

Pediatric Expandable Endoprosthesis (PEE)

**ME 282: Biomedical Product Design and Evaluation
Biomechanical Engineering Division
Mechanical Engineering Department
Stanford University**

March 2002

DePuy Orthopedics

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There are approximately 500 cases of pediatric bone cancer worldwide each year. In the majority of the cases, the cancerous bone must be resected. The limb can then either be amputated or the resected bone can be replaced. Limb preservation is becoming more common, but there are limitations to pediatric applications of the procedure. The current technique consists of replacing the resected bone with an endoprosthesis. Unfortunately most occurrences of bone cancer are in the growth plate region, so the epiphysis is usually removed. While the healthy leg grows as the child matures, the leg with resected bone will not grow, resulting in a leg length discrepancy as the child matures. One solution is to use modular endoprostheses. This results in several surgical procedures as an operation is required to insert a new modular component each time a leg lengthening is desired. Increased surgical procedures correlates to increased chances of infection, morbidity rates, recovery time, and pain and suffering.

An ideal solution would be to create an endoprosthesis that would expand periodically with non-surgical stimulus to grow as the child grows. The goal of the project is to prototype and test an implantable prosthesis capable of controlled lengthening. This device will be part of the DePuy Limb Preservation System for use in pediatric patients who have undergone a massive bone resection of the lower limb. The design, analysis and testing will be focused on satisfying the needs in children ages 6-15 within two standard deviations of the mean weight and height. Our deliverables include a working prototype demonstrating a functioning expansion mechanism for the endoprosthesis. In addition, theoretical calculations of strength and reliability of the product will be made available.

Our key accomplishments to date have been development and refining design specifications based on input from our sponsor and a musculoskeletal oncology / orthopedic surgeon with pediatric endoprosthesis experience. We generated design concepts and ideas, and then evaluated these ideas with analysis tools to choose the design idea to pursue. A modification of the ISKD device was chosen as the design, but several modifications are being further investigated and tested to determine the most feasible and reliable method. Initial prototypes of these designs are being constructed.

With these initial prototypes, the next step will be to perform initial testing on the ISKD modification designs. Based on these preliminary tests, we will select one design to pursue. We will then concentrate on creating a 3D CAD model and working prototype of expandable prosthesis. In addition we will perform theoretical and mechanical testing on the design.

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Sponsor Background

DePuy is the oldest manufacturer of orthopaedic implants in the United States. The company was founded in 1895 when Revra DePuy, a salesman, revolutionized the fracture management industry by introducing wire splints to replace the makeshift wooden splints then in use for stabilizing fractures. One of the divisions within Depuy is DePuy Orthopaedics, Inc., a leading designer, manufacturer and distributor of orthopaedic devices and supplies including hip, knee, ankle, shoulder, wrist, elbow, and finger replacements, and operating room products. DePuy has long been regarded as an innovator in new product development. DePuy researchers were on the forefront of the total hip replacement concept introduced in the early 1960s. It was this development that was primarily responsible for creating the orthopaedic market as we know it today¹.

A relatively new goal of DePuy has been to enter the limb preservation business with their new Orthogenesis Limb Preservation System (LPS). Currently, DePuy has created distal/proximal/total femoral, proximal tibial, and mid-shaft replacements. However, these components were all designed for use in adults. DePuy's current strategy is to adapt the current LPS system for pediatric use.

Clinical Background

Patients with bone cancer traditionally have undergone treatments involving chemotherapy, radiotherapy, and surgery. Until very recently, surgery usually resulted in amputation when the cancer was located in the lower extremity. However, recently developed surgical techniques allow excision of only the cancerous tissue, allowing the limb to be spared. Despite these selective excisions, massive bone loss is still often the result as the surgeon must be sure to remove all malignant tissue.

In order to restore structural integrity and functionality to the remaining bone, an endoprosthesis such as the DePuy Limb Preservation System is employed. The DePuy system consists of a variety of distal, proximal, mid-shaft, and total femur and tibia replacements depending on the location of the resection. The system is modular so that different sections can be combined to accommodate specific patient needs. The DePuy Limb Preservation System has received positive clinical trials in adults but is currently not usable in children because the DePuy system involves non-extendable components that do not accommodate for pediatric skeletal growth.

Current methods of treatment of affected children include amputation and in some cases implantable prostheses. There are more considerations in implanting prostheses in children than in adults, however. Because of the growth in children, multiple operations are often required to either extend the prosthesis periodically or replace the prosthesis after the child has reached maturity. In a study of 47 children with extendable tumor endoprostheses, the number of operations received by each child ranged from five to twenty-five with the average number being nine². The goal of implanting an expandable device is to decrease the number of operations.

Need/Market Analysis

Osteosarcoma and Ewing's Sarcoma are the most common types of pediatric bone cancer. There were 963 cases of Osteosarcoma and 576 cases of Ewing's Sarcoma reported worldwide between 1994 and 1998 for ages 0-19³. These patients would be the main targets for an expandable endoprosthesis device. Thus, the potential worldwide market would be approximately 300 patients per year. Despite the small numbers, the quality of life for these patients would be greatly improved if a successful expandable endoprosthesis device could be developed. Hence the implications of this project are still very important.

Benchmarking and Related Technology

Lewis Adjustable Expandable Prosthesis (LEAP)

The LEAP, introduced by Lewis in 1984⁴, was one of the first available expandable prostheses. The expansion of the LEAP prosthesis was achieved by a modified Jacob's chuck mechanism. Rotation of the outer sleeve engaged a threaded shaft that was advanced as rotation proceeded to achieve the desired expansion.

The LEAP expandable prostheses experienced early collapse of the expansion mechanism, which necessitated the development of ring spacers that solved this problem. Ring spacers are not supplied routinely and must be requested. Fatigue fracture was not common and only occurred in two patients in a twenty-two patient study. The first instance was at 5 years in a patient with a distal femoral LEAP prosthesis, and the second was at 9 years in a patient with a proximal femoral LEAP prosthesis. In addition, extensive Ti debris was common to the LEAP prostheses. Although the long-term effects of Ti debris are not known, its presence is considered a disadvantage. In addition, once the expansion was achieved by the Jacob's chuck mechanism, it was observed patients lost approximately 80% of their knee flexion capability. The pseudocapsule was found to be the restrictive element, and by resecting it completely not only was the metal debris removed, but knee flexion was restored. A complete pseudocapsulectomy became an integral part of the expansion process when employing the LEAP system⁵. Our surgeon advisor indicated that surgeons view the LEAP system as unreliable.

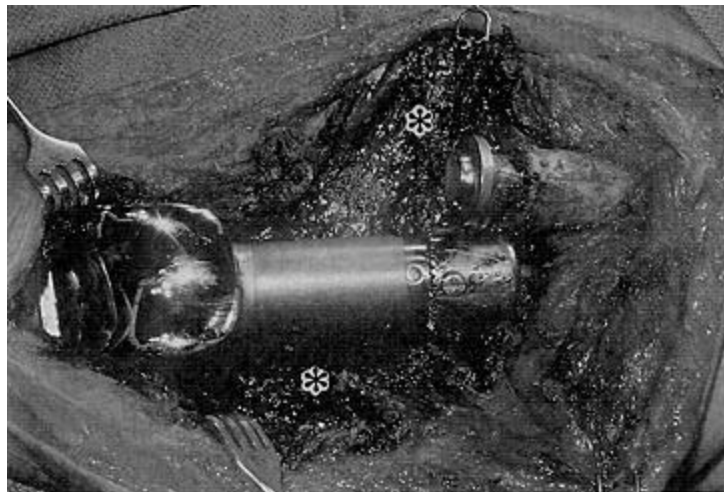


Figure 3.1: Intraoperative photograph of a patient with a LEAP distal femoral prosthesis showing a fatigue fracture 5 years after implantation. This prosthesis had collapsed 1.5 cm before fatigue fracture. The extensive Ti debris embedded into the thick pseudocapsule (*) can be seen⁵.

Howmedica (US Patent 5,326,360)⁶

Howmedica has developed² a non-invasive expandable endoprosthesis (see Figure 3.2). The device consists of a telescoping mechanism where the inner cylinder is extended by a threaded spindle. The spindle is rotated by a pinion, which is engaged by a ratchet tooth mechanism. The tooth mechanism is activated when two components on the underside of the knee which come in contact when the knee flexion angle is greater than 90°. The ratchet mechanism prevents any reverse rotation. In addition, a spring is connected to the pinion to ensure that it completes the revolution and returns to stable position. The device improves upon the earlier LPEA design because the distraction mechanism is isolation from the axial load.

This device replaced an earlier Howmedica endoprosthesis that used manual elongation (not shown, US Patent 4,892,546⁷) The manual elongation device also consists of telescoping mechanism extended by a threaded spindle. To elongate the mechanism, a small skin incision is made to access the turning screw with a screwdriver.

Typically, at the time of resection, a surgeon implants a standard modular endoprosthesis. In 12-18 months, a follow-up surgery is done where the pseudocapsule is resected and the standard module is replaced with an expandable module. The manual elongation device has been successful in expanding the endoprosthesis in children. Several patients have reached skeletal maturity. The non-invasive device is more recent and has been successfully implanted in two children². However, the device is limited to use in the distal femur. This device is currently available only in Europe and has not been FDA approved.

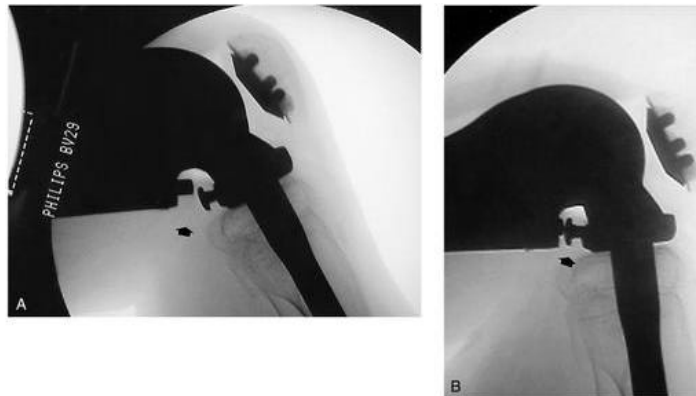


Figure 3.2: Intraoperative fluoroscopic view of the knee after implantation of an automatic elongation module of the distal femur shows (A) the ratchet mechanism before activation at flexion less than 90° (arrow). (B) Reaching flexion of 90°, the ratchet mechanism is activated (arrow)².

