

Decreased Survival of Medial Pivot Designs Compared with Cruciate-retaining Designs in TKA Without Patellar Resurfacing

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Abstract

Background The medial pivot TKA design was introduced in the 1990s. These are fixed-bearing, medial-conforming implants with virtually no translation in the medial part of

the knee, in contrast to the flat lateral part of the insert allowing for translation similar to the native knee during flexion and extension. Most primary TKAs performed in

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Each author certifies that his institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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Norway and Australia are cruciate-retaining. All of the medial pivot implants in our study are cruciate-sacrificing but without a post-cam mechanism. The medial pivot implant design was developed to more closely mimic native knee motion, in the hope of improving function, and not primarily as a more constrained knee for difficult cases. In the past 10 to 12 years, a second-generation medial-pivot design has emerged, but there are no larger registry studies on the survival of these implants. Both cruciate-retaining and medial pivot designs are reported in the Australian and Norwegian registries, allowing for large-scale, comparative survivorship studies.

Questions/purposes (1) Is there any difference in survival between the medial pivot design and the three most commonly used cruciate-retaining TKA designs? (2) Is there any difference in survival among the different medial pivot implant designs? (3) What are the main indications for revision of medial pivot TKAs?

Methods Registry data from the Australian Orthopaedic Association National Joint Replacement Registry and Norwegian Arthroplasty Register from 2005 until the end of 2017 were used to compare the five different brands of medial pivot TKA designs (total primary TKAs assessed: 6310). In Australia, the study group of medial pivot implants represented 9% (6012 of 72,477) of the total number of cemented/hybrid TKAs without patellar resurfacing; 345 had cementless femoral components. In Norway, the study group represented 1% (298 of 47,820) of the total number of TKAs with cemented tibias without patellar resurfacing; all had cemented femoral components. The control group consisted of the three most commonly used cruciate-retaining TKA designs (n = 70,870; Australia n = 54,554; Norway n = 16,316). All TKAs used a fixed-bearing, cemented tibial component and did not involve patella resurfacing. Kaplan-Meier survival analysis was assessed to estimate survivorship. We compared the groups by calculating the hazard ratios (HR) using Cox regression adjusted for age, gender and preoperative diagnosis with 95% CI. To answer our third question, we calculated the percentage of each revision indication from the total number of revisions in each group, and used a Cox regression analysis to compare revision causes and HRs. Analyses were performed separately by each registry. Accounting for competing risks (Fine and Gray) did not alter our findings [12].

Results After controlling for potential confounding variables such as gender, age and preoperative diagnosis, we found an increased revision risk for the medial pivot compared with cruciate-retaining TKA designs in Australia (HR 1.4 [95% CI 1.2 to 1.7]; $p < 0.001$), but not in Norway (HR 1.5 [95% CI 0.9 to 2.4]; $p = 0.1$). Two brands of the medial pivot design reported to the AOANJRR showed an increased risk of revision compared with cruciate-retaining designs: the Advance® II MP (HR 1.7 [95% CI 1.2 to 2.6]; $p = 0.004$) and the GMK® Sphere (HR 2.0 [95% CI 1.5 to

2.6]; $p < 0.001$), whereas the MRK™ (HR 0.7 [95% CI 0.4 to 1.5]; $p = 0.4$), the Evolution® MP (HR 1.4 [95% CI 1.0 to 1.9]; $p = 0.06$) and the SAIPH® (HR 0.9 [95% CI 0.5 to 1.5]; $p = 0.7$) showed no difference. The most common reasons for revision of medial pivot implants in Australia were infection (27%), pain alone (19%), patellar erosion (13%), loosening/lysis (12%); in Norway the primary indications were loosening/lysis (28%), instability (28%), malalignment (11%) and pain alone (11%).

Conclusions The medial pivot TKA design as a group had a higher revision rate than cruciate-retaining fixed-bearing controls in TKA performed without patellar component resurfacing. By brand, the Advance II MP and the GMK Sphere had inferior survivorship, whereas the MRK, the SAIPH and the Evolution MP had no differences in survivorship compared with cruciate-retaining controls. In Australia, TKAs with the medial pivot design without patella resurfacing had a higher rate of revisions for instability, malalignment, and patella erosion. In Norway, there was an increased risk of revision for lysis and loosening compared with the cruciate-retaining design. Several of these implants had short follow-up in this study. Further registry studies with longer follow up are therefore necessary.

Level of Evidence Level III, therapeutic study.

Introduction

TKA is a generally effective way to treat gonarthrosis. Still, not all patients achieve the desired result of decreased pain and increased function, and in some studies, as many as 20% are dissatisfied [3, 4]. Implants also perform differently with respect to survivorship, and the prosthesis design may contribute to these variations. Although there are a variety of prosthetic designs, primary TKA implants can be broadly classified into cruciate-retaining and posterior-stabilized implants [6]. Studies suggest that after TKA, there may be paradoxical motion of the lateral femoral condyle, and instead of femoral rollback during flexion, as occurs in the native knee [20], there may be anterior femoral translation [10]. This may lead to a sensation of instability, reduced quadriceps strength, and reduced flexion range of the knee [8-10, 35].

