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Comparable bone penetration between antibiotic-loaded and plain bone cement in total knee arthroplasty.

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Authors' Contributions

Albert Fontanellas-Fes: Study design, data collection, literature review, manuscript writing.

Pedro Hinarejos and Daniel Pérez-Prieto: Critical manuscript review, study design, data interpretation, study supervision.

Jan Martínez-Lozano, Juan Sánchez-Soler, Raúl Torres-Claramunt: Data collection assistance, data management and literature review.

Simone Perelli and Joan Carles Monllau: Study supervision and manuscript review.

All authors reviewed and approved the final manuscript.

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ABSTRACT

Introduction: One of the main concerns around the use of antibiotic-loaded bone cement (ALBC) is a possible reduction in the mechanical properties of the cement. The purpose of this study was to determine whether there is a difference between plain cement and ALBC in terms of radiological intrusion into the bone in total knee arthroplasties (TKA).

Methods: Prospective randomized study of 80 consecutive patients that underwent a TKA. Depending on the cement used, patients were divided in two groups by a computer-generated randomization program: the cement without antibiotic (group 1) or the ALBC (group 2). Cement intrusion was measured in postoperative radiographs in eight different regions in the tibial component and in six regions in the femoral component.

Results: The average cement intrusion was similar in both groups (*p=n.s.*). Group 1 (plain cement) had an average cement intrusion in the femur of 1.4 mm (± 0.4) and 2.4 mm (± 0.4) in the tibia. In Group 2 (ALBC), the average cement intrusion in the femur came to 1.6 mm (± 0.5) and 2.4 mm (± 0.5) in the tibia. In 80% of the patients, the cement intrusion in the tibia averaged minimum 2mm, being similar in both groups (*p=n.s.*).

Conclusion: There are no differences in bone intrusion when comparing plain cement to ALBC. Therefore, the use of ALBC in primary TKA may be indicated, achieving an optimal bone penetration.

Level of Evidence: Level I

The Authors affirm that there is no conflict of interest.

INTRODUCTION

Currently, the most common fixation method in total knee arthroplasty (TKA) is the cementing of the tibial and femoral components. Some studies have demonstrated survival rates of over 90% at 10 and 15 years [1, 2] and 85% at 21 years [22]. Micromotion at the implant-cement or cement-bone interface can lead to the generation of wear particles, which is believed to be one important reason for implant loosening [25]. Previous studies have shown that better cement penetration increases the tensile and shear strength of the cement-bone interface. This suggests that a minimum of a 1.0 to 1.5 mm cement intrusion distance is advisable to achieve enough strength [14, 17]. Loosening of cemented tibial baseplates has been correlated with the type of cement used (loaded with antibiotic, high/low viscosity), the cementing technique, the use of coated surfaces [13] and contamination with fat prior to the application of the cement [11].

One of the main concerns around the use of antibiotic-loaded bone cement (ALBC) is the detrimental effects it may have on the mechanical or structural characteristics of polymethylmethacrylate (PMMA) when antibiotics are admixed. Some *in vitro* studies suggest that it causes a decrease in the compressive and tensile strength of bone cement with small quantities of antibiotic powder [5]. Those same studies suggest that they continue to decrease as doses of antibiotic increase. However, no study that has examined the *in vivo* intrusion of ALBC into the bone was found after a thorough search of the literature.

The main purpose of the present study is to analyse whether there is difference in terms of radiological intrusion into the bone between plain cement and antibiotic-loaded bone cement when used in TKA. As a secondary objective, the aim was to assess the percentage of TKA in which the minimum required bone cement penetration was achieved. The initial hypothesis was that antibiotic-loaded bone cement has similar bone intrusion to plain cement in primary TKA.

METHODS

This is a prospective randomized study of a group of 80 patients operated on from September 2020 to December 2021 in Hospital del Mar, Barcelona. All eighty patients had had a cemented U2 Knee System TKA® (United Orthopedic Corporation, Taiwan) implanted.

The present study was given Institutional Review Board (IRB) approval by the hospital ethics committee. After the patients scheduled for TKA agreed to participate in this study, informed consent was obtained. The inclusion criteria were unilateral tricompartimental TKA surgery due to primary osteoarthritis and a patient age of between 18 and 90 years. The exclusion criteria were partial or revision knee arthroplasties, any prior open surgery on the knee, the use of prosthetic stems or augments and a diagnosis of inflammatory arthritis or post-traumatic osteoarthritis. Of the 90 patients screened for participation, 3 were excluded because of previous surgeries on the knee, 5 for post-traumatic osteoarthritis and a tibial stem had been used with 2 patients.

