Arthroplasty Rounds

A COMPARISON OF THE MECHANICAL STABILITY OF VARIOUS UNICOMPARTMENTAL TIBIAL COMPONENTS

Jack M. Bert, MD*
James D. Koeneman, PhD†

Unicompartmental knee replacements remain controversial in regard to indications, component design, and surgical technique. This article is important because, for the first time, a comparative study is conducted in regard to component stability. In all instances, it is the surgeon's responsibility to choose the optimal implant. This study provides guidance in regard to tibial component stability.

Arnold T. Berman, MD

Unicompartmental arthroplasty is useful in patients with single compartment disease and unicompartmental pain.¹ The advantages of this procedure include preservation of bone stock, retention of normal anatomy, improved range of motion, decreased blood loss, and decreased hospitalization and cost.²

Failures of cemented and uncemented implants have been reported. Some designs that were originally intended for cemented use were placed uncemented with a high incidence of poor results.³

Failures of previous designs have been attributed to poor instrumentation for implantation, poor designs leading to uncemented and cemented systems failure, and poor fixation capabilities of the components themselves.⁴,⁵

Metal backing of the tibial component has resulted in a decrease in the incidence of subsidence and some designs allow for utilization of screws for additional fixation.⁶,⁷

The question exists, however, as to what the optimal fixation is for immediate implant stability for a metal-backed unicompartmental component.

This study was designed to evaluate the effect of eccentric and shear load applications on five differently designed metal-backed, unicompartmental tibial components implanted noncemented, cemented, or cemented with screws for fixation into the tibia.

MATERIALS AND METHODS

To provide a repeatable test bed, composite tibiae with approximately the same elastic properties and anatomy as human bone were used. These composite tibiae were obtained from Pacific Research Laboratories (Vashon Island, Wash). The cortical walls of these tibiae had an elastic modulus of 13.5 GPa (2.7 million psi). Two partly raw materials (Daro RF 100) for making polyurethane foam were purchased from Daro Products (Butler, Wis). The polyurethane foam was prepared by manual mixing of the raw materials and water.⁸ The compression modulus of the foam core was measured to be 23 MPA (4200 psi). These values were within the low range of values of human cancellous bone in the proximal tibia.⁹

The shafts of the tibiae were cut and embedded in steel cups at a level 40 mm below the intended cut line. The plateaus of the tibia were machined on a milling machine and the cuts were made perpendicular to the shaft of the tibia. The proximal portion of each tibia was minimally removed until a completely flat continuous surface was obtained.

Five unicompartmental implants were tested: MGH (Zimmer Inc, Warsaw, Ind), Performance (Kirschner Medical Corporation, Timonium, Md), PCA (Howmedica Inc, Rutherford, NJ), Omnitfit (Osteonics Corp, Allendale, NJ), and Ortholoc (Dow Corning Wright, Arlington, Tenn) (Fig 1). Each implant was inserted into the composite tibia and tested three times for each load application. Mean results were tabulated and bar graphs formed (Figs 2-5).

The Performance and Ortholoc implants were tested three ways: uncemented with screws,
cemented with screws, and cemented only. The purpose of testing these prostheses utilizing cement with screws was simply to see if this would afford improved fixation as compared to cement alone. The MGH, PCA, and Omnifit were tested both with and without cement. These latter three prostheses do not have holes for additional screw fixation. Only the right medial compartment of the composite tibia was resected, matching the exact size of the sample tibial component. Attempts were made to match the sizes of corresponding tibial components with each other.

Implant stability of the tibial tray was tested using two types of loading. Lift-off was measured as an off axis vertical (eccentric) load. The vertical point load was applied to the posteromedial corner of the implant and lift-off of the anteromedial corner was measured (Fig 6). The load was applied by the ram of a Servo-Control Test Machine (Shore Western Manufacturing Co, Monrovia, Calif) in load control. The load was applied at a constant rate of 80 N/sec until failure of fixation occurred or to a maximum of .1 mm of displacement. The relative lift off was measured by a pin from the core of a linear variable differential transformer (Schaevitz Engineering, Pennsauken, NJ) which was attached in a perpendicular manner to the anteromedial tibial tray.

The coil of the LVDT was attached to the tibia (Fig 7). The applied load vs lift-off was recorded on an X-Y-T recorder (VP-5423S: Soltec, Sun Valley, Calif). The slope of the initial linear portion of this recording represented the compliance of the system. The larger the compliance, the larger the displacement for a given load. The maximum loads were identified and recorded. When testing the cemented prostheses, the maximum load occurred with a sharp cracking sound followed by a precipitous change in displacement or slope. The maximum load for the noncemented cases could not be determined because there was not a sharp change in slope. The noncemented results were presented as compliance (slope of the displacement—load line) since lift-off began at loads less than 5 N. Compliance is the inverse of stiffness, which is reported as the displacement at a given load divided by that load. Thus, the stiffness for the same test is the load at a given displacement divided by that displacement.

