

A Combination Application of Balloon and Fiducial Marker Implant for Brachy Radiation Control in Prostate Radiotherapy

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ABSTRACT

Purpose: To describe a fiducial-based geometric and dosimetric method for detecting rectal balloon spacer failure and evaluating hydrogel salvage during prostate stereotactic body radiotherapy.

Methods and Materials: A patient underwent transperineal implantation of a biodegradable rectal balloon spacer and three intraprostatic fiducial markers. The initial planning CT represented an intact balloon (S1). Pretreatment cone-beam CT demonstrated loss of spacer geometry; treatment was withheld, deflation was confirmed, and a repeat CT represented the deflated state (S2). After hydrogel spacer placement, repeat simulation and replanning defined the salvage state (S3). Singular value decomposition point registration quantified fiducial-defined rigid transformations. Plans were compared using target coverage and rectal D2cc.

Results: The S1-to-S2 transformation was predominantly translational (0.50, -0.36, and 0.63 cm along the 3 axes; net displacement, 0.88 cm). With the original plan applied to the deflated-spacer anatomy, planning target volume coverage at 36.25 Gy decreased from 99% to 68%, clinical target volume coverage at 40 Gy decreased from 95% to 56%, and rectal D2cc increased from 12.9 to 29.1 Gy. After hydrogel placement and replanning, target coverage recovered to 98% and 96%, respectively, and rectal D2cc decreased to 22.2 Gy.

Conclusions: Fiducial-based registration converted a qualitative spacer abnormality into a measurable geometric change associated with major dosimetric deterioration. Withholding treatment, confirming device failure, and performing repeat simulation and replanning after hydrogel salvage restored target coverage and rectal sparing in this case. Larger studies are needed before a numerical intervention threshold can be recommended.

Keywords

Prostate cancer, Rectal spacer, Fiducial markers, Stereotactic body radiotherapy, Image-guided radiotherapy, Adaptive radiotherapy.

Introduction

Rectal spacers have become increasingly adopted in prostate radiotherapy to reduce radiation-induced rectal toxicity. Randomized clinical trials and prospective studies have consistently demonstrated reduced rectal dose, lower gastrointestinal toxicity, and improved patient-reported quality of life following spacer placement [1-4]. Consequently, rectal spacers have become an

important adjunct in conventionally fractionated radiotherapy and stereotactic body radiotherapy (SBRT) [5,6].

Unlike injectable hydrogel spacers, which polymerize in situ and subsequently resorb, the BioProtect Balloon Implant System (BioProtect Ltd., Tzur Yigal, Israel) is a biodegradable inflatable spacer placed in the perirectal space and filled with saline. The intended geometry creates separation between the prostate and anterior rectal wall. Published experience has described implantation feasibility, prostate-rectum separation, and rectal dose reduction; however, the benefit depends on preservation of

spacer geometry throughout treatment.

Despite these advantages, the dosimetric benefit of a balloon spacer depends on preservation of its geometric integrity throughout treatment. Balloon deflation, leakage, displacement, asymmetric deformation, or partial collapse may reduce the intended prostate-rectum separation and compromise rectal sparing. At present, there is no standardized quantitative framework to detect or classify balloon failure during treatment, nor clear consensus guidance on the optimal salvage strategy when failure occurs. Because modern prostate radiotherapy employs steep dose gradients, even millimeter-scale geometric changes may produce clinically meaningful dosimetric degradation.

Previous studies have focused primarily on implantation, dosimetric benefit, and safety of balloon and hydrogel spacers. Quantitative assessment of spacer integrity after implantation and the dosimetric consequences of changing spacer modality as a salvage intervention remain less well described. We therefore applied a fiducial-based rigid-registration method to a case of balloon spacer failure followed by hydrogel salvage.

Study objective

The objective was to quantify the geometric and dosimetric effects of balloon spacer deflation and subsequent hydrogel salvage using fiducial-marker-defined coordinate systems, target coverage, and

organ-at-risk dose metrics.

Materials and Methods

Patient and clinical workflow

A patient with localized prostate cancer underwent transperineal placement of a rectal balloon spacer together with 4 intraprostatic fiducial markers before CT simulation for definitive stereotactic body radiotherapy. Simulation was performed in the treatment position using institutional immobilization and bladder and rectal preparation protocols. The planning CT represented the intact balloon geometry (scenario 1 [S1]). The clinical target volume (CTV), planning target volume (PTV), and organs at risk were contoured according to institutional practice, and a treatment plan was generated with prescriptions of 40 Gy to the CTV and 36.25 Gy to the PTV for 5 fractions.

