The use of a femoral revision stem in the treatment of primary or secondary bone tumours of the proximal femur

A PROSPECTIVE STUDY OF 31 CASES

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Endoprosthetic reconstruction following resection of 31 tumours of the proximal femur in 30 patients was performed using a Wagner SL femoral revision stem. The mean follow-up was 25.6 months (0.6 to 130.0). Of the 28 patients with a metastasis, 27 died within a mean follow-up period of 18.1 months (0.6 to 56.3) after the operation, and the remaining patient was excluded from the study 44.4 months post-operatively when the stem was removed. The two patients with primary bone tumours were still alive at the latest follow-up of 81.0 and 130.0 months, respectively. One stem only was removed for suspected low-grade infection 44.4 months post-operatively. The worst-case survival rate with removal of the stem for any cause and/or loss to follow-up was 80.0% (95% confidence interval 44.9 to 100) at 130.0 months. The mean Karnofsky index increased from 44.2% (20% to 70%) pre-operatively to 59.7% (0% to 100%) post-operatively, and the mean Merle d'Aubigné score improved from 4.5 (0 to 15) to 12.0 (0 to 18). The mean post-operative Musculoskeletal Tumour Society score was 62.4% (3.3% to 100%).

The Wagner SL femoral revision stem offers an alternative to special tumour prostheses for the treatment of primary and secondary tumours of the proximal femur. The mid-term results are very promising, but long-term experience is necessary.

Most of the nearly 560 000 people who die of cancer each year in the United States develop bone metastases. In the advanced stage of common malignancies such as myeloma and kidney, breast and prostate cancer, bone metastases are present in up to 100% of patients. After the spine, the proximal femur is the most common site for metastatic bone disease, with a high risk of pathological fracture. In primary bone tumours, limb salvage may be possible in about 85% of patients without an increased risk of recurrence and with a similar survival as amputation. In the last three decades, improvements in the diagnosis and treatment of bone malignancies have led to a significant increase in the survival time, and hence long-lasting reconstructions are necessary.

As a time- and cost-saving method of stabilising the proximal femur, osteosynthesis by plate, dynamic hip screw (DHS) or intramedullary nail may be performed as part of a palliative regimen in metastatic disease. Although additional osteosynthesis with bone cement after intralesional curettage or partial tumour resection may improve primary stability, complications such as implant failure and persistent pain due to local progression of the tumour are well known. En bloc resection and endoprosthetic reconstruction of the proximal femur is a well-accepted method for both curative therapy in primary bone tumours and palliative treatment of bone metastases. Depending on the length of resection, different endoprostheses may be used, including standard primary stems, modular revision, or cemented or cementless fixation as a hemi- or total arthroplasty.

The biomechanical situation of the proximal femur in cases of destructive bone tumour or after wide resection may be similar to that when excessive bone loss arises due to loosening of the stem after total hip replacement (THR). The deficient bone segment has to be bridged by a prosthesis fixed distally in the diaphysis. Because of the excellent long-term results with the Wagner self-locking revision stem in the treatment of large bone defects in revision hip arthroplasty, we started to use this implant in secondary and selected primary tumours of the proximal femur.

The aim of this study was to review our results of using this prosthesis to treat malignancies involving the proximal femur and to evaluate whether it offers a reasonable alternative to using a special tumour implant in these patients.
Table I. Histopathological diagnosis and staging at the time of the index operation

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number of patients (30), solitary/disseminated</th>
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<tbody>
<tr>
<td>Breast carcinoma</td>
<td>11 (1 of 10)</td>
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<tr>
<td>Cervical carcinoma</td>
<td>1 (0 of 1)</td>
</tr>
<tr>
<td>Cancer of unknown primary</td>
<td>1 (0 of 1)</td>
</tr>
<tr>
<td>Gall-bladder carcinoma</td>
<td>1 (0 of 1)</td>
</tr>
<tr>
<td>Giant cell tumour</td>
<td>1 (0 of 1)</td>
</tr>
<tr>
<td>Leukaemia</td>
<td>1 (0 of 1)</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>1 (0 of 1)</td>
</tr>
<tr>
<td>Osteosarcoma</td>
<td>1 (0 of 1)</td>
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<tr>
<td>Parathyroidal carcinoma</td>
<td>1 (1 of 0)</td>
</tr>
<tr>
<td>Plasmocytoma</td>
<td>2 (1 of 1)</td>
</tr>
<tr>
<td>Prostate carcinoma</td>
<td>3 (0 of 3)</td>
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<tr>
<td>Renal carcinoma</td>
<td>3 (1 of 2)</td>
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<tr>
<td>Synovial sarcoma</td>
<td>1 (0 of 1)</td>
</tr>
<tr>
<td>Thyroidal carcinoma</td>
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Table II. Indication for operative treatment

