

# 1

## The Qora™ Advantage Wider Patient Eligibility for Fecal Management Systems

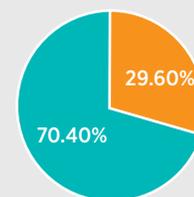


**BACKGROUND** Balloon cuff based catheters limits management of patients with poor anal sphincter tone, as it puts them at high risk for device expulsion.<sup>1</sup> Additionally, due to their design and indications for use, these catheters can only handle liquid to semi-liquid stool.<sup>2</sup>

**METHODS** A systematic literature review was conducted on sphincter dysfunction and stool consistency in patients with fecal incontinence (FI). Relevant search terms were used in the PubMed database. Articles were included if they reported prevalence or data enabling calculation of crude prevalence, and excluded if they focused on any specific disease state.

**RESULTS** Based on the reviewed literature, 70.4% of incontinent patients had dysfunction of external anal sphincter (EAS), internal anal sphincter (IAS) or both – putting them at risk for expulsion if managed with balloon cuff based catheters.<sup>3-9</sup> Compared to 29.6% of FI patients who exhibit adequate anal sphincter tone to support efficacious functioning of a balloon cuff based catheter, all patients, irrespective of sphincter tone, are eligible for safe and efficacious use of the Qora™ SMK. Furthermore, 29.8% of FI patients are estimated to have episodes of semi-formed stool.

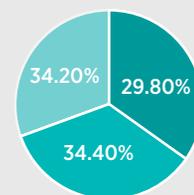
	TONIC SPHINCTER	ATONIC SPHINCTER		
		IAS Dysfunction	EAS Dysfunction	IAS+EAS Dysfunction
Mandaliya, et al 2015	26% (43/162)	30% (48/162)	11% (18/162)	33% (53/126)
Korah, et al 2010	34% (44/128)	35% (45/128)	2% (3/128)	28% (36/128)
Karoui, et al 1999	35% (117/335)	12% (40/335)	28% (94/335)	25% (84/335)
Deen, et al 1993	13% (6/46)	20% (9/46)	41% (19/46)	26% (12/46)
		21.20%	20.00%	27.60%
Maeda, et al 2009	19% (21/109)		81% (88/109)	
<b>Weighted Prevalence Sphincter Function</b>	<b>29.60%</b>	<b>70.40%</b>		



Weighted Prevalence Sphincter Function

Table 1: Sphincter Dysfunction in FI Patients

	Liquid Stool and Flatus OR	Loose Stool OR	Semi-Formed Stool OR
	Bristol Scale 7	Bristol Scale 6	Bristol Scale 5
Mandaliya, et al 2015	32% (165/514)	36% (185/514)	30% (154/514)
Korah, et al 2010	43% (52/120)	28% (33/120)	29% (35/120)
<b>Weighted Prevalence Sphincter Function</b>	<b>34.20%</b>	<b>34.40%</b>	<b>29.80%</b>



Weighted Prevalence Stool Consistency

Table 2: Consistency of Stool in FI Patients

**CONCLUSION** The Qora™ SMK is designed to manage patients with both tonic and atonic sphincters. This systematic literature review suggests that the Qora™ SMK potentially allows 3 times more FI patients to be managed with fecal catheters, due to its ability to manage patients with sphincter dysfunction and semi-formed stool who would be at risk for balloon catheter expulsion.

1 Whiteley I, et al., A Retrospective Review of Outcomes Using a Fecal Management System in Acute Care Patients. *Ostomy Wound Management* 2014;60(12):37-43

2 All Wales Guidelines for Faecal Management Systems. London: MA Healthcare Ltd 2010. Available from: [http://www.welshwoundnetwork.org/files/6313/8555/6979/all\\_wales-faecal\\_systems.pdf](http://www.welshwoundnetwork.org/files/6313/8555/6979/all_wales-faecal_systems.pdf)

3 Mandaliya R, et al., Survey of anal sphincter dysfunction using anal manometry in patients with fecal incontinence: a possible guide to therapy. *Ann Gastroenterol* 2015; 28(4): 469-74.

4 Korah AT, et al., Manometric spectrum of fecal incontinence in a tertiary care center in northern India. *Trop Gastroenterol* 2010; 31(3): 165-168.

