QORA™ STOOL MANAGEMENT KIT

New standard of care in fecal containment for bedridden patients

ABSTRACT

Constant exposure to fecal effluents in critically ill patients can result in several co-morbidities, which could be both labor and resource intensive. Seemingly benign, fecal incontinence (FI) and diarrhea are ubiquitous in nature and affect nearly 28 million patients across the globe. Fecal exposure causes several hospital-acquired complications (HACs) namely, incontinence-associated dermatitis (IAD), hospital-acquired pressure injury (HAPI), C. difficile infection (CDI), catheter-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI), and surgical site infection (SSI). The clinical and health-economic consequences of patients suffering from poor bowel control are frequently devastating. Traditionally, liquid stool incontinent patients are managed by use of absorbent pads and cleaning supplies. Over the last few years, several closed fecal management systems in the form of external collector pouches or indwelling bowel drainage catheters have shown promising results in preventing IAD and maceration of denuded skin. However, these newer management options have constricted indications of use and can manifest new morbidities in the form of rectal erythema, necrosis, bleeding, and sphincter dysfunction. The Qora™ Stool Management Kit (SMK), developed by Consure Medical is a novel approach for fecal containment in bedridden patients where a proprietary indwelling lattice diverts fecal effluents without interfering in the normal physiological functioning of the rectum. The Qora™ SMK is the first stool management solution that is suitable for use on patients that: exhibit stool consistency improvements from liquid to semi-formed stool, have suboptimal anal tone, are conscious but incontinent, and/or live in step-down units including nursing homes and hospice care. This paper discusses the safety, efficacy, and functionality of the Qora™ SMK technology and discusses potential clinical use-case scenarios including how this novel technology can provide patients and care providers with a management modality, especially when no closed fecal management solution is currently available.

INTRODUCTION

Fecal Incontinence

Fecal incontinence (FI) is a highly prevalent and debilitating condition that impacts patients and care providers across various healthcare settings. Although FI is a benign condition, its clinical sequelae and associated expenses are often devastating to both the patient and the health system. FI depends upon a wide variety of anatomic and physiologic factors. Colonic transit and stool consistency, rectal reservoir function, anorectal sensation, muscle innervation, and function of the internal and external anal sphincters all contribute to the maintenance of normal continence. The three main pathophysiological factors for incontinence, which often overlap, are (1) abnormal stool consistency and volume, (2) neurologic disorders leading to sphincter weakness, and (3) anatomic defects in the sphincter.

Pathophysiology

The rectum can accommodate approximately 300ml of possible stool volume before the increase in intrarectal pressure and subsequent distension of the rectal tissue triggers the "urge to defecate" sensation. The internal anal sphincter muscle (IAS), external anal sphincter muscle (EAS), and the three mucosal folds (rectal valves) play a role in controlled bowel movement. The IAS, which is innervated by the enteric nervous system and both the sympathetic and parasympathetic nerves, is usually contracted and contributes to approximately 80% of the anal canal resting pressure.[1] As an involuntary action that is facilitated by the enteric nerves, the IAS relaxes transiently when the rectum starts to distend. The EAS and puborectalis muscles, which are both innervated by the pelvic and pudendal nerves, are smooth muscles that control the voluntary functions of rectal motility.

The puborectalis muscle also wraps around the rectum, controlling the rectal angle between 60 and 105 degrees, to help control the containment and release of fecal effluents.[2] These muscles can double the pressure in the anal canal but this position can only be maintained for a few minutes.[2] Once the rectum has accumulated fecal matter, the rectum distends and relaxes the IAS,

which triggers an urge to defecate. If the patient chooses to defecate, the anorectal angle reduces and the intraluminal pressure increase due to thoracic and abdominal muscle contractions. The tonic activity of the EAS, which provides 15-20% of the rectal tone, is also inhibited and results in a successful bowel episode.[3]

An interruption in the normal defecation mechanism can result in fecal incontinence. Neurological disorders or trauma are commonly associated with fecal incontinence, especially amongst hospitalized patients. Conditions such as stroke, spinal cord trauma, diabetes mellitus, and degenerative disorders of the nervous system alter normal gastrointestinal sensation, feedback, or function that helps to maintain continence. These effects are especially exacerbated in bedridden and institutionalized patients.

Epidemiology

Fecal incontinence is predominantly found in critically ill patients in acute care facilities and other long-term care facilities such as psychiatric and rehabilitative institutions. FI affects nearly 3.4 million patients in the United States, and 28 million patients across the globe, with prevalence rates of 9-40% in Intensive Care Units (ICUs), 20-46% in Long Term Acute Care (LTAC), 42-50% in Skilled Nursing Facilities (SNFs), and 9.7-12% in home care facilities.[4-13] In addition to the prevalence, the duration of the condition is equally important. Incontinence in institutional patients typically lasts for 1 to 5 days depending on the clinical condition, prescribed treatment, and dietary intake. Outside the institution, incontinence in geriatric and psychiatric patients can last from 30 days to years, until a definitive therapy in the form of surgical intervention is undertaken.

