Profix/Profix Mobile Total Knee Investigation

Note: This analysis compares the Profix/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-2025.

Note: Procedures using prostheses with no recorded use in 2024 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Knee Replacement

The revision rate of the Profix/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)
Profix/Profix Mobile	117	1005	13662	0.86 (0.71, 1.03)
Other Total Knee	24707	721061	4535539	0.54 (0.54, 0.55)
TOTAL	24824	722066	4549200	0.55 (0.54, 0.55)

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Profix/Profix Mobile total knee combination is compared to all other total knee prostheses.

Table 2: Yearly Cumulative Percent Revision (95% CI) of Primary Total Knee Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
Profix/Profix Mobile	2.3 (1.5, 3.4)	5.0 (3.8, 6.6)	6.5 (5.1, 8.2)	7.3 (5.8, 9.1)	8.2 (6.6, 10.1)	8.7 (7.1, 10.7)	9.4 (7.7, 11.4)	9.6 (7.9, 11.7)
Other Total Knee	1.0 (1.0, 1.0)	1.8 (1.8, 1.9)	2.4 (2.4, 2.4)	2.8 (2.8, 2.8)	3.2 (3.1, 3.2)	3.5 (3.4, 3.5)	3.8 (3.7, 3.8)	4.1 (4.0, 4.2)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Profix/Profix Mobile	9.8 (8.0, 11.8)	10.0 (8.3, 12.1)	10.6 (8.8, 12.7)	11.1 (9.3, 13.3)	11.3 (9.4, 13.5)	11.8 (9.8, 14.0)	12.1 (10.1, 14.4)	12.3 (10.3, 14.6)
Other Total Knee	4.4 (4.3, 4.5)	4.7 (4.7, 4.8)	5.1 (5.0, 5.1)	5.4 (5.3, 5.5)	5.7 (5.6, 5.8)	6.0 (5.9, 6.1)	6.4 (6.3, 6.5)	6.8 (6.7, 7.0)

CPR	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
Profix/Profix Mobile	12.4 (10.4, 14.8)	12.7 (10.6, 15.1)	13.2 (11.0, 15.7)	13.6 (11.3, 16.3)	14.0 (11.6, 16.8)	14.0 (11.6, 16.8)	
Other Total Knee	7.3 (7.1, 7.4)	7.6 (7.4, 7.8)	7.9 (7.7, 8.1)	8.1 (7.9, 8.3)	8.4 (8.1, 8.6)	8.5 (8.2, 8.8)	8.6 (8.3, 8.9)

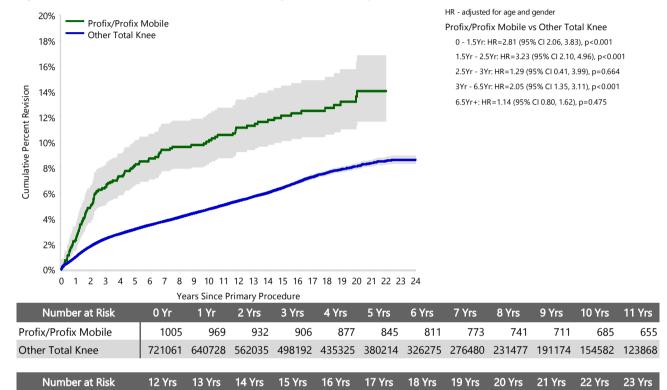
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Profix/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



Note: Prostheses no longer used in 2024 are excluded from the comparator.

Profix/Profix Mobile

Other Total Knee

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

	Profix/Profix Mobile		Other To	tal Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	114	97.4	23890	96.7
Rheumatoid Arthritis			301	1.2
Tumour			192	0.8
Other Inflammatory Arthritis	2	1.7	158	0.6
Osteonecrosis	1	0.9	90	0.4
Fracture			50	0.2
Other			25	0.1
Chondrocalcinosis			1	0.0
TOTAL	117	100.0	24707	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 Total Knee Replacement - Reason for Revision

