Prototype Description and Ex Vivo Evaluation of a System for Combined Endorectal Magnetic Resonance Imaging and In-Bore Biopsy of the Prostate

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Abstract: We describe early ex vivo proof-of-concept testing of a novel system composed of a disposable endorectal coil and converging multichannel needle guide with a reusable clamp stand, embedded electronics, and baseplate to allow for endorectal magnetic resonance (MR) imaging and in-bore MRI-targeted biopsy of the prostate as a single integrated procedure. Using prostate phantoms imaged with standard T_2-weighted sequences in a Siemens 3T Prisma MR scanner, we measured the signal-to-noise ratio in successive 1-cm distances from the novel coil and from a commercially available inflatable balloon coil and measured the lateral and longitudinal deviation of the tip of a deployed MR compatible needle from the intended target point. Signal-to-noise ratio obtained with the novel system was significantly better than the inflatable balloon coil at each of five 1-cm intervals, with a mean improvement of 78% ($P < 0.05$). In a representative sampling of 15 guidance channels, the mean lateral deviation for MR imaging–guided needle positioning was 1.7 mm and the mean longitudinal deviation was 2.0 mm. Our ex vivo results suggest that our novel system provides significantly improved signal-to-noise ratio when compared with an inflatable balloon coil and is capable of accurate MRI-guided needle deployment.

Key Words: prostate cancer, MRI, MRI-targeted biopsy

(*J Comput Assist Tomogr* 2024;48: 378–381)

Traditionally, prostate cancer is diagnosed by systematic transrectal ultrasound-guided biopsy, but standard transrectal ultrasound-guided biopsy misses many significant cancers and detects many insignificant cancers.[1–4] The steady improvement in prostate magnetic resonance imaging (MRI) over the last 3 decades have culminated in recent high-quality trials and guidelines suggesting men with suspected prostate cancer should first undergo MRI, with subsequent targeted biopsy of suspicious foci.[2–6] The role of systematic sampling remains under evaluation, although some have advocated for a target only approach in those with a positive MRI and deferred biopsy in those with a negative MRI.[2–4,6] While the optimal approach may be in evolution, MRI targeting is a central component of the new paradigm and obviously requires that both MRI and MRI-targeted biopsy are optimized to minimize the risk of missing significant cancer. For MRI, we believe that this means endorectal imaging. While many centers do not use an endorectal coil,[7] the reasons appear grounded more in convenience rather than science,[8] given that the coil increases signal-to-noise ratio (SNR) by 5 to 10 times[9] and significantly increases the tumor detection rate from 45% to 76%.[10] For MRI-targeted biopsy, we believe that in-bore biopsy may be preferred to fusion because it seems to have a higher target specific cancer detection rate,[11,12] possibly reflecting misregistration error associated with fusion of 2 different modalities. Performing endorectal MRI and in-bore biopsy as 2 separate invasive procedures is inefficient and inconvenient, so we are developing a novel system that allows them to be integrated as a "one-stop shop," fusing procedures rather than modalities. Same-day diagnostic testing is standard practice for women with suspected breast cancer. Arguably, men with suspected prostate cancer should be offered an equivalent level of patient-centered care, although the benefit in convenience may be offset by challenges to clinical implementation. The purpose of this report is to describe early ex vivo proof-of-concept testing of this novel system.

MATERIALS AND METHODS

One author (F.V.C.) is a majority shareholder in OmnEcoil Instruments, Inc, the medical device company developing the system described in this study. All other authors have no financial interest in the system, and these authors had full control of the inclusion of any data or information that might have presented a conflict for the author who is a shareholder in OmnEcoil Instruments, Inc. The study was in part supported by a phase 1 SBIR Grant from the National Science Foundation (FAIN#1747319). The system used in this study is described in the approved US Patent Number US 11,464,499 B2, issued October 11, 2022. F.V.C. is a named inventor in this patent.