In the 1990s, the medial pivot design was introduced [19]. The medial pivot design tries to mimic the in vivo kinematics of the native knee. These fixed bearing implants have a medial conforming articulation, similar to a ball and socket. In the lateral compartment, the tibial insert is flat, and together with laxity of the lateral collateral ligament, theoretically allows natural femoral rollback during knee flexion. All the medial pivot implants in our study are also cruciate-sacrificing but without a post-cam mechanism [25, 27-29, 42]. The first TKA with a medial pivot design was the Medial Rotation Knee (MRK™, MatOrtho, Surrey, UK)

which was introduced in 1994, followed by the Advance[®] Medial-Pivot Knee in 1998 (Wright Medical Group Inc, Memphis, TN, USA) [1, 25]. A second generation of prostheses further developed the medial pivot theme, including the Evolution[®] Medial-Pivot Knee (MicroPort Orthopedics Inc, Arlington, TN, USA [42]), the SAIPH[®] Knee System (MatOrtho [28]) and the GMK[®] Sphere (Medacta International AG, Castel San Pietro, Switzerland [29]). As medial pivot implants have increased in popularity, the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) now classifies them in a separate medial pivot design category, and they accounted for 7% of the primary TKAs in Australia in 2017 [18].

Despite the growth in use of the medial pivot design, there is little knowledge of the longevity of these implants as a group or of different brands. Most studies are smaller clinical studies on the longevity of the Advance MP [21, 24, 36], or smaller clinical or fluoroscopic studies on the different implants' function [19, 35, 38]. To our knowledge, there have been no larger registry studies that address the survival of medial pivot implants before this study.

We used the databases of the AOANJRR and Norwegian Arthroplasty Register (NAR) to ask the following questions: (1) Is there any difference in survival between the medial pivot design and the three most commonly used cruciate-retaining TKA designs? (2) Is there any difference in survival among the different medial pivot implant designs? (3) What are the main indications for revision of medial pivot TKAs?

Patients and Methods

Study Design and Setting

This study derived its data from two national registries, the NAR and AOANJRR. From those, we identified all medial pivot TKAs from 2005 until the end of 2017. We compared these with a control group of the three most commonly used cruciate-retaining designs of TKA in Norway and Australia. The NAR began registering TKA data in 1994 [14, 15] and the AOANJRR began registering data 1999. Both registries have a completeness of 99% and 98%, respectively [11, 18]. Emigration from both countries was negligible in the elderly [2, 30].

Participants

Datasets from Australia and Norway from 2005 through 2017 (Fig. 1) were merged by creating common endpoints using the Australian hierarchy of revision diagnoses [18]. In Australia, the study group of implants (medial pivot) included the Evolution MP, the MRK, the SAIPH, the GMK

Sphere, the Advance MP II, which represented 9% (6012 of 72,477) of the total number of TKAs with cemented tibias without patella resurfacing; 345 had cementless femoral components. In Norway, only the Advance MP II, Evolution MP, and GMK Sphere were used during this period and represented 1% (298 of 47,820) of the total number of TKAs with cemented tibias without patella resurfacing, all with cemented femoral components. We thus included only fixed-bearing prostheses with cemented tibial components in TKA without patella resurfacing. The control group consisted of the three most commonly used fixed-bearing, cruciate-retaining TKA implants with a cemented tibial component in each country. This comparison group was chosen as fixation with or without cement for the femoral component yields equivalent survival [18]. The medial pivot design was primarily developed to mimic native knee motion to improve function, and not as a constrained knee for difficult cases. This is, however, likely the case for many of the posterior-stabilized TKA designs used in the registries (10% and 23% of the total number of primary TKAs in Norway and Australia respectively) [14, 18]. The control group therefore consisted of cemented tibia and uncemented or cemented femoral components from NexGen[®] CR (Zimmer Biomet, Warsaw, IN, USA), Triathlon[®] Total Knee System (Stryker, Mahwah, NJ, USA) and Legion Total Knee System (Smith and Nephew, Memphis, TN, USA) from Norway (n = 16,316) and NexGen[®] CR, PFC[®] Sigma[®] (DePuy Orthopaedics Inc, Warsaw, IN, USA), and Triathlon[®] Total Knee System from Australia (n = 54,554). Patellar resurfacing is rarely performed in Norway, but the survival of both medial pivot and cruciate-retaining TKA designs has been shown to improve with patellar resurfacing [18]. In Sweden, about 2% of TKAs have the patella resurfaced [33], and The National Joint Registry of England and Wales reported 42% of their TKAs have resurfaced patellae [26]. In addition, for the medial pivot as a group reported in the AOANJRR, 47% (6740 of 14,421) of the TKAs did not have a resurfaced patella. In fact, 2017 was the only year in our study period (2005-2017) that patellar resurfaced TKAs outnumbered un-resurfaced patellar TKAs [18]. To minimize confounding because of the changing proportion of patellar component use over time, we therefore excluded all patients with patella resurfacing.

