# Axial Biomechanical Performance Evaluation of Locally-developed Modular External Fixator

Jan Francois B. Severo,[1] Miguel Sandino O. Aljibe,[1,2] Anjenina U. Durana,[1] Jason Pechardo,[1]
Dionella Jitka B. Quinagoran,[1] Eduardo R. Magdaluyo Jr.[3] and Emmanuel P. Estrella, MD, MSc, PhD[4]

*[1]UP Surgical Innovation and Biotechnology Laboratory, College of Medicine, University of the Philippines Manila, Manila, Philippines*
*[2]Department of Otolaryngology–Head and Neck Surgery, College of Medicine and Philippine General Hospital, University of the Philippines Manila, Manila, Philippines*
*[3]Department of Mining, Metallurgical, and Materials, Engineering, College of Engineering, University of the Philippines Diliman, Quezon City, Philippines*
*[4]University of the Philippines Manila, Manila, Philippines*

## ABSTRACT

**Background.** In the Philippines and other developing countries, access to high-stability external fixators for trauma-induced bone fracture management is limited, as modular external fixators, especially those with snap-on features, are manufactured overseas and are prohibitively expensive for most Filipino patients.

**Objective.** This study aimed to assess the biomechanical performance of a locally-developed modular external fixator prototype for tibial diaphyseal fractures in comparison to available external fixators, such as Roger Anderson and Hoffmann. This provides an initial evaluation for the use of the external fixator as an alternative in terms of its stability.

**Methods.** Using axial compression testing compliant with the ASTM F1541-24 standards, the ultimate strength, yield strength, safe strength, and stiffness were measured across various fixator types and tightening mechanisms, with or without the aid of a wrench. Statistical tools such as the t-test assuming equal variances, one-way analysis of variance, and Tukey-Kramer test with a 0.05 level of significance were used to determine any significant differences.

**Results.** The mechanical performance of the external fixator prototype increased by a factor of 1.5 to 2.5 after the clamps were tightened with the wrench. However, when hand-tightened, it still performed sufficiently, showing a comparable mechanical performance with the Roger Anderson Fixator. In terms of the ultimate, safe, and yield strengths, it performed competitively in comparison with the Hoffmann system. However, there is a significant difference in stiffness between the prototype and the Hoffmann system.

**Conclusion.** The locally-developed external fixator was comparable biomechanically to the commercially available external fixators and the prototypes in different studies.

*Keywords: external fixation, external fixators, fracture, biomechanical tests, modularity*

Corresponding author: Jan Francois B. Severo
UP Surgical Innovation and Biotechnology Laboratory
9F Henry Sy, Sr. Medical Sciences Building
College of Medicine
University of the Philippines Manila
Pedro Gil St., Ermita, Manila 1000, Philippines
Email: jbsevero@up.edu.ph

## INTRODUCTION

Fractures of the lower extremities, such as the tibia, are some of the most commonly recorded categories of injuries in the Philippines, as reported by the Global Burden of Disease (GBD) in the Online National Electronic Injury Surveillance System (ONEISS) 2014.[1] These injuries are usually caused by traffic and occupational accidents, both of which are presently prevalent in the country which accounts to annual mortality of 7,000 and thousands leading to disability.[2-4]

External fixation is one of the fundamental methods in managing these fractures. It is a low-risk, less invasive, temporary stabilizer of fractured bones, ideal for trauma cases that require good fracture site visualization in preparation for radiography and for identifying the need for additional vascular surgery. Casting and internal fixation would make these needs difficult to meet.[5,6]

For an external fixator to be effective for fracture healing, it must be mechanically stable in terms of stiffness and strength, based on patient requirements.[6,7] Based on different studies, fixators are able to withstand up to 700 N of load, which corresponds to the average weight of humans.[5,6] The mechanical stability of a fixator must be optimal to ensure high rates of healing, as excessive stiffness contributes to excessive stresses on the pins and bones, impeding healing, while low stability prevents ossification by allowing soft tissue movement.[3,5]

