Effect of Bone Cement Viscosity and Set Time on Mantle Area in Total Knee Arthroplasty

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Abstract

To assess the impact of bone cement viscosity on total knee arthroplasty, we compared 1 high-viscosity and 2 medium-viscosity cements with respect to mantle area and zone-specific intrusion depths into the tibial plateau. We analyzed postoperative radiographs to determine penetration area and depth in 72 consecutive patients (79 knees) in whom DePuy II (n = 11), Endurance (n = 34), or Simplex-P (n = 34) cement was used.

Penetration into the tibial plateau (anteroposterior zones 1-4) was significantly reduced with use of the high-viscosity DePuy II cement but did not differ significantly between the 2 medium-viscosity cements, Endurance and Simplex-P. Surgical and tourniquet times were significantly decreased with the quicker setting DePuy II cement.

Given these findings, additional studies are warranted to assess the long-term impact of the lower intrusion depths found with DePuy II cement. Such differences in cement penetration could jeopardize long-term fixation and lead to higher long-term device failure rates.

Achieving optimum cement penetration during fixation of the tibial tray component is an essential step in successful total knee arthroplasty (TKA). Mantle penetration 3 to 5 mm below the tibial base plate has been reported to improve the static strength of the implant–cement–bone construct and to ensure the long-term mechanical fixation of the implant by preventing infiltration of wear particles and thereby avoiding peripheral osteolysis and associated component loosening.[1-5] Multiple techniques for controlling preparation of the bone surface or cement and controlling pressure at the cement–bone interface during curing have been used to enhance the mechanical properties of the implant–cement–bone construct. Centrifugation and vacuum mixing techniques have been reported to reduce the voids in the cement, which serve as points of microcrack initiation[6-9]; pulsatile lavage of the bone bed is used to wash away blood, marrow, and other bone debris, which can reduce cement–bone interdigitation[10-12]; and cement pressurization techniques have been used to increase the depth of cement intrusion into the proximal tibia during TKA.[12-14]

Intrusion depth is thought to be a function of cement viscosity, bone permeability, and the pressure gradient applied to the curing methylmethacrylate. During any TKA, porosity of the native bone is fixed; during digital application of cement, the applied pressure should remain quasi-constant. Therefore, controlling cement viscosity during application to bone is of great importance in ensuring adequate intrusion, which leads to the long-term success of the TKA. Several cements with a wide range of viscosities and set times are available, and, though the high-viscosity, faster setting cements might significantly reduce operating room times, to our knowledge direct comparison of penetration depths between cement types has not yet been made with regard to TKA.[2,3,7,15,16]

In the study reported here, we compared mantle intrusion depth and operative time in TKAs performed with the quick-setting, high-viscosity DePuy II cement (DePuy, Warsaw, Ind) or a medium-viscosity cement, Endurance (DePuy) or Simplex-P (Stryker, Kalamazoo, Mich).

Methods

Study Design

This study involved retrospective review and analysis of data collected as part of a prospective device registry study. The study was approved by a local institutional review board.

Patient Groups

Patients were identified through a database query of the registry. Patients who had undergone TKA with the Zimmer NexGen LPS device (Zimmer, Warsaw, Ind), had the surgery performed by the same surgeon using the same surgical approach and cementation technique, and had been followed up for at least 1 year were included. Consecutive patients were placed into 3 groups based on type of cement used during the procedure: DePuy II,

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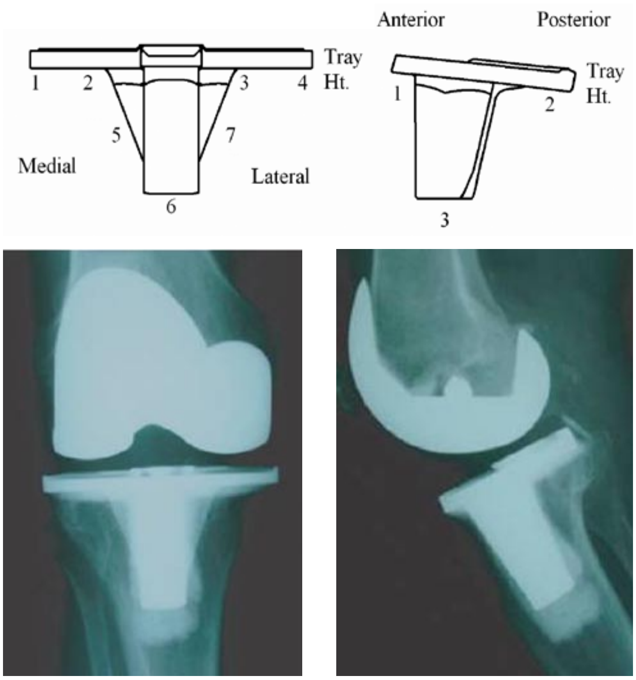

