Comparison of dual-mobility cup and unipolar cup for prevention of dislocation after revision total hip arthroplasty

GONZALEZ, Amanda, et al.

Abstract

Background and purpose - Revision total hip arthroplasty (THA) is associated with higher dislocation rates than primary THA. We compared the risk of dislocation within 6 months and all-cause re-revision during the whole study period using either the dual-mobility cup or the unipolar cup. Methods - We used a prospective hospital registry-based cohort including all total and cup-only revision THAs performed between 2003 and 2013. The cups used were either dual-mobility or unipolar; the choice was made according to the preference of the surgeon. 316 revision THAs were included. The mean age of the cohort was 69 (25-98) years and 160 THAs (51%) were performed in women. The dual-mobility group (group 1) included 150 THAs (48%) and the mean length of follow-up was 31 (0-128) months. The unipolar group (group 2) included 166 THAs (53%) and the mean length of follow-up was 52 (0-136) months. Results - The incidence of dislocation within 6 months was significantly lower with the dual-mobility cup than with the unipolar cup (2.7% vs. 7.8%). The unadjusted risk ratio (RR) was 0.34 (95% CI: 0.11-1.02) and the adjusted RR was 0.28 [...]
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Comparison of dual-mobility cup and unipolar cup for prevention of dislocation after revision total hip arthroplasty

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Background and purpose — Revision total hip arthroplasty (THA) is associated with higher dislocation rates than primary THA. We compared the risk of dislocation within 6 months and all-cause re-revision during the whole study period using either the dual-mobility cup or the unipolar cup.

Methods — We used a prospective hospital registry-based cohort including all total and cup-only revision THAs performed between 2003 and 2013. The cups used were either dual-mobility or unipolar; the choice was made according to the preference of the surgeon. 316 revision THAs were included. The mean age of the cohort was 69 (25–98) years and 160 THAs (51%) were performed in women. The dual-mobility group (group 1) included 150 THAs (48%) and the mean length of follow-up was 31 (0–128) months. The unipolar group (group 2) included 166 THAs (53%) and the mean length of follow-up was 52 (0–136) months.

Results — The incidence of dislocation within 6 months was significantly lower with the dual-mobility cup than with the unipolar cup (2.7% vs. 7.8%). The unadjusted risk ratio (RR) was 0.34 (95% CI: 0.11–1.02) and the adjusted RR was 0.28 (95% CI: 0.09–0.87). The number of patients needed to treat with a dual-mobility cup in order to prevent 1 case of dislocation was 19.

The unadjusted incidence rate ratio for all-cause re-revision in the dual-mobility group compared to the unipolar group was 0.6 (95% CI: 0.3–1.4).

Interpretation — Use of a dual-mobility rather than a unipolar cup in revision THA reduced the risk of dislocation within 6 months.

Patients and methods

Study design and study population
We used a prospective hospital registry-based cohort. All consecutive total or cup-only revision THAs performed between February 1, 2003 and December 30, 2013 were included. The patients were followed to June 30, 2014. The revision THAs included are part of our institutional hip arthroplasty registry, which has prospectively collected all data concerning primary and revision THAs since 1996. Revised THAs with only the head or polyethylene revised were excluded—as was stem-only revision.

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116 revision THAs with a unipolar cup (group 2; 53%). At revision THAs with a dual-mobility cup (group 1; 47%) and THAs (51%) were performed in women. There were 150 had more than 1 revision THA during the study period). The exposure of interest was revision THA with either a dual-mobility cup or a unipolar cup. Both types of cups were available during the whole inclusion period. Being an observational study, the choice of the implant—dual-mobility or unipolar—was made according to the surgeon’s preference.

Dual-mobility cup implants included the Polarcup (Smith and Nephew, Aarau, Switzerland) and the Versafit Double Mobility cup (Medacta, Castel San Pietro, Switzerland). The Polarcup was available from 2003 and the Versafit Double Mobility cup from 2010.

The Polarcup system is composed of an acetabular shell coated with titanium plasma in the uncemented version and an uncoated stainless steel shell in the cemented one. The mobile insert used was made of crosslinked polyethylene (XLPE). To avoid dislocation, this cup device includes a 6° skirt under the half-sphere equator and a self-centering design in the liner.

