

## CORAIL/Trident (Shell) Total Conventional Hip Investigation

Note: This analysis compares the CORAIL/Trident (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-2022>.

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 2021 are excluded from the comparator.

### TABLE 1

#### Revision Rate of Primary Total Conventional Hip Replacement

The revision rate of the CORAIL/Trident (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% CI)
CORAIL/Trident (Shell)	25	494	2087	1.20 (0.78, 1.77)
Other Total Conventional Hip	15835	452965	2719104	0.58 (0.57, 0.59)
<b>TOTAL</b>	<b>15860</b>	<b>453459</b>	<b>2721191</b>	<b>0.58 (0.57, 0.59)</b>

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 2

**Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement**

The yearly cumulative percent revision of the CORAIL/Trident (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
CORAIL/Trident (Shell)	2.9 (1.7, 4.9)	4.1 (2.5, 6.5)	4.8 (3.1, 7.5)	5.3 (3.4, 8.2)	5.8 (3.7, 8.9)	5.8 (3.7, 8.9)	5.8 (3.7, 8.9)
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.1, 2.2)	2.5 (2.5, 2.6)	2.8 (2.8, 2.9)	3.1 (3.0, 3.2)	3.4 (3.3, 3.5)	3.7 (3.6, 3.7)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
CORAIL/Trident (Shell)	6.5 (4.2, 10.1)	8.4 (5.3, 13.2)	8.4 (5.3, 13.2)	8.4 (5.3, 13.2)			
Other Total Conventional Hip	4.0 (3.9, 4.0)	4.3 (4.2, 4.4)	4.6 (4.6, 4.7)	5.0 (4.9, 5.1)	5.4 (5.3, 5.5)	5.8 (5.7, 5.9)	6.2 (6.1, 6.4)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
CORAIL/Trident (Shell)							
Other Total Conventional Hip	6.7 (6.5, 6.8)	7.1 (6.9, 7.3)	7.5 (7.3, 7.7)	7.9 (7.6, 8.1)	8.6 (8.3, 8.9)	8.9 (8.5, 9.3)	9.8 (9.0, 10.8)

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

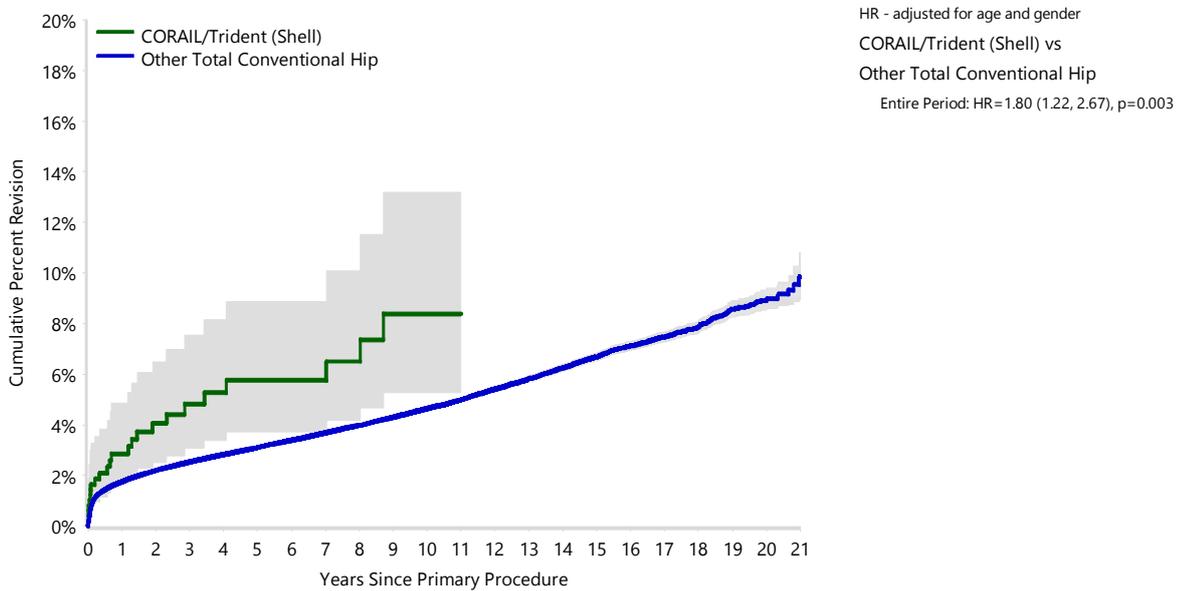
**FIGURE 1**

**Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement**

The yearly cumulative percent revision of the CORAIL/Trident (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**



