Abstract

Aims: The aim of this study was to determine the stability of a novel short femoral stem compared with a conventional femoral stem following cementless total hip arthroplasty (THA), in a prospective, randomized, controlled trial using radiostereometric analysis.

Methods: Fifty-three patients were randomized to receive cementless THA with either a short femoral stem (MiniHip) or a conventional length femoral stem (MetaFix). 26 patients received the short stem and 23 received the conventional stem. All patients received the same cementless acetabular component. Two-year follow-up was available on 38 patients. Stability was assessed via migration and dynamically inducible micromotion. Radiographs for radiostereometric analysis were taken post-operatively and at three, six, 12, 18 and 24 months.

Results: At two years, there was significantly less subsidence (inferior migration) of the short femoral stem (head: 0.26mm; 95% confidence interval [CI] +/-0.18; SD 0.38; tip: 0.11mm; 95% CI +/- 0.19; SD 0.42) compared with the conventional stem (head: 0.62mm, 95% CI +/-0.28, SD 0.56, *P*=0.02; tip: 0.43mm, 95% CI +/-0.22, SD 0.44, *P*=0.03). There was no significant difference in dynamically inducible micromotion.

Conclusion: This study demonstrates that the short femoral stem has a stable and predictable migration. However, longer-term survival analysis remains important.

Introduction

Cementless femoral stems are used in over 40% of primary total hip arthroplasties (THAs) performed in the UK[1]. The stems achieve stability through biologic bone ongrowth and have resulted in excellent long-term outcomes[2]. However, conventional cementless stems that have meta-diaphyseal or primarily diaphyseal fixation may lead to proximal stress shielding and a progressive reduction in proximal bone mineral density (BMD)[3,4]. Documented clinical consequences are thigh pain, higher incidence of periprosthetic fractures and more challenging revision procedures[1,5–7].

Short femoral stems that achieve cementless fixation in the femoral neck or proximal metaphysis were developed to allow more physiological, proximal bone loading[8]. Increased bone stock is preserved during their implantation, which may be advantageous at revision surgery. Concerns persist, however, that the reduced potential area for bony anchorage of short stems may be insufficient to provide adequate primary implant stability. Increased progressive migration of the femoral stem may result, which is associated with aseptic loosening and implant failure[9,10]. This was observed in a number of early short stem designs[11].

Novel short stem implants that preserve increased femoral neck bone stock were developed following *in vitro* work that demonstrated that increased preservation of the femoral neck provides increased resistance of the femoral stem to torsional loads[12]. One such implant is the MiniHip femoral stem (Corin, Cirencester, Gloucestershire, UK, figure I). Composed of titanium with a hydroxyapatite surface, the stem is designed to achieve stability through three-point fixation via the femoral neck, calcar and lateral femoral cortex. Manufacturer studies suggest the MiniHip design results in equivalent clinical outcomes at five years when compared to conventional stems.[13] Evidence predicting longer-term clinical success would be of benefit in guiding ongoing clinical use.

Early stem migration predicts later loosening and implant failure[9]. Radiostereometric Analysis (RSA) is the most accurate method of measuring migration of an implant relative to the host bone, with a detection threshold of approximately ten-fold superior to plain radiographs[14]. There is no formal consensus on the maximum acceptable limit of migration. Karrholm *et al*[10] suggested a maximum migration threshold of 1.0mm at two years, although this was largely derived from studies on cemented stems. Subsidence of 1.4mm at two years has been reported in a cementless stem with excellent long-term survival.[15]

This study aims to evaluate the two-year migration behaviour of the MiniHip short-stem femoral implant following cementless THA as compared with a conventional length femoral implant. Our hypothesis was that the MiniHip implant would not have a significantly higher migration pattern as compared with the conventional implant in vivo.

Methods

Power calculation

A power calculation was performed before commencing the study using the method of Altman[16]. A difference of interest of 1.0mm was chosen based on the work of Kärrholm *et al*[10], who suggest that an early migration of cementless stems within two years greater than this value is associated with increased risk of clinical failure. A standard deviation of 0.96mm was selected based on previous RSA studies[17]. The power calculation indicated that a total of 40 subjects was required (α=.05, β=.9). To account for 20% loss to follow-up, a sample size of 48 was targeted. This study was constructed as a non-inferiority study.

Patient selection

Fifty-three patients were recruited for this study from a routine NHS waiting list. Inclusion criteria were male and female patients between the ages of 18 and 80; diagnosed with hip osteoarthritis; scheduled to a hip replacement; with sufficient bone quality in the surgeons' opinion to receive a

cementless hip replacement; able and willing to give consent for participation and to comply with study requirements. The exclusion criteria applied to this study were: any other hip pathology, femur or pelvis deformity, and any significant disease that would impact the subject's ability to participate in study follow-up; only patients meeting inclusion criteria were approached for recruitment. The local ethics committee approved the study protocol (REC number 12/SC/0483) and informed consent was obtained from participants before the study commenced.

