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Modular tumor prostheses: are current stem designs suitable for distal femoral reconstruction? A biomechanical implant stability analysis in Sawbones

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Abstract

Introduction High loosening rates after distal femoral replacement may be due to implant design not adapted to specific anatomic and biomechanical conditions.

Materials and methods A modular tumor system (MUTARS®, Implantcast GmbH) was implanted with either a curved hexagonal or a straight tapered stems in eight Sawbones® in two consecutively generated bone defect (10 cm and 20 cm proximal to knee joint level). Implant-bone-interface micromotions were measured to analyze main fixation areas and to characterize the fixation pattern.

Results Although areas of highest relative micromotions were measured distally in all groups, areas and lengths of main fixation differed with respect to stem design and bone defect size. Regardless of these changes, overall micromotions could only be reduced with extending bone defects in case of tapered stems.

Conclusions The tapered design may be favorable in larger defects whereas the hexagonal may be advantageous in defects located more distally.

Keywords Implant fixation · Primary stability · MUTARS · Tumor prosthesis · Distal femur · Megaprosthesis

Introduction

Aseptic loosening of distal femoral replacement remains one of the main failure causes and is higher compared to proximal femoral reconstructions [4, 9, 17]. Similar design within one tumor system is used for proximal and distal replacement, but higher loosening rates with inferior results of distal femoral replacements were shown compared to proximal femoral reconstructions [3, 5, 9, 16]. Influence of implant length of a tapered design within the same setup has been investigated [18] as well as influence of cerclages on primary stability [11]. Influence of the stem design has not been investigated so far. For detailed in vitro analysis, direct comparison of two stem designs with the same length and within the same system would be helpful to analyze potential implant influences. The Modular Universal Tumor and Revision System (MUTARS) offers the possibility to choose between two stem designs, a tapered straight and a curved variant with hexagonal cross section [9, 10]. A decision may be derived whether primary stability can be achieved with these two designs and/or which design is favorable with respect to the underlying bone defect.

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The aim of this study was to analyze primary implant stability of two stems with identical length but different fixation philosophies in distal femoral replacement.

1. If MUTARS® is used with tapered stems instead of hexagonal stems for distal femoral reconstruction, relative micromotions will be decreased and thus implant stability will be increased.
2. If MUTARS® stems are used for distal femoral reconstruction in small (10 cm) instead of large (20 cm) bone defects, relative micromotions will be increased and thus implant stability will be decreased.

Materials and methods

Bones and implants

Eight synthetic femurs [composite bone 4th generation (#3406), Sawbones® Europe, Malmö, Sweden] were used with two consecutively created segmental bone defects, which have been resected 10 cm (defect Type 1) and 20 cm (defect Type 2) proximal to the knee joint level. Four groups with a group size of $n=4$ were measured with different settings of the modular tumor system MUTARS® (Implantcast GmbH, Buxtehude, Germany) to compare a curved hexagonal stem to a straight tapered stem in both defect situations (Fig. 1; Table 1).

Fig. 1 Curved hexagonal (**a**) and straight conical (**b**) cementless stem

Preparation

An experienced surgeon planned the corresponding implant sizes and prepared the bones according to the manufacturer's instructions. Implant fit has been checked with anterior–posterior (a–p) and medial–lateral (m–l) radiographs. Standardized press fit was generated by a material testing device (Frank-Universalprüfmaschine 81816/B, Karl Frank GmbH, Weinheim-Birkenau, Germany) with 25 axial load cycles of 2 kN (corresponding to intra-operative generated press-fit on the implant) and 4 kN representing the first post-operative loadings during rehabilitation [20].

