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Original Research

What Is the Most Appropriate Comparator to Use in Assessing the Comparative Performance of Primary Total Knee Prostheses? A Registry-Based Study

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A B S T R A C T

Background: The Australian Orthopedic Association National Joint Replacement Registry has developed a standardized multi-stage approach to identify prostheses with a higher-than-anticipated rate of revision when comparing a prosthesis of interest to all other prostheses within the same broad class. However, the approach does not adequately differentiate between the conventional and complex design prostheses, and the comparator classes need to be re-evaluated. This study aimed to identify a more relevant comparator to better reflect conventional and complex surgical practices according to the stability design and also explore how the rate of revision estimated in the comparator groups affects the identification of "*prosthesis outliers*."

Methods: The cumulative percent revision (CPR) was calculated for 640,045 primary total knee replacements (TKRs) undertaken for Osteoarthritis from 1 January 2003 to 31 December 2019. At first, survivorship analyses were undertaken to calculate the rate of revision for primary TKR by stability design. A modified TKR comparator group was developed by excluding the "complex" group of prostheses with fully stabilized and hinged designs. The effectiveness of the modified comparator groups, including cruciate retaining and posterior stabilized designs, was evaluated based on the ability to detect additional prostheses by performing the Australian Orthopedic Association National Joint Replacement Registry standardized method for identifying prosthesis outliers.

Results: The modified comparator to include only conventional designs had a 10-year CPR of 5.2% (5.1, 5.3). When the fully stabilized and hinged design groups were combined as a comparator group of complex devices to reflect devices used only for specific purposes in primary TKR, the CPR at 10 year was 10.3% (8.6, 12.0).

Conclusions: The use of modified comparator groups led to identifying additional conventional prostheses but fewer complex designs as being at risk and has the potential to improve the early assessment of TKR prostheses.

Introduction

The demand for knee replacement surgery is projected to rise due to the increasingly aging population [1,2]. It is commonly known that prostheses have variable outcomes, and while most perform well, some have outcomes well outside what would be

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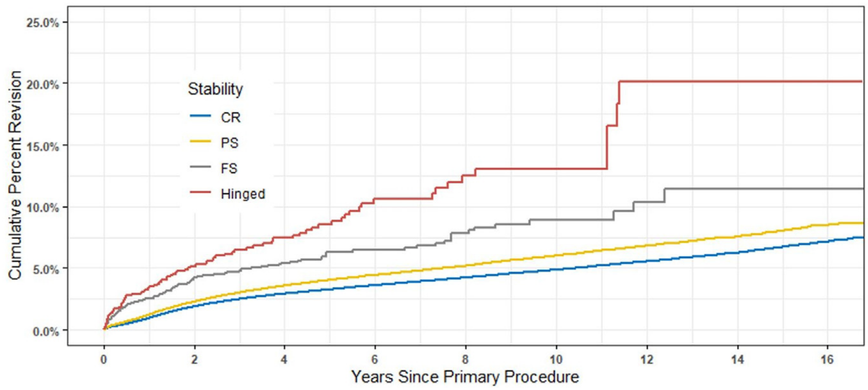

Figure 1. CPR of primary total knee replacement by stability.

regarded as acceptable. This variation in prosthesis performance emphasizes the importance of adequate pre-market evaluation and attentive post-market monitoring. Early detection mechanisms are required to identify prostheses with a higher-than-anticipated rate of revision—outliers with unreliable clinical outcomes for patients. The identification and documentation of outlier prostheses may reduce their usage, leading to better clinical outcomes [3].

Joint registries aim to reduce the revision rates of arthroplasty surgeries by early detection of outlier joint arthroplasty devices [4,5]. They provide population-based data on the comparative outcome of prostheses within the community. Survival outcome data are necessary to enable an evidence-based approach to identifying prostheses with statistically higher-than-anticipated rates of revision. As the Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) has demonstrated that outlier prostheses are used far less frequently after identification, the survivorship of primary total knee replacement (TKR) for osteoarthritis (OA) is 92% at 20 years [5].

There are different types of knee replacements that can be classified based on the type of articulation. All registries report variations in the outcomes of total knee prostheses by stability. In this article, stability refers to specific prosthetic features intended to substitute for the intrinsic stability of knee ligaments. Since 2017, the Australian Registry has expanded the classification to include the medial pivot designs separately. The 3 major categories now are cruciate retaining (CR), medial pivot design, and posterior stabilized (PS). Stability is used for various purposes, and the type of stability used for prostheses may affect the overall outcomes within the same class. Most total knee prostheses implanted are either CR or PS prostheses with long-term follow-up [6]. The AOANJRR defines CR prostheses as those with a flat or dished tibial articulation, regardless of congruency. PS prostheses provide additional posterior stability, most commonly using a peg and box design or less frequently using a cam and groove.

