

INTRODUCTION

Background

- 17,700 new spinal cord injuries in the United States each year¹
- A corpectomy (removal of a vertebrae) followed by the insertion of a system to stabilize the spine is often needed to prevent further injury and complications

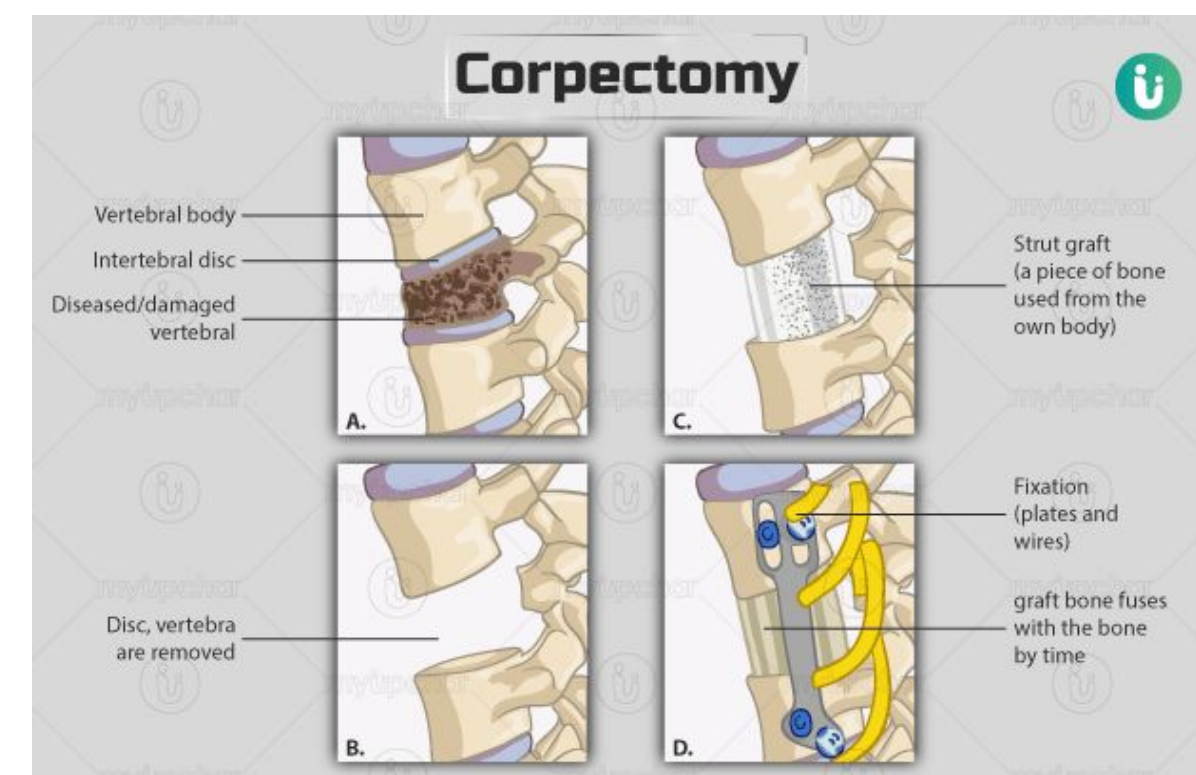


Figure 1: Example corpectomy procedure using a bone graft as replacement material²

Problem

- Training methods for corpectomies are limited, leading to support staff needing excess time and help identifying required tools/components

Needs Statement

- An augmented-reality application to **improve training processes** for, **effectively teach about**, and **assist OR staff** during spinal surgery in proper instrument recognition and use.

