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## Biomechanical Comparison of a Locking Compression Plate Combined With an Intramedullary Pin or a Polyetheretherketone Rod in a Cadaveric Canine Tibia Gap Model

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**Objective:** To compare the biomechanical properties of a 10-hole 3.5 mm locking compression plate (LCP) with 2 proximal and 2 distal bicortical locked screws reinforced with either a Steinmann pin of 30–40% the medullary diameter or a polyether-ether-ketone (PEEK) rod of ~75% the medullary diameter in a cadaveric tibia gap model.

Study Design: Ex vivo study.

**Sample Population:** Cadaveric canine tibias (n = 8 pair).

**Methods:** Each construct had a 10-hole 3.5 mm LCP with 2 screws per fracture fragment using a comminuted tibia gap model. The Steinmann pin constructs had a 2.4 mm intramedullary pin whereas the PEEK-rod constructs had a 6 mm intramedullary PEEK rod placed. Biomechanical testing included non-destructive bi-planar 4-point bending, torsion testing, and destructive axial compression. Testing produced the responses of failure load (N) in axial compression, stiffness (N/mm or N/°) in axial compression, torsion, lateral-medial and caudal-cranial 4 point bending. Screw position within the PEEK-rods was determined after explanation.

**Results:** The PEEK-rod constructs were significantly stiffer in axial compression (P < .005), lateral-medial 4 point bending (P < .001) and in torsional loading (P < .031) than the Steinman pin constructs. There was no significant difference between the constructs for stiffness in caudal-cranial 4 point bending (P = .32). The PEEK-rod constructs failed at a significantly higher load than the Steinmann pin constructs (P < .001). All constructs failed by yielding through plastic deformation. Each screw penetrated the PEEK rod in all constructs but the position of the screw varied.

**Conclusion:** PEEK-rod constructs failed at significantly higher loads and were significantly stiffer in 4 point lateral-medial bending, axial compression and torsion when compared with Steinmann pin constructs.

46 Bridge plating with or without the addition of an intra-47 medullary pin (Steinmann pin) can be performed while 48 adhering to the principles of biological osteosynthesis.<sup>1,2</sup> 49 The addition of an intramedullary pin to a bone plate to produce 50 a plate-rod construct has been shown to significantly reduce 51 plate strain, with a reported 10-fold increase in fatigue life 52 compared to a bone plate alone during *in vitro* modeling.<sup>3,4</sup> An 53 intramedullary pin can be placed with minimal disruption of 54 the fracture soft tissue envelope, can aid spatial alignment of 55 fracture fragments by indirect fracture reduction and can be

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strategically removed postoperatively to dynamize the repair which may promote fracture healing.  $^{1,2,5}\!$ 

One of the limitations of intramedullary pin placement in plate-rod constructs is that bicortical screw placement is not always possible.<sup>6</sup> This is a particular problem in the distal third of the canine tibia where the narrow cylindrical shape forces the plate to lay directly over the center of the medullary canal, making offsetting the screws difficult. The use of locked screws with locking compression plates (LCP) prohibits angling of the screws around an intramedullary pin.

Because of these limitations in application of locked LCProd constructs in the tibia, we tested a novel rod made of polyether-ether-ketone (PEEK) that allows screw placement

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directly through the rod. PEEK is an inert polymer that has been increasingly used as a biomaterial for trauma, and orthopedic and spinal implants in human surgery.<sup>7</sup> There is considerable scientific evidence to support the biocompatibility of PEEK, which is well tolerated in biological applications, has no known carcinogenic properties and exhibits a lack of cellular toxicity.<sup>8–10</sup>

Our purpose was to compare the biomechanical properties of a common construct (10 hole 3.5 mm LCP with 2 proximal and 2 distal bicortical locked screws) reinforced with either a Steinmann pin of 30–40% the medullary diameter or a PEEK rod of ~75% the medullary diameter in a cadaveric tibia gap model. We hypothesized that the PEEK-rod constructs would have a higher stiffness compared with the Steinmann pin constructs in bending, compression, and torsion. Furthermore, we hypothesized that the PEEK-rod constructs would fail at a higher load than the Steinmann pin constructs.

