The Migration Of CAD-CAM Hips Stems In Patients With Juvenile Rheumatoid Arthritis Over A Follow-Up Period Of Ten Years

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Citation

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Abstract

Background and Aims: The clinical results obtained after total hip arthroplasty in patients with juvenile rheumatoid arthritis were not encouraging when cemented implants were used. Therefore custom designed femoral components (uncemented and hydroxyapatite-coated) using computer-assisted-design and computer-assisted-manufacture (CAD-CAM) were used for these patients who required total hip replacement (THR). The minimal follow-up for these patients is now 10 years. The clinical results obtained with these implants were excellent. The purpose of this study is threefold; firstly to correlate the degree of migration of the femoral component with the clinical results, secondly to determine if CAD-CAM femoral components can achieve implant stability over 10 years and thirdly to determine if there in a correlation between the extent of migration and the degree of pain experienced by the patient. Methods: the hips were assessed clinically according to the Hospital for Special Surgery (HSS) hip rating system preoperatively and then at 1 year, 3 years, 5 years and 10 years postoperatively. The pain component of the HSS system was recorded separately in addition to the total HSS score. Migration of hip stems was measured by a technique developed in the Biomedical Engineering Department (BME) of the Institute of Orthopaedics and Musculoskeletal science, University College London (UCL). It involved digitisation of 16 points on an anteroposterior (AP) view radiograph in a manner prompted by the computer. The head diameter of the femoral component was inserted into the computer before digitisation. A specially developed computer program then used this information together with that obtained by digitisation to measure the distance between the top of the greater trochanter and the lateral aspect of the hip stem. This information was then used to measure the migration. Results: there was no significant correlation between the degree of migration and the clinical results at the end of the 10 year follow-up ($r = 0.032$, $P = 0.881$). However the migration of the CAD-CAM components over the 10 year period was significant ($p < 0.05$). This means CAD-CAM components were unable to achieve implant stability over the 10 year period. There was also no correlation between the degree of migration and the extent of pain experienced by patients at 10 years follow-up ($r = -0.213$, $P = 0.308$). Summary and conclusions: we conclude that the clinical results and degree of pain experienced by JIA patients with a THR are not related to the amount of CAD-CAM hip stem migration. Our study also established that CAD-CAM components undergo significant progressive migration over 10 years. However this rate of migration was not high enough to lead to radiological failure in most cases. Certain limitations were present in the method used to measure migration, thus the results of this study should be interpreted with caution.

ABBREVIATIONS

CAD-CAM Computer-assisted-design-computer assisted manufacture
JIA Juvenile rheumatoid arthritis
JRA Juvenile rheumatoid arthritis
RSA Roentgen stereophotogrammetric analysis
THR Total hip replacement
THA Total hip arthroplasty
SD Standard deviation
2D 2 Dimensional

INTRODUCTION

Juvenile rheumatoid arthritis (JRA) or what is called juvenile idiopathic arthritis (JIA) refers to a clinically heterogeneous group of arthrides of unknown cause which occur before 16 years of age in children (Ravelli A & Martini A 2007). Progress of the condition eventually leads to inflammatory arthritis of multiple joints and soft tissue contractures (Haber D & Goodman SB 1998). Joint destruction, especially in systemic and polyarticular subgroups, may lead to severe disability (Cage DNJ, Granberry WM, & Tullos HS 1992).

Major weight-bearing joints such as the hip and knee joints when affected cause a loss of mobility and pain with bilateral involvement leading to a loss of function (Odent T et al. 2005). This loss in the ability to walk, particularly when the hip joint is involved may lead to psychosocial problems in a child, adolescent or young adult because of the resultant isolation and dependency (Chmell MJ et al. 1997). Thus when management of the condition via conservative means and physiotherapy fails the patient is then considered for total hip replacement (THR). The main indicators for total hip arthroplasty (THA) in JIA patients include serious functional disability (such as the inability to ambulate without two crutches or a wheelchair) and a high degree of unremitting pain (Kitsoulis PB et al. 2006). However it must be appreciated that unlike THR in adults where the procedure is relatively straight-forward, THR in patients with JIA are complicated by the patients young age, small stature, abnormal bony anatomy, and poor bone stock (Kitsoulis PB et al 2006). Thorough preoperative planning is thus essential due to the factors mentioned above such as joint contractures, small size of the bone and poor bone quality (Kitsoulis PB et al 2006). Immaturity of the skeleton is not an absolute contraindication for THA, however open physes are a relative contraindication for the procedure(Kitsoulis PB et al 2006). If both the hip and knee on the same extremity are invloved, surgical intervention at the hip takes precedence due to its vital role in the gait cycle (Kitsoulis PB et al 2006). Total hip arthroplasty in patients with JIA provides significant relief of pain in addition to improving the patients range of motion and function (Goodman SB et al. 2006). This in turn greatly improves their quality of life, enables them to perform routine tasks of self-care and increases their ability to integrate into society.

