SMR/SMR L1 Total Stemmed Reverse Shoulder Investigation

Note: This analysis compares the SMR/SMR L1 humeral stem/glenoid combination with all other total stemmed 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-2023.

Note: Procedures using prostheses with no recorded use in 2022 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Stemmed Reverse Shoulder Replacement

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

Table 1: Revision Rates of Primary Total Stemmed Reverse Shoulder Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
SMR/SMR L1	423	9990	44399	0.95 (0.86, 1.05)
Other Total Stemmed Reverse Shoulder	1306	37267	143170	0.91 (0.86, 0.96)
TOTAL	**1729**	**47257**	**187569**	**0.92 (0.88, 0.97)**

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Stemmed Reverse Shoulder Replacement

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

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

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs
SMR/SMR L1	3.0 (2.7, 3.4)	3.7 (3.4, 4.1)	4.1 (3.7, 4.5)	4.3 (3.9, 4.7)	4.5 (4.0, 4.9)	4.7 (4.3, 5.2)
Other Total Stemmed Reverse Shoulder	2.2 (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)	4.4 (4.2, 4.7)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs
SMR/SMR L1	4.9 (4.4, 5.4)	5.3 (4.7, 5.9)	5.4 (4.8, 6.1)	5.6 (4.9, 6.3)	6.1 (5.2, 7.2)
Other Total Stemmed Reverse Shoulder	4.6 (4.3, 4.9)	5.1 (4.7, 5.4)	5.3 (5.0, 5.7)	5.7 (5.3, 6.2)	6.1 (5.6, 6.7)

CPR	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
SMR/SMR L1	6.4 (5.3, 7.6)	6.7 (5.5, 8.1)	6.7 (5.5, 8.1)	6.7 (5.5, 8.1)	
Other Total Stemmed Reverse Shoulder	6.6 (6.0, 7.4)	6.9 (6.1, 7.8)	7.8 (6.4, 9.5)	7.8 (6.4, 9.5)	

Note: Prostheses no longer used in 2022 are excluded from the comparator.

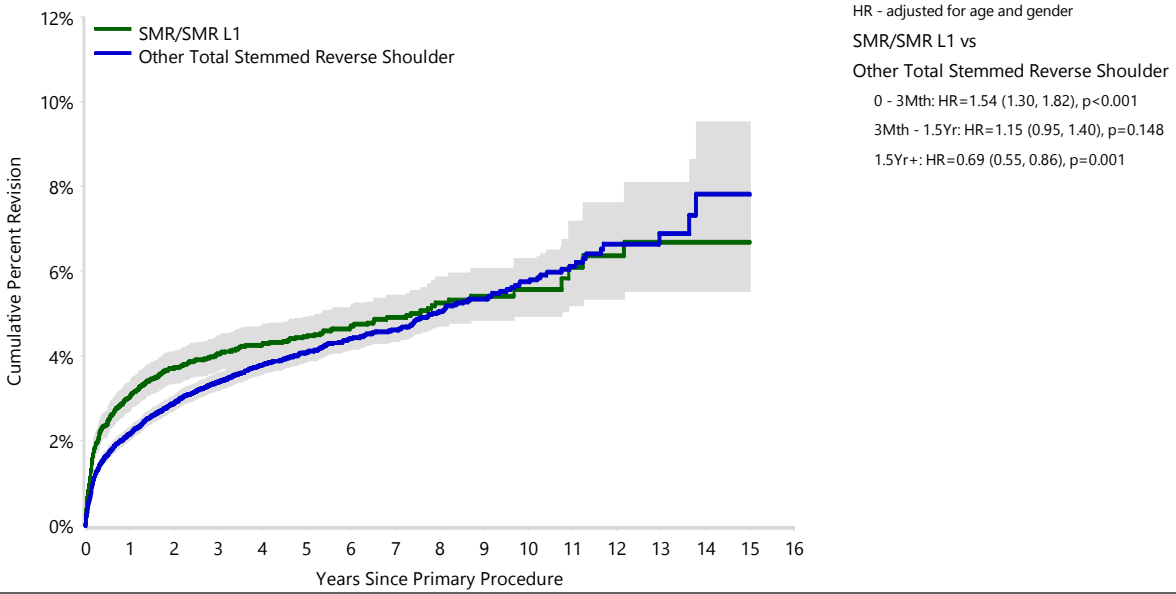
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Reverse Shoulder Replacement

The yearly cumulative percent revision of the SMR/SMR L1 total stemmed reverse shoulder combination is compared to all other total stemmed 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 Stemmed Reverse 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	9990	8586	7257	6113	4940	3837	2900	2044	1407
Other Total Stemmed Reverse Shoulder	37267	30647	24663	19583	14991	11088	7928	5731	4083

Number at Risk	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
SMR/SMR L1	927	520	350	311	271	141	43	7
Other Total Stemmed Reverse Shoulder	2804	1856	1131	655	373	153	48	8

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 3

Primary Diagnosis for Revised Primary Total Stemmed 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 stemmed reverse shoulder prostheses.

