

Vanguard PS/Vanguard Total Knee Investigation

Note: This analysis compares the Vanguard PS/Vanguard femoral/tibial combination with all other total 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-2022>.

Note: Procedures using prostheses with no recorded use in 2021 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Knee Replacement

The revision rate of the Vanguard PS/Vanguard total knee combination is compared to all other total knee prostheses.

Table 1: Revision Rates of Primary Total Knee Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Vanguard PS/Vanguard	334	5347	40187	0.83 (0.74, 0.93)
Other Total Knee	25727	722348	4688937	0.55 (0.54, 0.56)
TOTAL	26061	727695	4729125	0.55 (0.54, 0.56)

Note: Prostheses no longer used in 2021 are excluded from the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Vanguard PS/Vanguard total knee combination is compared to all other total knee prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Knee Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Vanguard PS/Vanguard	1.9 (1.5, 2.3)	3.5 (3.0, 4.0)	4.3 (3.8, 4.9)	4.8 (4.3, 5.5)	5.3 (4.7, 5.9)	5.9 (5.3, 6.6)	6.2 (5.5, 6.9)
Other Total Knee	1.0 (1.0, 1.0)	1.9 (1.9, 1.9)	2.5 (2.4, 2.5)	2.9 (2.8, 2.9)	3.2 (3.2, 3.3)	3.5 (3.5, 3.6)	3.8 (3.8, 3.9)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Vanguard PS/Vanguard	6.6 (5.9, 7.4)	7.0 (6.3, 7.8)	7.4 (6.7, 8.3)	7.6 (6.8, 8.4)	7.7 (6.9, 8.6)	7.8 (7.0, 8.8)	7.8 (7.0, 8.8)
Other Total Knee	4.1 (4.1, 4.2)	4.4 (4.4, 4.5)	4.7 (4.7, 4.8)	5.1 (5.0, 5.1)	5.4 (5.3, 5.5)	5.7 (5.6, 5.8)	6.0 (5.9, 6.1)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Vanguard PS/Vanguard	7.8 (7.0, 8.8)						
Other Total Knee	6.4 (6.3, 6.5)	6.8 (6.7, 7.0)	7.3 (7.1, 7.4)	7.6 (7.4, 7.8)	7.9 (7.7, 8.1)	8.2 (7.9, 8.4)	8.2 (7.9, 8.5)

Note: Prostheses no longer used in 2021 are excluded from the comparator.

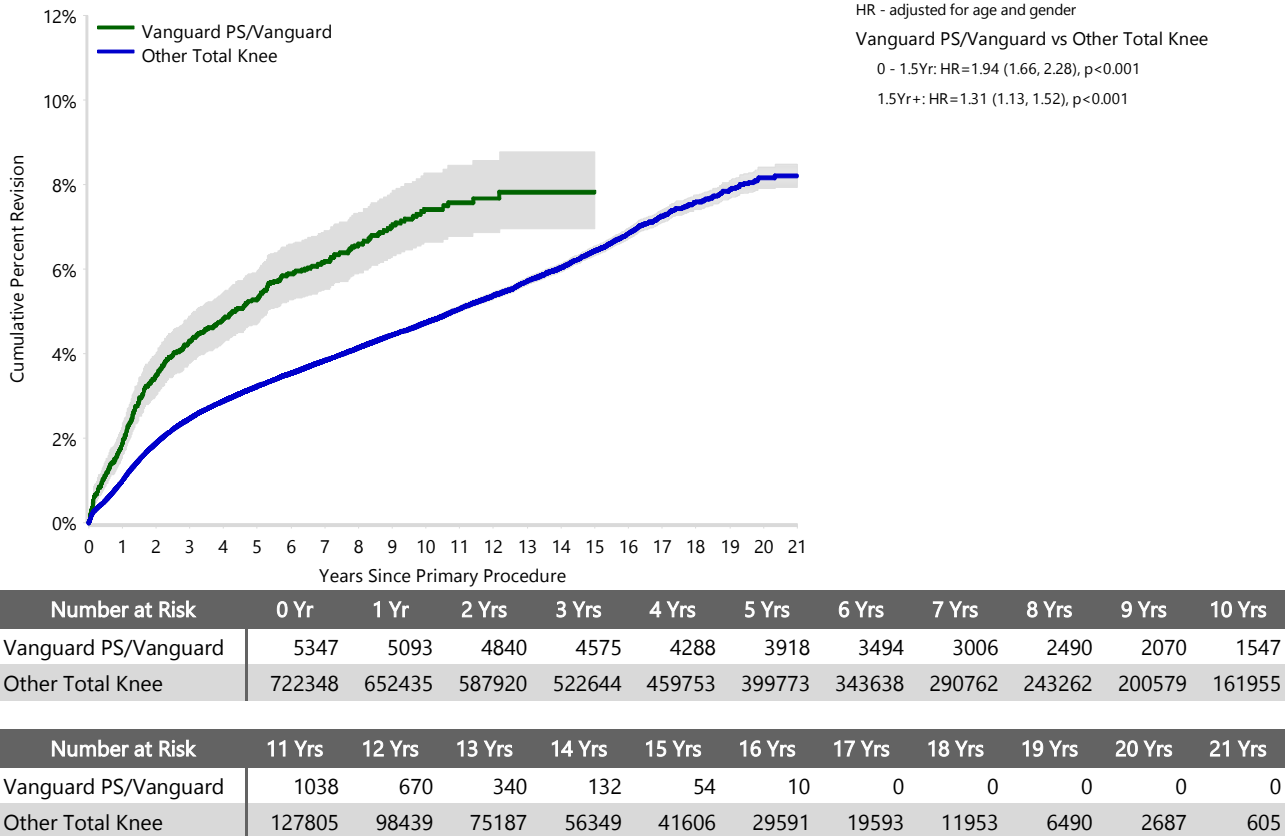
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Vanguard PS/Vanguard total knee combination is compared to all other total 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 Total Knee Replacement



