■ KNEE

An 11- to 15-year clinical outcome study of the Advance Medial Pivot total knee arthroplasty

PIVOT KNEE ARTHROPLASTY

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Aims

The Advance Medial-Pivot total knee arthroplasty (TKA) was designed to reflect contemporary data regarding the kinematics of the knee. We wished to examine the long-term results obtained with this prosthesis by extending a previous evaluation.

Patients and Methods

We retrospectively evaluated prospectively collected data from 225 consecutive patients (41 men and 184 women; mean age at surgery 71 years, 52 to 84) who underwent 284 TKAs with a mean follow-up of 13.4 years (11 to 15). Implant failure, complication rate, clinical (both subjective and objective) and radiological outcome were assessed. Pre- and post-operative clinical and radiographic data were available at regular intervals for all patients. A total of ten patients (4.4%; ten TKAs) were lost to follow-up.

Results

Survival analysis at 15 years showed a cumulative success rate of 97.3% (95% confidence interval (CI) 96.7 to 97.9) for revision for any reason, of 96.4% (95% CI 95.2 to 97.6) for all operations, and 98.8% (95% CI 98.2 to 99.4) for aseptic loosening as an end point. Three TKAs (1.06%) were revised due to aseptic loosening, two (0.7%) due to infection, one (0.35%) due to instability and one (0.35%) due to a traumatic dislocation. All patients showed a statistically significant improvement on the Knee Society Score (p = 0.001), Western Ontario and McMaster University Osteoarthritis Index (p = 0.001), Short Form-12 (p = 0.01),and Oxford Knee Score (p = 0.01). A total of 207 patients (92%) were able to perform age appropriate activities with a mean flexion of the knee of 117° (85° to 135°) at final follow-up.

Conclusion

This study demonstrates satisfactory functional and radiographic long-term results for this implant.

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The Advance Medial Pivot (AMP) total knee arthroplasty (TKA) (MicroPort Orthopaedics Inc., Arlington, Tennessee) was introduced into clinical practice in 1998. It was designed to reproduce the physiological anatomy and to replicate normal tibiofemoral kinematics. The geometry of the components was designed to achieve stability in the anteroposterior direction.[1,2] It was also designed with the aim of reducing the complications seen with the use of conventional cruciate retaining or cruciate substituting designs. These complications included irregular kinematics,[3-5] abnormal patellar tracking,[6,7] polyethylene wear[8,9] and poor range of movement.[10] Key design features are a femoral component with a single radius of curvature from 0° to 90° on the medial and lateral condyle, an asymmetrical polyethylene liner with a spherical concavity medially and an arcuate path laterally, a dovetail locking mechanism and an anatomical trochlear groove which is long, deep, orientated 3.6° from the midline in the frontal plane and with an increased height anterolaterally of between 2 mm and 6 mm.

As an extension of a previous paper,[11] we report the long-term results of AMP TKAs using both objective and subjective rating systems.

Patients and Methods

Between December 1999 and July 2004, 225 consecutive patients (284 knees) with osteoarthritis (OA) of the knee underwent TKA

Table I. The 11- to 15-year assessment of the Advanced Medial Pivot total knee arthroplasty with validated rating systems

Score	Pre-operative	Final	Mean change (%)	p-value
Knee score (objective)	31.6 (10 to 70)	89.2 (68 to 99)	182.0	p = 0.001
Function score (objective)	42.9 (5 to 60)	78.4 (33 to 98)	82.8	p = 0.01
Knee Society Score (objective)	76.2 (15 to 130)	167.2 (101 to 197)	119.4	p = 0.001
Physical component Short Form-12 (subjective)	26.6 (19 to 40.5)	46 (34 to 56.2)	72.9	p = 0.01
WOMAC Score (subjective)	30.8 (14 to 54)	69.2 (37 to 85)	124.7	p = 0.001
Oxford Knee Score (subjective)	44.4 (36 to 53)	25.1 (17 to 41)	43.5	p = 0.01

