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ORIGINAL STUDY

Achievement of Primary stability using 3D-CT guided custom design femoral stems in patients with proximal femoral deformity : EBRA-FCA analysis

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Hip replacement in patients with proximal femoral deformity and end stage arthrosis is technically challenging. The purpose of this study was to measure the subsidence rate of custom femoral stems using EBRA-Femoral Component Analysis (FCA) software, as an indicator of achievement of primary stability. We retrospectively reviewed 14 hips in 12 consecutive patients who underwent this procedure between June 2008 and Feb. 2011. There were 7 males and 5 females with a mean age 41 years (22-60). The primary diagnosis in the majority of the cases was Perthes and DDH with secondary osteoarthritis. The average follow up period was 36 ± 10 months (19-51 months). Average subsidence was the 0.96 mm ± 0.95mm (0-2.9 mm). All patients had signs of osteointegration at the metaphyseal level. We conclude that the 3D-CT guided custom made femoral stem produces reliable proximal 'fit and fill' and osteointegration without the need of a corrective osteotomy in patients with proximal femoral deformity but long term studies are needed to assess the performance of this femoral stem.

Key words : Custom design femoral stem, EBRA-FCA, primary stability

INTRODUCTION

There is no doubt that total hip replacement (THR) in patients with proximal femoral deformity and end stage arthrosis is technically challenging (*6*). The abnormal location of the hip centre of rotation, the intra / extramedullary bony deformity, and the soft-tissue contractures may lead to various intra-operative difficulties and a consequentially higher complication rate (*5, 13*).

A number of different approaches have been utilised to overcome these difficulties, including the use of miniaturised cemented implants (*23*), a subtrochanteric osteotomy to accommodate a standard stem (*24*), the use of modular or circular cross section stems (*2*), or using a custom-designed femoral components (*3*).

Achieving primary stability is a fundamental prerequisite for secondary bony in growth and long-term fixation when using an uncemented stem (*6*). This can be achieved in those patients with deformed proximal femur by either using an 'off the

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shelf' modular implant with the possible need for an osteotomy (*3, 14, 20*), or custom design femoral prosthesis to conform to the anatomic shape of the bone (*5, 6*).

Adequate metaphyseal 'fit & fill' and proximal load bearing is essential to prevent stress shielding, and is difficult to achieve while using uncemented 'off the shelf' implants in conjunction with an osteotomy. In addition, restoration of the extramedullary parameters like anteversion, offset, leg length and neck-shaft angle can also be difficult (*6, 21*).

Satisfactory outcome of performing THR in patients with proximal femoral deformity necessitates precise preoperative preparation to ensure success. Each case is unique and requires a distinct plan to address the intra and extra medullary deformity (*14*).

In our cohort of patients ; we used three dimensional (3D) CT guided custom design, proximally coated uncemented stems to match the patients' anatomy in order to achieve adequate metaphyseal fixation and restore the extramedullary parameters.

The aim of the study was to assess the achievement of primary stability using these custom design femoral stems and to assess the osteointegration of the stem.

PATIENTS AND METHODS

We retrospectively reviewed 12 patients (14 hips) who underwent this procedure between June 2008 and Feb 2011. The study group comprised of 7 males and 5 females with a mean age at the time of surgery of 41 years (*22-60*). The mean follow up period was 36 ± 10 months (range 19-51). No patients were lost to follow up. This study was approved by the Hospital Audit department.

All patients presented with advanced hip osteoarthritis (grade 3 according to TÖnnis classification) and proximal femoral deformity. The primary diagnosis was Perthes disease in 9/14 hips, hip dysplasia in 4/14 hips, and post traumatic arthritis in 1/14 hips. Previous proximal femoral osteotomy was performed in 7/14 hips. One patient had previous acetabular osteotomy (1/14 hips).

