Product Rationale

Surgical Technique

KAR™

CORAIL®
LONG STEM

UNIVERSAL

STABILITY

IN REVISION

DePuy
a Johnson & Johnson company

Consistency and reliability in revision surgery

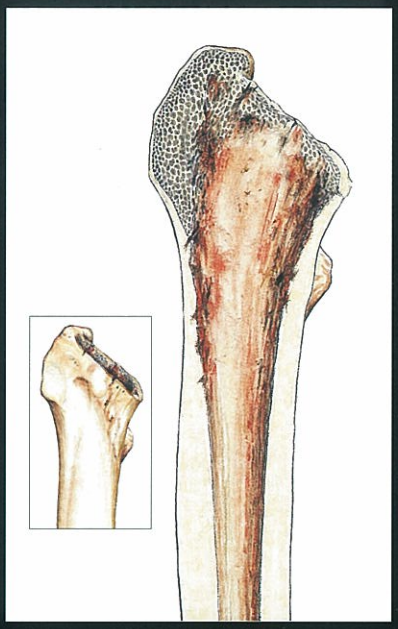
98% success at 7 years - a unique clinical experience

For all too many patients, the first operation to revise a hip implant will not be the last procedure they will undergo in order to correct their failed joint. The outcome of revision surgery is inevitably less predictable than primary implantation. Results achieved using the Kar™ prosthesis, however, have proved both consistent and reliable, with a survivorship rate of 98% at 7 years with the majority of patients (97%) expressing a high degree of satisfaction with their operation[1].

Kar™ uncemented revision system

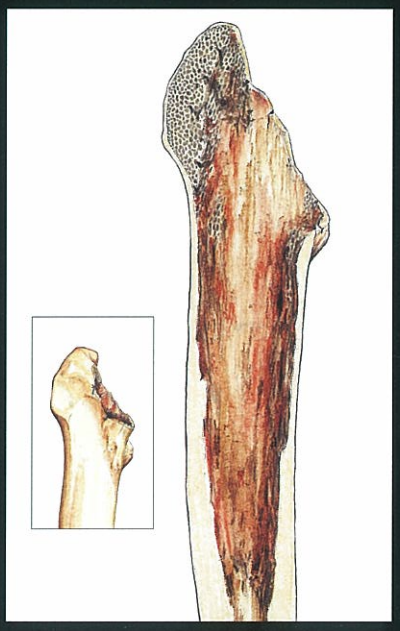
The long Kar™ stem has developed from the successful Corail® primary hip[2], specifically for revision surgery. Manufactured from forged titanium alloy[2], it shares the Corail® concept of stereostability, macro and micro surface detailing, HA coating, and includes both metal and ceramic head options.

The Kar™ System offers the surgeon a range of stems for mild to moderate situations (types 2 and 3A of Paprosky's classification) making it suitable for the majority of revision cases. Kar™ is also indicated for primary reconstruction of the cavernous femur. The surgical technique utilises the standard Corail® broaches and shares the same straightforward procedure for implantation.



Type 2

The calcar is non-supportive. Cancellous/cortical structural bone is absent – the metaphysis is not intact. The diaphysis has minimal damage.



Type 3A

The upper metaphysis is non-supportive. The diaphysis is not intact due to bone loss.

Kar™ revision stems address issues that are encountered in mild to moderate revision cases, i.e. within the range of type 2 and type 3A of the Paprosky's defect classification.

Kar™ 12 = Corail® 12 + 30 mm = 180 mm

Kar™ 14 = Corail® 14 + 40 mm = 200 mm

Kar™ 16 = Corail® 16 + 40 mm = 210 mm

Kar™ 18 = Corail® 18 + 40 mm = 220 mm

Kar™ 20 = Corail® 20 + 50 mm = 240 mm

Restoring initial and long-term mechanical stability

Achieving stem stability in the proximal femur

Like the Corail® primary stem, the long Kar™ revision stem is designed to achieve secure initial and long-term mechanical stability in the femur.

It is shaped to resist both axial and torsional loosening forces.

In the frontal plane, the stem's pronounced lateral flare and medial curve provide axial and rotational stability.

The lateral flare is fully supported by the infero-lateral aspect of the greater trochanter.

In the lateral plane a progressive anterior to posterior tulip flare fills the metaphysis and, in combination with horizontal grooves around the circumference of the stem, further reinforces axial stability.

The well-defined rectangular section and vertical grooves confer rotational stability.

The stem's proximal collar prevents axial migration. To compensate for weakness or absence of bone in the calcar region, the use of a structural horseshoe allograft is recommended.

The calcar graft is compressed and stabilised by the stem's collar and is loaded by its medial curve.

