Optetrak Logic CR (cementless)/Optetrak Logic (cemented) Total Knee Investigation

Note: This analysis compares the Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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-2023.

Note: Procedures using prostheses with no recorded use in 2022 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Knee Replacement

The revision rate of the Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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 Logic CR (cless)/Optetrak Logic (ctd)	51	1130	4551	1.12 (0.83, 1.47)
Other Total Knee	26786	756826	5065271	0.53 (0.52, 0.54)
TOTAL	26837	757956	5069822	0.53 (0.52, 0.54)

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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
CFR	1 11	2 115	2 112	4 115	5 115	0 115	/ 115	0 115
Optetrak Logic CR (cless)/Optetrak Logic (ctd)	1.3 (0.7,	2.0 (1.4,	3.8 (2.8,	4.8 (3.6,	5.6 (4.2,	5.9 (4.4,	7.2 (5.1,	
Optetrak Logic Cir (cless)/ Optetrak Logic (ctu)	2.1)	3.1)	5.2)	6.5)	7.5)	7.9)	10.1)	
0.1 7 . 1.6	1.0 (1.0,	1.8 (1.8,	2.4 (2.4,	2.8 (2.8,	3.1 (3.1,	3.5 (3.4,	3.8 (3.7,	4.0 (4.0,
Other Total Knee	1.0)	1.9)	2.4)	2.9)	3.2)	3.5)	3.8)	4.1)
CPR	9 Yrs	10 Yrs	11 Yr	rs 12`	Yrs 13	3 Yrs	14 Yrs	15 Yrs
Optetrak Logic CR (cless)/Optetrak Logic (ctd)								
	4.3 (4.3	, 4.6 (4.	6, 4.9 (4.9, 5.2	(5.2, 5	.5 (5.5,	5.9 (5.8,	6.2 (6.1,
Other Total Knee	4.4)) 4.	7)	5.0)	5.3)	5.6)	5.9)	6.3)
CPR	16 Yrs	17 Yrs	18 Yr	rs 19`	Yrs 20) Yrs	21 Yrs	22 Yrs
Optetrak Logic CR (cless)/Optetrak Logic (ctd)					·	·		
O4h - :: T-4-1 V:	6.6 (6.5	, 7.0 (6.	.9, 7.3 (7.2, 7.6	(7.4, 7	.8 (7.6,	8.0 (7.7,	8.2 (7.9,
Other Total Knee	6.8) 7.	2)	7.5)	7.8)	8.0)	8.2)	8.6)

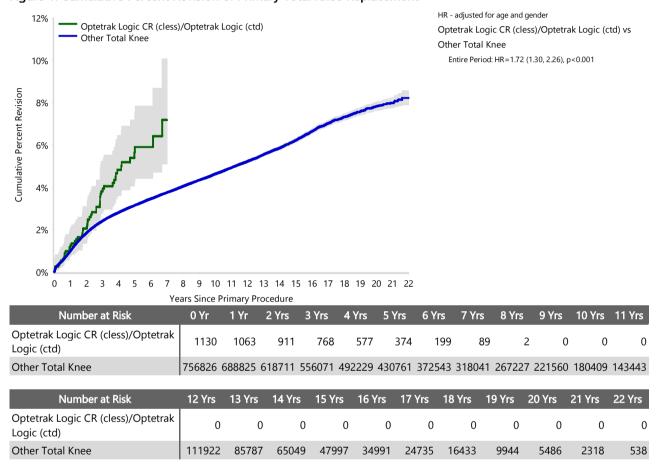
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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



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 Logic CR (cle	ss)/Optetrak Logic (ctd)	Other To	otal Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	50	98.0	25955	96.9
Rheumatoid Arthritis			342	1.3
Tumour			162	0.6
Other Inflammatory Arthritis	1	2.0	159	0.6
Osteonecrosis			101	0.4
Fracture			48	0.2
Other			18	0.1
Chondrocalcinosis			1	0.0
TOTAL	51	100.0	26786	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 (Follow-up Limited to 8.1 Years)