THAs are of two main types: those in which the components are fiaxated with cement and those in which cementless components are used. Several studies have demonstrated the benefits of cemented THR in terms of improving mobility and function in adolescents and young adults suffering from JIA. The short-term results for cemented THR in terms of longevity and survival have been good, however the intermediate and long-term outcome after cemented THA has not been as impressive (Haber D & Goodman SB 1998). A study carried out by Lachiewicz et al. looked into the results of cemented THA in patients with JIA (Lachiewicz PF et al. 1986). It involved 83 hips in 45 patients being followed up for a mean length of 6 years (range, 2 to 11 years). Radiographic analysis revealed migration of 8% of the femoral components and 26% of the acetabular components. Two hips required revision: one for a broken femoral component at 10 years after surgery and the other due to acetabular loosening. Witt et a. reviewed the results of 96 primary THRs in 54 patients with JIA at an average of 11.5 years (Witt JD, Swann M, & Ansell BM 1991). Seventeen hips had radiographic signs of loosening while 24 hips (25%) in 18 patients at an average of 9.5 years after primary surgery required revision. A study carried out by Learmonth et al. demonstrated a 57% radiographic rate of impending failure at an average of 8 years after surgery (Learmonth ID et al. 1989). Mogensen et al. studied 50 THAs in 33 patients suffering from JIA at an average of 77 months (Mogensen B et al. 1983). Ten hips were reported to be radiologically loose while 6 hips required revision. Chmell et al. reported on the results of 66 cemented THRs in 39 patients with JIA (Chmell MJ, Scott RD, Thomas WH, & Sledge CB 1997). It was noted that 12 (18%) of the 66 femoral components and 33 (35%) of the 66 acetabular components had to undergo revision after an average of 12.8 and 11.8 years respectively. Apart from unsatisfactory meduim and long-term results another important point to consider when using cemented components is their capacity for revision. Revision of cemented femoral components in patients with JIA is very likely at some point in the future because the THAs are done at a young age. Extraction of the cement can be particularly challenging in these patients due to their atypical femoral anatomy which is further complicated by osteopenia and poor bone stock (McCullough CJ et al. 2006).

Thus the complications that are involved when revising cemented THAs together with the fact that they do not demonstrate particularly good medium and long-term results have led to uncemented THAs being considered for use in these patients. Unfortunately studies describing the follow-up of uncemented THAs in JIA patients have been limited. A study by Maric and Haynes looked into 17 THAs with an average follow-up period of 9.3 years (Maric Z & Haynes R 1993). The study only included 4 cementless hips. However the results for the cementless hips were excellent compared to the cemented components, 5 of which were loose with impending failure. Haber and Goodman reported on 29 hips in 16 patients with an average follow-up of 53 months (Haber D & Goodman SB 1998). In 20 of the THAs cementless femoral components were used while in the remaining cemented components were used. Seventeen (85%) of the cementless components demonstrated either a stable bone or fibrous interface with no migration. The remaining 3 cementless stems displayed some migration, yet none of them were revised nor were they in need of impending revision. Infact 2 of the 3 unstable cementless components were thought to have become unstable due to excessive femoral offset and an initial varus stem position. This study thus provides encouraging evidence of the usefulness of cementless femoral components in the treatment of patients with JIA. Odent et al. reported the results of 62 noncemented THAs in 34 children with JIA after a mean follow-up of 6 years (range 3 to13 years) (Odent T et al 2005). Survivorship analysis carried out using the Kaplan-Meier method demonstrated a survival rate of 100% for the femoral component and 90.1% for the acetabular component at 13 years. However there has been limited use of cementless femoral components due to concerns that osteopenia in JIA patients may lead to femoral fracture during insertion (McCullough CJ et al 2006). In addition initial stability and fixation may be compromised by a possible miss-match between metaphyseal and diaphyseal sizing. Engh et al infact drew attention to the fact that if there was insufficient stability of uncemented porous-coated femoral component this could lead to inhibition of bone ingrowth into the stem due to persistent micromotion (Engh CA & Bobyn DJ 1995). This will then eventually lead to a vicious cycle of instability and lack of bone ingrowth.

To address these concerns McCullough et al. used Computer Assisted Design-Computer Assisted Manufacture (CAD-CAM) femoral components (McCullough CJ et al 2006) . These femoral components are custom designed for each patient thus maximising "fit and fill" in the proximal femur. This inturn enables the stem to achieve greater stability right from the initial stages of fixation. It has also been shown that the pattern of strain distribution in CAD-CAM hips tends to closely resemble the strain distribution observed in the unaltered femoral bone (Hua J & Walker PS 1995). This inturn helps to preserve bone mass (Hua J et al. 1995). In the study by McCullough et al. most of the femoral components had a lateral flare in order to fill the space between the component and the bone of the proximal and lateral part of the femoral canal. In addition the femoral components were coated with hydroxyapatite (HA) over the proximal third. This has the effect of enhancing contact and fixation by causing ingrowth of bone into the porous coating (Dumbleton J & Manley MT 2004). McCullough et al. reported the reuslts of 42 HA-coated CAD-CAM femoral stems in 25 patients aged 11 to 35 (mean 21 years), 21 of whom had JIA. A total of 4 (9.5%) femoral components had failed, of which 2 were radiologically loose and two were revised. The 4 failed components were in patients equal to or aged below 16 years at the time of surgery. Thus it can be concluded that HA-coated customised femoral components give excellent medium to long-term results in skeletally-mature young adults with inflammatory polyarthropathy. However the results for patients aged 16 years or less at the time of surgery don't appear too convincing in the long-term with a 28.5% risk of failure of the femoral component at approximately 10 years.

It can thus be observed form the studies described above that cemented THAs have shortcommings in terms of longevity in the medium to long-term in JIA patients. However with respect to improvement in daily function and relief of pain, cemented implants have displayed significantly better clinical results in comparison to those obtained preoperatively and in most cases the benefits of total hip arthroplasty have been maintained over the long-term in most patients (Chmell MJ, Scott RD, Thomas WH, & Sledge CB 1997; Lachiewicz PF, McCaskill B, Inglis A, Ranawat CS, & Rosentein BD 1986). Cementless THAs on the other hand have shown encouraging results in patients with JIA yet the avaiable evidence in no way confirms that the cementless THAs are superior to the cemented type. Uncemented CAD-CAM femoral components with a coating of HA on the proximal third of the stem inserted without cement also displays promising results yet the available evidence in no way proves its superiority over the other types of femoral components reviewed in this section when used in JIA patients.

