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Results of a cemented titanium alloy straight femoral shaft prosthesis after 10 years of follow-up

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Abstract Two-hundred fifty implantations of a cemented femoral stem made of titanium alloy in 239 patients were followed for 9.7 years (range 8.7–10.3 years). Eighty-nine patients with 93 hips have died and two could not be located. Five hips have been revised, two for infection, one for aseptic loosening and two during revision of the cup. Three stems showed radiological loosening but have not been revised. The average hip score was 85. The results are encouraging and comparable to other cemented femoral stems.

Résumé 250 implantations d'une tige fémorale cimentée en alliage de titane chez 239 malades ont été suivies pendant 9.7 années (8.7–10.3 années). 89 malades avec 93 prothèses sont morts et deux sont perdus de vue. Cinq hanches ont été révisées, deux pour infection, une pour descellement aseptique et deux pour une révision de la cupule acétabulaire. Trois tiges ont présentés un descellement radiologique mais n'ont pas été reprises. Le score moyen était de 85. Les résultats sont encourageant set comparables à ceux des autres tiges fémorales cimentées.

Introduction

Early functional results have demonstrated to be excellent in different types of prostheses, whether implanted with or without cement. Excellent long-term results are known for some cemented stems [1, 4]. On the other hand, implantation without cement may have some benefits and increasing interest in uncemented hip replacement is reflected in a high number of recent publications [3, 5, 6, 22].

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Although preoperative planning is mandatory in hip replacement surgery, the decision whether cemented or uncemented implantation is appropriate in an individual case can often first be made intraoperatively [22]. A femoral stem (BiCONTACT, Aesculap, Germany) designed for cemented as well as uncemented implantation was therefore designed.

Materials and methods

The femoral shaft prosthesis is a straight stem made of titanium alloy according to ISO5832-3. It is uncoated and smooth (Fig. 1) and in this study it was implanted together with a cemented polyethylene cup using a 32-mm cobalt-chrome head.

The first consecutive series of 250 implantations are included in this study. At the time of surgery, patient mean age was 70 years (range 42–87 years). The primary diagnosis was idiopathic osteoarthritis in 66%, and in 10% of the hips, prior surgery had been performed. All patients gave informed consent.

A standard lateral transgluteal approach was used. The surgical technique is identical for both modes of implantation and was previously reported [5, 22]. Postoperatively the use of crutches for

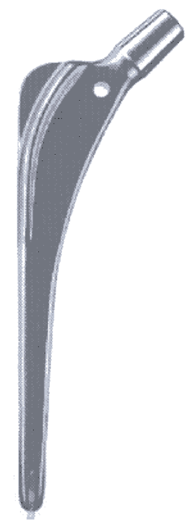

Fig. 1 The BiCONTACT femoral stem for cemented implantation

the first 3 months was encouraged. Full weight bearing was allowed. No prophylaxis against heterotopic ossifications was used.

All patients were invited for a clinical assessment and a radiological examination 9–11 years after implantation.

Clinical examination included soft tissue status, deformity and range of motion, leg length discrepancies, gait and calculation of the Harris hip score (HHS) [8].

Radiographs of the hip in two projections were taken. Subsidence was assessed by comparison of postoperative X-rays and actual films using anatomical landmarks and the medial edge of the prosthetic stem; only subsidence >2 mm was considered significant [12]. Radiolucent lines were classified in those less or more than 2 mm and allocated to the zones I–XIV [7, 9]. Osteolysis or endosteal cavitations are defined as areas of localized loss of trabecular bone or localized cortical erosion [6, 9]. Heterotopic ossifications were rated according to Brooker et al. [2].

In patients not willing to meet in our institution due to high age or distance a telephone interview with a standardized questionnaire was performed. Information whether the THR was still in situ and clinical data were gained from the patient and the family doctor. Radiographic analysis could not be performed in those patients.

A life table was constructed and the cumulative survival rate was calculated [14]. Confidence intervals were calculated according to Rothman [19]. Revision was defined as the endpoint.

Results

Two-hundred thirty-nine patients with 250 hips have been included in this study. During the follow-up period 89 patients with 93 hips died after a mean interval of 5.9 years. Two patients could not be located. In all deceased patients the prosthesis was in situ at the time of death. Follow-up data were thus obtained for 155 hips, clinical data but no radiographs were obtained for 84 patients. Average time of follow-up of the patients who were still alive and have been included in this survey was 9.7 years (range 8.7–10.3 years).

Five stems had been revised during the follow-up period. The average HHS at time of follow-up evaluation was 85 points. In 3% of the patients a leg length discrepancy of 2–3 cm and in 2% a discrepancy of 3 cm or more could be detected. Ninety-one percent of the patients were fully satisfied with the postoperative results at time of the follow-up evaluation. No patient stated not to be satisfied.

The life table analysis (Table 1) demonstrates the low annual failure rate and the calculation of an overall survival rate of 97% after 11 years. The figures for "lost to follow-up" are high in the postoperative years 9–11. This reflects the amount of patients who have had their hip replacement no longer than 9–11 years. The survival curve (Fig. 2) shows a calculated cumulative survival rate of 97% of femoral components after 11 years with confidence limits of 99.0% (upper) and 94.1% (lower).

An analysis of radiographs could be performed in 144 hips (Fig. 3). The position of the femoral shaft at time of follow up was neutral in 98%. In 81% of the radiographs no heterotopic ossifications could be found; 6% had ossifications grade III and 2% grade IV.

Radiolucent lines or osteolyses could be observed in four cases of which three stems where considered to be radiographically loose. Subsidence of the femoral stem could not be observed in any case, neither with respect to bone nor within the cement mantle.

