AUTOMATED GROWING ROD FOR THE TREATMENT OF JUVENILE SCOLIOSIS

Dissertation
Submitted to
The School of Engineering of the
UNIVERSITY OF DAYTON

In Partial Fulfillment of the Requirements for
The Degree
Doctor of Philosophy in Electrical Engineering

By
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May 2012
AUTOMATED GROWING ROD FOR THE TREATMENT OF JUVENILE SCOLIOSIS

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ABSTRACT

AUTOMATED GROWING ROD FOR THE TREATMENT OF JUVENILE SCOLIOSIS

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Severe scoliosis, when detected in a juvenile, can be treated and upon conclusion of the treatment, will result in a spine with little or no curvature. However, this treatment requires the child to undergo surgery where a device known as a growing rod is implanted on the spine of the juvenile. After the initial surgery the child then returns every six months to have the rods "lengthened" approximately one centimeter to keep up with the child's growth. The purpose of this project is to develop an automated growing rod system using an on-board microprocessor for treatment feedback control. The ultimate goal of the design of the automated growing rod is to limit or remove the requirement of a patient to undergo surgery for rod adjustments by the physician. Utilizing new control technology and hardware design, juvenile scoliosis can be treated in a non-invasive fashion with the efficacy that the current growing rod treatment provides, while reducing cost and improving treatment control. This study has designed and built a test automated growing rod system, demonstrated system functionality, and shown that the system is realizable in an ex-situ lab environment.
Dedicated to my loving wife Rosalie, to my kids Lewie and Tressa, to my parents, and to my sister
ACKNOWLEDGEMENTS

My most sincere thanks are extended to my dissertation advisor, Dr. John G. Weber, who has helped with his guidance and insight throughout the course of this project. His patience and expertise has been key to the success of this endeavor.

I also need to express gratitude to Mr. Casel Burnett who has been a partner in the development of the device discussed in this paper. Casel's encouragement and optimism kept me focused on the goal of changing people's lives. Additionally, Dr. Antiq Durrani and Matthew Wyatt have been instrumental in providing feedback and countless hours of expertise for the development of the growing rod device. Clearly without their guidance and influence this project would have stopped at just the idea phase.

Others that deserve acknowledgement include Dr. Mary C. McCarthy and Dr. Frank J. Lebeda who have helped with the review of presentations, and articles. Their extra reviews on the paper were greatly appreciated.
PREFACE

What has caused this electrical engineer to choose a topic so unrelated to any previous experience and background he currently possesses? Like most things that cause one to action, it is a deeply personal tie to the subject. In this case a good friend, Casel Burnett, has a daughter who suffers from juvenile scoliosis. Upon learning of the procedure she may be forced to endure, my mind began to race with thoughts of how the medical procedure could be improved. My main thoughts focused upon how to change the procedure to reduce suffering and discomfort the patient may feel.

This was the impetus for the development of the device described in this paper. What started as a quick sketch and some ideas on a white board, has turned into a fully developed system that could someday change the way that juvenile scoliosis is treated. I am aware that this is far a field from the areas I consider myself expert, but I know that the growing rod outlined in this paper can change lives. I hope that my naive perspective and unique ideas I present in this paper will help lead more skilled engineers to continue development on better treatment for juvenile scoliosis and bone growth disorders.
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CHAPTER I
INTRODUCTION

Research Area

This project’s objective is to study the possibility of developing a long term medical implant device that would eliminate the requirement of multiple surgeries for the treatment of severe juvenile scoliosis, while reducing the cost of the treatment for the condition. This goal would be achieved via the use of an embedded control processor on the implanted medical device. This project would utilize the power of an embedded microprocessor for closed loop feedback growing rod control, communication to the physician and recording treatment efficacy.

Background

Approximately 3 out of every 10 people have some type of curvature of the spine. This condition rarely requires medical treatment and often goes unnoticed by the person with the spinal curvature. However, a small percentage of the population, three percent by number, suffer from scoliosis[1, 2]. Scoliosis is defined as a curvature of the spine over 10 degrees from the vertical normal when read on an X-Ray. Of the total number of
people inflicted with scoliosis, 0.3 percent of this population will be forced to undergo multiple surgeries for this condition, coupled with the wearing of an external back brace and rehabilitation exercises[3]. This paper describes research into a minimally invasive method to treat the onset of juvenile scoliosis, and to provide a method of better controlling the outcome of the scoliosis treatment. In addition, this research is focused on providing a cost effective method of treating scoliosis via the use of automated growing rod implants. Use of automated growing rods will enable medical doctors to more effectively treat scoliosis, limit the number of invasive surgeries, and allow the option of treatment to a larger portion of the world's scoliosis population in remote areas where such a treatment is currently not an option[4].

Severe scoliosis, when detected in a juvenile (known as early onset scoliosis), can be treated and upon conclusion of the treatment, will result in a spine with little or no curvature. However, this treatment requires the child to undergo surgery where a device known as a growing rod is implanted in the spine of the juvenile[5-7]. Some surgical techniques have the unfortunate side effect of stopping a child's growth[8]. This may have the side effect of limiting the growth of the thorax, development of the lung, and the size of the patient's trunk. The theory of the growing rod operation is to allow for continued controlled growth of the spine, while guiding the straight growth of the spine. In general, the curve is spanned by one or two rods under the skin to avoid damaging the growth tissues of the spine. The rods are then attached to the spine above and below the curve with hooks or screws. The child then returns every six months to have the rods "lengthened" by one centimeter per visit to keep up with the child's growth. When the child becomes older and the spine has grown, the doctor will remove the instrumentation
and perform a formal spinal fusion operation. This treatment typically begins when the child is around the age of 7 years old and terminates at the end of adolescence, usually when the child is around the age of 18. The termination of the treatment ends in the fusion of the spine which also effectively ends the growth of the spine/9/.

**Statement of the Problem**

The purpose of this project is to redesign the functional equipment currently utilized when treating scoliosis with the method of implanted growing rods and braces. The purpose of the new design of the Growing Rod is to limit or even prevent the requirement of a patient to undergo surgery for rod adjustments by the physician. The proposal is to design a system utilizing threaded rods in lieu of the sliding pinned rods utilized today. The threaded rods of the growing rod shall be mechanically driven by an automatic lengthening device. By using this unique drive system, the threaded rods could be linearly positioned very precisely. An on-board microprocessor would control the system and move the growing rod into position. The processor would need to be able to accept wireless commands and would need to be able to control multiple axes.

**Investigation Procedure**

The first step in the investigation procedure is to study the existing growing rod devices and understand the mechanical forces the rods encounter while implanted in the patient's body. Next, a study is performed to determine if an automated medical implant
can be designed to mimic or perform as well as the existing growing rod equipment. If it is determined that automation can indeed perform the function of the automation, then the next step in the process is to develop the algorithms for the software control of the device. All of the software algorithms are tested by the engineer. The next part of the investigation procedure requires the fabrication of a scale model of the resulting design for performance testing. After the performance testing is completed, the entire beta unit built for performance testing is re-evaluated and re-packaged into a smaller final footprint package.

The development and tailoring of the system required a great deal of research from various sources. The primary sources that were utilized in the investigation procedure included: Medical journals and handbooks, interviews with Orthopediatric surgeons, interviews and feedback with general surgeons, discussions with medical implant manufacturers and basic physics and machine handbooks. Through these sources of information the knowledge base for the system design was developed.

The primary goal of this research was to develop a working prototype of an automated growing rod which could be recognized as a minimally invasive method for the treatment of juvenile scoliosis.
Purpose Of The Report

The purpose of this report is to detail the development of a working prototype of the automated growing rod. The results of the research are detailed as well as the goals accomplished during this project. The successful testing of a prototype automated growing rod is also described.

This paper is divided into seven primary parts which are described in the following outline. My conclusions and recommendations are summarized in Chapter 2. Chapter 3 will detail the functionality of the current growing rod system and the development of the proof equations for the development of the automated growing rod. Chapter 4 will describe the mechanical design and packaging for the automated growing rod. Chapter 5 will discuss the electronics and the microprocessor control of the system. Chapter 6 will detail the building and testing of the beta unit. Chapter 7 will explain the benefits of the automated growing rod system and the next steps for the system's future development.
CHAPTER II
RESULTS AND CONCLUSIONS

Introduction

In this chapter the results of the proof of concept or beta unit that was constructed are discussed. Also conclusions are drawn concerning the practicality of the system based upon the beta unit data. Finally, recommendations regarding improvements which could be made to the automated growing rod system are discussed.

Results of the Automated Growing Rod System

The beta unit growing rod system has been fabricated and tested for the amount of linear force the system can generate to accommodate the spine growth of juveniles. In the following chapters, the design and calculated force produced by the system is detailed. What is critical to note is that the findings of experimentation shows that the hardware performs as predicted by the calculations made. The beta unit has proven that the forces required for spinal scoliosis treatment is achievable in a small form factor package that could be implanted in the human body.
The solid model studies have borne out that the unit as designed as part of this study is able to be produced and able to manufactured. Additionally, the studies found in this paper have shown that the equipment required for the assembly of an automated growing rod is fairly inexpensive and off the shelf equipment can be used for most of the assembly of the growing rod. There appear to be no real technical drawbacks that prevent the production of the automated growing rod.

**Conclusions**

The automated growing rod as designed in this paper is a fully automated system that will eliminate subsequent surgeries for the growing rod length adjustment. The automated growing rod is completely implantable in the human body and utilizes the same hardware that is used to mount the current growing rod equipment in the human body. The final result is a growing rod that will mount in the human body as illustrated below.
Figure 2.1 Solid model of automated growing rod device

The system has the advantage of reusing the same hardware as is currently used by surgeons for the installation of automated growing rods. Also the benefit of reduced costs, reduced surgeries, and reduced risks are all realized by the use of the automated growing rod.

