

BalanSys Uni/BalanSys Uni Mobile Unicompartmental Knee Investigation

Note: This analysis compares the BalanSys Uni/BalanSys Uni Mobile 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-2023>.

Note: Procedures using prostheses with no recorded use in 2022 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Unicompartmental Knee Replacement

The revision rate of the BalanSys Uni/BalanSys Uni Mobile 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 Mobile	61	199	2440	2.50 (1.91, 3.21)
Other Unicompartmental Knee	4860	48950	350591	1.39 (1.35, 1.43)
TOTAL	4921	49149	353031	1.39 (1.36, 1.43)

Note: Prostheses no longer used in 2022 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 Mobile unicompartmental knee combination is compared to all other unicompartmental knee prostheses.

Table 2: Yearly Cumulative Percent Revision 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 Mobile	7.0 (4.2, 11.6)	11.1 (7.4, 16.3)	13.1 (9.1, 18.6)	14.1 (10.0, 19.8)	14.6 (10.4, 20.4)	16.2 (11.7, 22.1)	17.8 (13.1, 23.9)	18.4 (13.6, 24.5)
Other Unicompartmental Knee	1.9 (1.8, 2.1)	3.5 (3.3, 3.7)	4.5 (4.4, 4.7)	5.5 (5.3, 5.7)	6.3 (6.1, 6.6)	7.2 (7.0, 7.5)	8.3 (8.0, 8.6)	9.4 (9.0, 9.7)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
BalanSys Uni/BalanSys Uni Mobile	20.6 (15.5, 27.0)	21.7 (16.5, 28.2)	22.2 (17.0, 28.8)	24.5 (19.0, 31.2)	26.3 (20.6, 33.2)	29.3 (23.3, 36.5)	30.0 (23.9, 37.2)
Other Unicompartmental Knee	10.6 (10.2, 10.9)	11.7 (11.3, 12.1)	13.1 (12.7, 13.5)	14.4 (14.0, 14.9)	15.8 (15.3, 16.3)	17.4 (16.9, 18.0)	18.8 (18.2, 19.4)

CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
BalanSys Uni/BalanSys Uni Mobile	31.6 (25.3, 39.0)	34.6 (27.8, 42.6)					
Other Unicompartmental Knee	20.4 (19.7, 21.1)	22.1 (21.4, 22.9)	24.0 (23.2, 24.9)	25.7 (24.7, 26.7)	27.8 (26.6, 29.0)	29.7 (28.3, 31.2)	30.4 (28.7, 32.3)

Note: Prostheses no longer used in 2022 are excluded from the comparator.

