System Requirements Specification Document

Motorized Fixation to Tubular Retractor

Project for EN.601.456 Computer Integrated Surgery II

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1 Introduction

Purpose

The purpose of this document is to outline the build and design of a motorized fixation to improve the repositioning of tubular retractors in brain surgery. Retraction is a necessary part of many neurosurgical procedures. Access and surgical viewing field are often limited in deep target neurosurgical procedures, causing surgeons to compromise between surgical viewing field and minimizing tissue disruption. This project aims to enhance the precision with which surgeons can view deep target lesions during these procedures while minimizing parenchymal damage.

Intended Audience

The scope of our project is limited to the physical prototyping of an effective retractor movement control system. Our device is not prepared to undergo use as a medical device, and should be treated as an initial design that requires future exploration before application in brain surgery. This document aims to inform project partners of the specifications of our prototype.

Intended Use

Tubular retractors are quickly becoming ubiquitous in deep lesion brain surgery. These retractors resemble long tubes, and are inserted into the cerebrum to provide surgeons a corredor to access lesions beyond the surface of the brain. Most often, the retractor is inserted into the brain tissue, then constrained in place via stabilization apparatuses. This project intends to function as an intermediary between the retractor and the stabilization apparatus, allowing the retractor freedom of motion with respect to the orientation angle of insertion.

References

Agency for Healthcare Research and Quality. Diagnoses–ICD-9-CM Codes (ICD9), Principal Diagnosis: 191.0 Malign Neopl Cerebrum, 191.1 Malig Neo Frontal Lobe, 191.2 Mal Neo Temporal Lobe, 191.3 Mal Neo Parietal Lobe, 191.4 Mal Neo Occipital Lobe, 191.5 Mal Neo Cereb Ventricle. HCUPnet.

Eichberg DG, Buttrick SS, Sharaf JM, et al. Use of tubular retractor for resection of colloid cysts: single surgeon experience and review of the literature. Operative Neurosurgery. 2019;16(5):571-579.

Eichberg, Daniel G., et al. “Use of Tubular Retractor for Resection of Deep-Seated Cerebral Tumors and Colloid Cysts: Single Surgeon Experience and Review of the Literature.” World Neurosurgery, Elsevier, 15 Dec. 2017

“Embracing New Technologies to Save Lives.” Weill Cornell Brain and Spine Center, 22 July 2019, weillcornellbrainandspine.org/embracing-new-technologies-to-save-lives.

Shapiro S., Sabacinski K., Mansour S., Echeverry N., Shah S., Stein A., Snelling B., Use of Vycor Tubular Retractors in the Management of Deep Brain Lesions: A Review of Current Studies, World Neurosurgery, Volume 133, 2020, Pages 283-290, ISSN 1878-8750, https://doi.org/10.1016/j.wneu.2019.08.217.

2 Overall Description

Product Perspective

Our design will need to encompass the following functionalities.

1. **Accurate Retractor Movement**
   Retractor must be able to change target viewsight safely and effectively.
2. **Surgeon Interfacing**
   Retractor repositioning must be intuitive for surgeons to use without disrupting the surgical workflow.

Product Features

Users of the system should be able to realign a tubular retractor based on the orientation of their surgical forceps (or calibration object) during a deep seated lesion removal procedure. This system will support one type of user privileges: Surgeon. Surgeons should be able to do the following:

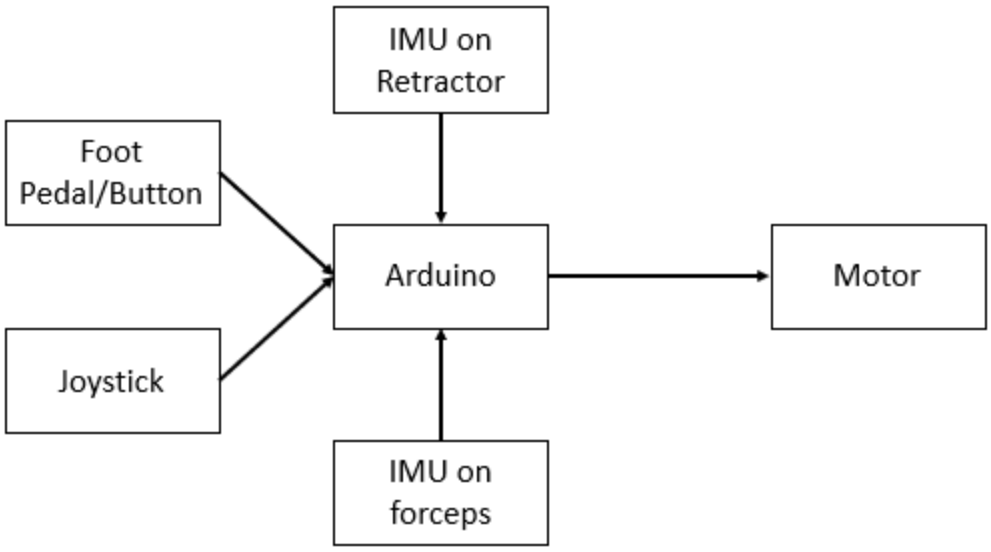
- Realign the tubular retractor
  - Via orientation of surgical forceps
  - Via orientation of calibration object
  - Via control pad or joystick

