DIPAOLA CONSULTING LLC
ENGINEERING AND MANAGEMENT SOLUTIONS

Medical Sensors: Enhancing Human Performance and A Peak into the Future

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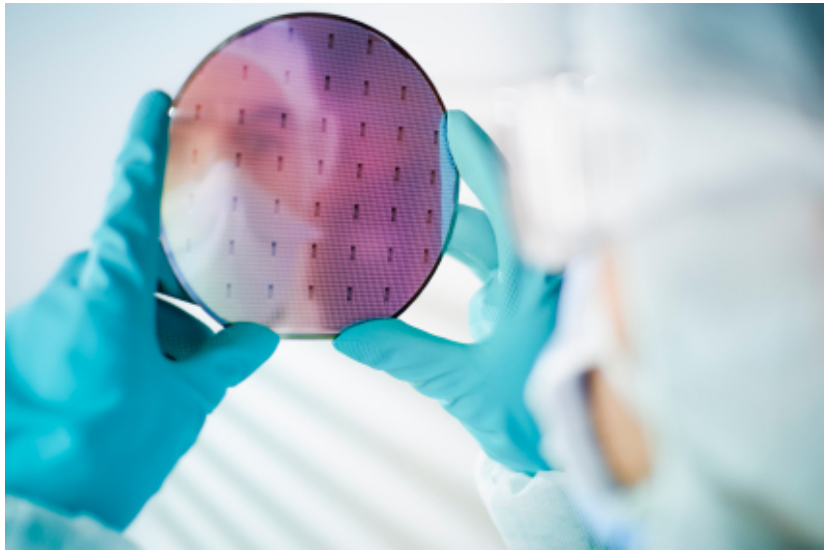

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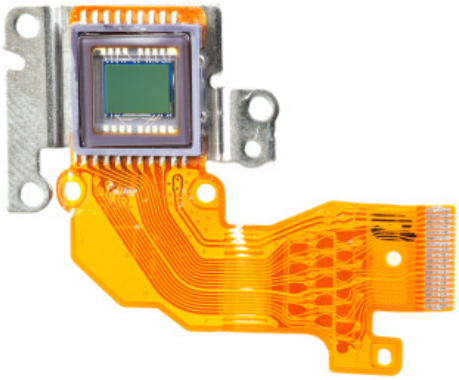
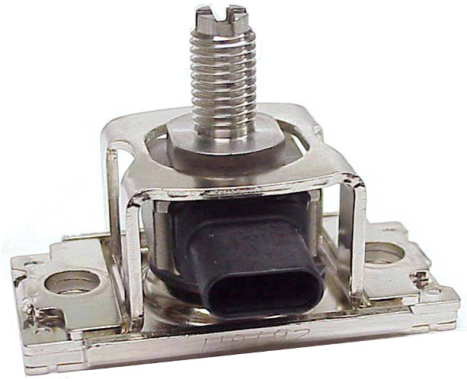


Who are we?



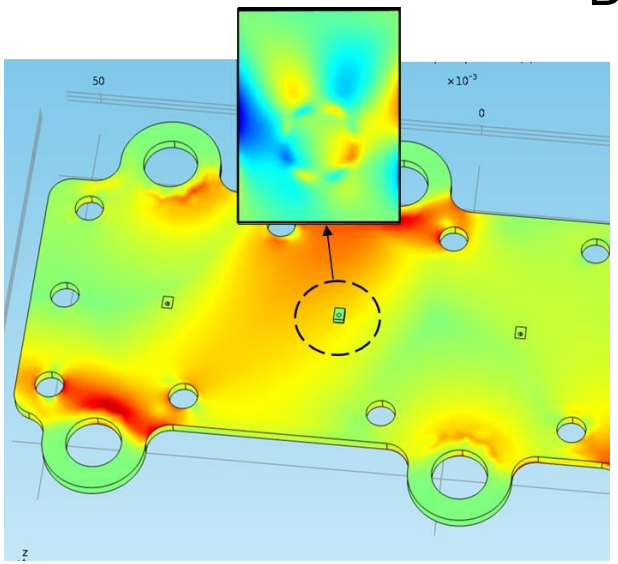
Problem Solving Based Company

Electromechanical, Sensors & MEMS Products

Design and Process Development

Concept to Production

Macro to Micro



North Potomac, MD

Medical Sensors: Enhancing Human Performance

Exploring Four Case Studies …

- Fitness
- Digital Medicine
- Sight Restoration
- Overcoming Paralysis

Why Fitness?