All patients were examined clinically and radiologically with plain radiographs and then further assessment was made by a CT scan. The scan was performed according to a CT protocol prescribed by Symbios Hip Plan™, Symbios, Yverdon les Bains, Switzerland. The CT protocol involves 1mm slices from top of the iliac crest to the isthmus of the femur, 2mm slices from top to the bottom of femoral condyles and top and bottom of the ankle joint. The intra and extra medullary parameters were assessed in 3D planes. The deformity was assessed to determine whether an 'Off the shelf implant' will achieve metaphyseal 'fit & fill' and stability without needing a corrective osteotomy. If the deformity was deemed unsuitable for an 'off the shelf' implant then a custom femoral stem was designed to achieve metaphyseal 'fit and fill', primary stability and to correct the extra medullary parameters. The metaphyseal intramedullary volume was assessed using Hip Plan Software™. This volume was used to design the metaphyseal part of the stem. The fit was assessed by the software algorithm simulation to demonstrate stability. (Fig 1)

The resultant custom implant was made of Ti Alloy and had proximal hydroxy apatite coating. The diaphyseal part of the implant was smooth, uncoated and is designed not take part in load transfer or osteointegration. The implant came with an operative plan to guide the neck osteotomy site, and with its own bone compacting or bone removing rasp according to the intramedullary cortical or cancellous bony architecture indicated by the 3D-CTplan.

All the procedures were performed by five specialist trained Arthroplasty surgeons using the anterolateral or posterior approach to the hip with the patient in the lateral position. The Uncemented custom Ti-alloy stem with proximal hydroxyapatite (HA) coating (Symbios, Yverdon-Les-Bains, Switzerland) was used in all patients. (Figs 2, 3)

Postoperative rehabilitation protocol included immediate full weight bearing with elbow crutches and active range of movement and muscle strengthening exercises.

In addition to a clinical review and oxford hip scoring, all patients had post- operative radiographs and were reviewed regularly at 6 weeks, 6 months

