Legion Revision Tibial Baseplate Total Knee Investigation

Note: This analysis compares the Legion Revision Tibial Baseplate tibial prosthesis with all other total knee prostheses.

This prosthesis 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 Legion Revision Tibial Baseplate total knee prosthesis 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)
Legion Revision Tibial Baseplate	80	1308	6520	1.23 (0.97, 1.53)
Other Total Knee	24853	734785	4681646	0.53 (0.52, 0.54)
TOTAL	24933	736093	4688166	0.53 (0.53, 0.54)

TABLE 2

The yearly cumulative percent revision of the Legion Revision Tibial Baseplate total knee prosthesis is compared to all other total knee prostheses.

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

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
Legion Revision Tibial Baseplate	3.0 (2.2,	4.0 (3.0,	4.7 (3.6,	5.2 (4.0,	6.0 (4.7,	7.1 (5.5,	7.5 (5.9,	8.4 (6.5,
	4.1)	5.2)	6.1)	6.7)	7.8)	9.0)	9.6)	10.7)
Other Total Knee	1.0 (0.9,	1.8 (1.8,	2.4 (2.3,	2.8 (2.7,	3.1 (3.1,	3.4 (3.4,	3.7 (3.7,	4.0 (4.0,
	1.0)	1.8)	2.4)	2.8)	3.1)	3.5)	3.8)	4.1)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Legion Revision Tibial Baseplate	8.7 (6.8, 11.1)	9.1 (7.0, 11.6)	10.1 (7.8, 13.2)	11.3 (8.6, 14.8)	11.3 (8.6, 14.8)	12.8 (9.2, 17.7)		
Other Total Knee	4.3 (4.3, 4.4)	4.6 (4.6, 4.7)	4.9 (4.8, 5.0)	5.2 (5.1, 5.3)	5.5 (5.5, 5.6)	5.8 (5.7, 5.9)	6.2 (6.1, 6.3)	6.6 (6.5, 6.7)

CPR	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
Legion Revision Tibial Baseplate							
Other Total Knee	7.0 (6.8, 7.1)	7.3 (7.1, 7.4)	7.5 (7.3, 7.7)	7.7 (7.5, 7.9)	8.0 (7.7, 8.3)	8.2 (7.9, 8.6)	8.2 (7.9, 8.6)

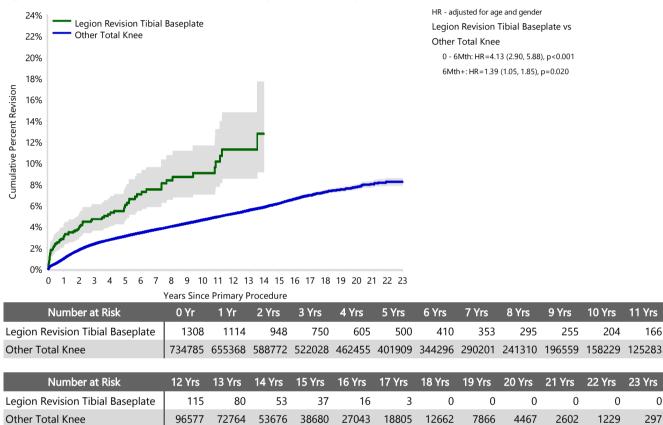
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Legion Revision Tibial Baseplate total knee prosthesis 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



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

	Legion Revision Tibial Baseplate		Other To	tal Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	70	87.5	24058	96.8
Rheumatoid Arthritis	2	2.5	311	1.3
Tumour			178	0.7
Other Inflammatory Arthritis	1	1.3	152	0.6
Osteonecrosis	2	2.5	87	0.4
Fracture	2	2.5	46	0.2
Other	3	3.8	20	0.1
Chondrocalcinosis			1	0.0
TOTAL	80	100.0	24853	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 17.5 Years)

	Legior	n Revision Tibial Ba		Other Total Knee		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	33	2.5	41.3	6964	0.9	28.1
Loosening	12	0.9	15.0	5260	0.7	21.2
Instability	8	0.6	10.0	2548	0.3	10.3
Pain	6	0.5	7.5	1823	0.2	7.4
Patella Erosion	2	0.2	2.5	1785	0.2	7.2
Patellofemoral Pain	2	0.2	2.5	1628	0.2	6.6
Arthrofibrosis	2	0.2	2.5	1017	0.1	4.1
Fracture	5	0.4	6.3	977	0.1	3.9
Malalignment				525	0.1	2.1
Wear Tibial Insert				340	0.0	1.4
Lysis				280	0.0	1.1
Incorrect Sizing				229	0.0	0.9
Implant Breakage Tibial Insert				182	0.0	0.7
Patella Maltracking	1	0.1	1.3	179	0.0	0.7
Bearing Dislocation	7	0.5	8.8	133	0.0	0.5
Implant Breakage Patella				129	0.0	0.5
Metal Related Pathology				101	0.0	0.4
Prosthesis Dislocation	1	0.1	1.3	79	0.0	0.3
Synovitis				64	0.0	0.3
Osteonecrosis				50	0.0	0.2
Implant Breakage Femoral				44	0.0	0.2
Wear Patella				42	0.0	0.2
Implant Breakage Tibial	1	0.1	1.3	33	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				302	0.0	1.2
N Revision	80	6.1	100.0	24775	3.4	100.0
N Primary	1308			734785		

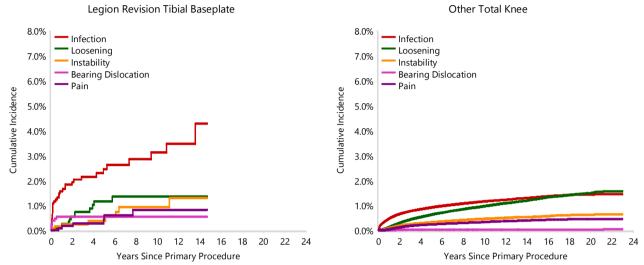
Note: This table is restricted to revisions within 17.5 years for all groups to allow a time-matched comparison of revisions.

