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# ProSpare's tolerability is independent of rectal anatomy

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***Abstract*** **-** ProSpare, a self-insertable rectal obturator, has shown promise in reducing prostate motion and anorectal dosimetry in prostate radiotherapy. However, initial data from a post-prostatectomy radiotherapy trial (POPS trial NCT02978014) revealed that 37% of patients could not tolerate ProSpare insertion, possibly because of a mismatch with rectal anatomy. Our study aimed to compare rectal anatomy between patients who could and could not tolerate ProSpare insertion and determine threshold values for anorectal angle, anal canal length, or rectum diameter conducive to insertion. We analysed the anorectal angle, anal canal length, and rectal diameter in patients who could tolerate ProSpare insertion (Group Y), those who could not (Group N), and those with ProSpare inserted (Group PS), by using planning CT scans from the POPS trial. There were no significant differences in the anorectal angle, anal canal length, or rectal diameter between Group Y and N ($p>0.05$). There were significant differences between Group PS and the others in anorectal angle ($p<0.01$) and rectal diameter ($p<0.001$). These results suggest rectal anatomy is unlikely the limiting factor for ProSpare tolerance; instead, it could be anal sphincter diameter or tone, or nociceptive sensitivity. Patients with ProSpare showed increased anorectal angles and rectal diameters, suggesting the rectum expands to accommodate the device. This supports ProSpare's efficacy as a rectal spacer during prostate radiotherapy. We recommend the future development of rectal obturators should follow the design of deployable or inflatable devices while emulating ProSpare's properties.

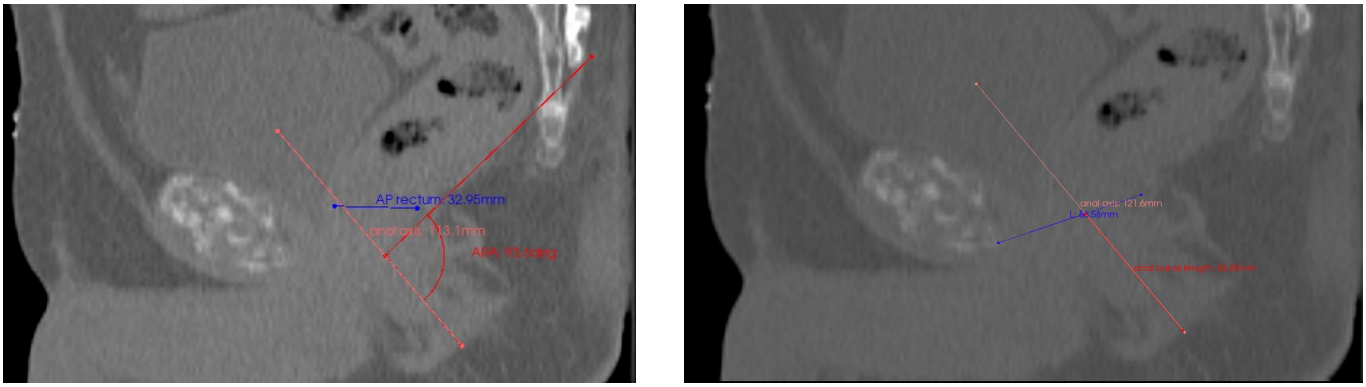
***Keywords*****:** Prostate Cancer, Radiotherapy, Rectal obturator, Tolerance

## 1. Introduction

ProSpare is a self-insertable rectal obturator that has been shown to decrease prostate motion [1] and anorectal dosimetry [2] in prostate radiotherapy. ProSpare is currently undergoing a trial in post-prostatectomy radiotherapy (POPS trial NCT02978014) where initial data has shown that 7/19 (37%) patients cannot tolerate the insertion of ProSpare. This is despite multiple design modifications because of poor tolerance in prior populations [3]. Patients who can tolerate the insertion of ProSpare can walk to the radiotherapy couch with the device inside and maintain it for the duration of the radiotherapy fraction, with no difficulty or discomfort. Other rectal devices for prostate radiotherapy, such as the rectal retractor, do not have such a high rate of intolerance. Rectal retractors and proctoscopes have similar diameters to ProSpare at 20 mm [4], 21-23 mm [5], and 23 mm, respectively. We hypothesise that ProSpare's tolerability is dependent on its shape matching the patient's rectal anatomy; ProSpare is a rigid device with a fixed shape, while rectal anatomy can vary significantly between patients. Firstly, the angle at the anorectal junction, the anorectal angle, can vary significantly in healthy individuals. Piloni et al [6] reported 95% of healthy volunteers (n=69) had an anorectal angle in the range of 84° to 125° and the American Society of Colon and Rectal Surgeons states the normal range is 90-110° [7]. Secondly, the surgical anal canal—the length from the anorectal junction to the anal verge—can vary from 3-5 cm [8]. Lastly, rectal diameter can vary from 2.67 cm to 4.72 cm [9]. Hence, we hypothesise, some patients may not be able to insert ProSpare because either: the length of the anal canal does not allow sufficient insertion for ProSpare's to follow the anorectal angle; the angle of the rectum is not matched to ProSpare, causing pain; or the rectum is too narrow, impacting insertion. The first aim was to ascertain differences in the rectal anatomy between patients who tolerated the insertion of ProSpare and those who could not tolerate the insertion. The second aim was to find a threshold for at least one of: anorectal angle, anal canal length, or rectum diameter, at which patients were able to insert ProSpare.

