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ORIGINAL PAPER

Long lasting outcome of hydroxyapatite-coated implants in primary knee arthroplasty: a continuous series of two hundred and seventy total knee arthroplasties at fifteen to twenty two years of clinical follow-up

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Abstract
Purpose This study is a long-term review of an hydroxyapatite (HA)-coated knee prosthesis. Our aim was to confirm that excellent previously reported results with HA knees could stand the test of time at the 15-year milestone.
Methods A total of 270 cruciate retaining HA-Omnifit knees, implanted in the same institution by a single surgeon with the same surgical procedure, were reviewed at 15–22 years of clinical follow-up (75 knees partially-coated and 195 fully-coated).
Results At review, IKS mean values were 95.6 points for knee score and 91.19 points for function score. Radiological review confirmed an excellent long-lasting fixation over years in the long run. Taking implant failure as the end-point, the survival rate was 97.1 % at 20 years.
Conclusions Our results were as good, and often better, than the best cemented or porous published studies. These very encouraging results at 15–22 years make us very confident in the ultimate outcome of bioconductive coatings in knee arthroplasty.

Keywords Hydroxyapatite · Total knee arthroplasty · Outcome study · Omnifit · Long-term follow-up · HA-coated implants · Cruciate retaining total knees · Clinical results

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Introduction

In the long run, lasting, stable implant fixation, without the use of acrylic cement, by means of a bioactive bond between the implant and the host bone, is a goal as important in the knee as it is in the hip. For years some papers have reported on promising results with hydroxyapatite (HA)-coated knees, e.g. from Verhaar [1] and Epinette [2] in 1995, or Nilsson et al. [3]. They concluded that the HA knees could potentially offer longer lasting stability.

Our experience with HA-coated TKA began in 1990 and afterwards until today HA-coated knees have been implanted as a routine procedure in primary knees at our institution. This study is a long-term review of the Omnifit Knee Prosthesis which was either partially HA-coated or fully coated. In a previous study published in 2007 [4], we had analysed separately these two groups of implants and concluded that, apart from some radiological patterns, no significant bias related to the location of coating could be found, hence allowing us to report in the present study on Omnifit Knee implants results as a whole be they fully or partially coated. The aim of the present work was to confirm that the previously reported results with HA knees could stand the test of time at the 15-year milestone.

Material and methods

Between June 1990 and December 1997, 270 HA-coated primary posterior cruciate-retaining knee replacements were implanted consecutively in 229 patients, 43 males (18.8 %) and 186 females (81.2 %). A single surgeon (JAE) used an identical surgical technique throughout. Average age at index surgery was 70.23 years (range 43–89, SD 8.03). Main diagnosis was osteoarthritis in 246 knees (91.11 %), rheumatoid

arthritis in 19 (7.04 %) and necrosis in the remaining five knees (1.85 %). The mean follow-up was 15.95 years (15–22 years). At the time of the review, only four patients who underwent a unilateral replacement (1.48 %) were lost to follow-up without any consistent information about the outcome of their prosthesis. Of the remaining patients, 124 knees remain "on file" (45.93 %), 128 (47.41 %) had died for unrelated reasons, seven (2.59 %) were revised for sepsis, two isolated femoral revisions (0.74 %) had been performed for traumatic not implant-related causes, and five knees (i.e. 1.85 %) underwent a revision for mechanical failure.

Of these 270 CR knees, 75 knees (27.8 %) received a series 3000 partially-coated HA-Omnifit knee and 195 (72.2 %) knees a series 7000 fully-coated HA-Omnifit. The knees (Stryker Orthopaedics, Mahwah, NJ, USA) were manufactured from cobalt chromium and both femoral and tibial components were plasma sprayed with HA upon a waffle-pattern grit-blasted surface. Between 1990 and 1992, the partially HA-coated Series 3000 Omnifit femoral were coated on the distal aspects of the femur while anterior and posterior zones were uncoated. The tibial component had HA coating on the tray only, while the cruciate keel was uncoated. Afterwards, the HA-coated, Series 7000 HA Omnifit implants with a fully-coated femoral surface and tibial component, and a delta keel design were implanted (Fig. 1). All knees used fixed-bearing tibial components. Titanium screws were used routinely in order to enhance fixation of the tray. A cemented polyethylene button was used in 113 knees (41.8 %), while a simple reshaping to fit the trochlear groove was performed in 157 knees (58.2 %). Partial weight-bearing was permitted immediately after operation and all patients had early mobilization, physiotherapy, and continuous passive motion (CPM). Full weight-bearing was achieved by between four and eight weeks.

