

Rotary scan of the prostate volume and ultrasound image showing color Doppler activity and 3-Dimensional model of the prostate gland and blood vessels in the neurovascular bundle

IN THIS ISSUE

Unnecessary Imaging for the Staging of Low-risk Prostate Cancer Is Common

Hugh J. Lavery, Jonathan S. Brajtbord, Adam W. Levinson, Fatima Nabizada-Pace, Matthew E. Pollard, and David B. Samadi
Page 274

Trends in the Medical Management of Urolithiasis: A Comparison of General Urologists and Endourology Specialists

Sutchin R. Patel, Kristina L. Penniston, and Stephen Y. Nakada
Page 291

Contemporary Lymph Node Counts During Primary Retroperitoneal Lymph Node Dissection

R. Houston Thompson, Brett S. Carver, George J. Bosl, Dean Bajorin, Robert Motzer, Darren R. Feldman, Victor E. Reuter, and Joel Sheinfeld
Page 368

Results of the AdVance Transobturator Male Sling After Radical Prostatectomy and Adjuvant Radiotherapy

Ricarda M. Bauer, Irina Soljanik, Claudius Fllhase, Alexander Buchner, Florian May, Christian G. Stief, and Christian Gozzi
Page 474

Tandem-robot Assisted Laparoscopic Radical Prostatectomy to Improve the Neurovascular Bundle Visualization: A Feasibility Study

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OBJECTIVES	To examine the feasibility of image-guided navigation using transrectal ultrasound (TRUS) to visualize the neurovascular bundle (NVB) during robot-assisted laparoscopic radical prostatectomy (RALP). The preservation of the NVB during radical prostatectomy improves the post-operative recovery of sexual potency. The accompanying blood vessels in the NVB can serve as a macroscopic landmark to localize the microscopic cavernous nerves in the NVB.
METHODS	A novel, robotic transrectal ultrasound probe manipulator (TRUS Robot) and three-dimensional (3-D) reconstruction software were developed and used concurrently with the daVinci surgical robot (Intuitive Surgical, Inc., Sunnyvale, CA) in a tandem-robot assisted laparoscopic radical prostatectomy (T-RALP).
RESULTS	After appropriate approval and informed consent were obtained, 3 subjects underwent T-RALP without associated complications. The TRUS Robot allowed a steady handling and remote manipulation of the TRUS probe during T-RALP. It also tracked the TRUS probe position accurately and allowed 3-D image reconstruction of the prostate and surrounding structures. Image navigation was performed by observing the tips of the daVinci surgical instruments in the live TRUS image. Blood vessels in the NVB were visualized using Doppler ultrasound.
CONCLUSIONS	Intraoperative 3-D image-guided navigation in T-RALP is feasible. The use of TRUS during radical prostatectomy can potentially improve the visualization and preservation of the NVB. Further studies are needed to assess the clinical benefit of T-RALP. UROLOGY 77: 502–507, 2011. © 2011 Elsevier Inc.

A precise resection of the tumor-containing prostate gland and the preservation of the neurovascular bundle (NVB) around the prostate are critical in preventing tumor recurrence and preserving sexual potency following radical prostatectomy.¹ However, it can be challenging to visualize NVB during surgery due to the periprostatic connective tissues and intraoperative hemorrhage, even using surgical loupes during open surgery or laparoscopic magnification during laparoscopic prostatectomy. A potential solution to this challenge is image-guided navigation.

A recent study by Ukimura et al suggested that image guidance with transrectal ultrasound (TRUS) of prostate can be used during laparoscopic radical prostatectomy (LRP) without robotic assistance.² They reported that the images can potentially provide a decreased rate of

positive surgical margins and improve the dissection of the NVB. In their study, gray-scale ultrasound images were used to localize hypoechoic lesions, suggestive of cancer. In addition, Doppler ultrasound images were used to identify the blood flows within the NVB. This approach, while innovative, also posed several challenges. For example, the TRUS probe was manipulated by a human assistant during LRP, compromising image stability. Also, during robot-assisted laparoscopic radical prostatectomy (RALP), which is more commonly performed than LRP, there is a limited space between the daVinci surgical robot (Intuitive Surgical, Inc., Sunnyvale, CA) and the patient, not enough for a human assistant. In addition, the precise positional information of the TRUS probe was not incorporated in interpreting TRUS images.

