

Genesis II Oxinium PS (cemented)/Genesis II (cementless) Total Knee Investigation

Note: This analysis compares the Genesis II Oxinium PS (ctd)/Genesis II (cless) 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 Genesis II Oxinium PS (ctd)/Genesis II (cless) 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)
Genesis II Oxinium PS (ctd)/Genesis II (cless)	17	56	467	3.64 (2.12, 5.83)
Other Total Knee	26044	727639	4728658	0.55 (0.54, 0.56)
TOTAL	26061	727695	4729125	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 Genesis II Oxinium PS (ctd)/Genesis II (cless) 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
Genesis II Oxinium PS (ctd)/Genesis II (cless)	19.6 (11.4, 32.7)	25.0 (15.6, 38.5)	26.8 (17.1, 40.4)	30.4 (20.1, 44.2)	30.4 (20.1, 44.2)	30.4 (20.1, 44.2)	30.4 (20.1, 44.2)
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
Genesis II Oxinium PS (ctd)/Genesis II (cless)	30.4 (20.1, 44.2)	30.4 (20.1, 44.2)	30.4 (20.1, 44.2)	30.4 (20.1, 44.2)	30.4 (20.1, 44.2)		
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, 5.2)	5.4 (5.3, 5.5)	5.7 (5.7, 5.8)	6.1 (6.0, 6.1)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Genesis II Oxinium PS (ctd)/Genesis II (cless)							
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.

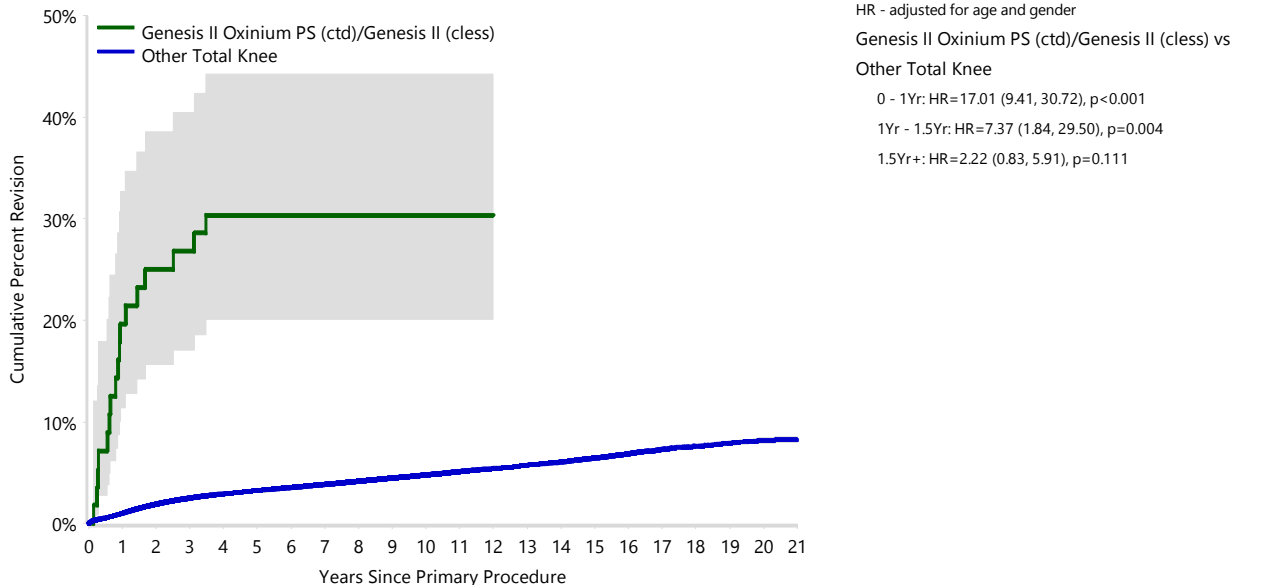
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Genesis II Oxinium PS (ctd)/Genesis II (cless) 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
Genesis II Oxinium PS (ctd)/Genesis II (cless)	56	45	42	41	39	38	37	37	36	36	34
Other Total Knee	727639	657483	592718	527178	464002	403653	347095	293731	245716	202613	163468

