Torque-Measuring Adapter For Spinal Surgical Instruments

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Problem

- ~300,000 spinal fusion surgeries / year in the US[1] for scoliosis and other spinal pathologies
- No quantification of torque applied to screws
  - "Surgeon feel"
  - Inconsistent application of torque may potentially lead to complications after surgery

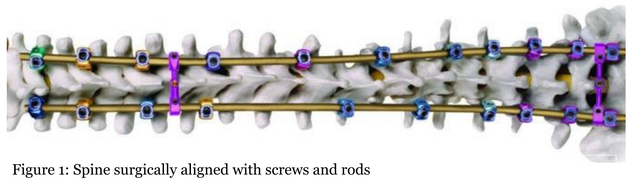


Figure 1: Spine surgically aligned with screws and rods

Proposed Solution

- Device that quantifies torque (up to 12.5 Nm) applied to screws during spinal surgery
- Compatible with Medtronic surgical drivers and handles
- Connected to OR computer monitors via wire

Device Key Features

- Measures, records, and displays torque
- Real time and peak display modes
- Tare option
- Customizable color feedback settings to indicate "safe" torque

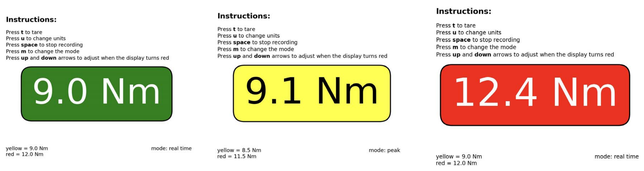
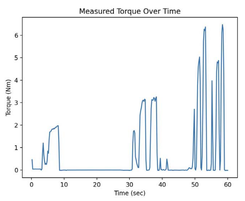


Figure 2: Device computer-user interface showing color feedback



- Data plotted and saved as a .txt file when finished
- Cover for mechanical and electronic components to increase sterility

Figure 3: Torque vs. time data collected by device and displayed on computer-user interface

Complete Device Design

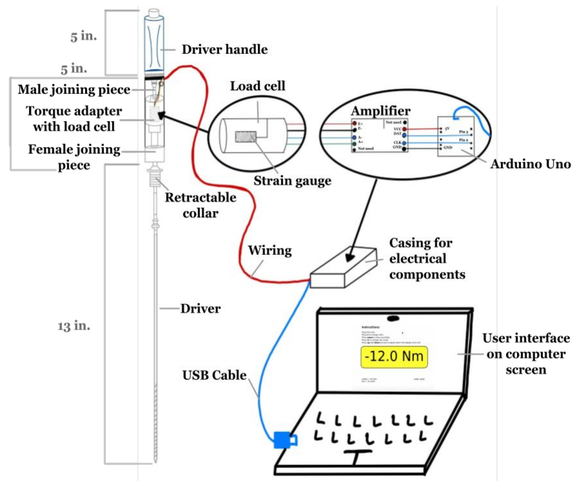


Figure 4. All device components (illustrated schematic, not drawn to scale).

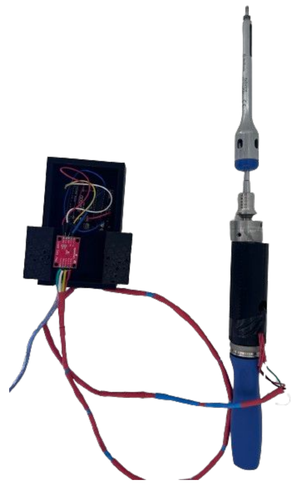


Figure 5. All device components (photographed).

Results

Calibration

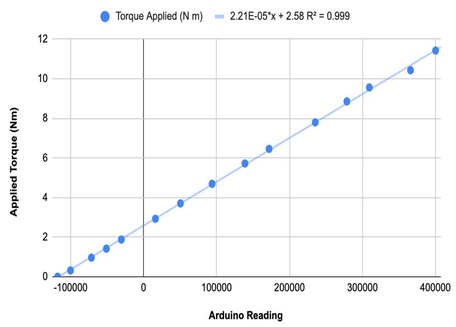


Figure 6: Sample calibration curve for torque meter using an applied torque wrench.

