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Comparison of Syringe Compression Force between ENFit and Legacy Feeding Tubes

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Abstract

Background—Since initial report in 1972, misconnections continue to be an issue especially in hospitalized patients with multiple access devices. A new small-bore connector standard (ENFit) has been proposed in order to minimize misconnections.

Methods—Commercially available finalized ENFit tubes of a variety of sizes (14Fr, 18Fr, 20Fr, 24Fr, and low-profile) were obtained for current testing. Variety of commercially available formulas including blenderized tube feeding (BTF) products (Jevity 1Cal, Nourish, and Real Food Blends, Mayo Clinic BTF recipe) were tested.

Results—Data from individual measurements were aggregated for ENFit and legacy tubes and revealed higher syringe compression force in legacy tubes compared to ENFit tubes for 20Fr size with Jevity formula. Our institution's BTF formula revealed that legacy tubes had lower syringe compression force than ENFit tubes for 14 Fr tube size. Remaining measurements revealed no significant difference. Model 1 of regression analysis revealed that only formula and tube size were significant with R^2 of 0.63. Model 2 evaluating the impact of tube size, blender, time of blending, and legacy versus ENFit revealed that tube size, blender used, and blending time were significant with legacy versus ENFit being non-significant (R^2 of 0.72).

Conclusion—Overall, only a small number of tube sizes (14 Fr and 20 Fr) with selected formulas revealed a significant difference between ENFit and Legacy tubes with remaining studies finding no significant difference. Regression analysis revealed that variables such as formula, size of tube, blender used, and time of blending may have more impact on compression force.

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Introduction

In 1972, Wallace et al reported one of the earliest cases of misconnection when a patient inadvertently received 100 ml of cow's milk intravenously instead of enterally, leading to the development of disseminated intravascular coagulation, fat embolism and significant hypersensitivity reaction¹. Since then, over 116 cases of misconnections have been reported showing significant morbidity and 21 deaths². Unfortunately, the number of misconnections may be much higher since most are not reported in peer review journals. Additionally, it is also not well known if most misconnections occur in a hospital setting or whether they are prevalent in the Home Enteral Nutrition population as well (HEN). This has led to multiple safety reports by organizations such as Joint Commission with the presence of universally compatible Luer lock connection being a common element contributing to misconnections²⁻⁵. State legislature has also raised awareness of the issue and the state of California has passed a law (HB 1867) mandating that enteral nutrition (EN) supplies only fit a connection port for which they were intended.

In an effort to address the issue of misconnections, major manufacturers and suppliers of EN have formed the Global Enteral Device Supplier Association (GEDSA). International Organization of Standards (ISO) standards for all major catheters have been developed with EN tubes falling under the small bore connector ISO 80369-3 standard⁴. GEDSA associated manufacturers have introduced ENFit tubes as ISO 80369-3 compatible small-bore connectors. Starting in 2015, with the availability of bags and tubing, a transition to ENFit was initiated with plan to subsequently introduce syringes and tubes. However, despite their availability, not all hospitals and medical centers have transitioned to ENFit, with some major manufacturers leaving GEDSA as well. Issues regarding medication delivery and dosing with ENFit syringes as well as flow rate with ENFit tubes have also been identified^{4,6-9}. Additionally, questions have also been raised about the ENFit design being able to meet the needs of the HEN population, who are more likely to provide blenderized tube feeding (BTF), gravity or syringe feeding, or to use the ENFit tubes for venting^{4,7}.

In order to assess the impact of ENFit transition in patients currently engaged in syringe feedings and BTF, we collaborated with the Food and Drug Administration (FDA) to develop a trial evaluating the performance parameters of commercially available ENFit tubes compared to the currently available legacy tubes. Primary aim of the study was to assess whether transition of ENFit tubes resulted in increased force required to provide syringe feedings with formulas of varying viscosity including BTF. Based on flow dynamic physiology as well as data from our previous trials assessing flow rate and force measurements of ENFit versus legacy tubes, we hypothesized that force would be higher in the 14 French (Fr) and 24 Fr sizes with ENFit tubes^{6,7,9}. The null hypothesis was that there would be no difference between the legacy and ENFit tubes.

