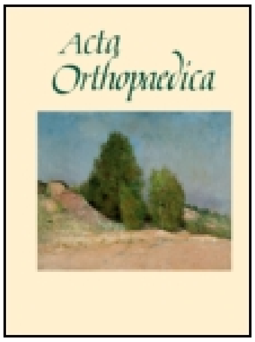

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All-polyethylene vs. metal-backed tibial component in total knee arthroplasty—a randomized RSA study comparing early fixation of horizontally and completely cemented tibial components

Part 1. Horizontally cemented components: AP better fixated than MB

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Background **Controversy still exists as to whether to mount the tibial bearing on a metal baseplate or not. Furthermore, the tibial component can be either horizontally or completely cemented. We evaluated metal backing versus all-polyethylene using horizontal cementing technique.**

Patients and methods **We randomized 40 patients with knee arthrosis (40 knees) to 2 groups: cemented total knee arthroplasty (AGC, Biomet) using either all-polyethylene (AP) or metal-backed (MB) tibial components (n = 20 for each group). All tibial implants had a total thickness of 8 mm. We used proximal cementing, including only the horizontal part of the tibia with avoidance of the stem-bone interface.**

Results **The positioning of the implants, as judged by the HKA angle, showed an average neutral alignment in both groups. Preoperatively and after 2 years, there was no statistically significant difference between the HSS scores in both groups (p = 0.6 and 0.4). After 2 years, the metal-backed components had rotated more around the longitudinal axis, median 0.5º vs. 0.2º (internal or external rotation, p = 0.002), and showed increased maximum total point motion, median 1.0 vs. 0.4 mm (maximum migration or MTPM, p = 0.003).**

Interpretation **Our study indicates that better fixation can be obtained with the all-polyethylene design if proximally cemented thin components are used.**

■

Until the late 1980s, fixation failure of the tibial component was considered to be the major reason for revision in total knee arthroplasty (TKA). This could be attributed to poor cementing, malalignment, and, in some cases, design problems related to component size, degree of constraint and lack of sufficiently accurate surgical instruments. TKAs of early design were always all-polyethylene (AP) single plateau. Excellent 10–20 year survival rates of 91–98% (Ranawat et al. 1993, Gill et al. 1999) of the gold standard "total condylar" (AP-monobloc until 1984) and its derivates were difficult to achieve with AP plateaus, which were proposed to inferiorly accommodate and improperly distribute stresses at the interfaces (Bartel et al. 1982).

In the 1980s, calculations based on finite element analysis indicated that metal backing of the tibial component would improve the distribution of forces and pressure between the implant and the cement, and thereby theoretically reduce the risk of clinical loosening (Bartel et al. 1982, 1986).

This concept spread rapidly to almost every design. The popularity of metal backing was enhanced because it opened the way for modular designs. At that time, the potential negative properties of these constructs—such as backside wear and wear of thin polyethylene inlays—were unknown or were disregarded. Modular polyethylene inserts

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still dominate the market. With the thinnest inserts, there is a risk of accelerated plastic damage, which may eventually result in need for revision, including the femoral component (Bert et al. 1998).

The excellent results reported with the total condylar design were based on an all-polyethylene monobloc tibial component (Insall et al. 1983, Vince et al. 1989), which justifies further studies of this concept. Manufacture of these designs is cheaper, which is another reason for the regained interest in all-polyethylene components (Rand 1993, Adalberth et al. 2000, Hyldahl et al. 2001, Udomkiat et al. 2001).

We compared two stemmed monobloc tibial components, one all-polyethylene and one with metal backing, inserted with the proximal cementing technique. All implants had the same design otherwise and equal thickness (8 mm). We used radiostereometric analysis (RSA) to measure migration over 2 years postoperatively. Our hypothesis was that the model with metal backing would improve fixation, in accordance with reported biomechanical results.