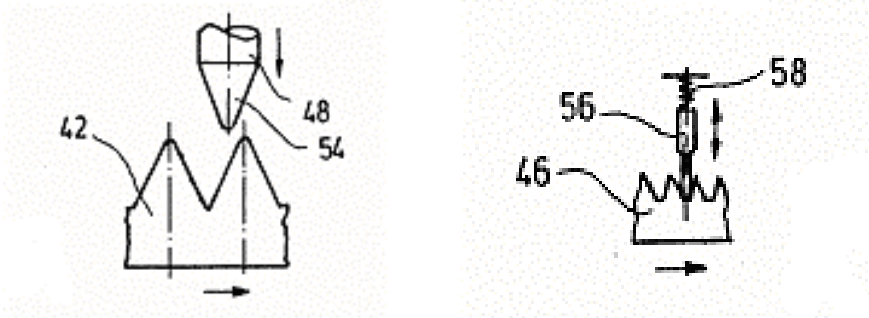
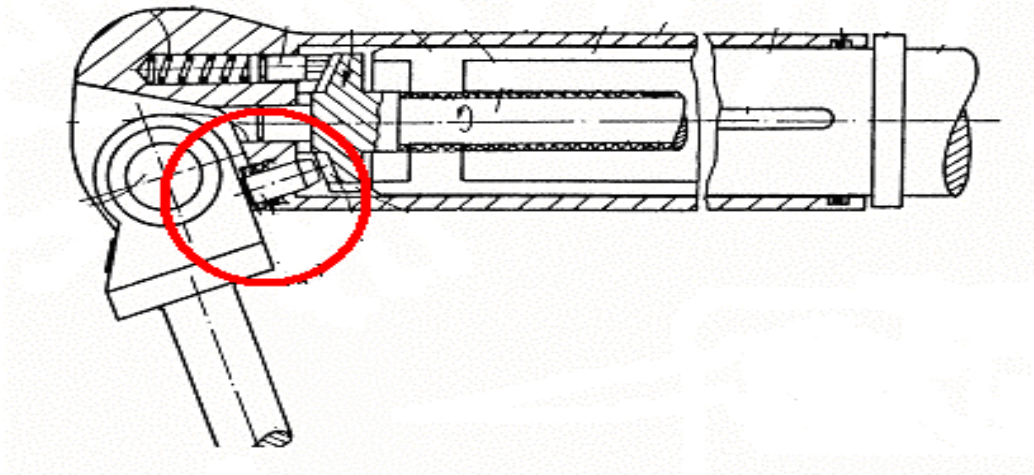


Figure 3.3: Schematic drawing of Howmedica device. The inner cylinder telescopes from the outer cylinder through unidirectional rotation of the threaded spindle. Ratchet and pawl mechanism is activated when knee flexion reach 90°. Ratchet (circled red) is isolated from the axial load⁶.

Phenix Expandable Prosthesis

PHENIX Medical of Paris, France has created and tested another design for a non-invasive expandable endoprosthesis. Instead of using the threaded rod extension mechanism as other expandable prostheses, the Phenix uses a compressed spring to create extension. The Phenix consists of a titanium tube with an annular protrubance inside a polyethylene tube with an outer casing (Figure 3.4a). The titanium protrubance extends into and is pushed tightly into the polyethylene tube. Between the two tubes is a spring that is initially compressed.

An external coil is used to create a magnetic field and induce current into antennae located inside the device (Figure 3.4b). This current heats up the device enough to soften the polyethylene at approximately 130° F. The polyethylene located directly around the titanium protrubance is heated and softens. This allows the spring to decompress and the titanium protrubance moves incrementally through the heated portion.

With the Phenix device, lengthening were received relatively pain free. Lengthening of 5 to 10 mm were achieved on average and the entire procedure typically lasted less than 10 minutes⁸. This device has been tested in Europe, but has not been FDA approved.



Figure 3.4, a,b: Phenix device: a)prosthesis inserted in leg, b)Coil used to cause lengthening of device⁹

Verkerke: Electric and Magnetically driven motion screw

Verkerke et al. have described another two other systems in 1989¹⁰. The first system is magnetic. It uses an external rotating electromagnet to induce rotation of a small permanent magnet inside the prosthesis. The smaller magnet then turns a motion screw via a gearbox. The motion screw is placed in the outer tube, which is threaded on the inside. When the motion screw rotates, it moves through the outer tube and forces the two tubes apart. Four keys on the outer tube slide in keyways in the inner tube preventing rotary movement between the tubes.

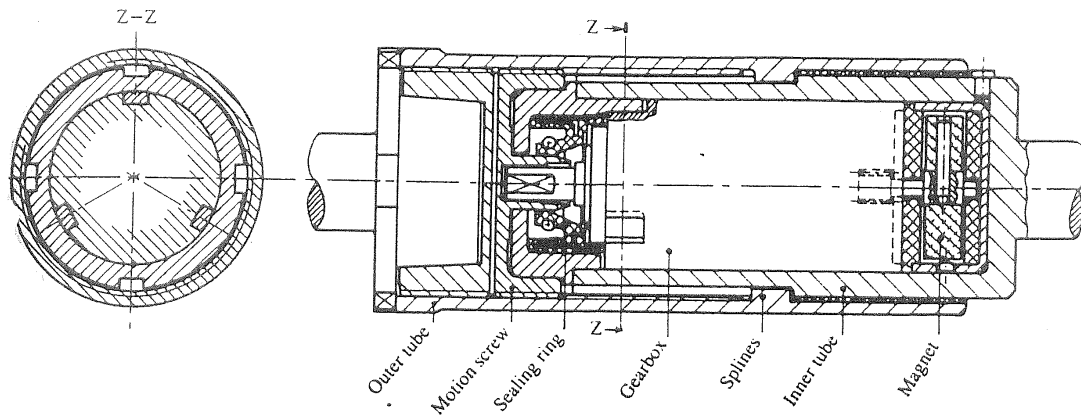


Figure 3.5: Verkerke's Magnetically Driven Model¹⁰



Figure 3.6: Verkerke's external magnet¹⁰

The second system uses electric power. It uses an electric motor to turn the motion screw instead of a magnet. Similarly, the motion screw forces two telescopic tubes apart. A coil is placed around the leg which converts electric current into an electromagnetic field. A coil inside the prosthesis converts this field into an electric current that powers the electric motor.

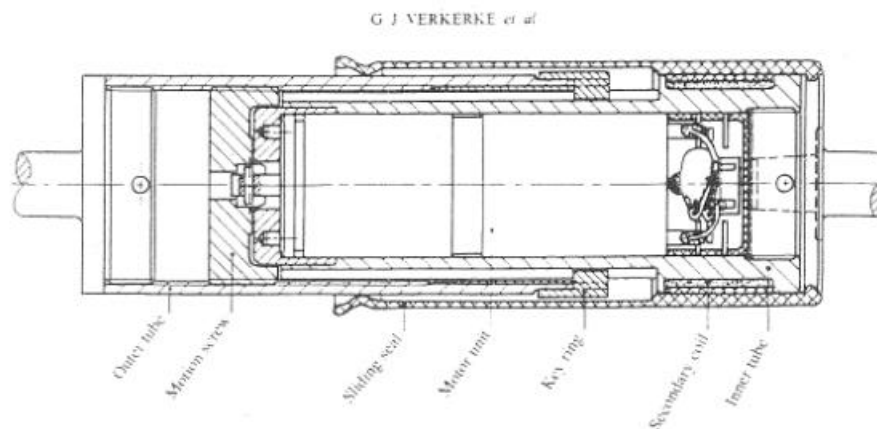


Figure 3.7: Verkerke's Electric Model¹⁰

In animal studies, both the electric and magnetic model showed to be effective lengthening mechanisms. Verkerke suggested using the magnetic one because it was more compact and potentially safer due to the absence of electric currents in the body. A preliminary clinical trial¹¹ conducted in 1997 involving one patient showed positive results but much more research needs to be completed on the reliability of these designs. No failure of the device was observed in the study but an infection due to an ingrown toenail necessitated the removal of the device 15 months postoperatively.

ISKD (US Patent: 6,336,929)¹²

The basic internal mechanism of the ISKD is shown in Figure 3.80¹³. The ISKD is designed to lengthen under physiologically tolerable movement. The ISKD lengthens as small oscillations between two telescoping sections are mechanically converted to one-way distraction. As the patient rotationally oscillates the limb either manually or during walking, the device gradually distracts. Since the device is designed to lengthen under rotational displacement as small as 3°, non-physiologic movement is not required to achieve distraction. However, rotational oscillations as large as 9° are allowed if greater rotation but fewer oscillations are desired. Thus, the rate of linear distraction depends on the frequency and intensity with which the patient oscillates the limb. The rate of distraction is monitored using an external hand-held sensing device. In a test of 40 adults¹³, findings were promising. No implant related infections, non-unions, malunions or joint contractures were observed. The ISKD expanded at an average rate of .82mm/day which is about thirty times greater than the rate required for use in children however. In addition, the maximum time that an ISKD remained implanted was 327 days but it would have

to last approximately 10 years in a child. The ISKD has received FDA approval for use in patients.