WOMAC, Western Ontario and McMaster University Osteoarthritis Index

using the AMP TKA. There were 41 men (18%) and 184 women (82%) with a mean age at surgery of 71 years (52 to 84). There were 149 right (52%) and 135 left (48%) knees. The diagnosis was idiopathic OA in 168 patients (75%), rheumatoid arthritis in 29 (13%), post-traumatic arthritis in 12 (5%) and seronegative arthritis in ten (4%). The mean body mass index (BMI) was 33 kg/m^2 (27 to 36), 87 patients (38.7%) were smokers and the mean age-adjusted Charlson comorbitity index was 1.84 (0 to 3).[12] A total of 172 knees (60.6%) had Kellgren-Lawrence type III OA and 112 (39.4%) type IV OA, as assessed on standing (ThK) short anteroposterior and lateral radiographs.[13] The study had ethical approval and all patients gave informed consent for inclusion.

Six surgeons specialising in adult reconstructive surgery performed the operations using conventional surgical and modern cementing techniques including power lavage and vacuum mixing. The posterior cruciate ligament was retained in 207 knees (73%). It was resected in 77 knees (27%) in order to balance varus and fixed flexion knee deformities. The patella was not resurfaced. Patellar denervation and reshaping was performed. In an attempt to improve the longevity of the implant, early in 2000, we used to advise our patients to avoid heavy labour and significant sporting activities in order to protect the bone/implant interface from over-loading and polyethylene from excessive wear.

Objective and subjective clinical and radiological data were prospectively collected pre-operatively and at three and six weeks, three and six months and at one year post-operatively, and yearly thereafter, and stored in the Orthowave database (Aria Ltd, Lyon, France). The following validated scoring systems were used:[14] the Knee Society system (KSS, Knee score and Function score),[15] the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) questionnaire,[16] the Short Form -12 (SF-12) questionnaire,[17] and the original (60 to 12) Oxford Knee Score (OKS).[18] The active range of movement (ROM), when sitting, was recorded using a goniometer (ThK, NR, KB). Standardised standing short anteroposterior and lateral radiographs were taken. The Knee Society system was used for radiological evaluation (ThK, NR, KB).[19] Changes in alignment and migration (α, β, γ, σ and tibiofemoral angles) of the components were analysed comparing the angles of the first and last available radiographs. All radiographs were examined for progressive radiolucent lines (RLLs) according to Ewald[19] by three authors (NR, SV, MH) and if all three found RLLs, this was defined as a consensus. The presence of RLLs measuring > 2 mm, subsidence or change in alignment of a component was considered to indicate loosening. The criteria for failure were the need for revision, either performed or planned, because of aseptic loosening, infection, patellar resurfacing and dislocation or ligament instability.

Patients were also asked to judge relief of pain subjectively (excellent, very good, good, fair and poor), fulfilment of expectations of surgery (excellent, very good, good, fair and poor), and the ability to perform either regular activities or age-appropriate heavy manual work or sports (excellent, very good, good, fair and poor).

Statistical analysis. Data were analysed for normal distribution using Kolmogorov-Smirnov analysis. Clinical scores (KSS, WOMAC, SF-12 and OKS) and α, β, γ, σ and tibiofemoral angles were normally distributed. In order to evaluate possible statistical differences at different time intervals, a student's *t*-test was used for paired samples. Kaplan-Meier analysis with calculation of 95% confidence intervals (CIs) was performed to calculate survivorship.[20-22] All statistical analyses were performed using SPSS version 12.0 (SPSS Chicago, Illinois) at the biostatistics department of the University of Thessalia. A p-value of ≤ 0.05 was considered significant.

Results

The mean follow-up was 13.4 years (11 to 15). The final evaluation was performed between June and July 2015 and 195 patients (86.7%) with 251 TKAs (88.4%) were available with 179 (92%) having complete recordings from all time intervals. The same cohort of patients had been evaluated in 2008.[11] Ten patients (4.4%; ten TKAs) were lost to follow-up and 20 patients (8.8%; 23 TKAs) had died of unrelated reasons with their TKAs performing well.

