

Vanguard PS/Regenerex Total Knee Investigation

Note: This analysis compares the Vanguard PS/Regenerex 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/Regenerex 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/Regenerex	38	465	3202	1.19 (0.84, 1.63)
Other Total Knee	26023	727230	4725922	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/Regenerex 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/Regenerex	3.2 (2.0, 5.3)	5.0 (3.3, 7.4)	7.1 (5.1, 9.9)	7.4 (5.3, 10.2)	7.4 (5.3, 10.2)	7.4 (5.3, 10.2)	7.8 (5.6, 10.8)
Other Total Knee	1.0 (1.0, 1.0)	1.9 (1.9, 1.9)	2.5 (2.4, 2.5)	2.9 (2.9, 2.9)	3.2 (3.2, 3.3)	3.6 (3.5, 3.6)	3.9 (3.8, 3.9)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Vanguard PS/Regenerex	7.8 (5.6, 10.8)	8.3 (6.0, 11.5)	8.9 (6.4, 12.4)	8.9 (6.4, 12.4)			
Other Total Knee	4.2 (4.1, 4.2)	4.5 (4.4, 4.5)	4.8 (4.7, 4.8)	5.1 (5.0, 5.2)	5.4 (5.3, 5.5)	5.7 (5.7, 5.8)	6.1 (6.0, 6.1)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Vanguard PS/Regenerex							
Other Total Knee	6.4 (6.3, 6.6)	6.9 (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 (8.0, 8.5)

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

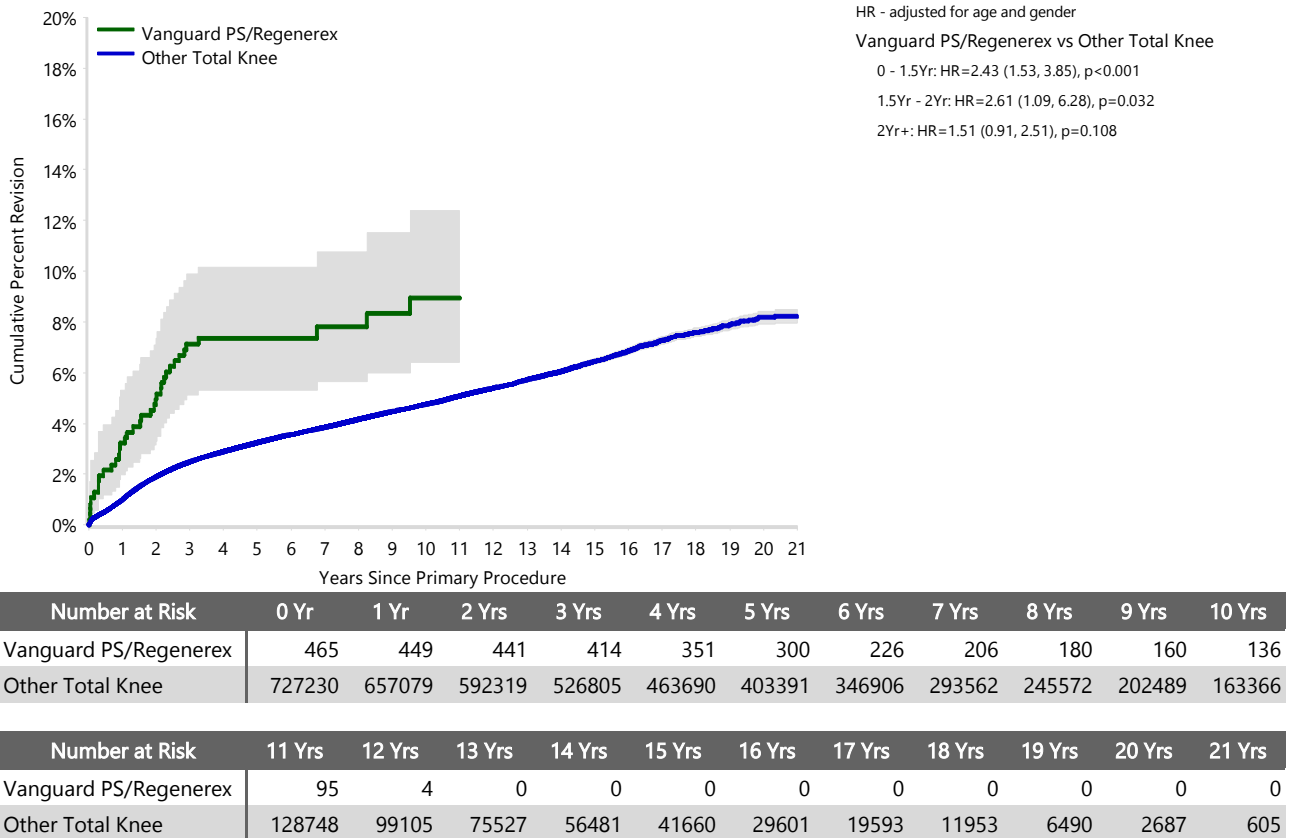
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Vanguard PS/Regenerex 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/Regenerex		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	38	100.0	25213	96.9
Rheumatoid Arthritis			331	1.3
Other Inflammatory Arthritis			161	0.6
Tumour			151	0.6
Osteonecrosis			98	0.4
Fracture			49	0.2
Other			19	0.1
Chondrocalcinosis			1	0.0
TOTAL	38	100.0	26023	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 12.2 Years)

