

USE OF sEMG TO INFORM GTC SEIZURE SEMIOLOGY

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BRAIN
SENTINEL[®]

DISCLOSURES



- The Brain Sentinel® Monitoring and Alerting System received FDA de-novo clearance for marketing on February 16, 2017 and sponsored this regulatory clinical trial
- JE Cavazos and MR Girouard are co-founders and stockholders of the company
- DP Cardenas, MR Girouard, and LE Whitmire are employees of the company
- JE Cavazos and JJ Halford are consultants for the company

Overview of Multicenter, Prospective, Blinded, Comparative Trial

- Automated detection using sEMG compared to vEEG review by three independent neurologists (ABPN certified in epilepsy) to identify GTC seizures
- 11 NAEC Level IV EMUs
- 199 Subjects from the U.S. and Europe



The length of tonic and clonic phases are similar between adults and adolescents as well as 1° and 2° generalized GTCS

Phase Lengths in Adults and Adolescents

2° generalized GTC seizures	Adults (22-61) (n=19) ^a	Adolescents (8-21) (n=7) ^b	ANOVA
Length of Tonic Phase (s)	16.5	14.3	0.50
Length of Clonic Phase (s)	39.7	46.0	0.21
Length of Tonic-Clonic Phases (s)	52.2	54.7	0.66

^a Nineteen adult subjects experienced a total of 21 2° generalized GTC seizures.

^b Seven adolescent subjects experienced a total of 18 2° generalized GTC seizures. Each subject contributed once to the average median length of each phase. Median values were calculated for subjects with replicate data.

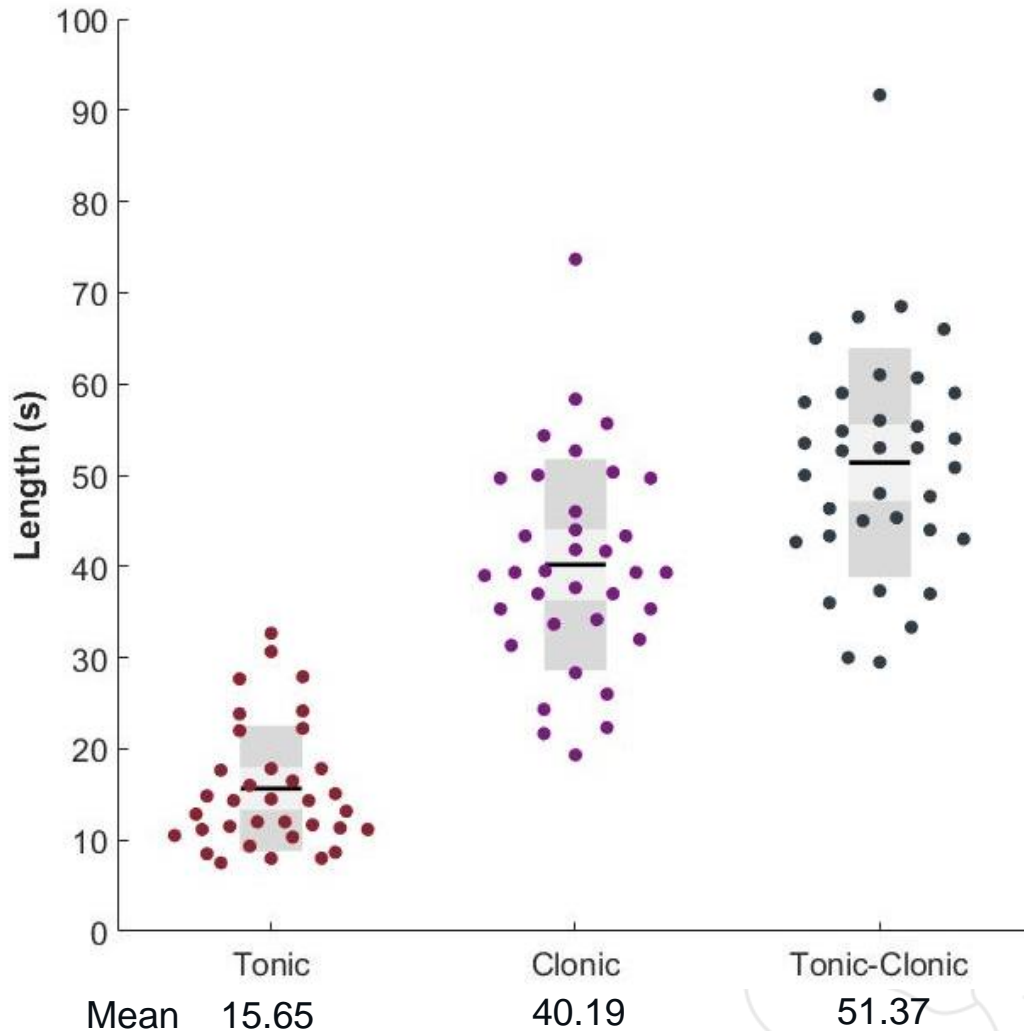
Phase Lengths in 1° and 2° Generalized GTC

