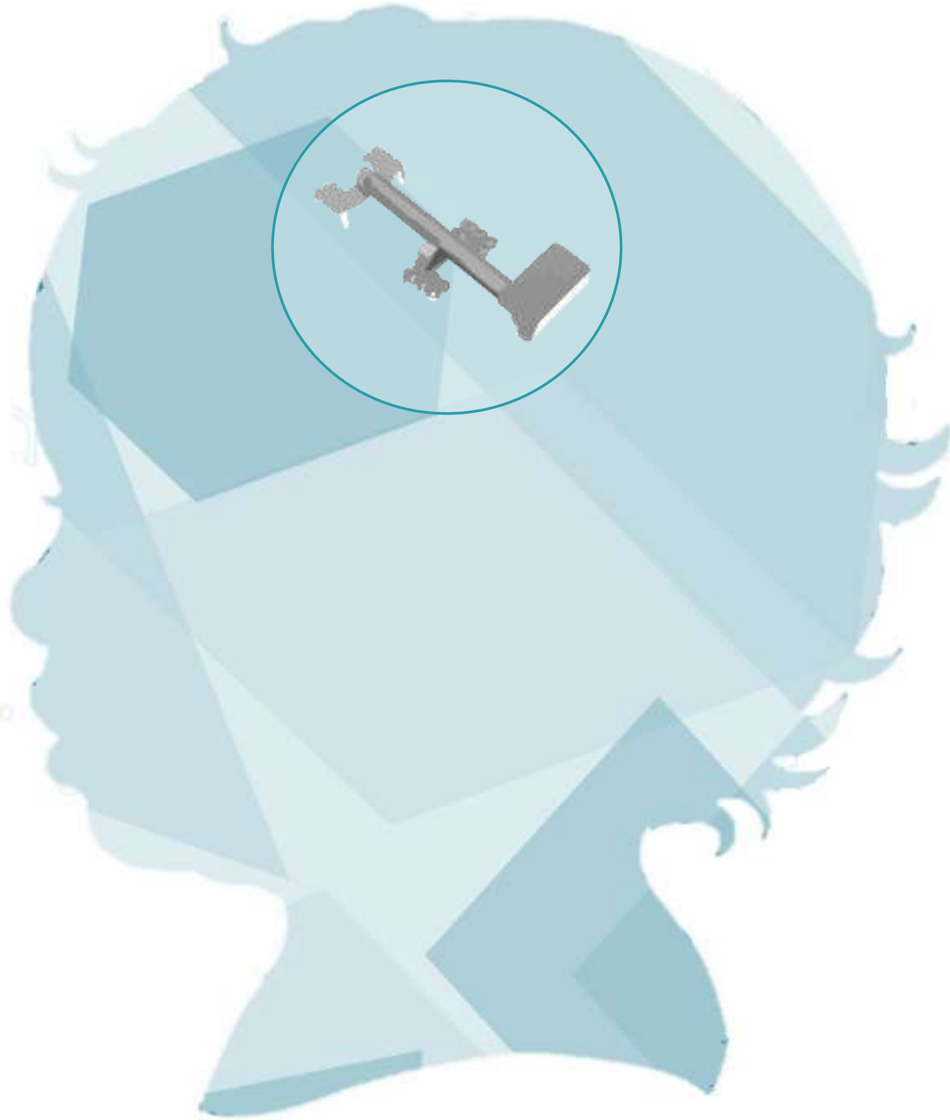
Magnetically Actuated Cranial Distraction Device

Design and Analysis

UNIVERSITY OF CALIFORNIA SAN DIEGO
DEPARTMENT OF MECHANICAL AND AEROSPACE ENGINEERING



ALEC SCHARDEIN ASHLEY QU DINGYI DUAN MACY CASTANEDA

PREPARED JUNE 2018 BY MAE 156B TEAM 21

PROFESSOR: DAVID GILLETT

SPONSOR: DR. AMANDA GOSMAN

Abstract

The aim of this project is to create a magnetically actuated cranial distraction device to treat the condition craniosynostosis. Current cranial distraction devices are mechanically actuated by rotating the arm of a lead screw. While the current design effectively displaces the skull, the arm that protrudes through the scalp is an open wound that is highly susceptible to infection by fecal matter. Our proposed solution completely internalizes the device and is magnetically actuated. This design solution includes a lead screw that is actuated using a 3/8 inch (height) by 3/16 inch (diameter) neodymium permanent magnet. The external remote control system uses one rotating neodymium permanent magnet, which is rotated by a DC motor. The distracted distance displayed on an LCD screen by is translated by the rotation of the magnets with a hall sensor. The plates that attach the device to the skull uses twelve M1 screws to account for the thinness of an age 3 to 6 months infant skull. This technology may be useful in other biomedical applications where complete internalizing is necessary to avoid infection. This novel system is also versatile in that it can be scaled for delicate systems, such as an infant skull, or larger systems, such as a femur or tibia.

<u>Keywords:</u> craniosynostosis, distraction, magnet, remote control, lead screw

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Chapter 1: Project Description

Background

The sponsor for this project is Dr. Amanda Gosman, associate professor of plastic surgery and director for Pediatric and Craniofacial Plastic Surgery at the University of California, San Diego Medical Center. Dr. Gosman performs posterior cranial vault distraction on infants and seeks to create a magnetically activated cranial distraction device that is completely internalized to minimize the risk of infection. Dr. Gosman emphasizes the need for this technology in her practice and ultimately aims to establish an FDA-approved device in the future that will be used to better treat craniosynostosis.

What is Craniosynostosis?

Craniosynostosis is a birth defect in which the sutures that divide the skull prematurely fuse together. Direct health consequences from this condition include distortion of the skull and craniofacial area, respiratory blockage, and stunted brain growth. This condition occurs approximately 1 in 2500 births and requires immediate diagnosis and treatment to avoid severe neurological complications [1]. The current technique to treat craniosynostosis for infants between ages 3 to 6 months is a surgical method called posterior cranial vault distraction. A surgeon will create the necessary incision in the skull and temporarily implant a device intended to promote proper cranial bone development by expanding the formed gap [2]. With the infant's unique ability to rapidly reform bone, the infant's body will attempt to bridge the gap by growing cancellous (or "soft, spongy") bone within the gap. This spongy bone then ossifies, or hardens, into the original bone. Distraction means bone formation, which is where these indwellings acquire their name: cranial distraction devices (**Fig. 1.1A**).

Cranial Distraction Device

A cranial distraction device is surgically screwed into the skull on either side of the incision using two plates. It is gradually extended until the appropriate gap size is reached for proper bone formation and brain development, as demonstrated in **Fig. 1.1B**. Devices remain implanted from between several days to two months, depending on the severity of the condition, and are distracted 1 mm, up to three times a day. Current devices are made of medical grade titanium with dimensions 10 cm length by 0.1 cm diam. Distraction is mechanically actuated by rotating the arm of a lead screw. While the current design effectively displaces the skull, it requires the rotating arm to protrude through the scalp for the duration of the treatment and leave an open wound after the first surgery, as seen in **Fig. 1.1C**. This open wound can be easily infected by fecal matter. As a result, approximately 1 in 3 patients suffer from infection. One study showed that internalizing distraction devices decreases the risk of infection. This study compared internal and external mandibular distraction devices and showed that nearly 30% of external devices became infected while only 6% of internal devices were infected [3]. **Thus, the goal of this project is to completely internalize the cranial distraction device to prevent infection using a novel actuation method: magnetic actuation.**

A. **B.** **C.**

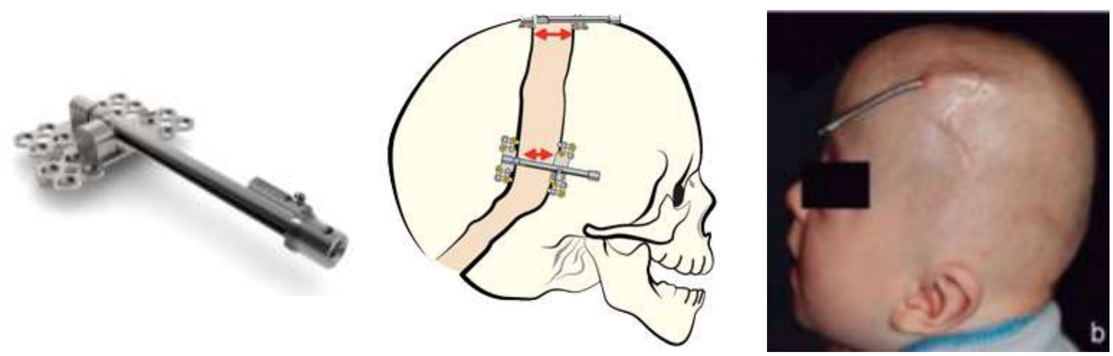


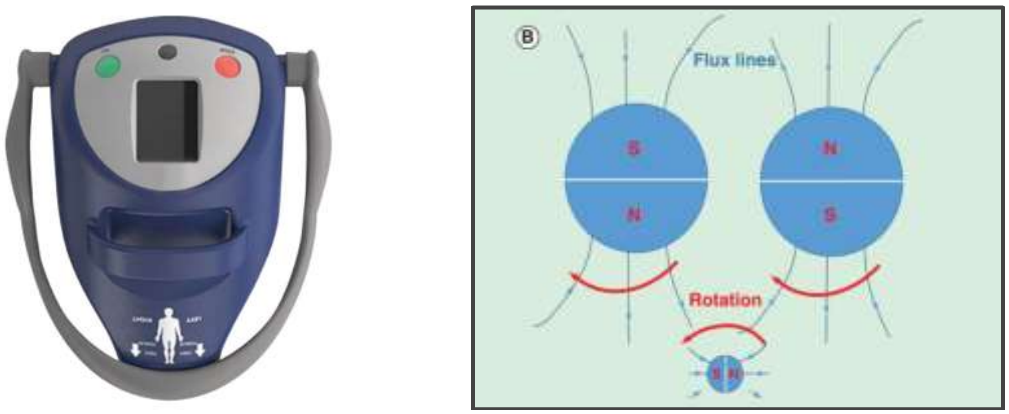
Figure 1.1. (A) A titanium cranial distraction device distributed by KLS Martin Group with dimensions 10 cm length by 0.1 cm diam. [4]. (B) The mechanism for posterior cranial vault distraction [5]. (C) Photo of device arm protruding from the scalp that is susceptible to infection [2].

Existing Magnetic Distraction Devices

A magnetically activated distraction device currently exists for the intramedullary system. This is the PRECICE® Antegrade Tibia Operative Technique by NuVasive Specialized Orthopedic, Inc. that is used for both the tibia and femur. Dr. Gosman highly recommends using this technology as a basis for the magnetic actuation in a cranial device. The PRECICE® system surgically implants nails that contain a lead screw mechanism activated by permanent magnets. The initial length of the nails vary between 155 to 365 mm and distract a total length of 50 to 80 mm. Distraction is actuated externally using a remote control system containing two powerful permanent magnets, as shown in **Fig. 1.2B**. These magnets are coupled together with the internal magnet, thereby rotating the internal magnet when the external magnets are rotated (**Fig. 1.2A**) [6,7].

For this project, scaling down the current technology is the biggest concern. Compared to PRECICE®, the cranial distraction device is less than 1/10th in size and must maintain a resolution of 0.5 mm. It is important to recognize a safety hazard involved when implanting a magnet near the brain of an infant. However, due to the time constraint of the project, this issue will not be pursued. Regardless of this issue, the NuVasive system is an excellent resource that will be thoroughly considered in this project.

A.



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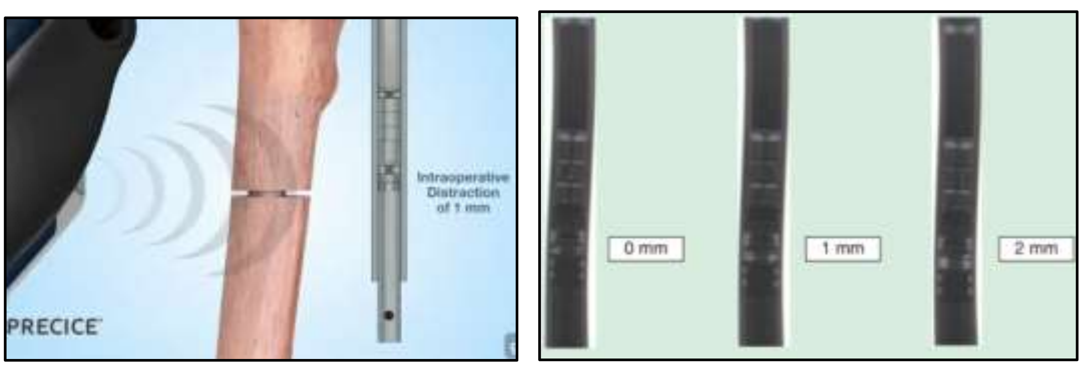


Figure 1.2. (A) A picture of the PRECICE® remote control and the magnetic mechanism that rotates the internal magnet using two external permanent magnets. (B) A picture of the remote control actuation and a photo of actual distraction using the magnets. [6,7]

	FUNCTIONAL REQUIREMENTS		SECONDARY REQUIREMENTS	DESIGN DECISION
MATERIAL				
FR1	Material is FDA approved for neonatal indwellings			**3D printed medical Grade 5 and Grade 2 Titanium (TI64) with 30-40μm resolution**
FR2	Material is or can be made biocompatible or biologically inert			
PLATES				
FR3	Attaches with screws, less than 1.5 mm in diam.	**SR1**	Flexible to follow the curvature of the skull	**2mm thick thin plates with 9 holes that hold 1.5 mm diam. screws**
FR4	Provides at least 15° in free movement			
DRIVE MECHANISM				
FR5	**Absolutely no penetration of the scalp** (i.e. no open wound)	**SR2**	Moves in forward and reverse direction	**Bevel Gear with 40mm threaded length that is 50 mm total length by 2mm diam. 3/8 in. height by 3/16 in. diam. Neodymium magnet attached to gear actuates the drive in both clockwise (forward) and counterclockwise (reverse) directions. Small ferromagnetic plates are implanted that prevent unintended magnet rotation.**
FR6	Resolution of 0.5 mm or less			
FR7	Locking mechanism to avoid unintended distraction			
FR8	Total distraction of 40 mm			
REMOTE CONTROL				
FR9	Magnetic actuation with enough force to move the skull	**SR3**	Outputs the distance of distraction	**Two Neodymium magnets coupled and parallel to the distraction magnet are rotated by a DC motor. A hall sensor guarantees coupling. LCD screen outputs the distraction distance using a hall sensor to count the rotations of the remote magnets. Computer mouse inspired shape allows for comfortable fit to hand.**
FR10	No emissions that are hazardous to infants	**SR4**	Portable and fits comfortably in the hand of a physician	

Table 1.1. Statement of requirements in newly designed cranial distraction device

Deliverables

The following items outlined in the table will be provided to Dr. Gosman at the end of the project:

TABLE OF DELIVERABLES	
SCALED MODEL	
SM1	Drive Mechanism
SM2	Attached Plates (2) (Stainless Steel)
SM3	Technical model with schematics and CAD drawings
MAGNETIC CONTROL REMOTE	
MCR1	High Torque Motor
MCR2	Magnet
MCR3	Functional Code (Arduino)
MCR4	User Manual

Table 1.2. Anticipated deliverables for sponsor

Chapter 2: Description of Final Design Solution

To satisfy the function requirements listed in **Table 1.1**, the cranial distraction device is required to be magnetically actuated by an external remote control. The device must be made of titanium and be strong enough to separate the two sutures of the surgical incision at which the plates are attached on. Specifically, it must have a resolution of 0.5 mm and distract at least 40 mm total.

Design Solution

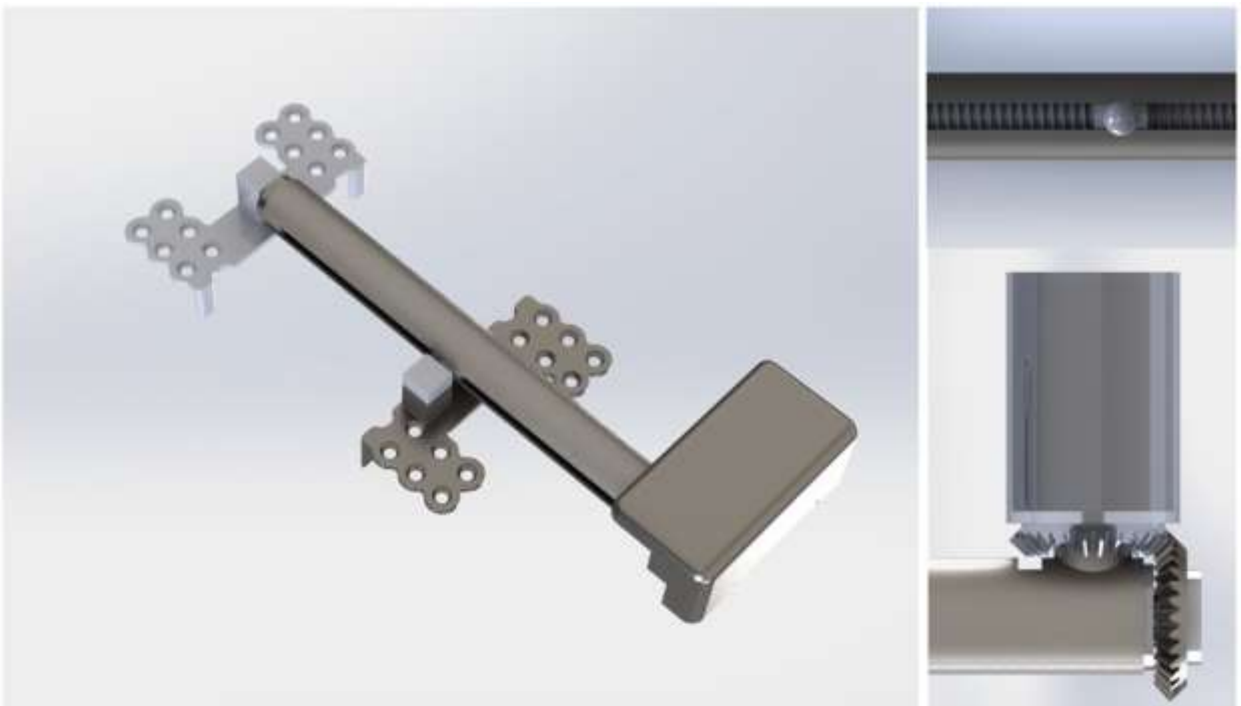


Figure 2.1. CAD rendering of final design of cranial distraction device (left). The drive mechanism is a lead screw (top right) that is driven by a bevel gear design (bottom right), with a magnet attached to the exterior gear. The magnet is actuated by external rotating magnets.

