SMR/SMR L1 Total Reverse Shoulder Investigation

Note: This analysis compares the SMR/SMR L1 humeral stem/glenoid combination with all other total reverse 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 Reverse Shoulder Replacement

The revision rate of the SMR/SMR L1 total reverse shoulder combination is compared to all other total reverse shoulder prostheses.

Table 1: Revision Rates of Primary Total Reverse Shoulder Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
SMR/SMR L1	378	8945	36685	1.03 (0.93, 1.14)
Other Total Reverse Shoulder	1079	31609	114417	0.94 (0.89, 1.00)
TOTAL	1457	40554	151102	0.96 (0.92, 1.02)

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Reverse Shoulder Replacement

The yearly cumulative percent revision of the SMR/SMR L1 total reverse shoulder combination is compared to all other total reverse shoulder prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Reverse Shoulder Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
SMR/SMR L1	3.0 (2.7, 3.4)	3.7 (3.3, 4.2)	4.1 (3.7, 4.5)	4.3 (3.9, 4.8)	4.6 (4.1, 5.1)
Other Total Reverse Shoulder	2.1 (2.0, 2.3)	2.9 (2.7, 3.1)	3.4 (3.2, 3.6)	3.8 (3.6, 4.0)	4.1 (3.8, 4.3)
CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
SMR/SMR L1	4.9 (4.4, 5.4)	5.0 (4.5, 5.6)	5.5 (4.9, 6.3)	5.8 (5.1, 6.6)	6.0 (5.2, 7.0)
Other Total Reverse Shoulder	4.4 (4.1, 4.7)	4.6 (4.3, 5.0)	5.1 (4.8, 5.6)	5.5 (5.1, 6.0)	5.9 (5.4, 6.5)
CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
SMR/SMR L1	6.5 (5.5, 7.8)	6.8 (5.7, 8.2)	7.1 (5.9, 8.7)	7.1 (5.9, 8.7)	
Other Total Reverse Shoulder	6.4 (5.7, 7.1)	7.0 (6.2, 8.0)	7.0 (6.2, 8.0)	8.4 (6.0, 11.7)	

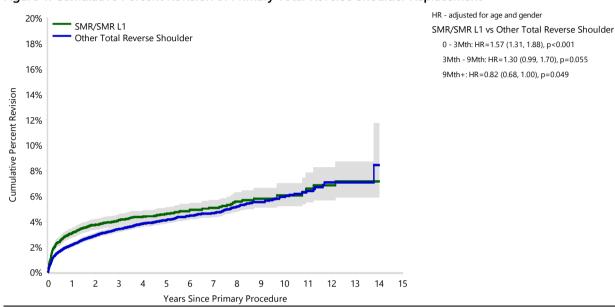
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Reverse Shoulder Replacement

The yearly cumulative percent revision of the SMR/SMR L1 total reverse shoulder combination is compared to all other total reverse 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 Reverse Shoulder Replacement



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
SMR/SMR L1	8945	7438	6317	5133	4001	3055	2174	1507
Other Total Reverse Shoulder	31609	25429	20249	15555	11612	8401	6092	4410

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
SMR/SMR L1	991	566	378	350	311	159	47	8
Other Total Reverse Shoulder	3047	2034	1285	741	427	177	53	8

Primary Diagnosis for Revised Primary Total Reverse 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 reverse shoulder prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Reverse Shoulder Replacement

	SMR/S	SMR L1	Other Total Rev	verse Shoulder
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	147	38.9	420	38.9
Rotator Cuff Arthropathy	127	33.6	398	36.9
Fracture	81	21.4	172	15.9
Rheumatoid Arthritis	6	1.6	28	2.6
Instability	8	2.1	22	2.0
Tumour	1	0.3	21	1.9
Osteonecrosis	6	1.6	11	1.0
Other Inflammatory Arthritis	2	0.5	6	0.6
Other			1	0.1
TOTAL	378	100.0	1079	100.0

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 Reverse Shoulder Replacement - Reason for Revision

