

Novation Total Conventional Hip Investigation

Note: This analysis compares the Novation femoral stem 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 Novation 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)
Novation	81	1423	9320	0.87 (0.69, 1.08)
Other Total Conventional Hip	17418	493472	3077273	0.57 (0.56, 0.57)
TOTAL	17499	494895	3086593	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 Novation 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
Novation	3.7 (2.9, 4.9)	4.2 (3.2, 5.4)	4.5 (3.5, 5.7)	4.9 (3.9, 6.1)	5.3 (4.2, 6.6)	5.5 (4.4, 6.8)	5.8 (4.6, 7.2)	6.1 (4.9, 7.5)
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
Novation	6.5 (5.2, 8.2)	6.5 (5.2, 8.2)	6.5 (5.2, 8.2)				
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
Novation							
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.

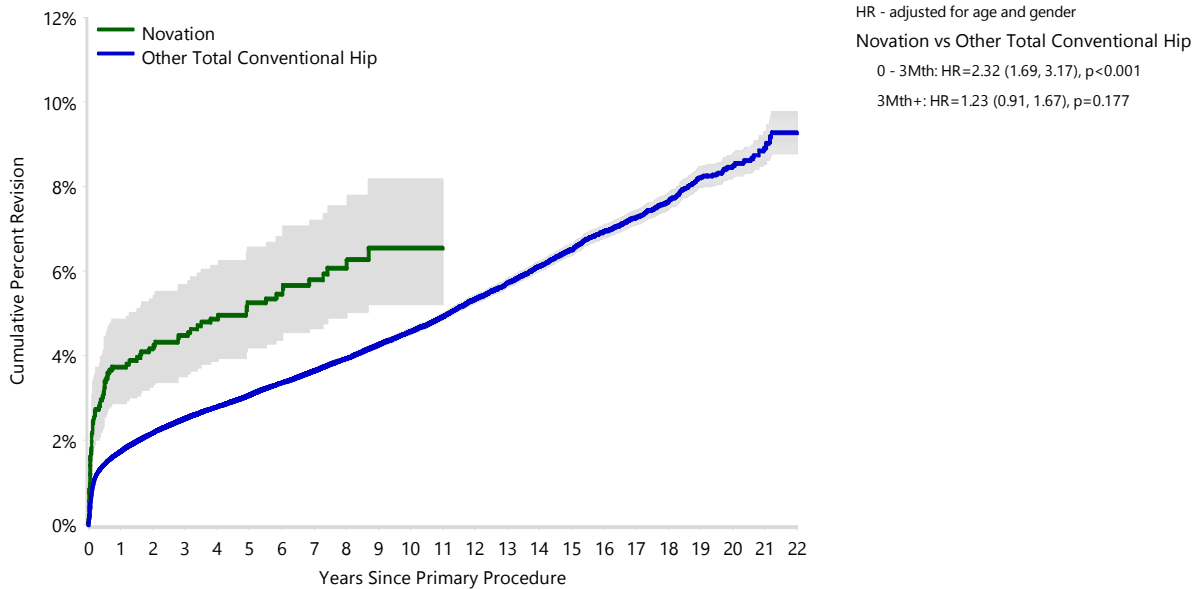
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Novation 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	8 Yrs	9 Yrs	10 Yrs	11 Yrs
Novation	1423	1340	1304	1237	1097	982	892	738	487	277	165	66
Other Total Conventional Hip	493472	436879	388122	343680	299238	257671	218926	183166	151123	124807	102533	83429

Number at Risk	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
Novation	28	3	0	0	0	0	0	0	0	0	0
Other Total Conventional Hip	66633	51984	39538	29740	22330	16535	11402	7013	3737	1435	252

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	Novation		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	74	91.4	14400	82.7
Fractured Neck Of Femur	3	3.7	1290	7.4
Osteonecrosis	3	3.7	796	4.6
Developmental Dysplasia			279	1.6
Rheumatoid Arthritis			186	1.1
Failed Internal Fixation			147	0.8
Tumour	1	1.2	145	0.8
Other Inflammatory Arthritis			99	0.6
Fracture/Dislocation			46	0.3
Arthrodesis Takedown			16	0.1
Other			14	0.1
TOTAL	81	100.0	17418	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 13.2 Years)

