

SMR/SMR L1 Total Stemmed Shoulder Investigation

Note: This analysis compares the SMR/SMR L1 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 L1 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 L1	388	2309	14786	2.62 (2.37, 2.90)
Other Total Stemmed Shoulder	311	6450	34421	0.90 (0.81, 1.01)
TOTAL	699	8759	49207	1.42 (1.32, 1.53)

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 L1 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 L1	6.0 (5.1, 7.0)	9.4 (8.3, 10.7)	11.4 (10.2, 12.8)	12.5 (11.2, 14.0)	13.8 (12.4, 15.4)
Other Total Stemmed Shoulder	1.7 (1.4, 2.1)	3.0 (2.6, 3.5)	3.7 (3.2, 4.2)	4.2 (3.7, 4.7)	4.6 (4.1, 5.2)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
SMR/SMR L1	15.0 (13.5, 16.6)	16.2 (14.6, 17.9)	17.8 (16.1, 19.6)	19.0 (17.1, 20.9)	21.0 (18.9, 23.4)
Other Total Stemmed Shoulder	4.8 (4.3, 5.5)	5.4 (4.7, 6.1)	6.0 (5.3, 6.8)	6.8 (6.0, 7.8)	7.3 (6.4, 8.3)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
SMR/SMR L1	22.1 (19.8, 24.6)	23.4 (21.0, 26.1)	25.6 (22.8, 28.6)	26.0 (23.1, 29.1)	
Other Total Stemmed Shoulder	8.4 (7.3, 9.7)	9.5 (8.1, 11.0)	9.7 (8.3, 11.4)	10.1 (8.5, 11.9)	

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

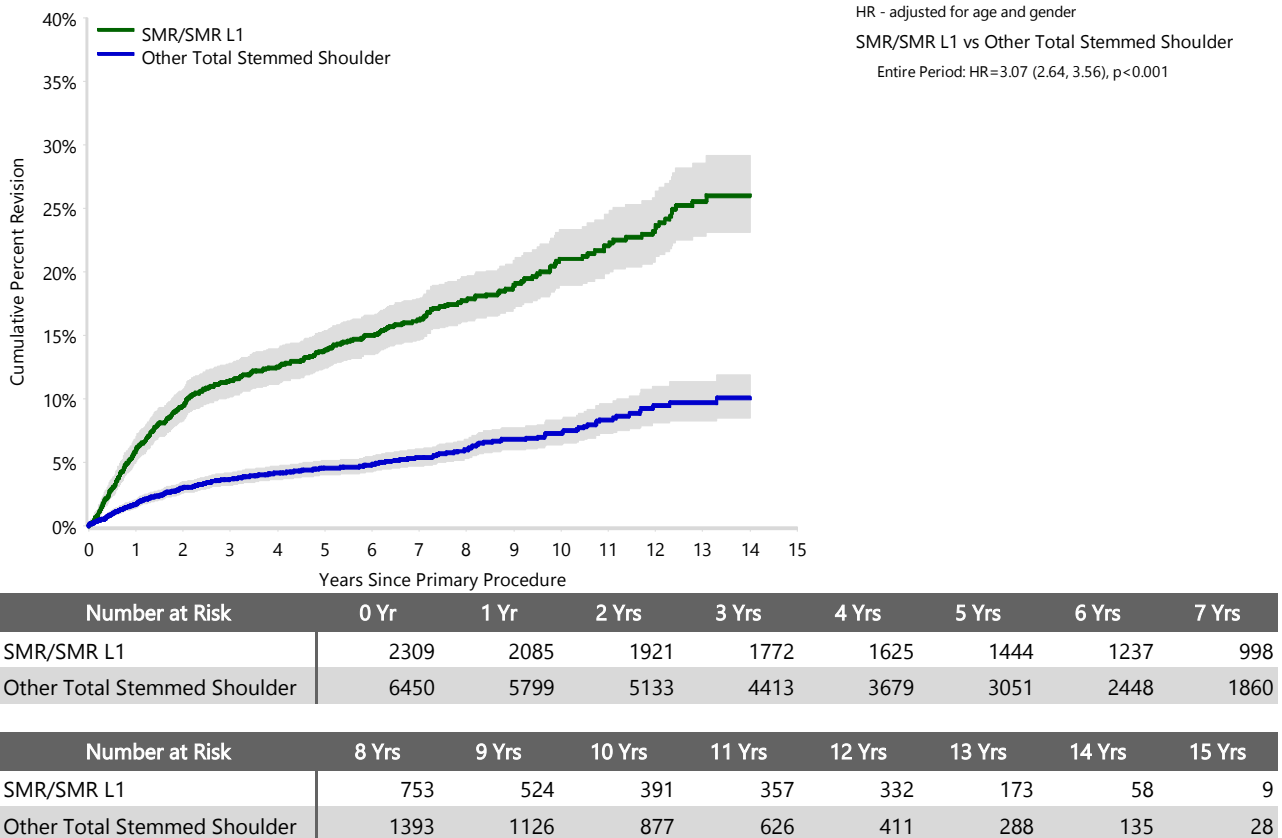
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

