

Renasis Total Knee Investigation

Note: This analysis compares the Renasis femoral prosthesis with all other total knee prostheses.

This prosthesis 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 Renasis total knee prosthesis 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) |
|------------------|--------------|---------------|----------------|------------------------------------|
| Renasis | 19 | 121 | 1507 | 1.26 (0.76, 1.97) |
| Other Total Knee | 26836 | 757949 | 5069780 | 0.53 (0.52, 0.54) |
| TOTAL | 26855 | 758070 | 5071287 | 0.53 (0.52, 0.54) |

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 Renasys total knee prosthesis 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 |
|------------------|----------------|----------------|----------------|-----------------|-----------------|-----------------|------------------|------------------|
| Renasys | 2.5 (0.8, 7.5) | 2.5 (0.8, 7.5) | 4.2 (1.8, 9.8) | 6.7 (3.4, 13.0) | 8.5 (4.6, 15.1) | 9.3 (5.3, 16.2) | 10.3 (6.0, 17.4) | 10.3 (6.0, 17.4) |
| 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 |
|------------------|------------------|------------------|------------------|------------------|------------------|-------------------|-------------------|
| Renasys | 11.2 (6.7, 18.5) | 11.2 (6.7, 18.5) | 12.3 (7.4, 19.9) | 14.5 (9.1, 22.7) | 14.5 (9.1, 22.7) | 15.7 (10.0, 24.2) | 15.7 (10.0, 24.2) |
| 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 |
|------------------|-------------------|----------------|----------------|----------------|----------------|----------------|----------------|
| Renasys | 17.4 (11.1, 26.5) | | | | | | |
| 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.

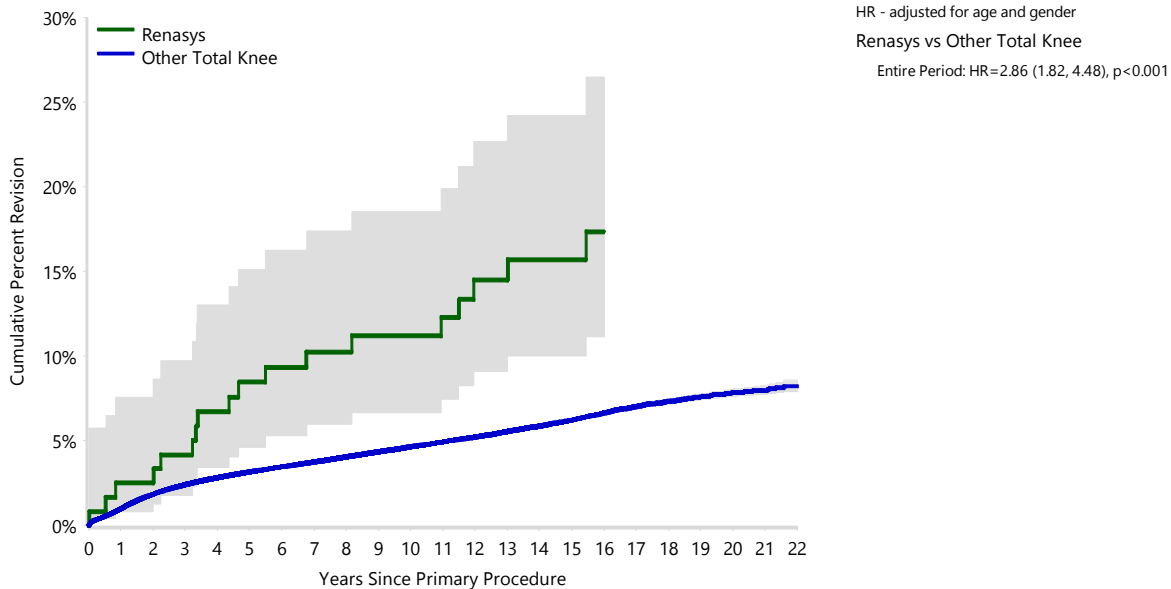
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Renasys total knee prosthesis 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



| Number at Risk | 0 Yr | 1 Yr | 2 Yrs | 3 Yrs | 4 Yrs | 5 Yrs | 6 Yrs | 7 Yrs | 8 Yrs | 9 Yrs | 10 Yrs | 11 Yrs |
|------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Renasys | 121 | 117 | 116 | 113 | 110 | 104 | 101 | 98 | 97 | 94 | 89 | 82 |
| Other Total Knee | 757949 | 689882 | 619616 | 556833 | 492801 | 431130 | 372737 | 318126 | 267229 | 221560 | 180409 | 143443 |

| Number at Risk | 12 Yrs | 13 Yrs | 14 Yrs | 15 Yrs | 16 Yrs | 17 Yrs | 18 Yrs | 19 Yrs | 20 Yrs | 21 Yrs | 22 Yrs |
|------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Renasys | 75 | 70 | 65 | 53 | 46 | 18 | 0 | 0 | 0 | 0 | 0 |
| Other Total Knee | 111922 | 85787 | 65049 | 47997 | 34991 | 24735 | 16433 | 9944 | 5486 | 2318 | 538 |

