Evolis (cementless)/Evolis (cementless) Total Knee Investigation

Note: This analysis compares the Evolis (class)/Evolis (class) 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 Evolis (class)/Evolis (class) 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)
Evolis (class)/Evolis (class)	10	87	787	1.27 (0.61, 2.34)
Other Total Knee	26051	727608	4728338	0.55 (0.54, 0.56)
TOTAL	**26061**	**727695**	**4729125**	**0.55 (0.54, 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 Evolis (class)/Evolis (class) 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
Evolis (class)/Evolis (class)	2.3 (0.6, 8.9)	5.7 (2.4, 13.3)	8.0 (3.9, 16.1)	8.0 (3.9, 16.1)	10.3 (5.5, 18.9)	10.3 (5.5, 18.9)	11.5 (6.4, 20.4)
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
Evolis (class)/Evolis (class)	11.5 (6.4, 20.4)	11.5 (6.4, 20.4)	11.5 (6.4, 20.4)	11.5 (6.4, 20.4)	11.5 (6.4, 20.4)	11.5 (6.4, 20.4)	
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
Evolis (class)/Evolis (class)							
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.

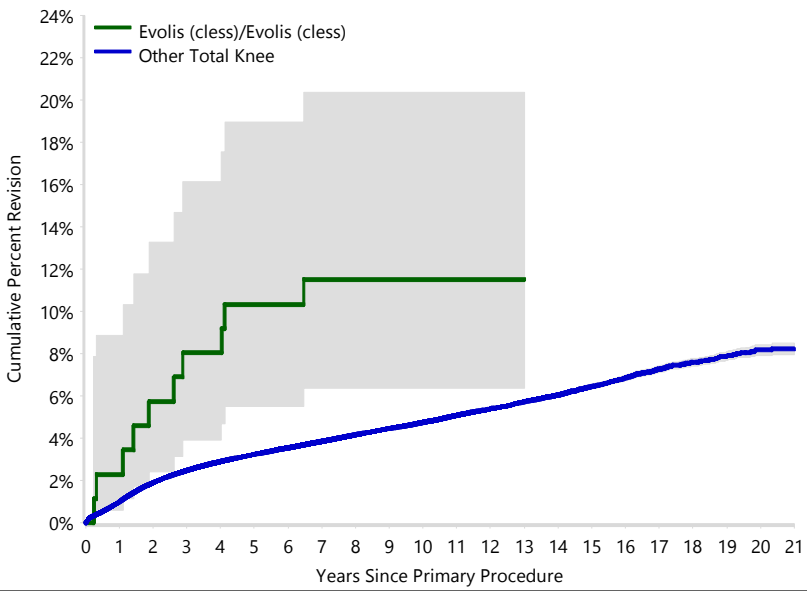
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Evolis (class)/Evolis (class) 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
Evolis (class)/Evolis (class) vs
Other Total Knee
Entire Period: HR=2.34 (1.26, 4.34), p=0.006

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
Evolis (class)/Evolis (class)	87	85	82	80	80	77	76	68	56	50	33
Other Total Knee	727608	657443	592678	527139	463961	403614	347056	293700	245696	202599	163469

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
Evolis (class)/Evolis (class)	28	17	13	0	0	0	0	0	0	0	0
Other Total Knee	128815	99092	75514	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

	Evolis (cless)/Evolis (cless)		Other Total Knee	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	10	100.0	25241	96.9
Rheumatoid Arthritis			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	**10**	**100.0**	**26051**	**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 13.9 Years)

Revision Diagnosis	Evolis (class)/Evolis (class)			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	3	3.4	30.0	6907	0.9	27.1
Loosening	5	5.7	50.0	5659	0.8	22.2
Instability	2	2.3	20.0	2440	0.3	9.6
Pain				2038	0.3	8.0
Patellofemoral Pain				2027	0.3	8.0
Patella Erosion				1635	0.2	6.4
Arthrofibrosis				992	0.1	3.9
Fracture				900	0.1	3.5
Malalignment				596	0.1	2.3
Lysis				310	0.0	1.2
Wear Tibial Insert				308	0.0	1.2
Incorrect Sizing				258	0.0	1.0
Patella Maltracking				181	0.0	0.7
Bearing Dislocation				152	0.0	0.6
Implant Breakage Tibial Insert				138	0.0	0.5
Implant Breakage Patella				132	0.0	0.5
Metal Related Pathology				112	0.0	0.4
Prosthesis Dislocation				76	0.0	0.3
Synovitis				76	0.0	0.3
Osteonecrosis				58	0.0	0.2
Implant Breakage Tibial				39	0.0	0.2
Implant Breakage Femoral				35	0.0	0.1
Wear Patella				29	0.0	0.1
Tumour				27	0.0	0.1
Heterotopic Bone				13	0.0	0.1
Wear Tibial				10	0.0	0.0
Progression Of Disease				5	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				301	0.0	1.2
N Revision	**10**	**11.5**	**100.0**	**25459**	**3.5**	**100.0**
N Primary	**87**			**727608**		

Note: This table is restricted to revisions within 13.9 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 Evolis (class)/Evolis (class) 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

