

Matched-Pair Analysis of All-Polyethylene Versus Metal-Backed Tibial Components

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Abstract: Forty-eight matched pairs of osteoarthritic knees from patients who underwent primary total knee arthroplasty with a round-on-round, Apollo Knee System were studied to evaluate the outcome between all-polyethylene and metal-backed tibial components. Patients were matched for patient factors, preoperative deformities, cruciate salvage or sacrifice, and surgical technique. At the last follow-up (average, 38.4 months), there was no statistically significant difference in terms of knee scores, patient self-assessment, and radiographic outcomes. No component required revision, and no revisions were pending. Maintenance of these results over time would project into better long-term success for all-polyethylene tibial components because of the amount of wear and osteolysis with current modular metal-backed tibial components. We advocate the use of a more cost-effective all-polyethylene tibial component in elderly patients (>70 years old) who are not likely to need the versatility of exchange of a modular polyethylene insert because of wear. **Key words:** knee arthroplasty, all-polyethylene, metal-backed, tibial component, matched pair.

Metal-backed tibial (MBT) components have become popular because of modularity. The MBT component allows the use of modular wedges, stems, and augments in complex situations, although these rarely are used in primary total knee arthroplasties (TKAs). Modularity provides the option of replacing only the polyethylene insert if wear or osteolysis requires reoperation. Laboratory studies showed that metal reinforcement would decrease the bending strains in the stem; reduce the compressive stresses in the cement and cancellous bone under the tibial baseplate, especially when the

tibia is loaded asymmetrically; and effectively distribute the eccentric load into the large area of proximal tibia through the use of a rigid metal stem [1–5]. The MBT component seemed to be less likely to allow cancellous bone failure, which had been the commonest cause of fixation failure [6].

Failure of TKA by tibial component loosening currently is unusual. Failure by wear or osteolysis with modular MBT components has become an increasingly common cause of revision [7,8]. Modular MBT components have micromotion and wear at the polyethylene insert–metal tray interface [9,10]. The use of an all-polyethylene tibial (APT) component eliminates this cause of polyethylene debris and osteolysis. Modularity provides the advantage of needing to perform only an exchange of the polyethylene insert in younger patients when wear and osteolysis occur. In patients ≥ 70 years old, the performance of only 1 operation is important. A metal tray could increase tilting tensile stresses at the bone–cement interface opposite to the load when lift-off occurs [2,3,5,11,12]. An APT component would not be stiff enough for these

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tilting stresses to occur, unless it were >13 mm thick. An APT component >13 mm thick is as stiff or stiffer than the MBT component of the same thickness [13].

Previous experience with successful use of an APT component in the Total Condylar Knee prosthesis (Howmedica, Rutherford, NJ) [14-6] gave us confidence to use an APT component with the Apollo Knee System (Sulzer Medica Orthopedics, Austin, TX). This knee system has conforming surfaces, as did the Total Condylar prosthesis. The purpose of this study was to evaluate whether the current round-on-round knees have clinical and fixation results with APT components equivalent to MBT components. A matched-pair analysis was conducted to eliminate differences in patient factors, cruciate salvage or sacrifice, and surgical technique.

Material and Methods

A total of 310 consecutive primary TKAs were performed in 261 patients between January 1994 and November 1996 by the senior author (L.D.D.). All knees were implanted with the Apollo Knee System (Sulzer Medica Orthopedics, Austin, TX), with either cruciate-retaining or posterior-stabilized designs. APT components were used in 160 knees, and MBT components were used in 150 knees.

Some of these patients had been included in a previous randomized study of medialization of the

patella [17]; otherwise, both designs were used in a random fashion. Sometimes intraoperatively the posterior cruciate ligament was cut from the tibia with the saw during preparation of the tibia, and a posterior-stabilized design was used. Otherwise, there were no specific indications for use of either design by age, gender, activity level, or quality of bone. We evaluated patients postoperatively at 6 weeks, 3 months, 6 months, 1 year, and annually thereafter. All patients were followed for a minimum of 2 years with an average follow-up of 37.8 ± 8.9 months (range, 24-71 months) for the APT components and 37.4 ± 9.2 months (range, 24-60 months) for the MBT components.

