

Univers 3D/Uniers 3D Total Stemmed Anatomic Shoulder Investigation

Note: This analysis compares the Univers 3D/Uniers 3D humeral stem/glenoid combination with all other total stemmed anatomic shoulder 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 Stemmed Anatomic Shoulder Replacement

The revision rate of the Univers 3D/Uniers 3D total stemmed anatomic shoulder combination is compared to all other total stemmed anatomic shoulder prostheses.

Table 1: Revision Rates of Primary Total Stemmed Anatomic Shoulder Replacement

| Component | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---------------------------------------|------------|-------------|--------------|------------------------------------|
| Uniers 3D/Uniers 3D | 17 | 34 | 295 | 5.76 (3.36, 9.22) |
| Other Total Stemmed Anatomic Shoulder | 672 | 7857 | 43714 | 1.54 (1.42, 1.66) |
| TOTAL | 689 | 7891 | 44009 | 1.57 (1.45, 1.69) |

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

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the Univers 3D/Univers 3D total stemmed anatomic shoulder combination is compared to all other total stemmed anatomic shoulder prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Stemmed Anatomic Shoulder Replacement

| CPR | 1 Yr | 2 Yrs | 3 Yrs | 4 Yrs | 5 Yrs | 6 Yrs |
|---------------------------------------|-----------------|------------------|------------------|------------------|-------------------|-------------------|
| Univers 3D/Univers 3D | 5.9 (1.5, 21.5) | 14.7 (6.4, 31.8) | 14.7 (6.4, 31.8) | 17.9 (8.4, 35.5) | 21.2 (10.7, 39.4) | 27.7 (15.4, 46.6) |
| Other Total Stemmed Anatomic Shoulder | 3.1 (2.7, 3.5) | 5.0 (4.5, 5.5) | 6.1 (5.5, 6.7) | 6.9 (6.3, 7.5) | 7.8 (7.1, 8.4) | 8.5 (7.8, 9.2) |

| CPR | 7 Yrs | 8 Yrs | 9 Yrs | 10 Yrs | 11 Yrs |
|---------------------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Univers 3D/Univers 3D | 31.0 (18.0, 50.1) | 34.3 (20.6, 53.5) | 34.3 (20.6, 53.5) | 44.7 (29.2, 63.7) | 44.7 (29.2, 63.7) |
| Other Total Stemmed Anatomic Shoulder | 9.3 (8.5, 10.0) | 10.4 (9.6, 11.3) | 11.5 (10.5, 12.5) | 12.7 (11.6, 13.9) | 13.4 (12.2, 14.7) |

| CPR | 12 Yrs | 13 Yrs | 14 Yrs | 15 Yrs | 16 Yrs |
|---------------------------------------|-------------------|-------------------|-------------------|-------------------|--------|
| Univers 3D/Univers 3D | 48.9 (32.7, 68.0) | 48.9 (32.7, 68.0) | 54.6 (37.0, 74.1) | | |
| Other Total Stemmed Anatomic Shoulder | 14.7 (13.3, 16.2) | 16.8 (15.1, 18.7) | 17.2 (15.4, 19.1) | 17.6 (15.7, 19.7) | |

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

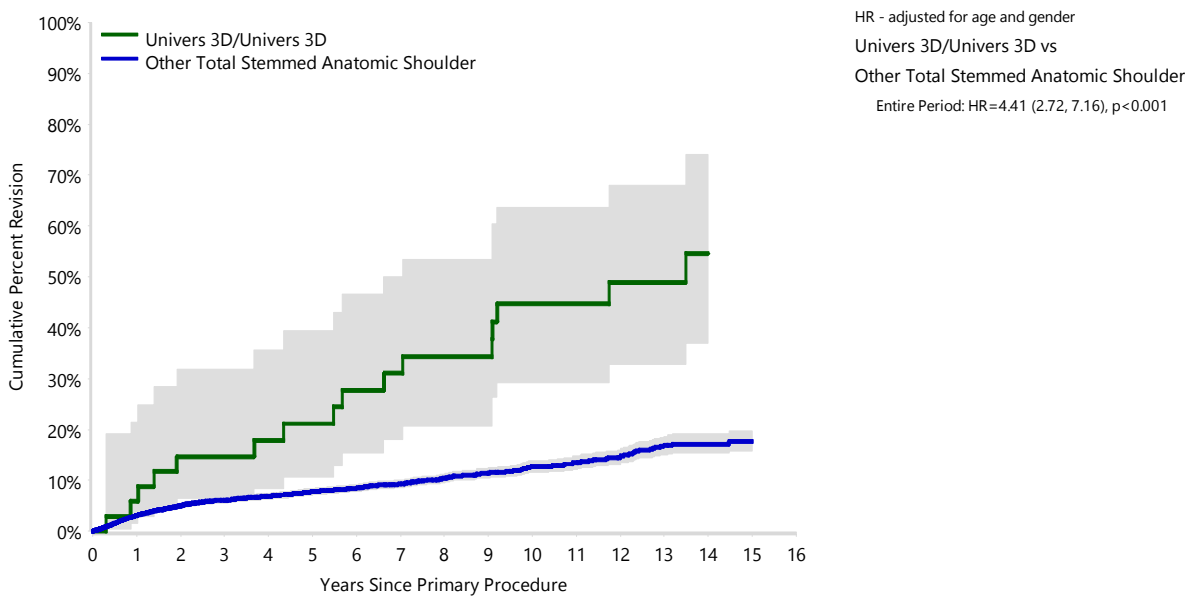
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Anatomic Shoulder Replacement