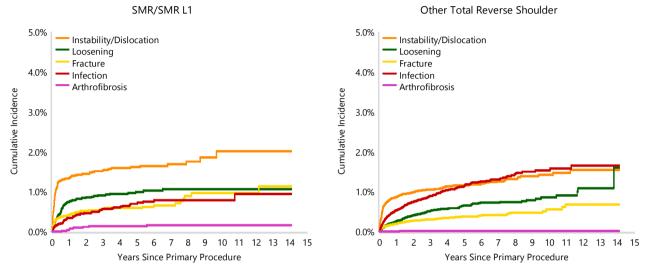
		SMR/SMR L1		Othe	Total Reverse Sho	oulder
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Instability/Dislocation	140	1.6	37.0	339	1.1	31.4
Infection	54	0.6	14.3	299	0.9	27.7
Loosening	81	0.9	21.4	166	0.5	15.4
Fracture	56	0.6	14.8	104	0.3	9.6
Dissociation	7	0.1	1.9	45	0.1	4.2
Pain	9	0.1	2.4	21	0.1	1.9
Lysis	3	0.0	0.8	15	0.0	1.4
Malposition	4	0.0	1.1	14	0.0	1.3
Arthrofibrosis	11	0.1	2.9	4	0.0	0.4
Implant Breakage Glenoid				10	0.0	0.9
Incorrect Sizing	2	0.0	0.5	9	0.0	0.8
Metal Related Pathology	5	0.1	1.3	7	0.0	0.6
Rotator Cuff Insufficiency	1	0.0	0.3	5	0.0	0.5
Wear Humeral Cup	1	0.0	0.3	4	0.0	0.4
Heterotopic Bone				3	0.0	0.3
Implant Breakage Humeral				2	0.0	0.2
Tumour	1	0.0	0.3	2	0.0	0.2
Implant Breakage Glenoid Insert				1	0.0	0.1
Wear Glenoid Insert	1	0.0	0.3			
Other	2	0.0	0.5	29	0.1	2.7
N Revision	378	4.2	100.0	1079	3.4	100.0
N Primary	8945			31609		

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Reverse 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 reverse shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total reverse shoulder prostheses.

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



Type of Revision Performed for Primary Total Reverse Shoulder Replacement

This analysis identifies the components used in the revision of the SMR/SMR L1 total reverse shoulder combination and compares it to the components used in the revision of all other total reverse 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 reverse shoulder prostheses i.e. is there a difference in the type of revision undertaken for the SMR/SMR L1 total reverse shoulder combination compared to all other total reverse shoulder prostheses.

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

	SMR/	SMR L1	Other Total Rev	erse Shoulder
Type of Revision	Number	Percent	Number	Percent
Humeral Component	84	22.2	248	23.0
Cement Spacer	12	3.2	116	10.8
Humeral/Glenoid	23	6.1	89	8.2
Glenoid Component	26	6.9	83	7.7
Removal of Prostheses	10	2.6	15	1.4
Reinsertion of Components			3	0.3
N Major	155	41.0	554	51.3
Cup/Head	72	19.0	227	21.0
Cup Only	69	18.3	195	18.1
Head Only	71	18.8	85	7.9
Minor Components	4	1.1	7	0.6
Reoperation	4	1.1	6	0.6
Cement Only	1	0.3	5	0.5
Head/Insert	2	0.5		
N Minor	223	59.0	525	48.7
TOTAL	378	100.0	1079	100.0

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

Fixation	N Revised	N Total
Cemented	0	10
Cementless	356	8514
Hybrid (Glenoid Cemented)	8	108
Hybrid (Glenoid Cementless)	14	313
TOTAL	378	8945

Revision Rates of Primary Total Reverse Shoulder Replacement by State

This enables a state by state variation to be identified for the SMR/SMR L1 total reverse shoulder combination and provides the comparative data for each of the states for all other total reverse 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 Reverse Shoulder Replacement by State

Component	State	N Revised	N Total
SMR/SMR L1	NSW	93	2625
	VIC	80	1500
	QLD	65	1312
	WA	87	1977
	SA	19	756
	TAS	9	259
	ACT/NT	25	516
Other Total Reverse Shoulder	NSW	345	10629
	VIC	204	6035
	QLD	269	7635
	WA	123	3470
	SA	104	2724
	TAS	13	571
	ACT/NT	21	545
TOTAL		1457	40554

Number of Revisions of SMR/SMR L1 Primary Total Reverse 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 reverse 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 Reverse Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	0	2
2006	1	19
2007	16	124
2008	29	262
2009	13	271
2012	22	249
2013	28	562
2014	28	633
2015	43	732
2016	40	914
2017	31	930
2018	34	1045
2019	32	1055
2020	37	1007
2021	24	1140
TOTAL	378	8945

Revision Rates of SMR/SMR L1 Primary Total Reverse 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	131315010-131315140	RESECTION STEM	NO	METAL
SMR	131515200-131515240	CEMENTED REVISION STEM	YES	METAL
Glenoid				
SMR L1	137520005-137520030	L1 METAL BACK GLENOID	NO	METAL
SMR L1	137520008-137520028	L1 METAL BACK GLENOID PEG	NO	METAL

Table 9: Revised Number of SMR/SMR L1 Primary Total Reverse Shoulder Replacement by Catalogue Number Range

Humeral Stem Range Glenoid Range	N Revised	N Total
130415110-130415130 137520005-137520030	26	445
130415140-130415240 137520005-137520030	330	8164
137520008-137520028	0	7
130615120-130615200 137520005-137520030	8	219
130815134-130815166 137520005-137520030	14	85
130915134-130915158 137520005-137520030	0	18
131215200-131215240 137520005-137520030	0	4
131315010-131315140 137520005-137520030	0	2
131515200-131515240 137520005-137520030	0	1
TOTAL	378	8945