Methods

As opposed to our previous force trial which utilized ENFit prototype tubes, major manufactures were able to supply commercially available finalized ENFit tubes of a variety of sizes (14Fr, 18Fr, 20Fr, and 24Fr) for current testing⁷. One manufacturer also provided

low-profile tubes (LP) as well. The brand/manufacture of the tube was removed, when possible, prior to shipment in order to maintain blinding of study staff. We also selected a variety of commercially available formulas including BTF products with range of viscosity (Jevity 1Cal, Nourish, and Real Food Blends).

Additionally, our own institution's BTF recipe was utilized for testing (supplement 1). This recipe was prepared using three commercially available blenders of varying cost (Oster, Ninja, and Vitamix) in order to assess the impact of blender on syringe compression force. The recipe was blended for 3 minutes and 6 minutes with each blender and subsequently tested to evaluate if blending for a greater time period impacted syringe compression force.

Similar to our previous design, force data was gathered with a dynamic mechanical analyzer (RSA G2 Solids Analyzer; TA Instruments, New Castle, DE). This machine had a maximum compression force reading capability of 36 Newtons (N). With each measurement, 30 ml of formula was placed in 60 ml syringe and the syringe was connected to ENFit or legacy tube being tested, replicating the provision of formula or BTF through syringe feeding. The syringe was subsequently compressed over 30 seconds or at a rate of 1 ml of formula per second. This rate was chosen as we typically recommend providing one syringe (60 ml of formula) over 1 minute. With the same formula and tube size, each measurement was repeated 3 times. With each repeat measurement, a new syringe was filled with new formula. The tube however was rinsed with water and reused to simulate patient experience of flushing in between feeds. All three measurements were then averaged. The same three measurements were performed with our institution's BTF recipe for each blender at 3 and 6 minutes of blending per tube size.

Syringe force compression measurements of all of the legacy tubes were combined for each respective formula and tube size and compared to syringe force compression measurement of all of the ENFit tubes for each respective formula and tube size. These data are presented as mean $\pm$ standard deviation and were analyzed using 2 sample t-test. Subsequently, in order to assess whether other variables played a role in syringe compression force, fit model regression analysis was performed using two different approaches. The first approach included formula, tube size, and legacy versus ENFit as the variables allowing us to evaluate all recipes. The second analysis only used our institution's recipe allowing for evaluation of the impact of tube size, blender used, time of blending, and legacy versus ENFit tubes. The average of 3 runs for each tube and formula were included in fit model regression analysis while values that reached the maximum force reading were excluded. The statistical analyses were performed using JMP®, Version 10 (SAS Institute Inc, Cary, NC, 1989-2007).

Results

Testing was initially performed with Nourish. At the time of this testing, 4 legacy tubes (L1-L4) and 2 ENFit tubes (E1 and E2) were available for testing for 14 Fr, 18Fr, 20 Fr, 24Fr sizes (Figure 1a). Additionally, one legacy (L6) and one ENFit (E4) 14 Fr low profile tube was available. Both right angle and straight adapters were tested with low profile tube (Figure 1a). Subsequent to this initial round, an additional legacy and ENFit tube was available for testing in limited quantities. Therefore, with Jevity and Real Food Blends, 5

legacy tubes (L1-L5) and 3 ENFit tubes (E1-E3) were available for testing for the 14Fr, 20Fr and 24Fr sizes (Figure 1b and 1c respectively). Only 4 legacy tubes (L1-L4) and 2 ENFit tubes (E1-E2) were available for 18Fr size. Additionally, one legacy 14Fr low profile tube (L6) and one ENFit 14Fr low profile tube (E4) was evaluated with the straight adapter connection. The right-angle adapter was not used in order to decrease the number of tests performed and due to the fact that our patients reported more predominant use of straight extension with syringe feedings. Individual tube and formula syringe compression readings are noted in Figure 1 with Real Food Blends syringe compression force exceeding 36 N with all 14Fr tubes and L1 18Fr and L2 18Fr tubes (Figure 1c). We noted that 18 out of 184 legacy tubes (9.8%) and 18 out of the 112 ENFit tubes (16.1%) reached maximum force (exceeding 36 N).

