Enhanced Preoperative Pancreatoduodenectomy Patient Education Using Mixed Reality Technology: A Randomized Controlled Pilot Study

Short title: Mixed Reality Education

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Abstract

Purpose: This study investigates the feasibility, effectiveness, and patient response to using Mixed Reality (MR) technology, specifically the HoloLens, for preoperative education in patients requiring pancreatoduodenectomy. It aims to determine if MR improves patient understanding, comfort, and comprehension during informed consent compared to traditional methods.

Methods: A single center randomized controlled pilot study was conducted with patients recommended for pancreatoduodenectomy due to pancreatic mass between February and May 2023. Exclusion criteria included age under 18, lack of English fluency, or severe visual/hearing

1

24   impairments. Participants completed pre- and post-intervention surveys assessing their

25   understanding of their condition and care. The control group received standard education, while

26   the intervention group used the HoloLens.

27   **Results:** Nineteen patients participated, with eight in the HoloLens group. Both groups showed

28   improved understanding post-intervention, but only the HoloLens group had a statistically

29   significant increase in overall comprehension (Z= -2.524, p= 0.012). The HoloLens group also

30   had a significant improvement in understanding surgical steps and other aspects compared to

31   controls. High comfort levels with the planned surgery were reported by 75% of participants in

32   both groups.

33   **Conclusions:** MR technology, such as the HoloLens, can significantly enhance patient

34   understanding and comfort in preoperative education for complex surgeries. Its integration into

35   clinical practice was feasible and non-disruptive, suggesting broader applicability. The small

36   sample size and single-center design limit generalizability, necessitating larger studies to confirm

37   these findings and assess the full impact of MR on patient surgical education.

38

39   **Keywords:** Mixed Reality, HoloLens, pancreaticoduodenectomy, patient education

40

41   **Introduction**

42   Over 8,000 pancreatoduodenectomies are performed annually in the United States with a

43   morbidity rate >50% [1]. Given the ubiquity and potential severity of complications, it is

44   imperative that patients understand their disease and its management. Unfortunately, verbal

45   descriptions and basic visual illustrations are poorly understood by patients [2].

2

46   Extended reality (XR) (virtual, augmented, mixed) devices have recently achieved a novel role

47   within medical education. HoloAnatomy (Case Western Reserve University, Cleveland, OH),

48   available on the HoloLens 2 (Microsoft Corp., Redmond, WA) platform, allows users to

49   visualize a holographic, 3D human model displaying selected organs of interest and

50   presentations while the user's physical surroundings remain visible. HoloAnatomy's teacher-

51   student function provides an interactive learning session for multiple users simultaneously and

52   has been shown to increase long-term information retention among medical students compared to

53   standard instruction alone [3].

54   Despite the growing role of XR within medical education, there has been an extreme

55   paucity of inquiry into its use in direct patient education. Particularly with respect to informed

56   surgical consent. This study aims to explore the feasibility, effectiveness, and patient response to

57   the use of HoloLens during pancreatoduodenectomy informed consent discussions.

58   **Materials and Methods**

59   This is a single-center, prospective, IRB-approved, randomized pilot study of patients

60   offered a pancreatoduodenectomy secondary to a pancreatic mass between February and May of

61   2023. Patients were excluded if they were <18 years old, lacked English fluency, or had severe

62   visual or hearing impairments.

63   Participants completed a pre-intervention survey assessing their date of tumor diagnosis,

64   age, sex, education level, and number of support members present during the visit. A 5-point

65   Likert scale evaluated the patient's perceived understanding regarding their diagnosis and

66   various aspects of their care. The control group received a standard discussion regarding

67   pancreatoduodenectomy accompanied by physician-drawn diagrams. The intervention group

