Influence of stem design on the primary stability of megaprotheses of the proximal femur

Stefan Kinkel · Jan Dennis Graage ·
Jan Philippe Kretzer · Eike Jakubowitz · Jan Nadorf

Received: 28 March 2013 / Accepted: 22 July 2013 / Published online: 18 August 2013
© Springer-Verlag Berlin Heidelberg 2013

Abstract

Purpose Extended bone defects of the proximal femur can be reconstructed by megaprotheses for which aseptic loosening constitutes one of the major failure modes. The basic requirement for long-term success of endoprotheses is primary stability. We therefore assessed whether sufficient primary stability can be achieved by four different megaprotheses in a standardised bone defect of the proximal femur and whether their different design leads to different fixation patterns.

Methods Four different designs of proximal femoral replacements were implanted into 16 Sawbones® after preparing segmental bone defects (AAOS type II). Primary rotational stability was analysed by application of a cyclic torque of ± 7 Nm and measuring the relative micromotions between bone and implant at different levels. The main fixation zones and differences of fixation patterns of the stem designs were determined by an analysis of variance.

Results All four implants exhibited micromotions below 150 μ m, indicating adequate primary stability. Lowest micromotions for all designs were located near the femoral isthmus. The extent of primary stability and the global implant fixation pattern differed considerably and could be related to the different design concepts.

Conclusions All megaprotheses studied provided sufficient primary stability if the fixation conditions of the femoral isthmus were intact. The design characteristics of the different stems largely determined the extent of primary stability and fixation pattern.

Understanding these different fixation types could help the surgeon to choose the most suitable implant if the fixation conditions in the isthmus are compromised.

Keywords Megaprotheses · Proximal femur · Tumour · Primary stability · Aseptic loosening

Introduction

Extensive bone defects of the proximal femur may require the implantation of megaprotheses to bridge the defect and preserve the limb [1–3]. These bone defects can be the result of tumour resections [1] and bone loss due to aseptic loosening of total hip arthroplasties (THA) [3, 4] or fractures [3, 4]. In the literature, high complication rates of such megaprotheses have been reported [1, 2, 5–7]. Apart from infection, aseptic loosening constitutes the major failure mode leading to operative revision in 8–27 % of patients [1, 5–7]. These high complication rates may be caused by the extent of the defects [8] resulting in impaired fixation. However, in consideration of the predominantly younger age of patients undergoing oncological resections, these complication rates seem to be unacceptable.

Aseptic loosening is the consequence of deterioration of secondary stability of the implant in the bone, for which its primary stability is the basic requirement [9, 10]. Different fixation methods have been developed to achieve adequate primary stability, which is reflected by differing design characteristics of the commonly used implants.

The aim of this study was to analyse the primary stability of proximal femoral replacements by pursuing different fixation concepts under standardised conditions. This might provide an understanding of the extent and mode to which primary stability is provided by the different implants and help the orthopaedic surgeon to choose the appropriate implant for

S. Kinkel (✉) · J. D. Graage · J. P. Kretzer · J. Nadorf
Laboratory of Biomechanics and Implant Research, Department of
Orthopaedics and Traumatology, University Hospital Heidelberg,
Schlierbacher Landstrasse 200a, 69118 Heidelberg, Germany
e-mail: stefankinkel@gmx.de

E. Jakubowitz
Laboratory of Biomechanics, Department of Orthopaedics,
University Hospital Giessen, Giessen, Germany

endoprosthetic reconstruction of extensive proximal femoral defects.

Our assumption was that adequate primary stability can be achieved with the studied implants (hypothesis 1) and that the different design characteristics of the implants result in diverse fixation characteristics (hypothesis 2).

Material and methods

Sixteen synthetic femora (composite bone 4th generation [#3406], Sawbones® Europe, Malmö, Sweden) were divided into four groups (Groups A–D; four femora each). To simulate a bone defect as encountered after resection of a tumour of the proximal femur, a segmental AAOS Type II defect [11] was created by osteotomy of the Sawbones® five centimetres distal to the lesser trochanter. Four stems of implant systems with diverse design characteristics (Table 1) were used. The implants were the Megasyncem-C® (group A: size 18, length 130 mm, LINK GmbH, Hamburg, Germany), the Modular

Universal Tumour and Revision System MUTARS® (group B: size 17, length 120 mm, Implantcast GmbH, Buxtehude, Germany), the Global Modular Replacement System GMRS™ (group C: size 17, length 125 mm, Stryker Orthopaedics, Mahwah, USA) and the Segmental System (group D: size 18, length 130 mm, Zimmer Inc., Warsaw, USA). Reaming and rasping of the synthetic femora were performed with implant-specific instruments by an experienced surgeon. To achieve a press-fit similar to surgery [12], the stems were implanted according to a standardised protocol (25 axial load cycles of 2000 N and 25 axial load cycles of 4000 N) [13, 14] using a material testing device (Frank-Universalprüfmaschine 81816/B, Karl Frank GmbH, Weinheim-Birkenau, Germany). The implant fit and sizing were checked by X-ray examination.

