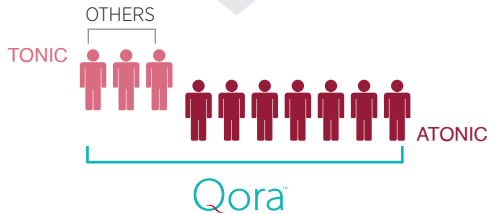


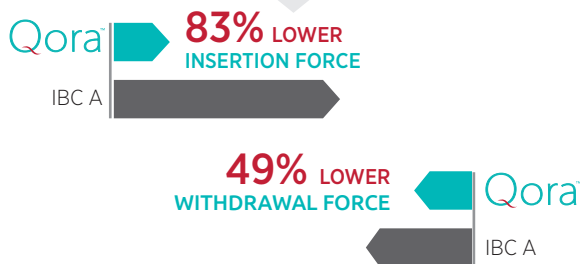
Qora™ ADVANTAGES

Qora™ SMK is a superior solution over traditional methods of fecal containment and management

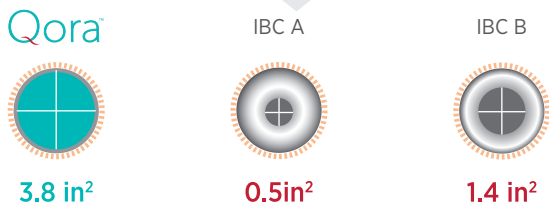
WIDER PATIENT ELIGIBILITY



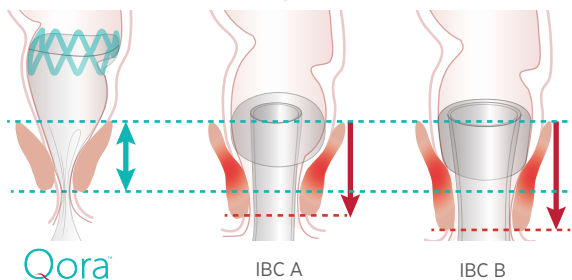
SAFER INSERTION & WITHDRAWAL FORCE



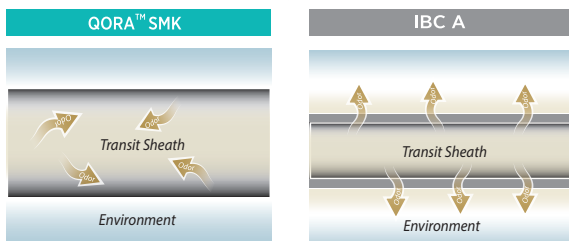
LARGE DIVERTING LUMEN



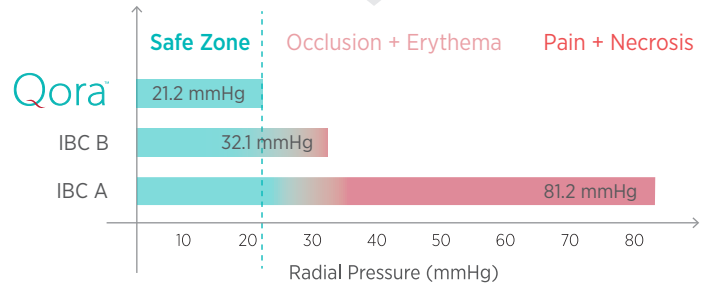
PRESERVED SPHINCTER TONE



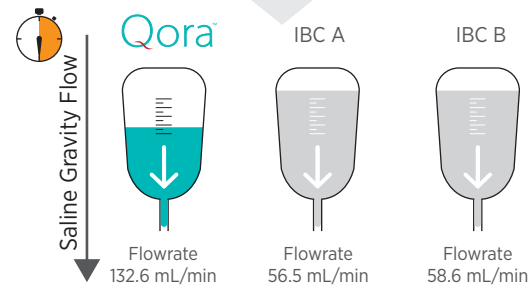
SUPERIOR MALODOR CONTAINMENT



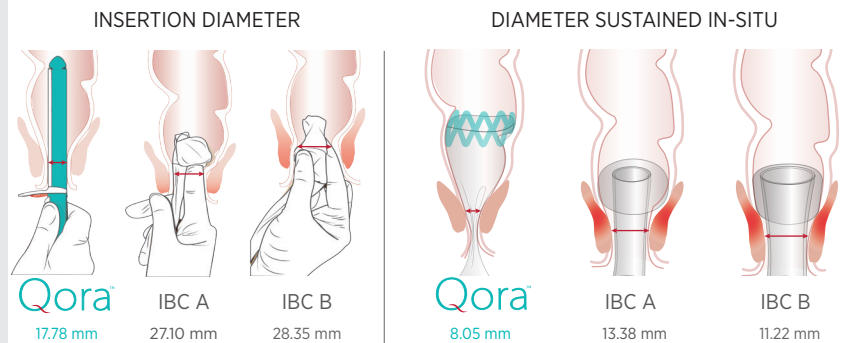
CALIBRATED INTRARECTAL PRESSURE



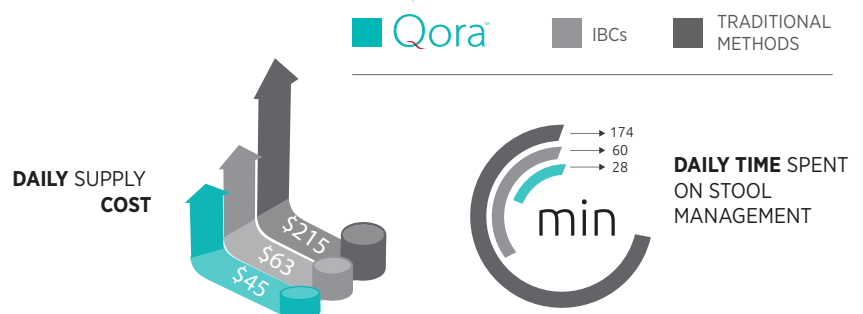
FASTER AND EASIER FLUID DELIVERY



INCREASED SAFETY AND COMFORT



INCREASED ECONOMIC BENEFITS



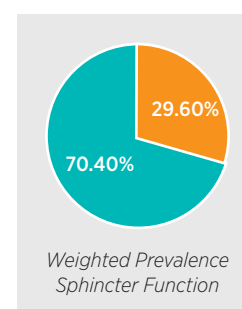
BACKGROUND Intrarectal balloon catheters limits management of patients with poor anal sphincter tone, as it puts them at high risk for device expulsion.¹ Additionally, due to their design and indications for use, these catheters can only handle liquid to semi-liquid stool.²

