Evaluating Factors Affecting Patellar Component Fixation Strength in Total Knee Arthroplasty

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Abstract

Complications related to the patellofemoral joint after total knee arthroplasty (TKA) represent up to 50% of TKA reoperations. Shear forces across the knee produce wear and occasionally result in failure of fixation of all-polyethylene patellar components.

We conducted a study to evaluate the effect of 2 factors on the shear strength of patellar component fixation: time between cement mixing and application of the patellar component, and amount of pressure applied during implantation. Fifty-four patellae were harvested from 27 cadavers and were prepared as for a TKA, allowing 3 different amounts of time for the cement to set or cure before application, and using 3 different pressures. The patellae were mounted and tested for fixation strength with a materials testing machine.

Fixation was significantly stronger (P = .006) at 42 pounds of pressure after curing the cement for 8 minutes (compared with 2 minutes) and was significantly stronger (P = .005) after 2 minutes of curing at 42 pounds of pressure (compared with 62 pounds of pressure).

We concluded that allowing the cement to cure while cementing the femoral and tibial components does not jeopardize fixation of the patellar component and that excessive compression of a patellar clamp may weaken fixation.

hile total knee arthroplasty (TKA) is an effective treatment for osteoarthritis of the knee, this procedure continues to be refined. Complications related to the patellofemoral joint after TKA represent up to 50% of the cases for TKA reoperation.^{1,2} Although these issues can be surgically addressed as necessary, the results of revision surgery for isolated patellofemoral complications have been disappointing. Leopold and colleagues³ reported that 37.5% of knees failed clinically or radiographically after revision surgery, and 20% of these required further surgery. Those results are comparable to those of Berry and Rand,⁴ who reported a complication rate of 33%, and a reoperation rate of 19% after isolated patellar revision at a mean follow-up of 3.5 years. Use of cemented, all-polyethylene patellar components has produced good long-term outcomes⁵; however, shear forces across the knee have been reported to consistently produce wear, and occasionally result in failure of all-polyethylene patellar components.⁶⁻¹⁰

During TKA, most surgeons implant the tibial and femoral components and then the patellar component. Cement is allowed to set or cure for several minutes before the patellar component is implanted. Our hypothesis was that, as the cement cures, it loses some of its ability to infiltrate patellar bone and produces a weaker bond. If this were the case, the surgeon might be able to mix a separate batch of cement for the patella, though that would increase cost.

Regarding the pressure applied to the patellar component, we were unable to find any specific recommendations in the literature. The cement manufacturer does not recommend any particular pressure, and surgeons vary widely in technique, some squeezing the component between finger and thumb, and others using a forceful grip on a patellar clamp.

We conducted a study to identify surgical techniques that would increase the fixation strength of the patellar button, thereby decreasing the chance that it would fail in shear. The 2 factors we evaluated were time between cement mixing and application of the patellar component, and amount of pressure applied during implantation.

Materials and Methods

Fifty-four patellae were harvested from 27 cadavers (13 male, 14 female). Mean age of the cadavers was 77.6 years. Cause of death was unrelated to bone disease. Specimens with severe degenerative changes eroding the bone on gross examination were discarded. The remaining patellae were cleared of all other soft-tissue. The specimens were then stored in airtight bags with a preservative moistened towel at 40°C.

Each patella was prepared as for a TKA. The articular surface was cut to a smooth surface with a reciprocating saw. We used

Authors' Disclosure Statement: Biomet provided the patellar components, the bone cement, the patellar clamp, and use of the patella drill guide and drill for this experiment.

a pair of calipers to ensure that 13 to 15 mm of bone remained. The patella was then prepared for the assembly of the patellar prosthesis by drilling 3 holes in the medial side of the cut surface using the same drill guide and bit (Biomet Inc, Warsaw, Indiana) that are used during surgery. The resulting specimen was then washed and dried with towel and wall suction before implantation of the patellar component.

All-polyethylene, 3-post patellar components (Biomet Inc, Warsaw, Indiana) were applied using 3 different pressures and allowing 3 different curing times. The implant manufacturer provided a specially designed clamp that functions just as the intraoperative clamp does, but it has a gauge for measuring pressure at 3 graduations. A force transducer was used to calibrate this clamp. The resulting pressures at the premarked lines on the clamp measured 42 pounds (P1), 50 pounds (P2), and 62 pounds (P3). The polyethylene implants were applied with these 3 pressures. The force transducer was clamped along with the patellar construct. In our experience, the pressure of 30 pounds is roughly equal to using finger and thumb to squeeze the implant to the patella. P2 appears roughly equal to "2-finger tightening" of the clamp, and P3 is similar to holding the clamp with a tight grip.

We also measured the variable of cement curing time. Radiopaque methyl methacrylate/methyl acrylate bone cement (Palacos G; Biomet Orthopedics Inc; Warsaw, Indiana) was used. It was mixed as directed on the package using a single mix kit (Optivac Vacuum Mixing System, Biomet Inc, Warsaw, Indiana). Time zero was started after the 2 components were combined in the kit, and the mixing was initiated.

