CORAIL/Trabecular Metal (Shell) Total Conventional Hip Investigation

Note: This analysis compares the CORAIL/Trabecular Metal (Shell) femoral stem/acetabular combination with all other total conventional hip 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-2024.

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 2023 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Conventional Hip Replacement

The revision rate of the CORAIL/Trabecular Metal (Shell) total conventional hip combination 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)
CORAIL/Trabecular Metal (Shell)	11	98	817	1.35 (0.67, 2.41)
Other Total Conventional Hip	19238	538443	3453824	0.56 (0.55, 0.56)
TOTAL	19249	538541	3454641	0.56 (0.55, 0.57)

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the CORAIL/Trabecular Metal (Shell) total conventional hip combination is compared to all other total conventional hip prostheses.

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

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
CORAIL/Trabecular Metal (Shell)	6.2 (2.8, 13.2)	8.4 (4.3, 16.0)	9.5 (5.1, 17.5)	11.9 (6.8, 20.5)				
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.1, 2.2)	2.5 (2.5, 2.5)	2.8 (2.7, 2.8)	3.1 (3.0, 3.1)	3.3 (3.3, 3.4)	3.6 (3.6, 3.7)	3.9 (3.8, 4.0)
CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
CORAIL/Trabecular Metal (Shell)	11.9 (6.8, 20.5)							
Other Total Conventional Hip	4.2 (4.2, 4.3)	4.5 (4.5, 4.6)	4.9 (4.8, 5.0)	5.3 (5.2, 5.4)	5.7 (5.6, 5.8)	6.0 (5.9, 6.2)	6.5 (6.3, 6.6)	6.9 (6.7, 7.0)
CPR	17 Yrs	18 Yrs	19 Yrs	20 Y	rs 21	Yrs	22 Yrs	23 Yrs
CORAIL/Trahecular Metal (Shell)								

CPR	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
CORAIL/Trabecular Metal (Shell)							
Other Total Conventional Hip	7.3 (7.1, 7.4)	7.6 (7.5, 7.8)	8.2 (8.0, 8.4)	8.5 (8.2, 8.7)	9.0 (8.7, 9.3) 9	0.7 (9.2, 10.1)	10.3 (9.5, 11.2)

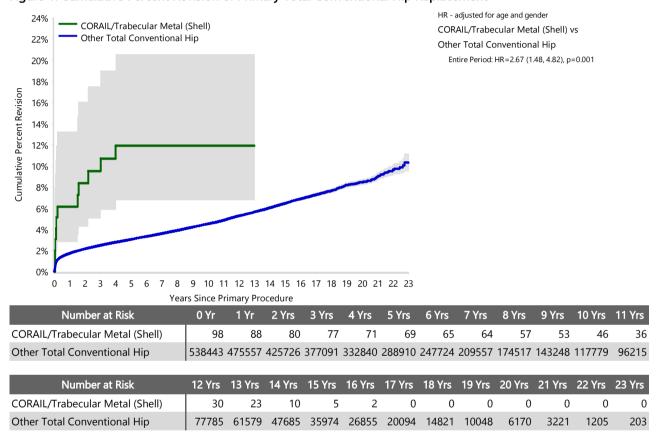
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the CORAIL/Trabecular Metal (Shell) total conventional hip combination 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.

Figure 1: Cumulative Percent Revision of Primary Total Conventional Hip Replacement



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

	CORAIL/Trabecular Metal (Shell)		Other Total Co	nventional Hip
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	7	63.6	15944	82.9
Fractured Neck Of Femur	1	9.1	1419	7.4
Osteonecrosis	1	9.1	858	4.5
Developmental Dysplasia			320	1.7
Rheumatoid Arthritis			208	1.1
Failed Internal Fixation			151	0.8
Tumour			149	0.8
Other Inflammatory Arthritis			106	0.6
Fracture/Dislocation	2	18.2	51	0.3
Other			17	0.1
Arthrodesis Takedown			15	0.1
TOTAL	11	100.0	19238	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 16.6 Years)

