

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

Note: This analysis compares the Genesis II Oxinium CR (cless)/Profix Mobile 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 CR (cless)/Profix Mobile 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 (cless)/Profix Mobile	57	88	624	9.13 (6.91, 11.83)
Other Total Knee	26061	727695	4729125	0.55 (0.54, 0.56)
TOTAL	26118	727783	4729749	0.55 (0.55, 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 CR (class)/Profix Mobile 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 CR (class)/Profix Mobile	24.0 (16.3, 34.4)	49.3 (39.4, 60.2)	52.8 (42.8, 63.5)	55.1 (45.0, 65.7)	57.4 (47.4, 67.9)	58.6 (48.5, 69.0)	58.6 (48.5, 69.0)
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 CR (class)/Profix Mobile	59.8 (49.7, 70.2)	61.1 (51.0, 71.3)	61.1 (51.0, 71.3)	62.3 (52.2, 72.5)	63.6 (53.5, 73.6)	64.9 (54.8, 74.8)	64.9 (54.8, 74.8)
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 CR (class)/Profix Mobile	64.9 (54.8, 74.8)	64.9 (54.8, 74.8)	64.9 (54.8, 74.8)	64.9 (54.8, 74.8)			
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.

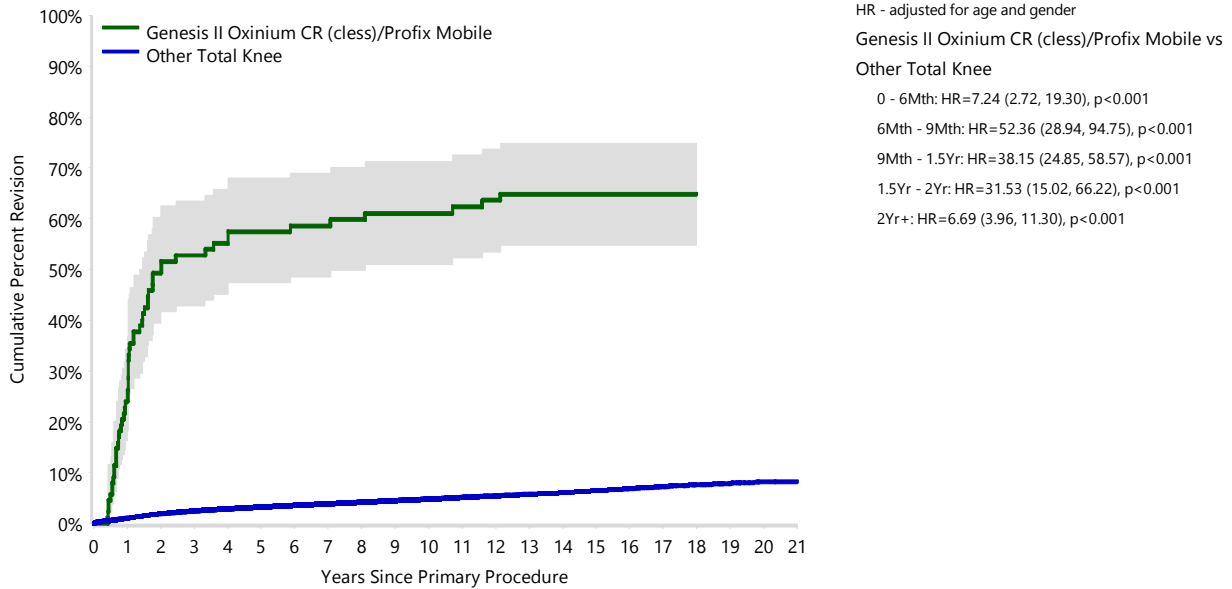
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Genesis II Oxinium CR (class)/Profix Mobile 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 CR (class)/Profix Mobile	88	66	44	41	38	36	35	34	33	31	31
Other Total Knee	727695	657528	592760	527219	464041	403691	347132	293768	245752	202649	163502

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 CR (class)/Profix Mobile	30	29	26	24	23	22	18	17	3	0	0
Other Total Knee	128843	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	Genesis II Oxinium CR (class)/Profix Mobile		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	56	98.2	25251	96.9
Rheumatoid Arthritis	1	1.8	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	57	100.0	26061	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 19.2 Years)

Revision Diagnosis	Genesis II Oxinium CR (class)/Profix Mobile			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection				6980	1.0	26.8
Loosening	55	62.5	96.5	5837	0.8	22.4
Instability	1	1.1	1.8	2486	0.3	9.5
Pain				2064	0.3	7.9
Patellofemoral Pain				2047	0.3	7.9
Patella Erosion	1	1.1	1.8	1693	0.2	6.5
Arthrofibrosis				997	0.1	3.8
Fracture				943	0.1	3.6
Malalignment				603	0.1	2.3
Wear Tibial Insert				364	0.1	1.4
Lysis				345	0.0	1.3
Incorrect Sizing				259	0.0	1.0
Patella Maltracking				181	0.0	0.7
Bearing Dislocation				153	0.0	0.6
Implant Breakage Tibial Insert				148	0.0	0.6
Implant Breakage Patella				134	0.0	0.5
Metal Related Pathology				117	0.0	0.4
Prosthesis Dislocation				80	0.0	0.3
Synovitis				78	0.0	0.3
Osteonecrosis				58	0.0	0.2
Implant Breakage Tibial				42	0.0	0.2
Implant Breakage Femoral				38	0.0	0.1
Wear Patella				33	0.0	0.1
Tumour				28	0.0	0.1
Heterotopic Bone				15	0.0	0.1
Wear Tibial				12	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				302	0.0	1.2
N Revision	57	64.8	100.0	26048	3.6	100.0
N Primary	88			727695		