The final design contained two 12-hole plates, one attached at the end of the device and the other attached to the lead screw drive mechanism. The primary design for magnetic actuation included a bevel gear design that could be actuated using an 3/8 inch (height) by 3/16 inch (diameter) neodymium permanent magnet. The gears were oriented 90 degrees to each other, with the teeth facing inward. The plates that attach the device to the skull each used twelve M1 flathead screws to maintain compact size and to account for the variance of skull thinness of infants from ages 3 to 6 months. The cranial distraction device is shown above in **Fig. 2.1** as a CAD rendering.

Figure 2.2. CAD rendering of RC featuring a single magnet system and an Arduino to control the micromotor, hall sensor, and LCD screen

Figure 2.3. CAD rendering of RC featuring a double magnet system. A high torque motor has been included to overcome the additional magnetic attraction and repulsion between the RC magnets.

The external magnetic remote control (RC) system iterated through 2 prototypes: a single magnet system and a double magnet system Both use a DC motor to rotate neodymium permanent magnets. The single magnet system used a micromotor with 0.246Nm torque and 96RPM powered by 6V. It uses a cylindrical magnet with dimensions 1inch (diameter) by 1inch (thickness) (**Fig 2.2**). The double magnet system must overcome the additional magnetic attractive and repulsive forces between the magnets, and thus uses a high-torque motor, 50kg-cm, at 48RPM powered by 12V. (**Fig. 2.3**). Both remotes feature two buttons: a power button and a 3-position (ON-OFF-ON) switch. The switch is connected the DC motor and can input either a negative or positive voltage to rotate the single magnet in the clockwise and counterclockwise direction. The distracted distance was displayed on a LCD screen. Calculations assumed zero resistance and perfect alignment of the internal and external magnets. This assumption is further discussed in Chapter 5. They were based on the rotation of the magnet with a hall sensor. The remote control can be plugged into a laptop to be calibrated and used remotely by plugging in a two-cell lithium polymer battery of 7.4V or a 12V battery.

Chapter 3: Design of Key Components

The final design was made up of two key components: the cranial distraction device and the external remote magnetic control.

Cranial Distraction Device

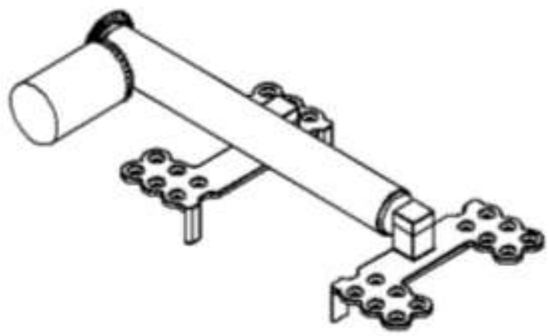


Figure 3.1. Drawing of cranial distraction device with lead screw mechanism without gear enclosure

Overview

The cranial distraction device featured a lead screw drive mechanism with a 1:1 bevel gear system that translates the rotational motion of the magnet into linear motion of the separating plate. One of the plates will remain stationary at the incision point, while the other plate will push the two sutures apart, encouraging bone distraction.

Functional Requirements

<u>Primary</u>

- Low Profile: *Must rest completely under the skin and on top of the skull* [FR5]
- High Resolution: *0.5 mm or less per actuation* [FR6]
- Applied Force: *At least a sustained amount of 35N* [FR7]
- Position Stability: *Must maintain position after power is removed* [FR7]

<u>Secondary</u>

- Reversible Drive: *Must travel forwards and backwards at will* [SR2]
- Flexibility: *Conform to curvature of skull* [SR1]
- Simplicity: *Minimize the number of moving parts*

Comparison of Designs Considered

ADVANTAGES	DISADVANTAGES	COST
RATCHET WITH LINEAR DRIVE		
Allows the moving mechanism to specified length to be simple	Contains any complex parts Requires complex ratcheting mechanism to maintain position	High
RATCHET WITH ROTATING DRIVE		
Simplifies into rotational motion	Similar to above. Many complex parts are required	High
LEAD SCREW WITH DIRECT DRIVE		
Contains no complex mechanisms Non-backdrivable	Requires magnet to lie perpendicular to skull Possibly not enough force to drive it before exceeding size constraints	Low
LEAD SCREW WITH BEVEL DRIVE		
Can place driving magnet parallel to skull Contains variability in drive angles, which allows multiple options for best fit Non-backdrivable	Adds complexity to the above mechanism. May be difficult to make gears small enough to withstand forces and to maintain low profile	Moderate

Table 3.1. Designs considered for drive mechanism of cranial distraction device

Justification of the Final Design Choice

The lead screw with the bevel drive system was the final design choice for the cranial distraction device. The friction seen in the ratcheting systems during the experimental stages made the ratcheting system designs unusable. Additionally, the convenience of an integrated non-backdrivable mechanism in the drive system increased the appeal of the lead screw concept. Comparing the two variants of the lead screw mechanism, the bevel gear permitted an overall reduction in the length and height of the device, increasing the ease of the device to fit completely under the skin. Although the design complexity was increased, the added advantages outweighed the additional cost.

External Remote Control

Overview

Neodymium magnets coupled and parallel to the distraction magnet were rotated by a DC motor. A hall sensor guaranteed coupling. A LCD screen displayed the distraction distance using a hall sensor to count the rotations of the remote magnets based on number of times the voltage jumps from low to high (or high to low), as shown in **Fig. 3.2**. A remote case was 3D printed to hold all the components and wiring. Two different RC systems were created, a single magnet and a double magnet (**Fig. 3.3**)

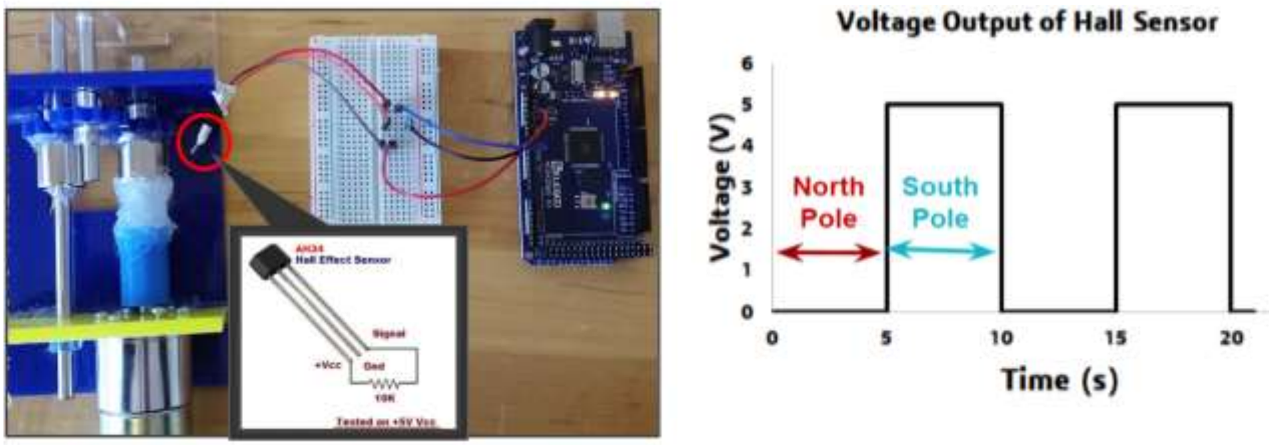


Figure 3.2. Photo of remote control setup that uses two magnets and a hall sensor (left) and the voltage output of the hall sensor to determine the number of rotations (right)

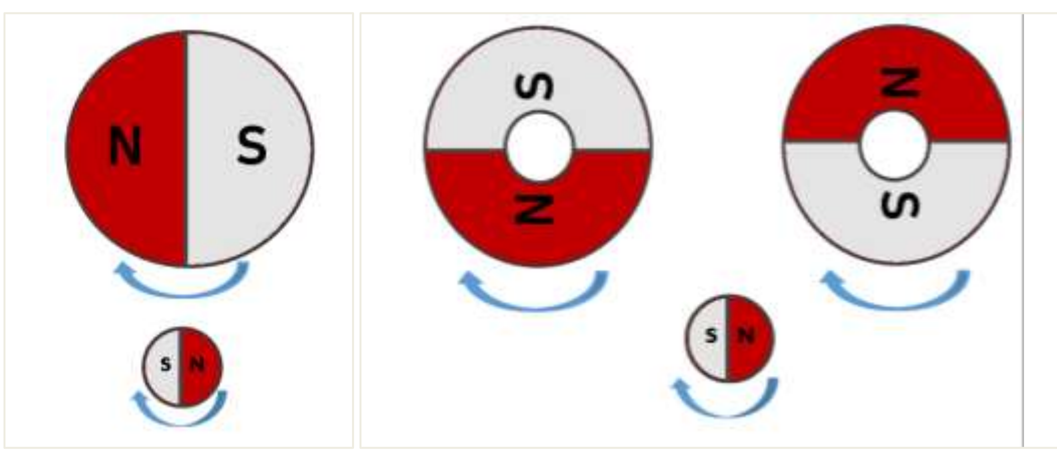


Figure 3.3. Remote control prototypes showing how the magnetic torque will actuate the internal (smaller) magnet. Single Magnet Configuration where the external magnet is 1 in (diameter) by 1 in (thickness) (left). Double Magnet Configuration where the external magnets are both ¾ in (outer diameter) by ¼ in (inner diameter) by ¾ in (thickness) (right).

Map of the Magnetic Field

The magnetic field changes as the RC magnet rotates. A Hall Effect sensor measures the field strength. It is based on the phenomenon such that when a current carrying conductor is approached by a permanent magnet, the electrons in the current are deflected to one side. This separation of charges creates a voltage difference that is proportional to the deflection and therefore magnetic field. The sensor resolution is determined by the amount of magnetic flux [Gauss, G] required to change the voltage output by a unit step [millivolts, mV]. The sensors used to measure the analog voltage signal, and not the digital as mentioned above, were the Allegro A1302 Linear Hall Effect Sensor. These sensors have a high resolution of 1.3mV/G and a total range of 5V (Refer to datasheet in Appendix).

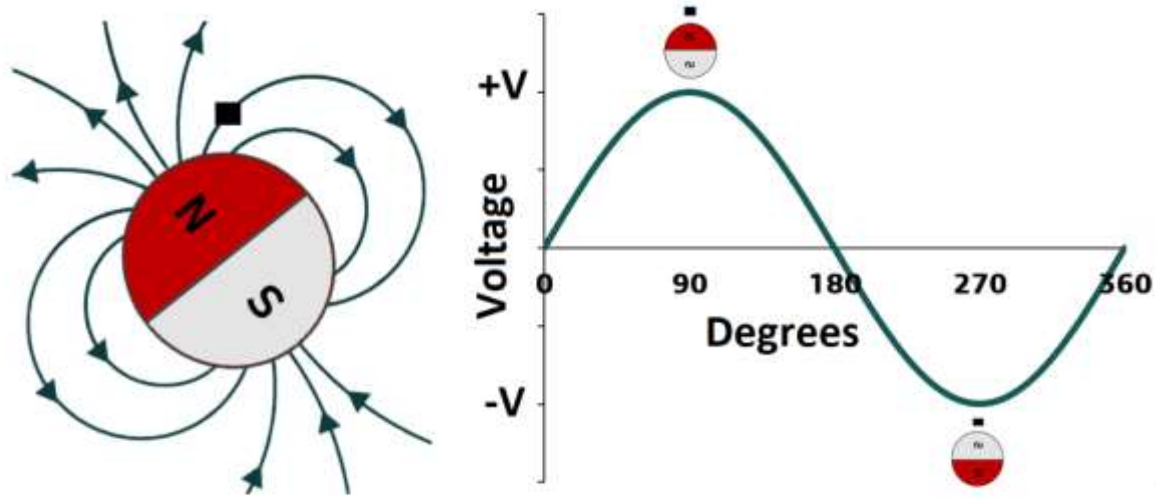


Figure 3.4. A Hall Sensor determines how the field changes with respect to angular position of the magnet. This diagram shows a schematic (left) and expected results (right) from data with a sinusoidal output for one revolution

Naturally, the magnetic field will change as the permanent dipole in the RC rotates, which is why it is important to characterize the field. **Fig. 3.4**. shows the experimental setup with the sensor next to the magnet. One full rotation creates a sinusoidal wave for both the voltage and magnetic field [14]. This is expected, since the field lines through the sensor oscillate between the North and South poles, thereby alternating between negative and positive voltage outputs respectively.

Functional Requirements

<u>Primary</u>

- Magnetic actuation with enough force to move the skull [FR9]
- No emissions that are hazardous to infants [FR10]

<u>Secondary</u>

- Outputs the distance of distraction [SR3]
- Portable and fits comfortably in the hand of a physician [SR4]

Comparison of Designs Considered

ADVANTAGES	DISADVANTAGES	COST
PERMANENT MAGNET - SINGLE MAGNET		
Transmits through skin	Constant magnetic force	Low
Passive Device	Uncertain as to hazard at this level of exposure	
Low radiation exposure		
PERMANENT MAGNET - DOUBLE MAGNET		
Transmits through skin	Many complex magnetic fields	Moderate
Passive device	Magnetic radiation may too powerful	
ELECTROMAGNET		
Transmits through skin	Heats up quickly	Moderate
Passive device	Range of less than 1in	
Variable and controlled magnetic force		

Table 3.2. Designs considered for magnetic remote control

Justification of the Final Design Choice

A permanent magnet system was superior to the electromagnet due to safety issues. When in use, electromagnets heat up quickly, which was determined after consultation with a NuVasive engineer who worked on the PRECICE system; if this magnet is to be pressed against an infant's skull and skin during treatment, electromagnets may pose a harm to the patient. Additionally, a double permanent magnet system was used in the limb lengthening system. Upon further testing of the double magnet system, the attractive force between the magnets was too large, and thus a single permanent magnet system was created to minimize the issue.

Chapter 4: Prototype Performance

Cranial Distraction Device

Theoretical Force to Displace the Skull

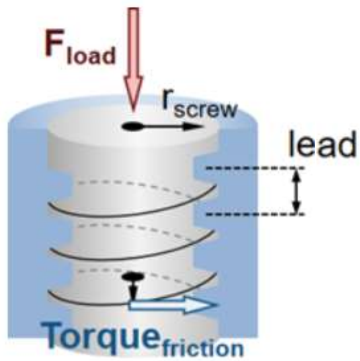


Figure 4.1. Free body diagram of a lead screw [9]

A free body diagram of the lead screw mechanism is shown in **Fig. 4.1**. From this, it was possible to determine the torque for the lead screw to output a maximum force of 35 N. Several assumptions were made with these calculations. First, the friction between the titanium nut and titanium screw was neglected. Second, since the device was on the scale of millimeters and made of a lightweight metal, the inertial forces from gravity, that is weight, were neglected.

The leadscrew was given efficiency ε, defined as its ability to convert the rotational energy into translational energy. The efficiency was calculated with the following equation:

$$\varepsilon = \frac{\tan(\alpha)}{\tan(\alpha + \arctan f)} \qquad \text{(Eq.1) [10]}$$

where f is the coefficient of friction, and α is the helix angle as a function of the leadscrew pitch and diameter. In the case friction between titanium surfaces, $f_{Ti} = 0.3$. In addition, for a leadscrew with 0.5 mm pitch with a 3 mm diameter, $\alpha = 0.053\ radians$. Thus, efficiency $\varepsilon = 0.15$. The efficiency is quite low, but a lower value is expected, since a smaller pitch to diameter ratio leads to a lower efficiency overall.

The equation to solve the force was given by the free body diagram:

$$\frac{Fp}{2\pi e} = \tau \qquad \text{(Eq. 2)}$$

Using the information known, **Eq. 2** was used to calculate the torque required to create a force of 35N. For pitch *p* = 0.5mm and force *F* = 35N, $\tau = 0.0093Nm$. Previous literature stated that a recommended value is 0.018 Nm [3] to create a modest factor of safety of 2.5.

Test Conditions and Results

Due to time limitations, the device was not tested experimentally. Based on basic assessment of the device, the delivered device still suffers from additional friction that can be minimized through precise machining techniques. Theoretically, it was found:

$$\tau = 0.0093Nm$$

$$F = 35N.$$

External Remote Control

Theoretical Predictions

Since the remote control relied solely on the torque created by permanent magnets, the system could be described using fundamental physics equations for magnetism. Specifically, we used the form for magnetic dipoles.

