

Profemur Z Total Conventional Hip Investigation

Note: This analysis compares the Profemur Z femoral stem prosthesis with all other total conventional hip prostheses.

This prosthesis 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-2022>.

Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator. Procedures using prostheses with no recorded use in 2021 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Conventional Hip Replacement

The revision rate of the Profemur Z total conventional hip prosthesis is compared to all other total conventional hip prostheses.

Table 1: Revision Rates of Primary Total Conventional Hip Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Profemur Z	30	186	2065	1.45 (0.98, 2.07)
Other Total Conventional Hip	15859	453455	2721137	0.58 (0.57, 0.59)
TOTAL	15889	453641	2723202	0.58 (0.57, 0.59)

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Profemur Z total conventional hip prosthesis is compared to all other total conventional hip prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Profemur Z	6.0 (3.4, 10.5)	8.7 (5.4, 13.8)	10.4 (6.8, 15.8)	11.0 (7.2, 16.5)	11.0 (7.2, 16.5)	11.6 (7.7, 17.2)	11.6 (7.7, 17.2)
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.2, 2.2)	2.5 (2.5, 2.6)	2.8 (2.8, 2.9)	3.1 (3.0, 3.2)	3.4 (3.3, 3.5)	3.7 (3.6, 3.7)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Profemur Z	12.2 (8.2, 18.0)	12.2 (8.2, 18.0)	12.2 (8.2, 18.0)	15.4 (10.7, 21.9)	15.4 (10.7, 21.9)	15.4 (10.7, 21.9)	15.4 (10.7, 21.9)
Other Total Conventional Hip	4.0 (3.9, 4.0)	4.3 (4.2, 4.4)	4.6 (4.6, 4.7)	5.0 (4.9, 5.1)	5.4 (5.3, 5.5)	5.8 (5.7, 5.9)	6.3 (6.1, 6.4)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Profemur Z	16.4 (11.5, 23.3)	20.4 (14.3, 28.6)					
Other Total Conventional Hip	6.7 (6.5, 6.8)	7.1 (6.9, 7.3)	7.5 (7.3, 7.7)	7.9 (7.6, 8.1)	8.6 (8.3, 8.9)	8.9 (8.5, 9.3)	9.8 (9.0, 10.8)

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

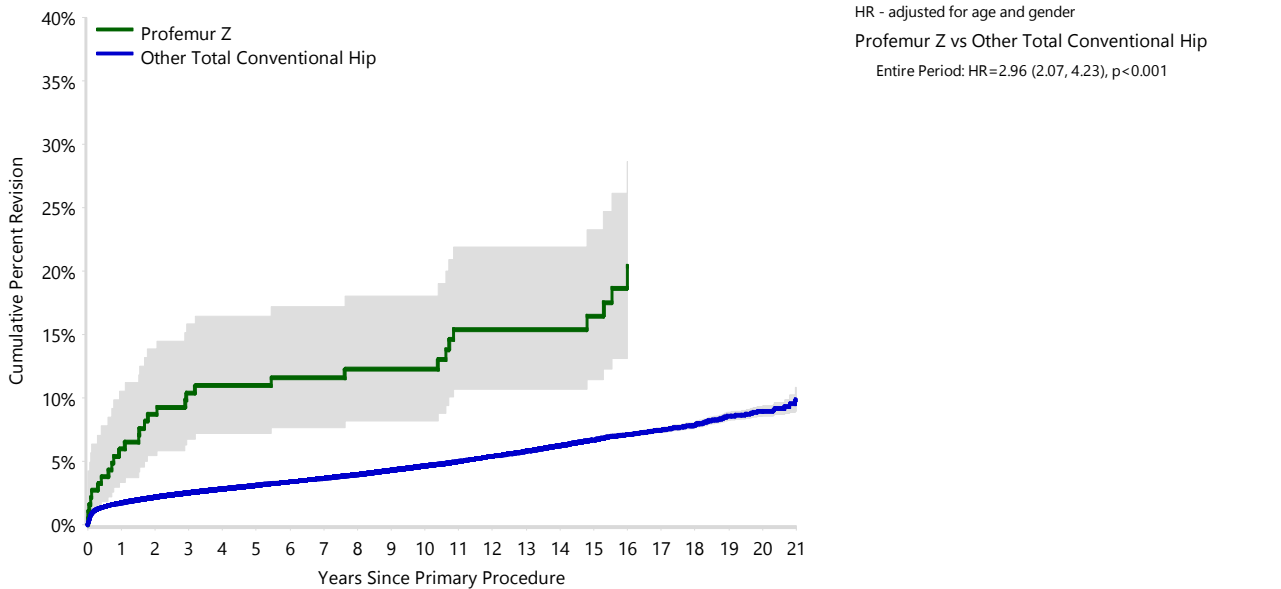
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Profemur Z total conventional hip prosthesis is compared to all other total conventional hip 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 Conventional Hip 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
Profemur Z	186	172	165	158	154	150	143	138	127	122	116
Other Total Conventional Hip	453455	398683	354053	309177	267205	228060	191587	158583	131210	108026	88155

