

CONTEXT

VR: Virtual reality; typically includes a headset and hand controllers to allow users to interact within a virtual environment.

Usability Testing: Evaluation done during product development to find and fix issues that the final user may encounter.

Formative studies: Studies done early in the development cycle, helps to shape continued product design. More informal than summative testing.

PROBLEM STATEMENT

Demonstrate Virtual Reality (VR) is a valid method for conducting formative studies and usability testing for the purposes of medical device development. Although VR has existed as a technology for several years already, it is just beginning to be considered as a useful tool in engineering development. Our team has been asked by Kaleidoscope to show that VR is a valid method for conducting formative studies and usability testing for the purposes of medical device development.

TECHNICAL APPROACH

Objectives:

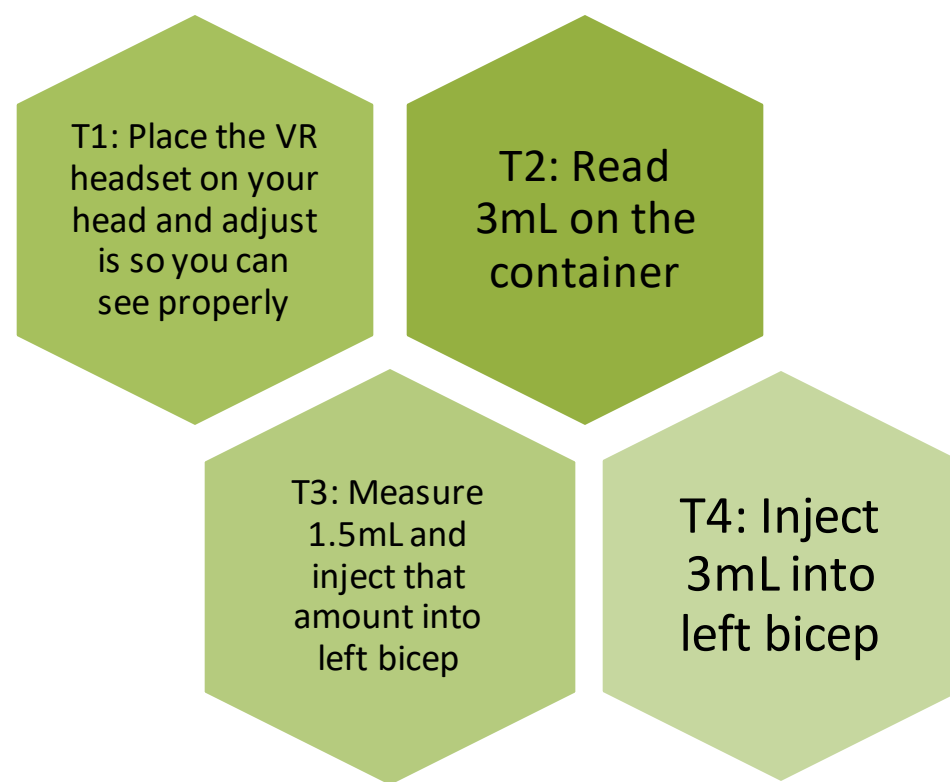
Demonstrate that VR can be used safely and effectively to conduct FDA approved formative studies.

Conduct a simulated formative study on a sample medical device, provided by Kaleidoscope.

Create documentation for the simulated study, including a screener, moderator's guide, and mock protocol.