The System

Our prototype, consisting of a disposable endorectal coil and converging multichannel needle guide combined with a reusable clamp stand, embedded electronics, and baseplate (Fig. 1), is fabricated by an MRI coil manufacture and repair company (ScanMed LLC, Omaha, NV). The system provides a 3-dimensional multichannel stereotactic platform to allow physicians to obtain biopsies from or place other devices in targeted sites within the prostate. The single-use patient-contacting part of the system is made of biocompatible materials and is terminally sterilized in compliance with the Food and Drug Administration requirements. Key system elements include the following:

Self-expanding Endorectal Coil

The coil is a 9.0 × 4.5-cm single loop, receive-only antenna constructed of Litz wire (multistrand cable of insulated wires braided to reduce alternating current losses in high frequency windings) threaded in a high tensile extruded polyamide 0.09375″ rod (nylon 101 PA66, OnlineMetals.com). The rod is enclosed in a silicon tube (HelixMark Tubing; Freudenberg

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Received for publication September 12, 2023; accepted November 18, 2023.

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This study was supported in part by the National Science Foundation (SBIR phase 1 Award/FAIN#1747319).

F.V.C. is a founder and shareholder in and consultant to OmnEcoil Instruments, Inc. The other authors declare no conflict of interest.

DOI: 10.1097/RCT.0000000000001583

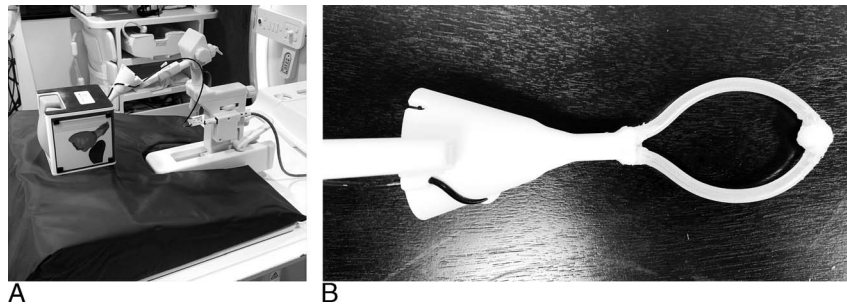

FIGURE 1. A, Photograph of the current prototype system, which consists of a disposable endorectal coil and converging multichannel needle guide combined with a reusable clamp stand, embedded electronics, and baseplate. B, Photograph of the disposable component of the system, showing the self-expanding endorectal loop and the conical converging array of multichannel needle guides. For scale, the base of the conical multichannel needle guide array is 6.1 cm.

Medical, Baldwin Park, CA) and coated in a commercially available polyvinyl chloride (Plasti-Dip; Plasti Dip International, Blaine, MN). Two capacitors connect the ends of the loop. The leading capacitor is in a smooth plastic bead for easy passage through the anus. We designed the coil to expand in the rectum posterior to the prostate while the narrow apex of the converging multichannel needle array sits naturally in the anus. The coil remains passively expanded throughout the imaging and biopsy portions of the combined procedure.

Multichannel Needle Guide

The conical multichannel converging needle array is 3D printed (Fortus F900; Stratasys, Los Angeles, CA) from a widely used thermoplastic polycarbonate (PC-ISO; Stratasys, Los Angeles, CA) with an accuracy of ±0.15 mm. The array is a 35-degree cone with a height of 8.47 cm and a 6.1-cm diameter base containing a rectilinear array of 177 holes spaced at 3.14-mm intervals that serve as converging needle guides, sized to allow passage of a commercially available MRI compatible 18G needle (Invivo, Gainesville, FL). We designed the array to optimize biopsy coverage of the prostate using a true-life dataset of anonymized diagnostic MR images from 10 patients who had undergone in-bore biopsy at our institution and to result in no more than 5-mm spacing between needles at a depth of 5 cm from the convergence point, because a depth of 5 cm corresponds to the upper limit of needle penetration required to access the vast majority of targets in clinical practice. The guidance holes and cone chamber are filled with sterile aqueous gel (Surgilube Surgical Lubricant, Sandoz, or equivalent) to allow visualization on T_2-weighted images.