Revision Diagnosis	Number	Novation		Other Total Conventional Hip		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	11	0.8	13.6	3937	0.8	23.5
Prosthesis Dislocation/Instability	18	1.3	22.2	3928	0.8	23.4
Fracture	25	1.8	30.9	3639	0.7	21.7
Loosening	20	1.4	24.7	3334	0.7	19.9
Pain				300	0.1	1.8
Leg Length Discrepancy	2	0.1	2.5	269	0.1	1.6
Malposition	1	0.1	1.2	240	0.0	1.4
Lysis				155	0.0	0.9
Implant Breakage Stem	1	0.1	1.2	154	0.0	0.9
Implant Breakage Acetabular Insert	1	0.1	1.2	115	0.0	0.7
Incorrect Sizing	1	0.1	1.2	101	0.0	0.6
Wear Acetabular Insert				71	0.0	0.4
Implant Breakage Acetabular				68	0.0	0.4
Metal Related Pathology				66	0.0	0.4
Wear Head				43	0.0	0.3
Tumour	1	0.1	1.2	40	0.0	0.2
Implant Breakage Head				28	0.0	0.2
Heterotopic Bone				26	0.0	0.2
Wear Acetabulum				8	0.0	0.0
Progression Of Disease				2	0.0	0.0
Osteonecrosis				1	0.0	0.0
Synovitis				1	0.0	0.0
Other				256	0.1	1.5
N Revision	81	5.7	100.0	16782	3.4	100.0
N Primary	1423			493472		

Note: This table is restricted to revisions within 13.2 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 Novation 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

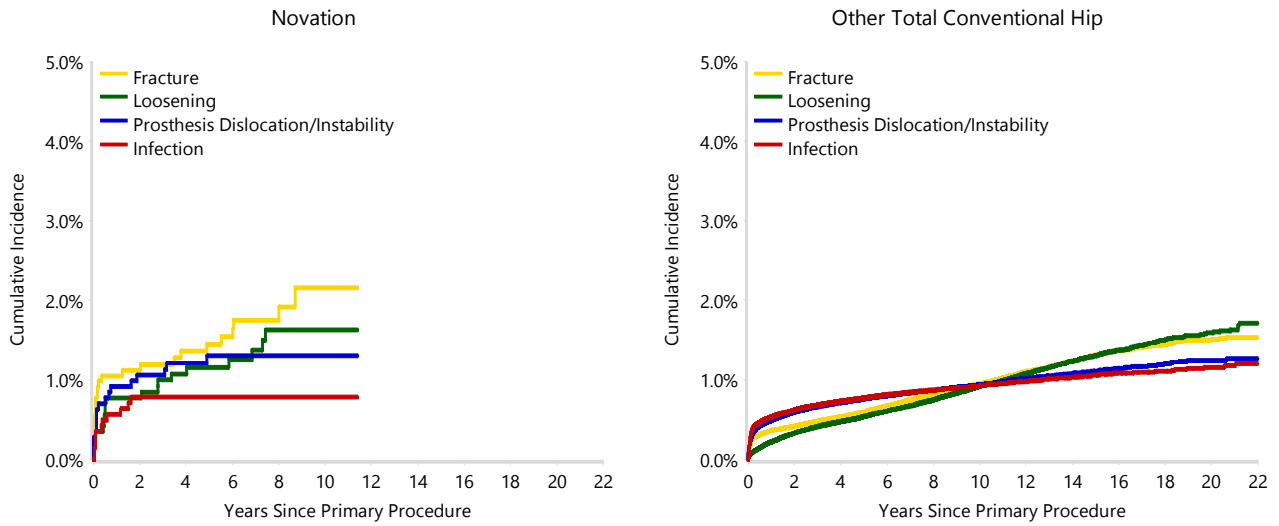


TABLE 5

Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Novation 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 Novation 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 13.2 Years)

Type of Revision	Novation		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	32	39.5	5492	32.7
Acetabular Component	18	22.2	3141	18.7
THR (Femoral/Acetabular)	6	7.4	1900	11.3
Cement Spacer	4	4.9	604	3.6
Removal of Prostheses			92	0.5
Reinsertion of Components			27	0.2
Total Femoral			6	0.0
Bipolar Head and Femoral			5	0.0
Saddle			1	0.0
N Major	60	74.1	11268	67.1
Head/Insert	13	16.0	4206	25.1
Head Only	6	7.4	836	5.0
Minor Components	2	2.5	289	1.7
Insert Only			179	1.1
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	21	25.9	5514	32.9
TOTAL	81	100.0	16782	100.0

