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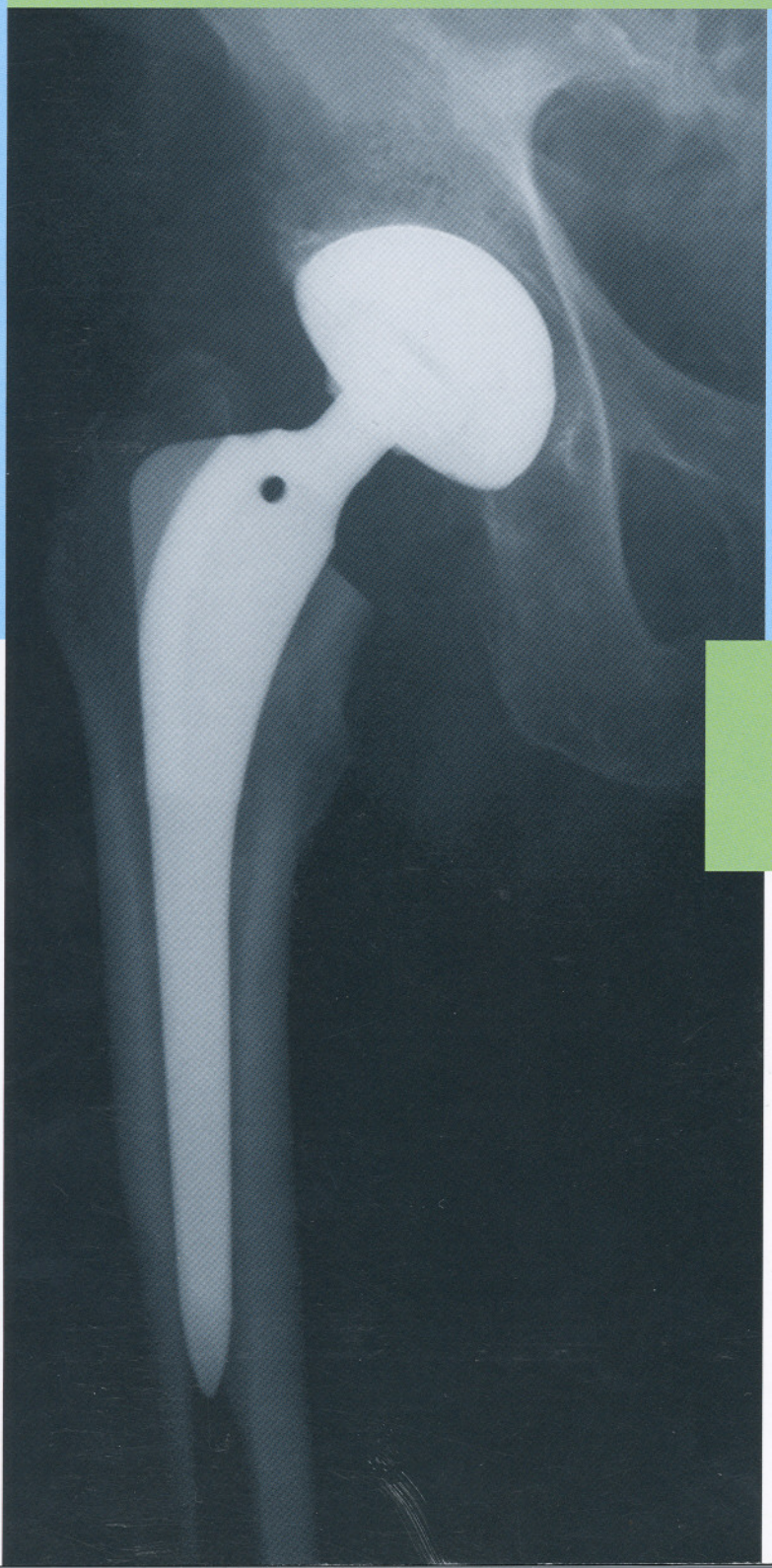

Supplement

- Hip Arthroplasty with the Bicontact System

- **20 Years of Experience 1987–2007**

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Zeitschrift für Orthopädie und Unfallchirurgie

Hip Arthroplasty with the Bicontact System

20 Years of Experience 1987 – 2007

Guest Editor:
S. Weller, Tübingen

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Verantwortlich für die Originalien:
Prof. Dr. Fritz-Uwe Niethard, Aachen
Prof. Dr. Kuno Weise, Tübingen

Kontakt Orthopädie und Unfallchirurgie aktuell
R. Engelhardt, Kamillenstraße 16, 12203 Berlin,
Tel.: 0 30/8 45 00 01, Fax: 0 30/8 18 49 69

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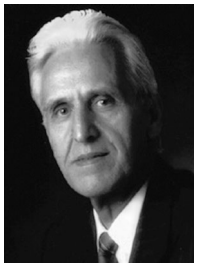
The Bicontact Hip Arthroplasty System

A Modular System for Cementless and Cemented Prosthesis Development and Experiences After 20 Years



S. Weller

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Korrespondenzadresse
Prof. Dr. med. Dr. h. c. mult. Siegfried Weller
Engelfriedshalde 47
72076 Tübingen
Phone: +49 70 71 6 26 34
Fax: +49 70 71 6 77 47
Siwetue@aol.com

Implant Development

"Constant, critical exchange of experience and opinion in the area of clinical and basic research is an essential requirement for progress!"

Numerous new constructive ideas and further developments in the area of hip arthroplasty have been communicated in recent decades, implemented and introduced into clinical practice. Looking back at the basic concepts, materials and types of prosthesis, they have led to fundamental and visible improvements.
Cement fixation of the prosthetic parts, initiated by *Charnley* in 1959/60, had a fundamental overall influence on joint replacement and promoted its clinical use with additional introduction of the "low friction principle" in joint replacement.
A *second era of joint replacement*, so to speak, was instituted in recent decades with the "cementless biological implantation technique". Many very unpleasant experiences with sometimes difficult situations after cemented hip replacements with extensive bone defects and abnormal perfusion, favour cementless implantation, whenever possible, especially in younger patients who have a longer life expectancy.

Even if the basic problem of permanent prosthetic fixation – i.e., a long-term connection between a "living tissue and a dead material" – has not yet been solved in principle: it will continue to be necessary to choose between and decide on cemented and cementless implantation, as far as possible intraoperatively, depending on the individual situation, particularly the patient's age and life expectancy, the quality and bearing capacity of the bone.

Biology and Bone Preservation

In view of the worldwide increase in newly implanted joint replacements and growing problems with revision operations, in future all our efforts will have to concentrate on improving the initial situation with less primary bone loss and also the long-term results in case implant revision becomes necessary later on. The causes of implant loosening on the *mechanical side* are implantation technique, a change in loading and wear, and on the *biological side*, bone remodeling and atrophy, influenced by disorders of physiological bone metabolism – osteoporosis, bone necrosis, immunological, and allergic reactions.

Bone is a living tissue that reacts to changing loads with constant adaptation and is not a plinth made of dead unalterable material into which an implant can be inserted and fixed permanently.

The biological environment with the demand for long-term preservation of bone metabolism that is disturbed as little as possible is best met by cementless fixation with growth of bone onto the implant – "osseointegration".
Thus biological causes play a particularly important part long-term – "*stability alone does not assure a good long-term result*". As in other areas of implant surgery, "biology" in the broadest sense has been too little regarded in joint replacement. Every primary implantation must consider the possibility of later revision and, therefore, aim to "*preserve as much bone as possible!*" No bone should be sacrificed unnecessarily as this is greatly needed in the long term, especially in the event of revision. In elderly patients with already marked osteoporosis, reduced bone strength and shorter life expectancy, however, these techniques are usually less help- and useful. In these cases, bone cement can act as a stabiliser during fixation. Immediate loading is particularly important, while long-term stability tends to be of secondary importance.
The answer to the question "*with or without cement?*" will have to continue to be: "*Both, cemented and uncemented, adapted to the individual situation*". In general, the decision on whether to use cement should always consider the hip arthroplasty that is optimal for the individual patient.

Bicontact System Experience

With the development and introduction of the Bicontact hip arthroplasty system 20 years ago, the intention was not just to add another model to the numerous developments of the most varied prosthesis types of the early years. Since its introduction, the overall modular system of the Bicontact hip arthroplasty and its philosophy

have taken into account the demands of a prosthetic system that are summarized below after many years of experiences and have borne them in mind, particularly from the clinical aspect.

Our demands for a hip replacement system 1985/86:
- Can be used universally (cemented/cementless – primary operation, revision, etc.).
- Simple and easily comprehensive instruments (for all surgical techniques).
- Substance- i.e., bone-preserving operation techniques (biological implantation technique).
- Optimal prosthesis design with high primary stability (especially rotational stability with cementless technique).
- Improvement of bearing materials with low wear (polyethylene, metal, ceramic, etc.).
- Improvement of long-term results (survival, prospective studies).
- Economically justifiable use (costs).

After 20 years of experience with these demands, the results of prospective control statistics with the Bicontact system – *without altering the basic concept and implant design* – confirm the intellectual approach from the earlier experiences and the considerations listed above.

This special supplement edition of the *"Zeitschrift für Orthopädie und Unfallchirurgie" ("Journal of Orthopaedics and Trauma Surgery")* on the occasion of the 20th anniversary of the introduction of the Bicontact hip arthroplasty system reports on various aspects and experiences of Bicontact users for many years and their collaboration. In the midst of the individual publications is our own recent study on "Prospective long-term follow-up of the cementless Bicontact hip stem with Plasmapore coating". Individual articles deal with the description of the basic concept, the biomechanical considerations and demands, the design, material and technical features in special indications, the operative technique together with after-care and follow-up. The problems of revision operations are addressed and the results of expanded solution possibilities with the Bicontact revision system are reported.

Patient Counselling

Critical considerations and communications on the question of the physical loading of the arthroplasty patient emphasise the necessity and prognostic importance of detailed pre- and post-operative instruction and counselling of the patient.

"The patient must deal with his artificial joint intelligently" (Küsswetter) in other words: "*He must learn to live with his joint replacement.*"

This demand is still far too little regarded as the indications for early joint replacement are being increasingly extended, especially in younger patients.

Acknowledgements

Particular thanks go to the authors of the individual articles and their colleagues, who with the reports of their experiences have helped to provide an up-to-date picture of our current knowledge of hip arthroplasty and especially of the use of the Bicontact hip arthroplasty system. The editors of the "Zeitschrift für Orthopädie und Unfallchirurgie" (Journal of Orthopaedics and Trauma Surgery), members of the editorial board and not at least the publishers have provided every assistance and support for this special edition.

Prospective Long-Term Follow-Up of the Cementless Bicontact Hip Stem with Plasmapore Coating

Authors U. Ochs[1], C. Eingartner[2], R. Volkmann[3], B. G. Ochs[1], C. Huber[1], S. Weller[1], K. Weise[1]

Affiliations
[1] BG Trauma Centre, University of Tuebingen, Germany
[2] Unit for Trauma and Reconstructive Surgery, Caritas Hospital, Bad Mergentheim, Germany
[3] Department for Trauma and Reconstructive Surgery, Clinical Center, Bad Hersfeld, Germany

Key words
- total hip arthroplasty
- cementless
- proximal fixation
- long-term results

Abstract

Aim: A prospective long-term study of the first 250 cementless Bicontact stems implanted in the BG Trauma Centre, Tuebingen, Germany.

Method: All of the patients in this series (treatment period June 1987 to April 1990) who were still contactable were invited for clinical and radiological follow-up. The radiographs were analysed for signs of loosening in the form of Gruen lysis zones, stress shielding, subsidence behaviour, heterotopic ossification and spot welds.

Results: The average follow-up period was 17.8 (16.7 – 19.5) years. The overall rate of follow-up was 65% (162 of 250) and 91% of patients who were still alive (162 of 179). The average patient age was 56.2 years at the time of operation and 74.0 years at follow-up. The average HHS was 81.6 points. In the course of the first 10 years (up to 03/1998), a total of 8 stem revisions had to be performed. In the period from 03/1998 to 01/2007, 2 cases of loosening requiring revision occurred in the patients still alive at the time of follow-up. The survival rate calculated was thus 95.6%.

Conclusion: These outstanding results provide enduring support for the philosophy of the cementless and bone-preserving fixation principles underlying the Bicontact hip stem with proximal intertrochanteric transmission of forces and high primary rotational stability.

Introduction

Permanent implant fixation after replacement of large joints continues to be an unsolved problem. Cemented prostheses are still regarded as the gold standard against which newer arthroplasty concepts must be measured [26,42].

The cementless Bicontact stem (B.Braun-Aesculap, Tuttlingen, Germany) has been used in the BG Trauma Centre in Tuebingen since 6/87 and a total of 4971 of these stems have been implanted up to 31.12.2006.

If a prosthetic stem design that has been unaltered since June 1987 and that is regarded as a criterion, then there are only a few arthroplasty systems that include an implant that has remained unchanged for at least over 15 years and gives comparably good results [38 – 40,43,45].

Total hip arthroplasty is currently undergoing rapid development with new implants constantly coming on the market and altered implantation techniques. Examples that can be mentioned are shorter hip stems or resurfacing prostheses. Minimally invasive implantation techniques with and without computer-assisted surgery supplement the developments in this field. Evaluation of these new techniques and implants, used in younger patients, can only take place in comparison with tried and tested cementless systems, which also provide correspondingly good long-term results [2,3,28,32,33].

Material and Method

Patients

The first 250 consecutive cementless Bicontact stems (**Fig. 1**) implanted in the BG Trauma Centre Tuebingen from June 1987 to March 1990 were included in a prospective study. Fiftyone percent of the operated patients were female and the right side was involved in 52% of cases. The average age of the patients at the time of the operation was 56.2 (22.3 – 84.3) years (**Fig. 2**). The main indication for total hip arthroplasty was idiopathic osteoarthritis in 66% and an unstable medial femoral neck fracture in 12%. The other indications in order of frequency were dys-

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Correspondence
Dr. Uwe Ochs, MD
Berufsgenossenschaftliche Unfallklinik
Schnarrenbergstr. 95
72076 Tuebingen
Germany
Phone: + 49 70 71 60 61 167
Fax: + 49 70 71 60 61 002
uochs@bgu-tuebingen.de

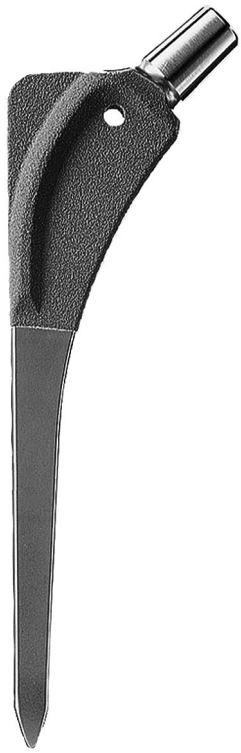

Fig. 1 Cementless Bicontact straight hip stem with proximal microporous titanium Plasmapore surface (B.Braun-Aesculap, Tuttlingen, Germany).

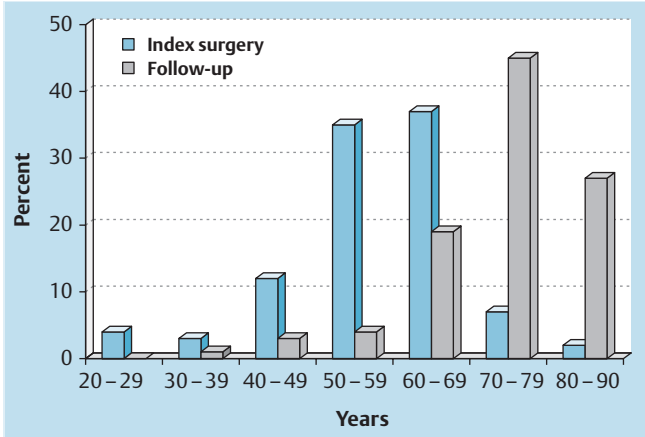

Fig. 2 Age distribution of the patients at the time of index surgery and at the time of follow-up in %.

plastic osteoarthritis, femoral head necrosis, posttraumatic osteoarthritis, and chronic polyarthritis. In 31 cases (12.4%), there had been previous surgery on the affected hip or thigh. These operations were mainly internal fixation and osteotomies.

Follow-up

The patients in this prospective study at the BG Trauma Centre Tuebingen had clinical and radiological follow-up at regular intervals, most recently between October 2006 and January 2007. Using a detailed examination and questioning, the Harris Hip Score [23] and the functional outcome as perceived by the patient subjectively using the Hannover function questionnaire were recorded (FFbH-OA) [31].

Radiological examination was performed with a.p. X-ray of the pelvis and X-ray of the affected hip and upper thigh in 2 planes. These radiographs were analysed with regard to stem position, signs of loosening in the form of Gruen lysis zones, stress shielding, subsidence, heterotopic ossification and spot welds. Radiologically visible zones of lysis were classified into larger or smaller than 2 mm and then into Gruen zones I to XIV [22].

Stress shielding was classified into grades 0 to IV according to the article by Engh [17]. Bony integration of the prosthetic stem in the sense of newly formed endostal bone with complete or partial bridging of the intramedullary canal was documented as spot welds or as pedestal formation at the tip of the prosthesis [19]. Any heterotopic ossification was classified into 4 groups after Brooker [7]. A stem was defined as loose if radiolucent lines wider than 2 mm occurred in the region of the proximal fixation zones of the implant or if the follow-up radiographs showed a change in implant position in the form of subsidence by more than 5 mm or varus/valgus tilting of more than 5 degrees [19, 20].

Statistical analysis

The statistical analysis was based on the articles by Murray and Dobbs [11,35] for constructing a survival table and used Rothmann's equation to calculate the cumulative survival rate [37]. Stem exchange or removal was defined as end point.

Results

At the time of follow-up, 71 patients had died and 7 patients had moved away or were abroad permanently and so could not be contacted for follow-up. Ten patients were confined to bed and required nursing care because of marked cerebral insufficiency so that no evaluable record of the functional outcome as perceived subjectively by the patient with the Hannover function questionnaire (FFbH-OA) was possible. However, in these 10 patients, the Bicontact stem was in situ unchanged and was subjectively painfree. Forty-four patients could be examined clinically and could complete the questionnaire but were unable to travel to the hospital for radiological examination.

The follow-up rate for the entire group was thus 67.0% (162 of 250), and 91% with reference to patients who were still alive. At the most recent follow-up, the average age of the patients was 74.0 (39.9 – 88.6) years (**Fig. 2**) and the average BMI (body mass index) was 26.5 (16.7 – 40.4). The average follow-up period was 17.8 (16.7 – 19.5) years.

At the time of the most recent follow-up, 10 of the 250 stems had been revised so the calculated survival rate according to Murray was 95.6% [34]. In the course of the first 10 years (up to 03/1998), 8 stem revisions had to be performed. In the period from 03/1998 to 01/2007, symptomatic aseptic loosening occurred in 2 of the patients still alive at the time of follow-up and the stem had to be exchanged after 13 and 16 years respectively. Questioning the relatives of all 71 patients who had died during the follow-up period revealed that stem revision had not been performed in any of these patients before their death.

In 2 patients (0.9%), septic revision was performed because of deep infection, once in the first postoperative year and once 7 years after the primary implantation. In one patient, early stem revision was necessary 1 month after the implantation because of recurrent hip dislocation. In 2 cases, the stem was too small with rapid subsidence and the need for revision 1 and 2 years re-

Table 1 Survival table with annual failure rate and calculated survival rate of the femoral component

Postop. year	Number	Revision	Deceased	No. at risk	Annual failure rate (%)	Annual success rate (%)	Survival rate (%)
1	250	2	5	246.5	0.8	99.2	0.992
2	243	0	0	243	0.0	100.0	0.992
3	243	0	3	241.5	0.0	100.0	0.992
4	240	1	1	239	0.4	99.6	0.988
5	238	0	3	236.5	0.0	100.0	0.988
6	235	0	4	233	0.0	100.0	0.988
7	231	3	4	227.5	1.3	98.7	0.975
8	224	1	5	221	0.4	99.6	0.971
9	218	0	6	215	0.0	100.0	0.971
10	212	0	5	209.5	0.0	100.0	0.971
11	207	1	4	204.5	0.5	99.5	0.966
12	202	0	6	199	0.0	100.0	0.966
13	196	1	3	194	0.5	99.5	0.961
14	192	0	6	189	0.0	100.0	0.961
15	186	0	2	185	0.0	100.0	0.961
16	184	1	3	182	0.5	99.5	0.956
17	132	0	5	129.5	0.0	100.0	0.956
18	52	0	4	50	0.0	100.0	0.956
19	10	0	0	10	0.0	100.0	0.956

spectively postoperatively. In one patient, aseptic prosthetic loosening of a stem that was initially inserted in varus deviation occurred 6 years after the first operation. Two patients had stem revision elsewhere because of loosening.

The median Harris Hip Score at the time of follow-up was 81.6 points, which corresponds to "good". 67.1% of the patients reported no pain, 11.9% had slight, and 4.2% had mild pain, 10.5% had moderate pain, 6.3% had severe pain, and 0% had extreme or rest pain.

The reasons for the moderate or severe pain reported by the patients were marked degenerative spinal disease with spinal canal stenosis in 3 cases, and pain due to knee osteoarthritis predominated in 7 cases. Acetabular loosening was found in 5 patients and cup revision was recommended to these patients. Two patients had pain after suffering a stroke with residual hemiparesis and corresponding gait disorder on the affected side. In another case, rheumatic fibromyalgia was the cause of the pain. Another patient with severe pain already had severe pain symptoms prior to the hip arthroplasty as a result of extensive soft tissue trauma in the hip region with injury of the femoral nerve. In none of these cases was the femoral component of the joint replacement loosened.

The Hannover function questionnaire showed an average functional capacity of 70.7 points, which corresponds to an assessment of "good". The functional capacity was normal in 42.7% of the patients, satisfactory in 29.3% and limited in 28.0% of the patients.

The comorbidities mentioned above lead to a marked worsening of the Harris Hip Score and particularly of the Hannover function scores, as all of the restrictions caused by these comorbidities influence the calculation.

Table 1 shows the low annual revision rate. The survival curve (**Fig. 3**) illustrates the cumulative overall survival rate of 95.6% after 19 years with a confidence interval of 0.911 (lower) to 0.979 (upper limit).

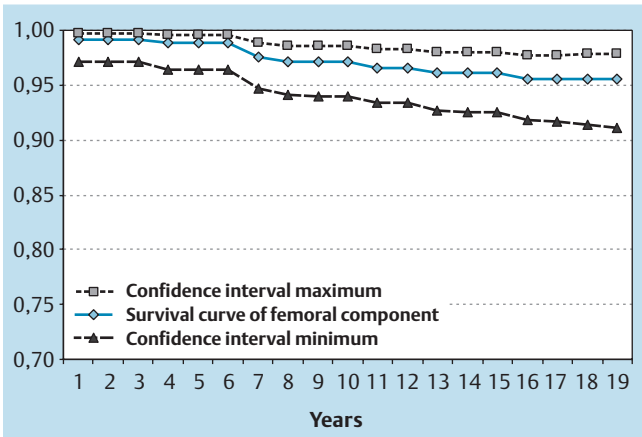

Fig. 3 Survival curve of the femoral component (n = 250), with confidence interval.

Radiologic follow-up results

Up-to-date radiological analysis of 118 hip joints was possible. Loosening of the *in situ* Bicontact stem was not found in any patient. 93.6% of the stems were in a neutral position, 4.8% were in varus position, and 1.6% had a valgus position. In 12.8% of the cases, slight subsidence was observed compared with the baseline radiographs and the average subsidence was 1.8 mm. In three stems, the subsidence was more than 3 mm (4 mm in one patient and 5 mm in two patients). However, in all cases this occurred within the first postoperative year and then halted. Progressive subsidence or other signs of loosening was no longer found during further follow-up. Reactive lines were discerned mainly in the distal Gruen zones and a reactive line was found in the intertrochanteric fixation zone in only one case. A reactive line greater than 2 mm in width was not identified in any patient. There was no case of osteolysis. Mild rounding of the calcar was observed in many cases (68.9%). Local bone hypertrophy in the distal zones (III – V, X – XII) was found in 17.2% of the cases.

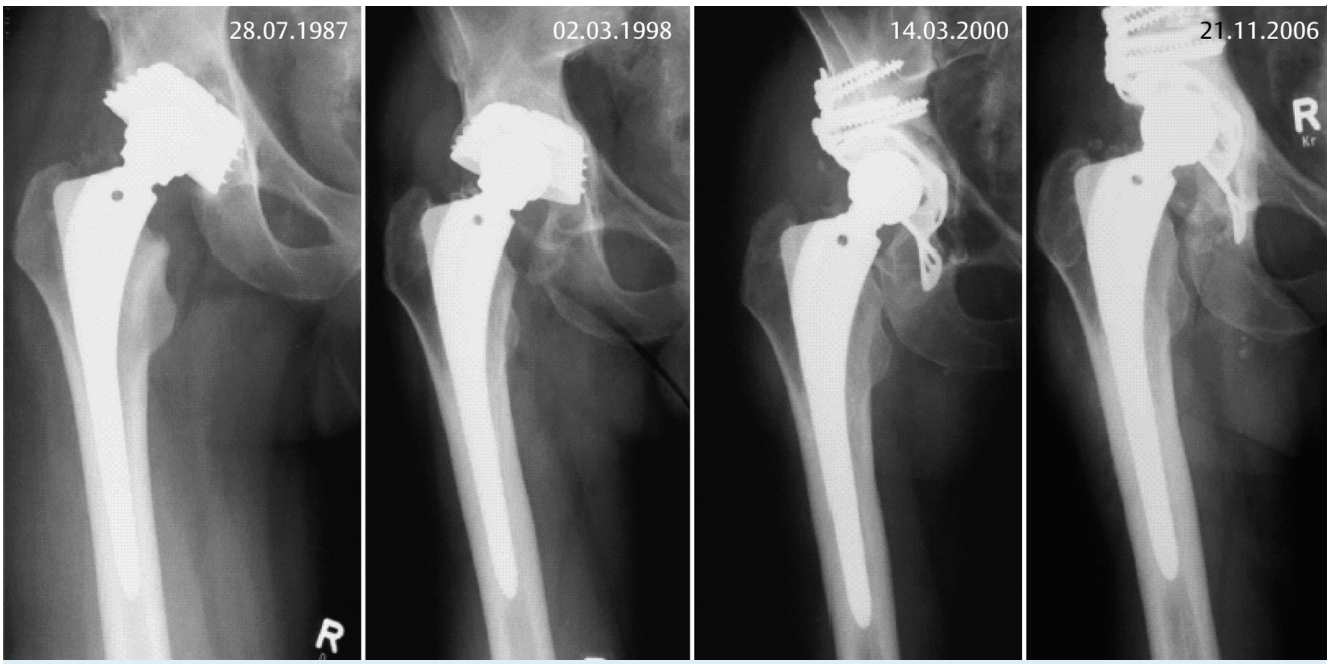

Fig. 4 Case example: Male patient, born 09.03.1956, index THA surgery right hip 23.07.1987. Follow-up 02.03.1998. Revision of aseptic loosened cup 08.03.2000 with autologous cancellous bone graft from the ipsilateral pelvis side and acetabular reconstruction ring. Harris Hip Score with 92 points at last follow-up 21.11.2006.

