Importance of a distal centralizer in experimental malpositioning of cemented stems. A biomechanical study on human femora

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Abstract

Introduction: Femoral centralizers in total hip arthroplasty (THA) are designed to improve the neutral implant position and ensure a homogeneous cement mantle without implant-bone impingement. To date there are no data about the cement mantle configuration and implant position after malinsertion, as seen in mini-open approaches or adipose patients with a limited view. The present biomechanical study was performed to investigate whether a distal centralizer may correct and optimize the position of a malinserted femoral stem.
Material and methods: Thirteen MS 30 stems with and without a distal centralizer each were implanted in paired fresh human femora. Malinsertion was performed using a 3D guiding device with 10° deviation to the femoral axis in the sagittal plane. The thickness of the cement mantle was measured on the anterior, posterior, medial and lateral side of the implanted stem at a distance of 1 cm each. For each side data were taken at 13 points.
Results: Digital evaluation of the cement mantle thickness revealed compareable values in frontal plane when a centralizer was used ($p > 0.4$). In contrast the cement mantle thicknesses without a centralizing device varied in the distal region between 3.38 mm and 5.09 mm ($p \leq 0.001$) and in the central region between 3.52 mm and 4.19 mm ($p \leq 0.009$).
Conclusions: A distal centralizer allows a more uniform cement mantle and neutral alignment even with a malinsertion of the femoral stem. This could reduce the failure rate and early loosening in complex THA.

Key words: hip arthroplasty, cement mantle, distal centralizer, femoral stem, biomechanical study.

Introduction

Polymethyl methacrylate (PMMA) bone cement has remained the most common technique in the fixation of the femoral component in total hip arthroplasty (THA) since its introduction by Charnley 30 years ago [1]. However, even the advanced third generation cementing technique including vacuum mixing, pulsatile lavage followed by drying of the canal, pressurization of the cement by retrograde filling with a cement gun and strengthening of the cement-stem interface by precoating the stem with

PMMA cannot control the implant position or cement mantle geometry [2–4]. Experimental studies have shown that implant malposition can lead to loosening of cemented hip stems [5–7]. The failure rate increases with reduced thickness of the cement mantle and direct metal contact with the bone [8, 9]. The thickness and homogeneity of the cement mantle are dependent on the quality of the cement placement, the stem size and the component position. The importance of mantle thickness has been borne out by finite element analysis, which predicts that the proximal medial cement mantle should be at least 3 mm thick, and the distal stem should occupy no more than 80% of the width of the medullary canal to minimize the probability of cement fragmentation [10]. These experimental predictions have been confirmed by long-term clinical studies showing that the rate of loosening of cemented stems is least when the proximal medial cement mantle is between 2.5 mm and 5 mm and the distal cement mantle is at least 2 mm in thickness [6]. Because of the importance of the correct position and alignment of the femoral stem within the cement mantle, centralizing devices fabricated from PMMA were introduced in THA more than 20 years ago [2]. Most of the recent studies have shown the efficacy of a centralizing device during an optimal insertion of the femoral stem in attaining the immediate goals of providing a uniform cement mantle and a neutral position for the prosthesis [11, 12]. However, modern THA with mini-open narrow approaches and limited view – especially in adipose patients – may impede or even prevent an optimal prosthesis position. To date, no study has shown the effect of a distal centralizer on the cement mantle thickness after controlled malinsertion of the femoral stem. Therefore the aim of the present study was to investigate the effectiveness of a distal centralizer under the premise of a malinserted femoral stem. Our hypothesis was that a distal centralizer can correct and optimize the position of a malinserted femoral stem.

