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ORIGINAL STUDY

Clinical and radiological short-term results for a calcar-guided short stem : multicentre study of 879 cases

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A variety of short stems have recently been introduced. The purpose of this study was to evaluate rates and reasons for revision, as well as postoperative short-term radiological and clinical results, after implantation of a short stem of the newest generation in short stem total hip arthroplasty.
In this prospective multicenter study, 879 total hip arthroplasties, using the optimys short stem combined with a cementless cup with a mean follow-up time of 27.3 months (standard deviation SD 7.9), and identical postoperative regimens with full weight bearing, were included. Complications and revisions were documented. Pre- and postoperative radiographs were obtained using a standardized technique. Radiographic alterations were analysed. Pre- and postoperatively, Harris hip score (HHS), rest pain, load pain and satisfaction using the visual analogue scale (VAS) were assessed.
In 13 cases (1.5 %) stem-related revision surgery was needed, five cases (0.6 %) of these involved treatment for aseptic loosening. In 2.2% of cases, radiolucent lines were observed at the prosthesis bone interface. HHS improved from a mean of 46.7 (SD 15.3) preoperatively to 95.7 (SD 8.7) ($p < 0.0001$) at last follow-up, with 94.1 % excellent or good results. Patient satisfaction using VAS improved from 2.7 (SD 2.4) to 9.6 (SD 1.1) ($p < 0.0001$). Rest pain and load pain decreased from 4.5 (SD 2.7) to 0.2 (SD 0.8) ($p < 0.0001$) and 7.4 (SD 1.9) to 0.5 (SD 1.3) ($p < 0.0001$), respectively.
The investigated meta-diaphyseal anchoring, calcar-guided short stem provides reliable radiological and clinical results in the short-term.

Keywords : Total hip arthroplasty ; femoral component ; short stem ; optimys.

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INTRODUCTION

With the introduction of minimally invasive approaches for total hip arthroplasty (THA), short stems have gained popularity during the past decade, in order to further facilitate the procedure. The number of young and active patients who undergo THA is constantly increasing, therefore the rate of revision surgery will rise and bone preservation is becoming increasingly important. In various conventional stem designs, abnormal stress distribution in the loaded diaphyseal femur causes thigh pain and leads to stress-shielding in the proximal bone *(10)*. As short stem designs do not extend into the diaphyseal bow of the femur, bony alterations, such as resorption of the proximal femoral bone, which arise due to stress shielding *(12)* are potentially decreased. As short stem designs are more metaphyseal-engaging, the proximal femoral bone is loaded and may retain more proximal bone mass over time. Current evidence suggests, that short stems show less stress shielding than conventional stem designs *(26,11)*. Given that only a few long-term results have been published, the clinical relevance of these findings, potentially facilitating revision surgery, is yet to be proven.

One main challenge in the development of short stem designs is the achievement of sufficient stability and safe osseointegration of the component, although short stem designs provide less bony contact than longer designs *(2)*.

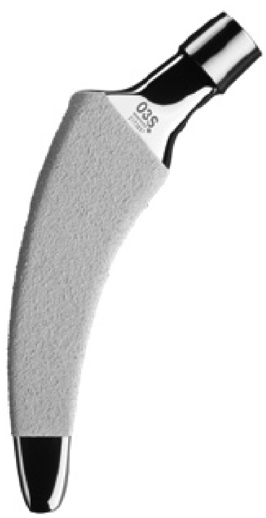

Fig. 1. — The optimys stem
(Mathys Ltd., Bettlach, Switzerland).

The stem design of the optimys stem (Mathys Ltd., Bettlach, Switzerland) allows good bone contact at the distal lateral cortex and the calcar (Fig 1). The stem is anchored either through classical three-point anchoring or by using the fit-and-fill principle. The triple conical shape is thought to achieve good primary stability and prevent migration. The rough titanium plasma-sprayed coating is believed to offer secure anchorage in the bone. Furthermore, the stem contains an overlying calcium phosphate coating in order to promote rapid osseointegration and achieve secondary stability.

