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AMIStem-H: Radiological results at 5 years

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AMIStem-H: Radiological results at 5 years

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ABSTRACT

This study analyses the radiological performance of a cementless triple tapered hydroxyapatite coated stem (AMIStem-H, Medacta International SA, Castel San Pietro) over a period of 5 years after surgery. A consecutive series of 178 hips in 170 patients, who didn't follow a specific rehabilitation protocol, were radiographically and clinically checked up at 1 year; 17 patients were unavailable to follow-up for health or logistics/compliance reasons, hence 139 hips in 132 subjects were available for 5-year assessment. Two patients underwent stem revision. Implant survival at five years was found at 98.9%. 31% of the hips showed no radiolucencies at all at 5 years; 9% showed proximal or multi-zone radiolucencies greater than 2mm but no correlation was found with pain or clinical limitations. A slight progression of radiolucencies is observed from 1 to 5 years, which is not considered critical as the ratio of relevant radiolucencies is low (5% at 1 year; 10% at 5 years) and these hips are mostly asymptomatic (72%). 96% of patients had no pain (82%) or slight pain (14%). No correlation was found between radiolucencies and other variables, such as bone morphology according to Dorr classification or early post-operative activity.

INTRODUCTION

The aim of this work is to display and discuss results of a radiological analysis on Total Hip Arthroplasty outcome after 5 years with a single device, Amistem-H (Medacta International SA, Castel San Pietro). This analysis is based on Gruen Zone Classification[1]. Radiological outcomes and survival analysis will be evaluated and correlated with selected clinical parameters.

Existing research shows good and consistent results using cementless stems[2]. It is also reported that a high percentage of radiolucencies (up to 86%) may be expected over the long term in patients with a successful prosthesis in situ[3]. This high percentage of radiolucencies is not necessarily associated with clinical symptoms: this is confirmed by excellent survival rates[2].

AMIStem-H is the first cementless stem specifically designed for AMIS (Anterior Minimally Invasive Surgery). The stem aims to facilitate broaching and easier stem insertion without compromising stem stability. The AMIStem-H, like other existing and well-proven stems, provides effective stability due to a triple tapered design. Biomechanical tests have verified stability with the AMIStem-H and they demonstrate reduced bone removal due to an optimized length and shoulder profile[4].

Figure 1. AMIStem-H

MATERIAL AND METHODS

Inclusion criteria in retrospective study

This study uses an open, retrospective clinical survey design. A consecutive series of 178 hips in 170 patients were implanted for any type of etiology between November 2009 and February 2011 and treated with total hip arthroplasty using an AMIStem-H cementless stem (Medacta International SA, Castel San Pietro). Patients were radiographically and clinically reviewed at 1 year and 5 years post surgery. Dorr Classification was used to categorize the patients based on femoral morphology. All operations were performed by F.K. and A.S. in Kantonsspital Winterthur, Switzerland. Patient demographic data and implant details are shown in Table 1a and 1b. Written consent from patients was obtained to collect and analyse retrospective data. There were no age limit criteria.

Date of surgery	*November 2009-February 2011*	
Patients *(N=170)*	Male	85 (50%)
	Female	85 (50%)
Dorr Classification *(hips)*	Type A	52 (29%)
	Type B	121 (68%)
	Type C	5 (3%)
Mean age at surgery *(years)*	67 (SD 11, range 25-97)	
Mean BMI *(kg/m²)*	26.9 (SD 4.1, range 14-42)	

Table 1a. Patient demographics

Implant details		**# hips**
AMIStem-H size	0-2	60 (34%)
	3-5	101 (57%)
	6-8	17 (9%)
Head Diameter *(mm)*	28	99 (56%)
	32	79 (44%)
Neck length	S	41 (23%)
	M	120 (67%)
	L	17 (10%)

Table 1b. Implant details

In this study, we present the radiological and clinical outcomes at a mean follow-up of 64.8 months (STD 6.2, range 40-76) for 178 hips. The parameters taken into consideration included number and type of radiolucencies present and any associated clinical symptoms.

The area around the stem has been divided into 7 different zones in the anteroposterior view as described by Gruen et al.[1]. Only radiolucencies greater than 2mm have been deemed relevant as current research suggests that these may be a potential early predictor of aseptic loosening[1].

