



Dosimetric benefits and preclinical performance of steerable needles in HDR prostate brachytherapy

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ABSTRACT

Prostate cancer patients with an enlarged prostate and/or excessive pubic arch interference (PAI) are generally considered non-eligible for high-dose-rate (HDR) brachytherapy (BT). Steerable needles have been developed to make these patients eligible again. This study aims to validate the dosimetric impact and performance of steerable needles within the conventional clinical setting.

HDR BT treatment plans were generated, needle implantations were performed in a prostate phantom, with prostate volume > 55 cm³ and excessive PAI of 10 mm, and pre- and post-implant dosimetry were compared considering the dosimetric constraints: prostate V₁₀₀ > 95 % (13.50 Gy), urethra D_{0.1cm}³ < 115 % (15.53 Gy) and rectum D_{1cm}³ < 75 % (10.13 Gy).

The inclusion of steerable needles resulted in a notable enhancement of the dose distribution and prostate V₁₀₀ compared to treatment plans exclusively employing rigid needles to address PAI. Furthermore, the steerable needle plan demonstrated better agreement between pre- and post-implant dosimetry (prostate V₁₀₀: 96.24 % vs. 93.74 %) compared to the rigid needle plans (79.13 % vs. 72.86 % and 87.70 % vs. 81.76 %), with no major changes in the clinical workflow and no changes in the clinical set-up.

The steerable needle approach allows for more flexibility in needle positioning, ensuring a highly conformal dose distribution, and hence, HDR BT is a feasible treatment option again for prostate cancer patients with an enlarged prostate and/or excessive PAI.

1. Introduction

High-dose-rate (HDR) brachytherapy (BT) for prostate cancer patients enables optimization of the dose distribution in the target volume. This is achieved through on-line adjustments of dwell times and dwell positions, resulting in excellent clinical outcomes [1]. However, certain challenges persist, including: 1) pubic arch interference (PAI), 2) too wide prostates, and 3) lesions ventral to the urethra. These situations may result in either underdosage of the target volume or excluding the patient and pursuing another therapy. Current clinical guidelines prescribe that a prostate volume (V_p) of > 50–60 cm³ requires special attention due to the risk of PAI affecting the anterolateral portion of the prostate [2,3]. To reduce the risk of encountering PAI during needle insertion, V_p is calculated prior to the procedure on the MRI, CT or ultrasound scan. This calculation employs an elliptical approximation

formula: $V_p \text{ (cm}^3\text{)} = \pi/6 \text{ (height} \times \text{width} \times \text{length of the prostate)}$ [4]. However, the volume calculation can be faulty, and an enlarged prostate is not necessarily a harbinger for PAI. This method potentially excludes eligible patients from this beneficial treatment option [5,6].

At our institution^(b), patients with a V_p ranging from 50 to 60 cm³, without any contraindications, may be admitted if no PAI is expected. To assess the risk of encountering PAI, a digital rotation of the segmented pelvis and prostate is performed using the preoperative 3D imaging set, simulating the lithotomy position of the patient [7]. However, this method lacks established guidelines, and discrepancies arise due to interpatient and interobserver variability. Occasionally, the implantation procedure must be aborted because of significant inaccessibility of the target volume. These patients require another curative treatment such as stereotactic body radiation therapy, e.g. using CyberKnife [8,9]. This introduces additional costs for the healthcare system and a

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considerable mental and physical burden on the patient.

As mentioned in [2] a widely employed approach to minimize the risk of PAI and enhance access to the prostate is by downsizing the prostate through a course of androgen deprivation therapy (ADT). However, in low and favorable intermediate risk ADT gives no clinical or biochemical control benefit and this 3–12-month therapy can be associated with a decrease in quality of life and the potential for increased (cardiac) morbidity and mortality. Therefore care should be taken when using ADT for the sole benefit of prostate volume reduction [2,10]. Alternative solutions include adjustments to the clinical set-up, workflow or patient positioning, but these may not always be practical or desired [11].

