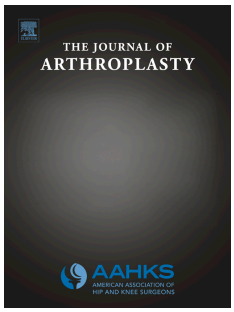
# Accepted Manuscript




Mid-term Performance of a Guided Motion Bicruciate Stabilized Total Knee System: Results from the International Study of Over 2,000 Consecutive Primary Total Knee Arthroplasties

Adam I. Harris, MD, Bernhard Christen, MD, Jan J. Malcorps, MD, Christopher P. O'Grady, MD, Branko Kopjar, MD, PhD, MS, FACE, Paul R. Sensiba, MD, Hilde Vandenneucker, MD, PhD, Bill K. Huang, MD, Harold E. Cates, MD, John Hur, MD, Dante A. Marra, MD

PII: S0883-5403(19)30146-9

DOI: https://doi.org/10.1016/j.arth.2019.02.011

Reference: YARTH 57067

To appear in: *The Journal of Arthroplasty*

Received Date: 1 December 2018

Revised Date: 30 January 2019

Accepted Date: 8 February 2019

Please cite this article as: Harris AI, Christen B, Malcorps JJ, O'Grady CP, Kopjar B, Sensiba PR, Vandenneucker H, Huang BK, Cates HE, Hur J, Marra DA, Mid-term Performance of a Guided Motion Bicruciate Stabilized Total Knee System: Results from the International Study of Over 2,000 Consecutive Primary Total Knee Arthroplasties, *The Journal of Arthroplasty* (2019), doi: https://doi.org/10.1016/j.arth.2019.02.011.

# Mid-term Performance of a Guided Motion Bicruciate Stabilized Total Knee System: Results from the International Study of Over 2,000 Consecutive Primary Total Knee Arthroplasties

Adam I. Harris, MD[a]
Bernhard Christen, MD[b]
Jan J. Malcorps, MD[c]
Christopher P. O'Grady, MD[d]
Branko Kopjar, MD, PhD, MS, FACE[e]
**Writing Committee:**
Paul R. Sensiba, MD[f]
Hilde Vandenneucker, MD, PhD[g]
Bill K. Huang, MD[h]
Harold E. Cates, MD[i]
John Hur, MD[j]
Dante A. Marra, MD[k]

[a]San Antonio Orthopaedic Specialists, San Antonio, TX USA
[b]ChristenOrtho AG, Bern, Switzerland
[c]Jessa Ziekenhuis, Herk-De-Stad, Belgium
[d]Andrews Research & Education Foundation, Gulf Breeze, FL USA
[e]University of Washington, Dept. of Health Services, Seattle, WA USA
**Writing Committee**
[f]University Orthopedics Center, State College, PA USA
[g]University Hospitals Leuven, Leuven, Belgium
[h]Everett Bone & Joint Proliance Surgeons, Inc, Everett, WA USA
[i] Tennessee Orthopaedic Foundation for Education and Research (TOFER), Knoxville, TN, USA
[j]ethodist Sports Medicine, Indianapolis, IN USA
[k]Marra Knee and Shoulder Center Inc., Wheeling, WV USA

**Corresponding Author:**
Adam I. Harris, MD
San Antonio Orthopaedic Specialists
325 East Sonterra Blvd
Suite 220
San Antonio, TX, 78258 USA
Phone: 210-614-5100
Fax: 210-614-5103
Email: aiharris@saorthospecialists.com

# Mid-term Performance of a Guided Motion Bicruciate Stabilized Total Knee System: Results from the International Study of Over 2,000 Consecutive Primary Total Knee Arthroplasties


## Abstract

**Background**: The JOURNEY™ II Bi-Cruciate Stabilizing Total Knee System (BLINDED) is a second-generation guided-motion knee implant that has been used in over 100,000 primary total knee arthroplasties (TKAs) worldwide. However, performance information is limited.

**Methods**: Data for 2,059 primary TKAs were abstracted at seven US and three European sites. Estimates of cumulative incidence of revision were compared with registry data for cemented posterior stabilized implants.

**Results**: Average age was 64.3 years (range 18-91); 58.5% were females; 12.3% TKAs were in subjects younger than 55 years. Patellae were resurfaced in 95.9%. Median time since primary TKA was 4.2 years; longest was 6.1 years; 78.9% were three years or more since primary TKA. Of 67 revisions (3.2%), 20 (30%) involved femoral or tibial component removal compared to 42% in the Australian Joint Registry (AOANJRR). All-component revisions accounted for 15/67, femoral component only for 2/67, tibial component only for 3/67, patellar component with/without tibial insert exchange for 17/67, and isolated tibial insert exchange for 30/67. In addition, there were 18 re-operations without component exchange. Component revision indications were infection (33%), mechanical loosening (21%), fracture of bone around the joint (16%), and instability (15%). Kaplan-Meier revision estimate was 3.1 and 3.6 per 100 TKAs at three and five years, respectively, compared to AOANJRR estimates of 3.1 and 4.1 per 100 TKAs.

**Conclusion:** The revision rate for the second-generation implant was similar to cemented posterior-stabilized registry controls.


**Key Words:** Total knee arthroplasty; Bi-cruciate; Guided motion; Kaplan-Meier; Revision; Posterior stabilized

## Introduction

Total knee arthroplasty (TKA) is a safe and effective procedure performed for reducing pain and improving function in patients with end-stage joint degeneration caused by arthritis [1]. Joint revision registries with long-term follow-up from the United Kingdom (the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR)) [2] and Australia (the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)) [3] show that TKA implants have a survival rate of over 90% at 10 years post-implantation. The American Joint Replacement Registry (AJRR) [4] has not yet provided survivorship estimates.

Revision surgery for failed TKAs poses a significant clinical and economic burden. In the United States (US), 5%-8% of all TKA procedures are revision surgeries [4,5], for which the average estimated cost is $75,000 [6]. Revision data from the UK and Australian joint registries are utilized to regulate joint implants on the market. Various countries, including Norway, Denmark, Belgium and Switzerland, have establishing their own joint registries.

Several new knee implants have been introduced aiming for better stability and a higher degree of flexion [7-9]. The JOURNEY™ II Bi-Cruciate Stabilizing Total Knee System (JOURNEY™ II BCS) (BLINDED) is a second-generation guided-motion total knee system. It replaced the first-generation system in November 2011. At this time there are no other bicruciate stabilized knee implant designs, thus the posterior stabilized (PS) design is the next closest comparator. The PS knee has a post that articulates with a posterior bar between the femoral condyles limiting posterior translation of the tibia relative to the femur. The bicruciate stabilized knee has this same articulating post, but the post also articulates with the femoral component at the top of the box limiting anterior translation, thus mimicking ACL function. Journey II BCS is currently the only marketed guided-motion knee implant. The system has been used in over 70,000 TKAs in the US and more than 30,000 TKAs outside the US (manufacturer sales data, December 2017).

