No increased risk of early revision during the implementation phase of new cup designs

Analysis of 52,903 hip arthroplasties reported to the Swedish Hip Arthroplasty Register

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Background and purpose — In Sweden, less than 5% of patients who undergo total hip arthroplasty (THA) have revision. Younger patients have an increased risk of revision. New prosthetic designs are being introduced in order to improve outcomes further. We investigated whether the introductory phase of new cup designs would increase the revision rate.

Patients and methods — All THAs and first-time cup revisions performed from 1993 through 2011 were identified in the Swedish Hip Arthroplasty Register. The 15 types of cups used in more than 500 operations and inserted in more than 50 cases in each hospital (n = 52,903) were selected. All cups were given an order number, based on the order in which the cup had been inserted at each hospital. The influence of order number on the risk of revision was analyzed in a regression model, which was adjusted for potentially confounding demographic and surgical data. Revision within 2 years for all reasons (n = 940) was used as primary endpoint. Changes in the risk of revision based on the order number were analyzed using a spline.

Results — The order number of the cup had no influence on the risk of early revision (p ≥ 0.7). Categorizing the order number using cutoff values obtained from the splines did not result in any statistically significant changes in risk of revision (p ≥ 0.2).

Interpretation — We did not find any increased risk of early revision during the implementation phase of new cup designs. This finding is unexpected, and partly conflicts with data from other registries. The structured and stepwise introduction of new prosthesis designs, facilitated by the annual feedback from the Swedish Hip Arthroplasty Register, may partly explain this discrepancy.

The average survival of the hip implants used in Sweden is about 94% at 10 years (Garellick et al. 2014). Younger patients, however, being more active and having a longer life expectancy, certainly have a higher risk of late revision, which has stimulated the introduction of new designs that supposedly have longer durability. Recently, there have been reports of increased risk of early failure when new implants are being introduced (Anand et al. 2011). Peltola et al. (2013) analyzed 39,125 THAs from the Finnish Arthroplasty Register and found an increased risk of early revision surgery during the introductory phase of new implants in Finnish Hospitals.

In Sweden, the Nordic country with the highest proportion of cemented fixation (Havelin et al. 2009), about half of all THAs inserted are still all-cemented (Garellick et al. 2014) and the choice of implant design is comparatively homogenous. 4 different cemented cups cover 90% of the market, but some of these have been introduced rather recently or have been subject to minor or more pronounced change in design during the last decade. There is, however, more heterogeneity in uncemented cups, where 5 cups have a market share of less than 70% and the ranking between them in terms of usage changes from year to year (Garellick et al. 2013, 2014). According to data from the Swedish Hip Arthroplasty Register (SHAR), the risk of revision due to dislocation is higher when uncemented acetabular designs are used, both in primary THA (Garellick et al. 2014) and in revision THA (Mohaddes et al. 2013). It could be argued that Swedish surgeons are more familiar with cemented fixation and would therefore experience difficulties when new uncemented cup designs are introduced. During the last 5 years, uncemented cups have been used in Sweden in about 20% of all THAs (Garellick et al. 2014).
and in about 50% of all first-time acetabular revisions (Mohaddes et al. 2014). In the USA, where a higher proportion of uncemented designs are used, the most frequent cause of revision is dislocation (Bozic et al. 2009). Based on the aforementioned studies and observations from the SHAR, we hypothesized that introduction of new acetabular designs in Swedish hospitals would be associated with a higher risk of early revision.

**Patients and methods**

All hospitals performing primary and revision THA in Sweden report to the SHAR. Data completeness in the SHAR number variable was created (Figure 2). This corresponded to the order in which the cup had been inserted in each hospital, and it was used as a surrogate variable to monitor the introduction of new cup designs.

![Flow chart with detailed information on case selection.](image)

Figure 1. Flow chart with detailed information on case selection.

![Date of operation 10/Nov/2009 11/Nov/2009 12/Nov/2009 13/Nov/2009](image)

| Date of operation | 10/Nov/2009 | 11/Nov/2009 | 12/Nov/2009 | 13/Nov/2009 |
|-------------------|-------------|-------------|-------------|-------------|
| Hospital A        | Cup design X | Cup design Y | Cup design X | Cup design Z |
| order number = 1  | order number = 1 | order number = 2 | order number = 1 |
| Hospital B        | Cup design Y | Cup design X | Cup design Y | Cup design Y |
| order number = 1  | order number = 1 | order number = 2 | order number = 3 |

2014) and in about 50% of all first-time acetabular revisions (Mohaddes et al. 2014). In the USA, where a higher proportion of uncemented designs are used, the most frequent cause of revision is dislocation (Bozic et al. 2009). Based on the aforementioned studies and observations from the SHAR, we hypothesized that introduction of new acetabular designs in Swedish hospitals would be associated with a higher risk of early revision.

