



Does coating an intramedullary nail with polymethylmethacrylate improve mechanical stability at the fracture site?

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ABSTRACT

Background: Treatment of tibia diaphyseal fractures with intramedullary nail fixation has proven to be effective. An increasingly popular practice is to coat the nail with bone cement incorporating antibiotics for the purpose of treating and/or preventing infection. To date, the effect of coating on the mechanical performance of the intramedullary nail once implanted is unknown. We hypothesize that cement coating does not change the cross-sectional stiffness of the nail, so that, when fixing tibia diaphyseal fracture with gapping, cement coated intramedullary nail provide stiffness comparable to that of standard conventional uncoated ones.

Methods: Tests of 4-point bending were conducted to compare the cross-sectional stiffness of uncoated to coated nails. In addition, mechanical tests of compression and torsion on tibia bone phantoms instrumented with coated and uncoated nails were performed, and the proximal-to-distal bone fragment rotations were compared.

Findings: The 4-point bending tests indicated that the cross-sectional stiffness of coated nails was not significantly different from that of the uncoated ones (p -value >0.05). Mechanical tests of compression and torsion corroborated these results by showing no statistical difference in the proximal-to-distal bone rotations attained with uncoated nails when compared to those measured for the coated ones (p -value >0.05).

Interpretation: Cement coating on the nail cannot be relied upon for increased mechanical stiffness of the implant, and should be solely considered as a vehicle for topic delivery of antibiotics.

1. Introduction

Intramedullary nail (IMN) fixation of diaphyseal fractures in the tibia and femur has proven to be an effective means of treatment ((SPRINT) StPERINiPwTF, 2008; Clawson et al., 1984; Johnson, 1986; Ricci et al., 2009). Methods of intraoperative manufacture of a polymethylmethacrylate (PMMA) coated nail have been described (Paley and Herzenberg, 2002; Riel and Gladden, 2010; Thonse and Conway, 2007). Coating IMNs with PMMA is typically carried out incorporating antibiotics within the cement. This allows for local delivery of high doses of antibiotics over a period of time following insertion of the intramedullary implant (Karek et al., 2017; Masri and Beauchamp, 1998). Local delivery of antibiotics via a PMMA coated nail can be very useful in situations such as treatment of an infected nonunion of the tibia or for infection prophylaxis when nailing a bone that has had external fixation pins for an extended period of time (Wasko and Borens, 2013; Kanakaris

et al., 2014; Pradhan et al., 2017; Qiang and Hang, 2007; Tomczak et al., 2019).

Despite the usefulness and increasing popularity of PMMA coated intramedullary nails, little is known on how the coating on the intramedullary implant may affect the mechanical rigidity of fixation. The strength and stiffness of an IMN increases with the fourth power of its radius. Adding a layer of PMMA to the outside of the nail creates a composite construct with a diameter greater than the metal nail itself. To the authors' best knowledge, the extent of change in the mechanical performance of an implant with an IMN, whose diameter has been augmented with a PMMA coating, has never been investigated.

The objective of this study was to compare the mechanical rigidity of PMMA cement coated IMN fixation for diaphyseal fracture of the tibia to that of conventional uncoated IMNs. This was achieved by conducting 4-point bending tests to determine whether cement coating would alter the cross-sectional stiffness of the IMN. In addition, biomechanical tests

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were conducted on bone phantoms to investigate the difference in magnitude and type of motion at a tibial diaphyseal fracture site found in fixations using standard intramedullary nails (S-IMN) and cement-coated intramedullary nails (CE-IMN). We hypothesized that (1) cement-coated nails have similar cross-sectional stiffness to the conventional, uncoated ones; (2) the addition of PMMA coating has no effect on the stiffness of the fixation construct at the fracture site.

2. Methods

2.1. Protocol for IMN coating

PMMA coated nails were manufactured using the same process that is applied in the operating room (Riel and Gladden, 2010). Specifically, titanium 8 mm DePuy ACE nails were used for both PMMA coated nails and for the comparison nails. An 11 mm Tygon sterile silicone tubing was used to facilitate coating of the nail. The holes of the intramedullary nail were filled with bone wax. Subsequently, the nail was placed in the 11 mm silicone tubing. An air hole was made at the proximal end of the tubing, at the site where the nail expands in diameter at the driving end. Then, PMMA was injected into the bottom of the tubing using a cement gun. Care was taken to ensure that the nail was as centered as possible within the cement mantle. The cement was allowed to harden and, just before it became solid, the extra cement at the end of the nail was cut off exposing the distal tip of the nail. The silicone tubing was removed with a scalpel blade by making a longitudinal cut and then peeling it off.