There are different configurations of external fixators, such as linear and circular, which are selected based on the required stability, allowable movements, and complexity of the fracture.[5] For most tibial fractures, uniplanar and unilateral frames were reported to be effective and easy to apply and have been noted to allow better access to wounds for management.[7] A linear or unilateral external fixator assembly consists of pins, a rod, and clamps. The pins are drilled into bone fragments, and then the rod acts as a stabilizer and connects the different pins in one or more planes through the clamps. The components of the fixator assembly each contribute to its stability, but usually, the clamps are the greatest determinant of the fixator's function and cost. The fixators known to possess great biomechanical performance are usually expensive, such as the Hoffmann and Orthofix fixators, which cost around $3,556 to $20,486.[3,6,8,9]

In the Philippines and other developing countries, there is a lack of access to high-stability external fixators for trauma-induced bone fracture management. In low-to-middle income (LMIC) and developing countries, trauma services such as external fixation are often neglected because the Sustainable Development Goals Agenda prioritizes infectious and non-communicable diseases.[3,10] As a result, treatments are directed towards long leg cast splinting, immobilization, and even prolonged traction, which have repercussions and are counterproductive to fracture healing.[3] Philippine public hospitals, such as the University of the Philippines - Philippine General Hospital (UP-PGH), use Roger Anderson (RA) fixators, which are affordable but not modular and allow limited degrees of freedom for multiplanar application. As a result, RA fixators are challenging to use in the management of complex fractures. This presents a problem in achieving quality clinical care, especially since the Philippines aims to implement its own Universal Health Care within the decade.[3]

A locally-designed and developed external fixator prototype was developed to address the challenges encountered while performing external fixation. It incorporates likeable features of available fixators, such as the modularity and snap-on or *clique fantastique* feature of Hoffmann, which improves the user-friendliness and usability of the clamps.[11] Its modularity allows a wider range of orientations accommodating to different types of fractures, resulting in ease of application. In addition to having these features, the prototype is targeted as a potent alternative because of its accessibility for Filipino patients by being locally manufacturable and reproducible. To ensure functionality, its biomechanical performance was evaluated under basic loads such as axial compression, representing a patient's weight. The use of additive manufacturing technologies such as stereolithography (SLA), which is an evolving manufacturing technique in the rapid design, development, and production of external fixators, was also explored for potential in developing the locally developed clamps.[6]

The study aimed to measure the stiffness, ultimate, safe, and yield strengths of the locally developed external fixator. The study also aimed to compare the local fixator's biomechanical performance against commercially available external fixators, such as the RA and Hoffmann external fixators. Finally, the study assessed the performance of the locally developed fixator in open fracture treatment, based on the acceptable parameters optimal for healing defined in the literature.[5,6]

This study limited its scope to evaluating the biomechanical performance of the external fixator system as a complete construct and did not seek to isolate or analyze the effects of its individual components. The study is limited to performing the said axial biomechanical parameters, given the constraints on available fixtures for the testing machine. Furthermore, there is subjectivity in the fastening of the clamps in the external fixator system, as it relies merely on the operator rather than torque-measuring tools in determining whether the fixator clamps are secured.

## METHODS

### Preparation of External Fixator Samples

The clamp prototypes were fabricated by stereolithography (SLA) (plastic iteration) and computer numerical control (CNC) mill machining (metal iteration). The plastic fixator clamps were manufactured through additive manufacturing, using the Formlabs Form 3L resin 3D printer and Rigid 4000 as the working resin material. To initialize the fabrication, the 3D models of the local external fixator were sliced using PreForm v3, the slicing software compatible with the 3D printer. The print layer height was set to a minimum of 0.05 mm for finer resolution. After printing, the prototypes were washed with 99% isopropyl alcohol for 15 minutes and were cured under ultraviolet light at 80 °C for 15 minutes.

Meanwhile, the metal iterations were fabricated at the Advanced Manufacturing Center (AMCen) of the Department of Science and Technology-Metals Industry Research and Development Center (DOST-MIRDC). The metal external fixator clamps are composed of Aluminum alloy 6061 T6, an alloy known for its high corrosion resistance, moderate strength, and good strength-to-weight ratio.[12,13]

