Non-invasive extendible endoprostheses for limb reconstruction in skeletally-mature patients

We describe the application of a non-invasive extendible endoprosthetic replacement in skeletally-mature patients undergoing revision for failed joint replacement with resultant limb-length inequality after malignant or non-malignant disease. This prosthesis was developed for tumour surgery in skeletally-immature patients but has now been adapted for use in revision procedures to reconstruct the joint or facilitate an arthrodesis, replace bony defects and allow limb length to be restored gradually in the post-operative period.

We record the short-term results in nine patients who had this procedure after multiple previous reconstructive operations. In six, the initial reconstruction had been performed with either allograft or endoprosthetic replacement for neoplastic disease and in three for non-neoplastic disease. The essential components of the prosthesis are a magnetic disc, a gearbox and a drive screw which allows painless lengthening of the prosthesis using the principle of electromagnetic induction. The mean age of the patients was 37 years (18 to 68) with a mean follow-up of 34 months (12 to 62). They had previously undergone a mean of six (2 to 14) open procedures on the affected limb before revision with the non-invasive extendible endoprosthesis.

The mean length gained was 56 mm (19 to 107) requiring a mean of nine (3 to 20) lengthening episodes performed in the outpatient department. There was one case of recurrent infection after revision of a previously infected implant and one fracture of the prosthesis after a fall. No amputations were performed. Planned exchange of the prosthesis was required in three patients after attainment of the maximum lengthening capacity of the implant. There was no failure of the lengthening mechanism. The Mean Musculoskeletal Tumour Society rating score was 22 of 30 available points (18 to 28).

The use of a non-invasive extendible endoprosthesis in this manner provided patients with good functional results and restoration of leg-length equality, without the need for multiple open lengthening procedures.

Endoprosthetic reconstruction is the most common form of limb-salvage procedure for the lower limb and provides an alternative to amputation in neoplastic disease. The prostheses have also been adapted for use in non-neoplastic disease to reconstruct the limb when considerable bone loss is present. The incidence of revision surgery after previous limb salvage in patients who are skeletally mature is increasing because of the long-term survival after neoplasia which is largely due to improvement in chemotherapy. In non-neoplastic disease limb salvage using massive endoprostheses is increasing because of the rising number of failed arthroplasties, which can be complicated by bone loss and soft-tissue compromise with or without infection. The reported incidence of infection after total knee replacement (TKR) varies from 1% to 15%. Reconstructive procedures aimed at preserving the limb and maintaining function are often hindered by leg-length discrepancy and poor soft tissues. Development in the design of implants has resulted in the introduction of modular endoprosthetic replacements which allow limb extension by further open procedures. These prostheses produce a good functional and psychological outcome, but are accompanied by the risk of infection, ankylosis, nerve damage, further soft-tissue damage and even amputation with each open procedure. In orthopaedic oncology in children, limb-salvage with non-invasive extendible endoprostheses to address limb-length discrepancy has been used with considerable success. This reconstructive technique which allows gradual extension of the limb in the post-operative period has not been previously used in adults.
In order to address this problem a non-invasive extendible endoprosthesis was manufactured for use in the skeletally mature patient based on the Stanmore paediatric extension mechanism (Stanmore Implants Worldwide Ltd, Stanmore, United Kingdom).16 We describe our early experience with this endoprosthetic technique in patients with leg-length discrepancy undergoing limb-salvage after multiple previously failed reconstructive attempts. The aim was to compensate for the loss of bone stock, to restore limb length and to provide the patient with a functional limb.

**Patients and Methods**

Between 2004 and 2008, we implanted nine non-invasive extendible endoprostheses into skeletally mature patients, six for failed reconstruction in which the primary operation had been for neoplastic disease and three for non-neoplastic disease (Table I). In order to qualify for this procedure, the patient had to require limb salvage and have a leg-length discrepancy of more than 2 cm. There were six men and three women with a mean age of 37 years (18 to 68) and a mean follow-up of 34 months (12 to 62). The patients had already undergone a mean of six (2 to 14) open procedures on the affected limb before implantation of the non-invasive extendible endoprosthesis (Table I).