To address these challenges, we propose the use of specially developed steerable needles, offering enhanced flexibility in needle positioning [12]. Using these steerable needles, curved trajectories can be created and PAI can be overcome to obtain a conformal dose distribution in the prostate. This can be achieved without requiring prior PAI risk assessments or any adaptations to the clinical set-up.

The aims of this work are twofold: firstly, to validate the dosimetric consequences of using steerable needles on a non-eligible HDR prostate BT case; and secondly, to assess the feasibility of using the steerable needles in the conventional HDR BT setting. The study entails a treatment planning investigation utilizing the Oncentra Prostate Treatment Planning System (TPS) (Elekta Instrument AB, Stockholm, Sweden). An anthropomorphic prostate phantom is developed and employed for the planning study, followed by actual needle implantations to evaluate performance, dosimetric parameters, and clinical workflow. If

conformal dosimetry is obtained by using steerable needles, exclusion of such patients from HDR BT could be unnecessary and preoperative ADT for prostate downsizing could be avoided in men with enlarged prostates and/or excessive PAI.

2. Materials and methods

A dataset was selected from the anonymized MRI patient database with enlarged prostates ($V_p > 55 \text{ cm}^3$) [7]. This dataset served as the basis for the development of a prostate phantom, which incorporated the average PAI of the patient database (10 mm). A comprehensive study encompassing treatment planning and evaluation of the implantation procedure was conducted. This study compared the conventional procedure employing rigid needles to the proposed approach that incorporated both rigid and steerable needles.

2.1. Study set-up

Treatment planning and needle implantations followed our current clinical HDR prostate BT protocol, utilizing the developed phantom, novel steerable needles, real-time transrectal ultrasound (TRUS) visualization, and the established clinical treatment planning and optimization protocol (Fig. 1). The steerable needle comprises of a 245 mm stainless spring steel (AISI 301) steerable inner obturator, placed inside a 240 mm flexible polyoxymethylene (POM) ProGuide sharp, conical shaped, 6F needle (Elekta Instrument AB, Stockholm, Sweden). The design of the steerable inner obturators is based on the steering principle

