State-of-the-Art BCI Device Technology

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STATE OF THE ART PATIENT BCI SOLUTIONS (CORTICAL INVASIVE AND NONINVASIVE, PERIPHERAL)

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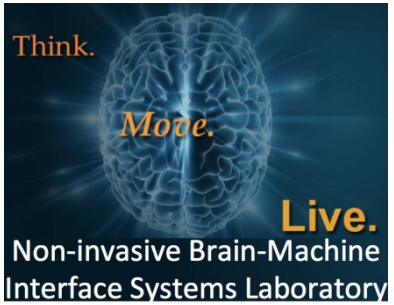
http://www.ee.uh.edu/faculty/contreras-vidal
https://www.facebook.com/UHBMIST



Scope

- "*Neuroprostheses that interface with the central or peripheral nervous system to restore lost motor or sensory capabilities*" (FDA's working definition of BCI)
- BCI Devices for Patients with Paralysis and Amputation
- Cortical (invasive and noninvasive) and Peripheral
- Human investigational studies of BCI devices reported in *clinicaltrials.gov*

Working definition of BCI systems

Neural interface –

Recording electrode

1

3

Prosthetic, exoskeleton, robotic or virtual effector

(usually + shared control)

2

Feedback system –

Neural stimulator

Closed loop

Sensor – response system

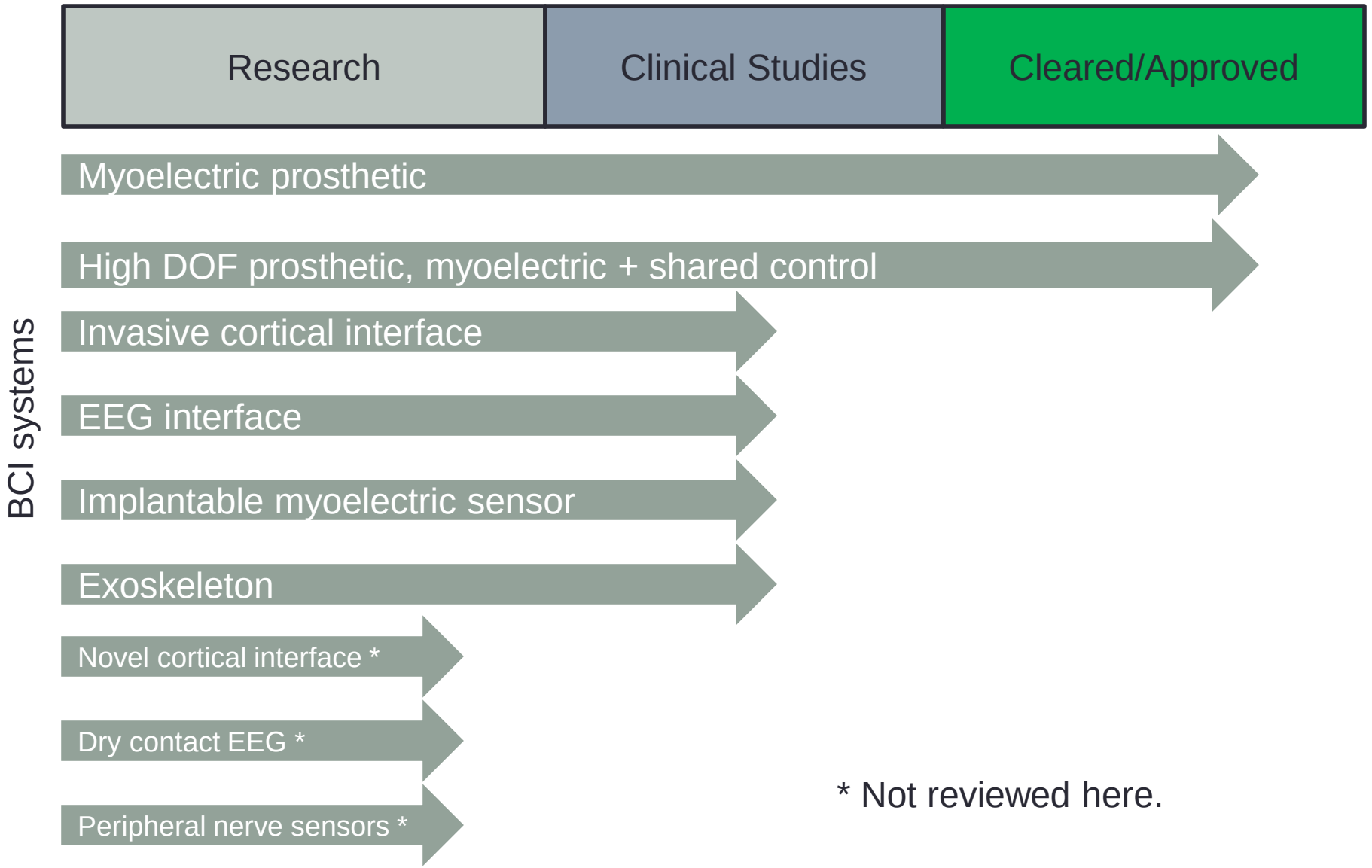
Definitions:

1 – interface, physical/virtual effector

2 – interface, physical effector feedback

3 – interface, feedback

Neural Interface to prosthetic, exoskeleton, robotic or virtual effector (definition 1)



* Not reviewed here.

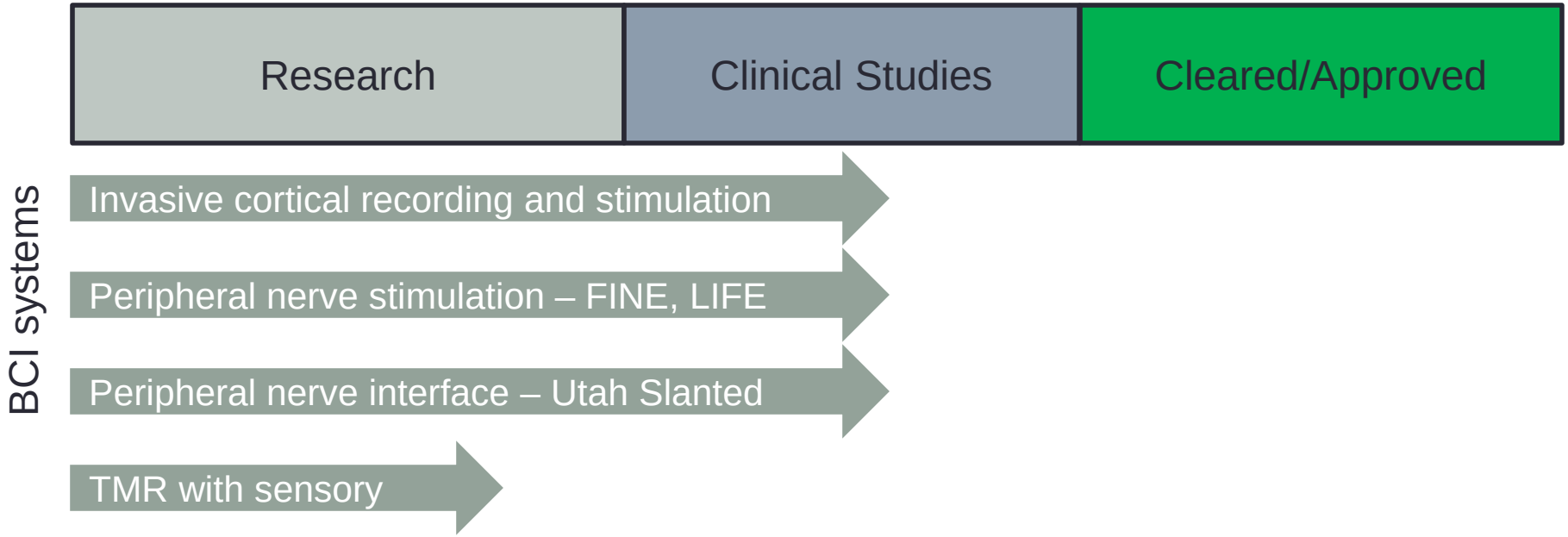
Neural Interface to prosthetic, exoskeleton, robotic or virtual effector (definition 1)

