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EVALUATION OF THE EFFECT OF CEMENT VISCOSITY ON CEMENT MANTLE IN TOTAL KNEE ARTHROPLASTY

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ABSTRACT

Aseptic loosening of the tibial implant remains one of the major reasons of failure in Total Knee Arthroplasty (TKA). The cement viscosity at the time of application to the bone is of great importance to ensure a long-term success of the arthroplasty, as it influences the cement penetration and stability of the prosthesis. Currently, there are number of cements available with a wide range of viscosities and set times. High viscosity faster-setting cements may significantly reduce operating room times. However, the concern is that this positive feature may be at the expense of decreased penetration into the bone, and hence reduced stability of the construct. The use of four cement types ((DePuy II (DePuy Inc. Warsaw, IN), Endurance (DePuy Inc. Warsaw, IN), Simplex-P (Stryker Corp Kalamazoo, MI), and Palacos (Zimmer, Inc, Warsaw, IN)) were compared and evaluated during TKA using surrogate tibiae, with respect to the depth of cement penetration according to the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation System. On radiographic analysis of the implanted surrogate tibiae, it was found that Simplex had the maximum commulative penetration of 19.2 mm in seven zones in Mediolateral view, and 12.7 mm in three zones in anteroposterior view. In zone seven, the difference was statistically significant when comparing Simplex with Palacos (11 mm vs 4.6 mm, two-tailed P value = 0.035), somewhat significant with Depuy 2 (11 mm vs 6 mm, two tailed P value = 0.08), but the different was not significant when compared with Endurance (11 mm vs 10 mm, two-tailed P value = 0.6345). In Zone 5, the difference was statistically significant with Simplex vs Endurance (0.3 mm vs 2.2 mm, P = 0.028), and with Simplex vs Depuy 2 (0.3 mm vs 2.17 mm, P = 0.012). This study enhances the understanding of the relation between cement viscosities and cement penetration into cancellous bone during TKA.

INTRODUCTION

Aseptic loosening of the tibial implant remains one of the major reasons of failure in Total Knee Arthroplasty (TKA) [1-3]. In most of the cases, implant failure is attributed to the micromotion at the cement-bone interface [4], which leads to bone resorption and finally loosening of the prosthesis [4-6]. The cementation techniques aim to improve the bone-cement micro-interlocking, and reduce the chances of aseptic loosening. The cement penetration depth has an inverse relationship with radiolucency [7], and influences the mechanical strength of the bone-cement interface [8, 9]. Though low viscosity cements yield higher penetration depths [10], controversy remains on the relation between viscosity, cement penetration into bone, and the shear strength at the interface [6, 11-16].

The acrylic bone cement is made of two parts mixture of liquid and solid, which when mixed form a solid load bearing material following an exothermic chemical reaction. It has been successfully used in numerous orthopaedic applications, with excellent clinical results for TKA [17, 18]. Achieving optimum cement penetration during fixation of the tibial tray component is essential for a successful total knee arthroplasty (TKA). Cement mantle penetration of 2-5 mm below the tibial base plate has been

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reported to improve the static strength of the implant-cement-bone construct, thereby ensuring the longevity of the implant by preventing the infiltration of wear particles, and avoiding peripheral osteolysis and associated component loosening [15, 19-22].

Multiple techniques have been described to enhance the mechanical properties of the implant-cement-bone construct by controlling the preparation of the bone surface preparation [5, 9, 19], method of cement application [9], the quantity of bone interdigitating with cement [7, 21], and the pressure at the cement/bone interface during curing cement[5, 6, 22, 23]. A recent study demonstrated the significant impact of cement mantle porosity on the mechanical behavior of the bone cement during in vivo use, with higher porosity corresponding to lower fracture toughness [24]. Centrifugation and vacuum mixing techniques have also been reported to reduce voids in the cement, which may serve as micro-crack initiation points [25-28]. Finally, cement pressurization techniques have also been used to increase the cement intrusion depth into the proximal tibia during TKA [29-31].

During any TKA, the cement viscosity at the time of application to the bone is of great importance to ensure a long-term success of the arthroplasty, as it influences the cement penetration and stability of the prosthesis. There are currently a number of cements available with a wide range of viscosities and set times. Currently more viscous cements are preferred as they set up faster, and reduce operating room time. The hypothesis is that this positive feature comes at the expense of decreased penetration into the bone, and reduced stability of the construct.

