We report the results of intramedullary leg lengthening conducted between 2002 and 2009 using the Intramedullary Skeletal Kinetic Distractor in 69 unilateral lengthenings involving 58 femora and 11 tibiae. We identified difficulties that occurred during the treatment and assessed whether they were specifically due to the implant or independent of it. Paley’s classification for evaluating problems, obstacles and complications with external fixators was adopted, and implant-specific difficulties were continuously noted. There were seven failures requiring premature removal of the device, in four due to nail breakage and three for other reasons, and five unsuccessful outcomes after completion of the lengthening. In all, 116 difficulties were noted in 45 patients, with only 24 having problem-free courses. In addition to the difficulties arising from the use of external fixators, there were almost the same number again of implant-specific difficulties.

Nevertheless, successful femoral lengthening was achieved in 52 of the 58 patients (90%). However, successful tibial lengthening was only achieved in five of 11 patients (45%).

The problems associated with the Ilizarov technique include pin-track infection, painful scars and the discomfort caused by the need to use the device for a long period of time.1-3 Contemporary methods of limb lengthening include modifications of the technique,4 combined procedures or purely intramedullary procedures including lengthening over a nail,5,6 also known as the monorail procedure,7 and lengthening by distraction osteogenesis followed by nailing.8

Two different fully implantable systems are available. Whereas the motorised Fibbone nail (Wittgenstein-Intens Inc., Igersheim, Germany) is available by a restricted licensing programme limited to one centre per country,9-12 the Intramedullary Skeletal Kinetic Distractor (ISKD; Orthofix Inc., McKinney, Texas) is available worldwide without restrictions. Cole et al13 reported on initial experience when the device became commercially available; other reports describe preliminary experiences or are small series.14-23 Kubiak et al24 described a high incidence of intra- and post-operative complications. Others have described the highly demanding nature of the procedure and the most frequent errors that occur when using the device.17,18,21 In the United Kingdom the National Institute for Health and Clinical Excellence (NICE) examined the available data,9,10,13,25 and did not recommend intramedullary limb lengthening.26 Among other things, the studies included in the review called for the method to be tested in investigations including larger numbers of patients.

Against this background, our study was designed to address the following points:

1. Does the ISKD successfully avoid the soft-tissue complications and joint stiffness which often follow external fixation? In addition, we wished to establish whether the ISKD had its own specific complications.

2. How should the outcome for patients who have undergone leg lengthening with the ISKD be evaluated, and how should the complications be managed?

Patients and Methods

We started using the ISKD for femoral and tibial lengthening in 2002 and reported our initial results in 22 patients in 2006.18 We now describe our experience in 69 procedures, 58 femoral and 11 tibial lengthenings, performed by or supervised by the senior author (RR), between August 2002 and June 2009.

The mean age of the patients at implantation was 24 years (12 to 51) and the mean planned extension was 43 mm (22 to 80). The diagnoses of the 69 patients are shown in Table I. The surgical method has been described previously.16 In brief, the osteotomy is performed through a small incision with multiple drill-holes and...
completed with an osteotome, after which reaming is undertaken with flexible reamers over a guide wire.

Details were recorded of operated bone, whether the nail was inserted antegrade or retrograde (in case of femur) side, nail type, latency period (post-operative days to the start of daily lengthening), duration of hospitalisation, the days post-operatively until the last pole change as the end of the distraction phase, the days post-operatively until bony consolidation, time to full-weight-bearing without crutches and time of removal of the ISKD. Follow-up was for a minimum of six months after implant removal or, if still in place, for at least six months after unrestricted full weight-bearing. This duration enabled later complications such as fractures in the regenerated bone to emerge.

Leg lengths, angular deformity and joint surface angles were measured pre- and post-operatively, and during the follow-up using digital bilateral long-leg standing radiographs. These enabled the initial leg-length discrepancy, planned lengthening and amount of lengthening achieved to be measured. Additional radiographs in two perpendicular planes were obtained at two-weekly intervals during the distraction phase and every six to eight weeks during the consolidation phase. The orientation of the joint lines pre-operatively were compared with the post-operative position and during follow-up. The quality of outcome was assessed as described by Paley. It was determined that the planned resulting leg-length discrepancy should not be ≥ 10 mm. If these conditions were not met, the outcome was classified as having a major complication.