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 | Renasys | | Other Total Knee | |
|------------------------------|-----------|--------------|------------------|--------------|
| | Number | Percent | Number | Percent |
| Osteoarthritis | 19 | 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 |
| TOTAL | 19 | 100.0 | 26836 | 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 Total Knee Replacement - Reason for Revision (Follow-up Limited to 17.7 Years)

| Revision Diagnosis | Number | Renasys | | Other Total Knee | | |
|--------------------------------|------------|---------------------|--------------|------------------|---------------------|--------------|
| | | % Primaries Revised | % Revisions | Number | % Primaries Revised | % Revisions |
| Infection | 3 | 2.5 | 15.8 | 7346 | 1.0 | 27.5 |
| Loosening | 5 | 4.1 | 26.3 | 5985 | 0.8 | 22.4 |
| Instability | | | | 2604 | 0.3 | 9.7 |
| Pain | 3 | 2.5 | 15.8 | 2035 | 0.3 | 7.6 |
| Patellofemoral Pain | | | | 1930 | 0.3 | 7.2 |
| Patella Erosion | 1 | 0.8 | 5.3 | 1778 | 0.2 | 6.6 |
| Arthrofibrosis | 1 | 0.8 | 5.3 | 1034 | 0.1 | 3.9 |
| Fracture | 1 | 0.8 | 5.3 | 1013 | 0.1 | 3.8 |
| Malalignment | | | | 602 | 0.1 | 2.3 |
| Wear Tibial Insert | | | | 365 | 0.0 | 1.4 |
| Lysis | 2 | 1.7 | 10.5 | 328 | 0.0 | 1.2 |
| Incorrect Sizing | 1 | 0.8 | 5.3 | 262 | 0.0 | 1.0 |
| Patella Maltracking | | | | 186 | 0.0 | 0.7 |
| Implant Breakage Tibial Insert | 1 | 0.8 | 5.3 | 172 | 0.0 | 0.6 |
| Bearing Dislocation | | | | 151 | 0.0 | 0.6 |
| Implant Breakage Patella | | | | 139 | 0.0 | 0.5 |
| Metal Related Pathology | | | | 107 | 0.0 | 0.4 |
| Prosthesis Dislocation | | | | 84 | 0.0 | 0.3 |
| Synovitis | | | | 75 | 0.0 | 0.3 |
| Osteonecrosis | | | | 55 | 0.0 | 0.2 |
| Implant Breakage Tibial | 1 | 0.8 | 5.3 | 42 | 0.0 | 0.2 |
| Implant Breakage Femoral | | | | 39 | 0.0 | 0.1 |
| Wear Patella | | | | 36 | 0.0 | 0.1 |
| Tumour | | | | 33 | 0.0 | 0.1 |
| Heterotopic Bone | | | | 14 | 0.0 | 0.1 |
| Wear Tibial | | | | 9 | 0.0 | 0.0 |
| Progression Of Disease | | | | 6 | 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 | | | | 316 | 0.0 | 1.2 |
| N Revision | 19 | 15.7 | 100.0 | 26750 | 3.5 | 100.0 |
| N Primary | 121 | | | 757949 | | |

Note: This table is restricted to revisions within 17.7 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 Renasys total knee prosthesis. 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

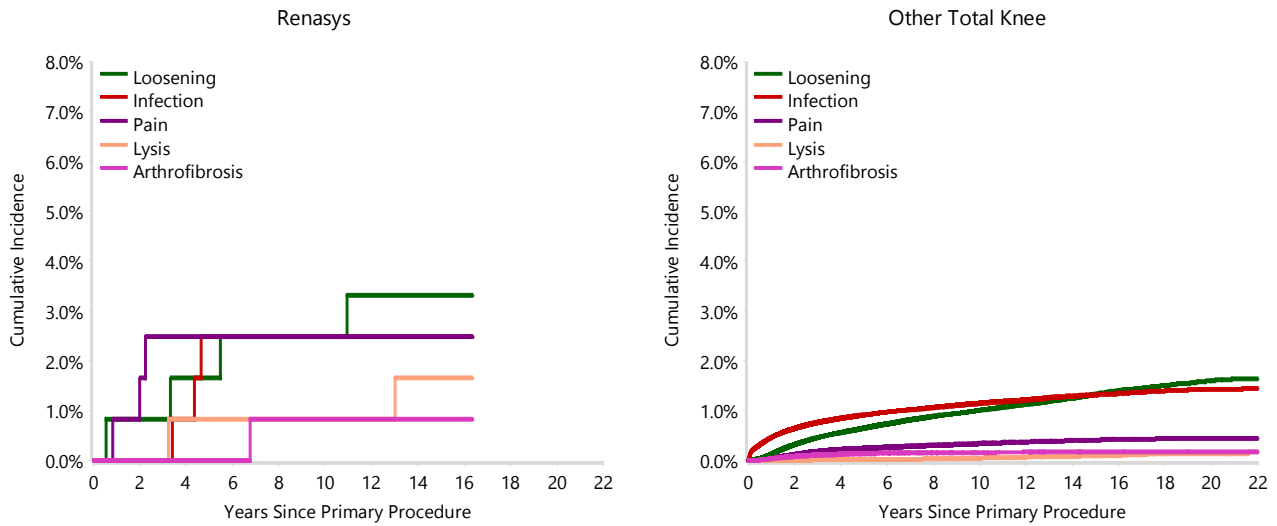


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Renasys total knee prosthesis 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 Renasys total knee prosthesis compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 17.7 Years)

