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Subsidence of titanium straight stems in combination with highly viscous bone cement

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Abstract Varying results and a high rate of subsidence have been reported for the straight femoral stem (M.E. Müller) made of titanium alloy. We examined subsidence in 135 titanium-alloy straight stems implanted with high viscosity cement after 68.8 ± 11.5 months using a digital high-precision method (EBRA-FCA). One revised implant showed a subsidence of 14.6 mm and another 2.5 mm over 5 years. A third implant without migration was found to be loose. The 122 implants without loosening showed a mean subsidence of 0.1 ± 0.1 mm, and focal osteolysis was seen in two. Altogether, we found subsidence of the titanium stems very small. The small subsidence may be related to the use of high viscosity bone cement.

Résumé Des résultats variables et un taux élevé d'enfoncement ont été rapportés pour la tige droite fémorale (Müller) en alliage de titane. Nous avons examiné l'enfoncement dans une série de 135 tiges droites en alliage de titane implantées avec un ciment de haute viscosité après $68,8 \pm 11,5$ mois en utilisant une méthode numérique de haute précision (EBRA-FCA). Sur un délai de 5 ans un implant révisé a montré un enfoncement de 14.6 mm et un autre de 2.5 mm. Un troisième implant sans migration a été considéré descellé. 122 implants sans descellement ont montré un enfoncement moyen de 0.1 ± 0.1 mm et une ostéolyse focale a été vue dans deux cas. Globalement nous avons trouvé très faible l'enfoncement des tiges en alliage titane. Le petit enfoncement peut être en rapport avec l'usage du ciment à haute viscosité.

Introduction

The straight stem according to M.E. Müller represents one of the most successful designs for cemented stem prostheses. In the Swedish prosthesis register, the 10-year results of the Müller straight stem prosthesis are superior to those of the Charnley prosthesis [12]. In other studies, a 15-year survival rate of 88% and a 10-year survival rate of 94% were found for the chromium–cobalt design [7, 19]. Good results were also reported in other studies with shorter follow-up examination intervals [11, 22, 25]. Generally, a high rate of subsidence of up to 50% or 56% and a rate of osteolysis up to 10% is attributed to the chromium–cobalt straight stem design [22, 25]. Other studies with chromium–cobalt stems report distal radiolucent lines without reference to osteolysis [6, 11].

In titanium stems especially, the correlation between the development of osteolysis and subsidence is not yet clear. A previous study from our institution shows a clinical and radiological rate of loosening of 3% over 6 years [20]. At the same time, an osteolysis rate of 3% and a significant subsidence of more than 4 mm was observed in only one of 202 cases using manual methods [20]. More recent digital measuring processes [3, 18] promise more precise statements about the subsidence of the stem. Thus, the aim of the present study was to measure digitally the subsidence of cemented Müller straight stem prostheses in titanium and correlate the results with the development of osteolysis.

Material and methods

Patients

The patient group was recently described [20]. In this retrospective study, 369 consecutive patients who received a Müller straight stem made of titanium between 1989 and March 1992 were included. A number of 111 patients died without implant revision, 42 patients were dependent on care, also whose implants were not revised, and 32 pa-

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tients had moved to unknown addresses. In total, 184 patients with 202 stems with complete clinical and radiological follow-up were included in this study.

The basic prerequisite for carrying out a migration analysis is the availability of at least three consecutive plain radiographs of the pelvis with sufficient image quality. These criteria were met by 135 of 202 implants: 83 women with 92 prostheses and 38 men with 43 prostheses. The mean age at operation was 72 ± 9 years; body mass index (BMI) was 27 ± 5 kg/m². Diagnoses were osteoarthritis ($n=104$), avascular necrosis of the femoral head ($n=17$), dysplasia ($n=7$), fractured femoral neck ($n=6$), and rheumatoid arthritis ($n=1$).