It is important to recognise that several factors affect the durability of total hip prosthesis in JIA patients. Firstly JIA patients display varying levels of osteopenia secondary to a host of factors such as medication, disuse, nutritional status and the disease itself (Kitsoulis PB et al 2006). Secondly structural osseous deformities and contractures of the lower extremity tend to complicate the technical performance of the THA and may alter the size and direction of forces borne by the implant after surgery (Kitsoulis PB et al 2006). Thirdly because the patients are young the rate at which skeletal remodelling occurs may interfere with the maintainence of fixation. In addition these young patients need to complete their education, begin a career and seek a spouse; these challenges may increase the demands placed on the prosthetic hip (Kitsoulis PB et al 2006). Finally patients with JIA are often treated with steroids to reduce inflammation. The use of steroids had been demonstrated to significantly reduce the survival of cemented THAs (Lehtimaki MY et al. 1997).

Several techniques are available to assess THAs. The most commonly used method of evaluating THAs is via anteroposterior and lateral radiographs. The appearance of the THA will depend on the prosthesis used, its method of fixation and whether it is a primary or revision procedure (Manaster BJ 1996). Cemented components may usually show 1-2 mm wide radiolucent zones at the cement interfaces. Loosening of the component is confirmed when there is progressive widening of the radiolucent zone, migration of a cemented component or change in alignment seen on the radiograph (Manaster BJ 1996). With cementless components on the other hand normal findings include endosteal sclerosis, cortical thickening, periosteal reaction, radiolucent zones upto 2 mm in width and femoral component migration that stabilises at less than 1 cm (Manaster BJ 1996). In cementless THA the most reliable signs of loosening include migration and titlting of the component (Manaster BJ 1996). Migration is a rather subtle change, thus in order to detect it measurements need to be performed on a series of radiographs. Apart from migration other signs of loosening include bead shedding (in prostheses coated with a porous layer), endosteal bone bridging at the stem tip, radiolucent zones wider than 2 mm, extensive cortical hypertrophy and endosteal scalloping (Manaster BJ 1996).

Migration or subsidence is one of the factors that lead to loosening of an implant and its eventual failure (Manaster BJ 1996). It is thought that migration of femoral components can lead to increased levels of pain being experienced at the hip and especially at the thigh. It has also been thought to reduce mobility and function of the THR. This inturn will have a negative impact on the clinical results. Thus the aim of this study is to explore the relationship between migration of CAD-CAM femoral components and the clinical results obtained over 10 years in patients with JIA. In addition we will analyse the migration data obtained in order to observe if these CAD-CAM components can achieve stability over a period of 10 years. When the clinical results were recorded, pain was recorded separately in addition to the total clinical score. Thus it was decided that we would also try to determine if there was a relationship between the extent of migration and the level of pain experienced by the patient.

Thus the subject of this study is threefold; firstly to correlate migration of CAD-CAM hip stems over 10 years to the clinical results obtained for these components in the same patients over 10 years, secondly to measure the migration of CAD-CAM components over a period of 10 years in order to determine if these components can achieve stability over this period and thirdly to determine if there is a correlation between pain and migration.

The first aim of this study is important because it will enable us to understand if there is a relationship between migration and the clinical results which inturn will enable us to classify migration as one of the factors affecting the clinical outcome and success of CAD-CAM femoral components. The second aim will enable us to get an appreciation of the time-span required by CAD-CAM components to achieve stability. The third will establish wether migration of femoral components can cause pain.

There is a dearth of literature on the use of custom designed components in patients with JIA and thus it is hoped that this study will make a significant contribution to those intrested in this area.

HYPOTHESIS

This is a longitudinal, retrospective study with the aim of testing two hypotheses:

HYPOTHESIS 1:

H = there is no correlation between the extent of migration and clinical results after 10 years (long-term) follow-up in JIA patients.

H_1 = there is a correlation between the extent of migration and clinical results after 10 year (long-term) follow-up in JIA patients.

To test this hypothesis clinical results obtained over 10 years will be correlated with migration over the same period using an appropriate statistical test.

HYPOTHESIS 2:

H = CAD-CAM femoral components will not undergo migration (i.e. they will be stable) over a period of 10 years in patients with JIA.

H_1 = CAD-CAM femoral components will undergo migration (i.e. they will not be stable) over a period of 10 years in JIA patients.

In order to test this hypothesis the migration of CAD-CAM hip stems over 10 years will be measured and the mean value of migration obtained at each point in follow-up (i.e. at 6 months, 1 year, 3 years, 5years and 10 years) will be compared with the value immediately previous to it using an appropriate statistical test.

HYPOTHESIS 3:

H0 = there is no correlation between the extent of migration and the level of pain experienced by the patient .

H1 = there is a correlation between the extent of migration and the level of pain experienced by the patient.

To test this hypothesis the pain scores obtained over 10 years will be correlated with migration over the same period using an appropriate statistical test

