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The technique of cement application has no influence on cement intrusion in total knee arthroplasty: randomized study comparing three different techniques

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Abstract

Purpose The aim of the study was to compare the distance of intrusion of the cement into the bone in different areas both in the femur and the tibia in vivo, measured in the radiograph after implanting a total knee arthroplasty (TKA) with three different cement techniques.

Methods A prospective randomized study of 90 consecutive patients operated on at our institution with a cemented U2 Knee System TKA and medium viscosity Simplex P® bone cement. After pulse lavage, the cement was applied on the bone surfaces (group 1), on the implant surfaces (group 2) or both on the bone and the implant surfaces (group 3). The cement intrusion was measured in the postoperative radiographs in eight different regions in the tibial component and in six regions in the femoral component. The cement employed was calculated by weighting the cement after mixing and weighting the discarded cement.

Results The average intrusion of the cement was similar in all three groups of cementing techniques in the femoral components (1.6 mm; $p = 0.386$), and in the tibial components (2.6 mm; $p = 0.144$). The intrusion of the cement in the tibia was greater in women than in men ($p = 0.04$). We used 21.1 (SD 5.8) g of cement in average. The amount of cement employed was greater when the cement was applied on both (implant and bone) surfaces (group 3: 24.03 g in average) than when it was applied only on the bone (group 1: 20.13 g; $p = 0.01$) or only on the implants (group 2: 19.20 g; $p = 0.001$). The amount of cement employed was greater in men than in women ($p = 0.002$) and it was also greater when a PS femoral component was used ($p = 0.03$). The amount of cement employed was directly correlated with the height of the patients ($p = 0.01$) and with the bigger size of the components ($p < 0.001$).

Conclusion All three cement application techniques have similar intrusion distance of the cement into the bone, and the intrusion depth of the cement into the trabecular tibial bone is greater than the minimum suggested for fixation.

Keywords Total knee arthroplasty · Bone cement · Cement technique · Cement intrusion · Cement weight

Introduction

The use of cement is the gold standard for fixation in total knee arthroplasty (TKA), but aseptic loosening remains as the main cause of late revision [16]. Because there is no adhesive bonding between bone and cement, fixation relies upon cement penetration to mechanically interlock the cement into the bone trabecular spaces. Several cadaveric studies have shown a strong relationship between the average interdigitation of the cement into the trabecular bone and the tensile strength in the cement–bone interface, suggesting that a minimum of 1.0–1.5 mm cement intrusion distance in the tibia is advisable to achieve enough strength [10, 12,

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25]. Some authors [11, 23] have suggested at least 3 mm of intrusion for an optimal fixation of the tibial component, but there is no clear evidence to support these opinions. As far as we know, the only study that has correlated the thickness of the cement intrusion and TKA survival has demonstrated a relationship between a poor cement mantle with less than 2 mm of intrusion and aseptic loosening in tibial components of TKA [7]. Moreover, there is no evidence about the ideal cement intrusion in the femoral components.

Many factors can influence on the depth and quality of interdigitation of the cement into the bone, as the use of bone irrigation with pulsatile lavage [12, 20], or drilling holes in sclerotic bone [18]. The way that cement is applied in the interface between the bone and the prosthesis could also have a significant role on the cement intrusion into the bone. Several techniques have been described to use cement, applying the cement on the bone cuts surfaces, on the implants or on both surfaces. It has been suggested that using different ways of cement application, the cement mantle thickness could be different, but until now, all the studies about the influence of cement application technique on cement intrusion into the bone have been made in cadaveric models [5, 21, 27], in animal models [1], or in sawbone models [22, 23], and no study comparing different cement application technique has been done in vivo.

The aim of the study was to compare the distance of intrusion of the cement into the bone in different areas both in the femur and the tibia in vivo with three different cement techniques. A secondary objective was to compare the amount of cement used when employing cement on the bone, on the implant or combined on both surfaces in vivo in TKA surgery, as an indicator of the thickness of the cement mantle. We hypothesized that applying cement on the surfaces of both the bone and the implants could increase the intrusion of the cement into the bone as well as the amount of the cement used to fix the implants.