A magnetic dipole was defined as a north and south pole separated by a distance *r* that has an associated magnetization $\widehat{M}$. The magnitude *M* can be calculated using a more universal value provided by manufacturers, the residual Flux Density B_r:

$$M = B_r/\mu_o \qquad \text{(Eq. 3)}$$

where the permittivity of free space $\mu_o = 4\pi \times 10^{-7}\, H/m$. Multiple dipoles could be summed together to create a larger, single dipole. Permanent magnets were the macroscale result after summing many dipoles from the atomic and even the electron level in a volume of material. In addition, every magnetic dipole has an associated moment $\hat{\mu}$ (which is based on the volume V) and magnetic field $\hat{B}$ (which is based on $\hat{\mu}$).

$$\widehat{\mu} = \widehat{M}\, V \qquad \text{(Eq. 4)}$$

$$\hat{B}(\hat{r}) = \frac{\mu_o}{4\pi}\left(\frac{r(\hat{\mu}\cdot\hat{r})}{r^5} - \frac{\hat{\mu}}{r^3}\right) \qquad \text{(Eq. 5)}$$

A magnetic dipole moment $\hat{\mu}$ conceptually meant that the magnet would rotate in the presence of a magnetic field from another magnet, which the remote control exploits. To determine the torque applied to the rotating magnet (in this case, the magnet implanted with the distraction device), the equation was used:

$$\hat{\tau} = \hat{\mu} \times \hat{B} \qquad \text{(Eq. 6)}$$

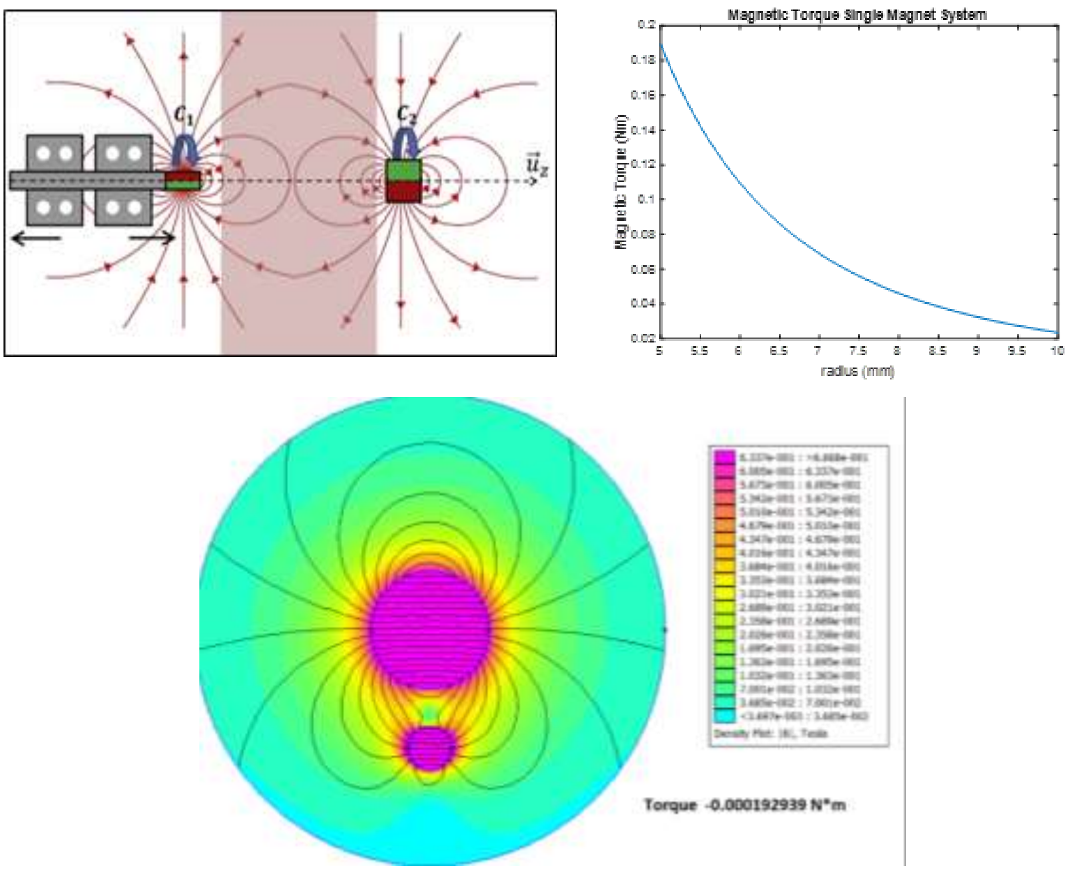


Figure 4.2. *Case 1:* Single magnet remote control. Model of magnetic field lines for a coaxial configuration (top left) [3] and torque applied to internal magnet for a given distance (top right). Finite Element Analysis to determine magnetic field and torque of the system (bottom).

<u>**Case 1:** Single magnet remote</u>

If the remote control had a single magnet (**Fig 4.2**), the torque calculation would be simple. Given you have magnet 1 ($\widehat{\mu_1}$ *and* $\widehat{B_1}$) and magnet 2 ($\widehat{\mu_2}$ *and* $\widehat{B_2}$), substitute **Eq. 4** and **Eq. 5**:

$$\widehat{\tau_1} = \widehat{\mu_1} \times \widehat{B_2}$$

$$\hat{\tau} = \frac{M_1 V_1 M_2 V_2}{2\pi r^3} \mu_o sin\theta \qquad \text{(Eq. 7)}$$

Using a hall sensor, which can detect and monitor magnet field, the remote would be guaranteed coupling between the magnets, therefore reducing $sin\,\theta = \sin(90°) = 1$.

Additionally, literature shows that the scalp has a thickness 5 to 8 mm [3]. Constants could be taken from product datasheets. For the magnets used in this system, $V_1 = 3/16"\ O.D. \times\ 3/8"\ thick$ and $V_2 = 3/4"\ O.D. \times\ 1/4"\ id\ \times 3/4"\ thick$. Using a Gaussmeter, the surface field of the magnets were measured as B_1 = 3800 G and B_2 = 6000 G. Magnetization was computed with **Eq. 3** and torque was then computed with **Eq. 7**.

Results are plotted in **Fig 4.2** from 5 mm to 10 mm away. At 5 mm, the remote produced a torque of 0.1892 Nm. At 10 mm, a torque 0.0236 Nm was produced.

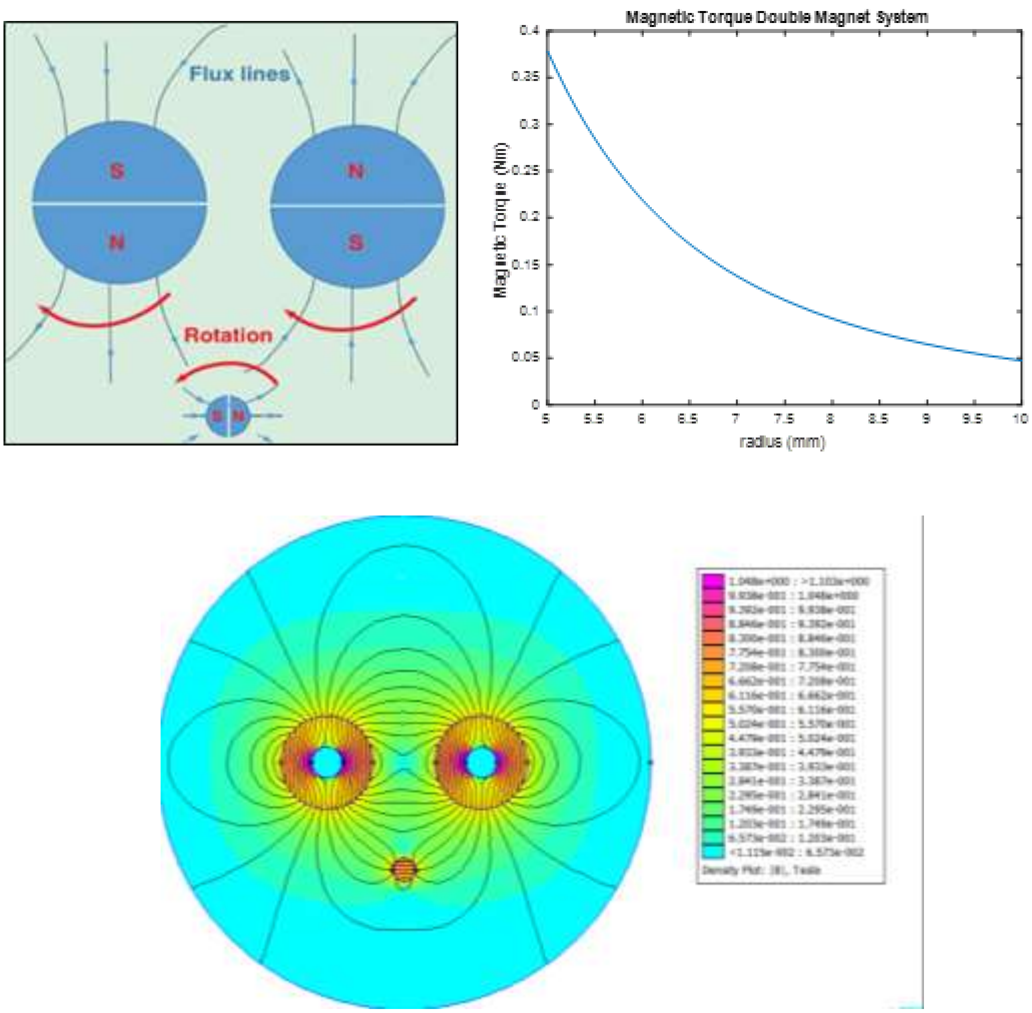


Figure 4.3. *Case 2:* Double magnet remote control. Magnetic field lines (top left) [4] and torque applied to internal magnet for a given distance (top right). Finite Element Analysis to determine magnetic field and torque of the system (bottom).

Case 2: Double Magnet Remote

For Case 2, the second magnet added complexity to the calculations. By the *Law of Superposition*, the magnetic field of two adjacent dipoles could be summed by their vector components acting on the third magnet. However, the position of the magnets shown in **Fig. 4.3** revealed that the implanted magnet was no longer along the symmetrical axis with the remote magnets. Thus, **Eq. 3** no longer applies. Formulas for such circumstances were only approximations and very complicated.

Case 2 can be approximated by being modeled as a single larger dipole with twice the volume of the remote magnet in Case 1. Using this, all previous equations applied. Using the same data as in Case 1, the results were plotted in **Fig 4.3**. At 5 mm the remote produced a torque of 0.3784 Nm. At 10 mm the torque produced was 0.0473 Nm. The assumptions for this approximation were not entirely valid.

Test Conditions

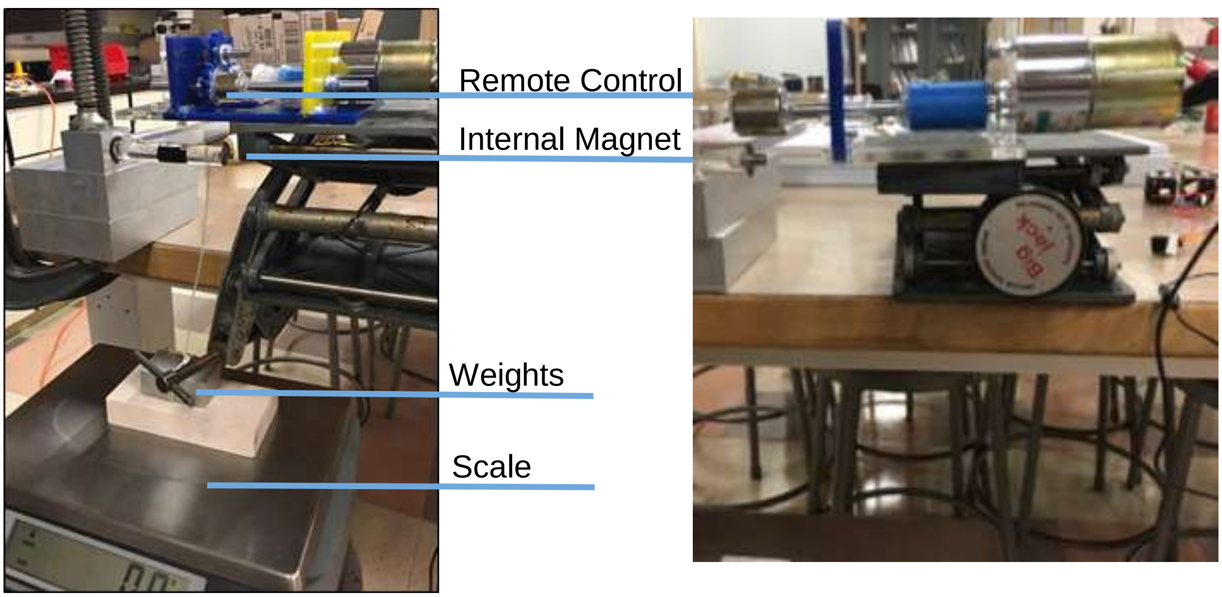


Figure 4.4 Experimental setup to measure the magnetic torque of Case 2 (double magnet, left) and Case 1 (single magnet, right).

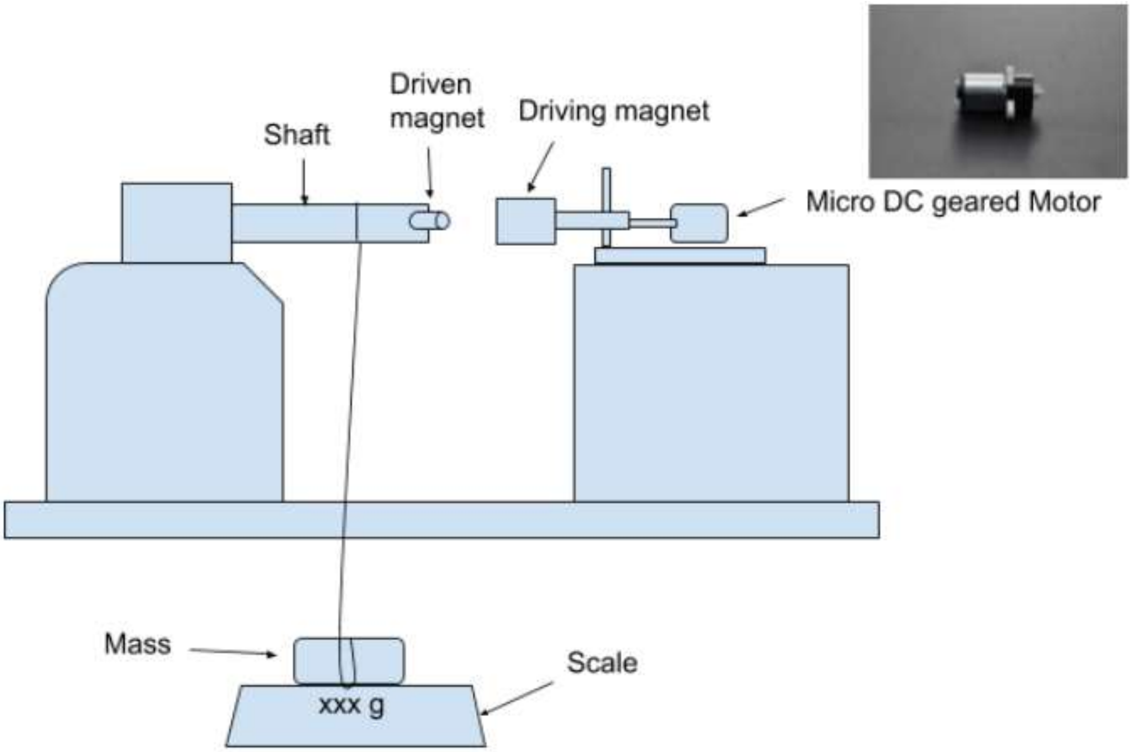


Figure 4.5. Schematic of experimental setup

<u>Procedure:</u>

1. Build the bearing mount for the rotating bearing with aluminum. Build the rotating shaft that fits in the bearing and the driven magnet.

2. Clamp the platforms for bearing mount and remote control on the table.

3. Position the remote control directly above the driven magnet.

4. Attach the shaft to a counterweight with an inelastic string.

5. Place the mass on a scale with no tension on the string. Zero the scale.

6. Activate the device and read the value at which the driven magnet takes away from the counterweight.

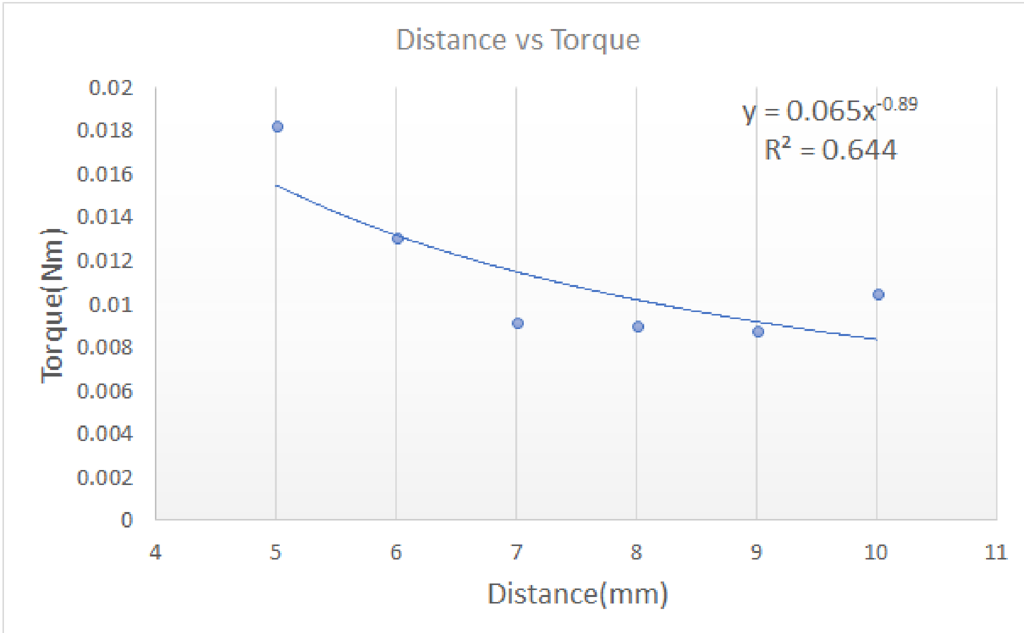
Results

Note: $r_{shaft} = 6.67 \times 10^{-3} m$		
Distance (mm)	**Weight reduced from mass (g)**	**Torque (Nm)**
5	280	0.0183
6	200	0.0131
7	140	0.00917
8	138	0.00903
9	135	0.00883
10	160	0.0105

Table 4.1. Torque values on magnet from remote control (Case 1)

Note: $r_{shaft} = 6.67 \times 10^{-3} m$		
Distance (mm)	**Weight reduced from mass (g)**	**Torque (Nm)**
30	37	0.00242
35	25	0.00229
40	27	0.00177
50	15	0.000981

Table 4.2. Torque values on magnet from remote control (Case 2)



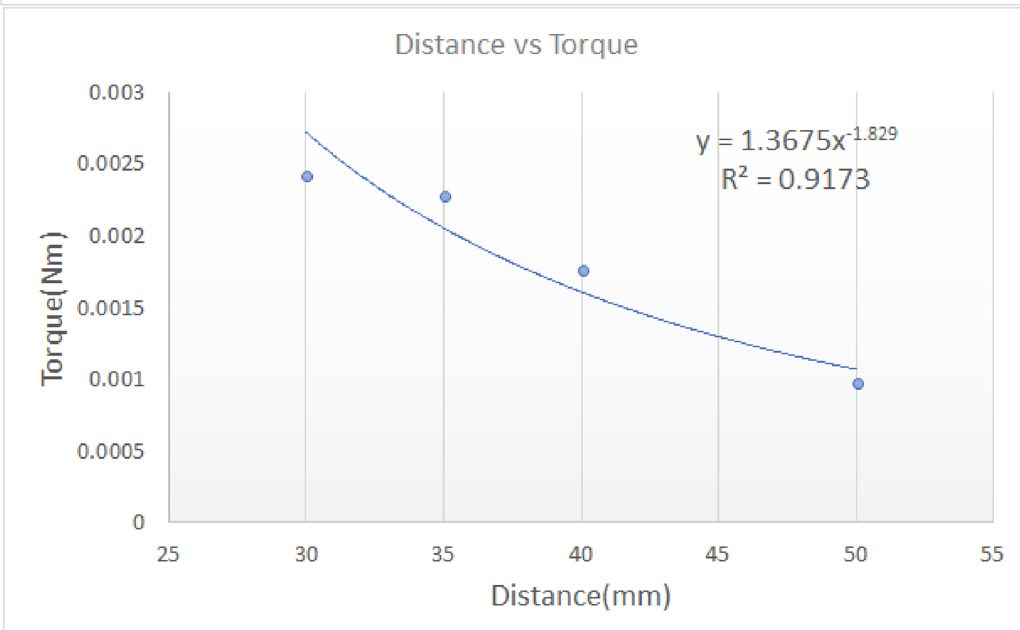


Figure 4.6. Plotted experimental data for Tables 4.1 (top) and 4.2 (bottom) respectively.

