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ORIGINAL PAPER

Twenty-year results of the cementless Corail stem

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Abstract The concept of an extensive hydroxyapatite (HA) coating for the fixation of a tapered femoral stem (Corail®) was introduced 25 years ago in the hope that we could achieve durable biological fixation while preserving normal periprosthetic bone activity. The value of uncemented fixation using HA-coated implants is now widely admitted. However, the characteristics of implant coating and more specifically its extent still remain a subject of debate or even controversy. This prospective study conducted over a 20-year period has greatly contributed to demonstrating the reliability of the Corail® prosthesis, in terms of functional abilities, radiographic evidence and global survivorship. A full HA coating applied on a straight and proximally flared stem induces substantial short-, mid- and long-term benefits without any deleterious effects reported. Modifications of the bone pattern have been strictly limited: slight resorption at the calcar level, absence of cortical hypertrophy and alleged stress shielding. The radiological "silence" is one of the paramount facts clearly demonstrated.

Introduction

The 20th year is a symbolic date in orthopaedics and an essential landmark in the life of a prosthetic device, first because it only applies to the implants able to reach that privileged level but also because long-term results can definitely be deduced from that date. Hydroxyapatite (HA) as a coating is one of the most generally accepted and commercialised bioactive materials. Although promising clinical results have been reported with HA-coated implants, concern had been expressed in the 1990s about delamination and degradation during implantation for a long period. The responsibility of loose HA particles has also been discussed in premature wear and osteolysis related with third body wear and foreign body reaction. To prevent so-called stress shielding resulting in proximal bone resorption, most cementless stems are coated only proximally. The combination of a tapered titanium stem with an extensive coating may increase fixation with harmonious stress distribution. The aim of this study was to assess the 20-year clinical and radiological results of the Corail® stem with an emphasis on periprosthetic remodelling. It represents a cohort of 347 prostheses in 320 patients (24 bilateral total hip replacements), operated upon between July 1986 and December 1990, in a single orthopaedic centre, by a single surgeon. The mean follow-up is 20.9± 1.2 years.

Materials and methods

This series involved primary total hip replacements and bipolar arthroplasties were excluded.

The implanted prosthetic components were identical on the femoral side: the standard Corail® stem (Fig. 1), the only available type during that period, was used in a collared (24%) or collarless (76%) version. The Corail® stem is made of forged titanium alloy (TiAl6V4). It is a straight implant, with a quadrangular cross section. The proximal part is flared in the sagittal and the coronal plane to provide three-dimensional stabilisation in the metaphyseal area. The distal portion has a tapered design, to produce a stiffness gradient

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Fig. 1 The standard Corail stem (collar option)

and to avoid medullary canal blocking. Macrotextural features (horizontal and vertical grooves) enhance primary mechanical stability, which may be further augmented by the use of an optional collar. The HA coating is applied to the entire stem in order to prevent the release of metal ions, to provide for maximum osseointegration at the interface and to prevent the interposition of a fibrous membrane around the distal portion of the stem. HA coating is applied using an atmospheric plasma spray process. The thickness of the ceramic layer is 150 μm.

Various acetabular components were implanted (cemented: 7, uncemented: 340 – HA coated: 268) and the first generation of cementless cups without HA coating (72) was indisputably the weak point in that system. The femoral head diameter was 32 mm in 47.4% of the procedures, but Biolox *Forte* ceramic femoral heads were mostly used.

The collected data were successively registered in paper-based medical records and then entered into a computer database whose softwares were in constant evolution during that period. Calculations were specifically performed for the study by an independent medical statistician. All conventional tests were conducted using the StatView software package; survival curves were drawn according to the Kaplan-Meier method with a one year interval.

This prospective series was conducted in the Annecy orthopaedic centre (Clinique d'Argonay) by one senior operator. All Corail® prosthesis implantations were performed through the anterolateral Watson-Jones approach on a traction table. A total of 347 records (320 patients) were included in the initial study; 165 patients died during the 24 years of clinical follow-up and 29 (9%) were lost to follow-up; 12 stems were removed for various reasons.

