

Nexgen LPS Flex (cementless)/Nexgen Total Knee Investigation

Note: This analysis compares the Nexgen LPS Flex (class)/Nexgen 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 Nexgen LPS Flex (class)/Nexgen 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)
Nexgen LPS Flex (class)/Nexgen	111	2114	13765	0.81 (0.66, 0.97)
Other Total Knee	26725	755838	5056037	0.53 (0.52, 0.53)
TOTAL	26836	757952	5069802	0.53 (0.52, 0.54)

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Nexgen LPS Flex (class)/Nexgen 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
Nexgen LPS Flex (class)/Nexgen	2.4 (1.8, 3.2)	3.5 (2.8, 4.4)	4.4 (3.6, 5.3)	4.8 (4.0, 5.9)	5.0 (4.2, 6.1)	5.1 (4.2, 6.1)	5.3 (4.4, 6.3)	5.4 (4.5, 6.5)
Other Total Knee	1.0 (1.0, 1.0)	1.8 (1.8, 1.9)	2.4 (2.4, 2.4)	2.8 (2.8, 2.8)	3.1 (3.1, 3.2)	3.5 (3.4, 3.5)	3.8 (3.7, 3.8)	4.0 (4.0, 4.1)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Nexgen LPS Flex (class)/Nexgen	5.5 (4.6, 6.7)	6.5 (5.1, 8.1)	6.5 (5.1, 8.1)	6.5 (5.1, 8.1)			
Other Total Knee	4.3 (4.3, 4.4)	4.6 (4.6, 4.7)	4.9 (4.9, 5.0)	5.2 (5.2, 5.3)	5.5 (5.5, 5.6)	5.9 (5.8, 5.9)	6.2 (6.1, 6.3)

CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
Nexgen LPS Flex (class)/Nexgen							
Other Total Knee	6.6 (6.5, 6.8)	7.0 (6.9, 7.2)	7.3 (7.2, 7.5)	7.6 (7.4, 7.8)	7.8 (7.6, 8.0)	8.0 (7.7, 8.2)	8.2 (7.9, 8.6)

Note: Prostheses no longer used in 2022 are excluded from the comparator.

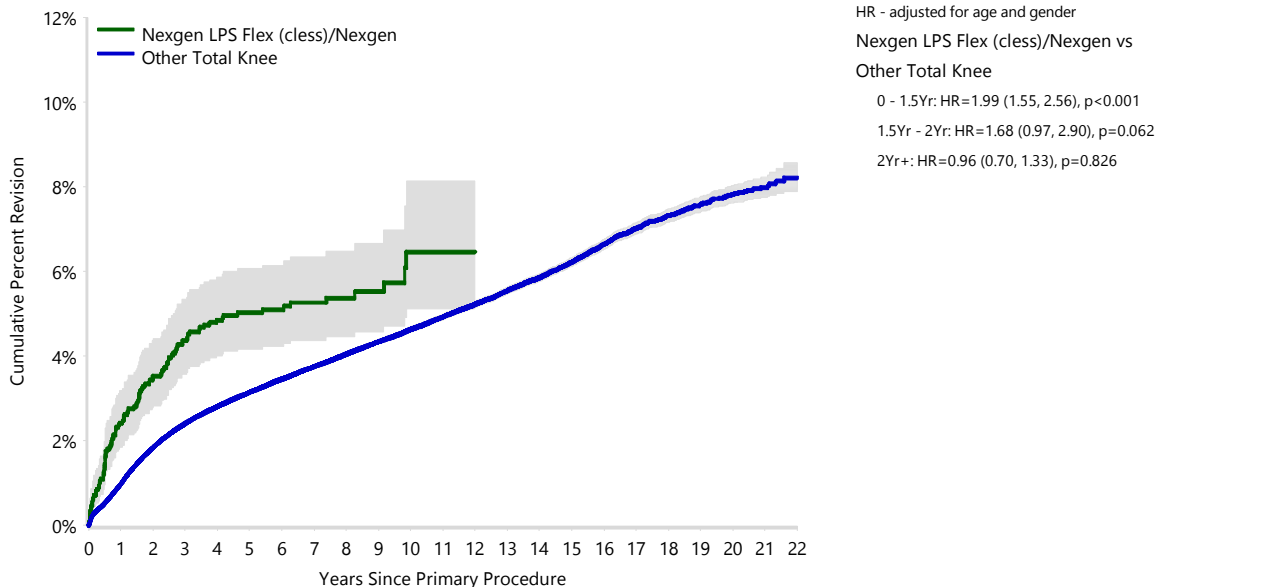
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Nexgen LPS Flex (class)/Nexgen 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



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	11 Yrs
Nexgen LPS Flex (class)/Nexgen	2114	2044	1998	1876	1666	1432	1185	954	700	475	225	109
Other Total Knee	755838	687841	617621	554960	491137	429700	371554	317174	266531	221086	180184	143334

