



# 2015 Science Writers Symposium

## Investigating the Early Detection of Traumatic Brain Injury

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**FDA**

U.S. Department of Health and Human Services  
U.S. Food and Drug Administration

# Facts about Traumatic Brain Injury (TBI)

- Traumatic brain injury (TBI), a form of acquired brain injury, occurs when a sudden trauma causes damage to the brain.

*<http://www.ninds.nih.gov/disorders/tbi/tbi.htm>*

- Each year in the United States, there are more than 1.5 million TBIs, resulting in 50,000 deaths.

*Corrigan, J.D. et al. 2010 J. Head Trauma Rehabil.*





# Diagnosis of TBI

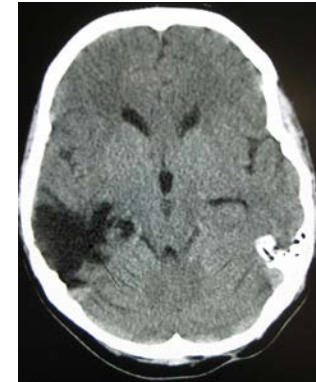
## ***How is TBI diagnosed?***

Clinical Exam and CT Scan

## ***Why is early diagnosis important?***

To prevent repetitive injury

To develop new therapeutics



*Advance the development of neurodiagnostic medical devices for head injury*

## ***What diagnostic methods are under investigation?***

Imaging

Biofluid

EEG (Electroencephalography)



