

Apex Knee CR (cementless)/Apex Knee (cementless) Total Knee Investigation

Note: This analysis compares the Apex Knee CR (cless)/Apex Knee (cless) femoral/tibial combination with all other total knee prostheses.

This combination has been identified as having a significantly higher rate of revision. For a detailed explanation of the process used by the Registry that results in identification of prostheses that have a higher than anticipated rate of revision please refer to the Prostheses with Higher than Anticipated Rates of Revision chapter of the most recent AOANJRR Annual Report, <https://aoanjrr.sahmri.com/annual-reports-2024>.

Note: Procedures using prostheses with no recorded use in 2023 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Knee Replacement

The revision rate of the Apex Knee CR (cless)/Apex Knee (cless) total knee combination is compared to all other total knee prostheses.

Table 1: Revision Rates of Primary Total Knee Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Apex Knee CR (cless)/Apex Knee (cless)	30	527	3702	0.81 (0.55, 1.16)
Other Total Knee	24901	735556	4684360	0.53 (0.52, 0.54)
TOTAL	24931	736083	4688062	0.53 (0.53, 0.54)

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Apex Knee CR (cless)/Apex Knee (cless) total knee combination is compared to all other total knee prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Knee Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
Apex Knee CR (cless)/Apex Knee (cless)	2.5 (1.4, 4.2)	4.7 (3.2, 6.9)	5.2 (3.5, 7.5)	5.6 (3.9, 8.0)	5.6 (3.9, 8.0)	6.2 (4.4, 8.8)	6.2 (4.4, 8.8)	6.2 (4.4, 8.8)
Other Total Knee	1.0 (0.9, 1.0)	1.8 (1.8, 1.8)	2.4 (2.3, 2.4)	2.8 (2.7, 2.8)	3.1 (3.1, 3.1)	3.4 (3.4, 3.5)	3.7 (3.7, 3.8)	4.0 (4.0, 4.1)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Apex Knee CR (cless)/Apex Knee (cless)	6.2 (4.4, 8.8)	6.2 (4.4, 8.8)	6.2 (4.4, 8.8)					
Other Total Knee	4.3 (4.3, 4.4)	4.6 (4.6, 4.7)	4.9 (4.9, 5.0)	5.2 (5.2, 5.3)	5.5 (5.5, 5.6)	5.8 (5.7, 5.9)	6.2 (6.1, 6.3)	6.6 (6.5, 6.8)

CPR	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
Apex Knee CR (cless)/Apex Knee (cless)							
Other Total Knee	7.0 (6.8, 7.1)	7.3 (7.1, 7.5)	7.5 (7.3, 7.7)	7.7 (7.5, 8.0)	8.0 (7.7, 8.3)	8.2 (7.9, 8.6)	8.2 (7.9, 8.6)

Note: Prostheses no longer used in 2023 are excluded from the comparator.

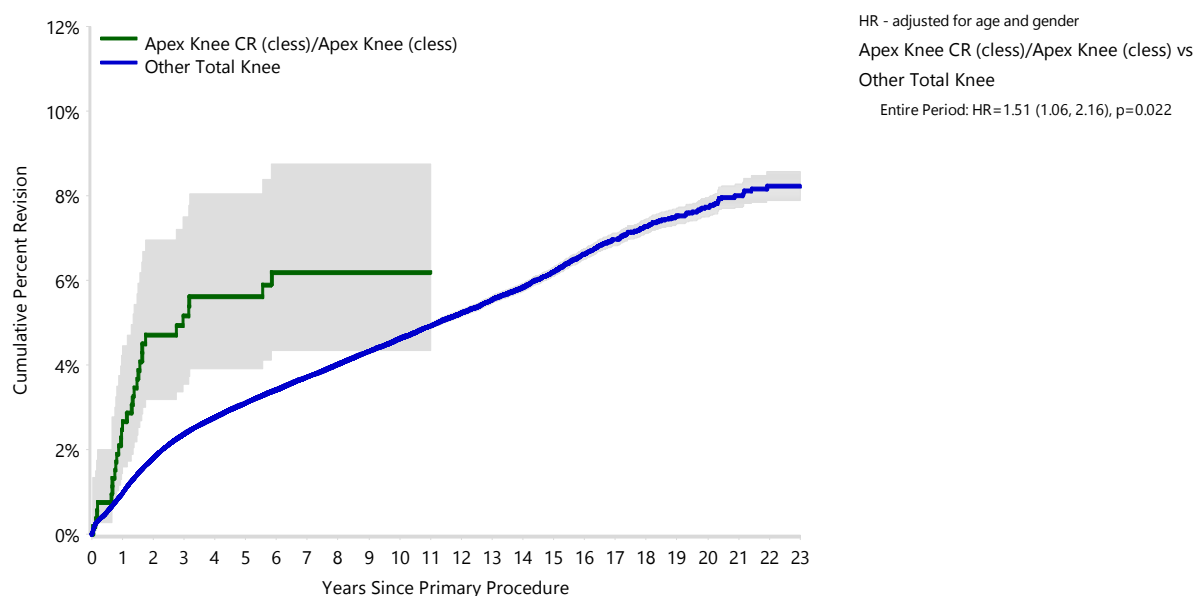
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Apex Knee CR (class)/Apex Knee (class) total knee combination is compared to all other total knee prostheses. In addition, hazard ratios are reported.

