Leveraging Mixed Reality in MitraClip Implantation: A Preliminary Case Series

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Introduction

Mixed Reality (MR) technology is revolutionizing the field of interventional cardiology, allowing for enhanced visualization and accuracy in procedures such as MitraClip implantation. The technology utilizes Hololens 2.0, enabling three-dimensional rendering of DICOM data to improve spatial awareness for surgeons, resulting in more efficient and safer procedures. You can see the principle of DICOM data remoting to Hololens 2.0 in Picture 1.

Objectives

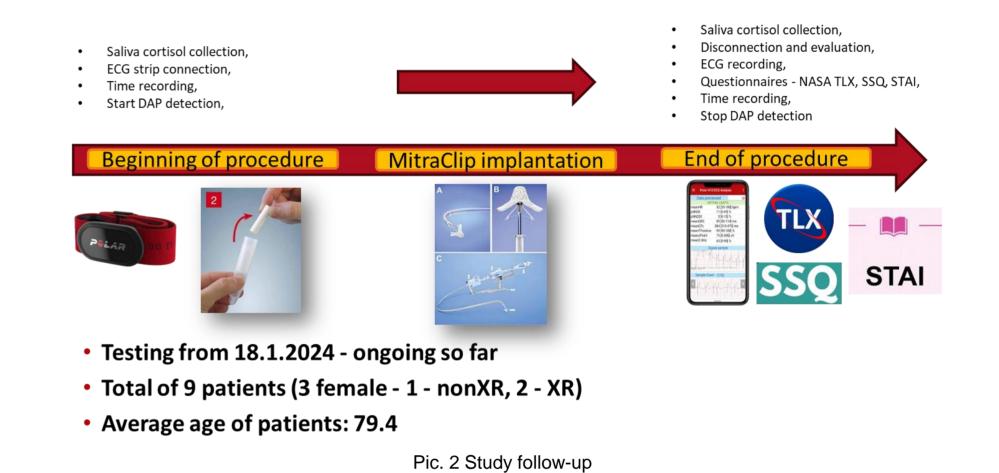
This study evaluates the impact of MR on MitraClip implantation by focusing on:

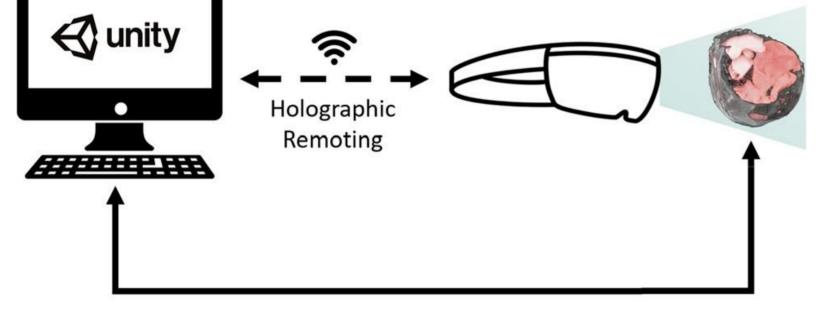
- Procedural efficiency
- Reduction in surgeon stress levels
- Enhanced spatial awareness for more accurate implantation.

The study also prepares for a larger pilot study to further explore these benefits.

Methods

A comparative analysis was conducted on 9 MitraClip implantations, with the procedures divided into two groups based on the use of MR support by the operating surgeon. Both objective (e.g., radiation exposure, cortisol levels, see Picture 2) and subjective (e.g., NASA TLX, SSQ, STAI questionnaires) parameters were evaluated to assess the impact of MR on procedural outcomes and surgeon stress.

