

Synergy Bipolar Hip Investigation

Note: This analysis compares the Synergy 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 Synergy 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)
Synergy	9	55	431	2.09 (0.95, 3.96)
Other Bipolar Hip	811	26711	79583	1.02 (0.95, 1.09)
TOTAL	820	26766	80014	1.02 (0.96, 1.10)

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 Synergy 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
Synergy	7.3 (2.8, 18.4)	7.3 (2.8, 18.4)	9.5 (4.1, 21.4)	12.2 (5.6, 25.4)	12.2 (5.6, 25.4)	18.0 (9.2, 33.4)	18.0 (9.2, 33.4)
Other Bipolar Hip	2.4 (2.2, 2.6)	3.0 (2.8, 3.3)	3.5 (3.3, 3.8)	3.8 (3.6, 4.1)	4.2 (3.9, 4.5)	4.4 (4.1, 4.8)	4.7 (4.3, 5.1)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Synergy	18.0 (9.2, 33.4)	18.0 (9.2, 33.4)	18.0 (9.2, 33.4)	22.1 (11.7, 39.5)	22.1 (11.7, 39.5)	22.1 (11.7, 39.5)	22.1 (11.7, 39.5)
Other Bipolar Hip	5.0 (4.6, 5.5)	5.3 (4.8, 5.8)	5.6 (5.1, 6.2)	5.7 (5.1, 6.3)	5.8 (5.2, 6.5)	6.1 (5.4, 6.8)	6.5 (5.7, 7.5)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Synergy	22.1 (11.7, 39.5)	22.1 (11.7, 39.5)	22.1 (11.7, 39.5)				
Other Bipolar Hip	7.0 (6.0, 8.2)	7.6 (6.3, 9.0)	8.0 (6.6, 9.7)	8.0 (6.6, 9.7)	9.1 (6.8, 12.3)		