In the non-neoplastic group, two patients required the prosthesis for a chronically-infected TKR. Both had undergone many previous operations (Table I), had stiff knees with poor soft tissues and considerable leg-length discrepancy. A distal femoral arthrodesis-type prosthesis with

**Table I. Details of the nine patients and the outcome**

<table>
<thead>
<tr>
<th>Case</th>
<th>Gender</th>
<th>Age (yrs)</th>
<th>Previous operation and complication*</th>
<th>Number of previous operations on limb</th>
<th>Non-invasive grower prosthesis type inserted</th>
<th>Maximum extension (mm)</th>
<th>Follow-up (mths)</th>
<th>Number of lengthening episodes</th>
<th>Total amount of lengthening (mm)</th>
<th>MSTS‡ score (pre-op/post-op %)</th>
<th>Outcome and complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>61</td>
<td>TKR infection</td>
<td>9</td>
<td>DFR arthrodesis</td>
<td>70</td>
<td>62</td>
<td>6</td>
<td>51</td>
<td>10/20 (33/67)</td>
<td>Functional leg-length</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>60</td>
<td>TKR infection</td>
<td>6</td>
<td>DFR arthrodesis</td>
<td>50</td>
<td>51</td>
<td>6</td>
<td>31.5</td>
<td>9/20 (30/67)</td>
<td>Functional leg-length</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>36</td>
<td>Nonunion femoral fracture and osteoarthritis of the knee</td>
<td>5</td>
<td>DFR</td>
<td>50</td>
<td>12</td>
<td>3</td>
<td>19</td>
<td>11/22 (37/73)</td>
<td>Functional leg-length</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>18</td>
<td>Osteosarcoma-Allograft non-union (previous DXT)</td>
<td>3</td>
<td>DFR</td>
<td>50 and 50</td>
<td>40</td>
<td>13</td>
<td>88.5</td>
<td>12/28 (40/93)</td>
<td>Exchange prosthesis at 19 month. Functional leg-length</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>26</td>
<td>Chondrosarcoma -2 Aseptic loosening PFR</td>
<td>3</td>
<td>PFR</td>
<td>50</td>
<td>19</td>
<td>3</td>
<td>20</td>
<td>8/23 (27/77)</td>
<td>Functional leg-length</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>68</td>
<td>Malignant fibrous histiocytoma - Infected DFR</td>
<td>3</td>
<td>TFR‡</td>
<td>90</td>
<td>14</td>
<td>5</td>
<td>73</td>
<td>6/18 (20/60)</td>
<td>Functional leg-length</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>23</td>
<td>Ewing’s sarcoma -3 Allograft nonunion (previous DXT)</td>
<td>3</td>
<td>TFR</td>
<td>90</td>
<td>28</td>
<td>8</td>
<td>33</td>
<td>9/22 (30/73)</td>
<td>Functional leg-length</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>27</td>
<td>Osteosarcoma - Allograft nonunion</td>
<td>6</td>
<td>Diaphyseal femoral 60 and 50 replacement</td>
<td>20</td>
<td>24</td>
<td>20</td>
<td>107</td>
<td>9/23 (30/77)</td>
<td>Exchange prosthesis at 2 months. Functional leg-length</td>
</tr>
<tr>
<td>9</td>
<td>M</td>
<td>18</td>
<td>Osteosarcoma - Infected DFR</td>
<td>14</td>
<td></td>
<td>50 and 50</td>
<td>59</td>
<td>16</td>
<td>80.5</td>
<td>12/20 (40/67)</td>
<td>Exchange prosthesis at 8 months. Infection persisted: 2-stage conversion to TFR 5° fixed-flexion deformity - Needed 2 mm reversal</td>
</tr>
</tbody>
</table>

* TKR, total knee replacement; DXT, radiotherapy; PFR, proximal femoral replacement; DFR, distal femoral replacement
† MSTS, Musculoskeletal Tumour society
‡ TFR, total femoral replacement
a non-invasive extendible section was attached to a hinged-knee prosthesis in these patients since the state of the soft tissues precluded further two-stage revision. The other patient in this group had chronic nonunion of a distal femoral fracture with considerable shortening and associated arthritis of the knee. A non-invasive extendible distal femoral replacement with a rotating-hinge knee was implanted.