Comparison of Results to Initial Performance Requirements

Torque calculations and experimental data were obtained for both cases (single magnet and double magnet). The experimental data for Case 1 and Case 2 are respectively shown in **Tables 4.1** and **4.2**, and plotted in **Fig. 4.6**. For Case 1, at 5 mm the remote produces a 0.1892 Nm torque. At 10 mm the torque is 0.0236 Nm. Experimentally for case 2, at 30 mm the torque is 0.00242Nm. For Case 2, at 5 mm the remote produces a 0.3784 Nm torque. At 10 mm the torque is 0.0473 Nm. Experimentally for case 2, at 30 mm the torque is 0.024 Nm.

The experimental result for Case 2 does not match the results from the theoretical values. This was expected as the theoretical calculations involved oversimplifications.

Regardless, it was clear that the double magnet was too powerful for the remote control system. Literature showed that a modest torque of 0.018 Nm is sufficient. Other publications claimed that only 0.0424 Nm is required to generate the necessary force for distraction [3]. Thus, considering the experiments revealed that at 30 mm distance – a factor of three times more than the thickness of the scalp – the generated torque is 0.024 Nm, the use of two magnets will not be necessary. The single magnet case produced a smaller torque value of 0.0236 Nm at the scalp thickness 10 mm. Although the original proof of concept was based on the NuVasive PRECICE design, which required much more torque and is used on a scale that is ten times larger, it is unclear that a single magnet system is the optimal design decision for cranial distraction.

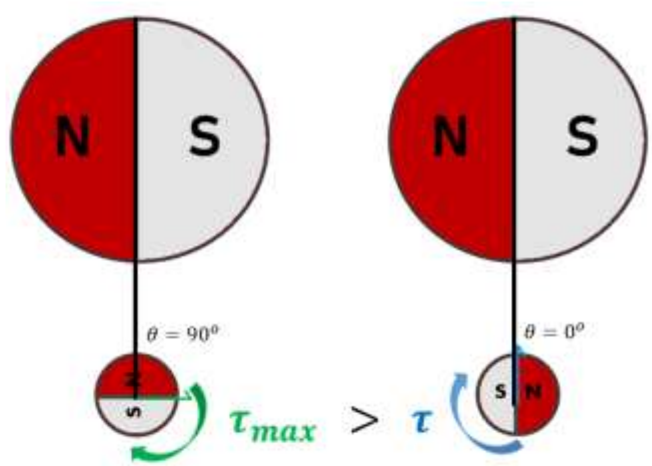


Figure 4.7. At the onset of slipping, which can reach a phase lag of 90 degrees, the max torque will occur between the magnets.

Finally, it is important to acknowledge that these torque measurements were at the maximum torque value. It was noticed that at this max value, the magnets were not in phase, but at approximately 90 degrees phase lag. A similar phenomenon is seen with the NuVasive technologies [14], and can be attributed to slipping. At the onset of slipping, the torque between the magnets will increase. Once slipping occurs, the torque will revert back to zero. Thus, the torque values from these tests are overestimates of the torque in the actual treatment setting. Slipping is not intended and the torque value without slipping will therefore be less than the values in these experiments. This is described in **Fig 4.7**. A more accurate result will use a dynamic torque value as the motor rotates continuously and while the magnets are coupled.

Chapter 5: Design Recommendations and Conclusions

Design Recommendations for the Future

External Remote Control

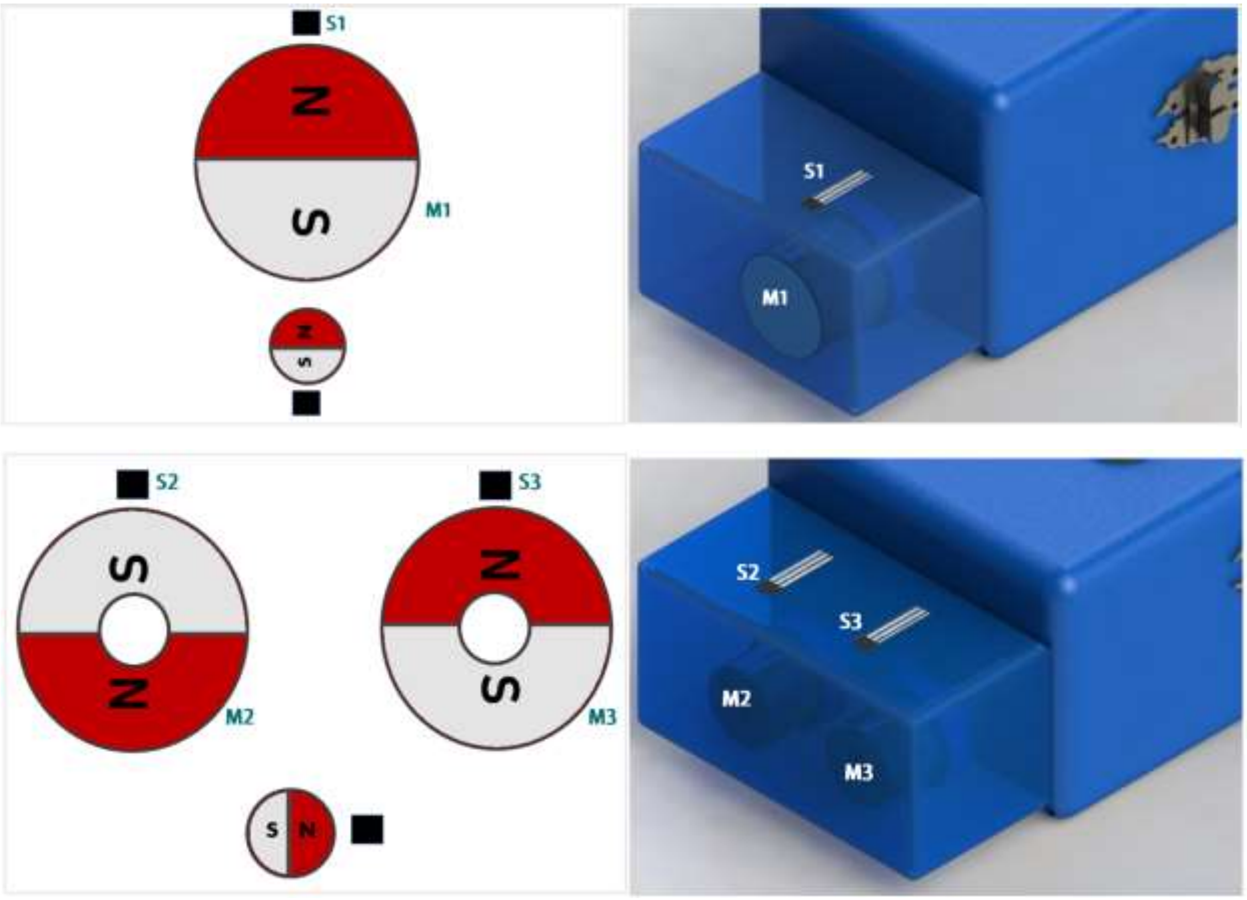


Figure 5.1. Experimental setup to determine if the internal magnet is in synch with the RC magnets and to determine if the two magnets in the double magnet configuration are in synch. Shown is the Single Magnet Configuration (top) and Double Magnet Configuration (bottom). A 3D printed cover was used to place the sensor in a stable position.

One experiment that was originally pursued, but data was not acquired because of lack of time, were calibrated rotation measurements. It is important to determine how well the internal magnet follows the external magnet's angular position and velocity as the system rotates. While the RC is turned on and rotating the internal magnet, a Hall sensor will act as a position sensor in order to determine if the internal magnet follows the same cycle as the RC magnet. The configuration for a single magnet is shown in **Fig. 5.1 (top)**.

First consider the single magnet system. Predicted results, as previously discussed, will be sinusoidal. A key note is that there will be a phase lag visible between sensor 1 (S1) that measure magnet 1 (M1) and the internal magnet. When the phase lag is constant, this means that there is an initial static threshold resistance torque present in the system. This is expected since friction is unavoidable. In addition, the phase lag will increase overtime even after the internal magnet begins moving due to dynamic friction, otherwise referred to as the dynamic resistance torque. For lab experiments, the phase will likely remain constant because the force applied to the system will be constant. However, in actual treatment the force of distraction increases overtime, thus increasing the force required to displace the skull which is evident through the increasing phase lag [14]. The resistance comes from the soft tissue attachments to the skull that requires the distraction device to push or pull with much greater force.

Now, consider the double magnet system shown in **Fig. 5.2 (bottom)**. The same results regarding static and dynamic resistance with sinusoidal outputs will apply. A new adjustment is that the voltage outputs for the sensors S2 and S3 will have a 180 degree phase difference because the magnets M2 and M3 are coupled at the start and forced to rotate in a de-coupled position during the one RC revolution

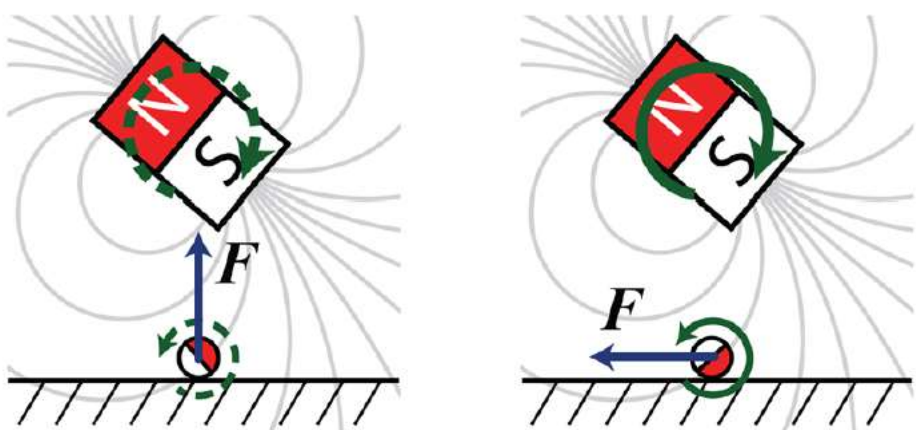


Figure 5.2. A pictorial representation showing how the attractive force (left) between the rotating external magnet and internal magnet can be converted to produce additional torque (right) by controlling angular velocity. In addition, the attractive force disappears [15].

A second improvement that was not pursued but considered was to minimize the attractive force between magnets. A single magnet system was investigated because the attractive force with the double magnet system was too large. In an interesting paper by *Mahoney and Abbot (2011)*, they research the possibility of translating the attractive force between rotating magnets into a torque. They conclude that it is possible to remove the attractive force, or at least make is negligible, by controlling the angular velocity of the actuating magnet, that is the RC magnet [15]. A pictorial representation is shown in **Fig 5.2.** In order to control the magnetic force, the actuating magnet must rotate with the following angular velocity:

$$\dot{\theta} = \frac{\mu_o|m||M|}{8\pi|p|^3c}\,(1 + 3\cos^2(\theta)^{\frac{3}{2}}) = K\,(1 + 3\cos^2(\theta))^{\frac{3}{2}} \qquad (Eq. 8)$$

Where K is the speed coefficient. Future work could integrate this system using a motor encoder to control the speed of the rotating magnet. Therefore, powerful magnets could be used without fear of a health hazard from an overpowering attractive magnetic force when bringing them close to the magnet temporarily implanted into the infant's skull. Equally as important, this would generate additional force to combat dynamic resistance torque.

Cranial Distraction Device

Future designs for this device can integrate novel ideas to optimize the design. For example, shape memory alloy (SMA) wire would be an interesting alternative technology to explore, as it can replace the low efficiency of the lead screw. Ideally, the device would adhere to the curvature of the patient's skull. While the current design attempts achieve this with thin pure titanium plates, their flexibility was limited, and the lead screw drive mechanism was still linear. One possible idea explored but not pursued by our team was the design shown in **Fig. 5.1,** which uses a pulley mechanism with metal wire and a curved metal backbone. While the backbone is still rigid, the curvature could have select sizes that would allow for some slight personalization to each patient's skull.

What was not pursued in this report, but still essential for eventual FDA approval, would be research on the health effects of the magnetic fields generated by the remote control and implanted magnet. In particular, studies on the magnetic flux through an infant skull and brain would be required. An improvement to aide in minimizing this hazard would be an additional plate made of magnetic shielding material, Mu-metal, that is inserted in between the magnet and the skull.

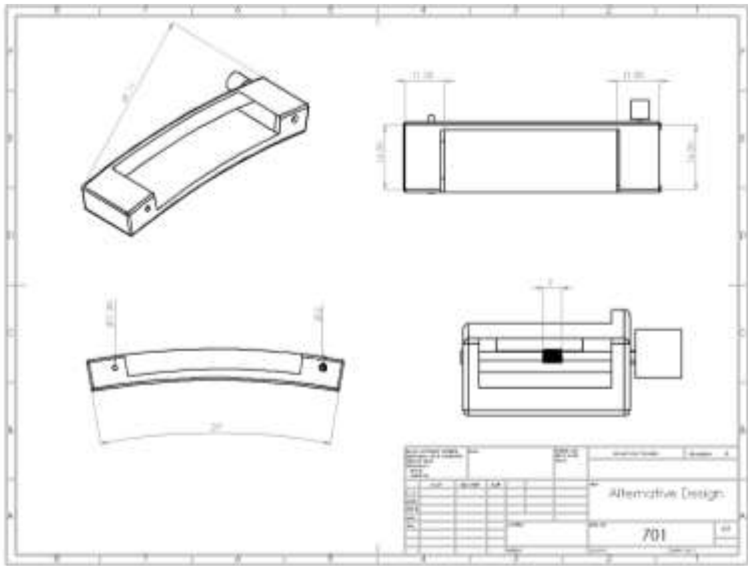


Figure 5.3. CAD drawing of alternative design

Safety Considerations

The magnetic remote control device contains extremely strong magnets. These magnets may pose non-ionizing radiation under prolonged exposure. Handle the remote control device with care. When handling the remote control, remove jewelry and any magnetic materials. It is strongly advised to keep other metal objects, tools, and magnetic media (such as computer disks, credit cards, tapes) away when handling the remote control device. Strong magnetic fields may pose a risk to those with implanted cardiac devices. Prolonged, concentrated exposure, especially to developing children, for over 15 minutes may cause tissue damage to the targeted area [11]. When the targeted area is near the brain, prolonged exposure may cause permanent tissue damage [12].

This remote control device also uses a 2-cell Lithium polymer (7.4V) battery. Keep remote control device away from water, other high voltage electronics, and high electric fields. Improper usage of device may cause harm to user and to patient.

Applicable Standards

TESTING	APPLICABLE STANDARDS
Distraction Device	
Component: Plates	ASTM F452 - 76
	ASTM F382 - 17
	ISO 9585
Component: Screws	ISO 9268
Component: Mechanical Drive System	ASTM F2129 - 17b
Material: Titanium / Grade 2	ASTM F2885 - 17
	ISO 5832 - 2
/ Grade 5	ASTM F560 -17
	ISO 5832 - 3
Biocompatibility	ISO 10993 - 1
	ISO 10993 - 5
	ISO 10993 - 6
Sterilization	ISO 11135
Magnetic Remote Control	
Magnetic Control	ASTM F2052 - 15
Magnet: Rare Earth	IEC 60404
CAD Drawings	ANSI/
Final Report / User Guide	ASTM F2809 - 10

Table A5.1. Applicable standards

Impact on Society

A magnetically activated cranial distraction device holds potential to effectively remove the risk of infection from the lives of infants diagnosed with craniosynostosis. While the current technology is successful at displacing the skull, 1 in 3 patients who wear a cranial distraction device suffer from infection. This is a markedly high statistic and dangerous hazard for infants. The technology from this report may be useful in other biomedical applications where complete internalization is necessary, whether to avoid infection or otherwise. This novel system is also versatile in that it can be scaled for delicate systems, such as an infant skull, or larger systems, such as a femur or tibia. Improving the overall treatment for posterior cranial vault distraction is likely to increase the orthopedic restorative process and better prevent any neurological damage, assuming the radiation is negligible. Such results would substantially increase the quality of life of the patient in their youth and adult life during and after full cranial and neurological development.

