Overview of the Use of the Intramedullary Skeletal Kinetic Distractor (ISKD) as a Limb Lengthening Technique

Katherine E. Ludwig

Introduction
The intramedullary skeletal kinetic distractor (ISKD) is a recently developed technique to increase the length of limbs and is currently used to extend the length of the femur and tibia. It has developed a reputation as a technique that allows minimal pain, due to the small degree of distraction, enhanced joint mobility and early rehabilitation. The differential component of this device, in comparison to other intramedullary limb lengtheners, is the ability to monitor the amount of the nail that has been distracted by an external monitor, thus allowing the patient to monitor his/hers process themselves.

Design and construction
The ISKD is a relatively simple device [1] in comparison to the ring-fixator of Ilizarov, which is used in the more classical treatment of a shortened limb [2]. The ISKD is composed of two parts, a distal section and a proximal section [3]. The two parts are of equal length, and are available in denominations of 50 or 80mm [1] to be chosen at the surgeon's discretion, depending on how far the limb in question needs to be lengthened. The diameter of the proximal section is larger than that of the distal section [3], and so it is the proximal diameter that is the important consideration when assessing how much needs to be reamed from the medullary canal. A threaded rod, which makes up the basis for the drive mechanism through which the ISKD functions [1], connects the two sections (Figure 1) [3]. In each of the sections there is a one-way roller clutch [1]; the distal section holding a “distal clutch” and the proximal section holding a “proximal clutch”. The clutch systems are conjoined in opposite directions by the threaded rod [1]. Therefore, as the “distal clutch” turns in a counter-clockwise direction the “proximal clutch” stops the threaded rod from turning, thereby forcing the “distal clutch” and hence the distal section to turn [1]. As the distal section turns the threaded rod locks and forces the proximal and distal sections

Figure 1: ISKD (taken from Hankemeier et al [3])
to lengthen. (Figure 2) [1]. Due to the one-way clutch system, any rotation of the distal section in a clockwise motion would not lead to distraction, because the threaded rod would be turning with the proximal clutch rather than against it [1]. The distraction is activated by a rotation of at least 3° [3]. The rotation that takes place happens in association with daily movement or in some cases manual manipulation [4]. Once the rotation has been made the ISKD cannot reverse thus only allowing lengthening [3]. In terms of clinical relevance, a 160° rotation equals about 1mm in distraction [3]. In order to monitor the length that is gained a magnet is placed inside the tip of the threaded rod. The north and south poles are perpendicular to the threaded rod and so the change in polarity can be measured by the external monitor [3]. The monitor reads the position of the pole facing towards it and then, taking into consideration previous readings, can evaluate the rotation and subsequently the length that has been distracted [1]. This mechanism allows the patient to monitor how much rotation has taken place at regular intervals, so that they can then increase or decrease their activity in order to keep within the daily distraction goal [3]. The ISKD is made from Ti6A14 ELI, an implant grade titanium alloy [1]. This titanium alloy has a strong clinical record for being well tolerated. However, in a case study carried out by Cole et al on a 20 month old female sheep, some black tissue staining was noted on examination after removal of the nail [1]. Although this appeared to be benign, and was presumed to be due to wear caused by the distraction and rotation [1], this observation raises some potential concerns for use in humans.

**Indication and contraindications for the use of ISKD**

It is essential to ensure that patients are suitable candidates for the ISKD. A length discrepancy of between 20 and 80mm of the femur or tibia is a good indication for use of ISKD in limb lengthening surgery [3]. Importantly, the ISKD can used to correct length discrepancies resulting from disparate underlying conditions including trauma, infection and childhood burn contracture [1]. The presence of an axial malalignment does not preclude the surgery as this can be corrected at the time of the osteotomy. However, the nerves, soft tissue, scars and the extent of the malalignment must also taken into consideration [3] to make sure that the function of all the surrounding tissue is maintained. As with all surgeries there are contraindications, which rule some patients out as potential candidates for ISKD surgery. The surgery cannot take place if there are still open epiphyses, thus indicating that there is still room for more growth [3]. As the mechanism is intramedullary, a small medullary canal is a clear
contraindication as it would present excessive problems on reaming and insertion of the nail [3]. Due to the fact that the ISKD creates irreversible lengthening, a high level of patient compliance is a necessity [3]. Continual monitoring of the ISKD using the external monitor is a fundamental part of a successful outcome. It is therefore essential that the patient is aware of how far the leg has been distracted and understands fully how this relates to the required increase or decrease in their movement [1]. Being incapable to bear full weight onto the patients opposite leg would also be a contraindication as the ISKD can only bear up to 50kg by itself.