Hazard ratios are reported for specific time periods during which the hazard ratio is constant. This is done to enable more specific and valid comparisons of the risk of revision over time. The pattern of variation in risk has important implications with respect to the underlying reasons for any difference.

Figure 1: Cumulative Percent Revision of Primary Total Knee Replacement



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs
Apex Knee CR (class)/Apex Knee (class)	527	507	446	416	404	353	319	311	290	218	118	53
Other Total Knee	735556	655965	589264	522352	462646	402047	344379	290236	241308	196589	158309	125391

Number at Risk	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
Apex Knee CR (class)/Apex Knee (class)	0	0	0	0	0	0	0	0	0	0	0	0
Other Total Knee	96689	72841	53727	38715	27059	18808	12662	7866	4467	2602	1229	297

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 3**Primary Diagnosis for Revised Primary Total Knee Replacement**

This table identifies the diagnosis of the primary procedure which was subsequently revised. This information is provided as there is a variation on outcome depending on the primary diagnosis. It is therefore important when considering the reasons for a higher than anticipated rate of revision that there is identification of the primary diagnosis. This information should be compared to the primary diagnosis for the revisions of all other total knee prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Knee Replacement

Primary Diagnosis	Apex Knee CR (cless)/Apex Knee (cless)		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	30	100.0	24096	96.8
Rheumatoid Arthritis			313	1.3
Tumour			178	0.7
Other Inflammatory Arthritis			153	0.6
Osteonecrosis			89	0.4
Fracture			48	0.2
Other			23	0.1
Chondrocalcinosis			1	0.0
TOTAL	30	100.0	24901	100.0

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 4

Reasons for Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

% Primaries Revised: This shows the proportional contribution of each revision diagnosis as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of being revised for that diagnosis. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

% Revisions: The number of revisions for each diagnosis is expressed as a percentage of the total number of revisions. This shows the distribution of reasons for revision within a group but cannot be used as a comparison between groups.

Table 4: Primary Total Knee Replacement - Reason for Revision (Follow-up Limited to 11.9 Years)

Revision Diagnosis	Apex Knee CR (cless)/Apex Knee (cless)			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	6	1.1	20.0	6839	0.9	28.7
Loosening	9	1.7	30.0	5026	0.7	21.1
Instability	1	0.2	3.3	2475	0.3	10.4
Pain	1	0.2	3.3	1770	0.2	7.4
Patella Erosion	7	1.3	23.3	1658	0.2	6.9
Patellofemoral Pain	1	0.2	3.3	1580	0.2	6.6
Arthrofibrosis	1	0.2	3.3	1012	0.1	4.2
Fracture				912	0.1	3.8
Malalignment	1	0.2	3.3	520	0.1	2.2
Wear Tibial Insert	1	0.2	3.3	268	0.0	1.1
Lysis				247	0.0	1.0
Incorrect Sizing				228	0.0	1.0
Patella Maltracking	1	0.2	3.3	178	0.0	0.7
Implant Breakage Tibial Insert				147	0.0	0.6
Bearing Dislocation				137	0.0	0.6
Implant Breakage Patella				127	0.0	0.5
Metal Related Pathology	1	0.2	3.3	93	0.0	0.4
Prosthesis Dislocation				79	0.0	0.3
Synovitis				63	0.0	0.3
Osteonecrosis				50	0.0	0.2
Implant Breakage Femoral				37	0.0	0.2
Implant Breakage Tibial				34	0.0	0.1
Wear Patella				34	0.0	0.1
Tumour				29	0.0	0.1
Heterotopic Bone				12	0.0	0.1
Progression Of Disease				5	0.0	0.0
Wear Tibial				5	0.0	0.0
Patella Dislocation				2	0.0	0.0
Incorrect Side				1	0.0	0.0
Wear Femoral				1	0.0	0.0
Other				300	0.0	1.3
N Revision	30	5.7	100.0	23869	3.2	100.0
N Primary	527			735556		

