Towards a Gastric Status Index (GSI) for Optimizing Enteral Feeding in the Neonatal Intensive Care Unit

[1,2]Rory Geoghegan PhD, [1]Justin Barron BS, [1]Saheel Sutaria MS, [1]Daniel Burnett MD, [3]Joanna Jain BS, [3]Anoop Rao MD, MS

[1]Gravitas Medical, Inc., [2]University of California, Los Angeles [3]Stanford University School of Medicine

Background

The widely practiced 3-hour feeding cycle in the neonatal intensive care unit has several limitations:

1. Nutrition is not tailored to the infants' metabolic requirements thus preventing optimal growth and prolonging length of stay [1]
2. Digestive rhythms exhibit inter- and intra-patient variability leading to missed feeding opportunities or conversely overfeeding which may result in the development of feeding intolerance [2]
3. It is currently not possible to advance feeding in synchrony with gastric maturity progression [3,4]

Consequently, there is a great need to develop monitoring technology capable of providing feedback on gastric status thus enabling optimal feeding practices.

Objective

To explore the utility of a novel Gastric Status Index (GSI) derived from impedance measurements acquired via a sensor-integrated feeding tube.

Methods

Gravitas Medical (Berkeley, CA) has developed a feeding tube (FT) with integrated impedance and temperature sensors. This system is capable of assessing gastric status through detection of reflux events and gastric impedance changes induced by filling/emptying of the stomach (**Fig. 1**).

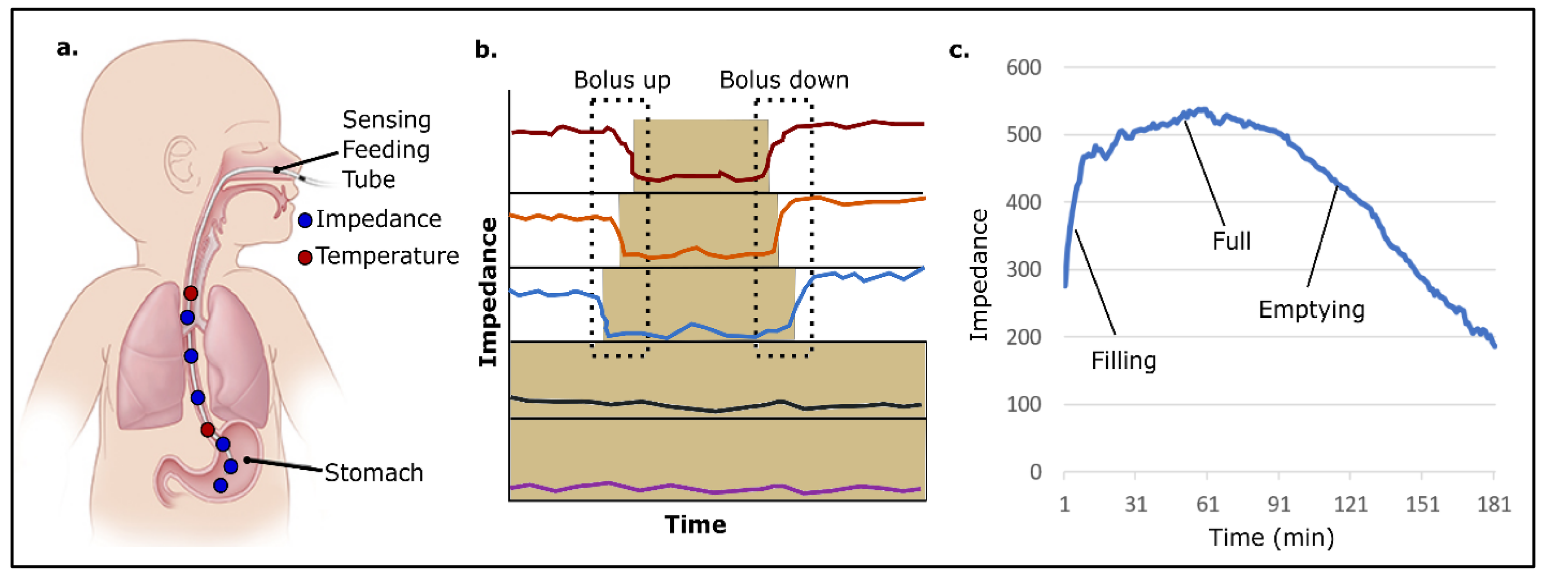

Figure 1 (a) Gravitas feeding tube calculates a Gastric Status Index based on detection of **(b)** reflux events from impedance sensors in the esophagus and **(c)** gastric impedance changes measured via sensors in the stomach.

