Measuring Jaw Distraction Length via Position-Aware Screwdriver

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Word Count: 2572
Number of Figures: 4
Number of Tables: 2
Number of Equations: 1
Number of Supplements: 0
Number of References: 12

Approved: ______________________________ Date: 5/4/21
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Abstract

Craniofacial anomalies are deformities that occur in the head and facial bones of children and can occur at birth or due to trauma. Mandibular distraction osteogenesis is a current modality, and involves creating a fracture in the mandible and using a device called a distractor. A distractor widens the fracture after being turned with a screwdriver, allowing for bone growth to fill in the gap. It is difficult for physicians and parents/caregivers to know how much the bone has been elongated, even with CT scans, physical examinations, and weekly x-rays. Physicians often have to estimate the amount and evenness of mandibular expansion by eye. The aim of this project was to accurately and reliably measure jaw distraction length via the introduction of a novel screwdriver. To do this, iterations of a computer aided design of a displacement-measuring screwdriver device were created and 3D printed. This screwdriver utilizes an MPU-6050, an Arduino Nano, and an OLED display to measure and output the length the jaw distractor extends. By using our custom algorithm, the screwdriver converts angular displacement readings from the MPU into translational displacement via a conversion factor of $\frac{2\pi}{360}$ (units: mm/°). An angle tolerance test was performed, and statistical analysis concluded that the device did not meet the tolerance of $\pm 1°$ ($p>0.1$). Overall, a working prototype was created to quantify distractor elongation, but further refinements are required to reach clinically acceptable efficacy.

Keywords: craniofacial anomalies, distraction osteogenesis, mandible

Introduction

Craniofacial anomalies are defined as deformities that affect a child's head and facial bones[1]. These deformities occur in 2-3% of all babies, and 1 in 1600 newborns in the United States are born with a craniofacial anomaly, excluding cleft lip and palate[2]. Two examples of craniofacial conditions relevant to our project include micrognathia (undersized lower jaw) and retrognathia (malocclusion of the posterior mandible)[3]. Complications can occur in the mandible and cause severe problems if left untreated, such as airway obstruction. In addition, trauma to the face can cause injuries that can create problems and therefore require medical intervention. Problems such as sleep apnea, airway obstruction, and psychological effects due to the societal stigma around individuals with craniofacial anomalies can arise if left untreated[3,4]. If there is concern about obstruction of the airway or any loss of functionality, many treatments consist of a procedure called distraction osteogenesis (DO). DO describes the growth of new bone through an osteotomy (intentional cutting or removal of bone) and the gradual separation of the two bony surfaces with a device called a distractor[3]. To separate the two bony surfaces, a fracture is induced within the mandible via surgery and a distractor is placed. A distractor consists of three different components: a drive rod (or activation rod), an activation arm, and a screwdriver. The drive rod includes 2-3 plates that are screwed into the bone on either side of the fracture (**Figure 1**). This part of the device remains in the patient for 3-6 months, or until the fractured bone is healed. The drive

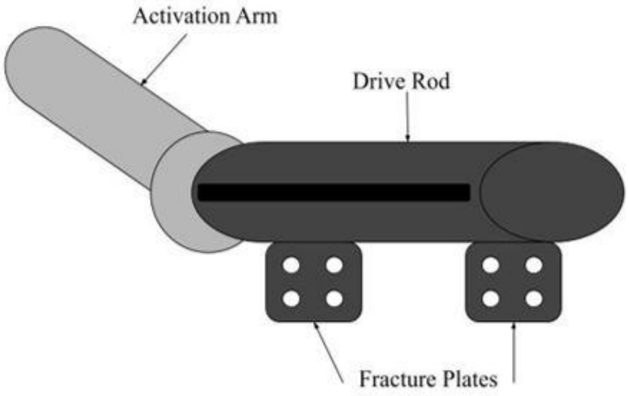


Fig. 1. Distractor Device. This figure visualizes the structure of the distractor device used in distraction osteogenesis.

rod is what becomes elongated to induce osteogenesis. The activation arm connects to the distractor plates and when rotated by the screwdriver, separates the two plates. Part of the activation arm remains inside of the patient connected to the plates while the other part sticks out of the patient through an incision in the cheek. This allows for rotational transmission from the screwdriver to the drive rod. Lastly, the screwdriver connects to the activation arm and is the component that the user interacts with to cause displacement of the plates.

