WIDER PATIENT ELIGIBILITY

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

CALIBRATED INTRARECTAL PRESSURE

- **Safer Insertion & Withdrawal Force**
  - **83% Lower Insertion Force**
  - **49% Lower Withdrawal Force**

SAFE ZONE

- **Occlusion + Erythema**
  - 21.2 mmHg
- **Pain + Necrosis**
  - 32.1 mmHg
  - 77.8 mmHg
  - 81.2 mmHg

81.2 mmHg

83% LOWER INSERTION FORCE

49% LOWER WITHDRAWAL FORCE

LARGE DIVERTING LUMEN

- **Flowrate**
  - Flowrate 132.6 mL/min for Qora
  - Flowrate 56.5 mL/min for IBC A
  - Flowrate 58.6 mL/min for IBC B

FASTER & EASIER FLUID DELIVERY

- **Daily Supply Cost**
  - Qora: $36
  - IBCs: $70
  - Traditional Methods: $186

- **Daily Time Spent on Stool Management**
  - Qora: 21 min
  - IBCs: 120 min
  - Traditional Methods: 348 min

INCREASED ECONOMIC BENEFITS

- **Diameter Sustained In-Situ (mm)**
  - Qora: 17.78
  - IBC A: 27.10
  - IBC B: 28.35

INCREASED SAFETY & COMFORT

- **Flowrate**
  - Flowrate 56.5 mL/min for IBC A
  - Flowrate 58.6 mL/min for IBC B

- **Inset Diameter (mm)**
  - IBC A: 17.78
  - IBC B: 28.35

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

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. 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.

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.

Table 1: Sphincter Dysfunction in FI Patients

<table>
<thead>
<tr>
<th>TONIC SPHINCTER</th>
<th>ATOMIC SPHINCTER</th>
<th>IAS Dysfunction</th>
<th>EAS Dysfunction</th>
<th>IAS+EAS Dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandalaya, et al 2015</td>
<td>26% (43/162)</td>
<td>30% (48/162)</td>
<td>11% (18/162)</td>
<td>33% (53/162)</td>
</tr>
<tr>
<td>Korah, et al 2010</td>
<td>34% (44/128)</td>
<td>35% (45/128)</td>
<td>2% (3/128)</td>
<td>28% (36/128)</td>
</tr>
<tr>
<td>Karouli, et al 1999</td>
<td>35% (117/335)</td>
<td>12% (40/335)</td>
<td>28% (94/335)</td>
<td>25% (84/335)</td>
</tr>
<tr>
<td>Deen, et al 1993</td>
<td>13% (6/46)</td>
<td>20% (9/46)</td>
<td>41% (19/46)</td>
<td>26% (12/46)</td>
</tr>
</tbody>
</table>

Weighted Prevalence Sphincter Function

<table>
<thead>
<tr>
<th>Liquid Stool and Flatus OR</th>
<th>Loose Stool OR</th>
<th>Semi-Formed Stool OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bristol Scale 7</td>
<td>Bristol Scale 6</td>
<td>Bristol Scale 5</td>
</tr>
<tr>
<td>Mandalaya, et al 2015</td>
<td>32% (165/514)</td>
<td>36% (185/514)</td>
</tr>
<tr>
<td>Korah, et al 2010</td>
<td>43% (52/120)</td>
<td>28% (33/120)</td>
</tr>
</tbody>
</table>

Weighted Prevalence Sphincter Function

**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. 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. 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 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 patients was 81.2 mmHg for IBC A, 32.1 mmHg for IBC B, 77.8 mmHg for IBC C, and 21.2 mmHg for the Qora℠ SMK.

**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.

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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 balloon cuff based fecal management catheter. 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 ± 0.92 N; however, the balloon cuff based fecal management catheter samples started to break the rectal model when removed without deflating balloon.\(^1\)

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.