Recent data *(15,8)* report good early clinical results using this specific design. Additionally, the physiological hip anatomy can be restored effectively *(16)*. However, long-term outcomes are not yet available.

It is crucial to evaluate new implants at the early stages in order to obtain data that may help predict their survival. The reaction of the environmental bone serves as an indicator of force distribution and sufficient osseointegration and may therefore help to predict long-term outcome, based on short-term results *(7)*.

The aim of this study was to analyze complications and revisions, the most common radiological alterations and clinical outcome in a short-term follow-up in a prospective study of 879 THAs, which involved the implantation of a neck preserving, calcar-guided short stem.

MATERIALS, PATIENTS AND METHODS

Patients and implants

In this prospective multicentre-study, 879 consecutive optimys short stems, implanted in 782 patients, were included (Fig. 2). The mean patient age was 64.9 (standard deviation (SD) 10.4) years. 438 hips of women (49.8 %) and 441 (50.2%) hips of men were operated on. In 97 patients, the treatment was done bilaterally. In all patients, a meta-diaphyseal anchoring short stem with titanium plasma-sprayed coating was used (optimys, Mathys Ltd. Bettlach, Switzerland). The implantations

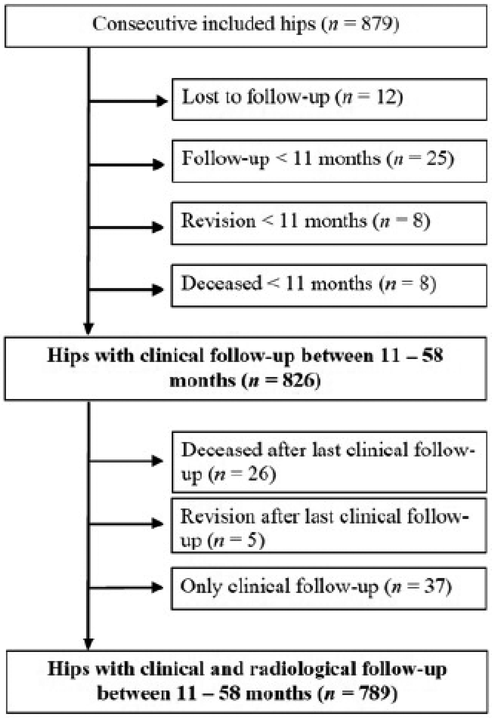

Fig. 2. — Flowchart of the clinical and radiological follow-up. Numbers indicate hips.

were performed in three German and two Swiss centres between December 2010 and May 2014. Three different surgical approaches were applied : 706 anterolateral approaches (80.3%), 157 direct anterior approaches (17.9%) and 16 transgluteal approaches (1.8 %). The indications for THA, as well as patient demographics, are presented in Table 1. Ethical review board approval was provided prior to patient inclusion (Feci Code 010/2071 ; Freiburg Ethics Commission International). All patients gave written informed consent and agreed to attend regular follow-up examinations.

Post-operative care

All patients were allowed full weight bearing as tolerated. Standard thromboembolic prophylaxis was administered for 30 days postoperatively with either low molecular weight heparin (LMWH) or a factor X antagonist.

Radiographic analyses

Standardized antero-posterior radiographs of the pelvis and lateral cross table views were taken at each follow-up visit. To control for the rotation, a positioning splint with 20° internal rotation of the hip joint was used. Follow-up included radiographs during hospital stay and 6 weeks, 6 months, 1 year and 2 years postoperatively. Magnification was controlled using a ball-device with known diameter as a scaling factor or the known diameter of the prosthetic femoral head as an internal reference. Osteolysis (cyst-like structures) and radiolucent lines (linear gaps between bone and implant) were rated as present or absent *(5)*. Bone resorption was analysed while scanning the femoral bone to find areas with enhanced bone transparency and thinned or resorbed trabeculae according to the Singh-Index *(23)*. The distribution of osteolytic areas and location of radiolucent lines in the femur was identified on the antero-posterior pelvic view according to the

