Primary stability of a proximally coated and tapered stem: a two-year radiostereometric analysis

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Aims

The aim of this prospective cohort study was to evaluate the early migration of the TriFit cementless proximally coated tapered femoral stem using radiostereometric analysis (RSA).

Methods

A total of 21 patients (eight men and 13 women) undergoing primary total hip arthroplasty (THA) for osteoarthritis of the hip were recruited in this study and followed up for two years. Two patients were lost to follow-up. All patients received a TriFit stem and Trinity Cup with a vitamin E-infused highly cross-linked ultra-high molecular weight polyethylene liner. Radiographs for RSA were taken postoperatively and then at 3, 12, and 24 months. Oxford Hip score (OHS), EuroQol five-dimension questionnaire (EQ-5D), and adverse events were reported.

Results

At two years, the mean subsidence of the head and tip for the TriFit stem was 0.38 mm (SD 0.32) and 0.52 mm (SD 0.36), respectively. The total migration of the head and tip was 0.55 mm (SD 0.32) and 0.71 mm (SD 0.38), respectively. There was no statistically significant differences between the three to 12 months' migration (p = 0.105) and 12 to 24 months' migration (p = 0.69). The OHS and EQ-5D showed significant improvements at 2 years

Conclusion

The results of this study suggest that the TriFit femoral stem achieves initial stability and is likely to be stable in the mid and long term. A long-term outcome study is required to assess late mechanisms of failure and the effects of bone mineral density (BMD) related changes.

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Introduction

Cementless femoral stems were introduced in the 1980s to address the problems of cement fixation, including osteolysis from cement and wear particles, fat embolism, and difficulty removing cement at revision surgery.[1-3] Cementless femoral stems now account for over 40% of primary total hip arthroplasties (THAs) performed in the UK[4], with many designs achieving excellent long-term outcomes.[4,5] However, cementless designs are not without complications and early revision is more common in cementless designs across all age groups, reaching statistical significance in those aged over 65 years.[4,6] The major causes of revision in cementless stems are periprosthetic fracture, dislocation, and thigh pain. These may result caused in part from reduced proximal loading leading to stress shielding and reduced proximal bone mineral density (BMD).[7] Cementless stem designs with proximal metaphyseal fixation and greater proximal loading have been introduced in recent years to address this potential problem. Proximal metaphyseal fixation was developed to allow more proximal bone loading and reduced subsidence and micromotion, therefore improving initial primary stability of the cementless stem.[8]

One of these implants is the Trifit femoral stem (Corin Group, UK). Literature from the manufacturer describes a short, proximally coated stem with a reduced lateral shoulder and narrow

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Table I. Migration of the landmarks of the Trifit at three, 12, and 24 months. Mann-Whitney U test p-values show the difference to baseline postoperative radiostereometric analysis.

Migration	0 to 3 mths			0 to 12 mths			0 to 24 mths		
	Mean	95% CI	p-value	Mean	95% CI	p-value	Mean	95% CI	p-value
Head, mm									
Anterior	-0.07	-0.18, -0.32	0.131	-0.07	-0.21 , 0.07	0.382	-0.08	-0.22 , 0.07	0.332
Medial	-0.12	-0.45 , -0.70	0.224	-0.11	-0.28 , 0.06	0.244	-0.08	-0.18, 0.01	0.110
Inferior	-0.15	-0.29, -0.54	0.041	-0.31	-0.46, -0.14	0.001	-0.38	-0.23, -0.52	0.001
Total	0.45								
Tip, mm									
Anterior	-0.03	-0.31, 0.24	0.491	-0.12	-0.25, 0.02	0.110	-0.12	-0.25, 0.02	0.112
Medial	0.02	-0.33, 0.37	0.761	-0.13	-0.32, 0.06	0.211	-0.16	-0.33, 0.009	0.084
Inferior	-0.46	-0.99, 0.07	0.001	-0.46	-0.61, -0.30	0.001	-0.52	-0.35, -0.67	0.001
Total	0.63								

There was significant improvement in Oxford Hip Score (OHS) between baseline and 24 months' follow-up (Mann-Whitney U test, $p < 0.001$). The median OHS at baseline was 12 points (95% confidence interval (CI) 8.47 to 14.19), which increased significantly to 39 points (95% CI 32.66 to 42.188) at two years. The EuroQol five-dimension questionnaire (EQ-5D) showed improvement in mobility ($p < 0.001$), activity level ($p < 0.001$), pain ($p < 0.001$), anxiety, and overall health VAS score ($p < 0.001$) between baseline and 24 months. However, there was no statistically significant difference in EQ-5D self-care ($p = 0.082$) or anxiety ($p = 0.346$) between baseline and 24 months.
CI, confidence interval.

triple taper geometry designed to minimize the amount of bone removal.[9] The stem is polished distally to prevent osseointegration and to encourage load transfer proximally. The stem subsidence and early migration has not been studied previously. Evidence predicting longer-term clinical success would be of benefit in guiding ongoing clinical use.

