A knee-sparing distal femoral endoprosthesis using hydroxyapatite-coated extracortical plates

PRELIMINARY RESULTS

We used a knee-sparing distal femoral endoprosthesis in young patients with malignant bone tumours of the distal femur in whom it was possible to resect the tumour and to preserve the distal femoral condyles. The proximal shaft of the endoprosthesis had a coated hydroxyapatite collar, while the distal end had hydroxyapatite-coated extracortical plates to secure it to the small residual femoral condylar fragment. We reviewed the preliminary results of this endoprosthesis in eight patients with primary bone tumours of the distal femur. Their mean age at surgery was 17.3 years (14 to 21). The mean follow-up was 24 months (20 to 31). At final follow-up the mean flexion at the knee was 102˚ (20˚ to 120˚) and the mean Musculoskeletal Tumour Society score was 80% (57% to 96.7%).

There was excellent osteointegration at the prosthesis-proximal bone interface with formation of new bone around the hydroxyapatite collar. The prosthesis allowed preservation of the knee and achieved a good functional result. Formation of new bone and remodelling at the interface make the implant more secure. Further follow-up is required to determine the long-term structural integrity of the prosthesis.

The distal end of the femur is the most common site of primary malignant bone tumours in children. A better understanding of the process of the disease, combined with dramatic improvements in imaging techniques, adjuvant chemotherapy and advances in surgical technique, has allowed limb-salvage operations to be performed for patients with sarcomas.1-3

Limb salvage using a cemented distal femoral endoprosthesis is an accepted method of filling the defect created by resection of a primary bone tumour in the distal femur. It has, however, two important limitations. First, it entails prosthetic replacement of the knee and secondly, there is a high incidence of aseptic loosening.4 This is because the mechanical demands placed on a long prosthesis are large and muscle control is often compromised after a major soft-tissue resection.5 In young patients, the results of cemented distal femoral replacement have been poor, although better than the proximal tibial replacements as reported by Grimer et al.6 7 Animal and clinical studies have demonstrated the osteoconductive properties of HA with excellent results at six to eight years.6

Our use of HA-coated extracortical plates is based on the recent work of Coathup et al8 and Cobb et al.9 The former carried out a study using goats to investigate the effect of coating titanium alloy plates with HA. They found that the HA-coated plates enhanced fixation and encouraged integration of the plate with the load-bearing structure of the cortex. In animal studies, triplate fixation using three flexible slotted plates provided better early stability and achieved consistent longer term fixation.10 Cobb et al11 adopted triplate fixation as a method for revising a loose endoprosthesis around the knee. In their study, “the triplate design incorporated well within a remodelled cortex to achieve osteomechanical integration with all patients regaining their original level of function within five months.” It was suggested that these plates could be used if, after resection of a bone tumour, the residual segment was too short to accommodate an intramedullary stem.11

We have developed a knee-sparing distal femoral endoprosthesis with hydroxyapatite (HA)-coated extracortical plates at the distal end. These are screwed to the small distal femoral remnant and allow retention of the knee. HA is known to increase the attachment of metal implants to bone.6 7 Ingrowth of bone appears to be well advanced by three weeks,8 and a study has shown it to be more than 90% at eight years.9 Animal and clinical studies have demonstrated the osteoconductive properties of HA with excellent results at six to eight years.6

Our aim was to study the early clinical results of the knee-sparing distal femoral endo-
prosthesis in patients undergoing limb-salvage surgery for malignant bone tumours.

**Patients and Methods**

**Details of the patients.** After gaining the approval of the local ethical committee, eight patients had a knee-sparing distal femoral endoprosthesis inserted for primary non-metastatic bone tumour of the distal femur. All met the criteria for limb salvage as follows: a biopsy-proven malignant tumour of the distal femur requiring complete excision, no involvement of the popliteal neurovascular structures by the tumour, no invasion of the knee by the tumour either clinically or on MRI, no crossing of the physis by the tumour, and after transection of the distal femur at a safe margin, the presence of sufficient bone to allow safe triplate fixation of the prosthesis.

There were five males and three females with a mean age of 17.3 years (14 to 21). Six had a high-grade, non-metastatic osteosarcoma (Enneking stage IIB) while two had a high-grade chondrosarcoma (Enneking stage IIB).

The distal transection point was planned using the pre-operative MR scan. The original staging scans and post-chemotherapy scans were reviewed. In all cases the tumour was confined to the metaphyseal region and the epiphysis was judged to be free from tumour. The distal horizontal resection was sited 2 mm beneath the lowest part of the physis allowing complete excision of the tumour and sufficient distal bone to accommodate the prosthesis (Fig. 1).

**Design of the prosthesis and the extracortical plates.** Each implant was custom-made after the transection points proximally and distally had been decided. Stanmore Implants Worldwide Ltd (Stanmore, United Kingdom), a section of
the Centre for Biomedical Engineering of University College, London, manufactured the prostheses.