Variables, Outcome Measures, Data sources, and Bias

Our primary study endpoint for our first question was to determine if there was a difference in survival between the medial pivot design and the three most commonly used cruciate-retaining TKA designs. We investigated this by assessing the Kaplan-Meier estimates of survivorship, and compared the groups by calculating the hazard ratios using Cox regression. We used this approach for our second

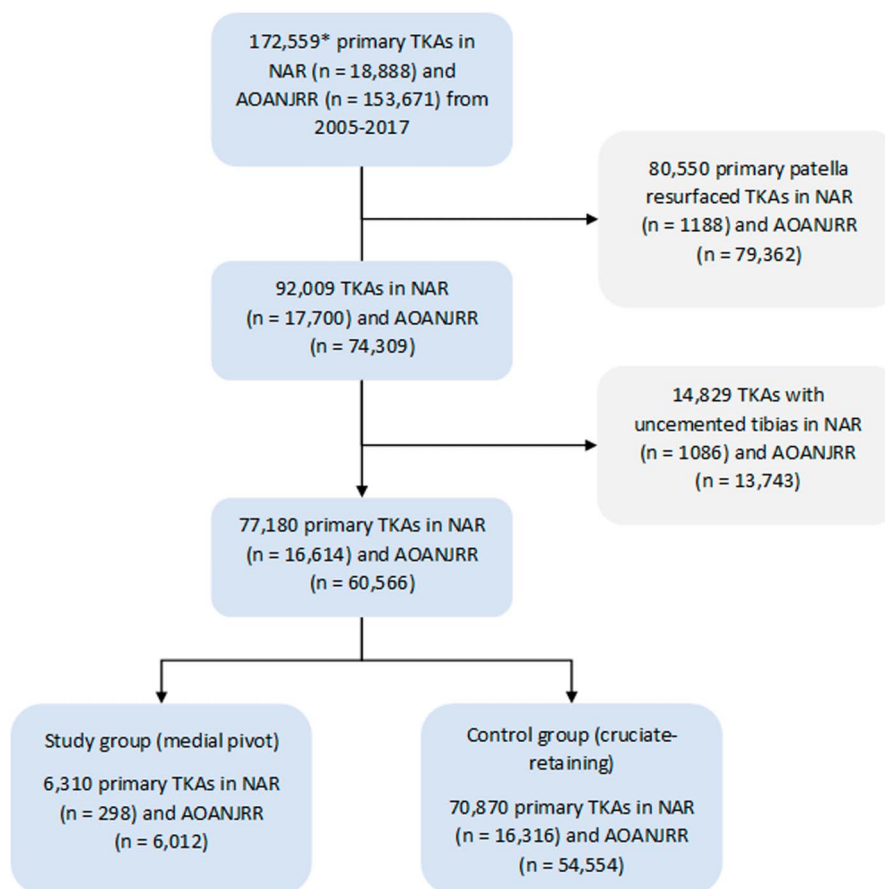


Fig. 1 This flowchart shows the patients who were included in the study; NAR = the Norwegian Arthroplasty Register, AOANJRR = the Australian Orthopaedic Association National Joint Replacement Registry. *Three most used cruciate-retaining and all-medial pivot TKAs.

question as well. For our third question, we calculated the percentage of each revision indication of the total number of revisions in each group for both nations. In addition, we calculated hazard ratios of the different revision causes, based on the Australian hierarchy of revisions [18]. To limit bias, we adjusted for gender, age, and preoperative diagnosis.

Demographics, Description of Study Population

The proportion of men in the study group was almost identical between the two databases (48% in the NAR versus 49% in the AOANJRR) (Table 1), whereas in the control group, there was a difference in the proportion of men between the databases (40% in the NAR versus 44% in the AOANJRR; $p < 0.001$). The mean ages in the study group (NAR, 68 years; AOANJRR, 68 years) and control group (NAR, 69 years; AOANJRR, 69 years) were comparable. The proportion of patients with a preoperative diagnosis of osteoarthritis differed between the countries (study group NAR 92% versus AOANJRR 99%;

$p < 0.001$; control group NAR 92% versus AOANJRR 99%; $p < 0.001$).

As the Advance MP I was reported in the AOANJRR as having an unfavorable result [18], we reviewed all of the catalog numbers of this implant in both countries; only four such tibial implants were used in Australia from 2005 to 2017. The remaining Advance MP implants in Australia and all implants in Norway were Advance® MP II implants (Table 2). Advance MP I was thus excluded from further analyses.

Statistical Analysis, Study Size

We used the chi-square test to compare dichotomous data (that is, gender and preoperative diagnosis) and a two-sided t-test for continuous distributed data (age differences). P values < 0.05 were regarded as statistically significant. Kaplan-Meier estimates of implant failure are clinically meaningful and straightforward to interpret for clinicians, and recommended by the Nordic Arthroplasty Register Association (NARA) study group [32] and used by the NAR

Table 1. Demographics of the study and control groups

Variable	Study group: medial pivot designs		p value	Control group: cruciate-retaining designs		p value
	Norway (n = 298)	Australia (n = 6012)		Norway (n = 16,316)	Australia (n = 54,554)	
Men (%)	48	48	0.9	40	43	< 0.001
Age (years), mean ± SD	68 ± 10	68 ± 9	0.6	69 ± 10	69 ± 9	0.8
Diagnosis (%)						
Osteoarthritis	92	99	< 0.001	92	99	< 0.001
Other	8	2		9	1	

