The Oley Foundation
Help along the way

SEPTEMBER/OCTOBER
2019

LifelineLetter

Living with home parenteral and/or enteral nutrition (HPEN)

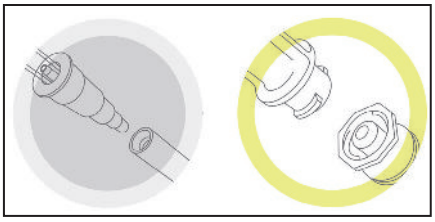
What's Inside:

FDA Research on ENFit-Based Feeding Tubes

Suvajyoti Guha, Joshua Silverstein, Mark Antonino
Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA)

Q1. Why did FDA conduct a study about enteral feeding tubes?

Response: Many types of medical devices share a common component, the small-bore connector. This connector provides a mechanism for the connection between a variety of medical devices. It is particularly common in hospital settings. However, the wide usage of luer small-bore connectors has led to serious injuries and deaths.



"Funnel-type" connector and ENFit connector.

To prevent misconnections from repeatedly happening—where something meant to be connected to one type of medical device is mistakenly connected to another type of medical device, for example, a feeding tube extension set connected to an IV line—the medical device community is standardizing several small-bore connector designs under ISO 80369. ISO 80369-3 covers enteral connectors. FDA recognized this standard in 2016. Medical device manufacturers started to make enteral devices such as feeding tubes with connectors that conform with ISO 80369-3 around the same time. A popular design that follows this standard is known as ENFit®.

When this new design was shown to patients, several of them expressed concern that the new ENFit connector design has a smaller internal diameter as compared to the funnel-type connector on existing larger bore feeding tubes (such as 20, 22, 24 French [Fr] sizes). The patients were concerned that the new connectors may interfere with a patient's ability to feed themselves home-prepared blenderized diets. FDA conducted a literature survey

FDA Research, cont. pg. 10 ☛

Update on IV Selenium

Penny Allen, RD, LDN, CNSC, National Director, Nutrition Support, BriovaRx Infusion Services

In July 2019, American Regent released a newly formulated and the first FDA-approved intravenous selenium product, Selenious Acid Injection, USP for Parenteral Nutrition. The previous, non-FDA-approved formulation of intravenous selenium is no longer being manufactured, although most companies may still have a good amount of supply remaining; they will use that up in the coming months.

Here are some of the product differences:

- The new strength, 600 mcg/10 mL (60 mcg/mL), may allow for easier delivery of the American Society for Parenteral and Enteral Nutrition (ASPEN) recommendations for trace element supplementation;
- New concentration allows for delivery of a smaller volume of product vs. the previously available non-FDA-approved Selenium Injection (40 mcg/mL);
- Price of the new product is considerably higher; depending on your hospital or home infusion provider, the new product could be as much as twenty times the price of the former selenium product;
- New product is preservative free;

Selenium, cont. pg. 6 ☛

Al hiked 272 miles through Vermont on tube feeding.

Al Mackay's Courageous Journey

By Debbie Gilbert Taylor

Sixty-one-year-old Al Mackay does not let tube feeding interrupt his life. Of course, he has many things to consider when stepping outside his home, but he has developed a rhythm to allow him to live life fully.

This summer, he hiked the Long Trail through Vermont, the first half of which is on the Appalachian Trail. Friends and family accompanied him for a day or a few during his hike. His plan was to spend about

Al Mackay's Journey, cont. pg. 4 ☛

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The ***LifelineLetter*** is a bi-monthly newsletter sent free of charge to those on home parenteral or enteral nutrition. There is no charge for others as well if they receive the newsletter electronically. **Items published are provided as an open forum for the homePEN community and should not imply endorsement by the Oley Foundation. All items/ads/suggestions should be discussed with your health care provider prior to actual use. Correspondence can be sent to the Editor at the address above.**

Our Mission

...is to enrich the lives of those living with home intravenous nutrition and tube feeding through education, advocacy, and networking.

The Oley Foundation provides its 21,000+ members with critical information on topics such as medical advances, research, and health insurance. The Foundation is also a source of support, helping consumers on home IV nutrition and tube feeding overcome challenges, such as their inability to eat and altered body image. All Oley programs are offered **FREE of CHARGE** to consumers and their families.

Oley Foundation Programs

- *LifelineLetter*
- Peer to Peer Support
- Conferences and Webinars
- Resources to Promote Living Well on Tube Feeding and IV Nutrition
- Equipment Supply Exchange
- Advocacy and Awareness

Resource Spotlight: *How to Prepare for an Emergency*

In light of potential medical supply issues, we urge you to take the following steps to prepare for future storms, fires, and other emergencies—even if you don't expect to be in the direct path of harm's way.

- Ensure that you have sufficient backup power available or batteries to power any necessary pumps or medical devices, as well as battery-powered radios and appropriately charged cell phones to receive the latest communications.
- Listen to governmental officials advising of precautions and evacuations.
- Check with home care suppliers and medical providers ahead of time to ensure that you have enough medications and nutritional supplies (formula, HPN, etc.) to last at least 48–72 hours, in case of supply chain delays.
- Write down important telephone numbers in case you cannot access the directory on your mobile phone. This includes, but is not limited to, your home care company branch, regional, and national offices.
- Check the National Hurricane Center or applicable government agency for the latest information on the storm/fire/emergency.

Go to www.oley.org/emergencyprepared for a complete list of articles and online resources.

How to Support Oley

Donations are tax deductible and are accepted at www.oley.org/donations or at the street address on left.

