The S-ROM hydroxyapatite proximally-coated modular femoral stem in revision hip replacement

RESULTS OF 397 HIPS AT A MINIMUM TEN-YEAR FOLLOW-UP

We report on 397 consecutive revision total hip replacements in 371 patients with a mean clinical and radiological follow-up of 12.9 years (10 to 17.7). The mean age at surgery was 69 years (37 to 93). A total of 28 patients (8%) underwent further revision, including 16 (4%) femoral components. In all 223 patients (56%, 233 hips) died without further revision and 20 patients (5%, 20 hips) were lost to follow-up. Of the remaining patients, 209 (221 hips) were available for clinical assessment and 194 (205 hips) for radiological review at mean follow-up of 12.9 years (10 to 17.7).

The mean Harris Hip Score improved from 58.7 (11 to 92) points to 80.7 (21 to 100) (p < 0.001) and the mean Merle d’Aubigné and Postel hip scores at final follow-up were 4.9 (2 to 6), 4.5 (2 to 6) and 4.3 (2 to 6), respectively for pain, mobility and function. Radiographs showed no lucencies around 186 (90.7%) femoral stems with stable bony ingrowth seen in 199 stems (97%). The survival of the S-ROM femoral stem at 15 years with revision for any reason as the endpoint was 90.5% (95% confidence interval (CI) 85.7 to 93.8) and with revision for aseptic loosening as the endpoint 99.3% (95% CI 97.2 to 99.8).

We have shown excellent long-term survivorship and good clinical outcome of a cementless hydroxyapatite proximally-coated modular femoral stem in revision hip surgery.

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Good long-term results of primary total hip replacement (THR) using hydroxyapatite (HA)-coated titanium stems have been reported in all age groups,1-3 but there are few reports of the long-term results of these stems in revision surgery.4

The S-ROM (DePuy, Warsaw, Indiana) femoral stem, which was introduced in 1984, is a cementless, modular, cylindrical component with a hollow proximal sleeve and separate stem. Good medium-term clinical results have been reported when the porous-coated version of this stem has been used in revision surgery.5-7

We present long-term clinical and radiological results of the HA version of this stem in revision THR.

Patients and Methods

Between April 1992 and December 2002, 397 consecutive revision cementless THRs were performed in 371 patients by the two senior authors (BAZ, WKW) in a single centre. WKW undertook 354 (89%) of the operations. The mean age of the patients at the time of revision was 69 years (37 to 93), and 203 (55%) were women. There were 208 (52%) right-sided and 26 (6.5%) bilateral operations. The mean weight of the patients was 70.8 kg (41 to 125) and the mean body mass index was 25.7 kg/m² (19.5 to 32.6).

All operations were performed in a vertical laminar flow theatre with balaclava head covers. In 300 (75.5%) operations, surgery was performed via the posterior approach with an enhanced posterior repair.8 A Hardinge approach9 was used in 84 (21%), and a trans-trochanteric approach in 13 (3.5%) where there had been nonunion of a previous trochanteric osteotomy. An S-ROM HA-coated modular femoral stem was used in all patients. This consists of a titanium alloy stem (Ti-6Al-4V), distally polished with thin sharp 0.6 mm flutes to engage the endosteal cortex, and a coronal slot to reduce stiffness. The 4 cm long cylindrical sleeve is coated with HA and is stepped. The interior of the sleeve has a Morse-taper connection, which is loaded in compression and connects to the stem. The modularity allows independent matching of the metaphyseal and diaphyseal anatomy of the patient.10,11

No patient required a structural allograft. Post-operative protocols were identical for all patients and included 48 hours of intravenous broad spectrum antibiotics, low molecular-weight heparin (LMWH) and thrombo-embolic deterrent stockings (TEDS) until discharge
home. Patients were routinely mobilised with protected weight-bearing for six weeks, depending on the mechanical integrity of the femur as judged at time of surgery.

The type of femoral component removed at revision was cemented in 229 hips (57.7%), cementless in 149 (37.5%), and a hemi-arthroplasty in 19 hips (4.8%). The indications for revision are summarised in Table I. Intra-operative swabs and tissue histology were used to eliminate sepsis as a cause of loosening prior to administration of antibiotics.

