Should we reconsider all-polyethylene tibial implants in total knee replacement?

S. D. Muller,
D. J. Deehan,
J. P. Holland,
S. E. Outterside,
L. M. G. Kirk,
P. J. Gregg,
A. W. McCaskie

*From the Freeman
Hospital, Newcastle
upon Tyne, England*

The role of modular tibial implants in total knee replacement is not fully defined. We performed a prospective randomised controlled clinical trial using radiostereophotogrammetric analysis to compare the performance of an all-polyethylene tibia with a metal-backed cruciate-retaining condylar design, PFC-Σ total knee replacement for up to 24 months. There were 51 patients who were randomised into two treatment groups. There were 10 subsequent withdrawals, leaving 21 all-polyethylene and 20 metal-backed tibial implants. No patient was lost to follow-up. There were no significant demographic differences between the groups. At two years one metal-backed implant showed migration > 1 mm, but no polyethylene implant reached this level. There was a significant increase in the SF-12 and Oxford knee scores after operation in both groups.

In an uncomplicated primary total knee replacement the all-polyethylene PFC-Σ tibial prosthesis showed no statistical difference in migration from that of the metal-backed counterpart. There was no difference in the clinical results as assessed by the SF-12, the Oxford knee score, alignment or range of movement at 24 months, although these assessment measures were not statistically powered in this study.

■ S. D. Muller, MD, FRCS(Tr & Orth), Specialist Registrar
■ D. J. Deehan, MD, FRCS(Tr & Orth), Consultant Orthopaedic Surgeon
■ J. P. Holland, FRCS(Tr & Orth), Consultant Orthopaedic Surgeon
■ S. E. Outterside, MCSP, Research Physiotherapist
■ L. M. G. Kirk, MCSP, Senior Research Physiotherapist
■ A. W. McCaskie, MD, FRCS(Tr & Orth), Professor of Orthopaedics
Department of Orthopaedics
Freeman Hospital, Freeman Road, High Heaton, Newcastle upon Tyne NE7 7DN, UK.

■ P. J. Gregg, MD, FRCS, Professor of Orthopaedics
James Cook University Hospital, Marton Road, Middlesbrough TS4 3BW, UK.

Correspondence should be sent to Mr S. D. Muller; e-mail: s.d.muller@ncl.ac.uk

©2006 British Editorial Society of Bone and Joint Surgery
doi:10.1302/0301-620X.88B12.17695 \$2.00

J Bone Joint Surg [Br]
2006;88-B:1596-602.
Received 26 January 2006;
Accepted after revision 15 June 2006

Uncertainty still exists concerning the optimal design of the tibial component in total knee replacement (TKR). Metal-backed modular tibial prostheses are most commonly used, with survival data demonstrating satisfactory long-term performance.¹ The advantages of modular metal-backed designs are well described and are outlined in Table I. However, problems with their use continue to emerge. Backside wear at the metal-polyethylene interface, dissociation of the tray and liner and macroscopic failure of thin polyethylene liners are major disadvantages.²⁻⁶ These complications can be avoided by elimination of the polyethylene-metal interface by using a non-modular monoblock all-polyethylene implant.

An inferior clinical performance of non-modular all-polyethylene tibial implants has been described in studies based on either posterior stabilised or non-conforming flat-on-flat designs.^{1,7,8} Irregularity in the dissipation of stresses in the absence of a metal tray may have contributed to the early failure of all-polyethylene designs.⁹ More recently, a randomised controlled clinical trial found equivalent performance of stemmed metal-backed and non-stemmed all-polyethylene Freeman-Samuelson (Sulzer Orthopaedics AG, Baar,

Switzerland) flat-on-flat tibial prostheses when assessed by radiostereophotogrammetric analysis (RSA).¹⁰ A similar clinical performance has also been noted in several randomised clinical trials.^{10,11}

RSA is accepted as the optimum method for the evaluation of micromovement of a prosthesis with a resolution of 0.1 mm. It is well suited to the knee, as orthogonal radiographic analysis is easy in a limb, it is well tolerated by the patient and has low exposure to radiation. It has been shown to be a reliable and reproducible predictor of implant failure. Progressive migration of an implant of > 1 mm at two years, as detected by RSA motion analysis, is known to be associated with early loosening and subsequent clinical failure.¹²

We carried out a prospective randomised controlled clinical trial to evaluate and compare the performance of the cruciate-retaining condylar PFC-Σ (Depuy, Johnson & Johnson, Leeds, United Kingdom) all-polyethylene, and metal-backed, tibial components of identical design, using RSA. We also assessed the clinical results. To our knowledge no such study has been performed using such an implant relevant to contemporary United Kingdom practice.

