

## 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-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-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% CI)
Optetrak-PS/Optetrak-PS	14	55	546	2.56 (1.40, 4.30)
Other Total Knee	26061	727695	4729125	0.55 (0.54, 0.56)
<b>TOTAL</b>	<b>26075</b>	<b>727750</b>	<b>4729671</b>	<b>0.55 (0.54, 0.56)</b>

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-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)	10.9 (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)	22.0 (13.1, 35.5)
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-PS	22.0 (13.1, 35.5)	24.4 (14.9, 38.5)	24.4 (14.9, 38.5)	24.4 (14.9, 38.5)	24.4 (14.9, 38.5)	24.4 (14.9, 38.5)	27.6 (17.1, 42.6)
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-PS	27.6 (17.1, 42.6)						
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.

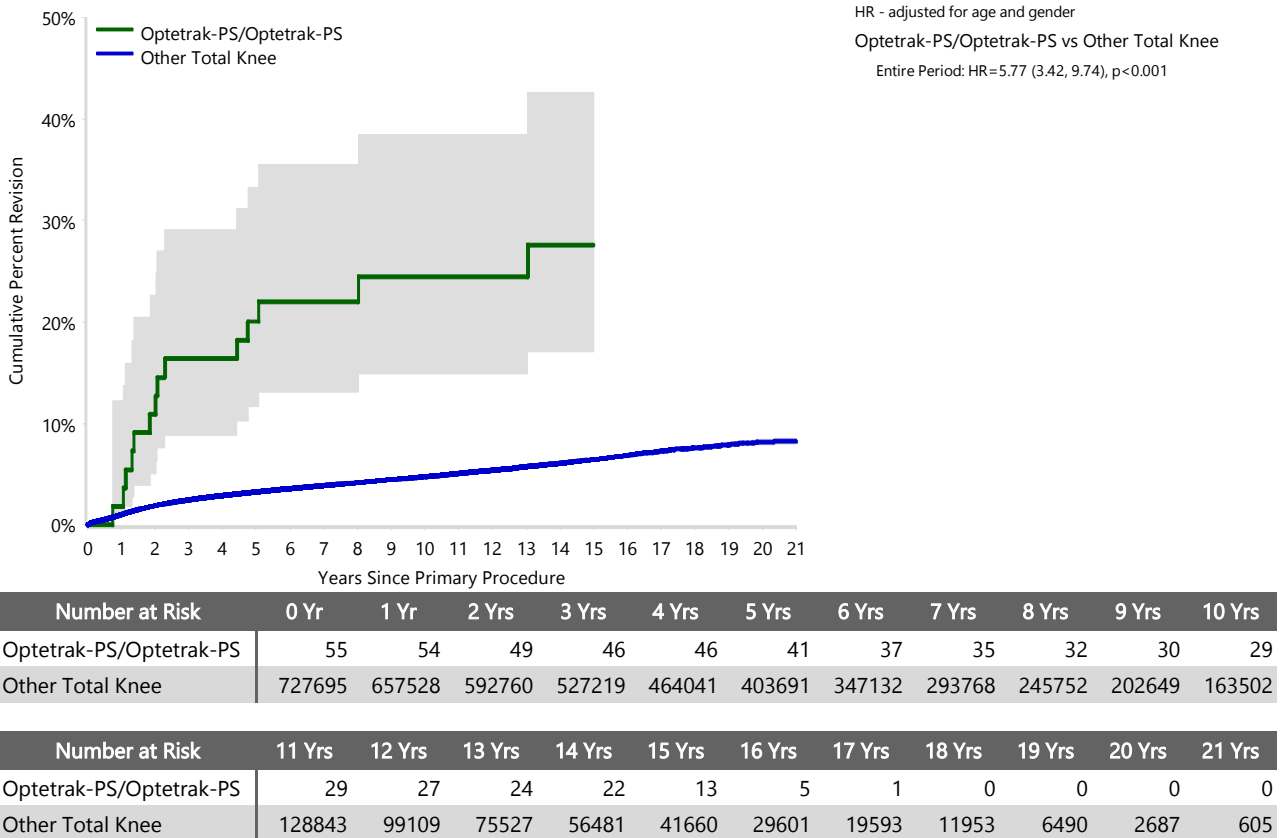
**FIGURE 1**

**Yearly Cumulative Percent Revision of Primary Total Knee Replacement**

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

**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-PS		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	12	85.7	25251	96.9
Rheumatoid Arthritis	1	7.1	331	1.3
Other Inflammatory Arthritis			161	0.6
Tumour			151	0.6
Osteonecrosis	1	7.1	98	0.4
Fracture			49	0.2
Other			19	0.1
Chondrocalcinosis			1	0.0
<b>TOTAL</b>	<b>14</b>	<b>100.0</b>	<b>26061</b>	<b>100.0</b>

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 17.1 Years)