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 intrarectal balloon catheters.³⁻⁹ Compared to 29.6% of FI patients who exhibit adequate anal sphincter tone to support efficacious functioning of an intrarectal balloon 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.

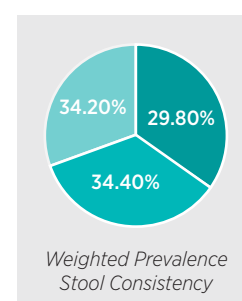
	TONIC SPHINCTER	ATONIC SPHINCTER		
		IAS Dysfunction	EAS Dysfunction	IAS+EAS Dysfunction
Mandaliya, et al 2015	26% (43/162)	30% (48/162)	11% (18/162)	33% (53/126)
Korah, et al 2010	34% (44/128)	35% (45/128)	2% (3/128)	28% (36/128)
Karoui, et al 1999	35% (117/335)	12% (40/335)	28% (94/335)	25% (84/335)
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)	
Weighted Prevalence Sphincter Function	29.60%		70.40%	

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
Korah, et al 2010	43% (52/120)	28% (33/120)	29% (35/120)
Weighted Prevalence Sphincter Function	34.20%	34.40%	29.80%

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 management systems**, due to its ability to manage patients with sphincter dysfunction and semi-formed stool who would be at risk for intrarectal 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

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.