2.2. Specimen preparation

A total of 8 Sawbones Generation IV (Sawbones®, Vashon Island, WA) Human Tibia were transversely cut by a saw at the mid-diaphysis, creating a gap of approximately 2 mm, representing a simple transverse fracture of the tibia. The S-IMN fixation was performed with an 8 mm nail after reaming the tibia to 9.5 mm. The fracture was fixed with a 2 mm gap and 2 proximal and 2 distal interlocking screws. A total of 8 nails were used (i.e., one nail per bone phantom). After testing the constructs, the nails were removed and coated with PMMA. The CE-IMN fixation was implemented by reaming the tibia to 12.5 mm in

preparation for the 11 mm diameter cement-coated nail. This procedure was followed to maintain an equal mismatch of 1.5 mm between nail diameter and canal diameter in both groups. Distal interlocking holes were drilled out, and the tibia was subsequently fixed with the cement-coated nail combined with 2 proximal and 2 distal interlocking screws. Each of these constructs then underwent the same series of tests.

2.3. Mechanical testing

The flexural properties of the nails were measured via 4-point bending tests. The experimental protocol adopted was compliant with the ASTM Standard 1264 test procedure (Wasko and Kaminski, 2015). Specifically, the nails were placed on a span and compressed by two loading points to generate a uniformly distributed bending moment, see Fig. 1a-b. The load fixture was secured to the top of the MTS testing system, and the support fixture was placed on the MTS base. The loading span and center span were both measured to be 10 cm each. The IMN was centered and secured on the support. The MTS generated a downwards force at a rate of 1 mm/s. The slope of the linear portion of the load-displacement curve was measured and used to calculate the effective cross-sectional stiffness as per ASTM Standard 1264 (Wasko and Kaminski, 2015).

To investigate the difference in magnitude and type of motion at the tibial diaphyseal fracture site between S-IMN and CE-IMN fixations, the instrumented tibias were mounted on an MTS 858 Mini Bionix II testing system (MTS Systems Corp., Eden Prairie, MN) for compression and torque testing. For compression, the tibial plateau was put in contact with a femoral total knee implant connected to a universal joint to exert a compressive load at 23 mm medial to the midline of the tibial plateau. The magnitude of the load applied spanned from 100 to 500 N, to simulate the alignment of the peak load on the tibia expected during partial weight bearing (Taylor et al., 2004), see Fig. 1c. The distal end of the bone rested upon a spherical pin located 9 mm medial to the center of the tibia allowing for rotation in all planes to mimic normal behavior, see Fig. 1d. For torque, both ends of the tibia were clamped in a vise. Specifically, the proximal end was aligned to the center of the MTS ram, while the distal end was mounted on an X-Y linear bearing table to allow the center of rotation to follow the natural rotational axis of the

