

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-2024>.

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 2023 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	32	186	2198	1.46 (1.00, 2.06)
Other Total Conventional Hip	19249	538541	3454641	0.56 (0.55, 0.57)
TOTAL	19281	538727	3456839	0.56 (0.55, 0.57)

Note: Prostheses no longer used in 2023 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	8 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)	12.2 (8.2, 18.0)
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.1, 2.2)	2.5 (2.5, 2.5)	2.8 (2.7, 2.8)	3.1 (3.0, 3.1)	3.3 (3.3, 3.4)	3.6 (3.6, 3.7)	3.9 (3.8, 4.0)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Profemur Z	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)	16.4 (11.5, 23.2)	19.6 (13.9, 27.3)
Other Total Conventional Hip	4.2 (4.2, 4.3)	4.5 (4.5, 4.6)	4.9 (4.8, 5.0)	5.3 (5.2, 5.4)	5.7 (5.6, 5.8)	6.1 (5.9, 6.2)	6.5 (6.3, 6.6)	6.9 (6.7, 7.0)

CPR	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
Profemur Z	20.9 (14.8, 28.9)	20.9 (14.8, 28.9)					
Other Total Conventional Hip	7.3 (7.1, 7.4)	7.7 (7.5, 7.8)	8.2 (8.0, 8.4)	8.5 (8.2, 8.7)	9.0 (8.7, 9.3)	9.7 (9.2, 10.1)	10.3 (9.5, 11.2)

Note: Prostheses no longer used in 2023 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

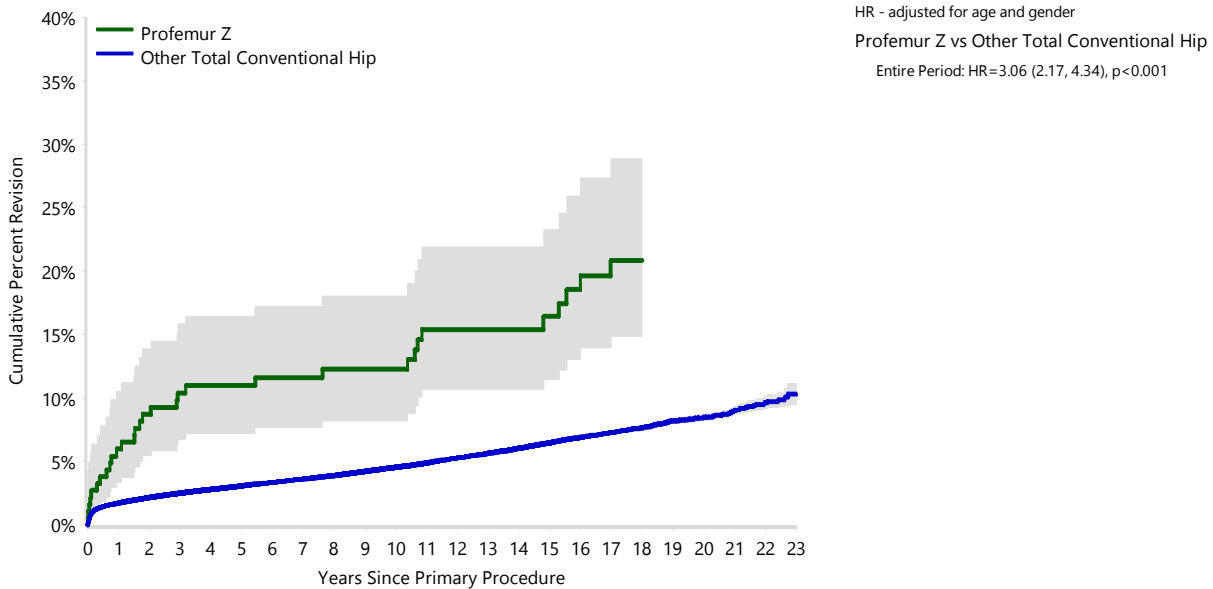
FIGURE 1

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	11 Yrs
Profemur Z	186	172	165	158	154	150	143	138	127	122	116	106
Other Total Conventional Hip	538541	475645	425806	377168	332911	288979	247789	209621	174574	143301	117825	96251

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
Profemur Z	100	93	89	81	73	65	40	10	0	0	0	0
Other Total Conventional Hip	77815	61602	47695	35979	26857	20094	14821	10048	6170	3221	1205	203

Note: Prostheses no longer used in 2023 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	30	93.8	15951	82.9
Fractured Neck Of Femur			1420	7.4
Osteonecrosis	2	6.3	859	4.5
Developmental Dysplasia			320	1.7
Rheumatoid Arthritis			208	1.1
Failed Internal Fixation			151	0.8
Tumour			149	0.8
Other Inflammatory Arthritis			106	0.6
Fracture/Dislocation			53	0.3
Other			17	0.1
Arthrodesis Takedown			15	0.1
TOTAL	32	100.0	19249	100.0

Note: Prostheses no longer used in 2023 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 19.6 Years)

