

Bionik Total Conventional Hip Investigation

Note: This analysis compares the Bionik acetabular 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-2023>.

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 2022 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Conventional Hip Replacement

The revision rate of the Bionik 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)
Bionik	155	608	5956	2.60 (2.21, 3.05)
Other Total Conventional Hip	17452	494145	3081462	0.57 (0.56, 0.57)
TOTAL	17607	494753	3087418	0.57 (0.56, 0.58)

Note: Prostheses no longer used in 2022 are excluded from the comparator. 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 Bionik 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	8 Yrs
Bionik	3.6 (2.4, 5.5)	5.3 (3.8, 7.4)	7.7 (5.8, 10.2)	10.9 (8.6, 13.7)	14.3 (11.7, 17.4)	16.9 (14.1, 20.3)	19.9 (16.8, 23.4)	22.1 (18.9, 25.8)
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.1, 2.2)	2.5 (2.5, 2.6)	2.8 (2.7, 2.8)	3.1 (3.0, 3.1)	3.4 (3.3, 3.4)	3.6 (3.6, 3.7)	3.9 (3.9, 4.0)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Bionik	23.2 (19.8, 26.9)	24.3 (20.9, 28.1)	26.2 (22.7, 30.2)	28.0 (24.3, 32.2)	29.1 (25.3, 33.4)	29.5 (25.6, 33.7)	30.4 (26.5, 34.9)
Other Total Conventional Hip	4.3 (4.2, 4.3)	4.6 (4.5, 4.7)	4.9 (4.8, 5.0)	5.3 (5.2, 5.4)	5.7 (5.6, 5.8)	6.1 (6.0, 6.2)	6.5 (6.4, 6.6)

CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
Bionik	30.4 (26.5, 34.9)						
Other Total Conventional Hip	6.9 (6.8, 7.1)	7.3 (7.1, 7.4)	7.6 (7.4, 7.8)	8.2 (8.0, 8.5)	8.5 (8.2, 8.8)	8.9 (8.5, 9.3)	9.3 (8.8, 9.8)

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

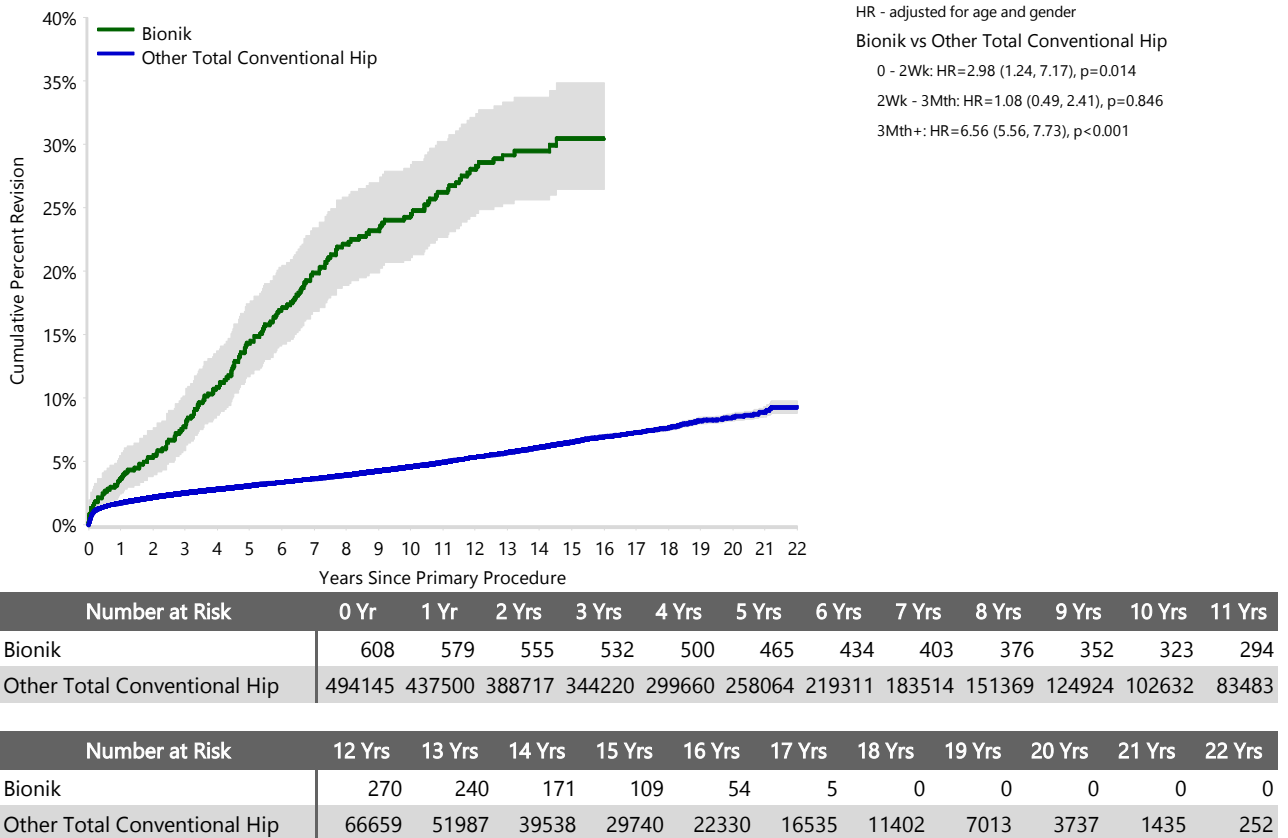
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Bionik 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