The device manufacturing process was designed for effective assembly, distribution, and overall accessibility to benefit as many patients and medical institutions as possible. The 3D printed titanium allows for low-cost mass production with high precision and replicability. The user-friendly remote control component could allow the patient (or their guardians) to perform distraction in the comfort of their own home rather than attending frequent appointments to the doctor’s office. In addition, the remote control component is not tethered to any one device, as many typical infrared or radio wave remote control systems are due to their specified frequency. This allows the remote control to be used for multiple patients, making it an economic advantage. With complete internalization, this device may be applicable to underdeveloped regions where risk of infection would otherwise be increased due to poor sanitation.

An important concern with the technology would be the proper recycling and disposal for the three active components: 1) titanium material, 2) remote control batteries, and 3) neodymium magnets. The indwelling condition generates a small volume of a few centimeters cubed of titanium material per device, and this material can likely be sterilized and melted down for other recycled purposes, as is common for titanium scraps [13]. The remote control system uses lithium-ion batteries to power the DC motor, and lithium-ion batteries are commonly disposed of in landfills that build-up and pose an environmental threat. While this device is clearly beneficial to society, it is still possible to determine a more effective power source. The magnets in both the device and remote control must also be taken into careful consideration. Presently, less than 1% of magnets have been known to be recycled after use, leaving a vast majority disposed of into the landfills. It would be ideal to degauss the magnets, melt and separate them down to their original components, and recycle the materials.

Given that the environmental and radiative health issues are resolved, this device development is overall a worthwhile medical and economic achievement for the sponsor, Dr. Gosman, to continue to pursue. It will prove invaluable for future patients and physicians associated with craniosynostosis.

Lessons Learned

It is important, especially during the start of the research process, to gather information from experts and companies in the field. This project would not have been able to succeed without speaking with representatives from NuVasive and KLS Martin, since the goal of this project was essentially the best way to integrate their novel technologies. The perspective from our sponsor Dr. Gosman was also essential so that each prototype was iterated to cater to physicians’ and patients’ needs.

To pursue any project that has not be undertaken before, it is key to understand that it will take time. Allocating a generous amount of time for areas of concern is important. In addition, be flexible with the time. It is always possible that one aspect that initially seemed high risk succeeds with little time, but another area that was meant to be completed quickly too much longer than expected. Perhaps the largest challenge throughout this project was 3D printing in titanium at such a small scale. To save on cost and maintain the precision required, we manufactured each part of the device using different methods depending on what was optimal. As an example, the plates were 3D printed because this was the only way to achieve such thin plates. Machining titanium in house was a longer and more dangerous struggle. However, the lead screw was purchased from a manufacturer. In this, the necessary resolution for the threads was achieved.

Finally, the key to engineering is to undertake tasks you are not familiar with. For all members on this project, there was a point where each of us required personal research on our assignment in order to succeed.

Conclusions

A magnetically actuated cranial distraction device is feasible, even at its small scale. The desired resolution, distraction length, and magnetic drive easily it into a form factor that is small enough to be comfortably implanted without an open wound. Our indwelling can provide enough torque to distract using a double magnet remote control, at the cost of additional bulk and the potential to interfere with other magnetic devices present or surrounding the patient. A single magnet remote control system is theoretically viable for proper cranial distraction, but it achieved a factor of safety less than 2.5. This factor of safety can be improved by increasing the gear ratio on the device; however, this would either require precise 3D printing or increase bulkiness. The final delivered devices are only a proof of concept of a scaled-down version of the limb lengthening system. Further work is required on this device to shrink the form factor, improve reliability, and assess the effects of large magnetic fields on an infant brain development. To push this design into clinical use, precise machining for manufacturing and research into magnetic field effects on infant brain development must be performed.

Acknowledgements

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We would also like to thank Professor David Gillett and Connor Watson for their invaluable advice and guidance through this project. Without their constant challenging, we would not have considered pursuing such ideas.

Lastly, we would like to thank Chris Cassidy in the Rapid Prototyping Center, Ian Richardson in the Machine Shop, and Gregory Specht in the Electronics Laboratory for their expertise and assistance with the prototyping process.

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Appendices

Appendix 1. Executive Summary

Magnetically Actuated Cranial Distraction Device for Craniosynostosis

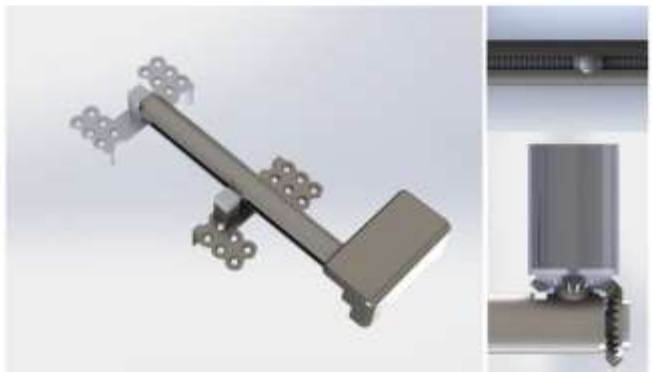


Figure: Final design of the cranial distraction device (left). The drive mechanism is a lead screw (top right) that is driven by a bevel gear design (bottom right), with a magnet that is actuated by remote control.

What is craniosynostosis?

Craniosynostosis is a birth defect in which the sutures that divide the skull into its respective lobes are prematurely fused together.

Direct health consequences from this condition include permanent distortion of the skull and face, respiratory blockage, and stunted brain growth. This condition occurs approximately 1 in 2500 births and requires immediate diagnosis and treatment to avoid severe neurological complications.

What is a distraction device?

Distraction is the medical term for the separation of two parts of a bone after an incision. A cranial distraction device is surgically screwed into the skull, and gradually extends the formed bone gap until the appropriate gap size is reached.

The current technique used for infants between ages 3-6 months to treat craniosynostosis is a surgical method called posterior cranial vault distraction. A surgeon will create the necessary incisions in the skull and temporarily implant a device intended to prevent pressure on the infant's brain and to provide space for proper brain development. This procedure has been proven effective due to infant's rapid ability to reform bone.

Why magnetic actuation?

With the current procedure, an open wound is required to use the distraction device. From this, approximately 1 in 3 patients suffer from infection!

A study [1] compared internal and external distraction devices and showed that nearly 30% of external devices became infected, while only 6% of internal devices were infected. Magnetic actuation allows the distraction device to be completely internalized underneath the skin. The remote control actuates the device through two rotating magnets that in turn mechanically extends the device! This device also allows a more low-profile design that fits better to the curvature of the patient's skull.

[1] "Pediatric/Craniofacial External versus Internal Distraction Devices in Treatment of Obstructive Sleep Apnea in Craniofacial Anomalies." Adi Rachmiel, DMD, PhD, Saleh Nseir, DMD, Omri Emodi, DMD, Dror Aizenbud, DMD

Appendix 2. Operation Manual

Please note, this operation manual is specific <u>only</u> to the remote magnet control component.

Operation Manual

External remote control for magnetically actuated cranial distraction device

Last edited on June 9, 2018

WARNINGS

This device is NOT waterproof or water-resistant.

Water may cause damage to internal circuitry.

Remove all metal jewelry and items before handling the remote.

It is strongly advised to keep other metal jewelry, objects, tools, and magnetic media (such as computer disks, credit cards, tapes) away when handling the remote control device. Strong magnets may attract or damage such items, and even create a choking hazard.

Keep device away from those with implanted cardiac devices.

Strong magnetic fields may pose a risk to those with implanted cardiac devices.

Keep device away from high voltage or high magnetic field devices.

Strong magnetic fields from the device may cause damage to other high voltage or high magnetic field devices.

Follow all directions carefully.

Improper usage of the device may cause temporary or permanent damage to the patient.

USERS

FOR CLINICAL USE ONLY

Until further approval and standards testing, this device is intended to be used only by licensed clinicians associated to the cranial distraction procedure.

MAINTENANCE

Clean properly before use.

Improper usage of the device may increase infection risk at the open wound from the surgical procedure.

Calibrate the device before EACH use.

The remote control is not tethered with a single distraction device. The remote may be used repeatedly for multiple distraction devices, given that it is calibrated correctly. Calibration instructions can be found on page 2.

Confirm battery life before EACH use.

The device may be battery powered for remote usage. The remaining battery life is shown on the LCD screen. For more information, see page 2.

Before Using the Device

Confirm battery life.

Before use, confirm that there is enough battery power for remote usage. Otherwise, plug the Arduino using the USB connector.

Calibrate the device

If the device is being used for the first time on a distraction device, connect to the device to a computer with Arduino.CC and turn on device while maintaining the switch position in the middle (OFF). Re-upload the code, and turn on the Serial Monitor, as labeled below.

If the voltage outputs as "0", confirm that Line 34 is "value >= 0.5"; if the voltage outputs as "5", confirm that Line 34 is "value <= 4.5". An example is shown below.

```
32   Serial.println(value);
33
34   if(value >= 0.5) // assume value=0
35   {
36      rotCount++;
```

Directions

Turn on device

Press the ON/OFF button.

Place device over marked magnet placement.

The device should be parallel to the head, hovering directly above the marking. The magnet should be about 5mm from the skin, facing the front of the face.

Increasing distraction

Switch the device up (FOR). This will power the geared motor that is attached to the rotating magnet. The distraction device will increase, as shown in the LCD screen.

Reverting distraction

To reverse the direction of the distraction, switch the device down (REV). This will rotate the magnet the opposing direction.

Remove device

Once the desired distraction is complete, switch the device OFF, and remove the device away from the patient. Power the device OFF. Keep the device away from any high voltage or magnetic items. It is suggested to replace the device in its original box.

Battery Life and Replacement

Determining remaining battery life

Once the voltage nears 4V, replace the battery after remote use and charge the drained battery. A Li-Po battery should not be used at less than 3.5V.

Replacing the battery

Place the device flat on a non-metallic surface. Remove the case top, and remove the battery pack directly underneath. Replace the drained battery with a charged 2-cell, 7.4V Li-Po battery.

Appendix 3. Fabrication Instructions

NOTE: Due to time and manufacturing limitations, the bevel gears in the prototype have been replaced with standard spur gears. The performance between these two designs is nearly identical, but the spur gears are much more accessible at its small scale and were integrated into the final device. Both a bevel gear drive and spur gear drive have been modeled, but all testing has been made with a spur gear driven prototype.

The plates were 3D printed in 316L stainless steel, courtesy of Xometry. To create the sockets, two holes were drilled in the plates, since the 3D printer did not have the required resolution. The lead screw was made from a commercially available M3x0.5mm threaded rod turned to size on a lathe. Similarly, the end caps, ball joint, and magnet holder were turned size from a piece of 316 stainless steel. The lead nut was drilled and tapped and then cut from a piece of 304 stainless steel with a wire EDM. The gear mount and socket caps were 3D printed in ABS plastic, and the nylon gears were commercially available parts. This mix of materials, however, is not ideal for mass for a mass produced device, especially since certain materials are not FDA approved for indwelling devices. Ideally, to mass produce this device, quotes would need to be gathered to create specialized tooling for each piece of the device. Additionally, all the parts would be fabricated in the respective grades of titanium previously mentioned.

The most important step to remember while assembling the prototype was to make sure that the lead nut is slotted inside the outer tube before permanently attaching the end caps. Since there are so few parts, the rest of the assembly can be completed by simply following the completed assembly pictures and the exploded view of the device. Super glue was used to adhere the end caps, plate caps, gear mount. It was also used to secure the gears to the shaft to ensure there was no slipping while the device was in use.

For the production model, the steps for assembling would be the same. However, glue would ideally be replaced with welds or a stronger FDA-approved adhesive.

Appendix 4. Drawings and Code

Drawings

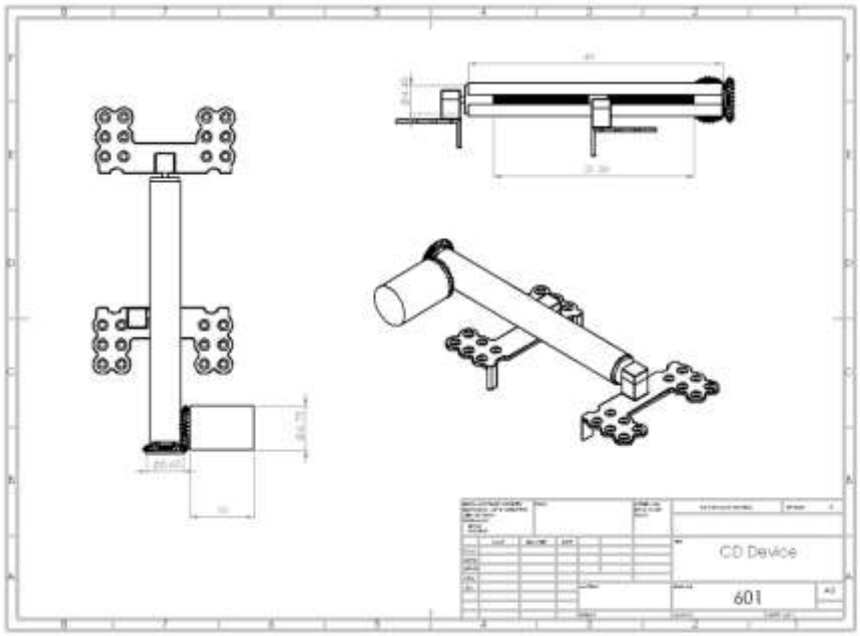


Figure A4.1. Annotated drawing of final cranial distraction device

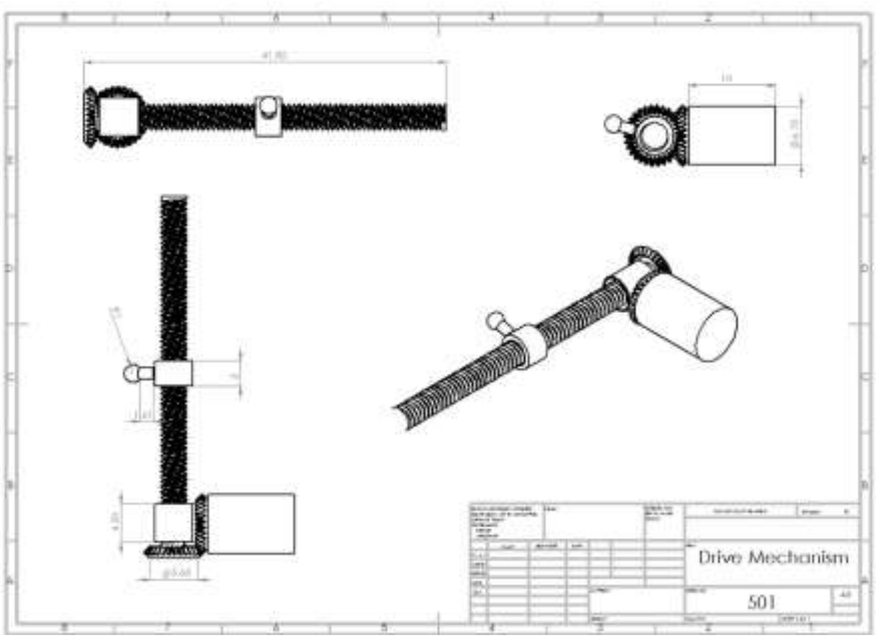


Figure A4.2. Annotated drawing of lead screw mechanism with bevel gears in final cranial distraction device

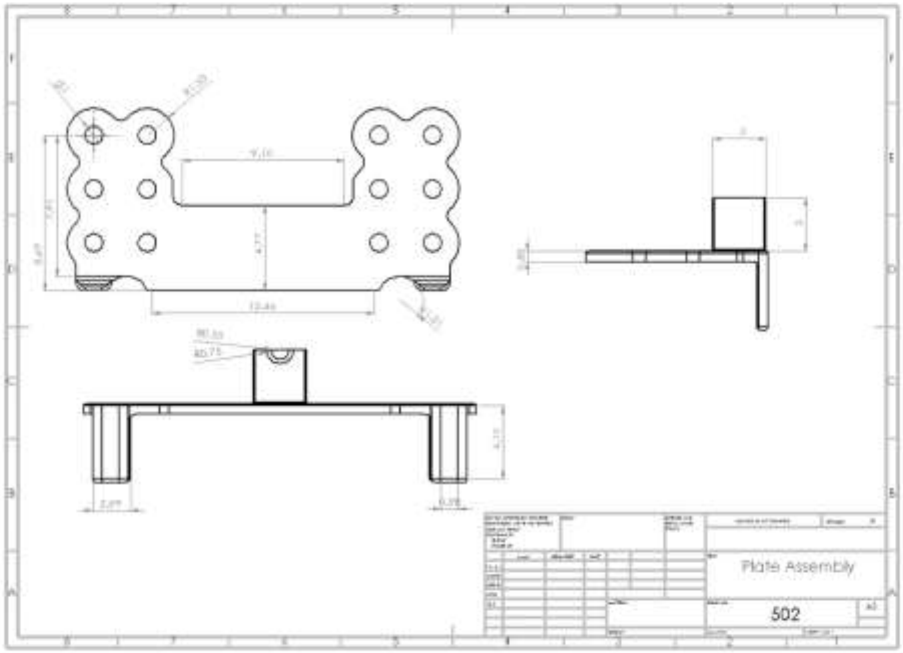


Figure A4.3. Annotated drawing of plates in final cranial distraction device

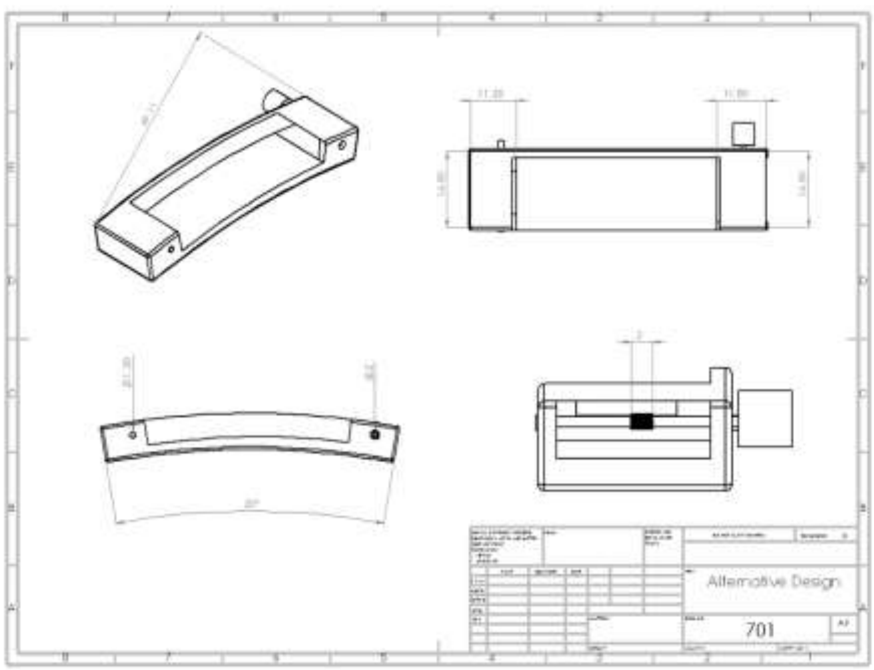


Figure A4.4. Annotated drawing of alternative drive mechanism for design recommendations

