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All-polyethylene tibia components have the same functional outcomes and survival, and are more cost-effective than metal-backed components in patients 70 years and older undergoing total knee arthroplasty

PROPENSITY MATCH STUDY WITH A MINIMUM FIVE-YEAR FOLLOW-UP

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Aims

The tibial component of total knee arthroplasty can either be an all-polyethylene (AP) implant or a metal-backed (MB) implant. This study aims to compare the five-year functional outcomes of AP tibial components to MB components in patients aged over 70 years. Secondary aims are to compare quality of life, implant survivorship, and cost-effectiveness.

Methods

A group of 130 patients who had received an AP tibial component were matched for demographic factors of age, BMI, American Society of Anesthesiologists (ASA) grade, sex, and preoperative Knee Society Score (KSS) to create a comparison group of 130 patients who received a MB tibial component. Functional outcome was assessed prospectively by KSS, quality of life by 12-Item Short-Form Health Survey questionnaire (SF-12), and range of motion (ROM), and implant survivorships were compared. The SF six-dimension (6D) was used to calculate the incremental cost effectiveness ratio (ICER) for AP compared to MB tibial components using quality-adjusted life year methodology.

Results

The AP group had a mean KSS-Knee of 83.4 (standard deviation (SD) 19.2) and the MB group a mean of 84.9 (SD 18.2; p = 0.631), while mean KSS-Function was 75.4 (SD 15.3) and 73.2 (SD 16.2 p = 0.472), respectively. The mental (44.3 vs 45.1; p = 0.464) and physical (44.8 vs 44.9; p = 0.893) dimensions of the SF-12 and ROM (97.9° vs 99.7°; p = 0.444) were not different between the groups. Implant survivorship at five years were 99.2% and 97.7% (p = 0.321). The AP group had a greater SF-6D gain of 0.145 compared to the MB group, with an associated cost saving of £406, which resulted in a negative ICER of -£406/0.145 = -£2,800. Therefore, the AP tibial component was dominant, being a more effective and less expensive intervention.

Conclusion

There were no differences in functional outcomes or survivorship at five years between AP and MB tibial components in patients aged 70 years and older, however the AP component was shown to be more cost-effective. In the UK, only 1.4% of all total knee arthroplasties use an AP component; even a modest increase in usage nationally could lead to significant financial savings.

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Introduction

Total knee arthroplasty (TKA) is one of the most common surgical procedures offered in the UK, with around 170,000 performed each year.[1,2] The ideal implant choice should provide reliable survivorship and functional outcomes while being cost-conscious.

Inspired by Charnley's total hip arthroplasty, early designs of the TKA used an all-polyethylene (AP) tibial component to articulate with the metal femoral component, many with excellent clinical results at ten or more years.[3] Some designs, however, were seen to have high failure rates of up to 17% at two years, with deformed AP tibial components observed during revision surgery,[4] and loosening at the implant-tibia interface.[5] Biomechanical studies into new implant designs showed a role for metal backing of the tibial component (MB), with the potential for decreased bending strains in the stem and more effective distribution of eccentric load to the whole underlying tibial surface.[6] Further advantages of metal backing are the ability to incorporate augments for bone loss, potential for porous coating for uncemented use, and increased intraoperative flexibility by changing polyethylene insert size. This may explain why AP tibia components have almost completely been phased out, with only 1.4% of all TKAs performed in the UK using an AP tibial component as reported in the National Joint Registry (NJR) annual report.[7]

MB tibial components do, however, have limitations. They have increased costs to manufacture and supply, and reduced polyethylene thickness with increased bony resection required. They have the potential for backside wear of the tibial tray on the metal base, with increased tensile stresses at the interface during eccentric loading.[8] Polyethylene continues to be used in other orthopaedic operations, leading to advancements in its manufacture to increase resistance to wear.[9] Furthermore, it was found that gamma radiation sterilization in air leads to oxidization and degradation of the surface; this was changed to gas plasma ethyl oxide to avoid the generation of oxygen free radicals and further enhance its durability (cross-linking). Subsequent packaging was also improved to reduce oxidation.[10]