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

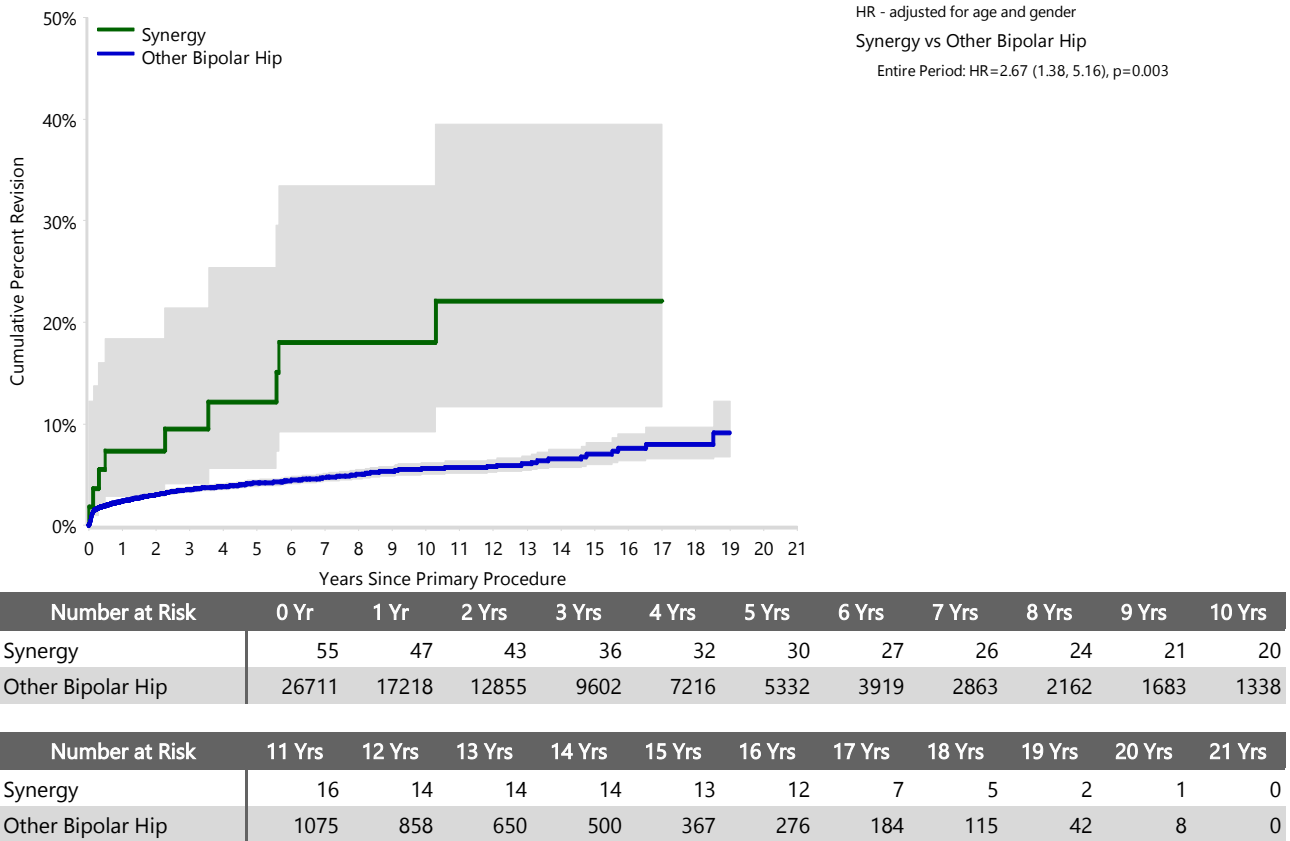
FIGURE 1

Yearly Cumulative Percent Revision of Primary Bipolar Hip Replacement

The yearly cumulative percent revision of the Synergy 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	Synergy		Other Bipolar Hip	
	Number	Percent	Number	Percent
Fractured Neck Of Femur	8	88.9	741	91.4
Osteoarthritis			27	3.3
Tumour			27	3.3
Failed Internal Fixation			8	1.0
Osteonecrosis	1	11.1	7	0.9
Other			1	0.1
TOTAL	9	100.0	811	100.0

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

Revision Diagnosis	Synergy			Other Bipolar Hip		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	2	3.6	22.2	238	0.9	29.3
Prosthesis Dislocation/Instability				198	0.7	24.4
Fracture	3	5.5	33.3	153	0.6	18.9
Loosening				79	0.3	9.7
Chondrolysis/Acetab. Erosion	2	3.6	22.2	69	0.3	8.5
Pain	1	1.8	11.1	49	0.2	6.0
Lysis				4	0.0	0.5
Tumour	1	1.8	11.1	4	0.0	0.5
Malposition				3	0.0	0.4
Implant Breakage Stem				2	0.0	0.2
Incorrect Sizing				2	0.0	0.2
Leg Length Discrepancy				2	0.0	0.2
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
N Revision	9	16.4	100.0	811	3.0	100.0
N Primary	55			26711		

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 Synergy 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