The Versafit Double Mobility cup is composed of an acetabular shell coated with porous titanium in the uncemented version and an uncoated stainless steel shell in the cemented version. The mobile inserts used were composed of ultra-high-molecular-weight polyethylene (UHMWPE) or crosslinked UHMWPE (Highcross; Medacta). To provide an additional cover to the articulating liner, the upper edge has a shape of 5°.

Both systems have a 28-mm head (either ceramic or cobalt-chromium) that is locked to the polyethylene liner with a linear pressure tool.

The unipolar cups implanted included several models: cemented all polyethylene cups (Müller cup; Zimmer, Winterthur, Switzerland); non-cemented monobloc titanium mesh polyethylene or metal-on-metal cups (Morscher cup; Zimmer); modular metal cups with PE liners (Fittmore cup; Zimmer; and Versafitcup CC Trio; Medacta); and metal-on-metal large-diameter Durom cups (Zimmer). The diameters of the dual-mobility group whereas in the unipolar group head sizes of > 32 mm were used in 31% of cases.

The mean follow-up time for the entire cohort was 42 (0–136) months, with a mean follow-up time of 31 (0–128) months in the dual-mobility group and of 52 (0–136) months in the unipolar group. Within the first 5 years after surgery, 17 deaths occurred in the dual-mobility group and 19 occurred in the unipolar group. 2 patients were lost to follow-up in the dual-mobility group and 5 were lost in the unipolar group.

**Exposure**

The exposure of interest was revision THA with either a dual-mobility cup or a unipolar cup. Both types of cups were available during the whole inclusion period. Being an observational study, the choice of the implant—dual-mobility or unipolar—was made according to the surgeon’s preference.

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<table>
<thead>
<tr>
<th>Exposure</th>
<th>Dual-mobility</th>
<th>Unipolar</th>
<th>Mean/Risk difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>73 (11.1) 65 (15.2)</td>
<td>−7.9 (−11 to −4.9)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>26 (5.8) 26 (5.2)</td>
<td>−0.2 (−1.4 to 1.0)</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Mean operating time (SD), min</td>
<td>152 (60) 185 (69)</td>
<td>33 (19 to 48)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Women (%)</td>
<td>84 (56) 76 (46)</td>
<td>10 (−0.7 to 21)</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td>BMI ≥ 30 (%)</td>
<td>38 (25) 39 (24)</td>
<td>1.8 (−7.7 to 11)</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>Smoking status (%)</td>
<td>58 (46) 59 (52)</td>
<td>−6.5 (−19 to 6.1)</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>ASA score (%)</td>
<td>96 (64) 116 (70)</td>
<td>−5.9 (−16 to 4.5)</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Indication for revision (%)</td>
<td>1–2</td>
<td>−5.9 (−16 to 4.5)</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>3–4</td>
<td>54 (36) 50 (30)</td>
<td>6.7 (−5.7 to 13)</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>26 (17) 19 (11)</td>
<td>5.9 (−1.9 to 14)</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Previous THA revision (%)</td>
<td>38 (25) 36 (22)</td>
<td>6.7 (−5.7 to 13)</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Surgical approach (%)</td>
<td>117 (78) 118 (71)</td>
<td>6.7 (−5.7 to 13)</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>With osteotomy</td>
<td>68 (46) 43 (26)</td>
<td>6.7 (−5.7 to 13)</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Anterior Hueter</td>
<td>15 (10) 14 (8.4)</td>
<td>6.7 (−5.7 to 13)</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Antero-lateral</td>
<td>34 (23) 61 (37)</td>
<td>6.7 (−5.7 to 13)</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Polarity</td>
<td>Mean/Risk difference</td>
<td>p-value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aseptic loosening</td>
<td>51 (34) 76 (46)</td>
<td>−12 (−23 to −11)</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>Dislocation</td>
<td>41 (27) 17 (10)</td>
<td>17 (8.6 to 26)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>22 (15) 26 (16)</td>
<td>−1.0 (−8.9 to 6.9)</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Pain/impingement</td>
<td>4 (2.7) 19 (11)</td>
<td>−10 (−19 to −1)</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>Adverse local tissue reaction</td>
<td>7 (4.7) 7 (4.2)</td>
<td>0.3 (−3.6 to 4.2)</td>
<td>0.9</td>
<td></td>
</tr>
<tr>
<td>Periprosthetic fracture</td>
<td>17 (11) 11 (6.6)</td>
<td>4.7 (−1.6 to 11)</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3 (2.0) 5 (3.0)</td>
<td>−1.0 (−4.4 to 2.4)</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Head size (%)</td>
<td>150 (100) 114 (69)</td>
<td>31 (24 to 38)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>≤ 32 mm</td>
<td>32 (22) 26 (15)</td>
<td>6.0 (−4.7 to 16)</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>&gt; 32 mm</td>
<td>118 (78) 98 (58)</td>
<td>6.0 (−4.7 to 16)</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Acetabular reinforcement ring (%)</td>
<td>53 (35) 77 (46)</td>
<td>−11 (−22 to −0.3)</td>
<td>0.05</td>
<td></td>
</tr>
</tbody>
</table>