Recently, a small study reported a short-term cumulative revision rate of 1.5% (95% C.I. 0.5% – 4.5%) at two years post-operative for the JOURNEY™ II BCS in 209 TKAs [10]. Due to the small sample, the confidence intervals of the revision estimate were wide. In Australia, the implant has had limited exposure with only 145 primary TKAs performed. Since 2016, the

implant has had greater exposure in the UK. The implant survivorship beyond the short-term follow-up is unknown.

We conducted a larger study to analyze the types and reasons for revision and to compare the mid-term risk of revision of JOURNEY™ II BCS with registry controls.

## Materials and Methods

This was a multicenter, international, retrospective, consecutive case-series study (clinicaltrial.gov BLINDED) involving seven sites in the US and three in Europe (one in Switzerland and two in Belgium). Sites were selected based on volume, logistical evaluation of quality and availability of the retrospective data and site willingness to participate in the study. All consecutive subjects who received a primary uni- or bilateral TKA for an approved indication (rheumatoid arthritis, post-traumatic arthritis, osteoarthritis, degenerative arthritis, or failed osteotomy in subjects with intact collateral ligaments) were included. For subjects with bilateral TKAs, both TKAs were included.

### *Ethics*

The implant is cleared for use by the US Food and Drug Administration (FDA) and is CE-marked in Europe. Prior to initiating any study related activities, all sites obtained approval from an Institutional Review Board (US sites) or Ethics Committee (European sites).

### *Data Quality Assurance*

Study operations and data quality were managed by an independent Contract Research Organization. All data were monitored for completeness and accuracy with a combination of on-site and remote monitoring. During the on-site monitoring, 100% source data verification (SDV) was performed for revision and post-TKA surgical interventions. All revisions, whether performed by the primary surgeon or another surgeon, were included in the analysis. Referrals

for revision to outside institutions, and revisions occurring elsewhere but known to the site, were included. All sites but one in Belgium had electronic medical records.

Orthopedic clinic records and all other pertinent medical records for all subjects were reviewed. All adverse events were centrally reviewed for possible missed revisions and non-revision secondary surgeries.

*Statistical Analysis*

There is no statistical methodology to determine the sample size for this type of study. Registries commonly use a threshold of 250 to 300 TKAs as a stable reliable estimate. We enrolled 2,059 TKAs of which 354 TKAs had at least a five-year follow-up. Consequently, the sample size was sufficient to provide reliable estimates of mid-term survivorship of the implant. Since the implant was released to the market in November 2011, the mid-term survivorship is the longest survivorship data currently available for JOURNEY II BCS.

Revision was defined as replacement of any component of the implant, which is the definition used by the joint revision registries. Kaplan-Meier (K-M) approach was used to obtain estimates of implant survival. Confidence bands and pointwise estimates for the K-M survivor function were based on the Hall-Wellner approach with a log-log transformation. Cumulative incidence of revision was calculated as (1-survival probability). Only four deaths were observed in the sample; therefore, no adjustment was made for the competing risks. Due to the virtual absence of competing risk, the K-M estimates obtained in this study are the estimates of the cumulative incidence. Time-to-event was calculated as time elapsed between the date of primary implantation and the date of revision surgery (N=67). For subjects who did not have revision surgery, the time was censored at the time of death (N=4), at the time when the subject moved out of the area and was no longer under the care of the institution that performed the index TKA (N=21), or at the time of completion of data abstraction (N=1,592), whichever occurred first.

There is no reliable national estimate of revision rates for primary TKA in the US. For a comparator, we used K-M estimates for posterior-stabilized TKAs from the 2017 AOANJRR

report [3]. The cemented posterior-stabilized primary TKAs are closest in design considerations to the study device. The AOANJRR registry control data are provided in the aggregated form only; therefore, no statistical testing was possible. However, lack of overlap in the confidence intervals between the study data and the registry controls indicates significant differences. The AOANJRR was selected for the registry controls instead of the UK NJR because the UK NJR is limited by a higher degree of underreporting of knee revisions than the AOANJRR [2]. Furthermore, the UK National Health Service has extensive waiting lists of patients requiring joint replacement surgery which may affect the comparability of the revision rates between our study and one in the UK.

All analyses were performed using SAS/STAT software, Version 9.4 of the SAS System for Windows (copyright © 2013 SAS Institute, Inc.).

**Results**

The data abstraction was performed between January and December 2017. Abstraction included 2,059 TKAs performed between November 2011 and February 2017 in 1,684 consecutive patients at seven US (1,721 TKAs) and three European (338 TKAs) sites. The average age was 64.31 (SD = 9.02) years; 41.52% were males (**Table 1**). Subjects younger than 55 years of age accounted for 12.3%; only 13.8% were 75 years or older. A majority (59.61%) of the subjects were obese (BMI 30 $kg/m^2$ or more). Four subjects expired during the study time of causes unrelated to TKA.

Average time since the primary TKA procedure was 3.87 years (range 0.02 to 6.08 years); median time was 4.2 years; longest time was 6.1 years. For a majority (78.88% TKAs), it had been three years or more since the primary TKA; for 17% (354 TKAs), it had been between five and six years since the primary TKA.

A majority (95.9%) of TKAs involved primary patella resurfacing. There were 61 surgeries that involved bilateral TKA implantation during the same surgery (122 TKAs); the remaining 1,937 TKAs were implanted during a single TKA surgery. Prophylactic antibiotics and deep vein

thrombosis (DVT) prophylaxis were provided in nearly all cases. Computer-assisted navigation was used in 16.0% of TKAs for femoral planning and in 14.2% of TKAs for tibial alignment.

The average duration of surgery for single TKA implantations was 81.2 minutes (SD=20.4, range 47- 202) and for bilateral implantations 102.4 minutes (SD=21.58, range 53- 148). The average length of hospital stay was 2.48 (SD = 1.02) days at the US sites and 8.00 (SD=2.63) days at the European sites ($P < .0001$).

There were 67 identified revisions. Of these, 30 (44.8%) were polyethylene tibial insert exchange only, 15 (22.4%) were total revisions, 17 (25.4%) were revisions of the patellar component (eight without polyethylene tibial insert exchange and nine with polyethylene insert exchange), three (4.5%) were revisions of only the tibial component, and two (3.0%) were revisions of only the femoral component. Altogether, 20 (29.85%) were classified as major revisions involving removal of the tibial plate or femoral component, compared to 41.6% of such revisions in AOANJRR data. The remaining 47 (70.15%) were minor revisions including removal of the patellar component and/or tibial insert (**Table 2**). Infection was the most common reason for revision, followed by mechanical loosening, fracture of bone around the joint, and implant instability (**Table 3**).

Twenty-seven percent (18/67) of all revisions occurred in the first 90 days. Simple exchange of polyethylene tibial insert accounted for 15/18 revisions that occurred in the first 90 days. The reasons for these 15 polyethylene exchanges were infection (n=10), instability (n=1), hematoma (n=1), trauma-related wound dehiscence (n=2), and mechanical impingement (n=1).

Cumulative incidence of revisions was 1.52 (95% C.I. 1.07 to 2.15) per 100 TKAs at one-year post-primary TKA, 3.12 (95% C.I. 2.44 to 4.00) per 100 TKAs at three-year post-primary TKA, and 3.58 (95% C.I. 2.82 to 4.55) per 100 TKAs at five-year post-primary TKA. There was a pronounced steep slope in the cumulative incidence of revision in the first 90 days post-TKA (**Figure 1**). The slope significantly reduced after three years post-operative.

