The intramedullary skeletal kinetic distractor (ISKD): first clinical results of a new intramedullary nail for lengthening of the femur and tibia

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Abstract

In 1986, a programme was initiated by the senior author to develop a reliable, mechanically activated, intramedullary lengthening device with a non-invasive means of measuring the progress of lengthening without X-ray. We report results of design, biomechanical testing, in vivo animal testing and clinical implantation of the first 20 intramedullary skeletal kinetic distractors (ISKDs) in adult patients with limb-length discrepancies.

Twenty ISKD devices were implanted in 18 patients (14 males and four females). Lengthening was required due to infection (ten), trauma (six), polio (one) and burn (one). Six femurs and 14 tibias were lengthened. Mean patient age was 40 years (range, 18–65 years).

No implant related infections, non-unions, malunions or joint contractures were observed. A design change was made following two initial hardware failures, after which there were no further breakages. Average lengthening was 49 mm (range, 29–110 mm). The average lengthening rate was 0.82 mm/day (range, 1.7–0.4 mm/day). Ability to work, walk and drive before, during and after treatment with the ISKD compared favourably with that of similar patients undergoing lengthening using the ‘monorail’ method in our practice.

The ISKD appears to be a safe and cost-effective alternative to external fixators that reduces lifestyle disruption and complications during adult limb-lengthening procedures. © 2001 Elsevier Science Ltd. All rights reserved.

1. Introduction

The potential for distraction osteogenesis to improve the quality of life for patients with limb-length discrepancies and deformities is now well established. However, external fixators, the traditional means for inducing distraction osteogenesis, have been associated with numerous complications.

The most frequent complication of limb lengthening by external means is pin site infection. Minor pin track infection rates ranging from 2–80% as well as major pin tract infection rates as high as 23% have been reported [1,2].

Neurovascular structures are also vulnerable both at the time of screw or wire insertion as well as during distraction [3,4].

Pain is the most common patient complaint during limb lengthening, and may be intense during the first postoperative days. Contraction of any muscle transfixed by a pin or wire is particularly painful and often requires medication with narcotics. Pain during the night and during therapy from stretching of muscles and nerves is most common [5] and can lead to loss of appetite [6] and even depression [7]. The continued presence of an awkward and painful external fixation device, combined with the mental stress and unknown outcome, can lead to detrimental psychological behaviours.

Hip and knee complications including dislocation and subluxation are often reported during and after limb lengthening. Joint stiffness occurs due to persistent contractures and increased pressure on the joint surface during lengthening [5]. Pain often inhibits functional loading and movement of the joints during the lengthening process, so loss of range of motion is also common.

During lengthening there is a tendency for the limb segments to gradually deviate due to the imbalance of muscle forces on different sides of the bone [5]. Since unilateral external distraction devices are eccentrically loaded, fixation pins can bend under high loads causing angulation of the bone as it lengthens. The occurrence of an angulation deformity may require reapplication of the external frame, premature cessation of lengthening, or reoperation following lengthening to correct the deformity.

Patients with limb-length discrepancy are also prone to re-fracture following limb lengthening [8]. Osteoporotic stress fractures are more likely to occur in regenerate bone, probably due to lack of weight bearing and the hypervascular response to distraction [5]. Adult patients often request frame removal due to prolonged exposure to pain, negative effects on lifestyle and employment considerations.

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associated with the presence of the external device, but this increases the risk of refracture. Virtually all of the aforementioned problems are associated with the external nature of current lengthening devices and the need to transfix soft tissues with pins or wires. It is therefore not surprising that numerous efforts have been made to reduce the time that the external device is required or to eliminate the need for external fixation altogether.

