Modular endoprosthetic replacement for tumours of the proximal femur

Endoprosthetic replacement of the proximal femur may be required to treat primary bone tumours or destructive metastases either with impending or established pathological fracture. Modular prostheses are available off the shelf and can be adapted to most reconstructive situations for this purpose. We have assessed the clinical and functional outcome of using the METS (Stanmore Implants Worldwide) modular tumour prosthesis to reconstruct the proximal femur in 100 consecutive patients between 2001 and 2006. We compared the results with the published series for patients managed with modular and custom-made endoprosthetic replacements for the same conditions.

There were 52 males and 48 females with a mean age of 56.3 years (16 to 84) and a mean follow-up of 24.6 months (0 to 60). In 65 patients the procedure was undertaken for metastases, in 25 for a primary bone tumour, and in ten for other malignant conditions. A total of 46 patients presented with a pathological fracture, and 19 presented with failed fixation of a previous pathological fracture. The overall patient survival was 63.6% at one year and 23.1% at five years, and was significantly better for patients with a primary bone tumour than for those with metastatic tumour (82.3% vs 53.3%, respectively at one year (p = 0.003)). There were six early dislocations of which five could be treated by closed reduction. No patient needed revision surgery for dislocation. Revision surgery was required by six (6%) patients, five for pain caused by acetabular wear and one for tumour progression. Amputation was needed in four patients for local recurrence or infection.

The estimated five-year implant survival with revision as the endpoint was 90.7%. The mean Toronto Extremity Salvage score was 61% (51% to 95%). The implant survival and complications resulting from the use of the modular system were comparable to the published series of both custom-made and other modular proximal femoral implants.

We conclude that at intermediate follow-up the modular tumour prosthesis for proximal femur replacement provides versatility, a low incidence of implant-related complications and acceptable function for patients with metastatic tumours, pathological fractures and failed fixation of the proximal femur. It also functions as well as a custom-made endoprosthetic replacement.

The proximal femur is a common site for primary bone tumours and the most common long bone to be affected by metastases.1,2 The use of endoprostheses for the treatment of primary malignant tumours of the proximal femur is well-recognised, and they are now also commonly used in the treatment of metastatic disease. The original endoprostheses were custom-made which caused some delay in treatment. Modular implants being readily available, have become popular and are especially useful for patients with pathological fractures caused by metastases. Many pathological fractures of the proximal femur will not heal, either as a result of the disease process itself or because of the use of radiotherapy. In patients with a good life expectancy and destruction of the upper femur, an endoprosthetic replacement is a sensible option both functionally and oncologically.

The overriding principles in treating any pathological fracture due to metastasis are that the fracture should be managed in such a way that the patient is able to resume near normal function as soon as possible, and that whatever implant is required, it should outlast the patient. The advantage of prosthetic replacement over internal fixation is that it allows removal of the tumour, thereby minimising the risk of further tumour-related problems such as nonunion and tumour progression.2,3 The main potential complications
are local recurrence, infection, aseptic loosening, mechanical failure and fracture of the prosthesis or bone.4-6 There are many publications on the use of custom and modular proximal femoral endoprosthetic replacements.7-11 We used custom-made endoprosthetic replacements for tumours of the proximal femur between 1970 and 2000 and the METS modular proximal femoral endoprosthetic replacement system (Stanmore Implants Worldwide, Stanmore, United Kingdom) since then.12

The aim of this study was to investigate whether we could identify any difference in the outcome between patients who had a modular prosthesis and those whose endoprosthetic replacement was custom-made.

Patients and Methods

Between 2001 and 2006, 100 consecutive patients underwent resection of the proximal femur and modular endoprosthetic replacement with a mean follow-up of 24.6 months (0 to 60). All had appropriate staging studies, including an MR scan of the pelvis and the proximal femur. CT scans were used as needed to identify the extent of acetabular involvement and to plan the type of acetabular reconstruction.

