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Design And Development Of Implantable And Remote Controlled Distraction Osteogenesis Device For Limb Lengthening Practice In Children

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DESIGN AND DEVELOPMENT OF IMPLANTABLE AND REMOTE CONTROLLED DISTRACTION OSTEOGENESIS DEVICE FOR LIMB LENGTHENING PRACTICE IN CHILDREN

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By

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ABSTRACT

Recent technology improvements have been positively affecting medical industry in recent years since procedures and equipment are more precise and reliable. Nevertheless, there are still surgical procedures and medical devices that not fully address specific needs according to medical experts. One of those necessities is focused on options available for children patients when subjected to a surgical procedure named distraction osteogenesis. In general, distraction osteogenesis is performed when skeletal deformities need to be corrected or when bone lengthening is required, typically a mechanism is utilized to elongate bone at a controlled rate. The existing osteodistraction methods for limb lengthening and feasible to be used in children are cumbersome ring metallic structures surrounding the leg, these external rings have metallic pins or wires penetrating the skin and muscle to finally get attached to the bone, it results in constant painful open wounds and high infection risk exposure for several months. On the other hand, most comfortable methods available in the market are designed for usage in adult patients only. For that reason, an implantable device is developed and proposed in this work. In addition, device conceptualization is guided by formal engineering design tools and established engineering design methods to simplify integration of the final device. Moreover, a design flow sequence exclusively developed for this thesis was dictating how components are affected among each other and facilitated design integration. Furthermore, when design revisions were needed, the proposed design scheme facilitated the final device concept refinement and integration, solving modifications for one or more particular conditions, even if revisions were related to one particular sub-component only. Design flow sequence allowed replication of design decisions and ordered its occurrence chronologically.

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1. INTRODUCTION

1.1 Research outline

The thesis work presented in this document is about the conceptualization and development of an implantable device intended to perform and control distraction osteogenesis surgical procedure (bone elongation) to correct skeletal abnormalities with special focus on limb lengthening for kids. Device concept embraces several internal sub-components, from which stand out the remote control unit which habilitates the doctor to manipulate elongation distance and growing rate without having physical contact with the patient or perform additional surgeries.

The proposed device concept differs from current devices available in the market since it eliminates external equipment carried out by the patient and at the same time prevents further damage in bone's growth plate because its installation technique is not intramedullary, concluding that can be safely used in children.

The projected device is a combination of several mechanical and electrical systems all together applied to the medical field, therefore it is considered as interdisciplinary conceptualization. For that reason, device development process is guided by formal engineering design tools to ensure a proper sequence is implemented. Furthermore, the interaction between several working systems at different disciplines is integrated to obtain a final design concept; the integration is commonly difficult to be regulated if engineering design principles are not taken into account while working with concurrent design projects in different areas. Every design decision is based on previous elements from different systems and would affect next design decisions entirely. For that reason, a design flow scheme is developed and presented in this work for this particular application, and

it became very significant to simplify the design work and had the flexibility to be applied to multidisciplinary projects in different industries by doing little revisions.

A design flow scheme can significantly aid in the conceptualization and development of every engineering design project, for that reason a design flow strategy is released in this document for the osteodistraction device construction in order to control the design process and allow making modifications based on previous work done. In addition, design flow sequence permits to replicate project decisions chronologically.

1.2 Theoretical background

Research work carried out in this thesis is closed related to basic medical concepts, therefore its understanding and comprehension is relevant. The topics covered in this section are related to bone fracture and healing process by natural organism reactions theory, along with surgical procedure named distraction osteogenesis and osteodistraction methods available in the market.

1.2.1 Bone fracture theory

Bone fracture is an alteration in bone's continuity or breakage of bone's path and can be caused by different factors such as high forces exerted to bone or high impact situations derived from injuries or accidents. Also, several medical affectations may produce bone fractures or increase its chances such as osteoporosis or bone cancer [1]. Moreover, in rare cases, muscles can reach unexpectedly high contraction forces caused by exposure to toxic substances or epileptic attacks, these forces may be high enough to provoke bone fracture.

Bone fracture healing occurs when the body starts a regenerative and physiological process to assist in the healing of a bone fracture. It would be as simple as to relocate the broken bone back

into its normal position and wait for the natural process to happen; this process is divided in phases of recovery. During these phases, the bone and tissues are regenerated and the time to complete healing depends on injury magnitude and extension.

The periosteum, which is the connective tissue surrounding bone, is essential for bone healing process because it derives the precursor cells that will become later chondroblasts and osteoblasts that are extremely important to complete bone healing [2]. Also, bone's core, endosteum, blood vessels and fibroblast are essential to activate precursor cells.

1.2.2 Distraction osteogenesis

Distraction Osteogenesis or callus distraction [3] is medical procedure in which a bone is fractured or separated into two individual sections by a surgical procedure (corticotomy or osteotomy), then the two parts are positioned close enough to allow natural bone healing process to occur and while soft cartilage callus is still manageable, it is elongated by moving apart the two segments at a small and controlled rate allowing continuous formation of new bone in the gap. Finally, when desired elongation distance is reached, distraction movement is stopped for enough time to allow solidification of bone per natural circumstances.

It is very important to control distraction rate because at lower rates the bone solidification can happen sooner than expected thus not accomplish required elongation distance. On the other hand, at high rates the soft callus can be outstretched and not allow new bone to fill in the gap producing pain [4]. The common accepted rate or optimum distraction rate is 1mm a day, but a patient evaluation must be carried out by a doctor to determine the ideal rate for every patient. If lengthening is too fast then bone would not completely fill the gap between segments and if it is too slow the bone is solidified without stretching the desired distance.

Callotasis [3] or osteodistraction [5] procedure is recommended by doctors for the treatment of several medical conditions, these disorders can be congenital or developmental deformities, injuries, infections, diseases and tumors, some examples are: bone defects, fracture resulting in shattered bones, growth plate fractures, malunion or non-unions, neurofibromatosis (overgrowth in one leg), enchondromatosis, congenital short femur, fibular hemimelia (absence of fibula), hemihypertrophy (growth greater in one side of the body), Ollier's disease, bow legs resulting from rickets (softening of bones due to lacking of vitamin D) or arthritis, osteomyelitis (bacterial bone infection), Septic arthritis, Poliomyelitis (muscle atrophy causing deformity), achondroplasia (arms and legs shorter non proportional to torso) and dwarfism disorder which may be caused by around 200 different medical ailments.

Additionally, limb lengthening is considered as an option of cosmetic enhancement. However, a great part of the medical community is not in favor of bone lengthening for beautifying purposes and allege that breaking functional and healthy extremities is inappropriate, because it exposes patients to pain, discomfort and limited mobility for a long period of time (around a year) and the possible risk of infection or severe damage in nerves and blood vessels is high. In addition, when adding surgery expenses and device cost it seems to be not very convenient. Still, if knowing the disadvantages and risks, the patient still insists in the surgery, a general health study is carried on to determine the ability of patient for recovering physically. Furthermore, a psychological study is needed to asses if an increment in height would represent a real improvement in patient's quality of life and if it would be a real and notable difference.

Osteodistraction is mostly practiced in long bones such as femur, tibia and radius but it is also very popular in the treatment of jaw related affections like midface and mandibular problems.

Osteodistraction can be described in four different phases:

Preparation.- This is the initial stage where the patient manifests his intention to be subjected to the surgery, several medical sessions occur so the doctor can examine the patient with x-rays and evaluate his physical and psychological condition.

Surgery.- If the subject is considered to be a good candidate for the osteodistraction, then the surgery is performed and internal or external devices are installed in the operating room. Mostly used attachments are nails, wires, pins or screws communicating the bone with the metallic structure.

Lengthening.- The main characteristic of this phase is the bone elongation, it starts about a week after the surgery and would last a couple of weeks or up to three months, depending on distraction rate and total desired lengthening distance assigned to the patient. In this stage new bone grows in the gap existing between the two bone segments, this soft callus filling the gap is stretched a control rate. Normally, use of crutches or wheelchair is required because high stresses applied to the overextended area would be a potential risk of breakage of the new bone in construction and would finish the elongation. In contrast, if successfully complete this stage, the length increase is noticeable.

Consolidation.- In this phase the bone is not stretched anymore and for a period of around five months, the new bone is becoming stronger for weight bearing and carrying daily life stresses. During this stint the patient still uses wheelchair or crutches and distraction apparatus is also in place to keep bones aligned and positioned correctly even if it is not elongating anymore. The consolidation phase ends with one more surgery to remove the osteodistraction device requiring around a month of cast usage to protect affected area until final recovery.

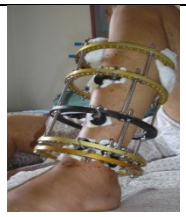
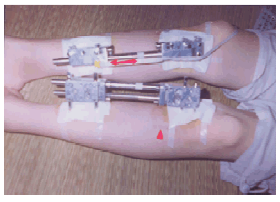
1.2.3 Osteodistraction methods

Different techniques have been developed to accomplish a controlled bone elongation at a precise rate by stretching the soft callus generated in a fracture gap, all methods need to perform a bone dissection (corticotomy) and stress tendons and nervous in the affected area during elongation process. Depending on device location, they can be classified as:

1.2.3.1 External methods

Devices employed are attached directly into the affected area, having the supporting structure located outer the skin but fastening the bone with metallic pins, wires, screws or other fixation attachments penetrating skin and muscle to reach the bone area. These methods are very painful and difficult to tolerate day by day. The activation mode to produce distraction is located in the external structure and controls the lengthening distance and distraction rate. The risk of infection is always high [6] because of the constant open wounds that they represent [7], however its usage has been very practiced for decades and most of their issues are very well known. External methods often represent the most economical methods for distraction osteogenesis. Table 1.1 describes the most common external methods in the market, Ilizarov [8], Salamehfix [9] and Micro-wound [10].

Table 1.1 External distraction osteogenesis methods.

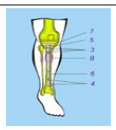
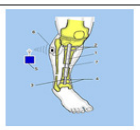
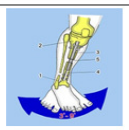
			
Method	Ilizarov	Salamehfix	Micro-wound
Type	External	External	External

Year	1951	2001	1995
Origin	Russia	Syria	China
Inventor	Dr. Gavriil Ilizarov	Dr. Ghassan Salameh	Dr. Helong Bai
Features	Metal rings surrounding the leg. Pins inserted into flesh and attached to bone	Different sized semi-circles for better adaptation. Full weight bearing is allowed	Covers only one side of the leg instead of surrounding it completely
Key points	Full rings + manual adjustment	Semi-circle + manual adjustment	Rails + manual adjustment

1.2.3.2 Internal methods

Internal methods were developed to prevent damage to muscles, nerves and soft tissues unlike the external methods. Internal methods are mostly metallic nails that are implanted into the medullar bone cavity and do not affect the function of tissues, nerves and muscles. They have no external structure at all. Its existence started a couple of decades ago, but they still hold a higher price compared to external methods. Table 1.2 describes the internal methods and its features, Albizzia [11], Guichet [12], Bliskunov [13], Fitbone [14] and [15], ISKD [16], and Precice [17].

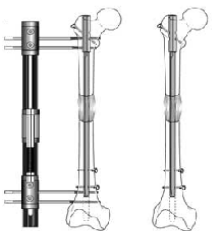
Table 1.2 Internal distraction osteogenesis methods.

						
Method	Albizzia	Guichet	Bliskunov	Fitbone	ISKD	Precice
Type	Intramedullary nail	Intramedullary nail	Intramedullary nail	Intramedullary nail	Intramedullary nail	Intramedullary nail
Year	1987	2009	1980	1997	2001	2001
Origin	France	France	Russia	Germany	Florida, USA	California, USA
Inventor	Dr. Jean-Marc Guichet	Dr. Jean-Marc Guichet	Dr. Bliskunov	Dr. Augustin Betz and Dr. Rainer Baumgart	Dr. J. Dean Cole	Ellipse Technologies
Features	Patient rotational movements produce elongation. Clicking sounds to control elongation	Stronger structure than Albizzia and customizable size for short bones	Patient presses a pendulum mechanism to elongate bone. Cliking sound to control lengthening	Implanted inductive plate receives external magnetical signal to produce elongation	External hand monitor measures lengthening. Two magnets inside the nail are the feedback inputs	First NDA approved external remote controlled (magnetic) unit. Reverse direction is possible.
Key points	Nail + move foot to distract (by patient) + click sound	Stronger Nail + move foot to distract (by patient) + click sound	Nail + press pendulum to distract (by patient) + click sound	Nail + external power signal to distract (by doctor)	Nail + move foot to click (by patient) + feedback in hand monitor	Nail + magnetic field remote controlled (by patient) + Feedback

1.2.3.3 Hybrid methods

Combined methods offer a nice option for secured fixation and effective elongation in the same device because they combine external structures to support and manage elongation distance and rate with metallic rod implanted into bone's cavity to provide bone stability in a better manner than external structures alone. Moreover, after the elongation period, the external structure portion can be removed to make the recovery time more comfortable. The internal nail remains during the solidification phase and it is removed after it is completed, accelerating the recovery period. Table 1.3 illustrates the most known combined method for osteodistraction and the main features associated with it, plus key points of the lengthening over nails method [18].

Table 1.3 Combined distraction osteogenesis method

	
Method	Lengthening Over Nails
Type	External and Intramedullary nail
Year	1990
Origin	Maryland, USA
Inventor	Dr. Paley and Dr. Herzenberg
Features	External structure helps for elongation phase and then removed for consolidation phase. Internal rod supports weight bearing
Key points	Nail + Rails + manual adjustment

1.3 Problem definition

Global medical market offers several methods of distraction osteogenesis for limb lengthening to achieve and control bone elongation. Nevertheless, the usage of these devices is very limited for children due to different reasons depending on the osteodistraction method. Basically, internal or intramedullary methods fracture or destroy the bone's growth plate when they are installed in the operating room, furthermore external methods are not comfortable to wear and the risk of infection is high.

During childhood, the bones of the body are growing fast until reach an adult age, this is accepted as a normal and natural process. The bone's enlargement while growing is produced by biological processes occurring in the growth plate, which is responsible to keep the bone elongation naturally year by year during childhood. Figure 1.1 illustrates bone's growth plate.

Figure 1.1 Bone's growth plate

Fracture of the growth plate may result in ending natural bone's growing process. Consequently, the usage of intramedullary nails is equivalent to fracture the growth plate because it drills the bone's core to insert the nail into it and for that reason the children, adolescents or active growth plate individuals do not qualify for distraction osteogenesis using internal methods.

However, it is a fact that distraction osteogenesis is required in infants with diverse health disorders like the ones mentioned in previous section but if internal osteodistraction methods are

not suitable for active growth plate individuals, then options are very limited for doctors to carry the procedure. Essentially, limb lengthening options for children are narrowed to external methods which are cumbersome and sometimes heavy weight for children patients at early ages. These devices are very uncomfortable for active youths and obligate them to use wheelchair or crutches. Table 1.4 shows the most common methods available for bone elongation in infants. In addition the figure 1.2 exposes the typical inconveniences for existing methods.

Table 1.4 Distraction osteogenesis options for children.

Method	Type	Year	Inventor (s)	Country	Features
Ilizarov	External Fixator	1951	Dr. Gavriil Ilizarov	Russia	Most representative method of distraction osteogenesis. Stainless steel rings and pins inserted into skin, muscle and attached to bone
Micro-wound	External Fixator	1995	Dr. Helong Bai	China	Structure covers only one side of the leg instead of surrounding the limb completely
Salamehfix	External Fixator	2001	Dr. Ghassan Salameh	Syria	Different sized semi-circles for better leg shape adaptation while full weight bearing is allowed

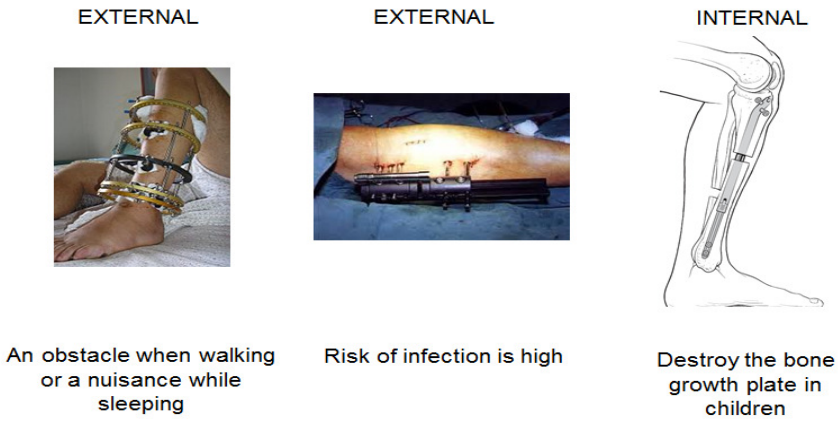


Figure 1.2 Disadvantages of existing osteodistraction methods for children.

1.4 Research objectives

Research objectives in this thesis are targeting two issues mainly. The first objective is about conceptualization and development of a distraction osteogenesis device which solves a specific problem in the medical field. Similarly, the second objective is to develop a method to systematize solution steps and taken decisions sequence derived from device development, therefore design steps and relations can be referenced at any time to enhance the device without disturbing the connection among components and do not break the structure of the concept.

Expanding the first objective, distinct features are combined together to obtain a unique design not available in the market which solves the specific problem of external cumbersome artifacts affecting children patients. Therefore, the proposal is a device with no external parts or structures and at the same time does not cause any damage to bone's growth plate by excluding intramedullary nails of all kinds. Also, the proposed device is implantable, remote controlled by medical professionals, affordable, easy to carry by the patient, friendly with growth plate, and a good option for adults too. More requirements are fully described in section 2.1 which summarizes the list of requirements. Fundamentally, the structure is implanted along the bone and attached with medical purpose screws to the bone. These screws are fastening along the longitudinal edge of the bone as figure 1.3 illustrates with a simple and general sketch. Since device will be implanted, there is a strong need of communication between device and the exterior, for that reason a remote control is added to the concept. The remote control unit shown in the figure below for reference purposes only and the same is true for the osteodistractor device colored in blue attaching the bone.

