Stryker HOFFMANN Limb Reconstruction Frame and Smith & Nephew Ilizarov External Fixation Systems: a mechanical comparison between gradual correction frames.

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Abstract

Introduction: The Stryker Hoffmann Limb Reconstruction Frame (HLRF) system has been developed to treat a wide range of indications typically managed with circular external fixation systems, including acute static frame applications as well as gradual correction procedures. This paper will focus on the HLRF gradual correction components, including telescopic motor struts and hinged telescopic struts, which are designed to augment the HLRF platform to take on indications that require gradual corrective adjustments (ie. ankle equinus deformities). The purpose of this study was to compare the static and dynamic mechanical performances of the HLRF gradual correction frame to the predicate Smith & Nephew (S&N) Ilizarov gradual correction frame.

Material: Frame assemblies of either system were built on bone substitutes featuring once an anterior motor and once a posterior motor. Method: Samples were statically and dynamically loaded in axial compression using material testing machines. The parameter of interest for the static test was the assembly stiffness and for the dynamic tests the amount of cycles before failure within the applied staircase regime. Results: Both HLRF gradual correction frame configurations showed improved stiffness compared to the respective predicate S&N frames. During the dynamic staircase testing, the HLRF frames withstood at least the same amount of load cycles than the predicate S&N frames. Conclusion: This biomechanical study provides data for the in vitro static stiffness and long term dynamic strengths of the HLRF gradual correction system. It shows higher static stiffness and comparative long term dynamic strength with respect to the predicate S&N product tested under the same loading conditions.

1 Introduction

This paper will focus on the HLRF gradual correction components, including telescopic motor struts and hinged telescopic struts, which are designed to augment the HLRF platform to take on indications that may require gradual corrective adjustments (ie. ankle equinus deformities).

Hinged telescopic struts (Figure 1) are designed to align and pivot around a specified axis of rotation. This is accomplished via universal hinged couplings integrated into the telescopic strut’s design.

Telescopic motor struts (Figure 2) are used to drive corrective motion around the intended axis of rotation in a controlled, gradual fashion. The motors feature threaded attachment posts that allow them to be outfitted with either universal or constrained hinge couplings based on the indication. Telescopic motor struts can be mounted in a variety of ways as per the indication and surgeon preference.

Figure 1: Universal Hinged Telescopic Strut
The purpose of this study was to compare the static and dynamic mechanical performances of the HLRF gradual correction frame to the predicate Smith & Nephew (S&N) Ilizarov gradual correction frame.

The test set ups and load conditions were based on ASTM standards methods [1] and on published literature [2] [3]. All the tests have been performed at the Stryker biomechanical laboratory in Selzach. The full test description and results can be found in the Stryker Trauma AG report [4].

2 Materials & Methods

2.1 Sample preparation

All the components were pre-conditioned by means of washing and steam sterilization to reflect clinical condition of use.

2.2 Frame assembly

Five HLRF and five S&N gradual correction frames with an anteriorly placed motor were assembled on hollow carbon fiber cylinders used as bone substitutes (Figure 3).

Equivalent frames were assembled in order to perform repeatable and comparable measurements. The material was chosen in order to build frames assembled in worst case conditions:

- Largest available foot ring diameter of each system (Ø210mm for HLRF and Ø180mm for S&N) to maximize lever arm forces on the implants and components.
- The struts were set to their maximum possible length and the universal hinges were centered on the ankle joint’s virtual axis of rotation. In the S&N frame, threaded rods outfitted with universal hinges were used.
- HLRF long connection bolts and washers were used to attach the hinged telescopic struts to the foot ring at the maximum possible height offset.
- In order to transmit the highest loads and stresses to the frame components, the stiffest rings and pins of each system (carbon rings for HLRF and TSF aluminum rings for S&N, Ø6mm pins for both) were used.

Figure 2: One exemplary length of HLRF Telescopic Motor 1) (top) and assembled with universal hinge coupling (bottom)

1) Telescopic Motors are designed with a modern clicking mechanism that provides visual, audible, and tactile confirmation of a corrective adjustment.
Five Ø1.8mm wires were tensioned on the foot ring. One Ø1.8mm wire and two Ø6mm pins were fixated on both the distal and proximal full ring.

The nuts and screws were tightened with a calibrated torque wrench. The wires were tensioned to 1300N by using the system dedicated wire tensioners.

In addition, five similar HLRF and S&N gradual correction frames were built with a motor placed posteriorly (see Figure 4).

2.3 Test setup

The frame was built in a neutral fashion, simulating the frame geometry at the end of the gradual correction period. To simulate a frame used during ambulation, two modified aluminium foot rings were mounted below the frame’s foot ring to mimic the usage of the rocker shoe. In order to ensure that these additional rings did not contribute to the load sharing capabilities of the core frame, each ring was cut in half longitudinally (see Figure 5).

The frame was then turned upside down and rigidly fixed on the jack of the hydraulic testing machine (Figure 5). A 15° setup was designed in order to simulate the forces applied on the frame during walking with a rocker shoe. This angle represents the maximum angulation allowed by the HLRF rocker shoe.