Operation method

All patients received Müller straight stem prostheses made of the titanium–aluminium–niobium alloy Protasul 100 (Protek, Berne, Switzerland). The stem surface was grit-blasted, resulting in a surface roughness of $R_a=1.0\text{--}2.0$ µm (manufacturers specification). In 93% of the cases, an uncemented Harris-Galante cup (Zimmer, Warsaw, IN, USA) was used; in 7% a polyethylene cup was cemented into position (Aesculap AG, Tuttlingen, Germany). All operations took place, after prior planning with sketches, in a supine position through a trans-gluteal approach. The femur was generally prepared up to the largest possible femur rasp that also corresponded to the final size of the prosthesis. A number of 114 standard stems and 21 lateralised stems were used. Stem sizes were 7.5 ($n=10$), 10.0 ($n=38$), 11.25 ($n=26$), 12.5 ($n=25$), 13.7 ($n=21$), 15.0 ($n=12$), 17.5 ($n=2$) and 20.0 ($n=1$). All stems were cemented with Refobacin-Palacos R (Biomet-Merck AG, Berlin, Germany) that had been pre-cooled to $+2^\circ\text{C}$. After placing the medullary cement plug, rinsing the medullary space with 500 ml of Ringer lactate and then drying the medullary space with swabs, the cement was mixed according to the manufacturer's specifications. The cement was applied in a retrograde fashion with a pressurised cement syringe and drainage through a polyethylene tube. The stem was inserted to the same level as the rasped depth and was left to harden under compression for 15 min. The recommended follow-up treatment was partial weight bearing of 20 kg with two elbow crutches for 6 weeks.

Follow-up examination

The mean period until the follow-up examination was 68.8 ± 11.5 months. Clinical and radiological evaluation took place according to the recommendations of the Consensus Study Group [9]. For the examination, a plain radiograph of the pelvis in a supine position and a Lauenstein projection with defined film focus distance were made.

Measurement of subsidence

The EBRA-FCA is a computer-supported method for measuring the subsidence of stem prostheses on plain radiographs of the pelvis (Department of Geometry, Institute of Mathematics and Geometry, University of Innsbruck, Austria). The measuring process has recently been described in detail [3]. The principle is based on comparing the stem contours of prostheses and bones over time by means of the so-called comparability algorithm that ensures the statistical comparability of X-ray projections.

Four reference points are required to carry out the measurements: centre of the head of the prosthesis, intersection of the shoulder and the axis of the prosthesis, intersection of two defined tangents at the lesser trochanter and intersection of the axis of the prosthesis and the tangent at the most prominent point of the greater trochanter. Plain radiographs of the pelvis were digitised on a 12-bit CCD scanner (Optotec, Hannover, Germany) and saved in the tagged image file format. To correct the measurement of the stem lengths, the manufacturer's specifications were used. After marking the reference points in a defined sequence, data were evaluated using the FCA-Graph program (Department of Geometry, Institute of Mathematics and Geometry, University of Innsbruck). Subsidence was referenced to the greater trochanter. The shoulder of the prosthesis or the centre of the head were chosen as reference points. Subsidence was read from the results diagram.

A mean of 4.3 ± 1 plain radiographs of the pelvis per patient were available for EBRA-FCA. A comparability limit between three and four was chosen for carrying out the measurement. Under these conditions EBRA-FCA is said to have an accuracy of 1.5 mm [3, 18]. Consequently, subsidence was assumed if the measurement exceeded 1.5 mm.

Results

Prosthesis outcome

A stem revision was carried out in three out of 135 implants. In two of these there was measurable subsidence, in the third case no subsidence was proven. Two other implants showed localised osteolysis without further radiological signs of loosening and no detectable subsidence. These patients were recommended for frequent clinical and

Table 1 Prosthesis outcome

Result	Number	Subsidence [mm]
No loosening, no subsidence	120	0.1 ± 0.1
No loosening, not evaluable	10	–
Loosening and subsidence	2	-2.5 and -14.6
Loosening, no subsidence	1	-0.2
Osteolysis, no subsidence	2	0.1 and 0.7
	$\Sigma 135$