The yearly cumulative percent revision of the Univers 3D/Univers 3D total stemmed anatomic shoulder combination is compared to all other total stemmed anatomic shoulder 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 Stemmed Anatomic Shoulder Replacement



| Number at Risk | 0 Yr | 1 Yr | 2 Yrs | 3 Yrs | 4 Yrs | 5 Yrs | 6 Yrs | 7 Yrs | 8 Yrs |
|---------------------------------------|------|------|-------|-------|-------|-------|-------|-------|-------|
| Univers 3D/Univers 3D | 34 | 32 | 29 | 27 | 26 | 24 | 22 | 21 | 19 |
| Other Total Stemmed Anatomic Shoulder | 7857 | 7043 | 6282 | 5568 | 4754 | 3936 | 3229 | 2539 | 1905 |

| Number at Risk | 9 Yrs | 10 Yrs | 11 Yrs | 12 Yrs | 13 Yrs | 14 Yrs | 15 Yrs | 16 Yrs |
|---------------------------------------|-------|--------|--------|--------|--------|--------|--------|--------|
| Univers 3D/Univers 3D | 19 | 15 | 14 | 12 | 9 | 8 | 3 | 0 |
| Other Total Stemmed Anatomic Shoulder | 1375 | 1028 | 780 | 616 | 477 | 274 | 90 | 15 |

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

TABLE 3**Primary Diagnosis for Revised Primary Total Stemmed Anatomic Shoulder 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 stemmed anatomic shoulder prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Stemmed Anatomic Shoulder Replacement

| Primary Diagnosis | Uniers 3D/Uniers 3D | | Other Total Stemmed Anatomic Shoulder | |
|------------------------------|---------------------|--------------|---------------------------------------|--------------|
| | Number | Percent | Number | Percent |
| Osteoarthritis | 17 | 100.0 | 619 | 92.1 |
| Osteonecrosis | | | 17 | 2.5 |
| Fracture | | | 12 | 1.8 |
| Rheumatoid Arthritis | | | 7 | 1.0 |
| Rotator Cuff Arthropathy | | | 7 | 1.0 |
| Instability | | | 5 | 0.7 |
| Other Inflammatory Arthritis | | | 5 | 0.7 |
| TOTAL | 17 | 100.0 | 672 | 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 Stemmed Anatomic Shoulder Replacement - Reason for Revision

