Two-year radiologic assessment of the Trident Peripheral Self-Locking cup using EBRA

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ABSTRACT: We performed a radiologic assessment of the Trident Peripheral Self-Locking cup 2 years after implantation to assess early migration behaviour and to establish if incomplete postoperative seating correlated with early instability. A retrospective analysis of 30 cases was performed using EBRA. No cups had acetabular screws. Average total migration was 1.5 mm (range 0.1 to 5.9 mm). Seventeen showed total migration >1 mm and 7 of these showed further migration >2 mm (range 2.3 to 5.9 mm). Twenty cups demonstrated incomplete seating on initial post-operative radiographs (mean 1.4 mm, range 0.3 to 3.0). No relationship between incomplete seating and migration was identified (p = 0.86). The majority of gaps consolidated at differing times within the 2 year period. Oxford Hip scores showed significant improvement after surgery (p = 0.001) and this was independent of migration (p = 0.76). At 5 years there were no revisions for aseptic loosening.

Conclusion: The majority of the cups demonstrated early radiographic instability, and this was not related to incomplete seating. Five-year functional outcome appears good and independent of migration and initial seating.

KEY WORDS: Trident, PSL, Early migration, EBRA

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INTRODUCTION

The migration of uncemented total hip components in the first two years after surgery as detected by EBRA (Ein-Bild-Roentgen-Analyse) has been shown to be a good predictor of later aseptic failure (1-3). The Trident hip system has been marketed since 1999. It offers peripherally self-locking (PSL) and hemispherical options. The peripheral self-locking cup is designed to maximise fixation at the peripheral lunate of the acetabulum and has not yet been the subject of any migration study.

EBRA is a simple method of measuring component migration using sequential antero-posterior radiographs of the pelvis (4). It has proven accuracy and sensitivity in detecting migration of more than 1 mm when compared to RSA (Roentgen Stereophotogrammetric analysis) (5, 6). Unlike RSA it can be performed retrospectively. It is hypothesised that incomplete cup seating would lead to instability and effect early migration behaviour. The aims of this study were to investigate the early migration rate of the Trident cup, assess the effect of incomplete seating on cup migration and to establish whether either factor affected clinical outcome.

MATERIALS AND METHODS

This was a retrospective radiologic analysis using EBRA (University of Innsbruck, Austria) (4). All Trident PSL cups (Stryker, Kalamazoo Michigan USA) implanted between October 2005 and June 2006 were identified and includ-
Early migration of Trident peripheral self-locking cups

Radiographs were nominally taken two days after operation then at three, twelve and twenty-four months follow-up. For each patient, post-operative antero-posterior pelvic radiographs, stored in the Picture-Archiving-System (KODAK), were imported into the EBRA software and assessed. Cup migration was calculated in both x (horizontal) and y (vertical) axes. A graph was produced plotting migration over time in each axis (Fig. 1) and total migration calculated using Pythagorean geometry. Non-comparable radiographs were excluded by the software. Furthermore, any patient who either had one radiograph missing or had a radiograph that did not show the appropriate landmarks had to be excluded from the analysis. The 95% confidence limit for EBRA results is 1.0 mm for longitudinal and 0.8 mm for transverse migration (4). The usual threshold for significant migration is 1 mm but studies have used 2 mm particularly for the femoral stem (3).

Post-operative films were assessed for incomplete seating. Visible gaps were measured using the PACS line measurement tool after calibration against the known femoral head size. Measurements were taken along a radial line at the point where the distance between the cup and the acetabulum was widest (which was frequently located around the central pole of the cup).

Demographic data and Oxford Hip Scores were taken from the case notes. Oxfords scores were collected and reported using the original method with best score at 12 and worse score 60. The head and cup sizes used for calibration were taken from the operation notes and implant stickers. The notes were also reviewed for relevant details that might affect migration such as the used of acetabular screws and bone quality.

All statistical analysis was completed using SPSS 17.0 (IBM Corporation, Somers, NY, USA). Fisher exact test was used to assess migration and the presence of incomplete seating, T-test was used to compare Oxford Hip scores and Chi-squared test was used to analyse gap sizes and time to consolidation.

RESULTS

During the inclusive period 57 Trident PSL cups were implanted. Of these 14 had incomplete sets of radiographs, 1 did not show the required landmarks in the pelvis, 6 had non-comparable radiographs and 6 were lost to follow up. Therefore a total of 27 patients were excluded from the study. Of the remaining 30 patients 13 were female and 17 were male. Mean age was 61 years (range 36-84 years) and mean Body

Fig. 1 - A) EBRA graph with no migration in both x and y axis. The first vertical line is the immediate post operative radiograph, followed by 3, 12 and 24 months. Each horizontal line is equal to 1 mm. B) EBRA graph showing medial migration in the x-axis but none in the y-axis.
Mass Index was 30.7 (range 19.6-40.7). Operations were undertaken by 5 surgeons. All cups were implanted using the posterior approach and line-to-line reaming per manufacturer’s recommendation. There were no intra-operative concerns regarding stability of the cups prior to closure. None of the cups had acetabular screws. All the cups were implanted in combination with a cemented Exeter stem. The bearing surface combination was ceramic-on-ceramic in 21, metal-on-polyethylene in 6 and ceramic-on-polyethylene in 3. The post-operative regime for all patients was full weight bearing immediately after operation.

The average total migration for the series was 1.5 mm (range 0.1 to 5.9 mm). Seventeen showed total migration of more than 1 mm and seven of these showed further migration of more than 2 mm (range 2.3 to 5.9 mm) (Tab. I).

