

Emperion Total Conventional Hip Investigation

Note: This is an analysis of the Emperion Femoral Stem Prosthesis.

This analysis compares the Emperion Total Conventional Hip Replacement Prosthesis with all Other Total Conventional Hip prostheses. This Prosthesis has been identified as having a significantly higher revision rate. 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-2016>.

Note: All procedures using metal/metal prostheses with head size larger than 32mm have been excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Conventional Hip Replacement

The Revision Rate of the Emperion 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)
Emperion	30	460	1928	1.56 (1.05, 2.22)
Other Total Conventional Hip	11883	330069	1807018	0.66 (0.65, 0.67)
TOTAL	11913	330529	1808946	0.66 (0.65, 0.67)

Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The Yearly Cumulative Percent Revision of the Emperion 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
Emperion	4.2 (2.7, 6.5)	4.4 (2.9, 6.8)	5.3 (3.5, 7.9)	6.3 (4.3, 9.2)	6.8 (4.6, 9.8)
Other Total Conventional Hip	1.6 (1.6, 1.7)	2.2 (2.1, 2.2)	2.6 (2.5, 2.6)	2.9 (2.9, 3.0)	3.3 (3.2, 3.3)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Emperion	7.3 (5.0, 10.6)	8.9 (5.6, 14.2)			
Other Total Conventional Hip	3.7 (3.6, 3.7)	4.0 (3.9, 4.1)	4.4 (4.3, 4.5)	4.9 (4.8, 5.0)	5.3 (5.2, 5.5)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Emperion					
Other Total Conventional Hip	5.9 (5.7, 6.0)	6.5 (6.3, 6.6)	7.1 (6.9, 7.3)	7.7 (7.5, 8.0)	8.3 (8.0, 8.6)

Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator

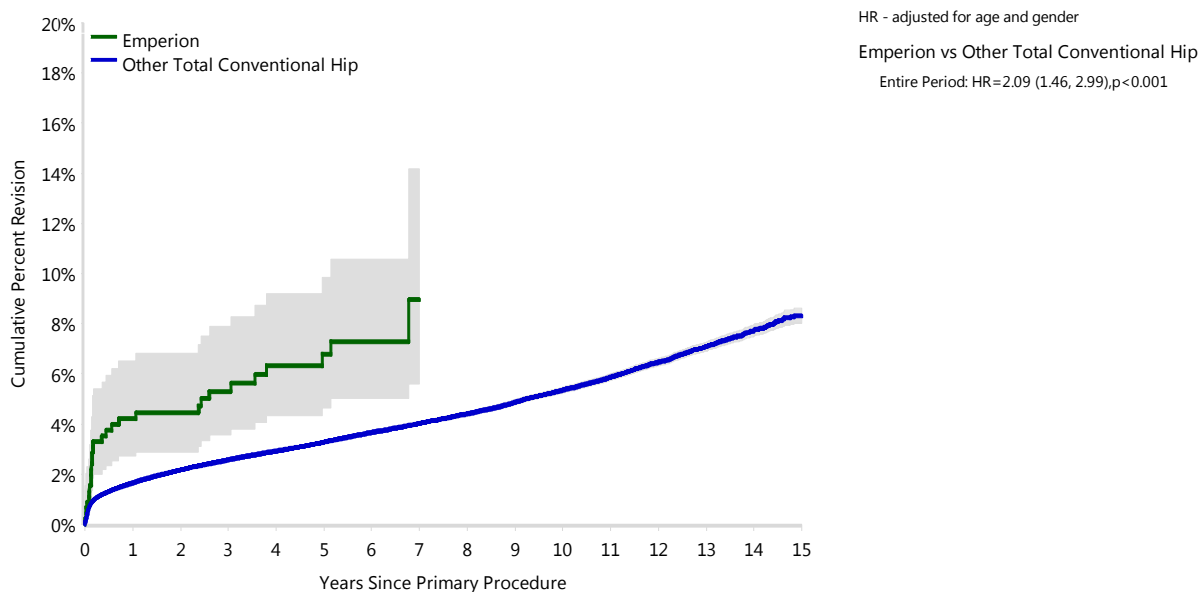
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The Yearly Cumulative Percent Revision of the Emperion 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