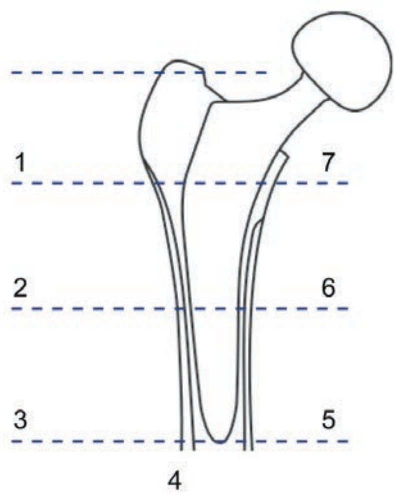

Figure 2. Gruen zones definition

The collected data allow evaluation of survival rates of the AMIStem-H implant and any associated radiological and clinical outcomes after a five-year follow-up.

STATISTICAL ANALYSIS

Descriptive statistics was performed for the continuous variables and frequency distributions of categorical variables. Results are reported as means and standard deviations. A Chi squared test was used to identify any correlation between radiolucencies and pain, radiolucencies and bone type, radiolucencies and cortex change density, radiolucencies and activity level, pain and bone type, or between pain and cortex change density. The Kaplan-Meyer method was used to define the survival rate of the stem[5].

RESULTS

Radiological results are available for 139 hips (78%) in 132 patients. Results were unavailable for 33 patients due to: death (13), revised stem (1 fracture, 1 aseptic loosening), deep infection (1), health reasons (4), living abroad (4) and non-compliance (9). Five patients, one of them bilateral, are awaiting follow-up at the time of this study. The total number of lost to follow-up is therefore 17 out of 170 (10%).

Survival rate analysis

One stem was revised at 37 months for bone fracture subsequent to a traumatic event. The patient was an 83-year-old male with BMI of 26.6 kg/m².

One stem was revised at 47 months for aseptic loosening. The patient was a 72-year-old female with a BMI of 22.9 kg/m².

According to the Kaplan-Meyer analysis, the survival of the stem at 5 years after surgery is 98.9% considering revision for any reason as endpoint, as shown in Figure 3.

