Subsidence of a cementless femoral component influenced by body weight and body mass index

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Abstract

Purpose This trial was designed to evaluate the impact of physical characteristics such as body mass index, body weight and height on distal stem migration of a cementless femoral component, as the influence of obesity on the outcome of THA is still debated in literature and conflicting results have been found.

Methods In this retrospective cohort study, migration patterns for 102 implants were analysed using the *Einzel-Bild-Roentgen-Analyse* (EBRA-FCA, femoral component analysis). In all cases the Vision 2000 stem was implanted and combined with the Duraloc acetabular component (DePuy, Warsaw, Indiana).

Results The mean follow-up was 93 months. EBRA-FCA evaluations revealed a mean subsidence of 1.38 mm after two years, 2.06 mm after five and 2.24 mm after seven years. Five stems loosened aseptically. Correlation between in-

creased migration over the whole period and aseptic loosening was highly significant ($p < 0.001$). Surgical technique had a significant influence on migration and stem stability ($p = 0.002$) but physical patient characteristics such as body weight over 75 kg and height over 165 cm also significantly influenced stem subsidence towards progressive migration ($p = 0.001$, $p < 0.001$). However, a high BMI did not trigger progressive stem migration ($p = 0.87$). Being of the male gender raised the odds for increased migration ($p = 0.03$).

Conclusion Physical characteristics such as body weight and height showed significant influence on migration patterns of this cementless femoral component. The operating surgeon should be aware that body weight above 75 kg and height over 165 cm may trigger increased stem migration and the surgeon should aim to fit these prostheses as tightly as possible. However this study demonstrates that a high BMI does not trigger progressive stem migration. Further investigations are needed to confirm our findings.

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Introduction

In total hip arthroplasty (THA) aseptic loosening is the most frequent cause for revision surgery with an incidence ranging between 55% and 75% [1, 2]. Recent studies have discussed the theory of a multifactorial aetiology for aseptic loosening [3, 4]. These studies propose that immunological mechanisms, implant design, surgeon skills and patient related factors were responsible for aseptic component failure. The influence of obesity on the outcome of THA is still debated in literature and conflicting results have been found: the majority of investigators have indicated that a high body mass index (BMI) does not affect the outcome of THA [5–10]. However the majority of studies indicate that body weight has negative effects on implant failure, component loosening and revision rate [11–14].

Data from new investigations emphasise that the acetabular component may be primarily exposed to biological factors while the fixation of the femoral component may be substantially affected by non-biological factors [15]. The influence of these non-biological factors such as body weight, BMI and height upon the migration behaviour of implants is still unresolved in the literature. Onsten et al. [16], demonstrated in a roentgen stereophotogrammetric study that body weight had no influence on stem migration of a cemented stem. We therefore examined the hypothesis that the impact of body weight might be different in cementless THA.

The purpose of the study was to evaluate the impact of physical characteristics on stem subsidence. We tried to focus on the influence of BMI, body weight and height upon stem migration of a cementless femoral component.

Patients and methods

This study was designed to evaluate the impact of physical patient characteristics on the subsidence of the Vision 2000 femoral component (DePuy, Warsaw, Indiana), a cobalt-chromium-alloyed, 50% porous-coated, proximally fixed, collared, distally tapered, cementless press-fit stem system. The stem was manufactured to be impacted into the cancellous bone of the proximal femur for proximal fixation and distal splinting.

The Vision 200 stem

In all cases the Vision stem was combined with the Duralac cup (DePuy, Warsaw, Indiana). We included 105 consecutive implants in 98 patients with an approximate 2/3 female and 1/3 male gender distribution and a mean age of 65 years (range, 36–82 years) at time of implantation. All patients who had had primary THA performed with the Vision 2000 and Duralac components were considered candidates for this study. The patients were then divided into groups according to their BMI, body weight and height as follows: non-obese ($\text{BMI} \leq 30 \text{ kg/m}^2$) and obese ($\text{BMI} > 30 \text{ kg/m}^2$), body weight $\leq 75 \text{ kg}$ and $> 75 \text{ kg}$ and small proportioned patients ($\leq 165 \text{ cm}$) and patients with height $> 165 \text{ cm}$. Body weight $\leq 75 \text{ kg}$ and $> 75 \text{ kg}$ and height $\leq 165 \text{ cm}$ and $> 165 \text{ cm}$ were cut-off values near the median of the total study group (median of body-size = 165 cm, median of body weight = 77 kg).