Clamp Stand and Baseplate

These reusable parts were also fabricated by 3D printing. The clamp stand has 3 cog-like mechanisms to facilitate 3-dimensional movement, allowing the operator to redirect the needle array to parts of the prostate that might be inaccessible at initial positioning.

Electronics

A cable is hard-wired to the coil to deliver the received signal back to a preamplifier mounted in insulated housing on the clamp stand, and another cable connects to the MRI system using the appropriate system-compatible connector. The connections are 2 way—the device output goes to the MR system while the power supply and control signals for detuning or decoupling the coil come from the system to the device. Space limitations preclude a full description of the electronic circuitry, but operational components provide detuning and grounding functions, prevent excess radiofrequency energy deposition with redundant decoupling strategies, and provide an ID recognized by the scanner to enable safe operation of the coil and prevent inappropriate MR sequence selection that could damage the coil or the patient. The assembly has been tested for high voltage leaks and is compliant with engineering, safety, and manufacturing guidelines of IEC60601.

Evaluation of MRI Performance

Closely following a previously described technique,[13] we measured SNR in a phantom consisting of a large lemon taped to the bottom of a rectangular water bath. We opted not to use a commercial pelvic phantom for this assessment because we found it did not allow for realistic physiologic expansion of either of the 2 coils being tested. We separately taped our prototype coil and a commercially available balloon inflatable coil (Medrad Prostate eCoil, Bayer Healthcare LLC, Whippany, NJ) on top of the lemon, simulating the relationship to the prostate. We imaged the phantom in a Siemens 3T Prisma MR scanner using our standard T_2-weighted Turbo Spin Echo sequence for clinical MR imaging of the prostate (7500-ms repetition time, 104-ms echo time, 2 signal averages, 3.5-mm slice thickness). Using a standard methodology,[14] we calculated SNR by measuring the signal intensity in 1-cm diameter regions of interest in left and right radial directions spreading at approximately 30-degree angles from the coil surface

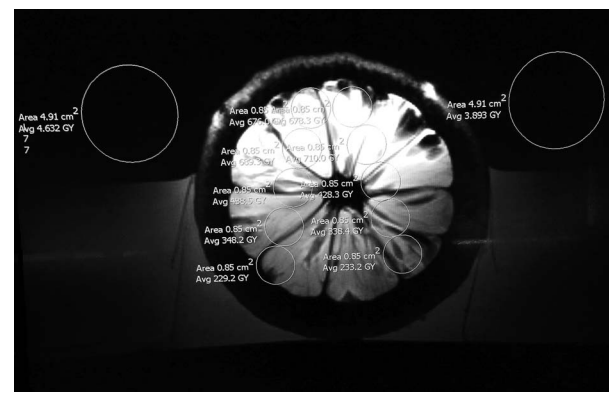

FIGURE 2. T_2-weighted MR image of the phantom, showing how SNR was calculated by measuring the signal intensity in 1-cm diameter regions of interest in left and right radial directions spreading at approximately 30-degree angles from the coil surface and measuring noise as the signal intensity of air above the surface of the water bath, taken as the mean of two 2.5-cm diameter regions of interest.

(Fig. 2). We measured noise as the signal intensity of air above the surface of the water bath, taken as the mean of two 2.5-cm diameter regions of interest. Using a paired *t* test, we compared the SNR obtained with our coil to that obtained with the inflatable balloon coil.