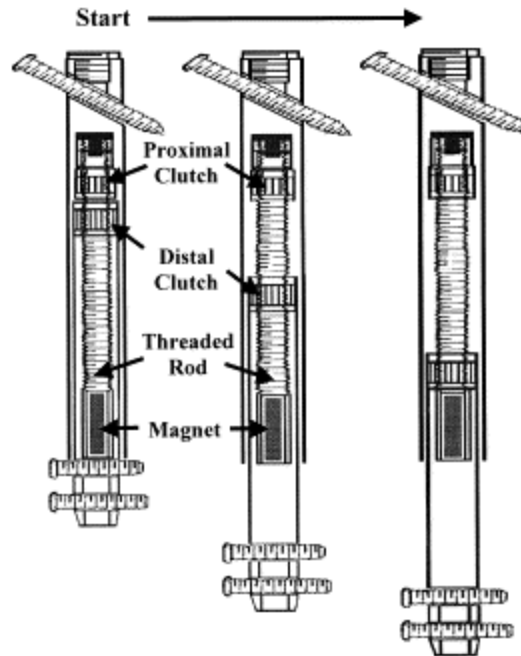


Figure 3.8: Function of the ISKD device¹³

Biomechanical Analysis of the ISKD device

Biomechanically, the ISKD mechanism is driven by the resultant torque from the moments in the z-direction on the tibia during normal gait. During the gait cycle, the center of pressure moves from the heel towards the toe (Figure 3.9a). This creates a moment arm around the ankle whereby the foot exerts a moment on the tibia (Figure 3.9b). Similarly, the femur exerts a moment on the tibia. Figure 3.9c illustrates the respective moments through the gait cycle, which varies from positive to negative. These momenta are balanced by muscle forces and a very small torsional deformation of the tibia (Figure 3.9d.) Bone has a very high torsional rigidity of compared to soft tissue. (Torsional rigidity characterizes a material's resistance to torsion and is the product of the polar moment of inertia and modulus of elasticity in shear.) When the ISKD is implanted on the tibia, the two clutch mechanism isolates the proximal tibia from the distal tibia and they are free to rotate in relation to each other. This lowers the tibial resistance to torsional motion, which increases the angle of tibial torsion. The proximal and distal sections of the tibia rotate in relation to reach other and drives the inner and outer cylinder apart.

The analysis is similar for the femur, where the moments are exerted from the tibia and the pelvis.

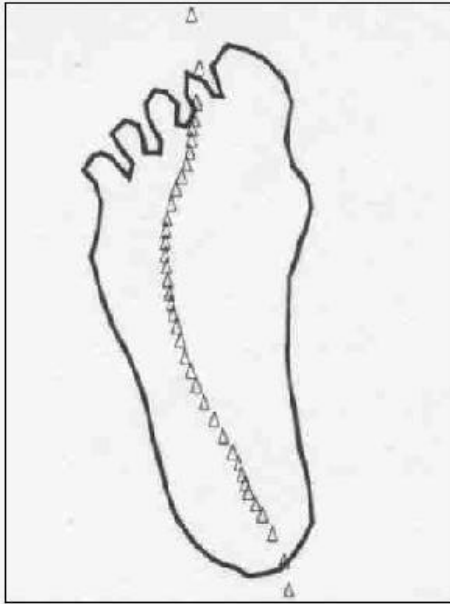


Figure 3.9a: Center of pressure during normal gait. The normal force moves from the heel to the toe as the gait cycle moves from heel strike to terminal stance¹⁴

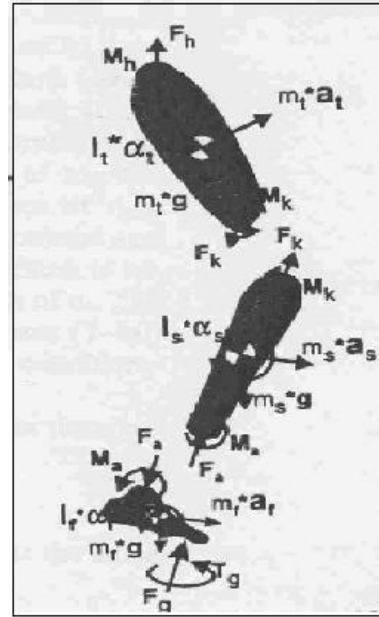


Figure 3.9b: Intersegmental forces and moments¹⁴

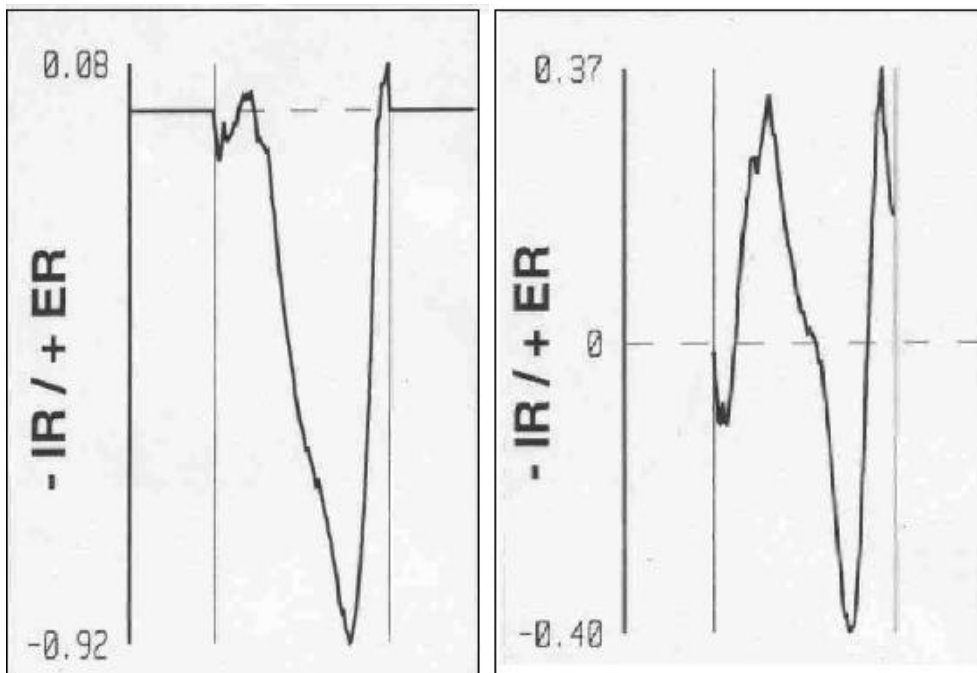


Figure 3.9c: Moment around the z axis in units of (% body weight * height). A is the moment exerted by foot on tibia. B is the moment exerted by tibia on femur¹⁴.

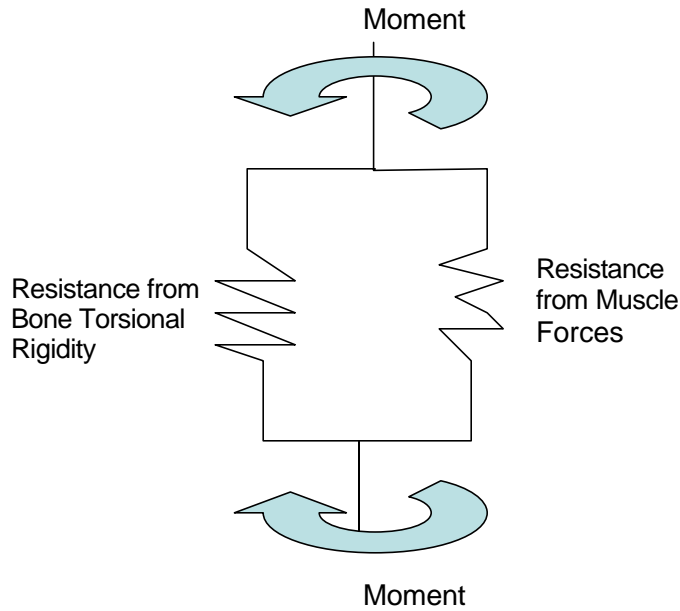


Figure 3.9d: Circuit representation of the moments on the tibia. The bone and muscles resist the moments from the foot and femur.

Scientific Background

Anatomy

For this project, the anatomical features of the lower extremity are of particular interest. In particular, the two large bones in the lower extremity, the tibia and the femur are of greatest concern. The femur (see Figure 3.10a) lies between the pelvis and the knee. It is the largest and strongest bone in the body. The main features of the femur are the head, the neck, the shaft and the condyles. The head is located in the most proximal section of the femur and interfaces with

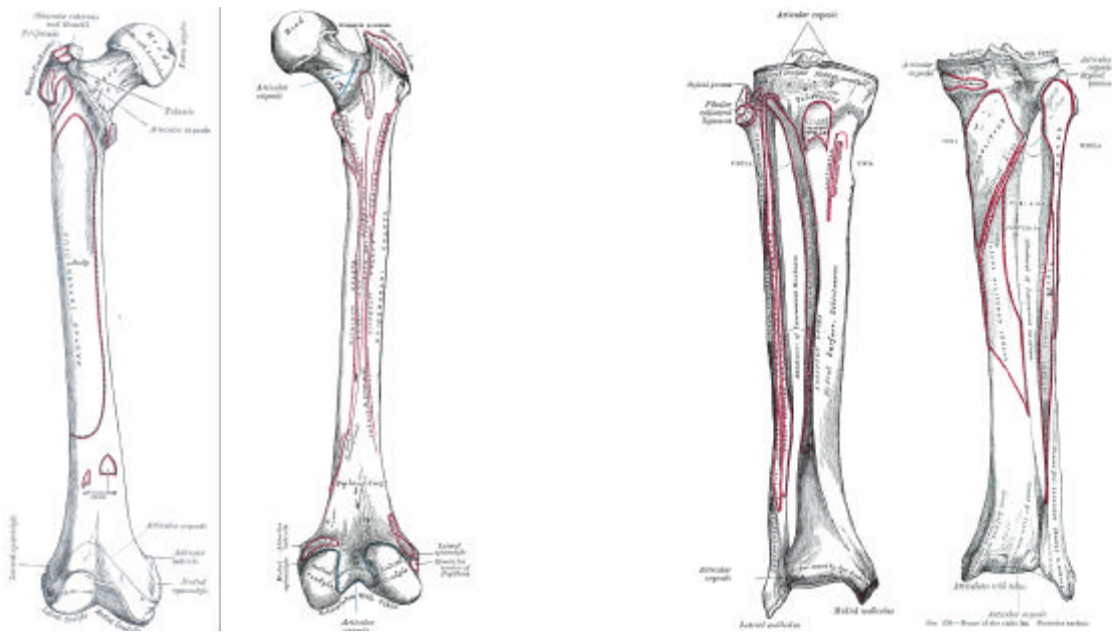


Figure 3.10 a,b: a)Femur, and b)Tibia

the pelvis in a ball and socket type of joint. The head connects to the shaft through an angled section of the femur called the neck. The diaphysis is the long, cylindrical portion of the femur distal to the head. It is slightly arched, being convex in front and concave behind. It is however strengthened by a prominent longitudinal ridge known as the *linea aspera*. The diaphysis terminates distally with the inner and outer condyles. The condyles are large eminences which articulate with the patella in the knee¹⁵.