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
CORAIL/Trident (Shell)	494	358	286	234	192	156	144	126	108	83	60
Other Total Conventional Hip	452965	398329	353770	308946	267016	227907	191446	158460	131105	107946	88098

Number at Risk	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
CORAIL/Trident (Shell)	42	30	19	17	6	3	2	1	1	0	0
Other Total Conventional Hip	70564	55316	42192	31895	24029	17718	12212	7611	4006	1573	276

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

**TABLE 3****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**

Primary Diagnosis	CORAIL/Trident (Shell)		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	22	88.0	13091	82.7
Fractured Neck Of Femur	1	4.0	1163	7.3
Osteonecrosis	1	4.0	717	4.5
Developmental Dysplasia	1	4.0	246	1.6
Rheumatoid Arthritis			173	1.1
Failed Internal Fixation			140	0.9
Tumour			137	0.9
Other Inflammatory Arthritis			91	0.6
Fracture/Dislocation			47	0.3
Arthrodesis Takedown			16	0.1
Other			14	0.1
<b>TOTAL</b>	<b>25</b>	<b>100.0</b>	<b>15835</b>	<b>100.0</b>

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm 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 Conventional Hip Replacement - Reason for Revision (Follow-up Limited to 19.7 Years)

Revision Diagnosis	CORAIL/Trident (Shell)			Other Total Conventional Hip		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	2	0.4	8.0	3715	0.8	23.5
Infection	8	1.6	32.0	3544	0.8	22.4
Fracture	3	0.6	12.0	3435	0.8	21.7
Loosening	11	2.2	44.0	3218	0.7	20.3
Pain				286	0.1	1.8
Leg Length Discrepancy				260	0.1	1.6
Malposition				225	0.0	1.4
Lysis				183	0.0	1.2
Implant Breakage Stem				151	0.0	1.0
Implant Breakage Acetabular Insert				114	0.0	0.7
Incorrect Sizing				95	0.0	0.6
Wear Acetabular Insert				90	0.0	0.6
Metal Related Pathology				69	0.0	0.4
Implant Breakage Acetabular				67	0.0	0.4
Wear Head				45	0.0	0.3
Tumour				37	0.0	0.2
Implant Breakage Head				30	0.0	0.2
Heterotopic Bone				23	0.0	0.1
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	1	0.2	4.0	227	0.1	1.4
<b>N Revision</b>	<b>25</b>	<b>5.1</b>	<b>100.0</b>	<b>15827</b>	<b>3.5</b>	<b>100.0</b>
<b>N Primary</b>	<b>494</b>			<b>452965</b>		

Note: This table is restricted to revisions within 19.7 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 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/Trident (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**

