

Global Unite/Global Unite Hemi Stemmed Anatomic Shoulder Investigation

Note: This analysis compares the Global Unite/Global Unite humeral stem/head combination with all other hemi 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-2025>.

Note: Procedures using prostheses with no recorded use in 2024 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Hemi Stemmed Anatomic Shoulder Replacement

The revision rate of the Global Unite/Global Unite hemi stemmed anatomic shoulder combination is compared to all other hemi stemmed anatomic shoulder prostheses.

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

| Component                            | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs<br>(95% CI) |
|--------------------------------------|-----------|---------|------------|------------------------------------|
| Global Unite/Global Unite            | 43        | 227     | 1374       | 3.13 (2.26, 4.21)                  |
| Other Hemi Stemmed Anatomic Shoulder | 375       | 3700    | 23821      | 1.57 (1.42, 1.74)                  |
| TOTAL                                | 418       | 3927    | 25195      | 1.66 (1.50, 1.83)                  |

Note: Prostheses no longer used in 2024 are excluded from the comparator.

TABLE 2

**Yearly Cumulative Percent Revision of Primary Hemi Stemmed Anatomic Shoulder Replacement**

The yearly cumulative percent revision of the Global Unite/Global Unite hemi stemmed anatomic shoulder combination is compared to all other hemi stemmed anatomic shoulder prostheses.

**Table 2: Yearly Cumulative Percent Revision (95% CI) of Primary Hemi Stemmed Anatomic Shoulder Replacement**

| CPR                                  | 1 Yr            | 2 Yrs             | 3 Yrs             | 4 Yrs             | 5 Yrs             | 6 Yrs             |
|--------------------------------------|-----------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Global Unite/Global Unite            | 6.8 (4.1, 11.0) | 14.2 (10.1, 19.6) | 16.8 (12.3, 22.6) | 19.0 (14.2, 25.1) | 20.1 (15.2, 26.3) | 20.1 (15.2, 26.3) |
| Other Hemi Stemmed Anatomic Shoulder | 3.5 (2.9, 4.2)  | 6.5 (5.7, 7.4)    | 8.4 (7.5, 9.4)    | 9.4 (8.4, 10.5)   | 10.2 (9.2, 11.3)  | 10.7 (9.7, 11.9)  |

| CPR                                  | 7 Yrs             | 8 Yrs             | 9 Yrs             | 10 Yrs            | 11 Yrs            | 12 Yrs            |
|--------------------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Global Unite/Global Unite            | 20.1 (15.2, 26.3) | 20.9 (15.8, 27.3) | 20.9 (15.8, 27.3) | 22.0 (16.6, 28.8) |                   |                   |
| Other Hemi Stemmed Anatomic Shoulder | 11.2 (10.1, 12.5) | 11.7 (10.5, 12.9) | 12.3 (11.1, 13.7) | 13.0 (11.7, 14.4) | 13.4 (12.1, 14.8) | 13.5 (12.2, 15.0) |

