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ORIGINAL PAPER

Development of periprosthetic bone mass density around the cementless Metha® short hip stem during three year follow up—a prospective radiological and clinical study

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Abstract

Purpose The purpose of this study was to check the concept of the cementless Metha® short hip stem in order to find out whether proximal physiological load transfer can be achieved.

Methods Fourty-three patients were included. Epidemiological factors were established. The Harris Hip Score was determined and measurement of bone mass density as well as osteodensitometric and radiological measurements was carried out pre-operatively, post-operatively, and after six, 12, 24, and 36 months.

Results Harris Hip Score improved from 55.9 ± 12.4 pre-operatively to 94.8 ± 8.2 after 36 months ($p < 0.001$). After initial reduction of bone density in zones 1 and 7 up to six months post-operatively, there was a steady approximation of bone density to the initial values ($p < 0.05$).

Conclusion The Metha® short hip stem shows good clinical results. Furthermore, there is an increase of bone density in the proximal zones 1 and 7 between six and 36 months serving as a sign of physiological load transfer.

Keywords Bone mass density · Physiological load transfer · Metha® short hip stem

Introduction

In our demographically aging society with its epidemiological change [1], the importance of hip arthroplasty is getting more apparent as the number of primary coxarthroses increases. In addition, more and more demands are placed on a hip endoprosthesis because patients want to stay active and mobile into old age. But also for younger patients, the hip endoprosthesis is important since their quality of life may be lessened due to a femoral head necrosis [2] or dysplasia [3]. This will without any doubt extend the requirements for a hip endoprosthesis. There is a high probability that young patients with a prior primary implantation will need a revision of their hip replacement in the course of their lives. In order to create good conditions for such a revision surgery, it is therefore important to save the trochanter and the femoral neck during implantation [4]. The lifetime of prosthesis is one of the most important criteria for or against the use of a special stem design. The most common cause of a limited lifetime of the prosthesis is aseptic loosening [5]. Remodeling processes lead to absorption, i.e., reduction of bone density and finally loosening which necessitates a revision [6]. The aim of this study was to investigate to what extent the concept of physiologically proximal load transfer could be realized with the Metha® short hip stem and whether the prosthesis could be considered osteointegrated after a follow-up period of 36 months.

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Patients and methods

Demographics

In this prospective study, between March 2010 and January 2013, 43 patients were consecutively treated with a

cementless short hip stem (Metha®, B. Braun, Tuttlingen, Germany) at the Department of Orthopedics and Orthopedic Surgery at the University Hospital Giessen and Marburg (UKGM). This study was preceded by approval from the University Ethics Committee (reference 152/09). Inclusion criteria included patients with a hip disorder indicating the implantation of short hip stem prosthesis and a written informed consent of patients to participate in this study. Patients with prior surgery on the contralateral hip were excluded. Twenty-two patients were men (51.2%), 21 patients were women (48.8%). The mean age of the patients was 56.9 ± 10.4 years (range 33–78) at the time of surgery. The average body mass index (BMI) was 27.2 ± 4.5 kg/m^2 (range 18–38). The right hip was treated 23 times (53.5%), the left hip 20 times (46.5%).

Surgical technique and implants

The operations were performed by four different experienced orthopaedic surgeons. In all cases, the implant was a Monoblock Metha® short hip stem. It is characterized by a cone shape which should provide the primary stability and the proximal load transfer. The stem features a microporous Titan Plasmapore® surface coated with calcium phosphate to promote faster osseointegration and therefore faster secondary stability in its upper two thirds. The distal stem tip is uncoated and polished to avoid any osteintegration [7] (Fig. 1). The design of this prosthesis allows a minimally invasive approach and offers the advantage that the bone and muscle structures, especially the trochanteric region, can be preserved. The anterolateral minimally invasive approach according to Frndak (ALMI) [8] was chosen in 40 cases, Bauer's lateral approach [9] in two cases, and in one case another approach. The preferred approach was the ALMI. If this was not possible due to previous surgery or difficult operating conditions such as obesity, the approach to Bauer or another modified approach was used. For 72%, the indication for surgery was primary coxarthrosis; for 16%, coxarthrosis due to dysplasia; for 7%, post-traumatic coxarthrosis; and for 5%, femoral head necrosis. Possible contraindications for treatment with a short hip stem are significant coxa vara and a short, wide, femoral neck [10].

