

## SMR/SMR L2 Total Stemmed Anatomic Shoulder Investigation

Note: This analysis compares the SMR/SMR L2 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-2024>.

Note: Procedures using prostheses with no recorded use in 2023 are excluded from the comparator.

### TABLE 1

#### Revision Rate of Primary Total Stemmed Anatomic Shoulder Replacement

The revision rate of the SMR/SMR L2 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)
SMR/SMR L2	324	856	6796	4.77 (4.26, 5.32)
Other Total Stemmed Anatomic Shoulder	704	7878	45983	1.53 (1.42, 1.65)
<b>TOTAL</b>	<b>1028</b>	<b>8734</b>	<b>52779</b>	<b>1.95 (1.83, 2.07)</b>

Note: Prostheses no longer used in 2023 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 SMR/SMR L2 total stemmed anatomic shoulder combination is compared to all other total stemmed anatomic shoulder prostheses.

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

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs
SMR/SMR L2	9.5 (7.7, 11.7)	17.2 (14.8, 19.9)	22.2 (19.6, 25.2)	26.5 (23.6, 29.6)	29.8 (26.9, 33.1)	32.5 (29.5, 35.8)
Other Total Stemmed Anatomic Shoulder	3.1 (2.7, 3.5)	5.0 (4.6, 5.6)	6.1 (5.6, 6.7)	6.9 (6.3, 7.5)	7.7 (7.1, 8.4)	8.5 (7.8, 9.2)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs
SMR/SMR L2	34.1 (31.0, 37.4)	36.0 (32.8, 39.4)	37.7 (34.5, 41.1)	38.7 (35.5, 42.2)	39.2 (35.9, 42.7)	39.6 (36.3, 43.1)
Other Total Stemmed Anatomic Shoulder	9.3 (8.6, 10.1)	10.5 (9.7, 11.3)	11.6 (10.7, 12.6)	12.8 (11.8, 13.9)	13.7 (12.5, 14.9)	14.8 (13.5, 16.3)

CPR	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs
SMR/SMR L2	40.2 (36.8, 43.8)				
Other Total Stemmed Anatomic Shoulder	16.9 (15.2, 18.7)	17.4 (15.7, 19.4)	18.3 (16.3, 20.4)	20.1 (17.5, 23.0)	

Note: Prostheses no longer used in 2023 are excluded from the comparator.

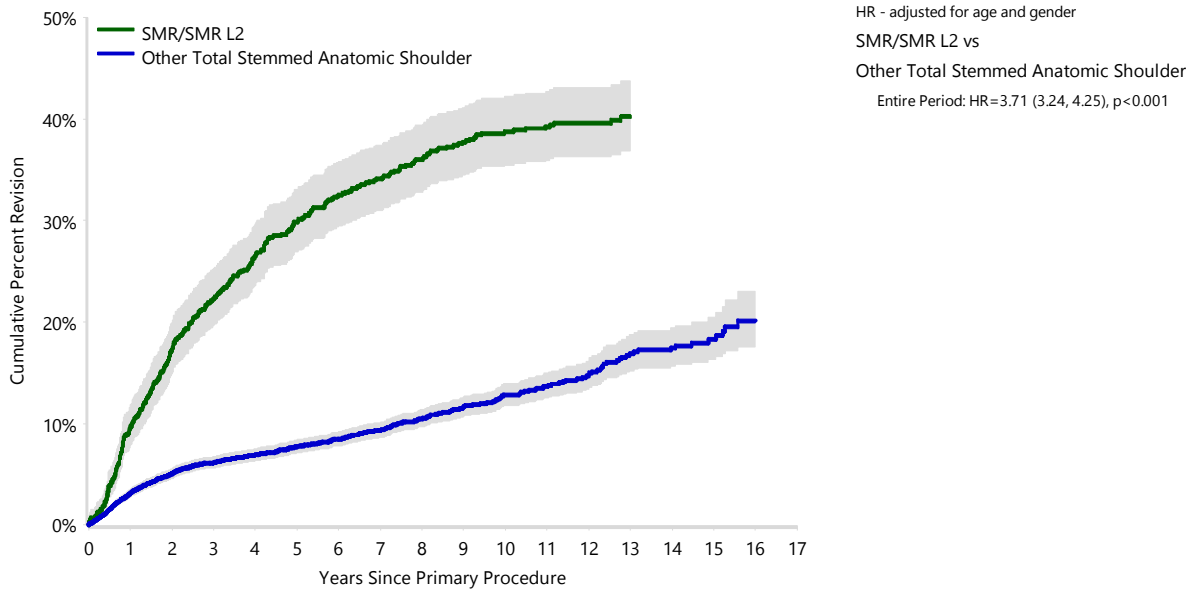
**FIGURE 1**

**Yearly Cumulative Percent Revision of Primary Total Stemmed Anatomic Shoulder Replacement**

The yearly cumulative percent revision of the SMR/SMR L2 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
SMR/SMR L2	856	767	698	647	596	557	524	496	455
Other Total Stemmed Anatomic Shoulder	7878	7121	6394	5700	5020	4249	3470	2787	2166

