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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 2. Completely cemented components: MB not superior to AP components

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Background Uncertainty exists as to whether metal backing (MB) of the tibial component is better than an all-polyethylene component (AP). This is valid for both horizontally and completely cemented components. We evaluated completely cemented MB vs. AP (Part 2).

Patients and methods In a randomized study, 39 patients (40 knees) with knee arthrosis were operated with cemented low-conforming total knee arthroplasty (AGC, Biomet) with a tibial component of uniform thickness (8 mm), cemented both beneath the tibial tray and around the stem. 20 patients had an all-polyethylene (AP) tibial component and 20 patients had an identical but metal-backed (MB) tibial component. We used clinical examination and radiostereometric analysis (RSA) to evaluate the hypothesis that MB improves component fixation. Fixation was evaluated using RSA up to 2 years after surgery. Clinical assessment was performed preoperatively and after 2 years using the Hospital for Special Surgeons (HSS) score.

Results We found no differences in micromotion, and no differences in clinical scores could be detected between the groups at any time point.

Interpretation Our findings indicate that there was equal initial fixation of the AP and MB stemmed monobloc components when they were cemented beneath the tibial plateau and around the stem.

Metal-backing (MB) was initially introduced as a one-piece, non-modular component to improve longevity of fixation of tibial components. This assumption has never been proven in clinical research. The metal back also enabled modularity and the use of cementless fixation. There are, however, reasons to question its use. After some years of widespread use, problems relating to increased wear and insufficient locking mechanisms appeared, which have become an increasingly common cause of revision (Schai et al. 1998, Ewald et al. 1999). In primary cases the need for modularity may be limited, whereas this concept is often beneficial in cases of revision. Cementless fixation may be associated with long-term success (Whiteside 1994), but has also shown inferior results compared to cemented fixation (Duffy et al. 1998). Finally, a metal tray may increase the cost of the implant by up to 30% or more.

For the reasons given above, there has been renewed interest in the AP components. In matched-pair or retrospective studies, several authors have been unable to detect inferior clinical outcome when comparing AP components with their non-modular MB equivalents (Apel et al. 1991, L'Insalata et al. 1992, Rand 1993). With modular MB design, such as Press Fit Condylar (PFC), one randomized study confirmed equal clinical outcome when com-

Table 1. Patient profile with APCC (all-polyethylene completely cemented components) vs. MBCC (metal-backed completely cemented components) after randomization. MBCC/RSA denotes patient profile in group included in RSA after exclusions, see Table 2

	APCC	MBCC	MBCC/RSA
No. of knees	20	20	16
Excluded from RSA	1	4	—
Women; men	16; 4	18; 2	15; 1
Age, median years	73	70	69
range	55–78	51–82	52–82
Weight, median kg	79	78	77
range	58–92	55–110	56–110
Deformity > 10°	1	0	0

paring MB and AP components with a minimum of 3 years follow-up (Gioe and Bowman 2000). In another retrospective report (PFC) with a mean of 5 years follow-up, revisions due to osteolysis were found only in the MB group—amounting to 5% of the cases (Rodriguez et al. 2001).

In vitro, whether or not cement is used around the stem has been shown to influence the fixation differently depending on whether metal-backing is used (Reilly et al. 1982, Murase et al. 1983, Seki et al. 1997, Bert et al. 1998). Cement around the stem appears to improve fixation more in MB components than in AP components (Bert et al. 1998). This improvement would be achieved at the expense of proximal stress-shielding, which in itself might reduce longevity of the implant (Reilly et al. 1982, Murase et al. 1983, Lonner et al. 2001). Thus, in any comparison between MB and AP components, the cementing technique and the extent of the cement mantle should be similar. We are not, however, aware of any previous randomized evaluation comparing the fixation of completely cemented all-polyethylene stemmed non-modular tibial components with their metal-backed equivalents.

Comparison of horizontal cemented components (AP vs. MB) has been performed, using the same prosthesis (AGC) by Adalberth et al. (2000) and Hyldahl et al. (2005). Adalberth found fixation "on par" but Hyldahl detected better fixation of AP components.

We used radiostereometric analysis (RSA; Selvik 1989) to compare the migration of all-polyethylene or metal-backed tibial components up to

Table 2. Patients in the MBCC group who were excluded from RSA. Patients are presented with their case letters in the series

Reason for exclusion	MBCC (n = 20)			
	Postop	3 m	12 m	24 m
<3 visible markers	1	2	1	3
cases	a	a,g	a	a,c,g
Missing examination	1	2	1	3
cases	b	b,d	b	b,d,h
Condition value too high	1	1	1	1
case	e	e	e	e
ME above accepted level	1	1	1	1
case	f	f	f	f
Remaining for examination	16	14	16	12
Excluded cases (n = 4): a,b,e,f				
MBCC/RSA study group: n = 20 – 4 = 16				

2 years after operation, where the cement mantle also included the stem of the prosthesis.

