



# All-polyethylene tibial components in young patients have stable fixation; a comparison RSA study



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## ARTICLE INFO

### Article history:

Received 2 May 2018

Received in revised form 4 October 2018

Accepted 5 December 2018

### Keywords:

Knee arthroplasty

All-polyethylene

Radiostereometry

Tibial migration

## ABSTRACT

**Background:** All-polyethylene (AP) tibial components in patients aged greater than 60 years have stable tibial migration patterns and favorable survival rates when compared to identical Metal-backed (MB) designs. Tibial component migration in younger patients has not been reported. The aim of this study was to examine the migration characteristics of patients aged less than 60 years compared to a previous cohort of AP and MB tibial components of identical design in older patients. **Methods:** A prospective consecutive study examined tibial component migration in 21 patients aged less than 60 years undergoing a cemented total knee arthroplasty with an AP tibial component by radiostereometric analysis (RSA) to 24 months. Results were compared to the authors' previous series of 21 patients aged greater than 60 years that were randomized to either an AP or MB tibial component.

**Results:** Both age groups of patients implanted with an AP component had stable migration patterns with no patient having greater than 0.2° rotation or 0.2 mm maximum total point motion. Five of 11 MB tibial components displayed continued migration between one and two years. Subsidence was similar in all groups, whilst maximum total point motion was greater for the MB cohort (0.34 mm, 0.33 mm, 0.61 mm; AP <60, AP >60, MB).

**Conclusions:** Young patients implanted with an AP tibial component had stable tibial migration patterns comparable to older patients with the same AP implant. Regardless of age, AP tibial components were at least as stable as MB tibial components.

**Level of evidence:** Level II, Prospective comparative study.

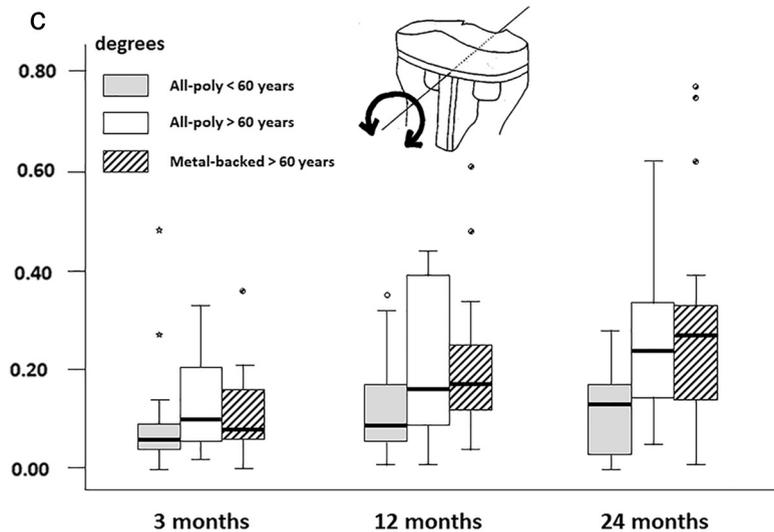
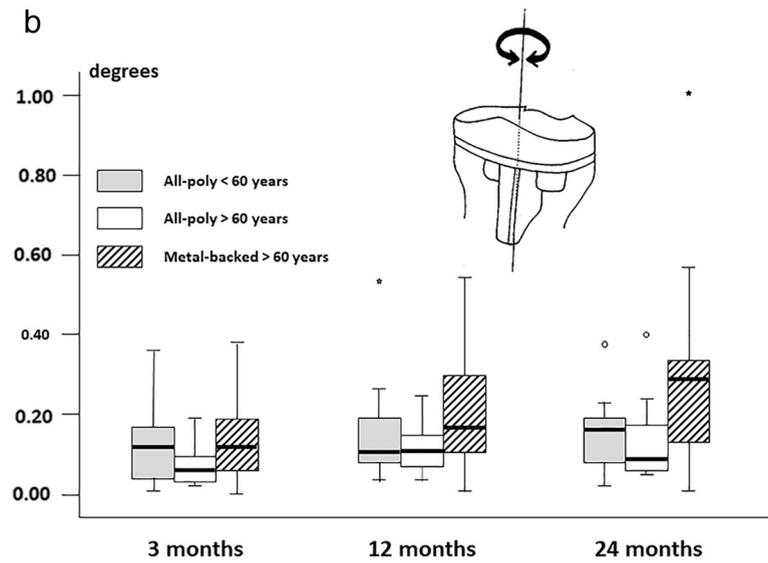
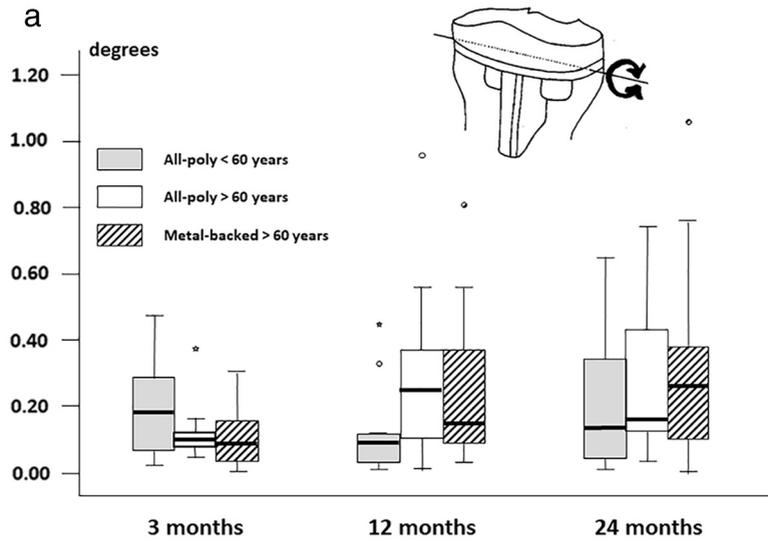
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## 1. Introduction

