

## 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-2022>.

Note: Procedures using prostheses with no recorded use in 2021 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	207	3.39 (1.36, 6.98)
Other Bipolar Hip	804	26627	79376	1.01 (0.94, 1.09)
<b>TOTAL</b>	<b>811</b>	<b>26711</b>	<b>79583</b>	<b>1.02 (0.95, 1.09)</b>

Note: Prostheses no longer used in 2021 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
Quadra-H	6.3 (2.4, 16.1)	6.3 (2.4, 16.1)	11.3 (5.1, 24.0)	15.3 (7.1, 31.2)	15.3 (7.1, 31.2)		
Other Bipolar Hip	2.4 (2.2, 2.6)	3.0 (2.8, 3.2)	3.5 (3.2, 3.8)	3.8 (3.5, 4.1)	4.1 (3.8, 4.5)	4.4 (4.0, 4.7)	4.7 (4.3, 5.1)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Quadra-H							
Other Bipolar Hip	5.0 (4.6, 5.4)	5.3 (4.8, 5.8)	5.6 (5.0, 6.2)	5.7 (5.1, 6.3)	5.8 (5.2, 6.4)	6.0 (5.3, 6.8)	6.5 (5.7, 7.5)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Quadra-H							
Other Bipolar Hip	6.9 (5.9, 8.1)	7.5 (6.3, 9.0)	7.9 (6.5, 9.7)	7.9 (6.5, 9.7)	9.1 (6.7, 12.2)		

Note: Prostheses no longer used in 2021 are excluded from the comparator.

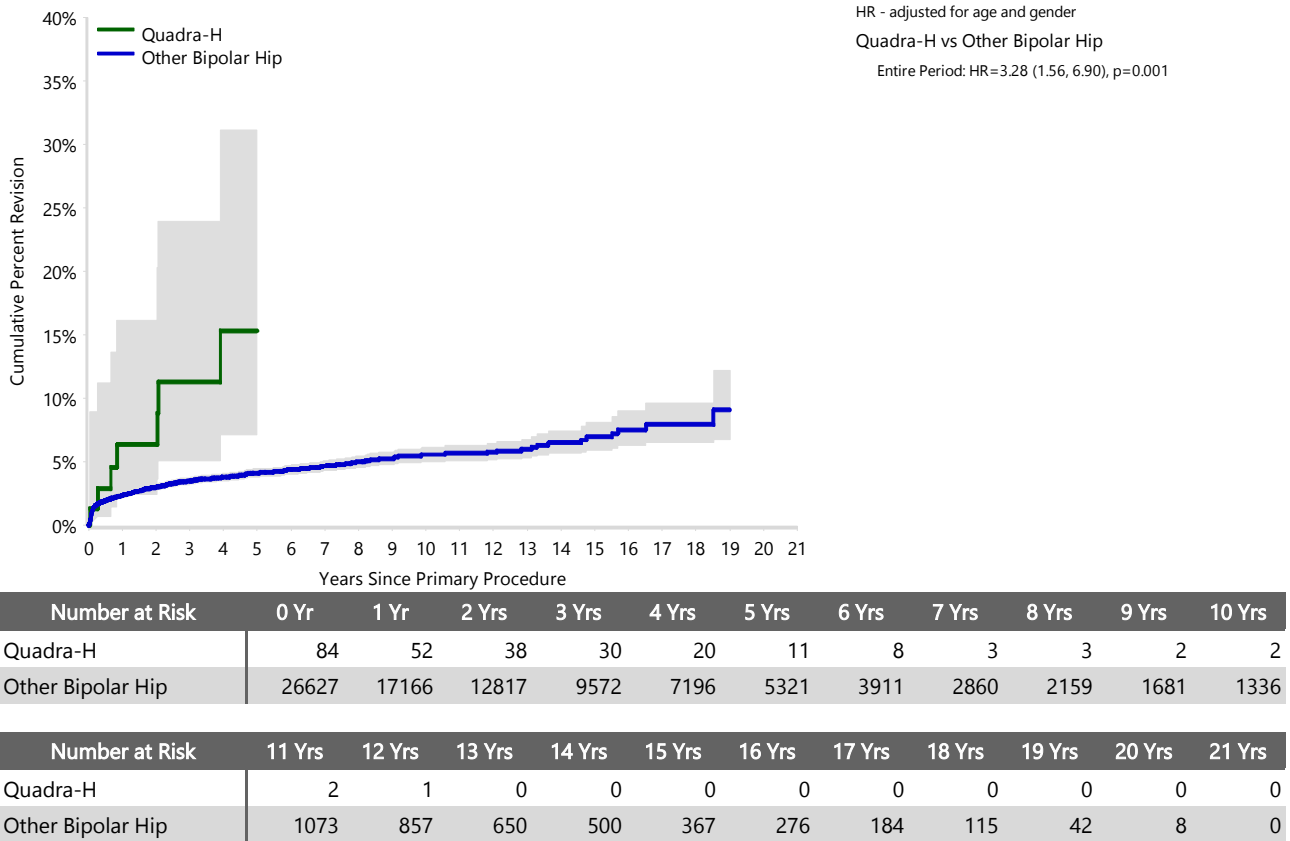
**FIGURE 1**

**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 2021 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	734	91.3
Osteoarthritis			27	3.4
Tumour			27	3.4
Failed Internal Fixation			8	1.0
Osteonecrosis			7	0.9
Other			1	0.1
<b>TOTAL</b>	<b>7</b>	<b>100.0</b>	<b>804</b>	<b>100.0</b>

