

## 3-Dimensional Elastic Registration System of Prostate Biopsy Location by Real-Time 3-Dimensional Transrectal Ultrasound Guidance With Magnetic Resonance/Transrectal Ultrasound Image Fusion

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### Abbreviations and Acronyms

3D = 3-dimensional

MR = magnetic resonance

MRI = MR imaging

TRUS = transrectal US

US = ultrasound

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**Purpose:** We determined the accuracy of the novel Urostation 3-dimensional transrectal ultrasound system (Koelis, La Tranche, France) for image based mapping biopsies in a prostate phantom. The system is capable of 1) registering the 3-dimensional location of each biopsy track in the 3-dimensional prostate volume data and 2) performing elastic image fusion of transrectal ultrasound with magnetic resonance imaging.

**Materials and Methods:** We used 3 CIRS-053 prostate phantoms containing 3 hypoechoic lesions to perform ultrasound guided biopsy and 3 CIRS-066 phantoms (Computerized Imaging Reference Systems, Norfolk, Virginia) containing 3 isoechoic but magnetic resonance imaging visible lesions to perform magnetic resonance fusion guided biopsy. Three targeted biopsies were done per lesion. Each biopsy tract was injected with gadolinium based magnetic resonance contrast mixed with india ink. Phantoms were then subjected to 1 mm slice magnetic resonance imaging and serial step sectioning to assess the accuracy of targeted biopsy.

**Results:** A total of 27 ultrasound guided biopsies were targeted into 9 hypoechoic lesions. All 27 biopsies (100%) successfully hit the target lesion. For hypoechoic lesions mean  $\pm$  SD procedural targeting error was  $1.52 \pm 0.78$  mm and system registration error was 0.83 mm, resulting in an overall error of 2.35 mm. Of the 27 magnetic resonance fusion biopsies 24 (84%) hit the lesion. For isoechoic lesions mean procedural targeting error was  $2.09 \pm 1.28$  mm, resulting in an overall error of 2.92 mm.

**Conclusions:** The novel, computer assisted, 3-dimensional transrectal ultrasound biopsy localization system achieved encouraging accuracy with less than 3 mm error for targeting hypoechoic and isoechoic lesions. The ability to register actual biopsy trajectory and perform elastic magnetic resonance/ultrasound image fusion is a significant advantage for future focal therapy application.

**Key Words:** prostate; biopsy; ultrasound, high-intensity focused, transrectal; magnetic resonance imaging; diagnostic imaging

CONVENTIONAL TRUS guided systematic biopsy has the clear limitation of being unable to register the precise 3D location of the biopsy core with

respect to patient prostate anatomy. Various methods, such as transperineal grid templates, have been used to achieve some degree of biopsy core

localization. With external grids needle deflection due to various inherent physical factors often result in the actual needle trajectory being different from the anticipated trajectory, resulting in inaccurate mapping of lesions.<sup>1-3</sup>

To develop and implement a clinically successful focal therapy protocol precise 3D localization of the interventional needle remains a critical prerequisite, whether to obtain biopsy or perform ablation.<sup>4-7</sup> Real-time 3D TRUS imaging acquisition to obtain the hyperechoic image of the metallic biopsy needle indwelling in the real 3D space of the prostate could precisely register the 3D site of each biopsy in the prostate as a reality. Such information would be critical to specifically target biopsy proven cancer foci.

Multimodal MRI is emerging as a more reliable modality to detect clinically significant prostate cancer.<sup>8-10</sup> MR/TRUS fusion image guidance could potentially increase the spatial accuracy of targeted biopsy or focal intervention, especially when targeting lesions visible only by MR.<sup>11,12</sup>

We evaluated the accuracy of targeted biopsies guided by a novel, computer assisted, real-time 3D TRUS registration system with an MR/TRUS image fusion function.<sup>13-15</sup> This system has achieved elastic image fusion with deformation estimation using a kinetic model of TRUS probe movements to calculate automatically plausible positions of the US beam, which is unaffected by patient movement.<sup>14</sup> This system could also provide image based 3D mapping of each biopsy tract on the 3D prostate model to

enable retargeting of a known cancer focus or biopsy of prior unvisited areas for focal therapy and repeat biopsy, respectively.

