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Primary stability of custom and anatomical uncemented femoral stems A method for three-dimensional in vitro measurement of implant stability

Per Olav Østbyhaug [a,*], Jomar Klaksvik [a], Pål Romundstad [b], Arild Aamodt [a,c]

[a] *Department of Orthopedic Surgery, Trondheim University Hospital, 7006 Trondheim, Norway*
[b] *Department of Public Health and General Practice, 7006 Trondheim, Norway*
[c] *Department of Neuroscience, Norwegian University of Science and Technology, 7006 Trondheim, Norway*

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ABSTRACT

Background: Lack of primary stability of cementless hip stems prevents bone ingrowth and may lead to loosening of the stem. Direct measures of the implant stability require drilled holes in the bone at the measuring site. These holes weaken the cortical bone, limit the number of possible measuring points and inhibit other biomechanical measurements. This in vitro study aimed to develop a method for indirect measurement of primary stability of femoral stems, leaving the specimen intact. The method was used to compare the primary stability of two uncemented femoral stems with different proximal fit and fill and different stem length.

Methods: An in vitro method for indirect full three-dimensional measurement of implant–bone interface motion was developed. Uncemented customized ($n = 10$) and anatomical stems ($n = 10$) were inserted in human cadaver femora and the primary stability during one leg stance and stair climbing was measured.

Findings: The method had high precision, and the errors due to necessary assumption of rigid body components were minimal. The customized stem with optimal proximal fit and fill provided the best initial stability for rotation in retroversion. The anatomical stem with longer stem length was more resistant to permanent rotation in varus.

Interpretation: During stem design development the primary stability can be measured at all wanted measuring sites with the presented method, leaving the specimen intact for further analyses.

1. Introduction

Lack of primary stability of cementless hip stems prevents bone ingrowth. Initial stability of a cementless femoral stem depends on the mechanical interlocking of the stem by press-fitting into the femoral canal. Migration is the permanent movement of the stem relative to the femur. The inducible movements at the implant–bone interface each time the implant is subjected to load is defined as micromotion. Micromotion at the implant–bone interface of 28 μm is reported to be compatible with bone ingrowth (Pilliar et al., 1986) whereas motion of more than 150 μm results in the formation of a fibrous membrane around the implant, preventing the osseointegration process (Bragdon et al., 1996; Pilliar et al., 1986; Soballe et al., 1992a,b).

In vitro, the movement at the implant–bone interface has been measured directly at the point of interest using extensometers and Linear Variable Displacement Transducers (LVDTs) (Andreas et al., 2009; Baleani et al., 2000; Gortz et al., 2002; Kassi et al., 2005; Monti et al., 1999) or optoelectric measuring devices (Buhler et al., 1997a,b; Nogler et al., 2004; Speirs et al., 2000). A direct measure of implant movement minimizes errors due to possible non-rigid deformations of bone, implant and measuring devices. A limitation of these methods is the requirement of drilling holes through the cortical bone at the measuring points. Primary stability of a femoral stem should be measured at several locations because relative micromotion at the bone-implant interface varies along the stem (Buhler et al., 1997a; Callaghan et al., 1992; Harman et al., 1995; Kassi et al., 2005; Schneider et al., 1989). Penetrating holes in the cortical bone introduce a mechanical weakening of the bone and restrict the number of measuring points. During stem design development it also should be possible to combine measurement of primary stability with other analyses, as strain gauge measurements, requiring intact cortical bone of the specimen.

The aim of the present study was to develop a reproducible method for in vitro measurements of implant–bone interface movements in all six degrees of freedom at all wanted levels of a femoral stem, leaving the specimen intact for other analysis. Furthermore the method was used to compare the primary stability of two uncemented femoral stems with different proximal fit and fill and different stem length.

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* Corresponding author.
E-mail address: Per-Olav.Ostbyhaug@stolav.no (P.O. Østbyhaug).

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2. Methods

2.1. Cadaver femurs

We included 20 femurs collected from 10 human cadavers (9 male) with an average age of 51.6 years (27–68 years). Standardized radiographs in two projections were obtained; no localized skeletal abnormalities were identified. For each pair of femurs the two stems were randomly allocated to the right and left femur.

2.2. Preparation of the femur

The medial offset and the anteversion of the femoral neck were measured before the condyles were removed. The distal part of the diaphysis was cemented into a steel cylinder with the vertical axis through the fossa piriformis aligned with the centre axis of the cylinder. The distance from the tip of the greater trochanter to the top of the cylinder was 25 cm for all of the specimens. To simulate the hip abductors a 35 mm nylon strap was attached to the lateral aspect of the greater trochanter (Aamodt et al., 2001). The strap was mounted in a plane defined by the centre axis of the cylinder and the centre of the femoral head to balance the bending moment induced by the axial load without creating a torsional force around the z-axis (Figs. 2 and 3).

