

## 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-2023>.

Note: Procedures using prostheses with no recorded use in 2022 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	42	465	3567	1.18 (0.85, 1.59)
Other Total Knee	26836	757949	5069780	0.53 (0.52, 0.54)
<b>TOTAL</b>	<b>26878</b>	<b>758414</b>	<b>5073347</b>	<b>0.53 (0.52, 0.54)</b>

Note: Prostheses no longer used in 2022 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	8 Yrs
Vanguard PS/Regenerex	3.2 (2.0, 5.3)	5.0 (3.3, 7.4)	7.1 (5.1, 9.9)	7.6 (5.5, 10.4)	7.6 (5.5, 10.4)	7.8 (5.7, 10.7)	8.6 (6.3, 11.7)	8.6 (6.3, 11.7)
Other Total Knee	1.0 (1.0, 1.0)	1.8 (1.8, 1.9)	2.4 (2.4, 2.4)	2.8 (2.8, 2.9)	3.1 (3.1, 3.2)	3.5 (3.4, 3.5)	3.8 (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
Vanguard PS/Regenerex	9.1 (6.6, 12.3)	9.6 (7.0, 13.0)	9.6 (7.0, 13.0)	10.3 (7.5, 14.1)			
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)	5.6 (5.5, 5.6)	5.9 (5.8, 5.9)	6.2 (6.1, 6.3)

CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
Vanguard PS/Regenerex							
Other Total Knee	6.6 (6.5, 6.8)	7.0 (6.9, 7.2)	7.3 (7.2, 7.5)	7.6 (7.4, 7.8)	7.8 (7.6, 8.0)	8.0 (7.8, 8.2)	8.2 (7.9, 8.6)