Our institution's BTF recipe was prepared using three different blenders (B1-B3) at two time points of blending (3 minutes and 6 minutes). Five legacy tubes (L1-L5) and 3 ENFit tubes (E1-E3) were available for testing for the 14Fr (Figure 2a and 2b), 20Fr (Figure 2e and 2f) and 24Fr sizes (Figure 2g and 2h). Only 4 legacy tubes (L1-L4) and 2 ENFit tubes (E1-E2) were available for 18Fr size (Figure 2c and 2d). Max compression force was reached with measurements in the 14Fr and 18Fr sizes but not in the 20Fr or 24 Fr sizes (Figure 2i and 2j).

The primary aim was assessed by combining Legacy tubes for each respective tube size and formula and comparing ENFit tubes combined in similar manner (Table 1). Data from tubes that reached maximum compression force were not included. With analysis in this manner, statistical significant was reached with 20Fr tubes using Jevity as the formula. In this case, legacy tubes had a significantly higher syringe compression force compared to ENFit tubes (11.6 ± 1.8 N versus 8.2 ± 0.6 N, p-value of 0.03). Additionally, our institute's BTF recipe revealed that legacy tubes had a significantly lower syringe compression force for the 14Fr tube size compared to ENFit tubes (24.0 ± 2.6 N versus 27.2 ± 2.6 N, p-value of 0.01).

Model 1 of the fit model analysis evaluating the impact of formula, tube size, and legacy versus ENFit revealed that only formula and tube size were significant with R^2 of 0.63 (Table 2a). Model 2 evaluating the impact of tube size, blender, time of blending (3 minutes versus 6 minutes), and legacy versus ENFit revealed that tube size, blender used, and blending time were significant with legacy versus ENFit being non-significant (R^2 of 0.72; Table 2b).

Discussion

In order to assess the impact of the transition to ENFit for patients who provide EN through syringe feedings or utilize BTF, we partnered with major EN supply manufacturers, GEDSA, FDA, and patient advocacy groups such as OLEY Foundation and Feeding Tube Awareness Foundation to design and carry out an assessment of syringe compression force with current legacy tubes compared to commercially available ENFit tubes. This is important because patients who deliver EN through bolus feeding or utilize BTF (which is delivered using syringes) may experience difficulties delivering nutrition if the force needed is increased in ENFit versus legacy tubes. Overall, combined data for legacy tubes and

ENFit tubes for each respective formula and tube size, revealed that there was not significant difference in force required to compress the syringe. Only two points were statistically significant with the 20Fr legacy tubes showing higher syringe compression force compared to ENFit with Jevity and the 14Fr tube showing higher compression with ENFit tubes with our Institution's BTF formula. In addition to this primary aim of comparing legacy versus ENFit, we also studied the impact of additional variables such as formula, type of blender used, time of blending, and tube size on the syringe compression force. Using a Fit Model regression analysis, we noted that with each model, after other variables were added, legacy versus ENFit was no longer significant.

Our previous research had focused on assessing the impact of ENFit transition on patients who provide EN through gravity flow^{8,9}. Those studies had revealed that for certain tubes in the 14Fr and 24Fr size, there was going to be a prolongation of feeding times with the transition to ENFit. Given the findings of recent surveys highlighting the increased prevalence of both HEN and BTF use within the HEN population, we felt that syringe feedings and BTF use needed to be evaluated as well^{6,10-12}. An initial survey of our patient population noted that more than 50% used BTF for a median of 4 days per week and 80% expressed a desire to use BTF if provided more information⁶. A subsequent survey of Oley foundation members noted an even higher prevalence with approximately 90% of the pediatric patients reporting BTF use for an average of 71% of their intake and 66% of adults reported BTF use for an average of 56% of their intake¹⁰. A pediatric specific survey of 433 parents of tube fed children demonstrated that 49.5% had responded that they used BTF. Other groups have also shown similar high rates of BTF use¹¹.

With the overall prevalence of HEN in the United States shown to have increased substantially from 150,000 in 1992 to 437,882 in 2013, a significant number of patients are engaged in the use of BTF and need to be supported through the ENFit transition¹². In addition, to our findings in our gravity flow study⁹, our previous work with an ENFit prototype revealed increased syringe compression force with ENFit tubes compared to legacy tubes for all formulas tested except for Jevity. Fortunately, our current study did not find that ENFit tubes themselves led to a significant increase in syringe compression force compared to legacy tubes in aggregate. In our current study, we utilized multiple finalized ENFit tubes as opposed to a single prototype, which could help explain some of the differences. Additionally, we were able to test a number of additional variables with the introduction of our institution's BTF recipe including type of blender and time of blending. From fit model regression analysis, it appears that variables such as the formula, type of blender, the amount of time the food is blended, and the tube size used seem to be more significant in predicting syringe compression force than the legacy tubes versus ENFit tubes in aggregate.

