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ORIGINAL ARTICLE

# Biomechanical Stiffness and Strength of New Versus Reused Stainless Steel Uniplanar Tibial External Fixator Constructs in a Low-Resource Setting*

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## ABSTRACT

**Introduction.** External fixation is used in the initial or definitive management of open fractures. Branded fixators are costly and often unavailable in low-resource countries. Low-cost locally available stainless steel fixators are relatively easy to procure. When these low-cost fixators are depleted in hospitals and purchase cost is prohibitive for patients, the reuse of non-implanted components (the rods and clamps, referred to as outriggers) is a frequent alternative. New Schanz pins should be implanted into bone to reduce the risk of infection. The reuse of outriggers translates to significant savings both for hospitals and patients. Knowing the stiffness and strength of reused versus new fixators will help guide their policies regarding reuse.

**Objectives.** The general objective of this study was to assess the biomechanical stiffness and strength of both new and previously used external fixator constructs available in our hospital. Specifically, this study compared the axial stiffness, bending stiffness, torsional stiffness, and ultimate strength of new versus previously used low-cost uniplanar tibial external fixator constructs. In addition, this study compared the axial stiffness and ultimate strength of an all-new low-cost uniplanar tibial external fixator constructs using five Schanz pins versus six Schanz pins.

**Methodology.** Forty-five plastic tibia were osteotomized at midshaft to create a fracture gap, simulating a comminuted diaphyseal fracture. Tibias were randomly divided into three groups of fifteen specimens. Each tibia was stabilized using five new Schanz pins in a uniplanar configuration held by one of three constructs: 1) with all-new components, 2) once-used and re-sterilized outriggers, or 3) twice-used and re-sterilized outriggers. Specimens were then biomechanically tested to determine fixation stiffness in axial compression, bending, and torsion. Static loading until failure was also performed to determine ultimate construct strength.

A fourth group of five specimens (osteotomized tibias) were stabilized using all-new components with six Schanz pins (three pins in each fracture segment). These specimens were tested to determine axial stiffness and ultimate strength. Results were then compared to the first group (5-pin all-new components).

**Results.** There were no significant differences among the first three groups in terms of axial stiffness, axial strength, and bending stiffness. In the torsion test, the reused fixators were even stiffer than the all-new group.

The all-new fixators using six Schanz pins were significantly stiffer and stronger versus the all-new fixators using five Schanz pins.

**Conclusion.** Reused, locally available stainless steel uniplanar tibial external fixators were mechanically comparable to new fixators in terms of axial stiffness, bending stiffness, and ultimate strength. Reused fixators were superior in terms of torsional stiffness versus new fixators. The reuse of non-implantable fixator components is a viable option without compromising construct mechanical strength even if the components have undergone two cycles of clinical use and reprocessing.

The study also concludes that in using new external fixators, increasing the number of pins from five Schanz pins to six Schanz pins increased the construct's axial stiffness two times and increased the construct's axial strength four times.

**Keywords.** external fixator, stiffness, strength, reuse

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## INTRODUCTION

Increasing urbanization and motorcycle use in developing countries expose people to more high-energy trauma.[1] Road traffic accidents result in open trauma, especially fractures; the tibia is at particular risk in motorcycle crashes.[2] Pedestrians are considered one of the most vulnerable road users in less developed countries such as the Philippines.[3] The poor infrastructure and hygiene conditions in some areas make internal fixation techniques inaccessible,[4] leaving external fixation the treatment of choice.

External fixation involves pins or wires percutaneously implanted in bone and connected outside the body using clamps and rods.[5] Although traditionally used to provisionally (and sometimes definitively) treat open tibial fractures,[6] they may also be used for certain closed fractures with severe soft tissue injury.[7,8] Unfortunately, external fixation is also expensive in some areas.[9] External fixators are considered disposable devices, adding a great burden to healthcare costs, especially in developing countries.[10]

There are numerous sophisticated external fixator models available on the market, but these are too costly for routine use in developing countries.[11] Many enterprising surgeons have devised cheaper models.[12] Simplifying the design, changing the material and overall finish can reduce manufacturing costs. These fixators generally achieve the same results as those that are more expensive when used properly.[12,13] However, the efficacy and safety of low-cost external fixators should be analyzed before being deployed in clinical settings.

Low-cost, locally manufactured external fixators are typically made of stainless steel. The construct's stiffness is key, as this helps maintain bone alignment under a mechanical load. When used for fracture management, the stiffness should be sufficient to overcome the forces during patient mobilization to prevent fracture displacement, avoid nonunion,[14] and enhance callus formation.[15]

Recycling external fixator components is often economical.[16] In developing countries, even locally manufactured external fixator stocks are often depleted and many patients cannot afford commercial devices. A common practice is to reuse, with the patient's consent, the non-implantable components (outriggers) of previously used external fixators, thus greatly reducing the cost of treatment. Biomechanical studies comparing new and previously used, low-cost, locally available uniplanar tibial external fixator constructs would be necessary to justify this practice. There is also a need to standardize the method of reprocessing used fixators to minimize differences in their properties.

According to the United States Centers for Disease Control and Prevention,[17] proper disinfection and sterilization in healthcare facilities may include cleaning using water with detergents or enzymatic products, disinfection by chemical disinfectants, and sterilization. The method depends on the type of material and the manufacturer's suggestions. In general, for cleaning and reprocessing heat-stable medical equipment like stainless steel external fixators and other surgical instruments, heat sterilization (i.e., autoclave sterilization) is the method of choice.[18] All external fixator constructs undergo cleaning with water and liquid detergent, disinfection by chemical products (such as povidone-iodine solution), and sterilization by steam and pressure from an autoclave.