The yearly cumulative percent revision of the SMR/SMR L1 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 L1		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Osteoarthritis	357	92.0	290	93.2
Osteonecrosis	10	2.6	4	1.3
Fracture	7	1.8	4	1.3
Rotator Cuff Arthropathy	7	1.8	2	0.6
Rheumatoid Arthritis	3	0.8	6	1.9
Other Inflammatory Arthritis	2	0.5	3	1.0
Instability	2	0.5	2	0.6
TOTAL	388	100.0	311	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

Revision Diagnosis	Number	SMR/SMR L1		Other Total Stemmed Shoulder		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency	171	7.4	44.1	67	1.0	21.5
Instability/Dislocation	120	5.2	30.9	67	1.0	21.5
Loosening	23	1.0	5.9	89	1.4	28.6
Infection	14	0.6	3.6	30	0.5	9.6
Fracture	10	0.4	2.6	11	0.2	3.5
Pain	5	0.2	1.3	10	0.2	3.2
Wear Glenoid Insert	10	0.4	2.6			
Incorrect Sizing				8	0.1	2.6
Arthrofibrosis	5	0.2	1.3	7	0.1	2.3
Malposition	2	0.1	0.5	7	0.1	2.3
Implant Breakage Glenoid Insert	6	0.3	1.5	1	0.0	0.3
Lysis	2	0.1	0.5	6	0.1	1.9
Metal Related Pathology	6	0.3	1.5			
Dissociation	5	0.2	1.3	1	0.0	0.3
Implant Breakage Glenoid	4	0.2	1.0	3	0.0	1.0
Progression Of Disease	2	0.1	0.5			
Other	3	0.1	0.8	4	0.1	1.3
N Revision	388	16.8	100.0	311	4.8	100.0
N Primary	2309			6450		

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 L1 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