Eleven revisions occurred in 338 TKAs at the three European sites and 56 revisions occurred in 1,721 TKAs at the seven US sites. There were no differences in cumulative incidence of revision between the US and the European sites (P=0.8292, **Figure 2**).

There was no difference in cumulative incidence of revision between TKAs implanted with and without computer assisted navigation (**Figure 3)**. Simple exchange of tibial insert had the highest cumulative incidence of 1.56 per 100 TKAs at five-year post-primary TKA, followed by patellar component revision (0.98 per 100 TKAs at five-year post-primary TKA), and total revision (0.80 per 100 TKAs at five-year post-primary TKA) (**Figure 4**).

The cumulative incidence of revisions was similar to the cumulative percent revision of cemented posterior stabilized AOANJRR registry controls **(Figure 5)**. There was a non-significant trend towards a lower rate in JOURNEY™ II BCS at five-years post-TKA.

**Figures 6a and 6b** show age- and sex-specific cumulative incidence estimates for JOURNEY™ II BCS subjects and cemented posterior stabilized AOANJRR registry controls. Compared to registry controls, the cumulative incidence of revisions was lower for males aged 55 or younger and higher for males aged 65-74 years. In females aged 55 years or younger, the cumulative incidence for JOURNEY™ II BCS subjects was lower compared to the registry controls. The cumulative incidences for other age groups were similar between the JOURNEY™ II BCS subjects and the registry controls.

There were eight secondary revisions in 7/67 TKAs (10.4%). One TKA with primary major revision (i.e., removal of the tibial or femoral component) required an additional minor revision; two primary minor revisions (i.e., removal of the patellar or tibial insert component) were converted into major revisions; three primary minor revisions required secondary minor revision; and one primary major revision required additional major revision.

**Discussion**

The mid-term revision risk of the second-generation guided-motion JOURNEY™ II BCS knee implant is similar to the registry controls for the cemented posterior-stabilized primary TKAs. The current study provides the longest available global revision risk estimate for the device. The sample size was large enough to provide reliable estimates at five years post-implantation. No other data source exists that can provide a similar estimate; foreign registries that contain data about the implant can provide short-term survival estimates only. At this time, the device has not been on the market long enough to provide an estimate of long-term revision rates.

Only about one in every five revisions involved all implant components and a conversion to a different implant. This figure is substantially less than the 63.9% reported in a recent large US claims data analysis [6]. Four out of 10 revisions were for tibial insert exchange only. Half of these isolated tibial liner exchanges occurred in the first 90 days post-TKA. The two primary indications for tibial liner exchange only were instability or infection, and infection is an established principal reason for revision in the first year following TKA [2]. Young patients who require TKA are a particularly challenging patient population. Registries show that the revision rates are highest in this patient population [2,3]. Activity levels decline with age [11-13]. When a patient is younger, and activity level is greater, a longer-surviving implant should be employed. The revision rate in young patients in this study is lower than the revision rates in young patients in the registry controls. This lower rate, which holds for both males and females when evaluated separately, could potentially be a promising observation given the concomitantly noted increasing incidence of TKAs that are performed in younger patients.

A surgeon's volume of cases is a factor associated with the risk for revisions [14]. The investigators in the current study were selected based on their volume of study device cases. Each of the participating surgeons had performed at least 100 TKAs using the study implant at the time of site selection, and a majority had experience with the first-generation implant. The study implant has a different design compared to standard knee implants, and a surgeon's experience may be a factor in the risk of revision. If there had been a learning curve, the early cases would have had a higher revision rate than later cases. We analyzed the data to see if there had been a learning curve and found no trend. However, a learning curve may be a factor in implant-naïve surgeons.

In addition to a surgeon's experience and volume of cases, implant design is just one of many other factors that can contribute to the risk of revision. Patient factors such as younger age and male gender are well-documented in the registries. While some surgical complications (e.g., peri-prosthetic fracture) are a clear indication for revision, other complications (e.g., residual pain and instability) may or may not lead to revision. One more factor that contributes to the risk of revision is the study setting and patient population, both of which could potentially affect study outcomes. Only one of the participating sites in our study was located at a university teaching hospital; all other sites were community clinics.

Patella resurfacing during the index surgery is a topic of continuous debate [15]. Data from the AOANJRR suggest that not performing patellae resurfacing during the index surgery increases the risk of revision of primary TKA [3]. In our study, a majority of patellae were resurfaced. Patellar resurfacing is a common approach used by surgeons in the US but the practice varies in other countries.

The strengths of our study are in the consecutive sample of subjects and the multi-prong efforts to assure that all revision events were captured and that all consecutive implantations were included. Data were cross-checked by manufacturer sales data to assure that all eligible consecutive cases were captured. Site personnel were trained in medical records data abstraction. All pertinent medical records, not just the orthopedic records, were accessed and abstracted. Remote and frequent on-site monitoring visits assured that no revision cases were missed. Data for more than 4,000 adverse events and nearly 1,000 serious adverse events underwent secondary central review to identify possible missed revisions. The revision risk at two years in our study is nominally but not significantly higher than the risk reported in a small prospective study of the same device by Harris et al. [2]. Our study had an advantage compared to the registries that do not have quality control systems in place and rely on accurate and consistent reporting by the participating institutions. An internal quality audit of the UK joint registry suggested about 4% of primary TKAs and about 10% of revision TKAs were underreported [2]. A review of the Australian registry suggested 2%-4% of both primary and revision TKAs were underreported [3]. In every registry, if the revision is not reported to the registry, the analysis assumes that the

knee did not undergo revision surgery. In addition, our use of consecutive patients is better than the design of prospective clinical studies, particularly randomized trials, which do not include consecutive patients and are therefore not a reliable source of implant revision risk [16]. The possible limitation of our study would arise from missing a revision event that occurred in a subject who received a revision elsewhere, without knowledge of the primary TKA site. This is, however, unlikely to be a source of significant bias. All but one of our centers were community, non-teaching settings with stable patient populations. Seven of 67 (7/67, 10%) revisions that were referred to or that occurred at other facilities, and were known to the participating site, were included in the analysis. We have access to data from a smaller, ongoing, prospective study [10] that is being performed in similar clinical settings as those in our study. In this smaller study, 2% of the patients moved out of the area and were no longer under the care of the participating site at five-years post-TKA. This rate is similar to the 1.2% of such cases in our study, which were censored and therefore did not impact the reliability of the estimates. We performed a sensitivity analysis of the possible impact of additional subjects moving out of the area but not being censored. These simulations resulted in the range of 0.1 to 1 (worst case scenario) missed revisions. We performed additional sensitivity analyses to evaluate the potential impact of hypothetically missed revisions, and found that the number of missed revisions would need to be unreasonably large to demonstrate that the revision risk of the implant is clinically inferior (measured by revision risk) compared to the clinical standard. Even if the proportion of missed revisions were as much as 20% (13 revisions), this would still not revert our findings.

