

Fixa Total Conventional Hip Investigation

Note: This analysis compares the Fixa 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 Fixa 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)
Fixa	62	1335	7193	0.86 (0.66, 1.10)
Other Total Conventional Hip	17394	492843	3074482	0.57 (0.56, 0.57)
TOTAL	17456	494178	3081675	0.57 (0.56, 0.57)

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 Fixa 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
Fixa	3.0 (2.2, 4.1)	3.5 (2.6, 4.7)	4.0 (3.0, 5.2)	4.0 (3.0, 5.2)	4.5 (3.4, 5.8)	4.9 (3.8, 6.3)	4.9 (3.8, 6.3)	5.5 (4.2, 7.2)
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
Fixa	5.8 (4.4, 7.6)	6.7 (5.0, 8.9)					
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
Fixa							
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.

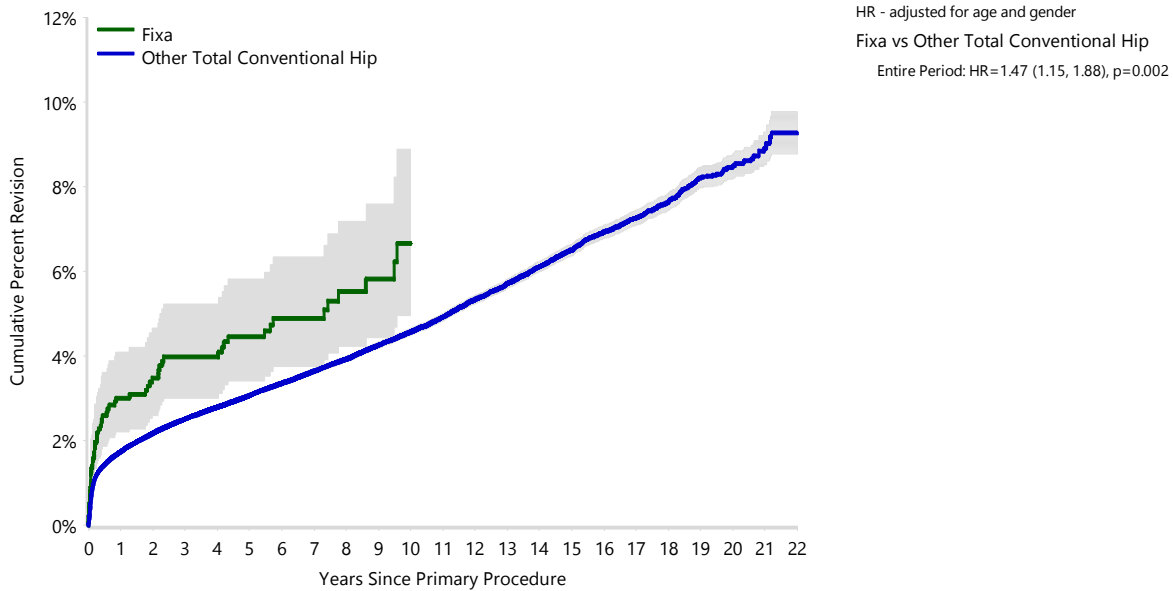
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Fixa 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
Fixa	1335	1130	997	895	808	721	620	514	385	288	154	33
Other Total Conventional Hip	492843	436400	387749	343353	298880	257371	218717	183020	150993	124636	102478	83450

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
Fixa	0	0	0	0	0	0	0	0	0	0	0
Other Total Conventional Hip	66659	51987	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	Fixa		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	55	88.7	14381	82.7
Fractured Neck Of Femur	3	4.8	1288	7.4
Osteonecrosis	3	4.8	794	4.6
Developmental Dysplasia	1	1.6	278	1.6
Rheumatoid Arthritis			186	1.1
Failed Internal Fixation			147	0.8
Tumour			145	0.8
Other Inflammatory Arthritis			99	0.6
Fracture/Dislocation			46	0.3
Arthrodesis Takedown			16	0.1
Other			14	0.1
TOTAL	62	100.0	17394	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 11.6 Years)

Revision Diagnosis	Number	Fixa		Other Total Conventional Hip		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	21	1.6	33.9	3883	0.8	23.7
Prosthesis Dislocation/Instability	12	0.9	19.4	3872	0.8	23.6
Fracture	14	1.0	22.6	3529	0.7	21.6
Loosening	5	0.4	8.1	3213	0.7	19.6
Pain	1	0.1	1.6	299	0.1	1.8
Leg Length Discrepancy				269	0.1	1.6
Malposition	1	0.1	1.6	240	0.0	1.5
Implant Breakage Stem	2	0.1	3.2	142	0.0	0.9
Lysis	1	0.1	1.6	135	0.0	0.8
Implant Breakage Acetabular Insert	2	0.1	3.2	108	0.0	0.7
Incorrect Sizing				101	0.0	0.6
Implant Breakage Acetabular	1	0.1	1.6	65	0.0	0.4
Wear Acetabular Insert				61	0.0	0.4
Metal Related Pathology	1	0.1	1.6	59	0.0	0.4
Tumour				40	0.0	0.2
Wear Head	1	0.1	1.6	40	0.0	0.2
Implant Breakage Head				28	0.0	0.2
Heterotopic Bone				26	0.0	0.2
Wear Acetabulum				7	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				253	0.1	1.5
N Revision	62	4.6	100.0	16374	3.3	100.0
N Primary	1335			492843		