68   received the same discussion while using the Mixed Reality (MR) device (Figure 1).
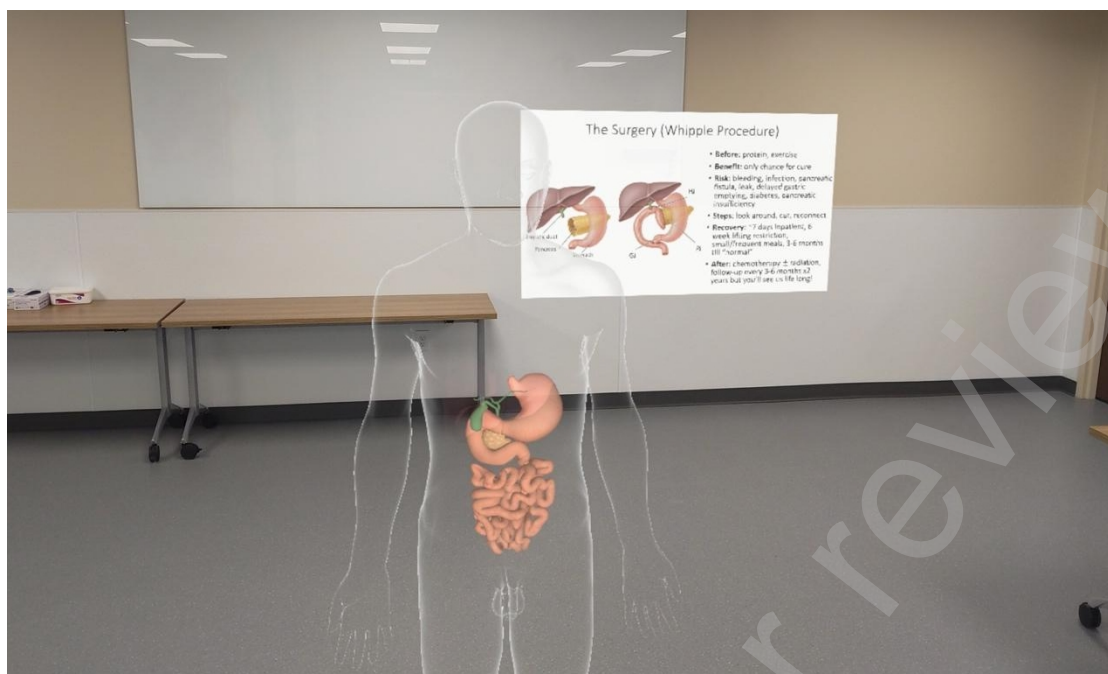
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Figure 1. The patient visual experience while using the HoloLens device. A presentation is

presented in the background while the holographic anatomy allows for an interactive patient

experience.

A post-intervention survey of the same, but re-ordered, 5-point Likert scale questions plus an

additional question about the patient's comfort level with surgery was completed.

Data were non-parametric. Comparisons between groups were performed by Mann-

Whitney U and related-samples Wilcoxon signed rank tests using SPSS for Macintosh, Version

28.0 (IBM Corp., Armonk, NY).

Results

Nineteen patients were included (89.4% participation) with 8 patients assigned to the

HoloLens arm. The median age was 67 (IQR 12) years with controls tending to be younger (64

vs 69 years, p= 0.181). Twenty-four days was the median time between diagnosis and

4

84 randomization. All but 5 patients had a post-high school degree with education levels well

85 distributed between groups (Table 1).

86 **Table 1.** Highest level of education completed by patient

	Counts	
Education level	*Control*	*HoloLens*
High school	3	2
Trade school	1	1
Bachelor's degree	4	4
Master's degree	3	0
Doctorate	0	1

93 Table 2 provides detailed survey results and Figure 2 provides a visual depiction of the pre- and

94 post-intervention survey results. There was no difference between overall pre- or post-

95 intervention survey totals between cohorts. The median pre-intervention score for the controls

96 was 40.0 (mean response 3.3), while the HoloLens median score was 45.5 (mean response 3.6)

97 (U= 49.0, p= 0.678). The post-intervention surveys revealed a median total score of 51.0 (mean

98 response 4.0) and 53.5 (mean response 4.4) for the control and HoloLens cohorts, respectively

99 (U= 59.0, p= 0.213). While the post-intervention survey results were grossly improved for both