The problem with the automated growing rod device is the same issue as is found with all new medical products, the amount of regulation required for satisfaction of regulation bodies, such as the FDA in the United States. This restriction by government regulation, has slowed development of the automated growing rod unit and has set up cost restraints for animal testing for future development. This restraint leads independent
development of the system at a standstill and forces independent developers to look for partnerships with larger companies that have the resources and relationships with the FDA for the development of the automated growing rod. Currently, this author is working with several industry partners to further the progress of the automated growing rod development. Currently discussions are under way with Johnson and Johnson and with the Orthopediatrics company. Both companies have shown interest in the automated growing rod and see the benefits of the device, additionally both companies have the ability to help with the regulation process which is needed to forward the development of the device. Hopefully an agreement can be worked out with one of these companies in order to proceed with further development of the automated growing rod.

**System Advantages**

The advantages of the system are detailed in chapter seven, but a general overview of the benefits are listed within this section. Benefits of the automated growing rod include reduced cost for the overall treatment of scoliosis requiring growing rods, more frequent but less painful adjustments, and the reduction of risks associated with the current method of treatment. The combination of all of these benefits result in a more effective growing rod treatment with a reduced cost, making the overall growing rod experience better for both the physician and the patient.

An additional advantage utilizing the automated growing rod include the removal of the requirement of the physician to be located with the patient in order to make
adjustments to the actual growing rod. This "non-locality" benefit allows the orthopaediatric physician to be located anywhere in the world while the adjustment data is sent to the attending physician with the patient. This benefit allows for third world or less developed countries, to have the same access to treatment that current first world countries have, removing the barrier of required expertise to be located near the patient.

**Recommendations**

Further development of the automated growing rod should be conducted leading to a fully automated adjustment process that allows the unit to autonomously make adjustments or at the minimum recommend to the physician the suggested adjustment parameters. Allowing simple feedback devices such as strain gages could provide a full closed loop control system for the automated growing rod. This would serve as a further aid for the treatment physician for diagnosis and corrective action that is currently unavailable.

Another feature that should be developed for the automated growing rod units is the ability of the unit to store the history of adjustments made by the growing rods on the resident on board memory of the automated growing rod. In doing so, the patient's records would be completely portable, traveling with the rods and the patient to any physician that is able to access the automated growing rod's memory. This would be the ultimate in patient record "portability" and would allow the patient to be treated by differing physicians in the case of an unforeseen emergency.
Summary

In this chapter, the outcome of the automatic growing rod system has been discussed, and the feasibility of the automatic growing rod system has been outlined. Additionally, the details of further developments needed for the system have been explained and benefits of the system have been detailed.
CHAPTER III

FUNCTIONALITY OF CURRENT GROWING RODS AND MATHEMATICAL DEVELOPMENT OF THE AUTOMATED GROWING ROD

Introduction

The purpose of this chapter is to describe to the reader the current state of technology of the juvenile scoliosis growing rod treatment. The basic treatment of juvenile scoliosis with the implanted growing rod will be detailed. Also within this chapter the basic mathematical development of the equations utilized for the design of the automated growing rod are detailed and explained.

Current Growing Rod Technology

If the juvenile suffering from scoliosis is determined to have a curvature of the spine with a Cobb angle of greater than 45° it is customary to treat the condition with the implantation of growing rods in the spine of the patient. Aside from the growing rod, all other treatments for scoliosis limit or stop the child's spinal growth. By limiting the growth of the child's spine, other future health related issues arise, including but not limited to unfavorable effects on growth of the thorax, lung development, and size of the
child's trunk. Therefore due to these complications, an internal growing rod is implanted into the scoliosis patient, coupled with the use of an external brace.

What is the Cobb Angle?

To determine the Cobb Angle of a scoliosis patient the following process is followed. On an X-Ray (radiograph) beginning at the head and moving toward the feet, identify the first vertebral body that is maximally angled or tilted. Draw a line on the top of this vertebral body extending toward the apex of the curve. Again going from the head to the feet, identify the last vertebral body that is maximally angled or tilted and draw a line on the bottom of this vertebral body extending toward the apex of the curve. On each of these two lines, draw a perpendicular lines (90 degree line) such that the perpendicular line intersect. The angle between the intersecting perpendicular lines is the Cobb angle.

Figure 3.1 Cobb angle illustration

The theory of the growing rod operation is to allow for continued controlled growth of the spine. This is done through the back of the spine. In general, the curve is spanned by one or two rods under the skin to avoid damaging the growth tissues of the spine. The rods are then attached to the spine above and below the curve with hooks or screws. The curve can usually be corrected by fifty percent at the time of the first operation. The child then returns every six months to have the rods "lengthened" approximately one centimeter to keep up with the child's growth. This is usually an outpatient procedure performed through a small incision. The incision is made and the
growing rods are adjusted with a surgical tool and the rods are pinned into position to remain in position until the next adjustment is made. These adjustments are typically made twice a year. [10]

![Figure 3.2 Typical installation of growing rods in a juvenile](image)

The adjustments to the rods are on the average of one centimeter of growth (distraction) per six month time period. During the adjustment surgery, studies have measured the force exerted by the physician in a range of 100 - 400 Newtons of force.[11] This translates into a exerted force for lengthening by the physician of 22 - 89 lbs. force. Additionally it was found that the final lengthening adjustment required approximately twice as much force as the initial adjustment made to the patients implant. That is to say, if the initial force required for adjustment in session number 1 is 100 Newtons, then the adjustment force required for the final treatment adjustment would be
around 200 Newtons. Currently, all of the adjustments are made manually with the surgeon physically forcing the adjustment of the rods.

Usually treatment using the growing rod procedure is completed when the child reaches maturity and the spinal growth has stopped. When the child becomes older and the spine has grown, the doctor will remove the instrumentation and perform a formal spinal fusion operation. [13]

**Mathematical Basis For The Automated Growing Rod**

In order to develop an automated growing rod device, a detailed mathematical study was performed to understand how to provide a sufficient amount of distraction force to the spine in a similar manner that an attending physician would apply to the patient's spine. The study would dictate the feasibility for an automated rod, and would give a rough idea of the size of the components required for the automated growing rod construction. The parameter of size becomes very important when considering solutions for the automated growing rod, since its utilization will be in pre-adolescent children with treatment lasting through age eighteen. The basic assumption for the initial study was that the device would need to provide a minimum of 20 lbs. of distraction force to the juvenile spine in order to be considered for a solution. This assumption was confirmed by the study by the British Scoliosis Research Foundation's study which showed that the forces required for distraction ranged from approximately 100 - 400 Newtons (22 - 90 lbs. force) in a population of 26 patients over a series of 60 lengthening procedures [14].
As discussed earlier, the earlier in the treatment with growing rods, the lower the amount of force required for the distraction.

A compact method to apply a force to a tool device is to apply a rotary torque to the device; this is demonstrated in everyday life in the use of rotary motors and engines in mixers, automobiles, drills etc.. This rotary motion can easily be translated into linear motion in a variety of ways. The method that was decided upon to be used is what is known as a linear screw drive or screw and turnbuckle arrangement. In this drive system, a linear threaded rod is held stationary on one end and a mating threaded nut is engaged on the opposite end of the threaded rod. The nut is also held into a linear position, but may turn freely. When the nut is turned, the rod crawls linearly and causes the rod to "grow" in a linear direction. One advantage of the linear screw drive is that a small amount of torque can produce a large amount of linear force. Additionally a screw gear holds an interesting property that allows the drive to be considered self locking if the screw thread taper is very small. This is to say, the system will not back out of its position after the applied drive force has been removed. This property is advantageous for the growing rod device design. It is because of the compact size, the ability to translate or reduce a small amount of torque into large linear force and its self locking properties that lead to the decision of using a screw drive system for the development of the automated growing rod.

With the decision of utilizing a linear screw gear device made, the next step in the development process was to develop a mathematical model to determine the motor size,
the threaded rod taper, and feasibility of the automated growing rod. Looking at the force / torque problem at an elementary physics level, and given that a turnbuckle principle would be used, the overall problem becomes a simple inclined plane problem.

Assuming a 1/4" rod with fine threads of 28 threads per inch or (tpi) yields an inclined plane diagram similar to this:

\[ \Theta = \tan^{-1}(0.036/0.25) \]

\[ \Theta = 8.2^\circ \]

Rod Diameter is equal to 0.25" and 0.036" is the inline of the thread of the rod.

Now from the above diagram it becomes quickly apparent that one must solve for the force \( F_{\text{APPLIED}} \) to the value desired to counteract the \( F_W \) of 100 Newtons. This value of 100 N was determined from earlier research as the least amount of force typically
required for distraction on the spine of a juvenile scoliosis patient. Based upon this information, this becomes an elementary physics torque problem or simple block and inclined plane problem. Thus one can quickly solve for the required force to counteract the \( F_W \) by utilizing the following equation:

\[
F_{\text{APPLIED}} = \frac{\text{Torque}}{\text{ROD}_{\text{RADIUS}}}
\]

Now since we need our \( F_{\text{APPLIED}} \) to at least equal our \( F_W \) we can set the values of \( F_{\text{APPLIED}} \) and \( F_W \) equal to one another. Thus:

\[
F_{\text{APPLIED}} = F_W = 100 \text{ N} = 22.4 \text{ lbs force}
\]

Then required torque can be solved as:

\[
F_w \times \text{ROD}_{\text{RADIUS}} = \text{Torque}
\]

or substituting in the given values from the above diagram:

\[
22.4 \times 0.125 = 2.8 \text{ in lbs of torque (0.3164 N m)}
\]

or

44.8 in ounces of torque.

The dimensions utilized in the inclined plane / screw example shown above are actually dimensions of off-the-shelf 1/4” threaded rod with fine cut threads of 28 threads per inch (TPI). This is utilizing a standard threaded rod for calculation purposes. Additionally, it
is apparent from the equations shown above, that the amount of torque required to
produce the force desired can be manipulated by adjusting the taper angle while holding
the diameter of the threaded rod constant. This is due to the fact that $F_{\text{APPLIED}}$ (from the
diagram) is:

$$F_{\text{APPLIED}} = (F_w \times \cos \theta) + (F_w \times \sin \theta)$$

In other words, by increasing or decreasing the angle of Theta ($\theta$) the amount of torque
required to produce the desired force ($F_{\text{APPLIED}}$) can be manipulated.