Note: Prostheses no longer used in 2022 are excluded from the comparator. 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	Bionik		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	141	91.0	14432	82.7
Fractured Neck Of Femur	5	3.2	1291	7.4
Osteonecrosis	4	2.6	797	4.6
Developmental Dysplasia	1	0.6	279	1.6
Rheumatoid Arthritis	2	1.3	186	1.1
Failed Internal Fixation	1	0.6	147	0.8
Tumour			145	0.8
Other Inflammatory Arthritis	1	0.6	99	0.6
Fracture/Dislocation			46	0.3
Arthrodesis Takedown			16	0.1
Other			14	0.1
TOTAL	155	100.0	17452	100.0

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm 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 Total Conventional Hip Replacement - Reason for Revision (Follow-up Limited to 17.4 Years)

Revision Diagnosis	Number	Bionik		Other Total Conventional Hip		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	20	3.3	12.9	4003	0.8	23.1
Infection	24	3.9	15.5	3995	0.8	23.0
Fracture	5	0.8	3.2	3791	0.8	21.9
Loosening	32	5.3	20.6	3501	0.7	20.2
Pain	6	1.0	3.9	309	0.1	1.8
Leg Length Discrepancy	1	0.2	0.6	270	0.1	1.6
Malposition	2	0.3	1.3	243	0.0	1.4
Lysis	15	2.5	9.7	188	0.0	1.1
Implant Breakage Stem	1	0.2	0.6	165	0.0	1.0
Implant Breakage Acetabular Insert	1	0.2	0.6	119	0.0	0.7
Incorrect Sizing				102	0.0	0.6
Wear Acetabular Insert	2	0.3	1.3	94	0.0	0.5
Metal Related Pathology	41	6.7	26.5	72	0.0	0.4
Implant Breakage Acetabular	3	0.5	1.9	69	0.0	0.4
Wear Head				44	0.0	0.3
Tumour				41	0.0	0.2
Implant Breakage Head				32	0.0	0.2
Heterotopic Bone				26	0.0	0.1
Wear Acetabulum				9	0.0	0.1
Progression Of Disease				2	0.0	0.0
Osteonecrosis				1	0.0	0.0
Synovitis				1	0.0	0.0
Other	2	0.3	1.3	257	0.1	1.5
N Revision	155	25.5	100.0	17334	3.5	100.0
N Primary	608			494145		

Note: This table is restricted to revisions within 17.4 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 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 Bionik 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