Fig. 1 Metha® short stem

Clinical evaluation

For clinical evaluation, the modified Harris Hip Score (HHS) was examined pre-operatively (t_1) and six (t_3), 12 (t_4), 24 (t_5), and 36 (t_6) months after surgery. This score includes the factors pain, gait, everyday activities, possible contractures/deformities, and range of motion [11].

Osteodensitometric analysis

Osteodensitometric measurements by means of dual-energy X-ray absorptiometry (DXA) were made using the Lunar Prodigy Primo device. The scans were processed with the usual software enCore 2010 GE Healthcare 13.31 and with the specific Orthopedic Hip Software (GE Medical Systems, Madison, WI, USA). To avoid any superposition, which could adulterate the results of the measurements, various positioning aids for the legs of both the treated and the contralateral hip sides were used. The first DXA examination was performed immediately during the first week after operation (t_2). This measurement presents a reference for the follow-up values. Furthermore, with every scan of the treated hip side, another scan of the contralateral side was carried out to provide an additional reference. Follow-up scans were performed t_3, t_4, t_5, and t_6 after operation. Two patients were lost at t_3, but were reincluded at t_4. One patient was lost at t_4, but was reincluded at t_5. Four patients were lost at t_5 but could be reincluded at t_6. Reasons for missing follow-up examinations were forgotten appointments, time problems, and illnesses of the patients at the particular follow-up examination. To evaluate the changes of the periprosthetic bone mass density of the prosthetic hip side, the periprosthetic region was divided into seven regions of interest (ROI) following the modified classification according to Gruen [12] (Fig. 2). The Gruen zones were adapted to the short stem design (R1–R7). Data are given as the absolute bone mass density (BMD) of every ROI 1–7 in grams per square centimeter.

For osteodensitometric evaluation, quotients (BMDQ) between the immediately post-operative BMD as the denominator and the follow-up BMD as the numerator were generated to focus on the relation between the two. A BMDQ = 1 means that there is no difference between the immediately post-operative (t_2) BMD values and the follow-up BMD values. A BMDQ > 1 means that the follow-up BMD value is higher than the immediately post-operative BMD (t_2) value. A

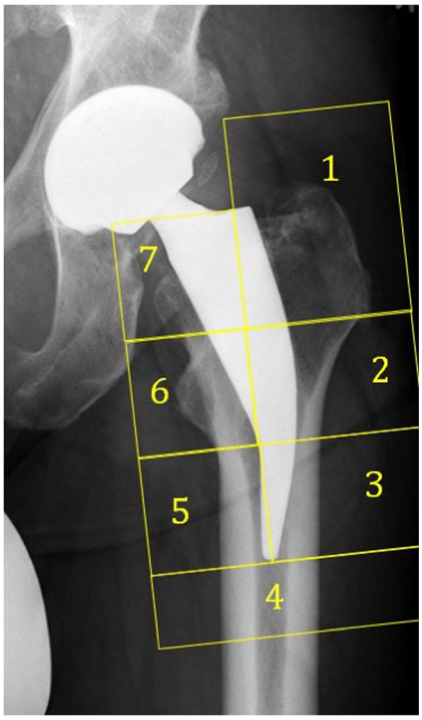

Fig. 2 ROIs according to Gruen

BMDQ < 1 means that the follow-up BMD value is smaller than the immediately post-operative BMD value (t_2).

Radiological analysis

For radiological analysis, radiographs of the pelvic area in the anterior-posterior and in the Lauenstein projection of the treated hip side were made at follow-ups t_1 to t_6. The radiographs were calibrated with a calibrating sphere. Again, the stems were examined in the seven ROIs according to Gruen [12]. In order to get descriptive statements about periprosthetic remodeling processes, osseointegration, load transfer, and possible stem failure, the radiological signs "stress shielding," "spot welds," and "reactive lines" were additionally observed by one single investigator (L.A.). According to Engh et al. [13], the lack of reactive lines of the coated area of the prosthesis (especially in zones 2 and 6, partly in zones 1 and 7) and the presence of spot welds are defined as main characteristics of osseointegration.