In 330 (83.1%) hips, the acetabular component was also revised. All acetabular components which were introduced were cementless, with either a grit-blasted or HA porous-coated surface. A total of 332 operations (83.6%) were first revisions, 49 (12.4%) were second and 16 (4%) were third revisions. The bearing surfaces used are summarised in Table II.

The status of the femoral bone at surgery was classified according to the criteria of Paprosky et al. A total of 101 (25.4%) were type I, 219 (55.2%) type II, 74 (18.6%) type IIIA and three (0.8%) were type IIIB; there were none of type IV.

Reconstruction involved removal of implants and any cement or fibrous tissue, followed by intramedullary reaming to a size 1 mm larger than the diameter of the stem to be introduced. This was achieved first with flexible reamers, then with straight reamers to achieve good endosteal contact. The proximal femur was then prepared to a size that ingrowth would allow a stable host bed for the HA-coated sleeve. The proximal femur was then prepared to a size 1 mm larger than the diameter of the stem to be introduced. This was achieved first with flexible reamers, then with straight reamers to achieve good endosteal contact. The proximal femur was then prepared to a size that ingrowth would allow a stable host bed for the HA-coated sleeve. The proximal femur was then prepared to a size 1 mm larger than the diameter of the stem to be introduced. This was achieved first with flexible reamers, then with straight reamers to achieve good endosteal contact. The proximal femur was then prepared to a size that ingrowth would allow a stable host bed for the HA-coated sleeve.

Results

During the study period, 223 patients (60%, 233 hips) died, of which only one death (0.4%) was related to the operation. The mean time between the surgery and death was 9.1 years (0.4 to 18.6). Of those that died, 114 patients (30.7%, 122 hips) died before the minimum ten-year follow-up period. None of these patients underwent further revision surgery or had evidence of clinical or radiological failure. At their final review, the mean HHS score was 82.6 (22 to 100). According to Engh’s criteria, 225 stems (96.6%) in patients who had died were solidly ingrown and 213 (95.5%) of these patients reported satisfaction with the outcome of their surgery.
A total of 20 patients (5%) (20 hips) were lost to follow-up, of whom five declined to attend for review; three of these were dissatisfied and two were satisfied with the result. None of the remaining 15 patients were recorded in the Australian National Joint Replacement Registry\(^2\) as having undergone further revision surgery or died. These 20 patients were censored from the at-risk group in the survival analysis on the date of their last follow-up.

Clinical evaluation was available for 209 (221 hips) of the 237 surviving patients at a mean of 12.9 years (10 to 17.7). Of these, 121 patients (57.9%, 123 hips) were able to walk without aids and 67 patients (32%, 73 hips) used one or two walking sticks intermittently or at all times. We found that 104 patients (49.8%, 106 hips) could walk outdoors for longer than an hour and 44 patients (21.1%, 50 hips) were limited to walking for less than 30 minutes at a time. Only 23 patients (11%, 26 hips) were confined to walking indoors and three patients (1.4%, 4 hips) were bedridden. A total of 110 patients (52.6%, 112 hips) were functioning without restriction or doing heavy work and 64 patients (30.6%, 71 hips) were able to engage in light housework. A total of 62 patients (29.7%, 69 hips) were able to climb stairs normally, 72 patients (34.4%, 80 hips) needed support and six patients (2.9%, eight hips) were unable to climb stairs. In all, 89 patients (42.6%, 91 hips) were able to rise from a chair without support. Limitation in movement was felt by 104 patients (49.8%, 112 hips) to be related to their operated hip. Of the remainder, 46 patients (21.5%, 48 hips) were limited by the other lower limb and 59 patients (27.6%, 61 hips) by their general physical or medical condition.

A total of 188 patients (90%, 198 hips) reported increased function after their surgery and 184 (88%) patients (194 hips) took less medication for pain relief. The mean HHS improved from 58.7 (11 to 92) pre-operatively to 80.7 (21 to 100) at final follow-up (p < 0.001); 128 patients (61.2%, 132 hips) had a good or excellent result (score 80 to 100). The mean post-operative Merle d’Aubigné and Postel hip scores were 4.9 (2 to 6), 4.5 (2 to 6) and 4.3 (2 to 6) for pain, walking and mobility respectively. A total of 170 patients (81.3%, 174 hips) had no or mild thigh pain, whilst 137 patients (65.5%, 11 hips) had no or mild groin pain at final follow-up. The mean post-operative VAS score for pain was 1.2 (0 to 8.0). The mean post-operative VAS score for activity-related pain was 2.1 (0.0 to 9.0).