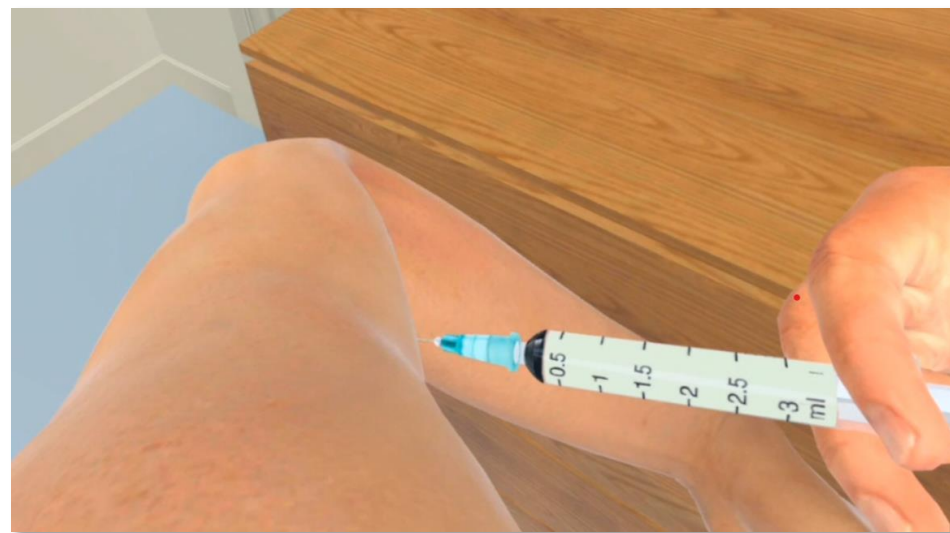


Steps:



Solution:

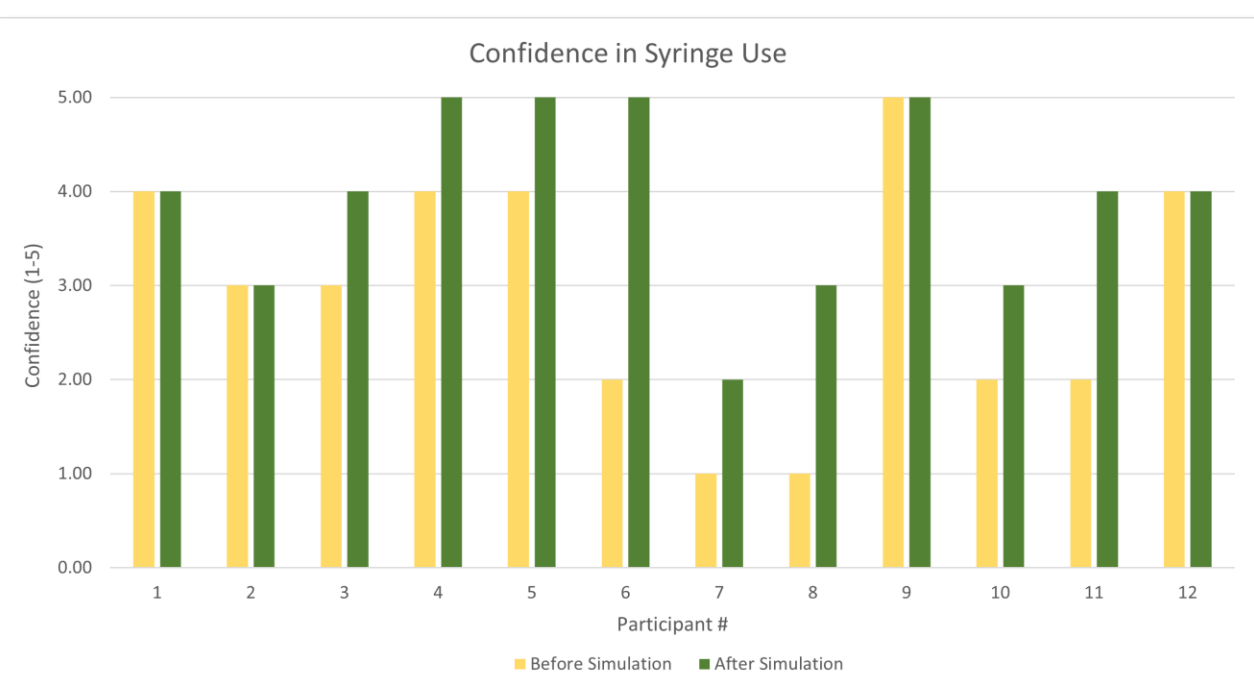
- Conduct a mock usability test using volunteers from Kaleidoscope
- Have participants complete a short series of tasks in the VR environment
- Collect qualitative and quantitative data including participant feedback



