Eius/Eius Unicompartmental Knee Investigation

Note: This analysis compares the Eius/Eius 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 Eius/Eius 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)
Eius/Eius	51	142	1698	3.00 (2.24, 3.95)
Other Unicompartmental Knee	4495	45809	315582	1.42 (1.38, 1.47)
TOTAL	4546	45951	317280	1.43 (1.39, 1.48)

TABLE 2
Yearly Cumulative Percent Revision of Primary Unicompartmental Knee Replacement

The yearly cumulative percent revision of the Eius/Eius 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
Eius/Eius	4.9 (2.4, 10.1)	8.5 (4.9, 14.5)	12.8 (8.3, 19.5)	16.4 (11.2, 23.6)	17.8 (12.4, 25.2)	19.3 (13.7, 26.9)	20.0 (14.3, 27.7)
Other Unicompartmental Knee	2.0 (1.8, 2.1)	3.6 (3.4, 3.7)	4.6 (4.4, 4.8)	5.6 (5.4, 5.9)	6.5 (6.3, 6.8)	7.4 (7.2, 7.7)	8.5 (8.2, 8.8)
CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Eius/Eius	20.8 (14.9, 28.5)	20.8 (14.9, 28.5)	22.3 (16.3, 30.2)	23.9 (17.6, 32.0)	27.1 (20.4, 35.4)	30.3 (23.3, 38.9)	33.0 (25.7, 41.8)
Other Unicompartmental Knee	9.7 (9.3, 10.0)	10.9 (10.5, 11.3)	12.1 (11.7, 12.5)	13.5 (13.0, 13.9)	14.8 (14.3, 15.3)	16.3 (15.7, 16.8)	17.9 (17.3, 18.5)
CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Eius/Eius	36.0 (28.3, 45.1)	39.3 (31.2, 48.6)					
Other Unicompartmental Knee	19.5 (18.8, 20.1)	21.1 (20.3, 21.8)	22.8 (22.0, 23.7)	24.8 (23.8, 25.7)	26.3 (25.2, 27.4)	28.3 (27.0, 29.8)	30.3 (28.2, 32.6)

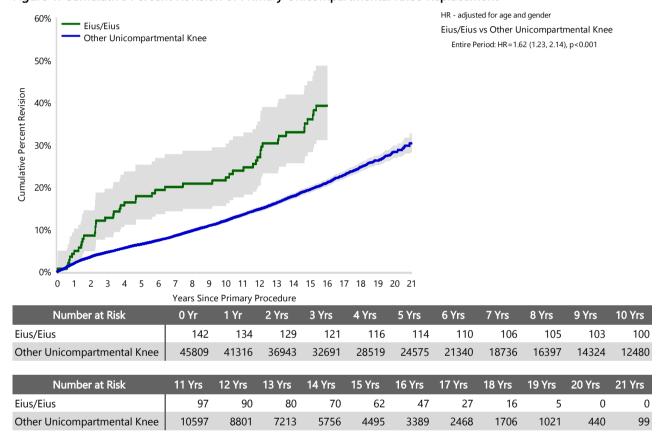
FIGURE 1

Yearly Cumulative Percent Revision of Primary Unicompartmental Knee Replacement

The yearly cumulative percent revision of the Eius/Eius 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



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

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

	Eius/Eius		Other Unicomp	artmental Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	50	98.0	4449	99.0
Osteonecrosis			26	0.6
Rheumatoid Arthritis	1	2.0	12	0.3
Other Inflammatory Arthritis			6	0.1
Fracture			1	0.0
Tumour			1	0.0
TOTAL	51	100.0	4495	100.0

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 19.1 Years)

		Eius/Eius		Other	· Unicompartmenta	al Knee
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Progression Of Disease	18	12.7	35.3	1597	3.5	35.7
Loosening	20	14.1	39.2	1462	3.2	32.7
Pain	8	5.6	15.7	345	0.8	7.7
Infection				239	0.5	5.3
Bearing Dislocation				167	0.4	3.7
Fracture	1	0.7	2.0	132	0.3	3.0
Instability				81	0.2	1.8
Lysis	1	0.7	2.0	79	0.2	1.8
Wear Tibial Insert	3	2.1	5.9	65	0.1	1.5
Malalignment				60	0.1	1.3
Implant Breakage Tibial Insert				34	0.1	0.8
Patellofemoral Pain				31	0.1	0.7
Incorrect Sizing				28	0.1	0.6
Prosthesis Dislocation				27	0.1	0.6
Implant Breakage Tibial				20	0.0	0.4
Osteonecrosis				15	0.0	0.3
Wear Tibial				15	0.0	0.3
Metal Related Pathology				10	0.0	0.2
Synovitis				10	0.0	0.2
Arthrofibrosis				8	0.0	0.2
Implant Breakage Femoral				4	0.0	0.1
Patella Erosion				3	0.0	0.1
Wear Femoral				3	0.0	0.1
Other				34	0.1	0.8
N Revision	51	35.9	100.0	4469	9.8	100.0
N Primary	142			45809		