### MATERIALS AND METHODS

Sample size estimation was made based on previous work that also used an *ex vivo* tibia gap model and similar testing methods. In that study,<sup>11,12</sup> effect sizes of up to 2.7 were noted. Assuming a more conservative effect size of 2 (difference in means/standard deviation), with  $\alpha$  set at 0.05, and power at 0.80, a sample size of 5 per treatment in a paired design would be sufficient to detect this effect. A more liberal sample size of 8 per treatment would detect effect sizes as small as 1.5 and was selected for this study.

#### Specimen Collection and Preparation

Paired tibiae were harvested from 8 skeletally mature greyhounds (mean and median weight 28.8 kg; range, 25.9-30.0 kg) that were euthanatized for reasons unrelated to this study and under approval from the Murdoch University Animal Ethics Committee The age, sex and bodyweight of each dog were recorded (4 entire males, 4 entire females; mean and median age 3.0 years; range, 1.5-4.5 years). Each tibia was stripped of all soft tissues and the adjacent fibula removed within 6 hours of euthanasia. The bone was wrapped in several layers of saline-soaked (0.9% NaCl solution) gauze sponges and stored in airtight bags at  $-20^{\circ}$ C before use.

Tibias were thawed at room temperature and kept moist with frequent saline solution irrigation throughout preparation and testing. Some specimens underwent testing over 2 different days during which they were re-frozen and thawed for use according to the above method. No tibia underwent more than 2 freeze-thaw cycles in the study.

Each tibia was examined, and cranial-caudal and medial-lateral radiographs were obtained to confirm skeletal maturity and the absence of gross pathology. From the radiographs, tibia length and the cortical and medullary diameter at the isthmus was recorded to ensure that the cadaveric bones were appropriately sized for the implants used in this study.

#### Implant Placement

Paired tibias were numerically assigned (Dogs 1–8) as they were used. Left and right tibias of each pair were randomly assigned to either the PEEK-rod or Steinmann pin construct based on a random table sequence. A 10 mm mid-diaphyseal ostectomy was performed to create a fracture gap model in all tibias.

For the PEEK-rod construct, a 6.5 mm drill bit was used to create a pilot hole in the proximal tibia midway between the tibial tuberosity and the intermeniscal ligament on the craniomedial aspect of the tibia, in the same position as described for intramedullary nail placement.<sup>13</sup> Normograde placement of a blunt-tipped 6 mm diameter PEEK rod (Ketron PEEK 1000, Quadrant EPP, Belgium, NV; Fig 1) was made through the pilot hole with a mallet until it was seated in the distal metaphysis based on both sensory feedback during placement and reference to an equivalent length rod outside of the bone. PEEK rods had a stainless steel pin placed into the central tip of the rod for radiographic determination of rod position.

A 10 hole 3.5 mm LCP (Vet LCP, Synthes GmbH, Oberdorf, Switzerland) was then applied to the medial aspect of the tibia, aligned such that the mid-point between hole 5 and 6 overlay the center of the ostectomy. Screw holes were numbered 1–10 from proximal to distal. In all plate applications, the stacked combi hole was located distally. Plate contouring was not performed. Plate standoff distance was standardized at 1 mm both proximally and distally using temporary aluminum spacers. Four bicortical 3.5 mm selftapping locking screws (Veterinary locking screw stardrive, Synthes GmbH) were placed in holes 1, 4, 7, and 10 adhering to standard AO/ASIF technique with the exception that the drill and screws engaged the PEEK rod during screw placement. Insertion torque was limited to 1.5 Nm (1.5 Nm torque limiter, Synthes GmbH).

For the Steinmann pin construct, the LCP plate was applied as for the PEEK-rod construct. A 2.4 mm diameter Steinmann pin was subsequently inserted with a powered drill (Makita 18V Cordless Drill, Makita Corporation, Anjo-City, Japan) in a proximal normograde direction<sup>14</sup> and seated in the distal tibial metaphysis.

All implants were applied by a single board-certified surgeon (MG). Both ends of all samples were potted into



Figure 1 Intramedullary implant types: (A) 2.4 mm Steinmann pin; (B) 6 mm poly-ether-ether-ketone rod with a  $(B_1)$  modified tip photographed end-on.

rectangular blocks with poly-methyl-methacrylate (Vertex SELF CURE, Henry Schein, Duisburg, Germany) and subsequently placed into custom test fittings.