Measurement setup

A rotational torque of ± 7 Nm was applied around the longitudinal axis of the stem with a well-established implant stability measuring device [8, 12, 13, 19]. Six sensors (LVDT type P2010A, Mahr GmbH, Goettingen, Germany) consecutively measured the three-dimensional motions of the implant and bone in reference to the distal end of the implant at several points of interest [8, 12]. To allow implant stability analysis, relevant measuring points were located at the stem (I_1: 0.5 cm; I_2: 5 cm; I_3: 9.5 cm and I_4: 11.5 cm proximal to the distal end of the stem) and bone (B_1, B_2, B_3 and B_4 at the same level as I_1, I_2, I_3 and I_4), which allowed to calculate the corresponding relative micromotions as a difference of bone and implant motions in the same area (rm_1, rm_2, rm_3 and rm_4). Two additional bone-measuring points (B_5: 23 cm and B_6: 35 cm proximal the knee joint level) and three additional implant measuring points (at the main component I_5: 5.5 cm, I_6: 7 cm and at the stem segment in case of defect Type 2 I_7: 17 cm proximal the knee joint level) should provide a comparable depiction of the results.

Statistics

SPSS (Version 22.0. Armonk, NY: IBM Corp) was used for the following statistical descriptions. Analysis of variance (ANOVA) with a least significant difference (LSD) test as a post hoc test was used to compare the relative micromotions rm_{1-4} within each single group (to characterize the specific implant fixation) and to compare different implant groups. A value of $p \leq 0.05$ was considered to be significant and data are shown as mean ± standard deviation (SD).

Table 1 Implant setting for Groups A–D

Group	Defect	Implant setting			
		Distal femoral main component STD 90 mm left	Stem segment 100 mm	Cementless curved hexagonal stem	Cementless straight tapered stem
A	Type 1	×		120 mm size 20	
B		×			120 mm size 21
C	Type 2	×	×	120 mm size 17	
D		×	×		120 mm size 17

Table 2 Measured micromotions (given in mdeg/Nm) for each measuring level ($rm_{1–4}$) and overall relative micromotions shown for each group (A: hexagonal stem in defect type 1, B: tapered stem in defect type 1, C: hexagonal stem in defect type 2, D: tapered stem in defect type 2)

Group	Relative micromotions in mdeg/Nm				
	rm_1	rm_2	rm_3	rm_4	Mean overall $rm_{1,2,3,4}$
A					
Mean	8	5	4	6	5.7
± SD	1.1	1.0	1.3	3.0	
B					
Mean	24	17	6	5	12.9
± SD	0.2	1.6	0.5	0.2	
C					
Mean	9	2	2	8	5.4
± SD	0.7	0.6	0.2	2.0	
D					
Mean	12	2	5	9	7.0
± SD	1.5	0.8	2.6	2.8	

Results are shown as mean and standard deviation (± SD)

Results

Based on an a priori sample size estimation, a group size of $n = 4$ was chosen referring to the results of a similar experimental setup [15].

Relative micromotions are summarized in Table 2 and fixation characteristics depending on rm_1 to rm_4 are shown in Fig. 2 for all groups. Measured motions (given in mdeg/Nm) were plotted against the longitudinal measuring level (given in cm). In addition to the micromotion results, a–p and m–l radiographs were used to analyze areas of implant fixation (Fig. 3).

The highest relative micromotions were measured at the distal ends of the bone in all groups, while lowest micromotions (area of main fixation) were measured in a small proximal area (Group B, rm_3/rm_4 vs. rm_1/rm_2, all $p \leq 0.01$), in the middle area (Group C, rm_2/rm_3 vs. rm_1/rm_4, all $p \leq 0.01$ and Group D, rm_3/rm_4 vs. rm_1/rm_2, all $p \leq 0.05$) or in a more extended combined middle and proximal area (Group A, rm_1 vs. rm_2/rm_3, all $p \leq 0.01$) of the distal femur.

Hexagonal vs. tapered stems

In small bone defects, relative micromotions of hexagonal stems decreased at the distal bone compared to tapered stems (rm_1 and rm_2, both $p \leq 0.01$). Similarly, motions of hexagonal vs. tapered stems decreased in extended bone defects at rm_1 and rm_3 (both $p \leq 0.01$).

Defect type 1 (small) vs. defect type 2 (large)

In hexagonal stems, larger defects reduced distal relative micromotions around the femoral isthmus (rm_2, $p \leq 0.01$) and increased relative micromotions proximal to the isthmus (rm_4, $p \leq 0.01$). Comparable results were measured for tapered stems, showing relative micromotions distally of the isthmus decreased (rm_1 and rm_2, $p \leq 0.01$) and proximally of the isthmus increased (rm_4, $p \leq 0.01$) with increasing bone defect situation. Although a similar reduction of distal micromotions was observed for both stem designs within extended defects, the area of main fixation was reduced for the hexagonal stem and increased for the tapered stem. In addition, overall relative micromotions were reduced only in case of tapered stems with increased defects.