The study group was clinically followed up for an average of 93 months (range, 72–120 months). Five patients required revision surgery due to aseptic loosening. They were clinically followed up until the date of reoperation.

The indications for THA were primary osteoarthritis in 79 hips (75%, 52 female, 27 male), avascular necrosis in 13 hips (12%, four female, nine male), dysplasia in seven (7%, seven female), post-traumatic osteoarthritis in three (3%, two female, one male), rheumatoid arthritis in two (2%, one female, one male) and osteoarthritis status post coxitis in one (1%, one female). A summary of demographic data is listed in Table 1.

The study included assessments of the clinical outcome using the Harris hip score rating system (HHS). Clinical and functional performance was evaluated preoperatively and upon each follow-up visit. For the radiological assessment standardised anterior-posterior radiographs of the pelvis centered over the symphysis were obtained one and six weeks postoperatively, three and six months postoperatively, and annually thereafter. Radiographs were reviewed by the treating physician during

Table 1 Patient baseline information and baseline characteristics

Variable	Value	
Number of patients	98	
Number of hips	105	
Females/males	63/35	
Mean age (y)	64.5	
Mean body-weight (kg)	78 (range, 36–82)	
Mean body-height (cm)	165 (range, 140–183)	
Mean BMI (kg/m ²)	28.3 (range, 20.1–42.2)	
Mean time to last follow-up	93 (range, 82–123)	
Preoperative diagnosis (%)	Primary osteoarthritis	75
	Avascular necrosis	12
	Dysplasia	7
	Post-traumatic osteoarthritis	3
	Rheumatoid arthritis	2
	Osteoarthritis status post coxitis	1

follow-up appointments. Stem subsidence was evaluated by the author (CS) using computer-assisted EBRA-FCA-method [17], reaching a specificity of 100% and a sensitivity of 78% for detection of subsidence over 1 mm [18].

The protocol of this retrospective analysis was developed by the investigators as approved by the local ethic committee (No 20–187 ex 08/09) and the study was performed without any industrial sponsorship. The trial was conducted in accordance with the Declaration of Helsinki.

All operations were performed using a standardised anterolateral transgluteal approach. Perioperatively, all patients received intravenous antibiotic and thrombosis prophylaxis using low-molecular-weight heparin. The patients received prophylaxis for heterotopic ossification with 150–200 mg of diclofenac per day for five days.

Mobilisation was initiated two days after surgery. Patients were permitted to bear their full weight but were advised to use two crutches for at least six weeks and a single crutch or cane for a further four to six weeks.

Statistical analyses were obtained using NCSS (Number Cruncher Statistical Systems, Hintze J., Kaysville, UT, USA). Categorical data was analysed with the use of the chi-square test and the Fisher's exact test as appropriate. The analysis for changes in HHS was performed using the paired Wilcoxon test. The analyses for changes in implant migration were performed by the analysis of variance (ANOVA) for repeated measurements. All tests were two-fold; probability values less than 0.05 were considered indicative of statistical significance. As the analyses are exploratory, no corrections for multiple testing were made.

Results

Clinical

All patients showed a significant increase in HHS after the surgery ($p < 0.001$). Preoperatively the median HHS was 43.5 (range, 12–78). At the most recent follow-up, the median score was 96 (range, 33–100). Clinical examination revealed that 66.7% (70/105) were free of pain, 16.2% (17/105) reported slight pain, 10.5% (11/105) had mild pain, 3.8% (4/105) declared they had moderate pain and 2.8% (3/105) suffered from severe hip pain. In this study group, being overweight and obese did not negatively influence the clinical outcome, since the differences in mean HHS at final follow-up were 0.1 points between obese patients (BMI over 30 kg/m²) and non-obese patients (BMI 30 kg/m² or less) and 1.6 points between patients weighing over 75 kg and patients with a body weight 75 kg or less. Statistics showed a correlation between HHS and age as the HHS was significantly lower in patients aged over 70 years at time of implantation ($p = 0.002$).

