The Philippine Journal of Orthopaedics

ORIGINAL ARTICLE

Biomechanical Evaluation of a Locally Manufactured Modular External Fixator for Tibial Shaft Fractures*

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ABSTRACT

Background. Modular external fixations used in the Philippines are manufactured abroad, leading to high costs and limited availability, making them unaffordable for most Filipino patients. The reliability of some external fixators is limited because not all have undergone biomechanical testing.

Objective. This study aimed to determine the biomechanical stability of locally manufactured modular external fixator clamps (iFIX) versus commercially available fixators (Roger-Anderson) for tibial shaft fractures.

Methodology. The biomechanical stability (stiffness, yield, ultimate strength) under loading of the local prototypes was compared with the commercially available fixators.

Result. No slippage was observed in all rods, pins, and clamps in all groups. No bending occurred in any rods or pins in all groups. There was also no apparent deformation of the internal threading of the pins within the tibial analogs. The commercial fixator group's ultimate load to failure up was double (110.57% difference) that of the local prototype.

Conclusion. The differences in the biomechanical performance between the iFIX and Roger-Anderson clamps may be attributed to variations in clamp material composition. The iFIX fixator exhibited lower stiffness but did not display deformation under axial loading, component displaced slippage, or thread loosening, making it comparable to the commercial fixator.

Keywords. external fixator, tibia, biomechanics

INTRODUCTION

Theoretical background

Tibia fractures are the most common long bone fractures, with an incidence of 17 in 100,000 person-years. Fractures most often occur in the diaphysis and are more likely to be open fractures due to the tibia's subcutaneous location, correlating with more complications and worse outcomes.[1] In a study conducted at the Philippine General Hospital from 1999 to 2002, which included 70 patients with open tibial fractures, the infection rates were as follows: 7% for type I, 23% for type II, 33% for type IIIa, 50% for type IIIb, and 100% for type IIIc. Moreover, infection was associated with a higher incidence of non-union or delayed union.[2] Temporary stabilization with external fixators followed by conversion to definitive internal treatment is recommended for Type IIIb, IIIc, and some IIIa fractures.[1]

ISSN 0118-3362 (Print)
eISSN 2012-3264 (Online)
Printed in the Philippines.

Received: May 19, 2024.
Accepted: June 26, 2024.
Published Online: August 2, 2024.
https://doi.org/10.69472/poai.2024.16

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**Oral presentation at the 31st Philippine Orthopaedic Association Midyear Convention. 19–21 April 2023.*

External fixation is used to stabilize fractures after trauma temporarily. It is generally favored because it does not need direct access to the fracture site, avoids infected regions, allows direct wound surveillance, minimizes further soft tissue injury, gives more freedom in wire and pin placement, and sometimes enables early mobilization.[3] External fixation allows compression, neutralization, and distraction of fracture fragments. It is also used for infected and non-infected non-unions.[4]

External fixation must adhere to several principles of frame stability. Frame stiffness is increased by using bicortical pin fixation, increasing the number of pins, increasing pin separation, increasing the distance of the most distant pins from the fracture, increasing the pin diameter (not exceeding 30% of the diaphysis), using a double stacked bar, decreasing the distance of the bar from the bone, and using a triangular or delta configuration.[1,4]

Ease of application and biomechanical properties are two important factors when choosing an external fixator. The pin-bar system is more commonly used in acute trauma cases due to its relatively simpler application. Moreover, external fixators may be applied in one, two, three, or more planes. Versatility is key in managing fractures that cannot be fixed with unilateral constructs. Most current monolateral systems can be applied in one or more planes using large multipin clamps, separate monolateral bars, Schanz pins, and other modular components.[1] These are known as modular external fixators, enabling fracture reduction and fixation primarily through highly adaptable multipin clamps. Despite its clamp complexity, the construct is relatively simple to apply and has exceptional rigidity. One example is the Hoffmann II Stryker system; both the uniplanar and biplanar structures were found to have similar application time and ease. However, the biplanar system demonstrated slightly higher biomechanical stability in torsion and bending.[5]

Burden of illness

At present, all modular external fixation systems being used in the Philippines are manufactured in other countries, most commonly in China. Because of this, they are not always readily available locally and tend to be more expensive. Most lack diversity in their designs and the construct sizes and directions for application are limited. Furthermore, not all have undergone testing for biomechanical stability. These factors have a great impact on the healthcare of our fellow Filipinos. Patients might not afford these fixators, and even when they can, may receive subpar products, causing greater morbidity.