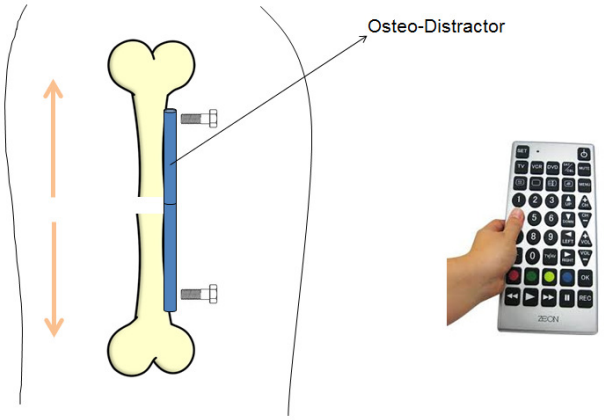


Figure 1.3 General solution proposal.

Research objectives cover the design of the internal mechanism responsible for bone elongation and selection of the most suitable components for the entire system. In addition, the process is guided by formal engineering design concepts so the second research objective is to keep track of a design flow scheme path specifically obtained for this device.

The second goal is basically about how to do it, that means to develop a design structure strategy that allows systematizing steps of design conceptualization and device evolution until come to a final design. The main reason to develop a scheme is because systematization allows to record important taken decisions. It permits modifying previous selected components if becomes necessary. Now, after final design concept is integrated, the record of the design process steps come to be very helpful to use the concept as it is and enhance any section, but still knowing exactly how that would affect other components and identify possible replacements in consequence.

It is expected that the final design meets all the requirements established in task clarification section of this document and that the design scheme can be applied to other interdisciplinary projects.

1.5 Research methodology

Research objectives are ambitious and to follow a working sequence is essential to success. The methodology followed in this research work is based on the information and flow sequence shown in figure 1.4. It is important to notice that development of biomedical concepts such the one presented in this thesis is related to several science fields such as medicine, electrical engineering, mechanical engineering, engineering design and creativity, etc. The research methodology proposed points out that there is a real necessity to be solved in the field and how it can be addressed with well-known established design steps to approach a solution.

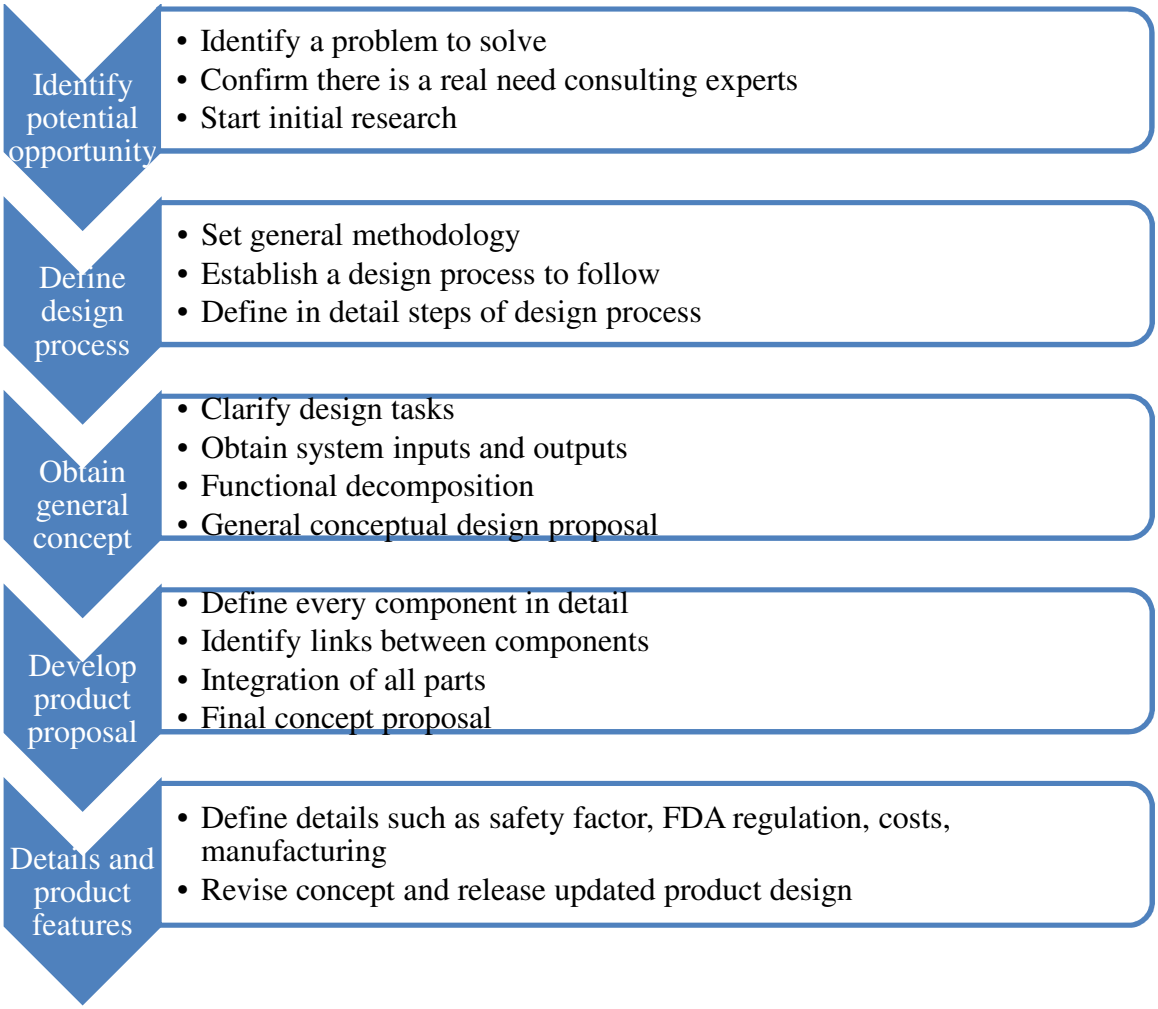


Figure 1.4 Research methodology.

1.6 Engineering design process

The research methodology explained in previous section is about how the project is approached in general. In contrast, engineering design process explained in this section is about which design tools can be used to find a solution to the problem in question. The main purpose is to analyze the situation and obtain final product design. It is worth to say, that the intention of this work is not to invent a design process again but to use existing tools from renowned authors to simplify the conceptual design. The method proposed by Pahl and Beitz exposed in their book "Engineering Design a Systematic Approach" [19] is considered enough to address our project needs because it tends to be very efficient and its methodology is very useful during different design stages. The phases of the Pahl and Beitz design process are briefly described below:

The first phase is about task clarification; in this section all product requirements are defined. This stage is crucial and future success in other stages depends on it and its proper resolution. In general, the customer starts a requirements list thinking about every aspect of the desired final product, and then specialized personnel in different areas add more items to the list to define a design specification document that can be continuously updated throughout the design process and device development.

For the second phase, the main purpose is to define a conceptual design which satisfies the requirements in general perspective. The final outcome is the proposed concept capable of solving the needs and addressing its functions. The ideal concept will satisfy the main functions identified as the priority and will answer questions like: what would be the main or general function of the product? What sub functions are really required? And how can they be solved? Moreover, to obtain the principle solution, the functions are decomposed in several sub functions

from an overall or main function to determine the working principles to solve every sub function. Furthermore, several steps have to be followed prior concept disclosure; these steps are explained and developed in future sections.

In the third phase, the embodiment design is the main topic. In this part the project a final outcome is expected in the form of final layout. This final sketch is obtained only after develop several preliminary layouts, analyze them and make revisions because every part of the system is technically examined in order to select the most suitable options to reach the optimum by integration of all parts to build a reliable final layout.

The fourth step is the detailed design; this phase is based on “final layout” generated in the previous stage. In this stage, the designer exhaustively examine every detail around the concept such as materials selection, specifications, technical documents, government regulations, manufacturing costs, product material costs, etc. In this phase, some additional design modifications determine the new final design layout after integration of all details.

The fifth phase is the overall design process and it is dedicated to inspect product concept and optimize most of the parts or at least the key elements to obtain a stronger design at the lower cost. It is not uncommon to revise the final design again in this stage to meet design goals or market targets in a better way.

2. DESIGN APPROACH

2.1 Task Clarification

The importance of this section is very significant to develop a conceptual design completely integrated at the end which will be capable of fulfill all or most of the functional expectations. The quality of the work performed in this section directly impacts every part of the concept; however the task clarification section is constantly updated until the final concept release.

2.1.1 Design Specification (Requirements)

At the beginning of this work there was a general idea of what was needed to solve the exposed problem; however, this section is to define the general and the specific requirements of the osteodistractor device concept. In the theoretical background section, a general idea about the distraction osteogenesis devices in the market is exposed, understanding how different companies approached the problem with diverse methods. The usage in children is part of the main focus in this project and several requirements reflect that intention. Osteodistraction techniques are carefully analyzed to determine how the damage in the growth plate can be avoided thus leaving any intramedullary method or technique out if the scope of this new development. Furthermore, kids' nature is hyperactive so they move constantly and in some cases ignoring imminent risk of accident. For that reason, external osteodistractor structures are considered cumbersome and generators of painful situations when hitting objects while moving around at home or outside. Therefore, the ideal concept would be an implantable device with no external structures or parts mounted in outer skin. In contrast, the proposed concept can be located inside the skin and muscle but attached to external bone walls with screws supporting the two bone segments. In addition, remote communication is needed for transferring data from the

implanted device to the outside and backwards, for that reason the remote control communication is something to consider as important. The list of requirements is shown is table 2.1 and is a compilation from several experts in different areas of study. In the medical field Dr. Amr Atef Abdelgawad defined the requirements related to size, device implantable location, surgery restrictions, weight, material compatibility with human body, etc. In addition, the mechanical engineering design section was advised by Dr. Noe Vargas Hernandez and included the structure profile, mechanical stresses, materials, energy consumption, ergonomics, safety, etc. As mentioned before, design process is based on the Pahl and Beitz methods [19] so the table 2.1 is the final requirements list after several iterations. The "D" stands for demands and the "W" stands for wishes.

Table 2.1. Requirements list.

UTEP	Rev 06	Requirements List (Design Specification) for an osteodistraction device to be used for children	Issued on 03/30/2014 Page: 1
Changes	D W	Requirements	Responsible
		Geometry	
2/1/2014	D	General package dimensions 2.5 cm x 20cm x 1.8 cm	
	D	Compact and small design, small enough to be implanted	
1/1/2014	D	Kind profile structure to adapt to the bone	
	D	No external connection ends	
	D	No external fixators	
		Kinematics	
	D	Controlled linear displacement in forward direction	
12/30/2013	W	Controlled linear displacement in backward direction	
	W	No backslash movement	
	D	1 mm per day displacement distance	
2/4/2014	W	1 mm distraction in less than 30 seconds	
		Forces	
	D	Produce at least 5N to reach bone elongation	
	D	Structure to support muscle stresses	
	D	Bending moment resistant	

	D	Torsion resistant	
	D	Not significant deformation in all directions	
	W	Carry patient weight (not constantly)	
		Energy	
	W	Low power consumption	
	W	Low voltage systems inside body	
	D	Power systems isolated or encapsulated	
	D	Low running temperature device	
		Material	
	D	Suitable to be inside body	
	D	High resistance to deformation	
	D	Strong materials	
	D	Not toxic elements	
1/16/2014	W	FDA approved	
	W	Moving mechanisms encapsulated	
	D	Waterproof	
	D	Corrosion-proof	
	D	Mechanical shock proof	
		Signals	
	D	Electrical or electromagnetic control	
	W	Feedback signal to measure the exact amount of growth	
	D	Remote control activation from outside	
11/13/2013	D	Communication frequency not dangerous to humans	
	W	Display to show growth conditions	
		Safety	
	D	Not affect bone growth plate	
	W	Easy to install	
	W	Easy to remove	
	W	Short surgery time	
	D	Not intramedullary nails	
	D	Not external fixation	
	W	Stop gaining at any time if required	
	W	Vary growth gain rate if required	
2/10/2014	W	Safety factor of 2	
		Ergonomics	
	D	Use in children	
	D	Light (less than 5kg)	
	D	Comfortable for patient	
	W	Adjustable for different size of patients	
	D	Infection risk low by carrying this device	
		Quality control	
	D	Meet biomedical devices standards	

2/10/2014	D D D	FDA approved High quality materials to keep safety factor lower Testing before usage	
	 D D D D	Assembly Fixed to the bone with screws At least 4 screws Device profile to fit bone's geometry Not dangerous surgery Not damage bone when install or remove	
	 D D D	Operation 6 cm of lengthening distance maximum Remote controlled High precision, error < 5%	
	 D D D	Maintenance One time use device, one patient only No maintenance required while implanted High reliability (6 months of operation)	
	 W W W	Recycling Internal components to be recycled Not toxic substances to earth Recollection of used devices after removal	
1/18/2014	 W D W	Costs Low cost, less than $10,000 USD High quality materials Costs for 500 units a year	
Final version of requirements list			

2.2 Conceptual design

The main objective of this section is to define a concept to meet the requirements listed in previous section. In order to obtain a positive outcome, several steps have to be tracked to generate various concepts and then evaluate the options until the most suitable alternative is defined, this option will be considered for the embodiment design. It is important to define the main function of the product and start working from that. Then, the main function can be divided into several sub functions. After that, the most reliable options to solve and manage every sub

function are evaluated to obtain a couple of good concepts and keep only one concept at the end considered as the most reliable and capable to meet the all requirements.

2.2.1 Overall function

In this section, the inputs and outputs from the entire system are identified so the proposed concept design takes into account the total incoming energy, materials and received/emitted signals. Additionally, undesirable or unexpected inputs are important to be identified since they represent the real conditions for a completely functional design in the field. In figure 2.1, it is shown the overall types of energy, materials and signals concerning the main function of the osteodistraction action required in this project.

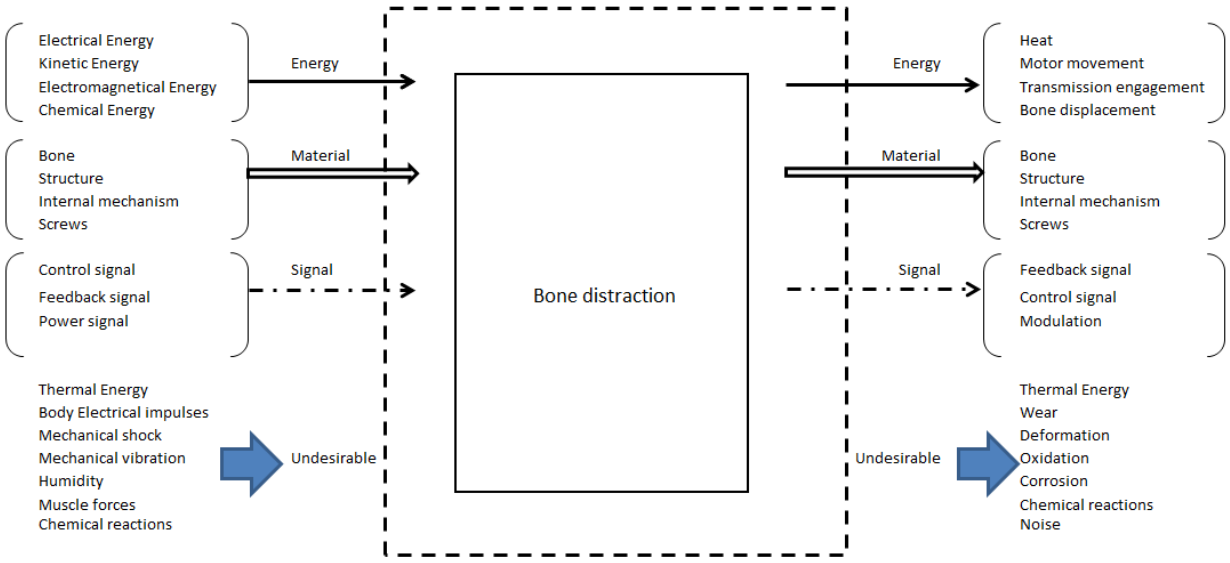


Figure 2.1 Overall function.

2.2.2 Functional decomposition

The main function of the previous section can be achieved by following several sub routines or sub functions in a decomposed sequence. All this sub functions are embedded in the main

function but are working together, these little and simple routines are obtained in a process called functional decomposition. The figure 2.2, shows all the sub functions contained in the main function of bone distraction, it becomes obvious that identified routines have to be completed and connected between each other to obtain the final outcome.

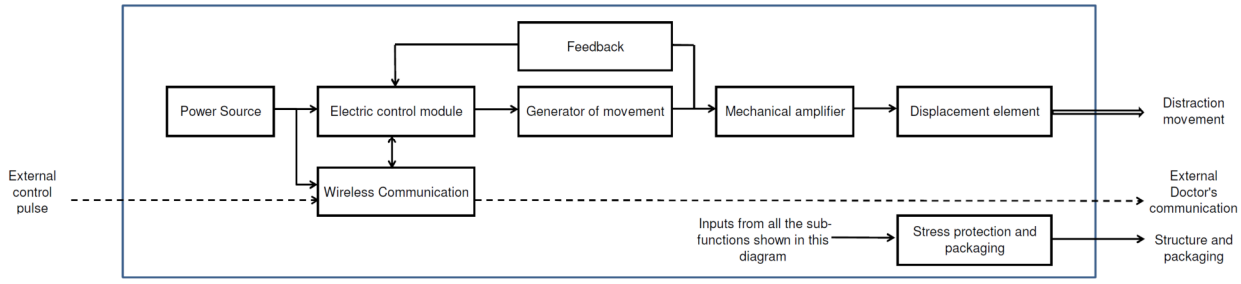


Figure 2.2 Functional decomposition

2.2.3 Morphological chart

The morphological chart is about comprise all possible options or working principles to solve every sub function, it shows how every sub function is approached to complete the main function. The possible solutions to every sub routine are important to construct the design concept because the integration of those will define the final product. Figure 2.3 shows the most relevant options for each sub function. The morphological chart is the opportunity to be creative and ignore the interaction with other parts of the device since proposed ideas are concentrated in one specific sub function only. It is common that when thinking in options for one function the flow gets blocked by trade-offs related to others sub functions and forecast difficulties in future steps giving up many ideas immediately. The psychological blockage may eliminate novel ideas and significant opportunities for improvement.

