

Comprehensive/Custom Made (Comprehensive) Total Stemmed Shoulder Investigation

Note: This analysis compares the Comprehensive/Custom Made (Comprehensive) 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 Comprehensive/Custom Made (Comprehensive) 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)
Comprehensive/Custom Made (Comprehensive)	6	18	42	14.14 (5.19, 30.78)
Other Total Stemmed Shoulder	698	8757	49188	1.42 (1.32, 1.53)
TOTAL	704	8775	49230	1.43 (1.33, 1.54)

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 Comprehensive/Custom Made (Comprehensive) 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
Comprehensive/Custom Made (Comprehensive)	16.7 (5.7, 43.2)	28.2 (12.8, 55.1)	28.2 (12.8, 55.1)		
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
Comprehensive/Custom Made (Comprehensive)					
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
Comprehensive/Custom Made (Comprehensive)					
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.

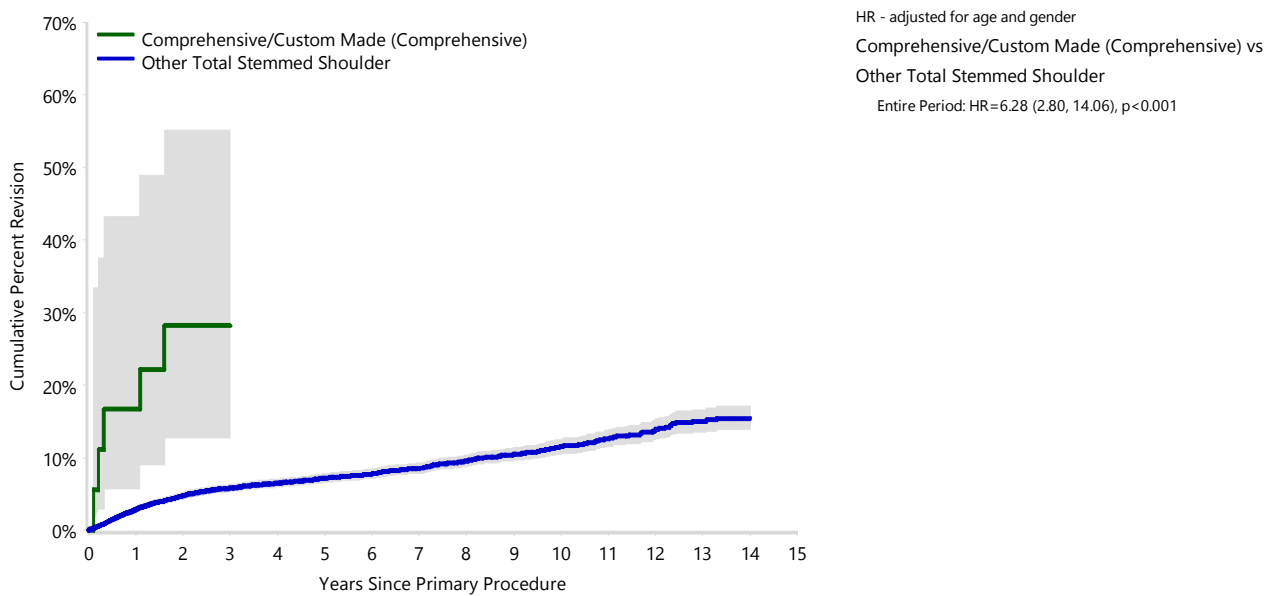
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

The yearly cumulative percent revision of the Comprehensive/Custom Made (Comprehensive) 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
Comprehensive/Custom Made (Comprehensive)	18	15	12	6	1	0	0	0
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
Comprehensive/Custom Made (Comprehensive)	0	0	0	0	0	0	0	0
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	Comprehensive/Custom Made (Comprehensive)		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Osteoarthritis	5	83.3	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	1	16.7	4	0.6
TOTAL	6	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 (Follow-up Limited to 4.1 Years)

Revision Diagnosis	Comprehensive/Custom Made (Comprehensive)			Other Total Stemmed Shoulder		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency	1	5.6	16.7	177	2.0	34.6
Instability/Dislocation	4	22.2	66.7	162	1.8	31.7
Loosening				58	0.7	11.4
Infection				34	0.4	6.7
Fracture				14	0.2	2.7
Pain				13	0.1	2.5
Arthrofibrosis	1	5.6	16.7	12	0.1	2.3
Malposition				9	0.1	1.8
Incorrect Sizing				8	0.1	1.6
Dissociation				4	0.0	0.8
Implant Breakage Glenoid				4	0.0	0.8
Wear Glenoid Insert				4	0.0	0.8
Implant Breakage Glenoid Insert				3	0.0	0.6
Lysis				3	0.0	0.6
Metal Related Pathology				1	0.0	0.2
Other				5	0.1	1.0
N Revision	6	33.3	100.0	511	5.8	100.0
N Primary	18			8757		

Note: This table is restricted to revisions within 4.1 years for all groups to allow a time-matched comparison of revisions.