PROPOSED SOLUTION

Final Design

- An augmented-reality application built in Unity for the Microsoft HoloLens 2 that helps scrub techs to train and gather information on the tools in the T2 Corpectomy System
- The scrub tech begins the training by staring at a specific physical marker to bring up a holographic menu containing a family of tools
- Tools can be selected to bring up additional information such as their name, description, and a gif of how to use or assemble the tool
- Below is an example scene of the tool menu as scene by the HoloLens
- The scrub tech can move around the tool, rotate it, and alter its size for better viewing



Figure 2: Tool menu scene visible by the HoloLens 2

Tool Menu

- The scrub tech can select specific tools on the menu using a head gaze and pinch command
- The scrub tech's head gaze is shown with a small, opaque circle. To select an object, they place their head gaze on the object and perform a pinch command anywhere in space
- We originally wanted to use a head gaze and dwell command to select tools but could not get this method working

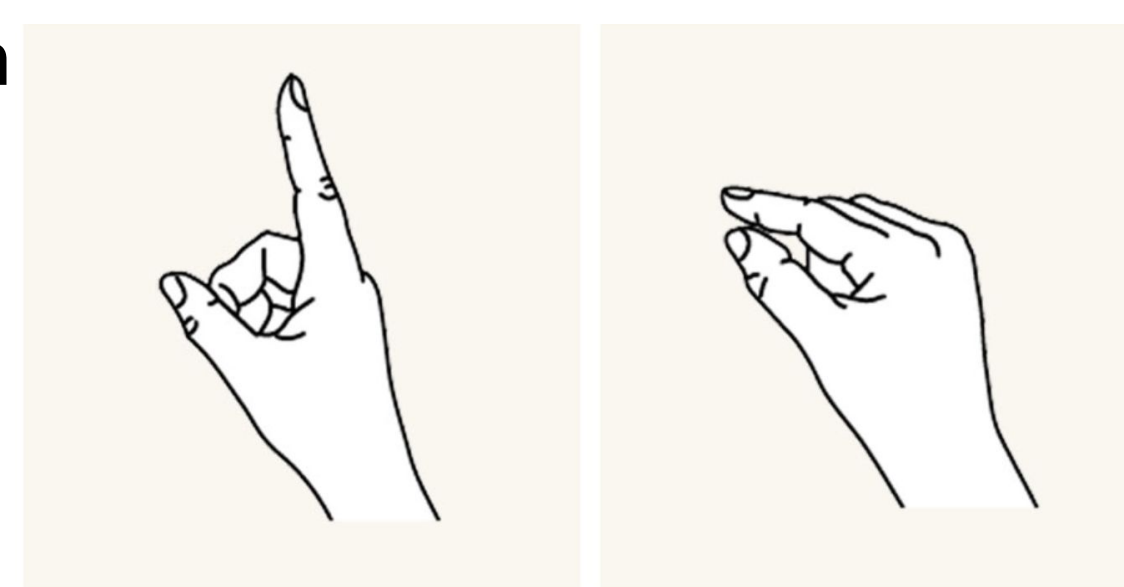


Figure 3: Step-by-step pinch command

Instructional Information

- Figure 4 represents an example of instructional information our application offers to the scrub tech
- There are multiple images in this step-by-step guide on how to attach a centerpiece to the inserter
- The scrub tech can scroll through the images with their hands to gain a better understanding of this process



Figure 4: Step-by-step instructions for attaching centerpiece to inserter which user can scroll through with their hands

IMAGE TARGET RELIABILITY TESTING

Methods

- Tested ability of HoloLens 2 to identify different image targets in varying orientations and at different distances

Results

- HoloLens 2 was able to correctly and reliably identify different image targets in different orientations in the same viewing space
- HoloLens 2 was able to correctly and reliably identify images targets at distances ranging from ~30cm to ~110cm
- Image targets provide a reliable method of user interface with the training system