Recently, we developed a robotic TRUS probe manipulator (TRUS Robot) and three-dimensional (3-D) reconstruction/navigation software. In this tandem robot approach using both the TRUS Robot and daVinci robot, we examined the feasibility of the image-guidance navigation using TRUS to visualize NVB during robot-assisted laparoscopic radical prostatectomy (RALP).

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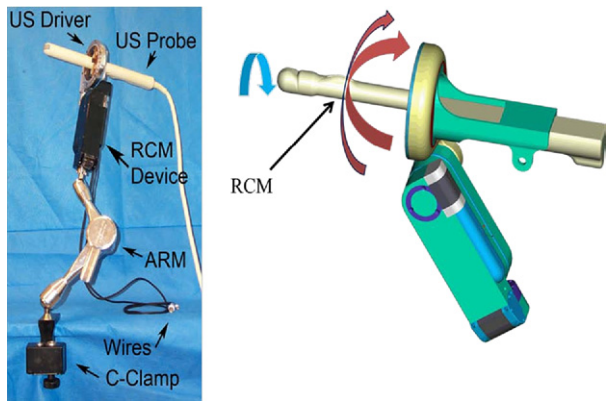


Figure 1. The TRUS Robot provides support and orientation of the TRUS probe. It is composed of a passive arm component attached to the table, a robotic orientation remote center of motion (RCM) module and an ultrasound probe driver module. It pivots the TRUS probe in 2 directions for orientation and rotates the TRUS probe about its axis.

MATERIAL AND METHODS

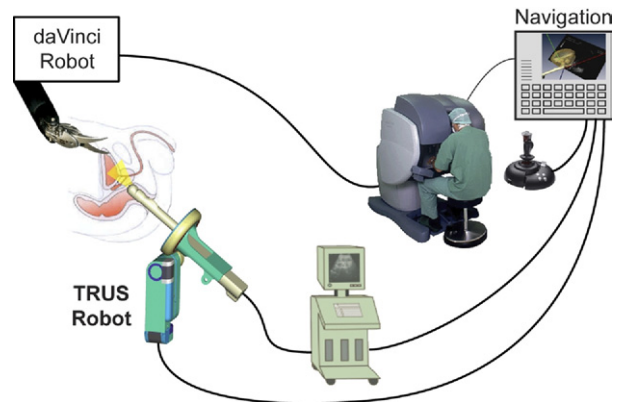
The TRUS Robot, a robotic arm to support and orient the TRUS probe, was developed at Johns Hopkins Urology Robotics Laboratory (<http://urobotics.urology.jhu.edu>). This novel instrument is composed of a passive support arm that is attached to the operative table, a robotic orientation Remote Center of Motion (RCM) module,³⁻⁵ and an ultrasound probe driver module (Figure 1). The orientation RCM module allows the TRUS probe to pivot about a fixed point with 2 rotations for changing the angulation of the probe. The ultrasound probe driver module allows the rotation of the probe about its axis. The probe depth can be manually adjusted by a surgeon. The total number of active degrees of freedom (DOF) of the TRUS Robot is 3. Most importantly, the TRUS Robot can provide measurements of the RCM and TRUS probe drive angles from which the images are acquired.

Figure 2a shows the schematic of the T-RALP setup where the daVinci surgical robot and the TRUS Robot are concurrently used. The 2 systems are not yet interconnected. A 3-D Image-Navigation interface was developed using the Amira Image Visualization software (Visage Imaging, Carlsbad, CA) with custom modules developed in Visual C++ (Microsoft, Redmond, WA).