Fig. 1 Migration diagram and X-rays of a patient with Müller straight stem left with primary osteoarthritis. The observation time is shown on the *abscissa*. A large graduation mark corresponds to 1 year; a small one corresponds to 1 month. The *ordinate* shows stem subsidence in millimetres: A large graduation mark corresponds to a

millimetre, a small one corresponds to half a millimetre. On the *left*, an X-ray from 1992; on the *right* from 1997. The *migration diagram* shows that for the whole observation period of 60 months, the stem implant shows a migration of 14.6 mm. The implant was revised.

radiological check-ups. Ten stems without any clinical and radiological signs of loosening or osteolysis could not be evaluated with EBRA-FCA. According to the clinical and radiological criteria, the other 120 stems showed neither signs of loosening nor signs of subsidence (Table 1).

Implants without loosening

Mean patient age was 74 ± 8 years for the 132 implants that were not revised, showed no signs of loosening and had no significant subsidence; there were 36 men and 80 women. Mean BMI was 27 ± 4 kg/m². Average period until the follow-up examination was 68.8 ± 11.5 months. The diagnosis was primary arthrosis in 115 cases, necrosis of the femoral head in seven, fractured femoral neck in six, hip dysplasia in three and rheumatoid arthritis in one. Average subsidence of all implants was 0.1 ± 0.1 mm at both 24 and 60 months (Table 1).

Loosened implants

Mean age of patients whose implants were replaced was 73.7 ± 9 years; they included two men and one woman. Average BMI was 27.2 ± 4.2 kg/m². In comparison to the group without revised implants, the mean period until follow-up examination was a little shorter—at 60 ± 7.6 months. Diagnosis in each case was osteoarthritis. After 24 months, in two cases the subsidence amounted to 2.8 and 0 mm and after 60 months 14.6 and 2.5 mm (Fig. 1).

The third implant replaced showed no subsidence after 24 (0.2 mm) and 54 months (0.2 mm) (Fig. 2). The individual stem sizes were 7.5, 10.0 and 11.25.

Focal osteolysis

The two cases with osteolysis without subsidence and without any other suspected loosening occurred in two female patients aged 70 and 67 with a BMI of 23 and 28 kg/m². The period until follow-up examination was 66 and

Fig. 2 Migration diagram and X-rays of a patient with a straight stem prosthesis with primary osteoarthritis. At the *bottom left*, an X-ray from 1992; *bottom right*, one from 1996. The *migration diagram* shows that during the observation period of 54 months, no subsidence was detected outside the measuring range of 1.5 mm despite the finding of osteolysis. Intra-operatively, stem loosening was detected.

Fig. 3 Migration diagram and X-rays of a patient with a cemented titanium Müller straight stem with primary osteoarthritis. On the left, an X-ray from 1991; on the right, one from 1996. The *migration diagram* shows that during the observation period of 72 months, no migration was found outside the measuring range of 1.5 mm despite the finding of focal osteolysis. As a result of the lack of clinical symptoms, the patient was recommended to have frequent clinical and radiological checkups.

68 months, respectively. Diagnoses were osteoarthritis in one case and fractured femoral neck in the other. Subsidence after 24 months was 0.0 and 0.7 mm and after 60 months 0.1 and 0.7 mm, respectively. Stem sizes were 11.25 and 10.00, respectively (Fig. 3).

Discussion

Various authors report great differences in results for the straight stem prostheses made of titanium–aluminium–niobium alloy. Thirty-two loosening in 239 prostheses were reported for this stem after 7.7 years [15]. In a follow-up note [23], after 10 years, an inferior survival (80.9% versus 98.2%) and a higher rate of subsidence (31% versus 16%) were found for titanium versus chromium–cobalt straight stems. In another institution for the same stem, two loosening in 126 stems were reported after 9.1 years [1]. These results are better than those of a control group with chromium–cobalt stems from the same hospital [25]. However, a 10% rate of osteolysis and a 30% rate of subsidence were also observed [1].

