

# Hydrogel spacer use for prostate cancer radiotherapy

## - 12 month toxicity and proctoscopy results

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# *Objective*

evaluation of the safety, dosimetric and clinical effects of a hydrogel prostate-rectum spacer

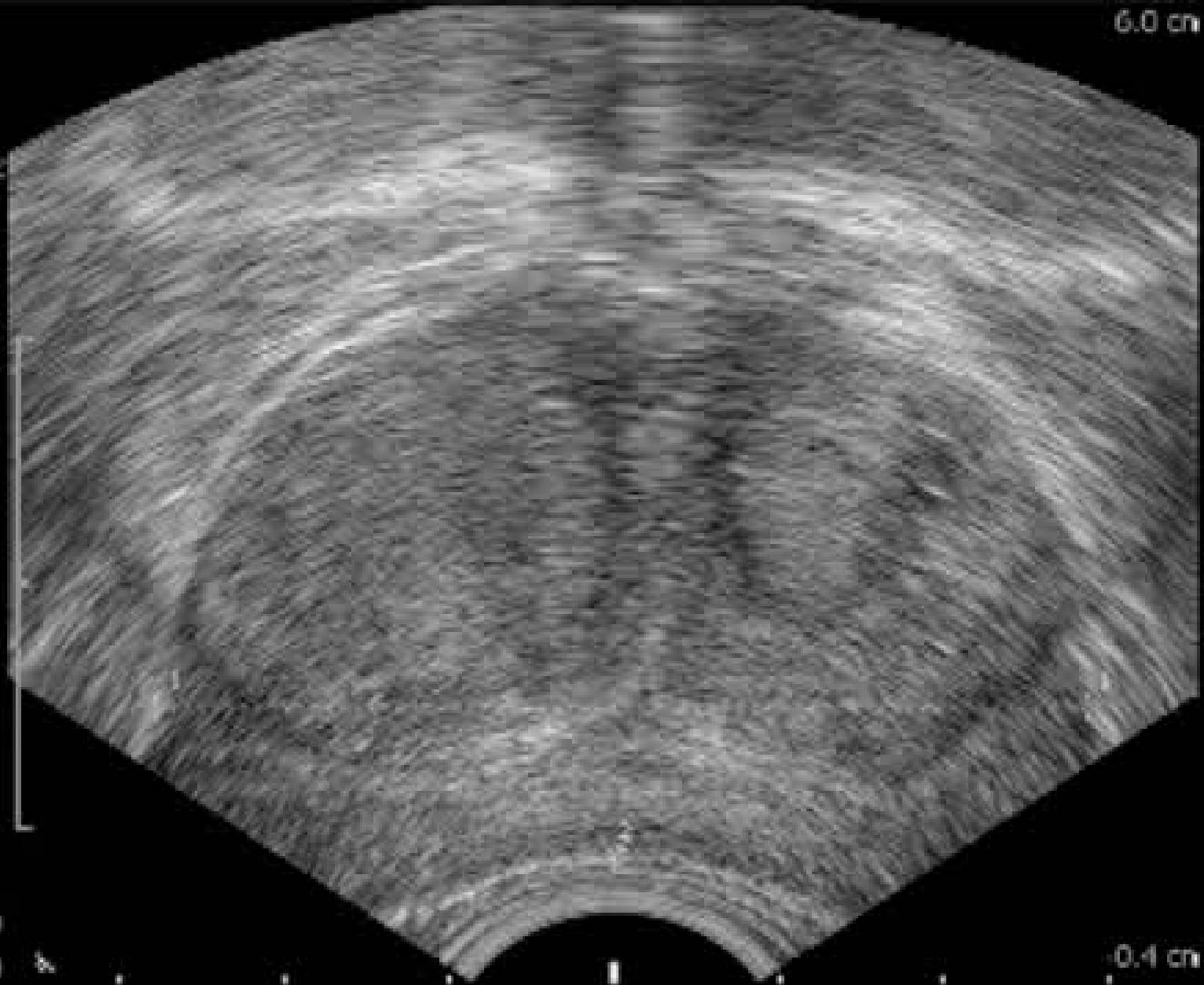
# *Methods*

- 52 patients with localized prostate cancer received a transperineal TRUS guided hydrogel (SpaceOAR, Augmenix Inc.) injection
- the initial hydrogel volume of 15ml was reduced to 10ml during the study
- all patients were treated with 2Gy fractions using an IMRT technique up to a total dose of 78Gy
- GI and GU toxicity were recorded during treatment and at 3, 6 and 12 months following irradiation by using the RTOG/EORTC criteria
- proctoscopy was performed 12 months after treatment and the results were scored using the Vienna Rectoscopy Score (VRS)



