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RESEARCH ARTICLE

Calcar-Guided Short Stems in Total Hip Arthroplasty: A Two-Year Prospective Multicentre Study

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Abstract:

Background:

Calcar-guided short-stem Total Hip Arthroplasty (THA) is increasingly being used to preserve proximal femoral bone stock for potential later revision surgery.

Objective:

In this study, we aimed to expand the clinical evidence on calcar-guided short-stem THA used in daily clinical practice, focusing on clinical outcomes as well as radiographic signs of stress shielding and femoral bone loss.

Methods:

In a prospective multicentre study, we enrolled 213 patients with a total of 224 THAs for mainly degenerative indications. The patients were examined clinically and radiographically 6 to 12 weeks, 12 months, and 24 months postoperatively.

Results:

All clinical outcomes improved significantly over the first 6 to 12 weeks compared to preoperative values ($P < 0.001$). At 24 months, the mean Harris hip score was 95.3 ± 6.7 , and the mean visual analogue scale for pain was 1.0 ± 1.7 under load and 0.5 ± 1.3 at rest. We observed early distal stem migration in six patients and late migration in one patient. Additionally, we found 16 cases of radiographic signs indicative of stress shielding. Four patients required stem revision surgery: two for stem migration, one for periprosthetic fracture, and one for deep infection.

Conclusion:

Overall, calcar-guided short-stem THA resulted in excellent clinical outcomes after two years of follow-up, and the radiographs revealed few signs of stress shielding. We, therefore, regard calcar-guided short-stem THA as a safe and effective treatment alternative in daily clinical practice.

Keywords: Total hip arthroplasty, Hip prosthesis, Short stem, Metaphyseal fixation, Stress shielding, Migration.

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1. INTRODUCTION

According to a retrospective analysis of data provided by the Federal Statistical Office of Germany from 2007 to 2016

including more than 2 millions of primary THA procedures, the cases of cemented standard Total Hip Arthroplasty (THA) and hip resurfacing decreased significantly, whereas the use of cementless standard THA and short-stem THA increased substantially, with a significantly higher application rate in the elderly population [1]. But THA is increasingly being indicated and used in young and active patients also [2 - 7]. In these

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patients, preserving bone stock is essential as they are likely to undergo revision surgery later on [3]. To this end, femoral implants with short stems have been designed to preserve proximal femoral bone; their metaphyseal fixation requires less bone removal during implantation and prevents bone loss by reducing stress shielding during the implant's lifetime. This being the underlying rationale for the use of short stems, it reflects a legitimate interest in this new implant design, although excellent long-term results of cementless flat tapered stems, which engage the metaphysis only and then taper quickly already exist. Metaphyseal fixation, however, may lead to reduced implant stability and alter the implant migration pattern [3]. Both stress shielding and implant migration can become clinically relevant as they may lead to aseptic loosening [4].

Recent clinical results on short-stem prostheses have been encouraging, with excellent clinical outcomes and survival rates of over 99% after 9 to 15 years of use [8 - 10]. Current evidence indicates that when implanting short-stem prostheses, it is crucial to consider the patient's anatomy, including leg length, caput-collum-diaphyseal angle, and most importantly, femoroacetabular offset [11, 12]. However, not all short-stem implants are able to reestablish the original anatomical conditions of each patient [13] and to achieve similarly high survival rates [14].

Calcar-guided short-stem prostheses have been designed to adapt to the anatomy of a wide range of hips. This was confirmed in a recent study where calcar-guided short-stem prostheses achieved accurate reconstruction of the hip joint in a large number of patients [15]. Furthermore, calcar-guided short-stem THA resulted in improved postoperative clinical outcomes in the short term, as well as a few major complications such as migration, loosening, or revision [7, 16, 17]. However, clinical data on calcar-guided short-stem prostheses remain limited.

In this prospective multicentre study, we aimed to expand the clinical evidence on calcar-guided short-stem THA in daily clinical practice. We used a modern calcar-guided short-stem prosthesis to investigate clinical and radiographic outcomes, focusing on signs of stress shielding, femoral bone loss, and the migration of such prostheses.