Using a well-established, implant-stability measuring device [13–15], a cyclic torque of ± 7 Nm was applied around the stem axis to classify the rotational implant stability. During load application, six LVDTs (differential transducers Type P2010, Mahr GmbH, Göttingen, Germany) were attached to

Table 1 Design specifications of all four stems

Group		A	B	C	D
Implant		Megasyncem-C® Link	Mutars® Implantcast	GMRS™ Stryker	Segmental System Zimmer
Alloy		TiAl ₆ V ₄	TiAl ₆ V ₄	TiAl ₆ V ₄	CoCrMo
Design	global	straight, conical	curved, hexagonal	straight, cylindrical	straight, cylindrical
	proximal	Fluted	-	4 longitudinal expansions	Trabecular Metal sleeve
	middle	Fluted	-	-	fluted
	distal	Fluted	cylindrical	tapered	fluted, double-slotted
Surface	proximal	porous-coated	HA-coated	HA-coated, porous-coated	-
	middle	porous-coated	HA-coated	porous-coated	-
	distal	porous-coated	polished	-	-

each measurement point to determine the micromotions at different levels (Fig. 1) along the stem axis between the bone and the implant. Four measurement points were defined ventral to the stem [0.5 cm distally (#1), 5 cm distally (#2) and 9.5 cm distally to the proximal end of the stem and at the distal tip of the stem (#4)]. Six measurement points were located on the femur. Four femoral points (#5–8) were located directly corresponding to the stem points (#1–4). Additionally two points, located 20 cm distally (#9) and 30 cm distally (#10) to the lesser trochanter, were placed to achieve a higher resolution of the femoral motion. Comparing the motion of the stem and the femur at different levels allowed the calculation of relative micromotions at the bone-implant-interface.

Statistics

An analysis of variance was performed to determine the main fixation zones for each stem separately. Additionally, an analysis of variance was applied to identify differences between the stems regarding their fixation behaviour and their range of relative motion. A “least significant difference” test (LSD) was used as a post-hoc test. A p -value <0.05 was considered to be significant. Data were expressed as means $\pm$ SD (standard deviation).

Results

Lowest relative micromotions were located near the isthmus for all groups (A: 3.88 ± 1.58 mdeg/Nm, B: 9.06 ± 1.87 mdeg/Nm, C: 7.57 ± 2.00 mdeg/Nm and D: 1.40 ± 0.94 mdeg/Nm), whereas highest relative micromotions were located at the proximal part of the stem for groups B and C (B: 15.23 ± 2.55 mdeg/Nm and C: 15.60 ± 5.05 mdeg/Nm) and at the distal tip for groups A and D (A: 20.79 ± 3.22 mdeg/Nm and D: 13.22 ± 1.65 mdeg/Nm). Detailed micromotion results are displayed in Fig. 2. Each graph shows the micromotions of the implant (continuous line) and the bone (dashed line) plotted against the measuring level. Differences between both lines are defined as relative motion.

In contrast to the remaining measurement points in group A, the micromotion at the distal tip was significantly increased (all $p < 0.01$). Compared to both ends of stem in group B, significantly lower micromotions were detected within the whole isthmus region (proximal isthmus vs. all: $p < 0.01$, and distal isthmus vs. all: $p < 0.03$), whereas motion at the end of the stem showed no relevant difference. Within group C, proximal motion significantly higher compared to the distal isthmus region ($p = 0.01$). The micromotions of the proximal part of the stem including the whole isthmus region were significantly lower compared to the distal tip of stem in group D (all $p < 0.01$).

Fig. 1 Defined measurement points of the implant (orange; #1–4) and of the bone (blue; #5–10) at different measuring levels

Compared to groups A, B and C, the global range of motion of group D resulted in significantly less relative micromotions ($p < 0.01$). However, if the micromotions are converted from mdeg/Nm into μm with maximum hip joint loads of 35 Nm [16], all groups showed micromotions of less than 150 μm (a maximum value of 102.33 μm occurred within measurement point #1 in group C).