These findings do need to be stated in the setting of a number of limitations however. The first being that the study was performed in a lab setting and not with the tubes inserted in patients. Certainly, force dynamics can change with the tip of the tube being in the stomach as opposed to being open in a laboratory. However, it can be postulated that both ENFit and legacy tubes will experience similar changes in force dynamics after they are inserted into the patient. What is difficult to determine however, is whether statistically significant

findings in the laboratory setting are also clinically significant since data regarding the maximum force generated by the hand to compress the syringe is quite variable and dependent upon disease state^{13,14}. Patients who are severely malnourished or debilitated can have lower hand grip strength making the impact of small increases in compression force more clinically relevant. However, in those who are not suffering from sarcopenia or malnutrition, a small change such as that noted in this study will be insignificant. Due to this, the absolute force numbers should not be used to make clinical determinations but instead to simply assess the impact of transitioning to ENFit, since both sets of tubes were studied under identical conditions. A prospective randomized clinical trial in patients with varying states of malnutrition and hand grip strength would be required to make these determinations. Additionally, the maximum force our equipment could measure was 36 Newtons. This could also have affected the overall results. We noted that out of 184 legacy tubes that were tested, 18 reached maximum force (9.8%). On the other hand, 18 out of the 112 ENFit tubes that were tested reached maximum force (16.1%). Our campus did not have the equipment to measure forces greater than 36 Newtons and purchasing such equipment was prohibitively costly.

The fit model regression analysis also revealed the significant impact of additional variables. Our group was only able to study a fraction of these variables due to the exponential increase in testing required with the addition of each variable. As an example, we selected three blenders of varying cost after some preliminary studies. However, this selection only covers a small fraction of the blenders available in the market and used by patients to prepare BTF. We also noted that time of blending affected syringe compression force. We were able to control the time of blending in the lab, however in practice patients may be using variable times of blending, which could affect ability to provide BTF. Choice of formula, especially the viscosity, also plays a large role in the force required to compress syringe. Thinner formulas tend to proceed with less force compared to thicker formulas. This was evident when comparing Jevity to Nourish or Real Food Blends. Again, only a select number of formulas that we felt were a good sampling of varying viscosities were tested. In clinical practice, a greater variety of formulas are in use especially if we account for homemade recipes.

Tube size also presents as an important variable with many of the smaller sized tubes showing higher syringe compression force. We did evaluate a wide breadth of tube sizes but were limited by manufacturer availability since all tubes were donated for study. Due to this, certain formulas such as Nourish had lower number of tubes tested. We felt that this was still valid as our aggregate data analysis was performed within each formula type and tube size. Manufacturer biases were minimized as the tubes were received in a de-identified manner. Additionally, our laboratory staff measuring syringe compression force did not have sufficient experience in the HEN practice to be able to identify manufacturer of tubes visually. We also took the additional step of having the individuals who analyzed the data do so in a blinding manner.

Conclusions

In an effort to decrease complications associated with misconnections, the HEN community is in the process of transitioning to ENFit (ISO 80369-3). Our group in collaboration with the FDA has previously assessed the impact of this transition in patients providing EN through gravity flow^{8,9}. Those studies revealed that the majority of our HEN patients who use commercial formula utilizing gravity feeding may note that the overall time it takes to infuse daily nutrition will be increased with ENFit versus legacy tubes. With evidence indicating high prevalence of BTF in the HEN community, current testing took place to assess the impact of transitioning to ENFit for patients who provide either formula or BTF through syringe feedings. Our current study was designed to assess the overall impact of transition to ENFit from legacy tubes and thus data from ENFit tubes from different manufacturers were combined and compared to aggregate data from legacy tubes. Only two tube sizes showed any statistically significant difference between ENFit tubes compared to legacy tubes and regression analysis revealed that perhaps other variables such as formula viscosity, size of tube, type of blender used, and time of blending may be more important variables in determining syringe compression force. The force and time required to infuse daily EN in those who syringe feed either commercial formula or BTF will likely not be impacted by the transition to ENFit outside of 14 French tubes for BTF. Clinicians may opt to use syringe feedings in HEN patients who are negatively impacted by the longer infusion times of gravity feeding. Neither force or flow is likely to be a problem with patients who have EN delivered using an infusion pump. Additional studies would allow for further evaluations of these variables including hand grip strength and assess the true impact of ENFit transition to the HEN practice.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Clinical Relevancy