Many orthopedic trauma surgeons have expressed interest in the reuse of external fixator components but have reported barriers to implementation including reprocessing logistics and concerns about litigation.[9] Others believe that components should not be reused due to issues with the device response, mechanical wear and fatigue, lack of reprocessing control, liability for device failure, fiduciary consideration, and advancement of fixator technology.[5]

A single center's experience with a reuse program for external fixators in the United States concluded that the reuse of external fixator components in good repair is safe and should be supported due to its advantages in cost reduction,[19] and that reused external fixators are still mechanically sound.[20]

A randomized clinical trial in a single center, level I trauma center in the United States involving the use of new versus refurbished non-implantable external fixator components concluded that it was safe and effective with actual cost savings of 25% of the cost of all new frames. It was also found that there were no statistical differences in the incidence of pin tract infections, loss of fixation, or loosening of components.[21] A prospective randomized interventional study in a tertiary care teaching hospital in India also found no significant difference in the incidence of pin tract infection, loss of fixation, and loosening of components. The conclusion was similar, that recycling external fixator components is safe and effective, with a sizable cost saving. Due to this demonstration of safety and the cost savings in the reuse of external fixation devices, reuse appears inevitable.[22]

Assessment of external fixator reusability using load- and cycle-dependent tests on unilateral DynaFix fixators determined that it can be reused no more than three times as the device accrues fatigue damage with more loading cycles.[23]

Stainless steel continues to be a popular material for a wide range of orthopedic implants. Most medical-grade stainless steel is an alloy called 316 L.[24]

The American Society for Testing and Materials (ASTM) sets the standard for mechanical testing of stainless-steel products including external skeletal fixation devices (ASTM designation F1541-17).[25] For uniplanar external fixator constructs, the tests include the axial compression test, bend test, and torsion test, as can be expected from clinical use.

In the Philippines, the price of a new, low-cost locally available stainless steel uniplanar tibial external fixator ranges from PhP5,000 to PhP15,000 and the price of a percutaneously implanted Schanz pin is about PhP 150 to PhP 300. Therefore, using new Schanz pins with a reused external fixator frame or outriggers results in significant cost reduction. Schanz pins should not be reused to avoid the risk of directly seeding pathogens into the patient's bone. The low-cost, locally available stainless steel uniplanar tibial external fixator constructs that are widely used in this country and other developing nations have rods and clamps that may be reused as long as they are mechanically sound in terms of axial compression, bending, and torsion. This study can be the basis for guidelines for reusing these external fixators, developing criteria for reuse, and standardizing procedures for recycling, disinfecting, and sterilizing external fixators.

We believe this study is the first of its kind in the country. The usual low-cost uniplanar tibial external fixators sold have five Schanz pins. However, increasing the number of pins increases the construct stiffness or rigidity.[26] We will also test an all-new uniplanar tibial external fixator construct using six Schanz pins.

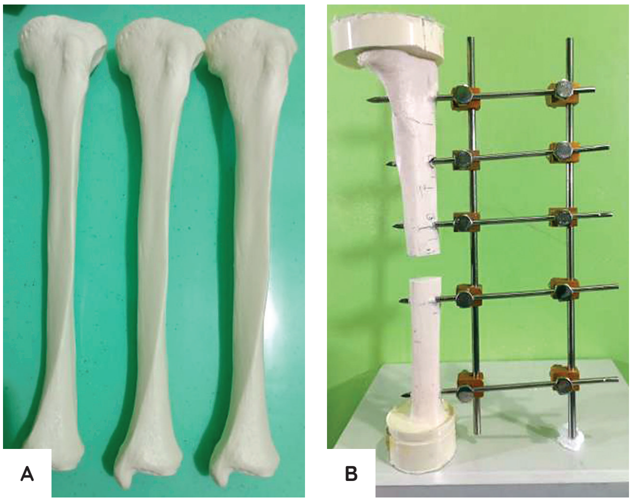

**Figure 1. (A)** Adult-size left tibias made of synthetic plastic polymer (polyvinylchloride) **(B)** External fixator construct attached to a plastic tibia with a fracture gap of 20 mm with bone ends potted in polyurethane.

## METHODOLOGY

### Type of study

This is an experimental study testing low-cost locally available uniplanar tibial external fixators. It uses non-human subjects and was given a certificate of exemption from ethics review.

### External fixator selection

All stainless steel uniplanar tibial external fixators were not branded, and were made of the same type, design, and materials. All Schanz pins used were new. The three groups were as follows:

1. The all-new group includes five new Schanz pins and new outriggers.
2. The once-used group includes five new Schanz pins and outriggers that had been used and reprocessed once.
3. The twice-used group includes five new Schanz pins and outriggers that had been used and reprocessed twice.

### Sample size

This study utilizes non-random sampling. A total of 45 external fixators were tested in this study, 15 in each group. From each group, 5 were tested for axial compression, 5 were tested for bending, and 5 were tested for torsion (Figure 2). Based on the guidelines from the ASTM Designation F1541-17 entitled "Standard Specification and Test Methods for External Skeletal Fixation Devices," a minimum sample size of 5 for any given load condition is considered adequate for the testing.

