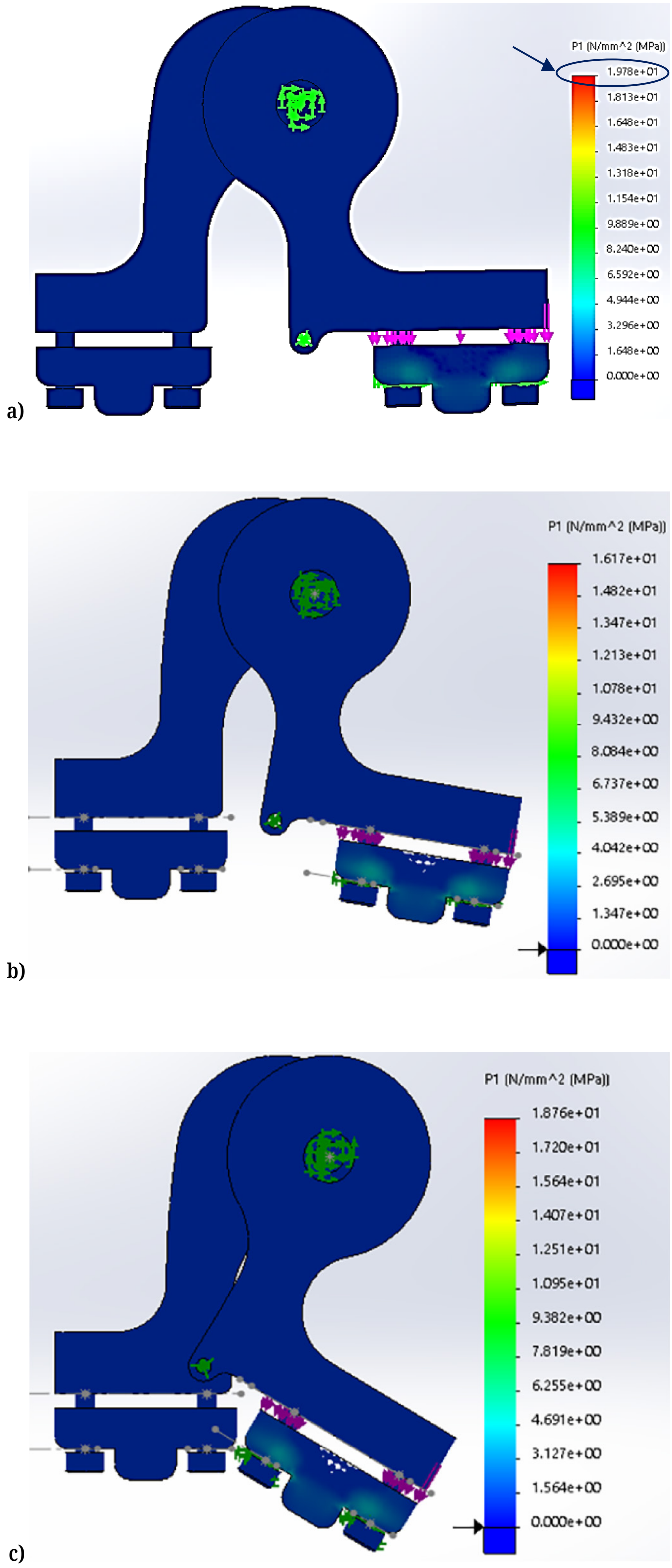


Fig. 11. Distribution of stresses for the model at a) position1, finger flexion by 0°; b) position 2, finger flexion by 25°; and c) position 3, finger flexion by 70°

