

The Potential for Reuse of Ilizarov Composite Half-Rings

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Introduction: External fixation is used in the treatment of open fractures, in limb lengthening, and for situations where rapid fracture stabilization is required. The Ilizarov external fixation system [Smith-Nephew, Memphis, TN] typically uses two rings above and below the fracture site connected by four vertical rods. The rings stabilize the bone fragments and carry a significant portion of the patient's body weight. As the bone heals, the load carried by the Ilizarov system decreases until the bone callus carries nearly all of the weight-bearing forces. [1]

Currently, the Ilizarov Composite Half Rings are sold by the manufacturer as single-use devices. Given their high strength and resistance to fatigue, they could potentially be used for more than one patient in a safe and cost-effective manner. By reprocessing single-use devices, the savings for a hospital can be up to 50% if done by a third party reprocessor or up to 90% if done in-house [2]. To evaluate the potential savings available from reusing the Ilizarov Composite Half-Ring, the maximum number of times the half-rings can safely be reused must be determined by collecting cyclic loading data. The average patient uses these rings less than six months, which is less than 500,000 cycles [3]. Ilizarov Composite Half Rings cost \$575 - \$675 each, depending upon the hospital's volume. Each patient may require up to eight half-rings, so the potential for savings is evident. However, FDA regulations and liability issues must also be considered before reusing devices.

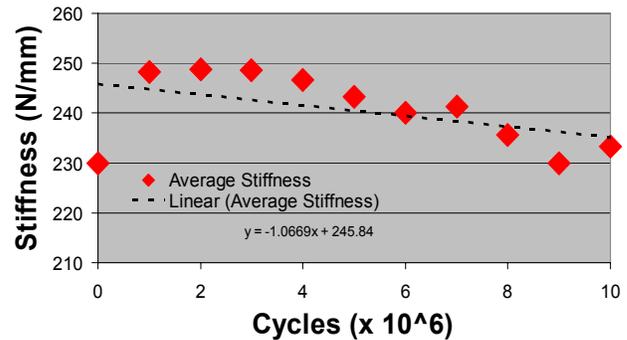
Methods: Six 160 mm diameter Ilizarov composite half-rings [Smith-Nephew, Memphis, TN] were cyclically loaded in 3-point cantilever bending (200-750 N) at 11.5 Hz (10^6 cycles/day) using a servohydraulic materials test frame [Bionix 858, MTS Corp., East Prairie, MN]. The half-ring's structural stiffness was measured every million cycles. (The half-rings were received used, so the amount of fatigue the half-rings experienced prior to the experiment is unknown.)

Results / Discussion: Structural properties were maintained up to 10 million cycles (equivalent to 20 patient uses) as long as no visible damage to the rings was evident. Even with damage evident on one ring, the 95% confidence interval showed no significant difference between the average stiffness values at zero and 10^7 cycles, with values of 229.89 ± 20.12 N/mm and 233.29 ± 68.88 N/mm, respectively.

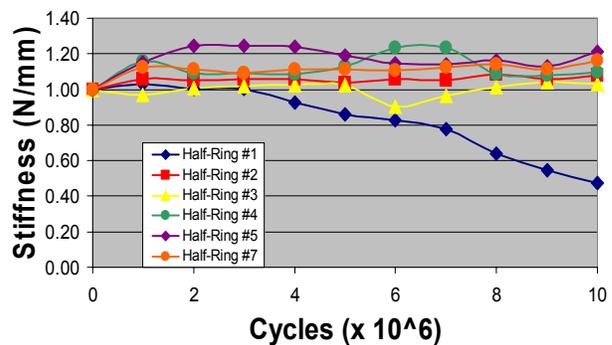
For half-ring #1, signs of failure – delamination on the compressive surface – were evident after 3 million cycles and its stiffness did decrease with continued loading. This demonstrates that damage is visible before significant loss of stiffness and suggests that the half-rings should not be used once damage is present. Since the half-rings are used for only a half million cycles, if the failure occurred during patient use, the stiffness values

would be maintained long enough for the patient to finish his or her treatment without adverse effects.

Average Stiffness Values



Normalized Stiffness Values



If 20 patients were treated with 8 new half-rings, each costing \$675, the total cost would be \$108,000. If these same 20 patients were treated by reusing the original 8 rings (estimating a reprocessed cost of \$337.50 (50%)), the total cost would be \$56,700. Thus, a savings of \$51,300 could be achieved if 20 patients were treated.

The reuse of single-use devices remains an underused option for healthcare savings. Current FDA regulations discuss this practice and liability issues present a serious concern. Reprocessing facilities are being developed to address these issues, but out-sourcing the reprocessing reduces the savings to the hospital or patients.

Conclusions: Ilizarov Composite Half-Rings can be safely reused, as long as care is taken to check the devices for visible defects prior to their placement on subsequent patients. Based on these results, the Ilizarov Composite Half-Rings can be reused up to 20 times without significant structural changes. Visual examination of each ring prior to reuse can prevent damaged rings from being reused.

References: 1. Shtarker H. CORR, 335:268-74, 1997.
2. Dunn D. AORNJ, 75:989-99, 2002.
3. Law MA. Trans. Soc. for Biomater., 21:410, 1998.