Related Technology – NOT BCI systems

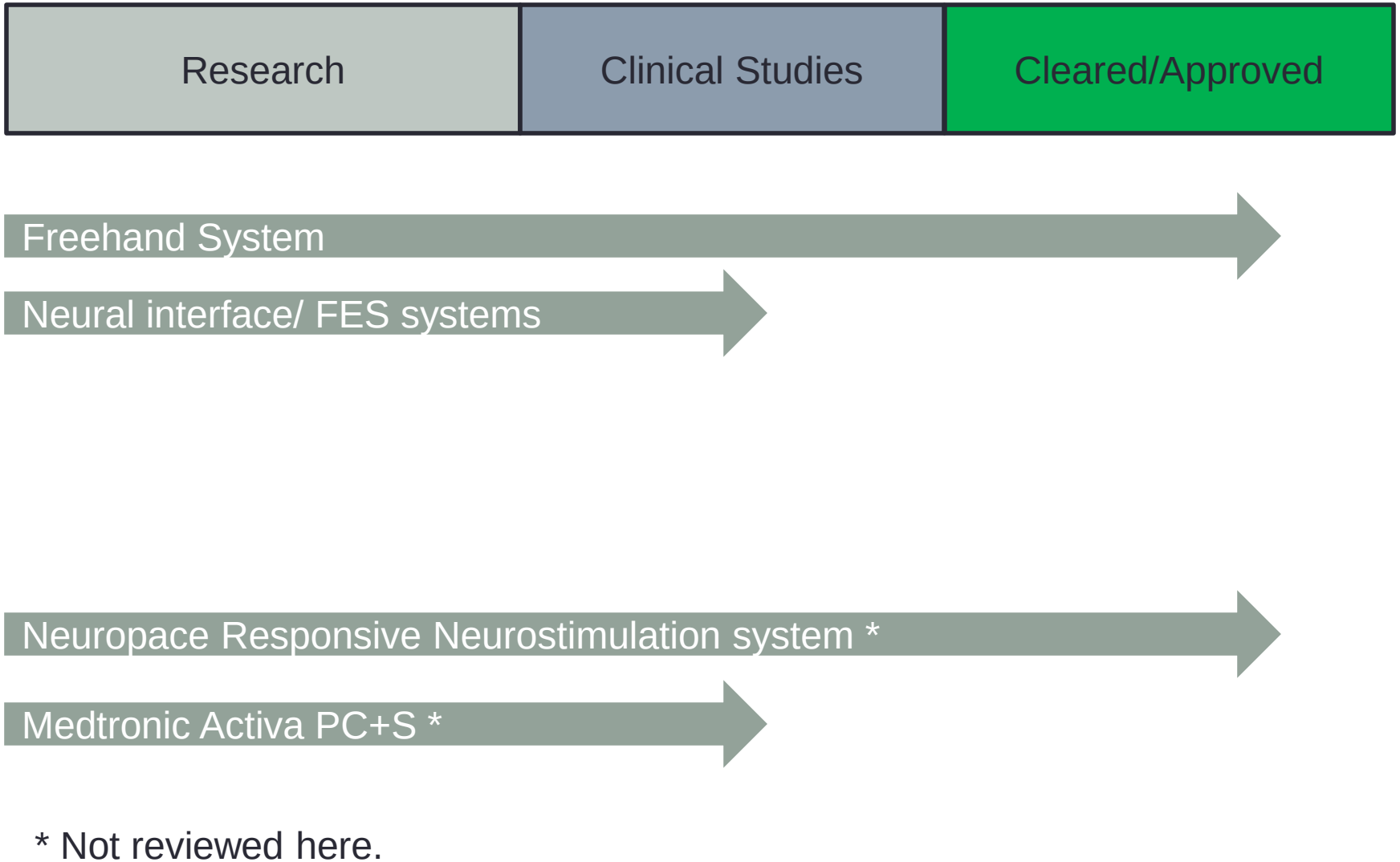
- Cortical and depth electrodes
- Conventional EEG *
- Cutaneous electrodes (EMG)
- EEG-based assessment aid *

* Not reviewed here.

Neural Interface to prosthetic, robotic or virtual effector with sensory feedback (definition 2)



Closed loop sensor-response system (definition 3)



* Not reviewed here.