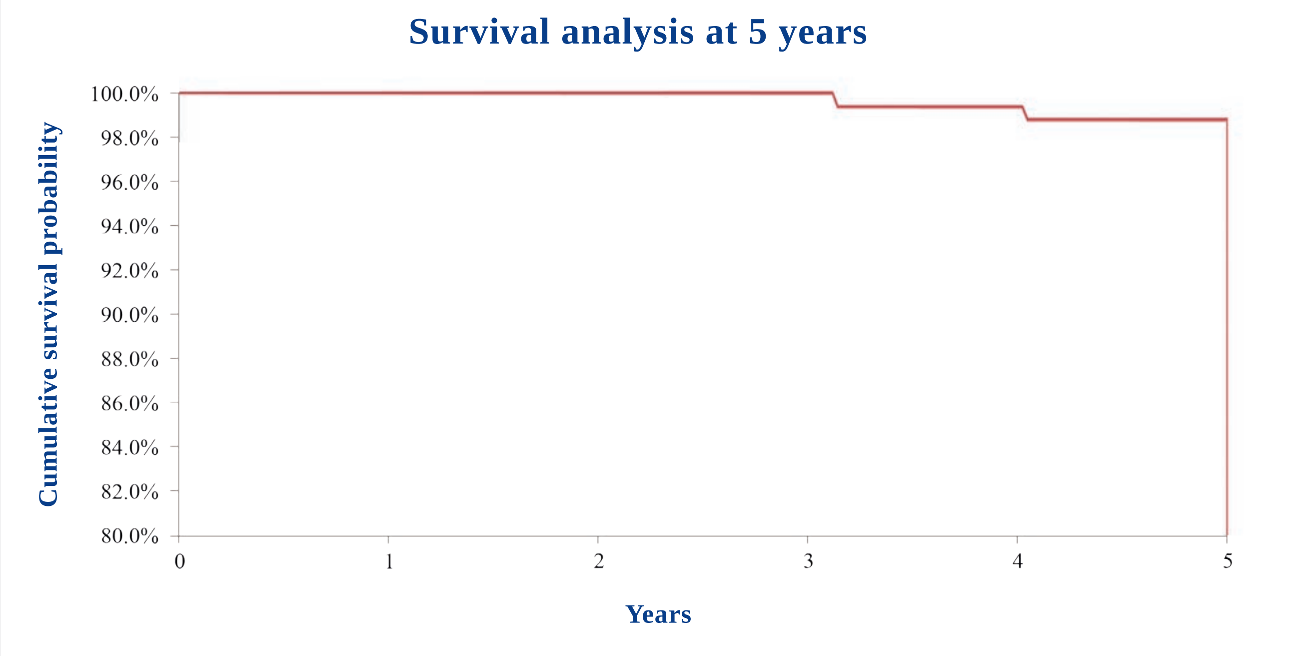

Figure 3. Kaplan-Meier survival curve

Radiological results

A special notation was used to categorise the radiological results to deeply analyse the progression of radiolucencies during the study. The attributes “minimal” and “relevant” classify the radiolucencies according to their severity: the radiolucencies greater than 2 mm were categorized as “relevant”, otherwise they were called “minimal”. Radiolucencies were defined: “proximo-lateral” if present in zone 1 only; “proximal” if the proximal radiolucency included (or was limited to) zone 7; “distal” if there was just one radiolucency between zone 2 and 6; “multi-zone” if there were more than one radiolucencency between zone 2 and 6 or there was a combination of proximal and distal radiolucencies.

Radiological analysis was performed by the authors. At 5 years 43 hips showed no radiolucencies, 34 proximo-lateral minimal, 25 proximal minimal, 4 distal minimal, 19 multi-zone minimal, 1 proximo-lateral relevant, 5 proximal relevant and 8 multi-zone relevant.

Figure 4 shows the difference between radiolucencies at 1 year and 5 years. The number of relevant distal radiolucencies is none at 1 and 5 years and therefore it’s not displayed in the figure.