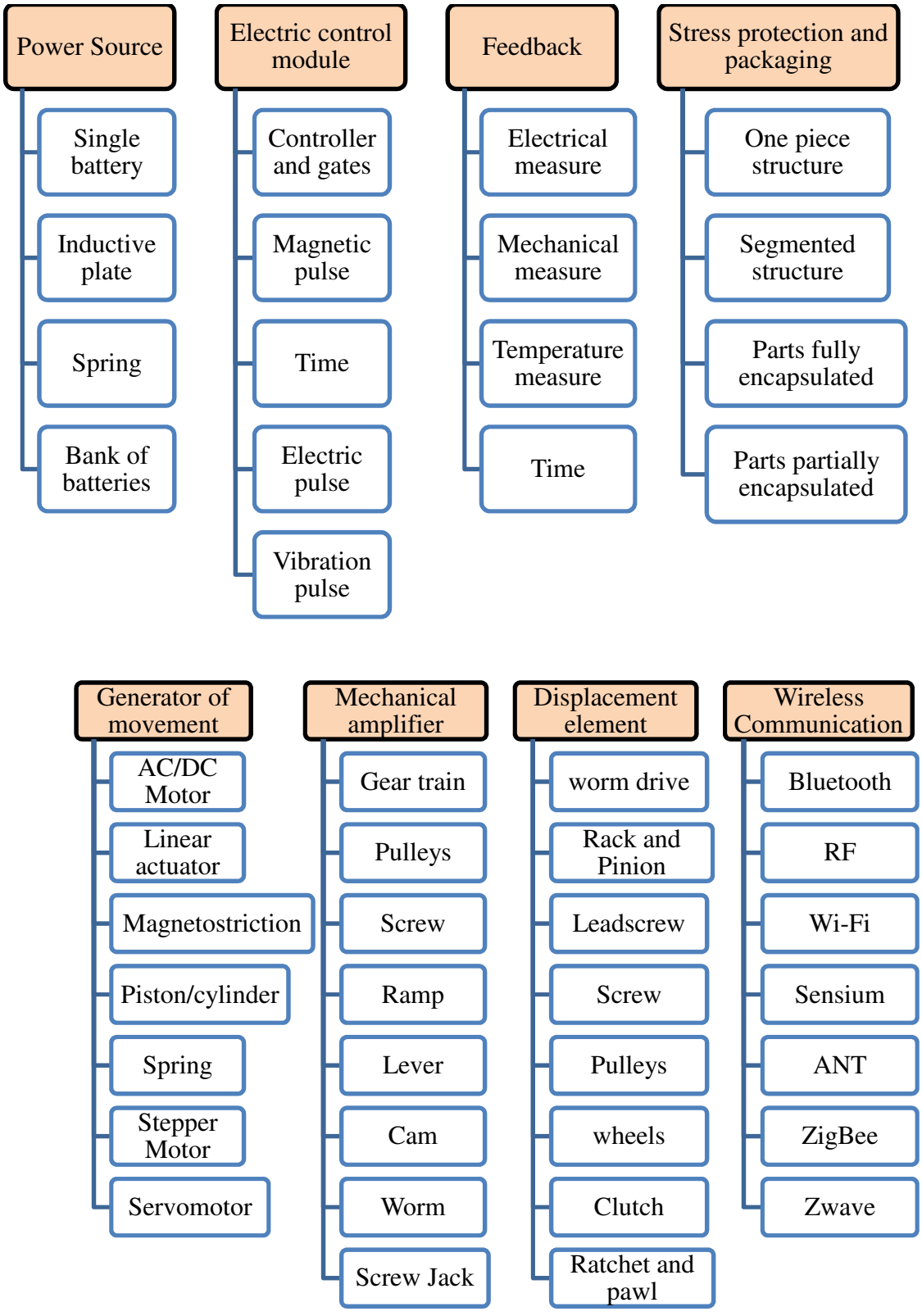


Figure 2.3 Morphological chart.

2.2.4 Solutions to sub functions and combinations

At this point, several assumptions were made to attain a conceptual design proposal. The information was based on the requirements list from previous section and results of the overall function diagram, which was then decomposed into several sub functions (functional decomposition), and options to solve every sub routine described in the morphological chart. The next step is to establish different combinations for the solutions available in every sub function. An important consideration is that because of the high amount of force needed compared to the proposed small package per implantation requirements, it was possible to identify 3 main options for mechanism configuration that would work properly. In table 2.2, the three main options are classified by sub function for better understanding.

Table 2.2 Solutions to sub functions and combinations.

Sub function	**Combination 1**	**Combination 2**	**Combination 3**
Power Source	Inductive plate	Bank of batteries	Single battery
Electric control module	Time	Electric pulse	Controller and gates
Feedback	Time	Mechanical measure	Electrical measure
Wireless Communication	Wi-Fi	ZigBee	RF
Generator of movement	Magnetostriction	Stepper Motor	AC/DC Motor
Mechanical amplifier	Screw Jack	Worm	Gear train
Displacement element	Clutch	Rack and Pinion	Leadscrew
Stress protection and packaging	Segmented structure	One piece structure	Parts fully encapsulated

2.3 General concept structure

The conceptual design phase is well approached in this stage and there is enough information to obtain a model to work with for future stages while meet the requirements. If the three options shown in table 2.2 are examined and assessed, the best option is the combination number three. The general concept is required to have at least the elements listed below so can meet specific sub functions to then combine them to complete the main function of osteodistraction product. Figure 2.4 displays the key elements for the general concept and its relation between each other.

1. Power Source – A single battery can support the electrical demands of the entire system and possible high energy unexpected demands.
2. Electric control module – Controller and gates are the potential array of electrical components to control the mechanical movement.
3. Feedback – Precise feedback can be obtained with electrical signals which can regulate the electric control of the system.
4. Wireless communication – RF is the most suitable communication interface to connect the implanted device with the external world.
5. Generator of movement – A motor is the selected option because it is widely available in small sizes and it is easy control.
6. Mechanical amplifier – Gear trains are well known as torque amplifier and per project size restrictions they seem to be a good option.
7. Displacement element – Leadscrew is the proper component to produce displacement in this project since it can be controlled for small distances very precisely and offers big advantages in force transmission.

8. Stress protection and packaging – Internal components have to be fully encapsulated since osteodistractor device is implanted and muscle stresses would affect the components. The packaging has to support muscle stresses to allow the internal mechanism to withstand distraction stresses only. Structure can be telescopic.

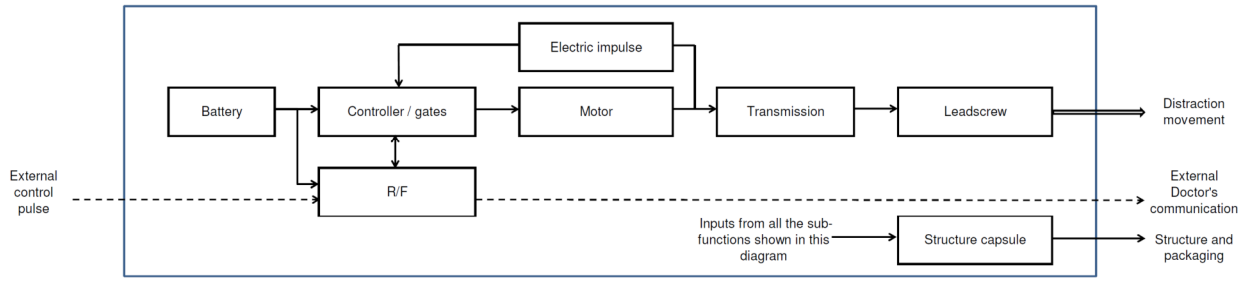


Figure 2.4 Proposed concept.

2.4 Design flow strategy

When approach a complex mechanism design or an interdisciplinary project, the deliberation of the possible paths to take regarding component selection in every sub function dilemma is important to be considered to release a working concept. In addition, the attaining of the concept idea and the identification of key elements per previous stages was not enough to procure an order of ideas about how to select the specific components or parts. Although the relationship between sub functions is clearly displayed in figure 2.4, there are still several concerns around it, such as: which would be the best component to start the selection with? Which would be the most critical sub function to procure the main function? How the design would be affected if one element is modified? If a component is revised halfway the project, would the entire design need to start from zero? In consequence, it was decided that specific order among sub functions is necessary to connect the elements of the concept in a unique sequence for selection purposes

only. For that reason, the design flow strategy structure is proposed in figure 2.5; every stage is defined by inputs and outputs for one or more sub functions until obtain the final product by integration of all stages.

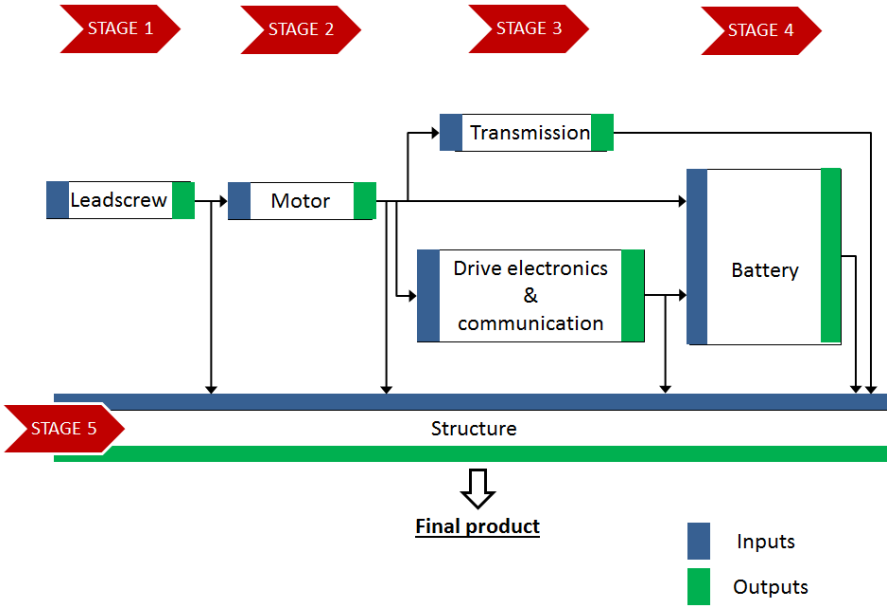


Figure 2.5 Design flow strategy.

The purpose of the design flow scheme presented in figure 2.5 is to establish a design order and define components based on the specific design criteria assigned for every sub function. The inputs in every stage are given by the outputs resulting in the previous stage. This connection permits to keep control of the design sequence in advanced phases even if a modification in early stages is necessary. If the modification is applied, then the inputs and outputs of each stage will cascade throughout the stages and will catch if any component is out of acceptable ranges based on design criteria specifically set for every sub function.

The first stage is designed for the leadscrew selection and becomes the starting point since it is the first contact with the load to move. The challenge here is to determine how much energy or

mechanical advantage could be obtained from different types of screws before even thinking in the force or torque that would have to be applied to the screw for bone distraction.

The second stage is assigned to the motor because at this point the torque required for activating the leadscrew and move the load is defined. Market exploration for motors is required until select the proper component.

The stage number three uses the outputs of the motor selection as the inputs for the transmission selection stage and the drive electronics with communication stage. It is suspected that size restrictions would limit the motor torque capabilities and mechanical power amplification would be necessary to meet the leadscrew torque requirements. In addition, drive electronics and communication are based on motor selection and determine the intelligent components and the connections of the control circuit.

The stage number four is designated for battery selection and how to support the electrical demands of the system, the motor, drivers and communication components are power consumption devices so it is essential to select a reliable product.

The stage number five is the last one because it takes the outputs from all previous stages as its own inputs. The trade-off of this stage is that a very small package has to support stresses produced by muscle and encapsulate all components at the same time.

Besides inputs and outputs, the design flow includes proper design selection criteria or metrics to define a solution for every sub function. Selection criteria are omitted from figure 2.5 but are included in the following sections of component selection. Mechanical, electrical and medical concerns are part of the design flow strategy too.

3. ENGINEERING DEVELOPMENT

3.1 Leadscrew analysis and selection.

3.1.1 Design flow inputs and possible outputs

In the first stage the only inputs available are the ones specified in the requirements list and the obvious functions of the leadscrew in the system like to produce linear displacement and capacity to be adapted to a motor. For that reason the starting point is the 5N force which is the force required for bone elongation to occur, also the maximum distraction distance of 6cm. Moreover, the expected outputs for stage 1 are shown in figure 3.1 which includes the specific selection criteria to define the most suitable component to use. The first stage finalizes when leadscrew selection is completed and torque required in the screw to move the load is calculated. The torque is examined with different thread types; screw diameter and screw lead distance. The outputs of this stage will serve as inputs for next stages.

<table>
<tr><th colspan="3">Leadscrew selection</th></tr>
<tr><th>Inputs</th><th>Design selection criteria</th><th>Expected Outputs</th></tr>
<tr>
<td>From requirements list:
Required force > 5N
6cm distraction distance

Linear movement capable
Adaptability with motor</td>
<td>Advantages and disavantages of different threads
Review leadscrew catalogues

Calculate required torque at different screws to move load

Square or buttress thread
$T_{raise} = \frac{Fd_m}{2}\left(\frac{l+\pi\mu d_m}{\pi d_m - \mu l}\right) = \frac{Fd_m}{2}\tan(\phi+\lambda)$

Trapezoidal threads
$T_{raise} = \frac{Fd_m}{2}\left(\frac{l+\pi\mu d_m \sec\alpha}{\pi d_m - \mu l \sec\alpha}\right) = \frac{Fd_m}{2}\left(\frac{\mu\sec\alpha+\tan\lambda}{1-\mu\sec\alpha\tan\lambda}\right)$</td>
<td>Screw thread type
Screw length
Screw diameter
Screw detailed technical data
Reuired torque to move the load
Cost
Material
Market availability
Manufacturing restrictions</td>
</tr>
</table>

Figure 3.1 Leadscrew inputs and possible outputs

3.1.2 Displacement mechanism

The analysis of the system starts with the last element in the torque transmission chain, this component produces the distraction effect in direct contact with the final load. The element is designated to be a screw system per positive mechanical effects in torque amplification, in specific a leadscrew seems to be the best option in this project. Nevertheless, more similar systems and mechanism were deeply explored to convert torque in linear displacement. Only the most relevant are mentioned below as reference since the complete list is mentioned in figure 2.3 Morphological chart.

Rack and pinion system is an array of components to produce linear motion in push or pull directions. A rotational motor is adapted with a pinion gear in the shaft, then the gear is placed to be engaged with a rack section, when the motor rotates its shaft the pinion gear will turn too and the engagement with the rack produces linear displacement in the rack section.

Ratchet and pawl is a mechanism typically found in wrenches, it allows movement in one direction only. It is a ratchet gear with a pawl attached and fixed to the structure, the gear can turn in one direction where pawl can slide with no issues, however if rotation is applied in the opposite direction the pawl stops the movement. This mechanism can be mixed with rack and pinion to create a one directional mechanism only by attaching the pawl in the pinion gear. Figure 3.2 shows the typical rack and pinion mechanism (left image) and the ratchet and pawl arrangement (center image).

Another option is a screw jack which is utilized to move or lift heavy loads by taking advantage of the incline plane principle in the screws. It uses a leadscrew and a lever to multiply the applied force and exert a higher force to a load, figure 3.2 (right image) is an illustration of this type of

mechanism. Some of these arrangements are self-locking and keep screw in the same position when remove the lever applied force regardless of the weight of the load, the leadscrew does not go backwards per linear load pressure.

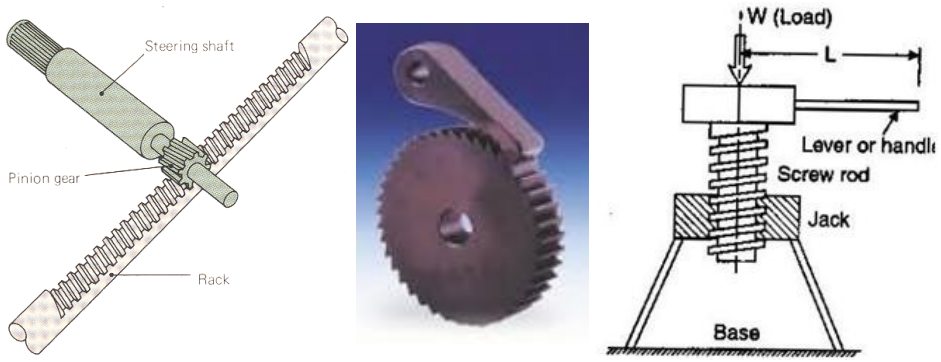


Figure 3.2 Screw mechanisms

Due to our packaging restrictions, rack and pinion is difficult to accommodate in a small package since vertical and horizontal positioned component are required. Also, jack screw system is depending on a lever which is typically activated manually, the packaging dimensions to include a lever and its activation method are the main issues with this system. However the same principle of leadscrew is a good approach in this project.

Leadscrew is used to convert rotational motion into linear displacement or force [20]. In certain systems is more convenient to have rotational motors even when required final movement is to push or pull a load linearly, in these cases a leadscrew or power screw is a suitable link between these movements. Figure 3.3 shows a leadscrew and counterpart in which one section of the system can be fixed to the screw and the other section can be attached to the nut so when the screw turns displacement movement is produced.

Figure 3.3 Leadscrew

Some of the most remarkable advantages of the leadscrew are the following:

- Self-locking capacity
- Precise for linear motion
- Efficient force multiplier
- High load capable
- Manufacturing is accessible
- Compact size
- Low maintenance

The mechanisms explored in this work aligned with requirements established, positioned the leadscrew principle as an optimum option for displacement in this device. As discussed in previous sections, the size requirements are tight and thrust force required is also high, therefore a system multiply the force is essential and leadscrew is able to help increasing the force produced by the motor at the same time still keep packaging size reasonable to implant the system inside the human body. Low maintenance features of leadscrew are suitable for this application since once it is implanted would be no way to perform maintenance service unless another surgery takes place.

