

Executive Summary

- Gastrojejunostomy (GJ) tubes are essential for pediatric patients with complex gastrointestinal conditions, including severe gastroesophageal reflux disease, scoliosis, and chronic vomiting.
- These devices deliver nutrition and medication directly into the jejunum, bypassing the stomach to ensure reliable treatment.
- However, GJ-tube dislodgment is a frequent complication caused by gastrointestinal movement and patient-specific anatomy, often interrupting nutrition and medication delivery.
- Current GJ-tube systems do not include mechanisms to prevent this problem.
- During the Clinical Immersion Program, our team observed the need for an improved solution.
- This project proposes the development of a safe, compatible expandable anchoring system designed to reduce the risk of GJ-tube dislodgment and improve continuity of care for pediatric patients.

Background

UT Southwestern doctors conveyed that for many children the ability to receive nutrition and medication depends entirely on the GJ-tube, thus its position inside the body is crucial.

- Yearly average of 4.6 tube replacements with each tube lasting on an average of 98 days.
- Of these replacements about 34.6% are accounted by dislodgement.
- A financial burden on the patient's families seeing as home care exceeds on average \$37,000 per family.

Without any current solutions on the market addressing GJ-tube dislodgement, a device is needed to address this issue without being too expensive or exhaustive to the body.

