

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-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 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	70	466	5168	1.35 (1.06, 1.71)
Other Total Conventional Hip	19249	538541	3454641	0.56 (0.55, 0.57)
TOTAL	19319	539007	3459809	0.56 (0.55, 0.57)

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 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	8 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)	9.0 (6.7, 12.1)	10.4 (7.8, 13.6)
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
UniSyn	12.1 (9.3, 15.6)	12.4 (9.6, 16.0)	13.8 (10.7, 17.6)	13.8 (10.7, 17.6)	16.6 (13.1, 21.0)	16.6 (13.1, 21.0)	17.7 (14.0, 22.3)	19.1 (15.0, 24.0)
Other Total Conventional Hip	4.2 (4.2, 4.3)	4.5 (4.5, 4.6)	4.9 (4.8, 5.0)	5.3 (5.2, 5.4)	5.7 (5.6, 5.8)	6.1 (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
UniSyn	20.8 (16.3, 26.3)	21.9 (17.1, 27.9)					
Other Total Conventional Hip	7.3 (7.1, 7.4)	7.7 (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.

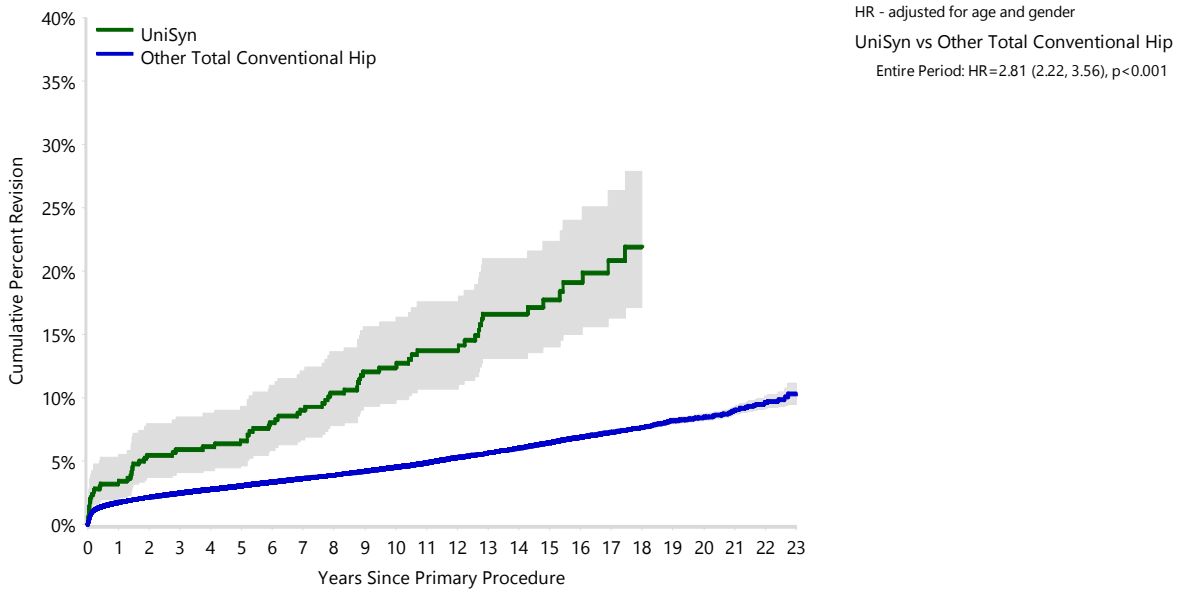
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the 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	11 Yrs
UniSyn	466	438	421	414	403	391	380	361	332	296	271	241
Other Total Conventional Hip	538541	475645	425806	377168	332911	288979	247789	209621	174574	143301	117825	96251

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
UniSyn	223	195	168	134	102	80	62	23	4	0	0	0
Other Total Conventional Hip	77815	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	UniSyn		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	46	65.7	15951	82.9
Fractured Neck Of Femur	2	2.9	1420	7.4
Osteonecrosis	6	8.6	859	4.5
Developmental Dysplasia	9	12.9	320	1.7
Rheumatoid Arthritis	1	1.4	208	1.1
Failed Internal Fixation	2	2.9	151	0.8
Tumour			149	0.8
Other Inflammatory Arthritis	1	1.4	106	0.6
Fracture/Dislocation			53	0.3
Other	1	1.4	17	0.1
Arthrodesis Takedown	2	2.9	15	0.1
TOTAL	70	100.0	19249	100.0

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 20.7 Years)