BACKGROUND Intrarectal balloon 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.¹ 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.² Cuff pressure over 22 mmHg are known to compress mucosal arteries and impair blood flow, with total occlusion of arteries occurring at 36 mmHg.³

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 two other intrarectal balloon catheters were gathered via literature review.⁴

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

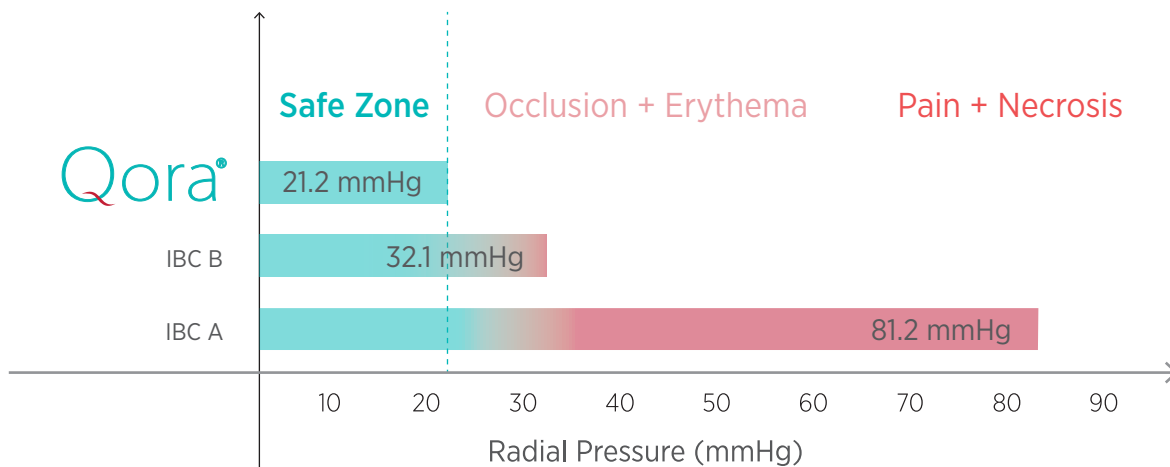


Figure 1: Comparison of mean radial pressures across catheters

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

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

2. Siamdoust SA, et al., Endotracheal tube cuff pressure assessment: education may improve but not guarantee the safety of palpation technique. Anesth Pain Med 2015;5(3):e16163

3. Seegobin RD, Hasselt GL. Endotracheal cuff pressure and tracheal mucosal blood flow: endoscopic study of effects of four large volume cuffs. British Medical Journal 1984;288(6422):965-968

4. Gloeckner DC, Carleo SA. Cuff Pressure and Friction in the Design of Indwelling Fecal Drainage Catheters. Bard, Inc., 2011.

BACKGROUND Fecal management systems 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 forces were studied on five samples each of the Qora® Stool Management Kit (SMK) and intrarectal balloon catheters. The forces of the study devices were measured using a linear tensile testing machine and a foam based anorectal model.

RESULTS Insertion forces were significantly less ($p < 0.05$) in the Qora® SMK samples. As compared to the intrarectal balloon catheter samples, the Qora® SMK was found to exert 83% lower insertion force on the patient's anatomy.

