

Quadra-H Bipolar Hip Investigation

Note: This analysis compares the Quadra-H femoral stem prosthesis with all other bipolar 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-2023>.

Note: Procedures using prostheses with no recorded use in 2022 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Bipolar Hip Replacement

The revision rate of the Quadra-H bipolar hip prosthesis is compared to all other bipolar hip prostheses.

Table 1: Revision Rates of Primary Bipolar Hip Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Quadra-H	7	84	223	3.14 (1.26, 6.48)
Other Bipolar Hip	936	30207	90034	1.04 (0.97, 1.11)
TOTAL	943	30291	90257	1.04 (0.98, 1.11)

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Bipolar Hip Replacement

The yearly cumulative percent revision of the Quadra-H bipolar hip prosthesis is compared to all other bipolar hip prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Bipolar Hip Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
Quadra-H	6.3 (2.4, 16.1)	6.3 (2.4, 16.1)	10.8 (4.9, 22.8)	14.3 (6.8, 29.0)	14.3 (6.8, 29.0)			
Other Bipolar Hip	2.5 (2.3, 2.7)	3.1 (2.9, 3.3)	3.6 (3.3, 3.8)	3.9 (3.6, 4.1)	4.2 (3.9, 4.5)	4.4 (4.1, 4.8)	4.7 (4.4, 5.1)	5.1 (4.7, 5.5)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Quadra-H							
Other Bipolar Hip	5.4 (4.9, 5.9)	5.7 (5.1, 6.2)	5.7 (5.2, 6.3)	5.8 (5.3, 6.5)	6.1 (5.4, 6.8)	6.5 (5.7, 7.3)	7.1 (6.1, 8.2)

CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
Quadra-H							
Other Bipolar Hip	7.6 (6.4, 8.9)	7.9 (6.6, 9.4)	7.9 (6.6, 9.4)	8.5 (6.8, 10.6)	8.5 (6.8, 10.6)		

Note: Prostheses no longer used in 2022 are excluded from the comparator.