Materials and methods

This is a prospective randomized study of a group of 90 patients operated on from January 2019 to February 2020 at our institution (an academic hospital), to whom a cemented U2 Knee System TKA® (United Orthopedic Corporation, Taiwan) was implanted. The U2 Knee System is a TKA with a femoral component made on CoCrMo alloy and available in Cruciate Retaining (CR) design and Posterior Stabilized (PS) design in six sizes (1–6). The tibial baseplate is forged Ti6Al4V alloy and it is available in six sizes (1–6) and the patellar polyethylene component used is dome shaped with onset design and three-pegs and it is available in seven sizes (26–44 mm in diameter).

The present study received IRB approval by the Parc de Salut Mar Ethical Committee. After informed consent, patients scheduled for TKA were asked to participate in this study. Inclusion criteria were unilateral TKA surgery because of primary osteoarthritis and age of the patient 18–90 years. Exclusion criteria were partial or revision knee arthroplasties, any prior open surgery on the knee, the use of prosthetic stems or augments, and diagnosis of inflammatory arthritis or post-traumatic osteoarthritis. From the 98 patients screened for participation, 3 were excluded, because the diagnosis was an inflammatory arthritis, 3 because they had prior surgeries on the knee and 2 because a tibial stem was used.

Before the beginning of the surgery, patients were randomized into one of the three groups with a 1:1:1 allocation as per a computer-generated randomization schedule to be treated with cementing only on the bone surface (group 1), cementing only on the implant surface (group 2) or cementing both on the bone and the implant surfaces (group 3). A total of 30 patients were allocated to each group of randomization. Patients were blinded to the group they had been assigned.

Of the 90 patients studied, 67 (74.4%) were females and 23 (25.6%) were males. The average age was 72.8 (SD 8.2) years. There were 52 (57.8%) right knees and 38 (42.2%) left knees. The mean weight of the patients was 77.6 (SD 14.6) Kg, the mean height was 157 (SD 9.0) cm and the mean body mass index (BMI) was 31.6 (SD 5.7) kg/m^2. There were no significant differences in any of these demographic variables among the different cementing technique groups (Table 1).

Operative technique

Prophylactic antibiotics were used in each case. Four different experienced knee surgeons were involved in the procedures. In all cases, the whole procedure was done under ischemia with pneumatic tourniquet. A standard anterior incision and a medial parapatellar approach were used. The use of a CR or a PS TKA was decided by the surgeon depending on the deformity and soft-tissue releases necessary on each knee. The prosthetic components were implanted with cement after standard bone cuts with standard intramedullary guide in the femoral side and extramedullary guide in the tibial side. When necessary, soft-tissue releases were performed to achieve the aimed flexion and extension balances. In all cases, the patella was replaced. After taking the bone cuts, the cut surfaces were cleaned and irrigated with pulse lavage with saline before cementing, as it is recommended by many authors [20].

In all cases, the cement used was the medium viscosity Simplex P® (Stryker Orthopedics, Limerick, Ireland) consisting of 20 mL of liquid component and 40 g of powder

Table 1 Demographic characteristics and characteristics of the prosthetic components in the three groups of patients

Variable	Group 1 (bone), $n=30$	Group 2 (implant), $n=30$	Group 3 (bone + implant), $n=30$	p value
Age (years)	70.7 (SD 8.0)	74.6 (SD 9.5)	73.2 (SD 6.8)	0.144
Gender (male/female)	5/25	8/22	10/20	0.371
Side (right/left)	(16.7/83.3%)	(26.7/73.3%)	(33.3/66.7%)	0.894
Weight (kg)	18/12	18/12	16/14	0.334
Height (m)	(60/40%)	(60/40%)	(53.3/46.7%)	0.892
BMI (kg/m^2)	77.2 (SD 15.6)	75.2 (SD 14.2)	80.5 (SD 13.9)	0.472
	1.57 (SD 0.08)	1.56 (SD 0.09)	1.57 (SD 0.08)	
	31.2 (SD 5.9)	30.7 (SD 5.3)	32.8 (SD 5.9)	
Type (CR/PS)	17/13	23/7	16/14	0.155
Femur size	(56.7/43.3%)	(76.7/23.3%)	(53.3/46.7%)	0.393
Tibia size	3.3 (SD 0.99)	3.03 (SD 1.13)	3.23 (SD 1.01)	0.156
Patella size	3.33 (SD 1.12)	2.77 (SD 1.17)	3.27 (SD 1.34)	0.143
	29.9 (SD 2.25)	28.7 (SD 1.82)	29.6 (SD 1.99)	