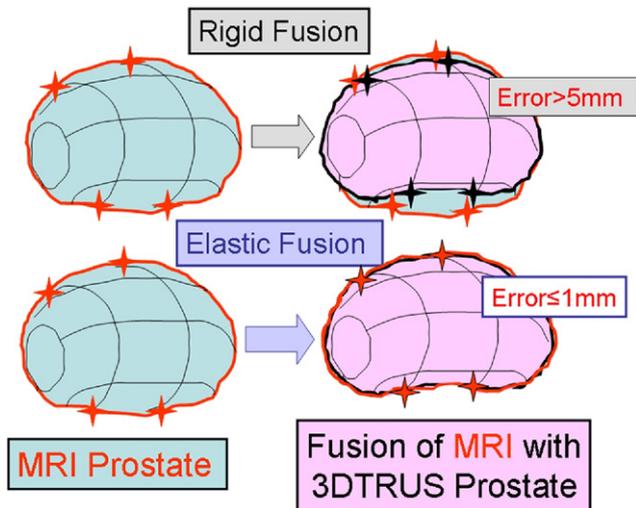
We evaluated the accuracy of targeted biopsy using this system in commercially available prostate phantoms containing hypoechoic or isoechoic but MR visible lesions.

## MATERIALS AND METHODS

### TRUS to Register Biopsy Trajectory

All biopsies were guided by an end firing, 3D 3D5-9EK TRUS probe and an Accuvix-V10 US machine (Samsung Medison America, Cypress, California) capable of 3D image acquisition. The novel Urostation external computer workstation has 2 functional modes for prostate biopsy guidance, including 1) real-time TRUS image guidance by a computer assisted, real-time 3D TRUS registration system to spatially map each biopsy needle trajectory using elastic image fusion of each 3D prostate model and 2) MR/TRUS fusion guidance using elastic fusion between the 3D prostate model of preoperatively acquired MR and that of real-time 3D TRUS (figs. 1 and 2).

In each mode each biopsy was done by holding the end firing 3D TRUS probe freehand. Initially a 3D referenced prostate image, named the panorama image, was constructed by integrating 3 sets of 3D TRUS volume data, which were acquired from 3 angles to capture the entire prostate image. Immediately after firing the needle the needle was left indwelling in the prostate. Real-time 3D TRUS data were acquired during only 3 seconds and transferred to the workstation to precede trajectory regis-



**Figure 2.** Difference in accuracy of registration technology between conventional rigid fusion registration technique and elastic fusion registration technique shows superiority of latter. There are critical different conditions at each image acquisition when registering 3D prostate model between MR and TRUS. TRUS probe or endorectal coil in rectum typically causes prostate deformation. Image based elastic fusion of 3D images allows deformation estimation using kinetic model of TRUS probe movements to calculate automatically plausible US beam positions. Thus, spatial corresponding anatomical points in prostate boundary (crosses) can be registered accurately with less than 1 mm error by elastic fusion but inaccurately with greater than 5 mm error by rigid fusion.

tration on the 3D referenced panorama image (figs. 1 and 3). The biopsy tract appeared as a hyperechoic trajectory and the operator kept the needle still to minimize motion artifact. This system also has the capability of recording the exact coordinates (x, y and z) of the proximal and distal ends of each needle trajectory.

We present 2 studies, including study 1—TRUS guided targeting of US visible (hypoechoic) lesions and study

2—MR/TRUS fusion guided targeting of MR visible but isoechoic lesions.

### Phantom MRI Analysis

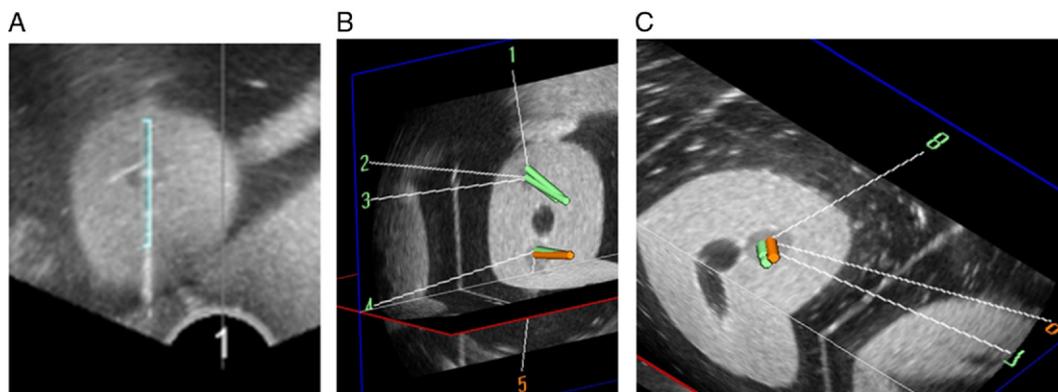
Using computer assisted, multiplanar analysis with eFilm-Lite software (Merge® Healthcare) we measured 3D coordinates of points of interest in the reconstructed 3D MR volume data. Voxel dimensions were 0.5 mm wide × 0.5 mm high × 1 mm thick. Distance in mm was calculated by the mathematical formula using the coordinates (x, y and z) of the 2 points in 3D space.