All patients, provided being eligible for such a prosthetic option, gave their informed consent prior to their inclusion in the study and thus were included in this non-selective series, which had been approved by the local ethics committee. The data were entered into a database (OrthoWave™, Aria, Bruay Labuissière, France), which allowed easy access to clinical and statistical information [5]. Clinical assessment was by the operating surgeon and two uninvolved persons using the International Knee Society score, which includes both the 100-point knee and the 100-point function score [6]. Of the remaining cases at the time of the study, only reviewed patients who completed clinical and radiological evaluations were included in the clinical study results, as long as their general health and any other potential not knee-related problem remain consistent with clinical knee scoring assessment. Conversely all 270 cases were taken into account for complication rates. Survivorship was calculated according to the Kaplan-Meier method for all patients, with two separate analyses according to either revision from any cause or specified implant related failure, as endpoints. Radiographs included anteroposterior (AP) and mediolateral, weight-bearing, skyline and standing views, and radiological zones were assessed using the International Knee Society criteria. The bone component interface was examined carefully for the presence of radiolucent lines or radiolucencies.

Results

Complications

Complications were recorded for all 270 knees in the series and are listed in Table 1.

There were no peri-operative adverse events. Postoperative complications included deep venous thrombosis in 43 knees (15.9 %) with pulmonary emboli in four (1.5 %), a deep

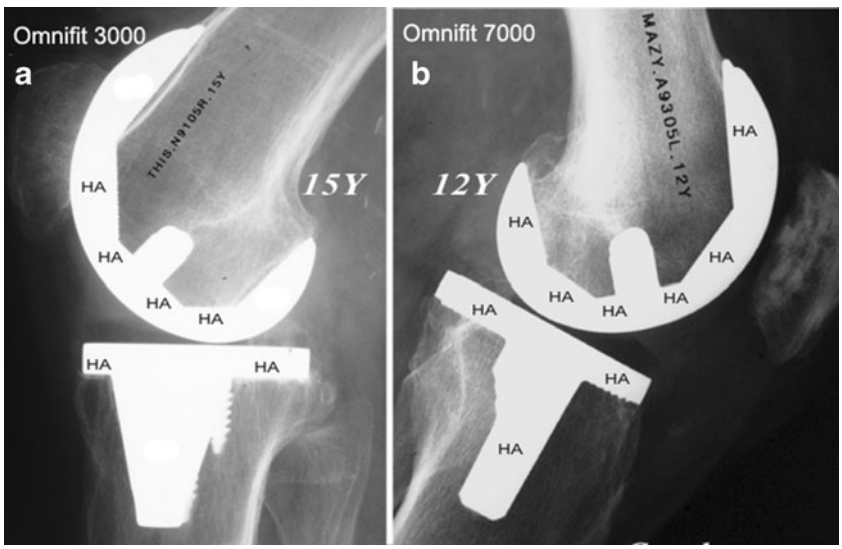

Fig. 1 Differences in hydroxyapatite coatings exhibited in these two lateral X-rays with Omnifit 3000 (partially coated; **a**) versus 7000 (fully coated; **b**). In Omnifit 3000, zones 1 & 4 according to IKS zones were left uncoated, and so for the cruciate keel. Conversely, all zones including the delta keel were HA-coated in series 7000

Table 1 Adverse events that occurred for the entire series (N = 270)

