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Abstract

4-U hybrid total hip arthroplasty (THA) system was specifically designed for patients with developmental dysplasia of the hip (DDH). Straight stem with an appropriate offset and various size variations are advantages. We followed 128 hips in 124 patients, 13 men and 111 women, for a mean of 6.5 years (range, 5.0–7.5 years). Two acetabular and femoral components in two patients had been revised for infection, one acetabular component had been revised for recurrent dislocation, and one femoral component had been revised for periprosthetic femoral fracture. None of the acetabular or femoral components were revised for loosening or found to be loose at follow-up. The Harris hip score increased from a preoperative average of 42 points to 88 points. Primary THA using 4-U system had a good mid-term result in patients with DDH. This system could be applied for all patients including those with the narrowest and deformed femur.

Key words: hybrid total hip arthroplasty, developmental dysplasia of the hip, cemented stem, clinical results

Introduction

Total hip arthroplasty (THA) for osteoarthrosis secondary to developmental dysplasia of the hip (DDH) presents specific problems that include femoral head deformity, short femoral neck, excessive anteversion of the neck, narrow and straight medullary canal, and insufficient acetabular bone stock [4, 5, 10, 19, 27]. Patients with DDH are smaller than average European or American people, therefore, these patients need smaller and straighter femoral stems [19, 27]. Appropriate fit of the stem to the femur was sometimes disturbed by proximal curve and large distal diameter of the standard stem, even if we used a small implant of available standard THA systems.

The hybrid THA combines insertion of an acetabular component without cement and a femoral component with cement [12, 25]. We designed and developed an original hybrid THA system for patients with DDH. The present study evaluated whether this system was appropriately fit to patients with DDH.

4-U Hip System (Nakashima Medical, Japan)

'4-U' represents four capital letters of the words; universal, upgraded, unique and ultimate. The shape and size variations of the stem are unique characteristic features of this system. Original three-dimensional (3D) CT data was obtained from patients with DDH and anatomical femoral shapes were evaluated [11]. Configurations of the 4-U stem were designed to appropriately fit every measured femoral canal (Fig. 1a, b). The shape of the stem below the proximal collar was designed straight and the femoral neck was designed long enough to restore the anatomical length of offset between the longitudinal axis of the stem and the center of the femoral head. Seven stems from No. 1 to No. 7 are available (Table 1, Fig. 1c). Long, standard and short neck lengths are available for each stem with monoblock. The femoral head is modular and two lengths of 0 mm and 3.5 mm are also available.

The No. 1 smallest stem has the most unique characteristic feature of this system, which was designed to fit to the smallest femoral canal. The largest offset of the No. 1 stem is 40 mm, which is longer than the available equivalent small cemented stems including Exeter smallest stem (Stryker-Howmedica-Osteonics, Allendale, New Jersey, USA) with 34 mm of the largest offset. The bending strength of No. 1 long neck stem is 15200N, indicating that the No. 1 long neck stem could endure various stresses caused by daily activity of patients [18]. A stem is made of cobalt-chromium alloy with the average surface roughness of 2.0 μm in the proximal half and 1.0 μm in the distal half, which is equivalent to the matte finish component.

The acetabular component is titanium alloy (Ti-6Al-4V) hemisphere with fiber-metal porous-coating. The outer shell has multiple screw holes, with diameters ranging from 40 to 62 mm in 2-mm increments. Both standard and 10° elevated polyethylene liners are available for 22, 26 and 28 mm-diameter head. The minimum thickness of the liner is 5.7 mm.

The purpose of this study was to evaluate early to intermediate-term results after primary hybrid THA using this system for the treatment of osteoarthrosis secondary to DDH.

Patients and methods

Between September 2002 and August 2004, 144 total hip arthroplasties using 4-U Hip System were performed in 140 patients for treatment of advanced osteoarthrosis secondary to DDH. Of these, 16 patients (16 hips) were excluded from the study: three patients (three hips) died before a minimum 5-year follow-up; eight patients (eight hips) were contacted by telephone and known to have well-functioning THAs but did not have radiographs for review; and five patients (five hips) had no data available after the early postoperative period. The remaining 128 hips in 124 patients were available for clinical and radiographical review. The average duration of follow-up was 6.5 years (range, 5.0–7.5 years). The average age at the time of the index operation was 62.5 years (range, 30–87 years). The average weight was 54 kg (range, 35–88 kg) and the average height was 152 cm (range, 132–169 cm). The average body mass index was 23.9 (range, 16.0–34.8). Thirteen patients were men and 111 were women. There were 68 right hips and 60 left hips. According to the classification system of Hartofilakidis et al. [10], 109 hips were type-1 (dysplasia), 13 were type-2 (low dislocation), and 6 were type-3 (high dislocation).

