

## Nexgen LPS Flex (cementless)/Nexgen Total Knee Investigation

Note: This analysis compares the Nexgen LPS Flex (cless)/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-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 Nexgen LPS Flex (cless)/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 (cless)/Nexgen	107	2110	11975	0.89 (0.73, 1.08)
Other Total Knee	25954	725585	4717150	0.55 (0.54, 0.56)
<b>TOTAL</b>	<b>26061</b>	<b>727695</b>	<b>4729125</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 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
Nexgen LPS Flex (class)/Nexgen	2.4 (1.9, 3.2)	3.6 (2.8, 4.4)	4.4 (3.6, 5.4)	4.8 (4.0, 5.9)	5.0 (4.2, 6.1)	5.1 (4.2, 6.2)	5.3 (4.4, 6.4)
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
Nexgen LPS Flex (class)/Nexgen	5.5 (4.5, 6.6)	5.7 (4.7, 6.9)	6.9 (5.1, 9.2)	6.9 (5.1, 9.2)			
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
Nexgen LPS Flex (class)/Nexgen							
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.

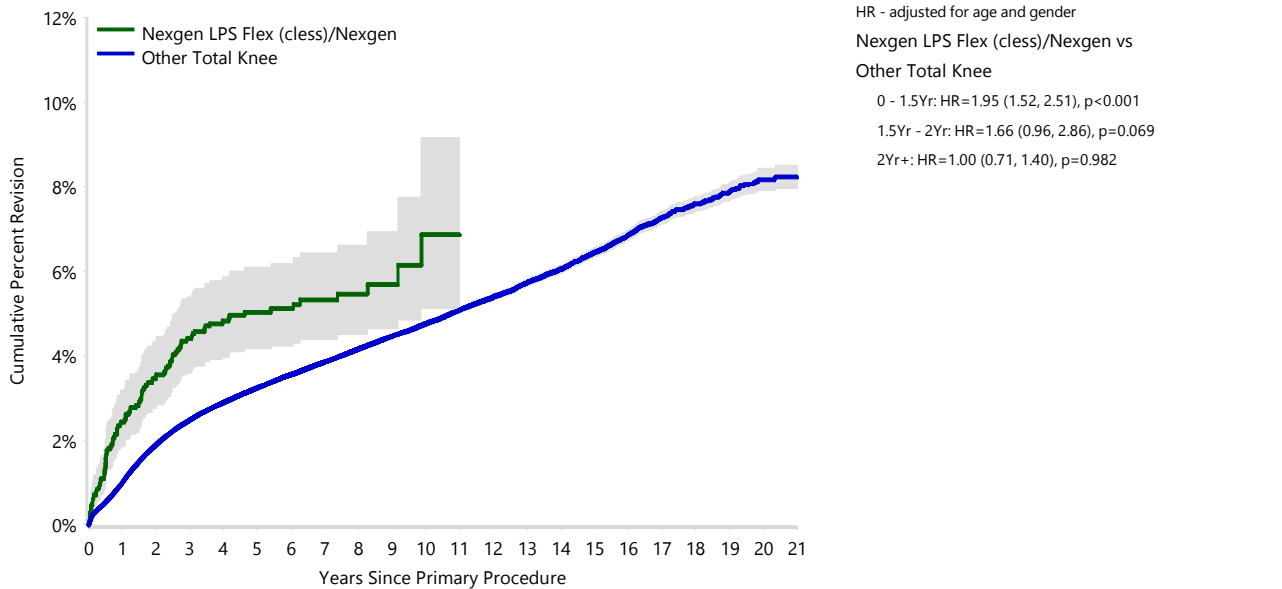
FIGURE 1

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

The yearly cumulative percent revision of the 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
Nexgen LPS Flex (class)/Nexgen	2110	2032	1918	1699	1459	1213	982	720	496	236	117
Other Total Knee	725585	655496	590842	525520	462582	402478	346150	293048	245256	202413	163385

