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Experimental pre-clinical assessment of the primary stability of two cementless femoral knee components

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ABSTRACT

To achieve long-lasting fixation of cementless implants, an adequate primary stability is required. We aimed to compare primary stability of a new cementless femoral knee component (Attune®) against a conventional implant (LCS®) under different loading conditions. Six pairs of femora were prepared following the normal surgical procedure. Calibrated CT-scans and 3D-optical scans of the bones were obtained to measure bone mineral density (BMD) and cut accuracy, respectively. Micromotions were measured in nine regions of interest at the bone-implant interface using digital image correlation. The reconstructions were subjected to the implant-specific's peak tibiofemoral load of gait and a deep knee bend loading profiles. Afterwards, the implants were pushed-off at a flexion angle of 150°. Micromotions of Attune were significantly lower than LCS under both loading conditions ($P \leq 0.001$). Cut accuracy did not affect micromotions, and BMD was only a significant factor affecting the micromotions under simplified gait loading. No significant difference was found in high-flex push-off force, but Attune required a significantly higher load to generate excessive micromotions during push-off. Parallel anterior and posterior bone cuts in the LCS versus the tapered bone cuts of the Attune may explain the difference between the two designs. Additionally, the rims at the borders of the LCS likely reduced the area of contact with the bone for the LCS, which may have affected the initial fixation.

1. Introduction

Total knee replacement (TKR) with an uncemented femoral and cemented tibial implant has shown promising survival (Australian Orthopaedic Association, 2013; Arnold et al., 2013; Pelt et al., 2013). Implant registries, such as the Australian Registry, have shown a 95% survival rate after 10 years (2013). However, revision rates are still higher for younger patients (< 55 years) than for older patients (> 75) (14% vs. 3% at 12 years) (2013). Therefore, there is still a need for improvement of implant survival, as younger and more active patients require more years of service and more demanding activities. Furthermore, recent high-flex designs introduce a new prospect for a wider range of motion and alternative loading conditions which have to be accommodated by the uncemented implant (Lee et al., 2013). There are some reports that suggest these high-flex activities may have a detrimental effect on the long-term success of some TKR systems (Bollars et al., 2011; Zelle et al., 2011).

To achieve a long-lasting fixation, an adequate primary stability is required (Jasty et al., 1997; Kienapfel et al., 1999; Pilliar et al., 1986). The primary stability of uncemented femoral knee components, which is often referred to as the inverse of 'implant-bone micromotion', is affected by several factors, such as the type of activity (Chong et al., 2010; Kassi et al., 2005), bone quality (Aro et al., 2012), surgical preparation (Abdul-Kadir et al., 2008), and implant characteristics. Loading profiles applied in experimental studies assessing micromotions have mainly been based on a simplified gait cycle according to ISO standards (Conlisk et al., 2012; Cristofolini et al., 2008, 2009; Spinelli et al., 2010), while higher ranges of flexion (> 120°) are usually omitted. However, it has previously been shown that it is important to test implants for various loading configurations representing various activities of daily living (Berahmani et al., 2016; Kassi et al., 2005). Periprosthetic bone quality (Berahmani et al., 2015a), and the accuracy of the bone cuts (Abdul-Kadir et al., 2008), may also have a significant effect on the initial press-fit stability of the implant. Finally, implant characteristics such as roughness (Berahmani et al., 2015b), shape, and material (Bahraminasab et al., 2013) also influence primary stability. In

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light of all these variables, it is crucial to assess the primary stability of new TKR implants in a pre-clinical stage.

In the current study we evaluate the primary stability of the Attune® (DePuy Synthes Joint Reconstruction, Warsaw, IN, USA) cementless femoral component, and compared it against a conventional implant as a successful clinical benchmark. Our main objective was to evaluate the micromotions of these two femoral implants under simplified gait and deep knee bend (DKB) loads, while accounting for bone quality and bone cut accuracy. After the experiments the implants were pushed off from the bone at a high flexion angle to assess the fixation strength. We aimed to answer the following research questions: 1) What is the difference in primary stability of the two implant designs under simplified gait and DKB loading conditions? 2) Do bone quality and bone cut accuracy have an effect on the primary stability? 3) Is there a difference in micromotion-force relationship between the two designs under simplified gait and DKB loading conditions? 4) What is the difference in primary stability and fixation strength of the two implant designs at a high flexion loading angle?

2. Materials and methods

2.1. Study design

Based on a power analysis to determine correct sample size, six samples were adequate when a mean micromotion difference of 50 µm and standard deviation of 30 µm were assumed. However, twelve pairs of fresh- frozen cadaveric femurs were obtained from the Anatomy department of the Radboud university medical center to select bone specimens with better quality based on their x-ray images and visual inspection. Subsequently, six pairs of femurs (82–93 years [average: 86 years], 4 males) were selected.