[14]. The AOANJRR uses the complement to this, the cumulative percent revision [18]. In the AOANJRR, Kaplan-Meier estimates were made for 9-year survival stratified by group and country, and 3-year and 9-year survival by medial pivot brand. Survival tables and curves were constructed. A Cox regression analysis of the groups, stratified by country with revision for any cause, and analysis for competing risk from death using the methods of Fine and Gray [12], was also performed. We also performed Cox regression analyses to investigate causes of revision and HR in Norway and Australia. Whenever crossing curves were displayed, we performed individual Cox regression analyses before and after they intersected to test whether the assumption of proportional hazards could be applied. Cox regression analyses of the main reasons for revision of medial pivot and cruciate-retaining implants in Norway and Australia were also performed. The Advance MP is under special follow-up in the AOANJRR, so we also constructed plots and Cox regression analyses of the study group without this implant. Many medial pivot implant revisions in Australia were performed for patella erosion or pain alone. For this reason, we performed a sensitivity analysis for Australia excluding all revisions for these two diagnoses whenever the revision involved a secondary patella insertion only or patella insertion and exchange of the insert. For Australia, we also performed Cox regression analyses of the individual medial pivot implants, with the cruciate-retaining group as a control. Such an analysis was not possible for the implants

reported in the NAR because of the low number of cruciate-retaining implants. All Cox regression analyses and Kaplan-Meier estimates are given with 95% CIs, the former always adjusted for age, gender, and preoperative diagnosis. SPSS® Statistics version 25 (IBM Corp, Armonk, NY, USA) and R version 3.5.3 (The R Foundation for Statistical Computing, Vienna, Austria) was used for the statistical analyses.

Results

Is There Any Difference in the Survival Rate Between Medial Pivot and Cruciate-retaining TKAs?

The medial pivot group had poorer survivorship than the cruciate-retaining group in Australia. After controlling for potential confounding variables such as age, gender and preoperative diagnosis, we found an increased HR for revision for any cause for medial pivot designs compared with cruciate-retaining TKAs in Australia (HR 1.4 [95% CI 1.2 to 1.7]; p < 0.001) but not in Norway (HR 1.5 [95% CI 0.9 to 2.4]; p = 0.1) (Table 3). The Fine and Gray analysis with death as the competing risk was identical [12]. In Australia, the Kaplan-Meier 9-year survival with revision for any cause was 94.8% (95% CI 93.4 to 96.3) for the medial pivot designs and 96.4% (95% CI 96.2 to 96.6) for cruciate-retaining TKAs (Fig. 2). In Norway, the corresponding survival for the medial pivot designs was 92.2%

Table 2. Number of implants by group and by brand in Norway and Australia

Medial pivot brands (n)	Medial pivot designs		Cruciate-retaining brands (n)	Cruciate-retaining designs	
	Norway	Australia		Norway	Australia
GMK® Sphere	31	2122	Triathlon® CR	2519	25,604
Advance® MP	0	4	Legion® CR	2703	
Advance® II MP	216	492	NexGen® CR	11,094	19,378
MRK™	0	425	PFC® Sigma®		9572
SAIPH®	0	834	Total cruciate-retaining	16,316	54,554
Evolution® MP	51	2135			
Total medial pivot	298	6012			

Table 3. Cox HR revision for any cause (HR1) and lysis or loosening (HR2) comparing the control (ref.) and study groups in Norway and Australia

Group	Implant type	Total (n)	Revised for aseptic loosening		Median follow-up (years)	Kaplan-Meier 9-year all cause		At risk (n)	Kaplan-Meier 9-year loosening		At risk (n)	Cox HR1 (95% CI)	Cox HR2 (95% CI)
			n (%)	n (%)		(95% CI)	p value ^a		(95% CI)	p value ^a			
Norway													
Control ^b	Cruciate-retaining	16,316	43 (0.3)	418	2.7	94.5 (93.8 to 95.2)	0.1	418	99.5 (99.3 to 99.7)	0.001	2158	1 (ref.)	1 (ref.)
Study ^c	Medial pivot	298	5 (1.7)	7	5.0	92.2 (89.0 to 95.4)		7	97.7 (95.7 to 99.7)		195	1.5 (0.9 to 2.4)	4.7 (1.8 to 12.0)
Australia													
Control ^d	Cruciate-retaining	54,554	242 (0.4)	4186	4.4	96.4 (96.2 to 96.6)	< 0.001	4186	99.4 (99.3 to 99.5)	0.3	4186	1 (ref.)	1 (ref.)
Study ^e	Medial pivot	6012	22 (0.4)	158	1.9	94.8 (93.4 to 96.3)		158	99.4 (98.3 to 99.5)		158	1.4 (1.2 to 1.7)	1.32 (0.8 to 2.2)

Both had 95% CIs and were adjusted for sex, age, and preoperative diagnosis.

^ap values are based on Cox regression analyses.

^bNexGen, Triathlon and Legend Study.

^cGMK® Sphere, Advance® II MP and Evolution® MP. Control.

^dNexGen® CR, Triathlon® CR and PFC® Sigma®. Study.

^eAdvance® II MP, Evolution® MP, SAIPH®, MRK™ and GMK® Sphere.

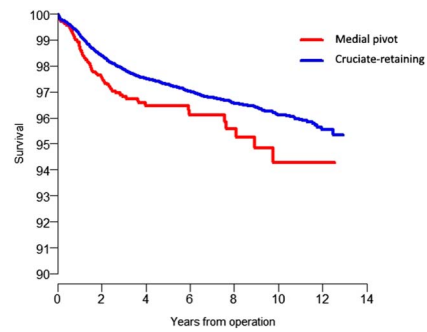


Fig. 2 This graph shows survival functions of the medial pivot and cruciate-retaining designs in Australia. Curves end when 20 patients are left at risk.

(95% CI 89.0 to 95.4) and for the cruciate-retaining it was 94.5% (95% CI 93.8 to 95.2) (Fig. 3). The Kaplan-Meier survival curves of Norway crossed at 1.7 years (Fig. 4A). The HR before this time point (0.5 [95% CI 0.1 to 2.1]; p = 0.4) and after (2.1 [95% CI 1.2 to 4.0]; p = 0.02) was therefore calculated (Fig. 4B).