## Conclusions

The mid-term implant survivorship of JOURNEY™ II BCS is similar to that of registry-reported cemented posterior-stabilized knees. Young patients treated with the study implant have a lower revision risk compared to young patients treated with established knee implant designs. Additional studies are needed to evaluate pain and functional outcomes.

## References

1. Lee JK, Choi C-H. Total knee arthroplasty in rheumatoid arthritis. *Knee Surg Relat Res*.

2012;24(1):1-6. doi:10.5792/ksrr.2012.24.1.1

2. National Joint Registry. *2017 14th Annual Report - National Joint Registry for England, Wales, Northern Ireland and the Isle of Man*. Vol 1821; 2017. http://www.njrreports.org.uk/Portals/0/PDFdownloads/NJR 14th Annual Report 2017.pdf.

3. Australian Orthopaedic Association. Hip, Knee & Shoulder Arthroplasty: Annual Report 2017. *Natl Jt Replace Regist*. 2017. https://aoanjrr.sahmri.com/documents/10180/397736/Hip%2C Knee %26 Shoulder Arthroplasty.

4. American Joint Replacement Registry. *Fourth AJRR Annual Report on Hip and Knee Arthroplasty Data*.; 2017. http://www.ajrr.net/images/annual_reports/AJRR-2017-Annual-Report---Final.pdf?hsCtaTracking=61a2fedc-0f48-4241-a282-2bca6e4b68ad%7Ce4ed88d8-6b8e-4d0c-9a47-d1c169759e83.

5. Kurtz SM, Ong KL, Lau E, Widmer M, Maravic M, Gómez-Barrena E, et al. International Survey of Primary and Revision Total Knee Replacement. *56th Annu Meet Orthop Res Soc*. 2007;(214):Paper No. 214.

6. Delanois RE, Mistry JB, Gwam CU, Mohamed NS, Choksi US, Mont MA. Current Epidemiology of Revision Total Knee Arthroplasty in the United States. *J Arthroplasty*. 2017;32(9):2663-8. doi:10.1016/j.arth.2017.03.066

7. Dai Y, Scuderi GR, Penninger C, Bischoff JE, Rosenberg A. Increased shape and size offerings of femoral components improve fit during total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc*. 2014;22(12):2931-40. doi:10.1007/s00167-014-3163-6

8. Rajgopal A, Aggarwal K, Khurana A, Rao A, Vasdev A, Pandit H. Gait Parameters and Functional Outcomes After Total Knee Arthroplasty Using Persona Knee System With Cruciate Retaining and Ultracongruent Knee Inserts. *J Arthroplasty*. 2017;32(1):87-91. doi:10.1016/j.arth.2016.06.012

9. Webb JE, Yang HY, Collins JE, Losina E, Thornhill TS, Katz JN. The Evolution of Implant Design Decreases the Incidence of Lateral Release in Primary Total Knee Arthroplasty. *J Arthroplasty*. 2017;32(5):1505-9. doi:10.1016/j.arth.2016.11.050

10. Harris AI, Luo TD, Lang JE, Kopjar B. Short-term safety and effectiveness of a second-generation motion-guided total knee system. *Arthroplast today*. 2018;4(2):240-3. doi:10.1016/j.artd.2017.11.007

11. Buchman AS, Wilson RS, Yu L, James BD, Boyle PA, Bennett DA. Total daily activity declines more rapidly with increasing age in older adults. *Arch Gerontol Geriatr*. 2014;58(1):74-9. doi:10.1016/j.archger.2013.08.001
12. Milanović Z, Pantelić S, Trajković N, Sporiš G, Kostić R, James N. Age-related decrease in physical activity and functional fitness among elderly men and women. *Clin Interv Aging*. 2013;8:549-56. doi:10.2147/CIA.S44112
13. Takagi D, Nishida Y, Fujita D. Age-associated changes in the level of physical activity in elderly adults. *J Phys Ther Sci*. 2015;27(12):3685-7. doi:10.1589/jpts.27.3685
14. Jasper LL, Jones CA, Mollins J, Pohar SL, Beaupre LA. Risk factors for revision of total knee arthroplasty: a scoping review. *BMC Musculoskelet Disord*. 2016;17:182. doi:10.1186/s12891-016-1025-8
15. Grassi A, Compagnoni R, Ferrua P, Zaffagnini S, Berruto M, Samuelsson K, et al. Patellar resurfacing versus patellar retention in primary total knee arthroplasty: a systematic review of overlapping meta-analyses. *Knee Surgery, Sport Traumatol Arthrosc*. January 2018. doi:10.1007/s00167-018-4831-8
16. Hughes RE, Batra A, Hallstrom BR. Arthroplasty registries around the world: valuable sources of hip implant revision risk data. *Curr Rev Musculoskelet Med*. 2017;10(2):240-52. doi:10.1007/s12178-017-9408-5

**Table 1. Baseline Demographics**

| | Subjects (N=1,648) | TKAs (N=2,059) |
|---|---|---|
| **Gender** | | |
| **-Male** | 704 (41.81%) | 855 (41.53%) |
| **-Female** | 980 (58.19%) | 1,204 (58.47%) |
| | | |
| **Side** | | |
| **-Right** | | 1,049 (50.95%) |
| **-Left** | | 1,010 (49.05%) |
| | | |
| **Bilateral TKA** | | |
| **-No** | 1,309 (77.33%) | |
| **-Yes** | 375 (22.27%) | |
| | | |
| **Age (years)[#]** | | |
| **-mean** | 64.58 | 64.44 |
| **-standard deviation** | 9.12 | 9.03 |
| | | |
| **<55 years** | 202 (12.00%) | 246 (11.95%) |
| **55 years to < 64 years** | 686 (40.74%) | 834 (40.51%) |
| **65 years to < 74 years** | 543 (32.24%) | 684 (33.22%) |
| **75 years and older** | 253 (15.02%) | 295 (14.33%) |
| | | |
| **Body Mass Index[*] kg/m$^2$** | | |
| **-mean** | | 32.64 |
| **-standard deviation** | | 8.08 |
| | | |
| **< 25 (Normal Weight)** | | 210 (10.48%) |
| **25 to < 30 (Overweight)** | | 599 (29.91%) |
| **30 to < 35 (Obesity Class I)** | | 561 (28.01%) |
| **35 to < 40 (Obesity Class II)** | | 364 (18.17%) |
| **40 and higher (Obesity Class III)** | | 269 (13.43%) |
| | | |
| **Tobacco smoking** | | |
| **-Current smoker** | | 126 (6.12%) |
| **-Previous smoker** | | 553 (26.86%) |
| **Never smoked** | | 1,202 (58.38%) |
| **Unknown** | | 178 (8.64%) |

[#]For subjects' column, the age is at the time of first qualified TKA

*BMI information missing for 56 TKAs

**Table 2. Revised Components**

| **Component** | **N (% of revisions)** |
|---|---|
| Patellar component only | 8 (11.9%) |
| Tibial insert revision only | 30 (44.8%) |
| Tibial insert and patellar component | 9 (13.4%) |
| Tibial plate and tibial insert | 2 (3.0%) |
| Tibial plate, tibial insert, and patellar component | 1 (1.5%) |
| Femoral component and tibial insert | 2 (3.0%) |
| Femoral component, tibial plate, and tibial insert | 7 (10.5%) |
| Femoral component, tibial plate, tibial insert, and patellar component | 8 (11.9%) |

