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SYSTEM AND METHOD FOR ALTERING ROTATIONAL ALIGNMENT OF BONE SECTIONS

Abstract

The disclosure describes systems and methods for altering bone sections in a patient. In one embodiment, a system may include an intramedullary implant including: a housing configured to be secured to a first section of bone, where the housing may include one or more shaft engaging grooves axially extending along an inner surface thereof; a distraction shaft configured to be secured to a second section of bone, where the distraction shaft may include one or more grooves axially extending along an inner surface thereof. The system may further include an actuator disposed within the housing and operably coupled to the distraction shaft, and in response to rotation of the actuator, the one or more grooves of the distraction shaft may engage with the one or more shaft engaging grooves of the housing, causing axial displacement of the distraction shaft relative to the housing.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation of U.S. patent application Ser. No. 17/810,469, filed on Jul. 1, 2022 and published as U.S. 2022-0346846, which is a continuation of U.S. patent application Ser. No. 16/841,925, filed on Apr. 7, 2020 and now U.S. Pat. No. 11,406,432, which is a continuation of U.S. patent application Ser. No. 15/989,672, filed on May 25, 2018 and now U.S. Pat. No. 10,646,262, which is a continuation of U.S. patent application Ser. No. 15/207,763, filed on Jul. 12, 2016 and now U.S. Pat. No. 10,105,167, which is a continuation of U.S. patent application Ser. No. 14/146,336, filed on Jan. 2, 2014 and now U.S. Pat. No. 9,393,117, which is a continuation of U.S. patent application Ser. No. 13/370,966, filed Feb. 10, 2012 and now U.S. Pat. No. 8,715,282, which claims the benefit of priority under 35 U.S.C. § 119 (c) of U.S. Provisional Pat. Appl. No. 61/442,658, filed Feb. 14, 2011 and U.S. Provisional Pat. Appl. No. 61/472,055, filed Apr. 5, 2011. All of the above applications are incorporated by reference herein and are to be considered a part of this specification. Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.

FIELD
[0002] The present disclosure generally relates to medical devices for treating conditions involving the skeletal system and in particular bone fracture applications.
BACKGROUND
[0003] Distraction osteogenesis, also known as distraction callotasis and osteodistraction has been used successfully to lengthen long bones of the body. Typically, the bone, if not already fractured, is purposely fractured by means of a corticotomy, and the two segments of bone are gradually distracted apart, which allows new bone to form in the gap. If the distraction rate is too high, there is a risk of nonunion, if the rate is too low, there is a risk that the two segments will completely fuse to each other before the distraction period is complete. When the desired length of the bone is achieved using this process, the bone is allowed to consolidate. Distraction osteogenesis

applications are mainly focused on the growth of the femur or tibia, but may also include the humerus, the jaw bone (micrognathia), or other bones. The reasons for lengthening or growing bones are multifold, the applications including, but not limited to, post osteosarcoma bone cancer; cosmetic lengthening (both legs-femur and/or tibia) in short stature or dwarfism/achondroplasia; lengthening of one limb to match the other (congenital, post-trauma, post-skeletal disorder, prosthetic knee joint), non-unions.

[0004] Distraction osteogenesis using external fixators has been done for many years, but the external fixator can be unwieldy for the patient. It can also be painful, and the patient is subject to the risk of pin track infections, joint stiffness, loss of appetite, depression, cartilage damage and other side effects. Having the external fixator in place also delays the beginning of rehabilitation.

[0005] In response to the shortcomings of external fixator distraction, intramedullary distraction nails have been surgically implanted which are contained entirely within the bone. Some are automatically lengthened via repeated rotation of the patient's limb. This can sometimes be painful to the patient, and can often proceed in an uncontrolled fashion. This therefore makes it difficult to follow the strict daily or weekly lengthening regime that avoids nonunion (if too fast) or early consolidation (if too slow). Lower limb distraction rates are on the order of one millimeter per day. Other intramedullary nails have been developed which have an implanted motor and are remotely controlled. The motorized intramedullary nails have an antenna which needs to be implanted subcutaneously, thus complicating the surgical procedure, and making it more invasive. These devices are therefore designed to be lengthened in a controlled manner, but due to their complexity, may not be manufacturable as an affordable product. Others have proposed intramedullary distractors containing and implanted magnet, which allows the distraction to be driven electromagnetically by an external stator (i.e., a large electromagnet). Because of the complexity and size of the external stator, this technology has not been reduced to a simple and cost-effective device that can be taken home, to allow patients to do daily lengthenings.

[0006] Fracture of long bones is often treated with trauma nails. These implants are placed intramedullary to hold the bones together. Often in cases of complex fracture having an irregular break geometry or having multiple bone fragments, it is difficult to secure the nail so that the bone is held at the correct length. Other times it is desired to hold the bone in a manner that apply compression. Every year in the United States, more than 90,000 tibia and femur shaft fractures are defined as complex. Many of these fractures are treated with trauma nails with varying results. Some of the possible complications from the treatment of these complex fractures include: infection, vascular injuries, non-union, neural injury, associated injuries to other bone or joint locations and heterotopic ossification. Also included in the possible complications is the possibility of unmatched bilateral bone lengths.

SUMMARY

[0007] In one embodiment, a rotational correction system includes an implant having a first section and a second section, the implant having a rotatable permanent magnet disposed in a housing of the first section, the rotatable permanent magnet mechanically connected to a nut operatively coupled to the second section of the implant. A keyed portion is interposed between the nut and one or more non-linear grooves disposed on an inner surface of the housing. The system includes an external adjustment device comprising at least one rotatable magnet configured to rotate the rotatable permanent magnet of the implant, wherein rotation of the rotatable permanent magnet of the implant in a first direction effectuates a clockwise change in the rotational orientation of the first section relative to the second section and wherein rotation of the rotatable permanent magnet of the implant in a second direction effectuates a counter-clockwise change in the rotational orientation of the first section relative to the second section.

[0008] In another embodiment, a rotational correction system includes an implant configured for implantation within a patient, the implant comprising a first section and a second section, the implant having a rotatable permanent magnet disposed in a housing of the first section, the

rotatable permanent magnet mechanically connected to nut via a lead screw, the nut operatively coupled to the second section of the implant. A keyed portion is interposed between the nut and one or more non-linear grooves disposed on an inner surface of the housing. The system includes a permanent magnet configured for movement external to the patient, wherein movement of the permanent magnet rotates the rotatable permanent magnet of the implant, thereby modifying the rotational orientation of the first section relative to the second section.

[0009] In still another embodiment, a method for changing the rotational orientation of two sections of a long bone of a subject includes forming an entry point in the skin of the subject in proximity to the long bone and at least partially clearing a canal through a center of the long bone. An implant having a first section and a second section is inserted into the canal and the first and second sections are secured to different portions of the long bone, the implant having a rotatable permanent magnet disposed in a housing of the first section, the rotatable permanent magnet mechanically connected to a nut operatively coupled to the second section of the implant, the nut being keyed with respect to non-linear grooves disposed on an inner surface of the housing. An external adjustment device is placed in proximity to the subject's skin, the external adjustment device comprising at least one rotatable magnet and the external adjustment device is operated so that a magnetic field of the at least one rotatable magnet causes the rotatable permanent magnet of the implant to rotate and thereby effectuate a change in the rotational orientation of the first section relative to the second section.

[0010] In another embodiment, an intramedullary implant includes: a housing configured to be secured to a first section of bone, the housing including one or more shaft engaging grooves axially extending along an inner surface thereof; a distraction shaft configured to be secured to a second section of bone, the distraction shaft including one or more grooves axially extending along an inner surface thereof; and an actuator disposed within the housing and operably coupled to the distraction shaft, where, in response to rotation of the actuator, the one or more grooves of the distraction shaft engage with the one or more shaft engaging grooves of the housing, causing axial displacement of the distraction shaft relative to the housing.

[0011] In another embodiment, an intramedullary implant includes: a housing configured to be secured to a first section of bone, the housing including one or more shaft engaging grooves axially extending along an inner surface thereof; a distraction shaft configured to be secured to a second section of bone, the distraction shaft including one or more grooves axially extending along an inner surface thereof; and one or more ball bearings interposed between the one or more shaft engaging grooves of the housing and the one or more grooves of the distraction shaft, where the one or more ball bearings are configured to rotationally lock the one or more grooves of the distraction shaft relative to the one or more shaft engaging grooves of the housing.