Discussion

Endoprosthetic reconstruction of bone defects with megaprostheses after tumor resection or failed arthroplasty has become a standard procedure during the last decades [3, 5].

For detailed in vitro analysis, direct comparison of two stem designs with the same length and within the same system would be helpful to analyze potential implant influences.

Primary stability is one major factor for secondary stability due to osseointegration and therefore long time durability [18]. This can be demonstrated in vitro by measuring

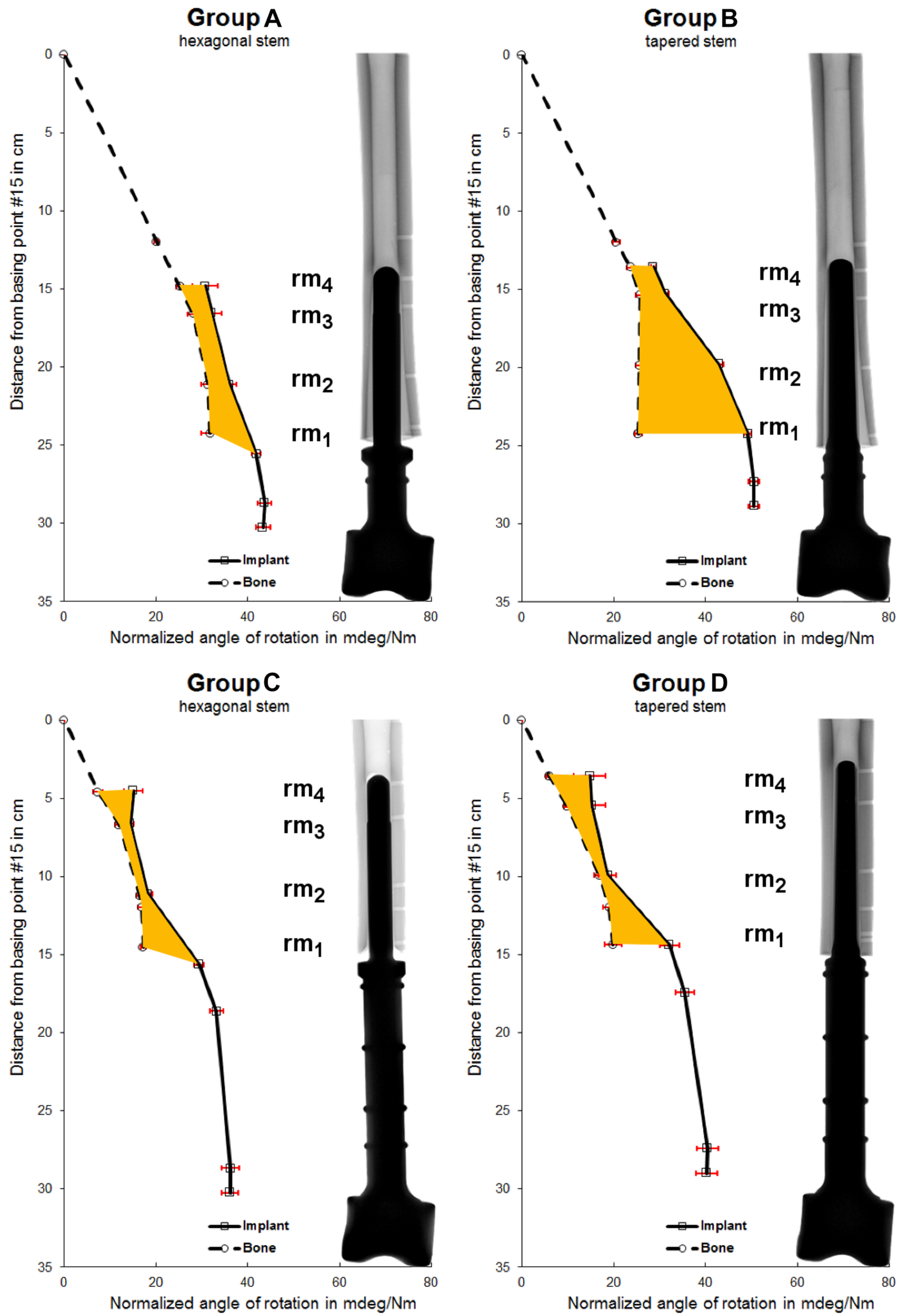

Fig. 2 Measured absolute micromotions (bone: dotted line and implant: continuous line) of all groups with the corresponding relative micromotions (rm_1–rm_4: orange colored area between bone and implant)