2. MATERIALS AND METHODS

2.1. Study Design

We conducted a prospective multicentre study involving six European orthopaedic centres. Between July 2012 and September 2013, we enrolled 213 patients (with a total of 224 THAs) for primary (67%) or secondary osteoarthritis (OA) (17.9%), avascular necrosis of the femoral head (8.0%), mild to moderate developmental dysplasia of the hip (DDH) (6.3%), femoral neck fractures (0.4%), and rheumatoid arthritis (RA) (0.4%). Patients who had undergone revision surgery or suffered from periprosthetic joint infection, severe DDH, or malignant tumours were excluded from this study. Further

reasons for exclusion included a body mass index of >35 or an American Society of Anesthesiologists score of >3.

The patients were examined clinically and radiographically at 6 to 12 weeks, 12 months, and 24 months postoperatively. Clinical outcomes were determined by the Harris hip score (HHS) and the visual analogue scale (VAS) for pain both under load and at rest (0: no pain, 10: worst pain) and for patient satisfaction (0: no satisfaction, 10: greatest satisfaction). Standardized anteroposterior radiographs (at 20° of hip internal rotation) and Lauenstein projections using reference spheres were conducted. To this end, the institutional radiology departments were accordingly instructed. Radiological assessment (including stem migration, resorption of the femoral bone, resorption of the calcar, interface radiolucent lines, or hypertrophy of the femoral bone) was visually accomplished by specifically trained readers in an independent manner.

All procedures involving human participants complied with the ethical standards of the institutional and / or national research committee as well as with the 1964 Declaration of Helsinki and its later amendments. The Ethics Committee of the University of Lübeck (AZ 12-112) and the Freiburg Ethics Commission International (feki cde 012/280) approved the study protocol. The Bundesamt für Strahlenschutz authorised the radiographic follow-up examination of the patients (AZ Z5-22462/2-2016-111). All patients participated on a voluntary basis and gave their informed consent.

The study received partial funding from Mathys Orthopädie GmbH Bochum, Germany.

2.2. Surgical Approach and Prosthesis

Eight senior orthopaedic surgeons from six centres were involved. We used an anterolateral approach in 60.7%, an anterior approach in 20.5%, and a transgluteal lateral approach in 18.8% of all surgeries.

All enrolled patients received the optimys® short-stem implant (Mathys Ltd Bettlach, Switzerland). We used standard stems in 62.1% and lateral stems in 37.9% of cases. This short-stem implant is based on a neck-preserving, calcar-guided design with metaphyseal fixation (Fig. 1). Its geometry follows the anatomy of the proximal femur, in particular, the calcar. The stem can be individually positioned to reconstruct femoroacetabular offset and caput-collum-diaphyseal angle in varus or valgus hips, thereby achieving soft tissue balance around the joint [7]. It also features a rough coating made of titanium plasma spray and calcium phosphate. Other prosthetic components (*i.e.*, the cups, liners, and ball heads) were used at the discretion of the treating surgeon.

2.3. Statistical Analysis

Descriptive data analysis involved means and standard deviations. The Wilcoxon signed-rank test was used to assess differences between the preoperative and follow-up examination values. All tests had a significance level of $P < 0.05$. All analyses were performed using SAS Enterprise Guide version 7.13 (SAS Institute Inc., Cary, NC, USA).

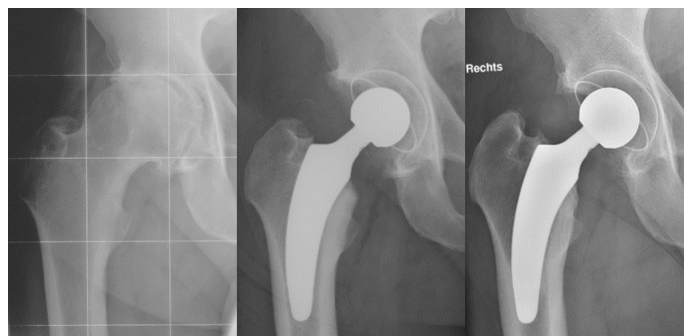


Fig. (1). Anteroposterior radiographs of a representative clinical case: 65-year-old male with primary osteoarthritis in the right hip. Left: preoperative radiograph, middle: postoperative radiograph at 6 weeks of follow-up, right: radiograph at 24 months of follow-up.