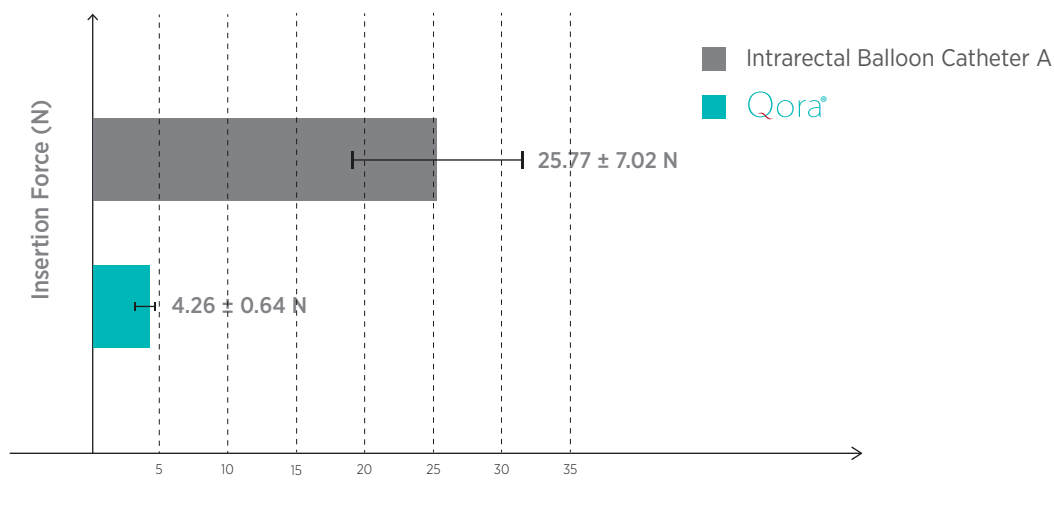


Figure 1. Comparison of insertion force among catheters

CONCLUSION The Qora® SMK exerts significantly less force upon the anorectal mucosa compared to intrarectal balloon catheters during device insertion. 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.

1. Data on company file.

BACKGROUND Stool diversion through intrarectal balloon catheters is obstructed due to the ledge created by the inflated balloon. This could result in accumulation of stool around the indwelling balloon, which can increase the risk of spontaneous device expulsion. Furthermore, normal peristaltic contractions may cause collapse or cause occlusion of the intrarectal balloon, compromising the integrity of the seal to the rectum leading to peripheral stool leakage.

METHODS The cross-sectional area of the catheter's lumen was measured for the Qora® SMK, while data on two other intrarectal balloon catheters were gathered via literature review.¹ Furthermore, the Qora® SMK and an intrarectal balloon catheter were then observed and photographed during rest and simulated peristaltic contractions in a rectal model.

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 intrarectal balloon 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 the changes in wall dimension. Conversely, the intrarectal balloon 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 the cross-sectional lumen area among catheters




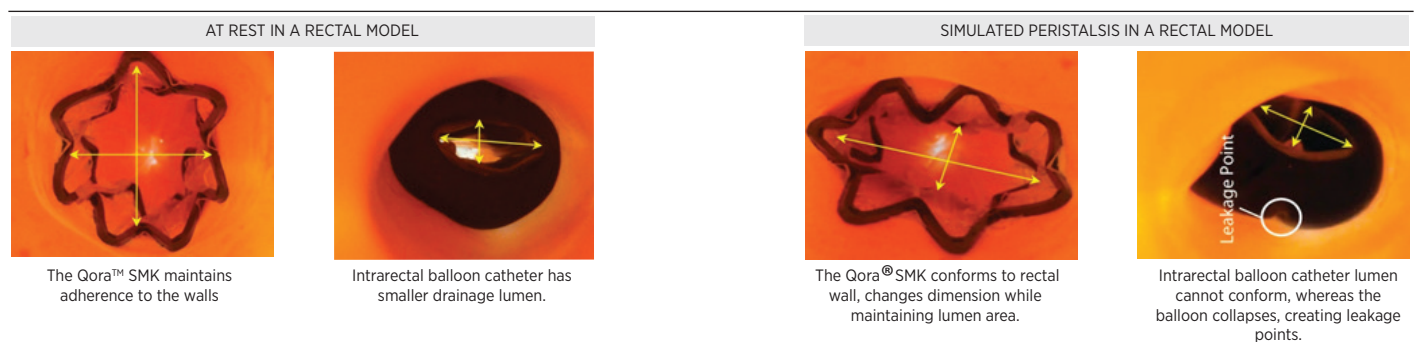
Qora®	IBC A	IBC B
		
3.8 in ² (2,451 mm ²)	0.5 in ² 903 mm ²	1.4 in ² 354 mm ²

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

1. 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.