**Surgery**

For the surgery itself the patient is placed in the supine position [3]. An osteomy is performed either using multiple drill holes and then completion with a chisel for a femur, or using a Gigli saw in the tibia [3]. To make sure that there is no subsequent turning of the cut bone, Kirschner wires are used as stablisation [3]. The medullary canal is widened using a flexible reamer in order that the ISKD can be inserted [3]. The ISKD is chosen so that it fits the patient’s measurements most precisely. The shortest ISKD that can accomplish the required lengthening is used in combination with the biggest diameter that can be accepted by the limb, in order to maximise the strength of the implanted device [1]. The ISKD is inserted and is fixed in place proximally using the “aiming device” accompanying the ISKD [3]. Distally the ISKD is secured using a freehand technique [3].

**Post-operative results**

It is after the surgery that the bulk of the procedure takes place as illustrated in Figure 3, which shows a successful response following the insertion of an ISKD [3]. The distraction starts after 3 days for a femoral lengthening and after 5 days for a tibial lengthening [3]. The current recommended rate of distraction is 1mm per day [3]. This limitation is to ensure that body can adapt to the bone growth that is taking place. By taking these measures there is a decreased risk of any soft tissue or nerve damage [4]. It has been established that nerves regenerate at about 1mm per day, which is a

![Figures 3 a-d](adapted from Hankenmeier et al [3])

a) Radiographs of a 18-year-old patient with a 20-mm congenital shortening of the right tibia.
b) Postoperative radiographs after implantation of a tibial ISKD (length 200 mm, diameter 12.5 mm). Discharge from hospital on day 9.
c) Completed distraction after 5 weeks. Distraction index: 1.0 mm/day. Full weight bearing after 2 months.
d) Radiographs showing a complete remodelling of the callus after 9 months (consolidation index: 4.1 days/mm).
There is some evidence that nerves may regenerate even faster than this [5], but the value of allowing the nerves to regain full functionality [5] before allowing more growth to take place would argue against attempting a faster rate of distraction. Because of this it is also important that a neurological test be conducted regularly in order to check the nerve function [4]. One of the more common complaints of the external fixator is that there is reduced joint mobility [3]. However, these problems did not arise with the internal fixator as Hankeimer et al., showed when they conducted a study into postoperative mobility of the knee and hip joints. (Table 1). [6]

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>After distraction</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hip Flexion</td>
<td>123°</td>
<td>116°</td>
<td>122°</td>
</tr>
<tr>
<td>Knee Flexion</td>
<td>126°</td>
<td>107°</td>
<td>124°</td>
</tr>
</tbody>
</table>

Table 1: Results for the joint mobility pre and post ISKD insertion study (Adapted from Hankeimer et al. [6])

