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Influence of implant length and bone defect situation on primary stability after distal femoral replacement in vitro

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ABSTRACT

Background: Aseptic loosening is the major reason for failure of distal femoral replacement using current modular megaprostheses. Although the same stems are used for proximal and distal replacement, survival rates in clinical studies with distal reconstruction were lower within the same system compared to proximal reconstruction. We analyzed whether primary stability as presupposition for long-term fixation can be achieved with a current tapered stem design. Additionally, we hypothesized that stem length affects primary stability depending on bone defect situations.
Methods: A modular tumor system (Megasystem-C®, Link GmbH, Hamburg, Germany) with two different tapered stems (100 and 160 mm) was implanted in eight Sawbones® in two consecutively created defect situations (10 and 20 cm proximal to knee joint level). Primary rotational stability was investigated by measuring relative micromotions between implant and bone to identify the main fixation areas and to characterize the fixation pattern.
Results: The fixation differed between the two stem lengths and with respect to both defect situations; however in each case the main fixation area was located at or close to the femoral isthmus. Highest relative micromotions were measured with the 160-mm stem at the distal end within small bone defects and at the proximal end when defects were increased.
Conclusions: The analyzed design seemed to create sufficient primary stability along the main fixation areas of the implant. Based on these results and with respect to oncologic or potential revision situations, we suggest the use of the shorter stem to be more favorable in case of primary implant fixation.

1. Introduction

Primary tumors of long bones are most often localized at the femur or proximal tibia. In terms of functional outcome and esthetic aspects, reconstruction by arthroplasty after tumor resection has become the method of choice in most cases [1,2]. In addition, patients' survival is not compromised compared to other surgical procedures like amputation or rotationplasty [3].

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In revision total hip arthroplasty (THA) with large bone defects, non-cemented stems with tapered designs have shown excellent results in clinical trials and have been tested in laboratory studies [4–6]. Conical designs have been adapted to tumor devices such as the Megasystem-C® (Link GmbH) or as one of two designs for the Modular Universal Tumor and Revision System (MUTARS®) system (Implantcast, Buxtehude, Germany). Most current tumor devices are modularly built and the same stem can be used for either proximal or distal femoral replacement. Although proximal femoral reconstruction by arthroplasty shows acceptable primary stability [7,8] as well as acceptable implant survival, aseptic loosening with less durability is reported after knee reconstruction within the same implant system [9,10]. Therefore, stem length, anatomical and biomechanical differences might influence this condition.

The aim of this study was to investigate primary stability of a distal femoral replacement in vitro and to analyze the influence of stem length in two adverse bone defect situations: (1) if Megasystem-C® is used with varying stem lengths, then an adequate primary stability with implant–bone interface motions below the threshold for successful osseointegration will be achieved independent of bone defect situation; (2) if long stems are used instead of short stems, then micromotions at the implant–bone interface will decrease and a more proximal implant fixation will be supported.

2. Methods

2.1. Assessment of bone defects and tested synthetic femora

As we aimed to obtain a standardized comparison within this biomechanical study, eight identical synthetic femurs (composite bone 4th generation [#3406], Sawbones® Europe, Malmö, Sweden) were used instead of human specimens. Two different dimensioned segmental bone defects were consecutively created and separately measured (Figure 1). Defect type 1 was resected 10 cm proximal of the knee joint level. The extended bone defect type 2 was located 20 cm proximal of the knee joint level and included parts of the femoral isthmus.

2.2. Implant and classification of groups

The tested cementless Megasystem-C® is a modular tumor and revision system with multiple component combinations. The main component (distal femoral replacement Hinged Knee SL®, left, size M) was used within all n = 4 groups in combination with a 30-mm stem segment compensating for the smaller defect type 1 (Figure 2). To reconcile the extended osseous defect type 2 situation, an additional 100-mm stem segment was used (Group C and Group D). Due to varying bone cavities, sizes (proximal/distal diameter) of the femoral modular stems differed depending on stem length and defect situations (length 100 mm, size Ø22/Ø19, Group A; length 160 mm, size Ø21/Ø16, Group B; length 100 mm, size Ø19/Ø16, Group C; length 160 mm, size Ø18/Ø13, Group D). All modular components were press-fit connected using taper fixation with two additional screws to prevent distortion of the parts. The distal femoral component was made of a CoCrMo alloy (ISO 5832-4); however, stem segments and stems were made of a TiAl6V2 alloy (Tilastan®; ISO 5832-3). The straight cementless stems were conical, narrowed at the end, longitudinally fluted, and had a microporous coating to improve stem fixation and osseointegration.

2.3. Preparation

All bones were prepared in a standardized manner by an experienced surgeon following the manufacturer's recommended surgical technique. The correct implant fit was checked with X-rays in anterior–posterior (a–p) and medial–lateral (m–l) directions and the proximal end of each bone was fixed distally afterwards. To maintain a comparable press-fit of the stems within the cortical bone during implantation, a material testing device (Frank-Universalprüfmaschine 81816/B, Karl Frank GmbH, Weinheim-Birkenau, Germany) was used to apply 25 axial load cycles of two kilonewtons (corresponding with intra-operative generated press-fit on the implant) followed by 25 axial load cycles of four kilonewtons (representing the first postoperative loadings during rehabilitation) [11]. The implant–bone compound was installed into a measuring device well-established for implant-stability testing [4,12–14]. The setting has been modified to allow measurements of distal femoral replacements. Using two actuators, connected with a rope system and a lever arm to the distal end of the implant, a pure rotational torque of ± 7 Nm around the longitudinal axis of the stem could be applied.

2.4. Measurement setup

A measurement cube with six linear variable differential transformers (LVDT type P2010A, Mahr GmbH, Goettingen, Germany) orientated in a three-two-one manner allowed the three-dimensional motions of the implant (Figure 3: #1–#8) and bone (Figure 3: #9–#15) to be determined at several points of interest in relation to the knee joint line [4,13]. Depending on the extent of the bone defect and the stem length used, the number of measuring points differed: the manufacturer's stem length '0' served as a length reference. Each group consisted of three implant measuring points at the stem (#1: 0.5 cm; #2: five centimeters; #3: 9.5 cm proximal to the reference), with two additional measuring points for longer stems in Groups B and D (#4: 11.5 cm; #5: 15.5 cm proximal to the reference). Furthermore, two implant measuring points were located on the main component (#6: four centimeters distal to the reference) and at the 30-mm stem segment (#7: 2.5 cm distal to the reference) in defect type 1. Consequently, in defect type 2 (Group B and Group D), three implant measuring points were located on the

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