

## Versafitcup DM Total Conventional Hip Investigation

Note: This analysis compares the Versafitcup DM 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 Versafitcup DM 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)
Versafitcup DM	58	1706	5932	0.98 (0.74, 1.26)
Other Total Conventional Hip	17399	492476	3075771	0.57 (0.56, 0.57)
<b>TOTAL</b>	<b>17457</b>	<b>494182</b>	<b>3081703</b>	<b>0.57 (0.56, 0.57)</b>

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 Versafitcup DM 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
Versafitcup DM	2.5 (1.9, 3.4)	3.3 (2.5, 4.3)	3.7 (2.9, 4.8)	3.7 (2.9, 4.8)	4.1 (3.1, 5.3)	4.1 (3.1, 5.3)	4.4 (3.3, 5.8)	
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
Versafitcup DM							
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
Versafitcup DM							
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.

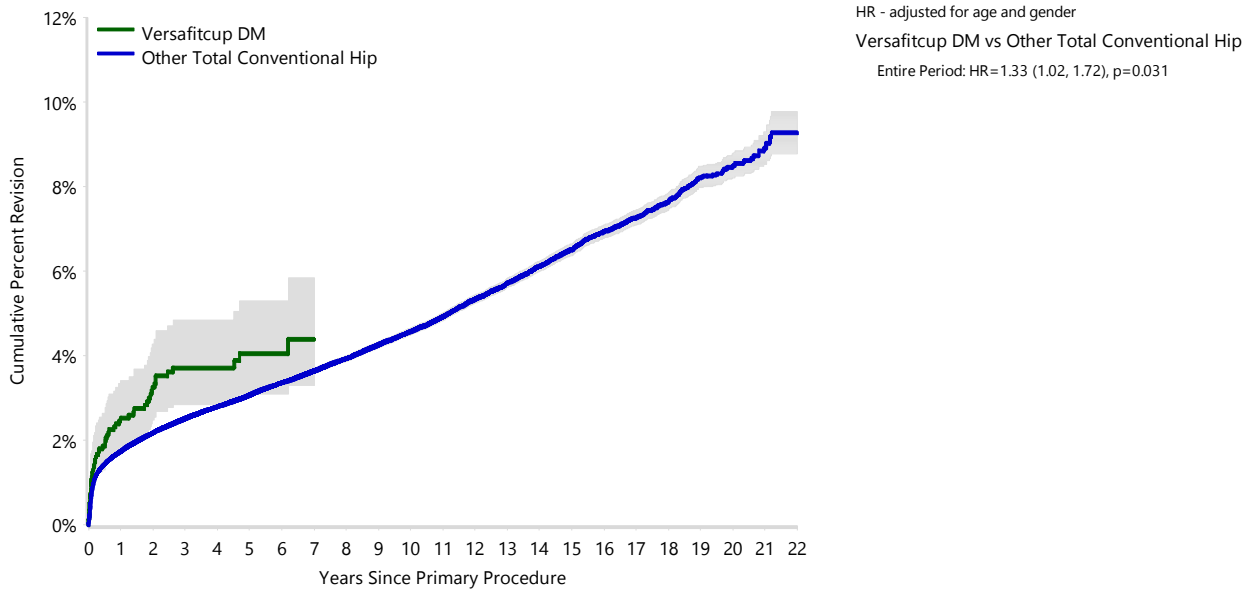
**FIGURE 1**

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

The yearly cumulative percent revision of the Versafitcup DM 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
Versafitcup DM	1706	1388	1121	870	692	499	322	157	36	17	14	5
Other Total Conventional Hip	492476	436146	387630	343379	298996	257590	219013	183380	151348	124914	102623	83478

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
Versafitcup DM	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	Versafitcup DM		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	48	82.8	14387	82.7
Fractured Neck Of Femur	4	6.9	1288	7.4
Osteonecrosis	3	5.2	794	4.6
Developmental Dysplasia	1	1.7	279	1.6
Rheumatoid Arthritis	1	1.7	185	1.1
Failed Internal Fixation	1	1.7	146	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
<b>TOTAL</b>	<b>58</b>	<b>100.0</b>	<b>17399</b>	<b>100.0</b>