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
Nexgen LPS Flex (class)/Nexgen	53	0	0	0	0	0	0	0	0	0	0
Other Total Knee	128790	99109	75527	56481	41660	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**

Primary Diagnosis	Nexgen LPS Flex (class)/Nexgen		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	106	99.1	25145	96.9
Rheumatoid Arthritis			331	1.3
Other Inflammatory Arthritis	1	0.9	160	0.6
Tumour			151	0.6
Osteonecrosis			98	0.4
Fracture			49	0.2
Other			19	0.1
Chondrocalcinosis			1	0.0
<b>TOTAL</b>	<b>107</b>	<b>100.0</b>	<b>25954</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 11.9 Years)

Revision Diagnosis	Nexgen LPS Flex (class)/Nexgen			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	32	1.5	29.9	6784	0.9	27.3
Loosening	28	1.3	26.2	5491	0.8	22.1
Instability	11	0.5	10.3	2393	0.3	9.6
Pain	4	0.2	3.7	2002	0.3	8.1
Patellofemoral Pain	4	0.2	3.7	1997	0.3	8.0
Patella Erosion	6	0.3	5.6	1571	0.2	6.3
Arthrofibrosis	2	0.1	1.9	985	0.1	4.0
Fracture	13	0.6	12.1	847	0.1	3.4
Malalignment	2	0.1	1.9	591	0.1	2.4
Lysis	1	0.0	0.9	282	0.0	1.1
Wear Tibial Insert				272	0.0	1.1
Incorrect Sizing				258	0.0	1.0
Patella Maltracking				181	0.0	0.7
Bearing Dislocation				150	0.0	0.6
Implant Breakage Patella				130	0.0	0.5
Implant Breakage Tibial Insert	1	0.0	0.9	125	0.0	0.5
Metal Related Pathology				103	0.0	0.4
Prosthesis Dislocation				76	0.0	0.3
Synovitis				72	0.0	0.3
Osteonecrosis				58	0.0	0.2
Implant Breakage Tibial	1	0.0	0.9	38	0.0	0.2
Implant Breakage Femoral				30	0.0	0.1
Tumour				26	0.0	0.1
Wear Patella				26	0.0	0.1
Heterotopic Bone				13	0.0	0.1
Wear Tibial				8	0.0	0.0
Progression Of Disease				4	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	2	0.1	1.9	296	0.0	1.2
<b>N Revision</b>	<b>107</b>	<b>5.1</b>	<b>100.0</b>	<b>24814</b>	<b>3.4</b>	<b>100.0</b>
<b>N Primary</b>	<b>2110</b>			<b>725585</b>		

Note: This table is restricted to revisions within 11.9 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 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**