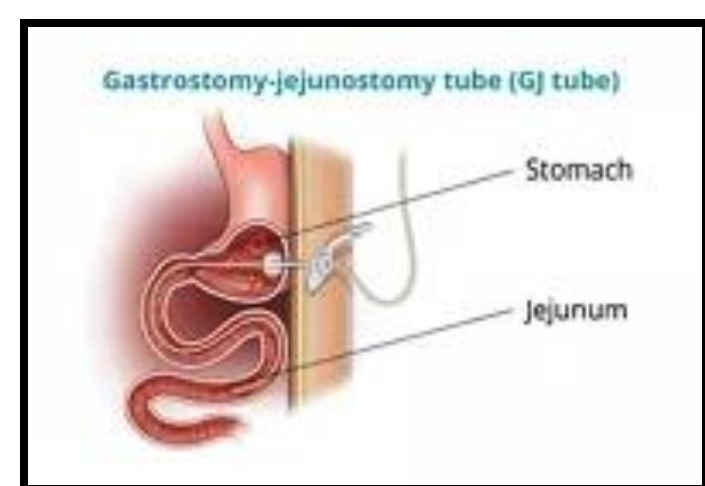


Figure 1. GJ-tube relative to the anatomical position

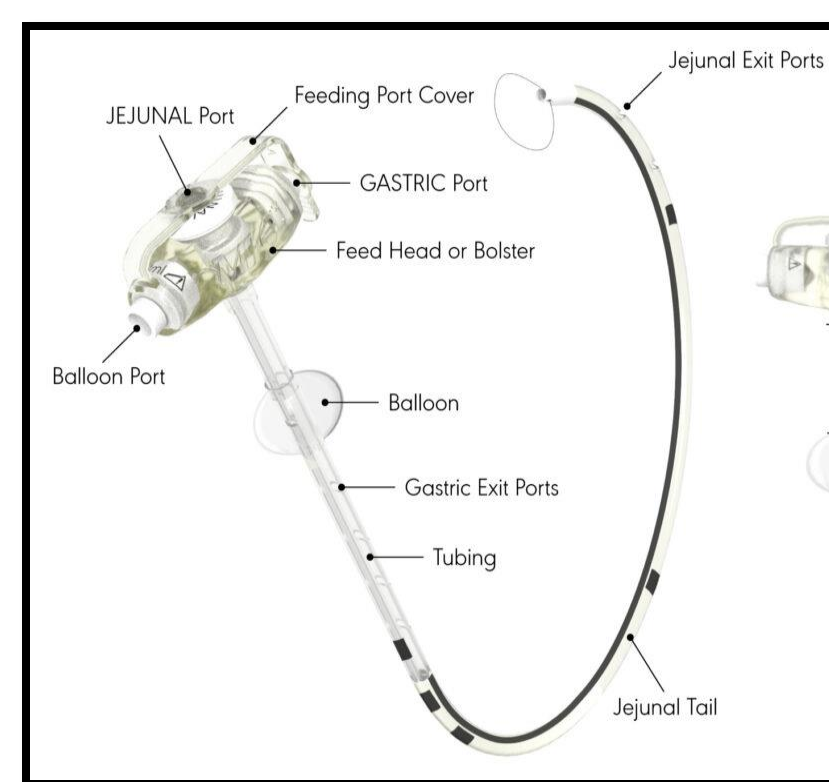


Figure 2. Different parts regarding the GJ-tube

Experimental Setup

The objective of this study is to develop a GJ-tube system that reduces the amount of dislodging events in pediatric patients. The system includes the Secure Lock, which is the proximal attachment at the J-port, the Anchor Cap, which is the attachment at the distal end of the GJ-tube, and the tungsten wire connecting the system together.

Functional requirements

- Prevent dislodgment: Maintain set position within 5cm of original placement in small intestine
- Does not block lumen of jejunum: Allows 100% passage of gastric/biliary contents into the small intestine
- Long term use: Must be able to withstand at least 3-6 months
- Motion Durability: Can still compress and expand after 3 months
- Durability of Expansion Wire: Insertion force ≤ 10 N; Removable force ≤ 30 N
- Compression: No permanent deformation under 50 N of compressive load

Physical requirements

- Materials: medical grade silicone, biocompatible wire
- Device Diameter: 5 mm tube; tube tip: 6 mm
- Length of GJ-tube: 60 cm

Experimental Test Plan

- The tungsten wire, connected to the Anchor Cap is guided from the distal tip of the GJ-tube through the J-port of the tube.
- The Anchor Cap is attached at the distal tip of the GJ-Tube.
- The wire is then guided through the wire port of the Secure Lock 3D printed device.
- The Secure Lock device is then locked into place at the J-Port of the tube.
- Tension applied at the proximal end is transmitted through the wire causing the distal tip to expand and anchor within the small intestine.
- This expansion helps maintain the position of the GJ-tube and prevents dislodgment while allowing normal lumen flow.
- The system was further evaluated through fluid flow and durability testing under simulated physiological conditions.