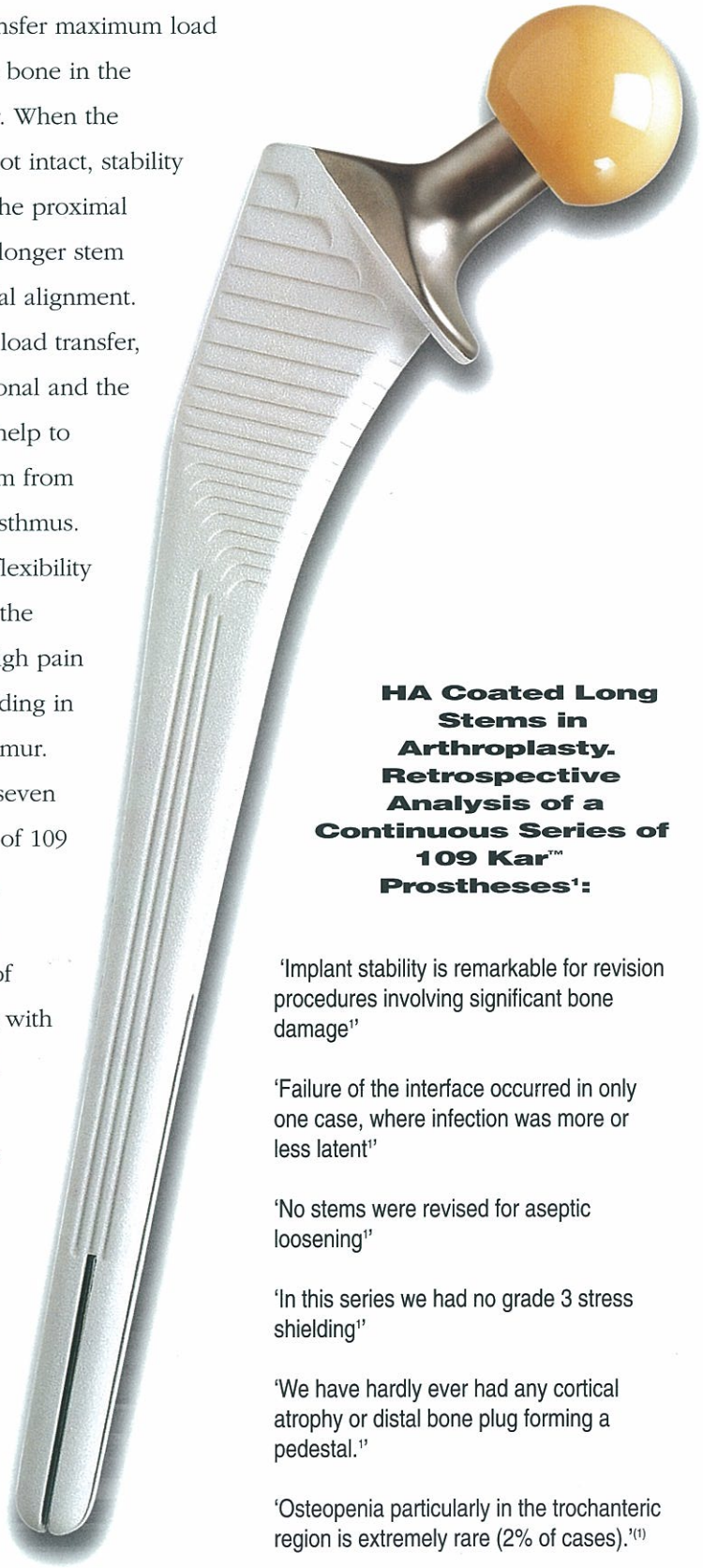
Proximal load transfer

The Kar™ revision stem has been designed to transfer maximum load to the available bone in the proximal femur. When the metaphysis is not intact, stability is achieved in the proximal diaphysis. The longer stem aids correct axial alignment.

To avoid distal load transfer, slots in the coronal and the sagittal planes help to prevent the stem from locking in the isthmus.

The increased flexibility also minimises the potential for thigh pain and stress shielding in the proximal femur.

In his three to seven year follow-up of 109 Kar™ revisions[1], Vidalain found minimal signs of stress shielding with no radiological signs of subsidence. No stems were revised for aseptic loosening.



HA Coated Long Stems in Arthroplasty. Retrospective Analysis of a Continuous Series of 109 Kar™ Prostheses[1]:

'Implant stability is remarkable for revision procedures involving significant bone damage[1]'

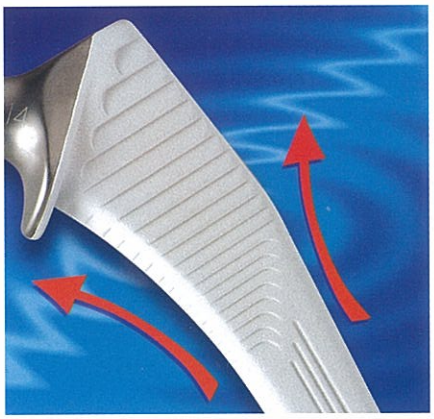
'Failure of the interface occurred in only one case, where infection was more or less latent[1]'

'No stems were revised for aseptic loosening[1]'

'In this series we had no grade 3 stress shielding[1]'

'We have hardly ever had any cortical atrophy or distal bone plug forming a pedestal.[1]'

'Osteopenia particularly in the trochanteric region is extremely rare (2% of cases).'[(1)]



In the frontal plane, the stem's pronounced lateral flare and medial curve provide axial stability and proximal load transfer.

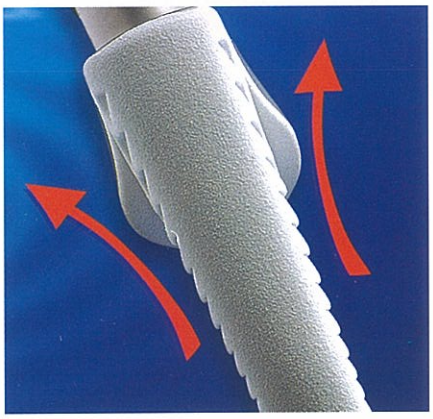


Illustration of the progressive anterior to posterior tulip flare.

