Increasing Modularity in the Medtronic Mazor X Stealth Edition

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Background

Adolescent Idiopathic Scoliosis

- Causes abnormal curvature in the frontal plane
- Appears without definite cause in late childhood or adolescence
- Most common spinal pathology for children[1]
- Affects 3-4 million children in US and 24-36 million children globally[2]
- Severe cases - when curvature > 50° - often require surgical intervention

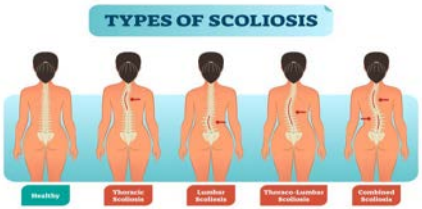

Figure 1: Examples of different presentations of scoliosis pathology[3]

Introduction

Medtronic Mazor X Stealth Edition

- Robotic system specialized to perform spinal fusion surgery
- Surgical tools are mounted to the robotic system via arm guide that matches the size of the tools
- In surgery, entire robotic system excluding arm guide is covered in plastic drape.
- Arm guide is attached by using screw to puncture through the drape and secure it to robot
  - Cannot be removed without compromising sterility of entire system

Figure 2: Surgeons using the Mazor X Stealth Edition. The surgical tools are guided through the arm guide to the patient.[4]

Figure 3: A close up of the arm guide attached to the robotic system with no plastic drape intermediary[5]

Needs

- A way to efficiently exchange arm guides while maintaining the sterile field
  - Allows surgeons to use different sized pedicle screws during spinal fusion surgery, most needed in AIS patients
  - Saves time in operating room

Current Design

Cam-locking mechanism

- Universal adapter plate uses same attachment method of piercing through the drape, but this can remain in place during the entire procedure
- Prevents assembly from being removed mid-procedure
- Exchangeable adapter guide comes in multiple sizes for different surgical instruments
- Guide slotted in via a specially designed slot and tab geometry on two components (Figure 4)
- Male tab on guide and female slot on adapter plate are tapered in order to pull guide into place
- Cam-lever 3D-printed using resin, future iterations will be metal (Figure 5)
- Cam-lock mechanism designed to lock adapter once slotted in
- Mechanism assembled by aligning and press fitting cam lever with adapter plate via pins (Figure 6)
- Cam lever can be turned to lock/unlock guide
- Well-received during user interviews but need to reduce size of cam and improve ease of slotting via a stopping point or slotting direction labels

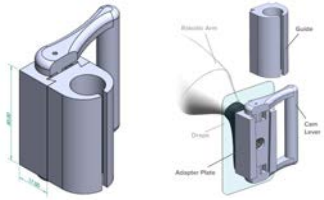

Figure 4: SolidWorks CAD model of assembly (left), attachment to robotic arm (right)

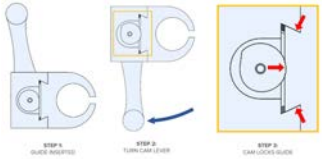

Figure 5: Guide inserted with cam unlocked (left), cam lever turned and locked (middle), and detailed view of locking mechanism (right)

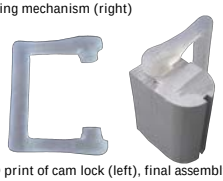

Figure 6: 3D print of cam lock (left), final assembly with cam lock (right).

Testing Procedure

Quantifying Tolerance Stackup

- Increased number of parts and complexity lead to increase in tolerance
- Used Coordinate-Measuring Machine (CMM) to measure central location of hole. Performed 10 tests, locking device each time.
- Compared with specified values from original design and precision requirements of the placement of surgical screws

Testing Results

- Mean positional error from specified center is 0.474±0.063 mm, which is much larger than the specified upper tolerance limit of 0.014 mm
- Translates to unacceptable positional error for surgery when locking mechanism is engaged
- Likely a result of manufacturing methods and deformation of materials: aluminum and resin

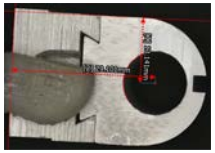

Figure 7: Example of optical view during CMM test

Conclusion

Clinical Relevance

- Easier workflow
  - Faster to place and remove arm guide
  - Exchangeable with alternate sized-guides
- Increased sterility
  - Punctured hole never has to be exposed to environment
- Surgeons utilizing the Mazor X can now implant multiple sizes of pedicle screws during a single procedure, achieving goal of modularity
- Allows for interfacing of to-be-developed tooling from Medtronic on existing Mazor X robots in the field

Future Work

- Improvements to manufacturing method that reduces tolerance issues
- Improving design of cam lever to reduce size
- Update existing attachment site on robotic arm so that it can be used as part of the mechanism
- Inclusion of materials to reduce interference of bodily fluids with mechanism
- Evaluation of different type of draping that could be used in this procedure
- Users interviews with surgeons suggested redesign of actuation may still be necessary

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References

1. Scoliosis Research Society, "Adolescent Idiopathic Scoliosis | Scoliosis Research Society.", www.srs.org/patients-and-families/conditions-and-treatments/parents/scoliosis/adolescent-idiopath ic-scoliosis."Coronary Artery Bypass Grafting." National Heart Lung and Blood Institute, U.S. Department of Health and Human Services, www.nhlbi.nih.gov/health-topics/coronary-artery-bypass-grafting
2. Kamtsiuris P, Atzpodien K, Ellert U, Schlack R, Schlaud M. Prevalence of somatic diseases in German children and adolescents. Results of the German Health Interview and Examination Survey for Children and Adolescents (KiGGS) Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2007;50(5–6):686–700. doi: 10.1007/s00103-007-0230-x.Suri RM, Antiel RM, Burkhart HM, et al. Quality of life after early mitral valve repair using conventional and robotic approaches. Ann Thorac Surg 2012;93:761-9
3. Rodts, Mary. "Types of Scoliosis." Spine Universe, www.spineuniverse.com/conditions/scoliosis/symptoms-scoliosis.
4. Medtronic. "Mazor X: How It Works." Medtronic, www.medtronic.com/mazorxstealthedition, 2020.
5. Medtronic. 2019. Workflow Guide: Mazor X Stealth Edition.