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-2024.

Note: Procedures using prostheses with no recorded use in 2023 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	370	5405	48313	0.77 (0.69, 0.85)
Other Total Knee	24931	736083	4688062	0.53 (0.53, 0.54)
TOTAL	25301	741488	4736375	0.53 (0.53, 0.54)

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	8 Yrs
Vanguard PS/Vanguard	1.8 (1.5, 2.2)	3.4 (2.9, 3.9)	4.2 (3.7, 4.8)	4.7 (4.2, 5.3)	5.2 (4.6, 5.8)	5.8 (5.2, 6.5)	6.1 (5.4, 6.7)	6.4 (5.8, 7.2)
Other Total Knee	1.0 (0.9, 1.0)	1.8 (1.8, 1.8)	2.4 (2.3, 2.4)	2.8 (2.7, 2.8)	3.1 (3.1, 3.2)	3.4 (3.4, 3.5)	3.7 (3.7, 3.8)	4.0 (4.0, 4.1)
CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Vanguard PS/Vanguard	6.8 (6.1, 7.5)	7.3 (6.6, 8.1)	7.6 (6.8, 8.4)	7.9 (7.1, 8.7)	8.3 (7.5, 9.3)	8.5 (7.6, 9.4)	8.9 (7.9, 10.1)	8.9 (7.9, 10.1)
Other Total Knee	4.3 (4.3, 4.4)	4.6 (4.6, 4.7)	4.9 (4.9, 5.0)	5.2 (5.2, 5.3)	5.5 (5.5, 5.6)	5.8 (5.7, 5.9)	6.2 (6.1, 6.3)	6.6 (6.5, 6.8)
CPR	17 Yrs	18 Yrs	19 Yr	s 20	Yrs 2	1 Yrs	22 Yrs	23 Yrs
Vanguard PS/Vanguard	8.9 (7.9, 10.1)						
Other Total Knee	7.0 (6.8, 7.1) 7.3 (7.1, 7	7.5) 7.5 (7.3	3, 7.7) 7.7 (7.5, 8.0) 8.0	(7.7, 8.3)	8.2 (7.9, 8.6)	8.2 (7.9, 8.6)

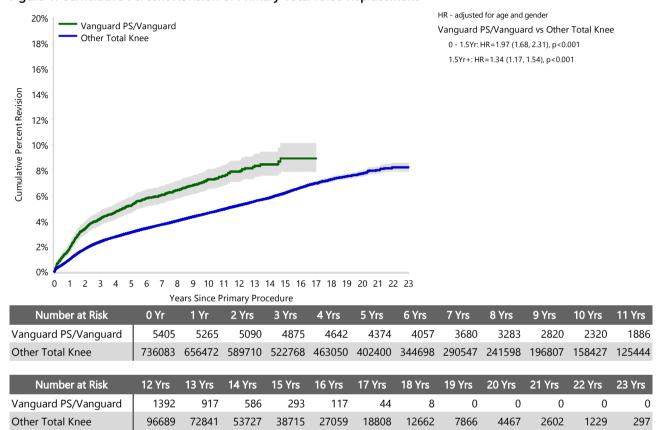
FIGURE 1

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



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

	Vanguard PS/Vanguard		Other To	tal Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	356	96.2	24126	96.8
Rheumatoid Arthritis	10	2.7	313	1.3
Tumour			178	0.7
Other Inflammatory Arthritis	3	0.8	153	0.6
Osteonecrosis	1	0.3	89	0.4
Fracture			48	0.2
Other			23	0.1
Chondrocalcinosis			1	0.0
TOTAL	370	100.0	24931	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 Knee Replacement - Reason for Revision (Follow-up Limited to 18.4 Years)

	٧	anguard PS/Vangua	ard		Other Total Knee	
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	96	1.8	25.9	7001	1.0	28.1
Loosening	121	2.2	32.7	5286	0.7	21.2
Instability	37	0.7	10.0	2559	0.3	10.3
Pain	26	0.5	7.0	1832	0.2	7.4
Patella Erosion	13	0.2	3.5	1789	0.2	7.2
Patellofemoral Pain	17	0.3	4.6	1631	0.2	6.6
Arthrofibrosis	7	0.1	1.9	1019	0.1	4.1
Fracture	13	0.2	3.5	988	0.1	4.0
Malalignment	5	0.1	1.4	525	0.1	2.1
Wear Tibial Insert	4	0.1	1.1	340	0.0	1.4
Lysis	4	0.1	1.1	281	0.0	1.1
Incorrect Sizing	4	0.1	1.1	229	0.0	0.9
Implant Breakage Tibial Insert	4	0.1	1.1	182	0.0	0.7
Patella Maltracking	1	0.0	0.3	180	0.0	0.7
Bearing Dislocation	1	0.0	0.3	140	0.0	0.6
Implant Breakage Patella	2	0.0	0.5	130	0.0	0.5
Metal Related Pathology	4	0.1	1.1	101	0.0	0.4
Prosthesis Dislocation	2	0.0	0.5	80	0.0	0.3
Synovitis				64	0.0	0.3
Osteonecrosis	1	0.0	0.3	50	0.0	0.2
Implant Breakage Femoral				44	0.0	0.2
Wear Patella				42	0.0	0.2
Implant Breakage Tibial	3	0.1	0.8	34	0.0	0.1
Tumour				31	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Progression Of Disease				7	0.0	0.0
Wear Tibial				5	0.0	0.0
Patella Dislocation				2	0.0	0.0
Incorrect Side				1	0.0	0.0
Wear Femoral				1	0.0	0.0
Other	5	0.1	1.4	302	0.0	1.2
N Revision	370	6.8	100.0	24890	3.4	100.0
N Primary	5405			736083		