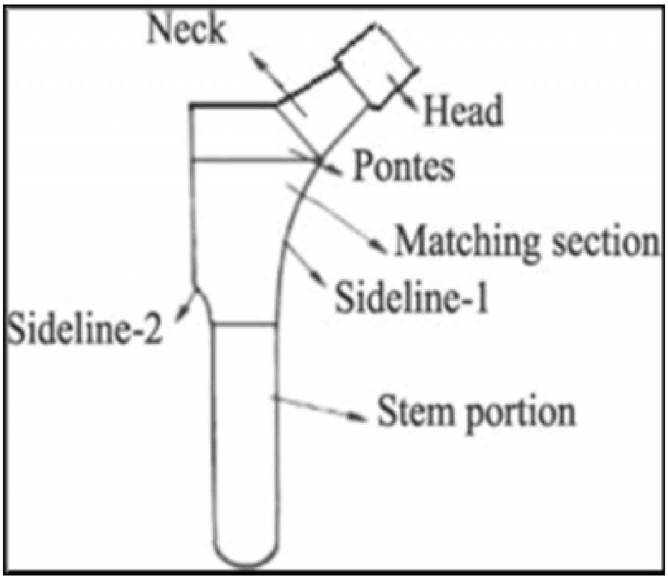
MATERIALS AND METHODS

Radiographs of 41 hips in 24 patients with JIA were available for this retrospective study. All the femoral components used were custom designed CAD-CAM stems with a proximal HA coating. Of the 41 hips the first 14 hips were straight-stemmed while the remaining 27 hips had a proximal lateral flare. The lateral flare was added, in theory, to try and increase the proximal stability of the femoral component and reduce subsidence (McCullough CJ et al 2006). All the femoral components used were of modular design. The head was made of cobalt-chrome with a diameter of either 22mm or 28mm.

The CAD-CAM hip stems were designed using radiographs from the patients. The prosthesis is designed based on the geometry of the femoral cavity and clinical requirements (Ruyu M et al. 2005). It includes a head, neck, pontes, matching section and stem (Figure. 1).

Figure 1

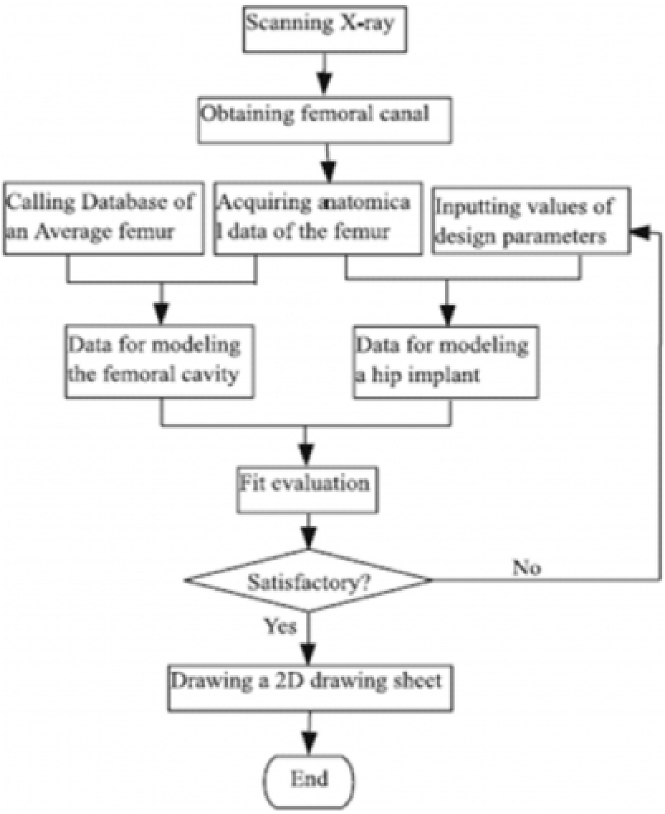
Figure 1. Structure of CAD-CAM femoral component (Ruyu M et al. 2005).



The design process of the CAD-CAM implant can be divided into several stages. It includes obtaining a femoral canal, collecting anatomical data of the femur, processing data, process fit evaluation and generating a 2D drawing sheet .A summary of the stages in the design given in figure 2 below.

Figure 2

Figure 2. Flow chart of design process (Ruyu M et al. 2005).



After processing the data the designer evaluates the extent to which the prosthesis fits in the proxmal portion of the corresponding rough femoral cavity and the extent to which the implant's stem matches the femoral canal (Ruyu M et al 2005). At this stage the designer may also contact the orthopaedic surgeon in order to take into account the surgeons preferences. Once a satisfactory prosthesis has been designed a 2D drawing sheet for manufacture is automatically generated along with the codes for manufacturing the implant (Ruyu M et al 2005). This information is then fed into computer numerical control (CNC) machine tools which manufacture the implant from a round-bar of the required metal which is used as a blank ((Ruyu M et al 2005).

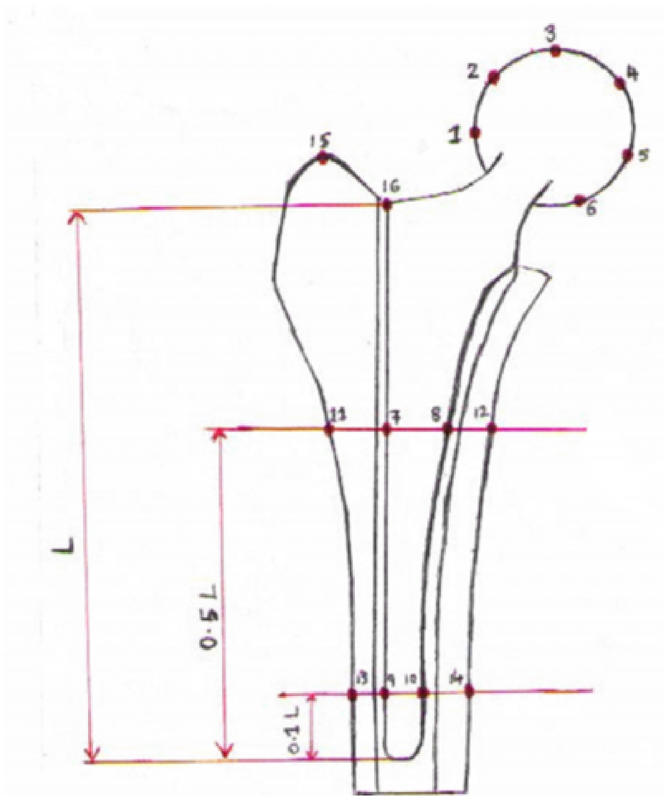
The patients underwent surgery between June 1991 and February 1995. Of the 24 patients involved in this study 17 were female and 7 were male. The mean age at the time of surgery was 21.7 years (range 11 to 37 years). Seven patients had unilateral THAs while 17 patients had bilateral THAs, making available a total of 41 hips for the study. Seven of the patients (14 hips) were aged 16 or less at the time of surgery. There were 20 THAs on the right-side and 21 on the left-side. All femoral components were inserted without cement.

