

seleXys (excluding seleXys PC) Total Conventional Hip Investigation

Note: This analysis compares the seleXys (excluding seleXys PC) 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-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 seleXys (excluding seleXys PC) 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% CI)
seleXys (excluding seleXys PC)	51	391	3419	1.49 (1.11, 1.96)
Other Total Conventional Hip	15831	453294	2719869	0.58 (0.57, 0.59)
TOTAL	15882	453685	2723288	0.58 (0.57, 0.59)

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 seleXys (excluding seleXys PC) total conventional hip prosthesis 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
seleXys (excluding seleXys PC)	4.6 (2.9, 7.2)	6.7 (4.6, 9.7)	7.8 (5.5, 11.0)	9.7 (7.1, 13.2)	10.6 (7.9, 14.1)	11.1 (8.3, 14.8)	12.3 (9.4, 16.1)
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, 3.4)	3.7 (3.6, 3.7)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
seleXys (excluding seleXys PC)	12.6 (9.6, 16.5)	13.0 (9.9, 16.9)	13.5 (10.3, 17.5)	13.5 (10.3, 17.5)	14.3 (10.9, 18.7)	14.3 (10.9, 18.7)	
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
seleXys (excluding seleXys PC)							
Other Total Conventional Hip	6.7 (6.5, 6.8)	7.1 (6.9, 7.3)	7.5 (7.3, 7.7)	7.8 (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.

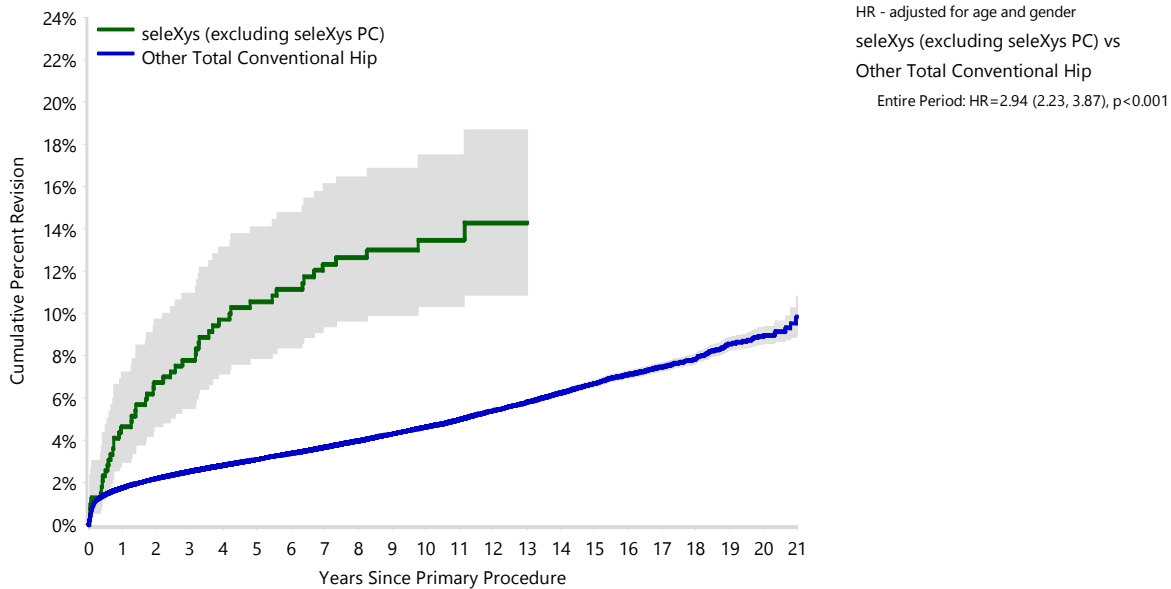
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the seleXys (excluding seleXys PC) 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.