Tube Talk

Send your tips, questions, and thoughts about tube feeding (enteral nutrition) to metzgel@amc.edu. Information shared in this column represents the experience of the individual and, while medical information is reviewed by an advisor, should not imply endorsement by Oley. The Foundation strongly encourages readers to discuss any suggestions with their clinician before making any changes in their care.

Review of FreeArm Flexible Tube Feeding Stand

We have tried out the FreeArm. It is very similar to the cell phone holder that we use* with the exception that it can handle the pump, which was an AMAZING feature that we looked forward to trying out. We liked how the FreeArm could be clamped on to just about anything and it could handle holding the syringe for our son's gravity feeds. However, we were really disappointed that it could not hold the bag he used for his pump feed.

My son has a 500 mL bag and the weight of it was too much for the end that holds up the bag. The pump itself fit nicely above the clamp and I was so excited to possibly be able to ditch the big IV pole/stand in my child's room. But the weight was just too much and it caused the arm to fall over.

I had read up on the device and saw some other reviews where people said the same thing, and that the company was actually coming out with a stronger model. We will have to keep a look out. Anything that will help free up our floor space and is portable is definitely going on the Christmas list!

Photo courtesy of FreeArm

When bent into a shape like one shown here, the company says the FreeArm can hold a pump and a 500 mL bag.

—Staci P.

*See "Tube Talk," *LifelineLetter*, May/June 2019 (www.tinyurl.com/MJ2019LifelineLetter).

FreeArm Company Responds

Thank you very much Staci for your honest review. We are so happy that the FreeArm Tube Feeding Assistant is helping with your son's gravity syringe feeds. We want it to work great for his pump feeds as well! I am happy to help you and anyone who may be having trouble with their FreeArm troubleshoot. Please reach out through email at info@freearmcare.com. I would love to see how your FreeArm is set up and offer suggestions.

When using your FreeArm for pump feeding, please bend it into a question mark shape so the bag hangs directly over the clamp. This balances the center of gravity to easily hold a 500 mL bag (see photo on left for clarification).

The new FreeArm Muscle will be available late this year. It will look very similar to the FreeArm and probably to your cell phone holder. We have been working with our manufacturer, who makes all types of clamps, clips and holders, to make it perfect for tube feeding and home infusion.

The FreeArm Muscle will still hold gravity feeds, but also heavier pumps and more feed volume. In addition, it will attach tightly to rounded surfaces, such as wheelchair bars. Watch for details on the release on our website.

—Misti S.

Al Mackay's Hike, from pg. 1

twenty-three days covering 272 miles, from the Massachusetts state line to the Canadian border.

Al said this trail is beautiful, rugged, and very demanding mentally. In planning, he knew he would largely be on his own, carrying three to four days' supplies (which includes feeding tube equipment and food). He and his wife planned for her to meet him at checkpoints to deliver his next few days of supplies. This plan worked well.

Al tube feeding in a lean-to along the trail.

Life "Before" Cancer

In the 1980s, Al and his wife raised two sons and two daughters, now ages 25, 27, 28, and 30. Al was a forester, and managed five thousand acres of family property. He also owned a small water utility, providing water to twelve hundred homes. He spent eight very stressful years (1990–1998) fighting a county water authority, as they attempted to take his water company by eminent domain.

In 1994, Al had started a process to get approval to build a golf course on his property. He received final approval in 1996, however, was unable to finance the project due to ongoing litigation with the county water authority. In 1999, the water authority withdrew their legal case, clearing the way to finance and build the course.

But during a tonsillectomy in 1999, the doctors diagnosed Al with cancer of the tonsils. He was confused. He never smoked or drank, so he suspected secondhand smoke or the solvents he worked with. He had twice daily radiation treatments for several weeks, as well as chemo. After a week off, he repeated the course. He rapidly lost weight, going from 210 pounds to 139 pounds.

Life After Treatment

Once Al recovered, he went back to his family activities: vacations at the beach, sports, eating normally, with some accommodations. He had sixteen good years, then retired in 2015 and moved to New Hampshire to start doing fun things.

Then, cancer struck again.

In 2015, Al began having difficulty swallowing, and bleeding. An exam revealed a non-cancerous fibrous growth. It was removed. He was on blood thinners from an earlier stroke and he developed atrial fibrillation (Afib) from his heart medications. Late in the year another growth was removed.

Then in 2017 yet another growth developed. Within six weeks of its removal, it grew back, covering one third of his airway. Upon removal, a sarcoma was diagnosed. It grew back some months later, blocking his airway. Al had to have a partial pharyngectomy, a feeding tube, and a tracheostomy for several months. He no longer can swallow normally. He can eat only small amounts of food if he washes it down with liquid. He adjusted by eating only soups and some soft vegetables so he does not feel deprived.

Al credits his wife, Annette, and his children with supporting him through his challenges. Many relatives spent endless hours with him around the clock, helping the family.

Al doesn't let any of this get in his way. He loves to travel and continues to do so. He plans ahead to be sure he has everything he needs that he can't pick up just anywhere. He brings his premixed food to restaurants. He has a sense of humor about others not understanding his routine. He good-humoredly tells about the time he was at a restaurant and was told he could not bring drinks in, when the manager saw his feeding supplies laid out. He educates curious children.

While Al and his family travel most often in the States, he spent fourteen days in Brazil. Driving is easier with all his equipment and he can avoid checkpoint delays at airports.

Al enjoys his cat and his son's dog. He builds boats in his wood shop. He and his wife will soon be moving to Albany, New York, to be closer to their grandchild.

Al's attitude is summed up in what he believes: "Limitations are a state of mind."