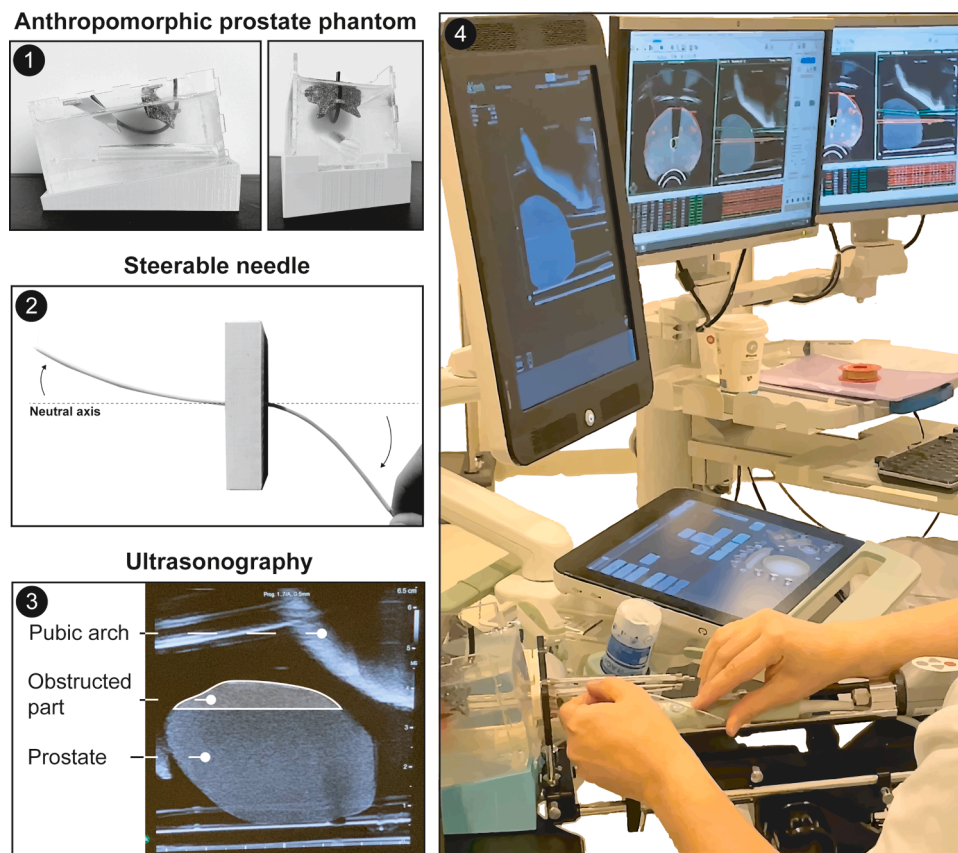


Fig. 1. The clinical set-up. 1) The anthropomorphic prostate phantom, placed on a 10° wedge to mimic patient's lithotomy position with the rectum parallel to the implanting direction to ensure proper ultrasound visualization, 2) The steerable needle, steered from the neutral axis by bending the proximal end, 3) The prostate and the pubic arch, visualized by using transrectal ultrasound (TRUS) imaging in a sagittal plane. The obstructed part of the prostate is outlined. 4) The overall set-up. The steerable needle is inserted in the prostate phantom by the physician under TRUS guidance. The equipment included rigid needles, comprising of 240 mm ProGuide sharp 6F needles and the 245 mm ProGuide Obturators, Oncentra Prostate TPS, OncoSelect Stepper and Endo-Cavity Rotational Mover, Martinez prostate transperineal template (Elekta Instrument AB, Stockholm, Sweden) and the multiplane 9 MHz TRUS transducer (E14CL4b) connected to the bkSpecto Ultrasound Machine (BK Medical, Nærum, Denmark).

described in de Vries et al. where proximal bending of the steerable needle allows distal tip steering over 360° in the axial plane [12]. This design serves two purposes: 1) to circumvent intermediate anatomical and sensitive structures and 2) to counteract unwanted deflections during a controlled insertion by utilizing the transperineal template as a pivot point.

2.1.1. Prostate phantom

A novel prostate phantom was developed because the commercially available prostate phantoms only replicate anatomical structures and provide contrast for multi-modality imaging. For the present study, the phantom needed to possess realistic mechanical properties to mimic instrument insertions and incorporate a pubic arch obstruction, reflecting the average PAI observed in the patient database. PAI was measured in an axial plane in terms of the greatest perpendicular overlap distance from the caudal edge of the pubic arch to the ventral prostate border, as indicated by de Vries et al. [7]. Two phantoms were produced, aiming for similarity to each other and mimicking the patient’s anatomy, including the prostate gland, pubic arch and the organs at risk (OARs) comprising of the rectum and the urethra. These

phantoms were fabricated from polyvinyl alcohol (PVA) as this biomaterial exhibits similar microstructure and mechanical properties as that of human soft tissue [13]. Slight variations resulted in the first phantom used for the treatment planning study having a V_p of 57.2 cm³, while the second phantom, employed in the implantation study, had a V_p of 59.3 cm³. The prostate tissue simulant contained 7 wt. % polyvinyl alcohol (PVA, Sigma-Aldrich, St. Louis, Missouri, United States) with a compressive modulus of elasticity of 54.6 ± 4.6 kPa after two freeze-thaw cycles (FTCs) in line with real prostate tissue (58.8 ± 8.2 kPa) and the prostate phantom developed by Shaaer et al. [14,15]. The prostate tissue simulant was embedded in a PVA solution with 6 wt. % with one FTC completed (29.4 ± 1.2 kPa). PVA was solved in 20 % demineralized water (Orphi Farma B.V., Dordrecht, the Netherlands) and 80 % dimethyl sulfoxide (DMSO 99.7+ %, Laboratorium Discounter, IJmuiden, the Netherlands) to form a transparent suspension for the prostate and the surrounding tissue [16]. Needle-tissue interaction forces in the phantom were considered comparable to clinical use by the physicians (MC & KV). To visually distinguish the prostate gland, 0.05 ml of contrast fluid (Food color, Tasty me, Tilburg, the Netherlands) was added to the prostate tissue suspension, while 3 wt. %