Revision Diagnosis	Number	UniSyn		Other Total Conventional Hip		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	7	1.5	10.0	4502	0.8	23.4
Prosthesis Dislocation/Instability	17	3.6	24.3	4380	0.8	22.8
Fracture	6	1.3	8.6	4262	0.8	22.2
Loosening	13	2.8	18.6	3819	0.7	19.9
Pain				335	0.1	1.7
Leg Length Discrepancy				291	0.1	1.5
Malposition				269	0.0	1.4
Lysis	3	0.6	4.3	212	0.0	1.1
Implant Breakage Stem	7	1.5	10.0	192	0.0	1.0
Implant Breakage Acetabular Insert	1	0.2	1.4	131	0.0	0.7
Wear Acetabular Insert				110	0.0	0.6
Incorrect Sizing	2	0.4	2.9	103	0.0	0.5
Metal Related Pathology	10	2.1	14.3	83	0.0	0.4
Implant Breakage Acetabular	2	0.4	2.9	72	0.0	0.4
Wear Head				47	0.0	0.2
Tumour				44	0.0	0.2
Implant Breakage Head				33	0.0	0.2
Heterotopic Bone				26	0.0	0.1
Wear Acetabulum				11	0.0	0.1
Osteonecrosis				2	0.0	0.0
Progression Of Disease				2	0.0	0.0
Synovitis				1	0.0	0.0
Other	2	0.4	2.9	293	0.1	1.5
N Revision	70	15.0	100.0	19220	3.6	100.0
N Primary	466			538541		

Note: This table is restricted to revisions within 20.7 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 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

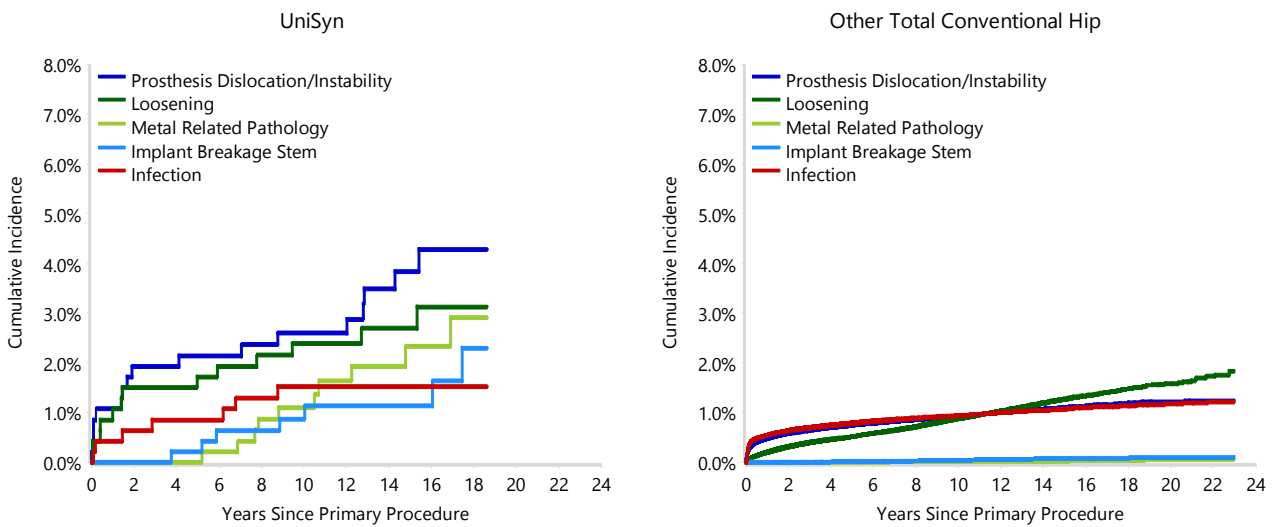


TABLE 5

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 20.7 Years)

Type of Revision	UniSyn		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	13	18.6	6343	33.0
Acetabular Component	34	48.6	3602	18.7
THR (Femoral/Acetabular)	8	11.4	2244	11.7
Cement Spacer	1	1.4	620	3.2
Removal of Prostheses			99	0.5
Reinsertion of Components			28	0.1
Total Femoral			9	0.0
Bipolar Head and Femoral			7	0.0
Saddle			1	0.0
N Major	56	80.0	12953	67.4
Head/Insert	3	4.3	4839	25.2
Head Only	8	11.4	926	4.8
Minor Components	3	4.3	311	1.6
Insert Only			187	1.0
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	14	20.0	6267	32.6
TOTAL	70	100.0	19220	100.0

Note: This table is restricted to revisions within 20.7 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 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	68	449
Hybrid (Femur Cemented)	0	2
Reverse Hybrid (Femur Cementless)	2	15
TOTAL	70	466

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	37	328
Ceramic/Non XLPE	1	2
Ceramic/XLPE	1	2
Metal/Metal	27	97
Metal/Non XLPE	2	25
Metal/XLPE	2	12
TOTAL	70	466

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
TOTAL	1	40

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	66	439
	VIC	3	13
	QLD	0	4
	WA	0	3
	ACT/NT	1	7
Other Total Conventional Hip	NSW	5207	157707
	VIC	4859	140681
	QLD	3791	94582
	WA	2546	63265
	SA	1825	49398
	TAS	452	18198
	ACT/NT	569	14710
TOTAL		19319	539007

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 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 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 UniSyn Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2002	0	1
2003	3	14
2004	5	41
2005	10	74
2006	6	33
2007	12	37
2008	9	46
2009	11	48
2010	2	36
2011	4	22
2012	0	19
2013	2	23
2014	5	27
2015	0	23
2016	1	17
2017	0	5
TOTAL	70	466

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
Femoral Stem					
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	3	5
346152222A-346153238A	65	452
347342200A-347343000A	2	8
TOTAL	70	466

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)	5	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	17	158
Fitmore	1	1
Icon	27	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
TOTAL	70	466