Discussion

Extensive bone defects of the proximal femur following tumour resection or aseptic loosening of THA may require the implantation of megaprotheses. High complication rates after implantation of such proximal femoral replacements have been reported with aseptic loosening being a major failure

Fig. 2 Rotational stability of the Megasystem-C® stem, the MUTARS® stem, the GMRS™ stem and the Segmental System stem in mdeg/Nm

mode. As aseptic loosening is related to the primary stability of the implant [17], the object of this study was to analyse whether adequate primary stability of the megaprotheses can be achieved to permit osteointegration (hypothesis 1). Furthermore, it should be analysed whether differing designs of the proximal femoral replacements have the intended impact on their fixation properties (hypothesis 2).

To allow osteointegration of the uncemented prosthesis relative motions of more than 150 μm between bone and implant are considered to be critical [9, 10, 18]. This threshold for primary stability was not exceeded by any of the implants with regard to their overall primary implant stability. It can therefore be concluded that sufficient primary stability seems to be achieved with the studied prosthetic designs in the given

defect situation. We expected this, and hypothesis 1 is therefore confirmed.

These findings do not explain the observed high rates of aseptic loosening of megaprotheses [1, 2, 5–7]. The discrepancy between our study results and the mechanical failures might be explained by other varying factors that can affect loosening and which we did not consider in this standardised biomechanical study. These include patient age, gender, diagnosis, experience of the surgeon, geometry of the femoral canal, and bone quality [19–22].

As surgeons are confronted with different bone defects and diverse fixation conditions, understanding the type of fixation of the different implants can be helpful in choosing an appropriate prosthetic design. We suspected an influence of diverse design characteristics on fixation pattern (hypothesis 2) and therefore compared the type of fixation of four different megaprotheses by interpreting the relative micromotions between bone and implant at different levels.

Apart from some modifications, the GMRSTTM (group C) has been in clinical use for about three decades [8] and its fixation parts are cylindrical, porous-coated, straight stems of titanium with round fins on the proximal portion (Table 1). With this design a fixation over a longer distance in the narrowest bone area and with the fins close to the proximal osteotomy can be expected. We observed a homogeneous fixation pattern with less relative motion on the distal third of the fixation area. This only partly reflects the expected fixation by the design. The homogeneous force transmission could be attributed to the cylindrical stem. But in contrast to the expected proximal accentuation of fixation, the observed fit at the distal portion might be caused by a close contact of the straight stem in the bowed femur.

The MUTARS[®] system (group B) can be characterised by a bent design with a cylindrical hexagonal titanium stem, which is coated with hydroxyapatite to enhance bony ingrowth. The cylindrical stem should transmit the forces over a longer distance to the bone. As expected we found a homogeneous fixation pattern of MUTARS[®], which resembled the behaviour of the GMRSTTM. But in contrast to the latter, a decrease of relative motion in the distal part of the stem was not observed. Unlike the GMRSTTM, MUTARS[®] is characterised by a bent stem. Therefore higher local stress in the curvature of the femur might be avoided, which could explain the difference of fixation patterns between these cylindrical implants.

The Megasytem-C[®] (group A) have a conical shape with longitudinal fins and a porous-coated surface of titanium. The intended fixation principle is to lock with its conical stem in the isthmus of the femur. This corresponds to the detected fixation pattern. We observed an area at the proximal third of the implant, which exhibited

small relative motions. Proximal and distal to this area greater relative motion was detected, indicating less rigid fixation of the implant.

The design concept of the Segmental System (group D) is different from those already described. It also has a cylindrical stem, but consists of more rigid CoCr alloy and has a fluted stem, which is double slotted at the distal third and round at the very proximal part. As a consequence a homogenous fit of the proximal two-thirds could be expected. Above the osteotomy, a Trabecular MetalTM sleeve is attached to the stem to enhance osteointegration. Surprisingly, an absolutely tight fixation of the proximal third of the stem was observed. This might have been caused by reaming to the internal diameter of the fluted part and pressing in of the wider non-fluted proximal part. However, the Trabecular MetalTM sleeve is attached to enable bony ingrowth, but in our experimental setting we did not expect a relevant stabilising effect. Therefore we did not consider the Trabecular MetalTM sleeve to be responsible for the proximal implant fixation. At the distal part more relative motion was observed. This is attributable to the double-slotted design, which can reduce local high stress at the tip of the more rigid stem compared to the titanium implants. Consequently the probability of diaphyseal stem pain might be decreased. Considering the absolutely tight fixation at the proximal part, care should be taken intraoperatively to avoid periprosthetic fractures while driving in the implant.