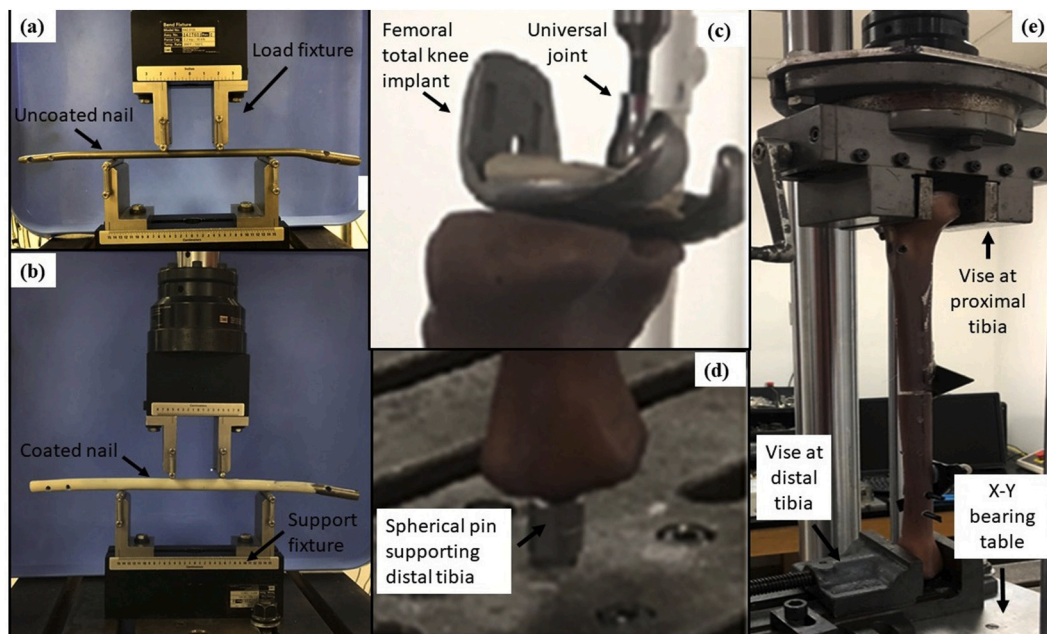


Fig. 1. Experimental setup used in this study: (a) 4 point bending test of a conventional IM nail; (b) 4 point bending test of a coated IM nail; (c) proximal tibia in contact with femoral total knee implant exerting a compressive load; (d) distal tibia resting upon a spherical pin during compression; (e) experimental setup for torque testing.

construct in the horizontal plane, see Fig. 1e. The construct was cycled in external-internal rotation in the horizontal plane, from ± 0.5 to ± 3.0 N·m at 0.25 Hz. For all the loading conditions applied, the relative range of motion (RoM) between proximal and distal bone fragments was measured by a motion capture system (MaxPRO, Innovision Systems, Inc., Marietta, GA) with camera tracking accuracy of 0.02 mRad. Specifically, rotations in the sagittal, coronal and axial planes were calculated.

2.4. Statistical analysis

Experiments were carried out on 8 IMN (coated or uncoated) and 8 bone phantoms. Hence, the sample size for each mechanical test conducted was 8 ($n = 8$). For the analysis of the results of the 4-point bending tests, paired *t*-test and F-test were used to determine statistically significant differences, if any, in the mean or variance of the flexural properties of coated vs. uncoated nails. In the analysis of the compression tests on bone phantoms, for all the magnitudes of load applied, a paired *t*-test was used to determine statistical differences, if any, in the difference of RoM of S-IMN vs. CE-IMN fixation. Additionally, an ANOVA test followed by a post-hoc Tukey test was used to determine whether a change in load magnitude may significantly affect the difference in RoM of S-IMN vs. CE-IMN fixation. The same approach was followed for the analysis of the results of the torque test. For each statistical test performed, the level of significance was set to 0.05 (i.e. $\alpha = 0.05$).

3. Results

Analysis of the 4-point bend testing indicated that the means of the cross-sectional stiffness of the nails with and without PMMA were not significantly different from each other (p -value >0.05), see Fig. 2. However, cross-sectional stiffness data relative to CE-IMN exhibited significantly larger standard deviations than those of S-IMN (p -value <0.01). Upon visual inspection after testing, no visible sign of deterioration of the PMMA coating was observed.

During compression, for all the magnitudes of load applied, the mean RoMs of S-IMN and CE-IMN fixations were not significantly different (p -value >0.05) in all three planes of motion, see Fig. 3. The largest difference in rotation ($\sim 3^\circ$) was observed in the axial plane when the compression reached 500 N. In general, the load magnitude did not significantly affect the extent of RoM in any anatomical plane (p -value >0.05).

When tested for torque, the difference in the RoMs of the two

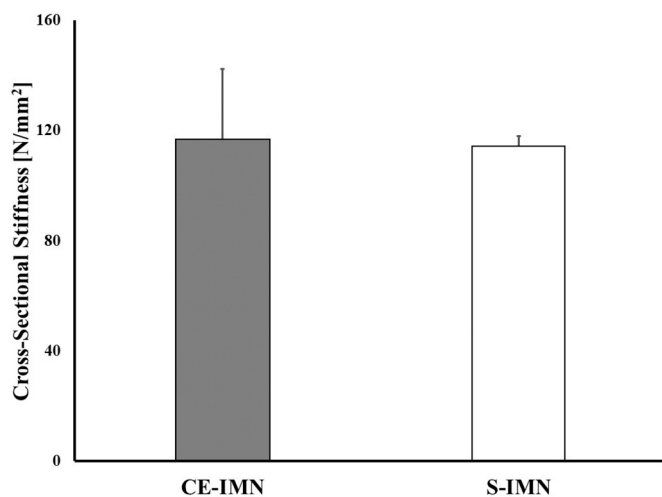


Fig. 2. Cross-sectional stiffness of CE-IMN (gray) and S-IMN (white) measured via 4-point bend testing.

constructs investigated was always less than 2° for each anatomical plane, and not statistically significant (p -value >0.05). Torque magnitude did not significantly affect the magnitude of the RoMs (p -value >0.05), see Fig. 4.

