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Original article

# Clinical feasibility and positional stability of an implanted wired transmitter in a novel electromagnetic positioning system for prostate cancer radiotherapy

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ABSTRACT

*Purpose:* Three aspects of the RayPilot real-time tracking system were investigated: (1) feasibility of the transmitter with respect to implantation and explantation procedures, (2) user and patients' experiences and (3) quantification of the transmitter positional stability in relation to fiducial markers.

*Methods and materials:* Ten prostate cancer patients scheduled for radiotherapy received transmitter implantation in the prostate, concomitantly with fiducial markers. Transmitter and marker positions were assessed in 3D by orthogonal kV-imaging at daily treatment setup in eight patients.

*Results:* The transmitter was successfully implanted in all patients. Patients reported mild to moderate discomfort and impact on daily activities due to the implant but overall subjective tolerability was good. One patient had spontaneous explantation of the transmitter after four fractions. One patient had transmitter 3D shifts >9 mm, but also inter-marker shifts >6 mm. The mean inter-marker shift in the remaining patients was <1 mm. In four patients, maximum transmitter 3D shifts were 5–7 mm (mean >2 mm). In three patients, mean transmitter 3D shifts were <2 mm.

*Conclusions:* Implantation and explantation of the transmitter is generally feasible and safe. Patient tolerability is good overall. However, due to interfractional transmitter positional instability in this cohort, use of the system for real-time tracking should be combined with other daily setup techniques.



The last 10–15 years has seen continuous technological improvement in the field of external beam radiotherapy (EBRT) with curative intent for prostate cancer. The introduction of intensity modulated radiotherapy (IMRT) and more recently volumetric modulated radiotherapy (VMAT) has taken place in parallel with the development of novel methods for image guidance. Image guided radiotherapy (IGRT) has made possible a gradual reduction in doses delivered to surrounding tissues while maintaining or even increasing dose to the target [1,2]. In the treatment of localized prostate cancer, decreasing uncertainties in target localization is dependent on accurate daily setup correction to account for interfractional motion as well as real-time monitoring of intrafractional motion during delivery of treatment.

Previous studies demonstrate that day-to-day variations (interfractional) in prostate position can be considerable in individual patients, indicating a need for daily image guidance in the setup procedure [3–5]. Various image guidance techniques have been developed and are now used to ensure accurate daily setup [4–13]. Several comparisons of setup correction methods have been performed but do not clearly identify a superior technique [13,14]. The magnitude of average intrafractional prostate motion is reported as limited [15,16], although it may be significant in a subset of patients [17–19]. Intrafractional motion has also been shown to be time-dependent with the risk of significant target motion increasing as treatment time is prolonged [19–21]. With the rapid introduction of hypofractionated treatment schedules [22], delivering a larger dose per fraction in fewer total fractions, the case for monitoring intrafractional target motion has increased since such fractions may take longer to deliver and the consequence of geographical misses may be more severe.

In addition to the localization techniques for daily setup presented above, several options for real-time tracking of intrafractional organ motion are available. The Calypso system (Varian Medical Systems, Palo Alto, CA, USA) using permanently implanted electromagnetic transponders was first introduced over a decade ago, providing both target localization and real-time tracking capabilities [23]. More recently, both cine-MRI and transperineal

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four-dimensional ultrasound have been utilized for monitoring intrafractional prostate motion [10,24].

The RayPilot system (Micropos Medical AB, Gothenburg, Sweden) evaluated in this study was developed as a stand-alone system for both target localization and continuous real time tracking without the need of additional X-ray irradiation. The system consists of a treatment table top extension containing a receiving system with an integrated antenna array, a wired transperineally implanted transmitter (removed after treatment completion) connected to the receiver during each fraction and proprietary software for positional analysis and presentation. A detailed technical description has been previously published [25]. In a prior study, the first temporary in vivo testing of the system was also reported, demonstrating high positional system accuracy [26].

In this study, the following aspects of RayPilot system use were evaluated: clinical feasibility of transmitter implantation and explantation, user and patient experience and finally positional stability of the intraprostatic implant in relation to standard fiducial gold markers throughout the full course of EBRT.

## Methods and materials

### *Patient population*

More than twenty patients with localized prostate cancer admitted at our clinic during 2011–2012 for curative EBRT were asked to participate in the study. Ten patients accepted to have the RayPilot transmitter implanted simultaneously with three fiducial markers prior to dose-escalated EBRT (2 Gy daily to 78 Gy). The patient age ranged from 67 to 77 years. Three patients had high-risk cancer while seven had intermediate risk cancer according to the ĎAmico classification. The study was approved by the regional ethical review board (743-09, T 788-1 Ethics committee Gothenburg University). Informed patient consent was obtained prior to transmitter implantation. The patient experiences were registered daily by treatment staff according to a study specific questionnaire, documented in Case report forms (CRF; tenderness, soreness, pain, impact on daily activities etc.) and through the Adverse event form (AE) for events not included in the CRF.