Distal to the knee are two large bones that form the lower leg: the tibia and the fibula. The tibia (see Figure 3.10b) has a larger diameter than the fibula. As the fibula is not targeted for an implantable replacement, the focus will be solely on describing the tibia. The tibia consists mainly of the head, and the shaft. The head articulates with the condyles of the femur through the internal and external tuberosities. The shaft is of a triangular prismoid form, broad above, gradually decreasing in size then enlarging again to its distal extremity¹⁶.

Forces and Stresses

Forces and stresses on the bones are one of the main design considerations as the device must be able to handle similar situations. For a 90.7 kg person, the compression and tension stress are shown in Figure 3.11. The design of the project focuses on the shaft, the average maximum forces experienced here are: maximum compression=8.6 MPa, maximum tension=6.3 MPa. For the standing position (“at attention”) these stresses are multiplied by 0.6, for walking by 1.6 and for running by 3.2⁹. One would expect an upper limit of the child to be about 90kg so one should design the minimum stress to be 27 MPa in compression and 18 MPa in tension. Furthermore, the number of steps in an active person is approximately 10,000 per day^{17,18} so the device should accommodate approximately 30,000,000 loading/unloading cycles to be able to last 10 years.

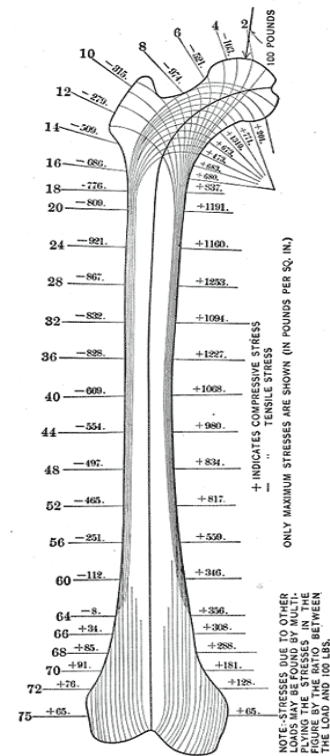


Figure 3.11: Forces on the femur

Pseudocapsle Formation

One of the main complications of endoprosthesis is the formation of overgrowth, or pseudocapsules around the implanted prosthesis². The stiff tissue, which grows as a result of inactivity, is more often associated with patients going through the chemotherapy process. The pseudocapsule restricts movement and can also prevent the device from expanding. Often a complete resection of the pseudocapsule is necessary after 12 to 18 months. After this resection, the pseudocapsule typically does not regenerate and the device can function normally. This is an important limitation of existing expandable endoprostheses.

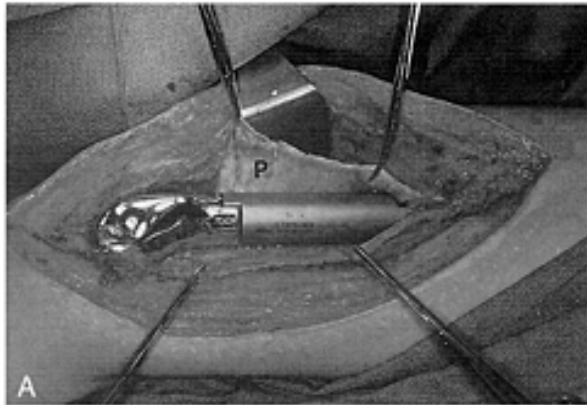


Figure 3.12: Surgery showing resection of the pseudocapsule (P)⁵

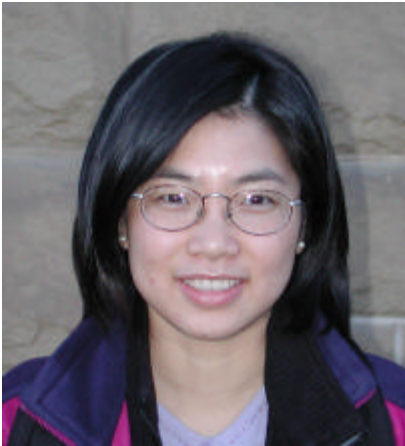
Problem/Needs Statement

This project is to design an implantable device to treat massive bone loss in the lower limb of pediatric patients due to a tumor resection or trauma. A key feature of this device is the ability to maintain limb length equality (through expansion of the device) during skeletal growth at regular intervals until the patient reaches skeletal maturity. The device should allow expansion (through external cues) without surgical intervention after initial implantation.

The device will be part of the DePuy Pediatric Limb Preservation System (LPS). The new device can be based off the FDA approved Intramedullary Skeletal Kinetic Distractor (ISKD) used to treat tibial and femoral pediatric fractures. The ISKD was not designed for massive bone loss and expands at too fast a rate for pediatric patients.

Project Team

Ying Jun Li

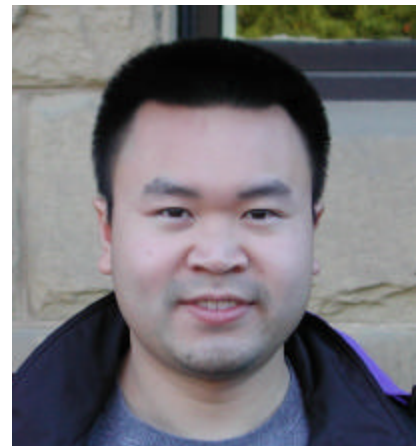


Ying is a first-year Masters student in Mechanical Engineering / Biomechanics Division. She grew up in New York City and graduated with a BS in Mechanical Engineering from Harvard University. Since Harvard, Ying worked as a management consultant for two and a half years, and more recently was a research assistant in the Stanford Cell and Molecular Biomechanics Laboratory. Ying's design experience included the design and construction of a laboratory scale model to study heat transfer from an aircraft engine. This work was sponsored by Boeing Company where she had spent a fun summer as an intern. In addition, Ying has basic knowledge of computer-aided machining and digital electronics design. Ying plans to pursue a PhD in

bioengineering.

Henry Liu

Henry attended the University of Toronto as an undergrad in Biomedical/Electrical Engineering. He is currently a first year Master's student at Stanford. He previously worked extensively with Profs Ethier and Flanagan at UofT in glaucoma type research. Henry is knowledgeable in C/C++ and Matlab programming languages. He has had some experience designing FEM models with Ansys during his senior thesis and solid 3D geometry with Solidworks.



Kate Tollon

Kate is a first-year Masters student in the Design Division of the Mechanical Engineering Department. She graduated from Georgia Tech with a BS in Textile Engineering in the spring of 2001. There her coursework consisted of mechanical engineering, textile, and polymer classes. Kate has worked as a research intern at the Institute of Paper Science and Technology on a project to characterize the permeability of paper using heat transfer and at Stanford is currently working on a project to characterize a haptic device for a laparoscopic surgical simulator. She is interested in smart product design as well as medical device



design.

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Purpose of Design/Model

Pediatric patients currently require multiple follow-up surgeries after massive bone resection and implantation of an endoprosthesis. The purpose of this design is to enable non-invasive and controlled lengthening of the endoprosthesis. This device will lower the number of follow-up surgeries; thereby lowering the risks of infection and patient pain and suffering.

Project Goals

The goal of this project is to prototype and test an endoprosthesis capable of controlled lengthening for use in pediatric patients who have undergone a massive bone resection of the lower limb. The design, analysis and testing will be focused on satisfying the needs in children ages 6-15 within two standard deviations of the mean weight and height.

Our deliverables include a working prototype demonstrating a functioning expansion mechanism for the endoprosthesis. In addition, theoretical calculations of strength and reliability of the product will be made available.

Due to strength and biocompatibility restrictions, the actual device will most likely be manufactured from titanium. However, titanium machining resources are not readily available at Stanford. The team will prototype the device to demonstrate the basic physics and design concepts using another material. The team will also provide design schematics of the device.

Scope of the Project

The scope of our project is as follows:

- ?? Preliminary exploration of other design concepts
- ?? Increased understanding of the ISKD device
- ?? If the team receives the ISKD device and engineering assistance from Orthofix in time, modification of the ISKD device to enable controlled lengthening
- ?? Theoretical calculations of the strength and reliability of the device
- ?? Prototype of the device using a material within the team's machining capabilities
- ?? Design schematics of the device
- ?? Documentation for the design logic and design choices

The following are excluded from the scope of our project:

- ?? If the team does not receive the ISKD device and assistance from Orthofix in time, the team will design and prototype the modification and a mock-up of the ISKD. More specifically, the device will not have the sophistication of the ISKD
- ?? The device will not necessarily lengthen to skeletal maturity. A maximum of one surgery will be allowed to exchange the lengthening module so that multiple telescoping cylinders are not required.

- ?? The team will not produce a titanium prototype
- ?? The team will attempt, but not necessarily complete, a finite element analysis of the device

The current scope of the project meets the spirit of the original project description proposed by the sponsor. This device will significantly improve the health and quality of life of pediatric endoprosthesis users. Modifications to the original project description stem from project constraints and conversation with a surgeon expert, e.g. licensing agreement with Orthofix and allowing one surgery to exchange the growth module,.