Of the 41 THAs 16 of them did not have a radiograph at 10 years. One patient with bilateral replacements had expired while the rest which included patients with bilateral and unilateral THRs were lost to follow-up. Thus at the 10 year follow-up period there were only 25 THAs with a radiograph to measure migration at this point in time.

Anteroposterior (AP) plain radiographs of the hip immediately after surgery and those approximately 6 months, 1 year, 2 years, 5 years and 10 years following surgery were obtained. Measurement of migration was carried out using a method developed in the Biomedical Engineering Department (BME) of the Institute of Orthopaedics and Musculoskeletal science, University College London (UCL). It involves feeding in the value of the diameter of the femoral head into a specially written computer program and digitisation of 16 points on the radiograph in an order prompted by the computer.

Figure 3

Figure 3 The 16 points that were digitised.(Ilustration by Mohamed Jabir).



Points 1 to 6 around the circumference of the femoral head is used by the program to determine the diameter of the femoral head on the radiograph (Walker PS et al. 1995). This value is then compared with the value of head diameter fed into it in order to determine the extent to which the THA has been magnified on the radiograph. Points 7-10 and 11-14 are used by the program to define the long axes of the stem and the femur (Walker PS, Mai SF, Cobb AG, Bentley G, & Hua J 1995). The vertical distance between point 15 on the top of the greater trochanter and point 16 on the superior lateral aspect of the hip stem are used to determine the vertical position of the hip stem and hence the migration. The greater trochanter and superior lateral aspect of the hip stem are the most accurate landmarks that can be used to measure the vertical position of the hip stem using this technique of digitisation. This is due to their relative insensitivity to the different orientations of the hip joint (Walker PS, Mai SF, Cobb AG, Bentley G, & Hua J 1995).

Digitisation was carried out on the series of radiographs obtained for each patient. Before the 16 points on the radiograph was digitised a transparent acetate sheet was placed on top of the radiograph and the 16 points required for digitisation marked on it. This was done as the radiographs had to be returned back to the patients. Points 7-10 were marked at 50% of the length from the tip of the stem to the superior lateral point on the hip stem while points 11-14 were at 10% of the same distance (figure 3 indicates the distance from the tip of the stem to the superior lateral point on the hip stem as L and the 50% and 10% proportion to this length as 0.5L and 0.1L respectively). The vertical distance between the top of the greater trochanter and the superior lateral aspect of the hip stem was determined after surgery and then again at 6 months, 1 year, 2 years, 5 years, and 10 years for each patient. The values were obtained in milimeters (mm). The value immediately after surgery was then subtracted from the value obtained at 6 months, 1 year, 2 years, 5 years and 10 years in order to determine the migration at these intervals of time. This technique of measuring migration using the top of the greater trochanter and lateral point on the stem, allowing for variation of up to 10 degrees rotation of the femur in any direction between successive radiographs gives a maximum error of 0.37 mm (Walker PS, Mai SF, Cobb AG, Bentley G, & Hua J 1995). At a more realistic 5 degree rotational variation, the error was only 0.13mm.

The hips were assessed clinically and given a score according to the Hospital for Special Surgery (HSS) hip rating system (Salvati EA & Wilson PD Jr 1973).The HSS system comprises of four component scores which includes 10 points each for pain, range of movement, mobility and function adding up together to give a maximum possible composite score of 40 points. In addition to the total HSS score the pain component was also recorded separately over the 10 year period for each of the THRs. The hips were scored preoperatively and at 1 year, 3 years, 5 years and approximately 10 years after surgery. At the 10 year follow-up only 36 of the 41 THRs were available for clinical assessment. One of the patients had expired (2 hips) while one patient (1 hip) had been lost to follow-up. Two other patients had undergone femoral component revision.

Statistics: Hypothesis one and hypothesis three were tested by calculating the Pearson product moment correlation coefficient (r) for each set of corresponding data. For e.g. the migration at 1 year was correlated with the total HSS score and the pain component at 1 year and so on up to the 10 year follow-up point to discern if there was any kind of correlation (either positive or negative) between these variables.

Hypothesis two on the other hand was tested by comparing the mean migration at a specific follow-up period with the one immediately after it using the paired t-test. For e.g. the mean migration at one year was compared with the mean migration at three years to see if there was a significant level of migration during the two year period between them.

RESULTS

Clinical:The mean pre-operative score was 14.1 (range 4 to 22) while the mean score after surgery at the 10 year follow-up point was 28.9 (range 22 to 34). The mean total HSS score at other points in time, namely 1 year, 3 years and 5 years did not differ considerably to that obtained at 10 years. A graph of the mean HSS scores preoperatively and thereafter at the various stages of follow-up is given in figure 4. Of significance is the large increase between the mean total HSS score preoperatively and post-operatively. This significant increase between the clinical results obtained pre-operatively and post-operatively enables us to get an appreciation of the considerable levels of improvement in terms of pain, function and mobility after THR in patients suffering from JIA.

Figure 4

Figure 4 Mean total HSS score for at various time points in follow-up.