Radiological signs of slight stress shielding (ENGH grade II) were apparent in 17.9% and moderate signs (ENGH grade III) in 2.8%. Marked stress shielding (ENGH grade IV) with atrophy of the proximal femoral fixation zone was not found in any patient. Radiologically detectable heterotopic ossification was classified according to Brooker [7]. No ossification was found in 34.0% of the patients. Ossification grade I was found in 32.1% of cases, grade II in 22.6%, grade III in 9.4%, and grade IV in 1.9%.

In 84.0% of the stems followed-up radiologically, spot welds in the form of newly formed endostal bone were found with complete or partial bridging of the intramedullary canal, indicating good bony integration of the prosthetic stem (case example **Fig. 4**).

Discussion

In the average follow-up period of 17.8 years, only 10 of this series of 250 cementless stems had to be revised. Revision was performed in 2 cases because of infection and in 3 cases because the stem was in a varus position or because the selected stem was too small. The other 5 cases were due to aseptic loosening for other reasons.

After an average of 17.8 years, 162 of the 250 stems were unrevised, which corresponds to a calculated survival rate of 95.6% [35].

For calculating this survival rate, revision was chosen as end point since complete radiological assessment of all of the patients was not possible. Calculation of the survival rate on the basis of complete radiological follow-up might yield a slightly different result.

Signs of loosening were not identified in any of the stems that were followed up radiologically recently. For this study, anatomical landmarks on the pelvic X-ray were used to determine subsidence behaviour.

A high clinical follow-up rate was the basis for calculation of the survival rate. Only 7 of 236 patients were no longer contactable after a follow-up period of 16.7 to 19.5 years. Patients who are lost to follow-up appear to have a poorer outcome than patients who are followed-up regularly [34]. On the other hand, the result in the patients who had died at the time of follow-up should be comparable to that of the surviving population. With a loss-to-follow-up rate of 0.375 according to Murray [34], which indicates that the number of lost patients is only about 1/3 of the patients with loosening, calculation of the survival rate in the present study can be regarded as very reliable. With regard to the survival rate, the results of this study are comparable with the good results obtained with cemented hip stems, which are often still regarded as the "gold standard" in hip arthroplasty [1, 8, 12].

Our results show that both the functional results and the long-term stability are at least equal when a cemented fixation technique is not employed. Various survival rates were published for uncemented stems, though not all of the published studies have adequately high follow-up rates. It must not be forgotten either that many of these prosthetic stems underwent corresponding design adaptations in the course of follow-up.

Proximal stress shielding with hypertrophy of the bone in the proximal fixation zone is regarded as detrimental to the long-term stability of femoral hip replacement components although an association between increased rates of aseptic loosening and proximal stress shielding has not so far been found in any study. This stress shielding depends on various factors, such as the extent of proximal coating of the stem, differences in the modulus of elasticity between the stem and femoral bone along with the rigidity of fixation in the diaphyseal part of the stem. In the cementless stems of the second generation, coating of the pros-

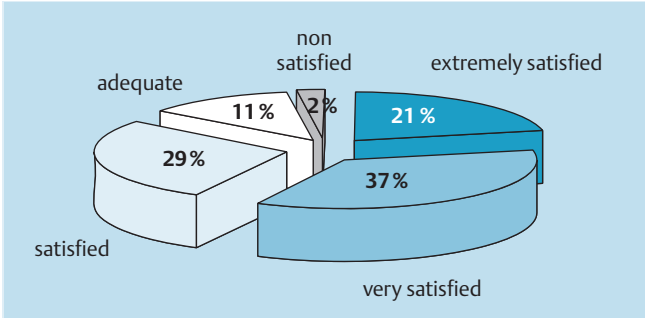

Fig. 5 Subjective satisfaction of the patients with hip joint replacement at follow-up.

thetic stem was therefore limited by many manufacturers to the proximal part [17].

Rounding of the femoral calcar was found relatively often in our series. Narrow reactive lines of less than 2 mm, combined with narrow lines of sclerosis, were observed predominantly in the distal Gruen zones. This shows that there is a minimal degree of movement between the distal uncoated parts of the stem and the inner cortex of the femur [9,30]. The majority of the force transmitted to the prosthetic stem is transmitted through the proximal microporous coated part to the intertrochanteric region [6,10]. The smooth distal part of the prosthesis remains free within the intramedullary canal and does not contribute to transmission of force [19]. In this way, proximal stress shielding can be avoided. In addition, the difference in the modulus of elasticity between the prosthetic stem and femoral shaft contributes to the development of the reactive lines [24,29]. Because of these considerations, reactive lines in non-coated distal parts of the stem cannot be regarded as signs of radiological loosening [18,20]. All of these results together support the validity of the biomechanical concept of intertrochanteric load transmission, proximal press-fit and proximal osseointegration [4].

During the recruitment phase of the study, different acetabular components were combined with cementless stems, both cementless threaded cups and cemented polyethylene cups and reinforcement rings. Unlike the outstanding results of the stem, there was an increased rate of loosening and revision with the acetabular component. The functional results are therefore markedly worsened by pain and restriction of gait when there is acetabular loosening and migration. There have now been several publications on the poor medium- and long-term results of uncoated threaded cups [41,44]. On the basis of our own experiences and reports in the literature, the uncemented threaded cup is no longer used in our hospital.

Overall, the good results with the cementless Bicontact stem demonstrate that the concept of proximal load transmission leads not only to a low rate of loosening but also actually leads to preservation of the bone in the proximal femur. This is shown clearly by the subjective assessment of the operation result by the patients: when surveyed, only 2% stated that they were dissatisfied with the result, which in these cases was attributable especially to the cup revision operations that had taken place (**Fig. 5**).

Potential disadvantages of bone cement such as cement aging, biological reactions to cement degradation products and difficulties in later revision operations are avoided through cementless implantation [27]. In our experience, the bone preserving implantation of the cementless Bicontact stem in patients under the age of 75 years is, therefore, the hip replacement method of choice.

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Bicontact Plasmacup THA in Patients with Staged Bilateral Hip Replacement

Authors A. Braun, M. Acker

Affiliation Vulpius Clinic, Bad Rappenau, Germany

Key words
- hip replacement
- staged bilateral
- cementless
- mid-term results

Abstract

Aim: In a retrospective study, all patients with bilateral cementless Bicontact-Plasmacup total hip arthroplasty in the period May 1993 to June 2000 were followed up clinically and radiologically.

Method: Out of 537 hip replacements performed in this period with this combination of implants, 46 patients had bilateral surgery. At follow-up, the Harris Hip Score, the radiological changes between primary implantation and most recent follow-up and the radiologically visible wear of the polyethylene cup component were studied.

Results: Thirty-seven patients were followed up. One patient had died and 8 patients could not be contacted. The average age at the first hip replacement was 57.8 years and it was 59.1 years at the second operation. The follow-up period was 6.5 years (min 4.8 and max 9.8 years). The average Harris Hip Score at the time of follow-up was 91 points. Up to the time of follow-up, no stem or cup implant had to be revised. There were no radiological signs of stem loosening. In the case of the cup components, increased linear wear values of more than 0.15 mm/year were found in 4 THAs that used a 28-mm ceramic-polyethylene bearing. In two of these cases, the cup was in a markedly steep position. One of these cup components was assessed as loosened.

Conclusion: The results of this study have confirmed the biomechanical concept of the implant system employed. In contrast to the stem design, the cup design and slide bearing options have been supplemented in the meantime. The ceramic bearing was only available from 1997 and was used less often in this group of patients than would be indicated today for patients of the same age and degree of activity.

Introduction

There are few descriptions in the literature of the results of bilateral cementless hip replacement. Most studies consider the procedure under the aspect of possible early complications or the treatment limits of one-stage compared to two-stage implantation [1,2].

In two-stage arthroplasty, following the successful first implantation and medical indication, the diseased opposite side is treated. The proportion of bilateral disease of the hip joints with successive implantation of a hip replacement is about 10% of the patients in our clinic. The period between the two operations depends on the underlying disease and the individual suffering. Nevertheless, the decision on whether bilateral hip arthroplasty is indicated must be made carefully as the patients are often younger [3].

Since 1987 we have treated our patients with the cementless Bicontact stem (B.Braun-Aesculap, Tuttlingen, Germany). The initial use of threaded rings [4] was succeeded after 1993 by implantation of the Plasmacup press-fit cup system [5].

Method

In a written survey of all patients treated with the Plasmacup between May 1993 and May 2000, we identified the patients who had bilateral cementless Plasmacup-Bicontact arthroplasty in this period. These amounted to 46 patients. This number represented 8% of the patients treated with this implant combination in this period. On this basis, a retrospective follow-up study was conducted. Apart from radiological follow-up, the Harris Hip Score and the polyethylene wear of the cup component were determined.

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Correspondence
Prof. Dr. Arnim Braun, MD, PhD
Vulpius Klinik GmbH
Vulpiusstraße 29
74906 Bad Rappenau
Germany
Phone: +49 72 64 60 140
Fax: +49 72 64 60 267
prof.braun@vulpiusklinik.de

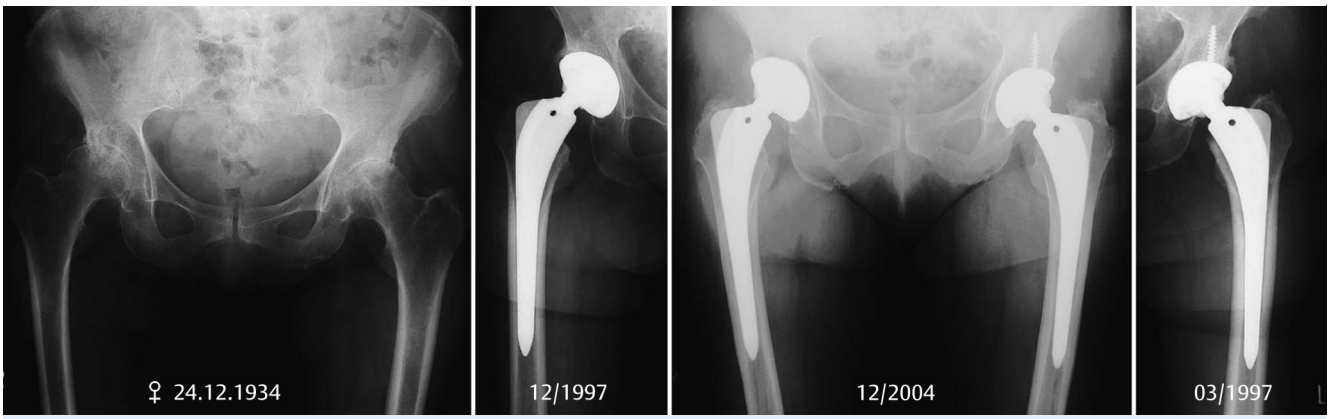

Fig. 1 Case example 1: Bilateral cementless arthroplasty with the Bicontact standard stem and a Plasmacup S (left) and the later Plasmacup SC model (right).

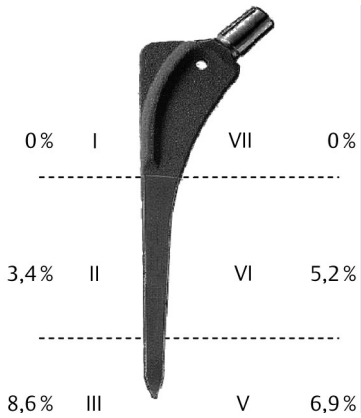

Fig. 2 Proportion of radiological lucent lines in ap Gruen zones I to VII. No radiolucent lines proximally, reactive lines in the distal part of the stem.

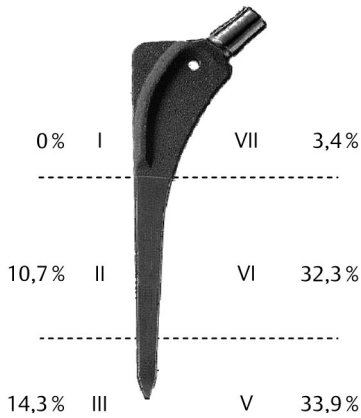

Fig. 3 Proportion of proximal atrophy and distal hypertrophy in ap Gruen zones I to VII. No atrophy proximally and laterally, higher proportion of hypertrophy distally and medially.

Results

Twenty-eight patients were followed up clinically and radiologically; one patient had died. Eight patients could not be contacted. A questionnaire was available for 9 patients. Thus, 82% of the patients were reached retrospectively. The proportion of women was 68%. Fourty-nine percent of the hip replacements were because of primary osteoarthritis, 29% because of secondary dysplastic osteoarthritis, 9% after femoral head necrosis, and 1% because of other joint disease. The average age at the first operation was 57.8 years and the average age at the second operation was 59.1 years. The joints were followed up after an average of 6.5 years (min 4.8 and max 9.8 years). The average patient age at follow-up was 65.7 years

The implant components used in these patients were 80 Bicontact Standard and 12 Bicontact SD stems, 23 Plasmacup S and 69 Plasmacup SC cups (case example 1, **Fig. 1**). 84% of the cups were implanted with a polyethylene insert and 16% with a ceramic insert, which was available from the middle of 1997. Apart from two metal CoCr-XL heads, ceramic prosthetic heads with a diameter of 28 mm were used in all cases. This resulted in the standard ceramic-polyethylene slide bearing in 79% of cases and ceramic-ceramic in 16%. Only two patients had a ceramic-ceramic bearing on both sides.

At the time of follow-up, the average Harris Hip Score (HHS) was 91 points (min 33 and max 100). 97.3% of the patients were subjectively satisfied with the result.

In 89.7% of the joints, no pain or occasional mild pain was reported (HHS pain score 40–44 points). Five patients reported pain. One subjectively satisfied patient with bilateral rheumatoid arthritis and marked residual symptoms in both hips had restricted activity with concomitant knee problems (HHS pain score 10 points). One patient had unclear bilateral pain and his application for pensioning had not yet been granted (HHS pain score 20 points). Three other patients reported unilateral symptoms (HHS pain score 20 in two, and HHS pain score 30 in one). In the patient with a pain score of 30, the painful left joint had been treated with a high hip centre because of the difficult initial situation.

With these three joints, the Harris Hip Score differed more than 10 points compared to the opposite side. In the overall group, the average difference in the Harris Hip Score between the two sides was 4 points.

The ability to walk was not limited in 56% of the patients; it was restricted to 1000 m and 500 to 1000 m, respectively, in 19% each and to the home environment in 6%. The average Harris Hip Score for walking ability was 8.75 points (min 2 points and max 11 points). The score was only two points in the two patients with the bilateral pain symptoms described above.

Analysis of the radiographs (**Figs. 2** and **3**) in the seven a.p. Gruen zones showed no radiolucent lines in proximal zones I and VII. Three joints showed slight proximal and medial atrophy in Gruen zone VII. In one-third of the arthroplasties, distal cortical hypertrophy was found, which was marked in two joints (case example 2, **Fig. 4**). In the distal Gruen zones II to VI there

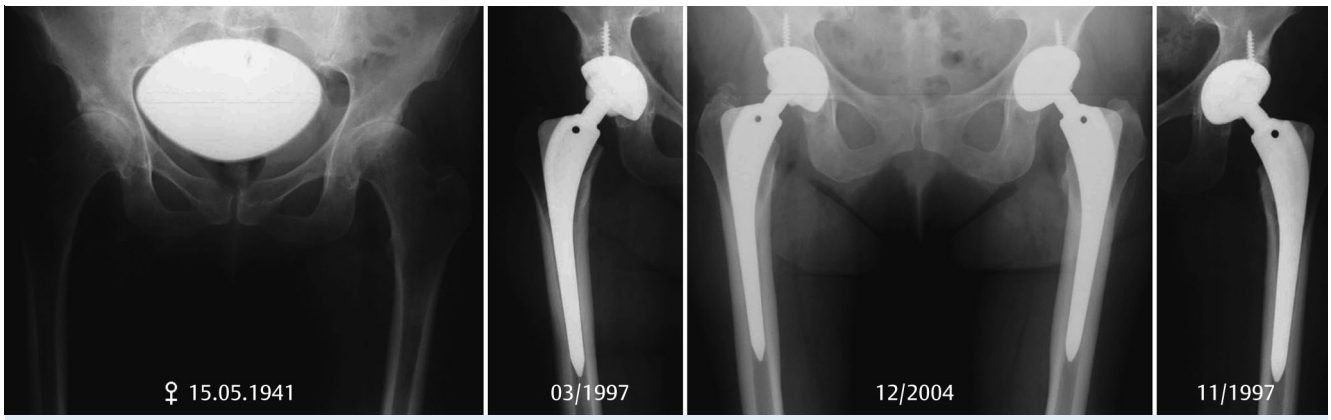

Fig. 4 Case example 2: Marked bilateral cortical hypertrophy, without pain symptoms and good periprosthetic proximal bone structure without signs of atrophy.

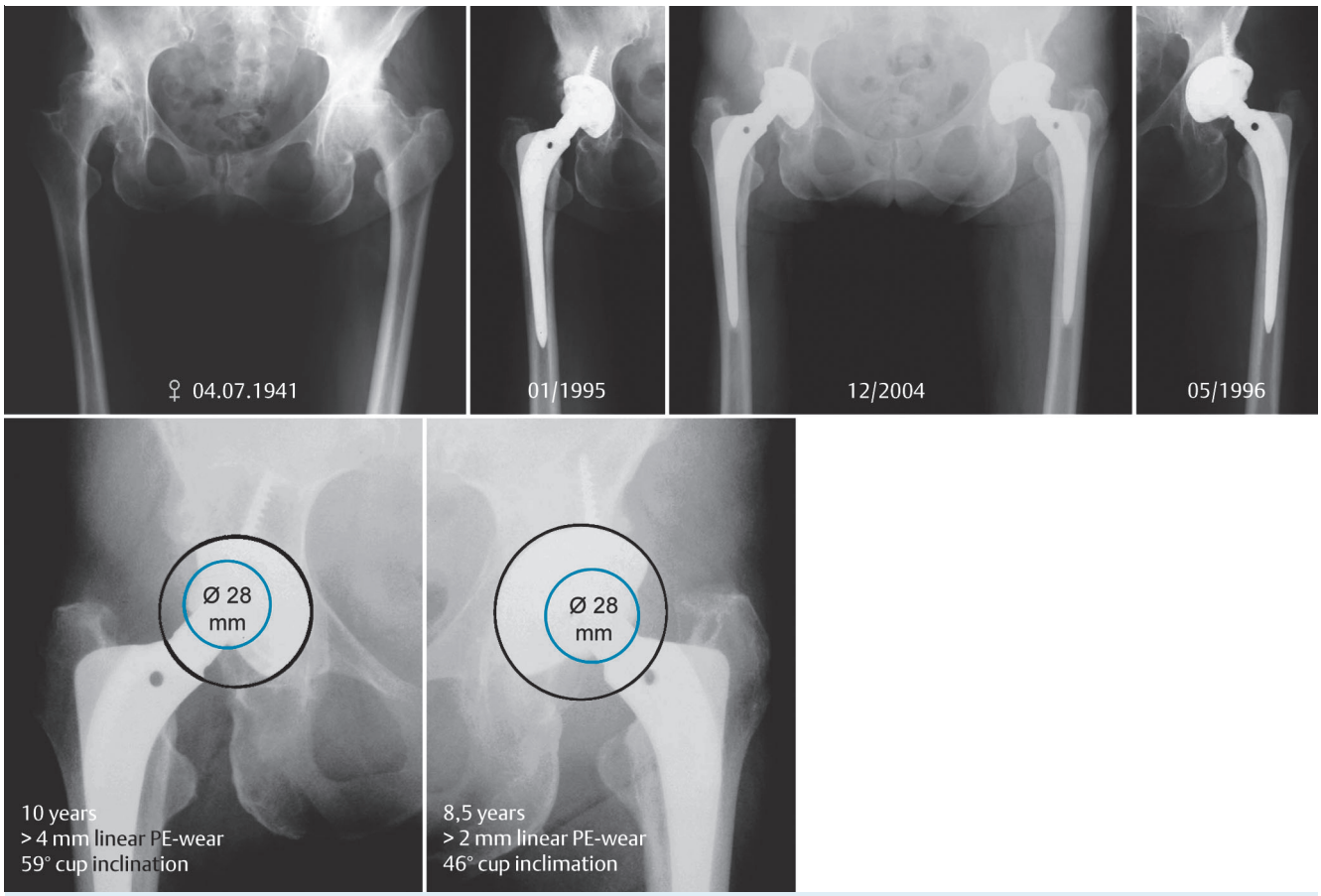

Fig. 5 Case example 3: Bilateral wear of the polyethylene insert in the Plasmacup S with steep position of the right cup and normal position on the opposite side. Right cup with acetabular osteolysis, requiring revision.

were radiographic reactions around the uncoated part of the Bicontact stem in 3.4% to 8.6% of cases.

At the time of follow-up, no joint had to be exchanged because of aseptic or septic complications. Two dislocations occurred with one joint in a "noncompliant" patient, which were managed with closed reduction. Linear wear of > 1.5 mm of the polyethylene cup was found radiologically in 4 joints, thereof two unilateral and one bilateral.

The bilateral polyethylene wear (case example 3, **Fig. 5**) occurred in a patient with a markedly steep position of the right cup (59° inclination, 4-mm linear wear after 10 years = 0.4 mm/year) and normal position of the left cup (46° inclination with 2-mm linear wear after 8.5 years = 0.24 mm/year). The right cup had marked acetabular osteolysis and was assessed as in need of revision; this has now been carried out. Measurable wear of the PE cups was found in two further patients (cup with > 60° in-

clination, 1.5-mm linear wear after 9 years = 0.17 mm/year) and 1,5-mm after 7 years (0.21 mm/year).

Discussion

Retrospective recruitment of patients limits the fundamental reliability of the results. Since we have been using the Bicontact stem since 1987, the study group was determined by the change of the cup system from threaded ring to press-fit cup fixation in order to study the improvement of the results with a new cup system. Our method of using an initial written survey of the patients who had the 537 Plasmacup procedures between 1993, the year it was introduced, and 2000 had a very high response rate of 81% and provided a good basis for the definition of a group of patients with bilateral treatment.

The patients represent a relatively young population. Follow-up took place after a medium-term period of 6.5 years, when the patients had an average further life expectancy of over 15 years. Differences in the assessment of the bilateral hip arthroplasty compared to a unilateral hip replacement with a functionally intact opposite side are not possible, as we understand it. If the ability to walk of patients treated bilaterally (average Harris Hip Score for walking 8.75 points after 6.5 years) is compared with the results of the Bicontact Multicentre [4] follow-up (average Harris Hip Score for walking 8.4 points after 8 years), the result is similar.

The results of the cementless Bicontact stem met the expectations and experiences of our earlier studies. There was a difference in the comparatively high proportion of distal hypertrophy. On radiographic analysis, we counted any visible evidence of a hypertrophic bone reaction. With these stems, there was a narrow distal relationship between cortical bone and prosthetic stem even postoperatively.

Overall, it was noticeable on analysis of the radiographs that patients had similar bone remodeling processes around the prosthetic stem on both sides. For instance, distal hypertrophy was observed in both femurs in over half of the patients.

The wear of the polyethylene inserts that was found in a few cases could be identified by analysis of the radiography only when the linear wear was over 1.5 mm. With a PE-ceramic bearing, linear wear of 0.1 to 0.2 mm per year is expected. With the average follow-up period of 6.5 years, these wear values were therefore below measurement accuracy. The greater wear in 4 cases represents a risk for the further course of the young patients and must be observed. It was found that the unfavourable cup position influenced PE wear in two of the cases. In the patient with bilateral PE wear, the wear of the correctly implanted cup on the right side is a sign that there is a patient-specific influence on material wear. In the longer term, the wear of the sliding joint surfaces must be observed further in this group of patients.

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12-Year Results with the Cementless Bicontact SD Stem in Dysplastic and Narrow Femoral Bone Conditions

Authors S. Kohler, V. Nahmmacher

Affiliation HELIOS Clinic for Orthopaedics, Bleicherode, Germany

Key words
- hip arthroplasty
- dyplasia
- narrow femoral bone conditions
- cementless

Abstract

Aim: The aim of the study was the evaluation of the medium- to long-term results of the cementless Bicontact SD hip arthroplasty, which was designed specially for narrow femoral medullary cavities.

