Genesis II Oxinium CR (cementless)/Genesis II Total Knee Investigation

Note: This analysis compares the Genesis II Oxinium CR (class)/Genesis II 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 Genesis II Oxinium CR (class)/Genesis II 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 CR (class)/Genesis II	47	110	1025	4.59 (3.37, 6.10)
Other Total Knee	26789	757839	5068755	0.53 (0.52, 0.53)
TOTAL	**26836**	**757949**	**5069780**	**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 Genesis II Oxinium CR (class)/Genesis II 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
Genesis II Oxinium CR (class)/Genesis II	11.8 (7.0, 19.5)	30.4 (22.7, 40.0)	38.9 (30.4, 48.7)	38.9 (30.4, 48.7)	39.8 (31.3, 49.7)	40.8 (32.2, 50.7)	41.8 (33.1, 51.7)	42.8 (34.0, 52.7)
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)	3.7 (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
Genesis II Oxinium CR (class)/Genesis II	42.8 (34.0, 52.7)	42.8 (34.0, 52.7)	42.8 (34.0, 52.7)	44.0 (35.2, 54.1)	44.0 (35.2, 54.1)	44.0 (35.2, 54.1)	
Other Total Knee	4.3 (4.3, 4.4)	4.6 (4.6, 4.7)	4.9 (4.9, 5.0)	5.2 (5.1, 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
Genesis II Oxinium CR (class)/Genesis II							
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.

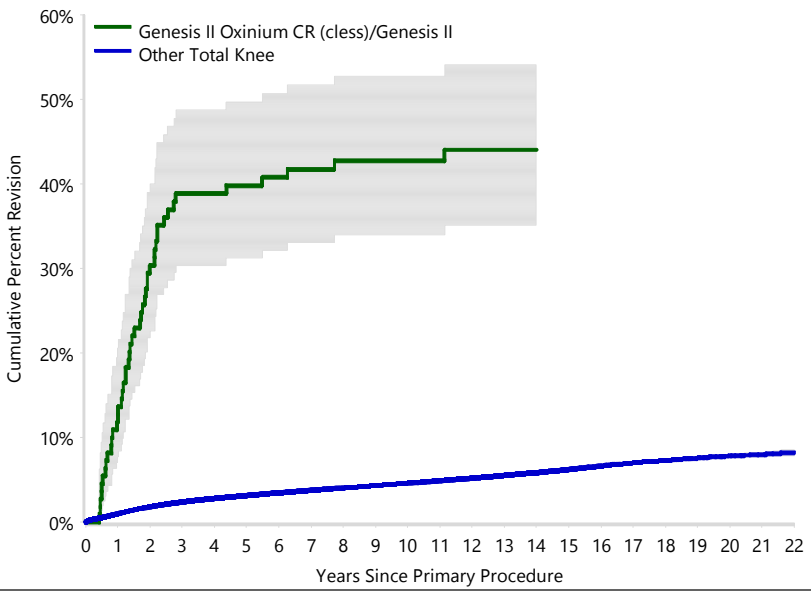
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Genesis II Oxinium CR (class)/Genesis II 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



HR - adjusted for age and gender

Genesis II Oxinium CR (class)/Genesis II vs Other Total Knee

0 - 1.5Yr: HR=14.15 (9.48, 21.11), p<0.001

1.5Yr - 2.5Yr: HR=24.86 (14.98, 41.28), p<0.001

2.5Yr+: HR=2.69 (1.35, 5.37), p=0.005

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
Genesis II Oxinium CR (class)/Genesis II	110	96	74	64	64	63	61	57	56	53	50	45
Other Total Knee	757839	689786	619542	556769	492737	431067	372676	318069	267173	221507	180359	143398

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
Genesis II Oxinium CR (class)/Genesis II	43	42	41	37	35	32	26	25	1	0	0
Other Total Knee	111879	85745	65008	47960	34956	24703	16407	9919	5485	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

