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ORIGINAL ARTICLE

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Long term results with the BiCONTACT system – aspects to investigate and to learn from

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Abstract The BiCONTACT femoral stem for cementless fixation is being used without any technical modification after 15 years. The long-term results should be evaluated in this study. A consecutive series was continuously monitored in a prospective follow-up study. A survival analysis was performed, clinical results were rated according to the Harris score. There were 236 patients with 250 total hip replacements (THR); mean age at time of implantation was 58.2 years. Indications for THR included osteoarthritis (62.4%), dysplasia (16.8%), trauma (8.4%) and femoral-head necrosis (16.8%). Average time of follow-up evaluation was 8.9 years (range 7.4–10.7 years). At follow-up, 27 patients had died and two could not be located. Seven patients were revised – two for infection, one for recurrent dislocation, two for component undersizing with rapid subsidence, and one for aseptic loosening of a varus-malaligned stem; one radiologically well-fixed stem had been revised during acetabular revision. Survival estimate showed an overall survival rate of 97.1% after 11 years (confidence limits: 98.7% upper and 93.6% lower). Radiologically, tiny reactive lines (<2 mm) were present in the distal zones of the femoral shaft, but no radiolucencies could be found in the proximal anchoring zone. Migration analysis with Ein-Bild-Röntgen-analyse/femoral component analysis (EBRA/FCA) demonstrated a very small amount of migration: in 31.0%, the overall migration was between 0.5 and 1 mm after 120 months; 8.5% had an absolute amount of subsidence exceeding 2 mm after 120 months (one case more than 3 mm). Mean subsidence was 0.2 mm after 3 months and 6 months, 0.3 mm after 12 months, and reached 0.5 mm after 10 years. An initial small amount of subsidence could be detected in 45.1%, and 15.5% had a late onset of subsidence. Continuous sinking could be found in 12.7%, while 26.8% had irregular patterns of migration. Clinical results were somewhat compromised by a higher-than-average rate of cup loosening (uncoated threaded cup). The average Harris hip score at follow-up was 84.3 points. Interestingly, no femoral osteolysis could be detected, even in cases with severe acetabular osteolyses, indicating sealing of the stem interface by tight osseointegration of the proximally-coated stem.

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Introduction

After continuos use of the BiCONTACT system over 15 years – during which time no major modification to the stem was required – results of the very first series now can be regarded as "long-term results" and can be compared to the data of other long-term follow-up studies published in the literature.

The Tübingen experience

Long-term stem survival

In a prospective series, the very first 236 patients, with a total of 250 total hip replacements (THRs) were included and followed up in a year-by-year schedule. Clinical assessment included gait, range of motion, leg-length discrepancies, soft-tissue status, and the calculation of the Harris hip score. A survival analysis was performed, and a survival curve was calculated with revision as the endpoint.

During the follow-up period, 27 (11%) patients died and two could not be located. In all patients who died, the prosthesis was in situ at the time of death. Follow-up data was obtained for 221 hips. Follow-up rate was 88.4% for the entire population and 99.1% for the patients still alive at time of follow-up evaluation. Average time of follow-up was 8.9 years (range 7.4–10.7 years) (Fig. 1).

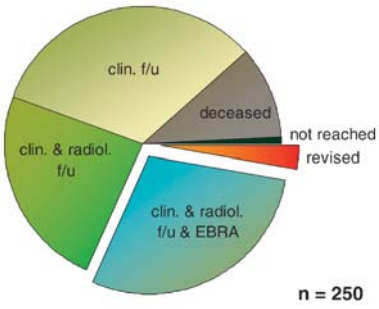

Fig. 1 Out of 250 patients included in the study, only two could not be reached; 22 patients died during the follow-up period. All other patients could be evaluated. In 72 cases, an additional analysis by Ein-Bild-Röntgen-analyse/femoral component analysis (EBRA/FCA) was done