5 Karoui S, et al., Prevalence of anal sphincter defects revealed by sonography in 335 incontinent patients and 115 continent patients. *AJR Am J Roentgenol* 1999; 173(2): 389-392.

6 Deen KI, et al., The prevalence of anal sphincter defects in faecal incontinence: a prospective endosonic study. *Gut* 1993; 34:685-688.

7 Maeda Y, et al., Physiological, psychological and behavioural characteristics of men and women with faecal incontinence. *Colorectal Dis* 2009; 11(9):927-32.

8 Bliss DZ, et al., Incontinence-associated dermatitis in critically ill adults: time to development, severity, and risk factors. *J Wound Ostomy Continence Nurs*. 2011; 38(4):433-445.

9 Park KH, et al., Adaptation and evaluation of the incontinence care protocol. *J Korean Acad Nurs* 2015; 45(3):357-366.

# 4

The Qora™ Advantage

## Larger Intrarectal Drainage Lumen Compared to Indwelling Balloon Catheters



**BACKGROUND** Stool diversion through balloon cuff based fecal management catheters is obstructed due to the ledge created by the inflated balloon. This could result in accumulation of stool around the indwelling balloon, increasing the risk of spontaneous device expulsion. Further, normal peristaltic contractions may cause collapse or occlusion of the balloon cuff, compromising the integrity of the seal to the rectum leading to peripheral stool leakage.

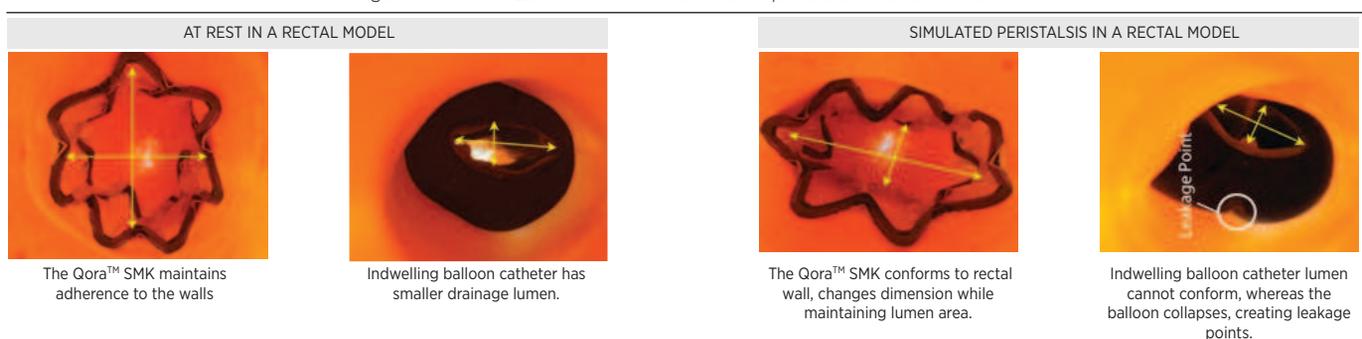
**METHODS** The catheter lumen cross-sectional area was measured for the Qora™ SMK, while data on three other fecal management catheters, the Flexi-Seal SIGNAL™ Fecal Management System (FMS, Device A), the DigniCare Stool Management System (SMS, Device B), and the Actiflo™ Indwelling Bowel Catheter System (IBC, Device C) were gathered via literature review.<sup>1</sup> Furthermore, the Qora™ SMK and a balloon cuff based catheter, Device A were then observed and photographed during rest and simulated peristaltic contractions in a model rectum.

**RESULTS** The Qora™ SMK likely maintains a larger lumen cross-sectional area in a resting state and in a simulated peristaltic rectal state when compared to balloon cuff based catheters. With increase in severity of peristaltic contractions, the Qora™ SMK stayed contiguous to the rectal walls, as the self-expanding lattice structure was able to conform to wall dimension changes. Conversely, the inflated balloon cuff folded over on itself, leading to creation of leakage points between the rectal walls and catheter. Cross-sectional areas for the various devices are given in Table 1 below.

