

RectalPro™

Prostate Endorectal Balloon (ERB)



Advanced Technology - Prostate ERB

Proton Therapy - IMRT/SBRT

Brachytherapy - Prostate Beds

RectalPro™

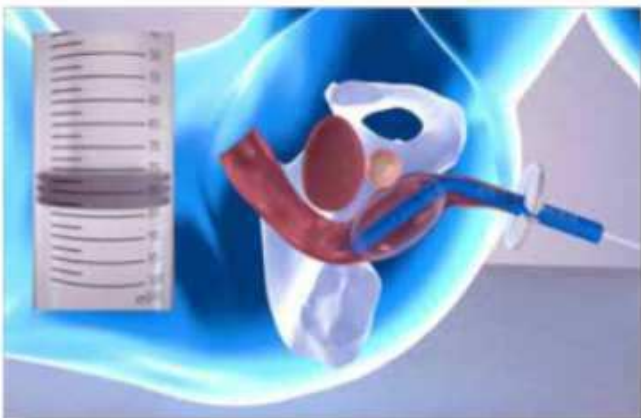
Prostate Endorectal Balloon (ERB)



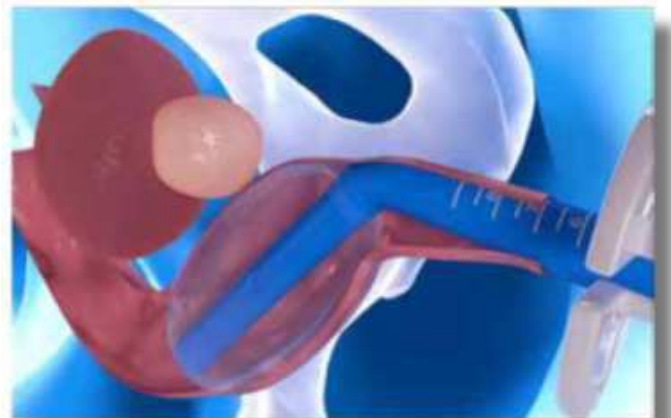
Insert the ERB tip towards the table/couch and follow the anatomical curve of the colon



ERB inserted



Slowly inflate with air/water 60-100cc with physician's directions



After inflation, pull down the ERB and affix the stopper

SBRT FOR PROSTATE CANCER A RANDOMIZED PHASE II TRIAL

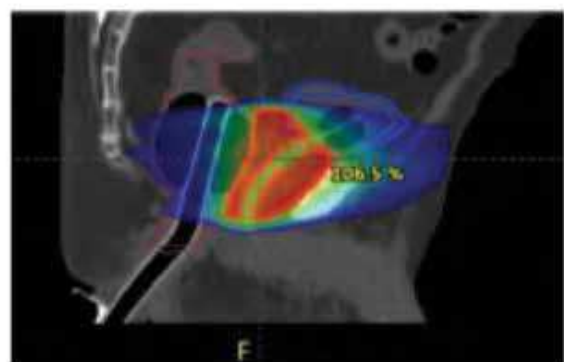
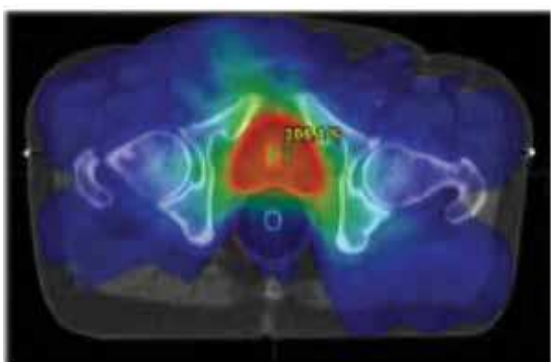
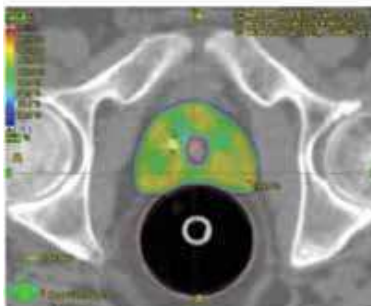
Thomas ZILLI, MD

Prof. Raymond MIRALBELL, MD



ESTRO meeting 2017 Vienna

- 170 randomized patients (2012-2015)
- Complete recovery to the GI baseline status at the 12 week follow-up
- 12-weeks results demonstrate for both study arms the feasibility, tolerance, and good acute toxicity of an SBRT