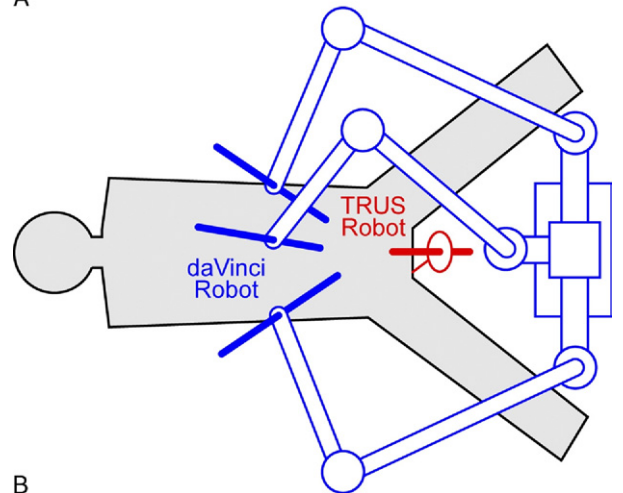
RESULTS

After obtaining the U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) and the Johns Hopkins institutional review board (IRB) approval, we performed the clinical feasibility study of the T-RALP. After signing informed consent, 3 subjects underwent nerve-sparing T-RALP without associated complications, such as rectal injury/discomfort or excessive blood loss requiring a transfusion.

In terms of patient demographics, the age of the patients ranged from 57 to 66 years. Their PSA ranged from 3.6 to 5.5 ng/mL. All had clinical stage T1(c) disease. Biopsy/prostatectomy Gleason score was 6 in 2 men and 4 + 3 = 7 in 1 man. Pathologic stage was pT2c in 2 men and pT3b in 1 man. Surgical margin was negative in all men.



A



B

Figure 2. (A and B). Schematic setup for tandem robot-assisted laparoscopic radical prostatectomy (T-RALP).

The prostate gland was measured to be between 30 and 40 g in size. The TRUS Robot setup and image acquisition processes required less than 30 minutes for each case.

After general anesthesia, a patient's legs were placed in spreader bars. Then, the TRUS Robot was mounted to the operative table between the patient's legs. The passive, C-clamp arm of the TRUS Robot was unlocked and the TRUS probe (a lateral fire probe, Hitachi EUP-U533) was manually placed transrectally so the probe does not put significant force on the rectal wall. After the passive arm was locked to hold the TRUS probe in place with a proper TRUS probe depth to visualize the whole prostate gland on a lateral/sagittal image, the daVinci surgical robot was docked carefully between the patient's legs with sufficient room for 2 robots to be operative in tandem without interference (Figure 2(b)).

The TRUS images of the prostate gland were acquired while the TRUS probe was supported and manipulated by the TRUS Robot using a joystick located next to the daVinci surgeon console, without the need for a dedicated assistant. The entire prostate was scanned by rotating the TRUS probe about its axis, minimizing prostate displacement and deformation. Accurate recording of 2-D images and corresponding TRUS frame coordinates were obtained. A rotary motion scan was used to