Statistics

Statistical analyses were performed using the software SPSS (IBM SPSS Statistics Version 20, Armonk, USA). Statistical analysis of BMD changes and possible improvement of HHS was provided by means of a linear regression model with repeated measurements (ANOVA = analysis of variance). Due to multiple test procedures, the alpha level was adjusted according to the Bonferroni correction. Correlations with epidemiological factors like age, sex, and BMI were determined using a mixed effects linear regression model with repeated measures. A p value of < 0.05 was considered statistically significant.

Results

Clinical results

The HHS improved in a highly significant manner ($p < 0.001$) from 55.9 ± 12.4 (range 31–73) at t_1 to 92.9 ± 11.3 at t_3, 94.4 ± 6.6 at t_4, 93.4 ± 8.9 at t_5, and 94.8 ± 8.2 (range 71–100) at t_6. At t_1, there were 38 patients with "poor" function. At t_6, no patient had a "poor" function but there were 37 patients with "excellent" function.

Osteodensitometric results

At t_3, there was a decrease in bone density in the proximal ROIs 1 and 7 compared to t_2 ($p < 0.05$). In the other ROIs, only marginal and not significant bone mineral density changes could be detected. During the follow-up period of 36 months, however, there was a bone density increase in the zones 1 and 7. This showed a continuous approximation to the directly post-operatively measured values of the proximal zones 1 and 7. At follow-up time t_6, a significant difference for zone 1 could no longer be detected. The same tendency was observed in the other proximal ROI 7, but there was still a significantly lower BMD compared to the value measured immediately after surgery ($p < 0.05$). In the course of 36 months, the coated ROI 6 showed a significant increase in bone density compared to the immediately post-operative BMD ($p < 0.05$) (Fig. 3). Correlations between BMD changes and Gruen zones ($p < 0.001$) and between BMD changes and follow-up time ($p < 0.0062$) were detectable. The factors sex ($p = 0.14$), age ($p = 0.85$), and BMI ($p = 0.95$) did not have any influence on BMD changes.

Radiological results

Reactive lines were especially discernible in the distal ROI 4 in 14 cases after 36 months. In the coated proximal ROI 2, there were only four cases and in the coated ROI 6, there were only two cases at t_6 showing an isolated reactive line. However, there were spot welds in ROI 2 and in ROI 6 in 24 cases at t_6 each (Fig. 4). First-scale stress shielding characterized by calcar rounding was observed in 16 cases at t_6. Second-scale stress shielding characterized by an apparent loss of bone density was observed in ROIs 1 and 7 in 18 cases. Higher-grade stress shielding could not be observed. Nine implanted stems showed no stress shielding at all after a follow-up of 36 months (Table 1).

