

PFC Sigma/Sigma HP Patella-Trochlear Knee Investigation

Note: This analysis compares the PFC Sigma/Sigma HP patella/trochlear combination with all other patella-trochlear 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-2024>.

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

TABLE 1

Revision Rate of Primary Patella-Trochlear Knee Replacement

The revision rate of the PFC Sigma/Sigma HP patella-trochlear knee combination is compared to all other patella-trochlear knee prostheses.

Table 1: Revision Rates of Primary Patella-Trochlear Knee Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
PFC Sigma/Sigma HP	48	117	953	5.04 (3.72, 6.68)
Other Patella-Trochlear Knee	547	3674	22157	2.47 (2.27, 2.68)
TOTAL	595	3791	23110	2.57 (2.37, 2.79)

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

TABLE 2

Yearly Cumulative Percent Revision of Primary Patella-Trochlear Knee Replacement

The yearly cumulative percent revision of the PFC Sigma/Sigma HP patella-trochlear knee combination is compared to all other patella-trochlear knee prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Patella-Trochlear Knee Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
PFC Sigma/Sigma HP	4.3 (1.8, 10.0)	10.3 (6.0, 17.5)	14.7 (9.4, 22.6)	17.3 (11.6, 25.6)	20.9 (14.5, 29.6)	26.4 (19.2, 35.5)	27.3 (20.0, 36.5)	35.6 (27.3, 45.4)
Other Patella-Trochlear Knee	1.4 (1.0, 1.8)	3.9 (3.3, 4.6)	6.5 (5.7, 7.4)	8.5 (7.6, 9.6)	10.4 (9.3, 11.6)	12.2 (11.0, 13.5)	15.4 (14.0, 16.9)	17.3 (15.7, 18.9)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
PFC Sigma/Sigma HP	37.8 (29.3, 47.8)	39.1 (30.4, 49.2)						
Other Patella-Trochlear Knee	19.7 (18.0, 21.5)	22.3 (20.4, 24.4)	24.4 (22.3, 26.7)	27.4 (25.0, 29.9)	29.4 (26.8, 32.2)	32.0 (29.0, 35.2)	35.4 (31.8, 39.3)	38.1 (33.8, 42.8)

