Duraloc Total Conventional Hip Investigation

Note: This analysis compares the Duraloc 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-2022.

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 2021 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Conventional Hip Replacement

The revision rate of the Duraloc 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)
Duraloc	634	5354	63503	1.00 (0.92, 1.08)
Other Total Conventional Hip	15859	453455	2721137	0.58 (0.57, 0.59)
TOTAL	**16493**	**458809**	**2784640**	**0.59 (0.58, 0.60)**

Note: Prostheses no longer used in 2021 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 Duraloc 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
Duraloc	1.8 (1.5, 2.2)	2.5 (2.1, 3.0)	3.0 (2.6, 3.5)	3.5 (3.0, 4.0)	4.1 (3.6, 4.7)	4.7 (4.2, 5.3)	5.3 (4.7, 6.0)
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.2, 2.2)	2.5 (2.5, 2.6)	2.8 (2.8, 2.9)	3.1 (3.0, 3.2)	3.4 (3.3, 3.5)	3.7 (3.6, 3.7)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Duraloc	6.2 (5.5, 6.9)	7.2 (6.5, 8.0)	8.3 (7.6, 9.2)	9.5 (8.6, 10.4)	10.6 (9.7, 11.6)	11.8 (10.8, 12.8)	13.1 (12.0, 14.2)
Other Total Conventional Hip	4.0 (3.9, 4.0)	4.3 (4.2, 4.4)	4.6 (4.6, 4.7)	5.0 (4.9, 5.1)	5.4 (5.3, 5.5)	5.8 (5.7, 5.9)	6.3 (6.1, 6.4)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Duraloc	14.0 (12.9, 15.2)	15.1 (14.0, 16.4)	16.8 (15.5, 18.2)	17.6 (16.3, 19.1)	18.4 (16.9, 19.9)	19.7 (18.0, 21.6)	20.2 (18.3, 22.2)
Other Total Conventional Hip	6.7 (6.5, 6.8)	7.1 (6.9, 7.3)	7.5 (7.3, 7.7)	7.9 (7.6, 8.1)	8.6 (8.3, 8.9)	8.9 (8.5, 9.3)	9.8 (9.0, 10.8)

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

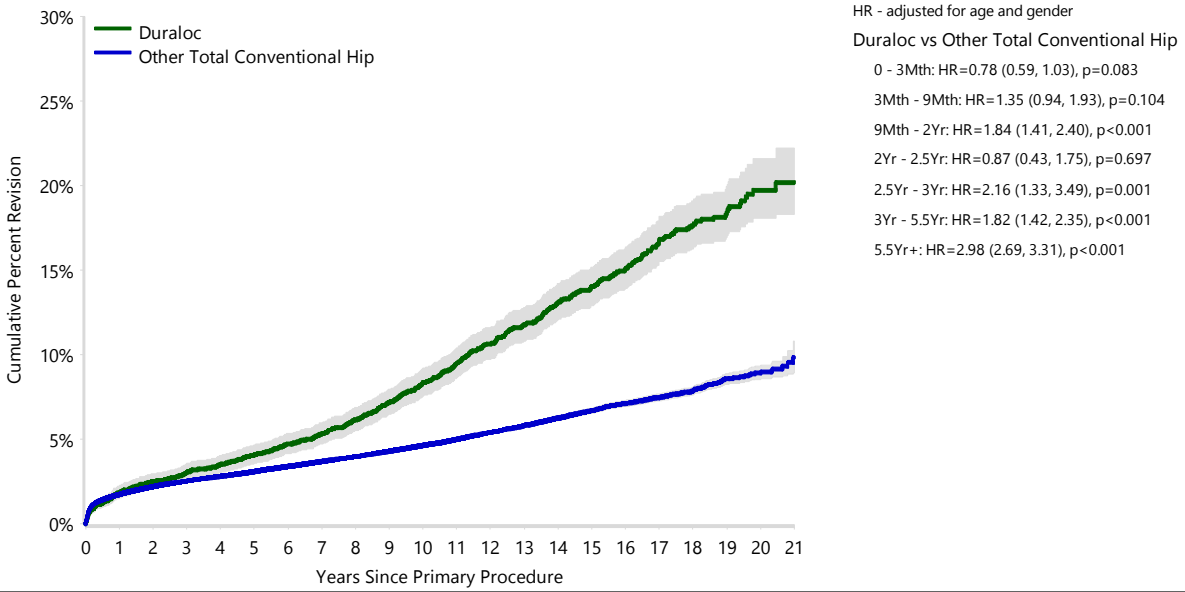
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Duraloc 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
Duraloc	5354	5170	5018	4857	4695	4511	4309	4104	3881	3636	3401
Other Total Conventional Hip	453455	398683	354053	309177	267205	228060	191587	158583	131210	108026	88155

Number at Risk	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Duraloc	3126	2843	2515	2164	1860	1581	1252	941	624	282	65
Other Total Conventional Hip	70603	55343	42208	31909	24032	17719	12212	7611	4006	1573	276

