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
- Affects 3-4 million children in US and 24-36 million children globally
- Severe cases - when curvature > 50° - often require surgical intervention

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 tool
- 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

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 2 and 3)
- 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 the arm guide is slotted in
- Mechanism assembled by aligning and pressing fit 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 cam lever through a stopping point or slotting direction labels

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

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 Procedure

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

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

Conclusion

Clinical Relevance
- Easier workflow
- Faster to place and remove arm guide
- Exchangeable with alternate sizes-guides
- Increased sterility
- Punctured hole never has to be exposed to environment


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References


Figure 1: Examples of different presentations of scoliosis pathology.
Figure 2: Surgeons using the Mazor X Stealth Edition. The surgical tools are guided through the arm guide to the patient.
Figure 3: A close up of the arm guide attached to the robotic system with no plastic drape intermediary.
Figure 4: SolidWorks CAD model of assembly (left), attachment to robotic arm (right).
Figure 5: Guide inserted with cam unlocked (left), attachment to robotic arm (right).
Figure 6: 3D print of cam lock (left), final assembly with cam lock (right).
Figure 7: Example of optical view during CMM test.

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