Before beginning the surgeries, a 1:1 allocation as per a computer-generated randomization was used to assign patients to either the group without antibiotics (Group 1) or ALBC group (Group 2), there being 40 patients per each group (Figure 1).

The plain cement used was the medium viscosity Simplex P® (Stryker Orthopedics, Limerick, Ireland). It is composed of a 20 mL monomer and 40 g of powder component. On the other hand, the ALBC used was Palacos® R + G. It is a high-viscosity bone cement with 0.5g of gentamicin, 40.8 gr of cement powder and 20 mL of monomer liquid (Heraeus. Wehrheim, Germany).

Operative technique

Prophylactic intravenous antibiotics were used in every case. Four experienced knee surgeons were involved in the procedures. In all cases, the whole procedure was done under ischemia with a pneumatic tourniquet. The use of a cruciate retained (CR) or a posterior stabilized (PS) TKA was decided by the surgeon depending on the deformity and soft tissue releases necessary for each knee. The CR model was implanted in 62 patients and the PS in 18. In all cases, the patella was replaced. After taking the bone cuts, surfaces were cleaned and irrigated with a saline pulse lavage before cementing, as it is recommended by many authors [15, 23].

The cement was prepared by mixing the liquid and powder components in a bone cement mixer under vacuum conditions. It was only applied on the implant surfaces in each case [9] at 2 minutes after the beginning of the cement mixing when the cement had reached a doughy state. As a line-to-line technique was performed, there was no need for adding cement on the keel and pegs. In both groups, all the components were cemented and impacted during the cement working time with a one-stage technique. It was done by cementing the tibial component first, the femoral one second and finally the patella, as suggested by Guha et al [7].

Afterwards, full extension of the knee was used to pressurize the cement on the tibial and femoral surfaces and a patellar clamp was used to pressurize the patellar surface. Wound closure was done in flexion once the cement was cured and one deep drain was left in the knee for 24 hours.

Radiographic analysis

On the first postop day, a standardized digital anteroposterior (AP) and a true lateral view of the knee were analysed. Cement bone intrusion was studied by measuring it in four areas at the tibia bone–cement interface in the AP view (areas 1–4 of The Knee Society

TKA roentgenographic evaluation system, two medial and two lateral to the keel [6]) as was described and validated by Pfitzner et al. [20]. Four areas in the lateral view (two anterior and two posterior to the keel) were also studied (Figure 2). The average of the eight areas was analysed. Femoral sagittal cement intrusion was studied in six areas (the anterior cut, anterior chamfer cut, two in the distal cut, posterior chamfer and posterior cut) (Figure 3) and the average of the six areas was also analysed, as has been described in previous studies [19, 20]. Cement depth was measured, using the measuring tool in the Picture Archiving and Communication System (PACS®), in millimetres (mm) within one decimal point.

The radiographic measurements were done by two blinded evaluators. The first measurement of the first evaluator was considered for the analysis.

Statistical analysis

All data collected for this study were entered into an Excel database (Microsoft Office 2003, Redmond, WA) and analysed using the IBM SPSS Statistic v18.0 software package (IBM Corp). A descriptive analysis of the sample was done using percentages for categorical variables, and the mean and standard deviations for continuous variables. To compare differences between the 2 groups, a Chi-square or a Fisher exact test was used for the analysis of categorical variables. The Student's 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. Based on the Student's t-Test for independent data, the distribution was similar in both groups with a power of 80% and α error < 0.05. Based on data from previous studies on sawbones models [25], a minimum of 25 patients had to be included to identify differences in the cement intrusion in the 2 groups. There was an expected mean difference in cement intrusion of 1.2 mm between the 2 groups.

RESULTS

Of the 80 patients studied, there were no differences in terms of demographic and prosthetic component characteristics between the two groups (Table 1).

The cement without antibiotic group had an average cement intrusion in the femur of 1.4mm (± 0.4) and 2.4mm (± 0.4) in the tibia. The ALBC group had an average intrusion in the femur of 1.6 mm (± 0.5) and 2.3 mm (± 0.5) in the tibia, there being no differences in terms of cement intrusion between the two groups (*p*=n.s.) (Table 2).