Group of complications	Type of complication	*n*	%
Postop adverse events	Deep venous thrombosis	43	15.9
	(Including pulmonari emboli)	4	1.5
	Deep haematoma	7	2.6
	Diaphyseal fracture	1	2.3
	Manipulation under anaesthesia	14	5.2
Reoperations (femoral and tibial implants left in situ), *n* = 9 (3.33 %)	Secondary patellar button after single reshaping	6 (out of 157)	3.8
	Loosening of a primary patellar button	2 (out of 113)	1.8
	Synovectomy / debridement for stiffness	1	0.4
Revisions due to a cause not related to the implant, *n* = 9 (3.33 %)	Supracondylar accidental fracture	3	1.1
	Deep Infection	6	2.2
Implant failure, *n* = 5 (1.85 %)	Pain and stiffness	1	0.4
	Severe lysis	3	1.1
	Isolated femoral revision for inflammatory bone loss	1	0.4

hematoma in seven (2.6 %), a diaphyseal fracture in one patient (0.4 %), and manipulation under anaesthesia in 14 knees (5.2 %).

Nine knees (3.33 %) developed complications which required re-operation with femoral and tibial components left in situ. A second procedure was performed in six knees to introduce a patellar button at a mean of 1.6 years (range one to five) for pain experienced after reshaping of the patella at the primary procedure (out of 157, 3.82 %), while loosening of a primary patellar cemented button was reported in two knees (out of 113, 1.77 %). A further patient required synovectomy and debridement for a stiff knee, with a good result over 15 years (i.e. active flexion at 95° and knee score of 92 points).

A revision with retrieval of implants due to accidental or septic events occurred in nine knees in seven patients, including three supracondylar accidental fractures (1.11 %, two patients) after a fall, and six deep infections (2.22 %; five patients). Two occurred during the first year due to an infected hematoma, and four at six to 12 years after index surgery, secondary to distal infected skin lesions. In all cases successful revision was achieved using retrieval and new cemented prostheses through a double procedure.

Finally, revision due to implant failure following unexpected pain, osteolysis or mechanical loosening was recorded in five knees (1.85 %; five patients), with four global and one isolated femoral revisions. One case of unexpected pain and stiffness with no loosening in a 68-year-old female underwent revision at two years. Three cases of severe lysis in three females (age range 73–77) for whom the initial diagnosis was osteoarthritis in all knees underwent revision at five, eight and 12 years, with satisfactory outcome. In the last case of isolated femoral revision, a flare-up of rheumatoid disease at seven years led to loss of bone density and pain on the femoral side of the articulation while the tibial side remained intact. No revision was related to isolated mechanical loosening or wear of the polyethylene insert during this study.

A breakdown according to age at index surgery versus implant failure was computed and we could not find a significant correlation via the Kruskal-Wallis test at a value of $p = 0.593$. Additionally, a cross-correlation between diagnosis and implant failure did not demonstrate a significant correlation at $p = 0.502$ with four failed out of 242 in the arthritis group, one out of 18 "rheumatoid", and no failure out of the five in the necrosis group.

Clinical results

Although only 134 of the 270 knees were available for review at the time of study, each patient who died had been followed until death. Their records up until death demonstrated no difference between their results and those of the survivors. Average age at latest follow-up was 80.66 years (64–96 years, SD 7.16), which may explain that complete clinical and radiological assessment after the 15th year could be achieved consistently only for 98 of both the knees still "on file" at latest review, and those of dead patients already assessed after the 15th year. In all other 36 knees, neurological disease or poor general health prevented consistent functional assessment, although their knees appeared to be functioning well with no significant pain or stiffness.

