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Robotic needle guide for prostate brachytherapy: Clinical testing of feasibility and performance

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ABSTRACT

PURPOSE: Optimization of prostate brachytherapy is constrained by tissue deflection of needles and fixed spacing of template holes. We developed and clinically tested a robotic guide toward the goal of allowing greater freedom of needle placement.

METHODS AND MATERIALS: The robot consists of a small tubular needle guide attached to a robotically controlled arm. The apparatus is mounted and calibrated to operate in the same coordinate frame as a standard template. Translation in x and y directions over the perineum ± 40 mm are possible. Needle insertion is performed manually.

RESULTS: Five patients were treated in an institutional review board-approved study. Confirmatory measurements of robotic movements for initial 3 patients using infrared tracking showed mean error of 0.489 mm (standard deviation, 0.328 mm). Fine adjustments in needle positioning were possible when tissue deflection was encountered; adjustments were performed in 54 (30.2%) of 179 needles placed, with 36 (20.1%) of 179 adjustments of >2 mm. Twenty-seven insertions were intentionally altered to positions between the standard template grid to improve the dosimetric plan or avoid structures such as pubic bone and blood vessels.

CONCLUSIONS: Robotic needle positioning provided a means of compensating for needle deflections and the ability to intentionally place needles into areas between the standard template holes. To our knowledge, these results represent the first clinical testing of such a system. Future work will be incorporation of direct control of the robot by the physician, adding software algorithms to help avoid robot collisions with the ultrasound, and testing the angulation capability in the clinical setting. © 2011 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

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Introduction

Permanent interstitial brachytherapy is a commonly used modality for the treatment of localized prostate cancer. Although the methodology of brachytherapy has been refined since the development of the transperineal approach, many of the general techniques remain unchanged. One example is the continued use of a template with parallel needle guidance holes spaced 5 mm apart along the *x* and *y* axes, which are calibrated to a grid superimposed on the ultrasound image to allow reasonably precise placement of the needles into a desired location in the prostate. However, in many instances the needle is deflected along its path of penetration through

the tissue, creating a deviation from its intended placement site (1-3). The resultant deviation in seed placement may create an alteration in the dose distribution. Alternatively, the needle may be removed and replaced in the desired position by manually "steering" the needle (if using a beveled needle), bending the needle, or using a device to deflect the needle as it emerges on the distal end of the template before it enters the patient (4,5). Such efforts increase the number of needle insertions and tissue trauma, with resultant exacerbation of urinary symptoms (6,7).

Another problem frequently encountered in brachytherapy is pubic arch interference. Although extended lithotomy positioning is a potential method to circumvent this issue to varying extents, not all patients are amenable to such maneuvers, and androgen deprivation may be required to downsize the prostate (8). In addition, because of the anterior curvature of the rectum near the anus, extended lithotomy positioning may result in penetration of the rectum by needles targeted at the posterior prostate.

We proposed to construct and clinically test a robotic needle guide that would allow greater adjustability of needle positioning and the future potential for needle angulation to avoid structures such as the pubic arch or urethra. Herein, we describe an initial study performed to assess the feasibility of a compact stepper-mounted robotic assist device.

Methods and materials

The device was designed and manufactured by PROFAC-TOR Research and Solutions GmbH (Seibersdorf, Austria) based on specifications from our institution. Figure 1a is a schematic image of the device mounted onto a conventional stepper apparatus; Fig. 1b depicts the device with the ultrasound probe in a prostate phantom. Comprehensive engineering specifications have been previously described in detail (9). Briefly, the robot assist device consists of two Cartesian stages (xy and $\alpha\beta$), where the $\alpha\beta$ stage is mounted on the xy stage. Each stage contains two computer-controlled motors with integrated incremental encoders (Maxon RE10, Sachseln, Switzerland) that drive linear ball screws of 3 mm diameter and 1 mm lead. Redundant position measurements are provided by linear incremental encoders with 10 µm resolution (Renishaw RGH34, Gloucestershire, UK). The initial (home) position of each motor is defined by a home switch. The two stages produce motions of two arms, which together hold the ends of an aluminum tube that serves as the needle guide and accommodates an 18-G implant needle. The needle guide tube is held by ball-and-socket type joints such that the tube can swivel in relation to the robotic arms, allowing for angulation of the needle. Moving the xy stage translates both arms (because the second $\alpha\beta$ stage is mounted on the first), thereby changing the needle guide position. Moving just the $\alpha\beta$ stage causes the second arm to move relative to the first, thereby changing the needle guide angulation. The entire apparatus mounts onto the ultrasound stepper

