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Minimum 10 Year Survivorship Analysis of a Partially Coated Hydroxyapatite Tapered Femoral Stem in Elderly Patients With an Average Age Over 75

Michele Ulivi, MD [a,b], Valentina Meroni, MD [a], Luca C. Orlandini, MD [a], Pedro Berjano, MD [a], Valerio C. Sansone, MD [b]

[a] Unità Operativa di Ortopedia Istituti Clinici Zucchi, Monza, Italy
[b] Università degli Studi di Milano, IRCCS Istituto Ortopedico Galeazzi, Milan, Italy

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ABSTRACT

This is a retrospective, non-comparative study of 212 consecutive patients who underwent Total Hip Arthroplasty with an uncemented hydroxyapatite (HA) coated stem system from November 1997 to March 2000. The objective of the study was to analyze the performance of the implant at a minimum of 10 years in older patients (mean age 79.6 years). The Kaplan-Meier survivorship of the femoral stem at 10 years was 100%, and 97.5% for the whole prosthesis. The mean Merle d'Aubigné clinical score improved from 4.4 ± 2.1 points pre-operatively to 13.39 ± 3.77 points at final follow-up ($p<0.05$), and the mean VAS score for thigh pain was 1.25. The radiographic analysis showed that there were no significant radiolucent lines or osteolysis compromising the fixation of the implant.

Total hip arthroplasty (THA) has been proven to be a successful, long-term procedure for the treatment of OA [1]. But, in spite of the continuous advances in surgical technique and implant design, long term survival of THA is still threatened by the possible occurrence of aseptic loosening [2–4]. It has been estimated that around 45% of all THA revisions can be attributed to loosening and periprosthetic osteolysis [2]. These data refer mainly to THA patients with a relatively young average age who are likely to have reasonable bone stock quality. The number of elderly patients undergoing hip replacement has greatly increased due to rising life expectancy. Although the effectiveness of this procedure in the older population has been demonstrated [2,4,5], concerns still exist with cementless fixation, due to the relatively poor bone quality and the morphological changes induced by ageing, particularly in women, and the reduced bone stock of the proximal part of the femur. For example, it has been postulated that patients with severe thinning of proximal femoral cortices and widening of the intramedullary canal (type C according to Dorr's bone quality classification) would have a delayed remodeling and a higher incidence of thigh pain [6].

Cementless fixation has proven to be able to ensure good bony ingrowth, thereby limiting the chances of loosening, in young and relatively young patients [7,8]. With uncemented stems, geometry and surface coating play a major role in providing a successful, long-term outcome. The debate about the most valid shape of the stem is still open, although the tapering concept with its optimal fitting into the proximal femoral metaphysis seems to have a valid and attractive theoretical basis [9], especially for elderly people. By achieving a secure proximal fixation, this design should provide a more appropriate redistribution of the mechanical loads, reducing proximal stress shielding and thigh pain observed with other designs [9]. Proper sizing is fundamental to the success of this type of stem; the risk of periprosthetic fracture may be of increased concern in older patients with poorer bone quality. To improve bone ingrowth, several cementless technologies are available on the market and hydroxyapatite (HA) coating is one of them. Excellent long-term survival rates of HA-coated stems have been reported in studies with mean follow-up of up to 17.5 years [10].

These considerations led us to choose and implant an uncemented tapered HA coated stem in a cohort of 212 consecutive older patients (mean age 79.6 yrs), and to analyze the survival and radiological appearance of this stem. The stem implanted was the Arcad (Symbios Orthopedie SA), which is a proximally HA coated, titanium alloy (Ti6Al4V) straight tapered stem (Fig. 1). The objective of the study was to assess the performance of this stem at more than 10 years by analyzing survivorship and the radiological findings. To our knowledge, this is the first mid to long-term study to have focused on the Arcad HA coated stem, and one of the very few that have analyzed the behaviour of a cementless, tapered, partially HA coated stem in an elderly patient population, with at least 10 years follow-up.