**Table 3. Reasons for First Revision**

| Reason | N = 67 | Percent |
|---|---|---|
| **Infection** | 22 | 32.8 |
| **Mechanical loosening** | 14 | 20.9 |
| **Fracture of bone around the joint** | 11 | 16.4 |
| **Instability of the implant** | 10 | 14.9 |
| **Synovitis** | 4 | 6.0 |
| **Pain** | 1 | 1.5 |
| **Other** | 9 | 13.4 |
| *Hematoma* | *1* | |
| *Arthrofibrosis* | *1* | |
| *Mechanical impingement* | *1* | |
| *Synovitis* | *4* | |
| *Wound dehiscence due to trauma* | 2 | |

**Figure Legends**

Figure 1 Kaplan-Meier Estimates of Revision Probability for Total Knee Arthroplasties for JOURNEY™ II BCS Implant (N=2,059)

Figure 2 Kaplan-Meier Estimates of Revision Probability for Total Knee Arthroplasties for JOURNEY™ II BCS Implant by Region (N=2,059)

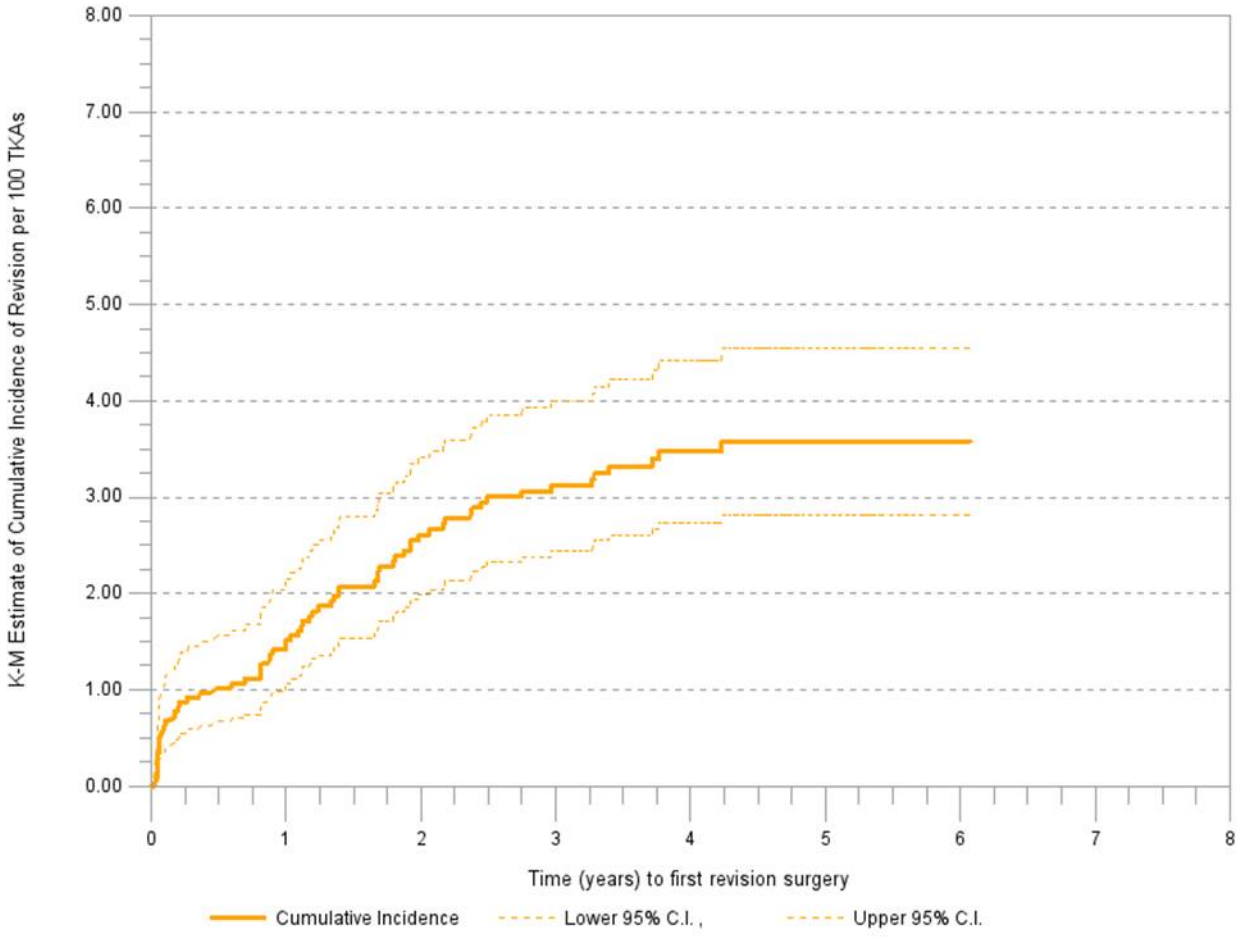
Figure 3 Kaplan-Meier Estimates cumulative incidence of revision in relation to navigation (N=2,059)

Figure 4 Kaplan-Meier Estimates of Revision Probability for Total Knee Arthroplasties for JOURNEY™ II BCS Implant by Extent of Revision (N=2,059)

