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-2024.

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 2023 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	88	1423	10477	0.84 (0.67, 1.03)
Other Total Conventional Hip	19249	538541	3454641	0.56 (0.55, 0.57)
TOTAL	**19337**	**539964**	**3465118**	**0.56 (0.55, 0.57)**

Note: Prostheses no longer used in 2023 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, 5.3)	4.5 (3.5, 5.7)	4.8 (3.8, 6.1)	5.2 (4.1, 6.5)	5.4 (4.3, 6.7)	5.7 (4.6, 7.0)	6.3 (5.1, 7.7)
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.1, 2.2)	2.5 (2.5, 2.5)	2.8 (2.7, 2.8)	3.1 (3.0, 3.1)	3.3 (3.3, 3.4)	3.6 (3.6, 3.7)	3.9 (3.8, 4.0)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Novation	6.9 (5.6, 8.6)	6.9 (5.6, 8.6)	7.4 (5.8, 9.3)	8.0 (6.2, 10.5)				
Other Total Conventional Hip	4.2 (4.2, 4.3)	4.5 (4.5, 4.6)	4.9 (4.8, 5.0)	5.3 (5.2, 5.4)	5.7 (5.6, 5.8)	6.1 (5.9, 6.2)	6.5 (6.3, 6.6)	6.9 (6.7, 7.0)

CPR	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
Novation							
Other Total Conventional Hip	7.3 (7.1, 7.4)	7.7 (7.5, 7.8)	8.2 (8.0, 8.4)	8.5 (8.2, 8.7)	9.0 (8.7, 9.3)	9.7 (9.2, 10.1)	10.3 (9.5, 11.2)

Note: Prostheses no longer used in 2023 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

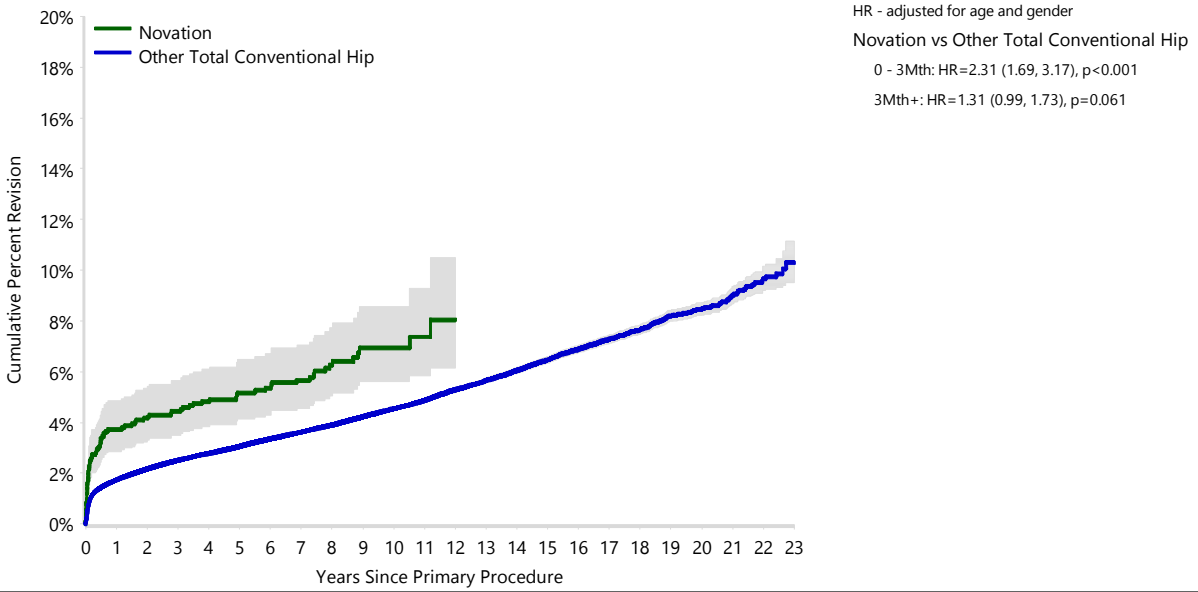
FIGURE 1

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	1360	1322	1280	1222	1071	964	866	710	468	262	155
Other Total Conventional Hip	538541	475645	425806	377168	332911	288979	247789	209621	174574	143301	117825	96251