After testing, the coated nails were extracted from the bones and visually inspected. No visible sign of deterioration of the PMMA coating was observed.

4. Discussion

Coating IMNs with bone cement is becoming increasingly popular for fracture fixation (Wasko and Kaminski, 2015). However, very little is known on the effect of PMMA coating on the mechanical performance of the IMN once implanted.

The first objective of this investigation was to determine whether the addition of PMMA cement on the surface of the nail increased its cross-sectional stiffness. We hypothesized that cement-coated nails have the same cross-sectional stiffness of the conventional, uncoated ones. The 4-point bending tests confirmed our research hypothesis by showing that the stiffness of the cement-coated nails was not significantly different from that of conventional nails, see Fig. 2. The magnitude of the measured cross-sectional stiffness was consistent with that reported in previous studies [17]. Cement coating is a manual process that can yield a slight variability in the final diameter of the coated nail. This may explain the larger standard deviation of the cross-sectional stiffness found in coated nails, when compared to the conventional, uncoated ones (p -value <0.01).

The other objective of this study was to compare the mechanical rigidity of PMMA cement coated IMNs to conventional IMNs when used for fixing diaphyseal fractures of the tibia. We hypothesized that the addition of the PMMA coating has no effect on the stiffness of the fixation construct at the fracture site. The results of our analysis indicate that CE-IMN and S-IMN produce a similar relative range of motion of bone fragments when either compression loads or torque are applied to the constructs, see Figs. 3 and 4. In particular, for all the magnitudes of compression and torque investigated, the difference of RoM was always less than 3° and 2° , respectively, indicating the mechanical equivalency of S-IMN fixation to CE-IMN fixation. It should be finally noted that, although data reported in Figs. 3 and 4 may suggest, for some cases, trends of variation of the mean values with the magnitude of the applied loads, there was no statistically significant difference in the RoMs with compressive load or torque (p -value >0.05).

To our knowledge, this is the first report investigating the effect on stability of adding a cement coating to an intramedullary nail. The comparable performance of cement-coated nails with conventional nails validates the use of the former as mechanically equivalent while allowing the added benefits of antibiotic delivery in clinical scenarios where this may be desirable, such as in cases of infection, open injuries, or prior prolonged external fixation.

However, it should also be recognized that coating the nail with PMMA does not improve its performance over the original implant. Clinically, this is important because it means that the optimal size nail should be chosen independent of the PMMA coating. In circumstances where a smaller nail (e.g. 8 mm diameter) will suffice, then coating may be easier because the size of the composite nail can still be less than 11 mm. However, when a larger nail is mechanically preferred (e.g. 10 mm diameter), then the canal may have to accommodate a 12 or 13 mm composite construct. This requires potentially reaming the canal to 14–15 mm, which is often not ideal. This is critical to understand prior to surgery because: (1) adequate canal size must be determined to assure the larger implant can be accommodated, and (2) a larger size tubing may need to be made available.

An obvious limitation of this study is that the experiments were conducted on bone surrogates, rather than cadaveric tissue. This was done to exclude any potential effect of size or shape on the mechanical performance of the constructs tested. The mechanical properties of the