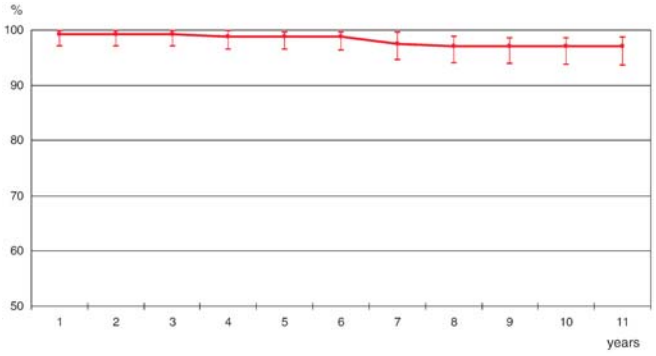

Fig. 2 The survival curve demonstrates a very low rate of revision (from any cause, including infections) and low confidence limits, indicating the power of the study

Table 1 Life table analysis. Life table (*n*=250). The high figures for "lost to follow-up" in the years 8–11 reflect the number of patients who have had their hip replacement no longer than 8–11 years

Years since operation	Number at start	Revision*	Died	Lost to follow-up	Number at risk	Annual failure rate (%)	Annual success rate (%)	Survival rate (%)
1	250	2	5	0	246.5	0.8	99.2	99.2
2	243	0	0	0	243.0	0.0	100.0	99.2
3	243	0	3	0	241.5	0.0	100.0	99.2
4	238	1	1	0	239.0	0.4	99.6	98.8
5	235	0	3	0	236.5	0.0	100.0	98.8
6	232	0	4	3	231.5	0.0	100.0	98.8
7	224	3	4	1	224.0	1.3	98.7	97.5
8	215	1	5	9 **	212.5	0.5	99.5	97.1
9	201	0	1	112 **	147.5	0.0	100.0	97.1
10	94	0	0	66 **	61	0.0	100.0	97.1
11	28	0	0	27 **	14	0.0	100.0	97.1

* Aseptic (*n*= 5) and septic (*n*=2) revisions
** Patients with less than 8–11 years of follow-up

Clinical findings

In 214 (96.8%) patients, the femoral prosthesis was unrevised. In seven patients, the stem was revised. Two patients (0.9%) had to undergo a septic revision due to a deep infection (one patient in the first year after operation, the other patient 7 years after initial surgery). In one patient, the stem was revised 1 month after implantation due to recurrent dislocations; the femoral shaft was well fixed at time of revision. In two patients, the initial stem was undersized, and rapid subsidence occurred; the stems were revised 1 and 2 years after surgery respectively. One patient underwent stem revision 6 years after implantation due to aseptic loosening of a stem that had been initially malpositioned in varus deviation. One patient underwent revision of a loose acetabular component in another hospital, and a shaft revision was combined with this procedure, although no signs of loosening were evident radiologically.

The average Harris hip score at time of follow-up was 84.3. No pain was reported by 27% of patients, 58% had slight pain, 9% had mild pain, 1% had moderate pain, and 4% had severe pain. All nine patients with a Harris pain score of 10 (of a possible 44) points underwent radiographic evaluation; two had loose acetabular components and two had recently undergone acetabular revision. Six had severe back pain. No patient experienced disabling pain (Harris pain score 0).

No leg length discrepancies could be found in 38% of patients, and 20% had a difference less than 1 cm. In 38%, a length difference of 1–2 cm was found, iIn 3% 2–3 cm, and in 1%3 cm or more.

In subjective terms, 72% of patients were fully satisfied with the postoperative results at follow-up evaluation, 25% were satisfied with some reservations, and 3% were not satisfied.

Survival estimate

The life table analysis (Table 1) demonstrates the low annual failure rate and the calculation of an overall survival rate of 97.1% after 11 years. Figures for "loss to follow-up" are high in the postoperative years 8–11. However, this figure reflects the number of patients who have had their hip replacement no longer than 8–11 years. The survival curve (Figure 2) shows a survival rate of 97.1% for femoral components after 11 years,