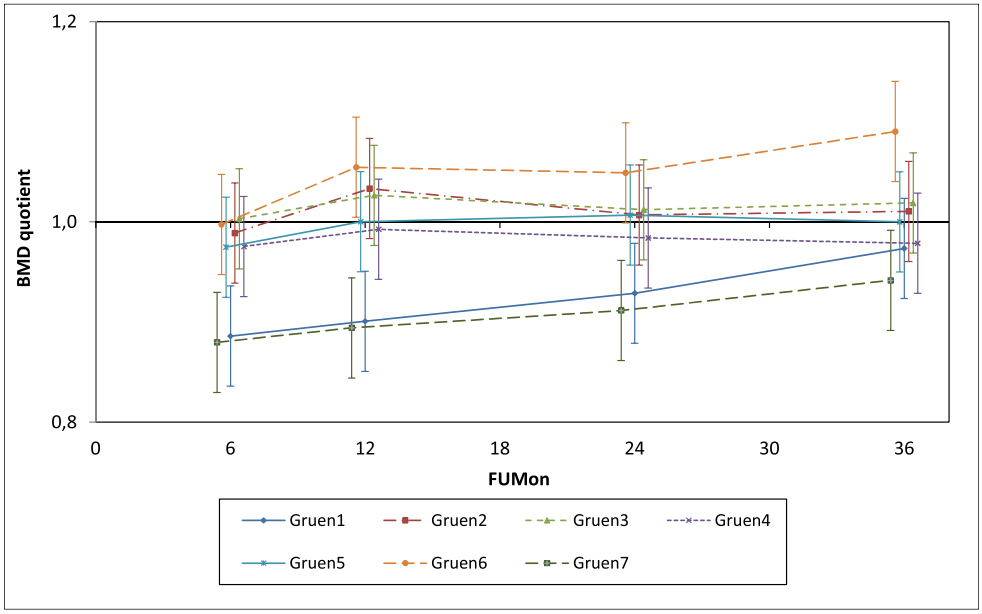

Fig. 3 Results of DXA

Discussion

Osteodensitometry using DXA (dual energy X-ray absorptiometry) is a gold standard method of examining periprosthetic changes in bone density in order to recognize remodeling processes at an early stage and to evaluate their development. In addition, this method is characterized by high reproducibility and the absence of effects of superposition [14]. However, it should be noted that the device used for this purpose must be very specific, which leads to different measurement results when different devices are being used [15]. In the present study, this problem was avoided by exclusive use of one and the same device which was subjected to periodical maintenance. Any sources of error due to incorrect or different positioning of the patients were minimized by using positioning aids. The sequential DEXA examinations of the contralateral untreated side taken at t_2, t_3, t_4, t_5, and t_6 ruled out a possible bias.

There are many studies that deal with the measurement of periprosthetic bone density changes using DXA [16–18], some of them observing the Metha® short hip stem [19–21]. This prospective study is the first one examining a cohort of 43 patients during a mid-term follow-up period of 36 months. According to Wolffs' Law, bone atrophy could be detected in unloaded ROIs and bone hypertrophy in ROIs where the load transfer took place [22].

Initially, we could observe that periprosthetic bone density reduction occurred in all zones until six months after surgery.

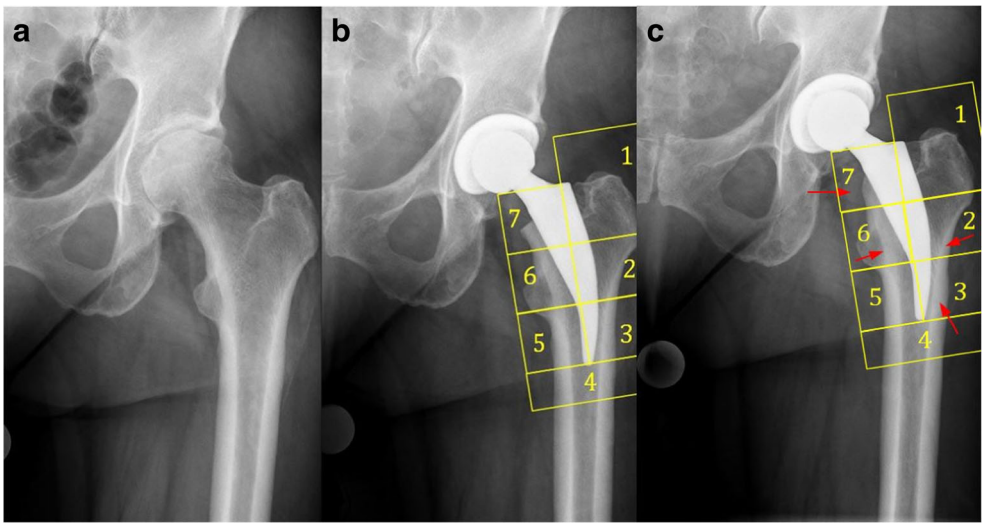

Fig. 4 Radiological follow-up controls **a** preoperatively (t_1), **b** direct post-operatively corresponding to the first DXA measurement (t_2), and **c** after 36 months (t_6). The red arrows indicate the typical bone mass density changes after 36 months. The calcar rounding in zone 7 and the bone hypertrophy in the medial zone 6 and the lateral zones 2 and 3 can be clearly perceived

Table 1 Radiological results

Reactive lines					Spot welds			
Gruen zone	t_3	t_4	t_5	t_6	t_3	t_4	t_5	t_6
1	1	1	4	7	0	0	0	1
2	0	0	0	4	3	12	17	24
3	0	2	1	4	1	1	4	2
4	4	16	15	14	1	1	0	1
5	0	3	4	4	0	0	1	1
6	0	0	1	2	9	23	30	24
7	0	0	0	1	0	1	2	5

