Non-Transcranial Electroanesthesia

Group 2
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Project Definition

• Design, build, and test a system for both administering and recording data related to electroanesthesia using vagal nerve stimulation in the range of $1,000 at cost.

• Topics to cover: Project Background, Vagal Nerve Information, Design, Stimulation (production and application) Techniques, Testing, Current and Overall Status, and BMEidea
Current Anesthetic Techniques

- Sedation
  - administered through vein
- Local anesthesia
  - locally numb area
- Regional anesthesia
  - block pain signals from single nerve bundle
- General anesthesia
  - Complete unconsciousness

Proposed New Technique

- Non-invasively electrically stimulating the right and left vagal nerves at the neck level to produce general anesthesia
Background of Electroanesthesia

- Electroanesthesia can occur by passing electric current through the scalp (Kano et al. 1976)
- Quicker recovery time and less biological effect during and after surgery than gas (Photiades, 218-225)
- Heal better (Sances & Larson, 21-27)
- Less of a buildup of gases in the body (Sances & Larson, 218-219)
- Few detrimental effects on EEG or ECG (Sances & Larson, 55-58)
- Electrolyte levels in extracellular and intracellular fluid of the brain (Sances & Larson, 148-175)
- Decreased gastric acid secretion (Sances & Larson, 33-46)
- FDA concerns
- Vagal nerve stimulation (Kirchner et al., Ness et al.)

Vagal Nerve Information

- 10th cranial nerve
- Location: both sides of the neck
- Composition:
  - A-fibers
    - Adapt to constant stimulus and exhibit presynaptic inhibition
    - Respond well to low stimulus (George et al. s56-s61)
    - Conduction Speed: 90 to 30 m/s
    - Selectively activated by low intensity VNS
    - No effect on EEG recorded in the rats studied by Hammond et al. (1992)
  - B-fibers
    - Respond well to low stimulus (George et al. s56-s61)
    - Conduction Speed: 20 to 10 m/s
    - No effect on EEG recorded in the rats studied by Hammond et al. (1992)
  - C-fibers
    - Continue to fire with constant stimulus
    - Conduction Speed: 1.6 to .3 m/s
    - Convey pain signals
- Function: motor and sensory (visceral afferent) signals
- Not fully myelinated until adulthood (Koo et al. 429-433)
- Parasympathetically innervates pharynx, larynx, lungs, heart, esophagus, stomach, small intestine, colon
- Shown to help control seizures and depression (VNS)
- Best route to the central nervous system (Rutecki 1990)
**Mechanism: efferent**

- Over-stimulation of vagal nerve can result in fainting
  - Parasympathetic innervations
  - Slows breathing and heart rate
  - Reduced $O_2$ to brain $\Rightarrow$ fainting

× Not desired effect!

**Mechanism: afferent**

- Over-stimulate pain centers in brain
  - Total loss of consciousness?
  - Loss of pain perception?

- Ideally stimulation needs to be more powerful than VNS, but low enough not to cause efferent effects
Risk Analysis

• Vagal Nerve Stimulators
  – Not around for long
    • No long term effects yet
    • Short term: hoarseness and throat pain
  • Long term effects?
    – Lightning: “severe headaches, chronic daily pain, epileptic seizures, dizziness, problems with eyes going blurry” (whyfiles.org)
    – But lightning is 30,000 Amps and over 1 million volts

Risk Analysis cont.

http://etrp.bsd.uchicago.edu/mission.html
Project Background

- Currently, electroanesthesia devices are in use in Europe.
  - S. Leduc
  - Europe, Japan, Russia, and Germany
  - Activation of a theoretical pain center
  - 35 V, 4 mA, 100 Hz, rectangular pulsating signal
- Alternative method
  - Descending mechanism and the interconnections within the brain
- In less developed countries where anesthesia technology is lacking, an electroanesthesia device would reduce both the cost of the procedure and the need for technical personal (anesthesiologist).

A. Shape of impulses and limits of frequency modulation.
B. 1 – Headset of electrodes  2 – Monopolar output impulse, rechargeable
  3 – For practitioners, mono- and bipolar output impulses, LCD, timer, frequency control, alarm
  4 – For hospitals and outpatient clinics, mono- and bipolar output impulses with or without frequency modulation, LD indicators, timer, automatic control, alarm and protection systems, verbal dialogue with user in process of adjustment of parameters, plug in
Cost

- Gas anesthesia
  • In the case of gas anesthesia, more is required for treatment and cost are around twenty to forty dollars a patient (Kurpiers et. al., 69-75, VUMC 2006).
- Liquids
  • between three and nine times as expensive as gas anesthesia per volume (Kurpiers et. al., 69-75).
- Electroanesthesia will reduce the high cost of anesthesia for surgery and other procedures by reducing the need to keep large quantities of liquid and gas anesthesia on hand.

Cost cont.

