Positional Stabilizer for Image Guided Surgery

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Introduction

Spinal Minimally Invasive Surgery

- Uses small incisions for instruments to enter body
- Faster recovery, lower rates of recurrence, smaller scars
- Uses in spinal deformities, trauma, degeneration, and tumors
- Market to reach $3 billion for devices and $1.5 billion for implants by 2019[1]

Medtronic StealthStation S8

- Able to see surgical instruments in patient anatomy
- NavLock Trackers with reflecting spheres attach to instruments
- Camera views trackers on instruments and patient
- Software combines with scans from O-arm

Problem Description

- Frontal face of tracker assembly must face IR camera
- Requires surgeon to hold tracker
- Need to develop a stabilization system to use tracker hands-free

Clinical Need

- In certain types of surgeries, surgeons need to use both of their hands to perform the surgery
- Lab technicians must hold onto the tracker
- Avoidable errors can occur
- 413,000 spinal fusion procedures done each year

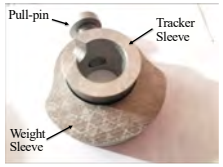
Regulatory

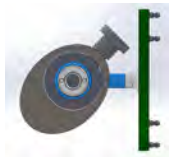
- Patents by Stryker, Neuter, and Johns Hopkins for image guided surgery
- Patent by Intuitive Surgical for tracking instruments relative to the body
- Not compatible with the Medtronic system

Final Design

Design Focuses

- Calculated moment and angle necessary to stabilize tracker
- Pull-pin holds Weight Sleeve (outer) to Tracker Sleeve (inner)
- Tracker Sleeve attaches to existing system
- 4 geometries: ellipse, pear, bell, rounded rectangle
- Geometry designed for ergonomics and aesthetics





Testing Procedure and Results

Functional Testing Focuses

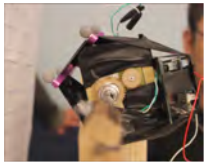
- Instrument (screwdriver) rotating and ratcheting
- Free body and rigid body tests
- Assembly and disassembly steps

Comparing Counterweight Design and Motor/Accelerometer Design

- Undefined behavior when the surgical instrument was vertical
- Motor/accelerometer design weight restricted effectiveness

Final Counterweight Design Functional Testing

- Use video camera to quantify error
- When moved quickly, could not hold certain positions

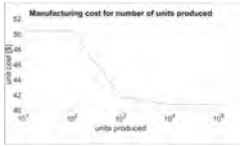


User Feedback for Counterweight Design

- Evaluated on Vertex system
- Evaluated weight, profile, ergonomics, ease of use
- Cervical and T-lift Procedure
- Gain information between the two different prototypes: oval and bell
- Assembly and Disassembly: neutral with assembly and positive with assembly

Manufacturing

- Weight sleeve
  - Steel
  - 3D printed or metal machined
- Tracker sleeve & Pull pin
  - Aluminum
  - 3D printed or metal machined
- Spring
  - Cut from spring stock



Reimbursement

- Buy or rent device with the Medtronic system
- Reimbursement for spinal procedure, not device specific

Future Work for Counterweight Design

Limitations

- Heavy counterweight can increase fatigue for surgeons
- Profile may interfere with field of view

User Testing

- Unstable at 80-90º angles – need method at vertical
- Better way of assembling
- Simpler pin mechanism
- Reduce friction between tracker and instrument

Future Work for Motor Design

- Improve housing to protect assembly
- Using a smaller microcontroller e.g. STM32
- Smaller motor
- Alternative powering
- Different attachment methods for assembly ease and security

Acknowledgments

The authors thank Dr. Jerald Redmond, Matthew Marrapode, and Erika Schwab for their guidance and support; Dr. Zapanta for discussion and critiques on the content of the poster; and Abraham Umo for general support.

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