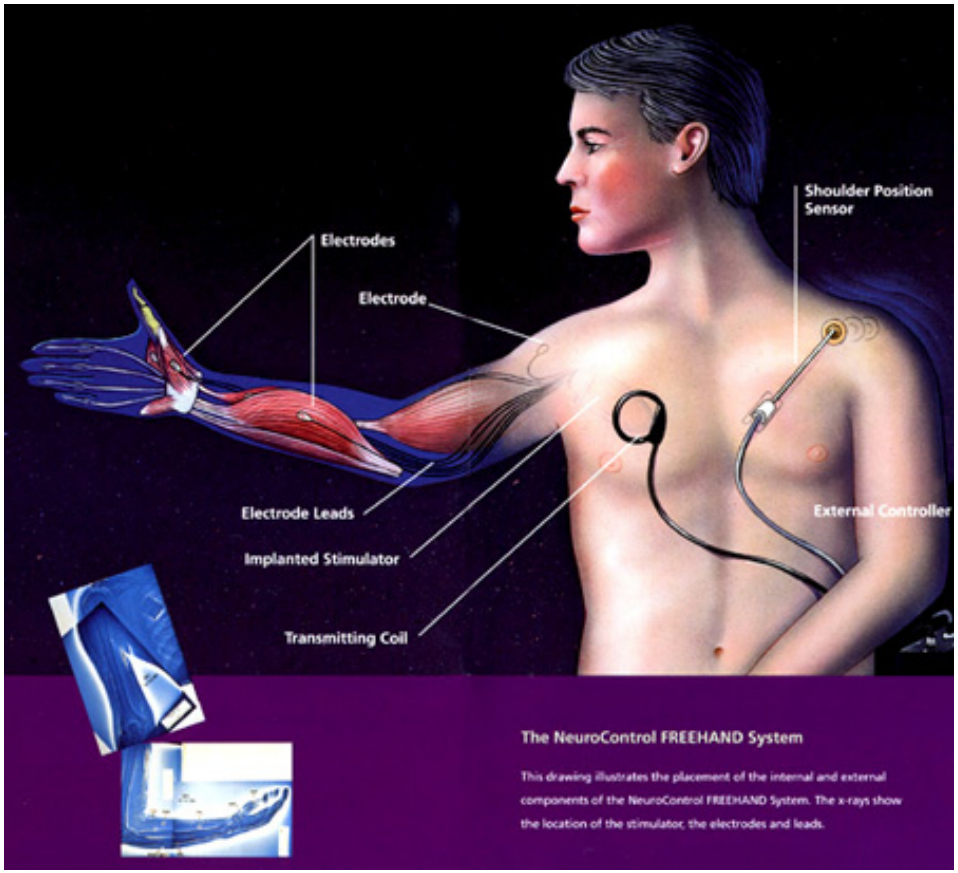
Marketed BCI systems

Sensor – Response system (Definition 3)

- Neurocontrol Freehand system – Implanted functional electrical stimulation (P950035 (8/1997), GZC) (Currently not marketed)

Surgically implanted neuroprosthesis that restores hand function in people with quadriplegia @ C5/C6 levels by neuroelectric stimulation of forearm and hand muscles.

Shared control (intent via shoulder mvts; palmar & lateral grasps via shoulder button)



http://www.scireproject.com/rehabilitation-evidence/upper-limb/neuroprostheses/types-of-neuroprostheses/freehand-system

Marketed BCI systems

Neural electrode to effector (Definition 1)

- Myoelectric prostheses (GXY)
  - Otto Bock Dynamic Arm (K032833; K123795)
  - Touch Bionics i-limb (IQZ)
  - RSL Steeper Bebionic
  - Motion Control Pro Hand System (IQZ)

Product codes

GXY: Cutaneous electrode

IQZ: Hand, External Limb Component, Powered

http://www.ottobockus.com/prosthetics/

http://www.touchbionics.com/products/active-prostheses/i-limb-ultra/

http://bebionic.com/the_hand

http://www.utaharm.com/motion-control-electric-hand-terminal-device.php

Marketed BCI systems

Neural electrode to effector (Definition 1)

- Upper extremity prosthesis w/multiple simultaneous dof (PAE)
  - Deka arm system (K121215; DEN120016; de novo (5/2014))
  - Shared control:
    - EMG electrodes
    - Foot switches
    - Force sensors
    - Movement sensors