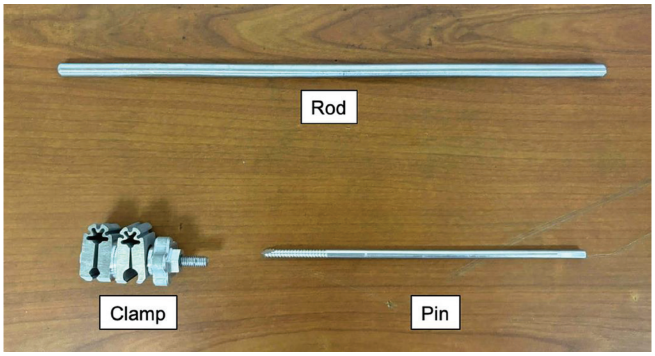


**Figure 1.** External fixator components.

The other components of the external fixator system, such as the Steinmann pins and rods (Figure 1), are outsourced from the Department of Orthopaedics, UP-PGH. The prototype clamps were designed to accommodate the pins and rods currently used in local hospitals. The Steinmann tibial pins have the following dimensions: a diameter of 5 mm, a length of 180 mm, and a threaded length of 35 mm at the sharp tip. Meanwhile, the rods have a diameter of 8 mm and a length of 300 mm. Both the pins and rods are composed of Stainless Steel 316L.

The Roger Anderson fixators, which are also commonly used in Philippine hospitals in treating tibial fractures, served as a control in the study. These fixators were sourced from the UP-PGH. The mechanical performance of the Hoffmann fixators was also measured to serve as a basis of comparison due to their known usability and reliability characteristics for external fixation. Both commercially available fixators shared the same Steinmann pins as the prototype. The Roger Anderson fixators share the same rod as the prototype, but the Hoffmann fixators use carbon fiber rods with a diameter of 11 mm and a length of 300 mm.

Listed in Tables 1 and 2 are the experimental settings used in this study. First, the different tightening mechanisms applied to the prototype were examined. Hand-tightened clamps are those that are solely preloaded by hand using the clamp's locking feature. For all samples, the same person tightened the clamps in the fixator setup to minimize subjectivity. Meanwhile, wrench-tightened clamps are those that are tightened with the aid of tools such as Allen and open-end wrenches. Plastic prototypes were used in this set of experiments. On the other hand, the prototype was then compared with the other commercially available fixators with the same tightening mechanisms.

**Table 1.** Codes and Treatment Settings for Tightening Mechanism Experiments

| Code | Treatment |
|---|---|
| *IHT* | Prototype (Rigid 4000, SLA-printed), Hand-tightened |
| *IWT* | Prototype (Rigid 4000, SLA-printed), Wrench-tightened |

**Table 2.** Codes and Treatment Settings for External Fixator Comparison Experiments

| Code | Treatment |
|---|---|
| *RA* | Roger Anderson, Wrench-tightened |
| *H* | Hoffmann, Wrench-tightened |
| *IF* | Prototype (Al T6 6061), Wrench-tightened |

## Biomechanical Test

The test followed the ASTM F1541-24 A2 (Standard Specification and Test Methods for External Skeletal Fixation Devices - Test Method for External Skeletal Fixator Connectors).[14] The compression test was conducted in the University of the Philippines Diliman Institute of Civil Engineering-Construction Materials and Structures Laboratory. The universal testing machine (UTM) available and appropriate for testing is the model Instron 5982 with a load cell of 10 kN. The schematic of the setup is indicated in Figure 2.

Ultra-High Molecular Weight Polyethylene (UHMWPE) rods with 30-mm diameter and 160-mm length were prepared as the bone analogues because of the material's comparable Young's modulus ($YM_{UHMWPE}$ = 33.2 GPa) with the tibia ($YM_{tibia}$ = 34.11 GPa).[6] All bone analogues were drilled with two 4.5 mm diameter slots; one slot was drilled 36 mm from a bone analogue's edge, and the other slot was drilled 44 mm away from the first slot, closer to the bone analogue's center. Pairs of bone analogues were then oriented such that the edges closest to a slot were juxtaposed, facing each other, leaving a 10mm space in between the analogues. A pair arranged in this way was considered a column. At both ends of a column, an 11.5-mm hole was bored along the column's axis to accommodate a 12-mm threaded rod and bolt fixture. This fixture would be attached to the grips of the UTM.

The rod was positioned 20 mm away from the edge of the bone analogues. Clamps were then placed to fix the positions of the rod and pins. The biomechanical setup was then loaded in the UTM while maintaining the distance between the two analogs. Before the actual compression tests, the samples were preloaded five to six times by 90 N, which is the observed approximate maximum load when the loaded samples are elastic. Preloading was done until the load-displacement curves became sufficiently uniform in shape and slope. The rate of the displacement was set to 0.1 mm/s.