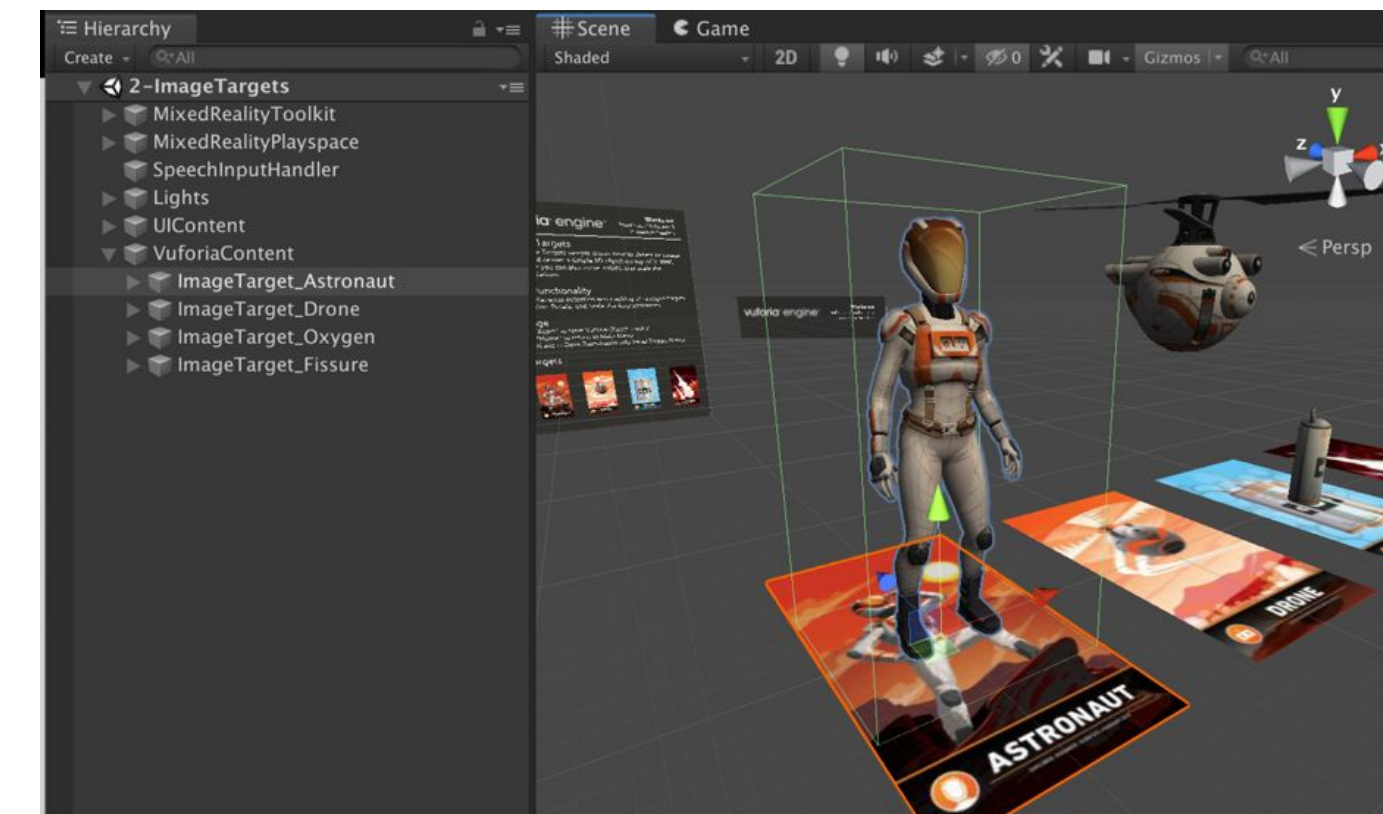


Figure 5: Sample scene in Vuforia showing the image targets and associated holograms

3D TOOL MANIPULATION TESTING

Methods

- Tested HoloLens 2's responsiveness to hand movements and intended tool manipulation

Results

- HoloLens 2 was able to correctly and reliably track the user's hand movements
- Intended tool manipulations were correctly tracked
- Due to current application settings, tools were only manipulable if in the very center of the HoloLens' field of view