To eliminate any confounding influences, a matched-pair analysis was done. A total of 48 matched pairs (96 knees) were available with the matching done for age within 5 years, weight within 20 lb., gender, diagnosis of osteoarthritis, Knee Society activity grade [17], preoperative deformity of varus or valgus within 5° , type of tibial component being either cruciate retaining or posterior stabilized, thickness of tibial component, and duration of follow-up being a minimum of 2 years and within 12 months (Table 1).

The articulating surface geometry of the Apollo tibial component mates with the femoral design in coronal and sagittal planes. In both planes, the condylar articulating surfaces have a full radius of curvature that provides natural conformity and stability. The center of rotation on the tibia is 3 mm

Table 1. Demographics

Parameter	All-Polyethylene Tibial Component	Metal-Backed Tibial Component	P Value
n	48	48	1.000
Age (y)*	70.3 \pm 9.4 (41-83)	70.7 \pm 9.6 (45-87)	.396
Weight (lb.)*	177.5 \pm 31.2 (130-245)	177.6 \pm 32.9 (108-268)	.987
Male/female	20/28	20/28	1.000
Diagnosis	Osteoarthritis (all cases)	Osteoarthritis (all cases)	1.000
Knee Society activity grade			1.000
A	13	13	
B	26	26	
C	9	9	
Preoperative anatomic axis*	0.1 \pm 7.7 varus (13 varus-26 valgus)	0.2 \pm 7.3 varus (10 varus-22 valgus)	0.862
Tibial component			1.000
CR	22	22	
PS	26	26	
Tibial component thickness			1.000
9 mm	32	32	
11 mm	14	14	
13 mm	2	2	
Duration of follow-up (mo)*	38.4 \pm 7.9 (24.6-69.1)	38.4 \pm 7.8 (24.0-60.0)	0.999

*Mean \pm SD (range).

CR, cruciate retaining; PS, posterior stabilized.

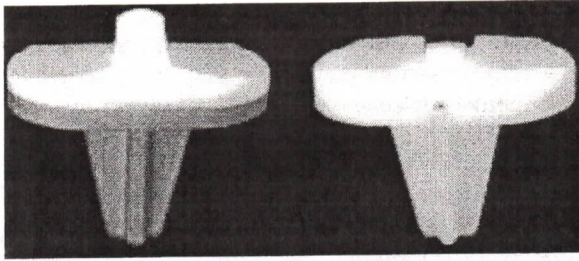


Fig. 1. Frontal view of the Apollo Knee (Sulzer Medica Orthopedics, Austin, TX) femoral and tibial components. The Apollo metal-backed, posterior-stabilized tibial component (left) and all-polyethylene, cruciate-retaining tibial components (right) are shown to illustrate both designs used and the type of metal reinforcement used.

posterior to the sagittal midline, which helps prevent anterior slide and promote flexion [18]. The tibial metal baseplate is a nonporous, cast cobalt-chrome symmetric tray designed for use with cement fixation (Fig. 1). Only 1 baseplate design is used with either the cruciate-retaining or posterior-stabilized polyethylene insert to provide the total component thickness of 9, 11, 13, 16, or 19 mm. The minimum polyethylene thickness on the 9-mm insert is 6 mm under the condyles, which has been determined to be the minimum safe thickness regarding wear and ultimate yield strength of polyethylene [19–23]. The polyethylene insert of the Apollo Knee System was fabricated by the method of RAM extrusion and machining 4150HP resins (Hoechst/Celanese, TX) into the final geometry of the device. The components were sterilized by gamma irradiation in an air environment and packaged in nitrogen. This packaging method prevents oxidation during shelf storage. The single, cruciform-shaped tibial stem in the APT and MBT components is positioned 3 mm anterior to the anteroposterior midline of the component. This position conforms to the intramedullary canal, which allows a 7° posterior tilted position of the component at the surgery. The Apollo femoral component is made of cast cobalt-chrome. The posterior-stabilized femoral component is identical to the cruciate-retaining component with regard to symmetry, patellofemoral groove, and condylar geometry. Only an all-polyethylene patellar component was available for use in the Apollo Knee System.

