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-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 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	63	1017	4738	1.33 (1.02, 1.70)
Other Total Knee	25999	726688	4724481	0.55 (0.54, 0.56)
TOTAL	**26062**	**727705**	**4729219**	**0.55 (0.54, 0.56)**

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 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

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Legion Revision Tibial Baseplate	3.3 (2.3, 4.6)	4.5 (3.3, 6.0)	5.2 (3.9, 6.9)	5.6 (4.2, 7.5)	6.3 (4.8, 8.3)	7.3 (5.6, 9.6)	7.9 (6.0, 10.4)
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
Legion Revision Tibial Baseplate	9.0 (6.8, 11.7)	9.4 (7.1, 12.2)	9.9 (7.5, 13.0)	9.9 (7.5, 13.0)	10.9 (8.0, 14.9)	10.9 (8.0, 14.9)	
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, 5.1)	5.4 (5.3, 5.5)	5.7 (5.6, 5.8)	6.0 (6.0, 6.1)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Legion Revision Tibial Baseplate							
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.

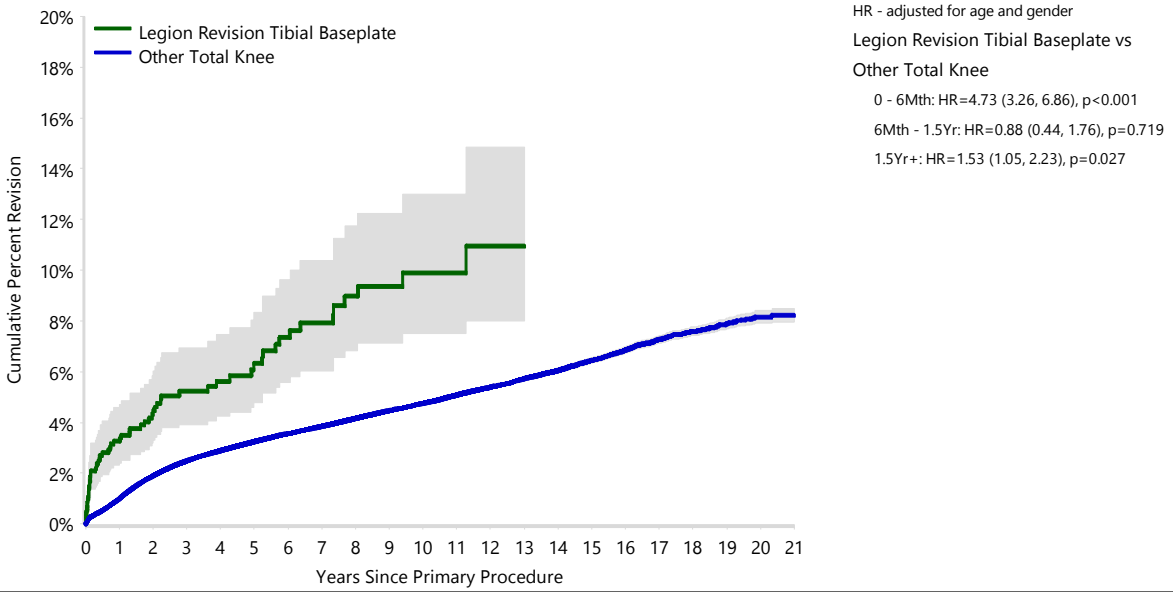
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the 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



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Legion Revision Tibial Baseplate	1017	810	659	548	452	392	331	286	237	193	129
Other Total Knee	726688	656728	592111	526681	463599	403308	346809	293489	245522	202463	163377

Number at Risk	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Legion Revision Tibial Baseplate	96	61	40	16	3	0	0	0	0	0	0
Other Total Knee	128751	99050	75489	56465	41657	29601	19593	11953	6490	2687	605

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

	Legion Revision Tibial Baseplate		Other Total Knee	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	54	85.7	25198	96.9
Rheumatoid Arthritis	1	1.6	330	1.3
Other Inflammatory Arthritis	1	1.6	160	0.6
Tumour			151	0.6
Osteonecrosis	2	3.2	96	0.4
Fracture	2	3.2	47	0.2
Other	3	4.8	16	0.1
Chondrocalcinosis			1	0.0
TOTAL	**63**	**100.0**	**25999**	**100.0**

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 15.5 Years)

	Legion Revision Tibial Baseplate			Other Total Knee		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	27	2.7	42.9	6915	1.0	26.9
Loosening	8	0.8	12.7	5749	0.8	22.4
Instability	5	0.5	7.9	2457	0.3	9.6
Pain	5	0.5	7.9	2045	0.3	8.0
Patellofemoral Pain	2	0.2	3.2	2037	0.3	7.9
Patella Erosion	1	0.1	1.6	1663	0.2	6.5
Arthrofibrosis	2	0.2	3.2	993	0.1	3.9
Fracture	5	0.5	7.9	918	0.1	3.6
Malalignment				600	0.1	2.3
Wear Tibial Insert				340	0.0	1.3
Lysis				326	0.0	1.3
Incorrect Sizing				258	0.0	1.0
Patella Maltracking	1	0.1	1.6	180	0.0	0.7
Bearing Dislocation	5	0.5	7.9	147	0.0	0.6
Implant Breakage Tibial Insert				145	0.0	0.6
Implant Breakage Patella				133	0.0	0.5
Metal Related Pathology				114	0.0	0.4
Prosthesis Dislocation	1	0.1	1.6	78	0.0	0.3
Synovitis				78	0.0	0.3
Osteonecrosis				58	0.0	0.2
Implant Breakage Tibial	1	0.1	1.6	39	0.0	0.2
Implant Breakage Femoral				38	0.0	0.1
Wear Patella				31	0.0	0.1
Tumour				27	0.0	0.1
Heterotopic Bone				15	0.0	0.1
Wear Tibial				11	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				301	0.0	1.2
N Revision	**63**	**6.2**	**100.0**	**25707**	**3.5**	**100.0**
N Primary	**1017**			**726688**		