Note: Prostheses no longer used in 2021 are excluded from the comparator.

TABLE 3**Primary Diagnosis for Revised Primary Total 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 total knee prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Knee Replacement

Primary Diagnosis	Vanguard PS/Vanguard		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	322	96.4	24929	96.9
Rheumatoid Arthritis	8	2.4	323	1.3
Other Inflammatory Arthritis	3	0.9	158	0.6
Tumour			151	0.6
Osteonecrosis	1	0.3	97	0.4
Fracture			49	0.2
Other			19	0.1
Chondrocalcinosis			1	0.0
TOTAL	334	100.0	25727	100.0

Note: Prostheses no longer used in 2021 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 Knee Replacement - Reason for Revision (Follow-up Limited to 16.4 Years)

Revision Diagnosis	Vanguard PS/Vanguard			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	86	1.6	25.7	6871	1.0	26.9
Loosening	108	2.0	32.3	5685	0.8	22.2
Instability	36	0.7	10.8	2440	0.3	9.5
Pain	21	0.4	6.3	2036	0.3	8.0
Patellofemoral Pain	17	0.3	5.1	2028	0.3	7.9
Patella Erosion	11	0.2	3.3	1669	0.2	6.5
Arthrofibrosis	7	0.1	2.1	989	0.1	3.9
Fracture	13	0.2	3.9	920	0.1	3.6
Malalignment	5	0.1	1.5	596	0.1	2.3
Wear Tibial Insert	3	0.1	0.9	350	0.0	1.4
Lysis	4	0.1	1.2	333	0.0	1.3
Incorrect Sizing	4	0.1	1.2	254	0.0	1.0
Patella Maltracking	1	0.0	0.3	180	0.0	0.7
Bearing Dislocation	1	0.0	0.3	151	0.0	0.6
Implant Breakage Tibial Insert	3	0.1	0.9	145	0.0	0.6
Implant Breakage Patella	2	0.0	0.6	131	0.0	0.5
Metal Related Pathology	3	0.1	0.9	113	0.0	0.4
Prosthesis Dislocation	1	0.0	0.3	79	0.0	0.3
Synovitis				78	0.0	0.3
Osteonecrosis	1	0.0	0.3	57	0.0	0.2
Implant Breakage Tibial	2	0.0	0.6	40	0.0	0.2
Implant Breakage Femoral				38	0.0	0.1
Wear Patella				31	0.0	0.1
Tumour				27	0.0	0.1
Heterotopic Bone				15	0.0	0.1
Wear Tibial				12	0.0	0.0
Progression Of Disease				6	0.0	0.0
Patella Dislocation				2	0.0	0.0
Wear Femoral				2	0.0	0.0
Incorrect Side				1	0.0	0.0
Other	5	0.1	1.5	297	0.0	1.2
N Revision	334	6.2	100.0	25576	3.5	100.0
N Primary	5347			722348		

Note: This table is restricted to revisions within 16.4 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total 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 Vanguard PS/Vanguard total knee combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total knee prostheses.

