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Initial stability of an uncemented femoral stem with modular necks. An experimental study in human cadaver femurs

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ABSTRACT

Background: Uncemented implants are dependent upon initial postoperative stability to gain bone ingrowth and secondary stability. The possibility to vary femoral offset and neck angles using modular necks in total hip arthroplasty increases the flexibility in the reconstruction of the geometry of the hip joint. The purpose of this study was to investigate and evaluate initial stability of an uncemented stem coupled to four different modular necks.

Methods: A cementless femoral stem was implanted in twelve human cadaver femurs and tested in a hip simulator with patient specific load for each patient corresponding to single leg stance and stair climbing activity. The stems were tested with four different modular necks; long, short, retro and varus. The long neck was used as reference in statistical comparisons. A micromotion jig was used to measure bone-implant movements, at two predefined levels.

Findings: A femoral stem coupled to a varus neck had the highest value of micromotion measured for stair climbing at the distal measurement level (60 μm). The micromotions measured with varus and retro necks were significantly larger than motions observed with the reference modular neck, $P < 0.001$.

Interpretation: The femoral stem evaluated in this study showed acceptable micromotion values for the investigated loading conditions when coupled to modular necks with different lengths, versions and neck-shaft angles.

1. Introduction

Total hip arthroplasty (THA) is considered to be a successful treatment for destructive diseases of the hip joint. The number of implant designs and the use of uncemented implants have increased (The Norwegian Arthroplasty Registry, 2013). Uncemented prostheses are dependent on adequate primary stability to achieve bony fixation and long term stability of the implant (Callaghan et al., 1992; Pilliar et al., 1986; Soballe et al., 1992b). The uncemented implants gain long-time fixation by osseointegration to the surface layer of the implant. Excessive interface motion reduces or inhibits bone ingrowth and may lead to loosening of the prosthesis (Cross and Spycher, 2008).

Initial stability of a femoral stem is dependent on a number of factors such as implant design, surface roughness, surgical technique and patient related factors like quality of bone (Khanuja et al., 2011). The movement at the bone-implant interface can be expressed as migration and micromotion. Migration is an irreversible movement of the stem into the femoral canal, typically occurring during the first postoperative period (Buhler et al., 1997). Micromotion is a reversible movement at the bone-implant interface that occurs under dynamic loading. Micromotion can be estimated by numerical analyses or by a multitude of methods, involving in vitro measurements (Baleani et al., 2000; Buhler et al., 1997; Gortchacow et al., 2011; Gortz et al., 2002; Kassi et al., 2005; Nogler et al., 2004; Tarala et al., 2011). Experimental studies have found that excessive micromotion can compromise or inhibit the biological integration of bone at the implant surface (Engh et al., 1999; Jasty et al., 1997; McKellop et al., 1991; Pilliar et al., 1986; Soballe et al., 1992b), however the exact range of motion that will allow osseointegration is not known.

Modular neck in THA is a concept allowing variations in neck-shaft angles, neck version and neck length. These necks have been introduced to improve accuracy when reconstructing the anatomy and hip joint biomechanics.

The use of modular necks in primary THA has increased in recent years. There are some reports of good mid-term outcomes (Matsushita et al., 2010; Omlor et al., 2010), but long-term documentation is limited. A few case reports and studies raise concerns of corrosion, mechanical failure and pseudotumour formation related to

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the concept of modularity (Dangles and Altstetter, 2010; Gill et al., 2012; Skendzel et al., 2011; Sotereanos et al., 2013; Viceconti et al., 1996, 1997). The Australian Joint Registry reports that THA with exchangeable femoral necks has twice the rate of revision compared to conventional THA after 7 years. The primary reasons for revision are implant loosening and dislocation (Australian Orthopaedic Association National Joint Replacement Registry, 2012).

The purpose of this study is to evaluate the primary stability of an uncemented femoral stem with four different modular necks varying version, length and neck-shaft angle.

2. Methods

2.1. General

This study was approved by the regional medical research ethics committee. Pilot studies were completed to develop a satisfactory testing sequence and structure, and the testing was performed according to a well-established procedure (Ostbyhaug et al., 2010; Wik et al., 2011).

2.2. Implant system

A collarless cementless titanium alloy stem fully coated with hydroxyapatite (HA) (Profemur® PRGLKITD Gladiator, Wright Medical Technology Inc., Arlington, TN 38002, USA)(Fig. 3) was implanted into 12 human cadaver femoral bones and randomly allocated to right or left sides. All implantations were done by an experienced orthopaedic surgeon according to the manufacturer's procedure (Wright Medical Technology, 2013).

Four different modular titanium necks with a 12/14 taper (Profemur® Modular Necks, Wright Medical Technology Inc., Arlington, TN 38002, USA) were evaluated: 1. straight long (PHAO 1204), 2. straight short (PHAO 1202), 3. retroversion short 15° (PHAO 1262) and 4. varus short 15° (PHAO 1242) modular components (Fig. 1). The necks were connected with the oval end of the appropriate femoral neck implant into the femoral stem pocket. A standard 28 mm femoral head was used.

