ORIGINAL ARTICLE

A Prototype Continuous Passive Motion Device Compatible with the Hinged Elbow Ilizarov Fixator

Juanito S. Javier, MD, MChOrtho,[1] Jose Mari S. Dychioco, MD[1] and Eunice O. Rusiana[2]

[1]*Department of Orthopedics, College of Medicine and Philippine General Hospital, University of the Philippines Manila*
[2]*Department of Mechanical Engineering, College of Engineering, University of the Philippines Diliman*

ABSTRACT

Background. Joint stiffness is a frequent concern in trauma or surgery of the elbow joint. Early resumption of elbow joint motion is said to limit the complication of stiffness. The Hinged Elbow Ilizarov Fixator has been reported to be useful in the management of elbow dislocations. However, early range of motion is not consistent in these cases since elbow movement were done only through patient-initiated exercises. The use of a continuous passive motion (CPM) device can potentially resolve this issue. However, presently available continuous passive motion devices for the elbow are not compatible with the Hinged Elbow Ilizarov Fixator.

Objective. The objective of the study is to determine the feasibility of using a specially designed continuous passive motion device on a Hinged Elbow Ilizarov Fixator as applied in a cadaver simulation model.

Methods. A Hinged Elbow Ilizarov Fixator was fixed in the elbow of a Thiel-preserved cadaver. The specially designed continuous passive motion device was applied.

Results. Test run showed sufficient continuous flexion-extension motion not accompanied by dislocation, subluxation, or disruption of the elbow joint. A point of stress in the current prototype was noted at the motor-screw interface. Limitations in programming and control were also noted.

Conclusion. A continuous passive machine adopted to the Hinged Ilizarov Fixator is a viable device. Further improvement in the design of the motor-screw interface needs to be made. Further improvement in programming and control are needed. Likewise, study on the safety and service life of the CPM device needs to be done.

Keywords: Hinged Ilizarov Fixator, continuous passive motion, elbow early motion, elbow joint

Corresponding author: Juanito S. Javier, MD, MChOrth
Department of Orthopedics
Philippine General Hospital
University of the Philippines Manila
Taft Avenue, Ermita, Manila 1000, Philippines
Email: jsjavier6@up.edu.ph

INTRODUCTION

Elbow stiffness causes limitation in functional capacity in activities of daily living.[1] The elbow is a joint prone to stiffness and loss of motion. Prolonged immobilization can lead to capsular contracture, which can be prevented by early active mobilization after initial injury.[2]

Trauma, which may lead to fractures or dislocations, is a common cause of elbow stiffness.[1] Early motion is important to prevent stiffness. This may be achieved by (1) Active Motion Exercises, and (2) Continuous Passive Motion (CPM). Mavroidis et al. stated that passive rehabilitation is one of the preferred methods in the early stages of therapy to help reduce swelling, alleviate pain, and restore range of motion.[3]

Hinged fixators are commonly used for complex elbow fractures and elbow dislocations. Hinged external fixation of the elbow joint is used in the management of complicated fracture-dislocations, joint instability after extensive contracture release, and distraction interposition arthroplasty.[4] Hinged external fixation is indicated if elbow joint instability persists after attempted fracture stabilization and ligament repair. It can also protect nonrigid fracture fixation and non-secure ligamentous repair during post-operative rehabilitation.

Hinged external fixation is also used during Distraction Interposition Arthroplasty.[5] Distraction and biological resurfacing of the elbow joint can be done to treat patients with incapacitating elbow pain and loss of motion. The hinged external fixator allows distraction to minimize shear across the interposed tissue and permits immediate post-operative motion.

Javier described the management of neglected elbow dislocations using Hinged Elbow Ilizarov Fixators to allow early joint motion.[4] The patients in the study performed self-rehabilitation after the necessary instructions.[4] Thus, the patient's clinical outcome depended a lot on the patient's determination to do the exercises.