| Type of Revision | Renasys | | Other Total Knee | |
|---------------------------|-----------|--------------|------------------|--------------|
| | Number | Percent | Number | Percent |
| TKR (Tibial/Femoral) | 5 | 26.3 | 6611 | 24.7 |
| Tibial Component | 4 | 21.1 | 2135 | 8.0 |
| Cement Spacer | | | 1362 | 5.1 |
| Femoral Component | | | 1322 | 4.9 |
| Removal of Prostheses | | | 152 | 0.6 |
| Total Femoral | | | 24 | 0.1 |
| Reinsertion of Components | | | 13 | 0.0 |
| N Major | 9 | 47.4 | 11619 | 43.4 |
| Insert Only | 9 | 47.4 | 7569 | 28.3 |
| Patella Only | | | 4720 | 17.6 |
| Insert/Patella | 1 | 5.3 | 2760 | 10.3 |
| Minor Components | | | 64 | 0.2 |
| Cement Only | | | 18 | 0.1 |
| N Minor | 10 | 52.6 | 15131 | 56.6 |
| TOTAL | 19 | 100.0 | 26750 | 100.0 |

Note: This table is restricted to revisions within 17.7 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 Renasys 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 Renasys Primary Total Knee Replacement by Fixation

| Fixation | N Revised | N Total |
|--------------|-----------|------------|
| Cemented | 19 | 121 |
| TOTAL | 19 | 121 |

TABLE 7**Revision Rates of Renasys 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 prosthesis are listed.

Table 7: Revised Number of Renasys Primary Total Knee Replacement by Bearing Surface

| Bearing Surface | N Revised | N Total |
|-----------------|-----------|------------|
| Non XLPE | 19 | 121 |
| TOTAL | 19 | 121 |

TABLE 8**Revision Rates of Renasys 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 prosthesis are listed.

Table 8: Revised Number of Renasys Primary Total Knee Replacement by Bearing Mobility

| Bearing Mobility | N Revised | N Total |
|------------------|-----------|------------|
| Fixed | 19 | 121 |
| TOTAL | 19 | 121 |

TABLE 9**Revision Rates of Renasys 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 prosthesis are listed.

Table 9: Revised Number of Renasys Primary Total Knee Replacement by Stability

| Stability | N Revised | N Total |
|----------------------|-----------|------------|
| Posterior Stabilised | 19 | 121 |
| TOTAL | 19 | 121 |

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Renasys total knee prosthesis 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 |
|------------------|--------|--------------|---------------|
| Renasys | NSW | 3 | 14 |
| | VIC | 8 | 43 |
| | QLD | 7 | 46 |
| | WA | 0 | 7 |
| | SA | 0 | 1 |
| | ACT/NT | 1 | 10 |
| 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 |
| TOTAL | | 26855 | 758070 |

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

TABLE 11**Number of Revisions of Renasys Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Renasys total knee prosthesis. 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 Renasys Primary Total Knee Replacement by Year of Implant

| Year of Implant | Number Revised | Total Number |
|-----------------|----------------|--------------|
| 2005 | 8 | 51 |
| 2006 | 10 | 53 |
| 2007 | 0 | 3 |
| 2008 | 1 | 14 |
| TOTAL | 19 | 121 |

TABLE 12

Revision Rates of Renasys 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 Renasys 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 |
|----------------|-------------------|---|--------|
| Femoral | | | |
| Renasys | 71932011-71932018 | PS OXINIUM FEMORAL COMPONENT W/ RSA BEADS | YES |
| Renasys | 74021134-74021147 | PRIMARY PS OXINIUM FEMORAL COMPONENT | YES |

Table 12: Revised Number of Renasys Primary Total Knee Replacement by Catalogue Number Range

| Femoral Range | N Revised | N Total |
|-------------------|-----------|------------|
| 71932011-71932018 | 1 | 16 |
| 74021134-74021147 | 18 | 105 |
| TOTAL | 19 | 121 |

TABLE 13**Revision Rates of Renasys Primary Total Knee Replacement by Component**

A prosthesis may be combined with multiple components. This analysis has been undertaken to determine if the revision rate varies according to the component with which it is combined.

Table 13: Revised Number of Renasys Primary Total Knee Replacement by Tibial Component

| Tibial Component | N Revised | N Total |
|------------------|-----------|------------|
| Genesis II | 16 | 87 |
| Journey | 3 | 34 |
| TOTAL | 19 | 121 |