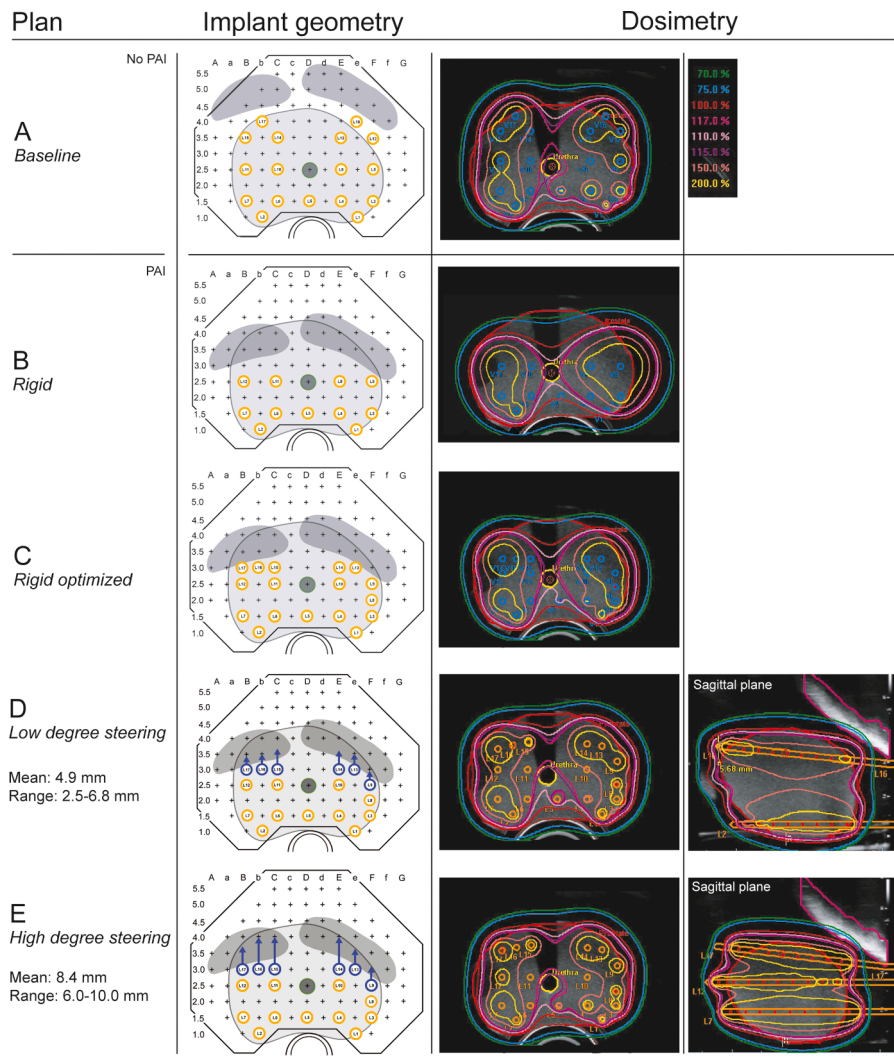


Fig. 2. Treatment planning study. Column 2 presents the implant geometry for each plan in the reference plane on the projection of the Martinez prostate transperineal template (Elekta Instrument AB, Stockholm, Sweden). Column 3 shows the corresponding dosimetry. Column 4 displays the curved trajectories for plans D and E around the pubic arch in a sagittal plane and the legend of the isodose lines. Plan A is the baseline plan with no pubic arch interference (PAI). Plans B-E show obstruction of the prostate due to PAI. Steerable needles are indicated in blue, vectors show the degree and direction of steering, and rigid needles are indicated in orange in column 2. The mean and range of distal tip steering with steerable needles are indicated in column 1. Other colors in column 2: light grey = prostate tissue, dark grey = pubic arch and green = urethra. [Color online].

of silica particles (Silica gel 60 0.015–0.040 mm, Merck KGaA, Darmstadt, Germany) was used for acoustic scattering on the ultrasound visualization [17]. The pubic arch was 3D-printed with polylactic acid (PLA) plastic and coated with metal particles for ultrasonography.