| Revision Diagnosis | Uniers 3D/Uniers 3D | | | Other Total Stemmed Anatomic Shoulder | | |
|---------------------------------|---------------------|---------------------|--------------|---------------------------------------|---------------------|--------------|
| | Number | % Primaries Revised | % Revisions | Number | % Primaries Revised | % Revisions |
| Rotator Cuff Insufficiency | 1 | 2.9 | 5.9 | 245 | 3.1 | 36.5 |
| Instability/Dislocation | 1 | 2.9 | 5.9 | 183 | 2.3 | 27.2 |
| Loosening | 12 | 35.3 | 70.6 | 95 | 1.2 | 14.1 |
| Infection | | | | 33 | 0.4 | 4.9 |
| Fracture | 1 | 2.9 | 5.9 | 18 | 0.2 | 2.7 |
| Pain | | | | 17 | 0.2 | 2.5 |
| Arthrofibrosis | | | | 12 | 0.2 | 1.8 |
| Wear Glenoid Insert | 1 | 2.9 | 5.9 | 11 | 0.1 | 1.6 |
| Implant Breakage Glenoid Insert | | | | 10 | 0.1 | 1.5 |
| Lysis | | | | 10 | 0.1 | 1.5 |
| Implant Breakage Glenoid | | | | 7 | 0.1 | 1.0 |
| Metal Related Pathology | | | | 7 | 0.1 | 1.0 |
| Dissociation | | | | 6 | 0.1 | 0.9 |
| Malposition | | | | 6 | 0.1 | 0.9 |
| Incorrect Sizing | | | | 5 | 0.1 | 0.7 |
| Progression Of Disease | | | | 2 | 0.0 | 0.3 |
| Other | 1 | 2.9 | 5.9 | 5 | 0.1 | 0.7 |
| N Revision | 17 | 50.0 | 100.0 | 672 | 8.6 | 100.0 |
| N Primary | 34 | | | 7857 | | |

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

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Stemmed Anatomic Shoulder 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 Univers 3D/Uniers 3D total stemmed anatomic shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total stemmed anatomic shoulder prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Stemmed Anatomic Shoulder Replacement

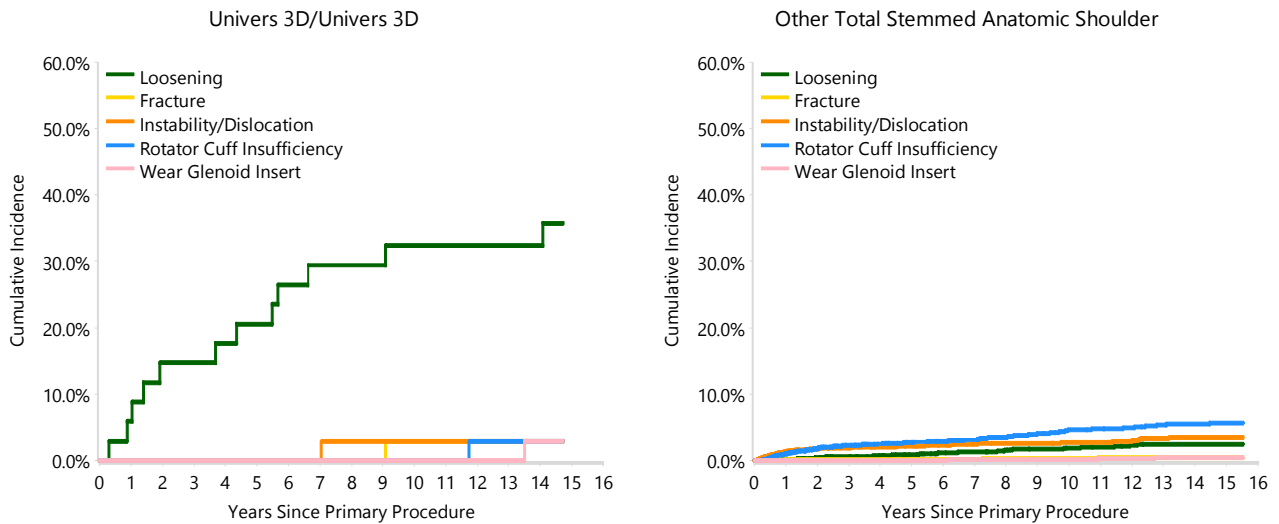


TABLE 5

Type of Revision Performed for Primary Total Stemmed Anatomic Shoulder Replacement

This analysis identifies the components used in the revision of the Univers 3D/Univers 3D total stemmed anatomic shoulder combination and compares it to the components used in the revision of all other total stemmed anatomic shoulder 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 stemmed anatomic shoulder prostheses i.e. is there a difference in the type of revision undertaken for the Univers 3D/Univers 3D total stemmed anatomic shoulder combination compared to all other total stemmed anatomic shoulder prostheses.

