Houve infecção em quatro casos (3,2%), refratura em dois casos (1,6%), soltura da plaça em um caso (0,8%), luxação da prótese em um caso (0,8%), piora da dor em um caso (0,8%) e um caso de óbito transoperatório (0,8%).

DISCUSSÃO

O desenvolvimento de uma fratura patológica não é obrigatoriamente um evento terminal, como se supunha há alguns anos.\(^{12,18,19}\)

O objetivo maior do tratamento cirúrgico das fraturas patológicas é aliviar a dor e restabelecer a mobilidade e a utilização do membro afetado.\(^{15,45}\)

Nos tumores radiosensíveis, a radioterapia pós-operatória é uma parte importante do tratamento.\(^{15,45}\)

O tipo de estabilização vai depender da localização da lesão e do seu tamanho e, sempre que a estabilização não for adequada, a utilização do metilmetacrilato é recomendada.\(^{15,45}\)

Na nossa experiência, a substituição por endoprótese não convencional, sempre que possível, é o melhor método para o tratamento das lesões ósseas metastásicas.

É importante salientar ainda o aspecto psicológico do paciente, que é devolvido mais rapidamente ao seu convívio normal, e também o aspecto dos custos hospitalares, diminuindo o período de internação e ocupação de leito hospitalar.

REFERÊNCIAS

AVALIAÇÃO BIBLIOGRÁFICA SOBRE O USO PROPOSTO DO PRODUTO

**PRODUTO:** Endoproteses 
**Modelos:** Proximal de Fêmur com cilindro

O artigo relata trabalho realizado entre 1987 e 1992 com 114 pacientes com fraturas patológicas. Dos 114 pacientes 89,4% apresentava carcinoma metastático e 10,5 apresentavam mieloma múltiplo. No total foram realizadas 124 cirurgias e em aproximadamente 70% dos casos, foi utilizado metilmetacrilato, onde os melhores resultados foram obtidos nos pacientes submetidos a substituição por endoprotese (10,6 meses de sobrevida em média).

O objetivo principal do tratamento cirúrgico das fraturas patológicas é aliviar a dor, restabelecer o mais rápido possível, a função do membro afetado, melhorando assim a qualidade de vida e a sobrevida do paciente.

O método de cirurgia adotado em maior número foi com cimento ósseo (49 casos, 39,5%) seguido pela endoproteese não convencional (35 casos, 28,2%).

A figura 2 demonstra um caso onde o paciente foi submetido a uma ressecção por endoproteese não convencional proximal de fêmur com cilindro e mostra o resultado funcional do paciente.

O objetivo principal do tratamento cirúrgico das fraturas patológicas é aliviar a dor e restabelecer a mobilidade e a utilização do membro afetado.

O tipo de estabilização depende da localização e do seu tamanho e, sempre que a estabilização não for adequada, a utilização do metilmetacrilato é recomendada.

Conforme os autores a substituição por endoprótese não convencional, sempre que possível, é o melhor método para o tratamento das lesões ósseas metastáticas.

É importante salientar ainda o aspecto psicológico do paciente, que é devolvido mais rapidamente ao seu convívio normal, e também o aspecto dos custos hospitalares, diminuindo o período de internação e ocupação de leito hospitalar.
SECTION II ORIGINAL ARTICLES

Zeegen, Erik N MD; Aponte-Tinao, Luis A MD; Homiecek, Francis J MD, PHD; Gebhardt, Mark C MD; Mankin, Henry J MD

Abstract:
Although our institution historically has been known for its use of osteoarticular allografts in limb salvage surgery for tumors, during the last 8 years there has been an increase in the use of metallic modular endoprostheses. A retrospective review of 141 patients in whom a modular endoprosthesis was implanted in the past 8 years was done, and survival data were compiled using Kaplan-Meier survival analysis. Clinical score was determined using a previously described system, and a multivariate regression analysis was done to identify independent risk factors. There were 13 failures (defined as need for revision of the majority of the prosthetic components, excluding cases of local recurrence) yielding an overall implant survival of 91%. Based on Kaplan-Meier estimates, the endoprosthetic survival rate was 88% at 3 years and 76% at 5 years; per location, it was 100% for the proximal humerus, 100% for the proximal femur, 87% for modular knees, and 53% for total femoral implants at 3 years. The clinical scores were good to excellent in 74% of the patients. Multivariate analysis showed that only location and infection were independent risk factors for prosthetic failure. Loosening, infection, and dislocation were independently predictive of a fair or poor clinical score. Age, gender, diagnosis, length of implant, dislocation, nor failed prior allograft had an independent effect on implant survival or clinical outcome. The proximal humeral and proximal femoral implants had greater survival rates than modular knee and total femoral implants. Conversion of failed allografts to modular endoprostheses had a trend for a higher failure rate, but after a multivariate analysis, did not prove to be an independent risk factor for failure. We think that our experience is similar to other endoprosthesis survivorship reports in the literature with short-term followup.
AVALIAÇÃO BIBLIOGRÁFICA SOBRE O USO PROPOSTO DO PRODUTO

PRODUTO: ENDOPROTESES
Modelos: Proximal de Fêmur, Proximal de Úmero e Joelho modular.

Este artigo relata estudo feito com 141 pacientes num acompanhamento de 8 anos até este ser realizado e os dados da sobrevivência foram compilados usando a análise da sobrevivência de Kaplan-Meier, a contagem clínica era determinada usando um sistema previamente descrito, e uma análise de regressão múltipla foi feita para identificar fatores de risco independentes.

Havia 13 falhas (definidas como a necessidade para a revisão da maioria dos componentes protéticos, com exclusão dos casos do retorno local) rendendo uma sobrevivência total do implante de 91%. Baseado em estimativas de Kaplan-Meier, a taxa de sobrevivência da endoprotoses era 88% em 3 anos e 76% em 5 anos; por região, era 100% para o úmero proximal, 100% para o fêmur proximal, 87% para joelhos modulares, e 53% para implantes femorais totais em 3 anos. As contagens clínicas eram boas a excelente em 74% dos pacientes. A análise múltipla mostrou que somente região e a infecção eram fatores de risco independentes para a falha da prótese.

As complicações em geral não influenciaram independentemente na sobrevivência do implante ou no resultado clínico. Os implantes proximais de fêmur e proximal de Úmero tiveram maiores taxas de sobrevivência do que o joelho modular e implantes totais de fêmur.

O estudo segundo os autores, concluiu de que os resultados obtidos foram similares a outras literaturas de acompanhamento em curto prazo.
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.


The proximal tibia is the second most common site for primary bone tumours. Some 12% to 15% of osteosarcomas, 11% of Ewing's sarcoma 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 Castr

5 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 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 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
Table 1. Diagnosis 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>
</thead>
<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>
</tr>
<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>

This site. The diagnoses are shown in Table 1. All patients with chemo- or 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 endoprostheses 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

Fig. 1
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 implant17 (Fig. 2).

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.18

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 10 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
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.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 al20 and Rougraff et al21 have shown that while there was an increased risk of local recurrence in patients with limb salvage there was no overall difference in survival. Others22,23 found no significant difference in the quality of life between patients with amputations and those whose limb had been salvaged. Interestingly, however, limb salvage has been shown to be cost-effective in comparison with amputation24 and patients generally prefer limb salvage.

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 Sneth25 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.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.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.29 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 exposure 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 II. Functional scores for the 50 patients with endoprostheses of the proximal tibia using the MSTS functional scoring system

<table>
<thead>
<tr>
<th>Score</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>0</td>
<td>4</td>
<td>9</td>
<td>21</td>
<td>16</td>
</tr>
<tr>
<td>Function</td>
<td>8</td>
<td>22</td>
<td>13</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Emotional acceptance</td>
<td>4</td>
<td>0</td>
<td>5</td>
<td>12</td>
<td>29</td>
</tr>
<tr>
<td>Need for support</td>
<td>3</td>
<td>7</td>
<td>0</td>
<td>3</td>
<td>37</td>
</tr>
<tr>
<td>Walking ability</td>
<td>0</td>
<td>4</td>
<td>12</td>
<td>21</td>
<td>13</td>
</tr>
<tr>
<td>Gait</td>
<td>2</td>
<td>6</td>
<td>9</td>
<td>24</td>
<td>9</td>
</tr>
</tbody>
</table>

THE JOURNAL OF BONE AND JOINT SURGERY
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 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 long-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 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


AVALIAÇÃO BIBLIOGRÁFICA SOBRE O USO PROPOSTO DO PRODUTO

PRODUTO: ENDOPROTESES
Modelos: Proximal de Tíbia c/ bizbra.

Foi executada a reconstrução com endoprosteses após a ressecção dos tumores da região proximal da tíbia em 151 pacientes durante 21 anos.

Durante este período a cirurgia de salvamento de membro foi conseguida em 88% dos pacientes com tumores proximais de tíbia. O implante e a técnica operatória foram se modificando gradualmente a fim de reduzir complicações. Uma taxa de infeção inicial de 36% foi reduzida a 12% utilizando uma técnica onde o tendão patelar dividido é unido. O afrouxamento e a ruptura do implante foram umas das causas mais presentes de falha.

Foi encontrado que a probabilidade de procedimentos cirúrgicos adicionais exigidos era 70% em dez anos e riscos de amputação, 25%.

O desenvolvimento de uma endoprosteses rotatória com dobradiça abaixou a incidência de problemas mecânicos. O salvamento do membro para tumores proximais de tíbia é preocupante devido às complicações, mas o bom resultado funcional nos casos bem sucedidos justifica seu uso continuamente.