Code

```
// Arduino code for remote control device

#include <Wire.h>

#include <LiquidCrystal_I2C.h>

// Set the LCD address to 0x27 for a 16 chars and 2 line display

LiquidCrystal_I2C lcd(0x27, 16, 2);


void printVolts()

{

  int sensorValue = analogRead(A1); //read the A0 pin value

  float voltage = sensorValue * (5.00 / 1023.00) * 2; //convert the value to a true voltage.

  lcd.setCursor(0,0); // set first line of LCD

  lcd.print("voltage = ");

  lcd.print(voltage); //print the voltage to LCD

  lcd.print(" V");

}


int val=0; // create val integer

int rotCount=0; // create rotCount integer


void setup() {

  //pinMode(A0,analog)

  Serial.begin(9600); //set baud rate

  // initialize the LCD

  lcd.begin();

}
```

```
void loop() {
  // put your main code here, to run repeatedly:
  val = analogRead(A0); // read input from hall sensor
  float value = val*(5.0/1023.0); // translate value to voltage
  Serial.println(value); // print value in serial monitor


  if(value >= 1)  // assume initially value=0. !!! Change as needed !!!
  {
    rotCount++; // increment for every full rotation
    Serial.print("=======");
    Serial.print("count Value = ");
    Serial.println(rotCount);
    Serial.println("=======");
    delay(3000); // delay 3s/reading. !!! Change as needed !!!
  }
  // Turn on the blacklight and print a message.
  lcd.backlight();
  String StrrotCount = String(rotCount);
  lcd.setCursor(0, 1);
  lcd.print("Displace " + StrrotCount + " mm");  // print displacement
  printVolts();
 }
```

Circuit Diagram

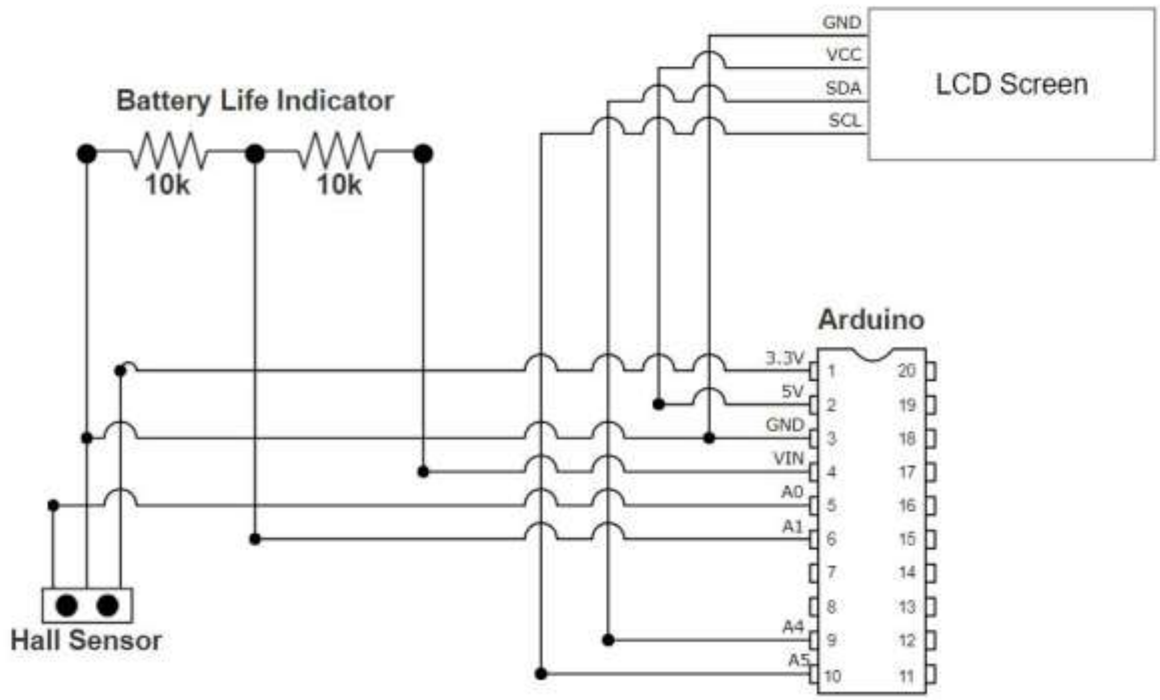


Figure 4.5. Schematic for Arduino wiring with LCD screen, hall sensor, and battery life indicator

Appendix 5. Bill of Materials

Part Numbering Legend

Category Digit	Description Category
1	Documents
2	Mechanical, electro-mechanical parts
3	Fabricated parts
4	Electronic, electrical parts
5	Assemblies, sub-assemblies
6	Top Level Assemblies - Saleable Items

Table A5.1. Part numbering for bill of materials

Bill of Materials by Assembly

Main Assembly			Cranial Distraction (CD) Device				
Part	REV	QTY	Level 0	Level 1	Level 2	Material	Cost
601	A	1	CD Device			ASSEMBLY	$1500+
501	A	1		Drive Mech		ASSEMBLY	
301	A	1			Lead Screw	Grade 5 Ti	$150
302	A	1			Outer Tube	Grade 5 Ti	$160
303	A	1			End Cap	Grade 5 Ti	$155
304	A	2			Bevel Gear	Grade 5 Ti	$270
201	A	1			Magnet (S)	Neodymium	$2.30
502	A	1		Plate Assembly		ASSEMBLY	
305	A	2			Plates	Grade 2 Ti	$300
306	A	2			Ball and Socket Cap	Grade 5 Ti	$244
		1		Epoxy (EP30Med)			$10

Main Assembly			External Remote Control (RC) Device				
Part	REV	QTY	Level 0	Level 1	Level 2	Material	Cost
602	A	1	RC Device			ASSEMBLY	$90.40
503	A			Case		ASSEMBLY	$10
307	A				Bottom	Plastic	
308	A				Top	Plastic	
309	A				Handles	Plastic	
504	A			Magnet Assembly		ASSEMBLY	$40
202	A	2			Magnet (M)	Neodymium	$19.18
203	A	2			Shaft	Aluminum	
204	A				Motor		$12.26
310	A				Motor wall	Acrylic	
311	A				Shaft wall	Acrylic	
312	A	6			Spacers	Acrylic	
401	A	2		Hall Sensor			$30.49
		1		Epoxy (EP30P)			$10

Table A5.2. Complete bill of materials per assembly

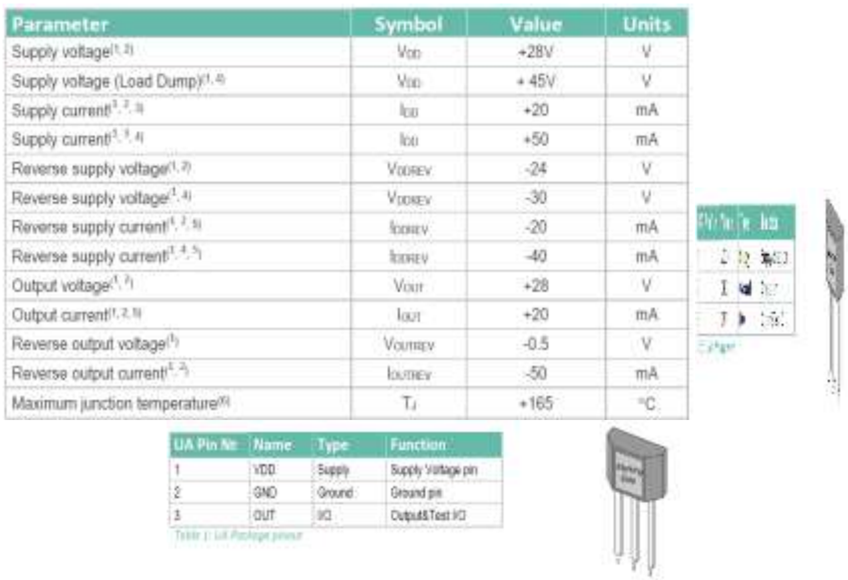
The following materials and components were purchased through a manufacturer or distributor:

Component	**Manufacturer/Distributor**	**Model/Part #**	**QTY**
Titanium Sheets	TITANIUM JOE	6Al-4V(G5):5.500:13.000:0.016	2
Ball Link Set	Great Planes	GPMQ3843	1
Gear Set	Amazon	B00SKD8Q1Y	1
Stainless Steel Rod (2mm)	uxcell	a14031300ux0184	1
Stainless Steel Rod (0.5in)	Industrial Metal Supply	316L Stainless Steel 0.5x12in	1
Stainless Steel Bar	Industrial Metal Supply	304 Stainless Steel 3/16x2x12in	1
Stainless Steel Tube	Industrial Metal Supply	304 Stainless Steel 0.25 OD 20GA	1
Threaded Rod	Mcmaster Carr	94185A578	1
Magnets (Small) (Medium)	K&J Magnetics, Inc.	 D48DIA RC4CDIA	 1 2
DC Geared Motor	DF Robot	FIT0492-A	1
3D Printer Filament	eSUN	PETG175U1	1
Hall Sensor	DigiKey	MLX92292LUA-AAA-000-SP-ND	2

Table A5.3. Bill of materials for purchased materials and components

Appendix 6. Datasheets and Parts Specifications

Figure A6.1. Geared Motor Specifications



Parameter	Symbol	Value	Units
Supply voltage[1,2]	V_{DD}	+28V	V
Supply voltage (Load Dump)[1,4]	V_{DD}	+ 45V	V
Supply current[1,2,3]	I_{DD}	+20	mA
Supply current[1,3,4]	I_{DD}	+50	mA
Reverse supply voltage[1,2]	V_{DDREV}	-24	V
Reverse supply voltage[1,4]	V_{DDREV}	-30	V
Reverse supply current[1,2,5]	I_{DDREV}	-20	mA
Reverse supply current[1,4,5]	I_{DDREV}	-40	mA
Output voltage[1,2]	V_{OUT}	+28	V
Output current[1,2,5]	I_{OUT}	+20	mA
Reverse output voltage[1]	V_{OUTREV}	-0.5	V
Reverse output current[1,2]	I_{OUTREV}	-50	mA
Maximum junction temperature[6]	T_J	+165	°C

UA Pin Nr.	Name	Type	Function
1	VDD	Supply	Supply Voltage pin
2	GND	Ground	Ground pin
3	OUT	I/O	Output&Test I/O

Table 1: UA Package pinout

Figure A6.2. Hall Sensor datasheet

Product Specifications

Type:	DISC
Dimensions:	0.25 dia x 0.5 thk (in)
Tolerance:	All dimensions ± 0.004 in
Material:	NdFeB, Grade N42
Plating:	NiCuNi
Max Op Temp:	176ºF (80ºC)
Br max:	13,200 Gauss
BH max:	42 MGOe

Figure A6.3. Small neodymium magnet specifications

Product Specifications

Type:	RING
Dimensions:	0.75 dia x 0.25 inner-dia x 0.75 thk (in)
Tolerance:	All dimensions ± 0.004 in
Material:	NdFeB, Grade N42
Plating:	NiCuNi
Max Op Temp:	176ºF (80ºC)
Br max:	13,200 Gauss
BH max:	42 MGOe

Figure A6.4. Medium neodymium magnet specifications

Specification:
- 1.75mm (Accuracy:1.7-1.8mm)
- 3.00mm (Accuracy:2.9-3.0mm)

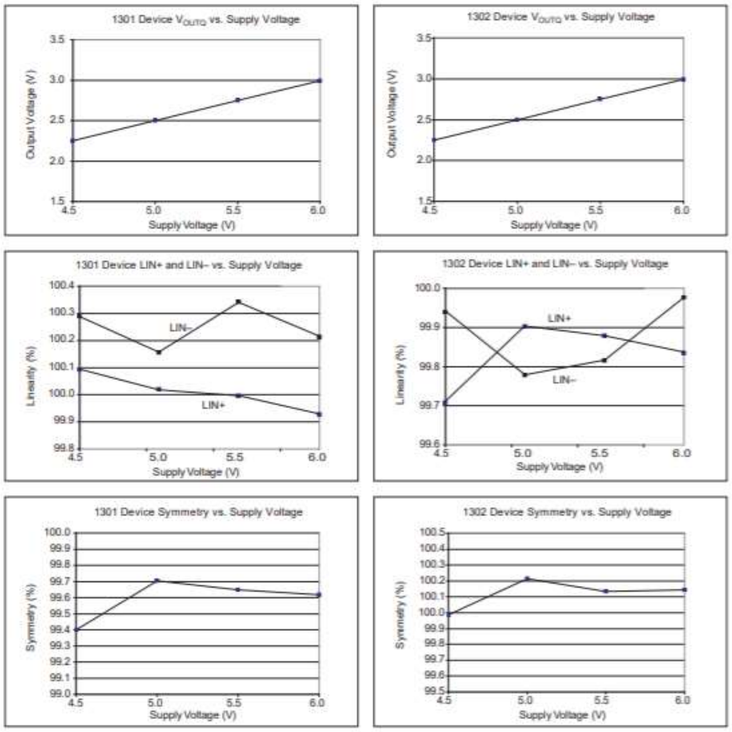
Characteristics:
- Odorless;little shrinkage rate;
- Hydrophobicity(Will not absorb water and as such clog the extruders);
- Outstanding toughness and high impact strength;
- Good liquidity(flows smoothly);
- High mehanical strength and excellent flexibility;
- High transparency;Good gloss;Recyclable.

Packing:
- 1kg /spool,10 Spools/ctn.
- 3kg /spool,4 Spools/ctn.

Figure A6.5. 3D printer filament characteristics

A1301 and A1302 — ***Continuous-Time Ratiometric Linear Hall Effect Sensor ICs***

Typical Characteristics, continued
(30 pieces, 3 fabrication lots)



Allegro MicroSystems, Inc.
115 Northeast Cutoff
Worcester, Massachusetts 01615-0036 U.S.A.
1.508.853.5000; www.allegromicro.com

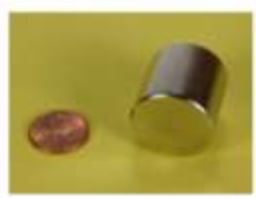
7

Figure A6.6. Allegro A1302 Linear Hall Effect Sensor

DX0X0DIA Specification Sheet

Product Specifications

Type:	DISC
Dimensions:	1 dia x 1 thk (in)
Tolerance:	All dimensions ± 0.004 in
Material:	NdFeB, Grade N42
Plating:	NiCuNi
Max Op Temp:	176°F (80°C)
Br max:	13,200 Gauss
BH max:	42 MGOe



Performance Specifications

Pull Force, Case 1, Magnet to a Steel Plate:	45.86 lb

Figure A6.7. Large neodymium magnet specifications

Appendix 7. Preliminary Component Analyses

I. Materials

Analysis completed by Dingyi Duan

Background
This analysis is for the material choice of the cranial distraction device. The material choice is significant and one of our first obstacles at beginning of the design for this project. Based on the requirements from the sponsor, this is also one of the biggest concerns for our new design.

Functional Requirements
<u>Primary</u>

- **High strength and toughness**: possesses tensile strengths from 30,000 psi to 200,000 psi (210-1380 MPa), in this specific case, the plates and screws must be able to take at least 30N force to against skull regrowth;
- **Corrosion resistance**: exhibits a high degree of immunity to attack by most mineral acids and chlorides, in this specific case, the device must remain the same state under condition of Cerebrospinal Fluid (**CSF**) and blood inside the skull;
- **Nontoxic**: needs to be biologically compatible with human tissues and bones.
- **Convenience**: easy to manufacture.

<u>Secondary</u>

- Consider adding a absorbable material for the "backing" of the screws to protect the sharp end of the screw from penetrating through the meninges;
- Consider using a flexible material for better fitting (if possible).

Investigation of Various Component Options
With these requirements, initial research was done on google to find potential alternatives. Many alloys have the required strength and corrosion resistance, but failed for being potentially toxic to human body. After taking advice from Dr. David Gillett, the list is narrowed down to three possible options. Properties are listed in **Table A7.1**. Advantages and disadvantages are listed in **Table A7.2**.

- **Commercially Pure Titanium/ Titanium 6AL-4V** (used on current device) $15- $30 / lb
  - Pure Titanium is also known as "Grade 2 Titanium."
  - Titanium 6AL-4V alloy is also known as "Grade 5 Titanium."
- **Shape Memory Alloy** (SMA) ~$6 / meter
- **Parylene coating** (Applied onto non-body-neutral material) ~$200 / lb

Conclusion
Overall, pure Titanium and Titanium 6AL-4V are still the optimal choice at this moment. SMA's ability of deform requires change of temperatures and change of the mechanism design to compensate the wire or spring form of it. Parylene coating is a good option when SMA is a

working prototype, but SMA is not FDA approved; specifically, FDA only regulates final finished devices instead of raw materials.