This finding is also confirmed by other studies in which the Metha® short hip stem was examined [19–21]. The reason for this could be remodeling processes due to the previous surgical manipulation, which could result from the rasping at the trabecular structures and the high primary stresses. These stresses may also cause circulatory disorders of the periprosthetic tissue. Especially the preparation of the femur is discussed as a reason for post-operative blood flow disorders causing a BMD loss [23, 19]. Due to the fact that the bone density in the proximal zones 1 and 7 increased between six and 36 months post-operatively, it can be assumed that in these zones, a continuous proximal load transfer took place during this follow-up period. Lerch et al. [21] reported a strong increase in BMD in ROIs 6 and 7 up to 24 months post-operatively. The observation made in our study that there is an increasing bone density in both proximal ROIs 1 and 7 and the fact that this increase is still observed after 36 months had not been made in former studies. Even for the predecessor of the Metha® short hip stem, the Mayo® prosthesis, no such increases of proximal periprosthetic BMD had been found after 12 months [24]. It is therefore obvious that even minor differences in prosthesis design have an effect on periprosthetic remodeling processes [25] and even investigations with similar study designs may lead to different results [26].

One sign of ingrowth of the prosthesis is the hypertrophy of BMD in the hydroxyapatite coated ROI 2 and in particular ROI 6, a result which corresponds to other comparable studies [19–21]. The coating could thus also be a factor that positively influences the ingrowth. This result can also be verified considering the radiographs, where spot welds could be seen in most cases at the coated stem section. This is an important sign of osseointegration [13]. However, more than 75% of our patients showed calcar rounding as quantitative atrophy of the bone. This calcar rounding is a stress-shielding criterion and cannot be detected by means of DXA measurements. It appears that there is a qualitative increase in measured BMD with DXA but a quantitative loss of bone structure on the radiographs. The reasons for this should be investigated in follow-up studies.

An appropriate method of preventing calcar atrophy has not been found so far. Short stems as well as standard stems show calcar rounding [27, 28]. Perhaps, there is a difference in load transfer within each ROI. In some cases, narrow reactive lines could be observed, but no single one exceeded the thickness of 1 mm and most of them were in the distal ROI 4, so we cannot assume this to be an indication of aseptic loosening. Nonetheless, the reactive lines are a sign of micromotions [29] in the distal ROI 4. Another dreaded complication, the periprosthetic fracture, which is one of the main causes of revision besides aseptic loosening [30], was not found in our collective. We did not find any correlations between changes of BMD and epidemiological factors, a fact which was also reported by Synder et al. [20]. Other studies, however, reported on correlations between BMD, gender, and BMI [31]. This may be explained by possible epidemiological differences between the collectives. There might be other factors that effect changes of BMD. For example, Skoldenberg et al. found correlation between BMD and stem size [32]. Sariali et al. found a correlation between BMD and anterior flare of the femur [33]. Finally, in our cohort, there was a very good clinical outcome which is comparable to the results of other studies of the Metha® short hip stem and short stems with similar study designs [19, 16, 34–37].

Our study has some limitations. No control group could be provided and therefore no randomization of the cohort was possible. The reason for this, however, was that due to the advantages of the examined short hip stem, which could already be confirmed in prior studies [19, 38]; it was ethically undesirable to provide a control group with standard prosthesis. Another limitation of our study consisted in a relatively small sample size.

Conclusion

In summary, this study shows very good clinical results for our cohort. No high grade stress shielding could be observed radiologically, but only first- and second-grade stress shielding. No signs of aseptic loosening were detected. BMD decreased in all ROIs, especially in the proximal ROIs 1 and 7 until six months post-operatively. Nevertheless, between six and 36 months, an increasing BMD in ROIs 1 and 7 and an approximation to the immediately post-operatively measured BMD could be observed. Therefore, at least a partial realization of the concept of proximal load transfer of the Metha® short hip stem can be assumed.

Further studies with an extended follow-up time are needed to assess the progress of osseointegration of the Metha® short hip stem and to find out whether such an almost physiological load transfer of the Metha® prosthesis is sufficient to lengthen its useful life in comparison with other established prostheses.

Compliance with ethical standards

This study was preceded by approval from the University Ethics Committee (reference 152/09).

Conflict of interest The authors declare that they have no conflict of interest.

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