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Similar survival between screw cementless and cemented tibial components in young patients with osteoarthritis

Alejandro Lizaur-Utrilla · Francisco A. Miralles-Muñoz · Fernando A. Lopez-Prats

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Abstract
Purpose The aim of this study was to compare the outcomes of tibial fixation with either a cemented or cementless with screw augmentation component in young patients with non-inflammatory arthritis.
Methods Ninety-three patients aged 55 or younger with non-inflammatory arthritis were randomized to compare outcomes between cemented tibial fixation (48 patients) and cementless fixation with screw augmentation (45 patients). The femoral component was cementless in both groups. Post-operative evaluation was assessed by the clinical and radiological criteria of The Knee Society and WOMAC questionnaire.
Results The median follow-up was 6.7 (5–12) years. Significant differences were found for knee score ($p = 0.02$), range of motion ($p = 0.04$), and WOMAC score ($p = 0.03$). In the cemented group, there was one deep wound infection, four tibial aseptic loosening, and one polyethylene wear, all of which were revised. In the cementless group there was one tibial aseptic loosening and one polyethylene wear, both being revised. There was no difference in revision rate, and the cumulative survival at 9-year for aseptic reason was 93.7 % (95 % CI, 82–100 %) in the cementless group and 90.0 % (95 % CI, 80–100 %) in the cemented group (n.s.).
Conclusions Cementless total knee arthroplasty was found to be a reliable option in younger patients with osteoarthritis. Although the revision rate and survival were similar in both groups, better clinical outcomes were obtained with cementless tibial components.
Level of evidence I.

Keywords Total knee arthroplasty · Cementless components · Young patients · Osteoarthritis

A. Lizaur-Utrilla · F. A. Miralles-Muñoz
Department of Orthopaedic Surgery, Hospital General Elda, Ctra Elda-Sax s/n, 03600 Elda, Alicante, Spain

A. Lizaur-Utrilla (✉)
Servicio de Cirugia Ortopedica, Hospital General Elda, Ctra Elda-Sax s/n, 03600 Elda, Alicante, Spain
e-mail: lizaur1@telefonica.net

F. A. Lopez-Prats
Department of Orthopaedic Surgery, Miguel Hernandez University School of Medicine, Elche, Alicante, Spain

Introduction

Total knee arthroplasty (TKA) has proven to be an effective treatment in young patients [23, 25], although they are more active and demanding, and thus, more mechanical complications and potential revisions could be expected over time. The commonest mechanisms of failure are aseptic tibial loosening, and polyethylene wear and osteolysis [15]. Cementless tibial fixation remains of interest in an attempt to avoid the problems of longevity of the cement and preserve bone stock for potential revisions [19]. Radiostereometric analysis [9, 10, 18] found that cementless tibial components had greater micromotion than those cemented during the initial three post-operative months and then stabilized, whereas the cemented tibial components had an initially lower migration, but continuously increasing micromotion over time. For cementless fixation to be successful, initial stabilization and rigid fixation to bone are crucial for bony ingrowth. This can be achieved by various means, such as screws. In in vitro studies, screws have been shown to increase the stability of the tibial component [22], but have also been referred

osteolysis around the screws [14]. Most studies in young patient have used cemented fixation because they focused on patients with poor bone quality, such as rheumatic arthritis. There are few clinical studies comparing cemented and cementless tibial fixation in patients younger than 55 years with diagnosis of osteoarthritis, but their follow-up was up to 2 years [9, 10, 18] or the study was retrospective [16].

Cementless fixation in young patients with reasonable bone quality was hypothesized to be at least as beneficial at medium term as the cemented fixation. The aims were to evaluate the outcomes and survivorship of primary TKA in younger patients with osteoarthritis using cementless with additional screws or cemented tibial components.

Materials and methods

A double-blind, randomized, controlled, prospective study was conducted. The study was approved by the Elda University Hospital Ethical Committee, and informed consent was required. Double blind was due to the fact that patient did not know the type of prosthesis, the surgeon was not involved in the randomization process, and the evaluation of results was performed by two independent observers. The inclusion criteria were patients who required primary TKA, aged 55 or younger, and diagnosis of primary or post-traumatic osteoarthritis. The exclusion criteria were rheumatic disease, other inflammatory arthropathies, neurological disorder, or metabolic diseases, which could compromise bone quality. Patients with gross preoperative instability were also excluded. Randomization was made by the office staff in the morning before the surgery using a computer-generated random numbers table. The surgeon was not involved in the randomization process, and the patient did not know the type of prosthesis. Between 1999 and 2007, 93 patients were randomized in one of two fixation types of the tibial component: cementless with additional screws (45 patients) or cemented (48 patients). A minimum post-operative follow-up of 5 years was required for analysis of results. There were no significant preoperative differences between groups (Table 1).