100 study arms, specifically HoloLens patients showed improvement in overall pre- and post-

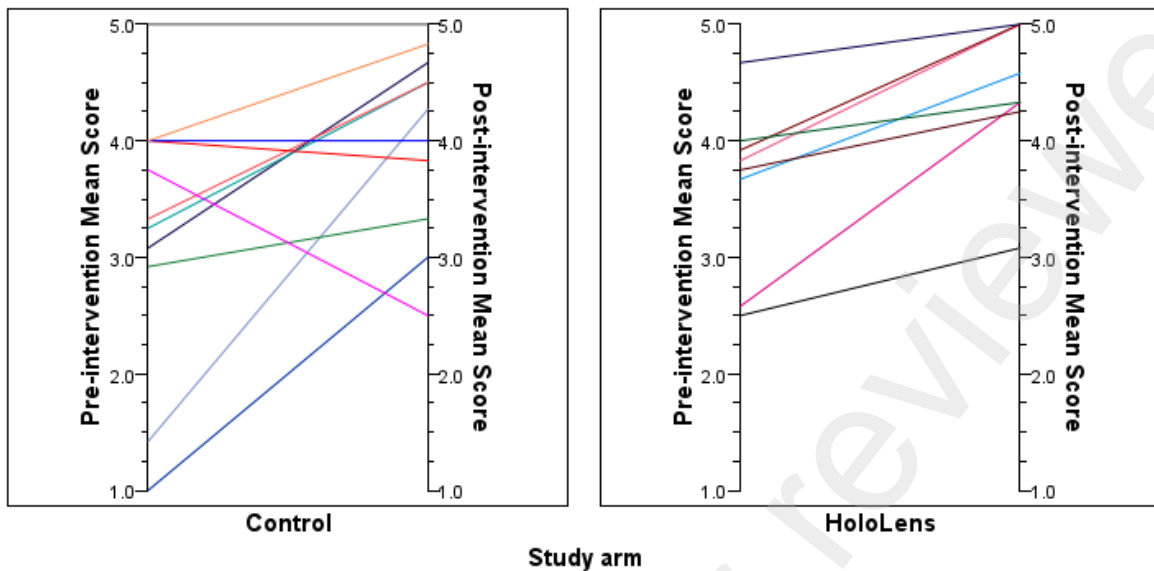101 intervention results (Z= -2.524, p= 0.012).

102

103 **Figure 2.** Comparison of the relationship between mean pre- and post-intervention survey results

104 between control and HoloLens groups. All subjects within the HoloLens arm saw an increase in

105 their average post-intervention survey score.

106

Table 2. 5-Point Likert Scale Survey Results Assessing Patient Perceived Understanding

Survey Component	Control (N=11)	HoloLens (N=8)
Condition/disease		
Pre-intervention, median (range)	3.5 (1-5)	4.0 (3-5)
Post-intervention, median (range)	4.0 (3-5)	5.0 (4-5)
Z-score (p-value)	-1.28 (0.200)	-1.90 (0.058)
Expected surgical benefit		
Pre-intervention, median (range)	3.5 (1-5)	4.0 (4-5)
Post-intervention, median (range)	4.0 (2-5)	5.0 (4-5)
Z-score (p-value)	-1.73 (0.083)	-1.73 (0.083)
Risks/side effects/complications		
Pre-intervention, median (range)	4.0 (1-5)[a]	3.5 (2-4)
Post-intervention, median (range)	4.5 (3-5)	5.0 (4-5)
Z-score (p-value)	-2.04 (0.041)[a]	-2.60 (0.009)
Other available treatment options		
Pre-intervention, median (range)	3.0 (1-5)[a]	4.0 (2-5)
Post-intervention, median (range)	5.0 (3-5)	4.0 (4-5)
Z-score (p-value)	-2.06 (0.040)	-1.63 (0.102)
Disease progression without surgery		
Pre-intervention, median (range)	4.0 (1-5)[a]	4.0 (2-5)
Post-intervention, median (range)	4.0 (3-5)	4.5 (3-5)

