Omnifit/Vitalock Total Conventional Hip Investigation

Note: This analysis compares the Omnifit/Vitalock 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 Omnifit/Vitalock 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)
Omnifit/Vitalock	15	66	884	1.70 (0.95, 2.80)
Other Total Conventional Hip	19249	538541	3454641	0.56 (0.55, 0.57)
TOTAL	**19264**	**538607**	**3455525**	**0.56 (0.55, 0.57)**

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.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Omnifit/Vitalock 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
Omnifit/Vitalock	1.5 (0.2, 10.3)	3.1 (0.8, 11.7)	6.2 (2.4, 15.8)	6.2 (2.4, 15.8)	6.2 (2.4, 15.8)	7.9 (3.4, 17.9)	9.6 (4.4, 20.1)	11.3 (5.5, 22.2)
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
Omnifit/Vitalock	13.0 (6.7, 24.4)	14.8 (8.0, 26.7)	14.8 (8.0, 26.7)	20.9 (12.4, 34.0)	20.9 (12.4, 34.0)	20.9 (12.4, 34.0)	20.9 (12.4, 34.0)	23.4 (14.1, 37.1)
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)	6.1 (5.9, 6.2)	6.5 (6.3, 6.6)	6.9 (6.7, 7.0)

CPR	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
Omnifit/Vitalock	28.6 (18.0, 43.6)	28.6 (18.0, 43.6)	28.6 (18.0, 43.6)	28.6 (18.0, 43.6)			
Other Total Conventional Hip	7.3 (7.1, 7.4)	7.7 (7.5, 7.8)	8.2 (8.0, 8.4)	8.5 (8.2, 8.7)	9.0 (8.7, 9.3)	9.7 (9.2, 10.1)	10.3 (9.5, 11.2)

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.

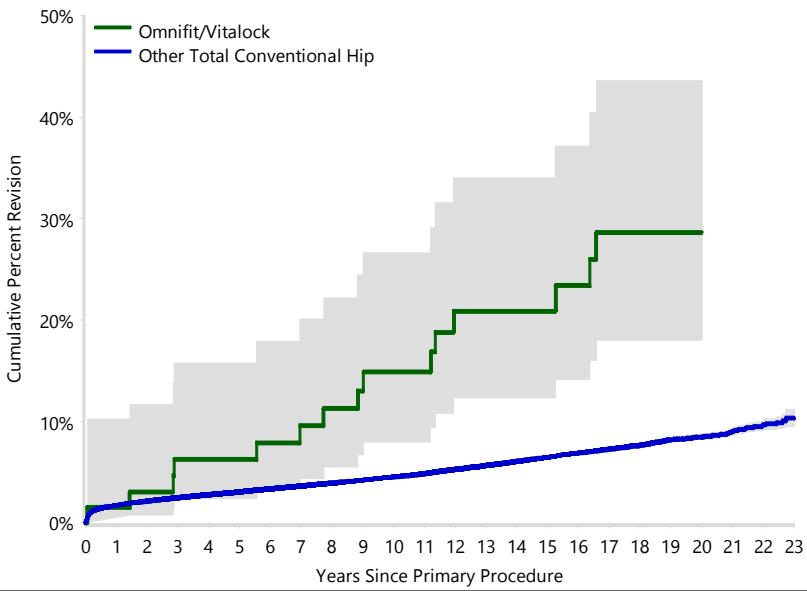
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Omnifit/Vitalock 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	11 Yrs
Omnifit/Vitalock	66	65	62	59	59	58	56	54	51	48	45	43
Other Total Conventional Hip	538541	475645	425806	377168	332911	288979	247789	209621	174574	143301	117825	96251

Number at Risk	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
Omnifit/Vitalock	38	35	34	32	30	26	19	14	8	7	4	1
Other Total Conventional Hip	77815	61602	47695	35979	26857	20094	14821	10048	6170	3221	1205	203

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.

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

	Omnifit/Vitalock		Other Total Conventional Hip	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	10	66.7	15951	82.9
Fractured Neck Of Femur	1	6.7	1420	7.4
Osteonecrosis	4	26.7	859	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			53	0.3
Other			17	0.1
Arthrodesis Takedown			15	0.1
TOTAL	**15**	**100.0**	**19249**	**100.0**

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.

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

	Omnifit/Vitalock			Other Total Conventional Hip		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	3	4.5	20.0	4504	0.8	23.4
Prosthesis Dislocation/Instability	3	4.5	20.0	4381	0.8	22.8
Fracture	1	1.5	6.7	4265	0.8	22.2
Loosening	6	9.1	40.0	3830	0.7	19.9
Pain				336	0.1	1.7
Leg Length Discrepancy				291	0.1	1.5
Malposition				269	0.0	1.4
Lysis	2	3.0	13.3	217	0.0	1.1
Implant Breakage Stem				192	0.0	1.0
Implant Breakage Acetabular Insert				131	0.0	0.7
Wear Acetabular Insert				113	0.0	0.6
Incorrect Sizing				103	0.0	0.5
Metal Related Pathology				84	0.0	0.4
Implant Breakage Acetabular				72	0.0	0.4
Wear Head				48	0.0	0.2
Tumour				44	0.0	0.2
Implant Breakage Head				33	0.0	0.2
Heterotopic Bone				26	0.0	0.1
Wear Acetabulum				11	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				294	0.1	1.5
N Revision	**15**	**22.7**	**100.0**	**19249**	**3.6**	**100.0**
N Primary	**66**			**538541**		

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 Omnifit/Vitalock 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