3.1.3 Leadscrew and thread analysis

In order to identify a potential leadscrew for this project, it is necessary to understand the differences between distinct thread types and how it affects the system performance. The most common leadscrew threads are illustrated in figure 3.4

Square thread has the advantage of a minimum friction movement and is good option for power loads however its manufacturing process is complicated due to its square geometry. In addition, square thread leadscrew can carry high power loads, however still a bit lower than trapezoidal threads despite of its low friction number. No radial pressure affects the nut in excess since there is no angle inclination.

Trapezoidal thread is recognized per a 30° angle profile forming its trapezoidal contour. This thread is the most one used for leadscrew since it is efficient and manufacturability is simple. One good example is the thread of the lathe where precision and big loads are crucial.

Acme thread is considered to be part of the trapezoidal family with an angle of 29°. In comparison with square thread, friction is higher and efficiency is lower, nevertheless acme thread is stronger because it is wider at a section closed to the screw body.

Buttress thread is in triangular shape. This thread is used where load force attacking screw is applied in one direction only. It is comparable with square threads in efficiency for leadscrew applications but still easier to manufacture.

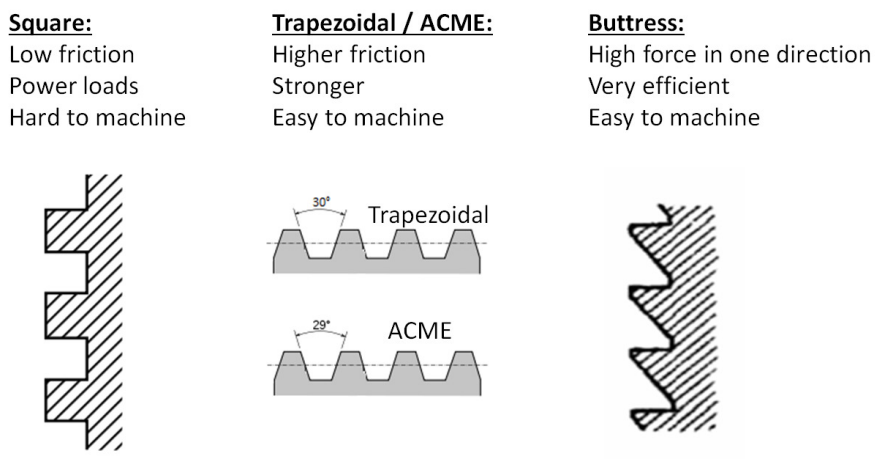


Figure 3.4 Leadscrew thread types

Moreover, besides knowing thread configurations it is important to understand screw lead, pitch, lead angle and starts in order to select the right screw profile. The lead of a screw thread is the axial advance of a helix or screw during one complete turn (360°) [21]. Therefore if the requirement is to displace 1mm per day, it means a screw with a lead of 1mm would give that millimeter distance linearly when turns 360°, in contrast a screw with 0.5mm lead would need two full turns to reach 1mm linear distance. Pitch is the linear distance between adjacent threads as illustrated in figure 3.5. Another important term is the number of starts, If the starts number is one then pitch and lead are the same and screw has only one helical thread along its length. In contrast if the number of starts is different than one, it means that there are intertwined threads, for example if starts number is 2 and the pitch is 1 mm, then lead is pitch times starts (2 x 1 = 2mm). Figure 3.5 illustrates these concepts graphically. Lead angle is the defined as the radial distance between the plane of rotation and the helix.

$$Lead\ angle = \ arc\tan\left(\frac{l}{\pi\ dm}\right)$$

Where *l* stands for lead and *dm* stands for mean diameter.

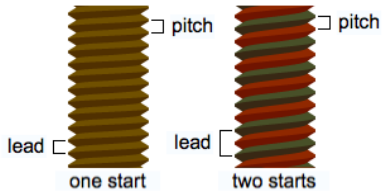


Figure 3.5 Pitch, lead and starts

The requirements list specifies a distraction rate of 1mm per day so it is decided that possible lead values for the screw can be 0.2mm, 0.25mm, 0.5mm and 1mm, but no more than 1mm. For this project is better to control the screw to turn at least one time to gain one millimeter linearly instead of turn screw 180 degree only to reach the same millimeter, the control and precision is easier with lower values of lead and error is expected to be lower too.

Furthermore, the application is well related with features of trapezoidal thread and is not desirable to have manufacturing process issues or excessive costs; therefore trapezoidal thread is the selected option. Now, having idea of thread profile and screw lead the next step is to determine the required torque to activate the leadscrew. Mathematical expressions are applied to determine torque to move the load based on different variables such as pitch and screw lead, mean diameter, expected load to be moved and coefficient of friction. The intention is to keep constant our load as 5N per requirements list along with phi angle and coefficient of friction while vary screw mean diameter and lead to obtain torque values and define possible options that could meet system requirements by having a motor alone or a motor in combination with a power transmission. The mathematical expressions described below [22] are used to calculate the torque to push a load.

$$T_{forward} = \frac{F d_m}{2}\left(\frac{l + \pi\mu d_m \sec\alpha}{\pi d_m - \mu l \sec\alpha}\right) = \mathrm{T_{forward}} = \frac{\mathrm{F d_m}}{2}\left(\frac{\mu \sec\alpha + \tan\lambda}{1 - \mu \sec\alpha \tan\lambda}\right)$$

Table 3.1 compares torque results obtained for different values of screw mean diameter and lead distance distributed in six cases. It is interesting that at higher diameter values, the torque required is also higher. Observe that case 3 and case 4 are calculated with same mean diameter but different lead distance resulting in lower the required torque at lower lead distance.

Table 3.1 Torque to move the load for different screws

Parameter	Symbol	Units	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
Mean diameter	**dm**	**mm**	**10.00**	**8.00**	**5.00**	**5.00**	**3.00**	**2.00**
Lead	**l**	**mm**	**1.00**	**0.50**	**1.00**	**0.50**	**0.50**	**0.20**
Lead angle	*λ*	*radian*	*0.03*	*0.02*	*0.06*	*0.03*	*0.05*	*0.03*
Half thread angle	*α*	*radian*	*0.02*	*0.01*	*0.03*	*0.02*	*0.03*	*0.02*
Load on the screw	*F*	*N*	*5.00*	*5.00*	*5.00*	*5.00*	*5.00*	*5.00*
Pi	*π*	*Unitless*	*3.14*	*3.14*	*3.14*	*3.14*	*3.14*	*3.14*
Coefficient of friction	*μ*	*Unitless*	*0.25*	*0.25*	*0.25*	*0.25*	*0.25*	*0.25*
Angle of friction	*φ*	*radian*	*0.24*	*0.24*	*0.24*	*0.24*	*0.24*	*0.24*
Torque w phi	**T-forward**	**mN m**	**7.10**	**5.43**	**3.99**	**3.55**	**2.30**	**1.42**
Torque w/o phi	**T-forward**	**mN m**	**7.10**	**5.43**	**3.99**	**3.55**	**2.30**	**1.42**

The optimum scenario would be to require the lower torque to perform bone elongation counteracting the 5N force and per table above it can be reached by having a very small diameter screw and the lowest possible lead distance, basically the case 6. However, a very small diameter is not a good option to support mechanical stresses in bending or torsion conditions and very small lead values may increase the execution time and the energy storage requirement. For that reason equilibrium is recommended, the case 4 seems to be the best option in size and lead distance no matter that torque requirements are around 3.55 mNm for a 5mm screw diameter. The torque can be amplified adding a transmission system in next stages but for now, screw selected is not very small in diameter making it robust enough to support stresses. The leadscrew selected is from the company Faulhaber and its cost is obtained directly from the company quoting 1 piece and 500 pcs a year for production purposes.

3.1.4 Design flow outputs

The completion if this stage is reflected in figure 3.6 where design flow outputs describe the leadscrew selection and prepare the inputs for stage number two following the sequence previously established by design flow proposal.

Leadscrew selection		
Inputs	**Design selection criteria**	**Final Outputs**
From requirements list: Required force > 5N 6 cm distraction distance Linear movement capable Adaptability with motor	Advantages and disavantages of different threads Review leadscrew catalogues Calculate required torque at different screws to move load Square or buttress thread $T_{raise} = \frac{Fd_m}{2}\left(\frac{l+\pi\mu d_m}{\pi d_m - \mu l}\right) = \frac{Fd_m}{2}\tan(\phi+\lambda)$ Trapezoidal threads $T_{raise} = \frac{Fd_m}{2}\left(\frac{l+\pi\mu d_m \sec\alpha}{\pi d_m - \mu l \sec\alpha}\right) = \frac{Fd_m}{2}\left(\frac{\mu\sec\alpha+\tan\lambda}{1-\mu\sec\alpha\tan\lambda}\right)$	Trapezoidal leadscrew Screw length 7cm Screw diameter 5mm Pitch 0.5mm Lead 0.5mm Starts 1 Lead angle 0.03 radian Reuired torque 3.55 mNm Cost $160 Material - Stainless steel Market availability is wide No manufacturing restrictions

Figure 3.6 Defined outputs for stage 1

3.2 Motion generator device analysis and selection

3.2.1 Design flow inputs and possible outputs

The information obtained from stage one about leadscrew selection is essential to understand the amount of torque necessary to perform osteodistraction. However it is understandable that power transmission would be indispensable. The figure 3.7 illustrates the stage two inputs which are the outputs from stage one combined with initial requirements listed in requirement list and the expected outputs at the end of this section.

Motor selection		
Inputs	**Design selection criteria**	**Possible Outputs**
Reuired torque 3.55 mNm Compact size Easy to control Low power consumption High cycling capable	Rated torque > Calculated torque Cycles > 100,000 Package < 13mm x 13mm DC Voltage < 24V Advantages and disavantages of different motor types Review motors catalogues	Motor size Motor type Motor torque Motor speed Motor Voltage Motor Current Electric control compatibility Cost Market availability Manufacturing restrictions

Figure 3.7 Motor inputs and possible outputs

The selection of the device that will create the motion to displace the bone is crucial understanding that required pushing force must be higher than 5N trying at the same time to keep power consumption rated low.

3.2.2 Movement generator options

Among an ocean of options mentioned in the morphological chart section, actuators can be considered as the best option due to recent technology improvements in achieving high torque or powerful linear motion in small packages or even miniature sizes. Actuators powered by air, liquid or electric sources are common. However, hydraulic actuators handle a high amount of torque or thrust but fluid storage and high working pressures is a risk for implantable devices plus working fluids are sometimes toxic or hazardous to human. On the other hand, pneumatic actuators are known as very efficient machines but tied to system's pressure so they need a compressor to maintain constant pressure which is very difficult to package in small and implantable systems. Regarding electric motors, they require an applied electric tension to move,

therefore power source is commonly attached in the system. The advantage is that battery technology is constant development and can be found in small packages so the best option is to select an electric motor or actuator.

In the world of actuators or motor powered by electrical sources many designs are available and working principles to move are diverse. However only two general options are discussed below as the main options, linear actuators and rotational motors, the other options were considered in morphological chart section.

3.2.2.1 Linear actuators

Linear actuators are popular to displace loads linearly and are broadly available in the market at distinct presentations, also designed around different working principles. The main linear actuators explored can be separated into four main groups illustrated in figure 3.8, electro-mechanical actuators, magnetostrictive actuators, piezoelectric actuators and ultrasonic actuators.

Electro-mechanical actuators convert rotational motion to linear displacement using an electric motor in arrangement with screws, gears and ball bearing components located internally to produce a linear movement of the shaft. Its force is respectable in proportion to its size.

Magnetostrictive actuators work under the physical principle that significant strain is produced when a special material it is subjected to magnetic field stimulation; the materials with this behavior are called mangnetostrictive materials. One of the best options in mangetostrictive actuators is the Terfenol-D alloy based actuators. They produce high linear force, high strain compared to other materials at low voltage operation with microsecond response within wide temperature ranges; however the strain generated is still in the range of micrometers. Displacement magnitudes are not very significant for this application and further mechanisms

would be required to amplify travel distance or stimulate actuators several times resulting in power consumption increase. In addition, magnetic field generation is mandatory to stimulate the actuator and there a risk of external magnetic signals to introduce noise into the system causing poor or unexpected activation.

Piezoelectric actuators are based in piezoelectricity principle in which certain materials accumulate electric charge when are subjected to mechanical stresses. The opposite is also true, if the material is electrically stimulated the strain rate is altered. Piezoelectric actuators are capable of produce high forces but the limitation is the very small amount of produced strain, another limitation for piezoelectric actuators it derived from its elaborated methods of control. The small size availability along with high force is always an advantage for these devices.

Ultrasonic motor actuators are tinny devices capable of produce small forces and little displacements. These devices are moved by ultrasonic vibration produced by an internal crystal then amplify the vibration with resonance. A camera lens in auto focus application is an example of this motor in action.

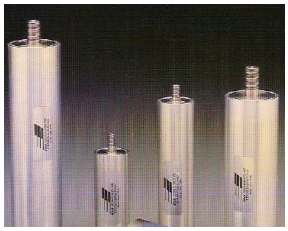
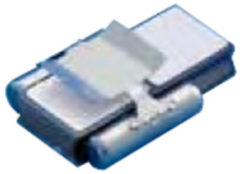
			
Electro-mechanical	Magnetostrictive	Piezoelectric	Ultrasonic

Figure 3.8 Linear actuators

Linear actuators biggest advantage is that there is no need to have an element to transform movement since they produce linear motion directly and are capable of move the required the 5N still meeting the small package requirement. On the other hand, they typically push once are energized and retrieve its original position once power is removed, for that reason an additional mechanism is needed to keep distracted position while the actuator is coming back to its original length. The big disadvantage is that back movements are hard to detect and correct.

3.2.2.2 Rotational motors

Rotational motors are very suitable for robotics or precision systems, size package and working principle mechanisms are diverse in the market. The main options considered for this project are listed explained below and can be classified in these groups illustrated in figure 3.9.

- Stepper motors
- Servomotors
- DC motors

Stepper motors have two or more individual coils that are activated in commutation sequence rotating the shaft one fraction of revolution at a time. The full rotation is divided in segments or steps of one revolution. Stepper motors are controlled by pulses that commute the activation of every coil separately and typically follow a sequence commanded by a microcontroller or external driver. Every step represents a defined number of degrees so shaft positioning is easy to calculate based on the number of required steps to reach the desired position. For example a stepper motor with steps of 3° requires 60 activation pulses to move half a revolution or 180°. These motors are high precision and leadscrew compatibles. However, the risk is to miss one step without notice it and lose location precision if the load is too heavy for the motor because

they are used without any electrical feedback or open loop. Another advantage is regarding driving control which is not that simple compared to DC motors for example. Unipolar and bipolar motors differ in coil connections and therefore number of external cables but still functionality and concept is the same.

Servomotors are mostly used for robotics and can be controlled precisely in regards to its position and velocity. Moreover, they have limited rotational range which is commonly less than 360° but as long as they run within range are very precise units. They are integrated by a small electric motor, reduction gears, a potentiometer connected to the shaft and feedback unit or encoder to make it a closed loop system in contrast with the stepper motors.

DC motors are very used for application that do not require positioning control but require high torque with open loop control systems. On the other hand can be used as close loop control units with simple control circuits if the application requires positioning or velocity strict control making them very versatile. Rotational motion produced by DC motors is reduce with gears train if torque requirements are higher and velocity is lower.

		
Stepper motor	Servomotor	DC Motor

Figure 3.9 Motor types

The DC motor is the best option for this project since its versatility allows controlling position and velocity with simple control circuits while adapting an encoder very easily for feedback purposes. In addition, DC motors have real possibility of adapting a gear train to multiply torque and lower velocity plus size project restrictions can be well addressed by many options available in the market showing very small diameter units. On the other hand, risk of miss steps and complex control are the reasons to leave the stepper motors outside the scope. Also, the ability to customized feedback components in DC motors in a more convenient package makes servomotors to lose advantage. DC motors capacity to add a transmission and obtain a high torque while slow motion are very consistent with the requirements of the osteodistractor concept thinking in bone elongation process.

Many options and companies were explored but at the end the selected motor is form Faulhaber company, the product is called DC Micromotor series 0816. Table 3.2 illustrates its appearance and more important parameters [23].

Table 3.2 Selected motor features

Appearance	
Diameter	8 mm
Rated Torque	0.7 mNm
Stall Torque	1.15 mNm
Nominal voltage	3 V
RPM (No load)	13250
Current (No load)	0.016 A
Speed constant	4526 RPM/V
Torque constant	2.11 mNm/A
Current constant	0.454 A/mNm
Rated speed	2540 RPM

Motor torque is lower than the one required by leadscrew (3.55 mNm) so elongation cannot be reached with a motor alone and needs something to amplify torque. In addition, revolutions per minute of the motor selected are extremely high and if screw lead is 0.5mm, in reality only two turns are needed to displace the 1mm distance. For that reason a reduction gearhead is introduced in the next section to magnify torque and reduce revolutions per minute.

3.2.3 Design flow outputs

Stage number two in completed with motor selection and it is possible now to obtain the final outputs which are reflect in figure 3.10 and will be used as inputs for the next stage. The outputs are basically related with selected motor characteristics and parameters.

