International Orthopaedics (SICOT) (2017) 41:39–45
DOI 10.1007/s00264-016-3226-z

ORIGINAL PAPER

Thirteen year follow-up of a cementless femoral stem and a threaded acetabular cup in patients younger than fifty years of age

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Received: 17 January 2016 / Accepted: 28 April 2016 / Published online: 30 May 2016

Abstract
Purpose Compared to older patients undergoing total hip arthroplasty (THA) younger patients are considered to be more active, thereby exposing the implant to significantly higher loads over a much longer period of time. Additionally, cases of secondary osteoarthritis caused by hip dysplasia, femoral head necrosis or rheumatic diseases are much more frequent than among the average patient population. Therefore, durable implant fixation and low wear rates are extremely important to achieve good long-term implant survival in this group of patients.
Objective The aim of this retrospective study was to evaluate the mid- to long-term survival of a cementless femoral stem (Zweymüller® SL stem) and a threaded cup (Bicon SL®) in patients younger than 50 years of age.
Methods Therefore, a consecutive series of 100 patients (111 hips) aged 50 years or younger (range: 30 to 50 years) was analysed at a mean follow up of 13.5 years. Follow-up assessment included physical examination and radiographic work-up. Hip disability osteoarthritis and outcome score (HOOS) and Harris hip score (HHS) were used to evaluate the pre- and post-operative functional outcome, respectively. Patient satisfaction with the surgical result was assessed by standardized questionnaires.
Results The overall survival rate with any revision as endpoint was 96.8 % (95 % CI: 90.5 % to 98.9 %) at ten years. Gender, operation time and the occurence of osteolyses had no influence on joint function or patient satisfaction. We recorded an overall failure rate of 7.4 % (six cases). In four cases (5 %) the prosthesis had to be revised due to aseptic loosening of the cup after 12 years, eight years, 12 years and 11 years, in one case (1.2 %) recurrent luxation led to a revision operation (acetabular cup and head) after three years of primary implantation. In one case an implant failure was recorded (acetabular cup breakage after eight years of implantation). We recorded the occurence of asymptomatic radiolucent lines of the cup in 21 % and of the stem in 35 % in our series. The HOOS was influenced by the presence or abscence of radiolucent lines of the stem. Patients with radiolucent lines of the stem had a median HOOS score of (74 points) compared to those without radiolucent lines (89 points). Other factors, such as "diagnosis led to operation" and "previous operations" had no influence on the HHS and HOOS.
Conclusion Our study demonstrates excellent long-term survival of cementless femoral stem in combination with a threaded cup in young patients undergoing total hip arthroplasty.

Keywords Cementless · Hip replacement · Hip surgery · Long term · Outcome · Total hip arthroplasty

Introduction

Compared to older patients undergoing total hip arthroplasty (THA) younger patients are considered to be more active, thereby exposing the implant to significantly higher loads over a much longer period of time. Additionally, cases of secondary osteoarthritis caused by hip dysplasia, femoral head necrosis or rheumatic diseases are much more frequent than among the average patient population. Therefore, durable implant fixation and low wear rates are extremely important to

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achieve good long-term implant survival in this group of patients.

Nowadays, cementless implant fixation is the procedure of choice in younger patients because unacceptable high revision rates have been reported for cemented implants [1, 2]. However, long-term survival of uncemented components in THA may be compromised by implant wear leading to osteolysis and aseptic loosening particularly on the acetabular side.

Although several studies showed high survival rates of contemporary cementless implant designs in unselected groups of patients, data for patients aged 50 years or less is limited. The aim of our retrospective study was to evaluate the clinical and radiological mid- to long-term outcome of a cementless stem (Zweymüller® SL) in combination with a threaded cup (Bicon SL®) in a cohort of patients aged 50 years or younger.

Materials and methods

Between 1995 and 1998, a consecutive series of 100 patients (111 hips) aged ≤ 50 years underwent THA using a cementless SL-Plus® femoral stem in combination with a threaded titanium-alloy Bicon-Plus® cup, *(Smith & Nephew Inc., Memphis, TN, USA)*. The tooth size, tooth thickness and tooth lenght increase with an increasing cup size, offering an excellent primary stability.

An ultra-high molecular-weight polyethylene liner articulating with a 32 mm ceramic head was used in all cases. All operations were performed at the same institution.

The mean age of the patients, (47 women and 53 men), at the time of surgery was 48 years (range: 30 to 50 years).