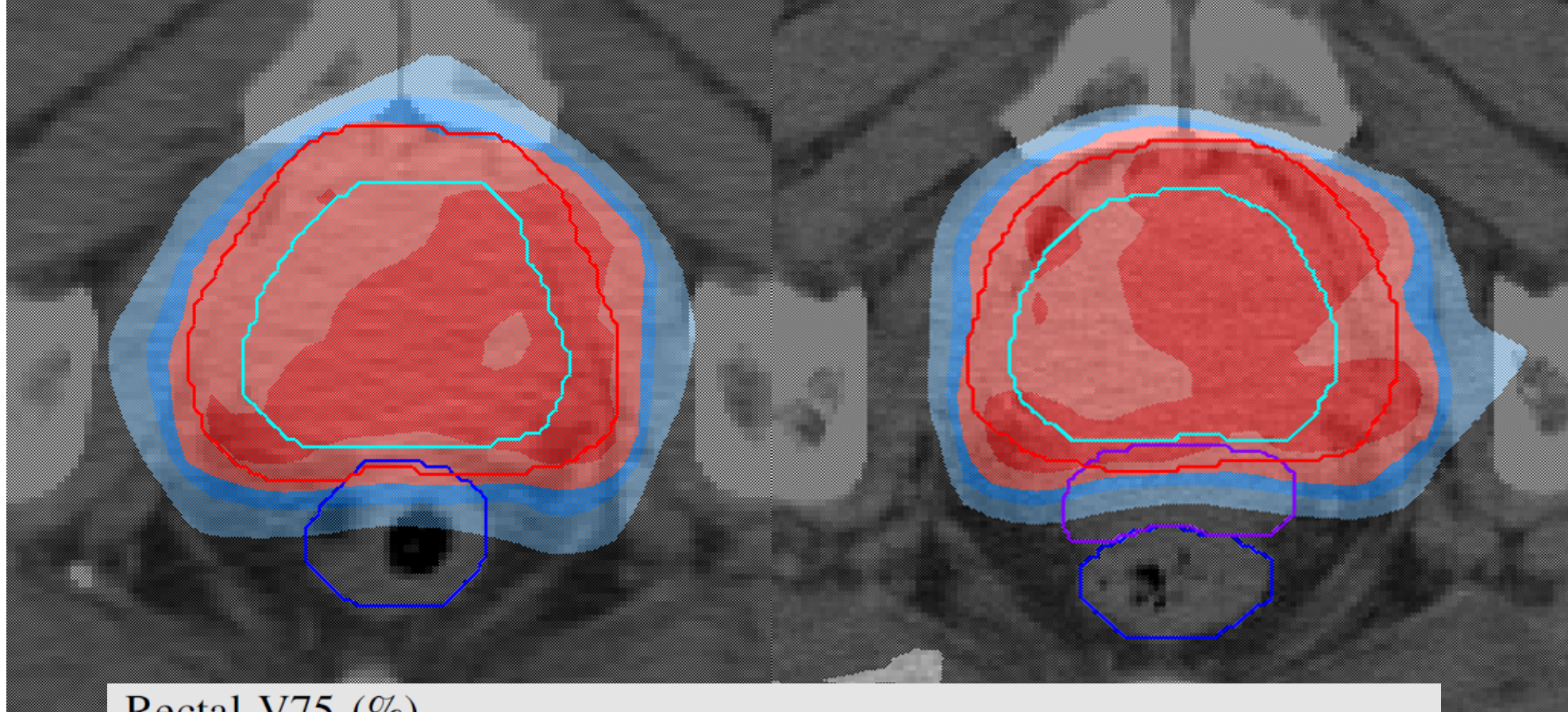
6.0 cm

MI: 1.23<1.50  
TIS: 1.0<2.0  
Res / Hz 3/48 Hz  
▶ Allg. Messung



0.4 cm

▼ Messungen  
Dist 2 1.01 mm  
Dist 1 56.5 mm



### Rectal V75 (%)

Mean ( $\pm$ SD)      5.5 ( $\pm$ 3.2)      1.2 ( $\pm$ 1.3)

Median (range)      5.6 (0.2-11.1)      0.9 (0.0-5.4)      <.001

### Rectal V70 (%)

Mean ( $\pm$ SD)      13.0 ( $\pm$ 6.2)      5.1 ( $\pm$ 4.2)