Motor selection		
Inputs	**Design selection criteria**	**Final Outputs**
Reuired torque 3.55 mNm Compact size Easy to control Low power consumption High cycling capable	Rated torque > Calculated torque Cycles > 100,000 Package < 13mm x 13mm DC Voltage < 24V Advantages and disavantages of different motor types Review motors catalogues	DC motor 8mm diameter Motor torque 0.7 mNm Motor speed 2540 RPM Motor Voltage 3V Motor Current 320 mA Easy electric control Cost $380 Market availability is wide No manufacturing restrictions

Figure 3.10 Motor inputs and final outputs

3.3 Mechanical torque amplifier analysis and selection

3.3.1 Design flow inputs and possible outputs

The outputs from stage number two are the inputs for stage number three but notice that stage three is divided in two different component selections; one is for drive electronics selection which is managed in next section and the mechanical transmission analysis and selection which is covered in this section. The design flow inputs and possible outputs for the transmission selection are shown in figure 3.11

Transmission selection		
Inputs	**Design selection criteria**	**Possible Outputs**
Motor torque 0.7 mNm Motor speed 2540 RPM 8mm diameter Reuired torque 3.55 mNm Adaptability with motor Adaptability with leadscrew Compact size High cycling capable	Transmission output torque > required calculated torque Cycles > 100,000 Package < 13mm x 13mm Advantages and disavantages of different gearhead types Review gearhead catalogues	Transmission size Gearhead type Output torque Gearhead output speed Transmission reduction ratio Motor Current Compatibility with motor and leadscrew Cost Market availability Manufacturing restrictions

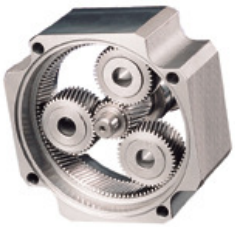
Figure 3.11 Transmission inputs and possible outputs

3.3.2 Gears train options

There are several options that can meet our torque requirements and the main options considered for this project are basically divided into planetary gearheads, spur gearheads and zero backslash.

The gearheads are available in 8mm and 10mm diameter size for our 8mm diameter motor and the difference is related to size only since the 10mm transmission is longer than the 8mm version. Furthermore for the spur gearheads there is one option compatible under the same diameter specification of 8mm. However, there is a suitable transmission for the project; the transmission from Faulhaber for 8mm of diameter has the particularity to warranty zero backslash movement which makes it suitable for this purpose. Table 3.3 shows the best options for this project.

Table 3.3 Gearhead types

Type	Diameter	General sketch
Planetary gearhead	6mm, 8mm, 10mm	
Spur gearhead	8mm & 12mm	
Zero backslash gearhead	8mm & 12mm	

The best option according to our needs is the zero backslash gearhead option which is available in 8mm diameter package. Table 3.4 shows main component features intended to be mounted in line with dc motor selected [24].

Table 3.4 Transmission selected features

Appearance	
Continuous operation	8000 RPM
Continuous Torque	15 mNm
Intermittent torque	25 mNm
Number of gears stages	6
Reduction ratio	120 : 1

The minimum torque to move a 5N load by a 5mm diameter leadscrew is 3.55 mNm according to calculations in previous sections. Also, dc motor selected has a rated torque value of 0.7 mNm which means it needs to be amplified around five or six times to meet torque leadscrew requirements. The gearhead selected can reach a continuous torque of 15 mNm after amplification which is around four times the required torque. The speed of the motor is 2540 RPM which is acceptable with the gearhead limit of 8000 RPM so they are fully compatible.

The lead value for selected leadscrew is 0.5mm which means two full turns are required to reach 1mm of distraction distance. Speed motor is 2540 RPM and if reduction ratio is 120:1 then screw will turn 21.16 times in one minute or one turn every 2.835 seconds, therefore it will take 5.67 seconds to displace 1mm linearly.

3.3.3 Design flow outputs

Now that optimum gearhead is selected, the design flow outputs in figure 3.12 are clear and can be considered as finished for mechanical transmission section included in stage 3 and will be taken as inputs for stage 5.

Transmission selection		
Inputs	**Design selection criteria**	**Final Outputs**
Motor torque 0.7 mNm Motor speed 2540 RPM 8mm diameter Reuired torque 3.55 mNm Adaptability with motor Adaptability with leadscrew Compact size High cycling capable	Transmission output torque > required calculated torque Cycles > 100,000 Package < 13mm x 13mm Advantages and disavantages of different gearhead types Review gearhead catalogues	Transmission size 8mm Gearhead type - Zero backslash gearhead Output torque 15 mNm Gearhead output speed - 21.16 RPM Transmission reduction ratio 120:1 Time to displace 1mm linearly - 5.67s Compatibility with motor and leadscrew Cost $270 Market availability is wide No manufacturing restrictions

Figure 3.12 Transmission inputs and final outputs

3.4 System control and communication

3.4.1 Design flow inputs and possible outputs

The motor selected and discussed in previous stage (number two) needs an electrical control to fully meet accuracy requirements of linear displacement. Figure 3.13 shows inputs required to analyze this second part of stage number three and define suitable combination of devices to fulfill controls.

Drive electronics and communication selection		
Inputs	**Design selection criteria**	**Possible Outputs**
Motor type - DC motor Motor Voltage 3V Motor Current 320 mA Wireless communication Feedback signal Close loop control Low response time Hign motor precision control Low power consumption Compact size	Package < 20mm x 30mm Advantages and disavantages of different controllers Advantages and disavantages of different control circuits Advantages and disavantages of different feedback devices Advantages and disavantages of communication signals Low voltage Low current Frequency approved for medical usage	Circuitry size Central control unit type Central control unit model Control circuit and components Feedback type and components Communication interface type Communication frequency Electric circuit design PCB board design Total power consumption Components cost Market availability Manufacturing restrictions

Figure 3.13 Control and communication inputs and possible outputs

Expected outputs are divided into sections to assemble an integral control, the main focus are controller, electronics, feedback, communication and final electrical schematic sections.

3.4.2 Controller

The control of a motor of dc voltage is a common scenario in electrical applications and for that reason there are many options. The most interesting and with high chances to be used in this project are analyzed.

Controllers are capable to electrically read and manipulate in both electrically and mechanically sense the condition of a complete system during a routine or assigned task. The main idea is that by setting a defined optimum set point for the process, the controller measures the error between the desired value and the value at certain time and then adapts the output signal to compensate that error until reach the preset value. Commonly, controller are divided in proportional (P), integral (I) and derivative (D) and are most frequently found in industry as combination. Some examples are: PI controller, PD controller and PID controller, etc. The proportional part is a function of the current error in contrast with the Integral portion which is a function of the past errors accumulation, also the derivative section is forecasting the errors based on the present rate of change of the system.

The Programmable Logic Controller or PLC is widely used in industrial applications since it maintains its functionality under vibration and mechanical shock conditions plus withstands extensive range of temperatures. PLC is designed to automate processes with multiple signals of inputs and outputs controlled by a preloaded program located in its internal memory. The interface with an external computer allows the user to modify the programmed commands and sequences information.

The PID controllers and PLC's are available in packages that do not meet our size requirements.

The Microprocessors are well known for being the integrated circuits capable of develop the functions of a central processing unit of the computer and for that reason is considered to be the brain of the hearth of the computer. It receives inputs and then following instructions located into the memory sends information through the outputs to perform the desired routine. These devices are designed to the personal computers market and require external components to complement

the system such as RAM and ROM memory. Microprocessors in combination with external memories can process high amount of data at very high speed while compute and store many variables

Microcontrollers are integrated circuits capable of store a processor, RAM and ROM memory and inputs/outputs in a single package. Its usage is very popular for simple and domestic applications such as TV remote controls, microwaves, printers, toys, electronics domestic appliances. Also, microcontrollers are used in more serious tasks such as power tools and medical implantable devices. It is important to notice that microcontrollers include a microprocessor of lower capacity and speed compared to the single and powerful microprocessors typically found in personal computers.

Microcontroller are well recommended when battery consumption is a concern in the application since they are very low power consumption in the range of miliwatts and while they are in sleeping mode may reduce power consumption to nanowatts range. These devices are considered to be single purpose computers because are dedicated to one task by running a program stored permanently in the memory. Another great advantage is the small size and low cost but still conserving its robustness to harder environmental conditions unlike the microprocessors.

The Peripheral Interface Controllers or PIC's are basically microcontrollers with independent coding and memory to manage code and address numerous functions. PIC's are very popular and have some advantages over other systems that make them the preferred option for some users. Some of the key points are: smaller size (some of them smaller than a coin), very low cost, readily available in the market and programming friendly interface along with free development tools.

The Object Oriented Programmable Peripheral Interface Controller (OOPic) is an integrated circuit with Integrated Development Environment allowing the user to program in simple code of Java or C among other common languages. Object oriented programing refers to the use a model based on virtual objects rather than model using pure code lines compilations.

The concept of the single-board microcontroller includes a microprocessor mounted in a PCB board along with the circuits of inputs and outputs, memory and all the electronics to support the system. These boards are famous in the education sector since allow the students to start in the microcontrollers world focusing in the programming of the microcontroller and forget about the adjacent circuitry, in addition they are low cost units compared to its capacity and convenience.

Two of the most well-known single board microcontrollers are the Arduino and Dwengo. The Arduino in based on Atmel AVR microcontrollers and the Dwengo board is based on the PIC18F4550 controller

In general, microcontrollers are developed and manufactured by many companies; most of the most known suppliers are Atmel, Epson, Fujitsu, Infineon, Intel, Microchip, NEC, Panasonic, Renesas, Toshiba and Texas Instruments among many others.

The size and cost requirements of this project suggest the usage of microcontroller as main option. Addressing communication needs detailed in section 3.4.6 of this document the microcontroller unit selected is the model PMA5110 [25] from the company Infineon illustrated in figure 3.14. This SMD microcontroller unit includes a 315/434/868/915 MHz RF transmitter, embedded 8051 Microcontroller, 125 KHz ASK LF receiver and 10 bit ADC all packaged together within an area of 9.7mm x 6.4mm x 1.2mm.

Figure 3.14 Microcontroller selected

3.4.3 Electronics

At this phase of the project the control circuit is expected to be simple and functional to simplify the system control loop and save as much room as possible in the structure. Furthermore, one important wish is that motion can be executed in two directions to allow elongation or have the ability to decrease the lengthening distance in case it is required. It is good to remember that recommended distraction rate is 1mm per day; however the optimum elongation rate would be slightly different from patient to patient so variation has to be part of the concept.

The simplest circuit to address two directional rotation movements is the H-bridge configuration shown in figure 3.15. The motor is connected with four gates or transistors which commute to polarize motor in both directions. Also some diodes are added to support reverse voltages when motor is turned off.

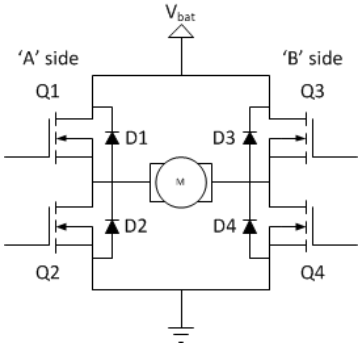


Figure 3.15 H-Bridge circuit

One option is to design the circuit by use diodes, resistors and transistors independently however it may consume more space than select a module with everything included plus thermal protection and other advantages are a plus.

Dual full H-bridge driver model L298 and packaged as PowerSO20 from STMicroelectronics Company [26] is suitable for our design. Figure 3.16 illustrates the packaging design with dimensions of 16mm x 11.1mm x 3.6mm prepared for surface mount processing (SMD).

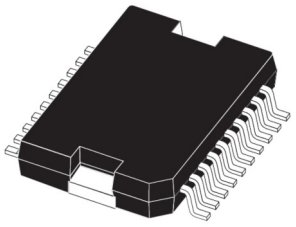


Figure 3.16 SMD H-Bridge module

3.4.4 Feedback signal

A mechanical system controlled by electrical circuits is one of the most precise ways to be aware of the system motion and position, either with poor or excellent confidence; it all depends on the feedback designed to the system and the elements to complement the arrangement. Our system requires to move at a rate of 1mm in sessions planed once a day, and it is crucial to maintain good control on the distraction distance at every time the motor rotates. For that reason our system requires feedback to detect the motor position and count the number of revolutions to ensure the 1 mm per day displacement. According to our motor characteristics and size restrictions, it is recommended to use an encoder to manipulate the motor's rotation at a precise level and avoid poor lengthening. Basically there are encoder to controlled linear motion (linear

encoders) and encoders to read and control rotational movement (rotational encoders). Since a rotational motor is the suitable option for this project per section 3.2, then the encoder to use is the rotational encoder. In definition a rotational encoder senses the position of a motor o generator of movement device by counting lines or positions in every rotation of the shaft. The encoder sends a digital signal to the control unit to let it know what is the position, direction and velocity of the motor at certain time and then the electrical brain or control unit decides if more rotation is needed or if the movement has to stop based on previously established number of rotations or angle of positioning. Also, when need to determine position and speed and incremental encoder is a good option since it creates several pulses. In contrast when position is the main focus of feedback, the absolute encoder is mostly used since signal is unique at different locations. Some encoders are mounted in the same structure with the motor and are even attached to the motor as a cap. They are commonly used in the medical industry in scanners and automated devices with strictly requirements of microscopic motion.

The table 3.5 shows the main features of the selected encoder for this project. It is an incremental encoder to allow velocity, direction and position to be fully controlled. This encoder is optical and manufactured by Faulhaber Company under model PA2-50 [27].

Table 3.5 Encoder features

Voltage	2.7 V
Current consumption	8.5 mA
Number of channels	2
Lines per revolution	50
Operation temp	-40C to 85C

3.4.5 Communication

Distraction osteogenesis device communication with the outside is a key element to meet requirements or accessibility and external remote control, at the same time to obtain a feasible design actively manipulated by a doctor while device is implanted. Several communication interfaces were exposed and analyzed in the morphological chart early this document; however the most important considered for this concept are Wi-Fi, Bluetooth low energy (BTLE) and Radio Frequency (RF) at different ranges.

Bluetooth is a wireless network technology with a band frequency of 2.4 GHz with a range distance of around 100m and current consumption of 15mA approximately.

On the other hand the Wi-Fi is a facilitator of data interchange between devices and allows internet access without wires. The band frequency for Wi-Fi is rated from 2.4 GHz to 5.0 GHz with range of around 20m.

In general, radio frequency (RF) is ranged between 3 kHz and 300 GHz which corresponds to radio waves oscillation. If humans are exposed to high power radio frequencies it can cause burns well-known as RF burns. However, in medicine radio frequency is present at lower level bandwidths in magnetic resonance images (MRI) and RF diathermy treatments running in ranges from 1 MHz to 915 MHz with non-harmful effects in human body.

The Federal Communications Commission (FCC) in 2009 created The Medical Device Radio communications Service (Med Radio) to regulate and specify the authorized frequencies for medical devices such as implantable pacemakers and defibrillators. The frequency ranges are: 401 MHz to 406 MHz, 413 MHz to 419 MHz, 426 MHz to 432 MHz, 438 MHz to 444 MHz and 451 MHz to 457 MHz.

Bluetooth and Wi-Fi operation frequencies are around 2.4 GHz so exceed the limits established by FCC. Moreover, they are commercial bandwidths and can be accessed by different users by accident. For that reason is preferable to have a dedicated FCC frequency range and prevent common users to interfere with the signal.

The microcontroller selected in section 3.4.2 handles a radio frequency in lower MHz range with 315/434 MHz RF transmitter included in package. The package size for microcontroller and communication devices in a single chip is very convenient for project size restrictions. However, before finding this chip, separate RF and microcontroller units were considered but are not shown in this document since are not relevant anymore.

3.4.6 Design flow outputs

The completion of this stage number 3 is closed with the outputs for drive electronics and communication shown in figure 3.17.

Drive electronics and communication selection		
Inputs	**Design selection criteria**	**Final Outputs**
Motor type - DC motor Motor Voltage 3V Motor Current 320 mA Wireless communication Feedback signal Close loop control Low response time Hign motor precision control Low power consumption Compact size	Package < 20mm x 30mm Advantages and disavantages of different controllers Advantages and disavantages of different control circuits Advantages and disavantages of different feedback devices Advantages and disavantages of communication signals Low voltage Low current Frequency approved for medical usage	Circuitry size 20mm x 30mm Microcontroller selected Microcontroller model PMA5110 H-bridge Incremental optical encoder for feedback Radio frequency (RF) Low frequency 434 MHz PCB board designed 24.5 mA current consumption at 3V Components cost $153 Market availability is wide No manufacturing restrictions

Figure 3.17 Control and communication inputs and final outputs

3.4.7 Remote control unit

Full and detailed remote control unit design and specific interface with the implanted device is out of the scope of this thesis work; however it is important to mention considerations and expectations for this remote control unit once developed.

Basically, communication has to exist in both directions, from remote control unit to the implanted device to activate the system and produce movement; same way from internal device to remote control unit to receive feedback about exact position of the osteodistractor device. Control remote unit is intended to display lengthening information recorded from first time movement, that way doctor can read total gaining, daily average rate or weekly distraction distance. Also the interface will allow doctor to program periodic distractions of less than 1 mm several times a day for several days or weeks in a row. For security purposes, doctor is the only one authorized to control the unit and a pass code is mandatory to unlock the usage of the remote control.

3.5 Battery

3.5.1 Design flow inputs and possible outputs

The reliability of the osteodistractor device is expected to be high, therefore the power requirements have to be met completely the needs of the system and still maintain a certain margin of security after the expected cycles. Basically the power source will distribute energy to various circuits, the logic control, communication and power movement in general. Following the flow structure described in figure 3.18 it is noticed that the power requirements are based on the outputs established in the previous stages when motor and drive electronics along with communication was evaluated. The stage four is defined to battery requirements.

Battery selection		
Inputs	**Design selection criteria**	**Possible Outputs**
Motor Voltage 3V Motor Current 320 mA Control circuits voltage 3.3V Control circuit current 24.5 mA Cycles/day On time/cycle Total cycles Driver and accessories info Safe low current Safe low voltage Compact size	**Equations** $Battery\ Life = \frac{Battery\ Capacity\ in\ Milli\ amps\ per\ hour}{Load\ Current\ in\ Milli\ Amps\ per\ hour}$ Watts = Voltage x current mAh = mA (motor & accesories) x Total cycles x On time per cycle (hr) Review battery catalogues	Battery type Battery size Battery current capacity Battery Voltage capacity Battery mA/h Cost Market availability Manufacturing restrictions

Figure 3.18 Battery inputs and possible outputs.

3.5.2 Battery calculations

The continuous on time of this device is not long and it is expected to happen only once a day for a period of 2 months approximately. Table 3.6 shows the power requirements calculated for a period of 6 seconds continuously turned on once a day to complete 1mm linear displacement as calculated in sections 3.2.2 and 3.3.2 pulling 0.32 A (0.016 A with no load) for motor activation. Also the encoder current demand is 8.5 mA added to the microcontroller's power consumption of 0.5 mA. The estimated total time of consumption is computed using 60 days or 2 months obtaining the battery capacity in miliamperes-hour (mAh).