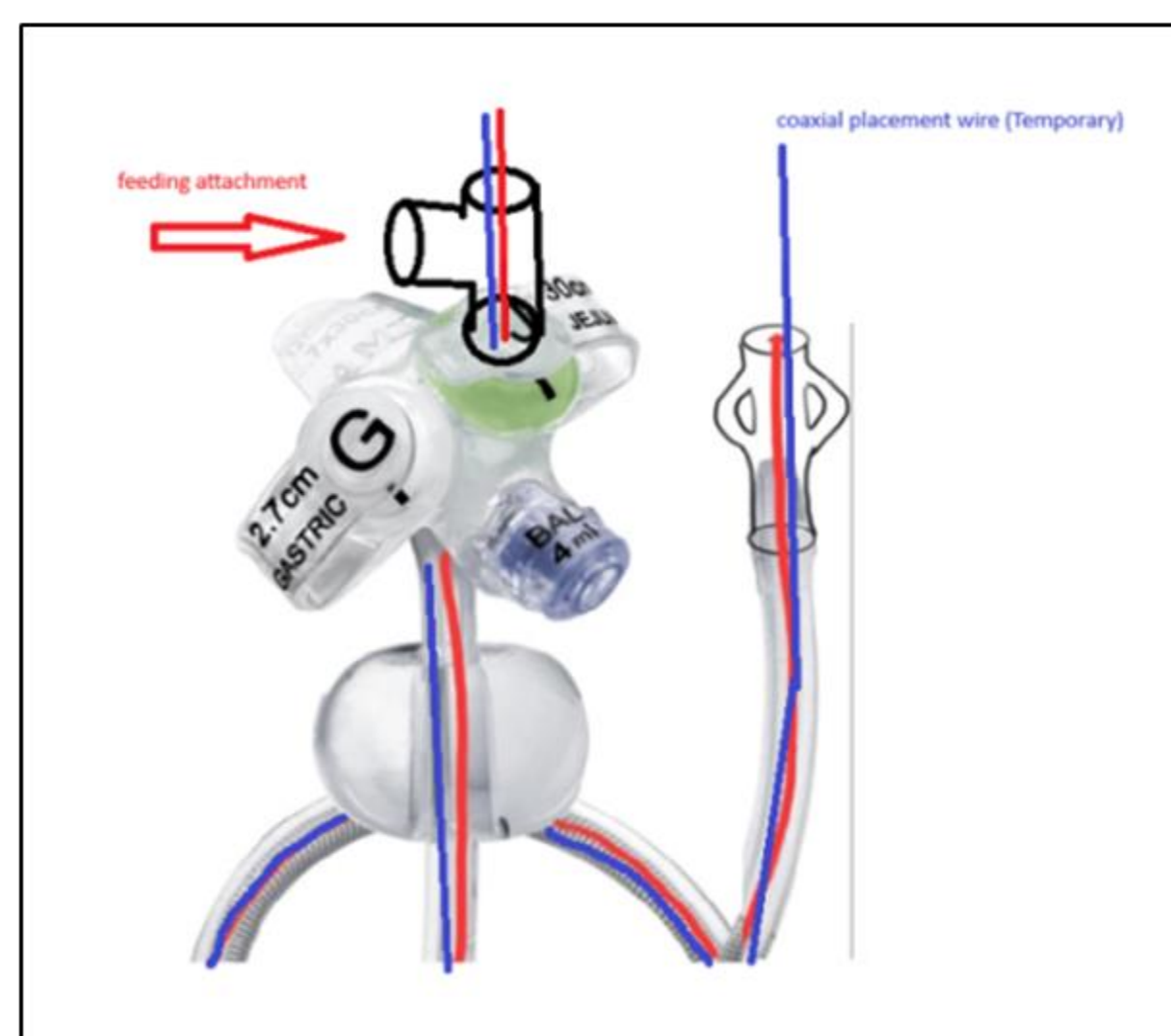


Figure 3. Complete anchoring system

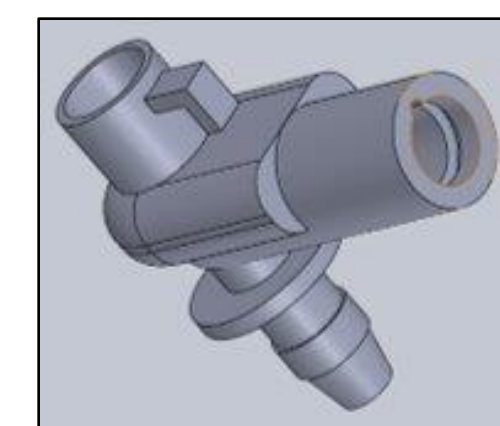


Figure 4. 3D Secure Lock model

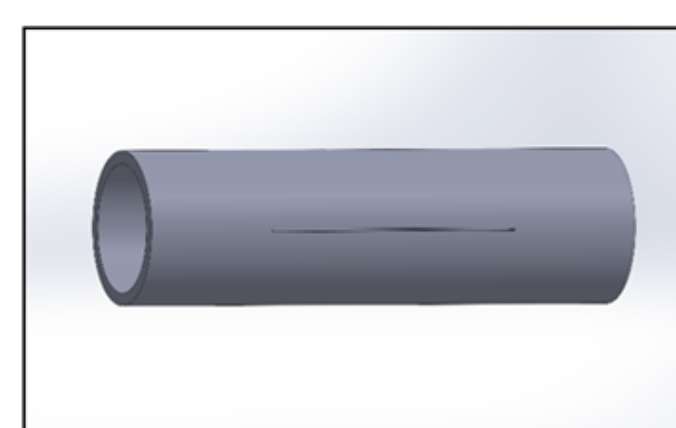


Figure 5. 3D Anchor Cap model

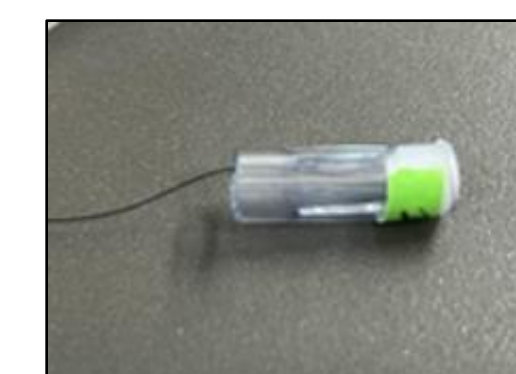


Figure 6. Physical prototype of the Anchor Cap

Experimental Results

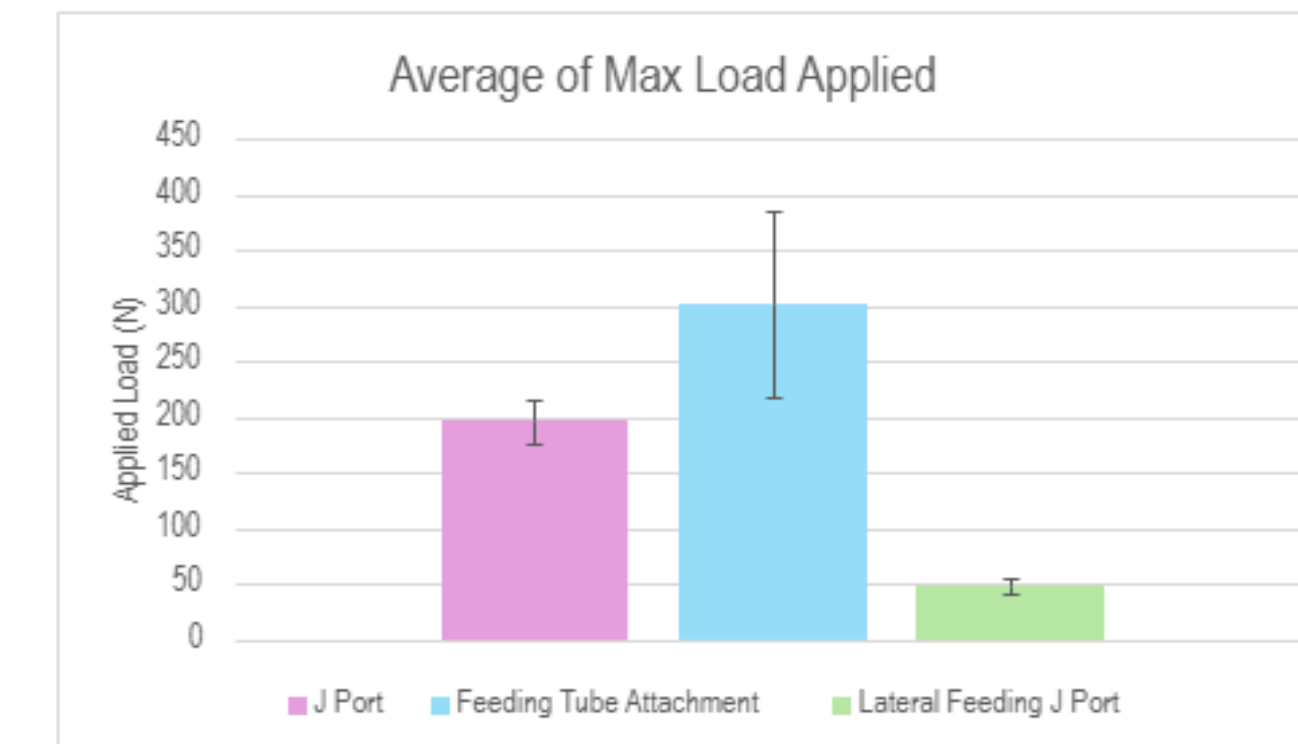


Figure 7. Average of max compression load applied

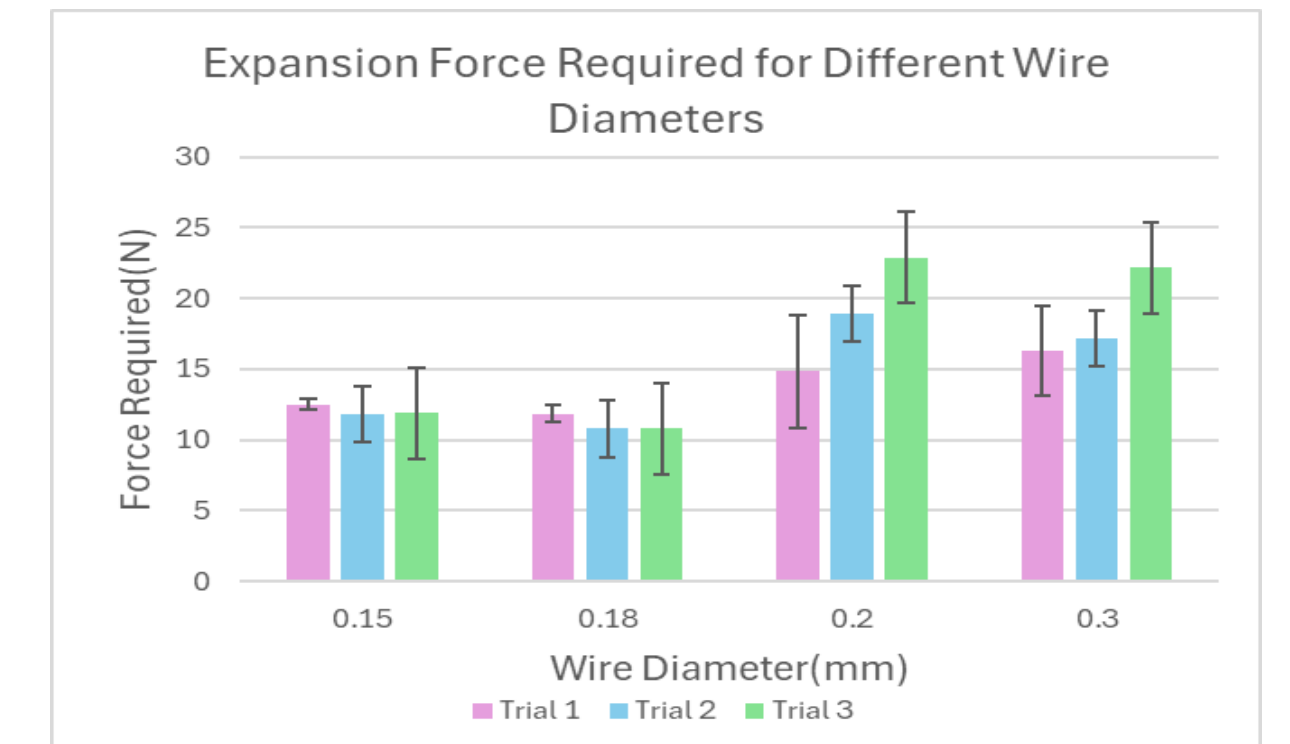


Figure 8. Force req. for wire diameters

Terms

Absorption %: amount of gastric fluid taken up into the anchor cap
Max compression load: force applied onto the Secure Lock until failure

Expansion force required for different wire diameters: force that the wires break at

