DOCUMENT 64

NR	Author	Title	Design	Abstract	Aim	Population	Number of implants	Outcome Measures	Scores	Results
1	M. Sielewicz, J. Scholz, L. Hanslik	A five years follow-up of 605 cases of the MCCL total hip prosthesis	Case Series	Between May 1983 and January 1988, 612 patients were submitted to MCCL prosthetic hip implants and 662 units of prostheses have been implanted. AP radiographs were obtained in 645 cases.	Postoperative hip function	612	662	AP radiographs were available for sturdy in 645 cases while 135 patients accepted the scintigraphic follow-up by using 99 m Tc-MDP.	Merle d'Aubigné	In particular, there were only 4 cases of intraoperative fracture of the femoral stem. In 565 patients the response to the prosthetic implant was excellent of good. In 635 cases, radiography showed no change in the position of the prosthetic stem.
2	H. Gollwitzer, L. Gerdesmeyer, C. Horn, P. Diehl, A. Topfer, R. Gradinger	8-year follow-up after cementless hip arthroplasty with a second generation spongy metal total hip replacement	Case Series	81 consecutive cementless primary THAs in 80 patients implanted between 1995 and 1998.	To examine the survival rates of the cementless spongy metal hip arthroplasty at a mean follow-up of eight years, particularly considering the young age of many of the patients.	80	81	Patients were evaluated clinically by an independent investigator. X-rays were taken if patients reported any complaints. The Merle d'Aubigné score was used to record pain, mobility and ability to walk to determine the clinical performance. The McNab score was also accessed.	Merle d'Aubigné / McNab	At the time of follow-up 7,9 years after implantation, 75 of the 76 implanted hip stems were still in situ, corresponding to an implant survival of 99%. One stem had to be revised after 3,9 years due to recurrent dislocation after trauma. No revision for loosening had to be performed for any femoral component.
3	C. Götze, A. Tschugunow, H.G. Götze, F. Bettner, W. Pötzl, G. Gosheger	Long-term results of the metal-cancellous cementless Lübeck total hip arthroplasty: a critical review at 12.8 years	Case Series	An amount of 137 THA with the cementless spongy metal Lübeck hip prosthesis were evaluated long-term, radiographically and clinically, with a mean follow-up time of 12.8 years.	To assess the efficacy of the implant in a long-term study.	201	231	To evaluate the clinical outcome the Harris Hip Score and the activity score by Sutherland et al. were used at follow-up. For the radiographic evaluation anteroposterior radiographs of the pelvis and lateral radiographs of the operated hip were recorded with the standard technique.	HHS / Sutherland / MOS SF-36 Health survey	Cumulative survival rates were 90% for the cups and 86% for the stems at 14,9 years. 4 stems fractured at the middle part without major trauma.
4	J. Scholz, D. Hubalek, C. Höpfner	Survival rate of the uncemented spongiosa metal surface hip system 15 to 18 year follow-up	Case Series	165 consecutive hip arthroplasties using the ESKA standard Spongiosa Metal® Surface Total Hip replacemnet were reviewed.	To assess the long-term success of total hip arthroplasty inserted without cement.	155	165	A survival rate was calculated using the Kaplan-Meyer method. Clinical follow-up of 53 patients using the Harris Hip Score showed a median of 81,9 points.	Kaplan-Meyer / HHS	The long-term survivorship analysis shows 88% survival of the ESKA prosthesis at 18 years with excellent scoring in the clinical examinations. 11 femoral stems were revised because of aseptic loosening, and in one hip stem fracture.
5	M. Matsui, K. Nakata, K. Masuhara, Ke. Ohzono, N. Sugano, T. Ochi	The metal-cancellous cementlesss Lübeck total hip arthroplasty - 5 to9 year results	Case Series	Between May 1987 and December 1991, 51 MCCL hips were implanted in 45 patients with dysplastic hips. Both clinical and radiological data were obtained for 43 patients.	To evaluate the mid-term clinical and radiological results of the MCCL prosthesis in patients with osteoarthritis secondary to hip dysplasia.	45	51	Patients were assessed clinically before operation and then at intervals of 6 months using the Merle d'Aubigné and Postel hip score. AP and lateral radiographs were taken at each follow-up by a standard technique.	Merle d'Aubigné / Postel hip score	49 hips have been followed for 5 to 9 years. 1 needed revision for stem fracture and one for infection, the other 47 hips were either excellent (63%) or good (37%).
6	J. Scholz, U. Böhling, H. Schamberger	Twenty Year Follow-up Of The Uncemented Spongiosa Metal Surface (SMS) Total Hip Arthroplasty	Case Series	199 patients received the operation and 209 prostheses have been implanted.	Long term success of cementless hip prosthesis is depending on a reproducible surgical technique by sophisticated instruments and a proven bone integration	199	209	To evaluate the clinical outcome the Harris Hip Score was used at follow-up. AP radiographs of the pelvis and lateral radiographs of the operated hip were recorded with the standard technique.	HHS	165 patients have been followed for 20 years. 14 revisions happened. The survival rate was 88%.

A FIVE YEAR FOLLOW-UP OF 605 CASES OF THE MCCL (METAL-CANCELLOUS CEMENTLESS LÜBECK) TOTAL HIP PROSTHESIS

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The porous surface of the MCCL prosthesis macroscopically resembles spongy bone, with a porous depth of up to 10 mm, the width of the pores measuring 1-2 mm, with reticular spaces forming an intercommunicating system. The superficial porous surface and the implant stem are combined in a single structure. The standard prosthesis is made up of four components; an acetabulum in cobalt-chrome-molybdenum alloy, an interposed layer of polyethylene, a ceramic head and a stem in cobalt-chrome-molybdenum alloy, the shape of which is anatomically matched to the proximal femur.

What emerges from the present study is the possibility of using right and left stems, each available in six sizes. The ceramic head may be attached to the neck of the femoral stem, which may be long, average, or short. An "extra-long" metal head is also available.

Between May 1983 and January 1988, 612 patients were submitted to MCCL prosthetic hip implants, 50 bilaterally, making 662 hips. Osteoarthritis, dysplastic arthritis, and necrosis of the femoral head were the main reasons for surgery. In 80 cases there were intra- or postoperative complications. In particular, there were 4 cases of intraoperative fracture of the femoral stem. The most common postoperative complication, observed in 31 cases, was deep vein thrombophlebitis of the leg. There were no cases of infection. There were 3 definite cases of loosening of the prosthesis due to incompatibility with cobalt, while there were two other suspected cases. In most cases at least 6 weeks of hospitalization were required, and generally the patients who left hospital were able to bear full weight on the limb with the help of crutches after a short period of time.

In 565 patients the response to the prosthetic implant was excellent or good; this may be considered good according to the Merle d'Aubigné scale, with 481 cases showing active flexion of the hip of 90 degrees or more. 575 patients were satisfied in their subjective evaluation of the results. The most common cause of dissatisfaction was discomfort in the thigh described as a vague sensation of pulsating pressure followed by pain. In 645 hips radiologically examined at follow-up, the prosthesis was shown to be unchanged and stable. Scintigrams at follow-up were obtained in 135 cases, in 5 of which loosening of the prosthesis was suspected.

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MATERIAL AND METHOD

662 prostheses were implanted in 612 patients (50 bilateral). Fifty-seven patients were either not available for follow-up or decided not to participate, leaving 605 hips available for study. 424 patients were females and 180 males. Ages ranged from 33 to 82 years (average 57 years). Osteoarthritis was the indication for surgery in 455 hips (69%). In the remaining 200 hips the indications are shown in Table 1.

Table 1
REASONS FOR OPERATION

	No. of cases	%
Osteoarthritis	462	69
Dysplastic osteoarthritis	85	13
Necrosis of the femoral head	60	9
Rheumatoid arthritis	25	4
Fracture of the head of the femur	20	3
Ankylosing spondylitis	5	1
Ankylosis	5	1
	662	100

555 patients were operated on only on one side, while 50 (8%) were operated on bilaterally; the average period of time between operations for the latter group was 10 months.

In 645 cases the hips were examined radiologically within 3 months of the follow-up date. Nine patients refused radiological examination and one patient who had been submitted to further surgery in another clinic, where another type of cementless prosthesis was implanted as a result of repeated dislocation, was not included in this study. AP radiographs were available for study in all but a few hips. The position of the prosthetic acetabulum was evaluated radiologically in terms of "position unchanged", "migration", "position shifted" or "protrusion". The femoral stem was evaluated as "valgus position", "varus position", "sinking of the stem", "radiotransparent medial area", "breakage of the implant site" or "fracture of the bone".

Initially, a scintigraphic follow-up was planned for each patient but 470 patients refused scintigraphy, so only 135 patients were actually studied, using 99 m Tc-MDP

The clinical assessment, based on the symptomatology and objective examination of the patient, was based on the Merle d'Aubigné scale, in which scores are assigned for range of movement, degree of pain, gait and walking ability.

CLASSIFICATION OF RESULTS (Merle d'Aubigné)

0 - Walking impossible; ankylosis in unfavourable position; permanent and very intense pain.

1 - Walking possible only with the help of crutches; ankylosis in satisfactory position; pain very intense, enough to disturb sleep.

2 - Walking possible only with the help of two canes; flexion < 40 degrees, abduction = 0; pain very intense, during walking, enough to limit some activities.

3 - Walking for less than one hour with the help of a cane; without cane walking possible only with great difficulty; flexion 40-60 degrees; pain moderately tolerable, but enough to limit some activities.

4 - Walking possible for one hour or more, with the help of a cane, for a brief period of time, without limping; flexion 40-80 degrees, the patient is able to put on his or her footwear; minimum pain during walking which is relieved by resting.

5 - Minimum limping; walking unlimited with the help of a cane; flexion 80-90 degrees, abduction > 25 degrees, a minimum amount of intermittent pain during walking, which does not limit activity.

6 - Walking unlimited with no support; flexion > 90 degrees, abduction > 25 degrees; no pain.

All the patients examined were asked to give their subjective impressions of the results based on pain, ability to walk and range of movement of the joint. The evaluation could be expressed as very good, satisfactory or unsatisfactory.

RESULTS

In 4 cases there was a fracture of the femoral shaft at operation. In all 4 cases there was an extremely narrow medullary canal and a very thin cortex. Initially, a special prosthetic stem for cases of dysplasia was not available but after it became available there were no further cases of fracture of the femoral shaft. The 4 cases were immobilised for 4 weeks after which there was full consolidation with solid anchoring of the prosthesis. In 2 cases there was a fracture of the lesser trochanter associated with a femoral neck which was very slender. In 11 cases there was dislocation of the prosthesis during hospitalization but all were successfully reduced by closed manipulation. In one case the prosthesis dislocated twice during the two month period after hospitalization. This patient underwent further operation at another clinic, and we were not able to determine the exact cause of these dislocations. Twenty patients underwent further surgery for pain due to periarticular calcification. Three cases of loosening of the prosthesis due to incompatibility with cobalt were submitted to further surgery. In 2 other cases loosening of the prosthetic stem was suspected, based on the radiological and scintigraphic findings. However, these patients had no significant clinical disorders, so were not treated. In 31 cases (4%) there was deep vein thrombosis, verified by phlebography and in 19 cases pulmonary embolism was diagnosed radiologically and scintigraphically; in 16 of these there were no clinical symptoms (Tables 1 and 2).

RADIOLOGICAL FINDINGS

Radiographs were obtained in 645 out of a total of 655 cases. In 635 cases radiography showed no change in the position of the prosthetic stem. In 5

Table 2
INTRAOPERATIVE AND POSTOPERATIVE COMPLICATIONS

	No. of cases	%
Fracture of the femoral shaft	4	0.6
Fracture of the greater trochanter	0	0
Fracture of the lesser trochanter	2	0.3
Breakage of the implant	0	0
Protrusion of the acetabulum	0	0
Dislocation of the prosthesis	11	1.7
Periarticular calcification requiring further operation	12	1.8
Infection	0	0
Loosening of the prosthesis	5	0.7
Deep vein thrombophlebitis	31	4.7
Pulmonary embolism	19	2.9

Table 3
POSITION OF THE ACETABULUM

	No. of cases
Position unchanged	640
Shifted	0
Migration	0
Protrusion	5

cases there was valgus with no clinical signs of loosening. In 5 other cases there was slight sinking of the prosthesis with no clinical signs of loosening. In 5 cases there was a radiotransparent medial zone in the radiographic follow-ups. In 3 of these cases there were also clinical signs of loosening, so that further surgery was required. In the remaining 2 cases there were no clinical signs of loosening. Periarticular calcification was radiologically demonstrated in 120 cases (18.6%) (Tables 3 and 4).

99 m Tc-MDP was used during scintigraphic follow-up in 135 patients. The remaining patients refused to undergo scintigraphy. Nine of the follow-ups showed signs of infection. In 3 cases the pathological uptake activity of the radioactive medium was at the apex of the femoral prosthesis and this was correlated to the radiotransparent medial zone in the radiographic follow-ups. Fifteen cases of periarticular calcification showed positive scintigraphic findings.

Our postoperative physical rehabilitation programme after the patients left hospital was based on progressive walking, first with crutches or canes, and then unsupported. 500 patients (76%) three months after surgery required no support.

565 (85%) of cases obtained a score of "good" or "very good", according to the Merle d'Aubigné scale. Sixty-five patients (10%) were "satisfactory" and 20 (3%) were "unsatisfactory". On this scale 9 points = unsatisfactory; 10-12 points = satisfactory; 13-15 points = good; 16-18 points = very good.

