Mid-term Subsidence and Periprosthetic Radiolucency of the AMIStem: A 5-year EBRA-FCA Analysis

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Abstract

Background: There has been an evolution in cementless total hip arthroplasty (THA) with newer short stem designs aim to preserve metaphyseal bone stock and facilitate implantation through minimally invasive approaches. While early subsidence has been correlated to aseptic loosening in conventional stems, there is a paucity of data regarding short stems. The current study aims to report on stem subsidence and midterm clinical outcomes of a cementless, metaphyseal-anchored short femoral stem, specifically designed for the direct anterior approach (DAA).

Methods: 94 consecutive patients (100 hips) with a minimum follow-up of 5 years following cementless THA were included in this single-center retrospective study. Subsidence was evaluated using the “Ein-Bild-Roentgen-Analyse” (EBRA). Periprosthetic radiolucency allocated to the Zones of Charnley and Gruen was assessed. Additionally, demographic and implant-related factors potentially associated with increased subsidence and clinical outcomes were evaluated.

Results: At the last follow-up, the average stem subsidence was 1.98 ± 1.20 mm, with 48% of the implants demonstrating subsidence of > 2 mm. Periprosthetic radiolucency of > 2 mm was found in 26% of the implants in Zone 1, and in 9% in Zone 7, respectively. Neither the amount of subsidence nor proximal periprosthetic radiolucency was associated with aseptic loosening or worse clinical outcomes.

Conclusions: Comparable to other proximally-fixed short stem designs, the highest subsidence was observed within the first 3 months following implantation. No demographic or implant-related factors were found to have a statistically significant influence on stem subsidence. Periprosthetic radiolucency and subsidence of the AMISstem is not correlated with worse clinical outcomes at 5-years follow-up.

Introduction

THA is a highly successful procedure with regards to restoration of function and pain relief in the treatment of symptomatic hip osteoarthritis(1). In the last decades, the prevalence of primary THA constantly increased, and the indications of THA have expanded to include younger and more active patients(2, 3). This led to a rising prevalence of revision THA (4, 5), with young, active patients being at higher risk of implant failure (6) and possibly multiple revision procedures within their lifetime. The development of a bone preserving cementless femoral short stem designs with metaphyseal press-fit fixation aims to preserve metaphyseal bone through proximal load transfer, thereby providing better bone stock for future femoral revision. Although these implants demonstrated good short- to mid-term outcomes(7, 8), there are concerns whether all short cementless proximally-fixed femoral stems are able to achieve an adequate primary stem fixation and stability. Various studies have reported on the subsidence of cementless hip stems, with some suggesting an inferior performance of short stem designs compared to conventional stems(9–22). This could be detrimental for implant survivorship, as several authors suggested a correlation of early stem subsidence with aseptic loosening(23–26).
Furthermore, periprosthetic radiolucency of > 2 mm, as well as progressive radiolucency over time, were reported to be suggestive for aseptic loosening of the femoral stem (25, 27).

The primary aim of this study was to analyse femoral stem subsidence and periprosthetic radiolucency of a cementless triple tapered short femoral stem with reduced lateral flare (AMIStem, Medacta International, Switzerland), which was specifically designed for the direct anterior approach (DAA), during a minimum follow-up of 5 years. The secondary aim was to identify potential patient- and implant-specific factors that could influence subsidence and to correlate subsidence with clinical outcome.

Material And Methods

This retrospective single-center study was approved by the institutional review board and the ethical committee (ID 2017 – 01448). It was conducted entirely at the authors’ institution with patient enrolment between January 2010 and December 2012. All patients who received a primary THA with a cementless short femoral stem (AMIStem, Medacta International, Switzerland) for primary or secondary osteoarthritis during the inclusion period were considered as potential candidates for the study.

Inclusion criteria

Adult patients > 18 years of age, who received a primary THA with the AMIStem implant for primary or secondary osteoarthritis and completed a minimum follow-up of 5 years were included. A further inclusion criterion was the acceptance of at least the direct postoperative and latest radiograph by the EBRA-FCA software.

Patient Characteristics

The medical records of all patients undergoing THA with the AMIStem implant in the above-mentioned timeframe were reviewed. Baseline characteristics including age, gender, BMI, and the patients’ physical status, according to the American Society of Anesthesiologists (ASA), were recorded. Peri- and postoperative complications, as well as postoperative outcome measures, were documented.