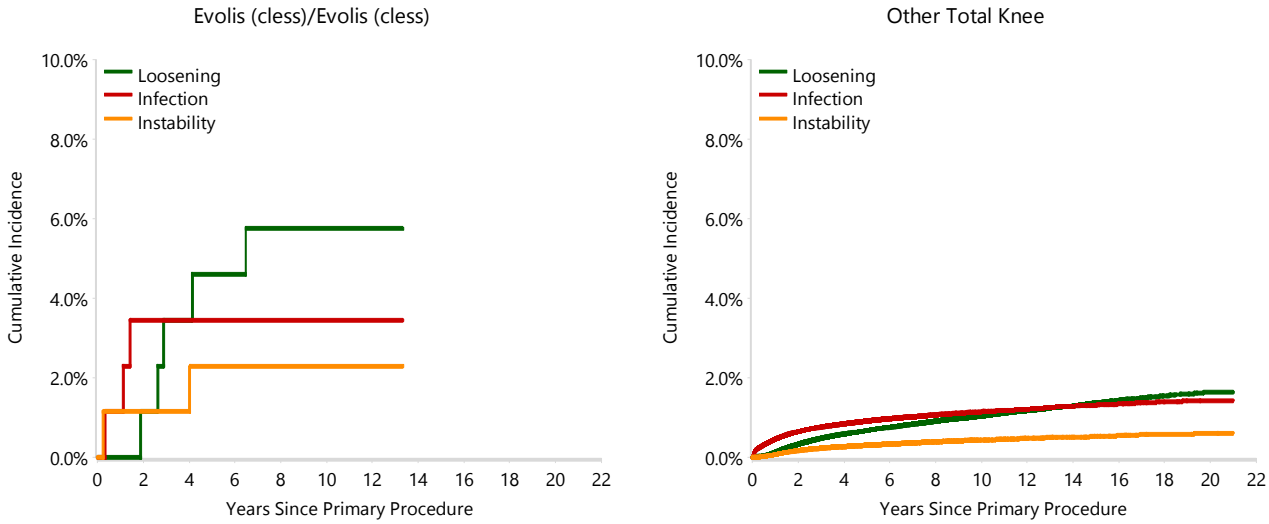


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Evolis (class)/Evolis (class) 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 Evolis (class)/Evolis (class) total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 13.9 Years)

	Evolis (class)/Evolis (class)		Other Total Knee	
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	4	40.0	6150	24.2
Tibial Component	3	30.0	2079	8.2
Cement Spacer	1	10.0	1343	5.3
Femoral Component	1	10.0	1306	5.1
Removal of Prostheses			149	0.6
Total Femoral			20	0.1
Reinsertion of Components			11	0.0
N Major	**9**	**90.0**	**11058**	**43.4**
Insert Only			7021	27.6
Patella Only			4734	18.6
Insert/Patella	1	10.0	2573	10.1
Minor Components			59	0.2
Cement Only			14	0.1
N Minor	**1**	**10.0**	**14401**	**56.6**
TOTAL	**10**	**100.0**	**25459**	**100.0**

Note: This table is restricted to revisions within 13.9 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 Evolis (class)/Evolis (class) 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 Evolis (class)/Evolis (class) Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cementless	10	87
TOTAL	**10**	**87**

TABLE 7

Revision Rates of Evolis (class)/Evolis (class) 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 Evolis (class)/Evolis (class) Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	10	87
TOTAL	**10**	**87**

TABLE 8

Revision Rates of Evolis (class)/Evolis (class) 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 Evolis (class)/Evolis (class) Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	10	87
TOTAL	**10**	**87**

TABLE 9

Revision Rates of Evolis (class)/Evolis (class) 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 Evolis (class)/Evolis (class) Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Minimally Stabilised	9	86
Posterior Stabilised	1	1
TOTAL	**10**	**87**

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Evolis (class)/Evolis (class) 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
Evolis (class)/Evolis (class)	NSW	10	84
	VIC	0	3
Other Total Knee	NSW	7712	253037
	VIC	5553	144484
	QLD	5690	153171
	WA	3235	77905
	SA	2837	63440
	TAS	418	16885
	ACT/NT	606	18686
TOTAL		**26061**	**727695**

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

TABLE 11

Number of Revisions of Evolis (class)/Evolis (class) Primary Total Knee Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Evolis (class)/Evolis (class) 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 Evolis (class)/Evolis (class) Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2008	2	17
2009	0	5
2010	1	11
2011	2	9
2012	2	20
2013	1	7
2014	2	11
2015	0	7
TOTAL	**10**	**87**

TABLE 12

Revision Rates of Evolis (class)/Evolis (class) 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 Evolis (class)/Evolis (class) 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			
Evolis	3010001D-3010006G	MIN. STAB. TI SPRAY STANDARD FEMUR	NO
Evolis	3012001D-3012006G	CEMENTLESS PS FEMUR	NO
Tibial			
Evolis	30310001-30310006	CEMENTLESS TIBIAL BASEPLATE	NO

Table 12: Revised Number of Evolis (class)/Evolis (class) Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
3010001D-3010006G	30310001-30310006	9	86
3012001D-3012006G	30310001-30310006	1	1
TOTAL		**10**	**87**