<table>
<thead>
<tr>
<th>Indication for operative treatment</th>
<th>Number of cases (31)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impending fracture</td>
<td>8</td>
</tr>
<tr>
<td>Impending fracture after biological reconstruction (tumour recurrence)</td>
<td>1</td>
</tr>
<tr>
<td>Impending fracture after total hip replacement</td>
<td>2</td>
</tr>
<tr>
<td>Impending fracture after osteosynthesis</td>
<td>1</td>
</tr>
<tr>
<td>Pathologic fracture</td>
<td>15</td>
</tr>
<tr>
<td>Pathologic fracture after total hip replacement</td>
<td>2</td>
</tr>
<tr>
<td>Pathologic fracture after osteosynthesis</td>
<td>2</td>
</tr>
</tbody>
</table>

Patients and Methods

We reviewed 31 endoprosthetic reconstructions in 19 women and 11 men with a primary or secondary tumour of the proximal femur using the Wagner SL revision stem. One man had bilateral procedures. A hemiarthroplasty using a Wagner revision stem was performed within three weeks, and both hips were included in this study. At the time of operation, the mean age of the patients was 58 years (18 to 86). In 20 patients the left side was operated on and in 11 the right.

The reason for surgery, the pathology of the underlying tumour and the staging at the time of operation are summarised in Tables I and II. The mean Mirels score in eight hips without fracture and without previous treatment was 10 (8 to 12). Eight hips had already been operated on, four by a primary THR. One patient with an osteosarcoma of the proximal femur sustained a fracture of the femoral neck 24 months after wide resection, extracorporal high-dose irradiation and re-implantation using an unreamed femoral nail with a twisted blade. In one patient, an osteoclastoma of the proximal femur recurred nine months after curettage, treatment with phenol and implantation of an autogenous fibular graft (Fig 1).

All patients were evaluated clinically and radiologically by one of the authors (OEB). The pre- and post-operative activity and general condition were measured using the Karnofsky index. Function was evaluated using the Musculoskeletal Tumor Society and the Merle d’Aubigné scores. As the mobility of these patients may be influenced by other independent factors, a modified Merle d’Aubigné score, which excluded mobility, was used.

Various radiological measurements were made. Preoperative MR and/or CT scans and plain radiographs, which were standardised and/or calibrated by marker buttons, were available for all patients for assessment of extension of the tumour. The tip of the greater trochanter and the knee joint line were used as reference points for the measurements. For classification of the defect the system previously described was used. The length of anchorage of the implant in femoral bone and the free length of the proximal stem after en bloc resection were measured. Stress shielding was deemed to be present when resorption and/or a clear reduction in bone density of the proximal femur occurred during follow-up. Migration was analysed according to the technique proposed by Callaghan et al.

Statistical analysis. This was performed with SPSS for Windows (SPSS Inc., Chicago, Illinois). A survival analysis was performed using the Kaplan-Meier method, with death, removal of the stem for any cause, aseptic loosening and loss to follow-up as the criteria for failure. A 95% confidence interval (CI) was ascribed to all survival data; the p-value for non-crossing survival curves was calculated with the log-rank test, and for crossing curves with Wilcoxon’s test. Associations or correlations between continuous and/or discrete variables were tested by Student’s t-, paired t- or chi-squared tests. All tests were two-sided and p ≤ 0.05 was considered significant.