Table 1. — Details of hip replacements: patient demographics, diagnosis

	Total	**Female**	**Male**
Numbers of hips	879	438 (49.8 %)	441 (50.2 %)
Age at surgery, years	64.9 (10.4)	65.9 (10.0)	63.9 (10.7)
Operation on right side	462 (52.6 %)	241 (55.0 %)	221 (50.1 %)
Primary osteoarthritis	661 (75.2 %)	310 (70.8%)	351 (79.6%)
Secondary osteoarthritis	87 (9.9 %)	54 (12.3%)	33 (7.5%)
Congenital dysplasia	71 (8.1 %)	54 (12.3%)	17 (3.9%
Osteonecrosis	48 (5.5 %)	14 (3.2%)	34 (7.7%)
Inflammatory arthritis	10 (1.1 %)	6 (1.4%)	4 (0.9%)
Fracture	2 (0.2 %)	0 (0.0%)	2 (0.5%)

Data presented as mean (SD) or n (%).

seven zones of Gruen et al. *(9)*. The presence of heterotopic ossifications according to Brooker *(4)* was noted.

Clinical analyses

Clinical examinations, performed at 6 weeks, 6 months, 1 year, and 2 years, included the assessment of Harris hip score (HHS). Pain at rest and pain at load, as well as global satisfaction, were assessed using a visual analogue scale (VAS). Clinical results for a total follow-up period of at least 11 months are presented. Complications both perioperatively and during follow-up were recorded and revisions were documented.

Statistical analyses

Statistical analyses were performed with SAS 9.2 software (SAS Institute Inc., Cary NC, USA). The Wilcoxon-test was used to compare pre- and postintervention data. Statistical significance was set at $p < 0.05$.

RESULTS

In all, 879 hips in 782 patients were considered eligible for inclusion. A total of 25 patients (25 hips) had follow-up periods shorter than 11 months and were excluded from further analysis. Twelve patients (12 hips) refused follow-up for personal reasons. Eight patients (eight hips) died before a minimum follow-up period of 11 months, for reasons unrelated to the procedure, and eight hips required revision before 11 months. The mean follow-up time of the remaining 826 hips with a clinical follow-up period of at least 11 months was 27.3 months (SD 7.9). Out of these 826 hips, 37 hips only had a clinical follow-up but no radiological follow-up, resulting in 789 hips with radiological follow-up in the short term. A flowchart of clinical and radiological follow-up is given in Fig. 2.

Complications and revisions

A total of 48 (5.3%) peri- and postoperative complications occurred. Minor complications, such as haematomas, seromas and wound healing disorders in a total of 29 cases (3.3 %) were not related to the femoral stem and needed no further surgical treatment. A total of 27 revisions (3.1%) for 25 hips were required ; the stem was revised in 13 cases (1.5%). In six hips (0.6%) the head and inlay were changed due to early infection. Of those, in one case a second revision was needed. In five hips (0.5%) the acetabular component was revised because of malpositioning, tilting or dislocation owing to periprosthetic fracture. Two fractures of the ceramic head occurred (0.2%). In the case of stem revision, no correlation to the learning curve was observed. The survival rate for endpoint stem revision at 24 months was 99.0% and at 48 months 98.6% (Fig. 4). In five cases (0.5%) aseptic stem loosening occurred (Fig. 5) and revision surgery was needed within 7.1, 7.9, 16.5, 33.5 and 34.8 months, respectively. Five patients (0.5%) were treated for periprosthetic femur fractures 2 days, 15 days (two patients) and 1