Shear loading was accomplished by mounting the prosthesis onto the tibia with its plateau vertically oriented. A load was applied to the posterior rim with the ram of the test machine as noted in this PCA component with its polyethylene insert removed (Fig 8). The test was run on the displacement control at a rate of .06 mm/sec.
This slow rate of loading was chosen to avoid dynamic induced motions in the test set-up. The load vs total displacement was recorded on the X-Y recorder. As in the lift-off test, the compliance of the fixation was measured as the slope of the displacement vs the load plot (Fig 9). The displacement load plot for a representative cemented case is shown in Fig 9A. Maximum load for the cemented cases occurred with a sharp crack and displacement. With a noncemented prosthesis, maximum load was reached more gradually with bending of the load displacement plot showing a rapid increase in displacement with the load increment.

Three specimens for each loading condition were tested and the mean results charted as compliance, peak load, or maximum load, depending on which testing modality was performed.

RESULTS

In noncemented cases, the compliance (slope of the lift-off vs load plot) for the vertical posterior load test was measured (Fig 2). The results with the MGH prosthesis were not illustrated, since this prosthesis had lift-off values greater than 3 mm with loads less than 4 N. The prosthetic implants without capability of screw fixation (PCA, Omnifit, and MGH) had larger displacements (Fig 2) than the prostheses implanted with screws (Performance and Ortholoc). The shear compliance results (Fig 3) showed that the prostheses utilizing screws resulted in lower displacements (less than .7 m/N) and failed at higher loads than the prostheses using just pegs.

In the cemented tests, lift-off opposite the posteromedial vertical load application was measured. The peak load is a load where separation between cement and foam (simulated cancellous bone) occurred (Fig 4). A cracking sound was heard and there was a sharp drop in load when separation resulted. The prostheses designed for use with cement exhibited a higher failure load (mean >3600 N), although the PCA and Omnifit failed at lower loads (<1380 N) than the Ortholoc, which is designed to be used without cement. The Performance implant resulted in the highest load prior to failure.

The cemented shear test did not indicate a dramatic difference among the various prosthetic designs when measuring loads prior to failure, with the exception of the PCA, which failed at 53% of the loads prior to failure of the MGH and Ortholoc (Fig 5).

Fig 5: Cemented shear maximum load testing results.

Fig 7: LVDT test method illustrated with load application.

Fig 8: Example of displacement vs load plot.
DISCUSSION

Unicompartmental tibial implant fixation failure is dependent on multiple factors. Prosthetic design, bone quality, fixation method, and whether cement is used all affect immediate and long-term implant stability.10-11

Before biological ingrowth can occur in a prosthesis that is implanted without cement, adequate initial fixation and stability must be present.12,13 Unless screws are used the implant must rely on an interference fit, which is quite difficult to achieve without the addition of screws.14 For biologic ingrowth to occur, micromovement of an implant must be minimal.15 Tibial implants that use screws result in a more stable pattern of immediate fixation than implants that utilize pegs alone.16

The purpose of this study was to evaluate the immediate implant stability of five different unicompartmental tibial components, both cemented and noncemented, under both shear and eccentric load applications. In this study, comparable testing was afforded by using artificial composite tibiae with identical cortical and cancellous elastic properties among specimens.

When loads were applied to a noncemented implant, gross discrepancies between the fixation methods were apparent. In noncemented lift-off, the prosthesis with three screws for fixation had the lowest compliance, indicating the greatest resistance to lift-off and the highest peak load measurements. The prosthesis with two screws performed well also, but the prostheses without screws exhibited dramatic micromotion with low loads, less than 15 N.

When shear loads were applied to noncemented implants, the prosthesis with two screws and a peg (the Performance) had the lowest compliance, indicating the greatest resistance to shear. It is hypothesized that the reason that the prosthesis with two screws (Performance) outperformed the prosthesis with three screws (Ortholoc) in noncemented shear testing is that the angle of the screws relative to the implant were relatively perpendicular in a Performance prosthesis as opposed to the cortical fixation of the Ortholoc prosthesis.

When shear loads were applied to the cemented implants, there was no dramatic difference in the results prior to failure, with the exception of the PCA prosthesis, which failed at loads less than 900 N.

Peak load measurements for cemented lift-off, however, showed a marked difference among the various prostheses. When measuring lift-off in a cemented fashion, the prosthesis with two screws and a peg (Performance) yielded the highest peak load with eccentric load application. The prosthesis with three screws (Ortholoc) performed poorly when cemented with eccentric load application. The Performance implant resisted higher loads than the Ortholoc prosthesis during cemented lift-off tests, most probably because the Ortholoc prosthesis had additional screw holes that reduced the area available for cement fixation.

CONCLUSION

When measuring different prosthetic implants with respect to initial implant stability in a noncemented fashion, those prostheses with a single peg (PCA and MGH) performed poorly when subjected to eccentric and shear stress load applications. The Omnifit performed poorly with eccentric load application but approximated the Ortholoc when shear stress loads were applied. The prostheses with two screws and a peg (Performance) and three screws (Ortholoc) performed well when both eccentric load and shear stress loads were applied.