Table I. Advantages and disadvantages of all-polyethylene and metal-backed tibial prostheses

	All-polyethylene	Metal-backed
Advantages	No backside wear No liner dissociation Increased polyethylene thickness/more conservative bone resection Lower unit cost	Excellent long-term clinical results Liner selection after tray insertion Compatible with mobile bearing total knee replacement Addition of augments/additional fixation Allows for cementless fixation Possible improved stress distribution to bone Possibility for liner exchange Possible smaller inventory
Disadvantages	Non-modular Possible difficulty retrieving posteriorly extruded cement Few long-term clinical results	Liner dissociation/dislocation Backside wear Increased osteolysis Reduced polyethylene thickness Increased bone resection to accommodate adequate polyethylene thickness

Fig. 1

Location of 1 mm tantalum marker beads within the prosthesis, antero-posterior and lateral projections. Modular metal-backed (top); monoblock all-polyethylene (bottom).

Materials and Methods

All patients who were seen by four consultant surgeons (DJD, JPH, PJG, AWM) and offered a primary TKR were considered eligible for the study. The inclusion criteria were a primary diagnosis of osteoarthritis or rheumatoid arthritis, and an age of 65 years or over. Exclusion criteria were previous surgery to the knee (excluding arthroscopy or meniscectomy), a renal transplant, Paget's disease, meta-

bolic bone disease, a contralateral knee in the study, a history of joint sepsis, recent high-dose steroid use, psychosocial or physical disability limiting rehabilitation, and bone deficiencies requiring augmentation. All patients were given written information and counselled by both the operating surgeon and the research physiotherapists overseeing the study (LMGK, SEO). Written consent was obtained for inclusion in the study, and patients were free to withdraw at any time. Patients who had been enrolled were withdrawn from the study if exclusion criteria, such as undiagnosed renal disease detected on pre-operative investigation, or bone deficiencies detected intra-operatively, came to light later. Randomisation to each group took place in theatre immediately before insertion of the prosthesis by means of sealed envelope block randomisation employing blocks of eight. Approval was obtained from the local ethical committee.

All prostheses had 1 mm tantalum markers inserted in a standard configuration after manufacture before packaging and sterilisation (Fig. 1). The standard PFC- Σ modular metal tray had five markers and the polyethylene inserts four. The all-polyethylene components were a non-modular single piece of identical external dimensions, articular geometry and type of polyethylene as the metal-backed components. They contained nine tantalum markers in the same configuration as the metal-backed prostheses. Seven to nine tantalum marker beads of 1 mm diameter were inserted into the proximal tibial metaphyseal bone using a standardised technique before insertion of the prosthesis.

The operation was through a longitudinal midline incision with a medial parapatellar arthrotomy. The bone was prepared according to the manufacturer's instructions, the cement was applied to dry clean bone, and the wound closed in a standard fashion. All patients received a formal schedule of post-operative rehabilitation.

After operation all patients had anteroposterior, lateral and skyline radiographs when they were able to bear weight on the affected knee.

Fig. 2

A flowchart of our patients using the CONSORT guidelines.²¹

RSA assessment was undertaken at zero, three, six, 12 and 24 months using RSA cage number 10 (UmRSA Bio-medical Innovations, Umea, Sweden) with standard over-penetrated biplanar simultaneous radiological exposures. These films were digitally transformed using a Umax Powerlook flat bed scanner (Umax Technologies Inc., Dallas, Texas) at 300 dpi resolution, and the Digital Imaging and Communications in Medicine (DICOM) images (National Electrical Manufacturers Association, Rosslyn, Virginia) were stored uncompressed. Subsequent UmRSA analysis assessed segment movement. The patient markers represented the reference segment and the initial post-operative examination was the reference examination. An effort was made to ensure that each patient had usable RSA

images for the crucial reference and 24-month examinations; it was occasionally necessary to recall a patient for a repeat examination.

The UmRSA system calculates the three-dimensional coordinates of each marker in relation to its location within the external calibrated cage. The collection of markers assigned to each segment constitutes a three-dimensional polygon whose shape should remain constant throughout follow-up. Migration of any bead by more than 300 μ m implies loosening and resulted in its exclusion from the analysis. The position of the motion segment (the prosthesis) relative to the reference segment (the tibial bone markers) was calculated between examinations. The translation and rotation of the segment in six degrees of freedom was

Fig. 3

Median and 95% confidence interval x plane translation at two years (medial/lateral). Mann-Whitney test: $p = 0.98$.

Fig. 4

Median and 95% confidence interval y plane translation at two years (proximal/distal). Mann-Whitney test: $p = 0.49$.

determined at each examination. The internal validity of the RSA methods was checked by assessing the calculated relative movement of the beads within the metal stem which were known not to move. This was found to be less than 0.1 mm.

