

UHR/ABGII Bipolar Hip Investigation

Note: This analysis compares the UHR/ABGII bipolar/femoral stem combination with all other bipolar hip 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 Bipolar Hip Replacement

The revision rate of the UHR/ABGII bipolar hip combination is compared to all other bipolar hip prostheses.

Table 1: Revision Rates of Primary Bipolar Hip Replacement

| Component | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|-------------------|------------|--------------|--------------|------------------------------------|
| UHR/ABGII | 23 | 177 | 1007 | 2.28 (1.45, 3.43) |
| Other Bipolar Hip | 936 | 30207 | 90034 | 1.04 (0.97, 1.11) |
| TOTAL | 959 | 30384 | 91041 | 1.05 (0.99, 1.12) |

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

TABLE 2

Yearly Cumulative Percent Revision of Primary Bipolar Hip Replacement

The yearly cumulative percent revision of the UHR/ABGII bipolar hip combination is compared to all other bipolar hip prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Bipolar Hip Replacement

| CPR | 1 Yr | 2 Yrs | 3 Yrs | 4 Yrs | 5 Yrs | 6 Yrs | 7 Yrs | 8 Yrs |
|-------------------|----------------|----------------|-----------------|-----------------|------------------|------------------|------------------|------------------|
| UHR/ABGII | 4.3 (2.1, 8.9) | 4.3 (2.1, 8.9) | 5.1 (2.6, 10.0) | 9.7 (5.7, 16.3) | 10.8 (6.5, 17.9) | 12.0 (7.3, 19.5) | 13.4 (8.2, 21.4) | 15.1 (9.3, 23.8) |
| Other Bipolar Hip | 2.5 (2.3, 2.7) | 3.1 (2.9, 3.3) | 3.6 (3.3, 3.8) | 3.9 (3.6, 4.1) | 4.2 (3.9, 4.5) | 4.4 (4.1, 4.8) | 4.7 (4.4, 5.1) | 5.1 (4.7, 5.5) |

| CPR | 9 Yrs | 10 Yrs | 11 Yrs | 12 Yrs | 13 Yrs | 14 Yrs | 15 Yrs |
|-------------------|-------------------|----------------|----------------|----------------|----------------|----------------|----------------|
| UHR/ABGII | 16.9 (10.6, 26.4) | | | | | | |
| Other Bipolar Hip | 5.4 (4.9, 5.9) | 5.7 (5.1, 6.2) | 5.7 (5.2, 6.3) | 5.8 (5.3, 6.5) | 6.1 (5.4, 6.8) | 6.5 (5.7, 7.3) | 7.1 (6.1, 8.2) |

| CPR | 16 Yrs | 17 Yrs | 18 Yrs | 19 Yrs | 20 Yrs | 21 Yrs | 22 Yrs |
|-------------------|----------------|----------------|----------------|-----------------|-----------------|--------|--------|
| UHR/ABGII | | | | | | | |
| Other Bipolar Hip | 7.6 (6.4, 8.9) | 7.9 (6.6, 9.4) | 7.9 (6.6, 9.4) | 8.5 (6.8, 10.6) | 8.5 (6.8, 10.6) | | |