Method: From February 1992 to December 1996 115 patients (123 joints) were treated with a Bicontact SD stem and various cup implants through a posterior approach. In one third of cases, the indication was dysplastic osteoarthritis of various degrees of severity.

Results: Between November 2006 and May 2007 90 patients (98 hip joints) were followed up in a retrospective study after an average of 12.2 (10.1 – 15.1) years. The average Harris Hip Score was 93 (60 – 100) points and the Merle d'Aubigné score was 16.7 (5 – 18) points. A stem implant had to be regarded as loosened according to radiological criteria. One patient died 7 days postoperatively of a pulmonary embolism.

Conclusion: The clinical and radiological results confirmed the proximal fixation concept in dysplastic femurs and narrow medullary cavities.

Introduction

Total hip arthroplasty is one of the most successful and best-documented operations in orthopaedic surgery. The anatomical diversity of the proximal femur has led to the realisation that a single model of the stem component does not cover all indications. The Bicontact Standard stem, which has been in successful clinical use since 1987 [2, 8,15] was extended by variants with increased offset while keeping the basic shape unchanged. The Bicontact-N stem, a version adapted to Asian anatomy, is also available. The Bicontact SD stem (SD = small dimension) was developed in 1991 for use in femurs with a particularly narrow medullary cavity that expands into a champagne-flute shape only at the level of the lesser trochanter. We have been using this stem since February 1992 primarily for narrow femoral medullary cavities, which are often found with hip dysplasia. The aim of our study was to assess the Bicontact SD stem after 10 to 15 years.

Material and Methods

Implant

The Bicontact SD stem is designed for narrow medullary cavities and is shorter than the standard implant. The section in contact with the calcar femorale is modified. The offset is 40.5 mm with the head in the middle for all stem sizes.

Perioperative management

All patients were operated in lateral position through a posterior approach. They were given single shot antibiotic prophylaxis with a cephalosporin. Medical thrombosis prophylaxis began the evening before the operation with low-dose heparin, and physical prophylaxis consisted of physiotherapy, instructions on using the muscle pump in the lower legs and early mobilisation from the first to second postoperative day on two forearm crutches with partial loading. The drains were usually removed on the second day after the operation.

Follow-up

All patients managed with a Bicontact SD stem between February 1992 and December 1996 in our institution were identified, partly manually

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Correspondence
Dr. Steffen Kohler, MD
HELIOS Klinik Bleicherode
Fachkrankenhaus für Orthopädie
Barbarastraße 11
99752 Bleicherode
Germany
Phone: + 49 3 63 38 6 52 74
Fax: + 49 3 63 38 6 52 84
steffen.kohler@helios-kliniken.de

and partly with computer assistance, and were invited by letter to attend for follow-up. In about one third of cases, extensive research was required to obtain information about the patients' whereabouts.

Scores

As part of follow-up, the Harris Hip Score [16] and the Merle d'Aubigné score [29] were recorded. We established the Trendelenburg sign as a semiquantitative indicator of the function of the hip abductors in three grades:

- 1 (negative) when the opposite half of the pelvis could be elevated by the subject against gravity by his own power.
- 2 (suggested) when this half of the pelvis could be held but could not be actively elevated and
- 3 (positive) when the opposite half of the pelvis could not be held actively.

The subjective impression of pain was determined with a 10-point visual analogue scale (VAS). The patients could also communicate their assessment of the operation outcome in a 4-stage evaluation between very satisfied, satisfied, dissatisfied and very dissatisfied.

Radiological assessment

The following were recorded on radiographs of the operated hip and thigh in two planes: Periprosthetic radiolucent lines and cortical hypertrophy [18, 37] with reference to the 7 Gruen zones [14] and extension to 14 zones in the lateral projection [20]. Ectopic ossification was evaluated according to Brooker [4].

Survival rate

The survival rate was determined according to Kaplan and Meier [21].

Complications

Complications were documented where clinically obvious.

Cup implant

The cup situation was assessed separately as spherical threaded rings were used during the treatment period, but were replaced by press-fit implants since 1996.

Results

General

In the study period, 123 cementless Bicontact SD femoral stems were implanted in 115 patients in combination with different cup implants. This corresponded to 5% of the total number of total hip arthroplasties in the observation period.

21 patients had died in the interim, 20 of causes unrelated to the operation, and one patient as a result of a pulmonary embolism 7 days after the operation. There was reliable information from the relatives or doctors of all who had died or from our hospital records that the implanted Bicontact stems had not been revised. The location of one patient has not been discovered and two patients were unable to come for follow-up because they are bedbound with chronic illness. Another patient was not able to join follow-up because of a malignoma and chemotherapy treatment.

In 90 patients (9 men) with 98 cementless implants, equivalent to 80% of the originally implanted stems and 96% of the Bicontact SD stems still in situ in patients who are still alive, it was possible to obtain radiological and clinical data an average of 147 months (122 – 181 months) after the first operation. The demographic details and operation diagnoses of these patients are summarised in **Tables 1** and **2**.

Previous operations: 4 patients previously had intertrochanteric osteotomies.

Table 1 Demographic data

	Mean	Range	Standard deviation
Age in years at the time of operation	57.4	26 – 81	10.7
BMI preoperative	28.0	16.2 – 37.5	4.5
BMI at follow-up	29.0	17.0 – 38.9	4.6

Table 2 Diagnoses (n = 98)

Dysplastic osteoarthritis	37
– Crowe 1	20
– Crowe 2	12
– Crowe 3	2
– Crowe 4	3
Primary osteoarthritis	31
Aseptic femoral head necrosis	16
Postraumatic osteoarthritis	2
Osteoarthritis with acetabular protrusio	9
Femoral neck fracture	1
Chronic polyarthritis	1
Psoriatic arthritis	1

Table 3 Pre- and postoperative Harris Hip Score, Merle d'Aubigné score and pain score (VAS)

	Mean	Range	Standard deviation
Harris Hip Score preoperative	28	3 – 51	7.5
Harris Hip Score at follow-up	94	60 – 100	8.9
Merle d'Aubigné Score preoperative	6.4	0 – 10	1.9
Merle d'Aubigné Score at follow-up	16.7	5 – 18	2.0
Visual analogue scale preoperative	9.7	4.5 – 10	0.9
Visual analogue scale at follow-up	0.5	0 – 6	1.1

Table 4 Distribution of the Trendelenburg sign preoperatively and at the time of follow-up

	preoperative	at follow-up
Negative	17	85
Suggested	38	8
Positive	43	5

Implants

The selection of the stem implants was size 10 (24%), size 11 (37%), size 12 (34%) and size 13 (5%). The cup implants consisted of 85 threaded rings Typ "Munich", 12 "Plasmacup" press-fit cups and one cemented PE cup.

Clinical results

The Harris Hip Score, Merle d'Aubigné score and pain score (VAS) preoperatively and at follow-up are shown in **Table 3**.

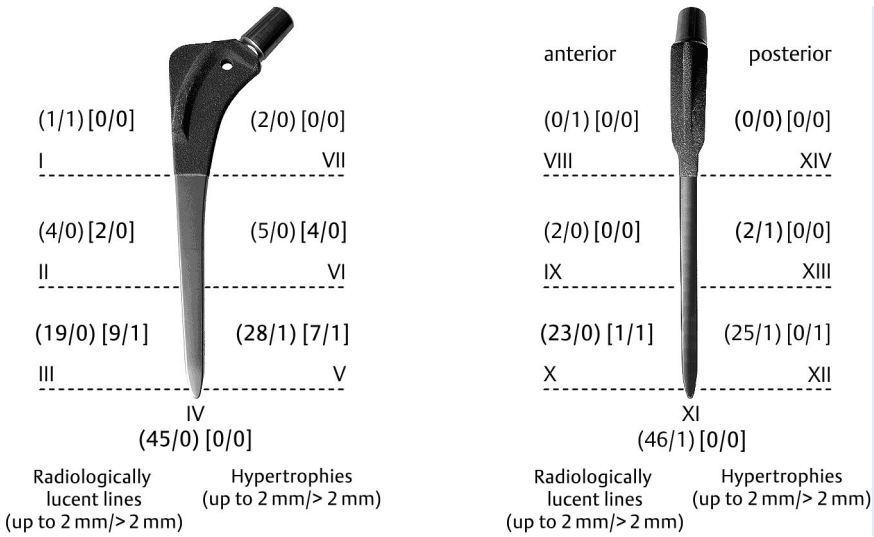

Fig. 1 Bicontact SD stem, distribution of the number of radiological lucency lines and hypertrophy in Gruen zones I to VII ap and VIII to XIV laterally. Total number of cases n = 98.

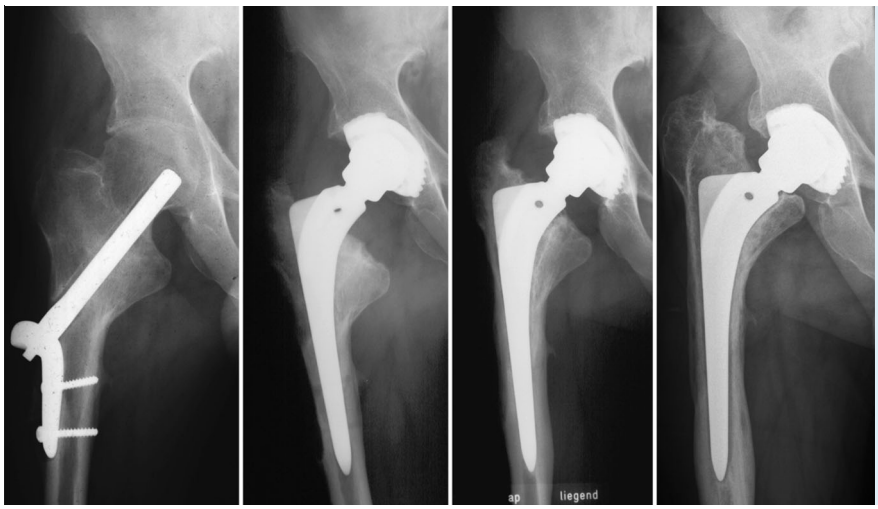

Fig. 2 Course of the failed THA: right hip preoperatively, 2 months, 73 months and 169 months after implantation. Subsidence of the stem, marked cortical reactions in the femur, periprosthetic femoral osteolysis.

In the Harris Hip Score 89 cases could be regarded as a very good or good result, 5 as satisfactory and 4 as unsatisfactory.

When the five positive Trendelenburg signs were analysed, the abnormalities found were a high hip centre in one case and cup loosening in four cases. In the five cases of a high hip centre, the Trendelenburg sign was negative in three and positive or suggested in one case each (**Table 4**).

86 of the patients were very satisfied with the result of the operation, 10 were satisfied, one was dissatisfied and one was very dissatisfied. In the case of bilateral operations, no patient reported a difference between the sides. The patient whose assessment was “very dissatisfied” had had to undergo revision of the threaded ring after 14 months because of a lateralised position. At follow-up, the stem was in situ 181 months without signs of loosening. The patient whose assessment was “dissatisfied” had a previous history of intertrochanteric osteotomy with a good functional result but unsatisfactory pain situation. The Harris Hip Score was 22 points before the total hip arthroplasty and 60 points at follow-up after 149 months with probable cup loosening (pain score: 20 points). This case represents the worst result with regard to pain. The pain score in the VAS had improved from 10 preoperatively to 6 at follow-up and by the patient’s own account had remained constant for years.

Radiological results

Fig. 1 shows the analyses of the radiolucent lines and cortical reactions.

Cortical hypertrophy in the femur was observed in 12 patients. This reaction was associated with loosening in one case (**Fig. 2**). In another patient, hypertrophic reactions in the femoral cortex were associated with a poorer pain score.

The development of a cortical pedestal under the stem tip, regarded under certain circumstances as evidence of loosening, was found in one case after 131 months and was not associated with loosening. This phenomenon was found as well in the case of the loosened stem (**Fig. 2**).

Ectopic ossification occurred in 9 patients, Brooker grade 1 in three, grade 2 in one, grade 3 in four and grade 4 in one case. The HHS was 64, 96, 100, 100 and 100 points in the five patients with grade 3 and 4 ossification.

Survival analysis

One single stem implant had to be regarded as loosened according to radiological (considerable subsidence with periprosthetic osteolysis) and clinical criteria (**Fig. 2**). The underlying diagnosis was osteoarthritis after a femoral neck fracture managed with internal fixation in a patient with brain damage in early childhood who was 43 years old at the time of the operation.

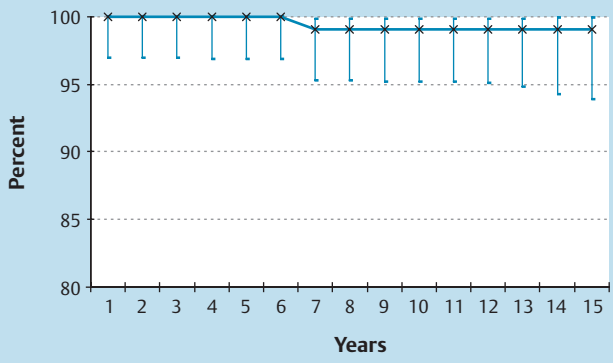

Fig. 3 Kaplan-Meier survival curve of the Bicontact SD stem (endpoint = loosening or revision).

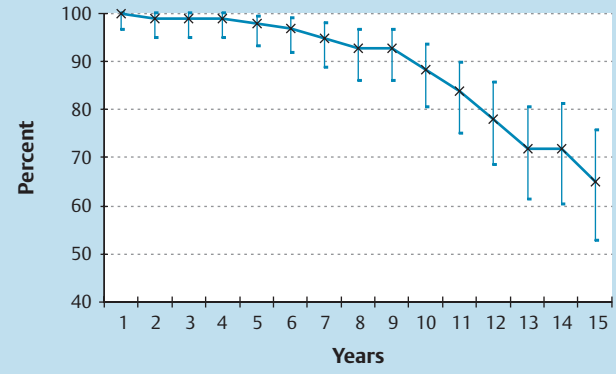

Fig. 4 Kaplan-Meier survival curve of the "Munich" threaded ring (endpoint = loosening or revision).

Among the acetabulum implants, at the time of follow-up 18 threaded rings had been revised 14 to 143 months after implantation and two Plasmacup implants each after 113 months. 11 other threaded rings could be regarded as loosened with varying degrees of resorption lines or osteolysis, sometimes with migration of the implant. In a further 13 threaded rings and one Plasmacup there was marked decentring of the femoral heads in the polyethylene inlay so that they were classified as at risk. Thus, 32% of all initially implanted cups were already revised or loosened and 15% were at risk.

Figs. 3 and **4** show the survival curves of the Bicontact SD stem and the "Munich" threaded ring, the cup implant used most in this series.

Complications

Two femoral shaft fractures were recorded in the operation years 1992 and 1994, which both healed on conservative treatment with temporary non-loading. In 1992 a lateral femoral perforation occurred when the first osteoprofiler was driven in; this also healed without complication on conservative treatment. After 1994 there were no more femoral fractures or perforations.

Dislocation occurred in 3 patients. In the first case, dislocation occurred four times and was reduced each time. The joint has now been stable for 8 years. In the other two cases, the dislocation occurred after cup revision. The rate of dislocation after primary implantation was thus one per cent.

One pelvic vein thrombosis became apparent clinically shortly after discharge from hospital and was confirmed by technical investigation.

One patient died of acute pulmonary embolism a few days after the operation.

Postoperatively, one patient developed pancreatitis, which led to acute transfer to a visceral surgery centre, where it was managed conservatively.

Discussion

Follow-up rate

When documenting the long-term results of total hip arthroplasty, there is always a certain number of patients who are not available for follow-up for various reasons. Fayard [11] was able to follow up 63 of 107 patients after up to 11 years and Grübl [13] saw 102 of the original 200 patients after up to 200 months. For Lee [24], 85 of 103 implanted joints were available for follow-up after 7 – 12 years and Marshall [26] investigated 129 of the 200 joints implanted originally after 10 – 15 years. Pieringer [32] succeeded in following up 81 of 124 hips after 133 – 169 months. Pospischill and Knahr [33] reported on the radiological examination of 99 of 148 patients after 10 – 17 years. Our results fit well with over 80% follow-up of the original patients.

Demographics and implants

The increase in weight and thus in BMI at follow-up observed in nearly all patients, although the baseline values were already quite high compared to Perka [30], contradicts the argument often heard from the patients that they had no opportunity for weight reduction because of the lack of mobility prior to joint replacement.

The large proportion of dysplastic hips of varying degrees of severity, accounting for over one third, is not surprising, since the SD stem is very suitable for the anatomical features of this femur because of its particular shape [1,25].

The predominant use of small stem sizes is also a tribute to the indication of the narrow medullary cavity. At present a stem size 9 is also available, which was not yet available in the period under consideration here. Because of new statutory test standards, there has been a weight restriction of 50 kg for sizes 9 and 10 since 2005. This limits the practical applicability of the stem.

Harris Hip Score and Merle d'Aubigné score

The average Harris Hip Score of well over 90 points at follow-up, like the Merle d'Aubigné score of 16.7, is a very good result compared to studies with similar follow-up times.

In general long-term results of cementless hip replacements, Pieringer [32] reported a change in the Harris Hip Score from a preoperative average of 36.4 to 89.7 at follow-up; in Kearns [22] the score improved from 46 to 86 and in Surdam [35] from 50 to 89 points. Petsatodes [31] saw an improvement from 7.9 to 16.9 and Fayard [11] from 10.6 to 15.8 points in the Merle d'Aubigné score.

The Bicontact stem fits well with these results. Eingartner [8] demonstrated an average Harris Hip Score of 84.3 points after up to 11 years. Badhe [2] showed an improvement in the Harris Hip Score from 41 to 92 and Ha [15] from 51 to 94 points.

In groups of patients with dysplastic osteoarthritis treated by hip replacement, sometimes using the cemented technique, the Harris Hip Score improved in Perka [30] from 34 to 84, in Eskeli-

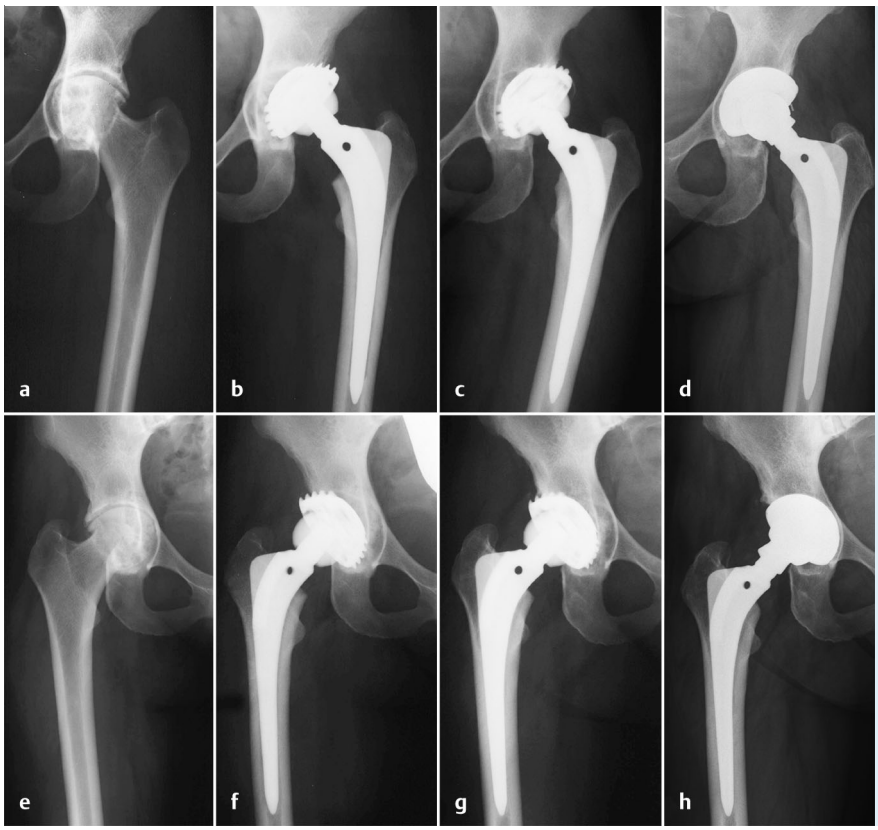

Fig. 5 a to **h** Patient treated because of bilateral osteoarthritis with protrusio, age at follow-up 51 years. Stem implants without radiological abnormalities but bilateral cup revision after 153 months on the left and 152 months on the right. Radiographs of the left side (top) preop, post-op, 152 and 178 months and left side (bottom) preop, postop, 144 and 170 months.

nen [10] from 54 to 84, in Hendrich [19] from 37 to 87 and in Sakai [34] from 43 to 98 points. Similar results are found using the Merle d'Aubigné score [9,17,23].

Comparisons with the results of other studies must always be interpreted with caution because of different preconditions and patient populations. However, it must be borne in mind in particular that one third of the cup components were revised in our patients, which probably leads to a marked improvement in the scores employed when the revision operations are predominantly successful.

The scores before the operative procedures are more comparable. The average scores recorded in our study, of 28 points in the Harris Hip Score and 6.4 points in the Merle d'Aubigné score, are comparatively low and thus poor baseline scores.

Trendelenburg sign

Interpretation of the Trendelenburg sign is problematic as the causes can be varied. These can include problems due to intraoperative mechanical changes in the gluteal muscles and damage to the corresponding nerves and poor biomechanical relationships with gluteal insufficiency. The sign can also be positive due to pain, e.g. with loosening of the stem and/or cup.

When patients with a high hip centre are analysed, in whom positioning of the cup component in the primary acetabulum was unsuccessful, it was apparent that this situation is not inevitably associated with a positive Trendelenburg sign. It was positive in only one of 5 cases. It is thus likely that the various circumstances listed above act at the same time.

Radiological results

The radiological results mirror the proximal fixation concept with regard to periprosthetic radiolucend lines. The distal micormotion of the implant is apparent in the occurrence of soft lucency lines around the distal third of the stem. Fayard [11] regards these lines as a normal reaction with proximal fixation. Eingartner [8] also found these reactions with the Standard Bicontact stem after 10 years.

In contrast, in radiological studies of a proximally fixed stem, Lee [24] observed lucency lines only in the proximal Gruen zones 1 and 7. In Surdam [35] too, Gruen zone 7 showed the most lucency lines.

The appearance of radiological lines mainly proximally around the stem is characteristic of cementless implants that do not follow the proximal fixation concept [13,32,33,36].

Wick and Lester [39] observed significant increases in osteolysis with only small changes in a proven stem implant with square cross section and sand-blasted surface, which underlines the importance of stem geometry.

The relative absence of periprosthetic stem osteolysis seen in our series, apart from the loosened subsided stem implant, is a phenomenon observed by several authors [3,8,26,28]. Burt [3] attributes this effect to the circumferential coating of the hip stem, an opinion shared by Marshall [26]. Nevertheless, there appear to be differences: the Bicontact stem apparently achieved a sealing effect even against osteolysis involving the trochanter massif, despite the poor preconditions in our series with many young and active patients, with polyethylene exclusively as bearing in the cup and frequent cup loosening with often extensive osteolysis. Using a different model with circumferential coating, Lee [24] and Yoon [41] found isolated larger areas of osteolysis in the region of the greater trochanter.

The stem survival rate of 99% (best case with the assumption that all patients not recorded radiologically do not have a loosened stem implant) is in the excellent range and thus confirms the outstanding results of the Bicontact Standard stem [8].

The only loosened stem demands separate consideration: the local pre- and intraoperative situation (**Fig. 2**) was such that the large lamella nail caused bony defects in the femoral calcar because of its position and osseointegration laterally was probably compromised by a bone defect at the site of penetration of the nail through the lateral femoral. A wedge of autologous corticocancellous bone driven in between the calcar and implant was resorbed rapidly and so was unable to impart the required stability long-term. The postoperative radiograph also suggests unintentional distal wedging of the stem. While we initially regarded the situation as stable after 73 months despite the incipient subsidence and osteolysis at the calcar, in retrospect we have to regard the stem as already loosened at this time, knowing the subsequent course.

In contrast, the results with the Munich threaded ring are disappointing. About 1/3 revisions and loosening are by no means acceptable. The tendency toward this result, which matches the meta-analysis by Yahiro [40], was already apparent in 1996 so we have since then abandoned this cup implant in favour of a press-fit cup.

With an ossification incidence of 10% of all degrees of severity, ectopic ossification was not important. The mean HSS for higher-grade ossification was 93 points, which corresponded to the reference range of all other patients. One patient with a HSS of 64 with grade 3 ossification had a high hip centre postoperatively on the one hand, but on the other hand she also had a very poor preoperative baseline value of 18 points. In addition, the preoperative BMI was 34.6 and was 37.6 at follow-up. Subjectively she was "very satisfied" with the operation result.

Complications

The three cases of femoral perforation or fracture are not unusual with a cementless stem, especially as this includes the complete learning curve, which Flamme [12] reported for the Bicontact stem. This is also suggested by the fact that two of the three events occurred in the first year of use and that no further fractures were found in the last two years of the observation period. Ha [15] also observed only 1.3% femoral fractures with the Bicontact stem. Our study did not come anywhere close to the combined incidence of trochanter avulsion and femoral shaft fissure of 20% reported by Flamme [12]. The 13.7% rate of femoral fractures reported by Badhe [2] for the Bicontact implant is far outside our experience. Perka [30] saw the cause of the increased fracture rate of 7 out of 121 implantations in their series for osteoarthritis due to hip dysplasia as the narrow medullary cavity and the need for correction of the increased antetorsion of the femoral neck. This view is reflected by the local anatomical situation in our study.

The dislocation rate of one per cent of the patients followed up is in the same range for the Bicontact stem as that reported by Flamme [12] with one per cent, Badhe [2] with 3.2% and Ha [15] with 2.6%. In contrast, dislocation rates of up to 11% were published in a more recent study by Surdam [35]. In Callaghan's study [5], more than 18% of the surviving patients with a cemented hip replacement had experienced at least one dislocation after 30 years.