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Repirnt requests: Valerio Sansone, MD, Istituto Ortopedico Galeazzi, Milan, Italy.

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Fig. 1. (A) The Arcad partially HA coated titanium alloy stem. (B). The Hilock Line Symbios uncemented acetabular cup.

Materials and Methods

Between November 1997 and March 2000, 212 consecutive patients were treated in our Institute for primary or secondary hip osteoarthritis. 67 patients were male and 145 were female, with a mean age of 79.6 years (range 43-99 years). A single surgeon performed a total hip replacement using the partially HA coated Arcad stem. The Arcad system consists of 3 straight tapered stems; there are two cemented versions, or an uncemented HA coated version (Fig. 1A). The uncemented version is available in nine different sizes: the cervico-diaphyseal angle increases with the size (from 134° to 142°); and the neck length increases 2.5 mm each size for the first 7 sizes, but remains the same for the two largest. The system offers metal or ceramic ball heads in different diameters and lengths. In all cases, the 28 mm ceramic head was used, in conjunction

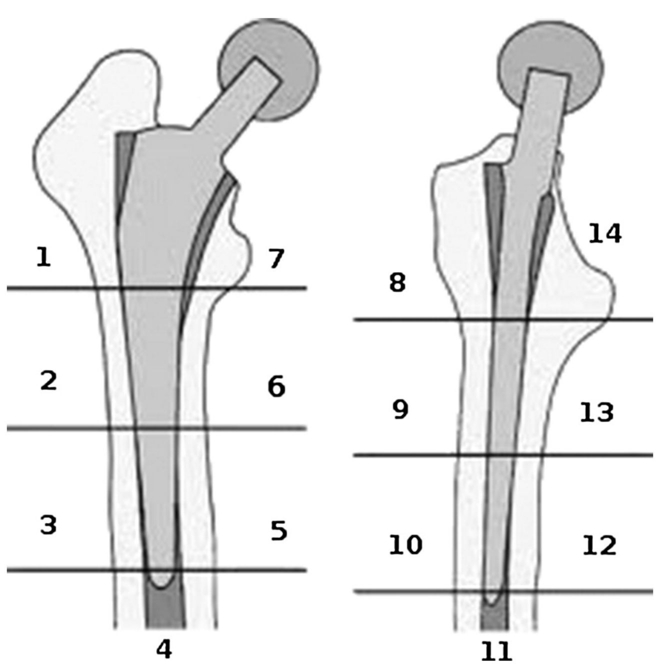

Fig. 2. AP and Lateral femoral zones, Gruen 1979.

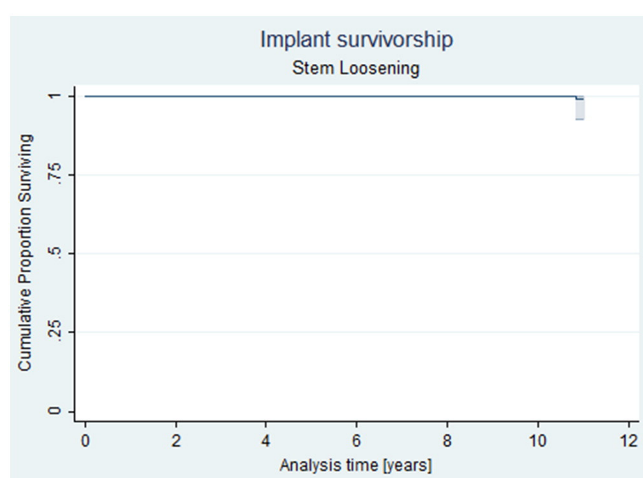

Fig. 3. Kaplan Meier survivorship of the femoral stem, with aseptic stem loosening as the endpoint.

