

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

Note: This analysis compares the Apex Knee CR (class)/Apex Knee (class) 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-2022>.

Note: Procedures using prostheses with no recorded use in 2021 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Knee Replacement

The revision rate of the Apex Knee CR (class)/Apex Knee (class) 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 (class)/Apex Knee (class)	27	471	2825	0.96 (0.63, 1.39)
Other Total Knee	26034	727224	4726299	0.55 (0.54, 0.56)
TOTAL	26061	727695	4729125	0.55 (0.54, 0.56)

Note: Prostheses no longer used in 2021 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 (class)/Apex Knee (class) 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
Apex Knee CR (class)/Apex Knee (class)	2.4 (1.3, 4.3)	4.9 (3.2, 7.3)	5.4 (3.6, 7.9)	5.6 (3.8, 8.2)	5.6 (3.8, 8.2)	6.2 (4.3, 9.0)	6.2 (4.3, 9.0)
Other Total Knee	1.0 (1.0, 1.0)	1.9 (1.9, 1.9)	2.5 (2.4, 2.5)	2.9 (2.9, 2.9)	3.2 (3.2, 3.3)	3.6 (3.5, 3.6)	3.9 (3.8, 3.9)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Apex Knee CR (class)/Apex Knee (class)	6.2 (4.3, 9.0)	6.2 (4.3, 9.0)					
Other Total Knee	4.2 (4.1, 4.2)	4.5 (4.4, 4.5)	4.8 (4.7, 4.8)	5.1 (5.0, 5.2)	5.4 (5.3, 5.5)	5.7 (5.7, 5.8)	6.1 (6.0, 6.1)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Apex Knee CR (class)/Apex Knee (class)							
Other Total Knee	6.4 (6.3, 6.6)	6.9 (6.7, 7.0)	7.3 (7.1, 7.4)	7.6 (7.4, 7.8)	7.9 (7.7, 8.1)	8.2 (7.9, 8.4)	8.2 (8.0, 8.5)

Note: Prostheses no longer used in 2021 are excluded from the comparator.