Note: This table is restricted to revisions within 11.9 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2023 are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement

This figure details the cumulative incidence of the most common reasons for revision. The five most common reasons for revision are included as long as each of these reasons account for more than 10 procedures or at least 5% of all revisions for the Apex Knee CR (cless)/Apex Knee (cless) total knee combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total knee prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Knee Replacement

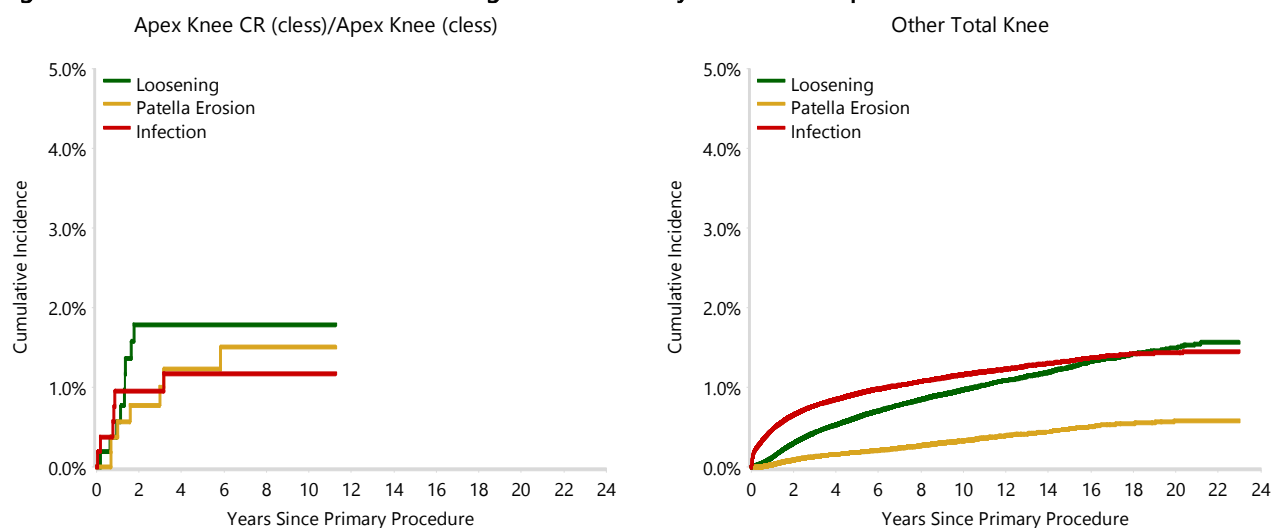


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Apex Knee CR (cless)/Apex Knee (cless) total knee combination and compares it to the components used in the revision of all other total knee prostheses.

The reason this analysis is undertaken is to identify whether there is one or more components which are being replaced that differ from the components replaced for revisions of all other total knee prostheses i.e. is there a difference in the type of revision undertaken for the Apex Knee CR (cless)/Apex Knee (cless) total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 11.9 Years)

Type of Revision	Apex Knee CR (cless)/Apex Knee (cless)		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	5	16.7	5574	23.4
Tibial Component	8	26.7	1819	7.6
Femoral Component			1240	5.2
Cement Spacer			1145	4.8
Removal of Prostheses			126	0.5
Total Femoral			21	0.1
Reinsertion of Components			7	0.0
N Major	13	43.3	9932	41.6
Insert Only	7	23.3	7272	30.5
Patella Only	7	23.3	4199	17.6
Insert/Patella	3	10.0	2401	10.1
Minor Components			57	0.2
Cement Only			8	0.0
N Minor	17	56.7	13937	58.4
TOTAL	30	100.0	23869	100.0

Note: This table is restricted to revisions within 11.9 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 6**Revision Rates of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Fixation**

This analysis is provided as some prostheses have more than one fixation option. Additionally there are prostheses where an alternative to the recommended approach to fixation was used e.g. a cementless prosthesis that has been cemented or vice-versa.

