

## 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-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 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	72	1468	8401	0.86 (0.67, 1.08)
Other Total Conventional Hip	19189	537228	3447139	0.56 (0.55, 0.56)
<b>TOTAL</b>	<b>19261</b>	<b>538696</b>	<b>3455540</b>	<b>0.56 (0.55, 0.57)</b>

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 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	3.2 (2.4, 4.2)	3.8 (2.9, 4.9)	4.3 (3.3, 5.5)	4.3 (3.3, 5.5)	4.7 (3.7, 6.0)	5.1 (4.0, 6.5)	5.1 (4.0, 6.5)	5.6 (4.4, 7.1)
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
Fixa	5.9 (4.6, 7.5)	6.5 (5.0, 8.3)	6.5 (5.0, 8.3)					
Other Total Conventional Hip	4.2 (4.2, 4.3)	4.5 (4.5, 4.6)	4.9 (4.8, 4.9)	5.3 (5.2, 5.4)	5.7 (5.6, 5.8)	6.0 (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
Fixa							
Other Total Conventional Hip	7.3 (7.1, 7.4)	7.6 (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.

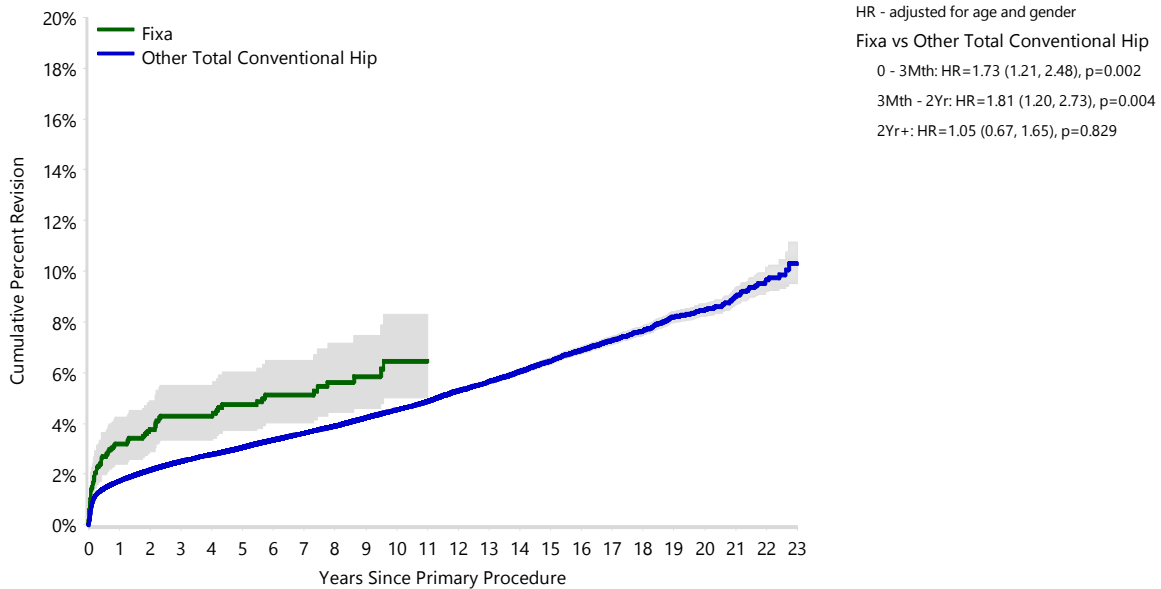
FIGURE 1

**Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement**

The yearly cumulative percent revision of the 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	1468	1283	1116	980	886	793	701	600	500	367	275	148
Other Total Conventional Hip	537228	474509	424833	376320	332143	288284	247163	209078	174104	142950	117556	96104

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
Fixa	30	0	0	0	0	0	0	0	0	0	0	0
Other Total Conventional Hip	77785	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**

Primary Diagnosis	Fixa		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	64	88.9	15899	82.9
Fractured Neck Of Femur	4	5.6	1416	7.4
Osteonecrosis	3	4.2	856	4.5
Developmental Dysplasia	1	1.4	319	1.7
Rheumatoid Arthritis			208	1.1
Failed Internal Fixation			151	0.8
Tumour			149	0.8
Other Inflammatory Arthritis			106	0.6
Fracture/Dislocation			53	0.3
Other			17	0.1
Arthrodesis Takedown			15	0.1
<b>TOTAL</b>	<b>72</b>	<b>100.0</b>	<b>19189</b>	<b>100.0</b>

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 12.6 Years)

Revision Diagnosis	Number	Fixa		Other Total Conventional Hip		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	24	1.6	33.3	4384	0.8	24.1
Prosthesis Dislocation/Instability	16	1.1	22.2	4251	0.8	23.3
Fracture	15	1.0	20.8	3988	0.7	21.9
Loosening	7	0.5	9.7	3517	0.7	19.3
Pain	1	0.1	1.4	325	0.1	1.8
Leg Length Discrepancy				290	0.1	1.6
Malposition	1	0.1	1.4	264	0.0	1.4
Implant Breakage Stem	2	0.1	2.8	171	0.0	0.9
Lysis	1	0.1	1.4	159	0.0	0.9
Implant Breakage Acetabular Insert	2	0.1	2.8	122	0.0	0.7
Incorrect Sizing				103	0.0	0.6
Wear Acetabular Insert				72	0.0	0.4
Implant Breakage Acetabular	1	0.1	1.4	67	0.0	0.4
Metal Related Pathology	1	0.1	1.4	66	0.0	0.4
Wear Head	1	0.1	1.4	44	0.0	0.2
Tumour				42	0.0	0.2
Implant Breakage Head				29	0.0	0.2
Heterotopic Bone				26	0.0	0.1
Wear Acetabulum				8	0.0	0.0
Osteonecrosis				2	0.0	0.0
Progression Of Disease				2	0.0	0.0
Synovitis				1	0.0	0.0
Other				290	0.1	1.6
<b>N Revision</b>	<b>72</b>	<b>4.9</b>	<b>100.0</b>	<b>18223</b>	<b>3.4</b>	<b>100.0</b>
<b>N Primary</b>	<b>1468</b>			<b>537228</b>		

