

Bionik/Bionik Total Resurfacing Hip Investigation

Note: This analysis compares the Bionik/Bionik head/acetabular combination with all other total resurfacing hip prostheses.

This combination 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-2020>.

TABLE 1

Revision Rate of Primary Total Resurfacing Hip Replacement

The revision rate of the Bionik/Bionik total resurfacing hip combination is compared to all other total resurfacing hip prostheses.

Table 1: Revision Rates of Primary Total Resurfacing Hip Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Bionik/Bionik	59	200	1887	3.13 (2.38, 4.03)
Other Total Resurfacing Hip	1788	18050	196674	0.91 (0.87, 0.95)
TOTAL	1847	18250	198561	0.93 (0.89, 0.97)

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement

The yearly cumulative percent revision of the Bionik/Bionik total resurfacing hip combination is compared to all other total resurfacing hip prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs
Bionik/Bionik	3.5 (1.7, 7.2)	8.0 (5.0, 12.8)	12.5 (8.7, 18.0)	14.6 (10.4, 20.3)	18.6 (13.8, 24.7)	20.1 (15.2, 26.4)
Other Total Resurfacing Hip	1.7 (1.5, 1.9)	2.4 (2.2, 2.7)	3.1 (2.8, 3.3)	3.8 (3.5, 4.1)	4.7 (4.4, 5.1)	5.7 (5.3, 6.0)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs
Bionik/Bionik	21.6 (16.5, 28.0)	23.1 (17.9, 29.7)	26.2 (20.7, 32.9)	27.4 (21.7, 34.2)	29.8 (23.9, 36.9)	29.8 (23.9, 36.9)
Other Total Resurfacing Hip	6.5 (6.2, 6.9)	7.4 (7.0, 7.8)	8.1 (7.7, 8.5)	9.0 (8.6, 9.5)	9.7 (9.2, 10.2)	10.4 (10.0, 10.9)

CPR	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs
Bionik/Bionik							
Other Total Resurfacing Hip	11.3 (10.7, 11.8)	11.9 (11.3, 12.4)	12.5 (11.9, 13.1)	13.1 (12.5, 13.7)	13.5 (12.9, 14.2)	13.9 (13.2, 14.6)	15.0 (13.8, 16.3)

FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement

The yearly cumulative percent revision of the Bionik/Bionik total resurfacing hip combination is compared to all other total resurfacing 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 Resurfacing Hip Replacement