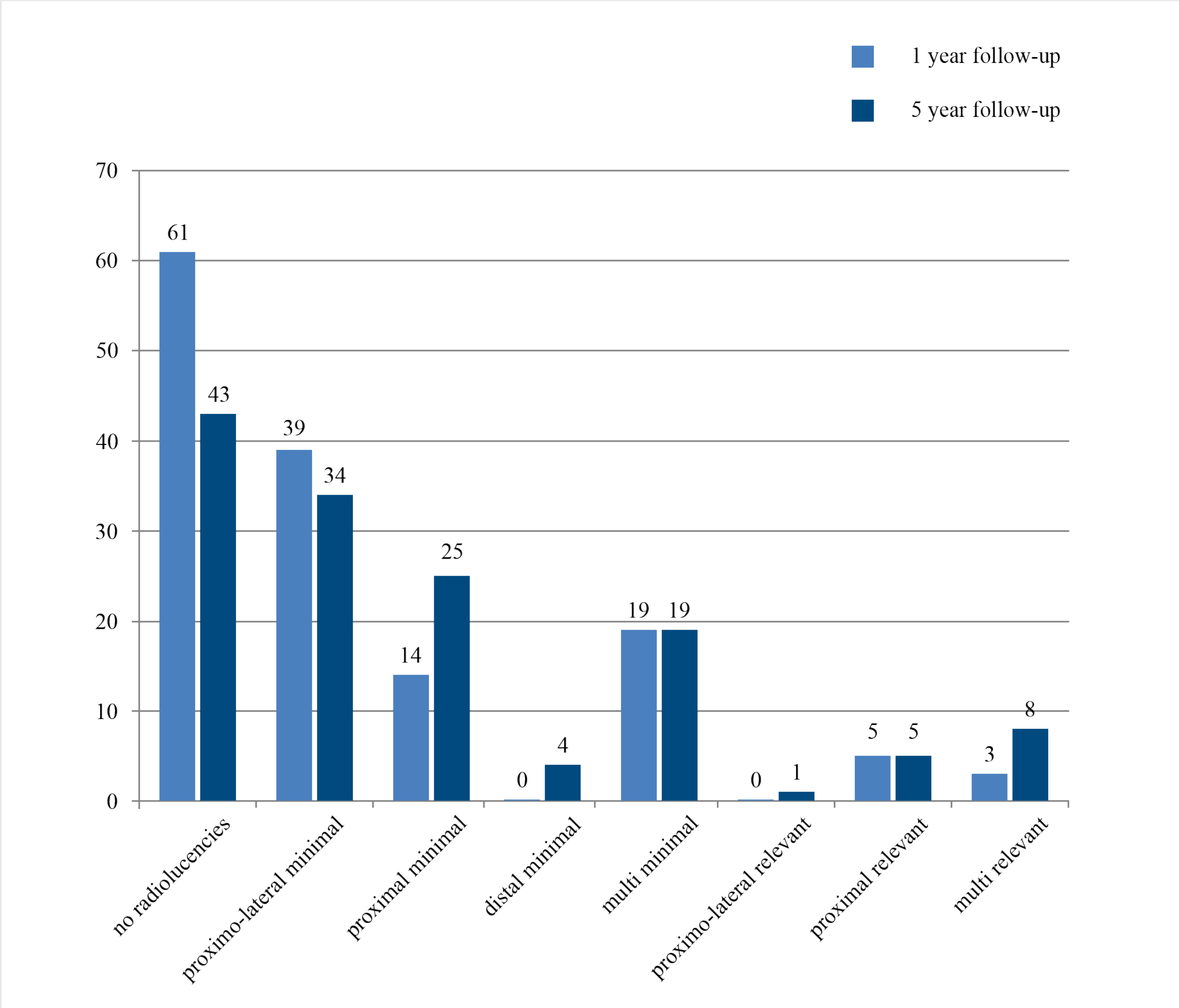

Figure 4. Comparison of radiolucencies present at 1 year and 5 year follow-up.The number of relevant distal radiolucencies is none at 1 and 5 years and therefore it's not displayed in the figure.

Patients presenting radiolucencies at 1 year were divided in 6 categories and analysed to determine the progression or regression of these radiolucencies at 5 years. These categories are: 1. no radiolucencies, 2. proximo-lateral minimal, 3. proximal minimal, 4. multi-zone minimal, 5. proximal relevant and 6. multi-zone relevant.

Figure 5a illustrates the radiological evolution at 5-year follow-up of the hips which didn't present any radiolucencies at 1-year. As shown in the figure, among the 61 hips without radiolucencies at 1-year follow-up, 34 (56%) remained without radiolucencies and 12 (18%) developed only proximo-lateral minimal signs. 7 (11%) showed minimal proximal radiolucencies and 2 (3%) relevant proximal.

Figures 5b through 5f illustrate the evolution at 5-year follow-up of the hips that, at the first follow-up, presented proximo-lateral minimal (39), proximal lateral (14), multi-zone minimal (19), proximal relevant (5) and multi-zone relevant (3) radiolucencies respectively.

At 1 year, no patient showed minimal radiolucencies in the distal area.

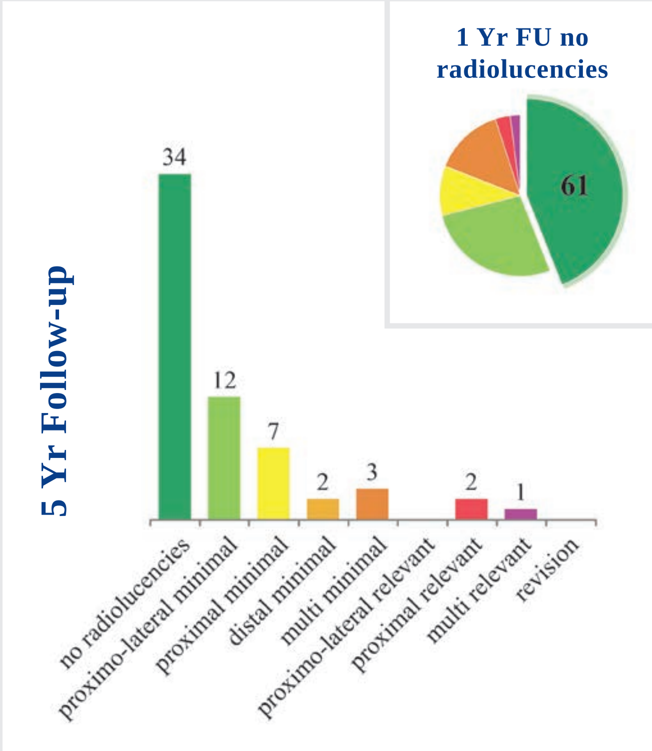

Figure 5a. Progression of radiolucencies at 5 years without radiolucencies at 1 year, total 61 hips (43.3%)