Since 2002, manufacturers in the UK have used the Orthopaedic Data Evaluation Panel (ODEP) rating to benchmark their hip prosthesis against agreed standards. The TriFit stem has an ODEP 5A rating, indicating a low revision rate at five years.[10] However, early surveillance data are less reliable in predicting the long-term success of products.[10] Radiostereometric analysis (RSA) remains the gold standard method for measuring early stem migration relative to host bone, which in turn predicts loosening and implant failure.[11] The maximum acceptable limit of migration for cementless stems is unclear, however migration less than 1 mm at two years has been associated with good long-term functional and clinical outcomes.[12,13]

The aim of this two-year prospective study was to evaluate the early migration of the TriFit cementless proximally porous-coated tapered femoral stem using RSA, and to use this information to predict stability in the long term. The study hypothesis was that the Trifit implant would not have significant migration at two years, which predicts good long-term survival.

Methods

This is a two-year prospective cohort study of the migration of the proximally coated cementless tapered wedge TriFit femoral stem using RSA. All patients were recruited from a routine public waiting list, and all surgery was performed by two consultant arthroplasty surgeons in a single unit. Any patient between the age of 18 and 80 years with a diagnosis of osteoarthritis and an ability to complete study follow-up was asked to participate. Patients with complex disease or deformity, significant comorbidities, or those requiring revision surgery were excluded from the study. The local ethics committee approved the study protocol (REC number 15/SC/0268) and informed consent was obtained from the participants before the study commenced. A total of 21 patients (eight male and 13 female) undergoing primary THA for osteoarthritis of the hip were initially recruited in this study. The median age at the time of surgery was 55 years (41 to 72). The median body mass index was 27.1 kg/m^2 (19.9 to 35.7). Nine were ex-smokers and three were still smoking. Two patients were lost to follow-up. One patient with inadequate insertion of the RSA beads could not be included in the RSA analysis but was included in the clinical outcome analysis. This left a total of 19 patients (seven male and 12 female) for inclusion in the RSA analysis.

All patients received a cementless, proximally coated double-wedged, tapered femoral stem (TriFit: Corin Group) and a porous titanium acetabular shell (Trinity; Corin Group UK). The bearing was a vitamin E-infused, irradiated, and highly cross-linked ultra-high molecular weight polyethylene liner (ECIMA liner; Corin Group, UK) coupled with either a 32 mm or 36 mm cobalt-chromium or Biolox δ ceramic femoral head (Ceramtec, UK). The size of the femoral head was decided by the operating surgeon.

Tantalum beads (0.8 mm diameter) were inserted into the greater trochanter, the lesser trochanter, and at the distal end of the femoral stem using a specialized bead gun inserter. Our RSA system has been previously described, and has a clinical accuracy of 0.1 mm in three dimensions.[14]

All surgery was performed using a posterolateral approach. After dislocation and resection of the femoral neck, the femoral canal was opened and broached in incremental sizes in a stepwise fashion using bone-preserving broaches. Correct stem size was judged by fill of the calcar area, rotational stability, and proper seating of the broach. Acetabular preparation and implantation were performed with a standard press-fit technique, with a cup size 1 mm larger than the final reamer. All patients received intravenous (IV) antibiotics at induction and VTE prophylaxis as per our institution policy.

All patients had postoperative RSA radiographs as soon as they were able to stand after surgery, which served as the baseline comparator for subsequent images taken at three, 12, and 24 months postoperatively. Radiographs were taken with the

