Can the Carbon Fiber Rods for the Hoffmann II External Fixation System Be Reused?

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Abstract

The Hoffman II External Fixator is the external fixation system used by the United States Army during Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF). To our knowledge, there have been no studies comparing the bending strength or stiffness of new to used or reprocessed rods. The purpose of our study was to determine if there was any difference in bending strength or stiffness of these rods.

Used rods were obtained from soldiers serving in OIF/OEF. The bending strength and stiffness of these rods was determined using 4-point bending. The location of rod failure was noted. Testing conditions simulated those utilized by the manufacturer for release of new rods.

There was no statistically significant difference in bending strength. There was a 6% difference in bending stiffness between new and used rods. Thirteen total used/refurbished rods broke at locations of previous clamping, the remainder breaking at one of the loading points on the testing jig.

The difference in bending stiffness among new, reprocessed, and used rods was only 6%. The clinical significance of this is unknown. There was no difference amongst the groups in bending strength.

Rods recovered from soldiers serving in OIF/OEF appear to be safe for reuse.

The Hoffmann II External Fixation System (Stryker Orthopaedics, Mahwah, New Jersey) is the external fixator that has been used by the United States Army during Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF). The manufacturer recommends that these components be used once only; however, our institution has begun sending used components to an outside facility for reprocessing. To our knowledge, no one has conducted a study to compare the bending strength or stiffness of new rods with that of used or reprocessed rods. We conducted a study to determine if new, used, and reprocessed 8-mm Hoffmann II carbon fiber rods differ in bending strength or stiffness.

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Materials and Methods

Six 8×300-mm unused carbon fiber rods (Stryker Orthopaedics) were tested according to the manufacturer's test protocol for validation of 8-mm Hoffmann II carbon fiber rods. Stryker specifies that 6 rods be used when analyzing a batch of new rods. We used 30 reprocessed 8×300-mm carbon fiber rods and 30 used rods removed from external fixators placed on soldiers during OIF/OEF. Our power analysis indicated that each group would require 30 rods to show a 12.5% decrease in strength, which Dr. Gerlinger deemed clinically significant. Used rods applied during OIF/OEF were collected from January through June 2006. Duration of use ranged from 5 to 42 days.

Rods were tested by applying 4-point bending loads in accordance with the Stryker test protocol. Deflection of each rod when 500 N of force was applied was recorded. These data were used to determine bending stiffness. For each rod, load to failure was recorded. Failure was defined as initiation of splintering or catastrophic failure of the rod. These data were used to determine bending strength. All testing was performed on a servohydraulic test system (Instron, Norwood, Massachusetts) in accordance with the Stryker test protocol. Data were collected with a computer and Labtech 10.1 software (Labtech, Andover, Massachusetts). The point on the rod where failure occured was recorded. Failure at the site of a prior clamp was recorded.

In this study, the independent variable was the rod (reprocessed, used), and the dependent variable was load to failure in kilonewtons (kN). The null hypothesis was that the rods would not differ in load to failure; the alternative hypothesis was that load to failure would be lower for the reprocessed rods and used rods. Estimated mean (SD) load to failure was 1.609 (0.062) kN for the new rods. A decrease of 12.5% in the reprocessed or used rods would be clinically significant. The appropriate test, 1-way analysis of variance (ANOVA), was followed by 1-tailed independent-sample *t* tests corrected for multiple comparisons.

The power analysis was performed with SPSS Sample

Table I. Bending Strength by Rod Type

		Bending Strength, kN	
Rod Type	n	Mean	SD
New	6	49.868	1.919
Reprocessed	30	50.426	2.075
Used	30	48.737	2.271

Table II. Bending Stiffness by Rod Type

		Bending Stiffness, kN^2	
Rod Type	n	Mean	SD
New	6	23.495	1.142
Reprocessed	30	22.217	1.214
Used	30	22.065	0.946

Power 2.0 (SPSS, IBM, Chicago, Illinois). A Bonferroni correction of $P = .05/2 = .025$ was applied. According to this method, the sample size is sufficient to detect a 1.29 SD effect size or a 5% difference in mean load to failure.

Results

There was a statistically significant difference in bending strength by rod on the ANOVA ($P = .013$) that was not supported by the post hoc Dunnett t test ($P>.05$). The largest difference was found between new and used rods, but this difference was only 2.2%. Table I lists bending strength values by rod type (new, reprocessed, used).

There was a statistically significant difference in bending stiffness by rod on the ANOVA ($P = .017$) that was supported by the post hoc Dunnett t test ($P = .008$, new vs reprocessed rods; $P = .018$, new vs used rods). The largest difference was between used and new rods, but this difference was only 6.1%. Table II lists bending stiffness values by rod type (new, reprocessed, used).

All 60 reprocessed and used rods had surface defects that correlated with points where clamps had been applied (Figure 1). Of the 28 rods that had clamp points within the loading zone of the jig, 13 failed at the clamp point, and the other 15 failed at the loading point on the jig (Figure 2).

Discussion

Several devices that are marketed as single-use are reprocessed for reuse in an effort to reduce the costs associated with medical care. Devices can be reprocessed by manufacturers, by independent reprocessing companies, or by the hospital itself. In the first 2 cases, hospitals buy back used equipment at up to half its original price. Hospitals rarely do the reprocessing themselves because of liability considerations.