The Hike

After Al completed his journey, he shared sections of his journal for inclusion. Highlighted are some of his specific challenges and decisions he had to make on the fly. They are condensed, paraphrased, or revised for brevity.

Challenge One

On day two, Al made it to a shelter by lunchtime, after a 1,000-foot vertical climb. He traversed a challenging brook, when his knee began to hurt. He had 7 miles to go this day before stopping, mostly uphill. He slowed down until he was going only 1 mph as the pain increased. The last 7 miles took six hours.

Feeling better in the morning, he started out, but within the first third of a mile, his knee pain was severe. He was puzzled since he had trained vigorously with a full pack and was in great shape. Realizing he had to seek medical attention, Al made his way out of the woods and saw an orthopedist, who confirmed an MCL (medial collateral ligament) sprain, but no structural damage. Al received treatment to get him back to his journey.

Al returned to the trail a week later with a brace. His sister, her husband, and a high school friend joined him for the next few days. They covered more than 13 miles over rugged terrain the first day back, without knee pain.

Challenge Two

The weather turned very hot and humid several days later, with steep and rocky climbs ahead, including a 4,083-foot hike uphill. The heat got to Al and he became dehydrated. It took him three hours to climb 3.7 miles. His first action was to infuse, by tube, a liter of water.

Challenge Three

On the eighteenth day on the trail, Al had four mountains to climb, before meeting his sister at 11:00 a.m., so he started out at 6:20 a.m. The temperature climbed as they headed up almost two steep miles to the top of the last mountain. On his way, he learned there was no water at the shelter they planned to stay at for the night. This is a problem for tube feeders, particularly when expending so much energy in the heat. A decision would have to made:

> "As a tube feeder, I can't emphasize enough, there are no limitations. It is a state of mind."

- Stay at a closer shelter with water, which would require they hike an extra 4.3 miles over a rugged peak the next morning,
- Fill a gallon of water at this stop and continue, but he'd have to hike with an extra 8.6 pounds (the weight of a gallon of water), or
- Hike an extra 1.8 miles and one mountain.

Al chose the last option as the best, knowing it would be dangerous to attempt carrying the extra weight in the heat, over a mountain, or to go without water.

He eventually made it to his intended destination, hot, tired, and achy.

Final Challenge

The next and last challenge Al faced to complete his journey was a 1.8-mile hike, with the first third a 500-foot vertical section uphill! To get him through, he counted steps to keep track of his climbing effort. With 50 feet left to the end of the climb, Al looked up to find his sister Barbie, who had walked in to be sure he was OK. She escorted him the last mile to her car at the trailhead. After the long, hot day, they arrived at her house where Al replenished his fluids before dinner.

Mission accomplished. ¶

Editor's Note: Al has a real passion for being in the great outdoors. We are so glad he could get back to backpacking—one of his favorite activities—and that he shared his story. Al proved to himself and others that "tube feeding is just a different way to get nutrition into the body" (The Daily Gazette, *August 4, 2019). He also raised more than $15,000 for Oley Foundation programs. Al has inspired many Oley members and generated a lot of interest from the general public. A celebration event is planned for September 26.*

Concert, Ebay Sales, Raise Funds and Awareness

A music concert was held May 9 by the Rotary Club in East Greenbush, New York. It featured music from the CD "One Step Forward" played and sung by Michael Francis McCarthy, with accompaniment by Debbie Reep MacLeod on flute. Mario Sevayega also entertained participants with guitar playing and singing.

Michael McCarthy

The concert was organized by Phil Kellerman, an Oley program associate, and proceeds of the event and CD sales benefitted Oley Foundation programs. Thanks to Phil, and everyone who helped with this fun event!

EBay Memorabilia Sales

Phil has also been using his EBay account to raise funds for Oley in a unique way. A serious collector of political and historical memorabilia, Phil sells donated material on EBay and donates a percentage of the proceeds to the Oley Foundation. In just three years, he has raised more than $3,000 for Oley!

Some of the donated items.

If you have collectibles, memorabilia, or antiques to donate to help Oley, please contact Phil at (518) 262-5079 or philkellerman.oley@gmail.com.

Selenium, from pg. 1

• Vial closure on new product is not made with natural rubber latex.

Since 2009, ASPEN has advocated for the need for reformulated multi-trace element and single trace element products in the U.S., because currently available products did not meet best practice recommendations. This new selenium product is the first to go through this process.

What does this mean for you as a home parenteral nutrition (HPN) consumer?

1. Unless you have had difficulty tolerating the multi-trace element product (MTE-5), or you have had elevated levels of some of the trace elements in the combination (for example, manganese), or you are a pediatric patient—you may not need the new product. There is selenium in the combination product MTE 5 (which is formulated for adults). **Check your PN label to see what you have in your current prescription.**

2. Your infusion provider should be adding the trace elements to the PN bags for you in the pharmacy. ASPEN has asked the manufacturer to clarify the stability of the new product so that we know the new IV selenium can continue to be added to the bag in the pharmacy and you will not have to add it yourself. ASPEN is waiting for a response to that request. Many companies still have plenty of the previous formulation of IV selenium on hand and are using weekly stability until their supply runs out and they have to purchase the new product. **Contact your company or physician if you are asked to add selenium to the bag yourself.**

3. It is your providers' responsibility, in concert with your physician, to make sure you get what you need in your PN, but you should be made aware of any changes to your prescription. **If you have any questions or notice a change on your label, call your physician and/or your home infusion company to ask questions.**

4. **There is no IV selenium shortage right now.** The issue is that the price of the new product is much higher, which has caused hospitals and companies to analyze who really needs separate IV selenium and who does not. You should be made aware if your provider has made any changes to your prescription. Some companies may ask you if you can absorb an oral form of selenium to supplement your PN (if you are an adult).

