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Rigidity of fixation with Cement-coated Intramedullary Nails for Unstable Diaphyseal Tibia Fractures

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INTRODUCTION: Intramedullary fixation of tibial diaphyseal fractures offers many advantages as a choice of fixation, and has proven to be an effective means for many of these injuries. Methods have been proposed for coating the nails with polymethylmethacrylate (PMMA) bone cement. Methods of intraoperative manufacture of PMMA nails incorporate the use of antibiotics within the polymer coating in order to allow for local delivery of antibiotics with insertion of the intramedullary nail. 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. Despite the usefulness and increasing popularity of PMMA coated intramedullary nails, there is no data on the mechanical effect of a PMMA coating on the intramedullary implant. The objective of this study was to compare the stiffness of cemented coated intramedullary nails and conventional intramedullary nails in controlling magnitude and type of motion at the fracture site, in a tibia diaphyseal fracture fixed with gapping at the fracture site. A biomechanical laboratory test was used to measure the stiffness of the investigated constructs.

METHODS: A total of 4 Sawbones Generation IV (Sawbones®, Vashon Island, WA) of a human tibia were transversely cut by a saw at the mid diaphysis, creating a gap of approximately 2 mm and representing a simple, transverse fracture of the tibia. The conventional intramedullary fixation (CO-IMF) was performed with an 8mm nail after reaming the tibia to 9.5mm. The fracture was fixed with a 2mm gap and 2 proximal and 2 distal interlocking screws. The cement-coated nail fixation (CE-IMF) was implemented by reaming the tibia to 12.5mm in preparation for the 11mm diameter cement-coated nail. The nail was prepared by placing 11mm internal-diameter silicon tubing over an 8mm diameter intramedullary nails; the tubing was vented proximally with a hole to allow the pressurized cement to distribute evenly around the nail without ballooning the tubing. One pack of cement was mixed and then applied using a caulking gun inserted into the distal end of the tubing. The nail was gently rolled after cementing to ensure uniform diameter and distribution of cement across the nail. After cement hardening, the tubing was cut off the prepared nail, distal interlocking holes were drilled out, and the tibia was subsequently fixed with the cement coated nail and 2 proximal and 2 distal interlocking screws, with 2mm of fracture gapping. The constructs were mounted on a MTS 858 Mini Bionix II testing system (MTS Systems Corp., Eden Prairie, MN) for compression and torque testing. For compression, the tibia plateau was put in contact with a femoral total knee implant connected to a universal joint to exert a compressive load whose magnitude spanned from 200 to 500 N to simulate the alignment of the peak load on the tibia expected during gait [2]. The distal end of the bone rested upon a spherical pin allowing for rotation in all planes to mimic normal behavior. For torque, both ends of the tibia were clamped in a vise. Specifically, the distal end was aligned to the center of the MTS ram, while the proximal end was mounted on an X-Y linear bearings table to allow the center of rotation to follow the natural rotational axis of the construct in the horizontal plane. The construct was cycled in external-internal rotation in the horizontal plane, from +/- 0.5 to +/- 3 Nm. During loading, 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). Data were reported in terms of rotations in the sagittal, coronal and axial planes. After testing, the nails were extracted from the bones and tested in 4-point bending per ASTM 1264 to measure their effective bending stiffness with vs. without the PMMA coating..

RESULTS: During compression, the ROMs of CO-IMF and CE-IMF were not significantly different ($p\text{-value} > 0.05$) in all three planes of motion. The largest rotations were observed in the coronal plane, see Figure 1. Within the magnitude of loads tested, no rotation was significantly different from zero ($p\text{-value} > 0.05$). Similarly, during torque, motion of CO-IMF and CE-IMF were not significantly different ($p\text{-value} > 0.05$) in all the three planes of motion. Only the horizontal plane had rotations significantly different from zero ($p\text{-value} < 0.05$), see Figure 2. Consistently, the stiffness of CE-IMG and CO-IMF with 4 point bend were not significantly different ($p\text{-value} > 0.05$), being 168.46 ± 6.79 $N\text{-}m^2$ and 166.46 ± 3.04 $N\text{-}m^2$, respectively.

