Verso/Verso Total Stemmed Reverse Shoulder Investigation

Note: This analysis compares the Verso/Verso humeral stem/glenoid combination with all other total stemmed reverse 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 Total Stemmed Reverse Shoulder Replacement

The revision rate of the Verso/Verso total stemmed reverse shoulder combination is compared to all other total stemmed reverse shoulder prostheses.

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

| Component | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|--------------------------------------|-----------|---------|------------|------------------------------------|
| Verso/Verso | 7 | 40 | 107 | 6.52 (2.62, 13.43) |
| Other Total Stemmed Reverse Shoulder | 2356 | 64596 | 278735 | 0.85 (0.81, 0.88) |
| TOTAL | 2363 | 64636 | 278842 | 0.85 (0.81, 0.88) |

Yearly Cumulative Percent Revision of Primary Total Stemmed Reverse Shoulder Replacement

The yearly cumulative percent revision of the Verso/Verso total stemmed reverse shoulder combination is compared to all other total stemmed reverse shoulder prostheses.

Table 2: Yearly Cumulative Percent Revision (95% CI) of Primary Total Stemmed Reverse Shoulder Replacement

| Table 2: Yearly Cumulative Percent R | Revision (95% (| CI) of Primary | Total Stemn | ned Reverse S | Shoulder Repla | acement |
|--------------------------------------|------------------|------------------|------------------|------------------|------------------|----------------|
| CPR | 1 Yr | 2 Yrs | 3 Yrs | 4 Yrs | 5 Yrs | 6 Yrs |
| Verso/Verso | 15.3 (7.2, 31.0) | 18.6 (9.3, 35.3) | 18.6 (9.3, 35.3) | 18.6 (9.3, 35.3) | 18.6 (9.3, 35.3) | |
| Other Total Stemmed Reverse Shoulder | 2.2 (2.1, 2.4) | 3.0 (2.9, 3.1) | 3.4 (3.3, 3.6) | 3.8 (3.6, 4.0) | 4.0 (3.9, 4.2) | 4.4 (4.2, 4.6) |
| | | | | | | |
| CPR | 7 Yrs | 8 Yrs | 9 Yrs | 10 Yrs | 11 Yrs | 12 Yrs |
| Verso/Verso | | | | | | |
| Other Total Stemmed Reverse Shoulder | 4.6 (4.4, 4.8) | 4.9 (4.7, 5.2) | 5.1 (4.9, 5.4) | 5.5 (5.2, 5.8) | 5.8 (5.5, 6.2) | 6.1 (5.7, 6.5) |
| | | | | | | |
| CPR | 13 Yrs | 14 Yrs | 15 | Yrs | 16 Yrs | 17 Yrs |
| Verso/Verso | | | | | | |
| Other Total Stemmed Reverse Shoulder | 6.2 (5.8, 6 | 6.7) 6.4 (5. | 9, 7.0) 6.6 | (6.0, 7.3) | 6.6 (6.0, 7.3) | 7.5 (5.9, 9.6) |

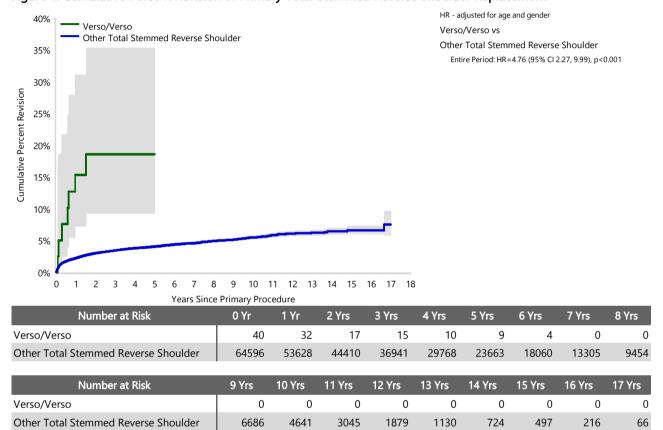
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Reverse Shoulder Replacement

The yearly cumulative percent revision of the Verso/Verso total stemmed reverse shoulder combination is compared to all other total stemmed reverse 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 Reverse Shoulder Replacement



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

3

Primary Diagnosis for Revised Primary Total Stemmed Reverse 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 reverse shoulder prostheses.

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

| | Verso/Verso | | Other Total Stemme | d Reverse Shoulder |
|------------------------------|-------------|---------|--------------------|--------------------|
| Primary Diagnosis | Number | Percent | Number | Percent |
| Osteoarthritis | 5 | 71.4 | 893 | 37.9 |
| Rotator Cuff Arthropathy | 2 | 28.6 | 883 | 37.5 |
| Fracture | | | 406 | 17.2 |
| Rheumatoid Arthritis | | | 54 | 2.3 |
| Instability | | | 44 | 1.9 |
| Tumour | | | 35 | 1.5 |
| Osteonecrosis | | | 29 | 1.2 |
| Other Inflammatory Arthritis | | | 11 | 0.5 |
| Other | | | 1 | 0.0 |
| TOTAL | 7 | 100.0 | 2356 | 100.0 |