A manifest fatal pulmonary embolism on the 7th day after the operation despite medical and physical thrombosis prophylaxis is the maximum thromboembolic complication. The patient population is too small for a statistical comparison. The thrombosis rate of one per cent in the patients followed up is lower than would be expected [38], which is explained by the retrospective study design, which was not designed to detect thromboembolic events.

Conclusions

- The Bicontact SD stem has demonstrated its capacity with a 99% survival rate after up to 15 years and few complications.
- Radiological lucency lines in Gruen zones III to IV and X to XII up to 2 mm in width are an expression of physiological oscillation of the distal third of the stem with proximal fixation.
- With precise operation planning and selection of sizes combined with a careful operative technique, the incidence of intraoperative bone injury of the femur is low.
- In the interest of broader use in coxa vara also, modification of the femoral offset with increasing stem size is desirable.
- The current weight limitations for small stem sizes require a technical solution.

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EBRA Migration Patterns of the Plasmacup with Ceramic or Polyethylene Inserts: A Randomised Study

Authors U. Ochs[1], T. Ilchmann[2], B. G. Ochs[1], J. Marx[1], K. Brunnhuber[1], M. Lüem[2], K. Weise[1]

Affiliations
[1] BG Trauma Centre, University of Tuebingen, Germany
[2] Department for Orthopaedics, Kantonsspital Liestal, Switzerland

Key words
- total hip arthroplasty
- press-fit cup
- EBRA
- ceramic on ceramic
- ceramic on polyethylene bearing

Abstract

Aim: In this prospective randomised study, the influence of different bearing materials on migration and wear was measured and their effect on the function of the artificial joint and the patient outcome was investigated. Mid-term results were recorded so that recommendations can be made on the use of certain bearings, which minimise wear and thus the danger of subsequent aseptic loosening.

Method: Sixty-six patients met the inclusion criteria and were willing to take part in the study. These patients were randomised to 2 groups. All of them had total hip arthroplasty with implantation of a cementless Bicontact stem and Plasmacup using a cementless press-fit technique. Thirty-five of these patients were given a ceramic-ceramic bearing and 31 patients a ceramic-polyethylene bearing (gamma sterilised/nitrogen environment). At the most recent follow-up, they underwent detailed clinical and radiological examination and evaluation by means of the Harris Hip Score, Hannover function questionnaire and single-film X-ray analysis (EBRA).

Results: The overall follow-up rate was 65.2% (43 of 66) and the mean follow-up period was 8.1 (7.1 – 9.2) years. The median Harris Hip Score at the time of follow-up was 90.1 (58.7 – 99.9) points. The average Hannover function score was 87.14% (63.9 – 100). In 4 of 66 cases (6.1%) there was a tendency for the Plasmacup to subsidence in the first postoperative months that was slight but detectable by EBRA; however, this stopped subsequently. This primary subsidence was independent of the chosen bearing material. No significant difference in the clinical and radiological parameters was found between the two groups.

Conclusion: The very good results with regard to the rate of loosening confirm the press-fit cup fixation concept. The study shows a similar medium-term result for the ceramic-ceramic and ceramic-polyethylene bearing so that use of both bearings can continue to be recommended. Only long-term studies with sufficiently large numbers of patients will be able to show whether significant differences can be detected between the two slide bearings with regard to wear and migration behaviour and so that a recommendation can be given to the surgeon.

Introduction

New materials and adaptations of design, together with the use of porous metal surfaces, have improved both the primary and the secondary stability of artificial hip joints and have thus prolonged the life of cup implants. Implant wear is one of the reasons for osteolysis and subsequent aseptic loosening following hip replacement [13, 19]. The wear particles cause a local inflammatory reaction and activate the cellular immune response [1]. It is now undisputed that there is a direct correlation between the types, size and number of these particles and the extent of the biological reaction [15]. In the past, bearings in total hip arthroplasty consisted predominantly of a metal-polyethylene combination. The development and improvement of new materials and sterilisation methods led to the increased use of hard bearings such as ceramic-ceramic and soft bearings such as ceramic-polyethylene in hip joint replacement [2]. It was shown in experimental studies that the wear of a modern ceramic-ceramic bearing could be reduced by a factor of 100 compared to the conventional metal-polyethylene combination and the particle size by a factor of 10 [4]. This should lead to a marked reduction in wear-induced osteolysis in the artificial joint.

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Correspondence
Dr. Uwe Ochs, MD
Berufsgenossenschaftliche Unfallklinik
Schnarrenbergstr. 95
72076 Tuebingen
Germany
Phone: +49 70 71 6 06 11 67
Fax: +49 70 71 6 06 10 02
uochs@bgu-tuebingen.de

Follow-up of these prospectively randomised patients was designed to provide information about the behaviour of the cup after the initial insertion and whether an improvement for the patient can be found clinically and radiologically in the medium and long term through the use of modern ceramic-ceramic bearings or whether there is a difference in the results between the two groups [3]. Single-film X-ray analysis (EBRA) was used for exact measurement of wear and cup migration [7].

Material and Method

Patients

The study was prospective and randomised and was approved by the ethics committee of the medical faculty of Tuebingen University.

Patients were included in whom routine elective total hip arthroplasty for osteoarthritis was planned in the BG Trauma Centre Tuebingen, who were younger than 70 years of age and who met the preoperative criteria for implantation of a cementless hip replacement. In addition, the physical activity of these patients should not be significantly impaired by other skeletal or systemic diseases apart from the hip osteoarthritis, in order to obtain as homogeneous a patient population as possible.

The implants used in all patients were the cementless Bicontact stem and the Plasmacup press-fit cup (B.Braun-Aesculap, Tuttlingen, Germany). All of the patients received a ceramic head (Biolox forte, Ceramtec, Plochingen, Germany) with a diameter of 28 mm. Fixation of the Plasmapore-coated Plasmacup was by press-fit in all cases, with the option of additional screw fixation [16].

The type of cup inlay was randomised by drawing an envelope in the operating theatre; one group of patients received a ceramic inlay and the other group a standard polyethylene inlay with the same metal cup in both groups.

The surgery was performed using the standardised operation technique by 4 surgeons highly experienced in arthroplasty.

Of the patients in whom implantation of a cementless total hip arthroplasty was planned in the BG Trauma Centre Tuebingen between 1997 and 1999, 66 met the inclusion criteria and were willing to take part in the study.

The inlay named in the randomisation could be implanted in all cases. In this way, 35 patients were selected for implantation of a ceramic-ceramic bearing and 31 for implantation of a ceramic-polyethylene bearing.

Follow-up

In this prospective randomised study, the patients had regular clinical and radiological follow-up after 3, 12, and 24 months and after at least 5 years, most recently between October 2006 and January 2007. Both the clinical findings, including soft tissue findings, any contractures and deformities, and the range of motion, leg length differences and gait were examined and recorded in the Harris Hip Score [5]. In addition, the functional outcome as perceived by the patient subjectively was recorded using the Hannover function questionnaire (FFbH-OA) [11]. This asks about pain, walking distance, climbing stairs, putting on shoes and socks, ability to sit, use of public transport, gait, use of walking aids, leg length, and mobility.

Radiological examination was performed with a standardised supine view of the pelvis, X-ray of the affected hip and upper thigh in 2 planes and a faux profile view. These radiographs were analysed with regard to stem and cup position, signs of loosening in the form of Gruen lysis zones, stress shielding, subsidence, heterotopic ossification and spot welds.

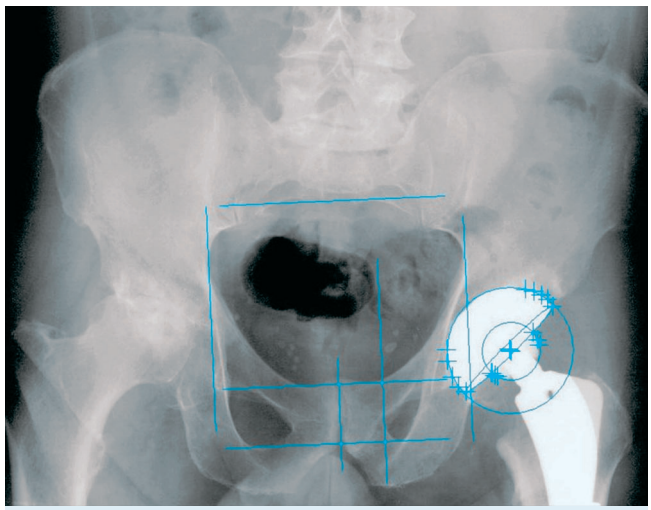

Fig. 1 Example of EBRA analysis of a pelvic film with determination of cup and femoral head position.

All of the radiographs of the pelvis taken since the operation were then digitalised with a high-resolution, distortion-free X-ray scanner. These image series were then measured with regard to cup migration using single-film X-ray analysis (EBRA) (**Fig. 1**) and analysed. The EBRA Digital Software (Release 2003) of the Institute of Geometry of Innsbruck University, Austria, was used. Analysis was possible above a series of at least 4 pelvic films in the course of the follow-up period. Through a corresponding comparability algorithm, unsuitable projections were excluded from the analysis. The comparability required for the described accuracy was set at 3 mm as standard, which corresponds to measurement accuracy of 1 mm [8]. Values greater than 1 mm were assessed as significant for analysis of horizontal migration. This applied both for positive (= lateral) and negative (medial) migration as both migration directions were possible. For vertical analysis only positive results over 1 mm were significant as caudal cup migration is not possible. The significance limit for wear of the slide bearings was stated as values greater than 0.5 mm [18].

The results were shown with the EBRAGRAF software of the Institute of Geometry of Innsbruck University, Austria [12].

Results

A total of 66 patients were included in the study. Thirty-one patients were given a polyethylene and 35 patients a ceramic inlay. There were no significant differences between the patient groups with regard to sex, age, weight, and diagnosis leading to implantation of the artificial hip (**Table 1**). The surgeons reported that there were no differences in intraoperative handling of the different inlays. There was no significant difference between the two groups in the average operation times either.

Early complications: in one case (ceramic-polyethylene group), there was severe tilting of the implanted Plasmacup a week after implantation with insufficient press-fit, which necessitated immediate cup exchange. A second patient (ceramic-ceramic

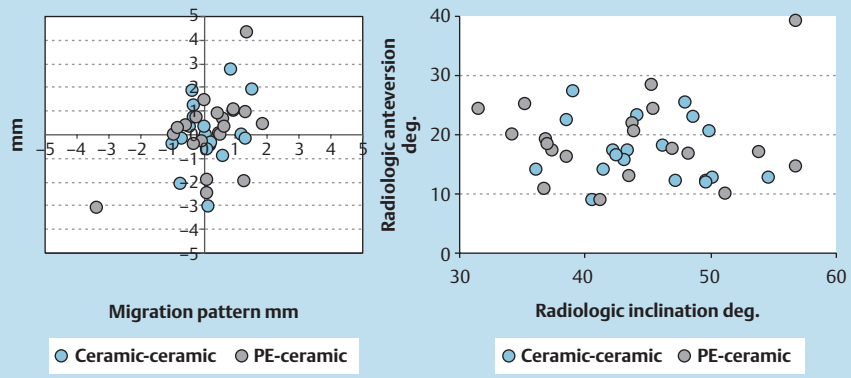

Fig. 2 Radiological cup positions and migration patterns for the two groups (ceramic-ceramic n = 22 and ceramic-polyethylene n = 21).

group) developed an early infection, which resulted in numerous revision operations but ultimately the joint replacement did not have to be exchanged. Two patients in the ceramic-polyethylene group had weakness of the femoral nerve directly postoperatively, but this resolved fully within three months. In another case in the ceramic-ceramic group, the artificial joint dislocated on the third postoperative day after accidentally sitting low; after closed reduction, operative revision was not necessary and the joint remained stable subsequently. One patient (ceramic-polyethylene group) suffered a deep vein thrombosis after 10 days. It was not found that this complication depended on the implanted inlay.

At the time of the last follow-up, 5 patients had died and 5 patients had moved or were abroad permanently and so could not be contacted. Thirteen patients were unwilling or unable to come for follow-up. The follow-up rate for the total group was thus 65.2% (43 of 66). At the most recent follow-up, the average age of the patients was 66.8 (40 – 76) years (**Table 1**). The average follow-up period was 8.1 (7.1 – 9.2) years. The median Harris Hip Score at the time of follow-up was 90.1 (58.7 – 99.9) points, which just meets the assessment of "excellent" (**Table 2**). The average Hannover function score was 87.14% (63.9 – 100). 53.6% of the patients reported no pain, 30.2% had slight and 11.6% had mild pain, 2.3% had moderate pain, 2.3% had severe pain and 0% had extreme or rest pain. Statistical analysis yielded no significant differences between the two groups with regard to hip mobility, pain and patient satisfaction with the artificial joint.

Radiological signs of cup loosening such as osteolysis or progressive bone cyst formation were not found in any of the patients followed up [10]. All of the cup implants were assessed clinically and radiologically as firmly enclosed.

There were 227 radiographs for the 43 patients (min 4, max 8). An average of 5.3 (4 – 8) films could be analysed per patient. Seven of the 227 pelvic films could not be measured with EBRA because of the absence of follow-up films or poor comparability of the projections. However, an adequate number of comparable and good-quality radiographs were available for all 43 patients followed up, so that determination of migration of the Plasmacup could be made by EBRA easily.

The outline of the ceramic head has a low X-ray contrast value and is often completely concealed by the Plasmacup (**Fig. 3**), especially when this is inserted in high anteversion. Correct determination of the centre of the head, which is essential for exact determination of the wear of the corresponding slide bearing, was, therefore, possible in only 10 cases.

Table 1 Sex, age, weight, and diagnosis of the patients at the time of operation and at follow-up

	All (n = 43)	PE (n = 21)	CC (n = 22)
Male	29	14	15
Female	14	7	7
Mean age (years) at operation (SD)	58.7 (7.8)	61.5 (7.0)	56.0 (7.6)
Mean age (years) at follow-up (SD)	66.7 (7.8)	69.2 (7.2)	64.4 (7.8)
Mean weight (kg) at operation (SD)	78.7 (15.9)	82.0 (15.9)	75.4 (15.4)
Follow-up period years (SD)	8.1 (8.2)	7.6 (6.5)	8.4 (7.2)
Primary osteoarthritis	35	17	18
Posttraumatic osteoarthritis	3	2	1
Dysplastic osteoarthritis	5	2	3

Table 2 Mean Harris Hip Score and FFbH-OA for each group at most recent follow-up

	All (n = 43)	PE (n = 21)	CC (n = 22)
Mean Harris Hip Score, points (SD)	90 (10.5)	89 (12.1)	91 (21.6)
HHS 90 – 100 [excellent], n (%)	29 (67.4)	13 (61.9)	16 (72.7)
HHS 80 – 89 [good], n (%)	7 (16.3)	5 (23.8)	2 (9.1)
HHS 70 – 79 [moderate], n (%)	4 (9.3)	0 (0)	4 (18.2)
HHS < 70 [poor], n (%)	3 (7.0)	3 (14.3)	0 (0)
Mean FFbH-OA, percentage (SD)	88 (12.8)	87 (10.8)	88 (14.8)

No difference in migration behaviour between the two groups was found with EBRA (**Fig. 2**). The measurements showed 4 cups with significant migration over 1 mm (9.3%), and 3 of these 4 cups are in the ceramic-ceramic group (**Table 3**). This migration occurred in the first 12 months postoperatively and stopped subsequently. The average migration of all cups shows no difference between the two groups and there is also no significant change in the inclination and anteversion angle both when comparing the two groups and overall in all the total hip arthroplasties.

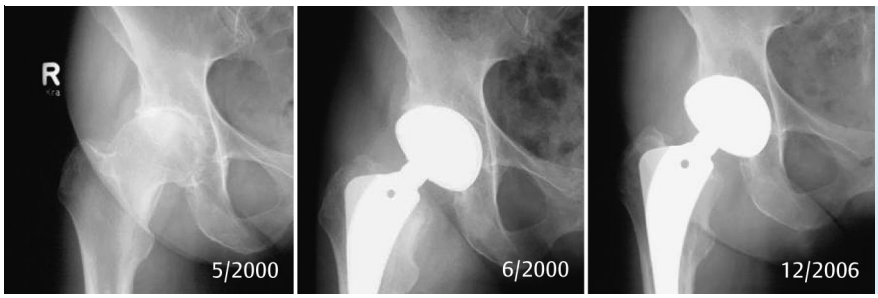

Fig. 3 Example for insufficient contrast of the ceramic head outline concealed by the Plasmacup shell.

Table 3 Radiological results of measurement with EBRA

	PE (n = 21)	Ceramic (n = 22)
Significant migration of the Plasmacup (n)	1	3
Migration in x-direction in mm (SD)	0.64 (0.42)	0.59 (0.56)
Migration in y-direction in mm (SD)	0.56 (1.09)	0.55 (0.93)
Inclination in degrees (SD)	44 (8)	46 (7)
Anteversion in degrees (SD)	19.5 (7.5)	18.0 (6.5)

Discussion

The patients randomised to the ceramic-ceramic and polyethylene-ceramic groups were comparable with regard to age, weight and diagnoses. The only difference between the two groups was the material of the implanted inlay: polyethylene or ceramic. Intra- or immediately postoperatively, no differences were found with regard to the implanted inlay. The mean follow-up period of the groups of 8.1 years is still too short to allow definitive statements about the wear and migration behaviour of the different combinations of materials. The EBRA measurement method is very accurate and can therefore be used even in this early period to determine migration behaviour [9]. Reliable measurements were possible in only a few cases because of the metal cup.

Up to the present time, no significant differences between the two groups were found either with regard to the clinical and radiological results concerning function and migration of the arthroplasty components or with regard to migration, wear and alteration of cup inclination and anteversion. Unfortunately, a large number of the original patients had to be excluded at the present time because the follow-up radiographs could not be compared correctly or were missing. However, further radiographs will be taken in the coming years and these will be able to be used for measurement, so that better follow-up is possible. The number of patients with initial migration was relatively high, which is explained by the fact that no additional securing screws were inserted and the Plasmacup was fixed only by press-fit [6,17]. This phenomenon is possibly further increased by the desirable early full loading. It is apparent now that this early migration in the y-direction stops after bony integration of the Plasmacup and no further migration is detectable. No difference is found in this respect between the two groups.

The comparative measurement of wear in the two groups unfortunately has a high rate of error because it is often difficult to identify the centre of the head. In addition, because of the extremely low wear with ceramic-ceramic bearings, it is not possible to measure this *in vivo*. This minimal wear can be determined exactly only in explanted cups using 3-D measurements, which have an accuracy of less than 10 micrometres. In the 10 X-ray series that could theoretically be analysed with EBRA with regard to wear, there is a higher number of inlays with supposed wear in the ceramic-ceramic group, and the calculated mean wear was also higher in this group. Because of the special design of the Plasmacup, this often conceals the ceramic head almost completely, thus making exact determination of the centre of the head impossible [9]. Exact comparison of the wear behaviour of the two groups is therefore not possible at the present time and the supposed greater averages wear in the ceramic-ceramic group should be regarded only with great reservations.

The very good results with regard to the rate of loosening confirm the cup fixation concept using press-fit and were also obtained in studies in other clinics [14,20,21]. The study shows similar medium-term results for the ceramic-ceramic and ceramic-polyethylene bearings so that use of both bearings can continue to be recommended. Only long-term studies with sufficiently large numbers of patients will be able to show whether significant differences can be detected between the two slide bearings with regard to wear and migration behaviour so that a recommendation can be given to the surgeon.

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Experiences with Bicontact Ceramic-Ceramic Total Hip Arthroplasty

Authors E. T. Takata, R. Basile, W. M. Albertoni

Affiliation University of São Paulo, Clinic for Orthopaedics, Paulista School of Medicine, Brasil

Key words
- cementless THA
- ceramic-ceramic
- mid-term results

Abstract

Aim: Mid-term result documentation of ceramic-on-ceramic cementless total hip replacement.
Method: From November 1998 to December 2005, 356 patients were submitted to 419 total hip arthroplasties of the hip with a cementless, ceramic-ceramic Bicontact/Plasmacup type of prosthesis. Patients were controlled in a consecutive prospective study.
Results: The average age of the patient group is 47.9 years, with an average follow-up of 48 months. There was no case with release of osteolysis of the acetabular or femoral components. There was one ceramic head fracture in an obese patient. Articular wear was negligible and could not be measured radiographically.
Conclusion: The ceramic-ceramic Bicontact hip joint replacement presents a low complication rate in young patients, with very low wear.

Introduction

The deleterious effect of polyethylene debris on periprosthetic bone leading to osteolysis and, consequently, to its release, has called for changes in the material of bearing surface in total hip replacement. Since its development, in 1970, the alumina ceramic-ceramic articulation by Boutin has undergone many modifications until the development of an articulation of excellent quality [1,2]. Fractures of the ceramic components have, since their introduction, always been the major concern of the surgeons. Their high level of hardness of first generation ceramics enabled the occurrence of fractures in up to 13% of the surgeries in the 1970s. The ceramics produced before 1988 reached an index of 0.22% of head fractures. At present, with the improvement in the quality of the ceramic, the fracture index floats between 0.01 and 0.07% [3].
As a result of the limitations of the first alumina ceramics, zirconic ceramic was developed in 1985. Zirconium is only used upon the ceramic-polyethylene combination, and cannot be used in ceramic-ceramic THA. Recently, a combination of alumina and zirconium with hardness above alumina and wear rate similar to alumina-alumina has been presented as a new option.
One of the characteristics of ceramic cracking is the "slow crack growth", responsible for the fracture out of fatigue. Most of the head cracks take place a few months after implantation. Alumina presents a higher rate of "slow crack growth" than that of zirconium since it is less fatigue resistant. The release of an acetabular component of a ceramic-ceramic prosthesis does not have a mechanism to produce debris, since the loose ceramic particles in the articulation represent a very low volume and have the advantage of being bio-inert.
Many factors are associated with the fracture of the ceramic, including trauma, intensive physical activity, obesity, head with a small diameter, manufacturing failures, and error in the implant placement and handling technique. In addition, there are doubts if the wear of the ceramic components is associated with malpositioning of the implant as long as there is no impingement.
The alumina liner inserted in the metal-back started to be used in 1983 and was one of the major revolutions that provided excellent results.
The purpose of our study was to follow-up a recent series of ceramic-ceramic THA with modular ceramic 28-mm implants introduced to our institution in 1998.

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Correspondence
Dr. Edmilson Takehiro Takata, MD
Universidade Federal
de São Paulo
Clínica Ortopédica
Escola Paulista de Medicina
Rua Borges Lagoa, 1065
Conj.126
Bairro Vila Clementino
04038-002 São Paulo
Brazil
Phone: + 55 11 55 73 52 97
Fax: + 55 11 55 73 52 97
edmilsontakata@uol.com.br

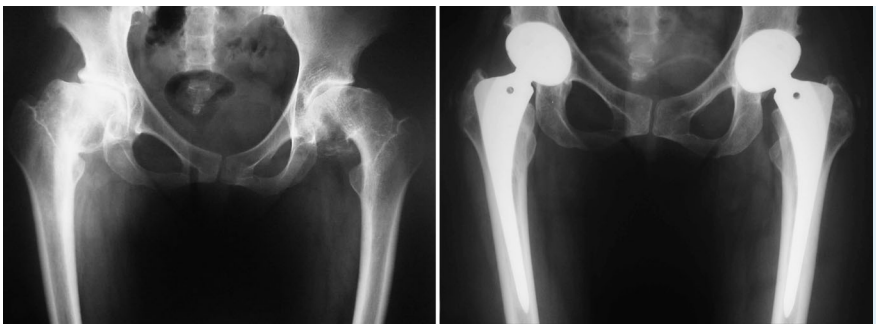

Fig. 1 Female, 32-year-old patient, with arthrosis and bilateral subdislocation of the hip. Operated bilaterally.

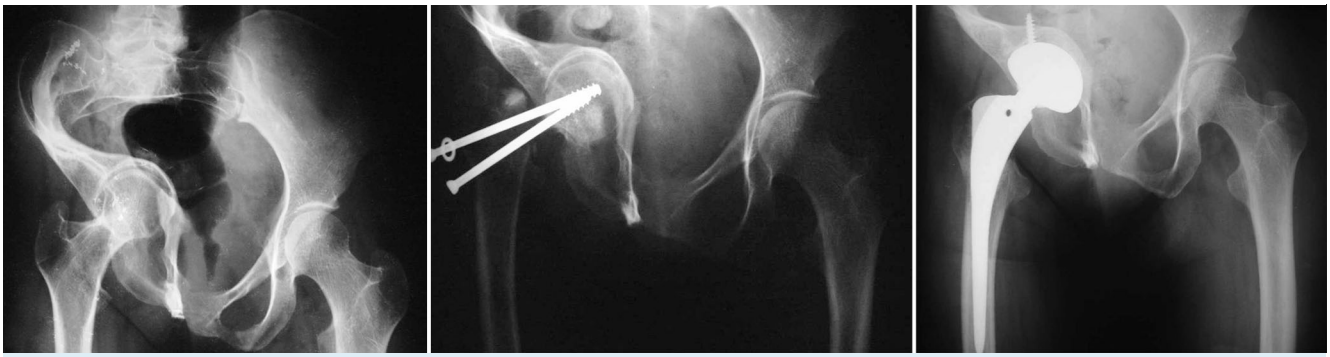

Fig. 2 Forty-year-old patient, with severe deformity, presented fracture of femoral head and failure of osteosynthesis. Arthroplasty performed, 3 years of postoperative treatment.

Material and Methods

Study performed at the Paulista School of Medicine-Federal University of São Paulo (Escola Paulista de Medicina-Universidade Federal de São Paulo), Brazil.

