CLINICAL SUMMARY

SpaceOAR Vue™ Hydrogel

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The Role of a Radiopaque Hydrogel Spacer in Image-Guidance for Prostate Stereotactic Radiotherapy

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The purpose of this study was to evaluate the potential of a CT-visible hydrogel spacer to serve as a surrogate fiducial marker for prostate IGRT.

Per standard practice, patients underwent placement of three intraprostatic gold markers for alignment and a SpaceOAR Vue Hydrogel to decrease rectal radiation dose before planning prostate SABR. During treatment, table shifts based on conebeam CT to the planning CT were performed by three-dimensional alignment of the SpaceOAR Vue Hydrogel (experimental arm) and then the fiducial markers (standard arm). Six directional shifts, three linear and three rotational, were recorded and the differences were compared.

An evaluation of 140 fractions across 41 patients showed the mean/median differences between SpaceOAR Vue Hydrogel and fiducial based in the three linear and three rotational shifts were 0.9/0.6mm, 0.8/0.5mm and 0.6/0.4mm and 0.38/0, 0.62/0 and 0.35/0 degrees, respectively. There was no gland volume correlation with shift differences. A learning curve was present with significantly less variability between alignment methods in the second half of fractions compared to the first in five of the six axes. There were no differences observed between alignment methods of the three rotational shifts in the latter 70 fractions.

Thus, proving daily alignment with visible SpaceOAR Vue Hydrogel was highly comparable to intraprostatic gold fiducial markers with an observed rapid learning curve for precise IGRT in prostate SABR.

Table 1: SOv-based vs. fiducial-based daily target alignment

Shift Axis	Overall Differences		Learning Curve		
	Median (IQR)	Mean ± Std	Mean: Fx 1-70	Mean: Fx 71-140	P value
Linear (mm)					
Vertical	0.6 (0.2-1.2)	0.9±0.9	1.1	0.6	0.0032
Longitudinal	0.5 (0.1-1.3)	0.8±.9	1.0	0.7	0.0464
Lateral	0.4 (0.1-0.8)	0.6±1	0.8	0.5	0.1244
Rotational (degrees)					
Rotation	0 (0-0.3)	0.381.15	0.7	0.02	<.0001
Pitch	0 (0-0.5)	0.62±.85	1.2	0.8	<.0001
Roll	0 (0-0.4)	0.35±.81	0.65	0.05	<.0001

IQR = interquartile range; std = standard deviation; Fx = fraction

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