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
Genesis II Oxinium PS (ctd)/Genesis II (cless)	33	13	6	3	0	0	0	0	0	0	0
Other Total Knee	128810	99096	75521	56478	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	Genesis II Oxinium PS (ctd)/Genesis II (cless)		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	17	100.0	25234	96.9
Rheumatoid Arthritis			331	1.3
Other Inflammatory Arthritis			161	0.6
Tumour			151	0.6
Osteonecrosis			98	0.4
Fracture			49	0.2
Other			19	0.1
Chondrocalcinosis			1	0.0
TOTAL	17	100.0	26044	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 14.3 Years)

Revision Diagnosis	Genesis II Oxinium PS (ctd)/Genesis II (class)			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection				6918	1.0	27.1
Loosening	13	23.2	76.5	5677	0.8	22.2
Instability	2	3.6	11.8	2444	0.3	9.6
Pain				2041	0.3	8.0
Patellofemoral Pain				2029	0.3	7.9
Patella Erosion				1645	0.2	6.4
Arthrofibrosis				992	0.1	3.9
Fracture	1	1.8	5.9	903	0.1	3.5
Malalignment				596	0.1	2.3
Wear Tibial Insert				317	0.0	1.2
Lysis	1	1.8	5.9	314	0.0	1.2
Incorrect Sizing				258	0.0	1.0
Patella Maltracking				181	0.0	0.7
Bearing Dislocation				152	0.0	0.6
Implant Breakage Tibial Insert				141	0.0	0.6
Implant Breakage Patella				133	0.0	0.5
Metal Related Pathology				112	0.0	0.4
Prosthesis Dislocation				77	0.0	0.3
Synovitis				76	0.0	0.3
Osteonecrosis				58	0.0	0.2
Implant Breakage Tibial				40	0.0	0.2
Implant Breakage Femoral				35	0.0	0.1
Wear Patella				29	0.0	0.1
Tumour				27	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Wear Tibial				10	0.0	0.0
Progression Of Disease				5	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	17	30.4	100.0	25530	3.5	100.0
N Primary	56			727639		

Note: This table is restricted to revisions within 14.3 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 Genesis II Oxinium PS (ctd)/Genesis II (cless) 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

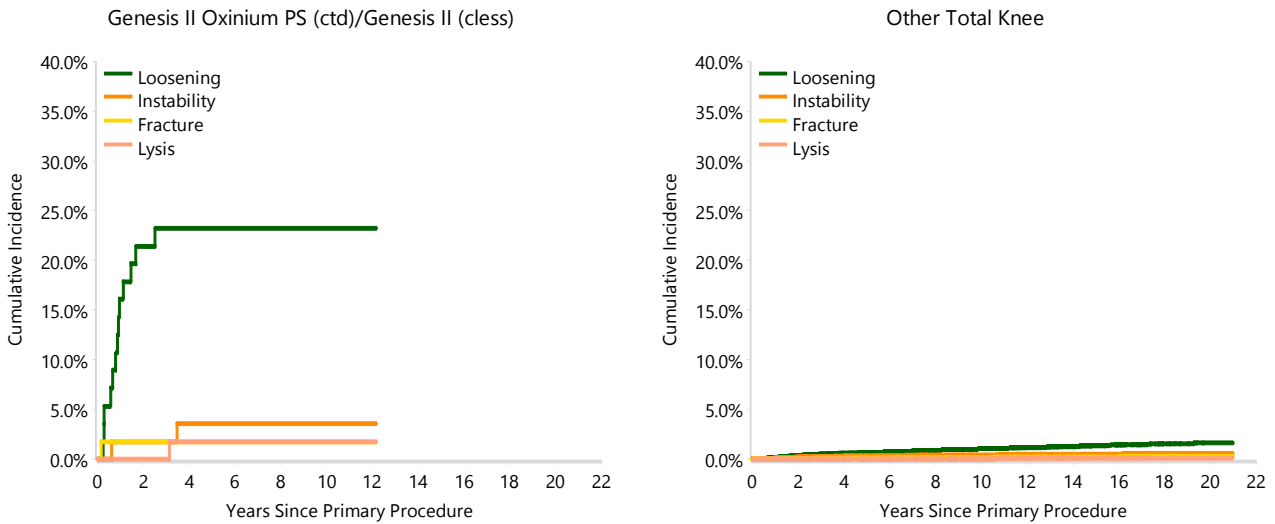


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Genesis II Oxinium PS (ctd)/Genesis II (cless) 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 Genesis II Oxinium PS (ctd)/Genesis II (cless) total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 14.3 Years)

