PFC Sigma PS (cemented)/MBT (cementless) Total Knee Investigation

Note: This analysis compares the PFC Sigma PS (ctd)/MBT (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-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 PFC Sigma PS (ctd)/MBT (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)
PFC Sigma PS (ctd)/MBT (class)	26	316	3396	0.77 (0.50, 1.12)
Other Total Knee	24707	721061	4535539	0.54 (0.54, 0.55)
TOTAL	**24733**	**721377**	**4538935**	**0.54 (0.54, 0.55)**

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

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the PFC Sigma PS (ctd)/MBT (cless) 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
PFC Sigma PS (ctd)/MBT (cless)	2.2 (1.1, 4.6)	3.8 (2.2, 6.6)	5.4 (3.4, 8.6)	6.4 (4.2, 9.8)	7.1 (4.7, 10.5)	7.1 (4.7, 10.5)	7.1 (4.7, 10.5)	7.4 (5.0, 10.9)
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
PFC Sigma PS (ctd)/MBT (cless)	7.4 (5.0, 10.9)	7.4 (5.0, 10.9)	7.8 (5.3, 11.5)	7.8 (5.3, 11.5)	9.3 (5.9, 14.4)			
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
PFC Sigma PS (ctd)/MBT (cless)							
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)

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

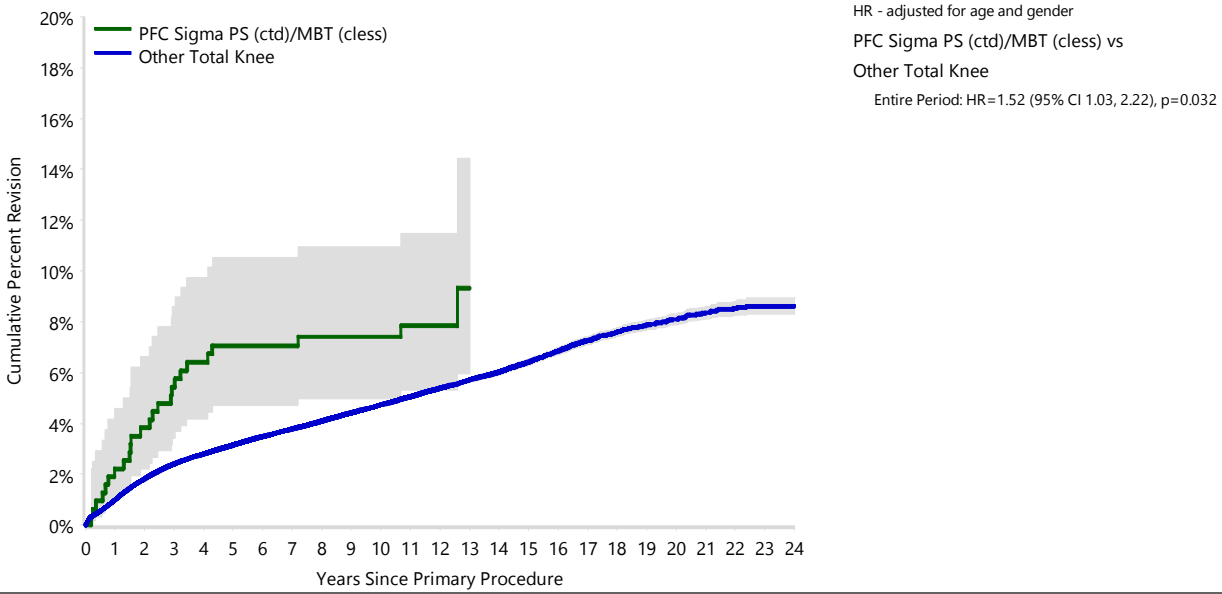
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the PFC Sigma PS (ctd)/MBT (cless) 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



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
PFC Sigma PS (ctd)/MBT (cless)	316	307	301	292	284	280	276	268	262	255	247	201
Other Total Knee	721061	640728	562035	498192	435325	380214	326275	276480	231477	191174	154582	123868