Our previous RSA experience with knee implants suggested a standard deviation of 0.35 mm could be expected. A sample size of 30 per group would be required to detect a 0.2 mm difference in migration at 24 months, with an alpha value of 0.05 and power set at 80%.

Statistical analysis was performed using SPSS v. 12.0, (Apache Software Foundation, Chicago, Illinois). Descriptive statistics were employed for group demographic data.

Non-parametric tests were chosen to analyse all numerical data, as normality could not be assumed or proved with small numbers.

Further plain radiological assessment was performed at six, 12 and 24 months and each was analysed according to the Knee Society scoring system¹³ to assess the alignment of the prosthesis.

All patients were assessed clinically using the Oxford knee score and the Short Form (SF)-12.^{14,15} The active and passive ranges of movement were measured before and after operation and at six, 12 and 24 months. All data were stored using a Medlog database (Medlog Systems, Crystal Bay, Nevada).

Results

There were 51 patients enrolled in the study. Figure 2 shows the patient flow according to the CONSORT^{16,17} guidelines.

There were no differences between the all-polyethylene and the metal-backed groups of patients in age (mean 74 years (66 to 89) and 73 years (65 to 82), respectively; Mann-Whitney, $p = 0.424$), gender ratio male:female (9:12 and 11:9 respectively; binomial test $p = 0.82$) or side of operation right:left (13:8 and 9:11, respectively; binomial test $p = 0.5$). There were three patients with rheumatoid arthritis in the metal-backed group, but none in the all-polyethylene group.

RSA outcome. All 21 patients receiving an all-polyethylene tibial prosthesis were suitable for RSA assessment, as all the prosthesis marker beads were visible in both radiological projections. Of the 20 patients in the metal-backed group, only 19 had usable RSA images both in the reference examination and at 24 months, owing to difficulty in identifying sufficient implant markers in both projections in one knee. This left 21 all-polyethylene and 19 metal-backed implants in the study.

There was no significant difference in the translation in the x, y and z planes (Figs 3 to 5 and Table II) at 24 months between the two groups, as analysed using the Mann-Whitney test, and no difference in rotational displacement between the groups at 24 months. By convention, positive translation in the x plane represents medial migration, in the y plane proximal migration (or lift-off), and in the z plane posterior migration. Therefore, negative translation in the y plane represents subsidence of the prosthesis.

Clinical outcomes. The median SF-12 score for the entire study population increased from a pre-operative value of 27 (± 2.2 SEM) to 35.5 (± 1.8 SEM) by six months ($p < 0.001$, Wilcoxon signed rank test). There was no significant difference between the SF-12 scores for the all-polyethylene group compared with the metal-backed group for the pre-operative, six-, 12-, or 24-month assessments (Fig. 6).

The median Oxford knee score for all the patients pre-operatively was 15 (± 1.2 SEM) increasing to 33 (± 1.1 SEM) at six months ($p < 0.001$, Wilcoxon signed rank test). There

Fig. 5

Median and 95% confidence interval z translation at two years (anterior/posterior). Mann-Whitney test: $p = 0.47$.

Fig. 7

Oxford knee score plus standard error of mean bars.

Fig. 6

Short-Form-12 scores plus standard error of mean bars.

was no difference between the two groups at six, 12 and 24 months (Fig. 7).

The median active range of movement did not change significantly before or after operation, with 104° before

($\pm 6.2^\circ$ SEM) and 101° ($\pm 5.9^\circ$ SEM) after six months ($p = 0.63$, Wilcoxon signed rank test).

There was no significant difference between the two groups at any of the assessments (Mann-Whitney test).

The median varus-valgus tibial alignment after operation as assessed on anteroposterior weight-bearing radiographs measured 88° ($\pm 1.5^\circ$ SEM). There was no significant difference between the two groups at six, 12 or 24 months ($p = 0.99$, Mann-Whitney test).

Discussion

No difference between the all-polyethylene and the metal-backed tibial prostheses was identified using RSA in the first two years after implantation. There were also no differences in the SF-12 and Oxford knee scores, nor in range of movement and alignment, although the power of the study did not allow these conclusions to be of statistical significance. RSA is an extremely sensitive instrument to predict mechanical failure from early migration, but it cannot predict late biological failure of implants that initially were soundly fixed. However, it remains the most sensitive instrument for predicting progressive mechanical failure.