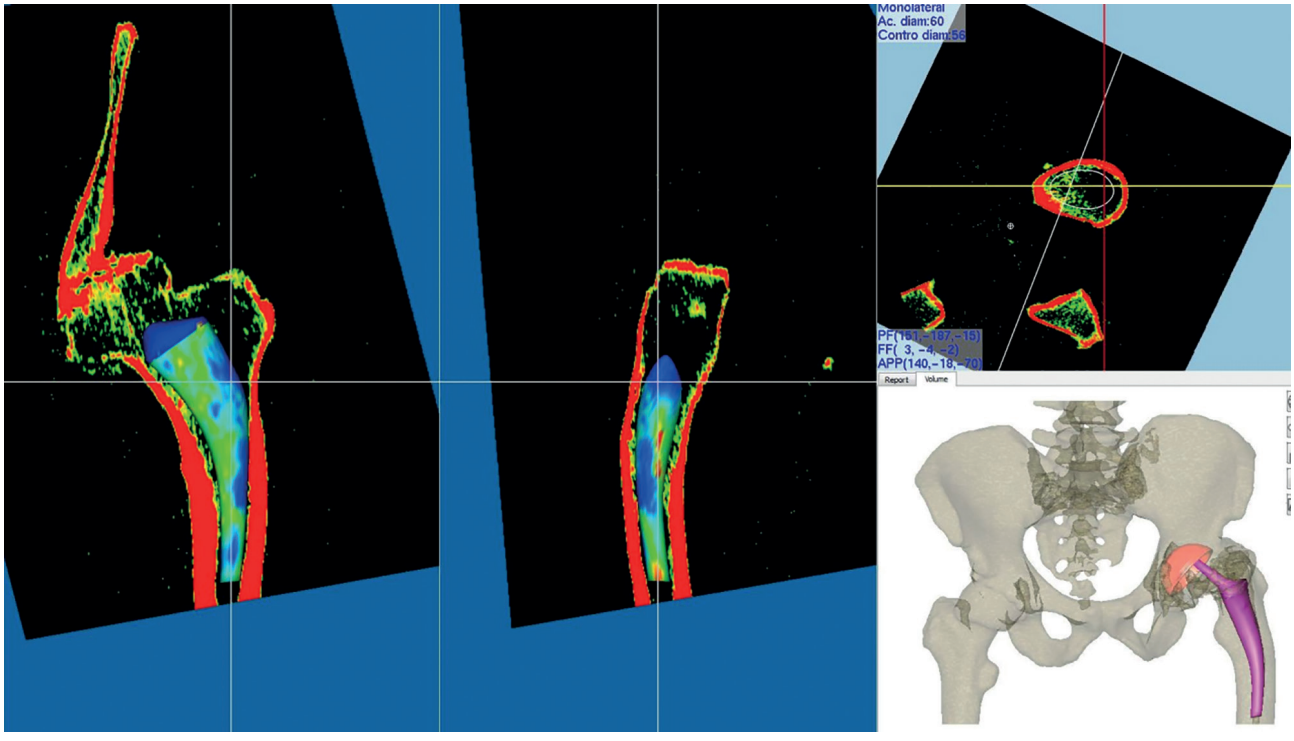

Fig. 1. — Screen shot of 'Fit and fill 'assessment in coronal, saggital, transverse planes and 3 D rendering from Hip PlanTM Software

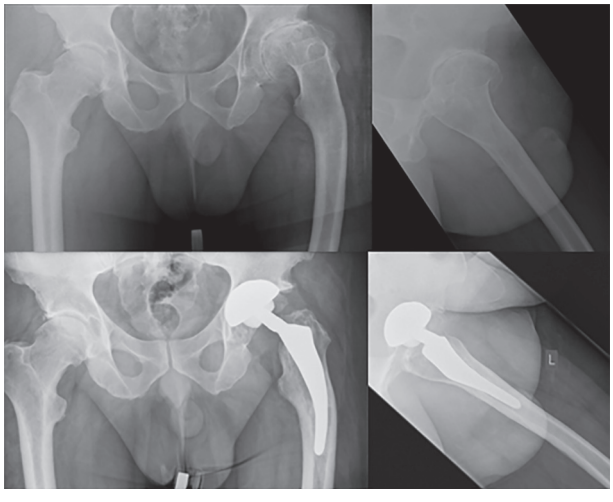

Fig. 2. — Fig 2a, 2b, Pre-operative anteroposterior (a) and lateral (b), pelvic radiograph of a 48-year-old man with post-traumatic proximal femoral deformity and end stage coxarthrosis. Fig 2c, 2d postoperative anteroposterior (c) and lateral (d) at four years showing placement of the custom-made femoral component.

and then yearly thereafter. The radiological examination were standardized with patient's foot facing forward and tube to film distance of 1100mm. We used Einzel-Bild-Roentgen-Analyse-femoral component analysis (EBRA-FCA) software programme (Innsbruck University, Austria) (*1*). The authors of the paper have had training and experience in using this software. All radiographs were analysed repeatedly by three authors to check for consistency in the measurements. Each series of radiographs is manually marked with reference lines based on an axis through the femoral component from which 19 reference points are entered for the femur and the prosthesis to measure migration of the stem. The EBRA-FCA program uses three parameters to assess the comparability of pairs of radiographs and accepts only pairs within chosen limits. The results for each are then weighted according to the comparability parameters. The final value for all acceptable radiographs in a series is then calculated