After preloading, the samples were then subjected to loading until failure, with the direction of applied load as shown in Figure 3. For the tests, failure was denoted by the gap closing between the two analogs. The generated load-displacement data was then collected and analyzed to determine mechanical performance.

## Data Interpretation

From the generated load-displacement curves, the different biomechanical performances of the fixator clamps

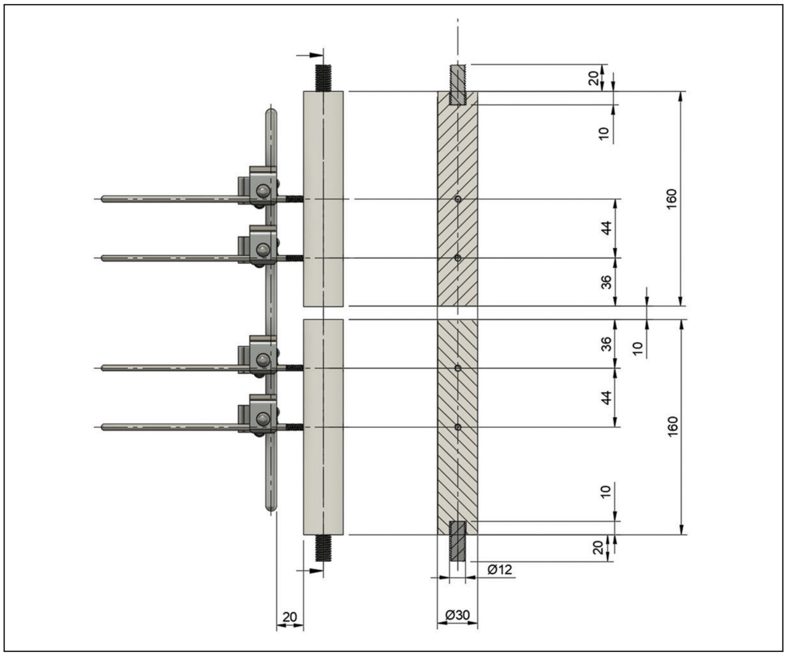


**Figure 2.** Biomechanical test setup following the ASTM F1541-17 standard.
Note: Ø indicates diameter measurements in mm

**Figure 3.** Direction of applied axial load in the fixator system.

were retrieved. The elastic region was determined by taking the range of points from zero displacement that gave the highest $R^2$ in the identified linear model. The slope of the curve in the elastic region described the stiffness of the fixator clamps.[6,15] The yield strength, which denotes the start of the permanent deformation, was determined through the intersection of the 0.1 mm offset of the elastic region and the load-deformation curve.[6] The safe strength, on the other hand, was denoted by the load causing the displacement of the setup to 1 mm.[6,9] The ultimate strength described the maximum load experienced by the setup until the gap between the bone analogues closed.[14]

To determine any significant difference between treatments of different tightening mechanisms, a t-test with a 0.05 level of significance was used. Among the different types of fixators, one-way analysis of variance (ANOVA) with a 0.05 level of significance was performed. To determine which specific groups were significantly different, a post-hoc Tukey-Kramer Test was performed, considering the different sample sizes for each treatment.

## RESULTS

### Tightening Mechanisms

Although no fractures or plastic deformation were identified by unaided visual inspection following UTM biomechanical testing, the overall assembly showed a degree of loosening when compared with its initial condition. As shown in Figure 4, there was an evident increase in the mechanical performance of the prototype after the clamps were preloaded with the aid of wrenches, which is represented by the upward shifting of the load-displacement curve. The wrench-tightening caused the stiffness, ultimate failure, and safe and yield strengths to increase by 1.5 to 2.5 times from the hand-tightened clamps, which are illustrated in Figure 5.

