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# **Compliance Assessment of the Anal Canal**

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– Introduction –

- Compliance describes the ability of a hollow organ, e.g. anal canal (AC), to distend when an intraluminal pressure is applied.
- The AC's compliance is assessed via the Functional Luminal Imaging Probe (FLIP).
- During controlled volumetric distension FLIP measures cross-sectional areas (CSAs) along the AC and intraluminal pressure.
- However, FLIP does not provide anatomic information.



#### Method

- In an observational study 20 healthy volunteers have been assessed (10 women, 10 men, age > 60years).
- Two independent setups were used to measure the AC's compliance
  - A clinical FLIP (Crospon Inc., Galway, Ireland) and
  - A custom-made MR-compatible catheter (MR-FLIP)
- The catheters were filled in 10ml steps from 0ml to 50ml.
- Compliance was calculated as the ratio between the increase in diameter and corresponding increase in pressure in the catheter.

#### Results

- No statistical difference was found between both measurement methods, i.e. FLIP and MRFLIP.
- FLIP and MR-FLIP measurements are reliable for volumes > 30ml.
- The smallest opening of the AC, being the least compliant, corresponds to the superior end of the EAS (Fig 1, Pos A).
- The measured compliance of men and women is not significant different at the height of smallest AC opening (Fig 2).







Figure 2: Compliance at the position of the smallest AC diameter, superior end of the EAS (Figure 1, Pos A) respectively. Values for male (filled markers) and female for balloon volumes of 30ml (diamonds), 40ml (circles), and 50ml (squares).

register the mechanical compliance measurements with the underlying muscle structures (hypointense and encircled with white dashed line).

### - Conclusion

- This is the first study to combine FLIP measurements with medical MR-imaging providing anatomical information.

- The most relevant zone for passive (in)continence corresponds to the upper end of the AC (puborectal sling).

## – Guideline parameters for the SmartSphincter implant

Passive parameters:

- Length (m/f):  $29 \pm 4 \text{ mm} / 24 \pm 5 \text{ mm}$
- Outer EAS radius (m/f):  $18 \pm 1 \text{ mm} / 14 \pm 2 \text{ mm}$
- E-modulus: several 10kPa

Active :

- Pressure @ rest (m/f): 52 mmHG / 47 mmHG
- Pressure @ squeeze (m/f): 156 mmHG / 77 mmHG