Early clinical experience with lengthening of the femur using both an external device and an intramedullary nail to eliminate the difficulty of controlling alignment of the bone fragments was first reported by Bost and Larsen [9]. They demonstrated the potential for the technique now known as 'lengthening over a nail' or the 'monorail method'. Recent refinements in both the science of callus distraction as well as intramedullary nailing have led to a rapid acceptance of this technique, which also allows early removal of the external device following distraction. Allowing the intramedullary nail to provide stability during the regeneration and consolidation phase of the lengthening process reduces pain and increases patient acceptance of the procedure [10–14]. This technique also retains all of the advantages of external devices during distraction, including the ability to externally monitor the progress of lengthening and stop or even back-up the lengthening process should it be necessary, but the complications and pain associated with external fixation continue to be problematic. In addition, the risks associated with pin track infections take on greater importance as the intramedullary nail has the potential to provide an ideal pathway for the spread of organisms throughout the intramedullary canal. Thus, there is the potential to turn a relatively minor pin track infection into a serious threat to the success of the entire lengthening procedure. In addition, complications including slow regenerate consolidation and fatigue failure of the intramedullary nail have been reported [15]. Although the monorail method does have some advantages over lengthening with an external device alone, it is still not the ideal lengthening method.

The goal of developing a completely internal lengthening device has been pursued since the concept of callus distraction has become widely accepted. Such a device would have to maintain mechanical alignment and stability of bone throughout the lengthening, and during consolidation of the regenerate. Further potential advantages include a lower risk of infection than external lengthening methods, reduced pain associated with fixation devices that pass through the soft tissues, and improved aesthetics and psychological well-being of the patient during and after lengthening by eliminating the bulky external frame and scars associated with the external pin sites.

Although fully implantable devices are being developed, there are added risks and problems associated with closed techniques. If a completely internal device fails mechanically, the consequences could be more severe than with an external device since the internal device must be removed surgically. Metallosis due to metallic wear or other consequences associated with the movement of an internal lengthening device could be a greater potential problem than with simple fixation pins or wires. Reliably controlling the rate and timing of lengthening and accurately measuring the amount of lengthening are also more difficult as an internal device cannot be readily observed without an X-ray.

Baumann and Harms [16] lengthened ten canine femurs using an implantable intramedullary extension rod that was driven by a flexible driver. Following insertion, the driver was passed through the soft tissues, into the intramedullary canal and engaged with the device. The percutaneous driver was left with part of the device protruding from the skin throughout the lengthening process. Once the desired length was reached, the driver was removed and the distracted bone allowed to consolidate. Distraction of as much as 10 cm was achieved. Although no infections were reported in this series, the flexible driver was certainly a potential pathway for infection and, since there have been no further reports of its use, we assume that the design has been abandoned or evolved into a more functional device.

Bliskonov [17] devised a technique whereby the patient was his own energy source for driving the lengthening device. Movement between the proximal femur and the iliac wing of the pelvis provided the driving force for the lengthening device. Forty-one such lengthening procedures were reported. Although Bliskonov stated that a desirable result was achieved in all but one patient, he also described numerous complications including severe pain and device failure.

Witt and Jaget [18] demonstrated the feasibility of using an electronically controlled implantable distracter in a sheep model. The design consisted of a power unit, a control unit and a two-part distraction plate. The linearly actuated plate attached to the lateral femur and was activated transcutaneously by a radio-controlled transmitter. Three femurs were successfully lengthened. The original Witt device proved to be too large to fit within the intramedullary canal. A more recent electronic linear actuator design has been described by Betz et al. [19]. Two versions of this design were evaluated clinically. Both versions consisted of a telescoping, elongating, cylindrical motorized actuator that was radio-controlled from outside of the body. One version was powered by a battery pack, the other by inductive current. Both required a receiver that was implanted subcutaneously and connected to the motorized actuator by an electronic cable. In the initial study, three femurs and one tibia were successfully lengthened. Baumgart et al. [20] further reported 12 additional successful femoral lengthening cases with a similar device. The electronically actuated design has tremendous potential since the amount, rate, and rhythm of lengthening can be precisely controlled. However, the reliability and regulatory acceptability of the device remains unproven.

