Advanced Platform Technology (APT) Center
Louis Stokes Cleveland
Department of Veterans Affairs Medical Center (LSCDVAMC)

APT CENTER

TECHNICAL FOUNDATIONS
FOR CLINICAL INNOVATIONS

A VA Research Center of Excellence

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ANNUAL REPORT
For activities during the period: January 1, 2007 – December 31, 2007

Annual Report
January 1, 2007 – December 31, 2007
Cleveland Advanced Platform Technology Center
Louis Stokes Cleveland Department of Veterans Affairs Medical Center

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A. SUMMARY OF YEAR

1. Mission of the APT Center

Mission: *The APT Center develops advanced technologies that serve the clinical needs of veterans with motor and sensory deficits and limb loss to provide clinician-researchers within the Department of Veterans Affairs (VA) with new tools for rehabilitation, treatment and scientific inquiry that lead to independence and enhanced societal participation. This is accomplished by collaborating with leading academic, industrial and clinical partners within and outside the VA system. The APT Center is a national leader in creating and delivering innovative products based on cutting edge technologies and a catalyst for the discovery and development of new technologies and techniques that can be employed in the rehabilitation process to provide independence for veterans and other individuals with disabilities.*

The primary strategy of the APT Center is to bring the clinical needs of veterans to the attention of the engineers and scientists pursuing new and emerging technologies in order to apply them for the purposes of reducing disability, improving daily function and enhancing quality of life. Our approach is based on the fundamental assumption that there is considerable untapped potential in new technologies that could be brought to bear on solving the pressing, real world clinical needs of disabled veterans. In many cases, these technologies are being developed for non-medical purposes and their potential in rehabilitation has not yet been appreciated.

The purpose of the Center is to identify high priority rehabilitation needs and then match them with potential technological solutions. We systematically gather, organize and analyze the needs of clinicians and potential consumers of assistive technologies before evaluating the portfolio of technologies at our disposal to see if possible solutions exist. Therefore, it is important that the Center maintain a broad base of collaborators in the various engineering and scientific disciplines. Where no potential matches between emerging technologies and clinical needs exist, the interactive process will facilitate the exploration of new approaches, techniques and technologies that might not otherwise have existed or been apparent.

It is critical to the mission of the Center that the platform technologies identified and developed become readily available to the veteran and accessible to clinician-scientists within the VA Healthcare System. Therefore, prototype devices and new technologies need to be developed in a manner that is consistent with the production and commercialization of medical-grade products. The APT Center is organized to ensure that the technologies that result from our efforts are suitable for regulatory approval, are manufacturable, and can be broadly disseminated. Our goals are accomplished by performing design and prototype functions under structured quality control systems so that large-scale production can be outsourced to contract fabrication facilities or transferred directly to commercial partners.

2. Stated Goals and Objectives Achieved

Goals: The overall five year goals of the APT Center are to:

1. Create an environment where the pressing clinical needs of clinicians and veterans with motor and sensory dysfunction and limb loss can be coherently represented to engineers and scientists developing advanced technology.
2. Foster multidisciplinary interactions between clinician-scientists and device designers in order to find creative solutions to real-world rehabilitation issues.
3. Design deployable and manufacturable rehabilitation products that address the unmet needs of veterans with disabilities.
4. Facilitate production of new rehabilitation technologies for a wide variety of applications.
5. Ensure access to the resulting rehabilitation products and disseminate them throughout the VA Healthcare System.
6. Protect intellectual property and enable technology transfer to commercial manufacturers.
7. Provide training opportunities for clinicians in rehabilitation engineering and technologists in rehabilitation science related to advanced technology.
8. Support rehabilitation research at other Centers of Excellence by adapting the foundational technical platforms to meet their specific needs for advanced prosthetic systems and sensory aids.

This section reports on the progress toward these goals completed in 2007. Center objectives established at the beginning of the reporting period are identified, followed by specific accomplishments and progress toward achieving them.

Objective 1: Establish an APT Center governing board and convene at least one meeting of this advisory panel.

Progress and Accomplishments:

The APT Center governing board was constituted and the first meeting of this new advisory group was scheduled during the reporting period. This governing board, called the *APT Executive Steering Committee* consists of representatives from the major institutional stakeholders of the Center who have all agreed to meet annually to provide continuing program evaluation and direction. The Department of Veterans Affairs is represented by the Chief of Staff (Dr. Murray Altose) and Associate Chief of Staff for Research (Dr. Neal Peachey) of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC), along with the National Director of Neurology for the VA Healthcare System (Dr. Robert Ruff). Case Western Reserve University is represented by the Deans of the Schools of Medicine (Dr. Pamela Davis) and Engineering (Dr. Norman Tien), along with the Chairs of the academic departments with faculty members actively collaborating on APT projects. Complete membership of this advisory group is listed in **Table 1, Section C:6.**

Objective 2: Complete facility renovations at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center for APT Center activities and the Technical Development Laboratory (TDL).

