

## UniSyn Total Conventional Hip Investigation

Note: This analysis compares the UniSyn femoral stem 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 UniSyn 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)
UniSyn	61	466	4636	1.32 (1.01, 1.69)
Other Total Conventional Hip	15859	453455	2721137	0.58 (0.57, 0.59)
<b>TOTAL</b>	<b>15920</b>	<b>453921</b>	<b>2725773</b>	<b>0.58 (0.58, 0.59)</b>

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 UniSyn 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
UniSyn	3.2 (2.0, 5.3)	5.5 (3.7, 8.0)	5.9 (4.1, 8.5)	6.1 (4.3, 8.8)	6.6 (4.7, 9.3)	8.1 (5.9, 11.0)	9.1 (6.8, 12.3)
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
UniSyn	10.3 (7.8, 13.7)	11.7 (8.9, 15.2)	12.0 (9.2, 15.7)	13.5 (10.4, 17.4)	13.5 (10.4, 17.4)	15.5 (12.0, 19.9)	15.5 (12.0, 19.9)
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
UniSyn	16.3 (12.6, 21.0)	18.3 (13.9, 23.7)					
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.

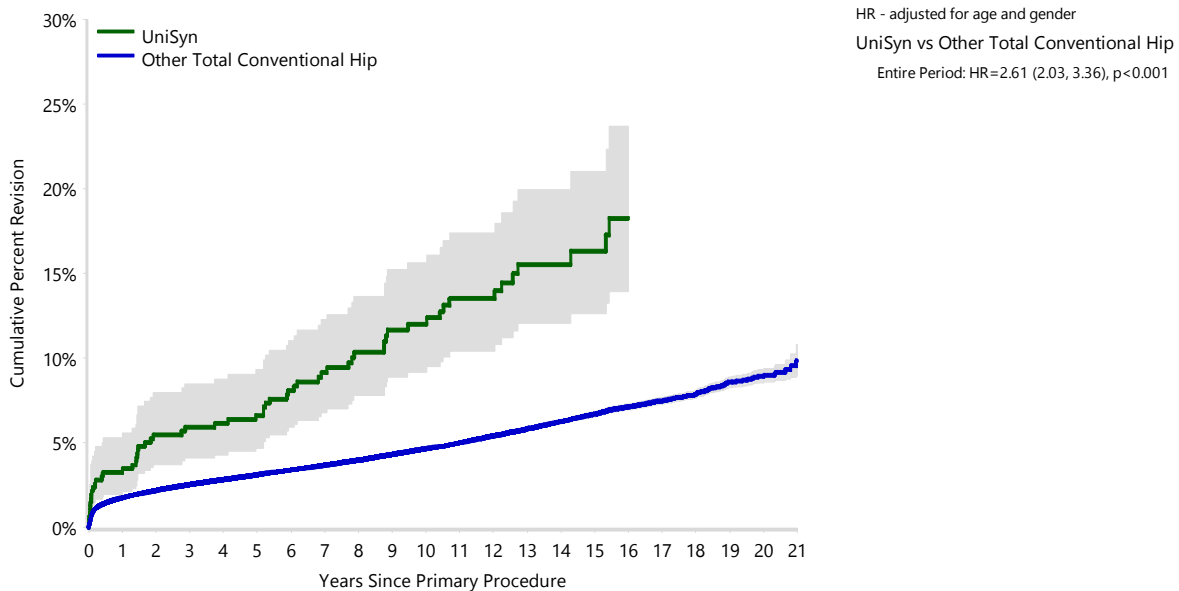
**FIGURE 1**

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

The yearly cumulative percent revision of the UniSyn 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
UniSyn	466	438	421	414	403	387	365	331	292	258	243
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
UniSyn	216	187	147	114	93	69	29	4	0	0	0
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**

Primary Diagnosis	UniSyn		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	40	65.6	13112	82.7
Fractured Neck Of Femur	1	1.6	1164	7.3
Osteonecrosis	6	9.8	718	4.5
Developmental Dysplasia	8	13.1	247	1.6
Rheumatoid Arthritis	1	1.6	173	1.1
Failed Internal Fixation	2	3.3	140	0.9
Tumour			137	0.9
Other Inflammatory Arthritis			91	0.6
Fracture/Dislocation			47	0.3
Arthrodesis Takedown	2	3.3	16	0.1
Other	1	1.6	14	0.1
<b>TOTAL</b>	<b>61</b>	<b>100.0</b>	<b>15859</b>	<b>100.0</b>