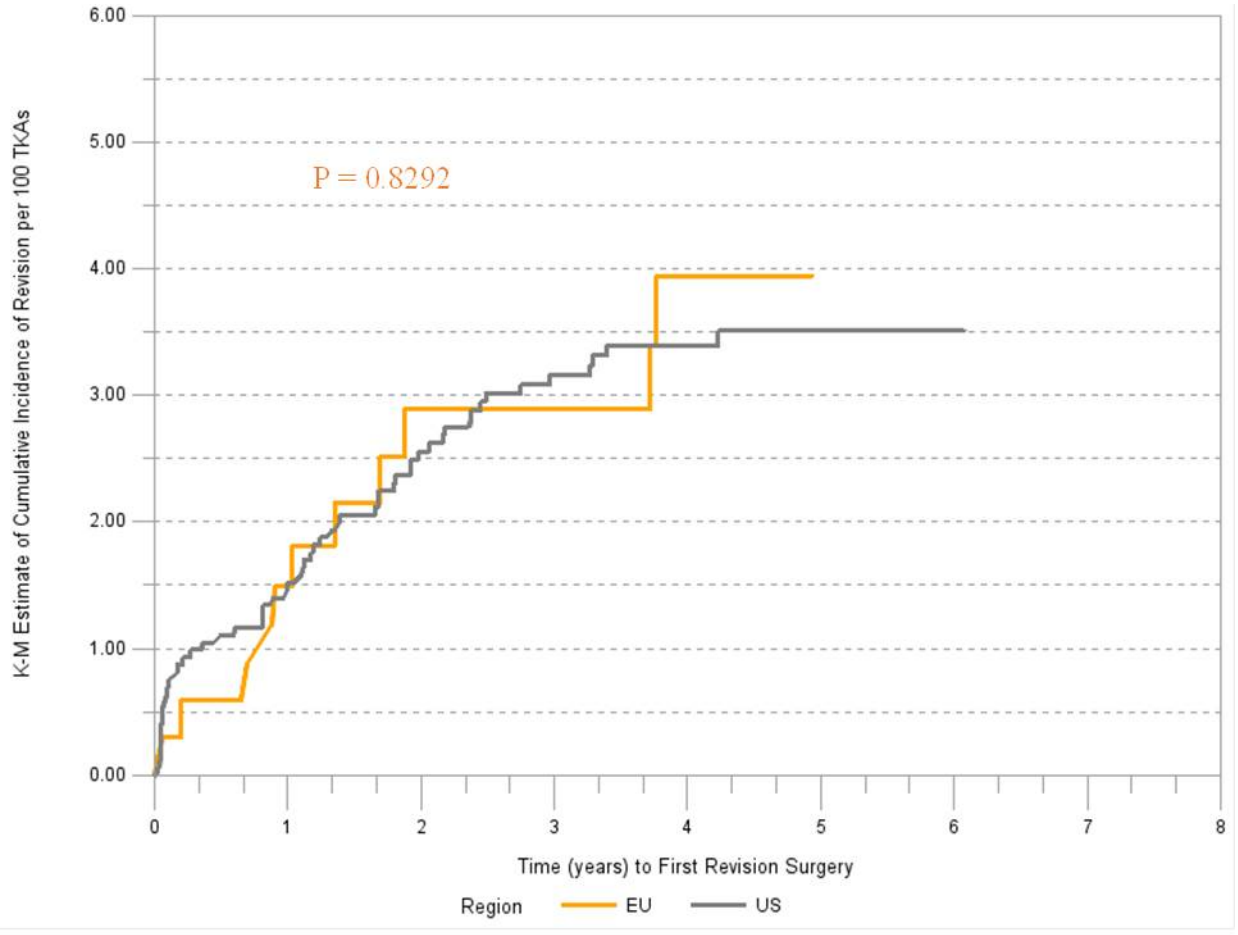
Figure 5 Kaplan-Meier Estimates of Revision Probability for Total Knee Arthroplasties for JOURNEY™ II BCS Implant (N=2,059) and Cemented Posterior Stabilized Total Knee Arthroplasties from the Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) (N=142,780)

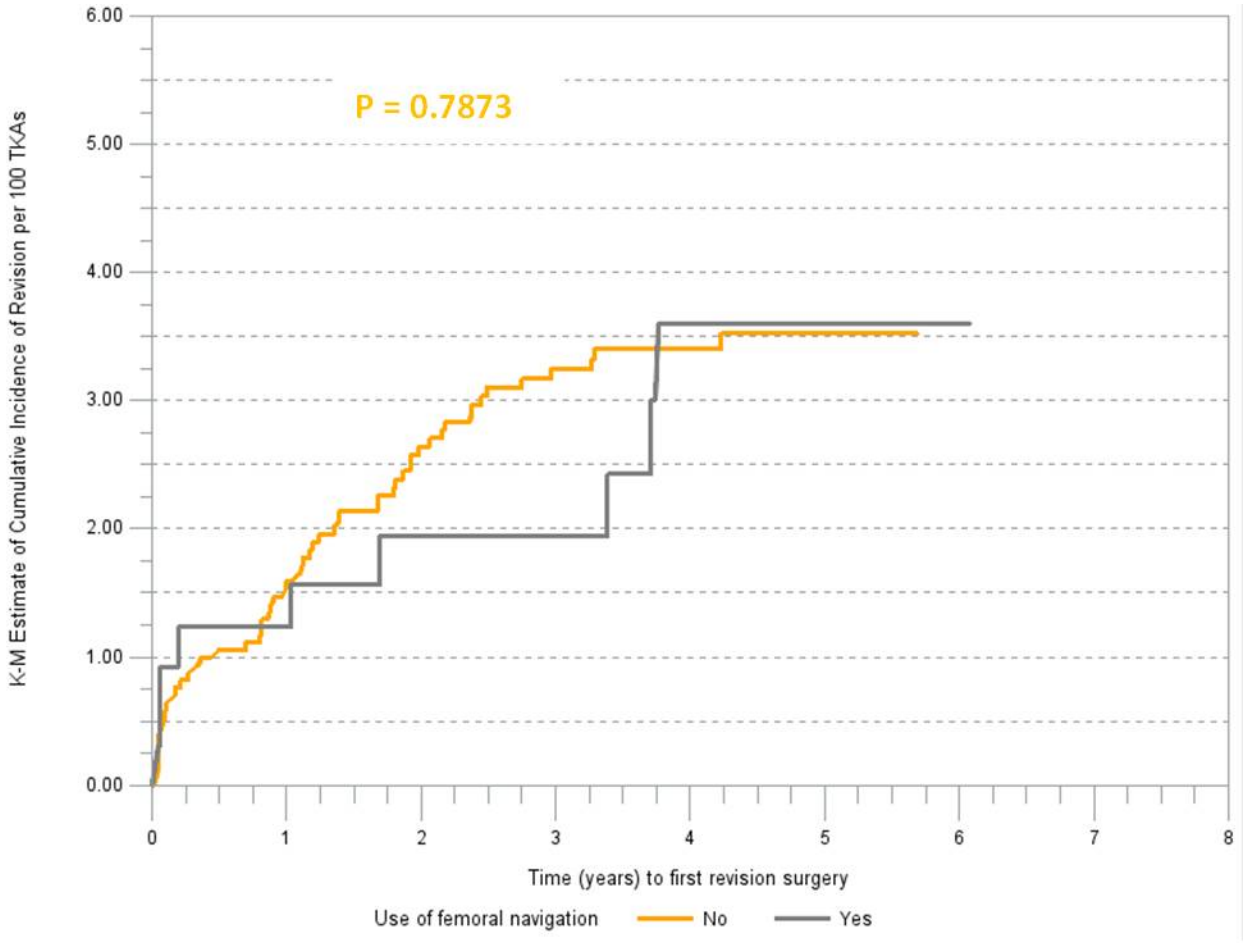
Figure 6a Kaplan-Meier Estimates of Revision Probability for Total Knee Arthroplasties for JOURNEY™ II BCS Implant (N=2,059) and Cemented Posterior Stabilized Total Knee Arthroplasties from the Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) (N=142,780) by Sex (Males) and Age

Figure 6b Kaplan-Meier Estimates of Revision Probability for Total Knee Arthroplasties for JOURNEY™ II BCS Implant (N=2,059) and Cemented Posterior Stabilized Total Knee Arthroplasties from the Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) (N=142,780) by Sex (Females) and Age