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Emperion	460	398	359	304	260	195	111	49
Other Total Conventional Hip	330069	286806	249870	216324	185486	156622	130418	107537

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Emperion	28	12	1	0	0	0	0	0
Other Total Conventional Hip	88183	71390	56331	42160	29064	17578	7977	2026

Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator

TABLE 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

Primary Diagnosis	Emperion		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	20	66.7	10016	84.3
Fractured Neck Of Femur			652	5.5
Osteonecrosis	3	10.0	560	4.7
Developmental Dysplasia	7	23.3	190	1.6
Rheumatoid Arthritis			182	1.5
Failed Internal Fixation			87	0.7
Tumour			82	0.7
Other Inflammatory Arthritis			61	0.5
Fracture/Dislocation			29	0.2
Arthrodesis Takedown			17	0.1
Other			7	0.1
TOTAL	30	100.0	11883	100.0

Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 4

Revision Rates of Emperion 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 4: Revision Rates of Emperion Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Cementless	30	455	1909	1.57 (1.06, 2.24)
Hybrid (Femur Cemented)	0	1	6	0.00 (0.00, 58.28)
Reverse Hybrid (Femur Cementless)	0	4	13	0.00 (0.00, 27.59)
TOTAL	30	460	1928	1.56 (1.05, 2.22)

TABLE 5

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

This analysis is provided as some prostheses are combined with a variety of different bearing surfaces. All bearing surfaces used with this Prosthesis are listed.

Table 5: Revision Rates of Emperion Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Ceramic/Ceramic	16	271	1120	1.43 (0.82, 2.32)
Ceramic/XLPE	0	3	17	0.00 (0.00, 21.41)
Metal/Metal	6	42	268	2.24 (0.82, 4.88)
Metal/Non XLPE	0	4	16	0.00 (0.00, 23.42)
Metal/XLPE	1	35	158	0.63 (0.02, 3.53)
Metal/XLPE Polyethylene + Antioxidant	0	1	3	0.00 (0.00, 120.9)
Ceramicised Metal/XLPE	6	99	340	1.77 (0.65, 3.84)
Ceramicised Metal/XLPE + Antioxidant	0	3	3	0.00 (0.00, 127.2)
Unknown	1	2	5	21.54 (0.55, 120.0)
TOTAL	30	460	1928	1.56 (1.05, 2.22)

TABLE 6

Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Emperion 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 Emperion Total Conventional Hip Prosthesis compared to all other Total Conventional Hip prostheses.

Table 6: Primary Total Conventional Hip Replacement - Type of Revision (Follow-up Limited to 10.5 Years)

Type of Revision	Emperion		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	11	36.7	3602	32.1
Acetabular Component	4	13.3	2493	22.2
THR (Femoral/Acetabular)	3	10.0	1286	11.4
Cement Spacer	1	3.3	526	4.7
Removal of Prostheses			73	0.6
Reinsertion of Components			11	0.1
Total Femoral			2	0.0
Bipolar Head and Femoral Saddle			1	0.0
N Major	19	63.3	7995	71.1
Head/Insert	8	26.7	2186	19.5
Head Only	2	6.7	590	5.3
Minor Components	1	3.3	196	1.7
Insert Only			142	1.3
Head/Neck/Insert			65	0.6
Head/Neck			54	0.5
Neck Only			5	0.0
Bipolar Only			4	0.0
Neck/Insert			1	0.0
N Minor	11	36.7	3243	28.9
TOTAL	30	100.0	11238	100.0

Note: This table is restricted to revisions within 10.5 years for all groups to allow a time-matched comparison of revisions.

Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 7

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 7: Revision Diagnosis of Primary Total Conventional Hip Replacement - Reason for Revision by Model (Follow-up Limited to 10.5 Years)

Revision Diagnosis	Emperion			Other Total Conventional Hip		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Loosening/Lysis	1	0.2	3.3	2989	0.9	26.6
Prosthesis Dislocation	2	0.4	6.7	2732	0.8	24.3
Fracture	4	0.9	13.3	2093	0.6	18.6
Infection	10	2.2	33.3	2029	0.6	18.1
Pain	1	0.2	3.3	218	0.1	1.9
Leg Length Discrepancy	3	0.7	10.0	161	0.0	1.4
Malposition				141	0.0	1.3
Instability				108	0.0	1.0
Implant Breakage Stem	5	1.1	16.7	102	0.0	0.9
Metal Related Pathology	1	0.2	3.3	97	0.0	0.9
Incorrect Sizing				90	0.0	0.8
Implant Breakage Acetabular	1	0.2	3.3	86	0.0	0.8
Implant Breakage Acetabular Insert				81	0.0	0.7
Wear Acetabular Insert				55	0.0	0.5
Implant Breakage Head				33	0.0	0.3
Wear Head				20	0.0	0.2
Tumour				18	0.0	0.2
Heterotopic Bone				16	0.0	0.1
Wear Acetabulum				9	0.0	0.1
Synovitis				2	0.0	0.0
Other	2	0.4	6.7	158	0.0	1.4
N Revision	30	6.5	100.0	11238	3.4	100.0
N Primary	460			330069		

Note: This table is restricted to revisions within 10.5 years for all groups to allow a time-matched comparison of revisions.

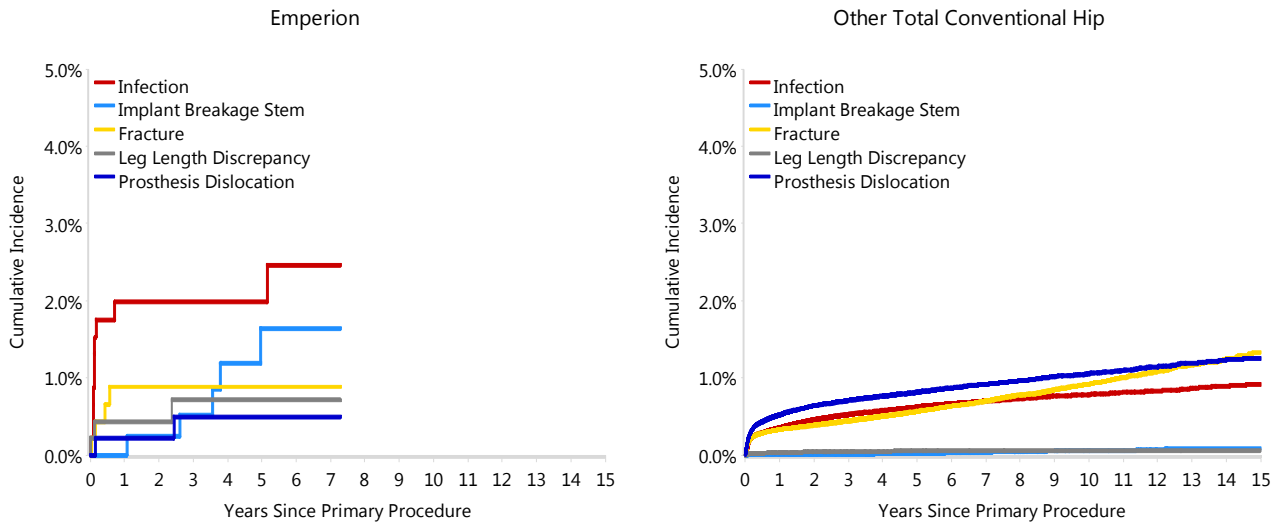
Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

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 Emperion 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



Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator

TABLE 8

Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the Emperion 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 8: Revision Rates of Primary Total Conventional Hip Replacement by State