Aseptic stem loosening necessitated revision in five patients, carried out at 25, 31, 49, 51 and 100 months post-operatively. Male patients dominated in incidence ($p = 0.06$). Our evaluations showed a likely tendency for patients aged 70 years or less at the time of implantation that implants become loose aseptically in comparison to the implants of patients over 70 years of age ($p = 0.08$).

Eighty percent (4/5) of patients who needed revision had body weight greater than 75 kg, 80% (4/5) had height more than 165 cm and in 20% (1/5) a BMI over 30 kg/m² was documented.

No correlation between HHS and increased stem subsidence (over two millimetres at two years) was found ($p = 0.44$), and no correlation between migration and HHS over the whole period could be demonstrated ($p = 0.86$, ANOVA). Equivalent evaluations were performed using the Harris hip pain score revealing similar results ($p = 0.59$, $p = 0.99$, ANOVA). Statistical evaluation showed no correlation between HHS and body weight, stem size and gender ($p = 0.83$, $p = 0.13$, $p = 0.52$).

Radiological

A total of 790 standardised, plain radiographs of the hip were digitally analysed using EBRA-FCA software. Due to lack of comparability, the algorithm of EBRA-FCA excluded three out of 105 hips from the evaluation. Thus migration patterns for 102 stems could be analysed. The mean migration was measured at six and 12 months and thereafter annually up to 120 months after operation. EBRA-FCA evaluations revealed a mean subsidence of 1.38 mm after two years, 2.06 mm after five and 2.24 mm after seven years (Table 2).

Out of 102 implants, 30 cases (30%) showed a migration of more than 1 mm after the first year and 19 (19%) stems showed subsidence of more than 2 mm after two years. Statistically, high significance could be detected between subsidence over 2 mm at two years and subsequent aseptic loosening ($p = 0.04$). Correlation between increased migration over the whole period and aseptic loosening was highly significant ($p < 0.001$, ANOVA).

Evaluation of the postoperative X-rays revealed that 91% of prostheses showed a tight fit, and 9% were implanted with an improper fit with spongy bone visible around the stem and inadequate stem/cortex contact, especially in Gruen zones 2, 3, 4, 5 and 6. Statistical evaluations revealed a significantly increased subsidence in stems with a poor postoperative fit. However, the distribution of these stems with a poor postoperative fit was similar in cases with averaged and increased migration: when the femoral component subsided 1 mm or more in the first 12 months after surgery, 90% ($n = 27$) of cases showed a tight fit and in 10% ($n = 3$) a poor fit. Analysing the stems with less than 1 mm migration in the first 12 postoperative months, 90.1% ($n = 65$) showed a tight and 9.9% ($n = 7$) an improper fit.

Table 2 Mean stem subsidence

Variable	12 months	24 months	36 months	48 months	60 months	72 months	84 months	96 months	108 months	120 months
Mean migration (mm)	0.97	1.38	1.64	1.89	2.06	2.07	2.24	2.45	1.85	1.00
<i>n</i>	102	102	102	102	102	74	56	40	15	1

The mean implant migration of patients weighing over 75 kg was 1.01 mm, 1.59 mm and 2.44 mm at 12, 24 and 60 months. Migration of implants in patients weighing 75 kg or less was just 0.87 mm at 12, 1.18 mm at 24 and 1.70 mm at 60 months. Hence, high significance could be placed on the correlation between body weight and migration ($p=0.001$, ANOVA) (Table 3). Statistics showed that implants in patients with a high BMI (BMI over 30 kg/m²) migrate slightly less than stems of patients with a BMI 30 kg/m² or less, so we could not demonstrate a correlation between subsidence and BMI ($p=0.87$, ANOVA) (Table 3).

Statistical evaluations revealed that height significantly influences stem subsidence ($p<0.001$, ANOVA). Progressive stem migration was found in implants of patients with heights over 165 cm, showing subsidence of 1.22 mm, 2.47 mm and 2.67 mm at 12, 48 and 60 months compared to implants of small proportioned patients (165 cm or less) migrating 0.77 mm, 1.41 mm and 1.57 mm in the same period (Table 3).