Revision Diagnosis	Optetrak-PS/Optetrak-PS			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection				6969	1.0	26.8
Loosening	1	1.8	7.1	5809	0.8	22.4
Instability				2482	0.3	9.6
Pain	4	7.3	28.6	2061	0.3	7.9
Patellofemoral Pain	6	10.9	42.9	2046	0.3	7.9
Patella Erosion				1686	0.2	6.5
Arthrofibrosis				996	0.1	3.8
Fracture				934	0.1	3.6
Malalignment				602	0.1	2.3
Wear Tibial Insert				357	0.0	1.4
Lysis				343	0.0	1.3
Incorrect Sizing				259	0.0	1.0
Patella Maltracking	3	5.5	21.4	181	0.0	0.7
Bearing Dislocation				152	0.0	0.6
Implant Breakage Tibial Insert				148	0.0	0.6
Implant Breakage Patella				133	0.0	0.5
Metal Related Pathology				116	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				42	0.0	0.2
Implant Breakage Femoral				38	0.0	0.1
Wear Patella				32	0.0	0.1
Tumour				27	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				302	0.0	1.2
<b>N Revision</b>	<b>14</b>	<b>25.5</b>	<b>100.0</b>	<b>25969</b>	<b>3.6</b>	<b>100.0</b>
<b>N Primary</b>	<b>55</b>			<b>727695</b>		

Note: This table is restricted to revisions within 17.1 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-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**

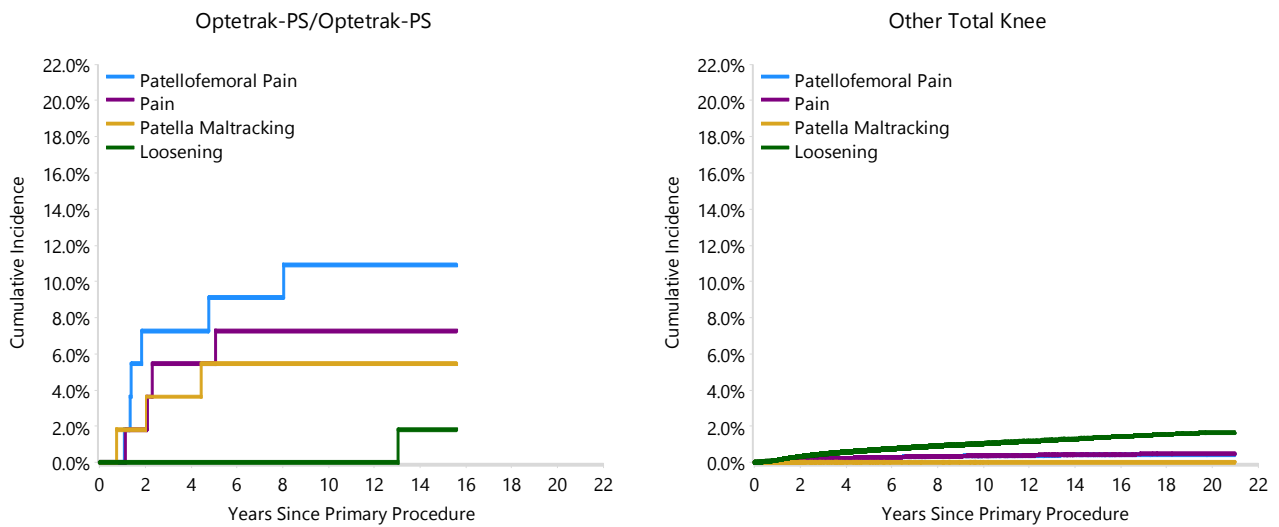


TABLE 5

**Type of Revision Performed for Primary Total Knee Replacement**

This analysis identifies the components used in the revision of the Optetrak-PS/Optetrak-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.

**Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 17.1 Years)**

Type of Revision	Optetrak-PS/Optetrak-PS		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	1	7.1	6379	24.6
Tibial Component			2096	8.1
Cement Spacer			1359	5.2
Femoral Component			1311	5.0
Removal of Prostheses			150	0.6
Total Femoral			21	0.1
Reinsertion of Components			11	0.0
<b>N Major</b>	<b>1</b>	<b>7.1</b>	<b>11327</b>	<b>43.6</b>
Insert Only			7105	27.4
Patella Only	13	92.9	4774	18.4
Insert/Patella			2690	10.4
Minor Components			59	0.2
Cement Only			14	0.1
<b>N Minor</b>	<b>13</b>	<b>92.9</b>	<b>14642</b>	<b>56.4</b>
<b>TOTAL</b>	<b>14</b>	<b>100.0</b>	<b>25969</b>	<b>100.0</b>

Note: This table is restricted to revisions within 17.1 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-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
<b>TOTAL</b>	<b>14</b>	<b>55</b>

**TABLE 7****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
<b>TOTAL</b>	<b>14</b>	<b>55</b>



**TABLE 8****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
<b>TOTAL</b>	<b>14</b>	<b>55</b>

**TABLE 9****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
<b>TOTAL</b>	<b>14</b>	<b>55</b>

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-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: Revised Number of Primary Total Knee Replacement by State**

Component	State	N Revised	N Total
Optetrak-PS/Optetrak-PS	QLD	14	55
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
	<b>TOTAL</b>		<b>26075</b>

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

**TABLE 11****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 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-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
<b>TOTAL</b>	<b>14</b>	<b>55</b>

TABLE 12

**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
<b>Femoral</b>						
Optetrak-PS	2040101-2040106	PS CEMENTED FEMORAL COMPONENT	YES			
Optetrak-PS	2340200-2340306	PS CEMENTED ASYMMETRIC FEMORAL COMPONENT	YES			
<b>Tibial</b>						
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
<b>TOTAL</b>		<b>14</b>	<b>55</b>