



## Patient Reported Quality of Life Outcomes After Definitive Radiation Therapy With Absorbable Spacer Hydrogel for Prostate Cancer

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### Limitations of this report include:

- Short-term follow-up of a median time just over a year. Although some patients were followed for a longer amount of time given the IQR of 507, the understanding of the long-term patient reported outcomes will depend on further data maturity.
- The study had an overall well-selected population at baseline. Patients as a whole had good initial urinary scores and relatively small prostate gland sizes.
- Patient population was treated with different modalities. However, overall positive QoL outcomes are still apparent throughout all groups.

The prospective study enrolled 59 patients with low- and intermediate-risk prostate cancer who received SpaceOAR Hydrogel along with prostate radiation therapy, including SBRT (n=34), HFRT (n=17), CFRT (n=2), and brachytherapy (n=6). The study also assessed the relationship between the dosimetry to the organs at risk (OARs) and the change in both, EPIC-26 and AUA-SI scores.

#### EPIC-26 scores

EPIC-26 composite score	Baselinemedian (IQR)	First F/Umedian (IQR)	Second F/Umedian (IQR)	P value
EPIC bowel composite	100 (4.1)	91 (20)	100(4.1)	.19
Sexual composite	68 (39)	57 (61)	72.5 (55)	.25
Urinary incontinence	93.1 (24)	81.2 (28.75)	87.5 (18)	.17
Urinary obstructive	93.7 (23)	81.25 (33)	87.5 (18)	.62
Urinary hormonal	87 (28)	90 (27.5)	95 (16)	.81

Abbreviations: EPIC = Expanded Prostate Cancer Index Composite; F/U = follow-up; IQR = interquartile range.

#### Most patients had exceptional QOL scores at follow-up.

***“ There were no significant changes in the AUA-SI score (P = .69) at final follow-up compared with baseline, nor was there any change in EPIC-26 domain scores (P = .19) during the course of the study period.”***

***“ In terms of longitudinal follow-up, patients had little change compared to their baseline scores, which likely is due to improved sparing of the OARs. In terms of dosimetry, SpaceOAR contributed to dramatic sparing of dose to the rectum.”***

#### AUA-SI review\*

AUA question	Total Base Line	Last F/U
Not emptying bladder	1 (2)	1 (1.5)
Urinate every 2 h	1 (3)	0.5 (1)
Stopped and started	1 (3)	1 (0.75)
Postponement of urine	1 (1)	0 (1.5)
Weak stream	1 (2)	0.5 (1)
Strain	1 (0)	0 (0)
Nocturia	1 (1)	1 (1.5)
Total	1 (2)	1 (2)

Abbreviations: AUA-SI = American Urology Association Symptom Index

Link to full article: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8655415/pdf/main.pdf>

SpaceOAR Hydrogel is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR Hydrogel to reduce the radiation dose delivered to the anterior rectum. SpaceOAR Hydrogel contains polyethylene glycol (PEG). Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events. As with any medical treatment, there are some risks involved with the use of SpaceOAR Hydrogel. Potential complications associated with SpaceOAR Hydrogel include, but are not limited to: pain associated with SpaceOAR Hydrogel injection, pain or discomfort associated with SpaceOAR Hydrogel, local inflammatory reactions, infection (including abscess), urinary retention, urgency, constipation (acute, chronic, or secondary to outlet perforation), rectal tenesmus/muscle spasm, mucosal damage, ulcers, fistula, perforation (including prostate, bladder, urethra, rectum), necrosis, allergic reaction (localized or more severe reaction, such as anaphylaxis), embolism (venous or arterial embolism is possible and may present outside of the pelvis, potentially impacting vital organs or extremities), syncope and bleeding. The occurrence of one or more of these complications may require treatment or surgical intervention.

\* Values expressed as median and interquartile range (IQR).

SBRT was not the method used in the SpaceOAR™ Hydrogel single-blind Phase III trial performed to evaluate dosimetric and clinical effects of SpaceOAR Hydrogel. IG-IMRT delivered at 79.2 Gy in 1.8-Gy fractions was the method used.

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