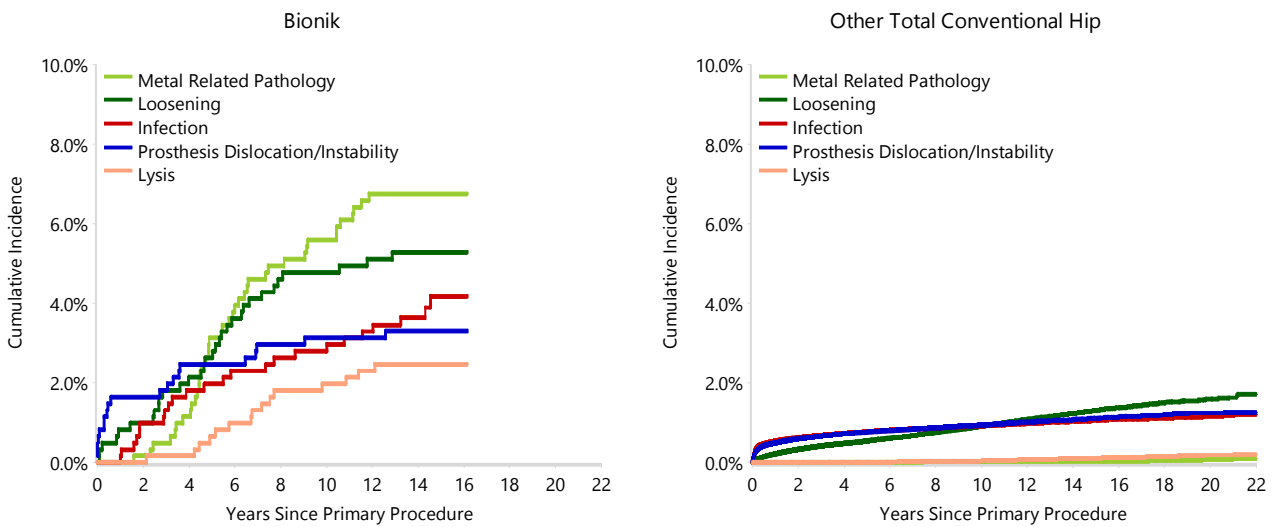


TABLE 5

Type of Revision Performed for Primary Total Conventional Hip Replacement

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

Table 5: Primary Total Conventional Hip Replacement - Type of Revision (Follow-up Limited to 17.4 Years)

Type of Revision	Bionik		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	17	11.0	5678	32.8
Acetabular Component	45	29.0	3279	18.9
THR (Femoral/Acetabular)	34	21.9	2007	11.6
Cement Spacer	6	3.9	618	3.6
Removal of Prostheses			94	0.5
Reinsertion of Components			27	0.2
Total Femoral			8	0.0
Bipolar Head and Femoral			5	0.0
Saddle			1	0.0
N Major	102	65.8	11717	67.6
Head/Insert	4	2.6	4294	24.8
Head Only	1	0.6	843	4.9
Minor Components	3	1.9	296	1.7
Insert Only	1	0.6	180	1.0
Head/Neck/Insert	39	25.2		
Head/Neck	5	3.2	1	0.0
Bipolar Only			2	0.0
Cement Only			1	0.0
N Minor	53	34.2	5617	32.4
TOTAL	155	100.0	17334	100.0

Note: This table is restricted to revisions within 17.4 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 6**Revision Rates of Bionik 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 Bionik Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cemented	1	2
Cementless	128	521
Hybrid (Femur Cemented)	26	84
Reverse Hybrid (Femur Cementless)	0	1
TOTAL	155	608

TABLE 7**Revision Rates of Bionik 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 Bionik Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	4	9
Ceramic/Non XLPE	8	45
Metal/Metal	108	425
Metal/Non XLPE	35	129
TOTAL	155	608

TABLE 8**Revision Rates of Primary Total Conventional Hip Replacement by State**

This enables a state by state variation to be identified for the Bionik 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: Revised Number of Primary Total Conventional Hip Replacement by State

Component	State	N Revised	N Total
Bionik	NSW	75	326
	VIC	17	87
	QLD	7	19
	WA	16	34
	SA	1	5
	TAS	39	136
	ACT/NT	0	1
Other Total Conventional Hip	NSW	4728	144768
	VIC	4348	128324
	QLD	3451	86927
	WA	2389	58888
	SA	1621	45638
	TAS	405	16382
	ACT/NT	510	13218
TOTAL		17607	494753

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

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

This analysis details the number of prostheses reported each year to the Registry for the Bionik 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 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 9: Number of Revisions of Bionik Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	2	11
2006	42	147
2007	29	136
2008	31	138
2009	35	134
2010	16	38
2011	0	4
TOTAL	155	608

TABLE 10

Revision Rates of Bionik 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 Bionik 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
Acetabular				
Bionik	10201050-10201064	METAL SHELL BS TINB COAT	NO	METAL
Bionik	10201150-10201164	METAL SHELL BS TINB COAT SCREW FIX	NO	METAL
Bionik	10201246-10201264	METAL SHELL CEMENTLESS TINB COAT SCREW FIX	NO	METAL
Bionik	10201346-10201366	METAL SHELL TINB CAP SCREW FIX	NO	METAL
Bionik	10202154-10202164	METAL SHELL CEMENTLESS DYSPL. TINB C. SCREW FIX	NO	METAL

Table 10: Revised Number of Bionik Primary Total Conventional Hip Replacement by Catalogue Number Range

Acetabular Range	N Revised	N Total
10201050-10201064	8	23
10201150-10201164	42	138
10201246-10201264	12	63
10201346-10201366	92	381
10202154-10202164	1	3
TOTAL	155	608

TABLE 11**Revision Rates of Bionik 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: Revised Number of Bionik Primary Total Conventional Hip Replacement by Femoral Stem Component

Femoral Stem Component	N Revised	N Total
Adapter (cless)	134	527
Adapter (ctd)	19	72
CORAIL	1	1
Custom Made (Eska)	0	1
Edinburgh	0	1
GHE	0	4
K2	1	1
S-Rom	0	1
TOTAL	155	608