It is the company's job to contact your insurance company to negotiate the difference in price of the IV selenium product if they have to, so this does not affect you financially, but they may ask you or your doctor to assist if they are challenged by the insurance company. ASPEN has also reached out to the manufacturer, American Regent, to ask for reconsideration of the new price. Hopefully we will have an update soon.

5. If PN is the sole source of nutrition, pediatric patients DO need individual selenium added to their PN bags since the neonatal and pediatric trace element combinations do not have selenium in them. Please check with your doctor and your company to make sure they are continuing to prescribe and provide the IV selenium in your child's PN bag.

As consumers, it makes sense to stay informed and ask questions. We are hoping for more information from American Regent and ASPEN on the stability and price of the new IV selenium and will share as it becomes available. ¶

Oley Regional Conferences

October 4
Las Vegas, Nevada

— and —

November 9
Ft. Lauderdale, Florida

Go to www.oley.org/event *to*

- Register **free** of charge
- Read information on **topics and speakers**

...or contact Andrea Guidi at (508) 460-1707, andreaguidi.oley@gmail.com.

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Takeda

Webinar for Caregivers

"You Need Self-Care!": What Can I Do to Cope with Being a Caregiver to a Loved One on HPEN?

October 8, 1–2 p.m. (EDT)

Tiffany Taft, PsyD

Register for free at www.oley.org/webinars. If you miss the live event, recordings of Oley webinars are available online—this includes the recording of a similar webinar for consumers held this September.

Tiffany Taft, PsyD, is a clinical psychologist from Chicago, Illinois, a research assistant professor and Director of Psychogastroenterology Research at Northwestern University Feinberg School of Medicine, and founder of Oak Park Behavioral Medicine, a private psychology practice specializing in treating patients with chronic digestive diseases. She has published extensively on psychosocial aspects of digestive diseases with interests in stigma, fatigue, and post-traumatic stress disorder (PTSD).

Dr. Taft presented "Psychosocial Issues Related to Intestinal Failure" at the Oley conference in June (video of the session available at https://vimeo.com/343199408; Dr. Taft's presentation begins approximately 25 minutes into the video) and an edited transcript of an interview with Dr. Taft on the subject of PTSD was published in the *LifelineLetter* (Sep/Oct 2018; www.oley.org/PTSD).

Spotted at the 2019 Oley/UI Hea










alth Combined Conference










FDA Research, from pg. 1

and found that few laboratory studies had been conducted to investigate the impact of transitioning to ENFit connectors for enteral devices. FDA conducted this study to bridge that research gap.

Q2. Can you outline the testing process?

Response: The testing was conducted in two phases. The first phase involved what we termed "commercial diets" (including water and orange juice, as well as standard enteral formulas and commercially available blended diets) and the second phase involved home-blenderized diets. To determine if the new ENFit connectors perform differently from the older, funnel-type connectors, devices with both types of connectors were tested in both phases of the study. A variety of commercial diets were chosen with different caloric content for the first phase in collaboration with the Mayo Clinic. [Editor's note: More about the studies done at Mayo Clinic can be found in the *LifelineLetter* (Nov/Dec 2017, www.oley.org/TransitioningtoNewEnteralConnectors) and in the *Journal of Parenteral and Enteral Nutrition* (Jan 2019 43[1] and 2018 Mar;42[3]). The diets were carefully selected either based on patient suggestions or as representing the diversity of standard enteral formulas used.

Patients typically feed themselves using enteral pumps, by gravity, or by pushing the diets through syringes (often called bolus). In this phase, differences in how the commercial diet went through the older generation (i.e., legacy tubes, with funnel-type connectors) and new ENFit-based tubes were studied in a simulated gravity-feeding procedure. The protocol is outlined in Figure 1. The syringe was attached to the small-bore connector of the tube being tested. The plunger was removed from the syringe and the syringe was filled to 60 mL while the feeding tube was kept clamped. Then the clamp was removed and the timer started. The time taken to dispense the 60 mL volume was measured. Dividing the volume by the time taken to dispense the volume gave us the flow rate for each sample and allowed us to compare legacy with the ENFit-based feeding tubes.

Given the increasing popularity of blenderized diets for tube feeding, FDA investigated home-blenderized diets during the second phase of the study. We solicited and received more than twenty blenderized diet recipes from patients through two patient advocacy groups: the Oley Foundation and Feeding Tube Awareness Foundation. From those, six recipes were chosen to represent the variety of thickness in