### Preparation of external fixator

Components showing mechanical defects were discarded. Preparation of the external fixators involved inspecting, cleaning, disinfecting, and sterilizing before testing. First, these fixators were soaked in a basin with 4 liters of tap water mixed with 1 sachet or 60 mL of ready-to-use liquid detergent, then scrubbed using a sponge and plastic brush. The fixators were then rinsed under running tap water. The fixators were then soaked in 1 liter of 7.5% povidone-iodine solution before being scrubbed using a sponge and plastic brush and rinsed under running tap water. The third step was the sterilization process, performed using moist heat and pressurized steam from an autoclave. Fixators were double-wrapped with linen and then sterilized in an autoclave for 45 minutes at a temperature of 121 degrees Celsius and pressure of 15 pounds per square inch.

### Bone and fracture model

Forty-five models of adult-size left tibia made of synthetic plastic polyvinyl chloride (Figure 1A) were divided into three groups. All the synthetic bones had the following measurements: 350 mm in length, 72 mm wide at the proximal tibia, 50 mm wide at the distal tibia, and 28 mm wide at the midshaft level. A fracture gap of 20 mm was created using a handle saw and measured with the aid of a Vernier caliper, to simulate a comminuted mid-shaft tibial fracture. The gap was created to ensure that there was no contact between the two ends of the fracture gap during axial loading. These were then implanted with the external fixators per group as described. All tibia were potted at each end using polyurethane (Figure 1B).

### External fixator construct assembly

Each external fixator set was assembled according to the test construct configuration parameter suggested by ASTM.[25] All clamps (or pin-rod connectors) were tightened to 10 Newton-meter of torque using a torque wrench. The following were the details of the components of the external fixator: partially

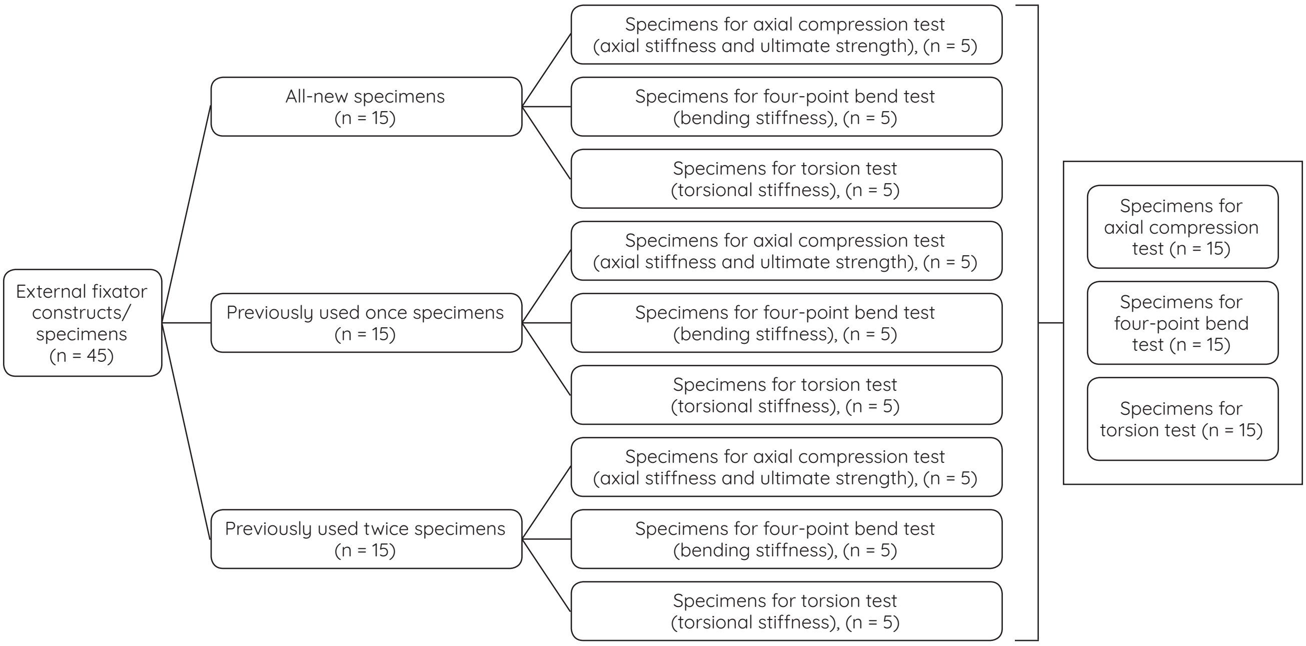

**Figure 2.** Schematic diagram of the distribution of the 45 external fixators.

threaded Schanz pins 4.5 mm diameter, 200 mm length, 30 mm threaded portion; pin-rod clamp or screw clamps with nuts and bolts; and longitudinal rods 6 mm diameter, 330 mm length. The following were the details of the bone-fixator assembly: fracture gap size of 20 mm; a bone-to-rod distance of 25 mm; rod-to-rod distance of 70 mm; Schanz pin-to-fracture distance of 20 mm; pin-to-pin distance in the proximal segment of 50 mm; and pin-to-pin distance at the distal segment of 80 mm.

## Biomechanical testing of the external fixator construct

All constructs were tested in an accredited material testing laboratory in Cagayan de Oro City, the TestLab Engineering & Geotech Sevices. The tests included axial compression, four-point bending, and torsion testing. The experiment set-up and procedures were performed in concordance with the ASTM Designation F1541-17 entitled "Standard Specification and Test Methods for External Skeletal Fixation Devices." The results include axial stiffness (N/mm), bending stiffness (N/mm), and torsional stiffness (N•m/degrees). In the axial compression test, the specimens were also loaded to failure to determine the ultimate strength (N).

A trial run ensured that the bone analog material was sufficiently tough so that the anchorage elements (Schanz pins) remained tightly embedded in bone throughout the test.