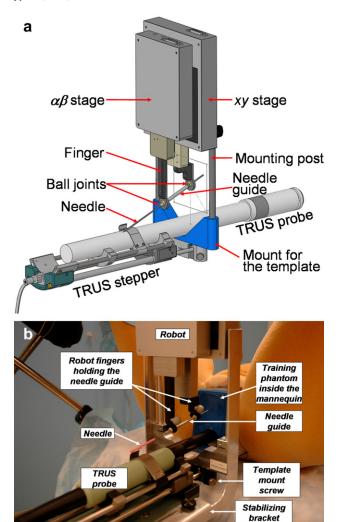


Fig. 1. (a) Computer-generated image of robot positioner mounted onto stepper with ultrasound probe, with depiction of xy and $\alpha\beta$ stages. (b) Photograph of robot positioner on stepper with ultrasound probe in phantom.

device where the posts of the standard transperineal template would normally attach. Given the increased weight of the unit compared with a standard template, stabilizing brackets were also fabricated to attach the robot sides to the sides of the stepper for enhanced stability relative to the ultrasound imaging probe. Calibration of the robot to the ultrasound unit was performed using guide needles located in a water bath, using the method as described in American Association of Physicists in Medicine Task Group report 128 (10). Software code for control of the robotic guide movement and a graphical user interface (GUI) was developed to run on the same laptop as the dosimetry planning software (Interplant version 3.3, Computerized Medical Systems, St Louis, MO).

A prospective pilot study for clinical testing was approved by the institutional review board. For simplification, the clinical protocol allowed for translational movement in the *x* and *y* directions only, and did not test the

capability for angulation of the needle guide. The purpose of the study was to test the clinical feasibility and ergonomics of using the device within an actual operating room environment. In addition, we sought to assess the potential value of the robot's ability to make fine systematic and random adjustments in needle insertion position to accommodate the effects of tissue deflection.

In preclinical testing, the robot had preneedle-insertion transverse errors (measured with a Polaris optical tracker relative to the template's coordinate frame) of 0.25 mm (standard deviation [STD] = 0.17 mm). Ultrasound measurements of needle tips inserted into phantoms showed errors of 1.04 mm (STD = 0.50 mm) (8). For purposes of assuring patient safety, a Polaris infrared tracking and guidance system (NDI, Waterloo, ON) was used for the first 3 patients to potentially identify any incorrect positioning of the robotic guide before needle insertion. The tracker was calibrated to the coordinate space of the template, then the template removed and the robotic guide placed; optical reflectors placed on each of the robot arms allowed direct determination of the robotic guide's positioning. In the unexpected event that a robotic movement error ≥ 3 mm were to be identified in either absolute x or y direction, then notification was to be given to the physician before needle insertion.

An intraoperative dosimetry method was used for treatment planning. In brief, the patient was anesthetized and placed in the lithotomy position. After catheter placement, transrectal ultrasound images were acquired at 5 mm increments then the organs of interest contoured. The ultrasound images were spatially registered to the implant software grid in typical fashion. A treatment plan was generated manually by the physician, and needles then placed and loaded one at a time using a Mick applicator. During the implant procedure, the physician would communicate to the physicist the needle to be placed, and the physicist would then identify the needle in the Interplant system. The Interplant software was previously modified such that the robot would automatically move to the appropriate position on identification of the needle to be inserted.

The physician then placed the needle through the needle guide, while visually confirming acceptable needle position on the real-time ultrasound image. Depth of the needle placement was controlled manually. Nonbeveled, trocar point (Mick) needles were used. One-time, needle-specific adjustments were made if the visualized needle position on ultrasound was >3 mm off the planned location relative to the ultrasound grid in absolute x or y direction, or as deemed clinically necessary because of changes in anatomy such as edema. For any such manual adjustments, the physicist would use the GUI to move the robotic positioner in the appropriate x or y direction. If repeated errors toward a given direction were noted, then a systematic adjustment could be made to change the registration of the robot to the ultrasound in a particular direction whereby all subsequent robotic movements were modified to counteract the observed deviation. Real-time dosimetry based on needle

trajectory in the ultrasound images (transverse and longitudinal) was used to allow intraoperative estimation of dose (11). To explore whether depth of the needle insertion or patient variation correlated with the need for needle adjustments, a random-effects model was applied to explore the correlation between depth of the needle placed vs. needle deviation vector (defined as a square root of sum of squares for x and y). In this model, patient was included as a random effect, whereas depth as a fixed effect.