Pretreatment cone-beam CT demonstrated loss of the expected balloon geometry inability to register all 4 fiducials together even with a 6D couch and prostate-rectum separation relative to the planning CT. Treatment was withheld, and balloon deflation was confirmed by MRI (scenario 2 [S2]). Because the deflated balloon could not restore the intended separation, the patient underwent placement of an injectable hydrogel spacer, repeat CT simulation, and replanning (scenario 3 [S3]) before treatment proceeded.

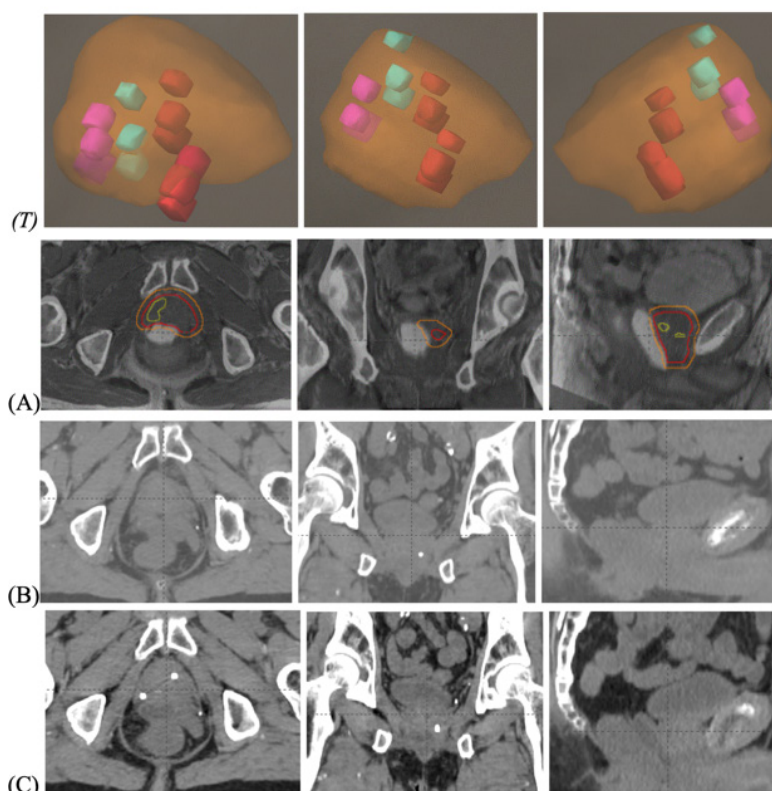


Figure 1: Imaging appearance of the 3 clinical scenarios. (T) Three-dimensional display of the 3 implanted fiducial markers. Axial CT images show (A) the intact rectal balloon spacer (S1), (B) the deflated balloon spacer (S2), and (C) the hydrogel spacer after salvage placement (S3). Fiducial markers used for rigid registration are visible in each dataset.

Fiducial-based coordinate system and rigid registration

The 3 implanted fiducial markers served as anatomical landmarks. Rigid transformations between S1, S2, and S3 were computed with a singular value decomposition point-registration algorithm that minimized fiducial registration error. Translation components (x, y, and z) and Euclidean displacement magnitude are summarized in Table 1. Because only 3 points were available, the transformation estimates were used descriptively and were not interpreted as evidence of prostate rigidity.

Dosimetric evaluation

Plans were compared across the 3 image sets to characterize the dosimetric effect of spacer geometry and salvage replanning. The principal reported endpoints were CTV coverage at 40 Gy, PTV coverage at 36.25 Gy, and rectal D2cc. Dose-volume histograms were reviewed for target and organ-at-risk trends. Metrics not available for all 3 scenarios were not used for quantitative comparison.

Geometric and dosimetric parameters were summarized descriptively. No inferential statistical testing was performed because this was a single-patient case report.

Results

The initial plan after balloon implantation showed CTV coverage at 40 Gy of 95% and PTV coverage at 36.25 Gy of 99%. The CTV

and PTV volumes were 28.9 and 58.6 cm³, respectively. Rectal D2cc was 12.9 Gy (Table 2).