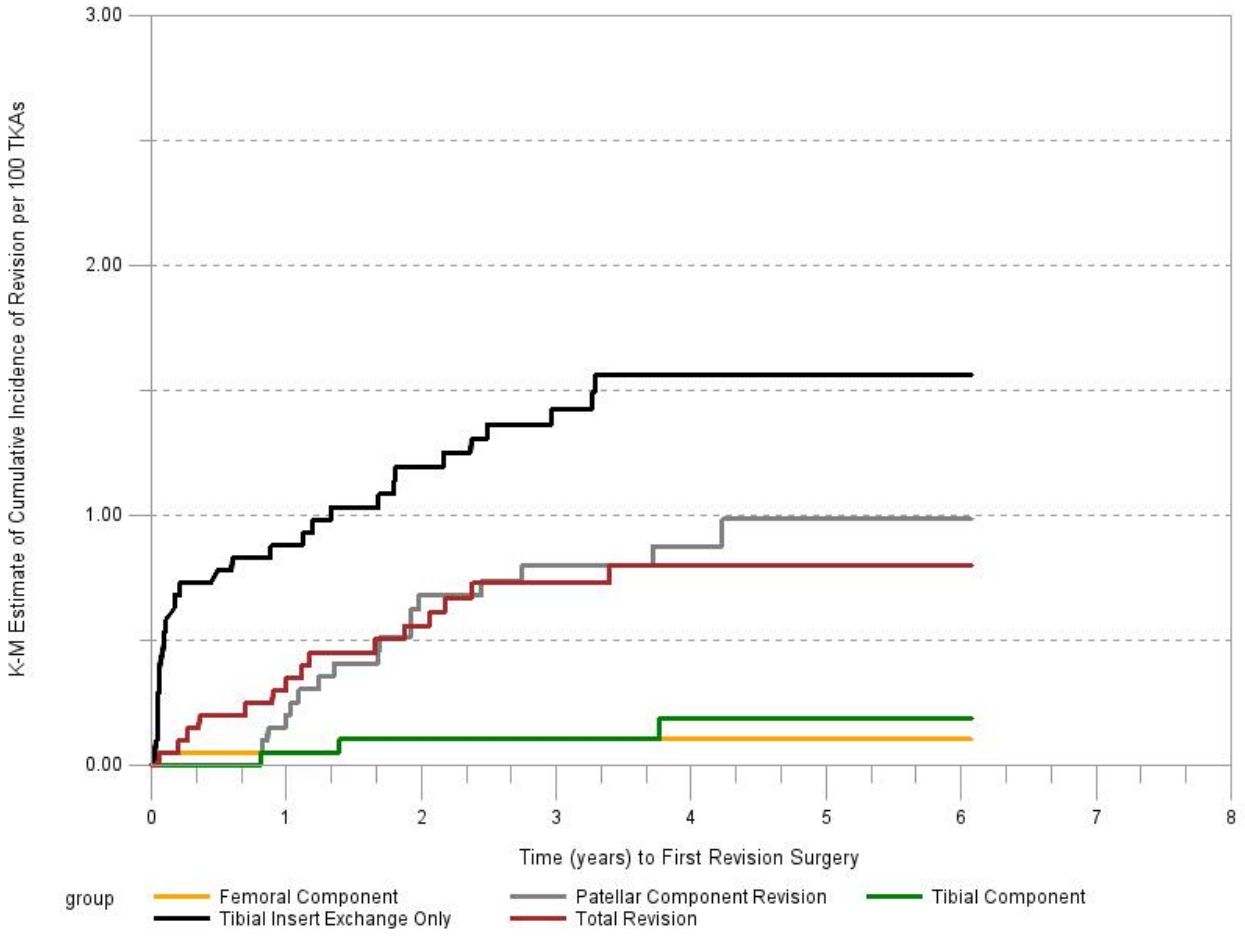


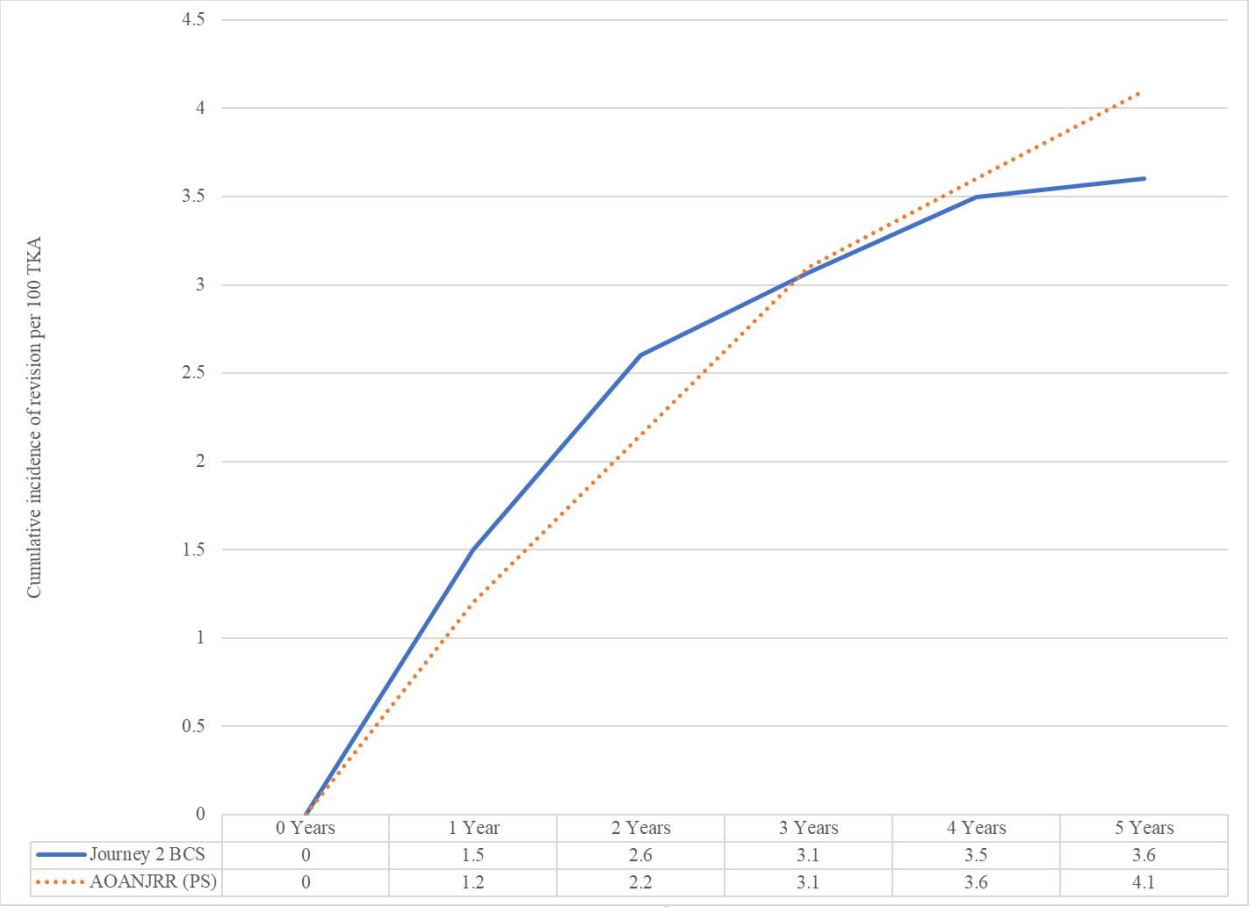

| Years post-TKA | 0 years | 1 year | 2 years | 3 years | 4 years | 5 years | 6 years |
|---|---|---|---|---|---|---|---|
| TKAs at risk | 2,059 | 1,978 | 1,784 | 1,575 | 1,101 | 354 | 1 |
| Cumulative incidence | 0 | 1.56 | 2.61 | 3.12 | 3.47 | 3.58 | 3.58 |