With the increase in use of enteral nutrition (EN), it is imperative to minimize complications including those that arise from misconnections between EN supplies and other access devices. A new standard small-bore tube has been finalized (International Organization for Standards 80369-3), which is designed so that EN supplies only connect to EN tubes. Despite this new standard being introduced, it is not well known if ENFit tubes will be able to meet all of the needs of home EN patients who typically provide EN through syringe or gravity feedings as opposed to using a pump. The present study was carried out to assess if additional compression force would be required to provide syringe feedings with commercially available formula and blenderized tube feeding.

Figure 1.

Denotes the averaged syringe compression measurements with 14Fr, 18Fr, 20Fr, 24Fr, and 14Fr Low profile legacy and ENFit tubes with Nourish (a), Jevity (b), and Real Food Blends (c).

Figure 2.

Denotes the averaged syringe compression measurements with our institution's BTF recipe with 14Fr blended for 3 mins (a) and 6 mins (b), 18Fr blended for 3 mins (c) and 6 mins (d), 20Fr blended for 3 mins (e) and 6 mins (f), 24Fr blended for 3 mins (g) and 6 mins (h), and low-profile blended for 3 mins (i) and 6 mins (j).

Table 1

Aggregate force values for each formula and tube size tested.

Formula and Tube type	Legacy tubes (N)	ENFit tubes (N)	p-value
Jevity			
-14Fr	16.1 ± 2.7	15.2 ± 2.8	0.65
-18Fr	13.6 ± 2.9	10.0 ± 0.6	0.17
-20Fr	11.6 ± 1.8	8.2 ± 0.6	0.03
-24Fr	9.9 ± 1.9	7.4 ± 0.8	0.10
-LP	14.1 ± 1.7	7.6 ± 0.9	0.32
Nourish			
-14Fr	16.7 ± 4.0	18.6 ± 1.0	0.35
-18Fr	16.3 ± 3.0	16.5 ± 1.8	1.00
-20Fr	15.6 ± 2.6	15.6 ± 0.5	1.00
-24Fr	15.0 ± 4.3	15.6 ± 0.2	0.64
-LP	16.1 ± 1.4	17.3 ± 1.4	0.44
Real Food Blends			
-14Fr	Max Compression	Max Compression	
-18Fr	27.9 ± 1.3	28.6 ± 0.5	0.44
-20Fr	25.5 ± 3.3	20.8 ± 4.4	0.18
-24Fr	19.0 ± 3.1	16.8 ± 3.3	0.18
-LP	28.4 ± 1.5	24.2 ± 1.0	0.32
Mayo Recipe			
-14Fr	24.0 ± 2.6	27.2 ± 2.6	0.01
-18Fr	20.7 ± 4.4	21.4 ± 3.3	0.76
-20Fr	16.8 ± 4.1	15.2 ± 3.2	0.17
-24Fr	12.7 ± 3.2	12.4 ± 2.6	0.88
-LP	17.4 ± 3.9	15.6 ± 2.3	0.27

FR – French size

Table 2

a: Fit Model 1 assessing recipe, tube size, and legacy versus ENFit.			
Source	Sum of Squares	F Ratio	Prob > F
Recipe	2303.99	64.17	<0.0001
Tube Size	3059.77	63.92	<0.0001
Legacy versus ENFit	32.11	2.68	0.10

b: Fit Model 2 assessing tube size, blender used, blending time, and legacy versus ENFit.			
Source	Sum of Squares	F Ratio	Prob > F
Tube Size	3008.37	84.35	<0.0001
Blender	97.17	5.45	0.0052
Blending time (3 versus 6 minutes)	442.75	49.66	<0.0001
Legacy versus ENFit	4.99	0.56	0.455