In the early 1980s metal-backed (MB) tibial components were introduced with the belief that improved load distribution, protection of porotic bone and additional modularity would improve knee outcomes and potentially facilitate subsequent revision surgery [1–6]. There have been several long-term clinical studies examining the question of MB versus all-polyethylene (AP) tibial implants. A meta-analysis by Cheng et al. [10] included nine randomized studies with 1758 patients and indicated no difference in survivorship between

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the two groups but increased lucencies in the MB group. Voight and Mosier [12] also reported no difference in survival between tibial implants at two, 10 and 15 years in 1798 patients. However, Voss et al. performed a meta-analysis including 28 articles with 95,847 knees and reported a decreased revision rate ratio of 0.709 when an AP implant was used [11].

An analysis of the Australian National Joint Registry (ANJR) confirmed the overwhelming adoption of MB implants with only 0.4% of knee replacement implants in Australia using an AP design [7]. Although the number of AP components is small, the ANJR data suggests the same survival rate between MB and AP designs in patients aged more than 65 years of age but there is limited data in younger patients. Conversely, AP components are used more commonly in 42.3% of 16,866 press-fit condylar implants in the Swedish Registry [8]. Gudnason et al. [8] reported that AP components had 0.75 relative risk of revision at 10-years compared to MB components. The Kaiser Permanente Registry also reports a markedly decreased revision rate for AP tibial components with a twofold reduction of revision when compared to MB components [9]. When used in patients aged less than 65 years the difference was even greater favoring AP components with a hazard ratio of 0.26% [9]. The clear disparity between the frequency of usage and similar or improved results in AP designs, which are less costly, is an unresolved paradox.

