

Evaluation and Perception of an External Fecal Management System to Provide Secure Containment of Feces and Fecal Matter

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INTRODUCTION

Fecal incontinence (FI) is the inability to control bowel movement leading to leakage of feces or stool without warning. FI can range from an occasional leakage of feces while passing gas to a complete loss of bowel control. Causes of FI include diarrhea, constipation, and changes in neurological integrity.^{1,2}

The prevalence of incontinent associated dermatitis (IAD) in the acute care setting can be high when associated with FI. In a recent study of patients in the acute care setting (n=5,342), the authors found that 46.6% of these patients were incontinent of urine, stool, or both. It was determined that the overall prevalence of IAD in this study was 21.3% and with those who were incontinent it was 45.7%.³

An external fecal management system (FMS) helps to provide containment and diversion of feces that are usually of liquid or semi-liquid consistency. This system intends to keep the skin clean and dry, and free from contaminants and moisture that can contribute to IAD.

OBJECTIVE

The purpose of this observational pilot study was to determine if a new external FMS* (Figure 1) adhered to the patient's skin for at least 24 hours and to seek the healthcare professional's (HCP's) perception of the FMS utility.

METHODS

- Thirty (30) patients were recruited from the Cardiothoracic Intensive Care Unit (ICU) at a large academic hospital.
 - Inclusion criteria: > 18 years of age with FI and require an external FMS.
 - Exclusion criteria: Known allergy to the material of the FMS; impairments/injuries or anatomical abnormalities that might interfere with adherence of the FMS; skin breakdown or wounds around the perianal area; ambulatory patients.
- Once consent was obtained, the external FMS was placed on the perianal skin of the patient by a member of the research team.
- Assessment for containment and leakage of feces or fecal matter was conducted within two hours after placement of the FMS and subsequently every two hours (\pm 15 minutes) thereafter, per the standard of care (SOC), for a 24-hour period and beyond (until 360 hours) or it fell off (spontaneous detachment) or was removed.
- Feedback from the bedside clinician on the usability of this FMS was obtained by completing questionnaires within two hours after placement of the FMS and then at every assessment thereafter.
- Once the FMS fell off or was removed, a skin assessment was performed to evaluate any adverse events along with obtaining the reason for the removal of the FMS.

Figure 1. External Fecal Management System (FMS).



RESULTS

- Patient demographics.
 - Mean age = 59.0 years (Range 18-81)
 - Male = 60%
 - Race = 80% White and 20% African American
- At the time of application there was one report of each of the following in the perianal area: erythema, redness, hypopigmented skin intact, and some redness.
- 93% (n=28) patients were cleaned with a non-residue soap and 27% (n=8) patients were shaved prior to application of the FMS.
- No association was found between prior shaving, and either number of hours attached or being attached for 24 hours or more.

Adherence of the FMS to the patient's skin (Figure 2)