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

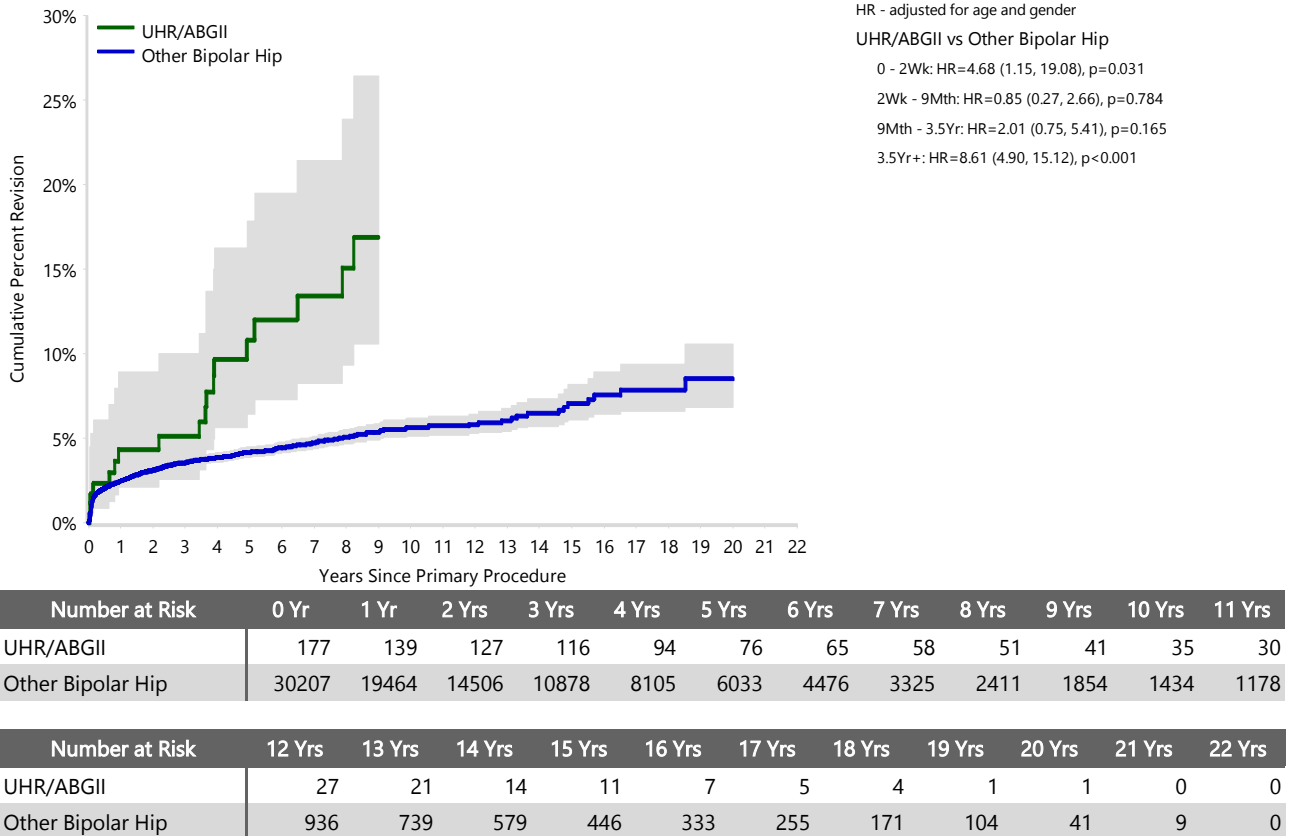
FIGURE 1

Yearly Cumulative Percent Revision of Primary Bipolar Hip Replacement

The yearly cumulative percent revision of the UHR/ABGII bipolar hip combination is compared to all other bipolar hip 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 Bipolar Hip Replacement



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

TABLE 3**Primary Diagnosis for Revised Primary Bipolar Hip 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 bipolar hip prostheses.

Table 3: Primary Diagnosis for Revised Primary Bipolar Hip Replacement

| Primary Diagnosis | UHR/ABGII | | Other Bipolar Hip | |
|--------------------------|-----------|--------------|-------------------|--------------|
| | Number | Percent | Number | Percent |
| Fractured Neck Of Femur | 23 | 100.0 | 858 | 91.7 |
| Tumour | | | 30 | 3.2 |
| Osteoarthritis | | | 29 | 3.1 |
| Failed Internal Fixation | | | 10 | 1.1 |
| Osteonecrosis | | | 8 | 0.9 |
| Other | | | 1 | 0.1 |
| TOTAL | 23 | 100.0 | 936 | 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 Bipolar Hip Replacement - Reason for Revision