Consolidation of the osteotomy was defined as the point when corticalisation in the regenerated bone was visible on both anteroposterior and lateral radiographs, and seen to involve at least three cortices. The distraction index, in millimetres per day, was defined as the length of callus regeneration on the radiograph in millimetres divided by the time from the start to the end of distraction in days. The consolidation index, in days per centimetre, was defined as the interval between the operation and radiological evidence of consolidation in the regenerate, divided by the length of the callus regeneration in days per centimetre.

The healing index can be used to assess healing and is defined as the total treatment period with the fixator in situ, divided by the length of bone growth in centimetres. With the ISKD, the full weight-bearing index can be used to provide a similar assessment. This is defined as the period from operation to the time when the patient is able to bear full weight without any walking aids.

Paley’s criteria for comparing the results of limb lengthening using external fixators and the classification of the difficulties encountered were adapted for our investigation. Problems. We adapted the definition of a problem in ISKD lengthening as a potentially expected or observed difficulty occurring during implantation, the latency phase, distraction or consolidation that could be completely resolved within the normally planned treatment period without the need for a repeat operation or intervention under anaesthesia. An example would be the need to carry out the daily pole change with the help of the physician or with analgesia administered in the outpatient department.

Obstacles. We adapted the definition of an obstacle as a need for manipulation under anaesthesia to carry out a pole change, to allow further pole changes and avoid premature consolidation, but still enabling treatment to be completed within the planned duration.

Complications. This category included all intra- and peri-operative complications, whether local or systemic, and any subsequent difficulties, including after removal of the ISKD. Minor complications were defined as occurring if the initial lengthening aim was achieved but a complication persisted beyond the normal completion of treatment.

Table I. Diagnoses of the 69 patients who underwent limb lengthening

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital LLD*</td>
<td>30</td>
</tr>
<tr>
<td>CSF, PFFD</td>
<td>8</td>
</tr>
<tr>
<td>Fibular hemimelia</td>
<td>6</td>
</tr>
<tr>
<td>Other longitudinal reduction deficiency</td>
<td>7</td>
</tr>
<tr>
<td>Klippel-Trenaunay-Weber, hemihypertrophy, hemihypotrophy</td>
<td>9</td>
</tr>
<tr>
<td>Acquired LLD</td>
<td>30</td>
</tr>
<tr>
<td>Post-traumatic</td>
<td>17</td>
</tr>
<tr>
<td>Aseptic necrosis hip, Legg-Calvé-Perthes’ disease</td>
<td>2</td>
</tr>
<tr>
<td>Tumour resection</td>
<td>7</td>
</tr>
<tr>
<td>Resection osteomyelitis</td>
<td>4</td>
</tr>
<tr>
<td>Idiopathic and other LLD</td>
<td>9</td>
</tr>
<tr>
<td>Idiopathic structural LLD</td>
<td>7</td>
</tr>
<tr>
<td>Functional (lumbar scoliosis)</td>
<td>2</td>
</tr>
<tr>
<td>For cosmetic reasons</td>
<td>0</td>
</tr>
</tbody>
</table>

* LLD, limb-length discrepancy; CSF, congenital short femur; PFFD, proximal focal femoral deficiency
although it was resolved without surgery. An example would be difficulty with mobilisation due to joint and/or muscle contractures that required physiotherapy.

Major complications were defined as occurring if the initial lengthening was achieved, but a complication was still present at the end of the planned treatment and had to be resolved with additional surgery, or remained unresolved; and failure to obtain the planned lengthening by ≥ 1 cm or not at all, and surgical treatment was required or the problem was left and persisted.

Results
The mean follow-up after consolidation was 16 months (6 to 49). The overall outcome is presented in Table II. In seven patients the ISKD was removed before bony consolidation was achieved, and a further five required the procedure to be changed to achieve healing. This resulted in 57 patients (83%) completing their treatment with the ISKD. This represented 52 of 58 femoral lengthenings (90%) and five of 11 tibial lengthenings (45%).

Using the modified Paley classification,2 a total of 116 difficulties were observed in 45 of the 69 patients during lengthening, comprising 53 problems, 30 obstacles and 33 complications. In all, 55 of the 116 difficulties (47%), 22 of the 53 problems (42%), 24 of the 30 obstacles (80%) and nine of the 33 complications (27%) were attributable to the ISKD itself.