Clinical Complications

Fecal incontinence is an established risk factor for skin breakdown, pressure injury, and spread of hospital-acquired infections (HAIs) in bedridden patients.[13-16] The manifestation of these complications arises when the acid mantle of the perineal or perigenital skin is suffused with stool and moisture, therefore causing perineal rashes. Sebum, an oily substance secreted by the sebaceous glands, maintains the skin integrity by maintaining an acidic pH of 4 – 6.8 (acidic mantle).[17-19] Feces containing protease and lipase, both alkaline in nature, can digest perianal skin and soft-tissue. These pathological manifestations can lead to further skin breakdown when combined with the physical forces of body weight and shear force from restlessness or patient agitation. An incontinent patient is 22 times more likely to develop HAPI, and is 37.5 times more likely to develop HAPI if both incontinent and immobile.[20]

Continual exposure to moisture from fecal matter through inefficient conventional fecal management practices causes the skin to macerate, thus compromising the skin's integrity as a barrier. Unattended or untreated macerated skin results in erythema and painful pressure points over a period of time. Skin that has an impaired barrier function can easily be invaded by bacteria causing IAD.[17] In addition to IAD, incontinent patients are also at risk of acquiring secondary infections such as urinary tract infections (UTIs).

Inefficient fecal containment is a major risk factor for the spread of HAIs, most commonly *Clostridium difficile* infection (CDI). *C. difficile* causes severe diarrhea and has seen an increasing incidence among nursing home and acute care patients.[21,22] CDI is easily transmittable in a healthcare setting and requires strict hand hygiene and contact precautions to avoid contamination.
Hospitalized patients are usually under heavy doses of antibiotics, which disrupts the equilibrium of intestinal microflora thereby allowing the pathogenic microbes to proliferate, resulting in HAIs. Bacteria found in stool is representative of the bacteria in the gastrointestinal tract, and causes infections such as CLABSI, CAUTI, and SSI through the spread of antibiotic-resistant microorganisms via healthcare workers and other surfaces contaminated with fecal bacteria. A combination of HAPI and exposure to nosocomial infections adversely impacts the patients' mortality, morbidity, treatment costs, and length of stay.[23-25]

MANAGEMENT OPTIONS

Treatment options for FI can be classified into four main categories: containment, pharmacological, electro muscular stimulation, and surgical repair of the anorectal anatomy. Due to multiple comorbidities in institutionalized patients and the care provider's focus on treating their primary condition, FI is most commonly managed by containment or pharmacological options. Options for fecal containment in bedridden patients are often the utilization of absorbent pads or diapers, fecal collectors in the form of collection bags or pouches, or indwelling balloon catheters (IBCs).

The use of absorbent pads requires cleaning of the patient after every defecation, which can lead to perineal dermatitis and maceration if not performed consistently and appropriately. Hence, the effectiveness of the absorbent pads is limited to preventing the soiling of patient's clothes and bed sheets.

The pouch-type collection devices have an open end, which adheres to a patient's anal opening using hydrophobic and derma-

friendly adhesives that are attached to a collection pouch. This was once considered a cost-effective 'closed' system that could potentially prevent exposure to fecal matter. Unfortunately, the use of such fecal pouches requires frequent replacement that can lead to denudation of the skin around the area of application. Furthermore, due to the irregularity in the anatomical topography around the anal opening, the fecal pouches are frequently plagued with fecal leakage, thereby providing minimal advantages in comparison to absorbent pads.[26] The lack of robustness of the pouch adhering mechanism prevents them from being used on agitated patients with altered sensorium – a common condition in acute care or long-term care patients.

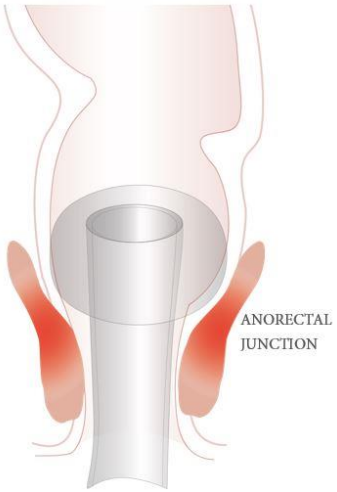

FIGURE 1: INDWELLING BALLOON CATHETERS ANCHOR UPON THE ANORECTAL JUNCTION

Indwelling balloon catheters (IBCs) are the most recent and effective solution currently available for managing liquid stool incontinence in acute care settings. Similar to a Foley's catheter for urinary drainage, indwelling catheters are placed inside the rectum and anchor upon the anorectal junction by an inflated balloon (Figure 1). The catheter tube is connected to a collection bag where fecal matter is collected. IBCs can be used up to 29 days, which is an advantage in certain use cases. However, they are very limited in their indication of use and have a high potential to manifest other comorbidities. Moreover, the region approximately 2-3 centimeters proximal and distal to the anorectal junction is most heavily innervated. Due to their inherent design, anchoring IBCs near or around the anorectal junctional region may lead to patient discomfort, the urge to defecate, peripheral leakage (40-78%), spontaneous expulsion (21 - 28%), over-inflation (14%), and cause sphincter dysfunction (8-25%), anal erosion (13%).[27-35] Currently, intrarectal balloon catheters are ideally suited for patients in the ICU with liquid stool incontinence who are sedated and have adequate sphincteric tone. Furthermore, IBCs can only be inserted by a trained care provider, require periodic monitoring the cuff pressure and placement, and are prone to mucosal erosion in the anal canal, necrosis, and rectal bleeding.[29,31,32,34-37] Consequently, indwelling fecal management catheters are rarely used outside of acute care settings because of the complexity of the current design and the potential adverse events which could result if used by semi-trained care providers.

HEALTH ECONOMICS

Fecal exposure causes over 135,000 HACs annually, attributing to over $1.34 billion in healthcare expenditure.[38] HACs associated with inadequate fecal containment, namely HAPI, CDI, CAUTI, SSI, and sepsis result in an additional cost of $0.6k - $30k per complication.[25,39-43] Table 1 summarizes the additional length of stay (LOS) per patient and cost per complication developed due to poor fecal management.