BMI body mass index, *CR* cruciate-retaining, *PS* posterior-stabilized

Fig. 1 In group 1, the cement was applied on the tibia bone surface without cementing the tibial component keel) and on the anterior, distal and chamfer cuts of the femur

Fig. 2 In group 1, the cement was only applied on the implant on the posterior condyles

component. It was prepared by mixing the liquid and powder components of the bone cement under vacuum conditions in a bone cement mixer. The cement was weighted on a weighing scale with a sensitiveness ranging from 1 to 500 g. It was applied 2 min after the beginning of the cement mixing, when the cement reached a doughy state.

In group 1, the cement was manually applied and digitally pressurized on the tibia bone surface with a finger-packing technique (without cementing the tibial component keel) before implanting the tibial tray. Then on the anterior, distal and chamfer cuts of the femur (Fig. 1) before implanting the femoral component with cement only on the implant on the posterior condyles (Fig. 2), and finally applied on the patellar surface before the patellar button was implanted. In group 2, the cement was applied on the cementing surfaces of the tibial (not on the keel), femoral and patellar components without using cement on the bone cuts (Fig. 3). In group 3, the cement was used on both surfaces: on the bone as explained in group 1 and on the prosthetic components as explained in group 2.

In all three groups, all the components were cemented and impacted during the cement working time in a one-stage technique, cementing first the tibial component, second the femoral one and finally the patella, as suggested by Guha et al. [6]. Afterwards, full extension of the knee was used to pressurize the cement in the tibial and femoral surfaces and the patellar clamp was used to pressurize the patellar surface. The extruded cement

Fig. 3 In group 2, the cement was applied on the cementing surfaces of the tibial (not on the keel) and femoral components without using cement on the bone cuts

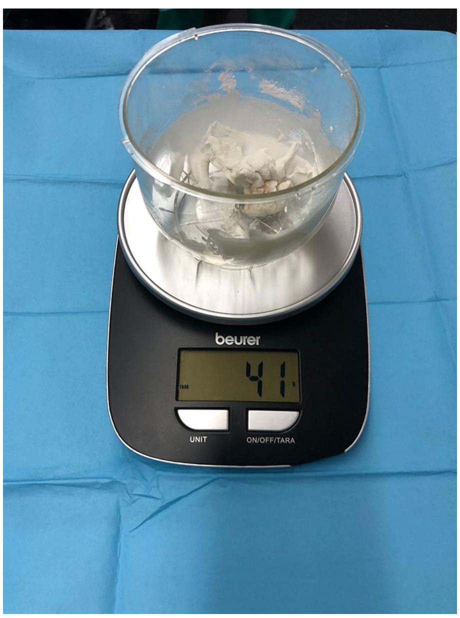

Fig. 4 Weighing scale used to weigh the cement the mixed cement before use and the discarded cement (extruded and not used)

was removed and added to the non-used cement remaining in the cement mixer and it was weighted together and named discarded cement (Fig. 4). The difference of weight between the mixed cement minus the discarded cement was the used cement, in grams.

The type of femoral component design (CR or PS) and the sizes of the components were variables considered to influence in the amount of the cement used, and they were noted.

Wound closure was done in flexion and one deep drain was left in the knee for 24 h.

Radiographic analysis

One day after surgery, a standardized digital anteroposterior view and a true lateral view of the knee centred in the joint line was analyzed. We studied the cement bone intrusion by measuring it in four areas in the tibia bone–cement interface in the AP view (areas 1–4 of the Knee Society TKA roentgenographic evaluations system—two medial and two lateral to the keel) [4] as it was described and validated by Pfitzner et al. [15], and in four areas in the lateral view (two anterior and two posterior to the keel) (Fig. 5a, b). Cement depth was measured in mm with one decimal, using the measurement tool in the picture archiving and communication system (PACS). The average of the eight areas was considered. In the femoral side, we could only study the lateral view, because the cement bone intrusion in the AP view was hidden by the femoral component. The femoral sagittal cement intrusion was studied in six areas (anterior cut, anterior chamfer cut, two in the distal cut, posterior chamfer and posterior cut) (Fig. 6) and the average of the six areas was considered.