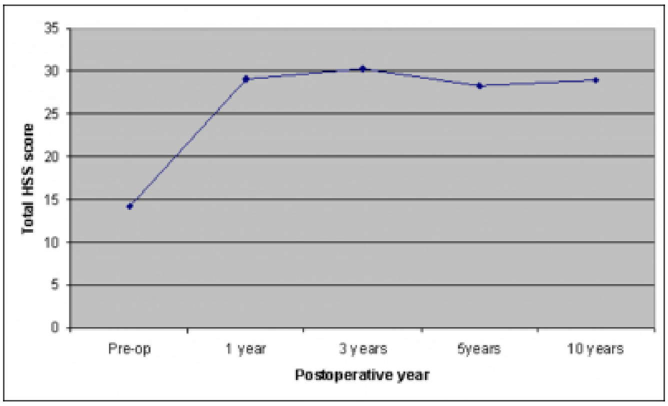
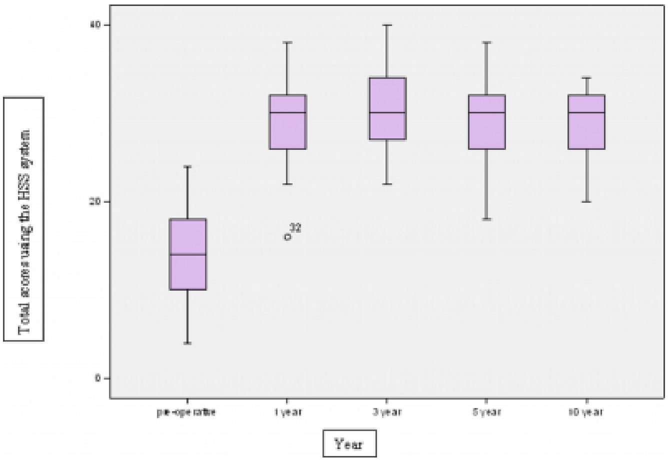


Figure 5 below enables us to look at the clinical results from another angle. In this case the range (outlines), interquartile range (box) and median (line) are given.

Figure 5

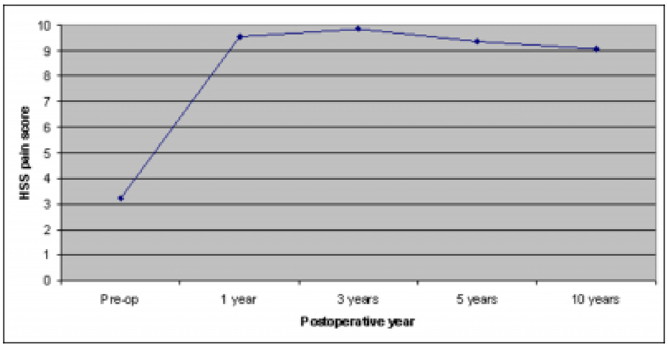
Figure 5 A box plot showing the median (line), interquartile range (box) and spread (outlines) of the clinical results pre-operativley and posteoperatively at the various follow-up periods.



Pain is one of the components of the HSS hip scoring system with a maximum of 10 points as mentioned above (Salvati EA & Wilson PD Jr 1973). Figure 6 below gives us an indication of the extent of the improvement in pain after THR. There is a clear decrease in pain following surgery. A small drop in the score can also be noticed over the 10 year follow-up period. In one patient the score for the pain component came down from an initial post-operative value of 10 to 6 at 10 years post-op, which was the same value it was prior to surgery. All other patients had a pain score of between 8 and 10 at approximately 10 years after surgery.

Figure 6

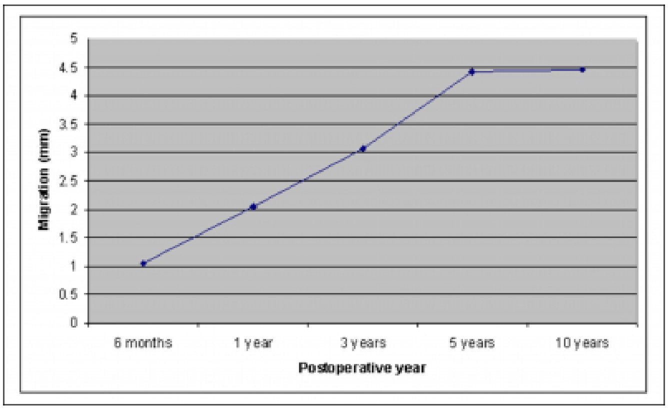
Figure 6. The pain score at various points in follow-up. The pain component has a maximum score of 10 points



Radiological:All 41 THRs showed some degree of migration when the radiograph taken immediately after surgery was compared to the last available radiograph in the series for each patient. All 25 THRs for which the 10 year post-operative radiographs were available showed considerable levels of migration when compared to that immediately after surgery. Four of femoral components had a migration of greater than 10mm (14.8%) with two of them requiring revision. The other two remaining femoral components were asymptomatic with no indication of pain, reduction in range of movement or reduction in mobility and function as indicated by their clinical results. Migration of upto 10 mm is considered a normal finding for cementless femoral components (Manaster BJ 1996). However migration beyond this value of 10mm is considered a significant indication of loosening and/or failure (Manaster BJ 1996). The mean migration over the ten-year period is shown in fig.4

Figure 7

Figure 7. Mean migration with standard deviation of the femoral component over ten years.



The migration rate for the various periods is given in table 1.

Of importance is the large initial rate of migration occurring in the first year after surgery followed by a subsequent reduction in the rate of migration. This is a characteristic pattern of migration for cementless femoral components.

Figure 8

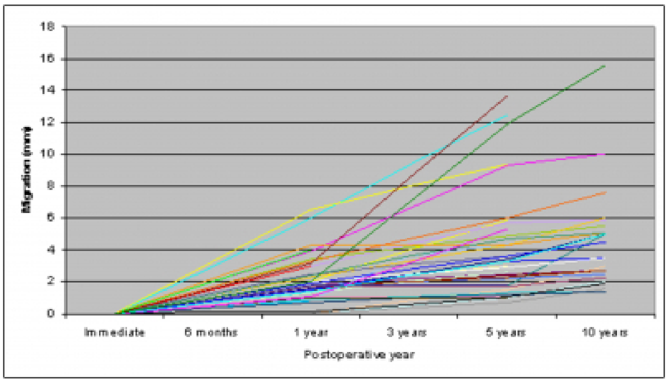
Table 1. Migration rate between various periods of time.