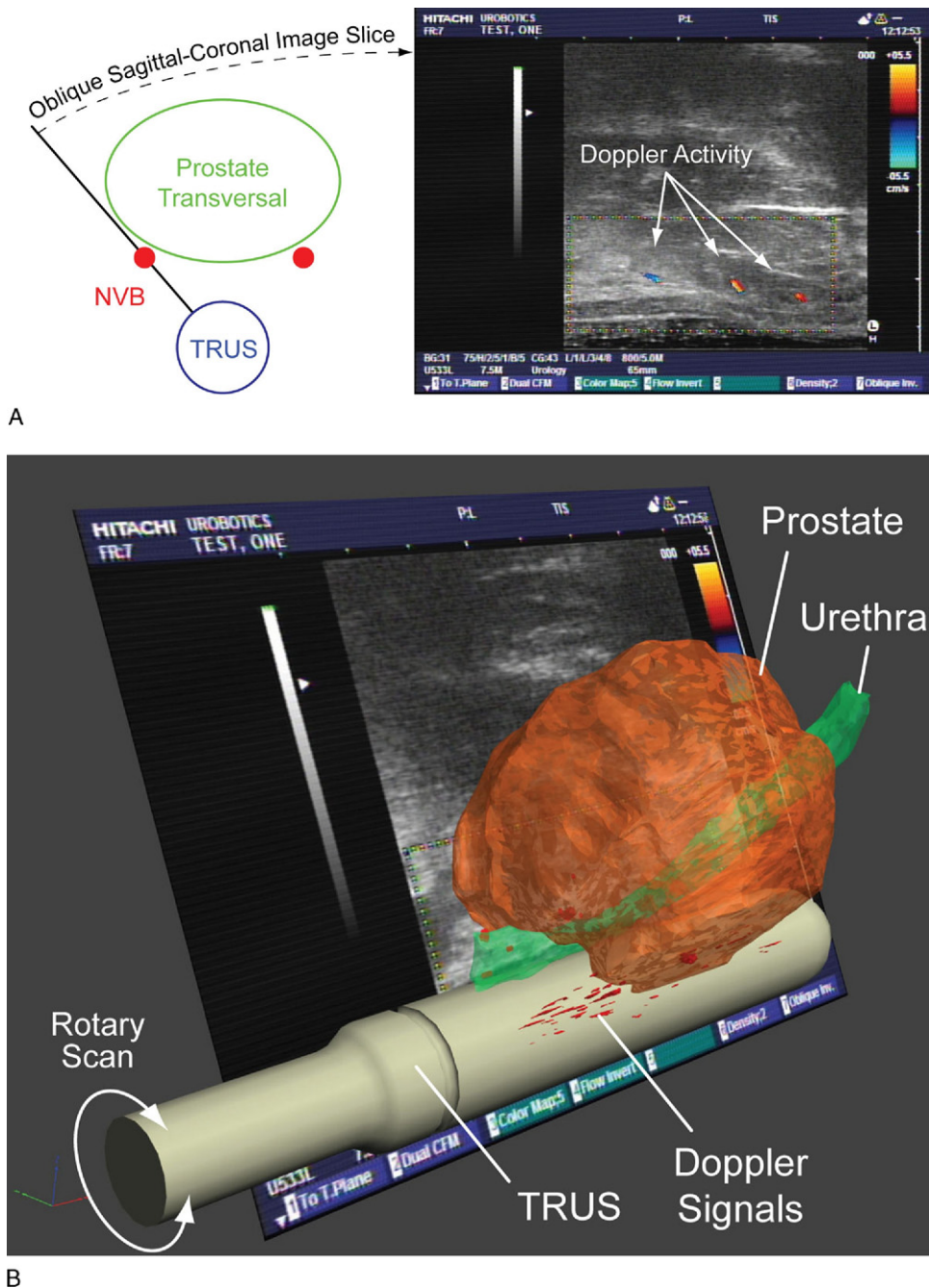


Figure 3. (A and B) Rotary scan of the prostate volume, ultrasound image showing color Doppler activity and 3-dimensional model of the prostate gland and blood vessels in the neurovascular bundle (NVB). Images acquired with Hitachi HiVision 6500, lateral fire endorectal probe EUP-U533 at 10.5 MHz.

sweep the prostate volume with ultrasound images. The gathered information was used in offline segmentation for the 3-D ultrasound image volume of the prostate gland and blood vessels in the NVBs (Figure 3). The tips of the daVinci instruments (hyperechoic marks) were visible in the live TRUS image during surgery, demonstrating a potential application of TRUS image-guided navigation.