Revision Diagnosis	Number	Profemur Z		Other Total Conventional Hip		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	2	1.1	6.3	4498	0.8	23.4
Prosthesis Dislocation/Instability	4	2.2	12.5	4379	0.8	22.8
Fracture	5	2.7	15.6	4256	0.8	22.2
Loosening	15	8.1	46.9	3812	0.7	19.9
Pain	2	1.1	6.3	335	0.1	1.7
Leg Length Discrepancy				291	0.1	1.5
Malposition				267	0.0	1.4
Lysis				211	0.0	1.1
Implant Breakage Stem	1	0.5	3.1	191	0.0	1.0
Implant Breakage Acetabular Insert				131	0.0	0.7
Wear Acetabular Insert	1	0.5	3.1	108	0.0	0.6
Incorrect Sizing				103	0.0	0.5
Metal Related Pathology	2	1.1	6.3	82	0.0	0.4
Implant Breakage Acetabular				72	0.0	0.4
Wear Head				47	0.0	0.2
Tumour				44	0.0	0.2
Implant Breakage Head				32	0.0	0.2
Heterotopic Bone				26	0.0	0.1
Wear Acetabulum				11	0.0	0.1
Osteonecrosis				2	0.0	0.0
Progression Of Disease				2	0.0	0.0
Synovitis				1	0.0	0.0
Other				293	0.1	1.5
N Revision	32	17.2	100.0	19194	3.6	100.0
N Primary	186			538541		

Note: This table is restricted to revisions within 19.6 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2023 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

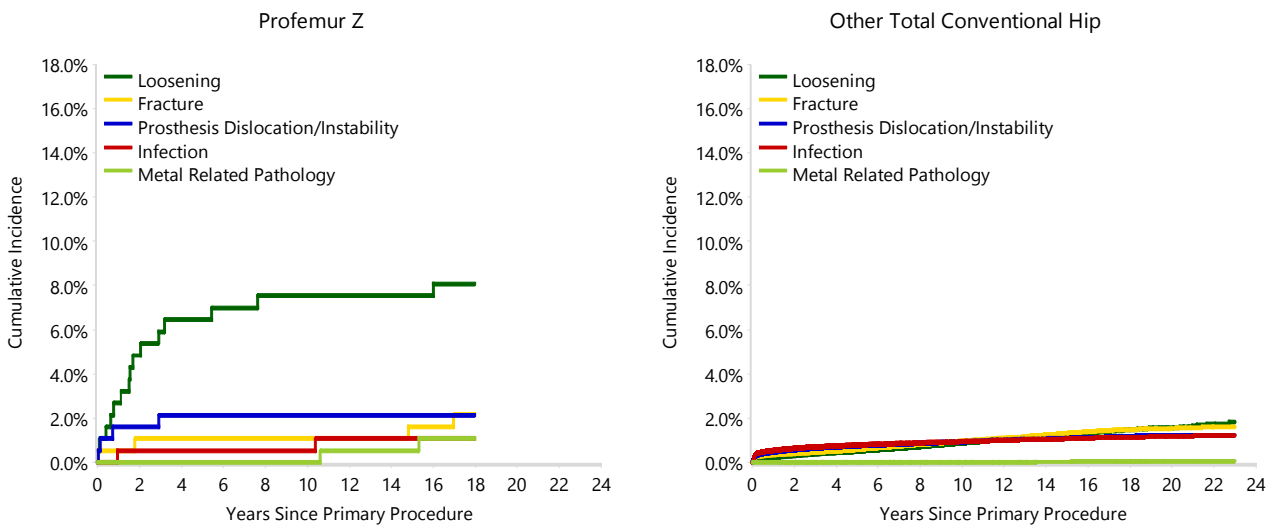


TABLE 5

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 19.6 Years)

Type of Revision	Profemur Z		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	15	46.9	6335	33.0
Acetabular Component	5	15.6	3596	18.7
THR (Femoral/Acetabular)	4	12.5	2240	11.7
Cement Spacer	1	3.1	620	3.2
Removal of Prostheses			99	0.5
Reinsertion of Components			28	0.1
Total Femoral			9	0.0
Bipolar Head and Femoral			7	0.0
Saddle			1	0.0
N Major	25	78.1	12935	67.4
Head/Insert			4831	25.2
Head Only			926	4.8
Minor Components	1	3.1	311	1.6
Insert Only			187	1.0
Head/Neck	3	9.4	1	0.0
Head/Neck/Insert	3	9.4		
Bipolar Only			2	0.0
Cement Only			1	0.0
N Minor	7	21.9	6259	32.6
TOTAL	32	100.0	19194	100.0

Note: This table is restricted to revisions within 19.6 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2023 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	32	186
TOTAL	32	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	16	92
Ceramic/Non XLPE	1	3
Ceramic/XLPE	0	2
Metal/Metal	7	47
Metal/Non XLPE	6	20
Metal/XLPE	2	22
TOTAL	32	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	12	90
	VIC	9	42
	QLD	5	22
	WA	6	29
	SA	0	3
Other Total Conventional Hip	NSW	5207	157707
	VIC	4859	140681
	QLD	3791	94582
	WA	2546	63265
	SA	1825	49398
	TAS	452	18198
	ACT/NT	569	14710
TOTAL		19281	538727

Note: Prostheses no longer used in 2023 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 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 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	22	79
2006	4	56
2007	0	6
2008	0	1
2009	0	2
2010	0	1
TOTAL	32	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	32	181
PHA00260-PHA00276	0	5
TOTAL	32	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	6	52
Procotyl L	0	3
Trabecular Metal (Shell)	1	11
Trident (Shell)	2	5
TOTAL	32	186