

## Trabecular Metal/Comprehensive Reverse Total Stemmed Reverse Shoulder Investigation

Note: This analysis compares the Trabecular Metal/Comprehensive Reverse 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 Trabecular Metal/Comprehensive Reverse 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)
Trabecular Metal/Comprehensive Reverse	16	313	789	2.03 (1.16, 3.29)
Other Total Stemmed Reverse Shoulder	1712	46938	186745	0.92 (0.87, 0.96)
<b>TOTAL</b>	<b>1728</b>	<b>47251</b>	<b>187534</b>	<b>0.92 (0.88, 0.97)</b>

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 Trabecular Metal/Comprehensive Reverse 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
Trabecular Metal/Comprehensive Reverse	4.3 (2.5, 7.3)	4.7 (2.8, 7.9)	6.1 (3.7, 10.0)	6.1 (3.7, 10.0)		
Other Total Stemmed Reverse Shoulder	2.3 (2.2, 2.5)	3.1 (2.9, 3.2)	3.5 (3.3, 3.7)	3.9 (3.7, 4.1)	4.1 (3.9, 4.3)	4.4 (4.2, 4.7)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs
Trabecular Metal/Comprehensive Reverse					
Other Total Stemmed Reverse Shoulder	4.6 (4.4, 4.9)	5.1 (4.8, 5.4)	5.3 (5.0, 5.6)	5.7 (5.3, 6.1)	6.1 (5.6, 6.6)

CPR	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Trabecular Metal/Comprehensive Reverse					
Other Total Stemmed Reverse Shoulder	6.5 (6.0, 7.1)	6.8 (6.1, 7.5)	7.3 (6.4, 8.3)	7.3 (6.4, 8.3)	

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

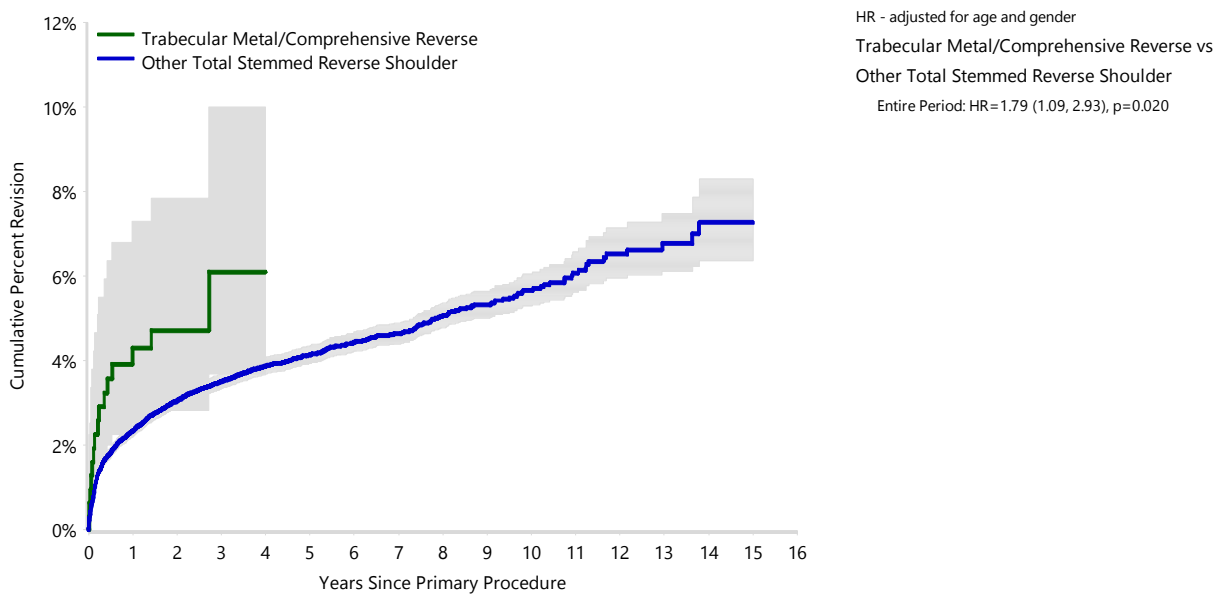
FIGURE 1

**Yearly Cumulative Percent Revision of Primary Total Stemmed Reverse Shoulder Replacement**

The yearly cumulative percent revision of the Trabecular Metal/Comprehensive Reverse 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
Trabecular Metal/Comprehensive Reverse	313	252	182	125	62	20	0	0	0
Other Total Stemmed Reverse Shoulder	46938	38976	31734	25568	19866	14902	10825	7772	5487