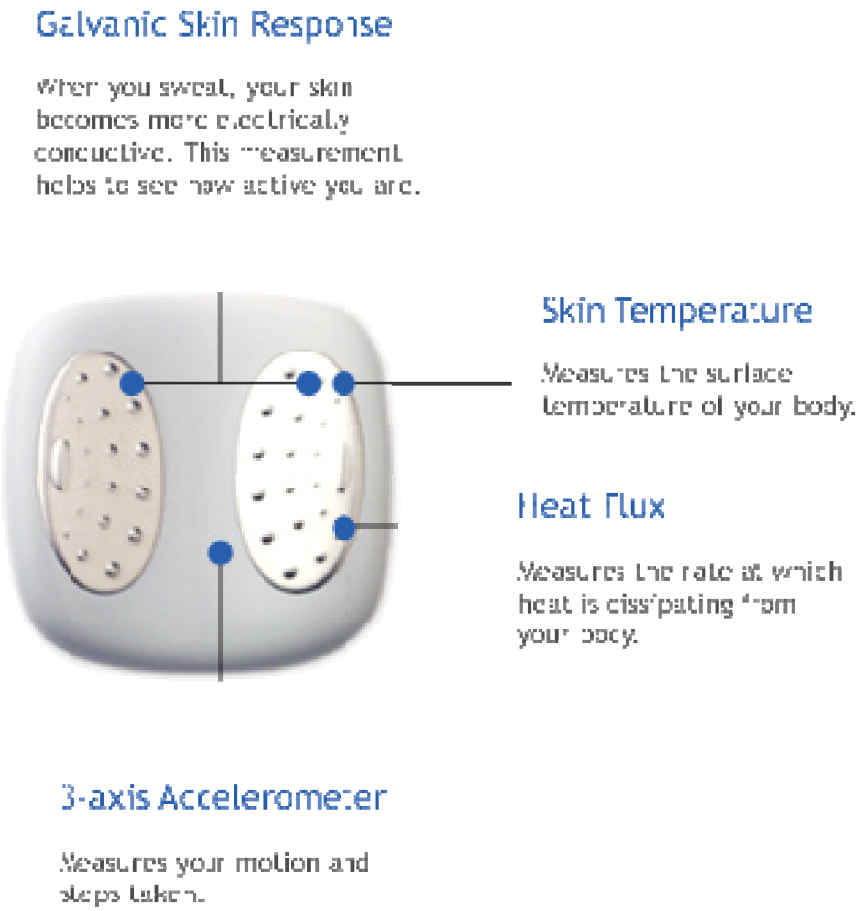
- Concern
  - Obesity is estimated to cost the US $150 Billion per year affecting 1 of 6 children and 1 of 3 adults resulting in physical wear, heart disease, cancer and diabetes
  - Solution is challenging with factors such as food quality, exercise, heredity, disease, sleep, location, life style, access and education all playing a role
  - *Information obtained from Obesity Society's Website 2012*
  - *http://clovisindependent.com/2012/09/12/children-show-obesity-can-be-overcome-with-the-help-of-their-families/*
    - Girl overcomes obesity by controlling diet and walking 4 miles per day even in the snow, rain and wind (no excuses)

Fitness: BodyMedia Fit

- A class II exempt medical device that automatically tracks the calories burned during your daily activities, monitors workout intensity and quality of your sleep
  - The on-body monitoring system consists of an armband device, online Activity Manager, optional display and mobile app