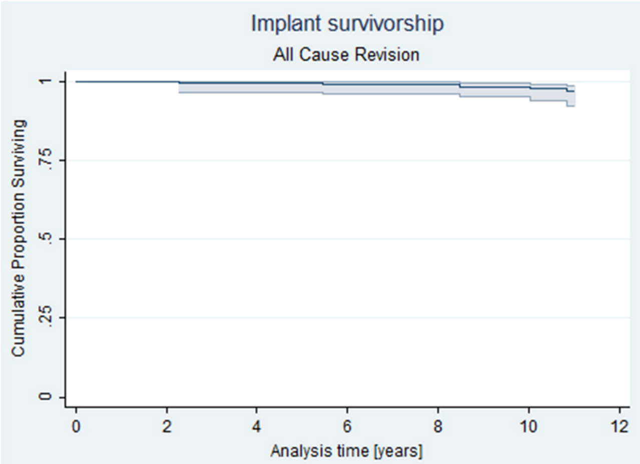

Fig. 4. Kaplan-Meier survivorship with failure of the hip prosthesis for any reason as endpoint.

with the uncemented Hilock Line Symbios acetabular cup (titanium alloy, porous titanium and hydroxyapatite coating – Fig. 1B), and a polyethylene (UHMWPE) liner.

The THA was performed through a postero-lateral approach with the patient lying on their side. In all patients two stabilization screws were used to guarantee fixation of the acetabular cup. Before closure, two transtrochanteric bone tunnels were drilled to reinsert the capsule and the pyriformis tendon. All patients were given a systemic antibiotic prophylaxis of 2 grams second-generation cephalosporin which was administered 15–60 minutes before incision, and a thromboembolism prophylaxis of subcutaneous enoxaparin for 45 days. For the first month post-operatively partial weight-bearing (50%) was allowed with the aid of crutches/ a walker. A daily physical therapy program was prescribed. After 30 days, full weight bearing was allowed with the aid of a controlateral crutch with respect to the operated side.

Clinical and radiological follow-ups were performed at 1, 6 and 12 months. A clinical evaluation was made according to the Merle d'Aubigné and Postel scale [11] pre-operatively and at all follow-ups. Radiological evaluation was performed using standing anterior-posterior and lateral radiographs of the hip. During the period January to May 2011, all patients were contacted by telephone to arrange a final follow-up appointment. At final follow-up patients were evaluated according to the Merle d'Aubigné scale, thigh pain was measured on a VAS 10 point scale, and radiographs were taken of the operated hip. In the case of patients who had died, members of the family or the patient's GP provided the most recent radiographs and gave information regarding whether any revision surgery had been carried out on the operated hip. The radiographs were compared with early post-operative films and analyzed according to Gruen zone [12] (Fig. 2) by an independent third party reviewer for occurrence of radiolucent lines (RLL), osteolysis, changes in bone density (defined as atrophy or hypertrophy), radiological signs of implant loosening and implant migration (according to the criteria of Engh [13]).

Additionally, the radiographs were used to make an analysis of the acetabular cup; RLL, osteolysis, changes in bone density, inclination, anteversion, and total polyethylene (PE) wear were all recorded. Cup inclination was measured according to Wetherell, where inclination = the angle between the sacro-iliac line and the major axis of the cup ellipse [14]. Cup anteversion was measured according to Lewinnek's formula where anteversion = sin-1 (B/A) [B = minor axis; A = major axis] [15]. PE wear was recorded as the distance between the centre of the cup and the centre of the prosthetic head. All measurements were made using Imagika software (View Tec, St-Maurice, France).

Two survivorship analyses were performed using the Kaplan-Meier method and the Peto method for confidence intervals (Stata statistical software, Statacorp Ltd, Texas USA). In the first analysis the endpoint was the requirement for revision of the femoral stem for aseptic loosening. The second survivorship considered the requirement for revision of the whole prosthesis for any reason as the endpoint.