Significance of the study

Given this background, we found that there is a role for locally manufactured external fixators. The goal is to open an avenue for self-sustaining design, biomechanical and clinical testing, production, and provision of affordable yet rigid and safe external fixators for Filipino patients.

Review of related literature

External fixation system

External fixation was first described by Hippocrates 2400 years ago, where it was characterized as a "shackle" external device for a tibial fracture, consisting of leather wraps, thick coats, and four European dogwood rods. Over the years, external fixation has evolved significantly, resulting in increasingly diverse designs and application techniques.[1]

Monolateral external fixation

Monolateral external fixators fall under two categories. The "mono-tube" type's large-diameter monotube connecting body, which is three to four times the size of monolateral bars, confers significant stability, but limits the options for pin placement, angle, and bone-bar distance, limiting its use. The "simple monolateral" system, on the other hand, is composed of individual pins placed at angles while connected to a bar. Various modifications include the double stacked bar in an anterior 4-pin frame, increasing bending and torsional stiffness,[3] and the "delta" plane, effectively allowing multiplanar constructs.[1,3,6]

Modular external fixation

The modular frame is highly versatile, making it useful for injuries that cannot be reduced and stabilized optimally with uniplanar systems. Modular systems boast improved stability,[7] speed and ease of application similar to uniplanar designs, and higher torsion and bending stiffness.[5] They allow straightforward reduction of complex fractures and possess superior biomechanical rigidity.

Role of fabrication and evaluation

In 1997, Goh et al. recognized the importance of designing a cheaper but biomechanically effective external fixator to provide medical devices for poorer countries.[8] They developed and tested the Alinoor-Goh (AG) fixator against a commercially available external fixator and found no significant difference in stiffness. Besides cutting costs, new materials and innovations must also be developed and tested.[6]

Currently, there is no available literature on the fabrication and testing of locally manufactured external fixator components (iFIX). This study aims to address this gap by describing the investigation, design, manufacture, and biomechanical testing of a locally manufactured modular external fixator.

OBJECTIVES

General objective

To describe the design, production, and biomechanical stability of a locally manufactured modular external fixator clamp (iFIX) prototype versus commercially available modular external fixators for tibial shaft fractures.

Specific objectives

1. To survey available biocompatible materials used for external fixator clamps in the market
2. To determine the most appropriate materials for manufacturing the modular external fixator clamp
3. To fabricate a modular external fixator clamp prototype
4. To establish the biomechanical properties and determine if there is a difference among the modular external fixators across different designs in terms of axial loading

METHODOLOGY

Study design

Experimental

Study venue and duration

Evaluations were conducted at the UP Diliman Mechanical Engineering Department and Philippine General Hospital. Fabrication of materials was done in cooperation with the Department of Mining, Metallurgical, and Materials Engineering and with the Advanced Manufacturing Center of the Department of Science and Technology – Philippine Council for Health Research and Development.

Patient selection

No human or animal subjects were used for this study. As such, no inclusion and exclusion criteria were stated.

Data collection procedures

Analysis and parametric study of external fixator parts and dimensions

An external fixator model was digitally designed based on previous research.[9] We applied the properties of Markforged Onyx™ to the clamps, while the remaining parts were assigned properties of 316L stainless steel. Markforged Onyx™ was chosen due to its availability, reasonable mechanical properties, and low cost. The Young's moduli and Poisson ratios of the materials were incorporated as well. Finite element analysis was then done to analyze the maximum deformation in the external fixator assembly.[10]

A parametric assessment was done to identify the most ideal parameters to increase the stiffness and stability of the design. A compressive axial stress amounting to 350 N load was applied to the proximal end of the tibia, which is 50% of the mass of a 70 kg person during the stance phase of walking.[11] Maximum stiffness was achieved in the finite element analysis when the rod-to-bone distance was decreased, the pin-to-pin distance was increased, and the pin-to-fracture gap was decreased. A modified external fixator model was then designed incorporating these parameters to achieve 51.76% of the original maximum deformation from the base design.[10]

Survey of commercially available external fixator materials and properties

Candidate materials were selected from studies focusing on inert and biocompatible materials with medical applications. Currently used external fixator materials across different suppliers and/or manufacturers in the Philippine market were documented. The simplicity of manufacturing the materials was also taken into consideration.