	Genesis II Oxinium CR (class)/Genesis II		Other Total Knee	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	46	97.9	25958	96.9
Rheumatoid Arthritis			342	1.3
Tumour			162	0.6
Other Inflammatory Arthritis			160	0.6
Osteonecrosis	1	2.1	100	0.4
Fracture			48	0.2
Other			18	0.1
Chondrocalcinosis			1	0.0
TOTAL	**47**	**100.0**	**26789**	**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 20.1 Years)

	Genesis II Oxinium CR (class)/Genesis II			Other Total Knee		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	3	2.7	6.4	7352	1.0	27.5
Loosening	41	37.3	87.2	5977	0.8	22.3
Instability	1	0.9	2.1	2607	0.3	9.7
Pain				2037	0.3	7.6
Patellofemoral Pain	1	0.9	2.1	1932	0.3	7.2
Patella Erosion	1	0.9	2.1	1784	0.2	6.7
Arthrofibrosis				1035	0.1	3.9
Fracture				1021	0.1	3.8
Malalignment				602	0.1	2.2
Wear Tibial Insert				368	0.0	1.4
Lysis				329	0.0	1.2
Incorrect Sizing				262	0.0	1.0
Patella Maltracking				186	0.0	0.7
Implant Breakage Tibial Insert				174	0.0	0.6
Bearing Dislocation				151	0.0	0.6
Implant Breakage Patella				140	0.0	0.5
Metal Related Pathology				107	0.0	0.4
Prosthesis Dislocation				84	0.0	0.3
Synovitis				75	0.0	0.3
Osteonecrosis				55	0.0	0.2
Implant Breakage Tibial				42	0.0	0.2
Implant Breakage Femoral				39	0.0	0.1
Wear Patella				36	0.0	0.1
Tumour				34	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Wear Tibial				9	0.0	0.0
Progression Of Disease				7	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				316	0.0	1.2
N Revision	**47**	**42.7**	**100.0**	**26779**	**3.5**	**100.0**
N Primary	**110**			**757839**		

Note: This table is restricted to revisions within 20.1 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 Genesis II Oxinium CR (class)/Genesis II 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

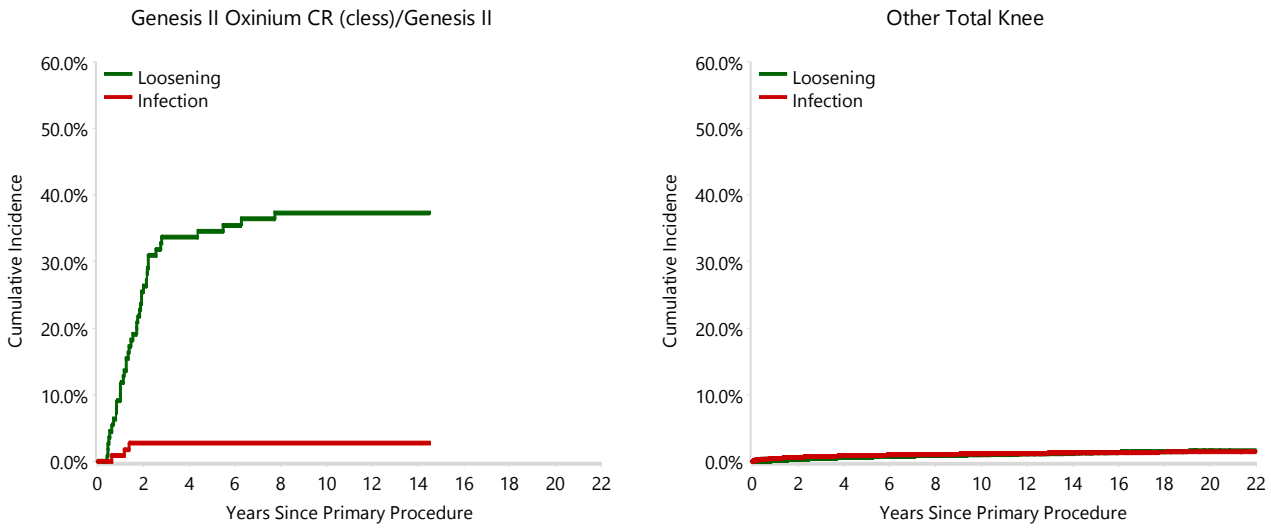


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

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

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 20.1 Years)