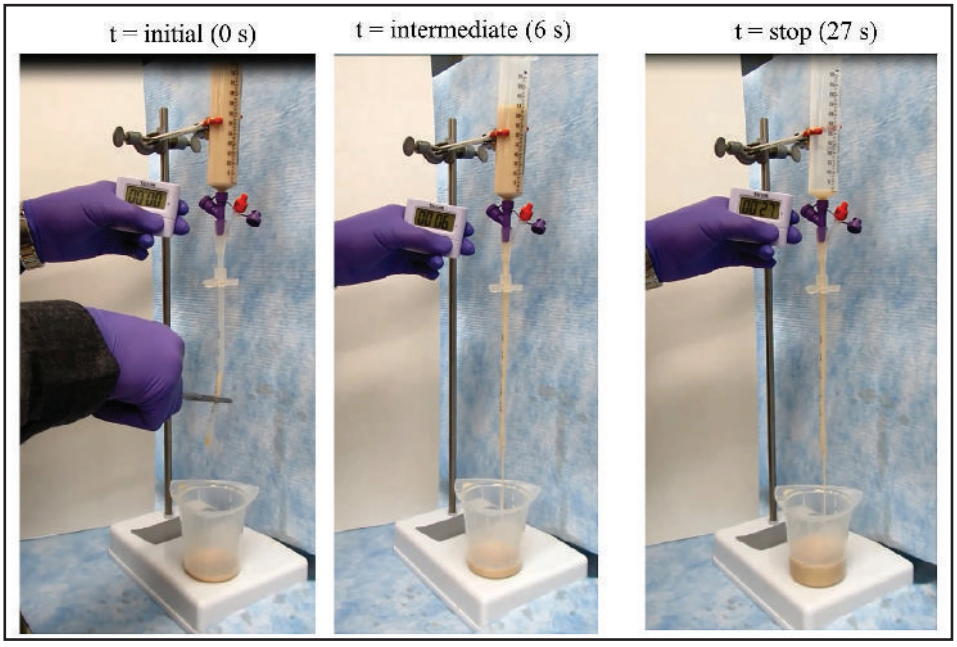

Figure 1. Gravity flow testing with one of the commercial diets at three different time points: 0 seconds (s) when the feeding tube is unclamped; 6 s is an intermediate time point when 15 mL had dispensed; and 27 s, when 60 mL was dispensed.

patient blends. Two modes of feed delivery were investigated—gravity and push (bolus) modes—with one diet tested using gravity, four diets tested using push, and another diet tested under both gravity and push modes.

In preparing the diets, FDA followed the patient-diet recipes as closely as possible. We acquired four different blenders varying in cost from forty dollars to several hundred dollars, to blend the diets. Blending times were provided by patients.

For gravity feeding, experiments were performed like those in phase one of the study. For the push mode, the syringe was filled with a diet by drawing it up with a plunger. Then the syringe, with plunger, was connected to a feeding tube (as shown in Figure 2). The force required to dispense the diet was measured using a force-testing machine. To include the diversity in the rate at which a patient may push their diets, we chose 5 seconds (s) and 60 s push times for dispensing the 60 mL volume.

In addition to these two phases of testing, FDA also did limited testing of commercial blended diets with push mode as well.

Q3. Can you give some examples of these diets?

Response: For the first phase of our study, we worked closely with the Mayo Clinic in selecting diets, starting with water, to diets with high caloric value (such as Boost 2.0), to commercial blended diets such as Nourish. This diversity ensured that we covered the thickness of diets that patients may use in hospitals or home settings for gravity feeding. Some limited experiments were also conducted in push mode with commercial blended diets such as Nourish and Real Food Blends with salmon and chicken flavors.

For the second phase of the study, we chose diets that ranged from very thin milk-based diets that can be gravity-fed to extremely thick diets with large particles (≈ 3 millimeters, or 1/8 inch, or roughly size of a fire ant) in them that can only be fed using push mode. Five of the six diets are shown in Figure 3 (see next page).

Q4. What were FDA's findings from the study using commercial diets?

Response: In phase one, with commercial diets, 14 Fr to 24 Fr feeding tubes were chosen to capture the range in size available in the U.S. market. At each size, 7 different diets were tested with 8 brands of tubes, leading to a total of 672 trials (4 sizes, 7 diets, 8 different brands, with 3 repeated trials of

FDA Research, cont. pg. 12 ☛

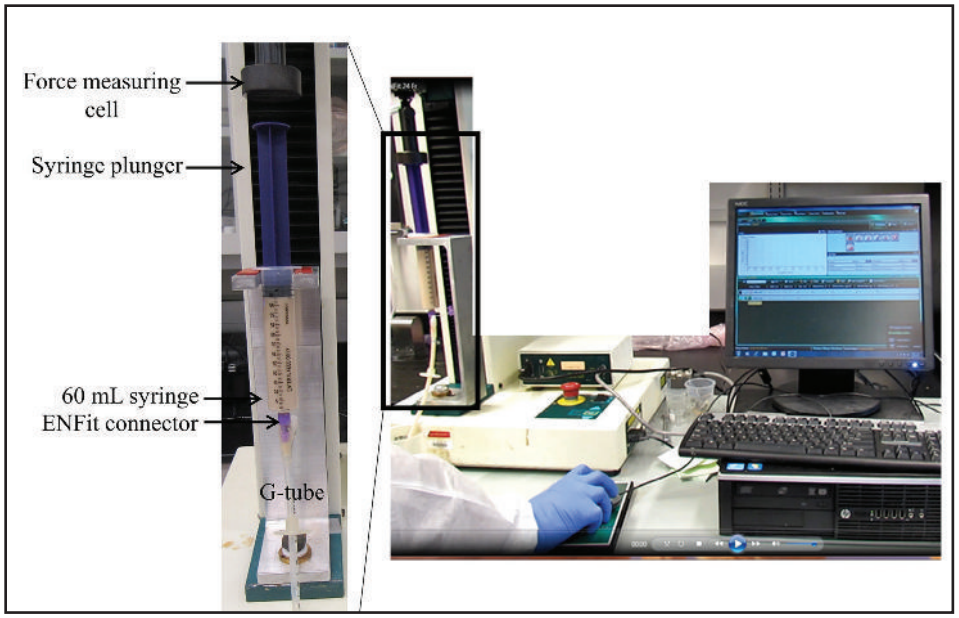

Figure 2. (A) Syringe–feeding tube set-up that connects with force measuring cell. **(B)** The universal testing machine that was used to measure the force required to push a diet through any syringe–feeding tube set-up. The force was recorded as a function of displacement and then the average force over the total displacement was calculated.