Component	State	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Emperion	NSW	13	244	1078	1.21 (0.64, 2.06)
	VIC	12	148	525	2.28 (1.18, 3.99)
	QLD	5	54	257	1.95 (0.63, 4.54)
	WA	0	7	41	0.00 (0.00, 8.96)
	SA	0	4	11	0.00 (0.00, 35.11)
	ACT/NT	0	3	17	0.00 (0.00, 21.70)
Other Total Conventional Hip	NSW	3431	98887	518260	0.66 (0.64, 0.68)
	VIC	3205	89840	495479	0.65 (0.62, 0.67)
	QLD	2077	53327	289560	0.72 (0.69, 0.75)
	WA	1557	37446	214053	0.73 (0.69, 0.76)
	SA	992	31431	184116	0.54 (0.51, 0.57)
	TAS	317	11327	63196	0.50 (0.45, 0.56)
	ACT/NT	304	7811	42354	0.72 (0.64, 0.80)
TOTAL		11913	330529	1808946	0.66 (0.65, 0.67)

Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator

TABLE 9**Number of Revisions of Emperion Primary Total Conventional Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Emperion 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 2015 has a maximum of one year to be revised, whereas a primary procedure performed in 2013 has a maximum of three years to be revised.

Table 9: Number of Revisions of Emperion Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	0	1
2006	1	13
2007	3	21
2008	3	26
2009	4	65
2010	2	87
2011	8	72
2012	3	44
2013	4	53
2014	0	38
2015	2	40
TOTAL	30	460

TABLE 10

Revision Rates of Emperion 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 Emperion 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	Stem Type
Femoral Stem				
Emperion	71290901-71290901	SZ 9 PRIMARY FEMORAL STEM REDUCED OFFSET	NO	REQUIRES MODULAR BODY
Emperion	71290902-71290902	SZ 9 PRIMARY FEMORAL STEM STANDARD OFFSET	NO	REQUIRES MODULAR BODY
Emperion	71291101-71291901	PRIMARY FEMORAL STEM STANDARD OFFSET	NO	REQUIRES MODULAR BODY
Emperion	71291102-71291902	PRIMARY FEMORAL STEM HIGH OFFSET	NO	REQUIRES MODULAR BODY
Emperion	71291150-71292351	REVISION FEMORAL STEM SH POLISHED	NO	REQUIRES MODULAR BODY
Emperion	71291170-71292375	REVISION FEMORAL STEM STANDARD COLLAR POLISHED	NO	REQUIRES MODULAR BODY

Table 10: Revision Rates of Emperion Primary Total Conventional Hip Replacement by Catalogue Number Range

Femoral Stem Range	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
71290901-71290901	1	11	58	1.72 (0.04, 9.59)
71290902-71290902	1	19	88	1.13 (0.03, 6.31)
71291101-71291901	17	290	1174	1.45 (0.84, 2.32)
71291102-71291902	9	111	488	1.84 (0.84, 3.50)
71291150-71292351	1	22	88	1.13 (0.03, 6.32)
71291170-71292375	1	7	31	3.18 (0.08, 17.71)
TOTAL	30	460	1928	1.56 (1.05, 2.22)

TABLE 11**Revision Rates of Emperion 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 11: Revision Rates of Emperion Primary Total Conventional Hip Replacement by Acetabular Component

Acetabular Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
BHR	5	30	198	2.53 (0.82, 5.90)
Brunswick	0	1	9	0.00 (0.00, 42.17)
Cormet	0	2	6	0.00 (0.00, 58.23)
Delta-TT	0	11	64	0.00 (0.00, 5.78)
DeltaMotion	0	46	259	0.00 (0.00, 1.42)
Mallory-Head	0	2	1	0.00 (0.00, 319.3)
Polarcup	0	1	7	0.00 (0.00, 54.24)
R3	22	330	1155	1.91 (1.19, 2.88)
RM Cup	0	1	1	0.00 (0.00, 712.9)
Reflection (Cup)	0	1	0	0.00 (0.00, 2642)
Reflection (Shell)	3	21	155	1.94 (0.40, 5.67)
Regenerex	0	2	6	0.00 (0.00, 67.00)
Trabecular Metal (Shell)	0	4	26	0.00 (0.00, 14.25)
Trident (Shell)	0	6	37	0.00 (0.00, 9.94)
Trident/Tritanium (Shell)	0	1	5	0.00 (0.00, 75.52)
Trinity	0	1	1	0.00 (0.00, 286.7)
TOTAL	30	460	1928	1.56 (1.05, 2.22)