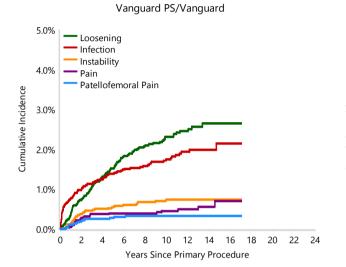
Note: This table is restricted to revisions within 18.4 years for all groups to allow a time-matched comparison of revisions.

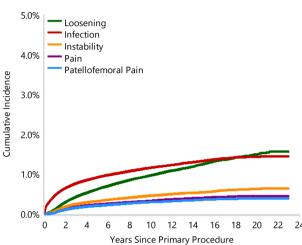
FIGURE 2

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





Other Total Knee

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 18.4 Years)

	Vanguard F	Vanguard PS/Vanguard		otal Knee
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	96	25.9	5951	23.9
Tibial Component	60	16.2	1856	7.5
Femoral Component	7	1.9	1259	5.1
Cement Spacer	29	7.8	1173	4.7
Removal of Prostheses			129	0.5
Total Femoral			22	0.1
Reinsertion of Components	3	0.8	7	0.0
N Major	195	52.7	10397	41.8
Insert Only	98	26.5	7461	30.0
Patella Only	52	14.1	4322	17.4
Insert/Patella	20	5.4	2644	10.6
Minor Components	5	1.4	57	0.2
Cement Only			9	0.0
N Minor	175	47.3	14493	58.2
TOTAL	370	100.0	24890	100.0

Note: This table is restricted to revisions within 18.4 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2023 are excluded from the comparator.

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	329	4679	
Cementless	1	13	
Hybrid (Tibial Cemented)	40	711	
Hybrid (Tibial Cementless)	0	2	
TOTAL	370	5405	

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	364	5289
XLPE + Antioxidant	6	114
Unknown	0	2
TOTAL	370	5405

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	370	5402
Rotating	0	1
Unknown	0	2
TOTAL	370	5405

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	370	5399
Unknown	0	2
TOTAL	370	5405

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/Vangua	rd NSW	47	1025	
	VIC	146	1795	
	QLD	140	1799	
	WA	2	4	
	SA	20	334	
	TAS	0	19	
	ACT/NT	15	429	
Other Total Knee	NSW	7326	251259	
	VIC	5374	148666	
	QLD	5361	153657	
	WA	3064	80125	
	SA	2756	64011	
	TAS	458	18786	
	ACT/NT	592	19579	
TOTAL		25301	741488	

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 2023 has a maximum of one year to be revised, whereas a primary procedure performed in 2021 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	27	321
2009	35	430
2010	46	478
2011	51	607
2012	45	561
2013	34	451
2014	39	523
2015	19	445
2016	11	331
2017	21	310
2018	9	205
2019	10	186
2020	2	136
2021	2	117
2022	0	56
TOTAL	370	5405

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			METAL		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			METAL		POLISHED
Vanguard	141250-141258	COCR FINNED MODULAR POLISHED INTERLOK TIBIAL TRAY	YES			METAL		POLISHED
Vanguard	141250TNBN-141258TNBN	COCR TINBN FINNED MODULAR POLISHED INTERLOK TIBIAL TRAY	YES			METAL		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			METAL		
Vanguard	189420-189528	VANGUARD PS MONO-LOCK DCM TIBIAL BEARING/I-BEAM BEARING ARCOM UHMWPE	YES	FIXFI)	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	54	410
	141221-141227	6	52
	141230-141238	12	334
	141241-141247	30	304
	141250-141258	222	3394
	141250TNBN-141258TNBN	2	35
	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	6
	141230-141238	0	12
	141241-141247	0	9
	141250-141258	1	47
	141480-141488	0	3
	189420-189528	0	8
184500-184536	141210-141219	1	18
	141230-141238	3	23
	141241-141247	0	26
	141250-141258	35	619
	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		370	5405