# Hydrogel Device Protects Rectum During Prostate Cancer RT

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A new device that has just been cleared for commercial use by the US Food and Drug Administration (FDA) offers men with prostate cancer who are undergoing radiotherapy (RT) some protection from collateral damage, specifically to the rectal tissues that are anatomically situated close to the prostate gland.

The new device, SpaceOAR (developed by Augmenix Inc.), consists of a hydrogel mixture that is injected through the perineum into the anatomical space between the prostate gland and the rectum. After injection into the body, the gel solidifies and creates a physical barrier between the two, thus shielding the anterior rectum from radiation directed at the prostate gland.

The solidified hydrogel stays in place for around 3 months, after which it is reabsorbed into the body.

The FDA clearance was granted after a manufacturer-sponsored multicenter pivotal clinical trial in 222 patients showed benefits to patients who received SpaceOAR. The study was completed in the United States at centers with physicians specializing in the treatment of prostate cancer. Patients who had the device inserted showed a "significant reduction in rectal radiation dose and severity of late rectal toxicity when compared to controls," the company said in a press release regarding the study findings.

Results from this trial have been submitted for publication in a peer-reviewed medical journal, and the company said that for this reason it cannot reveal full details. However, it arranged for *Medscape Medical News* to talk to one of the clinical investigators, Richard Hudes, MD, FACR, section chief of radiation oncology with the Saint Agnes Cancer Institute in Baltimore. Dr Hudes also treats patients at the Prostate Center of Chesapeake Urology Associates, which is where he conducted this research.

In an interview, Dr Hudes said that prostate cancer patients receiving external-beam radiation and/or brachytherapy with implanted radioactive seeds could both be candidates for the device. He envisages that both radiation oncologists and urologists would use the device, after being trained.

Injection of the hydrogel (which is a mixture of two separate syringes) through the perineum is guided by transrectal ultrasound. He explained a few milliliters of saline is injected first, "just to make sure that you are in the correct space," and then you inject the hydrogel. The hydrogel material flows into the space between the prostate and the rectum.

Most patients undergoing insertion of the device opted to have some intravenous sedation, similar to that used for colonoscopy, but about 20% to 25% of his patients opted to have local anesthetic with lidocaine, he commented.

Dr Hudes said that the pivotal trial awaiting publication was blinded, so the patients did not know if they had the SpaceOAR inserted or not. This was possible, he explained, because all patients were otherwise undergoing placement of prostate fiducials, which also involved transrectal ultrasound. The prostate fiducials are used for image-guided radiation therapy. After the fiducials had been inserted, the randomization then indicated whether or not they would also have the SpaceOAR hydrogel inserted or not.

In his experience using the device during the clinical trial, Dr Hudes said that patients did not report any notable discomfort from the device, nor did they report changes in bowel movements.

In terms of results, Dr Hudes said he could speak only generally: The device definitely reduced the radiation dose reaching the anterior rectum in the SpaceOAR patients, and there was also an improvement in quality of life regarding rectal aggravating symptoms, such as urgency, frequency, or discomfort.

"I certainly had a positive experience with the patients I treated during the clinical trial," Dr Hudes said, "and I anticipate that we will be incorporating this device into our clinical practice."



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