<table>
<tr><th>Material</th><th>Composition and Properties</th></tr>
<tr><td>

Titanium: Pure/6AL-4V Alloy

- Obtained from email with Kls Martin (manufacturer) and google scholar search

</td><td>

<table>
<tr><td>Commercial Pure Titanium consists of:

0.08 Max Carbon
0.03 Max Nitrogen
0.25 Max Oxygen
0.30 Max Iron
0.015 Max Hydrogen
Titanium=Balance of Material</td><td>Titanium 6AL-4V alloy consists of

5.5 - < 6.75% Aluminum
3.5 - < 4.5% Vanadium
Trace Materials<0.5%
Titanium =Balance of Material</td></tr>
</table>

Alloy	Tensile strength (UTS) (Mpa)	Yield strength (σ_y)	Elongation (%)	RA (%)	Modulus (GPa)
2. Pure Ti grade2	345	275	20	30	102.7
5. Ti–6Al–4V ELI (mill Annealed)	860–965	795–875	10–15	25–47	101–110
6. Ti–6Al–4V (annealed)	895–930	825–869	6–10	20–25	110–114

</td></tr>
<tr><td>

Shape Memory Alloy (SMA)

- Obtained from email with Dynalloy. Inc (manufacturer) and their website;

</td><td>

INGREDIENT	% BY WEIGHT	CAS NO.	OSHA PEL.	ACGIH TLV
Nickel	50-60%	7440-02-0	1 mg/m3 (TWA)*	1 mg/m3 (TWA)
Titanium	40-50%	7440-32-6	5 mg/m3 (TWA)+	10 mg/m3 (TWA)++

*As nickel metal and insoluble compounds
+As respirable TiO2 dust
++Considered a nuisance and covered by ACGIH nuisance dust standard of 10 mg/m3 total dust 8 hr. TWA.

Spring Wire Diameter in(mm), Outer Diameter in(mm)	SR Cold, SR Hot*	Displacement / Coil in(mm)	Resistance on Straight Wire ohms/inch (ohms/meter)	Heating Pull Force** pounds (grams)	Cooling Deformation Force** pounds (grams)	Approximate*** Current for 2 Seconds Contraction (A)	Cooling Time 194° F, 90°C "HT" Wire**** (seconds)
0.020 (0.51), 0.136 (3.45)	16, 7	0.18 (4.6)	0.11 (4.33)	0.536 (243.3)	0.215 (97.32)	3.4	15.0
0.015 (0.381), 0.10 (2.54)	15, 6	0.14 (3.4)	0.21 (8.27)	0.307 (139.3)	0.122 (55.72)	1.9	9.0
0.008 (0.203), 0.054 (1.37)	14, 5	0.07 (1.8)	0.74 (29.13)	0.089 (39.3)	0.035 (15.94)	0.7	3.0

</td></tr>
<tr><td>

Parylene

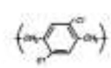
- Obtained from website of Parylene Engineering (a parylene conformal coating service).

</td><td>

Parylene C
The most widely used dimer; providing a useful combination of properties, plus a very low permeability to moisture, chemicals and other corrosive gases

Parylene N
Provides high dielectric strength and a dielectric constant that does not vary with changes in frequency. Best selection where greater coating protection is required

Parylene D
Maintains its physical strength and electrical properties at higher temperatures.



Characteristics and advantage

- Hydrophobic, chemically resistant coating with good barrier for inorganic and organic media, strong acids, caustic solutions, gases and water vapor
- Outstanding electrical isolation with high tension strain and low dielectric constant
- A biostable, biocompatible coating, FDA permission
- micropore and pin gol-free starting from 0.2 µm layer thickness
- Thin and transparent coating with high gap freedom of movement, suitably for complex arranged substrates also on edges
- Coating without temperature load of the substrates, coating takes place at ambient temperature in the vacuum
- Highly corrosion resistant
- Completely homogeneous surface
- Thermally stable up to 220 °C, mechanically stable from -200 °C to +150 °C
- Low mechanical stresses
- Resistant to friction
- Very low permeability to gases
- High electrical impedance

</td></tr>
</table>

Table A7.1. Components and properties of titanium, SMA, and parylene

Material	Pros	Cons
Titanium: **Pure / 6AL-4V**	High strength and toughness, nontoxic,corrosive resistant, can be achieved in various ways, relatively cheap.	Does not deform thus must rely on the mechanism to fit design purpose
SMA	Can deform and reform under different temperatures, have more freedom for design purpose, nontoxic,corrosive resistant,relatively cheap.	Only extend/retract under a variety of temperatures, can be challenging due to a stable human body temperature, relatively low strength and toughness compared to Titanium, not as common as Titanium
Parylene coating	Nontoxic, corrosive resistant.	High cost, will require extra work due to the small size of the actual device, may affect the efficiency of the mechanism

Table A7.2. Advantages and disadvantages of titanium, SMA, and parylene coating

- <u>Contacts:</u>

Erick Ortega, DYNALLOY, Inc.
Erick.Ortega@dynalloy.com
(714) 436-1206 main
(949) 502-8548 office
(714) 436-0511 fax

Shelby Belknap, KLS Martin | North America
shelby.belknap@klsmartin.com
904.641.7746 | Ext. 8091

II. Plates

Analysis completed by Ashley Qu

Background
After the first meeting with the sponsor, it was apparent that she wanted a device that was low-profile, magnetically-controlled, and placed completely underneath the skin and over the skull. On top of those basic requirements, she wanted the plates to be re-designed for smaller and more screws, as a common issue was that the screws were too long and too large for infants with smaller, thinner, or more porous skulls. Additionally, the plates were ineffectively designed such that the plate did not fit to the curvature of the skull, and sometimes the given amount of screws were not enough to attach the plate onto the skull properly. The current design contains ten holes, eight of which are designed for 1.5mm-diameter screws, on each plate, as shown in **Fig. 1A.** However, our sponsor actually utilizes all ten holes on each place.

Functional Requirements
Primary

- Accommodate screws of smaller than 1.5mm-diameter
- More than 10 screw holes (countersink)
- Tabs to hold onto skull at incision

Secondary

- Fits to the curvature of the skull
- Low-profile design

Investigation of Various Component Options
There are three designs considered in this component analysis: 8, 12, and 16-hole plate designs. The 8-hole plate design was primarily used as a baseline for the 12 and 16-hole designs. The advantages and disadvantages are shown in **Table A7.3**, and screenshots of the actual FEA analyses are shown in **Table A7.4**. All designs are adjustable in its length; therefore its length should not be considered as a factor. A total force of 70N, which is a factor of safety of 2 for the required force of 35N[4], was distributed amongst the holes and the two tabs.

Conclusion
Amongst these three designs, the 12-plate design demonstrates the best potential for a compact, low-profile, flexible plate. This design decision is supported by the comparisons between designs in **Table A7.3**, and FEA displacement and stress analyses in **Table A7.4**, based on a factor of safety of 2.

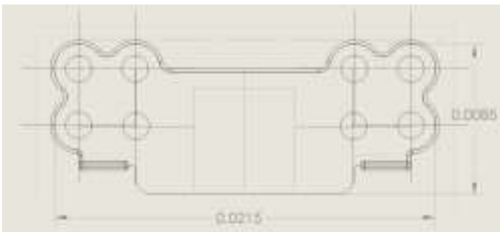
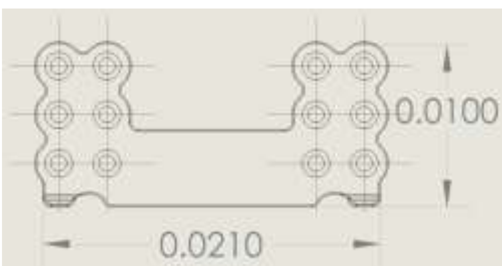
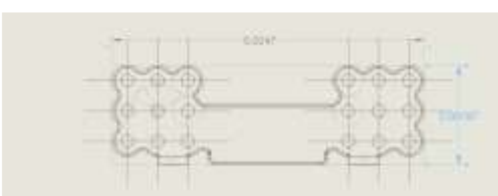
Plate Design and Description	Advantages	Disadvantages
8-hole plate design Dimensions of 21.5mm by 8.5mm by 0.58mm 	This plate design is the most low-profile and compact of the three designs.	Although this design does adhere to the smaller, 1mm-diamater screws, it does not allow for more screws. Additionally, according to the FEA, the les amount of holes results in more stress onto the tabs, such that the tabs deform.
12-hole plate design Dimensions of 21mm by 10mm by 0.58mm 	This plate design is a balance between the 8 and 18-hole designs. As shown in the FEA, there are negligible differences between the 12 and 18-hole plate designs. The slight slenderness of the hole area could allow for better fitting to the curvature of the skull.	Out of the three designs, this plate design was the least compact.
18-hole plate design Dimensions of 24.7mm by 7.87mm by 0.58mm 	According to the FEA, there is much less stress distributed amongst the holes.	This design may be over-constrained. This design adapts the current device design and expands it to more holes. It may additionally be less flexible due to the greater amount of material present.

Table A7.3. Advantages and disadvantages for 8, 12, and 18-hole plate designs.

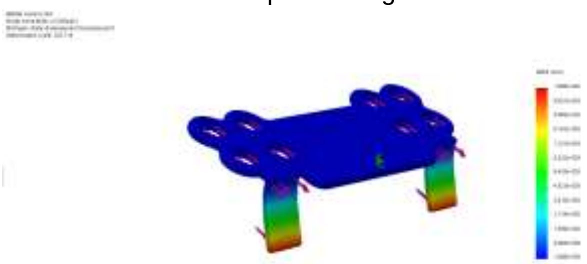
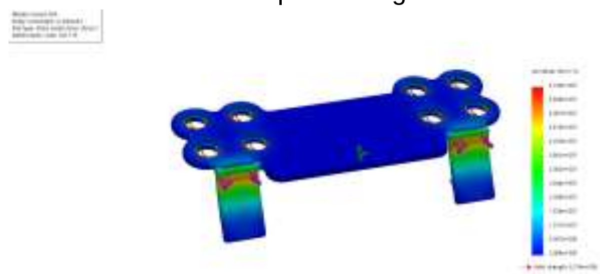
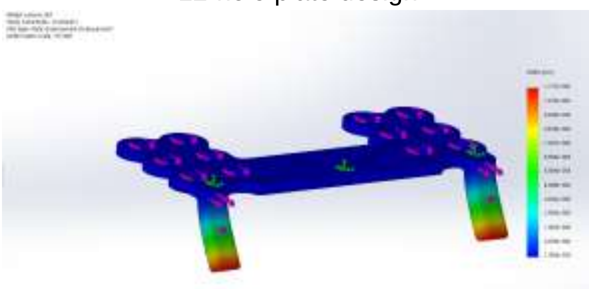
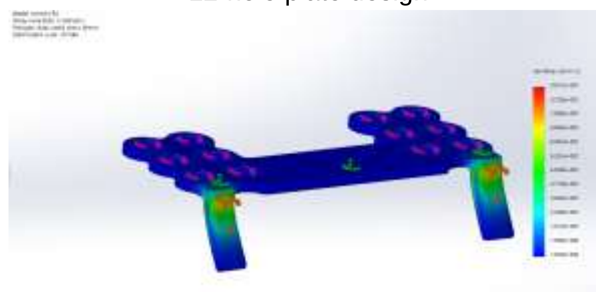
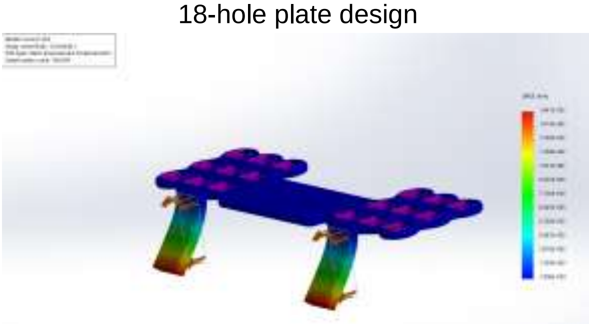
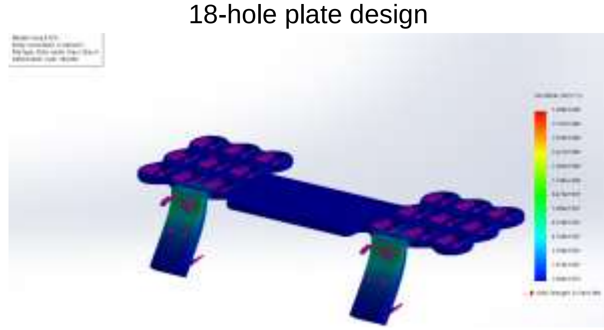
FEA: Displacement	**FEA: Stress**
8-hole plate design 	8-hole plate design 
12-hole plate design 	12-hole plate design 
18-hole plate design 	18-hole plate design 

Table A7.4. Screenshots of displacement and stress FEA analyses performed on the 8, 12, 18-hole plate designs.

III. Drive Mechanism

Analysis completed by Alec Schardein

Background

The ultimate goal of this project is to create an externally activated cranial distraction device that will fit completely underneath the skin and above the skull. Maintaining a low profile, reliable position, and high resolution will be of utmost importance in order for the device to operate successfully. Playing with the original, manually activated device demonstrated that the original drive mechanism was already successful in all of these areas. Adapting the drive mechanism to be externally activated and fit underneath the skin, however, will require some modifications. Alternative drive mechanisms will be explored to determine if a new drive system is required, or if it would be simpler to modify an existing mechanism.

Functional Requirements

<u>Primary</u>

- Low profile, must rest completely under the skin and above the skull
- High resolution of 0.5 mm or less
- Reversible drive, must travel forwards and backwards at will
- Pulling force of at least 30N [4]
- Position stability, must maintain position after power is removed

<u>Secondary</u>

- Flexibility, adherence to curvature of skull
- Simplicity, minimize moving parts

Investigation of Various Component Options

- Ratcheting linear slide with linear drive: This option would seek to redesign the current mechanism from scratch and implement a reversible ratcheting system with a permanent magnet being pulled in the direction of distraction (**Figure A7.1**)

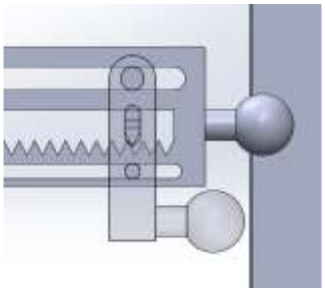


Figure A7.1. Ratcheting linear slide mechanism

- Ratcheting linear slide with rotating magnetic drive: Similar to the above option, this design would use a reversible ratchet on a linear slide, but replaces the linear traveling magnet with one that would rotate on a gear rack system on the top of the device shown above

- Lead screw with direct drive: With this mechanism the magnet is attached directly to the lead screw system to provide power to the system. (**Figure A7.2**)

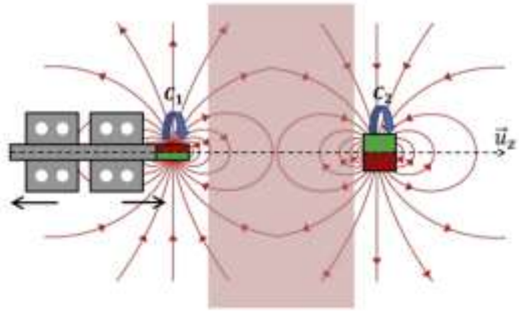


Figure A7.2. Direct driven lead screw[1]

- Lead screw with bevel gear drive: The drive mechanism for this option would be the same lead screw as in the original design, but power transmission would take place through a bevel gear system with a permanent magnet attached to the end

Conclusion

Although designing a mechanism from scratch would be more fun, it would make much more sense to consider the strengths of the existing mechanism and adapt it to fulfill the requirements that it doesn't already. A full list of considerations taken for this decision can be found in the comparison table (**Table A7.5**) below. Thus, the lead screw with the bevel drive seems to be the best option for ensuring that the device will have enough magnetic force in the smallest profile.

Drive	Advantages	Disadvantages	Cost
Ratchet with linear drive	-Moving the mechanism to specified length is simple	-Many complex parts. -Requires complex ratcheting mechanism to maintain position	High
Ratchet with rotating drive	-Implementing rotational motion is easy	-Similar to above, many complex parts are required	High
Lead screw with direct drive	-No complex mechanisms -Non backdrivable	-Magnet lies perpendicular to skull. -Thus there may not be enough magnetic force to drive it before exceeding size constraints	Low
Lead screw with bevel drive	-Can place driving magnet parallel to skull. Variability in drive angles allows multiple options for best fit -Non backdrivable	-Adds complexity to the above mechanism. May be difficult to make gears small enough to withstand forces and maintain low profile	Moderate

Table A7.5. Advantages and disadvantages of four different drive mechanisms

IV. Remote Control

Analysis completed by Macy Castaneda

Background
The current cranial distraction device design uses a lead screw mechanism such that the arm must penetrate the skin, which is highly susceptible to infection. The component under consideration is the remote control for this device, which is key to preventing such protrusions from the scalp.

Functional Requirements
Primary

- Must activate the device with absolutely no penetration of the scalp
- Cannot involve emissions or materials hazardous to infants (age 3-6 months)
- Must generate enough force to actuate the drive mechanism

Secondary

- Remote control can lock and unlock device externally
- Remote control can be used to measure or indicate the translation of the device
- Lightweight and comfortable to hold in the hand of a physician or patient at home
- Activation in both the forward and reverse direction

Investigation of Various Component Options
The current magnetically activated distraction technology exists from NuVasive. After contacting the company to speak with one of their engineers, the following considerations regarding their technology PRECICE were analyzed.