Table 1: Comparison of cross-sectional lumen area among catheters

Qora™	DEVICE A	DEVICE B	DEVICE C
			
3.8 in <sup>2</sup> (2,451 mm <sup>2</sup> )	1.4 in <sup>2</sup> 903 mm <sup>2</sup>	0.5in <sup>2</sup> 354 mm <sup>2</sup>	0.5in <sup>2</sup> 354 mm <sup>2</sup>

Figure 1. Catheter Lumen at rest and simulated peristalsis in a rectal model



**CONCLUSION** The Qora™ SMK relies on a soft self-expanding lattice with large indwelling drainage lumen for stool diversion. This *in-vitro* study suggests that the Qora™ SMK stool diverter design comparatively decreases undesired leakage outcomes by maintaining a large lumen during both resting and peristaltic states. These *in-vitro* observations are in line with observations in clinical studies conducted at tertiary care centers.

<sup>1</sup> Marchetti F, et al., Retention Cuff Pressure Study of 3 Indwelling Stool Management Systems: Randomized Study of 10 Healthy Subjects. J Ostomy Wound Continence Nurs 2011;38(5):569-573.

# 5

## The Qora™ Advantage Economic Benefits Over Traditional Bowel Management Methods



**BACKGROUND** The cost effectiveness of indwelling balloon cuff-based fecal management systems (FMS) has been studied.<sup>1,2</sup> However, such catheters rely on inflatable balloons to anchor on the anorectal junction and can cause leakage of feces, get expelled from the rectum, and cannot conform to varying patient physiology, leading to higher overall time and cost burden. Clinical complications associated with FI such as pressure ulcers and *Clostridium difficile* infection (*C. diff*) have a high cost burden. Prevention of such clinical complications may lead to avoidance of a penalty imposed by Medicare as per the Hospital-Acquired Condition Reduction Program.

**METHODS** Direct daily per patient costs (in USD) of fecal incontinence management by two methods (traditional using absorbent pads and using balloon-cuff based FMS) were taken from literature.<sup>2</sup> Direct costs for FI management with Qora™ were projected on the basis of relative stool diversion efficiency between balloon cuff-based FMS and Qora™, as seen from proportion of leakage episodes reported in literature<sup>4</sup> and from Qora™'s efficacy study<sup>5</sup>. Additionally, expanded patient eligibility<sup>4</sup> for Qora™ over balloon cuff-based FMS was factored in to project average annual cost savings to hospitals that switch to Qora™ from their current standard of care (absorbent pads only, or pads as well as FMS). Annual direct cost savings and complication costs due to FI suboptimal management were projected for sample scenarios in a 35-bedded ICU and a 20-bedded long-term acute care setting, by factoring in relevant parameters for the budget moel from hospital reporting to CMS and peer-reviewed literature.<sup>5</sup>

**RESULTS** Direct daily per-patient costs for FI management are \$152.60, \$79.60, and \$36.74 for each patient managed with absorbent pads, balloon-cuff based fecal management systems and Qora™ SMK respectively. Average annual cost savings of FI management were esimated to be 71-76% in these scenarios (Table 1) and complication cost burden was also computed.

Table 1. Projected Annual Cost Savings

Type Of Center		Annual Direct Cost Savings <i>(All patients managed with absorbent pads and/or balloon cuff-based FMS)</i>	Complications Cost Burden <sup>1</sup>
Center A	Tertiary care center with a 35 bed ICU	\$400,403 - \$503,257 (71.5% - 75.9% savings)	\$188,422 (PU) \$1,363,000 ( <i>C. diff</i> )
Center B	20 bed long term acute care hospital	\$38,985 - \$49,000 (71.5% - 75.9% savings)	\$12,154 (PU) \$245,285 ( <i>C. diff</i> )

\* Incremental cost burden of managing PU and contracting *C.diff*

**CONCLUSION** Adoption of Qora™ SMK over balloon catheters can decrease the average direct cost of managing fecal incontinence in non-ambulatory patients by almost 76%. Qora's novel design increases patient eligibility for efficacious catheter use threefold, leading to reduction in direct costs associated with FI management and reduced cost burden of complications in more patients, further helping to avoid CMS penalties for hospital-acquired conditions. Further studies are needed to validate these projections.

<sup>1</sup> Marchetti F, et al., Retention Cuff Pressure Study of 3 Indwelling Stool Management Systems: Randomized Study of 10 Healthy Subjects. J Ostomy Wound Continence Nurs 2011;38(5):569-573.



