The early results of joint-sparing proximal tibial replacement for primary bone tumours, using extracortical plate fixation


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This paper describes the preliminary results of a proximal tibial endoprosthesis which spares the knee joint and enables retention of the natural articulation by replacing part of the tibial metaphysis and diaphysis. In eight patients who had a primary malignant bone tumour of the proximal tibia, the distal stem, which had a hydroxyapatite-coated collar to improve fixation, was cemented into the medullary canal. The proximal end had hydroxyapatite-coated extracortical plates which were secured to the remaining proximal tibial metaphysis using cortical screws. The mean age of the patients at operation was 28.9 years (8 to 43) and the mean follow-up was for 35 months (4 to 48). The mean Musculoskeletal Tumour Society score was 79% (57% to 90%), the mean Oxford Knee score was 40 points of 48 (36 to 46) and the mean knee flexion was 112° (100° to 120°). In one patient, revision to a below-knee amputation through the prosthesis was required because of recurrence of the tumour. Another patient sustained a periprosthetic fracture which healed with a painful malunion. This was revised to a further endoprosthesis which replaced the knee.

In the remaining six patients the prosthesis allowed preservation of the knee joint with good function and no early evidence of loosening. Further follow-up is required to assess the longevity of these prostheses.

The proximal tibia is the second most common site for primary bone tumours after the distal femur. Before 1977, the main treatment for such tumours was above-knee amputation. However, subsequent improvements in adjuvant therapy with improved cure rates, and simultaneous advances in surgical technique and biomedical design have made limb salvage a viable option for these patients.

Limb salvage using a cemented proximal tibial endoprosthesis to replace both the affected portion of the tibia and knee joint, is an accepted method of filling the defect created by resection of the primary bone tumour. Initial results for this technique had a revision rate as high as 70% at ten years. Those poor results were mainly due to infection, which was related to inadequacies of soft-tissue coverage. A change in practice to include mobilisation and coverage of the prosthesis with a gastrocnemius rotation flap reduced the incidence of infection from 36% to 12%. The second problem was that proximal tibial replacements were prone to aseptic loosening, with one study reporting an incidence of almost 40% at 120 months; the authors found that implant survival was much poorer when > 60% of the tibia was resected. However, this incidence has been reduced by the introduction of a rotating hinge knee (SMILES: Stanmore Modified Individualised Lower Extremity System, Stanmore Implants Worldwide, Stanmore, United Kingdom) and a hydroxyapatite (HA) collar at the distal bone/prosthesis interface. Nevertheless, high loads still pass through the endoprosthesis, predisposing it to loosening. Preservation of the knee joint offers a reduction in the peak loads transferred at the bone-prosthesis interface.

A knee joint-sparing proximal tibial replacement has been developed with HA-coated extracortical plates which are screwed into the remnant of the tibia. The use of HA-coated extracortical plates follows experimental work in goats using various different designs of plate. It was found in these studies that three extracortical plates with horizontal grooves provided better early stability, easier insertion and consistent long-term fixation. Cobb et al described this technique mainly for revision surgery for aseptic loosening of prostheses of the distal femur, proximal tibia and humerus. They found the triplate design incorporated well within a remodelled cortex.
and achieved osseo-mechanical integration, with all patients regaining their original level of function within five months.7 As a result of this success, HA-coated extra-cortical plates have been used in joint-sparing surgery of the distal femur with excellent osseointegration at the prosthesis-proximal bone interface and formation of new bone around the HA collar. The prosthesis allows preservation of the knee and achieves a good functional result.9 We report the early outcome of eight patients who underwent joint sparing proximal tibial replacement for primary bone tumour.

**Patients and Methods**

Between November 2004 and July 2008, eight patients had knee-sparing proximal tibial endoprosthetic replacements for primary non-metastatic bone tumours of the proximal tibia. All patients met the criteria for limb salvage namely a biopsy proving malignant tumour of the proximal tibia requiring complete excision, no involvement of neuro-vascular structures, no invasion of the knee by the tumour, either clinically or on MRI, and the ability to resect the tibia with clear margins, leaving sufficient bone to allow safe fixation of the prosthesis. The mean horizontal transection point was 20.6 mm proximal (2 to 35) and 36.3 mm distal (10 to 80) to the tumour.

There were two males and six females with a mean age of 38.9 years (8 to 43). Of these, five had high grade osteosarcoma, one a malignant fibrous histiocytoma, one an adamantinoma and one an Ewing’s sarcoma. All patients received post-operative chemotherapy and none received radiotherapy.

