Proximal humeral replacement using a fixed-fulcrum endoprosthesis

Between 1997 and 2007, 68 consecutive patients underwent replacement of the proximal humerus for tumour using a fixed-fulcrum massive endoprosthesis. Their mean age was 46 years (7 to 87). Ten patients were lost to follow-up and 16 patients died. The 42 surviving patients were assessed using the Musculoskeletal Tumor Society (MSTS) Score and the Toronto Extremity Salvage Score (TESS) at a mean follow-up of five years and 11 months (one year to ten years and nine months). The mean MSTS score was 72.3% (53.3% to 100%) and the mean TESS was 77.2% (58.6% to 100%).

Four of 42 patients received a new constrained humeral liner to reduce the risk of dislocation. This subgroup had a mean MSTS score of 77.7% and a mean TESS of 80.0%. The dislocation rate for the original prosthesis was 25.9; none of the patients with the new liner had a dislocation at a mean of 14.5 months (12 to 18).

Endoprosthetic replacement for tumours of the proximal humerus using this prosthesis is a reliable operation yielding good results without the documented problems of unconstrained prostheses. The performance of this prosthesis is expected to improve further with a new constrained humeral liner, which reduces the risk of dislocation.

The proximal humerus is the third most common site for primary sarcoma of bone, and also a common site for metastatic lesions. The options for reconstruction include osteoarticular allograft, allograft-prosthesis composite, a sling procedure with a vascularised fibular graft, clavicula pro humero and endoprosthetic replacement of the proximal humerus.1-6 Most replacements of the proximal humerus act as functional spacers rather than as an articulating reconstruction. As part of the wide excision of the proximal humerus the rotator cuff is detached, the tendons of pectoralis major, latissimus dorsi and teres major are divided, and the axillary nerve is sometimes sacrificed. As a result, unconstrained proximal humeral endoprosthesis tend to sublux (Fig. 1), leading to wear of the glenoid and acromion, pain, and poor function.7-10 In order to prevent this complication we developed a constrained, fixed-fulcrum endoprostheses. It was designed by biomechanical engineers and surgeons and is now the standard method of reconstruction in our bone tumour unit. We here report our ten-year experience.

Patients and Methods
All patients in this study underwent the following standard staging investigations. MRI was used to determine the anatomy of the tumour and a core needle biopsy was obtained to confirm the histological diagnosis. We used CT scans of the chest and a technetium bone scan to identify distant metastases in those patients with malignant disease. All patients were discussed in a multidisciplinary team setting in accordance with NICE guidelines.11 Patients deemed suitable for proximal humeral replacement included those with primary malignant tumours who were suitable for limb salvage surgery, those with locally aggressive benign tumours which were deemed suitable for proximal humeral replacement, those with metastatic lesions in the proximal humerus where replacement was appropriate according to British Orthopaedic Association guidelines.12 Exclusion criteria were tumours involving the shoulder joint and requiring extra-articular resection13 and tumours which were not amenable to limb-salvage surgery, e.g. those that involved significant neurovascular structures.

Between March 1997 and February 2007, 68 patients fulfilling these criteria underwent proximal humeral replacement. The range of diagnoses of the tumours is shown in Table I. A total of 64 patients received the original ‘unconstrained’ design of glenohumeral articulation.
and four received the more constrained design. Post-operatively, they were routinely reviewed up every three months for two years, then six-monthly until year five and yearly until year ten. Ten patients were lost to follow-up and 16 died, leaving 42 in the study. Their mean age at presentation was 46 years (7 to 87). The mean age of those presenting with primary bone tumours was 38 years (7 to 77) and of those with metastatic lesions was 53 years (21 to 87). There were 38 males and 30 females in the original cohort, and 23 males and 19 females in the 42 patients at the end of the study. Clinical examination was performed and plain radiographs of the whole humerus and chest were obtained at each visit. Outcome data included survival, local recurrence, surgical complications and function as assessed by the Musculoskeletal Tumor Society (MSTS) and Toronto Extremity Salvage (TESS) scores.14,15 The former assigns numerical values (0 to 5) for each of six categories: pain, function, emotional acceptance, hand positioning, dexterity and lifting ability (Table II). A percentage rating is calculated to allow for comparison of results. The TESS evaluates physical disability on the basis of the patient’s report of function. It comprises 32 questions to assess the activities of daily living. As the axillary nerve was sacrificed in a large proportion of patients, we decided not to use a measurement of range of movement of the shoulder, and instead focus on function scores.