Male gender and large stem sizes (over 14 mm) showed a significant influence on stem subsidence ($p=0.03$, $p=0.04$, ANOVA). Patients aged over 70 years tended to have an increase stem subsidence ($p=0.07$, ANOVA), and preoperative diagnosis did not show any significant influence on stem migration ($p=0.23$, ANOVA). Statistical analyses regarding migration, weight and stem size were registered, showing that large stem sizes in patients weighing over 75 kg migrate significantly more than small stem sizes in patients weighing 75 kg or less ($p\leq 0.001$, ANOVA).

Statistical evaluations revealed a significantly increased subsidence in stems with a poor postoperative fit, demonstrating that improper surgical technique triggers progressive migration ($p=0.002$).

Discussion

It is generally known that the surgeon's experience and ability to impact the prosthesis tightly into the bone affects the outcome of THA [19, 20], but the significant underlying influence of physical patient characteristics in relation to the stability of cementless stems is a new approach. Several studies indicate that body weight affects implant failure, component loosening and revision rate [11–14]; however, we could only find one study claiming that body weight has no influence on prosthetic loosening [21]. Onsten et al. demonstrated in a roentgen stereophotogrammetric study that body weight had no influence on migration of a cemented femoral component [16]. This finding cannot be applied to our results since EBRA evaluations revealed increased stem subsidence in implants of patients weighing over 75 kg ($p=0.001$) (Table 3, Fig. 1). Considering that Onsten evaluated cemented implants, the effect of body

Table 3 Patient characteristics affecting stem migration. Significant impact of body weight, body-height and male gender towards stem migration. There was no significant interaction between BMI and stem migration

Factor	Migration (mm)					<i>p</i> -value ^a
	12 months	24 months	36 months	48 months	60 months	
Body weight >75 kg	1.01	1.59	1.91	2.24	2.44	0.001 ^b
Body weight ≤75 kg	0.87	1.18	1.39	1.57	1.70	
Body height >165 cm	1.22	1.78	2.14	2.47	2.67	<0.001 ^b
Body height ≤165 cm	0.77	1.04	1.23	1.41	1.57	
BMI >30	0.93	1.34	1.59	1.83	1.98	0.87
BMI ≤30	1.07	1.45	1.74	2.02	2.19	
Male	1.14	1.69	2.0	2.3	2.46	0.03 ^b
Female	0.9	1.22	1.46	1.69	1.86	

^aRepeated measures ANOVA, interaction^bIndicates a statistical significant value ($p>0.05$)

weight on implant migration appears to be different in cementless THA.

Few studies targeting the potential of BMI towards stem loosening are currently available and conflicting results have been found. The majority of investigators suggest that a high BMI does not affect the outcome of THA [5–10]. Other, studies have indicated that a high BMI is linked with stem loosening [22] and a poor clinical outcome [23]. Moreover it has been reported that each additional BMI unit increases the risk of loosening [4]. In our study, EBRA computed evaluations showed, surprisingly, more distal stem migration in the BMI group 30 kg/m² or less than in obese patients with a BMI over 30 kg/m² and no statistically significant correlation could be found ($p=0.87$, ANOVA) (Table 3). Our results indicate that a high BMI has no influence on stem subsidence and we believe that subsequent implant failure is not related to patients' high BMI. Apart from this, body weight over 75 kg triggers

increased distal migration and the stability of cementless femoral component ($p=0.001$, ANOVA).

In our study, EBRA evaluations revealed progressive subsidence in the stems of patients of over 165 cm in height ($p<0.001$, ANOVA). On the one hand, this might be attributed to the weight difference in patients of different heights. On the other hand, we believe that the anatomical condition of tall patients with long bones and wide medullary cavities in combination with increased stress due to their weight might favour distal stem migration.

Our findings were clinically relevant because 80% of patients who needed revision had a body weight over 75 kg and 80% had a height greater than 165 cm. The average body weight of patients requiring revision surgery was 88.4 kg compared to mean 77.4 kg of the rest of the study group. The mean height of patients requiring revision surgery was 174 cm; the average height of the rest of the study group was just 165 cm.

In view of the findings of the study, we want to emphasise that the operating surgeon should be aware of the physical characteristics of each patient. The surgeon should be aware that a body weight of over 75 kg and height of more than 165 cm may trigger significant increased distal stem migration in cementless THA. The surgeon should always aim to fit these prostheses as tightly as possible. Otherwise we believe that the patient's BMI is not relevant for the operating surgeon.