Type of Revision	Genesis II Oxinium PS (ctd)/Genesis II (cless)		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	2	11.8	6187	24.2
Tibial Component	13	76.5	2072	8.1
Cement Spacer			1345	5.3
Femoral Component			1308	5.1
Removal of Prostheses			149	0.6
Total Femoral			20	0.1
Reinsertion of Components			11	0.0
N Major	15	88.2	11092	43.4
Insert Only	1	5.9	7032	27.5
Patella Only			4740	18.6
Insert/Patella	1	5.9	2593	10.2
Minor Components			59	0.2
Cement Only			14	0.1
N Minor	2	11.8	14438	56.6
TOTAL	17	100.0	25530	100.0

Note: This table is restricted to revisions within 14.3 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 Genesis II Oxinium PS (ctd)/Genesis II (cless) 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 Genesis II Oxinium PS (ctd)/Genesis II (cless) Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	0	1
Hybrid (Tibial Cementless)	17	55
TOTAL	17	56

TABLE 7**Revision Rates of Genesis II Oxinium PS (ctd)/Genesis II (cless) 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 Genesis II Oxinium PS (ctd)/Genesis II (cless) Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	17	55
XLPE	0	1
TOTAL	17	56

TABLE 8**Revision Rates of Genesis II Oxinium PS (ctd)/Genesis II (cless) 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 Genesis II Oxinium PS (ctd)/Genesis II (cless) Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	17	56
TOTAL	17	56

TABLE 9**Revision Rates of Genesis II Oxinium PS (ctd)/Genesis II (cless) 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 Genesis II Oxinium PS (ctd)/Genesis II (cless) Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Posterior Stabilised	17	56
TOTAL	17	56

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Genesis II Oxinium PS (ctd)/Genesis II (cless) 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
Genesis II Oxinium PS (ctd)/Genesis II (cless)	QLD	1	3
	WA	15	45
	ACT/NT	1	8
Other Total Knee	NSW	7722	253121
	VIC	5553	144487
	QLD	5689	153168
	WA	3220	77860
	SA	2837	63440
	TAS	418	16885
	ACT/NT	605	18678
TOTAL		26061	727695

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

TABLE 11**Number of Revisions of Genesis II Oxinium PS (ctd)/Genesis II (cless) Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Genesis II Oxinium PS (ctd)/Genesis II (cless) 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 Genesis II Oxinium PS (ctd)/Genesis II (cless) Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2007	0	4
2008	1	4
2009	4	11
2010	12	35
2011	0	1
2012	0	1
TOTAL	17	56

TABLE 12

Revision Rates of Genesis II Oxinium PS (ctd)/Genesis II (cless) 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 Genesis II Oxinium PS (ctd)/Genesis II (cless) 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					
Genesis II Oxinium PS	71421012-71421118	NONPOROUS PS OXINIUM FEMORAL COMPONENT	YES		
Genesis II Oxinium PS	71930008-71930010	NONPOROUS PS OXINIUM FEMORAL COMPONENT	YES		
Tibial					
Genesis II	71422062-71422090	POROUS HA TIBIAL BASEPLATE	NO	HA COATED	BEADED
Genesis II	71930310-71930323	POROUS HA TIBIAL BASEPLATE	NO	HA COATED	BEADED

Table 12: Revised Number of Genesis II Oxinium PS (ctd)/Genesis II (cless) Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
71421012-71421118	71422062-71422090	1	9
	71930310-71930323	15	45
71930008-71930010	71422062-71422090	1	2
TOTAL		17	56