Number at Risk	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Trabecular Metal/Comprehensive Reverse	0	0	0	0	0	0	0	0
Other Total Stemmed Reverse Shoulder	3728	2375	1480	965	644	294	91	15

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**

Primary Diagnosis	Trabecular Metal/Comprehensive Reverse		Other Total Stemmed Reverse Shoulder	
	Number	Percent	Number	Percent
Osteoarthritis	3	18.8	657	38.4
Rotator Cuff Arthropathy	10	62.5	616	36.0
Fracture	3	18.8	301	17.6
Rheumatoid Arthritis			43	2.5
Instability			38	2.2
Tumour			26	1.5
Osteonecrosis			20	1.2
Other Inflammatory Arthritis			10	0.6
Other			1	0.1
<b>TOTAL</b>	<b>16</b>	<b>100.0</b>	<b>1712</b>	<b>100.0</b>

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 (Follow-up Limited to 6 Years)**

Revision Diagnosis	Trabecular Metal/Comprehensive Reverse			Other Total Stemmed Reverse Shoulder		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Instability/Dislocation	7	2.2	43.8	535	1.1	33.0
Infection	3	1.0	18.8	408	0.9	25.2
Loosening				268	0.6	16.6
Fracture	1	0.3	6.3	173	0.4	10.7
Dissociation	4	1.3	25.0	54	0.1	3.3
Pain				35	0.1	2.2
Malposition				20	0.0	1.2
Arthrofibrosis				18	0.0	1.1
Lysis				17	0.0	1.1
Implant Breakage Glenoid				13	0.0	0.8
Incorrect Sizing				12	0.0	0.7
Metal Related Pathology				10	0.0	0.6
Heterotopic Bone				6	0.0	0.4
Rotator Cuff Insufficiency				6	0.0	0.4
Tumour				4	0.0	0.2
Wear Humeral Cup				2	0.0	0.1
Glenoid Erosion	1	0.3	6.3			
Implant Breakage Glenoid Insert				1	0.0	0.1
Implant Breakage Humeral				1	0.0	0.1
Wear Glenoid Insert				1	0.0	0.1
Other				35	0.1	2.2
<b>N Revision</b>	<b>16</b>	<b>5.1</b>	<b>100.0</b>	<b>1619</b>	<b>3.4</b>	<b>100.0</b>
<b>N Primary</b>	<b>313</b>			<b>46938</b>		

Note: This table is restricted to revisions within 6 years for all groups to allow a time-matched comparison of revisions.

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 Trabecular Metal/Comprehensive Reverse 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

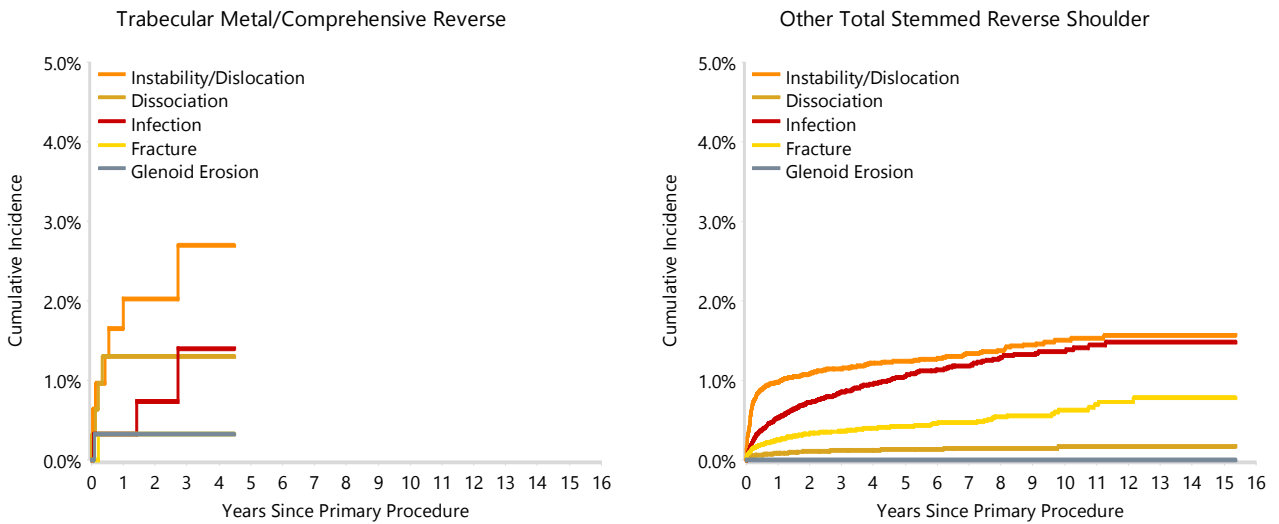


TABLE 5

**Type of Revision Performed for Primary Total Stemmed Reverse Shoulder Replacement**

This analysis identifies the components used in the revision of the Trabecular Metal/Comprehensive Reverse 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 Trabecular Metal/Comprehensive Reverse 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 (Follow-up Limited to 6 Years)**