The long flexion slot in the coronal plane and the shorter slot in the sagittal plane minimise distal thigh pain and the effects of stress shielding in the proximal femur.

The Kar™ femoral stem features a standard 12/14 Morse taper which is compatible with 22.225 mm, 28 mm and 32 mm femoral heads, available both in cobalt chrome and alumina ceramic.

Long term biological fixation

HA, the optimum implant-to-bone interface for revision surgery

The Kar™ stem is fully coated with pure ceramic hydroxyapatite. The stem's surface is corundum granule blasted to receive particles of source HA to a controlled average thickness of 155um, assuring optimal strength and a strong coating-to-implant bond. Laboratory testing shows the Kar™ HA coating to have a pull off strength of 35 MPa[9].

Hydroxyapatite is highly biocompatible and does not trigger an inflammatory or macrophagic reaction. As a consequence, histological studies show a notable absence of intervening fibrous tissue[6/8] between implant and bone. This highly osteoconductive medium, with its similarities in chemical and mineral content to human bone, stimulates fast implant to femur integration[6] – even in cases of significant bone deficiency. The biochemical process bridges gaps of up to 2 mm between implant and bone[9].

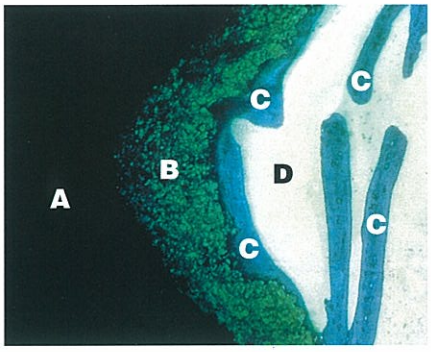
The macro and micro-textural contours of the Kar™ stem provide an extensive surface area, producing the ideal conditions for bone ongrowth and allowing the HA coating to produce strong apposition between implant and femur within weeks of surgery.

Optimum graft incorporation

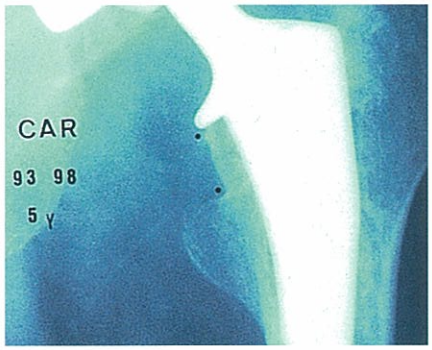
When used in conjunction with the appropriate bone impaction grafting techniques, the Kar™ HA coating encourages adequate incorporation of the graft, as demonstrated by experimental studies[5] and by histological analysis[4]. This is a process called creeping substitution.

A biological seal against wear debris

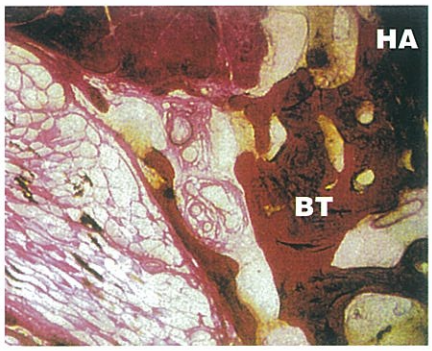
Total osteointegration of the implant creates a barrier against the ingress of wear debris from the joint capsule[3]. This significantly reduces the potential for osteolysis, implant loosening and re-revision.



Histological sections show extensive new bone ongrowth onto hydroxyapatite producing a strong interlock[8]. Magnification x 150
A : Metal
B : Hydroxyapatite coating
C : New bone formation (trabeculations)
D : Medullary cavity



X-ray showing the incorporation of a calcar allograft 5 years post-operatively. No radiolucency is observed.

