A new external ring fixator for limb reconstruction: a mechanical study.

Guillaume Bugnard1, Markus Behrens1, and Dr. Stefano Brianza1

1Stryker Trauma AG, Selzach, Switzerland

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Abstract

Background and purpose: The mechanical behavior of an external ring fixator has a direct influence on the bone healing process. In fact, the axial stiffness of the frame and the stability of its elements under repeated loading are essential to promote the bone healing process. In this study we aimed to compare the mechanical behavior of the Stryker Hoffmann LRF (Limb Reconstruction Frame) to two different configurations of the Smith and Nephew Ilizarov system.

Material and method: The axial stiffness was measured with quasi static loading on complete frames. The dynamic stability was assessed applying a cyclically increasing force on multiplanar connection elements, the ball joints and the conical washers. Finally, complete frames were tested dynamically under an angle of 15° to simulate the angularly scenario during walking.

Results: The Stryker Hoffmann LRF frame showed significantly higher stiffness than both Ilizarov frames under static loading. As multiplanar connecting elements, both ball joint and conical washer showed no slippage or rotation prior mechanical failure. Complete Hoffmann LRF frames showed higher number of cycles at failure compared to the Ilizarov frames.

Conclusion: The Hoffmann LRF frame showed higher axial stiffness with fewer components and a higher stability against permanent deformation under a repeated load than the Ilizarov system.

1 Introduction

Over the last decades circular ring fixators (CRF) have been widely used as external bone fixation devices, especially for fractures of lower extremities [1, 2, 3]. The various assembly possibilities allowed by the versatility of these systems permit treating different bone pathologies, but lead to complex frame configurations showing different mechanical behaviors. According to Watson et al.[4] the management of the interfragmentary motion (IFM) and the stability of the fixation for the duration of the treatment are essential conditions promoting bone fracture healing.

Aiming to meet these conditions, the Stryker Hoffmann LRF System features stiff rings and telescopic struts (Figure 1) that offer controlled axial dynamization if indicated. These struts are used to connect rings restrained to bone fragments and unload the bridged fracture. Their spherical joints allow the connection of non parallel rings as well as rings of different diameters. This feature also allows the surgeon to use the frame as a fracture reduction tool to acutely restore bone proper anatomic and mechanical alignment.

These dynamic frame features require special evaluation as they have a direct influence on frame stiffness and long term fatigue strength.

2 Purpose

In this study, the key properties of the H-LRF have been compared to those of the Ilizarov Ring Fixator (Smith & Nephew Inc., 7135 Goodlett Farms Parkway, Cordova, TN 38016, USA). Axial frame stiffness and resistance to cyclic loading have been investigated and compared between comparable frame components and constructs.

Our first goal was to investigate the axial stiffness on basic H-LRF and Ilizarov frames with no dynamization elements. Our hypothesis was that by using stiffer rings, the H-LRF frame would show statistically equal or higher axial stiffness than an equivalent Ilizarov frame.

Secondly, the dynamic behavior of the H-LRF struts was investigated. Our hypothesis was that the H-LRF ball joints can withstand a statistically equal or higher number of cycles than the Ilizarov conical washers when tested to slippage or to mechanical failure.

Lastly, complete frames were dynamically tested. It was expected to observe a higher number of cycles to failure for the H-LRF frames compared to the Ilizarov frames.
3 Material and method

3.1 Frame Stiffness Test

Basic constructs were chosen to test frame axial stiffness: (1) H-LRF frame featuring 180mm diameter carbon rings, (1) Ilizarov one ring frame featuring 180mm aluminum rings and (1) identical but double stacked ring Ilizarov frame (Figure 4). Three 6mm diameter threaded rods were used to connect the rings in all frames.

The constructs were loaded at a rate of 2mm per minute until 400N of force was obtained. During loading, the displacement and the corresponding force were recorded and the axial stiffness of the frame was calculated [5]. Six samples of each configuration were tested.

3.2 Component Dynamic Strength Test

The lizarov threaded rods and the H-LRF telescopic struts were fixed on a 155mm diameter aluminum ring. The aluminum rings were positioned on the testing machine with a 110mm lever arm between the center of the ring and the center of the actuator (Figure 2). The samples were then cyclically loaded in a stepwise increasing fashion until failure (Figure 3). Mechanical failure was defined as component fracture or 20° of component deflection of (40mm actuator displacement). Six samples of each configuration were tested.