**Study population**

The mean age of the study population (n= 52,903) was 67 (SD 12), which was slightly younger than for all THAs reported to the SHAR during years 1993-2011 (n = 251,638). There was a slightly larger proportion of men in the study group, and proportionately more patients were operated due to primary osteoarthritis. Uncemented fixation was more common, and a proportionately more patients were operated in university and private hospitals (Table 1).
Statistics

All patients were followed until revision (exchange or removal of the cup) or death. Since the main purpose of the study was to examine early failures, the follow-up was limited to 2 years after the operation. Any kind of revision, for any reason, was used as primary endpoint. Isolated acetabular revision, excluding cases performed due to infection, was used as secondary endpoint. Revisions due to infections were excluded, since there was an increased risk of revision due to infection after primary THA during the period 1995–2009 (Dale et al. 2012) and there is controversy regarding the best practice for treatment of the early postoperative infection (Parvizi et al. 2012). Nonparametric testing using Mann-Whitney U-test was applied for comparison of demographic and surgical data. Kaplan-Meier survival analysis was used to determine the survival at 2 years for the study group and other hips operated during years 1993–2011. The results from the survival analysis are presented as percentages with 95% confidence intervals (CIs).

A binary logistic regression analysis was used. The cup order number representing the order in which individual designs had been introduced in each hospital was entered as a continuous variable into an unadjusted regression model. The cutoff values for cup order number were identified using cubic residuals from the regression model and Akaike information criteria (Akaike 1987). The order numbers of cups were categorized into 4 groups (0–120, 121–280, 281–600, and > 600). The data were then adjusted for age, sex, primary diagnosis (3 categories: primary osteoarthritis, femoral neck fractures, or other diagnosis), type of surgery (primary/revision), hospital type (4 categories: university hospital, county hospital, rural hospital, or private hospital), and method of cup fixation (cemented/uncemented). The results from the adjusted regression models are presented as odds ratios (ORs) with 95% CIs and p-values.

Ethics

The study was approved by the regional ethics review board in Gothenburg (reference number 720-14).

Results

In the study group, 7 cemented cup designs and 8 uncemented cup designs had been used (Table 2). The Contemporary Hooded Duration (Stryker, Newbury, UK) was the most frequently used cemented design and the Trilogy cup (Zimmer, Warsaw, IN) was the most commonly used uncemented design. There were 940 revisions during the first 2 years. The most common reason for revision was dislocation (n = 326), followed by infection (n = 279) (Table 3). The most common reasons for isolated acetabular revision (n = 358) were dislocation (n = 199), infection (n = 55), and aseptic loosening (n = 48) (Table 4).
Using revision for any reason as endpoint, the unadjusted 2-year survival for the study population was 98.2% (CI: 98.1–98.3), and for all other hips it was 98.6% (CI: 98.5–98.6). Corresponding figures using isolated acetabular revision (excluding infections (n = 303)) were 99.4% (CI: 99.3–99.5) and 99.6% (CI: 99.6–99.6), respectively.

The overall risk of revision, adjusted for differences in baseline demographics was not influenced by the order number of the cup (OR = 1.0; p = 1.0) (Table 5). The overall risk of revision within 2 years was lower in females (OR = 0.7; p < 0.001). Patients with femoral neck fracture had a higher risk of revision (OR = 2.5; p < 0.001). The overall risk of revision was higher in patients who were operated with an uncemented design (OR = 1.4; p < 0.001) and in patients with first-time cup revisions (OR = 1.8; p < 0.001). In isolated acetabular revisions, the order number of the cup had no influence on the outcome (OR = 1.0; p = 0.68) (Table 5).

The splines suggested an increased risk for the first 120 cups and in cups implanted with order numbers 280–600. In the regression analyses, use of these limits as cutoff values did not result in any statistically significant changes in the risk of revision within 2 years (p ≥ 0.2) (Table 6).

**Discussion**

We studied 15 newly introduced cup designs used in 52,903 primary THAs and first-time cup revisions, which were

### Table 3. Reasons for all revisions performed during the first 2 years

| Reason for revision | n | % |
|---------------------|---|---|
| Dislocation         | 326 | 35 |
| Deep infection      | 279 | 30 |
| Periprosthetic fracture | 118 | 13 |
| Aseptic loosening   | 99  | 11 |
| Technical reasons   | 95  | 10 |
| Other reason        | 23  | 2  |
| **Total**           | 940 | 100|

### Table 4. Reasons for isolated cup revisions performed during the first 2 years

| Reason for revision | n | % |
|---------------------|---|---|
| Dislocation         | 199 | 56 |
| Deep infection      | 55  | 15 |
| Aseptic loosening   | 48  | 13 |
| Technical reasons   | 38  | 11 |
| Periprosthetic fracture | 6   | 2  |
| Other reason        | 12  | 3  |
| **Total**           | 358 | 100|