Results

The mean follow-up was 11.2 years (median 11 years), with a minimum of 10.5 years and a maximum of 13.9 years. 19 patients (9%) were lost to follow-up, therefore for 193 of them (91%) it was possible to retrieve information concerning their implant. Of these cases, 6 patients (3.1%) had undergone revision surgery and 134 patients (69%) had had no implant loosening. Of the six cases which were revised, in 3 hips (1.6%) only the polyethylene insert was revised (2 cases in the 7th year of implantation and one case after 10 years). There was one case (0.5%) of septic loosening after 3 years, and the whole prosthesis was revised in a 'two-step' process. The two patients (1%) who had had aseptic loosening underwent revision surgery of the stem at 11 and 12 years after first implant.

53 patients (27%) had died before the final follow-up was conducted, however at the time of death the implant was still in situ and no hip prosthesis problems were reported by the family or the GP, and there was no sign of loosening in the most recent radiographs. In this group, the implant had been in place for a mean of 7.2 years before death (median 8.1 years, minimum 8 months, maximum 12.7 years).

Table 1
Radiographic Results for Femoral Stem at Final Follow-Up.

	Stem	AP							LATERAL						
	Zone	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Radiolucent Lines	No	87%	97%	86%	92%	95%	100%	99%	93%	100%	80%	87%	92%	100%	96%
	1 mm	9%	3%	12%	6%	5%	0%	1%	4%	0%	20%	13%	8%	0%	4%
	2 mm	4%	0%	2%	2%	0%	0%	0%	2%	0%	0%	0%	0%	0%	0%
	>2 mm	0%	0%	0%	0%	0%	0%	0%	1%	0%	0%	0%	0%	0%	0%
Osteolysis	No	87%	100%	100%	100%	100%	100%	70%	83%	99%	100%	100%	100%	100%	83%
	Yes	13%	0%	0%	0%	0%	0%	30%	17%	1%	0%	0%	0%	0%	17%
Atrophy	No	86%	99%	99%	99%	99%	97%	49%	78%	97%	99%	99%	99%	97%	77%
	Minimal	3%	1%	0%	0%	0%	0%	30%	9%	0%	0%	0%	0%	0%	9%
	Moderate	8%	0%	0%	0%	0%	2%	19%	11%	2%	0%	0%	0%	2%	11%
	Severe	3%	0%	1%	1%	1%	1%	3%	2%	1%	1%	1%	1%	1%	3%
Hypertrophy	No	100%	77%	98%	97%	96%	63%	100%	100%	78%	100%	98%	99%	74%	100%
	Minimal	0%	12%	2%	2%	2%	16%	0%	0%	7%	0%	1%	0%	11%	0%
	Moderate	0%	11%	0%	1%	2%	21%	0%	0%	14%	0%	1%	1%	14%	0%
	Severe	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	1%	0%

N = 103 Femoral zones according to Gruen 1979 [11] – see Fig. 2.

The Kaplan Meier survival estimate for the femoral stem at 10 years, with endpoint being aseptic loosening, was 100% (Fig. 3).

The Kaplan Meier 10 year survival estimate for all components, with failure defined as revision for any reason, was of 97.65% with a 95% C.I (0.9385-0.9911) and s.e. 0.0116 (Fig. 4).

Of the 134 patients available for final follow-up who had the implant still in situ, 92 (69%) were able to provide recent radiographs of their implant whereas 42 of them (31%), although without clinical complaints regarding the implant, could not provide radiographs. In this last group, the reasons for failing to provide a recent X-ray were the following: illness (15), refusal (4), residence too far from our Institute (6), bedridden (5), hospitalised (7), no show at pre-booked radiological follow-up (3), no means of transport (6). In addition, we obtained the most recent radiographs for 11 of the patients that had died before final follow-up. The results of the radiological assessment of the 103 patients with recent X-rays of their implant are summarized in Table 1.