Surgical technique and post-operative care. The 31 operations were performed by seven surgeons, 25 by one of the authors (PMB). The mean operation time was 136 minutes (64 to 269) and the mean duration of hospital stay was 20 days (2 to 42). The general prognosis and surgical oncological criteria were used to plan either a curative or a palliative regime for each patient. For en bloc procedures, precise determination of the length of resection by radiographic measurement of the extension of the tumour was considered essential. We found that our published system for classification of the defect was very helpful in assessing the most proximal part of the intact femoral bone available for stable fixation of an endoprosthesis. Sufficient mechanical stability for diaphyseal stem fixation was assumed if the femoral canal was intact and cortical thinning was < 50%. Within a tolerance of one size, the diameter and length of the prosthesis needed for the reconstruction and the adjustment of leg length could be predicted. When the femur was fractured, the appropriate leg length was assessed by radiographic measurement of the intact contralateral femur.
In all patients except one, who had a transfemoral procedure, a lateral-transgluteal approach was used. The tendons of the pelvitrochanteric muscles were attached to the quadriceps or if vastus lateralis had been resected, to the dorsal aspect of the insertion of gluteus maximus and the adjacent fascia. The psoas tendon was fixed around the prosthesis with non-resorbable sutures. In order to prevent dislocation of bipolar components, the capsule of the hip was preserved when possible and repaired to produce a tight closure after repositioning of the prosthesis. The length of bone resection was assessed at operation by radiographic validation according to the pre-operative plan. In all patients deemed suitable for a locally curative regime, intra-operative frozen sections were performed after removal of the tumour before introduction of the prosthesis. In 14 hips resection of the proximal femur was undertaken, with a mean resection length of 12.0 cm (7 to 19). Of the 14 resections, 13 were histopathologically extralesional and one was intralesional. In 17 cases the tumour tissue was curetted (Table III). Bone cement was used to achieve distal fixation in five cases and to stabilise a deficient and fractured proximal femur in one hip. The femoral canal was prepared using rigid reamers. In our experience, the bed for the prosthesis can be prepared more precisely with high-speed rotation and low pressure, rather than reaming by hand. Radiographic control in two planes was used to determine the length of the anchorage with at least 8 cm in intact bone, filling of the femoral canal and to avoid perforation due to
anterior bowing of the femur. Leg length was estimated primarily using the scale on the reamers. A definitive assessment was made after insertion of the prosthesis by intra-operative evaluation and radiographic control in relation to the contralateral side and the pre-operative plan. The mean length of the femoral stem was 265 mm (190 to 345) and the mean diameter 16 mm (14 to 19). A bipolar component was inserted in 14 operations. In 17 cases an acetabular component was implanted. In two of them with a previous THR, the polyethylene component was cemented into the pre-existing and stable cementless press-fit shell. Antibiotics were given as a single dose in all patients, and a bacteriological smear test was taken routinely.

Two days post-operatively the patients started intensive physiotherapy and were mobilised. According to our standardised post-operative treatment protocol using the Wagner stem as a revision device, partial weight-bearing with 20 kg body-weight was allowed for the first six weeks. In 12 patients who were unable to partially weight-bear owing to their general condition, full weight-bearing was allowed. Full weight-bearing was achieved after a mean of 54 days (2 to 198). Active and passive movement of the hip was restricted to 60° of flexion for the first six weeks. Depending on the requirements for further adjuvant therapy, after-care at a specialised rehabilitation unit was organised.

Results
Follow-up data were available for all the patients. The mean follow-up was 25.6 months (0.6 to 130.0); 27 patients died at a mean of 19.3 months (0.6 to 56.3) after surgery, including the one treated bilaterally. The data for these patients were included until their most recent follow-up. Radiographic evaluation was possible for a mean of 12.8 months (0.3 to 125.3).

Complications and re-operations. Some general complications occurred within four weeks after surgery. One patient died of ventricular fibrillation 17 days after operation. A partial lesion of the sciatic nerve was diagnosed in one patient; after evacuation of a haematoma 27 days after operation there was a complete remission of the palsy. None of the 14 hips with bipolar components dislocated, but two of the 17 with an acetabular component did so, one after wide resection, and needed closed reduction. Both remained stable.

A two-stage revision of one stem was performed 44.4 months after operation because of pain after a fall, and a slight increase in the inflammatory parameters, which were interpreted as a low-grade infection. Pre-operative analysis of the synovial fluid and of intra-operative specimens of tissue showed no growth of micro-organisms.

Functional evaluation. Pre-operatively, constant care was necessary in 16 patients and none had a normal level of activity. At the latest follow-up, the two patients with primary tumours were still capable of normal mobility. The duration of a steady state of function and activity from full weight-bearing until a decrease in function due to general weakness lasted for a mean of 18.0 months (0.0 to 127.7). The mean Karnofsky index improved from 44.2% (20% to 70%) pre-operatively to 60.6% (0% to 100%) at the steady-state period. The mean Musculoskeletal Tumor Society score improved from 10.1% (0.0% to 63.3%) pre-operatively to 62.8 (3.3% to 100%) during the steady-state period. A total of 26 (86.7%) patients had no or mild pain (four or five points) with the need for non-steroidal anti-inflammatory drugs (NSAIDs) as the only medication for pain (Fig. 2).