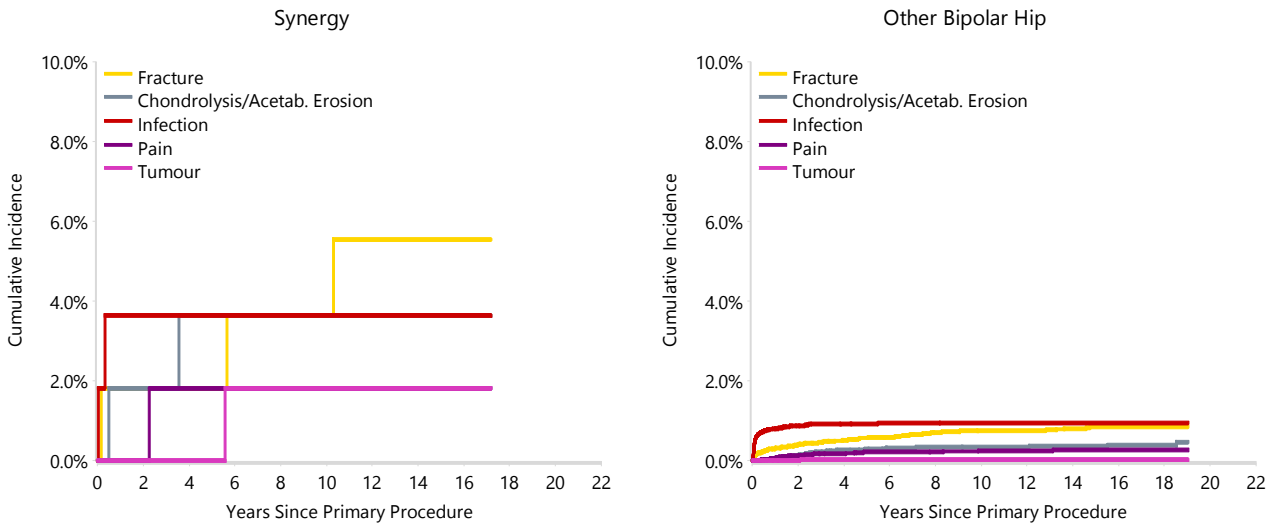


TABLE 5

Type of Revision Performed for Primary Bipolar Hip Replacement

This analysis identifies the components used in the revision of the Synergy 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 Synergy bipolar hip prosthesis compared to all other bipolar hip prostheses.

Table 5: Primary Bipolar Hip Replacement - Type of Revision

Type of Revision	Synergy		Other Bipolar Hip	
	Number	Percent	Number	Percent
Acetabular Component	3	33.3	268	33.0
THR (Femoral/Acetabular)	1	11.1	147	18.1
Bipolar Head and Femoral	2	22.2	104	12.8
Cement Spacer	1	11.1	37	4.6
Femoral Component			32	3.9
Removal of Prostheses			23	2.8
Reinsertion of Components			1	0.1
N Major	7	77.8	612	75.5
Bipolar Only	1	11.1	150	18.5
Head Only			26	3.2
Minor Components	1	11.1	23	2.8
N Minor	2	22.2	199	24.5
TOTAL	9	100.0	811	100.0

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 Synergy 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
Synergy	NSW	3	10
	VIC	0	14
	QLD	4	8
	WA	2	20
	ACT/NT	0	3
Other Bipolar Hip	NSW	267	9792
	VIC	161	4677
	QLD	181	5662
	WA	75	2093
	SA	64	2500
	TAS	23	545
	ACT/NT	40	1442
TOTAL		820	26766

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

TABLE 7**Number of Revisions of Synergy Primary Bipolar Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Synergy 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 Synergy Primary Bipolar Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2000	0	1
2001	0	1
2002	0	10
2003	2	13
2004	1	9
2005	4	10
2006	0	3
2007	1	2
2008	0	1
2009	0	1
2011	0	1
2013	1	2
2017	0	1
TOTAL	9	55

TABLE 8

Revision Rates of Synergy 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 Synergy 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	Fixation
Femoral Stem						
Synergy	71306109-71306118	POROUS HIGH OFFSET FEMORAL STEM	NO	METAL	HA COATED	
Synergy	71306709-71306718	HA STANDARD OFFSET PRESSFIT FEMORAL STEM	NO	METAL	HA COATED	
Synergy	71309009-71309018	POROUS PLUS HA STANDARD OFFSET FEMORAL STEM	NO	METAL	HA COATED	
Synergy	71309109-71309118	POROUS PLUS HA HIGH OFFSET FEMORAL STEM	NO	METAL	HA COATED	
Synergy	71316009-71316017	CEMENTED FEMORAL STEM	YES	METAL		MATT
Synergy	71316209-71316217	CEMENTED HIGH OFFSET FEMORAL STEM	YES	METAL		MATT

Table 8: Revised Number of Synergy Primary Bipolar Hip Replacement by Catalogue Number Range

Femoral Stem Range	N Revised	N Total
71306109-71306118	0	1
71306709-71306718	0	1
71309009-71309018	6	44
71309109-71309118	2	6
71316009-71316017	1	2
71316209-71316217	0	1
TOTAL	9	55

TABLE 9**Revision Rates of Synergy 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 Synergy Primary Bipolar Hip Replacement by Bipolar Component

Bipolar Component	N Revised	N Total
Convane	6	43
Tandem	3	11
UHR	0	1
TOTAL	9	55