Endoprosthetic replacement of the proximal humerus

LONG-TERM RESULTS

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We studied 100 patients who had undergone endoprosthetic replacement of the proximal humerus between 1976 and 1998. The outcome was assessed with regard to the survivorship of the patients, the salvaged limbs and the prostheses. Function was determined in the 47 surviving patients, of whom 30 were assessed using the Musculo-Skeletal Tumour Society (MSTS) rating scale and 38 completed the Toronto Extremity Salvage Score (TESS) questionnaire.

The median age of the patients was 34 years (10 to 80). The mean follow-up period for surviving patients was nine years (2 to 20). The mean MSTS score at follow-up was 79% and the mean TESS score was 72%. The length of bone which was resected influenced the functional outcome. Abduction of the shoulder was to 45° in most patients. The overall survival was 42% at ten years and that of the limb without amputation 93%. The survival of the prostheses using mechanical failure as the endpoint was 86.5% at 20 years.

Endoprosthetic replacement of the proximal humerus is a predictable procedure providing reasonable function of the arm with a low rate of complications at long-term follow-up.

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The proximal humerus is the third most common site for primary sarcoma of bone and a common site for metastatic lesions. Since the late 1970s, the treatment of primary sar-

coma of bone has changed from amputation to limb salvage because of advances in chemotherapy, imaging and surgical techniques. Several workers have subsequently shown that despite an increased risk of local recurrence, the survival after surgery for limb salvage is similar to that after amputation.¹⁻³ Limb salvage is socially and emotionally easier for patients to accept than amputation. A salvaged upper limb allows function which is markedly superior to that after forequarter amputation.⁴

The optimum method of reconstruction of the shoulder after resection of the proximal humerus remains controversial. Options include the use of a fibular or autoclaved humeral autograft, an osteoarticular allograft, an intercalary allograft prosthesis composite, the *clavícula pro humero* procedure or an endoprosthesis.⁵⁻¹¹ Endoprosthetic replacement of the proximal humerus (EPRPH) has been criticised as being little more than a prosthetic spacer rather than an articulating reconstruction.¹²⁻¹⁴ Nevertheless, it is the simplest form of reconstruction of the shoulder after resection of tumours of the proximal humerus. Endoprostheses are readily available and this treatment is less expensive than amputation.¹⁵ The principal technical difficulty is in obtaining a wide margin of excision because of the proximity of the neurovascular bundle to the bone, and also in restoring the function of the shoulder, particularly when the rotator cuff and deltoid have been sacrificed as is so often necessary in proximal humeral resections.

We reviewed the records of 100 patients who had undergone EPRPH in order to ascertain the survival of the patients, the salvaged limbs and the prostheses. All surviving patients, with a minimum follow-up of 24 months, underwent functional assessment of their salvaged limbs and all complications were recorded.

Patients and Methods

Between January 1976 and December 1998, 100 patients underwent EPRPH. Their median age was 34 years (10 to 80); the age distribution is shown in Figure 1 and the diagnoses in Figure 2. All patients with chemosensitive tumours received chemotherapy by the regime which was in use at the time of diagnosis. Early in the series, the tumours were assessed by plain radiography and bone scan and later CT and MRI were used. After 1980, all patients were staged at

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Fig. 1

The age distribution of patients undergoing endoprosthetic replacement of the proximal humerus.

the time of diagnosis and also before surgery, using the Musculo-Skeletal Tumour Society system.¹⁶ The distribution of the stages of the tumours at the time of surgery is shown in Figure 3. The mean size of the tumours was 10.78 cm (5 to 19; SD 4.4).

The endoprotheses. These were all custom made and designed and manufactured in the Department of Biomedical Engineering, Stanmore Implants Worldwide Ltd, Stanmore, UK (Fig. 4). The dimensions of the prosthesis were determined from anteroposterior and lateral radiographs of the proximal humerus. The intramedullary stem of the prosthesis was matched to the shape and size of the medullary canal of the remaining humerus, and the combined length of the head and shaft of the prosthesis was equal to the length of the resected bone. The prostheses were made of titanium alloy containing 6% aluminium and 4% vanadium and had a large unipolar head. Since 1993, they have been provided with a collar coated with hydroxyapatite at the bone implant junction for improved bony ingrowth.