All operations were carried out at a single institution (The Royal Orthopaedic Hospital, Birmingham). Adjuvant chemotherapy was administered where appropriate, according to nationally-agreed protocols at the patient’s local oncology unit. Patient, tumour, treatment and outcome data for all cases were prospectively entered into a database.

There were 52 males and 48 females with a mean age of 56.3 years (16 to 84). The indications for surgery are shown in Table I. A total of 46 patients presented with a pathological fracture, and 19 with metastases presented with failed fixation after a previous fracture (Fig. 1).

All the modular prostheses were designed and manufactured by Stanmore Implants Worldwide. This modular system provides a choice of different femoral head sizes, trochanteric reattachments, femoral component shaft size, and length. There is also an option to use a polished or a hydroxyapatite-coated collar at the bone-prosthesis junction in the expectation that there will be osseointegration with the prosthesis.

Each operation was performed in a clean-air theatre. Antibiotic prophylaxis was given at the time of surgery and for up to 24 hours post-operatively. The tumour resection was carried out following oncological principles, endeavouring to achieve a wide margin of resection for primary tumours. For patients with a secondary tumour, a pathological fracture and possible involvement of the hip joint, a palliative reconstruction was carried out avoiding extra-articular resection. Surgery was performed in the lateral position through a longitudinal incision, which excised the biopsy track. The appropriate portion of the proximal femur was resected. Patients who needed a proximal femoral replacement but whose disease spared the greater trochanter, underwent osteotomy of the trochanter and subsequent reattachment to the endoprosthesis with the trochanteric reattachment plate and screws or cable-grip wires. If it was not possible to preserve the greater trochanter the abductor mechanism was sutured to vastus lateralis and the fascia lata. Trial components were used to select the appropriate size of components to restore limb length and stability. The femoral head was either replaced with a monopolar head or acetabular replacement was undertaken, depending on the state of the acetabulum. A monopolar head was preferred when the reconstruction was for pathological fracture secondary to metastatic disease and when there was no acetabular involvement, whereas a cemented acetabular component was used in
patients with either degenerative change in the hip joint or with possible tumour involvement of the acetabulum. The components were cemented, using low-viscosity antibiotic-containing cement, introduced with a gun.

After surgery, patients were mobilised partially weight-bearing, and progressed to full weight-bearing by the time of discharge at two weeks. After six weeks they returned for a period of intensive inpatient physiotherapy. They were then followed up with three-monthly appointments for two years, and six-monthly thereafter.

The radiographs of patients who were still alive after 18 months were analysed using the International Society of Limb Salvage (ISOLS) protocol. Functional assessment of the surviving patients was assessed using the Toronto Extremity Salvage Score (TESS) questionnaire, which is a validated patient-completed assessment of function.

We analysed patient and prosthesis survival, the risk of revision of the prosthesis, the incidence of failure of limb salvage because of amputation, and complications including dislocation and infection. We used Kaplan-Meier survival curves to assess the failure rate of the prostheses. We also compared these outcomes with the published results of custom-made and modular proximal femoral replacements.

Results
A total of 91 patients had the hip joint replaced with a prosthesis carrying a unipolar femoral head, and nine had an acetabular replacement. We used large monopolar heads in 60 of 65 patients (92%) who had metastatic disease of the femur without acetabular involvement. Three young patients had a metal-on-metal hip replacement with a large femoral head, hybridising the METS prosthesis with Modular Birmingham Hip Resurfacing components (Smith and Nephew, London, United Kingdom): six had a cemented polyethylene acetabular component with a 28 mm diameter metal head. The mean length of femoral resection was 9.2 cm (4.5 to 21) and each patient had a cemented 15 cm intramedullary femoral component (Fig. 2). A total of 45 patients had a hydroxyapatite-coated collar.

There were two peri-operative deaths due to pulmonary embolism in elderly patients who had been on prolonged bed rest prior to surgery: a further three patients had a non-fatal pulmonary embolus at a later date. There were six post-operative dislocations of the hip, of which three occurred in the patients who had an acetabular reconstruction with a 28 mm diameter femoral head and a polyethylene acetabular component. The other three dislocations occurred in the 91 patients with a unipolar femoral head. The dislocations were managed by closed reduction in five patients; one patient required an open reduction. No acetabular component needed to be revised.