Antigamente em muitos dos casos envolvidos os pacientes eram amputados, mas com o avanço simultâneo de técnicas cirúrgicas e engenharia biomecânica o salvamento do membro se tornou uma opção prática para muitos pacientes com tumores ósseos.

As técnicas incluem recolocação com endoprosteses modulares ou não modulares e as seguintes circunstâncias devem aplicar-se se um membro deve ser salvo ou amputado: 1) A vida do paciente não deve ter risco aumentado. 2) O método do salvamento do membro deve fornecer um melhor resultado funcional. 3) A taxa de complicações deve ser de aceitável a baixa. 4) O paciente deve ser inteiramente informado e concordar.

Cada método de reconstrução da tíbia apresenta algumas desvantagens como diminuição da função e o risco de complicações.

Ao optar pela reconstrução com endoprosteses, uma análise cuidadosa deve ser feita das características do tumor a fim minimizar o retorno local e a atenção meticulosa dados à reconstrução a fim evitar a infeção e aperfeiçoar a função.

Apesar de possíveis complicações, a moderna técnica de reconstrução com endoprosteses da tíbia proximal podem produzir bom resultado funcional com um nível aceitável de risco, o cirurgião e paciente devem estar inteiramente cientes das limitações, dos perigos e das complicações do procedimento.
Clinical Study

The Use of Massive Endoprostheses for the Treatment of Bone Metastases


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Recommended by Adesegun Abudu

Purpose. We report a series of 58 patients with metastatic bone disease treated with resection and endoprosthetic reconstruction over a five-year period at our institution. Introduction. The recent advances in adjuvant and neoadjuvant therapy in cancer treatment have resulted in improved prognosis of patients with bone metastases. Most patients who have either an actual or impending pathological fracture should have operative stabilisation or reconstruction. Endoprosthetic reconstructions are indicated in patients with extensive bone loss, failed conventional reconstructions, and selected isolated metastases. Methods and Results. We identified all patients who were diagnosed with metastatic disease to bone between 1999 and 2003. One hundred and seventy-one patients were diagnosed with bone metastases. Metastatic breast and renal cancer accounted for 84 lesions (49%). Fifty-eight patients with isolated bone metastasis to the appendicular skeleton had an endoprosthetic reconstruction. There were 28 males and 30 females. Twelve patients had an endoprosthesis in the upper extremity and 46 patients had an endoprosthesis in the lower extremity. The mean age at presentation was 62 years (24 to 88). At the time of writing, 19 patients are still alive, 34 patients have died, and 5 have been lost to follow up. Patients were followed up and evaluated using the musculoskeletal society tumour score (MSTS) and the Toronto extremity salvage score (TESS). The mean MSTS was 73% (57% to 90%) and TESS was 71% (64% to 95%). Mean follow-up was 48.2 months (range 27 to 82 months) and patients died of disease at a mean of 22 months (2 to 51 months) from surgery. Complications included 5 superficial wound infections, 1 aseptic loosening, 4 dislocations, 1 subluxation, and 1 case, where the tibial component of a prosthesis rotated requiring open repositioning. Conclusions. We conclude that endoprosthetic replacement for the treatment of isolated bone metastases is a reliable method of limb reconstruction in selected cases. It is associated with low complication and failure rates in our series, and achieves the aims of restoring function, allowing early weight bearing and alleviating pain.

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1. INTRODUCTION

Bony metastases are the most common neoplasms of bone and the skeleton is the third most common site for metastatic diseases, after the lung and liver [1]. Advances in adjuvant and neoadjuvant therapies, especially in the fields of hormonal therapy and chemotherapy, have improved the prognosis of patients with cancer. This has subsequently led to an increase in the incidence of bony metastases and resultant pathological fractures of the long bones. The management of the patient with a pathological fracture presents a challenge to the orthopaedic surgeon and necessitates a multidisciplinary approach. A consensus statement by the British Orthopaedic Association and the British Orthopaedic Oncology Society has highlighted the fact that there remains a low level of awareness in the hospital and primary care settings of what can be achieved in the management of metastatic bone diseases [2, 3]. Skeletal complications can have a marked effect on the patient's quality of life, with bone pain being the most frequent clinical symptom. An actual or impending pathological fracture impacts on the patient's function and mobility. In principle, the aims of treatment should be to relieve pain and restore function by stabilising pathological fractures [2, 4–6]. Stabilising impending or actual pathological fractures allows early resumption of ambulation, which significantly improves patients' quality of life [7]. In addition to stabilisation, orthopaedic constructs should allow immediate weight bearing and be designed to last the expected lifetime of the patient [2, 8]. Fracture healing is often poor in diseased or irradiated bone and the surgeon must take into account the fact that these fractures may not unite [9]. Metastatic lesions with extensive bone loss or pathological
fractures affecting adjacent joints may be treated with resection and an endoprosthetic reconstruction. The load-bearing characteristics of endoprostheses offer immediate postoperative stability, and facilitate rapid rehabilitation [10, 11]. Over the last 20 years, the availability and improvement of modular endoprostheses has improved the treatment of bone metastases, but the treatment of isolated bone lesions, particularly in the treatment of isolated bone lesions, failed conventional reconstructions and lesions with extensive bone loss [12]. In selected cases, isolated lesions such as a metastasis from renal cell cancer are treated with complete excision and endoprosthetic reconstruction with the intent to cure [4, 13].

The purpose of this paper is to review our experience of patients with metastatic bone disease from carcinoma that had resection and an endoprosthetic reconstruction at our hospital over a five-year period.

2. METHODS

We performed a retrospective review of all patients with bone metastases referred to our regional musculoskeletal tumour centre from January 1999 to December 2003. Patients were identified from the tumour database. We determined the patient demographics, indications for treatment and the complications in patients who had resection of metastatic bone lesions and endoprosthetic reconstruction. The following inclusion criteria are applied for the sample collection: (1) a known metastatic lesion in the appendicular skeleton on the basis of histological diagnosis; and (2) no previous resection and endoprosthetic reconstruction. Other information, namely, age, gender, primary lesion if known, site of lesion, and duration of follow-up period, were also noted. All patients referred to our institution are discussed in a multidisciplinary team setting, attended by oncologists, radiologists, orthopaedic surgeons, and other allied health professionals.

Decisions regarding prophylactic surgery for patients with impending pathological fractures are made based on Mirels [14] scoring system (Table 1), with a score of >8 necessitating operative stabilisation.

The indications for endoprosthetic reconstruction were isolated single metastases in the long bones, lesions involving adjacent joints, and large lesions with extensive bone loss. In principle, these metastatic lesions were excised in a similar manner to primary bone tumours. Where possible, wide soft tissue margins were obtained and the shaft of the long bone was transected at least 2 cm away from the extent of the disease. In view of the fact that this is palliative surgery, important neurovascular structures were usually preserved at the expense of wide margins in order to maximise functional outcome. In patients with intraarticular spread of tumour, we performed conventional joint replacement surgery and did not attempt extraarticular resections. In the case of proximal femoral, distal femoral and proximal tibial reconstruction modular endoprosthetic tumour system (METS, Stanmore Implants Worldwide Ltd, Stanmore, Middlesex, UK) were used as it became available. For the proximal femoral replacements, this was in 2001 and for the distal femoral and proximal tibial replacements, this was in 2003. These above-mentioned prostheses are modular, off-the-shelf endoprosthetic reconstruction systems. For other tumour locations and before these dates, surgery required the manufacture of custom-made implants (Stanmore Implants Worldwide Ltd).

In patients requiring proximal femoral replacement and whose disease spared the greater trochanter, this structure was osteotomised and reattached to the endoprostheses using a trochanteric reattachment plate and screws. The proximal femoral endoprostheses contain a spiked, hydroxyapatite coated shoulder with two screw holes for this specific purpose. This enables gluteus medius and minimus to be reattached thereby preserving abductor function. Postoperative radiotherapy was offered to all patients with pathological fractures and those whose resection margins were positive. We did not routinely offer radiotherapy to patients who had a successful wide excision.

Functional outcome was assessed using the system adopted by the musculoskeletal tumour Society (MSTS) for the functional evaluation of reconstructive procedures after skeletal resection [15], and a patient-reported measure of disability, the Toronto extremity salvage score (TESS) [16]. The MSTS score is a clinician scored system assessing pain, function, and emotional acceptance in patients for upper and lower extremities. Patients with lower extremity reconstructions were also evaluated with regard to walking ability, gait, and the use of walking aids. Patients with upper extremity reconstructions were evaluated for manual dexterity, hand positioning, and lifting ability. The TESS was developed as a disease-specific measure for patients undergoing limb salvage surgery for tumours of the extremity. It evaluates physical disability based on the patients' report of their function using a self-administered questionnaire, which rates the difficulty experienced in performing certain activities. Both the MSTS and TESS scores are represented as a percentage, with a higher percentage indicating better functional outcome.

3. RESULTS

Between January 1999 and December 2003, 171 patients were diagnosed with metastatic bone tumours from carcinoma. Fifty-eight of which underwent an endoprosthetic reconstruction. There were 28 males and 30 females with a mean age at diagnosis of 62 years (range 24 to 88). The most common underlying diagnosis was renal cell carcinoma in

<table>
<thead>
<tr>
<th>Variable</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site</td>
<td></td>
</tr>
<tr>
<td>Upper limb</td>
<td></td>
</tr>
<tr>
<td>Lower limb</td>
<td></td>
</tr>
<tr>
<td>Peritrochanter</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>Functional</td>
<td></td>
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<tr>
<td>Lesion</td>
<td></td>
</tr>
<tr>
<td>Blastic</td>
<td></td>
</tr>
<tr>
<td>Mixed</td>
<td></td>
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<tr>
<td>Lytic</td>
<td></td>
</tr>
<tr>
<td>Size*</td>
<td></td>
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<tr>
<td>&lt; 1/3</td>
<td></td>
</tr>
<tr>
<td>1-3/2-3</td>
<td></td>
</tr>
<tr>
<td>&gt; 3/3</td>
<td></td>
</tr>
</tbody>
</table>

*As seen on plain X-ray, minimum destruction of cortex in any view. Maximum possible score is 19. If lesion scores 8 or above then prophylactic fixation is recommended prior to surgery.
### Table 2: Primary diagnosis of patients undergoing endoprosthetic reconstruction.

