HACTIV Total Conventional Hip Investigation

Note: This analysis compares the HACTIV 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 HACTIV 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% Cl)
HACTIV	86	2407	7586	1.13 (0.91, 1.40)
Other Total Conventional Hip	15775	451138	2714073	0.58 (0.57, 0.59)
TOTAL	15861	453545	2721659	0.58 (0.57, 0.59)

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the HACTIV 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

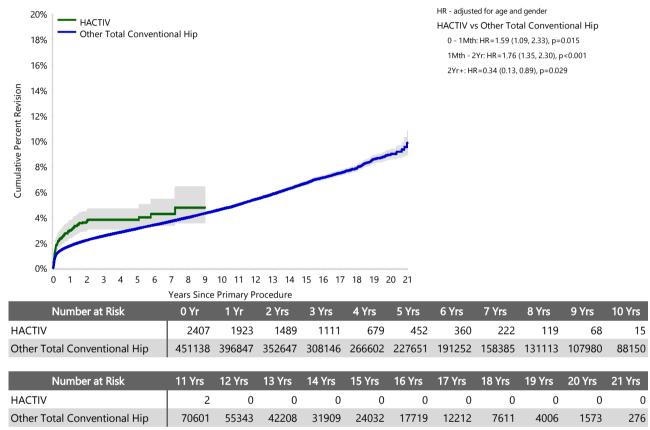
CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
HACTIV	3.0 (2.4, 3.8)	3.7 (3.0, 4.6)	3.8 (3.1, 4.7)	3.8 (3.1, 4.7)	3.8 (3.1, 4.7)	4.3 (3.3, 5.4)	4.3 (3.3, 5.4)
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.1, 2.2)	2.5 (2.5, 2.6)	2.8 (2.8, 2.9)	3.1 (3.0, 3.2)	3.4 (3.3, 3.4)	3.7 (3.6, 3.7)
CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
HACTIV	4.8 (3.5, 6.4)	4.8 (3.5, 6.4)					
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)	6.2 (6.1, 6.4)
CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
HACTIV							
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 HACTIV 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.





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

	HACTIV		Other Total Co	nventional Hip
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	81	94.2	13033	82.6
Fractured Neck Of Femur			1164	7.4
Osteonecrosis	2	2.3	716	4.5
Developmental Dysplasia	1	1.2	246	1.6
Rheumatoid Arthritis			173	1.1
Failed Internal Fixation			140	0.9
Tumour			137	0.9
Other Inflammatory Arthritis	1	1.2	90	0.6
Fracture/Dislocation			47	0.3
Arthrodesis Takedown	1	1.2	15	0.1
Other			14	0.1
TOTAL	86	100.0	15775	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 11.1 Years)

	HACTIV Other Total Conventional Hip				al Hip	
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	23	1.0	26.7	3558	0.8	24.1
Infection	23	1.0	26.7	3427	0.8	23.2
Fracture	21	0.9	24.4	3158	0.7	21.4
Loosening	11	0.5	12.8	2905	0.6	19.7
Pain	3	0.1	3.5	275	0.1	1.9
Leg Length Discrepancy	1	0.0	1.2	258	0.1	1.7
Malposition	1	0.0	1.2	221	0.0	1.5
Implant Breakage Stem	1	0.0	1.2	129	0.0	0.9
Lysis				116	0.0	0.8
Implant Breakage Acetabular Insert				100	0.0	0.7
Incorrect Sizing				94	0.0	0.6
Implant Breakage Acetabular				61	0.0	0.4
Metal Related Pathology				55	0.0	0.4
Wear Acetabular Insert				53	0.0	0.4
Wear Head				41	0.0	0.3
Tumour				36	0.0	0.2
Implant Breakage Head				25	0.0	0.2
Heterotopic Bone				23	0.0	0.2
Wear Acetabulum				6	0.0	0.0
Progression Of Disease				2	0.0	0.0
Osteonecrosis				1	0.0	0.0
Synovitis				1	0.0	0.0
Other	2	0.1	2.3	222	0.0	1.5
N Revision	86	3.6	100.0	14767	3.3	100.0
N Primary	2407			451138		

Note: This table is restricted to revisions within 11.1 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 HACTIV 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.