Radiostereometric analysis (RSA) is a highly sensitive and specific in-vivo measurement of implant migration and is a favored modality to assess long-term outcomes [13,14]. This is an ideal tool to differentiate the potential survivorship between tibial implants [15,16]. A meta-analysis of randomized RSA studies comparing MB and AP implants demonstrated no significant difference in the migration between the two groups [10]. The meta-analysis favored the AP group but failed to achieve statistical significance. One of the authors, Nilsson et al. [17] subsequently examined the migration of a moderately conforming cruciate retaining implant (Profix, Smith & Nephew, Tennessee, USA) in patients aged greater than 60 years and found improved early implant stability using AP components compared to MB components. At two years, five of 11 MB implants were migrating and none of the 12 AP implants were migrating. It was concluded that an AP design was the preferred implant for patients aged greater than 60 years but to the best of the authors' knowledge there is no reported RSA migration data on AP components used in younger patients. The current study attempts to address this knowledge deficit by including an additional study arm to the author's previous randomized trial [17] and measure the migration of the Profix AP tibial implant in patients aged less than 60 years using RSA.

## 2. Material and methods

A prospective observational study examined the migration pattern of patients aged less than 60 years implanted with an AP cruciate retaining implant (Profix, Smith & Nephew, Tennessee, USA). Ethics approval 05 CHREC-1411 Ramsay SA Acute Research & Ethics committee, Australian New Zealand Clinical Trials Registry study number ACTRN12618000107224. This cohort of patients was compared to a previous RSA study with patients aged greater than 60 years from the authors [17]. The comparison data comprised a randomized prospective study of 23 knees in 21 patients aged greater than 60 years receiving the same prosthesis and randomized to an AP or MB tibial implant.

Patients were recruited from the author's elective surgical practice. Inclusion criteria included age less than 60 years and body weight less than 120 kg, reside within the metropolitan area and able to attend RSA examinations within the two year review period. Patients with previous open surgery were excluded including previous reconstructive ligament surgery or osteotomy.

