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Background

- Intracranial hypertension (IH) is an important cause of secondary brain injury, and its association with poor outcome has been extensively demonstrated.
- Pathological IH is defined when intracranial pressure (ICP) rises persistently above 20-25 mmHg [1].
- Monitoring of ICP is invaluable in the management of these symptoms.

Approach

Vivonics, Inc. is developing a non-invasive optical device to assess ICP for use in forward clinics called **I-PASS: Intracranial Pressure Assessment and Screening System**.

- The IPASS system uses three near-infrared sensors, located on the supraorbital artery, earlobe and finger, to measure hemodynamic oscillations.
- Pulse Transit Time (PTT) [2] as measured between the supraorbital sensor and the two reference locations (earlobe and finger) provides indications of ICP changes.

Methods

Data has been collected under Institutional Review Board (IRB) and US Army Human Research Protection Office (HRPO) approval in both healthy human subjects on an inversion table (Figure 2) [3] and in a clinical study where hospitalized patients had invasive ICP monitoring.

Tilt-table Protocol

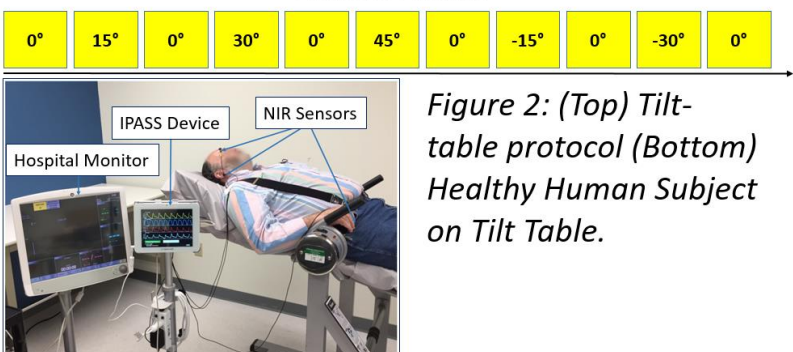


Figure 2: (Top) Tilt-table protocol (Bottom) Healthy Human Subject on Tilt Table.

Results

Tilt Table Study: Postural Influence on intracranial and cerebral perfusion pressure (CPP) were found to be consistent with our PTT calculations (Figure 3).

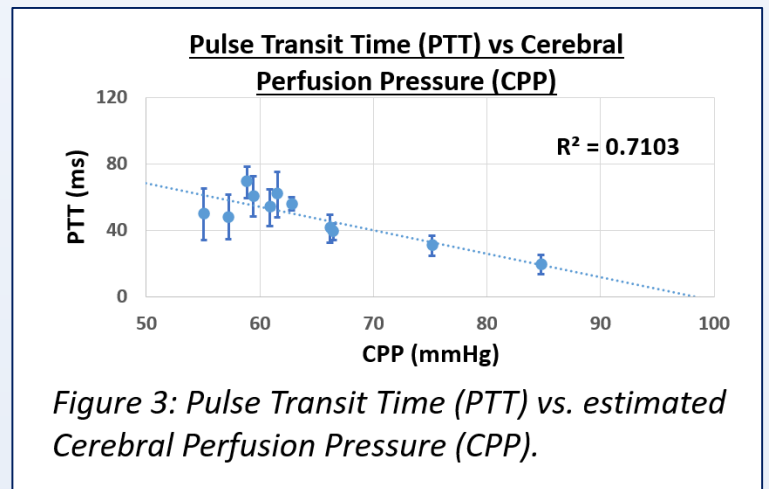


Figure 3: Pulse Transit Time (PTT) vs. estimated Cerebral Perfusion Pressure (CPP).

Clinical Study: IPASS measurements of PTT correlate with invasive measurements of ICP from hospitalized patients with diagnosed traumatic brain injuries (Figure 4).

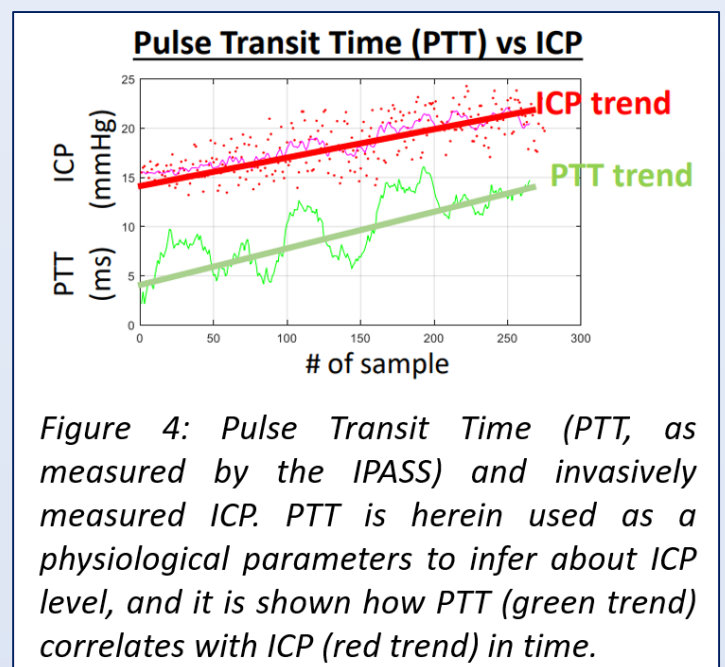


Figure 4: Pulse Transit Time (PTT, as measured by the IPASS) and invasively measured ICP. PTT is herein used as a physiological parameters to infer about ICP level, and it is shown how PTT (green trend) correlates with ICP (red trend) in time.

Conclusions

- The IPASS provided an indication of ICP trends on healthy human subjects following postural changes.
- The IPASS system showed a good degree of correlation between invasively measured ICP changes and the IPASS-estimated parameters.

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