Duration	Absorption %
1 Week	4.25
6 Weeks	24.43

Table 1. Gastric fluid absorption pertaining to weekly schedules

Conclusions and Future Works

- The prototype expansion wire consistently achieves uniform expansion within the target force range of ≤ 30 N for all diameters, with the optimized design exhibiting a 0.18 mm outer diameter and a force of 50 N.
- The Secure Lock device was successful in achieving ≥ 50 N, with the lower amount of force being in the lateral side of the J-port.
- The Anchor Cap demonstrated weight fluctuations for the 1-week data set with a 4.25 fluid absorption percentage and the 6-week data set with a 24.43 fluid absorption percentage.
- The Anchor Cap successfully showed the expansion mechanism without any visible degradation.

Future Work

- Evaluate the functional performance of the GJ-tube system for an extended period under continuous gastric fluid flow.
- Evaluate the cause of the weight fluctuation.
- Evaluate titanium wire as a more biocompatible alternative to tungsten.

References

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- Demehri, F. R., Simha, S., Herrman, E., Jarboe, M. D., Geiger, J. D., Teitelbaum, D. H., & Gadepalli, S. K. (2016). Analysis of risk factors contributing to morbidity from gastrojejunostomy feeding tubes in children. *Journal of Pediatric Surgery*, 51(6), 1005-1009.
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