Number at Risk	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
Nexgen LPS Flex (class)/Nexgen	49	0	0	0	0	0	0	0	0	0	0
Other Total Knee	111873	85787	65049	47997	34991	24735	16433	9944	5486	2318	538

Note: Prostheses no longer used in 2022 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	Nexgen LPS Flex (class)/Nexgen		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	110	99.1	25894	96.9
Rheumatoid Arthritis			342	1.3
Tumour			162	0.6
Other Inflammatory Arthritis	1	0.9	159	0.6
Osteonecrosis			101	0.4
Fracture			48	0.2
Other			18	0.1
Chondrocalcinosis			1	0.0
TOTAL	111	100.0	26725	100.0

Note: Prostheses no longer used in 2022 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 12.9 Years)

Revision Diagnosis	Nexgen LPS Flex (class)/Nexgen			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	33	1.6	29.7	7195	1.0	27.9
Loosening	30	1.4	27.0	5696	0.8	22.1
Instability	11	0.5	9.9	2533	0.3	9.8
Pain	5	0.2	4.5	1984	0.3	7.7
Patellofemoral Pain	4	0.2	3.6	1892	0.3	7.3
Patella Erosion	6	0.3	5.4	1677	0.2	6.5
Arthrofibrosis	2	0.1	1.8	1028	0.1	4.0
Fracture	13	0.6	11.7	940	0.1	3.6
Malalignment	2	0.1	1.8	591	0.1	2.3
Wear Tibial Insert				298	0.0	1.2
Lysis	1	0.0	0.9	285	0.0	1.1
Incorrect Sizing				261	0.0	1.0
Patella Maltracking				185	0.0	0.7
Implant Breakage Tibial Insert	1	0.0	0.9	152	0.0	0.6
Bearing Dislocation				149	0.0	0.6
Implant Breakage Patella				137	0.0	0.5
Metal Related Pathology				100	0.0	0.4
Prosthesis Dislocation				81	0.0	0.3
Synovitis				73	0.0	0.3
Osteonecrosis				55	0.0	0.2
Implant Breakage Tibial	1	0.0	0.9	38	0.0	0.1
Implant Breakage Femoral				34	0.0	0.1
Tumour				32	0.0	0.1
Wear Patella				31	0.0	0.1
Heterotopic Bone				12	0.0	0.0
Wear Tibial				8	0.0	0.0
Progression Of Disease				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	2	0.1	1.8	313	0.0	1.2
N Revision	111	5.3	100.0	25789	3.4	100.0
N Primary	2114			755838		

Note: This table is restricted to revisions within 12.9 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 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 Nexgen LPS Flex (class)/Nexgen 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

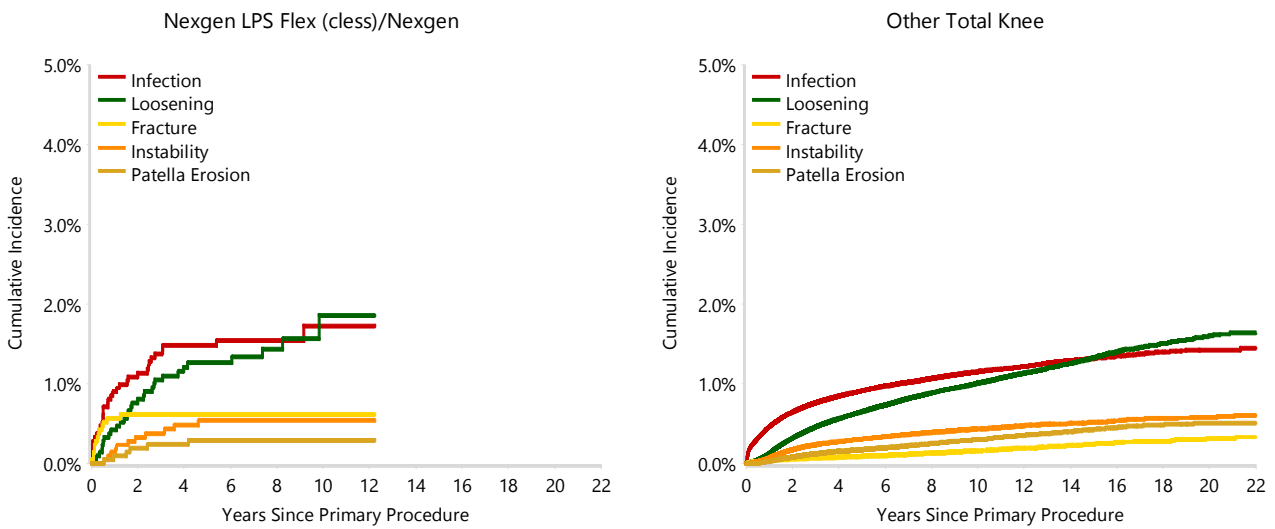


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Nexgen LPS Flex (class)/Nexgen 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 Nexgen LPS Flex (class)/Nexgen total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 12.9 Years)