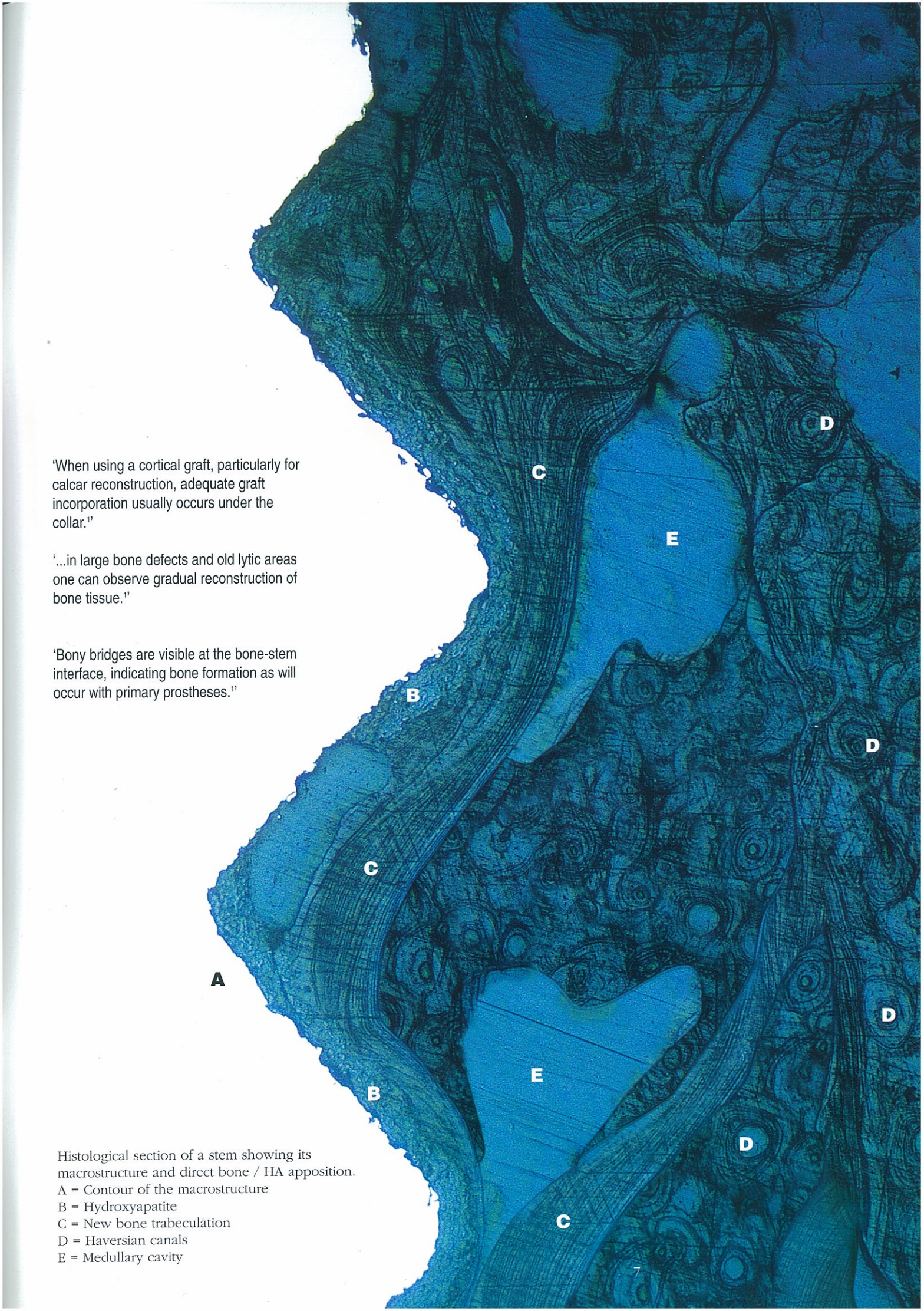


Histological section made at the calcar level of a stem implanted with allografts. The allogenic bone tissues seem to be perfectly osteointegrated. Magnification x 200.
HA = Hydroxyapatite
BT = Bone tissue.

'When using a cortical graft, particularly for calcar reconstruction, adequate graft incorporation usually occurs under the collar.[1]'

'...in large bone defects and old lytic areas one can observe gradual reconstruction of bone tissue.[1]'

'Bony bridges are visible at the bone-stem interface, indicating bone formation as will occur with primary prostheses.[1]'



Histological section of a stem showing its macrostructure and direct bone / HA apposition.
A = Contour of the macrostructure
B = Hydroxyapatite
C = New bone trabeculation
D = Haversian canals
E = Medullary cavity

Surgical technique

Pre-operative planning

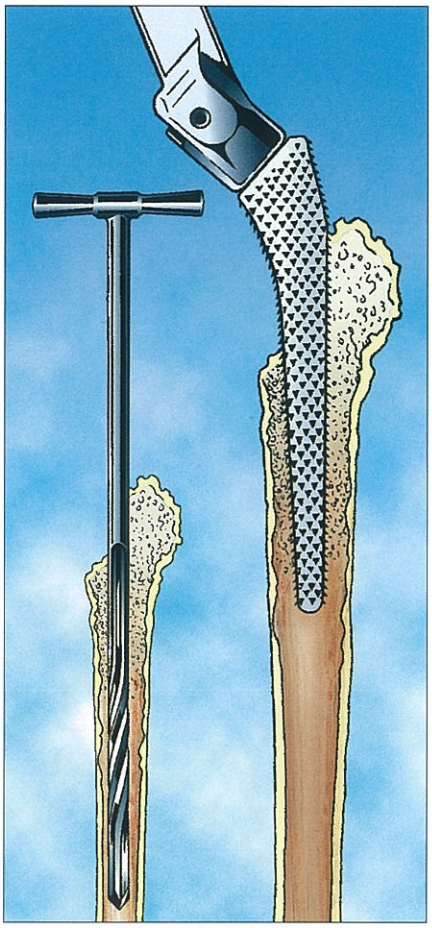
Pre-operative planning is essential for precise reconstruction of the hip joint. The Kar™ Hip System includes a comprehensive set of X-ray templates. These are used with radiographs showing the AP view of the pelvis and AP and lateral views of the affected femur, covering the full length of the prosthesis to be revised as well as any canal occluder.

The AP view provides the information needed to determine implant alignment and the size of component required to fit and fill the metaphysis (to obtain proximal stability) without risk of distal locking. Neck length is also determined to restore the patient's natural anatomy. Where necessary, the appropriate degree of calcar bone grafting is established.