3. RESULTS

3.1. Patient Follow-Up

Of the initially included 213 patients with 224 THAs, 203 THAs were left for discussion: 189 THAs with complete clinical and radiographic data, 13 with clinical data only, and 1 with radiographic data only. Four patients (four THAs) had undergone revision surgery of the short-stem prosthesis, and one patient died from unrelated causes (suicide). The remaining 16 patients (16 THAs) were lost due to voluntary withdrawal from the study for personal reasons (8 patients), failure to stay in contact (7 patients), or inability to attend the follow-up examinations due to poor general health (1 patient). The short-stem prosthesis remained *in situ* in all patients but one where the prosthesis status could not be verified.

The patients had a mean age of 60.9 ± 10.5 years (range, 27.6 to 93.6 years) and a balanced male-to-female ratio (102:111).

3.2. Clinical Outcomes

All clinical outcomes improved significantly over the first 6 to 12 weeks compared to preoperative values and continued to do so until the final follow-up examination at 24 months (Table 1). The mean HHS increased significantly from 50.8 ± 12.1 preoperatively to 95.3 ± 6.7 at 24 months ($P < 0.001$). Similarly, the mean VAS for pain, both under load and at rest, and the mean VAS for patient satisfaction improved significantly from preoperative values ($P < 0.001$).

Table 1. Clinical outcomes.

Clinical Outcome	Preoperative (n = 224)	6–12 Weeks (n = 210)	12 Months (n = 211)	24 Months (n = 202)	P value
HHS score	50.8 ± 12.1	87.7 ± 13.7	94.8 ± 7.0	95.3 ± 6.7	<0.001
VAS for pain	-	-	-	-	-
under load	7.7 ± 1.5	1.8 ± 2.0	1.1 ± 1.7	1.0 ± 1.7	<0.001
at rest	5.4 ± 2.6	1.1 ± 1.6	0.6 ± 1.3	0.5 ± 1.3	<0.001
VAS for satisfaction	2.3 ± 2.1	9.0 ± 1.7	9.2 ± 1.5	9.4 ± 1.3	<0.001

Values reported as means \pm SD. P values from two-sided exact Wilcoxon rank sum test compared to preoperative values. HHS: Harris hip score, n: number of total hip arthroplasties, VAS: visual analogue scale.

3.3. Radiographic Outcomes

Overall, the radiographs revealed few changes to the femoral bone and prosthetic stem position. We observed early distal stem migration in six patients, with mean subsidence of 8.8 ± 4.3 mm at 6 to 12 weeks postoperatively (Table 2). Two of these patients required revision surgery. We also found late migration in one patient whose stem migrated progressively, leading to an initial 6.0 mm of subsidence after 12 months and another 10.0 mm after 24 months. The overall revision rate due to migration was 1% (n=2) of all enrolled cases.

We found 16 cases of radiographic signs indicative of stress shieldings such as resorption of the femoral bone, resorption of the calcar, interface radiolucent lines, or hypertrophy of the femoral bone. Resorption of the femoral bone was found in one patient, affecting Gruen zones 1 and 7. Hypertrophy was found in five patients; it affected Gruen zones 3 and 5 in two patients, Gruen zone 3 in two patients, and Gruen zone 2 in one patient. Osteolyses of the femoral bone did not occur.

Table 2. Radiographic findings.

Radiographic Findings	6–12 Weeks (n = 199)	12 Months (n = 198)	24 Months (n = 190)
Stem migration	6 (3.0)	1 (0.5)	1 (0.5)
Osteolysis of femoral bone	0 (0.0)	0 (0.0)	0 (0.0)
Resorption of femoral bone	0 (0.0)	0 (0.0)	1 (0.5)
Resorption of calcar	4 (2.0)	3 (1.5)	2 (1.1)
Interface radiolucent lines	0 (0.0)	0 (0.0)	1 (0.5)
Hypertrophy of femoral bone	1 (0.5)	3 (1.5)	1 (0.5)
Heterotopic ossification	-	-	-
Brooker I (islands)	2 (1.0)	3 (1.5)	4 (2.1)
Brooker II / III (spurs)	1 (0.5)	3 (1.5)	1 (0.5)
Brooker IV (ankylosis)	0 (0.0)	0 (0.0)	0 (0.0)

Radiographic findings made at the three follow-up examinations, in comparison with the previous examination timepoint. Values reported as number of cases (%). n: number of total hip arthroplasties.