[0012] In yet another embodiment, a method of adjusting the first section of the bone with an intramedullary implant is provided. The intramedullary implant includes: a housing configured to be secured to a first section of bone, the housing including one or more shaft engaging grooves axially extending along an inner surface thereof; a distraction shaft configured to be secured to a second section of bone, the distraction shaft including one or more grooves axially extending along an inner surface thereof; and an actuator disposed within the housing and operably coupled to the distraction shaft, where, in response to rotation of the actuator, the one or more grooves of the distraction shaft engage with the one or more shaft engaging grooves of the housing, causing axial displacement of the distraction shaft relative to the housing.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. **1** illustrates side view of an intramedullary lengthening device in place within a bone

according to one embodiment.
[0014] FIG. **2** illustrates a side view of the intramedullary lengthening device of FIG. **1**.
[0015] FIG. **3**A illustrates a cross-sectional view of the intramedullary lengthening device of FIGS. **1** and **2** taken along the line of **3**A-**3**A of FIG. **2**.
[0016] FIG. **3**B illustrates a detailed view of the intramedullary lengthening device of FIG. **3**A from the area of circle **3**B.
[0017] FIG. **3**C illustrates a cross-sectional view of the intramedullary lengthening device of FIGS. **1** and **2** taken along the line **3**C in FIG. **2**.
[0018] FIG. **4**A illustrates a view of several of the internal components of the intramedullary lengthening device of the prior FIGS.
[0019] FIG. **4**B illustrates a lip seal configured for use in the intramedullary lengthening device of the prior FIGS.
[0020] FIG. **5** illustrates a detailed view of several internal components of the drive mechanism of the intramedullary lengthening device of the prior figures.
[0021] FIG. **6** illustrates a perspective view of an external adjustment device.
[0022] FIG. **7** illustrates an exploded view of the magnetic handpiece of the external adjustment device of FIG. **6**.
[0023] FIG. **8** illustrates a cross-sectional representation of a prior art electromagnetic external device being positioned around a patient's lower thigh.
[0024] FIG. **9** illustrates a cross-sectional representation of the external adjustment device handpiece of FIGS. **6** and **7** being positioned on a patient's lower thigh.
[0025] FIG. **10** illustrates a sterilizable kit for use with a modular intramedullary lengthening device.
[0026] FIG. **11** illustrates a modular intramedullary lengthening device according to one embodiment.
[0027] FIG. **12** illustrates one end of the actuator of the intramedullary lengthening device of FIG. **11**.
[0028] FIG. **13** illustrates an extension rod of the modular intramedullary lengthening device.
[0029] FIG. **14** illustrates a second view of the extension rod of FIG. **13**.
[0030] FIG. **15** illustrates a proximal drill guide for insertion and attachment of the modular intramedullary lengthening device.
[0031] FIG. **16** illustrates a removal tool for removal of the modular intramedullary lengthening device.
[0032] FIG. **17** illustrates a torque limiting driver for attaching the extension rod to the actuator of the modular intramedullary device.
[0033] FIG. **18** illustrates a section of the actuator of the modular intramedullary lengthening device.
[0034] FIG. **19** illustrates a gap (G) between a magnetic handpiece and an intramedullary lengthening device.
[0035] FIG. **20** illustrates a locking screw driver for use with the intramedullary lengthening device.
[0036] FIG. **21**A illustrates a locking screw for use with the intramedullary lengthening device.
[0037] FIG. **21**B illustrates the locking screw of FIG. **21**A taken along line **21**B-**21**B of FIG. **21**A.
[0038] FIG. **22** illustrates a side view of a variable length nail.
[0039] FIG. **23** illustrates a cross-section of the variable length nail of FIG. **22** taken along line **23**-**23**′.
[0040] FIG. **24**A through **24**F illustrate the several steps of the implantation, compression and distraction of a variable length nail implanted in a fractured femur.
[0041] FIG. **24**G illustrates cyclic micromovement being applied by a variable length nail to a fractured femur.

[0042] FIG. **24**H illustrates a non-movement period between applications of the cyclic micromovement of FIG. **24**G.
[0043] FIG. **25** illustrates an intramedullary rotational correction device according to one embodiment.
[0044] FIG. **26** illustrates a partial sectional view of the rotational correction device.
[0045] FIG. **27** illustrates a longitudinal section of FIG. **26**, taken along the line **27**-**27**′.
[0046] FIG. **28** illustrates a lockable and un-lockable rotational implant according to another embodiment.
[0047] FIG. **29** illustrates a detailed view of region A of FIG. **28**.
[0048] FIG. **30** illustrates a perspective view of an alternative interface between a rotary nut and a housing of an intramedullary rotational correction device like that illustrated in FIGS. **25**-**27**.
[0049] FIG. **31** illustrates a perspective view of the interface after axial and rotational translation of the rotary nut with respect to the housing.
[0050] FIG. **32** illustrates a perspective view of the rotary nut with the housing removed for illustration purposes.

DETAILED DESCRIPTION

[0051] FIG. **1** illustrates the side view of an intramedullary lengthening device **110** which has been placed through a hole or bore **108** contained within a bone **100**. The hole or bore **108** may be made by drilling, reaming and the like and may extend through both cortical bone (at the end) and through cancellous (spongy) bone. The intramedullary lengthening device **110** illustrated in FIG. **1** includes a housing **112** and a distraction shaft **114**. In order to grow or lengthen the bone **100**, the bone **100** either has a pre-existing separation **106** or is purposely cut or broken to create this separation **106**, dividing the bone into a first section **102** and a second section **104**. The cut may be done prior to inserting and securing the intramedullary lengthening device **110**, or may be done after the device **110** is inserted, for example by use of a flexible Gigli saw. The distraction shaft **114** of the intramedullary lengthening device **110** is attached to the first section **102** using one or more attachment fasteners **118** such as screws. Fasteners **118** other than screws known to those skilled in the art may also be used to secure the distraction shaft **114** to the first section **102** of the bone **100**. The housing **112** of the intramedullary lengthening device **110** is secured to the second section **104** of bone **100** using one or more attachment fasteners **116** such as screws. Again, fasteners **116** other than screws may be used to secure the housing **112** to the second section **104** of bone **100**.
[0052] Over the treatment period, the bone **100** is regularly distracted, creating a new separation **106**, into which osteogenesis can occur. Regularly distracted is meant to indicate that distraction occurs on a regular or periodic basis which may be on the order of every day or every few days. An exemplary distraction rate is one millimeter per day although other distraction rates may be employed. That is to say, a typical distraction regimen may include a daily increase in the length of the intramedullary lengthening device **110** by about one millimeter. This may be done, for example, by four lengthening periods per day, each having 0.25 mm of lengthening. The intramedullary lengthening device **110**, as disclosed in more detail below, has a magnetic drive system, which allows the distraction shaft **114** to be telescopically extended from the housing **112**, thus forcing the first section **102** and the second section **104** of the bone **100** apart from one another. As the distraction process is performed, a portion of the housing **112** is able to slide within the hole or bore **108** of the first section **102** if the housing **112** is located within a displacement section **120** as illustrated in FIG. **1**. Alternatively, if the housing **112** is completely contained in second section **104** then there is no sliding of the housing **112** relative to the hole or bore **108**. The orientation of the intramedullary lengthening device **110** within the bone **100** may be opposite of that shown in FIG. **1**. For example, the distraction shaft **114** may be coupled to the second section **104** of the bone **100** and the housing **112** may be coupled to the first section **102** of the bone **100**. For example, the intramedullary lengthening device **110** may be placed retrograde, from a hole or bore starting at the distal end of the bone **100**.

[0053] Turning to FIGS. **2** through **5**, the intramedullary lengthening device **110** has one or more apertures **122** in the distraction shaft **114** through which the fasteners **118** may be placed. Likewise, the housing **112** is attached to or otherwise integrated with an end cap **130** which has one or more apertures **124** through which the fasteners **116** may be placed. The housing **112** of the intramedullary lengthening device **110** includes a magnet housing **128** and a splined housing **126**. These housings **126**, **128** may be attached to each other by means of welding, adhesive bonding or other joining techniques. The magnet housing **128** is sealably closed at one end (the end opposite the interface with the splined housing **126**) by the attachment of the end cap **130**. The end cap **130** may be attached to the magnet housing **128** by means of welding, adhesive bonding or other joining techniques. In use, the distraction shaft **114** is driven from the housing **112** by means of a lead screw **136** which turns inside a nut **140** that is secured to an inner surface adjacent to a cavity **137** of the distraction shaft **114**. The lead screw **136** is mechanically coupled, in an indirect manner, to cylindrical permanent magnet **134** contained within the magnet housing **128**. As explained in more detail below, rotation of the cylindrical permanent magnet **134**, which is magnetically driven by an external adjustment device **180** as illustrated in FIG. **6**, effectuates rotation of the lead screw **136**. Rotation of the lead screw **136** then translates into axial movement of the distraction shaft **114** relative to the housing **128**.

