Biomedical circuits and systems to recuperate neuromuscular functions

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PART I

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Biomedical circuits and systems to recuperate neuromuscular functions

OUTLINE

- Introduction
  - Purpose and motivation
- Microelectronics activities
  - Design, construction & test of smart medical devices (SMDs)
  - Typical architecture of an SMD
- Focus on two main case studies
  - Neurostimulation to recuperate the bladder functions
  - Intracortical neurostimulation to create vision for the blind
- Required biocircuits & biosystems
- Research team and collaborations
- Conclusions

Main technological breakthrough of FES based SMDs

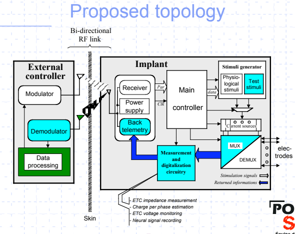
- 1947, transistor allows circuit designs suitable for implants.
- 1952, first external pacemaker which was the size of a table radio of the time and was powered by 110 VAC.
- 1957, electrical stimulation in the inner ear of the acoustic nerve in a totally deaf human was reported.
- 1960, totally implanted pacemaker (Buffalo).
- 1961, peroneal nerve stimulator for foot drop in hemiplegics.
- 1968, implantation of an electrodes array on the visual cortex.
- 1980, first microchip was used to design small pacemakers.
- 1984, FDA approved the first cochlear implant for adults
- 1991, recording of neural activities
- 1992+, FES is widely used in several applications.

Main technological breakthrough (Cont'd)

- Pacemaker: More than 350,000 pacemakers annually;
- Defibrillator: More than 50,000 implants annually;
- Cochlear implant: More than 50,000 people worldwide;
- Functional stimulation: Recuperate hands and legs movements of paralyzed patients;
- Stimulation for the treatment of Parkinson, respiration, pains, scleroses, etc;
- Automatic liberation of insuline in diabetics;
- Neuronal activities recording for better control;
- Devices for vision: Creation of adequate vision for blinds;
- Other implantable microsystems.

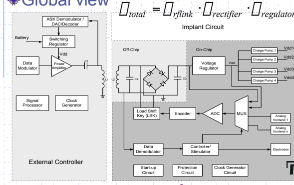
Smart medical devices

Proposed topology



Proposed SMD topology (cont'd)

- Global view $\eta_{total} = \eta_{rflink} \cdot \eta_{rectifier} \cdot \eta_{regulator}$

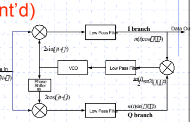


RF LINK to Transfer Power & Data (cont'd)

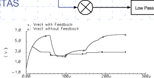
- Power Transfer
  - Efficiency and safety.

$$\eta_{total} = \eta_{rflink} \cdot \eta_{rectifier} \cdot \eta_{regulator}$$

- Data transmission
  - Manchester based codec
  - PSK based codec: BPSK Demodulator (COSTAS Loop)



- Link features
  - Full duplex mode
  - Transfer rate:
    - -LSK: 200Kb/s
    - -BPSK: 1Mb/s
  - PSK demodulator consumes only 529 µW.
  - QPSK may double the data rate.



- Recover the carrier and the data in the same loop

Without Feedback: 12.03%
With Feedback: 22.04%

The bladder controller: Dual-stimulator

- Lower urinary tract deficiency following a spinal-cord injury;
  - Incontinence and/or retention.
- Multiples complications at several levels (Sphincter, bladder and kidneys) due to repetitive catheterizations;
- Bladder hyperreflexia (hypertrophy or atrophy) hardly curable with traditional medicine;

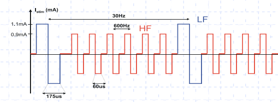
- Electrical stimulation of the detrusor muscle allows partly voiding and may induce kidney complication.

The bladder controller: Dual-stimulator

- Conventional electrical neural stimulation (ENS) induces contraction on both detrusor and sphincter, thus preventing from complete voiding;
- Conventional ENS combined with nerve rhizothomy is not accepted by patients;
- Early ENS tends to reduce the hyperreflexia phase, while limiting damage in the whole urinary system;
- Selective neural stimulation proposed by our team allows efficient voiding of the bladder;
- Permanent low frequency combined with selective stimulation are proposed by our team to improve bladder function.

The bladder controller: Dual-stimulator
Selective neural stimulation

- Selective stimulation allows improvement in voiding;
- This technique diplexes high and low frequency stimuli to activate both categories of sacral nerve fibres:
  - HF stimuli for somatic fibres which innervate the sphincter.
  - LF stimuli for parasympathetic fibres which innervate the detrusor.