All of the procedures were performed through the posterolateral approach without trochanteric osteotomy. The acetabular component was inserted with a line to line fit. An average of 3.1 screws (range, 2–5 screws) was used for fixation. The average outer diameter of the acetabular component was 52 mm (range, 40–60 mm). The diameter of the prosthetic femoral head was 22 mm in 82 hips and 26 mm in 46 hips. All polyethylene liners used in this study period were conventional, not highly cross-linked. The average polyethylene liner thickness was 10.9 mm (range, 5.7–15.7 mm). Standard polyethylene liner was used in 115 and 10° elevated liner was used in 13. Initial depth of the standard liner was 50% of the femoral head diameter. Initial dislocation rate was high and this shallow liner seemed related to high dislocation rate. Circumferential 1.5 mm rim was added to all the polyethylene standard liners from April 2004.

The smallest No. 1 was used in nine hips, No.2 in 12 hips, No. 3 in 35 hips, No. 4 in 58 hips, No.5 in 13 hips and No. 6 in one hip. All final femoral rasps used in this study for canal preparation over-rasped by 0.5 mm. The Simplex cement (Stryker-Howmedica-Osteonics, Mahwah, New Jersey) was prepared and applied into the femoral canal using a cement gun. A methylmethacrylate plug was used in all hips.

Clinical evaluations were made using hip scoring system [8]. An anteroposterior radiograph and a true lateral radiograph were made preoperatively and at each follow-up examination. Anteversion of the acetabular component was measured [22]. The acetabular interface on the anteroposterior radiograph was divided into three zones [3]. The acetabular component was classified as migrated if there was a change of at least 4 mm in the horizontal or vertical position of the center of the component [24]. Linear head penetration into the polyethylene liner was measured [15].

Cementing of the femoral stem was classified as Grade A, B, C-1, C-2, and D [17]. The dimensions and location of radiolucent lines at the bone-cement interface of the femoral component and osteolytic lesions were recorded [7]. The thickness of the femoral cement mantle was measured in 12 zones of the femur. The canal filling ratio of the femoral component was defined as the percentage of component width to intramedullary width at the midpoint of the component on an anteroposterior radiograph taken within one month after surgery [13]. Loosening of the femoral component was defined using the criteria described by Harris et al. [9].

The study design was approved by the Ethics Committee of Asahikawa Medical College (09-10-13, #607).

Statistical analyses were performed using SPSS software (SPSS Inc., Chicago, Illinois, USA). Clinical, radiographic, and surgical factors were evaluated with use of chi-square tests or Mann-Whitney U test where appropriate. Preoperative and postoperative Harris hip scores were compared with use of the Wilcoxon signed-rank test. Probability values less than 0.05 were considered significant. The Pearson linear correlation coefficient was used to assess correlations between wear and various measurements. Kaplan-Meier survival curves with end points defined as revision for any reason and aseptic loosening of the acetabular and femoral component were calculated. All survivorship data were reported with 95% confidence interval (CI).

Results

4-U Hip System could be applied for all patients including those with the narrowest and deformed femur. At the time of the most recent follow-up, two acetabular and femoral components in two patients had been revised for infection 2 and 22 months postoperatively. One acetabular component had been revised for recurrent dislocation 30 months postoperatively. One femoral component had been revised for periprosthetic femoral fracture 6.2 years postoperatively. None of the acetabular or femoral components were revised for loosening or found to be definitely loose on radiographs (Figs. 2 and 3). Kaplan-Meier analysis revealed that the survival rate was 100% with aseptic loosening of the acetabular or femoral component as the end point and 96% (95% CI: 94–98%) with revision for any reason as the end point.

The Harris hip score increased from a preoperative average of 42 points (range, 26–76 points), to 88 points (range, 40–100 points) at the most recent follow-up for patients who did not have a subsequent revision ($p < 0.001$); 88 points (range, 40–100 points) in type-1 hips, 92 points (range, 85–100 points) in type-2 hips and 83 points (range, 70–90 points) in type-3 hips ($p = 0.175$).