Material simulation testing and selection

Materials were selected using multi-criteria decision-making methods (Fuzzy Analytic Hierarchy Process (F-AHP) and Fuzzy Technique for Order Preference by Similarity to an Ideal Solution (TOPSIS).[12] The Fuzzy Analytic Hierarchy Process (F-AHP) involves breaking, grouping, and ordering solution problems into a categorized list. The method pairs criteria with a measurement scale and incorporates insights from experts. It also combines the logic of "degrees of truth" rather than "true or false" in the hierarchy.[13] Using F-AHP, weights were given to each criterion for the material needed for the external fixator parts.

Fuzzy Technique for Order Preference by Similarity to an Ideal Solution (TOPSIS), on the other hand, assesses several alternatives against chosen criteria. The alternative that is closest to the Fuzzy Positive Ideal Solution and farthest from the Fuzzy Negative Ideal Solution is chosen as the best option.[14] Fuzzy TOPSIS was used to generate a list ranking the most suitable materials for the parts. Materials were also considered for their ease of 3D printing, accessibility, and lightweight properties. The ideal materials were determined to be carbon fiber and stainless steel 304 for the rod, stainless steel for the nuts and bolts, and stereolithography-printed resin for the clamps.

Review and analysis of common clamp designs and design changes

The clamp components of several modular external fixator systems were sent to partner engineers for evaluation. Clamps from modular systems in catalogs and online sources were analyzed as well. A single-rod modular external fixator was computer-generated. The clamp was developed to have 360 degrees of movement in two planes.

Fabrication of prototype modular external fixator clamp

The finalized design was then used to initiate fabrication locally under the project "iFIX: Design and Fabrication of External Fixator," as shown in Figure 1. Like previous studies, the prototype was reverse-engineered from existing commercial external fixators and computerized models.[9] A stereolithography (SLA) 3D printer was used to fabricate the external fixator (iFIX clamp).

Figure 1. Single-rod modular external fixator prototype 3D render design.

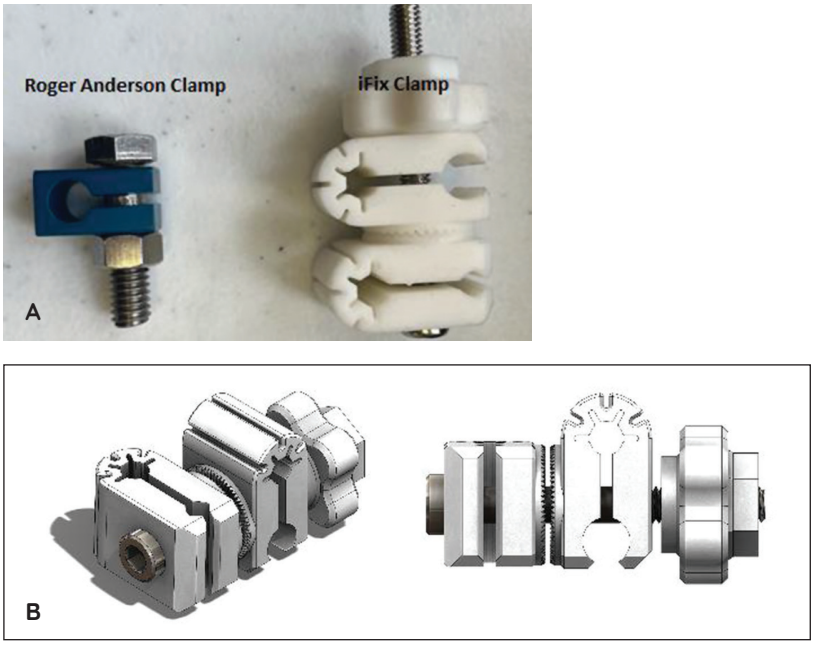

Figure 2. Standard Roger Anderson Clamp and iFIX Clamp **(A)**. Oblique and lateral 3D render views of iFIX Clamp **(B)**.

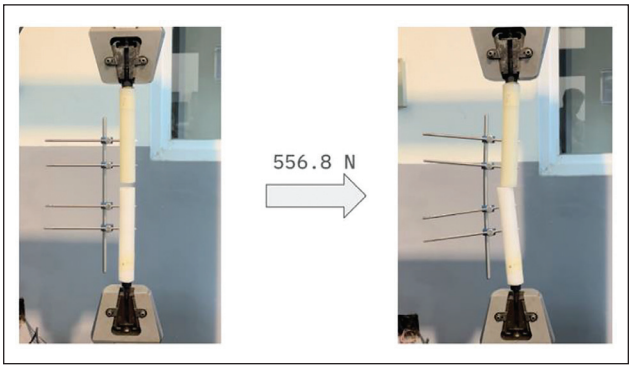

Figure 3. Roger-Anderson fixator-tibia analog setup upon failure.