### Axial compression test

Both ends of the construct were mounted and aligned axially with the use of spacers and a setting load—about 0.1% of the expected load—to hold the specimen axially in place before starting the test (Figure 3). The axial compression was tested with a Matest Servo Controlled Universal Testing Machine of 500 kN Capacity with a Digital Touch Screen Display. The applied load was gradually increased from 0 to a maximum of 700 N (corresponding to the weight of a 70 kg person during a one-legged stance) at a deformation rate of 0.1 mm/s. The displacement was measured simultaneously with the load using Neoteck Digital Indication—Model NTK021; 0–25.4 mm. Tangent stiffness was determined by the slope of linear-most of the bone-fixator construct response curve (Figure 4). The ultimate load was determined by locating the peak point on the response curve (Figure 4). All determinations were in conformance with ASTM F1541-17 Section A7 method.

### Four-point bending test

The constructs were mounted on a bending fixture with a 70 mm-loading span distance and 310 mm-support span distance (Figure 5). The four-point bend test was tested with Matest Sheartronic with a Load cell capacity of 25kN with 0.001kN readability at a rate of 1.0 mm/min. The applied loading was gradually increased until a deflection of 8–9 mm was achieved. The displacement was automatically logged by the machine using the Linear Variable Differential Transformer. Bending stiffness was determined by the slope of the curve (Figure 4). All determinations were in conformance with ASTM F1541-17 Section A7.

### Torsional stiffness

The proximal end of the construct was clamped on the load cell plunger while the distal end was clamped with a C-clamp which served as its lever arm (Figure 6). The distal end is then manually twisted clockwise until the load cell reading reads approximately 326 to 330 N to produce 9–10 Nm of torque. The lever arm distance from the center of the axis of twist is 0.18 m which serves as its lever arm for twisting. The angle of twist was manually logged corresponding to the 4-intervals within the specified max load cell reading. The machine used is the Matest Sheartronic Machine with a 5 kN capacity load cell. Torque force is the force that can cause an object to rotate about its axis and also cause an angular displacement. Thus, torque was determined by multiplying the force recorded by the load cell by the lever arm of 0.03 m. Torsional stiffness was then determined by the average slope of the reaction curve of the external fixator construct (Figure 4). All determinations were in conformance with ASTM F1541-17 Section A7 method.

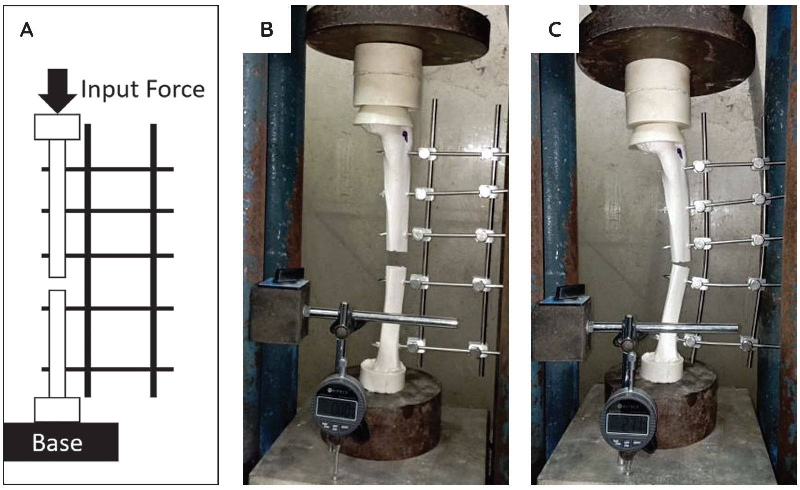

**Figure 3.** **(A)** Schematic test configuration for axial compression test of an external fixator (adapted from ASTM F1541-17). Actual axial compression before **(B)** and after **(C)** the test.

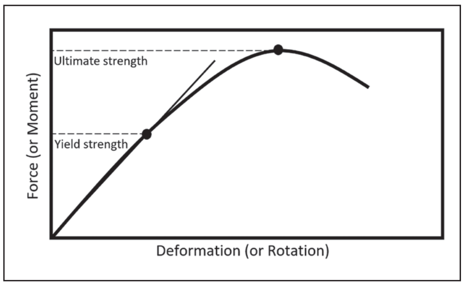

**Figure 4.** Typical fixator-bone construct response curve (adapted from ASTM F1541-17).

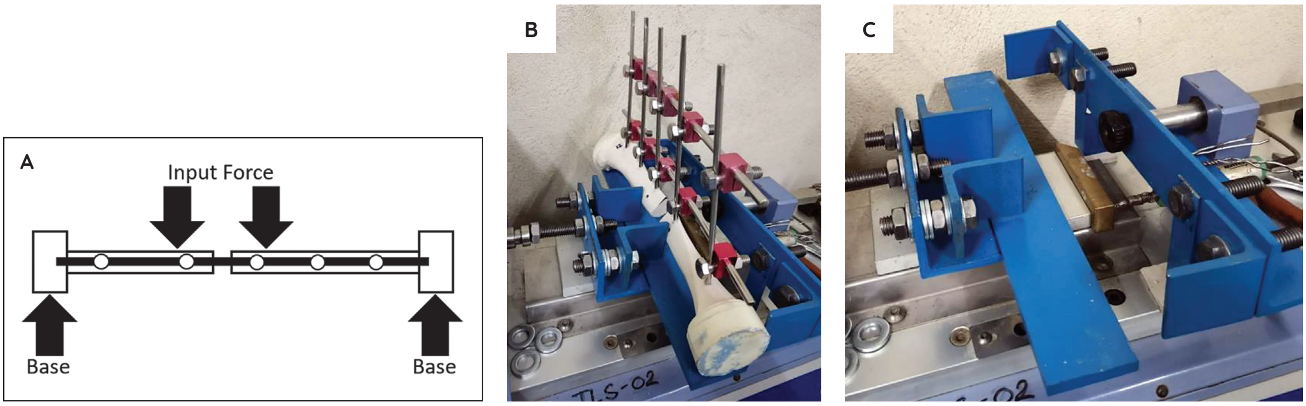

**Figure 5.** **(A)** Schematic test configuration for four-point bending test of an external fixator (adapted from ASTM F1541-17). Actual four-point bending test set-up with **(B)** and without **(C)** specimen inserted.

