Comprehensive/Custom Made (Comprehensive) Total Stemmed Anatomic Shoulder Investigation

Note: This analysis compares the Comprehensive/Custom Made (Comprehensive) humeral stem/glenoid combination with all other total 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-2025.

Note: Procedures using modular metal-backed glenoids are excluded from the comparator. Procedures using prostheses with no recorded use in 2024 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Stemmed Anatomic Shoulder Replacement

The revision rate of the Comprehensive/Custom Made (Comprehensive) total stemmed anatomic shoulder combination is compared to all other total stemmed anatomic shoulder prostheses.

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

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Comprehensive/Custom Made (Comprehensive)	7	18	75	9.35 (3.76, 19.26)
Other Total Stemmed Anatomic Shoulder	288	5413	31028	0.93 (0.82, 1.04)
TOTAL	**295**	**5431**	**31103**	**0.95 (0.84, 1.06)**

Note: Prostheses no longer used in 2024 are excluded from the comparator. Procedures using modular metal-backed glenoids are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the Comprehensive/Custom Made (Comprehensive) total stemmed anatomic shoulder combination is compared to all other total stemmed anatomic shoulder prostheses.

Table 2: Yearly Cumulative Percent Revision (95% CI) of Primary Total Stemmed Anatomic Shoulder Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs
Comprehensive/Custom Made (Comprehensive)	16.7 (5.7, 43.2)	27.8 (12.6, 54.4)	27.8 (12.6, 54.4)	33.8 (16.8, 60.4)	33.8 (16.8, 60.4)	33.8 (16.8, 60.4)
Other Total Stemmed Anatomic Shoulder	2.0 (1.6, 2.4)	3.1 (2.7, 3.6)	3.7 (3.2, 4.2)	4.3 (3.8, 4.9)	4.8 (4.2, 5.5)	5.3 (4.7, 6.0)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs
Comprehensive/Custom Made (Comprehensive)						
Other Total Stemmed Anatomic Shoulder	5.9 (5.2, 6.7)	6.6 (5.8, 7.5)	7.5 (6.5, 8.5)	7.9 (6.9, 9.0)	8.4 (7.3, 9.7)	9.2 (7.8, 10.8)

CPR	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs
Comprehensive/Custom Made (Comprehensive)					
Other Total Stemmed Anatomic Shoulder	9.5 (8.0, 11.2)	9.5 (8.0, 11.2)	10.0 (8.3, 12.1)	11.0 (8.6, 14.0)	

Note: Prostheses no longer used in 2024 are excluded from the comparator. Procedures using modular metal-backed glenoids are excluded from the comparator.

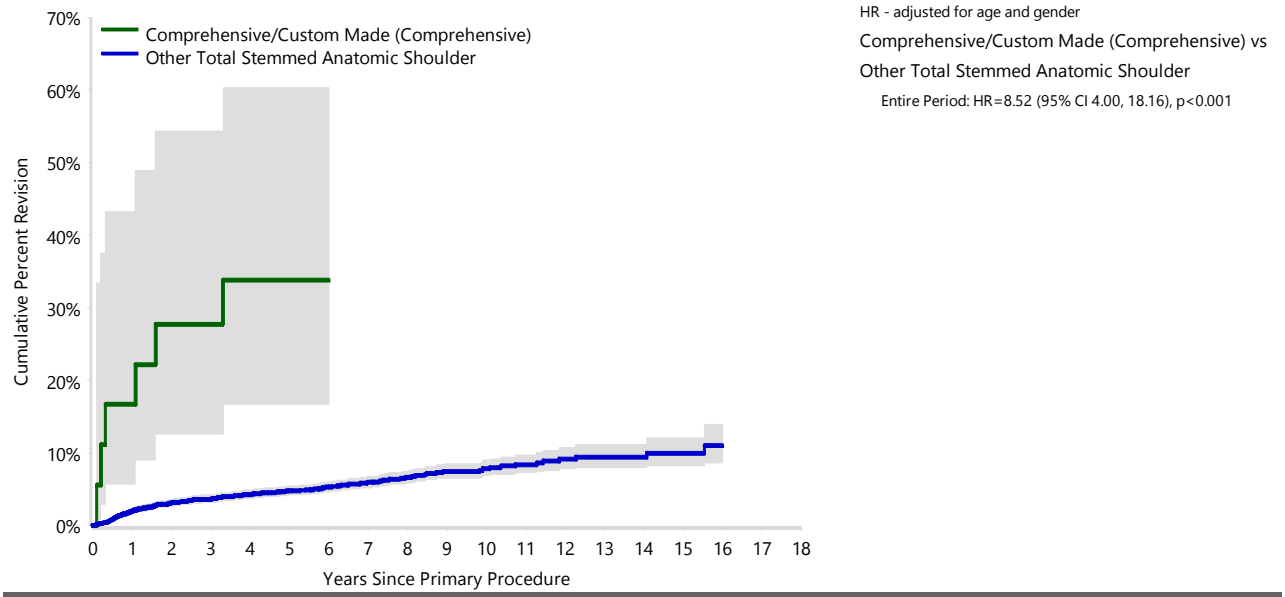
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the Comprehensive/Custom Made (Comprehensive) total stemmed anatomic shoulder combination is compared to all other total 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 Total Stemmed Anatomic Shoulder Replacement