Patients and methods

Between 1995 and 1998, 80 knees (77 patients) with knee arthrosis were operated on at St. Göran's Hospital, Stockholm, using the AGC total knee prosthesis (Anatomic Graduated Component; Biomet, Warsaw, IN). Patients with grade III–V primary arthrosis (Ahlbäck 1968) who were on our waiting list for TKA were included. Bilateral disease with or without surgery of the other knee was accepted. No age or weight limit was used. Patients with previous meniscectomy were included, but no other type of previous surgery was accepted. The patients were entered consecutively after giving informed consent. Immediately before surgery, the knees were allocated to one or other group using the minimization method (Pocock 1983). The groups were (1) only proximal cementing leaving the stem uncemented (this study) or (2) proximal cementing with cement around the stem (see part 2). Within each stratum, the choice of component—all-polyethylene (AP) or metal-backed (MB)—was allocated randomly. To further minimize any influence of confounders, the patients were also stratified according to age (< 65 years, ≥ 65 years), body weight (< 75 kg, ≥ 75 kg), degree of knee deformity (< 10°, ≥ 10°), and gender. 40 patients (40 knees; 20 AP and 20 MB), all operated with proximal cementing, constituted the study group for the present paper (Table 1). In 4 patients with metal-backed components, a sufficient number of tantalum markers could not be visualized at the RSA examinations, leaving 16 MB and 20 AP implants to be studied. Exclusion of these patients did not change the patient demographics statistically. The study was approved by the Ethics Committee of Karolinska Institute, Stockholm.

Table 1. Patient profile with APHC (all-polyethylene horizontally cemented components) vs. MBHC (metal-backed horizontally cemented components) after randomization. MBHC/RSA denotes patient profile in group included in RSA after exclusions

	APHC	MBHC	MBHC/RSA
No. of knees	20	20	16
Excluded from RSA	1	4	–
Women; men	16; 4	16; 4	13; 3
Age, median year	73	73	73
range	45–82	58–81	58–81
Weight, median kg	79	76	75
range	56–113	56–103	56–103
Deformity > 10°	1	1	1

Prosthesis

The AGC is a minimally constrained, posterior cruciate retaining prosthesis. It is well-documented and has a good long-term survival rate (Emerson et al. 2000). The tibial component (AP and MB) is a one-piece (nonmodular), press-moulded polyethylene type using resin GUR 1900. Sterilization was performed by gamma irradiation in argon. In metal-backed tibial components, the tray is 3.7 mm thick and made of cobalt-chromium alloy. The polyethylene is 3.8 mm at its thinnest part, whereas the all-polyethylene component has a minimum thickness of 8 mm.

The articulating surface is flat on flat in the coronal plane and has a slight anterior lip in the sagittal plane. The underside of the surface has a peripheral rim, which may contribute to increase cement compression during the insertion. Typically, the horizontal cement mantle becomes 1–2 mm wide with both the AP and the MB design. The stem is

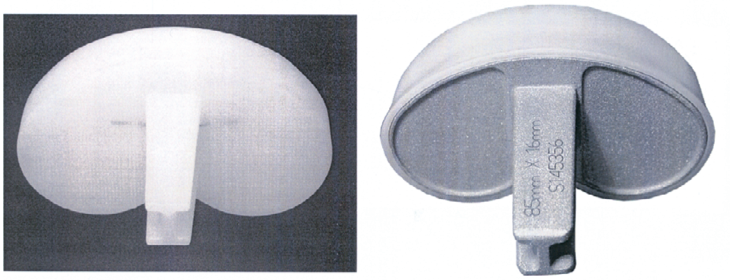

Figure 1. All-polyethylene and metal-backed tibia components of the AGC prosthesis. Both are non-modular, have identical articulating surface and are similar underneath. Stem geometry is identical.

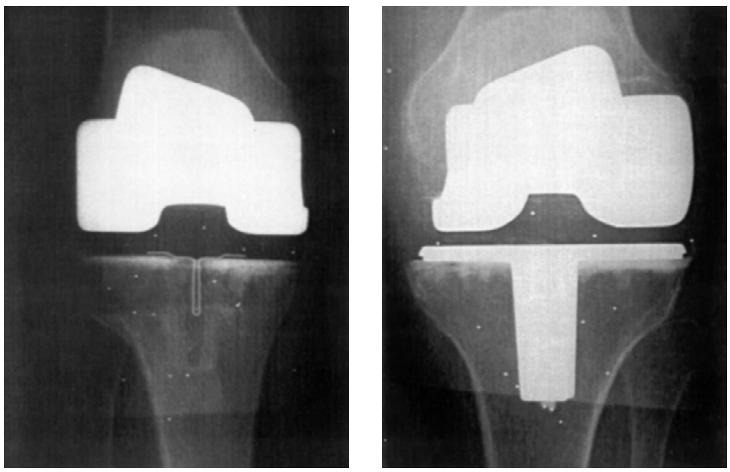

Figure 2. Standard anterior postoperative radiographs of the a) all-polyethylene, horizontally cemented (APHC), and b) metal-backed, horizontally cemented (MBHC) tibial components.