The surgical technique used was reported previously [24]. Exposure was accomplished through a midline skin incision, and the approach to the knee joint was made through a medial parapatellar incision. All components were fixed using a simultaneous cementing technique [24]. Two packages of

Simplex cement (Howmedica, Rutherford, NJ) were used; these were warmed in the autoclave before use to reduce the final setting time to 10 minutes. Two minutes after mixing, the patellar component was cemented; at 3 minutes, the tibial component was cemented; and at 5 minutes, the femoral component was cemented. After removal of excess cement from around the components, the knee was held in extension while the cement polymerized. The only exception for these sequences was to cement the femoral component before the tibial component when using an APT posterior-stabilized knee. Nineteen of 48 APT knees and 23 of 48 MBT knees required a lateral retinacular release ($P=.144$). The rate of release was a consequence of the philosophy that the lateral release would improve range of motion and reduce anterior knee pain. Currently, lateral release is done in approximately 20% of knees, and the decision to do a lateral release is not made until the tourniquet has been deflated. The lateral release was performed as an oblique release from the anterolateral edge of the tibia to the superior pole of the patella, which preserved the lateral superior geniculate artery.

Clinical evaluation was performed using the Knee Society rating system [17]. Function of the patient was scored on a 100-point system that grades walking distance and stair-climbing ability, and function of the knee was scored on a 100-point system that grades pain, stability, and range of motion. Patients were asked to assess the knee operation by rating the improvement of knee pain, resumption of activities, and level of satisfaction with the operative results, graded as *excellent*, *very good*, *good*, *fair*, or *poor* (modified SF-36 Orthographics, Salt Lake City, UT).

Radiographs were measured by using the Knee Society radiographic evaluation as a guideline [25]. The anteroposterior view was obtained of both knees on a 35-cm × 43-cm film with the patient standing. The lateral view of the knee was obtained with the knee in 60° of flexion and the patient lying on the affected limb. The skyline view of the patella was obtained with the patient supine at neutral femoral rotation and the knee flexed to 45°. Measurements included knee and prosthetic alignment, degree of proximal tibial bone resection [26], and fixation as measured by radiolucent lines at the prosthetic–bone interface. Progression of radiolucent lines was defined as an increase in length or width (or both) of ≥ 1 mm on sequential radiographs. The change in knee and prosthetic alignment was considered significant when it was $>3^\circ$ [27]. Joint line elevation and patellar component height above the joint line were determined on

lateral radiographs by the method described by Apel et al [26]. The skyline views of the patella were measured for tilt or displacement [28].

Preoperative and the most recent follow-up comparison of clinical and radiographic results of 48 matched pairs was done. Statistical analysis was performed on SPSS statistical software (SPSS Inc, Chicago, IL). Continuous variables, including age, weight, duration of follow-up, patient and knee functional scores, range of motion, and radiographic alignment, were compared using the paired samples Student's *t*-test. The measurements, including patient self-assessment and the presence of radiolucent lines, were compared using the Wilcoxon signed rank test. The minimum level of significance accepted was $P < .05$.

Results

Complete clinical and radiographic assessments were obtained for all 48 matched pairs (Table 2). Preoperatively, although patients were matched for activity grades, there was a significantly lower patient function and stair score in patients who received MBT knees. Patients who received APT knees were not those who had less demand on their knee.

The presence of a flexion contracture and the total arc of motion were not significantly different between the 2 groups preoperatively or at last follow-up. The mean preoperative extension was $5.7^\circ \pm 6.6^\circ$ for APT knees and $9.0^\circ \pm 9.7^\circ$ for MBT knees ($P = .088$). The mean preoperative flexion was $110.3^\circ \pm 9.3^\circ$ for APT knees and $107.9^\circ \pm 11.7^\circ$ for MBT knees ($P = .280$). The mean extension at the last follow-up was $0.2^\circ \pm 1.5^\circ$ for APT knees and $1.2^\circ \pm 3.1^\circ$ for MBT knees ($P = .088$); the mean flexion for APT knees was $120.5^\circ \pm 8.0^\circ$ and for MBT knees was $118.3^\circ \pm 10.4^\circ$ ($P = .300$).

