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-2023.

Note: Procedures using prostheses with no recorded use in 2022 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)	28	513	3253	0.86 (0.57, 1.24)
Other Total Knee	26808	757437	5066532	0.53 (0.52, 0.54)
TOTAL	26836	757950	5069785	0.53 (0.52, 0.54)

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)	2.3 (1.3, 4.0)	4.6 (3.1, 7.0)	5.1 (3.5, 7.5)	5.6 (3.8, 8.1)	5.6 (3.8, 6 8.1)	5.2 (4.3, 6.2 (4.3 8.8) 8.8	, , ,
Other Total Knee	1.0 (1.0, 1.0)	1.8 (1.8, 1.9)	2.4 (2.4, 2.4)	2.8 (2.8, 2.9)	3.1 (3.1, 3.2)	3.5 (3.4, 3.8 (3.7 3.5) 3.8	, , ,
CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yr	s 14 Yrs	15 Yrs
Apex Knee CR (cless)/Apex Knee (cless)	6.2 (4.3, 8.8)	6.2 (4.3, 8.8	3)				
Other Total Knee	4.3 (4.3, 4.4)	4.6 (4.6, 4.7	7) 4.9 (4.9, 5	.0) 5.2 (5.2, 5	5.3) 5.6 (5.5,	5.6) 5.9 (5.8, 5.9)	6.2 (6.1, 6.3)
CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yr	s 21 Yrs	22 Yrs
Apex Knee CR (cless)/Apex Knee (cless)							
Other Total Knee	6.6 (6.5, 6.8)	7.0 (6.9, 7.2	2) 7.3 (7.2, 7	.5) 7.6 (7.4, 7	7.8) 7.8 (7.6,	8.0) 8.0 (7.8, 8.2)	8.2 (7.9, 8.6)

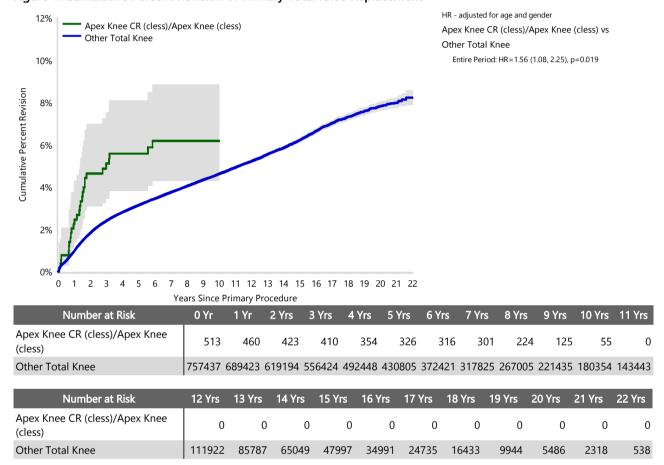
FIGURE 1

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. 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



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

	Apex Knee CR (cles	s)/Apex Knee (cless)	Other To	tal Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	28	100.0	25976	96.9
Rheumatoid Arthritis			342	1.3
Tumour			162	0.6
Other Inflammatory Arthritis			160	0.6
Osteonecrosis			101	0.4
Fracture			48	0.2
Other			18	0.1
Chondrocalcinosis			1	0.0
TOTAL	28	100.0	26808	100.0

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 10.9 Years)

	Apex Kne	e CR (cless)/Apex K	nee (cless)		Other Total Knee	
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	5	1.0	17.9	7101	0.9	28.3
Loosening	9	1.8	32.1	5518	0.7	22.0
Instability	1	0.2	3.6	2473	0.3	9.8
Pain	1	0.2	3.6	1937	0.3	7.7
Patellofemoral Pain	1	0.2	3.6	1851	0.2	7.4
Patella Erosion	7	1.4	25.0	1596	0.2	6.4
Arthrofibrosis	1	0.2	3.6	1022	0.1	4.1
Fracture				894	0.1	3.6
Malalignment	1	0.2	3.6	586	0.1	2.3
Incorrect Sizing				261	0.0	1.0
Lysis				258	0.0	1.0
Wear Tibial Insert	1	0.2	3.6	256	0.0	1.0
Patella Maltracking				185	0.0	0.7
Bearing Dislocation				147	0.0	0.6
Implant Breakage Tibial Insert				134	0.0	0.5
Implant Breakage Patella				133	0.0	0.5
Metal Related Pathology	1	0.2	3.6	97	0.0	0.4
Prosthesis Dislocation				80	0.0	0.3
Synovitis				69	0.0	0.3
Osteonecrosis				55	0.0	0.2
Implant Breakage Tibial				37	0.0	0.1
Tumour				31	0.0	0.1
Implant Breakage Femoral				30	0.0	0.1
Wear Patella				28	0.0	0.1
Heterotopic Bone				12	0.0	0.0
Wear Tibial				7	0.0	0.0
Progression Of Disease				4	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				312	0.0	1.2
N Revision	28	5.5	100.0	25118	3.3	100.0
N Primary	513			757437		

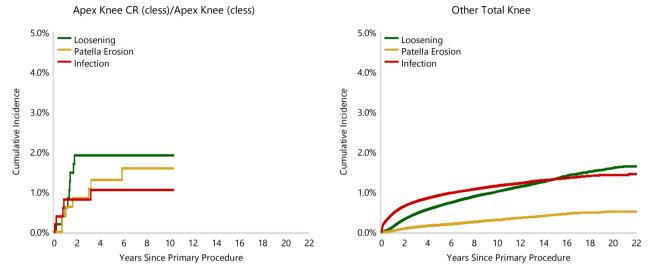
Note: This table is restricted to revisions within 10.9 years for all groups to allow a time-matched comparison of revisions.

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



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 10.9 Years)

Apex Knee CR (cless)/Apex Knee (cless)			Other Total Knee	
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	5	17.9	5944	23.7
Tibial Component	8	28.6	2065	8.2
Cement Spacer			1317	5.2
Femoral Component			1295	5.2
Removal of Prostheses			149	0.6
Total Femoral			22	0.1
Reinsertion of Components			13	0.1
N Major	13	46.4	10805	43.0
Insert Only	6	21.4	7274	29.0
Patella Only	6	21.4	4541	18.1
Insert/Patella	3	10.7	2419	9.6
Minor Components			62	0.2
Cement Only			17	0.1
N Minor	15	53.6	14313	57.0
TOTAL	28	100.0	25118	100.0

Note: This table is restricted to revisions within 10.9 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2022 are excluded from the comparator.

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	28	508
Hybrid (Tibial Cemented)	0	4
TOTAL	28	513

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	28	512
Unknown	0	1
TOTAL	28	513

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	28	512
Unknown	0	1
TOTAL	28	513

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	28	512
Unknown	0	1
TOTAL	28	513

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	221	
	VIC	15	260	
	TAS	2	32	
Other Total Knee	NSW	7948	262212	
	VIC	5810	152788	
	QLD	5766	157008	
	WA	3245	81139	
	SA	2967	66419	
	TAS	435	18101	
	ACT/NT	637	19770	
TOTAL		26836	757950	

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 2022 has a maximum of one year to be revised, whereas a primary procedure performed in 2020 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	21
2022	0	42
TOTAL	28	513

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 KC2	301L-KC2306R	16	353
KC2	401L-KC2406R	12	130
KC2	801L-KC2805R	0	30
TOTAL		28	513