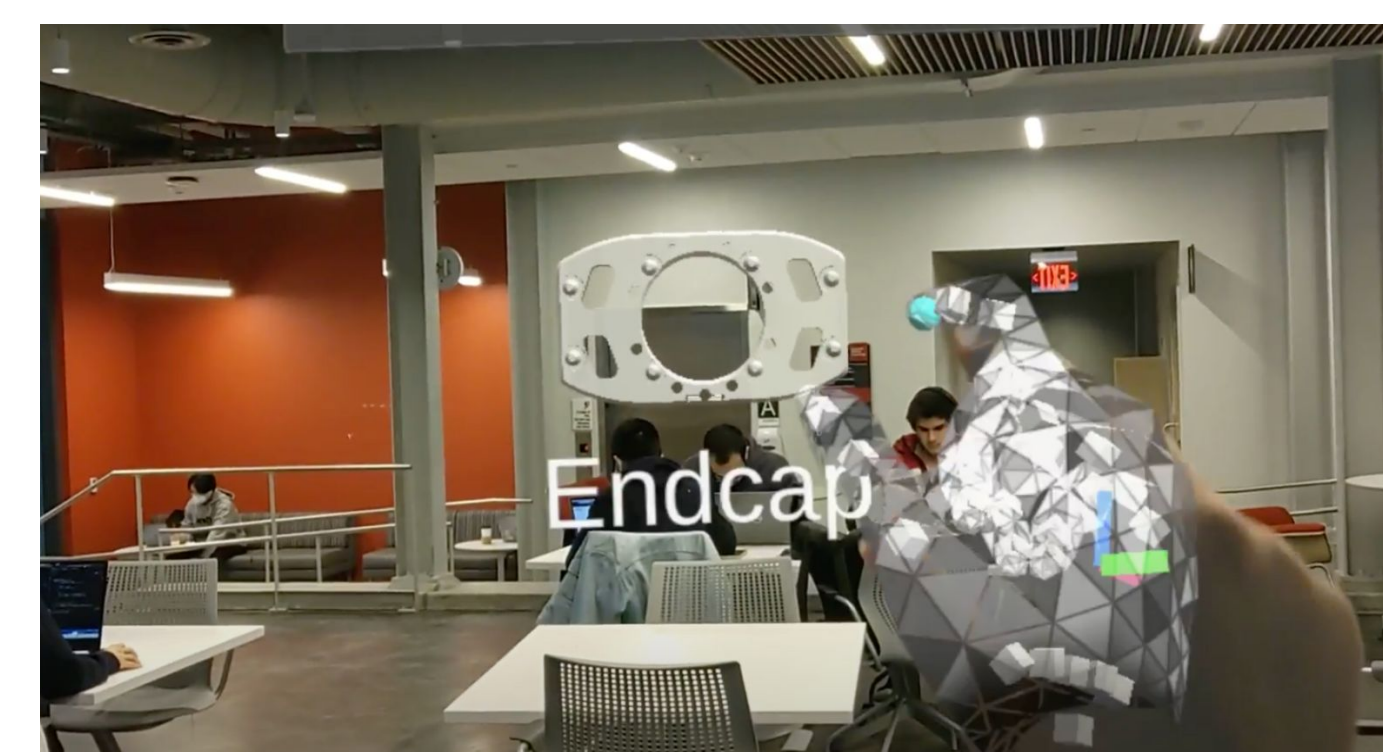


Figure 6: Endcap component opened in the application with hand gesture being recognized by HoloLens 2