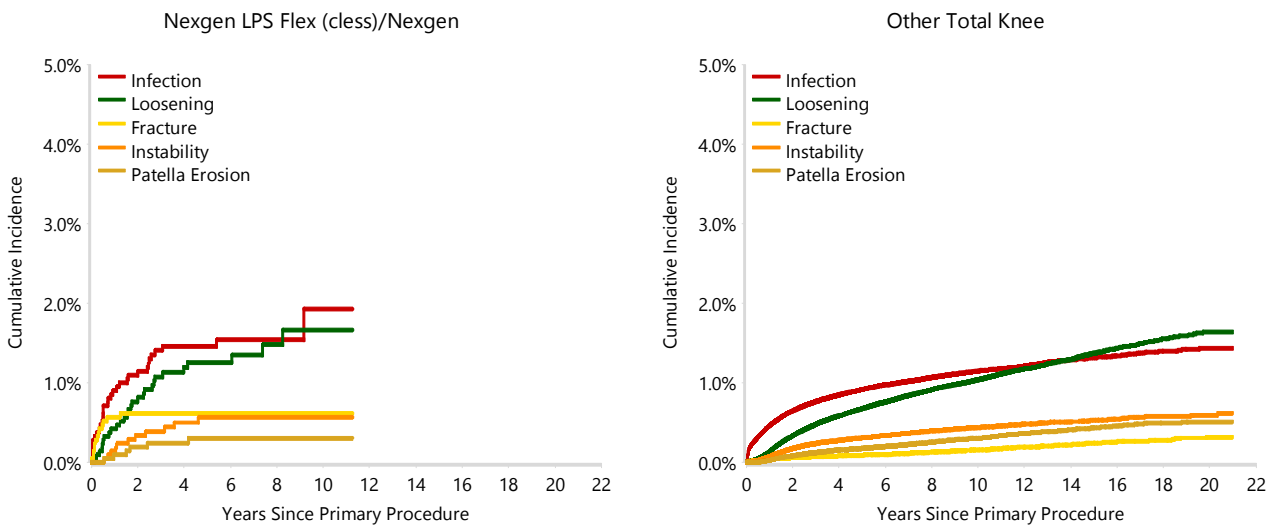


TABLE 5

**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 11.9 Years)**

Type of Revision	Nexgen LPS Flex (class)/Nexgen		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	24	22.4	5909	23.8
Tibial Component	14	13.1	2047	8.2
Cement Spacer	4	3.7	1318	5.3
Femoral Component	12	11.2	1285	5.2
Removal of Prostheses	1	0.9	146	0.6
Total Femoral			18	0.1
Reinsertion of Components			11	0.0
<b>N Major</b>	<b>55</b>	<b>51.4</b>	<b>10734</b>	<b>43.3</b>
Insert Only	38	35.5	6879	27.7
Patella Only	9	8.4	4660	18.8
Insert/Patella	4	3.7	2469	10.0
Minor Components	1	0.9	58	0.2
Cement Only			14	0.1
<b>N Minor</b>	<b>52</b>	<b>48.6</b>	<b>14080</b>	<b>56.7</b>
<b>TOTAL</b>	<b>107</b>	<b>100.0</b>	<b>24814</b>	<b>100.0</b>

Note: This table is restricted to revisions within 11.9 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 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	2	30
Cementless	50	1192
Hybrid (Tibial Cemented)	53	882
Hybrid (Tibial Cementless)	2	6
<b>TOTAL</b>	<b>107</b>	<b>2110</b>

**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	94	1781
Unknown	0	3
<b>TOTAL</b>	<b>107</b>	<b>2110</b>



**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	89	1796
Rotating	18	311
Unknown	0	3
<b>TOTAL</b>	<b>107</b>	<b>2110</b>

**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	107	2107
Unknown	0	3
<b>TOTAL</b>	<b>107</b>	<b>2110</b>

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	44	940
	VIC	28	499
	QLD	19	389
	WA	10	140
	SA	3	38
	TAS	1	25
	ACT/NT	2	79
Other Total Knee	NSW	7678	252181
	VIC	5525	143988
	QLD	5671	152782
	WA	3225	77765
	SA	2834	63402
	TAS	417	16860
	ACT/NT	604	18607
<b>TOTAL</b>		<b>26061</b>	<b>727695</b>

Note: Prostheses no longer used in 2021 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 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 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	18	312
2014	11	238
2015	17	280
2016	9	225
2017	17	252
2018	6	221
2019	7	188
2020	1	82
2021	0	12
<b>TOTAL</b>	<b>107</b>	<b>2110</b>

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
<b>Femoral</b>				
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
<b>Tibial</b>				
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	16	353
	00598002701-00598005704	11	221
	00598800300-00598800800	0	1
	00599602801-00599605804	0	2
	65598202701-65598205704	0	8
00596201151-00596201852	00594601001-00594608001	8	158
	00595402701-00595405702	35	827
	00598002701-00598005704	25	361
	00598202701-00598205704	0	1
	00598800300-00598800800	0	1
	00599602801-00599605804	0	3
	65598202701-65598205704	2	21
<b>TOTAL</b>		<b>107</b>	<b>2110</b>