The lateral view may then be used to confirm implant alignment, to identify any defects that cannot be seen on the AP view and to further ensure that the implant will not be locked distally.

Any of the standard approaches to total hip arthroplasty may be used.

Femoral preparation



Figures 1 & 2

Once the failed implant has been retrieved, the femur is cleared of any remaining cement and debris and an 11 mm rigid reamer is used to prepare the femoral canal (all sizes of Kar™ femoral stem have a distal diameter of 11 mm). It may be necessary to over-ream by 1 mm or 2 mm, using a 12 mm reamer (at a level indicated on the templates), to allow free passage of the trial stem to the desired depth (fig.1).

Access to the femoral canal should be enlarged laterally into the greater trochanter, using a chisel, to ensure that the broaches do not enter the femur in varus. Varus alignment of the implant may compromise implant stability and shorten the life of the implant.

Trial reduction

Figure 3

The smallest broach is attached to the broach handle and the proximal femur is prepared by progressively increasing broach sizes.

It is essential that the final broach is completely stable in the femur (fig.2) in order to ensure stem stability in the metaphysis. Distal stem stability alone is not sufficient.

The final broach is extracted and, using the same handle, the appropriate sized Kar™ trial stem is inserted into the femoral canal (fig.3).

A trial head is placed on the neck of the trial stem, and the hip is

Femoral component insertion

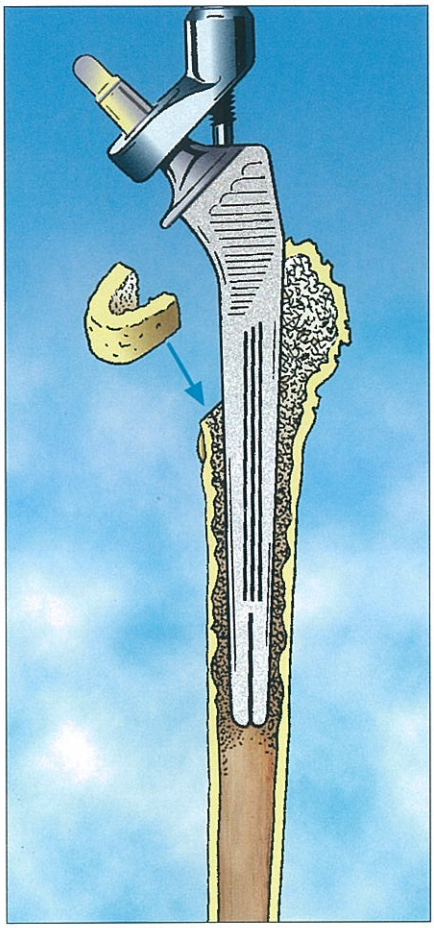


Figure 4

Trial reduction

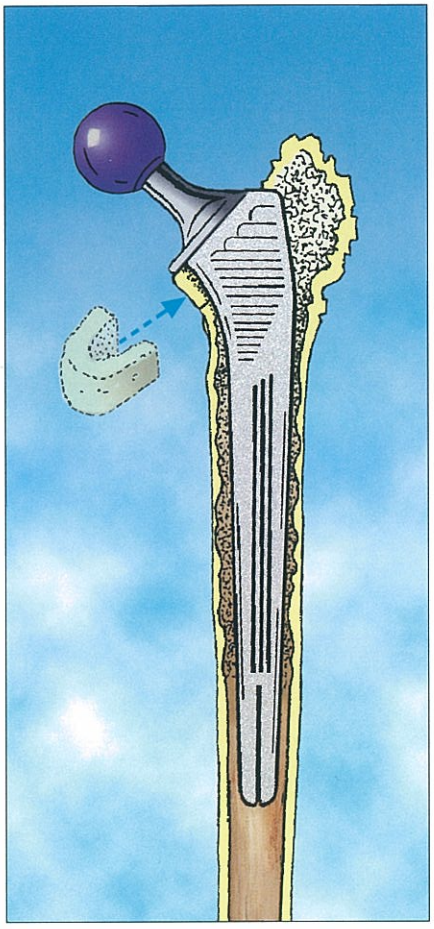


Figure 5

Femoral head impaction

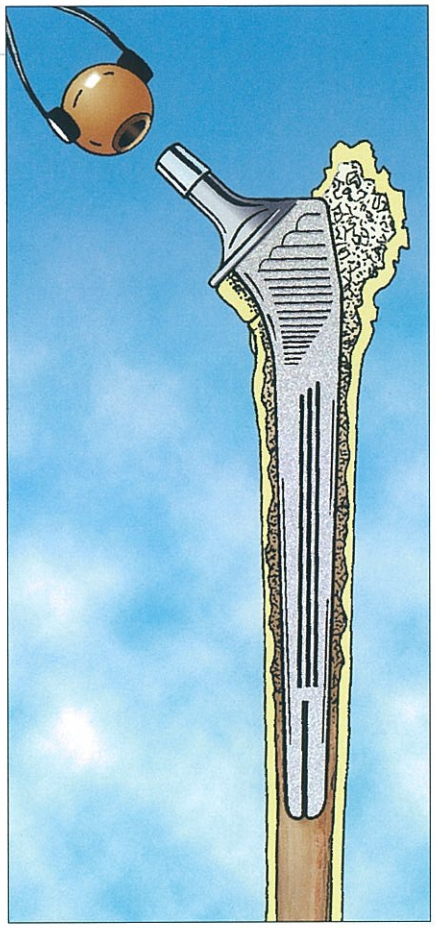


Figure 6

reduced and assessed for stability, through a full range of motion. (NB. When using the Kar™ prosthesis as a primary implant, the calcar mill should be passed over the neck of the trial stem. The femoral neck is milled to produce a flat surface to accept the implant collar).