A continuous passive motion (CPM) device causes movement to the extremities/joints as a method for restoration and physiotherapy.[6] The CPM device is most effective when used early after the injury or surgery as it minimizes joint hemarthrosis and periarticular edema.[6] CPM devices can help prevent intra-articular contracture formation in healing joints.[7]

In a review by Lindenhovius and Jupiter, the use of CPM Devices for the elbow was found to significantly improve flexion and greater ulno-humeral arc for patients.[2] The CPM device was demonstrated to have the advantage of continuously flexing and extending the elbow until the extremes of motion were achieved. In a meta-analysis by Schuster of clinical studies that included a CPM device in rehabilitation, it was found that the use of a CPM device brings about superior improvement in the degree of functional range of motion in patients who underwent surgical release or manipulation under anesthesia for a contracted elbow joint.[8] It was also found that a minimum of six weeks of use of the CPM was necessary to reach statistically significant improvement in function.[9] Elbow CPM Devices have also been shown to be valuable in the rehabilitation of stroke patients.[10] However, there are some who consider the role and use of CPM as debatable[1] since its use would entail additional cost for equipment and hospitalization.

The bulkiness of the Hinged Elbow Ilizarov External Fixator prevents the elbow from being cradled in the usual CPM devices for the elbow. The authors have found no report of any modifications in the elbow CPM device that will make it compatible with the use of the Hinged Elbow Fixator. The authors decided to develop a prototype CPM device (utilizing a lead screw mechanism powered by a gear motor) that can overcome the identified hindrance. One of its features must be its easy attachability to the hinged elbow Ilizarov.

OBJECTIVES

The objective of this study is to describe the production of a prototype continuous passive motion device adapted for a hinged elbow Ilizarov fixator on a Thiel cadaver. The specific objectives are as follows:

- To describe the design, components and features of a prototype continuous passive motion device adapted for a hinged elbow fixator
- To determine the arc of motion that can be achieved with the CPM device
- To assess the durability of the device by assessing the wear of the components after running sessions that simulate the rehabilitation process.

METHODS

Description of the Prototype CPM device

The prototype CPM device utilizes a lead screw mechanism which converts rotation into linear motion. It is attached to the Ilizarov frame via bearings/attachments at the proximal ring of the humeral component and the distal ring of the forearm component (Figure 1). The lead screw nut is attached near the distal ring and the proximal ring is attached to the gear motor (Figure 2). It is powered by an SGM37-3530 low rpm gear motor which is designed for low speed and high torque applications. Its speed and direction of rotation is controlled via the motor controller and Arduino board. The Arduino Micro Board microcontroller processes the data provided from the computer interface which controls the speed and duration of the CPM device and converts these signals into an output to the motor driver board and the gear motor (Figure 3).

The CPM prototype had been initially tried in a cadaver bone model set up and a maximum of 100 degrees (8 degrees/second) flexion/extension was achieved. The degree of flexion/extension that can be achieved by the CPM device was dictated by the initial position of maximum extension and the time duration set for the direction of the rotation of the motor.

Thiel-preserved Cadaver Model

The testing of the CPM device was done on a Thiel cadaver model. The Thiel method is an alternative embalming technique that maintains soft-tissue consistency similar to that of living tissue.[11] Thiel-preserved cadaveric elbows have already been used in in-vitro studies to test elbow stabilities in soft-tissue injury models.[12] Thiel embalming appears to preserve the soft-tissue properties so that they are similar to those in-vivo[13] and this is important in this preliminary trial since joint ligament integrity is a major contributor to elbow joint stability.

A Thiel-preserved elbow cadaver was acquired from the UP College of Medicine–Department of Anatomy. Specimen handling and disposal was done based on standard