<table>
<thead>
<tr>
<th>Primary diagnosis</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal carcinoma</td>
<td>27 (46.6)</td>
</tr>
<tr>
<td>Breast carcinoma</td>
<td>10 (17.2)</td>
</tr>
<tr>
<td>Unknown primary</td>
<td>8 (13.8)</td>
</tr>
<tr>
<td>Lung carcinoma</td>
<td>4 (6.9)</td>
</tr>
<tr>
<td>Squamous cell carcinoma</td>
<td>2 (3.4)</td>
</tr>
<tr>
<td>Prostate carcinoma</td>
<td>2 (3.4)</td>
</tr>
<tr>
<td>Thyroid carcinoma</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>Oesophageal carcinoma</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>Phaeochromocytoma</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>Ovarian carcinoma</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>Bladder carcinoma</td>
<td>1 (1.7)</td>
</tr>
</tbody>
</table>

27 (46.6%) of patients, followed by breast carcinoma in 10 (17.2%), unknown primary carcinoma in 8 (13.7%), lung carcinoma in 4, squamous cell carcinoma in 2, prostate carcinoma in 2, thyroid, oesophageal, ovarian, and bladder carcinoma in 1 patient each and a phaeochromocytoma (Table 2). Forty-six patients had lower extremity lesions, which were treated with 31 proximal femoral replacements, 11 distal femoral replacements, and 4 proximal tibial replacements. Twelve had upper extremity lesions, treated with 7 proximal humeral replacements, 4 distal humeral replacements, and 1 humeral diaphyseal replacement.

There were 5 superficial wound infections (8.6%), all of which resolved with oral antibiotics. Four dislocations occurred in the proximal femoral replacements group (12.9%). Three were reduced closed and one required an open reduction without requiring component repositioning and this patient was subsequently managed in an abduction brace for 8 weeks. There was one case of aseptic loosening in the humeral diaphyseal replacement, which required revision, one subluxation in a proximal humeral replacement, and one case of component malposition. The tibial component of a distal femoral replacement was found to be rotated 180 degrees requiring open exploration and repositioning.

Thirty-four patients had died at a mean of 22 months (range 2 to 51 months) from surgery and 5 were lost to follow-up. The remaining 19 had a mean follow-up of 48.2 months (range 27 to 82 months). They were functionally evaluated with the MSTS and the TESS scores (Table 3). For the group as a whole, the mean MSTS score was 73% (range from 57 to 90%) and TESS was 71% (range 46 to 95%). Looking specifically at lower limb reconstruction, the mean MSTS score was 77.9% (range 57 to 90%) and the mean TESS was 75.6% (range 46 to 95%). The group with proximal femoral replacements (11 patients) had a mean MSTS score of 72.4% (range 57 to 83) and a mean TESS of 68.4% (range 46 to 84). The group with distal femoral replacements (4 patients) had a mean MSTS score of 75% (range 60 to 90) and a mean TESS of 77.5% (range 63 to 95). One patient with a proximal tibial replacement had an MSTS score of 73% and a TESS score of 72%. In the upper limb, two patients with proximal humeral replacements had MSTS scores and TESS of 72% and 70%, and 73% and 71%, respectively. One patient with a distal humeral replacement had an MSTS score of 76% and a TESS of 77%.

No patients had local recurrence or required subsequent amputation and there was one revision of the humeral diaphyseal replacement as described above.

### 4. DISCUSSION

Endoprosthetic reconstruction has a role in the management of metastatic lesions with extensive bone loss, failure of conventional reconstruction, and large isolated lesions with the aim being curative. Although the conventional treatment of metastatic bone lesions with plates and intramedullary devices supplemented with methylmethacrylate is well established [7], lesions that involve adjacent joints often require resection and reconstruction to allow early and full weight bearing. The purpose of this study was to review our experience with endoprosthetic replacements and to objectively assess patient outcome using both a clinician-reported and a patient-reported score. The majority of the endoprosthetic reconstructions in our series were proximal femoral replacements, a finding reflected in other series of endoprosthetic replacements for bone metastases [5, 12], with the proximal femur being the most common site of long-bone involvement by metastatic disease [8, 17, 18]. The hip joint must bear as much as six times body weight and this necessitates that reconstruction must provide immediate stability and prolonged durability. This strongly favours the use of an endoprosthetic replacement rather than internal fixation [8]. Conventional fixation of pathological fractures or large lytic lesions especially around the hip or proximal femur has a high failure rate when compared to a standard or tumour prosthetic replacement [5, 19, 20]. It is therefore our preferred method of treatment to carry out a resection and endoprosthetic replacement for large lesions of the proximal femur. The extent of tumour in the proximal femur dictated the method of abductor repair and if the trochanter could be spared with an adequate margin of bone between the tumour and a trochanteric osteotomy, then the trochanter was reattached in the manner described previously. Tumour involving the trochanter resulted in resection of the proximal femur including the trochanter and a soft tissue abductor repair was done. In our series of 11 patients, only one patient was suitable for a trochanteric osteotomy and reattachment to the prosthesis. This patient subsequently had a dislocation on her first postoperative day and underwent a closed reduction. At 31 months follow-up, her MSTS score was 57% and her TESS was 46%. Due to the small numbers we are unable to comment on whether trochanteric reattachment significantly affects functional outcome or hip abductor function. Of the 11 patients with proximal femoral lesions, seven presented with a pathological fracture. Patients who had a pathological fracture on presentation had a mean MSTS score of 69.1% (range 57 to 80%) and a mean TESS of 65.9% (range 46 to 82%). Patients who presented without a pathological fracture had a mean MSTS score of 78% (range 70 to 83%) and a mean
Table 3: Functional outcomes of the 19 patients (out of 58) surviving 2 years or more.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Primary</th>
<th>Age</th>
<th>Operation*</th>
<th>TESS</th>
<th>MSTS</th>
<th>Follow-up (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Phaeochromocytoma</td>
<td>24</td>
<td>PFR</td>
<td>82</td>
<td>80</td>
<td>39</td>
</tr>
<tr>
<td>2</td>
<td>Thyroid carcinoma</td>
<td>42</td>
<td>PFR</td>
<td>72</td>
<td>74</td>
<td>41</td>
</tr>
<tr>
<td>3</td>
<td>Oesophageal carcinoma</td>
<td>42</td>
<td>PFR</td>
<td>69</td>
<td>63</td>
<td>35</td>
</tr>
<tr>
<td>4</td>
<td>Ovarian carcinoma</td>
<td>45</td>
<td>PFR</td>
<td>65</td>
<td>77</td>
<td>33</td>
</tr>
<tr>
<td>5</td>
<td>Breast carcinoma</td>
<td>49</td>
<td>PFR</td>
<td>46</td>
<td>57</td>
<td>31</td>
</tr>
<tr>
<td>6</td>
<td>Renal carcinoma</td>
<td>67</td>
<td>PFR</td>
<td>56</td>
<td>63</td>
<td>31</td>
</tr>
<tr>
<td>7</td>
<td>Unknown primary</td>
<td>77</td>
<td>PTR</td>
<td>71</td>
<td>70</td>
<td>44</td>
</tr>
<tr>
<td>8</td>
<td>Unknown primary</td>
<td>58</td>
<td>PFR</td>
<td>74</td>
<td>78</td>
<td>44</td>
</tr>
<tr>
<td>9</td>
<td>Breast carcinoma</td>
<td>68</td>
<td>PFR</td>
<td>53</td>
<td>70</td>
<td>27</td>
</tr>
<tr>
<td>10</td>
<td>Breast carcinoma</td>
<td>42</td>
<td>PFR</td>
<td>84</td>
<td>83</td>
<td>58</td>
</tr>
<tr>
<td>11</td>
<td>Renal carcinoma</td>
<td>36</td>
<td>PFR</td>
<td>80</td>
<td>81</td>
<td>46</td>
</tr>
<tr>
<td>12</td>
<td>Squamous cell carcinoma</td>
<td>49</td>
<td>PTR</td>
<td>72</td>
<td>73</td>
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</tr>
<tr>
<td>13</td>
<td>Renal carcinoma</td>
<td>46</td>
<td>DFR</td>
<td>72</td>
<td>71</td>
<td>82</td>
</tr>
<tr>
<td>14</td>
<td>Breast carcinoma</td>
<td>50</td>
<td>DFR</td>
<td>95</td>
<td>90</td>
<td>35</td>
</tr>
<tr>
<td>15</td>
<td>Renal carcinoma</td>
<td>56</td>
<td>DFR</td>
<td>80</td>
<td>79</td>
<td>66</td>
</tr>
<tr>
<td>16</td>
<td>Renal carcinoma</td>
<td>61</td>
<td>DFR</td>
<td>63</td>
<td>60</td>
<td>73</td>
</tr>
<tr>
<td>17</td>
<td>Renal carcinoma</td>
<td>52</td>
<td>PHR</td>
<td>71</td>
<td>73</td>
<td>73</td>
</tr>
<tr>
<td>18</td>
<td>Renal carcinoma</td>
<td>54</td>
<td>PHR</td>
<td>70</td>
<td>72</td>
<td>60</td>
</tr>
<tr>
<td>19</td>
<td>Unknown primary</td>
<td>59</td>
<td>DHR</td>
<td>77</td>
<td>76</td>
<td>60</td>
</tr>
</tbody>
</table>

*PFR = proximal femoral replacement, PHR = proximal humeral replacement, PTR = proximal tibial replacement, DFR = distal femoral replacement, DHR = distal humeral replacement.