A minority of surgeons have retained interest in AP tibial components, and continued to use them in their practice, producing outcomes comparable and, in some cases, superior to those of MB components.[11] A 2017 systematic review analyzed a total of 68,202 TKAs comparing AP to MB tibial component outcome scores, and found a significant difference in the Knee Society Score functional outcome (KSS-F)[12] in favour of MB component.[13] It has been suggested that, due to their intrinsic material properties, AP components could be more suitable for use in elderly (aged over 70 years) patients who are less active. Previous studies specifically on this issue has shown favourable results with equal functional outcome scores and survival, and significant cost savings.[14] Younger and more active patients may be more suited to MB components as they can afford to have greater bony resection, and may benefit more from improved intraoperative flexability.[15]

This concept has been adopted in the current institution, where surgeons are advised to consider using an AP component in patients aged over 70 years old. The primary aim of this study was to compare the five-year (medium-term) functional outcomes of AP tibial components to a matched cohort of MB tibial components. Secondary outcomes were to assess the health-related quality of life (HRQoL), range of motion (ROM), and implant survivorship between the two different components.

Methods

Patients. A retrospective cohort study was performed to compare the medium-term (five-year) outcomes of the AP tibial components with the MB components. The current institution has prospectively collected data on all patients undergoing total knee arthroplasty since 1995. Patients' age, weight, height, BMI, sex, American Society of Anesthesiologists (ASA) grade,[16] and KSS were recorded during a routine preoperative assessment. Patients were seen in pre-assessment clinic and are followed up at regular intervals of six months, 18 months, three years, and five years, with routine standing anteroposterior and lateral radiographs taken at these points, along with KSS and 12-Item Short-Form Health Survey questionnaire (SF-12) score collected at five years. The unit introduced the AP tibial component in 2009 and introduced this for use in patients over the age of 70 years. The MB component was also available for these patients if the operating surgeon required it intraoperatively. Inclusion criteria were any patient undergoing a routine primary TKA with AP or MB tibial component from 2009 onwards. Exclusion criteria were any MB patient prior to 2009, revision procedures, and complex procedures requiring higher levels of constraint or adjuncts to address bone loss. Formal ethical approval was not required as data were routinely collected for clinical audit purposes. All patients who filled out patient-reported outcome measures (PROMs) consented on the form to their results being used for audit and research purposes. All data were handled in accordance with local confidence and governance policy.

Propensity score matching produced two cohorts of patients with significant differences in age, sex, BMI, ASA grade, and preoperative KSS-K. This is summarized in Table I.

Surgical technique. All surgeries were performed or supervised by consultants. A tourniquet was used routinely. A midline medial parapatellar approach was used in all patients; intramedullary referencing was

Fig. 1
All-polyethylene and metal-backed components.

used for the femoral cuts and extramedullary referencing for the tibia. All patients in the study received either an AP tibial component or PFC Sigma cruciate-retaining TKA (Depuy Orthopaedics, USA) (Figure 1). While the AP component was recommended for patients over 70 years of age, ultimately this was the decision of the operating surgeon. Factors such as experience, familiarity with the AP option, supervision of a trainee, and complexity of the operation influenced this decision, but were not formally recorded. The patella was not routinely resurfaced. All patients received a single preoperative dose of prophylactic antibiotics (ceftriaxone) prior to inflation of tourniquet. Pharmacological thromboprophylaxis (dalteparin pre-2011, rivaroxaban thereafter) and graduated elastic stockings were used. Patients were actively mobilized on day one postoperatively as part of a standardized enhanced recovery protocol.

Functional outcomes. The American Knee Society Score was performed with both the knee-specific component (KSS-K) and general functional component (KSS-F).[17] This involves objective measurement by the assessor and reported global function by the patient. Both scores range from 0 (poor) to 100 (excellent). SF-12 is a general health questionnaire which produces a mental score (MCS-12) and a physical score (PCS-12).[18] Active knee ROM, defined as flexion minus extension, was measured using a goniometer with the patient lying supine.

