Custom Cementless THA in Patients with Skeletal Dysplasia Results in Lower Apparent Revision Rates than Other Types of Femoral Fixation

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Abstract

Background Patients with skeletal dysplasia are prone to degenerative hip disease thus requiring THA at a younger age than the general population. This is a technically demanding procedure with high complication and revision rates. Achieving good femoral fixation can be challenging because of the abnormal features of the hip.

Questions/purposes We therefore determined: (1) survivorship, (2) function, (3) radiographic findings, and (4) complications associated with a cementless custom-made femoral component used in THAs for patients with skeletal dysplasia and compared these parameters with those from other types of femoral fixation.

Patients and Methods Between 1992 and 2005, 40 THAs were performed in 25 patients with skeletal dysplasia using custom-made cementless femoral components. There were 15 men and 10 women with a mean age of 37.5 years (range, 18–61 years) and a mean height of 145 cm (range, 120–173 cm). Patients were followed clinically and radiographically for a minimum of 4.3 years (mean, 10.1 years; range, 4.3–18.2 years).

Results The survivorship rates for the femoral and acetabular components were 92% and 70%, respectively, at 220 months. Revision arthroplasty was performed in four of 40 hips (10%). In two, the acetabular component was revised for aseptic loosening, one had both components revised for aseptic loosening, and one had an isolated femoral component revision for deep infection. The mean Harris hip score improved from 41 (range, 27–57) preoperatively to 80 (range, 51–94) at final followup. There were two intraoperative proximal femoral fractures and one dislocation.

Conclusions When compared with studies with equal followup, custom-made cementless components in THAs for patients with skeletal dysplasia apparently had lower revision and complication rates with comparable function and higher midterm survival.

Level of Evidence Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Skeletal dysplasias are a diverse group of genetic disorders characterized by abnormal development and remodeling of bone and cartilage [6]. Alterations in development, biomechanics, and alignment commonly predispose to hip disorders at a young age [31]. Initially, soft tissue releases and corrective pelvic or femoral osteotomies may improve joint congruity, stability, and alignment [32]. When painful osteoarthritis (OA) develops, a THA usually relieves pain and restores function [8, 19, 23, 33]. This is a technically challenging procedure with a high complication rate owing to the abnormal features of the hip, especially on the femoral side, in addition to bone deformity and soft tissue contracture [31]. Intraoperative femoral shaft fractures or

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perforation are common and there is a high revision rate for aseptic loosening [8, 10, 12, 19, 25, 29]. The use of custom and modular hip implants, cemented and cementless, has been advocated [1, 12, 13, 16, 25, 33, 34]. Modular systems allow intraoperative adjustment of offset, neck length, and version. Lim et al. [25] implanted 23 modular cementless prostheses in 13 patients with multiple epiphyseal dysplasia and reported one revision (4.3%) and one intraoperative periprosthetic fracture at a minimum followup of 2 years. The midterm and long-term survival of modular femoral components are largely unknown. In patients with severe proximal femoral deformity and hypoplasia, some authors consider modular implants unsuitable and believe custom-made implants provide a better option, especially when addressing excessive femoral neck anteversion, which frequently is seen in patients with skeletal dysplasia [1, 8, 23]. In addition, customized components maximize the fit and fill in the proximal femur at the time of implantation and thereby provide better stability for the femoral component [14, 22]. Some authors have reported the use of standard THA implants in patients with short stature [8, 19, 25, 29]. Although some studies are limited by low patient numbers and short followups, revision rates of 4% to 30%, intraoperative femoral fracture rates of 3% to 17% and nerve palsy rates of 2% to 13% have been reported with mean followups of 4.8 to 11.5 years [8, 19, 25, 29]. One study [16] reported 79 patients with OA secondary to developmental dysplasia of the hip who had custom cementless devices. At a mean followup of 10 years they reported an 89.5% survivorship. We identified similar studies reporting survival of a cementless custom-made femoral component in patients with skeletal dysplasia.