**Table I. Tumour diagnoses at presentation**

<table>
<thead>
<tr>
<th>Tumour Type</th>
<th>Count</th>
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<tbody>
<tr>
<td>Metastasis</td>
<td>26</td>
</tr>
<tr>
<td>Chondrosarcoma</td>
<td>14</td>
</tr>
<tr>
<td>Osteosarcoma</td>
<td>11</td>
</tr>
<tr>
<td>Giant cell tumour</td>
<td>3</td>
</tr>
<tr>
<td>Myeloma</td>
<td>2</td>
</tr>
<tr>
<td>Malignant fibrous histiocytoma</td>
<td>2</td>
</tr>
<tr>
<td>Osteoclastoma</td>
<td>2</td>
</tr>
<tr>
<td>Ewing’s sarcoma</td>
<td>1</td>
</tr>
<tr>
<td>Aneurysmal bone cyst</td>
<td>1</td>
</tr>
<tr>
<td>Leiomyosarcoma</td>
<td>1</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>1</td>
</tr>
<tr>
<td>Chondroblastoma</td>
<td>1</td>
</tr>
<tr>
<td>Plasmacytoma</td>
<td>1</td>
</tr>
<tr>
<td>Spindle-cell sarcoma</td>
<td>1</td>
</tr>
<tr>
<td>Benign fibrous histiocytoma</td>
<td>1</td>
</tr>
</tbody>
</table>

**Endoprosthesis.** The Bayley-Walker proximal humeral replacement endoprostheses were manufactured by Stanmore Implants Worldwide Ltd (Elstree, United Kingdom). Before August 2006 they were all custom-made. Thereafter, a Modular Endoprosthetic Tumour System was introduced alongside the custom-made endoprostheses. The captive ball and socket mechanism was identical for both. The glenoid component consists of a ball on a tapered screw for fixation into the scapula. The humeral component has a shaft with a cup and polyethylene liner that ‘snap fits’ over the glenoid component to produce a constrained, reverse-polarity fixed-fulcrum type of replacement (Fig. 2).

The glenoid screw is coated with hydroxyapatite (HA), as is the collar of the humeral component. The dimensions of the humeral component were determined from antero-posterior and lateral radiographs of the humerus marked
with the intended transection point. The first prototype had an unacceptable dislocation rate, and so in August 2006 an extra constraint was added to the glenohumeral articulation in the form of an ‘O’ ring, which renders the head entirely captive within the cup in a similar way to captive acetabular components used in arthroplasty of the hip. This constrained version was used in four shoulders. An expandable version of this same design was used in five skeletally immature patients. Two skeletally immature patients received a minimally invasive growing prosthesis. Both underwent a lengthening procedure until equality of limb length was achieved.

Three patients developed a local recurrence of the tumour which led to forequarter amputation. In two of these the arm was analysed histologically to assess osseo-integration between the HA-coated implants and the host bone. Operative procedure. A deltopectoral approach was used, with excision of the biopsy track. A wide excision of the proximal humerus was carried out employing the usual principles applicable to tumour surgery. The glenohumeral joint was disarticulated by dividing the long head of biceps as well as the tendinous portion of the rotator cuff. The shaft of the humerus was transected 2 cm distal to the inferior extent of tumour, as determined by the MRI scans. The tendons of pectoralis major, latissimus dorsi, teres major and the long head of biceps were detached. A cuff of normal soft tissue was retained around the proximal humerus so as to complete the ‘wide excision’. Where possible, the axillary nerve was preserved in order to maintain deltoïd function.

Once the tumour has been excised, haemostasis was achieved. The glenoid and remaining humerus were prepared to accept the endoprosthesis. A guide wire was inserted into the glenoid over which a cannulated reamer was used to create a thread for the uncemented glenoid component. The humeral canal was reamed to accept the stem of a trial endoprosthesis, and a trial reduction was performed. The definitive implant was then cemented into place and the humeral component was ‘snap-fitted’ over the glenoid ball. Great care was then taken to reconstruct the soft tissues around the endoprosthesis using non-absorbable sutures inserted via the holes in the head and shaft of the endoprosthesis. As part of the tumour resection the axillary nerve was sacrificed in 45 of the 58 patients (78%) that we were able to follow-up (35 (83%) of the 42 surviving patients). In one case the radial nerve was sacrificed.

Post-operatively the arm was placed in a poly sling with the shoulder held in 45° degrees of abduction with an adjustable bolster. Initially only the hand, wrist and elbow were mobilised. After six weeks the sling was removed and passive mobilisation began, progressing to active movements at 12 weeks.

Results
The mean follow-up was five years 11 months (one year to ten years and nine months). Statistical significance was calculated using Student’s t-test. The mean MSTS score for the 42 patients at follow-up was 72.3% (53.3% to 100%) and the mean TESS was 77.2% (58.6% to 100%). Certain subgroups had better or worse function than others. Those with benign tumours (six patients) had a mean MSTS score of 77.2% (63.3% to 93.3%), compared with a mean score of 71.4% (53.3% to 100%) in patients with malignant tumours (p = 0.30). Those in whom the axillary nerve was sacrificed (35 patients) had a mean MSTS score of 71.3% (53.3% to 93.3%) compared with a score of 77.1% (60% to 100%) in those patients in whom it was preserved (p = 0.32). The subgroup of four patients who received the new constrained liner had a mean MSTS of 77.7% (73.3% to 86.7%) compared with 71.8% (53.3% to 100%) in the other 38 patients available for follow-up (p = 0.42). The skeletally immature patients (three) had a mean MSTS score of 56.7% (54.1% to 59.0%) compared with 71.8% (53.3% to 100%) in the other 38 patients available for follow-up (p = 0.42). There were two deep infections (4.8%), both of which were successfully treated with intravenous antibiotics combined with a two-stage revision. Two patients developed a neuropraxia of the radial nerve which recovered.