The proposed study evaluates and compares the use of four cement types (DePuy II (DePuy Inc. Warsaw, IN), Endurance (DePuy Inc. Warsaw, IN), Simplex-P (Stryker Corp Kalamazoo, MI) and Palacos (Zimmer, Inc, Warsaw, IN)) during TKA, with respect to radiolucency, and depth of cement penetration under identical surgical conditions. To the authors' knowledge a direct comparison of these cement types has not yet been made with regard to TKA, in terms of radiolucency, penetration depth, and interface characteristics.

MATERIALS AND METHODS

Twelve (12) sawbone open cell blocks (Pacific Research Laboratories, Inc., Vashon Island, WA) simulating tibial cancellous bone, were used for the study. The sawbone chosen has a subsurface quality and an open cell texture very closely matching the structure of proximal tibial cancellous bone. The ease of availability, consistency, and control in the variables like bone porosity, and quality of the bones influenced the choice of using the surrogate tibiae for the experiment. The tibiae were divided into four groups of three, with each group receiving the treatment with one cement type. The four bone cement types of varying viscosities which were used for comparison were DePuy II (DePuy Inc. Warsaw, IN), Endurance (DePuy Inc. Warsaw, IN), Simplex-P (Stryker Corp Kalamazoo, MI) and Palacos (Zimmer, Inc, Warsaw, IN). Standard arthroplasty cuts were performed on each proximal tibia utilizing the same surgical approach, prosthetic components (Zimmer NexGen LPS), and cementation technique. Surrogate open cell tibial construct with Zimmer NexGen LPS prosthetic surgical components mounted on it is shown in Figure 1. The Zimmer NexGen LPS tibial plate design includes cement wells on all component surfaces to facilitate cement pressurization (Fig. 2). All surgical procedures were performed by the senior orthopaedic surgeon.

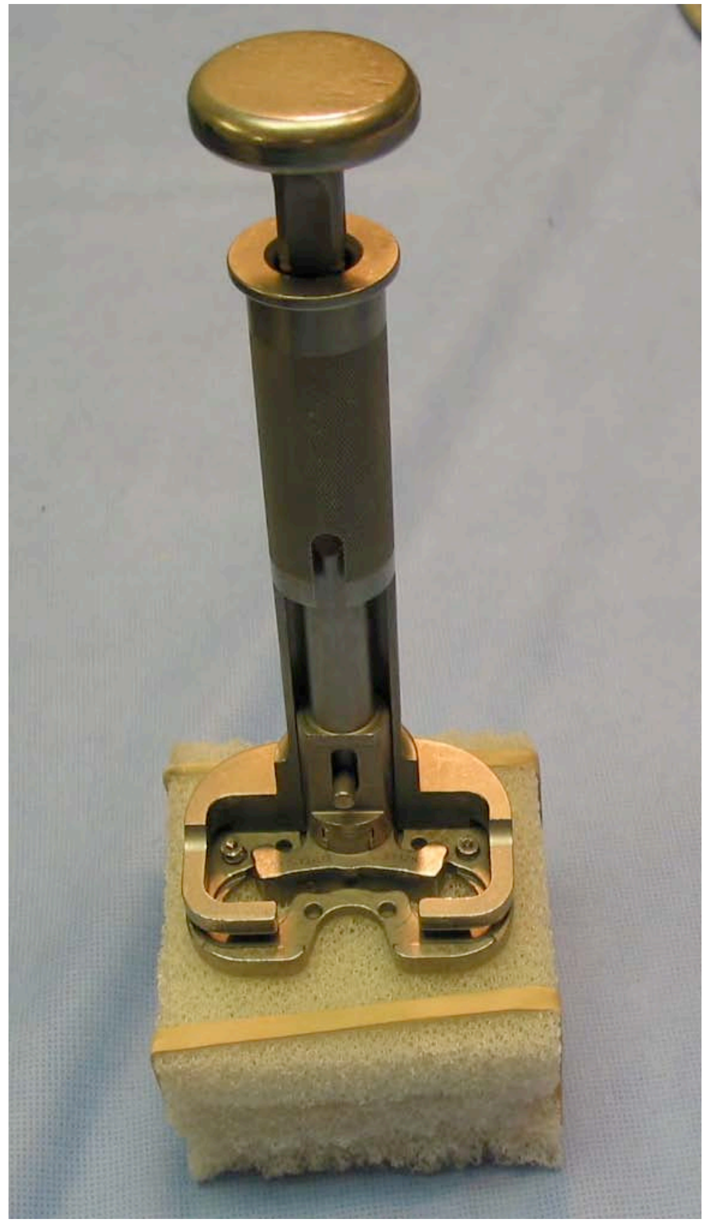

Figure 1. Zimmer NexGen LPS prosthetic components (Jig, fixture, reamer) fixed on the surrogate tibial construct