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	23 Yrs
Novation	64	25	3	0	0	0	0	0	0	0	0	0
Other Total Conventional Hip	77815	61602	47695	35979	26857	20094	14821	10048	6170	3221	1205	203

Note: Prostheses no longer used in 2023 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

	Novation		Other Total Conventional Hip	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	81	92.0	15951	82.9
Fractured Neck Of Femur	3	3.4	1420	7.4
Osteonecrosis	3	3.4	859	4.5
Developmental Dysplasia			320	1.7
Rheumatoid Arthritis			208	1.1
Failed Internal Fixation			151	0.8
Tumour	1	1.1	149	0.8
Other Inflammatory Arthritis			106	0.6
Fracture/Dislocation			53	0.3
Other			17	0.1
Arthrodesis Takedown			15	0.1
TOTAL	**88**	**100.0**	**19249**	**100.0**

Note: Prostheses no longer used in 2023 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 14.2 Years)

	Novation			Other Total Conventional Hip		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	12	0.8	13.6	4439	0.8	23.8
Prosthesis Dislocation/Instability	18	1.3	20.5	4309	0.8	23.1
Fracture	28	2.0	31.8	4111	0.8	22.0
Loosening	22	1.5	25.0	3634	0.7	19.5
Pain				329	0.1	1.8
Leg Length Discrepancy	2	0.1	2.3	291	0.1	1.6
Malposition	1	0.1	1.1	266	0.0	1.4
Implant Breakage Stem	1	0.1	1.1	180	0.0	1.0
Lysis				180	0.0	1.0
Implant Breakage Acetabular Insert	2	0.1	2.3	126	0.0	0.7
Incorrect Sizing	1	0.1	1.1	103	0.0	0.6
Wear Acetabular Insert				87	0.0	0.5
Metal Related Pathology				72	0.0	0.4
Implant Breakage Acetabular				70	0.0	0.4
Wear Head				46	0.0	0.2
Tumour	1	0.1	1.1	43	0.0	0.2
Implant Breakage Head				30	0.0	0.2
Heterotopic Bone				26	0.0	0.1
Wear Acetabulum				10	0.0	0.1
Osteonecrosis				2	0.0	0.0
Progression Of Disease				2	0.0	0.0
Synovitis				1	0.0	0.0
Other				291	0.1	1.6
N Revision	**88**	**6.2**	**100.0**	**18648**	**3.5**	**100.0**
N Primary	**1423**			**538541**		

Note: This table is restricted to revisions within 14.2 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2023 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

