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First in vivo validation of a DROP-IN β-probe for robotic Radioguided Surgery in prostate cancer

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Radio Guided Surgery (RGS) is a nuclear medicine technique that directs surgeons towards tissue targets preoperatively defined on imaging-roadmaps such as PET/CT.
To this aim a radiopharmaceutical is injected into the patient before surgery, and the surgeon is given an intraoperative detector enabling the real-time identification of areas with accumulated radiotracer.
Typically utilizing low-energy (<150keV) γ-emitting radiopharmaceuticals (e.g., 99mTc-based tracers), RGS faces challenges related to tissue penetration and shine-through effects, particularly in areas with high physiological uptake.
Since β radiation undergoes more tissue attenuation, penetration is reduced to a few mms, and this feature could help mitigate the shine through phenomenon. Moreover, the presence of a wide range β+ PET radiopharmaceuticals (e.g., 68Ga based radiopharmaceuticals) theoretically allows the technique to be applied to a large number of cases.
In this contribution we present the first in-vivo application of a DROP-IN probe based on the use of β particle detector offering real-time guidance during surgery as numerical and acoustical feedback proportional to the counting rate, and thus to the amount of radiopharmaceutical detected in the considered sample.
The sterilizable DROP-IN set-up consists of four main parts: 1) a β particle detector, 2) a DROP-IN housing, 3) an electronic processing and read-out unit, and 4) a dedicated statistical software algorithm for signal interpretation.
The core of the β detector itself consists of a cylindrical (6 mm diameter and 3 mm height) mono-crystalline para-terphenyl (doped with 0,1% in mass of (E,E)-1,4-Diphenyl-1,3- butadiene). This material has been shown to be highly effective for β+ detection, as it is transparent to the 511keV γ particles. Tests with 68Ga source suggest that it has an ˜80% efficiency to positrons above ˜110 keV while being, at the same time, substantially transparent to photons of ˜500 keV, with an efficiency of ˜3%. This intrinsic γ transparency therefore limits the need for collimation.
Scintillation light conversion was performed by a 3x3 mm2 silicon photomultiplier (SiPM Hamamatsu S13360-3050PE) powered and read-out by a custom microcontroller, connected to the device with a biocompatible and sterilizable latex-free cable.

The prototype was evaluated in 7 primary prostate cancer patients, having at least 1 lymph node metastases visible on PSMA-PET. At the beginning of surgery, patients were injected with 1.1 MBq/kg of [^{68}Ga]Ga-PSMA. The β probe was used to trace PSMA-expressing lymph nodes in vivo during the pelvic lymph nodes dissection. To support the surgeon in discriminating between probe signals coming from tumor and healthy tissue, a statistical software algorithm was developed and optimized on this dataset. The DROP-IN β probe helped provide the surgeon with autonomous and highly maneuverable tracer detection. A total of 66 samples (i.e., lymph nodes specimens) were analyzed in vivo, of which 31 (47%) were found to be malignant. After optimization of the signal cutoff algorithm, we found a probe detection rate of 78% of the PSMA-PET-positive samples, and a sensitivity of 76% and specificity of 93%, as compared to pathologic evaluation.
This study is the first-in-human validation of a DROP-IN β probe, supporting the integration of β radio guidance and robotic surgery. The obtained sensitivity and specificity values for nodal metastases were found to be competitive to values obtained for other RGS strategies, opening the world of robotic RGS to a whole new range of radiopharmaceuticals.

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