Preoperatively, clinical status of knees demonstrated severe impairment with IKS knee score at 24.05 points (i.e. graded as "poor" for all of them). IKS function score was 39.23 points

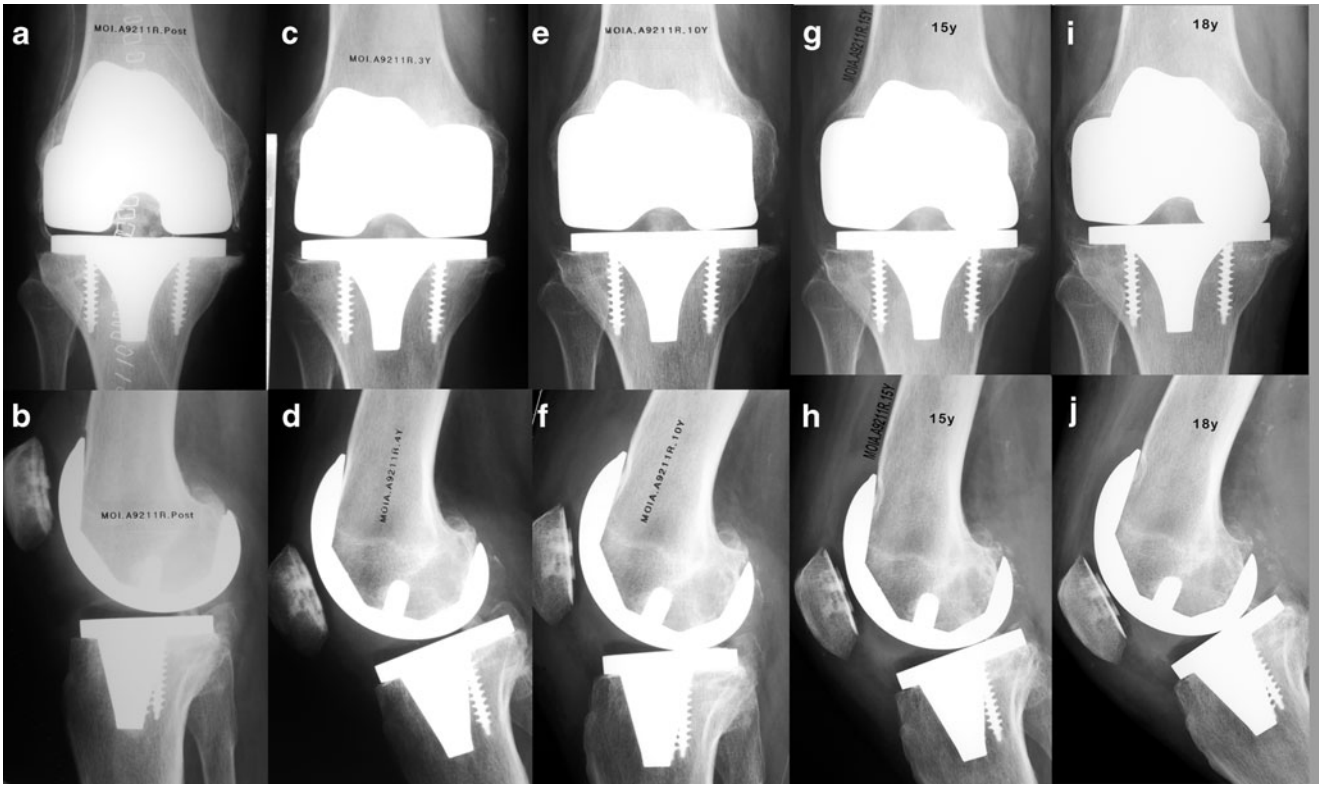

Fig. 2 Long-term radiological survey with AP and lateral views in a 61-year-old male who received a HA-Omnifit 3000 series in 1992, with follow-up at post-op (**a**, **b**), 3 years (**c**, **d**), 10 years (**e**, **f**), 15 years (**g**, **h**), and 18 years (**i**, **j**). There were no radiological changes over years and namely no extension of early femoral lysis onto uncoated zones 1 and 4. There was no revision to date due to wear with good clinical result (IKS K 89 and F 80 points) at 18 years

with 114 knees (82.01 %) as "poor", 22 (15.83 %) as "fair", 3 (2.16 %) as "good" and none of them as "excellent". Pain was the main cause for surgery with 46 % and 54 % of "continual" or "severe" pain, respectively.