Functional Requirements

After speaking with DePuy and a musculoskeletal oncology surgeon, the requirements for the project are:

- ?? Implantable prosthesis capable of controlled lengthening
- ?? Compatible with LPS system
- ?? Meets DePuy reliability standards
- ?? Use ISKD device as the basis for design
- ?? Initial length of 9 to 10 cm
- ?? Extends at least 6 cm beyond original length
- ?? Average lengthening of 1 mm per month
- ?? Maximum lengthening per session is 2 cm to avoid nerve and soft tissue damage. However, actually lengthening limited to approximately 5 mm per session due to resistance from pseudocapsule
- ?? Reliable functioning for 10 years
- ?? Maximum cost \$7500 each

The nice-to-haves requirements are:

- ?? Continuous lengthening preferred over monthly lengthening sessions
- ?? Lengthenings done at home preferred over physician visits
- ?? Retractable device

These requirements translate to the following specific design requirements:

Design Requirements	Importance (1-10)
Device Usage:	
Implantable in children	10
Surgery by trained orthopedic surgeon	10
Follow-up lengthenings by oncologist or primary care physician (not require orthopaedic surgeon)	8
Follow-up lengthenings by nurse or at home (not require physician supervision)	5
Device Geometry:	

Initial length: 9 to 10 cm	10
Extends at least 6 cm beyond original length	10
Outer diameter of device: 2 cm	10
Male connection dimensions*	10
Female connection dimensions*	10
Taper lock dimensions*	10
Biomechanics:	
Max sustainable compression**	9
Max sustainable tension**	9
Max sustainable vertical shear**	9
Favorable fatigue requirements**	9
Favorable wear / corrosion requirements**	9
Generates enough torque to overcome resistance from pseudocapsule	10
Device Operation:	
Average expansion 1 mm per month	10
Maximum lengthening per session is 2 cm	10
Telescoping mechanism (not require second operation)	4
Device continuous operation	5
Functions for 10 years	8
Maintain existing length during failure (not expand or collapse)	8
Retractable	2
Audible alarm is device fails	2
Materials:	
Biocompatible	10
Max surface temperature (if heat is involved)	10
Min surface temperature (if heat is involved)	10
Regulatory and IP:	
Capable of FDA 510K route	6
Do not require licensing of competitor product	6

Costs:	
Manufacturability in DePuy partner facilities	6
Total manufacturing costs not to exceed \$7500	8
Schedule:	
Target testing date*	8
Target marketing date*	8

* Specifications available in CAD file. See Appendix for representative dimensions

** Awaiting specifications from DePuy

Regulatory Considerations

The Pediatric Expandable Endoprosthesis is a medical device because it is used for the treatment of primary bone cancer but does not achieve its intended action through chemical action or being metabolized. We propose that the PEE follow the 510K route to FDA approval. It is similar to the ISKD device, which is already FDA approved.

However, a 510K route may not be permissible, because the intended use of the PEE is long-term lengthening vs. short-term lengthening of the ISKD. If that becomes the case, a FDA expert suggested 3 possible alternatives to the 510K: 1) Humanitarian, because DePuy will not profit from the device; 2) Compassionate, because it alleviates the pain and suffering of multiple surgeries; or 3) Emergency use if the surgeon deems that no other device is appropriate.

Vision/Strategy

Several designs concepts were developed as possible solutions to the problem. These designs were evaluated analytically to find the optimal solution. After conversations with the project sponsor, we determined that a modification of the ISKD would be the best route since DePuy is in the process of licensing the technology. Therefore, the design focus shifted to concentrate on possible solutions involving the ISKD as a basis for the design. Several possible solutions were developed and further analysis is underway to choose the best design option.

Overview of Work Completed

The mechanical function of this device can be divided into two main problems: achieving a lengthening and powering the mechanism. Two main mechanisms were investigated for lengthening the device: use of a threaded rod and use of scissor jacks. On the other hand, many different methods were devised to power the device.

A threaded rod was ultimately chosen as the lengthening mechanism because it was a proven technology. For the powering mechanism, electro-mechanical and simple mechanical methods were investigated. Several possible solutions were generated, and a conclusion was reached that a mechanical means of powering the device would be the best option due to regulatory constraints and the desire to simplify.

Several of the mechanical based options require further analysis. Construction of prototypes is underway with manufactured clutches. The designs all meet the dimensional and materials requirements, but they have not been proven to meet the expansion, stress and reliability requirements. With the developed prototypes, tests can be performed to quantitatively rate the designs based on reliability. With this measure, further analysis will be performed to choose one design that satisfies all of the critical design criteria.

Design Concepts Generated

Lengthening Mechanisms

Threaded Rod

The first method has been thoroughly explored by all past devices. The basic idea is to use a threaded rod in conjunction with a threaded receptor (or nut). As the receptor rotates down the rod, the device is lengthened.

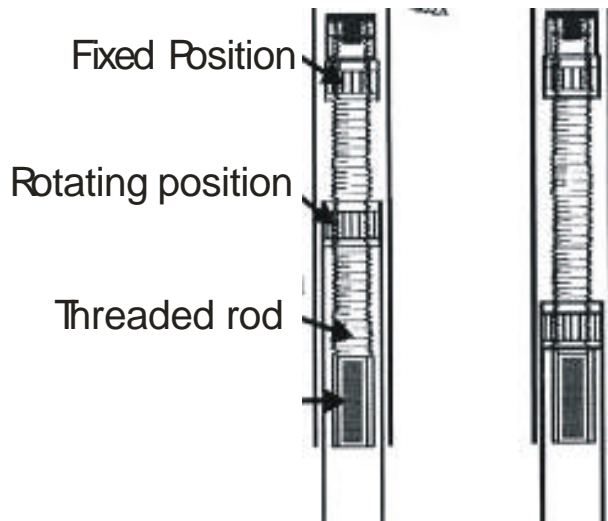


Figure 5.1: Threaded rod and rotating receptor cause elongation

Scissor Jacks

The second idea of expanding a device is a novel application of an existing technology not found in previous literature. It uses a series of scissor jacks to increase the length of the device. The advantage over the threaded rod is that the final length can be more than twice the original length. Referring to Figure xx, the purple members are brought in closer to the pivot on the bottom blue members by sliding along the groove. This causes the jacks to move into an upright position.

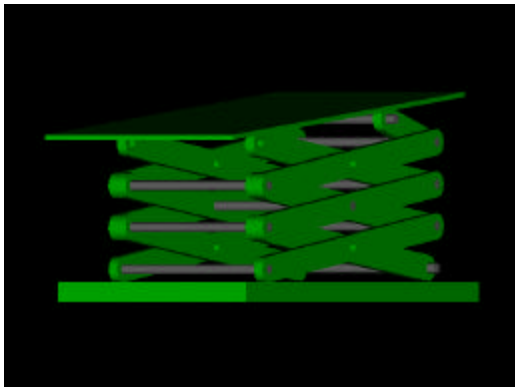


Figure 5.2a: Collapsed scissor jack¹⁹

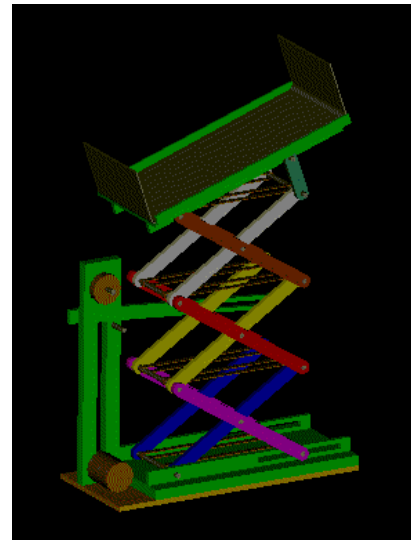


Figure 5.2b: Expanding Scissor Jack¹⁹

Lengthening Powering Methods

Replacement of the Proximal Clutch in the ISKD with a Free Clutch

The ISKD works on the premise that two clutches rotating in different directions causes a lengthening to occur because the distal clutch can move only in one direction with respect to the threaded rod. Replacement of the proximal clutch with a free clutch under the original design specification would imply the device would not function. However, the distal clutch is still biased to turn on one direction only. By using a free clutch, this bias combined with frictional forces maybe sufficient to elongate the device but at a much slower rate. Rotating the distal

clutch in the free direction quickly from rest before the threaded rod has had a chance to catch could be sufficient to extend the device. Since the rotation would only occur during a rapid rotational acceleration, it would be much more infrequent than the original design and perhaps sufficient to slow the device enough to be used in a pediatric application. The parameters to determine the average rotational amount would be the frequency of high rotational accelerations experienced by the patient, the inertia of the rod with respect to the distal clutch and any frictional parameters present in the system.

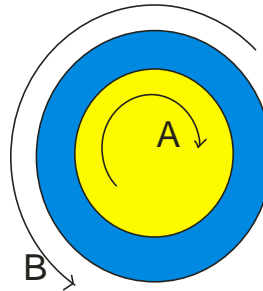


Figure 5.3: Rapid rotational acceleration of the distal clutch (blue) causes a rotation counter-clockwise (B). The rotational inertia of the threaded rod causes it to resist acceleration and appears to rotate in the opposite direction (A).

Modification of the ISKD Indicator Locking Mechanism

In the latest patent incarnation of the ISKD¹², a control mechanism already exists for controlling the rate of elongation. A piston and spring mechanism coupled with a series of bores allow easy rotations in finite steps of 90°. When the piston (548) is trapped inside one of the bores (526) then rotation is impossible counterclockwise due to the sharp slope (545) of the groove. Rotation is possible clockwise because the slope is less (541) and the bore is sloped similarly on one side (544). However, a much greater force is necessary to overcome the spring force when in a bore than the freely rotating position between bore holes. The idea behind the ISKD locking mechanism is to supply a high torsion a few times a day. This would move the piston out of the bores and allow normal activity to move it to the next bore. By controlling the number large torsion movements, the elongation rate can be controlled.

Further possible improvements to the design include varying the number of groves so that smaller extensions would be achieved. However, at the current rate of the device, the ISKD already elongates an acceptable .25mm per groove. Another possibility being explored is to have the piston powered magnetically or electrically to retract on demand. This coupled with a small amount of simultaneous torsion would be able to have finer control in determining the elongation rate rather than relying on physical activity.

Normal force exerted by spring equals spring constant \times compression distance.

