

Optetrak-PS/Optetrak Total Knee Investigation

Note: This analysis compares the Optetrak-PS/Optetrak 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 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	297	2410	25418	1.17 (1.04, 1.31)
Other Total Knee	26061	727695	4729125	0.55 (0.54, 0.56)
TOTAL	26358	730105	4754542	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 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	1.5 (1.1, 2.0)	3.4 (2.8, 4.2)	4.8 (4.0, 5.7)	5.7 (4.8, 6.7)	6.4 (5.4, 7.4)	7.3 (6.3, 8.4)	8.4 (7.4, 9.6)
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	9.2 (8.1, 10.5)	10.6 (9.4, 12.0)	11.7 (10.4, 13.1)	13.0 (11.6, 14.6)	13.7 (12.2, 15.3)	14.6 (13.1, 16.3)	14.8 (13.2, 16.5)
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	14.8 (13.2, 16.5)	15.2 (13.5, 17.1)	15.6 (13.8, 17.6)	16.8 (14.4, 19.4)	16.8 (14.4, 19.4)		
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.

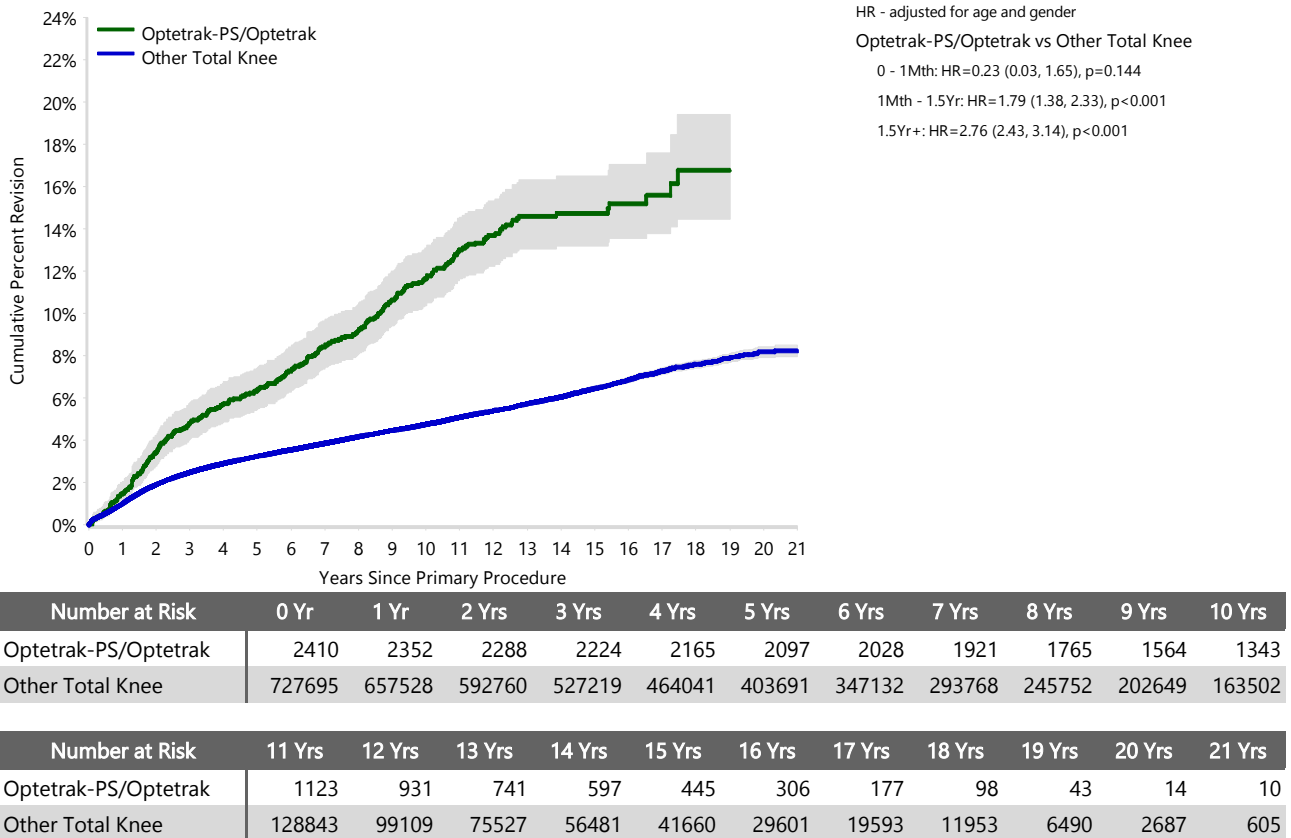
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Optetrak-PS/Optetrak 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



