The Journal of Arthroplasty 30 (2015) 1747–1751

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

MODULUS Stem for Developmental Hip Dysplasia: Long-term Follow-up

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ARTICLE INFO

Article history:
Received 10 July 2014
Accepted 18 April 2015

Keywords:
modular stem
developmental hip dysplasia
DDH
conical stem
total hip arthroplasty

ABSTRACT

Between October 2001 and December 2010, 143 patients with developmental dysplasia underwent hip arthroplasty surgery using a conical stem with modular necks (MODULUS system, Lima Corporate, Villanova di San Daniele del Friuli, Italy). Thirty (21.0%) patients had both hips replaced, for a total of 173 implants. The mean age at the time of surgery was 55 years (range: 22–81 years). The mean follow-up was 87 months (range: 36–146 months); average Harris Hip Score increased from 42 (range: 23–65) preoperatively to 92 (range: 76–100) at the last follow-up. Stem revision was required in two cases. The MODULUS stem showed good long-term clinical and radiographic results, with a Kaplan–Meier survivorship of 97.6% (95% CI: 94.8–100.0%) at 8 years.

Developmental dysplasia of the hip (DDH) is the most common underlying condition, resulting in secondary hip osteoarthritis [1–3]. Joint deformities, such as variations of the femoral neck version, excessive cervico-diaphyseal angle, reduced medullary canal size and a shallow and roofless acetabulum, contribute to making primary hip arthroplasty in DDH patients technically demanding [1–6].

Noble et al [7] evaluated the three-dimensional anatomy of dysplastic femurs, demonstrating how they presented shorter and more anteverted femoral necks, with smaller, narrower and straighter canals with respect to normal healthy controls. They also observed a proximal femoral deformity derived from a rotation within the diaphysis between the lesser trochanter and isthmus, generating an increase in anteversion between 5 and 16°, depending on the degree of hip subluxation. Sugano et al [8] reported that the observed deformities of both the femoral canal shape and the size and position of the femoral head worsened with increasing levels of subluxation. In addition, the center of rotation is often lateralized in dysplastic hips, thus increasing the body weight lever arm [9]. Crowe et al [10] described in their study a method of classifying dysplastic hips according to the grade of subluxation. Hips classified as Crowe type-III (75–100% subluxation) and type-IV (complete dislocation) presented the greatest degree of anatomical abnormality and were consequently among the most difficult and complex cases during hip arthroplasty procedures. Furthermore, the early onset of symptoms and degenerative joint changes, the relatively young age of patients and their usually high level of activity make the treatment of DDH particularly challenging in terms of implant survival [1–10].

Appropriate implant selection and a meticulous surgical technique are among the key factors to ensure implant optimal long-term performance in dysplastic patients. The choice of a modular femoral system, which consists of a conical stem and multiple modular necks, is motivated by the need to adapt to the specific joint abnormalities of the individual patient. Such a result can be difficult to obtain with a monoblock stem.

During the past few years, we have used a specific modular cementless system (MODULUS, Lima Corporate, Villanova di San Daniele del Friuli, Italy), where stem size, offset and neck length are all independent variables, granting the required flexibility to change the component size and position according to intraoperative findings. For instance, it is possible to couple a large diameter stem fitting a wide femoral canal with a short neck in case a small offset is required. MODULUS modular necks provide an engagement along the stem axis, which enables the appropriate correction of the version, leg length discrepancy and offset. Thus, this system is particularly used to restore physiological muscular tension and hip biomechanics in patients with altered anatomical conditions, such as dysplasia, trauma, and osteotomy [11–14].

The purpose of this prospective study was to assess the long-term clinical and radiographic outcomes of the MODULUS system in restoring joint biomechanics in DDH patients after total joint arthroplasty.

Materials and Methods

Patient Population

Between October 2001 and December 2010, 173 MODULUS stems were implanted in 143 patients. There were 29 (20.4%) males and 114

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to http://dx.doi.org/10.1016/j.arth.2015.04.021.

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http://dx.doi.org/10.1016/j.arth.2015.04.021
0883-5403/

(79.6%) females. Nineteen (13.3%) patients had previously undergone pelvic, femoral or combined osteotomy.

The patients included in this study had to meet the CROWE classification criteria. Pain and severe functional impairment with a limp, pelvic obliquity, flexion deformity of the hip and knee were the main indications for THA.

The average age at the time of surgery was 55 years (range: 21–81 years). Eighty (46.2%) and 93 (53.8%) implants were introduced on the right and left hip, respectively. Twenty-six (18.2%) patients underwent bilateral THA consecutively, not simultaneously. The average time between procedures was 19 months (range: 4–60 months). Four (2.8%) patients were operated on bilaterally in the same session, all belonging to Crowe 3.

Dysplasia evaluation was based on the Crowe classification [6]: 66 (38.1%) hips were classified as Crowe I, 50 (28.9%) hips as Crowe II, 33 (19.1%) hips as Crowe III and 24 (13.9%) hips as Crowe IV.

Clinical and Radiographic Evaluation

Clinical and radiographic examinations were performed at 1, 3, 6 and 12 months, then annually for the first 5 years and then every 2 years thereafter. Clinical evaluation was based on the Harris Hip Score (HHS, 0–100) [15] and a visual analogue scale (VAS, 0–10) [16, 17].

