Global Unite/Global Unite Hemi Stemmed Anatomic Shoulder Investigation

Note: This analysis compares the Global Unite/Global Unite humeral stem/head combination with all other hemi stemmed anatomic 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-2023.

Note: Procedures using prostheses with no recorded use in 2022 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Hemi Stemmed Anatomic Shoulder Replacement

The revision rate of the Global Unite/Global Unite hemi stemmed anatomic shoulder combination is compared to all other hemi stemmed anatomic shoulder prostheses.

Table 1: Revision Rates of Primary Hemi Stemmed Anatomic Shoulder Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Global Unite/Global Unite	40	208	1103	3.63 (2.59, 4.94)
Other Hemi Stemmed Anatomic Shoulder	365	3634	22767	1.60 (1.44, 1.78)
TOTAL	**405**	**3842**	**23870**	**1.70 (1.54, 1.87)**

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Hemi Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the Global Unite/Global Unite hemi stemmed anatomic shoulder combination is compared to all other hemi stemmed anatomic shoulder prostheses.

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

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs
Global Unite/Global Unite	7.3 (4.4, 11.7)	14.9 (10.6, 20.6)	17.6 (13.0, 23.7)	18.8 (14.0, 25.1)	20.1 (15.1, 26.5)	20.1 (15.1, 26.5)
Other Hemi Stemmed Anatomic Shoulder	3.2 (2.7, 3.8)	6.5 (5.7, 7.4)	8.3 (7.4, 9.4)	9.4 (8.4, 10.5)	10.2 (9.2, 11.3)	10.7 (9.6, 11.9)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs
Global Unite/Global Unite	20.1 (15.1, 26.5)	20.1 (15.1, 26.5)			
Other Hemi Stemmed Anatomic Shoulder	11.1 (10.0, 12.3)	11.5 (10.4, 12.7)	12.1 (10.9, 13.4)	12.6 (11.3, 14.0)	12.9 (11.6, 14.3)

CPR	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Global Unite/Global Unite					
Other Hemi Stemmed Anatomic Shoulder	13.1 (11.8, 14.5)	13.8 (12.3, 15.4)	14.3 (12.5, 16.2)	17.0 (13.6, 21.1)	

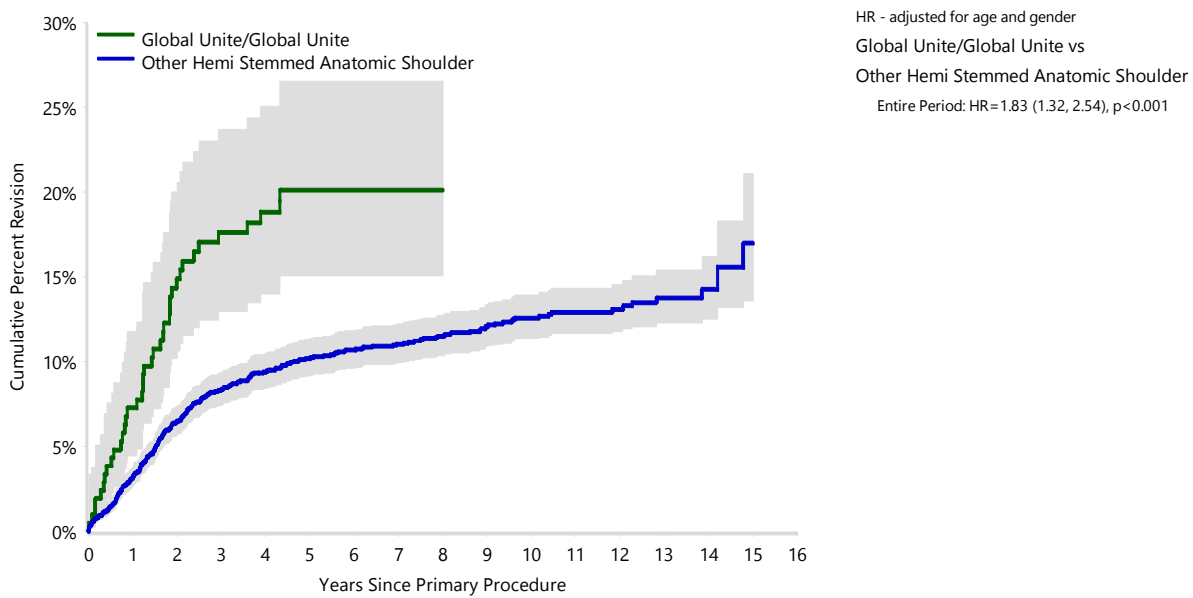Note: Prostheses no longer used in 2022 are excluded from the comparator.