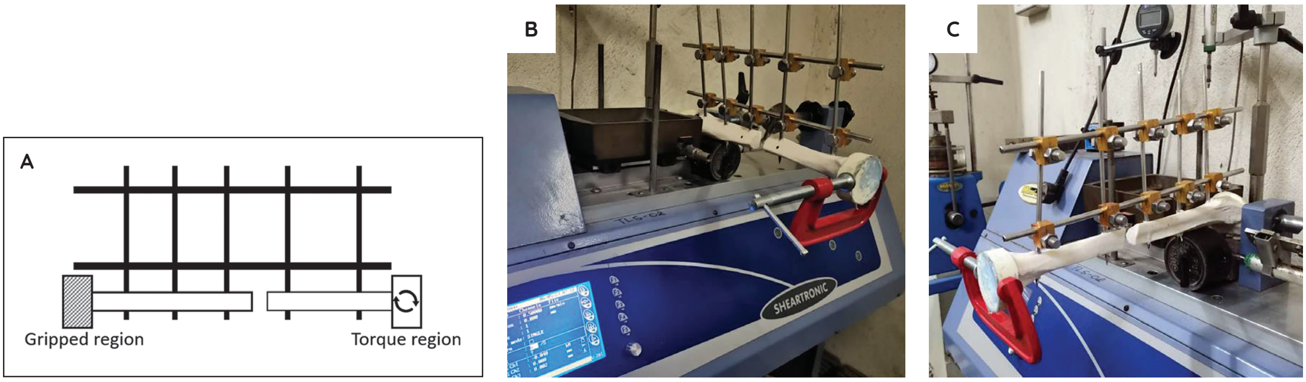

**Figure 6.** **(A)** Schematic test configuration for torsion test of an external fixator (adapted from ASTM F1541-17). Torsional stiffness test set-up **(B and C)**.

### Testing an all-new fixator construct with six Schanz pins

In the external fixator assembly described above, we inserted the sixth Schanz pin in between the pins of the distal fracture fragment. The same procedure was then performed for the axial compression test as described above (Figure 7). Results include axial stiffness and ultimate strength (Figure 4).

## RESULTS

The collected data (Table 1) were statistically analyzed using SPSS software. A one-way ANOVA test was chosen to determine significant differences between the means of the three independent groups. A $p<0.05$ was considered statistically significant. Post hoc testing was performed using the Tukey test, as applicable.

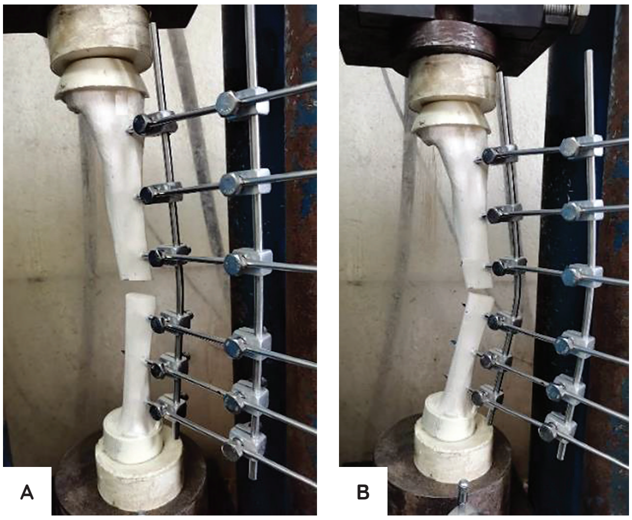

**Figure 7.** Axial compression test of the external fixator construct with 6 Schanz pins before **(A)** and after **(B)** the test.

The six Schanz pin construct ($n = 5$) was found to have greater stiffness ($p = 0.0028$) and strength ($p = 0.0002$) compared to its corresponding all-new five Schanz pin construct (Tables 2, 7 and 8).

## DISCUSSION

The stiffness of a fixation device is a principal determinant of interfragmentary movement, which has a significant effect on the mechanism and progression of fracture healing.[27-29] Excessive interfragmentary movement results in deficient callus formation, eventually leading to delayed union or even nonunion with ultimate implant failure.[27,30-32] Meanwhile, an external fixator with high strength can contribute to durable fixation to allow progressive functional training.[27,28]

The data showed that reused external fixator constructs are comparable to the all-new fixators in terms of stiffness and strength (Tables 3-5 and Figures 8-10). In torsion testing, previously used external fixators were even significantly superior to the all-new fixators in terms of torsional stiffness (Table 6 and Figure 11). The cause of this difference is uncertain.

The mean axial stiffness was very similar for the three constructs (Table 3 and Figure 8): all-new external fixators (102.4 N/mm), once-used external fixators (92.9 N/mm), and twice-used external fixators (85.7 N/mm). One-way ANOVA testing in all three groups demonstrated no significant difference ($p = 0.545$).

