

## 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-2025>.

Note: Procedures using prostheses with no recorded use in 2024 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	50	117	1009	4.95 (3.68, 6.53)
Other Patella-Trochlear Knee	478	3468	20025	2.39 (2.18, 2.61)
<b>TOTAL</b>	<b>528</b>	<b>3585</b>	<b>21034</b>	<b>2.51 (2.30, 2.73)</b>

Note: Prostheses no longer used in 2024 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 (95% CI) of Primary Patella-Trochlear Knee Replacement**

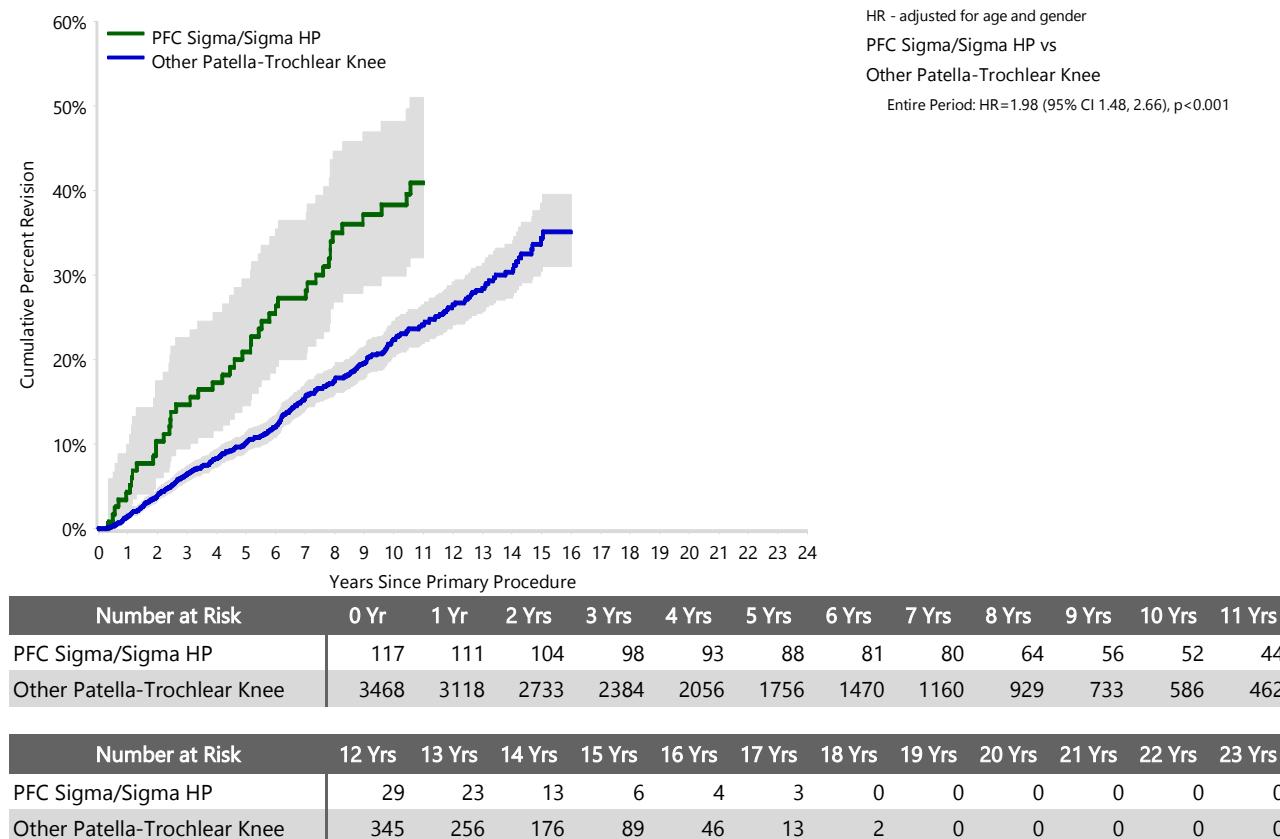
CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
PFC Sigma/Sigma HP	4.3 (1.8, 10.0)	10.3 (6.0, 17.5)	14.7 (9.4, 22.6)	17.3 (11.6, 25.6)	20.9 (14.5, 29.6)	26.4 (19.2, 35.5)	27.3 (20.0, 36.5)	35.0 (26.9, 44.7)
Other Patella-Trochlear Knee	1.5 (1.2, 2.0)	3.9 (3.3, 4.7)	6.5 (5.6, 7.4)	8.3 (7.3, 9.4)	10.2 (9.1, 11.4)	12.1 (10.8, 13.4)	15.5 (14.0, 17.1)	17.6 (16.0, 19.4)
CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
PFC Sigma/Sigma HP	37.1 (28.8, 47.0)	38.3 (29.9, 48.2)	40.9 (32.1, 51.0)					
Other Patella-Trochlear Knee	19.6 (17.8, 21.5)	22.4 (20.3, 24.6)	24.1 (21.9, 26.5)	26.5 (24.1, 29.2)	28.4 (25.7, 31.4)	30.4 (27.3, 33.6)	34.4 (30.5, 38.6)	35.1 (31.0, 39.5)

Note: Prostheses no longer used in 2024 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**

Note: Prostheses no longer used in 2024 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	50	100.0	473	99.0
Other Inflammatory Arthritis			2	0.4
Rheumatoid Arthritis			2	0.4
Other			1	0.2
<b>TOTAL</b>	<b>50</b>	<b>100.0</b>	<b>478</b>	<b>100.0</b>