Cost-effectiveness. A cost utility analysis (CUA) was performed the determine the cost incremental health benefit between AP and MB tibial components between the groups. An incremental cost-effectiveness ratio (ICER), which is the difference in cost between the treatments divided by the gain in HRQoL of the intervention to give a cost per quality-adjusted life year (QALY) gained. The analysis was performed using NHS costs in the UK and calculated in pounds sterling (£/GBP). An ICER of ≤ £20,000 per QALY is supported by the National Institute of Clinical Excellence as a cost-effective intervention.[19] The time horizon for the CUA was five years. The cost difference between the implants was obtained from the company supplying the TKA, which was £650 for the AP tibial implant and £1,056 for the MB tibial implant. The following assumptions were made: all other costs were the same perioperatively, and the complication (other than revision) would be the same for both groups and therefore not included in the CUA. The cost of revision was taken as £9,655 for aseptic and £30,001 for septic revisions.[20] The single preference-based index measure, the Short-Form Six-Dimension Health Survey (SF-6D), was used to calculate a QALY gained. The SF-6D is derived from the SF-12 and assesses six domains (physical functioning, role limitations, social functioning, pain, mental health, and vitality) to produce an index where 1 represents perfect health and 0 represents death.[21]

Statistical analysis. Data were assessed using R-Studio Version 4.0.1 (RStudio: Integrated Development for R, RStudio, USA). Parametric and non-parametric tests were used as appropriate to assess continuous variables for significant differences between groups. An independent-samples *t*-test was used to compare linear variables between groups. A chi-squared test was used to compare categorical variables between the groups. A Wilcoxon signed-rank test was used compare two sets of scores that came from the same patient or any change in scores from one time point to another. A p-value of < 0.05 was defined as significant.

Propensity score matching was used to derive two matched groups for comparison of outcomes. This technique is thought to offer a more accurate matching for case-control comparison, and aims to match patients over a wider range of baseline characteristics. First, a 'propensity score' is calculated, which represents the chances of being in the AP group compared with the MB group. The score is derived from a multivariable binary logistic regression model based on several baseline characteristics. The variables selected for this study were age at operation, sex, ASA grade, and preoperative KSS. The AP group were chosen as the base group and the closest matching control from the MB group was selected as the patients with a comparable propensity score. This yielded a final study population of 130 patients who received an AP tibial component and 130 patients who received a MB tibial component. Only MB patients from the same time period were used in matching (2009 onwards). After propensity score matching, the two groups were similar, with no statistically significant differences in patient demographic data. A ratio of 1:1 was the maximum achievable taking this into account (Table I).

A post-hoc power calculation was performed to the primary outcome measure, the KSS-K, using a minimal clinically important difference of 7.2 and a standard deviation (SD) of 14.2,[22] with an α of 0.05 for those assessed

Table I. Matched patient demographics.

Variable	All-polyethylene (n = 130)	Metal-backed (n = 130)	p-value
Mean age (SD; range)	78.5 (4.4; 55 to 90)	78.0 (6.6; 54 to 90)	0.433
Sex, n (%)			
Male	50 (38.5)	50 (38.5)	N/A
Female	80 (61.5)	80 (61.5)	N/A
Mean BMI, kg/m2 (SD; range)	30.2 (4.9; 20.2 to 45.9)	30.9 (5.0; 21.2 to 40.3)	0.201
ASA grade			
1	4	4	N/A
2	82	82	N/A
3	44	44	N/A
Mean preop KSS-K (SD; range)	39 (17.2; 21 to 57)	37 (17.5; 20 to 45)	0.157

*Wilcoxon signed-rank test.
ASA, American Society of Anesthesiologists; KSS-K, knee-specific Knee Society Score; N/A, not available; SD, standard deviation.

Table II. Five-year postoperative comparison.

