Design and Optimization of a Novel Intramedullary Robot for Limb Lengthening

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Abstract. Limb length discrepancy is a crucial problem that can seriously affect the life quality and likely leads to other diseases. Free from extracorporal surgery, the intramedullary limb-lengthening treatment has become increasingly popular in recent years as a method of long-bone distraction osteogenesis. To overcome the mechanical and electromagnetic problems caused by the medical device miniaturization, this paper presents a study on the design and optimization of a novel Intramedullary Robot for Limb Lengthening (IR4LL) with robust mechanical stiffness and surplus electromagnetic driving force. A solenoid-driven design with a large reduction ratio is proposed and analyzed. Based on the experimental and simulation results, IR4LL is proven to be safe and reliable for limb-lengthening operations, which can significantly reduce lifestyle disruption and medical complications during and after the treatment.

Keywords: Limb length discrepancy · Limb lengthening · IR4LL · Design and optimization

1 Introduction

Limb length discrepancy (LLD) is a crucial problem among clinicians because it can be caused by either congenital or acquired conditions, such as osteomyelitis, tumour, etc. [1]. In the 1980s, the Ilizarov fixator invented by Professor Gavriil A. Ilizarov unquestionable set off a revolution on limb lengthening and deformity correction [2]. However, the drawbacks of the Ilizarov fixator are long-term exposure causing inconvenience and uncomfortable, and some complication such as pin site infection, ankylosis, etc. [3–5].

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In order to shorten treatment duration and reduce patient's pain, implantable lengthening nail (ILN) [6] is proposed which can be implanted into a human body. The first public ILN is from Bliskunov which used a rotational motion machine for elongation [7]. In 1991, Baumgart and Betz invented an autonomous ILN with a receiver embedded under the skin to recept the movement instruction signal [8,9]. However, the signal might fail because the tiny thread that connects with ILN may fracture during daily activities.

In 2001, Food and Drug Administration (FDA) approve an Intramedullary Skeletal Kinetic Distractor (ISKD) from an Orthofix company and is delisted from the market due to over-distract and unable to control its distracion rate [10–12]. Although a magnetic drive ILN called Phenix which is invented by Arnaud Soubieran achieved good clinical result, but it is less reported around the world [13].

The latest and most successful ILN, PRECICE, is approved by FDA in 2011 and updated later to PRECICE 2(P2) in 2013. The main difference between PRECICE(P1) and P2 are welding and seamless connection and higher bending strength [6,12] which is proven later that P1 has a fracture at welding part on clinical result [11]. Although P2 has huge success in limb lengthening, there are some defects that need to be solved such as temporarily slowing down or stopping distraction and 1cm shortening at the regenerated bone during consolidation phase [14].

In this paper, Intramedullary Robot for Limb Lengthening (IR4LL) is aiming to carry out structural optimization [22] solving fracture issues and insufficient power when lengthening that often happens in ILN. Later on, the static structural and modal of IR4LL during the gait cycle, and magnetic field intensity for driving the IR4LL power mechanism is analyzed. It proves that IR4LL is well-designed and giving outstanding results.

2 IR4LL Design and Method

IR4LL is an apparatus based on the principle proposed by Ilizarov which considered two parts: a motion device that is implanted into a human body for lengthening the bone (Intramedullary Robot (IR)) and a driving device that provides torque for the motion device (magnetic drive) as Fig. 1 shown. Bone screws are used to fix IR in the bone cavity, where the distal part of the bone is lengthened together with IR's elongation part when torque is provided to the threaded rod which achieved the purpose of limb lengthening. In this paper, two devices are designed and their mechanisms are introduced.