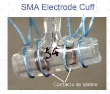


The bladder controller: Dual-stimulator
Selective neural stimulation

- First selective stimulator includes :
  - → Implant of 3.5 cm of diameter built around field programmable devices (FPD) and other discrete components;
  - → Shape Memory Alloy (SMA) based cuff electrodes to facilitate connecting to sacral roots;
  - → User friendly external controller based on FPD and other discrete components.

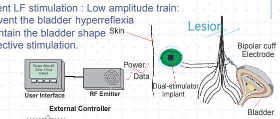
Selective Implantable Stimulator

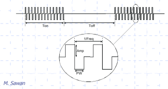
SMA Electrode Cuff



The bladder controller: Dual-stimulator
Permanent/Selective stimulations

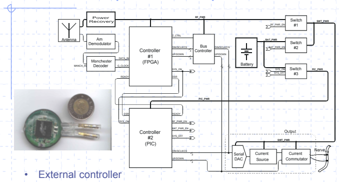
- Proposed dual-stimulator includes :
  - -Permanent LF stimulation : Low amplitude train:
    - - Prevent the bladder hyperreflexia
    - - Maintain the bladder shape
    - - Selective stimulation.





- The system includes:
  - - Battery to power the permanent stimulator;
  - - RF link for the selective stimulation.

The bladder controller: Dual-stimulator
Implant description

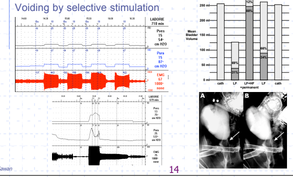


- External controller
- Subcutaneous Implant (~ 2.5cm)
- One cuff electrode pair

Bladder dual neurostimulation:
Results

- Intravesical and intraurethral pressures measurements and Electromyographic (EMG) recording of the pelvic floor muscles were performed.

Voiding by selective stimulation



The visual cortical stimulator
Evolution

- 1960s, few groups began to investigate the possibilities of exploiting the phenomenon of creating points of lights;
- 1990s, Researchers at NIH demonstrate that intra cortex stimulation allows to generate phosphenes;
- Progress in microelectronics and microfabrication motivate researchers to explore several approaches;
- Dobelle institute, New York, early in 2000 presented a patient holding a PC which drives a percutaneous connector toward the skull to extracortical visual region;
- We start this project in 1996
  - Early 2000, a prototype has been completed to prove the feasibility of a visual cortical stimulator
  - Miniaturized implant version is being achieved.

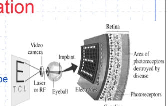
The visual cortical stimulator
Approaches

- Researchers worldwide are developing solutions
- Several approaches are being explored:
  - Artificial retina;
  - Cuff electrodes around the optic nerves;
  - Tongue stimulation;
  - Surface stimulation of the visual cortex;
  - Intracortical stimulation of the visual cortex.

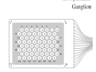
- Intracortical stimulation does not depend on the health of the eye or optic nerve; also, it requires stimuli at low current level. It can be the predominant one:
  - Artificial retina requires functional retina and optic nerve;
  - Surface stimulation of the visual cortex is imprecise;
  - Other techniques only allow sensory substitution .

Artificial retina / Extracortical stimulation

- Experimentation
  - Stable, non flickering phosphenes;
  - Able to distinguish shapes;
  - Lower threshold in macular region;
  - Resolution restricted by electrode shape
  - Mechanical properties challenges.



- Extracortical surface stimulation
  - Images feed from a digital camera to a belt-mounted processor;
  - commands send through the skull, and into the visual cortex

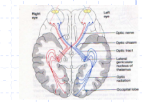


- **Optic nerve stimulation**
  - Fixed, stable phosphenes
  - Many phosphenes with few electrodes
  - Phosphene characteristics widely variable.

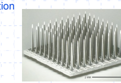
- **Tongue stimulation, and auditory or tactile input.**

Intracortical stimulation

- Intra-cortical stimulation
  - Better resolution
  - Better control on phosphenes
  - Lower power
  - Lower chances of seizure.

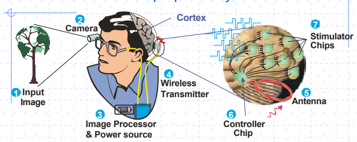


- Subject: 38 year old woman
  - Parameters affect brightness, not position
  - Elicits stable phosphenes
  - Threshold ~15 µA (as low as 1.9 µA)
  - Short term accommodation.



- Experiments in Monkey at IIT
  - Recently, report good news.

The visual cortical stimulator
The whole proposed system



- The system includes 4 main components:
  - Camera mounted onto a pair of glasses;
  - External controller to process the images and commands;
  - Bidirectional data & energy transmitted by RF link;
  - Implant to stimulate the region of the cortex controlling vision.

