# 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)

Key advantage:
- Repeatable positioning

Key disadvantage:
- Not flexible (realistic)

2) Red Phantom (Flexible design)

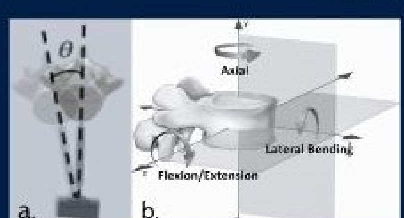
Key advantage:
- Physiologically realistic

Key disadvantage:
- Must constantly be re-calibrated (no home position)

Neither can 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.




a. Change in angle for home positioning
b. 3 rotational degrees of freedom

**Design Constraints**

1) Repeatable 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 vertebrae

## Initial Design

**First Full Prototype: November 2019**

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

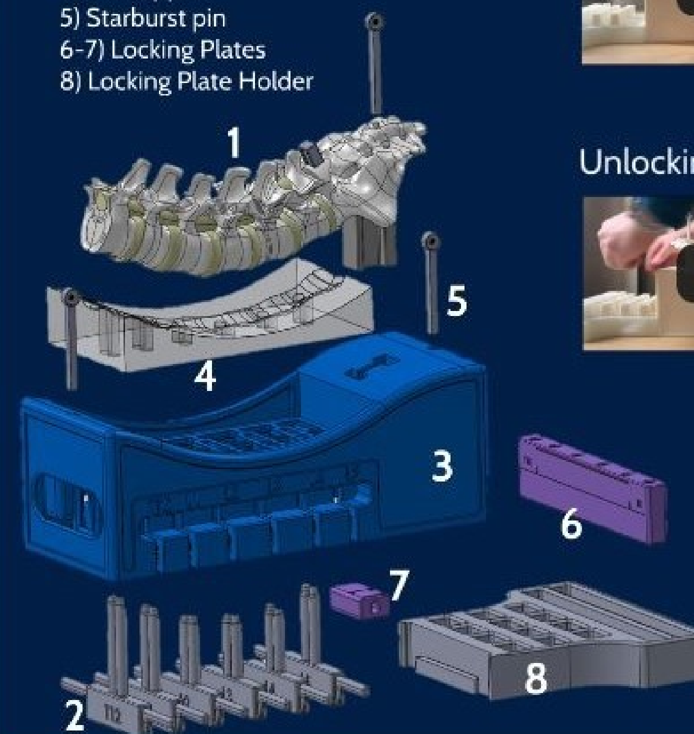
**Feedback from Medtronic Engineers**

- Locking pin design shows promise
- Desktop printer accuracy not great
- Pins from the side limit accessibility of the spine during use


## Final Design - Overview and Capabilities

**Key Features**

1) Spine: T12-S5 vertebrae
   - Connected with flexible spinal cord
2) Dual Pins from below
3) Base
4) Gel support
5) Starburst pin
6-7) Locking Plates
8) Locking Plate Holder




Locking Vertebrae

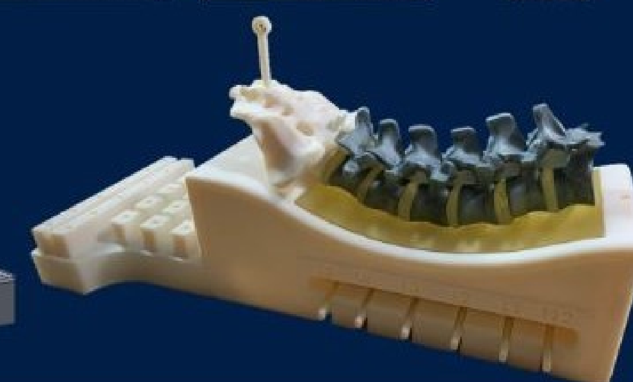
Compression

Lateral Bending

Unlocking Vertebrae

Flexion

Axial Rotation



## Validation Methods

### Imaging and Home Positioning

- Completed using Medtronic's StealthStation and O-Arm
- Reference landmarks checked prior to and after use

### Drilling

- Simulation of pedicle screw placement
- Use of hand drill and 0.25" drill bit

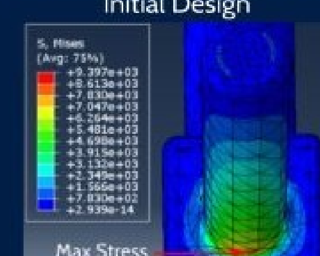
### Finite Element Analysis (FEA)

**Problem:** L4 Dual Pin experienced a fractured arm during use

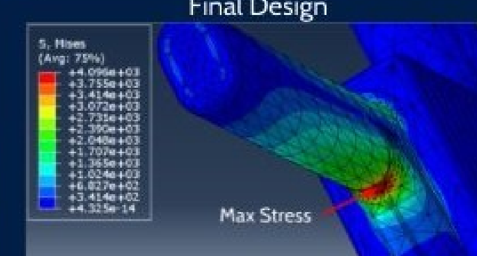
**Action taken:** Larger fillet applied to stress concentration

**Validation:** Using FEA, max stress was reduced by 56.4%

Initial Design




Final Design




## Results

### Home Positioning and O-Arm Imaging

Home positioning:
- Navigation remained accurate after manipulating and re-locking phantom

O-Arm Imaging:
- Clear contrast between vertebrae and Intervertebral Discs

### Drilling

- 0.25" 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.)

| | Initial Design | | | Final Design | | | |
|---|---|---|---|---|---|---|---|
| Month | OCT | NOV | DEC | JAN | FEB | MAR | APR |
| Average Risk Level | 4 | 3 | 3 | 3 | 2.5 | 1.5 | 1.5 |

## 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 (dremels, screws, etc.)
- Development of disease states such as Spondylolisthesis

## Acknowledgements

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