We therefore determined: (1) survivorship, (2) function, (3) radiographic findings, and (4) complications after implantation of a computer-aided design and computer-aided

manufacturing (CAD-CAM), cementless, custom-made femoral component for THA in patients with skeletal dysplasia and compared these observations with those for other types of femoral fixation.

Patients and Methods

We retrospectively reviewed all 27 patients who had 43 primary THAs using a custom-made cementless femoral component for advanced OA secondary to skeletal dysplasia between 1992 and 2005. The patients were identified from our biomedical engineering database. The indications for the custom-made cementless devices were (1) painful end-stage hip OA affecting the patient's quality of life associated with (2) substantial proximal femoral or acetabular deformity (Fig. 1). There were no absolute contraindications related to the use of this device. Clinical data were obtained from case notes, hospital databases, imaging studies, outpatient clinic reviews, and functional questionnaires. Two patients were lost to followup, leaving 25 patients with 40 THAs. There were 15 men and 10 women with a mean age of 37.5 years (range, 18–61 years) at the time of the surgery (Table 1). Mean patient height was 145 cm (range, 120–173 cm) and mean weight was 58 kg (range, 38–85 kg). THA was performed in 23 right hips and 17 left hips. Fifteen patients had staged bilateral THAs. Eight patients (32%) had undergone previous lower limb surgery, including eight lower limb osteotomies, two pelvic osteotomies, two lower limb epiphysiodeses, two hip arthrograms, and one internal fixation for previous proximal femoral fracture. The minimum followup was 4.3 years (mean, 10.1 years; range, 4.3–18.2 years). Functional scoring was done during telephone interviews and clinic reviews and all remaining data were obtained from medical records and radiographs.

Fig. 1 The typical features of a patient with pseudoachondroplasia in whom a CAD-CAM custom-made femoral stem was indicated are shown. (A) An AP radiograph and (B) an axial CT scan of the left hip show advanced osteoarthritic change with a hypoplastic proximal femur and excessive femoral neck anteversion (54.3°). (C) A standing

AP long-leg alignment radiograph shows the patient's short stature and severe femoral deformity. (D) A postoperative left hip radiograph shows a satisfactory appearance of the cementless CAD-CAM femoral stem with proximal press-fit loading.

Table 1. Primary diagnoses of patients

Diagnosis	Number of patients
Multiple epiphyseal dysplasia	14
Spondyloepiphyseal dysplasia	4
Morquio syndrome	2
Diastrophic dysplasia	1
Pseudoachondroplasia	1
Osteogenesis imperfecta	1
Schwachman syndrome	1
Cornelia de Lange syndrome	1

The femoral stem was custom-made (Centre for Bio-mechanical Engineering, University College London in association with Stanmore Implants Worldwide Ltd, Stanmore, UK) and manufactured using special software that used CAD-CAM technology to achieve a component with a precise cementless press-fit. By digitizing key anatomic landmarks on preoperative biplanar radiographs, lower limb measurement films, and CT scans of the hip, a 3-D image of the proximal femoral canal was generated, which allowed for the optimal femoral stem design to be calculated. Manipulation of the software enabled the designer to alter retroversion or anteversion of the femoral neck. Additional design features could be selected from a menu of choices, including antirotation cutting flutes and the presence, size, and position of a collar. On completion of the on-screen design, the automated software produces a machining code for the computer-controlled milling machines that are capable of producing patient-specific implants within 1 hour with extreme precision. The CAD-CAM stem was made of titanium alloy (Ti 6Al 4 V) with cobalt-chrome or ceramic interchangeable heads (22- or 28-mm diameter). It had a collar proximally and a lateral flare. The intertrochanteric portion had numerous macrogrooves measuring 1.5 mm in depth and 3 mm in width to increase the surface area for osseointegration. The distal end had longitudinal cutting flutes with a polished finish at the tip to optimize insertion. The implant surface was plasma-sprayed and coated with highly crystallized hydroxyapatite (Fig. 2). Concurrent mathematical modeling using finite element analysis combined with dual-energy x-ray absorptiometry (DEXA) studies suggest optimizing the “fit and fill” of the proximal femoral canal by incorporating a lateral flare permits more natural physiologic loading and preferential adaptive bone remodeling and osseointegration [21]. The strain pattern in the proximal femur using the CAD-CAM stem is closer to that of normal bone than with other types of prostheses, which preserves bone mass [21, 22].