Patients and methods

The set-up in this study was identical in all respects to that of a previous study (Hyldahl et al. 2005) except for one variable. The present study focused on the 2 groups of knees that were allocated completely cemented tibial components immediately before the operation: either all-polyethylene (APCC) or metal-backed MBCC), i.e. the stem was included in the cement mantle.

Consequently, there were 39 patients in the study group (40 knees, 1 operated bilaterally), all of whom received the 8-mm thick tibial component—either APCC or MBCC (or both in the bilateral case) (Table 1). Thus, there were 20 knees in each group. 40 knees, 1 operated bilaterally, one side AP, the other MB.

The study was approved by the Ethics Committee of Karolinska Institute.

4 patients in the MBCC group could not be analyzed by RSA due to difficulties in visualizing sufficient numbers of tantalum markers in the tibial component radiographically. Reasons for exclusion are presented in Table 2. 1 patient in the APCC group could not be analyzed due to a missing post-operative RSA examination. There were no differences between the 2 groups in patient demographics, including or excluding patients with missing observations (Table 1).

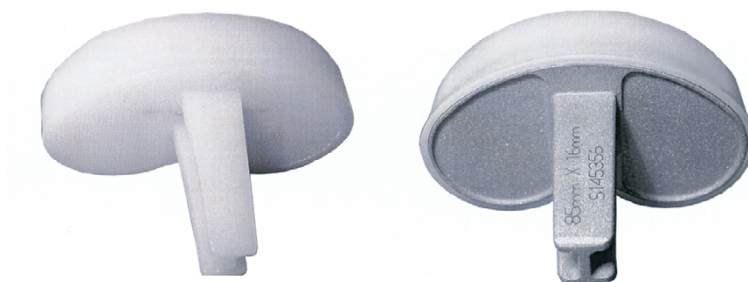


Figure 1. All-polyethylene (left) and metal-backed (right) tibial components of the AGC prosthesis. Both have non-modular, identical articulating surface and similar geometry.

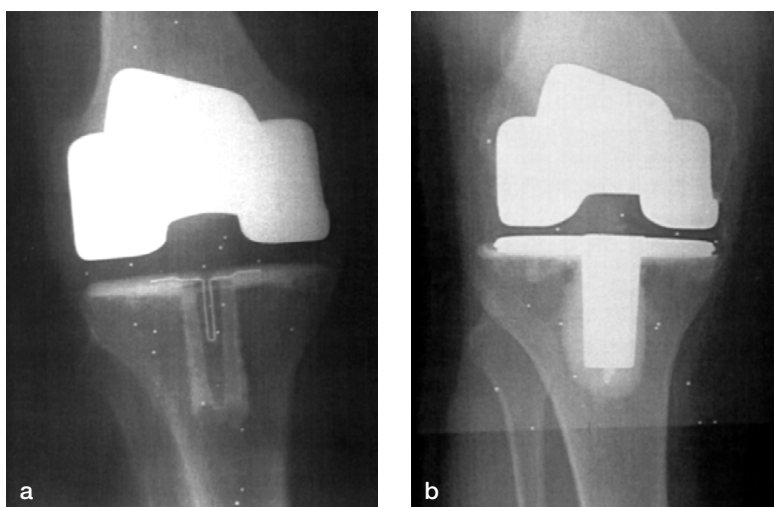


Figure 2. Standard anterior postoperative radiographs of the a) all-polyethylene completely, cemented (APCC), and b) metal-backed, completely cemented (MBCC) tibial components.

Prosthesis

See Part 1 (Hyldahl et al. 2005).

Operation

The method of operation was identical to that in Part 1 with one exception: before cement application a rectangular punch was used to create a cancellous cavity in the proximal tibia, and the cement gun was used for retrograde filling of the stem cavity. This was followed by application of cement to the horizontal tibial cut and the cut femoral surfaces. Postoperative radiographs using this complete cementing technique for AP and MB tibial components (Figure 1) are given in Figure 2.

Set-up, examinations, calculations and precision all corresponded to those described by Hyldahl et

al. (2005). The limit for acceptance of mean error (m.e.) of rigid body fitting (marker instability) was the same (0.25 mm). No examination exceeded this value.

The condition number reflects scattering of the markers. The smaller the value, the better is the scattering—and hence the precision of the investigation. On three occasions we accepted values of 157, 156 and 153 (MB, prosthetic segment). All other values were less than 100.

Statistics

Statistical analysis was carried out as in Hyldahl et al. (2005).

Table 3. HSS score (maximum 100 points). Values are median (range)

Group	n	HSS pre-operatively	HSS 2 years postoperatively
APCC	19	59 (37–83)	90 (70–100)
MBCC	20	62 (38–79)	94 (75–99)
MBCC/RSA	16	64 (38–75)	93 (75–99)

For abbreviations, see Table 1.

