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Impetus: Excessive dose to rectal mucosa and adjacent normal tissue was a limiting factor in treating deep (>1cm) targets, assessed on MRI. We wish to provide a conformal HDR treatment for a well visualized target.

Here, we describe for the first time, a new multichannel, MR compatible HDR-EBT applicator with a novel balloon-based design to provide improved treatment geometry.

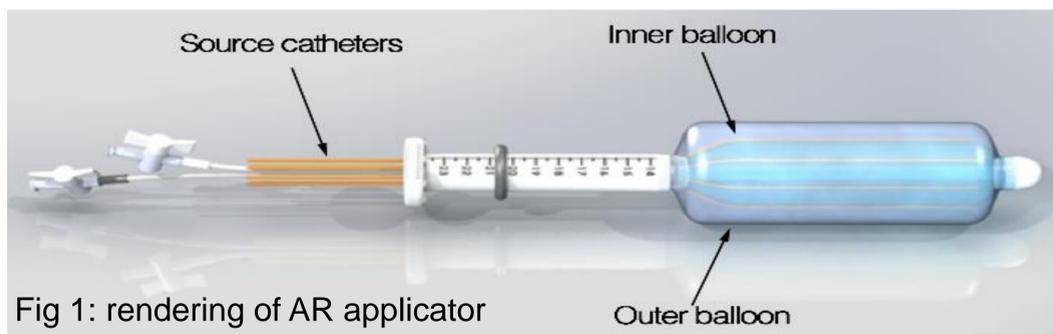


Fig 1: rendering of AR applicator

Materials and Methods: The newly designed ano-rectal (AR) applicator (figure 1) is a multichannel, single use applicator with two concentric balloons. The inner balloon supports 8 radially symmetric source lumens; the outer balloon provides separation between the mucosal wall and the source lumens. The effective treatment zone of the applicator, in which the source lumens maintain the cylindrical geometry, is 10 cm long and is delineated by two central markers for positioning and treatment verification. Imaging modalities used were CT (Philips Brilliance Big Bore, Philips Healthcare, Bothell, WA), CBCT/Fluoroscopy (O-arm, Medtronic Navigation, Littleton, MA) and MRI (Philips Ingenia 3T). The applicator was placed in a phantom, a cylindrical plastic tube with epoxy in one location to simulate the target, for imaging and planning. Brachyvision TPS (Varian Medical Systems, Charlottesville, VA) was used for treatment planning. Two scenarios were simulated: in Case I, a 1 cm deep tumor is protruding from the wall of the phantom into the applicator; in Case II, a 1 cm deep tumor is extending from the wall of the outer balloon away from

the applicator. Dose to the 'tumor' and 'mucosa' were analyzed as was the dose to 'normal tissue'.

Results: The applicator is well visualized in CT, and T1 and T2 MRI sequences. While it is also visualized in CBCT, for this modality soft tissue it is not expected to be well visualized in the clinical setting (fig 2). The latter may also be used to assess inflation and deformation of the applicator at the time of treatment.