Guichet et al. [21,22] designed a torsionally activated, mechanically driven, lengthening device that lengthened 0.07 mm each time it was ratcheted at least 20°. The device was implanted in sheep and proved to be capable of up to 63
mm of lengthening. After up to 2 years, the sheep femoral regenerate showed acceptable consolidation and trabecular remodelling. Further development and mechanical testing of this device suitable for human implantation was performed [23], demonstrating that it was technically possible to manufacture a purely mechanical intramedullary device with sufficient strength to perform adequately as both a lengthening device during the distraction process and as an intramedullary nail during the consolidation of the regenerate. Although this device is now available commercially outside the United States, at the time of writing we were unable to find any published results concerning clinical use of this device.

In 1989, having seen the potential advantages of an entirely intramedullary device for limb lengthening, the senior investigator (J.D.C.) initiated a programme to develop a reliable, cost-effective, mechanically activated intramedullary lengthening device with a non-invasive means of measuring the progress of lengthening without X-ray. An additional requirement was that the device be capable of lengthening as a result of physiologically tolerable movement by the patient.

We report the results of design, biomechanical and in vivo animal testing of the intramedullary skeletal kinetic distractor (ISKD) device. In addition, a clinical series was performed with the goal of determining whether the ISKD could be used in a diverse adult patient population with deformities resulting from bone loss due to trauma and/or infection. We report the results of implantation of the first 20 ISKD in adult patients.

2. Materials and methods

2.1. ISKD concept

The basic internal mechanism of the ISKD is shown in Fig. 1. The ISKD is designed to lengthen under physiologically tolerable movement. The ISKD lengthens as small oscillations between two telescoping sections are mechanically converted to one-way distraction. As the patient rotationally oscillates the limb either manually or during walking, the device gradually distracts. Since the device is designed to lengthen under rotational displacement as small as 3°, non-physiologic movement is not required to achieve distraction. However, rotational oscillations as large as 9° are allowed if greater rotation but fewer oscillations are desired. Thus, the rate of linear distraction depends on the frequency and intensity with which the patient oscillates the limb. The rate of distraction is monitored using an external hand-held sensing device.

2.2. ISKD design

All of the components of the ISKD have been manufactured from titanium alloy (Ti6Al4V) in order to maximize strength and biocompatibility of the device. The three main components of the ISKD are the telescoping sections, the drive mechanism and the length indication feedback mechanism. The proximal and distal sections are the only two components that have exposed surfaces. These sections have screw holes arranged in a typical pattern to attach the device to the bone segments. The drive mechanism consists of two one-way roller clutches and a threaded rod. The drive mechanism is designed to convert rotary oscillations of the proximal and distal sections relative to one another into linear distraction. The length indication mechanism consists of a magnet encased within the threaded rod that turns as the threaded rod turns. The rotation and relative position of the magnet can be detected by a hand-held external sensor and minicomputer that calculates the amount of lengthening that has occurred based on frequent non-invasive measurements of the magnet position.

2.2.1. Proximal and distal sections

The proximal section is the largest component of the ISKD. It is designed specifically for the bone to be lengthened. Consequently, the only difference between femoral, tibial and humeral ISKD is the design of the proximal section. The distal section telescopes inside the proximal section and has a diameter that is typically 15% smaller than that of the proximal section. Two parallel grooves 180° apart are machined into the distal section and mate with a removable key ring that fits over the distal end of the proximal section. This keyed mechanism allows the distal section to slide within the proximal section with limited rotational displacement. The distal section and proximal section are matched in length but are usually capable of a either 50 or 80 mm of distraction. Designs with proximal section diameters...
of 10.5, 12.5, 13.5 and 14.5 mm are currently used. Earlier designs including those used for mechanical testing described in this presentation were capable of 100 mm of distraction.