The study included patients with total hip arthroplasty between 11/1998 and 12/2005. In total, 356 patients were subject to the surgery, 419 hips having been operated on. Among deceased patients or those patients lost in the course of the study, there followed 309 patients (87%) and a total of 363 hip replacements.

Age varied between 13 and 75 years, with an average of 47.9 years in 77 female and 232 male patients. The indications of hip replacement were: 55 for primary osteoarthritis, 136 for secondary osteoarthritis, 97% for necrosis and 75 for fracture of the femoral head (**Table 1**). All surgeries were performed by the same surgeon and by the same surgical team. Bilateral staged THA (**Fig. 1**) and severe deformities (**Fig. 2**) were included in the study.

All implants were of the Bicontact STD and SD-type, cementless and Plasmacup (B.Braun-Aesculap, Tuttlingen, Germany) with Biolox forte ceramic-ceramic (Ceramtec, Plochingen, Germany). The sizes of the femoral components varied between small 9 SD sizes and large 21 STD sizes. The outside diameter of the acetabular components varied between 44 mm and 68 mm, with an average of 50 mm.

The femoral head that was mostly used was the one in leg length S, 28 mm in diameter. The patients were followed as outpatients with radiographic follow-up, using frontal and lateral X-rays. Follow-up was immediate post-surgery, 2 weeks, 6 weeks, 3 months, and then, each year.

Follow-up varied from 12 months to 85 months, with an average of 48 months.

Table 1 Indications for hip replacement

Indications for THA, n = 363	
Primary osteoarthritis	55
Secondary osteoarthritis	136
Avascular head necrosis	97
Femoral neck fracture	75

Pre-surgery template was used; intra-surgery fluoroscopy or navigation technology was not used. Sodium cefuroxime was used and prophylactic antibiotics. Prophylaxis of deep venous thrombosis was always started after 12 hours since the end of the surgery, with enoxeparine at the dosage of 40 mg 1×/day. Average surgical time of 63 minutes. Vacuum drain was used in all cases. Average duration of hospitalization was 5 days.

All patients had partial load cleared as of the second postoperative visit, when the drain was removed. During 6 weeks, the patients moved about with the help of two crutches or walker.

Results

Three prostheses underwent migration of femoral component larger than 5 mm. No acetabular component presented change in its position. Five prostheses dislocated and all were treated by closed reduction. None of these cases required revision. Three cases progressed with infection. Two early infections were cured with antibiotics and one late infection lead to implant removal. Two cases presented partial remission of the infection, with no need of implant removal and one presented an important infectious scenario that led to the removal of the implant.

One femoral head showed a crack. A 64-year-old female patient, 160 cm in height and 95 kg body weight, had a dislocation in the

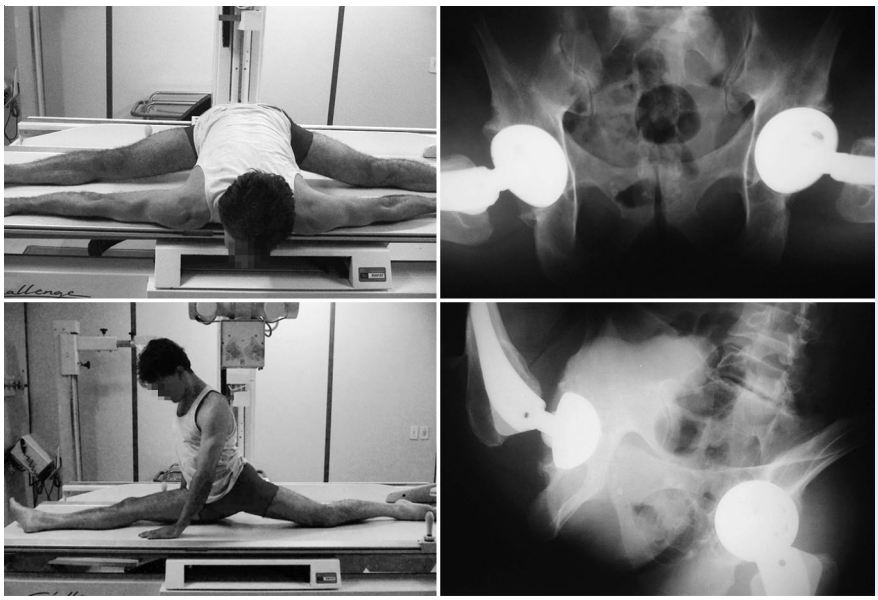

Fig. 3 Although the patient was alerted as to possible complications derived from the practice of sports, he returned, after 2 years, to practicing ballet daily.

immediate postoperative course, which was reduced. She presented with a crack in the ceramic head after 10 months, with no related trauma. During revision, the articulation was thoroughly cleaned, irrigated, all sinnovial tissue was removed and the liner and fractured head was exchanged for another alumina ceramic implant, however, 32 mm in size.

No sign of impact or malpositioning of the components was noticed and there was no case of liner breakage in the sequence. No prostheses presented with either acetabular or femoral osteolysis. There was no radiographically measurable wear in any of the cases.

Two patients presented a "noisy hip joint". One with squeaks and another with snaps, both audible. In the X-ray study, the prostheses components are in an excellent position and the patients do not present symptoms of pain or hip discomfort.

Discussion

The 3 prostheses stems that mostly underwent vertical migration higher than 5 mm and had to be revised, presented a size smaller than that which would have been necessary for the corresponding femur. After the substitution for larger-sized components, the problem was solved. The low rate of dislocation still tends to diminish with the higher diameter of 32-mm ceramic heads. Up to the present time, in three infection cases, there has been no revision of the components, but there was the need of a periodic surgical cleaning after 4 years, 2 years and 3 months, respectively. None of the two infected patients, who kept the prosthesis, presented with pain or any radiographic sign of release.

The study group has an average age of less than 50 years and patients' expectations for THA treatment are high (**Fig. 3**). The occurrence of one ceramic head fracture was seen 10 months after implantation. Undoubtedly, the excessive weight of this patient was a risk factor for the failure of the implant [4,5]. This same patient had a dislocation in the postoperative period that may have led to ceramic particles interposing itself in the articulation as three body wear and subsequently leading to implant breakage [6,7].

Although it has been frequently reported that the breakage of the head is an event that takes place during the first postoperative months, the described case may be a late breakage case. The fracture may occur many months – at times, years – after the surgery [8,9]. The calculated fracture rate of this sequence of 0.2% is caused by a single implant failure and is less than recently reported [5]. With the change in the size of the head from 28 mm to 32 mm, we believe that there will be a substantial reduction in the number of ceramic head cracks.

The articular noise is associated with the articulation of the hard-on-hard type; therefore, both metal-metal articulation and the ceramic-ceramic articulation can present this alteration. The reason for the sound emitted by the articulation continues to be uncertain and can be influenced by the cup implant position [10]. Although we have 2 cases with this type of alteration, none of them presents apparent radiographic or mechanical changes. The noisy hip has, up to the present time, had no relation with the operating performance of the prosthesis. The course of these cases will be subject of further follow-up.

The improvement in the quality of the ceramic and the design of the prosthesis has led to a significant reduction in the number of complications related with the ceramic-ceramic articulations [11]. The result of the cementless metal implants that uses this articulation surface has also been checked by us and we have found no case of implant loosening or osteolysis.

In our series, the cementless Bicontact prosthesis with ceramic-ceramic articulation presents an overall low rate of complications in mid-term follow-up.

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Treatment of Periprosthetic Femoral Fractures with the Bicontact Revision Stem

Authors C. Eingartner[1], U. Ochs[2], D. Egetemeyer[2], R. Volkmann[3]

Affiliations
[1] Unit for Trauma and Reconstructive Surgery, Caritas Hospital, Bad Mergentheim, Germany
[2] BG Trauma Centre, University of Tuebingen, Germany
[3] Department for Trauma and Reconstructive Surgery, Clinical Center, Bad Hersfeld, Germany

Key words
- total hip replacement
- periprosthetic fracture
- intramedullary nailing
- interlocking
- femoral revision

Abstract

Purpose: Periprosthetic fractures in cases without prior loosening of the stem can be treated with open reduction and internal fixation, but cases with preexisting loosening and/or bone defects present specific challenges to the surgeon. The keys to the success of intramedullary stabilization of femoral fractures – reconstruction of length, axis and rotation rather than meticulous reduction of the fragments and minimal impact on fragment vascularization by the surgical approach – can be transferred to the treatment of periprosthetic fractures.

Method: The Bicontact revision stem can be regarded as a combination of an interlocking nail in its distal part and a proximally coated femoral stem in its proximal part. The transfemoral approach respects the vascularization of the bone, although it is not minimally invasive. Forty-one patients with a mean age of 72.3 years and a periprosthetic fracture were included in this study. According to the Vancouver classification there were 2 type A fractures of the trochanteric region, 14 were B1, 8 were B2 with prior loosening, 13 were B3 with significant bone loss, and 2 fractures were distal to the tip of the prosthesis (type C).

Results: In all patients, intramedullary stabilization with a Bicontact revision stem was performed. All but three fractures healed (pathologic fracture with multiple myeloma in one case, impaired bone healing in two cases). In 7 patients, further procedures had to be undertaken (new periprosthetic fracture in 2, loosening and revision with a standard prosthesis in 2, revision with a long stem prosthesis together with bone grafting in 3 cases). At follow-up, after a mean of 4.3 years, all patients were able to walk, and the mean Harris Hip Score was 71.1 points.

Conclusion: In conclusion, combined application of the principles of intramedullary nailing and of uncemented total hip replacement by use of the distally interlocked Bicontact revision stem enables successful treatment of periprosthetic femoral fractures.

Introduction

Periprosthetic fractures of the femur are becoming increasingly common, as the number of patients with total hip replacements is getting higher and the life expectancy of these patients is also increasing. The cumulative postoperative risk for a periprosthetic fracture over a period of 15 years is estimated as 1 – 4% [10,21]. Patients who had their total hip replacement after trauma run a significantly higher risk than patients after other indications [22].

Several classifications [3,12] refer to the fracture morphology and the site of the fracture with respect to the prosthesis. Decision making can not be based solely on fracture morphology; in addition to the use of these classifications, prior loosening and bone loss also have to be taken into account [11,13,25].

Numerous procedures have been reported for the treatment of periprosthetic femoral fractures, including conservative treatment with or without traction [26], cerclage wiring for fractures of the trochanter and the shaft [2,5], stabilization with a specially designed clamp plate [17], a cable-plate system [24], fixation by traditional plating [25] or locked plating with an angular stable stabilization system (femoral LISS) [14]. Several modifications of cemented and uncemented revision have also been published [10,11]. Proximal femoral replacement has also been proposed as a reliable treatment option [15].

Periprosthetic fractures in cases without prior loosening of the stem can be treated with open

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Correspondence
Prof. Dr. Christoph Eingartner, MD, PhD
Caritas Krankenhaus
Unfall- und Wiederherstellungschirurgie
Uhlandstraße 7
97980 Bad Mergentheim
Germany
Phone: +49 79 31 58 30 01
Fax: +49 79 31 58 30 90
christoph.eingartner@ckbm.de

reduction and internal fixation, but cases with preexisting loosening and/or bone defects impose present challenges to the surgeon. In terms of biomechanics, loosening and bone loss are the main cause of instability, and most often there is no trauma or only inadequate trauma in the history. The fracture is only an epiphenomenon of the complex instability consisting of the lack of bone and the loss of fixation of the shaft. This instability has to be addressed rather than the fracture alone.

These considerations are reflected by the Vancouver classification of Duncan and Masri [6].

Intramedullary locked nailing represents a successful and proven procedure for femoral shaft fractures even in cases with extensive comminution and instability. The keys to success are the reconstruction of length, axis and rotation and minimal impact on fragment vascularization by the surgical approach rather than meticulous reduction of the fragments. This form of internal fixation, which is stable under partial weight-bearing though not completely rigid, generally facilitates healing of the bone fracture by callus formation and leads to restoration of a bone cylinder capable of weight-bearing. Full restoration of function can be achieved in almost all femoral fracture cases.

These experiences and principles can be transferred to the treatment of periprosthetic fractures. The Bicontact revision stem combines the principle of an uncemented femoral stem with locked intramedullary nailing. Although it is not minimally invasive like closed intramedullary nailing, the transfemoral approach enables easy exposure of the loose prosthesis, facilitates meticulous debridement of the intramedullary cavity and, most importantly, respects the vascularization of the bone. The restoration of the bone stock in the proximal femur can take place according to the mechanisms of fracture healing. The efficacy of this principle in femoral revision cases has been proven by several studies using different implant systems [4, 9, 23, 28, 29].

Distal load transfer is necessary during proximal bone healing, but it can be switched to proximal load transfer by removal of the interlocking screws [9].

This study demonstrates the operative principle and gives the results after mid-term follow-up of patients with periprosthetic fractures which are combined with or caused by loosening and loss of femoral bone mass.

Patients and Surgical Procedure

Patients

Forty-one patients with a periprosthetic fracture were included in this study. There were 18 men and 23 women and the mean age at the time of the fracture was 72.3 years (range 43 to 88 years). The involved side was left in 20 and right in 21 cases. In 24 cases, the femoral stem was cemented and 18 patients had an uncemented stem at the time of the fracture. The mean time between the primary total hip replacement and the periprosthetic fracture in 35 patients was 12.5 years (range 2 – 27 years), but 6 patients with an intraoperative or immediate postoperative periprosthetic fracture were also included in the study. Twenty-one patients had loose stems at the time of the fracture, 14 stems were well fixed and 6 fractures were perioperative or early postoperative during or after a primary replacement. According to the Vancouver classification, two fractures were type A, 14 were type B1 (including the perioperative fractures), 8 were type B2, 13 were type B3 and 2 fractures were distal to the tip of the prosthesis (type C).

In 19 patients, acetabular loosening was diagnosed in addition to the femoral problem.

Bicontact revision stem

The Bicontact revision stem (B.Braun-Aesculap, Tuttlingen, Germany) is manufactured from titanium and derived from the Bicontact standard stem for uncemented fixation. The major design parameters include a rectangular cross section, proximal coating with plasma-sprayed titanium, a lateral fin to enhance rotational stability and anterior and posterior support flanges plus a broad medial contour to support proximal press fit. Favorable results have been published with this stem [7]. The design of the distal part of the revision stem includes a star-shaped cross-section and two holes for distal interlocking. Diaphyseal fixation of the revision stem relies both on press-fit and distal interlocking, which has been shown to significantly increase primary stability [9].

Both an endofemoral and a transfemoral approach can be used for insertion of this stem.

Criteria for the decision on whether to use a conventional access or a lateral transfemoral approach include the morphology of the fracture, the extent of prior bone loss, the fixation of the primary femoral stem, the amount of bone cement and the question of whether acetabular revision has to be combined with the femoral procedure. In case of doubt, the transfemoral approach has been preferred by the authors.

Surgical procedure

The surgical technique of femoral revision by a transfemoral approach for periprosthetic fractures has been described in detail recently [8].

As in any case of shaft revision, meticulous preoperative planning is mandatory. For the transfemoral approach, the osteotomy should end as proximal as possible. In most cases, it is sufficient to do the osteotomy until 2 cm above the tip of the prosthesis, but this depends on the individual situation, especially with regard to the amount of cement distal to the tip of the prosthesis. The revision stem has to be anchored safely in the diaphysis distal to the zone of fracture, bone loss and instability, so it is wise to choose a shaft that is not too short. The distal interlocking holes should be at least 5 cm below the osteotomy. The stem should also not be too small in order to gain sufficient diaphyseal press-fit.

After intraoperative identification of the tip of the loose shaft, a safety cerclage is placed distal to the tip of the prosthesis. A long lateral osteotomy of the femoral shaft down to the tip of the prosthesis is performed, taking into account the fracture morphology. The femur is opened up by creating an anterior bone shell which is subsequently lifted to expose the loose shaft. Removal of the prosthesis and cement, debridement of the femoral canal and cup revision, if necessary, can now be performed easily.

The femoral canal distal to the osteotomy is now prepared by use of reamers. Tight press-fit in the diaphysis should be achieved. After insertion of the revision stem and trial reduction, distal interlocking can be performed by using either an aiming device or a radiolucent angular gear system.

After final reduction and adjustment of leg length and offset by use of different neck lengths, the anterior bone shell is reduced and fixed by circular cerclage wires. The major trochanter also has to be attached to the lateral fins of the prosthesis in order to avoid traction forces to the fragment by the abductor muscles.

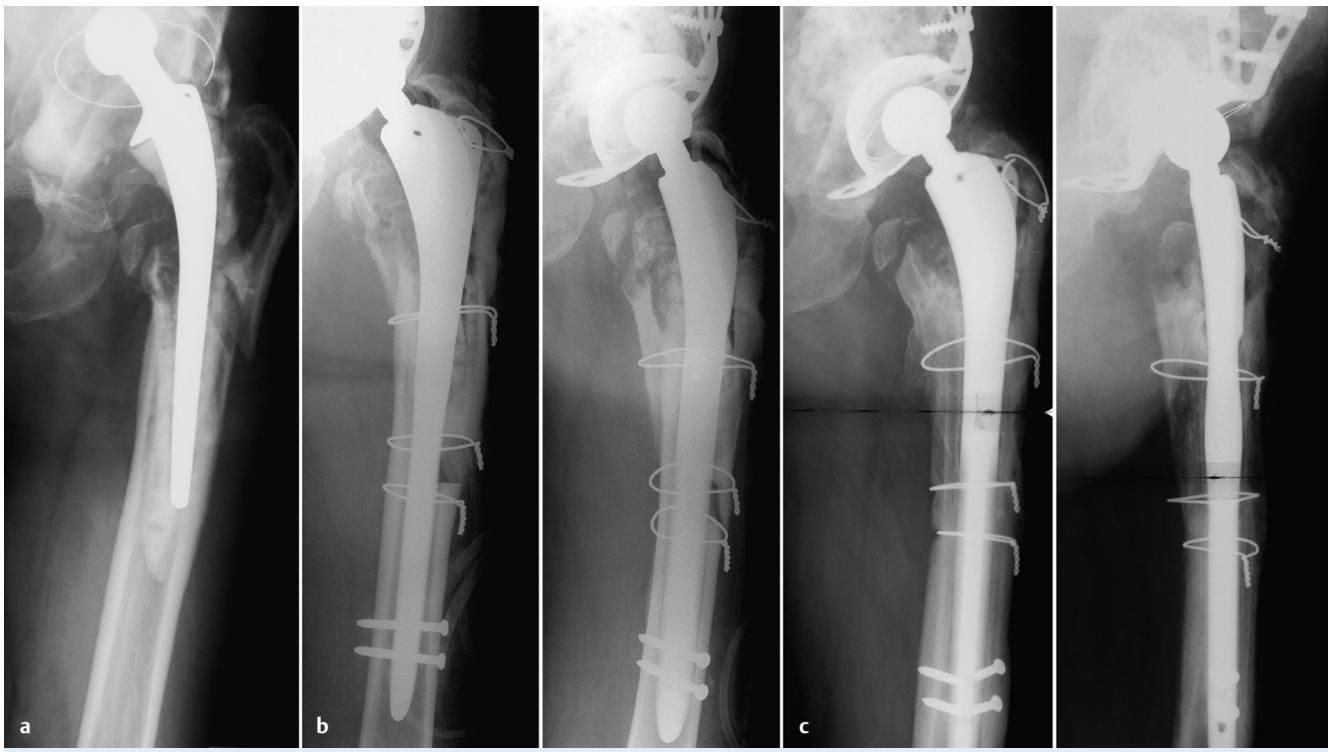

Fig. 1 a to **c** Case Example. **a** Preop: Male patient, 69 years, periprosthetic fracture, Vancouver Typ B3 with preexisting bone defect and implant loosening. Additionally, cup loosening with marked bone loss. **b** Postop: Stem revision via transfemoral approach and implantation of a distal locked cementless revision hip stem. Bone reconstruction with cryopreserved allogenic bone at acetabular and femoral side. **c** Five years follow-up: Consolidation of the fracture with good femoral bone remodelling. Subsidance of the revision hip stem by 5 mm and breakage of interlocking bolds. No further stem migration and stable fixation of the cementless revison hip stem. Good functional outcome with Harris Hip Score of 86 points.

Postoperative care includes bed rest for one week and partial weight-bearing for 12 weeks. During this time bone healing has to be monitored by X-rays after 6 and 12 weeks. After that, weight-bearing can be increased continuously.
The distal interlocking screws should be removed to avoid long-term distal load transfer and stress-shielding, but not earlier than 18 months postoperatively.
Follow-up visits are performed after 3, 6 and 12 months postoperatively and then on a yearly schedule.

Results

Femoral revision with a Bicontact revision stem was performed by use of a transfemoral approach in 41 patients, whereas a proximal (endofemoral) approach was sufficient in 14 patients. The mean length of the revision stem was 309 mm (range 240 mm – 380 mm), and the mean size was 17.6 (range 13 to 19) (size is not identical with the distal diameter in mm in the Bicontact revision system). Distal interlocking was performed in all but 2 cases, in which very tight diaphyseal press-fit could be achieved. Grafting, mostly with allogeneic cryoconserved cancellous bone, was performed in 16 cases. In 20 patients, an acetabular revision was combined with the femoral procedure, in 19 cases due to loosening and in 1 case due to wear of a non-modular cup. Mean surgical time was 183 minutes (range 77 – 270 minutes). A mean of 3.9 units of erythrocytes had to be transfused (range 0 – 10 units). The routine intraoperative swab was negative in all cases. All patients were given an antibiotic routinely (first generation cephalosporin).
Postoperative complications included hematoma (2 cases with surgical removal), two urinary tract infections and one case of deep vein thrombosis. In one case, the distal interlocking screws became loose within one month and had to be exchanged. Two patients sustained another periprosthetic fracture at the tip of the revision stem within the first postoperative months; it was resolved by additional plating in one case and by exchanging the stem for a longer one in another case.
In 7 patients, further revision had to be performed, including the already mentioned patient with a new periprosthetic fracture within the first postoperative month and another patient with a new periprosthetic fracture. In 2 patients, the revision stem was not properly osseointegrated and subsided after breakage of the interlocking screws, but the proximal femur was healed and a standard stem (one cemented, one uncemented) could be used in these cases. A revision stem had to be used in three cases of subsidence and loosening; allogeneic bone grafting was performed in two of these cases and transplantation of an autologous fibula graft in the third case.
Thirty-three patients could be followed up after a mean of 4.3 years (52 months, range 15 – 116 months). Six patients died during the follow-up period but the latest X-ray before death was included in the radiographic follow-up data. Two patients could not be contacted. Mean patient age at follow-up was 75.2 years. All patients were able to walk (**Fig. 1**), 14 patients did not make use of a cane or used it only for walking long distances, 13 patients used a cane most of the time or all the time, and 6 had to make use of two crutches. Mean Harris Hip Score was 71.1 points (range 30 – 95 points). Only one patient had a Harris pain score

of less than 20 points; the stem has subsided in this 82 years old patient with breakage of the interlocking screws.
Radiologically, all but three fractures were healed at the time of follow-up. In one patient the fracture lines were still visible and the remodeling of the proximal femur was insufficient. In one patient there was a multiple myeloma as the underlying cause of the periprosthetic fracture and the patient died some months after palliative intramedullary stabilization of his pathological periprosthetic fracture with the bone defect still visible. One 86-year-old patient showed impaired bone healing and absence of osseointegration together with a non-healed fracture; a second revision has been performed, again without radiologic confirmation of complete osseous healing. However, the patient was able to walk and the Harris Hip Score was 87 points.

Discussion

It is difficult to compare the treatment results of periprosthetic fractures in the literature, as the relevant patient populations are very heterogeneous regarding both the population and the selected surgical procedures [25]. Most publications dealing with periprosthetic fractures include only a small number of patients [11]. There are also some studies with a meta-analysis of a greater number of patients, but they also comprise more than a third of conservatively treated patients and can be regarded more or less as historical reports [1,18]. Fracture fixation by plating, screws and cerclages seems to have a greater rate of complications than revision arthroplasty [1,20]. Overall, the complication rate is high and the functional results are often disappointing [1,16,18].
Studies using a distinct stabilization system, like the LISS or a plate-cable system, usually report satisfactory results, but the selection criteria for this type of treatment always remain somewhat unclear. According to these publications, extramedullary stabilization seems to be a successful treatment option for fractures with non-loose femoral stems (Vancouver B1 and C) [14,24,25].
The Vancouver classification provides a clue to decision making in the treatment of periprosthetic femoral fractures, because it differentiates between periprosthetic fractures with and without loosening and bone loss [6].
Type A fractures of the trochanter region are rare and most often the result of direct trauma. Normally there is no loosening of the shaft and this type of fracture can be treated conservatively if undisplaced or operatively by cerclage wiring or plating.
Type B fractures are subdivided into B1 without loosening, which can be treated by open reduction and internal fixation (ORIF) with a plate, B2 with preexistent loosening and B3 with loosening and bone defect. In the latter cases, the problem of loosening and bone loss has to be addressed, hence simple plating is not able to resolve the underlying problem and is bound to fail within a short time [11,13,16].
Type C fractures are distal to the tip of the stem. Most often stress concentration in combination with osteoporosis is the underlying cause for this fracture type. If there is no loosening, these fractures can be treated by ORIF. However, in cases with reduced cortical stability and limited bone mass at the fracture site, it might be wise to bridge the zone of instability by intramedullary stabilization, i.e., a long revision stem.
In our series, the treatment of periprosthetic fractures according to this algorithm yielded acceptable results. The rate of postoperative complications and the need for further surgical procedures reflects the challenging population with a high proportion of patients with severe bone defects. The Harris Hip Score of 71 points demonstrates a satisfactory functional outcome.
Long-term results are still lacking, but there is some evidence that after fracture healing the results are comparable to those after revision due to aseptic loosening with defective bone in the proximal femur. In these patients, it could be demonstrated that a stable condition with a low loosening rate can be reached after the initial period with postoperative complications such as non-union and insufficient restoration of the proximal femoral bone stock [19]. If, however, the proximal bone defect has healed, no further loosening was observed in this population.
If repeat revision was necessary in some cases, the proximal bone stock and the fracture turned out to be consolidated; a standard stem could be used in these cases. Lack of distal press fit and stability despite interlocking, damage to the vascularization of the bone shells during the revision procedure, technical errors with limited contact of the bone shell fragments to each other and to the revision stem, and reduced biological bone healing activity may have contributed to the failures.
The study also has some limitations due to the small series. There are different subgroups with different fracture patterns and different degrees of bone loss so the patients and indications do not constitute a homogeneous group. Some patients with less loosening and bone loss (Vancouver type B1 and Type C), in whom a revision stem was used as intramedullary stabilization rod, were included in the study. Plating would also have been an alternative in these cases. However, in patients with intraoperative or early postoperative fractures after a primary THR (which are by definition type B1 fractures) intramedullary stabilization with a long-stemmed prosthesis seems to be the less invasive procedure.
In a large series of the Swedish Arthroplasty Registry there was a high risk for complications after operative treatment of periprosthetic fractures: nearly 25% failed and needed reoperation. The strongest negative factor was the use of a single plate for fixation in this study ($p = 0.001$). The authors speculated that many fractures classified as Vancouver type B1 were in reality type B2 fractures with a loose stem which were not recognized. Plate fixation was inadequate in these cases. The authors concluded that due to the difficulty in separating type B1 from type B2 fractures the prosthesis should be considered as loose until proven otherwise [16].
In this series, bone grafting was at the discretion of the surgeon. Further studies are required to elucidate the need for and the effect of different bone grafting options (autograft, cryoconserved allograft, processed allograft with autologous bone marrow stem cells).
Using different stems, both cemented and uncemented, reasonable results in Vancouver type B fractures could also be demonstrated [27]. Other modular and non-modular revision stems with and without distal interlocking can also be used to treat periprosthetic fractures according to the principles used in our series; however, only a few consistent studies have been published so far [30].

