Carbon Fiber Reinforced PEEK Versus Titanium Tibial Intramedullary Nailing: A Preliminary Analysis and Results

E. Kathleen O'Pry, Robert M. Harris MD, Bruce H. Ziran MD FACS

Introduction

- Over the past several years, carbon fiber reinforced polyether ether ketone (CFR-PEEK) product has become available for fracture care. It has been used outside of the United States with success and recently its cost basis that makes it competitive with traditional metallic implants. There have been several studies demonstrating CF's efficacy and safety, but no studies that attempt to compare its performance with metallic implants.
- The beneficial clinical attributes of CF include a modulus of elasticity closer to bone than metal, fatigue strength that greatly surpasses that of metal as well as radio-lucency allowing better advanced imaging techniques without the "scatter" and obscuration seen in traditional metallic implants. This characteristic of CF is especially useful when associated injuries of the adjacent joints are suspected and MRI studies are used for injury verification and further evaluation.
- As noted previously, an attractive feature of CF for fracture care is the flexural modulus and fatigue properties. Theoretically, a modulus closer to bone with enhanced fatigue properties might affect bone healing. In our review of the current literature we have not identified any clinical studies that evaluate this concept nor any studies that compare the performance of CF versus metal in fractures.
- The current study evaluated the performance of CF and metal tibial nails in a longitudinal fashion using a single provider to reduce any technical bias.



Images of tibial fracture treated with CF nail. Injury and 16 week time points.

Methods

- Single surgeon, longitudinal cohort evaluated retrospectively comparing two time-periods.
- Inclusion criteria: Tibia fractures suitable for IM nailing
- Exclusion criteria: Peri-articular involvement
- Time period 1: Titanium nails
- Time period 2: CF nails
- Standardized treatment protocol followed.
- Total of 56 tibial fracture patients suitable for intramedullary nailing over 5-year period.
- Data: Standard demographic data: OTA fracture classification, fracture location, nail type.
- Images were reviewed by independent traumatologist.
- Outcome parameters: cumulative healing at standard time intervals (clinical and RUST score), infection/non-union, associated injuries, knee/ankle, barometric pain, hardware removal. Statistical analysis comparing incident healing was done using STATA 12.1 software for computation with a Nelson-Aalen Cumulative Hazard Analysis Curve and Two sample Wilson Rank Sum test.

Results

Patient populations were not statistically different regarding demographics, fracture type/location although there was a trend toward greater fracture severity/more associated injuries in CF group.

In 56 patients, 26 received CFN; 30 received TN

Healing rates reported at each time interval:

Weeks Healed	Titanium Healed	Carbon Fiber Healed
8 Weeks	0%	19%
12 Weeks	17%	69%
16 Weeks	57%	92%
20 Weeks	87%	96%
24 Weeks	97%	96%

(p<0.0001 every interval except 24 weeks)

Each group had one infected non-union in open fracture that healed with subsequent treatment.

Trend towards less barometric pain with CF that did not reach statistical significance (p=0.065).

No statistical differences with knee/ankle pain (p=0.109)/removal of hardware (p=0.269) potentially due to low power of pilot study.

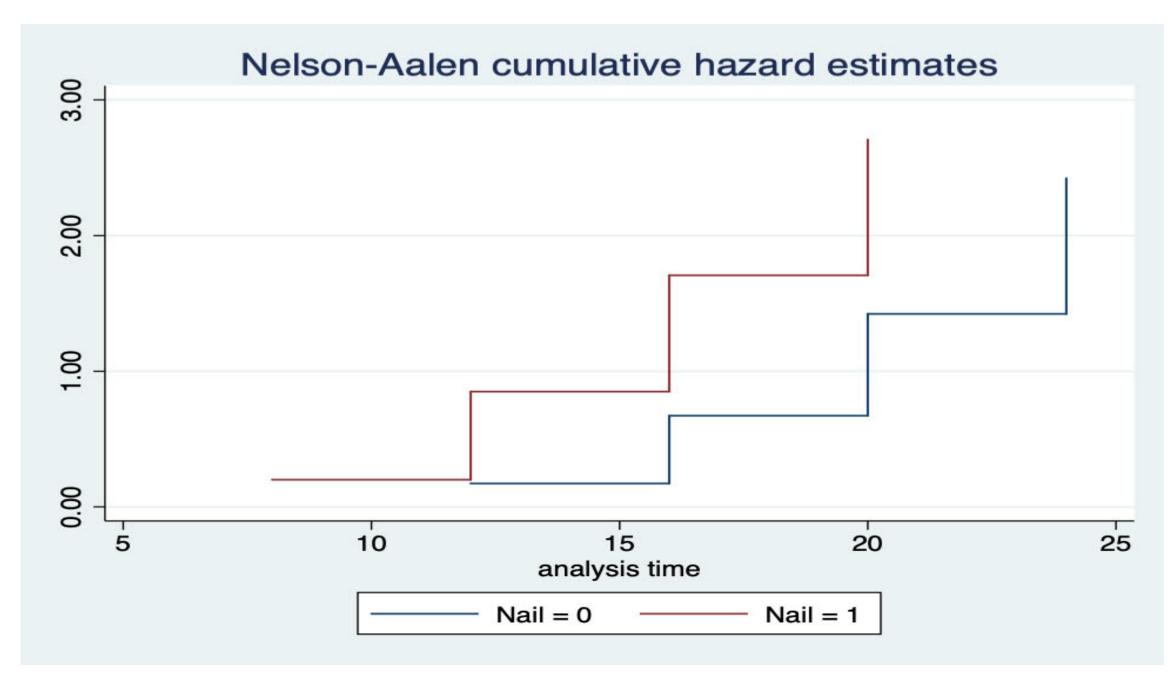
(1)Cantwell M, Wilson J, Lamoriniere S. Polyether Ether Ketone (PEEK) Carbon Fiber Composites May Improve Healing of Fractures Stabilized with Intramedullary Nails. Basic Science Focus Forum. Paper #4. 2014. 155.

Discussion

Historic healing times for tibial fractures ranges from 20-30 weeks. Our findings corroborate the reported results when metal implants were utilized but in this study, we found accelerated healing times with carbon fiber (CF) nails. The accelerated healing was characterized by a greater percentage of healed fractures at clinical evaluation time points. Since we kept indications, technique, and surgeon constant, the only different variable was implant type which demonstrated significant differences.

The enhanced healing rates found with the use of CF nails are most likely due to the biomechanical properties of CF that provides a "flexible but stable" construct. The lower modulus of elasticity with improved fatigue properties may provide a better healing environment, as corroborated with animal studies that demonstrated improved callus at shorter time intervals when CF and metal were compared. (1)

This study has the inherent limitations of being retrospective and without randomization. However, longitudinal studies in the same population and with a single technique provide some consistency that strengthen the findings. While other variables such as barometric pain are more subjective and did not reach statistical significance, there was a noticeable trend. Furthermore, the inherent advantages of radiolucency greatly improves image interpretation and allows for advance imaging (MRI, CT) without scatter artifact.



Nail 0 = Titanium; Nail 1 = Carbon Fiber

Conclusion

Using CFR-PEEK (CF) intramedullary nails for tibial fractures demonstrated accelerated healing times compared to titanium. We found that CF nails have advantages over titanium nails, most likely due to their material properties.

For additional information, please contact:

Bruce H. Ziran, MD FACS

Director of Orthopaedic Trauma

The Hughston Clinic at Gwinnett Medical Center

631 Professional Drive

Lawrenceville, GA 30046

Bruceziran1@gmail.com