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	Versafitcup DM			Other Total Conventional Hip		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	14	0.8	24.1	3892	0.8	23.8
Prosthesis Dislocation/Instability	2	0.1	3.4	3884	0.8	23.7
Fracture	21	1.2	36.2	3522	0.7	21.5
Loosening	10	0.6	17.2	3211	0.7	19.6
Pain	2	0.1	3.4	297	0.1	1.8
Leg Length Discrepancy	1	0.1	1.7	268	0.1	1.6
Malposition	2	0.1	3.4	240	0.0	1.5
Implant Breakage Stem				144	0.0	0.9
Lysis				137	0.0	0.8
Implant Breakage Acetabular Insert				110	0.0	0.7
Incorrect Sizing	2	0.1	3.4	99	0.0	0.6
Implant Breakage Acetabular	1	0.1	1.7	65	0.0	0.4
Wear Acetabular Insert				61	0.0	0.4
Metal Related Pathology				60	0.0	0.4
Wear Head				41	0.0	0.3
Tumour				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	3	0.2	5.2	250	0.1	1.5
<b>N Revision</b>	<b>58</b>	<b>3.4</b>	<b>100.0</b>	<b>16386</b>	<b>3.3</b>	<b>100.0</b>
<b>N Primary</b>	<b>1706</b>			<b>492476</b>		

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 Versafitcup DM 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**