2.2.2. Drive mechanism
The drive mechanism consists of a threaded rod, a threaded area within the distal section and two one-way roller clutches oriented in opposite directions to one another. The distal clutch is constrained by the movement of the distal section while the proximal clutch is constrained by the movement of the proximal section. As the distal section turns the distal clutch clockwise (with respect to the proximal section and proximal clutch), the threaded rod rotates with the clutch and the ISKD does not distract. As the distal clutch rotates counter clockwise, the proximal clutch prevents the threaded rod from turning and the distal clutch rotates with respect to the threaded rod. As the distal section rotates (with respect to the threaded rod), the low-friction female ACME threads in its threaded area traverse the threaded rod, forcing the proximal and distal sections to distract. Since the clutches only contact the perimeter of the threaded rod, compressive loads not involving rotation distribute from the lower distal section to the upper proximal section without affecting the clutches. The clutches also act as bearings providing stability to the threaded rod.

2.2.3. Length indication feedback mechanism
A natural magnet is encased within the tip of the threaded rod. The magnet is shaped in such a way that the north and south poles of the magnet are oriented perpendicular to the length of the nail (Fig. 2). As the threaded rod rotates during distraction, the magnet also rotates changing the orientation of the poles of the magnet relative to the vertical axis of the nail. An external magnetic sensing device is placed on the skin, and the strength of the magnetic field as well as the pole of the magnet that is facing the sensor is detected. A minicomputer within the sensing device records the time of the measurement of the magnet that is facing the sensor is detected. A minicomputer within the sensing device records the time of the measurement of the magnet that is facing the sensor and compares that measurement with the last previous measurement. The computer then calculates the amount of rotation of the magnet in degrees and multiplies the angular change by the pitch of the threads of the threaded rod. The result of this calculation is the amount of distraction that has occurred since the last previous measurement. The result of each consecutive measurement is added to the sum of the previous measurements recorded by the device and is displayed for the patient on a LCD screen on the monitor. The patient adjusts his activity relative to the doctor’s instructions concerning the rate of lengthening desired. The minicomputer within the sensor can download the full series of individual measurements to a PC computer to periodically permit analysis of the lengthening process and to check patient compliance. The device also has an alarm that signals the patient to take a measurement at regular intervals.

2.2.4. Animal in vivo evaluation
A prototype ISKD device with a diameter of 10 mm was manufactured specifically for use in the in vivo animal study. All components were manufactured from Ti6Al4V to ASTM F136 specifications, cleaned per ASTM F86 and sterilized. The ISKD was implanted in the left femur of a 20-month-old female sheep. The sheep was anaesthetized, the insertion site was exposed and the femur reamed to 11 mm. A transverse osteotomy was performed using an open technique and the ISKD inserted. The ISKD was locked proximally and distally with 4.7 mm locking screws. Following a brief postoperative recovery period, the animal was allowed full weight-bearing in a 1500 square foot outdoor pen. Radiographs of the femur with the ISKD in place were taken three times per week for the first 3 weeks. By design, the area of the threaded rod between the clutches is readily visible under X-ray. Lengthening was measured by counting the number of threads (one thread=1.0 mm) visible between the clutches as lengthening progressed. After 27 mm of distraction, the sheep was returned to a sheep farm and allowed to roam freely in a 70 acre field with other sheep. After 106 days, the femur was harvested, the ISKD removed and the regenerate X-rayed and sectioned for analysis.

2.2.5. Mechanical evaluation
Three types of tests were performed: a traditional four-point bend test, a torsion to failure test, and a test to measure performance of the nail during rotational oscillations under increasing compressive load [24].

2.2.5.1. Four-point bend test. A static bend test per ASTM F383 was performed on four 12 mm diameter tibial ISKD. One of each ISKDs were tested at start length, 25 mm distraction, 50 mm distraction and 100 mm distraction. The four-point bend test jig was set with the top supports at 38 mm and the lower supports at 114 mm, with the ISKD positioned such that the junction between the proximal section and the telescoping distal section was positioned across the span between the supports. An MTS 812 servo-hydraulic test system operating at a stroke rate of 0.1 mm/s was used on...
all specimens. For comparison, a Ti6Al4V, solid 8 mm diameter tibial nail (DePuy ACE Medical Company, Warsaw, IN, USA) and a Ti6Al7Nb 9.5 mm diameter solid titanium bar were tested using the same technique.