Conclusion

The Bicontact revision stem combines the principles of intramedullary nailing and uncemented total hip replacement. This stem offers a successful treatment option for periprosthetic femoral

fractures even in cases with preexisting loosening (Vancouver B2) or bone defect (Vancouver B3). A transfemoral approach is advisable in all cases with a high-grade bone defect, extended amount of cement or a distally osseointegrated uncemented stem. The fixation is stable although not absolutely rigid and enables healing of both the fracture and the periprosthetic bone loss. The functional outcome is quite satisfactory, especially when the advanced age and preexisting functional impairment of the study population are considered.

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Treatment of Large Femoral Bone Defects – 15-Year Experiences with the Cementless Bicontact Revision Stem with Distal Interlocking

Authors B. G. Ochs[1], R. Volkmann[2], C. Eingartner[3], I. Ludolph[1], S. Weller[1], K. Weise[1], U. Ochs[1]

Affiliations
[1] BG Trauma Center, University of Tuebingen, Tuebingen, Germany
[2] Department for Trauma and Reconstructive Surgery, Clinical Center, Bad Hersfeld, Germany
[3] Unit for Trauma and Reconstructive Surgery, Caritas Hospital, Bad Mergentheim, Germany

Key words
- total hip arthroplasty
- Bicontact revision stem
- long-term results
- femoral bone defect
- cementless

Abstract

Aim: With the steady growth in the number of hip arthroplasty revision operations, the concept and long-term results of the Bicontact revision stem with distal interlocking for the treatment of extensive femoral bone defects were investigated in this prospective study.

Method: The first 156 stem revision operations performed between January 1992 and December 2002 were evaluated. The indication for operation was aseptic loosening in 133, stem fracture in 14, recurrent dislocation in 2 and reimplantation following Girdlestone removal of a septic prosthesis in 7. The cup component was revised at the same time in 74 cases.

Results: Higher-grade femoral bone defects were found intraoperatively in 66%. The average age of the patients was 71.4 (34 – 88) years at operation and 76.9 (44 – 94) years at the last follow-up. The average period until follow-up, re-revision or loss to follow-up was 5.54 (0.1 – 14.9) years. The clinical and radiological follow-up rate (with reference to the total number of patients) was 35% (55 von 156), and 51% (55 of 107) with reference to patients still living. The median Harris Hip Score was 63.7 points. In the observation period, 12 stems were exchanged for a cemented standard stem, 5 stems were removed because of infection and 2 stems were revised because of periprosthetic fracture. The calculated survival rate for the stems after 14.9 years was 85.9%.

Conclusion: The 15-year results confirm the biomechanical concept of the Bicontact revision stem with optional distal interlocking for the treatment of extensive bone defects in stem revision surgery.

Introduction

Because of the steadily growing number of total hip arthroplasties and demographic changes, the number of hip revision operations is increasing accordingly. Approximately 60 000 hip revision operations are performed annually in Europe, approx. 16 000 in Germany alone [24], and over 20% are re-revisions [18]. With a relative proportion of 80%, aseptic loosening is the commonest reason for revision surgery. As in the acetabulum, treatment of existing femoral bone defects during revision surgery is one of the most difficult problems [16,25]. The need for preoperative planning is regarded universally as essential for the success of the operation. The surgeon must take into account the overall health of the usually elderly patients and the existing bone defect when devising a strategy for implant and cement removal in order to achieve a stable and lasting reconstruction. Apart from choosing a suitable implant, adequate biological reconstruction of any defect of the proximal femur can be regarded as a crucial requirement for a good long-term result.

The Bicontact revision stem (B.Braun-Aesculap, Tuttlingen, Germany), a straight stem, has been used in an unaltered design in the corresponding hospital since 1992 for both cementless revision of a loosened arthroplasty and for management of periprosthetic femoral fractures [13]. This revision stem is indicated particularly when the medullary canal has a thinned cortex and extensive bone loss and/or has been weakened by cortical bone windows after removal of cement. The design of the Bicontact revision stem (**Fig. 1**) enables primary diaphyseal stabilisation and then metaphyseal fixation by reconstructing bone around the proximal parts of the prosthesis (secondary reverse of the fixation principle). Axial primary stability is achieved by the conical stem design and by distal screw interlocking, similar to

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Correspondence
Dr. Uwe Ochs, MD
Berufsgenossenschaftliche Unfallklinik Tübingen
Schnarrenbergstraße 95
72076 Tuebingen
Germany
Phone: +49 70 71 6 06 11 67
Fax: +49 70 71 6 06 10 02
uochs@bgu-tuebingen.de

Fig. 1 Cementless Bicontact revision stem with distal interlocking (B.Braun-Aesculap, Tuttlingen, Germany).

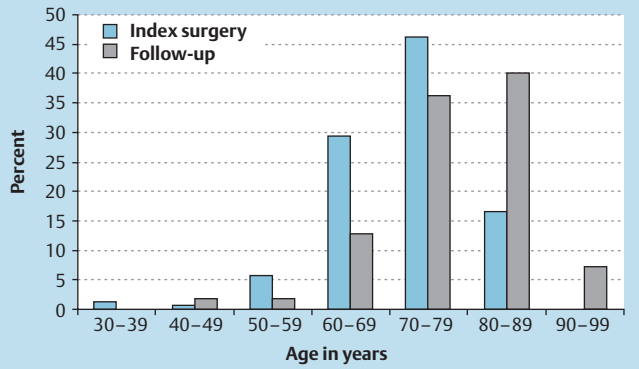


Fig. 2 Age distribution of the patients at the time of index surgery and at the time of follow-up (in %).

Table 1 Indications for revision surgery

Indication	Number	%
Aseptic stem loosening	59	37.8%
Aseptic cup and stem loosening	74	47.4%
Fracture of prosthetic stem	14	9.0%
Two-stage reimplantation with Girdlestone after septic prosthesis removal	7	4.5%
Recurrent dislocation	2	1.3%
Total	156	100.0%

an interlocking nail. Rotational stability is increased by the distal star-shaped cross section of the stem. The proven proximal Bicontact stem design with the microporous titanium Plasmapore coating supports secondary stability. This optimised restoration of the proximal femoral bed is the precondition for long-term fixation and stability.

In this article, the results of 15 years of experience with the Bicontact revision stem for cementless revision of the loosened total hip arthroplasty will be presented.

Material and Method

Patients

The first 156 stem revision operations performed between January 1992 and December 2002 were evaluated. The indication for operation was aseptic loosening in 133, stem fracture in 14, recurrent dislocation in 2 and reimplantation following Girdlestone removal of a septic prosthesis in 7. The cup component was revised at the same time in 74 cases. The consecutive study included the first 156 cementless Bicontact revision stems used in 149 patients (unilateral in 142 patients and bilateral in 7 patients) since the introduction of this stem. 56% of the patients were female. The right side was affected in 58% of cases. The average age of the patients at the time of operation was 71.4 (34–84) years (**Fig. 2**). The average body mass index was 26.4 (17.7–43.4) kg/m^2. In 108 cases, the described operation (index operation) was the first stem revision, in 39 cases the 2nd stem revision, in 8 cases the 3rd stem revision and in one case the 4th stem revision. Up to the index operation, the acetabular component had already been revised once in 45 cases and twice in 5 cases. Revision of the acetabular component was performed at the same time in 74 cases as part of the described revision operation. The indications for revision surgery are listed in **Table 1**. The average interval between the primary operation and the revision operation described here was 14.4 (1–30) years and the average period between the last and this stem revision was 7.2 (1–14) years. 87 patients already had a total hip arthroplasty on the opposite side; this system had already been revised once in 26 patients (isolated cup revision in 7; isolated stem revision in 3; cup and stem revision in 16) and twice in 4 patients (cup and stem revision in each case).

The stem revision operation was performed through a transfemoral approach in 113 cases [29] and endofemorally in 43 cases. The implant length of the revision stems was distributed as follows: 230 mm: 4, 240 mm: 13, 250 mm: 22, 260 mm: 1, 290 mm: 19, 300 mm: 64, 340 mm: 24, 360 mm: 1 and 380 mm: 8. Distal interlocking was performed in 94.3% of the revisions. One interlocking bolt was used in 19 cases and two bolts were used in 129 cases. Additional cancellous bone grafting was performed in 55% of cases (autologous iliac crest: 52; allogenic bone bank graft: 34). Supplementary internal fixation in the form of wire cerclages and/or trochanter tension banding was necessary in 85.9% of the operations. All patients were given perioperative antibiotic therapy.

Follow-up

All patients were evaluated both clinically and radiologically. The hip situation was assessed subjectively by the patients and the Harris Hip Score was recorded [17]. The radiological examination consisted of an a.p. radiograph of the pelvis and X-rays of the affected hip and proximal femur in 2 planes. These radiographs were analysed with regard to stem position, osseointegration of the stem or signs of loosening in the form of Gruen zones of lysis [15] and heterotopic ossification [3]. For migration analysis, the vertical subsidence of the stem was measured using the technique reported by Callaghan [4]. The preoperative bone substance defect in the femur was recorded with the Katthagen

Table 2 Peri- and postoperative complications

Complications	Number	%
Haematoma requiring revision	5	3.21%
Deep vein thrombosis	2	1.28%
Ileus	2	1.28%
Stroke	1	0.64%
Vascular injury requiring intervention	1	0.64%
Postoperative dislocation	1	0.64%
Persistent peroneus injury	4	2.56%
Fissure	2	1.28%
Fracture	1	0.64%
Superficial wound infection	2	1.28%
Total	21	13.46%

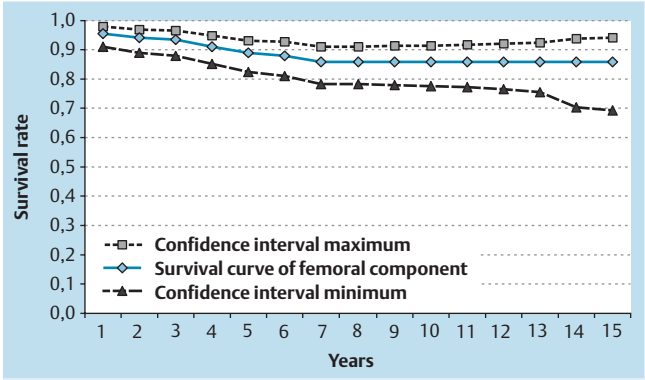


Fig. 3 Survival curve of the femoral component (n = 156, shown in blue).

classification [1]. The reconstruction and remodelling of the bone defect were analysed accordingly in the zones defined by Gruen [15].

Statistical analysis

The statistical analysis was based on the articles by Murray and Dobbs [11,22] for construction of a survival table and used Rothmann's equation to calculate the cumulative survival rate [26]. In a worst-case analysis, stem revision or removal and/or loss to follow-up was defined as end point.

Results

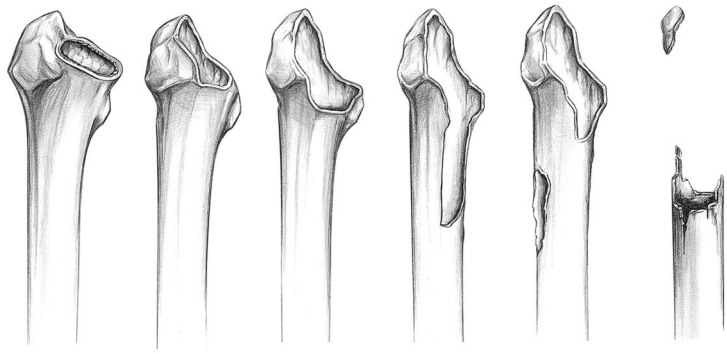
Up to the time of the most recent follow-up, 47 patients (49 revision stems) had died an average of 4.7 (0.1 – 10.3) years after the index operation. 8 patients had moved away or were abroad permanently and so could not be contacted for follow-up. 24 patients (25 revision stems) were fully confined to bed or required nursing care so that no evaluable record of the functional outcome as perceived by the patient was possible. 12 patients had further aseptic stem loosening an average of 3.0 (0.5 – 6.7) years after the index operation. In all 12 patients it was possible to implant a standard cemented prosthesis in the reconstructed proximal femur. In 5 patients, the prosthetic system had to be removed because of deep infection an average of 1.8 (0.7 – 3.9) years after the stem revision operation. In these 5 patients, the reason for revision was aseptic loosening in 3 cases, implant fracture in one and reconstruction of a Girdlestone resection following infection of the prosthesis in one. Thus, the reinfection rate after septic prosthesis revision was 14.3% and the infection rate after aseptic revision was 2.7%. In two other cases, a periprosthetic fracture occurred with an adequate fall, once after three months and once after 5.8 years; these required additional internal fixation with a plate.

The average follow-up period of all 156 cases until the last follow-up with the prosthesis in situ, removal of the prosthesis or death was 5.54 (0.1 – 14.9) years. The average follow-up of living patients with the prosthesis in situ (52 patients, 55 revision stems was 8.5 (4.2 – 14.9) years. The average age of these 52 patients at the time of follow-up was 77.9 (46 – 94) years (see **Fig. 2**). The follow-up rate for the entire group of patients was thus 35% (55 of 156), and 51% with reference to patients still living 51% (55 of 107). The peri- and postoperative complications of the revision operations are shown in **Table 2**. The calculated survival rate after Murray was thus 85.9% for the stems after 14.9 years with a confidence interval of 0.694 (lower) to 0.942 (upper limit) [22] (see **Fig. 3**).

The median Harris Hip Score at the time of follow-up was 63.7 points. In the subjective assessment at the time of follow-up, 19% of the patients were extremely satisfied, 24% were very satisfied and 35% were satisfied with the in situ prosthesis.

On radiological analysis, there was a major femoral bone defect preoperatively in 66%. **Fig. 4** shows the distribution according to the DGOT (today DGOOC) classification [1]. The remodelling of the bone substance defects in the zones defined by Gruen was analysed and is shown in comparison with the preoperative situation in **Fig. 5** [15]. In 86.6% of all 156 stems, the position was neutral, 8.1% had varus deviation and 5.4% had a valgus position. In 19% of all stem revisions that were initially interlocked distally, the interlocking bolts were removed an average of 12.2 (5 – 32) months postoperatively. In 15% of all stem revisions that were initially interlocked distally, where the bolts were not removed (**Fig. 6**), fracture of these occurred after an average of 15.3 (1 – 54) months after the index operation. In the observation period of 5.54 (0.1 – 14.9) years for all 156 cases (up to the last follow-up with the prosthesis in situ, removal of the prosthesis or death), stem sintering of an average of 9.6 (2 – 50) mm was observed in 31.5% of cases. Further stem sintering of up to 15 mm occurred in the patients from whom the interlocking bolts were removed. On the other hand, stem sintering of up to 50 mm was observed in the patients with fracture of the interlocking bolts. In the 9 revision stems not interlocked initially, sintering of 5 mm on average occurred in 2 cases. When the stem sintering was analysed with reference to the implantation technique, average sintering of 10 (2 – 50) mm was found in 34.2% with the transfemoral revision operations and average sintering of 8 (2 – 20) mm in 24.4% of the endofemoral revision operations. In the 12 patients in whom further aseptic stem loosening occurred after an average of 3.0 (0.5 – 6.7) years after the index operation, 9 stem revisions were transfemoral and 3 were endofemoral. In these 12 patients, the average sintering between the index operation and further stem revision was 11 (8 – 25) mm with the transfemoral approach and 12 (6 – 15) mm with endofemoral revision.

At the last follow-up of the 55 revision stems, reactive lines (< 2 mm) were found in 8% to 29% in all Gruen zones. Reactive lines wider than 2 mm were found in 2% to 8% in Gruen zones I, IV, VI and VII. Loosening of Bicontact revision stem was found in one patient, so that a further stem revision had to be recom-



Grade	I	II	III	IV	V	VI
%	14,5	11,2	8,6	15,1	50,0	0,7

Fig. 4 Distribution of the preoperative femoral bone defects after Katthagen [1].

mended. The radiologically detectable heterotopic ossification was classified according to Brooker [3]. There was no ossification in 34.5% of the patients. Grade I ossification was found in 21.8% of cases, grade II in 5.45% and grade III in 38.18%. Grade IV ossification was not found.

Discussion

When revising a loosened femoral component, it is possible to achieve stability of the new femoral component by cementing it in or by cementless fixation of the component. The disadvantage of the cemented revision technique is that the bone prosthesis bed is widened, thinned and sclerosed by the loosening of the primary prosthesis. This markedly weakens the adhesion of the cement in the bone. Studies have shown that the loading capacity of the bone-cement bond for shear forces is reduced by 79% with cemented revisions (at the first revision) and by 93% (at the second revision) compared to a cemented primary implantation [12]. This explains the markedly increased re-revision rate of cemented revision prostheses compared to cementless revision components [30]. Moreover, the cemented revision technique leads to further bone loss if there is further failure. However, this contradicts the actual aim of the revision operation, which consists essentially of avoiding further bone loss and if possible of building up any bone defect that is present. Thus the trend today is clearly toward cementless revision systems [5–10, 31]. Depending on the extent of bone loss that has occurred due to loosening, long-stem revision prostheses that bridge the defect are required, which are supported primarily in the diaphyseal region [19, 20]. Subsequently, however, proximal transmission of force is desirable even with long-stemmed implants in order to avoid further atrophy of the proximal bone stock or material fatigue fractures. Other challenges in the revision situation are the leg length difference, the choice of antetorsion and the function of the pelvitrochanteric muscles.

Among the hip revision prostheses, a distinction is made between monobloc implants and modular systems, on the one hand, and on the other hand between straight and curved stems. When planning the operation, it should be noted that longer straight stems (length > 225 mm) must usually be implanted through a transfemoral approach in order to avoid anterior perforation of the femur. On the other hand, antecurved stems even with greater lengths can be implanted endofemorally in the absence of femoral deformity. The Bicontact revision stem is a straight stem with the option of temporary distal interlocking. With this revision stem, the design concept of "reverse fixation" is enabled by primary diaphyseal stabilisation by means of temporary distal interlocking and secondary metaphyseal fixation by proximal bone remodelling. Following stem revision and corresponding remodelling of the proximal femur, this revision stem can be "dynamised" by removal of the interlocking bolts or by their fracture and can wedge in the proximally reconstructed bone by short-term secondary sintering. As a result, the transmission of force shifts from primarily distal initially to secondary proximal metaphyseal transmission and promises long-term biomechanical stability.

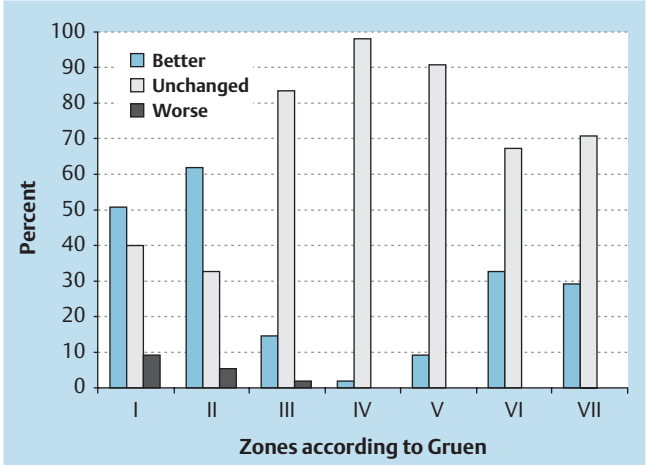


Fig. 5 Remodelling of the femoral bone substance defects in Gruen zones I–VII compared to the preoperative situation.

In studies of 109 patients with an average follow-up of 5.25 years (maximum 9.7 years), Volkmann [28] reports good medium-term results with the Bicontact revision stem. In their patients, the reason for revision of the in situ hip arthroplasty stem was aseptic implant loosening in 69%, implant failure (material fracture of the stem) in 14%, periprosthetic fracture in 11% and Girdlestone situation in 6% after septic prosthesis removal. The revision rate because of further aseptic stem loosening in the observation period was 12.8% and the calculated survival rate according to Murray was 85.3% for the stems after 9.7 years. The

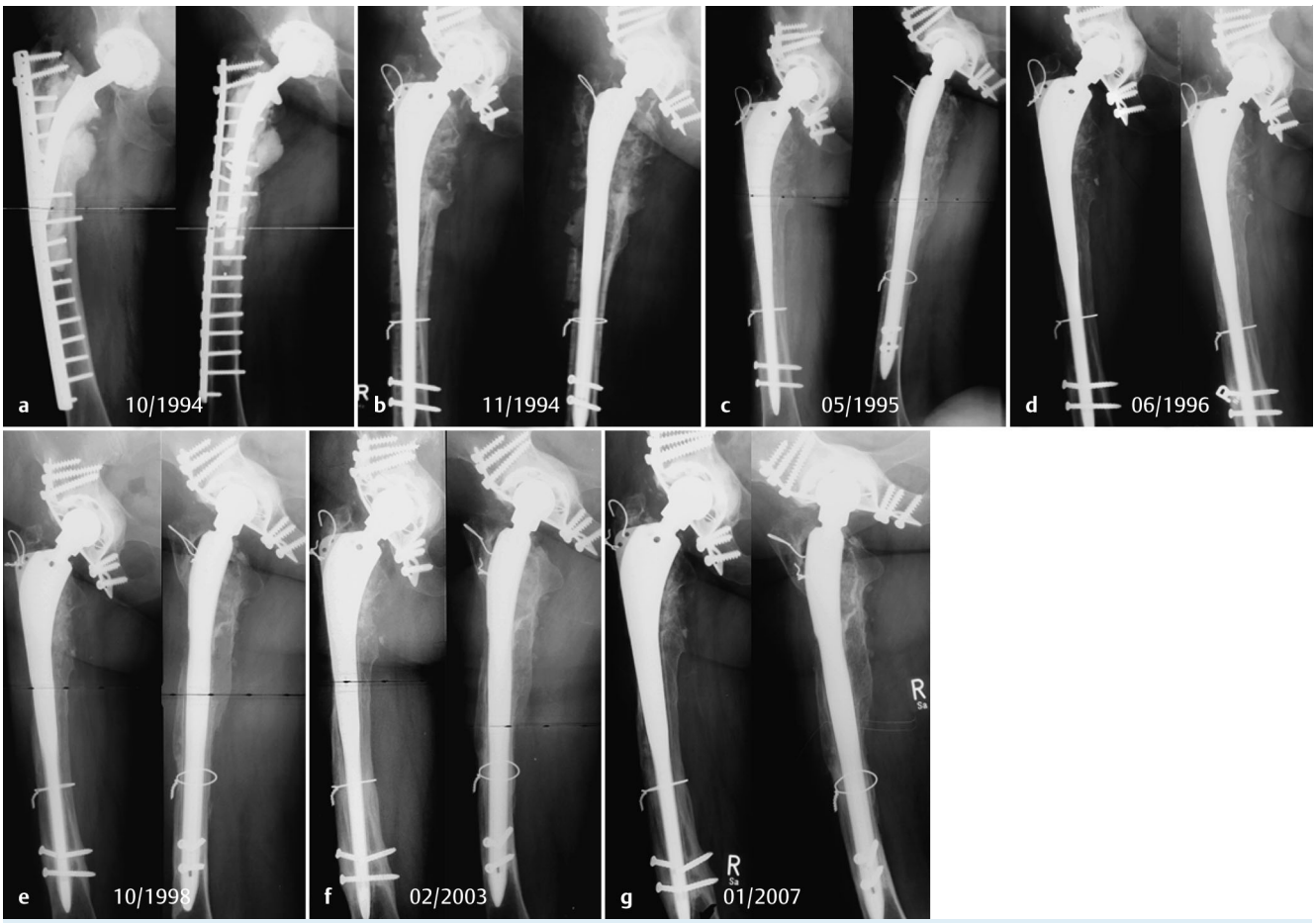


Fig. 6a to **g** A today 74-year-old female patient (AZ 4.4.1933) received THA (cemented stem with non modular 32 mm head and PE-cup) in the age of 46 in 1976. The third revision intervention followed at the age 61 years (1994) in a situation of complete periprosthetic femoral bone loss (Grade VI acc. to Katthagen classification). An acetabular reconstruction cage (Schneider Burch type), with autogenous acteabular bone reconstruction and a cementless Bicontact revision stem with distal interlocking was implanted (**a, b**). Periprosthetic bone remodelling needed more than one year and was delayed. Therefore the distal interlocking bolts remained in situ. 19 months after revision surgery one bolt broke as the proximal bone stock was not sufficiently stable (**c, d**). The further course showed proximal wedging of the revision stem into new formed proximal bone femoral stock (**e, f**). After 12 years follow-up shows the situation of the second bolt and only a small further sinking of the cementless revision hip stem (**g**).

recent follow-up described here of a total of 156 consecutive stem revision operations, which were performed in the period from January 1992 to December 2002, confirm the concept of the Bicontact revision stem, which was unaltered in design throughout the 15-year period, for the treatment of femoral bone defects in the stem revision situation. In contrast to the studies by Volkmann [28], patients who had stem revision because of periprosthetic fracture were excluded from our study and analysed separately [13]. In contrast to our study, Böhm [2] presented the 12-year results with the Wagner SL revision stem (1st generation). In the patients they described (129 cases), the indication for stem revision was aseptic loosening in 75%, periprosthetic fractures in 10% and infection or Girdlestone prosthesis removal in 15%. The re-revision rate in the observation period of 0.1 – 11.7 years was 5% and the survival rate for the stems was 93.5% after 11.7 years. Compared to our patients, the patients were an average of 6.5 years younger at the time of the index operation and there were bone defects limited to the proximal quarter of the femoral shaft in approx. 70% of all revision operations (stage 1 and 2a according Pak [23]).