Type of Revision	Trabecular Metal/Comprehensive Reverse		Other Total Stemmed Reverse Shoulder	
	Number	Percent	Number	Percent
Humeral Component	1	6.3	392	24.2
Humeral/Glenoid	1	6.3	139	8.6
Cement Spacer	2	12.5	133	8.2
Glenoid Component	7	43.8	117	7.2
Removal of Prostheses			31	1.9
Reinsertion of Components			3	0.2
<b>N Major</b>	<b>11</b>	<b>68.8</b>	<b>815</b>	<b>50.3</b>
Cup/Head			320	19.8
Cup Only	5	31.3	286	17.7
Head Only			165	10.2
Minor Components			11	0.7
Cement Only			10	0.6
Reoperation			10	0.6
Head/Insert			2	0.1
<b>N Minor</b>	<b>5</b>	<b>31.3</b>	<b>804</b>	<b>49.7</b>
<b>TOTAL</b>	<b>16</b>	<b>100.0</b>	<b>1619</b>	<b>100.0</b>

Note: This table is restricted to revisions within 6 years for all groups to allow a time-matched comparison of revisions.

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

TABLE 6

### Revision Rates of Trabecular Metal/Comprehensive Reverse 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 Trabecular Metal/Comprehensive Reverse Primary Total Stemmed Reverse Shoulder Replacement by Fixation**

Fixation	N Revised	N Total
Cemented	0	2
Cementless	12	234
Hybrid (Glenoid Cemented)	0	3
Hybrid (Glenoid Cementless)	4	74
<b>TOTAL</b>	<b>16</b>	<b>313</b>

TABLE 7

### Revision Rates of Trabecular Metal/Comprehensive Reverse 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 Trabecular Metal/Comprehensive Reverse Primary Total Stemmed Reverse Shoulder Replacement by Bearing Surface**

Bearing Surface	N Revised	N Total
Non XLPE/Metal	16	313
<b>TOTAL</b>	<b>16</b>	<b>313</b>



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 Trabecular Metal/Comprehensive Reverse 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
Trabecular Metal/Comprehensive Reverse	NSW	8	162
	VIC	3	52
	QLD	3	53
	WA	0	1
	SA	0	16
	ACT/NT	2	29
Other Total Stemmed Reverse Shoulder	NSW	511	15166
	VIC	339	8750
	QLD	396	10449
	WA	244	6336
	SA	147	4008
	TAS	25	1022
	ACT/NT	50	1207
<b>TOTAL</b>		<b>1728</b>	<b>47251</b>

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

**TABLE 9****Number of Revisions of Trabecular Metal/Comprehensive Reverse 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 Trabecular Metal/Comprehensive Reverse 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 Trabecular Metal/Comprehensive Reverse Primary Total Stemmed Reverse Shoulder Replacement by Year of Implant**

Year of Implant	Number Revised	Total Number
2017	2	24
2018	1	43
2019	2	68
2020	2	56
2021	5	73
2022	4	49
<b>TOTAL</b>	<b>16</b>	<b>313</b>

TABLE 10

### Revision Rates of Trabecular Metal/Comprehensive Reverse 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 Trabecular Metal/Comprehensive Reverse 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
<b>Humeral Stem</b>				
Trabecular Metal	00434900813-00434901817	TM REVERSE HUMERAL STEM	NO	METAL
<b>Glenoid</b>				
Comprehensive Reverse	010000589-010000589	GLENOSPHERE MINI BASEPLATE POROUS COAT HA Ti6AL4V	NO	METAL
Comprehensive Reverse	110032410-110032430	AUGMENTED BASEPLATE IMPLANT WITH TAPER ADAPTER	NO	
Comprehensive Reverse	115330-115330	GLENOSPHERE BASEPLATE POROUS Ti6AL4V	NO	METAL

**Table 10: Revised Number of Trabecular Metal/Comprehensive Reverse Primary Total Stemmed Reverse Shoulder Replacement by Catalogue Number Range**

Humeral Stem Range	Glenoid Range	N Revised	N Total
00434900813-00434901817	010000589-010000589	12	247
	110032410-110032430	4	62
	115330-115330	0	4
<b>TOTAL</b>		<b>16</b>	<b>313</b>