Proxima Total Conventional Hip Investigation

Note: This analysis compares the Proxima 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 Proxima 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)
Proxima	13	51	891	1.46 (0.78, 2.49)
Other Total Conventional Hip	19249	538541	3454641	0.56 (0.55, 0.57)
TOTAL	19262	538592	3455532	0.56 (0.55, 0.57)

TABLE 2
Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Proxima 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
Proxima	3.9 (1.0, 14.8)	5.9 (1.9, 17.3)	9.9 (4.3, 22.2)					
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
Proxima	9.9 (4.3, 22.2)	12.0 (5.6, 24.7)	12.0 (5.6, 24.7)	14.1 (7.0, 27.3)	16.2 (8.4, 29.8)	16.2 (8.4, 29.8)	18.3 (9.9, 32.2)	18.3 (9.9, 32.2)
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
Proxima	20.5 (11.6, 34.8)	20.5 (11.6, 34.8)	20.5 (11.6, 34.8)	23.2 (13.5, 38.2)	23.2 (13.5, 38.2)	28.0 (16.3, 45.6)	28.0 (16.3, 45.6)
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)

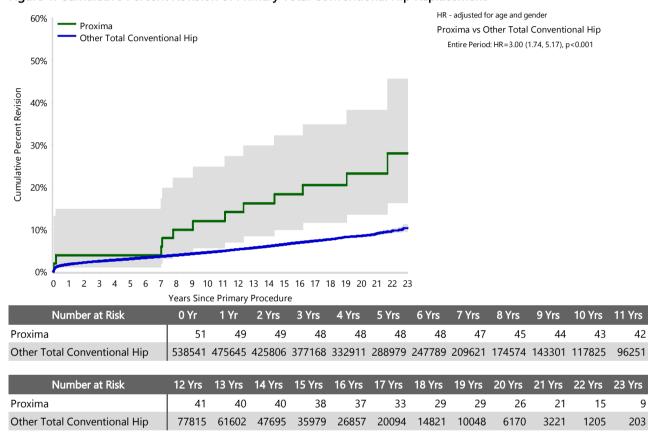
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Proxima 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



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.

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

	Proxima		Other Total Co	nventional Hip
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	12	92.3	15951	82.9
Fractured Neck Of Femur			1420	7.4
Osteonecrosis			859	4.5
Developmental Dysplasia	1	7.7	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	13	100.0	19249	100.0

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

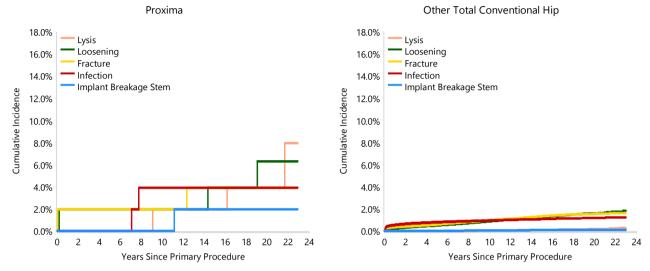
		Proxima Other Total Conventional Hip				al Hip
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	2	3.9	15.4	4504	0.8	23.4
Prosthesis Dislocation/Instability				4381	0.8	22.8
Fracture	2	3.9	15.4	4265	0.8	22.2
Loosening	3	5.9	23.1	3830	0.7	19.9
Pain				336	0.1	1.7
Leg Length Discrepancy				291	0.1	1.5
Malposition				269	0.0	1.4
Lysis	4	7.8	30.8	217	0.0	1.1
Implant Breakage Stem	1	2.0	7.7	192	0.0	1.0
Implant Breakage Acetabular Insert				131	0.0	0.7
Wear Acetabular Insert				113	0.0	0.6
Incorrect Sizing				103	0.0	0.5
Metal Related Pathology	1	2.0	7.7	84	0.0	0.4
Implant Breakage Acetabular				72	0.0	0.4
Wear Head				48	0.0	0.2
Tumour				44	0.0	0.2
Implant Breakage Head				33	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				294	0.1	1.5
N Revision	13	25.5	100.0	19249	3.6	100.0
N Primary	51			538541		

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 Proxima 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



Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Proxima 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 Proxima total conventional hip prosthesis compared to all other total conventional hip prostheses.

Table 5: Primary Total Conventional Hip Replacement - Type of Revision

Table 5. Trimary Total Co	Proxima Other Total Convention		nventional Hip	
Type of Revision	Number	Percent	Number	Percent
Femoral Component	3	23.1	6347	33.0
Acetabular Component	5	38.5	3609	18.7
THR (Femoral/Acetabular)	3	23.1	2255	11.7
Cement Spacer	1	7.7	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	12	92.3	12975	67.4
Head/Insert	1	7.7	4845	25.2
Head Only			927	4.8
Minor Components			311	1.6
Insert Only			187	1.0
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	1	7.7	6274	32.6
TOTAL	13	100.0	19249	100.0

Revision Rates of Proxima 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 Proxima Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	13	51
TOTAL	13	51

TABLE 7

Revision Rates of Proxima 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 Proxima Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	1	5
Ceramic/Non XLPE	4	21
Ceramic/XLPE	0	2
Metal/Metal	6	20
Metal/Non XLPE	0	1
Metal/XLPE	2	2
TOTAL	13	51

Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the Proxima 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

		ry Total Conventional Flip N	•	
Component	State	N Revised	N Total	
Proxima	NSW	4	15	
	VIC	0	1	
	QLD	6	31	
	WA	2	2	
	SA	1	2	
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		19262	538592	

Number of Revisions of Proxima Primary Total Conventional Hip Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Proxima 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 Proxima Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2000	3	12
2001	0	6
2002	2	7
2003	2	10
2004	0	1
2006	5	10
2007	1	4
2008	0	1
TOTAL	13	51

Revision Rates of Proxima 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 Proxima 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	Coating	Fixation
Femoral Stem							
Proxima	940050001-940050019	PROXIMA DUOFIX STEM STANDARD OFFSET	NO	METAL	MINI STEM	HA COATED	POROUS
Proxima	940050022-940050039	PROXIMA DUOFIX STEM HIGH OFFSET	NO	METAL	MINI STEM	HA COATED	
Proxima	S039212B-S039262B	STD STEM TIALLOY RIDGED TIALLOY POROUS+HAP	NO	METAL		HA COATED	
Proxima	S039212D-S039262D	MORGAN TIMOD FENESTRATED STEM MEDIUM DUAL COATED (TITANIUM)	NO	METAL		HA COATED	

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

Femoral Stem Range	N Revised	N Total
940050001-940050019	3	3
940050022-940050039	3	12
S039212B-S039262B	5	28
S039212D-S039262D	2	8
TOTAL	13	51

Revision Rates of Proxima 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 Proxima Primary Total Conventional Hip Replacement by Acetabular Component

Acetabular Component	N Revised	N Total
ASR	3	6
Cormet	3	14
Mallory-Head	4	22
PINNACLE	3	9
TOTAL	13	51