Table 1 Preoperative data in both groups

	Cementless	Cemented	*p* value
Patients	$n = 45$	$n = 48$	
Age (years)	51.4 (3.7)	52.0 (2.6)	n.s.
Females/males	34/11	33/15	n.s.
BMI (kg/m^2)	31.9 (4.6)	30.8 (4.3)	n.s.
Knee score[a]	32.4 (6.7)	29.3 (8.1)	n.s.
Functional score[a]	46.6 (11.6)	45.9 (11.7)	n.s.
Range of motion (°)	96.4 (15.1)	97.0 (14.7)	n.s.
Diagnosis (OA/PO)	42/3	44/4	n.s.

Data are presented as mean (SD), unless otherwise stated

OA primary osteoarthritis, *PO* post-traumatic osteoarthritis, *n.s.* not significant

[a] Preoperative Knee Society scores

Operative protocol

All operations were performed by the senior author (ALU). All patients were treated in a standardized way under epidural anaesthesia. An anterior midline skin incision and medial parapatellar arthrotomy was used. The surgical technique and instrumentation were similar in all cases. The Multigen (Lima, San Daniele, Italy) knee system was used in both groups, which was modern modular condylar-type prosthesis with posterior cruciate ligament-retaining design. In all cases, the femoral component was cementless in cobalt–chromium alloy with porous titanium coating and had two pegs for press-fit fixation. All tibial components were modular metal-backed designs, and they had a cruciform baseplate. The cemented tibial component was in titanium alloy, and it was fixed with bone cement (vacuum-mixed Palacos with Gentamicin). The cement was applied to the undersurface of the implant and around the proximal 2 cm of the stem. The cementless tibial tray was in titanium alloy with porous titanium coating and had four holes for screw augmentation. All cementless components in this study were performed with the four additional titanium screws to enhance primary fixation. Polyethylene tibial inserts were sterilized with ethylene oxide, and the mean thickness used in either group was 13.2 mm (SD 2.1). The patella was resurfaced if there was articular cartilage degeneration. Seventeen (37.8 %) patients in the cementless group and 20 (41.6 %) in the cemented group received a patellar component. All patellae were all-polyethylene dome-shaped cemented design with a three-pegged. Standard antibiotic and antithrombotic prophylaxis were given. Post-operatively, in all patients continuous passive motion machine was started on the first day. Active ROM exercise also was performed under the supervision of the therapist. On the second post-operative day, patients began standing or walking with crutches or a walker.

Evaluations

Clinical and radiological evaluations were made pre- and post-operatively at 3 and 6 months, 1 year, yearly until 5 years, and biannually thereafter. All clinical evaluation forms were completed at each visit by an independent experienced observer (FMM) who did not know which type of prosthesis had been used. The Knee Society scores [12] were used for clinical evaluations. A score 90–100 was

considered excellent, 80–89 good, 70–79 fair, and less than 70 poor. Reduced Western Ontario MacMasters University (short-form WOMAC) [2] was administered at each post-operative annual visit. The WOMAC was transformed to a 0–100 scale, so a higher value implies a better outcome.

All post-operative radiographs were analysed by one independent experienced surgeon (FLP) who did not know the names of the patients or their clinical evaluations. Radiological evaluation was performed using standing anteroposterior, lateral, and standard skyline views. The latest radiographs were assessed for alignment of the limb, position of the components, and presence and location of radiolucent lines on the basis of Knee Society zones [7]. Definitive loosening was defined as a complete radiolucent line wider than 1 mm in all zones, progressive radiolucent lines wider than 2 mm, subsidence greater than 2 mm, or a change in implant position. Polyethylene wear was considered when there was gross asymmetry or change in thickness.

Statistical analysis

Statistical analysis was performed using SPSS software (SPSS Inc., Chicago, USA). Independent t test or non-parametric Mann–Whitney U test was used for continuous variables, and chi-square test or Fisher's exact test for categorical variables. Within-group (pre- and post-operatively), paired t test, or Wilcoxon signed-rank test were used. Survival analysis was performed with Kaplan–Meier method, and failure was defined as revision for any reason. Survival of both groups was compared by Mantel–Haenszel log-rank test. Statistical significance was considered for p values less than 0.05.

Results

No patients were lost to follow up. The mean follow-up in the cementless group was 7.2 years (SD 2.1, range 5–12,) and in the cemented group was 7.0 years (SD 2.1, range 5–12) (n.s.).