In Australia, these 2 stability types have remained the most commonly used primary TKR procedures [5,7-9]. Medial pivot design prostheses have been used in small numbers since the Registry began collecting data. In 2021, the use of medial pivot design prostheses has increased in Australia and accounted for 9.2% of primary procedures [5]. Medial pivot design prostheses have a ball-and-socket medial portion of the articulation and are out of scope of this study. On the other hand, complex designs (ie, fully stabilized [FS] and hinged implants) are also used in a limited number of primary procedures based on clinical circumstances [5]. FS designs have a large peg in the tibial insert and box in the femoral component to give both posterior and varus-valgus constraint, and hinged knees are uncommonly used prostheses that provide additional collateral, as well as posterior ligament stability.

In 2021, CR and PS stability design prostheses accounted for 76.1% and 14.7% of primary procedures, respectively [5]. FS with a large peg and box design and hinged knees with additional collateral and posterior ligament stability are used less often in primary TKR. These designs are usually considered for revision components or only performed in complex clinical situations of primary surgeries with the diagnosis of tumors, fractures, severe malalignment, and rheumatoid arthritis [10-12]. When the outcome for OA alone is considered, the CR-stability TKR has lower rates of revision than PS, FS, and hinged knee prostheses [5].

The AOANJRR has developed a standardized multi-stage approach to identify primary total knee outliers by performing an initial screening test. The first stage is an automated screening test to identify prostheses that differ significantly from the combined revisions per 100 observed component years of all other prostheses belonging to the same broad total knee class. However, the current comparator does not adequately differentiate between conventional and complex procedures. This may result in less conventional and more complex devices being identified as being at risk [4,5]. The hypothesis is that the rate of revision surgery estimated in the knee comparator group impacts the early identification of prosthesis outliers (ie, the number of identified prostheses by the AOANJRR standardized approach). This retrospective cross-sectional study was designed to determine a more relevant comparator with the aim to better reflect conventional and complex surgical practices according to the stability design and also to explore how the rate of revision surgery estimated in the comparator groups affects the identification of prosthesis outliers.

Table 1
Number at risk for revision—primary total knee replacement by stability.

Number at risk	0 y	2 y	4 y	6 y	8 y	10 y	12 y	14 y	16 y
CR	463,863	371,776	290,055	216,691	152,699	99,904	59,975	30,425	8056
PS	172,530	144,816	114,903	85,841	60,467	37,653	19,667	7708	1603
FS	2519	1794	1165	716	410	218	98	45	8
Hinged	1133	716	443	275	161	73	33	15	4

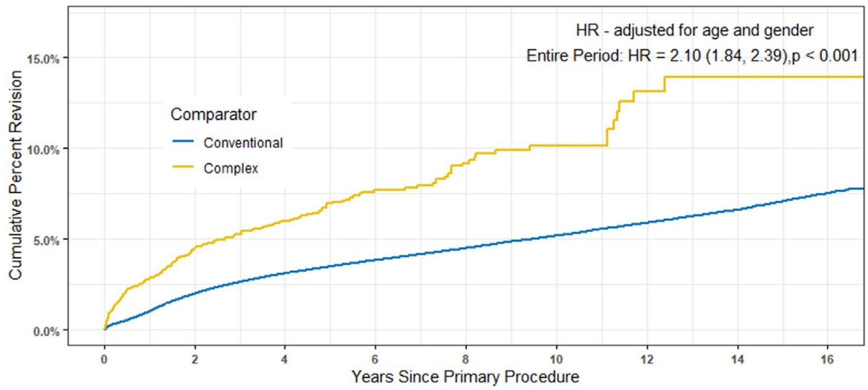

Figure 2. CPR of conventional and complex comparator groups.

Material and methods

The study period was from the first year that the AOANJRR collected TKR data from all Australian hospitals (January 2003) to the closure of the dataset at the end of December 2019. The study population included all patients undergoing a primary TKR for primary OA. This selection initially included 640,045 procedures. At first, survivorship analyses were undertaken to calculate the rate of revision for primary TKR by stability design. The conventional study population in primary TKR was then studied using Kaplan-Meier survival analysis. From the study population, specific exclusion of complex design (ie, FS and fully hinged) prostheses was undertaken to assess the impact on the revision rate (cumulative percent revision [CPR]). In addition, a group of complex prostheses were reconsidered as a new comparator to evaluate the effect on the identification of outlier prostheses with complex stability designs.