Median (range)      11.6 (3.1-32.7)      4.0 (0-19.5)      <.001

### Rectal V65 (%)

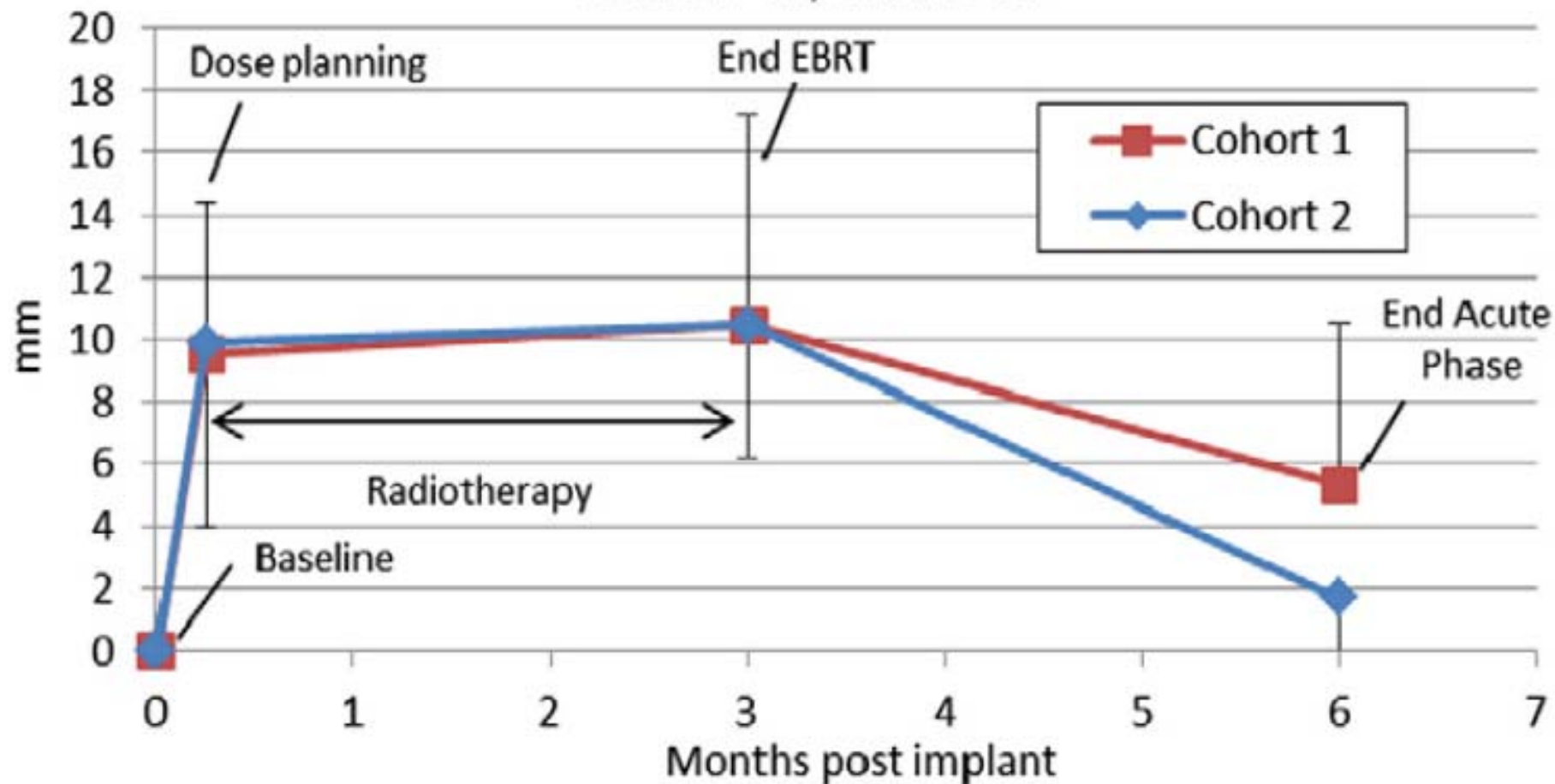
Mean ( $\pm$ SD)      17.9 ( $\pm$ 8.4)      8.8 ( $\pm$ 7.0)