2. Data on company file.

BACKGROUND The clinical and cost effectiveness of intrarectal balloon catheters has been studied.^{1,2} However, such catheters rely on inflatable balloons to anchor on the anorectal junction and can cause fecal leakage, get expelled from the rectum, and cannot conform to varying patient anatomy. These complications lead to higher overall time and cost burden. Clinical complications such as hospital-acquired pressure injury (HAPI) and *Clostridium difficile* infection (CDI) are associated with 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 (HACRP).

METHODS Direct daily costs of managing a patient with fecal incontinence using absorbent pads and intrarectal balloon catheters were gathered via literature.^{1,2} Similarly, the direct daily costs of managing a patient with the Qora® Stool Management Kit (SMK) were projected on the basis of time savings, relative stool diversion efficiency and device selling price when compared to intrarectal balloon catheters. Similarly, the average nursing time required to manage an incontinent patient was estimated based on the reviewed literature.^{1,2}

RESULTS The direct daily cost per patient for FI management with absorbent pads, intrarectal balloon catheters, and the Qora® SMK were \$215.37, \$62.93, and \$44.58 respectively. Based on projected cost analysis, Qora® SMK offers 79% and 29% direct cost savings over absorbent pads and intrarectal balloon catheters respectively.³ The average time spent by nurses in managing FI patients with absorbent pads and intrarectal balloon catheters is 6X and 2X when compared to Qora® SMK.

	ABSORBENT PADS	IBCs	QORA® SMK
Material & Containment Cost	\$ 110.37	\$ 43.13	\$ 35.25
Nursing Cost	\$ 105.00	\$ 19.80	\$ 9.33
Total Cost	\$ 215.37	\$ 62.93	\$ 44.58
Cost Savings Compared To Qora	79%	29%	

Table 1: Projected Daily Cost Savings



Figure 1. Daily Nursing Time

CONCLUSION Adoption of Qora® SMK over intrarectal balloon catheters can decrease the average direct cost of managing fecal incontinence in non-ambulatory patients by almost 79%. Qora's novel design with optimal device management procedures reduce the direct costs associated with FI management and help in reducing the complication cost burden, thereby avoiding CMS penalties for hospital-acquired conditions. Further studies are needed to validate these projections.

1. Langill M, et al. 'A budget impact analysis comparing use of a modern fecal management system to traditional fecal management methods in two Canadian hospitals'. *Ostomy Wound Manage.* 2012; 58(10): 25-33.

2. Popovich-Durnal A, et al. 'Budget impact of adopting a fecal management system in a hospital intensive care unit: a single center experience'. Poster presented at the Symposium on Advanced Wound Care Fall, Washington DC. September 2009.

3. Data on Company file, PPR02511-R-005-02

BACKGROUND Regular irrigation of fecal management systems 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 systems are quick and easy for care providers.

METHODS Ease of fluid delivery was compared between the Qora® Stool Management Kit (SMK) and one other fecal management systems. Both the devices were tested for simulated-use flow rate with fluid of different viscosities: saline, 20% lactulose, and 40% lactulose and suspension solution. The simulated-use procedures were carried out using a gravity-fed bag placed at a height of 1.5m from the ground with devices laid horizontally at a height of 0.7m.

RESULTS The Qora® SMK exhibited faster flow rates for both saline and low viscous lactulose solution tests. The simulated-use test utilizing saline is the most relevant to portray daily device management procedures. The Qora® SMK showed 32% improvement over IBC A.¹ Furthermore, the Qora® SMK is designed to ensure consistent performance. Unlike balloon catheters, Qora® SMK offers low resistance for fluid delivery and ensures efficient fluid retention with a self-conforming transit sheath clamp.