Note: Prostheses no longer used in 2021 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 12.2 Years)

Revision Diagnosis	Quadra-H			Other Bipolar Hip		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection				238	0.9	30.0
Prosthesis Dislocation/Instability	2	2.4	28.6	195	0.7	24.6
Fracture	3	3.6	42.9	145	0.5	18.3
Loosening	1	1.2	14.3	78	0.3	9.8
Chondrolysis/Acetab. Erosion				67	0.3	8.4
Pain	1	1.2	14.3	47	0.2	5.9
Tumour				4	0.0	0.5
Lysis				3	0.0	0.4
Malposition				3	0.0	0.4
Implant Breakage Stem				2	0.0	0.3
Incorrect Sizing				2	0.0	0.3
Leg Length Discrepancy				2	0.0	0.3
Heterotopic Bone				1	0.0	0.1
Metal Related Pathology				1	0.0	0.1
Osteonecrosis				1	0.0	0.1
Other				5	0.0	0.6
<b>N Revision</b>	<b>7</b>	<b>8.3</b>	<b>100.0</b>	<b>794</b>	<b>3.0</b>	<b>100.0</b>
<b>N Primary</b>	<b>84</b>			<b>26627</b>		

Note: This table is restricted to revisions within 12.2 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 are excluded from the comparator.

**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**

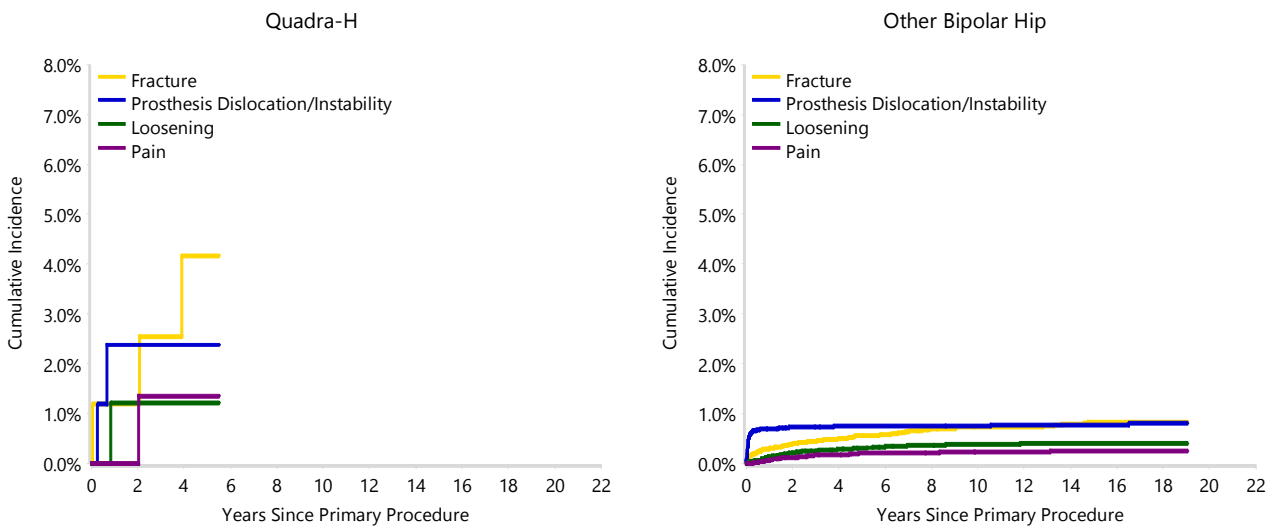


TABLE 5

**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 12.2 Years)**

Type of Revision	Quadra-H		Other Bipolar Hip	
	Number	Percent	Number	Percent
Acetabular Component	3	42.9	262	33.0
THR (Femoral/Acetabular)	1	14.3	141	17.8
Bipolar Head and Femoral	2	28.6	102	12.8
Cement Spacer			37	4.7
Femoral Component	1	14.3	31	3.9
Removal of Prostheses			23	2.9
Reinsertion of Components			1	0.1
<b>N Major</b>	<b>7</b>	<b>100.0</b>	<b>597</b>	<b>75.2</b>
Bipolar Only			150	18.9
Head Only			26	3.3
Minor Components			21	2.6
<b>N Minor</b>			<b>197</b>	<b>24.8</b>
<b>TOTAL</b>	<b>7</b>	<b>100.0</b>	<b>794</b>	<b>100.0</b>

Note: This table is restricted to revisions within 12.2 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 are excluded from the comparator.

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	263	9754
	VIC	159	4659
	QLD	180	5648
	WA	75	2092
	SA	64	2487
	TAS	23	545
	ACT/NT	40	1442
<b>TOTAL</b>		<b>811</b>	<b>26711</b>

Note: Prostheses no longer used in 2021 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 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 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
<b>TOTAL</b>	<b>7</b>	<b>84</b>

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
<b>Femoral Stem</b>					
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
<b>TOTAL</b>	<b>7</b>	<b>84</b>

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
<b>TOTAL</b>	<b>7</b>	<b>84</b>