Although all implants provided adequate stability in the simulated bone defect, differences in the type of fixation could be determined. These could be related to the different design characteristics which would confirm hypothesis 2.

Based on our observations, different implants might be appropriate for different bone quality and defects of the preserved bone. For patients with good bone stock of the femoral isthmus, all megaprotheses that we studied seemed to have sufficiently small micromotions and therefore might achieve adequate primary stability to allow osteointegration of the implant. However, the Segmental System provides absolutely tight fixation and the attached Trabecular MetalTM sleeve should additionally enhance the bone ingrowth in vivo.

If the bone structure and quality of the entire femoral isthmus is compromised and if cementless fixation is intended, a more homogeneous fixation with the MUTARS[®] or GMRSTTM system might be more favourable to avoid areas with higher local stress and decrease the associated fracture risk.

For defects of the very proximal isthmus, the conical Megasytem-C[®] might lock in the narrowest part of the isthmus below the defect. If more than the proximal third of the isthmus is affected a more homogeneous fixation should be chosen.

In cases of compromised bone of the distal isthmus, the Segmental System or Megasytem-C® might be appropriate due to their more proximal fixation pattern.

This study has several limitations. Instead of human specimens, Sawbones® were used as a synthetic testing medium. Although comparable characteristics of Sawbones® and human bone have been determined within biomechanical studies [23], we cannot exclude possible differences of the extent and pattern of fixation compared to in vivo. These might be influenced by variations while reaming and implanting the prostheses as well as diverse behaviour of the Sawbones® and implants during measurements. However, in previous biomechanical studies using the same experimental protocol [13], we were able to substantiate clinical observations with valid and reproducible findings, which we also assume for the results of this study.

With the method used, we can only evaluate the primary implant stability. A biological process of osteointegration with the resulting effect on implant fixation is beyond the scope of this study. While drawing conclusions from implant stability on osteointegration of the tested systems, it should be borne in mind that HA coating (MUTARS®) and the Trabecular Metal™ sleeve (Segmental System) could also influence this biological process.

Analysis of fixation patterns is based on the interpretation of the measured relative micromotions between implant and bone. It constitutes therefore a descriptive method, which does not provide evidence for the reported fixation characteristics. This limitation should also be considered for the assessment of implant fixation properties and their implications for different fixation conditions.

We conclude that the studied megaprotheses of the proximal femur might achieve an adequate primary stability to permit osteointegration in an AAOS type II segmental bone defect if the bone structure of the isthmus is not further compromised. Differing design characteristics of the anchoring stems seem to result in diverse fixation patterns and the extent of primary stability. An understanding of these differences and their effects on fixation patterns might help the surgeon to choose the optimal implant for impaired fixation conditions even for implantation of a proximal femoral replacement. This could contribute to lower rates of aseptic loosening of megaprotheses of the hip joint.