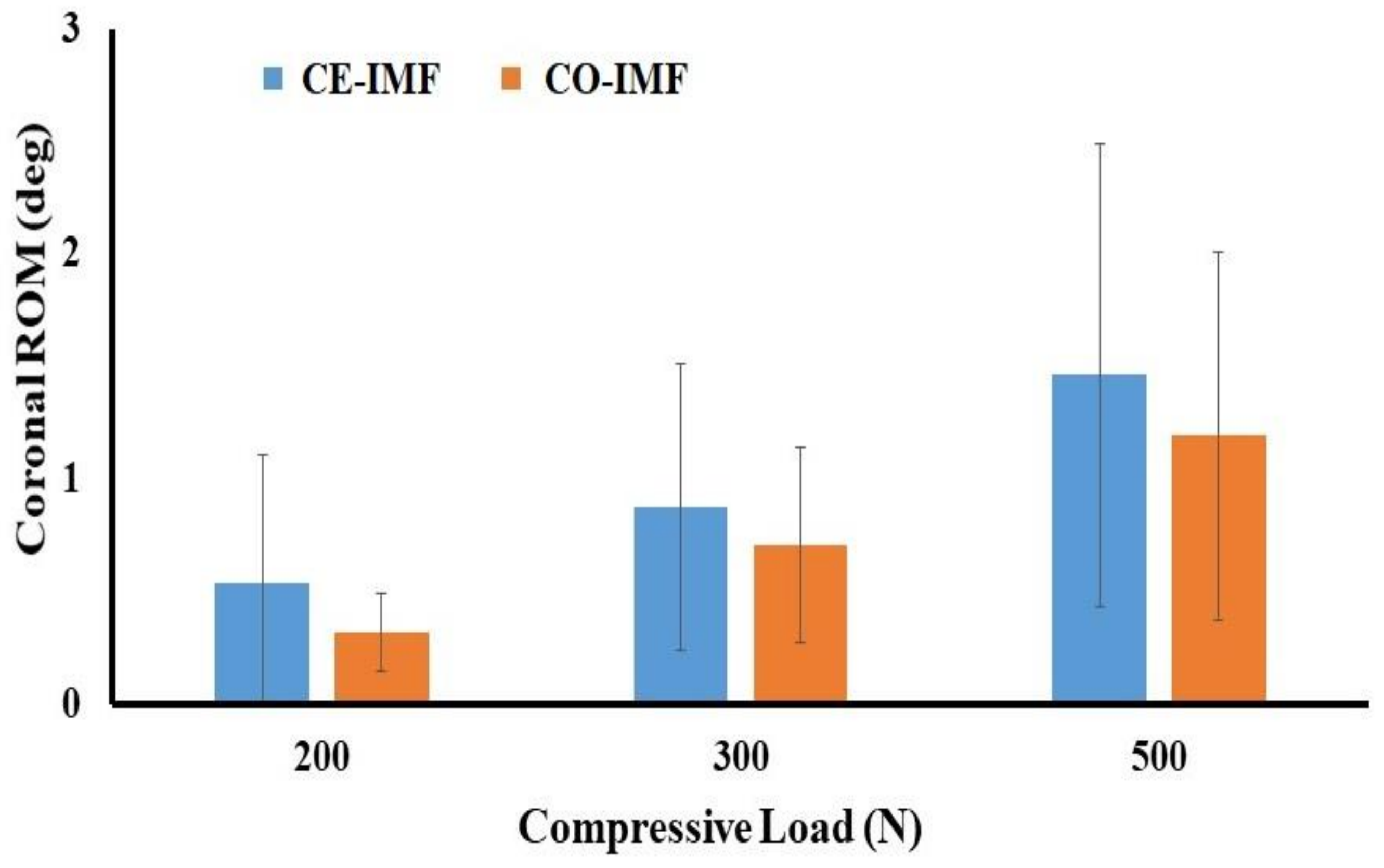

Figure 1. Range of motion of conventional and cemented coated IM constructs during compression.

DISCUSSION: Our study showed no significant difference in the ROM under compression or torque when comparing CO-IMF with CE-IMF. The 4-point bending tests corroborate these findings by showing that the stiffness of the cement coated nails is not significantly different from that of conventional nails. To our knowledge this is the first study reporting the mechanical stability of cement coated nails. The comparable performance of cement-coated nails with conventional nails validates the use of 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.