When all five prostheses were cemented and shear loads applied, all five prostheses performed approximately the same, with the exception of the PCA. However, when undergoing eccentric load application to measure lift-off, the Performance prosthesis, using two screws and a peg with cement, had a much higher peak load than the other four prostheses tested. Interestingly, the MGH prosthesis performed relatively well with eccentric load application and the PCA and Omnifit implants performed poorly. Because of the reduced
area as a result of its three screw holes for cement fixation in the Ortholoc implant, this prosthesis exhibited loads in the middle of the group tested.

There is clearly a trade-off when implanting a cemented prosthesis. Both the screw holes and/or pegs reduce the area available for cement fixation at the bone/prosthetic interface by reducing the amount of cement that is in contact with the tray, so there is less resistance to lift off for a given load. The MGH prosthesis, because of its large surface area and small peg, had a relatively high resistance prior to failure when measuring cemented lift off.

The prosthesis that used two screws and a peg (Performance) when cemented had the greatest initial implant stability to off-axis vertical load testing. However, when more than two screws were used with cement, the surface area at the bone/cement interface was reduced, so that peak loads decreased dramatically when subjecting the prosthesis to eccentric load application. The prosthesis with three screws (Ortholoc), therefore, should be used in an un cemented fashion, as is indicated by the manufacturer.

The results of the study clearly indicate that those prostheses without additional screw fixation capabilities should not be placed non cemented, as is recommended by the manufacturer. The initial implant stability in those prostheses without screws when implanted without cement, especially with eccentric load application, resulted in significant micromotion at very low load application.

REFERENCES


EDITORIAL DISCUSSION

ORTHOPEDICS: How can we evaluate the data for statistical significance?

Bert and Koeneman: The purpose of using synthetic materials that have repeatable dimensions and elastic properties was to obtain test measurements that have small variation. Based on the results of similar test programs we have performed at the Harrington Institute, the measurements have small deviations and the average results reported in the paper are representative of the relative performance of the various fixation methods. We address this under Materials and Methods, by stating that we were trying to provide a repeatable test bed utilizing composite tibiae with approximately the same elastic properties of human bone. We also state that we tested each composite tibia only three times for each load application. To use any of the standard statistical evaluation methods would be inappropriate with this many specimens. However, the deviations were so small between test specimens that clearly the average results did not represent the relative performance of the various fixation methods.

ORTHOPEDICS: How do you respond to the charge that using bone cement with screws is not a sound clinical practice and cannot be recommended?

Bert and Koeneman: The purpose of the paper was to test whether or not using bone cement with screws is appropriate. There are numerous authors who discussed the concept of cement with screws, such as J.E. Dalton and S.D. Cook (personal communication, 1992) from Tulane University School of Medicine who presented, at the 16th Annual Meeting of the Society
of Biomaterials in 1990, the concept of using screws with cement. They felt that a suboptimal cement layer thickness that occurred with screws with cement could result in loosening of the cement.

Furthermore, Aaron Hoffman (personal communication, 1991) from the University of Utah had been utilizing screws with cement for over 5 years in a select patient population without complication. Miller et al.¹ from Montreal General Hospital utilized screws with cement on the majority of their total knee replacements for over a decade, and lectured widely that it was their preferred method of fixation. However, there has not been any reported published material regarding utilization of screws with cement aside from presentations at various meetings and the suggestion by Krause and Miller² that this technique may be necessary for increased cement penetration.

To argue that it is "not sound clinical practice"³ is, in my opinion, strictly an anecdotal statement, and a conclusion that cannot be drawn from the literature. One of the authors (JMB) currently has a series of 102 unicompartmental knee replacements in which over 85 of these cases with screws with cement as the fixation method are now out a minimum of 6 years. Not one of these patients has had a failure of the tibial component, and the cement-bone interface in each case shows no evidence of lucency. It is our belief that screws with cement allow for deeper cement penetration than simple hand packing; this is the reason why it may make a great deal of sense to utilize screws with cement for additional cement penetration which, as noted in the article by Miskovsky et al.,⁴ results in improvement in resistance to eccentric loading in vitro.

REFERENCES (EDITORIAL DISCUSSION)

Section Editor: Arnold T. Berman

---

ILIZAROV METHOD COURSE

BALTIMORE, MARYLAND

JULY 7-10, 1994

ADVANCED PREOPERATIVE PLANNING
FOR COMPLEX DEFORMITIES

Program Co-Directors
Dror Paley, M.D. and John E. Herzenberg, M.D.

This course will teach advanced techniques in preoperative planning for limb deformity correction in children and adults. Bioskills workshop sessions will emphasize preoperative planning from radiographs and frame preconstruction as well as review new osteotomy techniques. The surgical techniques reviewed will include external fixation and intramedullary rodding.

Enrollment Fee – $450, Residents – $350
Prior Ilizarov Method course required

FOR MORE INFORMATION, CALL 1-800-344-9672

ORTH 6/94