# Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component

**Sponsor:** ESKA Australia
**Manufacturer:** ESKA

**NJRR Data:**

| # Implanted | # Revised | Revision Rate (%) |
|---|---|---|
| 175 | 9 | 5.1 |
| *13307* | *548* | *4.1* |
| **Observed Compt Yrs** | **Revns/100 Comp Yrs** | **CL on revs/100 c.yrs** |
| 327 | 2.8 | 1.26 - 5.23 |
| *55420* | *1.0* | *0.90 - 1.06* |

*The numbers in shaded italics are the comparison figures for the same type of implant. In most cases this is the numbers for all implants of the same type received by the NJRR*

Number of implanting hospitals: 25
Number of hospitals where revisions occurred: 5

| Reason for Revision | N | % |
|---|---|---|
| Loosening/Lysis | 5 | 55.6 |
| Fracture (Bone) | 3 | 33.3 |
| Pain | 1 | 11.1 |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| **Total** | 9 | 100% |

| Type of Revision | N | % |
|---|---|---|
| Femoral and Acetabular | 6 | 66.7 |
| Acetabular Only | 3 | 33.3 |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| **Total** | 9 | 100% |

## TGA Observations on NJRR Data

Loosening/lysis and fracture are the main reasons for revision of the Bionik Implant, Losening/lysis and pain are over-represented. That is the proportion of Bionik implants that are revised for these reasons is greater than the proportion of implants revised for this reasons in all other implants of the same type. Femoral neck fracture is a common cause for revision with this type of implant. Femoral neck fracture is considered to be related to the implant because preservation of the femoral neck is part of the design phylosophy of this type of implant (The cummulative revision rate of the implant appears to be increasing and diverging from the revision rate curve for all oter implants, but once again the certainty of this trend is difficult to establish due to the relatively low number of observed years.

## TGA Observations on Manufacturers Reply

There are 9 revisions reported by the NJRR in this series. The sponsor states that 1 was a ceramic on ceramic implant and the remaining 8 were metal on metal. The Sponsor dismisses them all as not being implant related:

> The revision of the ceramic on ceramic implant was due to a femur fracture due to AVM.
>
> Of the implants that the sponsor claims were metal on metal hips, 3 revisions were due to neck of femur fractures (2 of which are claimed to be due to trauma), 3 revisions are due to malposition of the acetabulr cup and in two cases the femoral heads were not in the varus position.

Note that this does not completely account for all revisions and is not consistent with the NJRR data, which cites 3 fractures, not 4.

ESKA have also supplied some published papers and abstracts about the performace of the ESKA implant. The following are some observations about this literature.

In a general article about hip joint surface replacement Rudert et al report a case series of 20 Bionik surface replacement prostheses inserted between 2003 and 2005. At an average follow up period of 18 months there were no infections of aseptic loosening, but there was one femoral neck fracture and one dislocation, placing the revision rate at approximately 10% (or (100 x 2 revisions / 1.5 years x 20 implants = 6.6 revisions/100 component years).

ESKA has provided a "Data Summary" on a series involving 248 patients (number of implants not stated). Enrolments began in February 2003 and patients were followed until February 2006 (estimated average follow up of 1.5 years). During that time ESKA reports that there were 7 revisions for various reasons - mostly femoral neck fracture. The revision rate is not calculted, but based on the information provided above, an estimate would be 100 x 7 revisions / 1.5 years x 248 implants = 1.88 revisions/100 component years.

Beaulé et al report a retrospective review of 94 cases for which the mean follow up was 4.2 years. 13 patients are reported to have had a bad outcome. A bad outcome is defined as conversion to THR, radiolucency of greater than 1mm or narrowing of the femoral neck by greater than 10%. It is not clear whether all 13 required revision, but if they did then the revision rate was 3.29 revisions/100 component years. To achieve the same revision rate as the average revision rate of similar implants in Australia, the number of implants that were revised should can be no greater than 4. However, Beaulé et al made an important observation: The number of failures is related to a neck shaft angle < 130°. The relative risk of problems with Bionik hips where the neck shaft angle is < 130° is 6 times that wwhere the neck shatf angle is > 130°. It is not clear whether this piece of information is conveyed to surgeons through product literature or training.

The paper by Gerdesmeyer et al on minimally invasive surgery reports that in a series of 31 patients using a minimally invasive approach, no instances of loosening or dislocation or other sequelae were observed after 12 months of follow up.

Two abstracts to papers are submitted with no accompanying citation... and are not discussed further here.

In summary the Sponsor asserts that none of the revisions reported in the NJRR against the Bionik implant are related to the design of the implant. ESKA has also provided papers and citations as evidence of implant performance elsewhere in the world, but the revision rates reported in the literature provided appears to be higher – sometimes much higher than the revision rate reported by the NJRR for this implant.

One author noted the importance of neck shaft angle - The TGA seeks the advice of the OEWG as to whether this affects all similar resufacing implants and whether this is a commonly known in the orthopaedics field.

[redacted]

# Adaptor (cementless) Total Conventional Hip Femoral Prosthesis

This analysis compares the Adaptor (cementless) Total Conventional Hip Femoral Prosthesis with all Other Total Conventional Hip prostheses. This Prosthesis has been identified as having a significantly higher revision rate.

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, http://www.dmac.adelaide.edu.au/aoanjrr/publications.jsp.

## TABLE 1

***Revision Rate of Primary Total Conventional Hip Replacement***

The ***Revision Rate*** of the Adaptor (cementless) Total Conventional Hip Femoral Prosthesis is compared to all Other Total Conventional Hip prostheses.