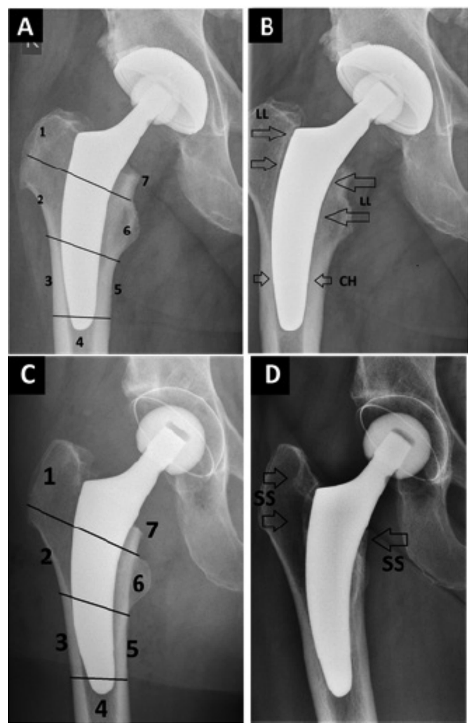

Fig. 3. — Radiographs of radiological alterations. (A) Postoperative radiograph with modified Gruen-zones, (B) 2-year follow-up with signs of lucent lines (LL) and cortical hypertrophy (CH). (C) Postoperative radiograph with modified Gruen-zones, (D) 2-year follow-up with signs of bony resorption and stress shielding (SS).

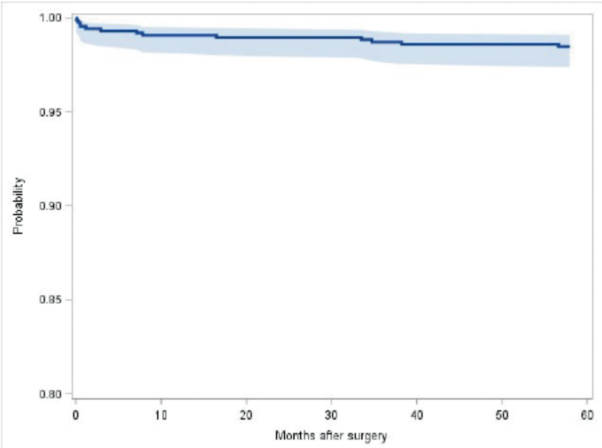

Fig. 4. — Kaplan Meier survival curve, including 95% confidence interval, for stem revision as endpoint.

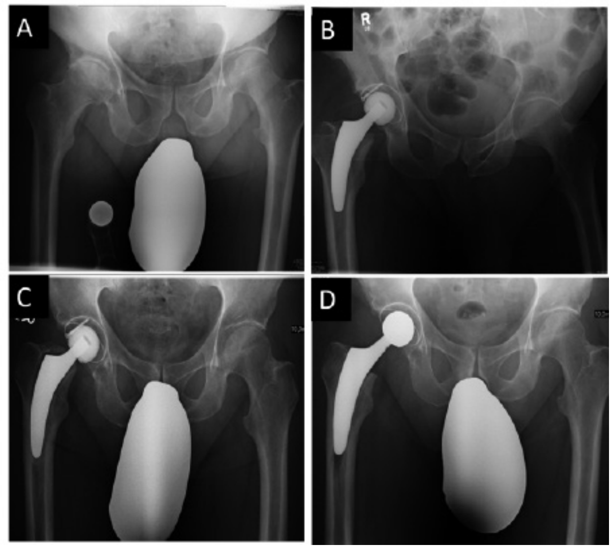

Fig. 5. — Pelvic radiographs of a 58 years old male patient. (A) Radiograph before surgery. (B) First day after surgery. (C) 16 months after surgery, showing aseptic loosening. (D) After revision surgery and implantation of an optimys stem with a larger diameter.

and 3 months after index surgery. In one hip (0.1%) the stem was reinserted after cup exchange. Stem revision as a result of infection was required in two hips (0.2%). All stem revisions are shown in detail in Table 2, including information on approaches and revision implants.

Radiological alterations

The radiological evaluation in 789 hips at last follow-up is summarized in Table 3.

At last follow-up 17 stems (2.2%) showed radiolucent lines with a maximum width of 2 mm. These were detected in Gruen zones *(9)* 1 (14 hips), 7 (6 hips) and in zone 2, 3, 4 and 5 (once each) (Fig. 3).