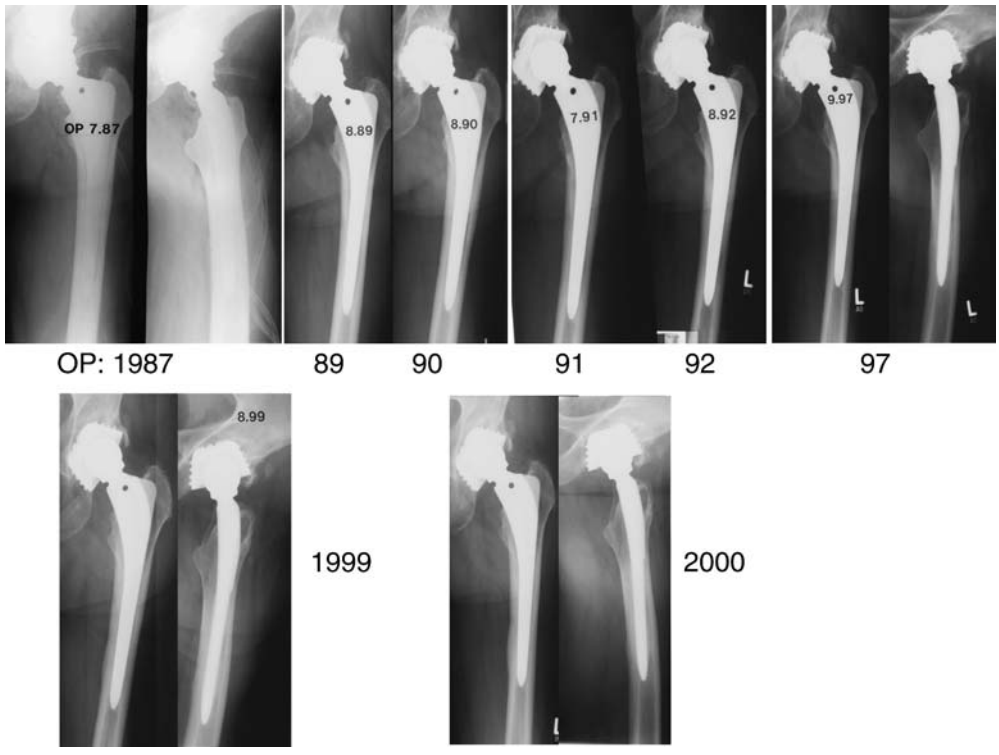

Fig. 3 Continuous follow-up of a case with a total hip replacement in 1987. Year-by-year radiographs show an unchanged position of the shaft, good quality of the bone stock without stress shielding and no radiologic signs of loosening

with confidence limits of 98.7% (upper) and 93.6% (lower).

Radiological analysis

An analysis of radiographs could be performed in 138 hips. No signs of radiographic loosening could be found in any stem (Figure 3). The position of the femoral shaft at time of follow up was neutral in 92.7%, in 5.8% a varus malpositioning could be observed, and 1.5% had a valgus position.

Radiolucent lines could be observed in the distal Gruen zones but were not found in the intertrochanteric anchoring area. No radiolucent line greater than 2 mm could be identified in any patient. Every radiolucent line was combined with a tiny (less than 2 mm) line of sclerotic bone. Osteolyses could not be found in any case. Mild rounding of the calcar could be found in most patients (79.4%). Bone hypertrophy could be observed in the distal zones (III–V, X–XII) in 12.7% of cases. Radiographic signs of mild stress shielding (second and third degree according to Engh [5]), with bone hypotrophy in the proximal femur observed in 15.1%. Severe stress shielding (fourth degree) with atrophy of the proximal femoral region could not be detected in any case. There were no radiolucent lines or other signs of loosening in these cases, and these particular patients did well without any pain.

Cup loosening and femoral osteolyses

During the first series of BiCONTACT stems, an uncoated threaded acetabular socket was used in 165 of 250 cases. All of those cups could be followed up. Radiologic loosening was defined as migration greater than 5 mm or change in inclination of more than 15°; all revised cups were also regarded as being loose.

With revision or radiologic loosening as an endpoint, the calculated survival after 14 years was 31.2% (95%, confidence interval: 21.3–43.1%). Severe ballooning acetabular osteolyses could be found in most cases. Interestingly, the interface of the stem was not affected in one single case. No femoral osteolysis could be observed in these cases (Fig. 4).