Prior to surgery, subjects were randomized to receive either a MiniHip stem (n=26) or a Metafix stem (n=27) during cementless THA. The MetaFix femoral stem (Corin) is a conventional length tapered femoral stem and has achieved >95% survival rate at five-year follow-up.[1] It is composed of titanium with a hydroxyapatite surface, and achieves fixation in the distal metaphysis and diaphysis. The collarless MetaFix stem has three femoral neck offset options available to facilitate restoration of natural biomechanics; the MiniHip stem has only one offset length available. Randomisation was carried out using SPSS 23 (IBM, Armonk, New York, USA); subjects were stratified by age and gender. There was no significant difference in age (Student's *t*-test, *P*=0.75) or weight (*P*=0.35) of the two groups at the time of surgery (Table I). Two patients were excluded at preoperative imaging: one had metastatic disease (MetaFix group) and one required cemented THA due to poor bone quality (MiniHip group). One patient withdrew on the day of surgery (MetaFix group). Patients were blinded to the type of implant inserted; blinding of surgeons and investigators was not possible.

Four surgeons operated on both groups over an 18-month period from March 2013 in a single centre. All operations were performed through a postero-lateral approach with the patient in the lateral position. All 50 subjects who underwent surgery received a cementless titanium Trinity acetabular shell (Corin) with a vitamin E-stabilized highly cross-linked polyethylene ECIMA liner (Corin). One patient, due to receive a MetaFix stem, suffered a calcar crack during surgery and the procedure was converted to the implantation of a cemented TaperFit femoral stem. One patient, due to receive a MetaFix stem, received a MiniHip stem, due to intra-operative communication error. This patient was included in the MiniHip group for analysis. 26 patients received a MiniHip implant and 23 patients received a collarless Metafix implant. Subjects underwent routine postoperative rehabilitation.

Follow-up data from 11 patients could not be obtained as a result of poor x-ray quality in three patients (tantalum beads were not visible on radiographs), of insufficient tantalum bead insertion due to intra-operative equipment malfunction in three patients, and because three patients were lost to follow-up, one patient became ill and withdrew, and one patient underwent revision surgery. This left 20 patients in the MiniHip group and 18 patients in the Metafix group who were followed up for two years. The CONSORT flow diagram is shown (Figure II).

Radiostereometric analysis

Our RSA system was used to assess the migration of the prostheses relative to the bone in three dimensions, and has been previously described.[18] The femoral coordinate system is established by implanting three 0.8mm tantalum beads at three standardized anatomical sites on the femur (greater trochanter, lesser trochanter, and distal to the tip of the prosthesis) during surgery. Stereo radiographs were taken postoperatively and at three, six, 12, 18 and 24 months, with patients weight-bearing equally on both legs and standing in a calibration frame that contained radio-opaque markers. Additional stereo radiographs were taken at six months with patients transferred from a double leg stance (DLS) to a single leg stance (SLS) on the implanted limb in order to permit investigation for dynamically inducible micromotion at the implant-bone interface. X-ray beams were angled at approximately 60^{o} to each other and perpendicular to films.

From the image of the calibration cage on the films, the position of the x-ray sources and films was determined in space. The position of the bone marker balls and implants was determined. Markers were not attached to the implants because geometric algorithms were used instead. To define the centre of the femoral head, at least six points were digitized around the periphery of the head, and the centre was determined automatically. Circles were fitted to the implant tip on both x-rays. A line was constructed from the centre of the tip circles to the centre of the head. A perpendicular to this line was produced one third of the way from the tip to the head. The points on the edge of the implant stem where it was crossed by this perpendicular were digitized, and the midpoint of these was defined as the centre of the stem. A line, known as the stem axis, was dropped from the stem centre to the centre of the tip circle, and the point where this passes through the end of the implant was defined as the tip. The relative three-dimensional positions of the prosthesis and the host bone were calculated. Analysis was performed by one author (SGJ) with RSA expertise.

Migration of the implant at the head centre and the tip was determined by comparing its position in post-operative and subsequent radiographs. Migrations are presented in the anatomical co-ordinate system (antero-posterior, x; mediolateral, y; supero-distal, z). Total migrations of the head and tip were calculated by the equation $\sqrt{(x^2 + y^2 + z^2)}$, where x, y and z represent the three orthogonal Cartesian axes.