Participant view inside the VR headset

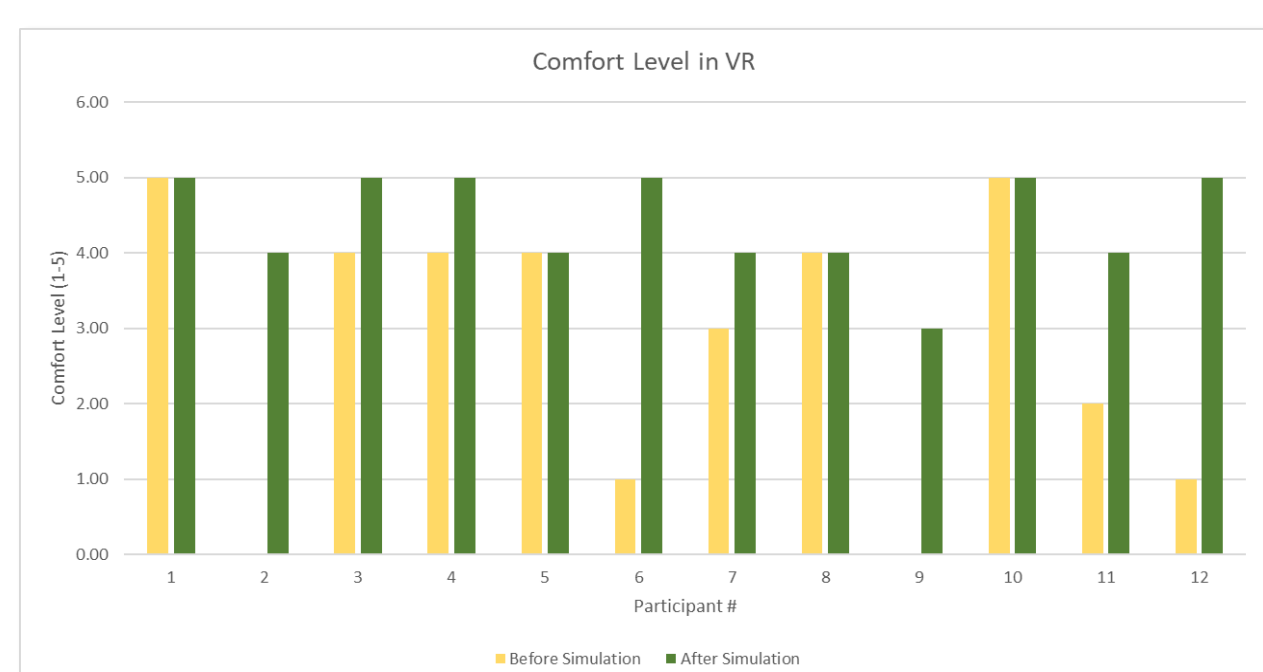
RESULTS

Patient #	User Group Type	T1 Objective Evidence	T2 Objective Evidence	T3 Objective Evidence	T4 Objective Evidence
1	Untrained	Met			Met
2	Untrained	Met	Met		Met
3	Untrained	Met	Not Met	Met	Met
4	Trained	Met	Met	Met	Met
5	Untrained	Met	Met	Met	Met
6	Untrained	Met	Met	Met	Met
7	Untrained	Met	Met	Met	Met
8	Untrained	Met	Met	Met	Met
9	Untrained	Met	Met	Met	Met
10	Untrained	Met	Met	Met	Met
11	Untrained	Met	Met	Met	Met
12	Untrained	Met	Met	Met	Met



Participant confidence in their ability to self-inject medication increased from an average of 2.92 out of 5 to 3.92 out of 5.

Participant comfort levels in VR increased from an average of 3.3 out of 5 to 4.42 out of 5.