COMMENT

The preservation of the neurovascular bundle (NVB) around the prostate is critical in preserving sexual po-

tency following radical prostatectomy. However, it can be challenging to visualize NVB during surgery. A possible solution is image-guided navigation using ultrasonography. The accompanying arteries and veins in the NVB, which are visible with a Doppler ultrasound,⁶ can potentially serve as a macroscopic landmark to localize the microscopic cavernous nerves in the NVB.^{1,7} In this feasibility study of tandem robot-assisted laparoscopic radical prostatectomy (T-RALP), we performed intraoperative navigation using a robotic TRUS probe manipulator (TRUS Robot) and three-dimensional (3-D) recon-

struction/navigation software. This feasibility study demonstrated that the prostate can be safely scanned during RALP with the TRUS Robot to reconstruct the 3-D images of the prostate gland with adjacent NVB and that the intra-abdominal daVinci instruments can be clearly visible in the TRUS images.

TRUS is an ideal modality for image-based navigation. Ukimura et al is the first group credited for using intra-operative TRUS imaging to visualize the prostate gland and NVB during laparoscopic radical prostatectomy (LRP).⁸ They reported that the intraoperative use of TRUS was helpful in imaging the location and local extent of hypoechoic area(s), providing real-time guidance for the surgeon during NVB release and apical dissection of the prostate, and monitoring a calibrated, lobe-specific, wider dissection around a cancer nodule with suspected extracapsular extension (ECE).⁹ With the enhanced visualization of the surgical field by TRUS imaging, they reported significant improvement in NVB preservation and a decreasing rate of positive surgical margin, which is a surrogate for the technical quality of the surgery.¹⁰ However, the concept of TRUS guidance during LRP did not gain wide acceptance because it requires an additional personnel manually manipulating TRUS probe during surgery.¹¹

Alternatively, we developed and used the TRUS Robot, a robotic arm to hold and manipulate the TRUS probe remotely, allowing the surgeon to manipulate the TRUS probe without the need for a human assistant during RALP. More importantly, the TRUS Robot allowed a continuous tracking of the TRUS probe position with the available reference frame, which is not available with manual handling of the TRUS probe. This additional positional information allowed the volume measurement, 3-D reconstruction and navigation display of the system. Typically, 3-D reconstructions in medical images, such as computed tomography (CT) or magnetic resonance imaging (MRI) are computed using linear interpolations from parallel images. With the TRUS Robot, the images were acquired using a rotary sweep about the axis of the TRUS probe. Therefore, a curvilinear interpolation had to be used to gather the volume from the rotary images.

There exist other TRUS tracking devices capable of reconstructing the 3-D image of the prostate, such as the Target Scan of Envisioneering Medical Technologies (St. Louis, MO) and the Eigen LLC system (Grass Valley, CA).^{12,13} The novelty of our approach derives from its robotic component that provides mobility in addition to tracking the position of the TRUS probe. Robots have been proposed for ultrasound-guided prostate biopsy and brachytherapy,¹⁴⁻¹⁷ but these typically handle the biopsy/brachytherapy needle not the TRUS probe.

Many parameters may affect the accuracy of ultrasound-guided navigation. Except for movement of organs, the most important factors influencing the accuracy may be the nature of the tracking system and ultrasound

probe calibration.¹⁸ Optical and electromagnetic systems are commonly used for tracking medical instruments but both systems have their limitations. Optical systems may have satisfactory accuracy, but require a clear line of sight between the sensors/markers and the cameras, which can be challenging in the operating room. In electromagnetic systems, distortions may occur due to metallic objects in the working space that induce perturbations of the magnetic field. The TRUS robot employs an alternative approach by measuring positions intrinsically without the need of a separate tracker. Moreover, because of its compact size, it can be ideally positioned in a limited space bounded by the patient's legs, operative table, and the daVinci surgical robot.

There are other potential applications for the TRUS Robot, such as prostate biopsy or brachytherapy. For example, after scanning the prostate with the TRUS Robot and 3-D navigation software, a systematic biopsy can be planned in 3-D. The robot can then be instructed to automatically orient the TRUS probe to designated locations, so the urologist can simply place the needle through the TRUS needle guide and perform the biopsy. This approach could potentially provide more uniform distribution of the biopsy regions as well as the accurate coordinates where the biopsies were obtained. A precisely localized biopsy sample holds substantially more clinical value because the coordinates of the biopsy cores may allow for building 3(D) cancer distribution maps combining pathology data with novel genomic, proteomic, and image biomarkers.