An analysis of the 20 unsatisfactory results showed that in 14 cases extensive periarticular calcification was responsible. In 4 cases there was severe polyarthritis and in the remaining 2 cases there was irritation of the sciatic nerve.

Table 4
POSITION OF THE PROSTHETIC STEM

	No. of cases
Position unchanged	635
Varus	0
Valgus	5
Sinking of the prosthesis	5
Radiotransparent medial zone	5
Breakage of the implant	0

The patients were asked to subjectively evaluate the results based on 1) pain, 2) ability to walk, 3) joint mobility. This evaluation was expressed as: very good, good, satisfactory, unsatisfactory. The evaluation was very good in 269 cases (41%), good in 312 cases (47%), satisfactory in 5 (1%) and unsatisfactory in 75 (11%). Of these 75 unsatisfactory results the reasons given were: in 45 cases pain in the thigh, in 15 because of limping, and in 15 because of a "pulsating sensation" in the thigh.

FIG. 1. - Radiograph 9 months after prosthetic implant (MCCL) in a patient aged 62 years.

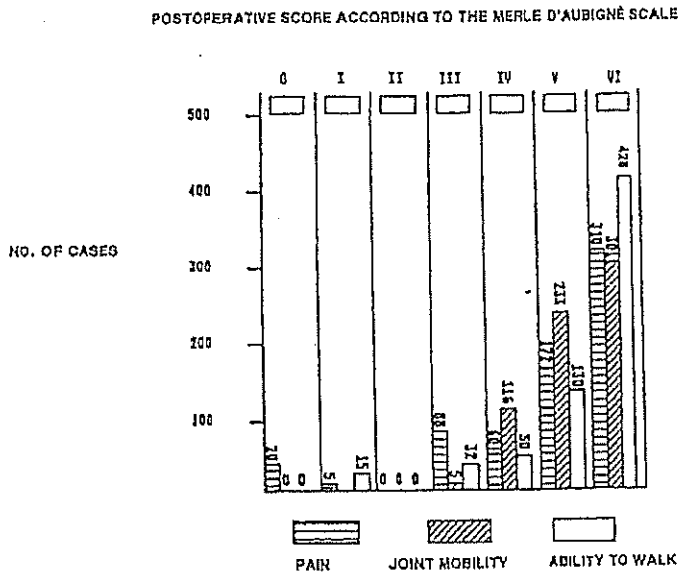
DISCUSSION

Coaptation at the implant-to-bone interface and the reaction of the bone to the implant material are the two most important factors in determining prosthetic stability (Cameron *et al.*, 1973; Pitz, 1981; Judet, 1952; Plitz and Griss, 1981; Hanslik, 1987; Homsy *et al.*, 1972). Both are strongly influenced by the shape of the prosthesis and its surface design (Parhofer *et al.*, 1984; Hanslik, 1987; Klawitter and Hulbert, 1971). The logical outcome of this is that long-term success is, among other factors, dependent on the choice of cementless prosthesis. The shape of prosthesis, closest to the anatomical features of the medullary canal guarantees optimal coaptation obtained by pressure ("fit-press") and primary stability of the prosthesis (Hanslik *et al.*, 1983; Kranz *et al.*, 1983; Henssge *et al.*, 1985; Walker, 1986). The design of the prosthetic surface determines the skeletal reaction towards the implant (Fung, 1981; Judet, 1952; Haddad and Cook, 1986; Häckel *et al.*, 1978; Dumbleton, 1981; Judet, 1979; Fuchs, 1982).

From 1970 onwards numerous researchers have shown that skeletal growth in porous material can cause a particular form of adhesion which

is capable of anchoring the prosthesis to the surrounding bone (Galante *et al.*, 1971; Klawitter and Hulbert, 1971; Peterson *et al.*, 1969; Welsch *et al.*, 1971). In 1971 Galante and Rostocker reported the first attempt to use a surface in metal fibre (titanium) with a reticular structure and a porous diameter of at least 10 mm to guarantee skeletal growth in the superficial structure of the porous prosthesis. Small pores, however, measuring less than 1.0 mm, would seem to favour the ingrowth of fibrous tissue (Collier *et al.*, 1984; Okuno *et al.*, 1984; Spector, 1982; Klawitter and Hulbert, 1971). To promote bony ingrowth the porous surface of the implant must meet two requirements: a porous surface of sufficient depth to ensure subsequent stability; the diameter of the pores must be sufficient to guarantee a maximal area of osteogenesis to withstand weightbearing stress.

The technical process of creating a porous surface predetermines the size of the pores and the resistance of the superficial surface. A typical feature



of porous surface structures produced in different ways, is, in fact, a minimum pore depth and diameter, for example, less than a millimetre. These considerations led to a different approach in the development of the porous surface of the MCCL prosthesis. As a result of the work of Grundei, Hanslik and Henssge in 1986 it was possible to perfect a process for the production of a special wax similar to that of human spongy bone, in which the superficial layer and main structure of the prosthesis are joined together in a single piece.

As a result of these considerations, this prosthesis was adopted in our Division in October 1983 for total hip replacements.

During the first year we limited it to patients aged from 60 to 70 years. For this reason the average of our patients is quite high (57.4 years) compared with other follow-ups carried out in other centres using other types of cementless prostheses (Mittelmeier, 1983; Arcq, 1985; Bountin, 1977; Frisch *et al.*, 1985; Schicha *et al.*, 1986; Winkelmann *et al.*, 1985; Menge, 1985). This

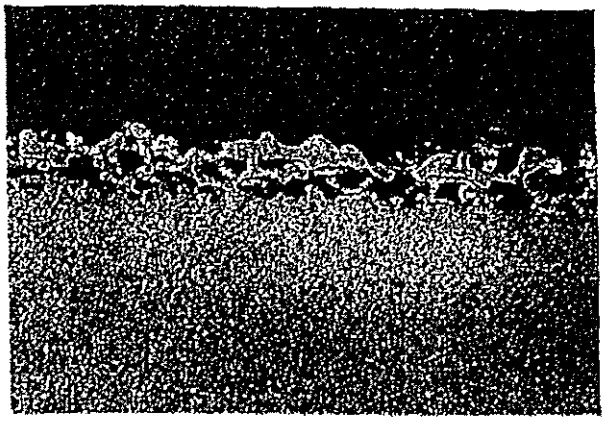


FIG. 2. - Transverse section of the MCCL prosthesis showing the design of the macroporous surface with intercommunicating cells.

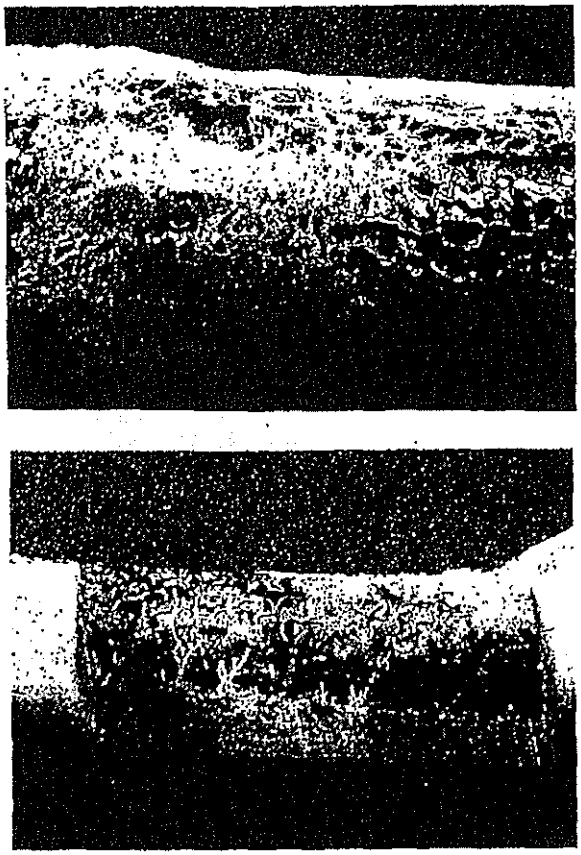
FIG. 3. - The four components of the MCCL prosthesis.

is due to initial restrictions in the use of a prosthesis which up to then had not been widely used. After very encouraging initial data we extended the indications to include both younger and older patients.

The advantages of a cementless total arthroplasty which retains its morphological and functional features in young patients avoids the need for further surgery due to loosening of the implant. The youngest patient in our series was 33 years of age suffering from severe and disabling necrosis of the femoral head. Six years after implantation, this patient was free of complications. When we extended the operation to include more elderly patients (the oldest was 82 years of age) it was observed that in patients with marked senile osteoporosis, the formation of new bone was actually stimulated and this was subsequently demonstrated in radiographs in our series. Favourable results were also obtained in patients with severe rheumatoid arthritis; with one exception, in whom the prosthesis was implanted bilaterally, 33 cases reported good or even very good results at follow-up. This was verified by radiographs which showed solid anchoring of the prosthesis. There was no correlation between senile osteoporosis and postoperative complications. These encouraging results agree with those reported by Arcq in 1985.

Pain in the thigh following implantation of a cementless prosthesis has been extensively discussed, but at present there is no general agreement on

the causes of the problem (Arcq, 1985; Schreiber *et al.*, 1983; Mittelmeier, 1983; Stewen and Schlegel, 1983; Hackenbroch and Bruns, 1985; Menge, 1985). In the 75 unsatisfactory results in this series, a variable degree of discomfort in the thigh was the first reason (80%) reported by the patients. In this group, with the exception of 20 cases of ascertained periarticular calcification, the follow-ups were not of particular significance and in all the cases, flexion of the hip was 90 degrees or more. This discomfort in the thigh reached a peak during the fourteenth month after which there was a marked tendency to decline. If this complication remains a permanent problem for some patients, it must be re-evaluated during successive follow-ups.



FIGS. 4-5. - Specimens of the proximal part of the femur obtained at autopsy in a patient aged 70 showing bone growth in the area of the prosthesis.

In 15 of the remaining unsatisfactory results limping was reported as the principal cause of discomfort. In 10 of these cases there was a positive Trendelenburg and 6 patients requested a walking aid. In one case of severe bilateral rheumatoid arthritis only one hip had been operated on. In 4 cases we could not ascertain the cause of limping.

Scintigraphic examination showed an enormous increase of uptake a few days after implantation. The uptake activity then became normal 12 months after surgery (Bessler and Schaub, 1979; Häckel, 1978; Gelman *et al.*, 1978; McInerney *et al.*, 1978; Schneider *et al.*, 1982). After this, uptake activity in the femoral stem or in the apical area of the prosthesis may be considered a relatively reliable sign of loosening or infection (Schneider *et al.*, 1982; Horoszowski *et al.*, 1980; Weiss *et al.*, 1979). In the MCCL prosthesis scintigraphic follow-ups showed greater deviations, particularly at the apex of the femoral stem, where higher uptake was correlated to an increase in bone remodelling, which could be radiographically demonstrated, and to reaction in the medullary canal.

A markedly increased uptake activity was observed in 31% of the cases up to 22 months after operation but with no clinical or radiological signs of loosening or infection. In 5 cases where loosening was suspected it was not shown scintigraphically. In 3 of these cases the scintigraphs were correlated to a radiotransparent area and clinical signs of loosening. Pathological findings in these 3 cases following a second operation showed marked cobalt incompatibility to be the cause of loosening. In the two other cases of scintigraphically suspected loosening there were no corresponding clinical signs, nor did the patients complain of greater discomfort.

If these 2 cases of suspected loosening are accepted, in the whole series 5 cases (0.7%) have been observed up to now, as opposed to 6.6% reported by Schreiber in 1982 following a Thrust-Plate 1-1 prosthesis 9 months after surgery; 1% by Walker in 1983 for the PM prosthesis 6-16 months after surgery; 5.6% by Menge in 1985 for the Zweymüller-Endler prosthesis 16-31 months after surgery; 11.9% by Schulitz *et al.*, for the Mittelmeier type 2 prosthesis 8 months after surgery; 5.9% by Stewen *et al.*, for the Lord prosthesis 5 months after surgery; 3.7% by Frisch *et al.*, in 1985 for the Judet prosthesis 27 months after surgery; and 1.4% by Hackenbroch and Bruns in 1984 for the MR prosthesis 6-30 months after implantation.