H-shaped in cross section and slightly conical. The stem is proportionally longer for the larger component sizes (range 32–48 mm). The femoral component is made of cobalt-chromium alloy and any femur fits any tibial component size (Figure 1).

Operation

All operations were done using epidural anesthesia, tourniquet, (300–350 mm Hg), straight anterior skin incision, and medial arthrotomy. We used the manufacturer's standard instrumentation with intramedullary femoral and extramedullary tibial guide, respectively. Size of prosthesis was chosen to obtain optimal coverage of the cut tibial surface. Before cement application with the press-fit stem, an H-shaped punch was used, thus creating a press-fit cancellous cavity in the proximal tibia. All bone cuts were cleaned by pulse-lavage and dried before application of cement. Cement was applied to the horizontal surface of the tibia, avoiding the stem cavity, and on the cut surface of the femur. Both components were cemented in a one-stage procedure using a cement gun and vacuum-mixed bone cement (Palacos cum gentamicin, Schering Corp., Labo, Belgium). The cement was allowed to cure with the leg in full extension. No patellar resurfacing was used (Figure 2). Two surgeons with long experience of total knee arthroplasty performed or participated during the surgical procedures. Drainage and epidural anesthesia-catheter were withdrawn within 24 h and full weight bearing (as much as could be tolerated, according to level of pain) was started on the postoperative day.

Clinical and radiographic evaluation

Clinical assessment was performed preoperatively and after 2 years using the Hospital for Special Surgery (HSS) score (Insall et al.1976). The Hip-Knee-Ankle angle (HKA) (Jeffery et al. 1991) was determined 2 months postoperatively.

Pre- and postoperative radiographs included anterior-posterior and lateral short weight-bearing radiographs. Merchant patellar view was only exposed postoperatively. We classified the radiographs as satisfactory if there was no obvious notching on the femur, no mismatching between the proximal tibia and the tibial component size, and no defects in the cement mantle. Tilting of components was only measured in cases where the observer classified component position as unsatisfactory. An independent radiologist who was blinded to the study evaluated all radiographs.

Radiostereometric analysis

During the operation, we prepared the skeleton and prosthesis for RSA by inserting 6–9 tantalum balls (diameter 0.8 mm) in the proximal tibial metaphysis, 6 balls (0.8 and 0.5 mm) in the polyethylene tray, and another marker into the tip of the polyethylene stem (AP group only). The manufacturer had inserted a corresponding marker at the end of the metal-backed stem. We used a biplanar technique (Kärrholm 1989, Selvik 1989, Nilsson and Kärrholm 1993). RSA examinations were done 3–4 days postoperatively and after 3, 12 and 24 months. The postoperative examination was used as reference for the position of the laboratory coordinate system and as starting position for subsequent measurements of migration. Accordingly, translations and rotations are presented as migration (mm and degrees, respectively) during the first 3, 12 and 24 months postoperatively. The stereoradiographs were scanned and the resultant digitized images were measured and evaluated using the UmRSA software (RSA Biomedical, Umeå, Sweden).

We evaluated the rotations and selected parameters representing translations of the tibial component. The rotations around the transverse (x-axis, anterior-posterior tilt), longitudinal (y-axis, internal-external rotation) and sagittal (z-axis, varus-valgus tilt) axes were evaluated in terms of signed and absolute values (indicating direction and disregarding direction, respectively).

Table 2. Precision in actual set-up

Migration	Mean error, 95% confidence limits
x-rotation	0.07° ± 0.13°
y-rotation	0.06° ± 0.17°
z-rotation	0.06° ± 0.13°
y-translation, mm	0.06 ± 0.22

We evaluated translations of standardized positions on the tibial tray according to Kärrholm (1989) and Nilsson and Kärrholm (1993). We chose to use maximum subsidence and maximum lift-off corresponding to any of the 8 standardized positions which displayed the most pronounced distal and proximal displacements, respectively. In addition, we evaluated the maximum total point motion (MTPM) corresponding to the vector length of the translation of the point on the tibial component exhibiting the most pronounced translation (irrespective of direction). The MTPM between 1 and 2 years has been shown to be of prognostic value (Ryd et al. 1995). Since the translation may change direction over time, this parameter was calculated using the 1-year examination as reference. Components with an MTPM of < 0.2 mm during the second year were classified as "stable", while an MTPM of > 0.2 mm was classified as "continuous migration", according to the definition of Ryd et al. (1995).