### Table 5. Adjusted binary logistic with revision within 2 years as endpoint. Cup order number has been entered as a numerical variable

| All revisions regardless of reason (n = 904) | Isolated cup revisions, excluding infections (n = 303) |
|---------------------------------------------|--------------------------------------------------|
| Age                                         | Sex                                              |
| 1.0 1.0–1.0 0.6                             | Male ref                                        |
| 0.7 0.6–0.8 < 0.001                         | Female ref                                      |
| 2.5 2.0–3.0 < 0.001                         | Primary osteoarthritis ref                      |
| 1.5 1.3–1.9 < 0.001                         | Femoral neck fracture ref                       |
| 1.8 1.4–2.1 < 0.001                         | Surgery ref                                     |
| 1.3 1.0–1.6 0.04                           | University ref                                  |
| 1.0 0.9–1.2 0.6                            | County ref                                      |
| 0.9 0.7–1.1 0.2                            | Rural ref                                       |
| 1.3 1.0–1.6 0.04                           | Private ref                                     |
| 0.9 0.7–1.1 0.2                            | Cemented ref                                   |
| 1.4 1.2–1.6 < 0.001                         | Uncemented ref                                  |
| 1.0 1.0–1.0 1.0                            | Cup order number ref                           |
| **OR**                                      | **95% CI**                                      |
| 1.0 1.0–1.0 0.6                            | 1.0 1.0–1.0 0.5                                 |
| 0.7 0.6–0.8 < 0.001                        | 1.1 0.9–1.4 0.4                                 |
| 2.5 2.0–3.0 < 0.001                        | 2.9 2.0–4.1 < 0.001                             |
| 1.5 1.3–1.9 < 0.001                        | 2.1 1.5–2.8 < 0.001                             |
| 1.8 1.4–2.1 < 0.001                        | 3.5 2.6–4.6 < 0.001                             |
| 1.3 1.0–1.6 0.04                           | 1.3 1.0–1.8 0.03                                |
| 1.0 1.0–1.0 1.0                            | 1.0 1.0–1.0 0.7                                 |

**OR**: odds ratio; **CI**: confidence interval.

### Table 6. Adjusted binary logistic with revision within 2 years as endpoint. Cup order number has been categorized using cubic splines

| All revisions regardless of reason | Isolated cup revisions, excluding infections |
|-----------------------------------|---------------------------------------------|
| Age                               | Age                                         |
| 1.0 1.0–1.0 0.6                   | 1.0 1.0–1.0 0.5                             |
| 0.7 0.6–0.8 < 0.001               | 1.1 0.9–1.4 0.4                             |
| 2.5 2.0–3.0 < 0.001               | 2.9 2.0–4.1 < 0.001                         |
| 1.5 1.3–1.9 < 0.001               | 2.1 1.5–2.8 < 0.001                         |
| 1.8 1.4–2.1 < 0.001               | 3.5 2.6–4.6 < 0.001                         |
| 1.3 1.0–1.6 0.04                  | 1.3 1.0–1.8 0.03                            |
| 1.0 0.9–1.2 0.6                   | 1.0 0.9–1.6 0.2                             |
| 0.9 0.7–1.1 0.2                   | 0.8 0.5–1.1 0.2                             |
| 1.3 1.0–1.6 0.04                  | 0.9 0.7–1.3 0.8                             |
| 0.9 0.7–1.3 0.8                   | **OR**: odds ratio; **CI**: confidence interval.
would have therefore been of interest to determine the influence of individual surgeons, including their operative volume, and any effect of these factors on the risk of early revision. However, the main purpose of our study was not to analyze the learning curve of individual surgeons but rather—from a national healthcare standpoint—address any concerns associated with increased risk of revision when new acetabular designs are being introduced. A second limitation was that patient-reported outcome measures (PROMs) were not studied. With a survivorship of about 98% at 2 years for the contemporary prosthesis designs and with about 10% of patients not being fully satisfied 1 year after THA (Garellick et al. 2014), new implants being introduced should not only be measured according to their early risk of revision. Although the SHAR has been registering PROMs on THAs since 2002, the revision cases are not included in the PROMs program. Furthermore, in the cohort selected the number of cases with complete PROMs data in the SHAR was most probably too low for a meaningful analysis. In future studies, such an analysis might very well be worthwhile. Thirdly, it could be argued that comorbidity of patients might influence the surgeons’ willingness to perform a second intervention, making patient-reported outcomes (PROs) a more valid outcome measure. However, according to a publication from the New Zealand Joint Registry (Rothwell et al. 2010), there is a correlation between PROs and the rate of revision.

In summary, by analyzing more than 50,000 primary THAs and first-time revisions reported to the SHAR during the years 1993–2011, we found that the risk of revision within 2 years is not increased during the introduction phase of a new cup design. Our findings may partly be explained by the structured and stepwise introduction of implants in Sweden, facilitated by the continuous feedback given from the SHAR.

MM had the original idea for the study, processed the data, performed the statistical analyses, and prepared the first version of the manuscript. All the authors took part in planning of the study, in analysis and interpretation of the data, and in writing of the manuscript.

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