SMR/SMR L1 Total Stemmed Anatomic Shoulder Investigation

Note: This analysis compares the SMR/SMR L1 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 L1 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 L1	447	2438	17975	2.49 (2.26, 2.73)
Other Total Stemmed Anatomic Shoulder	259	5446	28058	0.92 (0.81, 1.04)
TOTAL	**706**	**7884**	**46034**	**1.53 (1.42, 1.65)**

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 L1 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 L1	5.9 (5.0, 6.9)	9.3 (8.2, 10.6)	11.4 (10.2, 12.7)	12.4 (11.1, 13.8)	13.8 (12.4, 15.2)	14.9 (13.5, 16.4)
Other Total Stemmed Anatomic Shoulder	1.8 (1.5, 2.2)	3.0 (2.6, 3.5)	3.6 (3.1, 4.2)	4.2 (3.7, 4.8)	4.7 (4.1, 5.4)	5.2 (4.5, 5.9)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs
SMR/SMR L1	16.1 (14.6, 17.7)	17.7 (16.1, 19.4)	19.1 (17.4, 20.9)	20.6 (18.8, 22.5)	21.6 (19.7, 23.7)	22.9 (20.7, 25.2)
Other Total Stemmed Anatomic Shoulder	5.7 (5.0, 6.5)	6.4 (5.6, 7.3)	7.0 (6.1, 8.1)	7.6 (6.5, 9.0)	8.1 (6.8, 9.6)	9.0 (7.5, 10.9)

CPR	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs
SMR/SMR L1	25.7 (23.2, 28.5)	26.5 (23.9, 29.4)	27.3 (24.5, 30.4)	29.9 (26.3, 33.8)	
Other Total Stemmed Anatomic Shoulder	9.4 (7.7, 11.5)	9.4 (7.7, 11.5)	10.2 (8.0, 12.8)		

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

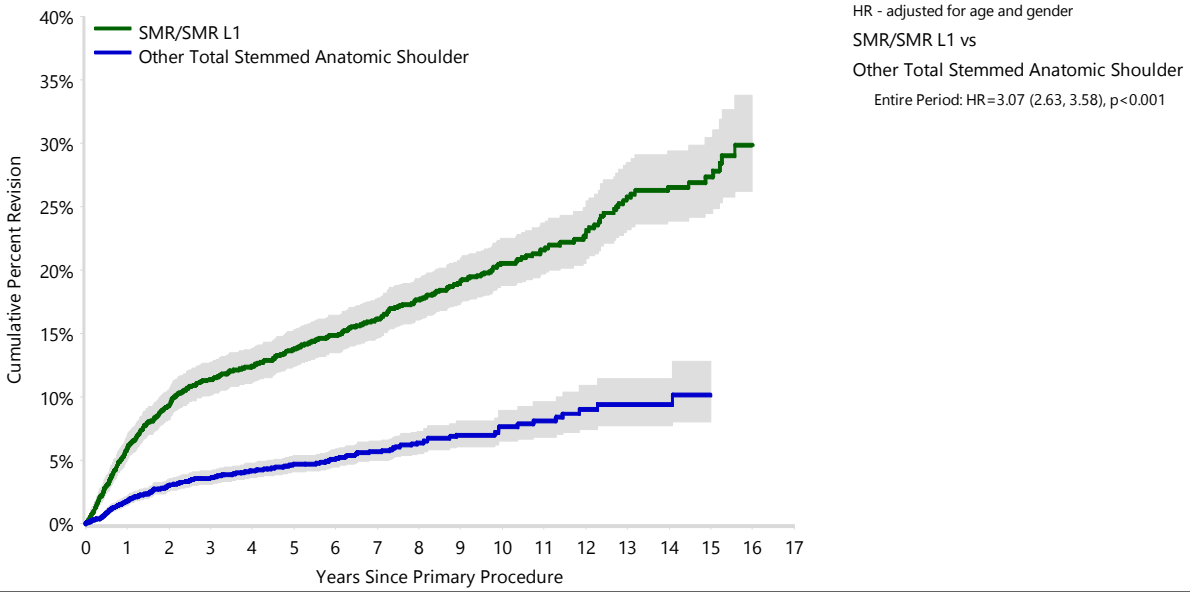
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the SMR/SMR L1 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 L1	2438	2213	2054	1920	1818	1684	1525	1329	1125
Other Total Stemmed Anatomic Shoulder	5446	4914	4346	3786	3208	2570	1950	1461	1043