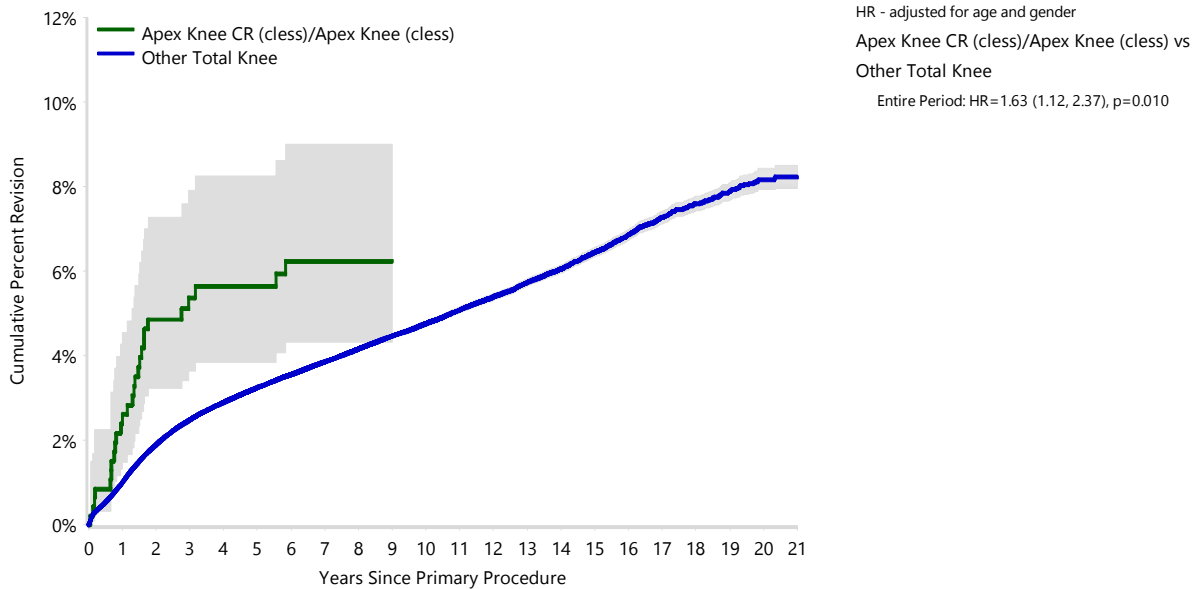
FIGURE 1

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
Apex Knee CR (class)/Apex Knee (class)	471	439	417	358	327	323	305	231	127	57	0
Other Total Knee	727224	657089	592343	526861	463714	403368	346827	293537	245627	202592	163502

Number at Risk	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Apex Knee CR (class)/Apex Knee (class)	0	0	0	0	0	0	0	0	0	0	0
Other Total Knee	128843	99109	75527	56481	41660	29601	19593	11953	6490	2687	605

Note: Prostheses no longer used in 2021 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 (class)/Apex Knee (class)		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	27	100.0	25224	96.9
Rheumatoid Arthritis			331	1.3
Other Inflammatory Arthritis			161	0.6
Tumour			151	0.6
Osteonecrosis			98	0.4
Fracture			49	0.2
Other			19	0.1
Chondrocalcinosis			1	0.0
TOTAL	27	100.0	26034	100.0

Note: Prostheses no longer used in 2021 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 9.9 Years)

Revision Diagnosis	Apex Knee CR (class)/Apex Knee (class)			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	5	1.1	18.5	6688	0.9	27.9
Loosening	9	1.9	33.3	5262	0.7	21.9
Instability	1	0.2	3.7	2331	0.3	9.7
Patellofemoral Pain	1	0.2	3.7	1962	0.3	8.2
Pain	1	0.2	3.7	1937	0.3	8.1
Patella Erosion	6	1.3	22.2	1469	0.2	6.1
Arthrofibrosis	1	0.2	3.7	980	0.1	4.1
Fracture				801	0.1	3.3
Malalignment	1	0.2	3.7	579	0.1	2.4
Incorrect Sizing				256	0.0	1.1
Lysis				239	0.0	1.0
Wear Tibial Insert	1	0.2	3.7	210	0.0	0.9
Patella Maltracking				179	0.0	0.7
Bearing Dislocation				147	0.0	0.6
Implant Breakage Patella				123	0.0	0.5
Implant Breakage Tibial Insert				111	0.0	0.5
Metal Related Pathology	1	0.2	3.7	99	0.0	0.4
Prosthesis Dislocation				74	0.0	0.3
Synovitis				70	0.0	0.3
Osteonecrosis				57	0.0	0.2
Implant Breakage Tibial				36	0.0	0.1
Implant Breakage Femoral				30	0.0	0.1
Tumour				25	0.0	0.1
Wear Patella				23	0.0	0.1
Heterotopic Bone				13	0.0	0.1
Wear Tibial				8	0.0	0.0
Progression Of Disease				4	0.0	0.0
Patella Dislocation				2	0.0	0.0
Wear Femoral				2	0.0	0.0
Incorrect Side				1	0.0	0.0
Other				294	0.0	1.2
N Revision	27	5.7	100.0	24012	3.3	100.0
N Primary	471			727224		

Note: This table is restricted to revisions within 9.9 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 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

