Measuring Torque to Guide Physicians during Spinal Fusion Surgery

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Introduction

Motivation: Increased Need for Solutions

- Lumbar spine degeneration can cause debilitating pain and abnormal spinal curvature, leading to imbalance of the spine
  - Prevalence of spinal degeneration is 50% for ages over 65[1]
  - Spinal fusion surgeries correct imbalances by using interbody devices (e.g: expandable cages) in the intervertebral space and fusing two vertebrae together[2]
    - Lack of knowledge on forces applied can lead to subsidence of the cage through the disc or under-expansion[3]
    - No current solutions available to visualize forces

Approach: Generate Guidelines and Gather Clinical Data

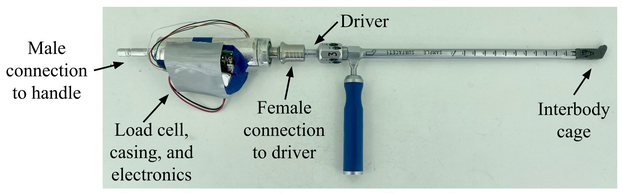
- Integrate with Medtronic's current Catalyft Interbody System
- Characterizing the forces exerted onto the anatomy during cage expansion will inform surgical decisions and establish trends with the expansion angle

Needs Statement:

To improve ease of implantation for the surgeon through designing a smart instrument that can be integrated into an existing interbody system to measure distraction forces

Catalyft PL40

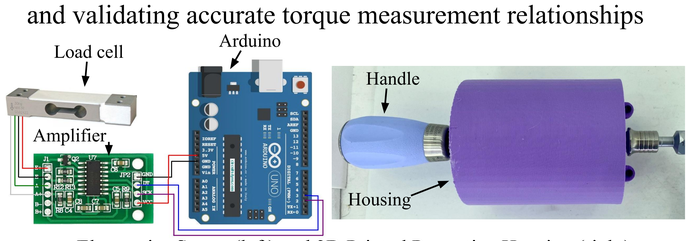
Proposed Solution



Catalyft Interbody System with Torque Sensor Attachment

Final Design

- Removable connector piece integrates seamlessly with current Catalyft system
- Outputs real time torque measurements to output console
- Distraction forces not displayed due to focus on establishing and validating accurate torque measurement relationships



Electronics Set up (left) and 3D Printed Protective Housing (right)

Electronics

- A load cell oriented axially deforms, providing a signal proportional to the torque
- Arduino amplifies signal and sends data to console

Housing and Connector

- Stronger CNC aluminum connector reduces potential damage to the female and male ends compared to 3D prints
- Current 3D printed housing allows the electronics to be held in place and protected from damage

Torque Equation Development Testing

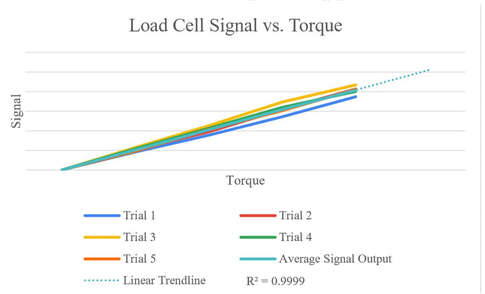
Methods

- Torsional testing
  - Used to observe load cell's signal output and derive the relationship between the force exerted and torque applied due to intended use in tension and compression
  - Shaft with load sensor is clamped on one end, and a universal socket is used from above to apply known torque
  - Tested torques up to 4 N-m to reflect maximum torque applied for cage insertion

Results

- The signal output of the device based on known torque (see below) permitted the derivation of a trendline by which torque is applied and then accurately predicted
- The linear equation derived is transmitted into the code allowing for a measurement to be displayed on a monitor or other device when an unknown torque is applied

Testing Set up From Top View (left) and Side View (right)

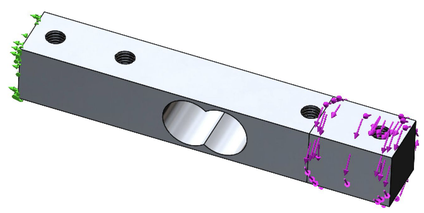


Best Fit of Signal Output vs. Applied Torque

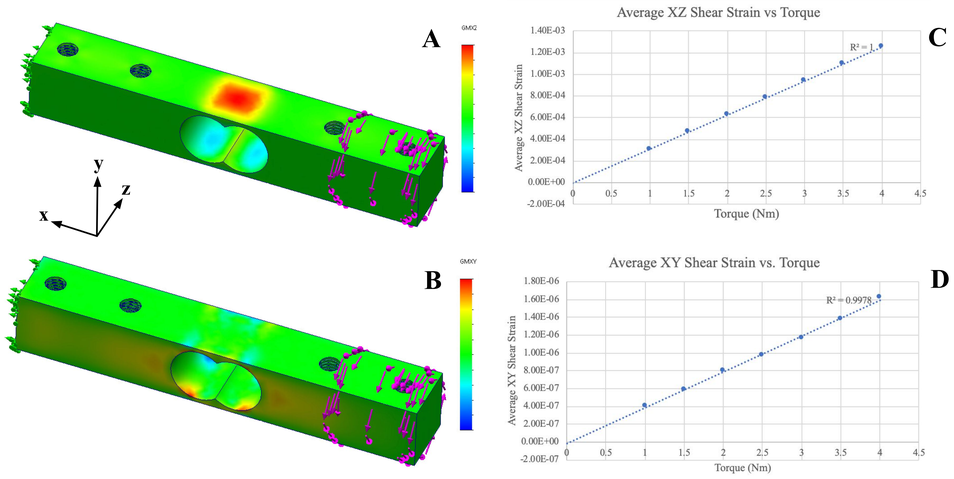
Load Cell Finite Element Analysis Validation Testing

Methods

- FEA explores torque loading conditions from 1 to 4 N-m to verify trends and equations derived from real world testing
- One end is fixed while a torque is applied to the other end
- Relevant strain components are isolated and averaged over the area of the strain gauge



Fixed End (left) and 4 N-m Torque Loading (right)



(A) XZ shear strain FEA; (B) XY shear strain FEA; (C) Best fit of mean XZ strain; (D) Best fit of mean XY strain

Results

- Shear strain has greater contribution than normal strain to the equivalent strain, with XZ shear strain being the largest shear strain component
- Both XZ and XY shear strain result in linear relationships, aligning with the empirically determined torque equation

Manufacturing, Reimbursement, Patents

Manufacturing Costs

Electronics	$46.10
Physical Components and Machining	$1794.99
Per Unit Cost	**$1841.09**
Total Cost for 20 Unit Batch	**$36,821.80**

- 510(k) submission as a Class II device would be the most appropriate regulatory pathway for this device

Reimbursement

- Unlikely to be reimbursed by insurance until clinical data supporting positive outcomes are established
- Medtronic to sell the instrument, use it to increase sales of the implant, or charge a fee per use of the instrument

Patentability

- Novel and non-obvious since no product has been able to measure force and torque during spinal fusion

Conclusions

Clinical Relevance

- Future surgeons will be able to aggregate data using this sensor module to establish trends between cage expansion and torque

Future Work

- Establish the correlation between torque and distraction force on the cage based on implant characteristics
- Reduce the size of the module to be the same profile as the handle of the Catalyft systemc
- Determine the best method of wireless data visualization

Acknowledgments

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