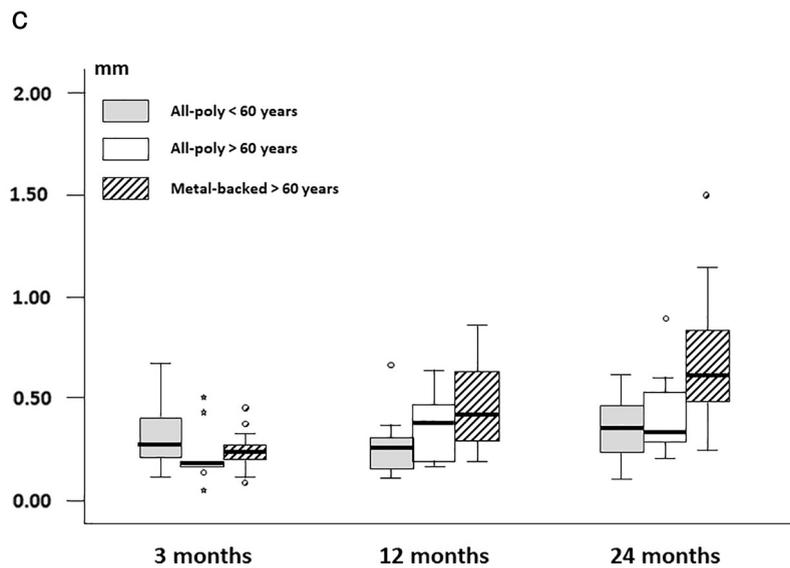
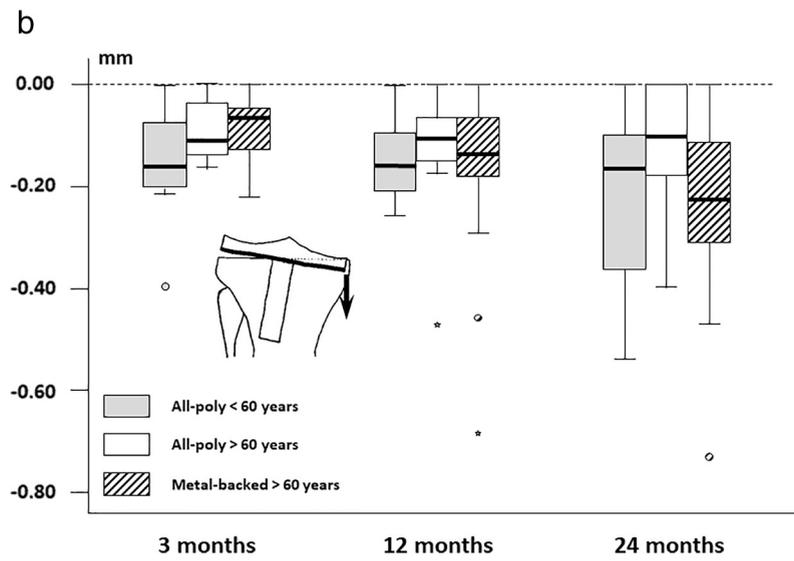
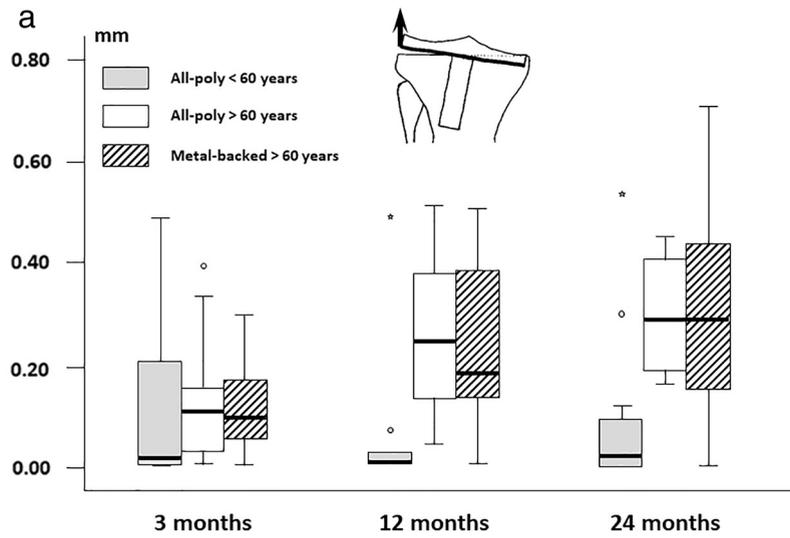
The operative procedure was identical to the previous published results [17]. The prepared surface of the proximal tibial was irrigated and dried before application of bone cement (vacuum-mixed Palacos with Gentamicin, Schering Plough, Labo, Belgium) applied to the proximal tibia and partly around the stem. The tibial component was kept under pressure whilst the cement was setting. During the operation nine tantalum markers (diameter 1.0 mm) were inserted into the proximal tibia and six markers into the polyethylene of the tibial component. After the operation, immediate full weight bearing exercises, as tolerated using two crutches, were enforced for all patients.

Patients were followed clinically and with supine RSA examinations at four to seven days, six weeks, and six, 12 and 24 months. The RSA evaluation was performed using RSA software as described previously with UmRSA software (version 6.0, RSA Biomedical Innovations, Umea, Sweden) [18–20]. Standardized positions for measurement of prosthetic translations were reconstructed on the tibial tray (i.e. medially, laterally, posteromedial and posterolaterally) as previously described.

The relative movement of the tibial components was recorded using tantalum markers in the tibia as the fixed reference segment. The rotations were expressed as rotations about the transverse (x-axis, anterior–posterior rotation), longitudinal (y-axis, internal–external rotation) and sagittal (z-axis, varus–valgus rotation) axes of the knee. Maximum lift-off and maximum subsidence were defined as the largest proximal and distal translations of the tibial component respectively. Maximum migration (MTPM), as defined by Ryd [21] represented the length of the three-dimensional (3D) translation vector of the part of the implant that moved the most. Based on the ability to predict further aseptic loosening, the tibial components were classified as being non-migrating (stable) or continuously migrating (unstable) as suggested by Ryd et al. [15].