Table 3 presents the mechanical performance of hand-tightened and wrench-tightened SLA-printed prototype fixators. A one-tailed t-test (assuming equal variances with a 0.05 level of significance) revealed that all mechanical performance parameters were significantly different between the two different tightening mechanisms. As shown in

**Table 3.** Mechanical Performance of SLA-printed Prototype Tightened Differently (hand-tightened vs. wrench-tightened) with $t_{critical}$ of 2.13

| | IWT | IHT | IWT/IHT | Calculated t |
|---|---|---|---|---|
| ***Ultimate (N)*** | 368.4 ± 14.9 | 220.8 ± 5.6 | 1.67 | 8.49 |
| ***Yield (N)*** | 55.7 ± 16.3 | 22.0 ± 0.8 | 2.53 | 2.52 |
| ***Safe (N)*** | 62.1 ± 10.5 | 30.5 ± 2.9 | 2.03 | 3.01 |
| ***Stiffness (N/mm)*** | 76.1 ± 5.1 | 47.9 ± 13.0 | 1.59 | 3.70 |

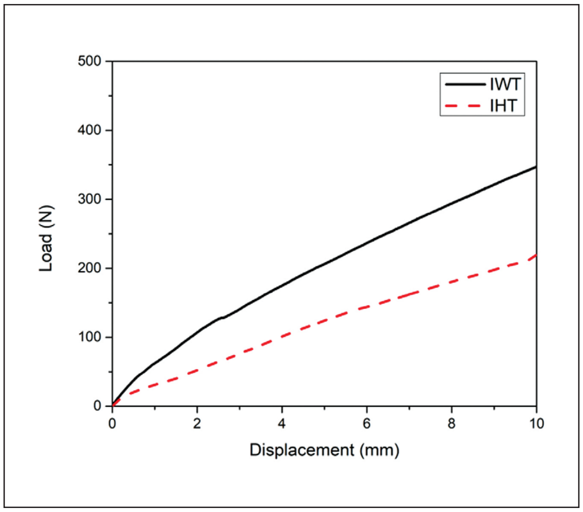


**Figure 4.** Load-displacement curves of SLA-printed external fixator prototypes.

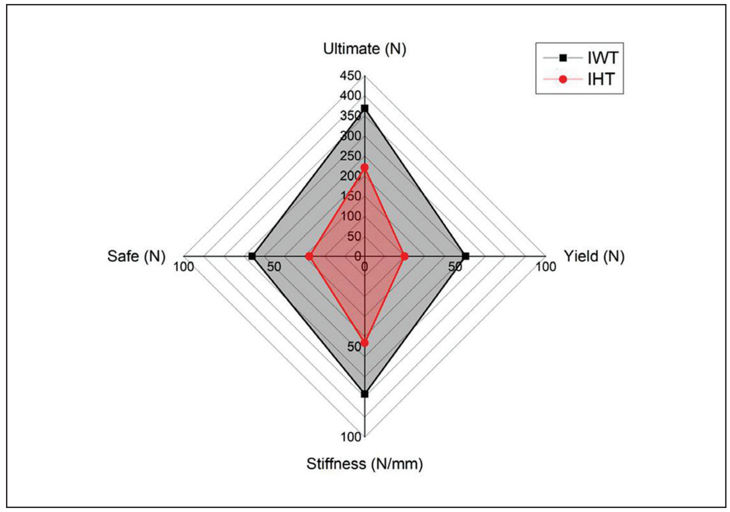


**Figure 5.** Mechanical performance disparity between hand-tightened (IHT) and wrench-tightened (IWT) prototypes.

Table 3, the calculated t-values were greater than the critical t-value of 2.13, confirming a significant difference.

## Comparison with Other External Fixators

Across all types of external fixator assemblies, their components did not experience obvious signs of plastic deformation, but there was loosening of the assembly. Upon mechanical performance testing shown in Figure 6, it was revealed that the Al alloy prototype performed better than the conventional RA but poorer than the Hoffmann external fixators. This is exemplified in the load-displacement curves of the samples in Figure 7, determined after the gap between the bone analogues closed, approaching 10 mm. There is a 1.8 factor increase in ultimate strength after substituting RA clamps with the metal prototype. Other mechanical performance parameters, such as stiffness, yield, and safe strength, are increased by approximately 1.2 times from RA to the prototype, as illustrated in Figure 8 and listed in Table 4. In comparison with the Hoffmann external fixator, the prototype almost performs on par in terms of yield strength. However, the prototype lags in performance on other performance parameters, especially on stiffness, which has a ratio reduction of 0.70.