All operations were performed at one institution by senior surgeons (SMA, SRC, TWB, GB) in the joint

Fig. 2 The photograph shows a CAD-CAM femoral stem with an accompanying custom-made rasp. The presence of a collar, lateral flare, numerous macrogrooves, longitudinal cutting flutes, polished tip, hydroxyapatite and plasma-sprayed intertrochanteric section, and custom-designed femoral neck anteversion optimize the press-fit.

reconstruction unit. The procedure was performed with the patient in the lateral decubitus position. An anterolateral or posterior approach [20] was used to expose the hip according to the presence of old skin incisions, extent of soft tissue contractures, bony deformities, and the operating surgeon's preference. After cutting the femoral neck, capsular, psoas, and adductor releases were performed when required to achieve appropriate access, range of movement, and lengthening. A greater trochanteric realignment osteotomy was considered when there was excessive proximal femoral angular deformity affecting the abductor muscles' function. We used the criteria of Ranawat et al. [30] to define the true acetabulum, which often was hypoplastic with limited bone stock, preventing excessive reaming. The acetabular cavity was prepared using sequential reamers. Cementless porous-coated components were used preferentially on the acetabular side with the potential for biologic fixation. They were positioned in the same anatomic version as the patient's native acetabulum. Any acetabular roof defects were reconstructed with autogenous femoral head autograft and/or augments to obtain satisfactory cover. Solid or flexible T-handled reamers were used to ream the distal femoral canal line to line so that the cutting flutes could cut into the cortical wall by 1 mm. The proximal femoral canal was prepared using a custom-made rasp, which has the same dimensions as the prosthesis. After rasping and trialing, the rasp was removed and the stem inserted with preset retroversion or anteversion depending on the patient's unique

hip anatomy. The aim was to achieve proximal implant fixation with even stress distribution and load transfer at the bone-implant interface. After lavage with normal saline, the hip was relocated and stability and range of movement assessed. In this series, no patient required a proximal femoral shortening or splitting osteotomy. When the hip abductor muscles were deficient, the remaining tendons were sutured directly to the greater trochanter transosseously.

Prophylactic intravenous cefuroxime was given at induction and for two postoperative doses. Patients were mobilized as soon as possible, initially partial weight-bearing, followed by full weightbearing once active hip abduction had been achieved and satisfactory pelvic radiographs obtained. Thromboprophylaxis consisted of thromboembolic deterrent stockings for 6 weeks and prophylactic dose low-molecular-weight heparin (40 mg subcutaneous Enoxaparin injection once daily for 7 to 10 days). NSAIDs were not used routinely as prophylaxis for heterotopic ossification.

Patients were reviewed clinically and radiographically at 6 weeks, 12 weeks, 6 months, 12 months, and annually thereafter. Functional evaluation using the Harris hip score [18] (HHS) was performed preoperatively and at the patient's last followup.

Serial AP and lateral plain radiographs of the hip were obtained postoperatively, at 6 months, and on an annual basis afterward. These were assessed independently by two reviewers (MDS, SAH) for the presence of progressive radiolucent lines at the acetabular bone-prosthesis interface in the zones described by DeLee and Charnley [11] and at the femoral bone-prosthesis interface in the zones described by Gruen et al. [17]. Periprosthetic radiolucencies were considered clinically important if they were greater than 2 mm [26]. Heterotopic ossification was graded according to Brooker et al. [5]. There was no interobserver variability in the radiographic observations. One observer can reliably record a femoral observation of lucency [4]. Accurate observations of acetabular lucencies frequently require more than one observer [4].

Kaplan-Meier survival curves [24] for the acetabular and femoral components were used to compare rates of survivorship for all hips in the study (Fig. 3). Prosthesis survival was analyzed with implant revision for any reason as the end point. We used SPSS[®] Version 17 (SPSS Inc, Chicago, IL, USA) for all analyses.