Deep infection occurred in six patients (7%): five were early (within three months of surgery) and one late (after three months). These were treated successfully in four patients by wound debridement and antibiotics, but the other two eventually required amputation, one due to infection alone and the other due to a combination of infection and local recurrence. None of the 11 patients who received radiotherapy developed a deep infection.

Local recurrence occurred in ten patients (11%), three in the nine patients with chondrosarcoma, two in the five patients with osteosarcoma, and five in the 65 patients with metastatic tumours. Local recurrence was more common in patients with a previous pathological fracture (eight patients 17% vs two patients 4%). Of these, six had palliative treatment because of widespread disease, two with metastases underwent a more extensive reconstruction, and two patients with primary tumours had an amputation as did one patient with extensive recurrence of renal cell carcinoma. In all, four patients had an amputation: three hindquarter (one for infection and local recurrence, one for local recurrence and one for intralesional excision of extraskeletal Ewing’s sarcoma) and one hip disarticulation for infection. The overall limb salvage rate was 96%.

Revision was required in six patients (7%). In one this was due to the result of local recurrence and acetabular erosion, in four conversion of the monopolar head for pain and one patient needed revision to a total femoral replacement for tumour progression. The use of a large monopolar head in 60 of 65 patients (92%) resulted in two patients needing further surgery for acetabular erosion. The one- and five-year survival of the implant was 94.9% and
18 months were analysed according to the ISOLS protocol. A total of four patients died within a month of the operation: 55 survived more than 12 months. The median survival was 21 months (0 to 60), and overall patient survival was 63.6% at one year and 23.1% at five years. Patients with primary tumours had significantly better survival at one and five years than did those with secondary tumours (82.3% vs 53.3% at one year and 44.2% vs 12.9% at five years) (log-rank test, p = 0.003).

The radiographs of 37 patients who survived for more than 18 months were analysed according to the ISOLS protocol. Greater trochanter-related problems were seen in seven patients, with proximal migration in three, broken wires in two and heterotopic calcification in two. Only one patient showed features of aseptic loosening at two years. No other patient had any adverse features on the radiographs.

The functional assessment questionnaire (TESS score) was sent to all 27 surviving patients, of whom 15 returned the completed questionnaire. The mean TESS score was 61% (51 to 95). The mean TESS score for the patients with a primary bone tumour was 74% (54 to 94), and 54 (52 to 88) for patients with metastatic bone tumours.

### Discussion

Limbsalvage using proximal femoral endoprosthetic replacement, allografts and allograft prosthesis composites has been extensively reported. The long-term results of custom-made proximal femoral replacement have shown that implant survival without revision is 77% at ten years and 57% at 20 years. Custom-made implants are not available at short notice, and it is undesirable to delay the treatment of patients with pathological fractures and those in whom trauma implants have failed because of the increased morbidity caused by enforced bed rest. For this reason, and based on extensive experience in the use of custom-made endoprostheses, Stanmore Implants Worldwide introduced the METS prosthesis for the proximal femur in 2001.

Patients with metastatic tumours of bone formed 65% of the present series, and most had an impending or established pathological fracture. By contrast, primary bone tumours have constituted the major indication for proximal femoral replacement in most published series. The success of a prosthesis is judged by its ability to provide a solid, functioning joint without complications for the remainder of that patient’s life. This was achieved in 68 of our 70 patients (97%) who died with the implant in situ.

The problem of infection following proximal femoral replacement has been highlighted by several authors: the infection rate ranges from 1.2% to 19.5% (Table II). The rate of infection in the present series was 6%, which is comparable to the incidence of 6.3% reported by Menendez et al using a modular prosthesis in a series of 96 patients, but considerably lower than the 19.5% reported by Goshger et al in 41 patients. They attributed their high infection rate to four patients who needed post-operative radiotherapy after resection of Ewing’s sarcoma. Radiotherapy has been reported as a significant risk factor for infection of an endoprosthetic replacement. However, in our series 11 patients received radiotherapy and none developed a deep infection.