Progress and Accomplishments:

- **Renovated Additional Space at the LSCDVAMC**

  An additional 1,754 additional square feet of research space was acquired and renovated for the APT Center in 2007. Part of this space is being used as a shared laboratory advanced prosthetics research and other APT sponsored projects. A separate laboratory area was also set up for tissue culture and other wet lab processes. Office, workspace and storage space were similarly consolidated for APT Program Support Information Technology (IT) personnel and IT workroom/storage functions.

Figure 1: Technical Development Laboratory.

- **Technical Development Laboratory (TDL) Renovation Completed**

  TDL Renovations were completed to include updated working space for 9 engineering staff. The addition of conference tables and white boards contributed to the creation of an open environment to foster creativity. The 5500 sq. foot lab features a class 1000 clean room, making fabrication of implantable micro-devices, surgical tools, and other cutting edge components possible.

Objective 3: Build capacity by recruiting at least two investigators with parallel research interests.

Progress and Accomplishments:

Three new investigators and one Medical Consultant joined the APT Center in 2007.

- **Jonathan Baskin, MD**

  Dr. Jonathan Baskin joined the APT Center in April 2007 as a principal investigator. Dr. Baskin is board certified in Otolaryngology with special research interest in general craniofacial surgery, and facial and plastic reconstruction. He is an Assistant Professor, Department of Otolaryngology-Head & Neck Surgery, Facial Plastic & Reconstructive Surgery, Craniofacial Surgery at the Louis Stokes VA Medical Center, University Hospitals of Cleveland, and Case School of Medicine. His research interests are in the areas of tissue engineering materials and bone scaffolding for craniofacial reconstruction after Blast & Orthopaedic Trauma (BOT).

Figure 2: Jonathan Baskin, MD.

- **Gilles Pinault, MD**

  Dr. Gilles Pinault has joined the APT Center as an investigator in 2007. Dr. Pinault is a Vascular Surgeon, and Medical Director, Surgical Intensive Care Unit (SICU) at the LSCDVAMC. Dr. Pinault also holds the positions of Assistant Professor of Surgery and Clinical Instructor for the Department of Anesthesiology, both at Case Western Reserve University. He has been the co-investigator on two VA Cooperative Trials and his research interests lie in applying implantable stimulation technology to correct gait deficits in persons with partial paralysis from Traumatic Brain Injury (TBI). He is actively involved in the intra-operative testing of new neural interfaces being designed and developed in the APT Center (see Project #9, "Enhancing Neuroprosthesis Performance with Nerve Cuff Electrodes," for more details).

Figure 3: Gilles Pinault, MD.

- **Roger Quinn, PhD**

  Dr. Quinn's research is dedicated to the advancement of the field of robotics using insights gained through the study of biological mechanisms. Dr. Quinn is Director of the Biorobotics Laboratory, a Professor of the Mechanical and Aerospace Engineering Department, and Arthur P. Armington Professor of Engineering, at Case Western Reserve University. He is actively pursuing the design of new joint mechanisms for orthoses and prostheses with other APT investigators (see Project #10, "A Hybrid Neuroprosthesis," for more details).

Figure 4: Roger Quinn, PhD.

- **Charles Yowler, MD**

  Dr. Charles Yowler agreed to serve as a medical consultant to the APT Center beginning April 2007. Dr. Yowler's expertise is in acute trauma care and the treatment of burns. He is currently Director, Division of Trauma, Critical Care, Burns and Metro Life Flight at MetroHealth Medical Center and an Associate Professor of Surgery, Case Western Reserve University. Dr. Yowler completed his residency and fellowship training at Walter Reed Army Medical Center, where he also served as Chief, Burn Study Branch, U.S. Army Institute of Surgical Research and Assistant Chief and Critical Care Medicine Service at Fort Sam, Houston,Texas.

Figure 5: Charles Yowler, MD.

Objective 4: Continue with deep implementation of our Clinical Needs Assessment series and survey the environment for potential additional technology development efforts.

Progress and Accomplishments:

Progress and accomplishments toward this objective included submission of grant applications focusing on TBI and Post Traumatic Stress Disorder (PTSD), organization of two specialty tutorials on wheelchairs and burns, and completion of a collaborative workshop on Lower Extremity (LE) prosthetics.