Results

Demographic data, 127 records are still being reviewed which represents 36.5% of the initial cohort. The long-term results are thus unquestionably penalised by the mortality (51.5%) inherent to this age bracket. Demographic data have no specificity: the total number of patients includes 155 women and 165 men, and the mean age at surgery was 63.3 ranging from 30 to 88 years; 12% of the patients were less than 50 years old and 30% were over 70 years old. However, more than 40% had a high level of activity. According to Devane's classification of patient activity level, distribution was: 1=7%, 2=20%, 3=32%, 4=24% and 5=17%.

The aetiology was dominated by osteoarthritis of the hip (76%) and avascular necrosis (6%). The systematic use of this implant in the management of neck fractures in the elderly (5%) should be noted. Less frequent indications included post-traumatic osteoarthritis (2%), dysplasia (5%) and inflammatory arthritis (1%).

The functional results (Table 1) were spectacular in particular regarding pain; 83% of the patients were pain free at last follow-up. Two thirds (61%) of the patients still report a Postel-Merle d'Aubigné (PMA) score of 18, which means that they have an essentially normal hip, with no pain, no limp and a full range of motion. Globally speaking, improvement in functional abilities still remains spectacular, despite the mean age at the last evaluation (more than 80 years): +7 points using the PMA scale and +44 points using the Harris hip score (HHS).

Table 1 Functional results (PMA score/HHS)

	PMA	HHS	Pre-op		Last control	
			PMA	HHS	PMA	HHS
Excellent	18	≥98	0%	0%	61%	0%
Good	≥15	≥80	2%	1%	32%	80%
Fair	≥12	≥60	39%	6%	6%	15%
Poor	<12	<60	59%	93%	1%	6%
Mean			10.1	41.3	17.1	85.1

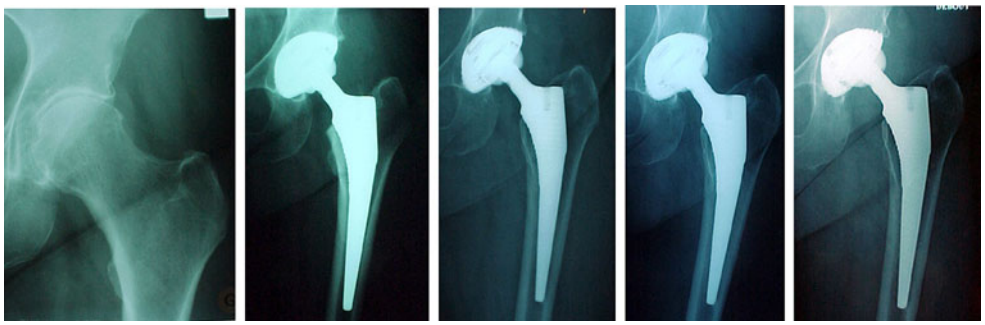

Fig. 2 A 54-year-old man operated upon in 1988 for osteoarthritis (**a**). Immediate postoperative radiograph (**b**): Corail KA11, ceramic on poly bearing, nice reconstruction of the hip geometry. Stem in a slight varus position. X-ray review 5, 15 and 20 years later (**c**, **d**, **e**): limited resorption at the calcar level; note the radiological "silence" with no significant modification of the periprosthetic bone pattern. No osteolysis on either side, despite significant PE wear

The radiographic analysis of the study has provided instructive information (Fig. 2). Some general observations will be noted: In the immediate postoperative radiographic view, the stem is usually centred or in slight varus. Correction of limb length discrepancies has been achieved. Unfortunately, at that time, there was insufficient data to provide adequate analysis of joint geometry reconstruction, in particular with respect to femoral offset and abductor muscle lever arm. Radiographic signs of osseointegration are observed in 82% of the records, particularly in the more distal part of the stem, but there is no evidence of pedestal formation or radiolucent line. Some reactive lines (0.6%) are observed in zone 1 and potential granulomas (8%) which mostly involve the trochanteric region. Implant stability is excellent and a single case of stem subsidence of more than 3 mm is reported. Regarding bone remodelling, discreet signs mainly situated in the calcar region (15%) and only two cases of grade III stress shielding were noted. Multivariate analyses confirmed the absence of any significant influence of some patient-related but above all prosthesis-related (collar, positioning and size) factors on femoral remodelling. With regard to polyethylene (PE) wear, there is no significant predisposing factor apart from the patient's age at the time of surgery: younger patients commonly demonstrate earlier evidence of PE wear. On the other hand, neither the diameter nor material of the prosthetic head appear as pejorative factors.