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 Legion Revision Tibial Baseplate total knee prosthesis. 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 Legion Revision Tibial Baseplate total knee prosthesis 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 Legion Revision Tibial Baseplate total knee prosthesis compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 17.5 Years)

	Legion Revision Tibial Baseplate		Other To	otal Knee
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	10	12.5	5920	23.9
Tibial Component	6	7.5	1849	7.5
Femoral Component	5	6.3	1253	5.1
Cement Spacer	2	2.5	1171	4.7
Removal of Prostheses	1	1.3	128	0.5
Total Femoral			22	0.1
Reinsertion of Components			7	0.0
N Major	24	30.0	10350	41.8
Insert Only	43	53.8	7415	29.9
Patella Only	8	10.0	4309	17.4
Insert/Patella	4	5.0	2636	10.6
Minor Components	1	1.3	56	0.2
Cement Only			9	0.0
N Minor	56	70.0	14425	58.2
TOTAL	80	100.0	24775	100.0

Note: This table is restricted to revisions within 17.5 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2023 are excluded from the comparator.

Revision Rates of Legion Revision Tibial Baseplate 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 Legion Revision Tibial Baseplate Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	73	922
Cementless	2	282
Hybrid (Tibial Cemented)	2	26
Hybrid (Tibial Cementless)	3	78
TOTAL	80	1308

TABLE 7

Revision Rates of Legion Revision Tibial Baseplate 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 prosthesis are listed.

Table 7: Revised Number of Legion Revision Tibial Baseplate Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	61	689
XLPE	18	616
Unknown	1	3
TOTAL	80	1308

Revision Rates of Legion Revision Tibial Baseplate 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 prosthesis are listed.

Table 8: Revised Number of Legion Revision Tibial Baseplate Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	79	1305
Unknown	1	3
TOTAL	80	1308

TABLE 9

Revision Rates of Legion Revision Tibial Baseplate 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 prosthesis are listed.

Table 9: Revised Number of Legion Revision Tibial Baseplate Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Fully Stabilised	36	390
Minimally Stabilised	9	432
Posterior Stabilised	34	483
Unknown	1	3
TOTAL	80	1308

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Legion Revision Tibial Baseplate total knee prosthesis 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	
Legion Revision Tibial Baseplate	NSW	11	201	
	VIC	12	192	
	QLD	44	736	
	WA	9	96	
	SA	2	69	
	TAS	0	3	
	ACT/NT	2	11	
Other Total Knee	NSW	7315	251062	
	VIC	5362	148474	
	QLD	5319	152926	
	WA	3055	80029	
	SA	2754	63942	
	TAS	458	18783	
	ACT/NT	590	19569	
TOTAL		24933	736093	

Number of Revisions of Legion Revision Tibial Baseplate Primary Total Knee Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Legion Revision Tibial Baseplate total knee prosthesis. 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 Legion Revision Tibial Baseplate Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2006	2	16
2007	3	33
2008	5	48
2009	3	40
2010	6	56
2011	8	47
2012	5	63
2013	7	54
2014	2	47
2015	3	38
2016	2	50
2017	3	50
2018	12	87
2019	5	93
2020	4	129
2021	3	173
2022	4	138
2023	3	146
TOTAL	80	1308

Revision Rates of Legion Revision Tibial Baseplate 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 Legion Revision Tibial Baseplate 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	Material
Tibial				
Legion	71424001-71424018	REVISION TIBIAL BASEPLATE	YES	METAL
Legion	71425300-71425326	POROUS TIBIA BASEPLATE WITH JRNY LOCK	NO	
Legion	71934162-71934174	TIBIAL BASE W/O HOLES POROUS HA COATED	NO	

Table 12: Revised Number of Legion Revision Tibial Baseplate Primary Total Knee Replacement by Catalogue Number Range

Tibial Range	N Revised	N Total
71424001-71424018	76	941
71425300-71425326	0	11
71934162-71934174	4	356
TOTAL	80	1308

Revision Rates of Legion Revision Tibial Baseplate Primary Total Knee Replacement by Component

A prosthesis may be combined with multiple components. This analysis has been undertaken to determine if the revision rate varies according to the component with which it is combined.

Table 13: Revised Number of Legion Revision Tibial Baseplate Primary Total Knee Replacement by Femoral Component

Femoral Component	N Revised	N Total
Genesis II CR	2	221
Genesis II FS	0	5
Genesis II Oxinium CR	0	21
Genesis II Oxinium PS	7	61
Genesis II PS	6	81
Journey Oxinium	2	4
Legion CR	5	108
Legion FS	0	1
Legion Oxinium CR	2	87
Legion Oxinium FS	38	393
Legion Oxinium PS	15	238
Legion PS	3	88
TOTAL	80	1308