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-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 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	353	2410	27976	1.26 (1.13, 1.40)
Other Total Knee	24931	736083	4688062	0.53 (0.53, 0.54)
TOTAL	25284	738493	4716038	0.54 (0.53, 0.54)

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	8 Yrs
Optetrak-PS/Optetrak	1.5 (1.1, 2.0)	3.4 (2.8, 4.2)	4.8 (4.0, 5.7)	5.7 (4.9, 6.8)	6.4 (5.5, 7.5)	7.3 (6.4, 8.5)	8.5 (7.4, 9.7)	9.4 (8.3, 10.7)
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, 3.2)	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
Optetrak-PS/Optetrak	10.9 (9.7, 12.3)	12.1 (10.8, 13.6)	13.9 (12.5, 15.4)	15.0 (13.5, 16.6)	16.3 (14.7, 18.0)	16.9 (15.3, 18.7)	17.4 (15.7, 19.2)	17.7 (16.0, 19.6)
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 Yr	s 20	Yrs 2	1 Yrs	22 Yrs	23 Yrs
Optetrak-PS/Optetrak	18.0 (16.3 20.0	,	•	(17.1, 19. 21.3)	8 (17.4, 22.4)			
Other Total Knee	7.0 (6.8, 7.1	7.3 (7.1,	7.5) 7.5 (7.3	3, 7.7) 7.7 (7	7.5, 8.0) 8.0	(7.7, 8.3)	3.2 (7.9, 8.6)	8.2 (7.9, 8.6)

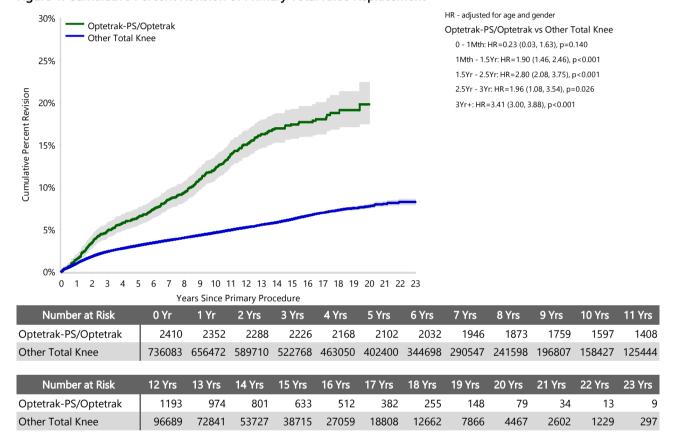
FIGURE 1

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 2023 are excluded from the comparator.

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

	Optetrak-PS/Optetrak		Other To	tal Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	343	97.2	24126	96.8
Rheumatoid Arthritis	10	2.8	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	353	100.0	24931	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

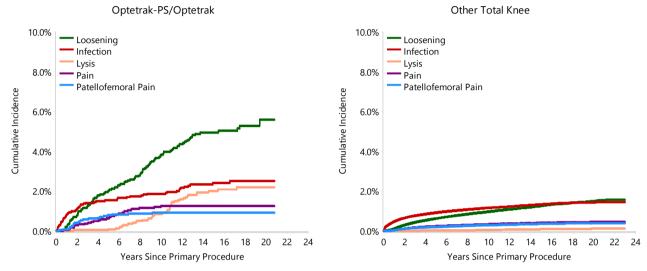
	(Optetrak-PS/Optetra	ak		Other Total Knee	
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	56	2.3	15.9	7004	1.0	28.1
Loosening	117	4.9	33.1	5304	0.7	21.3
Instability	14	0.6	4.0	2562	0.3	10.3
Pain	30	1.2	8.5	1833	0.2	7.4
Patella Erosion	8	0.3	2.3	1793	0.2	7.2
Patellofemoral Pain	22	0.9	6.2	1632	0.2	6.5
Arthrofibrosis	5	0.2	1.4	1019	0.1	4.1
Fracture	11	0.5	3.1	993	0.1	4.0
Malalignment	4	0.2	1.1	525	0.1	2.1
Wear Tibial Insert	14	0.6	4.0	343	0.0	1.4
Lysis	45	1.9	12.7	282	0.0	1.1
Incorrect Sizing	2	0.1	0.6	229	0.0	0.9
Implant Breakage Tibial Insert	4	0.2	1.1	182	0.0	0.7
Patella Maltracking	6	0.2	1.7	180	0.0	0.7
Bearing Dislocation				141	0.0	0.6
Implant Breakage Patella	4	0.2	1.1	130	0.0	0.5
Metal Related Pathology	1	0.0	0.3	101	0.0	0.4
Prosthesis Dislocation				80	0.0	0.3
Synovitis				64	0.0	0.3
Osteonecrosis				50	0.0	0.2
Implant Breakage Femoral				45	0.0	0.2
Wear Patella	6	0.2	1.7	42	0.0	0.2
Implant Breakage Tibial	3	0.1	0.8	34	0.0	0.1
Tumour				31	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Progression Of Disease				7	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	1	0.0	0.3	302	0.0	1.2
N Revision	353	14.6	100.0	24931	3.4	100.0
N Primary	2410			736083		

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



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

	Optetrak-F	PS/Optetrak	Other To	otal Knee
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	171	48.4	5972	24.0
Tibial Component	30	8.5	1857	7.4
Femoral Component	9	2.5	1259	5.0
Cement Spacer	13	3.7	1174	4.7
Removal of Prostheses	2	0.6	131	0.5
Total Femoral			22	0.1
Reinsertion of Components	1	0.3	7	0.0
N Major	226	64.0	10422	41.8
Insert Only	38	10.8	7464	29.9
Patella Only	53	15.0	4325	17.3
Insert/Patella	34	9.6	2654	10.6
Minor Components	1	0.3	57	0.2
Cement Only	1	0.3	9	0.0
N Minor	127	36.0	14509	58.2
TOTAL	353	100.0	24931	100.0

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	329	2236
Hybrid (Tibial Cemented)	24	174
TOTAL	353	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	353	2410
TOTAL	353	2410

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	353	2410
TOTAL	353	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	352	2409
TOTAL	353	2410

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	328	2246	
	WA	12	56	
	SA	0	3	
	ACT/NT	0	2	
Other Total Knee	NSW	7326	251259	
	VIC	5374	148666	
	QLD	5361	153657	
	WA	3064	80125	
	SA	2756	64011	
	TAS	458	18786	
	ACT/NT	592	19579	
TOTAL		25284	738493	

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 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 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	32	252
2006	43	253
2007	30	216
2008	13	168
2009	30	202
2010	27	198
2011	41	202
2012	39	200
2013	25	151
2014	13	115
2015	5	30
2016	1	3
2017	2	5
2018	0	3
2019	0	1
TOTAL	353	2410

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	51	414
2040421-2040612	15	94
2060101-2060106 2000421-2000612	19	132
2040421-2040612	1	6
2340200-2340306 2000421-2000612	34	184
2040421-2040612	111	862
2440200-2440305 2000421-2000612	16	94
2040421-2040612	102	584
2080411-2080454	0	1
2460200-2460305 2000421-2000612	3	19
2040421-2040612	1	20
TOTAL	353	2410