From S1 to S2, registration showed translations of 0.50, −0.36, and 0.63 cm along the x, y, and z axes, respectively, corresponding to a net displacement of 0.88 cm, with limited rotation (Table 1). With the original plan applied to the deflated-spacer anatomy, PTV coverage decreased from 99% to 68%, and CTV coverage decreased from 95% to 56%. Rectal D2cc increased from 12.9 to 29.1 Gy (Table 2; Figures 2 and 3). Thus, balloon deflation was accompanied by simultaneous loss of target coverage and rectal sparing.

In this case, an 8.8-mm fiducial-defined displacement accompanied a 31-percentage-point decrease in PTV coverage, a 39-percentage-point decrease in CTV coverage, and a 16.2-Gy increase in rectal D2cc. These observations support repeat dosimetric assessment when spacer geometry changes, but a general intervention threshold cannot be derived from a single case.

After hydrogel spacer placement and replanning, the S2-to-S3 transformation had a net displacement of 2.59 cm (Table 1), reflecting a different prostate-rectum relationship after re-spacing. CTV and PTV coverage recovered to 96% and 98%, respectively, and rectal D2cc decreased to 4.2 Gy (Table 2). These values were obtained from the re-spaced plan rather

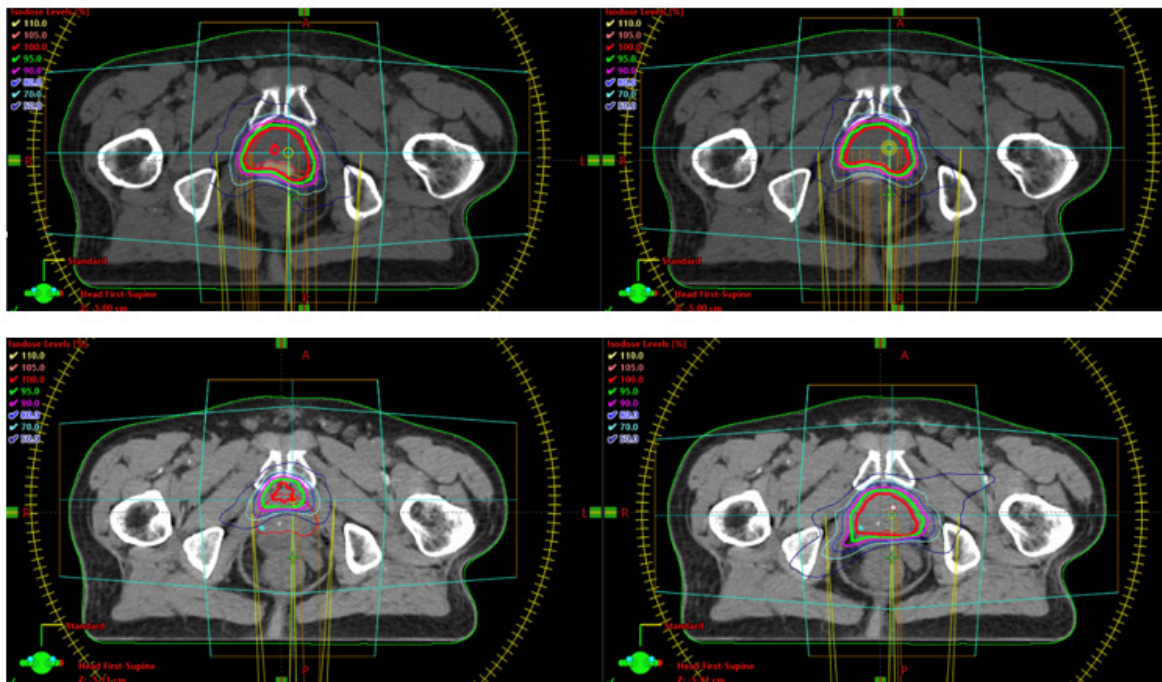


Figure 2: Axial dose distributions. Top row: S1 (intact balloon) and S2 (deflated balloon). Bottom row: S2 (deflated balloon) and S3 (hydrogel salvage after repeat simulation and replanning). Isodose levels are expressed as percentages of prescription dose.

than by applying the original plan unchanged. The comparison therefore represents the combined effect of restored separation and replanning.