- **Two grant applications submitted to Department of Defense (DOD)**

  As a result of our growing experience in the clinical needs assessment area, we submitted two grant applications to the DOD to conduct needs assessment workshops. The first was in collaboration with the **Brain Rehabilitation Research Center at the Malcolm Randall VA Medical Center, Gainesville, Florida.** The purpose of this grant submission was to 1) identify and prioritize the needs of veterans with blast related TBI and their families that might be met by applying new and emerging technologies, 2) identify new technologies with potential to make significant impact on diagnosis and measurement of TBI, and 3) identify members of a research network to design, develop, disseminate and evaluate these technologies, including potential members and stakeholders not present at the workshop.

  The second grant application was in collaboration with the **University Of Southern California Institute for Creative Technologies, Marina Del Rey, California**. The objectives were to 1) identify and prioritize the **needs** of veterans with Post Traumatic Stress Disorder (PTSD) and their families that might be met by applying new and emerging technologies, 2) identify new **technologies** with potential to make significant impact on these needs and 3) identify members of a **research network** to design, develop, disseminate and evaluate these technologies.

- **Wheelchair and Burns Tutorials conducted**

  A specialty Wheelchair Tutorial was held in February 2007 to further implement the findings of our Sensory and Motor Loss Needs Assessment workshop held in 2006. Richard Simpson, PhD of the **Pittsburgh VA Research Center of Excellence, Wheelchairs and Associated Rehabilitation Engineering (WaRE)** served as the principal instructor for the session. Potential collaborations in the areas of control and remote sensors, command conditioning and control strategies for wheelchair applications were explored as a results of the tutorial. These discussions continued when Drs. Simpson and Brewer attended Case Western Reserve University's annual Research Showcase to view demonstrations of APT technology. Jeremy Dunning, an APT Staff Engineer, then visited WaRE's facilities at the Pittsburgh VA to further evaluate opportunities for co-developing new rehab technologies and identify the potential for collaborative research and access to specialized Center resources and facilities.

  We held a second specialty tutorial focused on burns and the potential for technical interventions in burn treatment. Fourteen clinical experts, scientists, and engineers participated to further our discussion and refine potential research interests. Dr.

Charles Yowler was the key expert and shared his experiences as Chief of the Burn Study Branch in the U.S. Army Institute of Surgical Research at Fort Sam, Houston, Texas. Projects in the areas of tissue engineering and preparation of graft sites were identified with Letters of Intent (LOIs) expected to result from the effort.

- **Prosthetic Needs Assessment Workshop held in collaboration with VA Puget Sound Health Care System in Seattle, WA**.

  On **October 30-31, 2007,** we collaborated on a 2-day workshop to assess the needs, interests and experiences of lower limb prosthesis users and to begin design of potential improvements. The workshop featured the active participation of prosthesis users with amputations resulting from either trauma or diabetic dysvacularity. Twenty professionals working in lower limb prosthetics research and design, product testing, clinical practice, manufacturing and marketing also participated. To optimize workshop design, flow of events and harvesting findings, the planners contracted with professional action researchers (Water Cooler Logic, Inc.), experienced in qualitative research and participatory design.

  Day–One, Discovery, focused on eliciting experiences, interests and needs, starting with facilitated group discussions among participants within their interest groups: prosthesis users, researchers, clinicians, and industry representatives. Informal interview-conversations allowed participants to dig deeper into issues of use and needs.

  Day-Two, Design, involved small group design sessions on high priority topics from Day-One discovery work. Cross constituent teams brainstormed design specifications for specific parts and sub-systems of prospective new device components—e.g., sockets, ankle-foot actuators, liners, and 'smart devices'—as well as for areas of care provision, product testing and measurement. Informal café style conversations pushed these topics and introduced some new ones, including ways in which amputees could connect better to each other, with the VA and with industry.

Key Results of the workshop included identification of the following needs:

- Persistent unmet needs of prosthetic users are fit, comfort, function, stability, and performance.
- The funding environment needs to offer more options for research aimed at longer term outcomes that have potential to reduce economics costs and improve quality of life.
- Multi-center collaborations on both care protocols and research are needed to create methods for evidence-based improvement and standardization of the continuum of prosthetic care.
- An ongoing and comprehensive system of care is needed to match the wide spectrum of technical prosthetic solutions with the wide spectrum of users and their lifestyles.
- Education of prosthetic users and their families is needed to allow them to be more informed consumers of prosthetic devices and care, acute training, and lifelong fitness.