2.2.5.2. Torsional load to failure test. Two 12 mm diameter ISKDs were tested using ASTM F383 standard practice for torsional testing of intramedullary rods. The test was performed in rotational control on a MTS 858 Bionix servo hydraulic test system at a rate of 1°/s. This evaluation was performed in only one animal. For the first 10 days following insertion of the ISKD, the animal

walked with a slight limp, gradually increasing the use of
the limb with the implant over time. By the second week,
no noticeable preferential treatment was given to any limb
and the animal walked normally. Although the sheep limb
was not manipulated or constrained during the lengthening
period, lengthening occurred at a relatively constant rate
of 1.3 mm/day. Table 1 shows distraction versus time for the
sheep limb lengthening.

The proximal clutch, which only had a press fit into the
proximal section of this first prototype, migrated out of po-
sition after 27 mm distraction. As a result, the ISKD stopped
lengthening prematurely. The ISKD was not able to collapse
less than the 27 mm obtained, but was able to piston tor-
sionally as much as 10°. Consequently, the ISKD was later
redesigned to incorporate a proximal clutch that was posi-
tively locked into the proximal section with threads. Despite
the device malfunction, the sheep continued to walk and
feed normally without giving any preferential treatment to
the limb.

Callus formation was evident on radiography at 19 days.
Anterior bridge of callus was evident at 35 days. At no
time did the sheep show signs of infection or unusual
pain. At 78 days, radiographic evaluation of both undisturbed
bone and the lengthened bone showed remodelling of the
femoral diaphysis. On day 106, the ISKD was surgically
removed from the sheep. During the procedure, the sheep
died of anaesthetic complications unrelated to removal of
the ISKD. The regenerate bone was found to be comparable
with undisturbed callus. There was evidence of minor black
staining similar to that seen on removal of titanium plates
and screws. Presumably, this staining was of Ti6Al4V
from the implant. There were no apparent reactive changes
or inflammation in the surrounding tissues.

3.2. Biomechanical evaluation

3.2.1. Four-point bend test
Results of the four-point bend tests for bending strength
are shown in Table 2 along with some reported bending
strengths for intramedullary rods from other authors. The
bending strength of the ISKD decreases significantly as the
ISKD expands. The bending strength of the ISKD when it
is expanded to maximum length, (100 mm) is similar to those observed for 8.0 mm solid Ti6Al4V
ELI commercially available tibial nail and 10 mm slotted
316LVM intramedullary nails [24,26].

The bending rigidity of the ISKD at the different expanded
lengths is compared with the bending rigidity of solid rods
tested in this study as well as slotted and cannulated 316LVM
rods tested by Russell et al. [26] in Table 3. Bending rigidity
is an indication of an implant’s inherent flexibility. Bending
rigidity of the ISKD was found to linearly decrease as the
ISKD expands. However, the rigidity of the 12 mm diameter
ISKD remained higher than either the 8.0 mm commercially
available Ti6Al4V tibial nail or the solid 9.5 mm titanium
alloy bar and compared favourably with cannulated and
slotted 316LVM implants tested by other authors [25].

3.2.2. Torsion to failure test
Table 4 shows that the ISKD underwent approximately
25° angular displacement beyond the normal free rotation
before torsional failure occurred. In addition, the torsion
versus rotational displacement curves show that an aver-
age torsion of 40 Nm was necessary to achieve torsional
failure for one load cycle. The failure mode of the two
specimens was identical. In both specimens, the key ring
that limits rotation failed by torsional shear rupture. How-
ever, the magnitude of the torsion required to rupture the
keyed mechanism and the angular displacement required

### Table 1

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### Table 2

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### Table 4

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to deform the ISKD prior to failure were both greater than those values expected to be required clinically. The torsion values of 35 and 45 Nm required for torsional failure of the ISKD are within the range of values obtained by other researchers for conventional 11mm diameter intramedullary nails which ranged from 15 to 147 Nm [21,22].