Table 3.6 Battery electrical requirements

Expected usage	**Months**	**Days**	**Min/day**	**Minutes total**	**Hours**
	4	120	0.2	24	0.4
Motor requirements	**Current (mA)**	**Voltage (V)**			
	320	3			
Microcontroller and Communication	**Current (mA)**	**Voltage (V)**			

requirements	16	3
Encoder requirements	**Current (mA)**	**Voltage (V)**
	8.5	3.3
Battery requirements	**Current (mA)**	**Voltage (V)**
	344.5	3.3

Battery required has to deliver a minimum current of 344.5 mA rated at 3.3V and lasting capacity of 137.8 mAh (344.5 mA x 0.4 h).

There are many batteries in the market for general purposes and widely size packages such as camera batteries, cell phone batteries, watch batteries, MP3 rechargeable batteries, and toys batteries. On the other hand, there are more specialized purpose batteries such as medical external equipment batteries, pacemaker batteries, implantable devices batteries, etc.

In general, there are three main options to approach this power requirements, the first one is consider a battery with lower voltage or current capacity compared to what is needed but package several units to amplify voltage or current. The second option is to use an inductive plate that can be charged from the outside to store the amount of energy necessary to activate the mechanism for a certain time and remain inactive the rest of the time. Also there is still the option to find a suitable battery that can meet the requirements of energy for this concept without more complications.

In order to increase reliability and avoid having more components that may add more variables to the system and according to a market research, there are some options that would meet the specified requirements such as Flexcell battery, camera battery and lithium base batteries.

The common sense points out the medical equipment batteries are the way to go, however the osteodistractor device is more similar to external devices regarding power consumption than tinny implantable low power consumption devices such as pacemakers. For that reason and driven the level of power required and size constrictions, the options shown in table 3.7 were the ones which survived to the huge list of tentative battery options.

Table 3.7 Battery best options

Model	Manufacturer	Voltage	Current capacity	Size	Active chemistry
LTC 3PN	Keeper	3.5 V	350 mAH	16.51mm x 15.24mm x 6.731mm	Lithium-Thionylchloride
UBC322030	Ultralife	3.7 V	120 mAH	31mm x 21mm x 3.7mm	Lithium based
Flexcell	Infinite	7.4 V	330 mAH	82mm x 40mm x 2mm	Lithium polymer
1/4AAA80	Kamcy	2.4 V	80 mAH	10.5mm diameter x 11mm height	NI-MH
CR 2354	C-Techi	3 V	25 mAH	diameter 20mm x height 16mm	LiMnO2

The Eagle Picher battery model LTC 3PN [28] from Keeper@ illustrated in figure 3.19 is the suitable source of energy to meet the high reliability requirements along with the low space available.

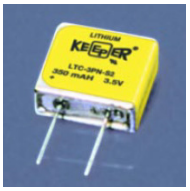


Figure 3.19 LTC 3PN battery

The electrical characteristics of the battery are reflected in the table 3.8 as well as weight and operating temperature.

Table 3.8 Selected battery features

Nominal Open Circuit Voltage at 25°C	3.67 V
Nominal Working Voltage at 25°C	3.5 V
Nominal Capacity (350 hr. rate) at 25°C	350 mAH
Volume	0.103 cu.in.
Weight	4.6 g
Operating Temperature	-40°C to +95°C

Some advantages of this battery compared to others are the following:

- Compliant with lead-free RoHS and WEEE EC directives.
- Corrosion resistance due to stainless steel construction.
- Hermetic seal body package.
- Hundreds of days at low rate continuous usage.
- After 15 years at room temperature still manage stand-by use with 80% capacity retention.
- The chemistry of this battery allows a high energy density profile compared to other products.
- No charging circuits are needed.
- Fewer cells and high reliability due to higher cell voltage
- Optimum voltage regulation due to flat discharge characteristics.
- High temperature usage capability due to non-pressurized system

3.5.3 Design flow outputs

The Figure 3.20 reflects the outputs related to the battery selected and at the same time these output parameters will be part of the inputs for stage number 5.

Battery selection		
Inputs	**Design selection criteria**	**Final Outputs**
Motor Voltage 3V Motor Current 320 mA Control circuits voltage 3.3V Control circuit current 24.5 mA Cycles/day On time/cycle Total cycles Driver and accessories info Safe low current Safe low voltage Compact size	**Equations** $Battery\ Life = \frac{Battery\ Capacity\ in\ Milli\ amps\ per\ hour}{Load\ Current\ in\ Milli\ Amps\ per\ hour}$ Watts = Voltage x current mAh = mA (motor & accesories) x Total cycles x On time per cycle (hr) Review battery catalogues	Lithium-Thionylchloride battery 16.51mm x 15.24mm x 6.731mm Battery Voltage 3.5V Battery capacity 350 mAh Cost $145 Market availability is limited No manufacturing restrictions

Figure 3.20 Battery inputs and final outputs.

3.6 Structure

3.6.1 Design flow inputs and possible outputs

The stage number five is designated for structure design where inputs from stage one, stage two, stage three and stage four are required. Also requirements from design specification section are considered. Figure 3.21 shows inputs and expected outputs of this final stage.

Structure selection		
Inputs	**Design selection criteria**	**Possible Outputs**
8mm diameter motor 8mm diameter gearhead 5mm diameter and 6cm long leadscrew PCB control board 20mm x 30mm Muscle compression loads Torsion and bending stresses Compact size	Size < 2.5 cm x 1.8 cm x 20cm Material selection Non corrosive Stresses resistant Fully encapsulated Protect internal components Prevent bone atrophy	Package size Profile Material Cost Market availability Manufacturing restrictions

Figure 3.21 Structure inputs and possible outputs

3.6.2 General concept

The structure design is intended to protect all the components from the body chemistry reactions and stresses, the intention is to encapsulate the entire mechanism to obtain a telescopic structure that can retract and displace doing controlled bone elongation. The structure concept is based on two parts with assemble to each other one sliding into the other. Internal components such batteries and PCB board are not design to be single implanted, also leadscrew may not support stresses produced by muscle and physical movement. For that reason the structure is designed to absorb all the stresses like tension, compression, bending and torsion and let the internal mechanism to do the unique function of bone distraction without external forces interruptions. In addition, the structure is the part of the system that be fixed to the bone, in where it is preferable to use screws since they are very common in bone attached metal plates or bars.

The shape of the structure has to be comfortable for patient since it will be implanted for some months, the profile is something very important to manage stresses and be pleased while implanted. Regarding stresses the cylinder profile may be the best option for bending but not really well for torsion. Moreover, the structure has to be adapted to bone shape for better fixation but still conserve rounded contour. The figure 3.22 shows the structure profile considered the best option for bone adaptation.

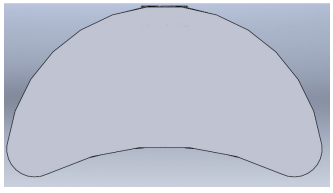


Figure 3.22 Structure profile

The other key part of the structure is dimensions, per requirements established in section 2.1.1 the maximum package dimensions are profile of 2.5 cm x 1.8 cm with a length of 20cm. In next section all component are tried to fit this package dimensions.

3.6.3 Mechanism integration

With the package size specified in requirements section, the challenge is now to encapsulate all the components preciously selected: motor, transmission, encoder, leadscrew, PCB board, battery, microcontroller with RF capacity, H-bridge driver, holes to fix the screws to the bone.

The figure 3.23 shows a base which includes mechanical and electrical parts that be mounted inside the structure.

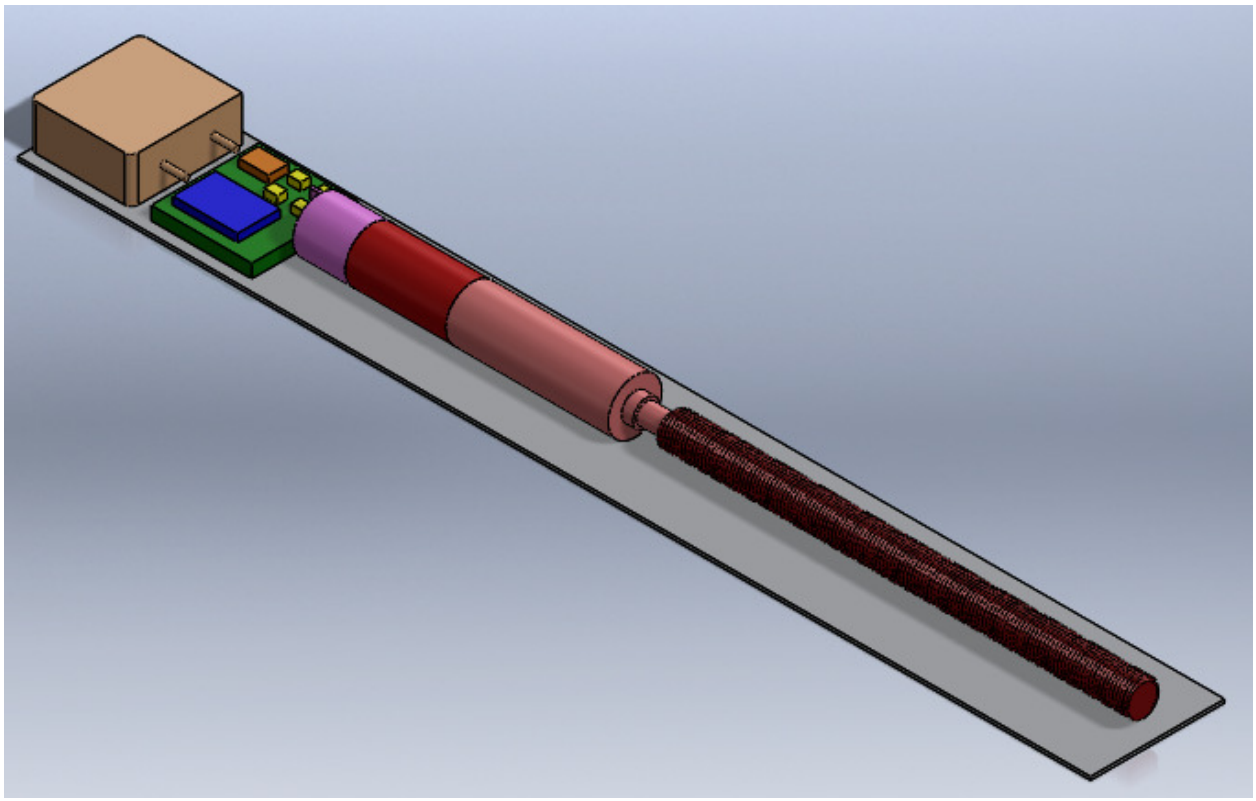


Figure 3.23 Internal component distribution

The external structure is a telescopic mechanism that allows 6 cm distraction distance as requirements list specify. The figure 3.24 shows how one side of the structure is distracted with respect to the other segment increasing the total device length.

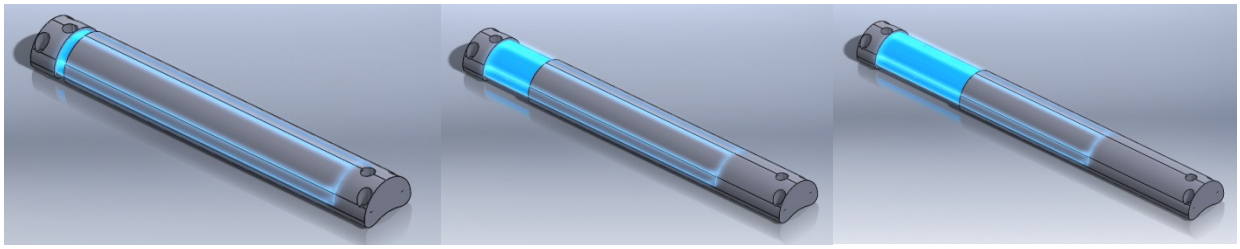


Figure 3.24 Structure telescopic movement

A transparent view is helpful to visualize the internal distribution of components as shown in figure 3.25 for the telescopic structure. A plate with all the components is fixed in one segment of the structure while the other segment includes a threaded nut where the leadscrew slides to produce the movement.

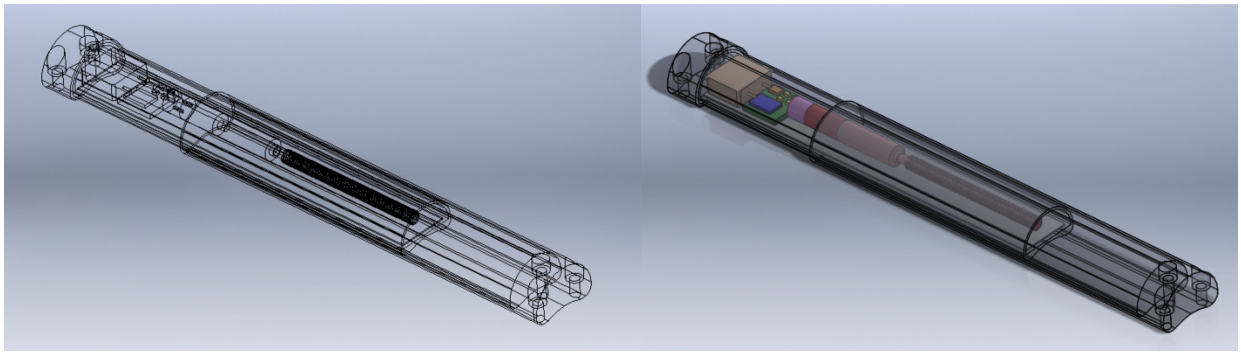


Figure 3.25 Structure transparent view

The structure profile is modified to better adapt to bone's geometry and reach an enhanced fixation. The top isometric view is illustrated in figure 3.26 which is concave to partially surround bone's contour.

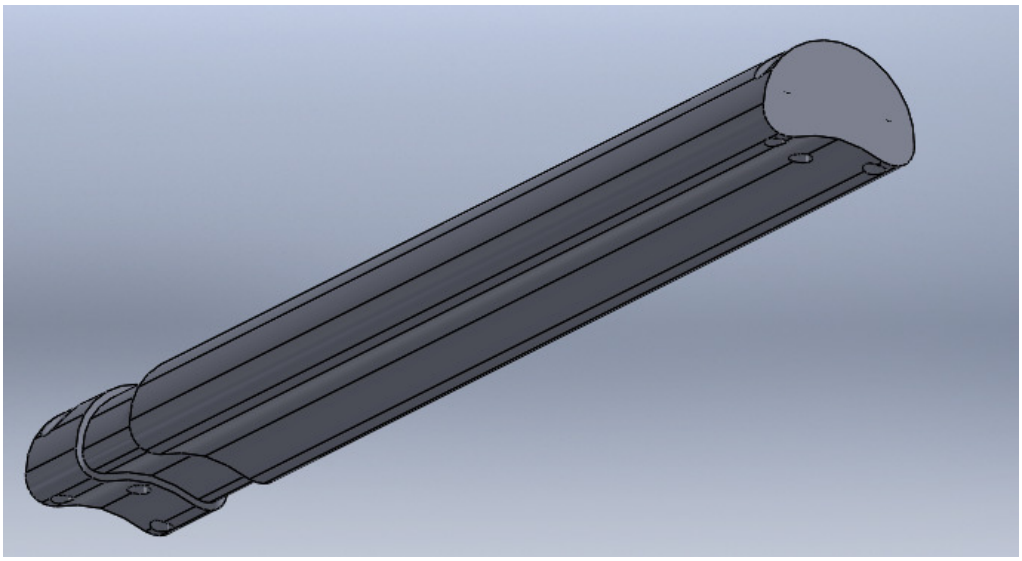


Figure 3.26 Structure profile adapted to bone's shape

The Figure 3.27 shows three holes for each structure segment designated for fixing screws, the screws are cortical screw type of 3.5mm body diameter and 6mm head with a hexagonal socket head of 2.5mm based on the OrthoMed catalogue. Polyaxial and monoaxyal screws are also considered but level of details is out of the scope of this document.

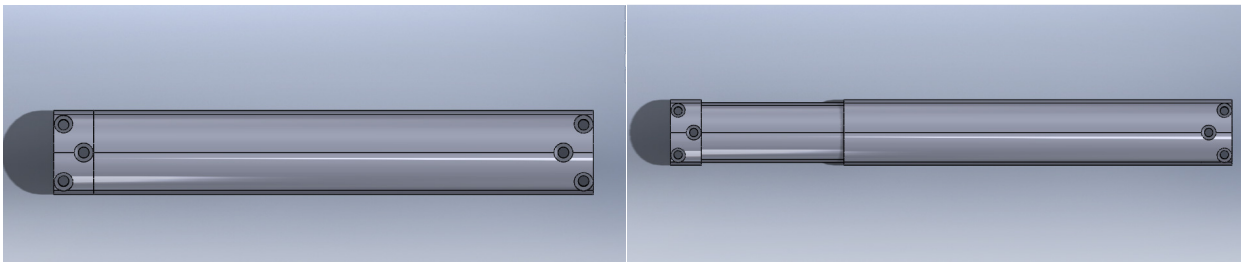


Figure 3.27 Structure with screws

Two of the three screws have a different angle of inclination with respect to the longitudinal axis of the osteodistractor to help with torsion stresses and improve fixation conditions. The figure 3.28 illustrates this slight incline position for the screws located left and right in the picture but keep the hole located in the middle completely aligned with longitudinal bone's axis.