RectalPro™ Prostate Endorectal Balloon (ERB)



Reduces ano-rectal
toxicity¹

Increases Gland
stability²

Improved daily
reproducibility³

Sparing effect of rectal
walls and sphincter^{4,5}

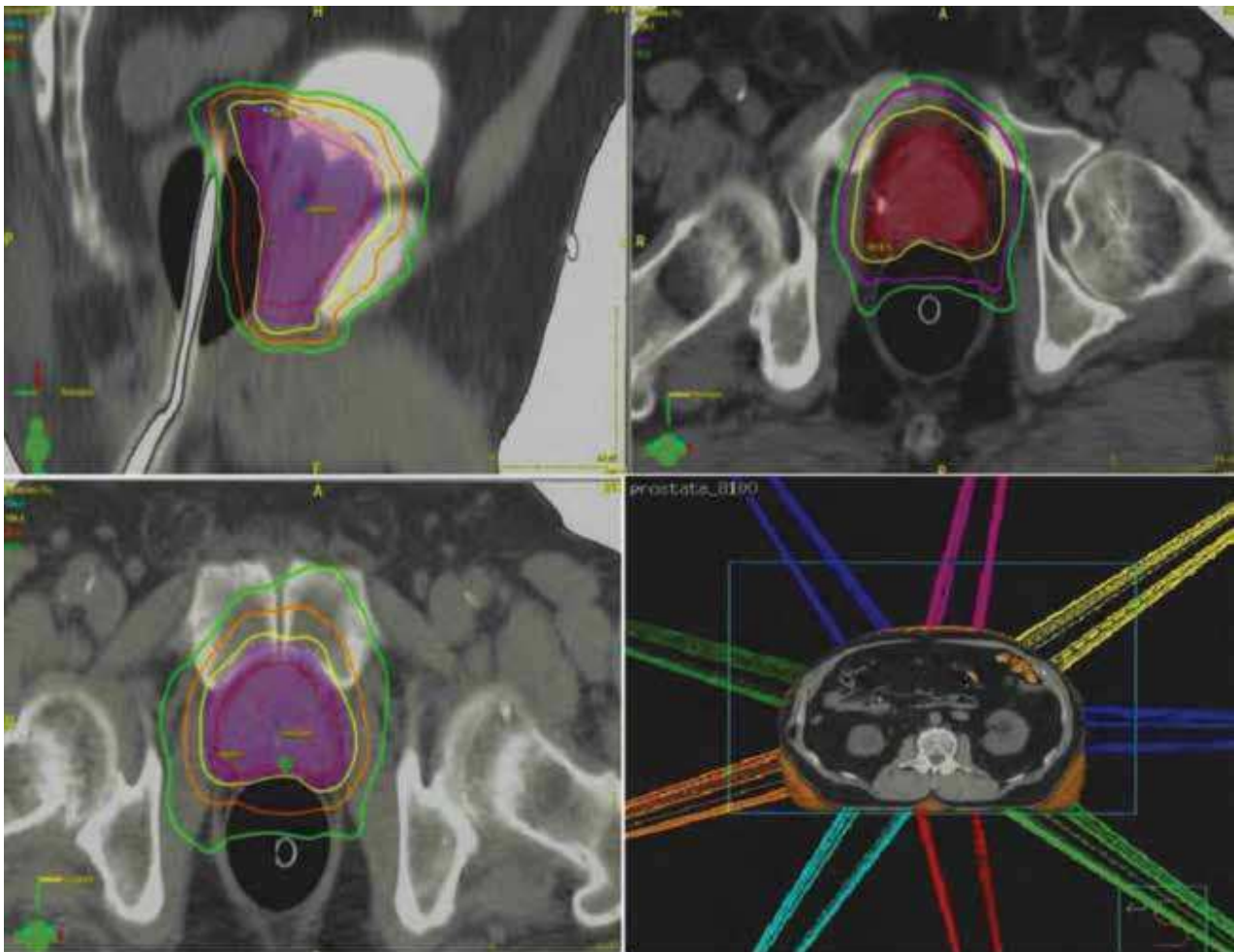
Reduces Intrafraction
prostate motion⁶

Features of the QLRAD ERB

- Curved shaft designed to promote patient comfort
- Reproducible balloon positioning
- Air/water fill volume able to be varied according to clinician preferences