DISCUSSION

Data Discussion:

- One of the key conclusions:
 - when analyzing the data was that there was a general improvement in the confidence of a self-administered syringe and the comfort level in the Virtual Reality environment.
- Confidence in syringe use analysis:
 - Every participant maintained or improved their confidence after the simulation.
 - 0% decreased. 66.6% Increased. 33.3% stayed the same.
 - Only one participant maintained below a confidence level of 3 but had only a confidence level of 1 resulting in an increase after simulation.
- Comfort in the virtual reality environment analysis:
 - Every participant maintained or improved their confidence after the simulation.
 - 2 participants did not give a comfort level before the simulation making the participant count 10.
 - 0% decreased. 60% increased. 40% stayed the same.
 - Every participant resulted in over a 3-comfort level after the simulation.
- The results of the tasks were one sided. This could point to the use of virtual reality as a reliable tool in useability testing:
 - 8.3% of participants were untrained on this type of experiment yet the pass rate for each task was positive (T1: 100%, T2: 91%, T3: 100%, T4: 100%).

Feedback:

The sensitivity of the controller:

- Use haptic feedback/touch for the injection
- Use a controller that better represents a syringe injection, even an actual syringe that can be measured.

The environment needed improvement:

- The syringe in environment was hard to read so improving the visuals
- The arm was not moveable so there could be improvements by adding another remote

Adding a help menu in the headset for instructions:

- Assists with those that are not familiar with device

CONCLUSION

- Our group was tasked with developing a plan to create a safe way to run a formative study using VR on a medical device and seeing if it is a viable means to provide results that indicate users developed skills in using that device.
- With eight Kaleidoscope employed volunteer participants in the study and the four project members, the study was run. Kaleidoscope allowed for the study to be run in their wet lab to ensure safety. The VR technology allowed for safe testing of a prefilled syringe since there was not a physical needle but still allowed for testing inserting a syringe needle into the left bicep.
- Data collected suggested that both individuals with or without experience in using syringes described improvement to operate a syringe. All individuals showed improved comfort levels with VR whether they had experience with VR or not in their past as well.
- Being a formative study, deviation could occur in the beginning of the study to ensure enough interaction within the VR environment and the syringe was accomplished to truly gauge the effectiveness of the study.



Kaleidoscope's Wet Lab



Participant Interacting with the VR Study

Future improvement includes creating a target area on the bicep to stick the needle as well as a depth level of how far a needle should be inserted. There was also the discovery of trying to implement an actual dummy syringe into the VR study or implementing a more resistant spring to really depict the resistance of a syringe while injecting fluid through it.

ABOUT PRESENTERS

Matthew O'Neill – Graduating as a Biomedical Engineering with plans to continue with education in medical school.

Bailey Krueger – Graduating as a Biomedical Engineer and working at AES as a Project/Process Engineer.

JaVonn Honaker – Graduating as a Biomedical Engineer with plans to work at CAVU as Quality Engineer.

Matthew Specht – Graduating as an Industrial Engineer with plans to work at Wright-Patt AFB as a project engineer.

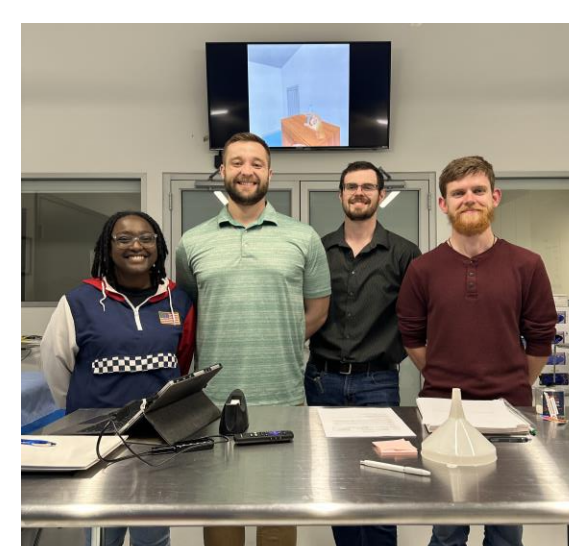


Image of the team.

Image of the team with our client. Depicted left to right: JaVonn Honaker, Bailey Krueger, Matt Specht, Matthew O'Neill and client Matt Suits.



ACKNOWLEDGEMENTS

We would like to thank Dr. Myers and our advisor Dave Kender.

We would also like to thank our client Matt Suits and Kaleidoscope for helping with the facilities and equipment to run our study.

Including a special thank you to the Kaleidoscope employees that volunteered their time to participate in our study.