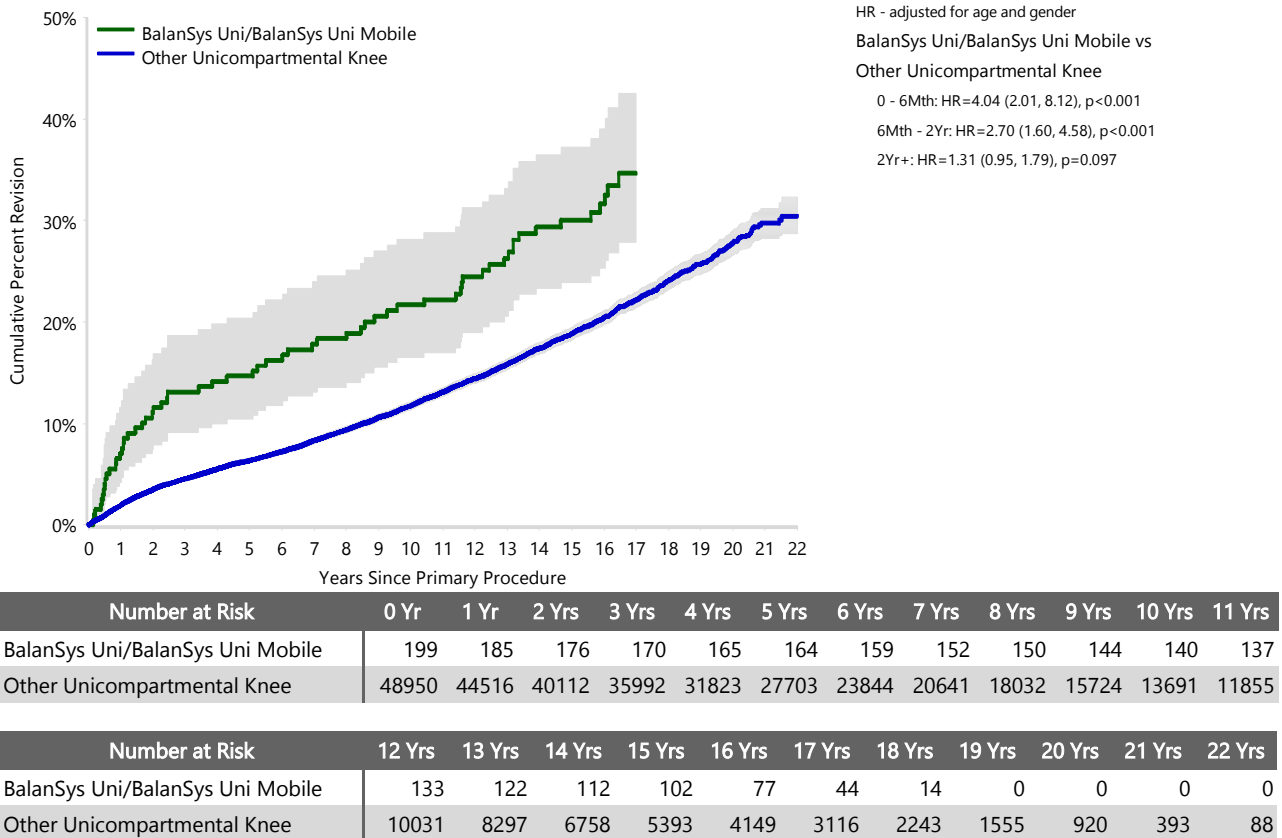
FIGURE 1

Yearly Cumulative Percent Revision of Primary Unicompartmental Knee Replacement

The yearly cumulative percent revision of the BalanSys Uni/BalanSys Uni Mobile 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



Note: Prostheses no longer used in 2022 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

Primary Diagnosis	Balansys Uni/Balansys Uni Mobile		Other Unicompartmental Knee	
	Number	Percent	Number	Percent
Osteoarthritis	60	98.4	4813	99.0
Osteonecrosis	1	1.6	27	0.6
Rheumatoid Arthritis			12	0.2
Other Inflammatory Arthritis			6	0.1
Fracture			1	0.0
Tumour			1	0.0
TOTAL	61	100.0	4860	100.0

Note: Prostheses no longer used in 2022 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 18.5 Years)

Revision Diagnosis	Balansys Uni/Balansys Uni Mobile			Other Unicompartmental Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Progression Of Disease	14	7.0	23.0	1747	3.6	36.5
Loosening	21	10.6	34.4	1541	3.1	32.2
Pain	4	2.0	6.6	360	0.7	7.5
Infection	1	0.5	1.6	256	0.5	5.3
Bearing Dislocation	8	4.0	13.1	180	0.4	3.8
Fracture	1	0.5	1.6	141	0.3	2.9
Instability				89	0.2	1.9
Lysis	1	0.5	1.6	84	0.2	1.8
Wear Tibial Insert	3	1.5	4.9	71	0.1	1.5
Malalignment				60	0.1	1.3
Implant Breakage Tibial Insert	2	1.0	3.3	40	0.1	0.8
Patellofemoral Pain				31	0.1	0.6
Incorrect Sizing				28	0.1	0.6
Prosthesis Dislocation	2	1.0	3.3	28	0.1	0.6
Implant Breakage Tibial	1	0.5	1.6	24	0.0	0.5
Osteonecrosis	1	0.5	1.6	15	0.0	0.3
Wear Tibial	1	0.5	1.6	15	0.0	0.3
Metal Related Pathology				12	0.0	0.3
Synovitis				10	0.0	0.2
Arthrofibrosis				9	0.0	0.2
Implant Breakage Femoral	1	0.5	1.6	5	0.0	0.1
Wear Femoral				4	0.0	0.1
Patella Erosion				3	0.0	0.1
Other				37	0.1	0.8
N Revision	61	30.7	100.0	4790	9.8	100.0
N Primary	199			48950		

Note: This table is restricted to revisions within 18.5 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 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 Mobile 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

