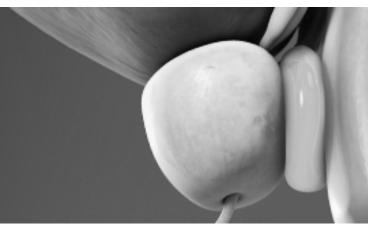
SpaceOAR™ Hydrogel



Association of the Placement of a Perirectal Hydrogel Spacer With the Clinical Outcomes of Men Receiving Radiotherapy for Prostate Cancer A Systematic Review and Meta-analysis

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A systematic review and meta-analysis were conducted to evaluate the correlation between perirectal hydrogel spacer placement and clinical outcomes of men receiving radiotherapy for prostate cancer. The review consisted of 7 studies (1 randomized clinical trial and 6 cohort studies) with 1011 patients (486 receiving hydrogel spacer and 525 controls) with a median duration of patient follow-up of 26 months.

In 6 studies, the success rate of hydrogel placement was 97.0% and the mean perirectal space creation was 11.2mm. In 6 studies, the hydrogel spacer group received 66% less v70 rectal irradiation compared to controls. In 6 studies, the risk of grade 2 or higher rectal toxicities were comparable in early follow-up. However, risk of grade 2 or higher rectal toxic effects were 77% lower in the hydrogel spacer group in late follow-up in 6 studies.

In 2 studies, bowel-related quality of life were similar between both groups in early follow-up but were greater in the hydrogel spacer group in late follow-up.

This concluded that an injection of a hydrogel spacer was safe, provided prostate-rectum separation sufficient to reduce v70 rectal irradiation, and was associated with fewer rectal toxic effects and higher bowel-related quality of life for patients receiving prostate radiotherapy.

Figure 1. Rectal Irradiation With vs Without Perirectal Hydrogel Spacer

Source	Mean (SE) difference	Mean difference (95% CI)	Favors Favor spacer contro	
Chao et al.,18 2019	-1.1 (0.33)	-1.10 (-1.75 to -0.45)	-	18.6
Mariados et al.,4 2015	-8.4 (0.58)	-8.40 (-9.54 to -7.26)		18.4
Pinkawa et al., ¹⁴ 2017	-10.0 (1.21)	-10.00 (-12.37 to -7.63)		17.5
te Velde et al., ²⁰ 2019	-5.3 (1.26)	-5.30 (-7.77 to -2.83)		17.4
Whalley et al., ²¹ 2016	-8.2 (2.87)	-8.20 (-13.83 to -2.57)		13.6
Wolf et al., 22 2015	-6.7 (2.53)	-6.70 (-11.66 to -1.74)	_	14.5
Total		-6.51 (-10.51 to -2.51)		100.0

Heterogeneity: $\tau^2 = 22.37$; $\chi_s^2 = 159.40$; P < .001; $I^2 = 97\%$

Overall effect: z = 3.19; P = .001

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

PBT was not the method used in the SpaceOAR™

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

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