Optetrak-PS/Optetrak-PS Total Knee Investigation

Note: This analysis compares the Optetrak-PS/Optetrak-PS 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-2021.

Note: Procedures using prostheses with no recorded use in 2020 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Knee Replacement

The revision rate of the Optetrak-PS/Optetrak-PS 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% Cl)
Optetrak-PS/Optetrak-PS	14	55	528	2.65 (1.45, 4.45)
Other Total Knee	23602	668852	4161212	0.57 (0.56, 0.57)
TOTAL	23616	668907	4161740	0.57 (0.56, 0.57)

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Optetrak-PS/Optetrak-PS total knee combination is compared to all other total knee prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Knee Replacement

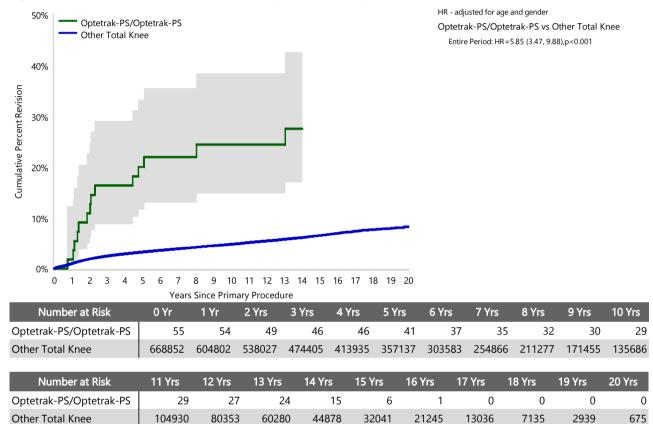
CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Optetrak-PS/Optetrak-PS	1.8 (0.3, 12.2) 1().9 (5.1, 22.7)	16.4 (8.9, 29.1)	16.4 (8.9, 29.1)	20.0 (11.6, 33.3)	22.0 (13.1) 35.5)	
Other Total Knee	1.0 (1.0, 1.0)	1.9 (1.9, 2.0)	2.5 (2.5, 2.6)	2.9 (2.9, 3.0)	3.3 (3.2, 3.3)	3.6 (3.6, 3.7)) 3.9 (3.9, 4.0)
CDD	0 V	0 \/==	10.14	- 11	V	12 \/	12 Vre
CPR	8 Yrs	9 Yrs	10 Yı	rs II	Yrs	12 Yrs	13 Yrs
Optetrak-PS/Optetrak-PS	22.0 (13.1, 35.5)	24.4 (14.9, 3	88.5) 24.4 (14.5	9, 38.5) 24.4 (1-	4.9, 38.5) 24.4	4 (14.9, 38.5)	24.4 (14.9, 38.5)
Other Total Knee	4.2 (4.2, 4.3)	4.5 (4.5,	4.6) 4.8 (4	1.8, 4.9) 5.2	(5.1, 5.2)	5.5 (5.4, 5.6)	5.8 (5.7, 5.9)
CPR	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs
Optetrak-PS/Optetrak-PS	27.6 (17.1, 42.6)						
Other Total Knee	6.1 (6.0, 6.2)	6.6 (6.4, 6.7)	7.0 (6.8, 7.1)	7.4 (7.2, 7.6)	7.7 (7.5, 7.9)	8.0 (7.7, 8.2)) 8.3 (7.9, 8.7)

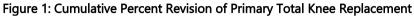
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

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





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-PS		Other To	tal Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	12	85.7	22899	97.0
Rheumatoid Arthritis	1	7.1	296	1.3
Other Inflammatory Arthritis			145	0.6
Tumour			115	0.5
Osteonecrosis	1	7.1	89	0.4
Fracture			41	0.2
Other			16	0.1
Chondrocalcinosis			1	0.0
TOTAL	14	100.0	23602	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.

	Ор	tetrak-PS/Optetrak	(-PS		Other Total Knee	
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection				6270	0.9	26.7
Loosening	1	1.8	7.1	5300	0.8	22.6
Instability				2212	0.3	9.4
Patellofemoral Pain	6	10.9	42.9	1976	0.3	8.4
Pain	4	7.3	28.6	1879	0.3	8.0
Patella Erosion				1471	0.2	6.3
Arthrofibrosis				885	0.1	3.8
Fracture				829	0.1	3.5
Malalignment				549	0.1	2.3
Lysis				299	0.0	1.3
Wear Tibial Insert				292	0.0	1.2
Incorrect Sizing				249	0.0	1.1
Patella Maltracking	3	5.5	21.4	159	0.0	0.7
Bearing Dislocation				148	0.0	0.6
Implant Breakage Tibial Insert				124	0.0	0.5
Implant Breakage Patella				121	0.0	0.5
Metal Related Pathology				111	0.0	0.5
Synovitis				72	0.0	0.3
Prosthesis Dislocation				66	0.0	0.3
Osteonecrosis				55	0.0	0.2
Implant Breakage Tibial				37	0.0	0.2
Implant Breakage Femoral				35	0.0	0.1
Wear Patella				25	0.0	0.1
Tumour				22	0.0	0.1
Heterotopic Bone				13	0.0	0.1
Wear Tibial				10	0.0	0.0
Progression Of Disease				5	0.0	0.0
Incorrect Side				1	0.0	0.0
Osteoarthritis				1	0.0	0.0
Patella Dislocation				1	0.0	0.0
Post Operative Haematoma				1	0.0	0.0
Wear Femoral				1	0.0	0.0
Other				262	0.0	1.1
N Revision	14	25.5	100.0	23481	3.5	100.0
N Primary	55			668852		