Time (yr)	Migration rate (mm/yr)
0.0 to 0.5	2.08
0.5 to 1.0	2.00
1.0 to 3.0	0.51
3.0 to 5.0	0.48
5.0 to 10.0	0.08

The migration of the femoral components for each individual THR is shown in figure 9. Of interest in this figure is the manner in which the migration of the femoral component, in many of the THRs, tends to continues to progress at a constant rate over the ten-year period.

Figure 9

Figure 8. Migration graph for each of the 41 THRs.



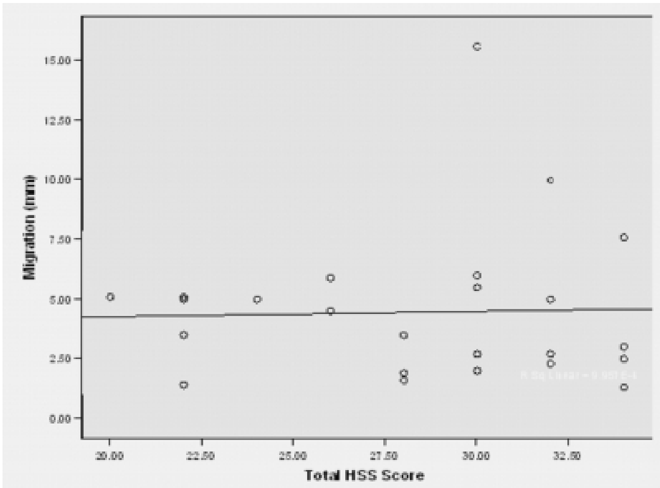
An important point to consider is that 7 of the patients in this study were aged 16 or below at the time of surgery. All four occasions in which migration was above 10mm were in the youngest patients within this group. The patients were aged 11, 12 and 13 years. The 13 year-old patient had a revision of the right femoral component while the left femoral component was radiologically lose with a migration value of 15.6mm. However the HSS score for the left femoral component indicated that there was no significant increase in pain or reduction in mobility and function even with this high value of migration.

Statistics: As mentioned in the section above, hypothesis one and three were tested by calculating the Pearson correlation coefficient. There was no significant correlation between migration and the clinical results at 10 years follow-up (r = 0.032, P = 0.881). In addition there was no significant correlation between migration and the amount of pain experienced by patients at 10 years follow-up (r = -0.213, P = 0.308). Thus we do not have sufficient evidence to reject the null hypotheses of hypothesis one and hypothesis three.

In terms of hypothesis two, we found that there were significant differences in the mean migration at the various follow-up points (P < 0.05). Thus we have sufficient evidence to reject the null hypothesis and can conclude that CAD-CAM femoral components cannot achieve implant stability over a period of 10 years. This statement will however be examined in more detail in the discussion section of this thesis.

Figure 10

Figure 9 Scatter plot of migration at ten years (y-axis) and HSS Score (x-axis). It is clear that there is no correlation between the two variables although a slight tilt upwards maybe be noticed.



DISCUSSION

This study had been carried out with the intent of exploring the answers to three important queries with regards to CAD-CAM femoral component usage in patients with JIA. Firstly we tried to observe if there is a correlation between the extent of migration of CAD-CAM femoral components and the clinical results obtained over a period of approximately 10 years. Secondly we have looked into whether CAD-CAM components can achieve stability in JIA patients over a period of 10 years. The third and final goal was to determine if there was a correlation between the degree of migration and the amount of pain experienced by JIA patients.

To the author’s knowledge there are currently no published studies looking into the relationship between the migration of CAD-CAM femoral components and clinical results. However a few studies are available looking into this relationship in standard cemented and uncemented femoral components. Loudon and Older reported on the outcome of the clinical results in relation to femoral subsidence in 102 patients between 9 to 13 years after low friction cemented arthroplasty (Loudon JR & Older MWJ 1989). The indication for THR was not mentioned. The clinical results were assessed using the Merle d’Aubigne and Postal grading for pain, function and range of movement. The clinical outcome was regarded as satisfactory if the patient had satisfactory function (usually grades 5 or 6) and minimal or no pain (grade 5 or 6) with the prosthesis in situ. If the prosthesis had been revised or removed, or there was an insufficient improvement in function, or it was unacceptably painful an unsatisfactory result was recorded. Migration was measured by the technique described by Louden and Charnley using the top of the femoral head, the top of the grater trochanter and a point on the trochanteric fixation wire (Loudon JR & Charnley J 1980). The mean subsidence for the clinically satisfactory group at 9 to 13 years follow-up was 2.01 mm while that for the clinically unsatisfactory group was 8.21 mm during the same follow-up period. The results were not analysed in order to obtain any statistically significant correlation between migration and the clinical results, however it was possible to deduce from the results presented that there was a substantial negative correlation between clinical outcome and migration in cemented femoral components. However some degree of caution should be exercised with this interpretation as all of the patients in the group with unsatisfactory clinical results had fracturing of the cement at the tip of the stem which would have contributed to the unsatisfactory clinical outcome. Kattapuram et al carried out a radiographic analysis and clinical correlation of uncemented porous-coated anatomic total hip prostheses on 37 patients with 46 THRs (Kattapuram SV et al. 1990). Several radiographic features were correlated with the clinical results. However the most important radiographic feature that correlated with the clinical results was migration. There was a significant negative correlation ($r = 0.72$, $P < 0.01$) between the amount of migration and the end result. The greater the migration the less satisfactory was the clinical outcome. Thus both these studies support the hypothesis that there is a correlation between migration and clinical results and also confirm that this correlation is a negative correlation. Our study on the other hand found no significant correlation, either negative or positive, between the degree of migration of the femoral component and the clinical results in JIA patients. It can be argued that the above studies do not involve CAD-CAM HA-coated femoral components and the indication for THR was not JIA and hence may be of no use to us when studying the relationship between the extent of migration and the clinical results in these CAD-CAM components in JIA. However what is important to recognise is that certain factors such as the design of the femoral component, its method of fixation (cemented or cementless) and the condition being treated may only play a small part in determining the relationship between migration and clinical results. Thus we can appreciate that in order to develop a greater understanding of the relationship between migration and clinical results in any type of femoral component, it would be worth to look at several different types of femoral components and study them in relation to each other.