Number at Risk	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs
SMR/SMR L2	426	390	367	288	134	12	0	0	0
Other Total Stemmed Anatomic Shoulder	1572	1103	797	594	474	397	222	74	13

Note: Prostheses no longer used in 2023 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**

Primary Diagnosis	SMR/SMR L2		Other Total Stemmed Anatomic Shoulder	
	Number	Percent	Number	Percent
Osteoarthritis	305	94.1	654	92.9
Osteonecrosis	4	1.2	15	2.1
Fracture	4	1.2	12	1.7
Rheumatoid Arthritis	4	1.2	7	1.0
Rotator Cuff Arthropathy	1	0.3	7	1.0
Other Inflammatory Arthritis	4	1.2	6	0.9
Instability	1	0.3	3	0.4
Other	1	0.3		
<b>TOTAL</b>	<b>324</b>	<b>100.0</b>	<b>704</b>	<b>100.0</b>

Note: Prostheses no longer used in 2023 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 14.4 Years)**

Revision Diagnosis	Number	SMR/SMR L2		Other Total Stemmed Anatomic Shoulder		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency	64	7.5	19.8	254	3.2	36.4
Instability/Dislocation	58	6.8	17.9	192	2.4	27.5
Loosening	10	1.2	3.1	97	1.2	13.9
Implant Breakage Glenoid Insert	82	9.6	25.3	11	0.1	1.6
Dissociation	47	5.5	14.5	7	0.1	1.0
Infection	12	1.4	3.7	35	0.4	5.0
Implant Breakage Glenoid	23	2.7	7.1	8	0.1	1.1
Fracture	1	0.1	0.3	20	0.3	2.9
Pain	2	0.2	0.6	18	0.2	2.6
Metal Related Pathology	12	1.4	3.7	8	0.1	1.1
Wear Glenoid Insert	1	0.1	0.3	12	0.2	1.7
Arthrofibrosis				11	0.1	1.6
Lysis	1	0.1	0.3	8	0.1	1.1
Incorrect Sizing	6	0.7	1.9	5	0.1	0.7
Malposition				5	0.1	0.7
Progression Of Disease	1	0.1	0.3	2	0.0	0.3
Glenoid Erosion	1	0.1	0.3			
Implant Breakage Head	1	0.1	0.3			
Implant Breakage Humeral	1	0.1	0.3			
Wear Glenoid	1	0.1	0.3			
Other				5	0.1	0.7
<b>N Revision</b>	<b>324</b>	<b>37.9</b>	<b>100.0</b>	<b>698</b>	<b>8.9</b>	<b>100.0</b>
<b>N Primary</b>	<b>856</b>			<b>7878</b>		

Note: This table is restricted to revisions within 14.4 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2023 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 SMR/SMR L2 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**