TESS of 72.8% (range 53 to 84%). The difference in scores are not statistically significant and larger studies will be required to determine if patients who present with pathological fractures have poorer functional outcome scores compared to patients who do not. With regard to overall functional outcome, patients with proximal femoral replacements had a mean MSTS score of 72.3% (range 57 to 83%) and a mean TESS score of 68.4% (range 46 to 84%). These scores compare to those reported in other series of proximal femoral endoprosthetic replacements using modular endoprostheses [21, 22].

Table 3 shows the functional outcomes of all the patients who survived 2 years or more who were treated with an endoprosthetic replacement. The functional outcomes for patients with upper and lower limb reconstructions are comparable; however, the number of patients followed up with upper limb reconstructions (three) is too small for any further significant conclusions.

There were five cases of superficial infection which resolved with oral antibiotics alone, but no cases of deep infection. In 58 endoprosthetic replacements, only one patient required a revision for aseptic loosening of a humeral diaphyseal replacement. There were four dislocations in the group of patients who had proximal femoral replacements (31 patients). All dislocations occurred within the first 3 weeks of surgery. Three were reduced closed and one required an open reduction without the need for component repositioning. They were all rehabilitated postreduction in an abduction brace for 8 to 10 weeks. None of these patients experienced any further dislocations. Two of these patients survived more than 2 years and in the latest follow-up, they were mobilising with a walking stick. Functionally their MSTS scores and TESS were 57% and 46%, and 70% and 53%, respectively.

The mean time to death of the 58 patients was 22 months (range 2 to 51 months). This wide range highlights the need for a stable reconstruction that allows early weight bearing, has a low incidence of failure, and outlasts the expected lifetime of the patient.

Our series was associated with relatively few, easily manageable complications and there were no implant failures.

Massive endoprostheses were originally developed for the treatment of primary malignant bone tumours. They have traditionally been custom-designed and hence there was a time delay to manufacture the implant. The gradual introduction of modular endoprostheses has provided greater flexibility making these reconstructions possible, and in shorter time frames, therefore aiding the overall management of metastatic bone disease. According to British Orthopaedic Association guidelines [2], patients should undergo a single procedure that allows early full weight bearing and lasts the expected lifespan of the patient. In our experience the use of an endoprostheses allows these criteria to be met.

Appropriate and prompt surgical management of metastatic bone lesions may be more cost-effective in terms of the overall management of cancer patients. This is reflected in earlier mobilisation and therefore potentially less time spent in hospital. Other studies are needed to assess the impact of these cost savings on hospital, nursing, and community cancer services. Patients who had an endoprosthetic
reconstruction in our series were able to return to a good level of function. Careful patient selection is crucial and the surgeon must take into consideration the patient's prognosis, comorbidities, and their ability to participate in postoperative rehabilitation.

REFERENCES


AVALIAÇÃO BIBLIOGRÁFICA SOBRE O USO PROPOSTO DO PRODUTO

PRODUTO: ENDOPROTESES
Modelos: Proximal de Fêmur, Proximal de Úmero, Distal de Úmero, Distal de fêmur com proximal de tíbia e Proximal de Tíbia.

O estudo relata casos de 58 pacientes dos quais eram 28 homens e 30 mulheres, tratada com a ressecção óssea e reconstrução com endoprostes, indicadas nos pacientes com perda óssea extensiva, reconstruções convencionais que falharam e metástases ósseas isoladas.

Doze pacientes receberam endoprostes no membro superior e 46 pacientes no membro inferior. A idade média dos pacientes era de 62 anos (entre 24 e 88). No período do estudo, 19 pacientes estavam vivos, 34 morreram, e 5 não continuaram a se apresentar.

Os pacientes foram acompanhados e avaliados usando a contagem do tumor osteomuscular da sociedade do tumor (MSTS) e a contagem do salvamento da extremidade de Toronto (TESS). O MSTS médio era 73% (57% a 90%) e o TESS era 71% (46% a 95%). O acompanhamento médio era 48.2 meses (escala 27 a 82 meses) e os pacientes morreram da doença em uma média de 22 meses (2 a 51 meses) da cirurgia. As complicações incluíram 5 infecções superficiais da ferida, 1 afrouxamento asséptico, 4 deslocações, 1 subluxação, e 1 caso, onde o componente tibial de uma prótese girou exigindo o reposicionamento aberto.

A tabela 3 mostra resultados funcionais dos 19 pacientes que estavam vivos há 2 anos ou mais no pós-operatório durante o período prescrito, relacionando a doença primária e o tipo de endoprostes utilizada. PFR (proximal de fêmur) PTR (proximal de tíbia) DFR (distal de fêmur) PHR (proximal de úmero) DHR (distal de úmero).

Os pacientes submetidos a reconstrução com endoprostes tiveram um bom nível de retorno das funções. A seleção cuidadosa do paciente é crucial e o cirurgião deve levar em consideração o prognóstico do paciente, e sua dedicação a realizar as recomendações pós-operatórias de reabilitação.

Os autores concluíram que a reconstrução óssea com endoprostes para o tratamento de metástases ósseas isoladas é um método de confiança da reconstrução do membro em casos selecionados. O método é associado à baixa taxa de falhas e complicações, conseguindo atingir o objetivo de restaurar a função, de permitir carga em menos tempo e de aliviar a dor e o principal a não amputação.
Endoprosthetic reconstruction for malignant bone and soft-tissue tumors.


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BACKGROUND: Nowadays, the results of the management of malignant bone and soft-tissue tumors have been dramatically improved because of the advance in imaging, chemotherapy, radiation therapy, and surgical techniques. Patients can have longer survival times with limb-salvage surgery. Several techniques of reconstruction have been advocated and gained more popularity following malignant tumor resection by using allograft, tumor prostheses, composite allograft prosthesis, or arthrodesis. OBJECTIVE: To report the preliminary results of 32 endoprosthetic reconstructions following malignant bone and soft-tissue tumor resection. The oncologic results, functional outcomes, and complications from the surgery were assessed in the present study. MATERIAL AND METHOD: Since September 1988, the authors have performed 188 limb-salvage surgical operations for the treatment of musculoskeletal tumors at Siriraj Hospital. From March 1994 to July 2006, 32 endoprosthetic reconstructions were performed on 30 patients following malignant bone or soft-tissue tumor removal. There were 16 males and 14 females with a mean age of 28 years (range 10-73). The diagnosis was conventional osteosarcoma in 16 patients, parosteal osteosarcoma in two patients, chondrosarcoma in two patients, leiomyosarcoma in two patients, failed allograft in two patients and one patient each of periosteal osteosarcoma, Ewing's sarcoma, Gorham’s disease, synovial sarcoma, malignant fibrous histiocytoma, metastatic renal cell carcinoma, and prosthetic loosening. Wide excision was performed with a mean length of 18.5 cm (range 10-41). Five proximal femurs, 17 distal femurs, 1 total femur 3 proximal tibias, 1 intercalary tibia, 4 proximal humerus and 1 distal humerus were used for reconstruction. Modular replacement systems (MRS, Stryker/Howmedica/Osteonics) were the most common prostheses used in the present series. RESULTS: The mean follow-up time was 26 months (range 6-128.7). Sixteen patients are continuously free of the disease, two are alive with the disease, two had no evidence of the disease, nine died of the disease, and one patient died from complication of hypertension. The mean Musculoskeletal Tumor Society functional analysis for upper extremity reconstruction was 93% (range 86.7-100) and for lower extremity was 89% (range 63.3-100). Two patients (6.7%) were determined to be a failure. Revision due to aseptic loosening was performed in one patient (3.3%) and one hip disarticulation was done related to local recurrence (3.3%). One patient with sciatic nerve palsy and two seromas was found and successfully treated in the present study.

CONCLUSION: Endoprosthetic reconstruction could yield satisfactory results as a wide excision and limb-salvage for patients with malignant bone and soft-tissue tumors. Most patients in the present report had good to excellent functions following surgery and few complications occurred in the present report.

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AVALIAÇÃO BIBLIOGRÁFICA SOBRE O USO PROPOSTO DO PRODUTO

PRODUTO: ENDOPROTESES
Modelos: Proximal de Fêmur, Distal de fêmur, total de fêmur, Proximal de Úmero, Distal de Úmero, Proximal de tibia.


A excisão larga foi executada com um comprimento médio de 18,5 cm (escala 10-41). Cinco proximais de fêmur, 17 distais de fêmur, um fêmur total, 4 proximais de tibia, 4 proximais de úmero e 1 distal de úmero foram usadas para reconstrução.

Os sistemas modulares de reconstrução mais usados comumente eram (Striker/Howmédica/Osteonics).

O tempo médio de acompanhamento foi de 26 meses onde até o feito do trabalho dezessete pacientes estavam livres da doença, dois estavam vivos com a doença, dois não tiveram nenhuma evidência da doença, nove morreram em decorrência da doença e uma paciente morreu da complicação da hipertensão.