2.2. Treatment planning study

Five pre-implant treatment plans were created for HDR BT monotherapy using the Flexitron afterloader (Elekta Instrument AB, Stockholm, Sweden) (Fig. 2). These plans involved delineating the target volume, the pubic arch and the OARs using TRUS images. The implant geometry was designed based on the implantation pattern from Mate et al. to cover the entire prostate [18].

Plan A represented a treatment scenario for a patient without PAI, making this case eligible for HDR prostate BT. This plan served as the baseline plan including 17 rigid needles, aligning with the simulation study of Kolkman-Deurloo et al. [19]. Plans B, C, D and E simulated a case with PAI. Plans B and C exclusively employed rigid needles. In plan B, six rigid needles were removed from plan A as they were virtually located within the obstructed region of the prostate. Compared to plan B, plan C introduced six rigid needles to the accessible part of the prostate, specifically in the ventral area to optimize the treatment plan.

Plans D and E took a different approach by replacing those six rigid needles with six curved source trajectories, reflecting the steerable needles to reach the ventral region of the prostate behind the pubic arch. This was performed at the discretion of the physicians to ensure coverage of the obstructed part of the prostate gland. Planning of the steerable needle trajectories was conducted in the TPS, with one pivot point per trajectory. A ventral steering up to 10 mm was applied after passing below the pubic arch to prevent needle-bone collisions and maintain the intended curved trajectories, in accordance with the principles described by de Vries et al. [12]. Plan E incorporated a higher degree of steering compared to plan D.

Dwell-time optimization was performed using the inverse optimization modality of the Oncentra Prostate software. For HDR BT monotherapy, the prescription dose for the target volume was set at 2×13.5 Gy according to Morton et al. [20]. The dosimetric objectives specified in Table 1, including prostate V_{100} , V_{150} and V_{200} , $D_{0.1\text{cm}}^3$ urethra, $D_{1\text{cm}}^3$ rectum, and the prostate V_{200}/V_{100} ratio, were utilized to assess the quality of the treatment plans via dose-volume histogram (DVH) outcomes. The ratio of prostate V_{200} to V_{100} showed the degree of dose heterogeneity within the treatment plans.

2.3. Implantation study

Needle implantations were carried out in accordance with treatment plans B, C and E by an experienced HDR BT physician (MC) with entry-level experience in the use of the steerable needles after an on-site hands-on training of 20 min. The steerable needle approach with a higher degree of steering (plan E) was performed solely because it yielded better DVH outcomes compared to plan D and training had shown that 10 mm of lateral steering could easily be achieved. Two conventional rigid needles were inserted into the prostate on either side of the urethra (template coordinate C3 and E3) to stabilize the prostate gland in analogy with current practice with prostate stabilization needles.

The implementation of plan E commenced with the physician choosing the needle type and determining the sequence for implantation. In current practice this implies first implanting ventrally located needles for visualization purposes and then implanting more dorsally. For each steerable needle, the planned curved trajectory was displayed, and a selected steerable needle was positioned at the desired template coordinate. While observing the sagittal plane on the ultrasound, the steerable needle was advanced, allowing for steering and making slight retractions as necessary to stay on the intended trajectory and mitigate potential unwanted deflections caused by interactions between the

Table 1 Dose-volume histogram information of the pre- and post-implant treatment plans. Comparison of dosimetry per treatment plan before implantation for all plans and after needle implantation for plans B, C and E. The dose-volume histogram (DVH) information indicates the dosimetric objectives and results. Per plan the amount of pubic arch interference and the type of needles used are reported. Implantation time is stated for plans C and E with 17 needles per type of needle used.