Fitness: BodyMedia Fit

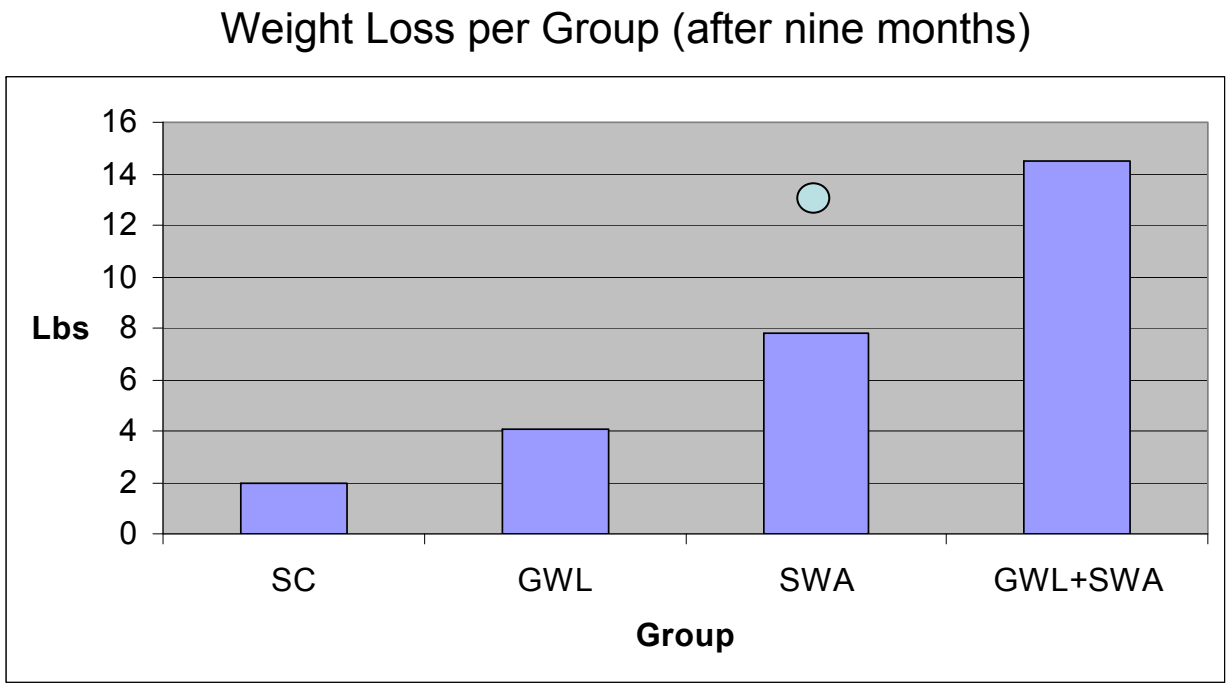
- Function
  - Using sensors monitoring glavanic skin response, skin temperature, heat flux and motion/steps, the armband monitor captures over 5,000 data points per minute and uses a complex algorithm to monitor calories burned
- “Data doesn't mean squat unless you can use it.”
  - Easy to use interface lets you track progress towards goals and monitor calories in and out



Fitness: BodyMedia Fit

- Benefits
  - Provides relevant, understandable and actionable data touching four important factors in weight loss and maintenance
  - >3X improvement in weight loss when system used (Shuger et al. 2011)

SC - Standard Care:
Self-directed weight loss, evidence-based programs
GWL - Group-based Behavioral Weight Loss:
Group program, weigh-ins, one on one sessions with emphasis on weight loss
SWA - Armband Alone:
Armband and access to weight loss management account
GWL + SWA:
Armband and group based behavior weight loss



what if

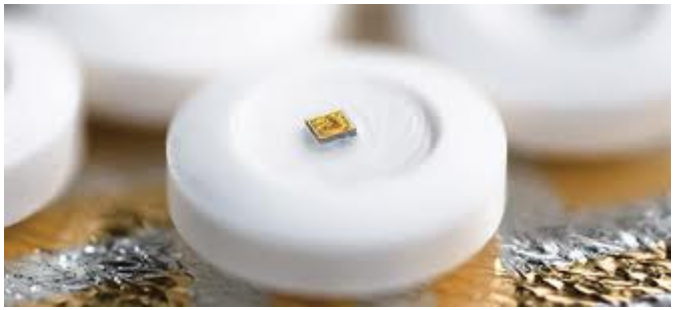
through collaboration we created …

A wellness monitoring system for early detection of illness and disease

- Systems may include monitors for ECG, blood pressure, heart rate, sleep patterns, body temperature, respiratory rate, stress, body weight, pain log, breath, eye, fertility, etc.
- System requirements
  - Private and Secure
  - Accurate
  - Easy to use and interpret
  - Actionable output
  - Nonintrusive
  - Non-burdensome and meaningful output for Physicians
  - Standardized
- The Nokia Sensing X CHALLENGE a $2.25 million global competition to stimulate the development of health sensors and sensing technology
- Qualcomm Tricorder X Prize a $10 million competition to stimulate innovation and integration of precision diagnostic technologies, making definitive health assessment available directly to “health consumers”

Digital Medicine: Proteus Digital Pill

- The ingestible sensor is a MEMS medical device that is used to monitor identity and timing of pill ingestion.
- The ingestion recorder or patch worn on the skin then wirelessly transmits the data to a computing device
- Displays the ingestion data as well as your activity, heart rate and body position (Proteus Digital Health 2012)
- FDA approved for use with placebo pills (Proteus Digital Health 2012, Murry 2012).