Is There Any Difference in Survival Between the Different Medial Pivot Implants?

There were prosthesis-specific differences in revision rates (Table 4). In Australia, the Advance MP II had a higher all-cause revision than cruciate-retaining implants (HR 1.7 [95% CI 1.2 to 2.6]; p < 0.004) (Fig. 5A). The same was true for the GMK Sphere (HR 2.0 [95% CI 1.5 to 2.6]; p < 0.001) (Fig. 5B). There was no difference in the HRs of the Evolution MP (1.4 [95% CI 1.0 to 1.9]; p = 0.06) (Fig. 5C), the MRK (0.7 [95% CI 0.4 to 1.5]; p = 0.4) (Fig. 5D), and the SAIPH (0.9 [95% CI 0.5 to 1.5]; p = 0.7) (Fig. 5E). The Kaplan-Meier plot of the medial pivot in the AOANJRR, excluding the Advance MP II, showed an HR of 1.4 (95% CI 1.1 to 1.7; p < 0.001) (Fig. 6).

What Are the Main Reasons for Revision of Medial Pivot TKA?

In Norway, the most frequent reasons for revision in the medial pivot group were lysis or loosening (28%, five of 18), instability (28%, five of 18), malalignment (11%, two of 18) and pain alone (11%, two of 18), while in Australia, they were infection (27%, 39 of 142), pain alone (19%, 27 of 142), patella erosion (13%, 19 of 142) and loosening (12%, 17 of 142) (Table 5). By comparison, the reasons for revision in Norway for the cruciate-retaining group were infection (34%, 176 of 519), instability (19%, 97 of 519), malalignment (13%, 70 of 519), and pain alone (12%, 64 of 519). In Australia, pain alone (30%, 393 of 1324), infection (25%,

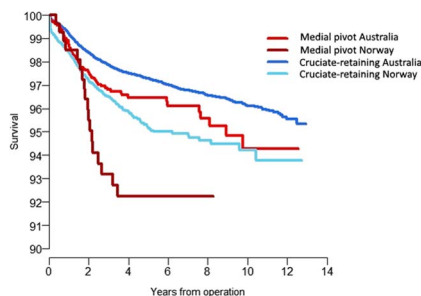


Fig. 3 This graph shows the survival function of the medial pivot and cruciate-retaining designs in Norway and Australia. Curves end when 20 patients are left at risk.

333 of 1324), lysis or loosening (15%, 199 of 1324) and patella erosion (10%, 130 of 1324) were the most frequent reasons for revision in the control group. The sensitivity analysis did not affect the HR for Australia (HR 1.5 [95% CI 1.2 to 1.9]; $p < 0.001$) (Fig. 7). Stratified by the reasons for revision, for Australia, we found there was an increased risk of revision in the medial pivot group for malalignment (HR 4.9 [95% CI 1.9 to 12.5]; $p < 0.001$), instability (HR 1.9 [95% CI 1.1 to 3.4]; $p = 0.03$), and patella erosion (HR 2.2 [95% CI 1.4 to 3.6]; $p < 0.001$) (Table 6). In Norway, there was an increased risk for loosening or lysis (HR 4.7 [95% CI 1.8 to 12.0]; $p < 0.001$) (Table 3).

Discussion

Despite the increased usage of medial pivot implants as documented in international registries, no registry studies on this design as a group have been published to our

knowledge. We therefore performed this large registry study to compare the survival of medial pivot TKAs with the most-used cruciate-retaining implants in Norway and Australia. Our main finding was that there was decreased Kaplan-Meier survival of the medial pivot designs compared with cruciate-retaining designs, although differences between individual brands existed.

Limitations

Our study has several limitations. First, because it was a national registry study, we cannot rule out selection bias, with the medial pivot design potentially chosen for a more active patient group. There were differences in gender distribution and preoperative diagnosis, but the Cox regression analysis adjusted for these differences. Second, although we adjusted for the preoperative diagnosis, we did not have any information about the severity of osteoarthritis or extent of preoperative malalignment. In the AOANJRR [18], more than 23% of all TKAs were posterior-stabilized designs, which are often preferred for more difficult procedures [33]. Theoretically, the medial pivot could be used as a substitute for posterior-stabilized designs in such cases, and this might partly explain the difference in HR. Third, we did not adjust for hospital or surgeon volume. Because medial pivots are newer implants, there might be more of a learning curve than with the cruciate-retaining design. Fourth, there was an uneven distribution of prosthesis types between the countries. The difference between the Advance MP I and II was the locking mechanism of the tibial insert [13]. In Norway, almost all medial pivot implants were the Advance MP II.