[0054] Cylindrical magnet **134** is fixedly contained within a magnet casing **158** using, for example, an adhesive such as an epoxy. The magnet casing **158** and cylindrical magnet **134** contained therein rotate relative to the stationary magnet housing **128**. The cylindrical magnet **134** may be a rare earth magnet such as Nd—Fe—B and may be coated with Parylene or other protective coatings in addition to being protected within the magnet casing **158**, for example hermetically potted with epoxy. The magnet casing **158** contains an axle **160** on one end thereof which attaches to the interior of a radial bearing **132**. The outer diameter of the radial bearing **132** is secured to the interior of the end cap **130**. This arrangement allows the cylindrical magnet **134** to rotate with minimal torsional resistance. At its other, opposing end, the magnet housing **158** includes an axle **161**, which is mechanically coupled to a first planetary gear set **154**. The axle **161** includes the sun gear of the first planetary gear set **154**, the sun gear turning the planetary gears of the first planetary gear set **154**. The first planetary gear set **154** serves to reduce the rotational speed and increase the resultant torque delivery from the cylindrical magnet **134** to the lead screw **136**. A second planetary gear set **156** is also illustrated mechanically interposed between the first planetary gear set **154** and the lead screw **136**, for further speed reduction and torque augmentation. The number of planetary gear sets and/or the number of teeth in the gears may be adjusted, in order to achieve the desired speed and torque delivery. For example, a lead screw **136** with eighty (80) threads per inch attached to two planetary gear sets of 4:1 gear ratio each inside a 9 mm device with magnet location in the distal femur can achieve at least 100 lb. of distraction force at a greater than average distance or gap from the external device (FIG. **9** or FIG. **19**). The planetary gear sets **154**, **156** output to a planetary gear output shaft **144**. The planetary gear output shaft **144** extends through a thrust bearing **138** and is secured (by welding and the like) to a lead screw coupling cap **146**. The lead screw **136** is secured to the lead screw coupling cap **146** by a locking pin **142**, which extends transversely through a hole in the lead screw **136** and corresponding holes in the lead screw coupling cap **146**. A cylindrical locking pin retainer **148** surrounds the locking pin **142**, holding this assembly together. Attaching the lead screw **136** to the rest of the magnet/gear assembly in this manner, assures that the design is not over-constrained, and thus that the lead screw **136** does not gall with the nut **140**. In addition, biocompatible grease, for example KRYTOX, may be used on the moving parts (lead screw, nut, bearings, housing, and distraction shaft) in order to minimize frictional losses. The lead screw **136** is able to freely rotate within a cavity **137** of the distraction shaft **114** and thus only needs to engage with the short length of the nut **140**. This feature advantageously minimizes frictional losses.

[0055] The thrust bearing **138** serves to protect the magnet/gear assembly of the drive from any

significant compressive or tensile stresses. The thrust bearing **138** consists of two separate races with ball bearings between the two races. When there is a compressive force on the device, for example, when distracting a bone **100**, and thus resisting the tensile strength of the soft tissues, the thrust bearing **138** abuts against a magnet housing abutment or lip **150** located in the magnet housing **128**. Additionally, though the device is not typically intended for pulling bones together, there may be some applications where this is desired. For example, in certain compressive nail applications it is the goal to hold two fractured sections of a bone together. Because the bone **100** may have fractured in a non-uniform or shattered pattern, it may be difficult to determine the desired length of the nail until after it is implanted and fully attached. In these situations, it can be easy to misjudge the length, and so a gap may exist between the separate sections or fragments of bone **100**. By placing a slightly extended intramedullary device **110** and securing it, the device **110** may be retracted magnetically, after it has been secured within the bone fragments, so that it applies the desired compression between the two fragments. In these compressive nail applications, there would be tensile force on the device **110** and the thrust bearing **138** would abut against a splined housing abutment or lip **152**. In both situations, the thrust bearing **138** and a rigid portion of one of the housing sections (e.g., lips **150**, **152**) take the large stresses, not the magnet/gear assembly of the drive system. In particular, the thrust bearing **138** is sandwiched between the abutment or lip **150** and the abutment or lip **152**.

[0056] Turning specifically to FIGS. **4**A and **5**, the housing components have been removed to reveal various internal features, including a lip seal flange **168** and linear ball cage **162** that allows sliding of the distraction shaft **114** within the housing **112**, and which also keeps the distraction shaft **114** from being able to rotate within the housing **112**. This allows full stability of the bone **100**. Distraction shaft **114** contains several axial grooves **166** as best seen in FIG. **3**C and FIG. **4**A. The grooves **166** have semi-circular indentation cross-sections which allow several balls **164** to roll within them. The balls **164** are trapped within the linear ball cage **162**. The splined housing **126** which fits over the balls **164** and linear ball cage **162** has axial grooves **163** (FIG. **3**C) along its inner diameter surface that are similar to the axial grooves **166** of the distraction shaft **114**. In this regard, the balls **164** and the ball cage **162** are interposed between the distraction shaft **114** and the splined housing **126**. Therefore, the balls **164** are held in place by the linear ball cage **162**, and mechanically lock the respective grooves to each other, thus impeding rotation of the distraction shaft **114** within the housing **112**. However, the balls **164** are able to roll within the linear ball cage **162**, thus allowing axial displacement of the distraction shaft **114** in relation to the splined housing **126** of the housing **112** with very low friction. The lip seal flange **168** as seen in FIG. **4**A contains a lip seal **169** as seen in FIG. **4**B which allows a sliding seal between the distraction shaft **114** and the splined housing **126**, thus protecting the inner contents of the entire assembly from the external (e.g., body) environment. The lip seal **169** includes a base portion **173**, which seals against the inner diameter of the lip seal flange **168** (and thus the splined housing **126** which is attached to the lip seal flange **168**). The lip seal **169** also includes protrusions **171** which slidingly seal against the axial grooves **166** of the distraction shaft **114**. Inner surface **175** of the lip seal **169** slidingly seals against the overall outer diameter of the distraction shaft **114**. It should also be noted that the lip seal **169** may be made from silicone, EPDM or other rubber materials, and may be coated with silicone oil, to aid in lubricity. Also, the balls, grooves and ball cage may be coated with silicone oil or a liquid perfluorinated polyether such as KRYTOX to aid in lubricity. FIG. **5** shows a portion of the magnet casing **158** removed so that the South pole **170** and North pole **172** of the cylindrical magnet **134** may be illustrated.

[0057] FIG. **6** illustrates an external adjustment device **180** which is used to non-invasively distract the intramedullary lengthening device **110** by means of a magnetic coupling which transmits torque. The external adjustment device **180** comprises a magnetic handpiece **178**, a control box **176** and a power supply **174**. The control box **176** includes a control panel **182** having one or more controls (buttons, switches or tactile, motion, audio or light sensors) and a display **184**. The display

184 may be visual, auditory, tactile, the like or some combination of the aforementioned features. The external adjustment device **180** may contain software which allows programming by the physician. For example, the physician may desire that the patient take home the external adjustment device **180** in order that the patient or member of the patient's family or friends make daily distractions of the intramedullary lengthening device **110** implanted in the patient. However, the physician is able to keep the person operating the external adjustment device **180** from over distracting the patient by programming this into the control box **176**. For example, the physician may pre-program the control **176** box so that only one (1) mm of distraction is allowed per day. The physician may additionally pre-program the control box **176** so that no more than 0.5 mm may be distracted during any two hour period, or that no more than 0.25 mm may be retracted during a five minute period. Settings such as these may serve to assure that the patient would not be capable of causing severe damage to the bone or tissue, nor disrupt the lengthening process.

[0058] Preferably, such instructions or limits may be pre-programmed by the physician or even the manufacturer in a secure fashion such that user cannot alter the pre-programmed setting(s). For example, a security code may be used to pre-program and change the daily distraction limit (or other parameters). In this example, the person operating the external adjustment device **180** will not be able to distract more than one (1) mm in a day (or more than two mm in a day), and will not have the security code to be able to change this function of the external adjustment device **180**. This serves as a useful lockout feature to prevent accidental over-extension of the intramedullary lengthening device **110**. The safety feature may monitor, for example, rotational movement of magnets **186** (FIG. **7**) of the external adjustment device **180**, described in more detail below, or the safety feature may monitor rotation of the cylindrical magnet **134** in the intramedullary lengthening device **110**, via non-invasive sensing means.