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

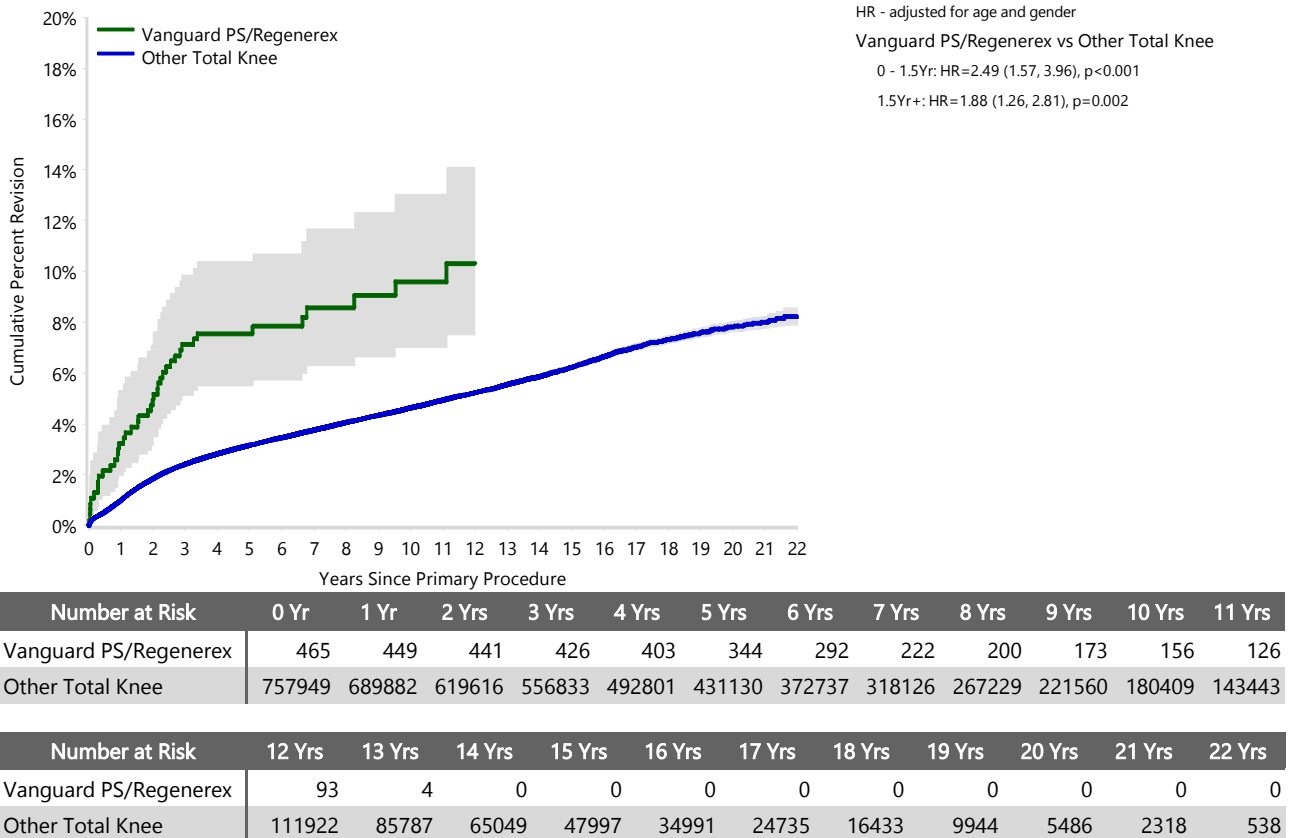
**FIGURE 1**

**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 2022 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	42	100.0	26004	96.9
Rheumatoid Arthritis			342	1.3
Tumour			162	0.6
Other Inflammatory Arthritis			160	0.6
Osteonecrosis			101	0.4
Fracture			48	0.2
Other			18	0.1
Chondrocalcinosis			1	0.0
<b>TOTAL</b>	<b>42</b>	<b>100.0</b>	<b>26836</b>	<b>100.0</b>

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 Total Knee Replacement - Reason for Revision (Follow-up Limited to 13.2 Years)

Revision Diagnosis	Vanguard PS/Regenerex			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	13	2.8	31.0	7245	1.0	27.9
Loosening	16	3.4	38.1	5756	0.8	22.1
Instability	2	0.4	4.8	2553	0.3	9.8
Pain	2	0.4	4.8	1997	0.3	7.7
Patellofemoral Pain				1900	0.3	7.3
Patella Erosion				1693	0.2	6.5
Arthrofibrosis	3	0.6	7.1	1030	0.1	4.0
Fracture	4	0.9	9.5	958	0.1	3.7
Malalignment				594	0.1	2.3
Wear Tibial Insert				310	0.0	1.2
Lysis				287	0.0	1.1
Incorrect Sizing	1	0.2	2.4	261	0.0	1.0
Patella Maltracking				185	0.0	0.7
Implant Breakage Tibial Insert				153	0.0	0.6
Bearing Dislocation				151	0.0	0.6
Implant Breakage Patella				137	0.0	0.5
Metal Related Pathology				100	0.0	0.4
Prosthesis Dislocation				81	0.0	0.3
Synovitis				73	0.0	0.3
Osteonecrosis				55	0.0	0.2
Implant Breakage Tibial				39	0.0	0.2
Implant Breakage Femoral				35	0.0	0.1
Tumour				32	0.0	0.1
Wear Patella	1	0.2	2.4	31	0.0	0.1
Heterotopic Bone				12	0.0	0.0
Wear Tibial				8	0.0	0.0
Progression Of Disease				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				315	0.0	1.2
<b>N Revision</b>	<b>42</b>	<b>9.0</b>	<b>100.0</b>	<b>26000</b>	<b>3.4</b>	<b>100.0</b>
<b>N Primary</b>	<b>465</b>			<b>757949</b>		

Note: This table is restricted to revisions within 13.2 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 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**