Material and methods

All procedures were performed using straight femoral components of the same design (MS 30, Zimmer, Germany; Figure 1) [13–15]. For better evaluation all stems were made of hard plastic, that could be cut with a band saw for digital measurement of the cement mantle thickness. The only modification was the distal centralizer, which was inserted into a corresponding tunnel at the tip of the prosthesis. The centralizer has the shape of a pyramid and is composed of PMMA (Figure 1). In the stems without a distal centralizing device the distal hole was plugged with cement [16]. Stems with and without a distal centralizer were implanted in paired human femora, that were obtained from an anatomic collection and fixed to a workbench. Twenty-six femora from 13 cadavers were provided for implantation. The femoral neck was cut in a standardized manner (1.5 cm above the minor trochanter in the horizontal plane with an angle of 30°); femora were then prepared with standard rasps of the implantation set following the manufacturer's protocol. Flexible reaming was not necessary. An autologous intramedullary bone plug was formed from the resected femoral head and inserted into the canal, approximately 20 mm below the ultimate position of the distal tip of the prosthesis. After canal lavage and canal drying, the Palacos bone cement (Biomet, Berlin, Germany) was mixed under vacuum and injected retrograde into the medullary canal with a cement gun and pressurized using a flexible proximal canal seal. As recommended by the manufacturer, in those femora with a centralizer, the size of the centralizer was chosen as the size of the largest rasp used during canal preparation.

Insertion of the femoral stem

In contrast to other studies we did not align the prostheses in a neutral position. Instead, ma-

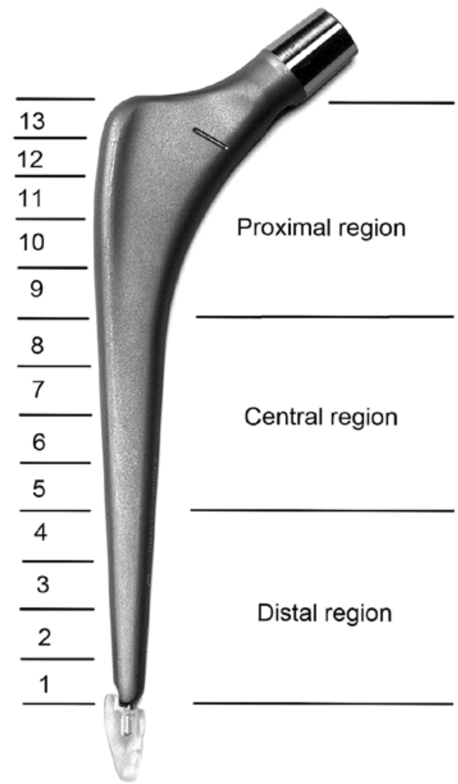

Figure 1. MS-30 stem by Zimmer with the attached centralizer at the bottom of the stem. The thickness of the cement mantle was measured on the anterior, posterior, medial and lateral side of the implanted stem at a distance of 1cm each. For each side data were taken on 13 points

linsertion of 10° in the anteroposterior plane was performed to simulate undesired intraoperative conditions. For a reproducible standardized insertion of the stem, a three-dimensional guiding device was developed and fixed on the femur.

Digital evaluation of the cement mantle thickness

After curing of the cement, the femora including the cement mantle and the inserted plastic stem were cut with a diamond band saw (Knuth, Wasbeck, Germany) in the anteroposterior and mediolateral planes.

This technique is much more precise compared to a radiographic evaluation of the stem position, since failures due to magnification factors and calculations of the real cement thickness can be excluded. For evaluation a digital sliding caliper (Mannesmann, Remscheid, Germany) with a resolution of 0.01 mm was used. The thickness of the cement mantle was measured on the anterior, posterior, medial and lateral side of the implanted stem at a distance of 1 cm each. For each side data were taken at 13 points. Therefore for each stem 52 data were detected. The measurement resembles the seven Gruen zones [17] in the mediolateral plane and the seven zones as described by Johnston *et al.* [18] in the anteroposterior plane. However, at a distance of 1 cm our measurement is still more detailed (Figure 1). If the cement mantle thickness was found to be less than 1 mm at any measured location, a cement mantle deficiency was recorded for that location. Approval for this study was given by the institutional review board. After the biomechanical tests all femora were restored to their human cadavers.

Statistical analysis

The cement mantle thickness was measured for each of the 52 points mentioned above. The mean value, the minimum, maximum and the standard deviation were scaled. For better evaluation the femora were divided into 3 regions: a distal (points 1–4), central (points 5–8) and a proximal region (points 9–13) (Figure 1). Evaluation of our data revealed little difference in the diameter of the femora, even if paired femora were used for better comparability. For this reason statistical evaluation was performed using the percentage of stem deviation from the femur center. Comparison of stem deviation within the femur cavity between stems with and without a distal centralizer was performed using the Mann-Whitney *U* test for non-parametric data (we used the Shapiro-Wilk test to determine that our data were non-parametric). All statistics were performed with SPSS (version 15.0, Chicago, Illinois, USA) and reviewed by an independent statistician. A p-value < 0.05 was taken to be statistically significant.