The radiographic measurements were done by two blinded evaluators. In 20 consecutive cases, the measurements were measured twice (at least 1 week interval between the two measurements) by two different evaluators, independent of the surgical team. The interclass correlation was 0.81–0.91 for inter-observer measurement correlation and 0.85–0.92 for intra-observer measurement correlation, indicating an excellent reproducibility of these measurements. The first measurement of the first evaluator was taken into consideration in those cases.

Statistical analysis

All data collected for this study were entered into an Excel database (Microsoft Office 2003, Redmond, WA) and analyzed using the SPSS 18.0 (IBM Corp) statistical program. A descriptive analysis of the sample was done using rates for categorical variables, and the mean and standard deviation for continuous variables. To compare differences between both groups, a Chi-square or a Fisher exact test was used for analysis of categorical variables. The Student *t* test was used for continuous variables. The distribution of each variable was checked for normality using the Shapiro—Wilk test. An a-priori power analysis was performed and based on the Student *t* test for independent data: as we expected, the distribution to be similar in the three groups, with a power of 80% and α error < 0.05, 25 patients should be included to identify differences in the cement intrusion used among groups according to data of previous studies in sawbone models [23], expecting a mean intrusion of 2.6 mm, a mean difference of cement intrusion between groups of 1.2 mm

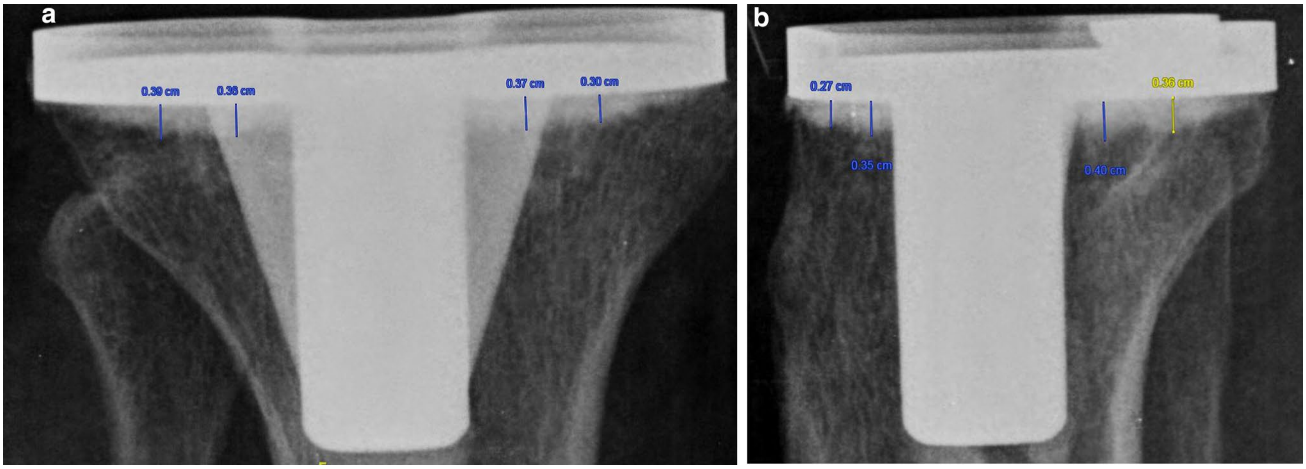

Fig. 5 **a**, **b** Radiographic measurement of the cement bone intrusion in the tibia in four areas in the AP view (two medial and two lateral to the keel) and in four areas in the lateral view (two anterior and two posterior to the keel)

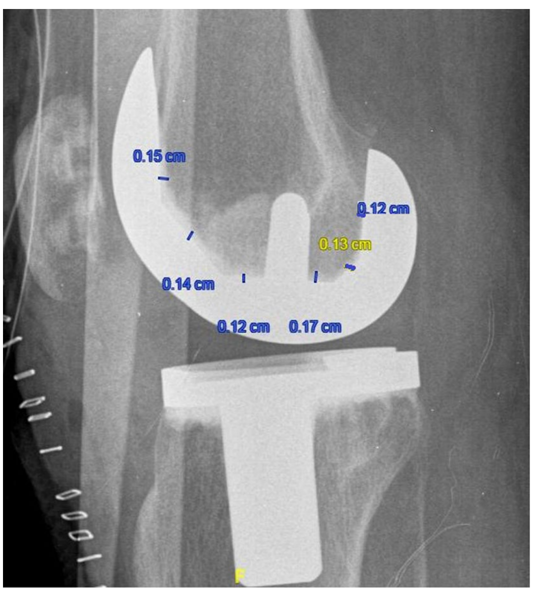

Fig. 6 Radiographic measurement of the cement bone intrusion in the femur in six areas: anterior cut, anterior chamfer cut, two in the distal cut, posterior chamfer and posterior cut

with a standard deviation of 1.5 mm. The level of significance was set at $p < 0.05$.