Alignment of the tibial component in relation to the tibia was measured as described by Nilsson et al. [22]. Radiographs, obtained with the beam tangential to the tibial component, were also used to determine the presence and size of radiolucent lines at the tibial

**Figure 1.** Boxplots displaying rotations of the tibial component. 1a. Rotations about the transverse axis (anterior–posterior rotation). 1b. Rotations about the vertical axis (internal–external rotation). 1c. Rotations about the sagittal axis (varus–valgus rotation). The line within the box is the median, the box is the interquartile range, and the whiskers are the highest and lowest values excluding outliers or extreme values. Circles (O) are outliers (values 1.5 to three-fold larger than the interquartile range) and asterisks (\*) are extreme values (values >three-fold greater than the interquartile range). Statistics were calculated with the Mann–Whitney U-test and repeated measures analyzed with one-way ANOVA to compare all three groups at the three time periods.



**Table 1**

Knee Society knee score and function in all-polyethylene (AP) patients aged &lt;60 years and &gt;60 years and metal-backed (MB) groups aged &gt;60 years (median, range).

	AP <60 years	AP >60 years	MB >60 years	P value
Knee score				
Preoperative	54 (35–70)	25 (1–36)	24 (7–50)	<0.001
24 months	93 (64–100)	77 (55–92)	76 (65–98)	<0.001
Function score				
Preoperative	60 (45–80)	33 (20–55)	40 (30–70)	<0.001
24 months	90 (60–100)	60 (40–90)	60 (30–100)	<0.001
Range of motion (degrees)				
Preoperative	120 (106–135)	93 (55–110)	100 (60–130)	0.0015
24 months	115 (75–125)	100 (90–115)	100 (90–115)	NS

P values calculated with the Mann–Whitney U-test; NS, not significant.

component interface as described by the Knee Society [23]. Clinical evaluation was carried out preoperatively, and at 12 and 24 months using the Knee Society scoring system.

A Mann–Whitney U test was used to compare the RSA results of AP <60 years to AP >60 years and MB >60 years at three, 12 and 24 months. A Kruskal–Wallis test was used to compare the three groups at three, 12 and 24 months. Additionally, repeated measures one-way Analysis of Variance (ANOVA) was used to compare all three groups at the three time periods. The Mann–Whitney U test and Fisher's Exact test were used to compare the clinical variables as well as the Knee Society score. For the RSA data, both the median and range, as well as the mean and 95% confidence limits of the mean, at two years are presented. To display changes in migration over time, box plot graphs are also presented. For the clinical data, median values and ranges are presented. P values <0.05 were considered significant.

### 3. Results

The data includes 21 patients examined in this study aged <60 years implanted with an AP tibia and a comparison group of 21 patients from the author's previous series of patients aged >60 years including 11 knees with an AP tibial component and 11 with a MB tibial component. For the current cohort there were three males and 18 females with a mean weight 85.4 kg (range 66–115). The magnitude and direction of migration of tibial components are presented in Figures 1 and 2. In the current cohort, AP tibial components had stable migration patterns between one and two years. Subsidence and maximum point migration demonstrated stable migration patterns with no patient exhibiting more than 200 µm of maximum point migration.

Migration of AP components in patients aged <60 years was comparable to patients aged >60 years. In general, dispersion from the mean or median values was similar in the young and older AP implant groups for all parameters examined as shown by similar 95% confidence limits and ranges. Median varus–valgus rotation and lift-off were less in the younger patients (0.13° compared to 0.24°; and 0.02 mm compared to 0.29 mm respectively) with a statistically measurable but clinically unimportant difference [15]. Rotation in the x-axis and y-axis, tibial subsidence and maximum point migration were similar in both groups.

MB implants had greater dispersion from the mean or median values compared to both younger and older patients with AP implants for all parameters examined with wider 95% confidence intervals and larger ranges. This indicates higher variability in the quality of the fixation among the MB implants. The median migration tended to be somewhat lower for the AP implants reaching statistical significance at 24 months for internal–external rotation. Varus–valgus rotation and lift-off were reduced in the AP <60 years cohort compared to AP >60 years and MB implants. Subsidence was similar in all groups. Maximal migration was greater in the MB group compared to young and older AP groups (0.34 mm, 0.33 mm, 0.61 mm; AP <60, AP >60, MB).