In a previous study using an old calibration frame, to assess the accuracy of the system we repeated the stereo radiographs in seven patients on two separate occasions.[19] For ethical reasons, we have not repeated this study, but we reanalysed the radiographs with the new equipment. We express accuracy as two standard deviations of the differences between the positions of the implant. For the head of the prosthesis, the accuracy was 0.33 mm proximally to distally, 0.24 mm medially to laterally, and 0.22

mm anteriorly to posteriorly. We expect the accuracy to be better with the improved calibration frame used in this study.

Bone Mineral Density (BMD) was measured by dual-energy x-ray absorptiometry (DEXA; Lunar iDXA, GE Healthcare, Boston, Massachusetts, USA) preoperatively and at 12-months postoperatively. Patients were positioned supine with knee and foot supports to ensure a neutral femur position. The Orthopaedic Software Package (GE Healthcare) was used by an author (RJF) to measure the BMD preoperatively in the femoral neck and postoperatively in seven Gruen zones[20]. Femoral offset, defined as the distance between the centre of the femoral head and long axis of the femur, was measured on anteroposterior radiographs of the pelvis were taken pre- and postoperatively, using a previously described technique[21].

Clinical outcomes were assessed using the Oxford hip score (OHS) preoperatively and at 2-years post-surgery. These data were collected pre-operatively and at each post-operative review by a research nurse (AH). The OHS is a patient-completed 12-item health questionnaire designed to assess function and pain, scored from 0 (worst) to 48 (best).[22] Comparisons were made between groups using both the post-operative raw OHS score and change in OHS score.

Statistical Analysis

Migration data were examined for distribution, visually using frequency histograms and by the Shapiro-Wilks test. Data were found to be normally distributed, allowing parametric statistical tests to be used (MiniHip, P=0.06; Metafix, P=0.61). The one-sample t-test was used to detect significant deviations of the mean movement from zero migration. The independent-sample t-test without assumption of equal variances was used to detect significant differences between the two groups. Bonferroni corrections were performed to account for multiple testing. The results from the OHS were shown to be not normally distributed and therefore the non-parametric Mann-Whitney U test was used for these statistical analyses. All calculations were performed using SPSS 23. A p-value $\leq$0.05 was considered to be significant.

Results

After one year, the mean subsidence of the head and tip for the MiniHip stem were 0.16 mm (one sample t-test, P=0.15) and 0.08 mm (t-test, P=0.43) respectively, and for the MetaFix stem were 0.45 mm (t-test, P=<0.01) and 0.41 mm (t-test, P=<0.01) respectively (Table II). Between one and two years, there was a small amount of further mean subsidence measured for each stem which was not significant. Mean subsidence was significantly different between the two stems at two years post-operatively

(independent sample *t*-test, head *P*=0.02, tip *P*=0.03; Figure III and IV). There was no significant dynamically inducible micromotion at six months for either stem (Table III).

There was no significant difference in mean femoral neck BMD between stems preoperatively (independent sample t-test, *P*=0.10) (Table IV). There was no significant correlation between preoperative BMD and migration at two years for either stem. At 12-months postoperatively, the BMD in Gruen zone two was significantly lower for the MiniHip stem (1.07IU) compared to the Metafix stem (1.86IU; *P*=<0.001); there was no significant difference in BMD in all other Gruen zones.

The pre- to post-operative change in mean femoral medial offset was 0.87cm (SD 0.80cm) for the Metafix stem and 1.45cm (SD 0.84cm) for the MiniHip stem (*P*=0.03). The mean pre-operative OHS was similar for both stems (Mann-Whitney U test, *P*=0.33). There was no significant difference in OHS or improvement in OHS at two years between the stems. Mean OHS at two years was 44.6 (SD 6.6) for the MiniHip stem compared with 45.0 (SD 6.4) for the Metafix stem (*P*=0.68), with improvement in OHS of 23.6 (SD 8.1) for the MiniHip stem compared with 24.1 (SD 10.0) for the Metafix stem (*P*=0.90). Two patients with the MiniHip stem reported pain (one mild, one moderate) and two patients with the MetaFix stem reported pain (one mild, one moderate) at two years. No MetaFix implants were revised during the study period. One MiniHip implant was revised at 21 months, due to acetabular periprosthetic fracture.

Discussion

We compared the migration of a new short femoral stem with that of a proven conventional stem design in a prospective, randomized, controlled trial.

Our results demonstrate that migration of both stems was well within the acceptable early (two-year) migration limit for cementless stems suggested by Kärrholm *et al*[10]. The MiniHip stem underwent significantly less subsidence than the MetaFix stem two years after THA. The subsidence of the MetaFix stem is comparable to equivalent long-stem cementless devices[23]. The lower subsidence in the MiniHip stem suggests that the device is stable, upholding the design philosophy that proposed that stability would be achieved through three-point fixation, with contact at the femoral neck, calcar and lateral femoral cortex. There was negligible (<0.4mm) antero-posterior migration in both stems. Similar migration has previously been observed in conventional stems[17]. This suggests that both devices are able to resist torsional forces across the implant in the axial plane.