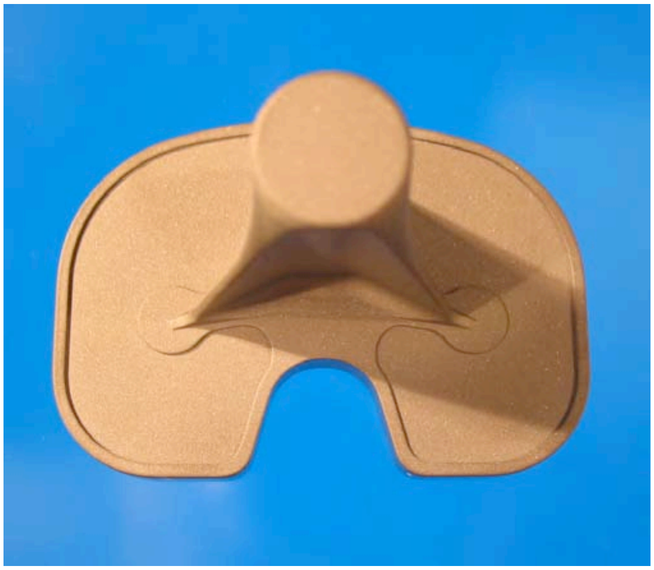

Figure 2. Zimmer NexGen LPS: Tibial plate

Cement preparation

The cement was prepared in a hand-mixing bowl and was allowed to cure until it no longer adheres to a Biogel powder-free latex glove in accordance with ASTM [33] and ISO [34]. The preparation time for each of the cements was recorded using a stopwatch. Guidelines for preparation time were used as provided by cement manufacturers. The operating room temperature and humidity set points were controlled and maintained at 65^o F and 55% respectively for all the procedures.

Cement application

The cement was applied under digital pressure in the cement wells of the tibial component (Fig. 3). As per the standard surgical procedures, prosthetic surgical components were used to ream the cavities to seat the tibial plate stem (Fig. 4). Cylindrical shaped bone cement dough was inserted in the cavity and then the tibial plate was seated on the surrogate tibia (Fig. 5). Finally, the tibial plate was pressed down by the surgeon using surgical components. An additional sample was prepared with a randomly picked bone cement, and quarter section of the tibial plate was cut using a water-cooled diamond saw (Buehler Ltd., Lake Bluff, IL), to verify the uniformity of the construct, and consistency of the open cell structure of the surrogate cancellous bone (Figure 6).

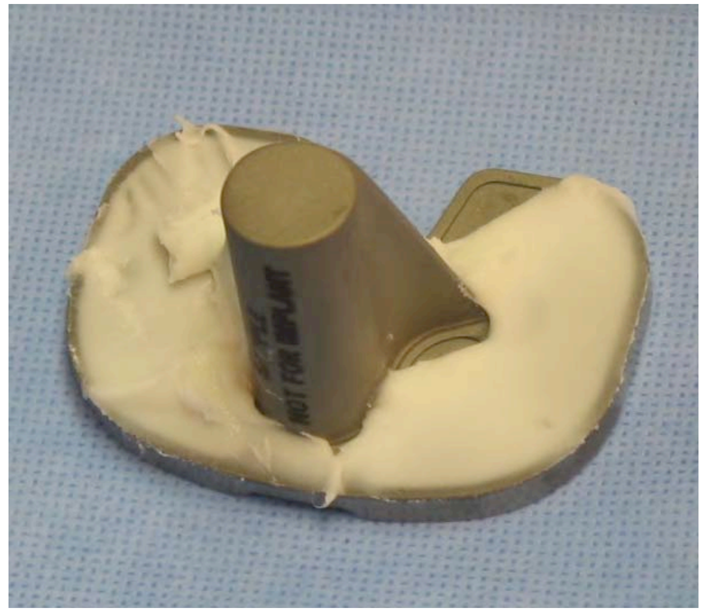

Figure 3. Preparation of the sample construct: tibial plate with bone cement applied