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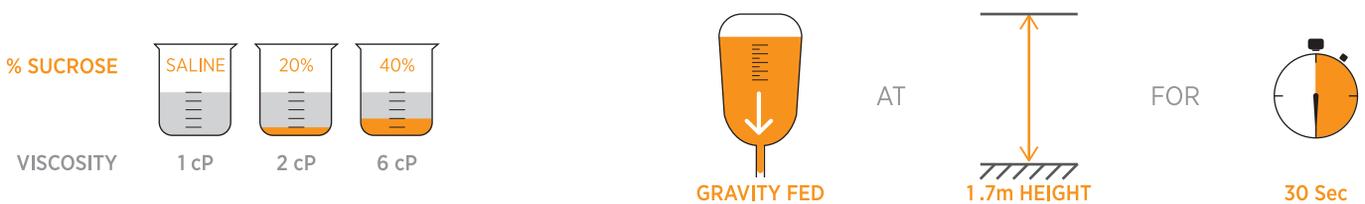
# 6

## The Qora™ Advantage Faster and Easier Fluid Delivery Compared to Indwelling Balloon Catheters



**BACKGROUND** Regular irrigation of fecal management catheters ensures easy fluid delivery and efficacious stool diversion. Patients utilizing these devices often suffer from several acute co-morbidities requiring significant resources to enable their recovery. For this reason, it is essential that daily management practices of fecal management catheters are quick and easy for care providers.

**METHODS** Ease of the fluid delivery procedure was compared between the Qora™ Stool Management Kit (SMK) and two other fecal management catheters, the Flexi-Seal SIGNAL™ Fecal Management System (FMS, Device A) and the DigniShield Stool Management System (SMS, Device B). All three devices were tested for simulated-use flow rate with fluid of different viscosities<sup>1</sup>: saline, 20% sucrose, and 40% sucrose. The simulated-use procedures were carried out using a gravity-fed bag placed at a height of 1.7m from the ground with devices laid horizontally at a height of 0.7m.



**RESULTS** The Qora™ SMK showed faster flow rates for both saline and sucrose solution tests. The simulated-use test with saline is the most relevant for daily device management procedures, where the Qora™ SM showed 135% and 126% improvement over Device A and Device B, respectively. Furthermore, the Qora™ SMK proved to have consistently enhanced performance by demonstrating faster flow rates with sucrose solutions of both 20% and 40%.