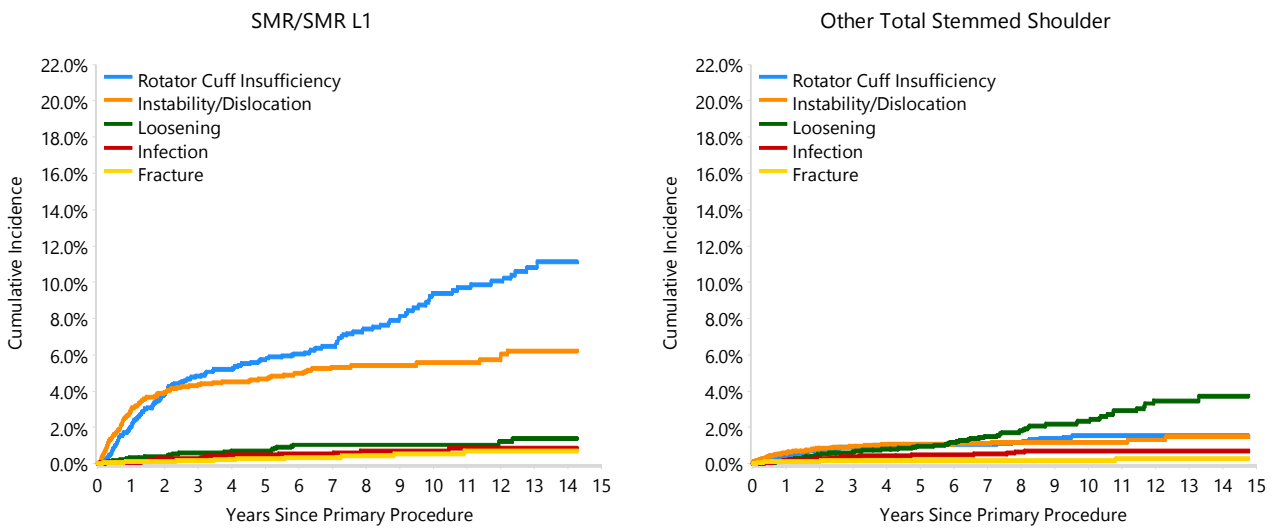


TABLE 5

Type of Revision Performed for Primary Total Stemmed Shoulder Replacement

This analysis identifies the components used in the revision of the SMR/SMR L1 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 L1 total stemmed shoulder combination compared to all other total stemmed shoulder prostheses.

Table 5: Primary Total Stemmed Shoulder Replacement - Type of Revision

Type of Revision	SMR/SMR L1		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Humeral Component	361	93.0	20	6.4
Humeral/Glenoid	8	2.1	189	60.8
Glenoid Component	2	0.5	26	8.4
Cement Spacer	4	1.0	18	5.8
Removal of Prostheses	2	0.5	4	1.3
Reinsertion of Components			1	0.3
N Major	377	97.2	258	83.0
Head Only	6	1.5	47	15.1
Reoperation	1	0.3	4	1.3
Head/Insert	2	0.5		
Minor Components	2	0.5	1	0.3
Cement Only			1	0.3
N Minor	11	2.8	53	17.0
TOTAL	388	100.0	311	100.0

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

TABLE 6**Revision Rates of SMR/SMR L1 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 L1 Primary Total Stemmed Shoulder Replacement by Fixation

Fixation	N Revised	N Total
Cemented	0	1
Cementless	379	2263
Hybrid (Glenoid Cemented)	0	1
Hybrid (Glenoid Cementless)	9	44
TOTAL	388	2309

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 L1 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 L1	NSW	114	719
	VIC	67	418
	QLD	50	355
	WA	87	419
	SA	31	195
	TAS	23	101
	ACT/NT	16	102
Other Total Stemmed Shoulder	NSW	77	1894
	VIC	90	1637
	QLD	50	1114
	WA	47	765
	SA	36	820
	TAS	3	100
	ACT/NT	8	120
TOTAL		699	8759

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

TABLE 8**Number of Revisions of SMR/SMR L1 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 L1 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 L1 Primary Total Stemmed Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2006	0	16
2007	22	119
2008	51	237
2009	52	247
2012	23	157
2013	68	301
2014	37	255
2015	44	242
2016	31	195
2017	26	172
2018	18	128
2019	10	98
2020	6	72
2021	0	70
TOTAL	388	2309

TABLE 9

Revision Rates of SMR/SMR L1 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 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 9: Revised Number of SMR/SMR L1 Primary Total Stemmed Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glenoid Range	N Revised	N Total
130415110-130415130	137520005-137520030	7	34
130415140-130415240	137520005-137520030	375	2239
130615120-130615200	137520005-137520030	5	30
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		388	2309