Compared to these two monobloc implants, the modular revision prostheses enable intraoperative variation of stem length and adjustment of the antetorsion angle to ensure a balanced leg length and corresponding function of the pelvitrochanteric muscles [5, 6, 9, 10]. However, the significance of the Morse taper junctions of modular prosthetic systems is still very controversial. Critics describe problems with regard to these junctions. These might be regarded as breaking points and possibly cause additional wear. Advocates of the modular systems do not see any difficulties [8, 10, 14, 21, 27]. A final assessment is not yet possible, however, because of the lack of long-term results with modular prosthetic systems for revision in the presence of large bone defects.

The 15-year results confirm the biomechanical concept of the Bicontact revision stem with optional distal interlocking for the treatment of extensive bone defects in stem revision surgery.

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The Uncemented Primary Bicontact Stem in Revision Total Hip Arthroplasty in Young Patients

Authors F. Thorey, M. Lerch, H. Kiel, G. von Lewinski, C. Stukenborg-Colsman, H. Windhagen

Affiliation Department of Orthopaedic Surgery, Hannover Medical School, Germany

Key words
- total hip arthroplasty (THA)
- revision
- young patients
- Bicontact

Abstract

Aim: The purpose of this study was to evaluate the uncemented primary Bicontact stem (B.Braun-Aesculap, Tuttlingen, Germany) as a possible adequate alternative to other revision systems in revision total hip arthroplasty.

Methods: Twenty patients aged up to 58 years (34 – 58 years, mean age 5.7 ± 5.8 years) with minor bone defects underwent a revision total hip arthroplasty with the uncemented primary Bicontact stem. The patients were assessed clinically and radiologically at follow-up (follow-up: 8.0 ± 3. years).

Results: The postoperative Harris Hip Score, Motion and Pain Score improved significantly. There was only one further revision in these patients because of infection and only one case with mild stress shielding.

Conclusion: The uncemented primary Bicontact stem seems to be a good alternative to other revision systems in total hip revision arthroplasty in young patients.

Introduction

The uncemented primary Bicontact stem (B.Braun-Aesculap, Tuttlingen, Germany) was developed for primary total hip arthroplasty. This implant allows biological fixation through osseointegration of the proximal part of the stem so that long implant survival can be achieved [1]. Fixation of the femoral component in the diaphyseal region depends on bone-implant contact, operative preparation of the medullary cavity and a high degree of initial torsional and axial stability of the implant. Use of a primary stem for revision was described in the past by different authors [2 – 6]. Even nowadays, revision of a THA is a technical and surgical challenge for the surgeon because of the lack of possibilities for fixation when there are defects in the femur. In many cases, the cortical bone is not sufficient to permit initial torsional or axial loading. Especially in younger patients, who often make higher demands on their implant than elderly patients, THA revision is a challenge for the surgeon. The implant is often subjected to far greater loading and stress in the patient's occupational and social life and loosens more readily than in elderly patients [7,8]. Moreover, the prompt reintegration of the patient at work nowadays plays an existential role and should be taken into consideration when choosing an appropriate implant [9]. In this retrospective study, the clinical and radiological results in young patients after a revision operation with the uncemented primary Bicontact stem were investigated. This was intended to show whether the uncemented primary Bicontact stem is suitable for use in young patients in the case of revision.

Material and Methods

In this study, 20 patients who had THA revision with the uncemented primary Bicontact stem between December 1991 and June 2003 were investigated (average follow-up period: 8.0 ± 3.7 years) (**Fig. 1**). The average age of the patients at the time of operation was 52.7 ± 5.8 years (min. 34 and max. 58 years). There were 11 female and 9 male patients with an average weight of 75 ± 16 kg (average body mass index BMI = 27.0). Three patients with Paprosky class I and II defects were included in this study [10, 11]. Two patients could not attend for follow-up and were interviewed by telephone and with a questionnaire. All patients were studied clinically using the Harris Hip Score, a mobility score

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Correspondence
Dr. Fritz Thorey, MD
Orthopädische Klinik
Medizinische Hochschule Hannover
Anna-von-Borries-Straße 1 – 7
30625 Hannover
Germany
Phone: +49 511 5354545
Fax: +49 511 5354683
fritz.thorey@annastift.de

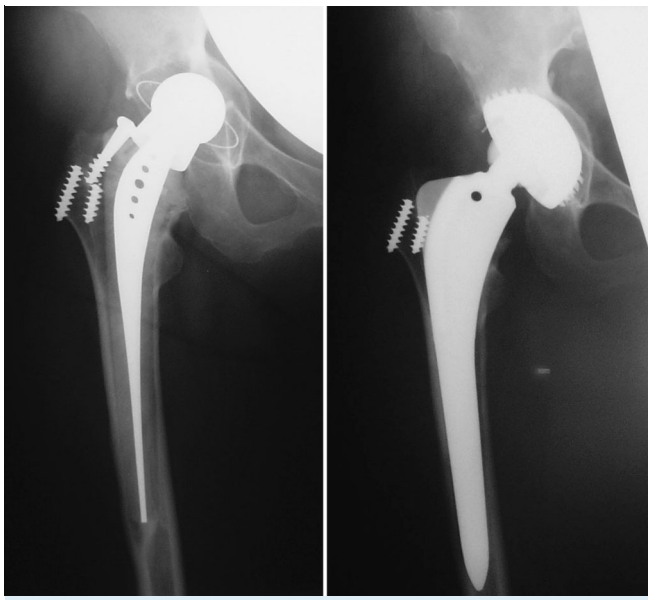

Fig. 1 Example of a patient who had femoral revision of a total hip arthroplasty with the cementless primary Bicontact stem. Pre- and postoperative a. p. radiographs

(from 0 = no flexion to 6 = maximal flexion) and a pain score (from 0 = no pain to 10 = severe pain). The pre- and postoperative conventional radiographs (antero-posterior and axial views) and repeat radiographs at the time of follow-up were assessed for femoral defects and proximal loss of bone substance and the quality of bony fixation of the stem was estimated. The femoral defects were graded according to the classification described by Paprosky [10,11]. The pre- and postoperative data were processed and analysed statistically (paired Student's t-test). Of the 20 revised total hip arthroplasties, five had first been implanted in the author's orthopaedic clinic. All preoperative radiographs were assessed with regard to metaphyseal bone defects, offset and leg length. All revision operations were performed through a lateral transgluteal approach. In one case, a transfemoral approach was also necessary for explantation of a cemented stem.

After removal of the loose stem, the femur is prepared for the stem size to be implanted using two different medullary cavity profilers according to the Bicontact system operation instructions. The uncemented primary Bicontact stem is a straight stem without a collar made of titanium-alloy, which can be used with a 28 mm or 32 mm ceramic or metal head. The proximal part consists of plasma-sprayed microporous titanium (average pore size 50 – 200 micrometres), which enables proximal ingrowth of the stem in the femoral bone. The stem has two antero-posterior flanges and one lateral wing, which enable proximal transmission of force to the bone, thus guaranteeing high primary stability. After insertion of the stem, intraoperative stability was tested by appropriate manipulations of the stem. Femoral fissures that occurred in four cases were managed with wire cerclages. Postoperatively all patients were given weight-adapted antithrombosis prophylaxis with low molecular heparin and a Spiker pressure bandage. An antibiotic was given for five days postoperatively to prevent infection.

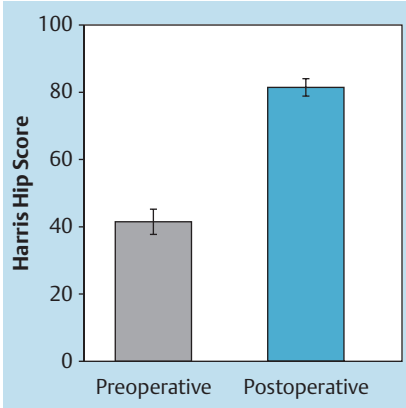

Fig. 2 The preoperative Harris Hip Score was 41.5 ± 15.9 and improved significantly to 81.4 ± 11.0 ($p < 0.001$) at the time of the last follow-up.

Results

The reasons for stem revision were: 12 aseptic loosenings, 2 infections, 2 recurrent dislocations and 4 other reasons. The two patients with the infected total hip arthroplasty were treated in a two-stage procedure with an interval of 6 weeks between the two operations with the Bicontact stem. In three cases the loose stem had been cemented primarily. In two patients long stems (Wagner type) had been used primarily and a short stem prosthesis (CUT 2000 type) had been used in one patient. The other explanted stem types could no longer be established retrospectively or from the radiographs. Precise assessment of intraoperative metaphyseal defects was not possible retrospectively. Simultaneous cup revision was performed in 13 patients. Access for prosthesis revision was through an anterolateral transgluteal approach. The average implanted stem size was 15 ± 2 mm (min. 12 mm, max. 19 mm).

During the follow-up period, re-revision of the prosthesis was necessary in only one case. This was because of re-infection in the second year after the revision operation. No periprosthetic fractures were seen intraoperatively. In four cases, small fissures occurred during removal or implantation of the stem. Slight stress shielding was seen radiologically in only one case. An allograft was used to fill the bone defect in six patients.

All of the patients in this study benefited from the operative procedure with regard to mobility and pain. The preoperative Harris Hip Score was 41.5 ± 15.9 and this improved significantly to 81.4 ± 11.0 ($p < 0.001$) at the time of the last follow-up (**Fig. 2**). The mobility score improved significantly from 2.2 ± 1.1 to 4.2 ± 0.8 ($p < 0.001$) and the pain score fell significantly from 7.1 ± 1.4 to 2.4 ± 1.3 ($p = 0.001$) after the revision operation.

Discussion

Revision of a total hip arthroplasty is even nowadays a technical challenge for the surgeon as the prosthesis must be fixed in bone that is often defective proximally. The first attempts at hip revision were undertaken with an uncemented prosthesis. The results of this study published by Kavanagh et al. in 1985 showed loosening rates of 44% after 4.5 years *in situ* [12]. In consequence, many authors switched to using mainly cemented long-stemmed prostheses in revision situations in order to improve fixation in the bone and the clinical outcome. Despite this, the improvement in the clinical results was negligible [13,14]. Uncemented stems were again used by many surgeons subse-

quently for revision as these showed good results in primary hip replacement. Nonetheless, a few authors described complications, such as early loosening [15–21], which were often associated both with inadequate initial stability of the stem and with a defective bone bed [16,20]. As a reaction to these problems, hip stems were increasingly inserted that had fixation far distally. Better osseointegration of the prosthesis with survival rates of up to 95% after 13.2 years was attributed to this prosthesis design [6]. However, the stems with extensive surface coating that were developed subsequently and frequently employed produced extensive proximal stress shielding in many cases [2,3, 22–24]. In addition, removal of a fully coated stem was markedly more difficult during re-revision [23]. Other authors described placement of allografts to improve the femoral bone bed. Both good and poor clinical results are described in the literature for this technique [25–27].

Since the primary total hip arthroplasty in younger patients has a much lower useful life than in elderly patients because of the obvious increased loading in the occupational and social sphere, a revision operation is a challenge particularly in patients who required hip replacement at a very young age [7,8]. Moreover, prompt reintegration at work nowadays and prolonged fitness for work play an existential role and should be taken into consideration when choosing an implant [9].

In this retrospective study in young patients, there was a significant increase in the Harris Hip Score and mobility score and a significant decrease in the pain score. Other studies showed similar improvements in the clinical outcome. Crawford et al. demonstrated an improvement in the Harris Hip Score to up to 86.0 in 58 patients (follow-up period 3.3 years) [22]. Kelly et al. presented a postoperative Harris Hip Score of 86.5 [28] in a study of 58 patients. Other studies found an increase in the postoperative Harris Hip Score from 76 to 85 [17,18,24,29]. However, these studies dealt with revision operations in both young and elderly patients. Although comparison appears reasonable, the results of this study cannot be compared with other revision systems as these are used with extensive and major defects. They can only be seen in context with other primary systems that are used in small defect situations.

The described failure rates in young patients with an average follow-up period of 8.0 ± 3.7 years can be compared with other studies that investigated both young and old patients in one study. These described failure rates of 1 to 6.9% after a follow-up period of up to 10 years [2,4,5,22,23,30]. In a few studies of porous coated stems, the authors assume that most mechanical failures occur within the first five years [4,5].

If the results are considered with omission of the described reinfection, no further implant failure would be present in the presented follow-up period. The patient with the reinfection was treated with two-stage revision surgery. During the follow-up period, this failure was apparent within the first two years.

The author is currently not aware of any studies describing revision of a total hip arthroplasty with a primary uncemented stem in young patients. In a study of 17 THA revisions (10 of them stem revisions) in young patients with juvenile chronic arthritis and an average follow-up period of 7 years (4–12 years), Goodman et al. showed a postoperative increase in the Harris Hip Score from 53 to 76 with a failure rate of 2 patients [31]. Nevertheless, the results of Goodman et al. are not directly comparable with this study since patients with juvenile chronic arthritis have marked changes of the hip, for instance, osteoporosis, a narrow medullary cavity and thinner cortex, which can make implant revision more difficult and thus worsen the outcome under these conditions [32–37].

Use of a primary stem in the case of revision demands accurate intraoperative assessment of the proximal bone condition. Use is often limited to smaller defects of the proximal femur in order to guarantee good primary stability. In addition, patients with metaphyseal defects in individual cases can be treated with a primary stem after an accurate inspection of the bone still present. If good primary stability cannot be guaranteed, a change should be made to a conventional revision system with a long stem.

The uncemented primary Bicontact stem in primary total hip arthroplasty has so far been described by different authors. Eingartner et al. showed a survival rate of 97.1% after a follow-up period of 11 years [38,39]. Other authors reported survival rates of over 93% with excellent clinical results [40,41]. The results of this study of use of the uncemented primary Bicontact stem in revision arthroplasty reflect the experiences of primary use.

The increasing life expectancy and higher demands made by young patients of a hip arthroplasty mean that future revisions and their ease of performance will come to the fore. Even with accurate and careful preparation in the revision case, major bone defects are often apparent, which can make subsequent revision operations much more difficult. It therefore appears reasonable to implant a primary stem in the case of small bone defects.

Compared to other studies that describe primary implantation in young patients [42], the relatively small number of patients and the assessment of the radiographs are limitations of this retrospective study. Assessment of radiographs was discussed controversially in the past by different authors [5,6,23,43]. Other methods such as bone density measurement (DEXA) or computed tomography (CT) were not used in this study to assess the bone defects and possible stress shielding. A further limitation of the study was the difficulty of determining retrospectively the exact bone defects found intraoperatively.

The uncemented Bicontact primary stem appears to be a good alternative to other revision systems in selected cases with small bone defects. Precise preoperative planning, intraoperative assessment of bone quality and an experienced surgeon are necessary. The results of this study in young patients correspond with those of other studies describing the use of an uncemented primary stem for revision in elderly patients also. Proximal fixation of the stem also minimises the risk of stress shielding. Use of an uncemented primary stem should therefore be considered in revision cases in younger patients with only slight proximal and metaphyseal defects.

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Revision Surgery in High Grade Acetabular Defects with Thermodisinfected Allografts

Authors R. Volkmann[1], K. Bretschneider[1], E. Erlekampf[1], S. Weller[2]

Affiliations
[1] Department for Trauma Surgery and Orthopaedics, Hospital Bad Hersfeld, Germany
[2] Tübingen, Germany

Key words
- aseptic acetabular loosening
- biological acetabular revision
- reinforcement ring
- allogenic thermodisinfected and cryoconserved bone substitute

Abstract

Aim: Due to new medical knowledge and legal restrictions, it is increasingly difficult to run a traditional allogenic bone bank so that alternative bone substitutes and methods of processing are being sought worldwide.

Method: In a prospective clinical study, the biological efficacy of thermodisinfected and then cryopreserved allogenic bank bone was investigated in 19 acetabular revisions in 18 patients. Simultaneously a newly developed titanium reconstruction ring was used. Any revision was regarded as an end point and the follow-up with radiological and clinical results were recorded.

Results: The mean follow-up period was 8.1 (7.9 – 9.8) years. The patients were 73.5 years old (46 – 91) at the time of the revision surgery. One case had a septic course necessitating revision surgery. The other cases showed increasing homogeneity compared to the opposite side and gradual adaptation to the radiological structures found there beforehand. Screw breakage was observed in 3 cases but no implant failure, migration tendency or change in the position of the reconstruction ring or PE-cup.

Conclusion: Despite the low case numbers and different baseline situations, it can be concluded that thermodisinfected cancellous bone chips enable similarly good acetabular reconstruction as the routinely tried and tested cryoconserved, non-processed bone bank allograft, which is becoming increasingly difficult to obtain because of altered guidelines and legislation. The newly developed reconstruction ring has proven itself because of the improved range of sizes and the possibility of adjustment to the anatomical circumstances together with its outstanding material characteristics in clinical use.

Introduction

Despite innumerable modifications and improvements of joint replacements, fixation philosophies and implantation techniques with the aim of fixing "dead implant material" permanently in the "living body" remain a hitherto unachieved vision.

Patients growing ever older and generous indications in young patients mean that more and more patients are experiencing the thus far unavoidable implant loosening. The insidious loosening process, which is often only noticed late, leads to sometimes grotesque bone substance defects, which in the past were often filled with solid plugs of cement, though only for a short time [1, 2, 9].

Acetabular cup loosening predominates, which can cause problems with regard to lasting re-fixation as a result of marked defects in the fixation region. Undoubtedly, operative strategies that fill the resulting defect with potentially revitalisable material and ensure loading capacity and bone remodeling with the use of bridging reinforcement rings are desirable. The efficacy of these measures was already demonstrated for the use of allogenic, cryopreserved bone and the tried and tested Burch-Schneider ring in 41 patients [10].

In contrast, biologically based revisions have become more and more desirable, where the acetabular defects are filled with homogeneous – ideally autologous – bone chips, which are remodeled to an autologous bearing acetabular floor in a highly grafted bed utilising so-called "creeping substitution".

It is well-known that there is often not sufficient autologous material available in the usually elderly and frequently polymorbid patients. The efficacy of allogenic, cryopreserved bank bone has

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Correspondence
PD Dr. Rüdiger Volkmann, MD
Klinik für Unfallchirurgie und Orthopädie
Klinikum Bad Hersfeld GmbH
Seilerweg 29
36251 Bad Hersfeld
Germany
Phone: +49 62 21 88 15 71
Fax: +49 62 21 88 15 60
ruediger.volkmann@klinikum-hef.de

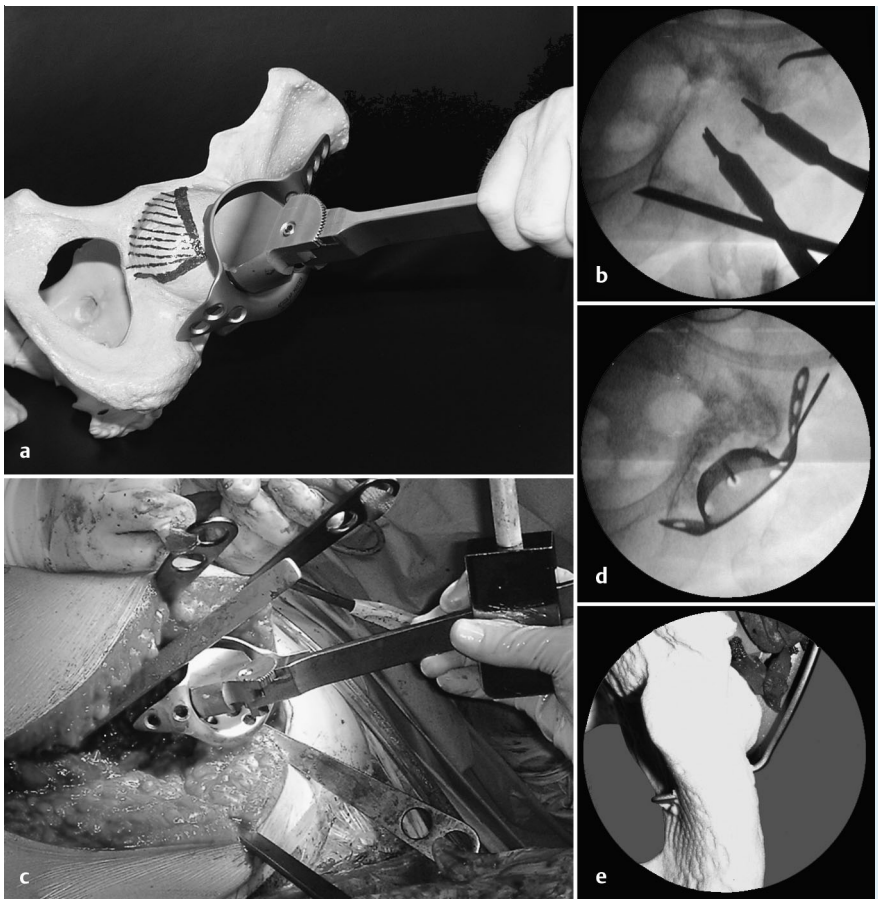

Fig. 1 a to **e** Method of implant and bone graft fixation: **a** Implantation of the reconstruction ring in a model using the positioning instrument after fitting the cranial flanges and ischium fixation. **b** Intraoperative marking of the ascending ramus of the ischium with a chisel under image intensifier control. **c** Insertion of the reconstruction ring. **d** Check of correct implant position with multidirectional image intensifier. **e** The horizontal perforation of the ischium improves primary stability and avoids neurovascular complications.

been proven [6] but is difficult to obtain because of incalculable disease transmission risks. Many hospitals also had to give up their banks because of logistical and financial problems. In this situation, unlimitedly available bone substitutes are becoming more and more the desired target material of users and industry. However, the biological value of filler material, which is vitalisable in principle, for use in advanced defect situations has not yet been adequately validated in the literature.

In an ongoing clinical study, the practicability of native allogenic thermodisinfected and immediately cryopreserved bone (femoral heads obtained at primary arthroplasty) was investigated at acetabular revision. Compared to the already tried and tested but only cryopreserved bone, this has the advantage of immediate availability as it can be rendered sterile by a recognised treatment [4] and can be used immediately without time-consuming investigations. Its biological value should be preserved with this method, even if perhaps with lower quality compared to autologous bone. Without changing the operation technique, the survival rate of allogenic thermodisinfected acetabular reconstruction in combination with a *newly developed* titanium reconstruction ring was investigated and their stability in vivo was tested.

The aim of this study was to establish whether allogenic cancellous bone processed by thermodisinfection gives follow-up results that are at least as good as cryopreserved bone alone and also to investigate the altered new reinforcement ring with regard to possible preshaping and stability compared to a clinically proven reinforcement ring.

Material and Method

In the period August 1997 to April 2000 nineteen cases of acetabular revision operations were performed in 18 patients (1 bilateral) in a defect reconstruction technique [8,10]. The acetabular defect classification [2] was grade 2 in 5 cases, grade 3 in 6 cases, grade 4 in 5 cases and grade 5 in 3 cases. A newly developed malleable titanium reinforcement ring (B.Braun-Aesculap, Tuttlingen, Germany) was used as stabilising implant with screw fixation at the ilium (two malleable fixation flanges) and caudal fixation to the ascending ramus of the ischium (**Fig. 1 a – e**).

The defect is filled with allogenic, thermodisinfected and cryopreserved cancellous bone chips ("Marburg System", Telos, Marburg, Germany), less for mechanical reinforcement but rather to fill the cavity and reconstruct the bone. The acetabular reconstruction rings, which are available in three different sizes (52, 58 and 64 mm external diameter), are placed depending on the initial anatomical situation as a bridge from the ascending ischium to the wing of the ilium. The resulting bony defect is filled with cancellous bone graft and after checking the position with the image intensifier, a polyethylene cup (internal diameter 32 mm) is "glued in" with bone cement (Refobacin-Palacos) used sparingly.

Follow-up (clinical and radiological) took place in our arthroplasty outpatient clinic after 3, 6 and 12 months and then at annual intervals. The failure rate, i.e. the time to repeat cup revision or removal of the acetabular reinforcement ring because of loosening or infection as provisional end point of treatment is shown in the following bar chart (**Fig. 2**).