The mean bending stiffness was very similar for the three constructs (Table 5 and Figure 10): all-new external fixators (19.56 N/mm), previously used once external fixators (22.3 N/mm), and previously used twice external fixators (23.32 N/mm). One-way ANOVA testing in all three groups demonstrated no significant difference ($p = 0.145$).

**Table 1.** Test results for axial compression, four-point bending, and torsion testing of new versus previously used fixators

| Construct | Specimen | Axial stiffness (N/mm) | Bending stiffness (N/mm) | Torsional stiffness (N•m/degrees) | Ultimate strength (N) |
|---|---|---|---|---|---|
| *New external fixator* | 1 | 112.1 | 25.5 | 0.829 | 655.4 |
| | 2 | 85.3 | 20.8 | 0.738 | 587.0 |
| | 3 | 144.2 | 15.1 | 0.751 | 736.1 |
| | 4 | 98.2 | 20.1 | 0.711 | 547.2 |
| | 5 | 72.3 | 16.3 | 0.658 | 684.6 |
| *Previously used once external fixator* | 1 | 93.5 | 25.5 | 0.969 | 793.6 |
| | 2 | 123.2 | 24.6 | 0.973 | 694.6 |
| | 3 | 75.0 | 20.4 | 0.890 | 694.7 |
| | 4 | 88.5 | 21.3 | 0.895 | 512.4 |
| | 5 | 84.1 | 19.7 | 0.835 | 673.9 |
| *Previously used twice external fixator* | 1 | 68.6 | 21.7 | 0.908 | 617.7 |
| | 2 | 116.3 | 23.0 | 1.019 | 679.2 |
| | 3 | 94.4 | 23.8 | 1.064 | 640.9 |
| | 4 | 56.5 | 24.7 | 1.001 | 584.8 |
| | 5 | 92.8 | 23.4 | 1.019 | 758.5 |

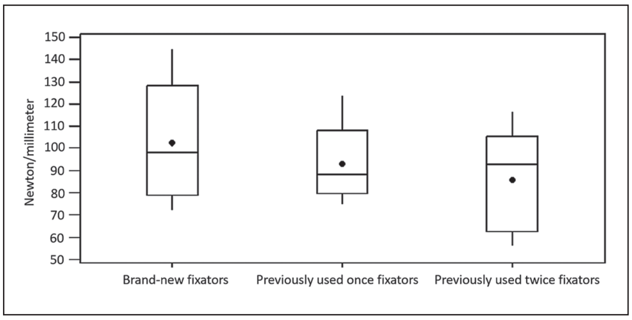

**Figure 8.** Box plot for axial compression stiffness (N/mm) testing showing no significant difference among the three constructs. Means are indicated by solid circles.

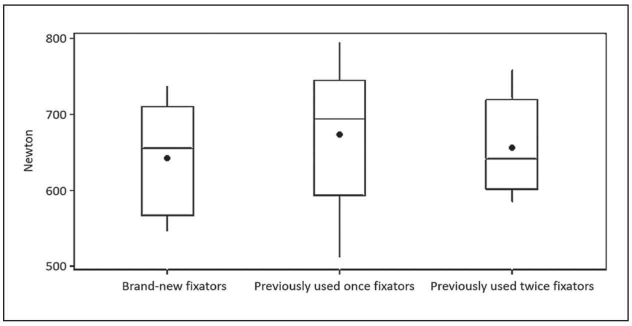

**Figure 9.** Box plot for axial compression strength (N) testing showing no significant difference among the three constructs. Means are indicated by solid circles.

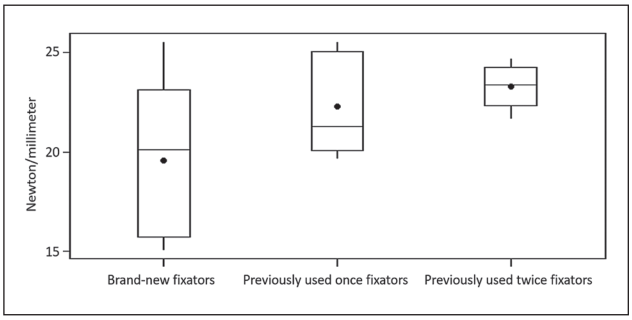

**Figure 10.** Box plot for four-point bend stiffness (N/mm) testing showing no significant difference among the three constructs. Means are indicated by solid circles.

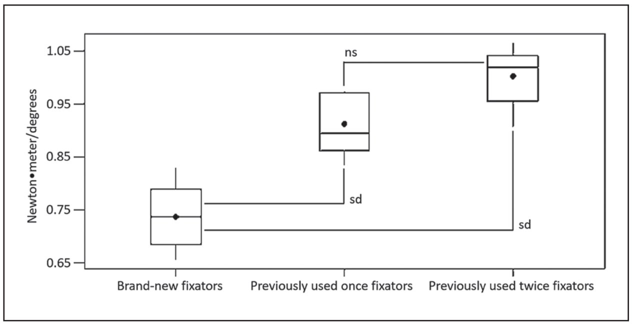

**Figure 11.** Box plot for torsional stiffness (N•m/deg) testing. Means are indicated by solid circles. ns indicates no significant difference. sd indicates a significant difference (p<0.0167).

There was a significant difference in mean torsional stiffness between new (0.7374 N•m/deg), previously used once (0.9124 N•m/deg), and previously used twice (1.0022 N•m/deg) fixators, as determined by one-way ANOVA. A Tukey post hoc test revealed that the torsional stiffness of the two groups of previously used external fixators were statistically higher than the new fixators ($p<0.0167$).