### Study 1

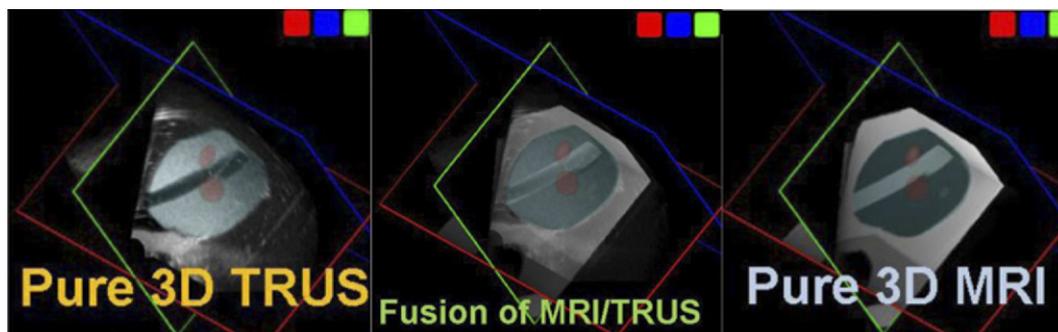
To evaluate the accuracy of the computer assisted, 3D TRUS guidance system to target US visible hypoechoic lesions we used 3 CIRS Model 053-MM phantoms, each containing 3 randomly located hypoechoic lesions with a volume of 0.5 cc. We performed 3 targeted biopsies per lesion, yielding a total of 27 tracts.

Since each needle pierced the targeted hypoechoic lesion through and through, it crossed the lesion boundary twice, that is at the lower (entry point) and upper (exit point) boundaries. We calculated the error in mm in the 3D site of the crossing points between the intended needle tract and the actual needle tract with the target boundary for each of the 27 biopsy tracts.

After acquiring the 3D image of the phantom and a fired needle the inner needle was removed, leaving the outer needle sheath indwelling. Through the sheath gadolinium based contrast agent mixed with india ink (using specific color coding with black, red or blue for biopsies 1 to 3, respectively) was injected into the needle track and the outer sheath was gradually removed. MRI of the phantom was subsequently performed using a 3 Tesla MR machine (GE Medical, Cape Coral, Florida). Accuracy was assessed by the reconstructed images of 1 mm step MRI analysis of the phantom and by direct visual inspection of 1 mm phantom step sections at the parts of interests. This allowed confirmation of the colored needle tracks defining biopsies 1 to 3.



**Figure 3.** Three-dimensional display to register biopsy needle trajectory. A, real-time TRUS image to guide biopsy 1 in center of hypoechoic lesion to visualize metallic needle hyperechoic trajectory at initial process of computer assisted localization of fired needle with real-time 3D TRUS. B and C, workstation 3D display of biopsy field. B, number of 1 to 3 biopsy trajectories (green area) targeting lesion 1 and number of 4 or 5 biopsy trajectories (orange area) into lesion 2. C, number of 7 to 9 biopsy trajectories (green and orange areas) targeting left side lesion 3.



**Figure 4.** MR/TRUS system to enable fusion of pure 100% 3D TRUS prostate volume data with pure 100% 3D MR prostate volume data to construct fusion image of 50% MR with 50% TRUS. Isoechoic, MR visible lesions are overlaid (red areas).

Biopsies were targeted to the center of the lesion. Targeted biopsy accuracy was defined as the distance from the actual crossing points of the needle tract at the lesion circumference to the crossing points of an imaginary line drawn through the center of the lesion and parallel to the actual needle tract. Since the biopsy 1 tract worked fiducially as a hyperechoic appearance in the US image due to bubble/fluid formation, biopsies 2 and 3 for each lesion were intentionally done from a different angle and not parallel to the biopsy 1 tract by manipulating the TRUS probe. Each needle tract pierced the targeted lesion through and through and so each needle track crossed the lesion boundary twice. When the targeted biopsy missed the target with the result that there was no crossing point with the lesion boundary, the error was defined as the perpendicular distance from the targeted point to the actual needle tract.