By one-way ANOVA, it is found that there were significant differences among external fixator designs in

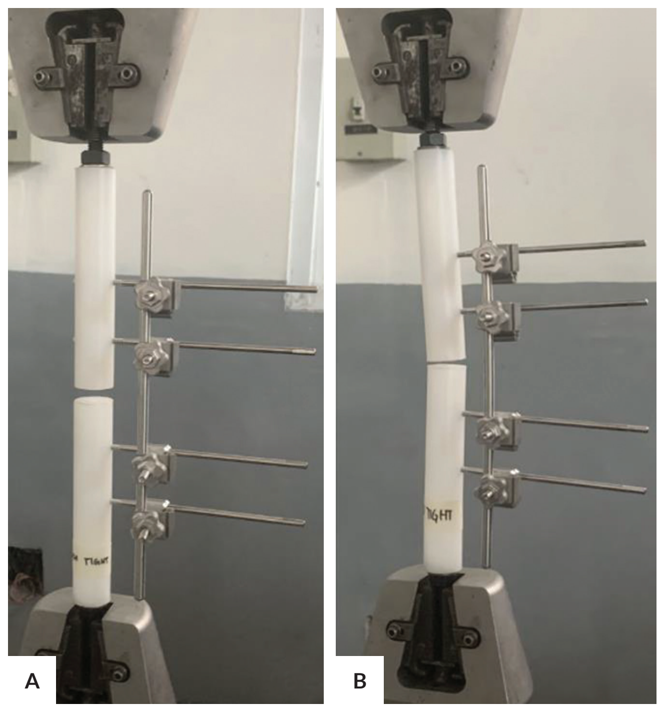


**Figure 6.** Metal external fixator prototype subjected to tensile biomechanical test until failure: **(A)** before application of load, **(B)** upon application of load.

**Table 4.** Mechanical Performance of Different External Fixators

| | Roger Anderson | External Fixator Prototype | Hoffmann |
|---|---|---|---|
| ***Ultimate (N)*** | 435.6 ± 24.6 | 820.4 ± 40.9 | 1016.7 |
| ***Yield (N)*** | 80.3 ± 5.1 | 93.8 ± 14.7 | 94.3 |
| ***Safe (N)*** | 86.1 ± 7.8 | 106.6 ± 2.4 | 133.2 |
| ***Stiffness (N/mm)*** | 106.7 ± 4.5 | 127.9 ± 1.7 | 183.4 |

