Secur-Fit Plus/Secur-Fit Total Conventional Hip Investigation

Note: This analysis compares the Secur-Fit Plus/Secur-Fit 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-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 Secur-Fit Plus/Secur-Fit 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)
Secur-Fit Plus/Secur-Fit	31	197	2673	1.16 (0.79, 1.65)
Other Total Conventional Hip	17452	494145	3081462	0.57 (0.56, 0.57)
TOTAL	17483	494342	3084135	0.57 (0.56, 0.58)

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Secur-Fit Plus/Secur-Fit 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
Secur-Fit Plus/Secur-Fit	3.1 (1.4, 6.7)	6.2 (3.6, 10.7)	7.3 (4.4, 11.9)	7.8 (4.8, 12.6)	7.8 (4.8, 12.6)	8.9 (5.6, 14.0)	9.5 (6.1, 14.6)	10.1 (6.5, 15.3)
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)	3.6 (3.6, 3.7)	3.9 (3.9, 4.0)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Secur-Fit Plus/Secur-Fit	10.1 (6.5, 15.3)	10.1 (6.5, 15.3)	10.7 (7.0, 16.1)	11.4 (7.6, 17.0)	14.3 (9.8, 20.5)	14.3 (9.8, 20.5)	15.8 (11.0, 22.3)
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, 5.4)	5.7 (5.6, 5.8)	6.1 (6.0, 6.2)	6.5 (6.4, 6.6)

CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
Secur-Fit Plus/Secur-Fit	17.5 (12.4,	18.5 (13.2,	19.7 (14.1,	19.7 (14.1,	19.7 (14.1,		
	24.4)	25.7)	27.2)	27.2)	27.2)		
Other Total Conventional Hip	6.9 (6.8, 7.1)	7.3 (7.1, 7.4)	7.6 (7.4, 7.8)	8.2 (8.0, 8.5)	8.5 (8.2, 8.8)	8.9 (8.5, 9.3)	9.3 (8.8, 9.8)

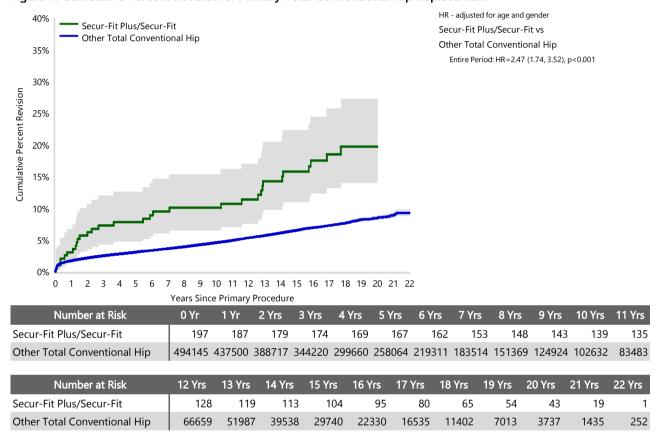
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Secur-Fit Plus/Secur-Fit 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

	Secur-Fit Plus/Secur-Fit		Other Total Co	nventional Hip
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	28	90.3	14432	82.7
Fractured Neck Of Femur			1291	7.4
Osteonecrosis	3	9.7	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	31	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

	Se	Secur-Fit Plus/Secur-Fit			r Total Convention	al Hip
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	12	6.1	38.7	4021	0.8	23.0
Infection	4	2.0	12.9	4009	0.8	23.0
Fracture	4	2.0	12.9	3811	8.0	21.8
Loosening	7	3.6	22.6	3535	0.7	20.3
Pain				310	0.1	1.8
Leg Length Discrepancy				270	0.1	1.5
Malposition				244	0.0	1.4
Lysis	1	0.5	3.2	197	0.0	1.1
Implant Breakage Stem				168	0.0	1.0
Implant Breakage Acetabular Insert				120	0.0	0.7
Incorrect Sizing				102	0.0	0.6
Wear Acetabular Insert	1	0.5	3.2	102	0.0	0.6
Metal Related Pathology				79	0.0	0.5
Implant Breakage Acetabular	1	0.5	3.2	70	0.0	0.4
Wear Head				45	0.0	0.3
Tumour				41	0.0	0.2
Implant Breakage Head				32	0.0	0.2
Heterotopic Bone				26	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	0.5	3.2	257	0.1	1.5
N Revision	31	15.7	100.0	17452	3.5	100.0
N Primary	197			494145		

20 22

Years Since Primary Procedure

FIGURE 2

0.0%

0 2

12 14

Years Since Primary Procedure

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 Secur-Fit Plus/Secur-Fit 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.