**Table 1: Revision Rates of Primary Total Conventional Hip Replacement**

| Component | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|
| Adapter (cementless) | 23 | 567 | 1092 | 2.11 (1.34, 3.16) |
| Other Total Conventional Hip | 5054 | 170537 | 651226 | 0.78 (0.75, 0.80) |
| **TOTAL** | **5077** | **171104** | **652317** | **0.78 (0.76, 0.80)** |

## TABLE 2

***Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement***

The ***Yearly Cumulative Percent Revision*** of the Adaptor (cementless) Total Conventional Hip Femoral Prosthesis is compared to all Other Total Conventional Hip prostheses.

**Table 2: Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement**

| CPR | 1 Yr | 3 Yrs | 5 Yrs | 7 Yrs | 9 Yrs |
|---|---|---|---|---|---|
| Adapter (cementless) | 2.7 (1.6, 4.5) | 5.4 (3.5, 8.3) | | | |
| Other Total Conventional Hip | 1.5 (1.5, 1.6) | 2.7 (2.6, 2.8) | 3.5 (3.4, 3.6) | 4.4 (4.3, 4.5) | 5.4 (5.1, 5.7) |

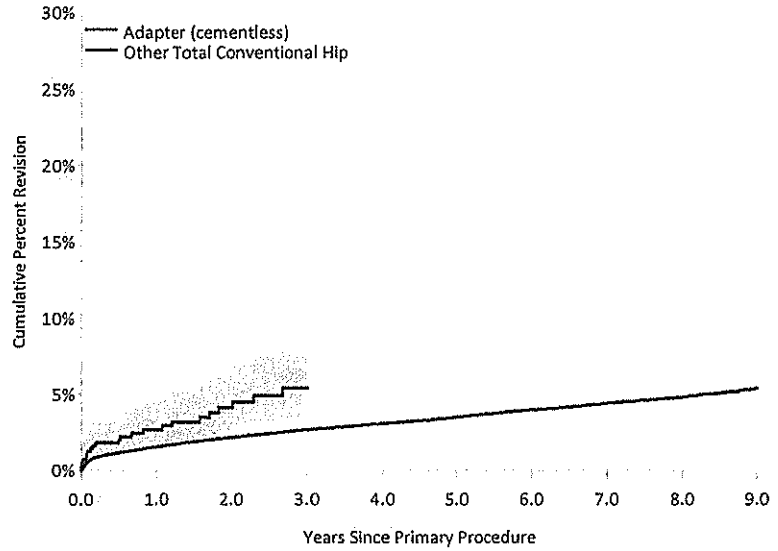
**FIGURE 1**

***Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement***

The ***Yearly Cumulative Percent Revision*** of the Adaptor (cementless) Total Conventional Hip Femoral Prosthesis is compared to all Other Total Conventional Hip prostheses. In addition, Hazard Ratios are also 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 Conventional Hip Replacement**




| Number at Risk | 0 Yr | 1 Yrs | 2 Yrs | 3 Yrs | 4 Yrs | 5 Yrs | 6 Yrs | 7 Yrs | 8 Yrs | 9 Yrs |
|---|---|---|---|---|---|---|---|---|---|---|
| Adapter (cementless) | 567 | 396 | 265 | 137 | 16 | 0 | 0 | 0 | 0 | 0 |
| Other Total Conventional Hip | 170537 | 142264 | 117871 | 96114 | 75956 | 57166 | 40037 | 24821 | 11582 | 2968 |

## TABLE 3

### *Primary Diagnosis for Revised Primary Total Conventional 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 Total Conventional Hip prostheses.

**Table 3: Primary Diagnosis for Revised Primary Total Conventional Hip Replacement**

| | Adapter (cementless) | | Other Total Conventional Hip | |
|---|---|---|---|---|
| Primary Diagnosis | Number | Percent | Number | Percent |
| Osteoarthritis | 22 | 95.7 | 4262 | 84.3 |
| Avascular Necrosis | | | 253 | 5.0 |
| Fractured Neck Of Femur | 1 | 4.3 | 249 | 4.9 |
| Rheumatoid Arthritis | | | 96 | 1.9 |
| Developmental Dysplasia | | | 87 | 1.7 |
| Failed Internal Fixation | | | 32 | 0.6 |
| Tumour | | | 32 | 0.6 |
| Other Inflammatory Arthritis | | | 29 | 0.6 |
| Fracture/Dislocation | | | 7 | 0.1 |
| Arthrodesis Takedown | | | 5 | 0.1 |
| Other | | | 2 | 0.0 |
| **TOTAL** | **23** | **100.0** | **5054** | **100.0** |

## TABLE 4

### *Revision Rates of Adaptor (cementless) Primary Total Conventional Hip 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 4: Revision Rates of Adapter (cementless) Primary Total Conventional Hip Replacement by Fixation**

| Fixation | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|
| Cemented | 0 | 1 | 3 | 0.00 (0.00, 115.0) |
| Cementless | 23 | 550 | 1071 | 2.15 (1.36, 3.22) |
| Hybrid | 0 | 16 | 18 | 0.00 (0.00, 21.04) |
| **TOTAL** | **23** | **567** | **1092** | **2.11 (1.34, 3.16)** |

**TABLE 5**

***Revision Rates of* Adaptor (cementless) *Primary* Total Conventional Hip *Replacement by Bearing Surface.***

This analysis is provided as some prostheses are combined with a variety of different bearing surfaces. All bearing surfaces used with this Prosthesis are listed.