2.3. Implants

The two implant systems used in this study were the uncemented, anatomical stem, ABG-I (Anatomique Benoist Girard, Stryker-Howmedica, Allendale, NJ, USA) and the *Unique*® customized femoral stem (SCP, Trondheim, Norway). Both prostheses are made of titanium alloy (Ti6A14V), they have modular femoral heads and no collar. The proximal part of the ABG-stem has an anatomical shape and this part of the stem also has a macro-relief of the surface. The proximal third of the stem is coated with a 50 μm layer of hydroxy-apatite (HA). The stem is non-polished distally. The size of the ABG-stem and the level of the osteotomy of the femoral neck is decided pre- and intraoperatively by the surgeon. The femoral canal is prepared with diaphyseal overreaming (1 mm wider than the tip diameter of the selected stem) and progressive broaching. For the individual design of the custom-made stem transversal CT scans with a slice distance/thickness of 5/2 mm are obtained. On each of the transversal CT scans of the proximal femur, a software algorithm is used to create closed contours along the corticocancellous interface of the medullary canal, defined by a CT density of 600 Hounsfield Units (HU) (Aamodt et al., 1999). Based on the 2-D transverse contours on the CT scans a 3-D computer model of the prosthesis is constructed, ensuring that the stem is insertable through the femoral neck after resection of the femoral head. Finally, the stem is manufactured using a computer numerical controlled (CNC) machining process. The proximal two-third of the stem is coated with a 50 μm layer of HA, whereas the distal third of the stem is polished and downscaled to prevent contact with endocortical bone and bone ingrowth. A resection guide mounted on an intramedullary reamer is used to achieve the preplanned resection level of the femoral neck. The femoral canal is prepared using a combination of standard and custom-made rasps, without any diaphyseal reaming. The *Unique*® stems were shorter than the ABG-stems with an average difference of 19 mm (11–27 mm).

2.4. Reference system and measurement points

A reference system for the implant was used for orientation of the measurement device and positioning of the selected measuring points. The reference system was defined by the centre axis and the medial–lateral direction of the prosthesis (Fig. 1). The distal part of ABG-stem was clamped and rotated in a drilling machine in order to define the centre axis and the centre axis point at the shoulder of the stem. The centre axis of the Unique stem was defined individually by the manufacturer. For both stems, the medial–lateral direction was defined as a line from the centre axis to the centre of the conus, rotated 10° of retroversion to compensate for the anteversion of the stem. In this study, the bone-implant interface motion was measured at three discrete locations on three different levels of the stem (Fig. 1). The distances from the centre axis of the prostheses to the measuring points at the anterior, lateral and posterior surface of the stem at the three selected levels were measured.

2.5. Micromotion jig design and setup

In order to measure movement between the stem and the femur, one part of the measuring device was attached to the stem and the counterpart attached to the femur. An attachment site for the measuring device was machined at the shoulder of each stem. The position of the attachment site was defined by the centre

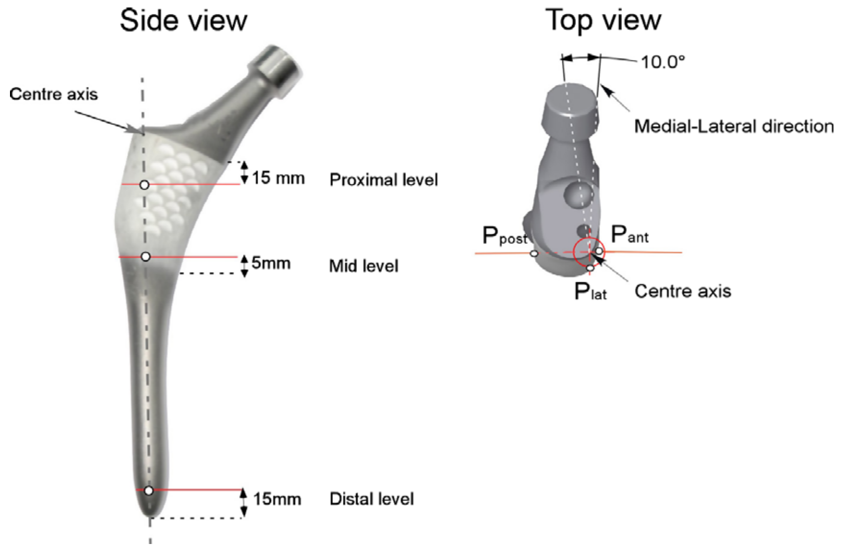

Fig. 1. Illustration of measurement levels, measurement points and centre axis of the prosthesis.