Resorption of femoral bone stock was detected in a total of 64 hips (8.1%), 24 in Gruen zone 1, two in zone 3, one in zone 5 and 30 in zone 7. Femoral cortical hypertrophy was seen in a total of 26 hips (3.3%). One in Gruen zone 2, 26 in zone 3 and 17 in zone 5. Osteolysis was seen in four patients (0.5%) (Fig. 3).

Brooker I heterotopic bone formation was found in 37 patients (4.7%) and Brooker II/III formation in 14 patients (1.8%). Brooker IV formation was not found.

Clinical outcome

The mean HHS improved significantly ($p < 0.0001$) from 46.7 (SD 15.3) preoperatively to 95.7 (SD 8.7) at last follow-up. Preoperatively, 93.3% of the patients had a poor HHS and 5% a fair HHS. At last follow-up, 87.7% had excellent, 6.4 % good and 3.6 % fair HHS values. In all, 95.4% of the patients showed a postoperative increase of HHS > 20 points ; this indicates a successful result *(20)*.

Mean patient satisfaction for the affected hip improved significantly ($p < 0.0001$) from preoperatively 2.7 (SD 2.4) to 9.6 (SD 1.1) postoperatively. Preoperatively, patients presented with a mean pain at rest of 4.5 (SD 2.7) and pain at load of 7.4 (SD 1.9) as rated on the VAS. Postoperatively there was a significant improvement ($p < 0.0001$) with a mean pain at rest of 0.2 (SD 0.8) and pain at load of 0.5 (SD 1.3). All clinical results are summarized in Table 4.

DISCUSSION

The presented results in a large multicentre study confirm the principle of using a calcar-guided short stem as being a safe procedure in the short-term. The strength of the investigated implant is due to it’s soft-tissue- and bone-sparing characteristics, along with a low intraoperative and early postoperative complication rate.

Table 2. — Overview of patients with stem revision

Patient	Age at index surgery	Gender	Approach at index surgery	Indication at index surgery	Reason for stem revision	Revision Implant	Time to revision
1	56.8	f	Anterior	Primary OA	Periprosthetic fracture	Conventional straight stem, cementless	0.1
2	57.7	f	Transgluteal	Primary OA	Aseptic loosening	Conventional straight stem, cementless	33.5
3	74.5	f	Anterior	Primary OA	Aseptic loosening	Modular revision stem, cementless	7.1
4	63.3	f	Anterolateral	Congenital dysplasia	Cup dislocation	optimys stem*	0.2
5	62.4	f	Anterolateral	Secondary OA	Periprosthetic fracture	Modular revision stem, cementless	0.5
6	80.4	f	Anterolateral	Primary OA	Periprosthetic fracture	Conventional straight stem, cementless	1.1
7	78.8	f	Anterolateral	Primary OA	Periprosthetic fracture	Conventional straight stem, cementless	2.9
8	79.0	f	Anterolateral	Primary OA	Periprosthetic fracture	Conventional straight stem, cemented	0.5
9	57.5	m	Anterolateral	Primary OA	Aseptic loosening	optimys stem	16.5
10	58.9	m	Anterolateral	Primary OA	Aseptic loosening	Conventional straight stem, cementless	7.9
11	70.7	m	Transgluteal	Secondary OA	Aseptic loosening	Conventional straight stem, cementless	34.8
12	60.7	m	Antero-lateral	Secondary OA	Deep infection	Conventional straight stem, cemented	56.6
13	78.7	m	Antero-lateral	Secondary OA	Deep infection	Conventional straight stem, cemented	38.2

Age at index surgery in years ; time to revision in months ; f : female, m : male; * stem was reinserted after cup exchange.

Table 3. — Radiological alterations at last follow-up

		N	%
Femoral bone resorption	No	746	94.6
	Yes	43	5.4
Cortical hypertrophy	No	763	96.7
	Yes	26	3.3
Lucent lines	No	772	97.8
	Yes	17	2.2
Osteolysis	No	785	99.5
	Yes	4	0.5

Tab. 4. — Clinical outcome: satisfaction, pain, HHS

	Preoperative (N = 879)		Last follow-up (N = 826)		p-value
	mean	SD	mean	SD	
Harris hip score	46.7	15.3	95.7	8.7	<0.0001
Satisfaction*	2.7	2.4	9.6	1.1	<0.0001
Rest pain*	4.5	2.7	0.2	0.8	<0.0001
Load pain*	7.4	1.9	0.5	1.3	<0.0001

*Visual analog scale.

