

Delta Xtend/Delta Xtend Hemi Stemmed Anatomic Shoulder Investigation

Note: This analysis compares the Delta Xtend/Delta Xtend humeral stem/head combination with all other hemi 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 Hemi Stemmed Anatomic Shoulder Replacement

The revision rate of the Delta Xtend/Delta Xtend hemi stemmed anatomic shoulder combination is compared to all other hemi stemmed anatomic shoulder prostheses.

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

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Delta Xtend/Delta Xtend	14	76	463	3.02 (1.65, 5.07)
Other Hemi Stemmed Anatomic Shoulder	391	3766	23407	1.67 (1.51, 1.84)
TOTAL	405	3842	23870	1.70 (1.54, 1.87)

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

TABLE 2

Yearly Cumulative Percent Revision of Primary Hemi Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the Delta Xtend/Delta Xtend hemi stemmed anatomic shoulder combination is compared to all other hemi stemmed anatomic shoulder prostheses.

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

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs
Delta Xtend/Delta Xtend	6.7 (2.8, 15.3)	13.5 (7.5, 23.7)	16.4 (9.7, 27.2)	16.4 (9.7, 27.2)	16.4 (9.7, 27.2)	16.4 (9.7, 27.2)
Other Hemi Stemmed Anatomic Shoulder	3.3 (2.8, 4.0)	6.9 (6.1, 7.7)	8.7 (7.8, 9.7)	9.8 (8.8, 10.9)	10.7 (9.6, 11.8)	11.1 (10.1, 12.3)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs
Delta Xtend/Delta Xtend	18.6 (11.1, 30.1)	18.6 (11.1, 30.1)	21.6 (13.0, 34.6)	21.6 (13.0, 34.6)	
Other Hemi Stemmed Anatomic Shoulder	11.4 (10.3, 12.6)	11.8 (10.7, 13.1)	12.4 (11.2, 13.6)	13.0 (11.7, 14.3)	13.3 (12.0, 14.7)

CPR	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Delta Xtend/Delta Xtend					
Other Hemi Stemmed Anatomic Shoulder	13.5 (12.1, 14.9)	14.1 (12.6, 15.8)	14.6 (12.9, 16.6)	17.4 (14.0, 21.6)	

