BalanSys Uni/BalanSys Uni Convex Unicompartmental Knee Investigation

Note: This analysis compares the BalanSys Uni/BalanSys Uni Convex femoral/tibial combination with all other unicompartmental knee 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-2025.

Note: Procedures using prostheses with no recorded use in 2024 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Unicompartmental Knee Replacement

The revision rate of the BalanSys Uni/BalanSys Uni Convex unicompartmental knee combination is compared to all other unicompartmental knee prostheses.

Table 1: Revision Rates of Primary Unicompartmental Knee Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
BalanSys Uni/BalanSys Uni Convex	21	54	625	3.36 (2.08, 5.14)
Other Unicompartmental Knee	5258	50910	389433	1.35 (1.31, 1.39)
TOTAL	**5279**	**50964**	**390058**	**1.35 (1.32, 1.39)**

Note: Prostheses no longer used in 2024 are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Unicompartmental Knee Replacement

The yearly cumulative percent revision of the BalanSys Uni/BalanSys Uni Convex unicompartmental knee combination is compared to all other unicompartmental knee prostheses.

Table 2: Yearly Cumulative Percent Revision (95% CI) of Primary Unicompartmental Knee Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
BalanSys Uni/BalanSys Uni Convex	1.9 (0.3, 12.4)	5.6 (1.8, 16.2)	7.4 (2.8, 18.5)	7.4 (2.8, 18.5)	7.4 (2.8, 18.5)	13.1 (6.5, 25.6)	17.0 (9.2, 30.1)	18.9 (10.6, 32.3)
Other Unicompartmental Knee	1.9 (1.8, 2.0)	3.4 (3.2, 3.6)	4.4 (4.2, 4.6)	5.3 (5.1, 5.5)	6.1 (5.9, 6.4)	7.0 (6.8, 7.3)	8.1 (7.8, 8.3)	9.1 (8.8, 9.4)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
BalanSys Uni/BalanSys Uni Convex	22.9 (13.7, 36.8)	24.9 (15.3, 39.0)	29.3 (18.7, 43.9)	29.3 (18.7, 43.9)	29.3 (18.7, 43.9)	32.5 (21.0, 47.9)	40.0 (26.5, 57.1)	49.8 (33.6, 68.8)
Other Unicompartmental Knee	10.2 (9.9, 10.5)	11.3 (11.0, 11.7)	12.5 (12.2, 12.9)	13.8 (13.4, 14.3)	15.2 (14.8, 15.7)	16.8 (16.3, 17.3)	18.2 (17.7, 18.8)	19.7 (19.1, 20.3)

CPR	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
BalanSys Uni/BalanSys Uni Convex							
Other Unicompartmental Knee	21.4 (20.7, 22.1)	23.0 (22.3, 23.8)	24.8 (23.9, 25.6)	26.7 (25.7, 27.7)	28.7 (27.6, 29.8)	30.4 (29.1, 31.7)	31.2 (29.7, 32.6)

Note: Prostheses no longer used in 2024 are excluded from the comparator.