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Original article

8-year follow-up after cementless hip arthroplasty with a second generation spongy metal total hip replacement

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ABSTRACT. *We studied a consecutive series of 81 cementless total hip arthroplasties in 80 patients using the second generation ESKA cementless spongy metal hip replacement. The study end-point was implant revision and both function as well as satisfaction with treatment outcome were assessed. Mean age at the time of surgery was 50.9 years [range 23-73]. No patient was lost to follow-up and 75 patients (76 hips) could be included in the final analysis at a mean follow-up of 7.9 years [range 7.0-10.0]. Survival rate without loosening as the end-point was 100% for the femoral component and 99% for the acetabular component (one cup revision). Two cups and one stem had to be revised for recurrent dislocation, resulting in a total implant survival at follow-up of 99% for the femoral component and 96% for the acetabular component. Very good functional results were obtained with a mean Merle d' Aubigné score of 15.5 ± 2.9 at 7.9 years after surgery. Satisfaction with treatment outcome was reported in 88%. 95% of patients would recommend the performed procedure to a friend. Perioperative complications without revision occurred in eleven patients (14%).*
We report excellent survival rates of the cementless spongy metal hip arthroplasty at a mean follow-up of eight years, particularly considering the young age of many of the patients. (Hip International 2009; 19: 359-66)

KEY WORDS. *Arthroplasty, Cementless, Hip, Integration, Joint replacement, Loosening, Young adult*

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INTRODUCTION

Total hip arthroplasty (THA) is known as one of the most successful surgical interventions ever developed with implant survival rates of over 90 to 95 % after ten years (1) and a high degree of patient satisfaction. Primary stability of the implant and bony integration are key objectives in the development of hip arthroplasty (2). After the introduction of polymetacrylate (PMMA) bone cement in component fixation, pioneered by Sir John Charnley, promising short-term and mid-term results were published, and cementless fixation techniques (3, 4) were used less frequently as a result. The Charnley hip arthroplasty provided good clinical results with excellent implant survival (5-8). However, young age was identified to contribute to failure of the procedure (8), and a dramatically increased rate of aseptic loosening. Im-

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plant survival rate has been reported as low as 68.7 % at 25 years follow-up in patients younger than forty (8, 9).
Technical evolution of cementless implants regarding surface structure, design and metallurgic aspects provided improvement towards better outcome regarding survival rates. Recently, results comparable to cemented implants have been reported (9), and cementless THA has been recommended especially in young patients (1, 8, 9). Specific implant characteristics promote primary stability and secondary long term integration. So called "mesostructured" surfaces with high porosity of approximately 60% to 80% and interconnecting pores between 100 and 2000 µm allow ingrowth of bone, and have been demonstrated to improve permanent osseous integration (10-14).
The ESKA spongy metal hip arthroplasty system of the first generation systematically addressed the requirements of permanent cementless implant fixation with an anatomic design and a 3-dimensional interconnecting porous surface topography. Excellent mid-term (15-18) as well as long-term results (19) have been reported. Since certification and official regulations required a better reproducibility of the open porous surface structure, regular trabeculae were introduced for the second generation implants instead of the randomly arranged pores of the first generation. Further implant modifications included limitation of the porous surface structure to the proximal two thirds of the stem and a gradual reduction of the structure height from proximal to distal. By this, proximal load transfer was improved to reduce thigh pain and proximal stress shielding of the cementless stem that had been observed in approximately 6 to 10 % and 20 to 50 % of patients, respectively, with the first generation implants (16, 20, 21). First publications of similar modifications of the new implant design reported promising results in short-term follow up (20-22). The purpose of the present study was to assess mid-term survival and functional outcome after hip arthroplasty with this second generation cementless spongy metal hip arthroplasty system.

METHODS

Study design and subjects

We studied 81 consecutive cementless primary THAs in 80 patients implanted in a university hospital between 1995 and 1998. All patients who received the second generation cementless G2 hip arthroplasty system (ESKA Implants, Lübeck, Germany) were included in the study. The underlying diagnoses and indications for THA are summarized in Table I. Demographic data were collected and the body mass index (BMI) of the patients was calculated

Implants and procedure

The second generation hip arthroplasty system (ESKA Implants, Lübeck, Germany) made of cobalt-chrome-molybdenum alloy was used in all patients (Fig. 1). The collared G2 stem was implanted as femoral component and is characterized by a typical mesostructured, so called "spongy metal II" surface covering the proximal two thirds of the stem (Fig. 1b). The dimensions of this interconnecting surface structure in regard to porosity and pore sizes have been developed to allow for optimized bony ingrowth (pore sizes 100 to 2000 µm, porosity approximately 70%). The implants were cast in a single piece including the surface structure. Compared to the first generation spongy metal structure, regular trabeculae that resemble tank traps have been implemented instead of the randomly assigned sponge structure to improve reproducibility of the surface, and the rough surface texture has been limited to the proximal two thirds of the femoral component to improve proximal integration and load transfer. The height of spongy metal II decreases gradually towards the tip of the stem to allow for a continuous reduction of load transfer, with maximum load applied to the proximal femur and reduced load applied to more distal bone (23). Furthermore, the G2 stem is curved in the a.-p.-direction to facilitate implantation into the human femur and to improve form fit. Both standard as well as lateralising stems are available in 7 different sizes with and without collar.
The corresponding press-fit metal socket is also based on cobalt-chrome-molybdenum alloy and is completely covered with spongy metal II (Fig. 1a). Initial stability of the metal socket was achieved by dual geometry undersized reaming and press-fit implantation. Additionally, three spikes wedged into the anterior and posterior parts of the

TABLE I - PREOPERATIVE DIAGNOSES

Diagnosis	N [%]
Developmental dysplasia of the hip (DDH)	27 (36%)
Primary osteoarthritis	22 (29%)
Aseptic necrosis of femoral head	12 (16%)
Epiphyseal varus deformity	7 (9%)
Posttraumatic osteoarthritis	3 (4%)
Other	5 (7%)

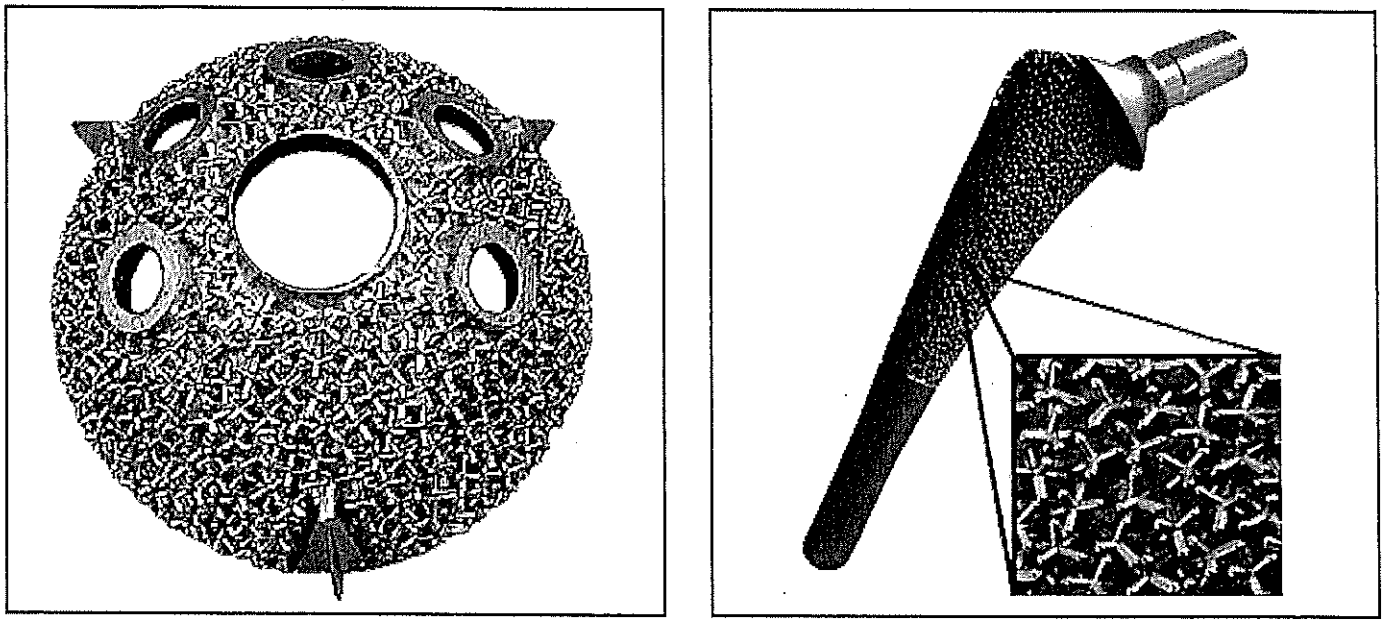

Fig. 1 - *Second generation spongy metal hip arthroplasty system (ESKA Implants, Lübeck, Germany) with a) fully structured press-fit cup, and b) proximally structured collared stem. Insert: Spongy metal II structured surface with regular trabeculae.*

acetabular rim provided further stability, and enforcement of primary fixation with one or two screws was realized. A total of 11 different cup sizes ranging from 44 to 68 mm in diameter were available. Polyethylene inserts were combined with alumina ceramic heads (Biolox, Plochingen, Germany) of 28 and 32 mm diameter.

Written informed consent was obtained from all patients. Antibiotics were administered perioperatively and prophylaxis for thromboembolism was performed in a standard manner until full weight bearing was achieved. Eight different surgeons performed the operation, using a standardized antero-lateral modified Watson Jones approach. Patients were allowed partial weight-bearing for six weeks and thereafter advanced to full weight-bearing without restrictions. Low-molecular weight heparin was administered for prevention of thrombosis and pulmonary embolism. Technical measures of thrombosis surveillance such as ultrasound or venography were only performed in cases with clinically suspected thrombosis.

Outcome measures

Patients were evaluated clinically by an independent investigator. X-rays were taken if patients reported any complaints and loosening was evaluated by the criteria defined by Engh et al (24) and Hodgkinson et al (25). The primary end-point of the study was determined as revision of the femoral or acetabular component. The Merle d'Aubigné score, recording pain, mobility and ability to walk from 0 (worst) to 6 (best) was used to determine clinical performance (26). The McNab score, a simple 4-point rating scale from excellent to poor (27), was also assessed. Furthermore, patients were asked if they would recommend the performed treatment to a friend, and patients' satisfaction with treatment was assessed by questionnaire on a 7-point scale ("very satisfied" to "very unsatisfied").

Statistical analysis

The Kaplan-Meier survivorship analysis (28) was used to estimate a cumulative function for the femoral and acetabular components, with revision as the end-point.

RESULTS

Study population and demographics

No patient was lost to follow-up and 75 of the 80 patients with 76 THAs were included in the final analysis (94%).

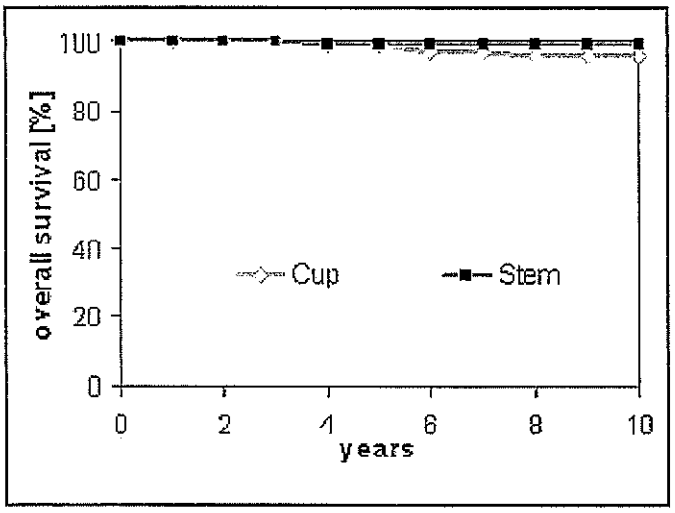

Fig. 2 - *Implant survival of the second generation spongy metal hip arthroplasty system.*

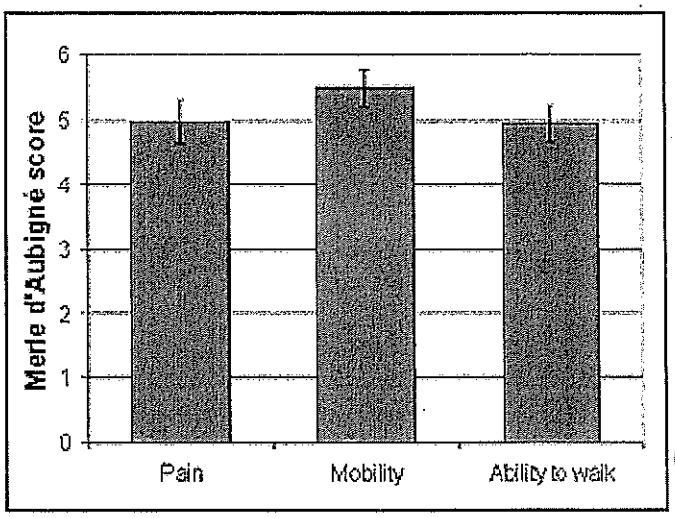

Fig. 3 - *Single items of the Merle d'Aubigné Score at follow-up 8 years after THR, showing means and 95% confidence intervals.*

Five patients died with the THA still in situ at time of death. Mean age was 50.9 years (range 23-73) at the time of surgery, and there were 48 women (48 hips) and 27 men (28 hips), with a mean follow up of 7.9 years (range 7.0-10.2). The average BMI was 26.7 kg / m² (range 18.5-50.0).

Implant survival and revisions

At the time of follow-up 7.9 years after implantation, 75 of the 76 implanted hip stems were still in situ, corresponding to an implant survival of 99% for the G2 stem. Overall implant survival is shown in figure 2. One stem had to be revised after 3.9 years due to recurrent dislocation after trauma (together with the corresponding acetabular cup). No revision for loosening had to be performed for any femoral component.