**Table 5: Revision Rates of Adapter (cementless) Primary Total Conventional Hip Replacement by Bearing Surface**

| Bearing Surface | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|
| Ceramic/Ceramic | 2 | 38 | 78 | 2.56 (0.31, 9.26) |
| Ceramic/Polyethylene | 1 | 53 | 99 | 1.01 (0.03, 5.65) |
| Ceramic/Modified Polyethylene | 0 | 11 | 2 | 0.00 (0.00, 219.1) |
| Metal/Metal | 17 | 356 | 759 | 2.24 (1.30, 3.59) |
| Metal/Polyethylene | 3 | 105 | 150 | 2.00 (0.41, 5.84) |
| Metal/Modified Polyethylene | 0 | 4 | 4 | 0.00 (0.00, 83.74) |
| **TOTAL** | **23** | **567** | **1092** | **2.11 (1.34, 3.16)** |

TABLE 6

*Type of Revision Performed for Primary Total Conventional Hip Replacement*

This analysis identifies the components used in the revision of the Adaptor (cementless) Total Conventional Hip Femoral Prosthesis and compares it to the components used in the revision of all Other Total Conventional 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 Total Conventional Hip prostheses i.e. is there a difference in the type of revision undertaken for the Adaptor (cementless) Total Conventional Hip Femoral Prosthesis compared to all Other Total Conventional Hip prostheses.

**Table 6: Primary Total Conventional Hip Replacement - Type of Revision**

| | Adapter (cementless) | | Other Total Conventional Hip | |
|---|---|---|---|---|
| **Revision Type** | **Number** | **Percent** | **Number** | **Percent** |
| Femoral Only | 6 | 26.1 | 1482 | 29.3 |
| Acetabular Only | 5 | 21.7 | 1260 | 24.9 |
| THR (Femoral/Acetabular) | 2 | 8.7 | 625 | 12.4 |
| Cement Spacer | 1 | 4.3 | 244 | 4.8 |
| Removal of Prostheses | | | 41 | 0.8 |
| Reinsertion of Components | | | 6 | 0.1 |
| Bipolar Head and Femoral | | | 2 | 0.0 |
| Saddle | | | 2 | 0.0 |
| **N Major** | **14** | **60.9** | **3662** | **72.5** |
| Head/Insert | 5 | 21.7 | 922 | 18.2 |
| Head Only | 1 | 4.3 | 285 | 5.6 |
| Minor Components | | | 82 | 1.6 |
| Insert Only | 1 | 4.3 | 70 | 1.4 |
| Head/Neck | 2 | 8.7 | 30 | 0.6 |
| Neck Only | | | 2 | 0.0 |
| Neck/Insert | | | 1 | 0.0 |
| **N Minor** | **9** | **39.1** | **1392** | **27.5** |
| **TOTAL** | **23** | **100.0** | **5054** | **100.0** |

**TABLE 7**

***Reason for Revision of Primary Total Conventional Hip Replacement***

This is reported in two ways; a percentage of all revisions and also as a percentage of all primary procedures.

This analysis includes a comparison of reasons for revision to all Other Total Conventional Hip prostheses.

This analysis is undertaken to identify if there are differences in the reasons for revision and the number of revisions performed for those reasons between the Adaptor (cementless) Total Conventional Hip Femoral Prosthesis and all Other Total Conventional Hip prostheses.

**Table 7: Primary Total Conventional Hip Replacement - Reason for Revision**

| | Adapter (cementless) | | | Other Total Conventional Hip | | |
|---|---|---|---|---|---|---|
| **Revision Diagnosis** | **Number** | **% Revision** | **% Primary** | **Number** | **% Revision** | **% Primary** |
| Loosening/Lysis | 5 | 21.7 | 0.9 | 1514 | 30.0 | 0.9 |
| Prosthesis Dislocation | 5 | 21.7 | 0.9 | 1395 | 27.6 | 0.8 |
| Infection | 3 | 13.0 | 0.5 | 843 | 16.7 | 0.5 |
| Fracture | 2 | 8.7 | 0.4 | 742 | 14.7 | 0.4 |
| Pain | 4 | 17.4 | 0.7 | 100 | 2.0 | 0.1 |
| Other | | | | 67 | 1.3 | 0.0 |
| Leg Length Discrepancy | 1 | 4.3 | 0.2 | 63 | 1.2 | 0.0 |
| Metal Sensitivity | 1 | 4.3 | 0.2 | 61 | 1.2 | 0.0 |
| Malposition | | | | 54 | 1.1 | 0.0 |
| Wear Acetabulum | 1 | 4.3 | 0.2 | 51 | 1.0 | 0.0 |
| Implant Breakage Stem | | | | 35 | 0.7 | 0.0 |
| Implant Breakage Acetabular | 1 | 4.3 | 0.2 | 32 | 0.6 | 0.0 |
| Incorrect Sizing | | | | 29 | 0.6 | 0.0 |
| Instability | | | | 28 | 0.6 | 0.0 |
| Implant Breakage Head | | | | 20 | 0.4 | 0.0 |
| Heterotopic Bone | | | | 8 | 0.2 | 0.0 |
| Tumour | | | | 8 | 0.2 | 0.0 |
| Avascular Necrosis | | | | 2 | 0.0 | 0.0 |
| Synovitis | | | | 2 | 0.0 | 0.0 |
| **N Revision** | **23** | **100.0** | **4.1** | **5054** | **100.0** | **3.0** |
| **N Primary** | **567** | | | **170537** | | |

**FIGURE 2**

***Revision Diagnosis Cumulative Incidence by Time to Revision for Primary Total Conventional 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 Adaptor (cementless) Total Conventional Hip Prosthesis. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all Other Total Conventional Hip prostheses.

**Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Conventional Hip Replacement**

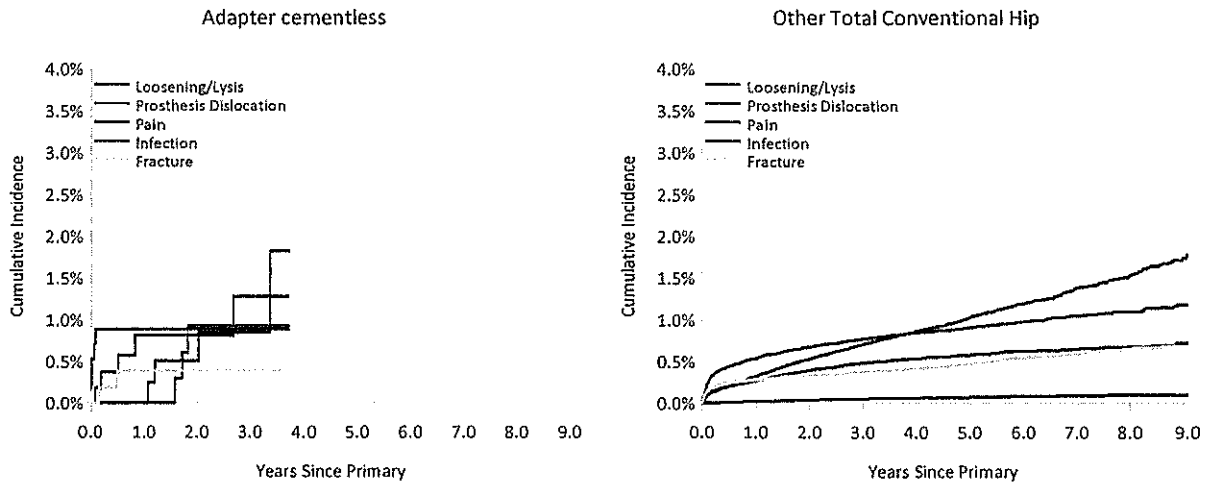


TABLE 8

***Revision Rates of Primary Total Conventional Hip Replacement by State***

This enables a state by state variation to be identified for the Adaptor (cementless) Total Conventional Hip Femoral Prosthesis and provides the comparative data for each of the states for all Other Total Conventional Hip prostheses.

This analysis is undertaken for similar reasons as those outlined above for Table 8.

**Table 8: Revision Rates of Primary Total Conventional Hip Replacement by State**

| Component | State | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|---|
| Adapter (cementless) | NSW | 14 | 308 | 575 | 2.44 (1.33, 4.09) |
| Adapter (cementless) | VIC | 3 | 74 | 141 | 2.13 (0.44, 6.22) |
| Adapter (cementless) | QLD | 1 | 19 | 55 | 1.83 (0.05, 10.17) |
| Adapter (cementless) | WA | 0 | 32 | 20 | 0.00 (0.00, 18.44) |
| Adapter (cementless) | SA | 0 | 5 | 5 | 0.00 (0.00, 69.02) |
| Adapter (cementless) | TAS | 5 | 128 | 296 | 1.69 (0.55, 3.95) |
| Adapter (cementless) | ACT/NT | 0 | 1 | 0 | 0.00 (0.00, 1773) |
| Other Total Conventional Hip | NSW | 1405 | 50347 | 180311 | 0.78 (0.74, 0.82) |
| Other Total Conventional Hip | VIC | 1378 | 46239 | 176185 | 0.78 (0.74, 0.82) |
| Other Total Conventional Hip | QLD | 867 | 27407 | 105373 | 0.82 (0.77, 0.88) |
| Other Total Conventional Hip | WA | 647 | 18985 | 76117 | 0.85 (0.79, 0.92) |
| Other Total Conventional Hip | SA | 462 | 17571 | 74846 | 0.62 (0.56, 0.68) |
| Other Total Conventional Hip | TAS | 163 | 6120 | 24233 | 0.67 (0.57, 0.78) |
| Other Total Conventional Hip | ACT/NT | 132 | 3868 | 14161 | 0.93 (0.78, 1.11) |
| **TOTAL** | | **5077** | **171104** | **652317** | **0.78 (0.76, 0.80)** |

TABLE 9

***Number of Revisions of Adaptor (cementless) Primary Total Conventional Hip Replacement by Year of Implant***

This analysis details the number of prostheses reported each year to the Registry for the Adaptor (cementless) Total Conventional Hip 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 2009 has a maximum of one year to be revised, whereas a primary performed in 2007 has a maximum of three years to be revised.

**Table 9: Number of Revisions of Adapter (cementless) Primary Total Conventional Hip Replacement by Year of Implant**

| Year of Implant | Number Revised | Total Number |
|---|---|---|
| 2005 | 1 | 19 |
| 2006 | 9 | 140 |
| 2007 | 6 | 131 |
| 2008 | 4 | 121 |
| 2009 | 3 | 156 |
| **TOTAL** | **23** | **567** |

## TABLE 10

### *Revision rates of Adaptor (cementless) Primary Total Conventional 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 Adaptor (cementless) femoral prosthesis.

This analysis has been undertaken to determine if the revision rate varies according to the catalogue number range.