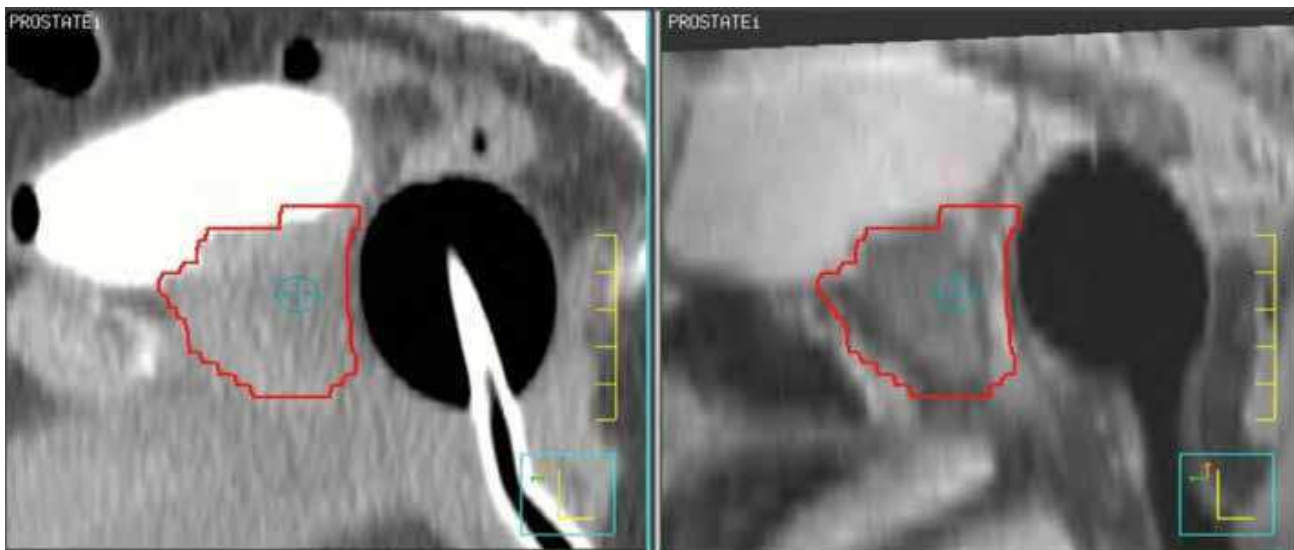
Potential Benefits of Endo-Rectal Balloons During IMRT for Localized Prostate Cancer

- Limit prostate intra-fraction motion during IMRT⁷
- Decrease anal and rectal late toxicity⁸
- Distends rectum, so lower percent of rectum treated⁹
- Reduces objective rectal mucosal telangiectasias¹⁰
- Limits prostate movement while “beam on”¹¹