### Mechanical Testing

Bending and axial testing were performed (Instron 5848, Instron, High Wycombe, UK) with a 2 kN load cell (Instron 2530-418 static load cell, Instron). Torsion testing was performed with an Instron 8800 and a 1 kN/25 Nm biaxial load cell (Instron 2527-203 Bi-axial dynacell). Control and all data were collected using software (Bluehill v2.5.391 software; Instron Canton,  $MA^{Q2}$ ) sampling at 10 Hz.

Non-destructive 4-point bending was performed in 2 planes. Constructs were initially tested in lateral-medial bending and then rotated 90° for caudal-cranial bending. Each sample was loaded at 10 mm/min up to a load of 380 N to produce a peak bending moment of 6 Nm. Two bending cycles were performed in each plane with stiffness determined from the 2nd cycle. Each plate was manually centered on a 4 point loading apparatus with a 426 mm outer span and a 300 mm inner span. Bending stiffness was automatically determined based on the maximum slope of the linear portion of the loaddeformation curve between 5 and 380 N. Each force-displacement curve had a consistent linearly elastic slope (see Fig 2).

Non-destructive torsion testing was performed on the Instron 8800 at 3 Nm/s between 0.5 Nm to 1.6 Nm for 4 cycles. Torsional resistance (N/ $^{\circ}$ ) was determined from the average of



Figure 2 Force-displacement graph during bi-planar 4 point bending for (A) a representative PEEK-rod construct (B) a representative Steinmann pin construct. Two cycles of bending was performed in each plane.

the maximal slope of the linear elastic portion of the 2nd, 3rd, and 4th torque displacement curves, based on pilot studies.

Axial compression testing was performed on the Instron 5848 at 6 mm/min with failure (N) defined as the yield point or displacement to 15 mm. Samples were constrained in axial alignment but unconstrained with respect to torsion or bending. Axial stiffness was determined from the mean maximal slope of the linear elastic portion of the load displacement curve.

All constructs were inspected grossly between tests for any changes in position or appearance, and orthogonal radiographs were obtained after failure (Fig 3). All implants were removed after testing and screw position within the PEEK rod was observed. Screws were recorded as completely penetrating the PEEK rod if there was intact PEEK either side of the screw hole or partially penetrating when there was no intact column of PEEK on one side of the hole.

Testing produced the responses of failure load (N) in axial compression and stiffness (N/mm or N/ $^{\circ}$ ) in axial compression, torsion, lateral-medial and caudal-cranial 4 point bending which were used for hypothesis testing in statistical analysis.

#### Statistical Analysis

The failure load and the 4 stiffness measures were all found to follow a normal distribution verified by failure to reject the null hypothesis of normality using the Shapiro–Wilk statistic set at  $P \leq .05$ . Each response was tested for a fixed effect of construct (PEEK-rod versus Steinman pin) using a mixed effect linear model which included the fixed effect of construct random variance of dog across treatments. Significance for the effect of construct was set at  $P \leq .05$ . The mean and 95% confidence intervals are reported.



**Figure 3** Orthogonal radiographs after implant testing demonstrating the Steinmann pin (A) and PEEK (B) constructs. A stainless steel pin is inserted in the distal end of the PEEK to aid radiographic identification.



Figure 4 Force-displacement graph during single cycle axial compression to failure for (A) a representative PEEK-rod construct (B) a representative Steinmann pin construct. The failure point (f) was detected at the maximum load reached.

The distribution of screw penetration (complete or partial) in the PEEK rod was tested for homogeneity across screw holes (1, 4, 7, 10) controlling for dog, and across dog controlling for screw hole, using Cochran–Mantel–Haenszel methods. The null hypothesis of homogeneity was rejected at  $P \le .05$ .

Statistical analysis was performed using software (SAS 9.3 [PROC UNIVARIATE, PROC MIXED, PROC FREQ]; SAS Institute, Cary, NC).

## RESULTS

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All 16 tibiae were confirmed to be skeletally mature and free of gross or radiographic abnormalities. PEEK-rod constructs were significantly stiffer in axial compression (P < .005; Fig 4), lateral-medial 4 point bending (P < .001; Fig 2) and in torsion (P < .031) than the Steinman pin constructs (Table 1). There was no significant difference between the stiffness of the

constructs in caudal-cranial 4 point bending (P = .32; Table 1). PEEK-rod constructs failed at a significantly higher load than the Steinmann pin constructs (P < .001; Table 1). Failure occurred by reaching the yield point of the force-displacement curve in all tests (Fig 4). All constructs failed through plastic deformation of the fixation, with no screw failure or bone fracture observed grossly or on radiographs.