The Radio-clinical score described by Laurent Sedel (Table 2), provides accurate information about the permanence of excellent function combined with normal periprosthetic bone pattern. Patients are distributed among four groups: group A: no pejorative functional and radiographic signs; group B: patients with stable clinical result but demonstrating progressively evolving radiographic alterations; group C: patients with deteriorating functional score but lack of any radiographic explanation; and group D: patients with bad clinical score associated with progressive radiographic deterioration.

In our series, 83% of the patients have a totally silent hip at latest follow-up and are classified in group A. Only 15% have evolving and pejorative radiographic signs particularly at the calcar level (scalloping process, osteolysis...), and more rarely because of proximal granulomas or lucencies; they do not have any disability and they are classified in group B. Of the cohort, 1% have reduced function scores with normal radiographic appearance: these patients are classified in group C. Finally, 1% of the patients have poor function associated with deterioration of the femoral bone pattern and are classified in group D. Considering the two subgroups, collared and collarless, there is a significant difference in terms of bone resorption, in favour of the collar support (group B: 10% versus 16%) .

Intraoperative complications (10.9%), in particular calcar cracks (33), fractures (3) and perforations (2), should be attributed not only to the learning phase, but, mainly, to the principle, at that time, of achieving a closer cortical contact than today. Early complications (18.5%) are mainly represented by deep venous thrombosis (DVT) and we have to consider eight cases of instability. Only two cases of unexplained thigh pain were observed. Late complications (25.9%) are dominated by revisions; 13 cases of recurrent dislocation were recorded and 62 hips were revised mostly for the management of acetabular complications (48). Twelve femoral stems were removed: four loosening,

Table 2 Sedel's score (function/X-ray evaluation)

Group	Corail (collared)	Corail (collarless)	Global
A	89%	81%	83%
B	10%	16%	15%
C	0%	1%	1%
D	1%	1%	1%

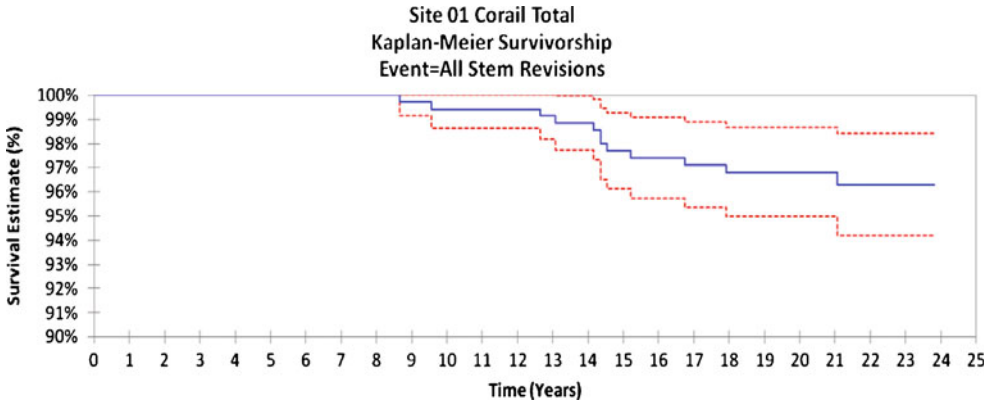

Fig. 3 Survival probability of the Corail stem. Stem extraction for any reason as end point

probably aseptic, were reported. Three stable stems were removed during acetabular revision due to the presence of extensive granulomas, one removal was related to a periprosthetic fracture, one well-fixed stem was removed to restore leg length and offset and finally three stable implants were extracted to facilitate the revision of the cup.

All causes of stem removal considered, the survival probability of the Corail® stem, in this series, is 97.7% at 15 years, 96.8% at 18 years, 96.8% at 20 years and 96.3% at 23 years (Fig. 3). On the other hand, survivorship of the cup is 88.9% at 15 years, 85.5% at 18 years, 84.4% at 20 years and 83.9% at 23 years. The global survivorship of all arthroplasties is respectively 87.3, 84.4, 83.0 and 82.5% at the same intervals (Fig. 4).