This understanding of the force problem is critical to development of the
automated growing rod. This shows that if off-the-shelf threaded rods can not be utilized
for the solution for the automated growing rod then the option is available to utilize a
custom cut threaded rod for the solution. In other words, options are available and on the
table for resolving a solution for the automated growing rod.

**Feasibility**

Based upon the calculated value as outlined above, the torque value would need to
be compared to actual torque values that can be achieved from small micro motors. It
was of great concern that the torque value calculated in combination with the sample rod
diameter and threads per inch value would be found in an off the shelf micro motor. If
the torque value is found on an off the shelf micro motor, then it is reasonable to assume
that a custom motor could be designed to fill any unique needs that the growing rod may require.

A search on the internet revealed that the most common application of micro motors was in the radio controlled scale model airplane and boat hobby marketplace. Continued research found that Futaba corporation was known for small high quality micro servo motors commonly used on RC model aircraft. By investigating the Futaba internet site, one can find that a 44.8 in oz of torque is met by most of the standard Futaba mini-servo motor product line. Additionally, Futaba produces a line of high torque mini-servo motors that produces greater than 100 in oz of torque in the same form factor as is found in the standard mini-servo motors. This finding showed that small motors are available in an off the shelf format that could produce the required torque to affect the linear force for the growing rod distraction.

Summary

In this chapter the reader has been given insight into the current state of the growing rod technology utilized today. The reader was given the basic definition of the concept of the Cobb angle, the measurement that determines if a growing rod implant is required. Generally if the Cobb angle is greater than 45° the method of treatment for the scoliosis is the implanted growing rod. The amount of force used to distract or lengthen the growing rod per adjustment was discussed, leading to the determination of the amount of force that would be required to automatically apply the distraction force. Given the
force required, the method and the mathematical derivation of the amount of torque
required to apply the distraction force was shown to the reader. Based upon the torque
calculation, a "sanity check" of the motor size was made to see if an off the shelf motor
existed within the torque range that could be sized to be implantable in the human body.
Research showed that motors of the required torque and size do exist and are commonly
used in radio controlled hobby aircraft and boats. These findings lead one to believe that
the concept of an automatic scoliosis growing rod is feasible in concept form and may
even be built using standard components.
CHAPTER IV
MECHANICAL DESIGN AND PACKAGING OF THE AUTOMATED GROWING ROD

Introduction

After proving the feasibility of the automated growing rod through the mathematical rigors shown in the previous chapter and confirming that current off-the-shelf components could satisfy the requirements of the growing rod, the actual mechanical design became the next consideration. In this chapter, the process of the mechanical design for the automated growing rod is described. Also, the process for developing the packaging for the automated growing rod is explained and detailed. This chapter will explain how the packaging plays an important part of the practicality of the automated growing rod, and the enabling design concepts created for this project that allows the automated growing rod to be small enough to implant in a human body.

Building a Beta Unit

As explained in chapter three, it is clear that an automated growing rod appears technically feasible. The next step in the investigation process was to build a scale model
of an automated growing rod to see if there were unforeseen complications that may arise, and to see if the lifting force generated in the beta unit matched the calculations demonstrated in chapter 3. The beta unit or proof of concept unit began with a concept sketch on paper based upon knowledge of the current growing rod hardware.

First, the diameter of the current technology growing rod was measured and it was found that the growing rod had a rod diameter of 6 millimeters. Since the current growing rod technology used today mates with pedicle screws and hooks which are dependant upon the diameter of the rod, it was decided that the automated growing rod should also be compatible with the existing rod and hook technology. Since 6 mm rod is roughly 0.25" in diameter, 1/4" rod was utilized in the design and construction of the proof of concept model for the automated growing rod. This decision was driven by the availability of 1/4" rod for the actual construction of the proof of concept unit. Initial concepts focused upon utilizing a servo motor which would rotate a turnbuckle or cylinder threaded to mate with a 1/4" rod. By holding one end of the rod fixed, and fixing the servo motor so that it could not rotate, the rod would be forced to move in a linear plane, producing upward force. The figure shown below is the original hand drawing of the growing rod concept.
For the proof of concept unit, Futaba mini-servo motors were used since these were inexpensive motors that would provide the torque required for the automated growing rod. Once the mini-servo motors were selected, a makeshift package or container could be designed to hold the components for the growing rod in a fashion for a working proof of concept model. A simple body for the growing rod was created utilizing ordinary construction wood, modified to hold the equipment as shown in the original proof of concept assembly drawing as detailed below.

Figure 4.1 Threaded rod and turnbuckle original hand drawing
In the drawing the body of the growing rod system is wholly made from standard home construction wood with the servo motors mounted as shown.

The rod and the turn buckle assembly were given their own wooden assembly "cap" which was mated to the main body of the unit which contained the servo drive. A direct drive of simple gears was mated to the servo from the turnbuckle section. This would allow the servo motor to drive or turn the turnbuckle apparatus. Thus the entire assembly when mated together looked like the following assembly drawing made by hand during the concept and design phase of the project.
In the drawing above, the turnbuckle and rod are in the area defined as "lock assembly", while the servo drives are in the area shown as the "servo assembly".

In order to mimic a turnbuckle unit, a extended socket was utilized for a cylinder device with a 1/4" nut welded into the body of the socket. The socket was then cut with gear teeth to mate with the servo in the main body of the unit. When the servo would
turn, the thread of the nut would be turned around the mating threads of the rod, and if the end of the rod is held firm so that it can not spin, the rod would extend.

The final device's appearance looked as depicted in the following photo.

*Figure 4.4 Final proof of concept automated growing rod unit*
Although it was not the most visually appealing device, the unit itself served its function well as a proof of concept for functionality. As can be seen in the photo, actuators were added to the system to provide a rudimentary encoder for the unit to determine how many times the servo turned, and consequently how far the rod growing rod has extended.

The proof of concept prototype was tested and in depth results of the unit are detailed in chapter two. The prototype performed to the expected values as calculated and designed. The proof of concept showed that the math and the calculations were validated and encouraged a re-design of the growing rod system into a newly packaged system that would allow for implantation in the body.

Packaging the Unit

The next phase of mechanical development of the system focused upon the packaging of the system in such a way that the automated growing rod could be implanted into a child's body. The method of bundling the items for the growing rod impacts not only the size of the growing rod but also its compatibility with existing auxiliary devices required to execute the growing rod surgery. In order to gain a more widespread acceptance for the device, the decision was made to keep the growing rod dimensions such that it is compatible with existing pedicle screws and fasteners.
To address the compatibility issues first, the automated growing rod unit was designed to fully utilize existing pedicle screws and fasteners. The rod design is of the diameter of 5.5 mm - 6.2 mm. The rod diameter for the growing rod was chosen to match the existing hardware commonly used in the current growing rod implant procedure. By keeping the rod diameter the same as industry standards, the automated growing rod shares compatibility with current off the shelf equipment such as pedicle screws which are used to affix the growing rod to the patient's spine.

The drive method for the automated growing rod is intimately linked to the size of the device. Clearly the device size would ideally have a diameter small enough to lie inside the imaginary radius that spans the spinous process and the transverse process of the vertebrae. That dimension in a child is on the average 10 mm less than that of an adult leading one to a diameter of approximately 26 mm.\[15\] This set the maximum

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**Figure 4.5 Pedicle screw illustration**

**What is a pedicle screw fixation system?**

A multi-component device constructed from stainless or titanium-based steel, consisting of solid, grooved, or slotted plates of rods that are longitudinally interconnected and anchored to adjacent vertebrae using bolts, hooks, or screws.
limit of the diameter of the automated growing rod at 26 mm. with final design refinement as reflected in this paper the automated growing rod has a diameter of 20 mm.

![Lumbar Vertebrae](image)

*Figure 4.6 Lumbar vertebrae with automated growing rod shown in dashed lines*

In order to fit the drive into such a compact package, it was decided to use a threaded rod and turnbuckle principle to produce the drive which is translated into linear force.

The mechanical design of the growing rod is as follows. Two threaded rods are driven by a hollow shaft micro-servo motor. The threaded rods are designed such that the rods can nest together and can collapse upon one another. The rods are then mounted to
the spine via the use of pedicle screws and hooks. When mounted, each end of the rod is held fast such that the rod is immobile and unable to turn. The hollow shaft servo motors then turn about the threaded rod and since the ends of the rod are held firm in place and unable to turn, the rotational motion of the servo is translated into linear motion. This linear motion allows the growing rod to lengthen or contract causing the bone distraction desired by the physician.

Given the outline of how the unit functions, a component level explanation will guide the reader how the aforementioned functionality is achieved. By examining the device piece by piece, one can gain a more detailed understanding of the device as well as the function of each piece.

The threaded rods are Cobalt-Chrome 1/4” diameter. The rods have a precision cut thread in the rods 32 TPI with a 2° taper. One of the rods is slightly larger in diameter, and hollow. This construction allows the rods to nest upon one another. This construction saves space and allows the overall mechanism to be small enough to be implantable in the human body. Additionally the threaded rods have a channel groove cut along the length of the rod which serves the dual purpose as a guide and as a means to brace the rod against its self-induced torque.

The rods' taper was designed to produce the largest amount of lifting force with the least amount of required input torque. This allows a very small motor to provide the input torque, consequently shrinking the size of the apparatus.
Two retaining plates are fitted around the growing rods with a notched key in the retaining plates fitted into the grooved channel machined into the growing rods. These retaining plates are affixed onto the main body of the growing rod device. The retaining plates serve as a means of bracing the main growing rod body to keep the body from rotating when the servo motors begin to rotate.

Two micro servo motor housing collars are also affixed to each end of the growing rod main body. The housing is made from PEAK resin and is affixed to the main body of the growing rod unit via a sonic weld and epoxy sealant. The motor housing collars house the micro servo motors and provide a raceway for the cables from the motors to the system's battery and microprocessor.