Clinical outcome. The pre- and post-operative outcome scores are shown in Table I and Figure 1. The mean range of movement showed a statistically significant improvement from 101° (70° to 125°) to 117° (85° to 135°) (p = 0.04). A

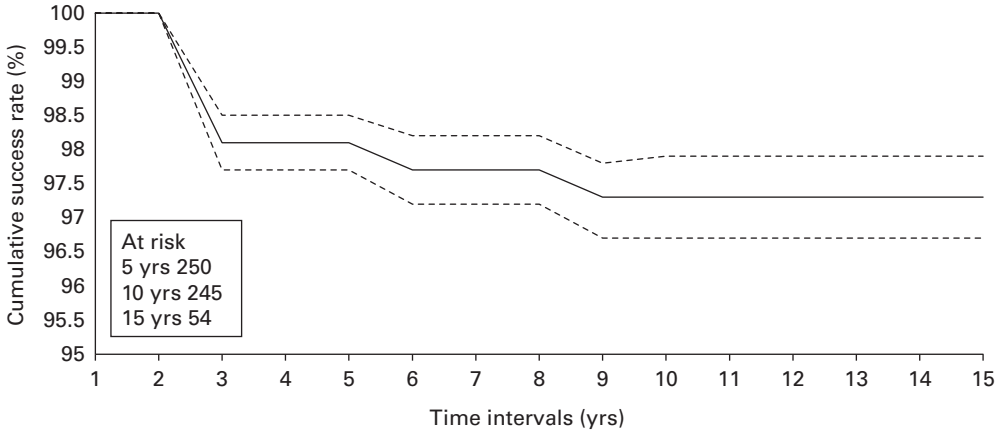

Fig. 2

Kaplan-Meier survivorship with revision for any reason as an end point (95% confidence intervals shown).

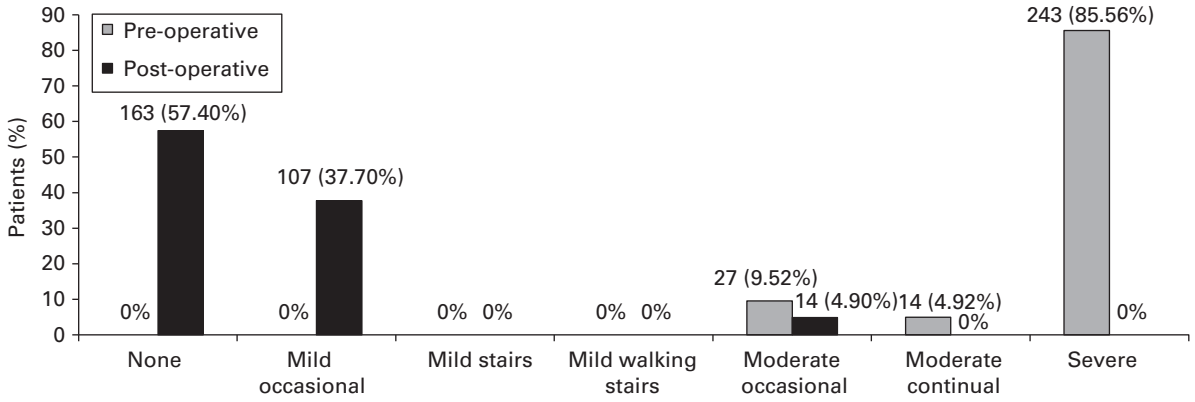

Fig. 1

Histogram showing the pre- and post-operative element of pain of the objective knee score.

fixed flexion deformity of up to 10º was found in 24 knees (8.5%) at final mean follow-up of 13.4 years (11 to 15).

Relief from pain was excellent in 133 (68.2%) of the patients, very good in 49 (25.1%), good in nine (4.6%) and fair in four (2%). Surgery fulfilled patients' expectations at an excellent level in 117 (60%) of the patients, at a very good level in 59 (30.3%), at a good level in 14 (7.2%) and at a fair level in five (2.6%). Concerning the ability to perform regular activities; 120 (61.5%) were able to perform at an excellent, 59 (30.2%) at a very good, six (3.07%) at a good and ten (5.13%) at a fair level. Concerning the ability to perform age appropriate heavy activities and sports; 24 (12.3%) were able to perform at an excellent, 31 (15.9%) at a very good, 93 (47.7%) at a good, 34 (117.4%) at a fair and 13 (6.7%) at a poor level. For the patients who gave negative replies concerning expectations, a second look at their records did not show objective unsatisfactory findings.

