Comparison of two different on-shelf femoral stems for Crowe type IV developmental dysplasia of the hip

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Abstract

Objective: This study was performed to evaluate the proximal anatomical compatibility of stems for treatment of Crowe IV developmental dysplasia of the hip (DDH) using a previously developed three-dimensional comparison technique.

Methods: Patients with Crowe IV DDH who underwent computed tomography were retrospectively analyzed. The femoral medullary canals were three-dimensionally reconstructed, and models of cementless modular (S-ROM; DePuy Synthes) and conical (Wagner Cone; Zimmer Biomet) implants were used for virtual implantation. The negative point percentages (NPPs) were applied to verify fitting. The average distance (deviation) and the root mean square of the distance (RMSd) were used to quantify geometric compatibilities.

Results: Four (16.7%) and 12 (50.0%) femoral medullary canals could not be fitted properly with either the modular or conical implant. The NPPs in the distal comparison region were significantly greater in the conical than modular group. The deviation was significantly smaller in the modular than conical group. The RMSd was also significantly smaller in the modular than conical group.

Conclusions: Compared with conical implants, modular implants might be more effectively used in patients with Crowe type IV DDH. However, some Crowe IV DDH femurs with severe deformity cannot be fitted with either of these two on-shelf implants.
Introduction

Developmental dysplasia of the hip (DDH) refers to a spectrum of developmental hip abnormalities ranging from a mildly dysplastic acetabulum and concentrically located femoral head to a severely dysplastic acetabulum and dislocated femoral head. DDH is diagnosed in 0.1% to 0.5% of live births, and it is four to eight times more common in women than in men. DDH leads to subluxation of the femoral head, causing it to rest on the posterior lip of the acetabulum, as well as to osteoarthritis and avascular necrosis of the femoral head.

Total hip arthroplasty (THA) is regarded as an effective method for treating late-stage hip osteoarthritis secondary to adult DDH. The anatomical deformities of the proximal femur in patients with DDH are recognized as major challenges by orthopedic surgeons. The proximal femoral medullary canals are smaller and narrower in patients with DDH than in the general population: Sugano et al. and Noble et al. found that the outline of the proximal femoral medullary canal on cross-sectional planes is oval-shaped rather than regular. Other studies showed significant differences in the intramedullary and extramedullary anatomical parameters of the proximal femur between patients with Crowe IV DDH and patients with normal hips as well as a dramatically more narrow medullary canal at the lesser trochanter level in patients with Crowe IV DDH than in patients with normal hips and Crowe I to III DDH. Moreover, in some extreme cases, a conventional femoral prosthesis cannot be properly placed, and intraoperative proximal femoral fractures can occur during THA when abnormalities in femoral morphology are present. Even when the operation is successful, the hip center of rotation is shifted inferiorly and medially after THA in Crowe III and IV hips, affecting the joint biomechanics.

Specifically designed femoral stems such as the cementless modular implant (S-ROM; DePuy Synthes, Warsaw, IN USA) and cementless conical implant (Wagner Cone; Zimmer Biomet, Warsaw, IN, USA) were developed to provide a better fit in femoral medullary canals with anatomical deformities, and the successful application of these designs has been supported by studies with short- to long-term follow-up. Nevertheless, complications such as proximal femoral fracture are still reported in patients with DDH.

We have found that for some patients with Crowe IV DDH in our clinical practice, it is difficult to insert any on-shelf prostheses (including the specialized designs mentioned above) into the femoral canal at a desirable position. Therefore, the present study was performed to evaluate the proximal anatomical compatibility of specifically designed stems in patients with Crowe IV DDH using our previously developed three-dimensional (3D) comparison technique.
Materials and methods

Patients
This retrospective study involved consecutive patients with Crowe IV DDH who consulted at our hospital from January 2012 to June 2018. The protocol was approved by the review board of our hospital (#20150904). Written informed consent for participation was obtained. All investigations were conducted in conformity with the ethical research principles and the Helsinki declaration.