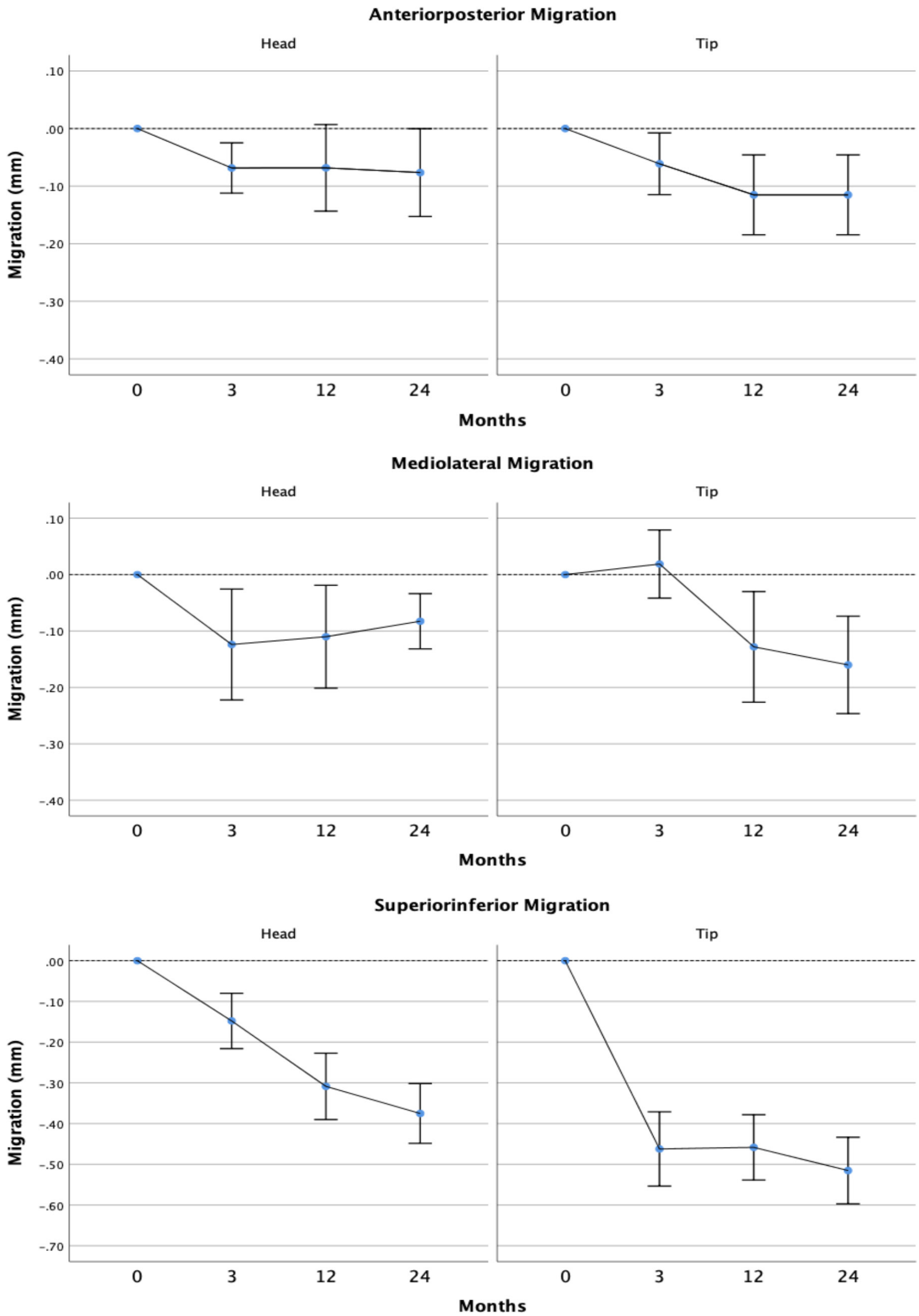

Fig. 1

Migration of the head and tip of the TriFit stems in three planes at two years postoperatively. Standard error bars are displayed.

patient standing in a calibration frame that contained accurately positioned radio-opaque markers. Radiograph beams were angled at approximately 60º to each other and perpendicular to the films. The position of the radiograph tubes and films were reconstructed from the images taken. In order to ensure no bone markers had moved, their movement relative to each other was determined. As previously reported, geometrical algorithms were used to determine the position of the implants without the need for marker balls.

The primary outcome was migration of the femoral stem, which was determined by comparing the position of the prosthesis in the postoperative image with the position in subsequent radiographs and presented in the anatomical coordinate system (anteroposterior, x; mediolateral, y; superoinferior, z).

In addition, the total movements of the head and the tip were calculated by the equation $\sqrt{(x^2 + y^2 + z^2)}$, where x, y, and z represented the motion along three orthogonal Cartesian axes.

The secondary outcomes were Oxford Hip Score (OHS)[15], EuroQol five-dimension questionnaire (EQ-5D), adverse events, and revision rate. The OHS and EQ-5D were assessed preoperatively and at 24 months post-surgery. The OHS is a patient-centred 12-item health questionnaire designed to assess function and pain and is scored from 0 to 48, with 48 representing the best score and 0 the worst. The EQ-5D English version is used to study quality of life metrics. Adverse events and revisions were documented at each follow-up and reported in this study. RSA data analysis was performed independently of the clinical outcome measures analysis.