| Revision Diagnosis | Number | UHR/ABGII | | Other Bipolar Hip | | |
|------------------------------------|------------|---------------------|--------------|-------------------|---------------------|--------------|
| | | % Primaries Revised | % Revisions | Number | % Primaries Revised | % Revisions |
| Infection | 1 | 0.6 | 4.3 | 287 | 1.0 | 30.7 |
| Prosthesis Dislocation/Instability | 1 | 0.6 | 4.3 | 230 | 0.8 | 24.6 |
| Fracture | 17 | 9.6 | 73.9 | 174 | 0.6 | 18.6 |
| Loosening | 3 | 1.7 | 13.0 | 85 | 0.3 | 9.1 |
| Chondrolysis/Acetab. Erosion | 1 | 0.6 | 4.3 | 75 | 0.2 | 8.0 |
| Pain | | | | 54 | 0.2 | 5.8 |
| Tumour | | | | 5 | 0.0 | 0.5 |
| Lysis | | | | 4 | 0.0 | 0.4 |
| Leg Length Discrepancy | | | | 3 | 0.0 | 0.3 |
| Malposition | | | | 3 | 0.0 | 0.3 |
| Implant Breakage Stem | | | | 2 | 0.0 | 0.2 |
| Incorrect Sizing | | | | 2 | 0.0 | 0.2 |
| Progression Of Disease | | | | 2 | 0.0 | 0.2 |
| Heterotopic Bone | | | | 1 | 0.0 | 0.1 |
| Implant Breakage Head | | | | 1 | 0.0 | 0.1 |
| Metal Related Pathology | | | | 1 | 0.0 | 0.1 |
| Osteonecrosis | | | | 1 | 0.0 | 0.1 |
| Other | | | | 6 | 0.0 | 0.6 |
| N Revision | 23 | 13.0 | 100.0 | 936 | 3.1 | 100.0 |
| N Primary | 177 | | | 30207 | | |

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

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Bipolar Hip 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 UHR/ABGII bipolar hip combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other bipolar hip prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Bipolar Hip Replacement

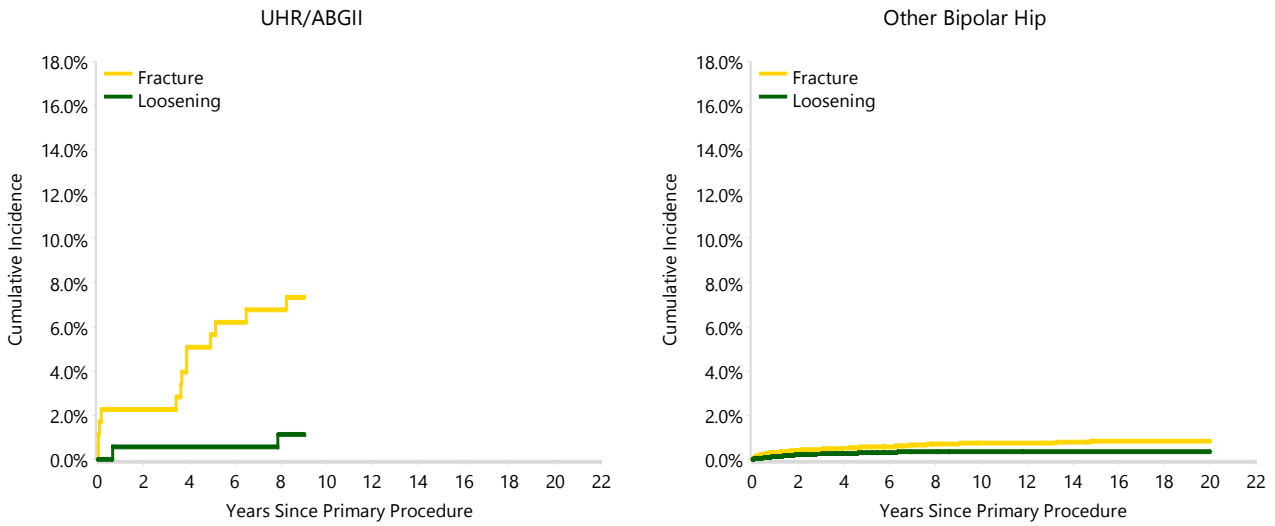


TABLE 5

Type of Revision Performed for Primary Bipolar Hip Replacement

This analysis identifies the components used in the revision of the UHR/ABGII bipolar hip combination and compares it to the components used in the revision of all other bipolar hip 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 bipolar hip prostheses i.e. is there a difference in the type of revision undertaken for the UHR/ABGII bipolar hip combination compared to all other bipolar hip prostheses.