Results

For both prostheses with and without a distal centralizer, there was no location around the femoral stem with a cement mantle thickness under 1 mm and subsequently no mantle deficiency.

Digital evaluation of the cement mantle thickness revealed in the frontal plane with a distal centralizer comparable values along the femoral stem in all regions ($p > 0.4$). In the distal region the thicknesses varied between 3.05 mm and 3.22 mm and in the central region between 3.36 mm and 2.74 mm. In contrast the cement mantle thicknesses without a centralizing device were significantly different in the distal ($p \leq 0.001$) and the central ($p \leq 0.009$) regions. The thicknesses varied in the distal region between 3.38 mm and 5.09 mm and in the central region between 3.52 mm and 4.19 mm. In the anterior-posterior plane the cement mantle thickness differed significantly with both devices ($p \leq 0.007$) (Table I).

Statistical evaluation of the percentage of stem deviation from the center of the medullary canal revealed significant differences in the distal region. In the sagittal plane stem deviation was 49% without a distal centralizer compared to 23% with a distal centralizing device ($p < 0.001$) (Figure 2 A). In the frontal plane stem deviation was 32% without a distal centralizer compared to 17% with a distal centralizing device ($p = 0.004$). In the central and proximal region there were no significant differences comparing the prosthesis with and without a distal centralizing device (Figure 2 B).

Discussion

The aim of the present study was to investigate the effectiveness of a distal centralizer under the premise of a malinserted femoral stem. We hypothesized that a distal centralizer can correct and optimize the position of a malinserted femoral stem. We were able to demonstrate that especially the distal part of the stem can be placed significantly better in the center of the prepared femoral cavity with a distal centralizer compared to the stem without a centralizing device. The digital measurements of the cement mantle revealed in the distal part of the stems in all cadaver femora a thickness over 2 mm. This result corresponds to long-term follow-up studies that have recommended a cement mantle of between 2 mm and 5 mm in thickness [6].

The ultimate position of the femoral component will depend on many factors including correct exposure, preparation of the medullary canal, insight to the anatomical landmarks and insertion of the stem [19–21]. However, once adequate exposure

Table I. Cement mantle thickness (mm) along the femoral stem in both planes

Parameter	Distal	Central	Proximal
With Centralizer:			
Medial	3.047 ±1.416	3.357 ±2.118	5.225 ±2.767
Lateral	3.216 ±1.565	2.739 ±1.312	4.692 ±1.959
Value of *p*	0.557	0.478	0.590
Without Centralizer:			
Medial	3.378 ±1.672	3.517 ±1.523	4.677 ±2.552
Lateral	5.086 ±1.925	4.187 ±1.436	4.048 ±2.048
Value of *p*	≤ 0.001	0.009	0.268
With Centralizer:			
Anterior	4.041 ±1.727	2.650 ±1.212	2.639 ±1.044
Posterior	2.891 ±0.948	4.180 ±1.202	3.500 ±1.422
Value of *p*	0.004	≤ 0.001	0.002
Without Centralizer:			
Anterior	5.465 ±2.649	3.775 ±1.158	3.252 ±0.965
Posterior	3.224 ±2.649	4.683 ±1.842	4.039 ±1.679
Value of *p*	≤ 0.001	0.007	0.007

Data are expressed as mean ± standard deviation (mm).