Parameter	Objective	Plan A Baseline		Plan B Rigid		Plan C Rigid optimized		Plan D Low degree steering		Plan E High degree steering	
		Pre-implant treatment plan	Post-implant treatment plan	Pre-implant treatment plan	Post-implant treatment plan	Pre-implant treatment plan	Post-implant treatment plan	Pre-implant treatment plan	Post-implant treatment plan	Pre-implant treatment plan	Post-implant treatment plan
Pubic arch interference		0 mm									
# Rigid needles		17	11	17	11	17	11	11	11	11	11
# Steerable needles		0	0	6	6	6	6	6	6	6	6
DVH information	Prescribed dose										
Prostate	V_{100}	97.00 %	72.86 %	87.70 %	81.76 %	93.54 %	96.24 %	93.54 %	96.24 %	93.74 %	93.74 %
	V_{150}	37.48 %	36.06 %	40.72 %	36.69 %	37.95 %	38.88 %	37.95 %	38.88 %	37.85 %	37.85 %
	V_{200}	13.34 %	21.24 %	18.84 %	18.37 %	15.10 %	13.20 %	15.10 %	13.20 %	16.02 %	16.02 %
	V_{200}/V_{100}	0.14	0.29	0.21	0.22	0.16	0.14	0.16	0.14	0.17	0.17
Urethra	$D_{0.1\text{cm}}^3$	114.71 % (15.49 Gy)	114.89 % (15.51 Gy)	114.71 % (15.49 Gy)	114.89 % (15.51 Gy)	114.61 % (15.47 Gy)	114.61 % (15.47 Gy)	114.61 % (15.47 Gy)	114.61 % (15.47 Gy)	114.89 % (15.51 Gy)	114.89 % (15.51 Gy)
Rectum	$D_{1\text{cm}}^3$	79.87 % (10.13 Gy)	79.37 % (10.72 Gy)	79.64 % (10.75 Gy)	68.92 % (9.30 Gy)	79.74 % (10.77 Gy)	79.73 % (10.76 Gy)	79.74 % (10.77 Gy)	79.73 % (10.76 Gy)	79.70 % (10.80 Gy)	79.70 % (10.80 Gy)
Total implantation time				12 min 48 s							
Rigid needles											6 min 56 s
Steerable needles											10 min 24 s

needle and the tissue. Throughout this procedure, all six steerable needles were tracked by manipulating the TRUS transducer while the live plan setting in Oncentra Prostate was enabled. Subsequently, rigid needles were inserted in pairs on either side of the urethra, and advanced to their designated end positions. This adhered to established practice, ensuring the completion of the implant geometry for plan E. Reconstruction of the implanted needles was performed in Oncentra Prostate TPS as in current practice. Next, six steerable needles were withdrawn from the phantom, leaving behind eleven rigid needles, thus replicating the implant geometry as specified in plan B. Finally, six rigid needles were added to the configuration of plan B to construct the implant geometry of plan C. The quality of the post-implant treatment plans was assessed based on DVH outcomes, and the time taken for each needle type during the implantation procedure was recorded.

3. Results

The pre-implant treatment plans are shown in Fig. 2. Ventral steering was applied over an insertion depth up to 58 mm after passing below the pubic arch.

Table 1 shows an increase up to 17.1 % in prostate V_{100} , which denotes the prostate volume receiving at least 100 % of the prescribed dose, in the pre-implant treatment plans that incorporate steerable needles (D and E), as compared to the plans employing rigid needles (B and C). The dose to the urethra remained below the dose constraint of 115 % in all pre-implant treatment plans. The DVH values in plan E closely resembled the outcomes observed in the baseline plan (A), where PAI was not a consideration. These findings signify an adequate dose coverage in the prostate while minimizing potential harm to the OARs.

The physician successfully implanted all needles, closely adhering to the planned curved trajectories with the steerable needles. There were only minor issues with two of the steerable needles, which were positioned somewhat too medially, resulting in a slight increase in urethral dose. All steerable needles were clearly visible during TRUS imaging, and there was sufficient working space to bend the proximal end of the needles for precise distal tip steering. Fig. 3 shows the implant geometry and post-implant dosimetry of the steerable needle plan E after needle reconstruction. The average implantation time of a steerable needle was 2.5 times longer compared to rigid needles, mainly due to the need for multiple evaluation moments during insertion. Besides, one steerable needle required reinsertion because it deviated more than 3 mm from the planned trajectory within the first 60 mm of insertion, as detected through real-time TRUS imaging. No changes in clinical set-up and no major changes in clinical workflow were required for executing plan E.

