

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-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 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	54	1392	4365	1.24 (0.93, 1.61)
Other Total Conventional Hip	15809	452095	2716977	0.58 (0.57, 0.59)
TOTAL	15863	453487	2721342	0.58 (0.57, 0.59)

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 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
Versafitcup DM	3.0 (2.2, 4.1)	3.8 (2.9, 5.1)	4.3 (3.3, 5.6)	4.3 (3.3, 5.6)	4.8 (3.6, 6.3)	4.8 (3.6, 6.3)	
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.1, 2.2)	2.5 (2.5, 2.6)	2.8 (2.8, 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
Versafitcup DM							
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)	6.2 (6.1, 6.4)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Versafitcup DM							
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.

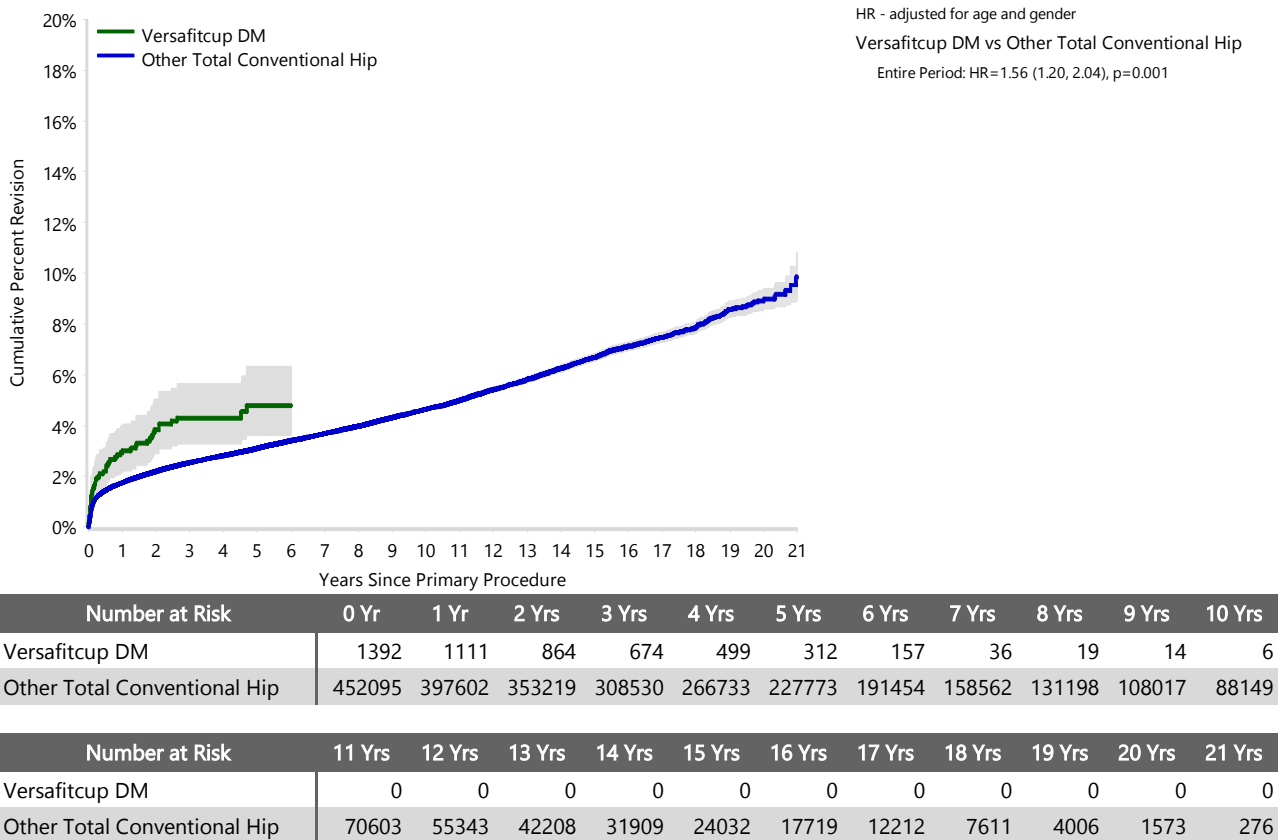
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the 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



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

Primary Diagnosis	Versafitcup DM		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	44	81.5	13071	82.7
Fractured Neck Of Femur	4	7.4	1160	7.3
Osteonecrosis	3	5.6	715	4.5
Developmental Dysplasia	1	1.9	247	1.6
Rheumatoid Arthritis	1	1.9	172	1.1
Failed Internal Fixation	1	1.9	139	0.9
Tumour			137	0.9
Other Inflammatory Arthritis			91	0.6
Fracture/Dislocation			47	0.3
Arthrodesis Takedown			16	0.1
Other			14	0.1
TOTAL	54	100.0	15809	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 (Follow-up Limited to 10.6 Years)

Revision Diagnosis	Versafitcup DM			Other Total Conventional Hip		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	2	0.1	3.7	3557	0.8	24.3
Infection	12	0.9	22.2	3422	0.8	23.3
Fracture	21	1.5	38.9	3125	0.7	21.3
Loosening	10	0.7	18.5	2863	0.6	19.5
Pain	1	0.1	1.9	277	0.1	1.9
Leg Length Discrepancy	1	0.1	1.9	258	0.1	1.8
Malposition	2	0.1	3.7	219	0.0	1.5
Implant Breakage Stem				127	0.0	0.9
Lysis				106	0.0	0.7
Implant Breakage Acetabular Insert				98	0.0	0.7
Incorrect Sizing	2	0.1	3.7	92	0.0	0.6
Implant Breakage Acetabular				60	0.0	0.4
Metal Related Pathology				55	0.0	0.4
Wear Acetabular Insert				49	0.0	0.3
Wear Head				39	0.0	0.3
Tumour				36	0.0	0.2
Implant Breakage Head				24	0.0	0.2
Heterotopic Bone				22	0.0	0.2
Wear Acetabulum				6	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	5.6	217	0.0	1.5
N Revision	54	3.9	100.0	14656	3.2	100.0
N Primary	1392			452095		

Note: This table is restricted to revisions within 10.6 years for all groups to allow a time-matched comparison of revisions.