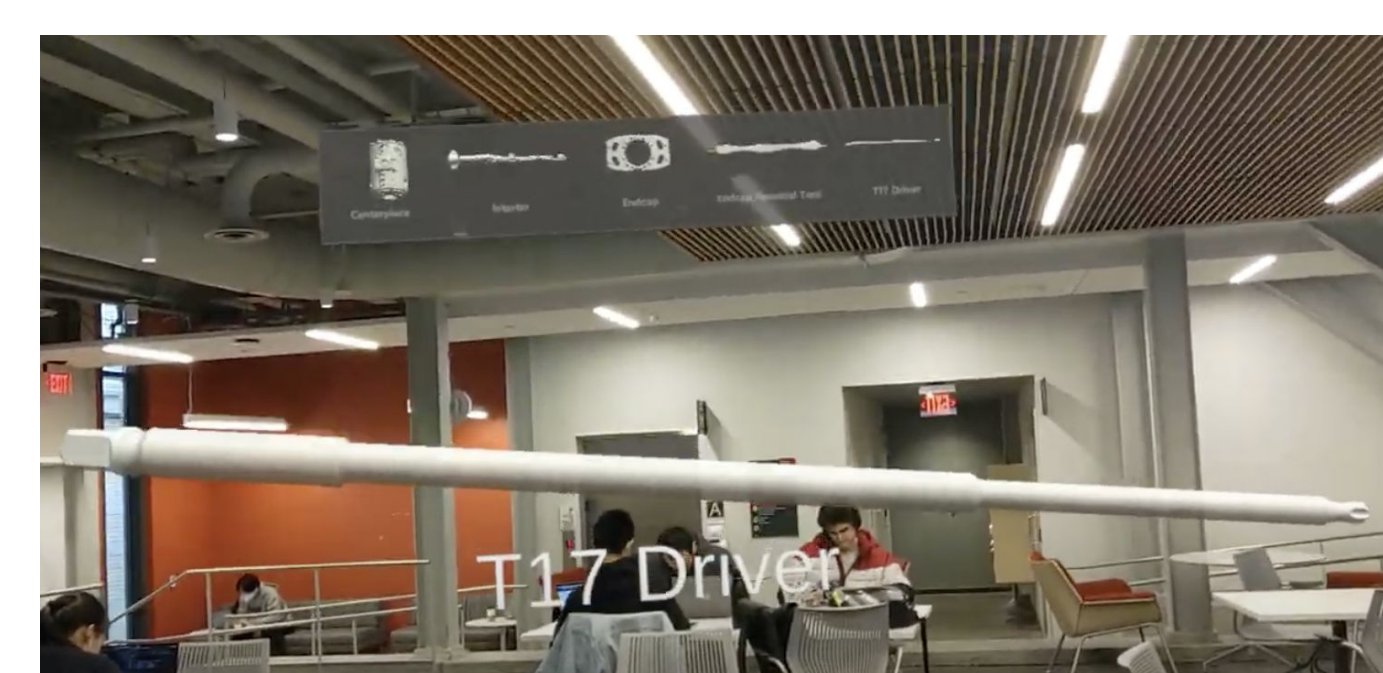


Figure 7: T17 Driver component opened in the application with the tool selection menu visible in the background

CLINICIAN FEEDBACK

Methods

- Provided Medtronic and two surgeons (Dr. Chua & Dr. Rajpal) with a prototype application/presentation to determine optimal uses and additional functionality

Results

- Ultimately determined that our application will likely be used as a training tool outside of the operating room
- Suggested inclusion of images, instructional videos, etc. to provide user with additional information about each tool
- Interactive learning with tools & components has great potential in clinical setting