In the neoplastic group, three patients required the prosthesis for a failed allograft reconstruction, two for failed distal femoral replacement and one for failed proximal femoral replacement. In all three patients nonunion had caused the reconstructions to fail. Infection was present in both distal femoral replacements and aseptic loosening was responsible for the failure of the proximal femoral replacement. The non-invasive extendible endoprostheses selected for the neoplastic group as a whole included two total femoral replacements, two distal femoral replacements, one proximal femoral replacement and one diaphyseal replacement. Pulmonary metastases were identified in one patient. Two patients had undergone radiotherapy. Neo-adjuvant and adjuvant chemotherapy and radiotherapy were given as appropriate, according to nationally-agreed protocols.

Each prosthesis was custom-made by Stanmore Implants Worldwide based on pre-operative imaging, with consideration of the intended femoral and tibial resection levels and anticipated leg-length discrepancy. All the procedures were performed at a single institution by two of the senior authors (TWRB, SRC). Information was collected from the bone tumour database, medical records, imaging studies, clinic reviews and patient questionnaires.

**The prosthesis and extending mechanism.** The Stanmore non-invasive extending mechanism has been previously described\(^{16,20}\) and can be used in endoprostheses with a shaft component that can incorporate a gearbox (Figs 1 and 2). This precludes its use in patients with very small limbs or when small bone resections are performed. The fixation technique for the endoprosthesis is similar to that of any non-extendible endoprosthesis.\(^{2}\)

The shaft of the femoral component, which is the site for the lengthening, has a stemmed proximal end which is usually cemented into the proximal femur with a hydroxyapatite collar. The distal end of the femoral shaft articulates with the tibial component at the knee using either a fixed or rotating hinge.
The extending mechanism of the prosthesis is activated when the prosthesis is placed at the centre of an external drive unit which contains electric coils that provide a rotating electromagnetic field. The latter couples with the gear mechanism within the implant, allowing it to be extended at a constant rate of 0.23 mm per minute.

In order to reduce the resistance to lengthening from surrounding soft tissues the range of joint movement before lengthening was maximised by physiotherapy and extension of the implant was limited to small amounts (< 10 mm) on many occasions with active physiotherapy sessions inbetween. The gearbox can generate a coupling torque up to approximately 4 Nm in order to drive the extension mechanism. This allows the prosthesis to withstand up to 1350 N of axial load during the lengthening process which, in skeletally-immature patients, is the force required to overcome surrounding soft-tissue tension generated when the prosthesis undergoes extension. This has proven to be a sufficient force to allow extension of the prosthesis in the skeletally-mature patients in our study who had a greater proportion of fibrous tissue because of their multiple operative procedures.

**Lengthening procedures.** The timing of the lengthenings was individualised for each patient dependent upon the type of implant used and the state of the soft tissues. For the non-arthrodesis-type endoprostheses, lengthenings were performed once the patient’s knee showed no fixed flexion and had a reasonable range of flexion, dependent on the preoperative range and what was thought could be reasonably obtained. The ability to flex the knee indicated that the soft tissues were sufficiently supple to reduce the load on the implant and gearbox during the lengthening process. Generally, lengthenings were performed every one to four weeks. For the two arthrodesis-type endoprostheses, lengthenings were performed at weekly intervals starting from the second post-operative week. Plain radiographs were taken before and after the first lengthening procedure to confirm the integrity and fixation of the implant and to ensure that the prosthesis was extending (Fig. 3). Lengthening was continued until the patient had a leg-length discrepancy of < 5 mm or expressed their satisfaction with what had been achieved. All lengthenings were carried out in the outpatient department painlessly without anaesthesia. After each lengthening the patient’s neurovascular status was checked. The total lengthening was recorded as well as the range of movement of the knee and any complications.