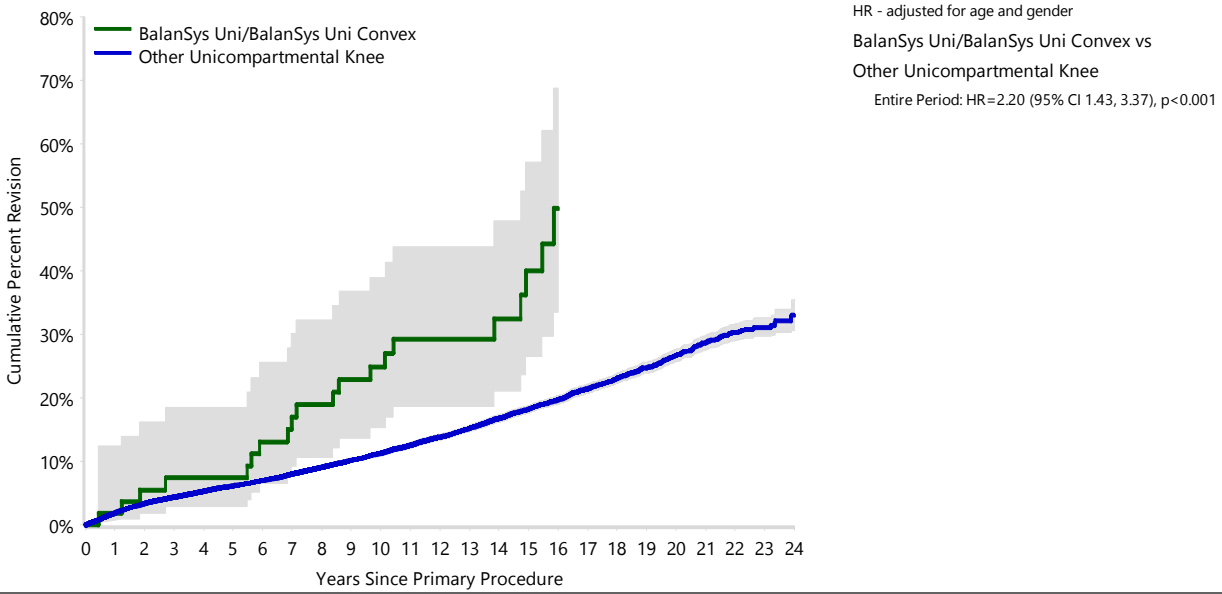
FIGURE 1

Yearly Cumulative Percent Revision of Primary Unicompartmental Knee Replacement

The yearly cumulative percent revision of the BalanSys Uni/BalanSys Uni Convex unicompartmental knee combination is compared to all other unicompartmental knee 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 Unicompartmental Knee 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
BalanSys Uni/BalanSys Uni Convex	54	53	51	50	50	50	45	43	41	39	35	31
Other Unicompartmental Knee	50910	46153	41711	37728	33767	30081	26631	23607	20764	18178	15807	13628

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
BalanSys Uni/BalanSys Uni Convex	29	28	21	16	9	5	0	0	0	0	0	0
Other Unicompartmental Knee	11723	10050	8412	6867	5506	4306	3270	2412	1742	1193	718	311

Note: Prostheses no longer used in 2024 are excluded from the comparator.

TABLE 3

Primary Diagnosis for Revised Primary Unicompartmental Knee 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 unicompartmental knee prostheses.

Table 3: Primary Diagnosis for Revised Primary Unicompartmental Knee Replacement

	BalanSys Uni/BalanSys Uni Convex		Other Unicompartmental Knee	
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	21	100.0	5206	99.0
Osteonecrosis			30	0.6
Rheumatoid Arthritis			14	0.3
Other Inflammatory Arthritis			5	0.1
Fracture			2	0.0
Tumour			1	0.0
TOTAL	**21**	**100.0**	**5258**	**100.0**

Note: Prostheses no longer used in 2024 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 Unicompartmental Knee Replacement - Reason for Revision (Follow-up Limited to 17.9 Years)

	BalanSys Uni/BalanSys Uni Convex			Other Unicompartmental Knee		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Progression Of Disease	7	13.0	33.3	1912	3.8	37.8
Loosening	5	9.3	23.8	1558	3.1	30.8
Pain				370	0.7	7.3
Infection				261	0.5	5.2
Bearing Dislocation				200	0.4	4.0
Fracture				157	0.3	3.1
Instability				106	0.2	2.1
Lysis				90	0.2	1.8
Wear Tibial Insert				74	0.1	1.5
Malalignment				66	0.1	1.3
Implant Breakage Tibial Insert	8	14.8	38.1	45	0.1	0.9
Incorrect Sizing				31	0.1	0.6
Patellofemoral Pain				30	0.1	0.6
Prosthesis Dislocation				27	0.1	0.5
Implant Breakage Tibial				21	0.0	0.4
Metal Related Pathology	1	1.9	4.8	13	0.0	0.3
Osteonecrosis				13	0.0	0.3
Wear Tibial				12	0.0	0.2
Arthrofibrosis				11	0.0	0.2
Synovitis				11	0.0	0.2
Wear Femoral				5	0.0	0.1
Implant Breakage Femoral				4	0.0	0.1
Patella Erosion				3	0.0	0.1
Other				33	0.1	0.7
N Revision	**21**	**38.9**	**100.0**	**5053**	**9.9**	**100.0**
N Primary	**54**			**50910**		

Note: This table is restricted to revisions within 17.9 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2024 are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Unicompartmental Knee 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 BalanSys Uni/BalanSys Uni Convex unicompartmental knee combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other unicompartmental knee prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Unicompartmental Knee Replacement

