Endoprosthetic replacement of the proximal tibia
From the Royal Orthopaedic Hospital Oncology Service, Birmingham, England

We have performed endoprosthetic replacement after resection of tumours of the proximal tibia on 151 patients over a period of 20 years. During this period limb-salvage surgery was achieved in 88% of patients with tumours of the proximal tibia. Both the implant and the operative technique have been gradually modified in order to reduce complications. An initial rate of infection of 36% has been reduced to 12% by the use of a flap of the medial gastrocnemius, to which the divided patellar tendon is attached. Loosening and breakage of the implant have been further causes of failure. We found that the probability of further surgical procedures being required was 70% at ten years and the risk of amputation, 25%. The development of a new rotating hinge endoprosthesis may lower the incidence of mechanical problems.

Limb salvage for tumours of the proximal tibia is fraught with complications, but the good functional outcome in successful cases justifies its continued use.

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The proximal tibia is the second most common site for primary bone tumours. Some 12% to 15% of osteosarcomas, 11% of Ewing’s sarcomas and 6% of chondrosarcomas will be located here. Before 1977, the conventional treatment for these primary bone tumours was amputation above the knee. The outlook, however, was poor and many patients died from metastases. In 1955 Cade advocated a regime of radiotherapy for osteosarcoma followed by amputation only if there was no evidence of distant spread at six months.

Since the 1970s there have been dramatic changes in the management of primary bone tumours. The advent of effective chemotherapy has meant that cure rates in excess of 60% can be expected for osteosarcoma and Ewing’s sarcoma. Simultaneous advances in surgical technique and biomechanical engineering have also meant that limb salvage rather than amputation is now a practical option for many patients with bone tumours.

Techniques for limb salvage in the proximal tibia include endoprosthetic replacement with either a custom-built or modular endoprosthesis, allograft replacement, resection followed by arthrodesis or a modified amputation in the form of the Van Nes rotationplasty.

The following conditions must apply if a limb is to be salvaged rather than amputated:
1) The patient’s life must not be put at increased risk.
2) The method of limb salvage should provide a better functional result.
3) The rate of complications should be acceptably low.
4) The patient must be fully informed and agree.

Of the available options for limb salvage, we have chosen to use an endoprosthetic replacement. Endoprostheses are readily available, reasonably inexpensive, and allow immediate weight-bearing. The principal technical difficulties with prostheses for the proximal tibia are the restoration of the extensor mechanism and the provision of soft-tissue cover.

We have reviewed all patients with endoprosthetic replacement of the proximal tibia carried out at the Oncology Service of the Royal Orthopaedic Hospital in order to confirm the survival of the patient, the limb and the endoprosthesis. We have also recorded all complications which have arisen and the functional outcome.

Patients and Methods

Between 1977 and 1996, endoprosthetic replacement of the proximal tibia was carried out in 151 patients, constituting 88% of our total cases of primary bone tumour at
the site. The diagnoses are shown in Table I. All patients with chemosensitive tumours were treated with the appropriate medical regime in use at the time of diagnosis.

Their median age was 21 years (10 to 74) and 44% were under 20 years of age. The youngest patients in this series had not completed skeletal growth, but had an adult-type endoprosthesis inserted longer than the length of bone removed so that the leg lengths would be equal at the completion of skeletal growth.

All patients were staged both at the time of diagnosis and before surgery by appropriate investigations. Early in the series the assessment of the extent of the tumour was by plain radiography and bone scan, but as more sophisticated techniques became available, CT and MRI were introduced.

We encourage surgeons to refer patients before biopsy so that it may be sited in line with our proposed incision for reconstruction. In the event of a positive finding, all patients had measured long-leg radiographs of both limbs to facilitate surgical planning.

The endoprostheses. The endoprostheses were designed and manufactured at the Department of Biomedical Engineering at Stanmore, UK. The 95 endoprostheses used before 1991 were based on the Stanmore hinged knee (Fig. 1). This has a restrained hinge with a central axle allowing flexion around polyethylene bushes. The femoral side of the implant was a conventional chrome-cobalt Stanmore component cemented into the femur with methylmethacrylate cement, but using a ‘plateau plate’ to spread the forces over a wider area at the end of the femur. The tibial component consisted of a scaled-down cobalt-chrome Stanmore tibial component. This was cemented into the custom-made portion of the endoprosthesis which consisted of a titanium shaft of the requisite length with a titanium intramedullary stem. The latter was manufactured to be as broad as would comfortably fit inside the tibia and was up to 150 mm long, depending on the length of bone available. The Stanmore knee allows about 5° of hyperextension; this range is particularly important in patients with proximal tibial replacements to allow passive ‘locking’ of the knee.

In 1988, the tibial component was changed to one made entirely of titanium. This proved unsuccessful when the soft titanium wore at full extension, causing unstable hyperextension of the knee. Most of these implants subsequently required revision.