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
Comprehensive/Custom Made (Comprehensive)	18	15	13	12	11	10	5	0	0
Other Total Stemmed Anatomic Shoulder	5413	4943	4459	3941	3434	2944	2394	1859	1418

Number at Risk	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs
Comprehensive/Custom Made (Comprehensive)	0	0	0	0	0	0	0	0	0
Other Total Stemmed Anatomic Shoulder	992	632	405	320	247	169	115	73	24

Note: Prostheses no longer used in 2024 are excluded from the comparator. Procedures using modular metal-backed glenoids are excluded from the comparator.

TABLE 3

Primary Diagnosis for Revised Primary Total 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 total stemmed anatomic shoulder prostheses.

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

	Comprehensive/Custom Made (Comprehensive)		Other Total Stemmed Anatomic Shoulder	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	6	85.7	268	93.1
Fracture			5	1.7
Rheumatoid Arthritis			5	1.7
Osteonecrosis			4	1.4
Other Inflammatory Arthritis			4	1.4
Instability	1	14.3	1	0.3
Rotator Cuff Arthropathy			1	0.3
TOTAL	**7**	**100.0**	**288**	**100.0**

Note: Prostheses no longer used in 2024 are excluded from the comparator. Procedures using modular metal-backed glenoids 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 Anatomic Shoulder Replacement - Reason for Revision (Follow-up Limited to 6.9 Years)

Revision Diagnosis	Comprehensive/Custom Made (Comprehensive)			Other Total Stemmed Anatomic Shoulder		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency	1	5.6	14.3	79	1.5	31.6
Instability/Dislocation	4	22.2	57.1	60	1.1	24.0
Loosening				57	1.1	22.8
Pain				12	0.2	4.8
Infection				10	0.2	4.0
Fracture				8	0.1	3.2
Incorrect Sizing				5	0.1	2.0
Arthrofibrosis	1	5.6	14.3	4	0.1	1.6
Implant Breakage Glenoid				4	0.1	1.6
Lysis				4	0.1	1.6
Malposition				3	0.1	1.2
Dissociation				1	0.0	0.4
Implant Breakage Glenoid Insert				1	0.0	0.4
Implant Breakage Head	1	5.6	14.3			
Other				2	0.0	0.8
N Revision	**7**	**38.9**	**100.0**	**250**	**4.6**	**100.0**
N Primary	**18**			**5413**		

Note: This table is restricted to revisions within 6.9 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2024 are excluded from the comparator. Procedures using modular metal-backed glenoids are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total 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 Comprehensive/Custom Made (Comprehensive) total stemmed anatomic shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total stemmed anatomic shoulder prostheses.