- Clinicians need expanded opportunities to learn how to incorporate additional devices and research results into treatment protocols.

Workshop Evaluations were positive and a publication summarizing the results will be submitted to the Journal of Rehabilitation Research & Development (JRRD) in early 2008.

For more information, please see Project #1, "Clinical Needs Assessment."

Objective 5: Increase the bandwidth of the APT Center Quality System: Assist other Centers of Excellence in implementing a Quality System for their projects.

The APT Center is committed to total customer satisfaction, which we achieve through the research, design, development, and manufacture innovative, and relevant medical product platforms. The APT Center Quality Management System is the foundation that supports the efficient operation of the Center and ensures compliance with all applicable regulations governing medical devices.

Progress and Accomplishments:

- We have generated 20 new Quality Standard Operating Procedures (SOPs) and completed a comprehensive APT Center Quality Manual within the past year.
- A master reference file with all the approved SOPs, forms and policies has been added to the APT Center Intranet for easy access of all individuals to the approved documents.
- We have assisted both the Cleveland Functional Electrical Stimulation (FES) Center and the Boston VA on the preparation of their own Quality documents by supplying them reference copies of all of the approved APT Center Quality documents and provide ongoing advice and counsel.

Objective 6: Transfer three ongoing development projects into the APT Center Design Controls.

Progress and Accomplishments:

- Five projects have been transferred into the APT Center Design Controls. This culminated in the preparation and submission of a Device Master File (DMF) submitted to the Food and Drug Administration (FDA) for the Flat Interface Nerve Electrode (FINE). The five projects are as follows:

  1. **Implanted Intramuscular Stimulating Electrode:**

     This device is inserted into a muscle minimally invasively via a cannula. A unique polypropylene anchor secures the device to the tissue while still allowing removal. Fabrication of this device has been transferred to a contract manufacturer and the design will be under inspection controls for quality assurance in the APT System in early 2008.

2. Epimysial Stimulating Electrode:

This device is sutured to the muscle surface or surrounding tissue at the nerve entry point. A reinforced skirt provides an interface by which the surgeon can affix the electrode to the muscle tissue near the neuromuscular junction. The platinum iridium (PtIr) disk is the means by which the stimulating current is delivered to the tissue. The lead is flexible and sufficiently robust to allow for joint motion and limb movement without compromising electrode integrity. The electrode is small enough to allow implantation into the extremities, yet large enough to allow the use of standard surgical tools and techniques. Quality inspection controls are in progress.

3. Spiral Cuff Nerve Electrode:

This electrode is designed to encircle the nerve for improved activation and recording selectivity. The spiral contains an array of one or more electrical contacts embedded within an elastomeric sheet which is biased to curl to a predefined radius. The device is uncurled to slip under the target nerve. When released, the electrode wraps around the nerve multiple times. As such it is self-sizing, does not require sutures, and allows removal of the intact electrode. The APT Center is in the process of transferring the spiral nerve cuff electrode to a contract manufacturer. Design controls are expected to be completed in 2008.

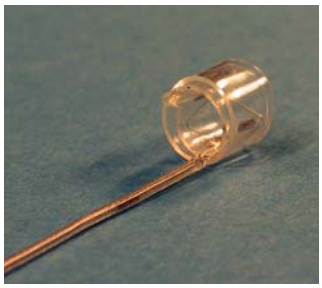


Figure 6: Spiral Cuff Nerve Electrode.

4. Flat Interface Nerve Electrode (FINE):

This nerve based electrode conforms to nerve geometry for increased stimulation and recording selectivity. The FINE contains an array of electrical contacts that can be implanted around a peripheral nerve trunk and both record electrical activity from the nerve to be used as a feedback control signal and deliver stimulation to the same nerve. In 2008, design controls and the transfer to contract manufacturing are expected to be complete.

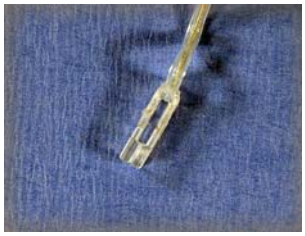


Figure 7: Flat Interface Nerve Electrode.

5. Implanted Intramuscular Myoelectric Signal (MES) Recording Electrode:

The Intramuscular Stimulating Electrode is a modification of the Intramuscular Stimulating Electrode that allows acquisition of myoelectric signal (MES) from contracting muscles. Addition of a second contact surface promises the ability to obtain bipolar recording of biopotentials for feedback or control.

Four additional projects are awaiting review and consideration for acceptance into the APT Quality System.