Regarding the acetabular component, 73 out of 76 cups were still in situ at the time of follow-up, an implant survival rate of 96% after 8 years. Only one acetabular cup had to be revised 7.1 years after implantation for aseptic loosening (1%) in an overweight patient with a BMI of 36.4 kg/m². Along with the femoral stem, one cup was revised for recurrent dislocation in the same patient. Inserts as well as femoral heads had to be exchanged in two cases with dislocation (5.1 and 5.7 years after primary surgery), and in one of these cases the cup finally had to be revised due to recurrent dislocation. On one occasion, the femoral

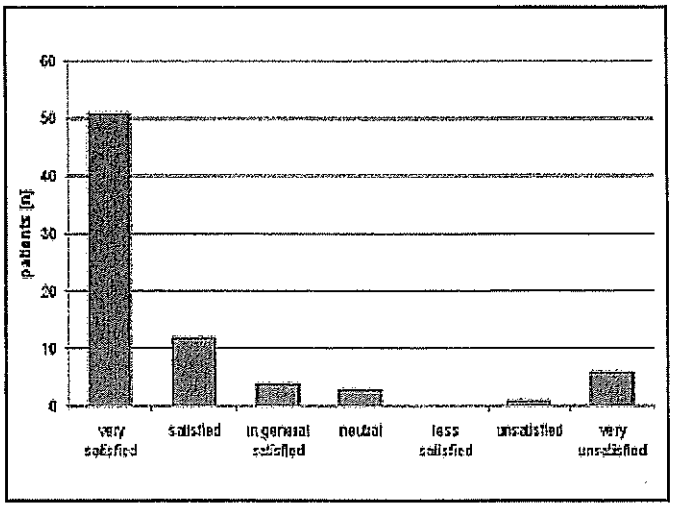

Fig. 4 - *Patients' satisfaction with treatment.*

head and insert were exchanged due to sciatic nerve palsy, which occurred after leg length increased by 4 cm following THA in a patient with severe developmental dysplasia and dislocation of the hip.

Function, pain and complications

The functional outcome was scored by using the Merle d'Aubigné rating system. High values were observed at

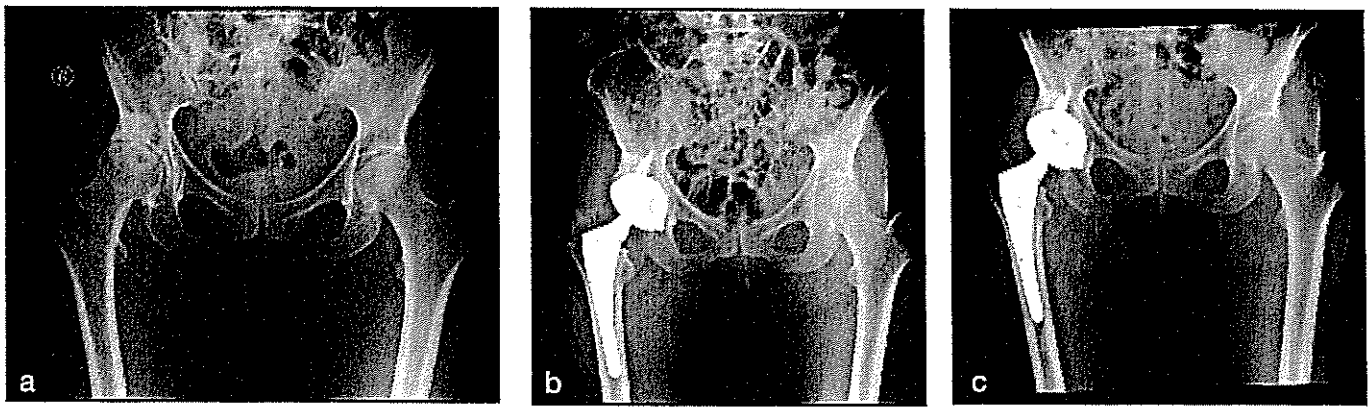

Fig. 5 - *Radiographs of a cementless spongy metal THA:* **a)** *Preoperative X-ray.* **b)** *6-weeks after the operation.* **c)** *7 years after the operation showing stable osseous fixation of the implant.*

follow-up for all items pain, mobility and ability to walk with a Merle d'Aubigné sum score of 15.5 ± 2.9 (Fig. 3). The positive outcome is emphasized by the fact that 95% of all patients would recommend the procedure of THA to a friend. The results found in the Merle d'Aubigné Score were confirmed on the 4-point McNab score, a subjective scale with patients rating their function from excellent to poor. 38 patients (50%) were classified as excellent, 24 (32%) as good, 6 (8%) as moderate and 8 (11%) were scored as poor. Additionally patients' satisfaction with the performed treatment was recorded on a 7-point scale from very satisfied to very unsatisfied (Fig. 4).

Poor McNab score corresponded with those patients who were not satisfied with treatment outcome. Regarding this subpopulation, two patients had revision surgery (one for dislocation, one for aseptic loosening of the cup), two had incomplete nerve palsy (one sciatic nerve after revision surgery for postoperative hematoma and one sciatic nerve after leg lengthening of 4 cm), one had to be revised for periarticular ossification, and three had significant concomitant disorders such as spinal stenosis requiring surgery, significant low back pain, and disabling osteoarthritis of the knee. A total of 11 complications were recorded in 11 patients (Tab. II). Apart from the above-mentioned stem and cup revisions, periarticular ossification had to be surgically removed in three cases, and one patient had to be revised due to postoperative hematoma. No clinically relevant deep vein thrombosis, pulmonary embolism or infection were observed. Patients were specifically asked regarding thigh pain, which was not reported.

TABLE II - POSTOPERATIVE COMPLICATIONS

Complication	N (%)
Dislocation	4 (5%)
Heterotopic ossification	4 (5%)
Nerve lesions	2 (2%)
Hematoma	1 (1%)

DISCUSSION

Cementless integration of the spongy metal implants is based on press-fit implantation and stable primary fixation with avoidance of micro-movement at the implant-bone interface, followed by bony ingrowth into the porous surface structures for permanent integration (29). The successful concept of bone anchorage with first generation spongy metal surfaces has been confirmed by several mid-term studies in hip arthroplasty, reporting excellent results with permanent osseous integration of the fully structured GHE femoral and acetabular components (15, 16, 30). Long-term survival of these first generation stems has now been assessed as well, with a survival rate of the femoral implant of 95% after 17 years (19).

A second generation of spongy metal implants was developed to address the requirements of exact reproducibility of the porous surface structure. In this respect, a regular trabecular structure was introduced (spongy metal II). Spongy metal II had demonstrated stable adherence to the implant, and provides pore sizes of 100 to 2000 µm with a porosity of more than 70%, thereby optimizing the effective implant surface that can be reached by bony ingrowth (14). The structured surface of the newly developed

G2 femoral component became limited to the proximal two thirds of the stem to emphasize proximal integration and proximal load transfer, and to reduce the risk of distal cortical thickening and proximal stress shielding due to stem stiffness and firm distal fixation (16, 20, 21, 31. 32). Burgkart and Glisson demonstrated optimized strain distribution of the proximally structured implant compared to the fully structured stem, with comparable primary stability and negligible micro-movement (33). Stems which are porous-coated only in their proximal part are increasingly popular because the more proximal stress transfer helps to prevent stress shielding, with less corrosion and release of metal ions, and easier removal of the implant if needed (34). Furthermore, gradual reduction of the trabecular height from proximal to distal was achieved in the second generation stem to allow for greater distal core diameter of the prosthesis – especially important in small implants to prevent stem fracture – and gradually reduced load transfer from proximal to distal (14).

Gradual reduction of load transfer may also help to reduce the risk of thigh pain, which has been reported with the fully structured first generation spongy metal stems and other cementless femoral components with an incidence up to 40% (16, 35). Permanent thigh pain has also been observed in firmly integrated proximally porous coated stems due to rotational and bending stresses causing micro-movement of the smooth tip of the stem (36). Other common causes are micro-movements at the bone-implant interface, peak stresses at the interface caused by stiff implants, periosteal irritation and risk factors such as osteopenia (35). In contrast to the reported data, we did not observe persistent thigh pain in any patient with a proximally structured stem, and our results corroborate the principle of continuous load transfer from proximal to distal.

Similarly, acetabular press-fit cups with first generation spongy metal have been evaluated in prospective series and have also demonstrated very good results. Decking and co-workers did not observe any loosening in 96 reviewed acetabular cups at 6-year follow-up (37), and Plötz et al observed a survival rate of 98% with radiological signs of osseous integration (16). Long-term results support the principle of permanent cup integration with 84% of the cementless first generation spongy metal cups in situ after 17 years (19).

Our study revealed excellent mid-term survival of a cementless second generation spongy metal hip arthroplasty system, with no aseptic loosening of the femoral component and only one aseptic loosening of the acetabular component. Thus, our data support the concept of permanent osseous integration (Fig. 5). Revisions of two cups and one stem were due to recurrent dislocation.

Survival rates of both femoral and acetabular component are at least comparable to other successful cementless implants at five to ten years of follow-up (38-41). In comparison, revision rates for aseptic loosening of up to 18% for femoral components and 30% for acetabular components have been published for other cementless implants (42, 43). The high survival rate of the implant is especially relevant with regard to the young patient population with a mean age of 50.9 years. Comparable studies with relatively young patients usually reported revision rates from 5.4% up to 20% at the midterm follow-up (42, 44). Functional assessment of our patient population showed good results with a mean Merle d'Aubigné score of 15.5 and a high patient acceptance and satisfaction. Treatment failures were mainly associated with dislocation, nerve lesions and heterotopic ossification, as well as significant concomitant medical disorders.

Follow-up studies on THA often have only limited value for daily clinical practice, since most of the THAs enrolled are performed by only one or two very specialized surgeons (42, 45), whereas the operations evaluated in the present study were performed by eight different surgeons. Thus, the positive results are of special value and can more easily be transferred to daily clinical practice.

We conclude that the evaluated cementless spongy metal II hip arthroplasty system showed excellent survival in a young and active patient population after a mean follow-up of 8 years. As a consequence, we recommend using cementless and surface structured implants for young and active patients, where stable and permanent osseous integration and anchorage is required.

Conflict of interest statement: This study was not supported financially or in any other way by any public or private organisation. R. Gradinger is holder of a patent concerning characteristics of the hereby described prosthesis. None of the other authors has proprietary or fiscal interests in the study or is in financial or proprietary association with one of the companies or their competitors named in the study.

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ORIGINAL ARTICLE

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Long-term results of the metal-cancellous cementless Lübeck total hip arthroplasty: a critical review at 12.8 years

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Abstract *Introduction*: The influence of a spongy metal surface total hip arthroplasty (THA) (S&G, ESKA, Lübeck, Germany) on the clinical, psychometric, and radiograhic long-term results were examined. *Material and methods*: An amount of 137 THA with the cementless spongy metal Lübeck hip prosthesis were evaluated long-term, radiographically and clinically, with a mean follow-up time of 12.8 years (range 10.1–14.9 years). The MOS SF-36 was used to assess the health-related quality of life (HRQL). *Results*: Cumulative survival rates were 90% (±8%) for the cups and 86% (±5%) for the stems at 14.9 years. Four stems fractured at the middle part (3%) without major trauma. In the remaining patients the clinical results expressed as Harris Hip Score (HHS) averaged 88 (range 34–100). Patients above 60 years undergoing THA had no significant difference in HRQL (MOS SF-36) in comparison to the age-matched healthy population ($P > 0.05$). Patients younger than 60 years had scores lower than normal in the physical function domains ($P < 0.01$), but were comparable in the mental health domains ($P > 0.05$). Radiolucent lines and bone atrophy related to stress shielding by distal fixation were found in the periprosthetic Gruen Zone I (19.8, 16.8%) and VII (10.3, 27.1%) of the proximal femur. *Discussion*: Whereas the rate of aseptic cup failures of the cementless spongy metal Lübeck hip prosthesis is among the best, the failure rate of the stems is attributable to osteolysis of the proximal femur. The fractures of the stem may be attributed to the combination of the lack of proximal support, the fully porous stem made of a cast cobalt-chrome-molybdenum alloy, and the narrow dimension of the stem core. The long-term results of the spongy metal cup are good, whereas the high loosening and fracture rate of fully coated stem are a source of concern especially with regard to the difficult revision scenario with frequent massive bone loss.

Keywords Primary hip arthroplasty · Uncemented fixation · Fully porous coating · Structure · Long-term results · Health-related quality of life

Introduction

The success of cementless fixation in total hip arthroplasties (THA) depends on the primary stability and secondary osseointegration of the prosthesis. For initial stability the accuracy of host bone preparation and the design of the prosthesis are critical, while the surface texture of the implant and the quality of the implant-bone contact determine secondary stabilization [28]. Numerous surface structures for bony ingrowth have been developed [22]. The cementless metallic-cancellous implants were developed in the late 1970 s and introduced in 1981 as hip endoprostheses that were cast with a two-dimensional porous surface structure. Because of insufficient spatial depth for bony ingrowth its surface structure was subsequently modified [13]. The fully porous structure was designed as a three-dimensional network mimicking natural cancellous bone. The Metal-Cancellous Cementless Lübeck (MCCL) endoprosthesis (S&G, ESKA) with a fully coated stem has been implanted since 1983 (Fig. 1). Mid- and short-term results have so far been satisfactory [20, 29, 31, 33]. Long-term results are not yet available. Our aim was to assess the efficacy of the implant in a long-term study.