\(^1\) Data on company file.
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 were gathered via literature review. Futhermore, the Qora™ SMK and a balloon cuff based catheter 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

<table>
<thead>
<tr>
<th>Catheter</th>
<th>Cross-sectional Area</th>
<th>Cross-sectional Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qora</td>
<td>3.8 in² (2.451 mm²)</td>
<td>0.5 in² (903 mm²)</td>
</tr>
<tr>
<td>IBC A</td>
<td>0.5 in² (354 mm²)</td>
<td>0.5 in² (354 mm²)</td>
</tr>
<tr>
<td>IBC B</td>
<td>1.4 in² (354 mm²)</td>
<td></td>
</tr>
<tr>
<td>IBC C</td>
<td></td>
<td></td>
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</tbody>
</table>

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.

2. Data on company file.
The Qora™ Advantage

Economic Benefits Over Traditional Fecal Management Systems

BACKGROUND

The clinical and cost effectiveness of indwelling fecal management catheters has been studied. 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 anatomy, leading 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 cost of managing a patient with fecal incontinence using absorbent pads and balloon-cuff based catheters were gathered via literature. Similarly, the direct daily cost 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 balloon-cuff based fecal management catheters. Similarly, the average nursing time required to manage an incontinent patient was estimated based on the reviewed literature.

RESULTS

The direct daily per patient cost for FI management with absorbent pads, balloon-cuff based fecal management catheters, and the Qora™ SMK were $186.05, $70.16, and $36.06 respectively. Based on projected cost analysis, Qora™ SMK offers 81% and 49% direct cost savings over absorbent pads and balloon-cuff based fecal management catheters respectively. The average time spent by nurse in managing a FI patient with absorbent pads and balloon-cuff based fecal management catheters is 16X and 6X when compared to Qora™ SMK.

CONCLUSION

Adoption of Qora™ SMK over balloon catheters can decrease the average direct cost of managing fecal incontinence in non-ambulatory patients by almost 81%. 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.

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

Table 1: Projected Daily Cost Savings

<table>
<thead>
<tr>
<th></th>
<th>ABSORBENT PADS</th>
<th>IBCs</th>
<th>QORA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material &amp; Containment Cost</td>
<td>$81.05</td>
<td>$50.36</td>
<td>$32.55</td>
</tr>
<tr>
<td>Nursing Cost</td>
<td>$105.00</td>
<td>$19.80</td>
<td>$3.51</td>
</tr>
<tr>
<td>Total Cost</td>
<td>$186.05</td>
<td>$70.16</td>
<td>$36.06</td>
</tr>
<tr>
<td>Cost Savings Compared To Qora</td>
<td>81%</td>
<td>49%</td>
<td></td>
</tr>
</tbody>
</table>

Graph 1. Daily Nursing Time

- ABSORBENT PADS: 348 min
- IBCs: 120 min
- Qora: 21 min

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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.

2. Data on company file.
BACKGROUND  Prolonged fecal incontinence has a diverse etiology and is a common condition for patients across the continuum of care. Current balloon cuff based catheters are placed in the anorectal junction, inflated with fluid, and utilize sphincter muscle contraction to support device patency. 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.

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 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 IBC A, and 74.25g for IBC B.

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.

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. 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. 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, IBC A, and IBC B, respectively. Furthermore, maximum diameters created during insertion procedures were 17.78mm, 27.1mm, and 28.35mm for the Qora™ SMK, IBC A, and IBC B, respectively.

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.

3. Data on company file.
BACKGROUND Hospital settings, often innervated with unpleasant malodor from urine, stool, and medical supplies, reduce 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. 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. 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 balloon cuff based fecal management catheter and the Qora™ Stool Management Kit (SMK) were assessed using 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 intuitively 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 Stool Management Kit exhibits significantly higher odor barrier properties as compared to balloon cuff based fecal management catheter. The OTR values were 13.53 cm³/m².24hr.0.1MPa and 35,517.57 cm³/m².24hr.0.1MPa for the Qora™ SMK and Device A respectively.

CONCLUSION The Qora™ Stool Management Kit 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 balloon-cuff based 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.

3. Data on company file.