

Delta Xtend/Delta Xtend Hemi Stemmed Shoulder Investigation

Note: This analysis compares the Delta Xtend/Delta Xtend humeral stem/head combination with all other hemi stemmed 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>.

TABLE 1

Revision Rate of Primary Hemi Stemmed Shoulder Replacement

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

Table 1: Revision Rates of Primary Hemi Stemmed Shoulder Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Delta Xtend/Delta Xtend	14	75	431	3.25 (1.78, 5.45)
Other Hemi Stemmed Shoulder	514	5467	35399	1.45 (1.33, 1.58)
TOTAL	528	5542	35830	1.47 (1.35, 1.60)

TABLE 2

Yearly Cumulative Percent Revision of Primary Hemi Stemmed Shoulder Replacement

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

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

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Delta Xtend/Delta Xtend	6.7 (2.8, 15.4)	13.6 (7.6, 23.9)	16.6 (9.8, 27.4)	16.6 (9.8, 27.4)	16.6 (9.8, 27.4)
Other Hemi Stemmed Shoulder	3.0 (2.5, 3.5)	6.0 (5.3, 6.6)	7.8 (7.0, 8.5)	8.6 (7.8, 9.4)	9.3 (8.5, 10.2)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Delta Xtend/Delta Xtend	16.6 (9.8, 27.4)	19.0 (11.3, 30.8)	19.0 (11.3, 30.8)	22.4 (13.3, 36.1)	
Other Hemi Stemmed Shoulder	9.8 (9.0, 10.7)	10.1 (9.2, 11.0)	10.6 (9.7, 11.5)	11.1 (10.2, 12.1)	11.7 (10.7, 12.7)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Delta Xtend/Delta Xtend					
Other Hemi Stemmed Shoulder	12.1 (11.1, 13.2)	12.3 (11.3, 13.5)	13.0 (11.8, 14.4)	13.0 (11.8, 14.4)	

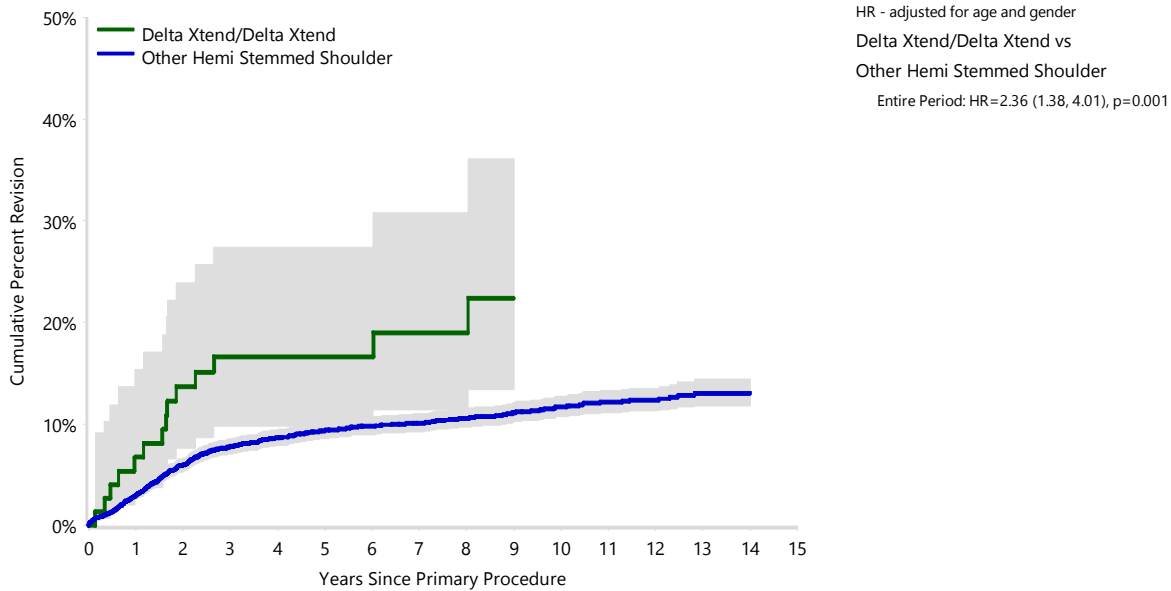
FIGURE 1

Yearly Cumulative Percent Revision of Primary Hemi Stemmed Shoulder Replacement

The yearly cumulative percent revision of the Delta Xtend/Delta Xtend hemi stemmed shoulder combination is compared to all other hemi stemmed 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 Shoulder Replacement



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Delta Xtend/Delta Xtend	75	69	61	55	45	41	35	30
Other Hemi Stemmed Shoulder	5467	4894	4369	3963	3588	3256	2882	2506

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Delta Xtend/Delta Xtend	24	15	8	7	3	2	2	0
Other Hemi Stemmed Shoulder	2119	1722	1314	966	652	370	133	17

TABLE 3**Primary Diagnosis for Revised Primary Hemi Stemmed 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 shoulder prostheses.