Results

Radiographic analysis

Cruciate-retaining TKA were used in 56 patients and PS TKA in 34 patients. The most used sizes in the femoral and tibial components were 2, 3 and 4. There were no differences in the component sizes among the three cement technique groups (Table 1).

The average intrusion of the cement in the femur was 1.6 mm (SD 0.6) and 2.6 mm (SD 0.8) in the tibia, and it was similar in all three groups of cementing techniques (p = n.s.) (Table 2).

In 88.9% of the patients, the intrusion of the cement in the tibia was at least 2 mm in average, and this was similar in the three groups (86.7% in group 1 and 90% in groups 2 and 3; p = n.s.). In all cases, a minimum of 2 mm of intrusion was

Table 2 Average intrusion of the cement in the three groups of patients in the tibia (anteroposterior and lateral views) and in the femur (lateral view)

Variable	Group 1 (bone), $n = 30$	Group 2 (implant), $n = 30$	Group 3 (bone + implant), $n = 30$	p value
Tibia-AP (mm)	2.4 (SD 1.0)	2.2 (SD 0.9)	2.6 (SD 0.9)	0.188
Tibia-LAT (mm)	2.9 (SD 1.2)	2.7 (SD 1.0)	3.1 (SD 1.3)	0.341
Tibia total (mm)	2.7 (SD 0.7)	2.4 (SD 0.7)	2.8 (SD 0.8)	0.144
Femur (mm)	1.6 (SD 0.7)	1.4 (SD 0.8)	1.7 (SD 0.9)	0.386

achieved in at least one of the eight zones evaluated in the radiographic analysis.

The intrusion of the cement in the tibia was greater in women (2.7 mm in average, SD 0.7) than in men (2.4 mm in average, SD 0.8) ($p=0.04$), but it was similar in the femur for both genders (1.6 mm vs 1.4 mm, respectively; $p=$n.s.). No other demographic variable or implant sizes influenced the cement intrusion ($p=$n.s.).

Amount of cement employed

The amount of cement employed was 21.1 (SD 5.79) g in average. The minimum amount of cement employed was 9 g and the maximum 36 g. It was greater when the cement was applied on both (implant and bone) surfaces (group 3: 24.0 g) than when it was applied only on the bone (group 1: 20.1 g; $p=0.01$) or only on the implants (group 2: 19.2 g, $p=0.001$) (Table 3).

The amount of cement employed was greater in men than in women ($p=0.002$) and it was also directly correlated with the height of the patients, and the size of the femoral, tibial and patellar components (Table 3).

Discussion

The most important finding of this study is that the three studied techniques of cement application in TKA surgery (on the bone, on the implants or combination of the bone and implants) have shown similar depth of the intrusion of the cement into the bone when applied in vivo after using pulse lavage. This intrusion of the cement into the bone is greater than 1.5 mm in average in the femur and greater than 2.5 mm in average in the tibia and probably guarantees a solid fixation of the implant to the bone. The amount of cement used for fixation was slightly greater when it was applied both on the bone and the implant surfaces than when it was applied only on the bone or only on the implants. However, the difference in the amount of cement is small enough not to significantly affect the intrusion of the cement into the bone and, consequently, not to affect the fixation of the implant.

Vaninbroukx et al. found that applying the cement both on the bone and the implant could increase the intrusion of the cement in the distal femur, but this study was done with sawbones [22]. Similarly, Vanlommel et al. reported a deeper cement intrusion of the cement in the proximal tibia when it was applied both on the bone and implant surfaces, but again this study was done in a sawbone model [23], and this could clearly be different in the bone in an in vivo setting. As far as we know, this is the first study to compare different techniques in the application of the cement in vivo in terms of cement intrusion.

