

Press release

## BioXmark® shows good feasibility and clinical performance in esophageal cancer IGRT study

The following concluding evaluations of BioXmark®, Nanovi's liquid fiducial marker, have been published from the study:

- Visibility on imaging and excellent positional stability
- Good MRI visibility
- Fast and easy endoscopic injection procedure

*DK-Copenhagen, 3 June 2020* - Nanovi informs that a published prospective study by the Amsterdam UMC, a leading university hospital in Amsterdam, the Netherlands, evaluated the technical feasibility and clinical performance of BioXmark® in a cohort of patients with esophageal cancers eligible for Image-Guided Radiation Therapy, IGRT.

BioXmark® is a liquid fiducial marker, developed by Nanovi to enhance target visibility on imaging and enable high precision radiation therapy across cancer indications.

### Study introduction

The publication introduces the study as follows:

“Radiation Therapy (RT) with concurrent chemotherapy plays a significant role in the treatment of patients with operable or inoperable esophageal cancers. Modern radiation delivery techniques can deliver radiation dose with high precision to the target. Subsequently, accurate delineation and subsequent accurate (patient) setup verification becomes more important.”

“RT in patients with esophageal cancer can still be optimized by more precise target definition and daily dose delivery with image guided RT (IGRT). Therefore, an easily applicable marker with good visibility on different imaging modalities and positional stability becomes more vital.”

### Study design

The study first analyzed the visibility of BioXmark® *ex vivo* in porcine tissue on different imaging modalities. Next, BioXmark® markers were injected under endoscopic ultrasound guidance in 10 patients with curable esophageal cancers, and the technical feasibility of the injection procedure and the clinical performance of the markers was evaluated. A total of 24 markers were placed in the clinical part of the study.

## Study conclusions and discussions

It was concluded in the publication that injection of a novel liquid fiducial marker (i.e. BioXmark®) for esophageal cancer RT is technically feasible with no adverse events identified.

Further, it was evaluated that BioXmark® marker volumes of > 0.05 ml have an appropriate visibility on CT, CBCT and MRI with an excellent positional stability, and that a liquid fiducial marker therefore is promising for use in IGRT.

The publication further concludes that the clear visibility of BioXmark® on MRI opens a new area of possibilities for MRI-guided delineation or registration. It is suggested that MRI-based esophageal delineation is feasible, and that DW-MRI might have complementary value in delineation. Also, for IGRT setup on an MRI-based linear accelerator, good MRI visibility of fiducial markers is of greatest interest.

In terms of application of a fiducial marker, the publication discusses that the largest advantage of BioXmark® over the gold fiducial markers is not the clinical performance during IGRT, which is also good with gold fiducial markers, but the easier and faster endoscopic injection procedure, especially when multiple markers are needed.

Reference to the publication:

*Machiels M., Voncken F. E. M., Jin P., van Dieren J. M., Bartels-Rutten A., Alderliesten T., Aleman B. M. P., van Hooft J. E., Hulshof M. C. C. M. A Novel Liquid Fiducial Marker in Esophageal Cancer Image Guided Radiation Therapy: Technical Feasibility and Visibility on Imaging. July 2019, Practical Radiation Oncology 9(6), pages 506-515.*



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## About BioXmark®

BioXmark® is a liquid fiducial marker, developed by Nanovi to enhance target visibility on imaging and enable high precision radiation therapy across cancer indications.

BioXmark® has the following features and benefits:

- *Liquid nature* for customizable implantation
- *Sticky and soft markers containing a proprietary contrast agent* for positional stability and visibility on relevant imaging modalities, including MRI
- *Non-metallic* for a low level of artefacts and low dose perturbation ensuring photon and proton compatibility

BioXmark® offers radiation therapy workflow benefits in the form of

- A fast and easy implantation procedure
- Less risk for procedure related complications
- No need for additional training nor special equipment

## **About Nanovi**

Nanovi A/S is a Danish medical device company specialized in precision marking for better cancer therapy. Our corporate dedication is to empower healthcare professionals with the best possible tools to support the delivery of high precision radiation therapy and surgery for the benefit of cancer patients and for healthcare efficiency.

We have a portfolio of unique in-house developed liquid fiducial markers for both human and veterinary use.

All our products are derived from a patented biomaterial technology platform, co-invented with the Department of Health Technology at the Technical University of Denmark, DTU.

The company's corporate offices are situated in Kgs. Lyngby, north of Copenhagen.

For more information, please visit: [www.nanovi.com](http://www.nanovi.com)