Revision Diagnosis	Vanguard PS/Regenerex			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	13	2.8	34.2	6824	0.9	27.3
Loosening	13	2.8	34.2	5531	0.8	22.1
Instability	2	0.4	5.3	2409	0.3	9.6
Pain	2	0.4	5.3	2010	0.3	8.0
Patellofemoral Pain				2008	0.3	8.0
Patella Erosion				1589	0.2	6.4
Arthrofibrosis	3	0.6	7.9	986	0.1	3.9
Fracture	3	0.6	7.9	861	0.1	3.4
Malalignment				594	0.1	2.4
Lysis				291	0.0	1.2
Wear Tibial Insert				280	0.0	1.1
Incorrect Sizing	1	0.2	2.6	257	0.0	1.0
Patella Maltracking				181	0.0	0.7
Bearing Dislocation				150	0.0	0.6
Implant Breakage Patella				131	0.0	0.5
Implant Breakage Tibial Insert				128	0.0	0.5
Metal Related Pathology				104	0.0	0.4
Prosthesis Dislocation				76	0.0	0.3
Synovitis				74	0.0	0.3
Osteonecrosis				58	0.0	0.2
Implant Breakage Tibial				39	0.0	0.2
Implant Breakage Femoral				31	0.0	0.1
Tumour				26	0.0	0.1
Wear Patella	1	0.2	2.6	26	0.0	0.1
Heterotopic Bone				13	0.0	0.1
Wear Tibial				9	0.0	0.0
Progression Of Disease				4	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				298	0.0	1.2
N Revision	38	8.2	100.0	24993	3.4	100.0
N Primary	465			727230		

Note: This table is restricted to revisions within 12.2 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/Regenerex 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

