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Influence of cerclages on primary stability of tumor megaprostheses subjected to distal femur defects



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ABSTRACT

Backround: Purpose of this experimental study was to investigate the influence of cerclages on the primary stability of the MUTARS[®] system using distally fractured synthetic femora. *Methods:* 4 MUTARS[®] prostheses were implanted in synthetic femora respectively. Groups consisted of

4 intact bones, 4 fractured with cerclages and 4 fractured bones without cerclages. Spatial micromovements were measured with a high-precision rotational setup.

Findings: The order from the weakest to the strongest torque transmission of the intact bones was rm₁-rm₄-rm₂-rm₃ (p = 0.011) and of the fractured bones with cerclages rm₄-rm₁-rm₃-rm₂ (p = 0.013). The MUTARS[®] stems broke out of the fractured femoral shaft by removing cerclages (p < 0.001) and by the influence of bone defect A (p < 0.001). Overall micromovements of the intact bones were lower than those of the fractured bones without cerclages (p < 0.001) and overall micromovements of the fractured bones with cerclages were lower than those of bones with cerclages were lower than those of bones without cerclages (p < 0.001).

Interpretation: Due to high press-fit at the proximal and distal isthmus region fissural fractures of the femur may occur. This should always be taken into account. It is advisable to secure them and provide a prophylaxis for these fissural fractures by means of cerclages.

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Introduction

The distal femur is the most common site for malignant bone tumors. In the past, standard treatment of these tumors consisted in transfemoral amputation or rotationplasty. Due to early diagnosis, neoadjuvant chemotherapy and the development and acceptance of modular megaprostheses around 95% of today's patients can be treated with limb salvage surgery [1–7] which is commonly used as conventional and satisfying therapy [1,5]. After surgery, femur reconstruction is primarily realized with megaprostheses to gain stable function and facilitate returning to social life [8]. However, there are various risks of these megaprostheses such as aseptic loosening, tumor progression, soft-tissue failures, infection and structural failures that may require revision or finally

ized with megaeturning to social distally fractured synthetic femora. megaprostheses ft-tissue failures, revision or finally *Prostheses*

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http://dx.doi.org/10.1016/j.injury.2015.10.031 0020-1383/© 2015 Elsevier Ltd. All rights reserved. The **M**odular **U**niversal **T**umor **A**nd **R**evision **S**ystem (MUTARS³⁶ Implantcast GmbH, Buxtehude, Germany) was examined in the *Laboratory of Biomechanics Giessen*. Stem size was 17, the length of

amputation of the extremity [9,10]. The majority of structural failures are established as fractures and may go unnoticed

intraoperatively and often occur at the distal third of the femur

[11]. In case of periprosthetic fractures either during implantation

[5,10] or high postoperatively stresses during knee flexion due to

high lever arms of the megaprosthesis [12], the fractured bone

requires reconstruction with allografts or cerclages [5,13,14]. Thus, the purpose of this experimental study was to investigate the

influence of cerclages on the reconstructed bones by means of



the implant was 120 mm. The implant is made of TiAl₆V₄ alloy. Its stem design is hexagonal and antecurvated and is hydroxyapatite-coated. The distal tip of the stem is cylindrical and polished. After statistical power analysis based on data according to similar studies [13–15] with alpha (5%) and beta (20%) errors (power = 80%) and relative movements of 15.2 and 15.8 (SD = 0.2) mdeg/Nm between two groups, the sample size was limited to n = 4.

Preparation

For standardized implantations, synthetic femora (Type #3406, Sawbones[®] Europe, Malmö, Sweden) were resected 21 cm distally below the lesser trochanter. Preparing of the medullary cavity of the femora was performed using an appropriate 17 mm hexagonal rasp by one experienced surgeon (O.B). The stem was implanted using the universal material testing machine (Inspekt table blue 20, Hegewald & Peschke, Nossen, Germany) according to a standardized protocol (25 axial loading cycles of 2 kN and 25 axial loading cycles of 4 kN) [13-15]. Due to the press-fit situation during the implantation, most femora models showed a provoked crack formation when the implant was set, which confirmed literature results, that fractures may occur during or after implantation when using this prosthesis [5]. If a crack formation was initiated during implantation, the implant was removed immediately and the originated bone defect was fixed by means of CoCrNi-alloy multifilament cerclages (Dall Miles Cable System, Stryker, Duisburg, Germany) with a diameter of 1.6 mm at 20.5 cm and 14.0 cm distal to lesser trochanter (Fig. 1). The wires were tightened with a force of \sim 300 N. Afterwards, the stem was reimplanted using the universal material testing machine again till the stem was set without restraining the potential expansion of the crack formation but only stabilizing the crack with cerclages. To attain reference measurements, implantations were continued till at least 4 intact bones were available. This procedure led to two groups of 4 intact bones as a reference measurement (bone # 1–4), and 4 fractured bones (bone # 5–8) which first were measured with cerclages and afterwards without cerclages.

Experimental setup

Primary implant-stability was examined using a well-established high-precision rotational measuring setup which has been published several times [14,16]. Cycling torques of ± 7 Nm were applied to examine the rotational stability of the implant at eight measurement points distributed at four equal levels of the prosthesis and the femora. Measurement sites of both the stem (P_X) and the bone (B_x) allowed for the calculation of relative movements rm_x of the implant-bone interface [17]: $(rm_1; distal metaphysis; B_1-P_1;$ 20.0 cm; rm₂; distal isthmus: B₂-P₂: 16.7 cm; rm₃; proximal isthmus: B₃-P₃: 13.3 cm; rm₄; tip of stem: B₄-P₄: 10 cm) (Fig. 1). For detecting relative micromovements at the bone and the implant surface during loading, six inductive extensometers (P2010, Mahr GmbH, Göttingen, Germany) with a resolution of 0.1 µm were attached to each measurement point. First the intact bones were measured as a reference. Subsequently the cracked bones with cerclages were measured. After finishing measurement with cerclages, the wires were removed to detect the outcome of the primary-stability of the implant subjected to each provoked bone defect without cerclages. Because of prior loading during the measurement with cerclages, the stem was re-implanted using the standardized protocol of the universal material testing machine. Afterwards rotational torques of \pm 7 Nm were applied using the same measurement protocol again. As already validated in prior analyses [14, 16], the axial torques T_Z and the measured rotational angles α_{Z} between bone and stem were always in a linear relationship and could therefore be normalized by



Fig. 1. Measurement protocol; Measurement points of the bone (B₁-B₄) and of the prosthesis (P₁-P₄) at four equal measurement levels.

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