Although several studies have been conducted on the biomechanical properties of used external fixators and on the savings associated with reuse,[1-7] none has been conducted on the biomechanical properties of the 8-mm carbon fiber rods used for the Hoffmann II external fixator. The United States Army uses this fixation system on the battlefield. The frames placed on United States soldiers are rarely the definitive form of management; once removed, the frames are sent out for reprocessing and reapplication. The reprocessing company mainly cleans the rods, and discards only those with gross surface defects or a permanently changed shape. The rods are then sold, at half their original price, back to our facility.

Studies of entire external fixator frame constructs[3-6] have shown them to be safe for reuse up to 3 times. To our knowledge, no published data exist on the bending strength and stiffness of reprocessed or used rods. Bending strength and stiffness are the parameters tested by the manufacturer before release. Our data showed a statistically significant difference ($P = .017$, 1-way ANOVA) in bending stiffness between new rods and rods reprocessed or taken directly from soldiers returning from OIF/OEF and cleaned at our facility. The difference in bending stiffness was 6%.

Arguments against reuse of external fixator parts include deformation and scoring caused by initial application, inability to uniformly reprocess components from different manufacturers, and liability associated with device failure.[8] In our study, the clamp marks were

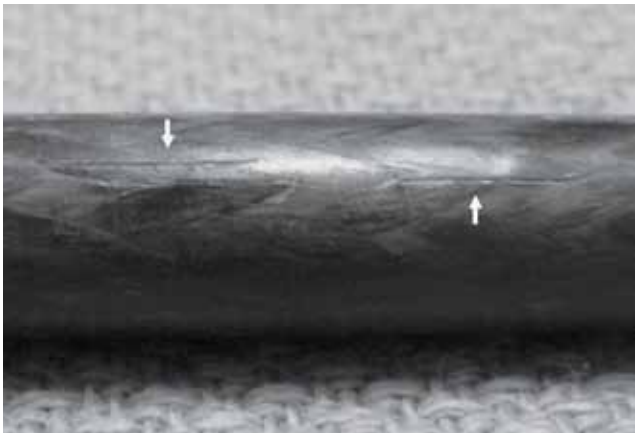

Figure 1. Clamp points on 8-mm rod.

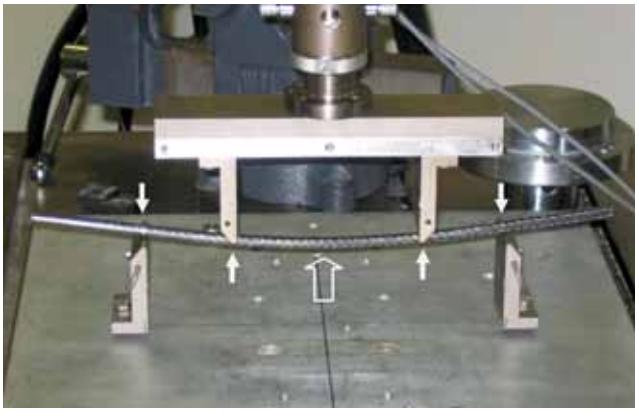

Figure 2. Loading points (solid arrows) and loading zone (open arrow) of loading jig.

not always the weakest points on the rods. Only half of the rods with clamp marks within the loading zone failed at these marks, and these loads were equivalent to failure loads associated with breakage of new rods. Regarding inability to uniformly reprocess components from different manufactures, in our clinical setting we use only a single product, which allows for a uniform reprocessing sequence. Liability is the major issue that prevents hospitals from reprocessing. However, new and reused external fixator systems evaluated as a whole have been found to have equal rates of complications.[1,2]

This study had limitations. The implants were tested to failure. This test did not simulate a clinical use as described by Matsuura and colleagues.[5] In addition, testing was performed only in bending. Torsional or axial strength and stability were not assessed. Further testing of rods may be necessary.

Our study was powered to detect a 12.5% decrement in bending strength and stiffness. The difference was far less than 12.5% and may not be clinically significant. In addition, our testing methods were based on the manufacturer's methods and were validated by the evaluation of new rods within our testing protocol.

Conclusion

Our results showed a 6% difference in bending stiffness among new, reprocessed, and used 8-mm carbon fiber rods used for the Hoffmann II external fixator. This difference may not be clinically significant. There was no statistically significant difference in bending strength. In addition, clamp marks did not weaken rods, and, for rods that failed at these points, the loads required were similar to those required to break new rods.

Given that the bending strength and stiffness of used rods were not significantly different from those advertised by the manufacturer for new rods, it appears that rods may be reused at least once. A potential weakness of the study is that fatigue strength was not measured and compared with that of new rods. Therefore, the safety of long-term application and subsequent reuse of a reused rod (third application, etc) is unknown. More studies are needed to determine how many times a carbon fiber rod can be safely reused.

Rods recovered from soldiers serving in OIF/OEF appear to be safe for at least a single reuse. Sending these rods to a third party for reprocessing appears unnecessary and costly. Unless there is a gross deficiency, these rods can be safely reused after appropriate cleaning and sterilization.

Authors' Disclosure Statement

The authors report no actual or potential conflict of interest in relation to this article.

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