LOWER LIMB

Mechanical failure of the Intramedullary Skeletal Kinetic Distractor in limb lengthening

Between October 2001 and September 2009 we lengthened 242 lower-limb segments in 180 patients using the Intramedullary Skeletal Kinetic Distractor (ISKD). Mechanical failure was defined either as breakage of the ISKD or failure of the internal mechanism to activate. Retrieved nails which failed mechanically were examined by the manufacturer for defects. In all, 15 ISKDs in 12 patients (13 limbs) failed mechanically representing an overall failure rate of 6.2%, with fracture of the device occurring in ten of the 15 failures. Two nails in one patient failed to lengthen and had to be replaced. The manufacturer detected an error in the assembly of the nail, which prompted a wide recall. One nail jammed after being forcefully inserted, and two nails failed to lengthen fully. Lengthening was achieved in all 12 patients, although three required a second operation to exchange a defective nail for a new, functioning device.

The ISKD is a complex mechanical device which lengthens by the oscillation of two telescopic sections connected by a threaded rod. The junction between these sections is surrounded by a keyring collar. This keyring collar is the weakest part of the device.

Limb lengthening using an external fixator is a widely accepted and well-proven procedure.\(^1\)\(^-\)\(^7\) Recently, intramedullary systems have been developed in an attempt to reduce the rate of complications and to improve patient comfort.\(^8\)\(^-\)\(^15\) Currently, three such devices are in use: the Intramedullary Skeletal Kinetic Distractor (ISKD; Orthofix Inc., Lewisville, Texas),\(^10\)\(^,\)\(^16\) the Albizzia nail (DePuy, Villeurbanne, France),\(^11\)\(^,\)\(^12\) and the Fitbone (Wittenstein Intens, Igersheim, Germany).\(^5\)\(^,\)\(^9\) The Albizzia nail and the ISKD are both unidirectional, mechanically driven devices which lengthen through torsional movement, while the Fitbone has an internal electrical motor that lengthens the device. Of the three devices, the ISKD is the only one which has the approval of the Food and Drug Administration (FDA) and is available for use in the United States.

Our aim was to report the mechanical failure of the ISKD and the clinical relevance of these failures.

Patients and Methods

We carried out a retrospective review of a consecutive series of 180 patients who had lengthening of the lower limb between October 2001 and September 2009. The study was approved by our Institutional Review Board. We inserted 242 ISKDs in 210 limbs in 180 patients (109 men and 71 women), with an age range from nine to 60 years. The indications for lengthening were congenital in 84 patients, post-traumatic in 50 and developmental in 19, as well as lengthening for short stature in 23 and for dwarfism in four patients. Our aim was to examine the mechanical failure of this device, which we defined as breakage of the nail or failure of the mechanism to lengthen fully, despite a complete osteotomy. We excluded biological complications related to the lengthening process such as premature consolidation of the regenerate bone or nonunion. We defined a successful lengthening of the ISKD as the achievement of length within 5 mm of the desired length.

The ISKD is a complex mechanical device which lengthens by the oscillation of two telescopic sections connected by a threaded rod. The junction between these two sections is surrounded by a keyring collar which has protrusions that fit into two opposing grooves in the male part of the nail. The keyring collar has two tabs which lock into corresponding notches of the female part of the nail. Without the keyring collar, it is possible to unscrew the male part to separate the two telescopic sections. The function of the keyring collar is to secure the connection between the rod segments and to prevent the nail from turning more than...
that required for lengthening (between 3° and 9°). The keyring collar is the weakest part of this device and has to withstand torsional impact during the lengthening process. Lengthening is performed by two one-way clutches which form a unidirectional drive mechanism through oscillating rotations of between 3° and 9°. Typically, 60 rotations of at least 3° are required to achieve distraction of 1 mm and are generally obtained through normal everyday physiological movement.\textsuperscript{10} A length indicator feedback system is positioned inside the nail, consisting of a static samarium cobalt rare-earth magnet which turns together with an internal threaded rod. An external hand held monitor registers the number of magnet pole changes to calculate the distraction gap.