[0059] FIG. **7** shows an exploded view of the magnetic handpiece **178** of the external adjustment device **180**, in order to elucidate the manner that the magnets **186** of the external adjustment device **180** serve to cause the cylindrical magnet **134** of the intramedullary lengthening device **110** to turn. As seen in FIG. **7**, there are two (2) permanent magnets **186** that have a cylindrical shape. The magnets **186** are made from rare earth magnets. The magnets **186** may have the same radial two pole configuration as the cylindrical magnet **134** seen in FIG. **5**. The magnets **186** are bonded or otherwise secured within magnetic cups **187**. The magnetic cups **187** include a shaft **198** which is attached to a first magnet gear **212** and a second magnet gear **214**, respectively. The orientation of the poles of each the two magnets **186** are maintained in relation to each other by means of the gearing system (by use of center gear **210**, which meshes with both first magnet gear **212** and second magnet gear **214**). For example, it may be desired that the south pole of one of the magnets **186** is facing up whenever the south pole of the other magnet **186** is facing down. This arrangement, for example, maximizes the torque that can be placed on the cylindrical magnet **134** of the intramedullary lengthening device **110**.

[0060] The components of the magnetic handpiece **178** are held together between a magnet plate **190** and a front plate **192**. Most of the components are protected by a cover **216**. The magnets **186** rotate within a static magnet cover **188**, so that the magnetic handpiece **178** may be rested directly on the patient, while not imparting any motion to the external surfaces of the patient. Prior to distracting the intramedullary lengthening device **110**, the operator places the magnetic handpiece **178** over the patient near the location of the cylindrical magnet **134** as seen in FIG. **9**. A magnet standoff **194** that is interposed between the two magnets **186** contains a viewing window **196**, to aid in the placement. For instance, a mark made on the patient's skin at the appropriate location with an indelible marker may be viewed through the viewing window **196**. To perform a distraction, the operator holds the magnetic handpiece **178** by its handles **200** and depresses a distract switch **228**, causing motor **202** to drive in a first direction. The motor **202** has a gear box **206** which causes the rotational speed of an output gear **204** to be different from the rotational speed of the motor **202** (for example, a slower speed). The output gear **204** then turns a reduction

gear **208** which meshes with center gear **210**, causing it to turn at a different rotational speed than the reduction gear **208**. The center gear **210** meshes with both the first magnet gear **212** and the second magnet gear **214** turning them at a rate which is identical to each other. Depending on the portion of the body where the magnets **186** of the external adjustment device **180** are located, it is desired that this rate be controlled, to minimize the resulting induced current density imparted by magnets **186** and cylindrical magnet **134** though the tissues and fluids of the body. For example, a magnet rotational speed of 60 RPM or less is contemplated although other speeds may be used such as 35 RPM or less. At any time, the distraction may be lessened by depressing the retract switch **230**. For example, if the patient feels significant pain, or numbness in the area being lengthened.

[0061] While the external adjustment device **180** is illustrated herein as including a motor **202** that is used to rotate or drive the magnets **186** in an alternative embodiment, the magnets **186** may be rotated manually. For example, the external adjustment device **180** may include a hand crank or the like that can be manipulated to rotate the magnets **186**. In still another embodiment, the external adjustment device **180** may include a single magnet (e.g., permanent magnet) that is manually rotated about an axis by hand. For example, the single magnet may include a hand-held cylindrical magnet that is manually rotated by the user.

[0062] A cross section of a patient's lower thigh **218** with the intramedullary lengthening device **110** implanted within the femur **220** is shown in FIGS. **8** and **9**. In FIG. **9**, the magnetic handpiece **178** of the external adjustment device **180** of the invention is shown in position to adjust the cylindrical magnet **134** of the intramedullary lengthening device **110**. In FIG. **8**, however, a scale depiction of a prior art magnetic stator “donut” **222** demonstrates the comparative efficiency of the two designs (FIG. **8** illustrates an intramedullary lengthening device **110** of the type described herein placed in a “prior art” magnetic stator “donut” **222**). Thus, the only part of FIG. **8** that is prior art refers to the magnetic stator donut **222** The prior art magnetic stator “donut” **222** is large, expensive, and difficult to transport to a patient's home for daily adjustments. In addition, the use of a circular cross-section as a one-size-fits-all device is not very efficient because of several reasons: the cross section of most limbs is not circular, the bone is usually not centered within the limb and patients' limbs come in many different sizes. In FIG. **8**, the thigh has been placed through the circular hole in the magnetic stator “donut” and the posterior portion **232** of the thigh rests at the lower portion **226** of the magnetic stator “donut” **222**. The strength of a magnetic field decreases in accordance with a power (such as the inverse square) of the distance, depending on the complexity of the specific field geometry. Therefore, in any magnetic design, making the distance between the driving magnetic field and the driven magnet as small as possible is desirable. The size of the patient's lower thigh **218** and the decision to how it is placed within the magnetic stator “donut” **222** in FIG. **8** create a geometry so that the distance L**1** between the cylindrical magnet **134** and the upper portion **224** of the magnetic stator “donut” **222** is about the same as the distance L**2** between the cylindrical magnet **134** and the lower portion **226** of the magnetic stator “donut” **222**. However, if the anterior portion **234** of the thigh were instead placed against the upper portion **224** of the magnetic stator “donut” **222**, the length L**1** would become less while the length L**2** would become greater. Because each patient has a different sized limb, and because small limbs like the upper arm as well as large limbs such as the upper leg are desired for treatment, the magnetic stator “donut” **222** of FIG. **8** is almost impossible to optimize. Therefore, an extra-large magnetic field needs to be generated as the standard magnetic field of the device, thus requiring more expense (for the hardware to power this larger field). This in turn means that each patient will be exposed to a larger magnetic field and larger tissue and fluid current density than is really required. It may be desired, in some embodiments, to maintain patient exposure to magnetic fields of 2.0 Tesla or less during operation of the device. It may also be desired, according to another embodiment, to maintain patient exposure of the patient's tissues and fluids to current densities of no more than 0.04 Amperes/meters2 (rms). In addition, because the intramedullary lengthening device **110** is secured

to the bone **100**, unnecessarily large magnetic fields may cause unwanted motion of the bone **100**, for example in any of the radial directions of the cylindrical magnet **134**. If the magnetic field is too high, the patient's leg may be moved out of ideal position, and may even cause the patient some annoyance, including pain.

[0063] The configuration of the magnetic handpiece **178** of the external adjustment device **180** as shown in FIG. **9** optimizes the ability of the magnets **186** to deliver torque to the cylindrical magnet **134** of the intramedullary lengthening device **110**, without exposing the patient to large magnetic fields. This also allows the cylindrical magnet **134** of the intramedullary lengthening device **110** to be designed as small as possible, lowering the implant profile so that it may fit into the humerus, or the tibia and femurs of small stature patients, such as those who might desire cosmetic limb lengthening. As mentioned, a 9 mm diameter intramedullary lengthening device **110** can deliver 100 lb. distraction force, and even 8 mm and 7 mm devices are possible. The alternating orientation of the two magnets **186** (i.e., north pole of one magnet **186** corresponding with south pole of the other magnet **186**) creates an additive effect of torque delivery to cylindrical magnet **134**, and thus maximizes distraction force for any specific cylindrical magnet **134** size. Also, the separation(S) between the centers of the two magnets **186** (for example 70 mm), and the resulting concave contour **238** (FIGS. **6** and **7**), match with the curvature of the outer surfaces of the majority of limbs, thus making the distances L**3** and L**4** between each of the magnets **186** and the cylindrical magnet **134** as small as possible. This is especially aided by the concave contour **238** of the magnetic handpiece **178**. Also, skin and fat may be compressed by the magnet covers **188** causing an indentation **236** on one or both sides which allows the distances L**3** and L**4** between each of the magnets **186** and the cylindrical magnet **134** to be yet smaller.

[0064] FIG. **10** illustrates a sterilizable kit **400** containing a plurality of extension rods **406** which are configured to be attached to an actuator **412** seen in FIG. **11** in order to construct a modular intramedullary lengthening device **410**. In a one embodiment, the actuator **412** is supplied sterile, and the extension rods **406** and the remainder of the contents of the sterilizable kit **400** are sterilizable by autoclave (e.g., steam), Ethylene Oxide or other methods known to those skilled in the art. The sterilizable kit **400** contents includes one or more of the extension rods **406** and accessories **408** for use in the insertion, attachment, adjustment and removal of the modular intramedullary lengthening device **410**. The contents are located within a first sterilizable tray **402** and a second sterilizable tray **404**. Second sterilizable tray **404** and first sterilizable tray **402** have a plurality of holes **405** to allow gas to enter. Other items in the kit **400** will be described in several of the following figures.

