Clinical evaluation of a transperineal access tool for MRI guided procedures

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PURPOSE: To present the preliminary results of a 30-patient clinical study evaluating a transperineal guidance system (Clear Guide SCENERGY TP) for MRI-guided procedures.

MATERIALS AND METHODS: We utilized the SCENERGY TP guidance system (www.scenergytp.com) to guide 14G needles towards selected targets through patients' perineum. Prior to imaging, the clinical staff mounted a grid template with embedded markers visible in the MRI next to the perineum. Once the initial MRI volume was acquired, we sent it to the SCENERGY TP for automatic registration (Fig. 1). Given the registration, the system projected the grid holes onto each slice of the volume as shown in Fig. 2. The physician then selected a target by browsing through the MRI scan and tapping on the screen. The system highlighted the target along with the alphanumerical identifier of the closest hole and the depth of insertion. The physician was able turn the grid projection off allowing them to track the planned trajectory of the needle path through the slices prior to insertion. An augmented reality (AR) view was also available for some cases which showed the planned grid hole and the depth of insertion (Fig. 3). The clinical trial recruited 30 patients undergoing MRI-guided transperineal procedures following the IRB protocol. The device has obtained FDA clearance following the successful completion of this trial. The procedures included 20 prostate cryoablations, 5 prostate biopsies, 3 seminal vesicle cryoablation, 1 pelvic lymph node cryoablation, and 1 combination of prostate biopsy and cryoablation in one session.

RESULTS: All the procedures were completed safely and successfully. The system worked as expected with needle placement verified by post-MRI scans. Needle accuracy was evaluated by manually segmenting the needle shaft at an average depth of 67mm (min:32.8mm, max: 127.4mm) and comparing it with the expected location based on the plan. The average error was 1.46±0.78mm.

CONCLUSIONS: Compared to the current alternatives, the device offers a superior workflow which is easy to follow. This workflow eliminates the need for manual segmentation of grid fiducials in MRI volumes since the markers are automatically detected. Accurate and fast placement of needle in the MRI suite is key for wide adoption of interventional MRI procedures. Combination of biopsy followed by cryoablation in one session can increase overall efficiency and potentially reduce patient anxiety.

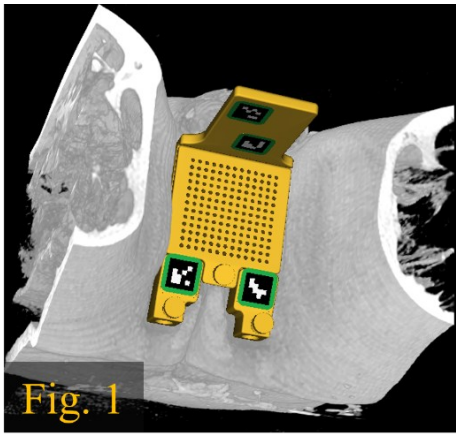
Fig. 1

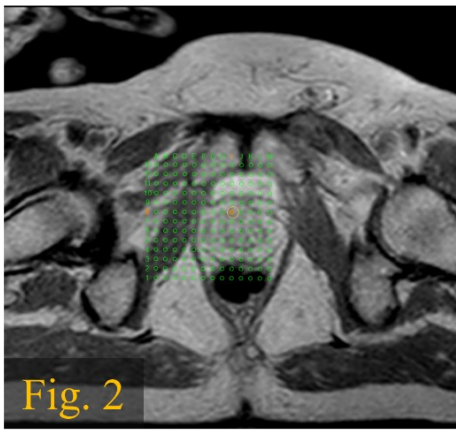
Fig. 2

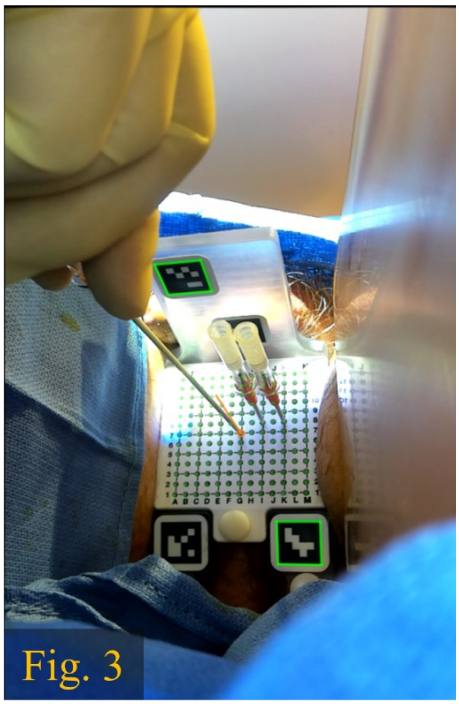
Fig. 3