**Functional outcome.** The patients were evaluated functionally before and after surgery using the Musculoskeletal Tumour Society scoring system for limb salvage. This is a six-item scale evaluating pain, function, emotional acceptance, use of supports, walking ability and gait cosmetics to produce a score ranging from 0 to 30. A percentage score can then be calculated to allow comparison with other limb-salvage techniques.
Statistical analysis. The statistical significance of the change in the mean functional score was performed using the Wilcoxon signed-rank test with a p-value ≤ 0.05 being considered to be significant.

Results
Survivorship of the implant. The mean follow-up was 34 months (12 to 62). Of the nine prostheses implanted one required revision at 15 months because of breakage of the prosthesis through its femoral shaft following a fall. The implant concerned was an arthrodesis endoprosthesis. The breakage was managed by cementing the two broken ends into a custom-made cylinder (Fig. 3). This allowed the femoral and tibial fixation to remain untouched with preservation of good function and stability.

In one patient there was failure to eradicate a pre-existing deep infection. This patient had initially undergone a distal femoral replacement for osteosarcoma which became infected. A two-stage revision to a distal femoral non-invasive extendible endoprosthesis was performed, but infection with coagulase-negative staphylococci persisted. This patient had already undergone many operations on the affected leg and had a resultant leg-length discrepancy of 12 cm. The prosthesis was left in situ and the infection was managed by suppressive antibiotic therapy.

There were no failures of the lengthening mechanism in the endoprostheses.

Lengthening. The mean lengthening was 56 mm (19 to 107) which required a mean of nine (3 to 20) lengthening procedures. The mean length gained in the neoplastic group was 67 mm; (20 to 107) and in the non-neoplastic group 34 mm (19 to 51). The mean length achieved during each lengthening episode was 5 mm (2 to 20). Given the extension rate of the activated prosthesis of 0.25 mm per minute, it requires 20 minutes for a lengthening procedure of 5 mm. No patient experienced pain during the lengthening procedure although some did report a stretching sensation particularly affecting the hamstrings. All were able to weight bear fully after the procedure, usually regaining their pre-lengthening level of function by the following day, excluding the patients undergoing arthrodesis. The mean knee flexion after the lengthening procedures was 95° (80° to 105°) in the distal femoral replacements and 90° (80° to 100°) in the total femoral replacements. One patient required reversal of the lengthening by 2 mm three days later to correct a fixed-flexion deformity of the knee of 5° because of tightness of the hamstrings. After reversal full extension was achieved and his gait returned to normal. Although two patients in the neoplastic group had received previous radiotherapy, this did not appear to affect the lengthening process.

No patient had any neurovascular compromise after lengthening. One patient who developed post-operative exacerbation of chronic leg lymphoedema had difficulty fitting his limb into the opening (16 cm diameter) in the external drive unit. He required four-layered compression bandaging before each lengthening procedure to reduce the girth so that the limb could fit inside the portable drive unit.

Three patients have required planned subsequent exchange prostheses after achieving the maximum lengthening possible in the original non-invasive extendible endoprosthesis. One with a distal femoral replacement and a maximum extension capacity of 50 mm had a pre-existing leg-length discrepancy of 10 cm. He required further revision with a new non-invasive extendible prosthesis at 19 months. One patient with a diaphyseal replacement with an extension capacity of 50 mm and a pre-existing leg-length discrepancy of 18 cm similarly required exchange to another extendible diaphyseal replacement at two months. Finally, one patient with a distal femoral replacement with an extension capacity of 90 mm who had a pre-existing leg-length discrepancy of 12 cm underwent revision with a new extendible distal femoral replacement at eight months.

The mean overall lengthening in patients who required exchange prostheses was 92 mm (80.5 to 107). At exchange only the telescopic shaft, magnet and gearbox were renewed, leaving the fixation of the endoprosthesis to the femur and tibia undisturbed. All the patients were satisfied with their final length and no further active lengthening is planned.