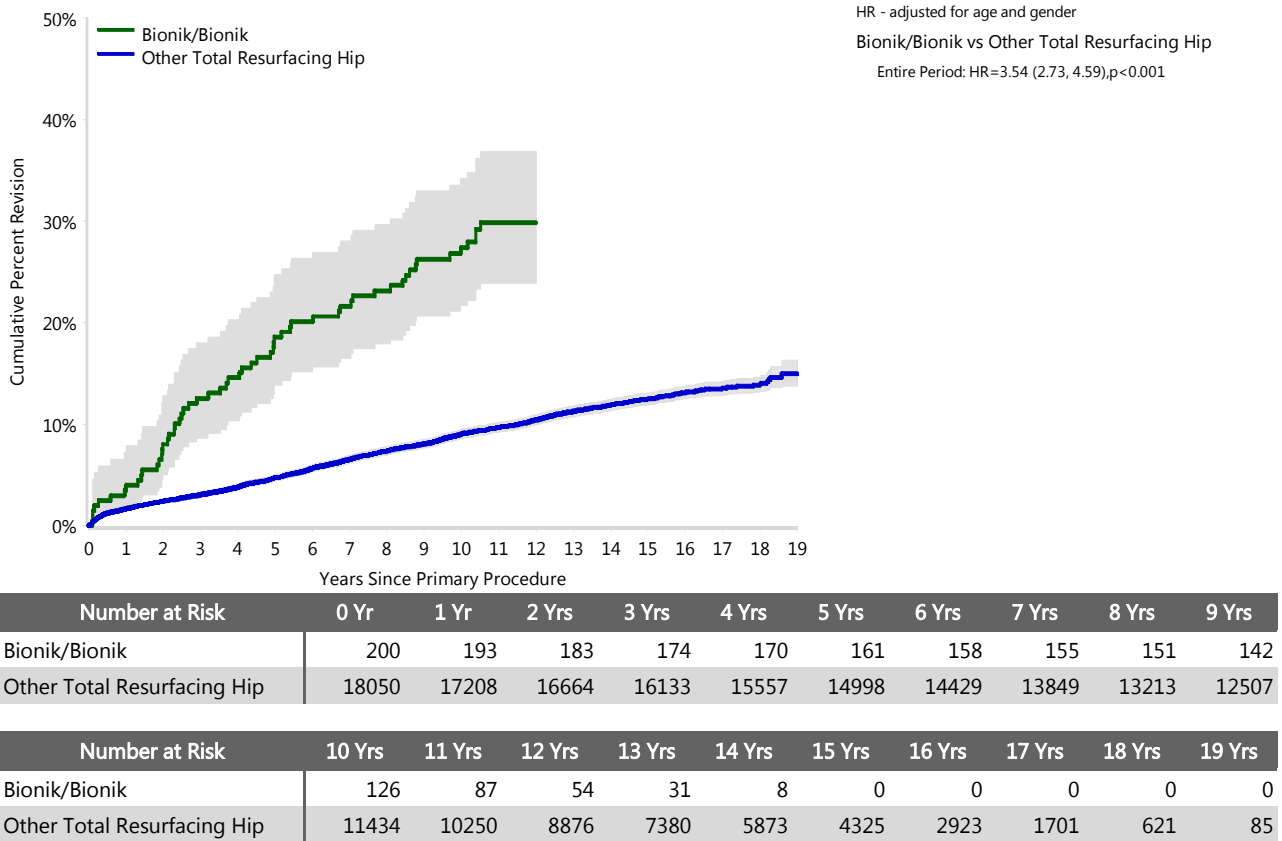


TABLE 3**Primary Diagnosis for Revised Primary Total Resurfacing Hip Replacement**

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 resurfacing hip prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Resurfacing Hip Replacement

Primary Diagnosis	Bionik/Bionik		Other Total Resurfacing Hip	
	Number	Percent	Number	Percent
Osteoarthritis	56	94.9	1638	91.6
Developmental Dysplasia	1	1.7	88	4.9
Osteonecrosis	2	3.4	40	2.2
Other Inflammatory Arthritis			11	0.6
Rheumatoid Arthritis			9	0.5
Other			2	0.1
TOTAL	59	100.0	1788	100.0

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 Resurfacing Hip Replacement - Reason for Revision (Follow-up Limited to 14.4 Years)

Revision Diagnosis	Number	Bionik/Bionik		Other Total Resurfacing Hip		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Metal Related Pathology	14	7.0	23.7	480	2.7	27.9
Loosening	14	7.0	23.7	438	2.4	25.5
Fracture	11	5.5	18.6	296	1.6	17.2
Lysis	6	3.0	10.2	158	0.9	9.2
Infection	1	0.5	1.7	109	0.6	6.3
Pain	5	2.5	8.5	104	0.6	6.0
Osteonecrosis				42	0.2	2.4
Prosthesis Dislocation				26	0.1	1.5
Malposition	3	1.5	5.1	20	0.1	1.2
Instability				7	0.0	0.4
Implant Breakage Head	1	0.5	1.7	5	0.0	0.3
Implant Breakage Acetabular	2	1.0	3.4	3	0.0	0.2
Progression Of Disease				3	0.0	0.2
Tumour	1	0.5	1.7	3	0.0	0.2
Wear Acetabulum				3	0.0	0.2
Leg Length Discrepancy				2	0.0	0.1
Synovitis				2	0.0	0.1
Heterotopic Bone				1	0.0	0.1
Incorrect Sizing				1	0.0	0.1
Other	1	0.5	1.7	18	0.1	1.0
N Revision	59	29.5	100.0	1721	9.5	100.0
N Primary	200			18050		

Note: This table is restricted to revisions within 14.4 years for all groups to allow a time-matched comparison of revisions.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Resurfacing 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/Bionik total resurfacing hip combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total resurfacing hip prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Resurfacing Hip Replacement