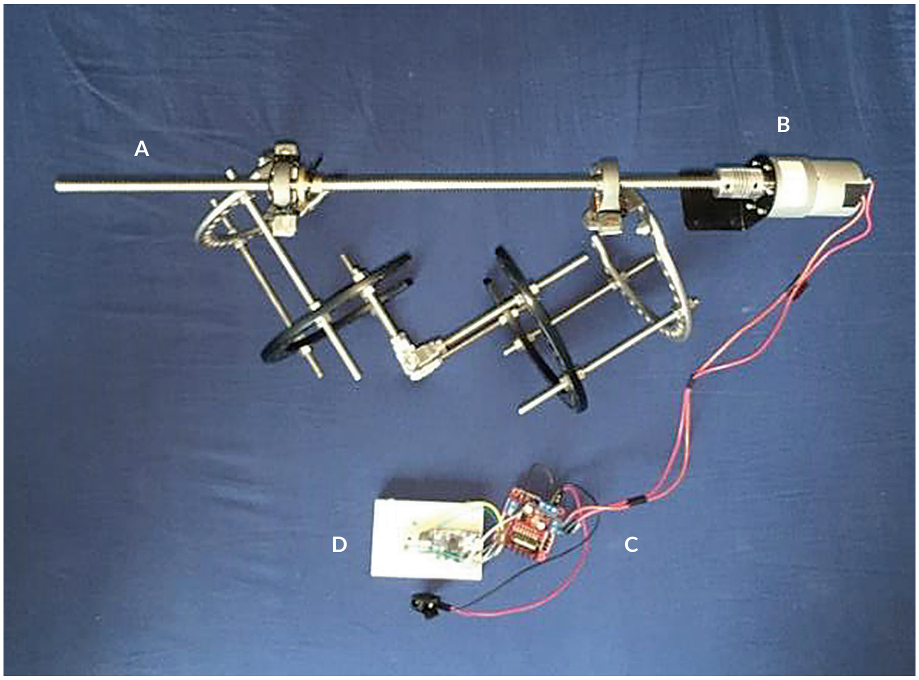

Figure 1. Labelled parts of the CPM device: **(A)** Lead screw mechanism. **(B)** 12V DC Gear Motor. **(C)** Arduino Micro Board. **(D)** Motor Driver Board.

Figure 2. Lead screw-motor coupling interface.

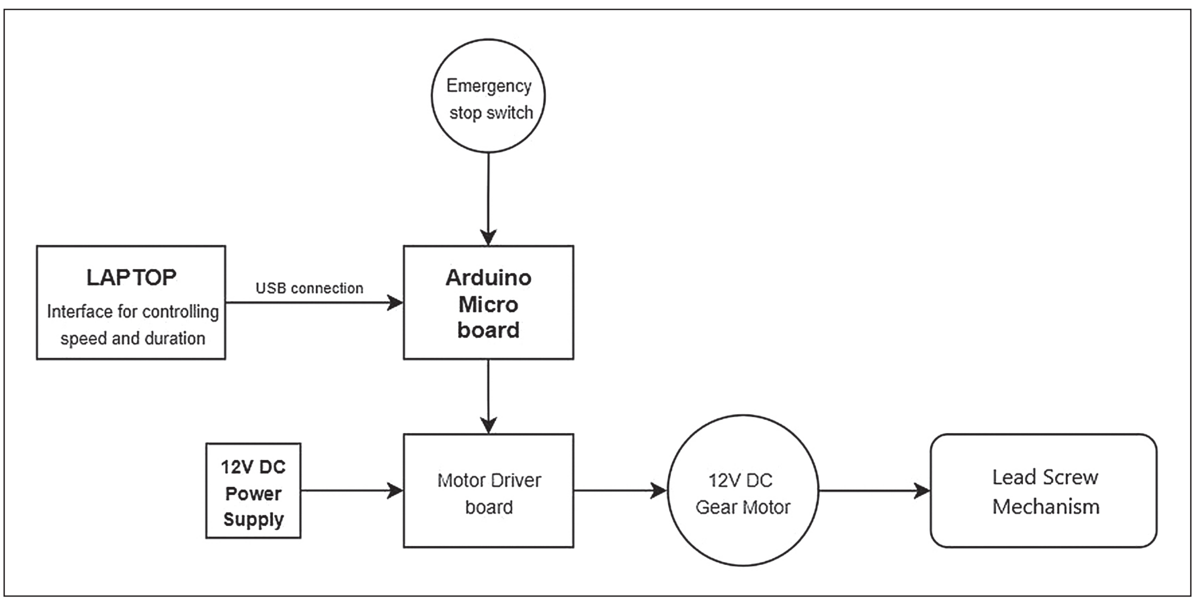

Figure 3. Schematic diagram of the Continuous Passive Motion (CPM) Device for Elbow-spanning Ilizarov fixator.

operating procedures of the UP College of Medicine Department of Anatomy.