In 32 of the 80 knees, we assessed the precision of RSA for knee replacements in our set-up by double examinations with an interval of about 10 min (Table 2). These values are on a par with other set-ups in other departments. The stability of individual markers within each segment is essential for accurate radiostereometric calculations. In RSA, the degree of marker stability is expressed in the mean error (m.e.) of rigid body fitting. High values indicate marker instability. The limit for acceptance was set to 0.25 mm. No examination exceeded this value. The condition number reflects scattering of the markers; the smaller the value, the better the scatter. In our study, all examinations were based on condition numbers less than 100—except on two occasions with values of 160 and 139 (follow-up of 12 months in the MB group).

Table 3. HKA (in degrees) 3 months postoperatively, for the separate groups. Figures denote number of individuals within each HKA interval

HKA °	180 ± 2	180 ± 4	180 ± 6	180 ± >6
APHC	8	5	3	2 [a]
MBHC	11	4	3	0
MBHC/RSA	8	3	3	0

For abbreviations, see Table 1.
[a] 167° and 187°

Statistics

We used non-parametric tests since the migration data were not normally distributed. Kruskal-Wallis analysis was performed on the complete material, including all 80 knees and at each follow-up occasion. If lack of homogeneity was indicated at the probability level of 90% or more ($p < 0.1$), pairwise testing focusing on the two subgroups with proximally cemented components was done for the purpose of the present evaluation. We considered p-values of < 0.05 to be statistically significant.

We used multiple regression analysis to study any influence of age and weight on rotation around the cardinal axes, subsidence, lift-off and MTPM at the 2-year follow-up. The Mann-Whitney U-test was used to evaluate any differences in migration between men and women and between surgeons.

Results

Clinical results

All patients attended the 2-year follow-up. The median HSS scores increased from 59 (37–83) to 88 (70–100) in the AP group and from 62 (37–72) to 88 (76–98) in the MB group without statistically significant differences between the two groups ($p =$ 0.65 and 0.43, preoperatively and at follow-up, respectively; Mann-Whitney U-test). There were no major complications, and no revisions. One 80-year-old woman in the AP group had an HSS score of 53 at 2 years, indicating poor outcome. The operated knee was painful during weight bearing and she had severe arthrosis in her other knee. RSA showed that the tibial component was "stable" during the second year (MTPM = 0.07).

Radiographic result

All prosthetic components were classified as satisfactory on conventional radiographs. The median HKA 3 months postoperatively was 180º (167–187) in the AP group and 179º (174–184) in the MB group (median, range), indicating an overall neutral leg alignment, and no statistically significant difference was observed between the groups. Grouping values are presented in Table 3. 1 patient in the AP group had an HKA of 167° (i.e. 13° varus). At 2 years, the HSS scores amounted to 88 and the MTPM in the second year was zero.

Radiostereometry

Since the metal tray and the stem act as radiographic "shadows", we had problems in detecting a sufficient number of tantalum balls in both exposures in the MB group. 4 knees in the MB group were therefore excluded, while another 3 knees were excluded on a separate occasion for similar reasons. All AP knees could be analyzed. On all occasions, there was a tendency for higher rotation of the MB than of the AP components. A statistically significant difference was found at 3 months concerning anterior/posterior and varus/valgus tilt in favor of the AP group. Increased internal/external rotation in the MB group was found on all 3 follow-up occasions (3, 12 and 24 months) (Table 4). In the AP group, the direction of rotation was evenly distributed around zero. In the MB group, there was a tendency for internal rotation and anterior tilt of the components.

On all follow-up occasions, the metal-backed components also demonstrated increased MTPM (Table 5). There was no difference in maximum subsidence, but the metal-backed components showed more lift-off at 3 months ($p = 0.001$) (Figure 3).