Outcome	All-polyethylene (n = 82)	Metal-backed (n = 72)	Difference (95% CI)	p-value
Mean KSS-K (SD)	83.4 (19.2)	84.9 (18.2)	1.5 (-7.6 to 4.6)	0.631*
Mean KSS-F (SD)	75.4 (15.3)	73.2 (16.2)	2.8 (-7.2 to 3.4)	0.475*
Mean SF-12 PCS (SD)	44.8 (6.0)	44.9 (8.1)	0.1 (-1.9 to 1.6)	0.897*
Mean SF-12 MCS (SD)	44.3 (7.1)	45.1 (8.8)	0.8 (-2.7 to 1.2)	0.464*
Mean ROM, ° (SD)	97.9 (13.2)	99.7 (15.6)	2.2 (-6.5 to 2.9)	0.442*

*Independent-samples *t*-test.
CI, confidence interval; KSS-F, general functional Knee Society Score; KSS-K, knee-specific Knee Society Score; MCS, mental component score; PCS, physical component score; ROM, range of motion; SD, standard deviation; SF-12, 12-item Short-Form Health Survey questionnaire.

at five years (82 (AP) vs 72 (MB)) achieved a power of 86.8%.

Results

Primary outcome. There was no significant difference in the observed KSS-K between the AP and MB groups (Table II).

Secondary outcomes. There was no significant difference in observed KSS-F. The mean was 75.4 (SD 15.3) in AP and 73.2 (SD 16.2) in MB (p = 0.471, independent-samples *t*-test) (Table II). Mean PCS-12 was 44.8 in AP and 44.9 in MB (p = 0.894, independent-samples *t*-test); mean MCS-12 was 44.3 and 45.1 (p = 0.463, independent-samples *t*-test). Mean ROM was 97.9° in AP and 99.7° in MB (p = 0.445, independent-samples *t*-test) (Table II and Figure 2).

Implant survival. Failure was defined as revision for any cause. There was one revision in the AP group for infection. There were three revisions in the MB group, one each for infection, tibial fracture, and pain. At five years, there was 99.2% survival for AP and 97.7% for MB. Log-rank test showed a chi-squared value of 0.996 (degree of freedom (df) = 1; p = 0.326) (Figure 3).

Cost economic analysis. The AP groups had a greater (better) SF-6D of 0.844, compared to that observed in the MB group of 0.815. The difference in the SF-6D of 0.029 resulted in a 0.145 greater gain over the five-year study period for the AP group compared to the MB group. As there was a cost saving of £406, and a gain in HRQoL, the ICER was negative: -£406/0.145 = -£2,800. Therefore, the AP tibial component was dominant, being a more effective and less expensive intervention (southeast quadrant). Although there was a difference in the revision rate between the two groups, this was not statistically significant. If this was taken into account, however, this would have made the AP group even more cost-effective, as there were two more revisions in the MB groups, costing an extra £19,310 (£9,655[18] × 2) or £148 per patient.

Discussion

This study demonstrates no difference in knee-specific outcome, HRQoL, ROM, or implant survival between AP and MB tibial components five years post-TKA in patients aged 70 years and older. The AP was shown to be more cost-effective, with associated lower implant cost and increased gain in QALY over the five-year period assessed.

Our results demonstrate equal functional outcome, measured by KSS, in both components. They are comparable to Najibi et al,[23] who retrospectively investigated 49 matched patients with a mean age of 78 years. They demonstrated no significant difference in KSS, ROM, and Hospital for Special Surgery (HSS) knee score. Gioe et al[24] reported their ten-year follow-up of a prospective randomized controlled trial of 97 AP and 70 MB components, demonstrating equivalent KSS-K (mean 92 in both), improved KSS-F in the AP group (55 AP vs 50 MB p = 0.04), and equal ROM (mean 110 in both).