FDA, from pg. 11

each). This number excludes preliminary experiments performed for establishing the final test protocol.

In about 450 experiments, the ENFit-based feeding tubes were found to be slower, meaning that it took more time for the diets to pass through the device. However, in a majority of these (7 out of 10), the slowing was no more than 6 minutes for a 20-minute feed. The extent of the flow-rate slowing was found to largely depend on the length of the ENFit connector, with longer length leading to slower flowing. (Editor's note: The external dimensions, e.g. length, of ENFit connectors can vary among manufacturers and devices. The ENFit standard refers to the parts of the connector that physically interlock with each other. The manufacturer has some discretion on how this standard is incorporated into the overall design of the device.)

We had anticipated that if there was a difference in flow rates, they would occur with the larger Fr sizes. We were surprised to find that one 14 Fr ENFit-based brand was significantly slower. We were able to attribute this slowing to the reduced internal tube diameter in this brand—the slowing was not because of the ENFit connector. The research findings discussed above have been published in the *Journal of Parenteral and Enteral Nutrition* (2018, 42[8]; available at www.onlinelibrary.wiley.com/doi/pdf/10.1002/jpen.1159 or by emailing Suvajyoti.Guha@fda.hhs.gov).

As mentioned previously, a limited number of experiments were performed in push mode with commercial blended diets. Syringe–feeding tube combinations that used the ENFit connectors typically required similar or less force in most cases. The results from this study were presented at the Oley annual conference in Connecticut in July 2017. (Video at www.youtube.com/watch?v=jjMMJjfyN_U, presentation begins at approx. 51 min.)

Q5. What were FDA's findings from phase two of the study, with home-blenderized diets?

Response: Like the first phase of the study, to capture the variety in the U.S. market, 5 brands of legacy and 3 brands of ENFit-based feeding tubes, ranging from 14 Fr to 24 Fr size, were selected. After performing over 100 preliminary experiments to set up test protocols, 612 experimental trials were conducted in both gravity and push mode, to investigate the impact of blenders, blending time, diets, and diet thicknesses. In addition, experiments were conducted to characterize the diet thicknesses and the particulates in the diets using other scientific means.

The findings of the study largely depended on the type of feeding tube used—standard feeding tubes (some patients refer to them as dangling type) or the popular low-profile feeding tubes. Our findings revealed that, for low-profile feeding tubes, transition from existing legacy designs to the ENFit connector–based feeding tubes will likely not result in any meaningfully relevant change in patient experience during gravity feeds or push mode feeding.

The results however, were mixed for standard (dangling) feeding tubes. We observed a potential increased feeding time for gravity feeds using

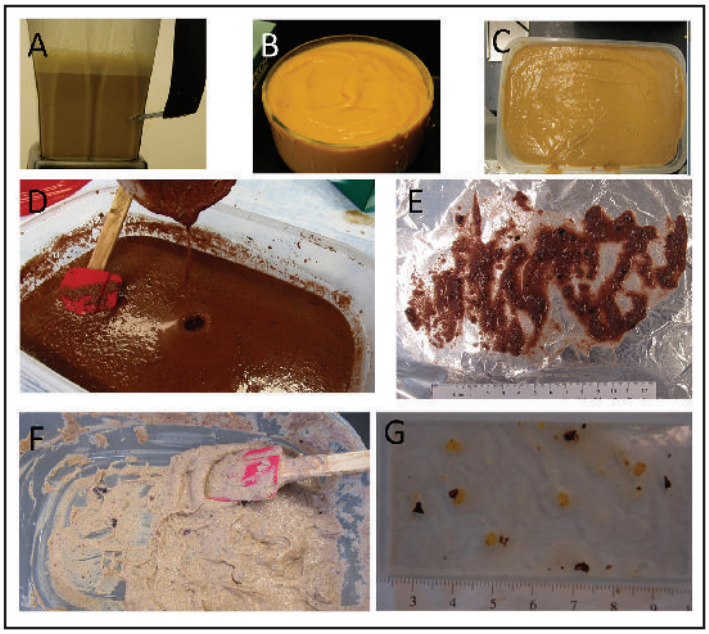

Figure 3. (A) Milk-based thin diet, delivered using gravity. **(B)** A chicken diet with yogurt-like texture that was delivered using push mode. The patient using this diet has already successfully migrated from a legacy feeding tube to an ENFit-based feeding tube. **(C)** A well-blended sirloin diet that another patient delivered using push mode. **(D)** Another patient used a thick nuts-strawberry-coffee diet that has lot of particulates. This diet was thoroughly investigated in gravity and push mode to determine how clogging in ENFit-based feeding tubes may be overcome with different blending practices. **(E)** Particulates found in the nuts-strawberry-coffee diet. **(F)** An extremely thick enchilada diet was used as worst-case testing. The diet visually looked as thick as peanut butter. **(G)** Dilution of the enchilada diet revealed large unblended rice, black bean particulates (2-3 mm). Both legacy and ENFit-based feeding tubes were able to successfully dispense this diet.

ENFit-based tubes vs. legacy. We also observed a noticeable reduction in force required for most diets in push mode of feeding using ENFit-based tubes. These research findings have been published in *Journal of the American College of Nutrition* (2019 38[4]; available at www.tandfonline.com/doi/full/10.1080/07315724.2018.1509247 or by emailing Suvajyoti.Guha@fda.hhs.gov).

