Stemmed Implants Improve Stability in Augmented Constrained Condylar Knees

Jeremy J. Rawlinson PhD, Robert F. Closkey Jr MD,
Nicole Davis, Timothy M. Wright PhD,
Russell Windsor MD

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Abstract We previously combined experimental and computational measures to ascertain whether tibial stem augmentation reduces bone strains beneath constrained condylar implants. Using these same integrated approaches, we examined the benefit of a stem when a wedge is used. Implants were removed from the eight paired cadaver specimens from our previous experiment, and oblique defects created that were restored with 15° metallic wedges cemented in place. We applied a varus moment and an axial load and monitored relative motion between implant and bone. Specimen-specific 3-D finite element models were constructed from CT scans and radiographs to examine bone stress in the proximal tibia. Implants with a wedge but no stem had greater motion than the previous control with no stem or wedge. Use of a modular stem with a wedge maintained the same level of motion as the primary case, suggesting that a stem is preferable when a

wedge is utilized. The computational models confirmed this conclusion with a 30% reduction in bone stress compared to 17% in the primary case without a wedge. The wedge carried more axial load compared to the primary implant due to its support on stiff metaphyseal bone.

Introduction

Most current literature reporting on implants used in revision knee arthroplasty focuses on the use of augments and bone grafting, while details of the combined role of stemmed implants is less emphasized [1, 6, 7, 9, 10, 14, 17–19]. The role of a stemmed implant to improve prosthesis stability is an intuitive concept that dates back to the earliest knee prostheses [11], though little scientific or clinical evidence exists describing the biomechanical effect of a stemmed component on bone implant micromotion or on stresses imparted by the stemmed component on the underlying cancellous bone.

In an earlier study, we integrated experimental tests with computational models to demonstrate the ability of modular tibial stem augmentation to reduce implant micromotion and stresses and strains in the underlying cancellous bone of the proximal tibia in constrained condylar knees [16]. The addition of a stem consistently reduced strains in the proximal cancellous bone from 20% to 60% depending on the stiffness of the bone. In this model, the tibia contained no bony defect and represented the bone stock of a primary TKA recipient. While strains were reduced, the effect on tray micromotion was small.

Defects in the proximal tibial metaphysis commonly exist at the time of revision knee arthroplasty. Many are small and contained and warrant only cementing into the defect. When a major structural defect exists, however, the

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J. J. Rawlinson
Cornell University, Ithaca, NY, USA

R. F. Closkey Jr (✉)
Ocean Orthopedic Associates, 530 Lakehurst Road,
Tom's River, NJ 08755, USA
e-mail: closkeyr@hss.edu

N. Davis, T. M. Wright, R. Windsor
Hospital for Special Surgery, New York, NY, USA

surgeon is faced with the challenge of achieving adequate stability of the implant. Treatment options for these more severe defects include translating the component away from the defect, increasing the tibial bone resection, using cement blocks around screws, incorporating autogenous or allograft bone substitution, or replacing the defect with custom or modular metallic augments. The benefits of modular augments lie in the simplicity in replacing the bone defect without the additional risks associated with bone grafts. In most situations involving proximal tibial reconstruction, a stemmed implant is commonly employed.

Modular metallic augments are being increasingly used in revision knee arthroplasty when proximal tibial bone stock is deficient. Several clinical studies reported on nonprogressive radiolucent lines under modular tibial augments in the early period after surgery, though the long-term importance of these radiolucencies is unknown. Likewise, little is known of the role of a diaphyseal stem to load share with a modular metallic augment and protect the often-weaker underlying metaphyseal bone with a constrained condylar device.

We hypothesized that intramedullary stems used in conjunction with tibial metaphyseal metallic augments reduce the mechanical burden in the surrounding bone by reducing bone stresses and micromotion between the implant and the adjacent bone.

Materials and Methods

To test our hypothesis, we combined an experimental approach with specimen-specific finite element (FE) models. For the experiment, pairs of cadaver specimens that had been implanted with constrained condylar knee implants in our previous study [16] were revised and an oblique defect introduced on the medial side; the specimens without a stem or wedge served as a control group. The tibial pairs were then randomized to receive either a stem with a metallic augment to fill the defect or an augment alone. Varus and axial loads were applied, and the global motions between the bone and the implant, as well as the reaction loads at the distal ends of the tibia, were measured. The same experimental loads were applied to the FE models (with the predicted versus the measured reaction loads used as validation of the models), and the stresses and strains in the bone beneath the wedge were calculated. The hypothesis was tested by comparing the stresses and motions between the tibial pairs. The key dependent variable was reduction in stress; based on our previous experiment and analysis, and assuming a stress reduction of 15% to be significant with the addition of a stem, the power was greater than 0.80 for a sample size of eight pairs and an alpha of 0.05. The 15% decrease was

based on previous work that examined the effect of a metallic backing to the tibial component on cancellous bone stresses [2].

