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

Note: This analysis compares the PFC Sigma PS (ctd)/MBT (cless) 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-2023.

Note: Procedures using prostheses with no recorded use in 2022 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Knee Replacement

The revision rate of the PFC Sigma PS (ctd)/MBT (cless) 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 (cless)	25	316	2952	0.85 (0.55, 1.25)
Other Total Knee	26811	757633	5066828	0.53 (0.52, 0.54)
TOTAL	**26836**	**757949**	**5069780**	**0.53 (0.52, 0.54)**

Note: Prostheses no longer used in 2022 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 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, 2.9)	3.1 (3.1, 3.2)	3.5 (3.4, 3.5)	3.8 (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
PFC Sigma PS (ctd)/MBT (cless)	7.4 (5.0, 10.9)	7.4 (5.0, 10.9)	8.8 (5.6, 13.8)				
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)	5.6 (5.5, 5.6)	5.9 (5.8, 5.9)	6.2 (6.1, 6.3)

CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
PFC Sigma PS (ctd)/MBT (cless)							
Other Total Knee	6.6 (6.5, 6.8)	7.0 (6.9, 7.2)	7.3 (7.2, 7.5)	7.6 (7.4, 7.8)	7.8 (7.6, 8.0)	8.0 (7.8, 8.2)	8.2 (7.9, 8.6)

Note: Prostheses no longer used in 2022 are excluded from the comparator.

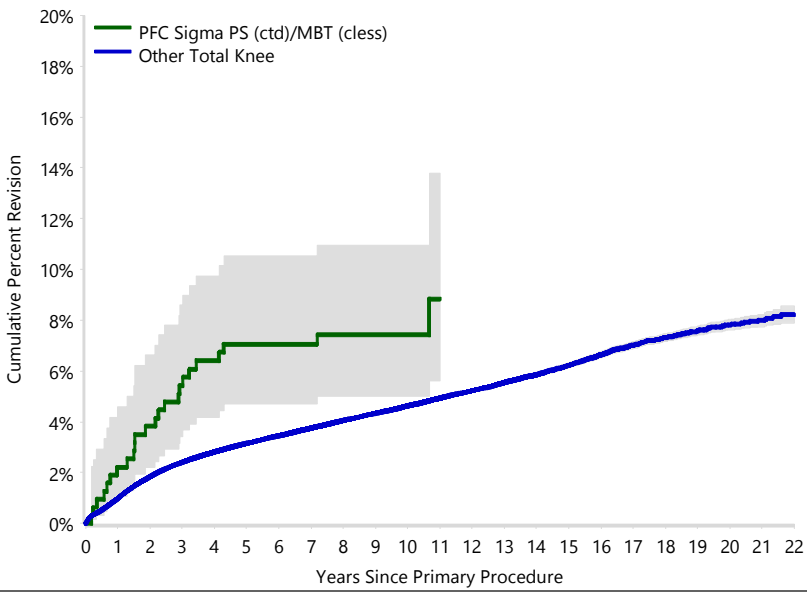
FIGURE 1

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



HR - adjusted for age and gender
PFC Sigma PS (ctd)/MBT (cless) vs
Other Total Knee
Entire Period: HR=1.61 (1.09, 2.38), p=0.017

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	267	261	220	123	46
Other Total Knee	757633	689575	619315	556541	492517	430850	372461	317859	266968	221340	180286	143397

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
PFC Sigma PS (ctd)/MBT (cless)	28	28	25	23	22	21	0	0	0	0	0
Other Total Knee	111894	85759	65024	47974	34969	24714	16433	9944	5486	2318	538

Note: Prostheses no longer used in 2022 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	24	96.0	25980	96.9
Rheumatoid Arthritis			342	1.3
Tumour			162	0.6
Other Inflammatory Arthritis			160	0.6
Osteonecrosis	1	4.0	100	0.4
Fracture			48	0.2
Other			18	0.1
Chondrocalcinosis			1	0.0
TOTAL	**25**	**100.0**	**26811**	**100.0**

Note: Prostheses no longer used in 2022 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 17.8 Years)

	PFC Sigma PS (ctd)/MBT (cless)			Other Total Knee		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	7	2.2	28.0	7340	1.0	27.5
Loosening	6	1.9	24.0	5983	0.8	22.4
Instability	1	0.3	4.0	2603	0.3	9.7
Pain	2	0.6	8.0	2033	0.3	7.6
Patellofemoral Pain	1	0.3	4.0	1929	0.3	7.2
Patella Erosion	2	0.6	8.0	1776	0.2	6.6
Arthrofibrosis	1	0.3	4.0	1033	0.1	3.9
Fracture				1013	0.1	3.8
Malalignment	1	0.3	4.0	601	0.1	2.2
Wear Tibial Insert				365	0.0	1.4
Lysis				328	0.0	1.2
Incorrect Sizing	1	0.3	4.0	261	0.0	1.0
Patella Maltracking				186	0.0	0.7
Implant Breakage Tibial Insert				172	0.0	0.6
Bearing Dislocation	1	0.3	4.0	150	0.0	0.6
Implant Breakage Patella	1	0.3	4.0	138	0.0	0.5
Metal Related Pathology	1	0.3	4.0	106	0.0	0.4
Prosthesis Dislocation				84	0.0	0.3
Synovitis				75	0.0	0.3
Osteonecrosis				55	0.0	0.2
Implant Breakage Tibial				42	0.0	0.2
Implant Breakage Femoral				39	0.0	0.1
Wear Patella				36	0.0	0.1
Tumour				33	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Wear Tibial				9	0.0	0.0
Progression Of Disease				6	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				316	0.0	1.2
N Revision	**25**	**7.9**	**100.0**	**26730**	**3.5**	**100.0**
N Primary	**316**			**757633**		