2.1 IR Design

The IR consists of four main parts, including the proximal part, middle part, distal part and elongation part. The components of IR are mainly manufactured by stainless steel which have high strength and good biocompatibility [15]. The proximal part, middle part and distal part are designed in different thicknesses

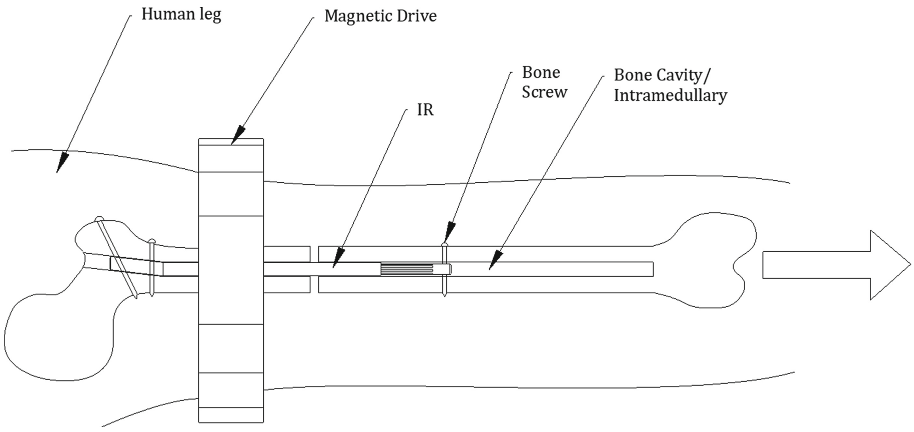


Fig. 1. The schematic figure of Intramedullary Robot for Limb Lengthening (IR4LL)

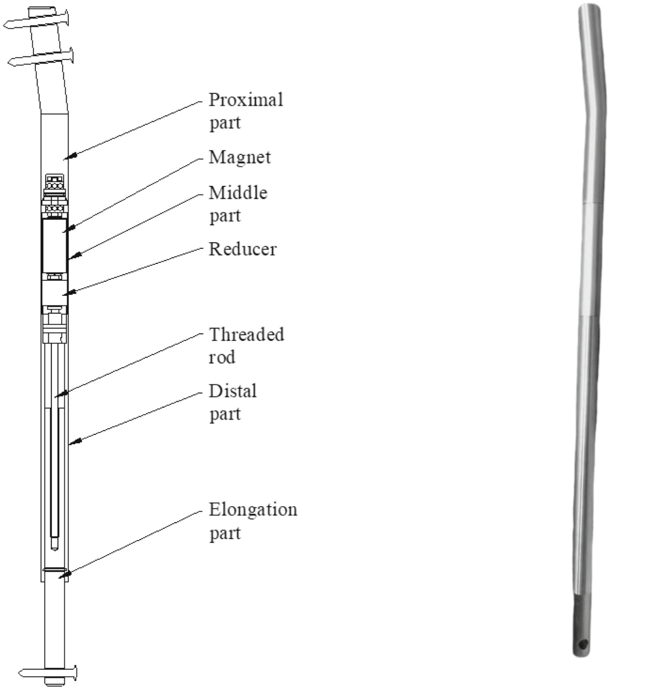
according to the forces acting on them during the human walking gait cycle. They are attached tightly through interference fit while the elongation part can move smoothly in the distal part track. As Fig. 2 shows, the proximal part and elongation part have screw holes arranged in conventional patterns which can fix the device tightly in the bone cavity.

The drive system of IR consists of a permanent magnet, a reducer, a threaded rod and an elongation part. When the permanent magnet is driven by the outer magnetic field and starts to rotate, the torque from the permanent magnet is amplified by reducer and transfers to the threaded rod. An elongation part and threaded rod which are threaded connection will do spiral motion meaning elongate as the driving torque is given. The distal part of the bone starts to lengthen as the elongation part is moving due to the existence of bone screws.

Stress and Modal. LLD is a corrective surgery that needs the ILN long term implanted in the human limb bone cavity. Therefore, safety and comfortability is the main concern for the patient. In order to ensure the IR will not break during the walking gait cycle after it is implanted, the maximum stress of the IR must not exceed the tensile strength of the material. Moreover, modal analysis is required to determine the dynamic behaviour of the system in the forms of natural frequencies, damping factors and mode shapes. Therefore, the natural frequency of IR must be much larger than the walking gait cycle frequency to avoid resonant damage.