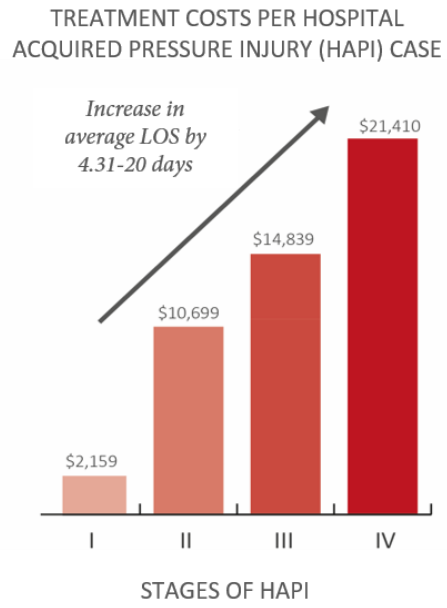

FIGURE 2: COST OF TREATING VARYING STAGES OF HOSPITAL ACQUIRED PRESSURE INJURIES

As a result of new regulations such as the Hospital-Acquired Complication Reduction Program (HACRP), healthcare facilities are incentivized to contain the spread of HAIs to avoid exorbitantly high penalties. In 2016, 758 U.S. hospitals were penalized $364 million for high incidences of HACs such as HAPI and HAIs in their institutions.[59] The government has recently suggested that such measures are also necessary in long term acute care facilities (LTACs) and Skilled Nursing Facilities (SNFs) to

improve clinical outcomes of the increasing number of admitted patients and to reduce the economic burden of chronically institutionalized patients.

TABLE 1: ADDITIONAL LENGTH OF STAY AND COST ASSOCIATED WITH HOSPITAL ACQUIRED COMPLICATIONS

Complication	Additional LOS (days)	Additional Cost ($)
HAPI[44-47]	4.31 - 20	$ 2,159 - $ 21,410
CDI[52]	2.95 - 11.1	$ 7,286 - $ 29,000
CLABSI[53-54]	8.8 - 10	$ 10,750 - $ 23,242
CAUTI[41,55]	0.4 - 2	$ 589 - $ 1,006
SSI[56-58]	4.9 - 10	$ 21,040 - $ 34,434

FIGURE 3: QORA™ STOOL MANAGEMENT KIT.

QORA™ SMK: A NOVEL APPROACH

Controlling a patient's urge to defecate, pain tolerance, and enhancing infection control are paramount when developing a new incontinence management solution. Consure Medical has reimagined fecal management with its novel Qora™ stool management kit. The value proposition of indwelling balloon catheters for the management of fecal incontinence over absorbent pads and diapers has been clinically and economically proven by commercially available products.[23,60-61] The Qora™ technologically solves a myriad of shortcomings that exist with indwelling catheters. It has been meticulously designed to provide a continuum of care within critical care settings and step-down units such as nursing homes and hospice care facilities.

Pain and Pressure Sensation in the Rectum

The anorectal junction has a high concentration of somatic nerve endings, which disqualifies it as a suitable location for diverter placement. Amongst the many variables of gastrointestinal motility, one key parameter associated with rectal sensation is the intrarectal pressure. High intrarectal pressures (above of 30 cms of water) result in an 'urge to defecate' sensation, which triggers the natural bowel movement physiology.[62] In a false-positive setting, such as the constant radial pressure (50 – 75 cms of water range) of a fully inflated intrarectal balloon catheter (Figure 1) on the rectal walls and anorectal junction, the patient can become extremely uncomfortable and develop an altered sensorium. Hence, it is advantageous for an indwelling fecal diverter to be positioned above the dentate line of the anorectal junction and exhibit a pressure on the rectal wall of no more than 30 cms of water.

The Qora™ SMK suite of products is designed to be safely placed near the transverse rectal valves, which is a divisional line between visceral and somatic nerves that only has a 'pressure sensory' response. Qora™'s proprietary fecal diverter self-conforms to the rectal walls when deployed, and exerts a calibrated radial pressure such that the diverter does not trigger an urge to defecate sensation, does not cause any injury (erythema, necrosis, mucosal erosion), does not migrate proximally or distally, and maintains lumen patency during peristaltic contractions by expanding and contracting with the rectum. Since the Qora™ SMK diverter does not anchor on the anorectal junction, patients do not need to have exhibited adequate sphincter tone for device patency (Figure 4).

Furthermore, the trans-sphincteric transit sheath that traverses the anal canal is made of specialty engineered high-strength amorphous polymeric films that maintain a profile diameter of less than 5 mm. This minimizes the foreign body sensation a patient may feel since the natural lumen diameter of the sphincter is 3-6 mm. By not exerting radial or longitudinal pressures on the sphincter muscles or forcing the anal canal to remain enlarged with a large bore tube, the Qora™ SMK resolves the pain, pressure induced necrosis, and sphincter dysfunction conundrum.