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 Patella-Trochlear Knee Replacement - Reason for Revision**

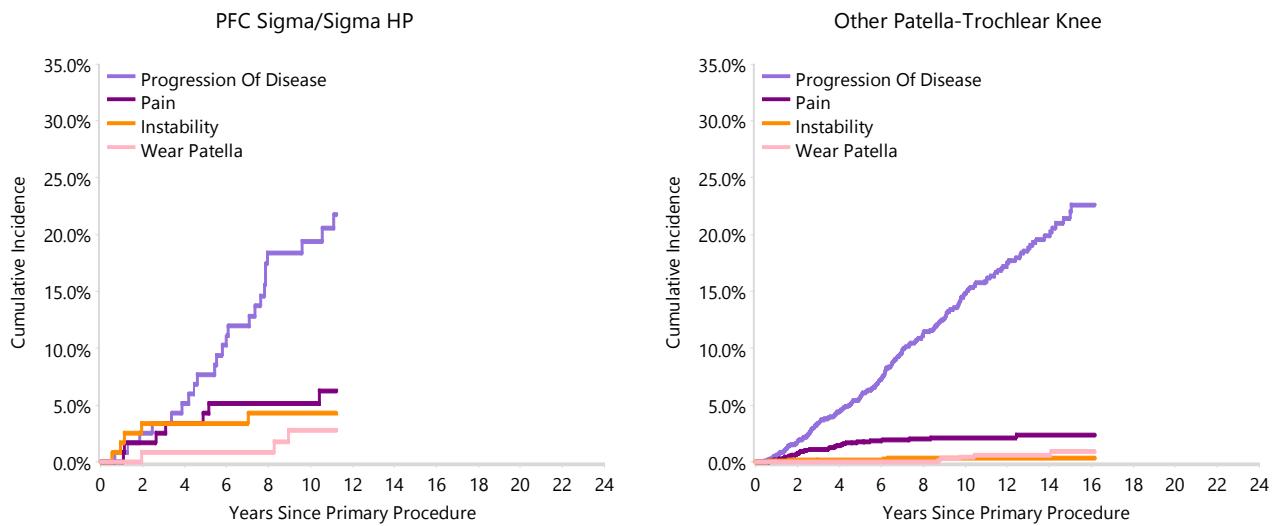
Revision Diagnosis	PFC Sigma/Sigma HP			Other Patella-Trochlear Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Progression Of Disease	28	23.9	56.0	308	8.9	64.4
Pain	7	6.0	14.0	55	1.6	11.5
Loosening	1	0.9	2.0	43	1.2	9.0
Infection				12	0.3	2.5
Instability	5	4.3	10.0	9	0.3	1.9
Patella Maltracking				9	0.3	1.9
Malalignment	2	1.7	4.0	8	0.2	1.7
Wear Patella	3	2.6	6.0	7	0.2	1.5
Lysis	1	0.9	2.0	6	0.2	1.3
Fracture	1	0.9	2.0	5	0.1	1.0
Implant Breakage Patella				3	0.1	0.6
Incorrect Sizing				2	0.1	0.4
Metal Related Pathology	2	1.7	4.0			
Patellofemoral Pain				2	0.1	0.4
Prosthesis Dislocation				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
Patella Erosion				1	0.0	0.2
Other				1	0.0	0.2
<b>N Revision</b>	<b>50</b>	<b>42.7</b>	<b>100.0</b>	<b>478</b>	<b>13.8</b>	<b>100.0</b>
<b>N Primary</b>	<b>117</b>			<b>3468</b>		

Note: Prostheses no longer used in 2024 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**

Type of Revision	PFC Sigma/Sigma HP		Other Patella-Trochlear Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	41	82.0	422	88.3
UKR (Uni Tibial/Uni Femoral)	1	2.0	10	2.1
Patella/Trochlear Resurfacing	4	8.0	8	1.7
Cement Spacer			3	0.6
Removal of Prostheses			3	0.6
Femoral Component			1	0.2
<b>N Major</b>	<b>46</b>	<b>92.0</b>	<b>447</b>	<b>93.5</b>
Patella Only	4	8.0	30	6.3
Minor Components			1	0.2
<b>N Minor</b>	<b>4</b>	<b>8.0</b>	<b>31</b>	<b>6.5</b>
<b>TOTAL</b>	<b>50</b>	<b>100.0</b>	<b>478</b>	<b>100.0</b>

Note: Prostheses no longer used in 2024 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	22	46
	WA	9	22
	SA	19	47
Other Patella-Trochlear Knee	NSW	163	1114
	VIC	115	895
	QLD	62	535
	WA	43	305
	SA	69	449
	TAS	8	78
	ACT/NT	18	92
<b>TOTAL</b>		<b>528</b>	<b>3585</b>

Note: Prostheses no longer used in 2024 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 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 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	9	14
2008	3	6
2009	3	5
2010	4	16
2011	5	15
2012	8	12
2013	8	20
2014	2	7
2015	4	7
2016	4	7
2017	0	8
<b>TOTAL</b>	<b>50</b>	<b>117</b>

**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
<b>Patella</b>				
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
<b>Trochlear</b>				
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	23	46
<b>TOTAL</b>		<b>50</b>	<b>117</b>