### Treatment procedure and patient protocol

Treatment was delivered in 2 Gy fractions five times weekly for a total dose of 78 Gy over a period of approximately 8 weeks (Clinac iX accelerator, 15 MV, Varian Medical Systems). A 3-field 3DCRT technique with a 7 mm CTV-to-PTV margin was used. Patients were treated in the supine position. Daily setup correction was applied by use of orthogonal kV-imaging (OBI® version 1.5, Varian Medical Systems) in the anterior–posterior (AP) and the right-to-left lateral (RLAT) projections and manual fiducial marker match by treatment room staff according to our standard protocol. The transmitter position compared to the fiducial markers was analyzed separately post treatment and did not influence the treatment of the patient. The additional feature of real time positioning data received from the Micropos RayPilot system was not analyzed in this study.

### Technical description

The RayPilot system was previously technically described [25,26]. In summary, the receiver consists of a flat receiving system positioned and locked in place on the usual linac treatment table (Fig. 1). The receiving antennas are located in an area in correspondence with the patient pelvis. The RayPilot transmitter is 17 mm long by 3 mm wide. The transmitter is implanted in the prostate gland in a subcapsular position. The transmitter is connected to the external receiving system by a coated wire, which passes through the patient perineum. Positional data are then recorded and accessed using the PC-based RayPilot software module.

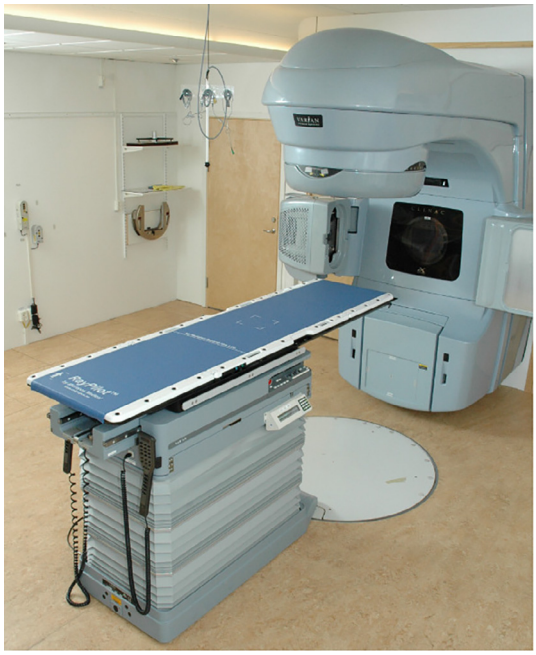

**Fig. 1.** The Raypilot receiving system placed on the treatment table.

### Implantation and explantation procedure

Patients were lightly anesthetized and were posted in footrest. Three fiducial gold markers (Goldlock, 5 mm length/1 mm width) were placed in the prostate under ultrasound guidance transrectally according to local clinical practice. A Chiba needle (0.95 m m × 400 mm) was then used to identify a subcapsular location laterally in one of the prostate lobes. With the patient in footrest, the direction of implantation was performed +15–20 degrees against the horizontal plane in order to achieve a horizontal direction of the transmitter during the EBRT treatment period where the patients are placed in leg fixation. The tolerance was gradually adjusted from the initial ±20 degrees to ±30 degree. When a suitable position was found the Chiba needle was exerted and the Seldinger set aimed to retrieve the same position. At this point the RayPilot transmitter was introduced with the Seldinger device and finally the transmitter would be placed in the prostate. The position of the fiducial markers and the transmitter was verified with planar X-ray images and the transmitter cable was then fixated by skin suture or a short tunnelated route subcutaneously. (No urethral catheter was used but the bladder could be emptied if needed.) The patients usually stayed in the hospital during the night, a few patients went home the same evening. After one week the sutures were removed and a 2D X-ray was performed to check the positions of fiducial markers and transmitter. The dose-planning CT was performed approximately 2 weeks after implantation from which the direction of the transmitter in the treatment position (leg fixation) was evaluated for each patient. Further 1 week later the treatment was started. Patients were scheduled for transmitter removal (explantation) 1–2 days before completion of radiotherapy since most of the patients traveled long range and were relieved not needing an extra appointment for removal of transmitter. The removal was performed by manual extraction via the coated wire with patients pre-medicated with oral Non

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