In 1991, the Stanmore knee hinge was discarded and a new rotating hinge implant was introduced – the SMILES knee (Stanmore Modular Individualised Lower Extremity System - Fig. 1). A total of 56 of these has been inserted. The theoretical advantages of the new design are that it will absorb some of the rotational stresses and that there will be less wear of the polyethylene bushes due to a broader bearing area and better alignment of the patella. Since 1993, a hydroxyapatite collar has been added to the base of the stem.

Operative technique. The guiding principle for resection of a bone tumour is to obtain a wide surgical margin. All patients were warned that amputation might be necessary if the tumour was to prove more extensive than expected.

Resection was carried out using a standard technique. The endoprosthesis was secured using methylmethacrylate cement into both the tibia and femur. After resection, no deep fascia remains anteriorly which leaves the metal endoprosthesis inadequately covered by fat and skin alone. At first, we covered this defect with a synthetic layer of Mersilene mesh in the hope that it would allow fibrous

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**Table I. Diagnoses and outcome for the 151 patients who had endoprosthetic replacement of the upper tibia**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number</th>
<th>Alive</th>
<th>Local recurrence</th>
</tr>
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<tbody>
<tr>
<td>Osteosarcoma</td>
<td>87</td>
<td>54</td>
<td>11</td>
</tr>
<tr>
<td>Ewing’s sarcoma</td>
<td>16</td>
<td>9</td>
<td>0</td>
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<tr>
<td>Giant-cell tumour</td>
<td>13</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Chondrosarcoma</td>
<td>11</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Metastases</td>
<td>6</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Malignant fibrous histiocytoma</td>
<td>6</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Others</td>
<td>12</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>151</td>
<td>100</td>
<td>16</td>
</tr>
</tbody>
</table>

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The two types of implant used. The original modified Stanmore endoprosthesis is shown on the left. The SMILES rotating-hinge knee is on the right with a hydroxyapatite collar at the proximal part of the stem.
ingrowth. This did not happen and in 1988 we reported an incidence of infection of 33% in the tibial implants inserted using this technique. As a result we now routinely use a rotation flap containing the medial head of gastrocnemius to cover the implant.

The extensor mechanism was repaired by a variety of methods. Initially, a synthetic ligament of braided Terylene was used. This was passed through holes in the tibial component and sutured to the patellar tendon, but it was abrasive to the local tissues and eventually ruptured. Since 1988, we have repaired the patellar tendon directly to the transposed medial head of gastrocnemius.

After operation, the limb was elevated with suction drainage continued for 48 hours. Antibiotics were given at the induction of anaesthesia but not repeated. The patient began partial weight-bearing at 48 hours and was gradually allowed to increase the level of activity. Flexion to 45° was permitted during the first few weeks and gentle isometric quadriceps exercises were encouraged.

At six weeks, patients were readmitted for a week of intensive physiotherapy and hydrotherapy. They were instructed in exercises for the whole of the lower limb. By the end of this week most could walk unaided, but some required the use of a single walking stick. They were taught further exercises to continue at home. While they had weak extension they were taught to stabilise the leg by hyper-
extending the knee using gluteus maximus in the same way as patients afflicted with polio and weak quadriceps. All patients have remained under regular review until either death or amputation.

**Results**

The average proportion of the tibia resected was 51% (19 to 85). The mean length of the intramedullary stem was 125 mm (35 to 160). Patients of short stature were those with the greater proportion of tibia resected.

Of the 151 patients, 100 are still alive after a mean period of 80 months. One has the original endoprosthesis still in situ 19.5 years from insertion.

As shown in Table I the patient survival in this series is related to the nature of the disease, with no deaths in the patients with benign aggressive tumours (giant-cell tumour) and a high mortality in those with highly malignant tumours (osteosarcoma and Ewing’s sarcoma).

Local recurrence occurred in 16 patients, 11 of whom had osteosarcoma (12.6% risk). This was associated with a poor response to chemotherapy and close margins of excision. Local recurrence of osteosarcoma was treated by amputation in eight patients and by local excision and radiotherapy in three. Three patients who had local recurrence are still alive, the rest having died from metastatic disease.

**Complications**

**Infection.** Infection appears to be related to inadequate soft-tissue cover aggravated by the use of abrasive synthetic materials. In patients operated on before the routine use of a gastrocnemius muscle flap, the risk was 36%, but since then it has dropped to 12% (p = 0.0049) (Fig. 3).

Infection developed at a mean of ten months after operation (1 to 49). Staphylococcus aureus and Staphylococcus epidermidis were the two most common infecting organisms. Of the 28 patients developing infection, 17 eventually came to amputation and seven had two-stage revisions, of which six were successful in controlling the infection; four patients still have persistent infection controlled with antibiotics and have declined amputation. Factors not statistically related to the incidence of infection included age, diagnosis, percentage of bone replaced, the administration of chemotherapy and previous surgery.