The final mechanical piece of the automated growing rod system is the actual body of the growing rod. The body is a central housing area for the growing rod's Lithium-Ion rechargeable battery, the system microprocessor and communication receiver. The body is also made from PEAK resin and also serves as a raceway for the conductors for the micro servo motors and the system input/output devices which allow the on board microprocessor to make "decisions" based upon the outside world conditions.
Figure 4.7 Mechanical drawing of the final automated growing rod package
Figure 4.8 Exploded view of the automated growing rod: 1) Threaded rod with keyway 2) Retaining plates and hubs 3) Hollow-shaft micro servo motor 4) Unit housing for battery and microprocessor

As shown in the figure above, the entire package is implantable within the human body with the largest diameter being 20 mm. Also as mentioned earlier, the components that are listed are all formed from body friendly components, that is to say the body will have no adverse reaction to the implanting of the growing rod due to material composition.

Summary

In this chapter the development of the mechanical proof of concept unit was described which in turn led to the design and packaging of the final growing rod unit. Fabrication details were described as well as fabrication materials were described that are friendly to the human body. Finally, the fully packaged unit was shown, demonstrating that the unit can be sized to be implanted in the human body.
CHAPTER V

ELECTRONICS AND MICROPROCESSOR CONTROL

Introduction

In this chapter the electronics and the microprocessor control is discussed. This chapter will describe the modification of the servo motors that was required for the proof of concept unit, the method for encoder feedback used on the proof of concept unit, the user interface for the proof of concept unit and the software programming and the microprocessor control used in this project. Discussion on how the control algorithms were developed and copies of the system wiring diagrams are also included in this chapter.

Basic Requirements for the Automated Growing Rod

In order to make a successful automated growing rod, the system required basic control for lengthening the rod, starting and stopping the rod on command, and knowledge of how far the rod had traveled linearly. All of the aforementioned information could be used in a simple control system using closed loop feedback control. Additionally, the control and feedback real world devices must be very small and
compact such that the devices are able to be encased inside the automated growing rod unit. Input and output devices for the automated growing rod system would need to be capable of being shrunk to a small integrated circuit board scale. This is a constraint that would guide the method of control and literally forced the designer to the "basic" electronics that have a long and proven track record for the selection of the input and output components.

Looking at the system as a whole, there is actually only one element that can be controlled, and that is the growing rod's servo motor. Additionally, it is the rotation of the motor that dictates how much the growing rod lengthens. Therefore it is reasonable to begin to look to the servo motor as the "hub" of the control activity. By knowing the pitch of the threaded rod used in the growing rod, one can determine the amount of linear growth of the rod per revolution of the servo motor. Therefore by using a very simple control schematic, the basis of the control is graphically expressed:

![Figure 5.1 Automated growing rod control schematic](image)

*Figure 5.1 Automated growing rod control schematic*
Now by the previous figure, the system will need a controller, and it was decided that the system will have an embedded microprocessor which will serve as a controller for the entire automated growing rod system. The microprocessor will serve as a bridge for the user interface, control for the position of the unit, and record keeper for the growing rod device activity. To be stated shortly, the microprocessor would serve as the automated growing rod's brain. The system as shown in the diagram is the servo motor and the sensor shown in the diagram would be the input device that would determine the rotations of the servo motor with the growing rod.

The logical input device to use for determination of the servo motor position is an encoder. This can actually be a very simple encoder to determine when the motor shaft has rotated a full rotation or some fraction of a rotation. With the size constraints of the automated growing rod in mind, the encoder for the automated growing rod would need to be made out of "board level" components instead of large assemblies. The components chosen for the encoder were light emitting diodes (LED) and photo resistors. These components were chosen due to the small form factor in which these may be fabricated and the low expense for the components. The way the components would be used as an encoder is as follows. The LED would serve as a light source and would be mounted opposite a photo resistor. An appendage attached to the rotating shaft would break the light shown on the photo resistor. The resistance level read from the photo resistor would change as the shaft's appendage would rotate between the LED and the photo resistor and would be read at the microprocessor. This "pulse" would indicate one rotation and could be tracked by the microprocessor, and used as an encoder. The
physical layout of the LED, the photo resistor and the motor shaft to make the encoder is
detailed in the following sketch.

Thus, as the shaft rotates, the photo resistor's resistance changes as the LED's light is
blocked and unblocked. A simple pulse is created and from that pulse or change of
resistance, the position of the shaft can be determined. Hence a simple encoder for the
feedback loop of the system.

Figure 5.2 Automated growing rod encoder concept sketch (above left), beta unit
automated growing rod encoder as-built (above right)

Thus, as the shaft rotates, the photo resistor's resistance changes as the LED's light is
blocked and unblocked. A simple pulse is created and from that pulse or change of
resistance, the position of the shaft can be determined. Hence a simple encoder for the
feedback loop of the system.
Servo Motor Modifications

One additional electrical modification had to be made for the proof of concept automated growing rod unit. For the proof of concept, a modification to the Futaba servo motor used needed a small modification. The servo motor selected typically only has a span of 180°; that is to say the shaft on the servo motor will only rotate from 0° to 180° until it is limited by a hard stop on the gearing of the motor. Modification of the servo motor needed to be performed in order to allow a complete 360° rotation.

Before the modification to the servo motor is described, a more detailed explanation of how the Futaba servo motors operate is in order. The Futaba Servo Motors come with three wires or leads. Two of these wires are to provide ground and positive supply to the servo DC motor. The third wire is for the control signal. These wires of a servo motor are color coded. The red wire is the DC supply lead and must be connected to a DC voltage supply in the range of 4.8 V to 6V. The black wire is to provide ground. The color for the third wire (to provide control signal) varies for different manufacturers, but it is white in the case of Futaba. Unlike DC motors, reversing the ground and positive supply connections does not change the direction (of rotation) of a servo. This may, in fact, damage the servo motor. That is why it is important to properly account for the order of wires in a servo motor.

The servo motor can be moved to a desired angular position by sending PWM (pulse width modulated) signals on the control wire. The servo understands the language
of pulse position modulation. A pulse of width varying from 1 millisecond to 2 milliseconds in a repeated time frame is sent to the servo for around 50 times in a second. The width of the pulse determines the angular position. For example, a pulse of 1 millisecond moves the servo towards 0°, while a 2 milliseconds wide pulse would take it to 180°. The pulse width for an in-between angular position can be interpolated accordingly. Thus a pulse of width 1.5 milliseconds will shift the servo to 90°. It should be noted that these values are only the approximations. The actual behavior of the servos differs based on their manufacturer.

A sequence of such pulses (50 in one second) is required to be passed to the servo to sustain a particular angular position. When the servo receives a pulse, it will retain the corresponding angular position for next 20 milliseconds. So a pulse every 20 millisecond time frame must be fed to the servo.
The DC motor is connected with a gear mechanism which provides feedback to a position sensor via a potentiometer. From the gear box, the output of the motor is delivered via the servo shaft to the servo arm. The potentiometer changes position corresponding to the current position of the motor. So the change in resistance produces an equivalent change in voltage from the potentiometer. A pulse width modulated signal is fed through the control wire. The pulse width is converted into an equivalent voltage that is compared with that of signal from the potentiometer in an error amplifier.
Figure 5.4 Servo motor internal control schematic

The difference signal is amplified and provided to the DC motor. So the signal applied to the DC servo motor is a damping wave which diminishes as the desired position is attained by the motor.

Figure 5.5 Servo control signal pulse train

When the difference between the desired position as indicated by the pulse train and current position is large, the motor moves fast. When the difference is the same or less, the motor moves slow.
For the growing rod application, the servo must move beyond the 180° angle span. This is possible with a small modification. The servo gear box has a mechanical stop which prevents the servo from being able to make a full rotation. The first step is to file off the mechanical stop(s) so that the gear box is free to make a complete rotation.

![Mechanical stop in the gear assembly](image)

**Figure 5.6 Futaba servo motor mechanical stop mechanism**

However, this is not the only modification required. The servo works on a feedback mechanism. So the potentiometer of the servo must be moved to the center position. This can be done by sending medium pulses to the servo by a microcontroller. Then fix the gears attached to the pot shaft with glue. This will fool the servo motor's control electronics to believe that the current position of the shaft is always at the middle position. So the servo would then move with respect to the middle position and not to the current position. This was the method used to make the proof of concept growing rod unit's servo motors turn 360° while maintaining control of the motors.
Battery Power

The entire growing rod system is powered via a small battery pack. The system is powered by an ultra small 7.2 V 230 mAh Lithium-Ion rechargeable battery cell. This battery supplies power to the micro servo motors and to the microcontroller circuit board. The battery is completely sealed and contained within the main body housing of the automated growing rod unit to protect the battery from the patient's body. The intent of the system operation is to have enough charge in the battery pack to power the on board microprocessor and power to make an adjustment to the length of the rod via the servo motor. Once the adjustment is made, the power in the batteries should be depleted and will not be able to make another adjustment until re-charged. This will make the system inherently safe until the next visit to the physician. The batteries would be re-charged via a sub-dermal implanted plate that would allow inductive charging of the batteries from outside of the patient's body.

Microprocessor and Software

The automated growing rod system has an on-board microprocessor that serves as the "brains" or overall controller of the system. The purpose of the microprocessor is to serve as a means for local control of the system and also serve as the bridge for communication to the outside world. For the proof of concept unit the Parallax Basic 2 microcontroller was selected. The BASIC Stamp is a microcontroller with a small, specialized BASIC interpreter (PBASIC) built into ROM. It is made by Parallax, Inc. and
has been popular with electronics hobbyists since the early 1990s because of its low learning threshold and ease of use due to its simple to understand BASIC language and excellent documentation.