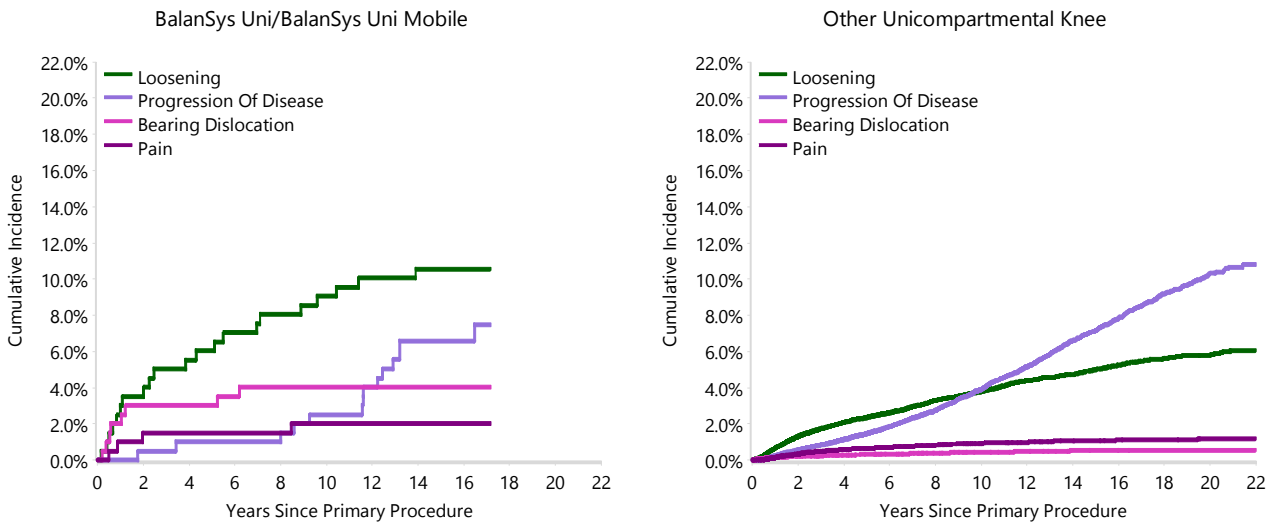


TABLE 5

Type of Revision Performed for Primary Unicompartmental Knee Replacement

This analysis identifies the components used in the revision of the BalanSys Uni/BalanSys Uni Mobile 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 Mobile unicompartmental knee combination compared to all other unicompartmental knee prostheses.

Table 5: Primary Unicompartmental Knee Replacement - Type of Revision (Follow-up Limited to 18.5 Years)

Type of Revision	BalanSys Uni/BalanSys Uni Mobile		Other Unicompartmental Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	43	70.5	4037	84.3
Uni Tibial Component	3	4.9	99	2.1
Uni Femoral Component	2	3.3	51	1.1
Cement Spacer			39	0.8
UKR (Uni Tibial/Uni Femoral)	2	3.3	35	0.7
Patella/Trochlear Resurfacing			17	0.4
Removal of Prostheses			5	0.1
Femoral Component			4	0.1
Reinsertion of Components	1	1.6	4	0.1
Tibial Component			2	0.0
N Major	51	83.6	4293	89.6
Uni Insert Only	10	16.4	496	10.4
Patella Only			1	0.0
N Minor	10	16.4	497	10.4
TOTAL	61	100.0	4790	100.0

Note: This table is restricted to revisions within 18.5 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 6

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

Fixation	N Revised	N Total
Cemented	61	199
TOTAL	61	199

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 Mobile 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 Mobile	NSW	2	8
	VIC	9	32
	QLD	19	62
	WA	5	12
	SA	26	85
Other Unicompartmental Knee	NSW	1478	12842
	VIC	921	10727
	QLD	856	9759
	WA	580	7520
	SA	671	5120
	TAS	181	1899
	ACT/NT	173	1083
TOTAL		4921	49149

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 8**Number of Revisions of BalanSys Uni/BalanSys Uni Mobile 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 Mobile 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 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 8: Number of Revisions of BalanSys Uni/BalanSys Uni Mobile Primary Unicompartmental Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2004	6	37
2005	20	51
2006	23	63
2007	9	33
2008	3	9
2009	0	2
2010	0	4
TOTAL	61	199

TABLE 9

Revision Rates of BalanSys Uni/BalanSys Uni Mobile 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 Mobile 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 Mobile	77150101-77150110	BALANSYS UNI MOBILE TIBIAL PLATEAU CEMENTED	YES	

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

Femoral Range	Tibial Range	N Revised	N Total
77150001-77150005	77150101-77150110	61	199
TOTAL		61	199