**Table 10: Revision Rates of Adapter (cementless) Primary Total Conventional Hip Replacement by Catalogue Number Range**

| | Catalogue Range | Catalogue Description |
|---|---|---|
| **Femoral Stem** | | |
| Adapter (cementless) | 11090302-11090373 | ADAPTER CEMENTLESS COLLARLESS |
| Adapter (cementless) | 11099012-11099044 | HIP STEM CEMENTLESS TINB-C COLLARLESS |

| Femoral Stem Range | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|
| 11090302-11090373 | 22 | 522 | 1061 | 2.07 (1.30, 3.14) |
| 11099012-11099044 | 1 | 45 | 31 | 3.27 (0.08, 18.23) |
| **TOTAL** | **23** | **567** | **1092** | **2.11 (1.34, 3.16)** |

## TABLE 11

### *Revision rates of Adaptor (cementless) Primary Total Conventional Hip 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 11: Revision Rates of Adapter (cementless) Primary Total Conventional Hip Replacement by Acetabular Component**

| Acetabular Component | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|
| 2000 | 0 | 2 | 6 | 0.00 (0.00, 61.89) |
| 2000 Plus | 2 | 55 | 121 | 1.65 (0.20, 5.97) |
| Allofit | 0 | 13 | 2 | 0.00 (0.00, 184.6) |
| Bionik | 21 | 489 | 948 | 2.22 (1.37, 3.39) |
| Eska Cup | 0 | 1 | 3 | 0.00 (0.00, 121.1) |
| R3 | 0 | 1 | 1 | 0.00 (0.00, 561.4) |
| Trabecular Metal Shell | 0 | 5 | 10 | 0.00 (0.00, 37.95) |
| Trilogy | 0 | 1 | 2 | 0.00 (0.00, 201.1) |
| **TOTAL** | **23** | **567** | **1092** | **2.11 (1.34, 3.16)** |

# Bionik/Bionik Total Resurfacing Hip Investigation

This analysis compares the Bionik/Bionik Total Resurfacing Hip Combination with all Other Total Resurfacing Hip prostheses. This Combination has been identified as having a significantly higher revision rate.

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, http://www.dmac.adelaide.edu.au/aoanjrr/publications.jsp.

TABLE 1

***Revision Rate of Primary Total Resurfacing Hip Replacement***

The ***Revision Rate*** of the Bionik/Bionik Total Resurfacing Hip Combination is compared to all Other Total Resurfacing Hip prostheses.

**Table 1: Revision Rates of Primary Total Resurfacing Hip Replacement**

| Component | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|
| Bionik/Bionik | 9 | 175 | 327 | 2.75 (1.26, 5.23) |
| Total Resurfacing Hip | 539 | 13132 | 55093 | 0.98 (0.90, 1.06) |
| **TOTAL** | **548** | **13307** | **55420** | **0.99 (0.91, 1.08)** |

TABLE 2

***Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement***

The ***Yearly Cumulative Percent Revision*** of the Bionik/Bionik Total Resurfacing Hip Combination is compared to all Other Total Resurfacing Hip prostheses.

**Table 2: Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement**

| CPR | 1 Yr | 3 Yrs | 5 Yrs | 7 Yrs | 9 Yrs |
|---|---|---|---|---|---|
| Bionik/Bionik | 3.8 (1.7, 8.4) | 6.6 (3.2, 13.6) | | | |
| Total Resurfacing Hip | 1.8 (1.6, 2.1) | 3.2 (2.9, 3.5) | 4.5 (4.1, 4.9) | 6.1 (5.5, 6.7) | 7.4 (6.4, 8.6) |

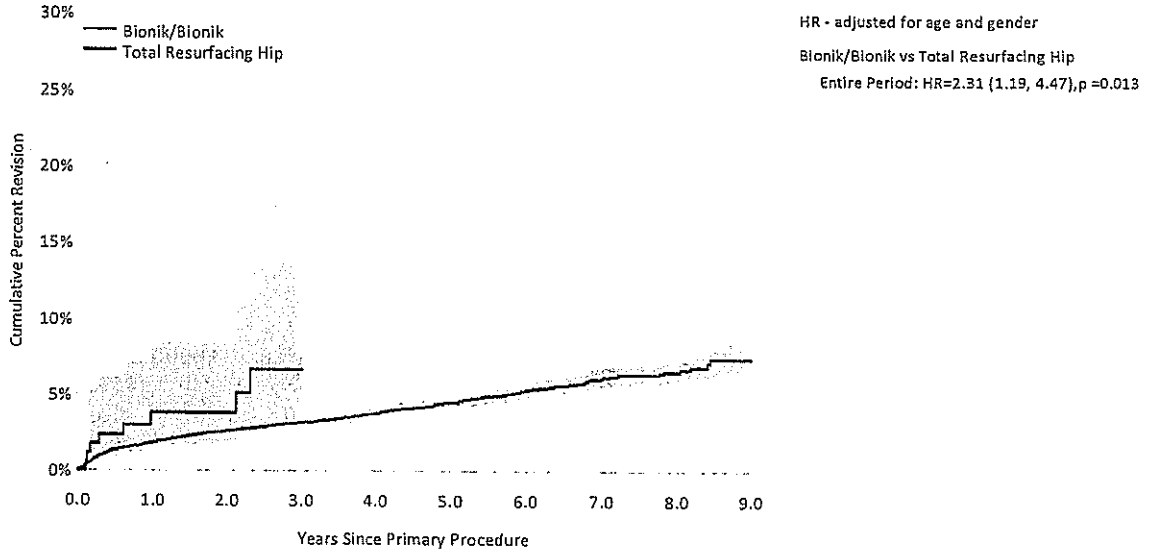
FIGURE 1

*Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement*

The ***Yearly Cumulative Percent Revision*** of the Bionik/Bionik Total Resurfacing Hip Combination is compared to all Other Total Resurfacing Hip prostheses. In addition, Hazard Ratios are also 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 Resurfacing Hip Replacement




| Number at Risk | 0 Yr | 1 Yrs | 2 Yrs | 3 Yrs | 4 Yrs | 5 Yrs | 6 Yrs | 7 Yrs | 8 Yrs | 9 Yrs |
|---|---|---|---|---|---|---|---|---|---|---|
| Bionik/Bionik | 175 | 117 | 73 | 43 | 12 | 0 | 0 | 0 | 0 | 0 |
| Total Resurfacing Hip | 13132 | 11736 | 10239 | 8597 | 6883 | 5090 | 3457 | 2000 | 703 | 88 |

TABLE 3

*Primary Diagnosis for Revised Primary Total Resurfacing 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 Total Resurfacing Hip prostheses.