**Implant design.** Each implant was custom-made using CT imaging to ensure accurate dimensions, after proximal and distal transection points had been determined by inspection of the pre-operative MR scans. The implants were manufactured by Stanmore Implants Worldwide Ltd, Elstree, England (Fig. 1). Distal fixation was with a cemented intramedullary stem and an HA-coated collar, as this method had proved successful in distal femoral replacements10 and may have contributed to the improved outcome at ten years of proximal tibial replacements with a fixed hinge, compared with a rotating-hinge design with an HA-collar.11 Proximal fixation to the tibial metaphysis was by HA-coated extracortical plates, through which 4.5 mm cortical screws were placed in the medial and lateral cortices. The HA plates were not slotted as described previously7 because they were too short to be able to incorporate any grooves. The mean width and length of the plates was 23.2 mm (13 to 30) and 17.8 mm (11 to 30) respectively. They were applied close to the joint line as the remaining proximal tibial bone was short, with the length of plate determined by the amount of retained proximal tibia. The mean length of the remaining metaphyseal bone was 26.3 mm (13 to 48) and the mean distance between the upper margin of the plates and the joint line was 8.5 mm (2 to 27, Fig. 2). On the proximal horizontal surface of the implant two HA-coated ridges 10 mm high were used to enhance fixation in the remaining medullary bone (Fig. 3). These ridges were positioned so that they abutted the internal cortices as closely as possible.

**Operative technique.** Under tourniquet control the tibia was resected at the pre-determined proximal and distal levels after marking the anterior tibial cortex as a reference for correct rotational placement of the component. The distal part of the prosthesis was cemented and the proximal part fixed to the remaining tibial metaphysis with a degree of impaction, so that the internal ridges became press-fitted into the cancellous bone. Holes were drilled and 4.5 mm cortical screws were inserted through the medial and lateral plates. The two parts were secured with two locking bolts. A rotation flap of the medial head of gastrocnemius was mobilised to cover the implant and sutured into place. In five patients the attachment of the patellar tendon was sacrificed, and it was repaired directly on to the transposed medial head of gastrocnemius. In one patient an osteotomy was made, preserving the anterior cortex and tibial tuberosity. The proximal part of the prosthesis was fixed in the method described previously, but the anterior bone was wired to the prosthesis, the anterior part of which was also...
HA-coated to allow for osseointegration of the tibial tuberosity. In the remaining two patients the transection point was distal to the tuberosity and therefore the patellar tendon was preserved.

Post-operatively the limb was elevated and a suction drain was used. Antibiotics were given at the induction of anaesthesia and continued for three days post-operatively. The patients remained in an extension brace for six weeks, undertaking only passive flexion and extension, and were required to remain non-weight-bearing on the affected leg. After this progressive weight-bearing was commenced. In the patient in whom the tibial tuberosity was preserved and attached to the prosthesis, a cylinder cast was used to prevent knee movement until eight weeks post-operatively to allow for osseointegration to occur.

**Functional outcome.** Patients were evaluated using the Musculoskeletal tumour society scoring system for limb salvage and the revised Oxford Knee Score (OKS). The former is a six-item scale evaluating pain, function, emotional acceptance, use of supports, walking ability and gait cosmetics in order to produce a score ranging from 0 to 30. A percentage can then be calculated to compare function with other limb-salvage techniques.

The OKS is a 12-question form scoring 0 to 4 points per question, producing a score ranging from 0 to 48. The questions are specific to the knee and cover pain, function, use of supports, walking ability and gait.

**Results**

**Implant function.** The mean follow-up was for 35 months (4 to 48), with an overall implant survival of six of the eight devices; the endpoint was revision.

One implant failed because the patient fell on the eighth post-operative day and sustained a fracture through the remnant of the tibial metaphysis. Open reduction and internal fixation with two cancellous screws was performed, but malunion with pain and limited mobility developed. At 19 months after the initial operation she required revision to excise the tibial metaphysis and insert a joint sacrificing proximal tibial replacement.

The patient with an adamantinoma developed a recurrence at the distal bone-prosthesis interface. She had undergone previous intrallesional curettage before referral. Further limb-salvage procedures were not considered possible and a below-knee amputation was performed through the prosthesis. The proximal component was retained and a small end cap was fashioned to fit over it and provide the skeletal structure around which a myocutaneous flap could be fashioned, thereby enabling the patient to retain the knee joint. This operation was performed 14 months after the initial surgery. Before the amputation, she was walking unaided and free of pain, and had been able to swim and cycle.

One patient complained of a prominent lateral metaphyseal screw, which was removed at six months. Another
patient complained of pain at the ankle joint. It was felt that this was due to syndesmotic instability and a diastasis screw was inserted at 41 months, with resolution of the symptoms.