A análise funcional da Sociedade osteomuscular média do tumor para a reconstrução do membro superior era 93% e para o membro inferior era 89%.

Foi concluída que a reconstrução com endoproteses pode render resultados satisfatórios com a cirurgia de salvamento de membro para pacientes com tumores malignos ósseos e do tecido macio. A maioria dos pacientes tiveram bons resultados relacionado as funções no pós-operatório e poucas complicações ocorreram.
Endoprosthetic Reconstruction for the Treatment of Musculoskeletal Tumors of the Appendicular Skeleton and Pelvis


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Endoprosthetic Reconstruction for the Treatment of Musculoskeletal Tumors of the Appendicular Skeleton and Pelvis

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Investigation performed at the Royal Orthopaedic Hospital Oncology Service, Birmingham, United Kingdom

Background: Excision of a bone tumor requires reconstruction if limb salvage is a priority. Reconstruction with an endoprosthetic implant is preferred in our unit, as the patient typically can return rapidly to full weight-bearing and functional activities. Long-term complications, such as deep infection, aseptic loosening, and mechanical failure of the implants, have led to concerns about the efficacy of reconstruction and the ability to revise failed implants while maintaining limb salvage in the longer term. The purpose of this study was to investigate the survival of endoprosthetic reconstructions in the medium to long term in order to determine the factors associated with their failure.

Methods: A consecutive series of 776 patients underwent endoprosthetic reconstruction following resection of a bone tumor at a minimum of ten years prior to this investigation. One hundred and nine children with a so-called growing endoprostheses were excluded as they often require revision to an adult prosthesis near skeletal maturity. Six patients were excluded because of a lack of adequate follow-up data, leaving 661 patients for analysis. Kaplan-Meier survival analysis of the implant was performed, with implant revision for any cause (infection, local recurrence, and mechanical failure), mechanical failure alone, and amputation used as the end points.

Results: The mean duration of follow-up was fifteen years for patients who survived the original disease. Two hundred and twenty-seven patients (34%) had revision surgery because of mechanical failure (116 patients), infection (seventy-five patients), and locally recurrent disease (thirty-six patients). Implant survival at ten years was 75% with mechanical failure as the end point and 58% with failure from any cause as the end point. The limb salvage rate was 84% at twenty years.

Conclusions: We believe these medium to long-term results with first-generation endoprostheses are encouraging and justify the continued use of endoprostheses for reconstruction following the excision of a bone tumor.

Level of Evidence: Therapeutic Level IV. See Instructions to Authors for a complete description of levels of evidence.

The surgical excision of bone tumors of the appendicular skeleton and pelvis requires a method of reconstruction of the bone defect if limb salvage is a priority. In the United Kingdom, reconstruction with endoprosthetic implants is the method of choice. It is believed that it affords the patient several advantages, including the ability to return rapidly to full weight-bearing functional activities, an important advantage when approximately 25% of the patients survive less than two years from the time of surgery. Other advantages of endoprosthetic replacements include their initial reliability, wide availability, and proven cost-effectiveness. However, the long-term complications of reconstructive surgery, such as deep infection, aseptic loosening, and mechanical failure of the implants, have led to concerns about the efficacy of this reconstruction method and the ability to revise a failed implant while maintaining limb salvage in the longer term. These concerns are heightened in younger patients.

The purpose of this study was to investigate the fate of endoprosthetic replacements in patients who had been followed for more than ten years, in order to determine the long-

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### TABLE I Diagnoses of Patients Treated by Endoprosthetic Replacement

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>No. (% of Patients)</th>
<th>10-Year Implant Survival Rate with Additional Surgery for Any Cause as End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteosarcoma</td>
<td>283 (42.8)</td>
<td>50%</td>
</tr>
<tr>
<td>Chondrosarcoma</td>
<td>112 (16.9)</td>
<td>67%</td>
</tr>
<tr>
<td>Ewing sarcoma</td>
<td>64 (9.7)</td>
<td>54%</td>
</tr>
<tr>
<td>Metastatic disease</td>
<td>64 (9.7)</td>
<td>88%</td>
</tr>
<tr>
<td>Malignant fibrous histiocytoma</td>
<td>43 (6.5)</td>
<td>54%</td>
</tr>
<tr>
<td>Other</td>
<td>32 (4.8)</td>
<td>64%</td>
</tr>
<tr>
<td>Giant cell tumor</td>
<td>29 (4.4)</td>
<td>61%</td>
</tr>
<tr>
<td>Fibrosarcoma</td>
<td>15 (2.3)</td>
<td>75%</td>
</tr>
<tr>
<td>Soft-tissue sarcoma</td>
<td>11 (1.7)</td>
<td>80%</td>
</tr>
<tr>
<td>Benign tumor</td>
<td>8 (1.2)</td>
<td>50%</td>
</tr>
</tbody>
</table>

The factors influencing implant survival were evaluated with univariate analysis with use of Kaplan-Meier curves and log-rank testing and with multivariate analysis performed with use of Cox proportional hazards. The factors tested included age at the time of the initial surgery, sex, diagnosis, stage, site, adjuvant therapy, and decade of implantation.

End points for survival analysis were revision surgery for any cause, revision for mechanical failure of the implant, and amputation. Review surgery was defined as removal or exchange of the endoprosthetic metallic implant for any cause (including mechanical failure, infection, and locally recurrent disease). Mechanical failure included aseptic loosening, implant fracture, instability, periprosthetic fracture, pain, and stiffness. Revision surgery did not include routine maintenance surgery, such as rebushing of the hinges of the constrained knee implants or patellar resurfacing. Rebushing was required in thirty patients in whom the polyethylene bushings were exchanged without interfering with the metallic implant. One patient underwent patellar resurfacing without exchange of the metallic implant. The level of significance was set at $p = 0.05$.

### Results

The overall patient survival was 52.7% at ten years and 45.7% at twenty years. The mean duration of follow-up was nine years for all patients and fifteen years (range, ten to thirty-five years) for the patients who survived the original disease. The most common site for the placement of the primary endoprosthesis was the distal end of the femur, which was involved in 228 patients (35%) (Table II).

A total of 227 patients (34%) underwent revision surgery. When the end point was revision surgery for mechanical failure, implant survival was 75% at ten years and 52% at twenty years (Fig. 1). Mechanical failure was inversely proportional to time ($y = 1 - 0.025x$; that is, a 2.5% rate of implant failure per year). However, with revision surgery for any cause as the end point, implant survival decreased to 58% at ten years.
and 38% at twenty years (Fig. 2). Failures due to all causes were treated with a one-stage revision in 141 patients, a two-stage revision in twenty-six patients, and primary amputation in sixty patients. The most common reasons for revision surgery were mechanical failure (116 patients; 51%), infection (seventy-five patients; 33%), and locally recurrent disease (thirty-six patients; 16%). The mean time to revision following primary surgery was 2.2 years (range, zero to thirty-four years) for mechanical failure. Aseptic loosening was the most common cause of mechanical failure (Table III), and it occurred in seventy-five patients at a mean of 9.4 years following implantation.

Two patients with deep infection were offered but declined revision surgery. One of them survived 10.3 years with modest intermittent wound drainage from a distal femoral replacement, and the other patient was living 10.5 years later with infection around a pelvic replacement; however, the implants in both patients were functioning well at the time of the last follow-up.

The only independent prognostic factors that were found to be significant on multivariate analysis, with revision for any cause as the end point, were the site of the prosthesis (p = 0.001) and the gender of the patient (p = 0.04). Factors such as the initial diagnosis, age at the time of implantation, adjuvant therapy, and tumor stage at presentation were associated with a trend to significance but failed to reach significance on multivariate analysis; however, they did reach significance on univariate analysis, which is a less robust method of analysis.

![Graph](Fig 1)

Survival of the implants, with revision for mechanical failure as the end point.
Implant survival varied with respect to the site of implantation (Table II). The ten-year survival rate of the upper limb implants (85%) was significantly different from that of the lower limb implants (53.3%) and the pelvic prostheses (59.9%) \((p = 0.0001)\). The cause of implant failure also varied among implantation sites (Table IV).

Patients with metastatic disease had the highest rate of implant survival because of the short life expectancy of the patients. The long-term survival rate for implants in patients with an aggressive benign condition was lower than that for implants in patients with a primary bone tumor because the former group had a high rate of infection (37.5%), which was commonly due to the multiple procedures that had been performed prior to the implantation of the prosthesis.

The decade when the prosthesis was implanted was found to be significant only with regard to the survival rate of tibial implants \((p = 0.01)\), with revision for any reason as the end point. For other sites, the ten-year survival rate was 64.3% for prostheses implanted before 1980, 58.1% for those implanted from 1980 to 1984, 48.7% for those implanted from 1985 to 1990, and 63.7% for those implanted after 1990. For the tibial implants, the ten-year survival rate significantly improved from 33% for those implanted between 1980 and 1984 to 52% for those implanted since 1990. This is attributed to the routine use of gastrocnemius muscle flaps starting in 1988.

The ten-year implant survival rate, with revision for any cause as the end point, was 60.6% for patients who were less than twenty years old, 62.1% for patients from twenty to fifty years old, and 79% for patients over fifty years old \((p = 0.008)\) (see Appendix). Young patients were more likely to have a failure.
because of mechanical causes (p = 0.001) (see Appendix). Men also had higher rates of failure than did women, with implant survival rates of 53% and 65%, respectively (p = 0.007).