Implants, surgical technique, and postoperative care

Preoperative templating was performed with acetate overlays on calibrated standard x-rays. Implants used were a cementless acetabular cup (Versafit, Medacta International, Switzerland) and a cementless triple tapered HA-coated short femoral stem with reduced lateral flare (AMIStem, Medacta International, Switzerland), designed to facilitate stem insertion through the DAA. Table 2 provides a summary of the implant characteristics. All procedures were performed through a standardized minimally invasive DAA on a traction table (AMIS® Mobile Leg Positioner, Medacta International SA, Castel San Pietro, Switzerland) by two DAA experienced arthroplasty surgeons in our institution (> 100 THA through the DAA/year). Intraoperative imaging was used for accurate insertion of the acetabular component. Stem preparation included compaction broaching with careful preservation of lateral metaphyseal bone and insertion of the proximal press-fit implant. The entry point of the stem was determined in relation to the calcar and the posterior wall of the femoral neck was used as a landmark to determine version of the
implant. Intraoperative fluoroscopy was performed in case of any doubt of complication. Starting on the first postoperative day, all patients followed a standardized physical therapy protocol with weight-bearing as tolerated on crutches. Patients were discharged from the hospital if they were medically stable, had adequate oral pain control, dry wounds and were able to safely climb stairs and undertake their daily activities.

| Implant Characteristics | Implants (n = 100) |
|-------------------------|--------------------|
| **Stem Size**           |                    |
| 1                       | 22 (22%)           |
| 2                       | 21 (21%)           |
| 3                       | 23 (23%)           |
| 4                       | 10 (10%)           |
| 5                       | 11 (11%)           |
| 6                       | 1 (1%)             |
| 7                       | 0                  |
| 8                       | 1 (1%)             |
| 9                       |                    |

| **Stem Offset**         |                    |
| Standard                | 67 (67%)           |
| Lateral                 | 33 (33%)           |

| **Head Size**           |                    |
| 28                      | 52 (52%)           |
| 32                      |                    |

**Clinical Evaluation**

Patients were followed-up clinically and radiographically at 3 months, 1 year, and 5 years after surgery. Orthopedic consultants and residents blinded to the study performed each clinical examination and Harris Hip Score (HHS) in a standardized matter.

**Radiologic Measurements**
On the first postoperative day and at each follow-up, radiographs of the hip were obtained following a standardized protocol with the patient lying in supine position on the X-ray table, the lower limbs held together in a neutral position and the anterior superior iliac spine parallel to each other. A standardized X-ray magnification was applied for each radiograph. The first postoperative radiograph was used as a baseline measurement for comparison with the following images. Two orthopedic residents assessed the morphology of the proximal femur according to the Dorr classification(28) on the preoperative anterior-posterior radiograph of every patient. Postoperative radiographs were evaluated at each follow-up period for periprosthetic radiolucency (29), and the radiolucencies were allocated to the zones 1 to 7 of Gruen et al(30) (Fig. 1A).

**EBRA measurements**

The “Einzel-Bild-Roentgen-Analyse-femoral component analysis” (EBRA-FCA software, Institute for Basic Engineering Sciences, University of Innsbruck, Innsbruck, Austria) was used to measure axial stem subsidence. This software analyses comparability of measurements between follow-up radiographs and rejects unsuitable images, therefore improving accuracy (31–33) (Fig. 1B). Comparison of EBRA-FCA with radiostereometric analysis (RSA) has shown excellent interobserver reliability and good measurement accuracy with a specificity of 100% and a sensitivity of 78% in the detection of subsidence of over 1 mm (31).

**Statistical Analysis**

Statistical analysis has been performed using SPSS Statistics (SPSS, IBM Corporation, 1 New Orchard Road Armonk, New York 10504 - 1722, USA). Continuous variables were reported as average and standard deviation (SD). Categorical variables are reported as numbers and percentages. The normality of distribution was assessed using the Shapiro-Wilk test. Stepwise multivariable regression analysis were established to evaluate potential relationships between radiographic subsidence and patient demographics, implant factors, progressive periprosthetic lucency, and clinical outcome. P-values < 0.05 were considered statistically significant for all statistical tests.