The average angle of abduction of acetabular components at the latest follow-up was 44.9° (range, 35–62°). The average anteversion of the acetabular components was 14.1° (range, 0–30°) and the average combined anteversion of the acetabular and femoral components was 46.9° (range, 18–80°). None of the acetabular components showed radiographic migration, rotation, or a continuous radiolucent line. Radiolucent lines were observed around six (5%) acetabular components. These lines were all 1 mm wide or less and no sockets showed a continuous radiolucent line. Small pelvic osteolytic lesions were observed adjacent to the acetabular component in two (1.5%) hips. The average rate of head penetration into the polyethylene liner was 0.09 mm (range, 0.01–0.40 mm) per year. There was a significant correlation between wear and abduction angle of the socket ($p = 0.023$). There were no correlations between wear and patient age ($p = 0.128$), gender ($p = 0.192$), body weight (p = 0.257), polyethylene thickness (p = 0.369), diameter of the femoral head (p = 0.134), anteversion angle of the socket (p = 0.136), anteversion angle of the stem (p = 0.128), and position of the hip center (p = 0.418).

None of the femoral components showed definite or probable loosening at the most recent follow-up. The position of inserted femoral components was neutral in 115, varus in nine and valgus in four. The cementing of the femoral component was grade A in 56, grade B in 64, grade C-1 in six, and grade C-2 in two. Grade C-1 was given mainly due to the presence of small voids and grade C-2 due to the presence of a thin mantle of cement. The average cement thickness around the femoral component was > 2 mm except for zone 5 (Table 2). Radiolucent lines were observed around three (2%) femoral components. All radiolucent lines were seen at the bone-cement interface located in the zone 1. No radiolucent line was observed at the implant-cement interface. No hips showed femoral osteolysis other than two hips with postoperative infection. The average canal filling ratio was 80% (range, 63–95%).

Fourteen hips (11%) dislocated posteriorly. All dislocations occurred in initial 106 hips with the original liner, and no dislocation occurred in 22 hips with the modified liner from April 2004. One hip had undergone revision of the acetabular component for recurrent dislocation as described. The remaining dislocations were successfully treated without reoperation. There was no significant relationship between dislocation and patient age (p = 0.162), gender (p = 0.182), weight (P = 0.150), diameter of the femoral head (p = 0.985), use of elevated liner (p = 0.692), abduction angle (p = 0.306) and anteversion angle (p = 0.299) of the acetabular component, combined anteversion angle of the acetabular and femoral components (p = 0.299), and the hip center (p = 0.456).

There was no intraoperative periprosthetic fracture, nerve palsy, or clinically evident pulmonary embolisms.

Discussion

The 4-U femoral component has several unique features including straight stem, long femoral neck, and size variations providing the surgeon with a wide choice. This system could be applied for all patients and implanted even for hips with the narrowest or deformed femur. The clinical and radiographic results of the 4-U Hip System for patients with DDH continue to be encouraging. From September 2002, we have consecutively used the 4-U Hip System for patients with DDH. The No. 1 smallest stem was used in nine (7%) hips, indicating that the small and straight stem has been needed for some patients with DDH. We believe that one of the main factors contributing to the excellent survival and outcome of this implant is the smaller, straighter design and adequate offset of the femoral component [2].

The ideal thickness of the cement mantle for the femoral component is controversial. Thin or incomplete cement mantles have been reported to be responsible for irregular stress distribution, cement mantle fracture, stem debonding, osteolysis, and aseptic loosening [6, 23]. At least 2 mm cement mantle thickness was recommended with use of sufficient intraoperative over-rasping or over-reaming of the femur [28]. On the other hand, the thin cement mantle technique was introduced by Postel [21]. Langlais et al. showed good clinical results with a thin cement mantle technique using Charnley-Kerboull and the Ceraver Osteal cemented femoral components [14]. These stems were intended to fully occupy the medullary canal of the femur. They emphasized that a marked increase in pressure at the cement-bone interface would be produced by vigorous insertion of a canal-filling stem into doughy cement, and stronger initial mechanical interlocking at the cement-bone interface could be obtained. Skinner et al. also reported good clinical results with a thin cement mantle technique [26]. We believe that the tighter fit of the femoral component is technically important for the patients with a narrow femoral canal, and our results support these previous studies.

Although one of the main concerns of using shorter and smaller stem is the failure or breakage of implants, this has not been observed in our study. To date, we have implanted more than 1000 4-U stems, and we have not encountered any implant fractures. The implant is clinically safe and can be used for suitable patients with DDH.

Cementless femoral components have no room for the cement mantle, and intraoperative fractures have been reported [1, 20]. Perka et al. reported that the high incidence of intraoperative fractures using cementless stems for patients with DDH [20]. Intraoperative fracture is not a common complication in cemented femoral component and was not observed in this study.

