**Development and Optimization of Clinical Workflow for MRI-guided Interventions with Augmented Reality**

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**Purpose.** CT and X-ray imaging for needle guidance exposes patients and interventionalists to ionizing radiation and can increase risk of some forms of cancer. While ultrasound imaging offers a radiation-free alternative for some procedures, use of MRI guidance would eliminate ionizing radiation exposure while also providing better soft tissue contrast and visualization of targets not seen with ultrasound and other imaging modalities. Therefore, especially in young children, MRI guidance for interventional procedures would be preferred. However, the MRI environment poses several challenges that have slowed widespread adoption. First, the closed bore size of MRI scanners places ergonomic restrictions on operators and limits access to some target locations. Second, the currently used "advance-and-check" approach used for CT-guided procedures is too time-consuming for MRI-guided interventions. To address these limitations, we developed an augmented reality guidance system for use in the interventional MR suite and we are evaluating this system through an ongoing clinical trial.

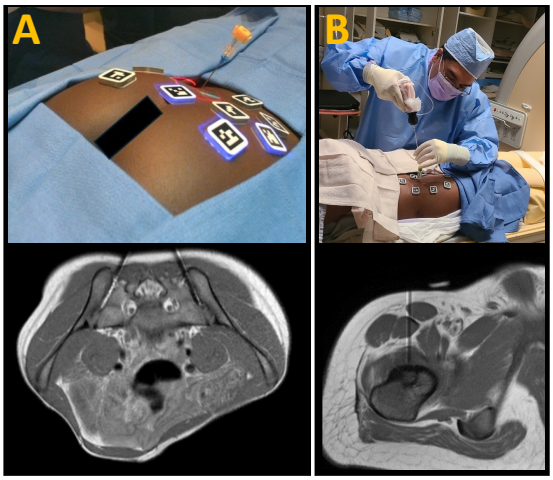


**Figure 1. MRI-guided needle-based procedures with the aid of augmented reality. Procedural images as well as post-insertion confirmatory MRI scans in (A) MR-guided injection of bilateral sacroiliac joints and (B) biopsy of a right femoral neck lesion in pediatric patients.**

**Materials and Methods.** The LUMENA AR system (Clear Guide Medical Inc., Baltimore, MD, USA) is designed to operate inside an interventional MRI suite. The system enables interactive path planning during needle insertion based on a registered high-resolution MRI dataset. The system tracks the needle and skin surface position and orientation using a combination of artificial intelligence-based tracking and optically tracked fiducials. During needle advancement, the system provides guidance to the interventionist by projecting a guidance plan onto the skin around the needle entry point in real time. The in-room planning console allows further optimization of workflow, enabling continuous visualization of progress based on MR images. Phantom and cadaver studies in which interventional radiologists used the system to place needles along planned trajectories to target bone, joint, and soft tissue targets demonstrated adequate needle placement accuracy and an acceptable clinical workflow. Based on these results, we began an early phase first-in-human clinical trial (NCT#06224933) to evaluate feasibility and safety of using this AR system in pediatric patients undergoing MRI-guided interventions.

**Results.** The LUMENA AE system operated as expected in phantoms and cadaver studies and all needles were placed successfully. The MRI-verified overall spatial targeting accuracy was 2.3±1.1 mm and 2.6±0.6 mm for the phantom and cadaver trials, respectively. The system was also subjectively judged as "easy to use" by the operators. We have successfully completed three of twelve clinical cases in the ongoing clinical trial and plan to complete the trial in twelve months. As in earlier studies, clinical cases required only 2 MRI scans: one for planning and one for confirmation of needle position (Figure 1), without intermediate scanning steps that characterize the time-consuming "advance-and-check" approach used in MRI-guided interventions.

**Conclusion.** Our studies demonstrate feasibility of using the LUMENA AR system to accurately place injection and biopsy needles under MRI guidance. The results of phantom and cadaver studies showed acceptable accuracy and allowed us to develop and optimize a clinical workflow that is currently being evaluated in a clinical trial. The system's features enable improvement of current clinical workflow for needle-based MRI-guided interventions, potentially shortening such procedures.

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