**Table 3: Primary Diagnosis for Revised Primary Total Resurfacing Hip Replacement**

| Primary Diagnosis | Bionik/Bionik | | Other Total Resurfacing Hip | |
|---|---|---|---|---|
| | Number | Percent | Number | Percent |
| Osteoarthritis | 9 | 100.0 | 481 | 89.2 |
| Developmental Dysplasia | | | 35 | 6.5 |
| Avascular Necrosis | | | 13 | 2.4 |
| Other Inflammatory Arthritis | | | 6 | 1.1 |
| Rheumatoid Arthritis | | | 4 | 0.7 |
| **TOTAL** | **9** | **100.0** | **539** | **100.0** |

TABLE 4

*Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip 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 4: Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Fixation**

| Fixation | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|
| Cemented | 0 | 1 | 1 | 0.00 (0.00, 349.1) |
| Cementless | 1 | 15 | 44 | 2.27 (0.06, 12.67) |
| Hybrid | 8 | 159 | 282 | 2.84 (1.23, 5.59) |
| **TOTAL** | **9** | **175** | **327** | **2.75 (1.26, 5.23)** |

TABLE 5

*Type of Revision Performed for Primary Total Resurfacing Hip Replacement*

This analysis identifies the components used in the revision of the Bionik/Bionik Total Resurfacing Hip Combination and compares it to the components used in the revision of all Other Total Resurfacing 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 Total Resurfacing Hip prostheses i.e. is there a difference in the type of revision undertaken for the Bionik/Bionik Total Resurfacing Hip Combination compared to all Other Total Resurfacing Hip prostheses.

**Table 5: Type of Revision for Primary Total Resurfacing Hip Replacement**

| | Bionik/Bionik | | Other Total Resurfacing Hip | |
|---|---|---|---|---|
| Revision Type | Number | Percent | Number | Percent |
| Femoral Only | 3 | 33.3 | 284 | 52.7 |
| THR (Femoral/Acetabular) | 6 | 66.7 | 195 | 36.2 |
| Acetabular Only | | | 41 | 7.6 |
| Cement Spacer | | | 15 | 2.8 |
| Removal of Prostheses | | | 4 | 0.7 |
| **N Major** | **9** | **100.0** | **539** | **100.0** |
| TOTAL | 9 | 100.0 | 539 | 100.0 |

TABLE 6

*Reason for Revision of Primary Total Resurfacing Hip Replacement*

This is reported in two ways; a percentage of all revisions and also as a percentage of all primary procedures.

This analysis includes a comparison of reasons for revision to all Other Total Resurfacing Hip prostheses.

This analysis is undertaken to identify if there are differences in the reasons for revision and the number of revisions performed for those reasons between the Bionik/Bionik Total Resurfacing Hip Combination and all Other Total Resurfacing Hip prostheses.

**Table 6: Reason for Revision of Primary Total Resurfacing Hip Replacement**

| | Bionik/Bionik | | | Other Total Resurfacing Hip | | |
|---|---|---|---|---|---|---|
| Revision Diagnosis | Number | % Revision | % Primary | Number | % Revision | % Primary |
| Fracture | 3 | 33.3 | 1.7 | 192 | 35.6 | 1.5 |
| Loosening/Lysis | 5 | 55.6 | 2.9 | 178 | 33.0 | 1.4 |
| Infection | | | | 45 | 8.3 | 0.3 |
| Metal Sensitivity | | | | 39 | 7.2 | 0.3 |
| Pain | 1 | 11.1 | 0.6 | 28 | 5.2 | 0.2 |
| Avascular Necrosis | | | | 17 | 3.2 | 0.1 |
| Prosthesis Dislocation | | | | 15 | 2.8 | 0.1 |
| Malposition | | | | 12 | 2.2 | 0.1 |
| Other | | | | 6 | 1.1 | 0.0 |
| Implant Breakage Head | | | | 3 | 0.6 | 0.0 |
| Instability | | | | 1 | 0.2 | 0.0 |
| Leg Length Discrepancy | | | | 1 | 0.2 | 0.0 |
| Synovitis | | | | 1 | 0.2 | 0.0 |
| Tumour | | | | 1 | 0.2 | 0.0 |
| **N Revision** | **9** | **100.0** | **5.1** | **539** | **100.0** | **4.1** |
| **N Primary** | **175** | | | **13132** | | |

FIGURE 2

***Revision Diagnosis Cumulative Incidence by Time to Revision for Primary Total Resurfacing 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 Bionik/Bionik Total Resurfacing Hip Combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all Other Total Resurfacing Hip prostheses.