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
seleXys (excluding seleXys PC)	391	369	353	341	325	314	302	288	268	220	165
Other Total Conventional Hip	453294	398535	353914	309044	267077	227935	191463	158469	131104	107944	88094

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
seleXys (excluding seleXys PC)	111	69	52	37	14	0	0	0	0	0	0
Other Total Conventional Hip	70577	55340	42208	31909	24032	17719	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	seleXys (excluding seleXys PC)		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	48	94.1	13085	82.7
Fractured Neck Of Femur	1	2.0	1164	7.4
Osteonecrosis	2	3.9	717	4.5
Developmental Dysplasia			247	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
TOTAL	51	100.0	15831	100.0

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 15.9 Years)

Revision Diagnosis	seleXys (excluding seleXys PC)			Other Total Conventional Hip		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	5	1.3	9.8	3693	0.8	23.6
Infection	2	0.5	3.9	3537	0.8	22.6
Fracture	4	1.0	7.8	3404	0.8	21.7
Loosening	31	7.9	60.8	3154	0.7	20.1
Pain	1	0.3	2.0	284	0.1	1.8
Leg Length Discrepancy				260	0.1	1.7
Malposition	3	0.8	5.9	223	0.0	1.4
Lysis	1	0.3	2.0	166	0.0	1.1
Implant Breakage Stem				146	0.0	0.9
Implant Breakage Acetabular Insert				114	0.0	0.7
Incorrect Sizing	1	0.3	2.0	95	0.0	0.6
Wear Acetabular Insert	1	0.3	2.0	85	0.0	0.5
Implant Breakage Acetabular				66	0.0	0.4
Metal Related Pathology	1	0.3	2.0	64	0.0	0.4
Wear Head				44	0.0	0.3
Tumour				36	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	0.3	2.0	227	0.1	1.4
N Revision	51	13.0	100.0	15664	3.5	100.0
N Primary	391			453294		

Note: This table is restricted to revisions within 15.9 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 seleXys (excluding seleXys PC) 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

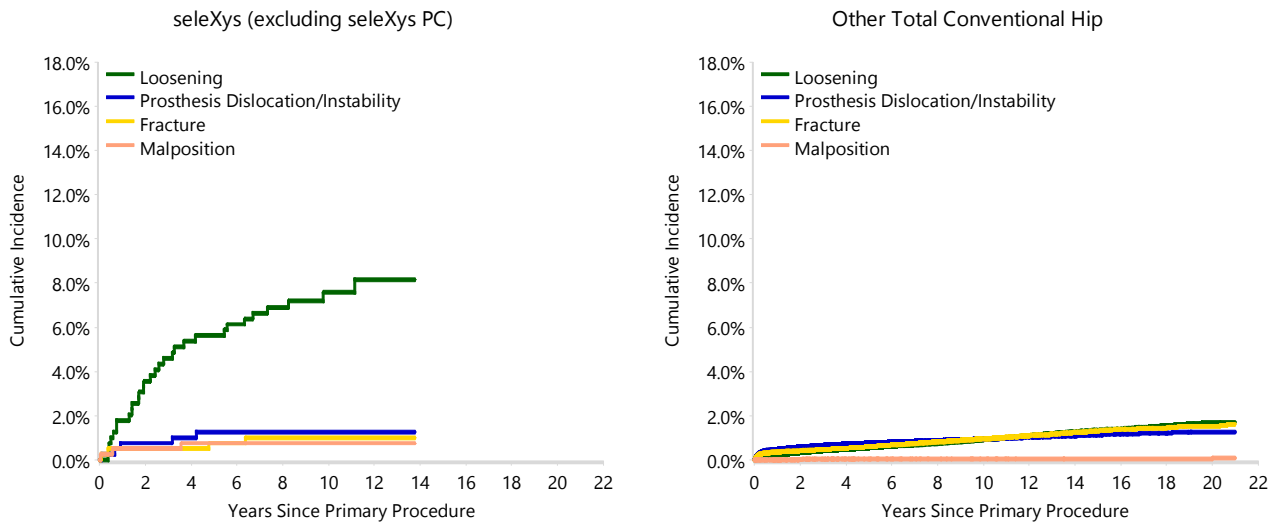


TABLE 5

Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the seleXys (excluding seleXys PC) 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 seleXys (excluding seleXys PC) total conventional hip prosthesis compared to all other total conventional hip prostheses.