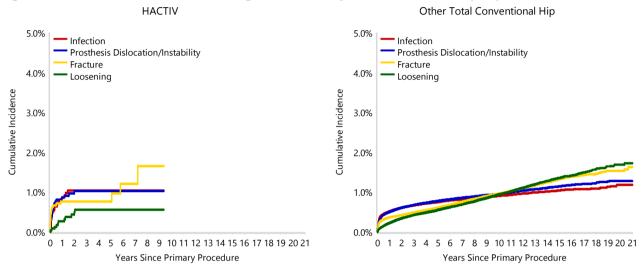


Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Conventional Hip Replacement

Type of Revision Performed for Primary Total Conventional Hip Replacement

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

Table 5: Primary Total Conv	entional Hip Replac	ement - Type of Revisi	on (Follow-up Limited	to 11.1 Years)
	HA	CTIV	Other Total Co	nventional Hip
Type of Revision	Number	Percent	Number	Percent
Femoral Component	23	26.7	4791	32.4
Acetabular Component	32	37.2	2786	18.9
THR (Femoral/Acetabular)	12	14.0	1609	10.9
Cement Spacer	3	3.5	567	3.8
Removal of Prostheses			93	0.6
Reinsertion of Components			25	0.2
Total Femoral			5	0.0
Bipolar Head and Femoral			4	0.0
Saddle			1	0.0
N Major	70	81.4	9881	66.9
Head/Insert	13	15.1	3687	25.0
Head Only	3	3.5	762	5.2
Minor Components			262	1.8
nsert Only			171	1.2
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	16	18.6	4886	33.1
TOTAL	86	100.0	14767	100.0

Note: This table is restricted to revisions within 11.1 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 HACTIV 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 HACTIV Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	86	2403
Hybrid (Femur Cemented)	0	3
Reverse Hybrid (Femur Cementless)	0	1
TOTAL	86	2407

TABLE 7

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

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	14	319
Ceramic/Non XLPE	7	511
Ceramic/XLPE	55	1256
Ceramic/XLPE + Antioxidant	4	126
Metal/Non XLPE	5	88
Metal/XLPE	1	101
Metal/XLPE + Antioxidant	0	4
Unknown	0	2
TOTAL	86	2407

Revision Rates of HACTIV 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.

Approach	N Revised	N Total
Anterior	12	387
Lateral	7	337
Posterior	52	1395
TOTAL	71	2119

Note: Excludes 288 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 HACTIV 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.

Component	State	N Revised	N Total	
HACTIV	NSW	29	674	
	VIC	0	4	
	QLD	1	14	
	WA	44	1411	
	SA	12	298	
	ACT/NT	0	6	
Other Total Conventional Hip	NSW	4269	132336	
	VIC	3982	116994	
	QLD	3145	80108	
	WA	2141	52563	
	SA	1404	41657	
	TAS	372	15098	
	ACT/NT	462	12382	
TOTAL		15861	453545	

Table 9: Revised Number of Primary Total Conventional Hip Replacement by State

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

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

Year of Implant	Number Revised	Total Number
2010	0	2
2011	3	19
2012	1	63
2013	3	61
2014	7	117
2015	2	146
2016	1	96
2017	15	240
2018	17	452
2019	20	388
2020	10	418
2021	7	405
TOTAL	86	2407

Revision Rates of HACTIV 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 HACTIV 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	Coating
Femoral Stem					
HACTIV	H49007-H49020	HA FEMORAL STEM	NO	METAL	HA COATED
HACTIV	H49C009-H49C020	HACTIV NON CEMENTED HAC COLLARED STEM	NO	METAL	HA COATED
HACTIV	H49L009-H49L020	HA LATERAL FEMORAL STEM	NO	METAL	HA COATED
HACTIV	H49LC009-H49LC020	FEMORAL STEM HIGH OFFSET COLLARED	NO	METAL	HA COATED

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

Femoral Stem Range	N Revised	N Total
H49007-H49020	21	688
H49C009-H49C020	23	656
H49L009-H49L020	18	556
H49LC009-H49LC020	24	507
TOTAL	86	2407

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

Acetabular Component	N Revised	N Total
C2	2	62
Cer-Met	0	12
Delta-TT	9	130
FMP	0	13
Fin II	0	41
G7	0	1
Logical G	58	1311
Marathon	0	1
PINNACLE	1	9
R3	0	5
Saturne	12	598
Trabecular Metal (Shell)	0	2
Trident (Shell)	0	1
Trident/Tritanium (Shell)	0	13
Trinity	4	208
TOTAL	86	2407