Patient self-assessment was completed by all 48 matched-pairs patients. Of patients APT knees, 47 experienced significant pain improvement. One pa-

tient with an APT knee thought the pain became a little worse than before surgery; this patient had an ipsilateral osteoarthritic hip that gave referred pain. Of patients with MBT knees, 46 experienced significant pain improvement, and 2 graded their results as having some improvement. Statistically, no difference was found between APT and MBT knees in pain improvement ($P = 1.000$).

There was no difference in the ability to resume activities after surgery ($P = .129$). Twenty-nine APT knees and 36 MBT knees could markedly resume usual activities after surgery; 16 APT knees and 10 MBT knees could moderately resume usual activities; 2 APT and 2 MBT knees could somewhat resume activities. One patient with an APT knee with an ipsilateral osteoarthritic hip resumed activities only a little.

No statistical difference was found for the patients' grading of their results ($P = .186$). Patients with APT knees rated the operative results as excellent in 29 knees, very good in 17, good in 1, and fair in 1. The knee with a fair result belonged to the patient with the ipsilateral osteoarthritic hip. Patients with MBT knees rated excellent in 38 knees, very good in 7, good in 2, and fair in 1. The patient who rated the result as fair had little pain improvement and stated that activity was only somewhat resumed. This patient's radiographs were unremarkable at the last follow-up.

Table 3 shows the reliability of patient self-assessment when compared with physician assessment using the Knee Society scoring system. Patients who rated their result excellent achieved the best mean patient function and knee function scores. Although patients with fair results had a slightly better mean patient function score than patients with good results, this was because the population sample had only 3 knees with good results and 2 with fair results.

The APT and MBT groups were comparable radiographically for preoperative and last follow-up measurements. Preoperative measurements, in-

Table 2. Clinical Comparison

Last Follow-Up Score	n	All-Polyethylene Tibial Component	n	Metal-Backed Tibial Component	P Value
Patient function score	48	86.9 \pm 12.2	48	88.3 \pm 15.4	0.674
Walking score	48	44.7 \pm 7.6	48	44.5 \pm 9.5	0.954
Stair score	48	42.7 \pm 6.9	48	44.3 \pm 7.0	0.342
Knee function score	48	94.0 \pm 6.9	48	95.2 \pm 5.0	0.316
Pain score	48	46.6 \pm 2.8	48	47.2 \pm 4.7	0.506

NOTE. Values are mean \pm SD.

Table 3. Comparison of Physician and Patient Self-Assessment

Patient Satisfaction	No. Knees	Patient Function Scores	Knee Function Scores
Excellent	67	91.5 ± 12.7	96.6 ± 3.2
Very good	24	81.7 ± 11.7	91.7 ± 8.1
Good	3	73.3 ± 23.1	86.7 ± 10.4
Fair	2	77.5 ± 17.7	85.0 ± 7.1

NOTE. Values are mean ± SD.

cluding the anatomic knee axis, tibial bone defect, and patellar tilt and displacement, did not differ. The average amount of proximal tibial resection was 8.9 ± 3.1 mm in APT knees and 8.2 ± 3.1 mm in MBT knees ($P=.426$). The average joint line elevation after surgery was 3.6 ± 3.7 mm in the APT knees and 3.6 ± 3.4 mm in the MBT knees ($P=.966$). At the most recent follow-up, the average anatomic axis was $6.4^\circ \pm 2.6^\circ$ valgus for APT knees and $5.6^\circ \pm 2.7^\circ$ valgus for MBT knees ($P=.190$). The average tibial component position was $0.2^\circ \pm 1.8^\circ$ varus and $7.0^\circ \pm 3.0^\circ$ posterior tilt in the APT knees and $1.0^\circ \pm 2.1^\circ$ varus and $6.7^\circ \pm 2.6^\circ$ posterior tilt in the MBT knees ($P=.059$,

and $P=.570$). Patellar height averaged 25.9 ± 8.4 mm in the APT knees and 27.0 ± 6.4 mm in the MBT knees ($P=.585$). No significant differences were found for component alignment, patellar tilt, and displacement on the last follow-up radiographs.