[0065] Turning to FIG. **11** the assembly of the modular intramedullary lengthening device **410** is shown. The actuator **412** is designed to be placed in the bone of the patient in the opposite orientation than that of the intramedullary lengthening device **110** of FIG. **1**. Therefore, the distraction shaft **413** is orientated towards the distal end of the bone (distal is the down direction in the case of FIG. **11**). Distal apertures **415** in the distraction shaft **413** allow the placement of distal locking screws **420** or other fasteners. The distal locking screws **420** (FIGS. **21**A and **21**B) have proximal threads **417** for engaging the bone, while the remainder of the shaft **419** of the distal locking screws **420** is of a constant diameter for maximum strength and stability. At the proximal end **421** of the actuator **412** there is a hexagonally-shaped male hub **414** containing a transverse set screw **416**, within a threaded hole **429** of the hexagonal male hub **414** (FIG. **12**). The extension rod **406** (FIGS. **13** and **14**) has a corresponding hexagonal hole **428** or female end into which the hexagonal male hub **414** of the actuator **412** is placed. The transverse set screw **416** is nested within the threaded hole **429** of the hexagonal male hub **414** so that it does not interfere with the hexagonal hole **428** of the extension rod **406**, when they are placed together. There are two set screw holes **422** in the wall of the extension rod **406** which are in line with each other. The actuator **412** and extension rod **406** are placed together so that the set screw holes **422** extend coaxially with the set screw **416**. This allows a male hex **490** of a set screw tightening driver, such as the torque

limiting driver **488** of FIGS. **10** and **17**, to be inserted into a hex hole of the set screw **416**. When the torque limiting driver **488** is tightened and ratchets at its set control torque, the other end of the set screw **416**, which is either threaded or a non-threaded peg, inserts into the opposite set screw hole **422**, thus tightly securing the actuator **412** to the extension rod **406**. The set screw holes **422** are sized to allow the male hex **490** to smoothly clear, but the non-threaded peg of the set screw **416** clear very slightly, making a static connection that cannot be easily loosened during implantation. If desired, bone cement may be placed in annulus of set screw hole **422**, to even further bond set screw **416**. Also, a second screw may be screwed in behind the head of the set screw into the female thread that the set screw **416** was originally nested in. The head of this second screw will add additional resistance to shear failure of the set screw **416**. In addition, the second screw can be tightened so that it jams into the set screw **416**, thus making back-out of the set screw **416** unlikely. Any non-circular cross-section may be used in place of the hex cross-section, for example a square or oval cross-section.

[0066] Proximal locking screws **418** insert through locking screw apertures **430** in the extension rod **406**. The extension rod **406** may be straight, or may have a specific curve **432**, for example, for matching the proximal end of the femur or tibia. It can be appreciated that the modular arrangement allows the actuator **412** to be attached to one of numerous different models of extension rods **406**, having different lengths, curves (including straight), diameters, hole diameters, and angulations. The first sterilization tray **402** may include many of these different extension rods **406**, which may be selected as appropriate, and attached to the actuator **412**. Because the actuator **412** is supplied sterile, this arrangement is also desirable, as only a single model need be supplied. However, if desired, several models of actuator may exist, for example, different diameters (10.5 mm, 12.0 mm, 9 mm, 7.5 mm) or with different distal screw aperture diameters, configurations or angulations. The preferred configuration for a multitude of patients and different bone types and sizes can be available, with a minimum number of sterile actuator models.

[0067] Turning to FIG. **15**, a proximal drill guide **434** is illustrated and is configured for attaching to the modular intramedullary lengthening device **410** to ease its insertion into the intramedullary canal, the drilling of holes in the bone and the attachment of the proximal locking screws **418** to the bone. The proximal drill guide **434** comprises an extension arm **436** attached to a connection tube **446** through which a locking rod **448** is inserted. The locking rod **448** has a locking knob **450** at the proximal end and a male thread **452** at the distal end. In order to temporarily attach the proximal drill guide **434** to the modular intramedullary lengthening device **410**, a locking tab **454** of the proximal drill guide **434** is inserted into a locking groove **424** of the extension rod **406** and the locking knob **450** is turned, threading the male thread **452** of the locking rod **448** into a female thread **426** of the extension rod **406**. Prior to the procedure a drill guide extension **438** is attached via a knob **440** to the extension arm **436**. After reaming the medullary canal of the bone to a diameter slightly larger than the outer diameter of the modular intramedullary lengthening device **410** (for example 11 mm), distal end of the modular intramedullary lengthening device **410** is inserted into the medullary canal and the flat proximal surf ace of the locking knob **450** is hammered with a mallet, allowing the modular intramedullary lengthening device **410** to be inserted to the correct depth. Dimension X is sufficient to clear large thighs or hips (in the worst case femoral application). For example, 8 to 10 cm is appropriate. Once the modular intramedullary lengthening device **410** is in place in the medullary canal, the proximal drill guide **434** is left attached and a guide sleeve **442** is placed through one of the holes **456**, **458**, **460**, **462** and slid so that the distal end **443** reaches the skin of the patient. The drill guide extension **438**, extension arm **436** and holes **456**, **458**, **460**, **462** are dimensioned and oriented so that the guide sleeve **442** is oriented at the exact angle to allow drilling and placement of screws through the locking screws holes **430** of the extension rod **406** and through the bone. The skin of the patient is cut and a drill bushing **444** is placed through the incision, with the tapered tip **445** passing through tissue and reaching the bone to be drilled. For example, drills and locking screws may be inserted down the

drill bushing **444**, or alternatively, drills may be inserted down the drill bushing **444** and then, after the drilling is complete, the drill bushing **444** is removed and proximal locking screw **418** is inserted down the guide sleeve **442**. Alternative guide sleeves **464** and drill bushings **466** can be placed through holes **460** and **462**, as seen in FIG. **10**.

[0068] Turning to FIG. **16**, a removal tool **468** is illustrated. The removal tool **468** is used after the distraction period and consolidation period are complete. To remove the modular intramedullary lengthening device **410** from the medullary canal, the skin is incised and bone exposed at the locations of the proximal and distal locking screws **418**, **420** and at the proximal end of the modular intramedullary lengthening device **410**. A removal rod **470** is connected to the female thread **426** of the extension rod **406** of the modular intramedullary lengthening device **410** by inserting the engagement tip **476** and screwing the male thread **474** into the female thread **426**, holding onto the locking knob **472**. The locking knob **472** contains a female thread **478** which allows the attachment of a male thread **486** of a removal extension **480**, which has an impact knob **482** and removal hammer **484**. The male thread **486** is coupled to the removal extension **480** by a pivot **477** of a pivoting base **479**. The male thread **486** is secured to the female thread **478** by grasping and turning the impact knob **482**. Prior to removing the modular intramedullary lengthening device **410**, the proximal and distal locking screws **418**, **420** are removed. They may be removed with the use of the locking screw driver **498** (FIGS. **10** and **20**), which has a male hex tip **497** to engage the proximal ends of the locking screws **418**, **420**. A screw capture rod **500** (FIGS. **10** and **20**) inserts down the center of the locking screw driver **498** and has a male threaded tip **501**. At a deeper portion past the female hex **513** in the locking screws **418**, **420** (FIGS. **21**A and **21**B) is a female thread **511**. The male threaded tip **50** I of the screw capture rod **500** threads into the female thread **511** of the locking screws **418**, **420**, and tightened by using the tightening handle **503** of the screw capture rod **500** which sits at the handle end **509** of the locking screw driver **498** so that once the locking screws **418**, **420** are removed from the bone, they are still secured to the locking screw driver **498**, and will not become prematurely displaced. For example, the locking screws **418**, **420** will not be lost or dropped into the patient. The modular intramedullary lengthening device **410** may now be removed from the medullary canal by grasping the removal hammer **484**, and moving it quickly in the direction (D) so that hammer impact surface **485** strikes knob impact surface **483**. This is done until the modular intramedullary lengthening device **410** is completely removed. It should be noted that locking knob **450** of the proximal drill guide **434** of FIG. **15** also has a female thread (not pictured) so that during the insertion of the modular intramedullary lengthening device **410**, if it is desired to remove the device for any reason, the male thread **486** of the removal tool **468** may be attached to the female thread of the locking knob **450**, and the removal hammer **484** can be used against the impact knob **482** to remove the modular intramedullary lengthening device **410**.

[0069] The torque limiting driver **488** of FIG. **17** comprises a handle **496** and a shaft **492** having a torque-specific ratchet **494** connecting them. The male hex tip **490**, fits into the hex hole of the set screw **416**, or even into the female hex **513** of the locking screws **418**, **420**. An exemplary ratcheting torque for the set screw **416** is 9 inch-pounds (1.0 Newton-meter), and an exemplary hex size is 1/16″ (1.59 mm).