After the distractor is surgically placed, the user is required to elongate the device in order for new bone to grow. The rate and length of elongation is determined by the physician, and is unique to the patient. Typically, patients are too young to operate the distractor on their own, so parents or caregivers are responsible for turning the device to separate the bone. There is no way for users to know how much they have turned the device, nor is there a way for doctors to know exactly how much the device has been elongated, even with x-rays, CT scans, and physical exams. In fact, there is an 8.8% incidence of an inappropriate distraction vector in mandibular DO patients, which could be attributed to improper elongation technique[5,6]. Discrepancies in distraction lengths can prolong treatment and/or cause problems such as premature osteogenesis (or the formation of bone too early in the process), therefore increasing the amount of time the distractor remains placed in the patient.

Our project aims to reliably and accurately measure the amount of distractor elongation through the introduction of a novel screwdriver. Rather than manipulating the part of the distractor that remains inside of the patient, our team chose to redesign the component that stays outside of the patient. This allows us to make more modifications without changing the distractor itself and poses a quicker, more efficient path for Food and Drug Administration approval. The engineered screwdriver will retain the functionality of the original screwdriver, but will additionally house an internal circuit that will allow for the conversion from rotational data to linear elongation. Furthermore, the screwdriver will possess an OLED screen that will display the distance of elongation, which will allow for users to know how much they have lengthened the device. This is important in verifying patient/parent compliance and for optimizing the treatment of the child. While conducting our research and testing, it was hypothesized that the device would be able to detect the correct number of degrees turned and subsequently output the proper length of elongation, within a tolerance as discussed in **Materials & Methods** below.

Prior Art

Currently, there is a technology that aims to measure how far the bone has been lengthened throughout the distraction process. The device utilizes two transponders placed within the distractor device that transmit interrogation signals to determine the distance between two bone fragments. The device focuses on intramedullary nails, but can be extended to any device that lengthens bone. It also includes the use of RFID tags within the distractor. However, this technology has not yet been implemented for clinical use in the United States and its patent is still pending[7]. Our project incorporates different elements into the design of our screwdriver, including a gyroscope to output translational displacement from rotation. Rather than the prior art which installs transponders into the distractor device components within the patient, our design introduces a novel screwdriver while keeping the drive rod and activation arm intact.

Materials and Methods

Computer Aided Design (CAD)

Prototypes of our design were drawn first by hand via pencil and paper, then sketched via computer, then developed via computer aided design (CAD). Once a 3-dimensional (3D) digital prototype was created, it was then 3D printed using ABS plastic.

In order to develop a CAD model, multiple CAD software were used. The group initially attempted to use SolidWorks, as it is an industry standard in biomedical engineering. However, given the constraints of the technologic devices the group had access to, not all group members could use SolidWorks due to the operating systems of their computers. Autodesk Fusion 360 was accessible to all group members during the winter break, so the group utilized Autodesk as the primary CAD software used in this project.

The actual process of developing prototypes was heavily dependent on the circuit and its hardware components. The prototype of the screwdriver needed to house both the circuit and all of its components and therefore was volumetrically constrained to the orientation and shape of the circuit. As the circuit was being developed in tandem with the prototype, it was difficult to coordinate the prototype housing to fit the developing progress of the circuitry. Thus, multiple iterations of the prototype were developed at a rapid pace, but few actually ended up being practical to house the circuitry. Therefore, a limited number of prototypes were actually printed.

Due to the COVID-19 pandemic, access to 3D printers was immensely difficult as the typical printers that students would have access to were no longer available. The team reached out to many professors, and Dean Guilford permitted the team to use the Stacey Hall printers for the first prototype. However, the team had limited access to Dean Guilford and Stacey Hall, which prolonged and delayed the printing process, causing delays in new prototype and circuitry development.

Circuitry and Hardware

The internal components of the device consist of the MPU-6050 motion processing unit (MPU) or inertial measurement unit (IMU), an Arduino Nano microcontroller, and a breadboard. An OLED display is external to the device, albeit connected to these internal components. The MPU-6050 gathers motion processing data; it consists of a gyroscope, an accelerometer, and a magnetometer. The MPU/IMU then forwards motion data from its gyroscope to the Arduino Nano, which uses our custom-made program and algorithm to transform this data and ultimately output it to the OLED display in real-time.