Results

The survivorship rates of the femoral and acetabular components were 93% and 70%, respectively, at 220 months (Fig. 3). Revision arthroplasty was performed in four hips

Fig. 3 Kaplan-Meier survival curves are shown for (A) acetabular and (B) femoral components with component revision from any cause as the end point. The femoral component had a survival of 93% (CI 82% to 100%) at 220 months while the acetabular component had a survival of 70% (CI 38% to 100%) at 220 months.

(10%). In two, the acetabular component was revised, one had both components revised, and one had a femoral component revision for infection. All three acetabular components (two cementless and one cemented) were revised for aseptic loosening at a mean of 11.7 years (range, 9.3–14.3 years). At revision surgery, one of these patients had aseptic loosening of the femoral component and underwent revision surgery at 112 months. Three progressive radiolucent lines were noted around three of the acetabular components (7.5%). All three underwent revision for aseptic loosening at a mean of 11.7 years (range, 9.3–14.3 years).

The mean HHS improved from 41 (range, 27–57) preoperatively to 80 (range, 51–94) at the time of last followup. All patients with low scores (< 70) had OA affecting the spine and other lower limb joints that compromised function. The Trendelenburg test was positive in

four of 25 patients (16%) postoperatively compared with 23 of 25 patients (92%) preoperatively. Walking aids were required by 20 patients preoperatively and eight patients postoperatively as a consequence of the underlying diagnosis and multiple joint OA (seven patients required one cane and one patient required two).

Nonprogressive radiolucent lines were observed around two femoral stems (5%) in two patients, but neither of these patients had thigh pain. Progressive radiolucent lines were observed around two femoral stems (5%) in two patients. In the first, no new correlating clinical symptoms were present at last followup and no action has been taken as a result. In the second, the loosening was associated with worsening thigh pain and raised inflammatory markers. The patient underwent a single-stage revision for deep infection. Periarticular heterotopic ossification was present in three hips (7.5%).

Four of the 25 patients (16%) underwent a reoperation. There were two intraoperative linear proximal femoral fractures. One occurred during insertion of the press-fit femoral stem and was managed by cerclage wiring with Dall-Miles cables (Stryker Corp, Kalamazoo, MI, USA), followed by partial weightbearing for 6 weeks. The other occurred during rasping of the proximal femur. This was considered a stable fracture intraoperatively and the patient was managed by touch weightbearing for 6 weeks postoperatively. This patient had persistent pain and underwent exploration of the THA at 7 months. The femoral and acetabular components were well fixed. Augmentation of the posteromedial cortex with a fibula strut allograft and cerclage wires was performed to strengthen the calcar. One patient with generalized ligamentous laxity and muscle hypotonia had an early dislocation at 1 month and was treated by open reduction. Change of prosthesis neck length from 0 to + 3.5 mm optimized offset and restored stability. This same patient had thigh pain develop at 20 months with mildly elevated inflammatory markers (C-reactive protein, 24; erythrocyte sedimentation rate, 36) and evidence of femoral radiographic loosening. Persistent pain necessitated a single-stage revision of the loose femoral component at 24 months. Specimens from the femoral medullary cavity grew *staphylococcus aureus* and the patient received 6 weeks of postoperative antibiotics, which eradicated the infection clinically, serologically, and radiographically. One patient had a transient sciatic nerve neurapraxia, and there was one superficial wound infection requiring oral antibiotics.

Discussion

A THA in a patient with skeletal dysplasia is technically challenging with high complication and revision rates

owing to abnormal features of the bone and soft tissue contractures. We therefore determined: (1) survivorship, (2) function, (3) radiographic findings, and (4) complications after implantation of a CAD-CAM cementless custom-made femoral component for THA in patients with skeletal dysplasia and compared these observations with those for other types of femoral fixation.