6

Z-score (p-value)	-1.13 (0.257)	-0.82 (0.414))
Preoperative sequence of events		
Pre-intervention, median (range)	4.0 (1-5)[a]	4.0 (1-4)
Post-intervention, median (range)	4.0 (3-5)	4.0 (2-5)
Z-score (p-value)	-2.06 (0.039)[a]	-2.06 (0.039)
Operative steps		
Pre-intervention, median (range)	4.0 (1-5)	4.0 (1-5)
Post-intervention, median (range)	4.0 (2-5)	5.0 (4-5)
Z-score (p-value)	-1.20 (0.230)	-2.46 (0.014)
Recovery		
Pre-intervention, median (range)	3.0 (1-5)	3.5 (1-4)
Post-intervention, median (range)	4.0 (2-5)	5.0 (4-5)
Z-score (p-value)	-1.59 (0.112)	-2.59 (0.010)
Operative results		
Pre-intervention, median (range)	3.5 (1-5)[a]	4.0 (2-5)
Post-intervention, median (range)	4.0 (3-5)	5.0 (2-5)
Z-score (p-value)	-2.26 (0.024)[a]	-1.89 (0.059)
Planned follow-up		
Pre-intervention, median (range)	3.5 (1-5)[a]	3.5 (2-5)
Post-intervention, median (range)	4.0 (3-5)	4.5 (4-5)
Z-score (p-value)	-2.05 (0.040)[a]	-2.12 (0.034)
Potential side effect management		
Pre-intervention, median (range)	2.5 (1-5)[a]	3.5 (2-5)
Post-intervention, median (range)	4.0 (3-5)	4.5 (2-5)
Z-score (p-value)	-2.33 (0.020)[a]	-1.89 (0.059)
Informational point of contact		
Pre-intervention, median (range)	3.0 (1-5)[a]	4.0 (2-5)
Post-intervention, median (range)	4.0 (2-5)	4.5 (2-5)
Z-score (p-value)	-2.04 (0.041)[a]	-1.73 (0.083)
Overall comfort level	4.0 (3-4)	4.0 (3-5)

Scale responses are indicated by 1= strongly disagree, 2= disagree, 3= neither agree nor disagree, 4= agree, 5= strongly agree.
[a] n=10; two participants with incomplete data.

When looking at the individual survey components, the HoloLens cohort reported a significantly

improved understanding of the operative steps of the pancreaticoduodenectomy compared to

their control counterparts (Table 2). Both cohorts reported a high degree of comfort with

proceeding with the planned pancreatoduodenectomy with nearly 75% they were either

'comfortable' or 'very comfortable'.

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Discussion

115

116   This study is the first of its kind to explore the use of MR technology, specifically the

117 HoloLens, in enhancing the preoperative education of patients undergoing

118 pancreatoduodenectomy. The results indicate that MR can be a valuable tool in improving

119 patient understanding and comfort with surgical procedures, which are critical aspects of the

120 informed consent process.

121   The use of HoloLens was linked to significant improvements in patient understanding of

122 various aspects of their condition and the surgical procedure. [4] Specifically, HoloLens patients

123 showed a statistically significant increase in their comprehension of the operative steps, potential

124 risks, side effects, and the recovery process. These findings are consistent with previous studies

125 that have demonstrated the efficacy of MR in enhancing learning and retention among medical

126 students. By providing a three-dimensional, interactive visualization of the surgical anatomy and

127 procedure, HoloLens likely aids in bridging the gap between abstract medical information and

128 patient comprehension.

129   High levels of patient comfort and satisfaction were reported with the use of HoloLens.

130 Nearly 75% of participants across both groups reported feeling either 'comfortable' or 'very

131 comfortable' proceeding with the planned pancreatoduodenectomy. However, those in the

132 HoloLens group expressed greater overall satisfaction. This increased comfort can be attributed

133 to the enhanced clarity and interactivity provided by the MR experience, which likely makes

134 complex medical information more accessible and less intimidating for patients.