After implantation, the steerable needle approach (plan E) had a sufficient prostate V_{100} of 93.74 % and a clinically appropriate dose distribution, indicated by the V_{200}/V_{100} ratio (Table 1). The doses to the OARs were similar to those in the pre-implant treatment plan. In comparison with all other plans, the steerable needle plan demonstrated the

closest adherence to the pre-implant treatment plan. This was attributed to the steerable needles' ability to mitigate undesired deflections, which was not possible with rigid needles. A decrease in prostate V_{100} of 2.5 % was observed in plan E, while the rigid needle plans exhibited a more substantial decrease of ~6 % when comparing post-implant to pre-implant treatment plans.

4. Discussion

This work presents the dosimetric benefits of a steerable needle approach in HDR prostate BT. It assesses the feasibility of planning curved trajectories, implanting the steerable needles according to the treatment plan in the clinical setting, reconstructing the needles and creating a post-implant treatment plan. We simulated a case by a phantom study in which a patient, normally non-eligible for HDR BT due to an enlarged prostate gland and excessive PAI, could effectively undergo treatment using a combination of conventional rigid needles and developed steerable needles. Six steerable needles were introduced, maintaining the same total needle count as in the baseline plan, which did not consider PAI and solely employed rigid needles. The steerable needle approaches showed both improved spatial distribution of all needles and target coverage compared to the rigid needle plans while sparing the OARs. The dosimetry of the steerable needle plan with high degree of steering closely approached the DVH outcomes for the plan without PAI consideration. To the authors knowledge, this is the first study where steerable needles are used in HDR prostate BT to overcome PAI in an anthropomorphic phantom and in which pre- and post-implant dosimetry outcomes are reported.

Two prostate phantoms were developed due to limitations in shelf life, preventing the use of the same model for both treatment planning and implantation phases. A minor difference of 2.1 cm³ in V_p was observed between the phantoms, attributable to possible mold leakage and intraobserver variability. Nevertheless, discrepancies from 4 to 10 % between both phases are common in current practice due to prostate deformations, edema and delineation variability [21,22]. Our phantoms exhibited similarities in volume and elasticity to the phantom developed by Shaaer et al. but are distinguished in two aspects. Firstly, we used heterogeneous PVA, which is a prostate-like material, instead of homogeneous gelatin. Secondly, we incorporated a pubic arch a feature not present in their phantom [15]. Similarly, Ryu et al. developed a 60 cm³ prostate phantom that included a pubic arch, but their model was made of homogeneous agar [23]. Noteworthy is the overdosing of the rectum in all plans. Row 1.0 of the Martinez template could not be placed properly for reaching the dorsal part of the target volume because of the small spacing between rectum and prostate in the phantom. Therefore, caution is advised when interpreting DVH data for the rectum, and future phantom models should consider increasing spacing to reduce rectal dose.

A decrease in target coverage was observed in all plans post-implant,

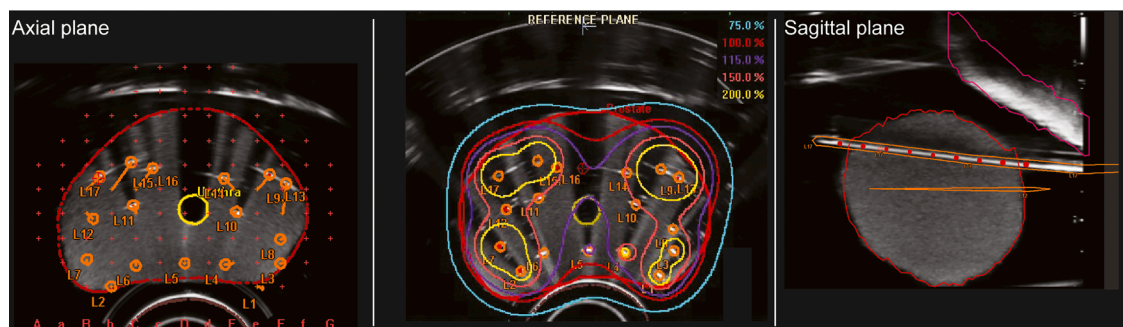


Fig. 3. Implant geometry and post-implant dosimetry of the steerable needle approach (plan E). Left image shows the implant geometry including 11 rigid needles and 6 steerable needles, central image displays the dosimetry and right image visualizes the curved trajectory of one steerable needle which was inserted below the pubic arch and reached the obstructed part of the prostate behind the pubic arch conform the planned curved trajectory indicated in orange. [Color online].