	Optetrak Log	ic CR (cless)/Optet	rak Logic (ctd)		Other Total Knee	
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	10	0.9	19.6	6812	0.9	29.1
Loosening	8	0.7	15.7	5072	0.7	21.7
Instability	8	0.7	15.7	2317	0.3	9.9
Pain	1	0.1	2.0	1807	0.2	7.7
Patellofemoral Pain				1753	0.2	7.5
Patella Erosion	2	0.2	3.9	1417	0.2	6.1
Arthrofibrosis	2	0.2	3.9	1004	0.1	4.3
Fracture				780	0.1	3.3
Malalignment	2	0.2	3.9	558	0.1	2.4
Incorrect Sizing				256	0.0	1.1
Lysis	1	0.1	2.0	191	0.0	0.8
Patella Maltracking	1	0.1	2.0	174	0.0	0.7
Wear Tibial Insert	7	0.6	13.7	158	0.0	0.7
Bearing Dislocation				138	0.0	0.6
Implant Breakage Patella				117	0.0	0.5
Implant Breakage Tibial Insert	3	0.3	5.9	100	0.0	0.4
Metal Related Pathology	1	0.1	2.0	88	0.0	0.4
Prosthesis Dislocation				77	0.0	0.3
Synovitis	3	0.3	5.9	63	0.0	0.3
Osteonecrosis				52	0.0	0.2
Implant Breakage Tibial				32	0.0	0.1
Implant Breakage Femoral				28	0.0	0.1
Tumour				28	0.0	0.1
Wear Patella	1	0.1	2.0	22	0.0	0.1
Heterotopic Bone				10	0.0	0.0
Wear Tibial				5	0.0	0.0
Progression Of Disease				4	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	0.1	2.0	307	0.0	1.3
N Revision	51	4.5	100.0	23374	3.1	100.0
N Primary	1130			756826		

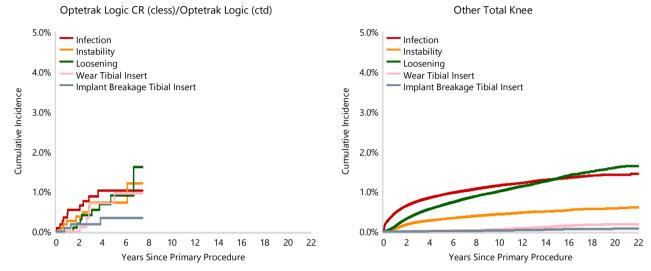
Note: This table is restricted to revisions within 8.1 years for all groups to allow a time-matched comparison of revisions.

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 Logic CR (cless)/Optetrak Logic (ctd) 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 Logic CR (cless)/Optetrak Logic (ctd) 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 Logic CR (cless)/Optetrak Logic (ctd) total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 8.1 Years)

	Optetrak Logic CR (cle	ss)/Optetrak Logic (ctd)	Other T	otal Knee
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	7	13.7	5318	22.8
Tibial Component			1982	8.5
Cement Spacer	1	2.0	1262	5.4
Femoral Component	8	15.7	1251	5.4
Removal of Prostheses			145	0.6
Total Femoral			20	0.1
Reinsertion of Components			11	0.0
N Major	16	31.4	9989	42.7
Insert Only	28	54.9	6935	29.7
Patella Only	4	7.8	4280	18.3
Insert/Patella	3	5.9	2097	9.0
Minor Components			56	0.2
Cement Only			17	0.1
N Minor	35	68.6	13385	57.3
TOTAL	51	100.0	23374	100.0

Note: This table is restricted to revisions within 8.1 years for all groups to allow a time-matched comparison of revisions.

Revision Rates of Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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 Logic CR (cless)/Optetrak Logic (ctd) Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	0	6
Hybrid (Tibial Cemented)	51	1124
TOTAL	51	1130

TABLE 7

Revision Rates of Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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 Logic CR (cless)/Optetrak Logic (ctd) Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	51	1130
TOTAL	51	1130

Revision Rates of Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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 Logic CR (cless)/Optetrak Logic (ctd) Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	51	1130
TOTAL	51	1130

TABLE 9

Revision Rates of Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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 Logic CR (cless)/Optetrak Logic (ctd) Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Minimally Stabilised	51	1130
TOTAL	51	1130

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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 Logic CR (cless)/Optetrak Logic (ctd)	NSW	41	866
	VIC	3	59
	QLD	2	99
	WA	4	81
	TAS	1	25
Other Total Knee	NSW	7918	261569
	VIC	5822	152988
	QLD	5764	156911
	WA	3241	81058
	SA	2967	66419
	TAS	437	18111
	ACT/NT	637	19770
TOTAL		26837	757956

Number of Revisions of Optetrak Logic CR (cless)/Optetrak Logic (ctd) Primary Total Knee Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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 2022 has a maximum of one year to be revised, whereas a primary procedure performed in 2020 has a maximum of three years to be revised.

Table 11: Number of Revisions of Optetrak Logic CR (cless)/Optetrak Logic (ctd) Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2014	0	2
2015	5	102
2016	9	117
2017	7	190
2018	6	205
2019	12	196
2020	8	125
2021	4	143
2022	0	50
TOTAL	51	1130

Revision Rates of Optetrak Logic CR (cless)/Optetrak Logic (ctd) 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 Logic CR (cless)/Optetrak Logic (ctd) 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
Femoral			·
Optetrak Logic CR	02010040200-02010040360	OPTETRAK LOGIC FEMORAL COMPONENT CR POROUS	NO
Tibial			
Optetrak Logic	02012450000-02012456060	OPTETRAK LOGIC FIT TIBIAL TRAY CEMENTED	YES

Table 12: Revised Number of Optetrak Logic CR (cless)/Optetrak Logic (ctd) Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
02010040200-02010040360 0	2012450000-02012456060	51	1130
TOTAL		51	1130