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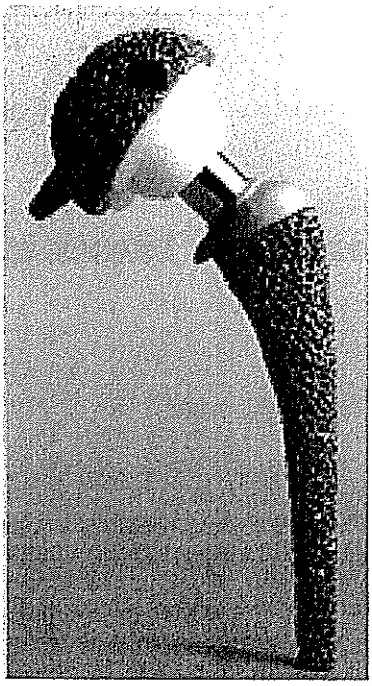

Fig. 1 The metal-cancellous cementless lübeck (MCCL) prosthesis (S&G, ESKA Implants GmbH)

Patients and methods

From September 1986 to December 1990, 231 consecutive primary THA's were performed. A cementless MCCL hip was implanted in 201 patients. The cementless metal-cancellous Lübeck prosthesis is made of a cobalt–chromium–molybdenum alloy [13]. The entire surface of the anatomical femoral stem and of the cup has an intercommunicating structure with a pore size ranging from 800 to 1,500 μm and a porosity of 60%. Specimens retrieved from patients demonstrated bone ingrowth into the surface (Fig. 2) [31]. On account of their anatomical design right and left stems are needed. These come in seven sizes. A 28-mm aluminum oxide ceramic head (Biolox; Feldmühle, Plochingen, Germany) available in three neck lengths was used for articulation in a polyethylene liner. The operations were performed by three surgeons and four residents.

Of the original 201 patients, 53 (26.4%) had meanwhile died. The cause of death was unrelated to the THA. For 31 patients follow-up data were incomplete or unavailable, either they failed to cooperate because they were too old [$n = 18$ (8.9%)] or forgot to follow-up [$n = 13$ (6.5%)]. In these, the patients' families denied a follow-up by telephone. For the remaining 117 patients (58.2%) clinical and radiologic data were available. Of these, 137 consecutive primary THA (59.1%) had been performed. Kaplan–Meyer survivorship was performed in all operated cases without selection to predict the outcome of surgery. Revision was the endpoint for the statistical evaluation in the survivorship analysis.

Fig. 2 Specimen of proximal femur retrieved during revision surgery: note bony ingrowth into the cancellous surface structure of the distal stem

Indications for arthroplasty were osteoarthritis in 79 hips (57.7%), osteonecrosis in 33 (24.1%), arthritis secondary to hip dysplasia in 22 (16%), and post-traumatic osteoarthritis in 3 (2.2%). Both hips were involved in 20 patients. These underwent bilateral two-stage procedures. The mean age at surgery was 59 years (range, 24.2–73.2 years) with 48.7% of THA's performed under age 60 years and 5.8% over 70 years. The mean interval between surgery and the last follow-up was 12.8 years (range, 10.1–14.9 years). Thirty-nine men and 78 women were entered in the study group. Their mean age at the last re-assessment was 70.8 years (range, 37.7–86.9 years). In 66 patients (48.2%) the prosthesis was implanted on the right and in 71 (51.8%) on the left side. The mean body mass index (BMI) at the last assessment was 29.7 kg/m^2 (range, 19.5–51.8 kg/m^2).

In general anesthesia surgery was performed through an anterolateral approach. All patients received antibiotics for 24 h and thrombembolism prophylaxis. In seven hips a graft taken from the resected femoral head was fixed with AO screws to reinforce the dysplastic acetabulum. The metal socket was placed in an anatomical position at 45° from the horizontal. The polyethylene inlay was inserted after implanting the acetabular component. After rasping the medullary cavity of the femur the stem was inserted at maximum press fit. Postoperative radiotherapy with 7.5 Gy to prevent ossification was performed in 70 hips (51.1%). Sixty-seven hips (48.9%) were not subjected to postoperative radiotherapy. Postoperatively the patients were mobilized without weight bearing for 6 weeks. Full weight bearing was allowed after 6 weeks.

Clinical outcome

To evaluate the clinical outcome the Harris Hip Score (HHS) [12] and the activity score by Sutherland et al. [34] were used at follow-up. The HHS scores over 90 were rated as excellent; 80 to 89 as good, 70 to 79 as fair,

and less than 70 as poor [12]. The Sutherland score evaluates mean impairments in activities of daily living of THA patients. The overall activity (range, 3–10 points) was calculated from the general activity (range, 1–4 points), the occupational activity (range, 1–3 points) and the recreational activity scores (range, 1–3 points) [34].

Questionnaire to assess health-related quality of life (MOS SF-36)

The evaluation of the quality of life with self-assessment questionnaires is widely accepted as an outcome measure of medical procedures [35]. The German cross-culturally adapted and validated version of the MOS SF-36 was part of the questionnaire. The SF-36 health survey is a generic instrument for assessing health-related quality of life (HRQL). It was developed as an abbreviated form of the instruments used in medical outcome studies [21, 38]. In association with the International Quality of Life Assessment Project (IQOLA) [1] Bullinger et al. [6] translated the questionnaire into German. Psychometric testing showed good validity and reliability [6]. The SF-36 includes eight health concepts. The physical component health summary (PCS) contains items like limitations in physical activities, limitations in usual role activities because of physical health problems, bodily pain, and general health perceptions. The items of the mental health component summary (MCS) include vitality, general mental health, limitations in social activities, and role activities because of emotional problems [6, 21, 38]. The PCS and MCS measures help to reduce the number of statistical comparisons [39]. Age and gender-related scores for PCS and MCS of the healthy German-speaking population ($n=2,914$) are known.

Radiographic assessment

For the radiographic evaluation anteroposterior radiographs of the pelvis and lateral radiographs of the operated hip were recorded with the standard technique. Preoperative and postoperative radiographs and those taken at the last re-assessment were available from all hips. Every effort was made to place the patients in the same position. Bone re-modeling, osteolysis, and implant-bone radiolucent lines on the acetabular side were evaluated with the scales of DeLee and Charnley [7], while the Gruen, McNeice, and Amstutz [11] classification was used for the femoral zones. A pedestal sign defined as an area of increased density extending across the width of the endosteal canal at the distal tip of the femoral prosthesis was recorded. On the acetabular side, migration of the implant was determined as described by Nunn et al. [25]. Cup migration was assessed from the horizontal and vertical distance between the femoral head center and the inter-tear drop distance. Differences of more than 2 mm or more than 5° in the opening angle of the acetabular cup were defined as migration [25]. On the femoral side stem subsidence was determined as described by Engh et al. [8]. The vertical distance between the tip of the greater trochanter to the collar of the prosthesis was evaluated. To verify the measurements the distance between the midpoint of the lesser trochanter and the collar of the stem was recorded. A difference of less than 3 mm was considered to be within the limits of error of the method. Subsidence of more than 5 mm was taken as a sign of significant subsidence. Ectopic ossifications, when present, were graded according to Brooker et al. [4].

The questionnaire data correlated with the clinical and radiologic data were interpreted by one of the authors (AT) who had not been involved in the treatment of the patients. All analyses were performed with a commercially available software package (SPSS Win. 2000 Inc., Chicago, USA). Changes of radiologic and clinical parameters were evaluated with Student's *t*-test for paired and non-paired data. The statistical correlation of the MOS SF-36 data with the radiologic and clinical results was analyzed with the ANOVA test for parametric data and the Kruskal–Wallis test for non-parametric data.

Results

Complications

Early complications were recorded in ten of the 231 operated patients (4.3%). Two fractures of the greater trochanter (0.9%) occurred intra-operatively. These were successfully stabilized by intra-operative wire cerclage. Two periprosthetic fractures (0.9%) were treated by immediate single-wire cerclage. One early infection was controlled by irrigation and debridement 5 weeks postoperatively and the ceramic head and the polyethylene liner were exchanged. In four hips (1.7%) incomplete femoral nerve palsy was present postoperatively. At the last follow-up this had resolved in all but one hip. One dislocation was treated by closed reduction.

Late complications were seen in 18 of the 137 re-assessed THA's (13.1%). Four *stem fractures* at the middle part (2.9%) were recorded without any major trauma at the follow-up (Fig. 3). Despite broken stems the patients were free from pain, clinically. In two hips the stem was exchanged (1.5%). A fracture of the ceramic head occurred in one patient. The broken ceramic head was replaced with a metal component and the polyethylene liner has been exchanged. Hematogenic late infection caused septic loosening in three hips (2.2%). These were revised in two-stage procedures. Aseptic loosening prompted the removal of the stems in seven patients (5.1%) and of the cups in two (1.5%). All incidents summarized show that 16 of the 137 completely documented THA's were aseptic implant failures.

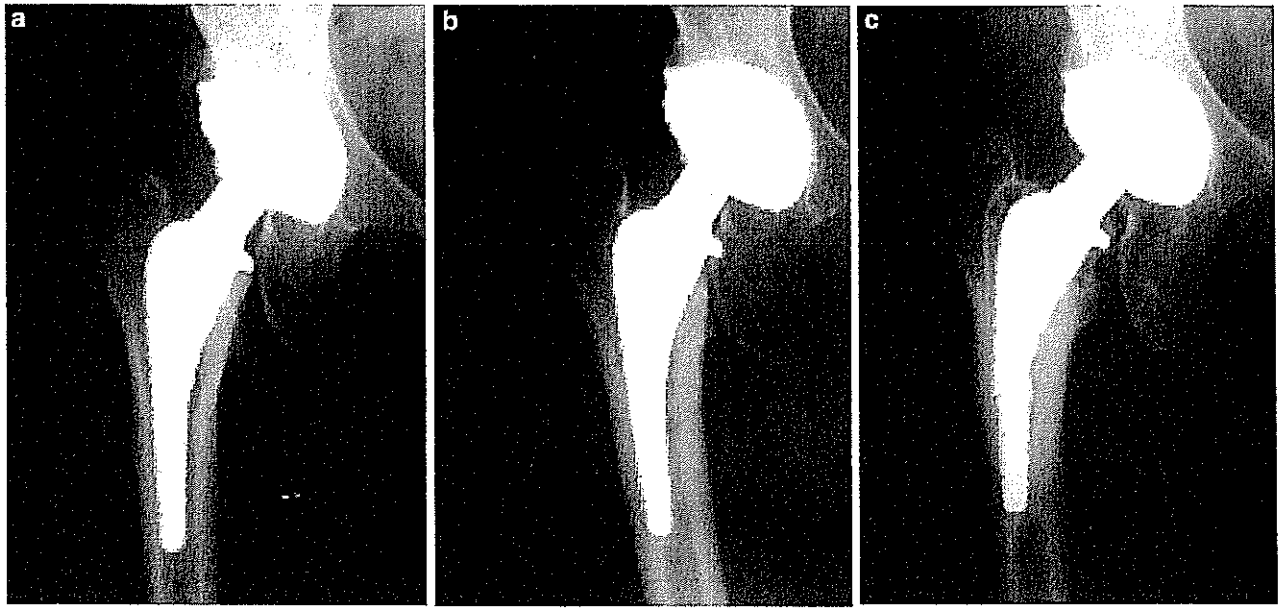

Fig. 3 a Postoperative radiograph of the right hip of a 69.3-year-old woman. b Note bone atrophy in the proximal periprosthetic femur combined with varus shift of the stem 7 years postimplantation. c Note mid-stem fracture 13 years postimplantation. Revision with replacement of the stem was refused by the asymptomatic patient

Cumulative survival rates were 90.1% (±8%) for the cups and 86.2% (±5.3%) for the stems at 14.9 years (Fig. 4).

Clinical data

The mean HHS at the last re-assessment was 88.3 (range, 33.7–100). The scores for pain averaged 33.8 (range, 0–44), those for activity 11.8 (range, 4–14), those for mobility 27.7 (range, 7–33), and those for function 4.8 (range, 3.8–5). At an average follow-up of 12.8 years more than 83% of the remaining hips were rated as good or excellent, 5% as fair and 11.6% as poor (Table 1). The mean Sutherland score for the activity level was 7.5 (range, 2–9). The correlation between the HHS and the Sutherland activity level score was highly significant ($P < 0.001$). The daily activity score of Sutherland was affected by the age of the patients ($P = 0.04$). Interestingly, this was not the case for the HHS ($P = 0.32$).