The inclusion criteria were Crowe IV DDH\(^{32}\) and no history of trauma or surgery on the affected hip.

Imaging
All patients underwent bilateral hip computed tomography scans for preoperative evaluations using an Aquilion 320 spiral computed tomography scanner (Toshiba, Tokyo, Japan). The tube voltage was 120 kV, current was 50 mA, pixel matrix was \(512 \times 512\), and slice thickness was 1.0 mm. All scans were performed from the iliac crest to the distal one-third of the femoral shaft. The scans were saved as Digital Imaging and Communications in Medicine data. The femoral head, cortical shell of the femoral shaft, and femoral medullary canal (including cancellous bone) were three-dimensionally reconstructed using Mimics 16.0 (Materialise, Leuven, Belgium).

3D prosthesis models
The geometries of the cementless modular implant (S-ROM; DePuy Synthes) and cementless conical implant (Wagner Cone; Zimmer Biomet) were obtained from public commercial information. The software 3-matic 9.0 (Materialise) was used to create the corresponding 3D implant models (Figure 1(a) A, B and 1(b) A, B).

Compatibility analyses of femoral stems
The analyses of femoral stem geometric compatibilities in Crowe IV DDH were conducted using Geomagic Qualify 13.0 (Geomagic, Research Triangle Park, NC, USA). This approach was established based on our previously developed 3D prosthetic comparison technique.\(^{31}\) A set of reconstructed femoral head, femoral cortical shell, and femoral medullary canal models was imported into the Geomagic Qualify software. Each modular implant and conical implant was placed properly within the femoral medullary canal model by an experienced orthopedic surgeon using a simulating surgical technique (Figure 1(a) C–E and 1(b) C–E). The sizes of the stems were first chosen according to the measured medullary canal diameter at the level of the femoral isthmus, and the stem was placed at this level to reproduce the center of rotation of the femoral head. If the chosen stem obviously protruded out of the proximal femoral medullary canal border (Figure 2C, D) and the surgeon determined that the implant had no chance of being fitted in the femur during actual surgery, then a smaller implant was placed instead. The sizes of the implants used in the simulating surgeries are presented in Table 1. Once implantation was satisfactory, dimensional comparisons between the reconstructed femoral medullary canal and femoral implant were made in the proximal area of the proximal femoral medullary canal (i.e., from the resection level to 45 mm distal) (Figure 1(a) D, E and 1(b) D, E). This segmentation of the proximal medullary canal was chosen because it is the vital region for proximal fitting and loading of the stem in THA. Negative point percentages (NPPs) were calculated between the point clouds of the reconstructed models to evaluate the percent of the implant surface that was outside of the medullary canal.
Figure 1. Examples of reconstructed femoral implants in the modular and conical groups. (a) Modular group. (A) Reconstructed femoral implant and (B) corresponding proximal assessment region. (C) The femoral shaft and medullary canal were reconstructed. (D) The modular stem was selected according to the measured medullary canal diameter of the femoral isthmus and placed at the appropriate depth to reproduce the femoral head center. (E) The proximal section of interest was isolated for dimensional comparison. (b) Conical group. (A) Reconstructed femoral implant and (B) corresponding proximal assessment region. (C–E) Steps in the evaluation process. (C) Reconstruction of the femoral shaft and medullary canal. (D) Simulated surgical technique. (E) Analysis.
Figure 2. (A–D) Examples of color maps comparing the implantation results in four cases. Two femoral medullary canals were properly fitted using the (A) modular and (B) conical implants. Another two examples associated with a large blue area (negative point percentage of $>15\%$) indicating mismatch between the canal and stem models in the (C) modular and (D) conical implant groups. (E–H) Examples of color maps comparing the results of mismatching (E, G) modular and (F, H) conical implants. (E, F) The proximal area of the proximal medullary canal and (G, H) the distal area of the proximal medullary canal were analyzed by separating the models with a coronal plane passing through the lesser trochanter tip.
model. After determination of the pilot protruding patterns of the modular and conical stems, the proximal area of the proximal medullary canal (Figure 2E, F) and the distal area of the proximal medullary canal (Figure 2G, H) of each model pair were analyzed by separating the models with a coronal plane passing through the lesser trochanter tip. Mismatch between the femoral medullary model and femoral stem was defined as the presence of large blue areas (NPP of >15%) on the 3D comparison color maps (Figure 2E, H) even when using the smallest available stems in each group. Successful compatibility was considered when there was at least one size of implant that could fit the hip.