Q6. You mentioned that some dangling-tube users may see some slowing in their feeding times. Can you please elaborate? What is being done for users who may be impacted?

Response: The results from both phases showed that post-transition to the ENFit connector–based feeding tubes, for one brand of 14 Fr dangling type and for a few brands of 18, 20 and 24 Fr dangling-type feeding tubes, the flow rates were more than 35 percent lower. This means that a typical feeding time of 20 minutes might require more than 27 minutes.

For the 14 Fr dangling brand that turned out to be slow, the slowing was not because of the ENFit connector, but because of narrowing of the distal end of the feeding tube. Transitioning to such a tube is expected to have a considerable increase in feeding time (almost doubling or tripling it, i.e., a 20-minute feeding time would increase to 40–60 minutes). According to a published Mayo Clinic survey, 14 Fr standard G-tubes are not widely used. Given this, we anticipate that the impact of this design change on U.S. users will be small. These patients should consider talking to their physicians to discuss options such as trying different brands or larger size devices.

Because ENFit connectors have a bore diameter of 2.9 mm—smaller than the funnel connectors in most legacy tubes—longer connector lengths (meaning a longer stretch with this smaller diameter) would lead to slowing in flow rate, which is what we observed for some of the standard (dangling) feeding tubes at 18, 20, and 24 Fr. For most of these cases, the sample 20-minute feeding time increased to less than 40 minutes. These brands tended to have ENFit connectors that extended for dozens of millimeters (e.g., 50 millimeters, or approximately 2 inches). In other words, it was not primarily the ENFit portion (the interlocking parts) of the connector, but the length of the connector (which can vary by manufacturer) that caused the reduction in flow rate (i.e. increased feeding time) for some of these brands. Patients that experience increased feeding time may consider talking to their physicians about options, including enteral pumps or push mode of feeding.

Lastly, when the new connector was short in length, as seen in the low-profile feeding tubes (also popularly referred to as "buttons"), the impact of the slowing of flow was minimal. Most often any slowing was less than 30 percent. This means a 20-minute feed would take under 26 minutes. Thus patients using low-profile feeding tubes, independent of the size, are not expected to be impacted by the connector design changes.

FDA values patient input and continues to engage with patient advocacy groups. FDA is making manufacturers aware of our findings and is advocating for the patients impacted by the design changes by suggesting that manufacturers design their feeding tubes such that the flow-rate reduction in larger-bore feeding tubes is minimized. We are also engaging with standards-development organizations to update existing standards that manufacturers use for feeding tube flow-rate testing.

Q7. Can users modify their practices to achieve better results?

Response: At the Oley Foundation's annual conference in 2017, we learned that some patients modify their devices or approaches to how they deliver their diets. In our paper on blenderized diets, we discussed several options for changing diet preparation practices, such as changing blenders, increasing blending time, or switching to alternative diets. According to our tests, these alternatives made the delivery of nutrition easier, with both gravity and push mode. There are other literature resources where users or clinicians have provided recommendations of how diet preparation can be changed to achieve better results with feeding tubes as well (e.g. using strainers or diluting agents such as broths, etc.).

Q8. What were the limitations of your studies?

Response: Both phases of the study had several limitations. First, the study was conducted in the laboratory without insertion of the tubes inside patients. Because of variability in gastric emptying or differences in stomach back pressure, the time required for gravity flow, or the force required in push mode, may be different in patients. Therefore, the absolute time or force reported by FDA may not be the same time that a patient will observe at home or in the hospital. However, our data may be useful in assessing the impact of transitioning to ENFit-based feeding tubes.

Second, we performed our tests with a limited number of legacy and ENFit-based devices. We could not include all brands that are available in the U.S. market. However, we tried to be inclusive in the different design features (e.g., connector type—long and short, narrow and wide) that exist in the U.S. market.

Third, we did not use gravity bags or enteral pumps in our testing. Fourth, we used new devices in each testing. Therefore, the effect of repeated use, occlusion from food residues, microbial growth, or

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Help Yourself and Others: Report Problems

If you have a shipment of leaky feeding bags, it may be clear to you that you need to call the supplier who delivered them to get them replaced. Did you know it can be helpful to report these and other problems you have with medical devices to the manufacturers and the FDA, as well? Your reports allow manufacturers and regulators to know if a problem is isolated or widespread, and to track patterns.

The FDA encourages patients and health care professionals to report product problems and medical device adverse events to them through their MedWatch, the FDA Safety Information and Adverse Event Reporting Program. Use the MedWatch program to report serious drug side effects, product use/medication errors, product quality problems, and therapeutic failures for medical devices (tubes, pumps, etc.), tube feeding formula, supplements, and medications, as well as biologics, foods, and cosmetics.

To report a problem to the FDA's MedWatch program, complete the online form at www.accessdata.fda.gov/scripts/medwatch/index.cfm or call (800) 332-1088 to request a reporting form, then complete and return it by mail to the address on the form or by fax to (800) FDA-0178.

For more information on reporting problems with medical devices to the FDA, visit www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

You can also look in the MAUDE database, maintained by the FDA, to see if problems have been reported with a medical device. Go to www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

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medications were not studied. Lastly, for the blenderized diet study, there are countless ways in which a diet can be prepared, including the blender used, time of blending, amount of dilution with water, variability in freshness of food, and straining. We limited the testing to specific conditions. Our batch-to-batch variability in preparing these diets was likely higher than what patients achieve in the home setting. The impact of this variability on testing was minimized by mixing different batches together before testing. ¶

Thank You Corporate Partners!