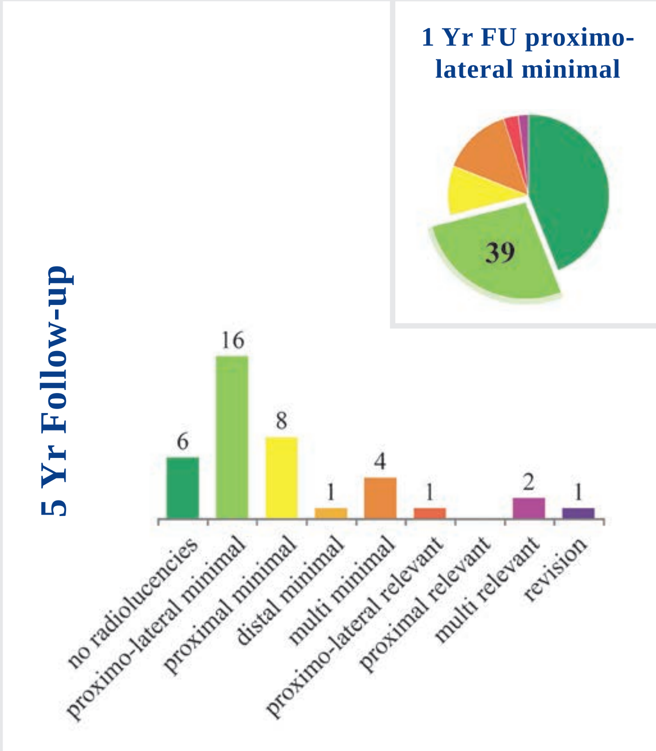

Figure 5b. Progression of radiolucencies at 5 years with proximo-lateral minimal radiolucencies at 1 year, total 39 hips (27.7%)

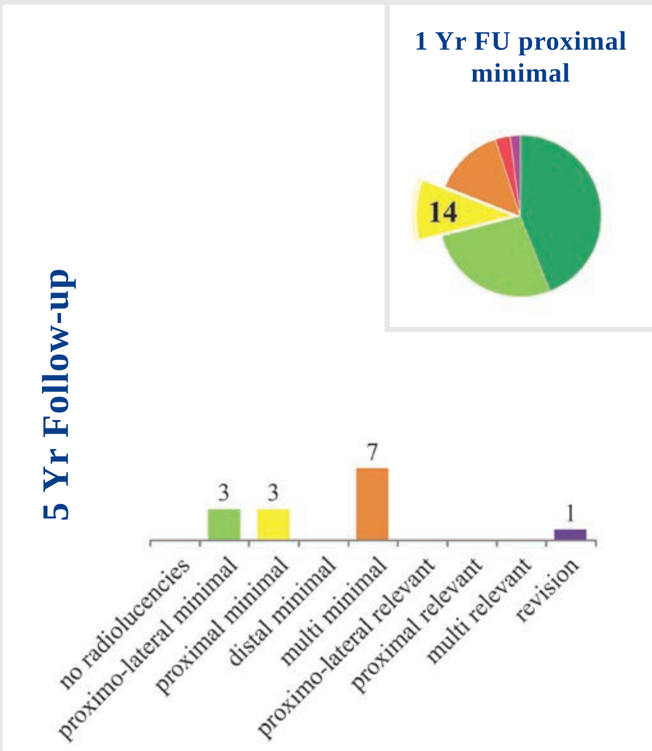

Figure 5c. Progression of radiolucencies at 5 years with proximal minimal radiolucencies at 1 year, total 14 hips (9.9%)

