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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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

Feedback system –
Neural stimulator
Closed loop
Sensor – response system

Prosthetic, exoskeleton, robotic or virtual effector
(usually + shared control)

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)

BCI systems

Research

Clinical Studies

Cleared/Approved

Myoelectric prosthetic

High DOF prosthetic, myoelectric + shared control

Invasive cortical interface

EEG interface

Implantable myoelectric sensor

Exoskeleton

Novel cortical interface *

Dry contact EEG *

Peripheral nerve sensors *

* Not reviewed here.
Neural Interface to prosthetic, exoskeleton, robotic or virtual effector (definition 1)

| Research | Clinical Studies | Cleared/Approved |

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)

- Invasive cortical recording and stimulation
- Peripheral nerve stimulation – FINE, LIFE
- Peripheral nerve interface – Utah Slanted
- TMR with sensory

BCI systems

Research | Clinical Studies | Cleared/Approved
Closed loop sensor-response system (definition 3)

Research

Clinical Studies

Cleared/Approved

Freehand System

Neural interface/ FES systems

BCI systems

Neuropace Responsive Neurostimulation system *

Medtronic Activa PC+S *

Related technology

* 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)

[Link](http://www.scireproject.com/rehabilitation-evidence/upper-limb/neuroprotheses/types-of-neuroprotheses/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
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

http://www.braingate.com/
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

• Implantable myoelectric sensor
  • IMES – Alfred Mann

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

http://www.clinicaltrials.gov/ct2/show/NCT01964261?term=neuroport&rank=1
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)
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Supplementary Information
Responsive neurostimulation

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

- Clinical use
  - Medtronic Activa PC+S
  - Parkinson’s patients

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)
- 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 intrafascicular 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

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