Statistical analysis. A power calculation was performed before commencing the study using the Altman nomogram method[16] and the methods set by Valstar et al[17] to detect significant migration of 1.0 mm at two years, which is associated with increased risk of early failure.[12,17] The power calculation indicated that a total of 16 subjects were required ($\alpha = 0.05$, $\beta = 0.9$). To account for loss to follow-up, a sample size of 18 was targeted. This is in keeping with most RSA total hip studies, which report a minimum sample size of around 12 to 15.[13,17]

The migration data were visually examined for distribution using frequency histograms and the Shapiro-Wilks test. They were found to be non-normally distributed for head, middle, and tip total subsidence (p = 0.003, p = 0.17, and p = 0.01, respectively), allowing non-parametric statistical tests to be used. The Mann-Whitney U test was used to detect significant deviation of mean movement from zero migration at baseline. The Kruskal-Wallis test was used to detect significant deviation between the 3, 6, and 12 months follow-up groups, with Dunn's post hoc test used to determine which groups differed from each other group. The results from the OHS were also shown not to be normally distributed, and therefore the non-parametric Mann-Whitney U test was used for these statistical analyses. All calculations were performed using SPSS v25 (IBM, Armonk, New York, USA). A p-value ≤ 0.05 was considered to be significant.

Results

The mean subsidence of the head and tip for the TriFit stem at one year was 0.31 mm (SD 0.35) and 0.46 mm (SD 0.35), respectively. The total migration of the head and tip was 0.59 mm (SD 0.37) and 0.62 mm (SD 0.62), respectively. After two years, the mean subsidence of the head and tip for the TriFit stem was 0.38 mm (SD 0.32) and 0.52 mm (SD 0.36), respectively. The total migration of the head and tip was 0.55 mm (SD 0.32) and 0.71 mm (SD 0.38), respectively.

There was a statistically significant difference (p = 0.027) between the mean ranks of at least one pair of the three, 12, and 24 months follow-up groups. Dunn's pairwise tests were carried out for the three pairs of groups. There was no statistically significant difference between the three to 12 months migration (p = 0.105) and 12 to 24 months migration (p = 0.69). There was a significant difference between three and 24 months migration (p = 0.037). The median migration at three months was -0.52 mm (95% confidence interval (CI) -0.2 to -0.07) compared to -0.11 mm (95% CI - 0.26 to -0.13) and -0.13 mm (95% CI -0.28 to -0.15) at 12 and 24 months, respectively.

The migration on the XYZ orthogonal Cartesian axes was analyzed using the Kruskal-Wallis test. This showed a statistically significant difference (p < 0.001) between the mean ranks within the axis's measurements. Dunn's pairwise tests showed that the stem migration was not different in X (anteroposterior) and Y (mediolateral) (p = 0.602). However, there was significant difference in the X (anteroposterior) and Z (superoinferior) migration (p < 0.001). The migration on Y (mediolateral) and Z (superoinferior) was also different (p < 0.001). Table I shows the result of migration at each follow-up point three, 12, and 24 months in comparison to baseline postoperative RSA. The only notable head migration was the inferior migration at three, 12, and 24 months (p = 0.04, p < 0.001, and p < 0.001, respectively). This was also the case in tip inferior migration (p < 0.001 in all follow-up). The 24 months head median inferior migration was -0.43 mm (95% CI -0.62 to -0.43) and stem tip median inferior migration was -0.51 mm (95% CI -0.75 to -0.51).

During the study period, one patient had pain and swelling postoperatively due to encapsulated haematoma confirmed by ultrasound scan. This had resolved completely by the three months' postoperative review. One patient had pain following a fall before the three months' follow-up. A radiograph confirmed an avulsion of the anterosuperior corner of the greater trochanter. The stem and cup were stable and no excessive subsidence was observed. The pain resolved at six months' follow-up. One patient had slight wound erythema, which was treated in primary care with amoxicillin. The wound healed completely with no evidence of infection. There were no dislocations and no revisions during the study period.

