

Univers 3D/Univers 3D Total Stemmed Shoulder Investigation

Note: This analysis compares the Univers 3D/Univers 3D humeral stem/glenoid combination with all other total stemmed shoulder prostheses.

This combination 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 prostheses with no recorded use in 2021 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Stemmed Shoulder Replacement

The revision rate of the Univers 3D/Univers 3D total stemmed shoulder combination is compared to all other total stemmed shoulder prostheses.

Table 1: Revision Rates of Primary Total Stemmed Shoulder Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Univers 3D/Univers 3D	16	34	289	5.54 (3.16, 8.99)
Other Total Stemmed Shoulder	698	8757	49188	1.42 (1.32, 1.53)
TOTAL	714	8791	49477	1.44 (1.34, 1.55)

Note: Prostheses no longer used in 2021 are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

The yearly cumulative percent revision of the Univers 3D/Univers 3D total stemmed shoulder combination is compared to all other total stemmed shoulder prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Univers 3D/Univers 3D	5.9 (1.5, 21.5)	14.7 (6.4, 31.8)	14.7 (6.4, 31.8)	17.9 (8.4, 35.5)	21.2 (10.7, 39.4)
Other Total Stemmed Shoulder	2.9 (2.5, 3.2)	4.8 (4.3, 5.2)	5.8 (5.3, 6.4)	6.5 (6.0, 7.1)	7.2 (6.6, 7.8)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Univers 3D/Univers 3D	27.7 (15.4, 46.6)	31.0 (18.0, 50.1)	34.3 (20.6, 53.5)	34.3 (20.6, 53.5)	44.7 (29.2, 63.7)
Other Total Stemmed Shoulder	7.8 (7.2, 8.5)	8.5 (7.9, 9.3)	9.6 (8.8, 10.4)	10.5 (9.7, 11.4)	11.5 (10.6, 12.5)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Univers 3D/Univers 3D	44.7 (29.2, 63.7)	48.9 (32.7, 68.0)	48.9 (32.7, 68.0)		
Other Total Stemmed Shoulder	12.6 (11.5, 13.8)	13.8 (12.6, 15.2)	15.0 (13.6, 16.6)	15.4 (13.9, 17.1)	

Note: Prostheses no longer used in 2021 are excluded from the comparator.

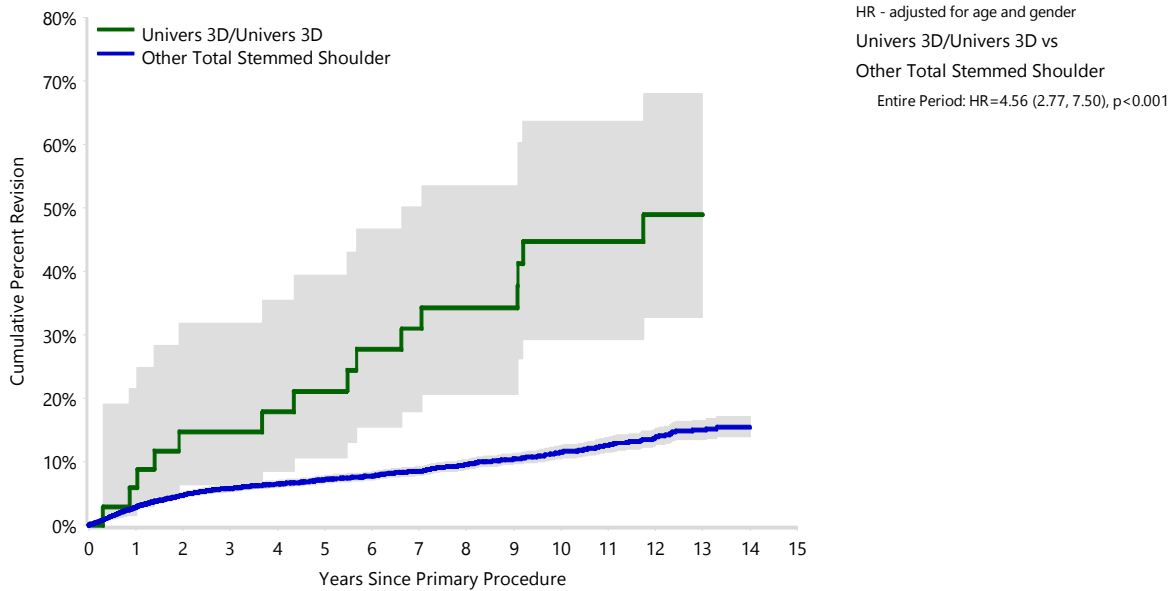
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