**Figure 2: Revision Diagnosis Cumulative Incidence by Time to Revision for Primary Total Resurfacing Hip Replacement**

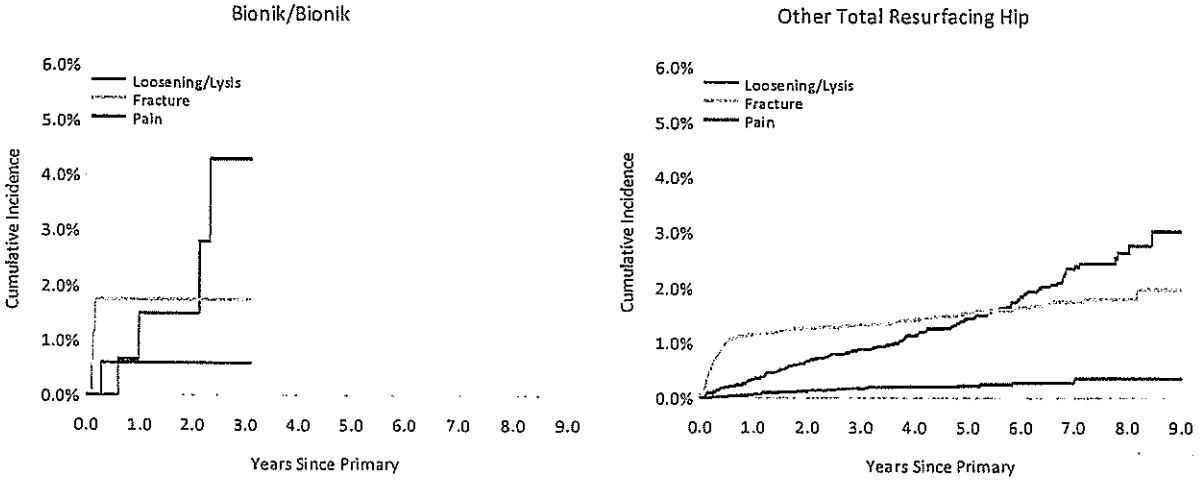


TABLE 7

*Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Hospital*

This table details the rates of revision in each of the individual hospitals in which the Bionik/Bionik Total Resurfacing Hip Combination was used. The hospitals are identified by number only.

The purpose of this analysis is to determine if the higher than anticipated rate of revision has widespread distribution between hospitals. 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 hospitals it is not possible to distinguish if the higher than anticipated rate of revision is related to the prosthesis, surgeon, technique or patient.

Table 7: Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Hospital

| Hospital Number | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|
| 1 | 0 | 2 | 7 | 0.00 (0.00, 52.96) |
| 2 | 0 | 21 | 16 | 0.00 (0.00, 23.13) |
| 3 | 0 | 4 | 11 | 0.00 (0.00, 34.82) |
| 4 | 2 | 6 | 15 | 12.92 (1.56, 46.66) |
| 5 | 0 | 3 | 4 | 0.00 (0.00, 85.44) |
| 6 | 0 | 1 | 1 | 0.00 (0.00, 528.4) |
| 7 | 0 | 12 | 35 | 0.00 (0.00, 10.60) |
| 8 | 0 | 2 | 3 | 0.00 (0.00, 141.5) |
| 9 | 0 | 3 | 3 | 0.00 (0.00, 112.6) |
| 10 | 2 | 10 | 11 | 17.83 (2.16, 64.41) |
| 11 | 0 | 4 | 5 | 0.00 (0.00, 67.30) |
| 12 | 0 | 4 | 6 | 0.00 (0.00, 60.88) |
| 13 | 0 | 1 | 2 | 0.00 (0.00, 168.2) |
| 14 | 0 | 22 | 51 | 0.00 (0.00, 7.17) |
| 15 | 0 | 1 | 0 | 0.00 (0.00, 8982) |
| 16 | 0 | 3 | 3 | 0.00 (0.00, 108.9) |
| 17 | 0 | 2 | 4 | 0.00 (0.00, 98.93) |
| 18 | 0 | 2 | 5 | 0.00 (0.00, 75.40) |
| 19 | 1 | 25 | 53 | 1.90 (0.05, 10.61) |
| 20 | 0 | 1 | 0 | 0.00 (0.00, 2750) |
| 21 | 1 | 15 | 11 | 9.04 (0.23, 50.36) |
| 22 | 3 | 23 | 68 | 4.39 (0.91, 12.83) |
| 23 | 0 | 1 | 1 | 0.00 (0.00, 344.6) |
| 24 | 0 | 5 | 6 | 0.00 (0.00, 63.17) |
| 25 | 0 | 2 | 5 | 0.00 (0.00, 75.10) |
| **TOTAL** | **9** | **175** | **327** | **2.75 (1.26, 5.23)** |

TABLE 8

*Revision Rates of Primary Total Resurfacing Hip Replacement by State*

This enables a state by state variation to be identified for the Bionik/Bionik Total Resurfacing Hip Combination and provides the comparative data for each of the states for all Other Total Resurfacing Hip prostheses.

This analysis is undertaken for similar reasons as those outlined above for Table 7.

**Table 8: Revision Rates of Primary Total Resurfacing Hip Replacement by State**

| Component | State | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|---|
| Bionik/Bionik | NSW | 7 | 118 | 225 | 3.12 (1.25, 6.42) |
| Bionik/Bionik | VIC | 0 | 24 | 53 | 0.00 (0.00, 6.91) |
| Bionik/Bionik | QLD | 0 | 2 | 7 | 0.00 (0.00, 52.96) |
| Bionik/Bionik | WA | 0 | 21 | 16 | 0.00 (0.00, 23.13) |
| Bionik/Bionik | TAS | 2 | 10 | 26 | 7.67 (0.93, 27.70) |
| Total Resurfacing Hip | NSW | 180 | 3899 | 15823 | 1.14 (0.98, 1.32) |
| Total Resurfacing Hip | VIC | 189 | 4747 | 21507 | 0.88 (0.76, 1.01) |
| Total Resurfacing Hip | QLD | 80 | 2212 | 8156 | 0.98 (0.78, 1.22) |
| Total Resurfacing Hip | WA | 16 | 370 | 1845 | 0.87 (0.50, 1.41) |
| Total Resurfacing Hip | SA | 49 | 1268 | 5560 | 0.88 (0.65, 1.17) |
| Total Resurfacing Hip | TAS | 9 | 83 | 279 | 3.22 (1.47, 6.12) |
| Total Resurfacing Hip | ACT/NT | 16 | 553 | 1923 | 0.83 (0.48, 1.35) |
| **TOTAL** | | **548** | **13307** | **55420** | **0.99 (0.91, 1.08)** |