Indications for THA were primary osteoarthritis in 19 cases (17.1 %), secondary osteoarthritis caused by congenital dysplasia in 60 cases (54.1 %) and end-stage osteonecrosis of the femoral head in 27 cases (24.3 %). In four cases (3.6 %) a previous fracture of the femoral head or the acetabulum caused a secondary osteoarthritis and in one case a pathological fracture due to metastasis of the femoral neck led to operation.

The median pre-operative body mass index (BMI) was 27 kg/m^2 ± 4 (range: 18 to 42). In 15 cases (13.5 %), a previous intertrochanteric corrective osteotomy was performed. Another 15 patients (13.5 %) had previous internal fixation due to fractures of the femoral neck, while one patient presented with pelvic triple-osteotomy due to hip dysplasia. In six patients (5.4 %), non-defined operations to the hip have had been performed. Of the patients 33.3 % underwent surgery under general anaesthesia while 66.7 % underwent surgery under spinal anaesthesia.

Patients' previous hip related operations and comorbidities were evaluated using the Charnley classification system. According to the published criteria 64 % of the patients were rated as Charnley class A and 36 % as Charnley class B.

Pre-operatively, standard pelvis anteroposterior (AP) and lateral radiographs of the hip were taken to determine the size of implant components using templates.

In all cases, an anterolateral approach (Watson-Jones) was used with the patient in supine position [3]. We used a pneumatic impact drill for stem implantation and started in a "varus" position to protect the greater trochanter from splitting. The final grater was then carefully positioned to shape the dorsal stem-bearing area.

Intravenous antibiotic prophylaxis, using a second generation cephalosporine, was administered 30 minutes before surgery and once in the evening at the day of surgery. Postoperative thromboprophylaxis consisted of low-molecular weight heparin for six weeks. Post-operatively, all patients were mobilized with 20 kg of partial-weight bearing for six weeks. After the first radiographic follow-up at six weeks post-operatively patients returned to full weight bearing and thromboprophylaxis was stopped provided that full weight bearing was achieved.

Prevention of heterotopic ossifications (HO) was performed by radiation in all cases. Patients received a fractionated total dose of 10 gray within the five post-operative days.

Clinical follow-up

Patients were clinically assessed by one of the co-authors (GA) who was not involved in the surgical procedure. Clinical assessment included evaluation of the Harris hip score (HHS) and the hip osteoarthritis outcome score (HOOS) [4]. Hip range of motion (ROM) was measured with a goniometer for flexion, extension, ab-/adduction and rotation. Patient satisfaction was evaluated by using standardized questionnaires (hip osteoarthritis outcome score (HOOS) [4].

Post-operative activity levels were determined using the criteria established by Johnston and co-workers [5].

Radiographic follow-up

Radiographic evaluation included standardized anteroposterior and lateral radiographs of the hip which was performed directly post-operatively, six weeks post-operatively and 13 years post-operatively. Taking the pelvic tear drop as a fixed landmark, cup migration was evaluated by the criteria published by Sutherland et al. [6].

The distribution of peri-acetabular radiolucent lines or osteolyses was determined according to criteria defined by DeLee and Charnley [7]. Femoral radiolucent gaps or osteolyses were assigned to the respective zones described by Gruen et al. [8]. Heterotopic ossification was classified according to the Brooker classification [9]. Varus and Valgus malalignement of the femoral component was defined in

"neutral", "varus up to 5°", "varus > 5°", "valgus up to 5°", and "valgus > 5°", respectively.

Statistical analysis

Kaplan-Meier survival analysis was performed with 95 % CI for both components with revision for aseptic loosening and revision for any reason as endpoints. We used Stata 12.1/ME (*StataCor, College station, Texas, 77845 USA*) for our statistic evaluation. A p-value of < 0.05 was considered statistically significant. For further tests we used the Shapiro-Wilk test, Mann-U- Whitney test, Kruskal-Wallis test, Chi^2 test, Fisher-Exact test and the Log–Rank test. No regression analysis was performed because we only had a few implant failures during our follow-up period.

Results

The mean follow-up of 100 patients (111 hips) was 13.5 years (9.7 to 16.9 years). Of this original cohort 81 hips (73 %) are available for follow-up. In total 23 patients (27 %) were lost to follow-up, nine patients (9 %), (ten hips) died, 11 patients (11 %) were lost to follow-up, three patients (3.6 %) did not want to take part in the study anymore.