	Genesis II Oxinium CR (cless)/Genesis II		Other Total Knee	
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	9	19.1	6641	24.8
Tibial Component			2136	8.0
Cement Spacer	2	4.3	1361	5.1
Femoral Component	33	70.2	1289	4.8
Removal of Prostheses			153	0.6
Total Femoral			24	0.1
Reinsertion of Components			13	0.0
N Major	**44**	**93.6**	**11617**	**43.4**
Insert Only	1	2.1	7580	28.3
Patella Only	1	2.1	4729	17.7
Insert/Patella	1	2.1	2771	10.3
Minor Components			64	0.2
Cement Only			18	0.1
N Minor	**3**	**6.4**	**15162**	**56.6**
TOTAL	**47**	**100.0**	**26779**	**100.0**

Note: This table is restricted to revisions within 20.1 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 Genesis II Oxinium CR (class)/Genesis II 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 CR (class)/Genesis II Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cementless	16	25
Hybrid (Tibial Cemented)	31	84
Hybrid (Tibial Cementless)	0	1
TOTAL	**47**	**110**

TABLE 7

Revision Rates of Genesis II Oxinium CR (class)/Genesis II 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 CR (class)/Genesis II Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	47	110
TOTAL	**47**	**110**

TABLE 8

Revision Rates of Genesis II Oxinium CR (class)/Genesis II 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 CR (class)/Genesis II Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	47	110
TOTAL	**47**	**110**

TABLE 9

Revision Rates of Genesis II Oxinium CR (class)/Genesis II 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 CR (class)/Genesis II Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Minimally Stabilised	47	110
TOTAL	**47**	**110**

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 CR (cless)/Genesis II 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 CR (class)/Genesis II	NSW	1	1
	VIC	23	50
	QLD	4	8
	WA	17	39
	SA	1	10
	ACT/NT	1	2
Other Total Knee	NSW	7958	262432
	VIC	5802	152997
	QLD	5762	157000
	WA	3228	81100
	SA	2966	66409
	TAS	437	18133
	ACT/NT	636	19768
TOTAL		**26836**	**757949**

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

TABLE 11

Number of Revisions of Genesis II Oxinium CR (class)/Genesis II 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 CR (class)/Genesis II 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 Genesis II Oxinium CR (class)/Genesis II Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2002	1	4
2003	46	106
TOTAL	**47**	**110**

TABLE 12

Revision Rates of Genesis II Oxinium CR (class)/Genesis II 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 CR (class)/Genesis II 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 CR	71421123-71421138	GENESIS II CR MACROTEXTURED OXINIUM FEMORAL COMPONENT	NO		MACROTEXTURED
Tibial					
Genesis II	71420160-71420191	NONPOROUS TIBIAL BASEPLATE	YES		
Genesis II	71420192-71420222	POROUS TIBIAL BASEPLATE	NO		BEADED
Genesis II	71422062-71422090	POROUS HA TIBIAL BASEPLATE	NO	HA COATED	BEADED
Genesis II	71926777-71926788	POROUS HA TIBIAL BASEPLATE	NO	HA COATED	BEADED

Table 12: Revised Number of Genesis II Oxinium CR (class)/Genesis II Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
71421123-71421138	71420160-71420191	31	84
	71420192-71420222	2	3
	71422062-71422090	5	8
	71926777-71926788	9	15
TOTAL		**47**	**110**