Comparison of a New Braid Fixation System to an Interlocking Intramedullary Nail for Tibial Osteotomy Repair in an Ovine Model
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Introduction: The most common treatments for tibial shaft fracture include external fixation with a cast, intramedullary (IM) nail systems, plates and screws, and external skeletal fixators. In order to simplify the IM nail procedure and avoid inserting locking screws and using fluoroscopy, a new construct composed of a Nitinol braid and hardened stainless steel rods (Braid system) was developed to be inserted and expanded in the tibial canal, followed by IM injection of polymethylmethacrylate (PMMA) bone cement. The purpose of this study was to evaluate bone healing of tibial fractures treated with a Braid system (OsteoLign Inc, Duluth, GA) in an ovine model, and compare this technique to standard interlocking IM nail fixation. We hypothesized that this minimally invasive surgical technique would shorten surgical times and result in similar bone healing to interlocked IM stabilization of tibial fractures.

Materials and Methods: The study was approved by the Institutional Animal Use and Care Committee. In vitro study: Ten mature female sheep were used in this study. Immediately after euthanasia, the right tibia of each sheep was randomly assigned to the Braid system group or IM nail group (n=5/group), the left tibia served as a non-treatment intact bone control. In the Braid system group, a mid-diaphyseal transverse osteotomy was created and the Braid system was inserted into the medullary canal.

PMMA cement was injected to fill the entire tibial canal. After the PMMA hardened, the osteotomy gap was checked to make sure that no PMMA had leaked into the osteotomy gap. In the IM nail group, the surgical procedure was identical to the Braid system group except that the IM nail was inserted in the tibial canal. Two interlocking screws at each end were inserted under fluoroscopy. Mechanical testing was performed via torsion in external rotation at 1.5° per second to a maximum of 45° or until failure using displacement control. Stiffness was calculated as the initial slope of the linear portion of each curve. Maximum torque was also obtained for each tibia. In vivo study: Twelve mature female sheep were used in this study. The right tibia of each sheep was randomly assigned to the Braid system group or IM nail group (n=6/group), the left tibia of each sheep served as a non-treatment control. The operative time was recorded from skin incision to completion of skin closure which excluded the time for creation of osteotomy for each surgery. After surgery, sheep were immobilized with lameness and radiographs were taken to evaluate bone union. Sheep were sacrificed at 12 weeks after surgery. After euthanasia, both right and left tibiae were harvested and mechanically tested. After mechanical testing, the tibiae were processed for undecalcified histology. Analysis of variance (ANOVA) was used to compare lameness scores, operative times, and the in vitro and in vivo stiffness and maximum torque between groups and for mechanical properties. Differences were considered to be significant at a probability level of 95% (P < 0.05).

Results: In Vitro Study: For the in vitro study, maximum torque of the IM nail group (20 ± 4.4 Nm)(P < 0.05); whereas there was no significant difference in the torsional stiffness between the two groups. For both groups, time 0 mechanical properties were significantly poorer than intact bone strength (21% and 36% of intact bone for Braid and IM group, respectively) and stiffness (15% and 21% of intact bone for Braid and IM group, respectively. In Vivo Study: Operative times for the Braid system group (52.4 ± 6.3 minutes) were significantly shorter than the time for the IM nail group (122 ± 27.1 minutes) (P < 0.05). At 1, 3 and 4 weeks after surgery, VAS scores for the Braid system group were significantly better than those for the IM nail group (P<0.05). Radiographic analysis demonstrated that there were no significant differences in bone union between IM nail and Braid system groups at any time interval.

Radiographic images demonstrating both Braid (A and C) and IM nail (B and D) treatment at 0 and 12 weeks after surgery.

There were no significant differences in either maximum torque or stiffness between IM nail and Braid system groups. Histologic analysis demonstrated that there were no significant differences in the cortical and periosteal healing scores between IM nail and Braid system groups.

Discussion: This new surgical technique decreased operating time by 50% compared to the interlocking IM nail technique based on the performance of 2 experienced orthopaedic surgeons. The PMMA cement was injected into the tibial canal and cohered with the Braid system to achieve similar fracture stability as achieved by interlocking screws with the IM nail. This technique avoided using the interlocking screw guiding device and fluoroscopy to insert 4 interlocking screws, which may result in longer operative times due to inadvertent misdirection of the locking screws. Several concerns regarding the Braid system need to be discussed. First and most critical, is the ability to remove the PMMA if refracture or infection occurs. Second, thermal necrosis may occur during PMMA cement polymerization and hardening in the tibial canal. This new treatment system warrants further investigation to verify its feasibility and safety.


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