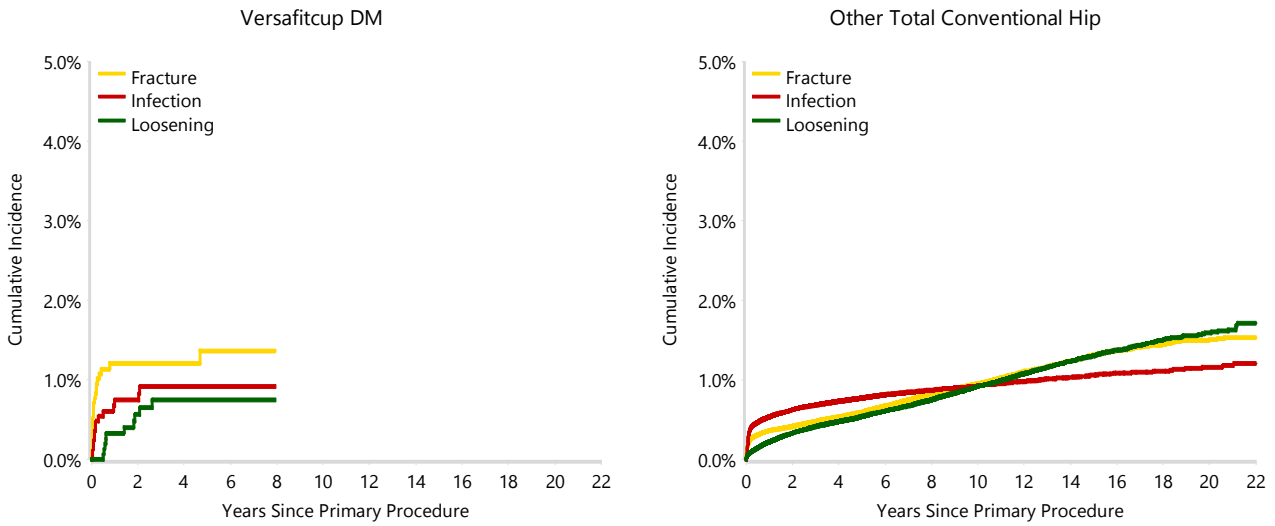


TABLE 5

**Type of Revision Performed for Primary Total Conventional Hip Replacement**

This analysis identifies the components used in the revision of the Versafitcup DM 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 Versafitcup DM 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	Versafitcup DM		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	26	44.8	5322	32.5
Acetabular Component	10	17.2	3065	18.7
THR (Femoral/Acetabular)	11	19.0	1827	11.1
Cement Spacer	1	1.7	600	3.7
Removal of Prostheses			91	0.6
Reinsertion of Components			27	0.2
Total Femoral			6	0.0
Bipolar Head and Femoral			5	0.0
Saddle			1	0.0
<b>N Major</b>	<b>48</b>	<b>82.8</b>	<b>10944</b>	<b>66.8</b>
Head/Insert	8	13.8	4142	25.3
Head Only			834	5.1
Minor Components	1	1.7	285	1.7
Insert Only	1	1.7	177	1.1
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
<b>N Minor</b>	<b>10</b>	<b>17.2</b>	<b>5442</b>	<b>33.2</b>
<b>TOTAL</b>	<b>58</b>	<b>100.0</b>	<b>16386</b>	<b>100.0</b>

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 Versafitcup DM 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 Versafitcup DM Primary Total Conventional Hip Replacement by Fixation**

Fixation	N Revised	N Total
Cemented	0	2
Cementless	54	1363
Hybrid (Femur Cemented)	4	341
<b>TOTAL</b>	<b>58</b>	<b>1706</b>

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

Bearing Surface	N Revised	N Total
Ceramic/Non XLPE	53	1497
Metal/Non XLPE	5	209
<b>TOTAL</b>	<b>58</b>	<b>1706</b>



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

Approach	N Revised	N Total
Anterior	36	1058
Lateral	0	53
Posterior	20	537
<b>TOTAL</b>	<b>56</b>	<b>1648</b>

Note: Excludes 58 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 Versafitcup DM 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
Versafitcup DM	NSW	20	340
	VIC	32	1078
	QLD	6	239
	WA	0	2
	SA	0	32
	TAS	0	15
Other Total Conventional Hip	NSW	4712	144459
	VIC	4317	127248
	QLD	3445	86692
	WA	2389	58886
	SA	1621	45606
	TAS	405	16367
	ACT/NT	510	13218
<b>TOTAL</b>		<b>17457</b>	<b>494182</b>

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 Versafitcup DM Primary Total Conventional Hip Replacement by Year of Implant**

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

Year of Implant	Number Revised	Total Number
2011	0	10
2012	0	12
2013	0	4
2014	1	19
2015	10	146
2016	12	193
2017	12	199
2018	10	194
2019	6	188
2020	4	229
2021	2	250
2022	1	262
<b>TOTAL</b>	<b>58</b>	<b>1706</b>

**TABLE 11****Revision Rates of Versafitcup DM 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 Versafitcup DM 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
<b>Acetabular</b>					
Versafitcup DM	012646MB-012664MB	DUAL MOBILITY ACETABULAR SHELL WITHOUT HOLES	NO	METAL	HA COATED

**Table 11: Revised Number of Versafitcup DM Primary Total Conventional Hip Replacement by Catalogue Number Range**

Acetabular Range	N Revised	N Total
012646MB-012664MB	58	1706
<b>TOTAL</b>	<b>58</b>	<b>1706</b>

TABLE 12

## Revision Rates of Versafitcup DM 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 Versafitcup DM Primary Total Conventional Hip Replacement by Femoral Stem Component

Femoral Stem Component	N Revised	N Total
AMiStem C	0	8
AMiStem H	1	135
CORAIL	0	6
CPCS	0	9
CPT	0	1
Collo-MIS	1	1
Cone	0	4
Exeter V40	0	1
GHE	3	14
LPS	0	2
M/L Taper	0	4
MasterLoc	1	23
MiniMax	5	125
Mistral	0	1
Modulus	0	1
Mutars	0	1
Polarstem	0	1
Quadra-C	3	292
Quadra-H	42	1018
Quadra-R	1	3
Redapt	0	1
Revision Hip	0	3
S-Rom	0	2
Taperloc	0	19
Wagner	0	4
X-Acta	1	27
<b>TOTAL</b>	<b>58</b>	<b>1706</b>