

Optetrak-PS/Optetrak RBK Total Knee Investigation

Note: This analysis compares the Optetrak-PS/Optetrak RBK 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 Optetrak-PS/Optetrak RBK 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)
Optetrak-PS/Optetrak RBK	94	1127	9709	0.97 (0.78, 1.18)
Other Total Knee	26061	727695	4729125	0.55 (0.54, 0.56)
TOTAL	26155	728822	4738833	0.55 (0.55, 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 Optetrak-PS/Optetrak RBK 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
Optetrak-PS/Optetrak RBK	1.8 (1.2, 2.7)	2.8 (2.0, 4.0)	4.6 (3.5, 6.0)	5.2 (4.1, 6.7)	5.9 (4.6, 7.5)	6.3 (5.0, 8.0)	7.0 (5.6, 8.7)
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
Optetrak-PS/Optetrak RBK	7.4 (6.0, 9.2)	8.1 (6.5, 10.0)	8.5 (6.8, 10.5)	9.1 (7.3, 11.2)	10.1 (8.1, 12.4)	11.0 (8.9, 13.6)	11.4 (9.2, 14.2)
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
Optetrak-PS/Optetrak RBK	12.2 (9.6, 15.5)						
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.

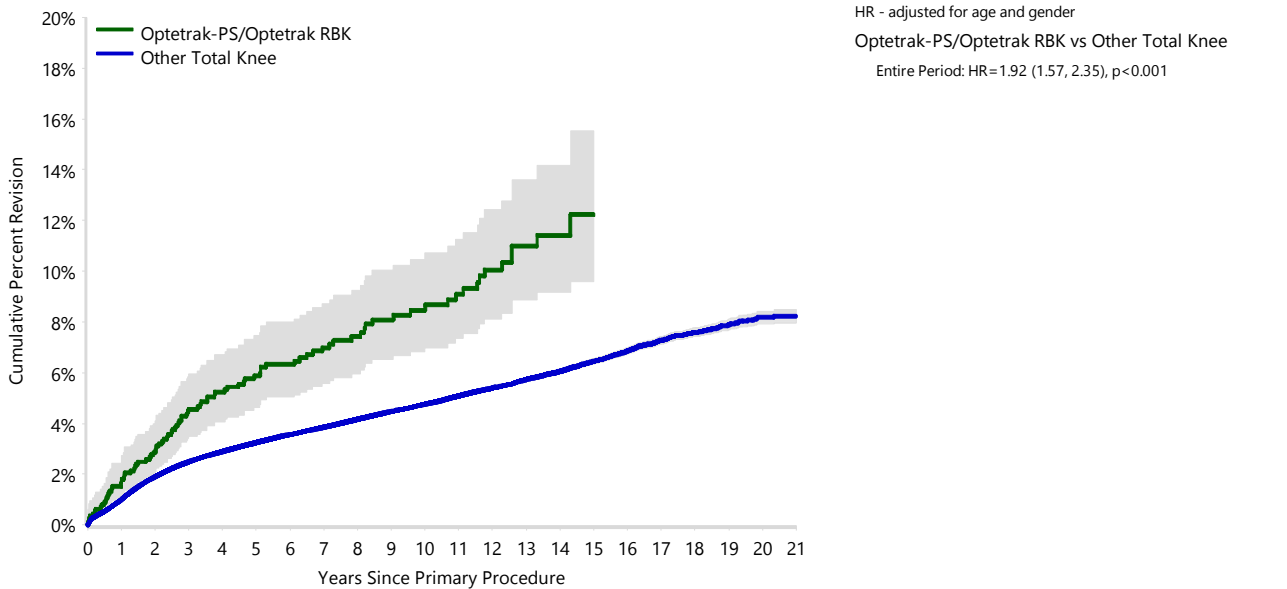
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Optetrak-PS/Optetrak RBK 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
Optetrak-PS/Optetrak RBK	1127	1105	1086	1035	939	827	764	694	576	508	458
Other Total Knee	727695	657528	592760	527219	464041	403691	347132	293768	245752	202649	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
Optetrak-PS/Optetrak RBK	413	343	241	128	43	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	Optetrak-PS/Optetrak RBK		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	92	97.9	25251	96.9
Rheumatoid Arthritis			331	1.3
Other Inflammatory Arthritis	2	2.1	161	0.6
Tumour			151	0.6
Osteonecrosis			98	0.4
Fracture			49	0.2
Other			19	0.1
Chondrocalcinosis			1	0.0
TOTAL	94	100.0	26061	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 15.9 Years)