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

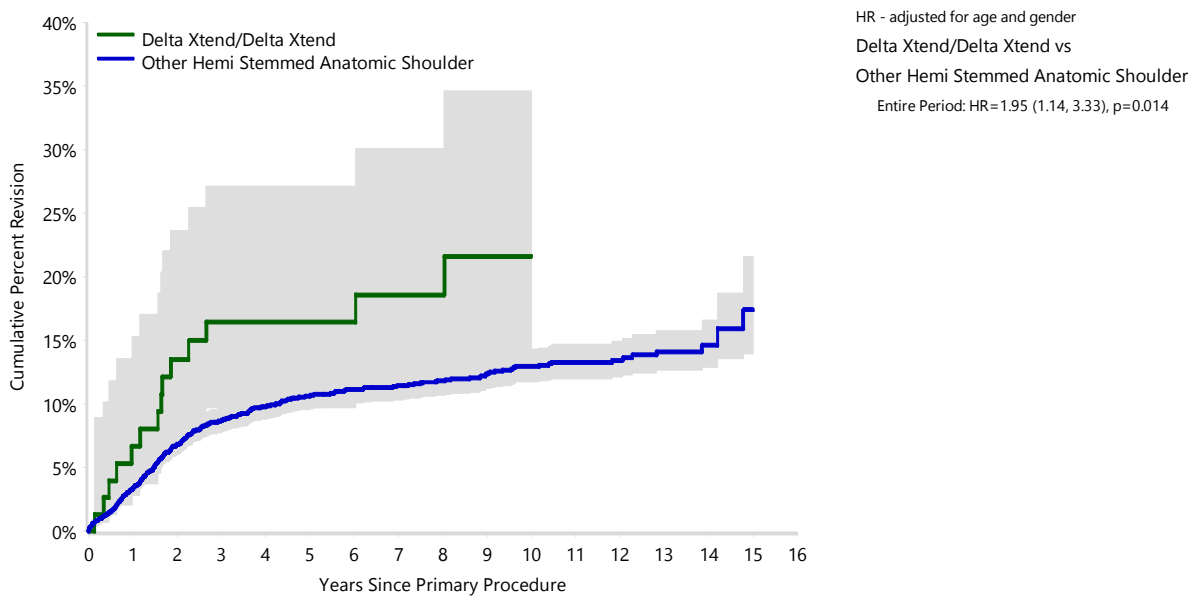
FIGURE 1

Yearly Cumulative Percent Revision of Primary Hemi Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the Delta Xtend/Delta Xtend hemi stemmed anatomic shoulder combination is compared to all other hemi 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 Hemi 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
Delta Xtend/Delta Xtend	76	69	62	56	51	42	39	31	27
Other Hemi Stemmed Anatomic Shoulder	3766	3344	2925	2577	2295	2067	1827	1599	1351

Number at Risk	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Delta Xtend/Delta Xtend	20	13	8	6	2	2	2	0
Other Hemi Stemmed Anatomic Shoulder	1119	883	663	456	295	158	41	5

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

TABLE 3

Primary Diagnosis for Revised Primary Hemi 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 hemi stemmed anatomic shoulder prostheses.

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

Primary Diagnosis	Delta Xtend/Delta Xtend		Other Hemi Stemmed Anatomic Shoulder	
	Number	Percent	Number	Percent
Fracture	4	28.6	235	60.1
Osteoarthritis	3	21.4	109	27.9
Osteonecrosis	1	7.1	17	4.3
Rotator Cuff Arthropathy	4	28.6	13	3.3
Rheumatoid Arthritis			6	1.5
Tumour			6	1.5
Instability	1	7.1	2	0.5
Other Inflammatory Arthritis	1	7.1	2	0.5
Other			1	0.3
TOTAL	14	100.0	391	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 Hemi Stemmed Anatomic Shoulder Replacement - Reason for Revision

Revision Diagnosis	Delta Xtend/Delta Xtend			Other Hemi Stemmed Anatomic Shoulder		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency				94	2.5	24.0
Instability/Dislocation	4	5.3	28.6	70	1.9	17.9
Glenoid Erosion	4	5.3	28.6	51	1.4	13.0
Infection	3	3.9	21.4	45	1.2	11.5
Pain				39	1.0	10.0
Fracture	1	1.3	7.1	32	0.8	8.2
Loosening	2	2.6	14.3	24	0.6	6.1
Arthrofibrosis				8	0.2	2.0
Dissociation				8	0.2	2.0
Incorrect Sizing				5	0.1	1.3
Malposition				5	0.1	1.3
Tumour				3	0.1	0.8
Heterotopic Bone				1	0.0	0.3
Implant Breakage Glenoid				1	0.0	0.3
Lysis				1	0.0	0.3
Osteonecrosis				1	0.0	0.3
Other				3	0.1	0.8
N Revision	14	18.4	100.0	391	10.4	100.0
N Primary	76			3766		

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

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Hemi 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 Delta Xtend/Delta Xtend hemi stemmed anatomic shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other hemi stemmed anatomic shoulder prostheses.

