

GMK-UNI/GMK-UNI Unicompartmental Knee Investigation

Note: This analysis compares the GMK-UNI/GMK-UNI femoral/tibial combination with all other unicompartmental 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 Unicompartmental Knee Replacement

The revision rate of the GMK-UNI/GMK-UNI unicompartmental knee combination is compared to all other unicompartmental knee prostheses.

Table 1: Revision Rates of Primary Unicompartmental Knee Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
GMK-UNI/GMK-UNI	40	167	887	4.51 (3.22, 6.14)
Other Unicompartmental Knee	4455	45642	314694	1.42 (1.37, 1.46)
TOTAL	4495	45809	315582	1.42 (1.38, 1.47)

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

TABLE 2

Yearly Cumulative Percent Revision of Primary Unicompartmental Knee Replacement

The yearly cumulative percent revision of the GMK-UNI/GMK-UNI unicompartmental knee combination is compared to all other unicompartmental knee prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Unicompartmental Knee Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
GMK-UNI/GMK-UNI	6.7 (3.7, 11.7)	12.2 (8.1, 18.3)	18.1 (12.9, 25.0)	21.6 (15.9, 28.9)	24.2 (18.1, 31.9)	26.2 (19.8, 34.3)	27.5 (20.8, 35.9)
Other Unicompartmental Knee	2.0 (1.8, 2.1)	3.5 (3.3, 3.7)	4.6 (4.4, 4.8)	5.6 (5.4, 5.8)	6.4 (6.2, 6.7)	7.4 (7.1, 7.6)	8.5 (8.2, 8.8)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
GMK-UNI/GMK-UNI	27.5 (20.8, 35.9)						
Other Unicompartmental Knee	9.6 (9.3, 10.0)	10.8 (10.5, 11.2)	12.0 (11.6, 12.4)	13.4 (13.0, 13.9)	14.7 (14.3, 15.2)	16.2 (15.7, 16.8)	17.8 (17.3, 18.4)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
GMK-UNI/GMK-UNI							
Other Unicompartmental Knee	19.4 (18.7, 20.1)	21.0 (20.3, 21.8)	22.8 (21.9, 23.6)	24.7 (23.7, 25.7)	26.2 (25.2, 27.4)	28.3 (26.9, 29.7)	30.3 (28.2, 32.5)