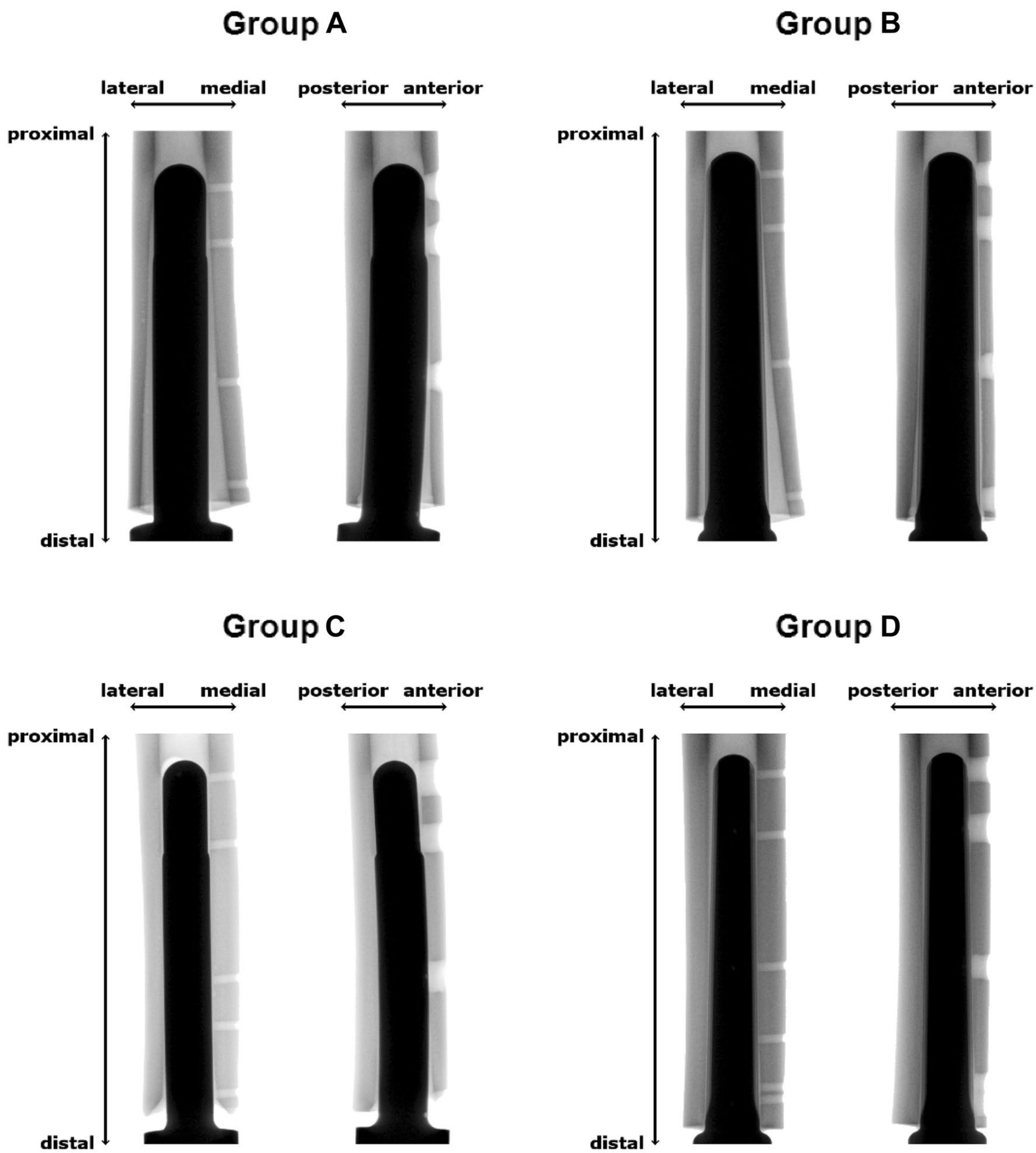

Fig. 3 A–p and m–l radiographs of the fixation area for all groups

micromotions between implant and bone. A micromotion threshold of 150 µm is known to be disadvantageous for successful osseointegration [7, 14].

Currently, there are no data available focusing on the influence of two stem designs with the same length and within the same system on reconstruction arthroplasty.

Limitations The study is limited by the use of synthetic bones, low applied loads and differences in implant size. Sawbones® were used instead of paired cadaver femurs to allow standardized conditions. Although the results might slightly differ to measurements in human specimens transferability between the synthetic device and human specimen has been shown [6]. As a linear relationship between micromotions and loads seems to exist [8], reduced loads were applied to allow a non-destructive repeatable measurement although clinically loads acting on hip and knee implants were known to be higher [1, 2]. In addition, a loading of 4 kN does not represent the first post-operative loadings during rehabilitation at all times. Weight-bearing procedures after cementless implantation of the MUTARS® stem with 20 kg are common. Different stem sizes were necessary for varying designs and in case of increased bone defect situation although this might affect the mechanical response of the implant on load application.

Discussion (1) If MUTARS® is used with tapered stems instead of hexagonal stems for distal femoral reconstruction, relative micromotions will be decreased and thus implant stability will be increased.

In our study, implant fixation decreased when tapered stems were used instead of hexagonal stems, so that hypothesis 1 could not be approved.

Press-fit anchoring may be easier to achieve by curved stems due to anatomical presupposition and natural femoral antecurvation can be adapted easier. This may be of low influence when using relatively short stems of 12 cm like in the present study. Especially near the isthmus, the tapered design seems to be of greater influence for primary stability than a curved profile. A more punctual fixation may result using longer straight designs with negative influence on primary stability. Micromotions were little in the hexagonal stem group in large defects. However, overall relative micromotions were reduced in case of tapered stems with increased defects.