**Amputation.** A total of 26 patients (17%) underwent amputation: in 17 for infection, in eight for local recurrence of tumour and in one for dissatisfaction with the functional result of her endoprosthesis. The risk of amputation was highest during the first three years. There was one late amputation at nine years for infection complicating a revision procedure. The risk of amputation was 11% for uninfected patients compared with 65% for those with infection.

**Revision.** In patients with salvaged limbs, further major surgery may still be required for aseptic loosening, infection or breakage of the endoprosthesis. The incidences of revision were 63% at ten years and 66% at 15 years (Fig. 4). The need for revision was not associated with the proportion of bone replaced or age.

**Implant failure.** Breakage of the stem occurred in five patients in whom the diameter of the stem was less than 9 mm. The mean age at insertion of the implant was 18 years with failure occurring after five. Failure occurred in titanium Stanmore prostheses which were manufactured between 1988 and 1991. We found that the cobalt-chrome femoral component abutted against the titanium tibial component in extension causing it to wear, allowing marked hyperextension. Ten patients required revision for this reason alone.

The need for revision from any cause does appear to have diminished since 1992, when the SMILES rotating hinge endoprosthesis was introduced, but it is too soon for reliable data to be available.

**Function.** We have analysed outcomes in 50 patients who

![Fig. 3](https://via.placeholder.com/150)

**Kaplan-Meier curves to show the survivorship of proximal tibial endoprostheses without infection.**

![Fig. 4](https://via.placeholder.com/150)

**Kaplan-Meier curves to show the survivorship of proximal tibial endoprostheses for both amputation and revision procedures.**
had the original endoprosthesis in place for more than two years, assessing range of movement, quadriceps power, extension lag and functional scores using the MSTS system.\textsuperscript{19}

**Movement.** The mean range of flexion was 104° (0 to 140) while the mean extensor lag was 30° (0 to 90).

**Power.** Quadriceps strength was graded according to the MRC scale (0 to 5). Only two patients had normal power (5), most having power 4, but a small proportion was weaker. The mean power was 3.63. A useful assessment of functional power is the ability to climb stairs. Of 40 patients tested on stairs, 17 could climb stairs normally while 23 could only go up one step at a time. None was unable to climb stairs.

**MSTS functional scores.** The overall score was 77% in the 50 patients analysed. The MSTS scoring system allocates up to five points for each of six different assessments (Table II). A score of five indicates normality and a score of one significant disability. A middle score of three would suggest partial problems such as the need for non-narcotic analgesics, being unable to play sports, the occasional need for a walking stick and a modest limp. A percentage score can then be given to each factor. The mean functional scores were as follows: pain 79%, function 62%, emotional acceptance 84%, need for support 85%, walking ability 77% and gait 73%.

There was no significant difference in functional scores between patients with a Stanmore and those with a SMILES endoprosthesis. In five cases, the extent of resection required the sacrifice of the peroneal nerve or excision of the muscles of the anterior compartment. These patients all had permanent footdrop. A few patients had a transient footdrop which recovered within four months.

**Discussion**

Several papers have addressed the controversy of limb salvage versus amputation. Simon et al.\textsuperscript{20} and Rougraff et al.\textsuperscript{21} have shown that while there was an increased risk of local recurrence in patients with limb salvage there was no overall difference in survival. Others\textsuperscript{22,23} found no significant difference in the quality of life between patients with amputations and those with a SMILES endoprosthesis. In five cases, the extent of resection required the sacrifice of the peroneal nerve or excision of the muscles of the anterior compartment. These patients all had permanent footdrop. A few patients had a transient footdrop which recovered within four months.

The results presented here in terms of patient survival reflect those expected for the various diagnoses and their management over the period involved. The overall incidence of local recurrence is higher than would nowadays be expected and reflects a learning curve for both surgery and chemotherapy during a period of continuing modification.

Papers dealing specifically with the complications of limb salvage show that the proximal tibia is one of the most difficult sites to obtain success. In 1989, Grimer, Carter and Sneath\textsuperscript{25} reported an incidence of infection of 33% in endoprosthetic replacement of the proximal tibia. Other authors have highlighted the problem of retaining useful extensor function.\textsuperscript{26}

The endoprostheses which we have used were initially based on the Stanmore hinged knee, the long-term results of which were not encouraging, with failure rates between 20% and 30% at eight years.\textsuperscript{27,28} After resection of a tumour around the knee, all knee ligaments are removed and there may well be considerable muscle loss. Any endoprosthesis must replace the length of bone missing, provide a stable knee and allow sufficient hyperextension for the knee to ‘lock’. Our first tibial replacement was performed in 1977 using the Stanmore knee but the subsequent high incidence of mechanical loosening became apparent.\textsuperscript{29,30} Since 1991 we have used the SMILES knee, a rotating hinge with a hydroxyapatite collar at the bone-prosthesis interface, but it is still too early to determine whether this diminishes mechanical loosening.