Results

Five patients were enrolled and treated using the system. The robotic needle guide functioned as planned for all the patients, although some minor modifications had to be incorporated after the initial experience. For the first patient treated, the length of the needle guide tube resulted in the inability to completely reach the base of the prostate because the hub of the Mick needle (20 cm length) would abut the end of the tube before reaching the base. Thus, after the placement of seeds in all the planes other than the base, the robot had to be replaced with the regular template to implant the seeds in the base plane. This problem did not occur for the second patient, who was treated on the same day, because his prostate was smaller. For the remaining three cases, we modified the needle guidance tube by shortening it 2 cm on the end facing the user (requiring a minor modification of the robotic arm on that end), and there were no further problems with reaching the prostate base. We also quickly learned that the robotic arms and needle tube had the potential to collide with the ultrasound probe if moved across the center of the prostate along the posterior-most grid row. The order of the needle placement was subsequently modified to avoid moving laterally across this area and no further collisions were encountered. Overall, these were minor issues and the system performed to meet clinical needs and expectations. With regard to intraoperative time, the duration of the implant (from initiation of anesthesia to completion of procedure) ranged from 104 to 159 min (median, 133). This was not statistically different when compared with a cohort of 21 consecutive patients treated with a standard template during the same period of time that the trial was open (range, 70–191 min; median, 121 min; p = 0.58).

When measuring accuracy of the robotic arm movements, the Polaris tracking system confirmed that robotic needle guide movement was performed with submillimeter errors (mean error, 0.49 mm; standard deviation, 0.33 mm). We chose to discontinue use of the Polaris after the first three cases because of the effort and room space required for setup (although the equipment did not obstruct the Polaris' line of sight) and the lack of any significant errors found in the measurements. Despite the accuracy of the robotic movements, at times the needle tip in tissue was seen on the ultrasound image to vary from the intended

location on the grid. This finding, attributed to tissue deflection of the needle, has also been observed by others during the implant process (1-3, 8). In these instances, the physician was able to use the robot to make an adjustment to offset the effect of the tissue deflection.

A systematic adjustment of robotic positioning was used in three cases (range, 2-3 mm in x direction and 2-4 mm in y direction, Patients B, C, D in Fig. 2). These were made if after placement of the first few needles the physician noticed a systematic tendency toward a given direction and felt that a systematic adjustment would result in fewer subsequent individual needle adjustments needed. Otherwise, one-time adjustments in various directions were performed in 54 (30.2%) out of 179 needles, with 36 (20.1%) of those adjustments >2 mm. Results of the analysis of insertion depth vs. adjustment vector showed the estimated intraclass correlation coefficient was 0.040, that is, approximately 4% of the variance in vector measurements was explained by patient variation, suggesting that patient variation was small relative to the variation because of needles. However, the data did not suggest a statistically significant correlation between vector and depth (p = 0.353). There was also no pattern of reinsertions occurring at a given relative time during each case (beginning, middle, or end). Figures 2a-e show the final seed locations and directions of the needle deflections, superimposed onto a standard template grid. Also shown are instances when needles were intentionally placed at intervals between the normal planned spacing intervals (i.e., between the holes available on a standard template). For Patient A, this was done because of deformation of the prostate, which occurred for the most posteriorly located row of needles. When these needles were placed in their original planned positions, the needle tip ended up very close to or within the rectal wall. Therefore, the physician decided to move the robotic needle guide away from the rectum, and the seeds were placed such that on tissue (prostate) relaxation they were in their intended positions within tissue. The robot was also used to adjust one needle because of pubic arch interference (Patient C, needle f3). Two needles were adjusted (Patient D, needle a2.5 and Patient E, needle e2) because of indications that the needle was in a blood vessel. In these instances, the robot was used for positional adjustments of ~3 mm, to minimize any alteration of the dosimetric plan.

Discussion

The concept of a robotic needle guidance device for prostate brachytherapy is not entirely novel. Several groups have described preclinical development of robotic needle-positioning devices. Some proposed uses of such robots are to allow treatment planning, which is not confined to the standard 5-mm spacing of a fixed template, and to allow the possibility of angled needles for avoiding the pubic arch (12, 13). Some of these robots (such as the one used in our

study) serve to position a guide for subsequent manual needle insertion; others are designed to position and drive the needle into tissue. An example of the former type of robot is the one described by Wei *et al.* (12), who calibrated a commercially available robot having 6 degrees of freedom to a three-dimensional transrectal ultrasound, which they developed in their laboratory. The robot is used to position and orient a single-hole template through which a needle is inserted manually.