Figure 1. At 6 weeks, cement mantle depth penetration measurements were made in zones numbered in anteroposterior and lateral views of tibial tray (top row). Total area of cement mantle was also assessed from radiographs. Representative patient's radiographs are shown for comparison.

Endurance, or Simplex-P. DePuy II is a quick-setting, high-viscosity cement, and Endurance and Simplex-P are medium-viscosity cements.

Device

Zimmer NexGen LPS Complete Knee System components were used exclusively for this study. All procedures were performed in an ultraclean room with the surgical team wearing body isolator systems. Polyethylene components were all gamma-sterilized in nitrogen.

Cementation Technique

For all TKAs, the cement preparation and application technique was identical. Each type of cement was hand-mixed in a bowl for 1 minute and probed every 15 seconds thereafter with a clean surface of a Biogel powder-free latex glove, as defined in standards published by the ASTM (American Society for Testing and Materials) and the ISO (International Organization for Standardization).[17,18] When the cement no longer adhered to the glove, it was deemed ready for use. Immediately after pulsatile lavage, suction, and drying, the cement was applied liberally to all surfaces of the prostheses and digitally impacted into the superior surface of the proximal tibia. In addition, a roughly cylindrical cement mass was formed and placed in the medullary canal. The components were impacted into place, and the surgeon carefully removed any excess cement. The tourniquet was inflated only for bone preparation, pulsatile lavage, and cementation of the TKA components. For all procedures, operating room temperature was 65°F and humidity set point was 55%.

Data Collection

Physical examination and standard radiographic evaluations were completed for each patient 6 weeks, 6 months, and 1 year after TKA. Outcome evaluations included Knee Society Score–Function (KSSF) and –Assessment (KSSA), range of motion (ROM) computation, and evaluation of occurrence of radiolucencies. In addition, data were collected from the surgical notes for each patient's procedure.

Six weeks after surgery, plain orthogonal radiographs were analyzed to determine cement penetration depth. Images were analyzed with digitalization techniques and MCID Elite 6.0 software (Imaging Research, St. Catharines, Canada), which was calibrated to control for magnification. Anteroposterior (AP) and lateral radio-

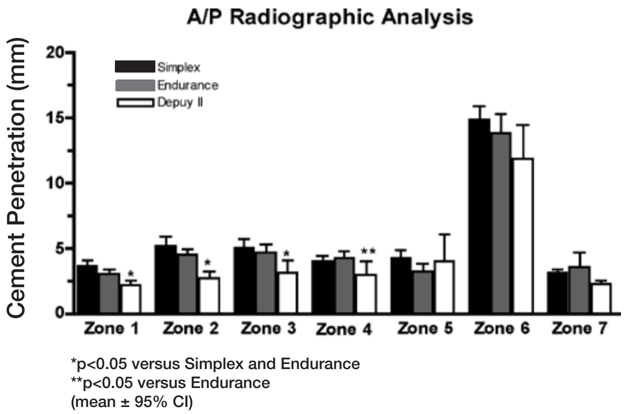

Figure 2. Penetration depth in anteroposterior radiographic plane is compared between cement types. Penetration was higher in all zones of the tibial plateau with use of medium-viscosity cements versus high-viscosity cement. Statistically significant differences were noted in zones 1 to 4.