Note: This table is restricted to revisions within 17.8 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2022 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

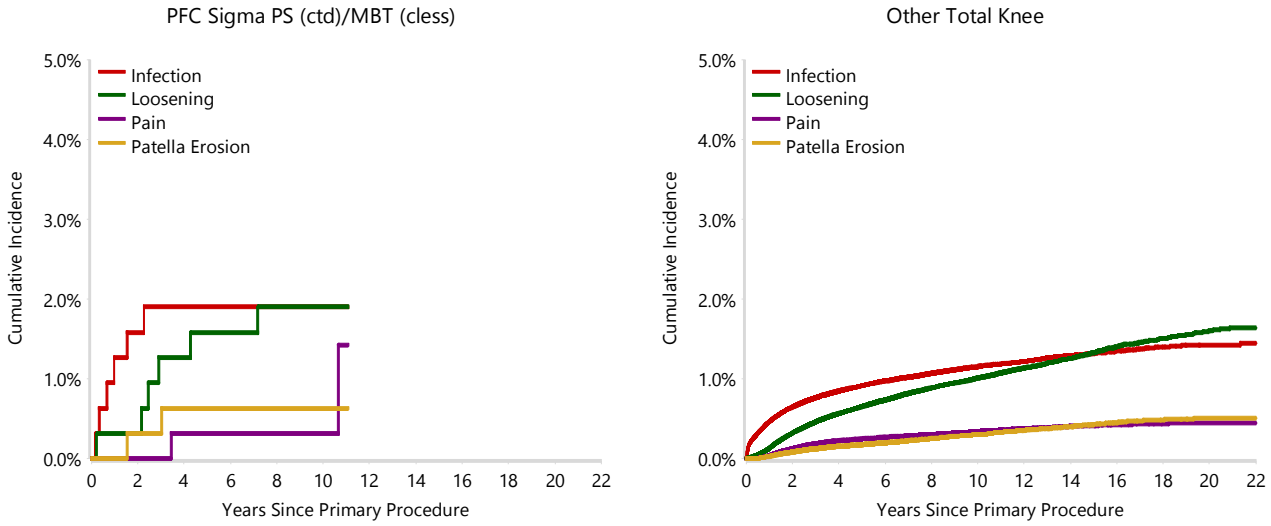


TABLE 5

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 17.8 Years)

	PFC Sigma PS (ctd)/MBT (cless)		Other Total Knee	
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	7	28.0	6607	24.7
Tibial Component	2	8.0	2133	8.0
Cement Spacer	3	12.0	1359	5.1
Femoral Component			1322	4.9
Removal of Prostheses	1	4.0	151	0.6
Total Femoral			24	0.1
Reinsertion of Components			13	0.0
N Major	**13**	**52.0**	**11609**	**43.4**
Insert Only	7	28.0	7563	28.3
Patella Only	4	16.0	4716	17.6
Insert/Patella	1	4.0	2760	10.3
Minor Components			64	0.2
Cement Only			18	0.1
N Minor	**12**	**48.0**	**15121**	**56.6**
TOTAL	**25**	**100.0**	**26730**	**100.0**

Note: This table is restricted to revisions within 17.8 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2022 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)	25	315
TOTAL	**25**	**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	25	316
TOTAL	**25**	**316**

TABLE 8

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

Bearing Mobility	N Revised	N Total
Rotating	25	316
TOTAL	**25**	**316**

TABLE 9

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

Stability	N Revised	N Total
Posterior Stabilised	25	316
TOTAL	**25**	**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	14	131
	WA	11	171
Other Total Knee	NSW	7959	262420
	VIC	5825	153046
	QLD	5752	156877
	WA	3234	80968
	SA	2967	66419
	TAS	437	18133
	ACT/NT	637	19770
TOTAL		**26836**	**757949**

Note: Prostheses no longer used in 2022 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 2022 has a maximum of one year to be revised, whereas a primary procedure performed in 2020 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	8	89
2013	5	110
2014	5	42
2016	0	1
TOTAL	**25**	**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	6	59
960042-960058	129432110-129432170	5	64
TOTAL		**25**	**316**