In total, six patients (7.4 %) had to be revised. We recorded four cases (5 %) of aseptic loosening, one case (1.2 %) of recurrent luxation and one case of implant failure (acetabular cup breakage).

The median operation time was 70 minutes ± 17.8 minutes (range: 38 to 135 minutes).

Functional outcome and use of pain medication

Pre-operatively we raised the activity index of our patients according to criteria pusblished by Johnston et al. Of our patients 29.7 % classified themselves as "strenous manual labour", 60.4 % as "moderate manual labor" and 9 % patients as "light manual labour".

After surgery 21 (25 %) patients went back to "strenous manual labour", 47 (58 %) to "moderate manual labour" and 13 (16 %) to "light manual labor".

Forty five patients (40.5 %) reported regular use of pain killers other than non steroidal inflammatory drugs (NSAID) pre-operatively and 51 (46.2 %) of patients used NSAID regularly. In 91 of the cases (82 %) we recorded no more use of pain killers during our follow-up, 8.6 % reported a continous use of anti-inflammatory medication (NSAID) and 8.6 % of our patients reported a continous use of pain killers other then NSAID because of intermittent hip related pain.

At our latest follow-up 92.6 % of patients had no positive "Trendelenburg gait", 3.7 % were tested positive for "Trendelenburg gait" and 2.46 % suspected for being positive.

Further we asked the patients for their grade of satisfaction after surgery. 75.3 % of our patients are "very satisfied" with the result, 17.3 % are "satisfied", 3.7 % are "partially satisfied" and 3.7 % are "not satisfied".

The mean HOOS score of the surviving 81 hips (81 patients) at the latest follow-up examination improved from 30.6 ± 15 pre-operatively to 84 ± 14 after surgery. HOOS score for stiffness improved from 32 ± 15 to 82 ± 18 after surgery and HOOS score for pain improved from 33.3 ± 14 to 87.7 ± 16 after surgery. HOOS score for physical activity also improved from 30 ± 15 to 83 ± 15 at the time of last follow-up.

The mean HHS improved from 45 ± 13 pre-operatively to 98 ± 13 at the time of last follow up.

Radiographic analysis

The radiographic results are available for 75 hips (92 %). The latest radiographs were taken at 9.7 to 16.9 years, mean 13.5 years after the index arthroplasty.

In 74 cases (98.7 %) the acetabular component was graded as stable and in 73 cases (97.3 %) the stem was also stable by using radiographic criteria (Fig. 1). In one case (1.3 %) the cup inclination changed to 15°, in two cases (2.7 %) we recorded a stem varization of up to 3° by comparison with the radiographs taken directly post-operatively. Nevertheless, the implants were considered for being radiologically stable. Regarding the cup, we recorded an osteointegration in 65 cases (86.6 %), moderate osteolysis was detected in eight cases (10.7 %), (Fig. 2). In four cases, (5.3 %) extensive osteolysis led to revison of the implanted cup.

With regard to stem osteointegration we recorded an osteointegration in 51 cases (68 %). Stress shielding occured in 17 cases (23 %), most commonly in zones 1, 8, 7 and 14, (Fig. 3).

In one case (1.3 %) we detected a radiolucent line in zone 1, 16 cases (21 %) showed osteolysis, most commonly in zone 1 and zone 4. In 17 cases (22.7 %) we detected radiolucent lines, most commonly in zones 1, 2 and 5. In 26 cases (35 %) we detected osteolysis, also most commonly in zones 1, 7, 8 and 14. Stress shielding occured in 26 cases (35 %), most commonly in the same zones mentioned above.

Heterotopic ossification occured in 45 cases (60 %). Of these, 29 cases (38.7 %) were class I, eight cases (11 %) were class II, six cases (8 %) class III and in two cases (3 %) class IV according to Brooker's classification, although all patients received a fractionated dose of in total 10 gray within the five post-operative days.

Complications

Overall we recorded five complications during the entire hospital stay. One patient developed a deep vein thrombosis which was treated medically and resolved without sequela.