In order to restore reliable long term proximal support for the implant, to restore Shenton's line and equalise leg length it may be necessary to reconstruct the calcar. This should be carried out with a horseshoe shaped structural allograft. The graft will be stabilised by the collar of the definitive stem during impaction (fig.4). Any other structural repairs should also be made at this stage.

The definitive implant is inserted into the femoral canal, using the stem impactor/extractor. A trial head is placed on the neck of the stem and the hip is reduced again to assess joint stability and range of motion (fig.5).

The trial head is removed, the joint is irrigated to clear away any debris and the taper on the neck of the stem is cleaned using a clean swab. The definitive femoral head is placed on the taper of the stem, using the femoral head positioner (fig.6), and then lightly impacted using the head impactor. The hip is reduced and the wound is closed in the normal way.

Post-operative management

The post-operative protocol is dependent upon the condition of the femur and the graft incorporation. If the proximal femur is supportive, weight bearing is allowed immediately.

The patient should be kept off weight bearing for at least 45 days if the femur has been grafted.

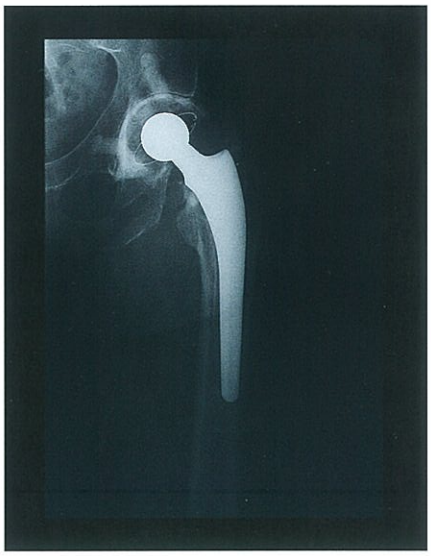
Radiographic cases

Case study

Pre-op Revision of a loose cemented femoral stem (Paprosky Type 3A) was performed in 1992. Subsidence of the loosened stem and thinning of the lateral cortex are observed.

Post-op 6-month follow-up shows good alignment of the Kar™ prosthesis.

5 years post-op The patient is satisfied with his hip replacement. The prosthesis is stable. Extensive regeneration of both cortices with endosteal ossification is evident.



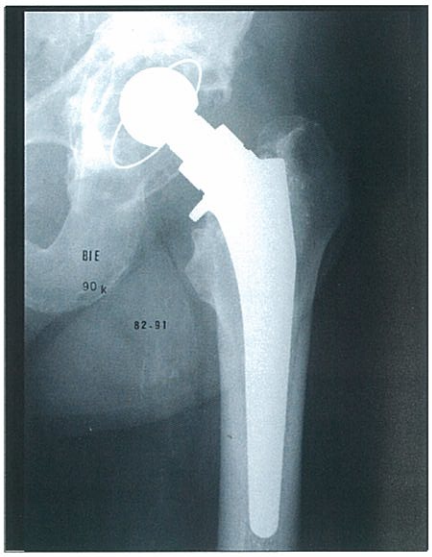
Pre-op

Case study

Pre-op Revision of a loose cemented femoral stem (Paprosky Type 2) was performed in 1991.

Post-op The radiograph at 12-months shows a good result achieved with the Kar™ femoral stem both in terms of stability and restoration of the centre of rotation.

10 years post-op The patient is asymptomatic and is satisfied with the hip replacement. Restoration of bone density is satisfactory and implant stability is confirmed.



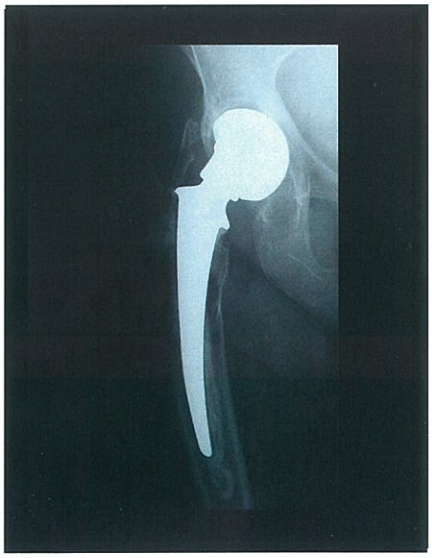
Pre-op

Case study

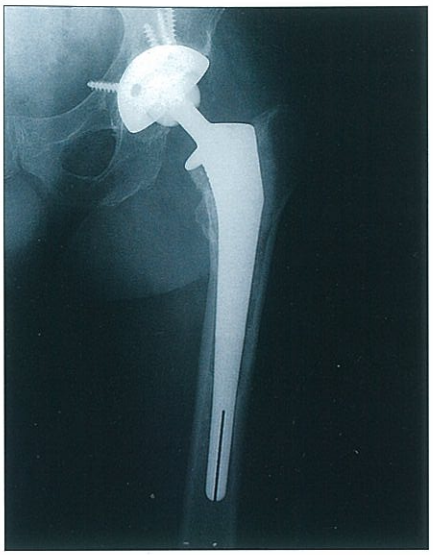
Pre-op Revision of a loose cemented femoral stem (Paprosky Type 2) was performed in 1993.