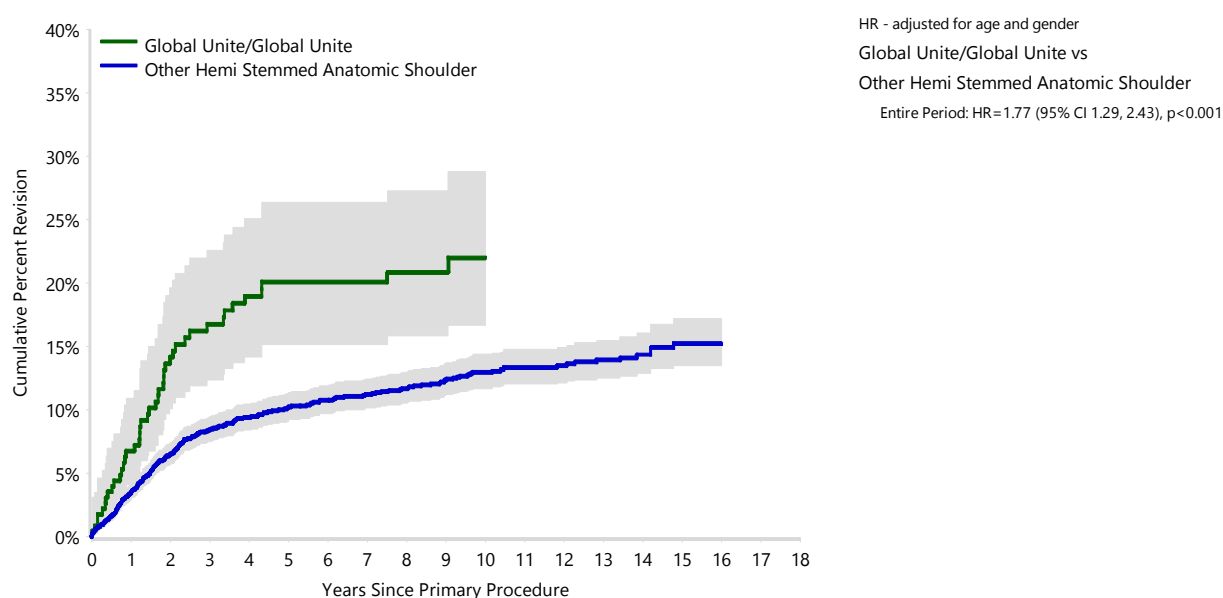
| CPR                                  | 13 Yrs            | 14 Yrs            | 15 Yrs            | 16 Yrs            | 17 Yrs |
|--------------------------------------|-------------------|-------------------|-------------------|-------------------|--------|
| Global Unite/Global Unite            |                   |                   |                   |                   |        |
| Other Hemi Stemmed Anatomic Shoulder | 13.9 (12.5, 15.5) | 14.4 (12.9, 16.0) | 15.2 (13.5, 17.2) | 15.2 (13.5, 17.2) |        |

Note: Prostheses no longer used in 2024 are excluded from the comparator.

**FIGURE 1****Yearly Cumulative Percent Revision of Primary Hemi Stemmed Anatomic Shoulder Replacement**

The yearly cumulative percent revision of the Global Unite/Global Unite hemi stemmed anatomic shoulder combination is compared to all other hemi 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 Hemi 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 |
|--------------------------------------|------|------|-------|-------|-------|-------|-------|-------|-------|
| Global Unite/Global Unite            | 227  | 196  | 169   | 156   | 143   | 133   | 117   | 108   | 96    |
| Other Hemi Stemmed Anatomic Shoulder | 3700 | 3208 | 2825  | 2521  | 2209  | 1951  | 1720  | 1503  | 1303  |

| Number at Risk                       | 9 Yrs | 10 Yrs | 11 Yrs | 12 Yrs | 13 Yrs | 14 Yrs | 15 Yrs | 16 Yrs | 17 Yrs |
|--------------------------------------|-------|--------|--------|--------|--------|--------|--------|--------|--------|
| Global Unite/Global Unite            | 70    | 43     | 26     | 6      | 0      | 0      | 0      | 0      | 0      |
| Other Hemi Stemmed Anatomic Shoulder | 1138  | 987    | 817    | 656    | 497    | 348    | 221    | 115    | 33     |

Note: Prostheses no longer used in 2024 are excluded from the comparator.

**TABLE 3****Primary Diagnosis for Revised Primary Hemi 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 hemi stemmed anatomic shoulder prostheses.

**Table 3: Primary Diagnosis for Revised Primary Hemi Stemmed Anatomic Shoulder Replacement**

| Primary Diagnosis            | Global Unite/Global Unite |              | Other Hemi Stemmed Anatomic Shoulder |              |
|------------------------------|---------------------------|--------------|--------------------------------------|--------------|
|                              | Number                    | Percent      | Number                               | Percent      |
| Fracture                     | 40                        | 93.0         | 215                                  | 57.3         |
| Osteoarthritis               | 1                         | 2.3          | 100                                  | 26.7         |
| Osteonecrosis                | 2                         | 4.7          | 18                                   | 4.8          |
| Rotator Cuff Arthropathy     |                           |              | 15                                   | 4.0          |
| Rheumatoid Arthritis         |                           |              | 9                                    | 2.4          |
| Tumour                       |                           |              | 8                                    | 2.1          |
| Instability                  |                           |              | 5                                    | 1.3          |
| Other Inflammatory Arthritis |                           |              | 4                                    | 1.1          |
| Other                        |                           |              | 1                                    | 0.3          |
| <b>TOTAL</b>                 | <b>43</b>                 | <b>100.0</b> | <b>375</b>                           | <b>100.0</b> |