Seven patients were excluded because they were unable to complete their treatment with the ISKD. Two patients with a non-functioning ISKD were switched to a different procedure (either lengthening with an external fixator or lengthening over the ISKD), four had nail breakages due to poor formation of regenerate, including two who also had deep-vein thrombosis in the leg, and one underwent bone grafting, with acute shortening owing to the development of a pseudarthrosis.

The results for the 62 patients who completed treatment are presented in Table III. The planned lengthening was compared with the length achieved. Femoral lengthening was more successful in reaching its target than tibial lengthening.
In 24 of the 62 patients (39%) lengthening was achieved without problems, and eight more (13%) developed problems that were resolved. All four retrograde femoral implantations were associated with some difficulties. The technique was particularly exacting and was subsequently abandoned. At least one obstacle without additional complications was observed in 17 patients (27%) who completed treatment, and complications arose in the remaining 13 (21%). The planned lengthening was missed by ≥1 cm in five patients, owing to premature consolidation in four cases and in one patient due to distal dynamisation and acute shortening to achieve bone healing. In all 62 patients who completed treatment, seven patients with nine major complications who achieved the treatment goal had residual findings that required surgery or persisted, including the two patients with a deep-vein thrombosis.

Discussion

Approximately half (47%) of the difficulties observed in 45 patients were specifically related to the ISKD. In the series reported by Simpson et al,21 including 33 femoral lengthenings, bony healing was not achieved with the ISKD and only following bone grafting in ten patients (30%). Kenawey et al27 reported an overall incidence of complications of 33% in 57 lengthenings, with insufficient bone regenerate as the main problem in 12 cases.

Comparability with other series was achieved by adopting the Paley classification of problems, obstacles and complications, established for external fixators.2 Kocaoglu et al28 have already proposed this for the lengthening-over-the-nail procedure, and Vitale et al22 used this system in a report on two ISKD patients. In this study, we developed a modification of the system that helps distinguish between implant-associated difficulties and the problems, obstacles and complications of lengthening that are due to the distraction osteogenesis procedure alone.

As with external fixators, painful manipulations to achieve distraction are sometimes required with the ISKD. Relative to the full weight-bearing index, the rehabilitation times did not differ from those with external or other procedures.2,3,8,27,29 However, the ISKD avoids the inevitable disadvantages of external fixators, such as pin-track infection, painful scars and discomfort caused by the need to use the device for a long period of time.

In the tibia, difficulties such as poor formation of regenerated bone and even pseudarthrosis and footdrop occur at similar rates with both the ISKD and external fixators.2 Likewise, the problems often seen with external fixators were also observed in the femur, including early consolidation and soft-tissue problems at the knee, including threatened subluxation.

Poor formation of regenerated bone over a long period was also the reason for the four nail fractures, three of which affected the femur and one the tibia. All developed during permitted full weight-bearing in weak regenerated bone at a mean of 15 months (10 to 19) after surgery (Figs 1 and 2). As full weight-bearing with the ISKD is not intended by the manufacturer until there is radiological evidence of consolidation, these nail fractures might be considered the responsibility of the surgeon and not strictly to be ISKD-specific complications.

In summary, there are two main groups of ISKD-associated problems: fast and slow starters. The problems in fast starters involve pole changes taking place too early and too often, often uncontrolled, with or without monitoring. With slow starters, patients are not able to achieve a
pole change, usually because of pain or mechanical problems, and it has to be done by an assistant with the patient receiving oral analgesia. Without this intervention early consolidation is a risk that requires mobilisation under anaesthesia. In this procedure, multiple pole changes are carried out with the patient under general anaesthesia, with up to 20 pole changes producing a 7.5 mm ad hoc lengthening. Adopting this approach, a repeat osteotomy was required in only one case.

The overall reliability of the ISKD in the femur was good, with 52 of 58 (90%) lengthening procedures being successful, it can be recommended with good patient selection and in pure lengthening up to 5 cm without associated correction of axial deformity. Our findings for the femur contrast with the recommendations made by NICE.26 In the tibia, although the implant functioned in nine of 11 cases, successful treatment was obtained in only five. The tibial results detracted from the overall success of this implant, with 57 of 69 (83%) patients reaching their goal, but it is still comparable with other experiences with this implant.

### Supplementary material

A table showing the full results of the 69 implantations is available with the electronic version of this article on our website at www.jbjs.org.uk

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