The diameter of the PEEK rod measured between 56% and 90% (mean and median, 75%) of the medullary width at the isthmus of the tibia whereas the Steinmann pin measured between 28% and 35% (mean and median, 31%). The PEEK rod and the Steinmann pin extended to the distal tibia metaphysis in all tibiae except for one where the PEEK rod only extended immediately distal to the end of the plate. The Steinmann pin coursed caudally to each screw as it passed through the medulla except for one construct where the pin deviated cranially to the most distal screw.

Each screw penetrated the PEEK rod in all constructs but the position of the screw varied (Fig 5) with complete penetration in 70/80 screws and partial penetration in 10/80 screws. Screw 4 was the most inconsistent with partial penetration in 4/8 tibias. Screw seven had partial penetration in 2/8 tibias. Screws 1 and 10 had partial penetration in 1/8 tibias each. There was no significant heterogeneity of screw placement across holes, controlling for dog (P=.31), or across dogs, controlling for holes (P=.614).

## DISCUSSION

As hypothesized, the PEEK-rod constructs were significantly stiffer in 4 point lateral-medial bending, axial compression, and torsion. Testing confirmed PEEK-rod constructs failed at significantly higher loads when compared with Steinmann pin constructs. These results can be explained by the support afforded by the thicker PEEK rod and the impact of screw contact with the PEEK. No significant difference in construct stiffness during 4 point caudal-cranial bending was identified. This may be explained by the much higher bending stiffness of the plate in this plane which dominates the stiffness of the construct and masks any small variation because of the rod.

Whereas intuitively a larger rod should result in increased stiffness, the effect of this size difference is reduced by the difference in material properties between the PEEK and stainless steel rods. The stiffness of a cylinder is proportional to the modulus of elasticity (a material property) and the radius raised to the fourth power (a geometric property). For these

 Table 1
 Mean (95%CI) Stiffness and Failure Load of 8 Paired Canine Tibia With a Mid-Diaphyseal 10 mm Ostectomy Stabilized With a 3.5 mm Locking

 Compression Plate and a 6 mm Intramedullary PEEK-Rod or 2.4 mm Intramedullary Steinmann pin

Construct	Lateral-Medial Bending Stiffness (N/mm)	Caudal-Cranial Bending Stiffness (N/mm)	Torsional Stiffness (Nm/°)	Axial Stiffness (N/mm)	Failure (N)
PEEK-rod construct	567 (518–616)	763 (714–812)	0.532 (0.487–0.577)	604 (501–707)	1202 (1046–1358)
Steinmann pin construct	349 (272-425)	737 (705–769)	0.464 (0.415-0.513)	260 (88–433)	361 (334–387)
<i>P</i> -Value	<.001	.32	<.031	<.001	<.001



**Figure 5** Screw penetration through the PEEK-rod: (A) Central penetration (complete); (B) off-central penetration (complete); and (C) partial penetration.

sizes and materials the PEEK rod is  $\sim 1.56$  times stiffer than the Steinmann pin; much less than the geometry alone would suggest.<sup>15,16</sup> The larger diameter PEEK rod may have provided a greater surface area for endosteal contact enhancing the effect of friction in increasing stiffness, although the extent of this contact effect was not examined. We used the largest commercially available PEEK rod that would fit in all tested specimens based on recommendations made for interlocking nail placement.<sup>17</sup> The larger diameter PEEK rod confers the mechanical advantage of increasing stiffness and the increasing likilihood of complete screw penetration without interfering with plate placement. It is possible that an implant of this size may be challenging to insert clinically and cause biological damage during placement. However our experience in the tested cadaver tibias from greyhounds weighing between 25.9 and 30 kg is that placement of a 6 mm PEEK rod is possible without causing articular damage. Because we did not test varying size PEEK rods, we are unable to make recommendations about changing rod size on mechanical behavior.