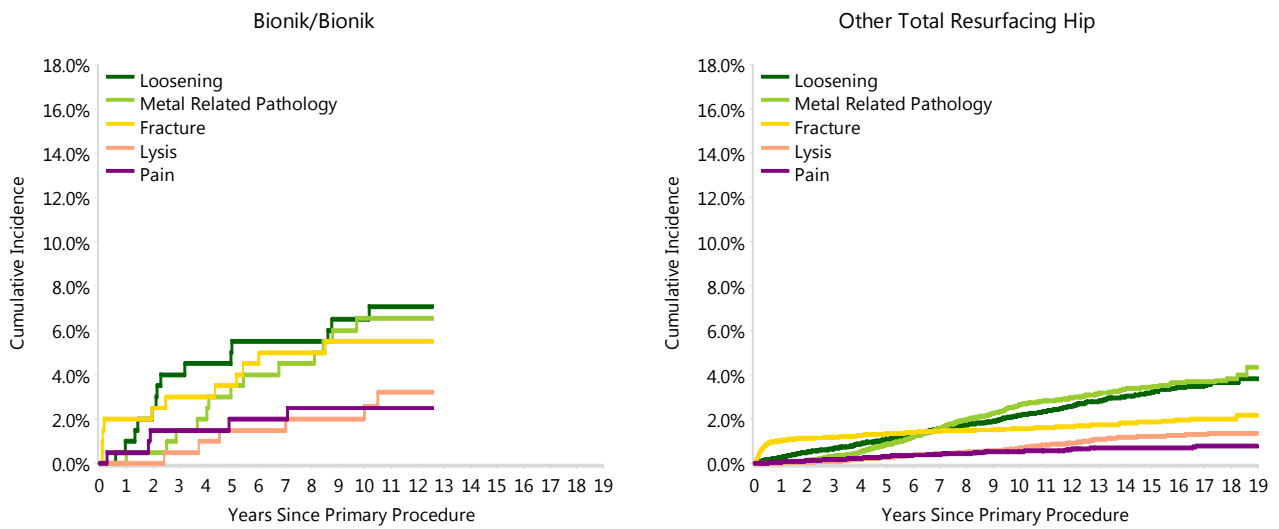


TABLE 5

Type of Revision Performed for Primary Total Resurfacing Hip Replacement

This analysis identifies the components used in the revision of the Bionik/Bionik total resurfacing hip combination and compares it to the components used in the revision of all other total resurfacing 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 resurfacing hip prostheses i.e. is there a difference in the type of revision undertaken for the Bionik/Bionik total resurfacing hip combination compared to all other total resurfacing hip prostheses.

Table 5: Primary Total Resurfacing Hip Replacement - Type of Revision (Follow-up Limited to 14.4 Years)

Type of Revision	Bionik/Bionik		Other Total Resurfacing Hip	
	Number	Percent	Number	Percent
THR (Femoral/Acetabular)	41	69.5	1239	72.0
Femoral Component	17	28.8	383	22.3
Acetabular Component			52	3.0
Cement Spacer	1	1.7	37	2.1
Removal of Prostheses			10	0.6
N Major	59	100.0	1721	100.0
TOTAL	59	100.0	1721	100.0

Note: This table is restricted to revisions within 14.4 years for all groups to allow a time-matched comparison of revisions.

TABLE 6**Revision Rates of Bionik/Bionik Primary Total Resurfacing 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: Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Fixation

Fixation	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Cemented	0	1	11	0.00 (0.00, 33.37)
Cementless	4	15	168	2.38 (0.65, 6.08)
Hybrid (Femur Cemented)	55	181	1674	3.29 (2.48, 4.28)
Reverse Hybrid (Femur Cementless)	0	3	34	0.00 (0.00, 10.72)
TOTAL	59	200	1887	3.13 (2.38, 4.03)

TABLE 7

Revision Rates of Primary Total Resurfacing Hip Replacement by State

This enables a state by state variation to be identified for the Bionik/Bionik total resurfacing hip combination and provides the comparative data for each of the states for all other total resurfacing 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 7: Revision Rates of Primary Total Resurfacing Hip Replacement by State

