Flexible and Navigation Enabling Spine Phantom

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**Background**

Medtronic
Restorative Therapies Group
Louisville, CO
Enabling Technologies
Design and produce technologies for brain and spine surgeries

**Problem**

Current spine phantoms
1) Blue Phantom (rigid design)
2) Red Phantom (flexible design)

Either cannot achieve both physiologically realistic motion and repeatable home positioning

**Project Goals and Constraints**

**User Needs**
- Primary Goal: In a single phantom, achieve physiologically realistic and repeatable home positioning capabilities

**Design Constraints**
- Change in angle for home positioning b 3 rotational degrees of freedom
- 1) Repeatability Home Positioning
- 2) 3 translational degrees of freedom
- 3) 3 rotational degrees of freedom
- 4) Compatible with surgical tools & tasks
- 5) Compatible with O-Arm imaging
- 6) Size of Spine: L2-S5 vertebral

**Initial Design**
- First Full Prototype: November 2019

- All components 3D printed
- Home positioning acquired from side alignment pins

**Feedback from Medtronic Engineers**
- Locking pin design shows promise
- Desktop printer accuracy not met
- Pins from side limit accessibility of the spine during use

**Key Features**
- Spine: T12-L5 vertebral
- Connected with flexible spinal cord
- Dual pins from below
- Base
- Gel support
- Sternum pin
- 6-7 Locking Plates
- Locking Plate Holder

**Validation Methods**

- Imaging and Home Positioning
  - Completed using Medtronic’s StealthStation and O-Arm
  - Reference landmarks checked prior to and after use

- Finite Element Analysis (FEA)

  **Problem:** L4 Dual Pin experienced a fractured arm during use
  **Action Taken:** Larger fillet applied to stress concentration
  **Validation:** Using FEA, max stress was reduced by 56.4%

**Results**

- Home Positioning and O-Arm Imaging
  - Navigation remained accurate after manipulating and re-locking phantom
  - O-Arm Imaging:
    - Clear contrast between vertebral and intervertebral discs

- Drilling
  - O 25° dia. x 2.25° depth
  - Drilling was successful
  - No damage around drill site

**Risk Analysis**

- Risk tracked for each component using 1 to 5 scale
- Risk consisted of:
  - Technological: Manufacturability, Imaging, Durability, Spine Mobility, Repeatability
  - Usability: Ease of use (Imaging, Locking, Drilling, etc.)

**Conclusions**

- T12-L5 can achieve six degrees of freedom
- Pin design enables repeatable home positioning
- Clear O-Arm imaging
- Spine is compatible with drilling procedures
- Obtained satisfactory risk levels on the monthly risk assessment
- Created a modular spine phantom to enable further improvements

**Future Work**

- Complete quantitative testing of home positioning accuracy
- Further testing of common surgical procedures (drills, screws, etc.)
- Development of disease states such as Spondylolysis

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