The development of focal osteolysis is seen as a particular problem of cemented straight stems made from titanium. The risk factors being debated are small stem size [15], body weight [8], young age, male gender and a high level of physical activity [15]. However, the cementing method seems to be the crucial element. While in the studies by Maurer et al. [15] and Schweizer et al. [23] a low-viscosity cement was used, Acklin et al. [1] and our institution used a high viscosity cement (Refobacin Palacos R). High viscosity bone cements showed more favourable results in larger analyses [5, 12]. The Capital hip [14] also showed a significantly higher rate of loosening after 26 months when CMW cement was used than with Palacos (15/36 versus 5/40). Similar outcomes have been reported for the Ultima titanium straight stem depending on the type of bone cement used: The use of low-viscosity CMW cement resulted in a 92% survival at 8 years and a high rate of early subsidence (16/114 implants >2 mm after 2 years) [16]. However, with Palacos R cement, a 97% survivorship at 7.5 years was found [4].

The straight stem according to Müller is one of the most successful cemented femoral prostheses [12, 19]. Despite predominantly good medium- and long-term results, subsidence of the chromium–cobalt stems was observed after only short follow-up examination periods and viewed as a specific characteristic of this stem design, without directly creating any suspicion of loosening [10, 11, 22].

In particular, the straight stem made of titanium alloys has shown varying results in different institutions [1, 15, 20, 23]. The cause of these differences is largely unclear as yet. Theoretically, the smoother titanium surface will result in a higher rate of subsidence [21]. The aim of the present study was to digitally measure the subsidence using a high-precision measuring process. It was intended to correlate the results with implant loosening and osteolysis development. Three hundred and sixty-nine consecutive implants served as the starting group, of which only 32 patients were lost to follow-up, leaving 337 implants for the analysis, of which 202 had complete clinical and radiological follow-up. Due to the requirement of at least three consecutive plain pelvic high-quality radiographs for the use of EBRA, only 135 prostheses were included in the study. The number with clinical and radiological loosening is considered to be low: six in 202 (3%) over 6 years [20]. In the EBRA study group consisting of 135 of 202 implants, four of those loosened implants were included.

From roentgenstereophotogrammetry (RSA) studies, it is known that a certain amount of micro-motion may be expected in cemented hip stems [2, 17]. While EBRA-FCA is regarded as having an accuracy of 1.5 mm [18], small amounts of subsidence up to 1.5 mm may be overlooked using this method. In comparison, conventional measuring methods for subsidence have an accuracy of 4–5 mm [13]. For the Müller straight stem, other authors have reported significantly higher rates of subsidence—between 30% and 56%—using manual techniques [1, 22, 25]. In a direct comparison after 10 years, the rate of subsidence of the titanium stems doubled that of the chromium–cobalt stems (31% versus 16%) [23]. Conversely we could not reproduce these high rates of migration in our group. Using manual measurement, subsidence of over 4 mm was proven in only one case. For this stem, the EBRA-FCA digital measuring

process found subsidence of 14.6 mm over 5 years. Using EBRA-FCA, another loosened stem showed a subsidence of 2.5 mm over 5 years. All other stems showed no significant subsidence outside of the measuring range of 1.5 mm.

Willert et al. [24] formulated a hypothesis concerning osteolysis development on the basis of 28 explanted titanium stems. According to this study, the initial trigger is de-bonding between the cement and the prosthesis in Gruen zone 7. Crevice corrosion takes place on the titanium surface, and acid is drawn distally via a gap pump mechanism into the bone where cortical hypertrophy or the development of osteolysis takes place. The critical gap geometry can only occur if proximal de-bonding takes place while, at the same time, the stem remains fixed distally [24]. This hypothesis would explain the osteolysis that we observed in two cases without stem subsidence.

On the whole, the mid-term results of our study show promise for titanium straight stems. The use of the highly viscous Palacos cement seems to play a decisive role. Using a second-generation cementing technique with titanium straight stems, a low rate of subsidence, loosening and osteolysis can be achieved.

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