Dislocation is a well-recognised complication of proximal femoral replacement, with rates varying from 1.7% to 20%. This is attributed to the extensive resection of soft tissues around the hip, which include the muscles and hip capsule in most cases. It is difficult to repair both the capsule and the abductor lever arm. Most authors have reported a high dislocation rate with the use of a small-diameter femoral head, and the use of a larger head size in an attempt to avoid this problem seems sensible. Our dislocation rate of 6% is comparable to that of other reported series (Table II). We have previously reported a dislocation rate of 17% in a series of 54 patients with primary bone tumours treated with custom-made implants. The use of a large-diameter monopolar femoral head gave good results, with only three dislocations from 91 patients with this type of reconstruction. Three of the nine patients who were reconstructed with a small head and an acetabular component implanted had a dislocation. We used a

### Table II. A comparison of complications and implant survival of the published series of custom and modular proximal femoral endoprosthetic replacement with the present series

<table>
<thead>
<tr>
<th>Author</th>
<th>Infection (%)</th>
<th>Local recurrence (%)</th>
<th>Dislocation (%)</th>
<th>Revision (%)</th>
<th>5-year survival (%)</th>
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<td>Kabukcuoglu (custom)</td>
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<td>11</td>
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<tr>
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<td>4.5</td>
<td>6.1</td>
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<tr>
<td>Goshger (modular)</td>
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<td>7.3</td>
<td>78.7</td>
<td></td>
<td></td>
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<tr>
<td>Menendez (modular)</td>
<td>6.3</td>
<td>10.4</td>
<td>82</td>
<td></td>
<td></td>
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<tr>
<td>Present series (modular)</td>
<td>6</td>
<td>4</td>
<td>6</td>
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<td>90.7</td>
</tr>
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</table>

* had revision surgery

90.7%, with revision as the endpoint. The one- and five-year implant survival for secondary tumours was 100% and 93.8%, and the one- and five-year implant survival for primary tumours was 90.9% and 87.4%.

A comparison of complications and implant survival of the published series of custom and modular proximal femoral endoprosthetic replacement with the present series
large monopolar head in 60 of 65 patients (92%) with metastatic disease of the proximal femur, and only two of the 60 (3%) needed further surgery for acetabular erosion, indicating that large monopolar heads can safely be used in patients with metastatic disease without acetabular involvement. Although large diameter monopolar heads were used in this series specifically to reduce the risk of dislocation, we have reported a significant risk of later revision secondary to acetabular erosion, especially in younger patients with primary tumours. In order to address this we now use either a bipolar or a total hip reconstruction using a metal-on-metal or an un cemented acetabular component in younger patients with primary bone tumours who have had no previous radiotherapy. We recommend a cemented acetabular component in patients who have had radiotherapy.

Aseptic loosening is a well-recognised complication with the use of custom-made and modular implants. We have used hydroxyapatite-coated collars for patients with anticipated long-term survival to reduce the risk of aseptic loosening. This has been shown to be very effective for both distal femoral and proximal tibial replacements. Long-term follow-up will be needed to establish whether this is equally effective for proximal femoral replacements.

The justification for using a proximal femoral replacement is debatable given the one-year mortality rate of 36%. For a patient with metastatic disease of the proximal femur, often with pathological fracture and failed fixation, surgery, despite its inherent risks, is often a better option than bed rest, palliation and radiotherapy. It is for the patient to make an informed choice based on the recommendations of the multidisciplinary team. The patients who died within the first year had a stable, pain-free proximal femur which afforded them some mobility during the last few months of their lives.

The overall risk of amputation after modular proximal femoral replacement in this series was 4%, and was related directly to the rate of local recurrence as well as to the risk of infection.

We conclude that modular proximal femoral replacement has fulfilled its aim of providing reasonable function with a low rate of complications. Careful attention to the type of hip replacement used should further reduce the risk of complications such as dislocation and wear.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