References

- Gosheger G, Gebert C, Ahrens H, Streitburger A, Winkelmann W, Harges J (2006) Endoprosthetic reconstruction in 250 patients with sarcoma. *Clin Orthop Relat Res* 450:164–171. doi:10.1097/01.blo.0000223978.36831.39
- Ilyas I, Pant R, Kurar A, Moreau PG, Younge DA (2002) Modular megaprosthesis for proximal femoral tumors. *Int Orthop* 26:170–173. doi:10.1007/s00264-002-0335-7
- Parvizi J, Tarity TD, Slenker N, Wade F, Trappier R, Hozack WJ, Sim FH (2007) Proximal femoral replacement in patients with non-neoplastic conditions. *J Bone Joint Surg Am* 89:1036–1043. doi:10.2106/JBJS.F.00241
- Harges J, Budny T, Hauschild G, Balke M, Streitburger A, Dieckmann R, Gosheger G, Ahrens H (2009) Proximal femur replacement in revision arthroplasty. *Z Orthop Unfall* 147:694–699. doi:10.1055/s-0029-1185710
- Shin DS, Weber KL, Chao EY, An KN, Sim FH (1999) Reoperation for failed prosthetic replacement used for limb salvage. *Clin Orthop Relat Res* 53–63
- Henderson ER, Groundland JS, Pala E, Dennis JA, Wooten R, Cheong D, Windhager R, Kotz RI, Mercuri M, Funovics PT, Hornicek FJ, Temple HT, Ruggieri P, Letson GD (2011) Failure mode classification for tumor endoprostheses: retrospective review of five institutions and a literature review. *J Bone Joint Surg Am* 93:418–429. doi:10.2106/JBJS.J.00834
- Mittermayer F, Krepler P, Dominkus M, Schwameis E, Sluga M, Heinzl H, Kotz R (2001) Long-term followup of uncemented tumor endoprostheses for the lower extremity. *Clin Orthop Relat Res* 167–177
- Heisel C, Kinkel S, Bernd L, Ewerbeck V (2006) Megaprotheses for the treatment of malignant bone tumours of the lower limbs. *Int Orthop* 30:452–457. doi:10.1007/s00264-006-0207-7
- Ducheyne P, De Meester P, Aernoudt E (1977) Influence of a functional dynamic loading on bone ingrowth into surface pores of orthopedic implants. *J Biomed Mater Res* 11:811–838
- Pilliar RM, Lee JM, Maniopoulos C (1986) Observations on the effect of movement on bone ingrowth into porous-surfaced implants. *Clin Orthop Relat Res* 208:108–113
- D'Antonio J, McCarthy JC, Bargar WL, Borden LS, Cappello WN, Collis DK, Steinberg ME, Wedge JH (1993) Classification of femoral abnormalities in total hip arthroplasty. *Clin Orthop Relat Res* 296:133–139
- Schmidbauer U, Brendel T, Kunze KG, Nietert M, Ecke H (1993) Dynamic force measurement in implantation of total endoprostheses of the hip joint. *Unfallchirurgie* 19:11–15
- Gortz W, Nagerl UV, Nagerl H, Thomsen M (2002) Spatial micromovements of uncemented femoral components after torsional loads. *J Biomech Eng* 124:706–713
- Jakubowitz E, Bitsch RG, Heisel C, Lee C, Kretzer JP, Thomsen MN (2008) Primary rotational stability of cylindrical and conical revision hip stems as a function of femoral bone defects: an in vitro comparison. *J Biomech* 41:3078–3084. doi:10.1016/j.jbiomech.2008.06.002
- Jakubowitz E, Kinkel S, Nadorf J, Heisel C, Kretzer JP, Thomsen MN (2011) The effect of multifilaments and monofilaments on cementless femoral revision hip components: an experimental study. *Clin Biomech (Bristol, Avon)* 26:257–261. doi:10.1016/j.clinbiomech.2010.11.004
- Bergmann G, Graichen F, Rohmann A (1993) Hip joint loading during walking and running, measured in two patients. *J Biomech* 26:969–990
- Rubash HE, Sinha RK, Shanbhag AS, Kim SY (1998) Pathogenesis of bone loss after total hip arthroplasty. *Orthop Clin North Am* 29:173–186
- Engh CA, Bobyn JD, Glassman AH (1987) Porous-coated hip replacement. The factors governing bone ingrowth, stress shielding, and clinical results. *J Bone Joint Surg Br* 69:45–55
- Kobayashi S, Saito N, Horiuchi H, Iorio R, Takaoka K (2000) Poor bone quality or hip structure as risk factors affecting survival of total hip arthroplasty. *Lancet* 355:1499–1504. doi:10.1016/S0140-6736(00)02164-4

20. Bordini B, Stea S, De Clerico M, Strazzari S, Sasdelli A, Toni A (2007) Factors affecting aseptic loosening of 4750 total hip arthroplasties: multivariate survival analysis. *BMC Musculoskelet Disord* 8:69. doi:[10.1186/1471-2474-8-69](https://doi.org/10.1186/1471-2474-8-69)
21. Kobayashi S, Takaoka K, Saito N, Hisa K (1997) Factors affecting aseptic failure of fixation after primary Charnley total hip arthroplasty. Multivariate survival analysis. *J Bone Joint Surg Am* 79:1618–1627
22. Berry DJ, Harmsen WS, Cabanela ME, Morrey BF (2002) Twenty-five-year survivorship of two thousand consecutive primary Charnley total hip replacements: factors affecting survivorship of acetabular and femoral components. *J Bone Joint Surg Am* 84-A:171–177
23. Cristofolini L, Viceconti M, Cappello A, Toni A (1996) Mechanical validation of whole bone composite femur models. *J Biomech* 29: 525–535