In this retrospective pilot clinical study, eleven (n=11) neonates received enteral feeding via the Gravitas FT. These infants were following the standard 3-hour feeding cycle. Patients with ongoing gastrointestinal pathology or malformations were not enrolled. Sensor data were analyzed to identify if there were opportunities for optimal feeding.

Results

The median gestational age (GA) for the 11 babies (n=5 female, n=6 male) was 28 weeks and median post menstrual age (PMA) at enrollment 39[3] weeks. Median birth weight was 860g. All babies were on goal feeds of 160 ml/kg/day at time of enrollment.

Reflux and gastric impedance were successfully recorded throughout the 3.1±1 days of the study without any device related adverse events. The Gravitas GSI identified missed feeding opportunities where feeds could have been administered before the end of the typical 3-hour cycle (**Fig 2**).

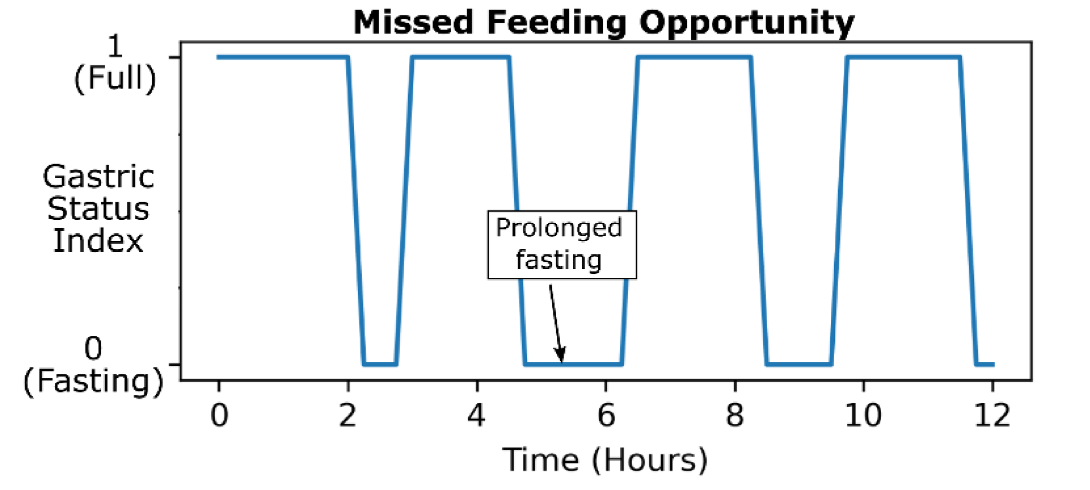

Figure 2: Missed feeding opportunities where GSI indicates prolonged fasting event

In this study, there was a wide range of feed volumes: 28 to 90ml (**Fig 3a**) with patients exhibiting reflux episodes ranging (within a single feeding cycle) from 0.07 minutes to 7.17 minutes (**Fig 3b**).

Post-prandial time to return to fasting ranged from 90-190 minutes (**Fig 3c**) highlighting the opportunity to administer feeds as needed rather than strictly adhering to the conventional 3-hour cycle. This is further supported by the duration of fasting (**Fig 3d**) which varied from <20 minutes in an ideal case (subject 5) to >60 minutes in a potentially under fed subject (subject 11).

GSI follows a characteristic emptying curve with considerable intra-subject variability observed (**Fig 3e**).

The average GSI curves show subjects with potential sub-optimal feeds such as subject 2 where it appears feeds could have been restarted at 118 minutes (**Fig 3f**). In contrast, subject 5, who received much larger feed volume remains in the near full state at 118 minutes and required almost the entire 3-hour period to reach empty.