Examples of robots which both position and drive the needle include that of Yu et al. (13), composed of a 2 degree-of-freedom ultrasound probe driver, 3 degree-offreedom gantry, 2 degree-of-freedom needle driver, automated seed pusher, and a control pendent for remote control. Another group led by Waspe et al. developed a needle-positioning robot for image-guided interventions in small animals. The device has two rotational axes (pitch and roll) to control needle orientation, and one linear axis to perform needle insertion; the 3 axes intersect at a point to create a remote center of motion that acts as a fulcrum for the orientation of the needle (14). Stoianovici et al. have developed a pneumatically driven, fully MRI-compatible robot that can be used for a variety of image-guided, needle-based interventions including prostate brachytherapy. With this robot, seed delivery is also performed using pneumatics (15). Another MRI-compatible robot, developed by Lagerburg et al., is unique in that it uses a method of repetitive "taps" to insert the needle into tissue to overcome and/ or minimize prostate deformation (16).

To our knowledge, ours is the first clinical trial using a prostate brachytherapy robot on patients. In this study, we demonstrated the clinical feasibility of a robotic needle positioner for use in permanent prostate brachytherapy, and the first implementation of a small compact robot, which mounts in the same manner as a conventional template guide. Our experience suggests some ways in which such a robot may be clinically useful, namely to perform <5 mm movements to correct for tissue deflection and/or deformation, adjust seed positions based on real-time dosimetry feedback, and avoid structures such as rectum, pubic arch, and blood vessels. Our experience does not allow for conclusions as to the impact of the robot on dosimetric outcomes or toxicity, as this was not the intent of this pilot study.

We calibrated the position of the robot relative to the ultrasound using a standard water bath/needle immersion procedure, but at times systematic adjustments were still required at the beginning of the procedures. Given the weight of the robot (1499 vs. 269 g for standard template), one potential explanation is that the weight of the robot created increased gravitational strain on the template holder. We created and attached custom-made brackets from the robot to the stepper apparatus, but it is possible that this did not completely prevent such effects. However, systematic adjustments for any miscalibration were easily performed. One might argue that extremely precise

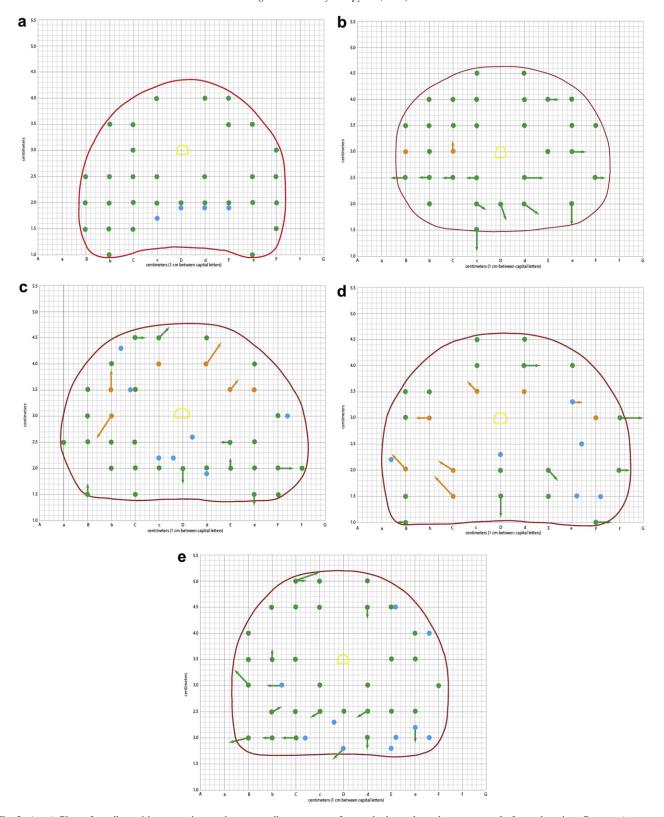


Fig. 2. (a—e) Plots of needle positions superimposed onto coordinate pattern of a standard template, shown separately for each patient. Prostate (as seen at midgland) is depicted in red, urethra in yellow. Dots show planned/final needle position, whereas tips of arrows depict initial needle placement before correction. Orange is used to depict needles placed before systematic correction (if performed), green depicts those placed after systematic correction. Blue depicts needles placed intentionally at irregular intervals, that is, between standard template holes. Note that for Patient A, posterior row of needles was altered because of tissue deformation; blue dots reflect needle position at time of placement, whereas tissue relaxation after needle removal resulted in a more posterior final seed position. Patient E had two needles placed at separate times, first near the base and later at the midgland for position C5.0.

preoperative systematic calibration becomes somewhat less important given the ability to perform intraoperative adjustment of calibration with the robot.

