Effect of Different Distal Fixation Augmentation Methods on the Pullout Strength of Fassier-Duval Telescoping Rods

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Abstract

Antegrade telescoping rods have been introduced for use in pediatric patients with osteogenesis imperfecta (OI) to decrease the incidence of long-bone fractures and to correct and prevent deformities. Recent studies have documented failures of telescoping intramedullary rods due to inadequate distal fixation. The purpose of this study was to evaluate the pullout strength of distal fixation of the telescoping rod with and without synthetic calcium phosphate or polymethylmethacrylate (PMMA) augmentation. Four sets of 6 telescoping distal fixation rods were fixed according to standard insertion technique into an open-cell rigid-foam synthetic bone block simulating OI bone. The groups tested were as follows: control (no augmentation), 0.75 mL of PMMA-augmented, 0.75 mL of PMMA-rescued (stripped distal fixation, then resecured after PMMA augmentation), and 0.75 mL of bioabsorbable-calcium phosphate (CP)-augmented. All rods were tested to failure. The peak load was recorded. Average pullout strengths were as follows: control, 20±6.6 N; PMMA, 125±16.8 N; PMMA-rescued, 137±11.9 N; bioabsorbable-CP, 81±10.3 N. All augmented groups had significantly higher pullout strength compared with the control (P<.001). The PMMA and PMMA-rescued groups failed at the PMMA/bone interface, whereas the bioabsorbable-CP group failed at the cement/rod interface. All augmented constructs improved pullout strength by at least 400% compared with the control. Bioabsorbable cement may be less detrimental to the physis if pullout still occurs despite augmentation due to its mode of failure. This study provides biomechanical evidence to support the further in vivo investigation of either PMMA or bioabsorbable cement augmentation to improve pullout strength of distal telescoping rod fixation. [Orthopedics. 2016; 39(2):e328-e332.]

The practicing orthopedic surgeon is faced with difficult treatment options when caring for patients with the hereditary disorder osteogenesis imperfecta (OI). The primary orthopedic manifestation in patients with OI is fragile bones that result in multiple fractures throughout life, with subsequent long-bone deformities.1-3 The management of these fractures is extremely challenging, primarily due to the continued need for internal splinting of the fragile bones in the skeletally immature patient while still allowing growth.

An increasingly popular strategy in the surgical treatment of long-bone fractures and deformities in patients with OI has become internal fixation with intramedullary (IM) rods. Expandable or telescoping rods were initially introduced in 1963 to allow prophylactic internal splinting without impeding longitudinal growth.4 However, several studies were published outlining these early devices and their...
complications. To overcome these complications, a more modern telescoping rod—the Fassier-Duval Telescoping IM System (Pega Medical, Laval, Quebec, Canada)—was developed. The Fassier-Duval rod is inserted through a completely antegrade approach that avoids a knee arthrotomy for femoral IM nailing.

Early clinical experience yielded favorable results; however, as with more traditional telescoping IM devices, recent anecdotal evidence and a clinical publication has demonstrated some similar complications. Proximal migration—or, more appropriately, distal epiphyseal disengagement with failure to telescope—has been seen more commonly as experience with this system has increased. This phenomenon can be attributed in part to the severely osteoporotic epiphyseal bone used to anchor the distal end of the device. To enhance distal fixation, the option of cross-pinning through a small hole in the distal end of the rod was made available to alleviate this problem. However, distal epiphyseal disengagement has still been reported.

The adult literature is replete with studies in severely osteoporotic patients and models evaluating strategies to enhance pullout strength of screw fixation. These strategies include the use of fixed-angle implants, bioabsorbable cement augmentation, and polymethylmethacrylate (PMMA) augmentation.

The current authors hypothesized that cement augmentation of the distal epiphyseal fixation would significantly enhance pullout strength and may result in decreased distal epiphyseal disengagement when treating these complex patients. Due to concerns for patient safety, the authors proposed a proof-of-concept biomechanical model to evaluate their hypothesis without placing patients at undue risk.