Note: Prostheses no longer used in 2024 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 Hemi Stemmed Anatomic Shoulder Replacement - Reason for Revision (Follow-up Limited to 12.8 Years)**

| Revision Diagnosis         | Global Unite/Global Unite |                     |              | Other Hemi Stemmed Anatomic Shoulder |                     |              |
|----------------------------|---------------------------|---------------------|--------------|--------------------------------------|---------------------|--------------|
|                            | Number                    | % Primaries Revised | % Revisions  | Number                               | % Primaries Revised | % Revisions  |
| Rotator Cuff Insufficiency | 10                        | 4.4                 | 23.3         | 86                                   | 2.3                 | 23.3         |
| Instability/Dislocation    | 7                         | 3.1                 | 16.3         | 65                                   | 1.8                 | 17.6         |
| Glenoid Erosion            | 6                         | 2.6                 | 14.0         | 53                                   | 1.4                 | 14.4         |
| Infection                  | 4                         | 1.8                 | 9.3          | 44                                   | 1.2                 | 11.9         |
| Pain                       | 3                         | 1.3                 | 7.0          | 34                                   | 0.9                 | 9.2          |
| Fracture                   | 4                         | 1.8                 | 9.3          | 29                                   | 0.8                 | 7.9          |
| Loosening                  | 3                         | 1.3                 | 7.0          | 28                                   | 0.8                 | 7.6          |
| Arthrofibrosis             | 1                         | 0.4                 | 2.3          | 7                                    | 0.2                 | 1.9          |
| Dissociation               | 1                         | 0.4                 | 2.3          | 6                                    | 0.2                 | 1.6          |
| Incorrect Sizing           | 2                         | 0.9                 | 4.7          | 4                                    | 0.1                 | 1.1          |
| Malposition                | 1                         | 0.4                 | 2.3          | 4                                    | 0.1                 | 1.1          |
| Tumour                     |                           |                     |              | 3                                    | 0.1                 | 0.8          |
| Heterotopic Bone           |                           |                     |              | 1                                    | 0.0                 | 0.3          |
| Implant Breakage Glenoid   |                           |                     |              | 1                                    | 0.0                 | 0.3          |
| Lysis                      |                           |                     |              | 1                                    | 0.0                 | 0.3          |
| Other                      | 1                         | 0.4                 | 2.3          | 3                                    | 0.1                 | 0.8          |
| <b>N Revision</b>          | <b>43</b>                 | <b>18.9</b>         | <b>100.0</b> | <b>369</b>                           | <b>10.0</b>         | <b>100.0</b> |
| <b>N Primary</b>           | <b>227</b>                |                     |              | <b>3700</b>                          |                     |              |

Note: This table is restricted to revisions within 12.8 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2024 are excluded from the comparator.

**FIGURE 2****Cumulative Incidence Revision Diagnosis of Primary Hemi 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 Global Unite/Global Unite hemi stemmed anatomic shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other hemi stemmed anatomic shoulder prostheses.