Discussion

More than a quarter century after the first human implantation of HA-coated implants, and from our personal experience [23], it appears possible to resolve some questions and to reduce the concerns and doubts which were the subject of debate between the supporters and opponents of HA bioactive properties. The clinical and radiographic results at more than 20-year follow-up provide sufficient evidence for the long-term efficacy of this original bioactive fixation, to ensure that the layer of phosphocalcic material prevents any adverse event and to claim that this option represents a decisive and unequalled advance in comparison with other non-cemented techniques [6, 14, 20]. Regarding the fundamental question: "is HA a simple starter in the osseointegration process or an essential and determining partner in the durability of arthroplasty", it is possible to answer that in the last analysis, as it has often been said, HA is not a magic powder since an optimal coating applied on a bad prosthesis or a good prosthesis improperly implanted may predispose the stem to failure. Nevertheless, in this essential triptych (interface/prosthetic design/implantation technique), HA has proven highly efficient regarding bone ingrowth and bioactivity. Evaluation of the respective part played by each component in the quality of the final result is challenging, since the combination of these three elements as a whole is what ensures fixation durability and long-term quality of the functional outcome. However, a progressive consensus was reached and the benefits can be classified into five levels. These will only be outlined briefly as they are no longer the focus of controversy.

Advantages

1. ***Osseointegration*** is the key element. For the first time, it is possible to create a real osseocoalescence between the living and reactive host bone and the prosthetic

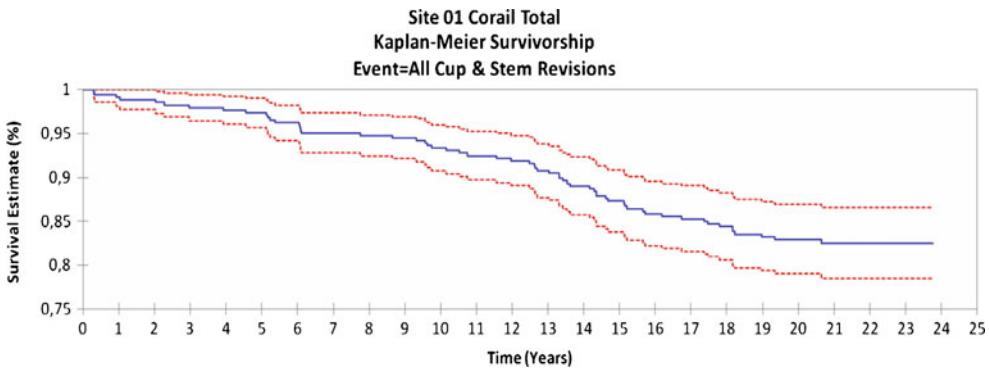

Fig. 4 Survival probability of the Corail stem. Removal of any component as end point

implant made from inert material [11]. This is a continuous, reproducible and reliable integration process. It can occur at any age, in any case, whatever the bone quality of the patient. This phenomenon is not a transitory stage in the life of a prosthesis, as demonstrated, even in long-term radiographic findings, by the absence of any radiolucent line revealing interposition of fibrous tissue. This fundamental property allows any selection criteria to be avoided regarding the surgical indications: young and very active patients [21, 25], older and osteoporotic patients [10] and those with poor bone stock achieved similar results. In the same way, sclerotic bone observed in revision surgeries [7, 17, 18, 20] or in septic situations [24] does not constitute a contraindication.

