Trabecular Metal Total Conventional Hip Investigation

Note: This analysis compares the Trabecular Metal 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 Trabecular Metal 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)
Trabecular Metal	122	1904	16457	0.74 (0.62, 0.89)
Other Total Conventional Hip	15859	453455	2721137	0.58 (0.57, 0.59)
TOTAL	15981	455359	2737594	0.58 (0.57, 0.59)

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Trabecular Metal 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
Trabecular Metal	3.5 (2.7, 4.4)	4.2 (3.4, 5.2)	4.8 (3.9, 5.8)	5.1 (4.2, 6.2)	5.4 (4.5, 6.6)	5.8 (4.8, 6.9)	6.2 (5.2, 7.4)
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
Trabecular Metal	6.5 (5.4, 7.7)	6.5 (5.5, 7.8)	6.7 (5.7, 8.0)	6.7 (5.7, 8.0)	7.0 (5.8, 8.4)	7.0 (5.8, 8.4)	7.0 (5.8, 8.4)
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
Trabecular Metal							
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)

FIGURE 1

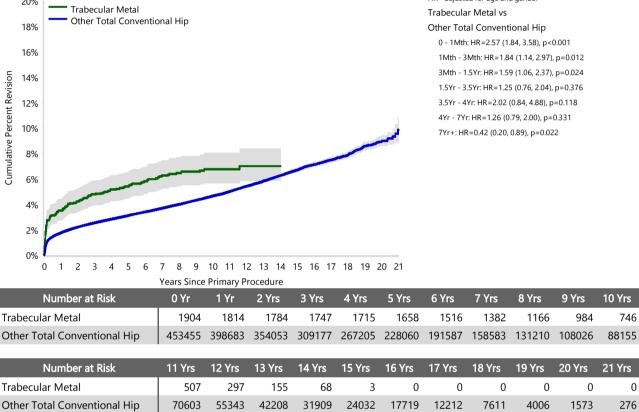
Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Trabecular Metal 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

20%
HR - adjusted for age and gender



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.

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

	Trabecular Metal		Other Total Co	nventional Hip
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	113	92.6	13112	82.7
Fractured Neck Of Femur	3	2.5	1164	7.3
Osteonecrosis	3	2.5	718	4.5
Developmental Dysplasia	1	0.8	247	1.6
Rheumatoid Arthritis	2	1.6	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	122	100.0	15859	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 (Follow-up Limited to 15.2 Years)

		Trabecular Metal		Othe	r Total Convention	al Hip
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	29	1.5	23.8	3687	0.8	23.6
Infection	26	1.4	21.3	3531	0.8	22.6
Fracture	17	0.9	13.9	3386	0.7	21.7
Loosening	23	1.2	18.9	3156	0.7	20.2
Pain	5	0.3	4.1	283	0.1	1.8
Leg Length Discrepancy	5	0.3	4.1	260	0.1	1.7
Malposition	2	0.1	1.6	225	0.0	1.4
Lysis	3	0.2	2.5	163	0.0	1.0
Implant Breakage Stem				145	0.0	0.9
Implant Breakage Acetabular Insert				113	0.0	0.7
Incorrect Sizing	4	0.2	3.3	95	0.0	0.6
Wear Acetabular Insert	1	0.1	0.8	81	0.0	0.5
Implant Breakage Acetabular	1	0.1	0.8	65	0.0	0.4
Metal Related Pathology	3	0.2	2.5	63	0.0	0.4
Wear Head				44	0.0	0.3
Tumour	1	0.1	0.8	36	0.0	0.2
Implant Breakage Head				29	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	2	0.1	1.6	228	0.1	1.5
N Revision	122	6.4	100.0	15626	3.4	100.0
N Primary	1904			453455		

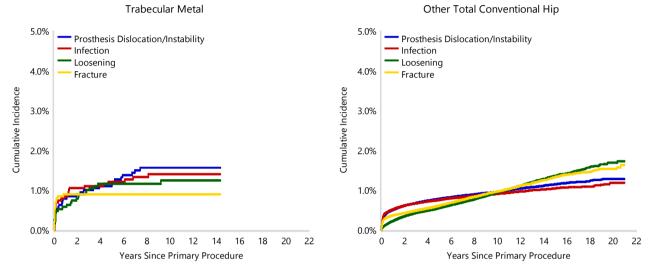
Note: This table is restricted to revisions within 15.2 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