Table 5: Primary Total Stemmed Anatomic Shoulder Replacement - Type of Revision

| Type of Revision | Univers 3D/Univers 3D | | Other Total Stemmed Anatomic Shoulder | |
|---------------------------|-----------------------|--------------|---------------------------------------|--------------|
| | Number | Percent | Number | Percent |
| Humeral Component | | | 396 | 58.9 |
| Humeral/Glenoid | 9 | 52.9 | 194 | 28.9 |
| Glenoid Component | 4 | 23.5 | 17 | 2.5 |
| Cement Spacer | | | 14 | 2.1 |
| Removal of Prostheses | 1 | 5.9 | 4 | 0.6 |
| Reinsertion of Components | | | 1 | 0.1 |
| N Major | 14 | 82.4 | 626 | 93.2 |
| Head Only | | | 39 | 5.8 |
| Reoperation | | | 3 | 0.4 |
| Head/Insert | 2 | 11.8 | 2 | 0.3 |
| Minor Components | 1 | 5.9 | 2 | 0.3 |
| N Minor | 3 | 17.6 | 46 | 6.8 |
| TOTAL | 17 | 100.0 | 672 | 100.0 |

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

TABLE 6**Revision Rates of Univers 3D/Univers 3D Primary Total Stemmed Anatomic Shoulder 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 Univers 3D/Univers 3D Primary Total Stemmed Anatomic Shoulder Replacement by Fixation

| Fixation | N Revised | N Total |
|---------------------------|-----------|-----------|
| Cementless | 14 | 27 |
| Hybrid (Glenoid Cemented) | 3 | 7 |
| TOTAL | 17 | 34 |

TABLE 7**Revision Rates of Univers 3D/Univers 3D Primary Total Stemmed Anatomic Shoulder 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 Univers 3D/Univers 3D Primary Total Stemmed Anatomic Shoulder Replacement by Bearing Surface

| Bearing Surface | N Revised | N Total |
|-----------------|-----------|-----------|
| Metal/Non XLPE | 17 | 34 |
| TOTAL | 17 | 34 |

TABLE 8**Revision Rates of Primary Total Stemmed Anatomic Shoulder Replacement by State**

This enables a state by state variation to be identified for the Univers 3D/Univers 3D total stemmed anatomic shoulder combination and provides the comparative data for each of the states for all other total stemmed anatomic shoulder 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 8: Revised Number of Primary Total Stemmed Anatomic Shoulder Replacement by State

| Component | State | N Revised | N Total |
|---------------------------------------|--------|------------|-------------|
| Univers 3D/Univers 3D | VIC | 15 | 28 |
| | QLD | 1 | 3 |
| | WA | 0 | 2 |
| | TAS | 1 | 1 |
| Other Total Stemmed Anatomic Shoulder | NSW | 178 | 2255 |
| | VIC | 150 | 1854 |
| | QLD | 95 | 1431 |
| | WA | 139 | 1132 |
| | SA | 54 | 738 |
| | TAS | 27 | 209 |
| | ACT/NT | 29 | 238 |
| TOTAL | | 689 | 7891 |

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

TABLE 9**Number of Revisions of Univers 3D/Uniers 3D Primary Total Stemmed Anatomic Shoulder Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Uniers 3D/Uniers 3D total stemmed anatomic shoulder 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 9: Number of Revisions of Uniers 3D/Uniers 3D Primary Total Stemmed Anatomic Shoulder Replacement by Year of Implant

| Year of Implant | Number Revised | Total Number |
|-----------------|----------------|--------------|
| 2005 | 1 | 1 |
| 2006 | 3 | 6 |
| 2007 | 8 | 16 |
| 2008 | 5 | 11 |
| TOTAL | 17 | 34 |

TABLE 10

Revision Rates of Univers 3D/Univers 3D Primary Total Stemmed Anatomic Shoulder 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 Univers 3D/Univers 3D 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 | Material |
|---------------------|-------------------|-------------------------|--------|-------------------------------|
| Humeral Stem | | | | |
| Univers 3D | AR910005-AR910015 | HUMERAL STEM | NO | METAL |
| Glenoid | | | | |
| Univers 3D | AR910101-AR910103 | METAL BACKED GLENOID | NO | METAL |
| Univers 3D | AR910401-AR910403 | ALL POLY KEELED GLENOID | YES | NON CROSS-LINKED POLYETHYLENE |

Table 10: Revised Number of Univers 3D/Univers 3D Primary Total Stemmed Anatomic Shoulder Replacement by Catalogue Number Range

| Humeral Stem Range | Glenoid Range | N Revised | N Total |
|--------------------|-------------------|-----------|-----------|
| AR910005-AR910015 | AR910101-AR910103 | 14 | 27 |
| | AR910401-AR910403 | 3 | 7 |
| TOTAL | | 17 | 34 |