Table 4. HKA (in degrees) for the separate groups. The figures denote the number of individuals within each HKA interval

HKA °	180±2	180±4	180±6	180±>6
APCC	9	4	5	1 (188)
MBCC	14	4	2	0
MBCC/RSA	11	4	1	0

For abbreviations, see Table 1.

Table 5. Absolute rotations degrees and translations mm. median with range in parenthesis

	3 months		12 months		24 months	
	APCC	MBCC/RSA	APCC	MBCC/RSA	APCC	MBCC/RSA
Anterior-posterior tilt	0.22	0.17	0.42	0.27	0.33	0.28
range	0.05–0.8	0.03–0.65	0.01–1.24	0.02–0.79	0.03–1.13	0.01–1.54
Inward-outward rotation	0.09	0.14	0.12	0.16	0.16	0.46
range	0.01–2.8	0.03–1.35	0.01–2.89	0.03–1.25	0.0–3.0	0.04–0.97
Varus-valgus tilt	0.12	0.12	0.24	0.24	0.26	0.26
range	0.02–1.02	0.01–0.55	0.01–0.71	0.07–0.65	0.01–1.25	0.06–1.06
Maximum subsidence ^a	–0.09	0.01	–0.16	–0.06	–0.21	–0.05
range	–0.86–0.08	–0.4–0.56	–0.78–0.11	–0.57–0.36	–0.72–0.07	–0.40–0.45
Maximum lift-off ^b	0.06	0.21	0.09	0.2	0.1	0.24
range	–0.10–0.53	–0.06–0.56	–0.14–0.68	–0.09–0.62	–0.08–0.79	–0.02–1.12

^aNegative values denote distal axial migration.^bRange of maximum lift-off always denotes positive maximal lift-off.

Results

Clinical result

There was no difference in preoperative HSS score and the HSS score at 2 years follow-up between the two groups: $p = 0.7$ and $p = 0.2$, respectively (Mann-Whitney U-test) (Table 3).

1 patient (APCC) was revised after 14 months because of patello-femoral pain, and received a cemented patellar component. The patient was not excluded since we felt that this operation did not affect prosthetic migration. No other revisions were performed within 2 years and no other complications requiring specific treatment occurred in any of the groups. No patients were lost to follow-up during the period of observation.

Radiographic results

The analysis of conventional radiographs showed that all prosthetic components were satisfactory, and we detected no technical errors or complications in the postoperative radiographs. The values

of HKA angle indicated an overall neutral leg alignment and no differences were observed between the groups (Table 4).

Radiostereometry

Rotations around the cardinal axes are given in Table 5. There were no statistical differences between the APCC and MBCC groups with regard to rotations, translations and MTPM at any time period. Regarding the direction of rotation, these were evenly spread around zero in the APCC group. In MBCC group, there was a tendency to anterior tilt of the components (11/14 at 12 months).

According to the definition of Ryd et al. (1995), 14 of 19 in the APCC group and 8 of 12 in the MBCC group could be defined as “stable” (i.e. MTPM < 0.2 mm during the second year). The difference was not statistically significant. The “continuously migrating implants” had the following MTPM values after 1–2 years: APCC: 0.25, 0.28, 0.3, 0.31 and 0.33; MBCC: 0.27, 0.40, 0.41 and 1.45. The three highest values in this latter

group correspond to the individuals previously described in which relatively high values of condition number were accepted. That is, the measured markers were suboptimally separated, which may have influenced these recordings. The patient with the highest MTPM (1.45 mm) had a maximal rotation (anterior tilt) of 1.5° after 2 years. HSS score improved from 38 to 75 in this patient, who was 82 years of age. To date, there have been no signs of clinical failure or radiographic loosening.

Discussion

Early designs of TKA were consistently of the all-polyethylene monobloc type and some of these have shown excellent long-term results. The 10-year survival of the Total Condylar knee prosthesis has reached 90% or more (Ranawat et al. 1993, Gill et al. 1999) and is still considered to be the gold standard. Loosening of the tibial component was, however, a substantial problem in the early period of TKA. The AP design was put forward as a possible explanation and metal backing was introduced in the early 1980s as a solution to this problem. The arguments for this were mainly theoretical. Metal backing resulted in a more even load distribution, if the load was applied symmetrically (Bartel et al. 1982, Lewis et al. 1982, Reilly et al. 1982). However, asymmetrically or peripherally applied load resulted in increased tensile forces when metal-backed components were used. Such loading is more likely to occur in the clinical situation.