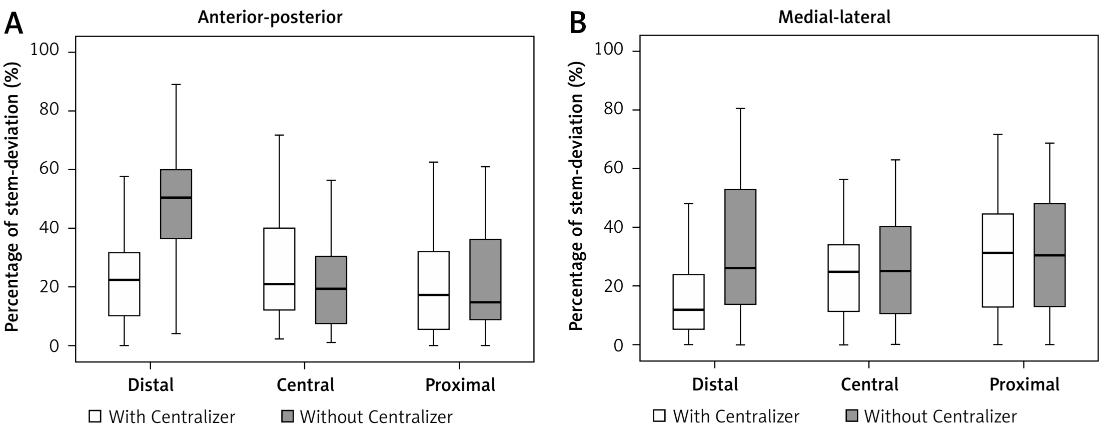

Figure 2. In sagittal plane stem deviation was 49% without a distal centralizer compared to 23% with a distal centralizing device ($p < 0.001$). In frontal plane stem deviation was 32% without a distal centralizer compared to 17% with a distal centralizing device ($p = 0.004$). In the central and proximal region there were no significant differences comparing the prosthesis with and without a distal centralizing device

and preparation of the femoral canal have been accomplished, the possibility of component malposition remains significant, especially in adipose patients and mini open approaches with limited view and soft tissue impingement. Therefore, an additional technique to ensure a more neutral prosthetic alignment during THA would be likely to decrease the incidence of failure [22–24]. In contrast to other biomechanical studies we first describe a controlled malinsertion of the stem with an anteroposterior deviation of 10° to the femoral axis. In our opinion, this technique is closer to realistic conditions since optimal positioning is often not possible. Without a centralizer, the surgeon attempts to control the distal stem position by manipulating the proximal prosthesis and seating the collar. Furthermore, the distal stem, which is not visible to the surgeon, may move as the prosthesis is manipulated to obtain a correct proximal position on the medial femoral cortex [25, 26]. Manipulation forces may increase with rising soft tissue tension, as seen in mini-open approaches and adipose patients. These worse implantation conditions are simulated in our experimental study with controlled malinsertion of the femoral stem. Our results have shown that the distal centralizer reproducibly controls the position of the distal stem, allowing the surgeon to align the proximal prosthesis without changing the position of the distal stem. Even in limited surgical conditions and with a bad view, the system enables the surgeon to more reproducibly achieve the desired alignment of the femoral prosthesis with a homogeneous cement mantle surrounding the stem. Clinical studies have shown that the highest incidence of cement failures occurs about the distal prosthesis [27, 28]. In this context, finite-element analyses [9, 10] and bench experiments [29, 30] have demonstrated that the distal cement is the area subject to the most stress under normal conditions. Distal cement mantle deficiencies lead to cement fissures and subsequent stem-bone impingement leads to bone changes and cement failures with loosening [8]. Finite-element analysis showed that a thickness less than 1 mm resulted in a dramatic increase in stress that can potentially lead to cement failure [10]. For the best comparability we always tested the same MS 30 stem with and without a distal centralizing device in paired femora of one specimen. However, even under these test conditions little difference in the diameters of the medullary channels could be detected. For this reason, statistical evaluation was performed using not the absolute diameter in mm, but the percentage of stem deviation from the femur center.

One limitation of our study is the heterogeneity of bones between the specimens, including different bone lengths, antecurvations, diameters, cortical thicknesses, moduli of elasticity, bone strengths and antetorsions. One other limitation is that we did not perform an a priori power analysis.

Nevertheless, our study is the first to show on human cadaver femora that a distal centralizer significantly and reproducibly facilitates proper positioning and cement uniformity even during controlled malinsertion of a femur stem. The insertion of the prosthesis was strictly standardized in 3 planes and cement thickness was evaluated by digital measurement. The insertion of the femoral stem is uncomplicated and no fracture of the distal centralizer – a very rare problem as described in the literature [2] – has occurred in our biomechanical tests. Future studies should be performed on larger test series with human femora using other insertion angles in different planes to evaluate the effect of a centralizing device on the final stem position under limited intraoperative conditions.

Acknowledgments

Andreas Kusserow and Andreas Ficklscherer both contributed equally.

Conflict of interest

The authors declare no conflict of interest.

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