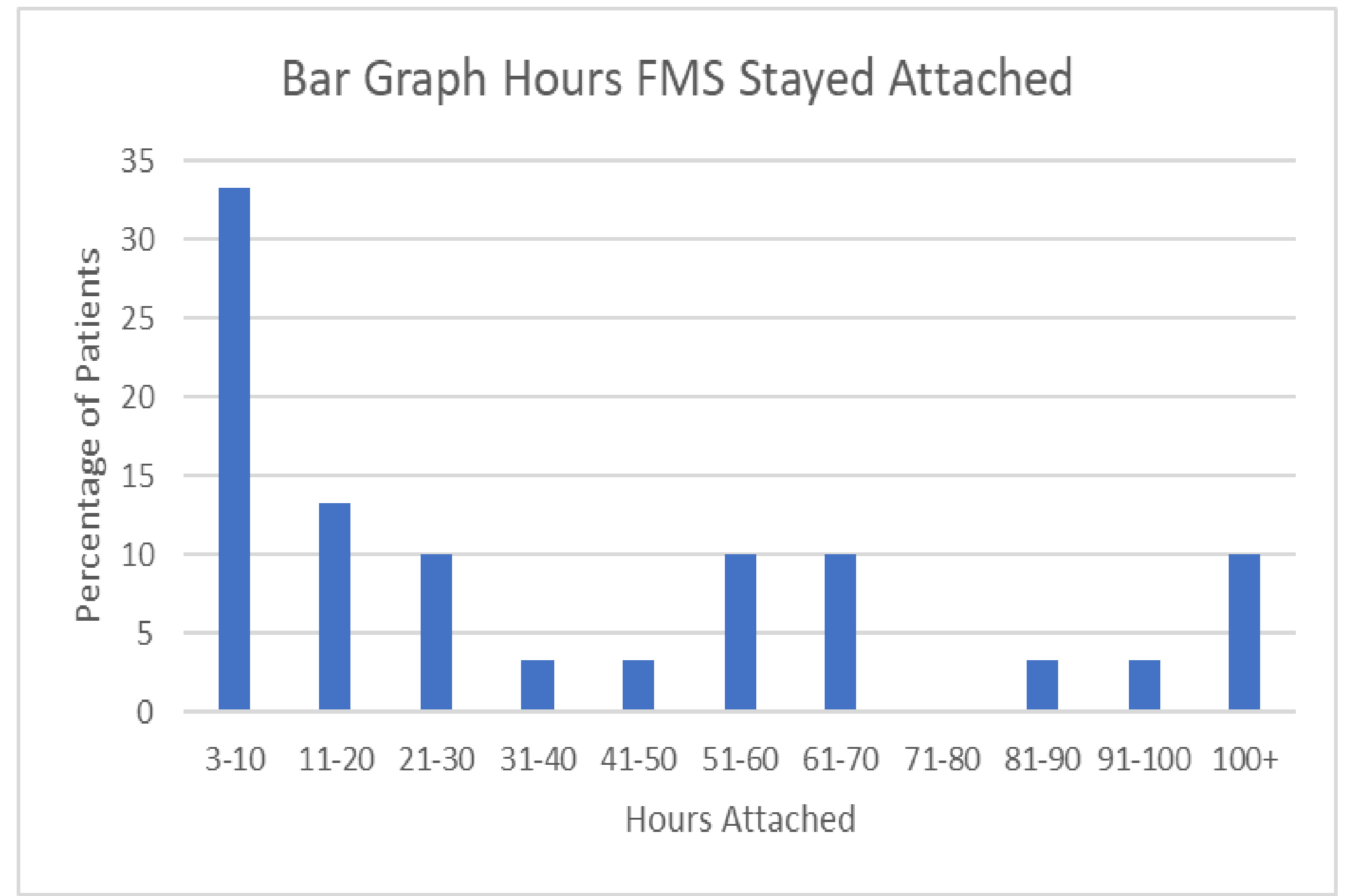
- FMS stayed attached for at least 24 hours in 53.3% of the patients (n=16), compared to 46.7% (n=14) for whom it did not stay attached for 24 hours
- The FMS stayed attached for an average of 42.4 hours (SD=44.7) (Range 3-179 hours).
 - It was removed by the study personnel 30% of the time (n=9). All nine patients had leakage listed as the reason for detachment. However, six of the nine had been in place for over 24 hours.
 - It stayed attached 70% of the time (n=21) until it spontaneously fell off.