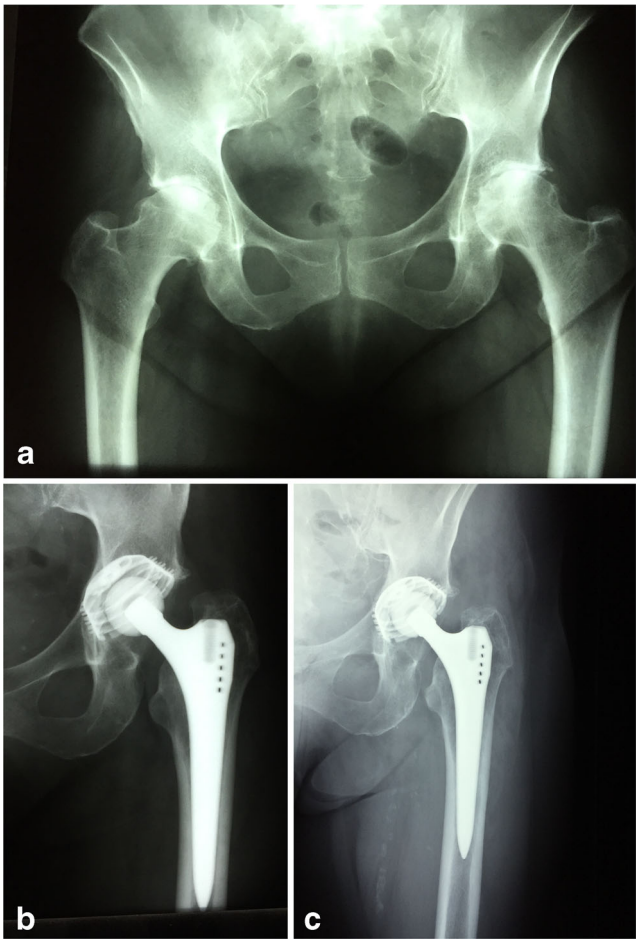


Fig. 1 (a) pre-operative, (b) follow-up after 6 weeks, (c) 13-year follow-up

One patient developed a urinary tract infection which could be treated medically. None of our patients required readmission for wound complications but two patients with superficial wound infections had to be treated by intravenous application of antibiotics. One patient developed a transient paresis due to stretching of the femoral nerve, one patient a transient meralgia paraesthetica.

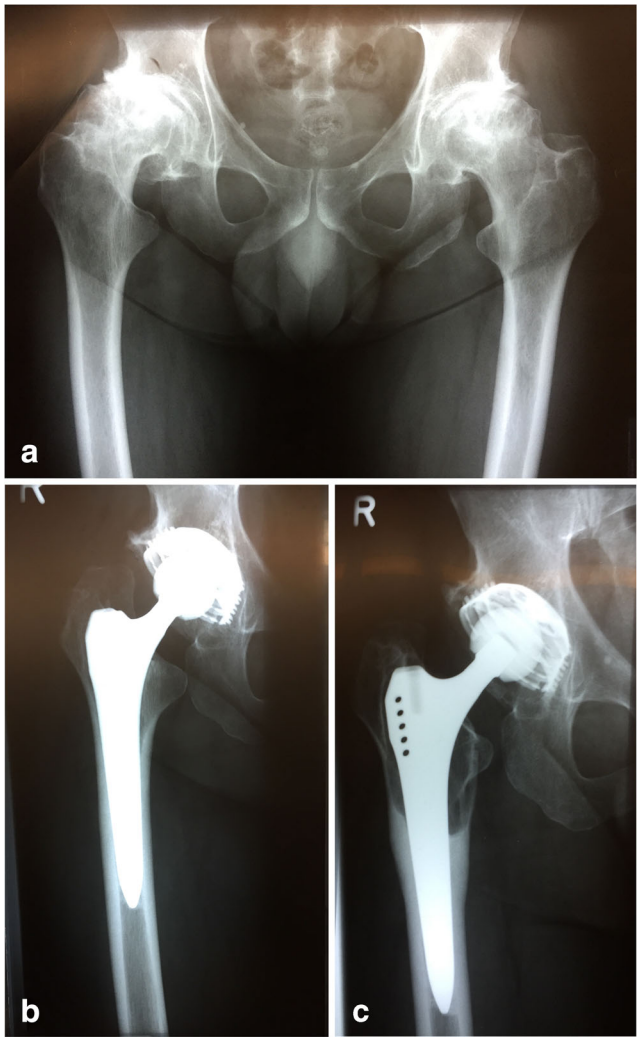
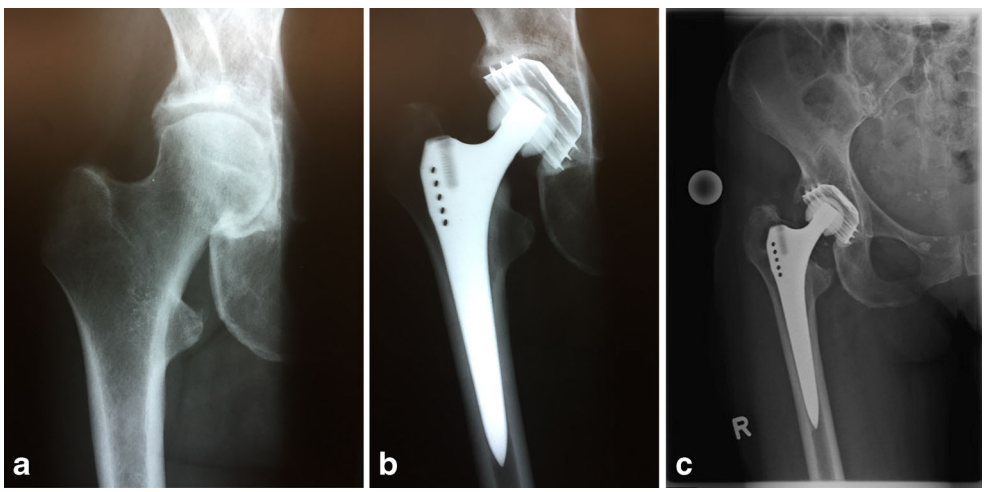