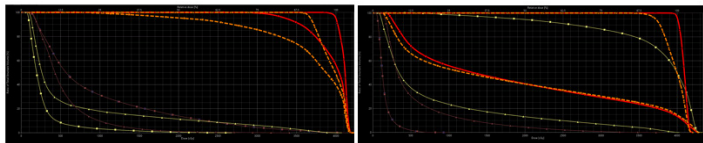


Figure 3: Dose–volume histogram comparisons. Left: S1 (intact balloon) versus S2 (deflated balloon). Right: S2 (deflated balloon) versus S3 (hydrogel salvage). Red denotes CTV, orange denotes PTV, yellow denotes bladder, and brown denotes rectum. Solid and dashed curves correspond to the scenarios identified in each panel.

Table 1: Singular value decomposition (SVD)-derived translation vectors and net displacement magnitude between imaging scenarios.

Scenario transition	X (cm)	Y (cm)	Z (cm)	Net displacement (cm)
S1 → S2 (balloon deflation)	0.50	−0.36	0.63	0.88
S2 → S3 (hydrogel reimplantation)	−0.02	1.23	−2.29	2.59
S3 → S1	0.47	1.00	−1.59	1.94

Table 2: Target coverage and rectal D2cc across the 3 clinical scenarios.

Volume of interest	Volume (cc)	S1 Intact balloon	S2 Deflated balloon	S3 Hydrogel reimplant
CTV, coverage at 40 Gy (%)	28.9	95	56	96
PTV, coverage at 36.25 Gy (%)	58.6	99	68	98
Rectum, D2cc (Gy)	—	12.9	29.1	22.2

(Note; table 2 rectum D2cc is based on the real treatment plan.)

Discussion

This case demonstrates that loss of rectal balloon integrity can alter prostate–rectum geometry and substantially degrade the dosimetric performance of an existing prostate radiotherapy plan. Fiducial-based registration provided an objective measure of geometric change, while repeat CT and dose–volume analysis quantified the clinical consequence. Hydrogel placement followed by repeat simulation and replanning restored target coverage and rectal sparing.

Impact of spacer integrity on prostate geometry

Balloon deflation in S2 was accompanied by an 8.8-mm fiducial-defined displacement and loss of prostate–rectum separation. Although the displacement was less than 1 cm, its direction moved target anatomy relative to a steep posterior dose gradient. The larger S2-to-S3 registration displacement should not be interpreted as residual instability; it reflects the new anatomy created by hydrogel placement and repeat patient setup.

Dosimetric consequences of spacer variation

The deflated-spacer state showed the greatest loss of target coverage and the highest rectal D2cc. After hydrogel salvage and replanning, CTV and PTV coverage returned near baseline and rectal D2cc decreased below the initial value. Because S3 involved both a different spacer and a new plan, the study does not isolate the independent contributions of spacer material, anatomical change, and replanning.

Clinical implications

Spacer appearance should be reviewed on pretreatment imaging rather than assumed to remain unchanged after implantation. When separation or device geometry differs materially from simulation, treatment should be withheld until the finding is evaluated and the dosimetric effect is understood. This case supports repeat simulation and replanning after salvage spacer placement; it does not establish that hydrogel replacement will be feasible or dosimetrically superior in every patient. And injecting contrast in the balloon is one method to help identify deflation at OBI.

Study limitations and future work

This report describes 1 patient and cannot provide population-level estimates or a validated geometric action level. Rigid registration based on 3 fiducials does not characterize deformable changes in the prostate, rectum, or spacer. In addition, S3 represents both hydrogel placement and replanning, so the salvage comparison is not a controlled comparison of spacer products. The reported dose metrics should be verified against exported treatment-planning-system DVH data before submission. Future studies should prospectively collect serial image guidance, spacer geometry, fiducial registration error, and standardized dose metrics in larger cohorts.

Conclusion

Rectal balloon spacer deflation was associated with an 8.8-mm fiducial-defined displacement, marked loss of target coverage, and increased rectal D2cc in this case. Withholding treatment and performing hydrogel salvage, repeat simulation, and replanning restored target coverage and rectal sparing. Fiducial-based geometric assessment may complement visual image review, but prospective validation is required before a numerical intervention threshold is adopted.

Disclaimer

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Data availability

Deidentified data supporting this case report may be available from the corresponding author on reasonable request, subject to institutional and patient-privacy requirements.

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