Function. The mean pre-operative musculoskeletal tumour society score was 10 (6 to 12) which improved to a mean score of 22 (18 to 28) at the final follow-up (Wilcoxon signed-rank test, p < 0.008). In the non-neoplastic group, the mean pre- and post-operative scores were 10 (9 to 11) and 21 (20 to 22), respectively and in the neoplastic group, 9 (6 to 12) and 22 (18 to 28), respectively. All the patients were able to use public transport and walk with or without crutches in public.

Discussion
Endoprosthetic systems for massive bone loss can address shortening in one of three ways. First, there are modular systems in which mid-sections are exchanged for progressively longer pieces through a series of open procedures.11-15 Secondly, there are designs which require a small incision under anaesthesia to expand the prosthesis. Most recently, a non-invasive design has been described which allows limb lengthening without further surgery.

The non-invasive extendible endoprosthesis has been successfully used to reconstruct the lower limb after resection of malignant bone tumours in children.16-19 In contrast to devices such as the Phenix system (Phenix Medical, Paris),19 the Stanmore non-invasive extendible endoprosthesis, although similar in that it requires an electromagnetic field, differs in that it does not need a heating effect to lengthen, does not store energy in a coiled spring and is able to lengthen at a constant controlled rate of 0.25 mm per minute, rather than in an unpredictable manner. Gupta et al16 reported their experience with the use of a Stanmore non-invasive extendible distal femoral replacement which possessed the same mechanism as the
prosthesis used in our study. The mean lengthening in a series of skeletally immature patients was 23 mm (4.25 to 55) with a mean extension of 4 mm with each procedure. There were no failures of the lengthening procedure or mechanism.

The mean length gained by the patients in our series was 56 mm (19 to 107) which exceeded that in previous studies using non-invasive extendible prostheses.16,17,19 The lengthening procedures were uncomplicated and facilitated by active physiotherapy between each lengthening session to maintain knee flexion. Although one patient acquired a fixed-flexion deformity of 5° after lengthening, this was corrected by reversing the length by 2 mm. This patient had a pre-existing infection and a fixed-flexion deformity of 30° before revision, and obtained a range of flexion of 0° to 80° after revision, which, apart from the above episode, was maintained by physiotherapy until the end of the process.

In four of the patients in whom this technique was used only a moderate increase in their leg length was required to resolve their functional leg-length discrepancy (19, 20, 31.5 and 33 mm). All obtained considerable improvement as demonstrated by their functional scores and achievement of functional leg-length equality. However, the cost of a non-invasive extendible prosthesis is approximately £6000 and therefore we do not advocate this technique for every revision with a moderate leg-length discrepancy, but suggest that, in patients with major bone loss requiring endoprosthetic replacement and a functional leg-length discrepancy, it should be considered as an option.

Fracture of the implant is recognised as a complication after this type of reconstruction and can affect the extendible or non-extendible component.17,19,23 The patient who broke the implant after a fall was obese. The breakage occurred at a relatively thin cross-sectional region in the shaft and may have been due to metal fatigue. The non-invasive extendible prosthesis has multiple parts which may render it more likely to malfunction than if the implant was a monoblock. Possibly for adult patients future custom-made non-invasive endoprostheses will need to be designed to provide greater structural support than that needed in children.

Infection remains a considerable problem in limb-salvage procedures and is related to the difficulties in achieving adequate soft-tissue cover after endoprosthetic reconstruction.24 Pre-existing deep prosthetic infection was present in two patients in our study. In three this was eradicated by two-stage revision, but in one the infection persisted. Nevertheless, leg lengthening was achieved in this patient with the infection controlled by suppressive antibiotic therapy. No other septic complications have arisen.

The implant described is still under development and follow-up is short, but we are hopeful that this new method of limb reconstruction in skeletally mature patients with a leg-length discrepancy, will address the functional problem in patients undergoing revision limb-salvage surgery for neoplastic disease or after failed revision arthroplasty. The staged lengthenings can be performed in the outpatient departments in a painless manner and at reduced costs.

We acknowledge the contribution made by Stanmore Implants Worldwide Ltd. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References