Subsidence assessment by Ein-Bild-Roentgen-Analyse (EBRA)

Early migration and continuous subsidence which otherwise could not be detected meant an increased risk for late aseptic loosening in various femoral components [7]. Unsophisticated measurements using plain radiographic films have a high error of measurement ranging from 3.9 to 12.3 mm, depending on the choice of landmarks [8]. A novel method for migration analysis of acetabular components – EBRA (single x-ray film analysis) has been developed at the University of Innsbruck, Austria [6]. A series of pelvic x-ray films is used and checked for comparability by application of an algorithm based on a system of tangents to prominent radiographic struc-

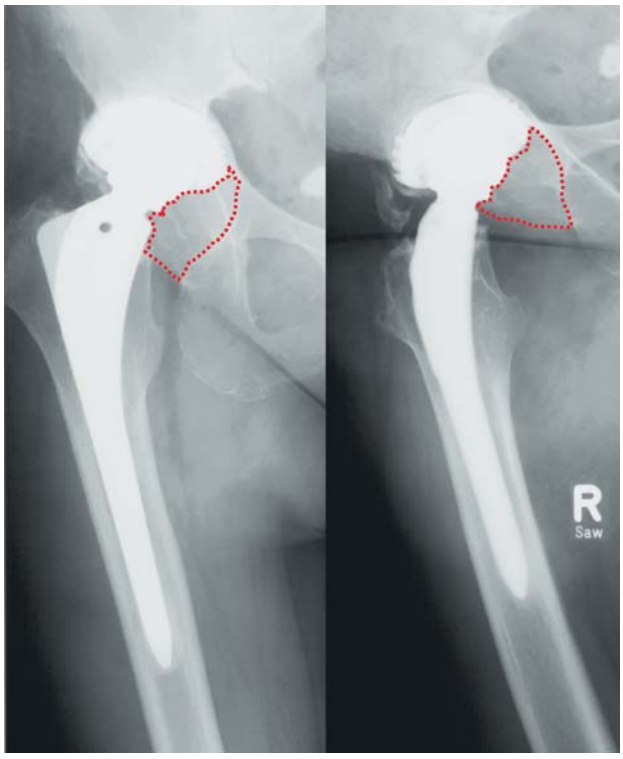

Fig. 4 Loosening of a threaded cup with severe acetabular osteolysis (*dotted lines*). There is no osteolysis in the stem interface, indicating tight bondage of the proximal shaft region and a complete sealing of the interface

tures. Implant migration is calculated in subgroups of comparable x-rays, the total migration calculated as mean of the subgroups. Recently, femoral component analysis (EBRA/FCA) has been developed and validated based on the principles of the EBRA method [1, 2]. Accuracy was estimated about 1.5 mm.

Out of our 250-patient cohort, all cases with no revision and available complete series of radiographs were included (n=93). In 22 hips (23.7%), no reliable measurement could be performed with EBRA/FCA, most commonly due to heterotopic ossifications impairing the definition of a reproducible anatomical landmark at the tip of the greater trochanter. Sixty stems (84.5%) had a subsidence below 1.5 mm at 10 years. Five stems (7.0%) showed a total migration between 1.5 and 2 mm. Six stems (8.5%) had more than 2 mm total subsidence. Initial migration in the first postoperative year without any further migration was found in 45.1%. Late onset of migration was detected in 12.7%; continuous subsidence could be seen in 12.7%. In 26.8% irregular movements forth, back and cranially, up to 2 mm was measured. The mean subsidence of all stems was 0.2 mm at 3 months with no further subsidence at 6 months. After 12 months, mean subsidence was 0.3 mm, and no significant further progress could was detected at 2 (0.4 mm), 5 (0.5 mm) and 10 years (0.5 mm) (Fig. 5). In no case was there any clinical evidence for aseptic loosening.

Three of the 250 stems with aseptic loosening did not undergo migration measurements by EBRA because

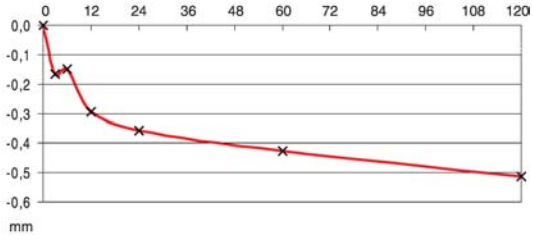

Fig. 5 Mean subsidence as assessed by Ein-Bild-Röntgen-analyse/femoral component analysis (EBRA/FCA) (n=72). Note the low rate of overall subsidence (0.5 mm) after 10 years

there were no complete series of x-rays. However, gross migration could be detected by visual analysis. In these stems, which were revised for aseptic loosening, gross migration over 5 mm occurred within 5 years. Primary malimplantation could be found for these cases (varus malpositioning (>10°) in two stems and severe undersizing in one). Malpositioning, migration and deterioration of the initial shaft position were evident without the use of sophisticated assessment procedures.