Radiological evaluation. On the immediate post-operative radiographs the mean femoral valgus angle (a) was 96º (92º to 102º), the mean tibial angle (b) was 89º (81º to 94º), the mean femoral flexion (γ) was 1º (-3 to 4º) and the mean tibial slope (σ) was 86º (80º to 93º). On the latest radiographs the mean femoral valgus angle (a) was 97º (92º to 102º), the mean tibial angle (b) was 88.5º (81º to 93º), the mean femoral flexion (γ) was 1º (-3º to 4º) and the mean tibial slope (σ) was 85.5º (80º to 93º). The mean alignment of the knee immediately post-operatively was 5º valgus (8º valgus to 5º varus) and at final follow-up it was 4.5º valgus (7º valgus to 5º varus). No statistically significant changes developed when post-operative and last final follow-up radiological parameters were compared.

At final follow-up, on radiological evaluation, β angle < 90º (varus placement of the tibial component) was found in 22 knees (8.8%). Non progressive RLLs were found in zones 1 and 2 on anteroposterior radiographs of the tibial component in 26 knees (10.36%). In three symptomatic knees, progressive RLLs were found; these were revised. In two, in the same patient, the post-operative β angle was 85º. On lateral radiographs of the tibial component there were non-progressive RLLs in zones 1 and 2 in ten knees (4%). On lateral radiographs of the femoral component

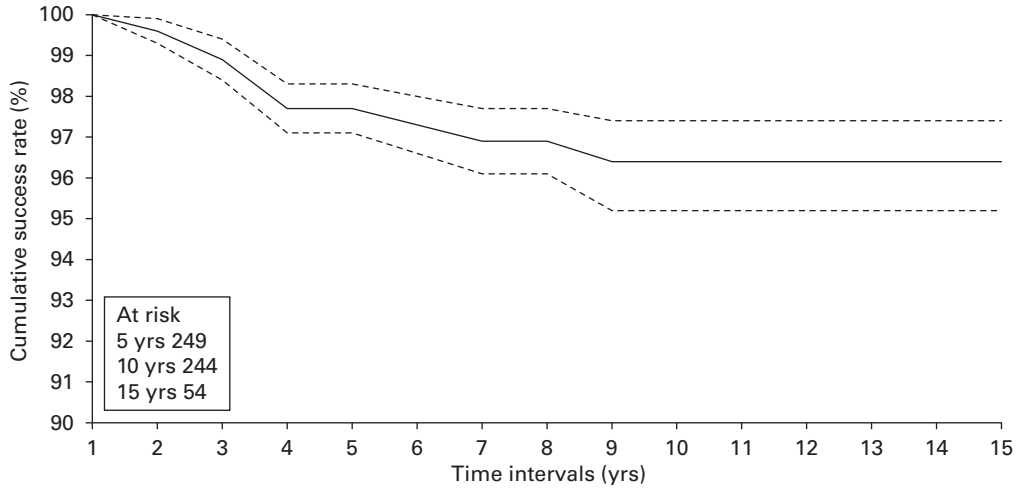

Fig. 3

Kaplan-Meier survivorship with revision for all reasons as an end point (95% confidence intervals shown).