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

Primary Diagnosis	Delta Xtend/Delta Xtend		Other Hemi Stemmed Shoulder	
	Number	Percent	Number	Percent
Fracture	4	28.6	322	62.6
Osteoarthritis	3	21.4	133	25.9
Tumour			17	3.3
Osteonecrosis	1	7.1	16	3.1
Rotator Cuff Arthropathy	4	28.6	14	2.7
Rheumatoid Arthritis			6	1.2
Other Inflammatory Arthritis	1	7.1	4	0.8
Instability	1	7.1	1	0.2
Other			1	0.2
TOTAL	14	100.0	514	100.0

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 Shoulder Replacement - Reason for Revision (Follow-up Limited to 14.1 Years)

Revision Diagnosis	Delta Xtend/Delta Xtend			Other Hemi Stemmed Shoulder		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency				119	2.2	23.2
Instability/Dislocation	4	5.3	28.6	98	1.8	19.1
Glenoid Erosion	4	5.3	28.6	69	1.3	13.4
Infection	3	4.0	21.4	54	1.0	10.5
Pain				51	0.9	9.9
Loosening	2	2.7	14.3	41	0.7	8.0
Fracture	1	1.3	7.1	34	0.6	6.6
Arthrofibrosis				10	0.2	1.9
Dissociation				9	0.2	1.8
Malposition				9	0.2	1.8
Incorrect Sizing				4	0.1	0.8
Tumour				4	0.1	0.8
Lysis				3	0.1	0.6
Heterotopic Bone				1	0.0	0.2
Implant Breakage Glenoid				1	0.0	0.2
Osteonecrosis				1	0.0	0.2
Other				6	0.1	1.2
N Revision	14	18.7	100.0	514	9.4	100.0
N Primary	75			5467		

Note: This table is restricted to revisions within 14.1 years for all groups to allow a time-matched comparison of revisions.

FIGURE 2

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

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

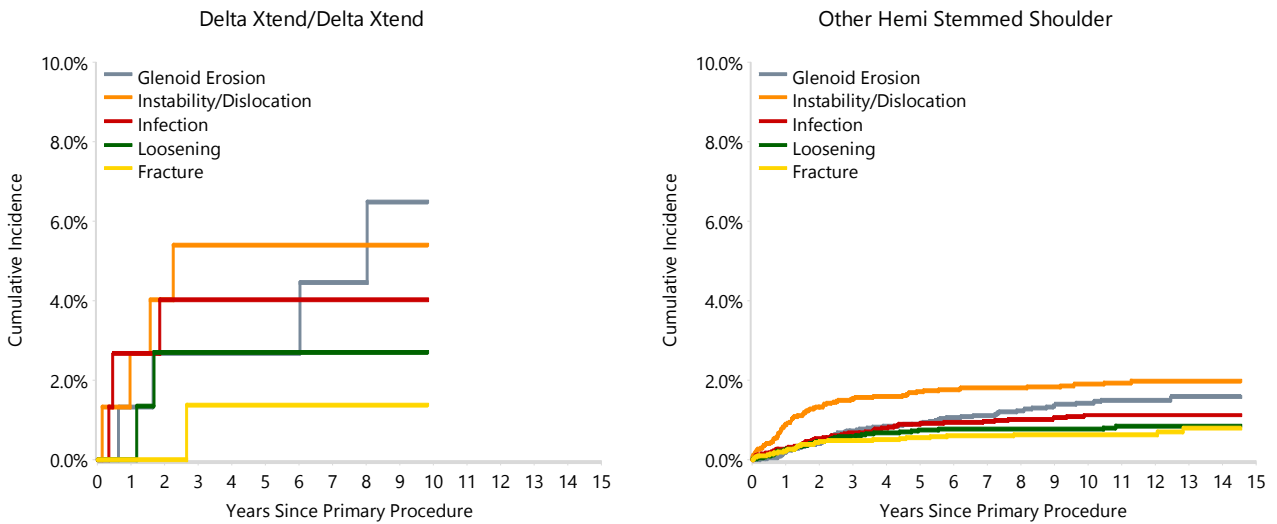


TABLE 5

Type of Revision Performed for Primary Hemi Stemmed Shoulder Replacement

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

Table 5: Primary Hemi Stemmed Shoulder Replacement - Type of Revision (Follow-up Limited to 14.1 Years)

Type of Revision	Delta Xtend/Delta Xtend		Other Hemi Stemmed Shoulder	
	Number	Percent	Number	Percent
Humeral/Glenoid	3	21.4	348	67.7
Glenoid Component	9	64.3	49	9.5
Humeral Component	1	7.1	49	9.5
Cement Spacer	1	7.1	26	5.1
Removal of Prostheses			8	1.6
N Major	14	100.0	480	93.4
Head Only			21	4.1
Reoperation			7	1.4
Cement Only			4	0.8
Head/Insert			1	0.2
Minor Components			1	0.2
N Minor			34	6.6
TOTAL	14	100.0	514	100.0

Note: This table is restricted to revisions within 14.1 years for all groups to allow a time-matched comparison of revisions.

TABLE 6**Revision Rates of Primary Hemi Stemmed Shoulder Replacement by State**

This enables a state by state variation to be identified for the Delta Xtend/Delta Xtend hemi stemmed shoulder combination and provides the comparative data for each of the states for all other hemi stemmed 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 Shoulder Replacement by State

Component	State	N Revised	N Total
Delta Xtend/Delta Xtend	NSW	3	15
	VIC	3	23
	QLD	0	11
	WA	1	5
	SA	1	2
	TAS	4	13
	ACT/NT	2	6
Other Hemi Stemmed Shoulder	NSW	138	1693
	VIC	136	1659
	QLD	120	1084
	WA	40	324
	SA	42	376
	TAS	20	212
	ACT/NT	18	119
TOTAL		528	5542

TABLE 7**Number of Revisions of Delta Xtend/Delta Xtend Primary Hemi Stemmed 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 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 7: Number of Revisions of Delta Xtend/Delta Xtend Primary Hemi Stemmed 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
TOTAL	14	75

TABLE 8

Revision Rates of Delta Xtend/Delta Xtend Primary Hemi Stemmed 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 Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Head Range	N Revised	N Total
130708100-130714200	130748021-130752026	6	30
130708110-130714210	130748021-130752026	0	3
130710000-130716000	130748021-130752026	8	42
TOTAL		14	75