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

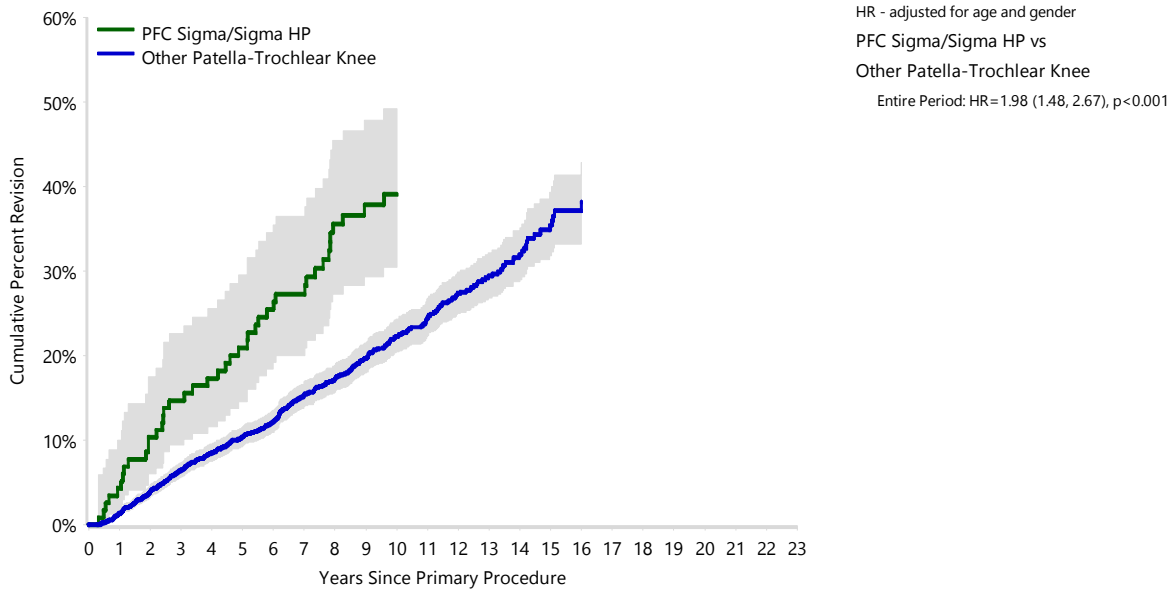
FIGURE 1

Yearly Cumulative Percent Revision of Primary Patella-Trochlear Knee Replacement

The yearly cumulative percent revision of the PFC Sigma/Sigma HP patella-trochlear knee combination is compared to all other patella-trochlear 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 Patella-Trochlear 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/Sigma HP	117	111	104	98	93	88	81	72	61	53	47	32
Other Patella-Trochlear Knee	3674	3313	2936	2566	2235	1937	1614	1329	1079	892	712	565

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/Sigma HP	24	14	6	4	4	0	0	0	0	0	0	0
Other Patella-Trochlear Knee	421	304	193	115	61	38	16	7	2	2	1	0

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

TABLE 3**Primary Diagnosis for Revised Primary Patella-Trochlear 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 patella-trochlear knee prostheses.

Table 3: Primary Diagnosis for Revised Primary Patella-Trochlear Knee Replacement

Primary Diagnosis	PFC Sigma/Sigma HP		Other Patella-Trochlear Knee	
	Number	Percent	Number	Percent
Osteoarthritis	48	100.0	540	98.7
Other Inflammatory Arthritis			4	0.7
Rheumatoid Arthritis			2	0.4
Other			1	0.2
TOTAL	48	100.0	547	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 Patella-Trochlear Knee Replacement - Reason for Revision (Follow-up Limited to 16.9 Years)

Revision Diagnosis	PFC Sigma/Sigma HP			Other Patella-Trochlear Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Progression Of Disease	27	23.1	56.3	351	9.6	64.4
Pain	7	6.0	14.6	59	1.6	10.8
Loosening	1	0.9	2.1	56	1.5	10.3
Infection				16	0.4	2.9
Malalignment	2	1.7	4.2	10	0.3	1.8
Wear Patella	3	2.6	6.3	9	0.2	1.7
Patella Maltracking				8	0.2	1.5
Instability	5	4.3	10.4	7	0.2	1.3
Fracture	1	0.9	2.1	6	0.2	1.1
Lysis				5	0.1	0.9
Implant Breakage Patella				4	0.1	0.7
Prosthesis Dislocation				3	0.1	0.6
Incorrect Sizing				2	0.1	0.4
Metal Related Pathology	2	1.7	4.2			
Patellofemoral Pain				2	0.1	0.4
Wear Tibial Insert				2	0.1	0.4
Arthrofibrosis				1	0.0	0.2
Implant Breakage Femoral				1	0.0	0.2
Osteonecrosis				1	0.0	0.2
Other				2	0.1	0.4
N Revision	48	41.0	100.0	545	14.8	100.0
N Primary	117			3674		

Note: This table is restricted to revisions within 16.9 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 Patella-Trochlear 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/Sigma HP patella-trochlear knee combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other patella-trochlear knee prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Patella-Trochlear Knee Replacement