Only one case (1%) showed a RLL over 2 millimeters (mm) which was situated in zone 8. Indeed the large majority of RLL observed were of 1 mm or less, and did not extend beyond the Gruen zone in which they were situated. RLL were found most commonly in zone 10 (20%) and zones 1, 3 and 11 (13%, 14% and 13% respectively) and there were no signs of progression.

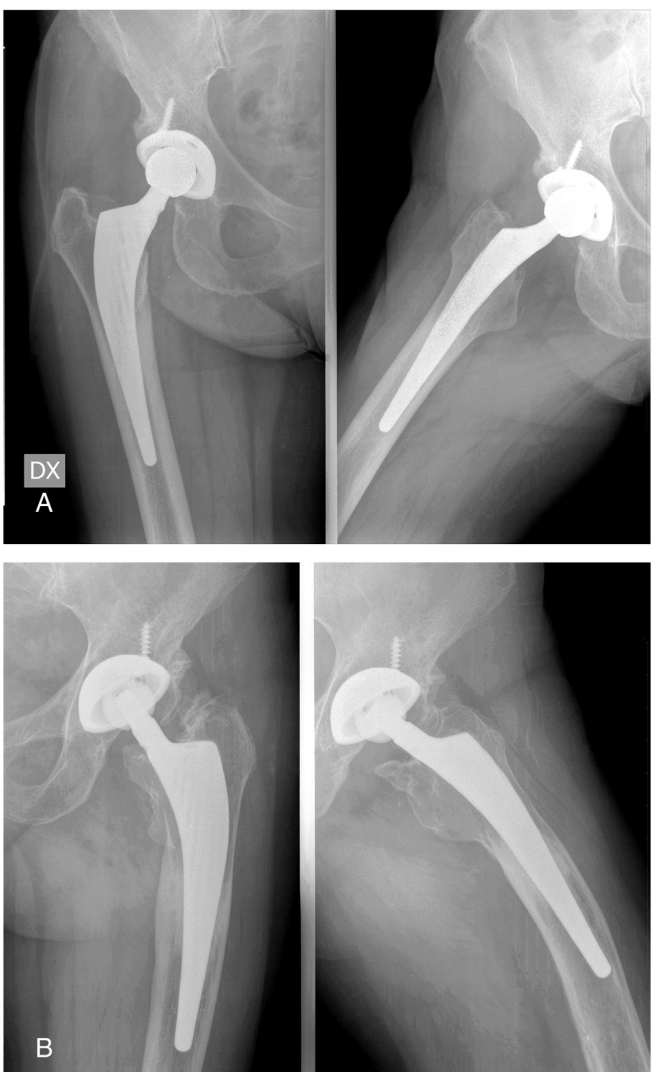

Fig. 5. (A) radiograph showing a well-fixed femoral stem. (B) Radiograph showing cortical hypertrophy in zones 2, 6, 9 and 13.

Table 2
Radiographic Results for Acetabular Cup at Final Follow-Up.

		Cup Zone		
		I	II	III
Radiolucent Lines	No	96%	99%	100%
	1 mm	3%	1%	0%
	2 mm	1%	0%	0%
	>2 mm	0%	0%	0%
Osteolysis	No	85%	59%	97%
	Yes	15%	41%	3%
Atrophy	No	79%	40%	93%
	Minimal	4%	14%	2%
	Moderate	11%	37%	3%
	Severe	6%	9%	2%
Hypertrophy	No	100%	100%	100%
	Minimal	0%	0%	0%
	Moderate	0%	0%	0%
	Severe	0%	0%	0%
Degrees of cup inclination		43° ± 10° (min 18°, max 74°)		
Degress of cup anteversion		13.5° ± 8.7° (min 1°, max 47°)		
PE wear in millimeters		1.18 ± 0.58 (min 0.1, max 2.72)		

N = 103 Data show the mean ± the Standard Deviation.

