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Identifying Engineering, Clinical and Patient's Metrics for Evaluating and Quantifying Performance of Brain- Machine Interface Systems

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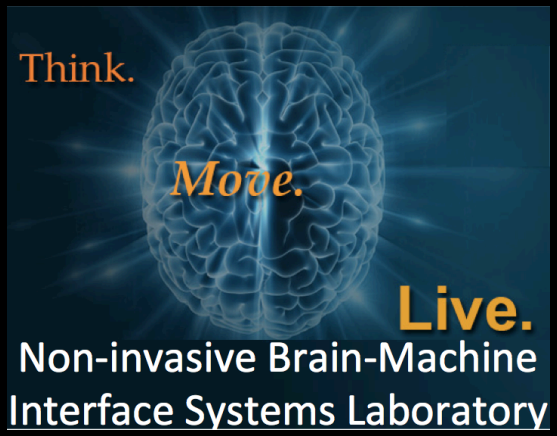

Methodist NIH Department of Veterans Affairs NSF NASA Mission Connect a project of TIRR Foundation TIRR MEMORIAL HERMANN Rehabilitation & Research

Challenges in Closed-loop BMI/BCI systems

Translation of closed-loop BMI devices from the laboratory to the market is challenged by:

- **Gaps in scientific data regarding long-term device reliability and safety (risk-benefit)**
- **Uncertainty in the regulatory, market and reimbursement pathways**
- **Lack of cost-benefit analysis**
- **Lack of metrics for evaluating and quantifying performance in BMI systems**
- **Patient- acceptance challenges that impede their fast and effective translation to the end user**

Proposed Metrics

International Classification of Functioning, Disability and Health (or ICF)

- International standard to describe and measure health and disability
- Describes changes in body function and structure, and
- Domains of activity and participation

1. What a person with a health condition can do in a standard environment (their level of capacity)

2. What they actually do in their usual environment (their level of performance).

http://www.who.int/classifications/icf/en/

Proposed Metrics

System Usability Scale (SUS)

- "quick and dirty", reliable tool for measuring the usability of a wide variety of products and services, including hardware, software, mobile devices, websites and applications.
- Industry standard
- 10-item questionnaire with five response options: from Strongly agree to Strongly disagree.
- Easy to administer
- Can be used on small sample sizes with valid and reliable results

http://www.usability.gov/how-to-and-tools/methods/system- usability-scale.html

Proposed Metrics

The Technology Readiness Levels (TRL)

- Used to assess the maturity level of a particular technology
- There are nine technology readiness levels (TRL 1-9)
- Safety strategy input is required early in the project life cycle as part of the technology development process.

http://www.nasa.gov/content/technology-readiness- level/#.U0_oza1dUcw

Proposed Metrics

Clinical Metrics must consider:

- Determination of the neurological profile of individuals who are capable of using a specific BMI device.
- Determination of the incidence of adverse effects in the use of the BMI system.
- Determination of the extent of mobility or function achieved by the use of the BMI system.
- Determination of any measurable health benefits with the use of the BMI system.
- Determination of improvement of quality of life with the use of the BMI system.

Engineering Metrics

- Reliability metric: The operational system availability, addresses the continued dependence of the patient on the neural interface for the execution of ADLs.
  - To assess how reliably and robustly a user through a closed-loop BMI can operate a wearable prosthetic.
  - It should be assessed on the complete system (including the patient in the loop), although reliability of system components may also be useful for inter-operability in modular designs.

- Availability metric: It reflects the probability that the system will operate satisfactorily at time *t* when called upon for use.
  - Total system up time divided by the total operating hours.

- Physics-of-failure analysis with respect to expected life cycle stresses & lifetime of the system

Factors in evaluating BMI performance

- Clinical population
- Experimental protocol, including testing conditions
- Evaluation metrics
- Source signals (EEG, NIRS, ECoG, LFP, spikes, etc)
- Use or degree of shared control
- Number of electrodes (or features)
- Feedback modality used
- Length of training
- Type of decoding (neural classification vs. continuous time trajectory decoding, etc.)

'Typical' BMI metrics

- Information transfer rate (ITR, bits/sec)
- Decoding accuracy
  - Pearson's correlation coefficient [13]
  - Signal to noise ratio (SNR)
  - Error rate (ER): percentage of the runs where a target is missed (a target could be missed because either a time limit expired or a false target was selected).
  - ISO 9241, part 9 standard for testing pointing device performance and user assessment
- Classification rates, confusion matrices, sensitivity and specificity
- Neural tuning or neural adaptation to BMI use.