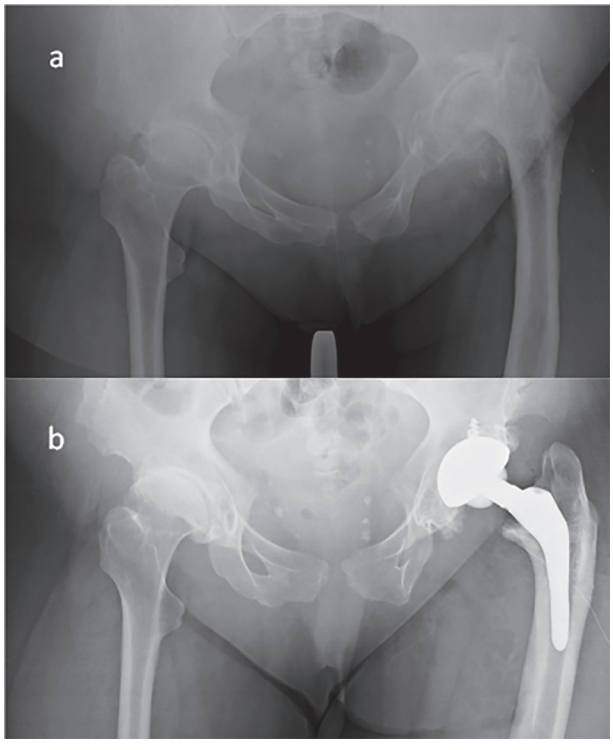

Fig. 3. — Fig 3a, 3b Pre-operative (a) and postoperative (b) anteroposterior pelvic radiograph of a 36-year-old woman with proximal femoral deformity and end stage coxarthrosis secondary to hip dysplasia.

from individual results. The EBRA-FCA program then provides information about subsidence, the medial and lateral distances between prosthesis and the bone margins, the angle between bone and stem, and the magnification in relation to head size and stem length (*1*).

Postoperative leg length discrepancy (LLD) was assessed radiologically by measuring the distance from the acetabular tear drop to the lesser trochanter. Hip Anteroposterior (AP) and Lateral X-rays were examined by two authors at two separate occasions to look for presence or absence of interface remodelling and periprosthetic remodelling. Presence or absence of trabecular remodelling, lucent lines, osteolysis, reactive lines, pedestal sign, 'spot welding', calcar resorption, local cortical atrophy, hypertrophy or hyperostosis in metaphyseal and diaphyseal regions were identified. These changes were defined as per accepted standards (*10*). This was recorded according to Gruen Zones 1 to 7 in AP view and further zones 8 to 14 in Lateral view (*8*). If any of these X-ray changes were seen in more than 50% of the area of that Gruen zone then they were recorded as positive for that change in that zone.

Data were analysed statistically using statistical package SPSS version 20 (SPSS version 20, IBM Corporation, USA). Kolmogorov-Smirov test was performed which showed the data followed a normal distribution and hence mean and standard deviation are reported where appropriate.

RESULTS

The mean follow up period was 36 ± 10 months (19-51 months). No patients were lost to follow up. The average pre-operative oxford score was 9 (ranging from 8 to 13) while the average post-operative oxford score was 46 (*41–48*).

No patient in this cohort had LLD greater than of 50 mm to need femoral shortening. Post-operatively none of the patient complained of limb length inequality. No patient described thigh pain on questioning. All patients were satisfied with the outcome of the procedure.

There were no encountered cases of infection, dislocation, or neurovascular injuries in this group of patients.

EBRA- FCA analysis

There were 63 X-rays available for the study, of which 57 were of good standard and met the comparability limits set by the EBRA software. On an average 4 X-rays were available per patients (range 3 -7). The average subsidence was the 0.95 ± 0.96 mm (0 – 2.9mm). The subsidence noted between 0 and 6 weeks, 6 weeks and 6 months X-rays. All stems had stabilised after this period.

Radiological Assessment

The preoperative leg length discrepancy (LLD) as measured by CT scan ranged between 5 to 25mm (average 14.9 mm). The postoperative LLD averaged 2.6 mm (0-7.2 mm) which was significantly better than the preoperative values (14.9 mm/ $P < 0.001$). 11/12 patients had less than 5 mm of discrepancy.

All hips (14/14) revealed signs of osteointegration in the form of weight bearing trabeculae, bony apposition to the implant in the proximal part of the prosthesis encompassing Zones 1, 7, 8 and 14. There were no lucent lines or reactive line in these zones. (Figs 4, 5) No patient showed evidence of calcar resorption indicating good proximal load transfer.