## 2. Materials and Methods

CT planning scans of patients in the POPS trial (NCT02978014) who could tolerate the insertion of ProSpare (Group Y), could not tolerate the insertion of ProSpare (Group N), and had ProSpare inside (Group PS) the rectum on planning scan were analysed using 3D Slicer. Group PS was also analysed to investigate how ProSpare affects the shape of the rectum. Measurements were taken in the sagittal plane at the level of the pubic symphysis. We measured the anorectal angle, length of the surgical anal canal, and rectal diameter at the location of the anorectal angle. Anal canal widths could not be measured because the anal sphincters could not be distinguished from the anal canals in the planning scans. Anorectal angle was defined as the angle between the longitudinal axis of the anal canal and a line parallel to the posterior rectal wall (Fig. 1a). This is how anorectal angle is defined in defecography studies [10,11]. Since the anorectal ring, the superior border of the surgical anal canal [8], could not be identified, a line was drawn from the most posterior point of the pubic symphysis to the most posterior point on the anorectal junction to define the superior border of the anal canal on the CT planning scans (Fig. 1b). The anal canal length was defined as the distance between this line and the anal verge along the longitudinal axis of the anal canal. Rectal diameter was measured in the anterior-posterior direction at the anorectal junction (Fig. 1a). Length measurements were rounded to the nearest mm and angles to the nearest degree. One-way ANOVA tests determined if any means were significantly different between groups. If ANOVA tests yielded $p<0.05$, then unpaired t-tests were carried out between the groups.




(a) (b)

Fig. 1: A patient's CT planning scan with annotations analysing the rectum shape and size to assess features between patients who could insert ProSpare and those who could not. (a) The anorectal angle (red) and anterior-posterior rectal diameter (blue) at the anorectal angle are measured. (b) Anal canal length (red) is measured. Pink = longitudinal axis of the anal canal.; Purple = upper boundary of the anal canal.

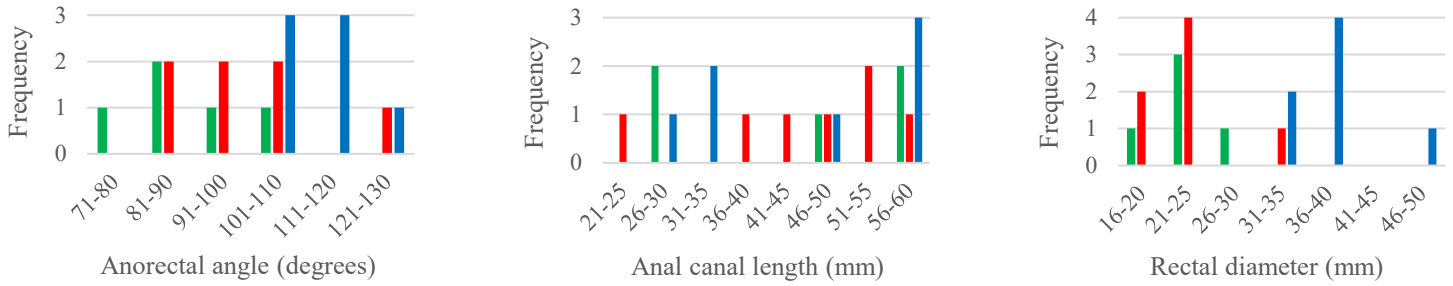
Table 1: Mean (±SD) anorectal angle, anterior-posterior rectal diameter at the anorectal junction, and anal canal lengths in patients who could tolerate ProSpare (Group Y), patients who could not tolerate ProSpare (Group N), and patients who had ProSpare inside (Group PS), as seen on planning CT scan; SD = standard deviation; [abc]Within the same row, values with a common superscript are statistically different ([a]$p<0.05$; [b]$p<0.01$; [cd]$p<0.001$).

