Improved Patient Reference Frame For Image Guided Spinal Surgery

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Background

Current System

- Medtronic's reference frame maps tools in space for image guided spinal surgery
- Current reference frame has 1 degree of freedom

Figure 1. Reference frame with one degree of freedom[2]

Medical Significance

- 266 million individuals worldwide have degenerative disc disease[1]
- Surgery needed for extreme cases of back pain

Problem

- Frame gets in the way of the surgeon
- If moved, reimaging is required
  - Patient exposed to more radiation
- Increases cost of surgery due to 25 minute delay ($62 per minute[3])

Needs Statement

A way to utilize a reference frame during image-guided spinal surgery such that equipment does not **hinder the execution of the procedure**, while offering improvements in **efficiency** for the **benefit of healthcare providers**.

Proposed Solution

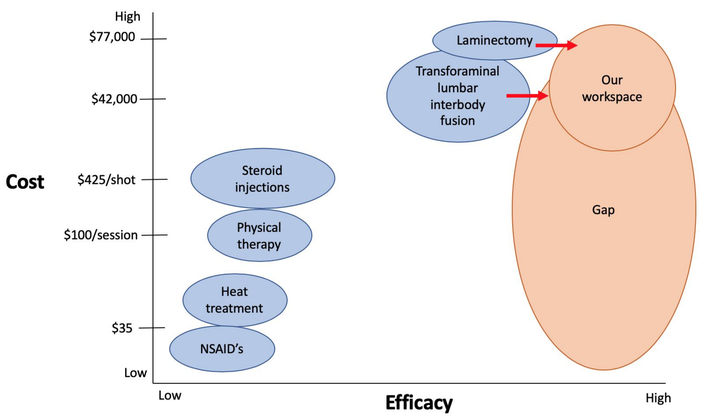

Figure 2. Gap in the current market regarding treatment options for spinal pain or disease

Design Requirements

- Compatible with existing system
- > 1 degree of freedom
- Rigid
- Biocompatible
- Easy to use
- Sterilizable
- Reusable
- Lightweight

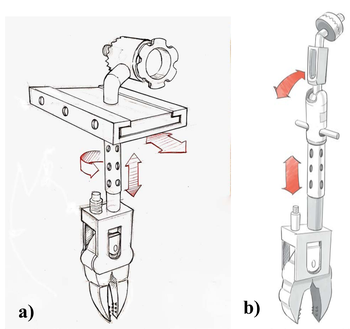

Figure 3. Early on sketches of the a) rail and b) ball and socket designs

Description of Design

Design 1: Rail

- 4 degrees of freedom
- Telescoping joint
  - Vertical translation - 1 inch
  - Rotation about vertical axis - 360°
  - 12 discrete positions possible
  - Held in place with screw
- Sliding rail
  - Transverse translation - 1 inch
  - 3 discrete positions possible
  - Held in place with screw
- Starburst adapter
  - Jagged teeth allow placement within 270 degrees

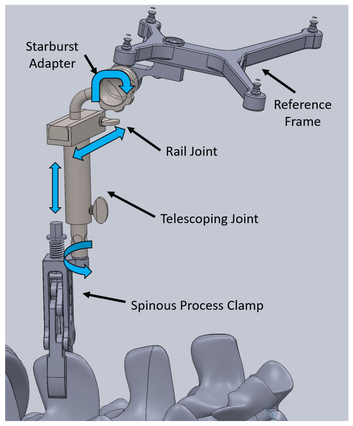

Figure 4. Design 1 with arrows showing 4 degrees of freedom

Design 2: Ball and Socket

- 4 degrees of freedom
- Telescoping joint
  - See above
- Swivel fixture
  - Locking ball and socket joint
  - Cone of angulation covers full hemisphere
- Starburst adapter
  - See above

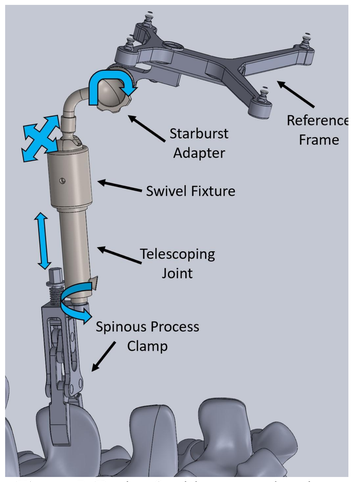

Figure 5. Design 2 with arrows showing 4 degrees of freedom

Functionality Verification / Testing

Mechanical Testing

- Torque Testing
  - Simulate a potential bump
- Cyclic Loading
  - Ensures no fouling between components
  - 120 cycles
- Indicative of the normal product lifespan

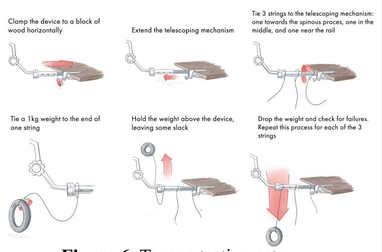

Figure 6. Torque testing setup

FEA Bump Testing

- Simulate 12 N load on reference frames
  - Rail Mechanism
    - Max deflection ~ 0.35 mm
  - Swivel Fixture
    - Max deflection ~ 0.40 mm

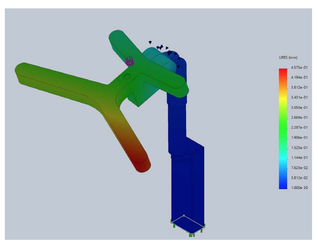

Figure 7. FEA results of 12N force applied to the top of the swivel fixture

FDA Pathway, Legal Information, & Cost

Regulatory Pathway

- Updated reference frame considered a Class II Device
- Requires a 510(k) Pathway for approval
- Must be approved by the Center for Devices and Radiological Health (CDRH)

Patent Information

- Medtronic is submitting a patent for this design
- Medtronic already owns patents surrounding this system

Reimbursement

- Will be covered by Medicare Part A and Medicaid
- Deductibles will vary

Manufacturing Cost

Part (Ti-6Al-4V)	Supplier	Manufacturing Process	Cost Per Component (USD)
Ball and Socket	Protolabs	Machined	$898
Telescope	Protolabs	Machined	$224
Rail Component	Protolabs	Machined	$352
Alligator Clamp	Medtronic	Machined	$230
Air Frame	Medtronic	Machined	$634
Starburst Adapter	Medtronic	Machined	$114

Prices for Protolabs components are for 1 unit, while Medtronic components are bulk

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