There are several potential shortcomings of the T-RALP that deserve mention. First, there is no interconnection between the daVinci system and the TRUS Robot. The communication between these 2 systems can be implemented in the future to allow the ultrasound navigation images to be visible as a part of multiple input display in the daVinci surgeon console (TilePro). This improvement will allow the surgeon to complete the surgery without toggling between the daVinci and TRUS monitors. Second, some have questioned the validity of the NVB as a distinct anatomic structure.^{19,20} For example, Kiyoshima et al observed true neurovascular bundles in the posterolateral region of the prostate in only half of the non-nerve-sparing radical prostatectomy specimens.²⁰ In the other half, they noted larger vessels and nerve trunks dispersed in the posterolateral region without an obvious bundle formation.²⁰ Therefore, the preservation of the blood vessels in the posterolateral region of the prostate should still serve as a surrogate for the preservation of the cavernous nerve in the T-RALP, regardless of the obvious "bundle" formation. Third, improvement is needed to quickly generate 3-D registration images so that a surgeon can potentially use an overlay image of the prostate and NVB in real time, yet the efficiency of the overlay modality will have to be determined. We are performing a NIH/NCI-funded quick trial to study the efficacy and safety of the T-RALP approach.

We plan to address these potential problems associated with T-RALP in this quick trial. In addition, we will evaluate the T-RALP by measuring image-to-real distances of prostatic landmarks, measuring the distance between the expected versus imaged locations of neurovascular bundles (NVB), and quantifying the incidence of associated complications, including rectal injury.

CONCLUSIONS

In conclusion, the current feasibility study of T-RALP demonstrated promising results for the proposed navigation system. The tandem robot approach was feasible and no interference between the 2 robots was observed. Using the TRUS Robot, intraoperative transrectal ultrasound imaging is possible even within the constraints of the daVinci robot and the prostate can be scanned by sweeping the gland with rotary ultrasound images acquired. The 3-D prostate images can be reconstructed from these rotary slices and the daVinci instruments can be clearly visible in the TRUS images. Finally, no associated complications related to the device were encountered. Additional studies are needed to prove clinical benefit of T-RALP.

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EDITORIAL COMMENT

For many years, surgeons have been trying to use real-time transrectal ultrasonography to enhance intra-operative imaging of the neurovascular bundles.¹ Manipulation of a rectal probe is cumbersome, however, when the da Vinci robot is used. Han and colleagues present an elegant approach demonstrating the use of a robotic arm to hold the ultrasound probe. In a small group of patients, the feasibility of this approach was tested. What remains to be seen is whether this will improve outcomes of erectile function. The theoretical basis for such an improvement is that the neurovascular bundles are 2 distinct structures, the vascular components of which can be identified with ultrasound, helping the surgeon to avoid damaging these structures. The concept that the neurovascular bundles are 2 distinct anatomic structures was based on limited cadaveric dissection, however. There is accumulating evidence that there is variability in nerve distribution and that, in many patients, the nerves responsible for erectile function are not found exclusively within this putative neurovascular bundle.^{2,3} Kiyoshima et al.³ and Eichelberg et al.² have noted and shown that there is a network or “curtain” of nerves on the lateral surface of the prostatic capsule in many patients. Although these studies do not address the physiological role of these nerves, there is clinical evidence of superior rates of erectile function when this tissue preserved, and even the surgeon who first described the neurovascular bundles has modified his surgical technique.⁴⁻⁷ In addition, most surgeons experienced in minimally invasive surgery are easily able to preserve the putative neurovascular bundles without the requirement for intraoperative ultrasonography. Thus, it remains to be seen whether intraoperative real-time ultrasonography will improve functional results.