There are limitations to this study. The first limitation is the lack of randomized control trial data with modular and custom, cemented and uncemented control groups. As these represent a rare group of patients, a long study period from multiple centers would be required to recruit sufficient patients for a prospective randomized controlled trial. All currently published studies [1, 12, 13, 16, 25, 33, 34] are retrospective and most do not distinguish between the use of custom and modular prostheses with or without cement, which makes comparison difficult. The second limitation is the long study period and relatively low patient numbers. The third limitation is the confounding effects attributable to the presence of multiple joint involvement. This makes interpretation of function difficult as the functional scores of one joint cannot be disentangled from the others. The final limitation is that selection, measurement, and interviewer bias may affect the functional assessment.

We used a cementless custom-made femoral component in all hips, with a cementless acetabular component in 35 hips and a cemented acetabular component in five. We had an overall revision rate of 10%. The femoral component had a survival rate of 93% at 220 months (Fig. 3) when compared with rates from a similar study [8], and component malposition was present in 5%. Aseptic loosening of the acetabulum was the most common cause of revision and occurred in 6% of cementless cups and 20% of cemented cups. Cemented acetabular components are associated with shorter longevity and higher revision rates, particularly in young patients [27]. We advocate the use of a cementless cup in these patients when acetabular bone stock provides greater than 75% cover to allow adequate secondary bone ingrowth. Autogenous bone graft and/or augments also may be used. Chiavetta et al. reported a 30% revision rate for 35 patients of short stature at a mean followup of 12.8 years [8]. Most of these patients had revision surgery for aseptic loosening and osteolysis. Intraoperative periprosthetic fractures occurred in two patients at the time of implant insertion, with an additional three patients experiencing periprosthetic fractures at followup [8]. Femoral component malposition was present in 25% with three patients experiencing dislocation despite adequate component position. One patient had transient sciatic nerve palsy develop and there were two deep infections [8].

Five percent of our patients had intraoperative proximal femoral fractures which compares favorably with

reported rates (3%–17%) from other published studies [8, 19, 25, 29]. For patients undergoing cementless THAs, a press-fit femoral component may be difficult to achieve with modular implants where there is a severely dysplastic proximal femur and proximal femoral splitting [2], and corrective osteotomies may be required [19, 29]. The custom-made femoral design optimizes metaphyseal bone contact in the proximal femur, which is an important requirement in cementless THAs [2]. With most femoral components used in our study, a lateral flare was added to fill the space between the component and the bone of the proximal and lateral part of the femoral canal. The bespoke stem design allows correction of marked femoral neck anteversion, which is a common feature in patients with skeletal dysplasia. A proximal femoral splitting osteotomy with the associated risks of nonunion [15] was not required by any of the patients in our series.

The requirement for a custom-made femoral component for patients with skeletal dysplasia is disputed [31]; however, some of the studies using modular implants have limited followups [25, 29, 33]. Lim et al. implanted 23 modular cementless S-ROM prostheses during THAs (DePuy/Johnson & Johnson, Warsaw, IN, USA) in 13 patients with multiple epiphyseal dysplasia [25]. They reported good function with one revision (4.3%) for polyethylene wear and osteolysis at mean followup of 4.8 years. One intraoperative Vancouver Type A2 femoral fracture occurred at the time of stem insertion, which was managed by cerclage wiring. Modular cementless femoral implants have been used in THAs for OA secondary to developmental dysplasia of the hip [28], but modular designs may introduce additional problems related to corrosion, fretting, and dislocation or fracture of the components [3, 7, 9].

Patients with skeletal dysplasia share many common features such as short stature, ligamentous laxity, spinal deformity, atlantoaxial instability, lower limb malalignment, foot deformities, and premature degenerative joint disease. These multiple problems predispose to lower HHSs than those for patients with primary OA. We found lower HHSs after THAs in patients with skeletal dysplasia than those for the primary OA group, but similar to HHSs in other published series for patients with skeletal dysplasia [1, 8, 19, 25].

When compared with the only other study in the literature reporting the midterm survival of THR for patients with skeletal dysplasia [8], we found relatively lower revision, component malposition, and complication rates, comparable function, and higher long-term survival. This suggests custom-made cementless prostheses for THAs are a reasonable treatment option for this young and challenging patient group.

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