Even with systematic adjustments, there were still needles, which at depth were deviated from their intended placement. Given that the Polaris measurements of relative robotic movement before needle insertion confirmed accurate movements to within 1 mm, we interpreted these deviations to be because of tissue-caused deflection. The variable direction and intermittent nature of these deviations argue against a systematic calibration error being responsible (see Figs. 2a-e). Notably, no needles were deflected in Patient A (see Fig. 2a), whereas 44% of needles required repositioning in Patient B (Fig. 2b). The observed variability of needle deflection among our patients and among different sites within an individual prostate is concordant with the variability in prostate resistance to needle insertion noted by Lagerburg et al. (16). It should be noted that the measurements of needle deflection are subject to the error inherent to measuring the needle tip on ultrasound because of the thickness of the needle and the resolution of the image. Multiple acoustic reflections may also blur the point resolution of the needle. Work by Ding et al. (17) demonstrated that needle segmentation has an accuracy of 0.6 mm in position and 1.0 degrees in orientation. The magnitude of ultrasound measurement errors are less than those of our observed needle deflections, but should be considered when reviewing these results.

Because the measurements of needle position were taken relative to the ultrasound grid and not the prostate itself, any movement of patient position or prostate relative to the robot (although they were not observed to occur) would not have impacted on our findings. We did not use stabilization needles because they would have interfered with the robot. However, we note that these deflections were observed at the time of initial penetration rather than occurring after relaxation of the tissues, which argues against prostatic rotation "pushing" the needles after placement. A potential method of overcoming needle deflection is to rotate the needle during insertion, as described in work by Meltsner et al. (18) and Wan et al. (1). Another consideration is that force exerted by the operator's hand on the needle and robotic guide during the process of insertion may cause a disturbance or perturbation of the needle path. Thus, it may be difficult to separate any potential robot error from that induced by the operator, and difficult to compare our findings with those observed during use of conventional fixed template-based procedure, although one would expect the same forces to be possible in the latter situation as well.

The capability for direct user manipulation and adjustment of the robot is critical for successful intraoperative implementation, with the bonus of increased flexibility in determining eventual exact needle position. Indeed, if tissue deflection of needles is frequent, one advantage of a robotic needle positioner is the ability to make fine positional adjustments to offset deflections. Other potential advantages are that the robot allowed for fine adjustments in needle/seed positioning, which we used at times to achieve insertion points between the standard template positions. We found this to be particularly useful toward the end of the procedure if real-time ultrasound dosimetry revealed gaps of dose where one or two precisely placed seeds were needed. In 1 patient, this feature was also used to adjust for tissue deformation at the prostate/rectal interface, otherwise the seeds would have been too close to the rectum. Although not part of our study, it may also be feasible to use continuum spacing with inverse optimization to create more conformal treatment plans, and reduce the number of needles required for a given target volume. However, confirmation and/or measurement of the magnitude of these effects requires further investigation.

One feature of our system is that the robot and template are interchangeable during the procedure, as they are mounted in the same location and are calibrated to operate in the same coordinate frame. If the need arises, the physician can revert to the conventional template without major interruption. This feature was used in our first case (when the needles were not able to reach the base). The procedure was paused, the robot detached from the base, a sterilized template inserted, and the procedure promptly resumed.

From an ergonomic standpoint, the physician interaction with the robot led to some subjective observations. One was that the need to relay changes in robot position verbally to a person controlling the software was cumbersome. A related issue was that the lack of direct, real-time control meant that there was the possibility of a collision of the needle guide with the ultrasound probe, because the desired adjustment was entered as x, y values and then the robot moved to the specific position. To address these concerns, we plan to incorporate an interface allowing direct physician control of template movement, and software prediction to help with avoidance of collisions with the ultrasound probe. In its current state, our robotic needle guide may be used with a preplanned or intraoperative dosimetry technique (11). An optical encoder may be incorporated to assist in monitoring the depth of needle placement, as described in work by Seidl et al. (19). Future plans also include testing of the angulation capability and modification of the robot to allow a real-time dosimetry technique in which most or all of the needles are placed before plan optimization (20). Further clinical trials are warranted to validate and quantify these and other potential benefits derived from using robots in brachytherapy.

Conclusions

Robotic needle positioning provided a means of compensating for needle deflections and the ability to intentionally place needles into areas between the standard template holes. To our knowledge, these results represent the first clinical testing of such a system. Future work will

be incorporation of direct control of the robot by the physician, adding software algorithms to help avoid robot collisions with the ultrasound, and testing the angulation capability in the clinical setting.

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