The ten-year implant survival rate, with revision for any cause as the end point, was 82% for patients treated with surgery alone, 60% for those treated with surgery and chemotherapy, 78% for those treated with surgery and radiation therapy, and 51% for those treated with all modalities (p < 0.0001). The ten-year implant survival rate for patients with an Enneking stage-I A or IB (low-grade) tumor (74%) or those with a stage-III (metastatic) tumor (86%) was better than that for patients with an Enneking stage-II A (high-grade intracompartamental) or stage-II B (high-grade extracompartamental) tumor (48%) (p = 0.0008). This is a reflection of adjuvant therapy, which distorts the implant survival rate: low-grade tumors often did not require adjuvant therapy, and patients with stage-III disease often had a poor prognosis, with only 7% of such patients alive at ten years following surgery.

Amputation was performed in seventy (10.6%) of the 661 patients. It was done because of local recurrent disease in thirty-five patients (50%), infection in thirty-four patients (48.6%), and implant fracture in one patient. At the time of writing, there had been no amputations following failure because of aseptic loosening. On the basis of the numbers, no significant difference was detected in amputation rates between endoprostheses implanted for benign or malignant disease in the basis of the age of the patient at presentation.

The rate of amputation decreased from 23% (fourteen) of the sixty patients treated prior to 1980 to 11% (fifteen) of the 136 patients treated from 1980 to 1984, to 11% (twenty-two) of the 209 patients treated from 1985 to 1990, and to 7.4% (nineteen) of the 256 patients treated in the years since 1990 (p = 0.01). The rates were also different with regard to the site of prosthesis implantation, with the highest rate for patients with a tibial implant (18.4%; twenty-five of 136 patients) and the lowest rate for those with a humeral implant (5.8%; six of 103 patients) (p = 0.04). The mean time to amputation was 3.9 years (range, 0.1 to 21 years), and 75% of the amputations occurred within 5.5 years (see Appendix).

A complication related to surgery occurred in 262 patients (40%) (Table III). Deep infection occurred in seventy-five patients (11.3%); twenty-six (35%) of them were treated by one-stage revision; twenty-six (35%), by two-stage revision; and twenty-three (31%), by primary amputation. The rate of primary amputation for infection among reconstructions performed prior to 1985 (twelve of nineteen patients) was higher than that of reconstructions done since 1985 (eleven of fifty-six patients) (p = 0.015), and an attempt at two-stage revision is now our routine procedure. One-stage revision was successful in controlling infection in nineteen (73%) of twenty-six patients, and two-stage revision was successful in twenty-two (85%) of twenty-six patients (p = 0.026). The median time to revision because of infection was 3.8 years after the time of the original reconstruction, with 13% (ten) of seventy-five deep infections seen more than ten years following the original reconstruction. The median time to revision for mechanical failure of an implant was 9.3 years after the time of the original reconstruction, with 10% (eleven) of 116 failures occurring eighteen years after the original reconstruction. The implants had survived without revision in 195 of 313 living patients at ten years, in thirty of seventy living patients at twenty years, and in only five of eight living patients at thirty years.

**Discussion**

The purpose of the study was to determine the durability of endoprosthetic replacements for the reconstruction of defects after tumor surgery. Patients with endoprostheses are exposed to major risks of infection, mechanical failure, and amputation; however, we demonstrated an ability to maintain limb salvage in 84% of the patients twenty years after reconstruction. The long-term survival of tumor endoprostheses may be regarded as poor compared with the 95% rate of sur-
vival at ten years for most modern hip implants\(^6\). However, patients with a tumor have a 10% rate of deep infection, a younger mean age at the time of surgery, and, frequently, reduced muscle function (from the radical dissection required for the wide tumor excision), causing altered joint biomechanics with consequent increased strain on both the prosthesis and the bone-prosthesis junction\(^4\). Patients with a tumor around the knee require removal of both the cruciate and the collateral ligaments, necessitating the use of a constrained fixed or a rotating-hinge prosthesis, which is accompanied by a weak extensor mechanism because of the soft-tissue excision, resulting in an increased rate of loosening and implant failure.

Our results are comparable with those in other reports on endoprosthetic replacements. Biau et al.\(^1\) described ninety-one patients with a bone tumor about the knee who were treated with an endoprosthetic: thirty-six patients required removal of the implant. Goshgari et al., in a study of 250 patients treated with the Mutars prosthesis (Implantcast, Buxtehude, Germany), reported a five-year survival rate of 68.5% for patients in the lower limb, with an 8% rate of aseptic loosening\(^5\). Fink et al. reported that twenty-six of eighty-three patients had a revision after five years\(^1\), and Torbert et al. reported an event-free prosthetic survival rate of 69% in a study of 139 patients at ten years\(^2\). Zeeger et al. showed a five-year prosthetic survival rate of 76%, with patients who underwent surgery for local recurrence excluded\(^3\). Metmayer et al., in a study of 251 patients with a Rostr prosthesis (Howmedica, Rutherford, New Jersey), reported a 76% rate of prosthetic survival without aseptic loosening at ten years\(^4\). Shin et al. reported fifty revisions of 208 prostheses, with a survival rate of 65% of the custom-made prostheses at ten years\(^4\), and Malawer and Chou noted a ten-year survival rate of 67% of the large-segment prostheses in eighty-two patients\(^6\).

The debate continues about the long-term survival of metallic implants compared with the short-term complications of biological (autograft or allograft) reconstructions. Both techniques have their place in the surgeon's armamentarium, and studies have shown little difference in long-term survival. Futani et al.\(^7\), in a study comparing the results of endoprosthetic reconstruction in twenty-eight children and those after biological reconstruction in twelve children, showed a ten-year survival rate of 51% for the endoprostheses and 46% for the biological reconstructions. In a report on allograft reconstruction around the knee in 116 patients, Brigman et al.\(^8\) found that 37% of the patients regarded the procedure as a failure, 34% had a nonunion, 16% had a deep infection develop, and 12% required a later amputation. Muscolo et al.\(^9\) reported good results after eighty allograft reconstructions. Of the sixty-two allografts available for release, fourteen failed (because of infection, local recurrence, bone resorption, or fracture) and the survival rate of the allograft was 78% at ten years. We are not aware of any published long-term results of a large series of biological reconstructions for all sites and diagnoses.

Our investigation is an observational retrospective cohort study, which has several weaknesses. The study period is long and the techniques and implants have evolved. The design of the distal femoral implant changed to include rotating platforms (to reduce torsional force) and hydroxyapatite-coated collars at the bone-prosthesis interface (to allow ongrowth of bone to decrease bending forces), leading to substantial improvements in implant survival\(^10\). The routine use of pedicled medial gastrocnemius flaps with tibial implants and the increased use of plastic surgery have enhanced implant survival, dramatically reducing infection rates\(^11\). Early on, infections around implants were frequently treated with primary amputation; however, two-stage revision is now advocated as the primary treatment with good results\(^12\), and no primary amputation for infection was performed after 1990.

This present study confirms the long-term durability of endoprosthetic reconstruction for limb salvage surgery, with the evolution of design and techniques improving the rate of implant survival but highlighting the problems of infection and aseptic loosening, which can have dire consequences for the patient and surgeon. Attempts to resolve both of these problems constitute the major challenge for the future of limb salvage surgery in patients with musculoskeletal tumors.

**Appendix**

A table showing the effect of patient age on implant survival and figures showing survival curves, with use of mechanical failure and amputation as the end points, are available with the electronic versions of this article, on our web site at jbis.org (go to the article citation and click on "Supplemental Material") and on our quarterly CD-ROM (call our subscription department, at 781-440-0780, to order the CD-ROM).

**References**


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AVALIAÇÃO BIBLIOGRÁFICA SOBRE O USO PROPOSTO DO PRODUTO

PRODUTO: ENDOPROTESES
Modelos: Total de fêmur, proximal de fêmur, distal de fêmur, Diafisária de fêmur, Tibia, úmero e pélvis.

O artigo exibe o trabalho de uma equipe onde a prioridade é o salvamento do membro quando é necessária a excisão de um tumor ósseo, utilizando para reconstrução como preferência endoprosteses, devido ao rápido retorno do paciente a se locomover e as atividades funcionais.

O objetivo do trabalho foi analisar a eficácia da reconstrução devido as complicações em longo prazo como infecção profunda, afrouxamento asséptico, falha mecânica dos implantes e a habilidade de revisar implantes falhados ao manter o salvamento do membro a longo prazo, com a finalidade de determinar os fatores associados as falhas.

Foi utilizada como base uma sequência de 776 pacientes que se submeteram à reconstrução com endoprosteses acompanhados após ressecção óssea durante 10 anos até esta investigação.

Excluindo cento e nove crianças com endoprosteses alongáveis devido a exigirem frequentemente a revisão por uma prótese adulta e seis pacientes por falta de dados durante o acompanhamento, restaram 661 pacientes para análise.

A análise da sobrevivência de Kaplan-Meier do implante foi executada, com a revisão do implante para toda a causa (infecção, retorno local, e falha mecânica), a falha mecânica sozinho, e a amputação usada como os pontos da extremidade.

A duração média do acompanhamento era quinze anos para os pacientes que sobreviveram à doença original. Duzentos e vinte sete pacientes (34%) tiveram a cirurgia da revisão por causa da falha mecânica (116 pacientes), da infecção (75 pacientes), e localmente da doença periódica (36 pacientes). A sobrevivência do implante em dez anos era 75% com falha mecânica como o valor-limite e 58% com falha de toda a causa como o valor-limite. A taxa de salvamento do membro era 84% em vinte anos.