Note: Prostheses no longer used in 2021 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

	Duraloc		Other Total Conventional Hip	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	536	84.5	13112	82.7
Fractured Neck Of Femur	33	5.2	1164	7.3
Osteonecrosis	35	5.5	718	4.5
Developmental Dysplasia	14	2.2	247	1.6
Rheumatoid Arthritis	8	1.3	173	1.1
Failed Internal Fixation	3	0.5	140	0.9
Tumour			137	0.9
Other Inflammatory Arthritis	4	0.6	91	0.6
Fracture/Dislocation			47	0.3
Arthrodesis Takedown	1	0.2	16	0.1
Other			14	0.1
TOTAL	**634**	**100.0**	**15859**	**100.0**

Note: Prostheses no longer used in 2021 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

	Duraloc			Other Total Conventional Hip		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	118	2.2	18.6	3717	0.8	23.4
Infection	56	1.0	8.8	3552	0.8	22.4
Fracture	94	1.8	14.8	3440	0.8	21.7
Loosening	214	4.0	33.8	3229	0.7	20.4
Pain	5	0.1	0.8	287	0.1	1.8
Leg Length Discrepancy				260	0.1	1.6
Malposition	3	0.1	0.5	226	0.0	1.4
Lysis	93	1.7	14.7	184	0.0	1.2
Implant Breakage Stem	9	0.2	1.4	151	0.0	1.0
Implant Breakage Acetabular Insert				114	0.0	0.7
Incorrect Sizing				95	0.0	0.6
Wear Acetabular Insert	32	0.6	5.0	91	0.0	0.6
Metal Related Pathology	1	0.0	0.2	70	0.0	0.4
Implant Breakage Acetabular				67	0.0	0.4
Wear Head				45	0.0	0.3
Tumour	1	0.0	0.2	37	0.0	0.2
Implant Breakage Head	1	0.0	0.2	30	0.0	0.2
Heterotopic Bone				23	0.0	0.1
Wear Acetabulum	4	0.1	0.6	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	3	0.1	0.5	228	0.1	1.4
N Revision	**634**	**11.8**	**100.0**	**15859**	**3.5**	**100.0**
N Primary	**5354**			**453455**		

Note: Prostheses no longer used in 2021 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 Duraloc 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

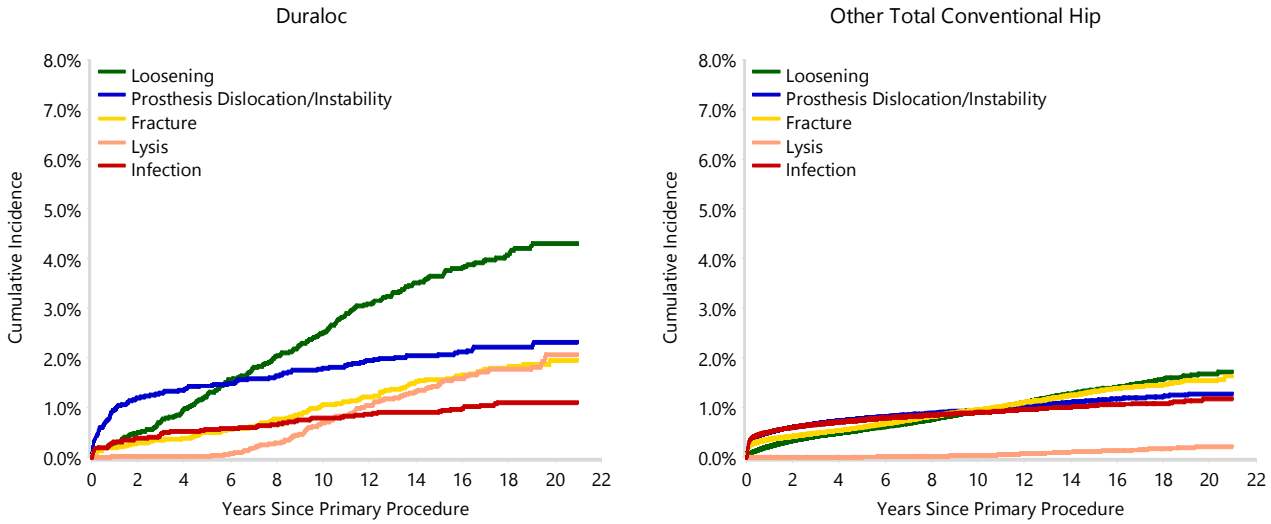


TABLE 5

Type of Revision Performed for Primary Total Conventional Hip Replacement

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

Table 5: Primary Total Conventional Hip Replacement - Type of Revision

	Duraloc		Other Total Conventional Hip	
Type of Revision	Number	Percent	Number	Percent
Femoral Component	230	36.3	5155	32.5
Acetabular Component	107	16.9	3059	19.3
THR (Femoral/Acetabular)	85	13.4	1815	11.4
Cement Spacer	17	2.7	594	3.7
Removal of Prostheses	1	0.2	97	0.6
Reinsertion of Components			25	0.2
Total Femoral	1	0.2	6	0.0
Bipolar Head and Femoral			4	0.0
Saddle			1	0.0
N Major	**441**	**69.6**	**10756**	**67.8**
Head/Insert	169	26.7	3875	24.4
Head Only	6	0.9	778	4.9
Minor Components	6	0.9	274	1.7
Insert Only	11	1.7	172	1.1
Bipolar Only	1	0.2	2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	**193**	**30.4**	**5103**	**32.2**
TOTAL	**634**	**100.0**	**15859**	**100.0**