Table 5: Primary Bipolar Hip Replacement - Type of Revision

| Type of Revision | UHR/ABGII | | Other Bipolar Hip | |
|---------------------------|-----------|--------------|-------------------|--------------|
| | Number | Percent | Number | Percent |
| Acetabular Component | 4 | 17.4 | 296 | 31.6 |
| THR (Femoral/Acetabular) | 5 | 21.7 | 168 | 17.9 |
| Bipolar Head and Femoral | 12 | 52.2 | 128 | 13.7 |
| Cement Spacer | | | 39 | 4.2 |
| Femoral Component | 2 | 8.7 | 38 | 4.1 |
| Removal of Prostheses | | | 24 | 2.6 |
| Reinsertion of Components | | | 1 | 0.1 |
| N Major | 23 | 100.0 | 694 | 74.1 |
| Bipolar Only | | | 191 | 20.4 |
| Head Only | | | 28 | 3.0 |
| Minor Components | | | 23 | 2.5 |
| N Minor | | | 242 | 25.9 |
| TOTAL | 23 | 100.0 | 936 | 100.0 |

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

TABLE 6

Revision Rates of Primary Bipolar Hip Replacement by State

This enables a state by state variation to be identified for the UHR/ABGII bipolar hip combination and provides the comparative data for each of the states for all other bipolar hip 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 6: Revised Number of Primary Bipolar Hip Replacement by State

| Component | State | N Revised | N Total |
|-------------------|--------------|-----------|------------|
| UHR/ABGII | NSW | 23 | 173 |
| | VIC | 0 | 2 |
| | TAS | 0 | 2 |
| Other Bipolar Hip | NSW | 303 | 10955 |
| | VIC | 190 | 5284 |
| | QLD | 202 | 6372 |
| | WA | 90 | 2380 |
| | SA | 80 | 3009 |
| | TAS | 23 | 618 |
| | ACT/NT | 48 | 1589 |
| | TOTAL | | 959 |

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

TABLE 7**Number of Revisions of UHR/ABGII Primary Bipolar Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the UHR/ABGII bipolar hip 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 7: Number of Revisions of UHR/ABGII Primary Bipolar Hip Replacement by Year of Implant

| Year of Implant | Number Revised | Total Number |
|-----------------|----------------|--------------|
| 2001 | 0 | 1 |
| 2002 | 4 | 24 |
| 2003 | 1 | 25 |
| 2004 | 5 | 36 |
| 2005 | 3 | 34 |
| 2006 | 1 | 10 |
| 2007 | 4 | 15 |
| 2008 | 4 | 20 |
| 2009 | 0 | 7 |
| 2010 | 1 | 5 |
| TOTAL | 23 | 177 |

TABLE 8**Revision Rates of UHR/ABGII Primary Bipolar Hip 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 UHR/ABGII 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 | Coating |
|---------------------|-------------------|---------------------------------------|--------|----------|-----------|
| Bipolar | | | | | |
| UHR | UH13622-UH17228 | UNIVERSAL HEAD BIPOLAR COMPONENT | NO | | |
| Femoral Stem | | | | | |
| ABGII | 48450101-48450208 | FEMORAL STEM W/ HYDROXAPATITE COATING | NO | METAL | HA COATED |

Table 8: Revised Number of UHR/ABGII Primary Bipolar Hip Replacement by Catalogue Number Range

| Bipolar Range | Femoral Stem Range | N Revised | N Total |
|-----------------|--------------------|-----------|------------|
| UH13622-UH17228 | 48450101-48450208 | 23 | 177 |
| TOTAL | | 23 | 177 |