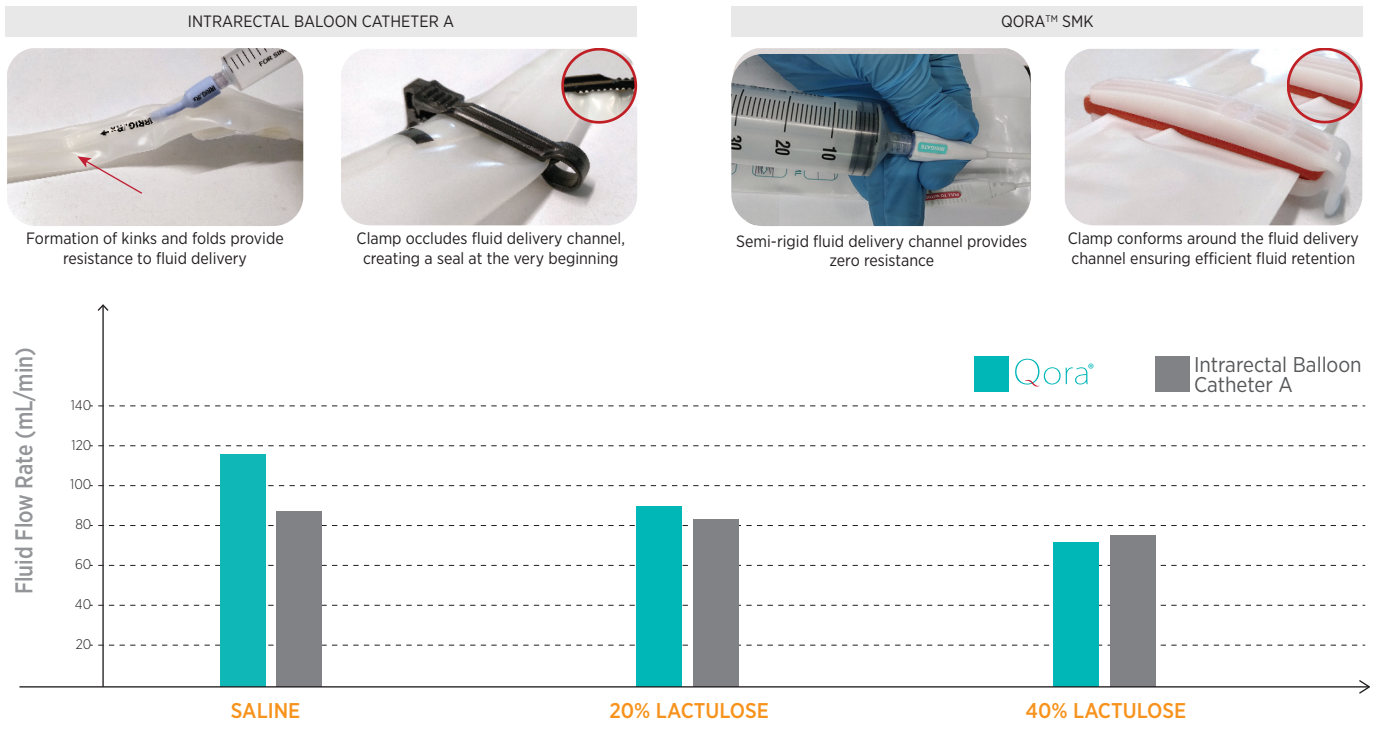


Figure 1: Comparison of fluid delivery rates among catheters

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.

1. Data on company file

BACKGROUND Prolonged fecal incontinence has a diverse aetiology and is a common condition for patients across the continuum of care¹. Current intrarectal balloon catheters are placed in the anorectal junction, inflated with fluid, and utilize sphincter muscle contraction to support device patency.² 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 catheters weakens the anal sphincter tone.^{3,4}

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. Devices were deployed *in-vitro* according to their instructions for use, with intrarectal balloon catheters being inflated with water and the Qora® SMK lattice being removed from the device applicator. The weight of the indwelling portion of each device was 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 systems was 8.75g for the Qora® SMK, 60.25g for IBC A, and 74.25g for IBC B.²