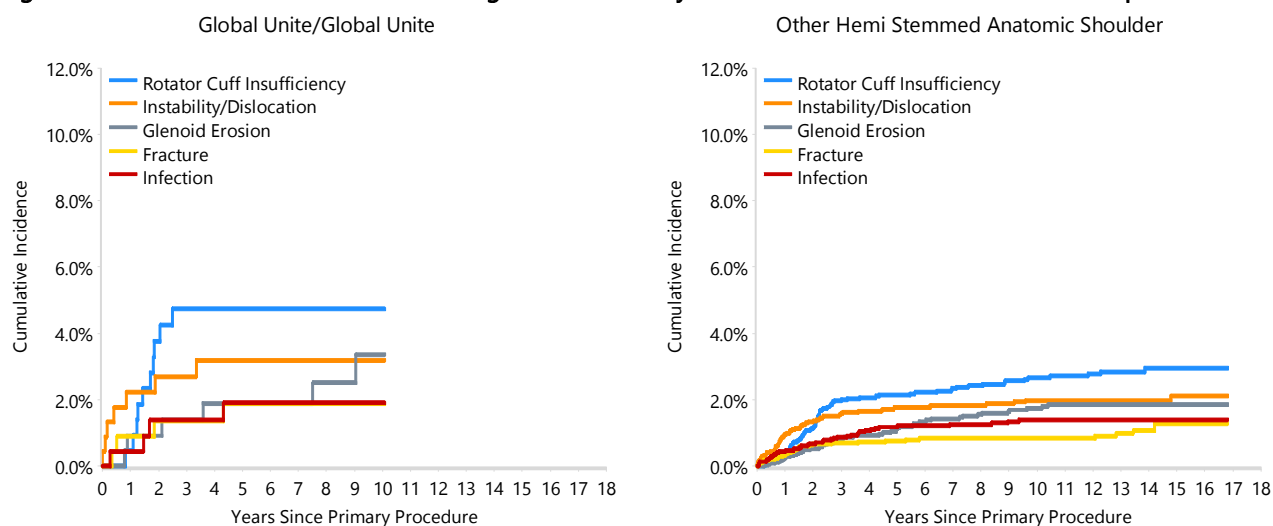
**Figure 2: Cumulative Incidence Revision Diagnosis for Primary Hemi Stemmed Anatomic Shoulder Replacement**

TABLE 5

**Type of Revision Performed for Primary Hemi Stemmed Anatomic Shoulder Replacement**

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

**Table 5: Primary Hemi Stemmed Anatomic Shoulder Replacement - Type of Revision (Follow-up Limited to 12.8 Years)**

| Type of Revision      | Global Unite/Global Unite |              | Other Hemi Stemmed Anatomic Shoulder |              |
|-----------------------|---------------------------|--------------|--------------------------------------|--------------|
|                       | Number                    | Percent      | Number                               | Percent      |
| Humeral/Glenoid       | 34                        | 79.1         | 250                                  | 67.8         |
| Glenoid Component     | 2                         | 4.7          | 36                                   | 9.8          |
| Humeral Component     | 4                         | 9.3          | 33                                   | 8.9          |
| Cement Spacer         | 3                         | 7.0          | 24                                   | 6.5          |
| Removal of Prostheses |                           |              | 5                                    | 1.4          |
| <b>N Major</b>        | <b>43</b>                 | <b>100.0</b> | <b>348</b>                           | <b>94.3</b>  |
| Head Only             |                           |              | 14                                   | 3.8          |
| Reoperation           |                           |              | 3                                    | 0.8          |
| Cement Only           |                           |              | 2                                    | 0.5          |
| Head/Insert           |                           |              | 1                                    | 0.3          |
| Minor Components      |                           |              | 1                                    | 0.3          |
| <b>N Minor</b>        |                           |              | <b>21</b>                            | <b>5.7</b>   |
| <b>TOTAL</b>          | <b>43</b>                 | <b>100.0</b> | <b>369</b>                           | <b>100.0</b> |

Note: This table is restricted to revisions within 12.8 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2024 are excluded from the comparator.

**TABLE 6****Number of Revisions of Global Unite/Global Unite Primary Hemi Stemmed Anatomic Shoulder Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Global Unite/Global Unite hemi 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 2024 has a maximum of one year to be revised, whereas a primary procedure performed in 2022 has a maximum of three years to be revised.

**Table 6: Number of Revisions of Global Unite/Global Unite Primary Hemi Stemmed Anatomic Shoulder Replacement by Year of Implant**

| Year of Implant | Number Revised | Total Number |
|-----------------|----------------|--------------|
| 2012            | 3              | 15           |
| 2013            | 8              | 37           |
| 2014            | 6              | 25           |
| 2015            | 8              | 38           |
| 2016            | 7              | 37           |
| 2017            | 4              | 14           |
| 2018            | 1              | 12           |
| 2019            | 3              | 11           |
| 2020            | 2              | 12           |
| 2021            | 0              | 6            |
| 2022            | 1              | 2            |
| 2023            | 0              | 7            |
| 2024            | 0              | 11           |
| <b>TOTAL</b>    | <b>43</b>      | <b>227</b>   |