

Renasis Total Knee Investigation

Note: This analysis compares the Renasis femoral prosthesis with all other total knee prostheses.

This prosthesis 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-2024>.

Note: Procedures using prostheses with no recorded use in 2023 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Knee Replacement

The revision rate of the Renasis total knee prosthesis 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)
Renasis	20	121	1557	1.28 (0.78, 1.98)
Other Total Knee	24931	736083	4688062	0.53 (0.53, 0.54)
TOTAL	24951	736204	4689619	0.53 (0.53, 0.54)

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Renasys total knee prosthesis 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
Renasys	2.5 (0.8, 7.5)	2.5 (0.8, 7.5)	4.2 (1.8, 9.8)	6.7 (3.4, 13.0)	8.5 (4.6, 15.1)	9.3 (5.3, 16.2)	10.3 (6.0, 17.4)	10.3 (6.0, 17.4)
Other Total Knee	1.0 (0.9, 1.0)	1.8 (1.8, 1.8)	2.4 (2.3, 2.4)	2.8 (2.7, 2.8)	3.1 (3.1, 3.2)	3.4 (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	16 Yrs
Renasys	11.2 (6.7, 18.5)	11.2 (6.7, 18.5)	12.3 (7.4, 19.9)	14.5 (9.1, 22.7)	14.5 (9.1, 22.7)	15.7 (10.0, 24.2)	15.7 (10.0, 24.2)	17.1 (11.0, 26.1)
Other Total Knee	4.3 (4.3, 4.4)	4.6 (4.6, 4.7)	4.9 (4.9, 5.0)	5.2 (5.2, 5.3)	5.5 (5.5, 5.6)	5.8 (5.7, 5.9)	6.2 (6.1, 6.3)	6.6 (6.5, 6.8)

CPR	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
Renasys	21.0 (13.7, 31.4)						
Other Total Knee	7.0 (6.8, 7.1)	7.3 (7.1, 7.5)	7.5 (7.3, 7.7)	7.7 (7.5, 8.0)	8.0 (7.7, 8.3)	8.2 (7.9, 8.6)	8.2 (7.9, 8.6)

Note: Prostheses no longer used in 2023 are excluded from the comparator.

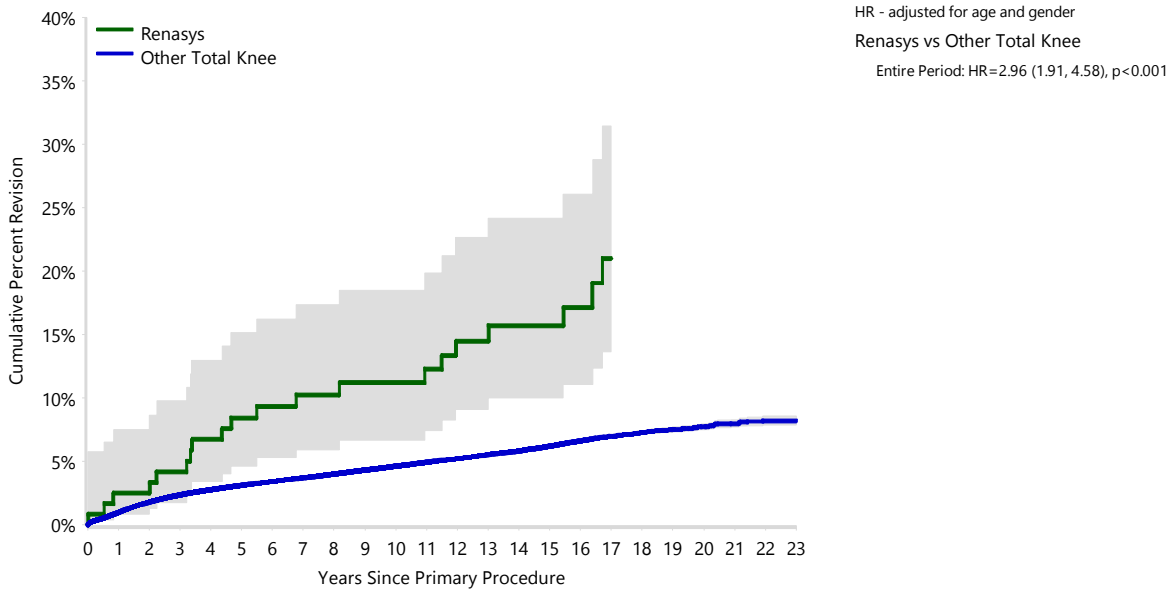
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Renasys total knee prosthesis 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	11 Yrs
Renasys	121	117	116	113	110	104	101	98	97	94	89	82
Other Total Knee	736083	656472	589710	522768	463050	402400	344698	290547	241598	196807	158427	125444