	Primary Generalized (n=9) ^a	Secondary Generalized (n=26) ^b	ANOVA
Length of Tonic Phase (s)	12.8	14.4	0.71
Length of Clonic Phase (s)	39.3	39.3	0.31
Length of Tonic-Clonic Phases (s)	50.8	52.8	0.22

^a Nine subjects experienced a total of 17 1° generalized GTC seizures.

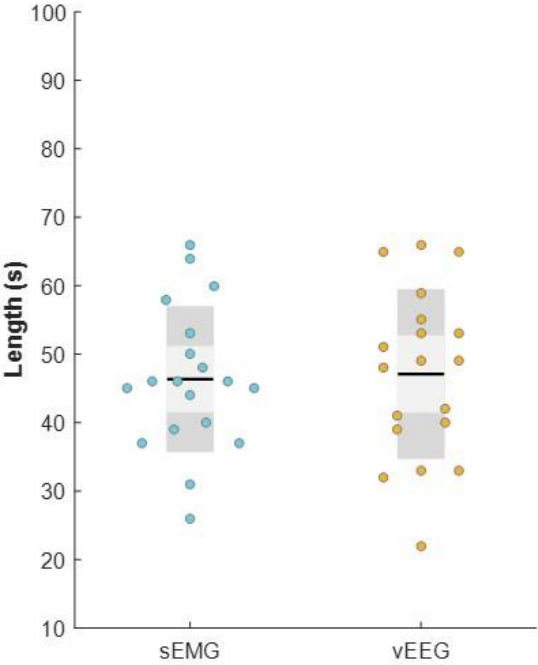
^b Twenty-six subjects experienced a total of 39 2° generalized GTC seizures. Each subject contributed once to the average median length of each phase. Median values were calculated for subjects with replicate data.

The average length of tonic-clonic motor activity of GTC seizures was 51 seconds



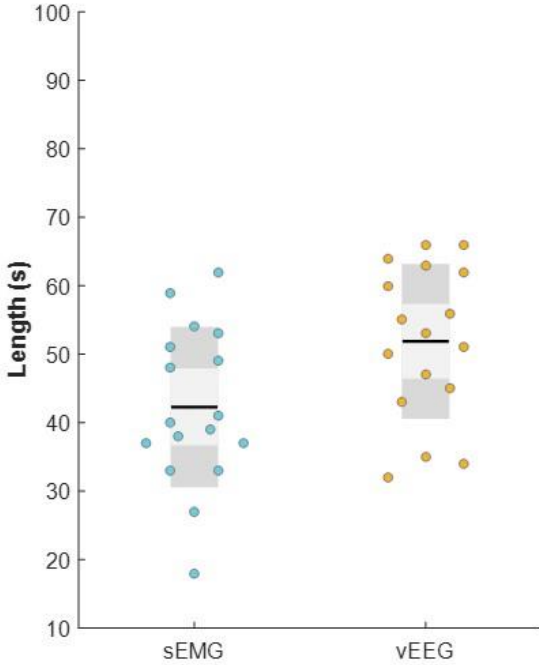
Length of tonic-clonic duration are similar by vEEG or sEMG