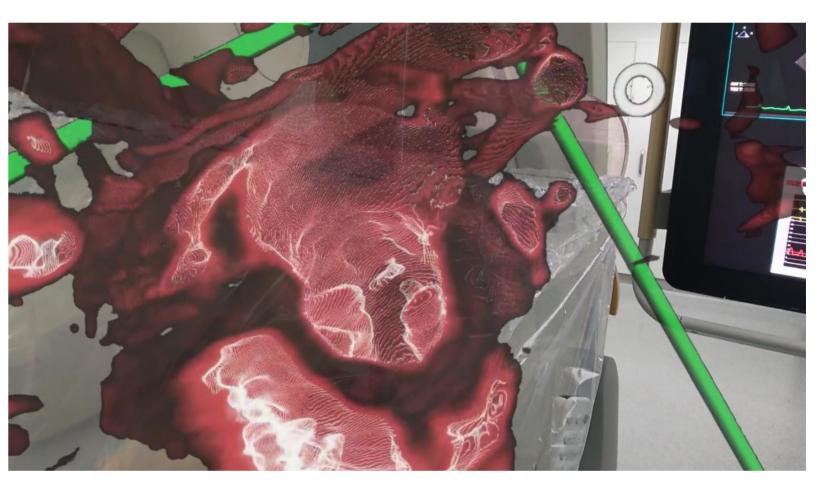






Pic. 1 Remote diagram

Tab. 1 Univariate Analysis of XR Use During MitraClip: Impact on Procedural XR use Stats **Characteristics and Physician Stress P-value Total** No Yes 1 [1;2] 1 [1;1] 2 [1;2] **MiClips_Implanted** 0.556 1:10 [1:05;1:10] 1:10 [1:05;1:45] 1:37 [1:02;2:25] **Procedure_Duration (h:min)** 0.556 19 [16;25] 28 [16;56] 19 [14;20] XRay_Time (min) 0.413 15.3 [13.1;16.9] 29.7 [12.5;72.5] 15.2 [13.1;15.3] XRay_Dose [Gy·cm²] 0.286 63 (11) 67 (11) 72 (9) **TLX_Score** 0.202 50 (3) 48 (3) 51 (2) **STAI_State** 0.056 45 (1) 46 (1) 45 (1) **STAI_Trait** 0.717 10 (6) 15 (4) 7 (5) SSQ_Total_Score 0.031 101 (8) 108 (8) 96 (2) HR_Mean (bpm) 0.01 394 [386;404] 411 [393;514] 386 [386;396] QTc_Mean [ms] 0.190 26 (4) 23 (3) 28 (1) HRV_Mean (ms) 0.007 4.6 (3.7) 3.6 (3.5) 2.3 (3.2) Salivary_Cortisol_Diff 0.345



Pic. 2 Rendered DICOM data navigation during implantation



Values are expressed as mean ± SD for normally distributed parameters and median [Q1; Q3] for nonnormally distributed parameters, as determined by Shapiro-Wilk test. Comparisons between groups were performed using the independent two-sided T-test for normally distributed data and the Mann-Whitney U test for non-normally distributed data. Statistically significant results (p < 0.05) are highlighted in bold.

Results

The results indicated statistically significant improvements in several key areas:

- Heart Rate (HR) Mean: Surgeons using MR had lower heart rates during procedures (p < 0.01).
- Heart Rate Variability (HRV): MR usage showed higher HRV, indicating lower stress (p < 0.007).
- SSQ Total Score: Surgeons reported lower stress and workload with MR (p < 0.031).

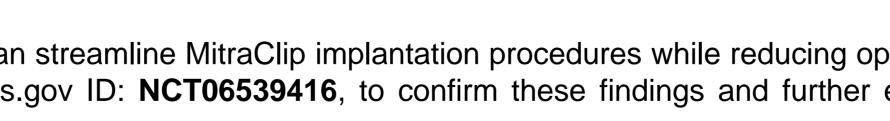
While some metrics like STAI State did not show significant changes, the trends observed suggest that MR can have a positive effect on both procedural efficiency and surgeon well-being.

Conclusion

This preliminary case series shows that Mixed Reality can streamline MitraClip implantation procedures while reducing operator stress. The data supports the need for a larger-scale pilot study, registered under ClinicalTrials.gov ID: NCT06539416, to confirm these findings and further explore the role of MR in enhancing patient outcomes.

Future Directions

The results of this study serve as a foundation for future investigations into the use of MR technology in other areas of interventional cardiology. A larger pilot study is already in development, aiming to refine procedural workflows and optimize patient outcomes.





Pic. 3 Doctor J. Januska using Hololens 2.0 during MitraClip procedures in this study



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