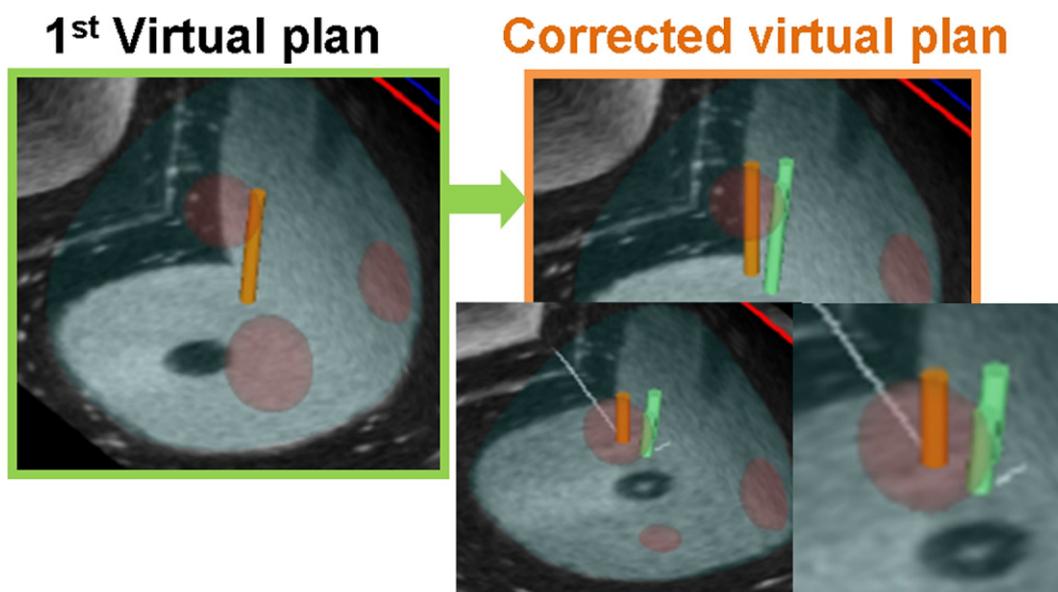
After MRI assessment each phantom was step sectioned at the parts of interests in 1 mm slices to distinguish track 1, 2 or 3 by visually identifying the specific ink color.

### Study 2

We then tested the accuracy of MR/TRUS fusion targeting to isoechoic and MR visible lesions. The CIRS Model 066 prostate phantoms used for this study each contained 3 randomly located, 0.5 cc isoechoic lesions that are visible on MRI.

We performed 3 biopsies using MR/TRUS fusion to target each isoechoic lesion. For MRI fusion guidance pre-biopsy MR of the phantom (1 mm thick slices) was acquired. Digital Imaging and Communications in Medicine data transferred to the computer workstation. Three-dimensional TRUS of the prostate phantom was also done. Subsequently 3D segmentation of the MRI and TRUS images was performed and the images were fused using elastic fusion technology (fig. 4).

Before firing the needle through the MR visible lesion a 3D simulation of the virtual tract was created and registered on the real-time TRUS image (fig. 5). After confirming the accurate site of the virtual tract the biopsy needle



**Figure 5.** MR/fusion biopsy planning using virtual trajectory simulation, which can be repeated for correction to achieve ideal direction for lesion targeting.

was fired. Similar to study 1, each needle track was inked with gadolinium based contrast agent mixed with a specific colored india ink (black, red or blue for biopsies 1 to 3, respectively). Accuracy was assessed by post-biopsy MRI (1 mm slice thickness) of the phantom as well as by step sectioning the phantom at 1 mm intervals at parts of interests and observing the uniquely colored tracts.

## RESULTS

### Study 1

For TRUS guided targeting of hypoechoic lesions a total of 27 needle biopsies were targeted into 9 hypoechoic lesions in a total of 3 prostate phantoms. Overall each of the 27 biopsies (100%) successfully hit the 0.5 cc target hypoechoic lesion. The success rate of registration was 96% (26 of 27 biopsies). One registration completely missed the lesion, possibly due to an artifact from the previous hyperechoic needle tract on the opposite side.