3.4. Complications

All THAs were free of intraoperative complications. However, we diagnosed several postoperative complications including wound healing disorders (three cases), prosthesis dislocation (two cases), nerve palsy (two cases), haematoma / seroma (two cases), periprosthetic fracture (one case), deep infection (one case), superficial infection (one case), wound

dehiscence (one case), and accentuated pain (one case). We also recorded 11 minor complications such as irritation of the lateral femoral cutaneous nerve. Six patients experienced more than one complication.

Four patients required stem revision surgery: Two for stem migration after 2.8 and 3.8 months, one for a periprosthetic fracture after 6.6 months, and one for deep infection after 3.2 months. The two patients with prosthesis dislocation showed reduction in a closed manner.

4. DISCUSSION

Our prospective multicentre study on calcar-guided short-stem THA yielded excellent clinical and radiographic results two years after surgery. Clinical outcomes such as the HHS and VAS for patient satisfaction increased, while the VAS for load and resting pain decreased postoperatively. All clinical outcomes differed significantly from the preoperative values already at the first follow-up examination ($P < 0.001$) and continued improving until the final follow-up at 24 months. These THA related results were somewhat to be expected with regard to one of the most successful surgical procedures, if any. And our clinical results are in line with a study conducted by Kutzner *et al.* [2].

Our radiographic results revealed a few relevant changes to the bone surrounding the implant. We observed stress shielding in 8.1% of cases over 24 months, which was in line with the incidence rate reported by Kutzner *et al.* [7]. Similar to a biomechanical study of Bieger *et al.* [18], stress shielding for resorption was restricted to Gruen zones 1 and 7. Additionally, we found hypertrophy in Gruen zones 3 and 5.

In our study, the proximal femoral bone loss occurred at a low incidence of 5.1% over 24 months. In the past, similar results have been correlated with a more physiological loading pattern of the proximal femur [8]. A short stem design and metaphyseal fixation should, therefore, have a lower risk of adaptive bone resorption, a hypothesis recently confirmed by direct clinical comparison of THA using short-stem *versus* conventional, tapered prostheses [9]. Therefore, the absence of a diaphyseal anchored stem appears to be crucial in preventing proximal femoral off-loading and adaptive bone loss [19 - 23].

In conclusion, short stems seem to be promising with respect to bone stock preservation along with the optimal restoration of offset and leg length, though implant stability is still a concern [3]. We observed stem migration in seven patients; in six at an early stage, and in one later on. Four of the six prostheses with early migration settled over the first 12 months of follow-up, and only two required revision. Considering revision due to subsidence a failure, the overall failure rate due to migration was 1.0% of our patients. Those two stems were most likely undersized and therefore had limited cortical contact, which might have caused them to migrate. This finding was recently confirmed by a large case series with the same short-stem prosthesis, where undersizing was also found to be the main cause of axial subsidence [5]. Schaer *et al.* also described stem size the only factor that affected stem migration [4]. Based on these results, we believe that this type of surgery may be associated with a short but relevant learning curve.

Kutzner *et al.*, reported a higher migration rate of 15.7% with this prosthesis; migration also mainly occurred early on but disappeared 12 to 24 months after surgery. The authors therefore concluded that the migration pattern of the calcar-guided short-stem prosthesis is characterised by an initially pronounced subsidence followed by subsequent stabilisation [7]. This assumption matches the most recent follow-up of the same study group revealing no further subsidence at 5-year follow-up [2]. And this observation is being supported by a current study conducted by de Waard *et al.* [3]. The authors used Radio Stereometric Analysis (RSA) and found initial proximodistal translation and anteversion-retroversion rotation at 6 weeks, after which the stem stabilised and showed no further significant movement. In contrast, Schaer *et al.*, used “Ein Bild Roentgen Analyse” (EBRA) and found progressing subsidence at 5-year follow-up even [4]. However, the clinical implications of this migration pattern remain unclear because early migration does not always translate into worsened clinical outcomes or complications [17]. This was also concluded by Schaer *et al.*, although demonstrating progressive subsidence later on [4]. Therefore, it remains debatable if early migration in short-stem THA should be considered detrimental or predictive of aseptic loosening and failure, as with conventional stems [24 - 26], and to what extent a lateralized stem leads to stress reactions remains unanswered.

