

Controllable Spacing for Modern Prostate Radiation Therapies

The BioProtect Balloon Spacer has demonstrated, uniform, stable, base-to-apex spacing with significant rectal dose reductions versus control,¹ supporting whole-gland treatment planning. Clinical data with BioProtect also reported greater apex, midgland, and base separation than gels.² Together, these findings suggest a dosimetric and geometric advantage for the balloon spacer.



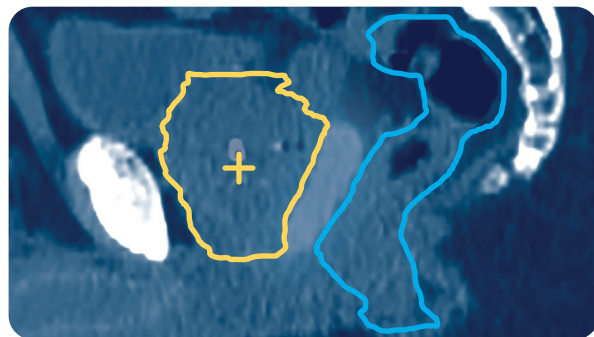
BioProtect Balloon Spacer Versus Hydrogel

	BioProtect Balloon Spacer	Hydrogel	Notes
Mean prostate-rectum spacing	$19 \pm 3.7 \text{ mm}^1$	$12.6 \pm 3.9 \text{ mm}^3$	Stability of spacing was maintained throughout the course of EBRT, with complete balloon resorption by 6 months in over 98% of patients. ¹
IMRT, moderate hypofractionation-equivalent plan rectal V70 dose reduction	$7.0\% \rightarrow 1.1\%$ ($p=0.001$)	$12.4\% \rightarrow 3.3\%$ ($p=0.0001$)	Reduction of more than 25% in rV70 in 97.9% of patients in the balloon group, resulting in a relative mean dose reduction of 84.8%.
VMAT, conventional fractionation plan rectal V70 dose ⁴	84.1%	67%	Balloon demonstrated 17.1% decrease in mean rectal V70 compared with hydrogel ($p = 0.001$), with significant differences observed at all dose levels. <i>Retrospective, non-randomized multicenter study. Dosimetric outcomes only.</i>
SBRT, ultrahypofractionated plan rectal V31.7 dose reduction ⁴	84.1%	68.1%	Balloon demonstrated 16.0% decrease in mean rectal V31.7 compared with hydrogel ($p = 0.001$), with statistically significant differences observed across all ultrahypofractionated dose levels. <i>Retrospective, non-randomized multicenter study. Dosimetric outcomes only.</i>

Precise Spacing. Confident Planning.

The BioProtect Balloon Spacer's substantial rectal dose reduction improves ability to meet planning constraints. In a pivotal trial, rectal V70 fell from 7.0% preimplant to 1.1% postimplant (84.8% relative reduction) and 97.9% of patients achieved $\geq 25\%$ V70 reduction.¹

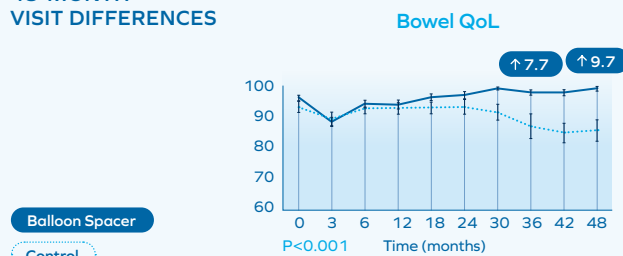
In a multicenter retrospective analysis, BioProtect was associated with lower rectal doses compared to a hydrogel spacer in both conventional and ultrahypofractionated treatment plans.⁴



Consistent Spacing Translates to Preserved Patient Quality of Life (QoL)

Adequate apical spacing has been associated with lower rectal dose and maintained bowel QoL. Apical separation ≥ 10 mm correlated with less QoL decline in a hydrogel spacer trial.⁵ Comparative data show that balloon spacers reliably create measurable apex spacing, while gel spacers may not always do so.² In the long-term study, EPIC-26 follow-up showed BioProtect patients preserved bowel, urinary, and sexual QoL scores at 48 months compared with control.^{6*}

48-MONTH VISIT DIFFERENCES



- ✓ Controllable space, from 10-18mm¹
- ✓ Significant rectal dose differences versus hydrogel in both conventional and ultrahypofractionated plans³
- ✓ Visible on ultrasound, CT, and MRI for accurate placement⁷
- ✓ Adjustable, repositionable design for real-time symmetric spacing^{8*}
- ✓ 98.5% balloon resorption by 6 months¹

References

1. Song, Daniel et al. "Prospective, Randomized Controlled Pivotal Trial of Biodegradable Balloon Rectal Spacer for Prostate Radiation Therapy." *International journal of radiation oncology, biology, physics* vol. 120,5 (2024): 1410-1420. doi:10.1016/j.ijrobp.2024.07.2145
2. Ben-Dor, Yossi et al. "Comparative Evaluation of Symmetry, Dosimetry, and Toxicity in Prostate Cancer EBRT with Spacing Techniques." *Frontiers in Oncology*. 2025;15:1668726. doi:10.3389/fonc.2025.1668726
3. Mariados, Neil et al. "Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy." *International journal of radiation oncology, biology, physics* vol. 92,5 (2015): 971-977. doi:10.1016/j.ijrobp.2015.04.030
4. Kos, Michael et al. "Multicenter, dual fractionation scheme, single core lab comparison of rectal volume dose reduction following injection of two biodegradable perirectal spacers." *Journal of applied clinical medical physics* vol. 24,10 (2023): e14086. doi:10.1002/acm2.14086
5. King, Martin T et al. "Evaluating the Quality-of-Life Effect of Apical Spacing with Hyaluronic Acid Prior to Hypofractionated Prostate Radiation Therapy: A Secondary Analysis." *Practical radiation oncology* vol. 14,3 (2024): e214-e219. doi:10.1016/j.prro.2023.11.010
6. Song, Daniel et al. "Long-term toxicity and patient-reported quality of life after prostate IMRT with or without biodegradable balloon rectal spacer: analysis of a pivotal randomized trial." Abstract presented at: American Society for Radiation Oncology (ASTRO) 67th Annual Meeting; 2025; San Francisco, CA.
7. BioProtect Balloon Implant™ System 510(k) K222972, August 2023.
8. Zimberg, Shawn et al. "Impact of Rectal Spacer Implant Quality on Rectal Dose and Toxicity in Prostate Radiotherapy: Results from a Prospective Clinical Trial." Abstract presented at: American Society for Radiation Oncology (ASTRO) 67th Annual Meeting; 2025; San Francisco, CA.

* Preliminary data are from a conference abstract; not yet peer-reviewed; values and follow-up may change upon publication.