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	23 Yrs
Renasys	75	70	65	63	47	41	17	0	0	0	0	0
Other Total Knee	96689	72841	53727	38715	27059	18808	12662	7866	4467	2602	1229	297

Note: Prostheses no longer used in 2023 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	Renasys		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	20	100.0	24126	96.8
Rheumatoid Arthritis			313	1.3
Tumour			178	0.7
Other Inflammatory Arthritis			153	0.6
Osteonecrosis			89	0.4
Fracture			48	0.2
Other			23	0.1
Chondrocalcinosis			1	0.0
TOTAL	20	100.0	24931	100.0

Note: Prostheses no longer used in 2023 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 18.7 Years)

Revision Diagnosis	Number	Renasys		Other Total Knee		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	3	2.5	15.0	7001	1.0	28.1
Loosening	6	5.0	30.0	5289	0.7	21.2
Instability				2559	0.3	10.3
Pain	3	2.5	15.0	1832	0.2	7.4
Patella Erosion	1	0.8	5.0	1789	0.2	7.2
Patellofemoral Pain				1631	0.2	6.6
Arthrofibrosis	1	0.8	5.0	1019	0.1	4.1
Fracture	1	0.8	5.0	989	0.1	4.0
Malalignment				525	0.1	2.1
Wear Tibial Insert				341	0.0	1.4
Lysis	2	1.7	10.0	281	0.0	1.1
Incorrect Sizing	1	0.8	5.0	229	0.0	0.9
Implant Breakage Tibial Insert	1	0.8	5.0	182	0.0	0.7
Patella Maltracking				180	0.0	0.7
Bearing Dislocation				140	0.0	0.6
Implant Breakage Patella				130	0.0	0.5
Metal Related Pathology				101	0.0	0.4
Prosthesis Dislocation				80	0.0	0.3
Synovitis				64	0.0	0.3
Osteonecrosis				50	0.0	0.2
Implant Breakage Femoral				44	0.0	0.2
Wear Patella				42	0.0	0.2
Implant Breakage Tibial	1	0.8	5.0	34	0.0	0.1
Tumour				31	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Progression Of Disease				7	0.0	0.0
Wear Tibial				5	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				302	0.0	1.2
N Revision	20	16.5	100.0	24895	3.4	100.0
N Primary	121			736083		

Note: This table is restricted to revisions within 18.7 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2023 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 Renasys total knee prosthesis. 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