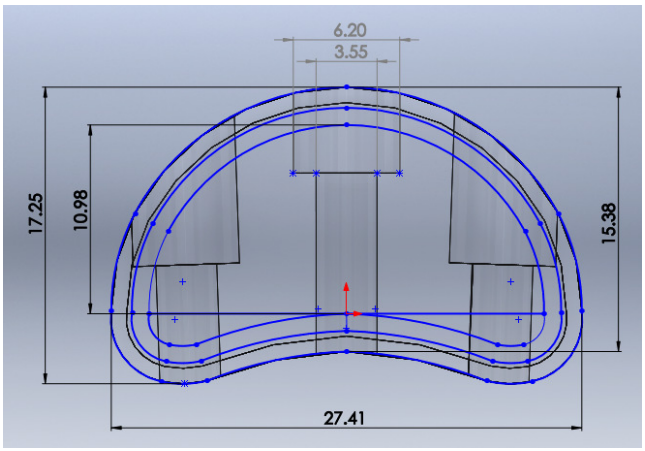


Figure 3.28 Screws location and orientation

General important dimensions:

- Total length at initial stage 176.4 mm
- Total length when completely distracted 236.4 mm
- Maximum distraction distance 60 mm
- Maximum height 17.25 mm
- Maximum width 27.41 mm
- Screws of 3.5 mm body and 6mm head.

3.6.4 Material selection

Besides bone elongation, the osteodistractor device structure is required to perform a special function. This embedded function is to act as bone plate similar to implantable metal sheets located to aid in complex fractures. Callus distraction [3] device needs to maintain separated bone segments aligned to allow proper healing and bone consolidation without complications. In order to achieve this function, the structure material becomes important part of the design process.

The osteodistractor device material is intended to be appropriate to be implanted inside human body, hence avoid allergic reactions or intoxication, besides not react chemically with internal body fluids. Despite many materials are candidates; the most important are metals like stainless steel, cobalt alloys and titanium alloys, polymers and biomaterials such as calcium phosphate ceramic.

Stainless steel decreases its tension after a period of time and fixation may lose compression. Compared to steel, titanium last longer ensuring well fixation for more time, however it is limited as well.

Polymers are being developed for many applications but its usage not seems to be a good option in this project since many polymers cause body reactions instantly or after prolonged time of exposure, moreover strength is not as good as metal structures.

Biomaterials are designed specifically to be human body compatible and some are destined to be absorbed by the body after certain time of being implanted or naturally break to release the injury once consolidation process is complete, however those materials has the limitation of the strength which is not as good as metals. If the structure is not restricted in size, biomaterials are good options but if size is specified stronger materials can be better options.

Despite of the material selected features, improper selection may derive in several issues like failure under muscle stresses or structure weak union with bone resulting in deformities or non-union. Moreover, galvanic corrosion appear if materials are not selected properly and disparate materials are combined in the same structure, some of these inappropriate combinations may be titanium telescopic structure fixed with stainless steel or cobalt-chromium alloy screws.

Another important consideration for material selection is derived from Wolff's Law, which states that if loading on a particular bone increases; the bone will remodel itself over time to become stronger to resist that sort of loading [29]; also the opposite is true, poor loading will become bone less dense (osteopenia) and weaker. For implantable plates stress shielding produces atrophy if plates or screws support the majority of the load applied to the bone. For that reason low modulus materials are recommended for bone implantable plates, titanium alloys are commonly selected suitable to avoid bone atrophy.

Among several options, titanium alloys are the best options for this particular device. In specific titanium alloy 6AL4V which is mutated with aluminum (6%), vanadium (4%) is mostly used in medical industry. The most relevant advantages of titanium for implantable applications are:

- Non toxic
- Corrosion resistant
- Bio compatible
- High strength
- Lightweight
- Long lasting
- Non-ferromagnetic (MRI compatibility)

Currently medical grade titanium is utilized to produce implantable pins, wires, bone plates, bars, rods, screws and prosthetics.

3.6.5 Stresses simulation FEA

The main function of the structure is to provide physical protection for internal mechanisms and components from external conditions such as muscle forces, body fluids and general physical conditions of the human body happening internally. For that reason, stress analysis are carried out in Ansys to determine structure stress limits under compression, torsion and bending forces, the intention is to determine if design structure profile and material are suitable for this application and can effectively protect the system under combined loads.

Compression analysis is shown in figure 3.29 the image of the top is sketching the fixed point and the compression direction. The image in the bottom is the mesh distribution. Compression analysis represents muscle contractions and weight carrying when implanted in tibia while stand up or walking.

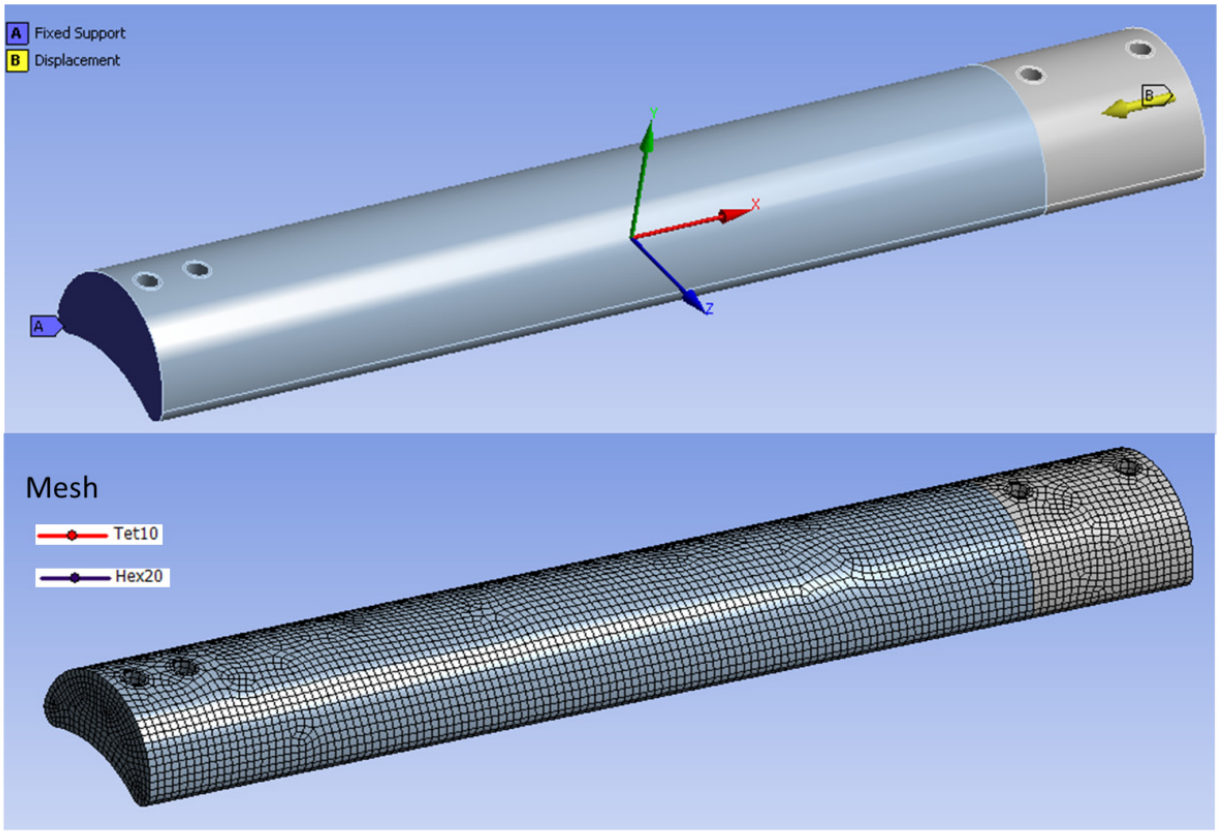


Figure 3.29 Structure FEA analysis for compression load

Figure 3.30 shows compression results where yield stress limit is 460 MPa for titanium, but the highest reached stress is around 387 MPa, this value is below yield stress limit and do not represent a failure condition.

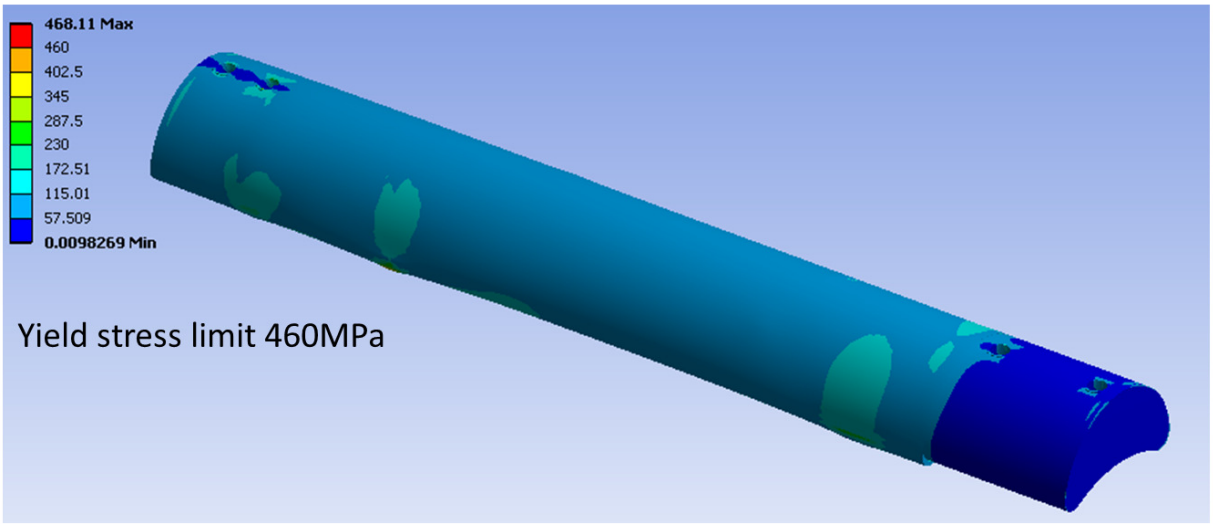


Figure 3.30 Structure FEA results for compression load

The maximum resulting force to reach elastic limit of the structure is 8,239.7 N which is an acceptable parameter if compared with measured forces for walking or jumping with peaks of 2,000 N according to measures on a force plate.

Besides compression, another structure parameter to measure is related to its capacity to resist torsion since internal body muscles are capable to produce torsional movements positioning distraction osteogenesis process at risk. The structure profile is design to counteract torsion as better as possible due to its curved profile. Torsion analysis represents internal muscle forces or natural leg movements from one side to another. Figure 3.31 illustrates the fixed and displacements application points and directions along with mesh distribution.

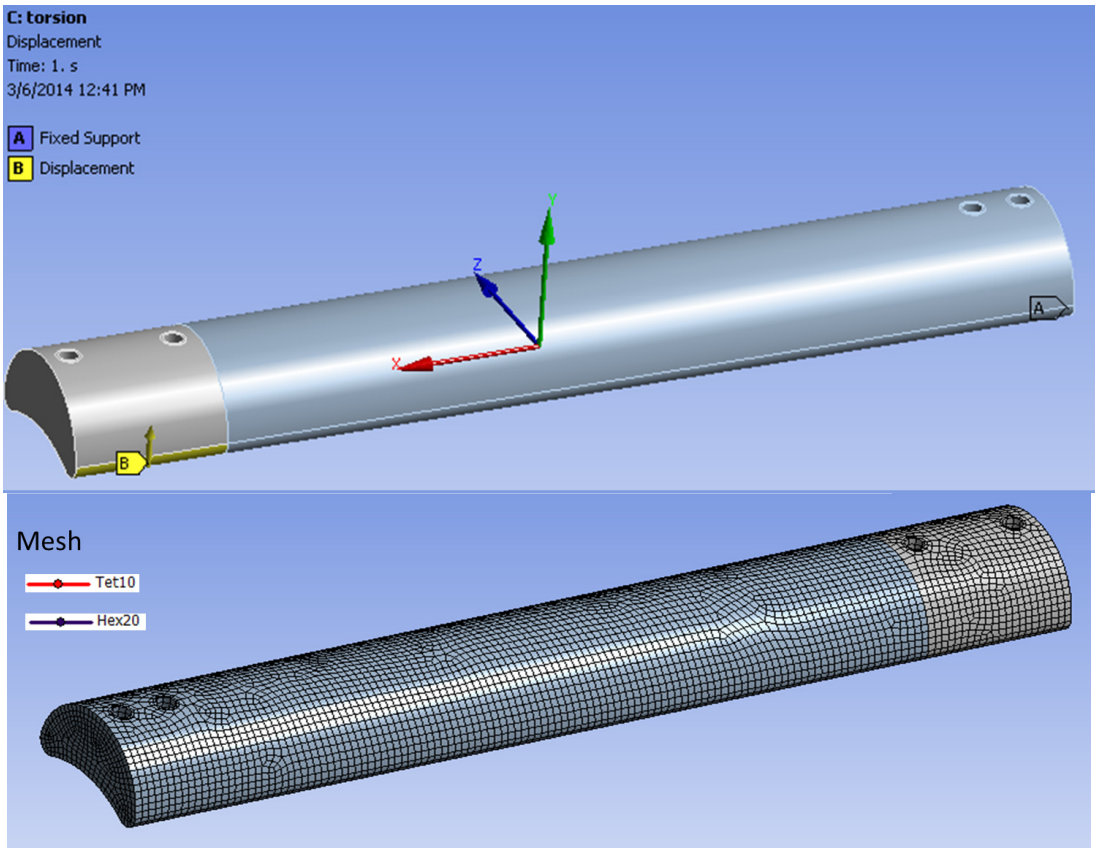


Figure 3.31 Structure FEA analysis for torsion

Figure 3.32 shows torsion loading results but present no complications as can be observed per low intensity blue color representing no risk for material properties.

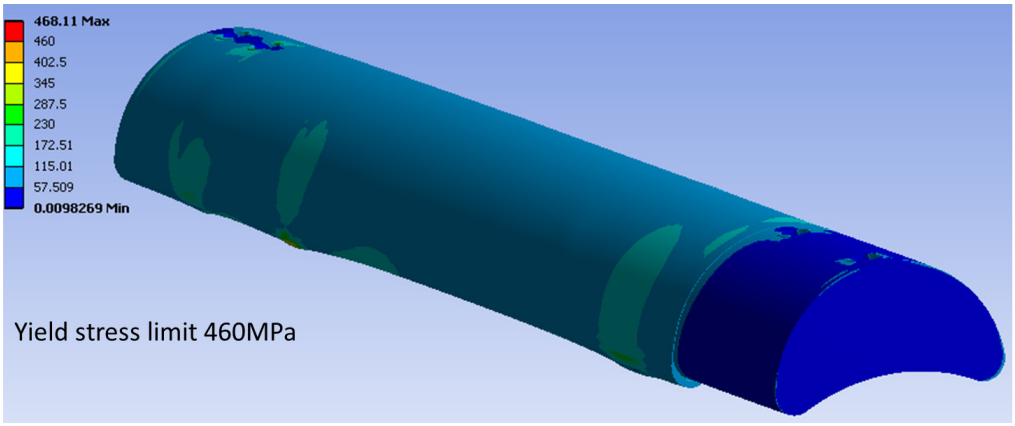


Figure 3.32 Structure FEA results for torsion

The maximum momentum to reach elastic limit of 460 MPa in the structure is 15,395 Nmm being fairly acceptable to record momentum stresses recorded for leg muscles at around 8,000 Nmm. For that reason designed structure is considered as acceptable to support torsion loads in this application.

Probably the most difficult test for this particular structure profile is the bending analysis. Figure 3.33 illustrates bending applied in the center of the longitudinal axis of structure while it is fixed on the screw contact points.

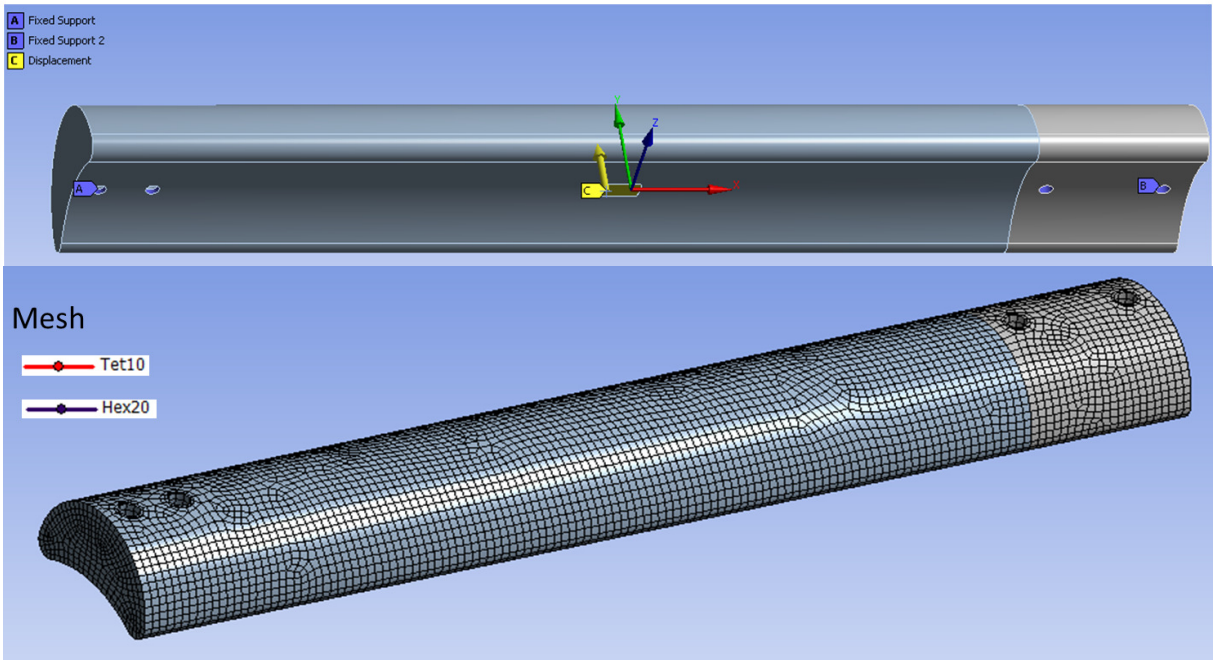
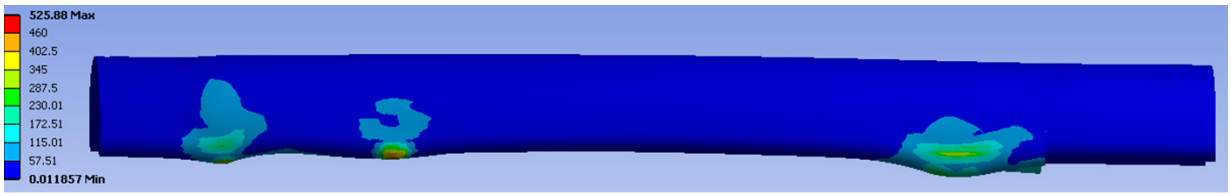


Figure 3.33 Structure FEA analysis for bending loading

Bending stresses represent again internal muscle loads but at the same time external supporting of the extremity in different angles since device is implanted along longitudinal bone axis. Also, external hitting accidental contacts or knockings are more likely under this stress type analysis category since most of them will not be compression or torsion loads. Figure 3.34 illustrates stress distribution for bending load applied in the center of the structure.