The yearly cumulative percent revision of the Univers 3D/Univers 3D total stemmed shoulder combination is compared to all other total stemmed shoulder 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 Stemmed Shoulder Replacement



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Univers 3D/Univers 3D	34	32	29	27	26	24	22	21
Other Total Stemmed Shoulder	8757	7882	7052	6183	5302	4493	3683	2857

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Univers 3D/Univers 3D	19	19	15	14	12	9	4	1
Other Total Stemmed Shoulder	2145	1649	1267	982	742	460	193	37

Note: Prostheses no longer used in 2021 are excluded from the comparator.

TABLE 3**Primary Diagnosis for Revised Primary Total Stemmed Shoulder 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 stemmed shoulder prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Stemmed Shoulder Replacement

Primary Diagnosis	Uniers 3D/Uniers 3D		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Osteoarthritis	16	100.0	646	92.6
Osteonecrosis			14	2.0
Fracture			11	1.6
Rheumatoid Arthritis			9	1.3
Rotator Cuff Arthropathy			9	1.3
Other Inflammatory Arthritis			5	0.7
Instability			4	0.6
TOTAL	16	100.0	698	100.0

Note: Prostheses no longer used in 2021 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 Stemmed Shoulder Replacement - Reason for Revision

Revision Diagnosis	Univers 3D/Univers 3D			Other Total Stemmed Shoulder		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency	1	2.9	6.3	237	2.7	34.0
Instability/Dislocation	1	2.9	6.3	187	2.1	26.8
Loosening	11	32.4	68.8	112	1.3	16.0
Infection				44	0.5	6.3
Fracture	1	2.9	6.3	21	0.2	3.0
Pain				15	0.2	2.1
Arthrofibrosis				12	0.1	1.7
Wear Glenoid Insert	1	2.9	6.3	10	0.1	1.4
Malposition				9	0.1	1.3
Incorrect Sizing				8	0.1	1.1
Lysis				8	0.1	1.1
Implant Breakage Glenoid				7	0.1	1.0
Implant Breakage Glenoid Insert				7	0.1	1.0
Dissociation				6	0.1	0.9
Metal Related Pathology				6	0.1	0.9
Progression Of Disease				2	0.0	0.3
Other	1	2.9	6.3	7	0.1	1.0
N Revision	16	47.1	100.0	698	8.0	100.0
N Primary	34			8757		

Note: Prostheses no longer used in 2021 are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Stemmed Shoulder 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 Unvers 3D/Unvers 3D total stemmed shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total stemmed shoulder prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Stemmed Shoulder Replacement