All components are connected with the I^{2}C protocol; the Arduino Nano's Serial Data Line (SDA) and Serial Clock Line (SCL) pins host both the MPU and OLED display. The SDA pin, A4, carries the data from component to component. The SCL pin, A5, synchronizes the data transfer between components[8].

These components are hosted on and wired together on the breadboard. The MPU and OLED displays were soldered onto breakaway pins, giving them a solid electrical and physical connection to the pins. The pins were then inserted into the breadboard. In addition to hosting the I^{2}C protocol's SDA and SCL lines, the Arduino Nano provides power to all components on the breadboard via its 5V and GND (Ground) pins. The Arduino Nano itself is powered by an external supply, and accepts power via a mini-USB port. Connections between the Arduino, breadboard, MPU, and OLED display are facilitated with jumper wires (**Figure 2**). With physical connections and power between components in place, code is executed on the Arduino microcontroller to measure, calculate, and output a real-time translational displacement to the OLED display.

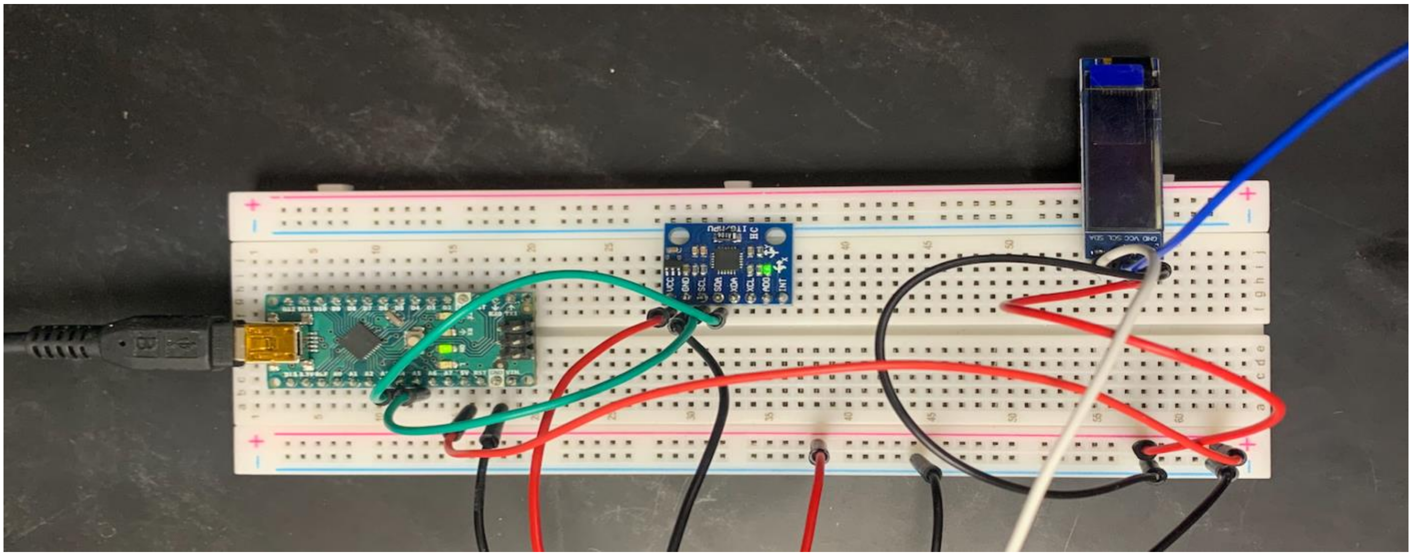
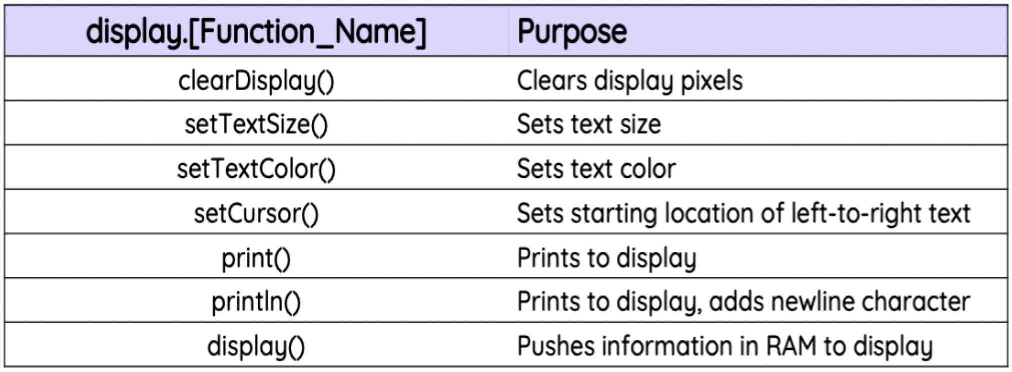