The average distance, also called the deviation, between the border of the reconstructed medullary canal and the femoral implant was estimated by measuring the distances between the closest point pairs between the point clouds of the reconstructed surfaces of two objects. Because minimal protruding of the femoral implant out of the medullary canal can be tolerated during actual implantation, negative values were presented in the analyses of deviation. Because positive and negative values can be neutralized during calculations, the root mean square of the distance (RMSd) was applied to demonstrate the dimensional compatibilities of the femoral prostheses, as we proposed in our previous study:\textsuperscript{31}

$$RMSd = \sqrt{\frac{\sum d_i^2}{n}},$$

where \(d\) is the distance between each of the \(n\) pairs of closest points between the surfaces of the femoral medullary canal model and femoral implant.

**Statistical analysis**

PASW Statistics 18.0 (IBM Inc., Armonk, NY, USA) was used for the statistical analysis. Continuous variables are presented as mean ± standard deviation. Categorical variables are presented as frequency and percentage. The mismatch to the femoral medullary canal between the modular and conical stem designs was compared using a chi-square test. Student’s t-test was used to compare the differences in the NPP, deviation, and RMSd between the modular and conical implant groups because the data were parametric and equal variances were observed in all comparisons between implant groups. A \(P\) value of <0.05 was considered statistically significant.

**Results**

**Characteristics of the hips**

From January 2012 to June 2018, 20 patients with 24 hips affected by Crowe IV DDH were recruited. Table 2 shows the patients’ demographic data. Two affected hips were from male patients and 22 were from female patients.

**Fitting of implants**

Among the 24 hips, 4 (16.7%) femoral medullary canals could not be fitted with any available size of the modular implant, and 12 (50.0%) femoral medullary canals could

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**Table 1.** Sizes of femoral implants used in the study.

| Implant   | Size                  |
|-----------|-----------------------|
| Modular   | 6-12(B), 7-12(B), 8-14(B), 9-14(B), 11-16(B) |
| Conical   | 13, 14, 15, 16        |

The size of the modular implants was defined as the distal diameter-proximal size of the sleeve. The size of the conical implants was defined as the distal diameter of the proximal section of the stem.
not be fitted with any available size of the conical implant ($P = 0.01$). The bilateral fitting results were similar in patients with bilaterally affected hips. For the modular implant, the mismatching areas (NPP of >15%) of the four mismatching cases were all located in the proximal triangle region of the design, indicating that the triangles were protruding out of the femoral medullary canal models. In the conical implant group, the mismatching areas were mostly found in the distal area of the proximal medullary canal; this was attributed to the smaller taper of the conical implants than of the Crowe IV DDH medullary canals. Between the modular and conical designs, the NPPs were similar in the proximal area of the proximal medullary canal (8.8% ± 6.0% vs. 8.1% ± 5.9%) and significantly greater in the conical design in the distal area of the proximal medullary canal (2.2% ± 3.3% vs. 27.5% ± 30.2%, $P < 0.01$) (Table 3).

### Table 2. Characteristics of 24 hips of 20 patients with developmental dysplasia of the hip.

| Characteristics | Hips (n = 24) |
|-----------------|--------------|
| Age, years      | 41 ± 10      |
| Sex             |              |
| Female          | 22 (91.7)    |
| Male            | 2 (8.3)      |
| Affected side   |              |
| Left            | 14 (58.3)    |
| Right           | 10 (41.7)    |

Data are presented as mean ± standard deviation or n (%).