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

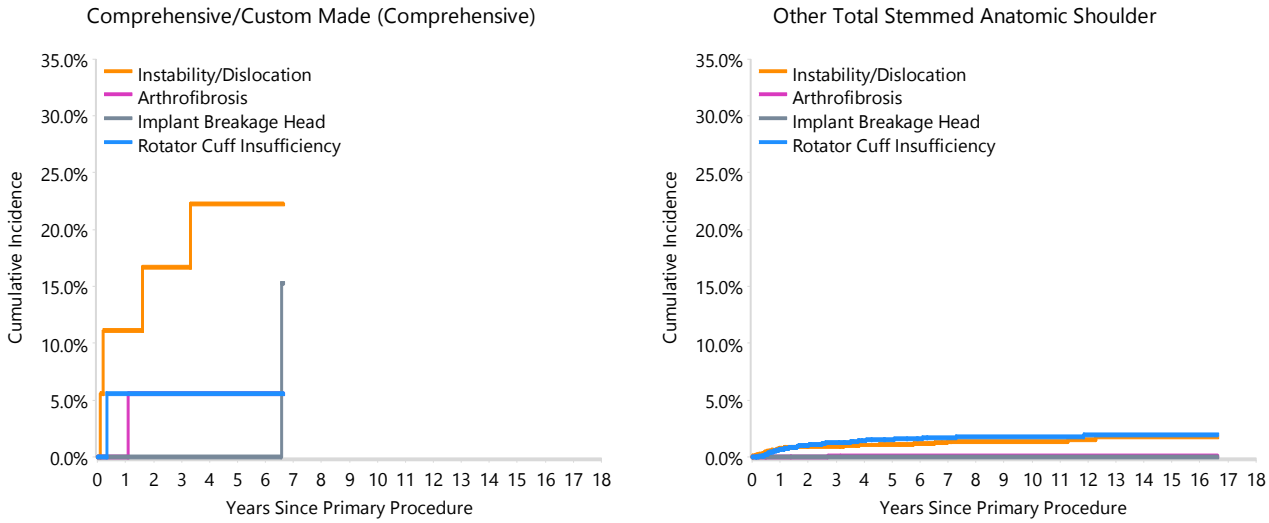


TABLE 5

Type of Revision Performed for Primary Total Stemmed Anatomic Shoulder Replacement

This analysis identifies the components used in the revision of the Comprehensive/Custom Made (Comprehensive) total stemmed anatomic shoulder combination and compares it to the components used in the revision of all other total 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 total stemmed anatomic shoulder prostheses i.e. is there a difference in the type of revision undertaken for the Comprehensive/Custom Made (Comprehensive) total stemmed anatomic shoulder combination compared to all other total stemmed anatomic shoulder prostheses.

Table 5: Primary Total Stemmed Anatomic Shoulder Replacement - Type of Revision (Follow-up Limited to 6.9 Years)

	Comprehensive/Custom Made (Comprehensive)		Other Total Stemmed Anatomic Shoulder	
Type of Revision	Number	Percent	Number	Percent
Humeral/Glenoid	1	14.3	191	76.4
Humeral Component	5	71.4	13	5.2
Glenoid Component			10	4.0
Cement Spacer			7	2.8
Removal of Prostheses			1	0.4
N Major	**6**	**85.7**	**222**	**88.8**
Head Only	1	14.3	27	10.8
Reoperation			1	0.4
N Minor	**1**	**14.3**	**28**	**11.2**
TOTAL	**7**	**100.0**	**250**	**100.0**

Note: This table is restricted to revisions within 6.9 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2024 are excluded from the comparator. Procedures using modular metal-backed glenoids are excluded from the comparator.

TABLE 6

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

Fixation	N Revised	N Total
Cementless	7	13
Hybrid (Glenoid Cemented)	0	4
Hybrid (Glenoid Cementless)	0	1
TOTAL	**7**	**18**

TABLE 7

Revision Rates of Comprehensive/Custom Made (Comprehensive) Primary Total Stemmed Anatomic Shoulder 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 combination are listed.

Table 7: Revised Number of Comprehensive/Custom Made (Comprehensive) Primary Total Stemmed Anatomic Shoulder Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Metal/XLPE	0	5
Metal/XLPE + Antioxidant	7	13
TOTAL	**7**	**18**

TABLE 8

Revision Rates of Primary Total Stemmed Anatomic Shoulder Replacement by State

This enables a state by state variation to be identified for the Comprehensive/Custom Made (Comprehensive) total stemmed anatomic shoulder combination and provides the comparative data for each of the states for all other total 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 8: Revised Number of Primary Total Stemmed Anatomic Shoulder Replacement by State

Component	State	N Revised	N Total
Comprehensive/Custom Made (Comprehensive)	NSW	2	3
	VIC	0	7
	QLD	1	2
	WA	1	1
	ACT/NT	3	5
Other Total Stemmed Anatomic Shoulder	NSW	64	1594
	VIC	89	1389
	QLD	54	1111
	WA	44	557
	SA	22	531
	TAS	4	87
	ACT/NT	11	144
TOTAL		**295**	**5431**

Note: Prostheses no longer used in 2024 are excluded from the comparator. Procedures using modular metal-backed glenoids are excluded from the comparator.

TABLE 9

Number of Revisions of Comprehensive/Custom Made (Comprehensive) Primary Total Stemmed Anatomic 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 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 2024 has a maximum of one year to be revised, whereas a primary procedure performed in 2022 has a maximum of three years to be revised.

Table 9: Number of Revisions of Comprehensive/Custom Made (Comprehensive) Primary Total Stemmed Anatomic Shoulder Replacement by Year of Implant

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

TABLE 10

Revision Rates of Comprehensive/Custom Made (Comprehensive) Primary Total 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 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
Glenoid				
Custom Made (Comprehensive)	PM0000279-PM0004767	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 10: Revised Number of Comprehensive/Custom Made (Comprehensive) Primary Total Stemmed Anatomic Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glenoid Range	N Revised	N Total
113604-113620	PM0000279-PM0004767	2	3
	PM0000992-PM0002501	0	1
	PM555355-PM555422	1	1
113624-113640	PM0000279-PM0004767	3	8
	PM0000992-PM0002501	0	4
113644-113664	PM0000279-PM0004767	1	1
TOTAL		**7**	**18**