The Basic stamp has the following features and specifications:

**Features:**

- Processor Speed: 20 MHz
- Program Execution Speed: ~4,000 PBASIC instructions/sec.
- RAM Size: 32 Bytes (6 I/O, 26 Variable)
- EEPROM (Program) Size: 2 KBytes; ~500 PBASIC instructions
- Number of I/O Pins: 16 + 2 dedicated serial
- Current Draw @ 5 VDC: 3mA Run, 50 µA Sleep
- Source/Sink Current per I/O: 20 mA / 25 mA
- Source/Sink Current per unit: 40 mA / 50 mA per 8 I/O pins
- PBASIC Commands: 42
- Package: 24-pin DIP
- Industrial-Rated since Rev J

**Key Specifications:**

- Power Requirements: 5.5 to 15 VDC (Vin), or 5 VDC (Vdd)
- Communication: Serial (9600 baud for programming)
- Dimensions: 1.20 x 0.63 x 0.15 in (30.0 x 16.0 x 3.81 mm)
- Operating Temperature: -40 to +185 °F (-40 to +85 °C)

The Parallax Basic Stamp is programmed with a basic like language on a personal computer and downloaded to the microprocessor for execution. The basic language allows for ease of programming and produces results very quickly. The microprocessor has a large install base among engineers and hobbyist and documentation for the microprocessor is very accessible. Additionally, the microprocessor has built in functions within its operating system for servo motor pulse width modulation signals that make integration for servo motor control very simple. The final benefit the basic stamp offers is its relative low cost. These benefits made the selection of the Basic Stamp microprocessor the correct choice for this system.

**System Software**

The heart of the automated growing rod system is the equipment's software. There are two primary software components utilized in the automated growing rod system, the on-board microcontroller software and the user interface software. This section will discuss both software packages, and how the software interacts together.
The User Interface Software

The more simple of the software packages is the software that serves as the human-machine interface for the physician with the on board microcontroller. The purpose of this software is to serve as a means for the attending physician to establish communication to the on-board growing rod processor and serve as a means to input the data for the growing rod lengthening adjustment. For the initial proof of concept unit, Microsoft Visual Basic was used as the programming environment of choice. In the proof of concept, four axes of motion were controlled. Microsoft Visual Basic was chosen because it is a quickly developed programming environment that allowed for easy changes, while providing a visual graphic experience for the end user.

The software use is very straightforward. The end user is presented with a graphical interface showing a human spine and the communications status of the user interface with the on-board growing rod microprocessor. The user selects the "Connect to Growing Rod" option and a communication link is established with the user interface and the growing rod microprocessor. Behind the interface, the software opens up a communication port and attempts to successfully ping the growing rod device. If a good communications link is established, an indicator is given on the user interface screen showing a "green light" beside the communication status area of the screen. If communication remains off-line, the communications indicator remains red, designating no communication to the implanted growing rod.
Assuming that a successful communication link is established with the growing rod, the end user has the option of choosing the "mode" of motion for the rod. The first mode is coordinated motion—this means that the selected rod axis will perform its motion in conjunction or together with another axis of the end user's choice. That is to say axis one of implanted growing rod "A" will move in lock step with the axis 1 of growing rod "B". When told to execute both of these axes will move together; "helping" one another to the final position specified by the user.

The second mode is independent motion—this means that the motion is designated for only one axis of motion and is to move independently and not in tandem with another axis.
The other option that must be chosen by the end user is the option of distraction or compression. This option chooses whether the axis of the rod will cause the rod to lengthen or retract based upon the choice. Thus, the end user could select the independent motion mode with some axes lengthening and other axes retracting, depending upon the choice of the physician. Clearly this option allows for the "undoing" of adjustments made by the physician, and will allow more flexibility in the treatment afforded to physician by the growing rod. In addition, it allows the physician the flexibility of automatically lengthening one rod while shortening the other. This added flexibility will give the physician options for treatment that are not currently available.

Once the appropriate selections are made, the physician chooses the "Execute Motion" selection. The software presents a prompt asking the end user to confirm the execute motion selection. If the end user chooses "cancel" at this point the motion can be aborted. However after confirmation, the motion of the growing rod axes will begin affecting distraction or compression.
As a final safety precaution, the motion for the growing rod cannot occur if 1) outside communication with the user interface is lost or 2) if positive feedback from the physician is lost. The positive feedback for a given user interface varies but for a computer with a tethered mouse, that would be the physician maintaining the mouse button depressed through the entire movement procedure. For an interface on a smartphone or tablet device, that would be the physician maintaining pressure on a screen push button through the entire procedure. By removing this pressure, the motion would cease and the physician would need to re-input the motion criteria. This is designed as a safety check to quickly stop the procedure if needed.
Under the wrapper, the software interface is performing several tasks. First it is establishing communications with the growing rod. Second, it is taking the motion setup parameters and creating a data packet that the growing rod can understand for instruction in motion. Next, the software sends the command to execute motion to the microcontroller embedded on the growing rod. Finally, the user interface software provides a positive check of the physician performing the motion acting as a safety switch.

*Figure 5.10 User interface device original concept and final application for smart phone*
The Microcontroller Software

The resident software on the microcontroller serves as the brains for the growing rod. The software used for this project is the Parallax Basic Stamp Editor for Windows. The basic stamp editor utilizes basic-like commands for control of the microprocessor. After the software is written it is then compiled into machine language and downloaded onto the EPROM of the microprocessor. The Parallax basic stamp was chosen because it had the built-in functionality of the pulse width modulated servos motor in the core microprocessor operating system.

The microprocessor receives wirelessly transmitted data via Bluetooth and parses out the motion command for each axis. The microprocessor then awaits the "execute" command to be transmitted and upon receiving the command, begins to execute motion based upon the axis command given to each axis. The microcontroller determines position based upon the optical encoder pulses. When the on-board microcontroller software determines via the encoder that the position for the input distraction or compression is reached, the microprocessor stops the motion and reports to the user interface that the motion is complete.

The Basic Stamp processor is programmed via the basic stamp editor software. This software environment is a basic-like language that is programmed on an external personal computer (PC) and is then downloaded to the Basic Stamp processor. Below is the software that was written for the Basic Stamp that was used in the proof of concept automated growing rod unit.
' {STAMP BS2}
' {PBASIC 2.5}

'VARIABLES

'serv13tenths      VAR     Nib   'tenths value
'serv13ones        VAR     Nib   'ones value
serv13rot          VAR     Byte  'total required rotations
serv13posval       VAR     Word  'servo current position
serv13poscnt       VAR     Word  'servo rotation counts
serv13posflag      VAR     Bit   'servo position flag
oldserv13posflag   VAR     Bit   'old servo position flag

'serv24tenths      VAR     Nib   'tenths value
'serv24ones        VAR     Nib   'ones value
serv24rot          VAR     Byte  'total required rotations
serv24posval       VAR     Word  'servo current position
serv24poscnt       VAR     Word  'servo rotation counts
serv24posflag      VAR     Bit   'servo position flag
oldserv24posflag   VAR     Bit   'old servo position flag

' GENERAL VARIABLES

go                   VAR     Byte   'make system go
upperlower           VAR     Byte   'flag for running upper or lower servos 0=upper servos 1=lower servos
servo1run            VAR     Bit   'flag for servo 1 ok to run
servo2run            VAR     Bit   'flag for servo 2 ok to run
servo3run            VAR     Bit   'flag for servo 3 ok to run
servo4run            VAR     Bit   'flag for servo 4 ok to run
servoneg             VAR     Byte   'flag for servo 1 negative direction
timecounter          VAR     Word   'time counter delay

' CALCULATE NUMBER OF ROTATIONS FOR EACH AXIS

'serv13rot = (((((serv13ones*10) + serv13tenths)*2)/10)

'serv24rot = (((((serv24ones*10) + serv24tenths)*2)/10)

Startup:
'SERIAL COMMUNICATION COMMANDS RECEIVED
DO
SERIN 16, 16780, [DEC serv13rot, DEC serv24rot, DEC upperlower, DEC servoneg, DEC go]
LOOP UNTIL go = 1

PAUSE 100

' TURN ON ALL LEDS FOR POSITION MEASUREMENT AND POWER UP PHOTORESISTOR

HIGH 0
HIGH 1
HIGH 2
HIGH 3
HIGH 4
HIGH 5
HIGH 6
HIGH 7
PAUSE 100

' MAKE A MEASUREMENT OF EACH SERVO POSITION

IF upperlower = 0 THEN GOSUB Measure12
IF upperlower = 1 THEN GOSUB Measure34

' FIGURE OUT WHICH SERVOS SHOULD RUN

IF serv13rot <> 0 AND upperlower = 0 THEN servo1run = 1
IF serv24rot <> 0 AND upperlower = 0 THEN servo2run = 1
IF serv13rot <> 0 AND upperlower = 1 THEN servo3run = 1
IF serv24rot <> 0 AND upperlower = 1 THEN servo4run = 1

' JUMP TO SUBROUTINE TO RUN THE CORRECT SERVOS

IF servo1run = 1 AND servo2run = 0 THEN GOSUB RunServo1only
IF servo1run = 0 AND servo2run = 1 THEN GOSUB RunServo2only
IF servo1run = 1 AND servo2run = 1 THEN GOSUB RunServo12both

IF servo3run = 1 AND servo4run = 0 THEN GOSUB RunServo3only
IF servo3run = 0 AND servo4run = 1 THEN GOSUB RunServo4only
IF servo3run = 1 AND servo4run = 1 THEN GOSUB RunServo34both
' TURN OFF ALL LEDS FOR END OF ROUTINE

LOW 0
LOW 1
LOW 2
LOW 3
LOW 4
LOW 5
LOW 6
LOW 7
LOW 8
LOW 9
LOW 10
LOW 11
PAUSE 100

' TURN OFF ALL SERVO RUN FLAGS

servo1run = 0
servo2run = 0
servo3run = 0
servo4run = 0

GOTO Startup

END

RunServo1only:

oldserv13posflag = serv13posflag
oldserv24posflag = serv24posflag
serv13poscnt = 0
serv24poscnt = 0

' TURN ON SOLENOID TO RELEASE LOCKS
HIGH 8
HIGH 9

PAUSE 1000

SELECT servoneg
CASE =0
DO
  PULSOUT 12,770
  PAUSE 20
  GOSUB measure12

55
IF oldserv13posflag <> serv13posflag THEN serv13poscnt = serv13poscnt + 1
oldserv13posflag = serv13posflag
LOOP UNTIL serv13poscnt >= serv13rot

CASE = 1
DO
  PULSOUT 12,730
  PAUSE 20
  GOSUB measure12
  IF oldserv13posflag <> serv13posflag THEN serv13poscnt = serv13poscnt + 1
  oldserv13posflag = serv13posflag
  LOOP UNTIL serv13poscnt >= serv13rot