http://www.dekaresearch.com/deka_arm.shtml

Clinical BCI systems

Neural electrode to effector

Invasive cortical sensors

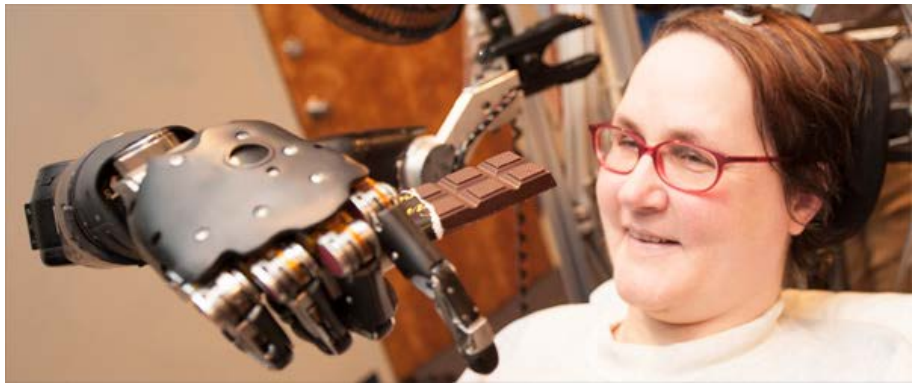
- **Blackrock NeuroPort**

  Brown, MGH (NCT00912041)

  U Pittsburgh (NCT01364480)

  Chronic implantation

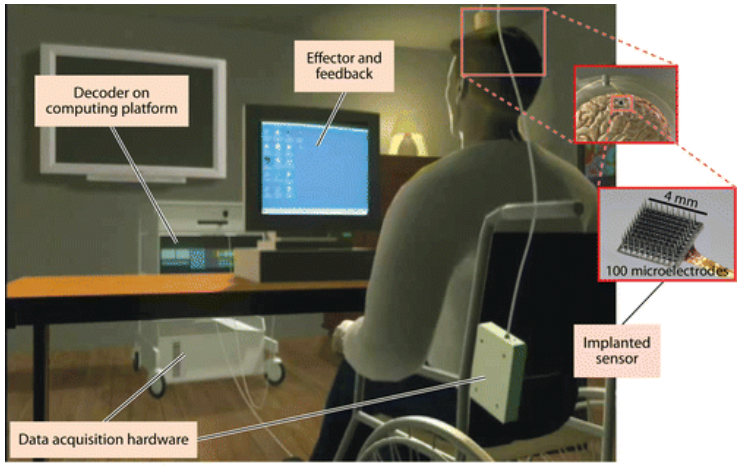
  Tetraplegic patients



- **Micro ECOG**

  < 30 days (U Pitt; (NCT01393444))

  Tetraplegic patients



Homer ML, et al. 2013.
Annu. Rev. Biomed. Eng. 15:383–405

http://www.braingate.com/
http://www.ncbi.nlm.nih.gov/pubmed/23253623
http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0055344

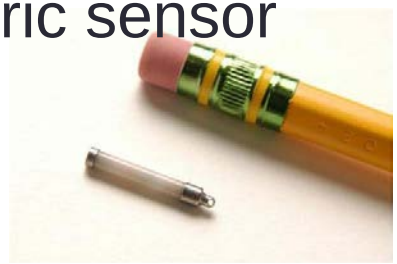
Clinical BCI systems

Neural electrode to effector

- Advanced wearable neuroprostheses/orthotics
  - Johns Hopkins University/Applied Physics Lab Modular Prosthetic Limb (MPL)
  - Virtual Integration Environment (VIE): soft MPL
  - Powered exoskeleton (K131798; PHL, de novo)
  - Multiple signal sources

MPL

- Implantable myoelectric sensor
  - IMES – Alfred Mann



IMES

BMI-REX

EMG-HAL

http://www.jhuapl.edu/prosthetics/scientists/mpl.asp
http://aemf.org/our-research/current-focus/limb-loss/
http://www.cyberdyne.jp/english/products/LowerLimb_medical.html
http://www.rexbionics.com

Clinical BCI systems

Neural electrode to effector

Highlights from clinicaltrials.gov:

Implanted Myoelectric Control for Restoration of Hand Function (Case Western U; NCT00583804)

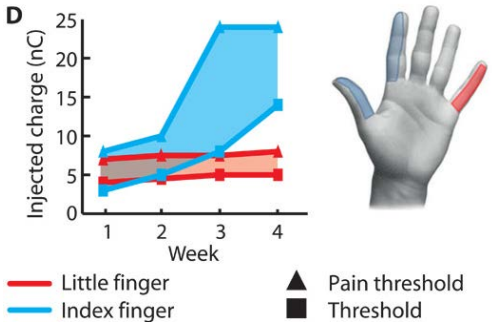
MAHI Exo-II – EEG based exoskeleton (U Houston; NCT01948739)