Discussion

The cementless femoral stem analyzed in this study is based on a clinically proven proximally coated triple-tapered geometry.[7,18,19] Specific design modifications of the TriFit include a reduced lateral shoulder, shorter length, and narrow geometry to minimize the amount of bone removed...[9]

RSA evaluation of new stem design is an important predictor of clinical longevity.[17] Although there are several tapered proximally coated stem designs in the UK National Joint Registry with good outcomes, their data cannot be used as surrogate for a new stem design.[4] Minor modifications to implant design may adversely affect implant stability and long-term survivorship. For example, seemingly minor changes to the Charnley Elite stem led to reduced eight-year survival from 95% to 60%.[20,21] The use of RSA is therefore an invaluable tool to help address these concerns and predict long-term survival.[11,22,23]

This study demonstrates that the TriFit stem has a predictable subsidence within the first 12 months following implantation. The maximum subsidence occurs within the first 12 months and it seems to plateau after this, with no significant migration between 12 and 24 months (Figure 1). As with previous RSA studies of cementless stems, the majority of the migration was inferior (subsidence), with small amounts of migration in other planes.[24,25] There was a small but significant posterior head migration and lateral tip migration as the implant subsided within the first 12 months.[25] The majority of the migration occurred within the first three months, suggesting that the stem achieved good primary stability.

Previous studies have proposed migration thresholds for cementless stems between 1 mm and 2.7 mm at two years, above which the risk for revision significantly increases.[11,26,27] This initial subsidence is attributed to a settling-in period, and may facilitate osseointegration and long-term fixation and stability.

The results of our RSA study of the TriFit hip at two years are encouraging, and confirm total migration of less than 0.63 mm at two years. The low subsidence of the TriFit stem suggests that the device is stable and upholds the design principle of achieving stability through three-point fixation with contact at the femoral neck, calcar, and lateral femoral cortex. The negligible anteroposterior migration (0.12 mm) suggests that the device is able to resist torsional forces across the implant in axial plain. This proven short-term stability is suggests that the TriFit implant is likely to be stable in the long-term.

There are a growing number of RSA studies reporting data on cementless proximally coated short femoral stems; however, the designs and migration patterns of the stems vary considerably.[7,8,18,19,25] Early proximally coated stems such as the ANL and APC systems did not have superior outcomes to cemented prostheses, with early loosening and thigh pain.[28] More modern implants with improved geometry have shown better survival and clinical outcomes. A study of the IPS stem (Depuy Synthes, USA) reported subsidence in 12 out of 72 hips, with an average of 4 mm in all cases[29] The Taperloc stem (Zimmer Biomet, USA) showed a subsidence of 0.03 mm with no significant change over time, although four out of 39 stems showed > 1.5 mm subsidence by year one.[24] In the present study, the TriFit stem subsidence was 0.52 mm at two years, with excellent patient reported outcome measures (PROMs). The Trifit therefore compares well to other collarless cementless short femoral stems.

The OHS measured in this study significantly improved in this study comparing to baseline. This was also mirrored by an improvement of EQ-5D domains. There were no cases with continuing thigh pain as has been evident in some other cementless hip stems.[29,30] The PROMs data from this study also support the short term benefit of the TriFit system.

There are limitations of this study that need to be considered. The insertion of Tantalum beads into the stem at the time of manufacturing, rather than our method of bead insertion into bone, would have allowed for the measurement of stem rotation and modelling of the entire stem, rather than relying on the femoral head alone. However, concerns about altering the integrity of the implant with this technique have been previously cited in the past.[14] Secondly, several patients did not receive RSA films until up to one week or so after surgery following discharge from hospital and therefore some of the initial stem subsidence in these cases may not have been captured. Finally, the mean and median age of the subjects of this study were slightly younger than those of other studies reporting on implant migration.[22,24,31] Bone quality is related to age, and implant stability is affected by bone quality. As such, the results of a younger population with potentially better bone quality may bias the results of this study. The late mechanisms of failure of this implant design are not yet known, meaning long-term survival predictions are limited and longer-term follow-up is required to investigate whether age-related BMD changes lead to increased risk of periprosthetic fracture or instability. Of the cohort who underwent surgery, 9% were lost to follow-up and 4% had inadequate RSA radiographs that were inadequate, and were therefore excluded from analysis. However, the study remained sufficiently powered.

The TriFit femoral component does not migrate significantly within two years of implantation, and its migration compares favourably with other cementless designs. The results of this study suggest that the implant is likely to be stable in the mid and long term. A long-term outcome study is required to assess late mechanisms of failure and the effect of BMD related changes.

Take home message

- The TriFit femoral stem achieves initial stability up to 24 months
- The stem is likely to be stable in the mid and long term.
- A long -term outcome study is required to assess late mechanisms of failure and the effects of bone mineral density (BMD) related changes.

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