ENDSELECT

serv13rot=0
serv24rot=0

' TURN OFF ALL SERVO RUN FLAGS

servo1run = 0
servo2run = 0
servo3run = 0
servo4run = 0

' TURN OFF SOLENOID TO ENGAGE LOCKS

LOW 8
LOW 9

RETURN

RunServo2only:

oldserv13posflag = serv13posflag
oldserv24posflag = serv24posflag
serv13poscnt = 0
serv24poscnt = 0

' TURN ON SOLENOID TO RELEASE LOCKS
HIGH 8
HIGH 9

PAUSE 1000
SELECT servoneg
CASE =0
DO
  PULSOUT 13,730
  PAUSE 20
  GOSUB measure12
  IF  oldserv24posflag <> serv24posflag THEN serv24poscnt = serv24poscnt + 1
  oldserv24posflag = serv24posflag
  LOOP UNTIL serv24poscnt >= serv24rot
ENDSELECT

CASE = 1
DO
  PULSOUT 13,770
  PAUSE 20
  GOSUB measure12
  IF  oldserv24posflag <> serv24posflag THEN serv24poscnt = serv24poscnt + 1
  oldserv24posflag = serv24posflag
  LOOP UNTIL serv24poscnt >= serv24rot

' TURN OFF ALL SERVO RUN FLAGS
servo1run = 0
servo2run = 0
servo3run = 0
servo4run = 0

' TURN OFF SOLENOID TO ENGAGE LOCKS
LOW 8
LOW 9

RETURN

RunServo12both:

oldserv13posflag = serv13posflag
oldserv24posflag = serv24posflag
serv13poscnt = 0
serv24poscnt = 0

' TURN ON SOLENOID TO RELEASE LOCKS
HIGH 8
HIGH 9

PAUSE 1000

SELECT servoneg
CASE =0
DO
  PULSOUT 12,770
  PULSOUT 13,730
  PAUSE 20
  GOSUB measure12
  IF oldserv13posflag <> serv13posflag THEN serv13poscnt = serv13poscnt + 1
  IF oldserv24posflag <> serv24posflag THEN serv24poscnt = serv24poscnt + 1
  oldserv13posflag = serv13posflag
  oldserv24posflag = serv24posflag
LOOP UNTIL serv24poscnt >= serv24rot OR serv13poscnt >= serv13rot
CASE = 1
DO
  PULSOUT 12,730
  PULSOUT 13,770
  PAUSE 20
  GOSUB measure12
  IF oldserv13posflag <> serv13posflag THEN serv13poscnt = serv13poscnt + 1
  IF oldserv24posflag <> serv24posflag THEN serv24poscnt = serv24poscnt + 1
  oldserv13posflag = serv13posflag
  oldserv24posflag = serv24posflag
LOOP UNTIL serv24poscnt >= serv24rot OR serv13poscnt >= serv13rot
ENDSELECT

serv13rot=0
serv24rot=0

' TURN OFF ALL SERVO RUN FLAGS
servo1run = 0
servo2run = 0
servo3run = 0
servo4run = 0

' TURN OFF SOLENOID TO ENGAGE LOCKS
LOW 8
LOW 9
RunServo3only:

oldserv13posflag = serv13posflag
oldserv24posflag = serv24posflag
serv13poscnt = 0
serv24poscnt = 0

' TURN ON SOLENOID TO RELEASE LOCKS
HIGH 10
HIGH 11

SELECT servoneg
CASE = 0
  DO
    PULSOUT 14,770
    PAUSE 20
    GOSUB measure34
    IF oldserv13posflag <> serv13posflag THEN serv13poscnt = serv13poscnt + 1
    oldserv13posflag = serv13posflag
  LOOP UNTIL serv13poscnt >= serv13rot

CASE = 1
  DO
    PULSOUT 14,730
    PAUSE 20
    GOSUB measure34
    IF oldserv13posflag <> serv13posflag THEN serv13poscnt = serv13poscnt + 1
    oldserv13posflag = serv13posflag
  LOOP UNTIL serv13poscnt >= serv13rot

ENDSELECT

serv13rot=0
serv24rot=0

' TURN OFF ALL SERVO RUN FLAGS

servo1run = 0
servo2run = 0
servo3run = 0
servo4run = 0
'TURN OFF SOLENOID TO ENGAGE LOCKS

LOW 10
LOW 11

RETURN

RunServo4only:

oldserv13posflag = serv13posflag
oldserv24posflag = serv24posflag
serv13poscnt = 0
serv24poscnt = 0

'TURN ON SOLENOID TO RELEASE LOCKS

HIGH 10
HIGH 11

PAUSE 1000

SELECT servoneg
CASE =0
  DO
    PULSOUT 15,730
    PAUSE 20
    GOSUB measure34
    IF oldserv24posflag <> serv24posflag THEN serv24poscnt = serv24poscnt + 1
    oldserv24posflag = serv24posflag
    LOOP UNTIL serv24poscnt >= serv24rot
  CASE = 1
  DO
    PULSOUT 15,770
    PAUSE 20
    GOSUB measure34
    IF oldserv24posflag <> serv24posflag THEN serv24poscnt = serv24poscnt + 1
    oldserv24posflag = serv24posflag
    LOOP UNTIL serv24poscnt >= serv24rot

ENDSELECT

serv13rot=0
serv24rot=0

'TURN OFF ALL SERVO RUN FLAGS
servo1run = 0  
servo2run = 0  
servo3run = 0  
servo4run = 0

' TURN OFF SOLENOID TO ENGAGE LOCKS

LOW 10  
LOW 11

RETURN

RunServo34both:

oldserv13posflag = serv13posflag  
oldserv24posflag = serv24posflag  
serv13poscnt = 0  
serv24poscnt = 0

' TURN ON SOLENOID TO RELEASE LOCKS

HIGH 10  
HIGH 11

PAUSE 1000

SELECT servoneg
CASE =0
DO
  PULSOUT 14,770  
  PULSOUT 15,730  
  PAUSE 20  
  GOSUB measure34  
  IF oldserv13posflag <> serv13posflag THEN serv13poscnt = serv13poscnt + 1
  IF oldserv24posflag <> serv24posflag THEN serv24poscnt = serv24poscnt + 1
  oldserv13posflag = serv13posflag  
  oldserv24posflag = serv24posflag
LOOP UNTIL serv24poscnt >= serv24rot OR serv13poscnt >= serv13rot

CASE = 1
DO
  PULSOUT 14,730  
  PULSOUT 15,770  
  PAUSE 20  
  GOSUB measure34
IF oldserv13posflag <> serv13posflag THEN serv13poscnt = serv13poscnt + 1
IF oldserv24posflag <> serv24posflag THEN serv24poscnt = serv24poscnt + 1
-oldserv13posflag = serv13posflag
-oldserv24posflag = serv24posflag
LOOP UNTIL serv24poscnt >= serv24rot OR serv13poscnt >= serv13rot

ENDSELECT

serv13rot=0
serv24rot=0

' TURN OFF ALL SERVO RUN FLAGS

servo1run = 0
servo2run = 0
servo3run = 0
servo4run = 0

' TURN OFF SOLENOID TO ENGAGE LOCKS

LOW 10
LOW 11

RETURN

Measure12:

timecounter=0

DO

HIGH 0
HIGH 1
HIGH 4
HIGH 5
PAUSE 10
RCTIME 4 , 1 , serv13posval
RCTIME 5 , 1 , serv24posval
PAUSE 1
timecounter = timecounter + 1
LOOP UNTIL timecounter >= 1

IF serv13posval < 100 THEN
serv13posflag = 1
ELSE
serv13posflag = 0
ENDIF

IF serv24posval < 100 THEN
serv24posflag = 1
ELSE
serv24posflag = 0
ENDIF

RETURN

Measure34:

timecounter=0

DO

HIGH 2
HIGH 3
HIGH 6
HIGH 7
PAUSE 10

RCTIME 6, 1, serv13posval
RCTIME 7, 1, serv24posval
PAUSE 1
timecounter = timecounter + 1
LOOP UNTIL timecounter >= 1

IF serv13posval < 100 THEN
serv13posflag = 1
ELSE
serv13posflag = 0
ENDIF

IF serv24posval < 300 THEN
serv24posflag = 1
ELSE
serv24posflag = 0
ENDIF

RETURN
Hardware Wiring

In conjunction with the software, the hardware must be wired correctly to the microprocessor for control. As shown on the block diagram of the Basic Stamp (reference Figure 5.7), the microprocessor has 16 pins that can interface to real world input or output devices. In a block diagram fashion, the system representation can be shown as follows:

![Figure 5.11 Microprocessor system I/O overview schematic](image)

This conceptual block diagram is then translated into a working schematic detailing the wiring of the input and output devices. The following drawing details the actual pin
wiring of the microprocessor and when compared to the aforementioned software, one can understand the connection of the hardware to the control software.

**Figure 5.12 Microprocessor wiring schematic of input / output pins**

The software calls for pin status and thus statements like HIGH 0 in the software corresponds to turning pin zero on or high. So the real world outputs are thus controlled by the software commands by the Basic Stamp editor software. A larger copy of the wiring schematic is included in the appendix of this paper.
**Summary**

In this chapter the details of the electrical system was outlined. This chapter explained the particulars of the electrical hardware, specifically the servo motors, the method of encoding the position of the growing rod, and the microprocessor used for the proof of concept automated growing rod. The user interface software was defined and the method of coding associated with the user interface was explained. Also, the microprocessor software was reviewed and the hardware interface to the growing rod microprocessor was detailed. Overall, this chapter served as a method to show how the electrical control and hardware was used to create the proof of concept automated growing rod unit.
CHAPTER VI
BUILDING AND TESTING OF THE BETA UNIT

Introduction

Since the hardware and software has been introduced in the previous chapters, the next step in the process naturally turns to the build of a proof of concept or beta unit. The purpose of the beta unit is to investigate the actual performance of the "real world" unit versus the predicted performance of the automated growing rod design. This chapter will detail the build of the beta unit, the flashes of inspiration, and some humor regarding some of the unorthodox build process utilized. It will be noted that this chapter reads more like a chronological story. Unfortunately, this method proves to be the most effective method for describing the activity associated with a beta unit build and subsequent testing. The chapter will discuss the testing activity and methods along with the results which are summarized in chapter two as well.