Table 5: Primary Total Conventional Hip Replacement - Type of Revision (Follow-up Limited to 15.9 Years)

Type of Revision	seleXys (excluding seleXys PC)		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	9	17.6	5109	32.6
Acetabular Component	32	62.7	2985	19.1
THR (Femoral/Acetabular)	4	7.8	1776	11.3
Cement Spacer	2	3.9	592	3.8
Removal of Prostheses			96	0.6
Reinsertion of Components			25	0.2
Total Femoral			6	0.0
Bipolar Head and Femoral			4	0.0
Saddle			1	0.0
N Major	47	92.2	10594	67.6
Head/Insert	2	3.9	3847	24.6
Head Only	1	2.0	775	4.9
Minor Components	1	2.0	272	1.7
Insert Only			172	1.1
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	4	7.8	5070	32.4
TOTAL	51	100.0	15664	100.0

Note: This table is restricted to revisions within 15.9 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 seleXys (excluding seleXys PC) 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 seleXys (excluding seleXys PC) Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	45	348
Hybrid (Femur Cemented)	6	43
TOTAL	51	391

TABLE 7**Revision Rates of seleXys (excluding seleXys PC) 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 seleXys (excluding seleXys PC) Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	4	89
Ceramic/Non XLPE	13	64
Ceramic/XLPE + Antioxidant	22	109
Metal/Metal	1	13
Metal/Non XLPE	5	41
Metal/XLPE + Antioxidant	6	74
Ceramicised Metal/XLPE + Antioxidant	0	1
TOTAL	51	391

TABLE 8

Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the seleXys (excluding seleXys PC) 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.

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

Component	State	N Revised	N Total
seleXys (excluding seleXys PC)	NSW	2	32
	VIC	33	174
	QLD	9	119
	WA	7	66
Other Total Conventional Hip	NSW	4298	132965
	VIC	3958	116898
	QLD	3142	80067
	WA	2184	53950
	SA	1415	41929
	TAS	372	15098
	ACT/NT	462	12387
TOTAL		15882	453685

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 9**Number of Revisions of seleXys (excluding seleXys PC) Primary Total Conventional Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the seleXys (excluding seleXys PC) 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 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 9: Number of Revisions of seleXys (excluding seleXys PC) Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2006	3	35
2007	4	33
2008	3	20
2009	0	21
2010	10	53
2011	12	70
2012	12	89
2013	7	57
2014	0	13
TOTAL	51	391

TABLE 10

Revision Rates of seleXys (excluding seleXys PC) 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 seleXys (excluding seleXys PC) 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
Acetabular				
seleXys	55400042-55400068	SELEXYS TPS SHELL	NO	METAL
seleXys	55420042-55420064	SELEXYS TH SHELL	NO	METAL
seleXys	55420142-55420164	SELEXYS TH+ SHELL	NO	METAL

Table 10: Revised Number of seleXys (excluding seleXys PC) Primary Total Conventional Hip Replacement by Catalogue Number Range

Acetabular Range	N Revised	N Total
55400042-55400068	21	245
55420042-55420064	4	28
55420142-55420164	26	118
TOTAL	51	391

TABLE 11**Revision Rates of seleXys (excluding seleXys PC) 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 11: Revised Number of seleXys (excluding seleXys PC) Primary Total Conventional Hip Replacement by Femoral Stem Component

Femoral Stem Component	N Revised	N Total
Alloclassic	0	2
CBC Stem	3	16
CBH Stem	12	105
Fullfix	2	27
MS 30	1	1
SL-Plus	12	48
twinSys (cless)	18	178
twinSys (ctd)	3	14
TOTAL	51	391