[0070] FIG. **18** illustrates the actuator **412** of FIG. **11** in a sectional view. The distal screw holes **415** are visible in the distraction shaft **413**. The distraction shaft **413** is shown in a fully extended position in relation to the housing **312**. The cavity **337** has opened to its maximum length. In this embodiment, the distraction shaft **413** has a purely cylindrical surface, and is dynamically sealed to the housing **312** by two o-ring seals **502**. The o-ring seals **502** may be made of silicone, EPDM, or other rubber materials, and may be coated with silicone oil, to aid in lubricity. There are four axially extending grooves **326** on the inner wall of the housing **312**. Tabs **504** on the end of the distraction shaft **413** fit into these grooves **326** to keep the distraction shaft **413** from being able to rotate with respect to the housing **312**. The housing **312** is welded to a magnet housing **328** and the

magnet housing **328** is welded to hexagonal male hub **414**. The set screw **416** on the hexagonal male hub **414** is used to attach the actuator **412** to the extension rod **406**. The cylindrical permanent magnet **334** is cased with epoxy inside magnet casing **358** having an end pin **360**. The end pin **360** inserts through radial bearing **332**, allowing it to rotate with low friction. As the magnet **334** is rotated by the external magnets, first planetary gear set **354**, second planetary gear set **356** and third planetary gear set **357** allow a total reduction of 64:1 (4×4×4). Each gear set allows a 4:1 reduction. Planetary gear output shaft **344** is attached to lead screw **336** by locking pin **342**, and locking pin **342** is held in place by cylindrical locking pin retainer **348**. Thrust bearing **338** abuts housing abutment or lip **352** and magnet housing abutment or lip **350** (thrust bearing **338** is sandwiched between housing abutment or lip **352** and magnet housing abutment or lip **350**). Therefore, thrust bearing **338** abuts housing abutment or lip **352** in tension and magnet housing abutment or lip **350** in compression. It should be noted that the sandwich arrangement allows for some slop or play between the thrust bearing **338** and the housing abutment or lip **352** and the magnet housing abutment or lip **350**. Lead screw **336** engages with nut **340**, which is secured within distraction shaft **413**. With the 64:1 gear reduction of this embodiment, distraction forces of greater than 300 pounds (1334 Newtons) have been consistently achieved with a gap (G in FIG. **19**) of 2 inches (5.08 cm) between the magnetic hand piece **178** and the intramedullary lengthening device **110**. This is sufficient for distracting a large range of typical patients.

[0071] It should be noted that although the embodiments of the intramedullary lengthening devices presented are shown to be used in a preferred orientation (distal vs. proximal), any of these embodiments may be used with the distraction shaft pointing distally or proximally. In addition, the invention may also be applied to distractable bone plates that are not located within the intramedullary canal, but are external to the bone.

[0072] An alternative lengthening scheme than those presented above may be also used. For example, one alternative includes the purposeful over-lengthening (to further stimulate growth) followed by some retraction (to minimize pain). For instance, each of four daily 0.25 mm lengthening periods may consist of 0.35 mm of lengthening, followed by 0.10 mm of retraction.

[0073] The materials of the accessories **408** are medical grade stainless steel, though other materials of varying densities may be used depending on the desired weight and the required size. The majority of the components of the intramedullary lengthening devices are preferably Titanium or Titanium alloys although some of the internal components may be made from stainless steel.

[0074] Intramedullary placed nails are commonly used in trauma of the long bones. Most nails are secured in place with transverse locking screws, much in a similar way to that described in the intramedullary lengthening device described here. In simple fractures it is relatively easy for the orthopedic trauma surgeon to place standard trauma nails correctly, so that the resulting fixture bone is close to the same length and configuration of the bone prior to fracture. However, in complex fractures, it is much more difficult to visually and physically “put the puzzle pieces back together” due to the nature of the fracture and the surrounding soft tissue trauma. Complex fractures many identified using a commonly used classification system such as the Muller AO Classification of Fractures. In addition, to promote healing, it is often desired to place compression between the separate segments of bone initially, for callus formation prior to callus ossification. Also, because it may be difficult to judge the ideal fixture length of the bone during the initial operation, it often would be desirable to adjust the length of the nail, and thus the bone during recovery from the operation, when a true comparison x-ray may be taken (length of bone on treated side vs. length of bone on contralateral side). It may be desired to take this x-ray with patient standing for an idealized comparison. The effect of the complex fracture may be such that a certain amount of distraction osteogenesis will be desired, to bring the fractured leg to a length that matches the other. During a lengthening period, it may be identified that the quality of the fracture callus is inadequate, and that a compression should be applied for a period of time. After this period of time, the lengthening process may be restarted, until the limb length is judged satisfactory. At

this point, the nail length would be held constant until ossification is completed.
[0075] FIGS. **22**, **23**, and **24**A-**24**H illustrate a variable length nail **616** according to one embodiment. The variable length nail **616** is configured for treating complex fractures of long bones, such as the femur, tibia and humerus. With reference to FIGS. **22** and **23**, the variable length nail **616** comprises a first end **618** having holes **624**, **626** for accommodating locking screws. The variable length nail **616** also comprises a shaft **652** with a second end **620** having screw holes **628**, **630**, **632** for accommodating locking screws. The variable length nail **616** also comprises a housing **622** that is secured to or otherwise integrated at one thereof to first end **618**. As seen in FIG. **22** and FIG. **23**, shaft **652** is telescopically moveable within the housing **622**. The shaft **652** is thus able to extend from or retract into the housing **622**. A dynamic seal between the housing **622** and the shaft **652** is provided by two o-ring seals **634** as seen in FIG. **23**. Still referring to FIG. **23**, tabs **654** on the shaft **652** slide within grooves **636** within the housing **622**. As in other embodiments disclosed herein, a cylindrical, permanent magnet **638** within a magnet casing **650** is located within the housing **622** and is rotatable between a thrust bearing **640** and a radial bearing **642**. In this particular embodiment, there are no gear sets interposed between the cylindrical magnet and the lead screw **646**, and the location of the thrust bearing **640** and the radial bearing **642** are reversed in comparison to FIG. **3**A and FIG. **18**, however the geared configuration and the bearing configurations of FIGS. **3**A and **18** are also possible. The non-geared configuration may be preferred, for example, in situations that do not require large distraction forces, and in situations where large adjustments are needed in a short amount of time. This is expected in many of the trauma scenarios described. In addition, a device without the gear sets will be less expensive to manufacture. A pin **644** couples a lead screw **646** to the magnet casing **650**. The lead screw **646** interfaces with a nut **648** that resides within a hollowed portion of the shaft **652**.
[0076] It should be appreciated that the variable length nail **616** is supplied to the user neither in its most retracted (shortest) configuration nor in its most distracted (longest) configuration. For example, in FIGS. **22** and **23**, the variable length nail **616** is depicted in the middle of its axial displacement. The variable length nail **616** of FIGS. **22** and **23** has a 10.5 mm housing **622** diameter and a 65 mm total axial displacement. Generally, the variable length nail **616** is configured for at least 5 mm of axial length change in each direction, and in at least some embodiments it is configured for at least 20 mm of axial length change in each direction. It is supplied so that it is about 50% distracted (32.5 mm in the case of FIGS. **22** and **23**). Alternatively, it may be desired to supply a device that is only 10% or 25% distracted. Or a model of device may be supplied that is 75% distraction, for example, specifically for patients who require more potential compression than lengthening.
[0077] The variable length nail **616** is inserted by making a first hole or incision in the skin of the patient in proximity to the fractured long bone and a canal is at least partially cleared through the center of the long bone. The variable length nail **616** is inserted into the canal and the first and second ends **618**, **620** thereof are secured to the different portions of the fractured long bone. The different portions of the fractured long bone may be physically separate from one another prior to insertion. Alternatively, the variable length nail **616** may be inserted into the bone while the different portions are connected to one another. The bone may be subsequent cut using, for instance, a Gigli type wire saw. For insertion of the variable length nail **616**, the proximal drill guide **434** may be used. The locking tab **454** of the proximal drill guide **434** is inserted into a locking groove **656** of the variable length nail **616**. Additionally, the male thread **452** of the locking rod **448** is tightened into the female thread **658** of the variable length nail **616**. The variable length nail **616** can be removed as described in other embodiments using the removal tool **468**.
[0078] In a complex fracture patient, the surgeon may be unsure whether a standard trauma nail will be successful at fixing the fractured bone without complications and will thus choose to implant the variable length nail **616**. FIG. **24**A illustrates the variable length nail **616** implanted in a canal **668** of a fractured femur **660**. In this patient, the fracture site **662** is between the proximal end

664 and distal end **666** of the femur **660**. The variable length nail **616** is secured to the femur **660** at the proximal **664** and distal ends **666** with locking screws (not shown). After the surgery, the hole or incision is allowed to close. After closure, and with the patient awake, the external adjustment device **180** is placed on the thigh of the patient and operated so that the length of the variable length nail **616** is reduced, placing compression on the fracture site **662** as seen in FIG. **24**B. This may be done, for example, the day after surgery, when the patient has recovered from anesthesia. Or it may be done a week or so after surgery, when the patient has fully recovered from the surgical procedure. It may also be done after several weeks, after significant tissue healing has occurred. When the fracture callus **670**, as seen in FIG. **24**C, is in the desired condition, distraction osteogenesis can be started by lengthening the variable length nail **616** (for example 1 mm per day) with the external adjustment device **180**. As the distraction period progresses as seen in FIG. **24**D, the bone begins to fill in between the distracted portions. At any time, it may be desired to add compression as seen in FIG. **24**E at the fracture site **662**, and in this case, the external adjustment device **180** is operated to shorten the variable length nail **616**. Once again, then the fracture callus **670** is in desired condition, distraction osteogenesis may be resumed as illustrated in FIG. **24** F, and may be continued until the target length of the femur **660** is reached.