Yield stress limit 460MPa

Figure 3.34 Structure FEA results for bending loading

The maximum force obtained to reach elastic limit of the structure is 245.44 N which is not very high but unless someone else will stand on the treated leg of the patient or significant accidental hit happens, there is no reason to worry about it. Moreover, patient under distraction osteogenesis procedures are indicated to stay in bed or use crutches along the process.

3.6.6 Design flow outputs

The outputs of this stage number five are basically dictating the final conceptualization design with all components integrated and structure consideration address in full. Figure 3.35 shows the design flow outputs of the final stage.

Structure selection		
Inputs	**Design selection criteria**	**Final Outputs**
8mm diameter motor 8mm diameter gearhead 5mm diameter and 6cm long leadscrew PCB control board 20mm x 30mm Muscle compression loads Torsion and bending stresses Compact size	Size < 2.5 cm x 1.8 cm x 20cm Material selection Non corrosive Stresses resistant Fully encapsulated Protect internal components Avoid bone atrophy	Package size 2.7 cm x 1.7 cm x 17.6cm Concave semi-circled profile Titanium alloy Cost $400 Market availability No manufacturing restrictions

Figure 3.35 Structure inputs and possible outputs

4. DETAILED DESIGN

4.1 Regulations

In order to determine what are the regulations that proposed osteodistractor device has to meet is necessary to classify the device in one of the three possible groups according to the U.S. Food and Drug Administration (FDA) [30]. These groups are defined with respect to the potential health risk that the patient may face when using certain device.

Class I devices are considered as low risk for patient health, therefore its control is not very restricted, some devices such as arm sling fall in this category.

Class II devices are more controlled and require FDA evaluation and approval after pass different testing conditions. The X-ray machines are part of this category.

Class III devices represent the highest risk for the patient in case something goes wrong, typically are the one sustaining the patient's life or have a significant impact in patient's life quality. Class III devices are the most observed by FDA and its approval is much stricter, a good example are the pacemakers. It may also be that these devices are not fully tested yet and that is the only reason to fall in class III.

This project is an implant which means that will be place inside the body [31], more specifically attached to the bone which means that Class II or Class III would be assigned. This is consistent with the fact that most of the implants are categorized as class II or III. Now, if we look at the bone plates classification, most of them are class II devices so by comparing the osteodistractor versus the bone plate, it is fair to expect a class II classification, moreover patient's life is not at risk by potential mechanical failures of this system. Depending on the classification and device

type, the FDA assigns different testing requirements and considers aspects such as: potential allergy risk due to materials of which device was made or substances derived from material reactions with organism, toxicity of the materials or components implanted that cause any kind of intoxication, materials that would be absorbed or would absorb internal tissue, procedure risks and complications by doing one or multiple surgeries are importantly considered.

The exact requirements are known until apply for product approval and might reference more than one specification in particular for class II and class III.

4.2 Safety Factor

This section is very relevant concerning the mechanical design of this part. The safety factor of design means how robust is the physical device when compared to calculated expected values in real cases. For example, it would be a general understanding that airplanes have to has high safety factor than cars based on the consequences of a failure, however the airplanes typically have a lower safety factor than automobiles since the quality of the parts of in airplane industry is higher than the quality of the auto industry parts, that means that low safety factor for high quality products can make more efficient designs.

The distraction osteogenesis device developed in this work has to be manufactured with high quality parts and processes since a failure can derive in physical risk to the patient. In addition the design is expected to be optimum as possible to reduce the size and weight of the implantable geometry and be more comfortable for the user. The best possible scenario is that the osteodistractor device can be small and light as much as possible and at the time of finishing the task fails completely, which means safety factor of one. Of course that an optimum design such the one described is very risky for the health of the patient and for that reason a reasonable safety

factor is required. The safety factor recommended for this project is 2, but only under the observance that materials are the best quality and manufacturing processes are very strict and controller. The Table 4.1 illustrates the selected components and its safety factors, some of them can be still optimized as soon as the market develops new technologies or enhance current technologies.

Table 4.1 Safety factor for all components

Part	**Design Criteria**	**Requirement**	**Device Capability**	**Safety Factor**
Motor	Minimum torque in mNm	0.7	0.7	1.00
Transmission	Minimum torque in mNm	3.55	15	4.23
Microcontroller	Inputs and outputs	2	8	4.00
H-Bridge	Maximum current mA	300	2000	6.67
Encoder	Resolution of lines per revolution	20	50	2.50
Battery	mAh requirements	137.8	350	2.54
Leadscrew	Push force in Newtons	5	21	4.20
Titanium structure	Max stresses MPa	300	460	1.53
Screws	Max stresses MPa	300	460	1.53
Mean Safety factor				**3.13**

4.3 Manufacturing

In order to develop the osteodistractor device and launch it in market, it is required to capture the implications of manufacture a product like this. There are different parts involved and for the same reason different manufacturing processes and stages may be required.

The structure is a component that needs to be built from raw material because it is completely customized to our needs. Moreover, it is mandatory to find a company to support with the forming or casting of the titanium alloy structure with proven high quality and few variations in dimensions.

Moreover, most of the individual components are readily available and supplied by established suppliers such as the motor, transmission, leadscrew and electronics. On the other hand, the PCB board was designed with customized characteristics so a reliable supplier has to be found to source this key part of the system.

As soon as all the individual parts are obtained, several manufacturing stations are tentatively required. For the mounting of the SMD electronics into the PCB board the soldering profile is very important and a good option can be the reflow process or the wave solder but either option has to be lead free. Furthermore, the insertion of all the components into the structures along with the PCB board is essential to get accomplished with the lower number of possible mistakes. Finally, due to the complexity of the design and the numbers of components, the manufacturing process is not a simple process but complex manufacturing and different stations and equipment are needed to complete the process.

4.4 Costs

The cost of the proposal is also a factor to consider once the product is launched in the medical market. This section is not intended to perform a market study but to understand the total material costs for the osteodistractor device at single volume and 500 pcs a year volume. The table 4.2 reflects the prices for the material required to build this device.

Table 4.2 Cost for every component for 1 and for 500 pieces a year

Part	**Usage**	**Unit Price for 1 pc only**	**Total Price for 1 pc only**	**Unit Price for 500/yr**	**Total Price for 500/yr**
Motor	1	$380.00	$380.00	$266.00	$266.00
Transmission	1	$270.00	$270.00	$189.00	$189.00

Microcontroller	1	$11.00	$11.00	$7.70	$7.70
H-Bridge	1	$15.00	$60.00	$10.50	$42.00
Encoder	1	$125.00	$125.00	$87.50	$87.50
Diodes	4	$2.00	$8.00	$0.50	$2.00
Battery	1	$145.00	$145.00	$101.50	$101.50
Leadscrew	1	$160.00	$160.00	$112.00	$112.00
Nut	1	$5.00	$5.00	$3.00	$3.00
Titanium structure	1	$400.00	$400.00	$280.00	$280.00
Screws	6	$5.00	$30.00	$3.50	$21.00
Total Cost			**$1,594.00**		**$1,111.70**

The costs shown in table 4.2 are for raw materials only and the final product costs have to include the manufacturing and human resources charges. In addition, resources to deliver production parts to final customers have to be added, validations, government permits, etc.

5. RESULTS AND CONCLUSIONS

5.1 Discussion and conclusions

The experience obtained in this thesis work is very important to approach other similar projects that involve several disciplines and mechanisms. Referencing figure 1.4 Research methodology, it is noticed that the first 3 phases “Identify potential opportunity”, “Define design process” and “Obtain general concept” are well defined by previous literature concerning engineering design process and could be assessed systematically. On the other hand, the fourth phase “Develop product proposal” was very difficult to address correctly since defined sequence for internal components or functions in previous conceptualization sections was not helpful to establish a design criteria for the specific components. For example, design conceptualization phase was able to indicate that a leadscrew was the best option for displacement, however the leadscrew type, lead, length, pitch, material, among others were not specified and depended on different inputs and independent design parameters. For that reason the design flow structure strategy was developed, it allowed to set an order for specific selection of component and assessed every component in detail but at the same time communicates the information from one component to another creating the design information links for the final detailed concept.

Moreover, to set a strong design flow path, identify clear steps and its correlation plus propose an order to execute every single step, enhance the taken decisions in components selection and positively impact relevant design modifications. In addition, the same design process structure can be used as the base for an algorithm to approach similar projects in the same or different discipline, as long as design goals are similar too.

It is worth to mention that this project started as a descriptive design model since no specific instructions were available to complete all the tasks and only known at that point the general idea of how things can be done but lacking of details. For that reason, the design flow structure strategy implementation was responsible to make our model a prescriptive type, which means that specific steps can guide the designer throughout the project helping him with decision making and selection criteria. In complex mechanisms or intricate interdisciplinary projects lacking of an order and connection among components may represent a waste of time and produce defective component selection non-established design criteria is defined.

Design flow strategy methodology developed in this thesis document resulted in a powerful tool for design approach of interdisciplinary projects where designer is not familiar with every field involved in the project. A design flow strategy algorithm built in a computer interface would allow user to design an osteodistractor device for limb lengthening with different requirement inputs but same working principles and save a lot of time in the conceptual design phase and component selection to allow the focus in additional requirements or details to enhance product and reach higher levels of optimization.

Definitely, design systematization is very important when approach parametric design projects and it is very helpful for engineers to design interdisciplinary projects such as biomedical devices, where the expertise area of designer is not wide enough to cover all the involved science fields related. However design systematic steps do not replace research work and full understanding of the entire project concerns and specific areas. Design systematization in biomedical or interdisciplinary projects aids in the arrangement of ideas and most important in the connection of those ideas with the final objective until obtain a functional product that can support the initial project requirements in full.

5.2 Contributions

The contributions of this research work are not restricted to one discipline only due to the interdisciplinary nature of this project, covering purely engineering design topics as well as biomedical engineering concerns.

In biomedical engineering, this research collaborated by proposed and developed a new concept for implantable and remote controlled distraction osteogenesis device for limb lengthening in order to resolve children needs not addressed by current osteodistractor methods.

In engineering design, this thesis contributed with a design flow structure strategy to simplify the design analysis, design conceptualization and actual component selection. The design flow structure strategy main contributions are:

- It defines how conceptual parts selected during design process stage will then interact between them and analyze that interaction to choose suitable and specific parts for each function or sub function meeting the design criteria parameters.
- It can be applied to enhance the current device concept because when modify a component the changes will cascade to other components or subcomponents throughout the structure without distort the conceptualization order and concept generalities, plus it can quickly determine if proposed changes are feasible or not.
- The same reasoning and structure can be used for different multidisciplinary projects that require disintegration of complex mechanisms where component selection order differs from the order in the design conceptualization section.

5.3 Future Wok

This section is divided into two different perspectives. The first one is in regards to the osteodistractor device product, its technology, application, technical development and commercialization. In contrast, the second perspective is about the design steps and methodology applied throughout this thesis work and how it would be applied to current designs and be promoted it for future biomedical complex mechanisms design.

Future work concerning the device is:

- Create a final prototype with the exact parts selected mentioned in this thesis work that allows device validation. Most of the parts selected are high technology mechanisms; therefore they are somewhat expensive. Financial limitations are projected to disappear in the near future.
- Add advanced control interface between device and user, including sensors to monitor organism behavior around the lengthening area, these measured parameters can be temperature, ph, density and produced forces and stresses by soft tissues, muscles, nerves and bone segments around the elongation section at any time. Including real time software, all measurement can be stored and shared via wireless, then if required to take any lengthening decision during the process like stop or accelerate the gaining, there is historical data to analyze and take a decision.
- Develop the external remote control technology to govern the implanted mechanism and show real time progress while acquiring data throughout the limb lengthening process, this data can be presented in charts or graphs for easy understanding and comparison purposes. Moreover, database can be uploaded to the internet from the remote control

directly via Wi-Fi to keep real time medical record posted online, allowing doctor to check patient status from his office or home any time.

- Validation testing is also expected to be conducted under The Food and Drug Administration (FDA) regulations and government requirements to approve the final release and usage of the osteodistractor device as a certificated biomedical device available in the market.
- Regarding commercialization, to find companies to manufacture some customized components of the system such as the titanium alloy structure and printed circuit board. Also, companies to assemble all components together with detailed manufacturing process and high quality standards. Furthermore, to find investments companies to support the project concept and perform a deep market study to obtain a forecast of the marketing information.

Future work concerning engineering design methodology is:

- Develop a computational algorithm based on the design flow structure strategy with preloaded design criteria and expected outputs for every stage. The only initial inputs for the algorithm would be the first stage inputs and then use a preloaded database of components to obtain the best option for each function or sub function. In the same way, if vary only one parameter or component, the algorithm calculates the affected outputs for every component and would revise other parts if necessary. Mechanical analysis can be included in the algorithm to show automatic results for stresses simulation in all directions depending on the concept geometry generate automatically by the system and depending on the loads specified.

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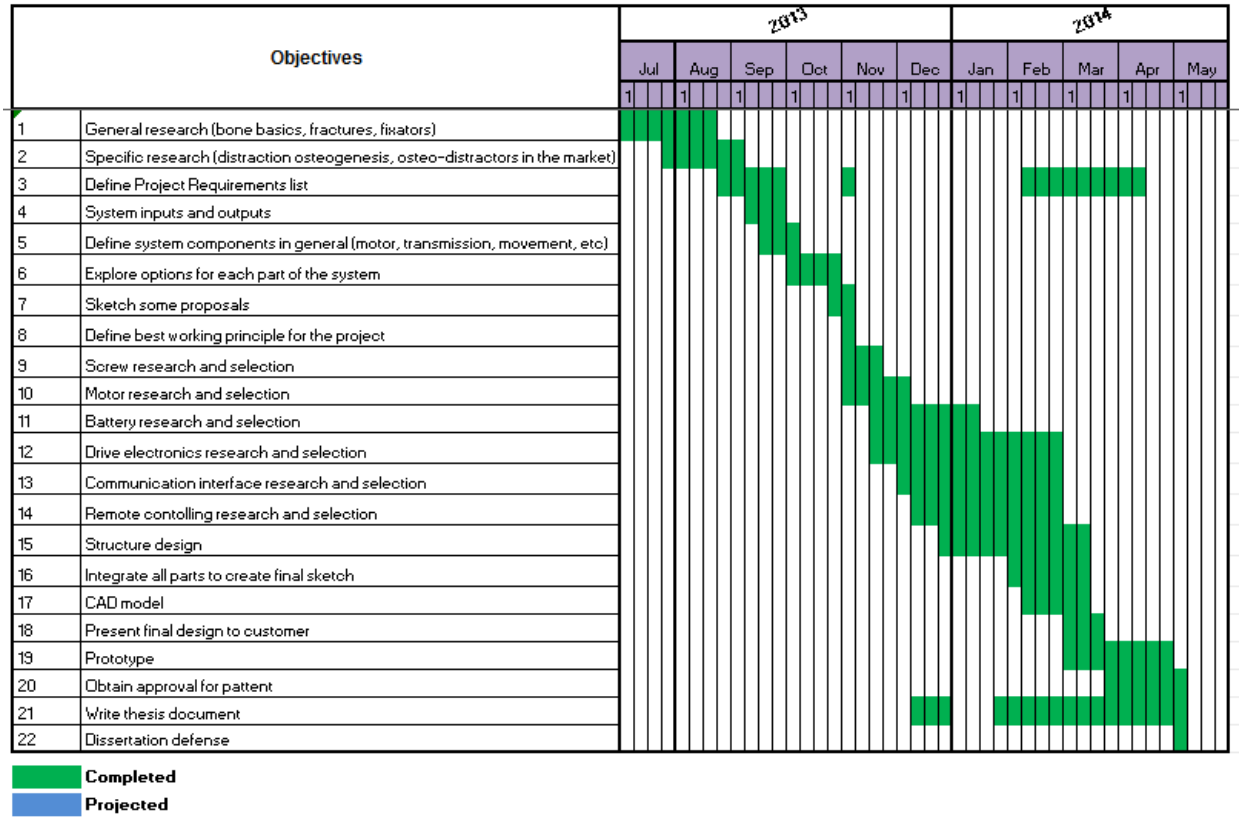
APPENDIX 1

Working activities calendar

UNIVERSITY OF TEXAS AT EL PASO

OSTEO-DISTRACTOR DEVICE DEVELOPMENT PROJECT



CURRICULUM VITA

Mario Eduardo Rodríguez De la O was born in Ciudad Juárez, Chihuahua, México in 1985. The first son of Aureliano Rodriguez Santos and Maria de Lourdes De la O Ontiveros. He obtained a Bachelor's degree in Electro-Mechanical engineering from Instituto Tecnológico de Ciudad Juárez funding his studies with the prestigious Mexican Government Scholarship of Excellent for 4 years and graduated with honors and top 3 of the class of 2009.

Then in 2012 he was accepted in the Master of Science in Mechanical Engineering program at The University of Texas at El Paso. From 2012 to 2014, he worked under supervision of Dr. Noe Vargas Hernandez in engineering design conceptualization and design metrics with focus on TRIZ methodology and sketching variations such as smart pen technology and its effects in design ideation processes to later jump to engineering design process and creative ideation applied to biomedical devices.

From 2007 to 2014 he also worked as relays, electronics and circuit protection devices engineer for Delphi Automotive Systems Company gaining automotive industry experience and was recognized as excellent employee 5 years in a row.

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