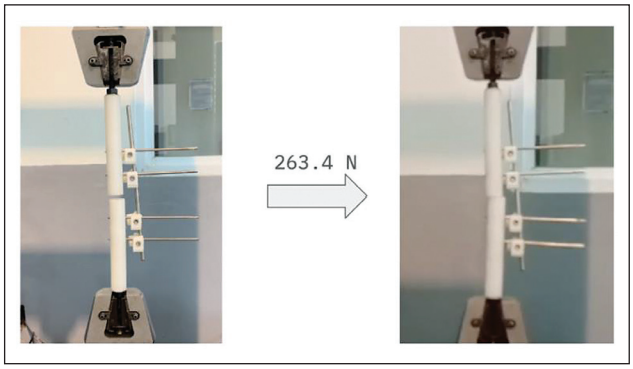

Figure 4. iFIX fixator-tibia analog setup upon failure.

Outcome assessment

The fabricated external fixator prototype was subjected to biomechanical testing following the standards set by the ASTM F1541-17 (Standard Specification and Test Methods for External Skeletal Fixation Devices). Ultra-High Molecular Weight Polyethylene (UHMWPE) cylinders (30 mm in diameter and 180 mm in length) were prepared as representatives for the tibia due to their comparable Young's modulus (YM_{UHMWPE} = 33.2 GPa) with the tibia (YM_{tibia} = 34.11 GPa). The tibial fracture was simulated by two of these cylinders with a gap in between. Each cylinder was drilled two holes transversely for 4.5 mm diameter pins 44 mm apart. At the end of one cylinder, an 11.5 mm hole was bored by 10 mm to mount the threaded rod fixture.

The Roger-Anderson external fixator (with Aluminum 6061-T4 clamps, Figure 2A) and iFIX external fixator (with stereolithography-printed resin clamps, Figure 2A, 2B) were then assembled onto the bone models. The same commercially available stainless steel pins and rods were used for both groups (Figure 3).

The bone analog and external fixator setups were independently subjected to axial compression using a Universal Testing Machine (UTM).[8,15,16]

Methods for quality control

Testing followed standards set by the ASTM F1541 (Standard Specification and Test Methods for External Fixation Devices) and ISO 10993 (Biological Evaluation of Medical Devices).

Statistical considerations

Sample size calculation

Two samples each of Roger-Anderson and iFIX external fixator were subjected to biomechanical testing.

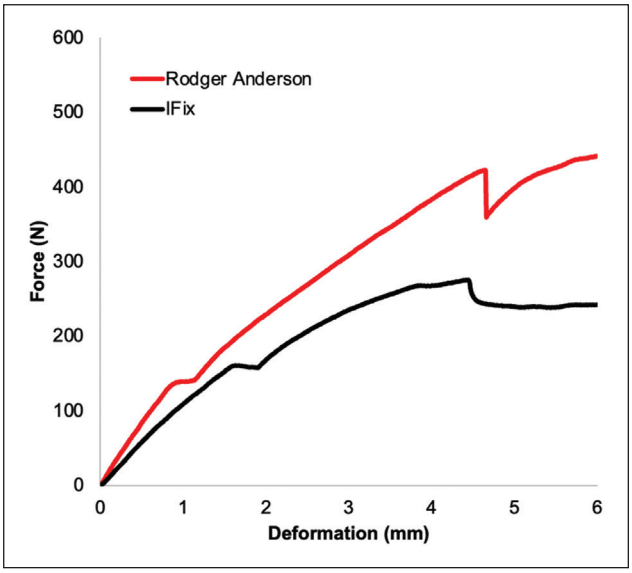

Figure 5. Force-Deformation curves of the Roger-Anderson fixator and iFIX fixator (n = 2).

Table 1. Comparison of mean axial stiffness, yield, and ultimate load to failure between commercial Roger-Anderson external fixator and locally fabricated external fixator

	Roger-Anderson (n = 2)	iFix (n = 2)	% Difference
Stiffness (N/m)	163.64	105.75	42.97%
Yield (N)	139.37	160.38	14.02%
Ultimate (N)	556.77	263.41	110.57%

Statistical methods

The stiffness coefficient for axial loading was calculated. Stiffness (k) was computed by dividing the axial load applied by the displacement of the bone model.[8,15] The Yield and Ultimate load to failure were also computed. The average values for each group are presented in Table 1. The average force deformation curves of both fixators were also plotted.