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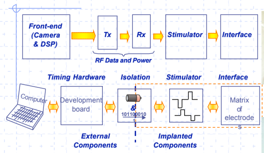
The visual cortical stimulator
Undertaken research projects



- System level optimization:
  - Front-end for efficient image processing;
  - Tx / Rx for power efficiency and data rate;
  - Power consumption, size, safety, biocompatibility;
  - Interface for shape and surface.

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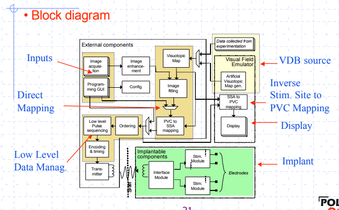
The visual cortical stimulator
Integrated smart devices

- Block diagram



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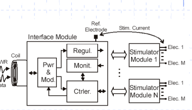
The visual cortical stimulator
Implant architecture

- Components of Multi-modules
  - Stimulator Modules (SMs)
    - Multi-channel stimulation
    - Electrode-tissue and stimulator monitoring
  - Interface Module (IM)
    - Bidirectional wireless Communication
    - Implant control
    - Power recovery / management
    - A/D Conversion of monitoring data



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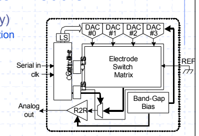
Implant architecture
Stimulator Module

- Features (flexibility/safety)
  - Current Constant Stimulation
    - Monopolar, Bipolar
    - Single/Multiple paths
  - Configurable Comm. protocol
    - One to 25 bits per pulse. Enables the use of a LF Clk
    - System power saving
  - Voltage Monitoring
  - RAM Configured Parameter continuous error checking
    - Disables stimulation in case of Parameter corruption
  - Compatible with electrode matrix dimensions
    - 4 x 4 electrodes (prototype)



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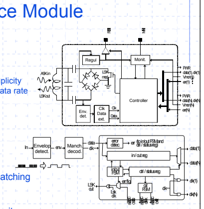
Implant architecture
Interface Module

- Power supply
  - External Coil, Rectifiers
- Communication
  - Downlink
    - ASK: keep OOK for its simplicity (Tx/Rx), but need higher data rate
    - «All digital» Demodulator
  - Uplink
    - Manchester LSK
- System Control
  - Power management
  - Communication Error detection/correction
  - Stimulator Instructions Dispatching
- Monitoring
  - Actual Stimulating Current
  - Voltage at every stimulation site



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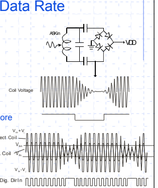
Downlink Communication
Power Efficiency vs Data Rate

- Downlink Tradeoff
  - High Q > Best efficiency, but
    - Envelop transition speed limited by Q-factor of receiver when rectifier diodes voltage is reversed.
  - … Limited Data Rate
    - Manchester encoding does not allow more than ~500 kbps @ 13.56 MHz.
    - Enhance Data Rate & Power Transfer by reducing carrier OFF period.
  - Digital decoder
    - Based on carrier signal attenuation
    - Toggling of attenuated carrier detected by extra toggling of direct carrier.



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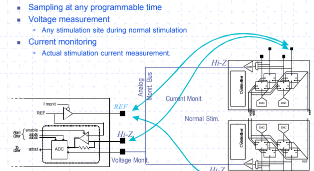
Monitoring & Data uplink

- V / I monitoring
  - Sampling at any programmable time
  - Voltage measurement
    - Any stimulation site during normal stimulation
  - Current monitoring
    - Actual stimulation current measurement.



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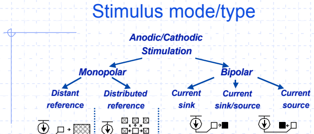
Cortical stimulation
Stimulus mode/type



- Flexibility
  - Modular: Variable number of stimulation sites
  - Stimulation modes: Mono / Bipolar, Single / distributed return terminal
- Safety
  - Electrical Isolation: Allows stimulation current / voltage monitoring.

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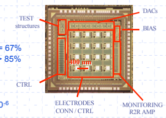
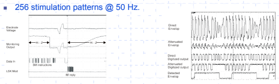
Implementation Results

- Stimulation Module (4 x 4 Matrix)
  - CMOS 0.18 µm, ~60 000 Gates
- Downlink
  - > 1 Mbps @ 13.56 MHz, Duty Cycle = 67%
  - 500 kbps @ 13.56 MHz, Duty Cycle > 85%
- Uplink : 200 kb/s
- Power: <1mW/SM @ 1MHz
  - > 100 mW load capability; P (err) < 10^{-6}
- Sufficient for 1000 stimulation sites
  - 256 stimulation patterns @ 50 Hz.