The starting point for inserting a femoral nail into the femur is the piriformis fossa, and for a tibial nail into the femur it is the greater trochanter. An osteotomy is initiated using a multiple drill hole technique, which helps to vent the intramedullary canal, and the bone reamings act as bone graft to assist in healing. The nail is inserted almost to the intramedullary canal, and the bone reamings act as a static samarium cobalt rare-earth magnet which turns together with an internal threaded rod. An external hand held monitor registers the number of magnet pole changes to calculate the distraction gap.

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Table I. Details of the 15 failures of the Intramedullary Skeletal Kinetic Distractor (ISKD) in 12 patients

<table>
<thead>
<tr>
<th>Patient (case) number</th>
<th>Gender</th>
<th>Age (yrs)</th>
<th>Location</th>
<th>Diagnosis</th>
<th>Amount of lengthening (cm)</th>
<th>Nail size (mm)\textsuperscript{*}</th>
<th>Failure details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (1)\textsuperscript{†}</td>
<td>M</td>
<td>54</td>
<td>Femur</td>
<td>Post-traumatic</td>
<td>4.0</td>
<td>F12.5 × 255 to 305</td>
<td>Key ring and female part broke after nonunion. Breakage likely due to torsional overload</td>
</tr>
<tr>
<td>2 (2)</td>
<td>F</td>
<td>16</td>
<td>Femur</td>
<td>CFD\textsuperscript{†}</td>
<td>5.0</td>
<td>T10.7 × 215 to 265</td>
<td>Key ring and female part broke. Breakage only noted upon device removal</td>
</tr>
<tr>
<td>3 (3)\textsuperscript{†}</td>
<td>M</td>
<td>36</td>
<td>Femur</td>
<td>Short stature</td>
<td>5.0</td>
<td>T10.7 × 215 to 305</td>
<td>Subject developed nonunion. Breakage likely due to torsional overload</td>
</tr>
<tr>
<td>4 (4)</td>
<td>M</td>
<td>28</td>
<td>Femur</td>
<td>CFD</td>
<td>2.0</td>
<td>F12.5 × 255 to 305</td>
<td>Disengaged key-ring noted upon device removal</td>
</tr>
<tr>
<td>5 (5)</td>
<td>M</td>
<td>16</td>
<td>Femur</td>
<td>Achondroplasia</td>
<td>5.0</td>
<td>F12.5 × 215 to 265</td>
<td>Disengaged key-ring noted upon device removal</td>
</tr>
<tr>
<td>6 (6)</td>
<td>F</td>
<td>15</td>
<td>Femur</td>
<td>Hemihypertrophy</td>
<td>2.7</td>
<td>T10.7 × 255 to 305</td>
<td>Disengaged key-ring noted upon device removal</td>
</tr>
<tr>
<td>7 (7)</td>
<td>M</td>
<td>12</td>
<td>Femur</td>
<td>CFD</td>
<td>5.0</td>
<td>T10.7 × 215 to 265</td>
<td>Disengaged key-ring noted upon device removal</td>
</tr>
<tr>
<td>8 (8)</td>
<td>M</td>
<td>54</td>
<td>Femur</td>
<td>Short stature</td>
<td>5.0</td>
<td>F12.5 × 255 to 305</td>
<td>Mirror image nail fractures of female component. Breakage likely due to torsional overload</td>
</tr>
<tr>
<td>9 (9)</td>
<td>F</td>
<td>19</td>
<td>Femur</td>
<td>CFD</td>
<td>5.0</td>
<td>F12.5 × 255 to 305</td>
<td>Mirror image nail fractures of female component. Breakage likely due to torsional overload</td>
</tr>
<tr>
<td>10 (10)\textsuperscript{†}</td>
<td>F</td>
<td>19</td>
<td>Femur</td>
<td>CFD</td>
<td>6.0</td>
<td>F12.5 × 255 to 335</td>
<td>Failure to lengthen. Determined to be an error in manufacturer's assembly</td>
</tr>
<tr>
<td>11 (11)</td>
<td>F</td>
<td>29</td>
<td>Femur</td>
<td>CFD</td>
<td>6.0</td>
<td>F12.5 × 255 to 335</td>
<td>Failure to lengthen. Determined to be an error in manufacturer's assembly</td>
</tr>
<tr>
<td>12 (12)\textsuperscript{†}</td>
<td>M</td>
<td>31</td>
<td>Femur</td>
<td>Post-traumatic</td>
<td>3.0</td>
<td>F12.5 × 255 to 305</td>
<td>Nail damaged during insertion. Exchanged during initial operation with no further problem</td>
</tr>
<tr>
<td>13 (13)</td>
<td>M</td>
<td>55</td>
<td>Tibia</td>
<td>Post-traumatic</td>
<td>2.0</td>
<td>T10.7 × 255 to 305</td>
<td>Failure to lengthen. Exchanged for a second nail which lengthened uneventfully</td>
</tr>
<tr>
<td>14 (14)\textsuperscript{†}</td>
<td>M</td>
<td>19</td>
<td>Femur</td>
<td>CFD</td>
<td>6.5</td>
<td>T12.5 × 255 to 335</td>
<td>Failure to lengthen. Exchanged for a second nail which lengthened uneventfully</td>
</tr>
<tr>
<td>15 (15)\textsuperscript{†}</td>
<td>F</td>
<td>15</td>
<td>Femur</td>
<td>CFD</td>
<td>6.5</td>
<td>T12.5 × 255 to 335</td>
<td>Breakage of male part after nonunion. Breakage likely due to torsional overload</td>
</tr>
</tbody>
</table>