Fig. 2. Partially Soldered Circuit. The green component is an Arduino Nano, the square blue component is an MPU-6050, and the black rectangular device is an OLED display. (Butler, Faruqi, & Schroter, 2021).

Code

The Arduino code consists of four key libraries: the Wire, Adafruit SSD1306, Adafruit GFX, and MPU-6050 libraries. The Wire library is used by the other three libraries to allow I^{2}C communication between devices. Adafruit's SSD1306 and GFX libraries are interdependent and facilitate the transfer of data from the Arduino to the OLED display. These libraries also define a "display" object and class, which hold key functions that execute code to display information on the OLED display. Key functions in the display class and their purpose are summarized in **Table 1**, though this list is not exhaustive.



display.[Function_Name]	Purpose
clearDisplay()	Clears display pixels
setTextSize()	Sets text size
setTextColor()	Sets text color
setCursor()	Sets starting location of left-to-right text
print()	Prints to display
println()	Prints to display, adds newline character
display()	Pushes information in RAM to display

Table 1. Key Functions. A non-exhaustive overview of critical functions in the Adafruit library, used for I^{2}C communication between the Arduino and OLED display.

The MPU-6050 library is a custom-made library, created by github user "jarzebski." This library contains example code and functions for the operation of the MPU and the extraction of motion data from its registers. Key functions include gyroscope calibration, threshold sensitivity (referring to the threshold that determines if the MPU is undergoing movement), and gyroscope data normalization and cleaning. Pitch, the rotational position of the MPU, is calculated by taking the vector norm of the y-axis angular velocity (in degrees/sec) and approximating its integral with respect to time. The timestep used fluctuates — it is dependent on the time it takes for information to transfer between all components and for the code itself to execute. In practice, this is usually 2-3 ms. This variation is accounted for by using the millis() function, which is built into the Arduino programming language. The millis() function returns the number of milliseconds passed since the Arduino began running the program, and is used to calculate the difference in time between each execution of the main code loop. This provides the time between angular velocity readings, which can then be used to approximate an integral by multiplying this value by angular velocity, according to **Equation 1:**

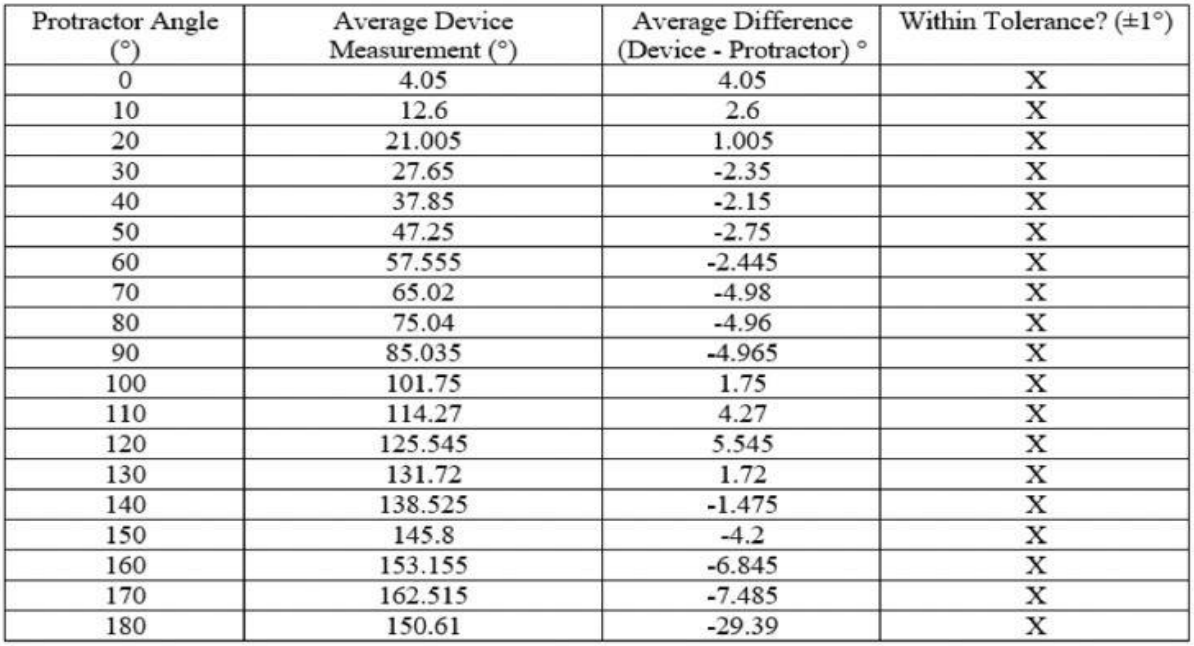
$$\theta = \int \omega \, dt \qquad [1]$$