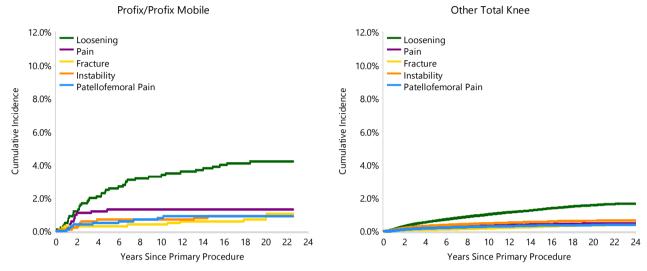
		Profix/Profix Mobile	e		Other Total Knee	
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	7	0.7	6.0	7091	1.0	28.7
Loosening	42	4.2	35.9	5262	0.7	21.3
Instability	9	0.9	7.7	2537	0.4	10.3
Patella Erosion	2	0.2	1.7	1817	0.3	7.4
Pain	13	1.3	11.1	1763	0.2	7.1
Patellofemoral Pain	9	0.9	7.7	1480	0.2	6.0
Arthrofibrosis	5	0.5	4.3	1047	0.1	4.2
Fracture	9	0.9	7.7	1017	0.1	4.1
Malalignment	1	0.1	0.9	488	0.1	2.0
Wear Tibial Insert	2	0.2	1.7	322	0.0	1.3
Lysis	7	0.7	6.0	264	0.0	1.1
Incorrect Sizing	2	0.2	1.7	210	0.0	0.8
Implant Breakage Tibial Insert	4	0.4	3.4	204	0.0	0.8
Patella Maltracking				175	0.0	0.7
Bearing Dislocation	4	0.4	3.4	142	0.0	0.6
Implant Breakage Patella				132	0.0	0.5
Metal Related Pathology				101	0.0	0.4
Prosthesis Dislocation				70	0.0	0.3
Synovitis				59	0.0	0.2
Osteonecrosis				46	0.0	0.2
Implant Breakage Femoral				45	0.0	0.2
Wear Patella				43	0.0	0.2
Implant Breakage Tibial				35	0.0	0.1
Tumour				30	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Progression Of Disease				8	0.0	0.0
Wear Tibial				6	0.0	0.0
Incorrect Side				1	0.0	0.0
Patella Dislocation				1	0.0	0.0
Wear Femoral				1	0.0	0.0
Other	1	0.1	0.9	296	0.0	1.2
N Revision	117	11.6	100.0	24707	3.4	100.0
N Primary	1005			721061		

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 Profix/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



Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Profix/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 Profix/Profix Mobile total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision

	Profix/Profix Mobile		Other To	otal Knee
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	45	38.5	5912	23.9
Tibial Component	5	4.3	1803	7.3
Femoral Component	6	5.1	1184	4.8
Cement Spacer	3	2.6	1082	4.4
Removal of Prostheses	10	8.5	126	0.5
Total Femoral			22	0.1
Reinsertion of Components			7	0.0
N Major	69	59.0	10136	41.0
Insert Only	18	15.4	7667	31.0
Patella Only	19	16.2	4164	16.9
Insert/Patella	9	7.7	2668	10.8
Minor Components	2	1.7	63	0.3
Cement Only			9	0.0
N Minor	48	41.0	14571	59.0
TOTAL	117	100.0	24707	100.0

Revision Rates of Profix/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 Profix/Profix Mobile Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	19	141
Cementless	36	272
Hybrid (Tibial Cemented)	61	579
Hybrid (Tibial Cementless)	1	13
TOTAL	117	1005

TABLE 7

Revision Rates of Profix/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 Profix/Profix Mobile Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	117	1005
TOTAL	117	1005

Revision Rates of Profix/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 Profix/Profix Mobile Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Rotating	117	1005
TOTAL	117	1005

TABLE 9

Revision Rates of Profix/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 Profix/Profix Mobile Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Minimally Stabilised	117	1005
TOTAL	117	1005

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Profix/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	
Profix/Profix Mobile	NSW	46	218	
	VIC	5	163	
	QLD	1	4	
	ACT/NT	65	620	
Other Total Knee	NSW	6834	236304	
	VIC	5457	148735	
	QLD	5317	152558	
	WA	3259	85158	
	SA	2886	66544	
	TAS	390	13242	
	ACT/NT	564	18520	
TOTAL		24824	722066	

Number of Revisions of Profix/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 Profix/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 2024 has a maximum of one year to be revised, whereas a primary procedure performed in 2022 has a maximum of three years to be revised.

Table 11: Number of Revisions of Profix/Profix Mobile Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2001	3	32
2002	28	165
2003	21	173
2004	34	258
2005	24	245
2006	4	51
2007	2	56
2008	0	11
2009	1	12
2010	0	2
TOTAL	117	1005

Revision Rates of Profix/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 Profix/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					
Profix	71502110-71502270	PROFIX POROUS FEMORAL COMPONENT	NO		POROUS
Profix	71503120-71503270	POROUS HA CR FEMORAL COMPONENT	NO	HA COATED	POROUS
Profix	71522110-71522270	NONPOROUS CONSTRAINED FEMORAL COMPONENT	YES		
Profix	71522111-71522271	NONPOROUS FEMORAL COMPONENT W/TAPER	YES		
Tibial					
Profix Mobile	71540102-71540208	POROUS TIBIAL BASEPLATE	NO		POROUS
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 Profix/Profix Mobile Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total	
71502110-71502270	71540102-71540208	0	2	
	71544102-71544208	5	42	
	71549101-71549208	33	282	
71503120-71503270	71544102-71544208	30	228	
	71549101-71549208	28	298	
71522110-71522270	71544102-71544208	1	12	
	71549101-71549208	20	139	
71522111-71522271	71549101-71549208	0	2	
TOTAL		117	1005	