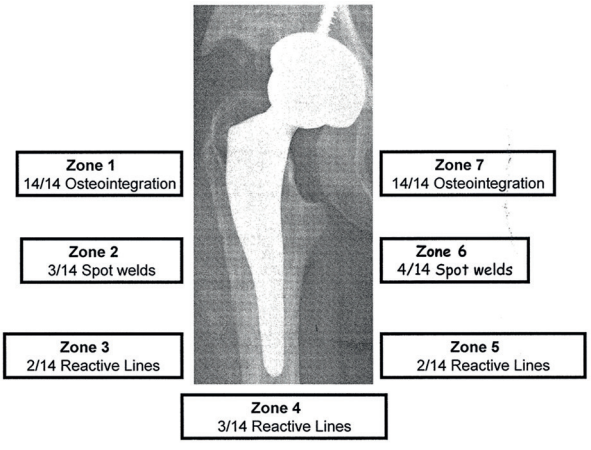

Fig. 4. — Radiological results according to Gruen zone in AP view

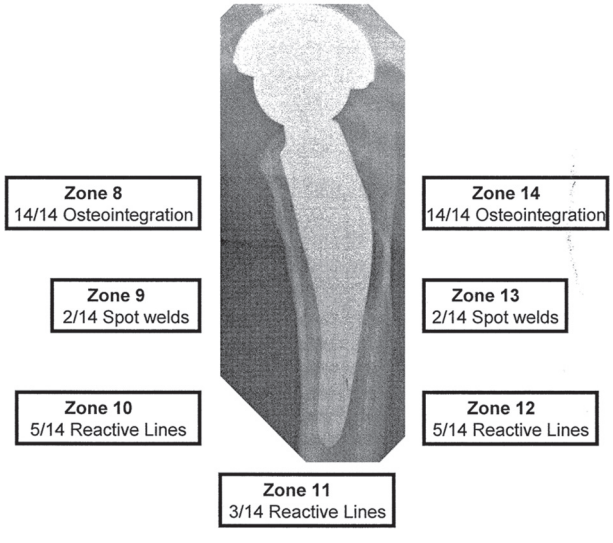

Fig. 5. — Radiological results according to zones in Lateral view

In few cases spot welding were seen in the subtrochanteric zones ; 3/14 in Zone 2, 4/14 in Zone 6, 2/14 in Zone 9, 2/14 in Zone 13. These spots weld were seen in 4/7 patients who have had previous femoral osteotomy and corresponded to the areas where the remodelling of bone around previous osteotomy was seen in preoperative planning CT scans. The spot weld indicates point contact weight transfer seen as localised cancellous bone hypertrophy arising from the cortex on to the coated part of the implant.

Reactive lines were seen around the distal third of the implant where the stems is smooth and uncoated in 2/14 in Zone 3, 3/14 in Zone 4, 2/14 in Zone 5, 5/14 in Zone 10, 3/14 in Zone 11, 5/14 in Zone 12.

There was no evidence of osteolysis, proximal stress shielding, lucent lines, localised periprosthetic cortical atrophy or hypertrophy and pedestal sign.

DISCUSSION

Proximal femoral deformity is a well known cause of secondary osteoarthritis of the hip. It alters the joint biomechanics and may result in impingement and abnormal loading and consequently secondary degenerative changes (*15*).

Reorientation of the articular surface of the hip with an osteotomy is an attractive procedure in those patients with mild degenerative changes allowing load transmission through a broader area decreasing the contact pressure. However in symptomatic patients with end stage coxarthrosis THR remains the gold standard treatment modality (*15, 16*).

Freeman and Plante-Bordeneuve suggests all new prosthetic configurations should be evaluated by migration measurements and pattern in the first two years (*7*).This information can be used to predict late aseptic failure of implant. The custom design femoral stem used in this study is based on the Symbios SPS stem design. This stem has a 100% survival rate at 10 years as reported by Sariali et al, but the survival results of Symbios custom design stem is not available (*17*). This study examines the short term outcome results of custom made design.