Incontinence and Hospital-Acquired Infections

Stool consistency changes over time as the patient's condition improves. The Bristol stool scale is generally used to assess the stool consistency. A patient with multiple liquid stool episodes per day is prone to prolonged exposure to effluent which results in cross-contamination and a sequela of HAIs. Effective containment

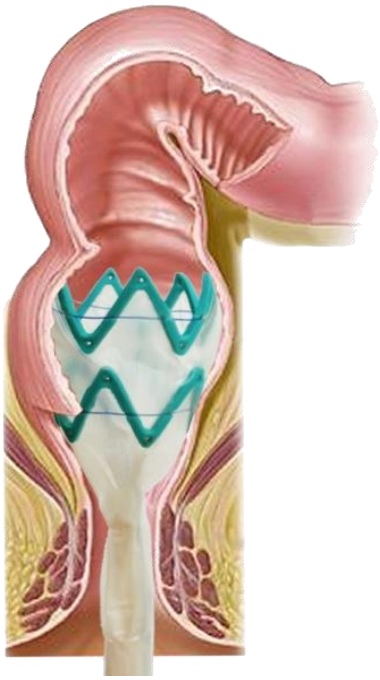

FIGURE 4: QORA ANCHORS ABOVE THE ANORECTAL JUNCTION BETWEEN THE RECTAL FOLDS.

of fecal matter is necessary to avoid spread of pathogenic bacteria and reduce the incidences of HAIs.

To address this issue, the Qora™ Stool Management Kit (SMK) comes with an applicator that is used to deploy the device, eliminating the direct contact between fecal matter and the care provider and ultimately reducing risk of contamination. The indwelling lattice technology is also the only fecal diverter that is designed for patients whose stool consistency improves from liquid to semi-formed stool while remaining bedridden and prone to dermal deterioration. The calibrated radial pressure exerted by the lattice provides an optimal rectal seal to efficiently divert fecal matter from the rectum into the collection bag via the transit sheath. This approach minimizes the risk of peripheral leakage and spontaneous expulsion of the device while helping to contain various infectious carriers found in fecal effluents from the external environment.

Nursing Preference and Patient Comfort

Fecal management requires significant time commitment from care providers. Managing incontinence along with dermatitis, maceration, and HAIs requires deft planning and prioritization. The Qora™ SMK technology is designed to provide a safe and effective fecal management solution and to help extend the continuum of care. By employing a user-design based approach, the Qora™ SMK can be used by a minimally trained individual and does not require rectal tone assessment or periodic maintenance of the indwelling portion.

The kit comes with a convenient stool sampling port that works with standard slip-tip syringes and sampling kits. The device has an intuitive and integrated irrigation port and withdraw port. The irrigation port can be used to flush the device with fluids in the event of a lumen obstruction or if stool softening is desired. The withdraw port, when activated, collapses the indwelling lattice diverter, and safely allows the device to be retrieved from the rectum without aggravating the anorectal mucosa. The fluid retention clamp allows care providers to perform procedures requiring fluid retention within the rectum (e.g., an enema).

The external collection bags and transit sheath are made of specially engineered barrier proof polymers that contain odor (e.g., provides an odor barrier) and do not aggravate sensitive skin. The bag exchange is designed to be linear in order to prevent any blockage. The easy-to-use collection bag has an integrated luminal one-way valve that prevents any accidental soiling or leakage during the bag exchange procedure. The collection bag is integrated with a flatus release filter for automatic odor-free degassing. The device is designed in pleasant neutral color and remains out of direct sight to maintain the dignity of the patient throughout the duration of hospitalization.

The Qora™ SMK has been cleared by the U.S. Food and Drug Administration (FDA) for patients incontinent with liquid to semi-formed stool in hospitals and nursing homes. Qora™ Stool Management Kit is MRI compatible. The maximum duration of use approved by the U.S. FDA is 29 days.

PILOT STUDY

A pilot clinical evaluation study was conducted on 10 patients at the All India Institute of Medical Sciences (AIIMS) to assess and confirm the safety of the novel device. In this initial evaluation, the stool management kit was evaluated in-situ for up to 20 minutes in patients who were scheduled for colonoscopy or sigmoidoscopy to investigate their irritable bowel. Topical lidocaine hydrochloride jelly (Xylocaine 2% Jelly, AstraZeneca, Cambridge, United Kingdom) was used at the time of device insertion. After device deployment, fluoroscopy of the pelvic region was performed in all patients to confirm deployment, positioning, retention, and lumen patency of the device as expected. Colonoscopy was performed after device removal to check for any anorectal pathology.

No patients experienced pain or discomfort when the device was in-situ, and there were no events of device expulsion. Minor erythema of the rectal mucosa was observed in 6 out of 8 patients during the colonoscopic examination, which is consistent with capillary hyperaemia due to insertion of any foreign body in the rectum. Three patients had internal haemorrhoids, which is commonly prevalent in patients with functional GI disease where incidence of excessive straining during bowel moments is high. Minor bleeding was observed on the haemorrhoids after the retrieval of device. There was minor superficial mucosal injury in one patient. However, there was no tear or bleeding in the relevant anatomy in any of the patients.

The average duration of device placement was 8.4 minutes (with a range of 5 to 11 minutes). The device maintained its structural and functional integrity over the duration of the study. This pilot study was performed in order to establish feasibility of the device design and incorporate design refinements from initial clinical experience. All end points and goals were met.