The torsional rigidity of the ISKD indicated by the slope of the torque versus displacement curves is 1.3 Nm/degree. This is also within the range of the reported torsional rigidity values obtained by others for 11 mm diameter intramedullary nails, which ranged from 1.1 to 4 Nm/degree [26,27].

3.2.3. Oscillatory movement under compressive load test
All of the ISKD devices tested continued to lengthen consistently at loads greater than 700 N, which has been reported to be the maximum load required to distract a limb clinically in experimental tests performed by other authors [28–31]. At higher loads up to 1400 N, more oscillations and torque were required to distract the ISKD. However, repetitive tests showed that these loads did not cause failure or degradation of the drive mechanism presumably because the drive mechanism was designed to be mechanically isolated from axial loads. Each step in the plots of compressive load versus oscillations required to distract the ISKD by 0.25 mm shown in Table 5 correlates to an increase in compressive force of 22.2 N (5 lbs). The number of oscillations required to distract the implant is shown on the horizontal scale.

Three ISKDs were tested in seven runs of the oscillatory movement under compressive load test. Table 6 combines the data from all of the tests and shows that the torque required to lengthen the ISKD increased proportionally as the applied compressive load increased. The solid lines on the right side of the graph show the range of the linear relationship between applied load and required torque as the ISKD lengthens. The solid lines on the left side of the graph show the relationship between applied load and the torque required to return to the neutral position without distraction. Due to the efficiency of the drive mechanism, even the highest loads of 1400 N (315 lbs) required a relatively low torque of 2.2 Nm (19.5 inch lbs) to distract the device.

3.3. Human clinical trial
The amount of lengthening required by the patients in the study ranged from 29 to 110 mm. The average lengthening for the series was 49 mm. The patient requiring 110 mm achieved lengthening using two tibial ISKDs implanted consecutively with a 5 month recovery time between the removal of the first ISKD and the insertion of the second ISKD. In this patient, the first lengthening achieved 60 mm while the second achieved 50 mm.

The average lengthening rate was 0.82 mm/day (range, 0.4–1.7 mm/day). The maximum time that an ISKD remained implanted was 327 days. This occurred in one patient who underwent two consecutive lengthening procedures. The second of the two nails was not exchanged for a standard intramedullary nail and consolidation was
permitted to occur with the ISKD in place. The minimum time that an ISKD was implanted was 27 days. This was in a patient who required only 29 mm of length in the tibia. The nail was removed immediately on achieving the required length and exchanged for a standard intramedullary nail during and after the lengthening. There were no refractures of the standard intramedullary nail.

There were two hardware failures. The first occurred in a 65-year-old diabetic female who had suffered an open pilon fracture of the right tibia, a fracture of the left tibial plateau, fracture of the distal femur, fracture of the right patella and a sternal contusion with a pulmonary embolus as the result of a motor vehicle accident. During rehabilitation, the patient suffered bone loss due to osteomyelitis of the distal tibia. The patient’s tibia was allowed to heal short with fusion of the resected bone ends. After resolution of the infection and fusion of the short tibia, an ISKD was inserted and lengthening initiated. Three months after completion of the required 70 mm lengthening, the patient was full weight bearing when the ISKD failed at the junction between the proximal and distal sections. The ISKD was removed and replaced with a standard intramedullary nail. The patient went on to heal without loss of length.

The second hardware failure occurred in an 18-year-old male who had suffered a motorcycle accident resulting in a supracondylar fracture of the left femur, a left femoral neck fracture, bilateral acetabular fracture, fracture of a left metatarsal, a severe degloving injury with devascularization of two-thirds of the left thigh, complete loss of the left gastrocnemius complex, and necrosis of the left foot resulting in a forefoot amputation due to gangrene. The patient also had suffered multiple deep wound infections and osteomyelitis of the femur. Following treatment of the numerous injuries, the residual severe bone loss of 8 cm in the left femur was addressed with an ISKD. A tibial ISKD was inserted retrograde through the knee due to the presence of an implant in the proximal femur. Lengthening of 7.1 cm was achieved with the patient fully weight bearing. The patient reported that while wrestling with his brother he fell down the front steps of his home. The broken ISKD was removed and replaced with a retrograde femoral nail. The patient went on to heal without loss of length and was able to walk without assistance shortly following insertion of the standard intramedullary nail.