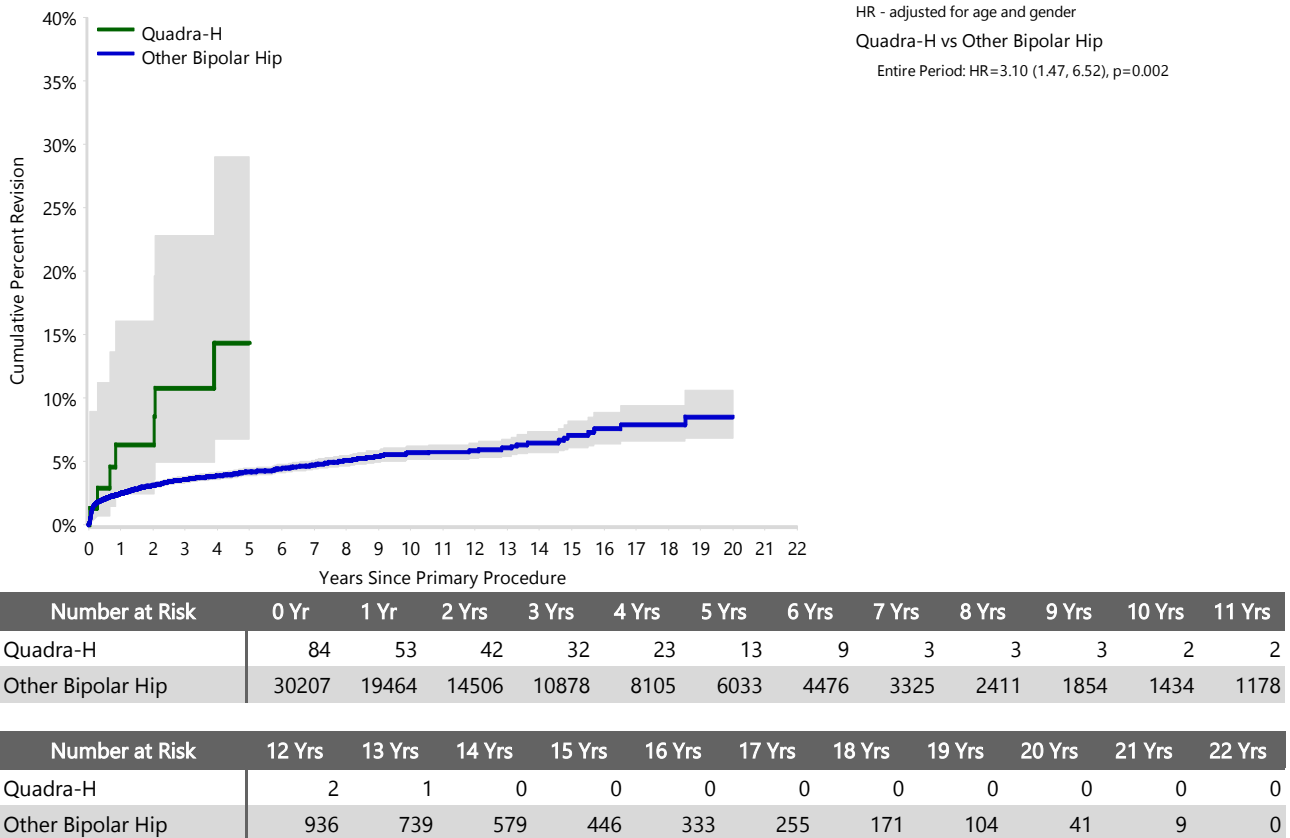
FIGURE 1

Yearly Cumulative Percent Revision of Primary Bipolar Hip Replacement

The yearly cumulative percent revision of the Quadra-H bipolar hip prosthesis is compared to all other bipolar 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 Bipolar Hip Replacement



Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 3**Primary Diagnosis for Revised Primary Bipolar 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 bipolar hip prostheses.

Table 3: Primary Diagnosis for Revised Primary Bipolar Hip Replacement

Primary Diagnosis	Quadra-H		Other Bipolar Hip	
	Number	Percent	Number	Percent
Fractured Neck Of Femur	7	100.0	858	91.7
Tumour			30	3.2
Osteoarthritis			29	3.1
Failed Internal Fixation			10	1.1
Osteonecrosis			8	0.9
Other			1	0.1
TOTAL	7	100.0	936	100.0

Note: Prostheses no longer used in 2022 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 Bipolar Hip Replacement - Reason for Revision (Follow-up Limited to 13.2 Years)

Revision Diagnosis	Quadra-H			Other Bipolar Hip		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection				287	1.0	31.0
Prosthesis Dislocation/Instability	2	2.4	28.6	229	0.8	24.7
Fracture	3	3.6	42.9	169	0.6	18.2
Loosening	1	1.2	14.3	85	0.3	9.2
Chondrolysis/Acetab. Erosion				73	0.2	7.9
Pain	1	1.2	14.3	54	0.2	5.8
Tumour				5	0.0	0.5
Leg Length Discrepancy				3	0.0	0.3
Lysis				3	0.0	0.3
Malposition				3	0.0	0.3
Implant Breakage Stem				2	0.0	0.2
Incorrect Sizing				2	0.0	0.2
Progression Of Disease				2	0.0	0.2
Heterotopic Bone				1	0.0	0.1
Implant Breakage Head				1	0.0	0.1
Metal Related Pathology				1	0.0	0.1
Osteonecrosis				1	0.0	0.1
Other				6	0.0	0.6
N Revision	7	8.3	100.0	927	3.1	100.0
N Primary	84			30207		

Note: This table is restricted to revisions within 13.2 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Bipolar 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 Quadra-H bipolar hip prosthesis. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other bipolar hip prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Bipolar Hip Replacement