After approximating this integral, the radius of the pediatric mandibular distractor's activation rod/drive rod, which is 1 mm, was used to create a conversion factor for the calculation of translational displacement. The conversion factor $\frac{2\pi}{360}$ (units: mm/°) is multiplied by the pitch angle to yield the translational displacement.

Angle Tolerance Testing

Once the circuit was properly assembled and the code was created, testing of the device's accuracy in assessing various angles was conducted. The angles output by the device were compared to the angles as measured by a protractor. To do this, we measured angles in 10° increments from 0° to 180° and drew these on a piece of computer paper as a guide for when we rotated the device. The Arduino Nano was reset before beginning at 0° and was rotated following the protractor guidelines created previously. This was repeated two times, yielding two device outputs for each protractor angle (**Table 2**). As discussed in the **Results** section, an unpaired one-sided t-test was performed following data collection.

Table 2. Results of an Angle Tolerance Test. The average output of the device at each protractor angle along with the difference between the two were calculated. The device failed to be within tolerance at each protractor angle.



Protractor Angle (°)	Average Device Measurement (°)	Average Difference (Device - Protractor) °	Within Tolerance? (±1°)
0	4.05	4.05	X
10	12.6	2.6	X
20	21.005	1.005	X
30	27.65	-2.35	X
40	37.85	-2.15	X
50	47.25	-2.75	X
60	57.555	-2.445	X
70	65.02	-4.98	X
80	75.04	-4.96	X
90	85.035	-4.965	X
100	101.75	1.75	X
110	114.27	4.27	X
120	125.545	5.545	X
130	131.72	1.72	X
140	138.525	-1.475	X
150	145.8	-4.2	X
160	153.155	-6.845	X
170	162.515	-7.485	X
180	150.61	-29.39	X

Results

Prototype

Ultimately, a final prototype was developed whose body was large enough to house the final iteration of the breadboard and its wiring. This prototype, as seen in **Figure 3a**, consists of the body and tip. The screwdriver body contains a window on the side of the device so that the OLED display, wired to the circuit board, can come through and be visible on the outside of the screwdriver. This allows for patients, physicians, and caregivers to see the display, which shows the distance the distractor device has been lengthened while rotating the prototype. The end of the prototype body contains a lid, so that the circuit is fully housed within the body. This lid contains a hole so that the power supply can connect to the circuit while keeping the lid on.

The tip of the prototype contains a notch that allows the prototype to connect to the distractor's activation arm in a single orientation, as seen in **Figure 3b**.