Post-op A radiograph taken at 2 weeks follow-up shows good stability of the Kar™ femoral stem, both in the proximal and distal regions. A cortical window has been performed to remove the cement restrictor. The metaphysis has been bone grafted, and the calcar has been reconstructed using a substantial allograft.

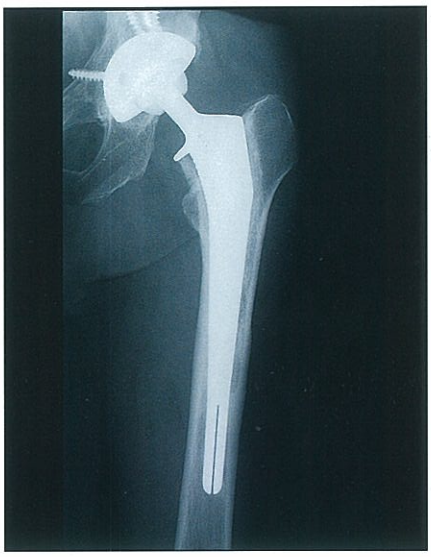
5 years post-op The patient is satisfied with his hip replacement. Good bone ingrowth can be noted, with signs of endosteal bone formation and restoration of adequate cortical density. No radiolucency is observed.



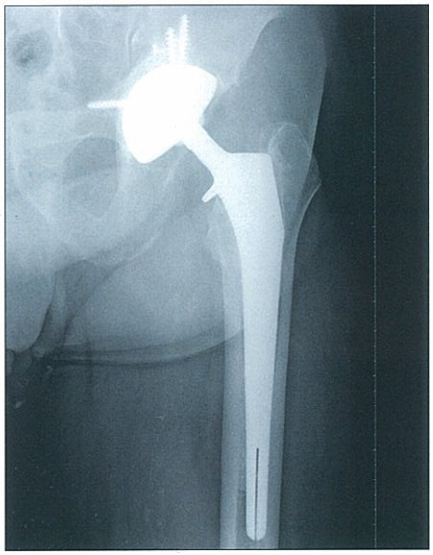
Pre-op



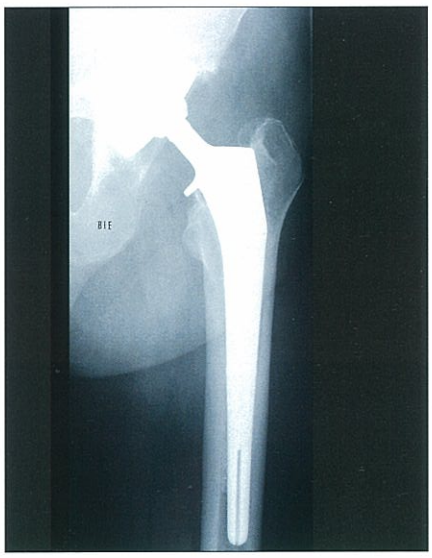
Post-op



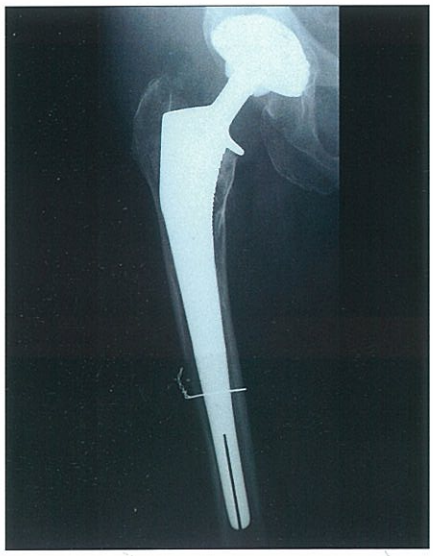
5 years post-op



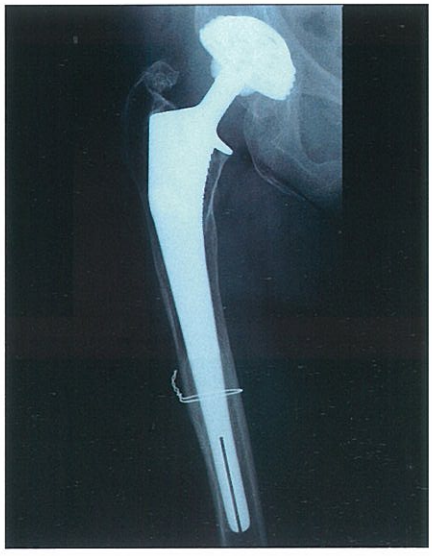
Post-op



10 years post-op



Post-op



5 years post-op

References:

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Cahiers d'enseignements de la SOFCOT n°51, Hydroxyapatite Coated Hip and Knee Arthroplasty, 1994

Ordering information

Kar™ femoral stem

L92522	Kar™ size 12
L92524	Kar™ size 14
L92526	Kar™ size 16
L92528	Kar™ size 18
L92530	Kar™ size 20