Epileptologist A



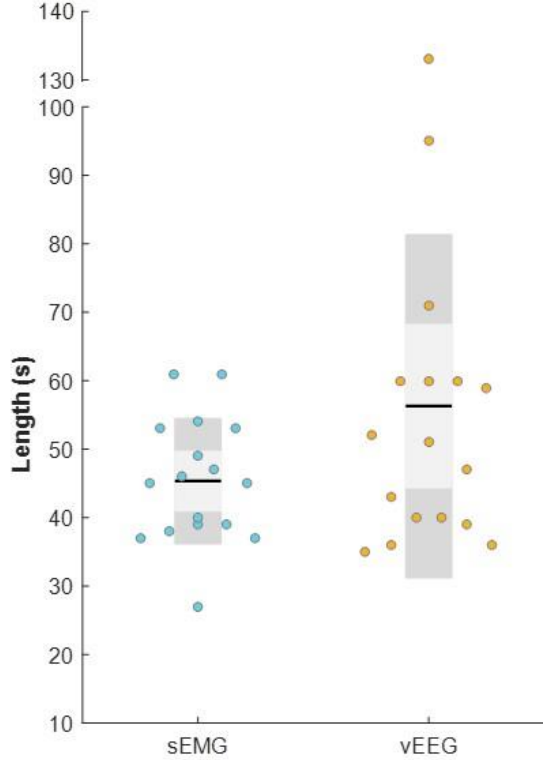
Paired t-test
P = 0.72

Epileptologist B



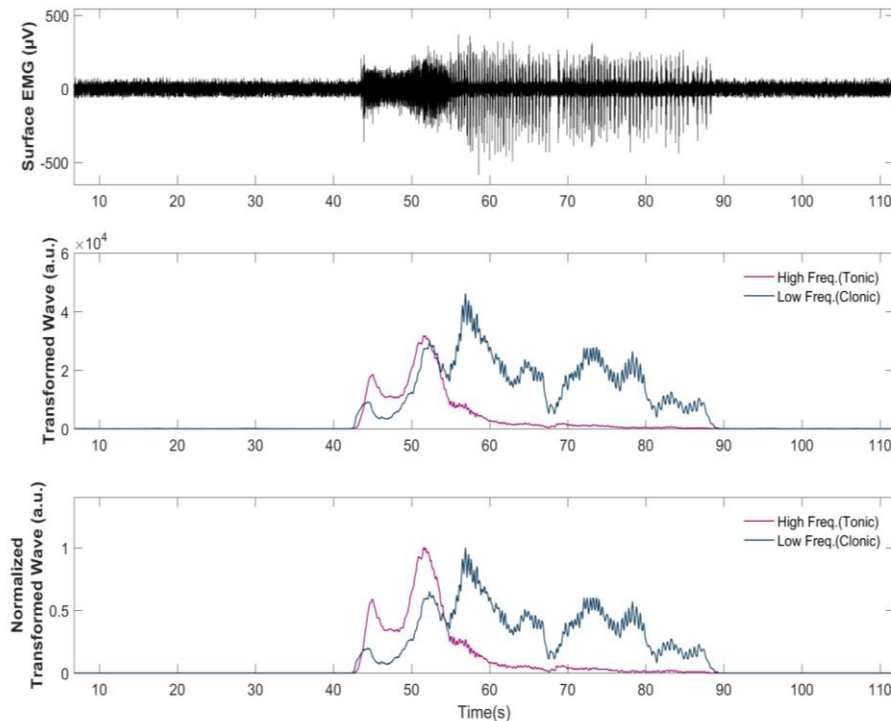
Paired t-test
P = 0.009

Epileptologist C



Paired t-test
P = 0.08

On the Horizon – Frequency and amplitude analysis to quantify length of tonic and clonic phases

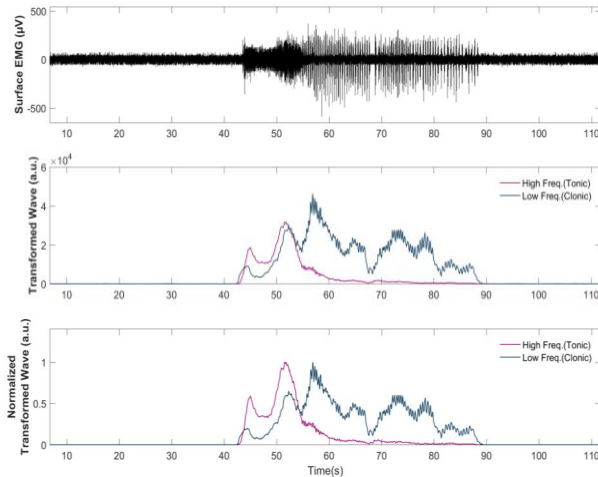


- Raw sEMG is broken down into 2 frequency range bins using the output from wavelet-transform operation show in the middle and bottom plots
- Frequency bins were selected to emphasize the difference between tonic (high frequency, pink) and clonic (lower frequencies, blue) phases of GTC seizures
- The bottom plot is scaled to highlight the transition from tonic to clonic phase for a GTC, and is meant to augment physician's review of sEMG data