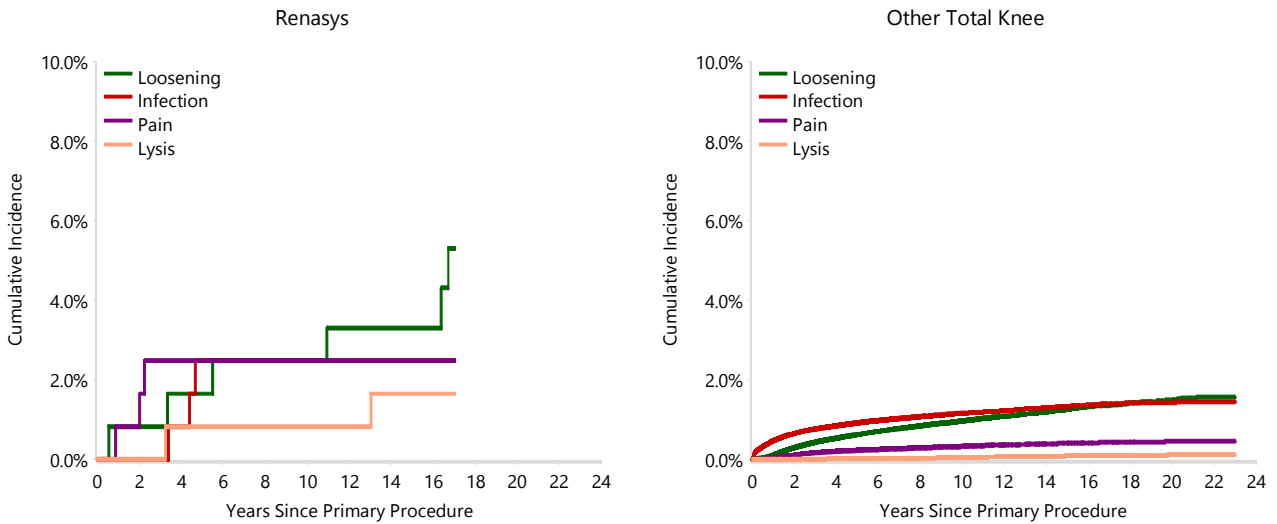


TABLE 5**Type of Revision Performed for Primary Total Knee Replacement**

This analysis identifies the components used in the revision of the Renasys total knee prosthesis 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 Renasys total knee prosthesis compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 18.7 Years)

Type of Revision	Renasys		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	5	25.0	5953	23.9
Tibial Component	5	25.0	1856	7.5
Femoral Component			1259	5.1
Cement Spacer			1173	4.7
Removal of Prostheses			130	0.5
Total Femoral			22	0.1
Reinsertion of Components			7	0.0
N Major	10	50.0	10400	41.8
Insert Only	9	45.0	7462	30.0
Patella Only			4323	17.4
Insert/Patella	1	5.0	2644	10.6
Minor Components			57	0.2
Cement Only			9	0.0
N Minor	10	50.0	14495	58.2
TOTAL	20	100.0	24895	100.0

Note: This table is restricted to revisions within 18.7 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 6**Revision Rates of Renasys 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 Renasys Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	20	121
TOTAL	20	121

TABLE 7**Revision Rates of Renasys 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 prosthesis are listed.

Table 7: Revised Number of Renasys Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	20	121
TOTAL	20	121

TABLE 8**Revision Rates of Renasys 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 prosthesis are listed.

Table 8: Revised Number of Renasys Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	20	121
TOTAL	20	121

TABLE 9**Revision Rates of Renasys 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 prosthesis are listed.

Table 9: Revised Number of Renasys Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Posterior Stabilised	20	121
TOTAL	20	121

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Renasys total knee prosthesis 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
Renasys	NSW	3	14
	VIC	8	43
	QLD	8	46
	WA	0	7
	SA	0	1
	ACT/NT	1	10
Other Total Knee	NSW	7326	251259
	VIC	5374	148666
	QLD	5361	153657
	WA	3064	80125
	SA	2756	64011
	TAS	458	18786
	ACT/NT	592	19579
TOTAL		24951	736204

Note: Prostheses no longer used in 2023 are excluded from the comparator.

TABLE 11**Number of Revisions of Renasys Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Renasys total knee prosthesis. 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 2023 has a maximum of one year to be revised, whereas a primary procedure performed in 2021 has a maximum of three years to be revised.

Table 11: Number of Revisions of Renasys Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	8	51
2006	11	53
2007	0	3
2008	1	14
TOTAL	20	121

TABLE 12

Revision Rates of Renasys 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 Renasys 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			
Renasys	71932011-71932018	PS OXINIUM FEMORAL COMPONENT W/ RSA BEADS	YES
Renasys	74021134-74021147	PRIMARY PS OXINIUM FEMORAL COMPONENT	YES

Table 12: Revised Number of Renasys Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	N Revised	N Total
71932011-71932018	1	16
74021134-74021147	19	105
TOTAL	20	121

TABLE 13**Revision Rates of Renasys Primary Total Knee Replacement by Component**

A prosthesis may be combined with multiple components. This analysis has been undertaken to determine if the revision rate varies according to the component with which it is combined.

Table 13: Revised Number of Renasys Primary Total Knee Replacement by Tibial Component

Tibial Component	N Revised	N Total
Genesis II	16	87
Journey	4	34
TOTAL	20	121