Current ~$120,000
- Monitor including vital signs  
  • $50,000
- The machine  
  • $70,000
- Gas  
  • $100
- Anesthesiologist  
  • ~250,000

Ours ~$3,500
- vital signs equipment  
  • $2,000 if added
- The Machine  
  • Price $2,500
  • Cost $1000
    - The laptop ($600)
    - electrical components ($20)
    - Housing ($150)
    - Production($30)
    - R&D ($200)
  • Profit $1500
- Electricity  
  • $1.00
Methods

- Computer system
- Vital signs monitoring equipment
- Testing
  - Phase I:
    - Device components connected and tested to assure compatibility
    - Software integrated and tested to assure compatibility and proper operation
    - Test inputs and outputs of device
  - Phase II: Applicator testing to assure proper outputs and operation
  - Phase III: Testing of device operation with a rat (Not at this time)

Final Design
Stimulation Parameters

- Stimulation of both Vagal Nerves
- 20 Hz Rectangular pulse signal
- Pulse length of 250 μs (Liporace et al. 885-886)
- 50 μA (Kirchner et al. 1167-1171)
- 25 V
Delivering Electroanesthesia

• Gain Stage
  – Using instrumentation amplifiers
    • low noise
    • High CMRR
    • Wide operating temperature range
    • Variable power supply range (2.5V to 18V)
    • Surrounded by foam to keep circuit in place
  – Two 5V fans
    • Keep circuit cool to prevent instrumentation amp
      from overheating from computer and foam insulation

Delivering Electroanesthesia

• Power Supply to Circuit
  – Entire circuit runs off two 9V rechargeable batteries in chargers
  – Extension cord connects computer and battery charger to one outlet
  – When circuit is not in use extension cord outlet is used to charge the
    entire device.
• Power Delivered
  – Amp uses 9V battery with a voltage divider to lower voltage to ~4V
    • Lower voltage saves power and extends life of circuit
  – Fans use 9V battery directly
    • Using voltage divider provides not enough current to the fans and won't
      operate. This means the life of the fans is ~30min.
    • Can use third battery and charger to extend life of fans to ~1hr.
Details

• Sound card
  – Output Range
    • 0.6 – 2.6V
  – Pulsed square wave output
  – LabVIEW allows pulse length, frequency, and amplitude to vary
• Gain (~23)
  – Therapy Range
    • 13.8 - 59.8V
• Enclosed Circuitry
  – On breadboard using wire wrapping.
  – Stored in box under computer

Application

• Electrodes placed in both vagal nerves.

  Needle Electrode
  - Better Application
  - Invasive
  - Skill needed to place

  Pad Electrode
  - Non-invasive
  - Easy to place

Advantages
- Better Application
- Non-invasive
- Easy to place

Disadvantages
- Invasive
- Higher Current Needed

Both methods can be used and the device setting adjusted for the different electrodes.
Patent Search

- #4,383,522
  - Transcranial method of delivering electroanesthesia
  - Electrodes placed on the neck and the forehead
- #6,393,319 May 21, 2002
  - Data for electrical waveforms stored on CD
  - Amplified and conditioned for stimulation via electrode on the skin

- However....

Current Status

- Work on Poster
- Fine tune LabVIEW
- Aesthetics
- Unethical and non-IRB approved testing
- Vital Signs Integration
Overall Status

<table>
<thead>
<tr>
<th>Month</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 2005</td>
<td>Look into previous research done on VNS and Electroanesthesia. Develop schematics and possible device physical designs. Start design development.</td>
</tr>
<tr>
<td>December 2005</td>
<td>Proceed with research and finalize our design approach. Assemble basic design components. Develop software and user interface.</td>
</tr>
<tr>
<td>January 2006</td>
<td>Begin designing prototype model and testing.</td>
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<tr>
<td>February 2006</td>
<td>Proceed with prototype design and testing. Obtain IRB approval to test our device as early as possible.</td>
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<tr>
<td>March 2006</td>
<td>Proceed with prototype design and testing. Continue work-up and finalize design.</td>
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<tr>
<td>April 2006</td>
<td>Prepare paper and presentation poster. Submit prototype to BMEidea competition.</td>
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BMEidea

- Problem to be solved
  - Present anesthesiology
  - Cost
  - Transcranial Electroanesthesia
- Problem objective statement
  - Applicator and Control Device
    - VNS
  - Portable, self sustaining, and rechargeable.
- Documentation of the final design, including applicable standards and risk analysis
  - Class III Medical Device Standards
  - Design Safe
- Prototype of the final design
  - LabVIEW
  - Computer Output
  - circuit
  - housing
  - Applicator
- Proof that the design is functional and will solve the problem
  - Theoretical
BMEidea

- Results of a patent search and/or search for prior art, assessment of patentability
  - See above
- Anticipated regulatory pathway
  - PMA
  - Product Development Protocol (PDP)
  - CES
- Estimated manufacturing costs
  - See Cost Slide
  - $1000
- Market analysis
  - market need
    - Reduction of anesthesia costs
  - competitive landscape
    - none (European Design)
  - potential market size
    - very large
      - replace most anesthesia devices

BMEidea

- Selling price
  - $4,500 including Vital Signs Equipment
- Reimbursement status
  - Produced inexpensively
    - Current $20,000
  - Selling price
  - Long term effects
- Executive Plan
  - Alternative to Chemical
  - Market for all physicians’ office
- Appendix
Most Important References

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Fries, Richard. E-mail interview. 5 2005.