The cadaver elbow has full flexion-extension with range of motion at 0-150 degrees. The joint was inspected via a posterior triceps-sparing approach and was found to be congruent and with no articular malunion. The Hinged Ilizarov Elbow Fixator was then applied as previously described by Javier.[4]

The prototype CPM device was attached to a Thiel cadaver (positioned at 45° sitted to simulate an actual patient's position while being treated) with a Hinged Ilizarov Elbow Fixator surgically fixed to span the elbow joint. The starting position of the elbow was in some flexion (arbitrarily chosen at 70 degrees). The cadaver model simulation set up was set to run at a duration of 10 second-cycles (between flexion and extension). The set up was then allowed to run

Figure 4. Elbow Ilizarov CPM Device during flexion-extension.

continuously for 4 hours to simulate clinical use (Figure 4). The model was observed for any hindrance to continuous elbow motion and durability of the construct. Afterwards, the device was disassembled to assess the wear of the components.

RESULTS

At the setting described, 30 degrees of flexion/extension was generated (arc of motion between 70-100 degrees of flexion or an angular velocity of 3 degrees/second). The degree of motion that could be achieved by the CPM device was dictated by the initial position at maximum extension and the time duration set for the direction of the rotation of the motor. There was also noted difficulty in adjusting the time duration demanded using the available software.

There was no dislocation or subluxation of the joint during the movement of the elbow when the fixator was in place. After completing 1 hour 30 minutes run and 270 cycles of flexion-extension, the lead screw-motor coupling interface gave way due to the stresses. The interface was repaired and 720 cycles (duration of 4 hours) were completed similar to the time of a continuous passive motion therapy session. To address the stresses in the CPM-Ilizarov frame interface, the attachment hinges of the CPM were revised to joints with added degree of freedom to accommodate the strain during flexion and extension.

Other difficulties noted during the trial include:

1. It is tedious to operate using the programmed duration/time of flexion and extension. It may be easier if instead of time, the specific desired arc of motion could be used.
2. The device does not have a "recall previous state function". This means that it does not take into account its current position. If the device is turned off midway while its working and then restarted, the program will read from the start.

DISCUSSION

This prototype continuous passive motion machine confirms that the attachable CPM device as designed can produce the desired continuous passive motion of the elbow in a Thiel cadaver with an attached Hinged Elbow Ilizarov Fixator. No subluxation or dislocation of the joint occurred.

However, the unplanned repair of the lead screw-motor coupling interface indicated unwanted stress in the coupling. This stress in the CPM-Ilizarov interface had been partly resolved by the use of more flexible joints in the connection between the Ilizarov rings and CPM device. However, there remained stress encountered at the motor-lead screw coupling interface. The plane of the fixator's hinges may not be in perfect alignment to the plane of the lead screw mechanism and motor. The diverging planes could lead to unwanted stress in the attachments as the joint moves. A proposed solution to this is to incorporate an added degree of freedom in the joint mechanism at the motor/Ilizarov ring interface to automatically compensate for any misalignment.

The predetermined set-up managed to continuously flex and extend the elbow in a 30° arc of motion for a period similar to actual clinical use after some modifications in the attachments. The range of motion generated can possibly be increased by prolonging the set time duration of flexion-extension cycles in the programming. A rotatory encoder is planned to be incorporated into the device so it may operate based on degree of angulation instead of time done for flexion and extension.

Based on this prototype testing, ease of use of the software needs to be addressed. The present prototype is made to run on a preset time in the software program. The control system to adjust the programming and duration of the device still requires a laptop system to modify the program codes. A user-friendly interface which will utilize knobs to control speed and duration is planned for future prototypes or the desired arc of motion could be used instead of time/duration. This will remove the need for a laptop computer. The control system also needs to be designed so that it would be patient/user friendly and less prone to user error. A "recall previous state function" could also be incorporated in the program.

CONCLUSION

This prototype CPM device has produced continuous passive elbow motion in a Thiel cadaver elbow with an attached

Hinged Elbow Ilizarov Fixator. This prototype overcomes the limitations found in commercially available elbow CPM device. This prototype was able to generate flexion-extension with no dislocation or disruption of the elbow joint. Points of improvement in the current prototype include modifications in the interfaces between the CPM device and Ilizarov rings. This is to address the stresses generated at the motor-screw interface. With further improvement in the functionality and safety of the CPM device, clinical studies can be done to determine its use in the post-operative phase of cases requiring the use of Hinged Elbow Ilizarov Fixators. Going further, minor addition or attachments may possibly make this prototype CPM device compatible with other elbow fixators that are not made of the Ilizarov type.