Note: This table is restricted to revisions within 16.1 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2020 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-PS total knee combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total knee prostheses.

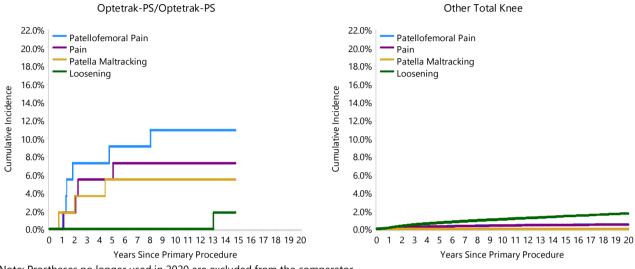


Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Knee Replacement

Type of Revision Performed for Primary Total Knee Replacement

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

	Optetrak-PS/	Optetrak-PS	Other Total Knee		
Type of Revision	Number	Percent	Number	Percent	
TKR (Tibial/Femoral)	1	7.1	5694	24.2	
Tibial Component			1969	8.4	
Cement Spacer			1249	5.3	
Femoral Component			1211	5.2	
Removal of Prostheses			139	0.6	
Total Femoral			17	0.1	
Reinsertion of Components			10	0.0	
N Major	1	7.1	10289	43.8	
Insert Only			6326	26.9	
Patella Only	13	92.9	4394	18.7	
Insert/Patella			2405	10.2	
Minor Components			54	0.2	
Cement Only			13	0.1	
N Minor	13	92.9	13192	56.2	
TOTAL	14	100.0	23481	100.0	

Table 5: Primary Total Knee Replacement -	Type of Revision (Follow-up Limited to 16.1 Years)
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Note: This table is restricted to revisions within 16.1 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2020 are excluded from the comparator.

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

Fixation	N Revised	N Total
Cemented	14	55
TOTAL	14	55

TABLE 7

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

Bearing Surface	N Revised	N Total
Non XLPE	14	55
TOTAL	14	55

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

Bearing Mobility	N Revised	N Total
Fixed	14	55
TOTAL	14	55

TABLE 9

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

Stability	N Revised	N Total
Posterior Stabilised	14	55
TOTAL	14	55

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Optetrak-PS/Optetrak-PS 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: Revision Rates of Primary Total Knee Replacement by State

Component	State	N Revised	Obs. Years	N Total
Optetrak-PS/Optetrak-PS	QLD	14	528	55
Other Total Knee	NSW	7032	1471357	233656
	VIC	5048	825327	133339
	QLD	5129	883319	140206
	WA	2964	428762	71603
	SA	2541	362456	58247
	TAS	344	88315	14884
	ACT/NT	544	101675	16917
TOTAL		23616	4161740	668907

Number of Revisions of Optetrak-PS/Optetrak-PS 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-PS 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 2020 has a maximum of one year to be revised, whereas a primary procedure performed in 2018 has a maximum of three years to be revised.

Table 11: Number of Revisions of Optetrak-PS/Optetrak-PS Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2004	2	8
2005	3	14
2006	4	18
2007	5	15
TOTAL	14	55

Revision Rates of Optetrak-PS/Optetrak-PS 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-PS 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	Mobility	Stability	Material
Femoral						
Optetrak-PS	2040101-2040106	PS CEMENTED FEMORAL COMPONENT	YES			
Optetrak-PS	2340200-2340306	PS CEMENTED ASYMMETRIC FEMORAL COMPONENT	YES			
Tibial						
Optetrak-PS	2041209-2041413	PS ALL POLYETHYLENE TIBIAL COMPONENT	YES	FIXED	POSTERIOR STABILISED	NON CROSS-LINKED POLYETHYLENE

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

Femoral Range Tibial Range	N Revised	N Total
2040101-2040106 2041209-2041413	6	24
2340200-2340306 2041209-2041413	8	31
TOTAL	14	55