Vaios/Vaios Total Stemmed Anatomic Shoulder Investigation

Note: This analysis compares the Vaios/Vaios humeral stem/glenoid combination with all other total stemmed anatomic 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 Anatomic Shoulder Replacement

The revision rate of the Vaios/Vaios total stemmed anatomic shoulder combination is compared to all other total stemmed anatomic shoulder prostheses.

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

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Vaios/Vaios	19	36	212	8.97 (5.40, 14.01)
Other Total Stemmed Anatomic Shoulder	672	7857	43714	1.54 (1.42, 1.66)
TOTAL	**691**	**7893**	**43925**	**1.57 (1.46, 1.69)**

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

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the Vaios/Vaios total stemmed anatomic shoulder combination is compared to all other total stemmed anatomic shoulder prostheses.

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

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs
Vaios/Vaios	13.9 (6.0, 30.2)	16.7 (7.9, 33.4)	27.8 (16.0, 45.5)	33.3 (20.5, 51.2)	39.1 (25.3, 57.0)	45.5 (30.8, 63.4)
Other Total Stemmed Anatomic Shoulder	3.1 (2.7, 3.5)	5.0 (4.5, 5.5)	6.1 (5.5, 6.7)	6.9 (6.3, 7.5)	7.8 (7.1, 8.4)	8.5 (7.8, 9.2)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs
Vaios/Vaios	48.7 (33.6, 66.4)	48.7 (33.6, 66.4)	57.0 (40.5, 74.6)	57.0 (40.5, 74.6)	57.0 (40.5, 74.6)
Other Total Stemmed Anatomic Shoulder	9.3 (8.5, 10.0)	10.4 (9.6, 11.3)	11.5 (10.5, 12.5)	12.7 (11.6, 13.9)	13.4 (12.2, 14.7)

CPR	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Vaios/Vaios					
Other Total Stemmed Anatomic Shoulder	14.7 (13.3, 16.2)	16.8 (15.1, 18.7)	17.2 (15.4, 19.1)	17.6 (15.7, 19.7)	

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

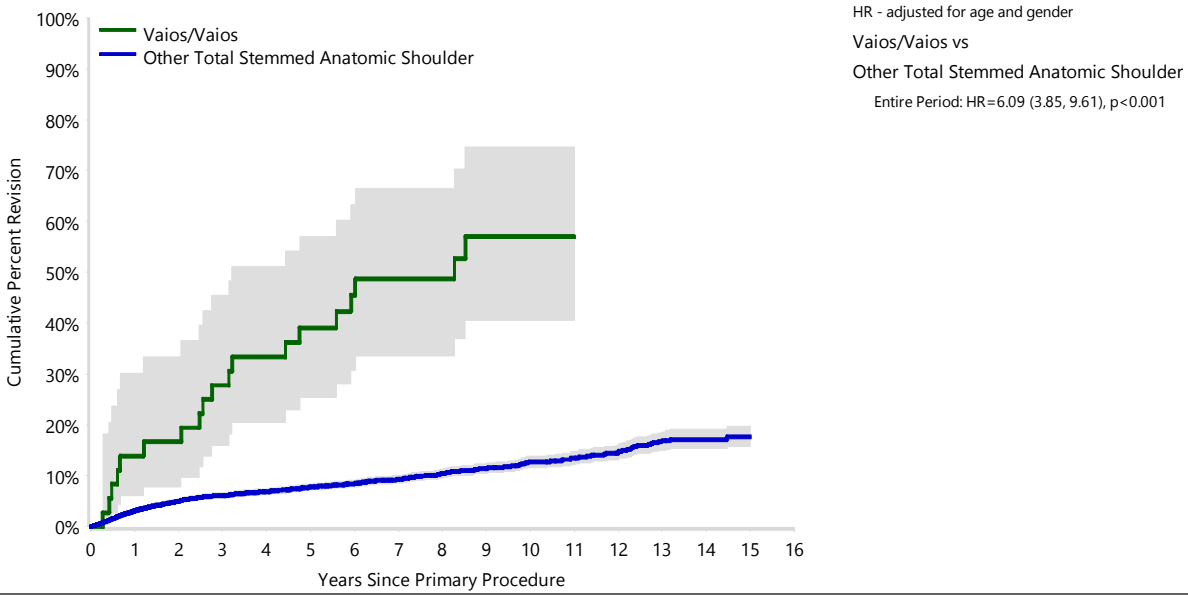
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the Vaios/Vaios total stemmed anatomic shoulder combination is compared to all other total stemmed anatomic 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 Anatomic Shoulder Replacement