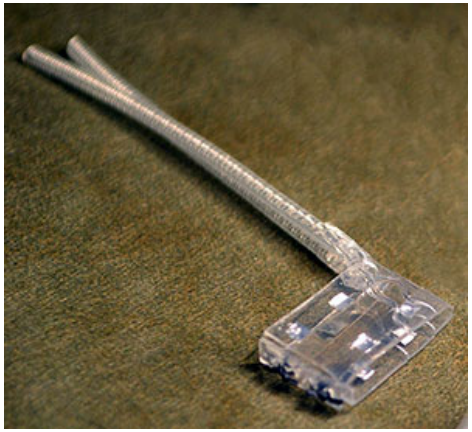
Cortical Recording and Stimulating Array Brain-Machine Interface (U of Pittsburgh; NCT01894802)

Clinical BCI systems

Sensory feedback

- Cortical recording and stimulating array – NeuroPort for recording and stimulating (California Institute of Technology; NCT01964261)
- Flat Interface nerve electrode (FINE) Case Western Reserve
- Longitudinal Intra-Fascicular Electrode (LIFE) - École polytechnique fédérale de Lausanne EPFL
- Utah Slanted Electrode array – acute implantation (University of Utah)
- Targeted sensory reinnervation





FINE

http://www.clinicaltrials.gov/ct2/show/NCT01964261?term=neuroport&rank=1
http://www.technologyreview.com/news/522086/an-artificial-hand-with-real-feelings/
http://www.ncbi.nlm.nih.gov/pubmed/24500407
http://www.clinicaltrials.gov/ct2/show/NCT02034461?term=utah+slanted+electrode+array&rank=1
http://www.ric.org/research/centers/bionic-medicine/Research/#Quantification

Clinical BCI systems

Closed-loop sensor response

Highlights from Clinicaltrials.gov:

- Neuroprosthesis for seated posture and balance (Case Western Reserve University; NCT01474148)
- BCI-Functional electrical stimulation for recovery of hand muscles in spinal cord injury (University of Glasgow; NCT01852279)

http://news.fiu.edu/2012/01/of-life-and-limb/34616

Acknowledgments

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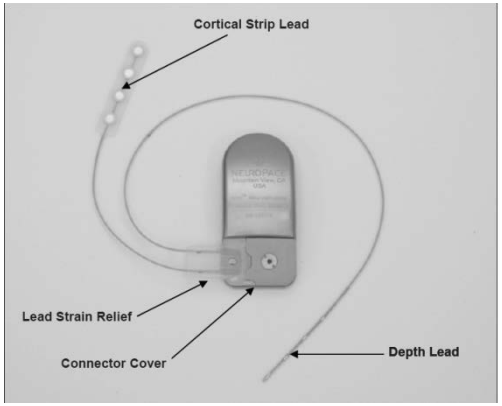
  - National Science Foundation(Award IIS-1313620)

Supplementary Information

Responsive neurostimulation

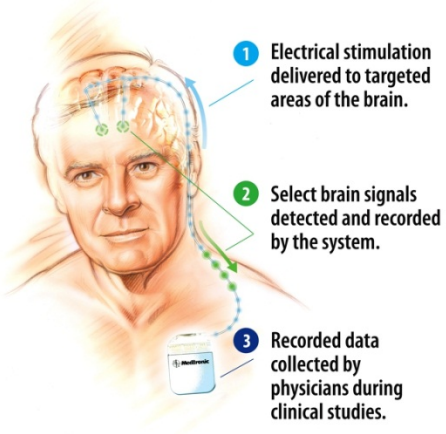
- Neuropace RNS System (P100026, PFN)
  - Closed loop responsive neurostimulation for epilepsy
  - strip and depth leads
  - Epilepsy patients



Neuropace

- Clinical use
  - Medtronic Activa PC+S

    Parkinson's patients



http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=1882373&highlight=%28Activa%29

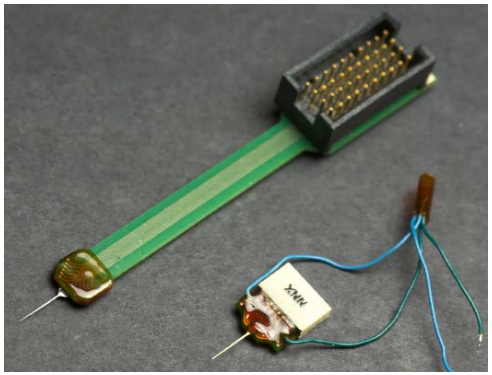
Product codes for peripheral nerve interface devices