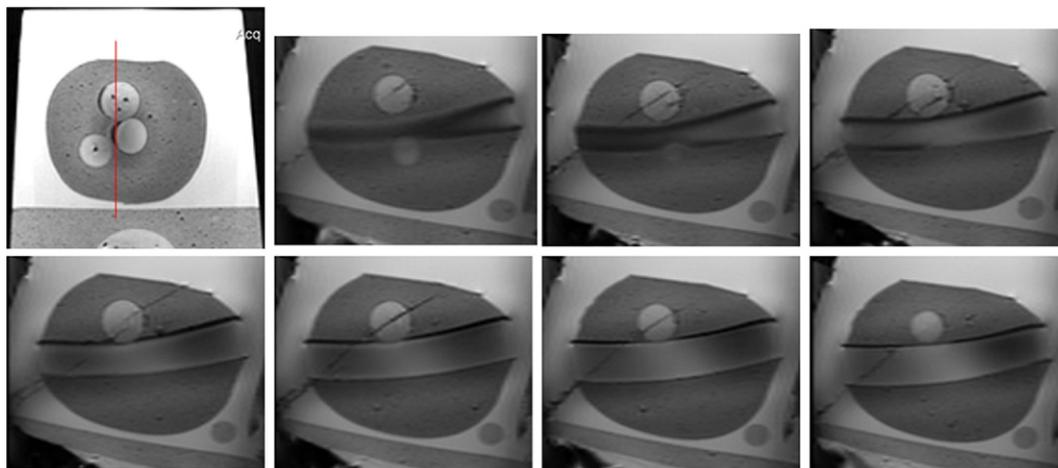
Since each needle track crossed the hypoechoic lesion circumference twice, first at the lower boundary and subsequently at the upper boundary, the total number of needle track crossing points was 54 (27 needle tracts  $\times$  2 crossing points). For these 54 crossing points there was no error (less than 1 mm) in 30 needle tracks (56%), minimal error (1 to 2 mm) in 22 (41%) and moderate error (2 to 3 mm) in 2 (4%) (fig. 6). The mean  $\pm$  SD procedural targeting error, ie the error on MR analysis and/or step-section measurement, was  $1.52 \pm 0.78$  mm. The mean system registration error inherent to the system software was  $0.83 \pm 0.54$  mm. Thus, the mean total targeting error in needle placement was 2.35 mm.

### Study 2

For MR/TRUS fusion guided targeting for isoechoic but MR visible lesions 24 of 27 needle biopsies (89%) targeted into a total of 9 isoechoic lesions successfully hit the target lesion. Of the 54 declared targeted points (2 target points per biopsy, including 1 at entry into and 1 at exit out of the isoechoic lesion) no error (less than 1 mm) was observed in 15 needle tracks (28%), minimal error (1 to 2 mm) in 21 (39%), moderate error (2 to 3 mm) in 5 (9%) and severe error (3 mm or greater) in 13 (24%). As recorded on MR analysis and/or step-section measurement, the mean targeting error was  $2.09 \pm 1.28$  mm. The mean system registration error was  $0.83 \pm 0.54$  mm. Thus, the mean total error (targeting error plus system registration error) was 2.92 mm.

## DISCUSSION

Due to the relatively low diagnostic value of conventional gray scale TRUS for prostate cancer its current role has been limited to delivering the biopsy needle to the gross anatomical sextant. A limitation of the conventional systematic biopsy technique is the inability to record 3D anatomical spatial distribution of the needle biopsy tract in the prostate. Even when a transperineal external grid based mapping technique is used, biopsy needle deflection and deformation, anatomical shift of the prostate, periprostate hemorrhage and edema may occur during the procedure, making precise 3D localization of the needle tract difficult. As such, refinement in TRUS technology should incorporate the ability to precisely document the actual needle position and the ability to accurately retarget the same location.



**Figure 6.** One mm step-section 3 Tesla MRI analysis of phantom to evaluate needle tract accuracy. Gadolinium based contrast agent mixed with black, red or blue india ink for biopsy 1 to 3, respectively, was injected into needle track through outer biopsy needle sheath. Thus, MRI clearly revealed crossing points of each needle tract with upper and lower boundaries of each lesion. Using computer assisted multiplanar analysis 3D coordinates of points of interest were measured and distance in mm in 3D space was calculated by mathematical formula.

This technological advance has the potential to improve prostate cancer diagnosis and facilitate therapy with active surveillance and focal therapy. It is also important to target the center of the contours of the suspicious area to achieve accurate diagnosis, staging and targeted therapy.