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

	SMR/SMR L1		Other Total Stemmed Reverse Shoulder	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	163	38.5	498	38.1
Rotator Cuff Arthropathy	142	33.6	484	37.1
Fracture	93	22.0	211	16.2
Rheumatoid Arthritis	6	1.4	37	2.8
Instability	9	2.1	29	2.2
Tumour	1	0.2	25	1.9
Osteonecrosis	6	1.4	14	1.1
Other Inflammatory Arthritis	3	0.7	7	0.5
Other			1	0.1
TOTAL	**423**	**100.0**	**1306**	**100.0**

Note: Prostheses no longer used in 2022 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 Reverse Shoulder Replacement - Reason for Revision

	SMR/SMR L1			Other Total Stemmed Reverse Shoulder		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Instability/Dislocation	157	1.6	37.1	408	1.1	31.2
Infection	68	0.7	16.1	368	1.0	28.2
Loosening	84	0.8	19.9	195	0.5	14.9
Fracture	59	0.6	13.9	132	0.4	10.1
Dissociation	9	0.1	2.1	52	0.1	4.0
Pain	11	0.1	2.6	24	0.1	1.8
Lysis	3	0.0	0.7	19	0.1	1.5
Malposition	5	0.1	1.2	15	0.0	1.1
Arthrofibrosis	13	0.1	3.1	5	0.0	0.4
Implant Breakage Glenoid				13	0.0	1.0
Incorrect Sizing	2	0.0	0.5	10	0.0	0.8
Metal Related Pathology	5	0.1	1.2	7	0.0	0.5
Heterotopic Bone				6	0.0	0.5
Rotator Cuff Insufficiency	1	0.0	0.2	5	0.0	0.4
Wear Humeral Cup	1	0.0	0.2	4	0.0	0.3
Implant Breakage Humeral				3	0.0	0.2
Tumour	1	0.0	0.2	3	0.0	0.2
Implant Breakage Glenoid Insert				2	0.0	0.2
Glenoid Erosion				1	0.0	0.1
Wear Glenoid Insert	1	0.0	0.2			
Other	3	0.0	0.7	34	0.1	2.6
N Revision	**423**	**4.2**	**100.0**	**1306**	**3.5**	**100.0**
N Primary	**9990**			**37267**		

Note: Prostheses no longer used in 2022 are excluded from the comparator.