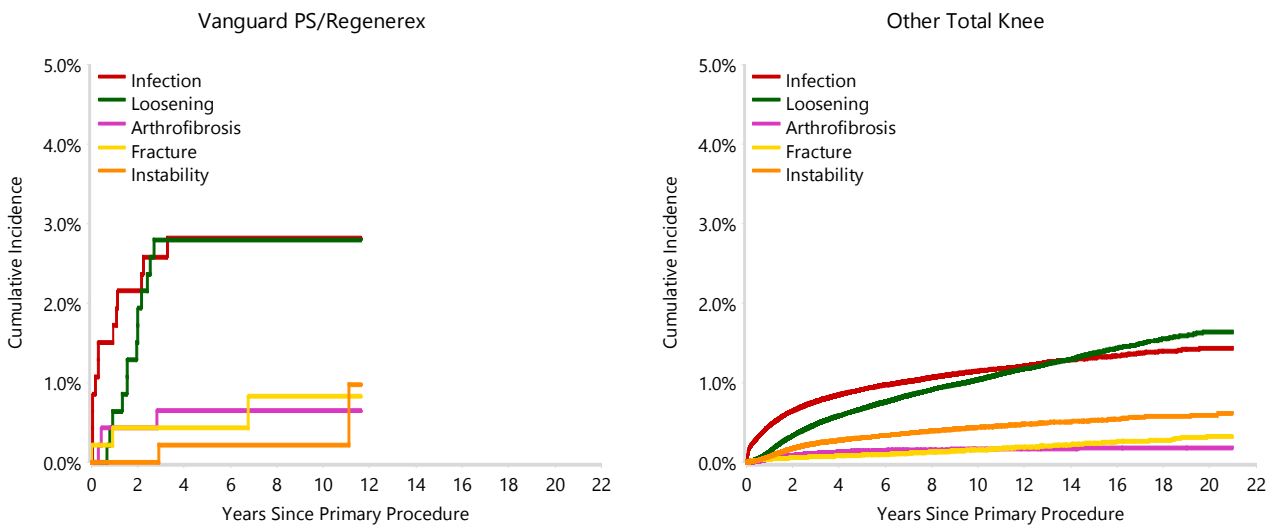


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Vanguard PS/Regenerex 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/Regenerex total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 12.2 Years)

Type of Revision	Vanguard PS/Regenerex		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	15	39.5	5953	23.8
Tibial Component	4	10.5	2064	8.3
Cement Spacer	4	10.5	1321	5.3
Femoral Component	2	5.3	1299	5.2
Removal of Prostheses			147	0.6
Total Femoral			18	0.1
Reinsertion of Components			11	0.0
N Major	25	65.8	10813	43.3
Insert Only	9	23.7	6934	27.7
Patella Only	2	5.3	4684	18.7
Insert/Patella	1	2.6	2490	10.0
Minor Components	1	2.6	58	0.2
Cement Only			14	0.1
N Minor	13	34.2	14180	56.7
TOTAL	38	100.0	24993	100.0

Note: This table is restricted to revisions within 12.2 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/Regenerex 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/Regenerex Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	0	2
Cementless	19	278
Hybrid (Tibial Cemented)	0	6
Hybrid (Tibial Cementless)	19	179
TOTAL	38	465

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

Bearing Surface	N Revised	N Total
Non XLPE	37	453
XLPE + Antioxidant	1	12
TOTAL	38	465

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

Bearing Mobility	N Revised	N Total
Fixed	38	465
TOTAL	38	465

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

Stability	N Revised	N Total
Posterior Stabilised	38	465
TOTAL	38	465

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/Regenerex 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/Regenerex	NSW	14	240
	VIC	21	194
	QLD	3	31
Other Total Knee	NSW	7708	252881
	VIC	5532	144293
	QLD	5687	153140
	WA	3235	77905
	SA	2837	63440
	TAS	418	16885
	ACT/NT	606	18686
TOTAL		26061	727695

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

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

Year of Implant	Number Revised	Total Number
2009	0	4
2010	10	121
2011	3	54
2012	3	27
2013	0	15
2014	1	21
2015	0	18
2016	5	76
2017	11	59
2018	3	56
2019	2	14
TOTAL	38	465

TABLE 12

Revision Rates of Vanguard PS/Regenerex 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/Regenerex 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	Fixation
Femoral				
Vanguard PS	183100-183136	VANGUARD PS OPEN BOX FEMORAL INTERLOK	YES	MATT
Vanguard PS	184500-184536	VANGUARD PS OPEN BOX FEMORAL POROUS COATED/BOND COATED	NO	POROUS
Tibial				
Regenerex	141270-141278	POROUS TIBIAL TRAY	NO	POROUS

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

Femoral Range	Tibial Range	N Revised	N Total
183100-183136	141270-141278	19	181
184500-184536	141270-141278	19	284
TOTAL		38	465