The patellar components were applied after cement curing times of 2 minutes (T1), 4 minutes (T2), and 8 minutes (T3). The clamps were left in place with the desired amount of pressure being applied for a total of 15 minutes.

The procedure was performed in a room similar to an operating room, set at a temperature of 17°C, which according to the cement manufacturer results in a total curing time of 14 minutes. The constructs were then left to dry for 2 to 3 days before further testing.

The patellae were mounted individually to test them for fixation strength. Polyvinyl chloride (PVC) pipe measuring 2 inches in diameter was cut into pieces 2.5 inches long, and cellophane tape was applied to one end of each piece to create a watertight seal. Then, PVC pipe measuring 1 inch in diameter was cut to an appropriate length to create a pedestal (to be placed in the wider pipe) for the patellar construct. The length of the pedestal was measured such that the patellar bone was submerged in the 2.5-inch PVC pipe with the polyethylene component exposed and parallel to the top of the pipe. The patellar construct was kept from rocking on the pedestal first by placing 3 small (4×4-mm) balls of putty (Play-Doh; Hasbro, Pawtucket, Rhode Island) on top of the pedestal. The pipe was then filled with adhesive (Bondo 432; 3M, St. Paul, Minnesota), which the manufacturer recommended for this experiment. The resulting construct was then left to dry overnight before testing.

The patellar components were loaded with isolated shear

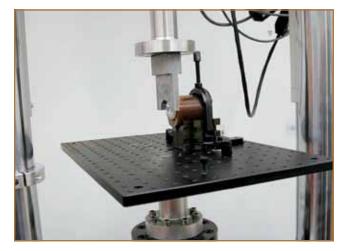


Figure 1. Materials testing machine (MTS; MTS Systems Corp, Eden Prairie, Minnesota) with guillotine-type shear-testing apparatus and patella mounted in polyvinyl chloride pipe.

stress using a guillotine-type device attached to a materials testing machine (MTS; MTS Systems Corp, Eden Prairie, Minnesota), which fits concentrically over the superior portion of the patellar component (**Figure 1**). Attached to the load cell was a base plate on which a V-block specifically designed to hold the patella–Bondo construct was placed. The testing machine was set to perform an axial displacement of 5 mm per minute. A compressive force was then applied directly to the patellar implant. The load–displacement curve was recorded until failure occurred at the bone–cement interface. Resulting curves and peak stress pressures were analyzed to determine which pressures and curing times provided optimum fixation strengths.

Comparison of the 3 curing times and 3 pressures resulted in 9 cells of data, each with 6 samples, for a total of 54 samples. Because 4 specimens were discarded, 4 cells had only 5 data points. In these cells, the mean of the remaining 5 data points was used as the sixth point. With the offset yield used as the failure point, the differences between cells were analyzed using a (3×3) 2-factor analysis of variance (ANOVA). If statistical significance was demonstrated, a Tukey HSD post hoc test would be used to determine significant differences between cells. Statistical significance was set at P<.05.

Results

We consistently identified 2 points of failure. The first point is the offset yield point. We define this as a noticeable horizontal change in the slope of the stress/strain curve, indicating failure occurring at the cement mantle. Plastic deformation occurs here because the polyethylene pegs are abutting cancellous patellar bone. Therefore, more force is required to cause complete failure of the patellar construct. Gross examination of the specimens at the offset yield point confirms this definition, as we were able to identify cracks in the cement mantle, while still having the patellar component firmly seated within the



Figure 2. Patella with patellar component after shear testing.

bone. We were seeking to identify factors that increase the strength of the cement fixation and used the offset yield as the failure point in this study (**Figure 2**).

The second failure point, peak offset, is the point at which the slope of the stress/strain curve becomes negative, and the patellar component completely dissociates from the bone. Here we noticed that either the pegs bent, allowing them to come out of the bone, or the patellar bone failed and the implant was dislodged. However, we did not witness any fracture occurring at the peg-plate junction, as has been reported to occur in vivo.⁷⁻¹⁰

We identified 4 curves in which the typical pattern did not occur. These displayed only 1 failure point, occurring with significantly less shear stress than the other 48 specimens. In these constructs, the patellar component had pulled completely out of the patellar bone, with no visible disruption of the cement mantle. These constructs were not included in the data analysis.

The 2-factor ANOVA did not identify statistically significant differences for the main effect of curing time (P = .380), the main effect of pressure (P = .595), or the interaction between curing time and pressure (P = .496). We expected a priori to have identified a significant interaction between a specific pressure and curing time. It was apparent that the 2-factor (3×3) ANOVA was unable to identify statistical significance between the 9 cells because the overall variance of the model was large and the N within each cell was small.