Dynamically inducible micromotion is believed to contribute to failure of femoral implants through the generation of raised fluid pressures, which leads to osteolysis. The absence of micromotion indicates successful osseointegration. At six months, there was no significant dynamically inducible

micromotion in both stems. Mean mediolateral micromotion of MetaFix stem was 0.8mm (*t*-test, *P*=0.02); however, having applied the Bonferroni correction, this result was found to be not significant. These data suggest that both devices were stable and osseointegration had occurred in all subjects.

One MiniHip implant required revision surgery due to a loose acetabular component after 21 months, with conversion to a hybrid prosthesis. There was no evidence of significant MiniHip migration prior to revision surgery, with head and tip subsidence of 0.69 and 0.07mm respectively at 18-month RSA. The MiniHip stem was well fixed at the time of surgery and there was no evidence of implant failure or loosening.

There are a growing number of RSA studies reporting data on cementless short femoral stems; however, the designs and migrations patterns of the stems vary considerably. The Nanos and Metha stems belong to the same groups of partial neck-sparing short stem implants as the MiniHip stem. A study of the Nanos stem reported subsidence of 0.22 ±0.39mm[24], comparable to the MiniHip stem, whilst a study of the Metha implant reported a higher subsidence of 0.7 ±0.4mm[25]. The CFP implant belongs to the same group of partial neck-sparing short stem implants; however, it has a collar which may affect migration. Indeed, CFP stem subsidence was reported as 0.05 ±0.06mm in one study of 26 hips and 0.13 ±0.15mm in a second study of 30 patients[26,27]. The CUT prosthesis, meanwhile, has an ultra-short stem design and resulted in higher subsidence of 0.92mm at one year[28]. The MiniHip stem therefore compares well to other collarless cementless short femoral stems.

The Oxford Hip Score outcome measured in this study was not different between groups, although our study was not powered to detect this. A recent report comparing the performance-based outcomes of a taper fit short stem, of similar design to the MiniHip stem, with a conventional length femoral component also found comparable OHS outcomes.[29] Our study showed no significant difference in the incidence of post-operative thigh pain between the MetaFix stem (10.5%) and the MiniHip stem (9.5%) at two years. Previous studies have reported similar incidences of thigh pain after cementless THA using conventional stems (8%) and short stems (8%).[30,31]

The MiniHip stem resulted in a greater post-operative increase in femoral offset compared to the Metafix stem. Although an increase in femoral offset is associated with improved muscle strength, greater range of movement and lower wear rate[32,33], it is also linked to increased medial bending load and risk of trochanteric pain[34]. The desired change in femoral offset remains controversial; current consensus is that restoration of pre-operative biomechanics through accurate anatomical reconstruction of the physiological femoral offset appears advantageous. A drawback of the design of short femoral stems may be that because they cannot offer different femoral neck offset options, successful restoration

of biomechanics is more difficult to achieve. Furthermore, previous literature has suggested that because short femoral stems lie in a more varus position, an increase in femoral offset is more likely[35].

Bone mineral density in Gruen zone two was 42% lower in the MiniHip group compared to the MetaFix group at 12-months, but not different in other zones. A previous study of the MiniHip reported greatest BMD loss in zones one and seven, and suggested it was due to stress-shielding of the proximal zones.[36] No investigation of the degree of change in BMD post-operatively was possible because patients only underwent one post-operative DEXA scan. It is unclear why BMD was lower in the MiniHip group in zone two, though may represent differential loading between the two implant types.

Implantation of short femoral stems requires a technically more demanding broaching technique due to the altered geometry. This may in part explain the higher rate of malalignment, most commonly due to excessive varus positioning, and of intraoperative fracture reported amongst short stem designs[37,38]. There were no cases of malalignment in this study. We report one case of intra-operative femoral calcar fracture in the MetaFix group; however, our sample size is too small to calculate fracture rate.

We note several limitations. Follow-up with RSA was limited to two years. Whilst implants appeared to stabilize between the first and second years, it is not possible to predict future migration. Additionally, the late mechanisms of failure of this implant design are not yet known, meaning long-term survival predictions are limited. Longer-term follow-up is required in investigate whether the reduced BMD of Gruen zone two leads to increased fractures. Of the cohort who underwent surgery, 10% was lost to follow-up and 12% had RSA radiographs that were inadequate, and were therefore excluded from analysis.

This study demonstrates that the MiniHip short stem has a stable and predictable migration. This suggests that the device is stable from 12 months following implantation. It is therefore likely to have an equivalent medium to long-term survivorship to more conventional longer stem cementless stems.

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