Operative technique. The tumours were resected using an anterior deltopectoral incision, excising the track of the biopsy. If the shoulder was thought to be involved with tumour, an extra-articular resection was undertaken by dividing the neck of the glenoid. Otherwise an intra-articular resection of the humeral head was performed. The rotator cuff was divided and as much deltoid preserved as possible. In most cases of malignant disease, the axillary nerve was sacrificed because of its proximity to bone. An endoprosthesis with an intramedullary stem was implanted using methylmethacrylate cement. The large unipolar head was reduced into the glenoid and in most cases was retained there using polyester knitted non-absorbable undyed mesh (Mersilene; Johnson & Johnson International, Brussels, Belgium), which was sutured to the labrum and around the humeral head in order to contain the prosthesis and prevent subluxation.

At six weeks all patients were readmitted for a week of intensive physiotherapy and hydrotherapy. They were then followed up at regular intervals for the rest of their lives and

Fig. 2

Pie chart showing the frequency distribution of the diagnoses (Mets, metastases; GcT, giant cell tumour).

Fig. 3

Pie chart showing the frequency distribution of the stages of the tumours at the time of surgery (Mets, metastases).

were assessed for local control, function and complications related to the prosthesis.

Assessment of survival and function. We assessed the function of the salvaged limb using the revised Musculo-Skeletal Tumour Society (MSTS) rating system.¹⁷ This was performed either by trained medical or physiotherapy staff. For a more critical and detailed assessment of function of daily living we also used the Toronto Extremity Salvage Score (TESS) questionnaire.¹⁸ A comparison of functional outcome was undertaken between patients in whom the deltoid

Fig. 4a

Design of the proximal humeral endoprosthesis (by courtesy of Stanmore Implants Worldwide Ltd).

muscle and the axillary nerve were preserved and those in whom they were not. Functional outcomes were also correlated with the amount of bone replaced. The range of flexion and abduction of the shoulder were also recorded.

StatView 5.0 (Statistical software; SAS Institute Inc, Berkeley, California) was used for various calculations including the Kaplan-Meier survival analysis.¹⁹

Results

Of the 100 patients, 47 are still alive with a mean follow-up of 108 months (24 to 241). Two were lost to follow-up after 8 and 18 months. Thirty-nine were disease-free at the time of the latest follow-up, six were alive with metastases, one with local recurrence and one with both local recurrence and metastases. Fifty-one died, seven due to unrelated causes, after a mean period of 33.5 months.

At ten years, the overall survival and the survival of the limb without amputation were 42% and 93%, respectively, while the survival of the prosthesis without further surgery for mechanical failure as the endpoint was 86.5% at 20 years (Fig. 5). The mean length of the replaced humerus was 17 cm (6.8 to 26.8; SD 4.5); and only four patients had an extra-articular resection.

Functional assessment. Thirty patients attended for MSTs assessment and 38 completed the TESS questionnaire. The mean MSTs score was 79% (23.74/30, SD 3.83). The mean scores for the components of the MSTs rating scale are shown in Figure 6. Sixteen patients had excellent results

Fig. 4b

Fig. 4c

Radiographs of a 32-year-old woman, taken 17 years after replacement of the left proximal humerus b) and c).

Fig. 5a

Fig. 5b

Fig. 5c

Kaplan-Meier curves showing the survival of the patients who had undergone replacement of the proximal humerus a), survival of the salvaged limbs without amputation b) and survival of the prostheses without further surgery c).

(>24 with no pain), 11 had good results (>18, with some restriction of sports and recreational activities) and three had poor results scoring <18 (two scored 17 and one 16).¹¹ The mean TESS was 72% (115/160, SD 23.17). The questionnaire comprised 32 questions for assessment of function including activities of daily living. Thirteen scored >90%, 18 between 70% and 90% and seven <70%. Most patients scored low in questions relating to their ability to lift an object to an overhead shelf and to participate in their usual sporting activities.

There was no overall difference in functional scores between patients in whom the deltoid muscle and axillary nerve were preserved and those in whom they were not. Anecdotally however, the only two patients who could elevate their hands satisfactorily above their heads had undergone EPRPH for benign tumours with preservation of both the deltoid muscle and the axillary nerve. They also had short lengths of bony resection. There were insufficient data to compare the outcomes after extra- and intra-articular resections. Functional scores had a negative correlation with the amount of bone resected, expressed as a percentage of total length of the humerus. However, this correlation was statistically significant for the MSTs scores (Pearson $r =$

-0.362 , $p < 0.05$), but not for the TESS scores (Pearson $r = -0.167$, $p > 0.05$).

The mean range of abduction of the shoulder was 44° (25 to 120) and the mean flexion was 55° (35 to 140). Many patients had an increased range of rotation, sometimes as much as 180° , of combined internal and external rotation. In some, this was an inconvenience, while in others, it was a 'party trick'.