Age, weight, sex or identity of the surgeon had no influence on the degree of micromotion recorded. In the MB group, 1 patient had an MTPM of 2.5 mm and a maximal inward rotation of 8.5°at 2 years, but the HSS score was 90 at 2 years. 2 other patients had an MTPM in the second year of 1.9 and 1.4 mm, respectively, and rotations of about 2–3.5º around all three axis. The HSS scores were 90 and 98. To date, none of these patients have been scheduled for revision. According to the definition of Ryd et al. (1995), 8 of 13 components in

Table 4. Rotations along the 3 cardinal axes. Figures denote degrees

	APHC median	APHC range	MBHC/RSA median	MBHC/RSA range	p-value
X-rotation					
3 months	0.12	0.02–1.8	0.37	0.07–2.5	0.03
12 months	0.18	0.01–1.2	0.38	0.12–3.5	> 0.1
24 months	0.25	0.04–0.80	0.47	0.02–4.0	> 0.1
Y-rotation					
3 months	0.08	0.00–0.60	0.25	0.03–2.3	0.008
12 months	0.14	0.00–0.65	0.47	0.04–6.5	0.001
24 months	0.15	0.01–0.63	0.47	0.08–8.5	0.002
Z-rotation					
3 months	0.14	0.06–1.0	0.56	0.06–2.1	0.009
12 months	0.28	0.04–1.6	0.48	0.02–3.6	> 0.1
24 months	0.24	0.03–1.1	0.92	0.06–3.2	> 0.1
Maximum lift-off					
3 months	0.06	-0.33–0.48	0.32	-0.17–1.1	0.001
12 months	0.13	-0.10–0.72	0.24	-0.41–0.91	> 0.1
24 months	0.14	0.00–0.58	0.26	-0.62–0.95	> 0.1

For abbreviations, see Table 1.

Table 5. Maximal total point motion (MTPM) in mm. Values are median (range)

Group	0–3 months	0–1 year	0–2 years	1–2 years	"unstable" [a]
APHC	0.22 (0.05–1.3)	0.43 (0.00–0.68)	0.36 (0.03–1.0)	0.12 (0.00–0.68)	5 of 20
MBHC/RSA	0.78 (0.16–2.3)	0.69 (0.33–6.4)	1.04 (0.25–8.7)	0.33 (0.06–2.5)	8 of 13
p-value	0.002	0.002	0.003	0.02	> 0.1

For abbreviations, see Table 1.
[a] The number of "unstable" components, i.e. migration > 0.2 mm during the second year, is presented.

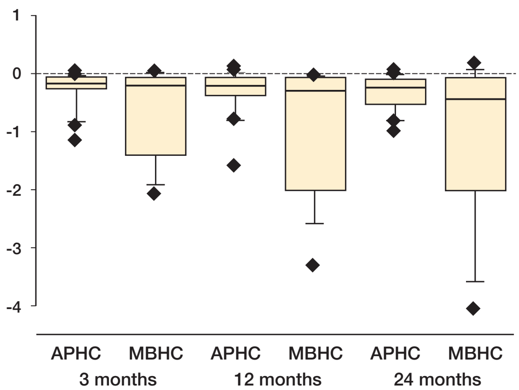

Figure 3. Box-plot illustrating subsidence of components in all-polyethylene, horizontally cemented (APHC) and metal-backed, horizontally cemented (MBHC) groups. There were no statistically significant differences. The line within the box denotes the median, the box represents the 25–75% range, and the whiskers represent non-outlier min and max. Extremes are marked "♦".

the MB group and 5 of 20 in the AP group could be classified as "continuous migration" during the second year. There was no statistically significant difference between the groups (Fischer's exact test, p = 0.07) (Table 5). 3 knees in the MB-RSA group could not be classified due to missing MTPM at either the 1- or 2-year examination.

Discussion

All patients in this study had the same diagnosis and were operated with the same cementing technique. They received components of the same thickness and of the same implant design. Even so, MB components migrated more than AP components, especially when measured as maximum migration regardless of direction (MTPM) and internal/external rotation.

We used the same RSA set-up and arrived at approximately the same degree of precision as Adalberth et al. (2000), indicating that relevant comparisons could be done. Adalberth et al. (2000) performed a similar study comparing proximally cemented all-polyethylene and metal-backed AGC TKAs. They found a "tendency" to higher MTPM and statistically significantly higher "lift-off" in the MB group, and concluded that the migration of AP implants was on a par with that of the MB implants. However, these authors compared components of different thickness, with higher total component thickness in the MB group and thicker polyethylene in the AP group. This can be expected to influence the results, since the influence of thickness becomes less with increasing height of the implant (Burstein 1990, Seki et al. 1998). Equal biomechanical rigidity of AP and MB is reached at a height of about 13 mm (Burstein 1990). Thus, the influence of metal backing on the fixation of the implant can be expected to be most pronounced when components thinner than 13 mm are used. Optimal comparison can be expected when the tibial components used are of equal height.