In 63 patients (80%), the cement intrusion in the tibia averaged a minimum of 2mm. This was similar in both groups, 32 patients (80%) in Group 1 and 34 patients (85%) in Group 2 (*p=n.s.*). In all cases, a minimum of 1.5mm cement intrusion in the tibia was achieved.

Neither the non-demographic variables nor implant sizes had an influence on cement intrusion. The cement intrusion in the tibia was greater in women (2.5mm ± 0.4) than in men (2.2mm ± 0.6), but the difference was not significant (*p*=n.s.).

The interclass correlation was 0.9 for inter-observer measurement correlation, indicating excellent reproducibility of the measurements (Table 3).

DISCUSSION

The most important finding of the present study is that ALBC shows optimal depth intrusion into the bone when applied *in vivo*. No differences were seen when it was compared to cement without antibiotic, being the intrusion of ALBC greater than the minimum suggested for fixation.

As aseptic loosening is the main cause of late revision TKA [21], achieving a good initial fixation to the underlying bone is crucial for the long-term performance. Although cementless implants have good outcomes and high survivor rates in midterm follow up [24], the use of cement is still the gold standard for fixation in TKA.

Radiolucent lines in the implant cement interface in postoperative radiographies are important to notice but are not always associated with aseptic loosening and revision surgery [19]. If present, close clinical follow up is needed.

Some studies [14, 27] show a strong relationship between the average interdigitation and tensile strength in the cement–bone interface. This suggests that a 1.5 mm cement intrusion distance was adequate to prevent implant micromotion that can initiate implant loosening, especially in the tibia. That distance determination was based on mechanical alignment. Nevertheless, other studies have shown a low risk of tibial baseplate loosening following unrestricted kinematic alignment TKA using a CR medial conforming insert [18].

Some studies have shown a reduction in bonding strength related to high viscosity cement and the use of coated surfaces [8, 11, 13].

Dinh NL et al. [4] analysed bone cement intrusion characteristics and found no differences between Palacos-R® and Simplex HV® (both with no antibiotics) when the negative pressure intrusion technique was applied.

In the present study, the average cement intrusion was greater than 1.4 mm in the femur and 2.2 mm in the tibia in both groups, suggesting adequate interdigitation of the cement into the bone.

To our knowledge, this is the first study to analyse the cement intrusion of the antibiotic-loaded bone cement *in vivo* in comparison to the intrusion of cement without antibiotics.

When focusing on the potential adverse effects with the addition of antibiotics, it is widely accepted that high-dose ALBC (more than 10% of PMMA weight) should only be used in cement spacers or beads, which are used temporarily in the treatment of prosthetic infections [3]. For its prophylactic use, the antibiotic should be used at low doses, less than 2g per 40g of cement as the main objective of the cement is the implant fixation [10].

Moran et al. [16] found that gentamicin in concentrations of 0.5g, 1.0g, and 2.0g per 40g of Palacos® acrylic bone cement has been shown to substantially reduce the shear strength of the cement, a factor that would influence crack nucleation in situations of prolonged dynamic loading.

It is important to note that those studies that demonstrated a theoretical disadvantage of ALBC were *in vitro*. When aseptic loosening was analysed to discount this theoretical negative effect on the mechanical properties, no difference was seen in its incidence when compared to the use of plain cement [3, 4].

Based on the results of the present study, the addition of gentamicin in low doses in bone cement is a valid option that does not affect its bone penetration for primary TKA. For this reason, when ALBC is used as a prophylactic method for prosthetic joint infection, this combination ensures good initial implant fixation.

There are some limitations in our study. The first one is that as cements with different viscosities are compared, bone penetration could be affected. Dual phase of Simplex P reduces this possible bias [12]. Another possible limitation is that the depth of cement penetration has only been measured on X-rays. The CT scan has been suggested to study cement penetration [26], but the use of X-rays to study it has been defended by many other authors [8] as a reliable method with less radiation exposure than a CT scan. Moreover, the use of different femoral implants (CR or PS) can have a direct impact on cement bone penetration as the contact area between bone and prosthesis is different depending on the model used. Finally, 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.

CONCLUSION

In conclusion, there are no differences in bone intrusion when comparing plain cement and ALBC. In all cases, a minimum of 1.5 mm cement intrusion in the tibia was achieved. Therefore, the use of ALBC to prevent prosthetic joint infection in primary TKA may be indicated in daily practice.