Number at Risk	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Profemur Z	106	100	92	88	80	47	12	0	0	0	0
Other Total Conventional Hip	70603	55343	42208	31909	24032	17719	12212	7611	4006	1573	276

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 3**Primary Diagnosis for Revised Primary Total Conventional Hip 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 conventional hip prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Conventional Hip Replacement

Primary Diagnosis	Profemur Z		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	28	93.3	13112	82.7
Fractured Neck Of Femur			1164	7.3
Osteonecrosis	2	6.7	718	4.5
Developmental Dysplasia			247	1.6
Rheumatoid Arthritis			173	1.1
Failed Internal Fixation			140	0.9
Tumour			137	0.9
Other Inflammatory Arthritis			91	0.6
Fracture/Dislocation			47	0.3
Arthrodesis Takedown			16	0.1
Other			14	0.1
TOTAL	30	100.0	15859	100.0

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm 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 Conventional Hip Replacement - Reason for Revision (Follow-up Limited to 17.6 Years)

Revision Diagnosis	Number	Profemur Z		Other Total Conventional Hip		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	4	2.2	13.3	3707	0.8	23.5
Infection	2	1.1	6.7	3542	0.8	22.4
Fracture	3	1.6	10.0	3425	0.8	21.7
Loosening	15	8.1	50.0	3207	0.7	20.3
Pain	2	1.1	6.7	286	0.1	1.8
Leg Length Discrepancy				260	0.1	1.6
Malposition				225	0.0	1.4
Lysis				177	0.0	1.1
Implant Breakage Stem	1	0.5	3.3	149	0.0	0.9
Implant Breakage Acetabular Insert				114	0.0	0.7
Incorrect Sizing				95	0.0	0.6
Wear Acetabular Insert	1	0.5	3.3	89	0.0	0.6
Implant Breakage Acetabular				66	0.0	0.4
Metal Related Pathology	2	1.1	6.7	65	0.0	0.4
Wear Head				44	0.0	0.3
Tumour				37	0.0	0.2
Implant Breakage Head				30	0.0	0.2
Heterotopic Bone				23	0.0	0.1
Wear Acetabulum				9	0.0	0.1
Progression Of Disease				2	0.0	0.0
Osteonecrosis				1	0.0	0.0
Synovitis				1	0.0	0.0
Other				228	0.1	1.4
N Revision	30	16.1	100.0	15782	3.5	100.0
N Primary	186			453455		

Note: This table is restricted to revisions within 17.6 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Conventional Hip 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 Profemur Z total conventional hip prosthesis. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total conventional hip prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Conventional Hip Replacement