Our study had a large number of exclusions (41) (Fig. 2), mostly because of the initial exclusion criteria (25). Five patients had medical comorbidities which were discovered on pre-operative assessment. Unexpected defects of bone which violated the trial protocol were discovered in five

Table II. Radiostereophotogrammetric analysis of median migration plus 95% confidence intervals (95% CI)

	Median (mm)	95% CI	Mann-Whitney p-value
x plane			
All-polyethylene	0.014	-0.254 to 0.229	0.98
Metal-backed	0.022	-1.396 to 0.422	
y plane			
All-polyethylene	-0.025	-0.287 to 0.368	0.49
Metal-backed	-0.065	-0.324 to 0.216	
z plane			
All-polyethylene	0.002	-0.117 to 0.143	0.47
Metal-backed	0.04	-0.757 to 0.156	

patients at operation. Failure of the gun for insertion of tantalum markers accounted for two withdrawals. Four patients refused consent to participate.

The introduction of tantalum markers into implants is expensive and time-consuming. A full range of implants was manufactured according to the numbers and sizes predicted before the study, but because of manufacturing costs, these implants were not restocked once used. In four polyethylene and six metal-backed components, this resulted in the required implants not being available, thus requiring insertion of a non-trial implant and withdrawal from the study.

We were concerned that the number of withdrawals relative to the initial power calculation might have underpowered the study. Our experience with RSA and knee arthroplasty suggested a two-year migration standard deviation of 0.35 mm, on which we based our initial power calculation. The observed standard deviation of migration in our data was 0.2 mm, thereby making the provisional power calculation an overestimate of the sample size required to detect a mean migration difference of 0.2 mm between the groups. A retrospective power calculation employing the actual standard deviation and the actual numbers enrolled in the study revealed the study to have a power of 86% ($\alpha = 0.05$). We therefore believe that the study was adequately powered to detect the stated difference of 0.2 mm with the groups of 21 and 19 patients.

Three patients with rheumatoid arthritis were randomised to the metal-backed group. These patients had similar SF-12 and Oxford knee scores as the osteoarthritic patients. Porotic bone found in rheumatoid arthritis may predispose to loosening of beads or migration of the implant. This was not borne out in the RSA analysis and none of the outliers identified in the scatter plots were rheumatoid arthritic patients.

We do not include the data for three, six and 12 months, because the most important examination in predicting loosening is at two years.¹²

No patients in the all-polyethylene group demonstrated migration of > 1 mm in any direction, whereas one metal-

backed implant demonstrated translation of the *x* plane of 1.3 mm.

The median subsidence at 24 months of -0.065 mm (95% CI -0.324 to 0.216 mm, Table II) and the range of migration observed is less than the median subsidence of 0.5 mm and range as recorded by Adalberth et al.^{10,18} This may reflect differences in the design of the prosthesis.

Using a prospective, randomised, controlled clinical trial, we have demonstrated no statistical difference in the RSA performance of all-polyethylene and metal-backed tibial prostheses. The advantages of modularity remain controversial. The potential for exchange of liners has been proposed as an advantage of modular tibial implants. However, isolated revision of tibial implants with well-fixed femoral components is associated with accelerated polyethylene wear and early failure.¹⁹ Micro-movement at the linear tray interface is known to liberate polyethylene debris, despite the apparent security of the mechanism for capture of the liner.⁷ The size of the liberated debris is within the biologically active range with respect to macrophage stimulation,⁶ which might account for the increased osteolysis seen after the introduction of modularity.

The optimal thickness of the polyethylene is not fully defined. It is generally accepted that a minimum thickness of 6 mm to 8 mm is required to avoid excessive peak stresses within the liner. The metal tray requires 2 mm to 3 mm of space, and unless the liner is reduced in thickness, risking failure or wear-through to metal-on-metal wear,²⁰ increased bone resection is required to accommodate it. Backside wear, liner dissociation, reduced polyethylene thickness or excessive bone resection can be avoided by using all-polyethylene implants. These non-modular prostheses are perhaps technically more difficult to implant and do not offer the intra-operative flexibility of metal-backed implants. However, in the uncomplicated primary case we believe that there are significant clinical and economic benefits in avoiding modularity.

The second Annual National Joint Registry Report²¹ for 2004 recorded 42 791 primary TKR procedures carried out in England and Wales (60% of the total performed in that year). Of these, only 248 were all-polyethylene. If 50% of the approximately 70 000 primary TKRs undertaken each year had been suitable for an all-polyethylene tibial implant there would have been a significant saving in cost. The list price unit cost for a metal-backed modular implant is £1139, and that of the all-polyethylene equivalent is £541, representing a potential net saving of £21 million per annum across England and Wales.

In the face of mounting RSA, clinical and economic evidence, is it time to reconsider the role of all-polyethylene tibial implants?

The authors wish to acknowledge the assistance of Mr A. Cleghorn, Superintendent Radiographer, and his colleagues, Department of Radiology, Freeman Hospital.

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