**Results**

**Patient characteristics**

A total of 151 consecutive patients were enrolled in the study. After exclusion of patients missing a 5-year follow-up, incomplete radiographic datasets and rejected images, 100 hips of 94 patients (Male: 42, female 52) with an average age of 69.4 years (SD +/- 9.4) remained for analysis (Table 1).
Table 1
Summary of patient characteristic. ASA: American Society of Anesthesiologist; BMI: body mass index. The values were given as average value and standard deviation or as numbers and percentages as appropriate.

| Patient demographics | Patients (n = 94; 100 hips) |
|----------------------|-----------------------------|
| Age (Years)          | 69.0 (± 9.8)                |
| BMI (kg/m²)          | 27.7 (± 4.4)                |
| Gender               |                             |
| • Male               | 42 (45%)                    |
| • Female             | 52 (55%)                    |
| ASA                  |                             |
| • 1 (n)              | 62 (66%)                    |
| • 2 (n)              | 25 (27%)                    |
| • 3 (n)              | 0 (0%)                      |
| • 4 (n)              |                             |
| Side                 |                             |
| • Left (n)           | 46 (46%)                    |
| • Right (n)          | 54 (54%)                    |
| Postoperative Harris Hip Score at latest follow-up | 94 (9.4) |

Complications
During an average follow-up of 64 (range 60 to 83) months, 4 THA had to be revised: One because of an early periprosthetic infection treated with polyethylene exchange and local debridement and one because of a periprosthetic fracture (Vancouver B2) following a fall. One patient showed aseptic loosening of the acetabular component, which had to be revised 6 years following primary THA. One patient presented with aseptic loosening of the femoral stem and had to be revised 4 years following THA. Anterior-posterior radiographs of this patient demonstrated progressive periprosthetic radiolucencies in all zones of Gruen (Fig. 2), and the EBRA analysis revealed a subsidence of 4.2 mm at the latest radiographic follow-up 4 years after primary implantation.

Functional outcome
At the latest follow-up, 96.3% of the patients had a good (80 to 90) or excellent (90 to 100) HHS and the average HHS of all included patients was 94 (SD +/- 9.4)(Table 1).

Radiographic measurements
While there was progressive periprosthetic radiolucency over time in the proximal zones 1, 2 and 7 of Gruen et al., the distal zones demonstrated only an increase in radiolucency within the first 3 months following implantation, with subsequent remodeling and radiolucency decrease at the 1-year follow-up (Fig. 3). However, the average increase of radiolucency in zone 1, 2, and 7 between follow-ups was not statistically significant at any point. The average periprosthetic radiolucency at the latest follow-up in Zone 1 was 1.42 ± 2.01 mm with a radiolucency of >2 mm in 26 THA (26%). The average periprosthetic radiolucency in Zone 7 was 0.71 ± 1.2 mm with 9 THA (9%) >2 mm. However, only 5 patients (5%) demonstrated simultaneous periprosthetic radiolucencies of >2 mm in Zone 1 and 7.

**EBRA-FCA subsidence analysis**

A total of 409 radiographs in 100 hips (94 patients) were analyzed, and 47 radiographs (11.5%) were rejected by the EBRA-FCA software. The average femoral stem subsidence was 0.85 ± 0.78 mm at 3 months, 1.48 ± 1.00 mm at 1 year, and 1.98 ± 1.20 mm at the latest follow-up. A subsidence >2 mm was observed in 7 THAs (7%) 3 months postoperatively, in 15 THAs (15%) 1 year postoperatively, and in 48 THAs (48%) at the latest follow-up. The highest subsidence occurred during the first 3 months, with gradual decrease up to the latest follow-up (Fig. 4).

**Factors affecting stem subsidence**

The multivariable analysis demonstrated that the femoral stem subsidence at the latest follow-up was not statistically significant correlated to patient demographics, stem characteristics (offset or femoral head), the morphology of the proximal femur, or the amount of periprosthetic radiolucency in any zone of Gruen (Table 3).
### Table 3
The influence of different demographics, proximal femur morphology, and different stem characteristics on subsidence at the latest follow-up.