A x-y table featuring a ball joint linked to the bone substitute tube was mounted on the baseplate of the testing machine. This setup allowed freedom of motion in all the directions except in compression/distraction, where the load was applied.

The tests were run on Schenck PSA (Schenck Trebel Corporation, USA) and MTS 858 Mini Bionix (MTS Systems Corporation, USA) hydraulic testing machines.

2.3.1 Static test

Prior to the dynamic testing a non-destructive stiffness measurement was performed applying an increasing axial compressive load within the elastic range of the construct. The construct stiffness was then calculated as the slope of the load-displacement curve.

The stiffness of the assemblies was statistically compared by using the nonparametric Mann-Whitney U test with Monte Carlo algorithm. The significance level was set to α=0.05.

2.3.2 Dynamic test

The dynamic test was run after completion of the static testing. It was designed to deploy a cyclical loading pattern where the peak force was increased in a stepwise approach (Figure 6 and Figure 8). The dynamic loads were applied under force control with 2 Hz sinusoidal wave form. The steps were based on results gained during pre-testing. The frames with the motor placed posteriorly showed a much higher
elasticity than the frames with anterior motors. This is why two different load profiles were defined (Figure 6).

The peak/valley ratio of the load cycles was set to 0.1. Each sample was tested until failure, which was defined as the rupture of any component or permanent deformation. To identify the initial deformation of the construct, the drift of the displacement curve was monitored and a deviation of 2 mm was defined as the stop criterion for the test. The maximum load at failure, the amount of load cycles, and the failure mode were recorded.

The quantity of load cycles of the HLRF and the predicate frames were compared with the statistical method described in section 2.3.1.

### Results

#### 3.1 Static testing

Both HLRF frame configurations (blue boxes) showed statistically significant higher stiffness (Figure 7) than the corresponding S&N frames (orange boxes). The median stiffness of the HLRF frame with the motor placed anteriorly as well as the HLRF frame with the motor placed posteriorly was +85% higher than the stiffness of the corresponding S&N frame.

![Graphical overview of frame testing with anterior motor](image)

**Figure 6:** Load step definition for the cyclic loading staircase test

![High-low plot of stiffness](image)

**Figure 7:** High-low plot of stiffness. The box represents the range of stiffness measurements. The circle within the box represents the median stiffness.

#### 3.2 Dynamic testing

##### 3.2.1 Frame with anterior motor

Both the HLRF and the S&N frame assemblies with anterior motor showed a breakage of the components connecting the foot ring with the distal full ring. In the HLRF frame assemblies the universal hinge strut broke while in the S&N frame assemblies the threaded rod experienced a breakage.

![Graphical overview of frame testing with anterior motor](image)

**Figure 8:** Graphical overview of frame testing with anterior motor
The HLRF assembly failures were grouped between the 8th (900N) and the 9th (1000N) load steps while the S&N assemblies showed a larger dispersion and spread between the 6th (700N) and the 10th load steps (1100N).

The statistical analysis showed no statistically significant difference (p = 0.145) for the number of cycles before failure for the HLRF frame with anterior motor compared to the respective predicate S&N frame (Figure 8).

### 3.2.2 Frame with posterior motor

All the HLRF frame assemblies with posterior motor passed the 11th load step (400N) without permanent deformation or breakage of any component. Three S&N assemblies were stopped due to a permanent deformation of the threaded rods, once during the 8th (370N) and twice during the 11th (400N) load step. One S&N assembly passed the 11th (400N) load step while another S&N assembly experienced a screw breakage at the level of the motor assembly during the 1st load step (300N).

The HLRF frame with posterior motor withstood at least the same amount of load cycles than the predicate S&N frame with posterior motor (Figure 9).

A statistical comparison of the number of cycles leading to frame failure was not performed since none of the HLRF test frames experienced a failure.

### 4 Discussion

The aim of this study was to assess the in vitro stiffness and strengths of the newly developed HLRF gradual correction frame components.

The static test showed that the HLRF gradual correction frame configurations are significantly stiffer than respective predicate S&N frames. The median stiffness of both HLRF frame configurations was +85% higher than the median stiffness of the corresponding S&N frames. During the dynamic staircase testing, the HLRF frames withstood at least the same amount of load cycles than the predicate S&N frames.

The tests have been performed on a very stiff bone substitute model by using the largest available pin diameter in order to maximize the stresses on the other system components. The design of these new external fixator components is therefore beneficial to increase the frame stiffness and strength as well as the long term dynamic strength.

This study has the following limitation. For verification purposes, the frames were built in minimal configurations combined with maximal loading. Nevertheless, for clinical usage, additional components to reinforce the frame shall be mounted before full weight bearing.

In addition the focus was set on two specific frame configurations. Although it may be expected that other frames built with the same components may show a similar trend in the results, this should be proven via biomechanical testing.
5 Conclusion

This biomechanical study provides data for the in vitro static stiffness and long term dynamic strength of the HLRF gradual correction system. It shows higher static stiffness and comparative long term dynamic strengths with respect to the predicate S&N product tested under the same loading conditions.

6 References


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