Mallory et al. reported that dislocations after THA occurred frequently in patients with DDH [16]. The present dislocation rate of 11% was equivalent or higher compared to those of the previous series of DDH [1, 12, 20, 25]. It is apparent that the technique described by Pradhan [22] for evaluating acetabular version cannot distinguish anteversion from retroversion but only the degree of version, however, anteversion of the acetabular component was intraoperatively confirmed by visual inspection for all patients. Our posterior approach without repair of the external rotators and the posterior part of the capsule might have been a factor leading to the high dislocation rate. Due to this relatively high dislocation rate, we had minor design change for the depth of polyethylene liner in April 2004 as described above. This design change seems to contribute to reduce the dislocation rate. Another disadvantage of this system was that we used only conventional polyethylene in the period of this study, which is now being changed to highly cross-linked polyethylene.

We conclude that 4-U Hip System provides an appropriate fit of the femoral component among size variations, and satisfactory clinical results for patients with DDH. This system could be applied for all our DDH patients including those with the narrowest and deformed femur. We believe that use of an appropriate shape and size of the femoral component, and technical tight fit within the cement are important factors to achieve good clinical results. On the basis of our results, we continue to use this system.

Conflict of interest and funding

No benefits or funds were received in support of the study.

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Figure Legends

Fig. 1 Photograph and measurements of the femoral component.

a Anteroposterior photograph showing the 4-U No. 1 long neck stem.

b Lateral photograph showing the same stem.

c Measurements of the femoral component. L1: length of the stem, L2: offset, L3: neck length, L4: proximal anteroposterior width.

Fig. 2 Preoperative and follow-up radiographs of the left hip of a 62-year-old woman.

a Preoperative radiograph showed high dislocation of the left hip.

b Postoperative radiograph taken one day after surgery. No. 1 standard stem was inserted.

c Radiograph taken at 7-year follow-up examination showed no radiolucent lines.

Although the acetabular component was fixed at a high location of the pelvis, enough offset of the stem has avoided impingement between the acetabulum and the femur. The patient reported no hip pain and the clinical result was good.

Fig. 3 Preoperative and follow-up radiographs of the right hip of a 52-year-old woman.

a Preoperative radiograph showed low dislocation of the left hip.

b Postoperative radiograph taken one week after surgery. No. 3 standard stem was inserted.

c Radiograph taken at 7.5-year follow-up examination showed no radiolucent lines. The patient had a good clinical result.

Table 1 Each size of the femoral component (see Fig. 1c)

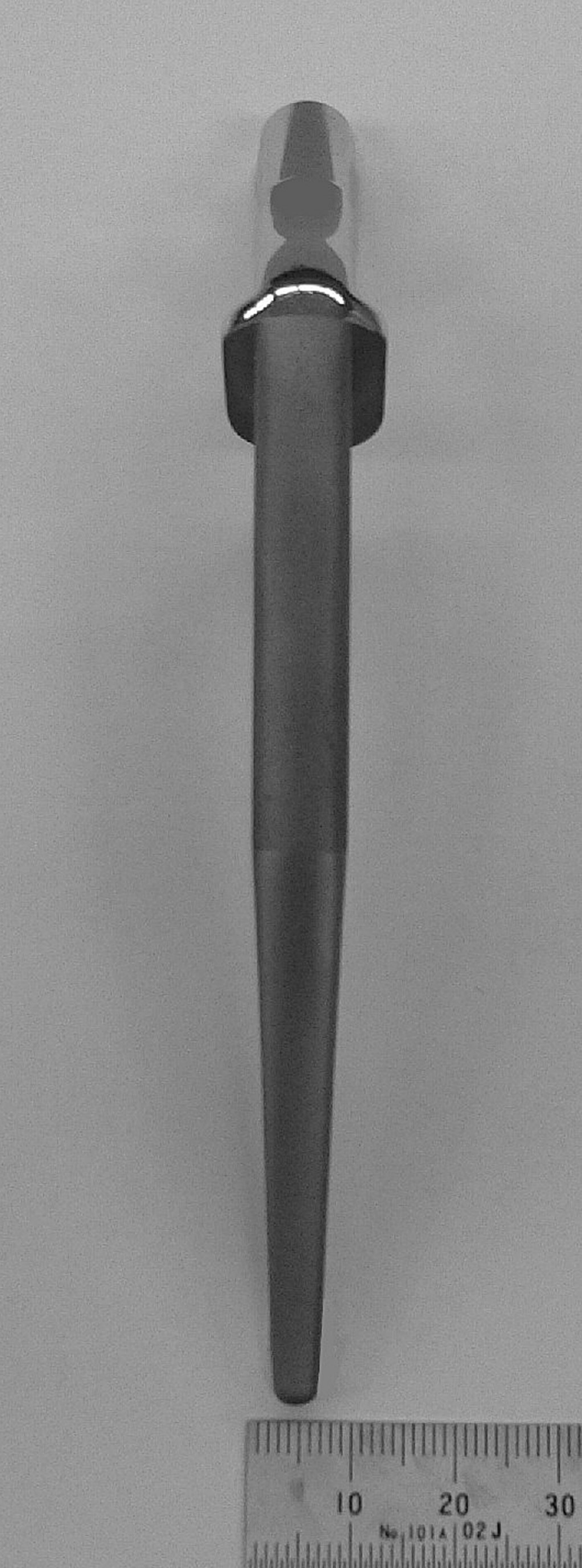
Number	Length of the stem (L1, mm)	Offset (L2, mm)	Neck length (L3, mm)	Proximal anteroposterior width (L4, mm)
1	94	27 / 32 / 37	27 / 34 / 41	9
2	104	29 / 34 / 39	30 / 37 / 44	10
3	113	31 / 36 / 41	32 / 39 / 46	11
4	123	33 / 38 / 43	35 / 42 / 49	12
5	127	33 / 38 / 43	35 / 42 / 49	13
6	131	33 / 38 / 43	35 / 42 / 49	14
7	140	35 / 40 / 45	37 / 44 / 51	16