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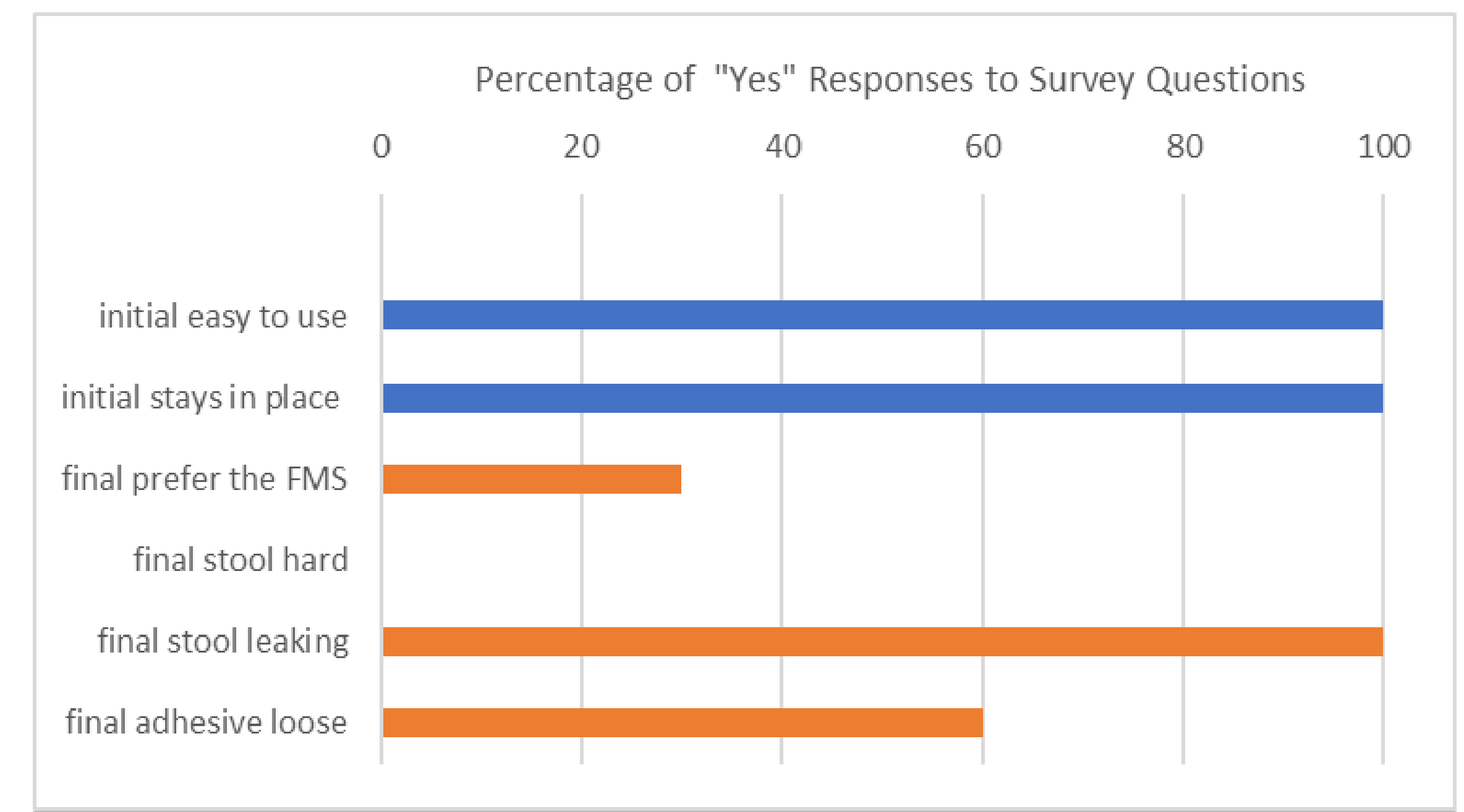
Figure 2. Bar graph showing hours the FMS stayed attached (n=30).



HCP's perception of the FMS utility (Figure 3)

- During the application of the FMS, all respondents reported that the FMS was easy to use (100%) and stayed in place (100%).
 - On the expanded scale of ease of use 53.3% reported 1 (very easy), 43.3% reported 2 (easy), and 3.3% reported a 4 (hard).
 - At the final detachment survey 30% of respondents said they preferred the FMS, 60% reported the adhesive was loose, and 100% reported stool leaking at removal.

Figure 3. Percentage of responses to the survey questions asked at the initial placement of the FMS and at the time the FMS either fell or was removed from the patient.



Note: Blue bars are from initial HCP survey and orange bars are from HCP final detachment survey.

Adverse device events (ADEs)

- 4 minor skin tears in four patients were noted during the removal of the product. (Figure 4).
- The casualty was reported as probable and likely due to insufficient adhesive remover application.

Figure 4. Representative image of a minor skin tear in the patient



CONCLUSIONS

- The FMS could provide secure containment of fecal matter at staying adhered to patients' skin for 24 hours or more.
- This FMS was favorably perceived by the HCPs providing bedside care in the ICU.
- Additional education around adhesive remover use prior to FMS removal may help prevent skin tears.

References:
 1) Fecal Incontinence. Mayo Clinic. <https://www.mayoclinic.org/diseases-conditions/fecal-incontinence/symptoms-causes/syc-20351397>
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 3. Gray, M., & Giuliano, K. (2018). Incontinence-associated dermatitis, characteristics and relationship to pressure injury. *J Wound Ostomy Continence Nurs.* 45(1), 63-67.

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