Infection has been the major problem and has yet to be completely solved. Contributory causes to the high rate of infection include the environment, the host and the implant. The operation itself takes between two and four hours during which there is a considerable expanse of tissue exposed. Many of the patients will be immunocompromised after chemotherapy.

The initial very high rate of infection of 33% was clearly unacceptable and this appeared to be due, in large part, to the thinness of the tissue covering the prosthesis. The Terylene rope used to repair the patellar tendon proved to be abrasive and irritant to adjacent tissues. As a result sinuses formed. Since abandoning the use of synthetic materials in favour of a gastrocnemius muscle flap, there has been a considerable reduction in the rate to 12%, although this is still hardly acceptable. Preliminary radiotherapy to the leg adds to the risk; almost half the patients who had had radiotherapy as part of their treatment developed infection at some stage.

The treatment of infected endoprostheses has also been a challenge. Simple debridement, washout and antibiotics have all proved unsuccessful. In our hands, the only successful method has been a two-stage revision. This has given a success rate of 85% if adequate soft-tissue cover is achieved. Some patients with overwhelming infection or poor tissues still need amputation, but two with intermittently discharging sinuses have chosen to delay operation indefinitely.

<table>
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<th>Score</th>
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<th>4</th>
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<td>4</td>
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<td>16</td>
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<td>6</td>
<td>9</td>
<td>24</td>
<td>9</td>
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</table>
The high risks of local recurrence, loosening and infection mean that by five years 40% have had a further operation of some sort, by ten years 70% and by 15, 73%. It must be remembered that many of these patients are young (44% were less than 20 years old when they had their operation) and are otherwise fit and healthy. They put their limbs to rigorous use, making revision surgery a common requirement. The results of revision remain encouraging in most, with preservation of function.

The functional outcome is not generally as good as in endoprosthetic replacement of the distal femur. Many patients will have lost muscle mass, and in all patients the extensor mechanism has been detached. Malawer and McHale described a method of reconstruction of the extensor mechanism using a flap of the medial head of the gastrocnemius. They emphasised the necessity of intensive postoperative rehabilitation. Petschnig et al have looked at extensor function after prosthetic replacement of the proximal tibia. They compared three groups who had had repair either with a gastrocnemius flap, a fibular transposition or a combination of the two. They found that active extension was better after the combined procedure and worst after a gastrocnemius flap alone although there was little difference in the functional scores.

Alternatives to endoprosthetic replacement include rotationplasty, which has produced excellent functional results in a small series of children. We have offered it to numerous patients at our centre, but only one has chosen it and most considered it unacceptable. Resection arthrodesis is an established procedure, but most patients accepted the increased risk of reconstructive surgery for the benefit of having a flexible knee.

Allograft reconstruction of the proximal tibia has the theoretical advantage of allowing reconstruction of the extensor mechanism by direct suture. The results of this technique are, however, little different from those reported above. Clohisy and Mankin reported 16 patients with osteoarticular allografts and found that almost half had failed by eight years, although there were only two infections. The authors comment that the results of allografts in this location are worse than those at other sites.

Other authors using endoprostheses have encountered similar problems to ours. Horowitz et al described 16 patients, all of whom had had an extra-articular resection of the knee and reconstruction with an endoprosthesis, followed for between two and ten years. The patella was screwed to the endoprosthesis to restore some extensor function. There was a high incidence of infection and loosening, and only one-third of the prostheses were in situ after eight years. Malawer and Chou reported a longer-term follow-up of 13 prostheses in 1995. In this group, there were four infections, three amputations and six revisions; less than 50% of the proximal tibial implants survived for four years.

Unwin et al had used the Stanmore knee modified to replace the proximal tibia. They found a rate of amputation of 13% and a risk of loosening of almost 50% by 12 years. Age (<20 or >60 years) did not seem to be a factor for loosening, but there was an increased risk related to the percentage of tibia replaced.

Every method of reconstruction of the proximal tibia has some disadvantages with less than optimal function and a significant risk of complication. Amputation will be required in some cases. When considering resection, careful note must be made of the characteristics of the tumour in order to minimise local recurrence and meticulous attention given to the reconstruction in order to avoid infection and optimise function. Despite these indifferent early results, the modern technique of endoprosthetic replacement of the proximal tibia can produce good functional results with an acceptable level of risk. There is no place for the occasional operator in this field, and both surgeon and patient must be fully aware of the limitations, dangers and complications of the procedure.

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References