Evaluation of Needle Deployment

We tested needle deployment using a commercial male pelvic phantom (multimodality pelvic phantom, Computerized Imaging Reference Systems, Inc, Norfolk, VA, as shown in Fig. 1A) in 2 separate sessions. We selected target points in the prostate phantom on T_2-weighted MR images at a depth of 7.5 to 8.0 cm from the tip of our prototype and directly in line with one of the holes of the needle array. This depth was chosen to exceed the routine clinical upper limit of 5 cm. We fired an 18G MRI compatible biopsy gun down the chosen access hole at the appropriate depth to place the tip of the deployed needle at the intended target point. A picture archiving and communication system (PACS) point co-registration tool was placed on the "before" image to identify the target point on the "after" image and measure longitudinal and lateral deviations of the needle tip from the selected target point (Fig. 3). This was repeated for a representative sampling of 15 biopsy holes.

RESULTS

Paired *t* testing showed the SNR obtained with the novel system was significantly better than that obtained with the inflatable balloon coil at each of five 1-cm intervals (Table 1), with a mean improvement in SNR of 78% ($P < 0.05$). Needle deployment testing demonstrated a mean lateral deviation of 1.7 mm (range, 0.0–4.3) and a mean longitudinal deviation of 2.0 mm (range, 0.8–4.8).

DISCUSSION

Our preliminary results suggest our endorectal coil offers superior SNR to a commonly used inflatable balloon coil, likely reflecting advanced electronic circuitry designed to leverage near field electromagnetic principles and the deployment of a self-expanding antenna in close apposition to the prostate, and our needle guide system allows for in-bore targeted biopsy with mean needle deviations of approximately 2 mm, similar to a mean error of 2.3 mm with a robotic system.[15] Our vision is that "screen positive" men would undergo endorectal MRI with our system. Those with a visible target would have a target biopsy. Systematic 12-core sampling could be performed in men with or without a target, although given the number of biopsy samples seems correlated with the risk of serious complications,[16–20] a target only in-bore approach may provide the optimal combination of high cancer yield and low complication rate.[2–4,6] We would note that such an integrated approach nullifies essentially it terminates the debate around the need for an endorectal coil; because transrectal biopsy requires a rectal introducer, it makes sense to combine an endorectal coil with the biopsy introducer. We believe that challenges to this disruptive vision, including the competitive environment, workflow practicalities, and other diagnostic advances, are all surmountable and that integrated MRI and in-bore biopsy is the future of prostate cancer diagnosis.

Currently, the majority of MRI-targeted biopsies are performed by a fusion approach with the UroNav (Philips North America, Cambridge, MA) system. The main in-bore system (DynaTRIM; Philips North America) is not widely used, likely because the fusion approach is generally performed and preferred by urologists. However, all current methods of MRI-targeted biopsy remain inconvenient for patients, requiring separate visits for the initial diagnostic MRI and the biopsy procedure. Our system integrates these 2 procedures into one while our multichannel needle guide allows for systematic sampling that is not viable with a single-channel introducer. Integrating MRI and biopsy may seem clinically impractical, and we appreciate that this approach would be challenging and substantially different to current practice. Potential workflow solutions could include batch scheduling of