Note: Prostheses no longer used in 2021 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 Duraloc 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 Duraloc Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cemented	1	13
Cementless	294	2444
Hybrid (Femur Cemented)	337	2890
Reverse Hybrid (Femur Cementless)	2	7
TOTAL	**634**	**5354**

TABLE 7

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

Bearing Surface	N Revised	N Total
Ceramic/Non XLPE	94	623
Ceramic/XLPE	31	463
Metal/Non XLPE	421	2766
Metal/XLPE	88	1499
Ceramicised Metal/Non XLPE	0	1
Unknown	0	2
TOTAL	**634**	**5354**

TABLE 8

Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the Duraloc 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
Duraloc	NSW	122	1128
	VIC	317	2660
	QLD	59	650
	WA	101	644
	SA	34	269
	TAS	0	2
	ACT/NT	1	1
Other Total Conventional Hip	NSW	4298	132969
	VIC	3982	116998
	QLD	3146	80122
	WA	2184	53952
	SA	1415	41929
	TAS	372	15098
	ACT/NT	462	12387
TOTAL		**16493**	**458809**

Note: Prostheses no longer used in 2021 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 Duraloc Primary Total Conventional Hip Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Duraloc 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 2021 has a maximum of one year to be revised, whereas a primary procedure performed in 2019 has a maximum of three years to be revised.

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

Year of Implant	Number Revised	Total Number
1999	8	19
2000	35	210
2001	123	799
2002	140	1119
2003	127	907
2004	73	631
2005	51	448
2006	25	301
2007	21	253
2008	17	293
2009	8	187
2010	3	82
2011	3	84
2012	0	18
2013	0	3
TOTAL	**634**	**5354**

TABLE 10

Revision Rates of Duraloc 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 Duraloc 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	Fixation
Acetabular						
Duraloc	124538503-124546503	BANTAM TITANIUM BEADED NONHA SHELL	NO	METAL		POROUS
Duraloc	124548000-124574000	1200 SERIES METAL SHELL	NO	METAL		POROUS
Duraloc	124580049-124580058	SECTOR TITANIUM BEADED NONHA SHELL	NO	METAL		POROUS
Duraloc	124648000-124674000	300 SHELL POROCOAT	NO	METAL		POROUS
Duraloc	124748000-124766000	100 SERIES TITANIUM BEADED NONHA SHELL	NO	METAL		POROUS
Duraloc	924580049-924580058	SECTOR SHELL POLISHED PORO-HYDROXY COATING	NO	METAL	HA COATED	
Duraloc	924748000-924766000	100 SHELL POLISHED PORO-HYDROXY COATING	NO	METAL	HA COATED	

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

Acetabular Range	N Revised	N Total
124538503-124546503	6	22
124548000-124574000	19	85
124580049-124580058	199	1449
124648000-124674000	95	853
124748000-124766000	100	740
924580049-924580058	105	914
924748000-924766000	110	1291
TOTAL	**634**	**5354**

TABLE 11

Revision Rates of Duraloc 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 Duraloc Primary Total Conventional Hip Replacement by Femoral Stem Component

Femoral Stem Component	N Revised	N Total
ABGII	1	3
Accolade I	15	74
C-Stem	104	983
C-Stem AMT	2	61
CLS	0	2
CORAIL	122	1438
CPT	1	2
Charnley	41	180
Definition	0	1
Elite Plus	132	1088
Exeter	9	89
Exeter V40	32	293
Fullfix	1	19
Generic Stem	0	1
Hip Fracture	0	1
IPS	1	44
Infinity Hip System	1	6
Integral	0	5
KAR	0	1
LYDERIC II	1	6
Lubinus SP II	1	10
MBA (exch neck)	0	3
MS 30	4	59
Meridian	5	15
Olympia	1	2
Omnifit	0	1
Primaloc	7	108
Prodigy	3	7
Restoration	1	1
Revision Hip	0	2
S-Rom	38	168
Secur-Fit Plus	1	2
Solution	1	5
Spectron EF	9	95
Stability	62	403
Summit	10	75
Synergy	0	2
Uni-Rom	15	60
UniSyn	0	1
VerSys	12	37
Wagner	1	1
TOTAL	**634**	**5354**