We have found only one randomized study comparing completely cemented AP and MB tibial components (Gioe and Bowman 2000). With a minimum of 3 years follow-up, these authors evaluated 111 AP and 102 MB press-fit condylar (PFC) prostheses and there were no differences regarding clinical or radiographic outcome. No aseptic loosening was observed. They included all diagnoses, but component thickness was not described. The conclusion was that a well-designed contemporary congruent AP component functions as well as a corresponding MB component over 3–5 years—and at lower cost.

There have been several retrospective studies comparing AP and MB tibial components, often biased chronologically; MB is often implanted

later in the surgeon's experience with the same total knee (Apel et al. 1991, Rand 1993, Ritter et al. 1994). The Total Condylar knee changed to MB 1979, and more than 10 years later several authors reported retrospective comparisons before and after this change with no apparent differences regarding revision rate or loosening of the tibial component (Apel et al. 1991, L'Insalata et al. 1992, Rand 1993). Apel concluded that "the use of AP in cemented TKA is recommended over MB because clinical results appear equivalent and the cost is lower". In a retrospective comparison of modular MB and AP tibial components of the PFC prosthesis with a minimum follow-up time of 5 years (243 knees, 175 patients), Rodriguez et al. (2001) reported a 5% revision rate (6 knees) for metal-backed prostheses caused by osteolysis and synovitis, but no revision in the AP group. The survival rate at 7 years was $96\% \pm 0.8\%$ for AP and $75\% \pm 10\%$ for MB. The authors stated that "modularity and MB was added to the PFC design to improve fixation. However, the superiority of the modular MB implants remains in question" (Rodriguez et al. 2001).

Udomkiat et al. (2001) reported a matched-pair analysis of 96 knees (Apollo Knee System) with either an MB (AP-insert) monobloc tibial component or an AP monobloc tibial component with complete cemented mantle. Clinical and radiographic assessments up to 3 years postoperatively revealed no differences in clinical scores, self assessment or radiographic evaluation between the components. The authors concluded, as did L'Insalata et al. (1992), that AP is preferable in the elderly because of a decreased risk of revision due to modularity. The restricted use of all-polyethylene components to cover only the elderly population can be questioned. There is published data favoring AP regardless of age (Rodriguez et al. 2001) and Forster (2003).

All these series evaluated congruent or semicongruent designs, and these designs are suggested to be optimal regarding AP tibial components. Based on these reports, AP and MB appear to allow equal fixation, whereas the AP component eliminates the risk of back-side wear—and at lower cost. Recently, Forster (2003) reported a meta-analysis of 5,950 knees (16 articles) with survival analysis with minimum 5 years follow-up. Comparing

posterior stabilized, non-stabilized, metal-backed or all-polyethylene cemented tibial components, the only design that showed significantly better survival was the non-stabilized all-polyethylene component.

We have found only one recent article reporting inferior results with AP tibial components compared with MB tibial components, both designs being completely cemented and followed for 10 years (Faris et al. 2003). This was a case series with a historic control group. AP tibial components at least 10 mm thick had a significantly higher revision rate regarding the AGC tibial component, basically due to medial collapse of the proximal cancellous tibia (3% revision, 14% medial collapse at 1 year). In most cases this was observed within 3 years postoperatively. The authors' hypothesis for this finding was that the AGC design, relatively low-conforming and "flat on flat" in the coronal plane, could not withstand edge loading.

Our findings after 2 years, using the same prosthesis as in the series of Faris et al., but even thinner, are not in accordance with their finding of early failure of the AP component within 3 years. There are no published data supporting major changes regarding fixation during the third year after surgery. There might be explanations other than the composition of the component (in this case polyethylene) to explain their findings. AP failures have been reported in older series, for example Ducheyne et al. (1978) who reported 7% failure at 2 years (UCI-prosthesis). In retrospect, the reasons for this were most probably multifactorial, such as use of thin components (5–7.5 mm), insufficient coverage of the cut tibial surface and perhaps an inferior cementing technique.

In our study, the comparatively small study population might imply a risk of type II error. If so, we may have failed to detect a superior initial fixation in AP components, which would not influence our overall conclusion that all-polyethylene components are preferable—based on lower cost, use of thicker polyethylene and reduction of surface area, which may generate wear particles. On the other hand, if we have failed to detect better fixation using completely cemented MB-stemmed components, there would still be a need for studies showing superior clinical results using a thin MB tibial component, which is a more expensive

component with potential wear complications. We conclude that MB tibial components give no better fixation than AP tibial components when the components are completely cemented.

We have found better initial fixation of AP than MB when the components were only horizontally cemented (Hyldahl et al. 2005). Reason for this is unclear but we believe that it reflects different rigidity, metal vs. all-polyethylene. The more rigid MB, transforming asymmetric load throughout the entire component, needs a larger cement-bone contact area to resist clinically excentric load. AP, more elastic, may partly absorb such excentric forces without need of extra cement.

No competing interests declared.

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