Beta Unit Build Process

As stated above, the goal of the build of the automated growing rod beta unit was to measure the performance of the unit compared to the predicted results found from
study. Although this beta unit as described in the following pages was built on a shoestring budget, great care was made to insure that all components could be "scaled" to the size of the finalized "production" automated growing unit. Additionally, electronic components used were selected based on the ability to scale the component to a small or "board" level component. Thus, the testing made with the beta unit is representative of conditions and forces a production automated growing rod would experience.

The components for the beta unit as outlined in the previous chapters are the threaded rods, the microprocessor, servo motors, and input / output devices for control. However, to make a working prototype unit, the components must be housed in a container. This container throughout this paper has been referred to as the body of the automated growing rod unit. For the purposes of the beta unit it was decided to make the body out of simple wood 2"x4" lumber. The wood was easily manipulated and could be cut and carved to accommodate housing the balance of the components. The servo motors used on the beta unit were simple Futaba model airplane motors. Since the torque these motors provide is the same as the torque calculated in the studies, the only difference was the physical size of the servo motor casing. In order to house the servo motors in the beta growing rod body, a pocket was carved out of the wood that was to become the body of the automated growing rod. The pocket was shaped to hold the Futaba servo motor such that its body sat flush with the edge of the wood. The axis of the motor and motor horn would then sit just above the edge of the wooden body. The motor horn would then mate with a second piece of the body which housed the hollow shaft area of the unit and the linear gear for the threaded rod.
The linear drive used for the first attempt at the beta unit consisted of a deep socket from a standard craftsman tool socket set. A 0.25” fine thread pitch nut was welded on one end of the socket, with the opposing end of the socket cut to mate with the horn of the servo motor. The threaded rod of the unit was run through the nut. These pieces were all housed in a wooden body with a cavity to hold the make-shift linear drive. The unit then mated with the servo half of the body, and the two halves would be secured together with screws. When the servo motor would spin, the socket would likewise turn and the nut welded into the end of the socket would force the threaded rod to "crawl" to a lengthened position, or a compressed position depending upon the direction of the servo's rotation.

![Beta unit growing rod illustration](image)

*Figure 6.1 Beta unit growing rod illustration*
Additionally, a frame was devised to simulate a spine and to provide a method to measure the force the growing rod would be able to provide. A wooden frame was devised that would have a central metal (non-threaded) rod serve as a central axis. Two pulleys would serve as spine vertebrae and the rod would be threaded through the central axis of the pulleys. The rod was mounted in the frame such that the rod was lengthwise perpendicular to the ground, with the axis of the pulleys parallel with the ground. The topmost pulley had a box mounted upon the pulley where weight could be added. The beta unit automated growing rods were mounted between the two pulleys and attached at the edge of each pulley. This arrangement would allow the topmost pulley to slide up and down the central axis of the frame as the growing rods were expanded or contracted. Additionally, the use of free-spinning pulleys around the central axis of the frame allowed the observance of whether torque would be exerted on the spine as the growing rod's servo motors turned. If the pulleys began to spin or turn when the micro servo motors started to turn, it would be quickly discovered indicating torque transmitted to the simulation frame.
After assembly of the frame, the beta unit growing rods were attached to the frame, and the top pulley was weighted with five lbs. and the electrical connections to the microprocessor were made. The initial tests were run on a single axis and single servo motor. The tests showed that the design concept of the system would work as designed. The initial tests were run using up to ten lbs. of force mounted on the top of the test apparatus. Due to the success of the initial test with one servo axis, this encouraged the continuation of a beta build, incorporating a total of four servo axis, two mounted on opposite ends of two hand fabricated bodies.

The second series of tests conducted integrated the four servo axes controlled by a single microprocessor. The test stand was weighted with a load and a coordinated test with two axes working together to raise the weight. However, it was discovered that the
growing rod unit would not lift a significantly larger amount of weight than the previous single axis 10 lbs. trial unit. This was significantly less than the value calculated of over 22 lbs. and caused an investigation as to the reason why the device was hitting a "ceiling" of such a low force value. After re-checking calculations and methodology of implementing the solution, it was affirmed that the calculations made prior to build of the beta unit were correct and consequently, the problem resided in the actual build of the beta unit.

Upon further investigation, it was found that as the beta unit began to feel the force that was loaded upon the unit, there was enough sloppiness in the system build to allow the rotating axes slide out of line with the axis of the driving servo motor. Consequently the forces were not being borne on the centerline of the device, but were borne at the geared junction of the servo motor and the rotating linear drive junction. That junction was not plumb, and caused the motor to bind under the force of the weight. However, it was clear that the concept would work if the unit could be fabricated such that the threaded rod, the linear gear and the servo motor could be kept in alignment. This forced a re-examination of the linear drive interface in order to keep the primary axis of the unit straight relative to each part of the system.

The solution presented itself in a rather mundane device that is commonplace. The re-work for the growing rod linear drive was modeled around the simple bicycle axle hub. By turning the hub 90° from the orientation typically associated with the bicycle,
the hub could freely turn around the threaded rod of the growing rod and if the rod was run through both ends of the hub, the rod would remain in a true straight axis relative to the driving servo motor. The hub design could provide the stability needed to keep the system straight and reduce internal friction due to the initial assembly's crude design.

With the revision as described, the tests on the four axis were re-started and a significant improvement was made on the performance of the beta unit. Tests were run starting at 5 lbs. of force acting counter to the growing rod, and incrementally 5 lbs. were added to each successive test. The unit provided the force predicted and at the apparent predicted ceiling of 22.4 lbs force, the beta unit growing rod lifted through that force value. At 25 lbs. force the unit began to stall, but did continue to lift the force to the position programmed into the processor. After the beta unit lifted the 25 lbs. load, no further tests of increasing loads were run, since the unit already performed beyond calculated expectations. Also, it was good that the unit "outperformed" the calculated
value of what the system's final calculated performance limits were predicted. The first reason the system may have outperformed its calculated value is because of the assumed losses in the system may have been greater than what was encountered. Another, more probable reason for the out performance may have been one of the servo motors actually performing higher than the rated value found on the included servo motor specification sheet. In other words, the "stall" torque listed on the specification sheet was actually higher, and the listed torque was simply the torque that the manufacturer had guaranteed the product to deliver. This analysis would make sense because the servos performed to 25 lbs of force (albeit with difficulty) which is roughly 10% above the expected value. This would mean that the manufacturer had 10% safety factor built into the specification of the servo motor, a typical value one might expect for a micro servo motor.

**Beta Unit Control**

The control system for the automated growing rod beta unit consisted of the Parallax Basic Stamp 2 as discussed in the previous chapters. The input and output for the system was thoroughly tested prior to installation on the actual beta unit. No unexpected results occurred once the beta unit was assembled. The software was thoroughly tested prior to installation on the beta unit. One change that was made after assembly of the beta unit was that it was discovered that the growing rod did not expand linearly as far as was expected based upon the number of turns that the servo motor made. In other words, if it was thought that the rod should increase a full millimeter after 4 pulses of the encoder, it was discovered that it only increased 75% of the expected
value. After checking the formula that controlled the linear expansion of the growing rod based upon the encoder value, it was discovered that a math error existed in the formula. A quick check showed that the error was coded into the control software of the automated growing rod, and after correcting the error in the software, the encoder rotation / rod length issue was corrected.

During the beta unit build, all of the software including the user interface software was tried out and debugged. This allowed the opportunity for all aspects of the automated growing rod system to work together as a single system. All serial communication connections to the microprocessor were checked and the interaction with the end user was refined during the beta unit build process.

**Removed Items**

Not only was the beta unit process used for making the features associated with the automated growing rod, it was also used as a process to pare unnecessary functions away from the unit. A perfect example of using the beta build process as a pruning opportunity is when considering the issue of the integration of an originally planned locking mechanism that would be used to lock the growing rod into position once the automated growing rod reaches the desired length. The original design required a small micro solenoid device that would engage the rod device to prevent rotation of the servo motor if the servo is not getting a rotation command. Throughout the beta unit integration process, the locking device proved to be troublesome. Eventually, the locking
device was made to work, but it was still cause for concern. However, continuing research on improving the locking device revealed that the pitch of the threaded rod being used by the automated growing rod made the threaded rod drive unit self-locking. The self-locking property means that applying a torque to the shaft will cause it to turn, but no amount of axial load force against the shaft will cause it to turn back the other way, even if the applied torque is zero. Hence the requirement of a locking mechanism for the system was removed and the overall system control and integration became simplified. Therefore the system is more simple and easier to maintain, as a direct result of the beta unit build and engineering check process. This is an example of the engineering design process being carried out and improving the product through every step of the creation of a new device.

**The SLA**

The positive results of the beta or proof of concept unit, lead to the next step of the product development. This is a creation of a model of the final product by a method known as Stereo Lithography Apparatus (SLA). Stereo lithography is an additive manufacturing process using a vat of liquid UV (ultra-violet)-curable photopolymer "resin" and a UV laser to build parts a layer at a time. On each layer, the laser beam traces a part cross-section pattern on the surface of the liquid resin. The first "product" sized automated growing rod unit, was made by stereo lithography. Since the initial work on the beta unit was all based upon scalable components, there is no doubt that the final
product will perform to requirements. However, without the groundwork of the beta unit, it would be questionable if the final form factor would perform as desired.

**Summary**

In this chapter the assembly of the proof of concept or beta unit of the automated growing rod was discussed. Additionally, the difficulties and the problems faced with the proof of concept were described, and how through the problems, refinements to the automated growing rod occurred. It was explained how the beta unit gave confidence for the final design of the unit and the final creation of a stereo lithography apparatus.
CHAPTER VII

BENEFITS OF THE AUTOMATED GROWING ROD SYSTEM AND NEXT STEPS IN DEVELOPMENT

Introduction

This chapter will discuss two basic points. The first topic is the benefits of an automated growing rod system. The second topic will discuss the next steps in the development of the automated growing rod system. The chapter will discuss all of the potential benefits that the next steps in development will provide for both doctors and patients.