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
Vaios/Vaios	36	31	30	26	24	21	17	13	13
Other Total Stemmed Anatomic Shoulder	7857	7043	6282	5568	4754	3936	3229	2539	1905

Number at Risk	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Vaios/Vaios	8	7	5	0	0	0	0	0
Other Total Stemmed Anatomic Shoulder	1375	1028	780	616	477	274	90	15

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

TABLE 3

Primary Diagnosis for Revised Primary Total Stemmed Anatomic 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 anatomic shoulder prostheses.

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

	Vaios/Vaios		Other Total Stemmed Anatomic Shoulder	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	18	94.7	619	92.1
Osteonecrosis			17	2.5
Fracture			12	1.8
Rheumatoid Arthritis			7	1.0
Rotator Cuff Arthropathy			7	1.0
Instability	1	5.3	5	0.7
Other Inflammatory Arthritis			5	0.7
TOTAL	**19**	**100.0**	**672**	**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 Anatomic Shoulder Replacement - Reason for Revision (Follow-up Limited to 11.6 Years)

	Vaios/Vaios			Other Total Stemmed Anatomic Shoulder		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency	5	13.9	26.3	238	3.0	36.6
Instability/Dislocation	3	8.3	15.8	177	2.3	27.2
Loosening	5	13.9	26.3	91	1.2	14.0
Infection				33	0.4	5.1
Fracture	1	2.8	5.3	18	0.2	2.8
Pain				17	0.2	2.6
Arthrofibrosis	1	2.8	5.3	12	0.2	1.8
Wear Glenoid Insert	2	5.6	10.5	10	0.1	1.5
Implant Breakage Glenoid Insert	1	2.8	5.3	9	0.1	1.4
Lysis	1	2.8	5.3	9	0.1	1.4
Implant Breakage Glenoid				7	0.1	1.1
Metal Related Pathology				7	0.1	1.1
Malposition				6	0.1	0.9
Dissociation				5	0.1	0.8
Incorrect Sizing				5	0.1	0.8
Progression Of Disease				2	0.0	0.3
Other				5	0.1	0.8
N Revision	**19**	**52.8**	**100.0**	**651**	**8.3**	**100.0**
N Primary	**36**			**7857**		

Note: This table is restricted to revisions within 11.6 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 Anatomic 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 Vaios/Vaios total stemmed anatomic shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total stemmed anatomic shoulder prostheses.