Discussion

Now, after 15 years of experience with the BiCONTACT stem, long-term results are encouraging. A competitive low rate of aseptic loosening could be found in this prospective follow-up study of 250 patients. Only two patients were lost to follow-up, resulting in a reliable calculation of the overall survival rate. In statistic terms, this can be seen in narrow 95% confidence intervals and in a low "loss-to-follow-up quotient" according to Murray. Including three cases of septic revision and one case in which stem revision had been performed due to operative-tactical reasons during cup revision, the overall revision rate is still as low as 2.9%. This can be compared to other successful stems, including the traditional cemented stems from the United Kingdom, in which very low loosening rates are claimed and which are still regarded to be the gold standard by several authors [3].

The radiological analysis of the interface demonstrates clearly that the stem is osteointegrated with its proximal part, which is coated by microporous pure titanium. This surface structure also has been shown to provide superior primary stability [9]. Distally, the stem is somewhat loose fitting, resulting in tiny reactive lines in the distal Gruen zones, which could be found in up to 40% of our cases. Stress shielding could be avoided in the majority of patients, with signs of minor stress shielding (grade II according to Engh) in 15.1%. Our data demonstrate quite clearly that the initial concept of proximal load transfer works after an observation period of more than 10 years. The important bone stock of the proximal femur can be preserved; no significant bone loss could be found.

In our first series, an uncoated threaded cup was used. The survival analysis for this specific cup shows a high rate of aseptic loosening, leading to revision in one third of

the cases. Another third showed clear signs of cup loosening. Clinical results, including the Harris hip score, were compromised by this poor socket. Inferior results have been reported with other threaded cups, and we have discontinued the use of those uncoated threaded cups [10]. A press-fit cup coated with Plasmapore (Plasmacup) is now being combined with the uncemented BiCONTACT stem.

From a scientific point of view, cup loosening with concomitant acetabular osteolyses offers an interesting aspect of the stem. The proximal osteointegration of the stem seems to provide strong bonding of the bone to the microporous titanium so that the interface is "sealed" from the osteolytic potency of polyethylene wear particles. Thus the osteolysis is restricted to the acetabulum.

Femoral migration assessment by EBRA/FCA has been established in recent years. A small amount of subsidence that could otherwise not be detected was shown to correlate to increased rates of aseptic loosening in different femoral components. In the BiCONTACT stem, only very small amounts of subsidence could be detected, well under the threshold of the association to aseptic loosening. In nearly 50% of the stems, a very small subsidence could be found within the first year, without any migration in the following years. The data suggest that mild migration represents some sort of initial borderline bone resorption within the prosthesis-bone interface, which leads to stable osteointegration in the subsequent time. This concept corresponds to the technique of insertion of the BiCONTACT stem: No removal of cancellous bone is performed and no maximum surface contact (like other concepts of press-fit anchoring postulate) between the prosthetic surface and the inner cortex is enforced at the cost of sacrificing osseous substance. Subsequent bone remodeling processes with osseous ingrowth can take place, and a very small amount of subsidence might be the noticeable effect. The occurrence of a high number of spot welds in the Gruen zones 2 and 6 during follow-up x-rays in this stem [4], which can be interpreted as direct radiographic signs of osteointegration (according to Engh et al. [5]), further supports this theory.

Conclusion

Clinical and radiological data, together with migration measurements, show a high degree of initial stability, which corresponds to very favorable long-term results. Proximal load transfer and proximal osteointegration can be achieved by this particular stem.

Further investigations are needed to confirm the long-term results after more than 15 years. Subtle assessment of the interface in loose cups with acetabular osteolyses will most probably prove that the proximal coating with microporous titanium is able to seal the interface and protect it from the osteolytic potency of polyethylene wear particles.

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