Benefits of an Automated Growing Rod System

The benefits of an automated growing rod are quickly realized by the reduction in costs associated with multiple surgeries, the reduced healing time between each lengthening adjustment, and the reduced risk associated with any invasive surgery. These benefits are seen by both the surgeon and the patient. However, beyond these immediate benefits, there are longer term values which the automated growing rod brings to the table which are not as easily recognized. This section will investigate these benefits
individually and reveal how they may have a lasting impact on the method of medical
treatment in the long term future.

The first and most quickly realized benefit of the automated growing rod system
is the reduced cost to the treatment of juvenile scoliosis. Clearly, today's treatment
requires the invasive surgery of the implanting of the growing rod, and then the
successive follow on surgeries of the lengthening of the growing rod for the child every
six months. Each of the surgeries, (the implanting and subsequent lengthening of the rod)
are treated as major surgeries with the same preparation for an operating facility, the
same skilled surgeon, and required support staff for every operation. The surgery cost is
typically over $120,000 for the implantation of the rod \([16]\). The successive surgeries,
although less expensive, range in cost from $10,000 - $20,000, executed twice per year.
If a growing rod system is in the child's body for four years, this can easily add up to a
cost of over $210,000 in that period of time. The proposed automated growing rod
system would still require the initial installation of the growing rod with as similar cost
for the surgery that is seen today. However, the automated growing rod system will
remove the necessity of further successive surgeries. Assuming that the growing rod
adjustments could be made incrementally on a standard Doctor's visit or at a primary care
center, the costs would likely fall to the typical cost of $5,400 per year. This would result
in a reduction in cost for the child over the same four year treatment period of $73,000 in
surgeries alone. This does not account for the time savings to the patient and surgeon
whose surgery room time would be reduced.
Additionally, with any surgery situation, there are certain risks that are associated with surgery. Typical risks associated with surgery include: anesthesia complications, bleeding and blood clots, slow healing, infections, scarring and bruising. All of the aforementioned problems directly affect the patient, and more importantly these items increase the risks associated with the procedure. By eliminating the additional follow on surgeries associated with a standard growing rod procedure, the automated growing rod removes the risks outlined above. This removal of risks, directly impact the cost of treating scoliosis and more importantly removes dangers that the patient may encounter throughout the course of treatment.

Another benefit that the automated growing rod system provides is the ability to more frequently make adjustments to the length of the growing rods. Since surgery is no longer required for the lengthening process, this means that the treating doctor has the option to lengthen the rods more frequently and during more mundane regular checkup appointments. The lengthening increments can be reduced, that is to say, instead of lengthening the rods a full 1 cm. during the rod lengthening process, the increment adjustments can be smaller, causing less trauma to the body. Currently, the rod adjustments are about 1 cm. every six months in order to keep up with the growth of the child. The every six month time frame for adjustment is in part dictated by the patient's ability to heal after each invasive surgery. After the adjustment, the patient must not only heal from the surgery, but must heal from the dramatic increment of the rod's lengthening. The automated growing rod will allow the doctor to make smaller lengthening adjustments more frequently, causing less of an impact to the child's body
and less pain for the treatment. For example, over a 6 month period, the doctor may choose to make a 2 mm adjustment to the patient every 5 weeks, yielding a result of a 1 cm adjustment over a six month period. Clearly, this method of treatment would be less of an impact on the patient. This method of adjustment would reduce the recovery time of the patient, and reduce costs by eliminating hospital stays and hospital recuperation / observation time of the patient.

Next Steps / Future Developments

The aforementioned benefits are readily realizable through the use of the automated growing rod. However, with a bit more development, the automated growing rod brings further benefits to the treatment of scoliosis that can only be realized by the system as proposed in this paper.

Since the automated growing rod is microprocessor based, a whole new ability of statistical process control is available as part of the treatment for scoliosis. By instrumenting the automated growing rod with a series of strain gages on the growing rod, the on board microprocessor can determine whether the rods are in compression or in tension. When the growing rods are implanted, the rods are experiencing a compressive force as a result of the patient's body weight and spine. As the patient grows, the spine lengthens and as a consequence, the growing rod begins to experience a tension force. When the rod is in tension, this is an indicator that the rod should lengthen, putting the rod back into a compressive force situation in relationship with the patient's spine. The
The microprocessor could measure the strain force on the growing rod daily, at a time when the patient's body is in a more gravity neutral position, such as at sleep. Over a given period of time the strain could be read, and after a pre-defined number of samples, the growing rod could perform one of two functions. The first function would be to use the data from the strain gage to recommend to the treating physician the amount of lengthening the rod needs to perform for efficacy of treatment. The recommendation could be displayed to the physician via the user interface software, and the physician could choose to adjust the rod by the recommendation or by another amount determined by the physician. The second function that would be available based upon the strain gage feedback would be that of an automatic lengthening function of the rod. This would allow a true closed loop feedback control system to be implemented on the automated growing rod. Needless to say, the benefit of having the automated growing rod automatically grow with the patient would reduce the doctor office time for the patient. However, this automated adjustment feature would take some time to gain acceptance by the medical community, and may not be easily accepted by medical device governing agencies such as the FDA. Thus, this is left as a future development.

Another benefit that can realized by using the automated growing rod is the removal of the requirement of the physician or expert to be physically located with the patient for adjustment of the growing rod. In other words, since the system is microprocessor based and controlled, the physician is not physically moving or manipulating the growing rods, instead the physician is providing data to the growing rod for adjustment. The actual rod adjustment is handled by the microprocessor. Hence, the
doctor could provide the rod adjustment data from a remote location to an attending physician or nurse practitioner located at the patient's site. Therefore, the growing rod adjustment process no longer requires the physical presence of the surgical doctor. This opens a large range of how the treatment for the scoliosis growing rod adjustments can occur. For example, a doctor in the United States could evaluate the condition of a patient in Europe and make the data file detailing the growing rod adjustment based upon the evaluation. The data file could then be sent via e-mail to an attending physician in Europe, and then downloaded to the microprocessor on board the automated growing rod device. The microprocessor would make the adjustment based upon the data sent by the doctor located in the United States, with the attending physician in Europe simply providing local support for the patient in case of complications. This ability of non-locality for the treatment has the potential to set a new paradigm for scoliosis treatment. Patients from all around the world could benefit from the expertise of doctors from the United States and other developed countries providing a level of care to patients in the non-developed world that has not been possible until the advent of this technology. This ability coupled with the reduced cost benefit of the automated growing rod system, would allow poorer nations to receive the same treatment that more wealthy countries receive, since the boundaries of cost and expertise are removed as barriers for treatment.

One further development to the system would allow the patient's treatment record to be stored on board the automated growing rod's microprocessor. The microprocessor software could be modified to store in EPROM the history of the automated growing rod's adjustments. In so doing, the adjustment records are always present with the
patient. In order to access the patient's growing rod adjustment data, the doctor would simply need the user interface software to access the data stored on the growing rod device. The benefit of this feature would include the ultimate portability of the patient's medical records. Additionally, if the patient is located in a remote area and unable to make a trip to his or her regular physician, any local physician with a copy of the user interface software could retrieve the patient's treatment history from the data stored upon the automated growing rod device. Once again, this future development is fairly easy to implement but provides an enormous benefit for both the patient and the physician.

**Summary**

This chapter presented the immediate benefits of the automated growing rod system and explained how the new technology would actually save money while providing a superior treatment technique for the patient. Additionally, the chapter discussed the future developments for the device and the benefits these developments could offer for both the patient and doctor alike. This chapter helped point the way for future improvements to the automated growing device.
APPENDIX A

GLOSSARY TERMS AND DEFINITIONS
GLOSSARY

TERMS AND DEFINITIONS

**Automated Growing Rod**: An improved growing rod system relying upon automation techniques such as closed loop feedback control and on board microprocessors to allow growing rod lengthening adjustments to take place without invasive surgery.

**Cervical**: In scoliosis cervical refers to the seven cervical vertebrae that make up the top part of the spine.

**Cobb Angle**: This is the name of the measurement of scoliosis that is obtained from an X-ray. It refers to the severity of the curvature and is measured in degrees. A measurement under 10 degrees is regarded as normal, between 10 degrees and 30 degrees is classed as mild, and anything over 60 degrees is severe.

**Congenital**: This refers to a condition that is present at birth, such as a malformed vertebra.

**Closed Loop Control**: a control system with a feedback loop that is active.
**Distraction**: separation of joint surfaces without rupture of their binding ligaments and without displacement.

**Efficacy**: The ability to produce a desired or intended result

**Growing Rod**: Metal rods implanted into a patient as a treatment for scoliosis. In general, the scoliosis caused curve is spanned by one or two rods under the skin to avoid damaging the growth tissues of the spine. The rods are then attached to the spine above and below the curve with hooks or screws. The curve can usually be corrected by fifty percent at the time of the first operation. The child then returns every six months to have the rods "lengthened" approximately one centimeter to keep up with the child's growth.

**Lumbar**: The lumbar region is the lower part of the spine and is made up of five vertebrae. It is the strongest part of the spine and bears a lot of weight.

**Neurological system**: Also known as the nervous system, the neurological system is the tissues, cells and organs that regulate the body’s response to internal and external stimuli or events.

**Pedicle Screw**: A multi-component device constructed from stainless or titanium-based steel, consisting of solid, grooved, or slotted plates of rods that are longitudinally interconnected and anchored to adjacent vertebrae using bolts, hooks, or screws.
**Prognosis**: This is a medical term which means ‘the likely outcome or course of a disease’ – i.e., a prediction of what will happen to the patient as a result of the disease/condition, such as the likelihood of recovery.

**Scoliosis**: Abnormal, side to side curvature of the spine (backbone). Larger curves can lead to posture imbalance, muscle fatigue, and back pain. Severe scoliosis can interfere with breathing.

**Symptomatic**: Showing symptoms as a result of a disease/condition. Symptoms are signs of the disease/condition that are usually noticed by the patient, or, more often in the case of scoliosis, someone close to the patient.
APPENDIX B

SCHEMATICS AND DRAWINGS
REFERENCES