Implant 28 Downlink

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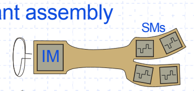
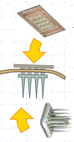
Cortical stimulation
Implant assembly

- Modular
  - One controller & several stimulation Units
- Flexible substrate
- Power/data link
  - Wireless
- Data rate >1 Mb/s
  - Max. Stim. Freq. : > 1 kHz @ 500 Elec.
- I / V Monitoring
- Assembly
  - Stim. Units.



- Physical Dimensions
  - SM's area : 3.5x3.5 mm2
  - Substrate : 50 µm
  - Stim Assembly: 1 mm thick
  - Electrode Length: 2 mm
  - IM's Area : ~ 2 x 2 cm2
  - Ctrler thickness : ~ 3 mm.



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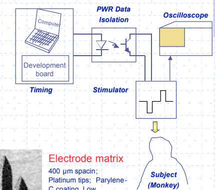
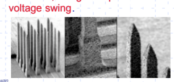
In vivo testing
Collaboration with the INM

- Parameters
  Amplitude, Pulse width, Inter-phase delay, Direction of first pulse, Pulse frequency, Pulse train duration, and Inter-train delay.
- Only electrodes in subject; Configurable hardware; "Large" output voltage swing.





Electrode matrix
400 µm spacin; Platinum tips; Parylene-C coating, Low Impedance.

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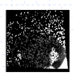
Image acquisition/processing

- Challenges and Need for Optimization
  - Stimulator
    - Physical Properties — Placement flexibility, wiring
    - Safety — Chronic usage
    - Data rate — High number of stimulation sites
    - Stimulation Flexibility — Prototype
    - Power efficiency — High parallelism
  - External Control
    - Relevance of Data — Low resolution

Acquired Image

Control on phosphene parameters



Actual Perceived Image (Direct Fit)

Irregular
- Density
- Size
- Sensitivity
- …

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Image acquisition/processing
Main specifications

- Dedicated image processor
  - Allow to transform images over visuotopic maps;
  - Follow a bottom-up approach until percepts are understandable;
  - Must deal with every image encountered in real world;
  - Be safe for patient.
- Required processing
  - Present image as the patient would see it;
  - Hardware implementation of processing algorithms;
  - Low power consumption topologies.
- Minimize power consumption with other techniques than circuit optimization approaches.

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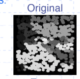
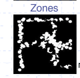
Image acquisition/processing
Electrically invoked phosphenes

- Visuotopic Maps
  - Experimental determination
  - Creation of random maps :
    - Investigation of representation needed for a VCS.
- Constructed from experiments or from
- Visual Data Base Generator
  - Realistic Visuotopic Map
    - Set of Phosphene Visual Field Coordinates
    - Generated from probabilistic parameters weighted with Schwartz retinotopic relationship and estimated electrode placement.
  - Probabilistic weighted PVFC variations and phosphene parameters:
    - Sensitivity, Size, Brightness, etc.

Original



Zones



Edges

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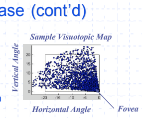
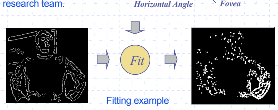
Image acquisition/processing
Visual Data Base (cont'd)

- Enhancement/mapping
  - Image has to be enhanced for clarity, then mapped to the available PVFCs.
  - The Visual Field Emulator allows perception prediction / evaluation from the research team.





Fitting example

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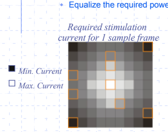
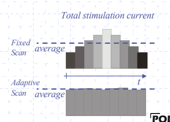
Image acquisition/processing
Power Optimization

- With large electrode arrays, stimulation current represents a major part of power consumption
  - Predetermined image scanning results in large current variations
  - Adaptive scanning method regulates current demand
    - Equalize the required power and reduce the peak demands





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Summary

- Typical topology of inductively coupled implantable electronic devices
- Dual-stimulator to recuperate the bladder functions
- Main issues of a visual cortical stimulator
  - Stimulation in the visual cortex may soon permit true artificial vision
  - Other undertaken research topics:
    - Design of dedicated image sensor
    - High voltage stimulation techniques
    - Modeling, simulation and in vivo validation
    - Measurement techniques of neuronal activities
    - Assembly several arrays
      - 128, 500, and 1000+ microelectrodes.
- Nanoelectronics will allow the design of additional devices.
- Microelectrodes & power sources are among the major works.
- Such medical devices include validation and involve physicians, engineers, health care professionals, families, etc.

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