135

136 Although not objectively quantified, integrating HoloLens into routine clinical practice did not

137 appear to cause significant workflow disruptions in our experience. This suggests that such tools

138 can be adopted in clinical settings without necessitating major adjustments. This ease of

139 implementation is crucial for the broader application of mixed reality in patient education, as it is

140 a key factor in the adoption of new technologies in healthcare.

141

142 **Limitations**

143   While the results are promising, this pilot study has several limitations that must be

144 addressed in future research. The small sample size and single-center design limit the

145 generalizability of the findings. Additionally, the study only included patients who were fluent in

146 English and did not have severe visual or hearing impairments, which may not represent the

147 broader patient population. Future studies should aim to include a more diverse patient cohort to

148 assess the effectiveness of MR across different demographic groups.

149   Moreover, while the HoloLens group showed significant improvements in specific areas,

150 the overall post-intervention scores between the control and intervention groups did not differ

151 significantly. This suggests that while MR enhances understanding in certain areas, traditional

152 methods also have their merits. Combining MR with traditional educational tools might provide

153 a more comprehensive educational experience. Finally, long-term outcomes related to patient

154 satisfaction and surgical outcomes were not assessed in this study. Future research should

155 explore these aspects to better understand the full impact of MR on patient care.

156 **Conclusion**

157   This study demonstrates the potential of MR technology to enhance patient education and

158 the informed consent process for complex surgical procedures. MR can play a crucial role in

159 patient-centered care by improving patient understanding and comfort. The successful

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160 integration of HoloLens into clinical workflows highlights its feasibility and paves the way for

161 larger, more comprehensive studies to further evaluate its benefits.

162

Statements and Declarations

163

164 The authors declare that no funds, grants, or other support were received during the preparation
165 of this manuscript.

166

167 **Competing Interests**

168 While the authors have no relevant conflicts of interest in regards to this work, D. Rohan

169 Jeyarajah is a consultant for Ethicon Inc., a consultant for Angiodynamics, a consultant for

170 SirTex Medical, and is on the Angiodynamics safety monitoring board. The remainder of the

171 authors have no relevant financial interests to disclose.

172

173 **Author Contributions**

174 All authors have made substantial contributions to the study design, acquisition of data,

175 interpretation of data, and drafting of the work. Dr. Heard performed the data analysis. All

176 authors have given their final approval for publication of this work and will remain accountable

177 for all aspects of the work.

178

179 **Ethics Approval**

180 This study was performed in accordance with the principles of the Declaration of Helsinki.

181 Methodist Health System, Protocol No. 001, HPB.2023.R,WCG IRB Protocol #20231226.

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183

184 **Consent to Participate**

This preprint research paper has not been peer reviewed. Electronic copy available at: https://ssrn.com/abstract=5126976

185   Informed consent was obtained from all individual participants included in the study.

186

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203   implantation of DBS or stereo-EEG electrodes. *Epilepsy Res*. 2020;159:106247.

204   doi:10.1016/j.eplepsyres.2019.106247

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Figure Legends

Fig 1 The patient's visual experience while using the HoloLens device. A presentation is

presented in the background while the holographic anatomy allows for an interactive patient

experience

Fig 2 Comparison of the relationship between mean pre- and post-intervention survey results

between control and HoloLens groups. All subjects within the HoloLens arm saw an increase in