For the experiment, the wedge defect was introduced using a modular cutting guide, simulating a revision procedure. A 15° metallic hemiwedge and appropriate tray were then cemented into place using the Insall-Burstein II Constrained Condylar Knee (Sizes 59, 64, 69; Zimmer, Inc, Warsaw, IN). The distal ends had been potted in polymethylmethacrylate as part of the previous experiment.

The implant without the stem augment was fully cemented, but the contralateral side had cement only applied to the proximal cut surface of the tibia and the underside of the tray, including the wedge. To insert a stemmed implant, the medullary canal was reamed until cortical “chatter” was felt, and a stem of equal diameter to the final reamer was inserted. Stem diameters ranged from 12 to 18 millimeters.

All eight pairs of tibiae (mean age, 66 years; range, 52–76 years) were tested using the previous experimental protocol [16]. A 3000-N medial axial load and a 10-Nm varus moment were applied to the upper constraint spine of the constrained condylar tibial component. The axial load represented a severe eccentric load of four times body weight; the moment was chosen as the functional limit of the polyethylene constraint spine [16]. We mounted a six-degree-of-freedom load cell distally beneath the potted specimens to optimize tibiofemoral conformity and prevent abnormal shear loads from occurring (Fig. 1). We initially applied a 100-N load. Once each specimen was aligned in the neutral position, three preconditioning axial loads of up to 3000 N were applied. A 10-Nm moment was then applied to the spine with a dead weight, and the axial load was ramped up to 3000 N at 500 N/second. This loading rate is comparable to that at which axial loads are applied during gait to the lower limb joints [5]. Three trials with this load and moment were conducted.

Global displacements of the wedge-tibial tray construct were recorded using an optical marker system (Qualisys, Glastonbury, CT). Two reflective markers were placed 20 mm apart on the anterior edge of the tibial tray and a further two on the medial side of the tibial tray. Four additional markers were placed on the proximal tibial bone (a medial marker was placed 10 mm beneath the metallic wedge, while on the lateral side, it was placed 20 mm beneath the wedge). Using three cameras, 3-D relative displacements between the implant and the bone could be determined.

Anteroposterior and lateral radiographs of the implanted tibiae were obtained to determine the implant position with respect to the bone. In our previous study, CT scans had been obtained in the transverse plane from the tibial eminence to the middiaphysis using hydroxyapatite rods of

Fig. 1 In the experimental setup, the distal ends of the tibiae were potted in polymethylmethacrylate. An oblique defect was introduced on the medial side using a modular wedge-cutting guide. A 15° metallic hemiwedge and appropriate tray were then cemented into place. For each pair of tibiae, one received a diaphyseal stem augment and the other did not. The tibiae were tested with experimental loading by applying a 3000-N axial load cell and a 10-Nm moment arm to the upper constraint spine of the constrained condylar tibial component. A six-degree-of-freedom (6 DOF) load cell was mounted distally beneath the potted specimen. Global displacements of the wedge-tibial tray construct were recorded using optical markers and three cameras. PE = polyethylene.

varying densities as density phantoms. In-plane resolution was 0.6 mm with a scan thickness of 1 mm and scan spacing of 1 mm in the metaphyseal region. The spacing

was increased to 10 mm in the diaphysis where geometric and material variations with length decreased.

The results of global displacements during testing were recorded, and the relative displacements of the tray-augment construct in relation to the adjacent bone were computed. Specimen-specific finite element (FE) models were built from the CT data. As with the previous study, two sets of boundary conditions were assumed at the fixation point for the distal tibia: one in which the tibia was modeled as completely constrained and a second in which the measured forces from the six-degree-of-freedom load cell were incorporated as constraining forces [16].

We computed descriptive data as the mean $\pm$ standard deviation. Differences in experimentally measured displacements and computationally calculated stresses were determined by repeated-measures analysis of variance with Tukey's multiple comparisons using SigmaStat software (version 3.1, Systat Software, Inc., San Jose, CA).