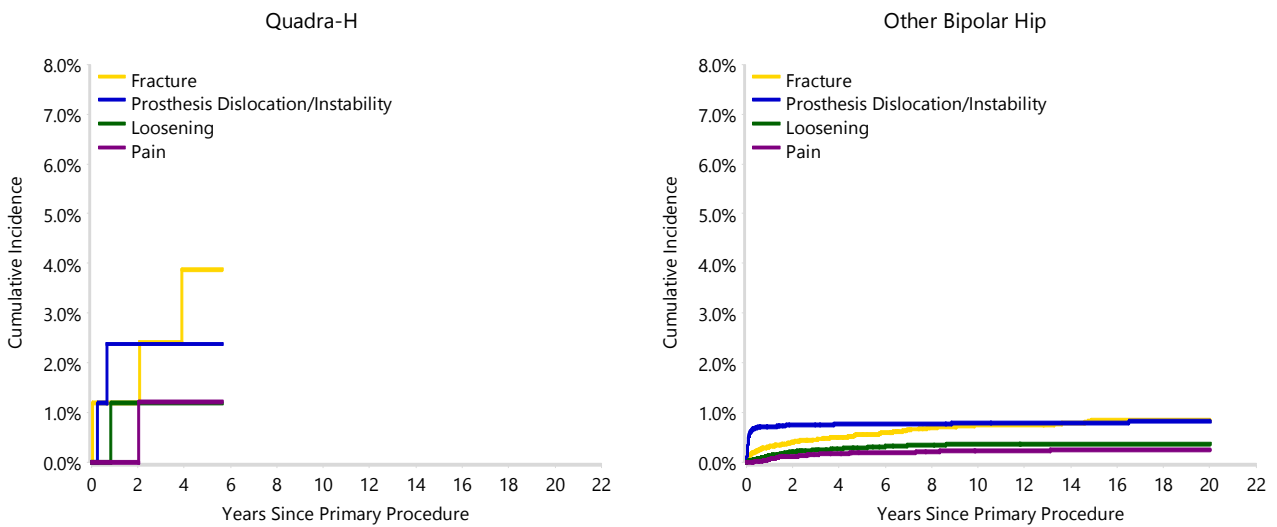


TABLE 5

Type of Revision Performed for Primary Bipolar Hip Replacement

This analysis identifies the components used in the revision of the Quadra-H bipolar hip prosthesis and compares it to the components used in the revision of all other bipolar 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 bipolar hip prostheses i.e. is there a difference in the type of revision undertaken for the Quadra-H bipolar hip prosthesis compared to all other bipolar hip prostheses.

Table 5: Primary Bipolar Hip Replacement - Type of Revision (Follow-up Limited to 13.2 Years)

Type of Revision	Quadra-H		Other Bipolar Hip	
	Number	Percent	Number	Percent
Acetabular Component	3	42.9	294	31.7
THR (Femoral/Acetabular)	1	14.3	164	17.7
Bipolar Head and Femoral	2	28.6	128	13.8
Cement Spacer			39	4.2
Femoral Component	1	14.3	37	4.0
Removal of Prostheses			24	2.6
Reinsertion of Components			1	0.1
N Major	7	100.0	687	74.1
Bipolar Only			191	20.6
Head Only			28	3.0
Minor Components			21	2.3
N Minor			240	25.9
TOTAL	7	100.0	927	100.0

Note: This table is restricted to revisions within 13.2 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 6

Revision Rates of Primary Bipolar Hip Replacement by State

This enables a state by state variation to be identified for the Quadra-H bipolar hip prosthesis and provides the comparative data for each of the states for all other bipolar 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 6: Revised Number of Primary Bipolar Hip Replacement by State

Component	State	N Revised	N Total
Quadra-H	NSW	4	38
	VIC	2	18
	QLD	1	14
	WA	0	1
	SA	0	13
Other Bipolar Hip	NSW	303	10955
	VIC	190	5284
	QLD	202	6372
	WA	90	2380
	SA	80	3009
	TAS	23	618
	ACT/NT	48	1589
TOTAL		943	30291

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 7**Number of Revisions of Quadra-H Primary Bipolar Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Quadra-H bipolar 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 2022 has a maximum of one year to be revised, whereas a primary procedure performed in 2020 has a maximum of three years to be revised.

Table 7: Number of Revisions of Quadra-H Primary Bipolar Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2009	3	11
2010	0	7
2011	1	5
2012	0	6
2013	0	4
2014	2	11
2015	0	9
2016	1	7
2017	0	4
2018	0	7
2019	0	5
2020	0	7
2021	0	1
TOTAL	7	84

TABLE 8**Revision Rates of Quadra-H Primary Bipolar 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 Quadra-H 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					
Quadra-H	0112020-0112030	HAP STANDARD FEMORAL STEM	NO	METAL	HA COATED
Quadra-H	0112031-0112037	HAP LATERALIZED FEMORAL STEM	NO	METAL	HA COATED
Quadra-H	011220SN-011230SN	HAP STANDARD SHORTNECK FEMORAL STEM	NO	METAL	HA COATED
Quadra-H	011231SN-011237SN	HAP LATERALIZED SHORTNECK FEMORAL STEM	NO	METAL	HA COATED

Table 8: Revised Number of Quadra-H Primary Bipolar Hip Replacement by Catalogue Number Range

Femoral Stem Range	N Revised	N Total
0112020-0112030	4	49
0112031-0112037	0	3
011220SN-011230SN	3	30
011231SN-011237SN	0	2
TOTAL	7	84

TABLE 9**Revision Rates of Quadra-H Primary Bipolar 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 9: Revised Number of Quadra-H Primary Bipolar Hip Replacement by Bipolar Component

Bipolar Component	N Revised	N Total
Bipolar Head (Medacta)	6	81
Multipolar Bipolar	0	1
UHR	1	2
TOTAL	7	84