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		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	290	97.6	25251	96.9
Rheumatoid Arthritis	7	2.4	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	297	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

Revision Diagnosis	Optetrak-PS/Optetrak			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	52	2.2	17.5	6981	1.0	26.8
Loosening	102	4.2	34.3	5841	0.8	22.4
Instability	14	0.6	4.7	2490	0.3	9.6
Pain	30	1.2	10.1	2064	0.3	7.9
Patellofemoral Pain	22	0.9	7.4	2048	0.3	7.9
Patella Erosion	8	0.3	2.7	1693	0.2	6.5
Arthrofibrosis	5	0.2	1.7	997	0.1	3.8
Fracture	8	0.3	2.7	944	0.1	3.6
Malalignment	4	0.2	1.3	603	0.1	2.3
Wear Tibial Insert	7	0.3	2.4	364	0.1	1.4
Lysis	24	1.0	8.1	345	0.0	1.3
Incorrect Sizing	2	0.1	0.7	259	0.0	1.0
Patella Maltracking	6	0.2	2.0	181	0.0	0.7
Bearing Dislocation				153	0.0	0.6
Implant Breakage Tibial Insert	3	0.1	1.0	150	0.0	0.6
Implant Breakage Patella	1	0.0	0.3	134	0.0	0.5
Metal Related Pathology				117	0.0	0.4
Prosthesis Dislocation				80	0.0	0.3
Synovitis				78	0.0	0.3
Osteonecrosis				58	0.0	0.2
Implant Breakage Tibial	4	0.2	1.3	42	0.0	0.2
Implant Breakage Femoral				38	0.0	0.1
Wear Patella	4	0.2	1.3	33	0.0	0.1
Tumour				28	0.0	0.1
Heterotopic Bone				15	0.0	0.1
Wear Tibial				12	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	1	0.0	0.3	302	0.0	1.2
N Revision	297	12.3	100.0	26061	3.6	100.0
N Primary	2410			727695		

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 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

