Blenderized Tube Feeding
ENFit® Connector Testing

1/17/2016
Goal – Establish impact of ENFit™ Connector on feeding tube performance and characterize current user practices with regard to blenderized tube feeding BTF

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FDA (Silver Springs, MD)
  • Suvajyoti Guha; Josh Silverstein

GEDSA and Oley supporting by supplying products and review of testing protocols only
• Testing Protocol
  • FDA and Mayo program based on previous Mayo and industry work
  • Tubes and Syringes blinded in all testing and reporting

• Products being tested
  • Feeding tubes – Legacy and ENFit
    • 14, 18, 20, and 24 FR Balloon G Tubes
    • Bolus extension sets for low profile
    • Head to head legacy vs. ENFit®
  • Syringes – Legacy and ENFit
  • Commercial Formulas
    • Standard 1, 1.5, 2.0 calorie from Nestle and Abbott
    • Peptamen 1.0, Boost VHC and Orange Juice
    • Nourish from Functional Formularies; Salmon from Real Food Blends
  • BTF recipes from Mayo and Oley members
• Measure viscosity and particulate size for each formula and BTF recipe

• Flow testing using gravity
  • Flow rates (in time) using standard set up and relying on gravity
  • 3x for each tube and formula
  • New tube for each test

• Pressure testing using syringe
  • Measure pressure to deliver formula using a rate of 60 mL per minute
  • 3x for each tube and formula
  • Limit syringe to 5 uses
  • Using a range of blenders and blending at 3 minutes and 6 minutes
Flow Testing Results – Commercial Formula

- **14 FR**
  - One ENFit® tube had slower than corresponding legacy tube
    - Unrelated to ENFit connector, but related to changes in overall tube design
      - Smaller diameter inner lumen and longer tube
  - All other products showed no difference between legacy and ENFit
- **18 and 20 FR** no difference between legacy and ENFit products in flow rates
- **24 FR** – slower flow rates for the ENFit design when compared to legacy
  - Typical rates – Legacy 275 mL to 300 mL/hr vs. ENFit® 150 mL to 165 mL
• Blending does matter
  • Particulate size and viscosity are important
  • “Higher” end blends do a better job of blending
  • Technique is critical
    • Minimum of 3 minutes
    • Sufficient water to allow ingredients to turn over and be chopped

• Results vary based on recipe, tube design and syringe
  • Impact of the connector change is hard to isolate

• Observed trends
  • 14 to 20 FR similar to gravity flow – no major difference
  • 24 FR may be less impacted by ENFit® connector
Next Steps

• FDA to compete syringe testing

• Data must be analyzed using best practice statistical methods

• Target for review by researchers is March
Home User Questionnaire - Background

- Create a validated, objective data base of home tube feeding practices from a broad patient that can be used for publication, input into standards and decision making

- Build on Mayo/Oley survey to identify home tube feeding practices
  - Demographics
  - Commercial vs. BTF use
  - Reimbursement
  - BTF practices such as – equipment used, foods used, motivation for BTF, challenges with current equipment

- Includes key stakeholders – Patients, Manufacturers, Clinicians and Suppliers
  
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• Survey live September 1 to October 15
  • Online link through Feeding Tube Awareness Foundation, Oley, Coram, Pediatric Home Services and ASPEN
  • Phone option through Oley

• Results:
  • 1703 respondents
  • 66.7% pediatric (under 18)/33.3% adult
  • BTF use not as prevalent as first Mayo/Oley survey – less than one quarter of respondents
  • BTF more common in pediatrics

• Journal Submission planned during Q2 2017