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

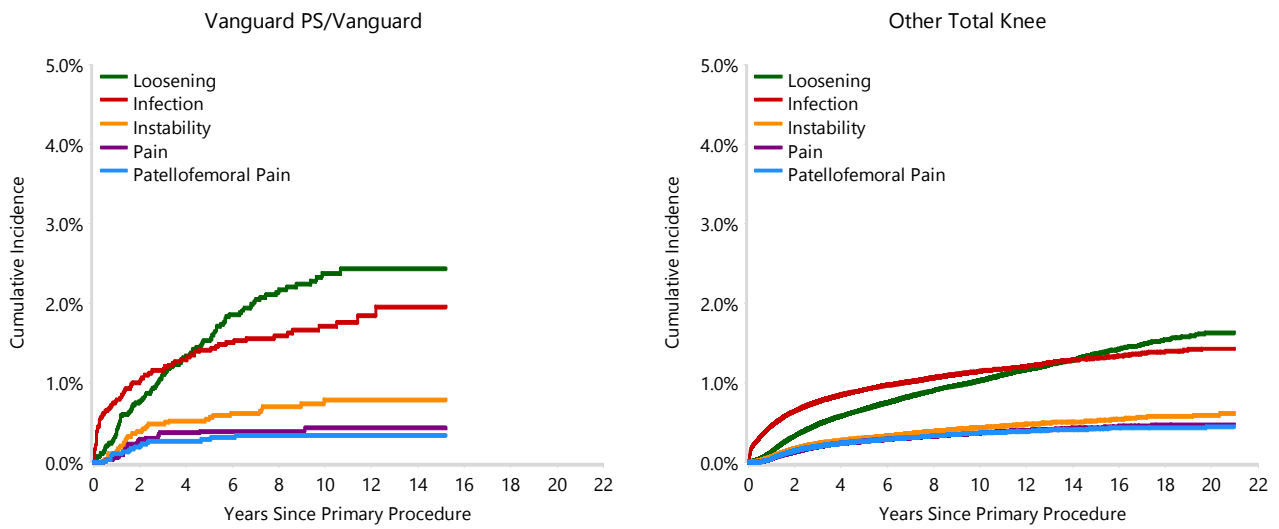


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

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

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 16.4 Years)

Type of Revision	Vanguard PS/Vanguard		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	81	24.3	6276	24.5
Tibial Component	58	17.4	2037	8.0
Cement Spacer	23	6.9	1330	5.2
Femoral Component	7	2.1	1304	5.1
Removal of Prostheses			149	0.6
Total Femoral			20	0.1
Reinsertion of Components	3	0.9	8	0.0
N Major	172	51.5	11124	43.5
Insert Only	91	27.2	7006	27.4
Patella Only	48	14.4	4720	18.5
Insert/Patella	17	5.1	2659	10.4
Minor Components	5	1.5	54	0.2
Cement Only	1	0.3	13	0.1
N Minor	162	48.5	14452	56.5
TOTAL	334	100.0	25576	100.0

Note: This table is restricted to revisions within 16.4 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 are excluded from the comparator.

TABLE 6**Revision Rates of Vanguard PS/Vanguard Primary Total 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 Vanguard PS/Vanguard Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	299	4625
Cementless	1	13
Hybrid (Tibial Cemented)	34	707
Hybrid (Tibial Cementless)	0	2
TOTAL	334	5347

TABLE 7**Revision Rates of Vanguard PS/Vanguard Primary Total Knee 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 Vanguard PS/Vanguard Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	328	5231
XLPE + Antioxidant	6	114
Unknown	0	2
TOTAL	334	5347

TABLE 8**Revision Rates of Vanguard PS/Vanguard Primary Total Knee Replacement by Bearing Mobility**

This analysis is provided as some prostheses are combined with a variety of bearing mobilities. All bearing mobilities used with this combination are listed.

Table 8: Revised Number of Vanguard PS/Vanguard Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	334	5344
Rotating	0	1
Unknown	0	2
TOTAL	334	5347

TABLE 9**Revision Rates of Vanguard PS/Vanguard Primary Total Knee Replacement by Stability**

This analysis is provided as some prostheses are combined with a variety of stabilities. All stabilities used with this combination are listed.