**Table 1. Baseline characteristics of the dual-mobility and unipolar THAs**

316 revision THAs in 281 patients were included (35 patients had more than 1 revision THA during the study period). The mean age of the entire cohort was 69 (25–98) years, and 160 THAs (51%) were performed in women. There were 150 revision THAs with a dual-mobility cup (group 1; 47%) and 166 revision THAs with a unipolar cup (group 2; 53%). At baseline, the 2 groups differed significantly in the mean age at revision and in main indications for revision (Table 1). Mean operation time was 152 (35–320) min in group 1 and 185 (48–400) min in group 2. The main causes of revision in the dual-mobility group were recurrent dislocation (27%) and aseptic loosening (34%). Aseptic loosening was the main indication for revision in the unipolar group (46%) whereas dislocation was the indication for revision in only 10%. A previous revision THA had already been performed in 25% of patients in the dual-mobility group as compared to 22% in the unipolar group. In the revision surgery, all heads used were ≤ 32 mm in size.
prosthetic heads used with these cups varied from 28 mm to 36 mm, with standard cups to large-diameter metal heads in cases of Durom cups.

Outcomes
The primary outcome was the occurrence of a dislocation within 6 months of revision THA surgery with either a dual-mobility cup or a unipolar cup. The secondary outcome was occurrence of re-revision for any reason during the whole study period.

Covariates
The following baseline characteristics were assessed: (1) sex, (2) age, (3) smoking status (ever-smoker vs. never-smoker), (4) preoperative BMI, (5) American Society of Anaesthesiology (ASA) score (grade 1–2 vs. 3–4), (6) diabetes, (7) previous revision THA surgery, (8) operating time, (9) surgical approach, and (10) indication for revision. Surgical approach was classified as trochanter/femur shaft osteotomy vs. no osteotomy. The subgroup without osteotomy included the following approaches: posterior, anterior Huetter, and antero-lateral. Indications for revision included aseptic loosening, recurrent dislocation, infection, pain, impingement, adverse local tissue reaction, periprosthetic fracture, and other.

Data collection
The operating surgeons routinely documented data regarding the preoperative status and the surgical intervention on specifically designed data collection forms. Information regarding patient comorbidities was routinely collected from the anesthesia records and the patient discharge summary. All the information on patient- and operation-related covariates was collected routinely in the Geneva Arthroplasty Registry. All surgery-related complications and their management were routinely documented in the registry during follow-up. Our institution is a large tertiary hospital, and the only public hospital in the canton (Swiss county). Thus, the vast majority of the revision THA patients included in this study who had a dislocation or required a re-revision were treated at our institution. Information on change of residency or death was obtained from the population registry of the canton.

Statistics
For the statistical analyses, patient- and surgery-related covariates were compared between the dual-mobility group and the unipolar group. For continuous variables, mean and standard deviation (SD) are reported. For categorical variables, frequency distributions are reported. Mean differences and 95% confidence intervals (CIs) were calculated for continuous variables, and risk differences with CIs were calculated for categorical variables. To compare the incidence of the primary outcome (dislocation within 6 months) between the 2 groups, we calculated the unadjusted risk ratio (RR) with CIs. The adjusted RR with CIs was obtained using the generalized linear model for the binomial family. Adjustment was done for age and sex.

The number needed to be treated (NNT) to prevent 1 case of dislocation was calculated based on the unadjusted risk difference (RD).