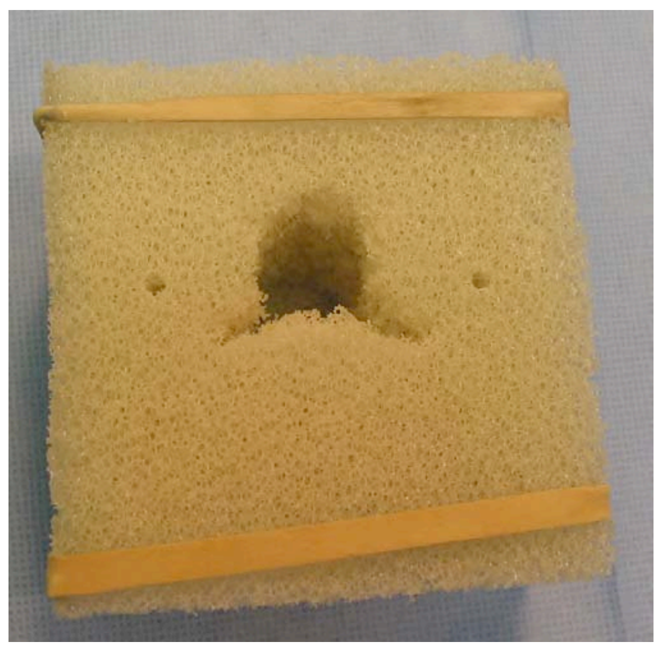

Figure 4. Preparation of the sample construct: Reamed cavity created using Zimmer prosthetic components

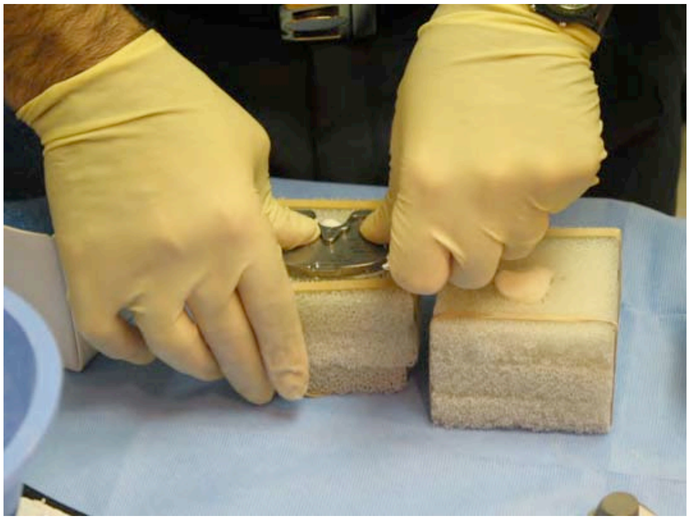

Figure 5. Preparation of the sample construct: digital pressure being applied on the cemented tibial plate. In the adjacent sample, the cement is seen filled in the reamed cavity