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

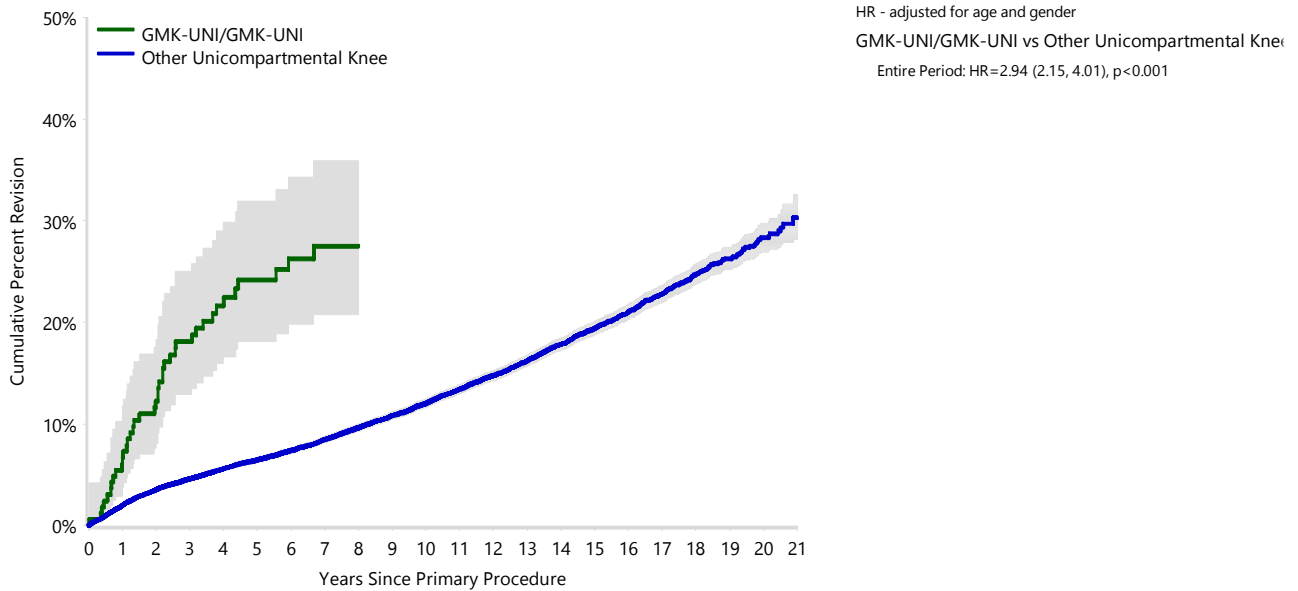
FIGURE 1

Yearly Cumulative Percent Revision of Primary Unicompartmental Knee Replacement

The yearly cumulative percent revision of the GMK-UNI/GMK-UNI unicompartmental knee combination is compared to all other unicompartmental 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 Unicompartmental 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
GMK-UNI/GMK-UNI	167	153	137	125	96	84	68	55	40	22	9
Other Unicompartmental Knee	45642	41163	36806	32566	28423	24491	21272	18681	16357	14302	12471

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
GMK-UNI/GMK-UNI	9	7	3	0	0	0	0	0	0	0	0
Other Unicompartmental Knee	10588	8794	7210	5756	4495	3389	2468	1706	1021	440	99

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

TABLE 3**Primary Diagnosis for Revised Primary Unicompartmental 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 unicompartmental knee prostheses.

Table 3: Primary Diagnosis for Revised Primary Unicompartmental Knee Replacement

Primary Diagnosis	GMK-UNI/GMK-UNI		Other Unicompartmental Knee	
	Number	Percent	Number	Percent
Osteoarthritis	40	100.0	4409	99.0
Osteonecrosis			26	0.6
Rheumatoid Arthritis			12	0.3
Other Inflammatory Arthritis			6	0.1
Fracture			1	0.0
Tumour			1	0.0
TOTAL	40	100.0	4455	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 Unicompartmental Knee Replacement - Reason for Revision (Follow-up Limited to 13.2 Years)

Revision Diagnosis	GMK-UNI/GMK-UNI			Other Unicompartmental Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Loosening	21	12.6	52.5	1353	3.0	33.8
Progression Of Disease	9	5.4	22.5	1339	2.9	33.5
Pain	2	1.2	5.0	337	0.7	8.4
Infection	2	1.2	5.0	228	0.5	5.7
Bearing Dislocation				161	0.4	4.0
Fracture	1	0.6	2.5	128	0.3	3.2
Instability	1	0.6	2.5	76	0.2	1.9
Lysis	1	0.6	2.5	62	0.1	1.5
Malalignment				59	0.1	1.5
Wear Tibial Insert	1	0.6	2.5	52	0.1	1.3
Patellofemoral Pain				30	0.1	0.7
Incorrect Sizing	1	0.6	2.5	27	0.1	0.7
Prosthesis Dislocation				24	0.1	0.6
Implant Breakage Tibial Insert				17	0.0	0.4
Wear Tibial				15	0.0	0.4
Osteonecrosis				14	0.0	0.3
Implant Breakage Tibial				12	0.0	0.3
Synovitis				10	0.0	0.2
Metal Related Pathology				9	0.0	0.2
Arthrofibrosis				8	0.0	0.2
Wear Femoral				3	0.0	0.1
Implant Breakage Femoral	1	0.6	2.5	2	0.0	0.0
Patella Erosion				2	0.0	0.0
Other				33	0.1	0.8
N Revision	40	24.0	100.0	4001	8.8	100.0
N Primary	167			45642		

Note: This table is restricted to revisions within 13.2 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 Unicompartmental 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 GMK-UNI/GMK-UNI unicompartmental knee combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other unicompartmental knee prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Unicompartmental Knee Replacement