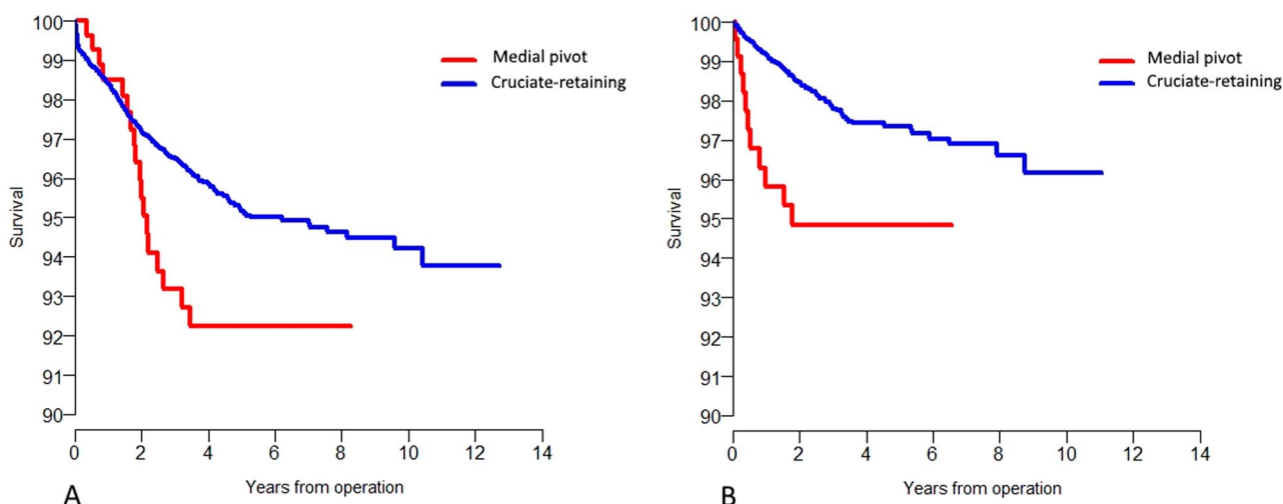


Fig. 4 A-B These graphs show (A) the survival function of the medial pivot and cruciate-retaining designs in Norway and (B) after crossing of the curves at 1.68 years. Curves end when 20 patients are left at risk

Table 4. Cox regression analyses comparing medial pivot brands to cruciate-retaining controls in Australia

Medial pivot brand	Cox HR ^a		Cox HR ^b		Kaplan-Meier ^e		Kaplan-Meier ^e		Median follow-up
	(95% CI)	p value	(95% CI)	p value	3 years (95% CI)	Left at risk	9 years (95% CI)	Left at risk	
Advance® II MP	1.7 ^d (1.2 to 2.6)	0.004	1.2 ^d (0.4 to 3.8)	0.7	96.2 (94.4 to 97.9)	413	93.5 (90.9 to 96.0)	202	7.9
MRK™	0.7 ^d (0.4 to 1.5)	0.4	1.2 ^d (0.3 to 4.9)	0.8	97.9 (96.5 to 99.4)	305	97.9 (96.5 to 99.4)	20	5.4
Evolution® MP	1.4 ^d (1.0 to 1.9)	0.06	1.9 ^d (0.9 to 4.1)	0.09	97.2 (96.2 to 98.1)	226			1.7
GMK® Sphere	2.0 ^d (1.5 to 2.6)	< 0.001	1.6 ^d (0.6 to 3.8)	0.3	95.9 (94.8 to 97.1)	289			1.5
SAIPH®	0.9 ^d (0.5 to 1.5)	0.7			97.9 (96.7 to 99.1)	323			2.3

Hazard ratio by ^arevision for any cause and ^blysis or loosening of medial pivot brands compared to minimally stabilized (NexGen® CR, Triathlon® CR and PFC® Sigma™) (^dreference HR = 1) controls in Australia. ^eKaplan-Meier survival estimates for 3 and 9 years when 20 or more implants were left at risk.

As stated earlier, the Advance® MP I was reported to have an inferior performance in the AOANJRR [18], so if similar performance plagues the Advance MP II, this could affect the survival and HR of the medial pivot group in Norway. The lack of findings in the Norwegian data could, of course, be partly explained by the small number of medial pivoting implants. Fifth, this study considered only survivorship and did not include patient-reported outcome

measures, which may be a more sensitive method of determining outcome differences and patient satisfaction. This was simply because we did not have this information. Furthermore, like most revision studies, the study does not account for those who may be candidates for revision, but who have too many comorbidities to undergo surgery or are awaiting surgery. Sixth, we only included TKAs with un-resurfaced patellae. This could affect the external