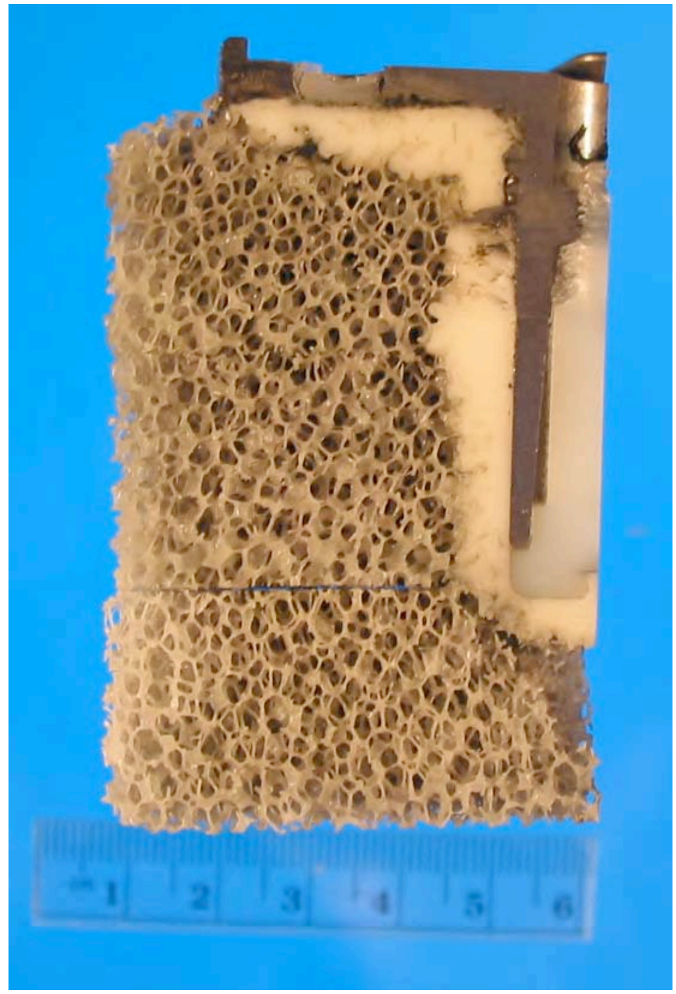

Figure 6. Zimmer NexGen LPS: Tibial plate quarter section showing the cement penetration in the open cells of the surrogate cancellous bone.

Radiographic analysis

All specimens were evaluated radiographically for radiolucency assessment in accordance with [17] (Fig. 7). All the specimens were placed on a radiography plate to capture lateral and antero-posterior (AP) characteristics of the cement penetration in the twelve sample constructs. The radiographs were digitized, scaled, and the mean cement penetration depth was determined for the seven zones in AP and lateral views.

Statistical Analysis

Student *t*-test was performed to assess the statistical significance of penetration depth with different cements; P value less that 0.05 was considered significant.

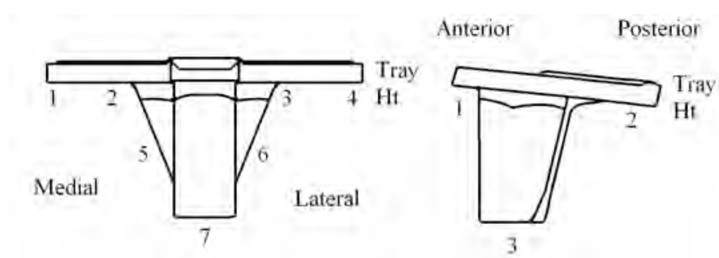

Figure 7. Cement mantle zone numbers (Knee Society Roentgenographic Evaluation System [17])