The mean Merle d’Aubigné score increased from 4.5 (0 to 1) pre-operatively to 12.0 (0 to 18) post-operatively and the mean modified Merle d’Aubigné score increased from 3.7 (0 to 10) to 9.8 (0 to 12) during the steady state. The mean pain score improved from 0.9 pre-operatively to 5.0 (0 to 6) at the end of the steady-state period, and the mean movement of the hip improved from 2.8 to 4.7 (0 to 6). The mean Merle d’Aubigné score in the resection group (n = 14) compared to the patients with curettage was 13.1 (8 to 17) versus 10.9 (0 to 18) (t-test; p = 0.179). The mean modified Merle d’Aubigné score was 10.6 (7 to 12) versus 9.1 (0 to 12). Pain, movement and the walking ability of the patients with resections scored a mean of 5.3 (3 to 6), 5.3 (4 to 6) and 2.5 (1 to 5) compared to the curettage group, with a mean of 4.8 (0 to 6), 4.3 (0 to 6) and 1.8 (0 to 6) points. The mean Musculoskeletal Tumor Society index of the resection group was 68.3% (30% to 100%) compared to 57.5% (3.3% to 100%) in the curettage group.

Radiographic evaluation. The mean pre-operative extension of the tumour with thinning of cortical bone was 10.3 cm (0 to 23), with an intact circumferential femoral head.
indicating sufficient mechanical stability for fixation of the stem at a mean of 10.6 cm (0 to 23) from the tip of the greater trochanter. The mean length of fixation of the stem with circumferential contact of the implant to bone was 14.9 cm (8 to 24). The pre-operative classification of the defect is shown in Table IV. There was no reduction in the stability of the prosthesis because of local recurrence or increasing bone destruction during follow-up.

At the latest evaluation, leg-length discrepancy of at least 1 cm was recorded in four patients with a mean of 1.3 cm (1 to -3). Lengthening of 1 cm occurred in one patient. Subsidence of 3 cm was seen in a patient with wide resection of 11 cm, resulting in a fixation length of the stem of 14 cm; migration occurred until the first control radiograph 14 days post-operatively, but remained stable during follow-up. The stem was fully osseo-integrated according to the radiographic criteria of Engh and Massin at the latest visit, 17.1 months post-operatively. No migration or subsidence was seen in the other patients.

One woman and one man with wide resections, followed up for 17.2 and 130.0 months, respectively, developed slight stress shielding of the fixation area. The woman, who had progressive breast cancer, was treated with local radiotherapy and chemotherapy after operation. The stress shielding occurred in irradiated bone and was restricted to the lateral area of the proximal bone-implant contact, corresponding to Gruen’s zone 1. The man, who had a high-grade osteosarcoma, had slight circumferential bone loss in the region of the calcar (Gruen zones 1, 7, 8 and 14) in bone which had been irradiated with a high dose previously. All other cases showed either no sign of stress shielding or slight new bone formation at the osteotomised site, with rounded edges.

Survival analysis. The survival of all patients was 8.1% (95% CI 0 to 18.3) at 130.0 months. The two patients with primary tumours were still alive with no evidence of disease at the latest follow-up 81.0 (Figs 1 and 2) and 130.0 months after surgery.

The mean survival time for the five patients with a solitary metastasis was 36.3 months (9.3 to 56.3), but all died. The patients with multiple metastases (n = 23) had a mean follow-up of 16.2 months (0.6 to 54.8). The only patient with implant failure after 44.4 months also had multiple metastases, but was still alive at the latest follow-up, 72.4 months after the index operation. The one- and three-year survival rate for the patients with a solitary metastasis was 80% at any one time, and in patients with disseminated disease was 50% and 17%, respectively. The log-rank p for non-crossing curves was 0.055%.

The worst-case survival rate of the stem was 80.0% (95% CI 44.9 to 100) at 130.0 months. Patients operated on with a metastasis of the proximal femur had a mean survival of 66.7% (13.4% to 100%) at 56.3 months, with one removal of the stem 44.4 months post-operatively for suspected low-grade infection.

Discussion

Patients may profit from surgical treatment of bony lesions even in advanced stages of malignant disease and with a life expectancy of only a few months. In most patients, the quality of life can be improved by a significant reduction of pain and at least partial restoration of function.27 Survival rates after surgical treatment of bone metastases from the lung, prostate, kidney or breast cancer of 40% after one year, and of 20% after three years, have been recorded.4 In patients with a good prognosis survival rates of 90% at one year and 20% at five years are described.13,28,29 If one uses the metastatic load as one of the factors predicting the general prognosis, the five patients with a solitary metastasis in our series showed a survival rate of 80% at three years, whereas those with disseminated disease had a survival rate of 50% at one year, decreasing to 17% at three years.