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 Reverse Shoulder Replacement - Reason for Revision (Follow-up Limited to 6.9 Years)

| | | Verso/Verso Other Total Stemmed Reverse Sho | | se Shoulder | | |
|------------------------------------|--------|---|-------------|-------------|------------------------|-------------|
| Revision Diagnosis | Number | % Primaries Revised | % Revisions | Number | % Primaries Revised | % Revisions |
| Instability/Dislocation | 2 | 5.0 | 28.6 | 727 | 1.1 | 32.3 |
| Infection | 1 | 2.5 | 14.3 | 576 | 0.9 | 25.6 |
| Loosening | 1 | 2.5 | 14.3 | 361 | 0.6 | 16.1 |
| Fracture | | | | 238 | 0.4 | 10.6 |
| Dissociation | 3 | 7.5 | 42.9 | 79 | 0.1 | 3.5 |
| Pain | | | | 48 | 0.1 | 2.1 |
| Arthrofibrosis | | | | 25 | 0.0 | 1.1 |
| Malposition | | | | 25 | 0.0 | 1.1 |
| Lysis | | | | 20 | 0.0 | 0.9 |
| Incorrect Sizing | | | | 17 | 0.0 | 0.8 |
| Implant Breakage Glenoid | | | | 16 | 0.0 | 0.7 |
| Heterotopic Bone | | | | 14 | 0.0 | 0.6 |
| Metal Related Pathology | | | | 11 | 0.0 | 0.5 |
| Rotator Cuff Insufficiency | | | | 8 | 0.0 | 0.4 |
| Implant Breakage Humeral | | | | 5 | 0.0 | 0.2 |
| Tumour | | | | 5 | 0.0 | 0.2 |
| Wear Humeral Cup | | | | 5 | 0.0 | 0.2 |
| Glenoid Erosion | | | | 2 | 0.0 | 0.1 |
| Implant Breakage Glenoid Insert | | | | 2 | 0.0 | 0.1 |
| Wear Glenoid Insert | | | | 1 | 0.0 | 0.0 |
| Other | | | | 63 | 0.1 | 2.8 |
| N Revision | 7 | 17.5 | 100.0 | 2248 | 3.5 | 100.0 |
| N Primary | 40 | | | 64596 | | |

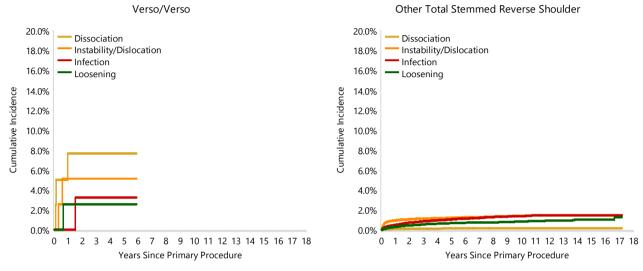
Note: This table is restricted to revisions within 6.9 years for all groups to allow a time-matched comparison of revisions.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Stemmed Reverse 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 Verso/Verso total stemmed reverse shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total stemmed reverse shoulder prostheses.

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



Type of Revision Performed for Primary Total Stemmed Reverse Shoulder Replacement

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

Table 5: Primary Total Stemmed Reverse Shoulder Replacement - Type of Revision (Follow-up Limited to 6.9 Years)

| , | Verso, | Verso | Other Total Stemme | ed Reverse Shoulder |
|---|--------|---------|--------------------|---------------------|
| Type of Revision | Number | Percent | Number | Percent |
| Humeral Component | 2 | 28.6 | 590 | 26.2 |
| Humeral/Glenoid | | | 225 | 10.0 |
| Cement Spacer | 1 | 14.3 | 196 | 8.7 |
| Glenoid Component | | | 171 | 7.6 |
| Removal of Prostheses | | | 38 | 1.7 |
| Reinsertion of Components | | | 4 | 0.2 |
| N Major | 3 | 42.9 | 1224 | 54.4 |
| Cup/Head | 2 | 28.6 | 428 | 19.0 |
| Cup Only | 2 | 28.6 | 355 | 15.8 |
| Head Only | | | 206 | 9.2 |
| Minor Components | | | 14 | 0.6 |
| Cement Only | | | 10 | 0.4 |
| Reoperation | | | 9 | 0.4 |
| Head/Insert | | | 2 | 0.1 |
| N Minor | 4 | 57.1 | 1024 | 45.6 |
| TOTAL | 7 | 100.0 | 2248 | 100.0 |

Note: This table is restricted to revisions within 6.9 years for all groups to allow a time-matched comparison of revisions.

Revision Rates of Verso/Verso Primary Total Stemmed Reverse 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 Verso/Verso Primary Total Stemmed Reverse Shoulder Replacement by Fixation

| Fixation | N Revised | N Total |
|-----------------------------|-----------|---------|
| Cementless | 7 | 38 |
| Hybrid (Glenoid Cementless) | 0 | 2 |
| TOTAL | 7 | 40 |

TABLE 7

Revision Rates of Verso/Verso Primary Total Stemmed Reverse 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 Verso/Verso Primary Total Stemmed Reverse Shoulder Replacement by Bearing Surface

| Bearing Surface | N Revised | N Total |
|-----------------|-----------|---------|
| Non XLPE/Metal | 7 | 40 |
| TOTAL | 7 | 40 |

Number of Revisions of Verso/Verso Primary Total Stemmed Reverse Shoulder Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Verso/Verso total stemmed reverse 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 8: Number of Revisions of Verso/Verso Primary Total Stemmed Reverse Shoulder Replacement by Year of Implant

| Year of Implant | Number Revised | Total Number |
|-----------------|----------------|--------------|
| 2018 | 1 | 5 |
| 2019 | 2 | 8 |
| 2020 | 0 | 1 |
| 2021 | 1 | 6 |
| 2022 | 3 | 5 |
| 2023 | 0 | 13 |
| 2024 | 0 | 2 |
| TOTAL | 7 | 40 |