# Advantages of EEG as a Biomarker

**Noninvasive**

**Inexpensive**

**Fast**

**Portable**

**Field-deployable**

**Research goal: To investigate the use of EEG to detect brain injury in a small animal model.**

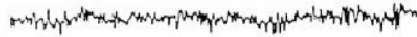
# EEG



Recording of neural electrical activity along the scalp

## Resting State

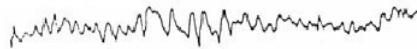
Beta - highly alert



Alpha - relaxed



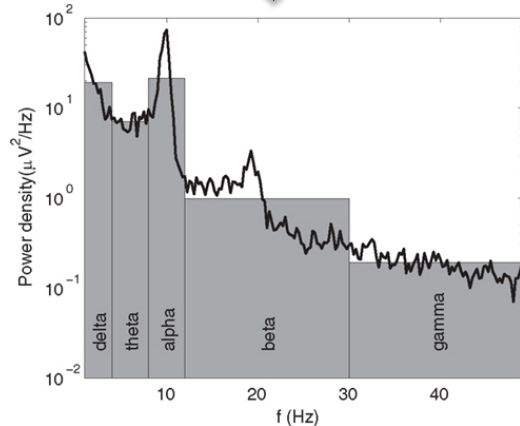
Theta - drowsy



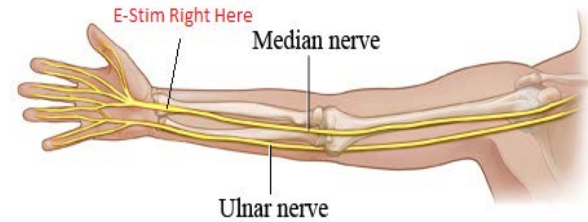
Delta - deep sleep



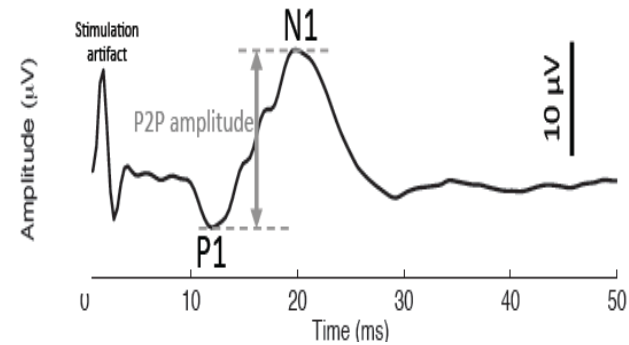
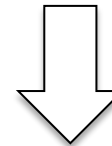
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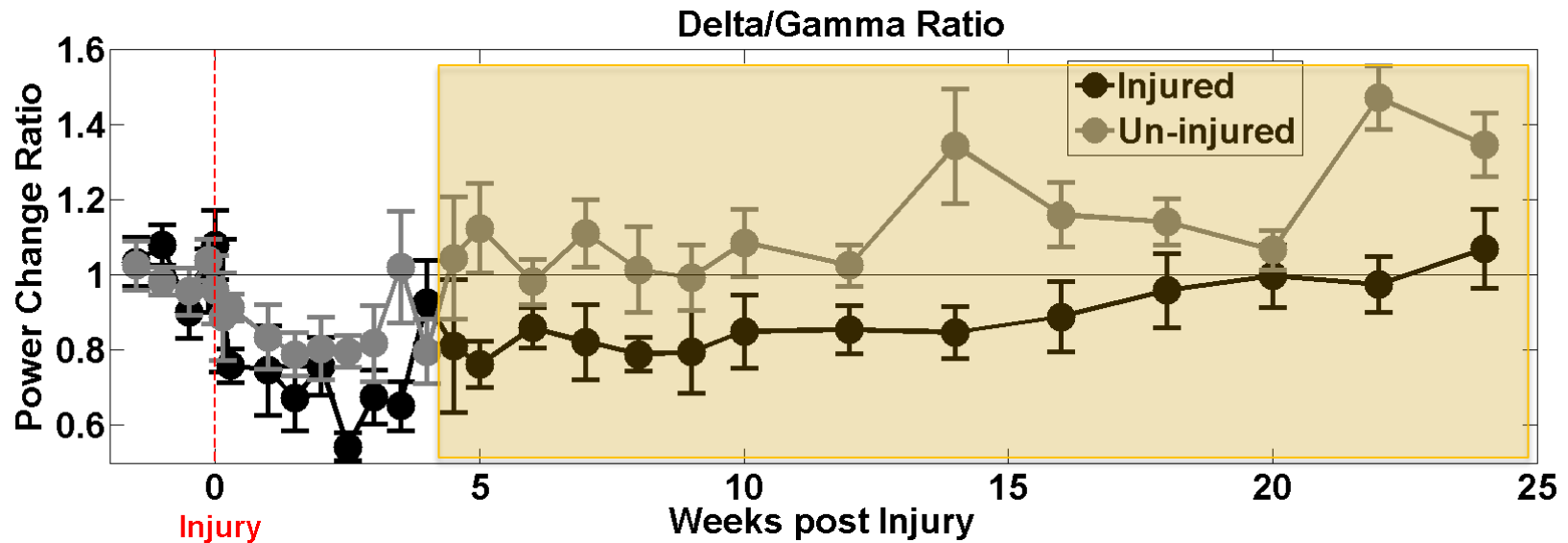
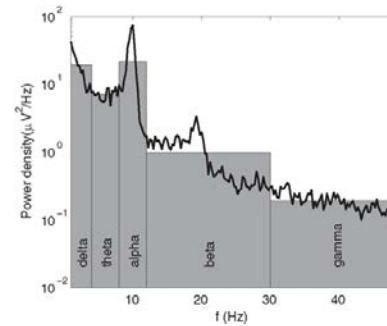
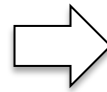
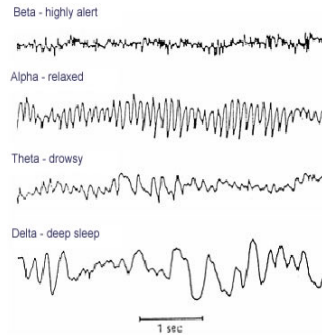
## Sensory Evoked Potential (SEP)