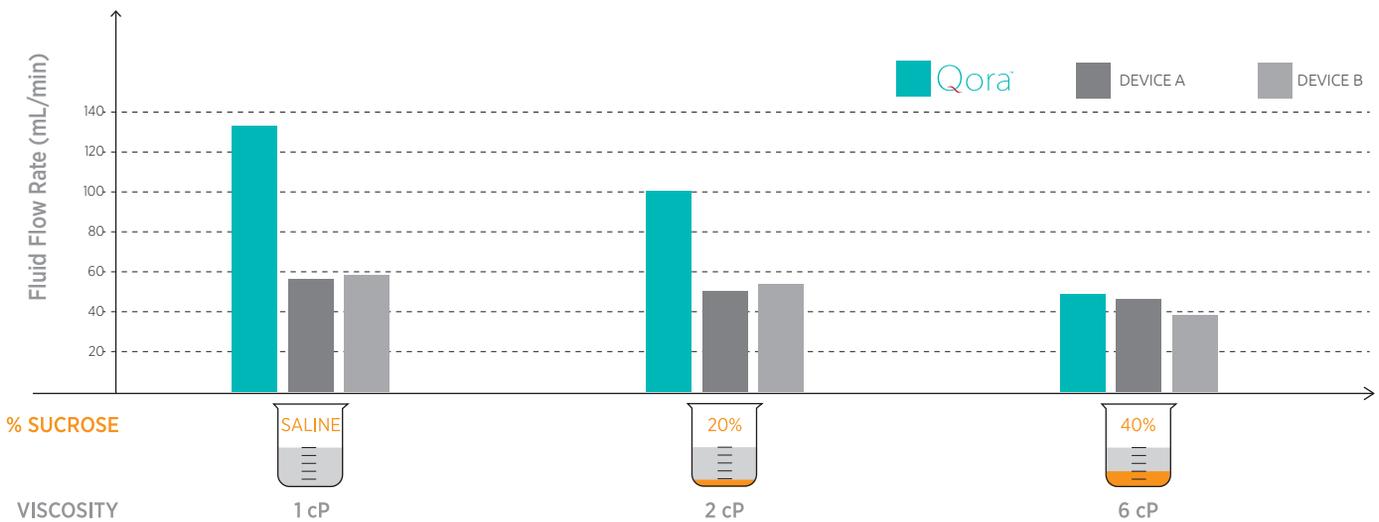


Figure 1: Comparison of fluid delivery rates among catheters

**CONCLUSION** The Qora™ SMK is designed to improve device management procedures for patients using fecal management catheters and reduce burden on care providers during daily device management. Enhanced flow rates under simulated-use conditions suggests that the Qora™ SMK enables care providers to spend less time on device management and more time on patient care.

<sup>1</sup>Swindells JF, Snyder CF, Hardy RC, Golden PE. Viscosities of Sucrose Solutions at Various Temperatures: Tables of Recalculated Values. United States Department of Commerce. Supplement to National Bureau of Standards Circular 440. Issued July 31, 1958.

**BACKGROUND** Prolonged fecal incontinence has a diverse aetiology and is a common condition for patients across the continuum of care<sup>1</sup>. Current balloon cuff based catheters are placed in the anorectal junction, inflated with fluid, and utilize sphincter muscle contraction to support device patency.<sup>2</sup> This constant state of strain is exacerbated by the weight of the fluid-filled balloon, which overwhelms the continence mechanism. Clinical literature confirms this by suggesting that long-term use of intrarectal balloon cuff based catheters weakens the anal sphincter tone.<sup>3,4</sup>

**METHODS** The weight of the indwelling structure of fecal management catheters was compared between the Qora™ Stool Management Kit (SMK) and two other fecal management catheters, the Flexi-Seal SIGNAL Fecal Management System (FMS, Device A) and the DigniShield Stool Management System (SMS, Device B). Devices were deployed *in-vitro* according to their instructions for use manual, with balloon cuff based catheters being inflated with water and the Qora™ SMK lattice being removed from the device applicator. Weight of the indwelling portion of each device was then taken with a digital measuring scale and recorded.

**RESULTS** Based on *in-vitro* testing, the deployed weight of the indwelling portion of the fecal management catheters was 8.75g for the Qora™ SMK, 60.25g for Device A, and 74.25g for Device B.

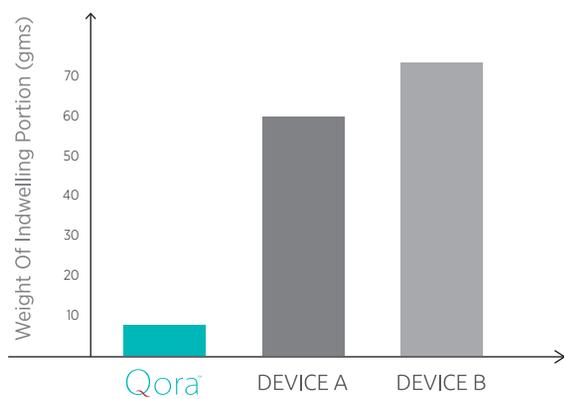


Figure 1: Weight comparison of indwelling fecal management catheters

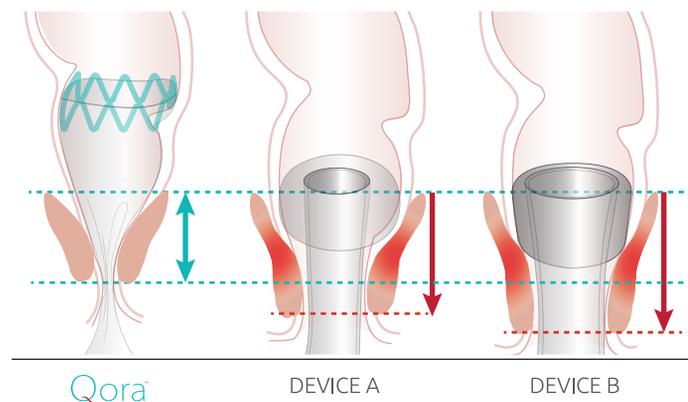


Figure 2: Graphical representation of sphincter muscles deformation due to indwelling fecal management catheters

**CONCLUSION** The Qora™ SMK is designed to be safely placed near the transverse rectal valves and therefore does not utilize the sphincter muscles for device patency. Furthermore, the lightweight design limits risk of the downward gravitational force inhibiting natural sphincter physiology. This *in-vitro* study suggests that patients who utilize the Qora™ SMK will preserve their sphincter tone over prolonged indwelling times, though further *in-vivo* studies may be needed to evaluate and confirm these findings.

