# Making a clinical device from a laboratory prototype: from Prosper to Prosper OR

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## INTRODUCTION

Prostate brachytherapy consists in inserting radioactive seeds in the prostate in case of localized cancer in order to kill cancerous cells whilst sparing healthy tissue or organ at risks (e.g. urethra, rectal wall). These seeds are inserted into the prostate using needles introduced through a guiding grid connected to a transrectal ultrasound probe. To handle limitations or difficulties of the conventional procedure, many systems have been designed worldwide (see [1] for a broad overview of systems existing in 2015). Developed systems provide different levels of assistance: from guiding the needle by positioning and orienting a guide out of the patient [2], to automatic insertion of the needle [3] or even injection of radioactive seeds through the needles into the patient [4]. Some of the systems also include ultrasound probe positioning and motion. Despite a very large number of prototypes, very few systems entered the operation room (OR). As far as we know, regarding brachytherapy applications, only the B-Rob system [2] developed by Johns Hopkins University and Queens University has been evaluated on patients. A feasibility study (NCT00381966 on ClinicalTrials.gov) was ended in 2012. The results of this study [5] confirm the interest of the robotic assistance in the needle placement. The EUCLIDEAN system [4], a fully automated device with needle insertion and seed injection, received FDA clearance for investigational studies. Reliability on phantoms was thoroughly studied [6] but, to the best of our knowledge, no clinical studies have been published. The reasons for such limited number of clinical evaluations and industrial developments come from the many issues to be solved such as safety, sterilizability, electromagnetic compatibility. The more invasive and autonomous is the robot, the most constraining and demanding are the regulations. In this paper, we will describe how the Prosper robot [3] has been modified based on our laboratory and cadaver experiments to be turned into a version usable in the OR for a clinical evaluation.

## MATERIALS AND METHODS

**PROSPER laboratory version:** this system (shown in Figure. 1) was designed as a proof of concept for automatic brachytherapy. It allowed us to develop methods to calibrate the robot with the 3D transrectal ultrasound (TRUS) probe and to automatically correct positioning errors due to prostate motion and deformation using 3DUS to 3DUS registration. It consist of two modules: one 5 degrees of freedom (DoFs) module for positioning and orienting the needle close to the patient skin and a 2 DoFs module for needle insertion in the prostate. It was studied on both phantoms and cadavers [3]. These studies showed very promising results allowing to position a needle with an error lower than 2 mm considering prostate motion up to 7 mm.

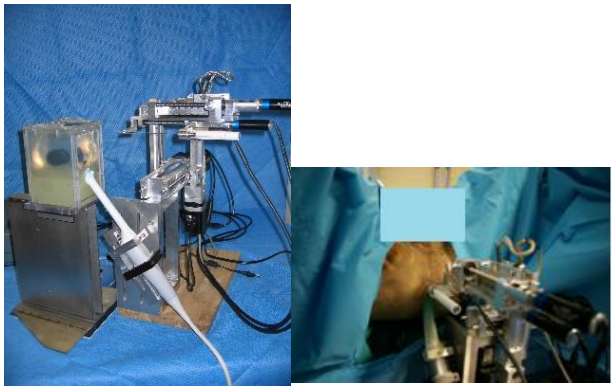

**Figure. 1.** Laboratory set-up of PROSPER (left: experiments on a deformable phantom; right: cadaver experiment).

Nevertheless, the system also showed some critical limitations. First, cadaver studies showed a lack of rigidity of the robot while inserting the needle. Moreover, from a clinical point of view, the system showed sterilization issues, and safety concerns because of the automatic needle insertion and the way the robot handled the needle (impossibility to quickly remove the needle).

**PROSPER$^{OR}$ version:** this new system (shown in Figure. 2) was designed to deal with the limitations previously mentioned. Off-the-shelf components (Faullhaber brushless motors couple with THK linear carriage for instance) were re-designed. A global quality approach and risk analysis were undertaken leading to this new system with extra capabilities.

## RESULTS

First, the robot workspace was increased to allow treatment of prostate with a larger volume and extra passive DoFs were added to ease the robot positioning with respect to the patient. Moreover, the structure of the system was reinforced and a fixation system to the OR table was added. This allows to make the system more rigid and ensure an accurate needle insertion.

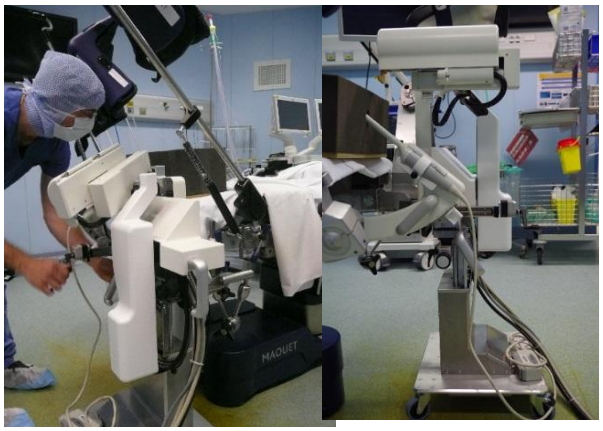

**Figure. 2.**Set-up of the PROSPER$^{OR}$ systemin the OR.

To tackle with security and sterilization, protection hoods covering all the mechanical parts of the robot were designed. All hoods are made of sterilizable biocompatible plastic and the hoods being in the close environment of the needle and/or in contact with it are designed to be removable and autoclave compatible. Thus, the sterilization process is simple, fast and safe as it relies on the most standard sterilization procedure. Moreover, the needle holder was modified to enable a safe and fast removal of the needle at any time. The insertion procedure was reviewed to enable manual and/or automatic insertion. In both insertion modes, the robot acts as a needle guide positioning the needle in accordance with the trajectory chosen on the ultrasound images, and a programmable mechanical stop limits the insertion depth based on the target planned. If the manual insertion mode is selected, the needle insertion is let to the urologist.

Finally, for the system to adapt with a number of TRUS probes (brachytherapy side-fire or biopsy end-fire), a probe holder was designed. It allows to adjust the probe position and orientation in the sagittal plane. The system was delivered in 2015 and is currently under tests to validate its electromagnetic compatibility and its sterilization process.

## CONCLUSION AND DISCUSSION

A very strict quality approach and risk analysis were led to bring the new PROSPER$^{OR}$ system to the patients. Specific tests were designed to ensure the quality and safety of the system on both mechanical and software point of view. The system is currently under strong quality tests, including registration with the TRUS probe, accuracy measurement on synthetic phantoms, evaluation of the sterilization process and electromagnetic compatibility.

To ensure the proper use of the PROSPER$^{OR}$ system, a new state-machine working with the CamiTK framework [7] has been designed. It allows, first to simply and rapidly implement complex medical protocols, second to ensure compliance with the established protocol in use.

Finally, a medical protocol is currently under discussion with urologists to bring the robot on patients and evaluate its accuracy and benefits to patients.

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