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 18.7 Years)

Revision Diagnosis	Number	UniSyn		Other Total Conventional Hip		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	15	3.2	24.6	3715	0.8	23.5
Infection	7	1.5	11.5	3547	0.8	22.4
Fracture	5	1.1	8.2	3435	0.8	21.7
Loosening	13	2.8	21.3	3220	0.7	20.3
Pain				286	0.1	1.8
Leg Length Discrepancy				260	0.1	1.6
Malposition				225	0.0	1.4
Lysis	1	0.2	1.6	182	0.0	1.1
Implant Breakage Stem	6	1.3	9.8	151	0.0	1.0
Implant Breakage Acetabular Insert				114	0.0	0.7
Incorrect Sizing	2	0.4	3.3	95	0.0	0.6
Wear Acetabular Insert				89	0.0	0.6
Metal Related Pathology	8	1.7	13.1	68	0.0	0.4
Implant Breakage Acetabular	2	0.4	3.3	66	0.0	0.4
Wear Head				45	0.0	0.3
Tumour				37	0.0	0.2
Implant Breakage Head				30	0.0	0.2
Heterotopic Bone				23	0.0	0.1
Wear Acetabulum				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	2	0.4	3.3	228	0.1	1.4
<b>N Revision</b>	<b>61</b>	<b>13.1</b>	<b>100.0</b>	<b>15829</b>	<b>3.5</b>	<b>100.0</b>
<b>N Primary</b>	<b>466</b>			<b>453455</b>		

Note: This table is restricted to revisions within 18.7 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 UniSyn 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**

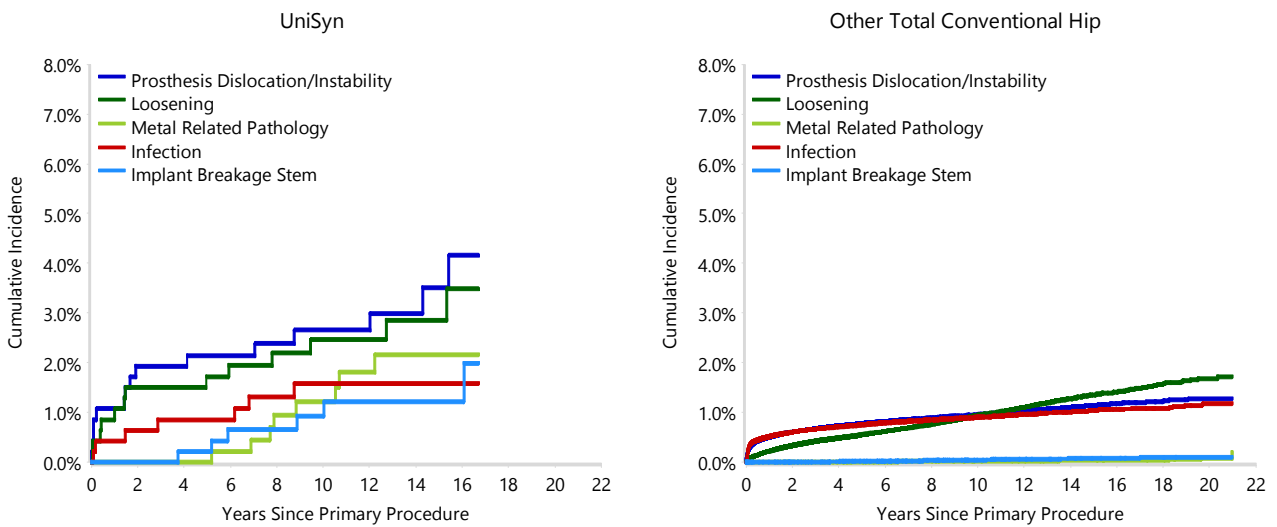


TABLE 5

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

This analysis identifies the components used in the revision of the UniSyn 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 UniSyn 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 18.7 Years)**