**Materials and Methods**

A biomechanical experiment was devised to evaluate both the initial and augmented pullout strength of the Fassier-Duval rod. The experiment was also used to determine the feasibility of creating a delivery system that could be used to perform the augmentation in a clinical setting. The Fassier-Duval rod is available in multiple sizes; however, a single size (4.0-mm diameter) was chosen for testing purposes. This size was felt to be one of the more common sizes chosen for femoral IM nailing. A synthetic open-cell cancellous bone model (Pacific Research Labs, Vashon, Washington) was used to simulate the properties of porous, severely osteoporotic human cancellous bone found in OI. This porous bone-model block had dimensions of 13 × 18 × 4 cm, with a density of 0.09 g/cc, compressive strength of 0.11 MPa, and compressive modulus of 6.2 MPa. The trabecular bone in the distal femur has been reported to have strength values ranging from 0.56 to 66.2 MPa and compressive modulus values ranging from 7.6 to 800 MPa. The 0.09-g/cc foam blocks were chosen for this study because OI bone has been shown to have inferior mechanical properties when compared with normal controls.

Four groups of 6 Fassier-Duval rods were used: control (group 1), PMMA-augmented (group 2), PMMA-rescued (group 3), and bioabsorbable cement-augmented (group 4). High-viscosity PMMA (SmartSet HV Bone Cement; DePuy, Warsaw, Indiana) was chosen to prevent permeation of the cement into the surrounding cancellous bone after injection. Similarly, a moldable bioabsorbable cement (Gamma-bsm; ETEX Corporation, Cambridge, Massachusetts) was chosen to maintain a concentrated depot of cement at the injection site without surrounding permeation. To maximize the reproducibility of rod implantation, a custom fixture was built. The fixture had 2 plates held rigidly above the bone model block with aligned holes to ensure the rods were inserted perpendicular to the block. All implants were inserted using a standard in vivo technique with implant-specific insertion devices and incubated at 37°C for 24 hours to simulate in vivo conditions prior to biomechanical testing.

**Fixation Techniques**

**Control.** The distal fixation was advanced and secured into the testing block by using the male inserter to capture the flanges in the distal end and perform a self-drilling and self-tapping technique until the screw threads were completely buried into the testing block. This technique is identical to in vivo insertion of the distal end of the IM rod into the distal epiphysis.

**PMMA-Augmented.** The distal fixation was initially performed as for the control group. The fixation was then temporarily removed by unscrewing the rod, and 0.75 mL of PMMA was injected into the screw tract, followed by reinsertion of the distal fixation.

**PMMA-Rescued.** This technique was created to simulate revision fixation in the same tract that was previously stripped or lost fixation by distal epiphyseal disengagement. The distal fixation was initially performed as outlined in the control technique. The rods were then manually pulled out of the testing block to strip the screw tract. The stripping was confirmed by reinsertion of the distal fixation and confirming loss of fixation. The stripped tract was then injected with 0.75 mL of PMMA, followed by reinsertion of the distal fixation.

**Bioabsorbable Cement.** The distal fixation was initially performed as outlined in the control technique. The fixation was then temporarily removed by unscrewing the rod, and 0.75 mL of bioabsorbable cement was injected into the screw tract through a 10-cm-long, 11-gauge biopsy trocar, followed by reinsertion of the distal fixation.

**Biomechanical Testing**

Pullout tests to failure were performed at a crosshead rate of 0.2 mm/sec on an Instron Model 1321 servohydraulic test machine with 8500 controllers (Instron Corp, Canton, Massachusetts). The rods were gripped with a tension grip attached to
the load cell with a ball joint to eliminate any off-axis bending from being applied to the rod (Figure 1). Data were recorded at 25 Hz on a computer equipped with a Keithley 1802 HC analog-to-digital data acquisition board (Keithley Instruments, Inc, Cleveland, Ohio) and TestPoint data acquisition software (Capital Equipment Corp, Billerica, Massachusetts). Observational data were also recorded to determine mode of failure.