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 Trabecular Metal 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 Trabecular Metal 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 Trabecular Metal 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 15.2 Years)

Table 3. Trimary Total Co		lar Metal		onventional Hip
Type of Revision	Number	Percent	Number	Percent
Femoral Component	36	29.5	5090	32.6
Acetabular Component	25	20.5	2993	19.2
THR (Femoral/Acetabular)	9	7.4	1763	11.3
Cement Spacer	6	4.9	591	3.8
Removal of Prostheses			96	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	76	62.3	10569	67.6
Head/Insert	30	24.6	3834	24.5
Head Only	12	9.8	776	5.0
Minor Components	1	0.8	271	1.7
Insert Only	3	2.5	172	1.1
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	46	37.7	5057	32.4
TOTAL	122	100.0	15626	100.0

Note: This table is restricted to revisions within 15.2 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.

Revision Rates of Trabecular Metal 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 Trabecular Metal Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	122	1899
Hybrid (Femur Cemented)	0	1
Reverse Hybrid (Femur Cementless)	0	4
TOTAL	122	1904

TABLE 7

Revision Rates of Trabecular Metal 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 Trabecular Metal Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	13	280
Ceramic/XLPE	31	472
Metal/Metal	13	75
Metal/XLPE	65	1077
TOTAL	122	1904

Revision Rates of Trabecular Metal Primary Total Conventional Hip Replacement by Approach

This analysis is provided as some prostheses are used with a variety of surgical approaches. All surgical approaches used with this prosthesis are listed.

Table 8: Revised Number of Trabecular Metal Primary Total Conventional Hip Replacement by Approach

Approach	N Revised	N Total
Anterior	0	1
Lateral	7	104
Posterior	6	141
TOTAL	13	246

Note: Excludes 1658 procedures with no approach recorded

Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the Trabecular Metal 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 9: Revised Number of Primary Total Conventional Hip Replacement by State

Component	State	N Revised	N Total
Trabecular Metal	NSW	56	1032
	VIC	20	373
	WA	17	167
	SA	2	17
	TAS	7	145
	ACT/NT	20	170
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		15981	455359

Number of Revisions of Trabecular Metal Primary Total Conventional Hip Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Trabecular Metal 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 10: Number of Revisions of Trabecular Metal Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2006	0	6
2007	9	101
2008	10	148
2009	12	198
2010	10	242
2011	13	272
2012	25	276
2013	17	186
2014	13	220
2015	5	112
2016	5	106
2017	2	32
2018	1	5
TOTAL	122	1904

Revision Rates of Trabecular Metal 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 Trabecular Metal 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
Femoral Stem				
Trabecular Metal	00786400900-00786401800	TRABECULAR METAL PRIMARY HIP FEMORAL STEM 12/14 NECK TAPER STANDARD NECK OFFSET	NO	METAL
Trabecular Metal	00786401120-00786401820	TRABECULAR METAL PRIMARY HIP FEMORAL STEM 12/14 NECK TAPER EXTENDED NECK OFFSET	NO	METAL

Table 11: Revised Number of Trabecular Metal Primary Total Conventional Hip Replacement by Catalogue Number Range

Femoral Stem Range	N Revised	N Total
00786400900-00786401800	58	993
00786401120-00786401820	64	911
TOTAL	122	1904

Revision Rates of Trabecular Metal 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 12: Revised Number of Trabecular Metal Primary Total Conventional Hip Replacement by Acetabular Component

Acetabular Component	N Revised	N Total	
Allofit	23	475	
Continuum	50	701	
Durom	10	52	
Exeter X3 Rimfit	0	1	
Fitmore	1	34	
PINNACLE	0	7	
Reflection (Cup)	0	1	
Trabecular Metal (Shell)	14	180	
Trilogy	24	453	
TOTAL	122	1904	