Ethical Considerations

This study was conducted in complete compliance with good clinical practice and was implemented after being granted permission by the University of the Philippines Research Ethics Board (UPMREB) to utilize cadaver elbow models for the demonstration of the functionality of the CPM Device. There are no known risks in this study and it will benefit patients in terms of prevention of elbow stiffness after treatment with a Hinged Elbow Ilizarov Fixator.

Acknowledgments

The authors would like to acknowledge the UP College of Medicine Department of Anatomy and the UP-PGH Department of Orthopedics Prosthesis Laboratory for their invaluable assistance in the conduct of the study.

Statement of Authorship

JSJ contributed in the conceptualization of work, acquisition and analysis of data, drafting and revising, and final approval of the version to be published; JMSD and EOR contributed in the acquisition and analysis of data, drafting and revising, and final approval of the version to be published.

Author Disclosure

JMSD has received grant incentive for the project from the University of the Philippines Technology Transfer and Business Office Invention Disclosure Awards.

Funding Source

The study is self-funded.

REFERENCES

1. Mittal R. Post-traumatic stiff elbow. Indian J Orthop. 2017 Jan-Feb;51(1):4-13. doi: 10.4103/0019-5413.197514.
2. Lindenhovius ALC, Jupiter JB. The posttraumatic stiff elbow: a review of literature. J Hand Surg Am. 2007 Dec;32(10):1605-23. doi: 10.1016/j.jhsa.2007.09.015.
3. Mavroidis C, Nikitczuk J, Weinberg B, Danaher G, Jensen K, Pelletier P, et al. Smart portable rehabilitation devices. J Neuroeng Rehabil. 2005 Jul;2:18. doi: 10.1186/1743-0003-2-18.
4. Javier JS. Management of neglected elbow dislocation using a hinged Ilizarov fixator. Tech Orthop. 2006 Jun;21(2):121-6. doi:10.1097/01.bto.0000225123.06223.fa
5. Ghadai S, Purohit PK. Design and development of a continuous passive motion device for physiotherapeutic treatment of human knee. (Unpublished) [Internet]. 2015 (cited 2017 Nov). Available from: http://ethesis.nitrkl.ac.in/7574/1/2015_Design_Purohit.pdf
6. Bundoc RC. The efficacy of a locally designed continuous passive motion machine in the post-operative management of traumatic knee injuries. Philipp J Orthop. 1996 Dec;15(1):31-37.
7. Maciejasz P, Eschweiler J, Gerlach-Hahn K, Jansen-Troy A, Leonhard S. A survey on robotic devices for upper limb rehabilitation. J Neuroeng Rehabil. 2014 Jan; 11:3. doi: 10.1186/1743-0003-11-3.
8. Schuster E. Elbow passive motion rehabilitation utilizing a continuous passive motion device following surgical release, manipulation under anesthesia, or post stable fracture: a review. Kinex Med. 2006;24.
9. Xiao CG, Mohamad Z, Omar WRW. Elbow joint rehabilitation device. Int J Voc Educ Train Res. 2016 Aug;2(4):24-7.
10. Viveen J, Doornberg JN, Kodde IF, Goossens P, Koenraadt KLM, The B, et al. Continuous passive motion and physical therapy (CPM) versus physical therapy (PT) versus delayed physical therapy (DPT) after surgical release for elbow contractures; a study protocol for a prospective randomized controlled trial. BMC Musculoskelet Disord. 2017 Nov;18(1):484. doi: 10.1186/s12891-017-1854-0.
11. Völlner F, Pilsl U, Craiovan B, Zeman F, Schneider M, Wörner M, et al. Stability of knee ligament complex of Thiel-embalmed cadaver compared to in vivo knee. J Mech Behav Biomed Mater. 2017 Jul;71:392-6. doi: 10.1016/j.jmbbm.2017.04.009.
12. Schnetzke M, Bergmann M, Wegmann K, Müller LP, Grechenig S, Grützner PA, et al. Determination of elbow laxity in a sequential soft-tissue injury model: a cadaveric study. J Bone Joint Surg Am. 2018 Apr;100(7):564-71. doi: 10.2106/JBJS.17.00836.
13. Beger O, Karagül Mİ, Koç T, Kayan G, Cengiz A, Yılmaz ŞN, et al. Effects of different cadaver preservation methods on muscles and tendons: a morphometric, biomechanical and histological study. Anat Sci Int. 2020 Mar;95(2):174-89. doi: 10.1007/s12565-019-00508-z.