Plasmacup Total Conventional Hip Investigation

Note: This analysis compares the Plasmacup acetabular prosthesis with all other total conventional hip prostheses.

This prosthesis 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 metal/metal prostheses with head size larger than 32mm are excluded from the comparator. Procedures using prostheses with no recorded use in 2022 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Conventional Hip Replacement

The revision rate of the Plasmacup total conventional hip prosthesis is compared to all other total conventional hip prostheses.

Table 1: Revision Rates of Primary Total Conventional Hip Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% Cl)
Plasmacup	38	482	4600	0.83 (0.58, 1.13)
Other Total Conventional Hip	17452	494145	3081462	0.57 (0.56, 0.57)
TOTAL	17490	494627	3086062	0.57 (0.56, 0.58)

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Plasmacup total conventional hip prosthesis is compared to all other total conventional hip prostheses.

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
Plasmacup	4.4 (2.9, 6.6)	5.4 (3.7, 7.8)	5.6 (3.9, 8.1)	5.6 (3.9, 8.1)	5.8 (4.1, 8.3)	6.3 (4.4, 8.8)		
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.1, 2.2)	2.5 (2.5, 2.6)	2.8 (2.7, 2.8)	3.1 (3.0, 3.1)	3.4 (3.3, 3.4)	• •	
CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 \	/rs	14 Yrs	15 Yrs
Plasmacup	7.7 (5.6, 10.6)	7.7 (5.6, 10.6)	8.2 (6.0, 11.3	3) 8.2 (6.0, 1 [°]	1.3) 8.2 (6.0), 11.3)	_	
Other Total Conventional Hip	4.3 (4.2, 4.3)	4.6 (4.5, 4.7)	4.9 (4.8, 5.0)) 5.3 (5.2, 5	5.4) 5.7 (5	.6, 5.8) 6	5.1 (6.0, 6.2)	6.5 (6.4, 6.6)
CDD	16 Yrs	17 Yrs	10 Vro	19 Yrs	20 \	lno	21 Yrs	22 Vra
CPR Plasmacup		17 Yrs	18 Yrs	19 ¥rs	20 \		21 115	22 Yrs
Other Total Conventional Hip	6.9 (6.8, 7.1)	7.3 (7.1, 7.4)	7.6 (7.4, 7.8	8) 8.2 (8.0, 8	8.5) 8.5 (8	.2, 8.8) 8	8.9 (8.5, 9.3)	9.3 (8.8, 9.8)

Table 2: Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

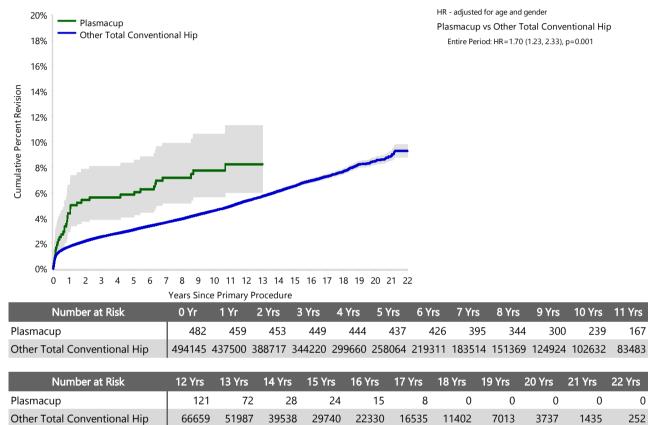
2

FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Plasmacup total conventional hip prosthesis is compared to all other total conventional hip 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.





Primary Diagnosis for Revised Primary Total Conventional Hip 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 conventional hip prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Conventional Hip Replacement

	Plasn	nacup	Other Total Co	nventional Hip
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	35	92.1	14432	82.7
Fractured Neck Of Femur			1291	7.4
Osteonecrosis	3	7.9	797	4.6
Developmental Dysplasia			279	1.6
Rheumatoid Arthritis			186	1.1
Failed Internal Fixation			147	0.8
Tumour			145	0.8
Other Inflammatory Arthritis			99	0.6
Fracture/Dislocation			46	0.3
Arthrodesis Takedown			16	0.1
Other			14	0.1
TOTAL	38	100.0	17452	100.0

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 Conventional Hip Replacement - Reason for Revision (Follow-up Limited to 17.2 Years)

		Plasmacup		Othe	r Total Convention	al Hip
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	4	0.8	10.5	4002	0.8	23.1
Infection	6	1.2	15.8	3993	0.8	23.1
Fracture	2	0.4	5.3	3788	0.8	21.9
Loosening	21	4.4	55.3	3495	0.7	20.2
Pain				309	0.1	1.8
Leg Length Discrepancy	2	0.4	5.3	270	0.1	1.6
Malposition				243	0.0	1.4
Lysis				185	0.0	1.1
Implant Breakage Stem				165	0.0	1.0
Implant Breakage Acetabular Insert				119	0.0	0.7
Incorrect Sizing	1	0.2	2.6	102	0.0	0.6
Wear Acetabular Insert				93	0.0	0.5
Metal Related Pathology				71	0.0	0.4
Implant Breakage Acetabular				69	0.0	0.4
Wear Head				44	0.0	0.3
Tumour				41	0.0	0.2
Implant Breakage Head				31	0.0	0.2
Heterotopic Bone				26	0.0	0.2
Wear Acetabulum				9	0.0	0.1
Progression Of Disease				2	0.0	0.0
Osteonecrosis				1	0.0	0.0
Synovitis				1	0.0	0.0
Other	2	0.4	5.3	257	0.1	1.5
N Revision	38	7.9	100.0	17316	3.5	100.0
N Primary	482			494145		

Note: This table is restricted to revisions within 17.2 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Conventional Hip 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 Plasmacup total conventional hip prosthesis. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total conventional hip prostheses.