The BMI is defined as an individual's body weight divided by the square of their height and obesity measurement is based on a standard which is influenced by height (Fig. 2). The BMI is inversely proportional to the square of the height, consequently any significant influence of the BMI towards stem migration is abrogated. Our results indicate that each kilogram puts stress onto the femoral component and triggers distal migration. Using the BMI formula it might be that tall patients with an appropriate weight (over 75 kg) may easily have a BMI less than 25 kg/m², which means "normal weight" per definition. However the femoral component of this specific patient would tend to migrate distally and would be more likely to become loose due to the weight. A very similar approach was taken

Fig. 1 Physical patient characteristics influencing stem migration. Progressive implant migration in patients weighing >75 kg ($p=0.001$, ANOVA) and in patients with height >165 cm ($p<0.001$, ANOVA)

Fig. 2 The body mass index (BMI). Height is inversely proportional to the BMI and abolishes its significant impact on stem migration

by Young et al. in 1998, who proposed that a male patient with a height of 193 cm weighing 75 kg is not obese, but a patient weighing 75 kg may place significant stress on the implant that could decrease the longevity [11]. Carrying this notion forward into our study, it was the fact in several cases that the BMI of patients was still 30 kg/m^2 or less although the weight was appropriate at over 75 kg. Hence distal stem migration was over-averaged due to the weight load, although the BMI was 30 kg/m^2 or less. This occurred in 20/54 cases of patients weighing over 75 kg in our study (Fig. 3).

Evaluation of the postoperative X-rays showed that 10% of stems were implanted with a poor fit, indicative of inadequate surgical technique. On the one hand, the distribution of these cases was balanced in the groups showing progressive versus averaged migration in the first 12 months after surgery (Table 2). But on the other hand it is generally known that improper surgical technique leads to a bad outcome for prostheses. This is confirmed by our evaluations, as the improper implanted stems show significantly higher odds of migration ($p=0.002$) (Table 2). We

are of the opinion that surgical technique certainly affects the migration patterns and outcome of cementless femoral components, but we have also shown that physical patient characteristics such as body weight and height significantly influence the migration and outcome. We want to emphasise the need for surgeons to be aware of this finding.

Our statistical evaluations revealed that the male gender was associated with increased stem subsidence ($p=0.03$, ANOVA) and tended to increase the risk of aseptic loosening ($p=0.06$). Significant values have recently been published, showing that men have greater propensity for stem loosening than women [4, 24]. We see the considerable weight difference in gender as one of the risk factors for the increased subsidence in male patients.

We want to note several limitations of our study. The preoperative HHS was missing in five patients. Seven patients had prostheses implanted bilaterally. One weakness is that only one implant design was used and the data therefore only applies to one form of collared proximally loaded implants and may not apply to tapered or anatomical shapes. The effect on cemented prostheses may be different. But, by using only one implant design, the homogeneity of the study is ensured. The small study group of patients participating is another limitation. Moreover, the number of implants in morbidly obese patients (BMI over 40) was very low. But compared to other EBRA studies, the reliability of the study group in our trial is considerable and we are confident of accurate results by having evaluated migration patterns of 102 femoral components. It must be said that the accuracy of the EBRA method is not the gold standard in migration analyses. Roentgen stereophotogrammetric analyses provide the highest accuracy [25] but the implantation of several tantalum marker beads as landmarks in bone tissue is necessary; something that can be avoided by using EBRA.

In conclusion, our findings indicate that body weight over 75 kg and height greater than 165 cm significantly impact on subsidence and the stability of cementless femoral components. If an improper fit of the femoral component was detected in the postoperative X-rays, the risk of progressive subsidence increased significantly. The operating surgeon should be aware that physical patient characteristics as mentioned above may trigger increased

Fig. 3 Progressive migration in the BMI <30 group. Progressive migration of stems in patients weighing >75 kg but with a BMI <30

stem migration and the surgeon should aim to fit these prostheses as tightly as possible. However, this study demonstrates that a high BMI does not trigger progressive stem migration. Further investigations will be needed to confirm our findings.

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