The main reasons for revision surgery during short-term follow-up, besides periprosthetic infection, were periprosthetic fractures and aseptic loosening. All of the fractures occurred during the first months after surgery. It remains unclear, whether these can be considered purely traumatic postoperative fractures. Potentially, in some cases those fractures had already occurred intraoperatively but were not recognized. Given, that all implantations were the first applications of the investigated stem worldwide, a learning curve has to be considered regarding the present collective. Early aseptic loosening, might have been caused by malpositioning and undersizing of the optimys stem. However, in most revision cases either an optimys stem could be re-implanted or a cementless conventional straight stem was used as a revision implant. A modular revision system was needed in only two hips.

In calcar-guided short stem THA, to ensure stability, contact is mostly induced with the endosteal cortex of the calcar and the lateral proximal diaphyseal area *(1)*. Metaphyseal anchorage might lead to increased physiological stress and might retain more proximal bone mass *(10)*. In this study, a low incidence of typical radiological alterations for stress shielding was found at last follow-up. Resorption of femoral bone was detected in 5.4% and femoral cortical hypertrophy in 3.3% of all hips. These findings are similar to previously published data of partially the same cohort by Kutzner et al. *(17)*, using the same implant with 3.9% femoral bone resorption and 4.4% cortical hypertrophy. Recently, Hochreiter et al. confirmed these findings using DEXA (dual energy X-Ray absorptiometry). Whereas in Gruen-zones 2, 3 and 5, bone density increased, in Gruen-zones 4, 6 and 7, bone density remained stable. The investigated stem design therefore successfully limited stress shielding and minimized periprosthetic bone loss *(11)*. Conventional implants showed higher rates of radiological alterations for stress shielding. For example, in a recent study using the Fitmore short stem (Zimmer, Inc., Warsaw, IN, USA), a cortical hypertrophy rate of 63% was detected without significant effect on the clinical outcome after a mean follow-up of 40 months *(19)*. This difference may be explained by the polished tip of the optimys stem accompanied with a potentially lower rate of distal bone ingrowth compared with the rough-blasted distal part of the Fitmore stem.

In our cohort, 6.5% of the patients showed heterotopic ossifications. In a study of 202 hips using the Nanos short stem (Smith & Nephew, Inc., Cordova, TN, USA), which is also a calcar-guided stem, in 7% of the cases, heterotopic ossifications were observed *(6)*. Using the Fitmore stem, however, heterotopic ossifications were found in 19% of the cases *(19)*. A possible explanation for the higher rate of heterotopic ossifications may be the surgical approach. In our cohort, minimally invasive and thus muscle sparing approaches, such as anterolateral (80%) or direct anterior (18%) approaches, were predominantly used, whereas the standard surgical approaches in the study of Maier et al. *(19)* were anterolateral and transgluteal. Additionally, such factors as intraoperative bone trauma, haematoma and postoperative administration of nonsteroidal anti-inflammatory drugs (NSAID) may also influence ossification rate *(13)*.

Decreased primary stability, potentially followed by aseptic loosening, reducing diaphyseal fixation of the femoral implant, is still a major concern when using short stems *(2)*. Previously published data on the migration pattern of the investigated stem, measured by EBRA (Einzel-Bild-Roentgen-Analysis), showed a mean initial subsidence of 1.43 mm with subsequent stabilization in most cases *(12))*. Undersizing of the stem could be identified as the main cause of pronounced subsidence potentially followed by aseptic loosening and revision surgery (Fig. 5). Given these findings, intraoperative radiography is highly recommended with this particular stem design, in order to prevent malpositioning and undersizing *(18)*. Recently, De Waard et al. *(25)* concluded, in a prospective 2-year follow-up study on the migration pattern using RSA (Roentgen stereophotogrammetic analysis), that the optimys stem achieves secondary stabilization after initial migration, suggesting a low risk of long-term aseptic loosening *(25)*.