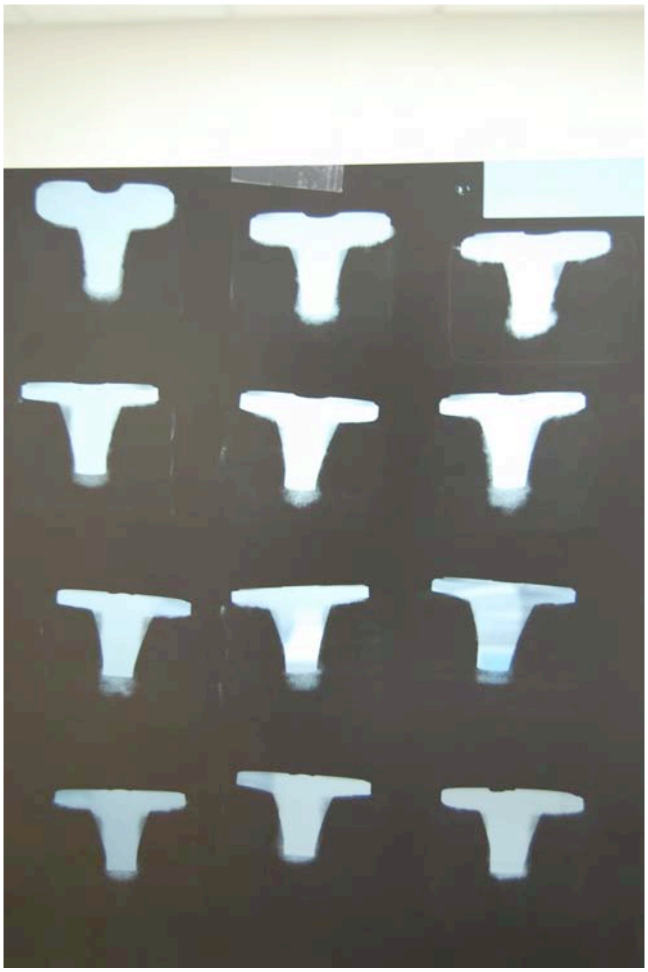

Figure 8. Radiographic analysis: Lateral view of the cement mantle

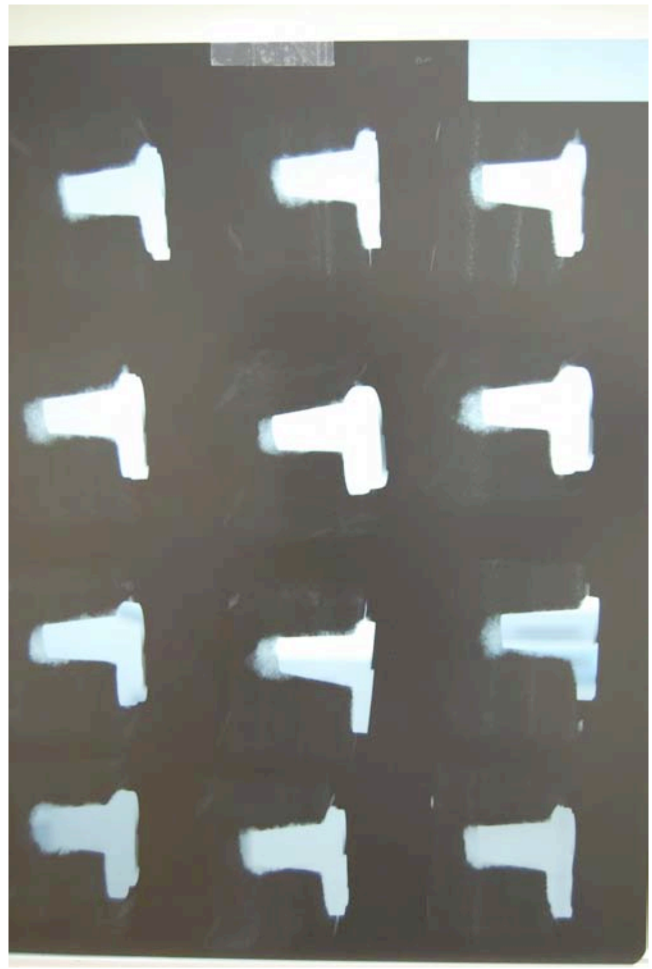

Figure 9. Radiographic analysis: AP view of the cement mantle

RESULTS

Table 1. Cement penetration (in mm) in seven zones: AP view

Zones	1	2	3	4	5	6	7	Σ
Depuy 2	1	2	1	1	2	3	8	18
	1	2	2	2	2	1	6	16
	1	1	1	1	3	5	4	16
Endurance	0	1	2	2	1.5	2	8	16.5
	0	2	0.5	0	2	1	10	15.5
	0	0.5	2	1	3	0	12	18.5
Simplex	0	0.5	2	1	0	0	15	18.5
	2.5	4	3	2	0	1	10	22.5
	0	2.5	2	1.5	1	1	8.5	16.5
Palacos	1	3	4	3	0	0	6	17
	0	1	2	1	7	2.5	4	17.5
	0.5	0.5	2	1	2	5	4	15

Table 2. Average cement penetration (in mm) in seven zones: AP view

Zone	1	2	3	4	5	6	7	Σ
Simplex	0.8	2.3	2.3	1.5	0.3	0.7	11.2	19.2
Endurance	0.0	1.2	1.5	1.0	2.2	1.0	10.0	16.8
Depuy 2	1.0	1.7	1.3	1.3	2.3	3	6	16.7
Palacos	0.5	1.5	2.7	1.7	3.0	2.5	4.7	16.5

Penetration depth with the four cements in AP view and lateral view is given in Table 1 & 2 respectively. Penetration depth is in mm with three samples for each cement type. On radiographic analysis of the implanted surrogate tibiae, it was found that Simplex had the maximum commulative penetration of 19.2 mm in seven zones in Mediolateral view (Table 3), and 12.7 mm in three zones in anteroposterior view (Table 4) (two-tailed P = 0.26). Figs. 10 & 11 presents the average cement penetration in seven zones in AP and three zones in lateral view respectively. The error bars represent standard deviation.