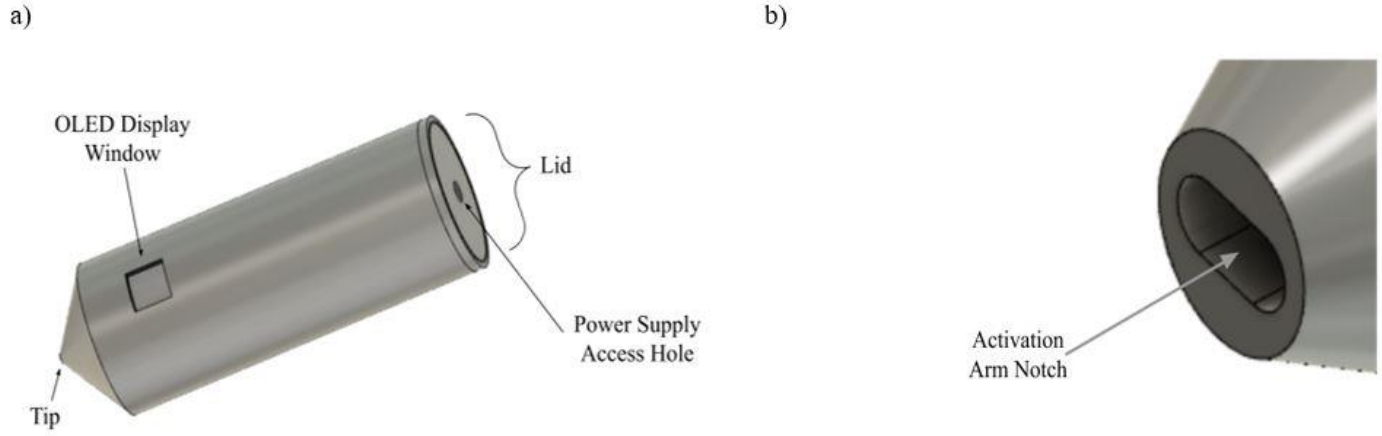


Fig. 3. Final Prototype Iteration and Prototype Tip Notch. a) This final iteration contains a window for the OLED display and an access hole for the power supply cord. b) The tip of the prototype is sized for the distractor’s activation arm.

This allows the prototype to rotate the activation arm while the prototype itself is being rotated by the user.

Statistical Analysis

After acquiring the data as mentioned in **Materials & Methods**, an unpaired one-tailed t-test was performed to determine whether or not the difference in the means between the average of the angles measured by the protractor and by the device were statistically significant (**Figure 4**). In our test, the null hypothesis (H_0) was that the difference between the two means is equal to 1.0° and the alternative hypothesis (H_A) was that this difference is less than 1.0°. After running the test with a significance value of 0.1, the p-value was found to be 0.458. Since the p-value is larger than the significance level, we fail to reject H_0 and therefore we reject H_A. In the context of our project, this means that the angles measured by the device were not within the required tolerance of ±1.0°.

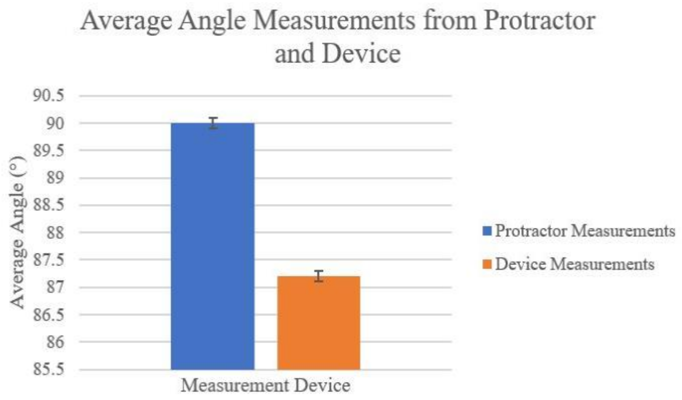


Fig. 4. Average Means of Protractor and Device Angle Measurements. The averages of the angles measured with each device were calculated. The data were analyzed using an unpaired one-sided t-test with a significance value of $p \leq 0.1$ to determine if the differences are less than 1.0 degrees. The findings were not significant with $p \geq 0.1$, and the null hypothesis could not be rejected.

Discussion

The results of the statistical analysis can be attributed to a variety of factors. The sample size was relatively small, with only two trials run from angles from 0° to 180° in 10° increments. Decreasing the sample size in statistical analysis creates a larger margin for error in the collected data. In addition, the position of the device at each angle was determined using the human eye, leading to human error in all of the measurements.