Os autores julgaram que estes resultados de médio em longo prazo com endoprosteses de primeira geração são encorajadores e justificam o uso contínuo das endoprosteses para a reconstrução quando necessária a excisão de um tumor do osso.
ARTIGO ORIGINAL

UMA NOVA ABORDAGEM PARA AS ENDOPRÓTESES PARCIAIS DE JOELHO EM SARCOMAS PRIMÁRIOS ÓSSEOS

A NEW APPROACH TO PARTIAL KNEE ENDOPROSTHESIS IN PRIMARY BONE SARCOMAS

Valter Penna¹,
Eduarao Areas Tollê²,
Carla Pinheiro³,
Ricardo Gehrke Becker⁴

RESUMO

Objetivo: As endopróteses parciais de joelho para as ressecções em sarcomas ósseos demonstraram serem boa solução para o tratamento de pacientes com imaturidade esquelética. O objetivo deste estudo é avaliar o escore funcional, as vantagens, as desvantagens e indicações para esta técnica cirúrgica em quatorze pacientes em um protocolo brasileiro de osteossarcoma e sarcoma de Ewing. Métodos: Análise retrospectiva realizada para identificar a evolução funcional e as possíveis complicações do procedimento. 14 pacientes com idade entre 10 e 22 anos avaliados funcionalmente pelos critérios de Enneking/ISOLS (International Society of Limb Salvage), sendo todos operados na mesma instituição e pelo mesmo cirurgião. Foram utilizadas endopróteses parciais das extremidades distal do fêmur e proximal da tibia com reconstrução ligamentar. Resultados: A análise do escore funcional de Enneking/ISOLS demonstrou 78,6% de excelentes resultados e 21,4% de bons. 14 pacientes, todos portadores de tumores primitivos ósseos em protocolo de quimioterapia, nove não apresentaram nenhum tipo de complicações e cinco indivíduos evoluíram com complicações relacionadas ao procedimento, sendo que houve relação estatística positiva entre os maus resultados e a presença de complicações (p=0,027). Conclusão: As endopróteses parciais de joelhos são menos prejudiciais ao estique ósseo de pacientes com esqueletto imaturo. As críticas sobre os maus resultados funcionais estão sendo suplantadas pelas novas técnicas de reconstrução, corretos protocolos de reabilitação, qualidade e tecnologia dos implantes, e o aumento da curva de aprendizado. Esse opção de tratamento permite a preservação do estique ósseo e a possibilidade de revisão da artroplastia não convencional de modo menos agressivo.

Descritores – Joelho; Sarcoma de Ewing; Osteossarcoma; Prótese do joelho; Estudos retrospectivos

ABSTRACT

Objective: Partial knee endoprosthesis to bone sarcomas resections seems to be a good solution to treat this immature skeletal patients. The purpose of this study is to evaluate the functional score in fourteen patients, advantages and the technique indications. Methods: Retrospective analysis was done to assess in this group of patients the functional evolution and the possible complications of the procedure. 14 patients between 10 and 22 years functionally evaluated in Ennekin/ISOLS (International Society of Limb Salvage) criteria, being all of them operated in the same institution by the same surgeon. Were used distal femur and proximal tibia partial endoprosthesis. Results: General analysis demonstrated that the functional results were over than 67 percent (ISOLS criteria) in 78,6 percent of the patients, being considered excellent. 21,4 percent were considered good results, being between 30 and 66 percent. Bone storage was preserved when avoiding the adjacent segment resection. Surgery time was not prolonged in ligament reconstruction. Conclusion: Knee partial endoprosthesis are less damage to bone storage in young patients. The critics about the bad functional results are being supplied by new surgical techniques, excellent rehabilitation protocols, implants technology and the consequent learning curve. This option of treatment permits the preservation of healthy bone and provides the possibility of a revision replacement less aggressive.

Keywords – Knee; Sarcoma Ewing’s; Osteosarcoma; Knee prosthesis; Retrospective studies

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Declaramos inexistência de conflito de interesses neste artigo
INTRODUÇÃO

Os tumores ósseos primários malignos mais comuns na infância e da adolescência são o osteossarcoma e o sarcoma de Ewing. Apresentam como um dos principais sitos de localização a extremidade distal do fêmur e proximal da tíbia. Estas localizações comprometem muitas vezes a articulação do joelho, necessitando, de cirurgias preservadoras com a substituição dos segmentos por endopróteses. Diversos modelos de endopróteses estão disponíveis para as mais variadas indicações cirúrgicas nas ressecções de tumores ósseos do joelho\(^3\). No entanto, em casos onde o tumor não respeita os limites da cartilagem de crescimento, invadindo a epífise dos ossos longos do joelho, sem invasão articular, é possível indicar a ressecção com substituição por endoprótese parcial. Esta técnica permite a ressecção em bloco da extremidade distal do fêmur ou proximal da tíbia, preservando a epífise adjacente articular e substitui apenas o segmento afetado pelo implante fixado no fêmur ou na tíbia.

A utilização de endopróteses parciais se restringe a pacientes portadores de tumores com as características descritas acima e com imaturidade esquelética na faixa etária entre 10 a 16 anos. Indivíduos com idade entre 17 e 22 anos também se beneficiam das endopróteses parciais devido à preservação do estoque ósseo e ao crescimento residual até próximo do limite etário de 22 anos\(^2\). Pacientes muito jovens, que não iniciaram o segundo estádio de crescimento, submetidos à substituição por implantes no membro inferior, com o passar dos anos apresentarão incompatíveis com a funcionalidade da extremidade inferior. Na opinião dos autores, nesses casos é mais prudente a cirurgia radical (amputação). Já em indivíduos que completaram o crescimento, as vantagens de preservar a região epifisária são muito menores, sendo mais indicada a endoprótese total de joelho\(^3\).

As ressecções com margem oncológica para tumores ósseos primários da infância e adolescência em passado não muito distante eram sinônimo de amputação de membro. O desenvolvimento de novas técnicas cirúrgicas, melhores condições hospitalares, a introdução da quimioterapia neo-adjacente com protocolos bem definidos, o aperfeiçoamento dos tipos de implantes cirúrgicos e a curva de aprendizado dos cirurgiões ortopedistas proporcionaram maior segurança e qualidade de vida aos portadores dessas enfermidades\(^3\).

O aumento da sobrevida livre de doença e cura em tumores como o sarcoma de Ewing e o osteossarcoma trouxe a preocupação da vida útil do implante utilizado\(^10\). Implantes como as endopróteses totais de joelho em pacientes jovens apresentam a desvantagem de necessitar de ressecção ou osteotomia fêmoral/tibial para fixação do implante no segmento adjacente, e por conseguinte, remover a região de crescimento meta-epifisária. Isso implica em disparidade de crescimento das extremidades inferiores, diminuição do estoque ósseo e complicações futuras para revisão do implante devido à cimentação e a ressecção de osso não acometido por tumor.

Com o objetivo de reduzir complicações como as descritas e avaliar a funcionalidade e características dos pacientes submetidos a esta indicação de exceção, analisamos os casos onde foram utilizados implantes parciais não articulados (endopróteses parciais) de joelho em pacientes jovens, associados a reconstrução ligamentar, nas ressecções com margem oncológica na extremidade distal do fêmur e proximal da tíbia.

MÉTODO

Todos os pacientes foram operados pelo grupo de oncologia ortopédica do Hospital de Câncer de Barretos, SP. Foram avaliados de modo retrospectivo 14 pacientes incluídos nos Protocols Brasileiros de Osteossarcoma e Ewing, com idade entre 10 e 22 anos, submetidos a ressecção da extremidade distal do fêmur ou proximal da tíbia devido a tumores ósseos primários com substituição por endoprótese parcial de joelho não articulada e reconstrução ligamentar.

A indicação cirúrgica foi baseada em características morfológicas do tumor no joelho, ou seja, tumores localizados no fêmur distal ou tíbia proximal com invasão da cartilagem de crescimento e epífise, mas sem comprometimento articular visível à Ressonância Magnética. A presença de metástases pulmonares não foi critério de exclusão.

Todos os casos foram operados com critérios oncológicos no período entre fevereiro de 2003 e fevereiro de 2008 na mesma Instituição e pelo mesmo cirurgião. Os 14 pacientes apresentaram margens cirúrgicas livres no exame anatomo-patológico.

Os implantes de escolha foram: Endoprótese para extremidade distal do fêmur Parcial Não Articulada (Impol\(^8\)) para tumores da extremidade distal do fêmur e Endoprótese de extremidade distal da tíbia Parcial Não Articulada (Impol\(^8\)) para as neoplasias da extre-
RESULTADOS

A análise dos dados obtidos demonstrou que onze dos pacientes (78,6%) obtiveram escore de Enneking excelente, e que três (21,4%) apresentaram resultado bom. A presença de complicações foi baixa, todas resolvidas no pós-operatório recente. Dos 14 pacientes, nove não apresentaram qualquer complicação em relação à artroplastia; um apresentou infecção superficial; um apresentou instabilidade articular, com subluxação, provavelmente devido a infração muito precoce da mobilização na cidade de origem; outros três evoluíram com complicações como: úlcera de pressão e ruptura do tendão patelar na prótese tibial. Dos pacientes com escore bom, 100% apresentaram complicações pós-operatórias (p=0,027), portanto as complicações no transcorrer do tratamento diminuíram a funcionalidade do joelho (Gráfico 1).

![Gráfico 1 – Associação entre o escore de Enneking com a incidência de complicações.](image)

O tempo médio de imobilização foi de 9,76±3,3 semanas (máximo 16,4 e mínimo 3,8 semanas) e o tempo médio de seguimento dos pacientes foi de 23,1±15,8 meses (máximo 68,2 e mínimo 2,2 meses). Verificamos que o grupo com maior tempo de imobilização apresentou melhor escore funcional (p=0,048) (Gráfico 2).