Median (range)      16.3 (3.7-43.4)      6.9 (0.0-31.6)      <.001

# Prostate - Rectum Space

Mean change from baseline

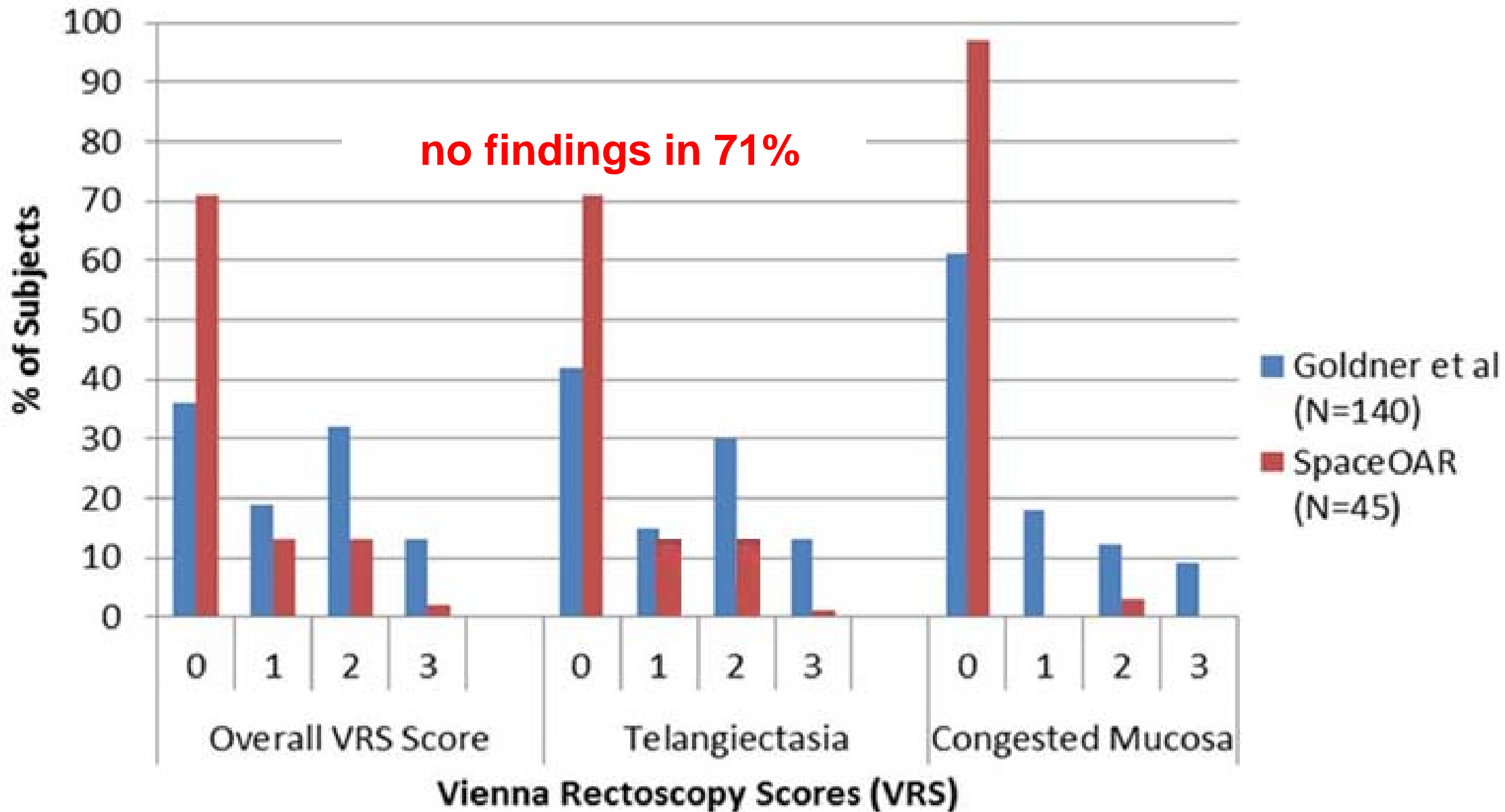
Cohort 1 + SD, Cohort 2 - SD



# Toxicity

Grade	GI Toxicity Scores (n %)		GU Toxicity Scores (n %)	
	Acute	Late	Acute	Late
0	23 (48.0%)	45 (95.7%)	10 (21.0%)	38 (80.9%)
1	19 (39.6%)	2 (4.3%)	20 (41.7%)	8 (17.0%)
2	6 (12.5%)	0 (0%)	17 (35.4%)	1 (2.1%)
3	0 (0%)	0 (0%)	1 (2.1%)	0 (0%)
4	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 1 or worse	25 (52.1%)	2 (4.3%)	38 (79.2%)	9 (19.1%)
Grade 2 or worse	6 (12.5%)	0 (0%)	18 (37.5%)	1 (2.1%)

# Vienna Rectoscopy Score



no evidence of ulceration, stricture or necrosis



# *Conclusions*

- the hydrogel spacer gel is a safe and effective method to increase the distance between the prostate and rectum
- late GI toxicity is hardly detectable and the rectal wall without radiotherapy related changes for the majority of patients on endoscopy