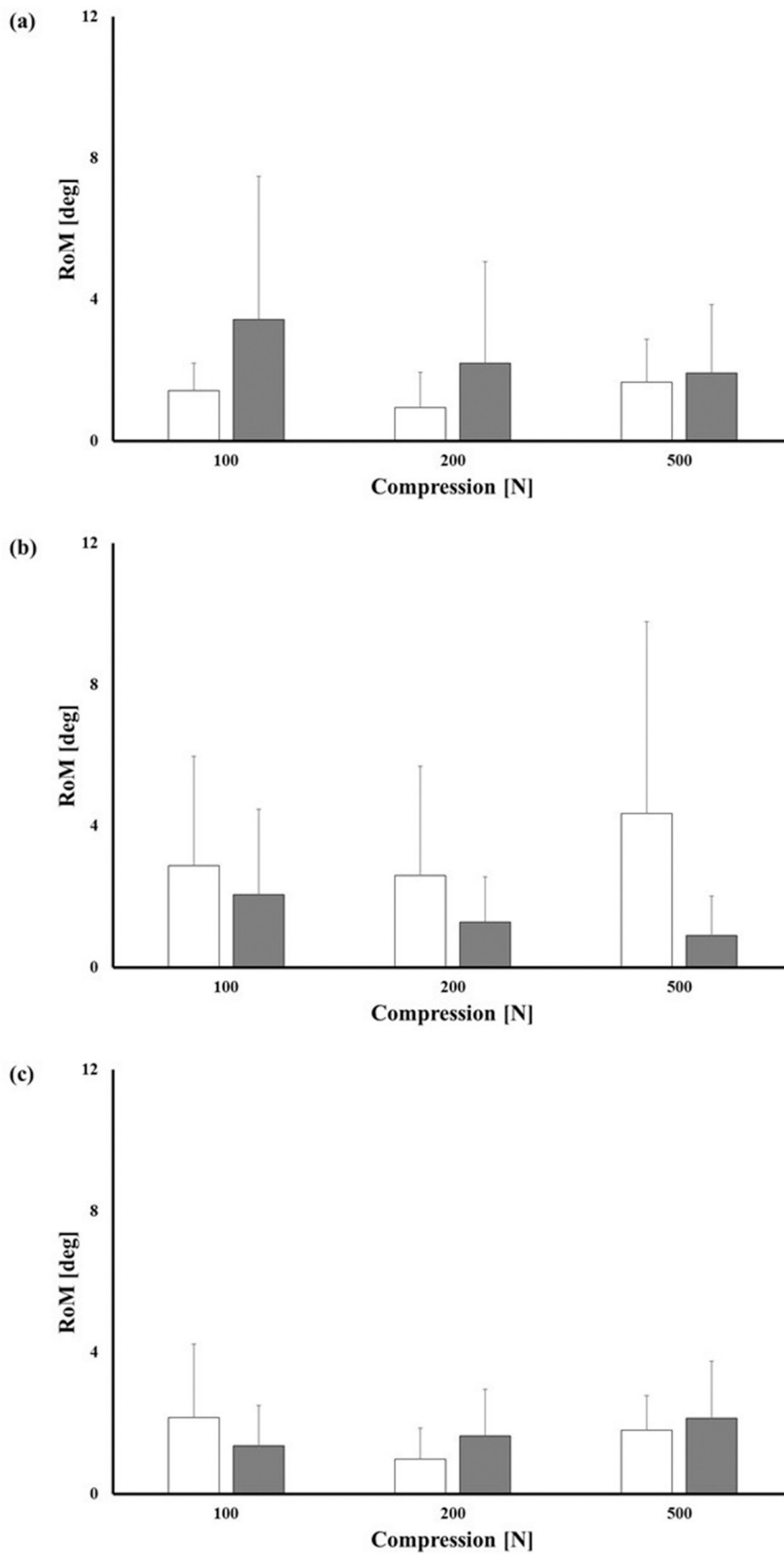


Fig. 3. RoM at the proximal-distal bone fragment of S-IMN (white) and CE-IMN (gray) fixation under compression: (a) rotations in the sagittal plane; (b) rotations in the axial plane; (c) rotations in the coronal plane.