The average penetration of cement into the bone in this study, which was 2.7 mm in the tibia, was similar or mildly greater than in previous studies. Walden et al. found an average of 2.2 mm of depth in the tibia with Simplex P cement [26], and Dinh et al. an average of 2.7 mm in the tibia with Simplex-HV cement [3]. Other studies in vivo also showed similar numbers with different types of cement [8, 9, 15].

Another finding of our study is that the intrusion of the cement in the tibia was greater in women than in men. This could be a consequence of a reduced bone mineral density of the proximal tibia in women in the typical age group of patients operated with a TKA [2]. A strong negative correlation between bone mineral density and mean cement penetration was found in a study by Raiss et al. [17]

Table 3 Factors correlated with the amount of utilized cement

Variable	Rho-Spearman	*p* value
Age (years)	0.000	0.999
Weight (kg)	0.171	0.106
Height (m)	0.259	**0.014**
BMI (kg/m^2)	− 0.021	0.848
Femur size	0.359	**0.001**
Tibia size	0.377	**< 0.001**
Patella size	0.422	**< 0.001**
	Amount of utilized cement (g)	
Cementation group (30 group 1, 30 group 2, 30 group 3)	20.1 (SD 4.4)/19.2 (SD 6.4)/**24.0** (SD5.4)	**0.001**
Gender (23 male/67 female)	**24.7** (SD 6.6)/19.9 (SD 5.0)	**0.002**
Side (52 right/38 left)	20.0 (SD 5.1)/22.6 (SD 6.4)	0.07
Femur type (56 CR/34 PS)	20.1 (SD 5.1)/**22.7** (SD 5.6)	**0.039**

Significant variables are shown in bold type

BMI body mass index, *CR* cruciate-retaining, *PS* posterior-stabilized

Nagel et al. in a cadaveric study recommended an intrusion of cement greater than 1.1 mm to neutralize pull-out forces occurring in the tibial tray during deep bending [12]. Mann et al. in a cadaveric model [10] and Waanders et al. in a finite element analysis study [25] showed a strong relationship between the average interdigitation and tensile strength in the cement–bone interface, suggesting that a 1.5 mm cement intrusion distance was adequate to guarantee enough tensile strength to prevent implant micromotion that can initiate implant loosening, especially in the tibia. In all three cement techniques used in this study, the average intrusion of the cement was greater than 1.5 mm in the femur and 2.5 mm in the tibial side, suggesting an adequate interdigitation of the cement.

The average amount of the cement employed in this study was 21.1 g per knee, but the range was wide (between 9 and 36 g), similar to the findings in the study by Satish et al. (average of 22 g of cement, between 11 and 40 g) [19]. We have found a greater amount of cement employed in male, in taller patients and in bigger component sizes, which is probably the consequence of a greater cementation surface, similar to another study [19], but these size factors were not correlated with an increase in the cement intrusion distance.

Vanlommel found a direct correlation between the amount of used cement (weight) and the depth of the cement intrusion [23], which has also been found in this study. Nevertheless, the differences among groups in our study are small. In group 3, the amount of cement was slightly increased and this difference was statistically significant, but the small increase in the intrusion of the cement into the bone was not statistically significant.

This study included several limitations to be recognized: first, in all surgeries, only a medium viscosity cement has been used, and the results on cement penetration would have been probably different with other types of cement as it was studied experimentally in vitro [13, 26]. Nevertheless, the aim of the study was not to compare different types of cement but only different techniques of cement application. Second, the study of the depth of cement penetration has been done only on X-rays. CT scan has been suggested to study cement penetration [19, 24], but the use of X-rays to study, it has been defended by many other authors [8, 9, 14, 15] as a reliable method with less radiation exposure than CT scan. Third, several surgeons have done the procedures, but we tried to standardize the technique used for each cementation technique. Fourth, the size of the sample and the length of the follow-up were not sufficient to correlate the cement intrusion distance with the loosening rates.

The main conclusion of this study is that all three cement application techniques have similar intrusion distance of the cement into the bone, and the intrusion depth of the cement into the trabecular tibial bone is greater than the minimum suggested for fixation. Regarding the clinical relevance, any of the studied cement application techniques is adequate to be used in the daily practice.

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Compliance with ethical standards

Conflict of interest Authors state that there are not conflicts of interest to declare.

Ethical approval The study has been approved by the local Ethical Committee

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