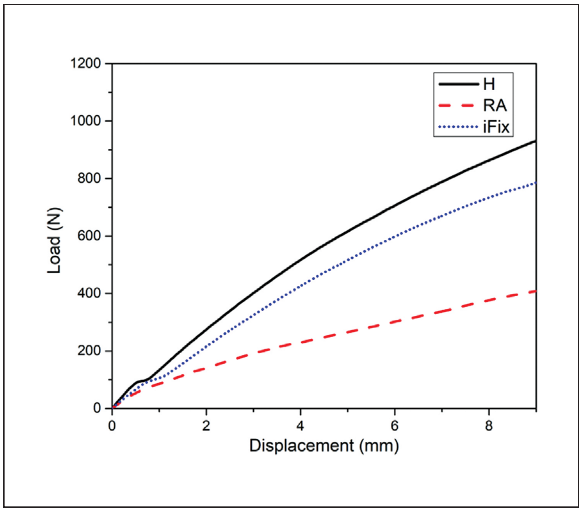


**Figure 7.** Load-displacement curves of different metal fixators.

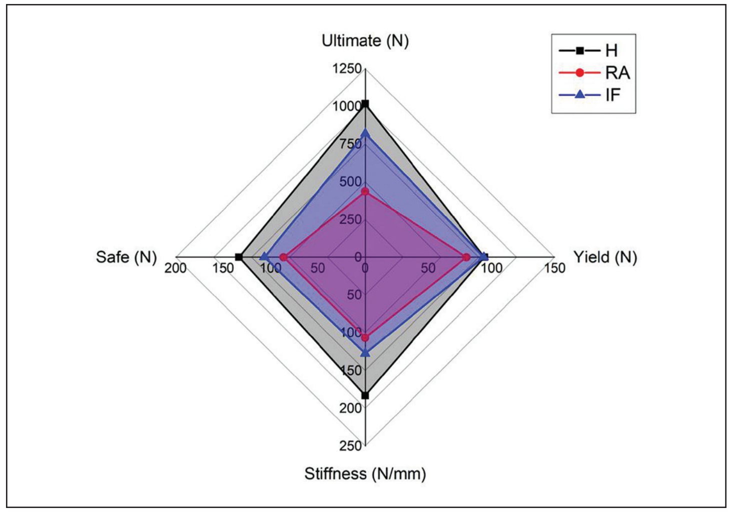


**Figure 8.** Mechanical performance of different external fixators.

terms of stiffness, ultimate strengths, and safe strengths, as the corresponding p-values were less than 0.05. Through the post hoc Tukey-Kramer tests, the specific pairings of external fixators with significant differences were identified. It revealed that in terms of ultimate strength, the difference between RA and the prototype was significant, while the difference between Hoffmann and the prototype was not significant. Meanwhile, the stiffness of the prototype was significantly different compared to both RA and Hoffmann. As for safe and yield strength, the differences are not significant.

## DISCUSSION

The locally-developed metal linear external fixator prototype was able to withstand up to 820.4 N loaded axially to close the set fracture gap of 1 cm. The load is beyond the 700 N benchmark for fixators, which corresponds to the average human body weight of 70 kg.[5,16] More importantly, the safe load, which corresponds to the allowable load for proper healing and ossification, reached up to 106.6 N only, which is approximately 15% of the average human body weight of 70 kg. This value falls below the commonly accepted 25% threshold for partial weight-bearing fracture stabilization but exceeds loads typically encountered during the swing phase of the gait cycle, which is approximated at 10% of the weight.[6,17] These findings suggest that the biomechanically-validated external fixator construct is appropriate for temporary stabilization and guarded mobilization for non-full-weight-bearing applications, but have limitations for early partial or full weight-bearing stabilization due to the risk of exceeding permissible deformation limits. These results indicate that the locally developed fixator shows clinical promise for external fixation in stable, reduced fractures, providing adequate support for soft tissue healing under guarded or limited weight-bearing conditions.

The metal prototype was then directly compared with pre-existing external fixators. This was a noted limitation of a previous study on the same type of external fixator (Landaeta). Based on the findings and statistical tests, the metal prototype performed competitively compared to Hoffmann and RA fixators. Its mechanical performance was closer to the Hoffmann fixator, the fixator brand known for its great versatility and biomechanical properties.[11,18] The carbon fiber rod compatible with the Hoffman fixator features a larger diameter compared to the rods used with the metal prototype and RA assemblies. Based on the beam deflection model, increasing the diameter of a circular cross-section substantially increases the moment of inertia, resulting in reduced bending-induced stress for a given applied moment. This feature may partly explain the greater mechanical performance observed in the Hoffman assembly under axial loading. In addition, the surface roughness of the carbon fiber rods is higher compared to the SS 316L rods, which may contribute to the stability of the Hoffmann construct by preventing interfacial slippage between components. The increased frictional resistance at the rod-clamp interface due to the roughness of the carbon fiber rod may have enhanced the overall stability of the assembly, suggesting that friction plays a contributory role in the mechanical performance of these contact systems.[19]

Other linear external fixators were also indirectly compared. Goh et al. noted that their developed fixator had a stiffness of 55.7 ± 0.197 N/mm as compared to the commercially available AO fixator of 57.7 ± 0.186 N/mm.[20] Landaeta et al. found that the axial compression stiffness of their 3D-printed clamps was 246.12 ± 8.87 N/mm.[6] The safe and yield loads were 177.14 ± 5.46 N and 122.92 ± 4.47 N, respectively. It is important to note that the external fixator assembly of Landaeta et al. featured a knurled rod, which provided increased friction between the clamp and the

**Figure 9.** Hand-tightening of external fixator prototype upon application.

rod, thereby promoting its stability. The axial compression stiffness of the Imperial Morutawa Mk2 external fixator was determined to be 64.7 ± 2.3 N/mm.[15] Ang et al. reported their unilateral external fixator to have a stiffness of 528 ± 42 N/mm.[21] The study also reported that the stiffness of these fixators ranges from 50 N/mm to 400 N/mm in their literature search.