The direction of rotation of the tibial component about the transverse, vertical and sagittal axes of the knee did not differ between AP <60 years, AP >60 years and MB implants. The location of maximal subsidence and lift-off did not differ between the groups. The AP implants were classified as stable according to the criteria by Ryd et al. [15] whereas five of the MB implants showed continuous migration of greater than 200 µm between 12 and 24 months, and were thus classified as unstable.

The results of the Knee Society knee and function scores before operation and 12 and 24 months are displayed in Table 1. All patients demonstrated a statistically significant and sustained improvement of knee function following surgery and were not statistically significant different between the three groups. Range of motion before surgery and at final review did not differ significantly between groups. Two patients in the AP <60 cohort had a low-grade arthrofibrosis and presented for manipulation at three months following surgery, one regained her range of movement to 125° and the other maintained a modest improvement to 100°. One patient in the AP <60 had an arthroscopic lateral release with some improvement of her patellofemoral pain. One patient

**Figure 2.** Boxplots displaying tibial migrations from the tibia. 2a. Maximum lift-off of the tibial component from the tibia. 2b. Maximum subsidence of the tibial component into the tibia. 2c. Maximum tibial point migration (MTPM) of the tibial component into the tibia. The line within the box is the median, the box is the interquartile range, and the whiskers are the highest and lowest values excluding outliers or extreme values. Circles (O) are outliers (values 1.5 to three-fold larger than the interquartile range) and asterisks (\*) are extreme values (values > three-fold greater than the interquartile range). Statistics were calculated with the Mann–Whitney U-test and repeated measures analyzed with one-way ANOVA to compare all three groups at the three time periods.

in the AP >60 years group sustained a deep infection before the two-year review, probably caused by hematogenous spread. She has refused reoperation and is being managed with antibiotics.

There was no difference in alignment of the knee between the three groups. Alignment of the tibial component in relation to the long axis of the tibia did not differ between the groups. In all groups the tibial component was inserted, as intended, with slight posterior tilt. There were no radiolucent lines in the immediate post-operative radiograph for any of the implants in this series. In the original cohort of patients aged greater than 60 years two AP implants and three MB implants had one millimeter thick radiolucent lines at the periphery of the tibial component which were non-progressive in all knees.

#### 4. Discussion

Despite perceived advantages, MB tibial implants have not demonstrated superiority in clinical studies [11,24–26], registry data [7,8,27] or RSA studies [4,28–31]. Due to the greater stiffness of the MB designs, increased tensile stresses at the interface during eccentric loading have been found in *in vitro* studies [2] with a tendency of increased subsidence and lift-off in clinical reports [31,32]. The occurrence of 'back side' wear in modular MB designs has also been established [33] and the addition of metal backing increases the cost of contemporary implants by approximately 30% [34–36]. The renewed interest in AP components has evolved and is supported by extensive biomechanical and clinical evidence [37]. However, there is relatively less evidence available for the AP tibial component assessment in patients aged less than 60 years [38].

The current study has examined the migration of AP tibial components in patients aged less than 60 years with RSA, which has been shown to have a high prognostic precision in early detection of late occurring aseptic loosening of total joint arthroplasty [13,15]. The current study has demonstrated that patients aged less than 60 years have stable patterns of migration similar to patients aged greater than 60 years implanted with the same AP implant. Compared to patients aged greater than 60 years with MB components, patients implanted with AP design have more stable patterns of migration irrespective of age.