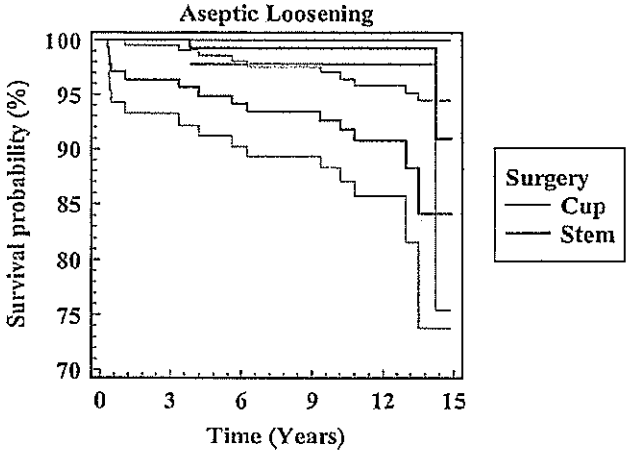

Fig. 4 Kaplan–Meier survivorship curve, with 95% confidence interval, showing a 90% (±8%) survival for the cups and an 86% (±5%) survival for the stems at 15 years. Numbers at risk at 5, 10, 12, and 14 years: 130, 109, 60, and 30 hips

MOS SF-36

The health-related SF-36 questionnaire was analyzed in relation to the age-matched healthy German-speaking population. Only patients with hip arthroplasties in situ were evaluated. Sixty-five patients were between 70 and 79 years old at the last re-assessment. Fig. 5 shows the items of the physical (PCS) and mental component summary (MCS). These were not significantly different from those of the age-matched healthy population ($n = 312$) ($P > 0.05$). The mean PCS score of age-matched healthy German-speaking individuals was 39.9 ± 11.3. In

Table 1 Harris hip score at follow-up in 121 total hip arthroplasties (%)

Harris hip score		Numbers = n	(%)
90–100 points	"Exellent"	74	61.16
80–89 points	"Good"	27	22.31
70–79 points	"Fair"	6	4.96
< 70 points	"Poor"	14	11.57
60–69 points		4	3.31
50–59 points	"Poor"	4	3.31
40–49 points		3	2.48
30–39 points		3	2.48

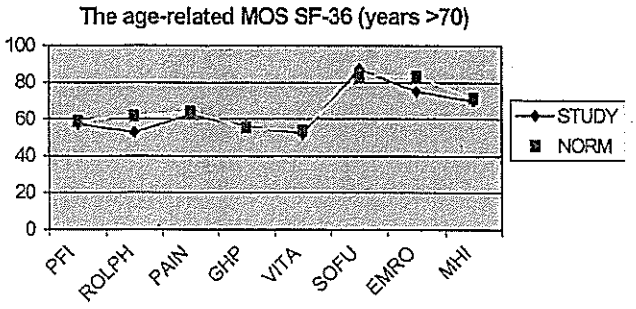

Fig. 5 Age-related MOS SF-36 scores of the domains physical function (*PFI*), physical role function (*ROLPH*), bodily pain (*PAIN*), general health (*GHP*) for the physical summary score; vitality (*VITA*), social function (*SOFU*), emotional role function (*EMRO*), mental health (*MHI*) for the psychologic summary score. No statistically significant impairments ($P > 0.05$) in the THA group ($n = 65$) versus the age-matched healthy population ($n = 416$)

the THA group the mean score was 39.1 ± 11.2. The mean MCS score of the THA group (51.8 ± 7.4) was the same as that of the healthy population (52.4 ± 8.9) ($P > 0.05$).

Twenty-four patients were between 61 and 70 years old at the last follow-up. Their age-related physical and mental component summaries did not show any statistical difference versus the age-matched healthy German-speaking population ($n = 416$) ($P > 0.05$).

Twelve patients were between 51 and 60 years old at the last re-assessment. Of these, six were operated because of osteonecrosis, two of them bilaterally. In three patients bilateral THA was performed because of dysplastic hips and in the remaining three because of post-traumatic osteoarthritis. The HHS averaged 84.9 (range, 50.9–100). The difference versus the mean HHS of the whole study group was not significant statistically ($P = 0.88$, Student's t-test for non-paired data). The physical HRQL was significantly lower than that of age-matched healthy German-speaking individuals ($n = 326$) (< 0.01) (Fig. 6). The score of the age-matched healthy population averaged 47.9 ± 9.7. In the THA group the mean physical component summary score was

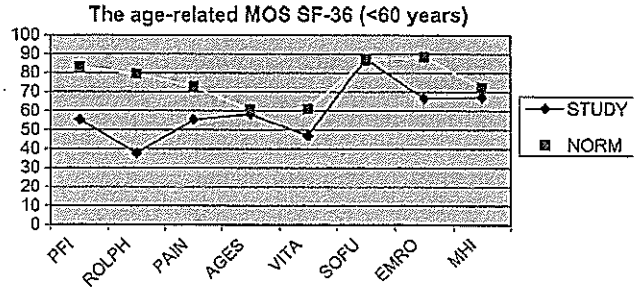

Fig. 6 Significantly lower physical component summary scores in the THA group ($n = 12$) versus age-matched healthy individuals ($n = 326$) ($P < 0.01$). The items' physical activities (*PFI*), bodily pain (*PAIN*), and limitations in usual role activities because of physical health problems (*ROLPH*) scored significantly lower than in the age-matched healthy population ($P < 0.01$)

37.2 ± 12.7. The items' physical activities, bodily pain, limitations in usual role activities because of physical health problems were significantly lower than in the age-matched healthy population ($P < 0.01$). The mental component summary of the study group (50.3 ± 11.2) was not significantly different from that of age-matched healthy individuals (51.2 ± 11.2) ($P > 0.05$).

Neither the physical nor the mental component score correlated with the follow-up time ($P > 0.05$). There was no significant correlation between PCS ($P = 0.6$) or MCS ($P = 0.5$) and the BMI. The gender did not influence the data of the SF-36 ($P = 0.51$). Whereas there was a significant correlation between the physical HRQL and both the HHS ($P < 0.001$) and the Sutherland activity score ($P = 0.002$), there was no correlation between the mental HRQL and the HHS ($P = 0.14$). The items' activity ($P = 0.008$), function ($P < 0.001$), and pain ($P < 0.001$) recorded by the HHS influenced the physical component summary of HRQL.

Radiographic analysis

Preoperative and immediately postoperative radiographic data and those from the last follow-up were available for all 121 primary THA's. Table 2 shows the periprosthetic bone changes on the femoral side. At the last re-assessment, segmental periprosthetic implant-bone radiolucent lines of more than 2 mm in width were present in Gruen zone I in 19.8% and in Gruen zone VII in 10.3% of the hips. Bone atrophy related to stress shielding was observed in zone I (16.8%) and in zone VII (34.6%) (Fig. 3). Distally, periprosthetic sclerosis and hyerthrophic bone were present in zone III (17.8%) and in zone V (14.0%). A pedestal sign was noted in 11% of the hips. Vertical stem subsidence of more than 3 mm was seen in 24% of the hips. Subsidence of more than 5 mm from the greater trochanter was found in 6% of the hips. Changes in the stem axis were present in four hips and two stems had shifted into varus (1.9%).

The distribution of radiodense lines around the acetabular component is shown in Table 3. Radiolucent lines were present in more than one zone in some of the hips. Circumferential radiolucent lines around the acetabular component were absent. The mean inclination of the acetabular component on anteroposterior radiographs of the pelvis was 45.9° postoperatively (range, 32–63°) versus 47° (range, 32–66°) at the last re-assessment. 87.6% of the acetabular components did not show a significant difference in inclination versus the immediate postoperative findings. In 5.2% of the hips the difference was 3 to 4° and in 7.2% more than 5°. Based on the criteria of Nunn et al. 8.4% of the acetabular components had migrated by more than 5 mm.

Radiologic measurements did not correlate with demographic (gender, follow-up time, age at surgery, BMI) or clinical data ($P > 0.05$).

Heterotopic bone was absent in 65 hips (53.7%). Thirty-nine hips (33.1%) showed ossifications Brooker

Table 2 Periprosthetic bone changes along the stem according to the classification of Gruen et al. [11]

	I (%)	II (%)	III (%)	IV (%)	V (%)	VI (%)	VII (%)
Linear radiolucencies	19.8	2.8	1.9	0.9	0.9	0.9	10.3
Resorption	16.8	1.9	1.9	0.0	0.9	1.9	34.6
Sclerosis	0	5.6	17.8	6.5	14.0	2.8	11.2
Cortical hypertrophy	0	0	5.6	2.8	3.7	0	0
Atrophy	0	0	0	0	0	0	27.1
Pedestal	0	0	0	11.0	0	0	0

class I, 11 hips (8.3%) class II, and six hips (4.9%) class III. There was an inverse statistical relation between postoperative radiation and ossifications ($P = -0.002$). Ossifications class III significantly influenced the physical component summary ($P = 0.02$) and the HHS ($P = 0.009$). The mental component summary was unaffected by them ($P = 0.11$). Ossifications classes I and II did not affect HHS and HRQL ($P > 0.05$).

Discussion

Clinical data

Since THA was introduced, attempts have been made to quantify the outcome of surgery [3, 5, 12, 34]. The results were assessed inconsistently by different measurements [3, 5]. In a prospective study of patients undergoing THA, Lieberman et al. [17] confirmed that patient assessments of pain sensitivity and medical assessments were contradictory and insisted that an additional patient-relevant assessment of the outcome of surgery was required. Unlike other measurements, self-assessment with the MOS SF-36 is highly correlated with the success of THA [14, 32]. Applying the SF-36 provides additional important quality of life domains that are influenced by THA [3].

In the current study 101 patients undergoing 121 THA's with a minimum follow-up time of 10 years were assessed. In a span of 12.8 years postoperative to the HHS, the Sutherland activity score and the MOS SF-36 were evaluated. Clinically 84.5% of the hips had excellent or good HHS scores at the last follow-up. Only 11% of the hips scored poorly with a HHS below 70. In these cases aseptic loosening of the prosthesis was excluded by radiography. Three of 13 cases were affected by chronical systemic rheumatoid arthritis. Four patients complained of insufficient abduction strength. In three hips heterotopic ossification hindered the mobility. The physical component summary of the MOS SF-36 was significantly correlated with the HHS and the Sutherland activity score. Lieberman et al. [16] also found a very high correlation between the HHS and the SF-36 domains in the physical component summary scores in 140 operated patients [16, 32].

In patients operated for degenerative osteoarthritis the good clinical results were confirmed by the data of the health-related SF-36. The age-related results suggested that the health-related quality of life in operated patients older than 60 years is attributable to an unrestricted physical and mental quality of life. However, the physical quality of life in patients younger than 60 years undergoing THA showed restrictions compared to the age-matched healthy population. Functional impairments, bodily pain, and limitations in usual role activities influence the physical component of the quality of life in younger patients. The mental HRQL remains unrestricted. Jones and Voaklander [14] found physical function to be restricted and bodily pain to be increased in operated patients compared to the general population. Lieberman et al. [16] reported a restricted physical HRQL particularly in patients younger than 65 years at a comparable mental HRQL. Particularly in younger individuals undergoing THA patient expectations may not be fulfilled because of the restricted functional outcome [18].

Table 3 Periprosthetic bone changes on the cementless socket according to De Lee and Charnley [7]

	Zone I		Zone II		Zone III	
Radiolucencies	7	6.6%	9	8.5%	12	11.3%
Resorption	5	4.7%	1	0.9%	6	5.7%
Sclerosis	5	4.7%	1	0.9%	1	0.9%

Radiographic analysis

Our long-term radiographic experience with the fully porous coated stem has shown a high incidence of radiolucent lines in the periprosthetic bone of the proximal femur. In keeping with stress shielding by distal stem fixation femoral bone loss was obvious in the proximal lateral and medial periprosthetic bone. On serial radiographs cortical hypertrophy was more frequent distally. This pattern of distribution is typical of the fully porous coated MCCL stem [20, 30, 33]. The stem transfers most of the load to the distal area. As a consequence bone atrophy may be seen in the proximal femur. Bone hypertrophy may occur at the tip of the stem. Yamaguchi et al. [37] reported a decreased periprosthetic bone mineral density in the proximal femoral bone with dual-energy X-rays. They followed 61 spongy metal implants in a longitudinal study for 12 to 18 months. Irrespective of the extent of the porous coating of the stem, they found 20% periprosthetic bone atrophy in the proximal femur. In comparison to other

contemporary cementless devices like the Zweymuller Prosthesis the presented design is based on a distal, diaphyseal fixation. Grubl et al. [10] and Vervest et al. [36] presented similar results with the rectangular Alloclassic prosthesis 10 to 12 years postoperative with cortical atrophy around the proximal part of the stem.

At 12.8 years postoperatively our results with the MCCL cup were among the best with only three aseptic failures. In one case the polyethylene liner was replaced by a fixed metal cup. Although 8.4% of the acetabular components showed migration of more than 5 mm, circumferential radiodense lines were absent throughout. Long-term radiographic analyses of fully porous coated cups confirmed sufficient bony ingrowth.

In our study low-dose irradiation after THA successfully prevented heterotopic bone formation. Postoperative single-dose irradiation with 7.5 Gy as described by Pellegrini et al. [27] significantly decreased heterotopic ossifications. Radiation therapy reduced the rate of unsatisfactory results and significantly increased the HHS and the HRQL in our study group.

Survival analysis

Survival rates over 90% at more than 10 years indicate whether or not an endoprothesis is a successful design [24]. For our study implant, failure was defined as revision with replacement or extraction of one or both prosthetic components including the polyethylene liner [23]. At 14.9 years postoperatively Kaplan–Meier survival including septic revisions was 86.2% for the MCCL stems and 90.1% for the cups. Short-term and mid-term outcomes with the MCCL endoprosthesis were reported elsewhere [20, 29, 31, 33]. Plotz et al.[29] reviewed 100 consecutive patients with a mean follow-up time of 34 months. None of the hips required revision. Among 72 cancellous-metal hip prostheses followed up for a mean time of 43 months, Runkel et al. [30] found three cups and two stems (6.9%) to be in need of revision because of aseptic loosening. Matsui et al. [20] reported a series of 51 MCCL prostheses implanted for dysplastic osteoarthritis. Five to 9 years postoperatively one of these had *to be revised* for stem fracture and another one for infection. Sugano et al. [33] confirmed the satisfactory results with the MCCL endoprosthesis in patients with osteoarthritis secondary to hip dysplasia. Of 66 hips, 31 of them with additional bone grafting, none failed after an average of 43 months.