Mean knee score, functional score, and range of motion improved post-operatively ($p = 0.001$) in both groups. At last follow-up, between the groups (Table 2) there were significant differences in knee score ($p = 0.022$), range of motion ($p = 0.042$), and WOMAC ($p = 0.036$). In the cementless group, 41 (91.1 %) patients were pain free, and 4 (8.8 %) had mild or occasional pain, while in the cemented group, there were 36 (75.0 %) patients pain free, 4 (8.3 %) had mild or occasional pain, and 8 (16.6 %) had continuous moderate pain. Two patients in the cemented group required a cane for walking. In the cemented group, continuous pain was significantly related to the presence of tibial radiolucent lines ($p = 0.013$).

Table 2 Post-operative clinical outcomes

Clinical parameters	Follow-up (months)	Cementless	Cemented	p value**
Knee score*	6	86 (11.1)	83 (10.4)	n.s.
	12	87 (8.1)	83 (11.4)	0.031
	24	90 (8.1)	87 (10.3)	0.042
	Last	94 (9.3)	89 (11.8)	0.022
Pain score*	6	45 (5.3)	45 (5.8)	n.s.
	12	47 (5.6)	45 (6.1)	n.s.
	24	48 (5.5)	45 (6.9)	0.043
	Last	47 (4.2)	44 (8.1)	0.024
Range of motion*	6	99 (12.1)	98 (12.6)	n.s.
	12	104 (11.2)	98 (11.9)	0.010
	24	102 (10.8)	97 (11.2)	0.011
	Last	104 (19.6)	96 (17.4)	0.042
Function score*	6	89 (10.2)	87 (10.4)	n.s.
	12	89 (9.8)	86 (11.2)	0.028
	24	91 (8.2)	87 (9.6)	0.046
	Last	89 (9.9)	86 (10.7)	n.s.
WOMAC	6	80 (17.1)	78 (16.4)	n.s.
	12	82 (20.2)	76 (23.8)	0.042
	24	86 (12.1)	82 (13.1)	0.031
	Last	88 (10.7)	83 (11.4)	0.036

Data are presented as mean (SD)

n.s. not significant

* Knee Society

** Mann–Whitney U test

In either group, there was no loosening of the resurfaced patellae or femoral component for aseptic reasons. The mean femorotibial anatomic angle and component positions at last follow-up did not differ between the groups (Table 3). Among unrevised knees, there were radiolucent lines in three (7.1 %) cementless and in seven (16.6 %) cemented tibial components (n.s.). In either group, location of radiolucent lines was mainly in zones 1, 3, and 4, and all were incompletes, less than 2 mm in width, and non-progressives. There was no osteolysis around the screws in the cementless tibial components.

In the cementless group, one patient was revised because of aseptic tibial loosening, and another patient showed radiological wear of polyethylene without loosening of the components and only the insert was exchanged. In the cemented group, one patient developed a deep wound infection 3 months after surgery, and she was successfully treated with 2-stage reimplantation. Other four patients had aseptic tibial loosening, all of which were revised. Another patient had polyethylene wear without loosening of the components, and only the insert was exchanged. Thus, aseptic tibial loosening was found in one (2.2 %) cementless knee and in four (8.3 %) cemented knees (n.s.).

Table 3 Post-operative radiological alignments[a] in both groups

	Cementless	Cemented	*p* value
Femoral valgus (↦)	94.3° ± 1.1° (90°–96°)	95.6° ± 1.3° (90°–98°)	n.s.
Femoral flexion (·)	6.1° ± 0.5° (0°–8°)	6.4° ± 0.8° (0°–6°)	n.s.
Tibial angle (β)	87.9° ± 1.3° (86°–96°)	88.3° ± 1.4° (86°–94°)	n.s.
Tibial slope (σ)	85.6° ± 2.9° (86°–90°)	87.9° ± 3.6° (86°–94°)	n.s.
Patellar tilt	1.0° ± 0.11° (0°–10°)	0.9° ± 0.09° (0°–8°)	n.s.

n.s. not significant

[a] According to Knee Society radiological evaluation. Mean ± SD (range)

The cumulative survival at 9 year for aseptic reason was 93.7 % (95 % CI, 82–100 %) in the cementless group and 90.0 % (95 % CI, 80–100 %) in the cemented group, being this difference not significant.

Discussion

Better clinical outcomes and patient activity level using screw cementless tibial components were the most important finding of the present study in younger patients with osteoarthritis, and thus, the study hypothesis was proved.

As far as we know, we found in the literature only four studies comparing both tibial fixations on younger patients with osteoarthritis. One of them [16] was a retrospective study with a mean follow-up of 7 years. The other three [9, 10, 18] were prospective RSA studies that included clinical and radiological outcomes with a follow-up up to 2 years. Publications by Henricson et al. [10] and Gao et al. [8] reported similar patients from the same institution, so we only consider the study of Henricson et al. [10] focused on the tibial component. As well as in others, weakness of the current study was its relatively small size, which was due to the low prevalence of primary osteoarthritis in young patients.