Number at Risk	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs
SMR/SMR L1	905	672	451	332	296	275	145	49	7
Other Total Stemmed Anatomic Shoulder	669	433	347	263	179	123	78	25	6

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

	SMR/SMR L1		Other Total Stemmed Anatomic Shoulder	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	411	91.9	245	94.6
Osteonecrosis	13	2.9	2	0.8
Fracture	8	1.8	4	1.5
Rotator Cuff Arthropathy	7	1.6		
Rheumatoid Arthritis	3	0.7	4	1.5
Other Inflammatory Arthritis	3	0.7	3	1.2
Instability	2	0.4	1	0.4
TOTAL	**447**	**100.0**	**259**	**100.0**

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

	SMR/SMR L1			Other Total Stemmed Anatomic Shoulder		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency	182	7.5	40.7	75	1.4	29.0
Instability/Dislocation	138	5.7	30.9	55	1.0	21.2
Loosening	29	1.2	6.5	69	1.3	26.6
Infection	22	0.9	4.9	14	0.3	5.4
Implant Breakage Glenoid Insert	13	0.5	2.9			
Pain	6	0.2	1.3	12	0.2	4.6
Wear Glenoid Insert	12	0.5	2.7			
Fracture	11	0.5	2.5	9	0.2	3.5
Metal Related Pathology	8	0.3	1.8			
Arthrofibrosis	6	0.2	1.3	5	0.1	1.9
Dissociation	6	0.2	1.3	1	0.0	0.4
Incorrect Sizing				5	0.1	1.9
Lysis	3	0.1	0.7	5	0.1	1.9
Implant Breakage Glenoid	4	0.2	0.9	4	0.1	1.5
Malposition	2	0.1	0.4	3	0.1	1.2
Progression Of Disease	2	0.1	0.4			
Other	3	0.1	0.7	2	0.0	0.8
N Revision	**447**	**18.3**	**100.0**	**259**	**4.8**	**100.0**
N Primary	**2438**			**5446**		

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 L1 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