Type of Revision	UniSyn		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	11	18.0	5148	32.5
Acetabular Component	28	45.9	3050	19.3
THR (Femoral/Acetabular)	7	11.5	1808	11.4
Cement Spacer	1	1.6	594	3.8
Removal of Prostheses			97	0.6
Reinsertion of Components			25	0.2
Total Femoral			6	0.0
Bipolar Head and Femoral			4	0.0
Saddle			1	0.0
<b>N Major</b>	<b>47</b>	<b>77.0</b>	<b>10733</b>	<b>67.8</b>
Head/Insert	3	4.9	3868	24.4
Head Only	8	13.1	778	4.9
Minor Components	3	4.9	274	1.7
Insert Only			172	1.1
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
<b>N Minor</b>	<b>14</b>	<b>23.0</b>	<b>5096</b>	<b>32.2</b>
<b>TOTAL</b>	<b>61</b>	<b>100.0</b>	<b>15829</b>	<b>100.0</b>

Note: This table is restricted to revisions within 18.7 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 UniSyn 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 UniSyn Primary Total Conventional Hip Replacement by Fixation**

Fixation	N Revised	N Total
Cementless	59	449
Hybrid (Femur Cemented)	0	2
Reverse Hybrid (Femur Cementless)	2	15
<b>TOTAL</b>	<b>61</b>	<b>466</b>

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

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	32	328
Ceramic/Non XLPE	1	2
Ceramic/XLPE	1	2
Metal/Metal	23	97
Metal/Non XLPE	2	25
Metal/XLPE	2	12
<b>TOTAL</b>	<b>61</b>	<b>466</b>



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

Approach	N Revised	N Total
Lateral	0	7
Posterior	1	33
<b>TOTAL</b>	<b>1</b>	<b>40</b>

Note: Excludes 426 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 UniSyn 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
UniSyn	NSW	57	439
	VIC	3	13
	QLD	0	4
	WA	0	3
	ACT/NT	1	7
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
<b>TOTAL</b>		<b>15920</b>	<b>453921</b>

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

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

Year of Implant	Number Revised	Total Number
2002	0	1
2003	3	14
2004	4	41
2005	10	74
2006	5	33
2007	11	37
2008	9	46
2009	8	48
2010	2	36
2011	4	22
2012	0	19
2013	2	23
2014	2	27
2015	0	23
2016	1	17
2017	0	5
<b>TOTAL</b>	<b>61</b>	<b>466</b>

TABLE 11

**Revision Rates of UniSyn 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 UniSyn 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>Femoral Stem</b>					
UniSyn	3460419280-3460421300	PLASMA STANDARD PROXIMAL BODY	NO	METAL	
UniSyn	346142222A-346143238A	PLASMA STANDARD PROXIMAL BODY	NO	METAL	HA COATED
UniSyn	346152222A-346153238A	PLASMA HA STANDARD PROXIMAL BODY	NO	METAL	HA COATED
UniSyn	347342200A-347343000A	PLASMA CALCAR PROXIMAL BODY	NO	METAL	HA COATED

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

Femoral Stem Range	N Revised	N Total
3460419280-3460421300	0	1
346142222A-346143238A	2	5
346152222A-346153238A	57	452
347342200A-347343000A	2	8
<b>TOTAL</b>	<b>61</b>	<b>466</b>

TABLE 12

## Revision Rates of UniSyn 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 UniSyn Primary Total Conventional Hip Replacement by Acetabular Component

Acetabular Component	N Revised	N Total
ABGII	0	1
Acetabular Shell (Global)	3	52
BHR	0	3
Brunswick	2	6
Cer-Met	10	74
Custom Made (Anatomics)	0	1
Delta-One-TT	1	1
Delta-TT	1	1
Duraloc	0	1
Durom	0	1
FMP	0	1
Fin II	14	158
Fitmore	1	1
Icon	23	88
Lineage	0	8
Muller	0	9
PINNACLE	0	6
Procotyl E	0	1
Procotyl L	1	4
R3	0	4
Ringloc	0	4
S-Rom	0	1
SPH-Blind	4	23
SPH-Revision	0	1
Trabecular Metal (Shell)	0	2
Transcend	0	2
Trident (Shell)	1	10
Trilogy	0	1
Versafitcup CC	0	1
<b>TOTAL</b>	<b>61</b>	<b>466</b>