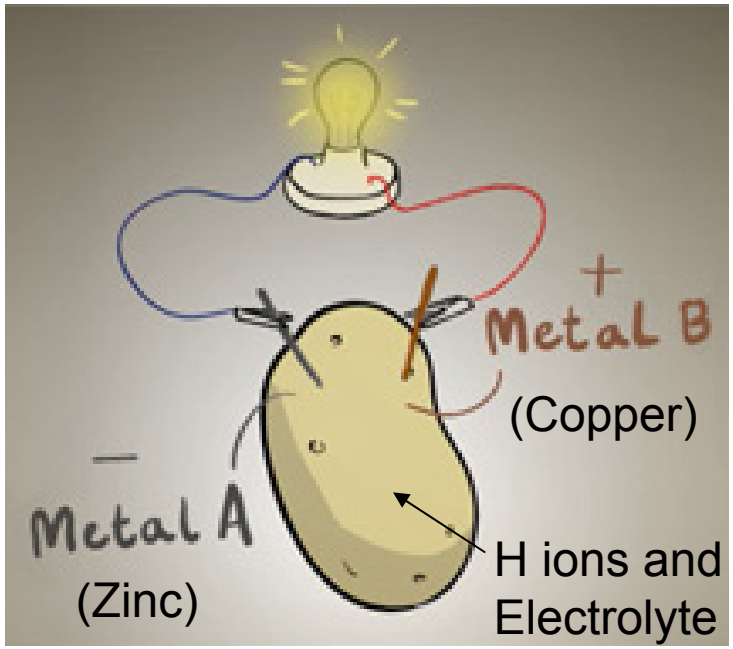


Digital Medicine: Proteus Digital Pill

Function likes a potato battery

- Two dissimilar metals such as zinc and copper are placed in a potato
- The phosphoric acid inside the potato acts as an electrolyte and contains hydrogen ions
- The zinc atoms enter the electrolyte leaving behind two electrons and the zinc metal becomes more negatively charged
- Two electrons enter solution from the copper and combine with hydrogen ions to form hydrogen gas hence the copper becomes more positively charged
- Electrons travel through the wire to maintain the system at a neutral state
- A resistance in the wire creates a voltage difference

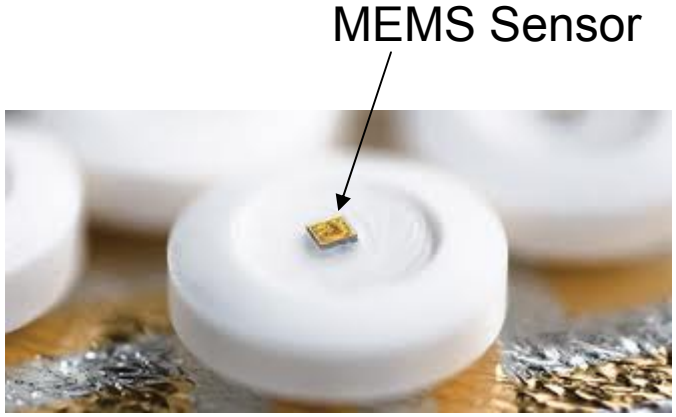
Potato Battery



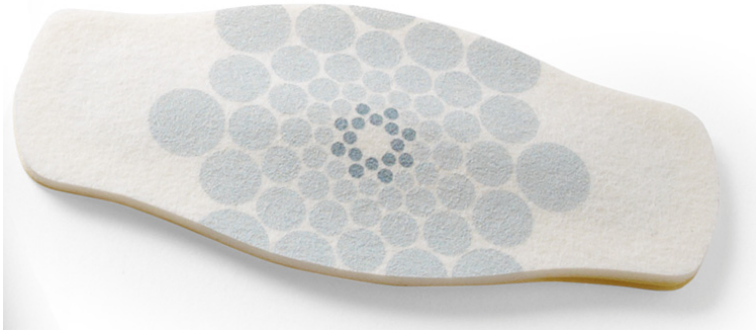
Digital Medicine: Proteus Digital Pill

Function of Digital Pill

- The MEMS sensor consists of a 1 mm square silicon chip that contains trace amounts of copper and magnesium
- When ingested, a small voltage is generated when it comes in contact with stomach fluid that is an electrolyte (Maxmen 2012)
- The electrical signal in your stomach quickly conducts through your cells and is sensed on the skin's surface using the ingestion recorder



Ingestion Recorder



Digital Medicine: Proteus Digital Pill

Benefits:

- Tracks daily intake of medicine
- System monitors health parameters such as heart rate, body position or activity that can provide valuable feedback on effectiveness of pharmaceutical treatment
- Information can be transmitted to loved ones or the person's physician for better point of care
  - A family member can remotely monitor pill ingestible for someone with Alzheimer's disease

what if

through collaboration we created …

- A system to detect when medicine reaches desired points in the body to attack diseased cells and the duration of drug activity (hugely complex problem)
- Solution will likely include collaboration by doctors, nanotechnologists, chemical, biomedical, mechanical, computer and electrical engineers
- Benefits would include
  - Faster feedback of targeted delivery
  - Better dosing
  - Potentially faster recovery time
- Preliminary Challenges
  - Accurate and noninvasive determination of target location
  - Noninvasive confirmation of disease type
  - Determination if diseased cells have rapid growth (aggressive) and will migrate to other organs in the body (metastatic)

Restoration of Sight to the Blind: Second Sight's Argus II

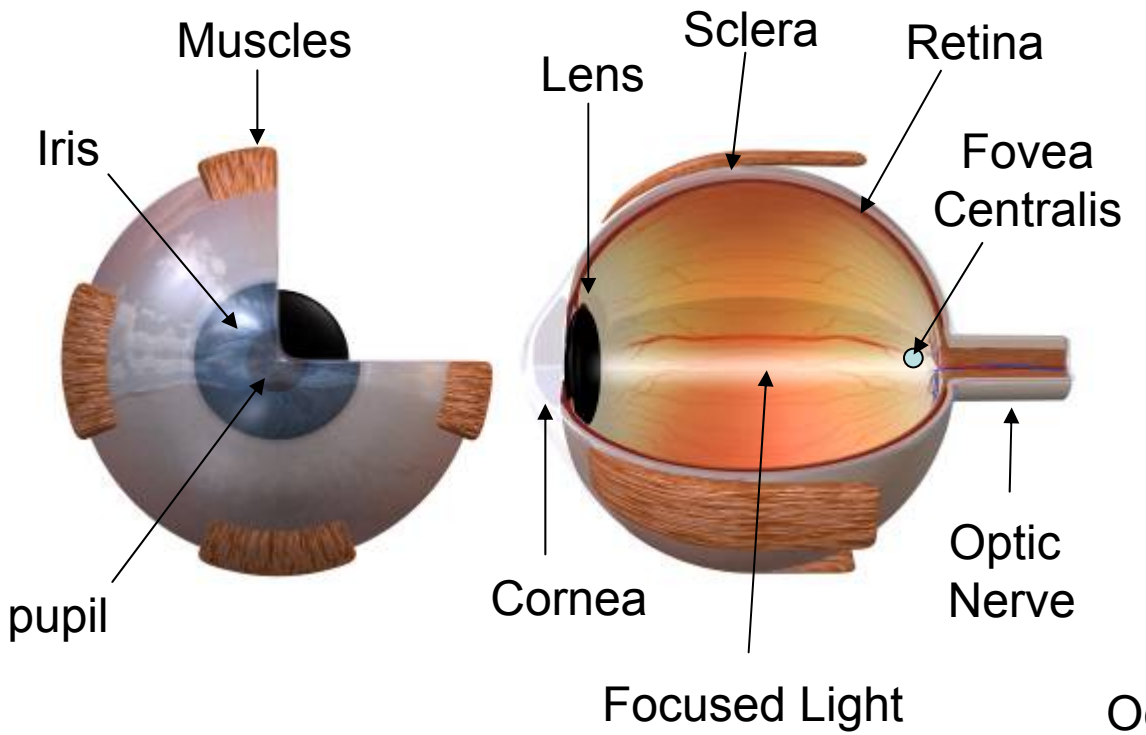
- The Argus II Retinal Prosthesis System ("Argus II") uses a video camera to capture a scene and provides electrical stimulation of the retina to elicit visual patterns of light
- Patients interpret these visual cues and can become more independent
- Intended for blind subjects with severe to profound retinitis pigmentosa (RP)
- Argus II has received approval from the FDA for commercialization under a humanitarian device exemption