These results are in contrast to clinical results for the proximal area. From technical view, hexagonal preparation in the isthmus area is less traumatic, since no or very few conicity and cortical bone has to be sacrificed [15]. Preparation can be performed more accurate and the blasting effect seems to be smaller. Additive measures such as cerclages with the corresponding disadvantages (invasive insertion, devascularization of the cortical bone) may not be necessary.

Discussion (2) If MUTARS® stems are used for distal femoral reconstruction in small (10 cm) instead of large (20 cm) bone defects, the relative micromotions will be increased and thus implant stability will be decreased.

As implant fixation was changed controversially for hexagonal stems and was decreased for tapered stems being used with the MUTARS® system in less extended bone defects, hypothesis 2 could only be approved in case of tapered stems.

Conical stems present advantages, especially in small defects [18]. Anatomic conditions with increasing cross-oval profile from the isthmus further distally seem to be less important. The rotation stability in conical radial designs appears to be higher even though according to radiological criteria only one contact can be established at two cortical bones (ventrally and dorsally) by preparing the medullary cavity with the corresponding reamers.

Comparable implant fixation has been observed for curved hexagonal stems in less extended distal femoral bone defects within a biomechanical study with similar experimental setup [11].

Overall micromotions of the intact bones were lower than those of the fractured bones without cerclages and overall micromotions of the fractured bones with cerclages were lower than those of bones without cerclages.

Conclusion

Based on these studies, a tapered stem presents less micromotions in larger defects than in smaller defects, whereas the more often used hexagonal design shows better primary stability near the isthmus.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest. This work was performed at the Laboratory of Biomechanics and Implant Research, Department of Orthopedics and Traumatology, University Hospital Heidelberg, Heidelberg, Germany.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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