Proximal fixation of the implant was achieved with a stem which was either cemented or uncemented. In cases in which the intramedullary stem traversed the femoral isthmus, no cement was used. If the transection point was distal to the isthmus in the flare of the proximal femur, the stem was cemented. The proximal shaft of the prosthesis had a HA collar.

The HA-coated distal flat surface of the implant fitted precisely on the large flat surface of the transected distal femoral condyle. Distal fixation to the small fragment of the femoral condyle was augmented with HA-coated extracortical plates (Figs 2 and 3). These were screwed into the bone of the medial and lateral femoral condyles. Bicortical screws were inserted through the plates to achieve as much grip as possible on the remaining distal femur. The HA-coated plates were slotted to increase the surface area for bony ingrowth and to retain the vascularity of the underlying bone. The plates were 12 mm wide and of tapering thickness, starting at 3 mm at the base and reducing to 2 mm towards the tip. All the plates were applied close to the knee since the remaining length of the femoral condyles after resection of the tumour was less than 5 cm. The mean length of the remaining condyles (the distance between the distal transection site and the knee joint line) was 35.6 mm (21 to 43; Table I). The mean plate length of 32 mm (14 to 38) provided stable fixation (Fig. 4). In a number of cases, small internal plates and keels were used to enhance fixation in the cancellous bone. The internal plates were orientated so that they abutted the internal cortical wall as closely as possible. The cortical surface of the extracortical plates, the internal plates and the keels were coated with HA.

For one patient (case 6; Table I) the endoprosthesis included a non-invasive expandable component controlled by computer-assisted design diagrams showing the knee-sparing distal femoral endoprosthesis (Fig. 2). Photographs of the knee-sparing distal femoral endoprosthesis (Fig. 3).
by a recently described electromagnetic induction mechanism.\textsuperscript{13,14}

**Operative technique.** A tourniquet was used, provided that it did not compromise the surgical field. The resection was performed using a standard technique which aimed to obtain a complete excision. The proximal transection point was 2 mm above the tumour and the distal transection described. The prosthesis was fixed proximally using a cemented or an uncemented intramedullary stem and distally using the HA-coated extracortical plates. At the end of the procedure the wound was irrigated with 3 l of normal saline and two drains were used. Post-operatively, the patients had early active and passive physiotherapy and continuous passive movement. They were allowed to walk

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**Table I. Details of the eight patients with tumour of the distal femur**

<table>
<thead>
<tr>
<th>Case</th>
<th>Gender</th>
<th>Age (yrs)</th>
<th>Reason for insertion</th>
<th>AB\textsuperscript{*}</th>
<th>Follow-up (mths)</th>
<th>Range of movement (˚)</th>
<th>MSTS\textsuperscript{†} score (%)</th>
<th>Outcome complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>21</td>
<td>Osteosarcoma</td>
<td>39</td>
<td>24</td>
<td>0 to 120</td>
<td>27 (90)</td>
<td>Septicaemia, recovered</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>16</td>
<td>Osteosarcoma</td>
<td>21</td>
<td>20</td>
<td>10 to 110</td>
<td>26 (57)</td>
<td>20˚ flexion for conventional DFR\textsuperscript{‡}</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>16</td>
<td>Osteosarcoma</td>
<td>42</td>
<td>31</td>
<td>0 to 110</td>
<td>29 (96.7)</td>
<td>Non-invasive extendable implant lengthened to 46 mm</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>17</td>
<td>Osteosarcoma</td>
<td>27</td>
<td>21</td>
<td>0 to 20</td>
<td>30 (66.7)</td>
<td>Non-invasive extendable implant lengthened to 46 mm</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>19</td>
<td>Osteosarcoma</td>
<td>36</td>
<td>26</td>
<td>5 to 120</td>
<td>21 (70)</td>
<td>Non-invasive extendable implant lengthened to 46 mm</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>14</td>
<td>Osteosarcoma</td>
<td>41</td>
<td>24</td>
<td>5 to 110</td>
<td>26 (87)</td>
<td>Non-invasive extendable implant lengthened to 46 mm</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>15</td>
<td>Chondrosarcoma</td>
<td>43</td>
<td>22</td>
<td>0 to 110</td>
<td>24 (80)</td>
<td>Non-invasive extendable implant lengthened to 46 mm</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>20</td>
<td>Chondrosarcoma</td>
<td>36</td>
<td>22</td>
<td>0 to 120</td>
<td>28 (93.3)</td>
<td>Non-invasive extendable implant lengthened to 46 mm</td>
</tr>
</tbody>
</table>

\textsuperscript{*}AB, length of the remaining epiphysis measured to the joint line

\textsuperscript{†}MSTS, musculoskeletal tumour society

\textsuperscript{‡}DFR, distal femoral replacement

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**Diagram of the knee-sparing distal femoral endoprosthesis.** The design plates and their orientation were based on implants used in the goat model and achieved using computer-aided techniques based on radiological measurements. The mean plate length of 32 mm provided stable fixation in the metaphysis (HA, hydroxyapatite).
A KNEE-SPARING DISTAL FEMORAL ENDOPROSTHESIS USING HYDROXYAPATITE-COATED EXTRACORTICAL PLATES

1371

partially weight-bearing for six weeks and were then allowed to bear weight fully. Post-operative chemotherapy was instituted in accordance with the current protocol.

