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CLINICAL RESEARCH SUMMARY
Gutting, et al. Study

Sealing Efficiency and Safety of a Polyurethane-Based Fecal Management System in Intensive Care—A Real-World Observational Study[1]

OVERVIEW

The hygh-tec® system is a novel, polyurethane-based fecal management system (FMS) designed to improve hospital workflows and outcomes for patients with fecal incontinence in critical care environments. The purpose of this study was to investigate the sealing efficiency and safety of the hygh-tec system in routine critical care.

METHOD

This was a prospective observational study, with analysis performed by descriptive statistics only.

39 patients admitted to the Intensive Care Unit at the University Hospital in Heidelberg, Germany between July 2022 and February 2023, were treated with the hygh-tech device in accordance with the manufacturer's instructions. During each 8-hour nursing shift, information on safety and sealing efficiency endpoints was analyzed and documented.

Safety:
Nursing shift documentation of perianal lesions and perianal skin status as described by GLOBIAD score measuring redness, skin loss, and clinical signs of infection.

Sealing efficiency:
Nursing shift documentation using predefined contamination score from 1 (no visible perianal contamination) to 4 (pronounced contamination of patient).

The hygh-tec system uses polyurethane, for greater flexibility and softness compared to traditional water-filled silicone balloons. Its air-filled dumbbell shaped balloon is designed to provide a low-pressure, responsive anatomical fit for effective seal function.

FINDINGS

Results indicate that the hygh-tec fecal management system provides safe, efficient sealing, and compared to published literature existing for other fecal management devices, these results appear to represent a clinically substantial improvement.

Superior sealing efficiency

Leakage rate:
This study reported a 10.7% leakage with hygh-tec.[1] A Cleveland Clinic study (2015) reported a 70% leakage rate for two competitive silicone-based fecal management systems.[2]

Effective sealing:
No visible perianal contamination observed in 76% of shift reports.

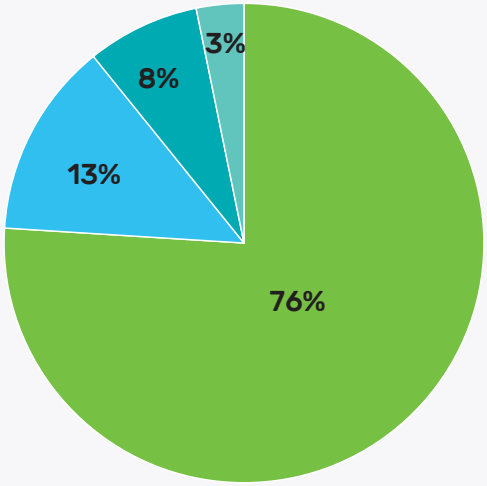
Reduced incidence of skin lesions and injuries

This study reported a 0.8% incidence of new anal lesions with hygh-tec.[1] A Cleveland Clinic study (2015) documented a 12.7% incidence of new anal lesions for two competitive silicone-based fecal management systems.[2]

Safety and comfort

hygh-tec system was well tolerated, with no serious adverse device-related events reported.

SEALING EFFICIENCY
(Observations from 1110 shift reports)



- **Rank 1** No visible perianal contamination
- **Rank 2** Visible perianal contamination
- **Rank 3** Visible contamination of patient pad
- **Rank 4** Marked patient contamination

ECONOMIC CONSIDERATIONS

This study did not evaluate the financial impact associated with the use of the hygh-tec system compared with traditional silicone-based devices. However, it is well established that the financial burden of uncontrolled fecal incontinence is significant. By minimizing fecal leakage and reducing contamination-related skin breakdown, hygh-tec could potentially provide substantial savings by:

- Reducing the likelihood of complications associated with HAPI, HAI and Incontinence Acquired Dermatitis (IAD)
- Reducing costs of linens, cleaning supplies and PPE
- Improving workflow efficiencies by reducing reactive care, allowing nurses to focus on critical care tasks

References

1. Gutting T., B. A., Strach L., Stricker E., Boxberger M., Trierweiler-Hauke B., Heine C., Michl P., Luntz S., Robert B., Göbel F., Pfützner A., Watts, K. (2024). Sealing Efficiency and Safety of a Polyurethane-based Fecal Management System in Intensive Care – Results from a Real-World Study [Real-World Observational Study]. University Hospital Heidelberg. Accepted for publication in the *Australian Critical Care Journal*. Data on file.
2. Sammon MA, Montague M, Frame F, Guzman D, Bena JF, Palascak A, Albert NM. Randomized controlled study of the effects of 2 fecal management systems on incidence of anal erosion. *J Wound Ostomy Continence Nurs*. 2015; 42:279-86.

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