2.3. Human cadaver femurs

The femoral stems were implanted into Caucasian human cadaver femurs. The femurs were collected from deceased patients that underwent medical post-mortem examinations within 24 h. Consents from the relatives were collected before interfering. Twelve human femurs completed the testing, mean donor age was 58 years (range 43–70 years), nine male and three female (Table 1).

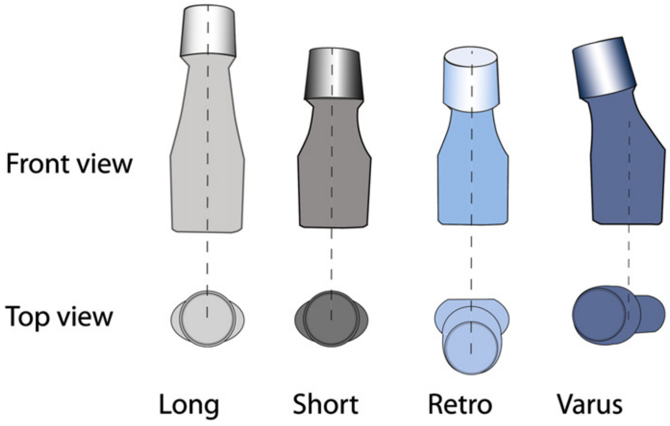

Fig. 1. Profemur® modular necks: Straight long, straight short, retroversion short 15° and varus short 15° in front view and top view.

Table 1
Data of the subjects; N = 1–12, gender, age, body mass index (BMI) and bone mineral density (BMD).

ID	Gender	Age	BMI	BMD
1	M	59	24	0.943
2	M	57	28	1.163
3	M	66	27	0.963
4	M	70	23	1.063
5	F	53	20	0.959
6	F	57	25	0.998
7	F	62	20	0.896
8	M	64	29	0.891
9	M	53	22	0.894
10	M	67	25	0.94
11	M	47	24	0.962
12	M	61	18	0.944

The femurs were handled and prepared according to an earlier described and well documented procedure (Aamodt et al., 1997; Wik et al., 2010). The femurs were wrapped in saline-soaked towels and stored at −80 °C immediately after dissection.

Standard radiographs in two projections were used to estimate the size of the prosthesis and to exclude any skeletal pathologies. Dual-energy X-ray absorptiometry (DXA) was obtained to point out possible osteoporotic femurs (Table 1). Bones with T-scores of the proximal femur below −2.5 were classified as osteoporotic and excluded.

Criteria for selection of femurs included age <70 years, body mass index (BMI) between 18–30, no previous fracture in the femur and no current or previous malignancy in the femur. Twenty-one pairs of femora were collected. Three patients were excluded due to osteoporosis and one pair was destroyed during preparation. Five femora failed during testing (three due to periprosthetic fractures and two due to trochanter band failure).

Before testing, the femurs were thawed at room temperature and remaining soft tissue removed. First the frontal plane of femur was defined by placing the femur on a horizontal surface resting on the posterior condyles and the greater trochanter. Second the anteversion of the femoral neck was measured and recorded for later orientation of the femur in the frontal and sagittal planes, before resecting the condyles. The femur was then fixed into a steel cylinder with an acrylic cement (Meliodent, Heraeus Kulzer GmbH, Hanau, Germany), where the centre axis of femur coincided with the centre axis of the cylinder. The femur was kept humid by a saline-soaked towel during preparation.

The distance from the tip of the greater trochanter to the top of the cylinder was 25 cm for all specimens. To simulate the hip abductor muscle a 40 mm polyamide strap was attached to the greater trochanter using glue (X60, HBM GmbH, Darmstadt, Germany) and 6 screws (cortical 2.5 mm) (Fig. 2).

2.4. Hip simulator

The implanted femurs were mounted into a hip jig and loaded in a servohydraulic testing machine (MTS 858 MiniBionix II, MTS System Corporation, Eden Prairie, Minnesota, USA). This constituted the hip simulator (Fig. 2). The femur was allowed to rotate freely around its longitudinal axis and to tilt freely in the medial/lateral plane, to avoid unphysiological bending moments.

The femur was tilted 12° into valgus, corresponding to physiological inclination during single leg stance (McLeish and Charnley, 1970). For the experiments an acetabular cup with an inclination of 45° and 0° anteversion was used. A trochanter strap was fixed to the lever arm at an angle of 15° to the load axis (McLeish and Charnley, 1970). The femur was prevented from rotating by the acetabular component and the trochanter strap.

Two human activities were tested; single leg stance and stair climbing. The femurs were loaded proportional to their individual donor body weight (BW). A single vertical force, originally planned to