Moreover, the short stem investigated in the present study seems to provide good secondary stability and osseointegration. Nevertheless, radiolucent lines were documented in 2.2% of patients, while osteolysis was observed in 0.5% of the patients. Five patients (0.5%) showed aseptic loosening of the stem, followed by stem revision. Regarding the Fitmore stem, radiolucent lines <2mm were reported in 25% of the hips, without negatively influencing the clinical outcome or requiring revision surgery *(19)*. Ettinger et al. *(7)* reported no stem revision on investigating the Nanos stem after a mean follow-up of 62 months in a smaller cohort of 72 patients. The same group published one early revision in a larger group with 172 patients *(6)*. The 7 year revision rate of the Metha short stem (B. Braun Aesculap AG, Tuttlingen, Germany) for aseptic loosening was 0.7% as found from data of 1090 hips *(22)*. These findings agree with our results.

The HHS and VAS scores significantly improved after surgery, with 94 % of the patients having excellent or good results and a high patient satisfaction of 9.6. These early clinical results are comparable to published results of other short stems. Ettinger et al. *(7)* reported a mean HHS of 97 after a mean follow-up of 64 months using the Nanos short stem. Braun and Sabah *(3)* used the Metha short stem and recorded a mean HHS of 95 after a follow-up period of 29 months. Thorey et al. *(24)* also used the Metha short stem and observed an HHS increase from 46 preoperatively to 90 after a mean follow-up of 70 months.

There are some limitations to this study. First of all, the follow-up with a mean of 27 months is short and inhomogeneous for the evaluation of a new implant in total hip arthroplasty. However the follow-up sufficiently allows for assessment of short-term results and further follow-up of the presented cohort will be provided. Secondly, the radiological analyses were performed by each institution but not by an independent investigator. Though analyses were standardized and in agreement with every involved investigator, slight differences in rating and interpretation of the radiological alterations cannot be ruled out. Given the high number of included cases, however, a potential bias might be neglected. Third, given the very large number of included cases, in this investigation, stem migration was not analysed. Given the multicentre design of the present study and owing to the involvement of various independent observers, results regarding migration have been found to be very inconsistent, potentially including a severe bias. However, EBRA measurements of partially the same cohort, regarding the migration pattern of the optimys stem, have been published previously *(14)*. Clearly, the strength of the study is its prospective and multicentre character with a large number of patients. This study presents an analysis of the first cases of the investigated stem worldwide, thus, the results include the learning curve. Furthermore, the results of this observational study are "real-life" outcomes, with the investigated stem being implanted by many surgeons in different indications using various approaches. Therefore, the present data may be very helpful for orthopaedic surgeons.

CONCLUSION

The optimys short stem shows excellent clinical and radiological short-term results and supports the principle of calcar-guided short stems with pronounced metaphyseal anchorage. The small incidence of bony alterations after a short-term follow-up indicates a stable and durable osseo-integration. The rate of early complications and necessary revision procedures is low. However, further studies are needed to investigate mid- and long-term outcomes.

Abbrevations

EBRA : Einzel-Bild-Roentgen-Analysis ;
DEXA : Dual Energy X-Ray Absorptiometry ;
HHS : Harris Hip Score ;
LMWH : low molecular weight heparin ;
NSAID : nonsteroidal anti-inflammatory drugs ;
OA : osteoarthritis ;
RSA : Roentgen stereophotogrammetic analysis ;
SD : standard deviation ;
THA : total hip arthroplasty ;
VAS : visual analogue scale.

Ethics approval and consent to participate : ethical review board approval was given for this study (Feci Code 010/2071 ; Freiburg Ethics Commission International). Informed consent was obtained from all individual participants included in the study.

Availability of supporting data : The datasets used and/ or analysed during the current study are available from the corresponding author on reasonable request

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