<sup>1</sup>Beitz JM, et al., Fecal Incontinence In Acutely and Critically Ill Patients: Options In Management. *Ostomy Wound Management* 2006;52(12):56-66.

<sup>2</sup>All Wales Guidelines for Faecal Management Systems. London: MA Healthcare Ltd 2010. Available from: [http://www.welshwoundnetwork.org/-files/6313/8555/6979/all\\_wales-faecal\\_systems.pdf](http://www.welshwoundnetwork.org/-files/6313/8555/6979/all_wales-faecal_systems.pdf) Accessed 28 July 2017.

<sup>3</sup>Whiteley I, et al., A Retrospective Review of Outcomes Using a Fecal Management System in Acute Care Patients. *Ostomy Wound Management* 2014;60(12):37-43.

<sup>4</sup>Garcia CB, et al., Expert Recommendations for managing acute faecal incontinence with diarrhoea in the intensive care unit. *J Int Care Society* 2013;14(4 suppl).

**BACKGROUND** The anal sphincter muscles keep the anal orifice closed in its resting state and play a critical role in the continence mechanism. The mean anal canal diameter during evacuation is  $17 \pm 6$  mm and clinical literature suggests the sphincter muscles experience strain at 10mm anal distension.<sup>1,2</sup> Therefore, the trans-sphincteric zone of fecal management catheters retaining larger diameters during long-indwelling times may cause pain and an uncomfortable foreign body sensation. This could also lead to further complications like pressure induced necrosis, and sphincter dysfunction.

**METHODS** The insertion diameter and the indwelling sustained diameter at the trans-sphincteric zone was compared between the Qora™ Stool Management Kit (SMK) and two other fecal management catheters, the Flexi-Seal SIGNAL Fecal Management System (FMS, Device A) and the DigniShield Stool Management System (SMS, Device B). Device insertion processes were carried out according to their instructions for use manual on a benchtop model. The maximum diameters created by each device were measured using a simulated compression fixture and recorded.

**RESULTS** Based on *in-vitro* testing, the diameters retained by the fecal management catheters at the trans-sphincteric zone were 8.05mm, 13.38mm and 11.22mm for the Qora™ SMK, Device A, and Device B, respectively. Furthermore, maximum diameters created during insertion procedures were 17.78mm, 27.1mm, and 28.35mm for the Qora™ SMK, Device A, and Device B, respectively.

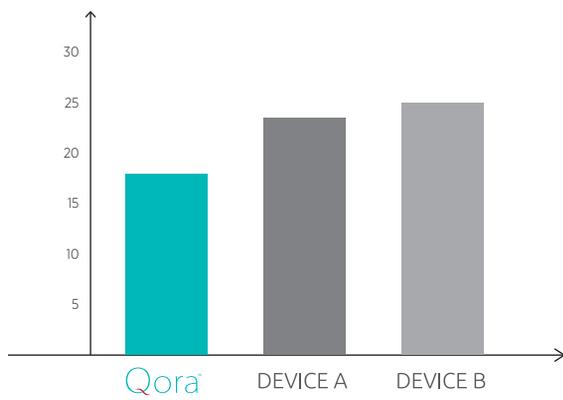


Figure 1: Comparison of insertion diameter among catheters

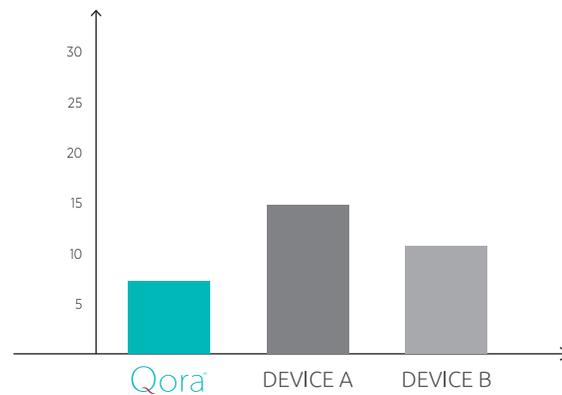


Figure 2: Comparison of indwelling sustained diameter at trans-sphincteric zones among catheters