In the remaining 98 knees eligible for clinical assessment, none of them reported any pain but one patient had mild pain on walking. The mean flexion for these patients was 113.2° (range 35–145°; SD 21.92). The mean International Knee Society score was 95.6 (range 60–100; SD 6.52) at final follow-up, including 62 knees (63.3 %) graded as "excellent", 21 knees (21.4 %) as "good", three knees (3.1 %) as "fair" and none graded "poor". With regards to functional abilities, walking distance was unlimited in 81.6 % of knees, with no "housebound" or "unable to walk" record. The use of stairs was unlimited for 61.2 % of knees and able with rail in all remaining knees. The mean IKS function score was 91.19 points (60–100, SD 12.61), including 60 knees (61.2 %) graded as "excellent", 22 knees (22.5 %) as "good", 16 knees (16.3 %) as "fair" and none graded "poor".

Radiological findings

Of the 98 radiologically assessed knees at the time of the review, the femoral component was partially coated in 16 knees (16.3 %; HA Omnifit 3000 series) and 82 were fully coated (83.7 %; HA Omnifit 7000 series). On the tibial side, 24 tibial plateaus had a cruciate keel that was not coated (24.5 %; 3000 series), while 74 tibial components were fully coated including the delta keel (75.5 %: Delta series).

The radiological review of all these cases could confirm an excellent fixation in the long run, with no case of confirmed mechanical loosening throughout our five implant failures, and to date no case of pending revision due to loosening, tilt or sinking of tibial plateau or femoral component (Fig. 2).

The HA–bone interface has been assessed separately for partially versus fully coated implants. Lines were found around uncoated zones in 31–42 % of femoral components and 33 % around the cruciate keel. Conversely, lines were scarcely ever found on coated zones in less than 3 % of knees. None of the femoral or tibial components which had lines was clinically loose. In either partially or fully coated tibial components, osteolysis around the screws has never been recorded in any case and at any follow-up period. In all cases of early lytic pattern beneath the tibial plateau (15 %), the radiological evaluation over years demonstrated formation of new bony bridges between bone and metal and

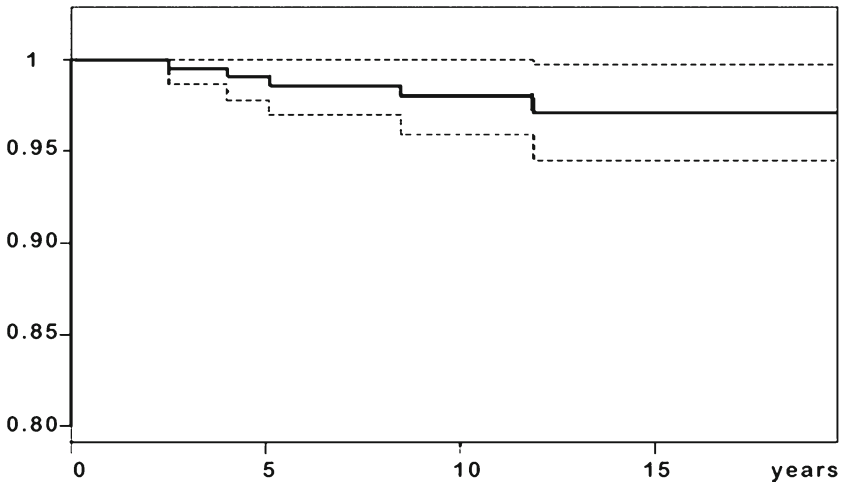

Fig. 3 Kaplan-Meier cumulative survivorship at 20 years at 97.1 % with all failures as endpoint

a progressive new bony structure filling in the gap, with a perfect bonding and no further modification over a period of 15 years.

Survival analysis

The cumulative survival rate, according to Kaplan-Meier analysis, was calculated for the 270 knees overall with 30 patients remaining at risk at 19.7 years.

Considering retrieval for any cause as the end-point (i.e. failures+traumatic+deep infection cases), the cumulative survival rate was 91.4 % (range 0.872–0.963; SD 0.023). Taking implant failure as the end-point (i.e. pain, osteolysis and mechanical loosening), the survival rate for the entire study was 97.1 % (0.945–0.997; SD 0.013) (Fig. 3).