To estimate the occurrence of all-cause re-revision in the 2 groups, incidence rates were calculated and expressed in cases per person-year. We calculated the person-time at risk for re-revision as the length of the interval between date of surgery for the revision hip arthroplasty and the date of either re-revision for any reason, death, leaving the area of residency, or end of follow-up (June 30, 2014). Survival analysis with the endpoint all-cause re-revision was performed using the Kaplan-Meier method, and the log-rank test was used to compare the survival distributions. We also did a competing-risk analysis (taking death into account as a competing event) and estimated an unadjusted sub-hazard ratio (Fine and Gray 1999).

Finally, we performed a subgroup analysis and evaluated the primary and secondary outcome including only the first revision THA.

The statistical analyses were performed using the statistical packages PASW statistics version 18 and STATA version 8.

Ethics
The study was approved by the ethics committee of our institution (reference no. CER: 05-017 (05-0419)).

Results
The risk of dislocation within 6 months (Table 2) after revision surgery was substantially lower in the dual-mobility group than in the unipolar group (2.7% and 7.8%, respectively). The unadjusted RR was 0.34 (CI: 0.11–1.02; p = 0.06). After adjustment for age and sex, the RR was 0.3 (CI: 0.09–0.9; p
The dislocation risk in the dual-mobility group within 6 months was similar to that in published case series. In these studies, involving between 29 and 163 revision THAs with a dual-mobility cup, the reported short-term risk of dislocation (within 6 weeks to 6 months after revision THA) varied between 2% and 4% (Vasukutty et al. 2012, Saragaglia et al. 2013, Philippot et al. 2009). Moreover, in a French prospective cohort study involving 2,107 revision THAs, of the 62% with a dual-mobility cup, the overall dislocation rate was 4% during the first 3 months (Delaunay et al. 2013). Good medium-term results have also been reported with the dual-mobility cup. In a recent large series evaluating 994 revision THAs, a dislocation rate of 1.5% at a mean follow-up time of 7.5 years was reported (Wegrzyn et al. 2015).

Intra-prosthetic dislocation has been reported with the dual-mobility cup (Philippot et al. 2013), but we did not observe any such cases in the present study. It is known that the risk of dislocation is highest in the first months after primary THA as well as after revision THA (Philips et al. 2003), and prevention of dislocation is of importance—particularly in the context of revision THA. Our results show that the use of a dual-mobility cup substantially reduced the incidence of dislocation.

Patient-related factors such as older age, a high number of comorbidities, previous THA revision, recurrent dislocation as an indication for revision, and surgery-related factors such as surgical approach have been associated with an increased risk of dislocation (Carter et al. 2011, Hailer et al. 2012b, Wetters et al. 2013, Stulberg 2011, Brooks 2013). Although the baseline characteristics of the dual-mobility group predisposed them to an even higher dislocation risk than the unipolar group, the unadjusted risk observed was lower. After adjustment for age and sex, the risk ratio remained in favor of the dual-mobility cup.

Taking all-cause re-revision as endpoint, the Kaplan-Meier analysis revealed a 4-year survival of 91% (CI: 79–96) for dual-mobility THAs. The occurrence of re-revision in the dual-mobility group observed in our study is consistent with published data from the Swedish Hip Arthroplasty Registry (Hailer et al. 2012a), which included 228 revision THAs. In that study, at a median follow-up time of 2 years, the occurrence of re-revision among THAs revised for recurrent dislocation with a dual-mobility cup was 8% (18/228); and a survival of any component for any reason of 89% at 4 years was reported. Considering only revision for failure of the dual-mobility cup as endpoint, reported survival rates ranged from 95% to 100% at 5 years in case series involving 50–155 revision THAs ( Vasukutty et al. 2012, Langlais et al. 2008, van Heumen et al. 2015). The dual-mobility cup has 2 articulations, the metal cup with the polyethylene liner and the polyethylene liner with the head; these bearing surfaces on the convex and concave sides of the system are exposed to wear (Adam et al. 2005). During our study period, re-revision for aseptic loosening occurred more

### Discussion

We found that the risk of dislocation within the first 6 months after revision THA was substantially reduced with the use of a dual-mobility cup rather than a unipolar cup. Regarding all-cause re-revision and survival within the first 4 years after surgery, we did not observe an increased risk in patients who were treated with the dual-mobility cup.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dual-mobility (n = 150)</th>
<th>Unipolar (n=166)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aseptic loosening</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Infection</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Dislocation</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Periprosthetic fracture</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Persistent pain</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Impingment</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

The unadjusted risk difference (RD) was −5 (−10 to −0.3; p = 0.04). The number of patients needed to be treated with a dual-mobility cup in order to prevent 1 case of dislocation was 19.