Limitations of ITR (cf. Speirer et al)

- Conditional probabilities for selection sequences have not been reported (e.g., for BCI spellers)
- Information about types of errors in BCI for communication are not used to improve their selection (errors are either ignored or deleted; time outs in 2D BCIs limit quantification of performance)
- Task constraints or 'shared control' are usually not factored in the quantification of BMI performance,
- it is unclear how low the ITR would need to be in order to understand the BCI output.
- ITR assumes that there is only one information channel that can be used to extract information from the brain

Neural tuning or adaptation:

- Metrics that examine how each neuronal unit (or electrode, or region of interest) modulates its firing rate (or neural activity) with respect to discrete and/or continuous states across sessions in BMI longitudinal studies are likely to provide the most useful information.
- Source analysis
- “Spectrome” metric
- Amplitude modulation metric

Enduser (patient) metrics

- Different clinical populations such as stroke, amputees or SCI patients might prioritize differently their needs, challenges, and have different benefit/risk profiles.

  e.g., in terms of accepting a certain degree of invasiveness in the BMI system, Functional capabilities, or a desired operating speed of the device.

- Patients also evaluate BMI devices in regard to usability (e.g., maintenance requirements, set-up time, cosmesis, etc.), functional gains as well as other psychological factors that influence patient's acceptance of the technology.

- Likert scales

BMI devices have unparalleled potential to restore functional movement capabilities to stroke, paralyzed and amputee patients

Case Study: NeuroRex

Spinal cord injury patient

BMI-exo metrics for paralyzed patients

- Incidence of adverse events associated with use of the system
  - Instability and falls
  - Injury to skin, joints and muscles
  - Pain and fatigue
  - Hypo- or hypertension
  - Arrhythmias

- Degree of mobility that can be achieved:
  - Standing from a sitting position (time to complete action);
  - Walking in a straight line (6 or 10 minute walk)
  - Turning right and left (modification of the 6 m and 10 m walks)
  - Navigating obstacles (time, number of errors)

BMI-exo metrics for paralyzed patients

- Health and quality of life due to training with NeuroRex:
  - Muscle strength, sensory function (ASIA motor and sensory examination,
    ASIA Impairment Score (AIS)
  - Cardiovascular Function (blood pressure and orthostatic hypotension)
  - Pulmonary Function (test of forced vital capacity)
  - Spinal Cord Independence Measure (SCIM), bowel, bladder and autonomic functions
  - Health, Quality of Life (Standardized Test: SF-36)
- ADLs, cognitive effort, multi-tasking capabilities
- Incorporation to sense of self (body image): Likert Scale

BMI-exo metrics for paralyzed patients

- Changes in scalp EEG due to NeuroRex use
  - Neural adaptation
  - Decoding accuracy
  - Source analysis
  - Usability
  - Effects of artifacts as a function of session
- Analysis of Failures
  - Neural, electromechanical, skin conditions, physical interface
- Risk-Benefit Ratio
- Cost-Benefit Ratio

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Non-invasive Brain-Machine Interface Systems Lab

Long-term reliability of closed-loop BMI/BCI systems is unknown

- Patient's internal states (e.g., fatigue, medication, stress, aging, health status, etc.)
- Non-stationarity of the brain signals used for decoding
- Learning effects
- Degradation of wearable prosthetics/orthotics
- Environmental changes

Critical needs:

- Analysis of failures of patient-in-the-loop system
- Long-term signal stability
- Prognosis of human-machine system
- Larger sample of subjects (reliable biometrics)

Standard metrics for evaluation & comparison of BMI/BCI systems are lacking

Combination of engineering, clinical, and end-user metrics:

(cf. Contreras-Vidal, Identifying Engineering, Clinical and Patient's Metrics for Evaluating and Quantifying Performance of Brain- Machine Interface Systems, SMC 2014)

- International Classification of Functioning (ICF)
- Reduction of secondary complications
- ADLs, cognitive effort, multi-tasking capabilities
- Incorporation to sense of self (body image)
- Usability
- Psychosocial (well-being)
- Cost

Closed-loop BMI/BCI systems

- Motor (efferent BMI), sensory (afferent BMI) or cognitive (memory, decision-making, emotion BMI)

Closed-loop BMI devices can have multiple benefits:

- Diagnostic and device self-tuning applications
- Therapeutic benefits across multiple physiological systems (e.g., gait, bladder, cardiovascular, bone, psychological)
- Assistive (e.g., for tetraplegia/paraplegia)
- Augmentation of function
- Reverse engineering the brain (reverse translational)