Steinmann pin size was selected to satisfy published recommendations to fill between 30-40% of the medullary cavity in plate-rod placement.<sup>3</sup> We did not use a larger sized Steinmann pin because of concerns over failing to consistently place bicortical locked screws. Implant size was not varied between samples to reduce study variability. The decision to place the Steinmann pin after plate application reflects our concern of interference by the intramedullary implant during placement of the fixed angle screws. We considered this necessary to ensure that each screw was bicortical and aligned perpendicularly to the plate. It is possible that the order of 52 implant placement caused bending of the pin which may have 53 influenced the results but we believe this variation was 54 minimal. The course of the Steinmann pin was documented to 55 be caudal to every screw in all but one construct, where it 56 deviated cranially to the most distal screw.

57 Screw interference with the PEEK rod likely had a 58 positive effect on stiffness. By shortening the working moment arm acting on the rod through either fixation with a screw or screw impingement of the rod against the medullary canal endosteum we expected an increase in axial, bending, and torsional stiffness. An increase in the torsional rigidity of a locked intramedullary implant because of a reduced working length has been reported.  $^{18,19}$  Dejardin showed an increase in axial and torsional resistance of a locked intramedullary implant over a loosely engaged intramedullary nail.<sup>20</sup> Whereas some screw thread interference likely occurred in the Steinmann pin constructs, we consider this was unlikely to be of the same magnitude as in the PEEK-rod constructs and more likely represents a situation similar to a loosely locked intramedullary nail as described by Dejardin et al.<sup>20</sup> Screws engaged in the PEEK during insertion by cutting a thread which produced a locked fit. This may further contribute to improving the mechanical properties of the resultant construct but this was not specifically evaluated.

Neither dog to dog, nor screw hole location significantly affected the screw penetration; however, large variations are required to meet the criteria for significance in this analysis. Partial penetration of the PEEK rod was more frequent at screw 4 (4/8 screws). This is likely because of the natural recurvatum of the tibia at this position which results in the plate sitting slightly cranial on the tibia and therefore the medullary canal slightly caudal to the plate. Provided that the sum of the screw diameter and the rod diameter exceed the bone diameter at the level of screw insertion, some degree of screw interference will occur. Complete penetration of the PEEK rod was missed only once in screw 1, despite the wide flare of the tibial crest at this level. This is a consequence of the caudal course of the medullary canal and corresponding caudal position of the plate at this screw position. It is difficult to predict whether or not incomplete PEEK penetration is likely to have an effect clinically and further work would be necessary to investigate this. All of the PEEK rods were retrieved intact from the tested bones without fracturing through the drilled holes.

Stiffness testing in lateral-medial 4 point bending, torsion and compression was performed in line with previous biomechanical assessments of plate-rod designs.<sup>21</sup> Ålthough caudal-cranial bending is an unlikely mode of failure in the canine tibia with a medially positioned bone plate, we tested this based on previous evidence that interlocking nail constructs are more compliant in this plane.<sup>22</sup> Whereas the PEEK-rod construct differs significantly from an interlocking nail, it does share the presence of an implant passing through the rod reducing its area moment of inertia at the hole.<sup>15</sup> The failure to find a significant difference in caudal-cranial 4 point bending most likely reflects the much greater contribution of the plate to overall construct stiffness in this plane. The plate width, which is almost 3 times its depth,<sup>23</sup> is parallel to the load in this plane, whereas in lateral-medial bending, the plate is loaded across its depth. As the stiffness of a rectangular section is proportional to depth cubed, <sup>15</sup> the plate is  $\sim$ 27 times stiffer in this orientation. It is likely that the plate resisted most of the load in caudal-cranial bending without either intramedullary implant becoming engaged against the endosteal surface. Further work would be needed to determine whether PEEK-rod constructs are "too stiff" to promote optimum conditions for fracture union.