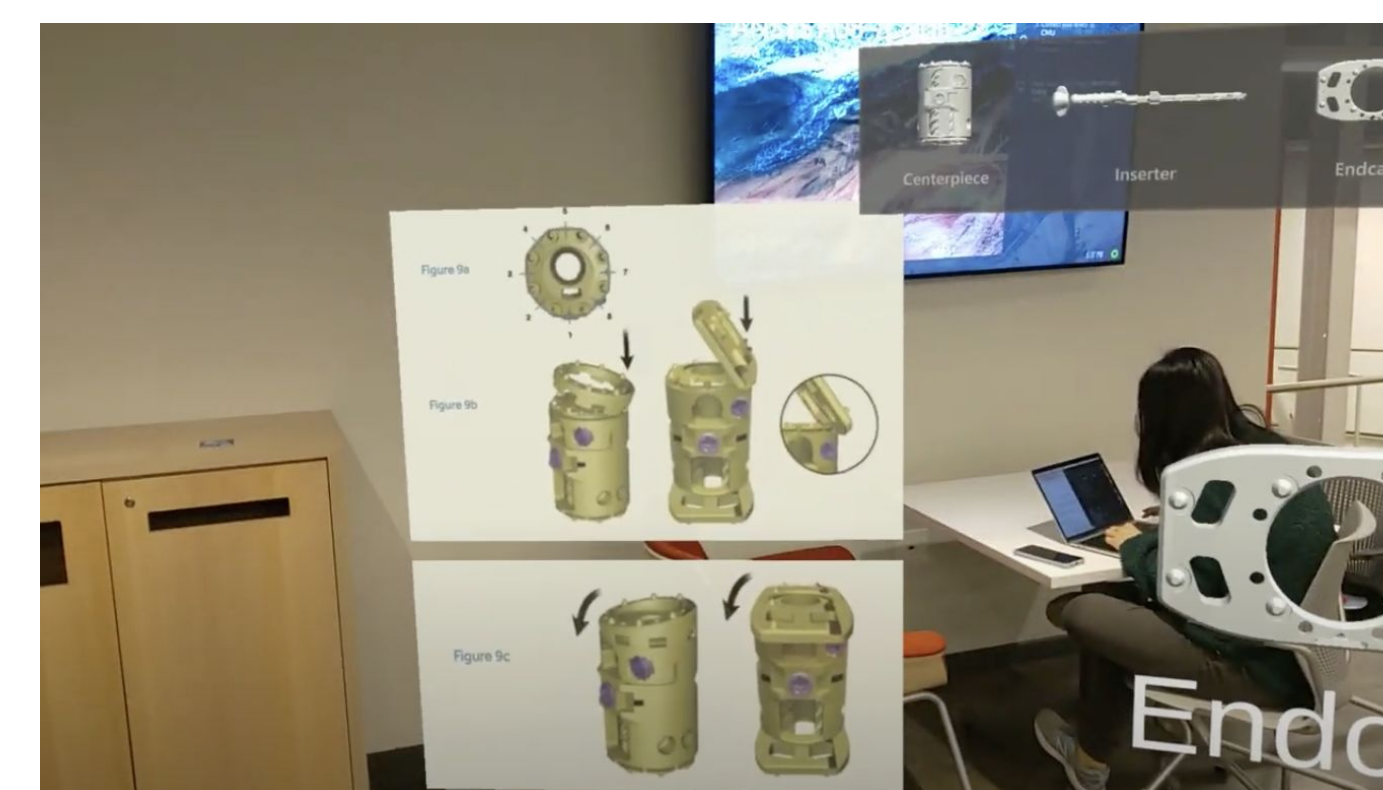


Figure 8: Additional photographs in the application containing instructions on how to use the selected tool



Figure 9: 3D component model in the application being manipulated by hand to show more points of view to better understand the component

MANUFACTURING COST, MARKET ANALYSIS, PATENTING, REIMBURSEMENTS

Manufacturing Costs

- HoloLens 2 is \$3500; outsourced
- No other physical components to manufacture
- Programming costs over the semester estimated ~\$10,000

Market Analysis

- Overall Market: Spinal pain industry costs the US \$88 billion per year
- Target Gap: A high efficacy, low cost system to help lower surgery cost
- Market Size: The 1.62 million spinal surgery patients and their hospital staff can benefit largely from the system
- The main userbase will be the OR staff, making the main customer target being the hospitals purchasing this system for its employees
- System costs will be offset by increased surgery efficacy and efficiency, limiting end effect on costs for the patients

Patentability

- No patent pending for our solution
 - Actual product (software) not patentable because it is a form of text
 - Solution workflow too ideologically simple to patent (it is just another method of training)

Reimbursement

- Our application will be integrated with Medtronic's T2 Corpectomy System, typically used for medically necessary corpectomies that are already covered by Medicare
- Increase in price of the procedure may or may not occur
- If there is an increase in price, the patient may or may not see this increase depending on their insurance
- Applicable codes:
 - 63081, 63082: Vertebral corpectomy

CONCLUSIONS

- Use of complex surgical systems involving unfamiliar tools can be improved with information available using augmented reality before the operation
- Our application uses augmented reality components to display information for scrub techs
- Use of head gaze allows for minimal hand navigation of tool information
- Our application can reduce sanitization costs for tool sets that were used to learn about the system

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