Secur-Fit Plus/Secur-Fit Other Total Conventional Hip 10.0% 10.0% Prosthesis Dislocation/Instability Prosthesis Dislocation/Instability Loosening Loosening Fracture Fracture 8.0% 8.0% Infection Infection Cumulative Incidence Cumulative Incidence 6.0% 6.0% 4.0% 4.0% 2.0% 2.0%

0.0%

0

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

20 22

Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Secur-Fit Plus/Secur-Fit 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 Secur-Fit Plus/Secur-Fit total conventional hip combination compared to all other total conventional hip prostheses.

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

	Secur-Fit Pl	us/Secur-Fit	Other Total Co	onventional Hip
Type of Revision	Number	Percent	Number	Percent
Femoral Component	4	12.9	5701	32.7
Acetabular Component	11	35.5	3314	19.0
THR (Femoral/Acetabular)	3	9.7	2031	11.6
Cement Spacer	1	3.2	619	3.5
Removal of Prostheses			95	0.5
Reinsertion of Components			27	0.2
Total Femoral			8	0.0
Bipolar Head and Femoral			5	0.0
Saddle			1	0.0
N Major	19	61.3	11801	67.6
Head/Insert	10	32.3	4324	24.8
Head Only	2	6.5	844	4.8
Minor Components			298	1.7
Insert Only			181	1.0
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	12	38.7	5651	32.4
TOTAL	31	100.0	17452	100.0

Revision Rates of Secur-Fit Plus/Secur-Fit 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 Secur-Fit Plus/Secur-Fit Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	30	196
Hybrid (Femur Cemented)	1	1
TOTAL	31	197

TABLE 7

Revision Rates of Secur-Fit Plus/Secur-Fit 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 Secur-Fit Plus/Secur-Fit Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Ceramic/Non XLPE	0	10
Metal/Non XLPE	29	185
Unknown	2	2
TOTAL	31	197

Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the Secur-Fit Plus/Secur-Fit 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	
Secur-Fit Plus/Secur-Fit	NSW	7	72	
	VIC	20	108	
	QLD	2	8	
	WA	2	9	
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		17483	494342	

Number of Revisions of Secur-Fit Plus/Secur-Fit Primary Total Conventional Hip Replacement by Year of Implant

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

Year of Implant	Number Revised	Total Number
2000	0	1
2001	4	40
2002	8	60
2003	7	27
2004	4	21
2005	5	26
2006	3	22
TOTAL	31	197

Revision Rates of Secur-Fit Plus/Secur-Fit 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 Secur-Fit Plus/Secur-Fit 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
Femoral Stem					
Secur-Fit Plus	60540509A-60541420A	SECUR-FIT PLUS MAX 127 DEG NECK ANGLE STEM	NO	METAL	HA COATED
Acetabular					
Secur-Fit	20512040-20512072	TITANIUM HA PSL CLUSTER ACETABULAR SHELL	NO	METAL	HA COATED
Secur-Fit	20513040-20513072	TITANIUM HA PSL NO HOLE ACETABULAR SHELL	NO	METAL	HA COATED
Secur-Fit	20532048-20532080	SECURFIT XTRA W DOME HOLES	NO	METAL	

Table 10: Revised Number of Secur-Fit Plus/Secur-Fit Primary Total Conventional Hip Replacement by Catalogue Number Range

Femoral Stem Range	Acetabular Range	N Revised	N Total
60540509A-60541420A	20512040-20512072	24	160
	20513040-20513072	4	26
	20532048-20532080	3	11
TOTAL		31	197