Note: This table is restricted to revisions within 13.2 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 Novation 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 Novation Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	79	1417
Hybrid (Femur Cemented)	1	3
Reverse Hybrid (Femur Cementless)	1	3
TOTAL	81	1423

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

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	36	637
Ceramic/Non XLPE	11	169
Ceramic/XLPE	23	477
Ceramic/XLPE + Antioxidant	0	2
Metal/Non XLPE	3	26
Metal/XLPE	8	110
Metal/XLPE + Antioxidant	0	1
Unknown	0	1
TOTAL	81	1423

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

This analysis is provided as some prostheses are used with a variety of surgical approaches. All surgical approaches used with this prosthesis are listed.

Table 8: Revised Number of Novation Primary Total Conventional Hip Replacement by Approach

Approach	N Revised	N Total
Anterior	15	270
Lateral	7	159
Posterior	18	341
TOTAL	40	770

Note: Excludes 653 procedures with no approach recorded

TABLE 9

Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the Novation 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 9: Revised Number of Primary Total Conventional Hip Replacement by State

Component	State	N Revised	N Total
Novation	NSW	31	530
	VIC	10	84
	QLD	13	164
	WA	18	396
	TAS	9	249
Other Total Conventional Hip	NSW	4714	144499
	VIC	4346	128309
	QLD	3444	86797
	WA	2380	58681
	SA	1621	45638
	TAS	403	16330
	ACT/NT	510	13218
TOTAL		17499	494895

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 10**Number of Revisions of Novation Primary Total Conventional Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Novation 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 10: Number of Revisions of Novation Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2009	0	4
2010	1	32
2011	7	53
2012	12	130
2013	9	137
2014	8	226
2015	10	266
2016	5	148
2017	6	90
2018	8	101
2019	12	145
2020	3	51
2021	0	19
2022	0	21
TOTAL	81	1423

TABLE 11

Revision Rates of Novation 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 Novation 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
Femoral Stem					
Novation	1600009-1600018	PLASMA TAPERED PRESS-FIT STANDARD OFFSET FEMORAL STEM	NO	METAL	HA COATED
Novation	1600109-1600118	PLASMA TAPERED PRESS-FIT EXTENDED OFFSET FEMORAL STEM	NO	METAL	HA COATED
Novation	1640108-1640118	HA COLLARLESS PRESS-FIT STANDARD OFFSET FEMORAL STEM	NO	METAL	HA COATED
Novation	1640208-1640218	HA COLLARLESS PRESS-FIT EXTENDED OFFSET FEMORAL STEM	NO	METAL	HA COATED
Novation	1640308-1640318	HA COLLARED PRESS-FIT STANDARD OFFSET FEMORAL STEM	NO	METAL	HA COATED
Novation	1641108-1641112	HA COLLARLESS PRESS-FIT STANDARD OFFSET FEMORAL STEM 12/14	NO	METAL	HA COATED
Novation	1641208-1641218	HA COLLARLESS PRESS-FIT EXTENDED OFFSET FEMORAL STEM	NO	METAL	HA COATED

Table 11: Revised Number of Novation Primary Total Conventional Hip Replacement by Catalogue Number Range

Femoral Stem Range	N Revised	N Total
1600009-1600018	0	10
1600109-1600118	1	3
1640108-1640118	44	912
1640208-1640218	24	353
1640308-1640318	10	101
1641108-1641112	2	32
1641208-1641218	0	12
TOTAL	81	1423

TABLE 12

Revision Rates of Novation 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 12: Revised Number of Novation Primary Total Conventional Hip Replacement by Acetabular Component

Acetabular Component	N Revised	N Total
Acetabular Shell (Global)	10	197
Adaptive	0	8
BSC-Cup	27	419
Cer-Met	1	2
Delta-TT	0	3
FMP	2	49
Fin II	1	16
Furlong	9	132
Logical G	16	231
Novae	1	99
Novae E	1	10
Novation	6	87
PINNACLE	1	41
Procotyl L	2	11
R3	0	1
Trident/Tritanium (Shell)	0	1
Trinity	3	115
ZCA	1	1
TOTAL	81	1423