A preliminary calculation indicates that:

$$M_z = 1\% \text{ body weight} \times \text{height} = 20 \text{ Nm (for a 100 kg, 2 m person)}$$

$$N_s = 4 \text{ kN (for 0.01 radius, 0.5 coefficient of friction between magnet and rod)}$$

We are in the process of refining these calculations to determine if the magnet ISKD is feasible. If so, the lengthening would be done during physician visits every 3 months. The patient would place his/her leg inside the electromagnet. Holding the knee so that it does not rotate, a physical therapist would rotate the foot and distract the device.

Potential limitations:

- ?? The spring force required to prevent clutch rotation is high. This may wear down the threads of the rod over time. One possibility is to thread the inner surface of the permanent magnet to increase the contact surface area between the magnet and the threaded rod.
- ?? The number of rotations necessary during the lengthening session is high and may become tedious. One possibility is to design a device that rotates the foot without need for physical therapist. Another possibility is to design the magnet to be an on/off switch where the ISKD could be locked/unlocked for extended periods of time.

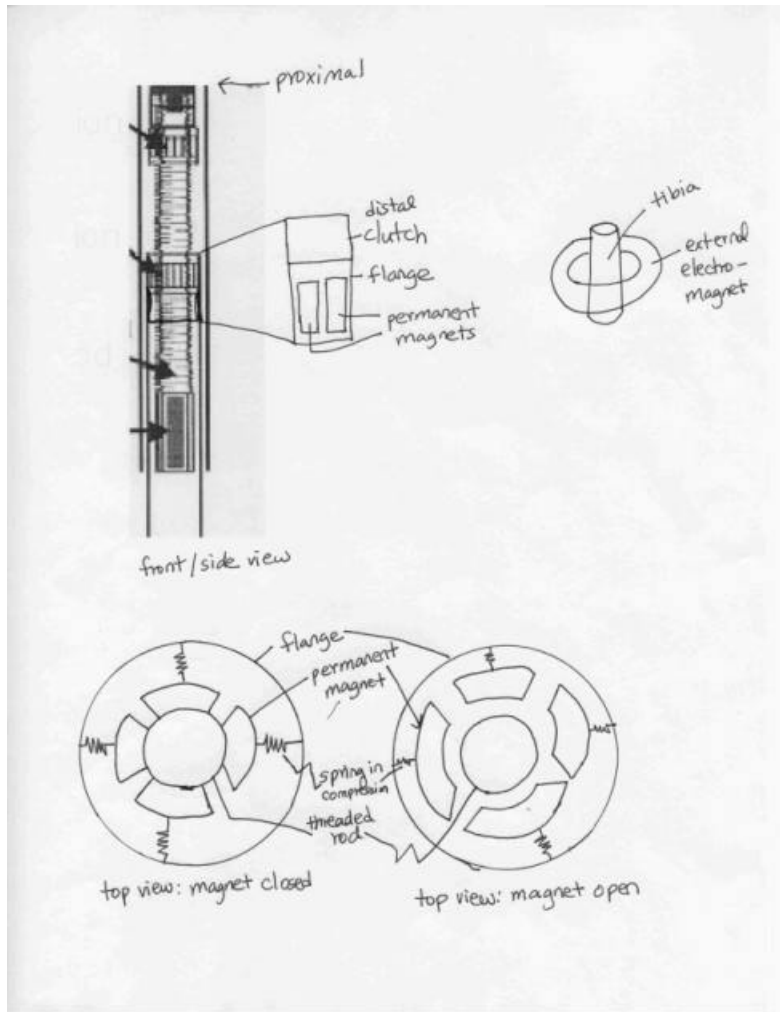


Figure 5.5: Top left: side view of the clutch with a flange attached to the distal end. Permanent magnets are attached to the flange. Bottom: The flange in locked and unlocked position. In the locked position, the magnet is pushed against the threaded rod and prevents the clutch from rotating. In the unlocked position, the magnets are pulled back to allow the clutch to rotate. Top right: Schematic of the electromagnet inside the tibia.

Tibial Rotator

The Tibial rotator also uses the rotation of the distal tibia with respect to the proximal tibia to drive the lengthening mechanism. In this case, the clutches are modified so that only a torsional angle beyond the physiological 2-5° would rotate the threaded rod. (Figure 5.6). The ratchet is linked to the LPS modular system on one end and the outer cylinder on the other. A spring roller clutch is connected to the threaded rod and is fit into the outer cylinder. As the ankle is rotated with respect to the knee, the ratchet mechanism is driven. The spring roller clutch allows the inner cylinder to move with the outer cylinder in one direction and decouples the two in the other direction. This allows the threaded rod to move with respect to the outer cylinder in one direction and creates a distraction.

The Tibial Rotator is set up so that the knee is held fixed and the foot is rotated. The foot is placed on a foot rest which is then turned to activate the ratchet mechanism.

Potential limitations:

- ✍ The rotational freedom of the clutch mechanism may result in uncomfortable gait. This may be exacerbated by this design which allows for more than the physiological rotation. Further analysis from speaking with engineers / physicians / users would provide the actual magnitude of the problem.
- ✍ The torque on the device might loosen the stem from the bone intramedullary canal overtime. On further reflection, the torque would be transmitted to the clutches because they have lower resistance than the stem / bone connection. We will further discuss this issue with our sponsor.

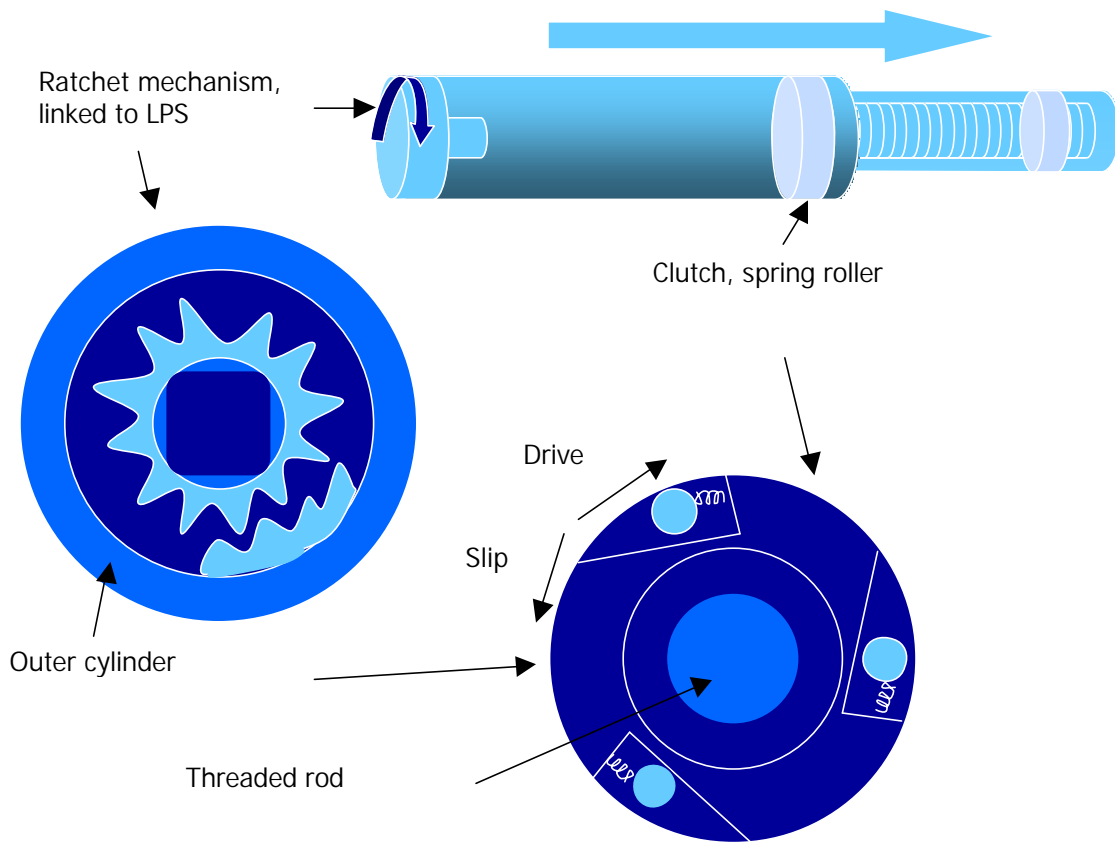


Figure 5.6: Tibial rotator design

Transcutaneous Energy Transfer Driven Ratchet

Transcutaneous Energy Transfer (TET) is under intense research as an external means of powering an internal system. In TET, an external coil is powered and produces an electromagnetic field. This electromagnetic field then induces a current in an internal coil located inside the body. The internal coil is implanted against the skin to decrease the distance from the external coil. Power is then provided inside the body (Figure 5.7).

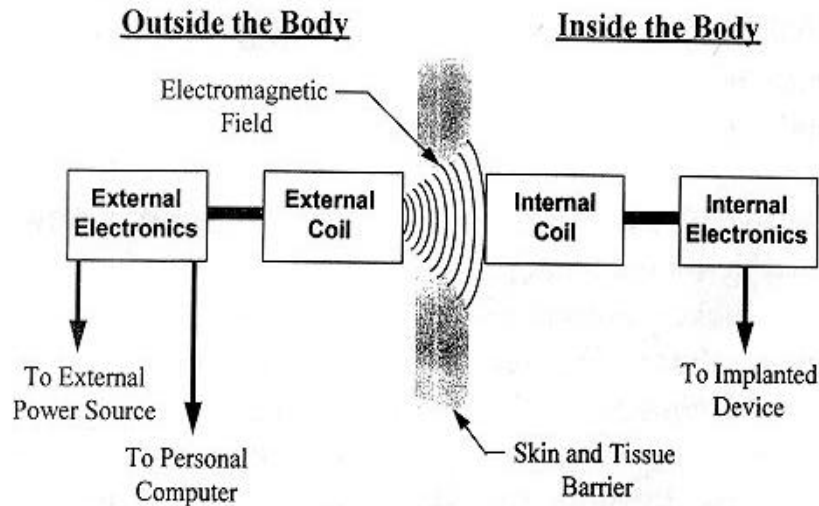


Figure 5.7: Schematic of Transcutaneous Energy Transfer

This principle could be used to power the expandable endoprosthesis. One idea is to use a magnetically driven ratchet. The ratchet has a permanent magnet as well as an electromagnet connected to a spring. The electromagnet is activated with an external coil using TET. The magnet is then attracted to the permanent magnet, and drives the ratchet forward. This advances the threaded rod and translates into a lengthening (Figure 5.8).