The patient with the non-invasive extendable prosthesis had lengthening once a leg-length discrepancy greater than 0.5 cm had occurred. The prosthesis was extended every four to six weeks in out-patients to match the growth of the contralateral limb.

All patients were evaluated at regular intervals both clinically and radiologically. Plain radiographs were taken to document the evolution of the implant-bone interface and functional assessment was carried out using the scoring system of the Musculoskeletal Tumour Society.

Results

All wounds healed well and each patient was fully weight-bearing after six weeks.

Each patient was functionally assessed using the Musculoskeletal Tumour Society scoring system at their last follow-up at a mean of 24 months (20 to 31) after surgery. The mean knee flexion was 102˚ (20˚ to 120˚) and the mean Musculoskeletal Tumour Society score was 80% (57% to 96.7%).

One patient (case 4) developed a stiff knee with flexion of only 20˚ which was resistant to physiotherapy. Manipulation under anaesthesia failed to improve movement substantially and open arthrolysis was carried out. Flexion did not improve after surgery and the patient is currently being considered for conversion to a conventional distal femoral replacement.

Another patient (case 2) developed septicaemia two weeks after surgery as a result of a chemotherapy-induced neutropenia. She recovered completely and achieved a range of movement of 0˚ to 80˚.

The patient with the non-invasive extendable prosthesis had lengthening of 46 mm without complications.

There were no cases of fracture of the stem, failure of the implant, aseptic loosening, infection, recurrence of the tumour or amputation.

Plain radiography showed progressive osteointegration of the prosthesis at the proximal prosthesis-bone interface with formation of new bone in the region of the HA-coated collar (Fig. 5).

Discussion

Hydroxyapatite is a bioactive ceramic which has been shown to be osteoconductive, both in vivo and in vitro. HA coating for cementless fixation of massive endoprostheses is thought to be successful in the short term.

Extracortical plate fixation is an alternative method by which a prosthesis may be fixed securely to bone. It has the advantage that it appears to allow incorporation of the prosthesis into the load-bearing structure of the bone as it remodels. It takes advantage of the biological phenomenon shown by callus at a fracture, in which bone is laid down outside the cortex. Bone forms on the periosteal surface in a centripetal fashion incorporating the plates into the newly expanded cortex. Three important features facilitate this incorporation: 1) slots within the plates, which increase the surface area for fixation; 2) plates of different lengths and tapering thickness which allow a gradual transfer of load; and 3) HA coating on both surfaces of the plates and collar of the implant using a plasma spray process which increases the strength of fixation.

Screws locking the plates to both cortices provide significantly better fixation in the short term. We believe that six bicortical screws (12 anchorage points) are the optimum number needed to provide sufficient initial stability to the endoprosthesis. The operative technique is straightforward. We use a standard method to resect the tumour which ensures complete excision. There is still debate amongst orthopaedic oncologists about the width of tumour free margin following excision of malignant bone tumours. In the United Kingdom it is accepted practice to try to achieve a margin of 2 cm, but this is based only on convention. In

Fig. 5

Radiograph showing osteointegration of the prosthesis at the prosthesis-proximal bone interface with formation of new bone visible in the region of the hydroxyapatite collar (inset).
adolescents, the physis of the distal femur seems to act as a better barrier to the tumour than cancellous bone. It is possible therefore that much narrower margins in the region of the physis are as safe as the conventional margin of 2 cm. Minimal additional soft-tissue dissection is required at the distal end of the femur to obtain adequate exposure of the bone for the fixation of extracortical plates. The medulla is not violated at all, thereby preserving the intra-osseous blood supply. The application of extracortical plates may disrupt the periosteal blood supply to the remaining bone and lead to cortical necrosis. However, our study showed radiological evidence of formation of new bone, implying that the viability of the bone was not significantly impaired.

In our study, one patient developed a flexion contracture of the knee, which was resistant to physiotherapy, manipulation under anaesthesia and arthroscopy. We feel that this was due either to the presence of the extracortical plates causing soft-tissue irritation and stimulating fibrosis and adhesions, or to stimulation of the soft-tissue adhesions by the HA coating on the distal end of the prosthesis and leading at the extracortical plates, which makes the interface more secure with time. They have extended the use of HA-coated extracortical plates into areas where a failed conventional prosthesis leaves insufficient bone for secure fixation.

Our preliminary results have been encouraging. The prosthesis allows preservation of the knee and achieves good functional results. New growth and remodelling of bone at the interface make the implant more secure. We now need to follow these patients closely to determine the long-term structural integrity of the prosthesis.

References