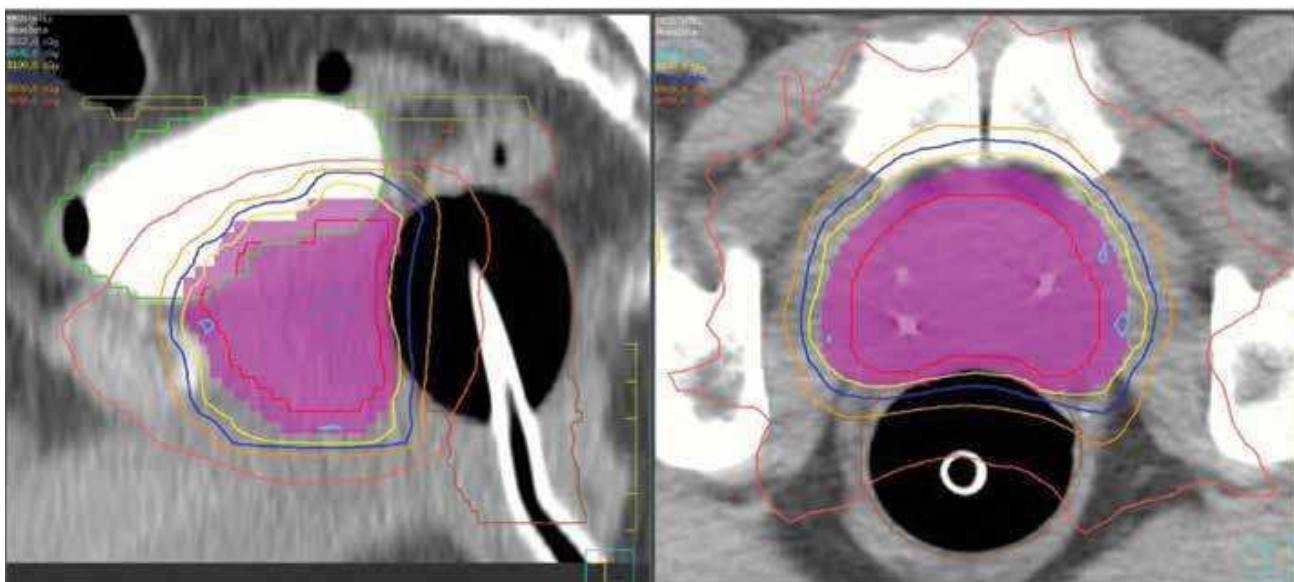


RectalPro™

Endorectal Balloon (ERB)



CT and MRI views



Sagittal view with isodose curves

Traverse view with isodose curves



- ¹ Smeenk RJ, Teh BS, Butler EB, van Lin EN, Kaanders JH. Is there a role for endorectal balloons in prostate radiotherapy? A systematic review. *Radiother Oncol.* 2010 Jun;95(3):277-82.
- ² Wachter S, Gerstner N, Dorner D, Goldner G, Colotto A, Wambersie A, Pötter R. The influence of a rectal balloon tube as internal immobilization device on variations of volumes and dose-volume histograms during treatment course of conformal radiotherapy for prostate cancer. *Int J Radiat Oncol Biol Phys.* 2002 Jan 1;52(1):91-100.
- ³ Smeenk RJ, Louwe RJ, Langen KM, Shah AP, Kupelian PA, van Lin EN, Kaanders JH. An endorectal balloon reduces intrafraction prostate motion during radiotherapy. *Int J Radiat Oncol Biol Phys.* 2012 Jun 1;83(2):661-9.
- ⁴ van Lin EN, Hoffmann AL, van Kollenburg P, Leer JW, Visser AG. Rectal wall sparing effect of three different endorectal balloons in 3D conformal and IMRT prostate radiotherapy. *Int J Radiat Oncol Biol Phys.* 2005;63(2):565-576.
- ⁵ Smeenk RJ, Hoffmann AL, Hopman WP, van Lin EN, Kaanders JH. Dose-effect relationships for individual pelvic floor muscles and anorectal complaints after prostate radiotherapy. *Int J Radiat Oncol Biol Phys.* 2012;83(2):636-644.
- ⁶ Smeenk RJ, Louwe RJ, Langen KM, et al. An endorectal balloon reduces intrafraction prostate motion during radiotherapy. *Int J Radiat Oncol Biol Phys.* 2012;83(2):661-669.
- ⁷ Smeenk RJ, Louwe RJ, Langen KM, et al. An endorectal balloon reduces intrafraction prostate motion during radiotherapy. *Int J Radiat Oncol Biol Phys.* 2012;83(2):661-669.
- ⁸ Wachter S, Gerstner N, Dorner D, et al. The influence of a rectal balloon tube as internal immobilization device on variations of volumes and dose-volume histograms during treatment course of conformal radiotherapy for prostate cancer. *Int J Radiat Oncol Biol Phys.* 2002;52(1):91-100.
- ⁹ Smeenk RJ, Teh BS, Butler EB, van Lin EN, Kaanders JH. Is there a role for endorectal balloons in prostate radiotherapy? A systematic review. *Radiother Oncol.* 2010 Jun;95(3):277-82.
- ¹⁰ van Lin EN, Kristinsson J, Philippens ME, et al. Reduced late rectal mucosal changes after prostate three-dimensional conformal radiotherapy with endorectal balloon as observed in repeated endoscopy. *Int J Radiat Oncol Biol Phys.* 2007;67(3):799-811.
- ¹¹ Smeenk RJ, Louwe RJ, Langen KM, et al. An endorectal balloon reduces intrafraction prostate motion during radiotherapy. *Int J Radiat Oncol Biol Phys.* 2012;83(2):661-669.

Full studies and presentations are available upon request.

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