Discussion

Our 270 HA Omnifit knee series at 15–22 years of clinical follow-up have confirmed the very encouraging results of previous HA-coated knee reports and may represent an interesting counterweight to both cemented and porous-coated knee series. This study indicates that TKRs do equally well whether partially (28 % of knees) or fully-coated (72 %) with HA. The cumulative survival rate of 97.1 % at 20 years using

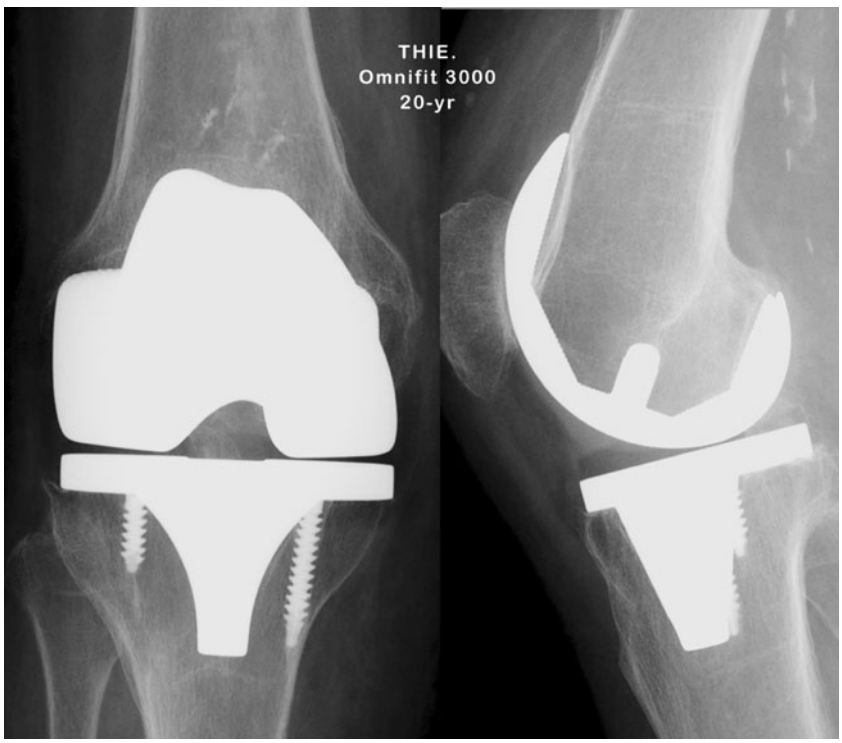

Fig. 4 Excellent radiological result in the long run on 20-year AP and lateral views of a partially coated HA Omnifit 3000 in a 67-year-old female. Note the lytic patterns onto #1 and #4 uncoated zones. Such lytic areas never extended to HA-coated distal zones of the femoral component and remain stable over years, without any progressive loosening. There was good behaviour of the uncoated cruciate keel despite frequent lines all around