Functional scores were made on the six patients who still had the joint-sparing prosthesis in situ. The mean musculoskeletal tumour society outcome score was 24 of 30 (79% (57% to 90%)) and the mean OKS was 40 (36 to 46) at final follow-up. All patients reported difficulty kneeling down and standing up owing to pain experienced when pressure was applied to the operated area. The mean knee flexion was 112° (100° to 120°). There was no statistical significance between the amount of physis remaining and functional outcome, although patient 2 had the least amount of remaining metaphysis (13 mm) and the worst musculoskeletal tumour society score (57%).

Varus and valgus instability of the knee was not encountered as the collateral ligaments remained intact and rotational malaignment was avoided.

Discussion
Extracortical plate fixation has the advantage of allowing incorporation of the prosthesis into the load-bearing structure of the bone as it remodels. It takes advantage of the biological phenomenon shown by callus at a fracture site or in a loose massive replacement, in which bone is laid down outside the cortex, away from the loosening prosthesis. Bone forms on the periosteal surface in a centripetal fashion, incorporating the plates into the new expanded cortex. This process is aided by the use of plates of different lengths and tapering thickness which allow gradual transfer of the load. Ridges on the proximal surface of the implant to aid stability as does HA coating of the inside and outside of the plates, the plateau and collar of the implant.

Minimal additional soft-tissue dissection was required at the proximal end of the tibia to obtain adequate exposure for fixation of the extracortical plates. This was achieved without evidence of disruption of the periosteal blood supply to the remaining bone which might have led to cortical necrosis. At 44 months, it was not possible to determine on plain radiographs whether there was evidence of extrasosseous bone formation, in contrast with the findings of our distal femoral series. The plates used in the tibial device were not slotted, as they were too short and this might partly explain the lack of extrasosseous bone. Despite this, there was no radiological or clinical evidence of loosening, indicating good stable fixation at the proximal interface.

The screws locking the extracortical plates from the medial and lateral sides provide strong fixation in the short-term. The smallest plates were 10 mm long, which allowed sufficient room to incorporate the cortical screws. The remaining metaphysis must be at least 2 mm longer than the plates so that they do not interfere with the function of the joint. In our series the maximum length of remaining metaphyseal bone was 48 mm. It is considered that these prostheses could be used when there is up to 60 mm of remaining metaphysis. In circumstances where there is a greater length of bone remaining a diaphyseal replacement is an option, as an intramedullary stem can be used to aid stability. The length of 60 mm has been defined as the cut-off, as the shortest stem is 50 mm and a further 10 mm is required to prevent the stem disrupting the articular surface.

Another treatment option for limb-salvage is the use of grafts, and research using osteoarticular or intercalary allografts to fill the defect created after tumour resection has been performed. A series of osteoarticular allografts reported failure in five of seven grafts. Results with intercalary grafting have been more favourable. A multicentre study performed by the European Musculoskeletal Oncological Society observed an 18.5% incidence of infection and a 21% prevalence of fracture of the graft in the tibia. Delayed or nonunion was observed in 63% of the intercalary grafts, with overall function reported as excellent or good in 63%. Another long-term follow-up study of intercalary allografts reviewed the results of 104 procedures, of which 38 were in the tibia. Infection occurred in 12%, nonunion in 30% and fracture in 17% and an additional 81 procedures were needed to obtain satisfactory results. Importantly, there was an overall success rate of 84% of patients, but in those who required adjuvant therapy, complications and failures occurred more frequently and the rate of success was reduced to 60%. A more recent study of 59 intercalary grafts, of which 19 were at the tibia, reported a five-year survival of 79%, with infection and fracture rates of just 5% and 7%, respectively.

Similar results have been observed in patients who received free vascularised fibular grafts, with four of ten reconstructions resulting in failure, including two stress fractures and two nonunions, one of which developed local recurrence and the other an infection requiring above-knee amputation. The functional outcome using the Musculoskeletal Tumour Society score was excellent in six patients, good in two and poor in two. The main problems associated with grafting procedures, are the increased complications, mainly infection, fracture and nonunion. Furthermore, with grafts the time to full weight-bearing is considerably longer than with an endoprosthesis.

In our series, one implant failed and one patient required an amputation for tumour recurrence. In the remaining six patients the joint-sparing prosthesis has comparable results to the joint-sacrificing prostheses analysed by Grimer et al. Comparing their results, the mean range of flexion in our patients was 112°, compared to 104°, and our overall functional score was 79% compared to 77%.

We feel our preliminary results are promising, with preservation of the natural joint, at least in the short term. Our patients need longer follow-up with regard to their susceptibility to aseptic loosenings, which is a known midterm problem in proximal tibial replacements.
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