

Rectal spacers for external beam radiotherapy

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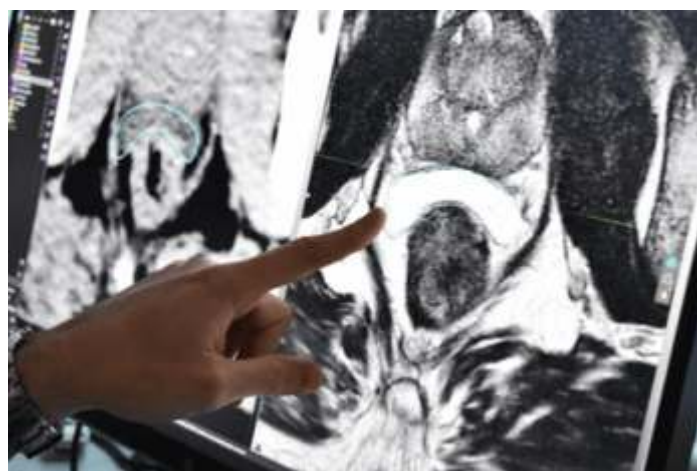
Dr. Chiranjan draws inspiration from Mother Teresa's words, "Not all of us can do great things, but we can do small things with great love," which guides her commitment to compassionate oncology care. Motivated by personal experiences with cancer, she has dedicated her career to supporting patients with a focus on prostate, breast, gynecological, head and neck, and central nervous system cancers.

As a member of esteemed organizations like ESTRO, SASCRO, and ICON, Dr. Chiranjan remains actively engaged in the oncology community. She frequently presents at congresses, participates in international courses, and contributes to publications aimed at supporting cancer patients and caregivers. Her involvement in multidisciplinary forums highlights her dedication to advancing cancer treatment and proactive screening processes.

Dr. Chiranjan's academic journey began with an MBChB from the University of Cape Town in 2006, followed by internships at McCord's Hospital and community service at Evander Hospital. In 2010, she joined the Radiation Oncology Department at Charlotte Maxeke Johannesburg Academic Hospital. She became a Fellow of the College of Radiation Oncologists in 2014 and is now a senior partner at DMO, consulting at the Ahmed Kathrada Cancer Institute, Johannesburg Surgical Oncology Hospital, Sandton Oncology, and West Rand Oncology Centre. Dr. Chiranjan is part of a team of seven oncologists at DMO's six practices.

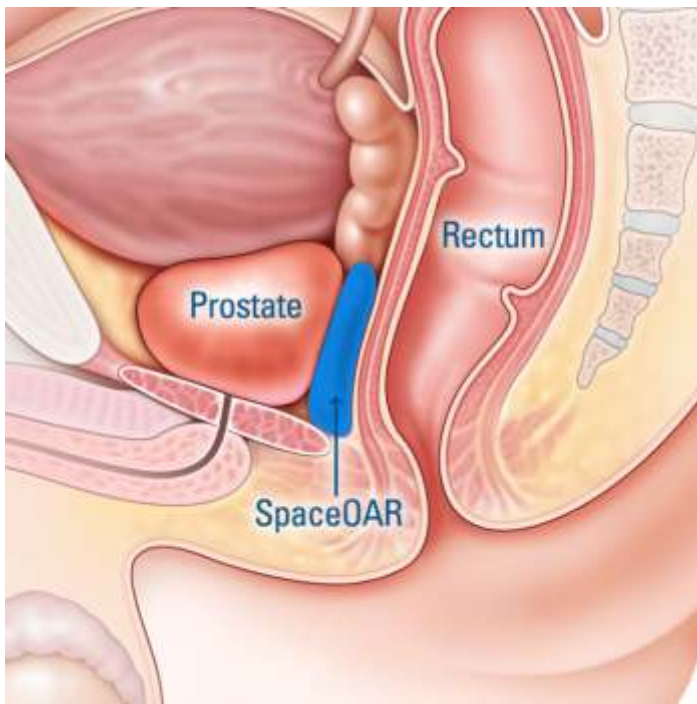
Radiotherapy is an important treatment modality for Prostate Carcinoma. Over the past few decades there have been major technological advances that have allowed for dose escalation. These newer techniques have translated into improved biochemical control and reduced the risk of distant metastases.^[1] The main challenge remains to deliver adequately high radiation dose to the prostate in order to achieve tumour control, while meeting the planning treatment constraints to ensure the safety of adjacent healthy tissues. Due to the proximity of the anterior rectal wall to the prostate, the rectum represents a dose limiting structure. Radiation related genitourinary and gastroenterological side effects can cause significant morbidity in the acute and late settings.^[2] The spacer approach which separates the prostate from the anterior rectal wall has been designed to reduce the rectal dose without compromising the prostate planning target volume (PTV), thereby potentially resulting in relatively low rates of rectal toxicity with higher RT dose delivery. Several physical devices such as endorectal balloons (ERBs), rectal hydrogel spacers, and rectal retractors (RR) have been developed.^[3-7]