Table 2 Analysis of the cement thickness of the femoral component

Femoral zone	Cement thickness (mm)
1	2.3 (0.6)
2	2.2 (0.9)
3	2.8 (0.8)
5	1.5 (1.2)
6	2.6 (0.9)
7	2.5 (1.0)
8	2.2 (0.6)
9	2.3 (0.7)
10	3.7 (1.8)
12	3.0 (1.1)
13	2.8 (0.9)
14	2.9 (0.6)

SD standard deviation

The values are the mean (SD) cement thickness (in mm).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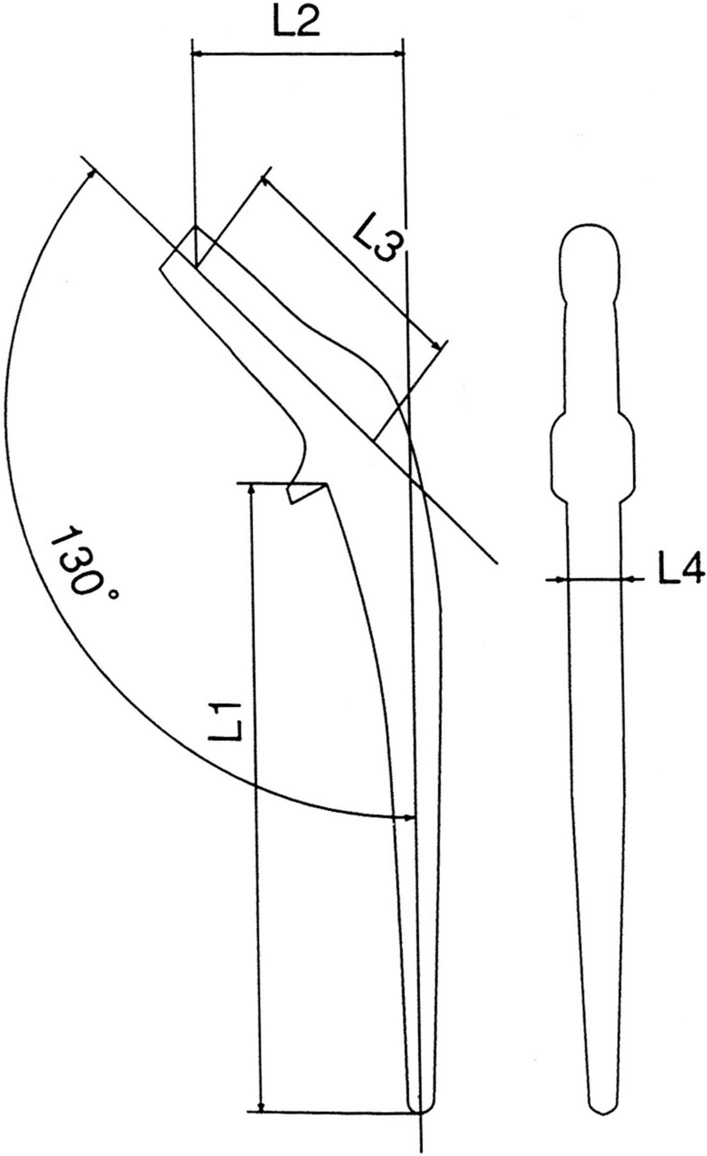
L2
L3
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L4