Failure data between the 4 groups was first analyzed with one-way analysis of variance (ANOVA). If ANOVA revealed a significant difference, then post hoc analysis was performed with Tukey-Kramer honest significant difference (HSD) test. A P value of less than .05 was considered significant. All data were analyzed with JMP 9 statistical analysis software (SAS Inc, Cary, North Carolina).

RESULTS

One-way ANOVA revealed a significant difference between the groups (P<.001). Tukey-Kramer HSD showed no significant difference between the PMMA-rescued and PMMA-augmented groups (P=.36). All other groups were significantly different (P<.001). Mean±SD pullout loads are shown in Figure 2. One typical load vs deflection curve from each group is shown in Figure 3.

All failures in the PMMA-rescued and PMMA-augmented groups occurred at the PMMA/bone interface, as shown in Figure 4. The PMMA remained firmly attached to the implant in all specimens. In contrast, all failures in the bioabsorbable cement group occurred at the cement/implant interface.

DISCUSSION

Pediatric orthopedic surgeons are faced with a complex dilemma when treating skeletally immature patients with OI. These patients often suffer multiple fractures and subsequent long-bone deformities. These fractures must be immediately stabilized to provide fracture healing to prevent deformities but also must allow prophylactic reinforcement to the growing bone. The growing bones are ideally treated with a telescoping intramedullary rod such as the Fassier-Duval telescoping rod. Although the Fassier-Duval rod allows for epiphyseal fixation and telescoping during growth, distal epiphyseal disengagement still occurs. Disengagement in OI patients is likely due to the significantly lower bone mineral density (BMD) compared with normal controls.18 To enhance fixation in low BMD bone such as osteoporotic bone, bone cement has been used. This study showed that bone cement augmentation improved pullout strength of Fassier-Duval rods by 400% in an OI low-density foam in vitro model. An in vitro model was tested to prove the concept without putting patients at risk.

Fracture and subsequent deformity management in patients with OI is a complex dilemma for pediatric orthopedic surgeons. The necessity to provide immediate stabilization for fracture healing while allowing for prophylactic reinforcement to the growing bone complicates the problem even further. Intramedullary nail fixation was described originally in 1959 by Sofield and Millar.19 Their treatment method enhanced treatment of OI patients with regard to fracture and deformity correction; however, nontelecsoping implants were used, and complications arose.
when longitudinal growth progressively uncovered unreinforced fragile bone, resulting in fragility fractures and the need for reoperation.

Telescoping intramedullary fixation was developed as a response to these issues. The Bailey and Debow rod became the mainstay of treatment. Although this rod design allowed for epiphyseal fixation and telescoping during growth, reoperation rates were still as high as 32%.20

Surgeons were also troubled by the fact that a knee arthroscopy was needed for femoral fixation and both knee and ankle arthrotomies were required for tibial fixation. Although minimal sequelae have been reported directly due to the arthrotomies, multiple studies demonstrate severe complications and need for revisions due to intra-articular migration and prominence, including chondral damage, motion limitation, and skin perforation.34.20.22

The main problem is that the rod ends are smooth and capped with a T-piece that has no direct bone fixation.

The Fassier-Duval telescoping rod was developed to address some of the aforementioned limitations of the first generation of telescoping rods. The major differences are antegrade insertion and threading proximal and distal fixation. Early reports, including those from the developer, showed a lower reoperation rate than other telescopic rods, and a recent study by Birke et al8 found a similar rate of 13%.

Despite advances in implants, distal epiphyseal disengagement still occurs, likely due to the significantly lower bone mineral density in OI patients compared with normal controls.18 Birke et al8 reported distal epiphyseal disengagement to be the most common complication, with a 33% (5 of 15) incidence in their series of OI patients.