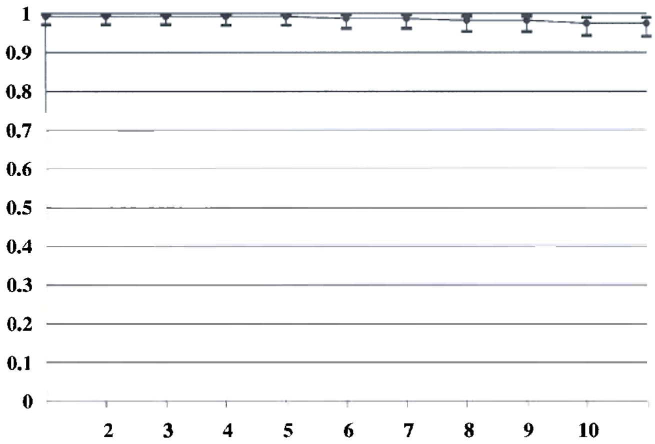

Fig. 2 Survival curve

Table 1 Life table analysis

Years since operation	Number at start	Revision[a]	Died	Lost to follow-up	Number at risk	Annual failure rate (%)	Annual success rate (%)	Survival rate (%)
	250	2	8		244.5	0.8	99.2	99.2
	239	0	3	0	237.5	0.0	100.0	99.2
	236	0	8	0	232	0.0	100.0	99.2
4	228	0	12	0	222	0.0	100.0	99.2
5	216	0	9	0	211.5	0.0	100.0	99.2
6	207	1	7	0	203	0.5	99.5	98.7
	199	0	13	1	192	0.0	100.0	98.7
8	185	1	16		176	0.5	99.5	98.2
9	167	0	10	5[b]	159.5	0.0	100.0	98.2
10	152	1	7	111[b]	92.5	0.7	99.3	97.5
11	33	0	1	33[b]	16	0.0	100.0	97.5

[a] Aseptical (n=3) and septical (n=2) revisions
[b] Patients with less than 9–11 years of follow-up, respectively

Fig. 3a–c Deforming osteoarthritis of the right hip. **a** Preoperative X-ray 1987. **b** Postoperative 1988. **c** After 10 years of follow-up 1998: no subsidence, no osteolysis, no radiolucency, intact cement mantle

Discussion

The rate of aseptic loosening after 10 years was 1.6% in our series. The overall revision rate regardless of cause was 2.0%. Published revision rates in cemented total hip replacements (THR) are within a range of 0–46% [1, 16, 17].

Cemented implantation is regarded to be the "golden standard" [11]. This study demonstrates that the cemented version of the BiCONTACT femoral stem produces excellent results, which are comparable to other cemented femoral components. The stem offers the possibility for both cemented and uncemented implantation depending on pre- and intraoperative findings, on anatomical properties and on bone quality. For the uncemented implantation of the stem good results have also been demonstrated [5].

Revision for any reason was chosen as the endpoint for the survival estimate. As not all patients could be examined, this information seemed to be the most reliable definition of the endpoint.

If deceased patients are excluded our follow-up rates were high. It has been shown that patients who have died had the same chance of failure as patients who continue to be assessed [15]. With the number of lost patients lower than the number of failures and a loss-to-follow-up quotient of 0.4% this study can be regarded as reliable [15].

Good or excellent early functional results represent the contemporary state of the art of THR. In our cohort of patients the mean age at time of follow-up evaluation was 81 years. A mean HARRIS score of 85 points can be regarded as an excellent result for this series of elderly patients.

The results of our study contrast reports with cases of early loosening and high loosening rates after cemented implantation of titanium alloy straight femoral prostheses [10, 13, 18, 21]. A mechanism of crevice corrosion has been described as a mechanism of loosening in cemented titanium stems [23]. On the other hand, excellent results have been described with cemented stems made of titanium alloy [16, 20].

Design parameters play an important role in the development of crevice corrosion and subsequent aseptical loosening. If there is any rough surface a very small amount of micromotion may be sufficient to cause destruction of the soft TiO_2 surface of the stem. Subsequent oxidation of the titanium surface leads to a decrease in local pH, leading to an acceleration of wear on the titanium surface. This may be the priming process in the development of cement destruction and consecutive loosening [23].

The structural and mechanical properties of the BiCONTACT stem with a polished surface and bilateral proximal support flanges are different from those of cemented titanium stems in which high rates of aseptical loosening have been reported. Micromotion is minimized by the broad cement-stem contact at the support flanges, and the smooth surface does not facilitate TiO_2 surface wear.

In our cases loosening, if any, occurred in the cement-bone interface, as it is usually seen in aseptic loosening of cemented prostheses. This suggests that interaction between the cement and the titanium alloy stem is not directly responsible for initiation and promotion of the loosening process and may be secondary to mechanical loosening. In all cemented cases of aseptic loosening or radiolucencies a specific cause not related to the combination of materials and not related to the individual design of the prosthesis stem could be evaluated.

However, the published basic principles of primary and secondary titanium-cement interactions [23] lead us in recent times to use CoCr-alloy for the cemented BiCONTACT stem.

The purpose of this study was to investigate the results of cemented stems, which were implanted according to our current strategy based on the intraoperative choice either to use cemented or uncemented implants after bone preparation. Destruction and removal of bone is avoided by both the uncemented and the cemented implantation technique. Promising long-term results for the cemented mode of fixation could be demonstrated. No specific mechanisms of loosening which might be associated with the combination of titanium alloy stem and cement could be found.

Statement on conflict of interest. The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article. In addition, benefits have been or will be directed to a research fund, foundation, educational institution, or other non-profit organisation with which one or more of the authors are associated.

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