| | **Group Y** | **Group N** | **Group PS** |
|---|---|---|---|
| **Anorectal angle (°)** | 91.4 (±11.2)[b] | 99.0 (±13.0)[a] | 113.6 (±9.1)[a b] |
| **AP rectal diameter at anorectal junction (mm)** | 27.8 (±4.9)[c] | 26.1 (±5.7)[d] | 39.3 (±3.1)[c d] |
| **Anal canal length (mm)** | 43.0 (±13.9) | 44.6 (±12.1) | 45.4 (±12.6) |

## 3. Results

Group Y consisted of five patients, Group N had seven patients, and Group PS had seven patients. Table 1 shows the means and standard deviations of anorectal angle, rectal diameter, and anal canal length for each group, as measured

on CT planning scans. One-way ANOVA tests found that no means between Groups Y and N were significantly different ($p>0.05$). The anorectal angle and rectal diameter were significantly different between Group Y and Group PS ($p<0.01$, and and $p<0.001$, respectively), and between Group N and Group PS ($p<0.05$ and $p<0.001$, respectively). Figure 2 shows the the distributions of anorectal angle, rectal diameter, and anal canal length. No group had a clear cut-off threshold at which which its distribution started uniquely to the other groups.




(a) (b) (c)

Fig. 2: Distributions of measurements of patients' rectums who could insert ProSpare (Green), could not insert ProSpare (Red), and had ProSpare inside (Blue). (a) Distribution of anorectal angles (b) Distribution of anal canal lengths. (c) Distributions of rectal diameter in the anterior-posterior direction at the anorectal junction.

## 4. Discussion

This preliminary study suggests macroscopic rectal anatomy is not the limiting factor in tolerating ProSpare. The anorectal angle measurements of patients in our study were within the 85-125° range, despite differences in positioning compared to traditional defecography studies: patients were supine for CT imaging, but in the left lateral decubitus position in defecography studies [7,12]. Anal canal lengths differ significantly because we were unable to identify the anorectal ring on CT scans. However, our systematic approach of approximating the upper boundary of the anal canal allows us to compare our groups. Lastly, our measured rectal diameters were below the normal range in Kuhlmann et al's study [9], because we measured at the anorectal junction, whereas Kuhlmann et al measured the widest part of the rectum. The anorectal junction is a narrower region transitioning to the anal canal and was our region of interest. We found no defining feature of macroscopic rectal anatomy that impacts the ability to insert ProSpare. However, once inserted, ProSpare was observed to increase the anorectal angle and rectal diameters, indicating its effectiveness as a spacer and rectal stabiliser in prostate radiotherapy, as the rectum conforms to ProSpare's shape and size.

Since the results were obtained using a small sample size in a modality that was readily available from an ongoing trial, a more comprehensive study investigating other parts of the anorectal anatomy—rectal wall thickness and stiffness, nociceptive sensitivity, and variations in shape, size, and stiffness, in surrounding tissue like the mesorectum and fascia—should be done to definitively exclude rectal anatomy as the limiting factor in ProSpare tolerance. However, this requires more time and imaging modalities. Nevertheless, it is reasonable to infer the problem is at the entry, since endorectal balloons are inflatable and have excellent tolerance, and linear devices like rectal retractors and proctoscopes have good tolerances; ProSpare's angle may make the device too bulky on insertion. The anal sphincter diameter or tone, or nociceptive sensitivity of the submucosa may be the limiting factor in tolerating ProSpare. Anal sphincter tone decreases with age, as sphincter thickness increases [13]. The age data of these patients were not available as all data were anonymised before image analysis. Burnett and Bartram [13] studied anal canal distension with an imaging probe and found that the anal canal maintains a diameter of approximately 5 mm with balloon inflation up to 40 mL of saline solution. Only at 50 mL did the anal canal distend to around 7 mm, demonstrating the anal canal's resistance to expansion. This resistance may explain why ERBs are easier to insert than ProSpare.

ProSpare's poor tolerance in prostate bed radiotherapy patients may not stem from rectal anatomy but possibly from anal sphincter tone or size. The former could be easily resolved: create multiple device iterations based on anatomy. Instead, a deployable device could improve tolerance while maintaining ProSpare's favourable features. Soft robotics are being used to develop such a device, reporting promising deployability and rigidity in initial validations [14].

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