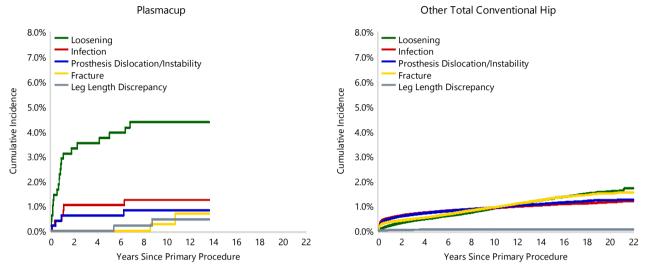


Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Conventional Hip Replacement

Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Plasmacup total conventional hip prosthesis and compares it to the components used in the revision of all other total conventional hip 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 conventional hip prostheses i.e. is there a difference in the type of revision undertaken for the Plasmacup total conventional hip prosthesis compared to all other total conventional hip prostheses.

	Plasn	nacup	Other Total Conventional Hip	
Type of Revision	Number	Percent	Number	Percent
emoral Component	14	36.8	5671	32.8
Acetabular Component	8	21.1	3274	18.9
THR (Femoral/Acetabular)	6	15.8	2003	11.6
Cement Spacer	3	7.9	618	3.6
Removal of Prostheses			94	0.5
Reinsertion of Components			27	0.2
otal Femoral			8	0.0
Bipolar Head and Femoral			5	0.0
Saddle			1	0.0
N Major	31	81.6	11701	67.6
Head/Insert	2	5.3	4292	24.8
Head Only	5	13.2	843	4.9
Ainor Components			296	1.7
nsert Only			180	1.0
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	7	18.4	5615	32.4
TOTAL	38	100.0	17316	100.0

Note: This table is restricted to revisions within 17.2 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2022 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

Revision Rates of Plasmacup Primary Total Conventional Hip 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 Plasmacup Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	32	382
Hybrid (Femur Cemented)	6	100
TOTAL	38	482

TABLE 7

Revision Rates of Plasmacup Primary Total Conventional Hip 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 prosthesis are listed.

Table 7: Revised Number of Plasmacup Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	34	413
Ceramic/Non XLPE	1	10
Metal/Non XLPE	3	58
Unknown	0	1
TOTAL	38	482

Revision Rates of Plasmacup Primary Total Conventional Hip Replacement by Approach

This analysis is provided as some prostheses are used with a variety of surgical approaches. All surgical approaches used with this prosthesis are listed.

Table 8: Revised Number of Plasmacup Primary Total Conventional Hip Replacement by Approach

Approach	N Revised	N Total
Anterior	2	50
Posterior	0	1
TOTAL	2	51

Note: Excludes 431 procedures with no approach recorded

Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the Plasmacup total conventional hip prosthesis and provides the comparative data for each of the states for all other total conventional hip 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.

Component	State	N Revised	N Total	
Plasmacup	NSW	38	473	
	VIC	0	4	
	QLD	0	5	
Other Total Conventional Hip	NSW	4728	144768	
	VIC	4348	128324	
	QLD	3451	86927	
	WA	2389	58888	
	SA	1621	45638	
	TAS	405	16382	
	ACT/NT	510	13218	
TOTAL		17490	494627	

Table 9: Revised Number of Primary Total Conventional Hip Replacement by State

Number of Revisions of Plasmacup Primary Total Conventional Hip Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Plasmacup total conventional hip prosthesis. 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 10: Number of Revisions of Plasmacup Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	0	10
2006	2	16
2007	1	13
2008	2	7
2009	7	54
2010	8	60
2011	6	59
2012	4	77
2013	3	70
2014	3	44
2015	2	51
2016	0	21
TOTAL	38	482

Revision Rates of Plasmacup Primary Total Conventional Hip 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 Plasmacup 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	Coating	Fixation
Acetabular						
Plasmacup	NC444T-NC468T	SC PLASMAPORE CAP	NO	METAL		POROUS
Plasmacup	NH140T-NH168T	MSC ACETABULAR SHELL	NO	METAL		POROUS
Plasmacup	NH340T-NH368T	NSC ACETABULAR SHELL	NO	METAL		POROUS
Plasmacup	NH544T-NH568T	DC ACETABULAR SHELL	NO	METAL		
Plasmacup	NH644D-NH654D	HA SHELL & BIOLOX DELTA CERAMIC LINER	NO	CERAMIC	HA COATED	

Table 11: Revised Number of Plasmacup Primary Total Conventional Hip Replacement by Catalogue Number Range

Acetabular Range	N Revised	N Total
NC444T-NC468T	24	289
NH140T-NH168T	1	3
NH340T-NH368T	1	13
NH544T-NH568T	0	5
NH644D-NH654D	12	172
TOTAL	38	482

Revision Rates of Plasmacup Primary Total Conventional Hip Replacement by Component

A prosthesis may be combined with multiple components. This analysis has been undertaken to determine if the revision rate varies according to the component with which it is combined.

Table 12: Revised Number of Plasmacup Primary Total Conventional Hip Replacement by Femoral Stem Component

Femoral Stem Component	N Revised	N Total
Accolade I	2	27
Excia	6	92
Excia (cless)	13	164
Friendly Hip	0	1
Furlong	1	3
Hip and Go	0	25
Metha	3	80
Metha (exch neck)	13	78
S-Rom	0	7
Spectron EF	0	4
Standard C	0	1
TOTAL	38	482