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List of abbreviations

ALBC: Antibiotic-loaded bone cement

TKA: Total knee arthroplasties

PMMA: Polymethylmethacrylate

IRB: Institutional review board

CR: Cruciate retained

PS: posterior stabilized

AP: Anteroposterior

mm: millimeters

PACS: Picture Archiving and Communication System

SD: Standard deviation

BMI: Body mass index

n.s: non-significance

TABLES AND FIGURES

Table 1. Demographic and prosthetic components data of both groups.

	Group 1 (Simplex P®) n=40	Group 2 (Palacos G + R®) n=40	P-value
Age (yr.)	72.2(SD ± 9.47)	71 (SD ± 8.88)	n.s
Gender (M/F) (%)	12/28	10/30	n.s
Side (right/left)	18/22	24/16	0.011
Weight (kg)	77.4 (SD ± 13.54)	77.9 (SD ± 13.5)	n.s
Height (m)	1. (SD ± 0.09)	1.6 (SD ± 0.08)	n.s
BMI (kg/m^2)	30.2 (SD ± 4.83)	31.9 (SD ± 9.62)	n.s
Type (CR/PS)	31/9	28/12	n.s
Femur size	3.5 (SD ± 1.20)	3.2(SD ± 1.20)	n.s
Tibia size	3.3 (SD ± 1.24)	3.2 (SD ± 1.24)	n.s
Patella size	29.3 (SD ± 3.37)	29.3 (SD ± 2.27)	n.s

*yr= year; M=male; F=female; CR= cruciate retained; PS: posterior stabilized

Table 2. Average intrusion of the cement in the tibia and in the femur in both groups.

	Group 1 (Simplex P®) n=40	Group 2 (Palacos G + R®) n=40	P value
Femur (mm)	1.4 (SD ± 0.4)	1.6 (SD ± 0.5)	n.s
Tibia total (mm)	2.4 (SD. ± 0.4)	2.4 (SD ± 0.5)	n.s
Tibia – AP (mm)	2.3 (SD ± 0.6)	2.3 (SD ± 0.6)	n.s
Tibia – LAT (mm)	2.4 (SD ± 0.8)	2.5 (SD ± 0.7)	n.s
Total intrusion (femur and tibia)	1.9 (SD ± 0.4)	2 (SD ± 0.3)	n.s

Table 3. Interclass correlation for inter-observer measurement correlation.

	Interclass Correlation
Total AP tibia (mm)	0.89 (0.83 - 0.93)
Total LAT tibia (mm)	0.93 (0.88 - 0.95)
Total tibia (mm)	0.94 (0.90 - 0.96)
Total femur (mm)	0.76 (0.57 - 0.86)
Total (mm)	0.91 (0.77- 0.95)

Figure 1. Flow-diagram of the randomized control study, showing patients that were initially screened for participation and which were finally included.