## Construct stiffness

The result of our experiment showed that new and previously used external fixator constructs were not significantly different in terms of axial and bending stiffness ($n = 15, p = 0.545$). New external fixator constructs were significantly less stiff than once- and twice-used external fixators in terms of torsional stiffness ($p<0.0167$).

The average axial stiffness of branded external fixators reported were: 469–528 N/mm,[33] 1157.8–1898.8 N/mm,[27] and 35–71.8 N/mm.[34] The average bending stiffness of branded external fixators reported in previous literature ranges from 15 to 26.7 Nm/deg.[27] The average torsional stiffness results of branded external fixators reported in previous literature are the following: 0.512–0.686 Nm/deg,[33] 1.3–3.0 Nm/deg,[27] and 0.8–1.8 Nm/deg.[34]

The stiffness values of our experiment in terms of axial stiffness, four-point bending stiffness, and torsional stiffness all fall within these ranges.

## Construct strength and failure mode

The ultimate strengths of all our constructs were not significantly different from each other. It ranges from a minimum of 512 N to 793 N with an average of about 650 N, comparable to a 65 kg person standing on one leg. The failure mode in our axial compression testing are the irrecoverable bending of Schanz pins, more prominent on the two distal

**Table 2.** Axial compression test results for 5 new external fixators using 6 Schanz pins

| Construct | Specimen | Axial stiffness (N/mm) | Ultimate strength (N) |
|---|---|---|---|
| ***New external fixators using 6 Schanz pins*** | 1 | 281.7 | 2460 |
| | 2 | 197.1 | 2350 |
| | 3 | 244.1 | 3020 |
| | 4 | 151.5 | 2240 |
| | 5 | 242.7 | 3260 |

pins, and the buckling of two longitudinal rods. All Schanz pin-bone interfaces were intact (no pin loosening) and there was no loosening of screw clamp or pin-rod connectors.

## Low-cost locally available uniplanar tibial external fixators

Branded tibia external fixators are costly and often not available in our locality. This experiment showed that our low-cost external fixators are mechanically sound and within the acceptable range in terms of axial stiffness, four-point bending stiffness, and torsional stiffness as compared to high-cost branded external fixators tested from other studies.[27,33,34]

However, our locally available external fixators have low axial compression strength with an average of only about 650 N versus some studies using expensive commercial external fixators with their ultimate strength to failure that ranges from 1769 N to 2792.2 N.[27]

## All-new fixators using five Schanz pins versus six Schanz pins

We also tested all-new external fixator constructs using six Schanz pins and compared them to the results from all-new external fixator constructs using five Schanz pins during axial compression testing. We copied the five Schanz pin external fixator assembly (Figure 3) and inserted the sixth Schanz pin between the pins of the distal fracture fragment (Figure 7).

After the test, careful examination of the fixators showed the same mode of failure in both constructs. The failure modes are the irrecoverable bending of Schanz pins and the buckling of two longitudinal rods or columns. There was

**Table 3.** One-way ANOVA (Axial compression test – tangent stiffness)

| Construct | Specimen | Axial stiffness (N/mm) | Mean | Standard deviation | *p* |
|---|---|---|---|---|---|
| *New external fixator* | 1 | 112.1 | 102.4 | 27.65 | 0.545 |
| | 2 | 85.3 | | | |
| | 3 | 144.2 | | | |
| | 4 | 98.2 | | | |
| | 5 | 72.3 | | | |
| *Previously used once external fixator* | 1 | 93.5 | 92.9 | 18.27 | |
| | 2 | 123.2 | | | |
| | 3 | 75.0 | | | |
| | 4 | 88.5 | | | |
| | 5 | 84.1 | | | |
| *Previously used twice external fixator* | 1 | 68.6 | 85.7 | 23.49 | |
| | 2 | 116.3 | | | |
| | 3 | 94.4 | | | |
| | 4 | 56.5 | | | |
| | 5 | 92.8 | | | |

**Table 4.** One-way ANOVA (Axial compression test – ultimate strength)

| Construct | Specimen | Ultimate strength (N) | Mean | Standard deviation | *p* |
|---|---|---|---|---|---|
| *New external fixator* | 1 | 655.4 | 642.06 | 75.60 | 0.833 |
| | 2 | 587.0 | | | |
| | 3 | 736.1 | | | |
| | 4 | 547.2 | | | |
| | 5 | 684.6 | | | |
| *Previously used once external fixator* | 1 | 793.6 | 673.84 | 101.58 | |
| | 2 | 694.6 | | | |
| | 3 | 694.7 | | | |
| | 4 | 512.4 | | | |
| | 5 | 673.9 | | | |
| *Previously used twice external fixator* | 1 | 617.7 | 656.22 | 66.72 | |
| | 2 | 679.2 | | | |
| | 3 | 640.9 | | | |
| | 4 | 584.8 | | | |
| | 5 | 758.5 | | | |

no pin-bone loosening and there was no loosening of screw clamp or pin-rod connectors. From Euler's column buckling theory, the stiffness of a component, not the strength of its materials, determines the load at which it buckles.[35] Increasing the number of Schanz pins increases construct stiffness. The critical load that causes the column to buckle is greater for the fixator with six Schanz pins versus five Schanz pins (Tables 7 and 8).