Radiographic assessment was performed by an independent radiologist using antero-posterior and axial view X-rays (preoperative, immediate postoperative and at each follow-up). The X-rays analysis included: orientation of the femoral component (i.e., stem alignment), which was classified as neutral, slightly varus or valgus (<5° of misalignment with respect to the femoral axis) and varus or valgus (>5° of misalignment with respect to the femoral axis); presence of osteolytic areas or radiolucent lines, which were identified according to the zones defined by Gruen et al [18]; signs of aseptic loosening, as indicated by Engh et al [19]; signs of subsidence of the shaft, which were considered to be significant only if they were greater than 2 mm; phenomena of stress shielding, cortical hypertrophy or atrophy [19]; signs of stable bone ingrowth at the bone–implant interface or at the shaft–neck junction [19]; and evidence of heterotopic ossifications, as indicated by Brooker et al [20].

Surgical Technique

A postero-lateral approach was used in all cases, with patients lying in a lateral decubitus position. All procedures were performed by a senior surgeon. Shortening femoral osteotomy was performed in 5 (2.9%) cases for implant reduction due to excessive tension: oblique osteotomy was employed in 3 cases, using the stem as a fixation device, while subtraction Z-osteotomy with two Dall–Miles cables was used in the other 2 cases. Supra-acetabular bone grafting was performed in 3 cases. In all cases, the cup was implanted at the level of the paleo-acetabulum or in the area between the paleo- and neo-acetabulum.

All patients were intravenously administered an antibiotic prophylaxis using 2 g of Cefazolin during the operation and 1 g every 6 hours for a total of 3 postoperative doses. Thromboembolic prophylaxis with low molecular weight heparin was administered postoperatively for 4 weeks. Indomethacin (100 mg/day) was administered postoperatively for 30 days to prevent heterotopic ossifications. Weight-bearing with walking aids was allowed starting the second day after surgery.

Prosthetic Implants

The MODULUS system consists of an uncemented conical tapered stem, coupled axially with a modular neck by a Morse taper that is secured with a locking screw. Femoral stems are finned, 100-mm long, conical tapered (5°), made of titanium alloy and available in 14 diameters (Ø 13–26 mm). Their tapered design was developed to promote a uniform stress distribution and to pursue a stable cementless fixation in the femoral canal [11–14].

The modular necks are available in four different models: there are 2 cervico-diaphyseal angles (CDA) (125 and 135°) and 2 lengths along the cervical axis (short and long); at the same length, the neck with a cervico-diaphyseal angle of 125° lateralizes the implant by 5 mm compared to the equivalent neck with a 135° angle, maintaining the same implant height, such that only lateralisation and not length is affected.

They are designed to enable free adjustment of their rotation alignment around 360°, regardless of the type of rotational deformity of the proximal femur. This feature allows a free anteversion and retroversion around the stem axis, thus enabling a physiological restoration of the center of rotation and the correct balance of tissue tension [11–14]. There are two neck-stem connection tapers to choose from: A (for stem Ø 13–15 mm), which mates with necks, resulting in a 29–34 mm off-set and B (for stem Ø 16–26 mm), which permits an extension in the range of off-sets up to 41 mm.

Three types of modular acetabular components (Lima Corporate, Villanova di San Daniele del Friuli, Italy) were used: SPH Blind cups in 62 (35.8%) cases, DELTA-PF in 78 (45.1%) cases and DELTA-TT in 33 (19.1%) cases. All three cups were hemispherical press-fitted uncemented cups. Coupling bearings were ceramic-on-ceramic in 138 (79.8%) cases, ceramic-on-polyethylene in 31 (17.9%) cases and metal-on-polyethylene in 4 (2.3%) cases. The head diameters were 28 mm in 54 (31.2%) cases, 32 mm in 84 (48.6%) cases and 36 mm in 35 (20.2%) cases (Fig. 1).

Statistical Analysis

Kaplan–Meier analysis was performed to assess the cumulative survivorship with a confidence interval of 95%. The endpoints of the survival analysis were failure of the femoral stem for any reason and failure of any implant component for any reason.

Results

Clinical Outcomes

The mean follow-up was 87 months (range: 36–146 months). The average HHS significantly increased from 42 (range: 23–65) preoperatively to 92 (range: 76–100) at the last follow-up examination. Significant clinical improvements were observed in all cases, particularly in terms of functional recovery and pain relief, as shown by the HHS scoring. The average level of patient satisfaction (VAS) was 9.4 (range: 6–10) at the last follow-up.

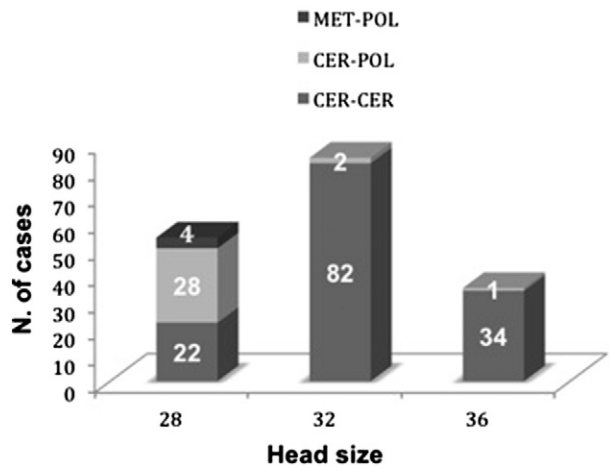

Fig. 1. Distribution of bearing couplings with respect to femoral head sizes used during the course of this study on the MODULUS stem.