This study had a number of limitations. The main limitation of our study is that it is a comparison of two prospective cohorts recruited at different locations and points in time. Specifically, migration of the tibial components in the patients aged greater than 60 years were recruited from a single surgeon's center in Sweden [17] and compared to the current series, which was a single surgeon series in Australia. Whilst both surgeons have extensive experience and have operated together for multiple cases it is likely there are some inherent technical differences between the groups. The patient groups were non-matched pairs and the younger than 60 years group were significantly heavier and more active than the Swedish group aged more than 60 years. The Australian Registry reports increased failure rates from aseptic loosening in patients aged less than 55 years [39] and it would be anticipated that the younger than 60 years group may have an increased rate of migration that was not observed in the current series. A second limitation is the small number of patients included in each cohort, which is common to most RSA studies due to the accuracy of the measurement method. A third limitation is the different location and radiographic equipment used for the RSA assessment. To minimize this confounder all radiographs obtained in Australia were measured and analyzed in Sweden using the same technique and software as in the previous study [17].

The present study confirms that patterns and magnitude of migration of the AP components were not inferior to, but rather equal to that of the metal back implants. In some aspects the stability of the AP implants was superior to the MB implants. More MB than AP implants showed continuously increasing migration over time, a finding known to be indicative of increased risk of future aseptic loosening. The results of this study are in accordance with previous prospective randomized RSA studies including a meta-analysis by Cheng et al. [10] which found AP implants performed as well as, or better than, MB components in all aspects. Importantly, AP components irrespective of age did not display collapse of either medial condyle or increased rates of radiolucent lines which have previously been reported with flat-on-flat AP designs [40]. *In-vivo* analysis of total knee arthroplasties suggests intermittent eccentric loading of the tibial component from the gait cycle that induces compressive and distractive forces at the interfaces [41–45]. Interfaces beneath the stiffer MB implant with its relatively thinner polyethylene may be more sensitive to these stresses, explaining the increased tilting of these implants. The relatively thicker and less stiff AP implant may absorb these stresses resulting in less tilting [37].

The use of AP implants in patients younger than 60 years has been avoided because of the lack of data in this younger age group. Whilst it is well described that patients aged less than 55 years have increased rates of failure from all causes [39], including loosening and lysis which is attributed to the interface, there has been no clinical or *in-vivo* data to suggest that younger patients are placed at increased risk if an AP implant is used. A limitation of this study and others is the limited number of designs studied; results may not be generalized to all implant designs, especially if the fixation topography differs between AP and MB implants. Cheng et al. [10] report a meta-analysis of nine randomized studies reporting no difference in survivorship in patients with an AP or MB component but there are relatively smaller numbers of young patients in this group.

Commercial and industry registry data now have sufficient patients to report survivorship of younger patients who have been implanted with AP tibial component and the results are favorable. The Kaiser Permanente Register reports 27,657 knee replacements including 2306 patients (8.3%) implanted with AP component [9]. The all-cause revision rate of per 100 years for AP implants was 0.5 and 0.6 for aseptic revisions compared to age adjusted MB implants. When age is considered, the hazard ratio for patients aged more than 65 years was 0.6 for the AP group indicative of a more favorable outcome. For patients aged less than 65 years the hazard ratio was 0.26 suggesting patients aged less than 65 years who had an AP implant were exposed to one quarter of the risk of revision for all causes. The institutional database from the Mayo reports 16,584 knee replacements and includes approximately 20% of patient who were implanted with AP implant [46]. For this group the AP hazard ratio was 0.3, P-value <0.001. Where the hazard ratios were stratified for risk age was not identified as an increased risk for the use of an AP tibial component. Patients aged less than 65 years had a decreased

revision rate if an AP implant was used. Body Mass Index has been ascribed to increased interface forces on the tibial implant, Berend et al. [47] found increased rates of loosening in both AP and MB components but conversely the Mayo reports improved results when an AP implant was used in patients with an increased BMI [48].

## 5. Conclusions

Migration patterns of patients implanted with an AP tibial design have consistently demonstrated comparable or improved migration patterns compared to patients implanted with a MB design. The current study indicates migration patterns in younger patients have a similar migration pattern to patients aged greater than 60 years with the same AP implant and both age groups performed better than older patients implanted with a MB implant.

## Acknowledgments

We thank Yvonne Johnstone (Dip Diag Rad) and Dr. Jones and Partners Medical Imaging (Adelaide, South Australia, Australia) for assisting with RSA radiographic examinations.

## Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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