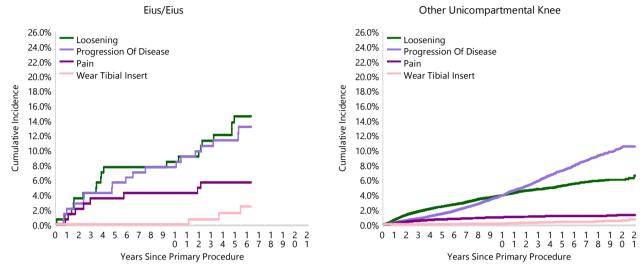
Note: This table is restricted to revisions within 19.1 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2021 are excluded from the comparator.

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 Eius/Eius 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



Type of Revision Performed for Primary Unicompartmental Knee Replacement

This analysis identifies the components used in the revision of the Eius/Eius 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 Eius/Eius unicompartmental knee combination compared to all other unicompartmental knee prostheses.

Table 5: Primary Unicompartmental Knee Replacement - Type of Revision (Follow-up Limited to 19.1 Years)

	Eius/	'Eius	Other Unicomp	artmental Knee
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	48	94.1	3760	84.1
Uni Tibial Component	2	3.9	98	2.2
Uni Femoral Component			50	1.1
Cement Spacer			37	0.8
UKR (Uni Tibial/Uni Femoral)	1	2.0	34	0.8
Patella/Trochlear Resurfacing			15	0.3
Removal of Prostheses			5	0.1
Reinsertion of Components			4	0.1
Femoral Component			3	0.1
Tibial Component			2	0.0
N Major	51	100.0	4008	89.7
Uni Insert Only			460	10.3
Patella Only			1	0.0
N Minor			461	10.3
TOTAL	51	100.0	4469	100.0

Note: This table is restricted to revisions within 19.1 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2021 are excluded from the comparator.

Revision Rates of Eius/Eius 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 Eius/Eius Primary Unicompartmental Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	51	142
TOTAL	51	142

Revision Rates of Primary Unicompartmental Knee Replacement by State

This enables a state by state variation to be identified for the Eius/Eius 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	
Eius/Eius	NSW	3	10	
	VIC	9	13	
	QLD	2	4	
	WA	1	5	
	SA	34	97	
	TAS	2	13	
Other Unicompartmental Knee	NSW	1381	12283	
	VIC	840	9788	
	QLD	805	9211	
	WA	519	6950	
	SA	622	4875	
	TAS	163	1713	
	ACT/NT	165	989	
TOTAL		4546	45951	

Number of Revisions of Eius/Eius Primary Unicompartmental Knee Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Eius/Eius 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 Eius/Eius Primary Unicompartmental Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2002	4	10
2003	7	21
2004	11	27
2005	9	37
2006	11	21
2007	4	9
2008	3	8
2009	2	7
2010	0	2
TOTAL	51	142

Revision Rates of Eius/Eius 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 Eius/Eius prosthesis.

This analysis has been undertaken to determine if the revision rate varies according to the catalogue number range.

Model	Catalogue Range	Catalogue Description	Cemen	t Mobility	′	Material
Femoral						
Eius	66362001-66362015	EIUS UNI KNEE FEMORAL COMPONENT	YES			
Tibial						
Eius	66362308-66362722	EIUS DURATION UNI KNEE TIBIAL COMPONENT	YES	FIXED	NON CROSS-	LINKED POLYETHYLENE

Table 9: Revised Number of Eius/Eius Primary Unicompartmental Knee Replacement by Catalogue Number Range

Femoral Range Tibial Range	N Revised	N Total
66362001-66362015 66362308-66362722	51	142
TOTAL	51	142