The realignment will have certain limits in terms of both speed and maximum angle. These limits are so as to prevent injury to a patient.

Operating Environment

The physical attachment contains two separate bipolar step motors, each rotating the retractor about a different axis. These motors are powered using an H-bridge controller connected to an arduino microcontroller.

Inertial Measurement Unit (IMU) sensors on both the retractor and orientation control tool also provide input to the arduino microcontroller. All IMU data is processed using C++ and additional Arduino specific libraries before outputting commands to the motors. A diagram of the electronic setup is illustrated below.



Assumptions and Dependencies

The project assumes that one single retractor remains in place for the majority of the neurosurgical procedure, and that once introduced to the brain tissue, it is rarely advanced further. While it is not necessary that these conditions be met, the physical attachment would make these maneuvers more difficult and tedious. It is also assumed that the retractor be fixed in place using a stabilizing system similar to the Layla surgical arm.

Dependencies to accomplish the project include all electronic components used in the design. This includes IMU sensors, motors, microcontrollers, and basic circuitry components. The design also depends upon access to a 3D printer for prototyping, use of a Layla surgical arm for test simulations, and general access to retractors and testing space.

3 System Features and Requirements

Functional Requirements

1. **Alignment of Retractor**
   At all times the retractor should have an estimate of its current orientation in world coordinates stored in a triplet of Euler angles. The retractor can then be called into a different orientation via a number of different methods of input.
   a. Via joystick or foot pedal control
      This type of input merely directs the retractor into a different angle by indicating a degree of rotation in two different axes. Essentially, either the input can be modeled in a series of 2 variables: movement in the x axis and movement in the z axis. The movement will continue until the user is finished interacting with the input control.
   b. Via orientation object.
      The orientation object is merely a tool a surgeon can angle at the desired orientation, and ask the retractor to mimic. The imu sensors on the orientation object provide feedback on the desired Euler angles, and the motors will move the retractor to achieve said angles.
   c. Via orientation forcep.
      In order to make surgeon interfacing more seamless, and to minimize the time spent switching between tools in order to achieve the desired orientation, the ultimate goal is to retrofit IMU sensors onto surgical forceps. This way, the surgeon can merely use the tool in their own hand to indicate the desired angle for the retractor to mimic. Clearly, feedback and mimicking will not be continuous, but rather input would only be taken from the orientation forcep at specific periods in which the surgeon seeks to reposition.

External Interface Requirements

In using the system, the surgeon should interact with only the orientation method, be that a joystick/pedal or orientation object. As such, there is no functional need for a user interface.

The hardware interface should include the orientation method as well as a button or switch used to indicate when orientation is desired (more specifically in the case of an orientation object, joystick and pedal control can function whenever interacted with). Additionally the physical attachment must be applied between the stabilizing arm and retractor by the surgeon.

Communication between the user and the system can be done through the serial terminal of the arduino, where current Euler angle readings can be displaced and interpreted.

Nonfunctional Requirements

1. Safety Requirements
   It is understood that retraction forces can place large strain on the brain depending on how quickly the retractor moves and how far it moves. Because of this, extensive testing on the exerted forces needs to be done as a part of the investigation into using the system on a human subject. Regardless, limitations should be made on the speed at which the retractor can change angles, and the maximum angle at which the retractor can be positioned.
2. Security Requirements
   It is imperative that the system be secure if it is to expect human use. However, the current model under development is only being designed and developed as a proof of concept. Hence, we are not worried about clinical setting use yet. However, in future iterations of the model, the system should be able to prevent and withstand attempted hacks in accordance with FDA guidelines. The security of this device will be tested with fuzz and penetration testing, along with other tests.
3. Software Quality Requirements
   All software generated for this system should be organized and readable, in accordance with good coding practice. Software should be tested using quality unit tests, and documented in the testing management plan.