Radiolucent lines (1 mm) at the tibial bone-cement interface were seen in 4 APT knees and 1 MBT knee ($P=.180$). All of the radiolucent lines were not progressive and located only on the medial plateau (Knee Society zone 1 and 2 in anteroposterior films) except for 1 APT knee, in which the radiolucent lines were seen on medial and lateral plateaus (zones 1–4, Fig. 2). No reason could be defined for radiolucent lines in these knees. There were no radiolucent lines around the femoral and patellar components, and no cement fracture or component subsidence was measured.

Complications included 1 prepatellar bursa infection 5 years after surgery, which required incision and drainage without component removal. One knee required lateral retinacular release 9 months postoperatively to correct patellar subluxation. Both complications were treated successfully. No components required revision, and no revisions were pending at the time of the latest follow-up.

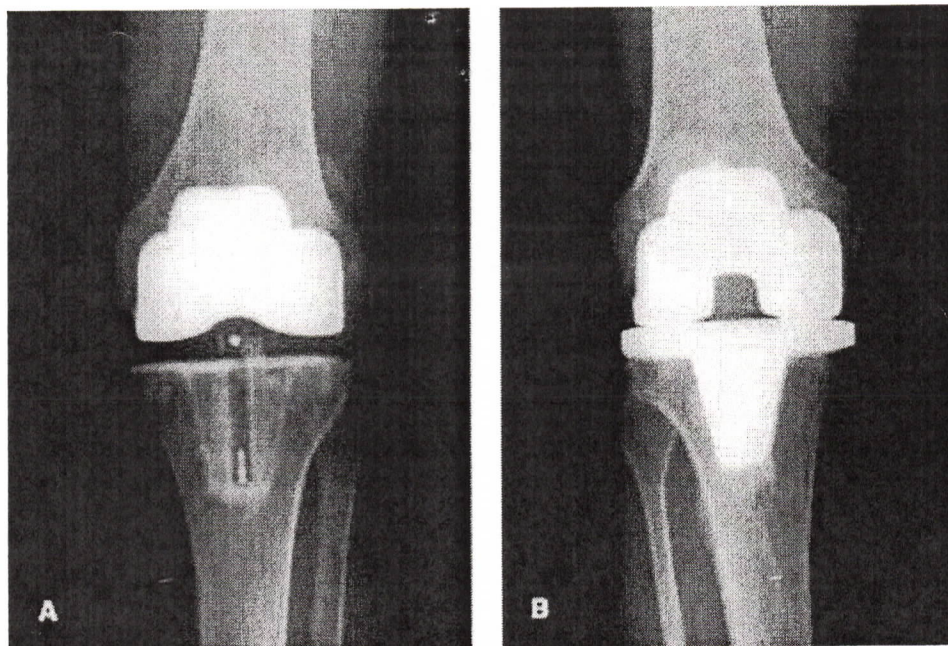


Fig. 2. (A) Anteroposterior radiograph of the knee implanted with an all-polyethylene, cruciate-retaining tibial component at the 5-year follow-up. A radiolucent line of 1 mm is visible on the medial plateau (zones 1 and 2). (B) Anteroposterior radiograph of the knee implanted with a metal-backed, posterior-stabilized tibial component at the 5-year follow-up. A radiolucent line of 1 mm is visible on the medial plateau (zones 1 and 2).

Discussion

This study failed to find any statistically significant differences between osteoarthritic knees implanted with the Apollo APT and MBT components for knee scores, patient self-assessment, and radiographic results at an average 3 years after surgery. No sign of mechanical failure was detected in any knee. Thin radiolucent lines of 1 mm about the tibial component in this study were of no clinical significance and were not a sign of imminent loosening [29–31]. According to Vince et al [32] and Lee et al [33], these radiographic results at 3 years could be projected to 10 years, and although these published results were with the cruciate-sacrificing Total Condylar design (Howmedica, Rutherford, NJ), the Apollo was designed with similar round-on-round geometry, which is encouraging for the possibility of longevity. These results confirm previously reported results with APT components. Rand and Ilstrup [34] reported comparable 5-year survivorship between APT and MBT components in TKA for rheumatoid arthritis. Ten- to 20-year results have found 91% to 98% survivorship of the APT component for the Total Condylar prosthesis and its derivatives [14–16,35–38].