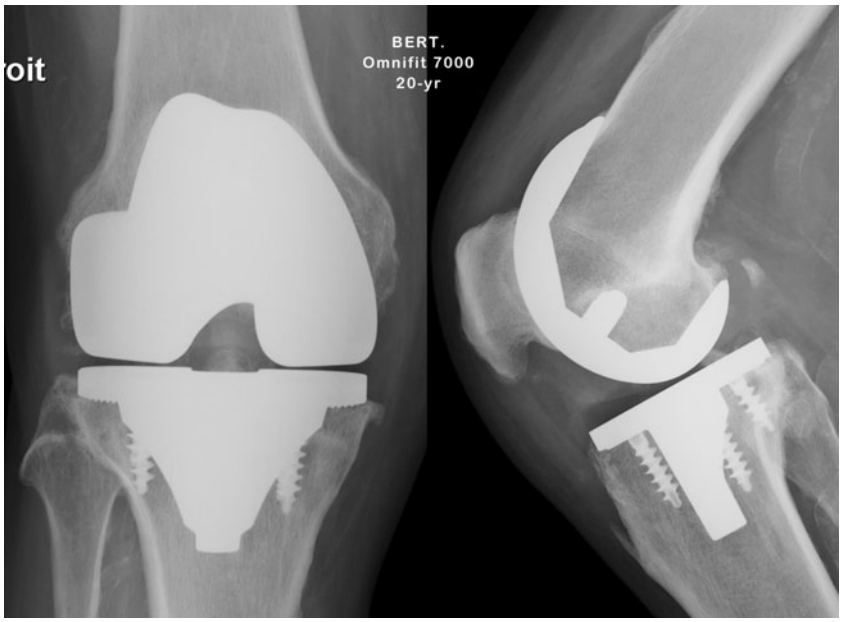

Fig. 5 One of our first fully-coated HA-Omnifit 7000 in a 67-year-old male at 20-year follow-up with AP and lateral views. An intimate bone bonding was achieved immediately with no modification over years on femoral interface, as well as onto the tibial tray and the delta keel. There was no lysis nor lines all around the screws

mechanical failure as an end-point compares favourably with previous studies of cemented or porous-coated knees replacements [3, 7–9]. These results confirm both our short-term and mid-term findings [2, 4, 10] and those published as long-term studies by Oliver et al. [11] at a mean follow-up of 11 years, or Melton et al. [12] with a 15–18-year follow-up and 96 % rate of survivorship.

As always, the principal limitation of our study is the difficulty of assessing long-term clinical results in older patients. The mean age at follow-up (80.66 years), and the frequent comorbidity which makes functional results in the elderly difficult to assess can reflect the low rate of survival for patients at review over 15 years. However results in this cohort in the long run did not demonstrate significant difference from previous figures recorded in larger groups of our patients at earlier follow-up, and no decrease in results was demonstrated over years. Complications and survivorship were recorded for the entire 270 TKAs in the series.

Our main aim was to study the behaviour of the HA–bone interface, so radiological analysis was critical, both for global findings and differences between the partial and full coatings. Radiological assessment showed very good interfaces between bone and the HA implant with intimate bony apposition in the HA-coated zones, obviously in favour of fully coated implants on both femoral and tibial components [4]. Few lytic lines were observed on HA-coated surfaces, and no extensive lysis was evident, especially beneath the tibial plateau and around the keel or screws. McCaskie et al. [8] and Nilsson et al. [3] also reported fewer lytic lines in HA compared with cemented components. More lytic lines have been reported with non HA-coated uncemented knee components when compared with cemented components [7]. We believe the HA coating provides the early tibial fixation needed for long-term success, and the findings of Nilsson et al. [3] support this. While the enhanced stability provided by the delta keel of the Omnifit 7000 series may have also contributed substantially to overall stability, these radiological findings clearly indicate the virtue of full HA coating of both femoral and tibial components.

In any case, hydroxyapatite is not a “magic powder”, and HA implants must prove their efficacy when compared to cemented or porous designs. Technical skills and appropriate design are certainly more important than the interface. Nevertheless, the present study demonstrates that we obtained excellent confirmed results in the very long run using HA-coated Omnifit knee implants [2, 4, 10] (Figs. 4 and 5). These results are as good, and often better, than the best-cemented or porous studies in the long run, as confirmed by RSA studies up to 16 years for Pijls et al. [13] or again Voigt et al. [14] through an extensive review of literature. In this way, the present study will serve as a reference for new developments and improvements in design or bioconductive coatings, and namely the new trabecular titanium or tantalum interfaces [15], with absolute need to exhibit a real benefit when compared to the actual findings.

We routinely use HA knees in our daily practice. The very encouraging results at 15–22 years reported in the present study make us very confident in the ultimate outcome of bioconductive coatings in knee arthroplasty.

Disclosure of interest

The author declares that his institution had received sponsoring from Stryker Orthopaedics in relationship with the current research. However no direct conflict of interest can be related to the present article.

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