Results

The experimental results recorded the micromotion between the tray and the bone in response to the applied load under two conditions: (1) a wedge with a stem and (2) a wedge without a stem. Average global tray micromotion of the wedged tray with the stem relative to the bone was $252 \pm 162 \mu\text{m}$; we found no difference ($p = 0.07$) in micromotion between the stemmed and unstemmed ($492 \pm 350 \mu\text{m}$) implants. From the specimen-specific FE computational models, the micromotion between the stemmed ($284 \pm 171 \mu\text{m}$) and unstemmed ($405 \pm 350 \mu\text{m}$) computational results was similar ($p = 0.07$) (Fig. 2). Using the experimentally recorded displacements in the specimen-specific FE computational model bone stress was computed. The minimum average principal stress in the bone with a wedge and stem was lower ($p = 0.005$) than that without a

Fig. 2 A graph shows global tray motion with and without wedges and stems. EXP I = prior study data [16]; EXP II = current study data; FEA = finite-element analysis.

stem ($26.7 \text{ MPa} \pm 4.5 \text{ MPa}$ versus $38.4 \text{ MPa} \pm 4.9 \text{ MPa}$, respectively). This 30% decrease in bone stresses was greater than the 17% decrease observed with the use of a stem alone. Additionally, the level of axial load sharing was 40% smaller ($p = 0.0001$) with an implant with a wedge than without a wedge.

Implants with a wedge but no stem had greater ($p = 0.012$) tray micromotion than the control group with no stem or wedge. The tray motion ranged between 200 and 400 μm .

Discussion

In this study we applied experimental loads to cadaver tibiae implanted with a wedged tibial tray under two different conditions: with a stem and without a stem. The displacement data from the experiment were used in a previously validated specimen-specific FE model to evaluate the mechanical stresses in the tibia, comparing those two implant scenarios.

A major limitation of this study is the simplification of the experiment to represent an implanted functioning knee replacement. However, the goal was to gain insight into the relative difference a stem has on the micromotion between implant and bone and the stresses in the underlying cancellous bone of the proximal tibia. In a given patient, the micromotion without or with a stem could vary substantially depending on numerous factors, but we have identified consistent relative differences given our experimental variability and parametric analyses. Another limitation of this study is that the experiment and FE model are similar but not identical. The boundary and loading conditions in the FE model are precise while variations inherently exist in any experimental setup. However, we believe that the consistency and validation of the FE model for this loading condition was demonstrated in our earlier study [16].

The computational portion of this study demonstrated that the stem reduced bone stress by 30%. The FE models supported our experimental findings by demonstrating substantial reductions in bone stresses. The wedge carried more axial load compared to the primary implant due to its support on stiffer metaphyseal cortical bone (with an elastic modulus of 1 GPa and greater), compared to that of the cancellous bone (with elastic moduli that ranged from 0.1–0.8 GPa) that the wedge replaced. The augment stem still provided increased support to axial and bending loads, in agreement with our previous findings [16]. Our results also agree with those of Brooks et al. [4], who performed in vitro axial and varus loading tests on cadaveric tibiae in which defects had been created and then filled with different materials. The least deflection of the tibial tray in their study occurred when a custom tibial component was

used. However, use of metallic wedge augmentation provided nearly equivalent support. Cement, either alone or with screws, gave the worst results. They reported a 70-mm long cemented central stem carried 23% to 38% of the axial load in the presence of a bone defect. Both studies, therefore, show that stems carry substantial loads.

When a stem was used in combination with a wedge, micromotion between the bone and implant decreased and bone stresses were reduced, suggesting that clinical results might be improved when a wedge and stem are employed to address tibial defects. Clinical data in support of these findings are available. Brand et al. [3] reported on 28 TKAs with modular wedges with a 3-year followup. In cases where bone stock was sufficient to support the wedge no stem was used, but a stem was employed when bone stock was poor. No failures had occurred at 3 years. Similarly, Rand [15] reported on 28 TKAs and Pagnano et al. [13] reported on a followup of 21 of those 28 TKAs. Wedges were used to fill defects in all cases, and stems were used when defects were larger than 5 mm. Again, no subsequent failures were reported. Nazarian et al. [12] reported poor bone quality treated with an unstemmed implant at revision surgery had a higher rate of loosening compared with a stemmed implant. The role of intramedullary stems was also addressed by Fehring et al. [8], who reported on revision TKA cases in which stemmed implants were used. Stem fixation using cement had a lower rate of loosening compared with a cementless stemmed implant. The results of these clinical studies suggest that a wedge can be used without a stem when sufficient bone stock exists.

Our study provides some insight as to why this may be so. The use of a stem in cases where bone stock is poor reduces bone stresses and limits micromotion between the wedge and the surrounding bone. Thus, our results combined with established clinical outcome of knee replacement surgery suggest that when poor bone stock and bone defects are encountered, the use of a metallic wedge augment with a stem lowers the stresses in the surrounding bone and lessens micromotion at the interface between the wedge and host bone.

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