Following the two nail breakages, a design change was made to the ISKD to increase the wall thickness of the proximal section and to decrease the maximum excursion of the device from 100 to 80 mm. No further implant failures occurred following these design changes.

All of the patients showed excellent regenerate formation during and after the lengthening. There were no refractures and most patients returned to full weight bearing shortly after exchange of the ISKD for a standard intramedullary nail.

**Table 7**

<table>
<thead>
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<th>Activity</th>
<th>Work</th>
<th>Walk</th>
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<td>94%</td>
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<td><strong>DURING</strong></td>
<td>34%</td>
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<td>100%</td>
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<tr>
<td><strong>AFTER</strong></td>
<td>99%</td>
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Table 7 shows the activity levels described by patients before, during and after lengthening using the ISKD both during and at the end of their treatment.

4. **Discussion**

Despite advances that have been made in the surgical correction of limb-length inequalities, complications continue to plague patients undergoing these procedures. A review of clinical studies using various limb-lengthening techniques shows that complications are prevalent with all methods [32–35]. Pin track infections and pain associated with fixation pins and wires are the most common source of complications. The source of both of these complications could be eliminated with the development of a reliable intramedullary distraction device.

The ISKD is one of a handful of experimental devices being developed for this purpose. The primary advantage of the ISKD appears to be that it is a relatively simple, completely mechanical device that does not require hydraulics or implanted electronics. It is also activated by small oscillations that appear to be well tolerated physiologically. The primary limitations of the ISKD are that it is not reversible, it is a dynamic device with articulating metal parts that...
could produce wear debris, and that the proximal and distal sections must be free to oscillate relative to one another, which places some limits on the ultimate biomechanical strength and durability of the device.

Because the rate of distraction of the ISKD is determined by the patient’s activity level and ability to tolerate the torsional movement required to drive the device the potential exists to lengthen either too slowly or to rapidly to allow effective osteogenic distraction. Consequently, patient compliance and effective monitoring of the distraction process are essential. Effective control of lengthening was achieved in this series without the aid of the Magnetic sensor device in 8/18 patients. Although it was reassuring to find that effective distraction control could be achieved without constant patient monitoring, the advent of the magnetic sensor device permitted both more controlled distraction and a greater degree of confidence in the function and effectiveness of the device for both the patient and the clinician. Ultimately, the development of a means for permitting intermittent locking of the ISKD device as well as a means for reversing the direction of telescoping of the ISKD remains as a goal for future development.

During the development process, Ti6Al4V ELI was selected as the most optimal implant alloy for manufacture of the ISKD. This alloy has a successful clinical history in orthopaedic implant applications, and wear debris of titanium alloys appear to be better tolerated by the body than alternative implantable iron or cobalt based alloys [36]. However, the wear properties of Ti6Al4V are not ideal and the minor black tissue staining as observed in the excised regenerate of the animal test subject, although appearing to be benign in nature, is of some concern. The ISKD material may change as newer alloys with better wear characteristics, such as beta-titanium alloys, are verified and approved for human implantation.

The in vivo study on one sheep demonstrated that the drive mechanism of the ISKD will function in the physiological environment and that, in the sheep, bony tissue regenerated under the mechanical conditions required for distraction of the ISKD. The biomechanical tests showed that it is feasible to design and use a small diameter, torsionally activated linear distractor to generate axial loads comparable with the loads generated by external distractors during limb lengthening in human subjects. The static mechanical tests showed that the bending and torsional strength properties of the ISKD are within the range of accepted intramedullary nails that experience similar loads. The dynamic compression tests showed that, given sufficient rotational movement, the ISKD will continue to lengthen under distraction loads greater than those measured clinically. Finally, the repetitive dynamic compression tests showed that even when heavily loaded the ISKD continued to lengthen without undue wear or damage to the drive mechanism, indicating that the reliability of the device was inherently good.