Restoration of Sight to the Blind: Second Sight's Argus II

Video Presentation: http://2-sight.eu/en/home-en

Restoration of Sight to the Blind: Second Sight's Argus II

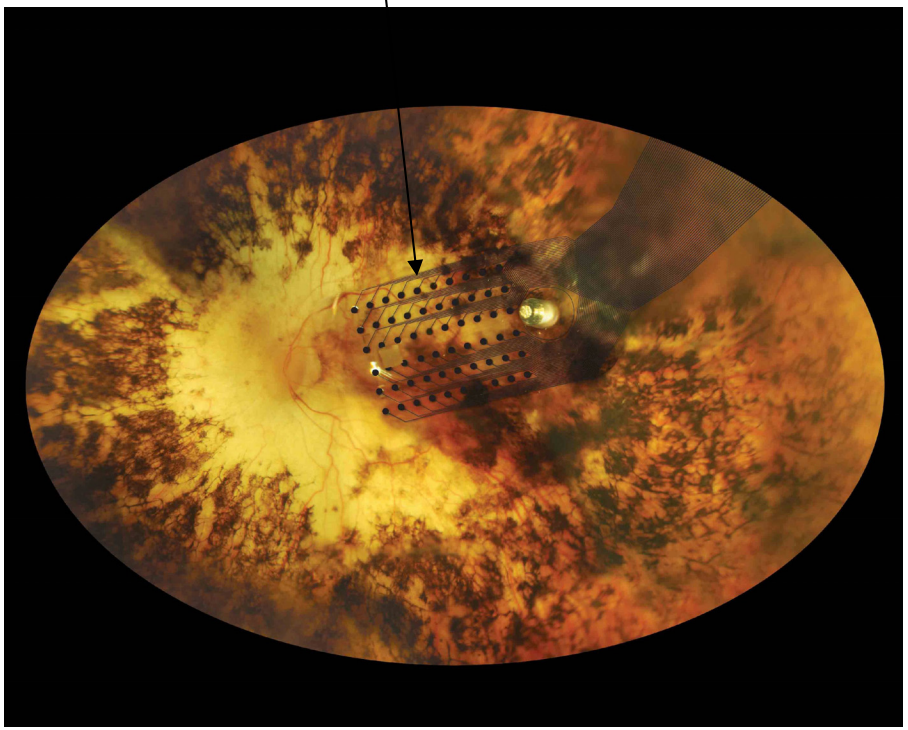
- In the retina, photosensitive cells called rods (light) and cones (color) convert incident light into signals carried to the brain by the optic nerve.
- Fovea Centralis is the center of the eye's sharpest vision and the location of most color perception.



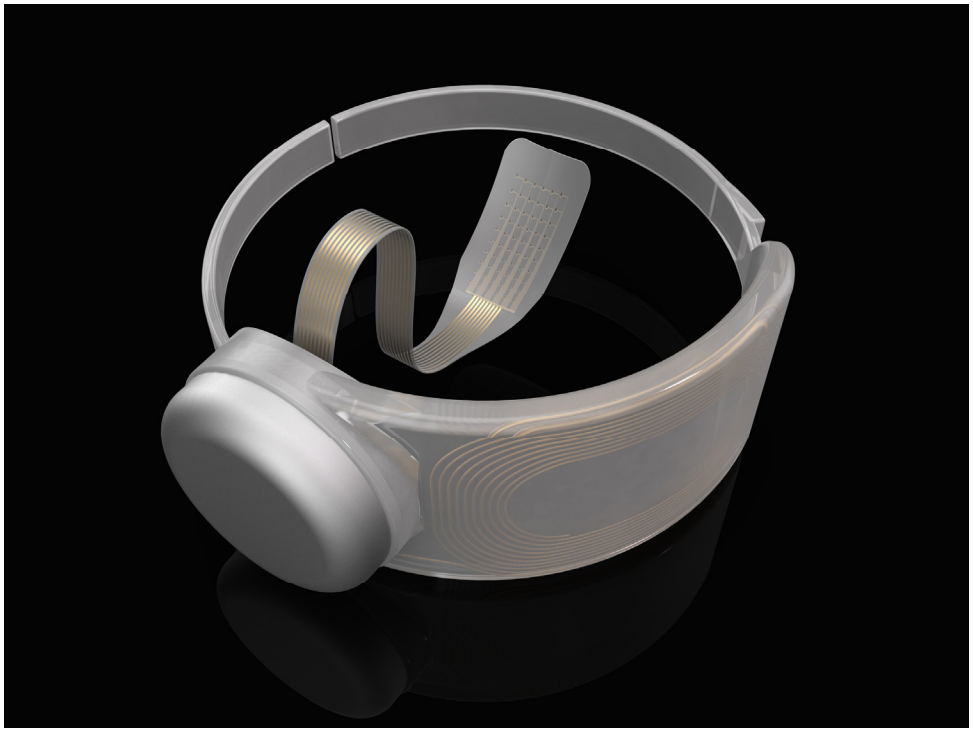
Occipital Lobe (Vision Processing)