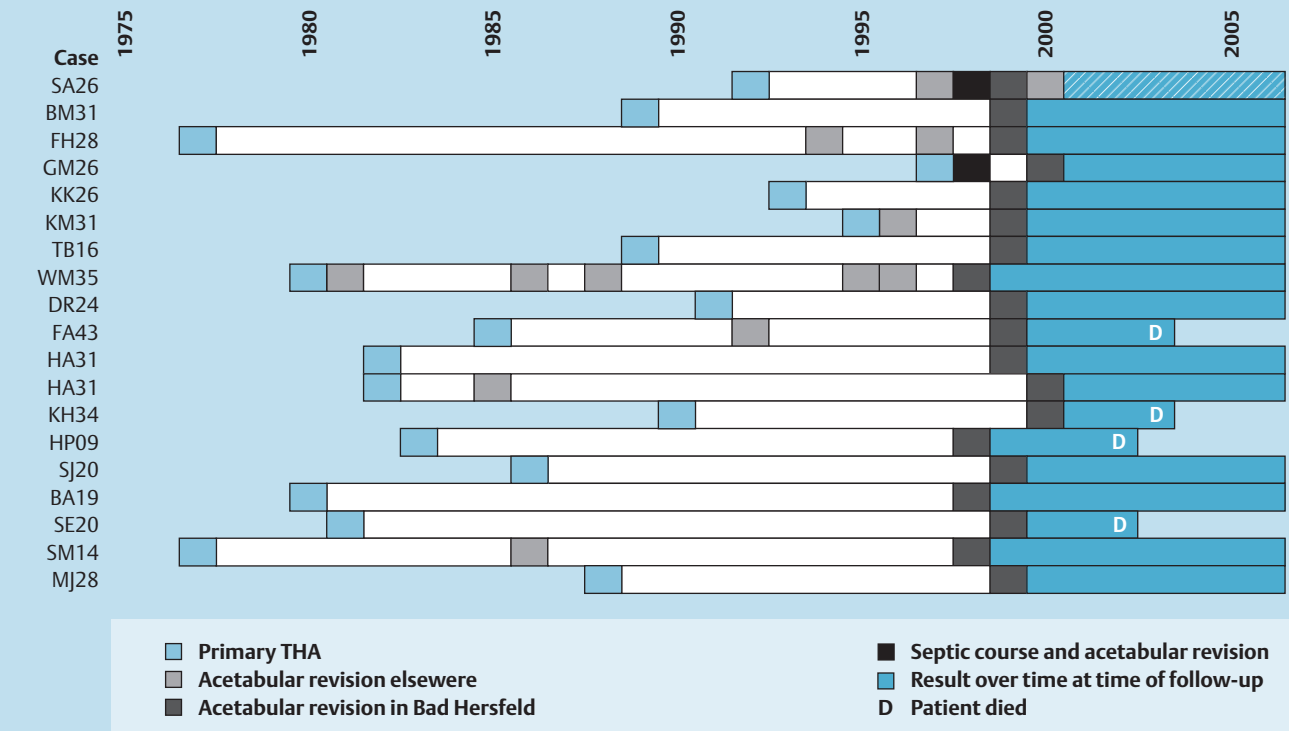

Fig. 2 Treatment course and results over time n = 19.

The average follow-up was 8.1 years (7.9 – 9.8 years). All patients who were mobile and had transport were examined clinically according to the criteria of the Harris Hip Score and radiographically with a standardised a. p. pelvis including the affected hip with the adjacent thigh in 2 planes to assess bone changes in the region of the acetabulum.

In the case of three patients with senile dementia, the family doctor was asked about the hip situation and confirmed that there are no problems in this regard.

Results

Up to the time of the last follow-up in April 2007, 4 patients with intact hips died of diseases not specific to the prosthesis or because of age. One patient (SA 26) who had already had revision and early infection elsewhere had a septic course postoperatively and was revised again in a different hospital. According to telephone information, the cup was exchanged and the stem was left in place. No further operation has been necessary so far. All other patients were recorded clinically and radiologically as described above so that there is practically a 100% follow-up rate for analysis.

The average age of the patients (12 female) at the time of operation was 73.5 (46 – 91) years; the right side required revision in 11 cases and the left side in 8.

With regard to the subjective clinical information and the examination findings, the preoperative Harris Hip Score improved by 23 points at the follow-up times, initially increasing slowly. The preoperative score could not be recorded in full in three cases, because of the particular baseline situation (periprosthetic shaft fracture, persistent infection).

When radiographs of the pelvis were compared, there were no measurable changes; in particular, no tendency to migration was found. Isolated screw fractures were evident in 3 cases but did not lead to instability.

There were no fatigue fractures of the titanium ring, fixation fingers and caudal fixation part; there was also no loosening of the polyethylene cup glued in with small amounts of bone cement.

Radiological assessment (2 independent investigators) of the bone reconstruction shows increasing homogenisation especially in the main loading zones; compared to the acetabulum on the opposite side there was gradual adaptation of the radiological structures found there previously. In no case was re-operation necessary in the study period because of a loosened revision cup (**Fig. 3 a – e**).

Discussion

The aim of treatment in revision operations of loosened arthroplasties consists on the one hand of regaining lost quality of life and on the other hand in preventing future threats of further implant loosening by rational treatment concepts. There is more and more a switch from primary stable cement filling of the defect zones to “biological” methods aimed at reconstructing the bone and protection with so-called acetabular reconstruction rings [1,8,10].

Vitalisation of the firmly impacted allogenic cancellous bone filling the cavity with subsequent remodeling of the acetabular defects was demonstrated clinically, radiologically and with the aid of positron emission tomography (PET) [10]. A requirement for the successful achievement of a highly grafted bone bed capable of load-bearing is primary stable bridging of the defect by a suit-

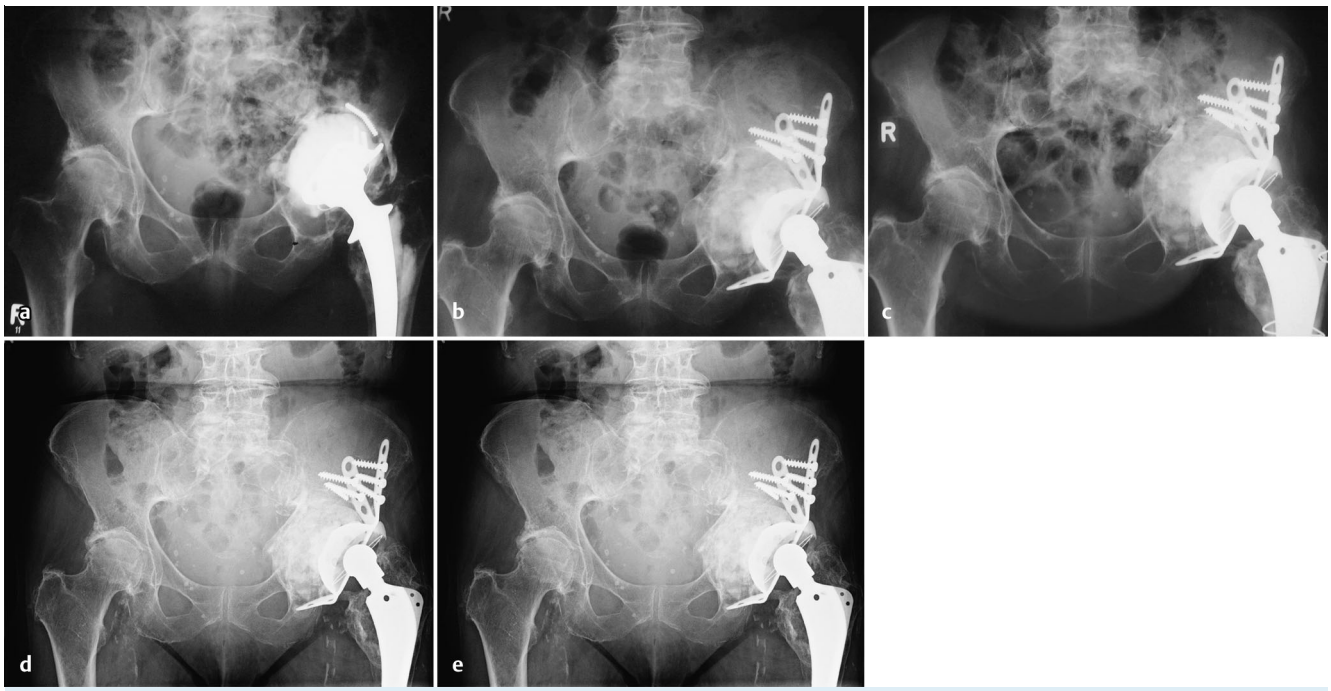

Fig. 3 a to **e** Radiographic course of acetabular reconstruction with thermodisinfected, allogenic cancellous bone filling the defect and bridging with a reconstruction ring with an external diameter of 64 mm. **a** Preoperative radiograph of an 85-year old patient with intolerable pain due to further aseptic loosening (first implantation in 1977, cup revision in 1986) with pelvic discontinuity (Katthagen grade 5). **b** Repeat radiograph 3 months after acetabular reconstruction (operation on 26.06.1998) in the described technique; patient mobile with full loading and without pain in the operated joint (note: broken screw remnant is from the first implantation). **c** Radiographic course (09/99) over the first postoperative year with stabilisation of gait and marked regression of the initial gluteal insufficiency. Slightly loosened screw at the proximal fixation tab, no migration of the reinforcement ring, increasing structuring of the cancellous bone. **d** After 7 years (02/05) unaltered position of the reconstruction ring; the bone graft in the floor of the acetabulum is consolidated. **e** At the last follow-up (03/07), the still sprightly 94-year old is safely mobile with a walking stick. Still no signs of loosening, homogeneous structure of the acetabular floor, which is fully vitalised, "creeping substitution" of the bank bone.

able acetabular reconstruction ring that is supported on the ascending ramus of the ischium with a stability advantage and that is also secured to the wing of the ilium. This ensures that "… an implant never has to be fixed to a graft" [9].

The high rates of loosening published with the use of reinforcement rings [5 – 7] were not found in our study. One reason may be that we devoted great attention to distal implant fixation (see above ▶ **Fig. 1**). Another reason might be the graft preparation. Increased rates of loosening were reported particularly when defects were filled with structured solid allografts (e.g. whole femoral head or femoral condyles) or xenogeneic material [3, 5, 7].

Similarly good medium-term results should be achievable with the thermodisinfected homogeneous bank cancellous bone according to the Marburg principle (Telos) even if there are no known direct references in the literature so far. The advantage of the Telos method is that the time-consuming and expensive tests of the grafts for safety, as stipulated in the guidelines on operating a bone bank, are not necessary to the full extent because of the heating of the removed femoral heads.

The carefully analysed disease course of the patients who were treated with this modification in our clinic since 1997 allow the conclusion that the bone structures, which are undoubtedly further denatured by the preservation process, obviously continue to have an adequate osteoconductive effect during the follow-up period. All of the revision operations performed (apart from the above-mentioned septic exchange in a different hospital) have been successful up to today and with a radiologically apparent gain of vital acetabular bone. This is an important prospective and prognostic aspect.

In the patients in this study we found no differences from the encouraging earlier results of the study published by Winter [10] of purely cryopreserved allogenic bank bone used with a reinforcement ring of the Burch-Schneider type. With relatively similar results, the provision of biologically high-quality bank bone can accordingly be simplified logistically.

Moreover, the newly developed reinforcement ring which was tested for its technical use and durability has also passed the test. We use it because of the improved variation in sizes and the altered construction with "malleability" in the ever more complex acetabular defect situations. Even if the working life of the respective primary operations has not yet been reached in the present follow-up period of nearly 10 years, the unaltered fixed position of the reinforcement rings and simultaneous biological structuring of the entire acetabulum show that lasting results can be expected from biological reconstruction, even when there is sepsis initially.

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The Orthopilot Navigation System for Primary Bicontact Total Hip Replacement

Authors H. Kiefer, A. Othman

Affiliation Department of Trauma and Orthopaedic Surgery, Lukas Hospital, Buende, Germany

Key words
- computer assisted surgery
- navigation
- THA
- cup inclination and anteversion
- leg-length
- femoral offset

Abstract

Aim: Navigated implantation of the cup and stem components enables additional parameters to be recorded for joint reconstruction. The results and reproducibility of the implant position were studied in a consecutive series of implantations with femoral transmitter (femoral C-clamp) close to the hip joint.

Method: 107 consecutive cementless THA operations with the Orthopilot Software THA 2.0 were analysed. The preoperative planning for cup and stem position were compared with the intraoperative data from the navigation system and the postoperative radiograph. Cup inclination and anteversion, leg lengths and offset changes and the rotation position of the Bicontact stem were investigated.

Results: 98% of the radiological cup positions were within 42.5 ± 10° inclination and all cases were within 10 ± 10° anteversion. The navigation system recorded 83% of the relative leg length changes with an accuracy of ± 5 mm. 15% were in a range of ± 10 mm. In 77% of the operations, the Bicontact stem or the Bicontact B osteoprofiler could be positioned in the position measured by the Orthopilot of ± 5° of the box osteotome (i.e. medullary cavity opening). In 20% the deviation was ± 10°. 73% of the arthroplasties gave a relative offset change in a range of ± 10 mm. A tendency to medialisation of the hip joint centre was seen in 62% of the procedures. The mean was a small offset change of only 1.2 mm with a high standard deviation of 17.8 mm.

Conclusion: The navigated implantation of stem and cup components with a femoral transmitter close to the joint leads to reproducible results. The distribution of femoral offset and leg length changes corresponds to clinical experience. Analysis of the radiographs does not appear sufficiently accurate for all the recorded parameters.

Introduction

When implanting a total hip arthroplasty, positioning of the cup component is particularly important in order to achieve joint stability and low-wear loading of the joint surfaces. When implanting the stem, leg length alteration and reconstruction of the femoral offset are crucial for the operation outcome and the degree of joint stability and free joint mobility that are achieved. Navigation methods for the implantation of arthroplasties are used with the aim of improved and reproducible positioning of the implant components.

An acceptable variance in the position of the acetabular component was described in the classical article by Lewinnek in 1978 [17], which described a range for inclination and anteversion within a "safe zone". Inclination in the range of 45 ± 10° and anteversion of 15 ± 10° were defined as the "safe zone". This has hitherto been generally recognised. The objective of computer-aided navigation is to find an "optimal" mean or target value, a reduction in variance and finally, exclusion of cup positions outside a defined "safe zone".

Measurements on non-navigated acetabular cups [2,4] show sometimes marked deviations from these empirical implantation rules for cup position. In contrast, better results are obtained with cups implanted using navigation [1,3,6,8,16,23]. These differences were also shown in anatomical preparations where the navigated and non-navigated implantation methods were compared directly [7,18,24]. The additional influence of the experienced or inexperienced surgeon on the navigated/non-navigated cup position in the preparation was also investigated for different navigation systems [5] and showed the funda-

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Correspondence
Prof. Dr. Hartmuth Kiefer, MD, PhD
Department of Trauma and Orthopaedic Surgery
Lukas-Krankenhaus Bünde
Hindenburgstraße 56
32257 Bünde
Germany
Phone: +49 52 23 16 72 16
Fax: +49 52 23 16 71 76
h.kiefer@lukas-krankenhaus.de

mental advantages of navigated implantation methods. There have so far been only a few studies with randomised groups of navigated/non-navigated patients [9,16].

Experience with the Orthopilot Navigation System

We have been using the Orthopilot navigation system [21] since 2002 for total hip arthroplasty and treat 90% of all hip replacements routinely with this navigation system. Over 1500 patients have been treated successfully in this way up to the end of 2006. In the navigated implantation of hip arthroplasty components, the surgeon obtains intraoperative values for the inclination and anteversion position of the cup component and values for leg length and the offset relationships of the total hip replacement. The free range of motion (ROM) is determined with the navigation system that we use through the relative alignment of the cup and stem components.

Our clinical experiences and studies with the Orthopilot acetabular navigation have demonstrated the desired improvement of cup position with the navigation system [10 – 12]. Other studies of the Orthopilot cup navigation in hip arthroplasty confirm our results [19,25]. When navigation is used for the cup and stem component also, the information from the navigation system can be used intraoperatively to influence changes of leg length, offset and ROM and be used to optimise positioning [13,15].

While the navigation system records and analyses all the measurement parameters with high accuracy, palpation of bony landmarks for reference leads to inaccuracies that cannot so far be compensated by the navigation system [22]. These inaccuracies are additive in clinical use so that the measurable results have a certain distribution. It is important to point out that this distribution of values in the treatment outcome do not lead to incorrect implantation of implant components. However, the bandwidths of the implant positions are not in the narrower range that would be possible through the accuracy of the navigation system.

Because of this, more precise recording of the bony landmarks with ultrasound was developed. In first pilot studies of THA patients treated with navigation, the fundamental function and safety of this recording method with the Orthopilot system were shown [14].

Material and Method

From March 2005 to September 2005, 107 consecutive cementless THAs were implanted and analysed with the Orthopilot Software THA 2.0 (B.Braun-Aesculap, Tuttlingen, Germany). All indications for a total cementless hip replacement with the Bicontact/Plasmacup system were included. The preoperative and inpatient postoperative radiographs (time = discharge, supine position) formed the basis for the analysis. The preoperative planning for cup and stem position was compared with the intraoperative data from the navigation system and the postoperative radiograph. Cup inclination and anteversion, leg lengths and changes in offset along with the rotational position of the Bicontact stem were investigated. The method of radiological anteversion according to Pradhan [20] was used for the cup position. The pre- and postoperative a. p. radiographs of the pelvis were used for cup inclination and leg length. The changes in offset and the rotation of the prosthetic stem were determined through the data from the navigation system.

The implantations were performed through a standard transgluteal approach with the patient in supine position. The pelvic transmitter was secured to the ipsilateral iliac spine and the femoral reference was with the Orthopilot C-clamp on the greater trochanter. After that the plane of the pelvic position was referenced with a pointer and the relative position between femur and pelvis with the patient supine was recorded. Following femoral osteotomy, the centre of the acetabulum and the medial boundary of the acetabulum were recorded. The cup component was then navigated and implanted. The cup was implanted in accordance with preoperative planning with a shallow inclination angle of 42.7 ± 7.5° and a positive anteversion angle > 10°.

Before implantation of the cementless Bicontact stem, navigated positioning of the box osteotome was performed with an antetorsion value aligned to the centre of the already implanted cup. Deviations due to bony circumstances were analysed by measuring the anterotation position of the Bicontact B osteoprofiler. Changes in leg length and offset were displayed as values relative to the initial situation of the as yet untreated joint and adjusted according to the preoperative planning and intraoperative possibilities by variation of the modular head lengths and axial fit of the prosthetic stem.

Results

Of 107 THAs, 100 patients could be analysed in whom there were complete data and a plausible navigation procedure was documented intraoperatively. In two operations loosening of the pelvic screw occurred, in two cases the data for the offset changes were not plausible and in 3 patients the radiographs could not be analysed because of treatment on the opposite side. 76 operations were performed by consultant surgeons and 24 by surgeons in training with consultant supervision.

The average age of the patients was 69.9 years and the average BMI was 26.8. The indications were primary osteoarthritis in 72%, dysplasia in 14% and secondary osteoarthritis in 4% (2% post-traumatic, 2% as a result of Perthes disease and after slipped femoral epiphysis).

The operation time (incision – suture) averaged 108 minutes and hospitalisation was for an average of 15.4 days.

The cup position was within 42.5 ± 10° inclination in 98% and within 10 ± 10° anteversion in all cases. 91% were within a smaller ± 7.5° range around the average target value of 42.5°/10° for inclination/anteversion (**Fig. 1**).

83% of the relative leg length changes were detected by the Orthopilot System with an accuracy of ± 5 mm (**Fig. 2**). 15% were in a range of ± 10 mm. In 77% of the THAs, the Bicontact stem or the Bicontact B osteoprofiler could be positioned in the position of ± 5° of the box osteotome measured by the Orthopilot (i.e. medullary cavity opening). In 20% the deviation was ± 10° (**Fig. 3**).

73% of the operations gave a relative change in offset in the range of ± 10 mm. A tendency to medialisation of the centre of the hip was apparent in 62% of the operations. The average offset change was small at 1.2 mm with a high standard deviation of 17.8 mm (**Fig. 4**).

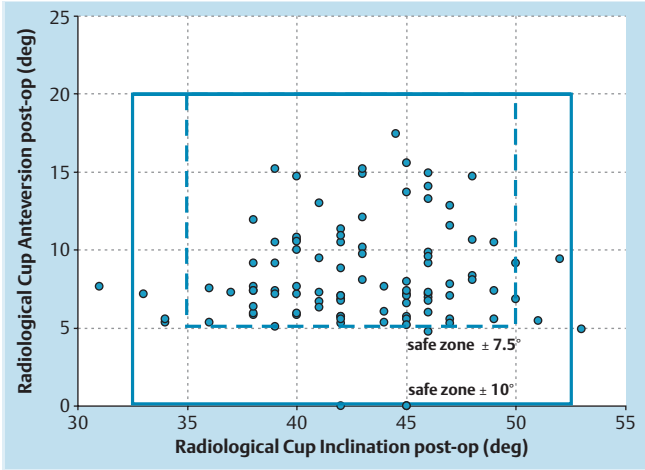

Fig. 1 Radiological cup inclination and anterversion post-operative.

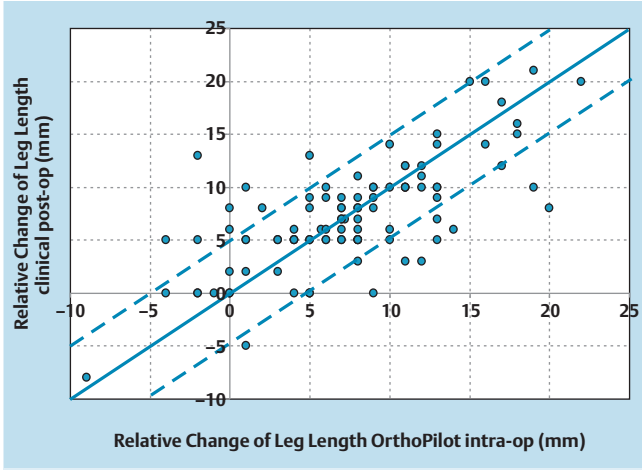

Fig. 2 Relative changes of leg length clinically and recorded by OrthoPilot data (mm).

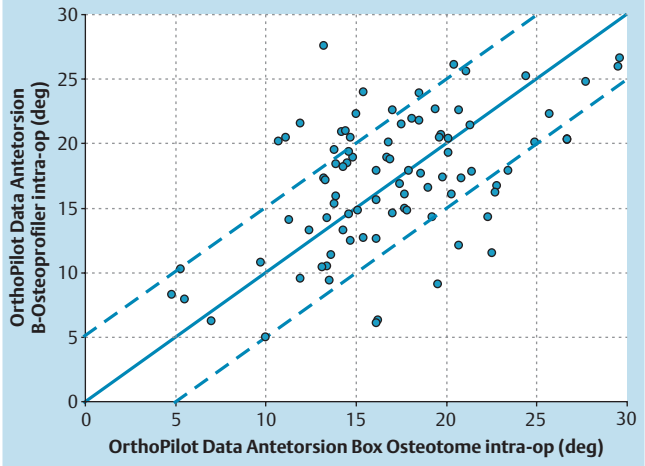

Fig. 3 Antetorsion for boxosteotome and Bicontact B-osteoprofiler.

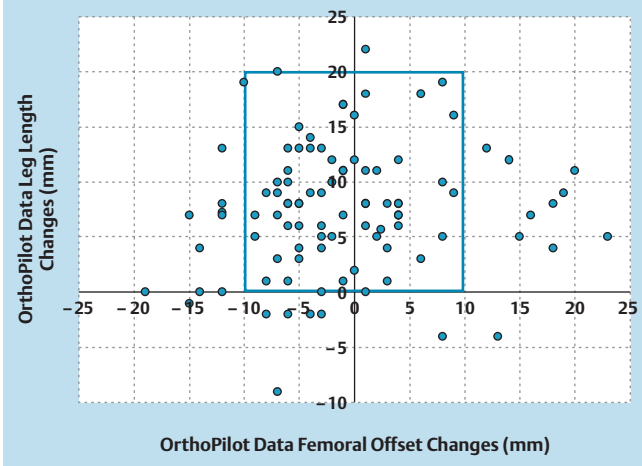

Fig. 4 Relative changes of leg length and femoral offset recorded by OrthoPilot [mm].

Discussion

The results confirm the reliable and safe cup positioning with the aid of kinematic navigation. No cup was implanted in retroversion and 98% of the values for inclination were within the range of the values defined and set intraoperatively.

The good radiological results for cup positioning are obtained despite a number of inaccuracies during intraoperative pelvis recording and analysis of the radiographs. Errors arise through pelvic tilting and soft tissue cover, which ultimately yield the bandwidth of the implant position. More precise recording of the pelvic plane (for instance by ultrasound) doubles the accuracy of the pointer recording, in our experience.

Analysis of the radiographs and the preoperative planning and assessment of a good implant position cannot be improved according to current knowledge.

An important result of our study is the data on stem position and ultimately the combination of stem and cup implantation for the achieved leg length and offset reconstruction. The increase in leg length derives from the degenerative change in the joint and also from the limitation of equivalent reconstruction of the offset. This does not always depend on the possibilities of the implants or the skills of the surgeon but on the variability of the hip being treated.

The possible geometric variations are in the range of ± 10 mm on the femoral side and well over ± 10 degrees in the acetabular region rather than in a theoretically possible range of a few millimetres or degrees. Operative implementation with navigation could achieve accuracy of ± 5 mm and ± 5 degrees if the preoperative and intraoperative assessment could be attributed to optimal treatment parameters.

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