All of the biomechanical tests were conducted under concentric axial loading conditions in the absence of a biological environment. In actual use, the ISKD must withstand the added mechanical stresses of eccentric loading and cyclic loading during weight bearing as well as exposure to a corrosive biological environment. The result of the human clinical trial in which there were no failures of the device to lengthen demonstrates that the drive mechanism is both durable and efficient in its intended application. The occurrence of two mechanical failures of the proximal section at the junction of the proximal and distal sections show that, despite the positive biomechanical testing results, a further increase in strength was warranted. Increasing the wall thickness of the proximal section by 0.5 mm in all diameters of the ISKD as well as decreasing the amount of excursion allowed from 100 to 80 mm was calculated to provide a strength increase of up to 30%. Although there were no further breakages of the ISKD following the design change, further biomechanical testing of the new configuration of the ISKD is currently underway to confirm the effectiveness of the change.

The preliminary results of the human clinical trial indicate that the ISKD is capable of lengthening both the tibia and the femur in a diverse group of adult patients that had suffered bone loss due to trauma, infection and other causes. The level of patient acceptance of the device was encouraging, particularly among those patients that had previously been treated with external fixators either for acute fracture fixation or for previous lengthening procedures. All of the patients in this series reported that they were very satisfied with treatment with the ISKD and would prefer treatment with the ISKD to treatment with an external device. The low requirement for narcotic treatment of pain is probably attributable to the fact that external fixation pins did not penetrate the soft tissues during the lengthening process. In addition, lower pain levels may also have resulted in a decreased urge by patients to hurry the lengthening process in an effort to speed removal of the lengthening device. The ability to precisely monitor the lengthening process and in some cases slow down the lengthening dramatically to match the patient’s ability to tolerate the pain associated with soft tissue stretching as well as their ability to form regenerate appears to be a major potential advantage of the ISKD.

In 15/18 patients, lengthening with the ISKD was preceded by a surgical shortening of the limb. Recently, there have been several reports of success with this technique for treatment of bone loss due to infection as well as acute trauma [10,37,38]. In general, this technique has been shown to be a clinically effective and cost-effective method for treatment of both simple and severe bone loss resulting from trauma and infection with high patient acceptance. With the advent of reliable intramedullary lengthening devices, this method of treating bony defects may become more widely accepted in the future. The reliability of the regenerate that was observed in this series of patients, many of whom had suffered severe trauma and infection, was extremely encouraging. In no case was there an indication of delayed regenerate formation or consolidation. There were no refractures and no recurrence of previous infection after
the lengthening. There were no non-unions or malunions, indicating that regenerate quality was good and that the ISKD maintained adequate stability during the lengthening process to overcome asymmetric muscle forces acting on the regenerate.

In this series, the ISKD was usually removed at the end of the lengthening process and exchanged for a standard intramedullary nail. The decision to perform the exchange was motivated by the desire to assure the least risk of device failure to the patient, to speed the patients’ return to full mobility and work activities, and to permit immediate study of the biomechanical characteristics of the retrieved devices. The fact that the ISKD was capable of providing adequate stability during the post-lengthening consolidation phase in two patients provides an early indication that the need for exchange of the ISKD for a standard intramedullary nail may be unnecessary. The results of new static biomechanical testing of the static and fatigue strength characteristics of the latest ISKD design may help to resolve this question.

We conclude that the results of this study demonstrate that the goal of developing a reliable, mechanically activated intramedullary, lengthening device with a non-invasive means of measuring the progress of lengthening without X-ray is achievable. In addition, the ISKD device has been shown to be capable of lengthening without the need for an external device through physiologically tolerable movement in both animal and human subjects. Finally, early results in 18 patients indicate that the ISKD may be a useful and effective alternative to external fixators and monorail techniques in treating a diverse group of adult patients with moderate to severe bone loss due to trauma and infection with a high degree of patient acceptance and reliability.

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References