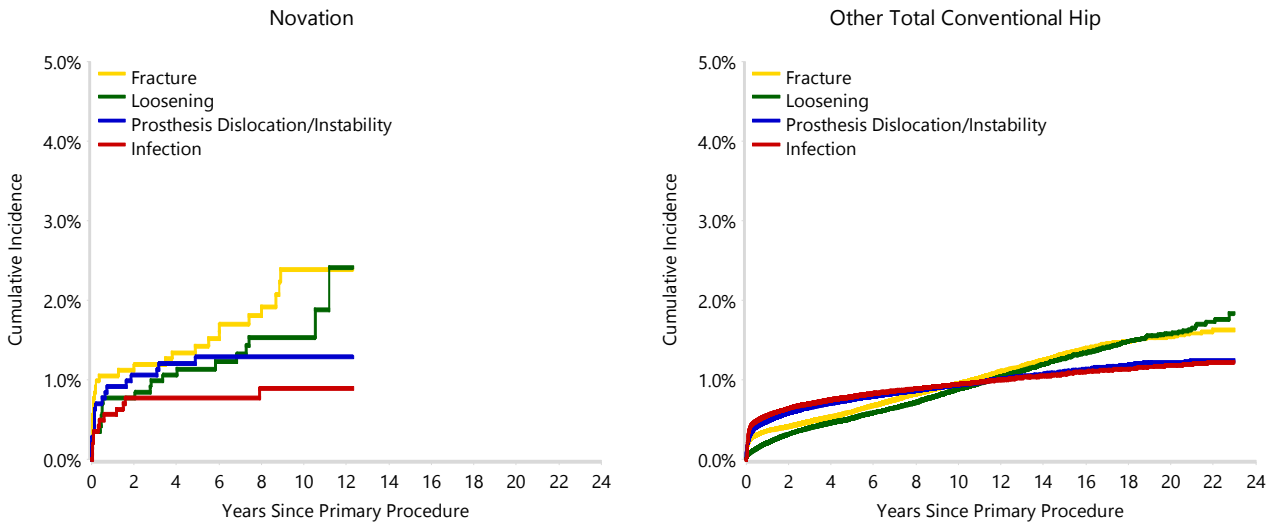


TABLE 5

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 14.2 Years)

	Novation		Other Total Conventional Hip	
Type of Revision	Number	Percent	Number	Percent
Femoral Component	35	39.8	6171	33.1
Acetabular Component	19	21.6	3438	18.4
THR (Femoral/Acetabular)	8	9.1	2127	11.4
Cement Spacer	4	4.5	613	3.3
Removal of Prostheses			97	0.5
Reinsertion of Components			28	0.2
Total Femoral			8	0.0
Bipolar Head and Femoral			7	0.0
Saddle			1	0.0
N Major	**66**	**75.0**	**12490**	**67.0**
Head/Insert	14	15.9	4752	25.5
Head Only	6	6.8	917	4.9
Minor Components	2	2.3	301	1.6
Insert Only			184	1.0
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	**22**	**25.0**	**6158**	**33.0**
TOTAL	**88**	**100.0**	**18648**	**100.0**

Note: This table is restricted to revisions within 14.2 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2023 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	86	1417
Hybrid (Femur Cemented)	1	3
Reverse Hybrid (Femur Cementless)	1	3
TOTAL	**88**	**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	38	637
Ceramic/Non XLPE	12	169
Ceramic/XLPE	26	477
Ceramic/XLPE + Antioxidant	0	2
Metal/Non XLPE	3	26
Metal/XLPE	9	110
Metal/XLPE + Antioxidant	0	1
Unknown	0	1
TOTAL	**88**	**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	17	270
Lateral	8	159
Posterior	18	341
TOTAL	**43**	**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	34	530
	VIC	12	84
	QLD	13	164
	WA	20	396
	TAS	9	249
Other Total Conventional Hip	NSW	5207	157707
	VIC	4859	140681
	QLD	3791	94582
	WA	2546	63265
	SA	1825	49398
	TAS	452	18198
	ACT/NT	569	14710
TOTAL		**19337**	**539964**

Note: Prostheses no longer used in 2023 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 2023 has a maximum of one year to be revised, whereas a primary procedure performed in 2021 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	13	130
2013	10	137
2014	10	226
2015	12	266
2016	6	148
2017	6	90
2018	8	101
2019	12	145
2020	3	51
2021	0	19
2022	0	21
TOTAL	**88**	**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	48	912
1640208-1640218	27	353
1640308-1640318	10	101
1641108-1641112	2	32
1641208-1641218	0	12
TOTAL	**88**	**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)	11	197
Adaptive	0	8
BSC-Cup	27	419
Cer-Met	1	2
Delta-TT	0	3
FMP	3	49
Fin II	1	16
Furlong	9	132
Logical G	16	231
Novae	2	99
Novae E	1	10
Novation	8	87
PINNACLE	1	41
Procotyl L	3	11
R3	0	1
Trident/Tritanium (Shell)	0	1
Trinity	4	115
ZCA	1	1
TOTAL	**88**	**1423**