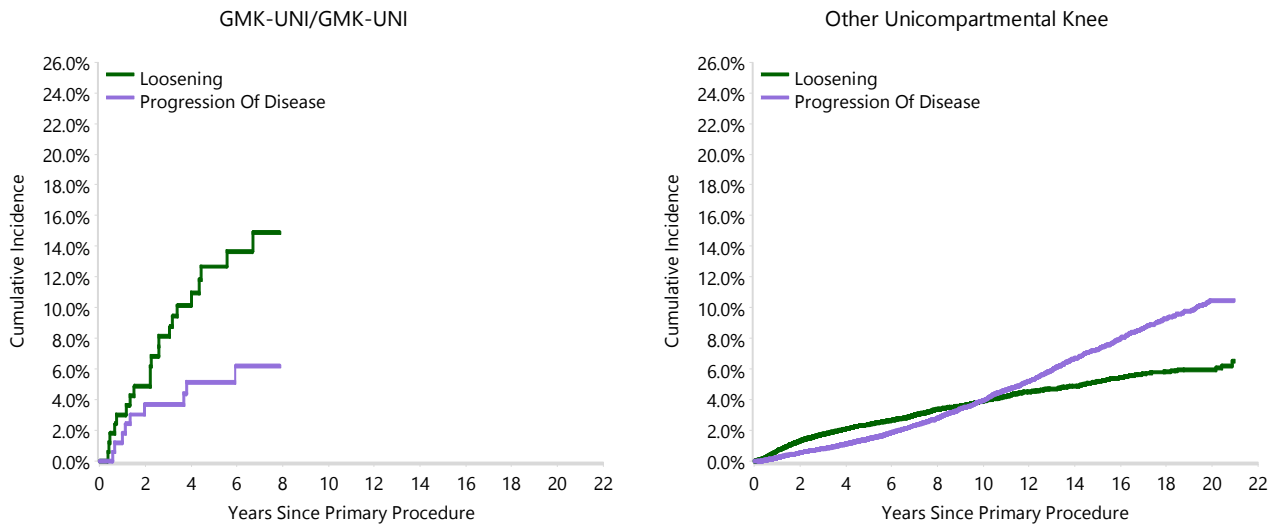


TABLE 5

Type of Revision Performed for Primary Unicompartmental Knee Replacement

This analysis identifies the components used in the revision of the GMK-UNI/GMK-UNI unicompartmental knee combination and compares it to the components used in the revision of all other unicompartmental 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 unicompartmental knee prostheses i.e. is there a difference in the type of revision undertaken for the GMK-UNI/GMK-UNI unicompartmental knee combination compared to all other unicompartmental knee prostheses.

Table 5: Primary Unicompartmental Knee Replacement - Type of Revision (Follow-up Limited to 13.2 Years)

Type of Revision	GMK-UNI/GMK-UNI		Other Unicompartmental Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	35	87.5	3322	83.0
Uni Tibial Component	1	2.5	97	2.4
Uni Femoral Component			50	1.2
Cement Spacer			36	0.9
UKR (Uni Tibial/Uni Femoral)	1	2.5	32	0.8
Patella/Trochlear Resurfacing			15	0.4
Removal of Prostheses			5	0.1
Reinsertion of Components			4	0.1
Femoral Component			2	0.0
Tibial Component	1	2.5		
N Major	38	95.0	3563	89.1
Uni Insert Only	2	5.0	437	10.9
Patella Only			1	0.0
N Minor	2	5.0	438	10.9
TOTAL	40	100.0	4001	100.0

Note: This table is restricted to revisions within 13.2 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 GMK-UNI/GMK-UNI Primary Unicompartmental 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 GMK-UNI/GMK-UNI Primary Unicompartmental Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	40	167
TOTAL	40	167

TABLE 7

Revision Rates of Primary Unicompartmental Knee Replacement by State

This enables a state by state variation to be identified for the GMK-UNI/GMK-UNI unicompartmental knee combination and provides the comparative data for each of the states for all other unicompartmental 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 7: Revised Number of Primary Unicompartmental Knee Replacement by State

Component	State	N Revised	N Total
GMK-UNI/GMK-UNI	NSW	28	101
	VIC	2	6
	QLD	4	9
	SA	6	51
Other Unicompartmental Knee	NSW	1353	12182
	VIC	838	9782
	QLD	801	9202
	WA	519	6950
	SA	616	4824
	TAS	163	1713
	ACT/NT	165	989
TOTAL		4495	45809

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

TABLE 8**Number of Revisions of GMK-UNI/GMK-UNI Primary Unicompartmental Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the GMK-UNI/GMK-UNI unicompartmental 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 8: Number of Revisions of GMK-UNI/GMK-UNI Primary Unicompartmental Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2008	0	5
2009	6	10
2010	0	2
2012	6	21
2013	5	22
2014	1	16
2015	7	19
2016	6	17
2017	2	12
2018	5	29
2019	0	3
2020	2	8
2021	0	3
TOTAL	40	167

TABLE 9

Revision Rates of GMK-UNI/GMK-UNI Primary Unicompartmental 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 GMK-UNI/GMK-UNI 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
Femoral			
GMK-UNI	02080001-02080004	GMK-UNI CEMENTED FEMUR	YES
Tibial			
GMK-UNI	0208TF1LMRL-0208TF5RMLL	GMK-UNI FIXED TIBIA BASEPLATE	YES

Table 9: Revised Number of GMK-UNI/GMK-UNI Primary Unicompartmental Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
02080001-02080004	0208TF1LMRL-0208TF5RMLL	40	167
TOTAL		40	167