	CORA	CORAIL/Trabecular Metal (Shell)			Other Total Conventional Hip			
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions		
Infection	4	4.1	36.4	4476	0.8	23.6		
Prosthesis Dislocation/Instability	2	2.0	18.2	4353	0.8	22.9		
Fracture	1	1.0	9.1	4213	0.8	22.2		
Loosening	4	4.1	36.4	3738	0.7	19.7		
Pain				334	0.1	1.8		
Leg Length Discrepancy				291	0.1	1.5		
Malposition				266	0.0	1.4		
Lysis				194	0.0	1.0		
Implant Breakage Stem				187	0.0	1.0		
Implant Breakage Acetabular Insert				130	0.0	0.7		
Incorrect Sizing				103	0.0	0.5		
Wear Acetabular Insert				98	0.0	0.5		
Metal Related Pathology				76	0.0	0.4		
Implant Breakage Acetabular				71	0.0	0.4		
Wear Head				46	0.0	0.2		
Tumour				44	0.0	0.2		
Implant Breakage Head				31	0.0	0.2		
Heterotopic Bone				26	0.0	0.1		
Wear Acetabulum				10	0.0	0.1		
Osteonecrosis				2	0.0	0.0		
Progression Of Disease				2	0.0	0.0		
Synovitis				1	0.0	0.0		
Other				292	0.1	1.5		
N Revision	11	11.2	100.0	18984	3.5	100.0		
N Primary	98			538443				

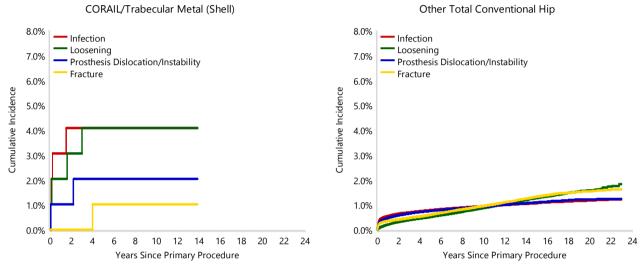
Note: This table is restricted to revisions within 16.6 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2023 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

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 CORAIL/Trabecular Metal (Shell) total conventional hip combination. 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 CORAIL/Trabecular Metal (Shell) total conventional hip combination 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 CORAIL/Trabecular Metal (Shell) total conventional hip combination compared to all other total conventional hip prostheses.

Table 5: Primary Total Conventional Hip Replacement - Type of Revision (Follow-up Limited to 16.6 Years)

Tuble 5. Trimary Total Co	CORAIL/Trabecular Metal (Shell) Other Total Conventional			
Type of Revision	Number	Percent	Number	Percent
Femoral Component	3	27.3	6279	33.1
Acetabular Component	2	18.2	3530	18.6
THR (Femoral/Acetabular)	1	9.1	2195	11.6
Cement Spacer			618	3.3
Removal of Prostheses	1	9.1	97	0.5
Reinsertion of Components			28	0.1
Total Femoral			9	0.0
Bipolar Head and Femoral			7	0.0
Saddle			1	0.0
N Major	7	63.6	12764	67.2
Head/Insert	2	18.2	4800	25.3
Head Only			924	4.9
Minor Components	1	9.1	307	1.6
Insert Only	1	9.1	185	1.0
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	4	36.4	6220	32.8
TOTAL	11	100.0	18984	100.0

Note: This table is restricted to revisions within 16.6 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2023 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

Revision Rates of CORAIL/Trabecular Metal (Shell) 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 CORAIL/Trabecular Metal (Shell) Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	10	85
Hybrid (Femur Cemented)	0	1
Reverse Hybrid (Femur Cementless)	1	12
TOTAL	11	98

TABLE 7

Revision Rates of CORAIL/Trabecular Metal (Shell) 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 combination are listed.

Table 7: Revised Number of CORAIL/Trabecular Metal (Shell) Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Ceramic/Non XLPE	0	1
Ceramic/XLPE	4	31
Metal/Non XLPE	1	3
Metal/XLPE	6	63
TOTAL	11	98

Revision Rates of CORAIL/Trabecular Metal (Shell) 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 combination are listed.