FIGURE 2

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

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

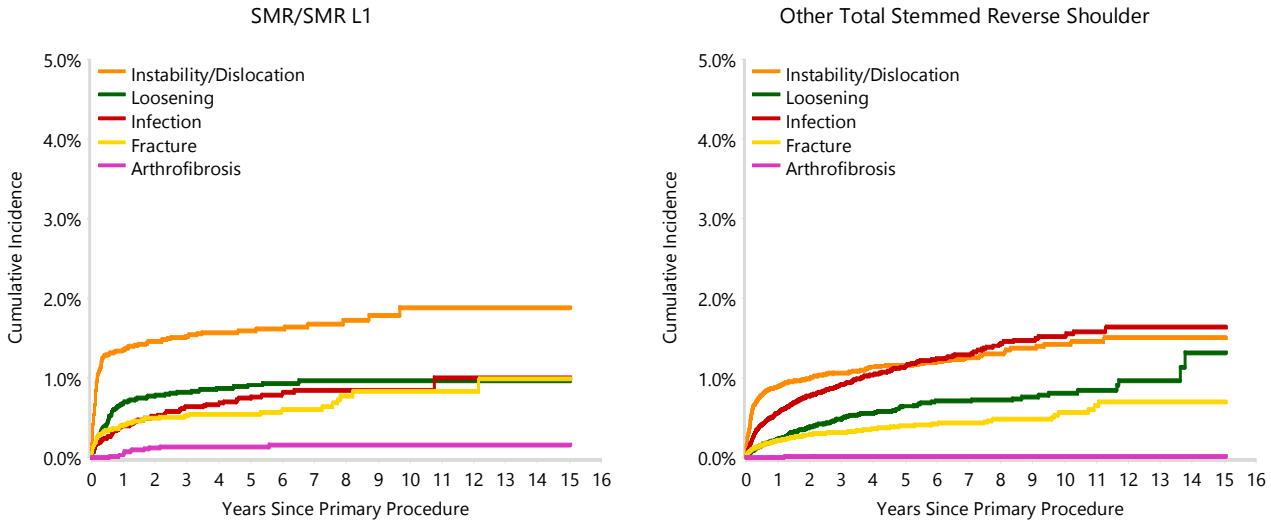


TABLE 5

Type of Revision Performed for Primary Total Stemmed Reverse Shoulder Replacement

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

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

	SMR/SMR L1		Other Total Stemmed Reverse Shoulder	
Type of Revision	Number	Percent	Number	Percent
Humeral Component	94	22.2	329	25.2
Cement Spacer	13	3.1	133	10.2
Humeral/Glenoid	27	6.4	119	9.1
Glenoid Component	28	6.6	100	7.7
Removal of Prostheses	10	2.4	21	1.6
Reinsertion of Components			3	0.2
N Major	**172**	**40.7**	**705**	**54.0**
Cup/Head	81	19.1	256	19.6
Cup Only	80	18.9	223	17.1
Head Only	77	18.2	99	7.6
Cement Only	3	0.7	8	0.6
Minor Components	4	0.9	8	0.6
Reoperation	4	0.9	7	0.5
Head/Insert	2	0.5		
N Minor	**251**	**59.3**	**601**	**46.0**
TOTAL	**423**	**100.0**	**1306**	**100.0**

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 6

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

Fixation	N Revised	N Total
Cemented	0	11
Cementless	394	9487
Hybrid (Glenoid Cemented)	11	128
Hybrid (Glenoid Cementless)	18	364
TOTAL	**423**	**9990**

TABLE 7

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

Bearing Surface	N Revised	N Total
Ceramic/XLPE	0	8
Metal/XLPE	274	7521
XLPE/Metal	149	2448
Unknown	0	13
TOTAL	**423**	**9990**

TABLE 8

Revision Rates of Primary Total Stemmed Reverse Shoulder Replacement by State

This enables a state by state variation to be identified for the SMR/SMR L1 total stemmed reverse shoulder combination and provides the comparative data for each of the states for all other total stemmed 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 8: Revised Number of Primary Total Stemmed Reverse Shoulder Replacement by State

Component	State	N Revised	N Total
SMR/SMR L1	NSW	107	2918
	VIC	87	1662
	QLD	71	1429
	WA	97	2254
	SA	22	817
	TAS	11	321
	ACT/NT	28	589
Other Total Stemmed Reverse Shoulder	NSW	412	12411
	VIC	255	7140
	QLD	328	9075
	WA	148	4085
	SA	125	3208
	TAS	14	701
	ACT/NT	24	647
TOTAL		**1729**	**47257**

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 9

Number of Revisions of SMR/SMR L1 Primary Total Stemmed 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 stemmed 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 2022 has a maximum of one year to be revised, whereas a primary procedure performed in 2020 has a maximum of three years to be revised.

Table 9: Number of Revisions of SMR/SMR L1 Primary Total Stemmed 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	248
2013	28	563
2014	28	633
2015	43	732
2016	42	914
2017	31	930
2018	35	1046
2019	33	1055
2020	42	1009
2021	38	1186
2022	22	996
TOTAL	**423**	**9990**

TABLE 10

Revision Rates of SMR/SMR L1 Primary Total Stemmed 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 10: Revised Number of SMR/SMR L1 Primary Total Stemmed Reverse Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glenoid Range	N Revised	N Total
130415110-130415130	137520005-137520030	33	483
130415140-130415240	137520005-137520030	365	9125
	137520008-137520028	0	9
130615120-130615200	137520005-137520030	11	260
130815134-130815166	137520005-137520030	14	87
130915134-130915158	137520005-137520030	0	19
131215200-131215240	137520005-137520030	0	4
131315010-131315140	137520005-137520030	0	2
131515200-131515240	137520005-137520030	0	1
TOTAL		**423**	**9990**