Femoral heads

L84008	Alumina head 28 mm -3,5
L84010	Alumina head 28 mm 0
L84012	Alumina head 28 mm +3,5
L84020	Alumina head 32 mm -4
L84022	Alumina head 32 mm 0
L84024	Alumina head 32 mm +4
L84164	Cobalt chrome head 22,225 mm -2
L84166	Cobalt chrome head 22,225 mm 0
L84168	Cobalt chrome head 22,225 mm +2
L84000	Cobalt chrome head 28 mm -3,5
L84001	Cobalt chrome head 28 mm 0
L84002	Cobalt chrome head 28 mm +3,5
L84003	Cobalt chrome head 28 mm +7
L84004	Cobalt chrome head 32 mm -4
L84005	Cobalt chrome head 32 mm 0
L84006	Cobalt chrome head 32 mm +4
L84007	Cobalt chrome head 32 mm +8
Or	
1365-29-000	Articul/eze® Head CoCr 22,225 +4
1365-30-000	Articul/eze® Head CoCr 22,225 +7
1365-11-000	Articul/eze® Head CoCr 28 +1,5
1365-12-000	Articul/eze® Head CoCr 28 +5
1365-13-000	Articul/eze® Head CoCr 28 +8,5
1365-14-000	Articul/eze® Head CoCr 28 +12
1365-15-000	Articul/eze® Head CoCr 28 +15,5
1365-21-000	Articul/eze® Head CoCr 32 +1
1365-22-000	Articul/eze® Head CoCr 32 +5
1365-23-000	Articul/eze® Head CoCr 32 +9
1365-24-000	Articul/eze® Head CoCr 32 +13
1365-25-000	Articul/eze® Head CoCr 32 +17
9111-121	Articul/eze® Head Alumina 28 +1,5
9111-122	Articul/eze® Head Alumina 28 +5
9111-123	Articul/eze® Head Alumina 28 +8,5
9111-131	Articul/eze® Head Alumina 32 +1
9111-132	Articul/eze® Head Alumina 32 +5
9111-133	Articul/eze® Head Alumina 32 +9

Instrumentation

L95119	Lid-tray n°1
L95120	Lid-tray n°2
L95121	Kar-tray n°1
L95122	Kar-tray n°2
CONTKAR1	Kar steri. case n°1
CONTKAR2	Kar steri. case n°2
J96150	Canal reamer dia. 10 mm
J96155	Canal reamer dia. 11 mm
J96160	Canal reamer dia. 12 mm
L95060	Handle for broach and trial stem
L95072	Broach 12
L95074	Broach 14
L95076	Broach 16
L95078	Broach 18
L95080	Broach 20
L95092	Trial stem 12
L95094	Trial stem 14
L95096	Trial stem 16
L95098	Trial stem 18
L95099	Trial stem 20
L95050	Calcar mill
L95680	Impactor / extractor
L95682	Stem impactor
L93206	Femoral head impactor
L93204	Femoral head forcep
L37242	Trial head for broach dia. 22,225 mm -2
L37244	Trial head for broach dia. 22,225 mm 0
L37246	Trial head for broach dia. 22,225 mm +2
L37220	Trial head for broach dia. 28 mm -3,5
L37222	Trial head for broach dia. 28 mm 0
L37224	Trial head for broach dia. 28 mm +3,5
L37226	Trial head for broach dia. 28 mm +7
L37230	Trial head for broach dia. 32 mm -4
L37232	Trial head for broach dia. 32 mm 0
L37234	Trial head for broach dia. 32 mm +4
L37236	Trial head for broach dia. 32 mm +8
L37532	Trial head dia. 22.225 mm -2
L37534	Trial head dia. 22.225 mm 0
L37536	Trial head dia. 22.225 mm +2
L37502	Trial head dia. 28 mm -3,5
L37504	Trial head dia. 28 mm 0
L37506	Trial head dia. 28 mm +3,5
L37508	Trial head dia. 28 mm +7
L37512	Trial head dia. 32 mm -4
L37514	Trial head dia. 32 mm 0
L37516	Trial head dia. 32 mm +4
L37518	Trial head dia. 32 mm +8
Or	
L85960	Articul/eze® trial head for broach 28 +1,5
L85961	Articul/eze® trial head for broach 28 +5
L85962	Articul/eze® trial head for broach 28 +18,5
L85963	Articul/eze® trial head for broach 28 +12
L85964	Articul/eze® trial head for broach 28 +15,5
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L85968	Articul/eze® trial head for broach 32 +9
L85969	Articul/eze® trial head for broach 32 +13
L85970	Articul/eze® trial head for broach 32 +17
2530-69-000	Articul/eze® trial head 22,225 +4
2530-70-000	Articul/eze® trial head 22,225 +7
2530-81-000	Articul/eze® trial head 28 +1,5
2530-82-000	Articul/eze® trial head 28 +5
2530-83-000	Articul/eze® trial head 28 +8,5
2530-84-000	Articul/eze® trial head 28 +12
2530-85-000	Articul/eze® trial head 28 +15,5
2530-91-000	Articul/eze® trial head 32 +1
2530-92-000	Articul/eze® trial head 32 +5
2530-93-000	Articul/eze® trial head 32 +9
2530-94-000	Articul/eze® trial head 32 +13
2530-95-000	Articul/eze® trial head 32 +17

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