2.2 Magnetic Drive Design

The IR magnetic drive consists of a group of stator core module, steel cable and winding coils as Fig. 3 shown. The stator core module has two nylon protective



(a) Section view of IR

(b) IR product

Fig. 2. The schematic figure of IR

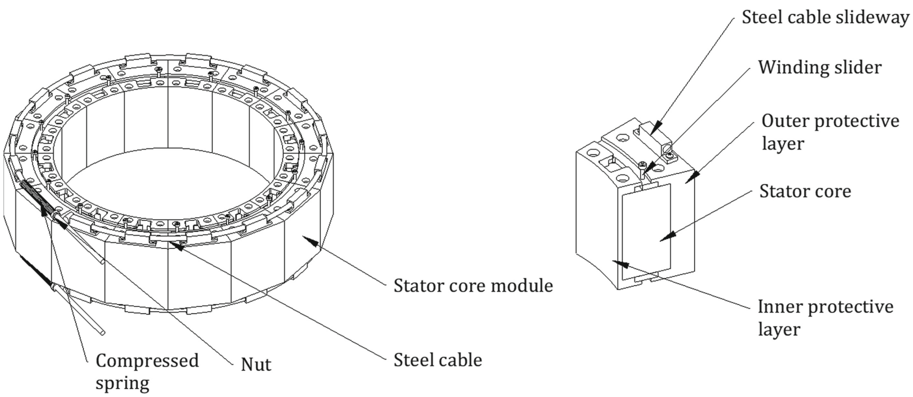


Fig. 3. IR Magnetic drive and its stator core module

layers on both inner diameter and outer diameter to prevent a direct contact on the stator core which is manufactured by silicon steel sheet. A steel cable slideway is fixed on the outer diameter while the winding slider is slid into the gap between the outer and inner protective layer. A group of the stator core module is connected in series to form a circular magnetic field generator that can be put on by the patient. A compressed spring and a nut are used at the end of the steel cable for adjusting the space between the stator core module. The purpose of the winding slider is to adjust the total diameter of the winding when the magnetic drive's diameter change.

Lifting Torque and Supplying Torque. Based on the combination of IR's permanent magnet and the magnetic drive, we can assume that it is similar to a permanent magnet brushless DC motor (PMBLDC) model. Supplying torque is contributed by the magnetic drive and acts as an input of the drive system while lifting torque is the output of the drive system to overcome the load. The lifting torque required for the threaded rod during limb lengthening can be calculated as:

$$T = \frac{Fd_m}{2}\left(\frac{l + \pi\mu d_m}{\pi d_m - \mu l}\right) \tag{1}$$

where F is the load, d_m is the mean thread diameter, μ is the coefficient of friction for thread, l is the screw's lead.

Apart from decreasing the lifting torque, increasing the magnetic field intensity of the magnetic drive can also increase the supplying torque. In this paper, we are using the PMBLDC motor principle to control the permanent magnet in IR in order to follow the stator magnetic field rotates synchronously. The total torque of the PMBLDC motor may be described with the relations [17]

$$T = 2PB_g I_s n_s L R_{si} \tag{2}$$

where P is the number of poles, B_g is the air gap flux density in the middle 120° of a pole, I_s is the DC source current, n_s is the number of turns in slot, L is the active length of the motor and R_{si} is the stator inner radius. Based on Eq. 2 given above, increasing the source current or number of turns in the PMBLDC motor is an effective way to increase its total torque.