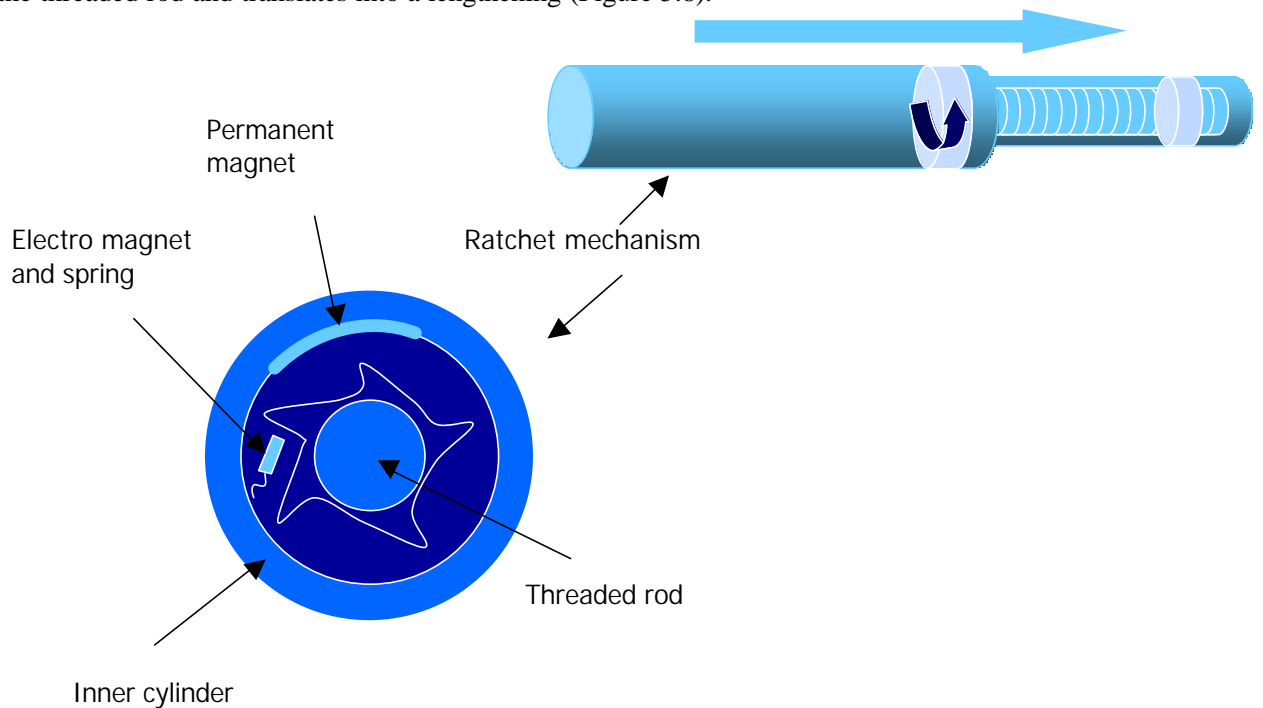


Figure 5.8: TET driven ratchet modification of ISKD

Evaluation of Designs

After some thought and pressure to conform to the ISKD design, the scissor jacks method of expansion was abandoned. The threaded rod designs have been proven mechanisms in several technologies as mentioned in the benchmarking section of this report.

The concentration of the group has thus been on developing a way to power the mechanism at a controllable fashion. Five designs were considered for the Pugh analysis: ISKD Free Clutch, ISKD Indicator, Magnetic ISKD, Tibial Rotator, TET Ratchet.

Criteria	Weighting	Design (Scale 1-10)				
		ISKD Free Clutch	ISKD Indicator	Magnetic ISKD	Tibial Rotator	TET Ratchet
Implantable in children	10	10	10	10	10	5
Surgery by trained orthopedic surgeon	10	10	10	10	10	10
Ease of followup lengthenings	8	10	6	6	6	6
Lengthening controllability	6	2	8	8	8	8
Initial length: 9 to 10 cm	10	10	10	10	10	10
Extends at least 6 cm beyond original length	10	10	10	10	10	10
Strength	9	8	8	8	8	8
Reliability	10	6	6	8	6	7
Average expansion 1 mm per month	10	5	10	10	10	10
Telescoping mechanism (not require second operation)	4	2	2	2	2	2
Capable of continuous lengthening	5	10	5	5	5	5
Maintain existing length during failure (not expand or collapse)	8	8	8	8	8	8
Retractable	2	1	1	1	1	1
Biocompatible	10	10	10	8	10	5
Capable of FDA 510K route	6	7	7	6	6	3
Do not require licensing of competitor product	6	8	8	8	8	2
Relative Cost	8	8	7	6	7	5
Total (% ideal)		80%	81%	80%	81%	69%

Based on the Pugh analysis, all four mechanical modifications of the ISKD design are closely matched in terms of following the critical criteria. The TET driven ratchet performed slightly worse in the Pugh analysis, mainly due to increased complexity and biocompatibility issues. Because the other four devices performed relatively equal on the Pugh analysis, it is difficult to determine which design idea should be chosen. An important characteristic of the designs would be their ability to withstand the forces and stresses applied and continue to function normally. Were this known, it would be a defining criteria that would help determine which design to pursue. Therefore, the next step is to perform reliability tests on the four devices to evaluate this characteristic. The results will then be used to make an informed decision to choose one device.

Overview

To satisfy the project deliverables, we have defined a series of tasks that must be accomplished and a timeline to describe by when they should be accomplished. We have outlined tests that we plan to perform to validate our device. We have also examined issues that could become hurdles in our project and determined steps to solve the problems if they arise.

Deliverables

Our deliverables will be a 3D CAD model and working prototype demonstrating a functioning expansion mechanism for the endoprosthesis. While the device would most likely be manufactured from titanium, the prototype might be machined out of a more manufacturable material.

In addition to the working prototype and CAD model, we will have theoretical calculations of strength and reliability. We will also perform mechanical testing on the device as a means of validation.

Methodology

The 3D CAD models will be created using SolidWorks. These drawings will be begun immediately and iterated as the design is refined.

Theoretical calculations will be performed initially as proof of concept, and some mechanical tests will be performed using initial prototypes. Once the working prototype is created, more robust mechanical testing will be performed to validate the design. FEM may be performed using the CAD drawings that were created.

Reliability and Validation

There are several tests that need to be performed to determine reliability and validate the design. Specific design requirements as outlined in the specifications will be tested according to the procedure that DePuy used to test the LPS devices.

The prototype will be tested for mechanical properties such as forces and torques during running and other high impact activities. An MTS machine is available at the Palo Alto VA Medical Center where the device can be tested.

One test that must be performed is cyclic loading. This is important because although the ISKD is a functioning device, it is designed to be implanted for several months to a year. The device we create will be intended to remain in the leg for up to 10 years. If the average person takes 1000 steps a day, the device must be able to function for three and a half million cycles. We plan to use the MTS machine for initial cyclic testing and project long-term use via established fatigue curves.

Torsion in the leg will need to be simulated as well to insure that the device components will not wear or loosen with respect to each other with repeated torsions.

Other tests might include vibrational and corrosion testing as needed.

Major hurdles

There are several difficulties expected during the course of our project. Some of the difficulties may prove to be more significant than others. We have tried to plan the project timeline accordingly, but if unexpected difficulties arise, the plan will be modified to accommodate the change.

- ?? **Availability of the ISKD device and specifications:** Most of our designs are based on the ISKD device. However, DePuy has not yet reached an agreement with Orthofix to license the product. If the team is not able to access the device, this is significantly impact our ability to modify it.
- ?? **Accounting for children activity level:** The existing LPS system is meant for patients who maintain a sedentary lifestyle, i.e. walking but not running. Children by nature will be more active and may not always follow physician instructions. This may create unexpected problems with device failure.
- ?? **Pseudocapsule growth on expandable device:** One issue raised in literature is the formation of a pseudocapsule around the implantable prosthesis. The pseudocapsule is scar growth that forms around the implant, usually in the first two years after surgery, because patients are on chemotherapy and therefore less active. This could cause a problem if the pseudocapsule interferes with the functions of the expandable device. The current solution is to have another surgery to remove the pseudocapsule. Our designs have accounted for the pseudocapsule by the doing small lengthening per session.
- ?? **Expandable device may cause infection or thrombosis:** If device disrupts soft tissue during lengthening, this leads to increased risk of infection or thrombosis. However, this is an improvement compared to the risks of additional operations if modular devices were used. This will be a design consideration.
- ?? **Using accurate testing methods:** In any medical device, accurate testing is critical. In our design process there will be a trade-off in the testing and allocation of time. One option is to prototype early and then have plenty of time for mechanical testing. The drawback here is you could prototype a design that might not even work in concept. Another option is to perform proof of concept tests and theoretical tests before prototyping. A drawback here is you might not have time to reach the point of mechanical testing, so the device might work in concept, but not withstand the forces in the body. To solve this problem, we will try to create preliminary prototypes before the actual working prototype and perform proof of concept tests on the preliminary prototypes. We hope to create a working prototype with enough time to perform some mechanical tests.
- ?? **Developing a 3-D CAD model:** The design is anticipated to contain complex and intricate components that may not be captured properly with the limited experience of the group members with CAD tools. Should the CAD model not be realizable, the group will alternatively offer hand drawings and descriptions. Should an accurate 3D CAD model be successfully created, the group will attempt to perform finite element analysis on the geometry to predict mechanical properties.

In the case that an accurate 3D CAD geometry is not available, the group will attempt either idealized FEM analysis or idealized hand calculations to predict mechanical properties.

The first three difficulties are ones that we need to take into account in the design of our device. If accounted for properly from the beginning of the design phase, they should not create major problems in the device.

The latter difficulties need to be considered, especially in developing the timeline. They are important keys to having successful deliverables. The CAD model will be started early, and training on the CAD software will be begun even earlier to address this issue.