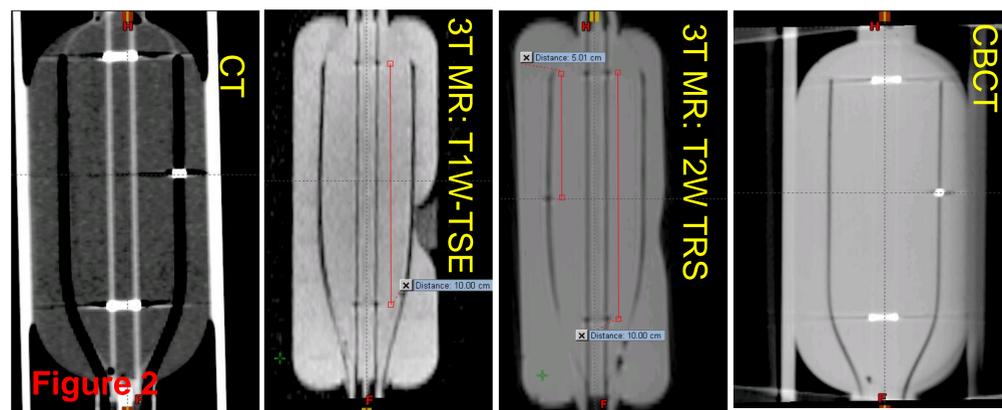
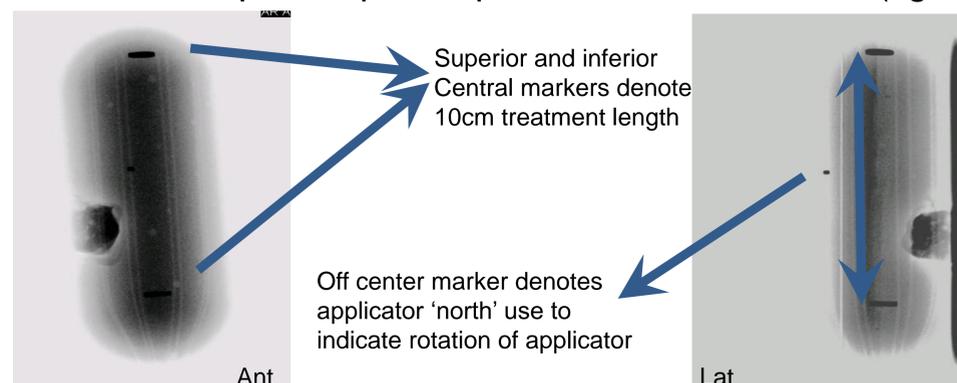


Figure 2

Fluoroscopy was used to assess the position/rotation of the applicator with respect to pre-implanted fiducial markers (fig 3).



Superior and inferior Central markers denote 10cm treatment length

Off center marker denotes applicator 'north' use to indicate rotation of applicator

MRI based treatment plans created with the intent to deliver 5Gy to the target volume and limit the rectal mucosa to no more than 200% of prescription achieved good conformity (figure 4 and table). Dose to the contra lateral rectal wall was strongly dependent on

target volume and treatment depth. In both cases, dose to the contra-lateral rectal wall was reduced to less than 50% of prescription.

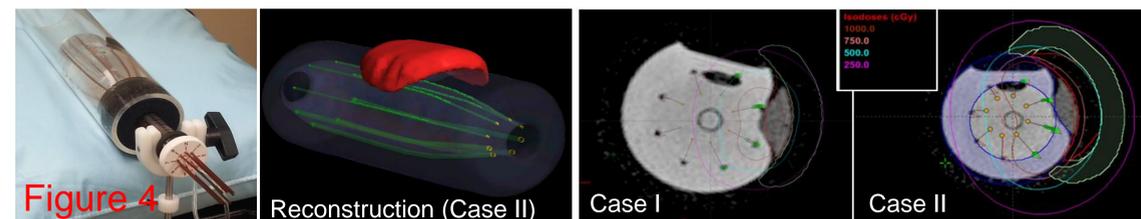


Figure 4

	V100	D90	Dmax	Mucosa Max
Case I	98%	113%	540%	121%
Case II	95%	108%	200%	195%

Conclusion: Mapping of the applicator with MRI offers clinical feedback, and the possibility of reducing the target volume as the treatment progresses. These preliminary results provide encouragement to proceed in a pilot clinical study.

Based on this phantom study, initial dosimetric results are promising, but will be highly dependent on:

- target geometry, and
- ability to push mucosa away from source
- Use of MRI expected to improve
 - target visualization, and by extension
 - help reduce normal tissue dose
- Clinical trial will be conducted under institutional IRB

Disclosures:

This work is the collaboration of MSKCC and Ancer Med Off-Label Use: FDA approval has been applied for. Patents pending.

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