A distal eyelet exists in the Fassier-Duval rod for salvage fixation in the epiphysis. The eyelet accepts a small-diameter, 0.7- to 1.1-mm pin, a seemingly difficult task. Another antegrade intramedullary device described by Cho et al9 uses distal interlocking fixation in an attempt to prevent distal epiphyseal disengagement. Disengagement still occurred in 12.5% (4 of 32) at 2.5 years postoperatively, despite interlocking fixation.

The current authors sought to explore alternative ways to improve distal fixation using the Fassier-Duval rod. They hypothesized that improving the relative density of the juxta-implant epiphyseal bone would improve pullout strength, similar to using cement around a fence post. Multiple studies in the adult osteoporotic and spine literature support the use of PMMA and various bioabsorbable bone cements as fixation augmentation for poor bone quality.10.12

Because of the unique aspect of augmentation placed in the epiphysis of the growing skeleton, additional consideration needed to be given to the mode of failure and safety of the physics. Although all tested augments showed an average of 400% increase in pullout strength, the PMMA remained firmly attached to the implant at failure. This is less desirable clinically because a large cavity defect and significant physeal injury would result from pullout. The moldable bioabsorbable-calcium phosphate (CP) augmented the fixation strength but still allowed failure to occur at the implant/cement interface. This mode mimics the failure seen in the control group and, therefore, theoretically results in less collateral physeal damage than the PMMA group.

The second consideration was limiting spread of the cement across the physis. This was accomplished by using the high-viscosity PMMA as well as the moldable (instead of injectable) bioabsorbable-CP. The authors found that adding an additional 1 mL of normal saline to the bioabsorbable-CP maintained pullout strength but was injectable as a paste. Clinically this seems to be more desirable than the injectable forms that have lower viscosity and may be more likely to cross the physis around the edges of the implant.

Although not tested clinically, the authors propose a straightforward method of cement augmentation in vivo. An 11-gauge biopsy needle is placed over a 2-mm smooth pin fluoroscopically placed at the distal tip of the implanted male threaded end. The cement is mixed and placed into a 3-mL syringe and injected under live fluoroscopy into the cavity left by the threaded end after it is manually backed up to the level of the physis. The threaded end is then readvanced into its tract.

This study has several limitations. The primary limitation is that this study only shows initial biomechanical support for the use of distal bioabsorbable cement augmentation and that no clinical data exist. The use of either the PMMA or bioabsorbable-CP in this fashion represents off-label use, and this study is intended for preliminary proof-of-concept analysis and needs further animal model studying. Clinical studies have shown the benefit of cement augmentation in spine and fracture cases; however, no literature exists regarding skeletally immature patients and epiphyseal augmentation.23

Another limitation is that the delivery method for this type of augmentation is conceptual. This is not a novel delivery technique, and a similar technique is commonly used in vertebroplasty and kyphoplasty to percutaneously introduce cement.24 The current authors only tested a single diameter and thread configuration of distal fixation. Smaller and shorter sizes intuitively would have lower pullout strength and may also benefit similarly from cement augmentation; however, formal testing would need to be performed to provide objective data. Finally, this was a single load-to-failure test, which may not simulate how clinical failures occur. Additional cyclic fatigue testing may be more clinically relevant and provide important data to support the conclusions. Furthermore, both PMMA and bioabsorbable-CP harden through exothermic reactions, and the authors did not specifically measure their temperatures during the process. Excessive temperature may cause thermal...
injury to the physis and growth arrest, as suggested in a prior study.25

CONCLUSION
This study provides preliminary biomechanical and observational data supporting the use of bioabsorbable-CP cement as a means of distal femoral epiphysyeal augmentation for Fassier-Duval telescoping rods. The method of augmentation in this study improved pullout strength by 400% when compared with the control. Clinical evaluation is needed to determine whether this biomechanical increase can ultimately lower the well-documented rate of distal epiphyseal disengagement.

REFERENCES