Objective 7: Submit at least one design dossier to FDA to apply for a Device Master File (DMF).

Progress and Accomplishments:

- The FINE DMF was submitted, accepted, and assigned a number from the FDA in October 2007.

Figure 8: Device Master File on Scale (6.5 lbs.).

All fabrication methods, materials and suppliers for the FINE were qualified under a formal design control process. This effort resulted in the submission of a DMF with the US FDA. This complete technical dossier specifying all aspects of device manufacture and expected performance is now available for investigators throughout the VA system who intend to utilize the device in their research to reference in the preparation of the Investigational Device Exemptions (IDE) for their specific clinical applications.

Objective 8: Maintain increased productivity levels of and access to APT Center products.

Progress and Accomplishments:

- We have delivered 7 custom designed spiral nerve cuffs to a small medical device company for both acute and chronic animal studies, with an order for 13 more pending initial results.
- We received an order for 3 standard spiral nerve cuffs from another medical device company for acute animal study, with an order for 10 more for chronic animal studies pending initial results.
- A third medical device company has submitted an order for one standard nerve cuff for evaluation.
- We are in the planning stages of establishing a subcontract on a Phase II SBIR that was submitted in December 2007 that will leverage our capability to build prototype intramuscular myoelectric signal (MES) recording electrodes.
- Manufacturing transfer of the intramuscular recording electrode to a separate small company began in 2007. Transfer of the standard spiral nerve cuff electrode to the same company was also initiated and will be completed in 2008.

Objective 9: Secure leveraged funding for APT Center projects from at least two sources and secure independent funding for three projects.

Progress and Accomplishments:

- During this period the APT Center secured independent funding for three (3) projects. The VA RR&D Service awarded two merit reviews: *Neural Interfaces for Prosthetic Command and Sensory Feedback* to Dr. Dustin Tyler and *Wireless Implantable Pressure Monitor for Clinical Application* to Dr. Margot Damaser. A third was awarded by the NIH to Dr. Ronald Triolo for *Enhancing Neuroprosthesis Performance with Nerve Cuff Electrodes.* Please see the leveraged funding table in **Section C: Project Reports** for a complete listing.

Objective 10: Submit at least 5 manuscripts for publication in peer reviewed journals and 10 presentations at national conferences.

Progress and Accomplishments:

- In 2007 APT Investigators published 72 manuscripts in peer reviewed journals and 26 manuscripts were under revision during this period. "Fibre pays off for nanocomposites" made the cover story of the December issue of *Nature Nanotechnology* (Figure 9). Our investigators also completed a total of 66 presentations at national conferences. Please visit the listing in **Section E: Information Dissemination** for additional information.

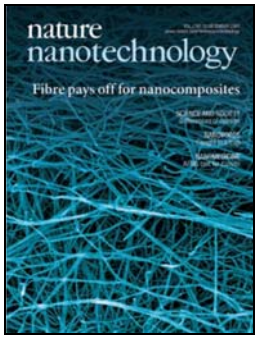


Figure 9: Nature Nanotechnology Cover.

Objective 11: Participate in one new collaborative project with clinical and/or research groups within the VA Healthcare System.

Progress and Accomplishments:

- Our Prosthetic Needs Assessment Workshop was held on October 30 and 31st in collaboration with VA Center for Limb Loss Prevention and Prosthetic Engineering in Seattle, WA. The evaluations for this event were positive and a joint publication is in progress.
- We also submitted grant applications with the **Brain Rehabilitation Research Center at the Malcolm Randall VA Medical Center, Gainesville, Florida** and **University of Southern California Institute for Creative Technologies, Marina Del Rey, California.**
- We have completed three site visits and are continuing discussions with the **Pittsburgh VA Research Center of Excellence, Human Engineering Research Laboratories,** regarding collaborations in the areas of control and remote sensors, command conditioning and control strategies for wheelchair applications

For more information please see **Section A.2, Objective 4.**

3. Future Goals and Objectives

The long-term goals of the APT Center remain unchanged from our original plan as articulated in the Center grant proposal. Specific short-term objectives for 2008 are as follows:

1. Supply the APT Center IM-MES devices for use in clinical trials.
2. Secure newly leveraged funding for APT Center projects from at least two sources.
3. Submit at least twenty (20) manuscripts for APT related projects for publication in peer reviewed journals and/or presentations at national conferences.
4. Build capacity by establishing junior investigators recruited to the APT Center.
5. Continue with deep implementation in the APT Center Clinical Needs Assessment series and begin an environmental survey on somatic-sensation applications.
6. Gain an understanding of the quality needs and clinical implications of the products produced in labs at other Centers of Excellence.
7. Transfer three (3) ongoing development projects into the APT Center Design Controls and expand design control teams.
8. Submit at least one (1) APT design dossier to the FDA to apply for a Device Master File.
9. Maintain the distribution and market penetration of APT Center products.
10. Transfer two (2) APT products to contract manufacturing.