Loosening or breakage of the prosthesis due to local progression of the tumour will become more likely with longer survival. This may lead to failure rates after osteosynthesis of 11% to 23%.12-15 Especially in tumours with very proximal extension in the femur, adequate fixation of the osteosynthesis device in bone proximal to the tumour may be difficult or impossible to achieve. Exceeding the limits of osteosynthesis may be one reason why some studies show significantly lower survival rates following osteosynthesis than after arthroplasty.30,31 Arthroplasty also offers the prospect of an extraroselial (marginal or wide) resection of the tumour, which is known to give a lower risk of local recurrence, especially in tumours with a poor response to radiotherapy, such as renal cancer.13,32 Based on our findings, we agree with Haentjens et al16 that bone pain due to a metastasis can be treated more effectively with wide resection and implantation of an endoprosthesis. The mean post-operative Musculoskeletal Tumor Society score of 62.8% was comparable to the series of Ogilvie et al,33 with 67.7%, but worse in relation to scores of 80% to 87% in studies that included patients with primary bone tumours.4,7,34-36 More than 80% of the patients had no pain or mild pain that could be treated effectively by NSAIDs, at least during the steady-state period. In this study, endoprosthetic reconstruction in patients with metastatic disease of the proximal femur showed a mean survival rate of 66.7% (13.4% to 100%) at 56.3 months, with one removal of the stem 44.4 months post-operatively for suspected low-grade infection. There are only a few comparable studies dealing with arthroplasty in metastases of the proximal femur. Chandrasekar et al37 recorded survival of a modular megaprosthesys with revision as the endpoint of 83% after five years. However, there are some studies of...
endoprosthetic reconstruction in patients with primary bone tumours. In these studies, the survival rates of megaprostheses are reported to be between 100% at eight years and 36% at ten years. With regard to the ten-year overall survival rates of Ewing’s, osteo- or chondrosarcoma of 54%, 44% and 67%, respectively, the surgeon has to cope with many young patients with an almost normal life expectancy. Compared to arthroplasty in osteoarthritis, the qualities demanded of the materials used and the surgical skills in tumour patients are much greater, with the potential durability of an arthroplasty for at least three decades or more. From a biomechanical view there is no difference between bony deficiencies of the proximal femur related to a malignancy and those related to a loosened stem after arthroplasty for osteoarthritis. Because of this, and the fact that cementless revision stems such as the Wagner SL and others show excellent long-term results in revision arthroplasty, their use as a tumour device should be considered. Cemented tumour systems have significantly poorer results with limited durability and higher local complications when used as a revision device compared to a standard cementless revision stem, which emphasises the importance of fixation, design and materials in producing a good result.

Fracture of the implant, infection, loosening and dislocation are the main complications of proximal femoral replacement. In relation to tumour devices, breakage is described in 11.0% of cemented CoCr alloys and in 2.1% of cemented TiAl alloys. In our series with the Wagner SL stem used as a revision or as a tumour device there was no mechanical failure.

Infection rates of 1.8% to 21% are reported after arthroplasty of the hip for tumour reconstruction. A higher incidence of 17% or 21% has been found when allograft bone is used and/or neo-adjuvant, intra-operative or direct adjuvant irradiation is performed. In our series irradiation and/or chemotherapy was administered to 20 patients, peri-operatively, but only one suspected infection occurred.

Dislocations have been described in up to 34% of these procedures. A rate of dislocation of 6.5% in our series seems to be acceptable compared with the data for tumour patients.

The outcome after operative treatment in patients with tumours is directly influenced by the experience of the surgeon. The higher complication rates of less experienced surgeons, or even lower survival rates after inadequate therapy, are recognised problems. Pre-operative planning is essential. There is a need for interdisciplinary treatment and the decision to perform intra- or extralesional surgery requires consideration of the general condition, staging, histopathology and life expectancy of the patient. In cases with massive bone loss or after wide en bloc resection, our defect classification, described previously, is very useful. The surgeon must know the most proximal part of intact femoral bone in the diaphysis where stable fixation of a stem is possible. This is necessary for the assessment of length and diameter of the stem needed. Endoprosthetic reconstruction of pathological fractures or impending fractures of the proximal femur in patients with a life expectancy of more than six months shows clear advantages over osteosynthetic reconstruction. Because of the increasing survival of these patients, selection of the implant must be made with care to minimise mechanical failures such as loosening, stress-shielding or breakage. Lower costs and better availability, as well as the design-associated advantages of a standard cementless revision stem, may be favourable compared to special tumour prostheses. As revision arthroplasty is often practised in centres that also treat tumours, these revision devices are in stock.

This mid-term follow-up series shows no disadvantages for the Wagner SL revision stem compared to tumour prostheses for the reconstruction of the proximal femur under these circumstances.

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