Fig. 3 (a) pre-operative, (b) follow-up after 6 weeks, (c) 13-year follow-up

Fig. 2 (a) pre-operative, (b) follow-up after 6 weeks, (c) 13-year follow-up



Survival analysis

The Kaplan-Meier survivorship with revision for *any reason* as the end point was 96.8 % (95 % CI 90.5 – 98.9) at a ten year follow up (Fig. 4).

Discussion

Even in younger patients undergoing total hip arthroplasty (THA), a high grade of physical activity and functional demand may increase the rate of implant failure. The current literature indicates a high failure rate of first-generation cemented THA's after five to 22 years follow-up [10–12]. Revision rates of 10 % up to 39 % after five to 12 years are also reported in current literature [13–16]. The new generation of cementing provided better outcome with revision rates up to 8 % of the implanted stem [1, 17], but retained high revision rates of the cup up to 50 % after ten years in long term studies [11, 12, 18–20]. As a result of this, cementless implants with ceramic on ceramic bearing for THA became the gold standard among younger patients.

With regard to young patients undergoing cementless primary THA there are only a few long-term studies on patients available. The survival rate of the stem is excellent and reported with 97 % at seven years of follow-up in the current literature [21]. Overall failure rates are reported from 2 to 4 % during long-term follow-up [15, 22, 23].

Regarding threaded cups, a revision rate up to 6 % is reported with 2 % for aseptic cup loosening. The survival rates for femoral and acetabular components at ten years range from 95 to 98 % in patients under age 55 [24]. Threaded cups achieved excellent survival results especially in combination with ceramic heads [25, 26]. Survival rates of 64 to 76 % have