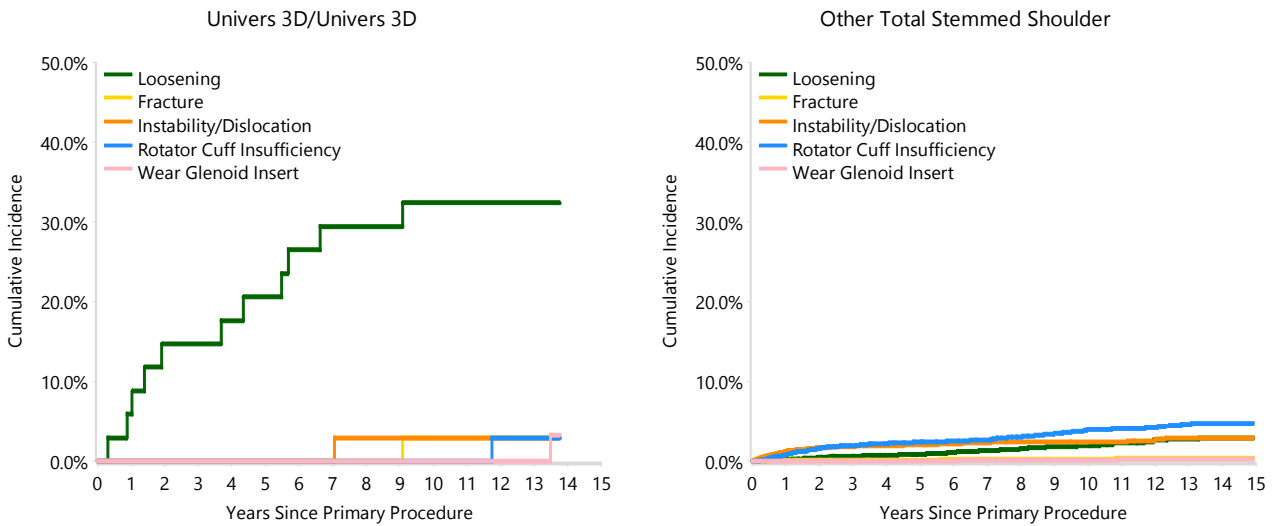


TABLE 5

Type of Revision Performed for Primary Total Stemmed Shoulder Replacement

This analysis identifies the components used in the revision of the Univers 3D/Univers 3D total stemmed shoulder combination and compares it to the components used in the revision of all other total stemmed shoulder 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 stemmed shoulder prostheses i.e. is there a difference in the type of revision undertaken for the Univers 3D/Univers 3D total stemmed shoulder combination compared to all other total stemmed shoulder prostheses.

Table 5: Primary Total Stemmed Shoulder Replacement - Type of Revision

Type of Revision	Univers 3D/Univers 3D		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Humeral Component			380	54.4
Humeral/Glenoid	8	50.0	197	28.2
Glenoid Component	4	25.0	28	4.0
Cement Spacer			22	3.2
Removal of Prostheses	1	6.3	6	0.9
Reinsertion of Components			1	0.1
N Major	13	81.3	634	90.8
Head Only			53	7.6
Reoperation			5	0.7
Minor Components	1	6.3	3	0.4
Head/Insert	2	12.5	2	0.3
Cement Only			1	0.1
N Minor	3	18.8	64	9.2
TOTAL	16	100.0	698	100.0

Note: Prostheses no longer used in 2021 are excluded from the comparator.

TABLE 6**Revision Rates of Uniers 3D/Uniers 3D Primary Total Stemmed Shoulder 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 Uniers 3D/Uniers 3D Primary Total Stemmed Shoulder Replacement by Fixation

Fixation	N Revised	N Total
Cementless	14	27
Hybrid (Glenoid Cemented)	2	7
TOTAL	16	34

TABLE 7**Revision Rates of Primary Total Stemmed Shoulder Replacement by State**

This enables a state by state variation to be identified for the Univers 3D/Uniers 3D total stemmed shoulder combination and provides the comparative data for each of the states for all other total stemmed shoulder 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 7: Revised Number of Primary Total Stemmed Shoulder Replacement by State

Component	State	N Revised	N Total
Uniers 3D/Uniers 3D	VIC	14	28
	QLD	1	3
	WA	0	2
	TAS	1	1
	Other Total Stemmed Shoulder	NSW	191
	VIC	157	2055
	QLD	99	1467
	WA	134	1184
	SA	67	1015
	TAS	26	201
	ACT/NT	24	222
TOTAL		714	8791

Note: Prostheses no longer used in 2021 are excluded from the comparator.

TABLE 8**Number of Revisions of Uniers 3D/Uniers 3D Primary Total Stemmed Shoulder Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Uniers 3D/Uniers 3D total stemmed shoulder combination. 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 8: Number of Revisions of Uniers 3D/Uniers 3D Primary Total Stemmed Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	1	1
2006	3	6
2007	8	16
2008	4	11
TOTAL	16	34

TABLE 9

Revision Rates of Univers 3D/Univers 3D Primary Total Stemmed Shoulder 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 Uniers 3D/Univers 3D 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
Humeral Stem				
Uniers 3D	AR910005-AR910015	HUMERAL STEM	NO	METAL
Glenoid				
Uniers 3D	AR910101-AR910103	METAL BACKED GLENOID	NO	METAL
Uniers 3D	AR910401-AR910403	ALL POLY KEELED GLENOID	YES	NON CROSS-LINKED POLYETHYLENE

Table 9: Revised Number of Uniers 3D/Univers 3D Primary Total Stemmed Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glenoid Range	N Revised	N Total
AR910005-AR910015	AR910101-AR910103	14	27
	AR910401-AR910403	2	7
TOTAL		16	34