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

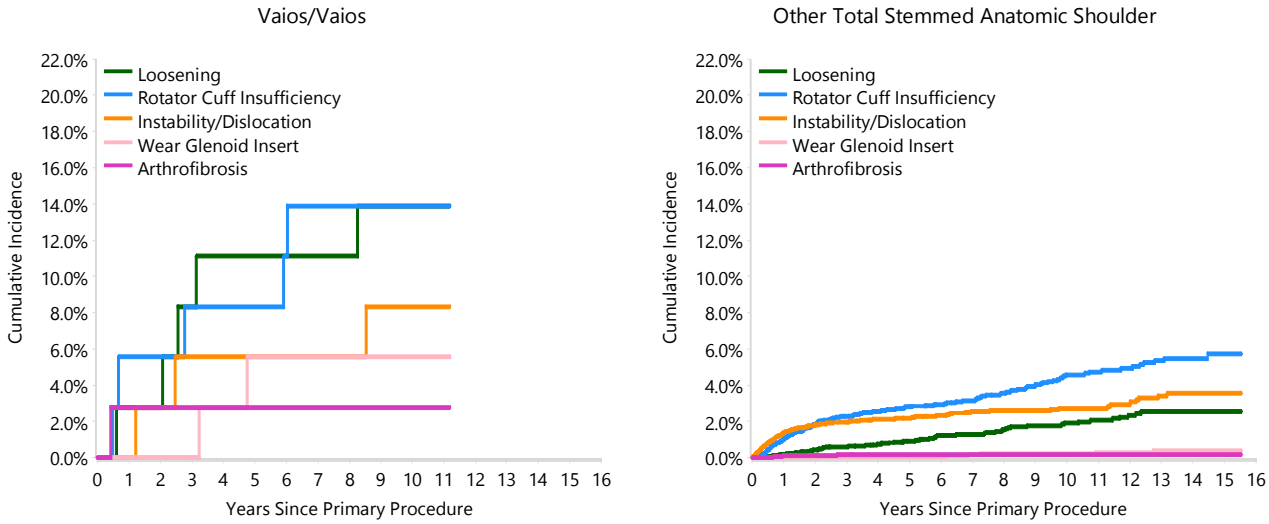


TABLE 5

Type of Revision Performed for Primary Total Stemmed Anatomic Shoulder Replacement

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

Table 5: Primary Total Stemmed Anatomic Shoulder Replacement - Type of Revision (Follow-up Limited to 11.6 Years)

	Vaios/Vaios		Other Total Stemmed Anatomic Shoulder	
Type of Revision	Number	Percent	Number	Percent
Humeral Component	11	57.9	380	58.4
Humeral/Glenoid	3	15.8	189	29.0
Glenoid Component	1	5.3	17	2.6
Cement Spacer			14	2.2
Removal of Prostheses			4	0.6
Reinsertion of Components			1	0.2
N Major	**15**	**78.9**	**605**	**92.9**
Head Only	3	15.8	39	6.0
Reoperation			3	0.5
Head/Insert			2	0.3
Minor Components	1	5.3	2	0.3
N Minor	**4**	**21.1**	**46**	**7.1**
TOTAL	**19**	**100.0**	**651**	**100.0**

Note: This table is restricted to revisions within 11.6 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 Vaios/Vaios Primary Total Stemmed Anatomic 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 Vaios/Vaios Primary Total Stemmed Anatomic Shoulder Replacement by Fixation

Fixation	N Revised	N Total
Cemented	1	1
Cementless	15	25
Hybrid (Glenoid Cemented)	2	8
Hybrid (Glenoid Cementless)	1	2
TOTAL	**19**	**36**

TABLE 7

Revision Rates of Vaios/Vaios Primary Total Stemmed Anatomic 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 Vaios/Vaios Primary Total Stemmed Anatomic Shoulder Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Metal/Non XLPE	19	36
TOTAL	**19**	**36**

TABLE 8

Revision Rates of Primary Total Stemmed Anatomic Shoulder Replacement by State

This enables a state by state variation to be identified for the Vaios/Vaios total stemmed anatomic shoulder combination and provides the comparative data for each of the states for all other total stemmed anatomic 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 Anatomic Shoulder Replacement by State

Component	State	N Revised	N Total
Vaios/Vaios	NSW	9	12
	VIC	3	5
	QLD	3	8
	WA	4	8
	TAS	0	1
	ACT/NT	0	2
Other Total Stemmed Anatomic Shoulder	NSW	178	2255
	VIC	150	1854
	QLD	95	1431
	WA	139	1132
	SA	54	738
	TAS	27	209
	ACT/NT	29	238
TOTAL		**691**	**7893**

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

TABLE 9

Number of Revisions of Vaios/Vaios Primary Total Stemmed Anatomic Shoulder Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Vaios/Vaios total stemmed anatomic 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 Vaios/Vaios Primary Total Stemmed Anatomic Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2011	8	16
2012	9	17
2013	2	2
2014	0	1
TOTAL	**19**	**36**

TABLE 10

Revision Rates of Vaios/Vaios Primary Total Stemmed Anatomic 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 Vaios/Vaios 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				
Vaios	8010108-8010116	STEM H-AC TI6AI4V	NO	METAL
Vaios	8020106-8020112	CEMENTED STEM	YES	METAL
Vaios	8022208-8022210	LONG DISTAL STEM CEMENTED	YES	METAL
Glenoid				
Vaios	8010900-8010911	METAL BACK GLENOID	NO	METAL
Vaios	8020342-8020458	UHMWPE CEMENTED GLENOID	YES	NON CROSS-LINKED POLYETHYLENE

Table 10: Revised Number of Vaios/Vaios Primary Total Stemmed Anatomic Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glenoid Range	N Revised	N Total
8010108-8010116	8010900-8010911	15	25
	8020342-8020458	3	9
8020106-8020112	8010900-8010911	0	1
8022208-8022210	8010900-8010911	1	1
TOTAL		**19**	**36**