TABLE 2: INCLUSION AND EXCLUSION CRITERIA FOR CLINICAL STUDY

Inclusion Criteria	
1.	Patients must be between 18 – 65 years of age (no gender bias)
2.	Fecal incontinence must be caused due to an intracranial cause
3.	Patients must be admitted for at least 48 hours and must be on a nasogastric feeding tube for at least 24 hours
4.	Patient has achieved hemodynamic stability
5.	Patient or a legal representative of the patient gives written consent for the study
Exclusion Criteria	
6.	Disease or trauma of the muscular apparatus of the anorectal region
7.	Pregnant or lactating females
8.	Recent history of colorectal surgery
9.	Patients suspected to have anorectal malignancy, ulcerative colitis, Crohn's disease or intestinal tuberculosis
10.	Sigmoidoscopy revealing hemorrhoids (Grade IV), internal ulcers, fissures, strictures or fecal impaction
11.	Scheduled MRI examinations over the study period
12.	Any other systemic condition having potential for undue risk to the patient as deemed by investigator
13.	Unwilling or unable to provide informed consent
14.	Already enrolled in another study

QORA™ CLINICAL STUDY METHODS

Study Design

A clinical evaluation was conducted on 20 patients at the All India Institute of Medical Sciences (AIIMS), New Delhi, India. The evaluation was conducted in a step-wise paradigm, in order to ensure that all risks were minimized for the enrolled patients.

Ten adult patients were enrolled from the neurological unit to evaluate the safety and efficacy of the device for up to 24 hours. Based on the safety performance, the device usage was extended for up to 120 hours (5 days), with an additional enrollment of 10 patients. Data from these 20 patients have been jointly considered in this analysis. Study procedures for each phase were reviewed and approved by the ethics committee of All India Institute of Medical Sciences, New Delhi, India. Written and informed consent were obtained from all enrolled patients or by their legally authorized representatives.

Patient Eligibility

Enrolled patients had at least one episode of fecal incontinence due to neurological disorders 24 hours prior to device usage. Patients receiving low molecular weight heparin or antiplatelet therapies were enrolled under the discretion of their care provider. The inclusion and exclusion criteria are detailed in Table 2.

Interventions and Assessments

Patients underwent a complete anorectal examination using a flexible sigmoidoscope prior to device insertion to exclude any pre-existing anorectal pathology. Topical lidocaine hydrochloride (Xylocaine 2% Jelly, AstraZeneca, Cambridge, United Kingdom) was used for lubricating the applicator during insertion. A supine anteroposterior pelvic radiogram was performed after the device deployment to verify device expansion and positioning.

All the patients were maintained on absorbent pads with the device in-situ. Follow-up was performed on each participant every 4 to 6 hours. At each assessment point, the individual's blood pressure, pulse rate, and temperature were measured, and an abdominal examination was performed. The perineal region was examined for evidence of device related bleeding or fecal contamination. The absorbent pads, patients' clothes, and bed linen were evaluated for soiling. The external components of the SMK, including the transit sheath and collection bag, were examined for structural integrity and collection of fecal effluents. A repeat sigmoidoscopy was performed after withdraw of the SMK to evaluate for any anorectal mucosal trauma compared to the baseline.

Safety Assessments

The safety evaluation of the device was measured using the following endpoints:

1. Pre- and post- device use impact was investigated by sigmoidoscopy to evaluate the anorectal mucosa.

2. Anorectal bleeding – defined as visualization of any blood in the perineal region, absorbent pads, transit sheath or collection – was evaluated.

Efficacy Assessments

The evaluation of the device efficacy was measured using the following endpoints:

1. Successful fecal diversion – defined as the collection of fecal effluents in the transit sheath and/or the collection bag.
2. Device leakage: 1) Classified as Minor, if the leakage was non-problematic, incidental, and confined to the perineal area, and 2) Classified as Major if there was significant soiling around the device.
3. Duration of device use.

Feasibility Assessments

The feasibility evaluation of the device was measured using the following endpoints:

1. Radiographic visualization to assess the self-expansion of the SMK at the pre-determined location.
2. Device dislodgement: Classified as inadvertent removal of the device due to external interference by the caregiver, family member or patient.
3. Spontaneous expulsion: Classified as a device being expelled in the absence of any external forces, solely by the patient, due to either change in stool consistency or peristaltic contraction.

Statistical Analysis

All relevant study data were evaluated using Microsoft Excel 2010 (Microsoft Corporation, Washington, USA) software. Safety data and device performance descriptions were summarized from the enrolled patients in the study. The results are presented as absolute values, percentages, with mean ± standard deviation, wherever applicable.

QORA™ CLINICAL STUDY RESULTS

Twenty patients were enrolled for the clinical evaluation. Their mean age was 56.7±13.6 years (mean ± SD), range: 27-80 years; where 16 patients (80%) were males. The mean period of hospitalization of patients prior to the enrollment in the study was 20.3±15.7 days. The majority of the participants were admitted following cerebrovascular accident. 3 patients (15%) were receiving either an anticoagulant (e.g., low molecular weight heparin), an antiplatelet agent (e.g., clopidogrel), or a combination of both an antiplatelet and an anticoagulant, and continued to take these drugs during the study period.

All devices were successfully deployed on the first attempt. A supine anteroposterior pelvic radiogram was obtained in 16 patients (80%) to verify expansion of the fecal diverter at the correct anatomical site. The pelvic radiogram confirmed proper expansion of the fecal diverter above the anorectal junction in all instances. In two cases, the radiogram could not be obtained and the device's location was confirmed by the efficient collection of feces in the transit sheath and/or collection bag.

The participants underwent a total of 186 assessment points, with 43 points during the 24-hour study and 143 points during the 120-hour study. Device performance was evaluated in 18 patients who completed at least one follow-up assessment. Most of these patients (n=17; 85%) revealed successful fecal diversion while the device was in-situ. Of 186 assessment points, no leakage was seen in 174 (93.5%) and minor leakage in 12 (6.4%) time points. There was no episode of major device leakage. All instances of minor leakage were spontaneously resolved in one to four follow-up assessment points. In one instance, the leakage was observed at the connection of the transit sheath to the collection bag due to a loose connection. There was no perineal soiling in this case.