Note: This table is restricted to revisions within 15.5 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 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

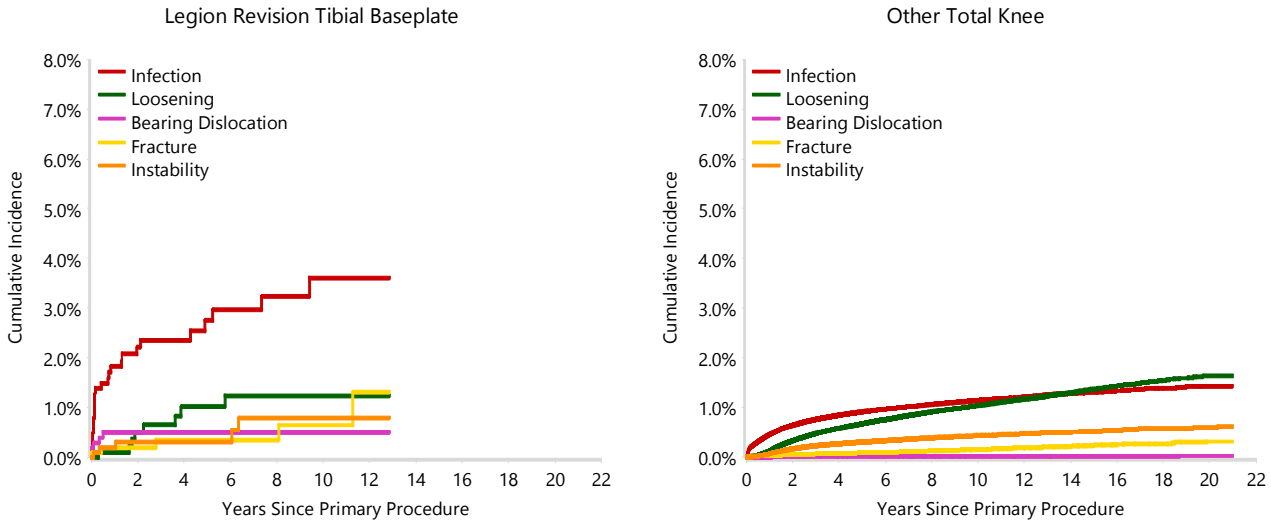


TABLE 5

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 15.5 Years)

	Legion Revision Tibial Baseplate		Other Total Knee	
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	9	14.3	6285	24.4
Tibial Component	3	4.8	2091	8.1
Cement Spacer	2	3.2	1350	5.3
Femoral Component	5	7.9	1305	5.1
Removal of Prostheses	1	1.6	148	0.6
Total Femoral			20	0.1
Reinsertion of Components			11	0.0
N Major	**20**	**31.7**	**11210**	**43.6**
Insert Only	33	52.4	7036	27.4
Patella Only	7	11.1	4752	18.5
Insert/Patella	2	3.2	2637	10.3
Minor Components	1	1.6	58	0.2
Cement Only			14	0.1
N Minor	**43**	**68.3**	**14497**	**56.4**
TOTAL	**63**	**100.0**	**25707**	**100.0**

Note: This table is restricted to revisions within 15.5 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 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	59	810
Cementless	1	152
Hybrid (Tibial Cemented)	2	24
Hybrid (Tibial Cementless)	1	31
TOTAL	**63**	**1017**

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	51	618
XLPE	11	397
Unknown	1	2
TOTAL	**63**	**1017**

TABLE 8

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	62	1015
Unknown	1	2
TOTAL	**63**	**1017**

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	29	314
Minimally Stabilised	6	247
Posterior Stabilised	27	454
Unknown	1	2
TOTAL	**63**	**1017**

TABLE 10

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	187
	VIC	8	164
	QLD	35	545
	WA	5	51
	SA	2	59
	TAS	0	2
	ACT/NT	2	9
Other Total Knee	NSW	7711	252938
	VIC	5545	144323
	QLD	5656	152631
	WA	3230	77854
	SA	2835	63381
	TAS	418	16883
	ACT/NT	604	18678
TOTAL		**26062**	**727705**

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

TABLE 11

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 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 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	5	56
2011	6	47
2012	4	63
2013	7	54
2014	2	47
2015	3	38
2016	2	50
2017	3	50
2018	8	87
2019	4	93
2020	4	129
2021	2	166
TOTAL	**63**	**1017**

TABLE 12

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
Tibial			
Legion	71424001-71424018	REVISION TIBIAL BASEPLATE	YES
Legion	71424022-71424077	PRESSFIT STRAIGHT STEM	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	62	827
71424022-71424077	0	1
71934162-71934174	1	189
TOTAL	**63**	**1017**

TABLE 13

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	117
Genesis II FS	0	5
Genesis II Oxinium CR	0	18
Genesis II Oxinium PS	7	60
Genesis II PS	5	80
Journey Oxinium	1	4
Legion CR	4	75
Legion FS	0	1
Legion Oxinium CR	0	37
Legion Oxinium FS	30	323
Legion Oxinium PS	11	213
Legion PS	3	84
TOTAL	**63**	**1017**