Selected Clinical Evidence Supporting the BioProtect Balloon Spacer

BIOPROTECT

Published pivotal trial and multi-center studies demonstrate meaningful reductions in rectal dose and toxicity, with preliminary data on long-term quality-of-life preservation.

Phase III Pivotal Trial and Linked Long-Term Outcomes

Published Trial

Prospective, Randomized Controlled Pivotal Trial of Biodegradable Balloon Rectal Spacer for Prostate Radiation Therapy

International Journal of Radiation Oncology, Biology, Physics 2024;120(4):897-908. doi:10.1016/j.ijrobp.2024.06.014

Song, Daniel et al.

Prospective, multi-center, randomized, concurrently controlled trial; N=222 men with T1–T3 prostate cancer.

Key Findings

- Rectal V70: 84.8% mean relative reduction vs. control ($p < 0.001$).
- 97.9% of balloon patients achieved a ≥25% reduction in rectal V70 ($p < 0.001$).
- Physician-reported Grade ≥1 rectal toxicity during follow-up occurred in 9.8% of balloon patients vs. 21.5% of controls.
- 98.5% rate of balloon degradation by 6 months.

Abstract

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*

ASTRO 2025 Conference Abstract

Song, Daniel et al.

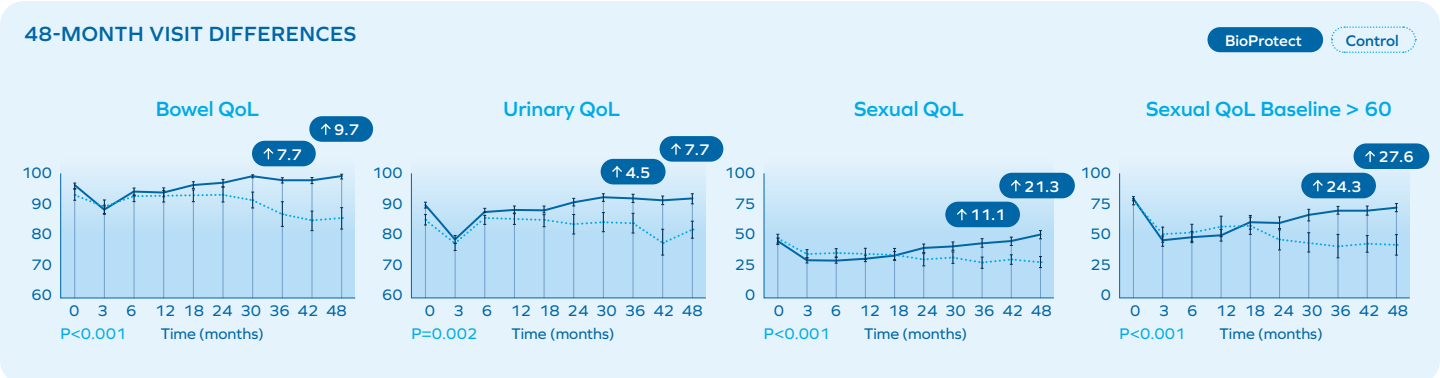
Linked long-term analysis of pivotal trial outcomes. Results are preliminary, have not undergone full peer review, and may change upon publication.

Key Findings

Patient-Reported Quality of Life

- Bowel: Significant benefit for balloon group over 48 months ($p<0.001$).
- Urinary: Significant benefit over 48 months ($p=0.018$).
- Sexual: Significant benefit over 48 months ($p<0.001$).

* Preliminary data are from a conference abstract; not yet peer-reviewed; values and follow-up may change upon publication.



Comparative

Published Study

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 2023;24(11):e14086. doi: 10.1002/acm2.14086

Kos, Michael et al.

Multicenter, double-arm, central core lab retrospective study comparing rectal dosimetry of two biodegradable perirectal spacers; N=59 (EU & US; mix of conventional fractionation and ultrahypofractionation).

Key Findings

- Balloon achieved significantly greater mean rectal V70 reduction than gel spacer in conventional fractionation, with rectal dose reductions observed across all dose levels in both conventional and ultrahypofractionated regimens.

Efficacy Results	BioProtect Balloon Spacer (n=24)	SpaceOAR/ Gel Spacer (n=35)
Mean rV70 relative reduction	84.1%	67.0%
Mean rV70 absolute reduction	7.2%	5.8%
Mean space	1.6 ± 0.6 cm	1 ± 0.3 cm

Other Peer-Reviewed Studies

Published Study

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

Ben-Dor, Yossi et al.

Retrospective dual-arm comparative study of geometry, symmetry, rectal dosimetry, and GI/GU toxicity of BioProtect Balloon Spacer and a PEG gel spacer; N=67.

Key Findings

- Balloon achieved more uniform separation, including apical symmetry.
- Balloon achieved anterior-posterier spacing that was significantly greater at apex, mid-gland, and base ($p<0.001$).
- Apical spacing was absent in 8.8% of gel spacer subjects — and achieved in 100% of balloon subjects.

Published Study

Toxicity, Quality of Life, and PSA Control After 50 Gy Stereotactic Body Radiation Therapy to the Dominant Intraprostatic Nodule With the Use of a Rectal Spacer: Results of a Phase I/II Study

British Journal of Radiology 2023 Apr 1;96(1145):20220803. doi: 10.1259/bjr.20220803

Cloitre, Minna et al.

Phase I/II trial evaluated SBRT to the whole prostate (36.25 Gy/5 fractions) with focal dose escalation to the dominant intraprostatic nodule (DIN) up to 50 Gy using the balloon spacer.

Key Findings

- No Grade ≥3 toxicity; 3% late G2 GI.
- Quality of life outcomes: Patient-reported assessments indicated preservation of urinary, gastrointestinal, and sexual domains, consistent with physician-reported toxicity.