\textsuperscript{*} F, femoral nail; T, tibial nail
\textsuperscript{†} CFD, congenital femoral deficiency
\textsuperscript{‡} required additional operation for nonunion repair, ISKD replaced by standard intramedullary nail
\textsuperscript{§} required additional operation for insertion of new ISKD that lengthened uneventfully

Results

Of the 242 ISKDs, 15 nails in 12 patients had a mechanical failure giving an overall rate of 6.2% (Table I). This included three males and nine females with a mean age of 29.6 years (12 to 55). A total of 14 lengthenings were performed in the femur (eight of which received femoral nails and six received tibial nails) and one was performed in the tibia. Indications for lengthening were congenital femoral deficiency in five patients, post-traumatic in three, short stature in two, achondroplasia in one and hemihypertrophy in one. The...
mean length to be obtained was 4.4 cm (2.0 to 6.5). The limbs of all 12 patients were lengthened successfully, although three required an unplanned second operation to remove a defective nail and to exchange it for a new device (cases 10, 12 and 14, Table I). These problems involved eight femoral ISKDs and seven tibial ISKDs. We observed no bending or breaking of locking screws in any implant.

In ten cases (9 patients) the cause of failure was a fracture of the device and/or its external parts, noted either radiologically during the consolidation phase or visually on elective retrieval. Two of these ten failures occurred in one patient (patient 8, cases 8 and 9, Table I) who was undergoing lengthening for constitutional short stature. Both ISKDs had similar axial fractures of the male part of the nail, noted only upon retrieval (Fig. 1). In two patients, the keyring collar of the nail and the distal tip of the female part of the telescopic nail fractured (cases 1 and 2, Table I, Fig. 2). In four other patients, the keyring collar separated from the female nail section (cases 4 to 7, Table I, Fig. 3). In one of the ten nails, the two telescopic pieces of the nail separated and the keyring collar disengaged (case 3, Table I). The remaining nail fractured in the male section in a patient with insufficient formation of new bone (case 15, Table I).

Of the five remaining nails with mechanical failure, two were sequentially implanted in one patient and failed to lengthen, requiring an additional operation for the insertion of a third ISKD, which lengthened successfully (patient 9, cases 10 and 11, Table I). The two malfunctioning nails were sent to the manufacturer who determined that there had been an assembly error, prompting a complete recall of all nails in that particular manufacturing series. In another attempted lengthening, the nail failed to lengthen fully after initially distracting 2 cm uneventfully
In these patients that would indicate a need to reconsider safer. We have not observed an increase in complications femoral head in whom a trochanteric entry hole would be this technique in patients with a short femoral neck, and accommodate the 12.5 mm femoral ISKD. We also use a tibial ISKD into the femur is a common technique in