Please join Oley in thanking the companies that support Oley year round. Learn more about our most recent corporate contributors below, as they describe themselves and their products in their own words. For a complete list of corporate partners go to www.oley.org/PartnerShowcase

Coram / CVS Specialty Infusion Services

CVS Specialty and Coram strives to provide personalized, compassionate, high-quality infusion care to patients where they live, work or travel. With more than thirty years of experience and nearly 1,200 skilled clinicians, Coram / CVS specialty infusion services leads with commitment from the heart. The company maintains a 96 percent patient satisfaction rating.

ThriveRx

ThriveRx, a division of Diplomat Specialty Infusion Group, provides customized customer service and clinical care for the home parenteral and enteral (HPEN) nutrition consumer. Its mission is to foster independence and empower patients and their families.

Baxter Healthcare Corporation

Baxter International Inc. has over eighty years of experience in developing parenteral nutrition products that work together to help improve patient outcomes. Baxter offers clinicians and patients parenteral nutrition solutions, IV fat emulsions and automated compounding systems.

Kate Farms

Kate Farms is a medical nutrition company offering a high standard of enteral formulas: well tolerated, made with organic ingredients without commonly used allergens, and broadly covered by insurance. The company says its formulas are "widely preferred because of improved tolerance, quality of ingredients, and delicious taste."

Nestlé Health Science

Nestlé Health Science, a wholly owned subsidiary of Nestlé S.A., is engaged in advancing the role of nutritional therapy in healthcare. Through investing in innovation and leveraging leading edge science, it brings forward innovative nutritional solutions with clinical, health economic value and quality of life benefits.

Zealand Pharma

Zealand Pharma is changing patients' lives with innovative peptide therapeutics. Patients inspire the company to provide the best possible solutions for gastrointestinal and metabolic disorders. The company is building upon twenty years of expertise in developing treatments for patients with short bowel syndrome.

Notable Individual Gifts

Among the contributions we receive, there are always several dedicated to those who have inspired the donor. We share this list of honorees below. We are grateful for the following gifts received from July 13, 2019, through August 21, 2019.

Tributes: *In honor of* Al Mackay; Paul Butzin's 30th birthday; Andrea and Brent Cantor's 25th wedding anniversary; Craig Donaldson; everyone who has been afflicted with cancer of any type; Aidan Koncius; Bev and George Lillquist's 50th wedding anniversary; Dashiell Lyon; Mavis Thayer; Diane Wardrip; Eli and Lynn Wolfson's 33rd wedding anniversary

Memorials: *In memory of* Jacques Lamar Alexander; Chris Goll; Peter Joseph Michalski; Kay and "Oley" Oldenburg; Sophie Prunty; Liz Tucker; Beatrice Williams

Matching Gift: Johnson & Johnson

Fund-raisers: Al Mackay's Long Trail hike; Amazon Smile; Facebook; Shire, now part of Takeda Pharmaceuticals, booth fund-raiser at Digestive Disease Week

Thank you for all gifts and the kind comments we receive throughout the year. Your support overwhelms us and continues to be a source of inspiration.

Oley Horizon Society

Many thanks to those who have arranged a planned gift to ensure continuing support for HPEN consumers and their families. Learn how you can make a difference by calling (518) 262-5079 or visiting www.oley.org/plannedgifts.

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The following companies provide over one-half of the funds needed to support Oley programs. Corporate relationships also strengthen our educational and outreach efforts. We are grateful for their strong commitment.

TITANIUM LEVEL PARTNER ($150,000+)

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Albany Medical Center, MC-28
99 Delaware Avenue
Delmar, NY 12054

Oley Calendar

Ongoing: Applications being accepted for Oley Tim Weaver Camp Scholarship

October 4: Oley/Association for Vascular Access (AVA) collaborative education day, Las Vegas, NV

October 4–7: Oley exhibiting and participating in Association for Vascular Access Annual Scientific Meeting, Las Vegas, NV

October 8: Oley webinar, *"You Need Self-Care!": What Can I Do to Cope with Being a Caregiver to a Loved One on HPEN?* (caregiver centered)

October 14–18: HPN Awareness Week

October 21-22: Oley attending the National Organization of Rare Disorders (NORD) Rare Summit, Washington, DC

November 8: Oley exhibiting at Michigan Society for Parenteral and Enteral Nutrition (MSPEN) conference, Detroit, MI

November 9: Oley Regional Conference, Fort Lauderdale, FL

March 28–31, 2020: Oley exhibiting at and attending the ASPEN Nutrition Science and Practice Conference, Tampa, FL

For updates or if you are able to help at one of the Oley exhibits listed above, please email harrinc@amc.edu or call (518) 262-5079.

Additional Meetings of Interest

October 25–30: American College of Gastroenterology (ACG) meeting, San Antonio, TX

November 22: PNDU social gathering, Adelaide, Australia

November 23: AuSPEN HPN Consumer Workshop, Adelaide, Australia

January 24–25, 2020: Feeding Matters International Pediatric Feeding Disorder Conference, Virtual Meeting

Halloween Is Almost Here!

Support kids who cannot eat the usual candy treats by participating in the Food Allergy Research & Education's Teal Pumpkin Project®. It's as simple as buying inexpensive non-food treats, such as glow sticks or small toys, and placing a teal pumpkin on your doorstep to show non-food treats are available.

You'll find details and lots of free resources at www.tealpumpkinproject.org, including:

- a free poster to hang in your window (if you don't have a teal pumpkin);
- directions for adding your home to the interactive map, making it easier for kids to find your house;
- ideas for non-food treats; and
- tools and tips to help spread the word via social media!