Note: This table is restricted to revisions within 12.6 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 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**

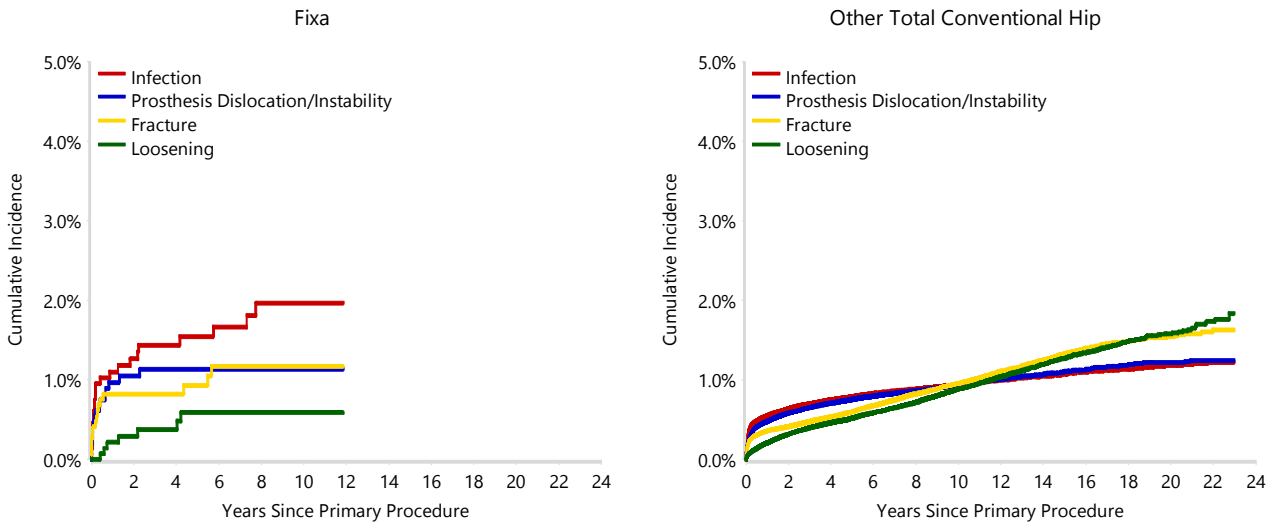


TABLE 5

**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 12.6 Years)**

Type of Revision	Fixa		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	24	33.3	6011	33.0
Acetabular Component	13	18.1	3348	18.4
THR (Femoral/Acetabular)	15	20.8	2042	11.2
Cement Spacer	1	1.4	609	3.3
Removal of Prostheses	1	1.4	94	0.5
Reinsertion of Components			28	0.2
Bipolar Head and Femoral			7	0.0
Total Femoral			7	0.0
Saddle			1	0.0
<b>N Major</b>	<b>54</b>	<b>75.0</b>	<b>12147</b>	<b>66.7</b>
Head/Insert	15	20.8	4679	25.7
Head Only	3	4.2	910	5.0
Minor Components			299	1.6
Insert Only			184	1.0
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
<b>N Minor</b>	<b>18</b>	<b>25.0</b>	<b>6076</b>	<b>33.3</b>
<b>TOTAL</b>	<b>72</b>	<b>100.0</b>	<b>18223</b>	<b>100.0</b>

Note: This table is restricted to revisions within 12.6 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 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	26	414
Hybrid (Femur Cemented)	46	1040
<b>TOTAL</b>	<b>72</b>	<b>1468</b>

**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	30	749
Ceramic/XLPE	19	484
Metal/XLPE	23	235
<b>TOTAL</b>	<b>72</b>	<b>1468</b>



**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	18	347
Posterior	28	644
<b>TOTAL</b>	<b>46</b>	<b>1006</b>

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	188
	QLD	47	1037
	WA	0	10
	SA	10	215
	ACT/NT	1	2
Other Total Conventional Hip	NSW	5205	157692
	VIC	4857	140635
	QLD	3746	93547
	WA	2546	63261
	SA	1815	49187
	TAS	452	18198
	ACT/NT	568	14708
<b>TOTAL</b>		<b>19261</b>	<b>538696</b>

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 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 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 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	11	134
2022	8	162
2023	4	133
<b>TOTAL</b>	<b>72</b>	<b>1468</b>

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
<b>Acetabular</b>					
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	72	1454
0772144-0772258	0	14
<b>TOTAL</b>	<b>72</b>	<b>1468</b>

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	1	89
Exeter V40	39	907
Hydra	8	120
Hydra-Fix	3	37
Mutars	0	1
Origin	1	83
Parva	4	32
SMR	0	1
Secur-Fit Plus	2	14
Short Exeter V40	6	55
VerSys	0	1
<b>TOTAL</b>	<b>72</b>	<b>1468</b>