The outcome was time to first revision surgery, defined as reoperations of previous knee replacements where one or more prosthetic device components are replaced, removed, or added. Death was treated as a censored case with survival time based on the date those cases exited the study. Patients with no revision or death had survival times based on the time elapsed between the initial surgery and the end of follow-up. Further analyses were conducted to compare the most common reasons for revision, and the AOANJRR standardized approach was employed to determine the impact of modified comparator groups on the number of identified outliers. The research was conducted according to the ethical principles of the Helsinki Declaration II. The Southern Adelaide Clinical Human Research Ethics Committee has also provided ethics approval for this study (No. 485.13).

Statistical methods

Two study populations with primary TKR performed for OA were studied using Kaplan-Meier survival analysis [5]. The unadjusted CPR was estimated after the primary surgery. This measure was calculated using unadjusted pointwise Greenwood estimates with an accompanying 95% confidence interval (CI). To compare revision rates between the 2 modified comparator groups, the Cox proportional hazard model calculated age- and gender-adjusted hazard ratios (HRs) for the entire period. The secondary outcome measure was the cumulative incidence of reasons for revisions. This was performed to approximate the risk of being revised for each of the diagnoses. Differing percentages between groups with the same follow-up time distribution may identify further details for variations in the revision rate according to the modifications. The effectiveness of the modified comparator in the identification of outlier prostheses was evaluated by performing the first 2 stages of the AOANJRR standardized approach. This standardized approach includes comparing the revision rate of prostheses to twice the average revision rate of all prostheses belonging to the same broad device class. The impact of confounding factors is then examined by calculating age- and gender-adjusted HRs to check for a significant difference compared to the combined HR of the comparator group. In this study, the statistical analyses were performed using *R* software [13], including the packages *Survival* [14] version 3.2-11 and *Survminer* [15] version 0.4.9.

Results

FS and fully hinged designs show higher CPR rates than CR and PS over the entire period (Fig. 1 and Table 1). Prostheses with CR (4.8% [95% CI 4.8, 4.9]) and PS (6.0% [5.9, 6.1]) designs had significantly lower 10-year CPR than FS (8.9% [7.0, 1.07]) and hinged (13.5% [9.8, 17.2]) prostheses. The use of a PS design led to a higher overall CPR than the CR design for conventional prostheses, and the hinged design had a higher CPR than FS for complex prosthesis constructs. Overall, the results show a higher risk of revision for the 2 complex design prostheses than the conventional prostheses.

Figure 2 and Tables 2 and 3 present results among the comparator groups for conventional and complex procedures showing the proportion revised. When the CR and PS groups were combined as the final conventional comparator group, the 10-year CPR was 5.2% (5.1, 5.3). When the FS and hinged design groups were combined as a comparator group of complex devices to reflect devices used only for specific purposes in primary TKR, the CPR at 10 years was 10.3% (8.6, 12.0).

The AOANJRR initial screening was employed by comparing the revision rate of prostheses to twice the average revision rate of all prostheses belonging to the same class and calculating age- and

Table 2
Number at risk for revision—conventional and complex comparator groups.

Number at risk	0 y	2 y	4 y	6 y	8 y	10 y	12 y	14 y	16 y
Conventional	636,393	516,592	404,958	302,532	213,166	137,557	79,642	38,133	9659
Complex	3652	2510	1608	991	571	291	131	60	12

Table 3
Yearly CPR of the comparator groups.

CPR	N Revised	N Total	1 y	2 y	3 y	4 y
Conventional	24,131	636,393	1.0 (1.0, 1.1)	2.0 (1.9, 2.0)	2.6 (2.6, 2.7)	3.10 (3.0, 3.1)
Complex	225	3652	2.8 (2.3, 3.4)	4.5 (3.8, 5.2)	5.3 (4.5, 6.1)	6.0 (5.1, 6.9)
	5 y	6 y	7 y	8 y	9 y	10 y
Conventional	3.5 (3.4, 3.5)	3.8 (3.8, 3.9)	4.2 (4.1, 4.2)	4.5 (4.4, 4.5)	4.9 (4.8, 4.9)	5.2 (5.1, 5.3)
Complex	7.0 (6.0, 8.0)	7.7 (6.6, 8.8)	7.9 (6.8, 9.0)	9.2 (7.8, 10.6)	9.9 (8.3, 11.4)	10.3 (8.6, 12.0)
	11 y	12 y	13 y	14 y	15 y	16 y
Conventional	5.5 (5.5, 5.6)	5.9 (5.8, 6.0)	6.2 (6.1, 6.3)	6.6 (6.5, 6.7)	7.1 (6.9, 7.2)	7.5 (7.4, 7.7)
Complex	10.3 (8.6, 12.0)	13.1 (10.2, 16.0)	13.9 (10.6, 17.0)	13.9 (10.6, 17.0)	13.9 (10.6, 17.0)	13.9 (10.6, 17.0)