After the dynamic test, the same alignment instrument used for the initial alignment of the H-LRF ball joint was used for a qualitative evaluation of the residual angulation.
3.3 Frame Dynamic Strength Test

A foot frame was dynamically tested with a 15° tilt (Figure 5) which simulates the worst loading condition applicable when the patient is walking with a rocker shoe [6], (6) Ilizarov and (8) LRF frames were tested.

A cyclical load (peak 600N, valley 60N) was applied on the frame at 3.5Hz frequency. This loading magnitude was chosen to allow for at least 100000 cycles before failure.

![Figure 5: Construct mounted at a 15° angle and held in place by the proximal ring. A cyclical load was applied to the distal foot ring through a slide bearing – universal joint assembly.]

3.4 Statistics

For statistical analysis, all relevant descriptive parameters for each group were identified to assess central position and spread. Due to the small sample sizes, the Mann-Whitney U-test with a Monte-Carlo simulation (10'000 runs) were used for the statistical comparison of the groups.

The survival rate was analyzed using the Kaplan-Meier method. The Breslow test was performed to compare the survival rates between the groups.

The significance level for all tests was 95% (α = 5%). All calculations were performed with the software package SPSS V.20.

4 Results

4.1 Frame Stiffness

The H-LRF axial frame stiffness was statistically significantly higher (Figure 6) than the Ilizarov double stacked ring configuration (p = 0.004) as well as the Ilizarov one-ring configuration (p = 0.002)[7]. The Ilizarov double stacked ring configuration showed also a statistically significantly higher stiffness than the Ilizarov one ring configuration (p = 0.011)[7].

![Figure 6: Axial stiffness of the three frames (force range of 6N to 400N). The H-LRF frame was stiffer than the Ilizarov one ring construct (p=0.002) and stiffer than the Ilizarov two ring (p=0.004) construct.]

4.2 Component Dynamic Strength

On average, the H-LRF component samples showed a higher number of survived cycles to failure compared to the Ilizarov samples. However, the difference was not statistically significant (p = 0.301). All the Ilizarov samples failed due to plastic deformation of the threaded rods. In all cases, the machine stopped testing when 20° of component deflection was achieved. All H-LRF samples failed due to fatigue fractures at the level of the strut shaft. No permanent angulation of the ball joints occurred.

Furthermore the survival rates of the LRF device was not statistically different compared to the Ilizarov device (p = 0.261 Figure 7)[7].
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4.3 Frame Dynamic Strength

With a mean number of 259323 cycles at failure (see results in figure 8), the H-LRF frames showed a statistically higher amount of cycles (p=0.009) than the Ilizarov frame that showed a mean number of cycles at failure of 113225 [6]. The survival rate of the LRF frame was statistically higher (p=0.002) than the Ilizarov frame (Figure 8).

5 Discussion

The static test setup showed that the H-LRF frame with carbon rings is stiffer than an equivalent Ilizarov frame featuring either one or two aluminum rings. This higher stability might be beneficial since with the HLRF system adequate frame stiffness can be reached using fewer parts.

The results of the component dynamic testing confirmed our hypothesis concerning the H-LRF ball joints: no slippage occurred. Furthermore the ball-jointed HLRF struts can withstand a comparable number of cycles before failure compared to the combination of conical washer and threaded rods of the Ilizarov system.

The test as described in section 3.2 focused solely on individual components. This approach is an acceptable means of comparing the mechanical performance of individual, isolated frame components - i.e. the HLRF ball-jointed telescopic struts and the conical washer/threaded rod strut assemblies. Although useful, this component-specific analysis cannot be used to compare overall construct performance. To close this gap a dynamic test with complete frames was conducted.

The frame dynamic test showed that the H-LRF assembly withstood a higher number of cycles before failure compared to the Ilizarov frames.

In conclusion, the present data shows that the HLRF system can offer a stiffer construct with fewer components compared to the Ilizarov system. Additionally, the aforementioned data supports that the HLRF construct is able to withstand a higher number of dynamic loading cycles compared to a comparable Ilizarov frame. Finally, the data also demonstrates that the telescopic struts ball-joint H-LRF is stable enough to adequately withstand the dynamic loads deployed on the frame during ambulation.
6 References


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