

SMR/SMR L2 Total Stemmed Shoulder Investigation

Note: This analysis compares the SMR/SMR L2 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 SMR/SMR L2 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)
SMR/SMR L2	317	856	6116	5.18 (4.63, 5.79)
Other Total Stemmed Shoulder	698	8757	49188	1.42 (1.32, 1.53)
TOTAL	1015	9613	55304	1.84 (1.72, 1.95)

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 SMR/SMR L2 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
SMR/SMR L2	9.5 (7.7, 11.7)	17.2 (14.8, 19.9)	22.2 (19.6, 25.2)	26.4 (23.5, 29.5)	29.7 (26.8, 33.0)
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
SMR/SMR L2	32.4 (29.3, 35.7)	34.0 (30.8, 37.3)	35.9 (32.7, 39.3)	37.6 (34.3, 41.0)	38.7 (35.4, 42.1)
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
SMR/SMR L2	38.9 (35.6, 42.3)				
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.

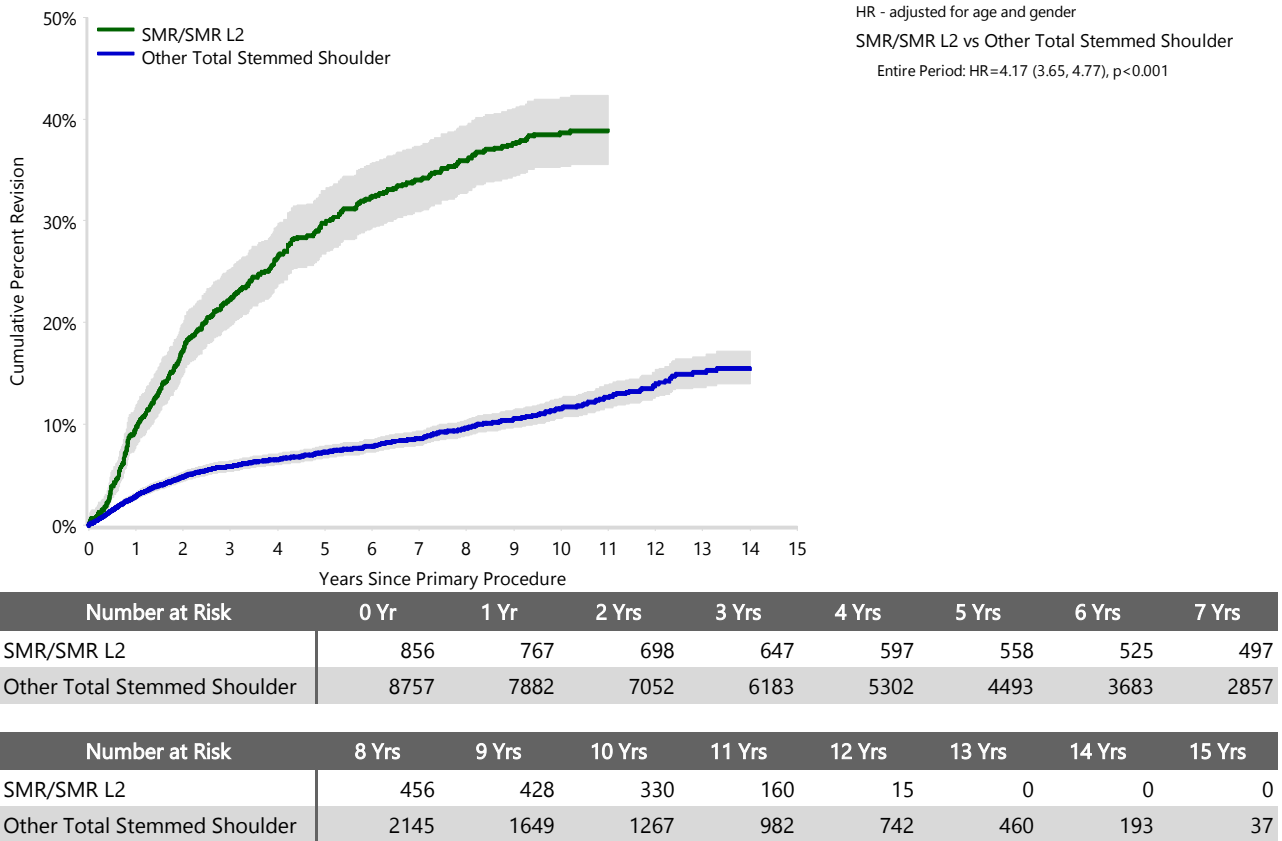
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

The yearly cumulative percent revision of the SMR/SMR L2 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



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	SMR/SMR L2		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Osteoarthritis	298	94.0	646	92.6
Osteonecrosis	4	1.3	14	2.0
Fracture	4	1.3	11	1.6
Rheumatoid Arthritis	4	1.3	9	1.3
Rotator Cuff Arthropathy	1	0.3	9	1.3
Other Inflammatory Arthritis	4	1.3	5	0.7
Instability	1	0.3	4	0.6
Other	1	0.3		
TOTAL	317	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 12.4 Years)