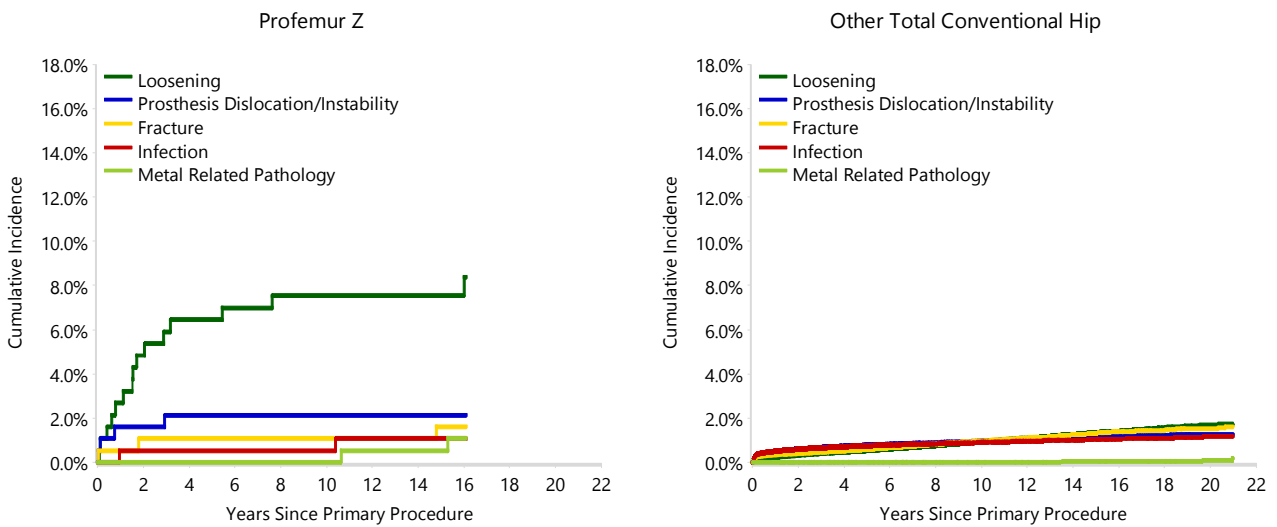


TABLE 5

Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Profemur Z total conventional hip prosthesis and compares it to the components used in the revision of all other total conventional hip 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 conventional hip prostheses i.e. is there a difference in the type of revision undertaken for the Profemur Z total conventional hip prosthesis compared to all other total conventional hip prostheses.

Table 5: Primary Total Conventional Hip Replacement - Type of Revision (Follow-up Limited to 17.6 Years)

Type of Revision	Profemur Z		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	15	50.0	5139	32.6
Acetabular Component	4	13.3	3035	19.2
THR (Femoral/Acetabular)	4	13.3	1796	11.4
Cement Spacer	1	3.3	593	3.8
Removal of Prostheses			97	0.6
Reinsertion of Components			25	0.2
Total Femoral			6	0.0
Bipolar Head and Femoral			4	0.0
Saddle			1	0.0
N Major	24	80.0	10696	67.8
Head/Insert			3860	24.5
Head Only			777	4.9
Minor Components			273	1.7
Insert Only			172	1.1
Head/Neck	3	10.0	1	0.0
Head/Neck/Insert	3	10.0		
Bipolar Only			2	0.0
Cement Only			1	0.0
N Minor	6	20.0	5086	32.2
TOTAL	30	100.0	15782	100.0

Note: This table is restricted to revisions within 17.6 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 6**Revision Rates of Profemur Z Primary Total Conventional Hip 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 Profemur Z Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	30	186
TOTAL	30	186

TABLE 7**Revision Rates of Profemur Z Primary Total Conventional Hip 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 prosthesis are listed.

Table 7: Revised Number of Profemur Z Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	14	92
Ceramic/Non XLPE	1	3
Ceramic/XLPE	0	2
Metal/Metal	7	47
Metal/Non XLPE	6	20
Metal/XLPE	2	22
TOTAL	30	186

TABLE 8

Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the Profemur Z total conventional hip prosthesis and provides the comparative data for each of the states for all other total conventional hip 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 8: Revised Number of Primary Total Conventional Hip Replacement by State

Component	State	N Revised	N Total
Profemur Z	NSW	10	90
	VIC	9	42
	QLD	5	22
	WA	6	29
	SA	0	3
Other Total Conventional Hip	NSW	4298	132969
	VIC	3982	116998
	QLD	3146	80122
	WA	2184	53952
	SA	1415	41929
	TAS	372	15098
	ACT/NT	462	12387
TOTAL		15889	453641

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 9**Number of Revisions of Profemur Z Primary Total Conventional Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Profemur Z total conventional hip prosthesis. 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 2021 has a maximum of one year to be revised, whereas a primary procedure performed in 2019 has a maximum of three years to be revised.

Table 9: Number of Revisions of Profemur Z Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2004	6	41
2005	20	79
2006	4	56
2007	0	6
2008	0	1
2009	0	2
2010	0	1
TOTAL	30	186

TABLE 10**Revision Rates of Profemur Z Primary Total Conventional Hip 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 Profemur Z 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	Stem Type
Femoral Stem					
Profemur Z	PHA00232-PHA00248	TITANIUM TAPERED FEMORAL STEM	NO	METAL	REQUIRES FEMNECK
Profemur Z	PHA00260-PHA00276	TITANIUM 1/3 TP COATED TAPERED FEMORAL STEM	NO	METAL	REQUIRES FEMNECK

Table 10: Revised Number of Profemur Z Primary Total Conventional Hip Replacement by Catalogue Number Range

Femoral Stem Range	N Revised	N Total
PHA00232-PHA00248	30	181
PHA00260-PHA00276	0	5
TOTAL	30	186

TABLE 11**Revision Rates of Profemur Z Primary Total Conventional Hip Replacement by Component**

A prosthesis may be combined with multiple components. This analysis has been undertaken to determine if the revision rate varies according to the component with which it is combined.

Table 11: Revised Number of Profemur Z Primary Total Conventional Hip Replacement by Acetabular Component

Acetabular Component	N Revised	N Total
Allofit	1	3
Conserve Plus	5	31
Duraloc Option	1	2
Lineage	16	79
PINNACLE	4	52
Procotyl L	0	3
Trabecular Metal (Shell)	1	11
Trident (Shell)	2	5
TOTAL	30	186