FIGURE 1

Yearly Cumulative Percent Revision of Primary Hemi Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the Global Unite/Global Unite hemi stemmed anatomic shoulder combination is compared to all other hemi stemmed anatomic 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 Hemi Stemmed Anatomic Shoulder Replacement

HR - adjusted for age and gender
Global Unite/Global Unite vs
Other Hemi Stemmed Anatomic Shoulder
Entire Period: HR=1.83 (1.32, 2.54), p<0.001

Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
Global Unite/Global Unite	208	188	162	143	131	117	101	75	48
Other Hemi Stemmed Anatomic Shoulder	3634	3225	2825	2490	2215	1992	1765	1555	1330

Number at Risk	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Global Unite/Global Unite	32	7	0	0	0	0	0	0
Other Hemi Stemmed Anatomic Shoulder	1107	889	671	462	297	160	43	5

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 3

Primary Diagnosis for Revised Primary Hemi Stemmed Anatomic 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 hemi stemmed anatomic shoulder prostheses.

Table 3: Primary Diagnosis for Revised Primary Hemi Stemmed Anatomic Shoulder Replacement

Primary Diagnosis	Global Unite/Global Unite		Other Hemi Stemmed Anatomic Shoulder	
	Number	Percent	Number	Percent
Fracture	37	92.5	202	55.3
Osteoarthritis	1	2.5	111	30.4
Rotator Cuff Arthropathy			17	4.7
Osteonecrosis	2	5.0	16	4.4
Rheumatoid Arthritis			6	1.6
Tumour			6	1.6
Instability			3	0.8
Other Inflammatory Arthritis			3	0.8
Other			1	0.3
TOTAL	**40**	**100.0**	**365**	**100.0**

Note: Prostheses no longer used in 2022 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 Hemi Stemmed Anatomic Shoulder Replacement - Reason for Revision (Follow-up Limited to 10.8 Years)

Revision Diagnosis	Global Unite/Global Unite			Other Hemi Stemmed Anatomic Shoulder		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency	10	4.8	25.0	81	2.2	22.7
Instability/Dislocation	6	2.9	15.0	67	1.8	18.8
Glenoid Erosion	5	2.4	12.5	50	1.4	14.0
Infection	4	1.9	10.0	44	1.2	12.3
Pain	3	1.4	7.5	36	1.0	10.1
Fracture	4	1.9	10.0	25	0.7	7.0
Loosening	2	1.0	5.0	24	0.7	6.7
Arthrofibrosis	1	0.5	2.5	7	0.2	2.0
Dissociation	1	0.5	2.5	7	0.2	2.0
Malposition	1	0.5	2.5	4	0.1	1.1
Incorrect Sizing	2	1.0	5.0	3	0.1	0.8
Tumour				3	0.1	0.8
Heterotopic Bone				1	0.0	0.3
Implant Breakage Glenoid				1	0.0	0.3
Lysis				1	0.0	0.3
Osteonecrosis				1	0.0	0.3
Other	1	0.5	2.5	2	0.1	0.6
N Revision	40	19.2	100.0	357	9.8	100.0
N Primary	208			3634		

Note: This table is restricted to revisions within 10.8 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2022 are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Hemi Stemmed Anatomic 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 Global Unite/Global Unite hemi stemmed anatomic shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other hemi stemmed anatomic shoulder prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Hemi Stemmed Anatomic Shoulder Replacement
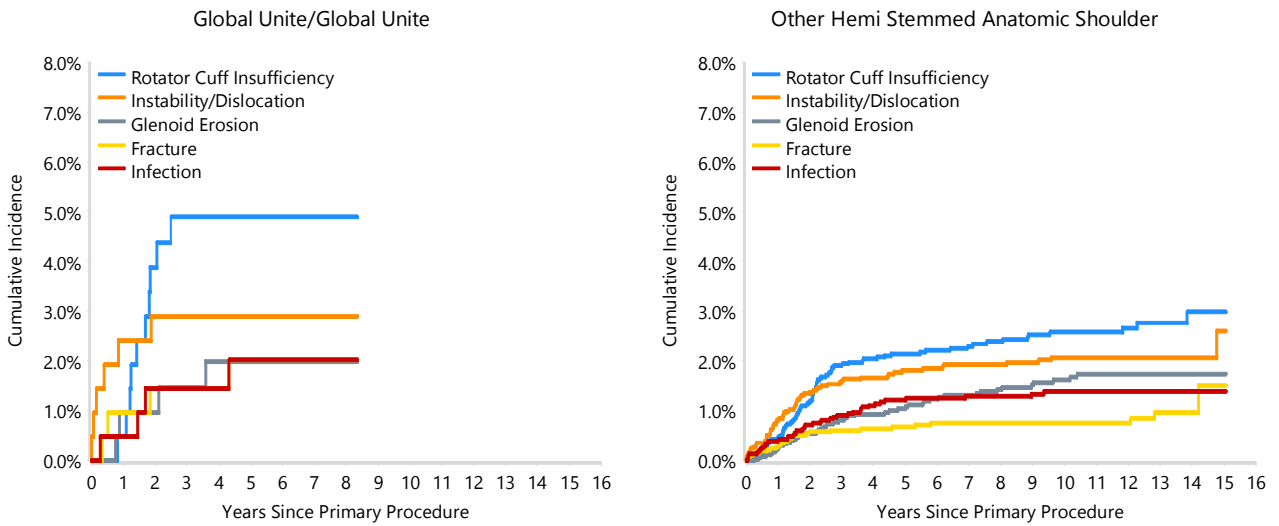
TABLE 5