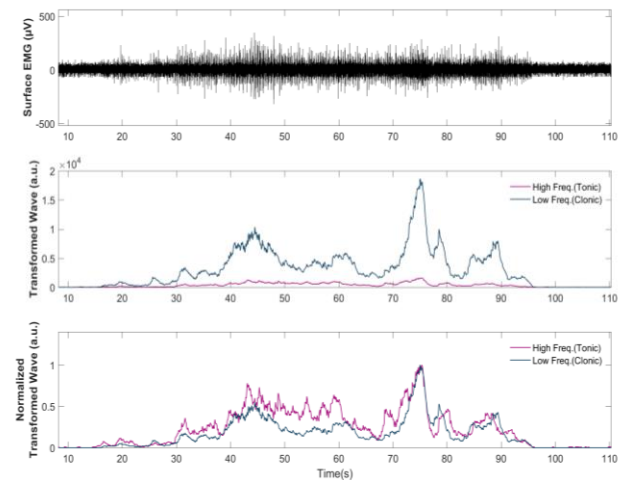
Differentiating PNES from GTC using single channel sEMG

- This data processing technique has been applied to GTC seizures and other seizure or seizure-like events, particularly psychogenic non-epileptic spells (NES)
- High frequency sEMG is associated with the tonic phase of GTC seizures and less prevalent in PNES than GTC seizures
- The middle plot, or unscaled frequency-transformed waves, best elucidates this case

GTC



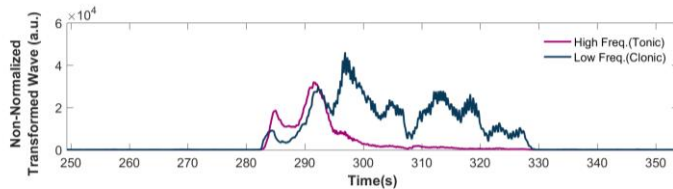
PNES



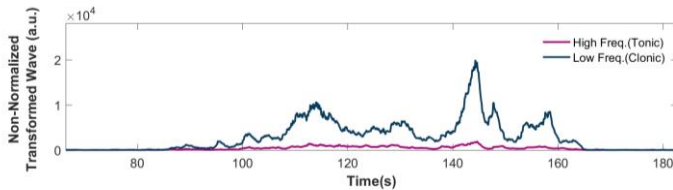
AUC Analysis – PNES vs. GTC

- Using an area under the curve (AUC) analysis of the frequency bin components provides a mechanism for quantitative evaluation
- The ratio of the AUC for both the high frequency and low frequency ranges were statistically different ($P < .01$) between GTCS and PNES

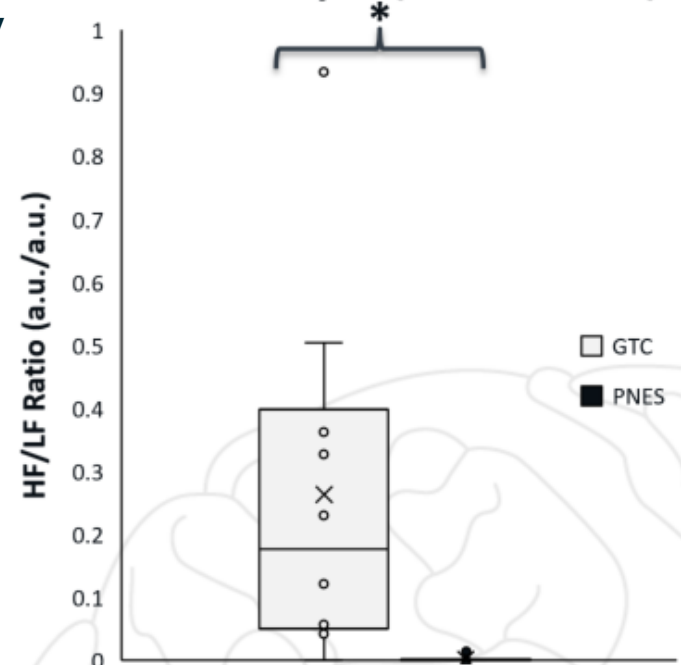
GTC



PNES



AUC Ratio Analysis (GTC vs. PNES)



* - PNES data is significantly different ($P < .01$) from GTC for AUC analysis (n = 10 events)

SUMMARY



- The Brain Sentinel® Monitoring and Alerting System detected 100% of GTC seizures when properly placed
- The length of tonic and clonic phases are similar between adults and adolescents as well as 1° and 2° generalized GTCS
- The average length of tonic-clonic motor activity of GTC seizures was 51 seconds
- Length of tonic-clonic duration are similar by vEEG or sEMG

➤ May be able to differentiate PNES from GTC using single channel sEMG