3 Analysis and Simulation

In this section, finite element analysis which has a wide range of applications in mechanical design and manufacturing [21] is used in IR4LL to ensure the structure of IR is not breakable during the human walking gait cycle and the rotating magnetic field formed by the magnetic drive are sufficient for limb lengthening. The design specifications of IR is shown in Table 1:

3.1 Analysis and Simulation of Mechanical Stiffness

Static Structural and Modal Analysis. In order to avoid IR breakage after it is implanted into the bone cavity, 3 different directions of forces (frontal force, lateral force and axial force) during the walking gait cycle [16,20] must not

Table 1. IR design specifications

Material	Maximum diameter	Maximum allowable elongation	Threaded rod specification	Reduction ratio
SS316L	12.5 mm	80 mm	M4	50

exceed the material's tensile strength. In this paper, we assume IR is implanted for femur lengthening and the walking gait cycle of a 100 Kg body weight patient is decomposed into 6 steps.

Table 2. The average frontal, lateral and axial force acting on the femur and the minimum, maximum and average stress on IR during walking gait cycle

Steps	1	2	3	4	5	6
Frontal force (N)	119.7	119.7	119.7	119.7	359.1	119.7
Lateral force (N)	−91.8	−198.9	−91.8	−91.8	0	0
Axial force (N)	499.52	854.83	1128.38	769.35	0	512.9
Minimum stress (MPa)	1.806e−3	3.124e−3	4.075e−3	2.779e−3	4.659e−3	1.823e−3
Maximum stress (MPa)	330.2	486.89	344.12	335.78	550.51	266.07
Average stress (MPa)	57.132	88.828	62.684	59.389	128.26	46.247

The load from Table 2 is applied on the screw hole of the elongation part while fixed support is applied on the screw holes of the proximal part. According to the result shown in Table 2 and Fig. 4, the Von Mises Stress is mainly taking part at the middle part of IR which is around 550.5 MPa at the 5th step. The maximum stress is smaller than its yield strength (946 MPa), but it is not encouraged to use it while doing intense activities such as running. The base frequency given in modal analysis is 213.55 Hz which is larger than the walking gait cycle (shown in Table 3).

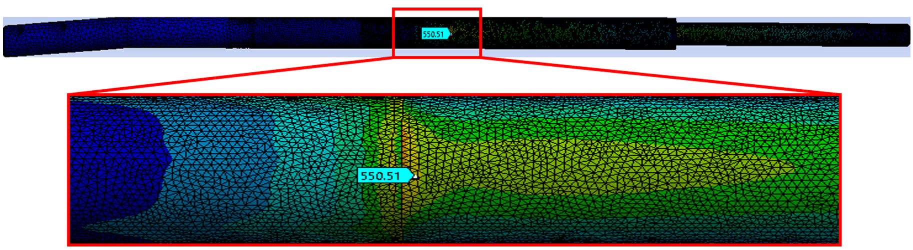


Fig. 4. Von Mises stress simulation shows that the maximum value occurs at IR's middle part

Table 3. The first 8 mode of natural frequency

Mode	1	2	3	4	5	6	7	8
Frequency (Hz)	213.55	213.56	1274.1	1274.2	2232.8	3809.4	3810.8	4558.6

3.2 Analysis and Simulation of Electromagnetic Driving

Lifting Torque. In order to calculate the lifting torque required for the threaded rod, the load acting on IR during lengthening is our main concern. According to Zhang et al. [18], the distraction rate of ILN is 0.5 to 1.32 mm/day and the force is related to the body mass of the patient during the distraction period [19]. Therefore, the assumption of the lifting torque is given in Table 4.

Table 4. Assumption for the lifting torque

Distraction rate	Distraction period	Forces in relation to the body mass at the end of the distraction period	Coefficient of friction
1 mm/day	80 days	9.5 N/Kg	0.15