The external fixator prototype is designed to be easily applied, especially during emergencies. Contributing to the ease of application is the decreased need for tools provided by the large mechanical nut design used to fasten the clamps during fixation, seen in Figure 9. In this study, the hand-tightening mechanism through the SLA printed prototypes was assessed for its sufficiency to be applied for fixation applications. However, based on the data, wrench tightening showed a significant improvement in all the mechanical performance evaluated as compared to hand tightening, and consequently improved performance by 1.5 to 2.5 times.

Although wrench tightening can improve its mechanical performance, the metal prototype was still found to be satisfactorily functional even when hand-tightened. Based on the measured mechanical performance and computed hand-tightened to wrench-tightened performance ratios, it was found to be able to withstand up to 492 ± 25 N until gap closure, i.e., failure, and safely carry 52.4 ± 1.2 N without expecting a displacement exceeding 1 mm. The 1 mm separation is important since it is within the allowable distance at which osteosynthesis is initiated in fractured bone.[5,6,22,23] Considering both experimental and computational estimates, compared to RA, the metal prototype had a lower estimated safe strength but a higher ultimate strength.

Another implication of the biomechanical test results is the potential of the 3D printed clamps for low-volume, high-resolution, and customizable production. The tested SLA clamps made of Formlabs Rigid 4000 resin were determined to perform similarly to the fixators mentioned in the literature. It can also be applicable to smaller bones such as those in the upper extremities, which do not bear loads approaching the average human weight.

External fixator components such as rods and clamps have reportedly been reused to cut costs, especially in LMIC settings.[3] However, reusing fixator clamps leads to reduced mechanical performance in terms of torque and axial load bearing.[24] Plastic deformation is also evident in weaker clamps when loaded repeatedly. These eventually lead to a decline in functionality. With these stability and mechanical performance findings, the metal prototype demonstrates significant potential as an effective substitute for RA fixators in LMIC settings. Given its superior mechanical performance compared to RA, the metal prototype clamps may be more suitable for repeated use without compromising their functional capacity. These findings will be substantiated further upon conducting unperformed tests such as fatigue tests, conforming to ASTM F1541-24.

## CONCLUSION

A locally-developed external fixator is designed to be modular, easily usable (i.e., can be applied with limited tools), and accessible to Filipinos. Its biomechanical performance was evaluated by axial compression testing compliant with the ASTM F1541-24. Parameters relevant to fixator stability were extracted from experimentally generated load-displacement curves. These were ultimate strength, yield strength, safe strength, and stiffness.

Based on the biomechanical tests performed, the metal prototype was able to withstand the permissible weight of an average human until the fracture gap of 1 cm closed. In terms of safe load, which corresponds to the 0.1 cm displacement, it was at 15% of the average weight, which is short for non-full weight bearing for fracture stabilization, yet is enough for withstanding the weight applied upon the swing phase of the gait cycle.

The metal prototype performed competitively compared to readily available external fixators, such as Roger Anderson and Hoffmann fixators. The locally developed fixators had better mechanical performance than the Roger Anderson fixators, which are conventionally used in UP-PGH. Although Hoffmann had higher strength values, there was no significant difference between Hoffmann and the locally developed fixators in terms of ultimate strength, safe strength, and yield strength by the Tukey-Kramer test.

In the SLA-printed prototypes, the difference in mechanical performance between wrench-tightened and hand-tightened clamps was found to be significant. Tightening the clamps with tools resulted in a 1.5- to 2.5-

fold improvement in mechanical performance. By applying this ratio to the wrench-tightened metal prototype, its performance under hand-tightened conditions was inferred, and it was found that the prototype performed comparably to Roger Anderson fixators.

The results of the biomechanical tests support the case for its reusability, which may be further assessed upon conducting fatigue and multiple usage tests. This is due both to the improved bulk mechanical performance and the potential of the 3D printed clamps for quick and adjustable fabrication, allowing the accommodation of bones requiring smaller loads. To safely use the locally developed external fixators in clinics, it is recommended to explore other variables, such as other load orientations (i.e., torsion, AP, and ML bending), to observe the influences of different biomechanics apart from compression by weight and gait.

## Statement of Authorship

All authors certified fulfillment of ICMJE authorship criteria.

## Author Disclosure

All authors declared no conflicts of interest.

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None.

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