Revision Diagnosis	Optetrak-PS/Optetrak RBK			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	10	0.9	10.6	6948	1.0	26.9
Loosening	23	2.0	24.5	5772	0.8	22.3
Instability	5	0.4	5.3	2468	0.3	9.6
Pain	9	0.8	9.6	2054	0.3	8.0
Patellofemoral Pain	15	1.3	16.0	2044	0.3	7.9
Patella Erosion	9	0.8	9.6	1671	0.2	6.5
Arthrofibrosis	3	0.3	3.2	995	0.1	3.9
Fracture	1	0.1	1.1	927	0.1	3.6
Malalignment	3	0.3	3.2	601	0.1	2.3
Wear Tibial Insert				343	0.0	1.3
Lysis	1	0.1	1.1	332	0.0	1.3
Incorrect Sizing	3	0.3	3.2	258	0.0	1.0
Patella Maltracking	6	0.5	6.4	181	0.0	0.7
Bearing Dislocation				152	0.0	0.6
Implant Breakage Tibial Insert				147	0.0	0.6
Implant Breakage Patella				133	0.0	0.5
Metal Related Pathology				115	0.0	0.4
Prosthesis Dislocation				79	0.0	0.3
Synovitis	1	0.1	1.1	78	0.0	0.3
Osteonecrosis	1	0.1	1.1	58	0.0	0.2
Implant Breakage Tibial				41	0.0	0.2
Implant Breakage Femoral	1	0.1	1.1	38	0.0	0.1
Wear Patella	1	0.1	1.1	31	0.0	0.1
Tumour				27	0.0	0.1
Heterotopic Bone				15	0.0	0.1
Wear Tibial				11	0.0	0.0
Progression Of Disease				6	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	2	0.2	2.1	301	0.0	1.2
N Revision	94	8.3	100.0	25831	3.5	100.0
N Primary	1127			727695		

Note: This table is restricted to revisions within 15.9 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 Optetrak-PS/Optetrak RBK 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