Restoration of Sight to the Blind: Second Sight's Argus II

60 Electrode Array Implant in Eye



Electrode Array System



Restoration of Sight to the Blind: Second Sight's Argus II

Future Advances:

- Second Sight's Argus II (Oliwenstein 2008)
  - Greater number of electrodes (200 – 300)
  - Software enhancements to improve recognition
  - Future generations may include color
  - Move the video camera into the eye having the size of a Tic Tac
- Competing Technology, Nano Retina, Inc. (2012)
  - http://www.nano-retina.info/nanoretina_movie.htm
  - Near lift like images (anticipated) with 5000 pixels
  - Size of a child's fingernail
  - 30 minute procedure under local anesthetic
  - Charged by Infrared laser from rechargeable normal looking glasses
  - First clinical trials scheduled for 2013
  - Challenges include protection of the camera from the potentially corrosive environment

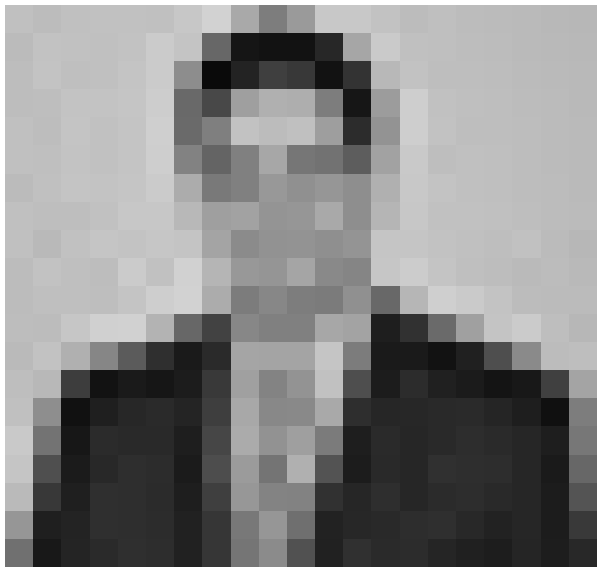
what if

through collaboration we created …

Sight restoration that is in color and life like

- Contained mostly in the eye requiring minimal power consumption
- Remotely recharged or energy harvesting
- Highly robust to the environment with long life expectancy
- Normal use glasses for external portions (system use cannot be perceived)

400 Pixels



5800 Pixels

5 Million Pixels

Overcoming Paralysis: Human Locomotion Research Center (UofL)

- The patient suffered complete paralysis in the lower extremities (below chest) with only some sensation in the legs
- > 2 years of Locomotor Training was completed with no significant impact
- Using an epidural stimulator and electrode array implanted in the lower spinal cord, electric current was use to stimulate (or activate) the nerve circuits
- Once stimulated, the nervous system can generate enough commands to contract muscles to allow the patient to stand, move toes, ankles, knees and hips and even take steps with the aid of a harness and trainer
- The electrical stimulation sensitized the cord and makes it receptive to this sensory information
- Its was found that the nervous system is smart and when certain sensory information is provided (aided treadmill stepping), the spinal cord can recognize this information and respond by generating a stepping pattern of muscle activity
  - This is improved with repetition and training (generates functional change)
- It as been shown that certain drugs increase the cord's sensitivity and outcome of locomotive training but none are approved for humans (Harkema et al. 2011)
- Video: http://uoflblog.com/epi/video3.mov

Overcoming Paralysis: Human Locomotion Research Center (UofL)

Challenges

- Pharmaceutical drugs to aid in nerve activation are very expensive to guide through FDA approval
- The epidural stimulator was designed to relieve pain not to awake the nervous system
- Sample size is 1 with 4 additional patients in the clinical study not yet complete
  - First patient was a prior athlete in excellent physical condition prior to the accident
  - There was some sensation in his legs prior to the start of the study
- Very preliminary stages of understanding circuitry and its activation (Harkema et al. 2011)
- Video Presentation: http://uoflblog.com/epi/video4.mov
- Video Presentation: http://uoflblog.com/epi/video3.mov