Table 6: Revised Number of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	0	1
Cementless	30	522
Hybrid (Tibial Cemented)	0	4
TOTAL	30	527

TABLE 7**Revision Rates of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Bearing Surface**

This analysis is provided as some prostheses are combined with a variety of bearing surfaces. All bearing surfaces used with this combination are listed.

Table 7: Revised Number of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	30	526
Unknown	0	1
TOTAL	30	527

TABLE 8**Revision Rates of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Bearing Mobility**

This analysis is provided as some prostheses are combined with a variety of bearing mobilities. All bearing mobilities used with this combination are listed.

Table 8: Revised Number of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	30	526
Unknown	0	1
TOTAL	30	527

TABLE 9**Revision Rates of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Stability**

This analysis is provided as some prostheses are combined with a variety of stabilities. All stabilities used with this combination are listed.

Table 9: Revised Number of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Minimally Stabilised	30	526
Unknown	0	1
TOTAL	30	527

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Apex Knee CR (cless)/Apex Knee (cless) total knee combination and provides the comparative data for each of the states for all other total knee prostheses.

The purpose of this analysis is to determine if the higher than anticipated rate of revision has widespread distribution between states. If there is widespread distribution then the reason for the higher than anticipated rate of revision is unlikely to be surgeon specific. If the prosthesis has been used in only a small number of states it is not possible to distinguish if the higher than anticipated rate of revision is related to the prosthesis, surgeon, technique or patient.

Table 10: Revised Number of Primary Total Knee Replacement by State

Component	State	N Revised	N Total
Apex Knee CR (cless)/Apex Knee (cless)	NSW	13	235
	VIC	15	260
	TAS	2	32
Other Total Knee	NSW	7313	251024
	VIC	5359	148406
	QLD	5361	153657
	WA	3064	80125
	SA	2756	64011
	TAS	456	18754
	ACT/NT	592	19579
TOTAL		24931	736083

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 11**Number of Revisions of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Apex Knee CR (cless)/Apex Knee (cless) total knee combination. It also provides the subsequent number of revisions of the primaries reported in that year.

Primary procedures performed in later years have had less follow up time therefore the number revised is expected to be less than the number revised in earlier years. For example, a primary procedure performed in 2023 has a maximum of one year to be revised, whereas a primary procedure performed in 2021 has a maximum of three years to be revised.

Table 11: Number of Revisions of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2012	2	69
2013	6	83
2014	12	118
2015	5	78
2016	0	11
2017	0	3
2018	1	29
2019	2	53
2020	0	6
2021	0	23
2022	2	47
2023	0	7
TOTAL	30	527

TABLE 12

Revision Rates of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Catalogue Number Range

Many prostheses have a number of catalogue ranges. The catalogue range is specific to particular design features; more than one catalogue range usually indicates a minor difference in design in a particular Apex Knee CR (cless)/Apex Knee (cless) prosthesis.

This analysis has been undertaken to determine if the revision rate varies according to the catalogue number range.

Model	Catalogue Range	Catalogue Description	Cement
Femoral			
Apex Knee CR	KC1410L-KC1460R	CR POROUS COCR FEMORAL COMPONENT	NO
Tibial			
Apex Knee	KC2301L-KC2306R	POROUS COATED COCR TIBIAL BASEPLATE	NO
Apex Knee	KC2401L-KC2406R	POROUS COCR TIBIAL BASEPLATE W/HOLES	NO
Apex Knee	KC2801L-KC2805R	PEGGED TIBIAL BASEPLATE UNCEMENTED	NO

Table 12: Revised Number of Apex Knee CR (cless)/Apex Knee (cless) Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
KC1410L-KC1460R	KC2301L-KC2306R	17	367
	KC2401L-KC2406R	12	130
	KC2801L-KC2805R	1	30
TOTAL		30	527