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
PFC Sigma PS (ctd)/MBT (cless)	106	43	25	23	22	21	18	18	0	0	0	0
Other Total Knee	97988	75221	56549	41508	30003	21223	14967	10421	6807	4051	2359	1090

Note: Prostheses no longer used in 2024 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

	PFC Sigma PS (ctd)/MBT (cless)		Other Total Knee	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	25	96.2	23890	96.7
Rheumatoid Arthritis			301	1.2
Tumour			192	0.8
Other Inflammatory Arthritis			158	0.6
Osteonecrosis	1	3.8	90	0.4
Fracture			50	0.2
Other			25	0.1
Chondrocalcinosis			1	0.0
TOTAL	**26**	**100.0**	**24707**	**100.0**

Note: Prostheses no longer used in 2024 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 19.8 Years)

	PFC Sigma PS (ctd)/MBT (cless)			Other Total Knee		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	7	2.2	26.9	7088	1.0	28.7
Loosening	7	2.2	26.9	5251	0.7	21.3
Instability	1	0.3	3.8	2536	0.4	10.3
Patella Erosion	2	0.6	7.7	1815	0.3	7.4
Pain	2	0.6	7.7	1761	0.2	7.1
Patellofemoral Pain	1	0.3	3.8	1480	0.2	6.0
Arthrofibrosis	1	0.3	3.8	1047	0.1	4.2
Fracture				1014	0.1	4.1
Malalignment	1	0.3	3.8	488	0.1	2.0
Wear Tibial Insert				320	0.0	1.3
Lysis				264	0.0	1.1
Incorrect Sizing	1	0.3	3.8	210	0.0	0.9
Implant Breakage Tibial Insert				204	0.0	0.8
Patella Maltracking				175	0.0	0.7
Bearing Dislocation	1	0.3	3.8	141	0.0	0.6
Implant Breakage Patella	1	0.3	3.8	132	0.0	0.5
Metal Related Pathology	1	0.3	3.8	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				296	0.0	1.2
N Revision	**26**	**8.2**	**100.0**	**24682**	**3.4**	**100.0**
N Primary	**316**			**721061**		

Note: This table is restricted to revisions within 19.8 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2024 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 PFC Sigma PS (ctd)/MBT (cless) 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

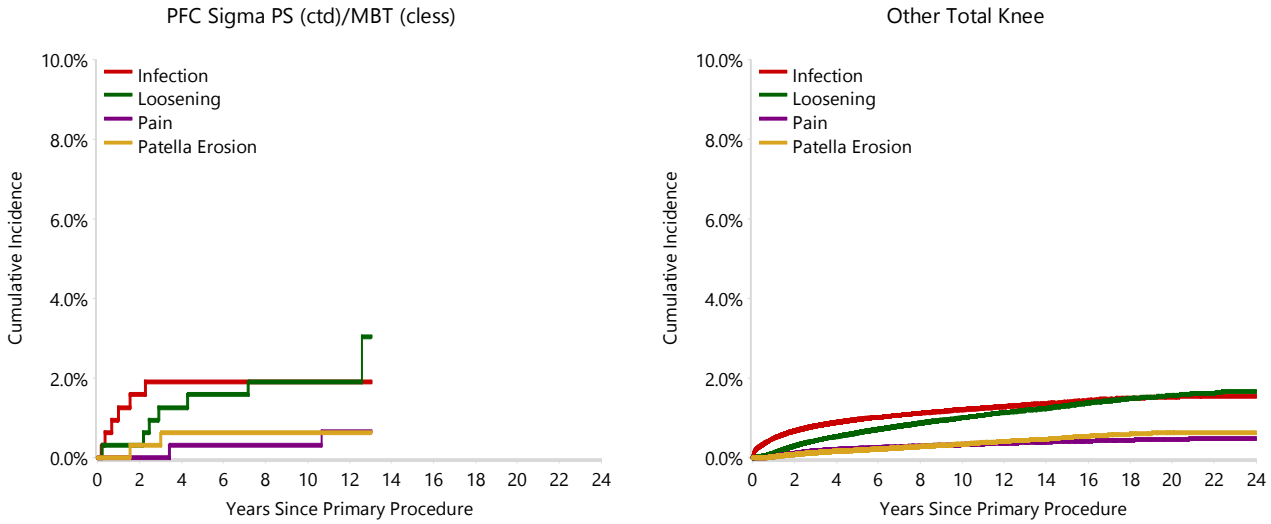


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the PFC Sigma PS (ctd)/MBT (cless) 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 PFC Sigma PS (ctd)/MBT (cless) total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 19.8 Years)