The rectal hydrogel is injected between the Denonvilliers' fascia and the rectum about one week prior to radiotherapy to separate the anterior rectal wall from the prostate which results in

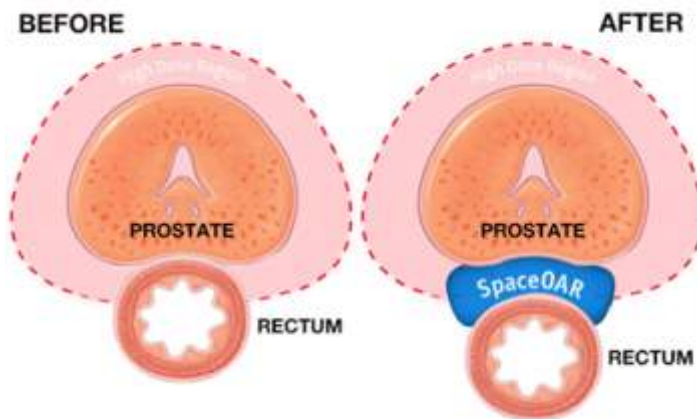


significantly reduced rectal volumes irradiated to high doses. The hydrogel is injected under general or local anaesthetic via a transperineal approach with transrectal ultrasound guidance. The injection of hydrogel does not serve as a stabilizing device for prostate motion. This invasive implantation procedure can have severe side effects and complications. The routine use of rectal spacers is not cost-effective. Further studies are needed to determine which subset of prostate patients would benefit from the implantation of hydrogel to decrease rectal toxicities in a cost-effective manner.

[3-7]



Illustrations of SapceQAR perirectal. Courtesy of Boston Scientific.



Boston Scientific South Africa are currently conducting a feasibility study in South Africa to determine the feasibility of launching SapceQAR here. For more information contact: Johan at: johan.jansevanrensburg@bsci.com

Determining which patients should receive a rectal spacer during their prostate cancer radiation therapy treatment is based on multiple factors.

Treatment Considerations

- Rectal spacers are suitable for all treatment modality applications including external beam radiotherapy (EBRT) and brachytherapy.
- Rectal spacers should only be used in patients receiving definitive doses and not in the palliative setting.
- Treatment fractionation alone is not an indicator for rectal spacer use.
- Rectal spacers may be considered in the setting of moderate hypofractionation with dose escalation of dominant nodules (identified with

MRI) located posteriorly, close to the anterior rectal wall.

- Rectal spacers may be considered in the setting of ultra-hypo fractionation/stereotactic body radiotherapy (SBRT) particularly when the GTV is situated posteriorly close to the anterior rectal wall.