The results show that the patients regained almost all movement of the joint in comparison to movement that they had post-operatively. Another study conducted by Vitale et al. on the rehabilitation of patients after the insertion of an ISKD provides a good overview of the general methods to be used to successfully rehabilitate the patient to a level of daily function [4]. The two cases that were documented both had a shortened femur, one due to a malunion of a fracture and the other due to a congenital abnormality [4]. Both had successful osteotomies and ISKD placements, as well as prophylactic low molecular weight heparin to exclude venous thromboembolism [4]. However, during rehabilitation the patients showed differing responses. In the first case, the patient had good mobility from the beginning and was started on isometric lower limb exercises. By day 9 post-operatively she was transferred to the rehabilitation unit where she continued physical therapy with partial weight bearing of up to 50kg, which was coupled with pool therapy to improve her general movement [4]. Any pain was controlled by oral analgesics and she was successful discharged after 14 days of therapy with no outstanding medical issues [4]. In the second case however, there was a marked decrease in the patient’s mobility post-operatively [4]. This lack of movement meant that no distraction was taking place, and so the surgeon had to manually maneuver the leg so that the 1mm daily goal was reached [4]. Similarly to the first case, the patient was transferred to a rehabilitation unit at day 8 post-operatively where mobility continued to increase and partial weight bearing of at least 50kg was started [4]. However, the daily manipulation was not discontinued, resulting in a distraction rate of more than the recommended 1mm per day. In response to this, the manual distraction was ceased and the patient continued with therapy. Pain was controlled by oral analgesia and the patient was discharged after 10 days of therapy [4]. In their discussion of the results, the authors of this study highlighted the importance of the availability of pool therapy, as this provided good synergy with standard rehabilitation physiotherapy [4]. The authors also pointed out that the patients “gait pattern” should be observed, as their previous compensation for the length discrepancy would need to change post-treatment [4]. As a general rule for
recovery from ISKD insertion therapy, patients are allowed out of bed on the day following the operation [3]. It is important that the patient is taught how to use the external monitor properly, making sure that it is placed at the same level of the limb everyday to ensure that the distraction is successful [3]. The monitor makes an audible alert every 3 hours to ensure that the patient is constantly checking the monitor and thus adapting movement activity [3]. If further distraction is required, the patient can achieve this by internally and externally rotating the limb in question, either in a sitting position or supine with knee flexed. However, some patients find it easier if another party performs the manipulation for them [3]. In most cases, manual manipulation does not tend to be necessary as full weight bearing is recommended as soon as “consolidation of one cortex is evident radiologically” [3].

Advantages and disadvantages of using the ISKD technique opposed to other limb lengthening techniques.

The biggest advantage of the ISKD is the avoidance of the most common issues that present during the use during the more traditional limb lengthening techniques, chiefly pin infection, pain around the pins and reduced joint mobility [4]. In particular infection can become a larger problem than just an infection around the pins, as the pins provide the perfect opportunity for an infection to spread into the intramedullary canal. This can create a much more serious issue which might threaten the success of the limb lengthening [1]. As the ISKD is entirely internal there are no pins and thus no risk of pin infection. There is also more joint mobility and patients are able to start the rehabilitation program earlier, including immediate weight bearing [3]. However, the ISKD is not without its disadvantages. The biggest concerned is the absolute dependence on patient compliance for the success of the operation [3]. Because there is no possibility of shortening ISKD once it has been distracted, it is critical that the patient limits his movements in order to keep with in the recommended distraction rate [3]. As described by Reynders in his case report of “The Runaway Nail” the outcomes of a quickly distracting ISKD can be more severe than initially apparent [2]. In this case, the patient had an ISKD placed into his right femur to fix a length discrepancy. 2 days post-operatively, he presented with acute pain and increasing numbness of his right leg [2]. On examination there had been a 4cm distraction of the ISKD, which required the distal locking system to be removed and reinserted after the femur had been shortened [2]. One year after the numbness had remained, although the bone was found to have consolidated [2].

Discussion

The ISKD has proven to be very intriguing and potentially extremely useful technique in relation to limb lengthening. The combination of removing all external devices, coupled with ability to monitor progress by an external devices makes it a ground breaking method in its field. Although the risk of nerve damage and the necessity of reliable patient co-operation is a considerable
drawback in comparison to the more traditional methods, these may be seen to be outweighed by the avoidance of constant pain and infection that present as problems in a large proportion of patients undergoing conventional therapy [6]. Taking the advantages and disadvantages into consideration, it seems clear that the intramedullary skeletal kinetic distractor is paving the way for new procedures to address the challenges of limb lengthening.

References