TABLE 9

*Number of Revisions of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Year of Implant*

This analysis details the number of prostheses reported each year to the Registry for the Bionik/Bionik Total Resurfacing 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 2009 has a maximum of one year to be revised, whereas a primary performed in 2007 has a maximum of three years to be revised.

**Table 9: Number of Revisions of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Year of Implant**

| Year of Implant | Number Revised | Total Number |
|---|---|---|
| 2005 | 0 | 12 |
| 2006 | 3 | 33 |
| 2007 | 4 | 33 |
| 2008 | 0 | 43 |
| 2009 | 2 | 54 |
| TOTAL | 9 | 175 |

TABLE 10

*Revision rates of Bionik/Bionik Primary Total Resurfacing 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 Bionik/Bionik prosthesis.

This analysis has been undertaken to determine if the revision rate varies according to the catalogue number range.

**Table 10: Revision Rates of Bionik/Bionik Primary Total Resurfacing Hip Replacement by Catalogue Number Range**

| | Catalogue Range | Catalogue Description |
|---|---|---|
| **Head** | | |
| Bionik | 10260050-10260050 | HIP RESURFACING CEMENTLESS SILVER |
| Bionik | 10270042-10270058 | HIP RESURFING CEMENTED SILVER |
| Bionik | 10270238-10270258 | CERAMIC HEAD HIP SURF. REPLACEMENT |
| Bionik | 10280046-10280050 | HIP RESURFACING CEMENTLESS SILVER |
| Bionik | 10280142-10280156 | HIP SURFACE REPLACEMENT CEMENTED BIOSURF SILVER |
| Bionik | 10280642-10280654 | HIP RESURFACING CEMENTLESS SILVER CAP-COAT |
| Bionik | 10282038-10282058 | FEMORAL HEAD SHELL BIOSURF CEMENTED |
| **Acetabular** | | |
| Bionik | 10201050-10201064 | METAL SHELL BS TINB COAT |
| Bionik | 10201150-10201164 | METAL SHELL BS TINB COAT SCREW FIX |
| Bionik | 10201248-10201264 | METAL SHELL CEMENTLESS TINB COAT SCREW FIX |
| Bionik | 10201346-10201366 | METAL SHELL TINB CAP SCREW FIX |

| Head Range | Acetab Range | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|---|
| 10260050-10260050 | 10201150-10201164 | 0 | 1 | 4 | 0.00 (0.00, 85.01) |
| 10270042-10270058 | 10201150-10201164 | 0 | 6 | 23 | 0.00 (0.00, 15.72) |
| 10270042-10270058 | 10201248-10201264 | 0 | 4 | 16 | 0.00 (0.00, 23.28) |
| 10270042-10270058 | 10201346-10201366 | 2 | 11 | 36 | 5.51 (0.67, 19.90) |
| 10270238-10270258 | 10201150-10201164 | 0 | 1 | 1 | 0.00 (0.00, 343.7) |
| 10270238-10270258 | 10201248-10201264 | 0 | 1 | 1 | 0.00 (0.00, 471.1) |
| 10270238-10270258 | 10201346-10201366 | 1 | 9 | 7 | 14.32 (0.36, 79.77) |
| 10280046-10280050 | 10201050-10201064 | 0 | 1 | 4 | 0.00 (0.00, 83.69) |
| 10280046-10280050 | 10201150-10201164 | 0 | 1 | 4 | 0.00 (0.00, 83.90) |
| 10280142-10280156 | 10201050-10201064 | 0 | 1 | 3 | 0.00 (0.00, 107.4) |
| 10280142-10280156 | 10201150-10201164 | 0 | 3 | 10 | 0.00 (0.00, 38.45) |
| 10280142-10280156 | 10201248-10201264 | 0 | 10 | 22 | 0.00 (0.00, 16.80) |
| 10280142-10280156 | 10201346-10201366 | 2 | 46 | 87 | 2.30 (0.28, 8.31) |
| 10280642-10280654 | 10201050-10201064 | 0 | 2 | 7 | 0.00 (0.00, 50.24) |
| 10280642-10280654 | 10201150-10201164 | 1 | 2 | 7 | 15.23 (0.39, 84.83) |
| 10280642-10280654 | 10201248-10201264 | 0 | 3 | 8 | 0.00 (0.00, 46.30) |
| 10280642-10280654 | 10201346-10201366 | 0 | 7 | 18 | 0.00 (0.00, 20.84) |
| 10282038-10282058 | 10201150-10201164 | 1 | 3 | 6 | 15.58 (0.39, 86.82) |
| 10282038-10282058 | 10201248-10201264 | 1 | 36 | 31 | 3.18 (0.08, 17.73) |
| 10282038-10282058 | 10201346-10201366 | 1 | 27 | 30 | 3.34 (0.08, 18.58) |
| **TOTAL** | | **9** | **175** | **327** | **2.75 (1.26, 5.23)** |