During the study period, 7 revision THAs in the dual-mobility group required re-revision at a mean follow-up time of 16 (1–46) months; of those, re-revision was total in 1, cup-only in 2, head-only in 1, and stem-only in 1. 2 had a 2-stage prosthesis exchange. In the unipolar group, 21 revision THAs required re-revision at a mean follow-up time of 31 (0–97) months. The incidence rate for all-cause re-revision during the follow-up was 18 and 29 cases per 1,000 person-years for the dual-mobility group and the unipolar group, respectively, and the unadjusted incidence rate ratio was 0.6 (CI: 0.3–1.4). Indications for re-revision for the 2 groups are given in Table 3.

In the sensitivity analyses including only the first revision THA, the unadjusted RD for dislocation within 6 months postoperatively was more pronounced by −8% (CI: −13 to −2.5; p = 0.006). The unadjusted incidence rate ratio for re-revision was 0.5 (CI: 0.2–1.3) for the dual-mobility group vs. the unipolar group.

Considering re-revision for any reason as endpoint, the Kaplan-Meier analysis revealed similar survival at 4 years after surgery in the 2 groups: 91% (CI: 79–96) in the dual-mobility group and 90% (CI: 83–94) in the unipolar group (log-rank test, p = 0.2). The proportion of patients who died was similar in the 2 groups. Within the first 5 years after surgery, 17 deaths occurred in the dual-mobility group (11%) and 15 occurred in the unipolar group (9%). 2 patients were lost to follow-up in the dual-mobility group and 5 were lost to follow-up in the unipolar group. Taking death into account as a competing event, the sub-hazard ratio was 0.5 (CI: 0.2–1.2).

### Table 3. Indication for re-revision

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dual-mobility (n = 150)</th>
<th>Unipolar (n=166)</th>
</tr>
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<tr>
<td>Aseptic loosening</td>
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<td>1</td>
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<tr>
<td>Impingment</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
often in the unipolar group than in the dual-mobility group (5% and 0.7%, respectively). However, the follow-up was short in both groups. The implementation of the dual-mobility cup started in 2003 and progressed, while the unipolar cup was already widely in use, thus explaining the shorter mean follow-up time for the dual-mobility group. An in vitro study has shown satisfactory performance of the dual-mobility bearing (Loving et al. 2015), but the results may be different in vivo. A review on the use of dual-mobility cups in THA revealed a lack of long-term results concerning wear and aseptic loosening (Grazioli et al. 2012). The potentially enhanced risk of aseptic loosening with the use of dual-mobility cups due to polyethylene liner wear must be considered when implanting the dual-mobility cup in younger and active patients. In fact, differences have been reported in revision for aseptic loosening between patients younger and older than 50 years in primary THAs using a dual-mobility cup (Boyer et al. 2012).

Our study had several limitations. First, the number of outcome events was small, leading to large confidence intervals. Secondly, concerning our second endpoint (all-cause re-revision), a larger sample size and longer follow-up are required. Thirdly, because of the observational nature of the study, bias—and particularly confounding by indication—was an important limitation when comparing the dual-mobility with the unipolar revision THAs. We attempted to minimize it by adjusting for age and sex. It should also be noted that the dual-mobility cup group was at a disadvantage regarding their risk of dislocation because the surgeons chose to use it specifically in high-risk patients, as illustrated by the distribution of the baseline characteristics between the 2 groups. Fourthly, as this was a non-experimental study, different types of dual-mobility and unipolar implants were freely available to the surgeon during the whole inclusion period. Stratification by type of implant in each group and subgroup comparison analyses were not performed due to sample-size restrictions. And finally, data on cup positioning and degree of soft-tissue damage, which are both known risk factors for dislocation (Lewinnek et al. 1978, Charissoux et al. 2014) were not analyzed. This may have led to residual confounding.

In summary, the use of the dual-mobility cup rather than the unipolar cup in revision THA substantially reduced the risk of dislocation within 6 months. The number of patients needed to be treated with a dual-mobility cup in order to prevent 1 case of dislocation was 19. Moreover, we did not observe an increased risk of re-revision for any reason or any survival disadvantage within the first 4 years after surgery associated with the use of the dual-mobility cup.

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