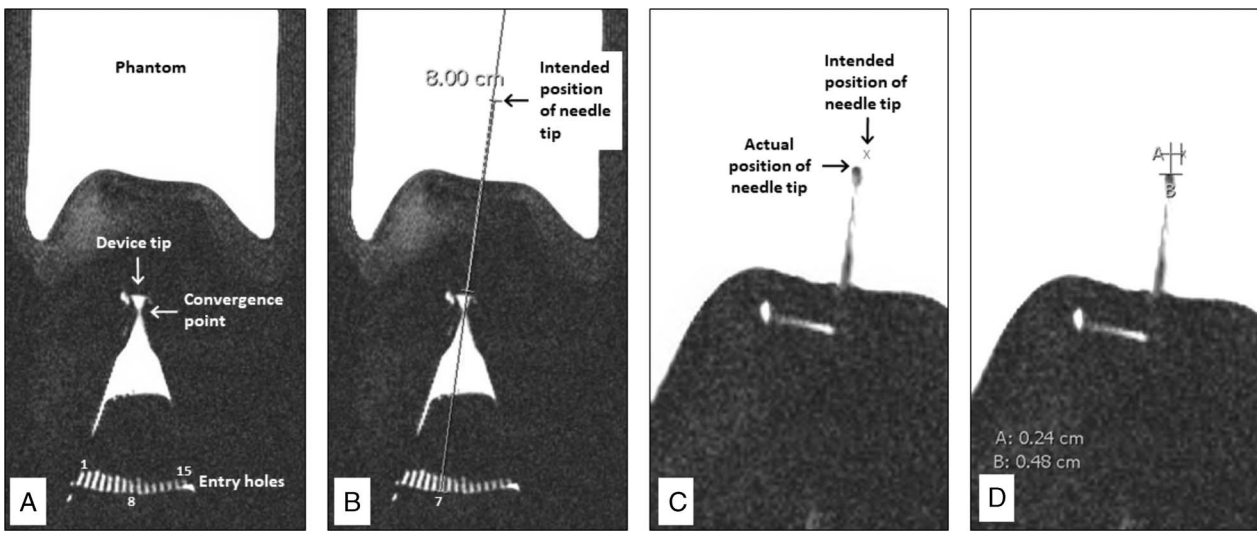

FIGURE 3. Photomontage showing the methodology for measurement of needle deviation after deployment. Images obtained using the setup illustrated in Figure 1A. A, Predeployment T_2-weighted image obtained in an oblique axial image to include the 15 needle entry points (numbered) in the central horizontal row of the multichannel array and the convergence point. The prototype device has been partially filled with aqueous gel to assist visualization. B, Predeployment T_2-weighted image with lines drawn on the image using standard PACS markup tools to show the intended deployment point of the biopsy needle when fired through hole #7 to reach a depth of 8 cm from the device tip. **C,** Magnified postbiopsy T_2-weighted image shows the actual needle tip position after deployment. The intended needle tip position (X) has been marked on the image using an electronic PACS co-registration tool to identify the same point on the postbiopsy image as identified on the prebiopsy image in B. D, Measurement of transverse (A) longitudinal (B) deviation of the needle using a standard PACS measurement tool to find the distance between intended and actual needle tip positions.

TABLE 1. Numerical and Graphical Results of SNR Performance of the System Compared With a Commonly Used Inflatable Balloon Coil

Depth From Coil, cm	Mean SNR (Prototype)	Mean SNR (Balloon Coil)	*P*
0–1	162	107	<0.05
1–2	134	72	<0.05
2–3	84	43	<0.01
3–4	64	35	<0.05
4–5	46	26	<0.01

patients, with timing intervals allowing for the predicted biopsy conversion rate of approximately 50%.[3] Focused image review for identification of targets can be performed in 118 to 131 seconds,[21] so studies could be rapidly reviewed in real time to determine the need for biopsy. Patients could provide informed consent before the scan and could receive sedation and single-dose antibiotic prophylaxis[22] using the intravenous line placed for gadolinium administration. We see our system as inherently future proofed because it is synergistic with other ongoing advances. Improved liquid biopsy markers should result in a smaller but higher yield "screen positive" population requiring biopsy. Novel techniques for immediate analysis of MR images[23] and pathology specimens[24] could facilitate rapid target identification and characterization. We plan to develop software to assist users in identifying the appropriate needle channel and depth to optimally biopsy a selected target. We also plan a transperineal version by offsetting the convergence point of the showerhead anteriorly relative to the endorectal loop so that the coil would be in the rectum while the convergence point abuts the perineum, given that the transperineal approach is increasingly recommended to reduce infection risk.[6]

In conclusion, our preliminary ex vivo results suggest that our novel system provides significantly improved SNR when compared with an inflatable balloon coil and is capable of accurate MRI-guided needle deployment, allowing for combined endorectal imaging and in-bore targeted biopsy of the prostate as a single procedure.

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