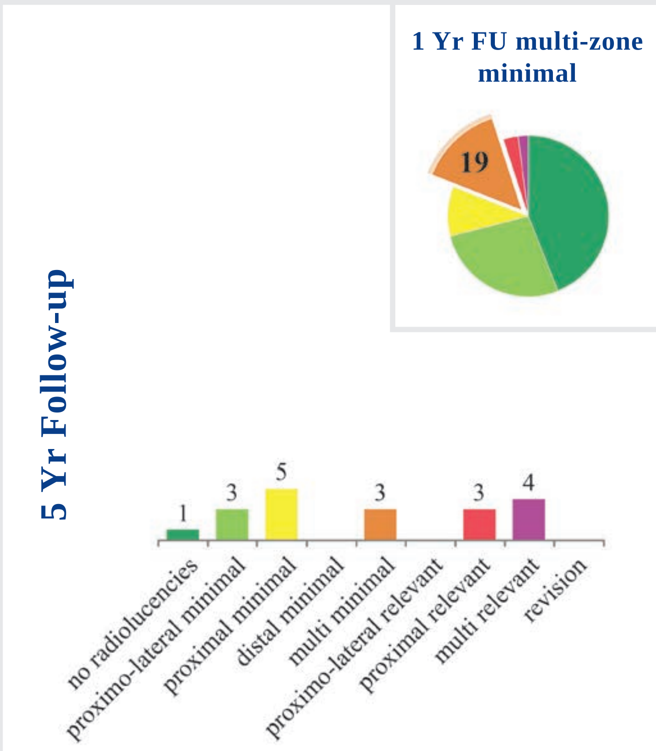

Figure 5d. Progression of radiolucencies at 5 years with multi-zone minimal radiolucencies at 1 year, total 19 hips (13.5%)

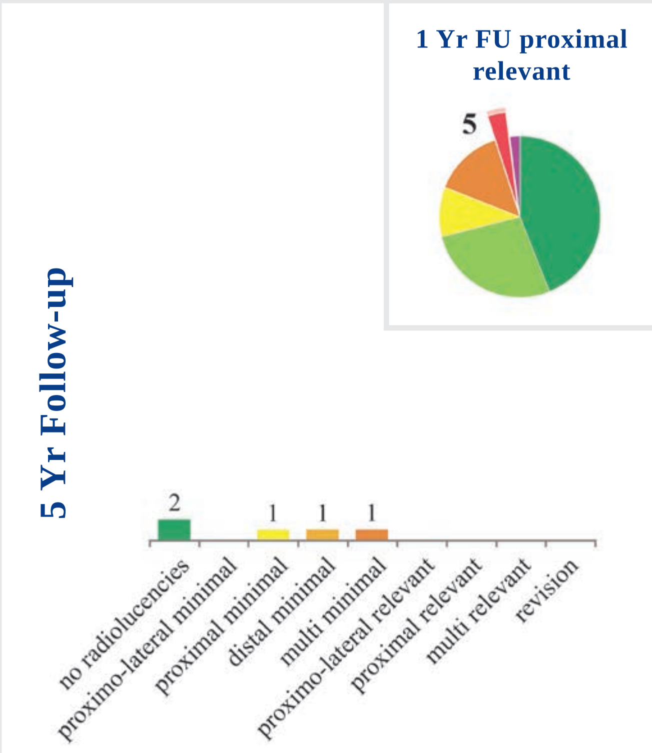

Figure 5e. Progression of radiolucencies at 5 years with proximal relevant radiolucencies at 1 year, total 5 hips (3.5%)

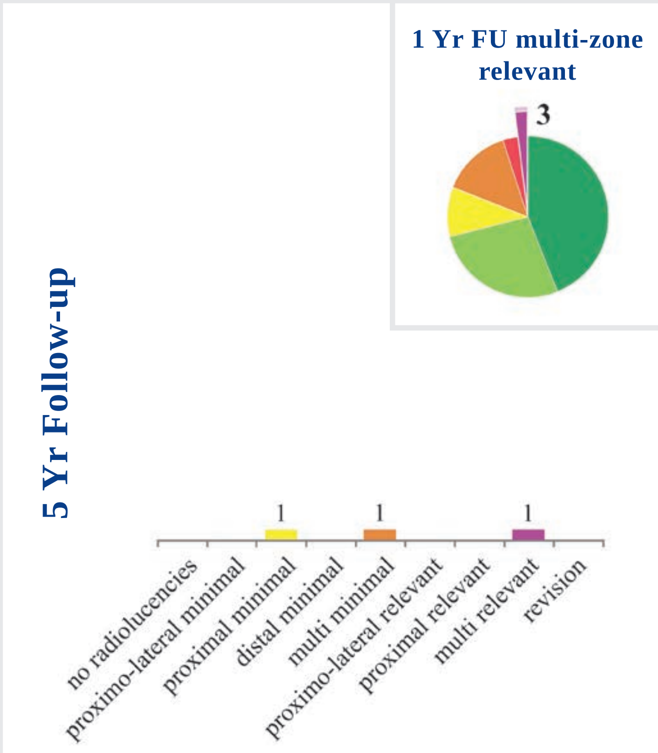

Figure 5f. Progression of radiolucencies at 5 years with multi-zone relevant radiolucencies at 1 year, total 3 hips (2.1%)

No stem fracture or stem subsidence has been recorded. There was 1 progressive tilt of the stem in valgus, which subsequently stabilized.