gender-adjusted HRs according to the comparator. There were 2 additional prostheses identified using the modified comparator focusing on the routinely used devices (Table 4). Using the specific comparator for complex design prostheses reduced the number of identified outliers by the AOANJRR standardized approach (Table 5). The revision rates of these devices exceeded first stage, but there was no significant difference between the HRs of the listed components and the complex comparator. The use of modified comparator groups caused a meaningful change in the number of identified prostheses as being at risk. The use of modified comparator groups led to identifying additional conventional prostheses but fewer complex designs as being at risk.

Figure 3 details the cumulative incidence of the most common reasons for revision for complex design prostheses in primary total knee surgeries. Figure 4 illustrates a comparative graph that provides the cumulative incidence of the same revision causes for the conventional comparator group. The 10-year cumulative incidence with 95% CI of infection for the complex group was 4.8%, which is higher than the 1.1% incidence for the conventional designs. The overall risk of other revision causes for the complex designs was also higher than that of the conventional prostheses. Early infection is the most common cause of revision, particularly for the complex devices with 6-month cumulative incidences of 1.4%.

Discussion

It is well-understood that complex primary TKRs have generally higher risks of revision than routine procedures. Martin et al. reported higher revision rates in patients undergoing complex primary TKRs than the routine TKRs [10]. Through undertaking the AOANJRR standardized approach, fewer complex designs and additional conventional prostheses were identified as being at risk by using the modified comparator groups. In primary TKR, the conventional comparator improved the comparative assessment of standard-design prostheses, and a focus on complex prostheses generated a more relevant approach for the early identification of prostheses used for specific purposes. These findings may enhance the early identification of prostheses with higher revision rates in a more appropriate and effective comparative statistical analysis.

Increased survivorship and improved functional performance are expected when a new knee system supersedes a previous model. These novel systems have design justifications to address wear, stability, and patellofemoral articulation. However, all design modifications do not result in improved survivorship [16]. Due to these ongoing changes to reduce complications, extend implant lifespan, and improve functional outcomes, the comparator needs to be reconsidered to improve the relevance of comparative analyses.

The safety and effectiveness of medical devices such as knee arthroplasty prostheses are significant public health concerns [17,18]. The identification of outlier prostheses will continue to evolve by measuring the outcomes of the improvements made periodically in prosthesis design and use. Joint registries are ideally placed to monitor the ongoing performance of new designs [19]. An international collaboration between joint arthroplasty registries may enhance the process by generating a more comprehensive comparator for total conventional and complex knee prostheses [20].

This study has several limitations. There was no further subdivision by other potential factors such as patella usage, fixation, bearing surface, and bearing mobility. However, each factor may influence the survivorship of comparator groups for conventional and complex designs [7,9,21]. At this stage, the authors believe that further subdivisions may adversely impact the effectiveness of initial screening for a meaningful comparison of the prosthesis performance. By reducing the number of available observations and consequently the power of the comparative statistical analysis. One important consideration is that the success of the screening process relies on identifying relevant component characteristics. The process would be compromised if some attributes that contribute to the prosthesis survival are not accounted for. In addition, we did not include medial pivot designs in the analysis because of relatively small usage. The AOANJRR annual report shows that medial pivot design TKR provides satisfactory pain relief and functional improvement [5].

Conclusions

This article suggests relevant comparator groups for a more appropriate comparison of primary TKR prostheses within the

Table 4
Additional identified conventional prostheses using the modified comparator.