The main reason as to why a HA-coated CAD-CAM femoral component may be used in a patient is because of the belief that custom designed femoral components achieve a superior “fit and fill” compared to standard femoral components (Hua J et al. 1995). This enables them to attain maximum stability immediately after fixation. In addition good initial stability is essential to enable bone ingrowth to occur into the HA-coating to achieve a stable bone-stem connection which is essential for femoral component stability in the long-term. A report by Walker et al into the stability of custom designed revision hip stems found that at 2 years the mean migration was 1.5 mm in 62 THRs (Walker PS et al. 2000). This was only slightly above the amount of migration seen in custom primary HA-coated hip stems which had a mean migration of about 1.2 mm in 40 cases. This study thus clearly demonstrates the benefits of CAD-CAM femoral components in terms of stability and fixation especially because achieving this level of implant stablility is quite a challenge in cases which involve revision of a THR(Walker PS et al 2000). A study by Aamodt et al looked into the migration of CAD-CAM femoral components in 17 THRs (Aamodt A, Benum P, & Lund-Hanssen H 2000). At 24 months the migration of the femoral component was less than 0.14mm, again giving us an indication of the very stable nature of fixation. These studies only included a few patients with JIA but it is possible to get an appreciation of the degree of stability of CAD-CAM femoral components from them.

McCullough et al reported an annual percentage success of 83% for CAD-CAM femoral components in JIA patients between 13 and 14 years after THR(McCullough CJ et al. 2006) McCullough et al however did no perfom a detailed analysis of the manner in which migration occurred in these patients. Our study revealed, to the contrary, that there was a statistically significant increase in the degree of migration at each point in follow-up. This inturn means the CAD-CAM femoral components had a significant amount of migration occuring in a progressive fashion through-out the 10 year follow-up period. The mean migration at 10 years in out study was 4.46mm (range 1.3mm to 15.6mm). This amount of migration however is well below the figure which is indicative of radiological failure. Migration of an uncemented femoral component beyond a value of 10mm is considered to be indicative of radiological failure (Manaster BJ 1996) Thus we can conclude that CAD-CAM components cannot achieve implant stability over 10 years, however niether did they progress to radiological failure during this period of time. It is very likely though that if they do continue to progress in this fashion failure will eventually occur.

The final aim of this study was to see if there was any correlation between the extent of migration and the amount of pain experienced by the patient. This study found that there was no significant correlation between the amount of migration of the femoral component and the degree of pain experienced by the patient.

One other important observation in this study was the age of the patients who had a migration value of above 10mm. As noted previously, all four occasions in which the migration was above 10mm were in patients below the age of 16 years. McCullough et al also reported the fact that younger patients had a 28.5% rate of failure compared with no failures in patients over the age of 16 (McCullough CJ et al 2006). Thus the age at the time of surgery may be an important factor when considering the long-term survival of the implant. The relationship between age and the survival/failure of the CAD-CAM implants in JIA patients would be an area that requires further investigation in the future.

This study has brought to light some important considerations with regards to the use of CAD-CAM femoral components in patients with JIA. Future work should concentrate on trying to develop a better understanding of the pattern of migration seen with CAD-CAM components in JIA patients. The follow-up should be ideally around 15-20 years as this will enable us to determine the extent of failure of the components. In addition another initative that could be undertaken in the the future is to use an alternative method of measuring migration such as Roentgen stereophotogrammetric analysis (RSA) and follow patients in a prospective manner rather than a retrospective one.

Limitations:One of the most important limitations of this study was the difficulty in locating the identical points for digitisation on each of a series of radiographs for each patient .This particularly applicable to radiographs from patients with JIA as significant changes in the bony anatomy of the femur may occur over a period of 10 years. If the same points on successive radiographs from each patient are not digitised, it could affect the value obtained for migration. Another limitation was imposed the acetate sheet on which the points for digitisation were marked. A minor shift in the position of the acetate sheet could lead to a point being digitised which is slightly displaced from the required point of digitisation. This again would affect the value obtained for migration.

CONCLUSION

It is clear from our study that there is no correlation between the degree of migration of CAD-CAM components in JIA patients and the clinical results that are obtained in these patients. This is of clinical significance as we can exclude migration as being one of the factors that affect the clinical outcome after THR in JIA patients. In addition this study had enabled us to understand the pattern of migration CAD-CAM femoral components undergo in patients with JIA. The components tend to migrate progressively in significant amounts over a period of 10 years. Understanding the pattern of migration of CAD-CAM components is important as it would influence our choice of femoral component being used for a THR in a particular patient. Finally we also found that there was no correlation between te degree of migration of the CAD-CAM component and the degree of pain experienced by the patient. This enables us to exclude migration as being one of the factors that lead to pain after surgery in the long-term. However the results of this study should be interpreted in a cautious manner because there were quite important limitations with regards to the measurement of migration.

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