Radiographs were available for evaluation in 194 patients (82%, 205 hips) at a mean follow-up of 12.9 years (10 to 17.7). Heterotopic ossification was present in 100 patients (52%, 106 hips). In 81 patients (41.8%, 85 hips), this was Grade I or II; in 14 patients (7.2%, 15 hips) it was Grade III and in five patients (2.6%, six hips) it was Grade IV. The stems were in neutral alignment in 190 hips (92.7%). There was slight varus alignment in 12 hips (6.2%) and slight valgus alignment three hips (1.5%). The varus and valgus alignment was non-progressive in these 15 hips.

In 186 hips (90.7%), there were no radiolucencies around the proximal HA sleeve portion of the stem. In 13 hips (6.3%) there was one proximal zone of lucency and in six hips (2.9%) there was more than one proximal lucent zone. This most commonly involved zones 1 and 7 (16%). A radiolucent line was found around the distal aspect of the stem in 16 hips (8.2%). There was no osteolysis noted around 153 stems (7.4%). A osteolysis was noted proximally in 41 stems (20%) and distally in 11 stems (5.4%).

No osteolysis was seen when ceramic-on-ceramic bearings were used. A total of 21 hips (40%) of patients with osteolysis had a ceramic on ultra-high molecular weight polyethylene (UHMWPE) bearing, 18 hips (34.6%) had a metal on UHMWPE bearing, 11 hips (21.1%) a ceramic on cross linked polyethylene (XLPE) bearing and two hips (4%) a metal on XLPE bearing.

Cortical hypertrophy was observed around the stem in 23 hips (11.2%). This predominantly involved zone 3 and zone 5 in 22 of these patients (10.7%). In general, the quality of the femoral bone around the stem seemed to improve after several years of weight-bearing (Fig. 1). This was particularly notable in the areas below the ingrowth portion of the implant on the proximal sleeve. There was stress-shielding above these load bearing areas in 61 hips (29.7%) and 39 (19%) had stress shielding in zone 1; 21 hips (10.2%) had stress shielding in zone 7, three (1.5%) had stress-shielding in zone 2, and three (1.5%) had stress shielding in zone 6.

Endosteal spot welds were noted in 79 hips (38.5%). In 72 hips (35%), spot welds were observed at the inferior end of the HA-coated proximal sleeve. In the remaining patients, there was close apposition of bone to HA, suggesting the presence of a bone ingrowth interface. Only four hips (1.95%) showed clear demarcation around the entire HA-coated sleeve, suggesting that there was no ingrowth but stable fibrous fixation with no evidence of instability; two stems (1%) had migrated and were judged to be loose. A small reactive bony pedestal was noted in 17 hips (8.3%) at the tip of the stem, but did not appear to be associated with loosening. Using Engh’s criteria, 199 stems (97%), for which we have radiological evaluation at a minimum of ten-year follow-up, were judged to be ingrown bone. (Fig. 2).

A total of 83 hips (out of 397) (20.9%) had complications (Table III). Intra-operative fracture occurred in 29 hips (7.3%), with cerclage wiring used to stabilise the fracture in all cases. Late peri-prosthetic fracture (> three months) occurred in 12 hips (3.2%) at a mean of 6.8 years (0.3 to 15.9) post-operatively. All three acetabular fractures were treated non-operatively. Three femoral fractures required operative fixation. Revision of a loose femoral component to a longer one was required in one patient with a Vancouver B2 fracture\(^2\) that occurred 3.7 months post-operatively. All fractures united.

A total of 29 patients (7.3%, 29 hips) had a dislocation. The mean time to dislocation was 1.8 years (0.02 to 8.9); of these, ten hips (2.5%) required further revision. In four, the anteverision of the stem was changed; in two, both the
acetabular and femoral components were revised; in three, only the stem was revised, and in one only the acetabular component was revised. In these ten patients, the diameter of the modular head was increased from 28 mm to 32 mm in seven, and an elevated liner was used in four. No further dislocations occurred.