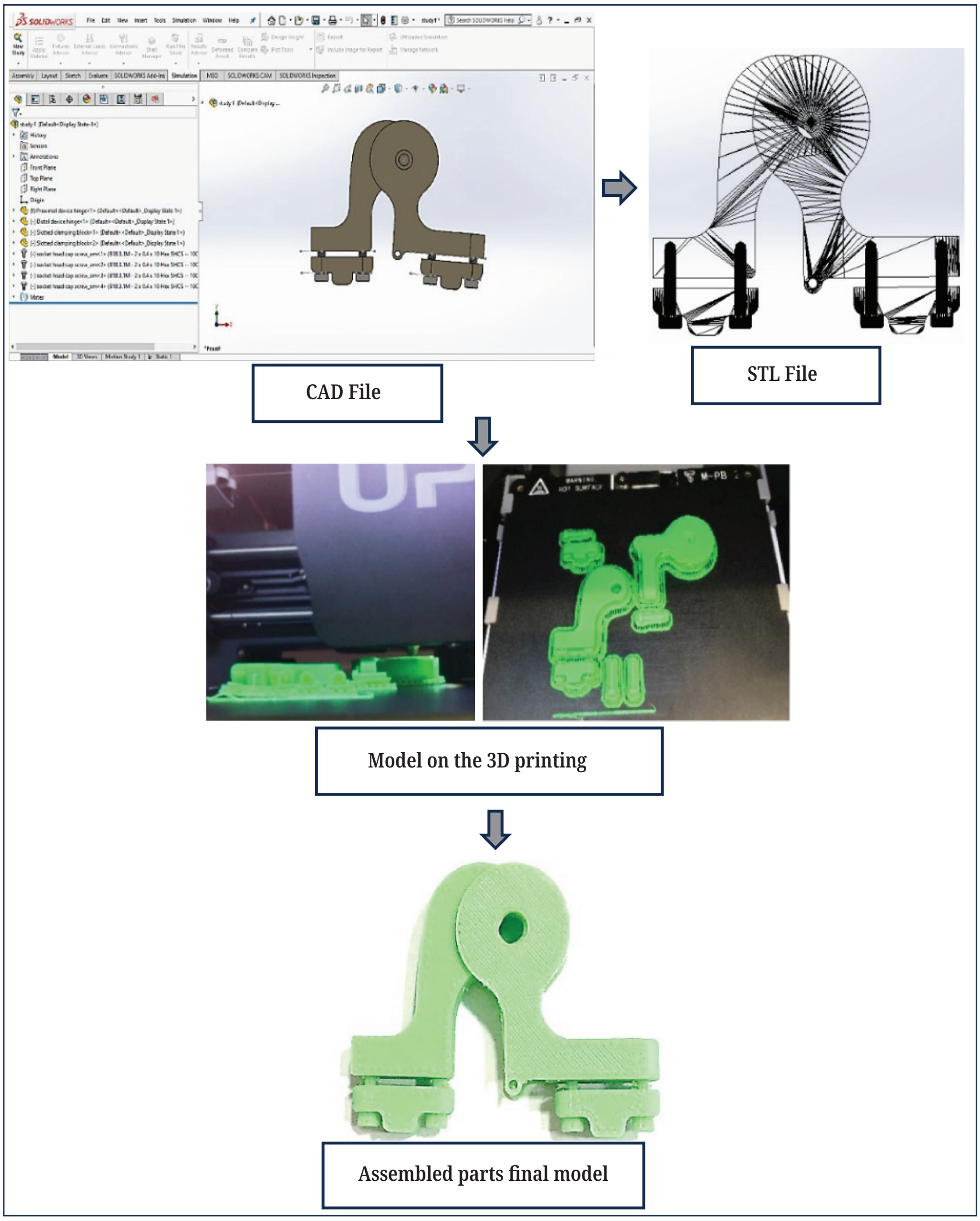


Fig. 12. Fabrication steps of physical prototype model

A prototype model for the control digit part, as shown in Figure 13, was manufactured by Maker Electronic Company using a CR-10 V2 3D printer (Creality, Shenzhen, China) with a build volume of 300 mm × 300 mm × 400 mm and a nozzle diameter of 0.4 mm, operating at a nozzle temperature of 210 °C. The manufacturing material used was thermoplastic PLA with a filament diameter of 1.75 mm at Mechanism Company in Alexandria, Egypt. A prototype of the proposed fixator, assembled from mechanical and electronic components, is shown in Figure 14.