[0079] An alternative method for using the variable length nail **616** and external adjustment device **180** is depicted in FIGS. **24**G and **24**H. A technique known as dynamization (also known as controlled early cyclic micromovement) is being applied in FIG. **24**G. FIG. **24**H represents the rest period between applications of the micromovement. Micromovement has been shown with external fixation devices to enhance callus formation to promote rapid healing and return of bone strength. The user programs the control box **176** of the external adjustment device **180** to cause the magnets **186** of the external adjustment device **180** to cycle in one direction and then the other, such that the variable length nail **616** is lengthened and shortened cyclically (FIG. **24**G). For example, a strain of 30% can be achieved by cycling from a 1.0 mm gap between bone sections to a 1.3 mm gap and back again, many times. For example, 500 cycles may be desired over short periods (for example 17 minutes per day). The period should be between 10 minutes per day and one hour per day, to be both feasible in practice and worth performing. It is desirable to keep the strain between 5% and 60%, because at these extremes, the cyclic process has been shown to actually inhibit healing. In between the applications of the cyclic micromovement, the sections of bone are held in place without movement as illustrated in FIG. **24**H. It may be desired to perform the cyclic micromovements at a relatively high rate, but a rate of greater than 30 cycles per minute can be effective. It is typically desired to perform some micromovement at the fracture site within the first two weeks after the injury.

[0080] Alternatively, the femur depicted in FIGS. **24**A-**24**H could be treated using a retrograde placed variable length nail **616**, where the device is inserted through a drilled hole which starts at the distal end of the femur and extends proximally. The same methods can be used on tibia, humerus or even smaller bones.

[0081] In cases of complex trauma, it often occurs that the bone may heal the correct length, or at least close to the desired length, but that one main bone portion may be misaligned angularly (in relation to the longitudinal axis) in relation to another bone portion. It may be desirable to correct this rotation of the bone using an alternative embodiment, as depicted in FIGS. **25** through **27**. This embodiment discloses an intramedullary rotational correction device **700** having a first section **702** which is configured to be rotated in relation to a second section **708**. The first section **702** comprises a housing **728** and an extension rod **720** which contains holes **704**, **706** for placement of fasteners such as locking screws (not shown). The second section **708** comprises a shaft **718** and contains holes **710**, **712**, **714** for placement of locking fasteners such as screws (not shown). Depicted in FIG. **25**, the extension rod **720** is attached to the housing **728** by means of set screw **716**, which is accessible through one or more screw holes **722**. In this assembly, a locking groove **724** is configured to engage with locking tab **454** of the proximal drill guide **434** of FIG. **15**. Also, a

female thread **726** is configured to engage with male thread **452** of the locking rod **448** of the proximal drill guide **434**.

[0082] The mechanism is similar in some ways to the axial distraction mechanisms of other embodiments disclosed herein, but additional features allow the rotation of a lead screw **746** to create controlled angular displacement of the second section **708** (and shaft **718**) instead of axial displacement. As seen in FIG. **26**, a radially-poled cylindrical magnet **730** and three gear sets **734**, **736**, **738** are held in the housing **728** (which is exposed in FIG. **26**) between a radial bearing **740** and a thrust bearing **742**. The radial bearing **740** is held within a hollow portion **774** of an end cap **762** as seen in FIG. **27**, with the end cap **762** being secured to the assembly with a weld **776**. The cylindrical magnet **730** is contained within a protective magnet casing **732** as seen in FIG. **26**. Rotation of the cylindrical magnet **730** causes rotation of each successive gear set **734**, **736**, **738**. An external adjustment device **180** such as those described herein (e.g., FIGS. **6** and **7**) may be used rotate the cylindrical magnet **730**. Alternatively, a hand crank or the like can be used to rotate the cylindrical magnet **730**. In still another embodiment, the external adjustment device **180** may include a single magnet (e.g., permanent magnet) that is manually rotated about an axis by hand to impart rotational movement to the cylindrical magnet **730**.

[0083] Depicted in FIGS. **26** and **27** are three 4:1 planetary gear sets, which create an overall 64:1 gear ratio. Other gear ratios and numbers of gears sets, however, may be used. The design may also be used without any gear sets or with no gear sets in which case the cylindrical magnet **730** drives the lead screw **746** in a one-to-one fashion. As shown in FIGS. **26** and **27**, the output of the third gear set **738** is coupled to the lead screw **746** with a pin **764** which is held in place by a circumferential pin retainer **752** (FIG. **26**). The lead screw **746** is engaged with an internal thread **772** of a rotary nut **744**. The rotary nut **744** includes a screw engagement portion **766** and an axial sliding hex portion **768**. The screw engagement portion **766** of the rotary nut **744** includes one or more non-linear splines **748** which are configured to slide along non-linear grooves **750** within the internal wall of the housing **728**. The screw engagement portion **766** of the rotary nut **744** includes the internal thread **772** and a cavity **778** for clearance and free passage of the lead screw **746**. When an external rotating magnetic field, for example from the rotating magnets **186** of the magnetic handpiece **178**, is applied to the cylindrical magnet **730**, the cylindrical magnet **730** is turned and via transmission with the gear sets **734**, **736**, **738** turns the lead screw **746** in a first direction. As the lead screw **746** is turned in this first direction within the internal thread **772**, the rotary nut **744** extends axially, i.e., away from the cylindrical magnet **730**. Because both the non-linear splines **748** and the non-linear grooves **750** have matched helical curve shapes, the rotary nut **744** rotates slightly as it axially extends. For example, the non-linear spines **748** may be configured to extend around the rotary nut **744** a quarter of a turn for every 9.5 mm of length. In concordance, the non-linear grooves **750** may be configured to extend around the interior of the wall of the housing **728** a quarter of a turn for every 9.5 mm of length. Alternatively, the non-linear grooves **750** may be configured to extend a quarter turn for every 18 mm of length. In yet another alternative, the non-linear grooves **750** may be configured to expand a quarter of a turn every 6 mm of length. In this regard, the relative pitch of the non-linear grooves **570** may be adjusted to modify the degree of rotational movement. As yet another alternative embodiment (not shown), the non-linear grooves **750** may be disposed on the external surface of the rotary nut **744** and the non-linear splines **748** may disposed on the internal wall of the housing **728**.

[0084] As the rotary nut **744** axially extends and rotates, the axial sliding hex portion **768** slides inside a female hex receptacle **770** of the shaft **718**. The axial sliding hex portion **768** and the female hex receptacle **770** are rotationally keyed, each having a hexagonal shape, so that when the axial sliding hex portion **768** turns, the female hex receptacle **770** is turned with it thus turning the shaft **718**. This construction allows relative axial sliding, namely, the shaft **718** rotates without any axial extension. The cross sectional shape may be any non-circular shape that is conducive to keying. For example, alternatives include a square shape or an elliptical shape. The shaft **718** is

held axially on one end by a retaining collar **754** and on the other end by a lip **780**, which in this embodiment is shown integral to the shaft **718**, though alternatively, it can be made from a separate piece. An o-ring flange cap **756** is secured to the housing **728** (for example by welding or other direct boding technique) and contains one or more o-ring seals **758** within one or more o-ring flanges **760**, thus sealing the internal contents of the housing **728**.

[0085] The intramedullary rotational correction device **700** is preferably supplied to the customer in a sterile condition (for example by Gamma irradiation), and it may be supplied to the customer in numerous configurations. Three specific configurations will now be described. The supplier may supply the device in each of these configurations, or the supplier may supply the device in a single configuration, and the user may adjust the device into their desired configuration. The intramedullary rotational correction device **700** may be supplied with the internal thread **772** positioned towards a first end **782** of the lead screw **746** (near the pin **764**). In this condition, the maximum amount of clockwise rotation may be applied to the second section **708** and shaft **718**. Alternatively, the intramedullary rotational correction device **700** may be supplied with the internal thread **772** positioned towards a second end **784** of the lead screw **746**. In this condition, the maximum amount of counter-clockwise rotation may be applied to the second section **708** and shaft **718**. If it is not known at time of implantation, which direction a rotational discrepancy is possible (or probable), it may be desired to supply (or adjust) the intramedullary rotational correction device **700** so that the internal thread **772** is positioned at an intermediate section **786** of the lead screw **746**. In this configuration, either clockwise rotation or counter-clockwise rotation will be available to the user.