A total of 14 patients who were implanted with the original glenohumeral articulation suffered dislocations (25.9%). Closed reduction was attempted but was unsuccessful in each case. Open reduction was performed in four patients, and in ten patients who were minimally symptomatic, the dislocation was left untreated and the endoprosthesis allowed to act as a functional spacer. None of the
patients given the modified constrained liner had a dislocation after a mean of 14.5 months (12 to 18).

**Histopathology.** Clear margins were obtained in 61 of 68 patients (89.7%). Six patients developed a local recurrence (two chondrosarcomas, one osteosarcoma, one spindle-cell sarcoma, one giant cell tumour, one leiomyosarcoma of bone); two of these underwent wide further excision, three underwent forequarter amputation, five received radiotherapy, and one was left untreated. In two of the patients who underwent forequarter amputation, histological assessment of osseo-integration was performed. In both cases, both the glenoid and humeral components showed osteoid formation in direct contact with the HA-coated surface, indicating complete osseo-integration (Fig. 3). There have been no cases of aseptic loosening.

Considering all 42 patients successfully followed, this meant that most patients were left with a shoulder that was comfortable, functioned well between waist and shoulder height including lifting, and had full use of the elbow and hand. There was no mechanical failure of the prostheses in the follow-up period.

**Discussion**

There are several options for reconstruction of the proximal humerus after excision of a bony tumour. The selection of the method depends on the site and size of the tumour, the histological diagnosis, the level of resection required to obtain a clear margin, and the surgeon’s preference. A number of alternatives to endoprosthetic replacement have been used, including prostheses-allograft composites, fibular autografts (both vascularised and non-vascularised), claviculo-probhumero and osteoarticular allografts.  

Each has had its problems, particularly with fracture, infection and nonunion. Vascularised fibular grafts specifically require microsurgical expertise, and entail longer operating times and increased blood loss without an improved functional outcome.

We have been using massive endoprostheses since the late 1950s. Our early proximal humeral endoprosthetic design was unconstrained and it tended to sublux superiorly in the absence of the resected rotator cuff causing pain and stiffness as it abutted the acromion, and occasionally it would ‘escape’ superiorly, testing the skin. The Bayley-Walker proximal humeral replacement, by its constrained design, alleviates this problem. It is a relatively straightforward operation to perform because of the excellent access to the glenoid afforded by the proximal humeral resection. There was no unintentional injury to the axillary nerve in our series, but the radial nerve was injured on three occasions. This nerve is at greatest risk in dissecting out the proximal humerus. We think this incidence of radial nerve injury is acceptable in tumour surgery.

This study included patients with metastases in the proximal humerus, provided there was resectable disease, and the patients involved were predictably older than those treated for primary tumours. The number of patients was large considering the specialist nature of the surgery, but inevitably there was a high mortality rate (27.6%), which had a large impact on the number of patients for whom an assessment of function was available.

The dislocation rate in this study using the ‘old’ humeral liner was 25.9%, yet functional scores are comparable with those of previous similar studies. The dislocations did not appear to occur in any one tumour subgroup specifically. It is our opinion that in this situation, where reduction is not performed, the dislocated endoprosthesis then acts like an unconstrained endoprosthesis. With the new constrained liner the risk of dislocation seems to have been eradicated, and hence functional results will improve further. The four cases in which the new constrained liner was used showed no dislocations and improved functional results. It was not completely clear why the MSTS scores in the skeletally immature subgroup were worse than in the other groups. It may be because young patients do not have a strong enough deltoid muscle to power the bulky endoprosthesis. This is the subject of further investigation. However, the ability in the skeletally immature to lengthen the endoprosthesis non-invasively is a great advantage.
The mean MSTS in those patients in whom the axillary nerve was sacrificed was lower than in those where the nerve was preserved. This is to be expected because patients in whom the rotator cuff has been completely resected rely solely on their deltoid muscle for abduction.

It was also not surprising that those who underwent the procedure for benign tumours had higher functional scores than those with malignant tumours. This is mainly because the tumours were smaller and the excision margins were much closer, thereby sacrificing less normal tissue and preserving vital neurovascular structures.

One might expect the uncemented glenoid component to loosen, given the forces applied to such a constrained articulation. On examination of two retrieved specimens, however, we found excellent osseo-integration of the HA-coated parts of both humeral and glenoid components. None of the endoprostheses showed evidence of loosening on plain radiographs, and none were revised for aseptic loosening.

Thus the Bayley-Walker proximal humeral replacement gives good results in limb-salvage surgery for proximal humeral tumours. It is currently the method of choice for reconstruction at the London Bone and Soft-Tissue Sarcoma Service, and we also recommend it as an option for non-tumour limb salvage.

References