| Parameter                             | Subsidence at the latest follow-up | p-value |
|---------------------------------------|------------------------------------|---------|
|                                       | Mean (SD)                          |         |
| Gender                                |                                    | >.05    |
| • Male (n = 42)                       | 2.22 ± 1.23 mm                     |         |
| • Female (n = 52)                     | 1.80 ± 1.15 mm                     |         |
| BMI                                   |                                    | >.05    |
| • > 30 kg/m² (n = 31)                 | 2.31 +/- 1.18 mm                   |         |
| • < 30 kg/m² (n = 69)                 | 2.04 ± 1.29 mm                     |         |
| Age                                   |                                    | >.05    |
| • > 65 years (n = 65)                 | 2.04 ± 1.29 mm                     |         |
| • < 65 years (n = 35)                 | 1.87 ± 1.01 mm                     |         |
| Offset                                |                                    | >.05    |
| • Standard (n = 67)                   | 2.05 ± 1.13 mm                     |         |
| • Lateral (n = 33)                    | 1.84 ± 1.32 mm                     |         |
| Head size                             |                                    | >.05    |
| • 28 mm (n = 48)                      | 1.83 ± 1.03 mm                     |         |
| • 32 mm (n = 52)                      | 2.12 ± 1.33 mm                     |         |
| Dorr proximal femur morphology       |                                    | >.05    |
| • Type 1 (n = 18)                     | 1.96 ± 1.20 mm                     |         |
| • Type 2 (n = 68)                     | 1.92 ± 1.07 mm                     |         |
| • Type 3 (n = 14)                     | 2.41 ± 1.49 mm                     |         |

**Clinical outcomes and stem subsidence**

Neither the amount of stem subsidence nor the occurrence of periprosthetic radioluency in the proximal part of the prosthesis had an impact on the functional outcome (p > 0.05).

**Discussion**
The current study demonstrated comparable subsidence patterns of the AMIStem to those of previously published short stems (15, 18, 21, 34) with the highest subsidence in the first 3 months. At the latest follow-up, the average stem subsidence was 1.98 ± 1.20 mm, with 48% of the implants demonstrating subsidence of > 2 mm. Periprosthetic radiolucency of > 2 mm was found in 26% of the implants in Zone 1, and in 9% in Zone 7, respectively. Furthermore, no patient-related or implant-related factors were found to have a statistically significant influence on stem subsidence.

The examined short stem demonstrated almost 50% of the overall subsidence within the first 3 months and then slowed down markedly. However, there was some subsidence up to the last follow-up, which is in accordance with recent findings of Schaer et al. (34), who studied the Optimys short stem (Mathys, Bettlach, Switzerland) and Thalmann et al. (14) who studied the Fitmore short stem (Zimmer Inc., Warsaw, Indiana, USA). In contrast, most previously published data on cementless short stems found stabilization of subsidence during a shorter follow-up of 3 months(21, 22), 6 months(20), 12 months(19), or 24 months(15). Applying radiostereometric analysis (RSA), Acklin et al. observed an average subsidence of 0.39 mm at 3 months after implantation of a Fitmore stem (Zimmer Inc., Warsaw, Indiana, USA) with no further distal subsidence until a 2-year follow-up(21). Freitag et al. using EBRA-FCA observed an average subsidence of 1.1 mm (range: -5 mm to 1.5 mm) at a 5-year follow-up with stabilization from the 2-year mark with the same implant (15). For the Optimys short stem (Mathys, Bettlach, Switzerland), subsidence of 0.96 +/- 0.76 mm at 3 months and 2.04 +/- 1.42 mm at 5 years has recently been reported(34). Kutzner et al. published a mean axial subsidence of 0.55 mm (SD 0.78 mm) at 6 weeks and 1.43 mm (SD 1.45 mm) at final follow-up at 2 years in the same stem design(19), while in another study, the same author reports subsidence of > 2 mm in 15.7% of implants, which subsequently stabilized (20). However, they did not use EBRA-FCA for measurements. Brinkmann et al. analyzed subsidence of the Nanos stem (Smith & Nephew plc, London, UK) and the Metha stem (Aesculap AG, Tuttlingen, Germany) during a 1-year follow-up and reported an average distal subsidence of 2.04 +/- 2.65 mm and 1.96 +/- 2.37 mm, respectively(18).

