Assessment of Mechanical Properties of an Affordable External Fixator (AEFIX) Designed for Resource-Limited Settings

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Introduction: Over 15 million open fractures occur annually in low- and middle-income countries where safe and affordable surgical options remain largely unavailable. External fixation is an essential and versatile tool used for the temporary stabilization of open and unstable fractures, but it is not widely available in sub-Saharan Africa, with many hospitals relying on unsustainable donations. To address this critical need, we have developed a simple, reproducible, and affordable external fixator clamp (AEFIX), which allows for pin-to-rod or rod-to-rod connections. AEFIX costs just $5, compared to ~$500 for similar combination clamps used in the United States.

Methods: We developed a comprehensive testing methodology based on ASTM F1541-17 standards. This study had two primary objectives: first, to test the clamps independently to establish the reproducibility and generalizability of the findings based on ASTM standards (tests 1 - 4), and second, to evaluate the clamps' efficacy in stabilizing fractures during axial loading tests (tests 5 - 8). The clamps were integrated into a uniplanar frame configuration, mimicking the uniplanar external fixation of a simple femoral diaphysis fracture featuring a 4cm fracture gap. The goal of these studies was to mimic non-weight-bearing temporary fixation under physiologically comparable loading scenarios. The testing conditions consisted of Fixator-Pin and Connecting-Bar Slippage (tests 1 and 2), Fixator-Pin Rotation (test 3), Clamp Bolt Axis Pivot (test 4), Axial Loading Fatigue Tests (tests 5 to 7, 100 cycles of 100N, 300N, and 500N correspondingly) and Axial Static Load (700N load to deformation). The displacement-controlled Instron testing system was utilized for all experiments, and each test underwent preconditioning cycles to eliminate initial behavior. The preload cycles were tailored to the specific test type. The testing was carried out with 5mm Schanz pins and 11mm connecting rods. Anodized and non-anodized AEFIX clamps were evaluated alongside the high-end Stryker Hoffmann 3 clamps to determine their non-inferiority to commercially available clamps in the US market. A motion capture device was used to record interfragmentary distance during cycle testing. One-way ANOVA or the Kruskal-Wallis test (based on Shapiro-Wilk normality results) was used to assess force-deformation and interfragmentary data, followed by post-hoc comparisons. GraphPad software was used for data analysis. Two-tailed values of $p<0.05$ were considered statistically significant.

Results: For the Fixator-Pin and Connecting-Bar Slippage testing (tests 1 and 2), we discovered that AEFIX performed similarly to or even better than the market leader Stryker (test 1). Stryker clamps performed much better than AEFIX clamps in Fixator-Pin Rotation (test 3), Clamp Bolt Axis Pivot (test 4), and other components failed during those tests before any movement was observed within the Stryker clamps. However, when the clamps were employed in complete uniplanar assemblies, this relative rotational weakness was eliminated and the overall construct stiffness was comparable between AEFIX and Stryker. Up to 300N cycle loading (half body weight), both anodized and non-anodized AEFIX clamps performed similarly to Stryker clamps in maintaining the interfragmentary distance. Stryker, on the other hand, outperformed the non-anodized AEFIX at 500N cyclic loading ($p < 0.05$). Although statistically significant, the interfragmentary distance altered at most 4 to 6mm for the AEFIX clamps at 500N load, which is clinically inconsequential. Under axial static loading of 700N, discernible distinctions in construct stiffness among AEFIX, Anodized AEFIX, and Stryker were not observed. The similarity in the percentage alteration of interfragmentary distance was also evident across these three constructs. The yield force and the point of transition to plastic deformity consistently exceeded 400N for all constructs. Notably, Stryker exhibited superior performance compared to Anodized AEFIX ($p < 0.05$), though this difference was not evident when compared with non-anodized AEFIX.

Discussion: AEFIX is an affordable external fixation device with comparable strength to industry-standard devices. With the data observed from these tests, users will be able to safely stabilize fractures using AEFIX in preparation. Our hope is that AEFIX will improve the availability of essential trauma surgery in resource-limited settings and during humanitarian crises. Its development highlights the importance of surgical innovations that allow improved access to gold-standard treatments for low- and middle-income settings.

Clinical Significance: This study holds profound significance in addressing the critical gap in safe and affordable surgical solutions for open fractures prevalent in low- and middle-income countries. By demonstrating AEFIX's comparable strength and effectiveness through comprehensive mechanical testing, this research provides a foundation for enhancing trauma surgery accessibility in resource-constrained settings and humanitarian emergencies.