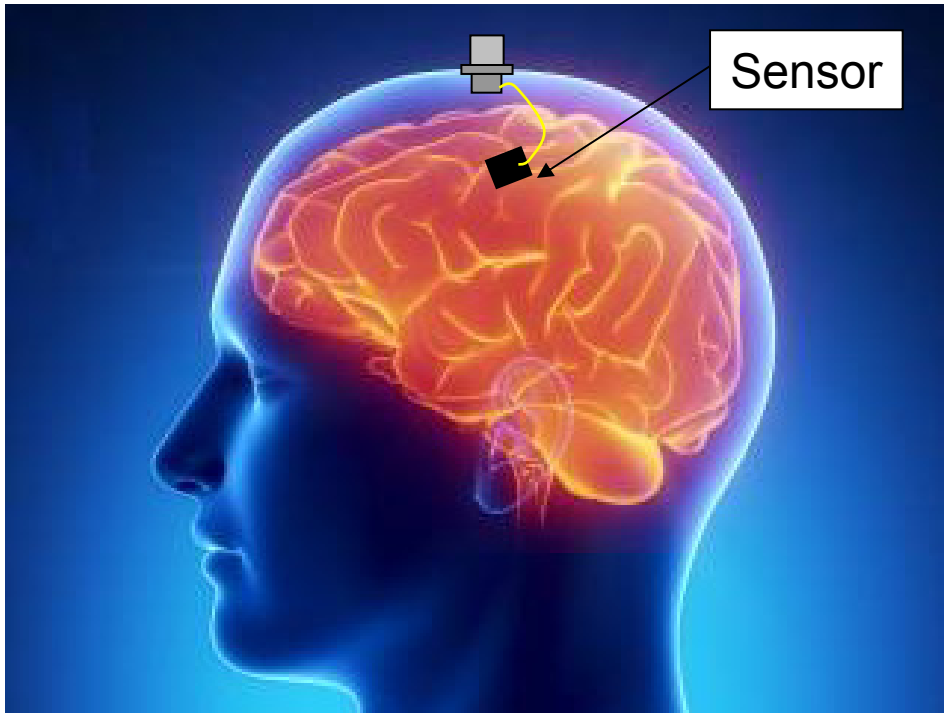
Overcoming Paralysis: Brown Institute for Brain Science

Reach and Grasp with Neurally Controlled Robotic Arm by Tetraplegic Patient

- Persons with tetraplegia have used cursors to control a computer cursor and control physical devices
- Able body monkeys have used neural interface systems to control robot arms and feed themselves
- Although significant, the above work did not prove people with profound upper extremity paralysis or limb loss could direct useful arm actions with cortical neuronal ensemble signals
- Hochberg et al. have demonstrated two people with long standing tetraplegia used the neural interface system to control a robotic arm in three-dimensional space and grasp movements. (Hochberg et al. 2012)

Overcoming Paralysis: Brown Institute for Brain Science

- A microelectrode 96 channel sensor array (size of baby aspirin) was implanted on the surface of the brain just below the skull
- Using this sensor and the neural interface system, participants controlled a robot arm over a board space with no training using signals from a small population of motor cortex neurons (Hochberg et al. 2012)



Overcoming Paralysis: Brown Institute for Brain Science

- Video Presentation: http://www.youtube.com/watch?v=cg5RO8Qv6mc
- Video Presentation: http://www.youtube.com/watch?v=C7H_M8-dBHc

what if

through collaboration we created …

Overcoming Paralysis: Brown Institute for Brain Science & Human Locomotion Research Center (UofL)

- Systems using neural sensing, epidural stimulation, innovative packaging, sophisticated equipment, training, pharmaceutical drugs and complex algorithms to
  - Regain arm movement
  - Stand for longer periods of time
  - Use arms and legs simultaneously
  - Walk
  - Run

Collaboration Needed for Enhancing Human Performance

- Experts in the fields of medicine, engineering, chemistry, physics, software development, materials, microelectronics, sensors and more hold knowledge in part and it isn't until these pieces of information come together that truly innovative products come to fruition
- Productive workshops that provide interdisciplinary networking are essential to foster new relationships and discuss opportunities for collaboration
- The integration of bottoms (starting at the atomic level) up and top (macro level) down assembly techniques is expected to see increased focus
- In Ohio and surrounding states there are excellent universities, medical centers, microfabrication capabilities, consultants and packaging centers that can significantly benefit from each others' knowledge
- Some of the outstanding work discussed today was performed with off-the-shelf or suboptimal equipment … imagine what can happen when collaboration occurs to provide optimal solutions

Questions?

Works Cited

BodyMedia

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Proteus Digital Health

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  - Including the press release, background and FAQs to the article above
  - http://louisville.edu/medschool/neurosurgery/harkema/research/epidural-stimulation.html