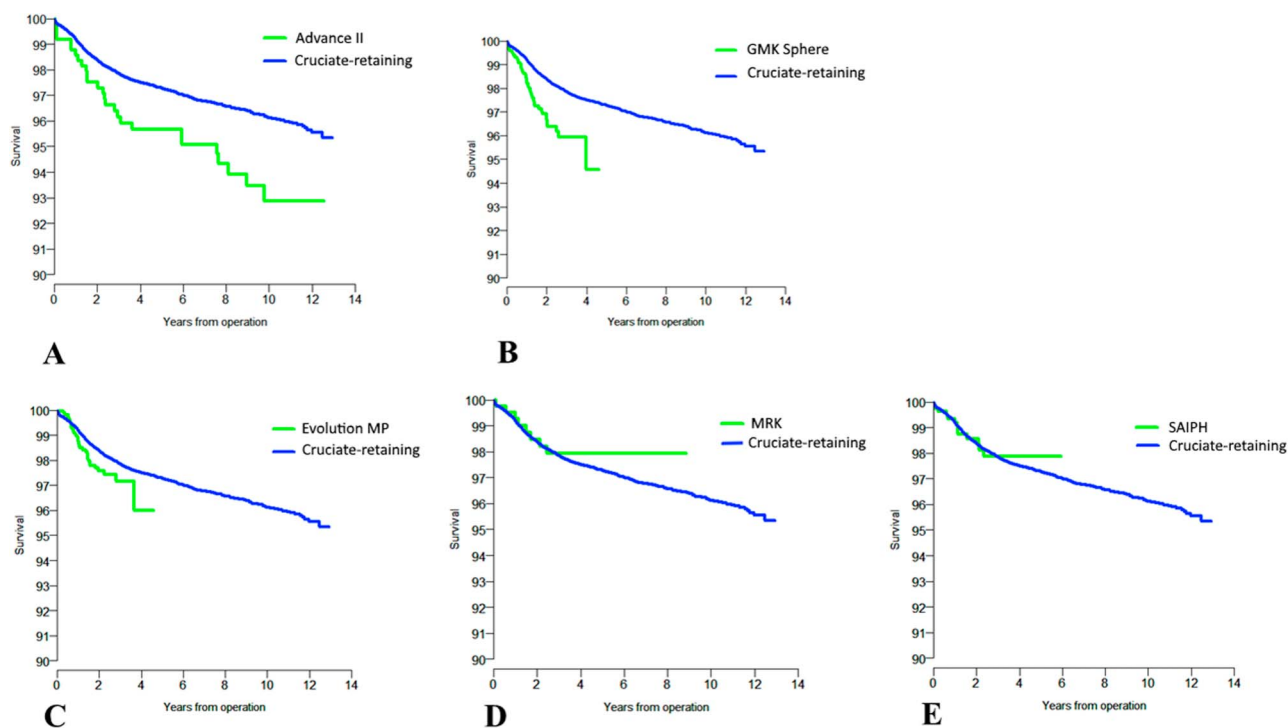


Fig. 5 These graphs show the survival function of the (A) Advance® II MP, (B) the GMK® Sphere, (C) the Evolution® MP, (D) the MRK™, and (E) the SAIPH® versus cruciate-retaining in Australia. Curves end when 20 patients are left at risk.

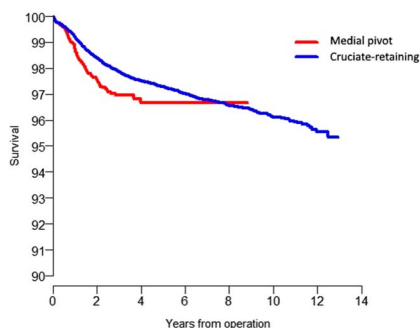


Fig. 6 This graph shows the survival function of the MP = medial pivot design, excluding the Advance® MP, versus cruciate-retaining design in Australia. Curves end when 20 patients are left at risk.

validity of the study, but only in countries where resurfacing is done more or less by default for reasons stated earlier [14, 18, 33]. One study recently implied that post-operative retropatellar pressure is low in medial pivot implants [17], yet our study showed there is an increased risk for revision due to patellar erosion.

Is There Any Difference in the Survival Rate Between Medial Pivot and Cruciate-retaining TKAs?

Medial pivot implants have a higher revision risk than cruciate-retaining implants do in Australia for primary

Table 5. Reason for revision of medial pivot and cruciate-retaining implants in Norway and Australia following the hierarchy of the AOANJRR

Revision diagnosis	Medial pivot		Cruciate-retaining	
	Norway n = 298	Australia n = 6012	Norway n = 16,316	Australia n = 54,554
Not revised (n)	280	5870	15,797	53,230
Total number revised (%)	18 (6)	142 (2)	519 (3)	1324 (2)
Infection	1 (6)	39 (27)	176 (34)	333 (25)
Malalignment	2 (11)	6 (4)	70 (13)	17 (1)
Loosening or lysis	5 (28)	17 (12)	43 (8)	199 (15)
Instability	5 (28)	13 (9)	97 (19)	97 (7)
Pain alone	2 (11)	27 (19)	64 (12)	393 (30)
Patella erosion ^a	0 (0)	19 (13)	3 (1)	130 (10)
Other ^b	3 (16)	21 (15)	66 (13)	155 (12)

Numbers in parentheses are the percentage of all revisions in each category.

^aPatella erosion or progression of disease.

^bOther means the remaining reasons for revision are not listed here; AOANJRR = Australian Orthopaedic Association National Joint Replacement Registry.

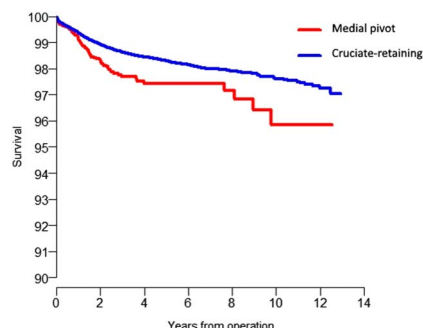


Fig. 7 This graph shows the sensitivity analysis for Australia. All revisions for “pain alone” and “patella erosion” and minor revision surgery for “patella only” or “patella/insert” combined were excluded before the Cox regression analysis. Curves end when 20 patients are left at risk.

cemented TKAs without patella resurfacing. We found no such difference in Norway, and the confidence intervals were very wide. To our knowledge, there have been no larger registry or clinical studies on the medial pivot design TKA as a group. There was one smaller registry study [5], and one review article [13], but they assessed only the Advance MP and in a limited number of patients. Both studies concluded with excellent survival results. Furthermore, one other review article assessed medial pivot implants [44], but this also included primarily studies on the Advance MP. They compared the medial pivot design with non-medial stabilized design and were “unable to reach a clear conclusion in the clinical performance of medial stabilized knee replacement construct” [44]. Only three studies included in this review were not on the Advance MP, and only one was a high-quality study on the MRK™ [19]. Our study is to date the most comprehensive study on the matter, and therefore, we think it adds substantial knowledge to the field of interest; however, the results should be treated with caution because the follow-up period for most of the implants was short.