Table 8: Revised Number of CORAIL/Trabecular Metal (Shell) Primary Total Conventional Hip Replacement by Approach

Approach	N Revised	N Total
Lateral	1	6
Posterior	1	9
TOTAL	2	15

Note: Excludes 83 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 CORAIL/Trabecular Metal (Shell) total conventional hip combination 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.

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

		Total Conventional Flip Replacer	•
Component	State	N Revised	N Total
CORAIL/Trabecular Metal (Shell) NSW	0	3
	VIC	6	34
	QLD	1	26
	WA	3	29
	SA	0	2
	TAS	1	4
Other Total Conventional Hip	NSW	5207	157704
	VIC	4853	140647
	QLD	3790	94556
	WA	2543	63236
	SA	1825	49396
	TAS	451	18194
	ACT/NT	569	14710
TOTAL		19249	538541

Number of Revisions of CORAIL/Trabecular Metal (Shell) Primary Total Conventional Hip Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the CORAIL/Trabecular Metal (Shell) total conventional hip 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 2023 has a maximum of one year to be revised, whereas a primary procedure performed in 2021 has a maximum of three years to be revised.

Table 10: Number of Revisions of CORAIL/Trabecular Metal (Shell) Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2007	2	5
2008	3	10
2009	1	17
2010	2	20
2011	0	9
2012	1	8
2013	0	8
2014	0	6
2015	0	1
2016	2	6
2017	0	2
2018	0	4
2019	0	1
2020	0	1
TOTAL	11	98

Revision Rates of CORAIL/Trabecular Metal (Shell) 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 CORAIL/Trabecular Metal (Shell) 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
Femoral Stem	ı					
CORAIL	3L92498-3L92521	STANDARD CEMENTLESS FEMORAL STEM W/COLLAR	NO	METAL	HA COATED	
CORAIL	3L92507-3L92520	STANDARD CEMENTLESS FEMORAL STEM W/OUT COLLAR	NO	METAL	HA COATED	
CORAIL	3L93709-3L93720	CEMENTLESS LATERALISED FEMORAL STEM W/COLLAR	NO	METAL	HA COATED	
CORAIL	L20309-L20320	CEMENTLESS HIGH OFFSET FEMORAL STEM W/OUT COLLAR	NO	METAL	HA COATED	
CORAIL	L971109-L971120	CEMENTLESS FEMORAL STEM HIGH OFFSET COLLAR	NO	METAL		
Acetabular						
Trabecular Metal (Shell)	00620203820-00620208020	TRABECULAR METAL MODULAR ACETABULAR SHELL WITH MULTI HOLES POROUS TIVANIUM/TANTALUM	NO	METAL		HIGHLY POROUS
Trabecular Metal (Shell)	00620203822-00620208022	TRABECULAR METAL MODULAR ACETABULAR SHELL WITH CLUSTER HOLES POROUS TIVANIUM/TANTALUM	NO	METAL		HIGHLY POROUS
Trabecular Metal (Shell)	00700004820-00700008070	TRABECULAR METAL ACETABULAR REVISION SHELL TANTALUM/TITANIUM ALLOY	NO	METAL		HIGHLY POROUS

Table 11: Revised Number of CORAIL/Trabecular Metal (Shell) Primary Total Conventional Hip Replacement by Catalogue Number Range

Femoral Stem Range	Acetabular Range	N Revised	N Total
3L92498-3L92521	00620203820-00620208020	1	8
	00620203822-00620208022	0	15
	00700004820-00700008070	0	2
3L92507-3L92520	00620203820-00620208020	2	17
	00620203822-00620208022	3	19
	00700004820-00700008070	1	2
3L93709-3L93720	00620203820-00620208020	2	6
	00620203822-00620208022	0	16
	00700004820-00700008070	0	1
L20309-L20320	00620203820-00620208020	2	8
	00620203822-00620208022	0	1
	00700004820-00700008070	0	1
L971109-L971120	00620203820-00620208020	0	1
	00700004820-00700008070	0	1

Femoral Stem Range	Acetabular Range	N Revised	N Total
TOTAL		11	98