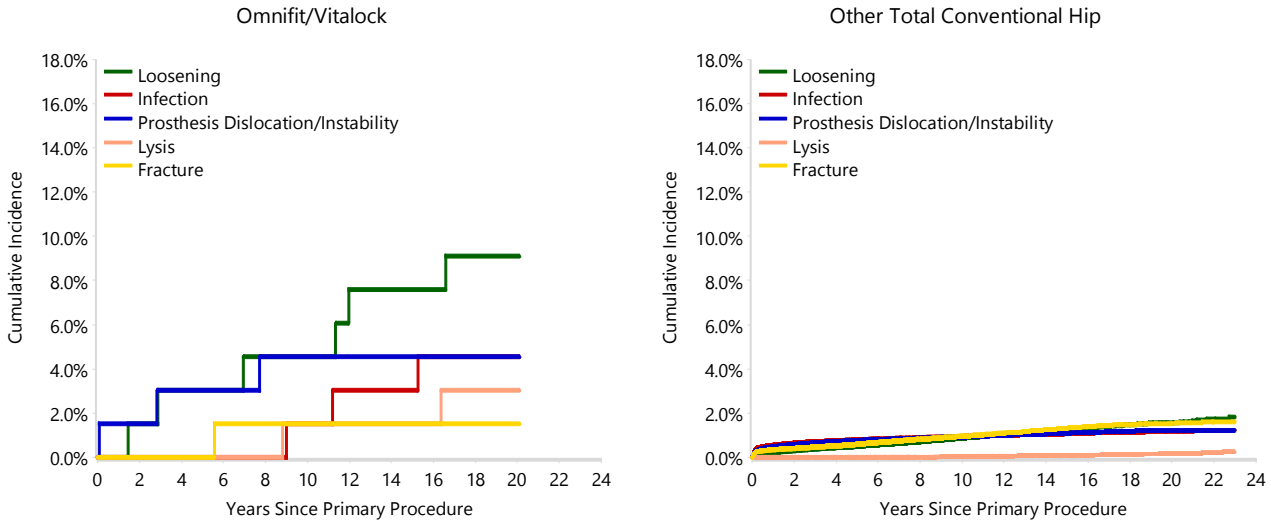


TABLE 5

Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Omnifit/Vitalock 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 Omnifit/Vitalock total conventional hip combination compared to all other total conventional hip prostheses.

Table 5: Primary Total Conventional Hip Replacement - Type of Revision

	Omnifit/Vitalock		Other Total Conventional Hip	
Type of Revision	Number	Percent	Number	Percent
Femoral Component	1	6.7	6347	33.0
Acetabular Component	2	13.3	3609	18.7
THR (Femoral/Acetabular)	5	33.3	2255	11.7
Cement Spacer			620	3.2
Removal of Prostheses			99	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	**8**	**53.3**	**12975**	**67.4**
Head/Insert	7	46.7	4845	25.2
Head Only			927	4.8
Minor Components			311	1.6
Insert Only			187	1.0
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	**7**	**46.7**	**6274**	**32.6**
TOTAL	**15**	**100.0**	**19249**	**100.0**

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.

TABLE 6

Revision Rates of Omnifit/Vitalock 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 Omnifit/Vitalock Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	15	63
Hybrid (Femur Cemented)	0	3
TOTAL	**15**	**66**

TABLE 7

Revision Rates of Omnifit/Vitalock 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 Omnifit/Vitalock Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Ceramic/Non XLPE	2	10
Metal/Non XLPE	13	55
Metal/XLPE	0	1
TOTAL	**15**	**66**

TABLE 8

Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the Omnifit/Vitalock 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 8: Revised Number of Primary Total Conventional Hip Replacement by State

Component	State	N Revised	N Total
Omnifit/Vitalock	VIC	1	3
	WA	0	1
	SA	0	4
	ACT/NT	14	58
Other Total Conventional Hip	NSW	5207	157707
	VIC	4859	140681
	QLD	3791	94582
	WA	2546	63265
	SA	1825	49398
	TAS	452	18198
	ACT/NT	569	14710
TOTAL		**19264**	**538607**

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.

TABLE 9

Number of Revisions of Omnifit/Vitalock Primary Total Conventional Hip Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Omnifit/Vitalock 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 9: Number of Revisions of Omnifit/Vitalock Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2000	0	4
2001	1	8
2002	2	9
2003	3	9
2004	4	14
2005	4	11
2006	1	11
TOTAL	**15**	**66**

TABLE 10

Revision Rates of Omnifit/Vitalock 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 Omnifit/Vitalock 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						
Omnifit	60330425-60331340	NORMALIZED UNPOLISHED COLLARLESS HIP STEM	YES	METAL	HA COATED	MATT
Omnifit	60410425-60411440	M-HA TI FEMORAL STEM	NO	METAL	HA COATED	
Omnifit	60700525-60701140	ODC FEMORAL HIP STEM	YES	METAL		MATT
Acetabular						
Vitalock	63021040-63021076	VITALOCK CLUSTER ACETABULAR SHELL	NO	METAL		
Vitalock	63022042-63022076	VITALOCK SOLID-BACK ACETABULAR SHELL	NO	METAL		
Vitalock	63062042-63062070	VITALOCK HA SOLID-BACK ACETABULAR SHELL	NO	METAL	HA COATED	

Table 10: Revised Number of Omnifit/Vitalock Primary Total Conventional Hip Replacement by Catalogue Number Range

Femoral Stem Range	Acetabular Range	N Revised	N Total
60330425-60331340	63021040-63021076	0	1
60410425-60411440	63021040-63021076	11	47
	63022042-63022076	3	14
	63062042-63062070	1	3
60700525-60701140	63021040-63021076	0	1
TOTAL		**15**	**66**