Timeline

For the first few weeks of the project, the majority of the time was spent brainstorming to generate ideas, performing background research, benchmarking, and determining concise product specifications. Patents and other related technology were researched. The causes and possible solutions for massive bone loss in children were researched, as were the anatomy of the area in question, specifically the femur and the tibia. We met with an orthopaedic surgeon for a customer's perspective. He was able to provide detailed information about pediatric endoprostheses and give us feedback on our designs. Design requirements, specifically stated and prioritized, were developed and refined. After these tasks were completed, we evaluated the ideas that had been generated. The design concepts were narrowed down and refined, and then the design requirements were used to create a selection matrix for design evaluation. Two designs were chosen to pursue further. The creation of preliminary prototypes was begun.

After the preliminary prototypes have been constructed, these prototypes will be used to perform some initial testing. We will do some rough tests to determine the feasibility of each idea. After this feedback, we will review the ideas and select one idea to pursue. We plan to do this by April 8th.

With the idea selected, we will move forward with the concept, refining our original prototype to create a more detailed prototype. The detailed prototype will be constructed by April 15th. The next step will be to validate the prototype. We will do this theoretically and possibly mechanically depending on the selected final design. The prototype will be validated by April 24th.

In parallel with the prototyping and validation, the 3D CAD model will be developed. This model will be begun in the first week of April, and using the refined prototypes, the CAD model will be improved and updated as the design is refined. The 3D CAD model should then be completed by April 24th.

The next step will be to create a working prototype from the CAD model. This prototype will be machined out of metal, but most likely not out of titanium. While the prototype is being created, FEM will be performed using the CAD drawings. After completion of the prototype, mechanical tests will be performed on the prototype as a final validation of the design. The prototype should be completed by May 1st and the mechanical tests will be completed by May 15th.

In order to maximize the time available to produce the deliverables, the team will perform many tasks in parallel. We will achieve this by having one person assigned as a lead in each task.

Individual responsibilities of team members

We have divided up the main tasks in the project and assigned task leaders to each task based on the team's individual skills and preferences. For the administrative roles and to some degree the technical research roles, the task leader will perform the majority of the work in that area. In the design and fabrication and testing and validation, the entire team will participate in the tasks with the task leader taking on a leading role in the process. A breakdown of the main tasks and corresponding task leaders is shown below:

Task	Team Leader
<i>Administrative</i>	
Project Management	Kate Tollon
Treasurer	Ying Li
Sponsor Contact	Kate Tollon
Surgeon Contact	Ying Li
<i>Technical Research</i>	
Benchmarking/Patents	Kate Tollon
Biological/Anatomical	Henry Liu
Regulatory	Kate Tollon
<i>Design and Fabrication</i>	
CAD	Henry Liu
Prototyping	Ying Li
<i>Testing and Validation</i>	
Finite Element Analysis	Henry Liu
Mechanical Testing	Kate Tollon
Theoretical Testing	Ying Li

Acknowledgements

The DePuy team gratefully acknowledges the help of:

ME 282 Staff

Dr. Scott Delp

Dr. Thomas Andriacchi

Nikhil Batra

Melanie Cole

DePuy Orthogenesis

John Bonitati

Stephen Hazebrouck

Surgeon

Philip Z. Wirganowicz, MD

Stanford Biomotions Laboratory



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Presentation slides

Expenses

Expenditures to date

<u>Date</u>	<u>Buyer</u>	<u>Description</u>	<u>Amount</u>
2/15/02	All	Shop licenses—usage of PRL shop for 2 quarters for 3 team members	\$510.00
2/13/02	All	Supplies—threaded rod	\$27.55
2/13/02	All	Supplies—nuts, bolts	\$4.17
2/13/02	All	Supplies—ratchets, threaded rods, tubing, glue gun	\$65.17
2/24/02	Ying	Supplies—tubing, springs, heater	\$30.79
3/1/02	Henry	Clutches—variety of clutches for prototyping of ISKD modifications	\$280.00
3/5/02	Kate	Solid Works—CAD program software, student version plus manual	\$200.00
Total Expenditure for Winter Quarter			\$1117.68

Projected expenditures for next quarter

<u>Date</u>	<u>Buyer</u>	<u>Description</u>	<u>Amount</u>
		Phone calls / Mailings	\$100.00
		Reports / Presentations	\$200.00
		Travel (gas)	\$150.00
		Construction Materials / Outsource Machining	\$3400.00
Total Projected Expenditure for Spring Quarter			\$3850.00

Resources

The following people will be helpful:

- ?? Philip Z. Wirganowicz, M.D.—Orthopaedic surgeon in Bay Area. He has surgical experience using DePuy LPS. We hope to meet with him 2 to 4 times during this project, his time permitting.
- ?? Steve Hazebrouck—DePuy Project Engineer. Our main contact at DePuy and an invaluable resource for technical information and feedback. We plan to have weekly update phone meetings and to meet in person when Steve visits.
- ?? Todd Lincoln, M.D.—Stanford Hospital orthopaedic surgeon. We hope to meet with him semi-regularly for his insights and feedback.
- ?? Stanford Faculty—Dr. Tom Andriacchi, Dr. Scott Delp, Dr. Christopher Jacobs. We will request assistance as questions come up.

The following physical resources will be utilized:

- ?? Stanford Faculty—Dr. Tom Andriacchi, Dr. Scott Delp, Dr. Christopher Jacobs. We will request assistance as questions come up.

- ?? Product Realization Lab—Facility for prototyping. Some training for machines and assistance from lab TAs.
- ?? DePuy Machine Shop—DePuy will produce functional prototype based on CAD model
- ?? Stanford Hospital—Potential opportunity to watch an operation. Facilities for product testing

Patent Search Information

Justin, D. (2002). Orthodyne Inc. Intramedullary skeletal distractor and method. US6336929.

Kotz, R. and Windhager, R. (1993). Howmedica GMBH. Endoprosthesis for the knee joint. US5326360.

Kotz, R. and Windhager, R. (1990). Howmedica GMBH. Adjustable Prosthesis for a Joint Bone. US4892546.

Original Sponsor Descriptions

Design Description

This is an implantable device to treat massive bone loss in the lower limb of pediatric patients due to a tumor resection or trauma. A key feature of this device is the ability to maintain limb length equality (through expansion of the device) during skeletal growth at regular intervals until the patient reaches skeletal maturity. The device should allow expansion (through external cues) without surgical intervention after initial implantation.

The device will be part of the DePuy Pediatric Limb Preservation System (LPS). The new device can be based off the FDA approved Intramedullary Skeletal Kinetic Distractor (ISKD) used to treat tibial and femoral pediatric fractures. The ISKD was not designed for massive bone loss and expands at too fast a rate for pediatric patients.

Goals of Project – Final Deliverables

A working prototype that is compatible with the DePuy Limb Preservation System. The prototype should permit expansion without surgical intervention. Expansion should be able to accommodate growth ranging to skeletal maturity. In addition, the device should sustain the loads needed generated during ambulatory activities. Thus, a structural analysis of the device and mechanical testing will be needed. The 3-D CAD model of the final device assembly and individual components should be provided.

Checklists from Executive Committee

Regulatory and Standards Checklist

1. What is your project?

Please briefly describe the project you are working on:

To develop an implantable device for pediatric patients with massive bone loss that will expand slowly to allow for equal leg growth.

Please describe potential solutions that you are considering for your project:

Using a magnet to release stops on the spring loaded rod that is the implantable device. It will move up to the next position and remain there until magnet is used again.

Using ultrasound to vibrate the threaded rod inside the device causing it to elongate.

Using a magnet to move the threaded rod in a counterclockwise direction causing it to elongate.

List and briefly describe any potential solutions that have biological or chemical components.

None

List and briefly describe any solutions that emit radiation.

None

2. Project Scope

List which solutions involve developing a completely new device.

Solution #1

List solutions reusing a known technology, approach, or process.

Solutions #2 and #3

Are any solutions based on other devices?

Yes

If so which devices?

ISKD – Intramedullary Skeletal Kinetic Distractor

Were the device(s) developed before 1976?

Yes

How are they similar?

Our solution would use the method of expansion currently used in the ISKD, but it would use different means to actuate the expansion.

Does your solution pose any new risks?

Perhaps risks associated with ultrasound or magnets, but these could be easily monitored.

Utilize any new technologies?

Our solution might use ultrasound or magnets which the ISKD does not.

Are any of your solutions used with other devices or treatments?

Yes

If so, what devices or treatments?

All of the solutions will incorporate DePuy's LPS system modular segments.

Are they life critical?

No

3. Safety

Does your project pose any dangers to patients, physicians, or others?

Not if used correctly

If so, how?

Is it life threatening?

4. Sponsor recommendations

What classification does your sponsor want your group to aim for?

If we use the ISKD, it already has FDA approval and 501K clearance.

What premarket approval process do they envision for your project?

5. Assuming your project is a device:

This last section of the checklist is intended to help start your project's FDA identification/classification process and to document your progress. In order to guide you through this process, this document utilizes the FDA website's device advisor (see step 1). Note: at various points along the process the website offers more information to help you answer questions; these questions/links are not in this checklist.

Steps:

Open <http://www.fda.gov/cdrh/devadvice/31.html>

Does the product emit radiation? Yes / No

Does Your Product Meet the Definition of a Medical Device? Yes / No

Do you know the class of your device?

If yes jump to 5

If no:

Read section on "How to determine Classification"

Use the Classification Database or the Device Panels (circle which you used)

Record the following information:

Device: Rod, Fixation, Intramedullary and accessories

Medical Specialty: Orthopedic

Product Code: HSB

Device Class: Class 2

510(k) exempt?: No

Regulation Number (7 digit): 888.3020

Device Description: An intramedullary fixation rod is a device intended to be implanted that consists of a rod made of alloys such as cobalt-chromium-molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures.

Which are required: 510k / PMA / Exempt

(circle which apply – known from the above classification)

The next steps in the regulatory process depend greatly on your specific project. See the regulatory team for guidance if you are uncertain of your next steps.