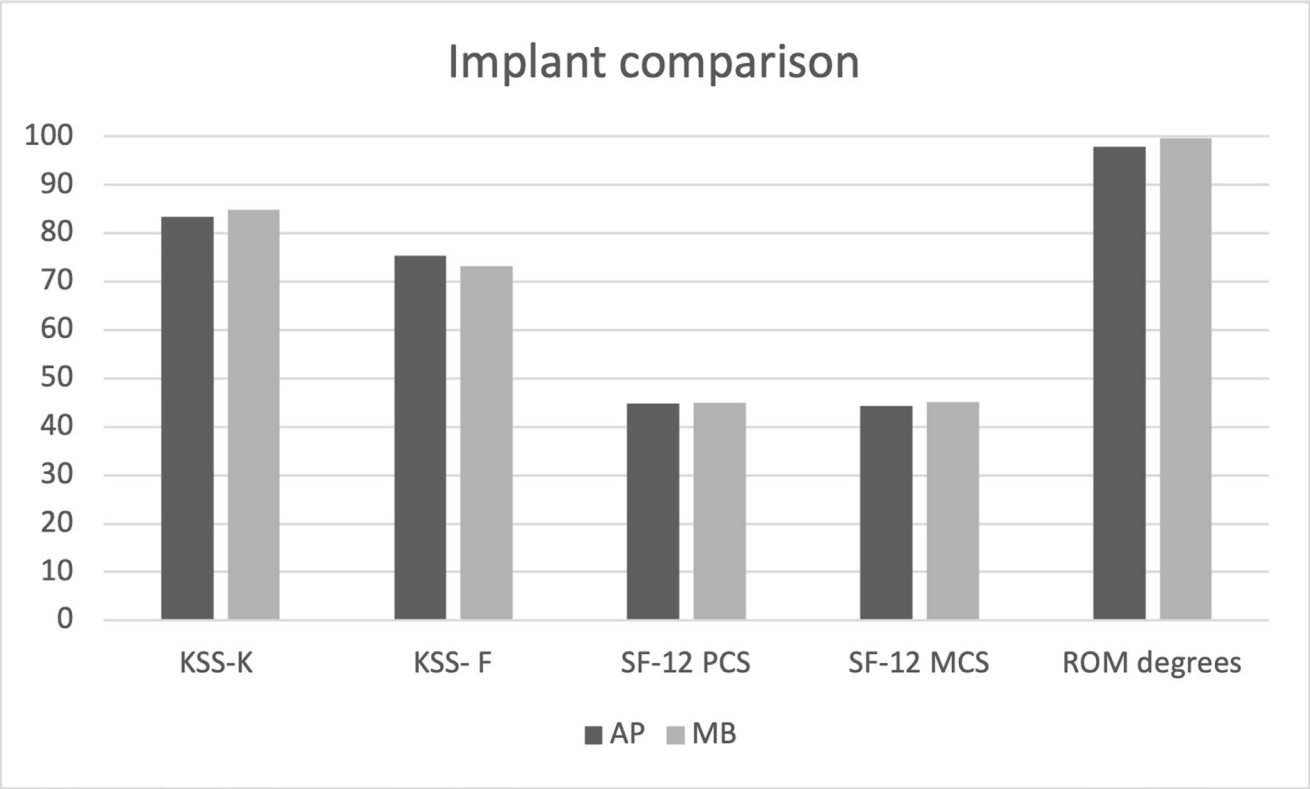

Fig. 2

Implant comparison. AP, all-polyethylene; KSS-F, general functional Knee Society Score; KSS-K, knee-specific Knee Society Score; MB, metal-backed; MCS, mental component score; PCS, physical component score; ROM, range of motion; SF-12, 12-item Short-Form Health Survey questionnaire.

The current study has demonstrated 99.2% survival for AP and 97.7% survival of MB at five years. Houdek et al[25] reported the long-term survivorship of 31,939 TKAs, comprising 3,715 (12%) AP components and 28,224 (88%) MB components. They reported significantly improved survivorship of AP compared with MB components across all timepoints ($p < 0.0001$), including five-, ten-, 20-, and 30-year survival of 98% vs 94%, 96% vs 88%, 91% vs 72%, and 83% vs 55%, respectively. The authors suggest AP components should be considered in all patients regardless of age. Gioe et al[26] report equally impressive results of 99.4% survival at 14.3 years' follow-up of 443 AP TKAs.