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

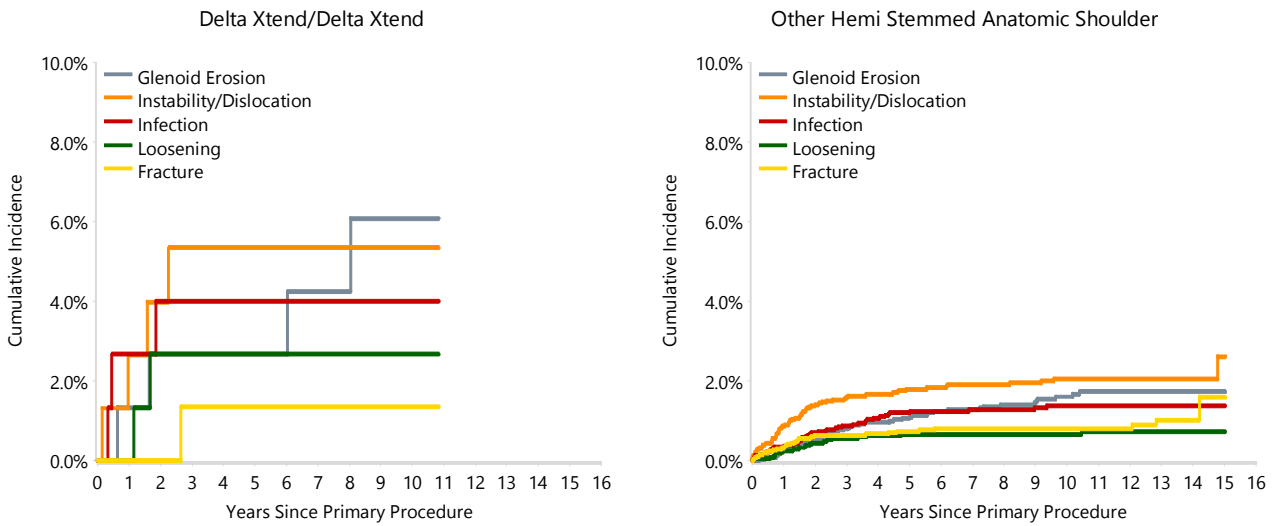


TABLE 5

Type of Revision Performed for Primary Hemi Stemmed Anatomic Shoulder Replacement

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

Table 5: Primary Hemi Stemmed Anatomic Shoulder Replacement - Type of Revision

Type of Revision	Delta Xtend/Delta Xtend		Other Hemi Stemmed Anatomic Shoulder	
	Number	Percent	Number	Percent
Humeral/Glenoid	3	21.4	271	69.3
Humeral Component	1	7.1	39	10.0
Glenoid Component	9	64.3	28	7.2
Cement Spacer	1	7.1	25	6.4
Removal of Prostheses			4	1.0
N Major	14	100.0	367	93.9
Head Only			14	3.6
Reoperation			5	1.3
Cement Only			3	0.8
Head/Insert			1	0.3
Minor Components			1	0.3
N Minor			24	6.1
TOTAL	14	100.0	391	100.0

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

TABLE 6

Revision Rates of Primary Hemi Stemmed Anatomic Shoulder Replacement by State

This enables a state by state variation to be identified for the Delta Xtend/Delta Xtend hemi stemmed anatomic shoulder combination and provides the comparative data for each of the states for all other hemi 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 6: Revised Number of Primary Hemi Stemmed Anatomic Shoulder Replacement by State

Component	State	N Revised	N Total
Delta Xtend/Delta Xtend	NSW	3	15
	VIC	3	23
	QLD	0	12
	WA	1	5
	SA	1	2
	TAS	4	13
	ACT/NT	2	6
Other Hemi Stemmed Anatomic Shoulder	NSW	94	1179
	VIC	109	1052
	QLD	101	871
	WA	30	219
	SA	27	210
	TAS	14	131
	ACT/NT	16	104
TOTAL		405	3842

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

TABLE 7**Number of Revisions of Delta Xtend/Delta Xtend Primary Hemi Stemmed Anatomic Shoulder Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Delta Xtend/Delta Xtend hemi 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 7: Number of Revisions of Delta Xtend/Delta Xtend Primary Hemi Stemmed Anatomic Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2007	0	2
2008	0	5
2009	2	9
2010	2	9
2011	1	5
2012	3	10
2013	1	7
2014	1	6
2015	3	5
2016	0	4
2017	0	3
2018	0	6
2019	1	3
2020	0	1
2022	0	1
TOTAL	14	76

TABLE 8

Revision Rates of Delta Xtend/Delta Xtend Primary Hemi 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 Delta Xtend/Delta Xtend 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				
Delta Xtend	130708100-130714200	MONOBLOC HUMERAL CEMENTED EPIPHYSIS STANDARD	YES	METAL
Delta Xtend	130708110-130714210	MONOBLOC HUMERAL CEMENTED EPIPHYSIS REVISION	YES	METAL
Delta Xtend	130710000-130716000	MODULAR HUMERAL STEM	NO	METAL
Head				
Delta Xtend	130748021-130752026	CTA HEAD EXTENDED LIP	NO	METAL

Table 8: Revised Number of Delta Xtend/Delta Xtend Primary Hemi Stemmed Anatomic Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Head Range	N Revised	N Total
130708100-130714200	130748021-130752026	6	31
130708110-130714210	130748021-130752026	0	3
130710000-130716000	130748021-130752026	8	42
TOTAL		14	76