Clinical Evaluation: Industry's First Automated Stool Management Kit

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BACKGROUND

Fecal incontinence in non-ambulatory ICU patients poses significant clinical challenges. Traditional management relies on absorbent pads and manual hygiene, which are labor-intensive and prone to cross-contamination. Indwelling balloon catheters (IBCs) were introduced to mitigate these issues, offering improved containment over pads. However, IBCs present critical drawbacks, including high-pressure balloon-related complications such as necrosis, trauma, anal erosion, peri-anal skin breakdown, and leakage rates ranging from 40-78%[1]. These limitations exacerbate patient morbidity, increase caregiver burden, and compromise protocol adherence in vulnerable populations. A paradigm shift toward innovative technologies is imperative to address these persistent pain points.

INTRODUCTION

An Automated Stool Management Kit represents a pioneering advancement in fecal containment, leveraging negative pressure suction and irrigation to overcome the shortcomings of existing solutions. Key features include:

1. Zero radial pressure (**0 mmHg**), eliminating trauma associated with balloon inflation
2. Proactive fecal containment, **reducing leakage** to a benchmark of 1.8%[1]
3. Automation of suction and irrigation, minimizing manual intervention, enhancing compliance with clinical protocols, and **reducing caregiver strain**.

This technology achieves a transformative reduction in leakage compared to traditional methods (40 - 78% to 1.8%), offering a safer, more efficient alternative that prioritizes patient outcomes and operational efficacy in critical care settings.

METHODS

Inclusion Criteria

- Age ≥ 18 years, no gender restrictions.
- Non-ambulatory, hospitalized patients with documented stool passage within the prior 24 hours.

Exclusion Criteria

- Rectal mucosal impairment, recent rectal surgery (<1 year), bleeding, significant hemorrhoids, strictures, tumors, constipation, or pediatric status.
- Enrollment in conflicting clinical studies.

Interventions and Assessments

- Efficacy of fecal diversion via automated suction and irrigation.
- Leakage severity (minor vs. major).
- Device dwell time and unintended expulsion rates.
- Nursing time allocation for device management and patient care.
- Caregiver burden quantified via the Caregiver Strain Index (CSI).
- Patient comfort during insertion, use, and removal.

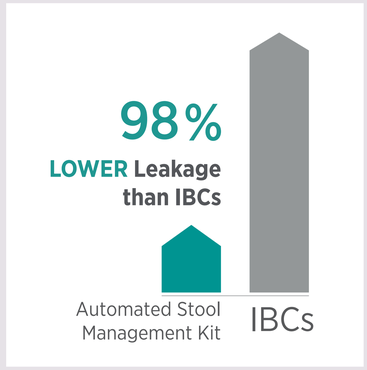
STATISTICAL ANALYSIS

Data were analyzed using Microsoft Excel, with results reported as absolute values, percentages, and means ± standard deviations. Safety and performance metrics were derived from all enrolled patients.

RESULTS

In a cohort of 20 patients across 341 assessments:

- 100% success in fecal diversion was achieved using automated suction and irrigation.
- Leakage was minimal (1.8%), requiring only 6 under-pad changes throughout the study, a stark contrast to the 40-78% leakage rates of IBCs.
- Mean device dwell time was 4.4 days, with only 2 incidental expulsions, promptly addressed per protocol.
- Nurses spent an average of 6.8 minutes daily on initial management and <1 minute per follow-up, reflecting significant time savings.
- Caregiver feedback was 95% positive for ease of use, with CSI scores indicating reduced workload.
- No necrosis, anorectal trauma, bleeding, or device malfunctions were observed.
- Patient comfort was consistently reported as exceptionally superior to traditional methods.



DISCUSSION

Current fecal incontinence management products, particularly IBCs, impose substantial clinical and operational burdens due to high leakage rates, pressure-related injuries, and labor-intensive protocols[1].

An Automated Stool Management Kit addresses these concerns through a novel negative pressure suction and irrigation system. By eliminating radial pressure, internal injuries are reduced to absolute zero. With proactive suction, leakage is reduced to 1.8%—with the benefit of having used the product once or twice before, experienced staff have achieved 0% leakage—surpassing the performance of balloon-based devices and expectations of the nurses.

The system also streamlines nursing workflows, saving time, reducing manual errors, and improving adherence to clinical hygiene, skin-care and pressure injury protocols.

The absence of adverse events, including in anticoagulated patients, underscores the safety and tolerability of this approach.

All devices were found to be structurally and functionally intact upon removal.

This technology redefines fecal incontinence management, offering a compelling case for transitioning from outdated methods to automated, negative pressure-based stool management kits.

CONCLUSION

An Automated Stool Management Kit sets a new standard for fecal incontinence management, resolving the limitations of traditional products. By integrating negative pressure suction and irrigation, it minimizes leakage, protects patient dignity, and optimizes nursing efficiency—paving the way for improved outcomes and protocol compliance in ICU settings

References: 1. Data on company file.