Type of Revision Performed for Primary Hemi Stemmed Anatomic Shoulder Replacement

This analysis identifies the components used in the revision of the Global Unite/Global Unite hemi stemmed anatomic shoulder combination and compares it to the components used in the revision of all other hemi stemmed anatomic 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 hemi stemmed anatomic shoulder prostheses i.e. is there a difference in the type of revision undertaken for the Global Unite/Global Unite hemi stemmed anatomic shoulder combination compared to all other hemi stemmed anatomic shoulder prostheses.

Table 5: Primary Hemi Stemmed Anatomic Shoulder Replacement - Type of Revision (Follow-up Limited to 10.8 Years)

Type of Revision	Global Unite/Global Unite		Other Hemi Stemmed Anatomic Shoulder	
	Number	Percent	Number	Percent
Humeral/Glenoid	31	77.5	235	65.8
Humeral Component	4	10.0	36	10.1
Glenoid Component	2	5.0	35	9.8
Cement Spacer	3	7.5	23	6.4
Removal of Prostheses			4	1.1
N Major	**40**	**100.0**	**333**	**93.3**
Head Only			14	3.9
Reoperation			5	1.4
Cement Only			3	0.8
Head/Insert			1	0.3
Minor Components			1	0.3
N Minor			**24**	**6.7**
TOTAL	40	100.0	357	100.0

Note: This table is restricted to revisions within 10.8 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 6

Revision Rates of Primary Hemi Stemmed Anatomic Shoulder Replacement by State

This enables a state by state variation to be identified for the Global Unite/Global Unite hemi stemmed anatomic shoulder combination and provides the comparative data for each of the states for all other hemi stemmed anatomic 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 6: Revised Number of Primary Hemi Stemmed Anatomic Shoulder Replacement by State

Component	State	N Revised	N Total
Global Unite/Global Unite	NSW	7	38
	VIC	12	50
	QLD	15	81
	WA	1	13
	SA	3	11
	TAS	0	9
	ACT/NT	2	6
Other Hemi Stemmed Anatomic Shoulder	NSW	90	1156
	VIC	100	1025
	QLD	86	802
	WA	30	211
	SA	25	201
	TAS	18	135
	ACT/NT	16	104
TOTAL		**405**	**3842**

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 7

Number of Revisions of Global Unite/Global Unite Primary Hemi Stemmed Anatomic Shoulder Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Global Unite/Global Unite hemi stemmed anatomic 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 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 7: Number of Revisions of Global Unite/Global Unite Primary Hemi Stemmed Anatomic Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2012	3	15
2013	8	37
2014	6	25
2015	7	38
2016	7	37
2017	4	14
2018	1	12
2019	3	11
2020	0	12
2021	0	6
2022	1	1
TOTAL	40	208

TABLE 8

Revision Rates of Global Unite/Global Unite Primary Hemi Stemmed Anatomic 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 Global Unite/Global Unite 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	Stem Type
Humeral Stem					
Global Unite	110006100-110016100	STANDARD STEM POROCOAT	EITHER	METAL	FRACTURE
Global Unite	110006600-110012600	REVISION STEM POROCOAT	EITHER	METAL	
Head					
Global Unite	110040500-110056520	STANDARD HUMERAL HEAD	NO	METAL	
Global Unite	110040600-110056620	ECCENTRIC HUMERAL HEAD	NO	METAL	

Table 8: Revised Number of Global Unite/Global Unite Primary Hemi Stemmed Anatomic Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Head Range	N Revised	N Total
110006100-110016100	110040500-110056520	30	161
	110040600-110056620	10	41
110006600-110012600	110040500-110056520	0	2
	110040600-110056620	0	4
TOTAL		**40**	**208**