4. Plan adjustments

There have not been any plan adjustments in calendar year 2007.

B. PROJECT REPORTS

During the reporting period, APT Center investigators submitted a total of 44 applications for research funding to various federal and private agencies. Twelve (12) submissions were VA Merit Review applications. Peer review of 14 of these opportunities is still in process, with funding decisions pending.

1. Project Submissions/Approvals (VA, Other Federal, and Private Funding)

	Status	PI	Title	Sponsor	Period	2007 Direct Costs[1]	2007 Indirect Costs[1]	2007 Award	Total Award
1.	Submitted	Baskin	Achieving Osteointegration and Mechanical Strength in Biomaterials	VA RR&D	10/07-09/08	N/A	N/A	N/A	$748,433
2.	Approved	Bogie	Advances in Pressure Relief Technology using Dynamic Materials	VISN RIP	10/06-09/07	N/A	N/A	$2,500	$10,000
3.	In Review	Bogie	Chronic Wound Therapy: A Wireless Surface Electrical Stimulation System	VA RR&D	06/08-05/11	N/A	N/A	N/A	$746,300
4.	Approved	Bogie	Effects of Weight Shifting on Pressure Ulcer Risks	NIDRR	10/07-09/12	$13,500	$5,200	$18,700	$400,000
5.	In Review	Capadona	Development of Advanced Materials for Direct CNS Interfacing	VA RR&D CDA-2	06/08-05/10	N/A	N/A	$239,550	$479,100
6.	Submitted	Creasey	Matching New Technologies to New Brain Injuries	USAMRAA	06/08-12/09	N/A	N/A	N/A	$187,500
7.	Submitted	Creasey	Design on New Technologies for Management of PTSD	USAMRAA	06/08-12/09	N/A	N/A	N/A	$187,500
8.	Approved	Damaser	Wireless Implantable Pressure Monitor for Clinical Application	VA RR&D	10/07-09/10	$246,300	N/A	$246,300	$742,800
9.	Approved	Damaser	Feasibility of Electrical Stimulation for Fecal Incontinence in a Rat Model	American Medical Systems, Inc.	08/07-07/08	$30,000	N/A	$12,500	$30,000
10.	Approved	Damaser	Mechanical Characterization of Air-charged and Water-filled Catheters	TDOC LLC	11/07-10/08	$1,166	N/A	$1,166	$7,000
11.	Approved	Garverick	High-Temperature ASIC for Orbital Sensor Interface	DOD	11/06-05/07	$11,637	$6,342	$17,979	$27,930
12.	Approved	Garverick	Electrode Arrays for Neurodynamic Studies	NSF	09/07-08/10	$125,065	$68,160	$193,225	$375,196

	Status	PI	Title	Sponsor	Period	2007 Direct Costs[1]	2007 Indirect Costs[1]	2007 Award	Total Award
13.	Submitted	Garverick	High-Temperature Microsystems for Combustion Diagnostics	NASA	01/07-12/09	N/A	N/A	N/A	$1,321,352
14.	Submitted	Garverick	Integrated surface electrical stimulation device for therapeutic applications	NIH	04/07-03/09	N/A	N/A	N/A	$424,875
15.	Submitted	Garverick	Flexible Electronics and Communication Technology for Clinical Surface, Closed-Loop Diagnosis and Therapy	NSF	06/07-05/10	N/A	N/A	N/A	$330,000
16.	Submitted	Garverick	Miniature High-Resolution Ultrasound Array	NIH via CCF	07/07-06/11	N/A	N/A	N/A	$382,688
17.	Submitted	Garverick	Electronics and Substrate Fabrication for an Integrated Surface Stimulation Device	NIH STTR	11/07-10/08	N/A	N/A	N/A	$88,466
18.	Submitted	Garverick	Electronics and Communication Technology for 64-Channel Neural Recording and Stimulation	NSF	09/07-08/10	N/A	N/A	N/A	$240,007
19.	Submitted	Garverick	SoftWorm - A Soft, Biologically Inspired Worm-Like Robot	DARPA	01/08-12/09	N/A	N/A	N/A	$2,990,000
20.	Submitted	Garverick	Thermal Sensing Grid for Integrated Vehicle Health Management	NASA via Haric, LLC	10/07-09/10	N/A	N/A	N/A	$204,212
21.	Submitted	Garverick	LANdroids	DARPA	12/07-11/10	N/A	N/A	N/A	$1,313,260
22.	In Review	Garverick	Conformable Electrode Arrays with Integrated Sense/Stimulation Wireless Electronics for Neurodynamic Studies	NIH	09/07-08/09	N/A	N/A	N/A	$424,875
23.	In Review	Garverick	Nanofabrication Using Local Probes	DARPA	01/08-06/12	N/A	N/A	N/A	$2,996,402
24.	In Review	Garverick	Miniature High-Resolution Ultrasound Array	NIH via CCF	07/08-06/12	N/A	N/A	N/A	$1,699,200
25.	Approved	Mohseni	Implantable Microsystems for Anatomical Rewiring of Cortical Circuitry: A New Approach for Brain Repair	DOD	07/08-12/09	N/A	N/A	N/A	$204,388
26.	Submitted	Pinault	Gait Impairment Correction after TBI with Implanted Neural Prosthesis	DOD	03/08-02/12	N/A	N/A	N/A	$1,499,998