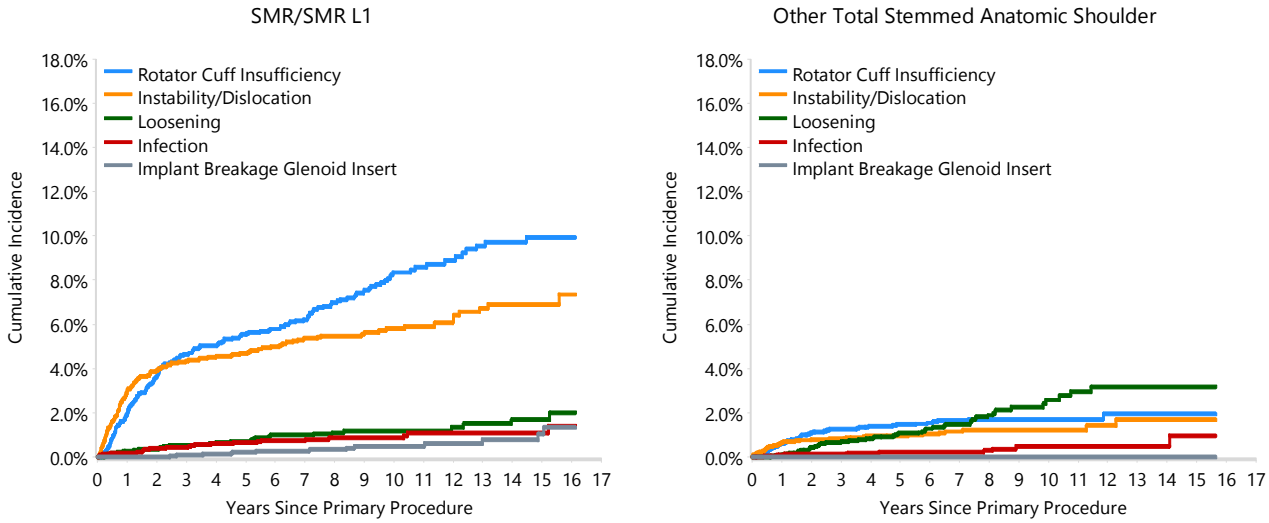


TABLE 5

Type of Revision Performed for Primary Total Stemmed Anatomic Shoulder Replacement

This analysis identifies the components used in the revision of the SMR/SMR L1 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 L1 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

	SMR/SMR L1		Other Total Stemmed Anatomic Shoulder	
Type of Revision	Number	Percent	Number	Percent
Humeral Component	414	92.6	14	5.4
Humeral/Glenoid	12	2.7	189	73.0
Glenoid Component	2	0.4	13	5.0
Cement Spacer	5	1.1	12	4.6
Removal of Prostheses	2	0.4	2	0.8
N Major	**435**	**97.3**	**230**	**88.8**
Head Only	7	1.6	28	10.8
Head/Insert	2	0.4		
Minor Components	2	0.4		
Reoperation	1	0.2	1	0.4
N Minor	**12**	**2.7**	**29**	**11.2**
TOTAL	**447**	**100.0**	**259**	**100.0**

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

TABLE 6

Revision Rates of SMR/SMR L1 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 L1 Primary Total Stemmed Anatomic Shoulder Replacement by Fixation

Fixation	N Revised	N Total
Cemented	0	1
Cementless	438	2393
Hybrid (Glenoid Cemented)	0	1
Hybrid (Glenoid Cementless)	9	43
TOTAL	**447**	**2438**

TABLE 7

Revision Rates of SMR/SMR L1 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 L1 Primary Total Stemmed Anatomic Shoulder Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Metal/Non XLPE	447	2436
Unknown	0	2
TOTAL	**447**	**2438**

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 L1 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 L1	NSW	130	737
	VIC	79	457
	QLD	55	369
	WA	100	461
	SA	37	195
	TAS	26	101
	ACT/NT	20	118
Other Total Stemmed Anatomic Shoulder	NSW	52	1491
	VIC	83	1504
	QLD	46	1079
	WA	45	641
	SA	16	490
	TAS	6	106
	ACT/NT	11	135
TOTAL		**706**	**7884**

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

TABLE 9

Number of Revisions of SMR/SMR L1 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 L1 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 L1 Primary Total Stemmed Anatomic Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2006	0	16
2007	22	119
2008	58	237
2009	57	247
2012	26	156
2013	71	302
2014	40	255
2015	54	242
2016	37	195
2017	31	172
2018	19	128
2019	11	98
2020	9	72
2021	3	70
2022	8	65
2023	1	64
TOTAL	**447**	**2438**

TABLE 10

Revision Rates of SMR/SMR L1 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 L1 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				
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
SMR	130915134-130915158	CEMENTED REVISION STEM	YES	METAL
SMR	131215200-131215240	REVISION STEM CEMENTED	YES	METAL
SMR	131515200-131515240	CEMENTED REVISION STEM	YES	METAL
Glenoid				
SMR L1	137520005-137520030	L1 METAL BACK GLENOID	NO	METAL

Table 10: Revised Number of SMR/SMR L1 Primary Total Stemmed Anatomic Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glenoid Range	N Revised	N Total
130415110-130415130	137520005-137520030	8	35
130415140-130415240	137520005-137520030	433	2368
130615120-130615200	137520005-137520030	5	29
130815134-130815166	137520005-137520030	1	2
130915134-130915158	137520005-137520030	0	1
131215200-131215240	137520005-137520030	0	2
131515200-131515240	137520005-137520030	0	1
TOTAL		**447**	**2438**