RESULTS

In both biomechanical testing setups, there was no slippage of rods, pins, and clamps. On increasing the axial load, failure eventually occurred (indicated by the closing of the gap between the two tibial fracture fragment analogs) (Figures 3 and 4). No bending occurred for all rods and pins. There was also no apparent deformation of the internal threading of the pins within the tibial analogs. The derived Force-Deformation curves from the UTM are plotted in Figure 5. Based on the curves, stiffness was then calculated (Table 1). The ultimate load to failure of the tibia-external fixator set-up was double (110.57% difference) for the control Roger-Anderson fixator as compared to the iFIX fixator.

DISCUSSION

Biomechanical properties differed between the two fixators likely due to their material composition; metals, particularly stainless steels, are generally stiffer than polymers. The effect of the material on the holding capacity of the clamps onto rods and pins could also influence stability.

Failure was defined in this research as clamp slippage. The breaking point of the external fixator was not tested. The iFIX external fixator, despite possessing lower stiffness, exhibited properties important to an external fixator. It did not display deformation under axial loading and none of the components of the fixator displaced slippage of loosening of threads onto the bone models.

This study cannot be compared to existing literature due to differences in the definition of load to failure. Landaeta et al. allowed no mode of failure, and determined only the behavior of the fixator under loading. The stiffness of their fabricated construct was 246.12 N/mm.[9] Goh et al. defined failure as touching of the bone surfaces; their fabricated fixator had a stiffness of 55.7 N/mm.[8]

CONCLUSION

The iFIX stereolithography-printed resin clamp showed potential in an external fixator construct. Its biomechanical testing showed no slippage between rods, pins, and clamps, similar to the Roger-Anderson commercial external fixator, but with a lower ultimate load to failure. Despite lower stiffness, the iFIX model exhibited relevant properties of an external fixator, being capable of resisting deformation and preventing slippage. These findings contribute to advancing the local fabrication of external fixators, potentially enhancing orthopedic care.

The AO/Synthes external fixator clamp would have been a good comparator. However, the purpose of this research is to establish a baseline comparison of the fabricated external fixator with the simplest, cheapest, and most available design in the Philippine market. In the future, we plan to compare our model with the AO/Synthes modular external fixator and test its modularity. Current testing was limited to comparison with the Roger-Anderson external fixator in one plane to be consistent with the ASTM testing standards.

The design process follows a sequence of Finite Element Analysis (FEA), biomechanical testing, design changes, the next round of FEA, the next round of biomechanical testing, and so forth. Given this sequence, axial loading was tested in this study, but additional biomechanical testing such as load to failure, bending stiffness, and cyclic loading will be facilitated once the design has matured. Further research is also recommended to explore more samples for material fretting/brittleness, corrosion analyses, and cadaveric applicability. Comparative testing and cost analysis can be done for different materials.

The main strength of this study is that it is one of the first documented studies on a fabricated modular external fixator that underwent the stages of the US Food and Drugs

Administration (FDA) design control process. This research also presents the early-stage results of an iterative design process that is guided by simulation. This early stage also presents a weakness. More design developments, comparisons, and biomechanical tests are needed before cadaveric and clinical testing can be done. The fabrication process will be optimized once the final design undergoes the full set of examinations.

ACKNOWLEDGMENTS

The authors thank their research consultant, Dr. Emmanuel Estrella, whose enthusiasm for research and meticulous attention to detail have motivated them to pursue this endeavor. Assoc. Prof. Eduardo Magdaluyo, Jr., Engr. Earl Caburnay, and Dr. Miguel Aljibe have also played special roles in this protocol by combining their engineering knowledge and skills with the authors' medical expertise in planning the design and enabling the manufacturing of the research prototypes. This protocol, being under the iFIX project of SIBOL (Surgical Innovation and Biotechnology Laboratory), would not have come to fruition without the support of its research staff. They also thank the DOST-PCHRD (Department of Science and Technology – Philippine Council for Health Research and Development) for the research grant.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHORS DISCLOSURE

Dr. Emmanuel P. Estrella is an Associate Editor of the Philippine Journal of Orthopaedics.

FUNDING SOURCE

The primary investigator and the Philippine Council for Health Research and Development (PCHRD) provided funding for the research.

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