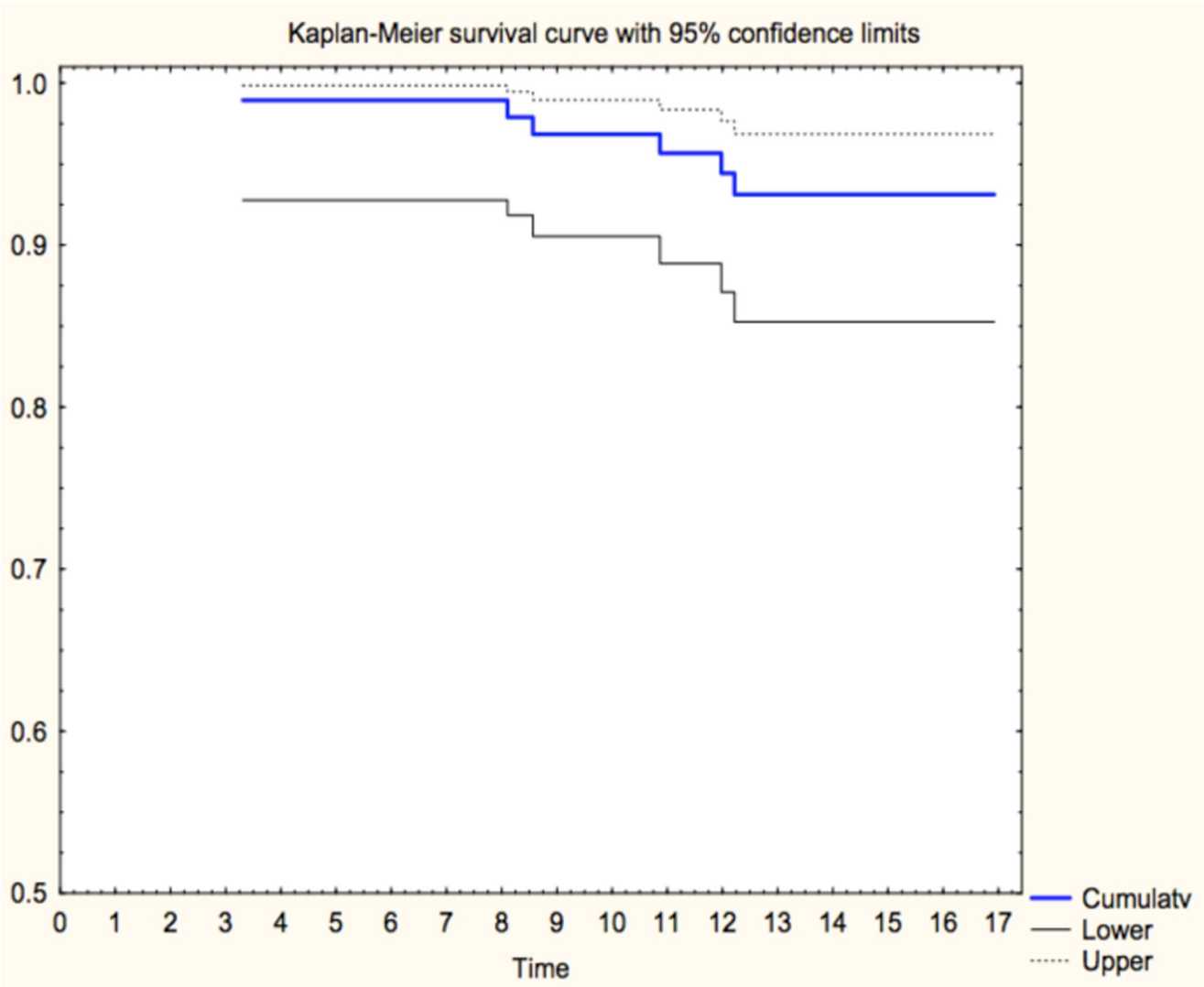


Fig. 4 Kaplan Meier survivorship

been reported for this after ten years of surgery. Howewer, 32 % of the cups showed radiolucent lines [27].

Our data is comparable to the current body of literature. We recorded the occurence of asymptomatic radiolucent lines of the cup in 21 % and of the stem in 35 % in our series. This is also comparable to already published data [28–30]. Howewer, we expect a certain number of implant loosening in the further follow-up period.

We recorded the occurence of a positive "Trendelenburg gait" with 3.7 % in our study, which is also comparable with published data [31]. Further we recorded more radiolucent lines in men and more radiolucent lines in Gruen zones 1-7 in patients with primary osteoarthritis. However this was not statistically significant. The HOOS was influenced by the presence or abscence of radiolucent lines of the stem. Patients with radiolucent lines of the stem had a median HOOS score of (74) compared to those without radiolucent lines (89). Other factors, such as "diagnosis led to operation" and "previous operations" had no influence on the HHS and HOOS.

With regard to the long-term survival, our data also is comparable to other published studies [32–35]. We recorded an overall failure rate of 7.4 % (six cases). In four cases (5 %) the prosthesis had to be revised due to aseptic loosening of the cup after 12 years, eight years, 12 years and 11 years, in one case (1.2 %) recurrent luxations led to a revision operation (acetabular cup and head) after three years of primary implantation. In one case an implant failure was recorded (acetabular cup breakage after eight years of implantation). We recorded a high mortality rate of in total 9 % (nine patients) in the entire follow-up period.

Limitations of our study is the retrospective design, the small sample size of our cohort and the relatively high number of patients lost to follow-up (27 %).

In conclusion, this prosthetic design seems to provide an excellent survival in patients younger than 50 years of age in long term surveillance of median 13.5 years. Further studies, even regarding register data, are necessary for a more in depth evaluation in the future.

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