Table 9: Revised Number of Vanguard PS/Vanguard Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Fully Stabilised	0	2
Hinged	0	1
Minimally Stabilised	0	1
Posterior Stabilised	334	5341
Unknown	0	2
TOTAL	334	5347

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Vanguard PS/Vanguard total knee combination and provides the comparative data for each of the states for all other total 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 10: Revised Number of Primary Total Knee Replacement by State

Component	State	N Revised	N Total
Vanguard PS/Vanguard	NSW	43	974
	VIC	130	1795
	QLD	128	1798
	WA	2	4
	SA	17	328
	TAS	0	19
	ACT/NT	14	429
Other Total Knee	NSW	7679	252147
	VIC	5423	142692
	QLD	5562	151373
	WA	3233	77901
	SA	2820	63112
	TAS	418	16866
	ACT/NT	592	18257
TOTAL		26061	727695

Note: Prostheses no longer used in 2021 are excluded from the comparator.

TABLE 11**Number of Revisions of Vanguard PS/Vanguard Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Vanguard PS/Vanguard total 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 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 11: Number of Revisions of Vanguard PS/Vanguard Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2005	1	22
2006	4	81
2007	14	145
2008	26	321
2009	32	430
2010	43	478
2011	44	607
2012	41	561
2013	30	451
2014	37	523
2015	17	445
2016	9	331
2017	19	310
2018	6	205
2019	9	186
2020	1	136
2021	1	115
TOTAL	334	5347

TABLE 12

Revision Rates of Vanguard PS/Vanguard Primary Total 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 Vanguard PS/Vanguard 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	Mobility	Stability	Material	Coating	Fixation
Femoral								
Vanguard PS	183100-183136	VANGUARD PS OPEN BOX FEMORAL INTERLOK	YES					MATT
Vanguard PS	183100TNBN-183136TNBN	VANGUARD PS OPEN BOX FEMORAL INTERLOK TINBN COATED	YES					MATT
Vanguard PS	183200-183236	VANGUARD PS CLOSED BOX FEMORAL INTERLOK	YES					MATT
Vanguard PS	184500-184536	VANGUARD PS OPEN BOX FEMORAL POROUS COATED/BOND COATED	NO					POROUS
Tibial								
Vanguard	141210-141219	TITANIUM PRIMARY INTERLOK TIBIAL TRAY	YES					MATT
Vanguard	141221-141227	COCR I-BEAM MODULAR INTERLOK TIBIAL TRAY	YES					MATT
Vanguard	141230-141238	COCR FINNED MODULAR INTERLOK TIBIAL TRAY W/LOCKING BAR	YES					MATT
Vanguard	141241-141247	COCR I-BEAM MODULAR POLISHED INTERLOK TIBIAL TRAY	YES					POLISHED
Vanguard	141250-141258	COCR FINNED MODULAR POLISHED INTERLOK TIBIAL TRAY	YES					POLISHED
Vanguard	141250TNBN-141258TNBN	COCR TINBN FINNED MODULAR POLISHED INTERLOK TIBIAL TRAY	YES					POLISHED
Vanguard	141260-141268	TITANIUM PRIMARY POROUS TIBIAL TRAY	NO					POROUS
Vanguard	141361-141367	COCR FINNED HIGHLY POLISHED POROUS & HA TIBIAL TRAY	NO				HA COATED	POROUS
Vanguard	141480-141488	TITANIUM OFFSET INTERLOK TIBIAL TRAY	YES					
Vanguard	185200-185208	360 TIBIAL TRAY W/ TI LOCKING BAR & SCREW	YES					
Vanguard	189420-189528	VANGUARD PS MONO-LOCK DCM TIBIAL BEARING/I-BEAM BEARING ARCOM UHMWPE	YES	FIXED	POSTERIOR STABILISED	NON CROSS-LINKED POLYETHYLENE		

Table 12: Revised Number of Vanguard PS/Vanguard Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
183100-183136	141210-141219	48	410
	141221-141227	6	52
	141230-141238	11	334
	141241-141247	24	304
	141250-141258	205	3347
	141250TNBN-141258TNBN	2	32
	141260-141268	0	3
	141480-141488	2	23
	185200-185208	0	27
	189420-189528	0	3
183100TNBN-183136TNBN	141210-141219	0	1
	141250TNBN-141258TNBN	0	7
183200-183236	141210-141219	0	5
	141230-141238	0	12
	141241-141247	0	9
	141250-141258	1	44
	141480-141488	0	3
	189420-189528	0	8
184500-184536	141210-141219	1	18
	141230-141238	3	23
	141241-141247	0	26
	141250-141258	29	615
	141250TNBN-141258TNBN	1	7
	141260-141268	0	1
	141361-141367	1	13
	141480-141488	0	3
	185200-185208	0	2
	189420-189528	0	15
TOTAL		334	5347