**CONCLUSION** The trans-sphincteric zone of the Qora™ SMK is designed to increase patient comfort by minimizing foreign body sensations. This *in-vitro* study showed that compared to balloon-cuff based catheters, Qora™ SMK maintains smaller anal diameters both during insertion and extended indwelling times. By reducing strain on the sphincter muscles, patients have reduced risk of discomfort and potential injury from long-term use.

<sup>1</sup> Palit S, et al., Evacuation proctography: a reappraisal of normal variability. The Association of Coloproctology of Great Britain and Ireland 2014;16:538-546

<sup>2</sup> Lestar B, et al., The composition of anal basal pressure. Int J Colorect Dis 1989;4:118-122

# 2

The Qora™ Advantage

## Safer Intrarectal Pressures Compared to Indwelling Balloon Catheters



**BACKGROUND** Balloon cuff based fecal management catheters rely on a large silicone retention balloon that anchors on the anorectal junction. If the pressure applied by this balloon increases beyond hydrostatic pressure in the rectal microvasculature, it can lead to necrosis of the rectal wall, which has been observed and documented in clinical findings.<sup>1</sup> Clinical literature studying the trachea suggests that 14-22 mmHg is the optimal range of radial pressure for creating a sufficient seal without risking necrosis.<sup>1</sup> Cuff pressure over 22 mmHg are known to compress mucosal arteries and impair blood flow, with total occlusion of arteries occurring at 36 mmHg.

**METHODS** The radial pressure exerted by the Qora™ SMK was measured *in-vitro* using linear tensile testing – the industry standard equivalent method used to measure radial forces of cardiovascular stents. Five Qora™ SMK samples were tested, while data on three other fecal management catheters, the Flexi-Seal SIGNAL™ Fecal Management System (FMS, Device A), the DigniCare Stool Management System (SMS, Device B), and the Actiflo™ Indwelling Bowel Catheter System (IBC, Device C) were gathered via literature review.

**RESULTS** Based *in-vitro* testing and analysis of clinical literature, the average radial pressure exerted on the rectal mucosa of patient was 81.2 mmHg for Device A, 32.1 mmHg for Device B, 77.8 mmHg for Device C, and 21.2 mmHg for the Qora™ SMK.

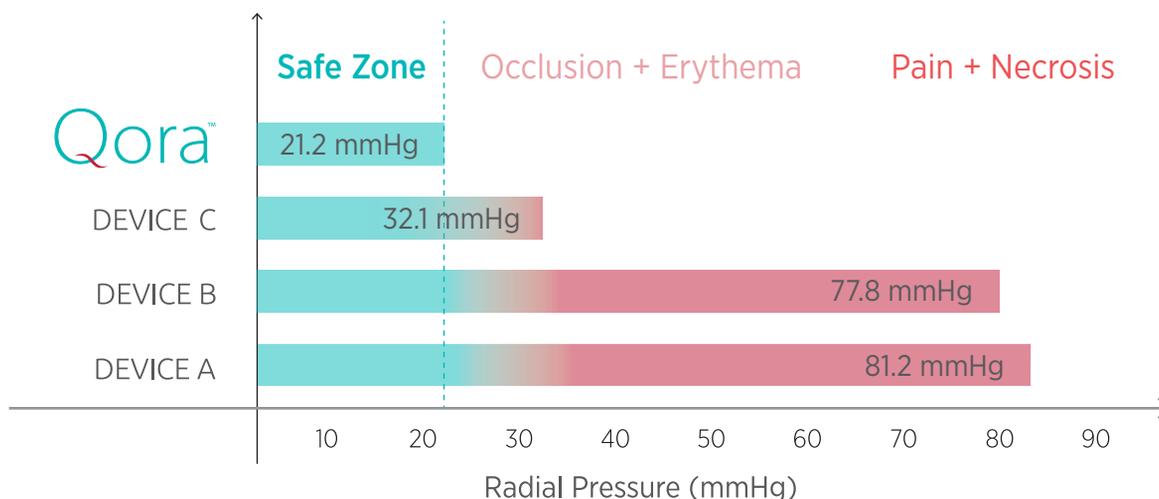


Figure 1: Comparison of mean radial pressures across catheters

**CONCLUSION** The Qora™ SMK self-expanding lattice is designed to exert calibrated radial pressure to avoid complications like erythema, necrosis, and mucosal erosion. This *in-vitro* study, along with pilot clinical findings, suggests that the Qora™ SMK technology exerts lower pressure when compared to other balloon cuff based fecal management catheters. Further *in-vivo* studies may be needed to determine the relevance of these findings in varying patient positions and patient profiles.