Osteolysis was observed in zones 1,7,8,9 and 14 with by far the highest number of cases having osteolysis in zone 7 (30%). This corresponded closely with mild or moderate bone atrophy which was found in over half the radiographs in zone 7, with a lower proportion in zones 1,7,8, and 14. Severe bone atrophy was found in 3 patients: 2 had localized proximal atrophy, and one patient was suffering from significant osteopenia and all zones (except zone 2) showed severe atrophy, but with no RLL or signs of implant loosening. Minimal to moderate hypertrophy was found in up to 37% of radiographs, predominantly in zones 2,6,9 and 13 (Fig. 5). One case had severe hypertrophy in zone 13, and moderate hypertrophy in zones 2,6 and 9, with spot welds in each of these zones.

Acetabular Cup

On the cup side osteolysis was found in 41% of cases in Charnley zone II for the cup (with a corresponding 9% severe bone atrophy – see Table 2). Cup inclination and anteversion occurred in the great majority within the “safe zone” and no correlation could be found between cup inclination and polyethylene wear (Table 2).

Clinical Assessments

Pre-operative and 10 year follow-up clinical results were available for 106 patients. The mean Merle d' Aubigné (maximum score = 18 points) was 4.4 ± 2.1 points pre-operatively (range 1-7) and 13.4 ± 3.77 points at final follow-up (range 5-18, $p < 0.05$). The mean VAS score at final follow-up was 1.25 ± 2.22 (median 0), with 31 patients (29.2%) complaining of mild, activity-related thigh pain.

Discussion

As prosthetic designs have improved, THA surgery is becoming indicated for a wider age range of patients. The question remains as to whether the same fixation method and component design can give optimal outcomes in all age groups. In older patients, cemented fixation of the femoral stem could appear a more suitable solution with respect to uncemented fixation. As proximal femoral osteopenia is frequently observed in the elderly, a quick and effective fixation seems most suitable for these patients, avoiding the risk of periprosthetic fractures related to the pursuit of a perfect press-fit with an uncemented stem. On the other hand, the use of cement in older patients has not been shown to provide better fixation, function and implant longevity over cementless implants [16], whereas it has been suspected to increase pulmonary embolism and cardiac arrest [17,18]. The geometry of the proximal femur has long been known as critical to the design of femoral components for THA. However studies have shown that proximal femoral geometry changes with age. Firstly, widening of the isthmus (zones 3, 4, 5) occurs in elder patients, but particularly in females [19]. Secondly cortical bone atrophy can be observed in the lateral portion of the proximal femur (zones 1-2) in both males and females, but again, particularly in females [19]. In the medial proximal femur, primary compressive forces promote bone growth and stabilization. Laterally, secondary tensile forces are transmitted, and therefore it is likely that more cortical bone is lost with age due to lesser loading.

These anatomical changes provide a rationale for the use of a tapered stem for elderly patients. The aim of a tapered stem is to gain fixation primarily in the metaphysis owing to its self-locking properties. Axial forces are converted into radial compressive forces, which transfers load more evenly to the proximal metaphysis, thereby limiting stress shielding [20]. Although the long-term consequences of stress shielding have not yet been correlated with adverse effects on implant survival [21], it nevertheless does cause concern regarding prosthetic loosening and periprosthetic fracture. Given the theoretical advantages of the tapered design, it should also reduce proximal osteolysis and thigh pain.

Although tapered stem geometry is reasonably associated with improved likelihood of long-term success, variable amounts of subsidence have been described [22–25]. For these reasons, various surface treatments have been applied to femoral stems with the aim of increasing the rate of bone ingrowth and, thus stem stability. Hydroxyapatite (HA) coating has been developed to encourage osseous bonding in uncemented stems due to its osteoconductive properties. It enhances direct bone formation at the periprosthetic interface without an intermediate layer of fibrous tissue, to give a stable and strong bond even when the joint is loaded. The impact of HA-coating on osteointegration of a device has been widely studied [26–32]. From this compendium of investigations it comes forth that the addition of HA is either superior or gives no appreciable improvement in fixation. In other words, no study has demonstrated the inferiority of an HA-coated device when compared to a non-coated counterpart, whilst several authors have observed superior osteointegration [33,34]. If we consider the specific case of elderly patients where bone stock loss is a common finding, experimental studies have shown that osteopenic bone has a high potential of bone ingrowth around hydroxyapatite material — even more so than normal bone [35]. Indeed, Kirsh et al showed no significant clinical or radiological difference between osteoporotic and non-osteoporotic patients who received a proximally HA coated tapered femoral stem [32].