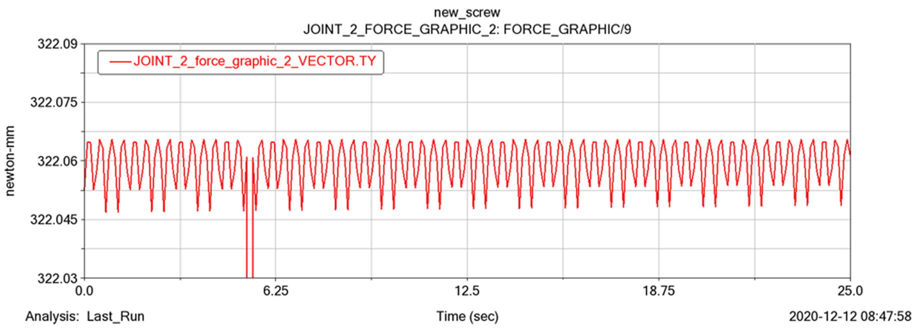


Fig. 5. The result of lifting torque simulation

Based on the result shown in Fig. 5, we can approximate the minimum torque required for the linear motion is 325 Nmm. According to Table 1, the reduction ratio of the reducer is 50 which gives the final lifting torque will be at least 6.5 Nmm.

Supplying Torque. The proposed magnetic drive which is similar to PMBLDC model has 2 magnet poles and a stator core that has three-phase six salient poles. The design specifications of the magnetic drive and IR's PM are shown in Table 5 where the material of PM and stator core are NdFe35 and M27_29G respectively.

Table 5. Stator core and rotor core design specifications

Stator dimension			
Outer diameter	Inner diameter	Length	Stacking factor
250 mm	200 mm	40 mm	0.95
Stator winding			
Conductors per slot	Number of strands	Wire wrap	Wire diameter
75	1	0.2 mm	1.829 mm
Rotor dimension			
Outer diameter	Inner diameter	Length	Embrace
11 mm	3 mm	25 mm	1

Although PMBLDC motor's current source is DC current, its commutation can be implemented in software using a microcontroller, or may alternatively implemented using analog or digital circuits. The commutation sequence of PMBLDC motor is one winding energized positive, one winding energized negative and one winding non-energized. In this paper, the maximum current of the magnetic drive is restricted to below 10 A because the allowable current for 1.829 mm diameter wire is 10.368 A. From Fig. 6, the average supplying torque of the magnetic drive is 8.6 Nmm which is larger than the minimum lifting torque 6.5 Nmm.

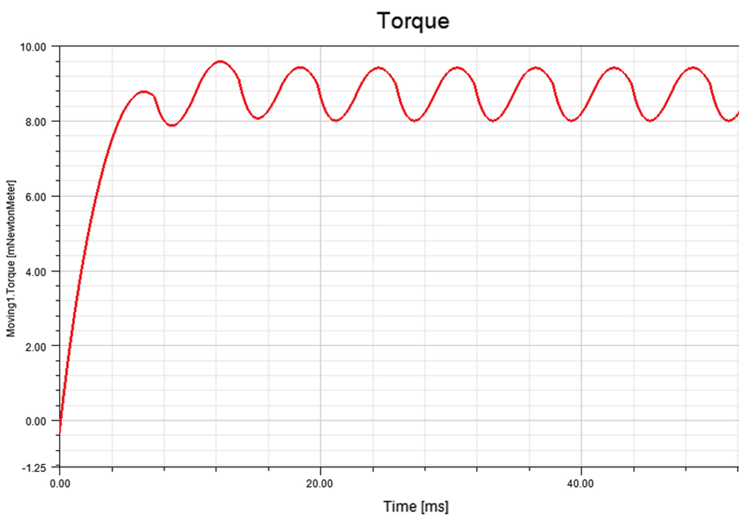


Fig. 6. Average supplying torque of magnetic drive

4 Conclusion and Future Work

In this article, we have successfully designed an ILN named IR4LL which is aimed to solve LLD disease that has been troubling clinicians. The IR which is implanted into the bone cavity is driving by the magnetic flux formed from the magnetic drive. The rotating magnetic field rotates the PM inside IR to transfer the rotational motion to linear motion that can lengthen the bone. Either increasing the source current or number of turns in the magnetic drive enhances the supplying torque while increasing the reduction ratio in the reducer lessens the lifting torque required. As further work, IR4LL will be manufactured and the animal experiment will be carried out to prove it is effective in solving the LLD problem.

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