Component	State	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Bionik/Bionik	NSW	41	128	1194	3.43 (2.46, 4.66)
	VIC	4	25	279	1.43 (0.39, 3.67)
	QLD	0	2	18	0.00 (0.00, 20.01)
	WA	11	35	298	3.69 (1.84, 6.61)
	TAS	3	10	98	3.06 (0.63, 8.95)
Other Total Resurfacing Hip	NSW	486	5335	58263	0.83 (0.76, 0.91)
	VIC	556	5971	71233	0.78 (0.72, 0.85)
	QLD	283	3661	34171	0.83 (0.73, 0.93)
	WA	62	846	7034	0.88 (0.68, 1.13)
	SA	324	1408	16743	1.94 (1.73, 2.16)
	TAS	14	95	1079	1.30 (0.71, 2.18)
	ACT/NT	63	734	8151	0.77 (0.59, 0.99)
TOTAL		1847	18250	198561	0.93 (0.89, 0.97)

TABLE 8**Number of Revisions of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Bionik/Bionik total resurfacing hip combination. 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 2019 has a maximum of one year to be revised, whereas a primary procedure performed in 2017 has a maximum of three years to be revised.

Table 8: Number of Revisions of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	4	12
2006	9	33
2007	8	33
2008	13	46
2009	20	54
2010	5	20
2011	0	2
TOTAL	59	200

TABLE 9

Revision Rates of Bionik/Bionik Primary Total Resurfacing 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/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
Head				
Bionik	10260038-10260058	HIP RESURFACING CEMENTLESS SILVER	NO	METAL
Bionik	10270042-10270058	HIP RESURFACING CEMENTED SILVER	YES	METAL
Bionik	10270238-10270258	CERAMIC HEAD HIP SURF. REPLACEMENT	YES	CERAMIC
Bionik	10280038-10280058	HIP RESURFACING CEMENTLESS SILVER	NO	METAL
Bionik	10280138-10280158	HIP SURFACE REPLACEMENT CEMENTED BIOSURF SILVER	YES	METAL
Bionik	10280642-10280654	HIP RESURFACING CEMENTLESS SILVER CAP-COAT	NO	METAL
Bionik	10282038-10282058	FEMORAL HEAD SHELL BIOSURF CEMENTED	YES	METAL
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

Table 9: Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Catalogue Number Range

Head Range	Acetabular Range	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
10260038-10260058	10201150-10201164	0	1	14	0.00 (0.00, 25.73)
10270042-10270058	10201150-10201164	5	6	42	12.00 (3.90, 28.00)
	10201246-10201264	0	4	56	0.00 (0.00, 6.61)
	10201346-10201366	3	11	121	2.48 (0.51, 7.24)
10270238-10270258	10201150-10201164	1	1	6	16.62 (0.42, 92.59)
	10201246-10201264	2	2	2	131.38 (15.91, 474.6)
	10201346-10201366	9	9	31	29.50 (13.49, 56.00)
10280038-10280058	10201050-10201064	0	1	14	0.00 (0.00, 25.61)
	10201150-10201164	0	1	14	0.00 (0.00, 25.63)
10280138-10280158	10201050-10201064	0	1	13	0.00 (0.00, 27.46)
	10201150-10201164	0	3	40	0.00 (0.00, 9.32)
	10201246-10201264	2	10	107	1.86 (0.23, 6.73)
	10201346-10201366	8	52	537	1.49 (0.64, 2.94)
10280642-10280654	10201050-10201064	0	2	27	0.00 (0.00, 13.49)
	10201150-10201164	2	2	12	17.20 (2.08, 62.13)
	10201246-10201264	2	3	27	7.33 (0.89, 26.46)
	10201346-10201366	0	7	88	0.00 (0.00, 4.21)
10282038-10282058	10201150-10201164	1	3	26	3.79 (0.10, 21.09)
	10201246-10201264	14	46	399	3.51 (1.92, 5.89)
	10201346-10201366	10	35	312	3.21 (1.54, 5.90)
TOTAL		59	200	1887	3.13 (2.38, 4.03)