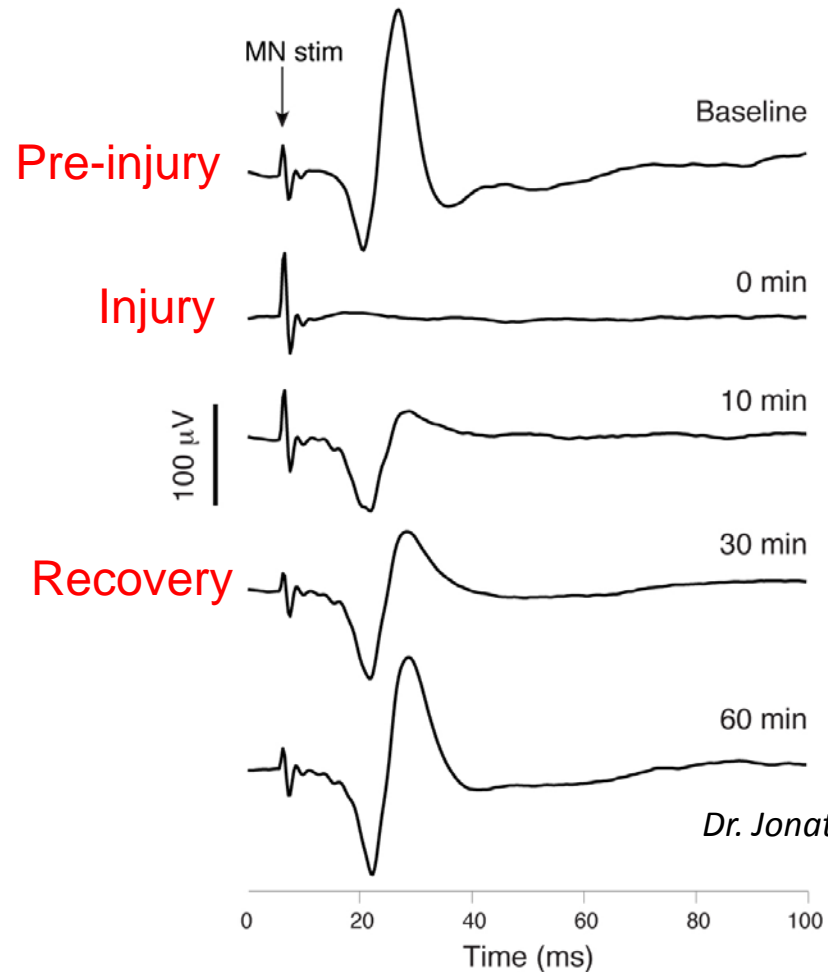
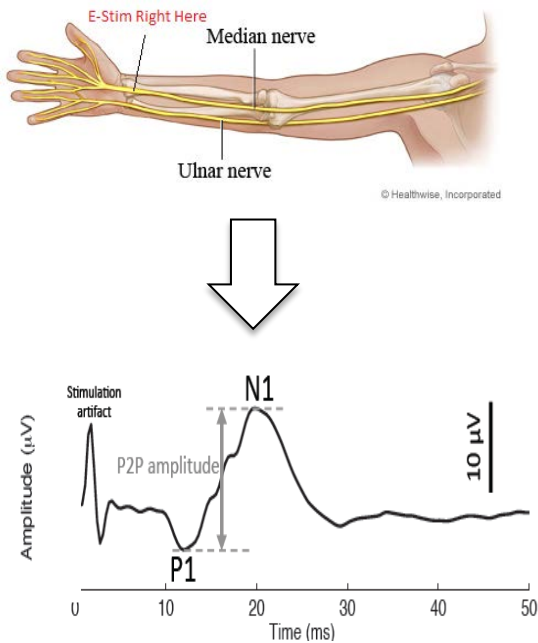
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# EEG: Resting State