Testing

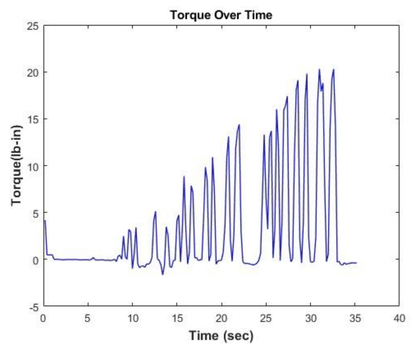


Figure 7: Torque measured by device while screwing pedicle screw into sawbone

- Calibration curve: linear relationship between Arduino output and applied torque
- Torque wrench upper limit = 10 N m, tolerance of .25 Nm
- Per ISO 6789:2017 [2, 3]

Stakeholder Testing

Strengths	Implemented Feedback
• Provides live torque readings • Appropriate for cadaveric setting • Graphical output of torque over time	• Reduced length of adapter • Conversion between metric and US units • Color feedback to indicate "safe" torque

Other Considerations

Medical Reimbursement

- Medicare/Medicaid: billing under spinal fusion procedures (subsets of the M43.2 code)

Intellectual Property

- No existing threat to patentability of device
  - Existing solutions include:
    - Torque wrenches/ gauges (not medical grade)[4, 5, 6]
    - Torque limiting devices (no real-time quantitative torque feedback)[7, 8]
    - Custom spinal screws with torque-reading sensors (still in early stages of development)[9]

Costs

- $100.29/unit (~$250.29 with labor)

Conclusion

- Can measure up to 11 Nm of Torque with a tolerance of .25 Nm
- Compatible with with Medtronic surgical drivers
- Can provide surgeons with quantitative feedback of torque with an easy-to-use computer-user interface

Future Work

- Make device wireless
- Manufacture out of stainless steel
- Develop water-tight seal for electronics
- Calibrate at higher torques
- Test device in cadaveric setting
- Develop computer app for UI

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References

1. GoFortress. (2021, March 12). "4 facts about spinal fusion." MidAmerica Orthopaedics. https://midamericaortho.com/blog/22/4-facts-about-spinal-fusion#:~:text=More%20than%203000%2C000%20lumbar%20spinal,%2C%20scoliosis%2C%20and%20even%20infections
2. International Standards Organization (2017). "ISO-6789-1-2017: Assembly tools for screws and nuts- hand torque tools, Part 1." https://cdn.standards.iteh.ai/samples/62549/da74a7fd1bcf49c5a46f86d1f25ee39f/ISO-6789-1-2017.pdf
3. International Standards Organization (2017). "ISO-6789-1-2017: Assembly tools for screws and nuts- hand torque tools, Part 2." https://cdn.standards.iteh.ai/samples/62550/993acb11d4c134c6e66c366e69b5d65d/ISO-6789-2-2017.pdf
4. Tomoyuki Ozawa, Ashman, R. B., Brantley, A. G. U., Coe, J. D., Esses, S. I., Halvorson, T. L., Hirano, T., & Itami, Y. (2015a, December 28). "Insertional torque of the lumbar Pedicle screw during surgery." Journal of Orthopaedic Science. https://www.sciencedirect.com/science/article/abs/pii/S0949265815327443
5. Oh, B. H., Kim, J. Y., Lee, J. B., Hong, J. T., Song, J. H., Than, K. D., Lee, H. J., & Kim, I. S. (2023, March). "Strategies for globalizing endoscopic spine surgery." Neurospine. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10762421/
6. Sand, B., Olerud, C., Larsson, S., & Robinson, Y. (2010, September 3). "Insertion torque is not a good predictor of pedicle screw loosening after spinal instrumentation: A prospective study in 8 patients - patient safety in surgery." BioMed Central. https://pssjournal.biomedcentral.com/articles/10.1186/1754-9493-4-14
7. Esposito, Marco, et al. "Interventions for Replacing Missing Teeth: Different Times for Loading Dental Implants." Cochrane Database of Systematic Reviews, edited by Cochrane Oral Health Group, vol. 2013, no. 5, Mar. 2013. DOI.org (Crossref), https://doi.org/10.1002/14651858.CD003878.pub5
8. "High-Performance Instruments for Surgical Applications." ARCH Medical Solutions, https://arch-medical.com/products/medtorque/medtorque-overview.html
9. "Spinal and orthopaedic Advanced Surgical Tools and devices." HITEC Sensors. (n.d.). https://hitec.humaneticsgroup.com/perspectives/spinal-and-orthopaedic-advanced-surgical-tools-and-devices#:~:text=Custom%20spinal%20screws%3A%20Custom%20spinal,over%2D%20or%20under%2Dloaded

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