The device was dislodged or retrieved in five (25%) of the 20 patients. In two patients, the device was removed within an hour of deployment, one expulsion was due to inadvertent dislodgement and the other was retrieved early on request of the treating physician due to deterioration of the patient's underlying condition not attributed to the device. In both patients, pelvic radiogram and post-device sigmoidoscopy were not completed. One patient experienced spontaneous expulsion of the device after 74.5 hours due to change in stool consistency (liquid to formed stool). Two patients experienced device dislodgement due to inadvertent pulling of the catheter either by the patient, the caregiver, or other external interferences. This occurred approximately 17 hours and 41 hours after placement.

The remaining 15 patients, 8 patients from the 24-hour study and 7 patients from the 120-hour study successfully retained the device for the duration of the study or until it was no longer clinically required. The devices remained in-situ for 21±0.2hours and 84.5±38.9 hours during the 24-hour and 120-hour study, respectively. The device was successfully retrieved in 16 enrolled patients, of which one was retrieved prior to the end of study period upon request by the treating physician.

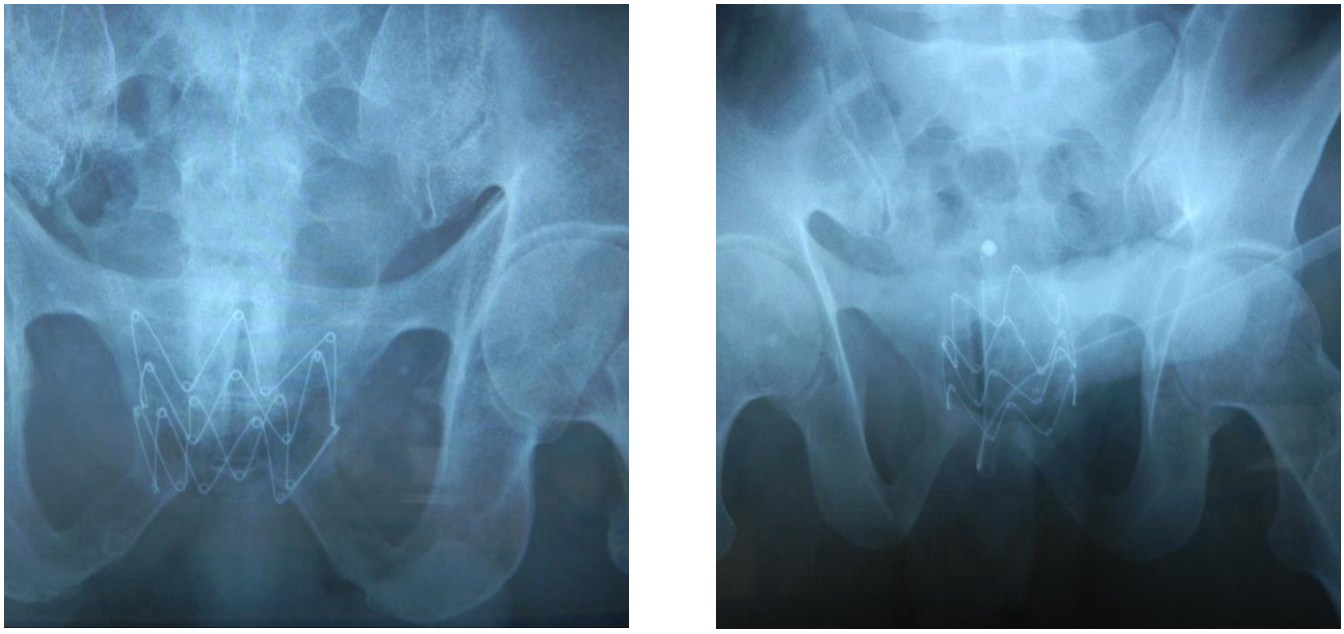

FIGURE 5: RADIOGRAPHIC IMAGING WAS PERFORMED IMMEDIATELY POST DEVICE DEPLOYMENT (LEFT) AND BEFORE DEVICE REMOVAL (RIGHT) TO DEMONSTRATE HOW THE QORA™ SMK DEVICE EXPANDS AS DESIRED AND DOES NOT MIGRATE DURING USE.