Não identificamos correlação estatística entre a idade dos pacientes e o escore funcional. Os indivíduos mais jovens não obtiveram melhor funcionalidade do joelho.

A localização do tumor na extremidade proximal da tibia ou distal do fêmur não foi responsável por variação no escore de Enneking com significância estatística.
DISCUSSÃO

A introdução da quimioterapia neoadjuvante nos anos 80 aumentou muito a possibilidade de ressecção tumoral com preservação de membro. Mais de 80% dos pacientes com osteossarcoma de extremidade se tornaram candidatos à cirurgia preservadora de membro\(^{(4)}\). A cirurgia preservadora para tumores ósseos primários muito volumosos necessita de grandes ressecções no nível do joelho e criam defeitos segmentares importantes que necessitam de algum tipo de substituição que conserve a funcionalidade articular (Figuras 1 e 2). Os métodos de substituição podem ser mais variados, entre eles estão alternativas biológicas, como o uso de enxerto livre ou vascularizado do próprio paciente ou de outros indivíduos (aloenxerto). Outras opções incluem as endopróteses distais do fêmur e proximais da tibia. Entre as diferentes endopróteses comercializadas podemos descobrir as articuladas fixas, rotatórias e as do tipo artrodese. Algumas utilizam cimento para a fixação femoral e outras são fixadas pelo método press-fit\(^{(4)}\).

**Figura 1** – Raio X do joelho

A indicação cirúrgica para tumores localizados na extremidade distal do fêmur e proximal da tibia depende da relação anatômica da neoplasia com as estruturas que fazem parte do joelho normal. Tumores que invadem a articulação do joelho tornam o paciente candidato ressecção extra-articular com ou sem artrodese, e
consequentemente, restrição funcional parcial ou total. As neoplasias que não invadem a articulação, mas que comprometem a cartilagem de crescimento e a epífise, limitam as alternativas cirúrgicas e obrigam o cirurgião ortopedista a lançar mão de certos procedimentos mais específicos. Entre eles, o aloenxerto osteoarticulat foi descrito como boa alternativa em trabalho realizado por Muscolo et al. com 80 pacientes portadores de tumores na extremidade distal do fêmur submetidos a esse método e com seguimento de cinco a 10 anos. Essa alternativa, no entanto, é deserta por muitos autores apresentando complicações como fratura do enxerto, pseudoartrose, infecção, osteoartrose secundária a osteonecrose condilar.

Uma alternativa que é usada há muito tempo para tumores localizados no joelho de jovens são as endoprôteses totais articuladas para extremidade distal do fêmur e proximal da tibia. Este implante fornece estabilidade, retorno mais rápido às atividades e melhor qualidade de vida ao portador de tumores ósseos. No entanto, em pacientes esqueléticamente imaturos seu uso compromete a epífise do osso adjacente, resultando em diminuição do estoque ósseo e piora da discrepância entre os membros inferiores. A indicação deste tipo de implante se encaixa melhor em indivíduos que não apresentam mais cartilagem de crescimento aberta ou que já estejam encerrando, pelo menos, o segundo estirão de crescimento.

Optamos nesse estudo por um implante que substituiu apenas a extremidade distal do fêmur ou a extremidade proximal da tibia (Figuras 3, 4 e 5). Todos pacientes apresentavam invasão tumoral da cartilagem de crescimento, mas sem penetrar na cavidade articular ou extensão para ligamentos cruzados. O implante permitiu a preservação da epífise do osso adjacente (tibia ou fêmur), reduzindo o risco de discrepância e problemas futuros com o pouco estoque ósseo nas revisões da prótese. Foi necessária a reconstrução ligamentar.
dos cruzados e colaterais; além do tendão patelar nas substituições da extremidade proximal da tíbia. Aper-
sar da necessidade de reconstrução dos ligamentos, o
tempo cirúrgico permaneceu muito semelhante ao das
endopróteses totais de joelho, pois não se perdeu tempo
com osteotomia do segmento adjacente.

Não há artigos que descrevam este implante parcial
sendo avaliado isolado das endopróteses totais de jo-
elho. O método apresenta uma série de vantagens em
relação aos implantes articulados em pacientes com imata-
tudade esquelética. Clinicamente, a avaliação dinâmi-
ca da marcha se assemelha muito às artroplastias não
convencionais totais.(19,20) Apesar de haver certo grau
de hiperlaxidade estática, não há instabilidade durante o
ortostatismo ou deambulação. A ação muscular nas fases
de apoio e balanço mantém o joelho estável. Esse estudo
de 14 pacientes demonstra excelentes resultados na ava-
liação funcional, sendo que os indivíduos que evoluíram
com alguma complicaçã acabaram apresentando escore
inferior. A análise biomecânica na marcha in vivo de
dendopróteses parciais necessita ainda investigação mais
aprimorada, sendo esse estudo realizado no Hospital de Cáncer de Barretos um dos primeiros passos para a
afirmação dessa técnica cirúrgica.

CONCLUSÃO

As endopróteses parciais de joelho proporcionam
ao ortopedista e ao paciente um método preservador da
extremidade com excelente funcionalidade, manutenção
do estoque ósseo para revisão, e redução de discrepâ-
cias em indivíduos esqueleticamente imaturos.

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AVALIAÇÃO BIBLIOGRÁFICA SOBRE O USO PROPOSTO DO PRODUTO

**PRODUTO:** ENDOPROTESES  
**Modelos:** Distal de Fêmur Parcial

**RESUMO**  
Objetivo: As endopróteses parciais de joelho para as ressecções em sarcomas ósseos demonstram serem boa solução para o tratamento de pacientes com imaturidade esquelética. O objetivo deste estudo é avaliar o escore funcional, as vantagens, as desvantagens e indicações para esta técnica cirúrgica em quatorze pacientes em um protocolo brasileiro de osteossarcoma e sarcoma de Ewing. Métodos: Análise retrospectiva realizada para identificar a evolução funcional e as possíveis complicações do procedimento. 14 pacientes com idade entre 10 e 22 anos avaliados funcionalmente pelos critérios de Enneking/ISOLS (International Society of Limb Salvage), sendo todos operados na mesma Instituição e pelo mesmo cirurgião. Foram utilizadas endopróteses parciais das extremidades distal do fêmur e proximal da tíbia com reconstrução ligamentar. Resultados: A análise do escore funcional de Enneking/ISOLS demonstrou 78,6% de excelentes resultados e 21,4% de bons. Dos 14 pacientes, todos portadores de tumores primitivos ósseos em protocolo de quimioterapia, nove não apresentaram nenhum tipo de complicação e cinco indivíduos evoluíram com complicações relacionadas ao procedimento, sendo que houve relação estatística positiva entre os maus resultados e a presença de complicações ($p=0.027$). Conclusão: As endopróteses parciais de joelhos são menos prejudiciais ao estoque ósseo de pacientes com esqueleto imaturo. As críticas sobre os maus resultados funcionais estão sendo suplantadas pelas novas técnicas de reconstrução, corretos protocolos de reabilitação, qualidade e tecnologia dos implantes, e o aumento da curva de aprendizado. Essa opção de tratamento permite a preservação do estoque ósseo e a possibilidade de revisão da arthroplastia não convencional de modo menos agressivo.

**CONCLUSÃO**  
As endopróteses parciais de joelho proporcionam ao ortopedista e ao paciente um método preservador da extremidade com excelente funcionalidade, manutenção do estoque ósseo para revisão, e redução de discrepâncias em indivíduos esqueleticamente imaturos.
AVALIAÇÃO GERAL DAS BIBLIOGRAFIAS

As fraturas patológicas afetam milhares de pessoas no Brasil e no mundo. Antigamente em todos os casos de tumores ósseos os pacientes sofriam a amputação do membro.

Com o avanço das técnicas cirúrgicas e da engenharia biomecânica houve uma grande evolução nos métodos de ressecção do tumor, sendo possível a substituição do segmento ósseo por endoprosteses.

Porém ao optar pela recolocação com uma endoprotese, uma análise cuidadosa deve ser feita das características do tumor a fim de minimizar o retorno local e a atenção meticulosa dados a reconstrução a fim de evitar a infecção e aperfeiçoar a função.

O objetivo principal da cirurgia preservadora do membro é a não amputação, aliviar a dor, restabelecer a mobilidade e a utilização do membro afetado devolvendo mais rapidamente o aspecto psicológico do paciente ao seu convívio normal, evitando novas consultas, diminuindo período de internação dando liberdade para o mesmo se locomover a exames periódicos e consultas pós-operatórias.

As técnicas de recolocação com endoprostese não aumentam o risco de vida do paciente, os resultados funcionais são melhorados, as taxas de complicações são muito baixas, o nível de risco é aceitável, levando em consideração que o mesmo poderia ter sido amputado os pacientes não hesitam em optar pela reconstrução com endoprostese, quando esta é possível conforme as características do tumor.

Os especialistas julgam que a cirurgia com substituição por endoprosteses é o melhor método para o tratamento das fraturas patológicas.

Os pacientes submetidos a reconstrução por endoprosteses não são amputados, a dor é aliviada, a função do membro restaurada, permite a carga e locomoção em curto tempo, o aspecto psicológico para o convívio normal em sociedade é devolvido normalmente, diminui o período de internação e ocupação do leito hospitalar, tem a possibilidade de se deslocar quando da necessidade de exames ou consultas no pós-operatório dando a ele uma boa qualidade de sobrevida, onde os benefícios são recompensadores com relação aos riscos.