- JXI – nerve cuff (non-electrode). Surgisis, nerve repair, collagen
- PAZ, ODH, PAT - implantable bladder-evacuation electrical stimulation system
  - PAZ – bowel evac, HDE, Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD) Urology and Lithotripsy Devices Branch (ULDB)
  - PAT, ODH – sacral anterior root stimulator, bladder evac, HDE, Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD) Urology and Lithotripsy Devices Branch (ULDB). Inappropriate shock
- GZE implanted diaphragmatic/phrenic nerve stimulator
  - PMA device, Avery biomedical. Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) Respiratory Devices Branch (RPDB)
- LYJ – Vagal nerve stimulator for epilepsy
  - PMA, Cyberonics, DNPMD, loss of clinical effectiveness, lead breakage.
- GZF - stimulator, peripheral nerve, implanted (pain relief)
  - 510k, Medtronic, St. Jude, Avery, high impedance, lead breakage, insulation loss
- GZB
- MNQ – Inspire stimulator for sleep apnea (2014)
- GZC – Neurocontrol Freehand FES system.

Research pipeline

Neural electrode to effector

- Floating microelectrode array (Microprobes)
- Silicon micro-machined shank-style array (Neuronexus)
- Flexible electrodes
- Bioabsorbable materials
- Wireless systems
- Regenerative channels for peripheral nerve
- Longitudinal intrafasicular electrode (LIFE) Florida International University
- Spinal cord interfaces



Research pipeline

Neural electrode to effector

Dry contact EEG

- Advanced Neurometrics – EEG monitoring
- Cognionics
- Brainscope – TBI detection
- Neuronetrix – Alzheimer's
- Emotiv – BCI
- MindRider
- g. tec

Neuronetrix

Cognionics

MindRider

Emotiv

http://advancedneurometrics.com/
http://www.cognionics.com/index.php/products
http://neuronetrix.com/in-the-news-i-41.html
http://www.brainscope.com/index1.shtml
http://emotiv.com/store/hardware/epoc-bci-eeg/developer-neuroheadset/
http://web.media.mit.edu/~arlduc/projects/mindrider/
http://www.gtec.at/Products

Related Technology – cortical interfaces

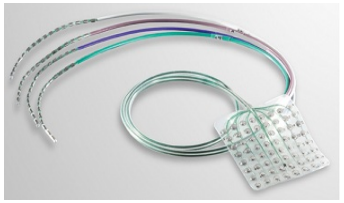
not BCI indications

Neural interfaces – Acute(<24 hours or <30 days) for brain mapping, intraoperative monitoring

- Surface penetrating array (Blackrock: GZL)

  < 30 days

  brain mapping



- ECOG strip and grid (AdTech, PMT, Integra Medical: GYC)

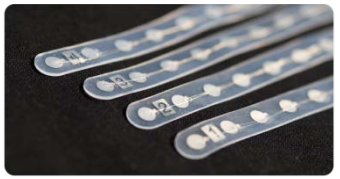
  < 30 days

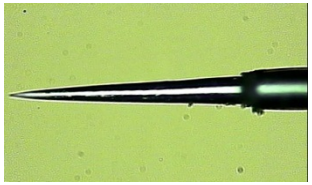
  brain mapping

- Microtargeting electrodes (FHC, PMT, AdTech: GZL)

  < 24 hours

  intraoperative monitoring





http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Related Technology – EEG
not BCI indications

- Cutaneous EEG electrodes (GXY)
- Conventional EEG (GWQ)
  - EEG monitoring
  - Polysomnography
- 11 new Product Codes for EEG/MEG devices
  - Analysis software (code OMB)

Gtec‘s EEG

ABM’s Stat X24

EGI’s Geodesic sensor net

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm360811.htm

Related Technology – EEG

not BCI indications

- Neuropsychiatric EEG-Based Assessment Aid (NEBA), NEBA Health (K112711, NCG)
  - Diagnostic assessment aid for pediatric ADHD
  - Theta/beta ratio of the EEG measured at electrode CZ

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm360811.htm

- Investigational
  - BioControl CardioFit