Four of 137 stems fractured in our study group. Most of the failures occurred in the middle one-third of the stems. Radiography of all cases suggests a lack of rigid support in the proximal area and a rigid fixation in the distal area (Fig. 3). The revision of a broken stem can be a difficult procedure associated with massive bone loss. Kishida et al. [15] criticized the high rate of implant failures because of stem fractures. In five out of 201 stems mid-stem fractures necessitated revision. While bony ingrowth was noted distally, fibrous tissue surrounded the proximal part. The authors attributed the high incidence of stem fractures to the small core diameter of small-size stems due to the porous coating, a trumpet-shape canal and the lack of proximal stabilization on account of distal stem fixation.

The Swedish total hip replacement register based on 86,000 observations reported a 10-year survival rate of 87.7% for nearly 3,000 uncemented implants [19]. The 17-year survival rate of 1,772 uncemented THA's averaged 57%. At 12.8 years postoperatively the present study showed at least comparable results for the MCCL system. However, in comparison to contemporary devices like the Zweymuller stem [10, 36] with cumulative survival of 96–99% at 10 to 12 years and the CLS stem [2] with cumulative survival of 95% at 12 years the metal-cancellous stem showed a higher failure rate with cumulative survival of only 86%. The high-fracture rate of the stem is unacceptable. On the basis of these difficulties the design of a fully porous-coated stem was changed to a proximally porous-coated stem.

A cumulative survival rate of 90% at 15 years for the metal-cancellous cup is at least comparable to the results of the Zweymuller threaded cup [10, 36] with a cumulative survival of 93–96% at 10 to 12 years or the Harris–Galante cup [9, 26] with a cumulative survival of 91–94% at 15 years. Thus, the metal-cancellous acetabular component was confirmed to be a reliable implant up to 15 years postoperatively.

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Survival Rate of the Uncemented Spongiosa Metal® Surface Hip System Fifteen to Eighteen Year Follow-Up

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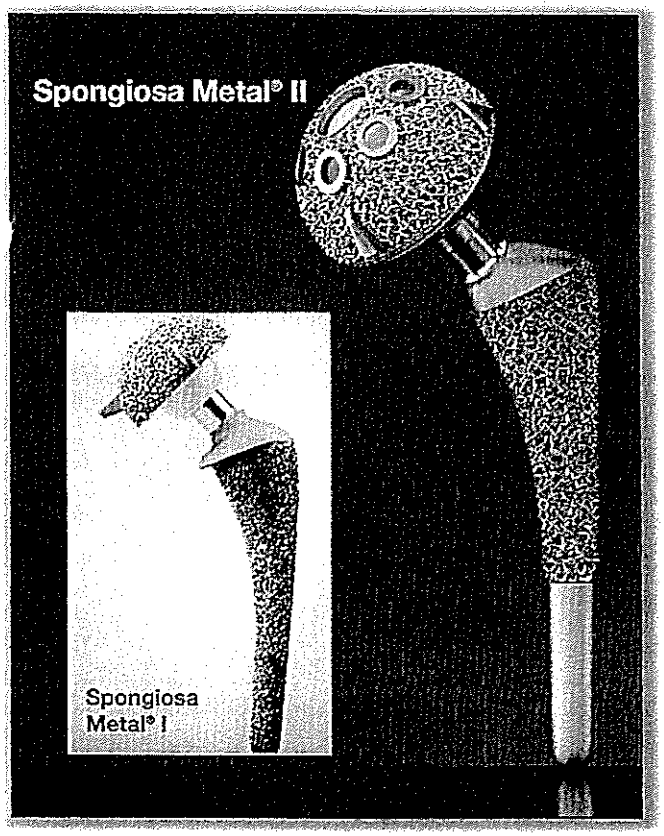
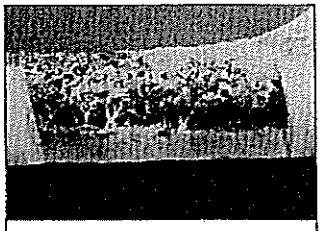
Problem:

Non-cemented hip systems differ in the material, the surface structure and the manner of primary anchorage. This paper reports on our eighteen year experience with the Spongiosa Metal Surface Hip System.



Implant cross-section showing open-cell macroporous surface design of the ESKA Prosthesis.



Specimen of resected proximal femur showing bone ingrowth into the stem area of the ESKA Prosthesis following autopsy on a 72 year-old patient (6 month postoperatively). (Courtesy of Dr. Peter Wigt, Abteilung Orthopädie, Ziekenhuis sit Antoniushove, Leidschendam, Netherlands).

Process for the production of an implant as a bone substitute.
Inventor: Hans Grundei, Lübeck, Fed. Rep. of Germany
Foreign Application Priority Data June. 28, 1982 [DE] Fed. Rep. of Germany..3224265.

Material and Methods

The ESKA Total Hip Prosthesis has a macroporous surface structure with a pore depth of up to 3 mm, and a pore-size of 1-2 mm, similar to that of cancellous bone, whereby the mesh spaces form an intercommunicating system. The porous surface structure and implant core are moulded in one piece.

As a result a larger pore size can be attained without a marked decrease in the metal resilience of the stem. Secondly, a continuous, homologous core-surface structure is achieved, not a surface coating, decreasing the possibility of surface "break-off" phenomenon.

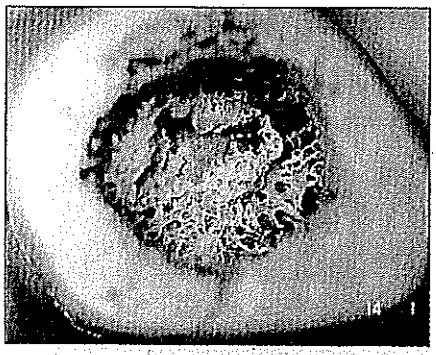
The ESKA standard Spongiosa Metal® Surface Total Hip Prosthesis is a four component system consisting of a metalback (cobalt-chromium-molybdenum alloy), polyethylene inlay, a 28 mm or 32 mm ceramic head, and a metal stem (cobalt-chromium-molybdenum alloy), whose form is anatomically adapted to that of the proximal femur. This allows for excellent proximal fit minimising the need for proximal reaming or rasping. The acetabulum and the stem are available in 7 sizes. A morse taper is used for the stem neck-length adjustment. Head and inlay system in the material combination of metal - polyethylene, ceramic - polyethylene, ceramic - ceramic, ceramic - ESKA-CERAM® and metal - metal is possible.

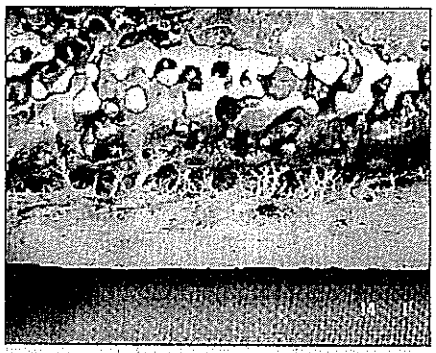
To assess the long-term success of total hip arthroplasty inserted without cement 165 consecutive hip arthroplasties using the ESKA standard Spongiosa Metal® Surface Total Hip replacement were reviewed. From 1983 to 1985 165 ESKA Spongiosa Metal® prosthesis were implanted into 155 patients. No patient was lost of follow up. At the latest time of follow up 32 patients had died unrelated to surgery and 14 hips had been revised. Of the remaining 43 patients with 53 total hip arthroplasties were clinically examined (minimum follow-up time was 12 years, mean 156 month). For 66 patients follow-ups were conducted by telephone. A survival rate was calculated using the Kaplan-Meyer method.

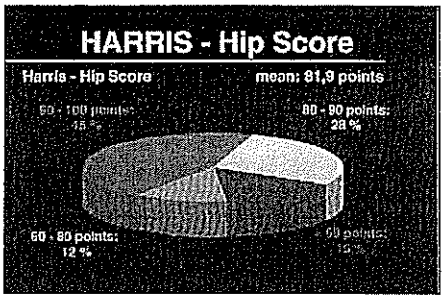
Results

14 hips had to be revised. Both components were revised in one case of infection, the femoral stem only in 11 hips because of aseptic loosening, and in one hip stem fracture. In one case the cup only was revised for aseptic loosening. In no revision case the surface structure came loose. The survival rate was 88 % at 15 years. Clinical follow-up of 53 patients using the Harris Hip Score showed a median of 81,9 points.

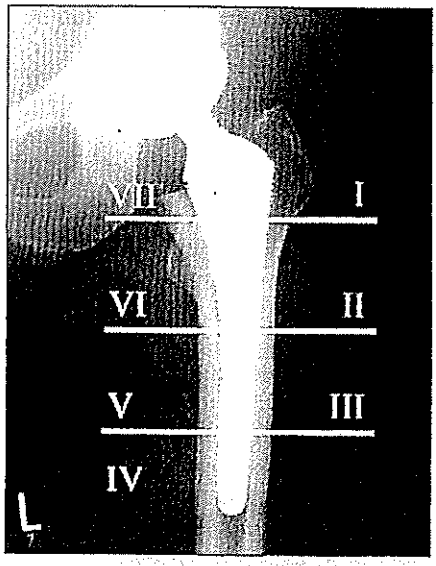
Bony ingrowth into the macroporous surface structure of the Spongiosa Metal® Surface Hip Prosthesis apparently provides a good shield against osteolysis. Although we did see stress shielding in the area of the greater trochanter frequently, without any relation to clinical results. The long-term survivorship analysis shows 88 % survival of the ESKA prosthesis at 18 years with excellent scoring in the clinical examinations.



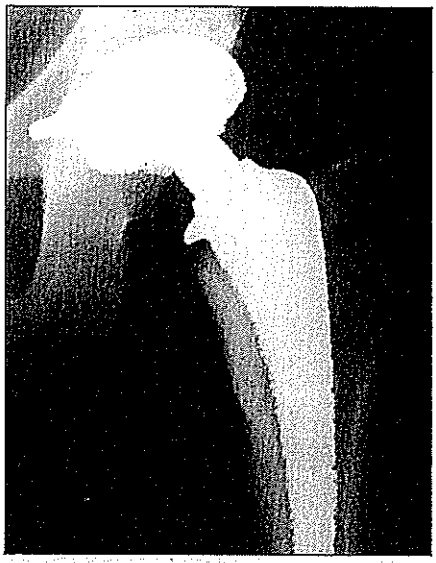




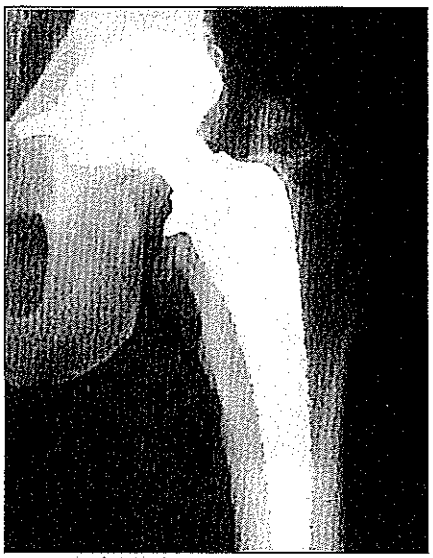
Explant of a cementless metallic-spongiosa hip endoprothesis from 1983. The patient died of cardiac infarction 9 months after implantation. The magnification of the preparation gives excellent evidence of the bony fusion between corticalis and implant. The left preparation shows trabecular suspension of the tip of the implant stem.
On the basis of this and other experiences, the fusion process through the bone ingrowth seems to be macroscopically completed after six months.



Seven Zone Radiological Analysis Of Amstutz



postoperativ 1983



after 15 years 1998

Discussion:

The macroporous Spongiosa Metal® Hip System shows a survival rate of 88% after 15-18 years. We believe that the anatomically adapted form of the implant secures primary stability that allows the histological and electronic microscopical proven deep ingrowth of trabecular bone stabilizing the system for a very long time. The use of the low friction system ceramic head - polyethylene inlay reduces polyethylene wear rate and guarantees stable anchorage of the system and restricts osteolytical activities of giant cells. Since treating patients with postoperative radiation (1 session with 9 Gray) we don't see anysignificant ossifications any more and the clinical follow-up shows a median of 81,9 points.