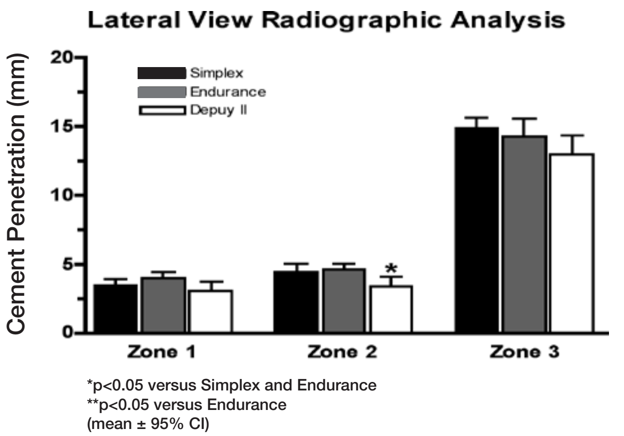

Figure 3. Penetration depth in lateral radiographic plane. Cement penetration was lower in all zones with use of high-viscosity cement versus medium-viscosity cements. In zone 2, the difference between the DePuy II and Endurance cements was statistically significant.

Table. Patient Demographics

Demographic	Bone Cement Simplex	Endurance	DePuy II
Patients (n)	32	30	10
Knees (n)	34	34	11
Mean age (y)	70.1± 9.8	71.5±9.6	66.0±6.8
Sex (% female)	69	57	80
Median tibia size	5	5	4
Operating room time (minutes)	68.0±13.7	71.2±12.2[a]	57.8±10.8
Tourniquet time (minutes)	22.7±5.9	21.7±8.8	17.7±7.4
Manufacturer's listed set time (minutes at 65°F)	14.3	14	6.5

[a]*P*<.01 when compared with DePuy II.

graphs were analyzed by Knee Society zones[19] with regard to cement intrusion depth and total area of cement mantle achieved (Figure 1). Tibial tray height was measured in AP and lateral planes to assess radiograph magnification and tray rotation (all trays were 3.5-mm thick) relative to the plane of the radiograph.

Statistical Analysis

Between-group comparisons of nominal data were made with 1-way analysis of variance, and categorical data were compared with the χ^2 test. All comparisons were made with SPSS software (Version 13.0), and statistical significance was assumed at *P*<.05.

Results

Of the 72 patients identified from the study inclusion criteria, 32 (34 knees) underwent TKA with Simplex-P bone cement, 30 (34 knees) underwent TKA with Endurance cement, and 10 (11 knees) underwent TKA with DePuy II cement. The Table lists the group demographics. No statistically significant differences between cement groups were found for age (*P* = .27) or tibial component size (*P* = .28). Eight (80%) of 10 patients in the DePuy II cement group were female, but this difference was not statistically significant (*P* = .35).

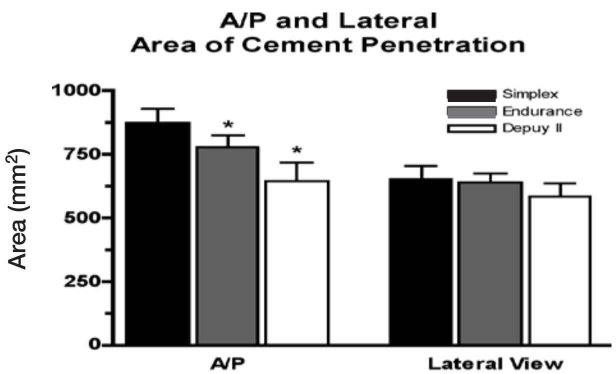

Figure 4. Penetration area was significantly increased in anteroposterior and lateral radiographic planes with use of medium-viscosity cements versus high-viscosity cement. A statistically significant difference was also found between medium-viscosity cements.

Mean operating room time was not significantly different between the longer setting Simplex-P (mean, 68 minutes) and Endurance (mean, 71 minutes) groups but was shorter for the quick-setting DePuy II group (mean, 58 minutes), and the difference between this group and the Endurance group was statistically significant (*P*<.05). Tourniquet time was also shorter for the DePuy II group, but this difference was not statistically significant (*P* = .18).