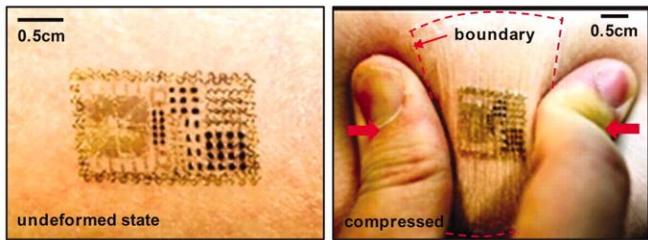


# EEG: Sensory Evoked Potential (SEP) Through Median Nerve Stimulation



*Dr. Jonathan Fisher*

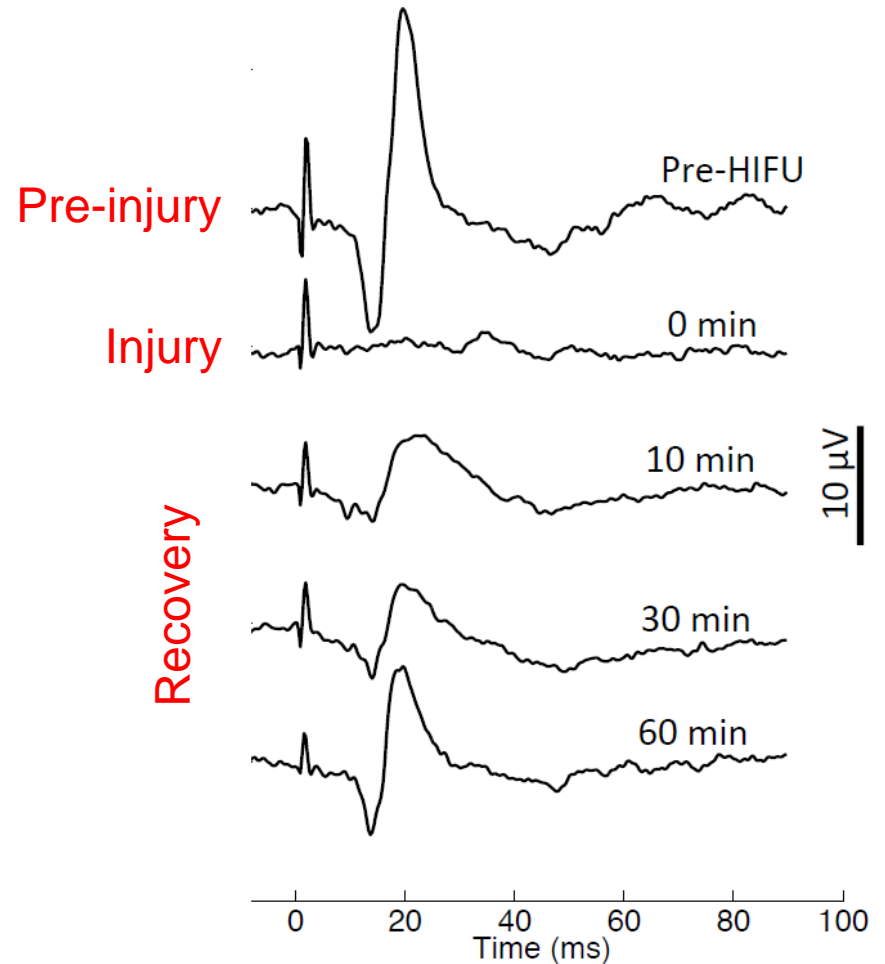
# Novel Flexible Epidermal EEG Electrodes



*Dae-Hyeong Kim et al. Science 2011*



*Dr. Stanley Huang, in collaboration with Dr. Todd Coleman in UCSD*







# Take-Home Messages

- EEG can detect brain injury: short-term SEP reduction and long-term delta/gamma ratio reduction.
- Novel flexible epidermal electrodes have the sensitivity to detect SEP changes after brain injury.
- Regulatory science at CDRH can contribute to the TBI scientific community and efforts to develop diagnostic devices for TBI.



## Next Steps

- Use SEP and resting state EEG to detect *impact* brain injury in a small animal model.
- Start clinical investigations in military service members with brain injury in 2016; in collaboration with Walter Reed National Military Medical Center and Uniformed Services University of the Health Sciences.
- Refine epidermal electrode design, in collaboration with University of California, San Diego.



# Acknowledgements

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