Literature results seem convincing that with proper implant selection and surgical technique, APT components yield a result as good as MBT components for primary TKAs. Proper surgical technique includes the level of the tibial cut and avoidance of varus alignment. Dorr et al [39] and Gill et al [37] found that too much proximal resection could influence the deformation in the APT component. Tibial resection of ≤ 1 cm is a surgical technical factor that prevents deformation of APT components, which was a cause of failure of these implants [40–43]. Although the MBT component first was developed to offer a stronger baseplate to prevent polyethylene deformation, several authors found that thin polyethylene was still a cause of failure that a metal tray did not prevent [20,44–46]. Aglietti et al [47] and Colizza et al [48] reported that the MBT component reduced the incidence of tibial loosening in the Insall-Burstein posterior-stabilized prostheses. The failure of APT components was related to varus knee alignment, however, and these authors agree with Ritter et al [49] that varus alignment had a higher rate of loosening.

The best implant design for APT components has round-on-round articulation surfaces. Bartel et al [2] found with finite element analysis that compressive stresses on the cancellous bone were in-

creased substantially when the load was applied to a single plateau. The stresses were greatest when extreme edge loading occurred, which was seen when varus-valgus tilt occurred in implants with flat contours in the coronal plane. Ritter et al [50] reported a 1-year revision rate of 3% with APT components when using a flat-on-flat nonconforming tibial component. In flat-on-flat designs, an MBT component better reduces the compressive stresses. Bartel et al [2] reported that when loading on the 2 plateaus was distributed more equally, the stresses in the cancellous bone under either the APT or the MBT component were nearly the same. Surgical technique is mostly responsible for reduction of lift-off because this can occur with any design [51], but round-on-round designs help in minimizing lift-off and edge loading [46,52]. The success of round-on-round APT components performed by good surgeons has resulted in survivorship without revision of 91% to 98% at 10 to 20 years [14–16,35–38].

Modularity has versatility for the surgeon during the operation and can allow exchange of the polyethylene insert if excessive wear or osteolysis become evident. Modularity has increased the reoperation rate of TKA, however, by permitting undersurface wear with increased osteolysis [9,10] and polyethylene dissociation [53]. Parks et al [9] found that all modular knee implants have motion at the modular interface of the tibial component. Clinical results have deteriorated with the use of modularity. The prevalence of revision for reasons other than infection with the monoblock, metal-backed Insall-Burstein tibial component was 0.11% at 7 years [16], whereas with the modular insert it was 4.26% at 10 years [54]. Survivorship of the monoblock tibial Insall-Burstein TKA was 98.8% at 7 years and with the modular Insall-Burstein was 92.3% at 10 years [16,54]. Ritter et al [55] reported a 98% survivorship of the monoblock AGC TKA (Biomet, Warsaw, IN) at 10 years. Schai et al [7] reported much lower survivorship of 90% at 10 years with the modular PFC TKA (Johnson & Johnson, Raynham, MA). Overall, the survivorship of these modular implants is not better than the 91% to 98% survival rate reported for APT components at 10 to 20 years [14–16,35–38].

Conclusion

Current modular MBT components are not superior to APT components for bone preservation or revision rates. No differences could be found or predicted in this study of the same design with

round-on-round surfaces and of the same surgical technique by the same surgeon. The stresses in the prosthesis and bone are controlled almost completely by surgical technique, provided that the design materials are satisfactory [56,57]. Although metal backing is 1 factor that could reduce the compressive stresses in the cancellous bone, it does not seem to be crucial for a primary TKA. Until modularity of tibial components is proved to be secure, we suggest the use of APT components in patients >70 years old, which provides them with the best predictable results for no further surgery. The use of modular inserts in elderly patients may require the patients to have additional surgery for wear and osteolysis. In this patient population, the use of APT components also provides a 30% cost savings [58]. In patients <70 years old, the advantage of exchanging only the tibial insert if wear and osteolysis occurs is the paramount reason to use modularity in these patients.

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