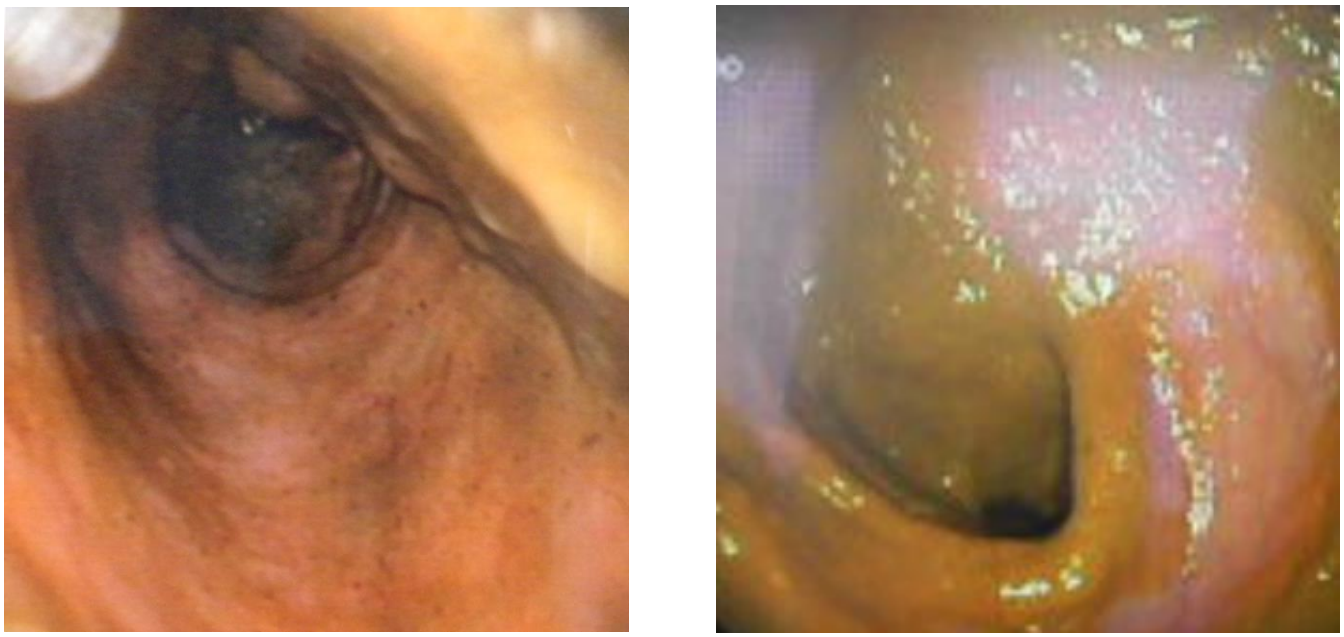

FIGURE 6: BEFORE (LEFT) AND AFTER (RIGHT) DEVICE USE SIGMOIDOSCOPY WAS PERFORMED TO ASSESS ANY ANORECTAL INJURY DUE TO DEVICE USAGE

The insertion of the device did not affect routine patient care including patient mobility, feeding, sitting or standard maneuvering performed on bedridden patients. The devices were evaluated for structural and functional integrity post retrieval. Data was available for 19 devices. In one instance, the device was discarded by the caretaker without informing the investigator, hence further device assessment could not be performed. All of the available devices were found to be structurally and functionally intact after removal. There was no evidence of any tear in the transit sheath or any damage to the retrieval mechanism.

All enrolled patients had a normal rectum and anal canal as confirmed by sigmoidoscopic examination prior to device deployment. There was no episode of any anorectal bleeding throughout the study period. Post-device removal sigmoidoscopy was done in 16 patients. Minor mucosal erythema at the site of diverter placement was seen in two patients. None of the patients with minor mucosal injury had device dislodgement or spontaneous expulsion.

DISCUSSION

Effective fecal containment in institutionalized patients is often under-addressed and overlooked. Patients with FI or diarrhea are 22 times more likely to develop pressure injuries; this risk rises to 37.5 higher odds when the individual is bedridden.[20] The risk of serious complications also extends to patients exposed to fecal bacteria such as *Clostridium difficile, Escherichia coli*, or *Pseudomonas aeruginosa*.[21,39,63] Such pathogens, which are easily transmitted fecal-orally, result in hospital-acquired complications that further complicate treatment and increase healthcare-related expenditure. Health-economic studies have shown that CAUTI, CLABSI, and SSI due to fecal contamination can increase mortality rates by 4 - 40% and extend the length of hospitalization by 4-22 days, thereby adding an incremental cost of US $0.6k-$30k per complication.[25,39-43]

This study was undertaken to determine the safety and efficacy of a novel self-expanding fecal diversion system in bedridden patients suffering from fecal incontinence. Current evidence suggests that intrarectal balloon catheters (IBCs) are better management options for FI when compared to absorbent pads in acute care settings, but they are less frequently utilized due to their high rates of peripheral leakage (40 – 71%) and spontaneous expulsion (17 – 28%).[27-28] Furthermore, there are safety concerns

due to the high risk of mucosal erosion in the anal canal, mucosal bleeding, and sphincter atony caused by the catheters' inherent design.

Qora™ SMK is designed to overcome functional and safety constraints with existing IBCs. Results of the clinical study suggest that it is safe to use Qora™ SMK in bedridden patients with fecal incontinence and diarrhea. Post-deployment imaging validated consistent anatomical positioning of the device inside the rectum and above the anorectal junction.

Over the duration of use, 80% of the devices remained deployed in-situ, efficiently diverting liquid or semi-formed fecal effluents into the collection bag. In twelve assessments, minimal peripheral leakage was observed, but episodes ceased within 4 to 48 hours.[64] Comparison of the findings of sigmoidoscopic examination before and after use of the device revealed no adverse effect of the device to the anorectal mucosa, except for minor mucosal erythema in two patients. Device positioning within the rectum did not cause any anorectal erosion – a complication often associated with IBCs. No incidents of fistulae, fissures, ulceration, or other adverse events occurred during the study period. Patients predisposed to bleeding were handled cautiously. Study participants did not show any adverse events while on anticoagulant or antiplatelet drugs. The ability to use the SMK in such patients could be an advantage over IBCs. However, a further detailed investigation would be required to arrive at even more conclusive recommendations.

Qora™ SMK provided an effective barrier between perineal skin and fecal matter, avoiding the risk of further skin breakdown that could potentially lead to severe complications. Furthermore, the design and placement of the device may allow for patients with poor anal tone or altered sensorium to retain the device when compared to an IBC. An added benefit of the novel design of Qora™ SMK is the large indwelling lumen size, which allows patients transitioning from liquid to semi-formed stool to continue using the device without the need for routine medication to modify and maintain liquid stool consistency. The applicator design ensures safe, painless, and hustle free deployment of the device. Care should be taken to deploy the device immediately after the rectum has been cleared and should only be placed in the patients with liquid stool. However, in the event the device is deployed into semi-formed or formed stool, the pliable nature of the device should prevent the risk of injury to the rectum, anorectal junction, or anal canal even if the device is expelled.