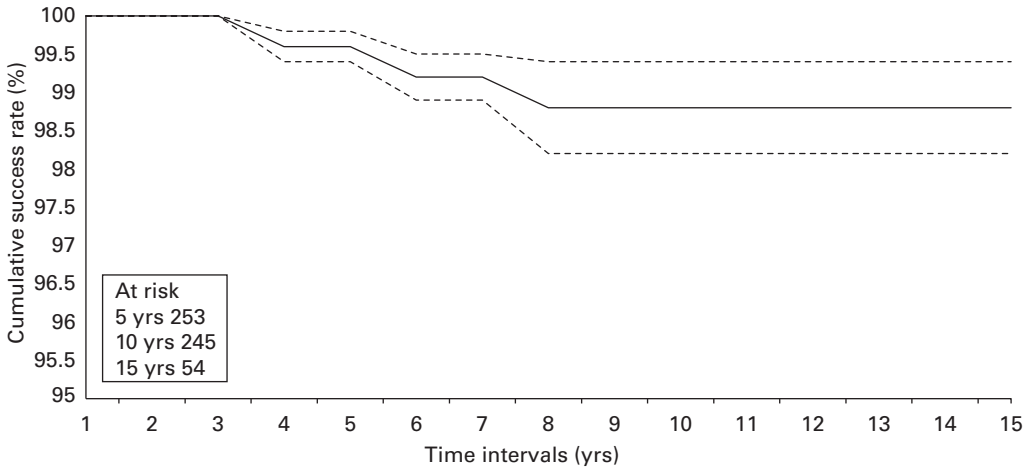

Fig. 4

Kaplan-Meier survivorship with revision for aseptic loosening as an end point (95% confidence intervals shown).

there were non-progressive RLLs in zone 1 in three knees (1.2%). There was no radiological evidence of osteolysis due to polyethylene wear debris.

In total, three TKAs (1.06%) were revised for aseptic loosening at three, five and nine years, respectively (two in a very active overweight patient, BMI 41 kg/m^2). In all, two (0.7%) became infected and underwent a two-staged revision two and three years post-operatively, respectively. One patient (0.35%) underwent a revision for traumatic dislocation following a fall from a height four years post-operatively. The ten patients who were lost to follow-up were contacted by telephone and one TKA (0.35%) was found to have been revised elsewhere due to instability, two years post-operatively.

A total of ten patients (ten TKAs; 3.5%) had anterior knee pain, in two of whom the patella was resurfaced one-year post-operatively. In four knees a manipulation under anaesthetic was performed to improve flexion after the fourth post-operative week. Overall one patient (one TKA; 0.35%) developed a mild complex regional pain syndrome which improved after the sixth post-operative month.

Kaplan-Meier survivorship analysis showed a cumulative success rate of 97.3% (95% CI 96.7 to 97.9) at ten and 15 years with revision for any reason (including aseptic loosening, instability, infection and dislocation) as the end point (Fig. 2), of 96.4% (95% CI 95.2 to 97.6) at ten and 15 years with revision for all indications including secondary patellar resurfacing as the end point (Fig. 3), and 98.8% (95% CI 98.2 to 99.4) at ten and 15 years with revision for aseptic loosening as the end point (Fig. 4).

Discussion

Based on both objective and subjective outcome scores, patients who had an AMP TKA had satisfactory pain relief. Anterior knee pain was observed in ten of the cases (3.5%) and secondary patellar resurfacing was only needed in two patients. The low rate of anterior knee pain may be explained by the geometry of the patellofemoral design of

this implant. This TKA system was also one of the first to provide instruments (femoral cutting jigs and blogs) for accurate rotational placement of the femoral component, which allows for improved patellar tracking. Recovery of function was also satisfactory, with 207 patients (92%) being able to perform normal activities. Despite the advice at this time (early 2000) to avoid heavy use of the TKA, 171 patients (76%) stated that they were able to perform age-appropriate heavy manual work or sport. Surgery fulfilled the expectations of 203 patients (90%). A small number of patients (seven, 3.6%) were not satisfied, despite the fact that the TKA was objectively satisfactory – such findings have been observed elsewhere.[23] This may reflect aspects of attitude and personality which are difficult to identify pre-operatively.

There was a statistically significant improvement in all objective and subjective outcome scores and the cumulative success rate was high, at 97.3% (95% CI 96.7 to 97.9), at 15 years with revision for all causes as the end point. An analysis of failure indicated that in the two TKAs (in the same patient) in which the tibial components failed due to aseptic loosening, both components had been introduced in some varus. Thus, these failures could have been prevented. In a third TKA which failed due to aseptic loosening, severe osteoporosis due to hyperparathyroidism with a hip a bone densiotometry *t*-score of -4.5 standard deviation was a predisposing factor. Progressive insufficiency of the medial tibial condyle led to loosening in this patient. The instability requiring revision in one TKA was clearly the result of surgical error (failure to balance the medial compartment in both flexion and extension). The other three revisions for infection and traumatic dislocation are within the expected causes of failure in a series of TKAs. There was no implant related failure in this series.

The relatively small number of patients and the lack of a control group are perhaps weaknesses of the study. The low rate of loss to follow-up and the use of both objective and subjective scoring systems are, however, strengths.