Our study suggests that the computer assisted 3D TRUS localization system achieves these objectives with reasonable accuracy. In our pilot study the system attained encouraging accuracy to register needle tracts within a 2.4 mm error between the intentional and the actual targeting point when targeting a 0.5 cc US visible lesion. Also, 3D MR/TRUS image fusion targeted biopsy provided accuracy within a 3 mm error when targeting an MR visible 0.5 cc lesion. Since a volume of 0.5 ml in the targeted lesion is the critical threshold of clinically significant cancer,<sup>16</sup> this study shows the clinical relevance of future interventional use of this system.

This technology also shows additional possibilities that may impact focal therapy. This novel software allows for combining biopsy histological data on the 3D image data, creating a prostate 3D histogram that could facilitate targeted focal therapy only to the cancer foci. The individual record of the spatial location of previous biopsy specimens would enable a revisiting intervention. Since the current repeat biopsy technique relies on conventional sextant location, as identified on the specimen report, there could be differences of many mm between the previous biopsy site and the repeat biopsy site, resulting in a lack of credibility for determining tumor growth or up-grading due to significant sampling error.

Precise registration (image fusion) between 2, 3D images has been technically challenging. Images acquired at different times could reflect different anatomical conditions with potential organ deformation. A rigid registration technique is a complex process that requires segmentation of the prostate boundary and computerized adjustment, including calculating motion compensation. Technology is being developed to decrease registration error and reduce computing time for efficient use in clinical practice.<sup>17,18</sup>

An important improvement in image fusion technology is to provide elastic (nonrigid) registration.<sup>19</sup> A rigid registration technique may lead to significant error unless compensation for deformation is calculated (fig. 2). The elastic image fusion technique is superior to rigid registration and provides a rapid, automated estimation of organ deformation.<sup>14</sup> To our knowledge this system is the first clinically ready 3D image guidance system to provide elastic registration capability for prostate intervention.

Recently real-time MR guided biopsy technology became clinically available.<sup>20,21</sup> However, MR compatible biopsy techniques are still expensive, complicated and time-consuming. As a result, various

MR/TRUS fusion technologies are being developed to avoid the need for the rather cumbersome MR guided procedures.<sup>11,22-25</sup>

An additional advantage of the MR/TRUS fusion systems is availability in the urologist office using standard metallic equipment. Precise targeting using MR/TRUS fusion guidance necessitates 1) the registration accuracy of the 2 images and 2) alternative ways for 2-dimensional image fusion for real-time guidance or 3D image fusion for virtual guidance. To achieve an ideal direction to target the center of the lesion a virtual targeting simulation process is needed before actual needle firing to identify and correct the appropriate TRUS-probe orientation. The system allowed actual superimposition of the virtual biopsy trajectory image on the 3D prostate model to confirm the appropriateness of targeting according to US probe orientation.

In our study virtual simulation was applied for guidance, resulting in 3 of 9 initial biopsies (33%) missing the 0.5 cc targeted lesion. Clearly biopsy 1 to lesions visible only on MRI was more difficult due to the lack of anatomical landmarks in the real-time US image. Since subsequent biopsies 2 and 3 were done with the visible biopsy 1 trajectory as a reference landmark in the space, they were more accurate than biopsy 1.

Since the more severe error (greater than 3 mm) occurred in 13 of 54 targeting points with MR/TRUS fusion guidance, freehand manual use of US probe orientation could increase error during the time lag between the virtual planning process and actual needle firing. Robotic handling of the US probe could potentially further improve targeting accuracy since it allows for stable orientation of the probe during 3D image acquisition as well as during the process through virtual planning and real targeting. This is currently being investigated at our institution.

Since we used phantoms, this limitation of the study is obvious. In the clinical setting the needle deflection secondary to human prostate tissue elasticity or stiffness may affect inaccuracy and patient movement under local anesthesia may contribute to potential inaccuracy during 3-second 3D image acquisition. Although the unique ability of the elastic fusion of this system could compensate for certain deformation of the prostate, the effects of greater deformation by the clinical scenario, such as edema or bleeding, should be assessed in the clinical setting. Targeting to lesions visible only to MRI is a more complex procedure and so potential repetition of the virtual targeting process might be associated with patient discomfort due to the additional time of the intrarectal operation. The learning curve of the clinical practice of this system must also be addressed in further study.

## CONCLUSIONS

This novel real-time 3D TRUS localization system with MR/TRUS image fusion capability provides reasonable accuracy (less than 3 mm) to register 3D biopsy sites in

prostate volume data. The computer assisted, real-time 3D TRUS based biopsy mapping approach is fundamental if the goal of high precision, focal targeted therapy to biopsy proven cancer foci is to be realized.

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