	PFC Sigma PS (ctd)/MBT (cless)		Other Total Knee	
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	8	30.8	5899	23.9
Tibial Component	2	7.7	1803	7.3
Femoral Component			1184	4.8
Cement Spacer	3	11.5	1082	4.4
Removal of Prostheses	1	3.8	125	0.5
Total Femoral			22	0.1
Reinsertion of Components			7	0.0
N Major	**14**	**53.8**	**10122**	**41.0**
Insert Only	7	26.9	7664	31.1
Patella Only	4	15.4	4162	16.9
Insert/Patella	1	3.8	2662	10.8
Minor Components			63	0.3
Cement Only			9	0.0
N Minor	**12**	**46.2**	**14560**	**59.0**
TOTAL	**26**	**100.0**	**24682**	**100.0**

Note: This table is restricted to revisions within 19.8 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2024 are excluded from the comparator.

TABLE 6

Revision Rates of PFC Sigma PS (ctd)/MBT (cless) 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 PFC Sigma PS (ctd)/MBT (cless) Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	0	1
Hybrid (Tibial Cementless)	26	315
TOTAL	**26**	**316**

TABLE 7

Revision Rates of PFC Sigma PS (ctd)/MBT (cless) 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 PFC Sigma PS (ctd)/MBT (cless) Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	26	316
TOTAL	**26**	**316**

TABLE 8

Revision Rates of PFC Sigma PS (ctd)/MBT (cless) 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 PFC Sigma PS (ctd)/MBT (cless) Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Rotating	26	316
TOTAL	**26**	**316**

TABLE 9

Revision Rates of PFC Sigma PS (ctd)/MBT (cless) 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 PFC Sigma PS (ctd)/MBT (cless) Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Posterior Stabilised	26	316
TOTAL	**26**	**316**

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the PFC Sigma PS (ctd)/MBT (cless) 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
PFC Sigma PS (ctd)/MBT (cless)	NSW	0	13
	VIC	0	1
	QLD	15	131
	WA	11	171
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		**24733**	**721377**

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

TABLE 11

Number of Revisions of PFC Sigma PS (ctd)/MBT (cless) Primary Total Knee Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the PFC Sigma PS (ctd)/MBT (cless) 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 PFC Sigma PS (ctd)/MBT (cless) Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	3	47
2006	1	2
2011	3	25
2012	9	89
2013	5	110
2014	5	42
2016	0	1
TOTAL	**26**	**316**

TABLE 12

Revision Rates of PFC Sigma PS (ctd)/MBT (cless) 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 PFC Sigma PS (ctd)/MBT (cless) 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	Fixation
Femoral				
PFC Sigma PS	196004400-196005400	CS CEMENTED FEMORAL COMPONENT	YES	
PFC Sigma PS	196008400-196009400	PS RPF COCR FEMORAL COMPONENT	YES	
PFC Sigma PS	196040100-196050600	PS CEMENTED FEMORAL COMPONENT	YES	
PFC Sigma PS	950010-950027	RPF COCR CEMENTED FEMORAL COMPONENT	YES	
PFC Sigma PS	960042-960058	CRUCIATE SACRIFICING NONPOROUS FEMORAL COMPONENT	YES	
Tibial				
MBT	129432110-129432170	POROCOAT TIBIAL TRAY	NO	POROUS

Table 12: Revised Number of PFC Sigma PS (ctd)/MBT (cless) Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
196004400-196005400	129432110-129432170	0	1
196008400-196009400	129432110-129432170	4	20
196040100-196050600	129432110-129432170	10	172
950010-950027	129432110-129432170	7	59
960042-960058	129432110-129432170	5	64
TOTAL		**26**	**316**