<sup>1</sup> Whiteley I, et al., A retrospective review of outcomes using a fecal management system in acute care patients. *Ostomy Wound Manage* 2014;60(12):37-43.

**BACKGROUND** Fecal management catheters that rely on inflatable balloon cuffs require digital insertion by the care provider, exposing the rectal mucosa to variant forces. Also, due to the usage of the dominant finger for insertion, the overall profile of the device is large during insertion, and can lead to pain and discomfort for the patient.

**METHODS** Insertion, withdrawal, and expulsion forces were studied on five samples each of the Qora™ Stool Management Kit (SMK) and the Flexi-Seal SIGNAL™ Fecal Management System (FMS). The insertion, withdrawal, and expulsion forces of the study devices were measured using a linear tensile testing machine and a foam based anorectal model. Expulsion force was measured by withdrawing the device without following indicated removal process as per their instructions for use manual.

**RESULTS** Insertion and withdrawal forces were significantly lesser ( $p < 0.05$ ) in the Qora™ SMK samples as compared to samples. Expulsion force for the Qora™ SMK was found to be  $10.38 \pm 0.92$  N; however, the Flexi-Seal SIGNAL™ FMS samples started to break the rectal model when removed without deflating balloon.

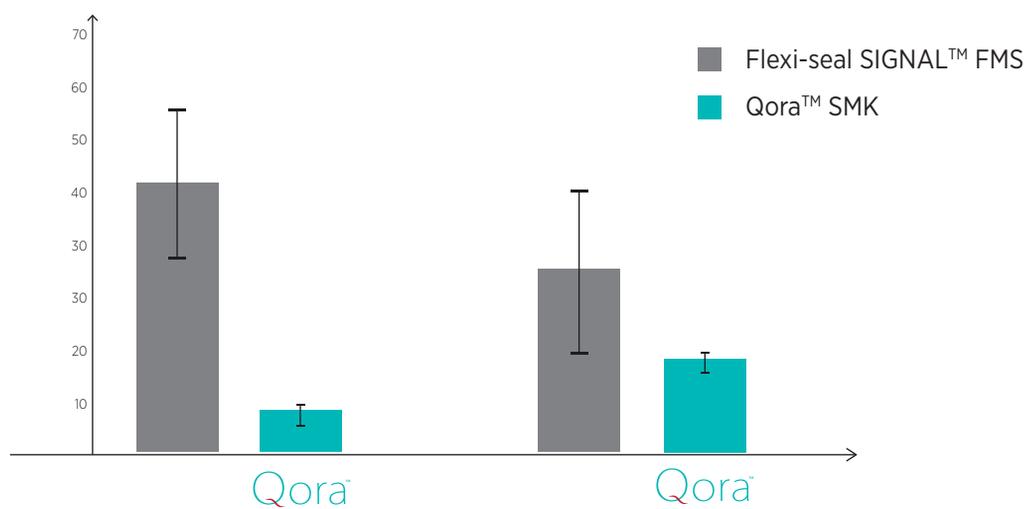


Figure 1. Comparison between Insertion force, withdrawal force and insertion diameters for Flexi-Seal SIGNAL™ FMS as well as Qora™ SMK

**CONCLUSION** The Qora™ SMK exerts significantly less force upon the anorectal mucosa compared to balloon cuff based catheters during insertion, withdrawal, and accidental expulsions. The Qora™ SMK insertion applicator may reduce likelihood of trauma to the patient during device insertion while ensuring hygiene. The intuitive device applicator and innovative self-expanding stool diverter of the Qora™ SMK may help reduce the risk of anorectal injury during device insertion, withdrawal, or accidental device expulsions.