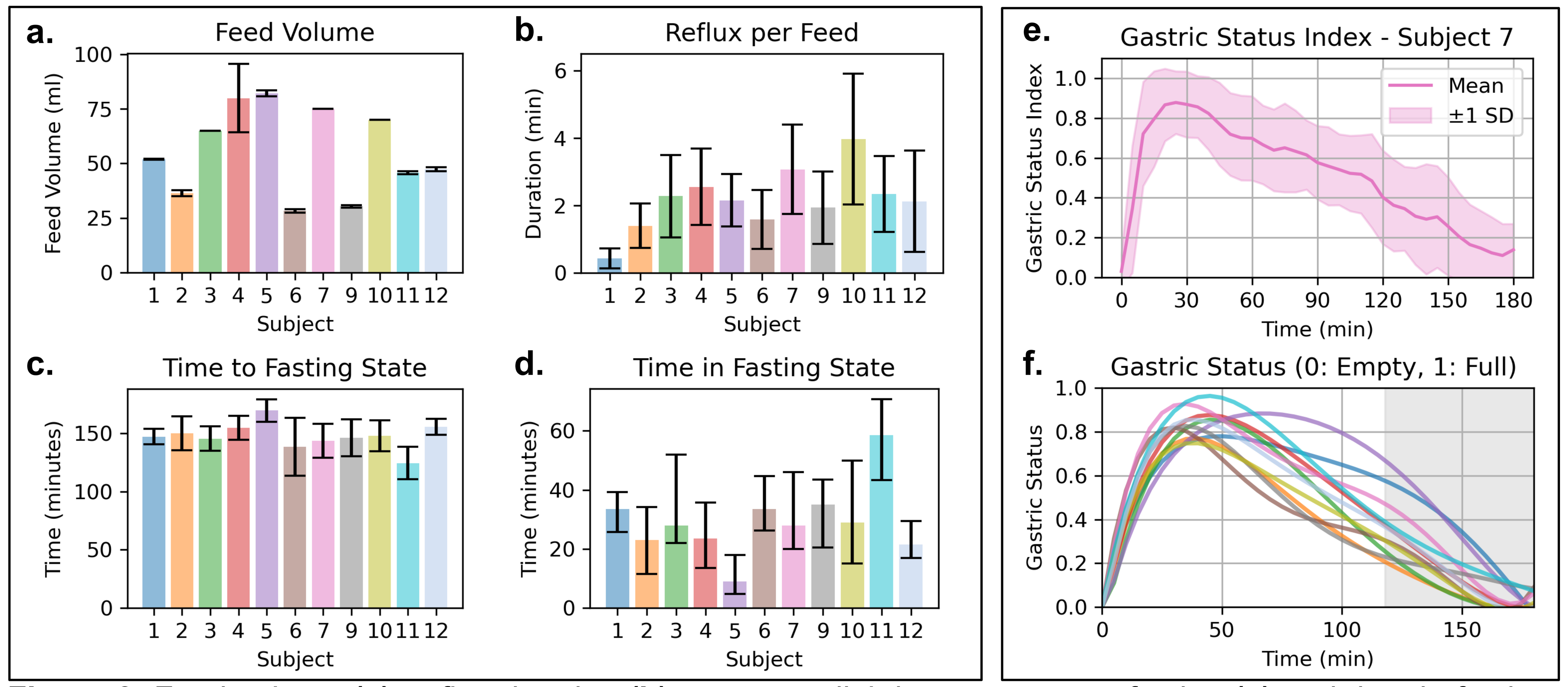

Figure 3: Feed volume **(a)**, reflux duration **(b)**, post-prandial time to return to fasting **(c)** and time in fasting state **(d)** throughout study. All data are represented as mean ± SD except d which shows interquartile range. **e** – Exemplary Gastric Status Index curve showing intra-subject variability **f** – Average Gastric Status curves for all subjects. Grey area indicates potential opportunity to restart feeds. Note subject 2 could have received feeds at 118 minutes. Subject 8 excluded due to inadequate data collection.

Conclusion

Sensor-integrated feeding tubes can monitor gastric status and have the potential to enable optimized patient-specific feeding in the NICU, potentially maximizing growth and development while minimizing the risk of feeding intolerance and unnecessary prolonged length of stay.

Future Directions

- The study device is currently being tested in a multi-site clinical trial
- Future analysis with larger sample size is required to optimize and validate the Gravitas Gastric Status Index.
- Randomized control trials will be necessary to demonstrate that availability of the Gravitas Gastric Status Index enables optimized feeding leading to improved outcomes including more rapid growth and potentially reduced length of stay.

References

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