[0086] In use, a patient is implanted with the intramedullary rotational correction device **700** and locking screws are used to secure the first section **702** and second section **708** to the bone to be treated. If a pre-existing rotational deformity is to be corrected, the implant is chosen with the correct amount of either clockwise or counter-clockwise rotation available, for example, as in the first two conditions described. If instead, the intramedullary rotational correction device **700** is being used as a trauma nail, knowing that the specific type of trauma may cause imprecise fixation, and thus a rotational discrepancy, it may be desired to have both clockwise and counter-clockwise rotation available. In this case, the third condition (allowing both clockwise and counter-clockwise rotation) would be the one desired. In this third condition, after the device is implanted, if the rotational discrepancy is discovered early, before consolidation of the bone fragments, the device may be operated as described to change the rotational orientation of the fragments gradually. If, however, the rotational discrepancy is discovered after the bone fragments have consolidated, an osteotomy may be made to allow the rotation between the fragments to be imparted.

[0087] FIGS. **28** and **29** illustrate a lockable and un-lockable rotational implant device **800** according to another embodiment. The implant **800** has a similar cylindrical magnet/lead screw/nut arrangement to other embodiments described here, except the magnet **788**, held between a thrust bearing **790** and a radial ball bearing **792**, turns a lead screw **794**, moving a nut **796**, the nut **796** having teeth **810** on an axial face at the end which interlock with teeth **812** at a matching end of a rotation rod **802** (as best seen in detail section in FIG. **29**). The rotation rod **802** is dynamically sealed to a housing **814** by an o-ring seal **806**, and held axially in relation to the housing **814** by a retaining collar **804**. The nut **796** has anti-rotation ears **808** to keep the nut **796** aligned rotationally with the housing **814**. In particular, the anti-rotation ears **808** may interface with corresponding grooves or recesses in the interior surf ace of the housing **814**. If it is desired to manually change the rotational orientation of two bone pieces of a patient, the magnet **788** is rotated by a moving magnetic field of an external adjustment device (e.g., external adjustment device **180**), so that the teeth **810** of the nut **796** move away from the teeth **812** of the rotation rod **802**. Then the teeth **810**, **812** are disengaged from each other, the limb can be grasped and one bone piece may be manually rotated with respect to the other bone piece. When the rotational orientation of the two bone pieces is as desired, the magnet **788** is turned in the opposite direction by the external adjustment device

180, so that the teeth **810** of the nut **796** move towards and engage with the teeth **812** of the rotation rod **802**, thereby locking the housing **814** and the rotation rod **802** together. An optional slip clutch (not shown) located between the magnet **788** and the lead screw **794** may be used to prevent binding.

[0088] FIGS. **30-32** illustrate an alternative embodiment of the interface between a rotary nut **900** and a housing **902** of an intramedullary rotational correction device like that illustrated in FIGS. **25-27**. In the embodiment illustrated in FIGS. **26** and **27**, non-linear splines **748** located on the rotary nut **744** interface with corresponding grooves **750** disposed along an inner surface of the housing **728**. In the alternative embodiment illustrated in FIGS. **30-32**, the rotary nut **900** includes one or more non-linear grooves **904** disposed along all or a portion of an exterior surface of the rotary nut **900**. Located opposite the non-linear grooves **904** disposed on the rotary nut **900** are corresponding non-linear grooves **906** disposed along an interior surface of the housing **902**. For example, both the non-linear grooves **904** disposed on the rotary nut **900** and the non-linear grooves **906** disposed on the inner surface of the housing **902** may be helical. A plurality of ball bearings **908** are interposed between the non-linear grooves **904** of the rotary nut **900** and the non-linear grooves **906** of the housing **902**. As seen in FIG. **32**, the plurality of ball bearings **908** may be held stationary by respective cages **910**. The cages **910** may include a strip of material substantially aligned with the non-linear grooves **904**, **906** and have a plurality of circular pockets **912** that surround and retain individual ball bearings **908**. In this manner, the ball bearings **908** are held in a stationary position (for example, in relation to the housing **902**) but allowed to spin or rotate within the non-linear grooves **904**, **906**. For instance, the ends of the cages **910** may be clipped to the ends of the non-linear grooves **906** disposed along the interior surface of the housing **902**. In this embodiment, other features of the intramedullary rotational correction device described with respect to FIGS. **25-27** remain the same.

[0089] While embodiments of the present invention have been shown and described, various modifications may be made without departing from the scope of the present invention. As one example, the devices described herein may be used to lengthen or reform a number of other bones such as the mandible or the cranium. Thus, while several embodiments have been described herein it should be appreciated that various aspects or elements are interchangeable with other separate embodiments. The invention, therefore, should not be limited, except to the following claims, and their equivalents.

Claims

1. An intramedullary implant comprising: a housing configured to be secured to a first section of bone; a distraction shaft configured to be secured to a second section of bone; an actuator disposed within the housing and operably coupled to the distraction shaft; and one or more ball bearings connecting the housing and the distraction shaft, wherein rotation of the actuator causes axial displacement of the distraction shaft relative to the housing and the one or more ball bearings prevent rotation between the housing and distraction shaft during axial displacement.

2. The intramedullary implant of claim 1, wherein the actuator comprises a rotatable permanent magnet positioned within the housing and a lead screw coupled to the rotatable permanent magnet.

3. The intramedullary implant of claim 1, wherein the distraction shaft comprises one or more grooves that include a semi-circular indentation configured to allow the one or more ball bearings to roll therein.

4. The intramedullary implant of claim 3, wherein the one or more ball bearings are configured to rotationally lock the one or more grooves of the distraction shaft relative to one or more shaft engaging grooves of the housing.

5. The intramedullary implant of claim 4, comprising a plurality of recesses between the one or more shaft engaging grooves of the housing and the one or more grooves of the distraction shaft,

the plurality of recesses configured to retain the one or more ball bearings therein.

6. The intramedullary implant of claim 2, comprising a slip clutch disposed between the rotatable permanent magnet and the lead screw, the slip clutch configured to prevent binding of the rotatable permanent magnet and the lead screw.

7. The intramedullary implant of claim 1, comprising a sliding seal between the distraction shaft and the housing for providing protection of the implant from an external environment the implant is exposed to.

8. The intramedullary implant of claim 7, wherein the sliding seal includes a plurality of protrusions configured to slidingly seal against one or more grooves of the distraction shaft.

9. The intramedullary implant of claim 1, wherein the implant is configured to aid in treatment of a limb length discrepancy or a bone defect in the patient's body.

10. An intramedullary implant comprising: a housing configured to be secured to a first section of bone; a distraction shaft configured to be secured to a second section of bone; an actuator disposed within the housing and operably coupled to the distraction shaft; and a sliding seal between the distraction shaft and the housing for providing protection of the implant from an external environment the implant is exposed to, wherein rotation of the actuator causes axial displacement of the distraction shaft relative to the housing.

11. The intramedullary implant of claim 10, wherein the sliding seal includes a plurality of protrusions configured to slidingly seal against one or more grooves of the distraction shaft.

12. The intramedullary implant of claim 10, comprising one or more ball bearings connecting the housing and the distraction shaft, wherein the one or more ball bearings prevent rotation between the housing and distraction shaft during axial displacement.

13. The intramedullary implant of claim 10, wherein the actuator comprises a rotatable permanent magnet positioned within the housing and a lead screw coupled to the rotatable permanent magnet.

14. The intramedullary implant of claim 10, wherein the distraction shaft comprises one or more grooves that include a semi-circular indentation configured to allow the one or more ball bearings to roll therein.

15. The intramedullary implant of claim 12, wherein the one or more ball bearings are configured to rotationally lock the one or more grooves of the distraction shaft relative to one or more shaft engaging grooves of the housing.

16. The intramedullary implant of claim 10, comprising a plurality of recesses between one or more shaft engaging grooves of the housing and one or more grooves of the distraction shaft, the plurality of recesses configured to retain the one or more ball bearings therein.

17. The intramedullary implant of claim 13, comprising a slip clutch disposed between the rotatable permanent magnet and the lead screw, the slip clutch configured to prevent binding of the rotatable permanent magnet and the lead screw.

18. The intramedullary implant of claim 1, wherein the implant is configured to aid in treatment of a limb length discrepancy or a bone defect in the patient's body.