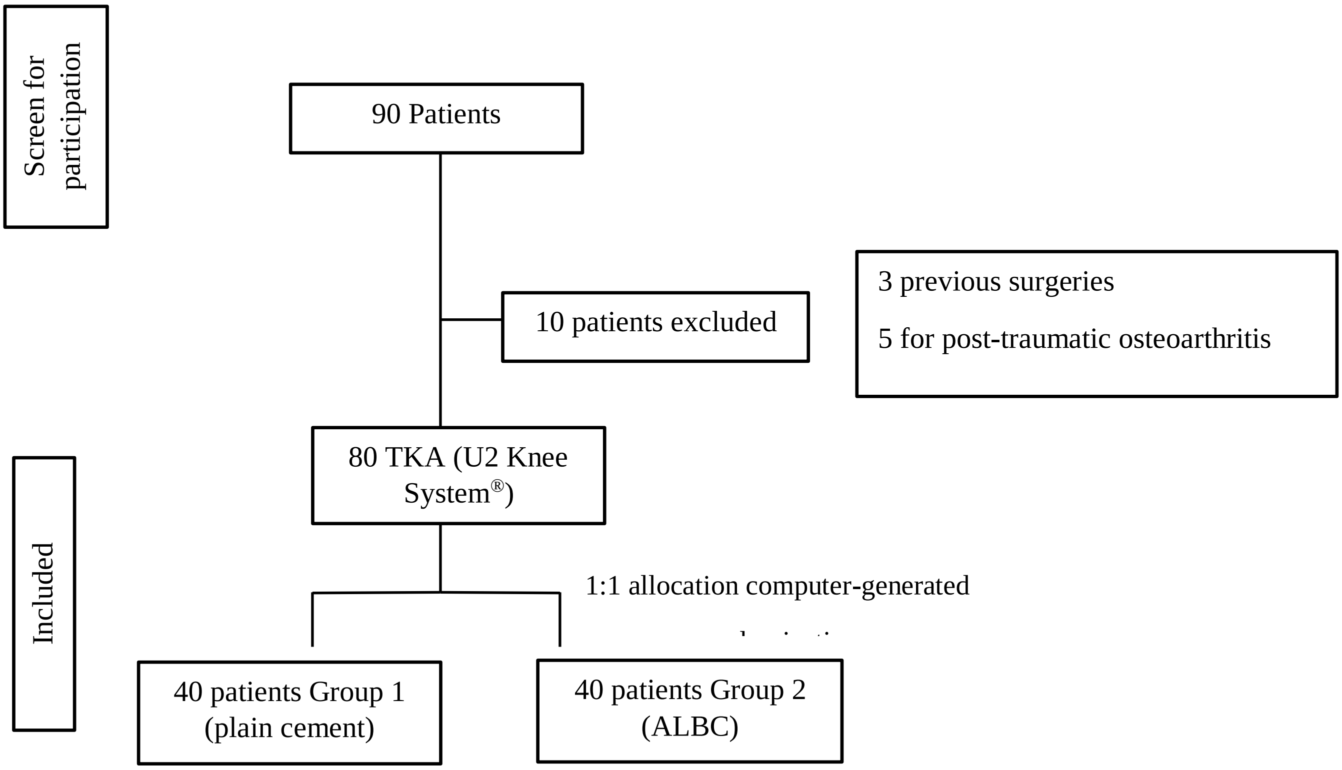
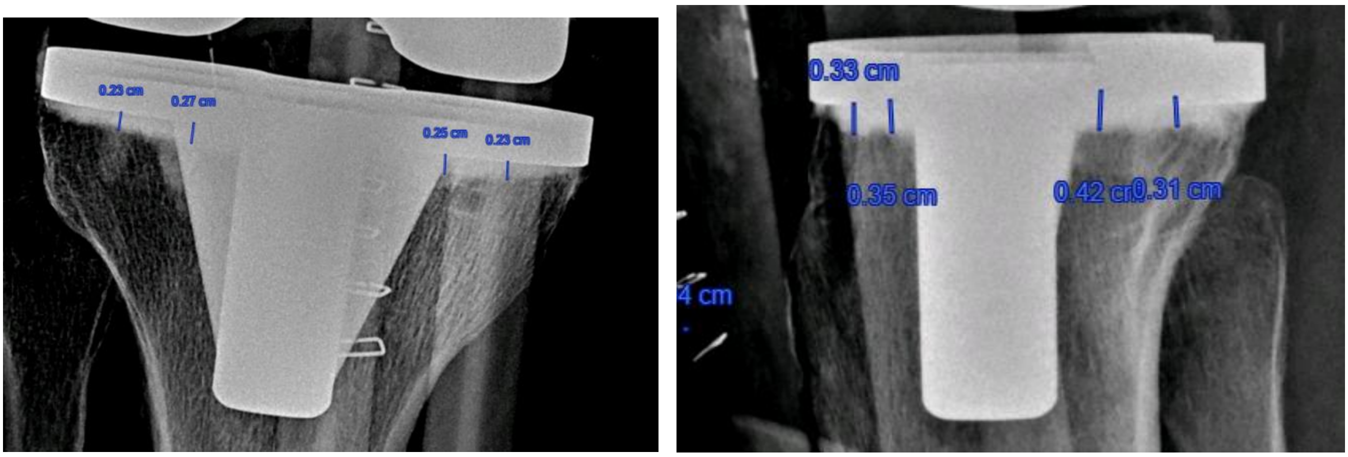


Figure 2. (a) Radiographic measurement of the cement bone intrusion in the tibia in four areas in the anteroposterior (AP) view (b) and in four areas in the lateral view.



(a) (b)

Figure 3. Radiographic measurement of the cement bone intrusion in the femur in six areas of a CR implant.