Overall, we observed relatively few complications. Most notably, we had one patient who had a periprosthetic fracture in our series. Our periprosthetic fracture rate of 0.5% correlated favourably with a large observational study by Tamaki *et al.*, who found a periprosthetic fracture rate of 2.7% with short-stem THA [27]. We found no intraoperative femoral fractures, which confirms that short-stem prostheses lead to reduced intraoperative fracture rates compared to traditional straight stems [28]. Additionally, we also observed two cases of dislocation accounting for a dislocation rate of 1.0%. Several patients experienced irritation of the lateral femoral cutaneous nerve. While this was a transient occurrence in most cases, we believe that this may have been caused by the anterolateral surgical approach, which was the preferred approach in our study. Finally, deep infections were uncommon in our series and occurred at a similar rate as reported in other studies [29, 30].

A strength of our study is its prospective multicentre design, which included a large number of patients from different health institutions throughout Europe. It was an independent study; none of the study centres were involved in the development of the prosthesis. Furthermore, we included several indications, and every surgeon was free to choose the surgical approach and postoperative treatment protocol and to combine the short-stem prosthesis with the appropriate prosthetic components to best suit the patient's needs. We believe that this real-life setting reflects an independent view on everyday clinical practice and that our results can be transferred to what can realistically be expected in the field.

Nevertheless, we must also acknowledge some limitations of our study. First, it lacks a control group, making our results difficult to compare with other treatment options. However, a whole variety of different implants and bearings exist to date, and decision-making is often up to the surgeon's preference.

To achieve scientific evidence, availability and accessibility of related data are inevitable. To this end, even prospective and descriptive studies are supportive as demonstrated by Kutzner *et al.* [2]. Second, we used standard radiographs for our radiographic outcomes and measured migration manually. RSA would have provided more detailed information on radiographic outcomes such as stem migration, but it would have made data analysis considerably more complex. Nonetheless, the detection of even marginal 3D motion, migration of a stem is one of the key features of RSA [3]. Our long-term follow-up on the optimys® short-stem implant is currently in progress, and we are planning on implementing RSA, Bone Mineral Content (BMC) and Bone Mineral Density (BMD) measurements eventually. Finally, we followed the patients for a relatively short period of two years. Longer follow-up periods would provide a complete picture of the clinical advantages and disadvantages of calcar-guided short-stem prostheses. We therefore continue to follow the enrolled patients.

CONCLUSION

In conclusion, calcar-guided short-stem THA resulted in excellent clinical outcomes after two years of follow-up. Postoperative radiographs revealed few signs of stress shielding, which support the concept of femoral bone stock preservation through metaphyseal fixation. Additionally, we were able to confirm the typical behaviour of initial migration, followed by subsequent settling and stabilisation. The clinical implications of this migration pattern, however, remain a matter of debate. Overall, our results identify calcar-guided short-stem THA as a safe and effective treatment alternative in daily clinical practice. However, longer periods of follow-up are necessary for conclusiveness.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The Ethics Committee of the University of Lübeck (AZ 12-112) and the Freiburg Ethics Commission International (feki cde 012/280) approved the study protocol. The Bundesamt für Strahlenschutz authorised the radiographic follow-up examination of the patients (AZ Z5-22462/2-2016-111).

HUMAN AND ANIMAL RIGHTS

No animals/humans were used for studies that are the basis of this research.

CONSENT FOR PUBLICATION

All patients participated on a voluntary basis and gave their informed consent.

AVAILABILITY OF DATA AND MATERIALS

Not applicable.

FUNDING

The study received partial funding from Mathys Orthopädie GmbH Bochum, Germany.

CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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