Since the rotator cuff had been sacrificed in most cases, there was usually some proximal subluxation of the prosthesis resulting in it lying directly beneath the acromion. Actual dislocation, usually anteriorly, allows the prosthesis to migrate proximal to this and can be symptomatic.

Complications

Local recurrence. Fifteen patients developed a local recurrence; two are still alive (one with metastasis) and 13 have died. The mean time to the development of local recurrence was 12 months. All but two had metastases at the time of death and all but one died within 12 months of recurrence.

Infection. Five patients developed infection, four superficial and one deep. The causative organism in all was *Staphylococcus aureus*. The superficial infections were successfully treated by antibiotics. The deep infection occurred in a

Fig. 6

The mean scores (out of a maximum of 5) for the components of the MSTS rating scale.

patient who had EPRPH after radiotherapy and was treated by revision.

Nerve injury. Five patients had symptoms of injury to the radial nerve; four with neurapraxia had complete recovery, one had incomplete recovery.

Implant failure. There was no case of implant breakage.

Secondary procedures

Revision surgery. Seven patients required a revision procedure, one for infection after radiotherapy and six for aseptic loosening of which three followed trauma.

Forequarter amputation. Eight patients with local recurrence but without metastases were treated by forequarter amputation; one remains alive.

Excisional biopsy. Five patients required excisional biopsy for suspected recurrence.

Relocation. Two patients required open reduction of a dislocated prosthesis.

Discussion

Patients prefer limb salvage if their survival is not compromised. It has been shown to be more cost-effective than amputation.¹⁵ Most observers have noted a reduction in the ability to lift and function of the upper limb after resection of the proximal humerus with any form of limb-sparing reconstruction with, however, good positioning of the hand, manual dexterity and emotional acceptance.²⁰⁻²² Most observers agree that resection of the proximal humerus results in function which is superior to that after forequarter amputation.³

The main controversy surrounds which form of reconstruction should be used. The selection of the method of reconstruction depends on the site and size of the tumour, the level of resection which is required to obtain wide, clear margins, the resources available and the surgeon's choice and familiarity with the procedure. Osteoarticular allografts, prosthesis allograft composites and fibular (vascularised or non-vascularised) autografts are alternatives to endopro-

thetic replacement which are commonly used. Although the early functional results have been found to improve after osteoarticular allografts, high rates of complication (fracture and infection) and deterioration of function with the passage of time have been reported and many surgeons have abandoned this procedure.^{23,24} Similarly, non-vascularised autografts have a high rate of fracture and delayed and non-union.²⁵ A vascularised fibular graft has a long operating time, major intraoperative blood loss and requires expertise in microsurgical techniques, without a better outcome.²⁶ The *clavícula pro humero* procedure has been used predominantly in younger patients and those in whom less bone needs to be resected. It has been shown to have a slightly better functional outcome (MSTS score 82%) compared with allografts or prostheses, but also has a significantly higher rate of complications.¹⁰

We chose to use endoprotheses because of their availability and predictability and we believe our results have justified this. We found EPRPH to be a reliable method with a low rate of failure. The functional results were acceptable with a high level of patient satisfaction despite the fact that there was reduced movement of the shoulder. With improved techniques, we did not find the incidence of symptomatic subluxation or dislocation to be as high as reported in previous series.^{5,14,27,28} Our data suggest that resection of a short segment of the proximal humerus is associated with better function. Although we have not been able to prove it from our data, we believe that patients who undergo resection of the proximal humerus with preservation of an innervated deltoid muscle will have better function than those who do not.

Local recurrence remains a significant problem after resection of malignant tumours around the shoulder.²⁸⁻³⁰ This is largely due to the proximity of the neurovascular bundles to the bone and only marginal margins may be achieved because of the significant soft-tissue component of the tumour. Our relatively low rate of extra-articular resections (5%) may also have contributed, as in other series, this rate has been as high as 50%.¹⁰ Microsurgical reconstructive techniques in the form of microneural dissection and vascular reconstruction can be used for tumours close to the major neurovascular bundles.³¹ The incidence of local recurrence has been found to be inversely proportional to the effectiveness of the chemotherapy^{30,32,33} and effective chemotherapy will decrease its incidence even in marginal excisions.³³

We recommend EPRPH as a predictable method of reconstruction after excision of tumours of the upper humerus. Most patients will lose active abduction of the shoulder, but will have a useful functioning limb with a low risk of subsequent complications. Most are satisfied with the result, and at 20 years, less than 15% have required further surgery for mechanical failure or for complications relating to the prosthesis.

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