Twenty cups showed incomplete seating with a visible gap between the cup and the acetabulum on the immediate post-operative radiograph (Fig. 2). The gap measurements ranged from 0.3 mm to 3.0 mm (mean 1.4 mm). These were arbitrarily divided into less than 2 mm (range 0.3 to 1.8) and 2 mm or more (range 2.3 to 3.0) (Tab. I).

There was no relationship between polar gap and migration of >1 mm (p = 0.86) or migration of >2 mm (p = 1.00).

Fourteen of the 20 polar gaps had fully consolidated on twelve month radiographs and a further 3 had consolidated at twenty-four months. Three cups still showed visible gap on the twenty-four month radiographs. The gap size did not correlate with consolidation time (p = 0.49).

The average preoperative Oxford Hip score was 45 (range 29 to 58) and improved to a mean score of 17 at 2 years after surgery (range 12 to 44). This improvement was statistically significant (p = <0.001). The two-year Oxford Hip scores were not significantly different between those that exhibited migration and those that did not (p = 0.768). At 5 years, there was no further improvement in the Oxford Hip score (mean 16.6, range 12-31). Between 2 years and 5 years there was not any further significant improvement in clinical scores, p = 0.324 (Tab. II). The case exhibiting

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**TABLE I - TOTAL MIGRATION VS. INCOMPLETE SEATING ON THE INITIAL POST-OPERATIVE RADIOGRAPH**

<table>
<thead>
<tr>
<th>Fully seated</th>
<th>Gap &lt; 2 mm</th>
<th>Gap ≥2 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>No migration</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Migration &gt;1 mm</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Migration &gt; 2 mm</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>15</td>
</tr>
</tbody>
</table>

**TABLE II - TOTAL MIGRATION VS. OXFORD HIP SCORES**

<table>
<thead>
<tr>
<th>Average Oxford Score</th>
<th>No migration (n = 13)</th>
<th>Migration &gt;1 mm (n = 10)</th>
<th>Migration &gt;2 mm (n = 7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative</td>
<td>46</td>
<td>44</td>
<td>44</td>
</tr>
<tr>
<td>2 years</td>
<td>18</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>5 years</td>
<td>19</td>
<td>16</td>
<td>15</td>
</tr>
</tbody>
</table>
the largest migration in the series (5.9 mm) was functioning well at 5 years with an Oxford Hip score of 12. At 5 years follow-up there had been no revisions for aseptic cup loosening. There was one revision for infection and one for aseptic loosening involving the stem. Two patients had died and three were lost to follow-up.

DISCUSSION

Early migration of total hip arthroplasty components within the first two years of has been linked to later aseptic failure (1-3). Various factors have been cited to be related to early migration i.e. cup size, the presence of radiolucency between the cup and bone as well as high wear rate (7-9). Using 1 mm as the threshold for significant migration, Stockle et al reported a 48% (30/63) migration rate in the first two years with the Duraloc cup 100 series with a mean total migration of 1.13 mm (10). With the same strict criteria our migration rate was similarly high at 56% (17/30) with 7 cups migrating further beyond 2 mm. Migration beyond 2 mm have been previously correlated to post-operative radiolucency in DeLeey-Charnley Zone 1 (7). In our series, two-thirds of the cups showed lucency due to incomplete seating in the immediate post-operative radiograph but we were not able to show a correlation between this observation and increased migration.

Although it is not within the scope of this study to determine the exact cause of incomplete seating, we speculate this could be due to a number of factors such as variation in surgical technique, instrument design, reamer sizing, cup size selection and bone quality. The Trident PSL cup is 1.8 mm wider than that the stated size. This is designed to achieve interference fit at the periphery of the implant as the product name implies. The manufacturer advises however that this amount of interference fit is not always necessary depending on the quality of bone stock (Trident Acetabular System PSL Surgical Protocol 2009). Thus, intraoperative judgement is required to determine the appropriate amount of reaming that is necessary to fully seat the implant and achieve adequate primary stability. In addition a previous in-vitro study performed in our department showed that the seating force required for the PSL cup was 20% higher than for the hemispherical design when tested on high density substrate (unpublished). The same study also highlighted the discrepancy between the stated size of the Trident reamer and the actual size of the reamed cavity which on average was 1 mm smaller. The combination of the above factors may have contributed to the observed incidence of incomplete seating in this series. Regardless of the cause, incomplete seating did not seem to adversely affect migration in this subgroup compared to those that were fully seated, and the majority of gaps eventually consolidated, albeit at a different time. Also It was noted that none of the cups in this series had acetabular screws; however, in the absence of a control group, it is difficult to say that this is the probable cause of the high migration rate in this cohort.

Overall despite the radiologic appearances, clinical scoring did not show significant difference between the cups that migrated and those that did not, and at 5 years, there had not been any revision for aseptic cup failure. In conclusion, this study shows that a significant portion of Trident PSL cups undergo migration in the first 2 years but patients continue to function well at five years. Additionally there was no correlation observed between migration and the presence of incomplete seating on immediate postoperative radiographs.

The biggest limitation of this study was the low sample size. Although the initial cohort size seemed acceptable, the lack of standardised high quality pelvic AP radiographs limited the final number of subjects that could be included in this study. Thus the study might be underpowered with the possibility of a type 2 errors.

We recommend a larger sized long-term prospective study to better define the migration behaviour and eventually the survivorship of this relatively new yet very popular implant.

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