The prototype Attune implant (DePuy Synthes Joint Reconstruction, Warsaw, IN, USA) was available for the left side only, restricting randomization between left and right femurs (Fig. 1B). Conventional uncemented LCS® (low contact stress) femoral knee implants (DePuy Synthes Joint Reconstruction, Leeds, UK), which have a long-lasting clinical history (Stiehl, 2002), were allocated to the right femurs (Fig. 1A). Both implants were coated with a Porocoat® porous surface morphology (DePuy Synthes Joint Reconstruction, Warsaw, IN, USA).

2.1.1. Femoral preparation

Bone specimens were thawed at room temperature (22 °C) for 24 h before the cutting session. An experienced orthopedic surgeon (W*R*) performed the bone cutting session following the normal surgical procedure and also determined the implant size, which resulted in one size 6 and five size 7 Attune components and two standard + and four large LCS components.

2.1.2. Bone quality assessment

The bone specimens were 3D-scanned using computed tomography (CT) (530 mA, 120 kV, pixel spacing of 0.352 mm, and slice thickness of 0.6 mm;Siemens Somatom Sensation 64, Siemens AG, Germany), along with a hydroxyapatite calibration phantom (solid, 0, 50, 100, 200 mg/ml calcium hydroxyapatite, Image Analysis, Columbia, KY) to compute bone mineral density (BMD). We measured BMD values using a previously protocolized technique (Berahmani et al., 2015b). Briefly, the press-fit fixation mainly depends on the bone quality in the anteroposterior (AP) direction. Hence, regions of interests (ROIs) were selected in the anterior region and in the posterior condyles based on the nominal implant dimensions. The average BMD of the three ROIs was used for the statistical analysis.

2.1.3. Cut accuracy assessment

To investigate the effect of bone cut variation, 3D-optical scans of the resected bone specimens were made (ATOS 3D-scanner, GOM mbH, Braunschweig, Germany) (Fig. 2A). Each scan was compared with the nominal bone cuts in all cutting planes and the deviation from the nominal cutting planes was defined for twelve different bony regions (Fig. 2B).

2.1.4. Implantation

Implantation was done by a second surgeon (SvdG), who received an extensive training session for implantation of both designs. After implantation, the distal femurs were cut off 100 mm proximally from the most distal end, after which the proximal side of the specimen was cast in a cylindrical pot using bone cement for the fixation purpose in later stages.

2.2. Mechanical tests

2.2.1. Preconditioning

Before performing measurements, to settle down the implants each specimen was preconditioned by applying a dynamic loading regime using a servo-hydraulic testing machine (MMED, MATCO, La Canada Flintridge, CA) for 15 min at 1 Hz. The loading regime was the same as the applied load configuration during the micromotion measurement, which is explained in the next section. The preconditioning phase was followed by a minimum period of 15 min of relaxation.

2.2.2. Loading conditions

Due to the potential effect of the loading configuration on the micromotion, an implant-specific loading profile was applied (Berahmani et al., 2016). In collaboration with Denver University, implant-specific loading profiles of the stance phase of gait and a deep knee bend (DKB) were derived from a validated Finite Element (FE) model of the Kansas knee simulator (Berahmani et al., 2016; Fitzpatrick et al., 2014),which successfully reproduced in vivo forces measured in the Orthoload

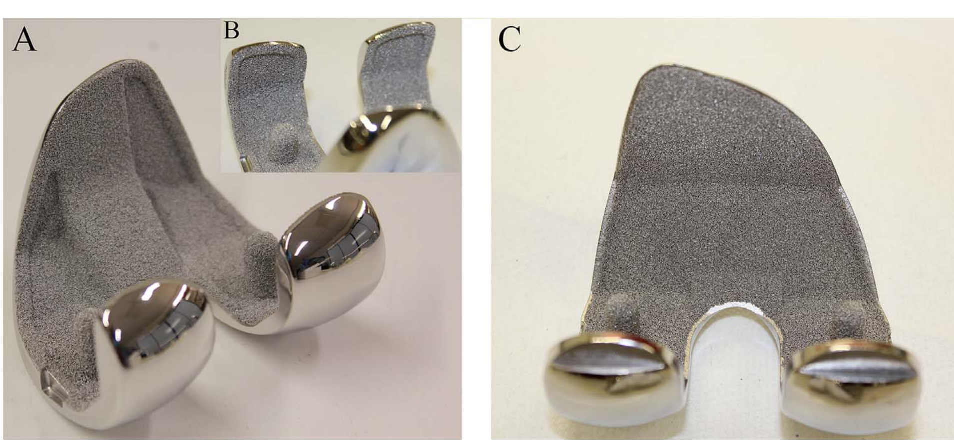

Fig. 1. A) anterior view of LCS implant. B) Posterior view of LCS implant. C) Attune.