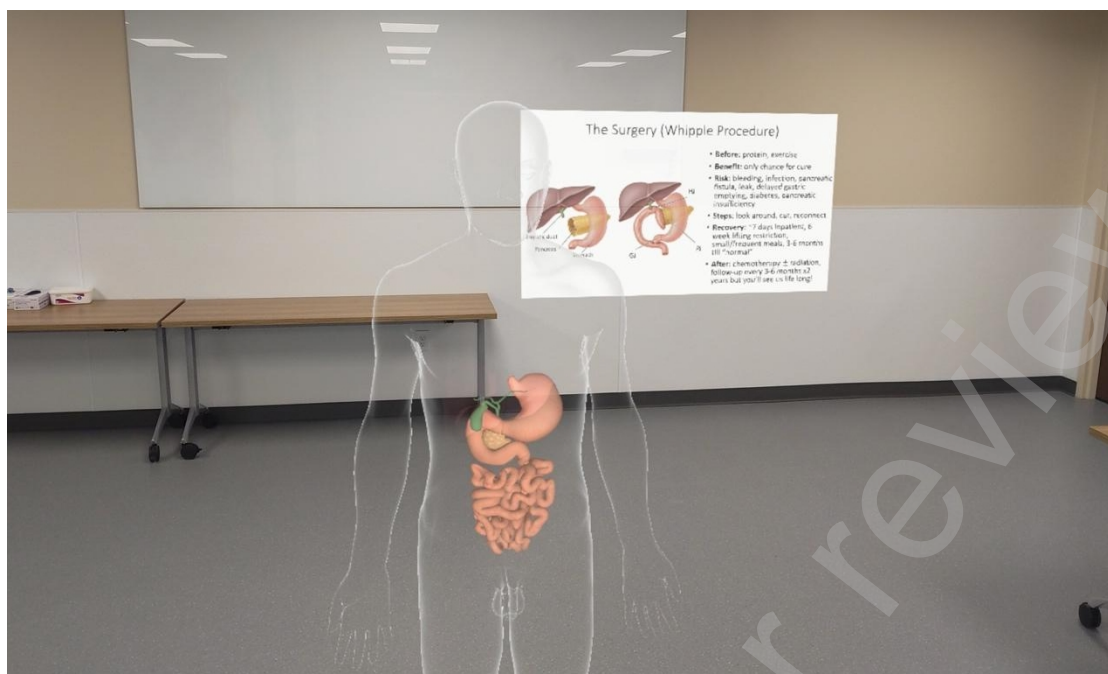their averaged post-intervention survey score

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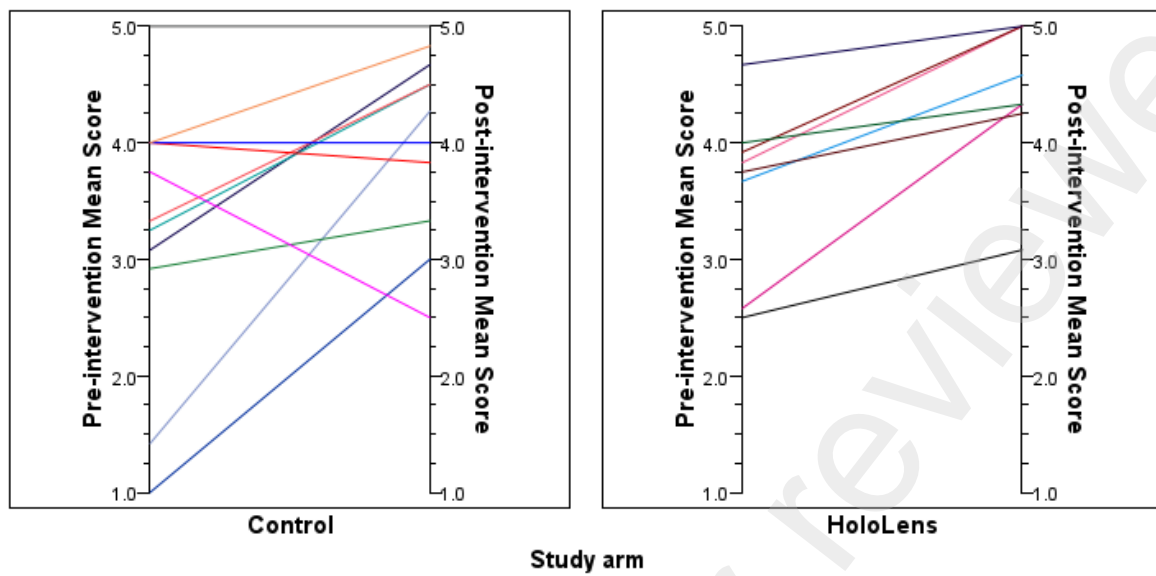
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