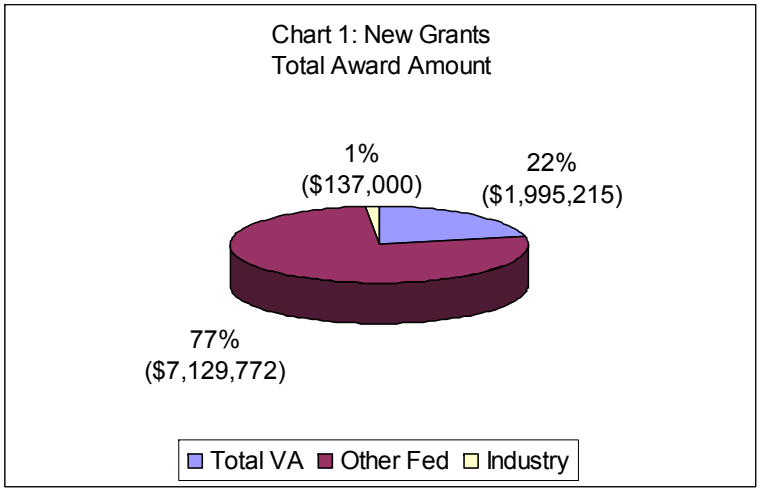
	Status	PI	Title	Sponsor	Period	2007 Direct Costs[1]	2007 Indirect Costs[1]	2007 Award	Total Award
27.	Approved	Potkay	A High Efficiency, Micro Machined Artificial Lung	VISN RIP	10/07-09/08	N/A	N/A	$10,000	$10,000
28.	In Review	Potkay	Safety and Efficacy of an Implantable Power source	VA RR&D	10/08-09/10	N/A	N/A	N/A	$193,600
29.	Approved	Rowan	The Development of MetalloSupramolecular Materials	NSF-CHE	08/07-07/10	$496,717	$270,710	$767,427	$1,490,151
30.	In Review	Rowan	Novel Molecular-Actuator-Based Active Nanostructures: Synthesis, Nanomechanical Behavior and Electrical Conductance	NSF-CMMI	08/07-07/10	N/A	N/A	N/A	$1,074,129
31.	Approved	Rowan	Healing Polymers: The Self Assembly Approach	NSF	08/06-07/09	$420,000	$228,900	$648,900	$1,260,000
32.	Approved	Rowan	Multifunctional Metallosupramolecular Materials	ARO	07/06-08/09	$273,575	$149,098	$422,673	$820,725
33.	Approved	Triolo	Facilitating Ambulation After Incomplete SCI [2]	VA RR&D	07/07-06/10	N/A	N/A	$89,708	$645,900
34.	Approved	Triolo	Enhancing Neuroprosthesis Performance with Nerve Cuff Electrodes	NIH	09/07-06/11	$1,434,547	$745,070	$243,073	$2,179,617
35.	Approved	Triolo	Senior Research Career Scientist	VA RR&D	10/07-09/14	N/A	N/A	$20,947	$586,515
36.	In Review	Triolo	A Neuroprosthesis for Seated Posture and Balance [2]	VA RR&D	N/A	N/A	N/A	N/A	$738,100
37.	In Review	Kobetic	Control of a Hybrid Neuroprosthesis for Walking in SCI	VA RR&D	N/A	N/A	N/A	N/A	$672,300
38.	In Review	Tyler	Neural Interfaces for Prosthetic Command and Sensory Feedback	VA RR&D	06/08-09/10	N/A	N/A	N/A	$722,400
39	Approved	Tyler	Peripheral Nerve Implementation of Functional Neuroprosthesis [2]	NIH-NINDS	08/07-07/09	$51,635	$28,140	$79,776	$371,765
40.	Approved	Weder	Mechanochromic Polymers	Alcoa	01/07-12/07	$100,000	N/A	$100,000	$100,000
41.	In Review	Weder	Hyperbranched Conjugated Polymers	ACS-PRF	01/08-12/10	N/A	N/A	N/A	$150,000
42.	In Review	Weder	Homeland Security – From Molecules to Materials, From Science to Society	NSF-IGERT	07/08-06/13	N/A	N/A	N/A	3,000,000