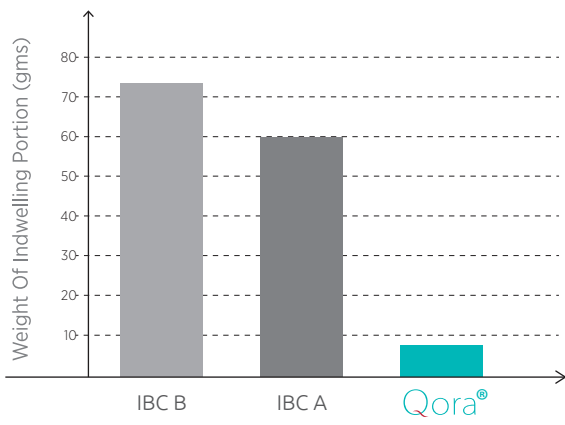


Figure 1: Weight comparison of indwelling fecal management catheters

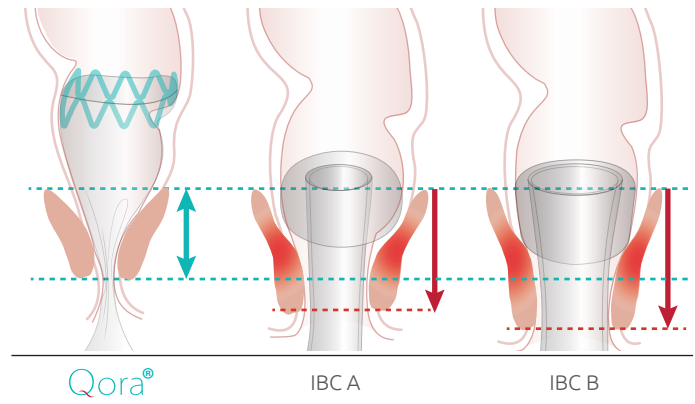


Figure 2: Graphical representation of sphincter muscles deformation due to indwelling fecal management catheters

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.

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

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 Accessed 28 July 2017.

3. 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.

4. 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).

5. Data on company file.

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 ± 6 mm and clinical literature suggests the sphincter muscles experience strain at 10mm anal distension.^{1,2} Therefore, the trans-sphincteric zone of fecal management systems 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 systems. Device insertion processes were carried out on a bench top model according to their instructions for use. The maximum diameters created for both insertion and indwelling sustained diameters 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 systems at the trans-sphincteric zone were 8.05mm, 13.38mm and 11.22mm for the Qora™ SMK, IBC A, and IBC B, respectively. Furthermore, maximum diameters created during insertion procedures for the Qora™ SMK, IBC A, and IBC B, were 17.78mm, 27.1mm, and 28.35mm respectively.³

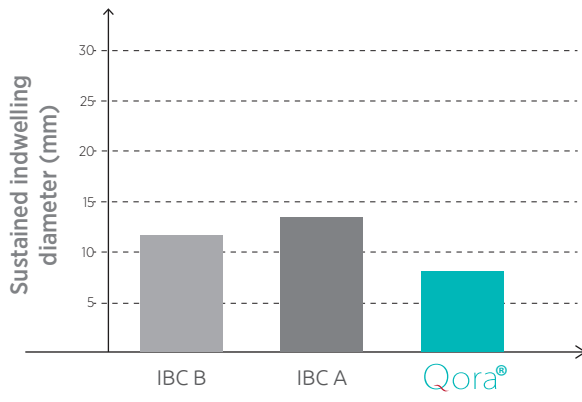


Figure 1: Comparison of indwelling sustained diameter at trans-sphincteric zones among catheters

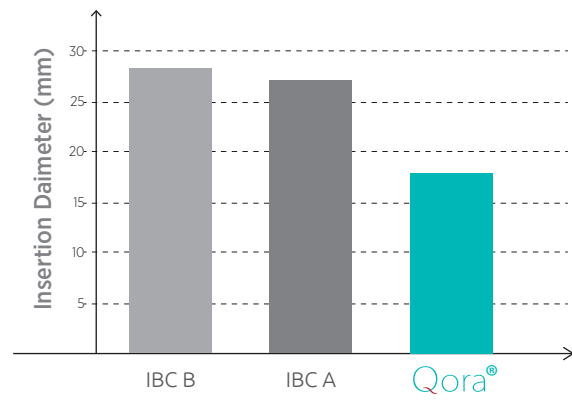


Figure 2: Comparison of insertion diameter among catheters

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 intrarectal balloon 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.