Measurement of early prosthetic migration has been shown to be a useful surrogate outcome marker after THR. The long term survival of the implant can be predicted by the early migration pattern and measurements (*7, 12, 19*). The average follow up in our study is 36 ± 10 months with a range between (19–51 months) hence we needed a reliable way

of accessing the migration pattern. Søballe et al reported that roentgen stereo photogrammetric analysis (RSA) had an accuracy of 0.02mm to detect migration but this method is costly and need to be planned prospectively by implanting tantalum sphere in the bone during surgery and is not available widely (*18*). Hence we used the EBRA- FCA method which is cheaper and can be retrospectively used. The accuracy of this method has been reported to be better than ± 1.5 mm (95% percentile) with a cronbach's coefficient alpha for interobserver reliability of 0.84 (*1*). This level of precision is sufficient to detect the clinically relevant threshold migration of 1 mm measured from serial radiographs.

Jacobs et al used EBRA-FCA software to measure migration and reported the total migration of a blade type Uncemented femoral stem used in primary hip replacement 1.7mm ± 2mm at 1 year follow up (*9*). Krismer reported that subsidence of Greater than 1.5mm during the first two years and continuing subsidence of 1mm/ year has sensitivity of 69%, specificity of 80% and an accuracy of 79% in predicting failure of the implant (*12*). The average subsidence in this study was 0.96 ± 0.95 mm (0 -2.9mm). This is well within the normal range for an uncemented stem. All migration happened in the early follow up period up to 6 months and all the stems in the study had stabilised after this period. This pattern is well described in the literature in uncemented femoral stems.

Engh et al studied the radiological signs of osteointgration in porous coated uncemented femoral stem and suggested that evidence of ostetointegration include absence of lucent lines, presence of weight bearing trabeculae and spot welds (*4*). Further, he reported that those reactive lines around a proximally coated stem indicate that motion occurs at this interface and indicate failure to achieve osteointegration in this area but reactive lines around the distal portion of uncoated stem alone is not a sign of failure of the stem as a whole. In this study reactive lines were only observed around the distal smooth uncoated part of the stem in 6/14 patients and no signs of loosening in the proximal part indicating all the stem were osteointegrated at final follow up.

Despite being challenging ; restoring the extra-medullary anatomy like the femoral offset and leg length is considered an essential prerequisite to good functional outcome, patient's satisfaction, and long term survival rates following THR with in patients with deformed proximal femur (*6, 11, 21*). According the literature, LLD more than 1 cm may be found in up to 62% in patients following cementless replacements which might result in patient's dissatisfaction and low clinical scores (*11*). Using custom designed stems Fletcher et al reported postoperative LLD of 2.3 mm, and 94% of their patients had less than 5 mm of discrepancy (*6*). The average postoperative LLD in this series was 2.6 mm, and 11/12 patients had less than 5 mm of discrepancy.

Limitations of this study include short follow up period and the small cohort of patients as we were strict in using these implants in patients with a deformity that was deemed unsuitable for 'Off the shelf implant' to achieve metaphyseal 'fit & fill' and stability without needing a corrective osteotomy. In addition, EBRA tends to slightly underestimate total migration compared to RSA studies. The use of bony landmarks for measurements allows for inaccuracies over time owing to bone remodelling and heterotopic ossification as reported in the literature (*22*).

CONCLUSION

We concluded that this 3D-CT guided custom design femoral stem produces reliable proximal 'fit and fill' and primary stability with restoration of LLD in this group of patients with complex proximal femoral deformity without the need of a corrective osteotomy. It also achieves good metaphyseal osteointegration in the short term. However further studies are needed to assess the performance and long term survival of these implants.

Conflict of Interest and funding

None of the authors have any proprietary interest in this data. No author has received or will receive any financial support relating to this project.

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