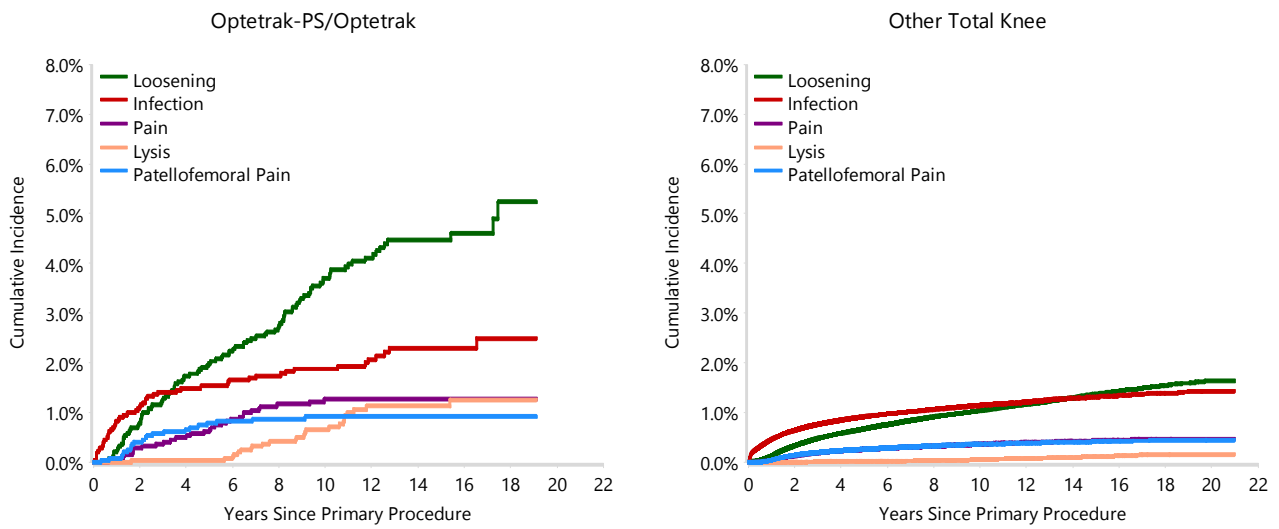


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

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

Table 5: Primary Total Knee Replacement - Type of Revision

Type of Revision	Optetrak-PS/Optetrak		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	136	45.8	6419	24.6
Tibial Component	27	9.1	2100	8.1
Cement Spacer	13	4.4	1360	5.2
Femoral Component	7	2.4	1311	5.0
Removal of Prostheses	2	0.7	150	0.6
Total Femoral			21	0.1
Reinsertion of Components	1	0.3	11	0.0
N Major	186	62.6	11372	43.6
Insert Only	36	12.1	7123	27.3
Patella Only	53	17.8	4783	18.4
Insert/Patella	21	7.1	2710	10.4
Minor Components			59	0.2
Cement Only	1	0.3	14	0.1
N Minor	111	37.4	14689	56.4
TOTAL	297	100.0	26061	100.0

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

TABLE 6**Revision Rates of Optetrak-PS/Optetrak 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 Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	273	2236
Hybrid (Tibial Cemented)	24	174
TOTAL	297	2410

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

Bearing Surface	N Revised	N Total
Non XLPE	297	2410
TOTAL	297	2410

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

Bearing Mobility	N Revised	N Total
Fixed	297	2410
TOTAL	297	2410

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

Stability	N Revised	N Total
Fully Stabilised	1	1
Posterior Stabilised	296	2409
TOTAL	297	2410

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 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	NSW	8	55
	VIC	5	48
	QLD	273	2246
	WA	11	56
	SA	0	3
	ACT/NT	0	2
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		26358	730105

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

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

Year of Implant	Number Revised	Total Number
2000	1	14
2001	3	22
2002	9	90
2003	16	130
2004	23	155
2005	30	252
2006	41	253
2007	29	216
2008	9	168
2009	25	202
2010	22	198
2011	30	202
2012	28	200
2013	17	151
2014	9	115
2015	3	30
2016	1	3
2017	1	5
2018	0	3
2019	0	1
TOTAL	297	2410

TABLE 12

Revision Rates of Optetrak-PS/Optetrak 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 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	2040101-2040106	PS CEMENTED FEMORAL COMPONENT	YES	
Optetrak-PS	2060101-2060106	PS POROUS FEMORAL COMPONENT	NO	POROUS
Optetrak-PS	2340200-2340306	PS CEMENTED ASYMMETRIC FEMORAL COMPONENT	YES	
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	2000421-2000612	CEMENTED FINNED TIBIAL TRAY	YES	
Optetrak	2040421-2040612	CEMENTED TRAPEZOID TIBIAL TRAY	YES	
Optetrak	2080411-2080454	CEMENTED OFFSET TIBIAL TRAY W/SCREW	YES	

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

Femoral Range	Tibial Range	N Revised	N Total
2040101-2040106	2000421-2000612	50	414
	2040421-2040612	15	94
2060101-2060106	2000421-2000612	19	132
	2040421-2040612	1	6
2340200-2340306	2000421-2000612	33	184
	2040421-2040612	75	862
2440200-2440305	2000421-2000612	16	94
	2040421-2040612	84	584
	2080411-2080454	0	1
2460200-2460305	2000421-2000612	3	19
	2040421-2040612	1	20
TOTAL		297	2410