Gustke and Gelbke[27] investigated 227 AP components in patients aged 80 years and above with a mean follow-up of 5.6 years, demonstrating 100% survivorship. The authors also showed favourable KSS (mean 94 and 57) and ROM (114°). They found a 33% implant cost saving with no detriment to the patients. Further comparison with MB components has been performed by Nouta et al,[28] who performed a systematic review and meta-regression encompassing over 12,500 TKAs. They found no significant difference in any functional outcome or survivorship at five and ten years.

The majority of studies on the AP component have been aimed at older patients (aged 70 years and over). Biomechanical studies have shown that when loads, constraints, and geometries of high-demand activities, such as squatting to 120° of flexion, are applied, an AP component shows increased micromotions at the implant bone interface and increased uneven stress distribution in underlying cancellous bone.[15,29] This has led to the use of AP components by many surgeons (the authors of this study included) exclusively in older patients, who are seen as potentially having lower functional demand on their TKA. In contrast, some surgeons have retained an interest in using AP components in younger patient groups. Meftah et al[30] demonstrated excellent functional outcomes in younger patients (aged < 60 years), with mean KSS-K of 97%, and 62% of patients reporting participation in physical activities such as running, gym, tennis, and golf. In their report from the Swedish Knee Arthroplasty Register, Gudnason et al[31] showed up to 97.2% implant survivorship at ten years for patients aged under 75 years. These reassuring clinical outcomes have been supported by biomechanical study, wherein a recent radiostereometric analysis (RSA) of AP and MB components in patients aged under 60 years has shown stability and micromotion patterns at least equal to MB components, with no patient having greater than 0.2° rotation or 0.2 mm maximum total point motion.[32] With such reassuring clinical and