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 Comprehensive/Custom Made (Comprehensive) 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

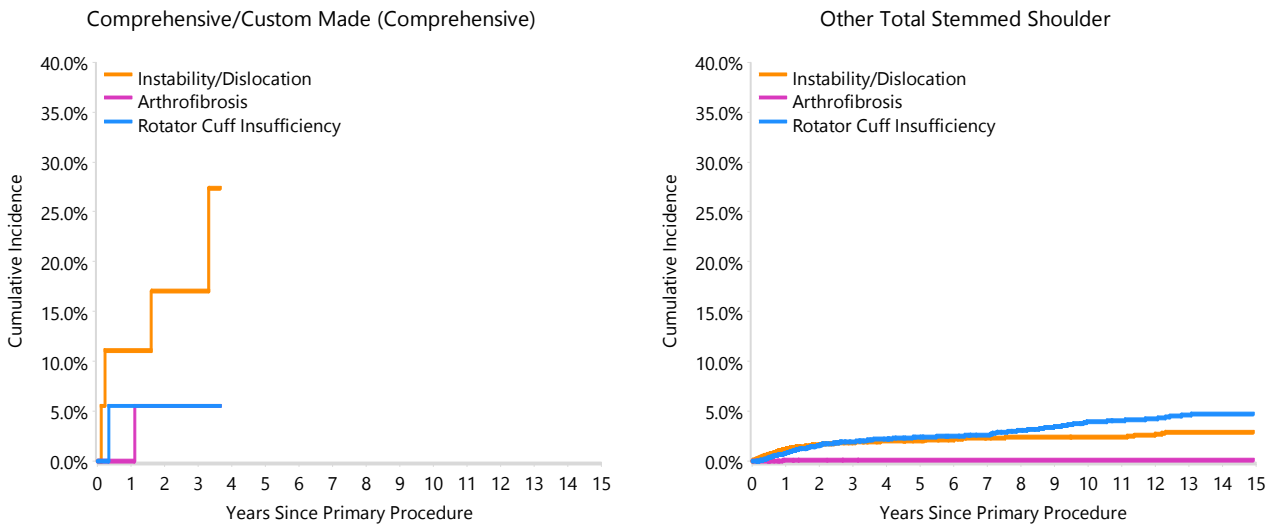


TABLE 5

Type of Revision Performed for Primary Total Stemmed Shoulder Replacement

This analysis identifies the components used in the revision of the Comprehensive/Custom Made (Comprehensive) 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 Comprehensive/Custom Made (Comprehensive) total stemmed shoulder combination compared to all other total stemmed shoulder prostheses.

Table 5: Primary Total Stemmed Shoulder Replacement - Type of Revision (Follow-up Limited to 4.1 Years)

Type of Revision	Comprehensive/Custom Made (Comprehensive)		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Humeral Component	4	66.7	273	53.4
Humeral/Glenoid	1	16.7	148	29.0
Glenoid Component			17	3.3
Cement Spacer			14	2.7
Removal of Prostheses			3	0.6
Reinsertion of Components			1	0.2
N Major	5	83.3	456	89.2
Head Only	1	16.7	46	9.0
Reoperation			5	1.0
Minor Components			2	0.4
Cement Only			1	0.2
Head/Insert			1	0.2
N Minor	1	16.7	55	10.8
TOTAL	6	100.0	511	100.0

Note: This table is restricted to revisions within 4.1 years for all groups to allow a time-matched comparison of revisions.

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

TABLE 6**Revision Rates of Comprehensive/Custom Made (Comprehensive) 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 Comprehensive/Custom Made (Comprehensive) Primary Total Stemmed Shoulder Replacement by Fixation

Fixation	N Revised	N Total
Cementless	6	13
Hybrid (Glenoid Cemented)	0	4
Hybrid (Glenoid Cementless)	0	1
TOTAL	6	18

TABLE 7

Revision Rates of Primary Total Stemmed Shoulder Replacement by State

This enables a state by state variation to be identified for the Comprehensive/Custom Made (Comprehensive) 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
Comprehensive/Custom Made (Comprehensive)	NSW	2	3
	VIC	0	7
	QLD	1	2
	WA	0	1
	ACT/NT	3	5
Other Total Stemmed Shoulder	NSW	191	2613
	VIC	157	2055
	QLD	99	1467
	WA	134	1184
	SA	67	1015
	TAS	26	201
	ACT/NT	24	222
TOTAL		704	8775

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

TABLE 8**Number of Revisions of Comprehensive/Custom Made (Comprehensive) Primary Total Stemmed Shoulder Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Comprehensive/Custom Made (Comprehensive) 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 Comprehensive/Custom Made (Comprehensive) Primary Total Stemmed Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2016	1	1
2017	3	4
2018	2	7
2019	0	5
2020	0	1
TOTAL	6	18

TABLE 9

Revision Rates of Comprehensive/Custom Made (Comprehensive) 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 Comprehensive/Custom Made (Comprehensive) 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				
Comprehensive	113604-113620	POROUS PRIMARY MICRO LENGTH STEM	NO	METAL
Comprehensive	113624-113640	POROUS PRIMARY MINI LENGTH STEM	EITHER	METAL
Comprehensive	113644-113664	POROUS PRIMARY STANDARD LENGTH STEM	NO	METAL
Glennoid				
Custom Made (Comprehensive)	PM0000279-PM0001813	CUSTOM COMPREHENSIVE CONVERTIBLE GLENOID	NO	METAL
Custom Made (Comprehensive)	PM0000992-PM0002501	CUSTOM COMPREHENSIVE HYBRID GLENOID	YES	CROSS-LINKED POLYETHYLENE
Custom Made (Comprehensive)	PM555355-PM555422	CUSTOM COMPREHENSIVE CONVERTIBLE GLENOID	NO	METAL

Table 9: Revised Number of Comprehensive/Custom Made (Comprehensive) Primary Total Stemmed Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glennoid Range	N Revised	N Total
113604-113620	PM0000279-PM0001813	2	3
	PM0000992-PM0002501	0	1
	PM555355-PM555422	1	1
113624-113640	PM0000279-PM0001813	3	8
	PM0000992-PM0002501	0	4
113644-113664	PM0000279-PM0001813	0	1
TOTAL		6	18