Access to an experienced physician with currency of skill who can insert rectal spacer is an important treatment consideration ^[8]

Patient Considerations

- Rectal spacer use is not dependant on prostate cancer risk group.
- Rectal spacers could potentially provide benefit in the salvage SBRT setting following previous EBRT failure. However, this should be considered in the context of risk associated with fibrosis or adhesions in the tissue plane from previous treatment.
- Rectal spacer should be used with caution in patients with extra-capsular extension ($\geq T3$ disease). The location of the extra-capsular extension (eg. anterior or laterally) may still allow use of a rectal spacer in some circumstances.
- Rectal spacer use should be considered for patients with bi-lateral prosthetic hips. This should be balanced with alternative options such as brachytherapy or surgery in these individuals.
- Patient age and BMI are generally not considerations for determining rectal spacer use.
- The life expectancy of a patient should be considered when deciding on rectal spacer use, however this is typically integrated with assessment of patient ECOG status and treatment intent.
- Rectal spacer should only be considered for patients who are able to give informed consent following discussion of potential risk of insertion.
- Rectal spacer can be considered in patients with risk factors associated with increased acute or late rectal toxicity such as: long-term anticoagulation use; inflammatory bowel disease ;pre-existing rectal or gastrointestinal disorders; disorders increasing vasculopathy and connective tissue diseases. ^[9]

Contraindications for rectal spacer use include:

- High anaesthetic risk.
- Previous treatments that may have caused fibrosis or adhesions of the tissue plane between the prostate and rectal wall (eg. pelvic surgery,

- cryotherapy, radiotherapy).
- Anticoagulation that cannot be stopped .
- Active local infection in rectum.
- Previous misplaced rectal spacer. ^[8]

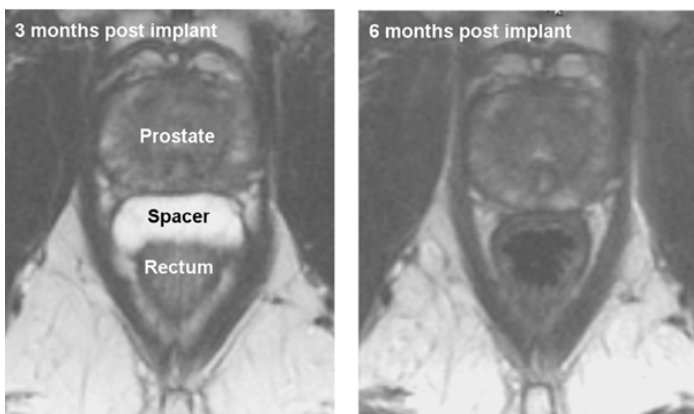
Product Selection

Safety, reproducibility and reversibility are important parameters to take into consideration when selecting a rectal spacer.

Rectal spacer products are SpaceOAR™ Hydrogel, SpaceOAR Vue™ Hydrogel, and Barrigel®. These products are not yet commercially available in South Africa.

Radio-opaque rectal spacer (SpaceOAR Vue™) may reduce the need for MRI scans in patients with contraindication to MRI or easily visible prostate apex on CT imaging.

Barrigel® rectal spacer provides the ability to be shaped in situations of spacer misplacement (has the potential to be hydralysed) and should be considered in all contexts, but especially in the setting of a very large prostate or salvage SBRT following failed EBRT. ^[8]



T2-weighted magnetic resonance images of a spacer patient showing hydrogel persistence through completion of radiation therapy (left), and absorption 6 months after implantation (right). ^[9]

Side effects, cost and possible complications

The injection of hydrogel does not serve as a stabilizing device for prostate motion. This invasive implantation procedure can have severe side effects and complications.

Insertion of a rectal spacer carries the risk of misplacement which can lead to lateral displacement of the target area or toxicities such as inadvertent intravascular insertion, severe anaphylaxis, rectal wall infiltration, pelvic abscess, rectal wall ulceration, recto-urethral fistula, tenesmus, pulmonary embolus and pain.

The routine use of rectal spacers is not cost-effective. Further studies are needed to determine which subset of prostate patients would benefit from the implantation of hydrogel to decrease rectal toxicities in a cost-effective manner. [8]

Conclusion

In patients with prostate carcinoma who receive EBRT, rectal spacer is an effective means to substantially reduce the rectal radiation dose. Out-of-pocket cost and possible lack of medical funding is a barrier to patients accessing rectal spacers. Additional studies are required to establish long-term safety data and to define potential benefits in bowel, urinary, and sexual quality of life parameters.

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