We believe that our findings reflect different rigidity of the tibial components, as proposed by Murase and co-workers (1983). They performed an in-vitro evaluation of cemented all-polyethylene components with 3- and 6-cm-long stems. They found proximal bone stress reduction when stems were used. In a corresponding series of metal-backed tibial components, higher proximal stress reduction was found due to the cemented stem. This harmonizes with the "teeter-totter" effect. Using metal-backed trays, peripheral compressive load on one side will induce tensile forces on the opposite side due to the stiffness of the implant (Bartel et al. 1982). Adalberth et al. (2000) found significantly more lift-off using metal-backed tibial components. We detected such a difference at 3 months. Exclusion of the stem from the cement mantle might imply that the metal tray has less resistance to eccentric loading.

Previous clinical studies comparing AP with MB have not been consistent regarding the optimum choice (Apel et al. 1991, Rand 1993, Adalberth et al. 2000, Udomkiat et al. 2001). The reason for this is not clear, but the presence of confounding factors and inclusion of various thicknesses of tibial components could be of importance. As long as AP designs perform as well as MB designs, the cost speaks in favor of the former. In the past, many authors have concluded that AP functions as well as MB in "low demand" patients (L'Insalata et al. 1992, Rand 1993). Important arguments for AP are simplicity, thicker polyethylene with higher resistance to wear, absence of back-side wear and avoidance of mechanical interlocking problems. Age and activity level do not affect any of these arguments. The argument that a modular insert can be exchanged more easily will lose its importance if modularity in itself introduces new, more severe hazards.

Hvid (1988) showed that the strength of the metaphyseal tibial bone became reduced with increasing proximal bone resection. This observation and the risk of future loosening and revision favor minimal bone resection and the use of thin tibial components. Although the metal backing was developed to offer a stronger baseplate and prevent deformation of the polyethylene, several authors found that thin plastic remained a cause of failure despite the presence of metal backing (Engh et al. 1992, Wright et al. 1992). This means that a metal-backed component requires more bone resection than an all-polyethylene component to achieve equal polyethylene thickness.

During the past decade, the frequency of fixation failure of TKA has decreased, whereas wear and osteolysis have become increasingly common (Schai et al. 1998, Ewald et al. 1999). One reason for this could be that plastic inserts used on metal-backed designs frequently show micromotions, which may result in back-side wear (Wasielewski et al. 1997, Parks et al. 1998). Modularity has advantages, as it facilitates any revision procedure by offering a wide selection of implant designs in difficult cases. In the primary situation, the need for modularity can be debated. Bert et al. (1998) described revisions of 62 modular TKAs due to tibial insert failure, where almost 90% required total revision due to significant scoring and/or damage of metal tray, and secondary damage to femur components. Babis et al. (2002) reported a similar series of 56 insert exchanges where all other reasons for failure were excluded. Cumulative 6-year survival was 64% and these authors concluded that change of insert should only be performed with “caution”. Failure of an all-polyethylene tibial component can be expected to cause less damage to the femoral component.

We studied a “flat on flat” arthroplasty design, which is considered not to be associated with optimal load transfer between the components. This “fact” seems to trace its origin from the classical studies of Bartel and co-workers (Bartel 1982), where infinite element analysis this single-plateau design showed low resistance to protect edge-loaded compressive forces to cancellous bone when varus/valgus tilt was applied. The only article we have found giving support for these in-vitro biomechanical findings is the work by Faris et al. (2003), where substantially inferior results comparing AP components (10 mm or thicker) with MB components were reported in a retrospective series lasting up to 10 years. This was a case series with a historical control group. 75% of failures were due to medial tibial collapse, the majority of tibial loosening occurring within three years. The discrepancy between these results and ours is obvious.

We found that AP components had better fixation than MB tibial components using 8 mm plateaus and only proximal cementing. Based on these findings, we believe that AP components should be used more frequently, especially in the standard patient when thin components are to be inserted.

No competing interests declared.

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