A. Permanent magnet: A permanent magnet system is used in current NuVasive distraction devices for the spine and femur [9]. Two large diametrically magnetized cylinders, rare earth magnets, are integrated into the remote control. A small permanent magnet is integrated in the distraction device. Using the magnetic torque between the internal and external magnets, the internal magnet will rotate and cause a lead screw in the device to translate [9]. The two most valuable features in this design are 1) the ability for reverse and forward rotation simply by rotating the magnets in different directions 2) actuation using a passive device mechanism.

B. Electromagnet: An electromagnetic system is very similar to a permanent magnet system. Many of the advantages are shared However, unlike a permanent magnet, an electromagnet can heat rapidly, requiring a cooling system. Although the additional advantage would be complete control over the magnetic force by simply changing the current or coil number.

Two other alternative remote control mechanisms were considered, since these are the more traditional remote control technologies that may have provided enhancements of the prior technology.

C. <u>Infrared</u>: An infrared remote control works using the electromagnetic spectrum in between the visible light and radio wave spectrum. The most common wavelength is 980nm. Infrared is seen mostly in television sets and involves a transmitter and receiver. Pressing a button on the T.V. control will complete the integrated circuit inside the remote that creates a series of digital output voltage signals to an LED. This LED sends these light pulses to the television, which in turn reads the sort of Morris code light emission using a sensor in order to determine the function to execute [8]. In this project, IR would be useful because it uses non-hazardous light emissions. In addition, using different digital pulses, the remote control can have multifunctional commands. This includes for forward and reverse translation along with a locking mechanism that prevents unintended rotation. The biggest issues with IR is that it requires direct line of sight [8]. Even the scalp would prevent signal transmission. In addition, a receiver must be implanted with the device, which would require an active electric circuit on the skull.

D. <u>Radio Frequency</u>: RF remote controls are also used to manage multiple systems. To avoid interference, a filter will remove any noise frequencies. Operational frequencies range from Hz to MHz and can transmit more than 200 ft [8]. An additional advantage compared to IR is that a direct line of sight between the transmitter and receiver is not required [8]. Radio waves will be bounce from object to object throughout the room forever and will eventually reach the receiver. This would be most useful in the distraction device because RF can transmit through skin.

Conclusion

Proceeding forward, the first prototype is going to use a **permanent magnet system**. This design poses the least amount of hazards, such as active electronic circuits and heated components. Although the hazards of magnetic flux to an infant's brain are unknown, the magnets required at this scale are so small (on the scale of millimeters) that this safety hazard until further notice will be considered negligible.

Remote Control	**Pros**	**Cons**	**Cost**
Infrared	-not hazardous at this level of exposure -Multifunctional -Range of 30ft	-waves do not transmit through skin -requires active electronic indwelling	$30-50
Radio Wave	-not hazardous at this level of exposure -Multifunctional waves transmit through skin range of more than 200ft	-requires active electronic indwelling	$30-50
Permanent Magnet	-transmits through skin -Passive device	-Constant magnetic force uncertain as to hazard at this level of exposure -range of less than 1in	$10-20
Electromagnet	-transmits through skin -passive device	-Heats up quickly -Variable magnetic force -Range of less than 1in	$10-20

Table A7.6. Advantages and disadvantages of various remote control designs. Costs considered the price of the components required to build these devices (from K&J Magnetics, Digikey), and not the costs of remote controls already on the market.

Contact: Adam Beckett, NuVasive PRECICE systems
Email: info@nuvasive.com or abeckett@nuvasive.com

Appendix 8: Project Management

Task Distribution

Sponsor
Amanda Gosman, MD.
Director, Pediatric and Craniofacial Plastic Surgery
UC San Diego Medical Center

Team 21 Project Members

Macy Castaneda
Sponsor Liaison
Technical (RC) Lead

Dingyi Duan
Machine Shop Safety Manager
3D Printing Company Liaison

Alec Schardein
Financial Manager
Technical (MD) Lead

Ashley Qu
Website Manager
Project Manager

Scheduling

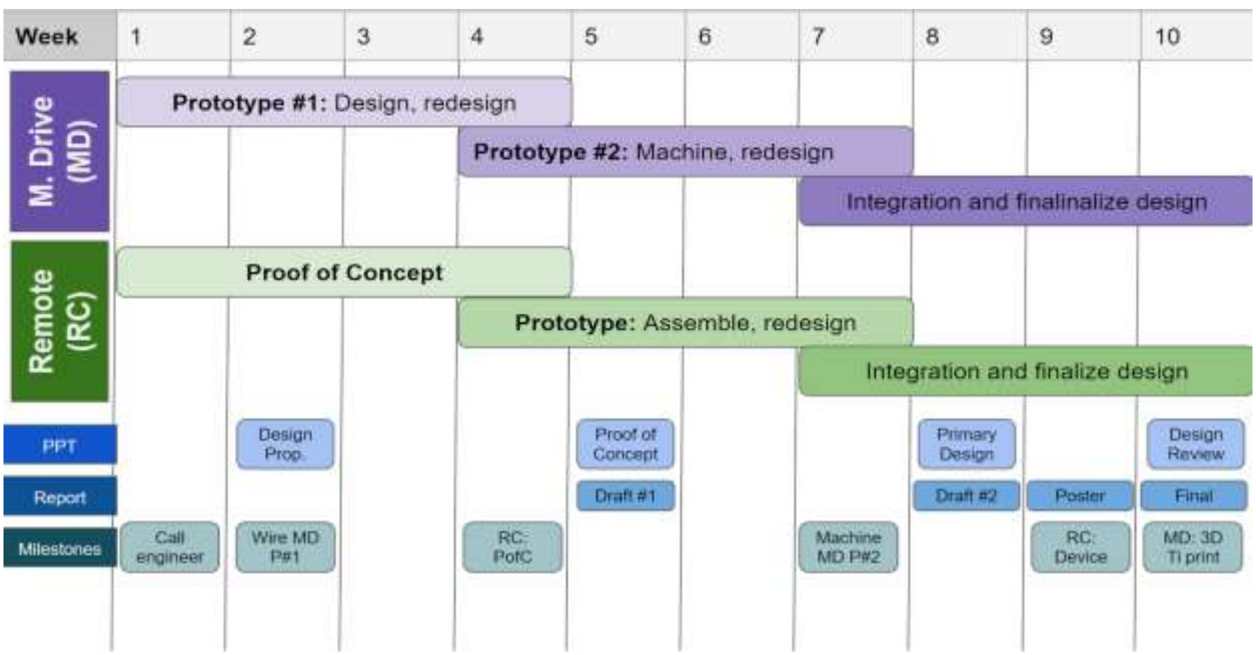


Figure A8.1. Visual Gantt Chart of prospective project timeline

A more detailed schedule with specific task distributions is shown in **Figure A8.2** below.

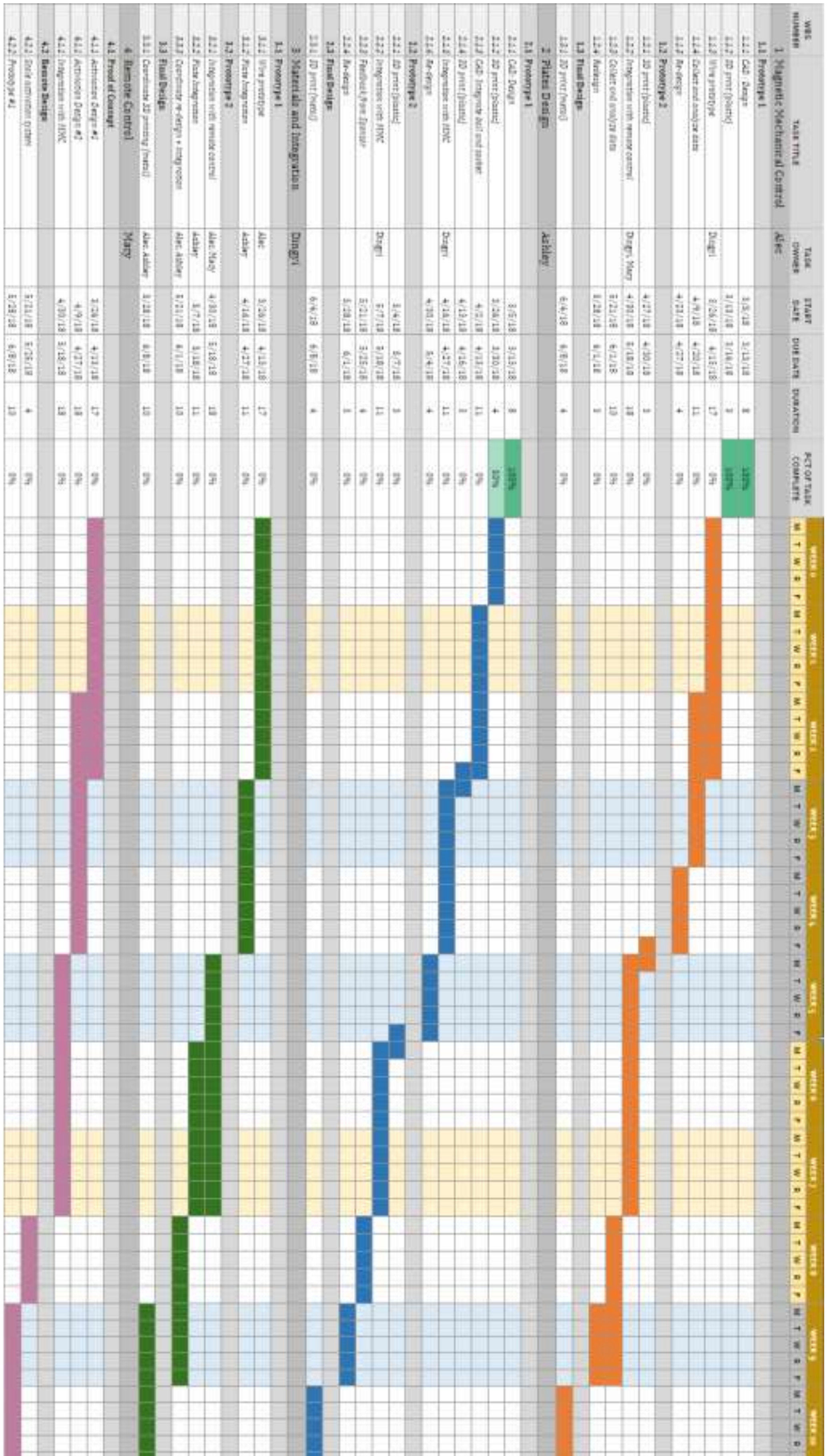


Figure A8.2. Gantt chart with task distribution for Spring 2018

Project Milestones

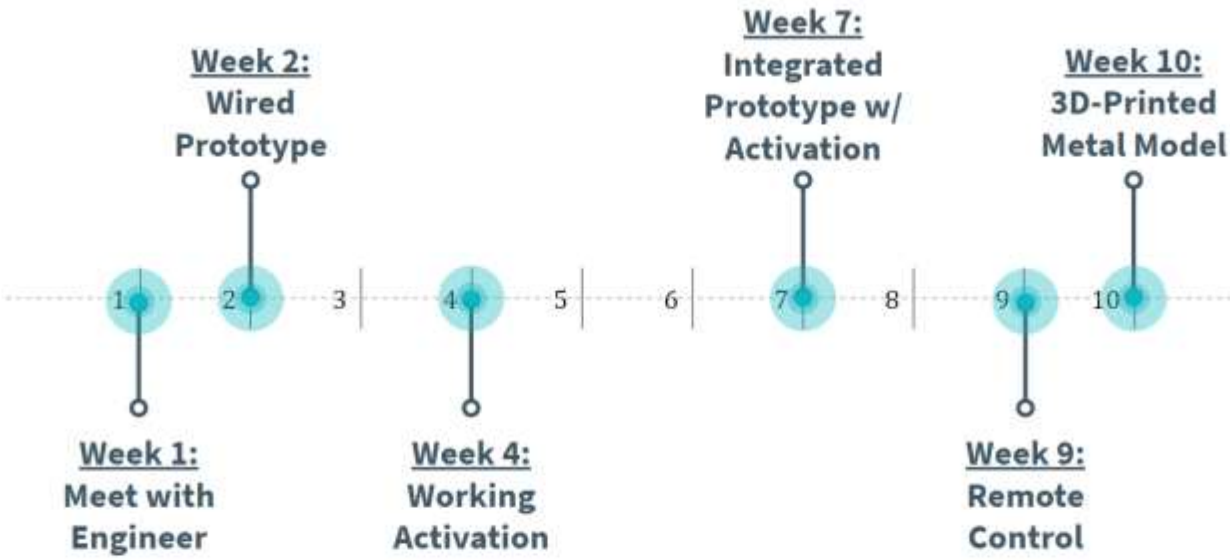


Figure A8.3. Cranial distraction device project milestones set by Team 21 for spring 2018

Week	Date	Milestone Achievements
Winter 2018		
9	March 9	CAD of prototype #1 completed
10	March 16	3D printed scaled model of prototype #1
Spring 2018		
2	April 9 April 11	Wired model of prototype #2 completed Spoke with NuVasive engineer regarding activation system
3	April 16	CAD alternative design for prototype #2 completed
4	April 26 April 27	3D printed scaled model of prototype #2 – functional Proof of concept of working activation – functional
5	April 30	3D printed to-scale version of prototype #2 – functional
8	May 25	Experimental data of concept of single magnet
9	May 30	3D printed stainless steel plates (1:1 scale)
10	June 7 June 7	Completed machined proof of concept device Completed remote control design and code

Table A8.1. Team milestone achievements in duration of project

Risk Reduction

<u>3D Printed Prototypes</u>
To reduce the risk of jamming and unsuccessful designs for the cranial distraction device, all designs were prototyped at a scaled (300%+) 3D-printed model. Once the final design was chosen, a 1:1 scale model was printed. Dimensions and specifications were refined, and any unforeseen issues were redesigns and resolved.

<u>FEA</u>
In order to determine the limitations of the plates, all plate designs were drawn in SolidWorks and finite element analyses (FEA) was performed on each design, for a variety of thicknesses, orientations, and force orientations. More details can be found in the plate design section of Appendix 7.

Budget

Our sponsor provided us a budget limit of $4000.00. We have spent $851.14.

Description	**Vendor**	**Specified by**	**Order Method**	**Amount**
3 x Magnetic Sensor TLV493DA1B6HTSA2	Digi-Key	Macy Castaneda	Personal Reimbursement	$5.49
3 x Rotation Angle Sensor EM3242	Digi-Key	Macy Castaneda	Personal Reimbursement	$14.37
3 x Magnetic Switch TSOT23-3	Digi-Key	Macy Castaneda	Personal Reimbursement	$4.86
3 x Magnetic Switch 3SIP	Digi-Key	Macy Castaneda	Personal Reimbursement	$6.66
3 x High Resolution Angle Sensor	Digi-Key	Macy Castaneda	Personal Reimbursement	$30.49
				$61.87
3 x RA2ADIA	K&J Magnetics	Macy Castaneda	Personal Reimbursement	$12.32
3 x RC4CDIA	K&J Magnetics	Macy Castaneda	Personal Reimbursement	$19.18
3 x D36DUA	K&J Magnetics	Macy Castaneda	Personal Reimbursement	$1.22
3 x D48DIA	K&J Magnetics	Macy Castaneda	Personal Reimbursement	$2.30
3 x RC4C-N52	K&J Magnetics	Macy Castaneda	Personal Reimbursement	$21.82
				$87.79

2 x SWITCH SLIDE DPDT 0.4VA 20V	Digi-Key	Macy Castaneda	Personal Reimbursement	$4.90
2 x SWITCH SLIDE SPDT 100MA 30V	Digi-Key	Macy Castaneda	Personal Reimbursement	$10.08
2 x SWITCH SLIDE SPDT 100MA 6V	Digi-Key	Macy Castaneda	Personal Reimbursement	$2.22
2 x SWITCH SLIDE SPDT 0.4VA 28V	Digi-Key	Macy Castaneda	Personal Reimbursement	$8.26
2 x MICRO METAL GEARED MOTOR W/ENCOD	Digi-Key	Macy Castaneda	Personal Reimbursement	$24.52
2 x MICRO DC GEARED MOTOR 6V 96RPM	Digi-Key	Macy Castaneda	Personal Reimbursement	$10.10
2 x TT MOTOR WITH ENCODER (6V 160RPM	Digi-Key	Macy Castaneda	Personal Reimbursement	$15.24
TURBO METAL GEAR WORM MOTOR (6V	Digi-Key	Macy Castaneda	Personal Reimbursement	$19.47
METAL DC GEARED MOTOR - 12V 50RP	Digi-Key	Macy Castaneda	Personal Reimbursement	$12.26
2.15" EPD A-MB WITH ITC	Digi-Key	Macy Castaneda	Personal Reimbursement	$13.18
LCD COG GRAPH 128X64 REFLECT	Digi-Key	Macy Castaneda	Personal Reimbursement	$12.05
				$132.28
2 x 0.063" x 5.5" x 6.5" CP Grade 2 Surplus Ti Sheets	Titanium Joe	Dingyi Duan	Personal Reimbursement	$36.36
2 x Direct Metal Laser Sintering/3D Printed Stainless Steel 316L/Standard	Xometry	Dingyi Duan	Personal Reimbursement	$ 432.39
3D print filament	Amazon	Alec Schardein	Personal Reimbursement	$ 28.30
Threaded ball link set	Amazon	Alec Schardein	Personal Reimbursement	$ 10.76
Plastic gears	Amazon	Alec Schardein	Personal Reimbursement	$ 5.50
316 Stainless steel bars/tubes	Amazon	Alec Schardein	Personal Reimbursement	$ 3.30
316 Stainless steel accessories	Mcmaster-carr	Alec Schardein	Personal Reimbursement	$ 19.80
				$ 556.41

Precision Bit and Driver Kit for Electronic and Precision Devices	Amazon	Ashley Qu	Personal Reimbursement	$ 9.90
12 Kinds M1 M1.2 M1.4 Screws Assortment Kit	Amazon	Ashley Qu	Personal Reimbursement	$ 12.79
[redacted]				$ 23.11
			TOTAL	**$ 851.14**

Table A8.2. Budget table with ordered items