Differences in clinical results between the two groups at a mean of 7 years after surgery were found in the present study. Patients with cemented tibial component showed a significantly lower Knee Society scores, which was mainly due to range of motion and pain. Other comparative studies [10, 18] in young patients found no significant clinical differences at last follow-up, but they had a follow-up up to 2 years. Mont et al. [16] also found no clinical difference between cementless and cemented replacements at a mean follow-up of 7 years, but it was a retrospective study.

No clinical differences have been shown in other prospective randomized studies compared cementless and cemented fixation [13, 20], but these studies included a mixture of age groups and primary diagnoses. The cause of the difference in clinical outcomes from the present study is unclear. There was no difference between groups in the radiological position of the components, radiological patellar tilt, or ligament balancing according to the items of the Knee Society score, but continuous pain in the cemented group was significantly related to the presence of tibial radiolucent lines. The patients younger than 55 years had generally higher physical activity, and they put greater demands and stresses on their implants. We believe, based on published RSA studies [10, 18], that cementless components have stability increased at medium- and long-term while the cemented may have progressive defects of fixation, though not necessarily loosening, and this could cause pain and mobility restriction affecting the scores.

Aseptic tibial loosening rate was not significantly different between groups in the present study. Nilsson et al. [18] prospectively studied 85 patients, and they found no revision in both cemented and cementless groups, but their patients were less active with age up to 65 years, and the follow-up was only 2 years. Mont et al. [16], in other comparative study of 30 patients younger than 50 years with mean follow-up of 7 years, also found no tibial loosening, but it was a retrospective study. Several case series studies where patients younger than 55 years with osteoarthritis had received cementless implants [23, 25] reported rates of aseptic tibial loosening from 0 to 1 %, while those studies with cemented components [5, 6, 15, 19] reported rates from 1 to 12 %, which was similar to the present study. Meta-analysis [8, 24] and studies with evidence level 1 [3, 4] comparing cemented and cementless fixation in total knee arthroplasty have been published with controversial results regarding the revision rate, but they provide overall results and not according to age groups. The Swedish knee arthroplasty register [21] showed no significant difference in risk of revision in the whole ages with regard to the cementing of the femoral component, but the cementless tibial component had 1.4 times higher risk of revision than the cemented tibial component; interestingly, this difference was significant only in osteoarthritis but not in rheumatic arthritis. On the other hand, reports from knee registers in Australia [1] and England [17] showed no difference in revision rate between cemented and cementless components, both countries where cementless arthroplasties were more used.

The presence of radiological radiolucent lines was similar to other studies [11, 19]. For cementless fixation to be successful, initial stabilization and rigid fixation to bone are crucial for bony ingrowth. The most studies of the tibial fixation with radiostereometric analysis in young patients

found that the cementless components migrated more than those cemented the first 3 months and then stabilized [18], with the exception of external rotation which did not stabilize until 12 months [10], while the cemented components had continuously increasing migration over the time. Nilsson et al. [18] thought that continuous migration in cemented tibial components may lead to a more permanent exposure of the interface, adding to the continuous migration. Henricson et al. [10], although using a trabecular metal tibial component which was more elastic than conventional implant used in the present study, observed that most of the cementless trays showed subsidence only, probably due to the elasticity of the implant, and they thought that this pattern of subsidence was regarded as being beneficial for cementless fixation. However, Nilson et al. [18] found that the magnitude and pattern of migration of the cementless tibial components fixed with or without screws were identical. In vitro studies have shown that the screws increase the stability of the tibial component in TKA [22] but have also been reported osteolysis around the screws [14]. In the present study, like others [25], this was not found.

The strengths of the present study were prospective controlled design, use of only one system of TKA performed by only one surgeon, homogeneous sample of patients, and no loss. Limitations of the study were its relatively small size although greater than most of the other comparative studies and a mean follow-up of 7 years. Although for elderly patients this follow-up may be acceptable, for patients younger with greater physical activity would be desirable increased follow-up. Further studies are needed to confirm these results.

We believe that in patients younger than 55 years cementless knee prosthesis is a method with very satisfactory clinical results and facilitates the revision if necessary.

Conclusion

Cementless total knee arthroplasty was found as a reliable option in younger patients with osteoarthritis. Although the revision rate and survival were similar in both groups, better clinical outcomes were obtained with the cementless tibial components.

Conflict of interest The authors declare that they have no conflict of interest.

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