Utility, Safety and Effectiveness of a Novel Enteral Feeding System: A Prospective Cohort Study

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BACKGROUND

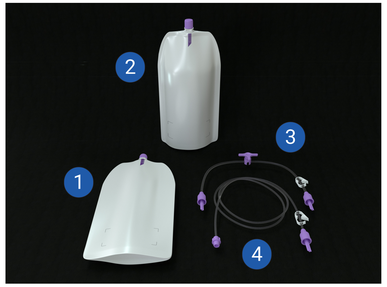
Patients on home enteral nutrition (HEN), many of whom are mobile[1], can experience significant hardships and reduced quality of life (QoL) due to limitations of mobility, on top of burdens due to underlying disease processes.[2] Improving mobility while feeding could reduce burdens associated with HEN and potentially improve QoL.

NOVEL ENTERAL FEEDING SYSTEM

A novel lightweight portable enteral feeding system (EFS) designed to allow for enhanced mobility and ease of use, compared to current infusion pumps.

View the EFS instructional videos by scanning the QR code.

1. Feeding pouch; the reservoir for feed
2. Feeding pouch; filled with 500ml (16.9oz) of feed
3. Filling-set tubing: used to fill pouch
4. Giving-set ('feeding-set') tubing: delivers feed to feeding tube



The System is intended for patients aged 2 years and older. It works mechanically without need for gravity or electricity. It is wearable, for single-patient use over a 24-hour period in home or clinical settings, and is disposable.

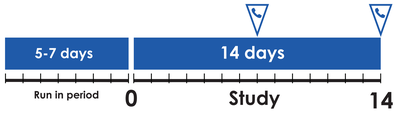
OBJECTIVE

This prospective cohort study aims to evaluate participants' perspectives on their mobility, ease of performing physical activities while feeding, and QoL following the use of a novel enteral feeding system (EFS).

METHODS

A prospective single-center study was conducted to evaluate a novel EFS, which is an FDA-cleared elastomeric system (Mobility+™) that consists of a lightweight feeding pouch (reservoir for 500mL feed), a filling set (used in conjunction with a syringe to fill EFS) and a feeding set to deliver EN formula to an extension set/feeding tube with an ISO 80369-3 compatible connector.

Adult HEN-dependent patients were recruited by invitation to use the study EFS for a minimum of 2 feeds a day for 14 days, preceded by a familiarization period of 5-7 days.



Participant perspectives on how they rated performing typical daily activities while feeding (e.g., moving, traveling, socializing) and feeding system parameters (ease of use, portability, noise, discretion, performance) were evaluated using HEN-expert validated questionnaires. A score was given for each rating from 1 to 5, with 5 being the most positive response. An overall score was calculated and averaged for the cohort.

Participants were followed up during the familiarization period. On days 7 and 14, additional telephone interviews were conducted regarding compliance, enteral feed intake, participant perspectives on study EFS vs. current system, and other measures. We excluded those with reduced functional capacity due to their underlying disease(s).

RESULTS

Seventeen participants completed the study (mean age 63.8 ± 12 years; 70.6% male). Participants were Adult HEN-dependent patients. Participants used various feeding systems, including gravity, bolus method, and pump, with the majority (82.4%) having a G-tube placed (Table 1).

Table 1. Baseline Demographics and Clinical Characteristics (n=17)

Variable	Units	n (%) / Mean ± SD
Gender		
Male		12 (70.5)
Female		5 (29.5)
Diagnosis		
Malignancy related		13 (76.5)
Dysmotility		2 (11.7)
Bariatric surgery-related		1 (5.9)
Functional Disorder		1 (5.9)
Type of EN tube		
G tube		14 (82.4)
J Tube		3 (17.6)
The feeding system used before the study		
Gravity (+/- Syringe/bolus)		10 (58.8)
Pump		4 (23.6)
Syringe/bolus		3 (17.6)
Working or studying		8 (47.1)
Variable	**Units**	**Mean ± SD**
BMI at enrolment	kg/m^2	23.3 ± 3.4
Age at enrolment	years	63.8 ± 12
HEN Regimen before the study		
EN formula volume consumed	mL/d	1174 ± 353
EN daily calories	kcal/d	1907 ± 553
Number of feeds a day		2.9 ± 1.1

Table 2. Compliance (n=17)

Variable	Units	Mean ± SD
HEN Regimen while on the study		
EN formula volume consumed using EFS	mL/d	1050 ± 363
EN formula volume consumed using other system(s)	mL/d	256 ± 294
EN daily calories using study EFS	kcal/d	1657 ± 555
Average EN volume per feed using study EFS	kcal/d	466 ± 107
Number of feeds a day		2.4 ± 0.8

Sixteen (94.1%) patients achieved use of study EFS for at least two feeds a day (and majority of daily EN calories) for all study days. There were no adverse events.

An improvement in ratings was noted for the ease of performing common daily activities, including moving between rooms or on stairs, taking short and long walks, traveling by car or public transport, engaging in moderate- to high-intensity activities, sleeping, and socializing with family and friends, between the time point before enrolment and end of study (day 14) (p-value< 0.0001).

Ratings of feeding system parameters were significantly different between systems used before the study and the study EFS (p< 0.0001), with the largest increases in positive ratings noted in relation to ease of carrying, noise level, and ability to feed discreetly.

Ratings for overall satisfaction with the performance of study EFS did not differ from the ratings for the systems used before the study, with participants reporting that the main influencing factors were the length of time and the effort needed to fill study EFS. No difference was noted in the QoL rating.

CONCLUSIONS

The studied EFS is safe and effective as an enteral feeding modality that provides an alternative option for HEN recipients. Participants reported a significant positive impact of study EFS on their activities of daily living.

Although the overall QoL rating remained the same, improvements of mobility, discretion, and ease of carrying— aspects of QoL—were associated with the use of study EFS.

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