Fig. 13. The control digit part physical model

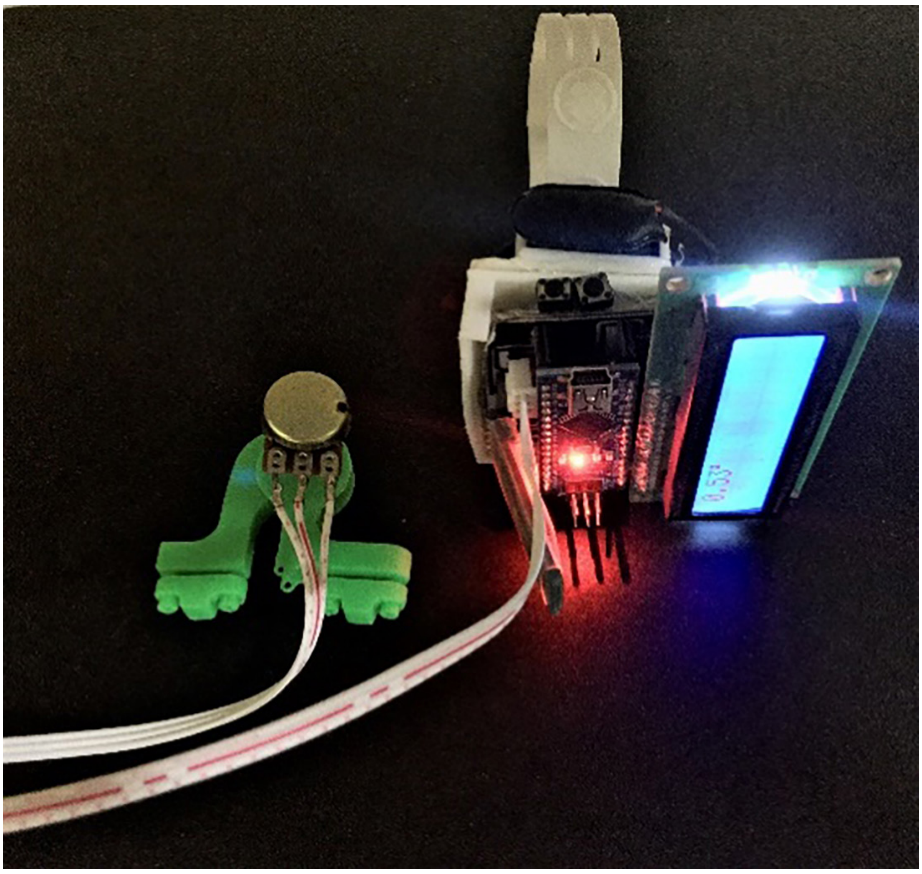


Fig. 14. A prototype for the new finger fixator

3 DISCUSSION

This study developed a prototype for a new external therapy device designed to function as a finger fixator. The design is based on previous devices' development, incorporating a novel digital control system for accurate and accessible measurements of the flexion and extension of the PIP joint angle. The device in question is classified as an external dynamic digit fixator, which is a preferred option for surgeons. Our design incorporates various mechanical movement features from the DigiFix and Compass hinge devices. It also integrated the lock pivot movement mechanism, similar to DigiFix, but with precise control measurements and readings of PIP angles.

The main assembly process concept is the same for the proposed Compass and DigiFix devices, providing additional body support to withstand the stresses generated during therapy. The new idea was strongly validated by the results of the simulation modeling analysis. Three different case studies were selected to demonstrate the range of motion of the human finger during normal daily activities. The final report presented that the maximum stress occurred in the most critical study case, where the human finger was at full extension in the model. The stress was 82% less than the yield strength of the selected polymer material, PEEK. This percentage is high for reliability.

Compared to the Compass hinge device, the new device shows a reduction in mechanical part failures, with no slippage occurring between its components. The new design allows for several positions to support the two surgical stainless-steel pins at each finger phalanx, in contrast to the two available options in the DigFix fixator. According to the selected polymer material, its radiolucent property helps surgeons guide support pins in digit phalanxes during operations, providing an advantage that other fixators lack. Furthermore, it makes it accurate and easy to follow up on monitoring therapy procedures.

The new design incorporates the essential benefits required by most surgeons from other devices. The benefits are as follows:

- **a)** A new small device has been designed to be easily held between human fingers.
- **b)** It is suitable for attaching to an adult's hand.
- **c)** It can be applied to both the radial and ulnar sides of a diseased digit.
- **d)** The device is beige, a color close to human skin tone, which aesthetically motivates patients to use it.
- **e)** It is made from a biocompatible, radiolucent polymer material to facilitate the surgical device support technique by making the K-wires visible on radiographs.
- **f)** The selected material has excellent mechanical properties, particularly fatigue resistance, to meet the demands of finger therapy.
- **g)** The new design offers a continuous working mechanism for the finger PIP joint, enabling both active and passive movements.
- **h)** The unique advantage of the current design is the PIP joint movement control system, which is electrically controlled for the first time rather than mechanically controlled.
- **i)** Digital angle measurement assists patients in conducting home therapy during the healing process without the need for a therapist.

4 CONCLUSIONS

In conclusion, a new finger fixation device that meets design goals and clinical criteria has been developed. It is a unique and innovative external fixator that uses an electrical control system to effectively manage PIP joint extension and flexion angles with high precision. For the first time, real-time readings of the PIP joint angle are displayed on a small LCD monitor. The device is better than earlier external fixators like the Compass Hinge, Protractor Hinge Device, and DigiFix. It has a digital reading for PIP joint measurement, is small, has a simple electromechanical control movement, and is made of a clear polymer material. Each component of the device was designed using the latest SolidWorks software, and finite element analysis was employed to validate the design from an engineering standpoint. A physical prototype was created using 3D printing technology. The newly manufactured model meets the requirements of surgeons and is easy to use for therapists during rehabilitation sessions and for patients at home.

5 ACKNOWLEDGMENT

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