Constructs using six Schanz pins are significantly stiffer ($p$ = 0.0028) and stronger ($p$ = 0.0002) as compared to constructs using five Schanz pins ($p<0.05$) (Table 7). From the results of our study, if the average ultimate strength of constructs using five Schanz pins is about 650 N, a comparison to a 65 kg person standing on one leg, then the average ultimate strength of constructs using six Schanz pins is about 2500 N, a comparison to a 250 kg person standing on one leg. This proves our claim and the results of other studies that increasing the number of pins increases the construct stiffness and strength. In using six Schanz pins, our low-cost fixator's mean ultimate strength (2666 N) already matches that of other expensive commercial fixators with their ultimate strength to failure ranging from 1769 N to 2792.2 N.[27]

## LIMITATIONS

The following are the limitations of the study. First, we used a synthetic plastic polyvinyl chloride tibia bone instead of a fresh cadaver bone or a synthetic composite bone (sawbone). Despite the use of a plastic bone, there was no pin-to-bone loosening after testing which may have affected the result of the experiment. Second, static loading was done due to equipment unavailability and not cyclic load testing which more closely simulates multifaceted bone loading

**Table 5.** One-way ANOVA (Four-point bend test – bending stiffness)

| Construct | Specimen | Bending stiffness (N/mm) | Mean | Standard deviation | *p* |
|---|---|---|---|---|---|
| *New external fixator* | 1 | 25.5 | 19.56 | 4.11 | 0.145 |
| | 2 | 20.8 | | | |
| | 3 | 15.1 | | | |
| | 4 | 20.1 | | | |
| | 5 | 16.3 | | | |
| *Previously used once external fixator* | 1 | 25.5 | 22.3 | 2.59 | |
| | 2 | 24.6 | | | |
| | 3 | 20.4 | | | |
| | 4 | 21.3 | | | |
| | 5 | 19.7 | | | |
| *Previously used twice external fixator* | 1 | 21.7 | 23.32 | 1.10 | |
| | 2 | 23.0 | | | |
| | 3 | 23.8 | | | |
| | 4 | 24.7 | | | |
| | 5 | 23.4 | | | |

**Table 6.** One-way ANOVA (Torsion test – torsional stiffness)

| Construct | Specimen | Torsional stiffness (Nm/degrees) | Mean | Standard deviation | *p* |
|---|---|---|---|---|---|
| *New external fixator* | 1 | 0.829 | 0.7374 | 0.0624 | 0.0000469 |
| | 2 | 0.738 | | | |
| | 3 | 0.751 | | | |
| | 4 | 0.711 | | | |
| | 5 | 0.658 | | | |
| *Previously used once external fixator* | 1 | 0.969 | 0.9124 | 0.0585 | |
| | 2 | 0.973 | | | |
| | 3 | 0.890 | | | |
| | 4 | 0.895 | | | |
| | 5 | 0.835 | | | |
| *Previously used twice external fixator* | 1 | 0.908 | 1.0022 | 0.0576 | |
| | 2 | 1.019 | | | |
| | 3 | 1.064 | | | |
| | 4 | 1.001 | | | |
| | 5 | 1.019 | | | |

**Table 7.** T-test of all-new external fixators using five versus six Schanz pins (Axial compression test – tangent stiffness)

| Construct | Specimen | Axial stiffness (N/mm) | Mean | Standard deviation | *p* |
|---|---|---|---|---|---|
| *New external fixator using 5 pins* | 1 | 112.1 | 102.42 | 27.65 | 0.0028 |
| | 2 | 85.3 | | | |
| | 3 | 144.2 | | | |
| | 4 | 98.2 | | | |
| | 5 | 72.3 | | | |
| *New external fixator using 6 pins* | 1 | 281.7 | 223.42 | 50.15 | |
| | 2 | 197.1 | | | |
| | 3 | 244.1 | | | |
| | 4 | 151.5 | | | |
| | 5 | 242.7 | | | |

**Table 8.** T-test of all-new external fixators using five versus six Schanz pins (Axial compression test – ultimate strength)

| Construct | Specimen | Axial stiffness (N/mm) | Mean | Standard deviation | *p* |
|---|---|---|---|---|---|
| *New external fixator using 5 pins* | 1 | 655.4 | 642.06 | 75.60 | 0.0002 |
| | 2 | 587.0 | | | |
| | 3 | 736.1 | | | |
| | 4 | 547.2 | | | |
| | 5 | 684.6 | | | |
| *New external fixator using 6 pins* | 1 | 2460 | 2666.00 | 447.75 | |
| | 2 | 2350 | | | |
| | 3 | 3020 | | | |
| | 4 | 2240 | | | |
| | 5 | 3260 | | | |

patterns in vivo. Also, material testing of the exact metallic composition of our stainless steel was not performed.

## CONCLUSIONS

The study concludes that once- and twice-used low-cost, locally available uniplanar tibial external fixators have comparable mechanical strength to new fixators, in terms of axial stiffness, bending stiffness, and ultimate strength. Used fixators were superior in terms of torsional stiffness versus new fixators. Without compromising function, significant cost savings are possible when components are reused.

The study also concludes that in using new external fixators, increasing the number of pins from five Schanz pins to six Schanz pins increases the construct's axial stiffness two times and increases the construct's axial strength four times.

In low-resource countries where cost-saving is a priority, reusing non-implantable external fixator components up to two times is an acceptable option, provided no mechanical defects are seen on inspection. Since our low-cost, locally available constructs have less axial strength as compared to high-cost branded external fixators, we recommend using a total of six Schanz pins (three Schanz pins in each fracture segment) to increase construct strength and stiffness. In reusing components, processing should be standardized to include manual cleaning using liquid detergent and tap water, disinfection using liquid disinfectants such as povidone-iodine solution, and sterilization using heat and pressurized steam in an autoclave. Labeling used components (i.e., with a metal engraver) would help in tracking the number of uses.

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All authors certified fulfillment of ICMJE authorship criteria.

## AUTHORS DISCLOSURE

The authors declared no conflict of interest.

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