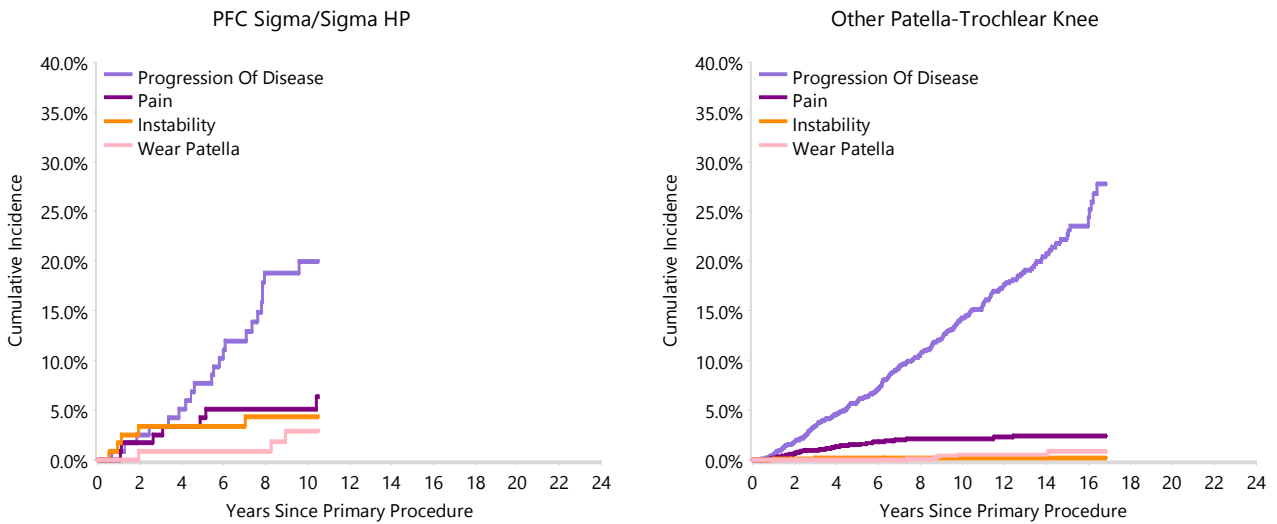


TABLE 5

Type of Revision Performed for Primary Patella-Trochlear Knee Replacement

This analysis identifies the components used in the revision of the PFC Sigma/Sigma HP patella-trochlear knee combination and compares it to the components used in the revision of all other patella-trochlear 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 patella-trochlear knee prostheses i.e. is there a difference in the type of revision undertaken for the PFC Sigma/Sigma HP patella-trochlear knee combination compared to all other patella-trochlear knee prostheses.

Table 5: Primary Patella-Trochlear Knee Replacement - Type of Revision (Follow-up Limited to 16.9 Years)

Type of Revision	PFC Sigma/Sigma HP		Other Patella-Trochlear Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	39	81.3	492	90.3
UKR (Uni Tibial/Uni Femoral)	1	2.1	11	2.0
Patella/Trochlear Resurfacing	4	8.3	8	1.5
Cement Spacer			3	0.6
Removal of Prostheses			3	0.6
Femoral Component			2	0.4
N Major	44	91.7	519	95.2
Patella Only	4	8.3	25	4.6
Minor Components			1	0.2
N Minor	4	8.3	26	4.8
TOTAL	48	100.0	545	100.0

Note: This table is restricted to revisions within 16.9 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 Primary Patella-Trochlear Knee Replacement by State

This enables a state by state variation to be identified for the PFC Sigma/Sigma HP patella-trochlear knee combination and provides the comparative data for each of the states for all other patella-trochlear 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 6: Revised Number of Primary Patella-Trochlear Knee Replacement by State

Component	State	N Revised	N Total
PFC Sigma/Sigma HP	NSW	0	2
	QLD	20	46
	WA	9	22
	SA	19	47
Other Patella-Trochlear Knee	NSW	195	1194
	VIC	124	929
	QLD	70	573
	WA	45	323
	SA	87	487
	TAS	7	74
	ACT/NT	19	94
TOTAL		595	3791

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

TABLE 7**Number of Revisions of PFC Sigma/Sigma HP Primary Patella-Trochlear Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the PFC Sigma/Sigma HP patella-trochlear 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 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 7: Number of Revisions of PFC Sigma/Sigma HP Primary Patella-Trochlear Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2007	8	14
2008	3	6
2009	3	5
2010	4	16
2011	5	15
2012	7	12
2013	8	20
2014	2	7
2015	4	7
2016	4	7
2017	0	8
TOTAL	48	117

TABLE 8**Revision Rates of PFC Sigma/Sigma HP Primary Patella-Trochlear 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/Sigma HP 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	Material
Patella				
PFC Sigma	960100-960111	ALL POLY OVAL DOME PATELLA	YES	NON CROSS-LINKED POLYETHYLENE
PFC Sigma	960120-960122	PFC INSET PATELLA	YES	NON CROSS-LINKED POLYETHYLENE
Trochlear				
Sigma HP	102403100-102404500	COCR FEMORAL TROCHLEAR	YES	

Table 8: Revised Number of PFC Sigma/Sigma HP Primary Patella-Trochlear Knee Replacement by Catalogue Number Range

Patella Range	Trochlear Range	N Revised	N Total
960100-960111	102403100-102404500	27	71
960120-960122	102403100-102404500	21	46
TOTAL		48	117