Note: This table is restricted to revisions within 19.2 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 CR (cless)/Profix Mobile 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

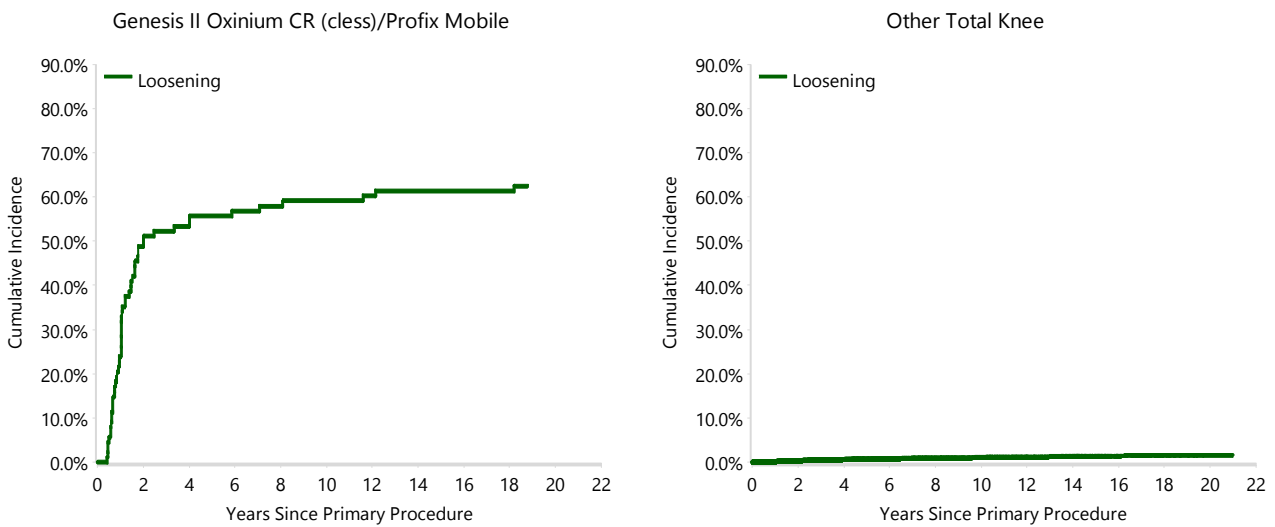


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

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

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 19.2 Years)

Type of Revision	Genesis II Oxinium CR (class)/Profix Mobile		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	11	19.3	6415	24.6
Tibial Component			2099	8.1
Cement Spacer			1360	5.2
Femoral Component	45	78.9	1311	5.0
Removal of Prostheses			150	0.6
Total Femoral			21	0.1
Reinsertion of Components			11	0.0
N Major	56	98.2	11367	43.6
Insert Only			7120	27.3
Patella Only			4782	18.4
Insert/Patella	1	1.8	2706	10.4
Minor Components			59	0.2
Cement Only			14	0.1
N Minor	1	1.8	14681	56.4
TOTAL	57	100.0	26048	100.0

Note: This table is restricted to revisions within 19.2 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 CR (class)/Profix Mobile 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)/Profix Mobile Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cementless	45	61
Hybrid (Tibial Cemented)	12	27
TOTAL	57	88

TABLE 7**Revision Rates of Genesis II Oxinium CR (class)/Profix Mobile 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)/Profix Mobile Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	57	88
TOTAL	57	88

TABLE 8**Revision Rates of Genesis II Oxinium CR (class)/Profix Mobile 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)/Profix Mobile Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Rotating	57	88
TOTAL	57	88

TABLE 9**Revision Rates of Genesis II Oxinium CR (class)/Profix Mobile 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)/Profix Mobile Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Minimally Stabilised	57	88
TOTAL	57	88

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)/Profix Mobile 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 (cless)/Profix Mobile	NSW	1	4
	VIC	12	25
	QLD	44	59
Other Total Knee	NSW	7722	253121
	VIC	5553	144487
	QLD	5690	153171
	WA	3235	77905
	SA	2837	63440
	TAS	418	16885
	ACT/NT	606	18686
TOTAL		26118	727783

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

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

Year of Implant	Number Revised	Total Number
2002	17	22
2003	40	66
TOTAL	57	88

TABLE 12

Revision Rates of Genesis II Oxinium CR (cless)/Profix Mobile 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 (cless)/Profix Mobile 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					
Profix Mobile	71544102-71544208	POROUS HA TIBIAL BASEPLATE	NO	HA COATED	POROUS
Profix Mobile	71549101-71549208	NONPOROUS TIBIAL BASEPLATE	YES		

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

Femoral Range	Tibial Range	N Revised	N Total
71421123-71421138	71544102-71544208	45	61
	71549101-71549208	12	27
TOTAL		57	88