SIGNIFICANCE: Our study shows that cement-coated intramedullary nails demonstrate similar to standard, non-cement coated nails in respect to compression and torque. This validates the choice of cement-coated intramedullary nails for fixation in clinically indicated scenarios as a stable construct that will provide appropriate stability for healing.

REFERENCES: [1] Perren, Clin Orthop Rel Res, 1979. [2] Taylor et al., J Orthop Res, 2004

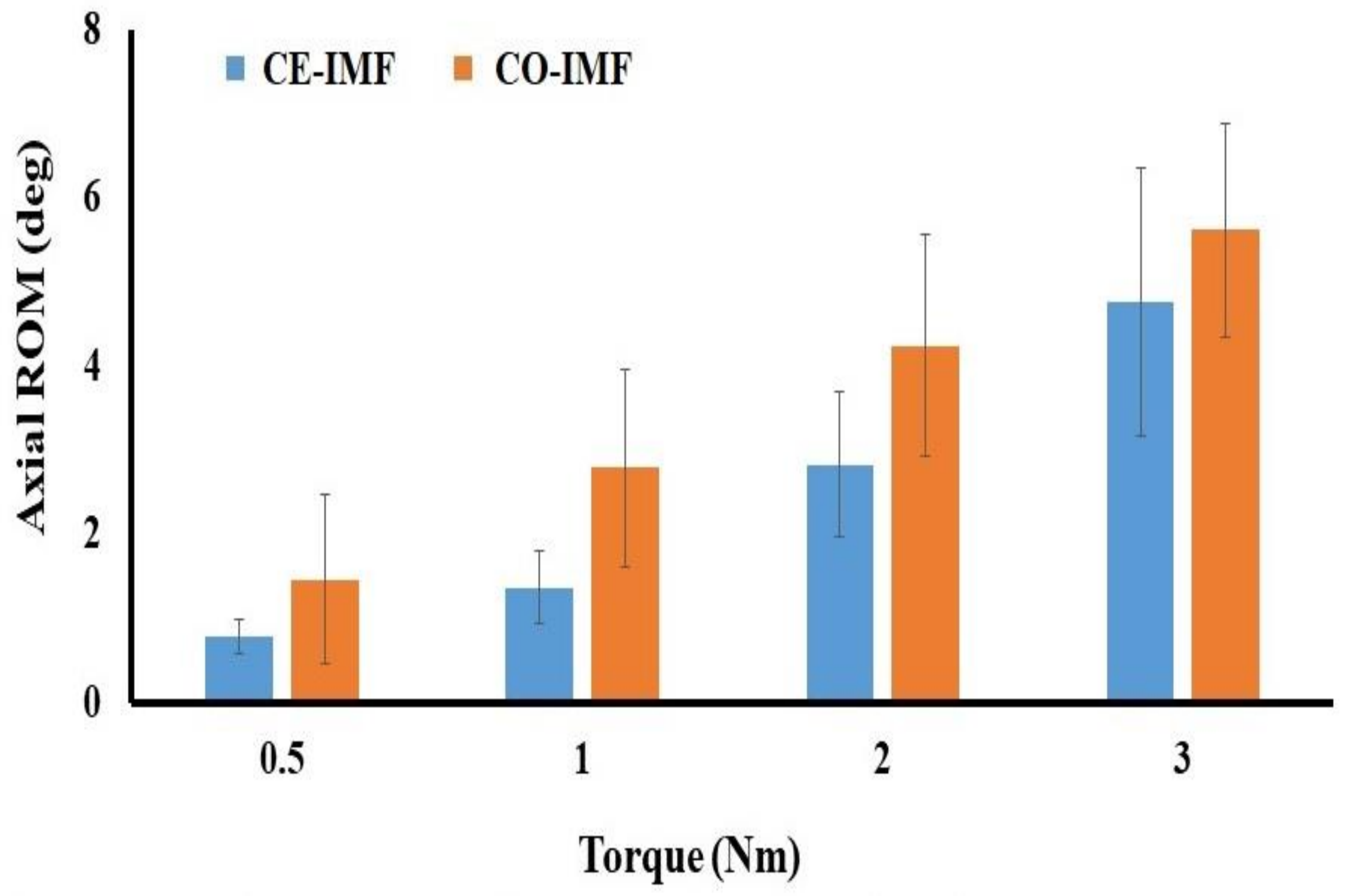

Figure 2. Range of motion of conventional and cemented coated IM constructs during torque.

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