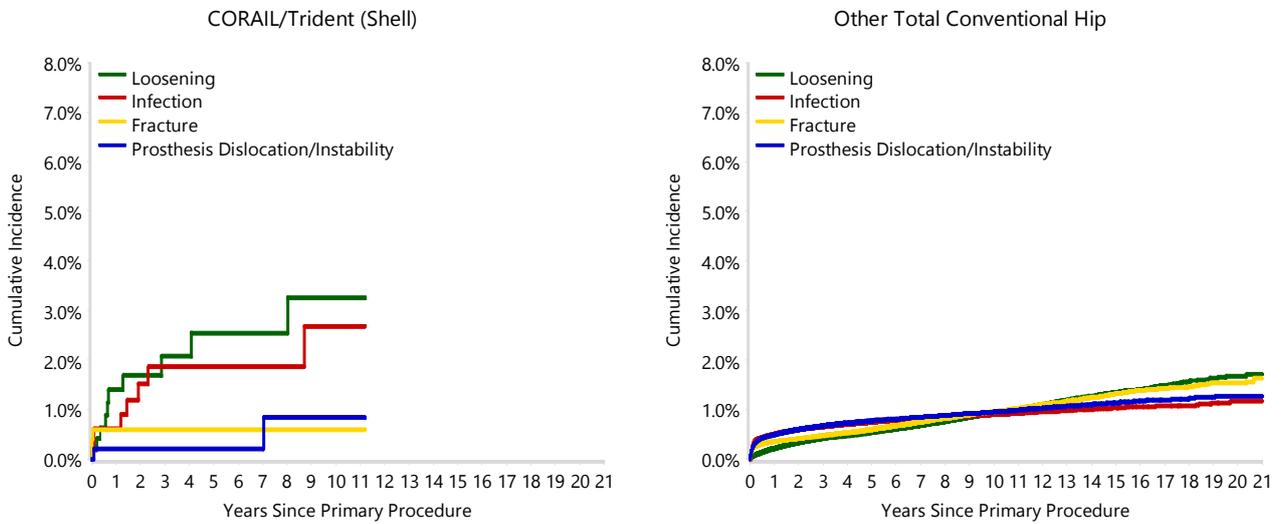


TABLE 5

### Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the CORAIL/Trident (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/Trident (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 19.7 Years)**

Type of Revision	CORAIL/Trident (Shell)		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	7	28.0	5146	32.5
Acetabular Component	3	12.0	3054	19.3
THR (Femoral/Acetabular)	6	24.0	1807	11.4
Cement Spacer	4	16.0	590	3.7
Removal of Prostheses			97	0.6
Reinsertion of Components			25	0.2
Total Femoral			6	0.0
Bipolar Head and Femoral			4	0.0
Saddle			1	0.0
<b>N Major</b>	<b>20</b>	<b>80.0</b>	<b>10730</b>	<b>67.8</b>
Head/Insert	4	16.0	3870	24.5
Head Only	1	4.0	777	4.9
Minor Components			274	1.7
Insert Only			172	1.1
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
<b>N Minor</b>	<b>5</b>	<b>20.0</b>	<b>5097</b>	<b>32.2</b>
<b>TOTAL</b>	<b>25</b>	<b>100.0</b>	<b>15827</b>	<b>100.0</b>

Note: This table is restricted to revisions within 19.7 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 6

**Revision Rates of CORAIL/Trident (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/Trident (Shell) Primary Total Conventional Hip Replacement by Fixation**

Fixation	N Revised	N Total
Cementless	25	494
<b>TOTAL</b>	<b>25</b>	<b>494</b>

TABLE 7

**Revision Rates of CORAIL/Trident (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/Trident (Shell) Primary Total Conventional Hip Replacement by Bearing Surface**

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	1	4
Ceramic/XLPE	11	189
Metal/Non XLPE	0	1
Metal/XLPE	13	300
<b>TOTAL</b>	<b>25</b>	<b>494</b>

**TABLE 8****Revision Rates of CORAIL/Trident (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/Trident (Shell) Primary Total Conventional Hip Replacement by Approach**

Approach	N Revised	N Total
Anterior	1	29
Lateral	1	21
Posterior	8	279
<b>TOTAL</b>	<b>10</b>	<b>329</b>

Note: Excludes 165 procedures with no approach recorded

TABLE 9

## Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the CORAIL/Trident (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

Component	State	N Revised	N Total
CORAIL/Trident (Shell)	NSW	4	65
	VIC	8	132
	QLD	8	187
	WA	5	75
	SA	0	33
	TAS	0	2
Other Total Conventional Hip	NSW	4295	132906
	VIC	3974	116867
	QLD	3138	79935
	WA	2179	53878
	SA	1415	41896
	TAS	372	15096
	ACT/NT	462	12387
<b>TOTAL</b>		<b>15860</b>	<b>453459</b>

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

**TABLE 10****Number of Revisions of CORAIL/Trident (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/Trident (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 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 10: Number of Revisions of CORAIL/Trident (Shell) Primary Total Conventional Hip Replacement by Year of Implant**