possibly caused by the increase in V_p and unwanted needle deflections during the insertions. Nonetheless, the steerable needle approach demonstrated better adherence to the pre-implant treatment plan. This was attributed to the steerable needles' ability to be controlled during insertion, allowing for precisely following the planned trajectories, which was not possible with the rigid needles. Considering the limited amount of training, this finding implies a steep learning curve for using the steerable needles.

Next to unwanted deflections, inaccessibility of the prostate may only become apparent during the procedure. Various techniques can be applied in such cases, including TRUS transducer angulation, needle manipulations or extending patient's lithotomy position. However, these actions can compromise dose conformity and patient's comfort. As a result, alternative approaches have been explored, such as customized templates with angulated needle paths and non-parallel needle implantations [4,23–27]. Ryu et al. performed a study for low-dose-rate (LDR) BT, using oblique needles in a 60 cm³ prostate phantom, aiming to overcome PAI [23]. Their results were promising, with a prostate V_{100} of 97 %, V_{150} of 41.8 % and V_{200} of 17.1 %. However, 25 needles were required for obtaining this level of dose coverage while sparing the OARs. Gibbons et al. implanted up to seven LDR BT needles free-hand behind the pubic arch in eight patients with a mean V_p of 46 cm³ [4]. Their results showed a prostate V_{100} of 96.3 % and V_{150} of 81.6 %, but they did not investigate dose to the urethra. While these previous studies have shown potential in addressing the challenge, our study stands out as it achieved similar outcomes to these approaches without necessitating significant changes in the clinical set-up [4,23–25]. Only some minor changes to the clinical workflow were required, which were very easy to implement. First, the Oncentra Prostate TPS did not allow for applying smooth curved trajectories in the pre-implant treatment plan setting, thus one pivot point per trajectory was incorporated to simulate a curvature. Secondly, implantation of the steerable needles was performed in the live-plan setting. This may challenge visualization if steering in multiple directions is applied; tilt scanning with TRUS imaging produces 3D images for the live-plan while reconstruction in the TPS is performed in orthogonal planes. Thirdly, the steerable needles were inserted one by one, directly at the planned end position each time, which slightly increased implantation time compared to inserting rigid needles performed in pairs.

For future optimization, steerable needles hold the potential to circumvent the urethra for treatment of ventrally located tumors, treat wider prostates than the transperineal template allows, address small prostates with a narrow pubic arch, avoid the penile bulb and neurovascular bundle, or enhance overall dosimetry outcomes. In case of a targeting error with a rigid needle, reported to be up to 3.8 mm [28], the steerable inner obturator can be employed to mitigate the unwanted deflection without additional tissue damage associated with a full reinsertion. Additionally, steerable needles can be implanted conforming the prostate's geometry. Earlier studies have shown that this approach required 30 % to 80 % fewer needles, and Podder et al. have discussed the potential reduction of edema and urinary incontinence [27,29].

5. Conclusions

The utilization of steerable needles offers increased flexibility in needle positioning, necessitating only minor adjustments to the existing clinical workflow. The curved trajectories can be easily planned in the Oncentra Prostate TPS, and the implantation process can be executed with minimal impact on implantation time, while maintaining excellent agreement between pre- and post-implant treatment plans. This work clearly demonstrates that a highly conformal dose distribution can be achieved using steerable needles, and hence, HDR BT is a feasible treatment option again for prostate cancer patients with enlarged prostates and/or excessive PAI. Importantly, this may eliminate the necessity for preoperative ADT for prostate downsizing. The steerable

needles are ready for implementation in clinical practice with no further developments or investments required.

Ethical approval

Not required.

Declaration of competing interest

The authors declare no conflicts of interest.

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