Is There Any Difference in Survival Between the Different Medial Pivot Implants?

In the analysis of individual implants, the Advance MP II and the GMK Sphere had a higher revision risk than the other implants, the latter at only 3 years of follow-up. The Evolution MP, the SAIPH, and the MRK, in contrast, have survival results similar to the three most-used cruciate-retaining implants in Australia. The SAIPH and the MRK had some revisions within the first 2 years of implantation, but no further revisions in the time frame studied, in contrast to the Advance MP II, the GMK Sphere and the Evolution MP. The latter three continue to have documented revision surgery after 2 years postoperatively (Fig. 5). The Advance MP I has

Table 6. Cox regression hazard ratios (95% CIs) of various causes of revision for medial pivot versus cruciate-retaining controls in Norway and Australia

Cause for revision	Norway ^a		p value	Australia ^a		p value
	Cruciate retaining	Medial pivot		Cruciate retaining	Medial pivot	
Number	16,316	298		54,554	6012	
Infection	0.3 (0.0 to 1.9)		0.2	1.3 (0.9 to 1.8)		0.1
Malalignment	1.0 (0.3 to 4.3)		1.0	4.9 (1.9 to 12.5)		< 0.001
Instability	2.1 (0.9 to 5.2)		0.1	1.9 (1.1 to 3.4)		0.03
Pain alone	1.4 (0.3 to 5.6)		0.7	1.0 (0.7 to 1.5)		1.0
Patellar erosion ^b	c		c	2.2 (1.4 to 3.6)		0.001

^aCruciate-retaining controls have HR = 1 for the various revision causes.

^bPatellar erosion or disease progression.

^cNo operations for this indication were performed in Norway.

been shown to have a higher-than-anticipated revision rate [18], and we therefore excluded the Advance MP II from the Cox regression analysis. This did not affect the relative risk of the medial pivot as a group. One explanation for this could be that the total number of Advance MP II implants accounted for only 8% of the medial pivot implants used between 2005 and 2017, and thus had a relatively low impact on the overall results. There have been numerous studies on these individual implants. Some have suggested the in vivo kinematics of their design are like the native knee [38, 39], but some of the studies included very few patients [23, 37]. Smaller survivorship studies also show they have good-to-excellent survivorship [22] and patient satisfaction [34], but others report they do not have better functional results than other designs [43]. The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) report excellent results of the MRK, and good results of the Advance MP. In their report they did not discriminate between Advance MP I and II [26]. Despite numerous studies on the design, ours is the first to document inferior results with the Advance MP II and the GMK Sphere. It therefore highlights a gap in the documentation on the different medial pivot implants because we do not know the reason why they perform differently. Further studies are thus necessary.

What Are the Main Reasons for Revision of Medial Pivot TKA?

The main reasons for revision in absolute numbers, in the medial pivot group in Norway were lysis or loosening, instability, malalignment, and pain alone. The total number of revisions was, however, very small. In Australia, the main reasons in absolute numbers were infection, pain alone, patella erosion, and loosening/lysis. Infection, loosening/lysis, and pain alone are frequent reasons for revision of cruciate-retaining implants in the AOANJRR as well. In terms of

Kaplan-Meier survival, only patella erosion as a revision indication showed poorer survival. All of these are frequent and well-known reasons for TKA revision [14, 18, 31], although the main indications differ in other reports [40]. However, we documented a near fivefold risk of revision for malalignment, and a doubled risk of revision for instability in Australia for medial pivot designs compared with cruciate-retaining implants. Some reports indicate that medial pivot design improve patellofemoral biomechanics [1, 17, 42], possibly due to the lack of medial translation and the lateral femoral rollback [39]. However, other studies fail to report this [7]. We excluded all primary resurfaced patellar implants from our study, and therefore performed a sensitivity analysis to examine whether there was a change in the HR when we excluded secondary patella insertions combined with patella erosion or pain alone as revision indications. This did not affect the HR. We do not think that the status of the patella in terms of resurfacing affected the relative risk of revision for malalignment and instability. Therefore, it is likely that this finding applies for all medial pivot design TKA procedures, regardless of resurfacing. Although all the medial pivot implants in the study were cruciate-sacrificing, they still have no post-cam mechanism and are dependent on the medial femoral condyle resting snugly in the congruent insert for appropriate kinematics. If this is not achieved, instability might partially explain the higher revision risk due to patella erosion and subsequent increased forces on the patella. The medial congruency of these implants could in theory also lead to loosening [16, 41].

Conclusions

This large registry study that captured data from two countries between 2005 and 2017 showed that the medial pivot TKA design as a group had a higher revision rate than cruciate-retaining fixed-bearing controls in TKA

performed without patellar component resurfacing. By brand, the Advance II MP and the GMK Sphere had inferior survivorship, whereas the MRK, SAIPH and the Evolution MP had no differences in survivorship compared with cruciate-retaining controls. In Australia, TKAs with the medial pivot design without patella resurfacing had a higher rate of revisions for instability, malalignment, and patella erosion. In Norway, there was an increased risk of lysis and loosening compared with those with the cruciate-retaining design. Several of these implants had short follow-up in this study. Further registry studies with longer follow up are therefore necessary.

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