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

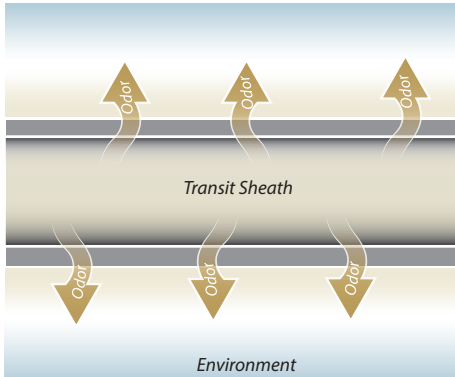
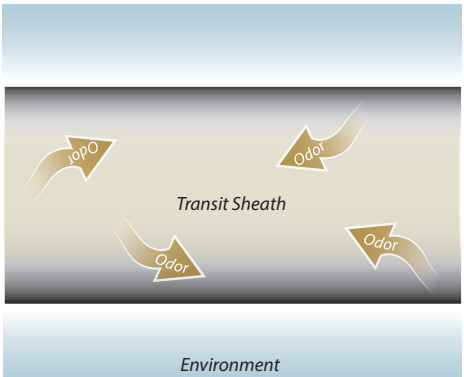
2. Lestar B, et al., The composition of anal basal pressure. Int J Colorect Dis 1989;4:118-122

3. Data on company file.

BACKGROUND Hospital settings are often filled with unpleasant malodor from urine, stool, and medical supplies, reducing the overall air quality. The efficiency and effectiveness of one's cognitive ability is known to be influenced by the air quality of one's environment. Multiple studies show that a significant increase in air quality dissatisfaction can result in decreased work performance.¹ Furthermore, clinical literature suggests that an odious environment in a hospital setting can significantly increase the risk of medical errors potentially affecting patient's health and safety.² Therefore, maintaining a comfortable and pleasant environment in hospital settings is necessary to avoid medical errors, reduce stress, and improve patient recovery environments.

METHODS The odor barrier property of the intrarectal balloon catheter and the Qora® Stool Management Kit (SMK) were assessed using an Oxygen Transmission Rate (OTR) test - the industry standard to compare the barrier properties of films. Films with "lower OTR values" are considered to have "high oxygen barrier" properties, which in turn mean better odor control. The OTR tests were based on ASTM D1434-1982 R2015e1, Standard Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting.

RESULTS The Qora SMK exhibits significantly higher odor barrier properties as compared to intrarectal balloon catheter. The OTR values were 21.551 (cm³/m²)/24hr.0.1MPa and 35,517.57 (cm³/m²)/24hr.0.1MPa for the Qora®SMK and IBC A, respectively.³

Oxygen Transmission Rate (cm ³ /m ²)/24hr.0.1MPa)	IBC A	QORA® SMK
	35, 517.57	21.551
		

CONCLUSION The Qora® SMK is designed for efficient diversion of fecal effluents while ensuring complete malodor containment. The multi-faceted transit sheath with specialty engineered polymeric films, puncture-resistant collection bag, and flatus release valve provide a multi-level end-to-end odor barrier fecal management system. The OTR test results suggest that when compared to intrarectal balloon catheters, Qora® SMK has higher oxygen barrier properties and thereby provides superior malodor containment. Therefore, Qora® SMK assists in maintaining pleasant work environment for better patient recovery, reduces stress, and avoids the risk of medical errors.

1. Wargocki P, et al., Productivity is affected by the air quality in offices. Proc of Health Buildings 2000;(1):635-640

2. Horiguchi M, et al., Nurse odor perception in various Japanese hospital settings. International Journal of Nursing Sciences 2015;(2):355-360

3. Data on company file.