Discussion

The anatomical deformities seen in the proximal femur in patients with Crowe IV DDH are recognized as major surgical challenges. Therefore, in the present study, we evaluated the proximal anatomical compatibility of stems in hips affected by Crowe IV DDH using a previously developed 3D comparison technique. The results indicate that compared with conical implants, modular implants might be more effectively used in patients with Crowe type IV DDH, but some Crowe IV DDH femurs with deformities cannot be fitted with either of the two on-shelf implants.

One major cause of intraoperative femoral fracture during THA is mismatch between the femoral stem and the femoral medullary canal. The risk of intraoperative femoral fracture during hip replacement is increased in patients with osteoarthritis secondary to DDH. The major cause of this problem can be attributed to alterations in the femoral anatomy such as stenosis of the femoral medullary canal. Zhao et al. investigated the risk factors for intraoperative femoral fracture in primary THA based on 904 THA procedures and reported a 2.7-fold higher rate of intraoperative femoral fracture in patients with than without DDH ($P = 0.034$). Miettinen et al. performed a case-control study in which they investigated the risk factors for intraoperative calcar fracture in cementless THA (3207 patients) and found that the incidence of hip dysplasia significantly higher in the calcar fracture group than in the control group (20.0% vs. 9.3%, respectively; $P = 0.001$).
To overcome the stenosis and anatomic alterations of the femoral medullary canals in DDH, specifically designed femoral prostheses such as cementless modular and conical implants are recommended for THA in patients with DDH.\textsuperscript{20–24,27} However, evidence of intraoperative proximal femoral fracture is still observed in some cases.\textsuperscript{20–24,29,30}

In the present 3D comparison study, four (16.7\%) femurs in patients with Crowe IV DDH could not be fitted with any size of on-shelf modular or conical implants. This might have been caused by the severe stenosis of the femoral medullary canals. These results support the anatomic difficulties encountered by surgeons when performing THA in patients with DDH and may explain the high incidence of intraoperative proximal femoral fracture during THA in patients with Crowe IV DDH.\textsuperscript{10} These findings might explain the difficulties encountered by surgeons. A modified 3D comparison method developed in a previous prosthetic evaluation study by our group\textsuperscript{31} was applied for comparisons between the femoral stems and the medullary canal models. Advantages of such a method are the ability to obtain quantitative results and use color maps during visualization.

The present study revealed the geometric compatibilities of widely applied modular and conical femoral implants in Crowe IV DDH femoral medullary canals. Significantly smaller deviation and RMSd values were observed in the modular than conical group, suggesting that modular implants fit better within Crowe IV femoral canal models than do conical implants. Such results can be explained by the proximal-sleeve-attached triangle region in modular implants; this region was originally designed partially to offer more proximal loading of the stem.\textsuperscript{28} The triangle region of the femur is defined as the triangle made by the trochanters and the apex.\textsuperscript{35} However, because dramatic morphological changes

| Parameters                              | Modular | Conical | P    |
|-----------------------------------------|---------|---------|------|
| NPP, \%                                 | 8.8 ± 6.0 | 8.1 ± 5.9 | 0.37 |
| Proximal area of the proximal medullary canal | 2.2 ± 3.3 | 27.5 ± 30.2 | <0.01 |
| Distal area of the proximal medullary canal | 2.7 ± 0.7 | 3.7 ± 0.8 | <0.01 |
| Deviation, mm                           | 4.4 ± 1.0 | 5.6 ± 1.1 | <0.01 |
| RMSd, mm                                | 2.7 (83.3) | 12 (50.0) | 0.01 |

Data are presented as mean ± standard deviation or n (%).

NPP, negative point percentage; RMSd, root mean square of the distance.

\textbf{Table 3. Comparison of implant compatibility.}
are associated with Crowe IV DDH, the modular stems could not be implanted properly in 4 of 24 (16.7%) canal models, even when using the smallest sleeve (12B-Small). In these cases, the triangle region of the modular sleeves played a crucial role in the incompatibility by massively protruding into or even out of the calcar cortex bone of the femurs (Figure 2C, E). Cone sleeves lack this region and are available for selected stems in the modular design, but the smallest sleeve (14D, with a stem of \( \geq 9 \) mm in the distal diameter) was still too large for most of our cases.