Femoral/Tibial	Descriptive information			First stage	Second stage	Comparator	
	N Revised	N Total	Obs. years	Revisions/100 Obs. years (95% CI)	HR, adjusted for age and gender, *P* value	Current	Conventional
Device I	43	481	3555.67	1.21 (0.87, 1.63)	2.17 (1.61, 2.93) $P < .001$	0.61 (0.6, 0.61)	0.60 (0.59, 0.61)
Device II	58	438	4844.40	1.20 (0.91, 1.55)	2.37 (1.83, 3.06) $P < .001$	0.61 (0.6, 0.61)	0.60 (0.59, 0.61)

The first stage is a screening test to identify prostheses that differ significantly from the combined revisions per 100 observed component years of all other prostheses in the same class. The second stage examines the impact of confounders by calculating age and gender adjusted HRs.

Table 5
Nondetected complex prostheses using the modified comparator.

Femoral/Tibial	Descriptive information			First stage	Second stage	Comparator	
	N Revised	N Total	Obs. years	Revisions/100 Obs. years (95% CI)	HR, adjusted for age and gender, *P* value	Current	Complex
Device III	11	124	655.64	1.68 (0.84, 3.0)	1.18 (0.64, 2.16) *P* = .594	0.61 (0.6, 0.61)	1.42 (1.23, 1.61)
Device IV	21	211	974.43	2.15 (1.33, 3.29)	1.44 (0.92, 2.26) *P* = .108	0.61 (0.6, 0.61)	1.42 (1.19, 1.58)
Device V	27	478	2121.66	1.27 (0.84, 1.85)	0.92 (0.62, 1.38) *P* = .694	0.61 (0.6, 0.61)	1.42 (1.25, 1.66)
Device VI	7	124	476.05	1.47 (0.59, 3.03)	0.85 (0.40, 1.82) *P* = .685	0.61 (0.6, 0.61)	1.42 (1.24, 1.62)
Device VII	3	38	231.81	1.29 (0.27, 3.78)	0.96 (0.31, 3.01) *P* = .947	0.61 (0.6, 0.61)	1.42 (1.24, 1.62)
Device VIII	8	115	371.31	2.15 (0.93, 4.24)	1.31 (0.64, 2.65) *P* = .456	0.61 (0.6, 0.61)	1.42 (1.22, 1.60)
Device IX	17	295	1074.08	1.58 (0.92, 2.53)	1.04 (0.63, 1.71) *P* = .874	0.61 (0.6, 0.61)	1.42 (1.22, 1.62)
Device X	6	75	433.59	1.38 (0.51, 3.01)	0.85 (0.38, 1.92) *P* = .701	0.61 (0.6, 0.61)	1.42 (1.24, 1.62)

The first stage is a screening test to identify prostheses that differ significantly from the combined revisions per 100 observed component years of all other prostheses in the same class. The second stage examines the impact of confounders by calculating age- and gender-adjusted HRs.

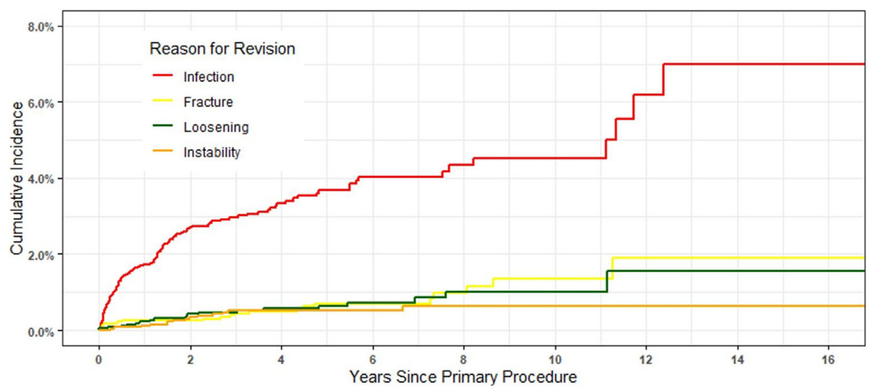

Figure 3. Cumulative incidence of reason for revision—complex primary total knee.

community. Using the modified comparator, we identified more conventional TKRs at risk than previous estimates. In addition, the reconsideration of complex-design prostheses developed a more specific approach for the early identification of prostheses used for particular purposes. The modified comparator groups led to identifying fewer complex and additional conventional prostheses above the initial screening process as being at risk.

Conflicts of interest

L.B.S. is in the speakers' bureau of/gave paid presentations for AO Recon and receives research support from a company or supplier as a principal investigator from Zimmer Biomet. M.T. receives research support from a company or supplier as a principal investigator from DePuy Synthes and 360MedCare. All other authors declare no conflicts to disclose.