The load to failure that a construct must resist clinically is unknown. The load ranges we used were based on previous work.<sup>11</sup> In both lateral-medial and caudal-cranial bending, a peak bending moment of 6 Nm was chosen to remain within the elastic limits of the LCP, based on previous work which found the 3.5 mm LCP failed at 11.5 Nm in bending.<sup>23</sup> As the torque around the canine tibia during ambulation is unknown, 1.6 Nm was chosen as this is the maximum torsional moment about the femoral shaft in 25–35 kg dogs in the middle of a stance phase.<sup>24</sup> The torsional load of 1.6 Nm also remains below the maximum failure torque  $(13.9 \pm 0.07 \text{ Nm})$  for tibias from medium-sized canine cadavers, confirming we would not fracture the tibias during testing.<sup>25</sup>

Failure was produced under displacement control rather than load control to avoid unpredictable, catastrophic, implant failure in the laboratory setting. Peak vertical forces in pelvic limbs of normal dogs have been estimated up to 50% of body weight at a walk and 107% at a trot.<sup>26,27</sup> The mean body mass of these greyhound cadavers was 28.8 kg, which corresponds to an estimated walking load of 141 N and a trot load of 300 N. The 95% CI of the mean failure load for the Steinmann pin construct (334-387 N) only slightly exceeds this estimate whereas the failure load for the PEEK-rod construct (1046-1358 N) far exceeds this. Goh found the mean failure load in axial compression for a 11 hole 3.5 mm semi-contoured LCP with 4 monocortical locked screws per fracture fragment and a 40% diameter intramedullary pin in a cadaveric femoral gap model to be 1493 N which is comparable to our PEEK-rod construct results.<sup>6</sup> The difference between our Steinmann pin constructs and that examined in Goh's study is likely a consequence of increased screw numbers and a larger diameter intramedullary pin. The biomechanical impact of varying either monocortical or bicortical screw numbers in a plate-rod LCP model has not been evaluated further confounding this comparison and represents an area of future evaluation. However, it is likely that these loads are supraphysiologic and early plate failure is unlikely.

Comminuted tibial fractures in dogs can be successfully repaired with a variety of techniques including bone plating, plate-rod, and external fixation and interlocking nail stabilization.<sup>1,2,11,17,28–31</sup> We selected a plate-rod model with 2 screws per fracture fragment to model current minimally invasive plate osteosynthesis techniques for the situation where limited bone stock is available for screw placement.<sup>2</sup> The LCP was selected because of its beneficial biomechanical properties and successful use in small animals.<sup>32,33</sup> Clinical experience at our hospital with placement of an intramedullary pin to indirectly distract and align the fracture and LCP application in tibia fractures indicates bicortical locked screw placement is sometimes impeded by the pin path. Strategies for avoiding screw impingement on the intramedullary pin include removal of the pin, use of a smaller intramedullary pin, angling of screws away from the pin or the use of monocortical screws. Removal of the pin sacrifices the biomechanical advantage of the plate-rod construct. Placement of a smaller diameter reduces the stiffness and fatigue life of the construct and compromises frictional pin-bone contact proximally and distally.<sup>3,4</sup> Reduction of the size of Steinmann pin from 50%

to 30% the size of the medullary canal has been shown to significantly decrease construct stiffness.<sup>3</sup> Angling of locking screws away from the pin is not possible with fixed angle locked screws with the LCP design. Monocortical screw placement may or may not be possible depending on the bone size, the relative position of the pin within the medullary canal and implant size availability. Re-drilling for cortical screw placement may compromise the thread–bone interface of the cis-cortex and results in loss of the biomechanical role of a locked screw at this position.<sup>34</sup>

The PEEK we used is readily available from engineering plastic suppliers and is approved for food grade applications by the US Food and Drug Administration (FDA). Poly-etherether-ketone approved for medical applications has met stringent testing criteria set down by the FDA and we are unaware of the safety of using food grade PEEK for implantable purposes. Previous mechanical testing comparing food grade PEEK and medical grade PEEK failed to identify any differences (data held on file). It tolerates repeated steam sterilization cycles without altering its mechanical behavior facilitating its use in animals.7 Whereas PEEK has been shown to be biologically inert there is no published work exploring the biological impact of PEEK wear debris within the intramedullary canal. This study was not designed to evaluate the use of PEEK clinically but instead to provide evidence of its biomechanical behavior to support the investigation of its clinical applications.

Our results showed that a 75% medullary diameter PEEKrod construct was biomechanically superior to a 31% medullary diameter Steinmann pin construct in this cadaveric tibial fracture gap model. The PEEK rod offers the advantage over a stainless steel rod of ease of subsequent placement of fixed angle constructs such as locked plates. Further work to investigate clinical outcomes of this technique is needed.

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#### DISCLOSURE

The authors report no financial or other conflicts related to this report.

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