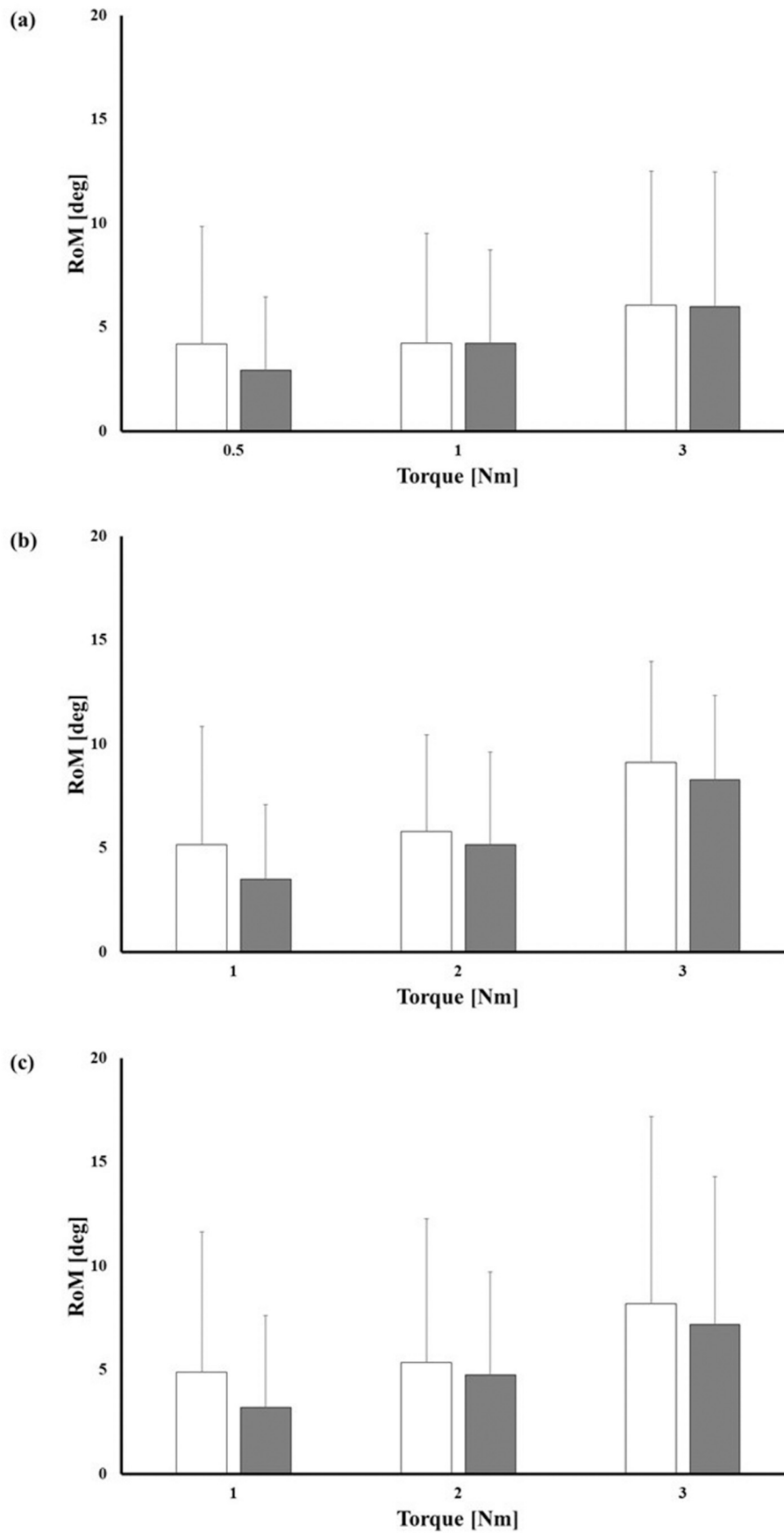


Fig. 4. RoM at the proximal-distal bone fragment of S-IMN (white) and CE-IMN (gray) fixation under torque: (a) rotations in the sagittal plane; (b) rotations in the axial plane; (c) rotations in the coronal plane.

surrogates may differ, to some extent, from those of the actual bones. However, the tests were conducted within the elastic range of behavior of the constructs and, therefore, related only to the rigidity of the constructs. In addition, each bone was tested first with the nail uncoated, and then with the same nail coated. Respecting this testing order was necessary since the diameter of the coated nail is larger than the uncoated one, and requires additional reaming of the intramedullary canal of the bone. Aimed at mitigating a potential bias in the results due to this ordering effect, the loads applied to the construct never overcame the limits of plasticity.

5. Conclusion

This study suggests that coating intramedullary nails with PMMA does not significantly change the mechanical flexural stiffness of isolated nails or the elastic characteristics of a locked nail construct in a tibial fracture gap model, when compared to standard, non-cement coated nails. Our findings provide helpful guidance for implant selection and preoperative planning, knowing that the PMMA coating on the nail cannot be relied upon for increased mechanical stiffness of the implant. Additionally, when deciding on the diameter that can be reamed for a given tibia, one will need to use a smaller, less rigid nail in order to accommodate the PMMA coating. Therefore, the PMMA coating should be solely considered as a vehicle for delivery of the desired antibiotics.

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Authors' contribution

Stephen Quinnan and Max Seiter conceived the study and prepared the specimens; Loren Latta, Abeer Al-Barghouthi, Edward Milne and Francesco Travaschio designed the study, collected and analyzed the data. All authors contributed to drafting, editing and reviewing the manuscript. All authors read and approved the final manuscript.

Declaration of Competing Interest

The authors declare that they have no competing interests.

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