Cortex change in density was analysed and categorized as shown in Table 2.

Cortex change in density	1 Year follow-up	5 Year follow-up
None	137 (98.6%)	100 (71.9%)
Atrophy	-	4 (2.9%)
Hypertrophy localized	1 (0.7%)	25 (18.0%)
Hypertrophy localized and periosteal reaction	-	1 (0.7%)
Increased	1 (0.7%)	9 (6.5%)

Table 2. Cortex change in density

Clinical results

Patient questionnaires were completed at one and five year follow-up intervals to measure the level of pain experienced (Table 3).

Level of pain experienced	1 Year follow-up	5 Year follow-up
None	113 (82%)	114 (82%)
Slight	17 (12%)	19 (14%)
Mild	2 (1%)	2 (1%)
Moderate	4 (3%)	1 (1%)
Marked	2 (1%)	3 (2%)

Table 3. Level of pain

Among the 14 hips with radiolucencies greater than 2mm (10% of the total), 10 were asymptomatic (72%), 2 experienced slight pain (14%), 1 moderate (7%) and 1 marked pain (7%).

All patients were engaged in physical activity ranging from minimal (4%) to heavy (16%) with the majority being engaged in moderate (46%) and light (34%) physical activity.

Hip pain, cortex change in density, and bone classification variables showed no correlation with the presence of radiolucencies.

DISCUSSION

The Kaplan Meyer survival analysis curve demonstrates that the AMIStem-H sustained a 100% survival rate until 36 months. At 5 years, a 1.12% decrease is observed: this is a good performance if compared against other cementless stems used for THR detailed in the English and Australian National Joint Registries. The English Registry (NJR - 2015) [5] describes a 2.89% probability of revision at five years for the Corail/Pinnacle stem/cup (2.75%-3.03%). The Australian Joint Registry[6] reports a cumulative percentage of revisions at five years for Corail/Pinnacle of 3.0% (2.7-3.2) and of 3.0% for Taperloc/Mallory-Head (2.1-4.2).

The low incidence of femoral fractures (1 case, traumatic event) and the absence of subsidence was reassuring: for instance, a stem traditionally considered to be stable and reliable but significantly more invasive, such as Alloclassic (a Zweymuller-type stem, SulzerMedica) was reported to have 3.4% of early subsidence[7].

Lucencies appear mostly in the proximal femur, which is in line with outcomes in literature for cementless, straight, tapered femoral stems[2,8,10,11,12,13,14]. The question of radiolucencies being a possible predictor of stem loosening is still open. Wick and Lester[8] demonstrated that radiolucencies, especially if not symptomatic, should not be considered a reliable predictor of stem loosening. Several ten-year follow-up studies with the Alloclassic stem have failed to show that these radiological changes lead to loosening of the femoral stem or clinical compromise. Mostly, the lucencies appeared in the proximal femur and didn't progress[8,11].

Cortex change in density or bone classification variables were found to have no correlation with pain in this study. This contradicts literature where a correlation was found between distal femoral bone thickening and thigh pain ($p < 0.019$)[9]. Also, from this study there was no evidence that the AMIStem had a different performance depending on femoral morphology. Specifically, no difference was found in terms of clinical or radiological outcome among the different Dorr classifications.

No specific rehabilitation protocol was prescribed for these patients: they were allowed to self-select any level of physical activity in the immediate postoperative period, depending on their personal well-being. No correlation was established by the surgeons during follow-up visits between physical activity and lucent lines although this was not a specific object of investigation in the present study. Since 2011 a postoperative protocol was adopted and these patients are now scheduled for their 5-year follow-up visit and radiological examination. Results will be reported in a future paper.

The same operative technique - the AMIS method - was used by both surgeons who were experienced with this method. Therefore, there was no learning curve associated with the conduct of these procedures.

CONCLUSION

The clinical results of this study are promising, as the great majority of patients reported early relief from any significant pain and were able to engage in a self-selected level of physical activity. These favourable results were maintained over the five-year period of the study. The AMIStem implant provides reproducible and successful radiological outcomes after a mean of five years after primary total hip arthroplasty. The number of patients suffering from pain did not increase over time and any radiolucencies were independent of patient or implant characteristics. The survivorship of 98.88% at 5 years compares favourably with data reported in the England and Wales National Joint Registry 2015 and in National Joint Replacement Registry of Australia.

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