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 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

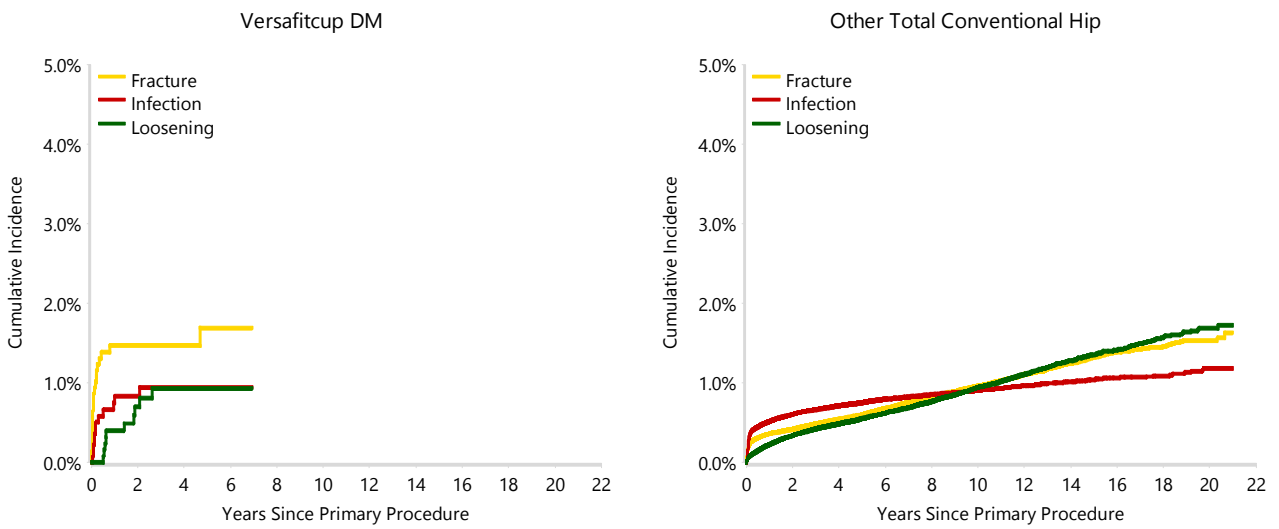


TABLE 5

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 10.6 Years)

Type of Revision	Versafitcup DM		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	26	48.1	4738	32.3
Acetabular Component	9	16.7	2779	19.0
THR (Femoral/Acetabular)	8	14.8	1589	10.8
Cement Spacer	1	1.9	566	3.9
Removal of Prostheses			93	0.6
Reinsertion of Components			25	0.2
Total Femoral			5	0.0
Bipolar Head and Femoral			4	0.0
Saddle			1	0.0
N Major	44	81.5	9800	66.9
Head/Insert	8	14.8	3659	25.0
Head Only			764	5.2
Minor Components	1	1.9	259	1.8
Insert Only	1	1.9	170	1.2
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	10	18.5	4856	33.1
TOTAL	54	100.0	14656	100.0

Note: This table is restricted to revisions within 10.6 years for all groups to allow a time-matched comparison of revisions.

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 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	1
Cementless	50	1115
Hybrid (Femur Cemented)	4	276
TOTAL	54	1392

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	49	1242
Metal/Non XLPE	5	150
TOTAL	54	1392

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	34	897
Lateral	0	45
Posterior	18	394
TOTAL	52	1336

Note: Excludes 56 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	303
	VIC	29	846
	QLD	5	203
	WA	0	2
	SA	0	30
	TAS	0	8
Other Total Conventional Hip	NSW	4281	132696
	VIC	3954	116153
	QLD	3141	79920
	WA	2184	53950
	SA	1415	41899
	TAS	372	15090
	ACT/NT	462	12387
TOTAL		15863	453487

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 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 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 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	9	139
2016	11	184
2017	12	196
2018	10	182
2019	6	185
2020	3	229
2021	2	232
TOTAL	54	1392

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
Acetabular					
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	54	1392
TOTAL	54	1392

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	2
AMiStem H	1	71
CORAIL	0	6
CPCS	0	9
Collo-MIS	1	1
Cone	0	4
Exeter V40	0	1
GHE	3	14
LPS	0	2
M/L Taper	0	4
MasterLoc	0	20
MiniMax	5	120
Mistral	0	1
Modulus	0	1
Mutars	0	1
Polarstem	0	1
Quadra-C	3	235
Quadra-H	39	844
Quadra-R	1	3
Redapt	0	1
Revision Hip	0	3
S-Rom	0	2
Taperloc	0	17
Wagner	0	4
X-Acta	1	25
TOTAL	54	1392