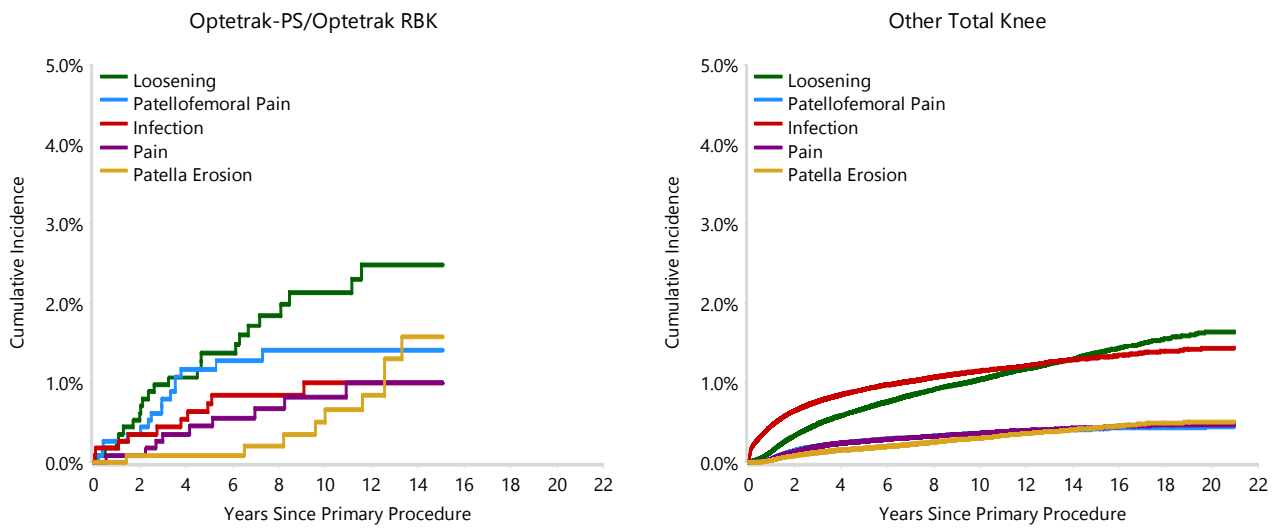


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Optetrak-PS/Optetrak RBK 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 Optetrak-PS/Optetrak RBK total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 15.9 Years)

Type of Revision	Optetrak-PS/Optetrak RBK		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	27	28.7	6317	24.5
Tibial Component	3	3.2	2095	8.1
Cement Spacer	3	3.2	1353	5.2
Femoral Component	4	4.3	1310	5.1
Removal of Prostheses	1	1.1	149	0.6
Total Femoral			20	0.1
Reinsertion of Components			11	0.0
N Major	38	40.4	11255	43.6
Insert Only	12	12.8	7080	27.4
Patella Only	34	36.2	4763	18.4
Insert/Patella	8	8.5	2660	10.3
Minor Components	2	2.1	59	0.2
Cement Only			14	0.1
N Minor	56	59.6	14576	56.4
TOTAL	94	100.0	25831	100.0

Note: This table is restricted to revisions within 15.9 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 Optetrak-PS/Optetrak RBK 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 Optetrak-PS/Optetrak RBK Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	62	944
Hybrid (Tibial Cemented)	32	183
TOTAL	94	1127

TABLE 7**Revision Rates of Optetrak-PS/Optetrak RBK 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 Optetrak-PS/Optetrak RBK Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	94	1127
TOTAL	94	1127

TABLE 8**Revision Rates of Optetrak-PS/Optetrak RBK 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 Optetrak-PS/Optetrak RBK Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Rotating	94	1127
TOTAL	94	1127

TABLE 9**Revision Rates of Optetrak-PS/Optetrak RBK 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 Optetrak-PS/Optetrak RBK Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Posterior Stabilised	94	1127
TOTAL	94	1127

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Optetrak-PS/Optetrak RBK 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
Optetrak-PS/Optetrak RBK	NSW	28	173
	VIC	17	98
	QLD	41	818
	WA	7	34
	ACT/NT	1	4
Other Total Knee	NSW	7722	253121
	VIC	5553	144487
	QLD	5690	153171
	WA	3235	77905
	SA	2837	63440
	TAS	418	16885
	ACT/NT	606	18686
TOTAL		26155	728822

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

TABLE 11**Number of Revisions of Optetrak-PS/Optetrak RBK Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Optetrak-PS/Optetrak RBK 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 Optetrak-PS/Optetrak RBK Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	1	1
2006	11	81
2007	26	173
2008	22	166
2009	11	119
2010	10	82
2011	1	40
2012	0	37
2013	0	50
2014	2	100
2015	4	56
2016	1	46
2017	3	88
2018	2	75
2019	0	13
TOTAL	94	1127

TABLE 12

Revision Rates of Optetrak-PS/Optetrak RBK 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 Optetrak-PS/Optetrak RBK 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	Fixation
Femoral				
Optetrak-PS	2440200-2440305	PS CEMENTED HI FLEX FEMORAL COMPONENT	YES	
Optetrak-PS	2460200-2460305	PS POROUS HI FLEX FEMORAL COMPONENT	NO	POROUS
Tibial				
Optetrak RBK	2600411-2600455	CEMENTED FINNED TIBIAL TRAY	YES	

Table 12: Revised Number of Optetrak-PS/Optetrak RBK Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
2440200-2440305	2600411-2600455	62	942
2460200-2460305	2600411-2600455	32	185
TOTAL		94	1127