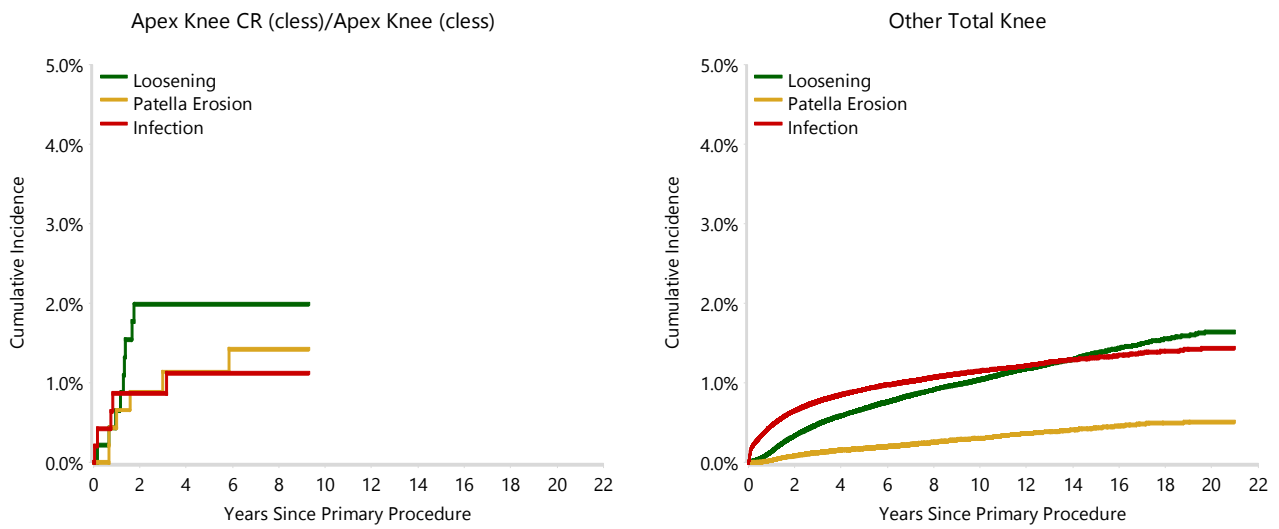


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Apex Knee CR (class)/Apex Knee (class) 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 (class)/Apex Knee (class) total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 9.9 Years)

Type of Revision	Apex Knee CR (class)/Apex Knee (class)		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	5	18.5	5590	23.3
Tibial Component	8	29.6	2010	8.4
Cement Spacer			1307	5.4
Femoral Component			1280	5.3
Removal of Prostheses			145	0.6
Total Femoral			17	0.1
Reinsertion of Components			10	0.0
N Major	13	48.1	10359	43.1
Insert Only	6	22.2	6753	28.1
Patella Only	5	18.5	4545	18.9
Insert/Patella	3	11.1	2284	9.5
Minor Components			57	0.2
Cement Only			14	0.1
N Minor	14	51.9	13653	56.9
TOTAL	27	100.0	24012	100.0

Note: This table is restricted to revisions within 9.9 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 are excluded from the comparator.

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

Fixation	N Revised	N Total
Cemented	0	1
Cementless	27	467
Hybrid (Tibial Cemented)	0	3
TOTAL	27	471

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

Bearing Surface	N Revised	N Total
Non XLPE	27	470
Unknown	0	1
TOTAL	27	471

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	27	470
Unknown	0	1
TOTAL	27	471

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	27	470
Unknown	0	1
TOTAL	27	471

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	11	179
	VIC	15	260
	TAS	1	32
Other Total Knee	NSW	7711	252942
	VIC	5538	144227
	QLD	5690	153171
	WA	3235	77905
	SA	2837	63440
	TAS	417	16853
	ACT/NT	606	18686
TOTAL		26061	727695

Note: Prostheses no longer used in 2021 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 2021 has a maximum of one year to be revised, whereas a primary procedure performed in 2019 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	1	53
2020	0	6
2021	0	21
TOTAL	27	471

TABLE 12

Revision Rates of Apex Knee CR (class)/Apex Knee (class) 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 (class)/Apex Knee (class) 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

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

Femoral Range	Tibial Range	N Revised	N Total
KC1410L-KC1460R	KC2301L-KC2306R	15	341
	KC2401L-KC2406R	12	130
TOTAL		27	471