When compared to conventional stems, short stems are reported to subside slightly more. Clauss et al. reported mean subsidence of 0.66 mm at 5 year follow-up in the twinSys® stem (Mathys Ltd., Bettlach, Switzerland) with 9.8% of the implants showing subsidence > 2 mm using EBRA-FCA(12). Campbell et al. used RSA to evaluate stem subsidence of a corail stem (Corail; Depuy Orthopaedics Inc., Warsaw, Indiana, USA) to find an average subsidence of 0.58 mm (range – 0.23 to 3.71 mm) 2 years after surgery(35). Some authors compared the subsidence patterns of short stems to conventional stem designs. In a randomized controlled trial, Ferguson et al. showed substantially lower subsidence (0.36 +/- 0.38 mm) of the Meta Fix conventional stem (Corin Group, Cirencester Gloucestershire, UK) compared to the MiniHip (Corin Group, Cirencester Gloucestershire, UK) short stem (0.62 +/- 0.56 mm) at 2 years (16). McCalden et al. found a higher, yet not significant, subsidence of the SMF short stem (Smith & Nephew plc) compared to the Synergy conventional stem (Smith & Nephew plc) (0.94 +/- 1.74 mm versus 0.32 +/- 0.45 mm) at 2-years follow-up using RSA (17).
Several authors focused on defining a threshold value of early subsidence for the prediction of aseptic failure. Freeman et al. described a threshold subsidence of 1.2 mm per year during the first 2 years for the prediction of aseptic failure with a specificity of 86% and a sensitivity of 78%. Using RSA, Kärrholm et al. reported a risk of over 50% of aseptic loosening, if subsidence of over 1.2 mm occurred within the first 2 years after surgery. If a subsidence of more than 2.4 mm was reached, the risk increased to 95%. In a similar study, Krismer et al. investigated subsidence of the femoral stem using EBRA-FCA. Early aseptic loosening could be predicted with a sensitivity of 69% and a specificity of 80%, if subsidence exceeded 1.5 mm during the first two years. However, none of these studies examined cementless short femoral stems. Studying a proximally-fixed Vision 2000 stem (Depuy Orthopaedics Inc, Warsaw, Indiana, USA), Stihsen et al. described subsidence of > 2 mm in 19% out of 102 implants after two years and found a highly significant correlation of subsidence > 2 mm at two years and subsequent aseptic loosening. On the other hand, studying the metaphyseal-anchored Fitmore hip system (Fitmore®, Zimmer Inc., Warsaw, Indiana, USA), Gustke et al. described subsidence of more than 2 mm on plain radiographs in 34% of 100 examined THA after a mean follow-up of 1.3 years. However, none of these implants had to be revised during this short follow-up. In our study, 15% of the implants showed axial subsidence > 2 mm after the 1-year follow-up and 48% after a mean follow-up of 64 months with only one case of aseptic stem loosening during the observation period. Considering this, the above-mentioned threshold values might not be applicable for proximally-fixed short femoral stem designs. However, due to the limited sample size as well as the average follow-up time of 64 months, the current study might be underpowered to detect a potential correlation of subsidence with aseptic loosening, where rates as low as 0.4% at 10 years in the DAA have been reported.

The present study should be interpreted in light of its potential limitations. First, the EBRA-FCA method was used instead of RSA, which is currently considered the gold standard for analyzing distal stem subsidence. However, the widely established, computer-assisted EBRA-FCA system is able to detect subsidence of more than 1 mm with a specificity of 100% and a sensitivity of 78% and is therefore considered a reproducible and accurate tool for evaluation of distal femoral stem subsidence. Second, we only evaluated axial subsidence of the stem while tilt and rotation were not evaluated. Third, the small size of our cohort limits the power of our study, especially regarding aseptic loosening, where rates as low as 0.4% at 10 years in DAA have been reported. Fourth, our study is prone to some attrition bias with a high rate of rejected X-rays by EBRA-FCA and incomplete radiographic datasets resulting in the inclusion of 62.3% of initially enrolled patients. Finally, only the AMIStem femoral component was investigated in our study. Although the EBRA-FCA software was used by various authors to measure subsidence of different femoral implants, our findings might not apply to other stem designs.

**Conclusion**

The evaluated cementless short stem specifically designed for insertion through DAA revealed average subsidence of 1.98 +/- 1.20 mm with 48% of the implants showing subsidence > 2 mm at a mean follow-up of 64 months. Subsidence was most pronounced during the first 3 months, with further slow progression up to the last follow-up. A quarter of the implants showed periprosthetic radiolucency >2mm
in Zone 7, a tenth in Zone 1, and 5% in both zones simultaneously. Neither the amount of subsidence nor proximal periprosthetic lucency was associated with worse clinical outcomes. Surgeons who perform THA with the examined cementless metaphyseal-anchored short femoral stem should be aware of its subsidence and periprosthetic radiolucency pattern.

Declarations

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Conflict of interest statement:

Naeder Helmy has Royalties from Medacta International (Switzerland) and is Speaker for Mathys Ltd Bettlach (Switzerland) and Medacta International (Switzerland).

Contributors

hip: JH, NH und MF researched literature and conceived the study. IH, NH and MF were involved in protocol development and gaining ethical approval. IH, AF and JH were involved in data analysis. JH and MF wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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