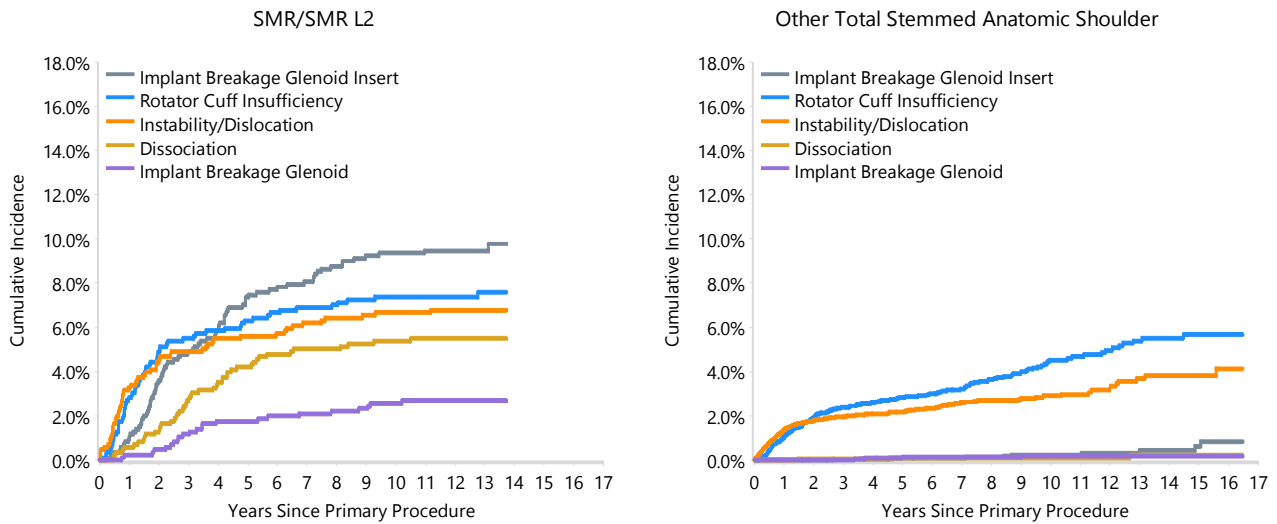


TABLE 5

**Type of Revision Performed for Primary Total Stemmed Anatomic Shoulder Replacement**

This analysis identifies the components used in the revision of the SMR/SMR L2 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 SMR/SMR L2 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 14.4 Years)**

Type of Revision	SMR/SMR L2		Other Total Stemmed Anatomic Shoulder	
	Number	Percent	Number	Percent
Humeral Component	266	82.1	422	60.5
Humeral/Glenoid	6	1.9	199	28.5
Cement Spacer	6	1.9	17	2.4
Glenoid Component	8	2.5	15	2.1
Removal of Prostheses	2	0.6	4	0.6
<b>N Major</b>	<b>288</b>	<b>88.9</b>	<b>657</b>	<b>94.1</b>
Head Only	7	2.2	35	5.0
Head/Insert	28	8.6	2	0.3
Minor Components			2	0.3
Reoperation			2	0.3
Insert Only	1	0.3		
<b>N Minor</b>	<b>36</b>	<b>11.1</b>	<b>41</b>	<b>5.9</b>
<b>TOTAL</b>	<b>324</b>	<b>100.0</b>	<b>698</b>	<b>100.0</b>

Note: This table is restricted to revisions within 14.4 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2023 are excluded from the comparator.

**TABLE 6****Revision Rates of SMR/SMR L2 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 SMR/SMR L2 Primary Total Stemmed Anatomic Shoulder Replacement by Fixation**

Fixation	N Revised	N Total
Cemented	0	1
Cementless	320	841
Hybrid (Glenoid Cementless)	4	14
<b>TOTAL</b>	<b>324</b>	<b>856</b>

**TABLE 7****Revision Rates of SMR/SMR L2 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 SMR/SMR L2 Primary Total Stemmed Anatomic Shoulder Replacement by Bearing Surface**

Bearing Surface	N Revised	N Total
Metal/XLPE	324	855
Unknown	0	1
<b>TOTAL</b>	<b>324</b>	<b>856</b>



**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 SMR/SMR L2 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
SMR/SMR L2	NSW	107	291
	VIC	45	136
	QLD	56	160
	WA	51	100
	SA	44	119
	TAS	13	35
	ACT/NT	8	15
Other Total Stemmed Anatomic Shoulder	NSW	182	2228
	VIC	161	1958
	QLD	100	1446
	WA	145	1102
	SA	53	684
	TAS	32	207
	ACT/NT	31	253
<b>TOTAL</b>		<b>1028</b>	<b>8734</b>

Note: Prostheses no longer used in 2023 are excluded from the comparator.

**TABLE 9****Number of Revisions of SMR/SMR L2 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 SMR/SMR L2 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 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 9: Number of Revisions of SMR/SMR L2 Primary Total Stemmed Anatomic Shoulder Replacement by Year of Implant**

Year of Implant	Number Revised	Total Number
2009	14	43
2010	134	343
2011	127	336
2012	49	134
<b>TOTAL</b>	<b>324</b>	<b>856</b>

TABLE 10

### Revision Rates of SMR/SMR L2 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 SMR/SMR L2 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
<b>Humeral Stem</b>				
SMR	130415110-130415130	CEMENTLESS FINNED MINI STEM Ti6AL4V	NO	METAL
SMR	130415140-130415240	FINNED STEM	NO	METAL
SMR	130615120-130615200	CEMENTED STEM	YES	METAL
SMR	130815134-130815166	REVISION STEM	NO	METAL
<b>Glenoid</b>				
SMR L2	137525050-137525080	L2 METAL BACK GLENOID	NO	METAL

Table 10: Revised Number of SMR/SMR L2 Primary Total Stemmed Anatomic Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glenoid Range	N Revised	N Total
130415110-130415130	137525050-137525080	2	4
130415140-130415240	137525050-137525080	319	842
130615120-130615200	137525050-137525080	2	9
130815134-130815166	137525050-137525080	1	1
<b>TOTAL</b>		<b>324</b>	<b>856</b>