2. The ***stability*** of the fixation is also a proven concept. Since the experimental work of Søballe on radiostereometric analysis (RSA) in 1995, it has now been established that HA-coated implants demonstrate early and definitive stability, significantly improved in comparison with porous metal-coated implants of similar geometry [16, 22]. The various studies conducted by the Artro Group confirm this longitudinal stability and a recent RSA analysis, performed on the Corail stem in Australia [5], reports a convincing stability: a mean 1 mm of vertical migration and 1° of anteversion, these displacements occurring within the first postoperative weeks.
3. The absence of ***unexplained pain*** is also a determining factor as underlined by all authors. Whatever the chosen method for functional score evaluation, the usual absence of pain, particularly in the thigh and inguinal regions, strongly contrasts with complaints reported by patients with conventional cementless implants [2].
4. It is known that ***bone remodelling*** occurs after any prosthetic implantation. The quality of bone remodelling perfectly reveals a harmonious load transfer to the bone [1, 8]. This evolving radiographic feature has been the subject of several independent studies. The newly formed bone trabeculae are long-lasting and reflect the tensile, compressive and rotation forces which maintain bone trophicity. The calcar region is subjected to changes in 34% of the cases with thinning of Merkel's femoral thigh spur and rounding of cortical ridges, but no diaphyseal anomaly is usually observed and the rate of grade 3 stress shielding, lower than 1%, may be considered as insignificant. Numerous densitometry studies have also confirmed this benefit with regard to bone sparing [15].
5. The original quality of bone-implant interface offers an authentic ***seal*** which slows down wear particle migration responsible for granulomas and bone resorption. This specific point has been accepted for a long time. Granulomas may appear proximally, particularly in the calcar region, but slowly progressing and never observed in the diaphyseal region. Complete stem osseointegration constitutes a more secure fixation.

These advantages explain why, in the majority of the cases, no radiographic changes of the implantation site are reported even at latest follow-up (Fig. 2a–e), which confirms the principle of a "silent hip" or a "totally forgotten" surgery.

Concerns

In the 1990s, the potentially deleterious effects were described in a few articles [3, 4]. During the past few years, an extensive literary output has dissipated any remaining doubts [5, 6, 9, 14, 19].

1. The more or less complete ***coating resorption*** is now a well-accepted phenomenon [12]. However, in mechanically stimulated areas, this phenomenon is always followed by the appearance of lamellar bone affixed to the residual coating which provides long-term fixation: the metallic surface may be exposed at the level of the medullary cavities but fibrous tissue never develops. This key point has already been underlined by Dominique Hardy in the analysis of various explantations [13].
2. The risk of ***delamination*** is now perfectly documented. With current technologies, this theoretical risk can be considered as negligible up to a ceramic thickness of 150 μm. In all histological studies, notably those from Dominique Hardy [13], HA fragments have never been seen, in particular in the soft tissues, and the rate of ectopic bone formation is not significantly increased in comparison with procedures using non-HA-coated implants.
3. The phenomenon of ***osteolysis*** has only been described in earlier articles and remains a marginal event [3]. The lysis phenomenon is not attributable to HA but induced by the migration of other particles which are the main predisposing factors or consequences of loosening. It is an established fact that HA has no inflammatory or allergenic effects. It does not possess any toxic and carcinogenic potential.
4. Excessive ***wear*** might occur as a result of third body abrasion wear if coating fragments were present within the joint space. However, this theoretical risk has never been proven. Fragments released after coating degradation remain in the immediate environment of the intramedullary part of the stem and early reintegrate the local bone metabolism. These fragments do not migrate into the surrounding soft tissues or in the joint cavity. Calcium phosphates sometimes observed over the PE

liner surface have a natural origin and commonly appear with cemented implants. In fact, the reported wear rates in all series of long-term follow-up of HA implants are not significantly different from those reported in other types of arthroplasties.

5. Lastly, the ***extraction*** of a well-osseointegrated implant has long been considered a challenging procedure. In fact, a specific strategy and technique with dedicated instrumentation considerably decreases the risks and complications induced by prosthesis removal.

Conclusions

The concept of full coating for the fixation of a femoral stem whose geometry allows a digressive gradient of stiffness was introduced 25 years ago. This long-term prospective analysis confirms the durability of the functional and radiographic results. Osseointegration is a continuous phenomenon which occurs on a regular basis with no prior selection criteria. Good stem stability is responsible for the absence of any unexplained pain. Early return to normal activities is allowed; radiographic "silence" is common and not related to implant positioning. Aseptic loosening is rare despite acetabular complications. All acetabular components featured a PE liner which demonstrated significant wear in more than 50% of the cases; granulomas were always limited to the metaphyseal region and the Corail® stem survival probability is 96.3% at 23 years.

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