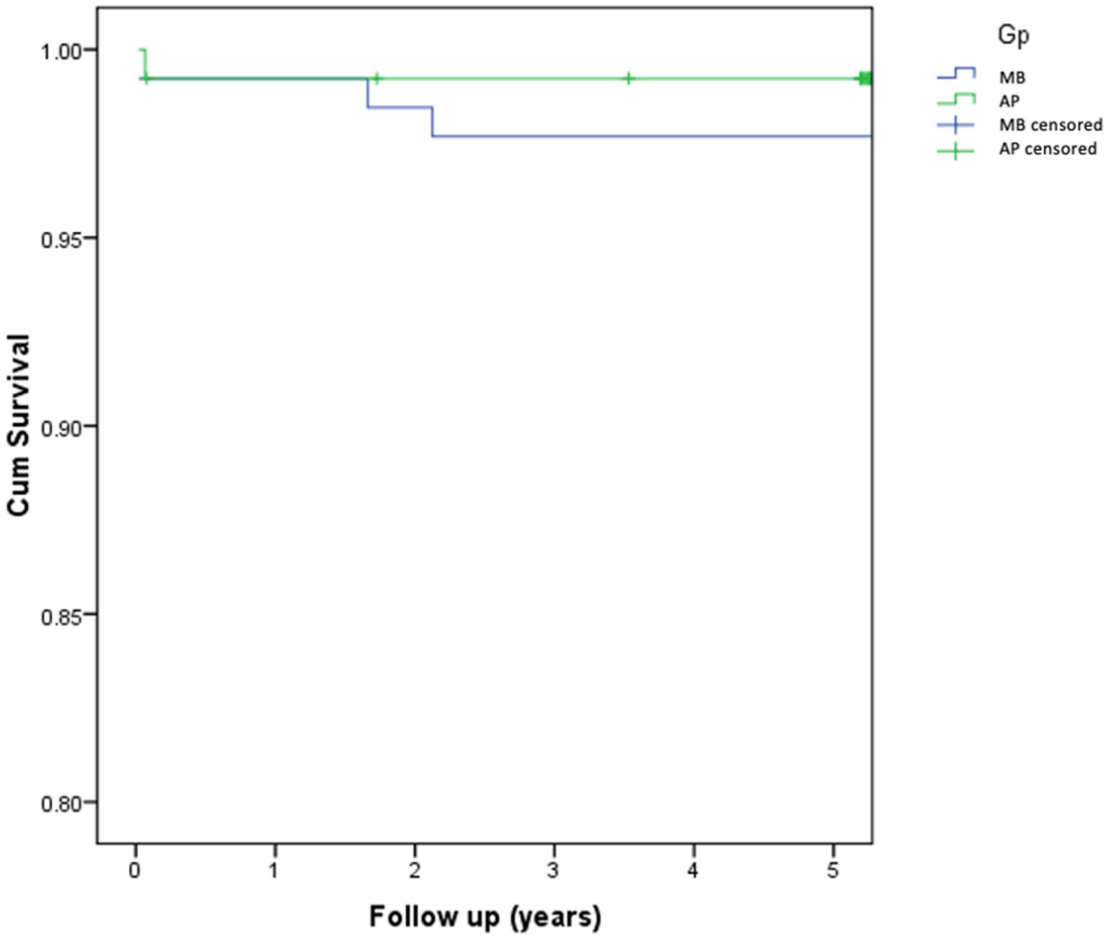

Fig. 3

Kaplan-Meier survival estimate. AP, all-polyethylene; Gp, group; MB, metal-backed.

biomechanical studies demonstrating AP components to offer good function, many suggest they have been incorrectly perceived as inferior to MB components. Advocates of the AP component argue that the previous early failures of AP could have been attributed to poor mechanical alignment, poor fixation, and inadequate ligamentous balancing.[33,34]

The NJR of England and Wales reports only 1.4% of all primary TKAs use an AP component.[7] In the current institution, 25% of all primary TKAs use an AP component; the supply cost is £406 cheaper than the MB component. In the current study's group alone, this represents a saving of £53,000 with no detrimental effects on the patients. Assuming that 25% of the 170,000 TKAs performed each year[1,2] were in patients aged 70 years or older, who could have an AP tibial component, this would result in an annual saving for the NHS of more than £17 million. Analysis of the NJR rates and population trends predicts a national increase in primary TKA of 117% by 2030;[35] even a modest increase in the use of AP components nationally has the potential to bring substantial savings to healthcare trusts, which can be re-invested in fulfilling this demand. As previously mentioned, Gioe et al[26] reported favourable outcomes in their study (mean age at operation was 77 years), and they estimated that if every patient in their registry (16,500 total joints) over the age of 75 received an AP tibial component, there is a cost saving on implants alone.

Strengths of this study include the prospective collection of data, and matched cohort for comparison. Limitations include its retrospective study design, and relatively short follow-up period. A further limitation is the possibility that patients in the MB group represented a more complex operation, as there may have been an intraoperative decision to opt for MB over AP. No indication for choice of MB over AP was recorded. Further study should be done to review the long-term outcomes in this patient group, and radiological analysis to assess implant position and loosening. The current study has demonstrated equal functional outcomes and survivorship of AP tibial components when compared to MB components at five years. This has led to substantial cost savings with no detriment

to patients. This study adds to the growing body of evidence that AP components are not inferior to MB components, and their increased use should be considered by arthroplasty surgeons.

In conclusion, there were no differences in functional outcomes or TKA survivorship at five years between AP and MB tibial components in patients aged 70 years and older, however the AP component was shown to be more cost-effective. In the UK, only 1.4% of all TKAs use an AP component, even a modest increase in usage nationally could lead to significant financial savings.

Take home message

- No difference in functional outcomes was observed at five years postoperatively between all-polyethylene and metal-backed tibial trays in patients over 70 years.
- There was no difference in survivorship at five years between all-polyethylene and metal-backed tibial trays in patients over 70 years.
- All-polyethylene tibial components are a cost-effective alternative in total knee arthroplasty.

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