Table 3. Cement penetration (in mm) in three zones: Lateral view

Zones	1	2	3	Σ
Depuy 2	2	2	6	10
	2	3	5	10
	3	2	4	9
Endurance	1	1	11	13
	1	1	7	9
	2	1	10	13
Simplex	1	2	10	13
	2	1	12	15
	1	1	8	10
Palacos	1	2	6	9
	1	2	5	8
	1	2	5	8

In zone seven, the difference was statistically significant when comparing Simplex with Palacos (11.2 mm vs. 4.7 mm, two-tailed P value = 0.0350), somewhat significant with Depuy 2 (11.2 mm vs 6.0 mm, two tailed P value = 0.08), but the different was not significant when compared with Endurance (11 mm vs 10 mm, two-tailed P value = 0.63). In Zone 5, the difference was statistically significant with Simplex vs Endurance (0.33 mm vs 2.17 mm, P = 0.028), and with Simplex vs Depuy 2 (0.33 mm vs 2.17 mm, P = 0.012). The difference in penetration depth for zones 2, 3 & 4 was not statistically significant for all four cements ($P>0.05$). However there was a significant difference in penetration depth for Zone 5 for Simplex vs. other relatively more viscous cements. Simplex had the minimum cement penetration in zones 5 & 6 respectively, and consistently maximum in zone 7 in AP view, and in zone 3 in lateral view.

Simplex is considered as gold standard when evaluating bone cement performance. In the present study, simplex had the maximum cumulative penetration in all seven zones, followed by Endurance, Depuy 2, and Palacos, respectively in AP as well as lateral view (Table 2 & 4). Relative higher viscosities of Endurance, Depuy 2, and Placos may attribute to lower penetration in zone 7 (AP view), and zone 3 (lateral view). This study enhances the understanding of the relation between cement viscosities and cement penetration into cancellous bone during TKA.

Table 4. Average cement penetration (in mm) in three zones: Lateral view

Zone	1	2	3	Σ
Simplex	1.3	1.3	10.0	12.7
Endurance	1.3	1.0	9.3	11.7
Depuy 2	2.3	2.3	5.0	9.7
Palacos	1.0	2.0	5.3	8.3

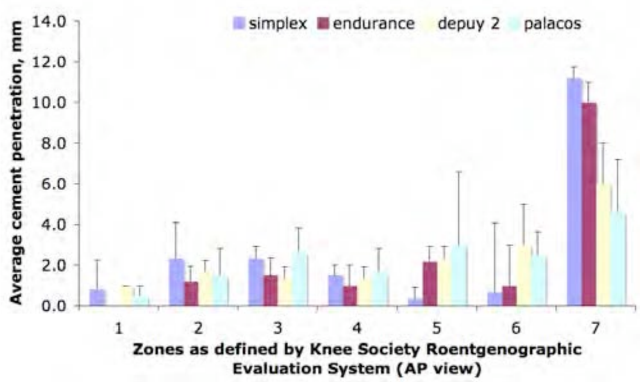

Figure 10. Average cement penetration in the 7-zones: AP view

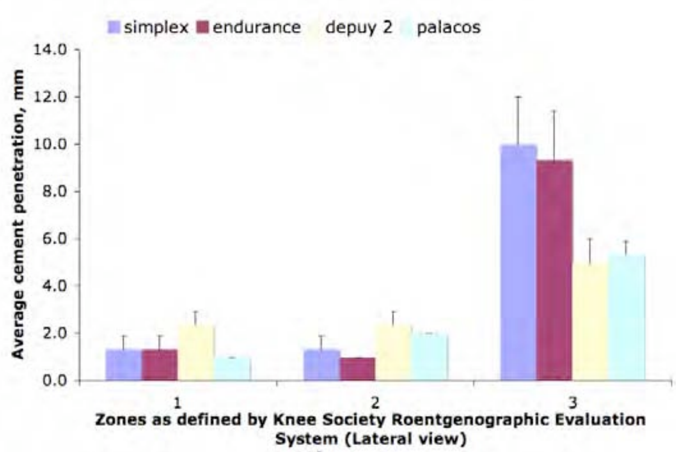

Figure 11. Average cement penetration in the 3-zones: Lateral view

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