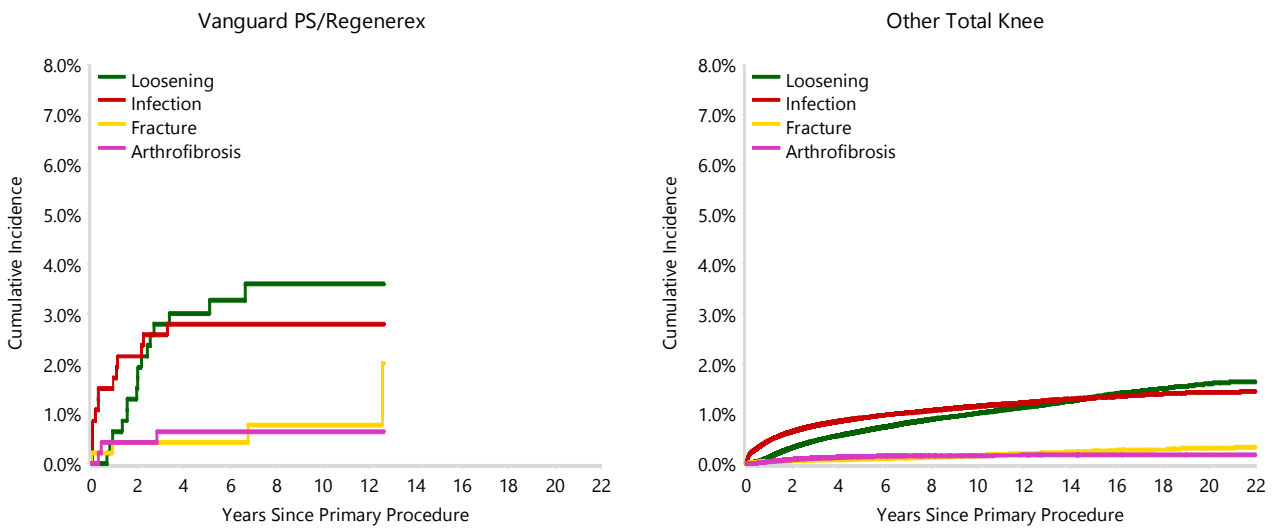


TABLE 5

**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 13.2 Years)**

Type of Revision	Vanguard PS/Regenerex		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	18	42.9	6275	24.1
Tibial Component	4	9.5	2111	8.1
Cement Spacer	4	9.5	1339	5.2
Femoral Component	3	7.1	1314	5.1
Removal of Prostheses	1	2.4	150	0.6
Total Femoral			24	0.1
Reinsertion of Components			13	0.1
<b>N Major</b>	<b>30</b>	<b>71.4</b>	<b>11226</b>	<b>43.2</b>
Insert Only	8	19.0	7451	28.7
Patella Only	2	4.8	4644	17.9
Insert/Patella	1	2.4	2599	10.0
Minor Components	1	2.4	63	0.2
Cement Only			17	0.1
<b>N Minor</b>	<b>12</b>	<b>28.6</b>	<b>14774</b>	<b>56.8</b>
<b>TOTAL</b>	<b>42</b>	<b>100.0</b>	<b>26000</b>	<b>100.0</b>

Note: This table is restricted to revisions within 13.2 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 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	20	278
Hybrid (Tibial Cemented)	0	6
Hybrid (Tibial Cementless)	22	179
<b>TOTAL</b>	<b>42</b>	<b>465</b>

**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	41	453
XLPE + Antioxidant	1	12
<b>TOTAL</b>	<b>42</b>	<b>465</b>



**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	42	465
<b>TOTAL</b>	<b>42</b>	<b>465</b>

**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	42	465
<b>TOTAL</b>	<b>42</b>	<b>465</b>

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	24	194
	QLD	4	31
Other Total Knee	NSW	7959	262433
	VIC	5825	153047
	QLD	5766	157008
	WA	3245	81139
	SA	2967	66419
	TAS	437	18133
	ACT/NT	637	19770
<b>TOTAL</b>		<b>26878</b>	<b>758414</b>

Note: Prostheses no longer used in 2022 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 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 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	11	121
2011	3	54
2012	3	27
2013	0	15
2014	1	21
2015	0	18
2016	6	76
2017	12	59
2018	4	56
2019	2	14
<b>TOTAL</b>	<b>42</b>	<b>465</b>

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
<b>Femoral</b>				
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
<b>Tibial</b>				
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	22	181
184500-184536	141270-141278	20	284
<b>TOTAL</b>		<b>42</b>	<b>465</b>