Radiographic image analysis in the Knee Society zones (Figure 1) in the AP and lateral planes revealed higher penetration depths in all zones for the medium-viscosity cements compared with the high-viscosity DePuy II cement. The Simplex-P group had the most cement penetration in AP zones 1, 2, 3, 5, and 6, and the Endurance group in zones 4 and 7. Statistically significant differences were noted in zones 1 to 4 (Figure 2). Cement penetration depths in the lateral radiographic plane are shown in Figure 3. Penetration of the high-viscosity DePuy II cement was again lower in all zones when compared with the medium-viscosity cements. In zone 2, the difference between DePuy II and Endurance was statistically significant. Figure 4 shows total area of cement penetration in the AP and lateral planes. Significant differences were detected in the AP plane but not in the lateral plane.

No significant differences in postoperative knee scores or functional assessments (KSSF, KSSA, ROM) were detected between the 3 groups at 6 weeks, 6 months, or 1 year. Potential device-related adverse events identified during the 1-year follow-up included 2 cases of deep venous thrombosis and 1 case of hemarthrosis treated with synovectomy and polyethylene liner exchange.

Two radiolucencies were identified in the tibia of the DePuy II group at 1-year follow-up but none in the Simplex-P and Endurance groups. No device failures were observed in any group at 1-year follow-up.

Discussion

Previous studies using sawbones (femur) and porcine tibial plates successfully examined cement depth and penetration characteristics for TKA components.[13,20] The approach used in our study was similar but was performed with radiographic review and image analysis. In general, we identified mean cement depths of 2 to 5 mm in most tibial plate zones regardless of cement type used. Cement penetration was consistent with that previously reported as yielding optimum fixation of the tibial tray.[2-4]

Our results indicate that, with the interface pressures created by this particular implant type (Zimmer NexGen LPS) and surgical technique (bowl mixing, pulsatile lavage, drying, hand-packing), use of medium-viscosity cement significantly increased penetration depth in AP zones 1 to 4 of the tibial plateau. Penetration depths were also significantly increased in lateral zone 2 (posterior) when compared with the high-viscosity cement. Difficulty in effecting deep penetration in this zone has been noted in the literature; this zone is one of the more difficult to thoroughly lavage and cement.

Increasing cement intrusion depth without increasing cement porosity or sacrificing prosthesis–cement interface quality is thought to prolong the life of TKA components. Although mechanical fixation might be improved with use of longer setting medium-viscosity cement, use of such cement (vs quick-setting high-viscosity cements) is also associated with significantly increased operating room time (mean, 10 minutes per case). Increased operative times might be associated with increased tourniquet times and would likely be associated with increased institutional costs. Functional assessment results at 6 weeks, 6 months, and 1 year did not differ significantly between cement types.

We tried to control for the variable of cement viscosity at time of application. As any number of chemical or environmental factors can affect time needed for curing before use, ASTM and ISO standards for dough time determination were used.[17,18] These standards define dough time as the postmixing time at which a gloved finger separates cleanly from a freshly exposed surface of the cement. Although this measurement depends to a certain extent on the observer and has been reported to vary widely between glove types,[21] we feel that using this method is easier than attempting to control for all environmental variables and wait a predetermined amount of time to apply the cement. Environmental variables that affect set time include mixing technique and chemical content of the unmixed cement. Ideally, if the glove test accurately represents a measure of cement viscosity, then all cements should have the same viscosity when removed from the mixing bowl. Therefore, any penetration depth difference would be attributed to the part of the curing process between when cement is removed from the bowl and when it is pressurized beneath the TKA component, as the higher viscosity cement cures at a faster rate. However, dough time is not a direct measure of viscosity but rather a measure of the time it takes for the storage and loss moduli to equal each other (ie, the time when the viscous and elastic material properties are roughly in equilibrium).[22] The difference in curing rates and the larger storage and loss moduli (ie, stiffer and more viscous) of high-viscosity cements at dough time are most likely the major factors in producing the different penetration depths found in this study.

In general, the results presented here agree with the conventional wisdom regarding cement penetration into cancellous bone, which is to say that cement permeability decreases with increasing viscosity.[23] The faster setting cement significantly reduced operative time, but its effect on postoperative knee scores was not conclusively demonstrated at the time points examined in this study. Additional studies using similar approaches in this patient population are warranted and should include long-term (>5 years) follow-up to further clarify the relationship between cement viscosity and long-term mechanical fixation of TKA components.

Authors' Disclosure Statement and Acknowledgments

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