Supported by clinical evidence and a strong technological value proposition, a careful assessment of the Qora™ SMK demonstrates clear advantages over intrarectal balloon catheters. More importantly, the benefits of this technology enable a significantly wider patient applicability since device placement does not depend on sphincter tone. Additionally, the device does

not cause any pain sensation, enables varying consistencies of stool to be diverted, and requires minimal resources for maintenance and management. Listed below are cases where incontinent bedridden patients have benefited from the Qora™ SMK technology:

*A) **Long-term Acute Care**: An 88-year old male patient was admitted in the ICU for the treatment of urosepsis. The patient had developed a grade 2 pressure ulcer 7 cm in diameter. Initially, the patient's diarrhea was managed by diapers. After 22 days of admission, Qora™ SMK was deployed into the patient. The device remained in-situ for 26 days, providing the patient with a dignified, hygienic, and infection-free bowel management system. It reduced nursing time and assisted in healing the pressure ulcers by eliminating contamination due to stool.*

Qora™ SMK offers a closed system for efficient infection control and prevention of wound contamination in long-term bedridden patients.

*B) **Wound Care**: A 52-year old male was admitted into the ICU due to Myasthenia Gravis. The patient had a grade 4 pressure ulcer on the sacrum along with external haemorrhoids. The patient was completely bedridden and had frequent urinary and bowel movements which caused soiling to the wound dressing. This resulted in multiple dressing changes each day in order to keep the wound clean. The device was deployed after 57 days of admission. Over the span of next 30 days, 43 one-litre bags were used with an approximate stool output of 800 ml per day. Due to mismanagement of the product and stool modification, more than one device was used by the patient.*

Qora™ SMK addresses the pain points in managing bedridden patients by simplifying stool management, ensuring ease of nursing, and minimizing skin contact with the fecal matter and therefore reducing further degradation of skin or wounds.

*C) **Wide Patient Eligibility**: A 92-year male was admitted into the ICU with type 2 respiratory failure and Acute Kidney Injury. Due to low Total Leukocyte Count the patient was prone to infections. A Foley catheter was deployed to monitor the urine output. The patient had external haemorrhoids and a grade 1 pressure ulcer. After 18 days of admission, Qora™ SMK was deployed. The approximate stool output was 350ml per day. Even though the patient's anal tone was weak, it was reported that there was no leakage of stool during the 17 days of use.*

Since the device forms a seal around the Houston values and not around the anorectal junction, the patients with weak anal tone are also able to use the device without concerns of device expulsion or further weakening of the sphincter muscles.

The Qora™ SMK is designed for use in resource-constrained environments. The diverter is designed for self-positioning and self-expansion and is easy to maintain once deployed. The diverter is positioned above the transverse rectal valve, avoiding any pain or foreign body sensation in a conscious patient. It is recommended to ensure the rectum is empty prior to deploying the Qora™ SMK.

CONCLUSION

The results of this detailed pilot clinical evaluation demonstrated that the Qora™ stool management kit provides patients and care providers with a superior alternative to standard methods of fecal containment and management. Patients enrolled in the clinical study underwent a baseline sigmoidoscopy that was later compared with a sigmoidoscopy post-device removal. No cases of anorectal erythema or mucosal injury of clinical significance were observed throughout the study. Patients with varying neurological conditions in a wide range of consciousness successfully tolerated the device during insertion, deployment, while *in situ*, and removal. Peripheral leakage was not observed in 93.5% of the patients.[64] The pliable nature of the device ensures patient safety regardless of patient setting and use case.

Adoption of Qora™ SMK can decrease the average direct cost of managing FI by up to 81% when compared to traditional methods of bowel management (Table 3).[65] With the advanced indwelling diverter technology, Qora™ SMK provides additional savings by reducing the treatment costs associated with IAD, HAPI, and HAIs. Although direct costs associated with traditional and indwelling balloon catheters have been studied, the indirect costs due to new complications, which can be quite costly, are often neglected (Table 1). Existing balloon catheters contribute to complications in the form of mucosal necrosis and sphincter dysfunction, which can result in significant intervention costs in the form of surgery. Detailed studies will be performed to clearly quantify the economic benefit of Qora™ SMK over other management modalities. However, an initial analysis portrays a clear expectation of economic advantage.

TABLE 3: PROJECTED DIRECT COST SAVINGS WITH QORA OVER TRADITIONAL METHODS

	Absorbent Pads	IBCs	Qora™ SMK
Material & Containment Cost	$ 110.37	$ 43.13	$ 35.25
Nursing Cost	$ 105.0	$ 19.8	$ 9.33
Total Cost	$ 215.37	$ 62.93	$ 44.58

It is worth noting that although the Qora™ SMK offers the widest indications of use for a fecal management system, the device must be used with proper patient screening. Care should be specially exercised when planning to use this device in patients who have a tendency to bleed due to ongoing anticoagulant or antiplatelet therapy. Other underlying conditions, previous procedures, and expected treatments must be crosschecked with the device's contraindications and safety warnings. When appropriately used, the results of the pilot clinical evaluation discussed in this paper illustrate the Qora™ device as a significant improvement over traditional bowel management practices.

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