Infection occurred in eight patients (2%) (eight hips) at a mean of 4.7 years (0.2 to 14.5) post-operatively and of these, seven (1.8%) had deep sepsis; four were treated successfully, with two stage surgery and targeted antibiotic treatment, and three were treated with long-term antibiotics after debridement. A sciatic nerve palsy which presented four months after surgery, secondary to heterotopic ossification, resolved after excision and neurolysis. There was one fatal (0.3%) myocardial infarction, which occurred 48 hours after surgery. Of the 351 patients (377 hips) with a known outcome, 28 patients (7.8%) underwent a further revision. (Table IV).

The survival of the S-ROM stem at 15 years with revision for any reason as the endpoint was 90.5% (95% confidence interval (CI) 85.7 to 93.8) (Fig. 3), and with revision for aseptic loosening as the endpoint was 99.3% (95% CI, 97.2 to 99.8) (Fig. 4).

Discussion
Good results have been reported following the use of cementless fully porous-coated cylindrical stems in revision THR, but these results can be adversely affected by extensive meta-diaphyseal deficiency and a widened femoral canal. Proximal stress shielding has also been a concern, though fluted, tapered grit blasted stems which by-pass metaphyseal defects have been associated with remodelling of bony defects and recovery of bone stock at long-term follow-up. High rates of bony ingrowth, particularly in proximal areas of the femur have been reported following the use of extensively porous-coated modular stems, with good mid-term results.

Proximally porous-coated stems have been unpredictable in revision surgery. The porous-coated S-ROM has performed relatively well in mid-term reports but we have previously reported a high failure of bone ingrowth in patients with multiple proximal bony defects. Stems that rely on proximal fixation require excellent proximal bone contact for reliable bony ingrowth. Although the S-ROM stem was our implant of choice for all difficult revisions during the study period, it is now our current practice to bypass severe proximal femoral defects with a modular tapered cone-conical distal fit cementless stem.

HA is osteoconductive, inducing the formation of new bone onto its surface. The femoral bone loss present in most revisions may be seen as an indication to use HA-coated implants. Our results demonstrate that once a secure biological bond is formed between the implant and the host femur, it persists and does not appear to weaken.

Animal studies have shown that HA coating inhibits the peri-implant migration of particles of debris by creating a seal through enhanced bone ingrowth. The junction between the HA sleeve and the S-ROM stem theoretically acts in this way to exclude the lower part of the stem from the effective joint space, as long as there is bony ingrowth into the sleeve. This may explain why distal osteolysis was only present in 11 stems (5.4%).

We found that proximal osteolysis was present around 41 stems (20%) but we do not believe that this is a concern. Other types of dual modular femoral stems, where there is an additional junction between the body and neck of the stem, have a high rate of failure with evidence of corrosion, metal debris and severe adverse local tissue reactions. We have
no evidence of metal debris causing osteolysis in our study group, although we have identified products of corrosion at the stem-sleeve junction and head-neck taper in retrieved stems. In our experience, the metal debris seen at the stem-sleeve junction has not been of any clinical relevance.

Reports of proximal osteolysis when the S-ROM stem is used in primary THR, range from 18% to 58% at between 10 and 20 years follow-up.\textsuperscript{38,39} In our study 52 hips (25.4%) with radiographic results developed osteolysis. All of these hips had a polyethylene acetabular liner; 39 hips (75%) had a standard UHMWPE liner and 13 hips (25%) had a XLPE liner. The standard UHMWPE used was gamma irradiated-in-air, and was < 5 mm thick when coupled with a 32 mm head. No osteolysis was seen when ceramic-on-ceramic bearings were used. This may support our theory that fretting at the stem-sleeve junction of this component does not cause osteolysis.

Proximal stress-shielding, seen in 61 hips (29%), did not appear to affect the long-term outcome, which is in agreement with a previously published report of the use of this stem in primary THR.\textsuperscript{40} The incidence of thigh pain was low compared with other series involving cementless...
Our results represent those of a non-designer surgeon series from a single centre, with most operations performed by one surgeon. They suggest that proximal HA-coated fixation in conjunction with a modular stem is reliable and predictable for revision THR in the long-term.

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### Table IV: Indications for further revision

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References