Revision Diagnosis	Number	SMR/SMR L2		Other Total Stemmed Shoulder		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency	63	7.4	19.9	234	2.7	33.7
Instability/Dislocation	57	6.7	18.0	187	2.1	26.9
Loosening	10	1.2	3.2	111	1.3	16.0
Implant Breakage Glenoid Insert	79	9.2	24.9	7	0.1	1.0
Dissociation	46	5.4	14.5	6	0.1	0.9
Infection	12	1.4	3.8	44	0.5	6.3
Implant Breakage Glenoid	23	2.7	7.3	7	0.1	1.0
Fracture	1	0.1	0.3	21	0.2	3.0
Pain	2	0.2	0.6	15	0.2	2.2
Arthrofibrosis				12	0.1	1.7
Metal Related Pathology	12	1.4	3.8	6	0.1	0.9
Wear Glenoid Insert	1	0.1	0.3	10	0.1	1.4
Malposition				9	0.1	1.3
Incorrect Sizing	6	0.7	1.9	8	0.1	1.2
Lysis	1	0.1	0.3	8	0.1	1.2
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			
Wear Glenoid	1	0.1	0.3			
Other				7	0.1	1.0
N Revision	317	37.0	100.0	694	7.9	100.0
N Primary	856			8757		

Note: This table is restricted to revisions within 12.4 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 SMR/SMR L2 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

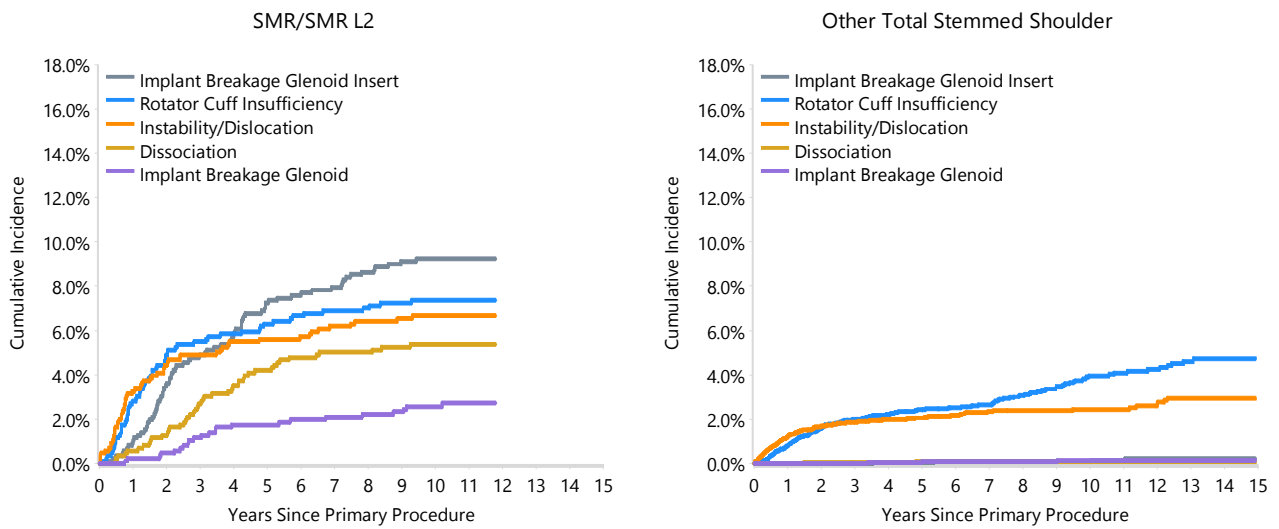


TABLE 5

Type of Revision Performed for Primary Total Stemmed Shoulder Replacement

This analysis identifies the components used in the revision of the SMR/SMR L2 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 SMR/SMR L2 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 12.4 Years)

Type of Revision	SMR/SMR L2		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Humeral Component	259	81.7	377	54.3
Humeral/Glenoid	6	1.9	196	28.2
Glenoid Component	8	2.5	28	4.0
Cement Spacer	6	1.9	22	3.2
Removal of Prostheses	2	0.6	6	0.9
Reinsertion of Components			1	0.1
N Major	281	88.6	630	90.8
Head Only	7	2.2	53	7.6
Head/Insert	28	8.8	2	0.3
Reoperation			5	0.7
Minor Components			3	0.4
Cement Only			1	0.1
Insert Only	1	0.3		
N Minor	36	11.4	64	9.2
TOTAL	317	100.0	694	100.0

Note: This table is restricted to revisions within 12.4 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 SMR/SMR L2 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 SMR/SMR L2 Primary Total Stemmed Shoulder Replacement by Fixation

Fixation	N Revised	N Total
Cemented	0	1
Cementless	313	841
Hybrid (Glenoid Cementless)	4	14
TOTAL	317	856

TABLE 7**Revision Rates of Primary Total Stemmed Shoulder Replacement by State**

This enables a state by state variation to be identified for the SMR/SMR L2 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
SMR/SMR L2	NSW	104	291
	VIC	44	136
	QLD	53	160
	WA	51	100
	SA	44	119
	TAS	13	35
	ACT/NT	8	15
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		1015	9613

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

TABLE 8**Number of Revisions of SMR/SMR L2 Primary Total Stemmed 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 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 SMR/SMR L2 Primary Total Stemmed Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2009	14	43
2010	132	343
2011	123	336
2012	48	134
TOTAL	317	856

TABLE 9

Revision Rates of SMR/SMR L2 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 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
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
Glenoid				
SMR L2	137525050-137525080	L2 METAL BACK GLENOID	NO	METAL

Table 9: Revised Number of SMR/SMR L2 Primary Total Stemmed 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	312	842
130615120-130615200	137525050-137525080	2	9
130815134-130815166	137525050-137525080	1	1
TOTAL		317	856