Discussion
In our series of 242 ISKDs we observed an overall mechanical failure rate of 6.2% (15 nails). Mechanical failure can result from either a manufacturing defect of the nail or a biologically-related situation. In three of these nails nonunion developed, which presumably caused an overloading of the nail and resulted in breakage. None of our patients reported any trauma. When breakage occurred before the bone was fully consolidated, it is possible that the nail was damaged through an overload during the vulnerable period of the lengthening process. If this is the case, it may be prudent to extend the period before allowing full weight-bearing. Additionally, patients should be advised to restrict weight-bearing to less than 50 lbs (22.7 kg) until sufficient consolidation has taken place, as the manufacturer recommends. This may have been the problem in one patient (patient 8, cases 8 and 9) who underwent lengthening which healed uneventfully, but in whom bilateral fractures of the ISKD occurred. Since both limbs had been treated, it was difficult to comply with the instructions to bear partial weight. Furthermore, in our experience, if bone healing fails to progress within a period of three months, additional surgery such as exchange rod ding and/or bone grafting should be considered to protect the nail from the risk of breakage.

When examining a tibial ISKD of 10.7 mm in diameter which had fractured after femoral insertion (case 3), the manufacturer noted that this nail was not intended for femoral insertion. However, at our centre, the insertion of a tibial ISKD into the femur is a common technique in cases in which the intramedullary canal is too narrow to accommodate the 12.5 mm femoral ISKD. We also use this technique in patients with a short femoral neck, and in adolescent patients with an open growth plate in the femoral head in whom a trochanteric entry hole would be safer. We have not observed an increase in complications in these patients that would indicate a need to reconsider our procedure.

In the patient (patient 9) in whom the two nails failed to lengthen during the initial surgery, the manufacturer reported an error in assembly as the cause of the faulty proximal and distal clutch rollers and springs, prompting a wide recall of all nails in that manufacturing series.

In another patient (patient 11, case 13), the ISKD was damaged by forcefully hammering it through an unreamed segment. This damage demonstrates that a mechanically complex nail requires more delicate handling than a standard intramedullary nail.

There have been many reports regarding broken intramedullary rods that focus predominantly upon the reasons for the breakage and the removal techniques for the broken fragments of nail. It is difficult to compare a mechanically complex lengthening device such as the ISKD with a one-piece trauma nail. Because of the complexity of this nail, we typically remove all nails after consolidation is complete, approximately 12 to 18 months after insertion.

In their series, Franklin et al described 56 broken intramedullary rods inserted between 1962 and 1987. They found that nails with smaller diameter failed more often, especially in patients with nonunion or delayed union. The rods broke mostly at the site of the fracture or the nonunion. In the other cases with no clear handling problems, the nails broke at stress risers such as the interlocking holes, the welded junction of the top insertional portion, or the proximal slot. Interestingly, none of our ISKD breakages occurred through the interlocking holes.

Our experience indicates that the connection junction of the telescopic mechanism is the weakest part of the ISKD, as opposed to standard trauma nails, which tend to fail at the locking screw holes. In the ten cases in which the nail fractured or the keyring collar disengaged, we believe that the cause was chronic torsional overload, except the one case (case 15) where the male part actually fractured, possibly through bending overload.

As most failures were recognised radiologically at follow-up visits or during removal of the nail, special attention should be paid to the early recognition of implant fractures on radiography. Retrieved nails should undergo a careful inspection by the surgeon for visible defects and to ensure that no broken pieces remain in the limb after surgery.

Despite these failures, we think that the ISKD is well constructed and is acceptably reliable. We observed 15 failures, but only three patients required an additional operation to gain the desired length. Furthermore, none of the failures resulted in catastrophic complications or led to loss of length.

Because the ISKD is the only FDA-approved internal lengthening device, we have no direct knowledge of the other devices and were unable to find any literature regarding the mechanical failure rates of either the Albizzia nail or Fibbone.

In order to avoid these complications, patients with delayed consolidation need special attention. We believe they should avoid full-weight-bearing until solid radiological healing has been achieved. In the event of nonunion, consideration should be given to bone grafting and nail exchange earlier than in those with normal trauma.

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