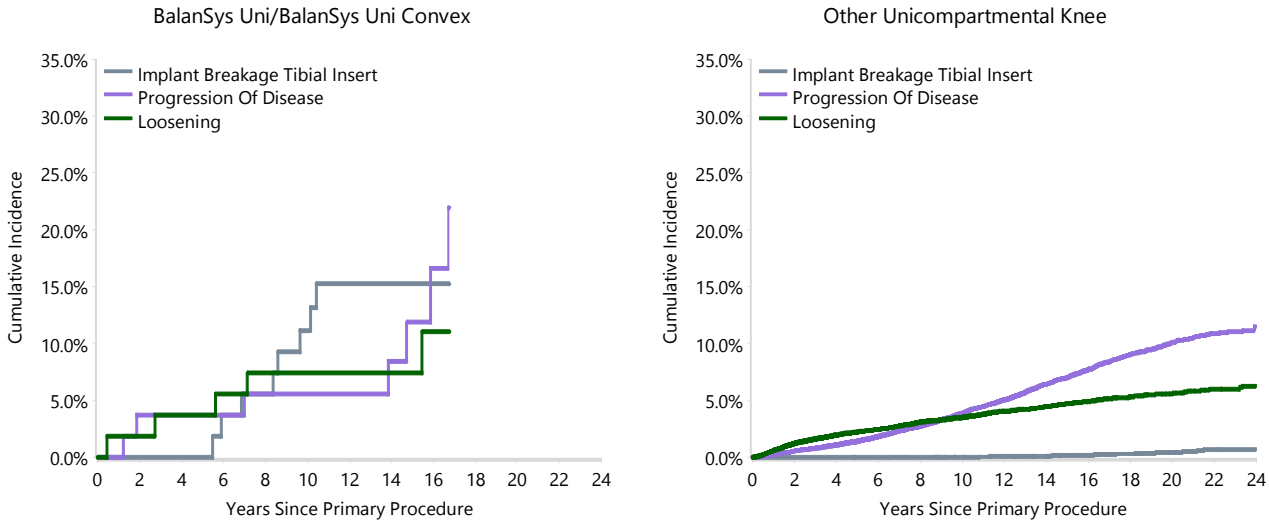


TABLE 5

Type of Revision Performed for Primary Unicompartmental Knee Replacement

This analysis identifies the components used in the revision of the BalanSys Uni/BalanSys Uni Convex unicompartmental knee combination and compares it to the components used in the revision of all other unicompartmental knee 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 unicompartmental knee prostheses i.e. is there a difference in the type of revision undertaken for the BalanSys Uni/BalanSys Uni Convex unicompartmental knee combination compared to all other unicompartmental knee prostheses.

Table 5: Primary Unicompartmental Knee Replacement - Type of Revision (Follow-up Limited to 17.9 Years)

	BalanSys Uni/BalanSys Uni Convex		Other Unicompartmental Knee	
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	14	66.7	4254	84.2
Uni Tibial Component	1	4.8	95	1.9
Uni Femoral Component			47	0.9
Cement Spacer			39	0.8
UKR (Uni Tibial/Uni Femoral)	1	4.8	35	0.7
Patella/Trochlear Resurfacing			16	0.3
Removal of Prostheses			5	0.1
Femoral Component			4	0.1
Reinsertion of Components			4	0.1
Tibial Component			1	0.0
N Major	**16**	**76.2**	**4500**	**89.1**
Uni Insert Only	5	23.8	552	10.9
Patella Only			1	0.0
N Minor	**5**	**23.8**	**553**	**10.9**
TOTAL	**21**	**100.0**	**5053**	**100.0**

Note: This table is restricted to revisions within 17.9 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2024 are excluded from the comparator.

TABLE 6

Revision Rates of BalanSys Uni/BalanSys Uni Convex Primary Unicompartmental Knee 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 BalanSys Uni/BalanSys Uni Convex Primary Unicompartmental Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	21	54
TOTAL	**21**	**54**

TABLE 7

Revision Rates of Primary Unicompartmental Knee Replacement by State

This enables a state by state variation to be identified for the BalanSys Uni/BalanSys Uni Convex unicompartmental knee combination and provides the comparative data for each of the states for all other unicompartmental knee 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 7: Revised Number of Primary Unicompartmental Knee Replacement by State

Component	State	N Revised	N Total
BalanSys Uni/BalanSys Uni Convex	VIC	2	2
	QLD	3	16
	SA	16	36
Other Unicompartmental Knee	NSW	1479	12313
	VIC	1049	11729
	QLD	958	10315
	WA	700	8024
	SA	729	5299
	TAS	194	2150
	ACT/NT	149	1080
TOTAL		**5279**	**50964**

Note: Prostheses no longer used in 2024 are excluded from the comparator.

TABLE 8

Number of Revisions of BalanSys Uni/BalanSys Uni Convex Primary Unicompartmental Knee Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the BalanSys Uni/BalanSys Uni Convex unicompartmental knee 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 2024 has a maximum of one year to be revised, whereas a primary procedure performed in 2022 has a maximum of three years to be revised.

Table 8: Number of Revisions of BalanSys Uni/BalanSys Uni Convex Primary Unicompartmental Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2007	4	12
2008	7	10
2009	0	4
2010	3	7
2011	3	9
2012	0	1
2013	1	3
2014	1	3
2015	2	5
TOTAL	**21**	**54**

TABLE 9

Revision Rates of BalanSys Uni/BalanSys Uni Convex Primary Unicompartmental Knee 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 BalanSys Uni/BalanSys Uni Convex 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
Femoral				
BalanSys Uni	77150001-77150005	BALANSYS UNI FEMUR CEMENTED	YES	METAL
Tibial				
BalanSys Uni Convex	77150201-77150210	BALANSYS UNI CONVEX TIBIAL PLATEAU CEMENTED	YES	METAL

Table 9: Revised Number of BalanSys Uni/BalanSys Uni Convex Primary Unicompartmental Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
77150001-77150005	77150201-77150210	21	54
TOTAL		**21**	**54**