On our a priori assumption, we performed a series of unpaired t-tests between pairs of cells at curing times T1 (2 minutes), T2 (4 minutes), and T3 (8 minutes), and compared the 3 times within each of the pressures P1 (42 pounds), P2 (50 pounds), and P3 (62 pounds). Analyzing the differences between the patellar constructs at each curing time across all 3 distinct pressures, we found a trend toward stronger fixation with longer curing time, and at 50 pounds of pressure the difference in shear force, 366 pounds at 8 minutes versus 261 pounds at 2 minutes, was significant (P = .006). In addition, there was a trend toward stronger fixation with lower pressure, and at

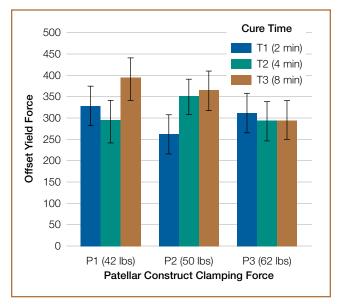


Figure 3. Graph of results of shear testing.

2 minutes the difference in shear force, 359 pounds at 42 pounds versus 328 pounds at 50 pounds, was significant (P = .005) (Figure 3).

Discussion

Patellofemoral complications can be related to surgical technique, including cementing of components. The rate of component failure using an all-polyethylene patellar component is low. Brick and Scott,⁶ reporting on 1462 Kinematic and 1309 Duopatellar cemented all-polyethylene patellar components, found a 1.1% rate of patellar fracture and a 1% rate of loosening. Francke and Lachiewicz⁷ and Larson and colleagues⁸ reported on failure of a cemented all-polyethylene 3-peg component of a press-fit condylar knee arthroplasty (Johnson & Johnson, Braintree, Massachusetts) in which all 3 pegs fractured at the peg-plate interface. Huang and colleagues⁹ reported on 4 cases of the all-polyethylene patellar implant breaking at the pegbutton interface and 1 case of the patellar component loosening by cutting out the patellar bony base. In addition, Shafi and colleagues¹⁰ reported on 1 case of a 3-peg all-polyethylene patellar component failure in a patient diagnosed 10 years after surgery by arthroscopy. As with the other reported cases, all 3 pegs of the implant were found sheared off.

The cause of failure of all-polyethylene components appears to be shear stresses across the patellofemoral joint. Shear forces can be explained by studying the normal kinematics of the knee. Ahmed and colleagues¹¹ demonstrated that, during knee flexion, the articular contact surfaces of the patella shifts from distal to proximal. As a result of this movement of the retropatellar contact pressures, noncentric loading of the patella occurs, resulting in shear force. The entire range of the retropatellar surface is subject to force vectors occurring during normal activities of daily living, with the most proximal to distal directed (shear) force occurring when knee flexion

exceeds 45°, such as in stair climbing and rising from a seated position. The eccentricity of the patellar load is also influenced by surgical factors, such as joint-line lowering, rotational malalignment, patellar thickness, and patellar component shape.¹

To prevent deformation of the all-polyethylene components and provide a substrate for porous coating, investigators in the early 1980s added metal backing to tibial and patellar components without cement; however, the first-generation designs of metal-backed patella components were plagued by a high rate of failure.^{4,12} Revision of these components was related to loosening, fracture, polyethylene wear to the metal backing, dissociation of polyethylene from the metal base plate, and fracture of the fixation pegs.

In the present study, we evaluated the effects of cement curing time and pressure applied to the implant on component fixation strength against shear forces. In our experience, most surgeons performing TKA place the patellar component after the femoral and tibial components have been placed. As a result, the cement used for the patella is subject to longer curing before application. One study objective was to determine if this additional time resulted in weaker fixation of the patellar construct and would justify the cost of mixing an additional batch of cement. The pressure at which the patellar component should be applied is another variable lacking recommendations. We hoped to demonstrate the optimal amount of pressure to be applied during patellar component cementation.

The results of this investigation demonstrated that component fixation was significantly stronger after curing the cement for 8 minutes than for 2 minutes. This finding is contrary to our hypothesis. We now theorize that cement of a firmer consistency could force penetration into cancellous bone and may have less extrusion, thereby avoiding a thin, weak cement mantle. After 8 minutes, the cement begins to harden at an accelerated rate, becoming more difficult to eject from the applicator. Furthermore, 42 pounds of pressure yielded stronger fixation than 62 pounds of pressure did, consistent with our initial hypothesis.

There are several limitations to this study. First, we used cadaveric patellae with various bone qualities. However, assignment to a specific pressure/curing-time cell in the experimental design was random. Second, we used a failure mechanism different from the cyclic loading seen clinically. The pegs of the patellar component were not broken off, but bent after the cement mantle failed. In the study, however, we examined the point at which the cement mantle failed, which consistently occurred before peg bending. We believe that increasing the strength of the cement mantle will result in less failure of the patellar component clinically. Third, the sample size was not adequate to obtain statistical significance using the ANOVA.

In conclusion, we believe that fixation of the patellar component in TKA is stronger with longer cement curing time, and thus fixation is not compromised by using the same cement batch for all 3 components. In addition, fixation may be stronger when less pressure is applied. We continue to apply a clamp and use 2-finger pressure.

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