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CRediT authorship contribution statement

Khashayar Ghadirinejad: Writing – original draft, Methodology, Investigation, Formal analysis. **Stephen Graves:** Writing – review & editing, Supervision, Methodology. **Richard de Steiger:** Writing – review & editing, Supervision, Methodology. **Nicole Pratt:** Writing – review & editing, Supervision, Methodology. **Lucian B. Solomon:** Writing – review & editing, Supervision. **Mark**

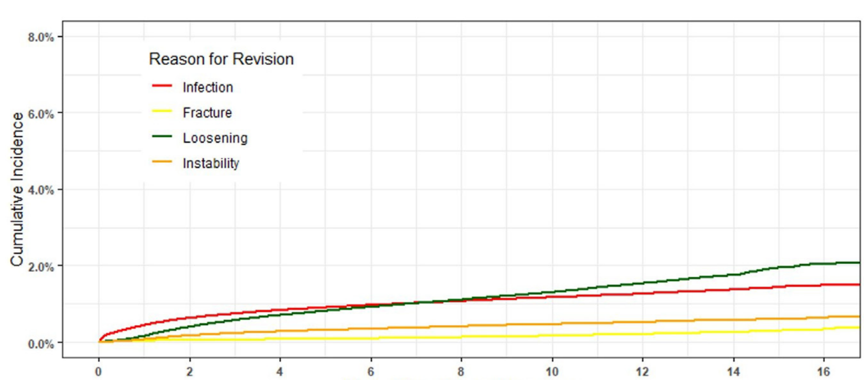

Figure 4. Cumulative incidence of reason for revision—conventional primary total knee.

Taylor: Writing — review & editing, Supervision. **Reza Hashemi:** Writing — review & editing, Supervision.

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Table A1
Yearly CPR of primary total knee replacement by stability.

CPR	N Revised	N Total	1 y	2 y	3 y	4 y
CR	16,406	463,863	0.9 (0.9, 1.0)	1.9 (1.8, 1.9)	2.5 (2.4, 2.5)	2.9 (2.9, 3.0)
PS	7725	172,530	1.2 (1.2, 1.3)	2.2 (2.2, 2.3)	3.0 (2.9, 3.1)	3.6 (3.5, 3.7)
FS	139	2519	2.6 (1.9, 3.2)	4.2 (3.4, 5.1)	4.8 (3.9, 5.7)	5.4 (4.4, 6.4)
Hinged	86	1133	3.5 (2.4, 4.6)	5.3 (3.9, 6.7)	6.5 (4.8, 8.1)	7.7 (5.8, 9.4)

	5 y	6 y	7 y	8 y	9 y	10 y
CR	3.3 (3.2, 3.3)	3.6 (3.5, 3.7)	3.9 (3.8, 4.0)	4.2 (4.1, 4.3)	4.5 (4.5, 4.6)	4.8 (4.8, 4.9)
PS	4.0 (3.9, 4.1)	4.4 (4.3, 4.5)	4.8 (4.7, 4.9)	5.2 (5.1, 5.3)	5.6 (5.5, 5.7)	6.0 (5.9, 6.1)
FS	6.3 (5.1, 7.4)	6.5 (5.3, 7.7)	6.8 (5.6, 8.1)	8.1 (6.5, 9.6)	8.6 (6.8, 10.2)	8.9 (7.0, 1.07)
Hinged	8.8 (6.7, 10.9)	10.6 (8.1, 13.1)	11.0 (8.4, 13.6)	12.5 (9.3, 15.5)	13.5 (9.8, 17.2)	13.5 (9.8, 17.2)

	11 y	12 y	13 y	14 y	15 y	16 y
CR	5.2 (5.1, 5.3)	5.5 (5.4, 5.6)	5.9 (5.8, 6.0)	6.2 (6.1, 6.4)	6.7 (6.6, 6.9)	7.1 (6.9, 7.3)
PS	6.4 (6.3, 6.6)	6.8 (6.6, 7.0)	7.2 (7.0, 7.4)	7.5 (7.3, 7.8)	8.0 (7.7, 8.3)	8.5 (8.1, 8.9)
FS	8.9 (7.0, 1.07)	10.6 (7.8, 13.7)	11.4 (8.0, 14.7)	11.4 (8.0, 14.7)	11.4 (8.0, 14.7)	—
Hinged	13.5 (9.8, 17.2)	13.5 (9.8, 17.2)	13.5 (9.8, 17.2)	13.5 (9.8, 17.2)	13.5 (9.8, 17.2)	13.5 (9.8, 17.2)