Surprisingly, given the positive theoretical rationale for a tapered, straight, proximally HA coated stem, there are relatively few mid to long term studies that have investigated this design, particularly in older populations. However, all the studies report excellent survivorship rates ranging from 100% at 10 and 12 years follow-up to 97.5% at 10 years and 98.6% at 17 years [28,36–40]. Of the studies specifically focusing on similar stem designs implanted in older patients, it must be noted that the follow-up periods are considerably shorter than in our study. Berend et al. and Keisu et al. both reported 100% survivorship at five year mean follow-up in patient cohorts that were over 75 years and over 80 years, respectively [25,41]. At a mean follow-up of 7 years, there were no revisions for aseptic loosening in Kirsh et al.'s study group which had a mean age of 73 years, although two stems were revised due to post-operative fractures [32].

There is less consistency in the radiological findings regarding this type of stem. Three of the studies with lower mean age, and all of the studies specifically reporting on THA in older patients reported no, or only one case of, osteolysis [25,28,32,39–41]. Other studies report an occurrence of osteolysis in between 32-56% of cases, particularly in zones 1,7,8 and 14 which corresponds with our results [24,36,37]. Distal osteolysis of 1.7% and 5% of cases was reported, although it was absent from our series [24,37]. Cortical hypertrophy was reported in many of the studies, with distal hypertrophy, which indicates stress shielding [24,32,36,40]. Although there was a low incidence of RLL of 2 mm or more in the studies relating to mixed age populations with a maximum of 6.6% of cases reported, smaller reactive lines were quite common [19,22,32]. The findings were similar in older patients: Berend et al. reported RLL of <2 mm limited to one zone in 7% of patients [25]; whilst in Kirsh et al.'s cohort of patients, 69% of patients showed small reactive lines in zone 4 and 20% in zone 3 [32]. In our study, almost all RLL observed were of 1 mm or less, and were concentrated in zones 1, 3, 10 and 11. One patient had a RLL >2 mm in zone 8, but we observed no radiographic signs of either pedestal formation or subsidence. This compares favorably with the other studies of elderly cohorts: Berend and Kirsh both reported two patients with pedestal formation (4.6% and 2.8% respectively). Berend et al. also reported subsidence in two cases (4.6%) of 5 mm and 17 mm.

Our clinical results at final follow-up were influenced to some extent by the age of the patients and the presence of age-related comorbidities, which is demonstrated by the range of functionality scores we recorded (from 5 to 18 points). However, we did see a 9-point improvement in mean pre-operative and final follow-up score overall, and over 87% of our patients had no, or only mild, thigh pain as reported on the VAS scoring system. This result is in line with other elderly study groups reported in the literature where between 87% and 96% of patients have no, or mild, pain with this type of uncemented stem.

Conclusion

The current study seems to confirm the theoretical benefits of uncemented tapered femoral stems in terms of functional results and mechanical stability, even in elderly patients. Osteointegration and implant longevity were not negatively affected by the bone quality of the elderly patient. Our results at more than 10 years follow-up compare favorably with any published results in THA, and show that HA coating allows for optimal long term osteointegration of stem implants. Although the influence of the proximal HA-coating can not be clearly elucidated, the cumulative scientific data and our recent experience favour its continued use in adjunct to cementless tapered femoral fixation.

Acknowledgments

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