6.00
5.00
4.00
3.00
2.00
1.00
0.00
K-M Estimate of Cumulative Incidence of Revision per 100 TKAs
P = 0.8292
0
1
2
3
4
5
6
7
8
Time (years) to First Revision Surgery
Region
EU
US

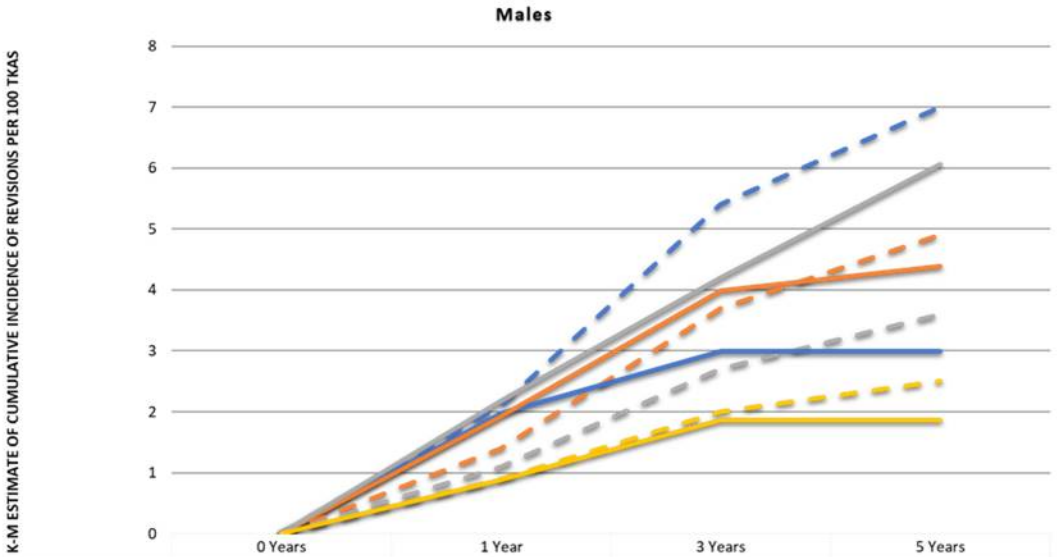



| Use of navigation | 0 years | 1 year | 2 years | 3 years | 4 years | 5 years | 6 years |
|---|---|---|---|---|---|---|---|
| No | 1,706 | 1,646 | 1,521 | 1,333 | 947 | 292 | 0 |
| Yes | 324 | 307 | 243 | 224 | 139 | 59 | 1 |

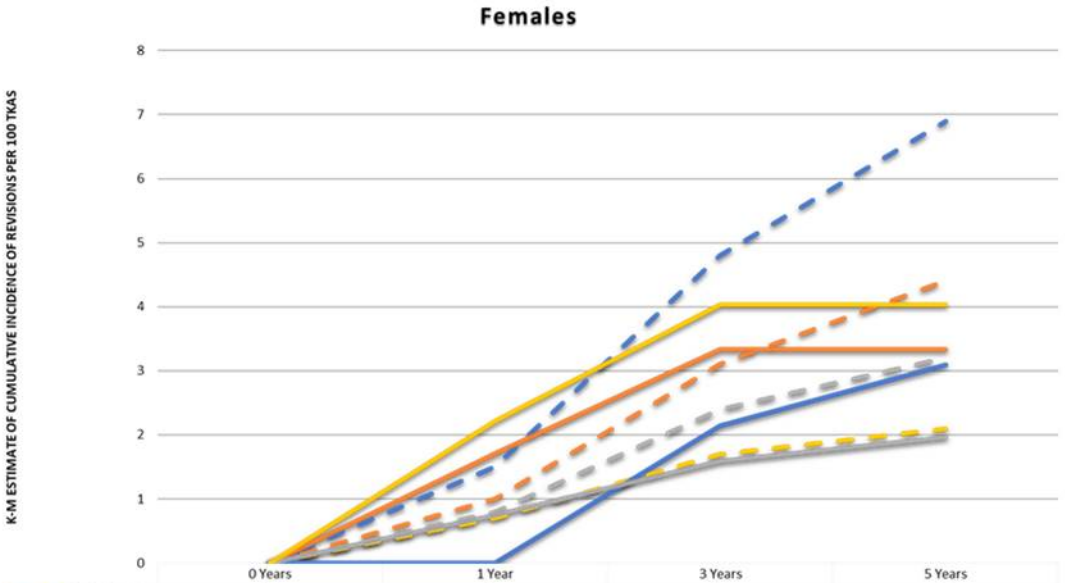

3.00
2.00
1.00
0.00
K-M Estimate of Cumulative Incidence of Revision per 100 TKAs
0
1
2
3
4
5
6
7
8
Time (years) to First Revision Surgery
group
Femoral Component
Tibial Insert Exchange Only
Patellar Component Revision
Total Revision
Tibial Component




| | 0 Years | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years |
|---|---|---|---|---|---|---|
| Journey 2 BCS | 0 | 1.5 | 2.6 | 3.1 | 3.5 | 3.6 |
| AOANJRR (PS) | 0 | 1.2 | 2.2 | 3.1 | 3.6 | 4.1 |




| | 0 Years | 1 Year | 3 Years | 5 Years |
|---|---|---|---|---|
| AOANJRR <55 | 0 | 2.1 | 5.4 | 7 |
| AOANJRR 55-64 | 0 | 1.4 | 3.7 | 4.9 |
| AOANJRR 65-74 | 0 | 1.1 | 2.7 | 3.6 |
| AOANJRR >=75 | 0 | 0.9 | 2 | 2.5 |
| JIIBCSR <55 | 0 | 2.0 | 3.0 | 3.0 |
| JIIBCSR 55-64 | 0 | 1.9 | 4.0 | 4.4 |
| JIIBCSR 65-74 | 0 | 2.2 | 4.2 | 6.1 |
| JIIBCSR 75+ | 0 | 0.9 | 1.9 | 1.9 |




| | 0 Years | 1 Year | 3 Years | 5 Years |
|---|---|---|---|---|
| AOANJRR <55 | 0 | 1.5 | 4.8 | 6.9 |
| AOANJRR 55-64 | 0 | 1 | 3.1 | 4.4 |
| AOANJRR 65-74 | 0 | 0.8 | 2.4 | 3.2 |
| AOANJRR >=75 | 0 | 0.7 | 1.7 | 2.1 |
| JIBCSR <55 | 0 | 0.0 | 2.1 | 3.1 |
| JIBCSR 55-64 | 0 | 1.7 | 3.3 | 3.3 |
| JIBCSR 65-74 | 0 | 0.7 | 1.6 | 2.0 |
| JIBCSR 75+ | 0 | 2.2 | 4.0 | 4.0 |