To the best of our knowledge, this is one of the first reports of the long-term clinical outcome of this design of TKA. There are four early reports of its use. Satisfactory pain relief and range of movement comparable to posterior stabilised designs were reported with the patients preferring the AMP TKA in those who underwent staged bilateral TKA.[24-26] In a Level I study conducted by Kim et al,[27] including 92 patients who had an AMP TKA in one knee and a PFC Sigma mobile bearing TKA (Depuy, Synthes, Warsaw, Indiana) in the other, the authors reported that the early outcome was worse with the AMP TKAs. The methodology used in this study has, however, been criticised.[28,29] Several authors have reported favourable mid-term outcomes using the AMP design without recording implant related complications. Favourable mid-term rates of survival of > 97% with satisfactory radiological findings, low rates of complications with adequate flexion and stability have also been reported.[30-35] We have previously reported the mid-term outcome of this cohort of patients at mean follow-up of seven years.[11] Most patients had very good or excellent pain relief and the cumulative success rates were 99.1% (95% CI 86.6 to 100) and 97.5% (95% CI 65.6 to 100) at five and nine years post-operatively, respectively.[11] The mid-term outcome of 50 consecutive AMP TKAs was evaluated and compared with the results in the Australian Orthopaedic Association National Joint Replacement Registry by Brinkman et al.[36] They found that the AMP TKA provided pain relief, functional improvement and rates of complications and revision which were similar to registry data.[36] A systematic review and meta-analysis of the AMP TKA included clinical results from eight studies from 12 centres in six countries, with a sample size of 1146 TKAs and showed a pooled survivorship of the components of 99.2% (95% CI 97.7 to 99.7) and 97.6% (95% CI 95.8 to 98.6) at five and eight years post-operatively, respectively.[37] The National Joint registry of England, Wales and Northern Ireland reported a survival rate of 96% at ten years for 5985 AMP TKAs, which was similar or better than those reported for other cemented designs of TKA.[38] The Danish Knee Arthroplasty registry also reported a survival rate of 95.7% at ten years follow-up for > 1400 AMP TKAs.[39] Clinical outcomes reported in our study compare favourably with those reported in the single study with a mean follow-up of > ten years.[40] Satisfactory mid-term clinical outcomes with no implant related failures have also been reported with the use of the MRK TKA (MatOrtho, Leatherhead, United Kingdom), which is one of the three existing medial rotating designs.[41-44] The superior rates of survival which we report in this study might be explained by the fact that most arthroplasties were performed by a small number of high-volume dedicated TKA surgeons.

The AMP TKA was not designed as a "high flexion" knee; however, the patients in our series gained a mean range of movement of 117° which is greater than historical control series[45,46] and this partly explains the satisfactory functional outcomes. Similar satisfactory ranges of movement have been reported by others.[26,31,34,35] Stability is also an aim of TKA surgery. All those in our series were found to be stable using conventional methods of evaluation and we were thus able to confirm a previous report.[47] There is a theoretical concern of increased transfer of stress at the bone–implant interface due to the constraining effect of the convex hemispherical medial femoral condyle articulating medially in a matching concavity in the polyethylene insert. This concern proved to be unfounded as there were no changes in alignment, no migration of the components and a low incidence of non-progressive RLLs.

In conclusion, satisfactory clinical and functional long-term outcomes can be obtained using the AMP TKA which has a spherical medial compartment intended to replicate tibiofemoral kinematics and confer stability. The rate of failure was low and not related to the design of the components. This study does not demonstrate that this design is necessarily better than other existing designs, including the

other three with a medial spherical compartment, but it demonstrates that the long-term outcome is satisfactory with no implant-related failures.

Take home message:

The Advance Medial Pivot total knee arthroplasty showed satisfactory functional and radiographic long-term outcomes with no implant related failures.

Supplementary material

Figures showing the Advance Medial Pivot total knee arthroplasty with a ball in socket-like medial compartment and satisfactory radiological outcome at 15 years follow-up are available alongside the online version of this article at www.bjj.boneandjoint.org.uk

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K. Bargiotas: Data collection, Performed surgeries.
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N. Roidis: Data collection, Performed surgeries.
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