It is worth noting that the device performs better in regards to accuracy at small angles, as seen in **Table 2**. The reason for this is an accumulation of error over time due to the way in which the algorithm calculates angular displacement, which is detailed under the *Code* subsection of **Materials and Methods**. The integration over time is an approximation of the true integral (shown by **Equation 1**), as the timestep variable, which is used as the differential variable for integration, is itself an approximation measured by the Arduino programming language. This leads to an accumulation of error, which becomes more noticeable as the angle reaches greater magnitudes. This is compounded by the fact that the MPU-6050 is prone to suffering from freezing/hanging issues, evidenced by the abundance of forum posts attempting to troubleshoot the issue[9–11]. Anecdotally, Professor Seongkook Heo, who has been instrumental in the development of our device, has informed us that in the past he himself had used the MPU-6050 chipset for projects but found the freezing/hanging issues so cumbersome that he turned to an alternative MPU. Based on our own testing, we suspect the freezing issue largely has to do with power input to the MPU, as we found that powering the device with a larger power supply significantly improved the MPU-6050's performance and stability.

Furthermore, it is worth noting that mid-sized handles with a diameter of 30-40 mm are rated as the most comfortable to use[12]. However, the current prototype diameter is 75 mm wide, thus the current prototype design is sub-optimal for user use and comfort. The prototype's diameter is currently constrained to the size of the breadboard that is placed within the prototype, without taking user comfort into account.

In conclusion, a working prototype was created to quantify distractor elongation, but further refinements are required to reach clinically acceptable efficacy. Recommendations and guidelines to address these limitations are detailed in **Future Works.**

Future Works

The work our team has accomplished this year has paved the way for many improvements and subsequent innovations for others who wish to continue this project. To begin, the size of the screwdriver itself can be improved upon for a multitude of reasons. First, it should be improved to better fit the grip of users of all hand sizes for user comfort and functionality. This would require a smaller breadboard to be used, or for all the circuitry components to be directly soldered together, removing the need for a breadboard. Furthermore, the design of the handle itself should consist of grooves or a rubberized grip to maximize traction and prevent any possible slippage that could damage the device or rotate the distractor device in the wrong direction.

The project could further be expanded to incorporate a mobile power supply. Currently, a port exists on the top of the device to allow for connection to a power supply such as a laptop or wall outlet. A key feature of the device in the future would be to have a battery to power the device. This would make it more user-friendly and more efficient in regards to its transportation and use.

In our Proposal for this device, the team set out to incorporate a mechanosensor or activation button into the tip of the screwdriver that would activate the circuit when proper connection between the screwdriver and activation arm is made. This would close the circuit and allow for the device to be turned "on" and ready to convert from rotational motion to translational displacement. This feature is key in ensuring that the device does not prematurely convert rotational data and therefore can output the most accurate amount of elongation.

With respect to circuitry and hardware, our team recommends using a different MPU/IMU model to carry out measurement of device position due to the MPU-6050's historical freezing/hanging issues, which are detailed in the previous section. Possible alternatives are the SparkFun 9DoF IMU Breakout, the Adafruit 9DoF Absolute Orientation IMU Fusion Breakout, or the 10DoF MPU9255. Additionally, using a stable power supply with high amperage output would help mitigate any freezing issues with any component in the circuitry. As a guideline, 500 mA should suffice, though it would be prudent to test a variety of power supplies in order to find the minimum effective voltage and amperage.

Regarding the algorithm and code, a new MPU/IMU would necessitate a change to the coding libraries used — instead of the MPU-6050 library, a new library would need to be incorporated in order to extract motion data from whatever new MPU/IMU is chosen. Additionally, it is highly recommended to consider alternative methods of calculating the pitch angular position — the current method of integral approximation with an Arduino-measured time differential is prone to error. Instead, we recommend using methods that may incorporate sensor fusion techniques (already done onboard some of the alternative IMU/MPUs listed) and that involve measuring device position with respect to some physical constant (e.g. the Earth's gravitational or magnetic field).

Acknowledgments

Thank you to our advisor, Dr. Jonathan Black, for his guidance through the process of creating the device and for introducing us to the issues with mandibular distraction osteogenesis. Thank you to the UVA Biomedical Engineering Department for their support and advice; especially Professors Shannon Barker, Timothy Allen, and Dean William Guilford. Another thank you to Professor Harry C. Powell Jr. of the Electrical Engineering Department at UVA for his advice with hardware. A special thank you to Professor Seongkook Heo of the UVA Computer Science Department, whose generous guidance in circuitry, hardware, and coding made the creation of this device possible.

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