In the conical femoral stem group, 12 of 24 (50%) femurs could not be fitted with a conical stem in an ideal position because of the unavailability of smaller implants (minimum of 13 mm) (Figure 2D). In the calculation of femoral fitting, the conical implants exhibited less proximal compatibility. This is expected because the conical design relies on distal fixation rather than metaphyseal compatibility, and it should not be considered a strong disadvantage. Nevertheless, with an ideal insertion distance of the conical stems in the femurs, the currently available sizes were too large to be properly used in our cases, especially in the distal region. This may have been due to the smaller taper in the conical stems than in the Crowe IV DDH medullary canal models. Notably, the current analyses were conducted within the proximal and distal areas of the proximal femoral medullary canals, while the compatibility advantages of conical implants mainly involve the distal part of the medullary canal and were not examined. Additionally, this study involved Asian patients; whether the conical implants perform better in Western patients is unclear. Geometrical improvements could be used to achieve better morphological fitting in femurs of patients with Crowe IV DDH for the modular and conical implants. The triangle region in the modular implants provides extra compatibility in proximal femurs but plays a major role in the incompatibility observed in severe cases. Therefore, a smaller triangle (at least half in proximal length) or absolute removal of the triangle in the smallest sleeve is advised for extremely small femurs of patients with Crowe IV DDH. According to the present study, smaller sizes are always recommended for THA in patients with severe Crowe IV DDH. Regarding the geometric improvements of the current conical stems, either reducing the implant diameter or increasing the implant taper would be acceptable for their use in Crowe IV DDH.

Based on the above findings, most cases of Crowe IV DDH can be treated with modular or conical stems in the clinical setting. However, in femurs with extremely thin medullary canals, stem implantation remains incredibly challenging using either of the two on-shelf designs, and customized implants can be applied in such conditions. Preoperative anatomical assessment of the femur is always critical for surgical planning in DDH. Further investigation is warranted to improve the currently available stems. In addition, the efficacy of combining osteotomy techniques with different stem designs should be evaluated to determine the distal stabilization of the femur in patients with DDH.

This study had some limitations. First, the simulations of the femoral stems were performed by an experienced orthopedic surgeon with the implantations in the optimal positions. In clinical practice, a higher location of the femoral stems in anatomically difficult cases could be tolerated to some extent; however, the lengthening of only one lower limb, changes in soft tissue tension, and weakening of the fixation strength must be considered as complications of surgery. Second, shortening osteotomies of the lower extremity, which are sometimes applied in patients with Crowe IV DDH, were not discussed in the present study.
However, because the most widely used subtrochanteric osteotomy technique only has minimal impacts on the morphological features of the proximal femoral region (mostly above the resection level) evaluated in the current study, we only performed comparisons with the original bone models to obtain easy-to-read data. Third, the sample size was small. However, because adult patients rarely have Crowe IV DDH, we believe that 24 patients is an acceptable sample size. Finally, biomechanical analyses could not be performed because cadaveric specimens of Crowe IV DDH could not be obtained.

The modular design might be more effectively used in patients with Crowe type IV DDH than the conical design, but some femurs with severe deformities may not be able to be properly fitted using currently available on-shelf modular or conical stems.

Authors’ contributions
Jianlin Zuo conceived and coordinated the study; Tong Liu designed, performed, and analyzed the experiments; and wrote the paper. Yuhui Yang, Xianyue Shen, Jianlin Xiao, Jianlin Zuo, and Zhongli Gao collected and analyzed the data and revised the paper. All authors reviewed the results and approved the final version of the manuscript.

Declaration of conflicting interest
The authors declare that there is no conflict of interest.

Funding
This work was supported and funded by the National Nature Science Foundation of China (No. 81601908) and the Outstanding Youth Foundation (20180520108JH) from the Science and Technology Department of Jilin Province. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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