Note: This table is restricted to revisions within 11.6 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 Fixa 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

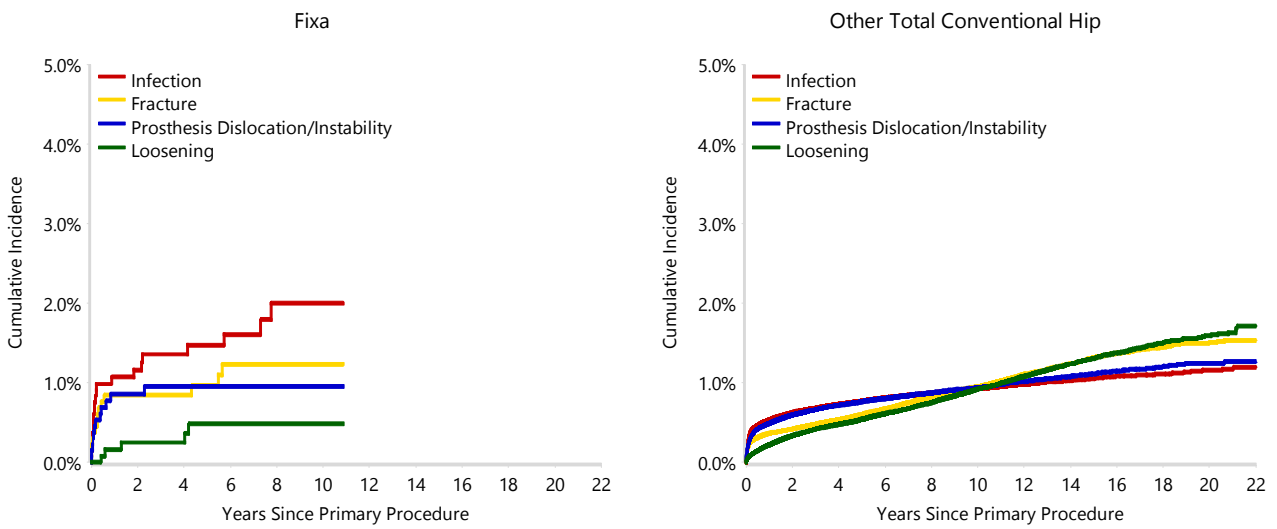


TABLE 5

Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Fixa 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 Fixa 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 11.6 Years)

Type of Revision	Fixa		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	22	35.5	5324	32.5
Acetabular Component	10	16.1	3062	18.7
THR (Femoral/Acetabular)	14	22.6	1822	11.1
Cement Spacer			601	3.7
Removal of Prostheses	1	1.6	90	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	47	75.8	10938	66.8
Head/Insert	12	19.4	4137	25.3
Head Only	3	4.8	831	5.1
Minor Components			286	1.7
Insert Only			178	1.1
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	15	24.2	5436	33.2
TOTAL	62	100.0	16374	100.0

Note: This table is restricted to revisions within 11.6 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 Fixa 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 Fixa Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cemented	0	14
Cementless	23	353
Hybrid (Femur Cemented)	39	968
TOTAL	62	1335

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

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	29	749
Ceramic/XLPE	16	404
Metal/XLPE	17	182
TOTAL	62	1335

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

Approach	N Revised	N Total
Anterior	0	15
Lateral	15	283
Posterior	21	575
TOTAL	36	873

Note: Excludes 462 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 Fixa 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
Fixa	NSW	2	16
	VIC	12	180
	QLD	41	973
	WA	0	10
	SA	7	154
	ACT/NT	0	2
Other Total Conventional Hip	NSW	4726	144753
	VIC	4340	128176
	QLD	3410	85954
	WA	2389	58878
	SA	1614	45484
	TAS	405	16382
	ACT/NT	510	13216
TOTAL		17456	494178

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 Fixa Primary Total Conventional Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Fixa 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 Fixa Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2011	1	44
2012	9	161
2013	8	153
2014	7	99
2015	3	134
2016	4	100
2017	7	91
2018	2	78
2019	2	84
2020	6	95
2021	9	134
2022	4	162
TOTAL	62	1335

TABLE 11

Revision Rates of Fixa 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 Fixa 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	Fixation
Acetabular					
Fixa	0753142-0753566	TI-POROUS HEMISPHERICAL SHELL	NO	METAL	POROUS
Fixa	0772144-0772258	FIXA DUPLEX CEMENTED ACETABULAR CUP	YES	METAL	

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

Acetabular Range	N Revised	N Total
0753142-0753566	62	1321
0772144-0772258	0	14
TOTAL	62	1335

TABLE 12

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

Femoral Stem Component	N Revised	N Total
CORAIL	0	4
CPT	0	1
Corae	8	122
E2	0	1
Evolve	0	72
Exeter V40	34	858
Hydra	7	93
Hydra-Fix	2	25
Mutars	0	1
Origin	0	61
Parva	4	32
SMR	0	1
Secur-Fit Plus	2	14
Short Exeter V40	5	49
VerSys	0	1
TOTAL	62	1335