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Twenty Year Follow-up Of The Uncemented Spongiosa Metal Surface (SMS) Total Hip Arthroplasty

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Long term success of cementless hip prosthesis is depending on a reproducible surgical technique by sophisticated instruments and a proven bone integration

Implant Characteristics

- Spherical cup design
- Anatomical adapted stem design
- Pore size > 500 microns
- Pore depth up to 3000 microns
- Porosity 70 %

Patient Characteristics

Number of Patients	199
bilateral	10
Total	209
Clinical examination	53
Questionnaire	75
Revision	14
Death	32
Lost of Follow-up	35

Patients Charateristics

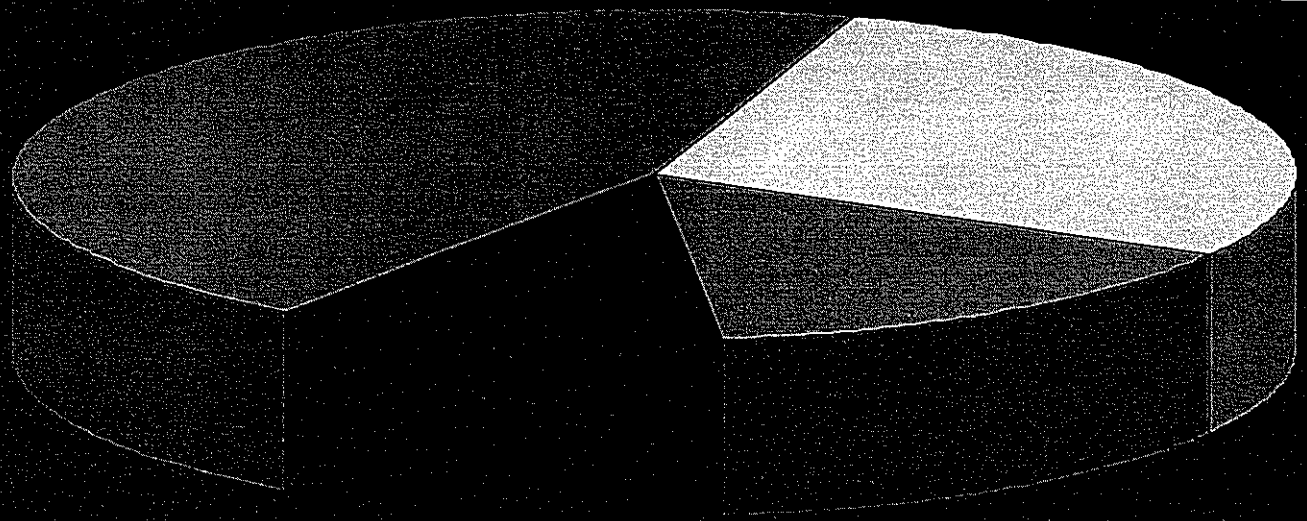
Age at time of surgery		57,1 years
	min.	33 years
	max.	75 years
Sex		
	female	146 (70 %)
	male	63 (30 %)

HARRIS - Hip Score

Harris - Hip Score mean 81,9 points

90 - 100 points:
45 % patients

80 - 90 points
28 % patients



60 - 80 points
12 % patients

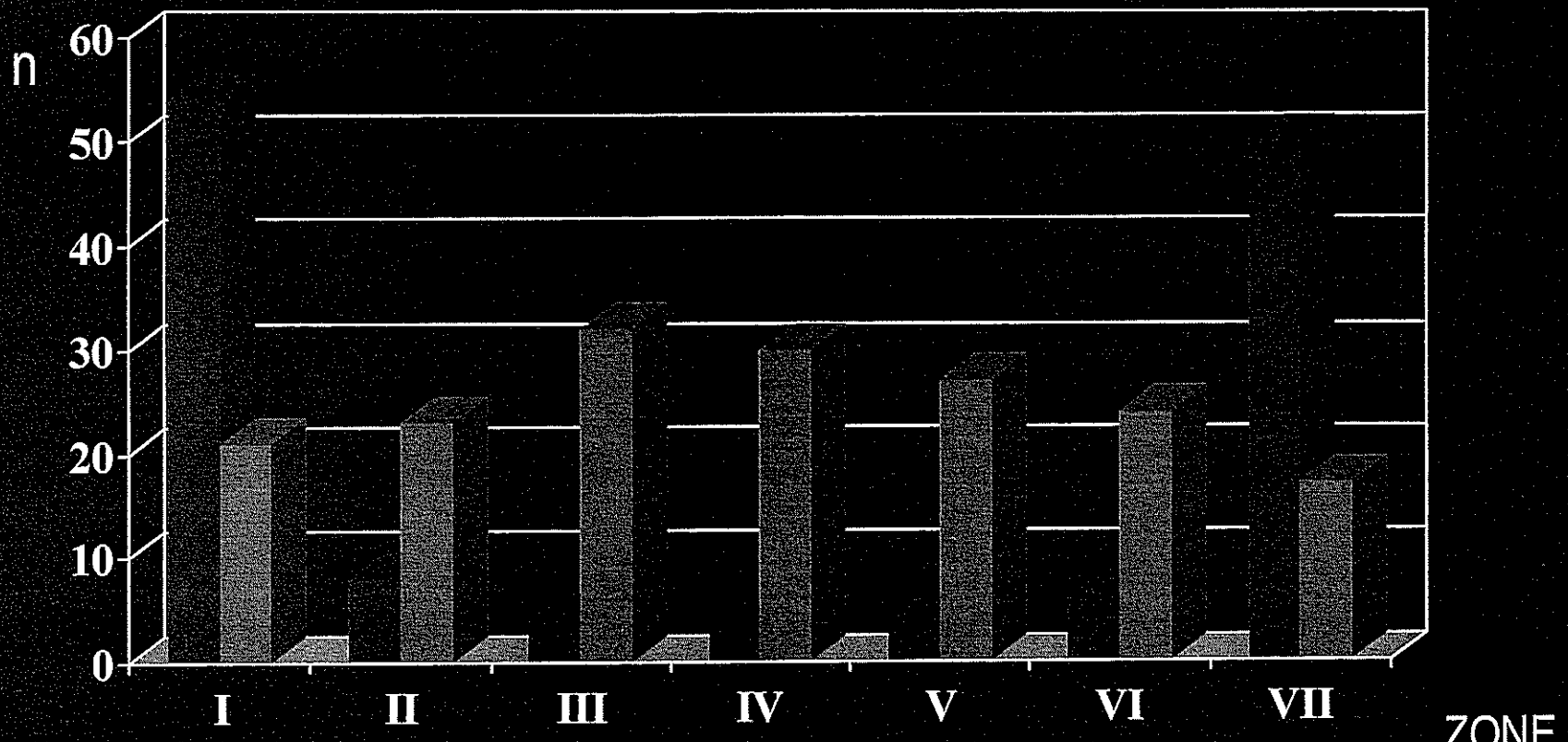
< 60 points
15 % patients

Postoperativ 1983

1986

2002

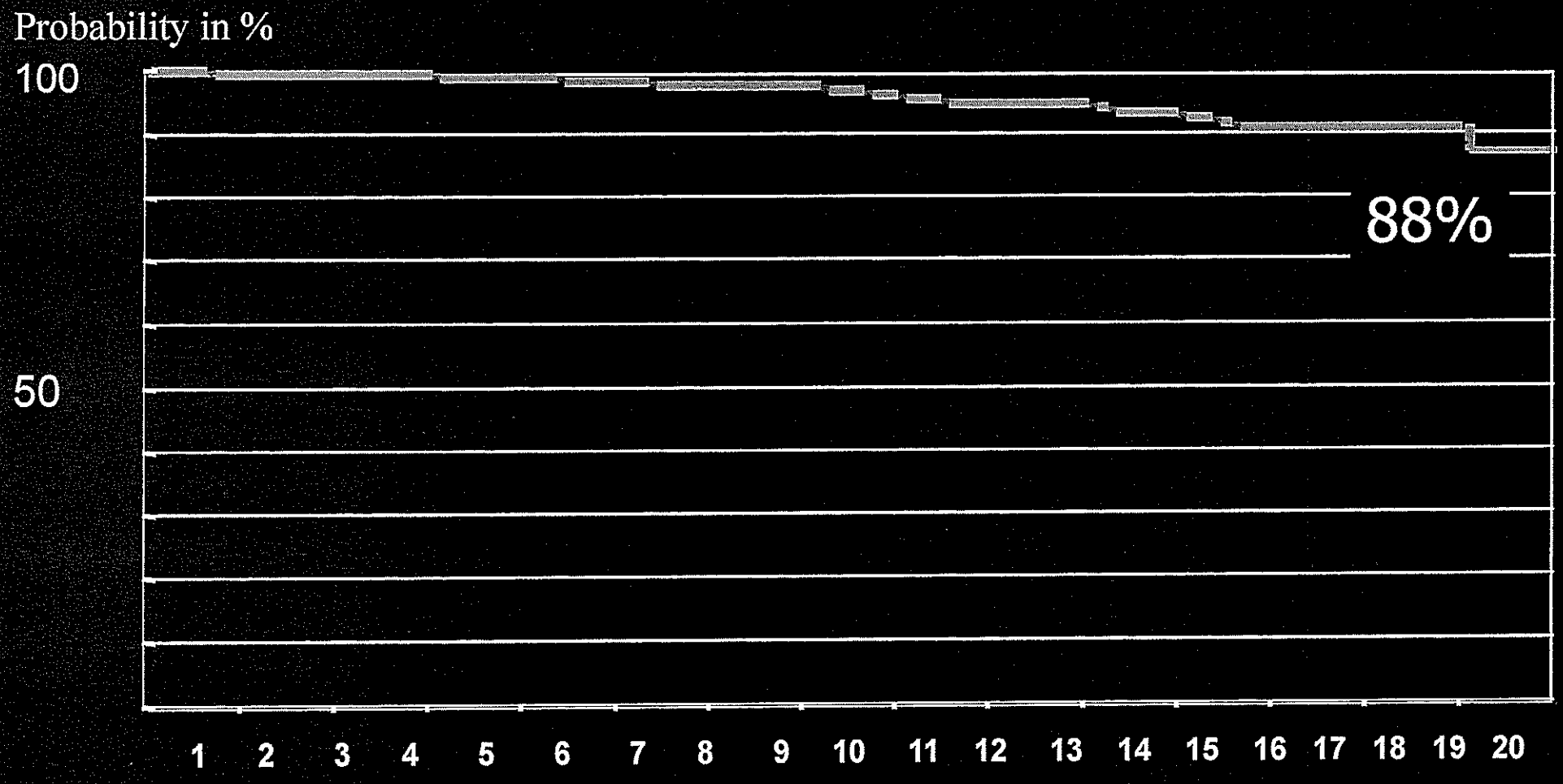
Radiological Analysis (7 Zones)



Bone atrophy

Cortical hypertrophy

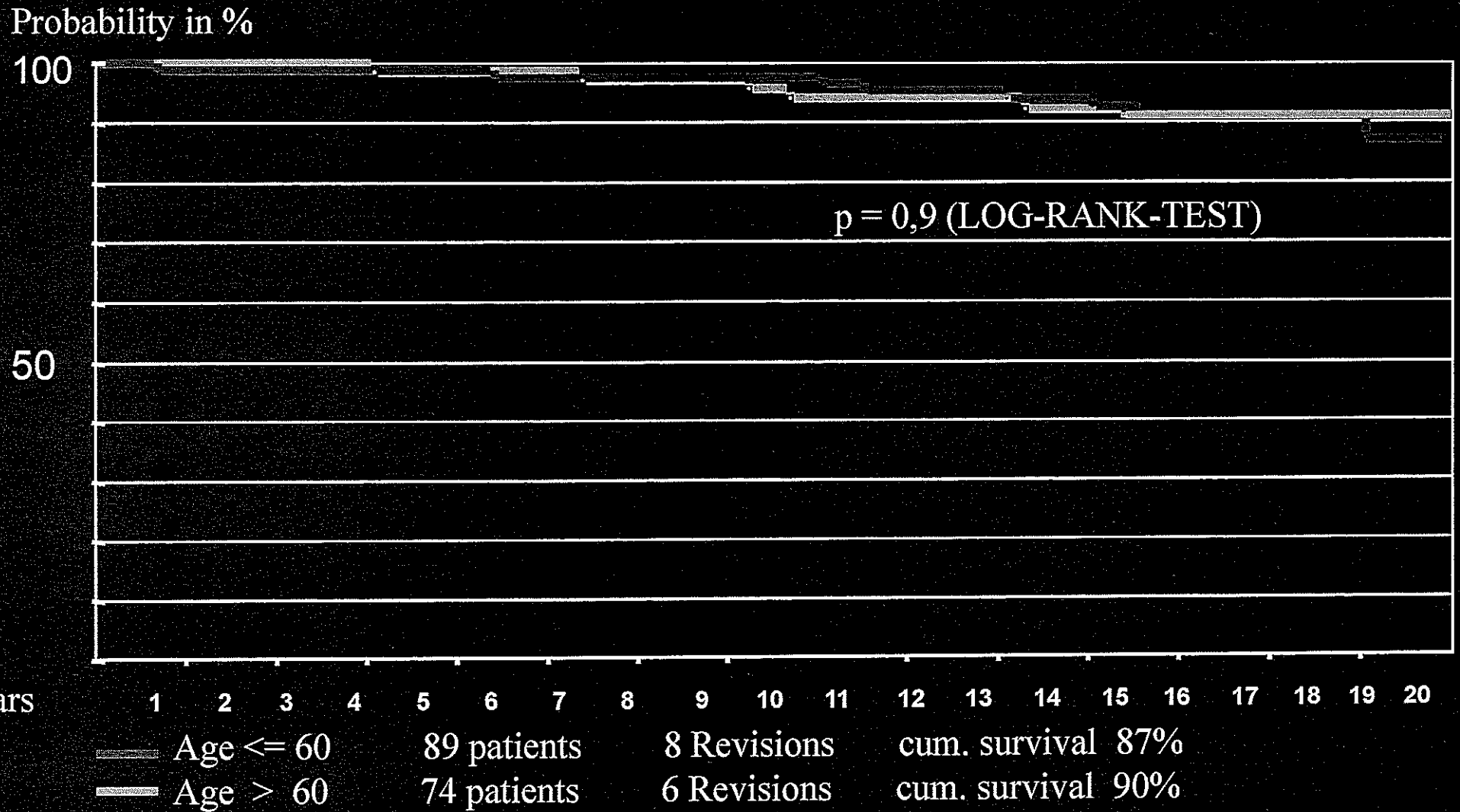
Survival rate



165 Patients 14 Revisions

Survival rate

Age > and < 60 years



Revisions

1 Cup dislocation after 8 month
1 Stem breaking after 7 years
3 Change of position (stem size to small)
1 Septic loosening after 8 years
1 No bone integration (stem), Revision after 3 years
5 aseptic loosening of stem
2 reason for revision unknown