Year of Implant	Number Revised	Total Number
2001	0	1
2002	1	2
2004	0	2
2005	0	2
2006	0	4
2007	2	22
2008	1	10
2009	1	13
2010	2	16
2011	3	25
2012	2	26
2013	2	24
2014	1	14
2015	0	13
2016	0	11
2017	2	32
2018	1	37
2019	0	47
2020	1	66
2021	6	127
<b>TOTAL</b>	<b>25</b>	<b>494</b>

TABLE 11

**Revision Rates of CORAIL/Trident (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/Trident (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
<b>Femoral Stem</b>					
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	L20106-L20106	CEMENTLESS DYSPLASIA FEMORAL STEM W/OUT COLLAR	NO	METAL	HA COATED
CORAIL	L20309-L20320	CEMENTLESS HIGH OFFSET FEMORAL STEM W/OUT COLLAR	NO	METAL	HA COATED
CORAIL	L92509-L92520	CEMENTLESS FEMORAL STEM W/OUT COLLAR HAC	NO	METAL	HA COATED
CORAIL	L971109-L971120	CEMENTLESS FEMORAL STEM HIGH OFFSET COLLAR	NO	METAL	
CORAIL	L971208-L971214	CEMENTLESS FEMORAL STEM STANDARD COLLAR	NO	METAL	
CORAIL	L971308-L971314	CEMENTLESS FEMORAL STEM SHORT NECK COLLAR	NO	METAL	
CORAIL	L981208-L981210	CEMENTLESS FEMORAL STEM 125° STANDARD STD NO COLLAR	NO	METAL	
<b>Acetabular</b>					
Trident (Shell)	5000142A-5000168I	HEMISPHERICAL SOLID SHELL	NO	METAL	
Trident (Shell)	5001142A-5001174J	HEMISPHERICAL HA SOLID SHELL	NO	METAL	HA COATED
Trident (Shell)	5021142A-5021174J	HEMISPHERICAL HA CLUSTER HOLE SHELL	NO	METAL	HA COATED
Trident (Shell)	5081142A-5081174J	TITANIUM HEMISPHERICAL HA MULTI-HOLE CUP	NO	METAL	HA COATED
Trident (Shell)	5401140A-5401174K	PSL TITANIUM HA NO HOLE CUP	NO	METAL	HA COATED
Trident (Shell)	5421140A-5421172J	PSL TITANIUM HA CLUSTER HOLE CUP	NO	METAL	HA COATED

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

Femoral Stem Range	Acetabular Range	N Revised	N Total
3L92498-3L92521	5001142A-5001174J	0	40
	5021142A-5021174J	5	141
	5081142A-5081174J	0	3
	5401140A-5401174K	0	10
	5421140A-5421172J	4	59
3L92507-3L92520	5000142A-5000168I	1	1
	5001142A-5001174J	1	15
	5021142A-5021174J	3	25
	5401140A-5401174K	0	2
	5421140A-5421172J	2	11
3L93709-3L93720	5001142A-5001174J	0	33
	5021142A-5021174J	1	28
	5401140A-5401174K	0	4
	5421140A-5421172J	0	5
L20106-L20106	5021142A-5021174J	1	1
L20309-L20320	5000142A-5000168I	0	1
	5001142A-5001174J	0	9
	5021142A-5021174J	1	16
	5401140A-5401174K	1	1
	5421140A-5421172J	0	1
L92509-L92520	5421140A-5421172J	1	3
L971109-L971120	5001142A-5001174J	0	8
	5021142A-5021174J	0	30
	5081142A-5081174J	0	1
	5401140A-5401174K	0	3
	5421140A-5421172J	0	7
L971208-L971214	5001142A-5001174J	2	5
	5021142A-5021174J	0	8
	5401140A-5401174K	0	1
	5421140A-5421172J	1	7
L971308-L971314	5001142A-5001174J	0	4
	5021142A-5021174J	0	4
	5401140A-5401174K	1	3
	5421140A-5421172J	0	3
L981208-L981210	5001142A-5001174J	0	1
<b>TOTAL</b>		<b>25</b>	<b>494</b>