Type of Revision	Nexgen LPS Flex (class)/Nexgen		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	25	22.5	6210	24.1
Tibial Component	14	12.6	2091	8.1
Cement Spacer	4	3.6	1330	5.2
Femoral Component	12	10.8	1302	5.0
Removal of Prostheses	1	0.9	148	0.6
Total Femoral			24	0.1
Reinsertion of Components			13	0.1
N Major	56	50.5	11118	43.1
Insert Only	39	35.1	7392	28.7
Patella Only	11	9.9	4625	17.9
Insert/Patella	4	3.6	2575	10.0
Minor Components	1	0.9	62	0.2
Cement Only			17	0.1
N Minor	55	49.5	14671	56.9
TOTAL	111	100.0	25789	100.0

Note: This table is restricted to revisions within 12.9 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 6**Revision Rates of Nexgen LPS Flex (class)/Nexgen 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 Nexgen LPS Flex (class)/Nexgen Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	3	30
Cementless	51	1195
Hybrid (Tibial Cemented)	55	883
Hybrid (Tibial Cementless)	2	6
TOTAL	111	2114

TABLE 7**Revision Rates of Nexgen LPS Flex (class)/Nexgen 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 Nexgen LPS Flex (class)/Nexgen Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	13	326
XLPE	98	1785
Unknown	0	3
TOTAL	111	2114

TABLE 8**Revision Rates of Nexgen LPS Flex (class)/Nexgen 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 Nexgen LPS Flex (class)/Nexgen Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	93	1800
Rotating	18	311
Unknown	0	3
TOTAL	111	2114

TABLE 9**Revision Rates of Nexgen LPS Flex (class)/Nexgen 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 Nexgen LPS Flex (class)/Nexgen Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Posterior Stabilised	111	2111
Unknown	0	3
TOTAL	111	2114

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Nexgen LPS Flex (class)/Nexgen 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
Nexgen LPS Flex (class)/Nexgen	NSW	45	943
	VIC	30	500
	QLD	19	389
	WA	11	140
	SA	3	38
	TAS	1	25
	ACT/NT	2	79
Other Total Knee	NSW	7914	261490
	VIC	5795	152549
	QLD	5747	156619
	WA	3234	80999
	SA	2964	66382
	TAS	436	18108
	ACT/NT	635	19691
TOTAL		26836	757952

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 11**Number of Revisions of Nexgen LPS Flex (class)/Nexgen Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Nexgen LPS Flex (class)/Nexgen 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 Nexgen LPS Flex (class)/Nexgen Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2010	5	73
2011	8	78
2012	8	149
2013	19	312
2014	11	238
2015	17	280
2016	9	225
2017	17	252
2018	6	221
2019	10	188
2020	1	82
2021	0	12
2022	0	4
TOTAL	111	2114

TABLE 12

Revision Rates of Nexgen LPS Flex (class)/Nexgen 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 Nexgen LPS Flex (class)/Nexgen 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 Coating	Fixation
Femoral				
Nexgen LPS Flex	00576201351-00576201752	LPS-FLEX POROUS GSF FEMORAL COMPONENT	NO	POROUS
Nexgen LPS Flex	00596201151-00596201852	LPS-FLEX POROUS FEMORAL COMPONENT	NO	POROUS
Tibial				
Nexgen	00594601001-00594608001	COCR PCT MOBILE FLUTED STEMMED TIBIAL COMPONENT	YES	PMMA
Nexgen	00595402701-00595405702	NEXGEN CKS MIS TRABECULAR METAL TIBIAL TRAY FIXED BEARING	NO	
Nexgen	00598002701-00598005704	PRECOAT TITANIUM STEMMED TIBIAL PLATE	YES	PMMA
Nexgen	00598202701-00598205704	POROUS STEMMED TIBIAL COMPONENT	NO	POROUS
Nexgen	00598800300-00598800800	PRECOAT TITANIUM A/P WEDGE STEMMED TIBIAL PLATE	YES	PMMA
Nexgen	00599602801-00599605804	7 DEGREE FLUTED STEMMED TIBIAL PLATE	YES	PMMA
Nexgen	65598202701-65598205704	POROUS HATCP STEMMED TIBIAL COMPONENT	NO	POROUS

Table 12: Revised Number of Nexgen LPS Flex (class)/Nexgen Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
00576201351-00576201752	00594601001-00594608001	10	153
	00595402701-00595405702	17	355
	00598002701-00598005704	13	222
	00598800300-00598800800	0	1
	00599602801-00599605804	0	2
	65598202701-65598205704	0	8
00596201151-00596201852	00594601001-00594608001	8	158
	00595402701-00595405702	35	828
	00598002701-00598005704	26	361
	00598202701-00598205704	0	1
	00598800300-00598800800	0	1
	00599602801-00599605804	0	3
	65598202701-65598205704	2	21
TOTAL		111	2114