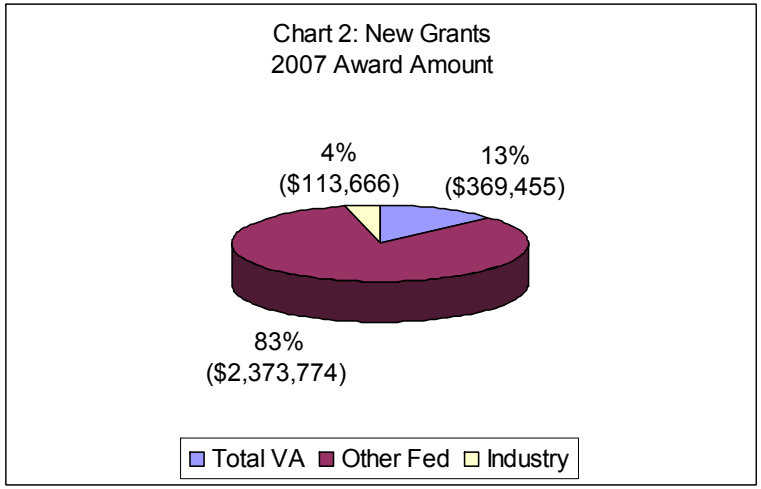
	Status	PI	Title	Sponsor	Period	2007 Direct Costs[1]	2007 Indirect Costs[1]	2007 Award	Total Award
43.	In Review	Weder	A Biomimetic Approach to Adaptive Nanocomposites	NSF-NIRT	07/07-06/11	N/A	N/A	N/A	$1,400,000
44.	In Review	Zorman	IGERT Program for the Development of Integrated, Implantable Micro and Nanofabricated Sensor Technologies for Biomedical Applications	NSF	07/08-06/13	N/A	N/A	N/A	$3,161,247
	Total VA			12	-			$369,455 Approved $239,550 In Review	$1,995,215 Approved $3,551,800 In Review
	Total Other Federal			29	-			$2,373,774 Approved	$7,129,772 Approved $13,905,853 In Review
	Industry			3	-			$113,666 Approved	$137,000 Approved
	Grand Total			**44**	**-**			**$2,856,895 Approved** **$239,550 In Review**	**$9,261,987 Approved** **$17,457,653 In Review**

[1] Calendar Year Non-VA grants only

[2] Joint Project with Cleveland FES Center

The APT Center is exceeding the 5:1 leveraged fund requirements with a 10:1 level for total awards in 2007 (Chart 1). We are also exceeding the requirement that 10% of leveraged funds need to be from sources beyond VA RR&D, with 87% of our funding coming from other sources in calendar year 2007 (Chart 2).





2. *Ongoing Funded Projects (VA, Other Federal, and Private Funding)*

The APT Center participated in thirty-two (32) ongoing projects funded by various sources that were initiated prior to the reporting period. Projects listed as complete were completed during calendar year 2007.

	Status	PI	Title	Sponsor	Period	2007 Direct Costs[1]	2007 Indirect Costs[1]	2007 Award	Total Award
1.	Ongoing	Capadona	Stimulus-Responsive, Mechanically-Dynamic Nanocomposite for Cortical Electrodes	VA RR&D CDA-1	10/06-09/08	N/A	N/A	$82,680	$165,360
2.	Ongoing	Damaser	Research Career Scientist	VA RR&D	10/04-09/09	N/A	N/A	$61,250	$306,250
3.	Ongoing	Damaser	Mechanisms of Female Incontinence in Diabetes	NIH	09/05-09/08	$275,000	$149,875	$424,875	$825,000
4.	Ongoing	Damaser	Recovery of Stress Urinary Incontinence in Diabetes	VA RR&D	10/06-09/09	N/A	N/A	$249,000	$747,000
5.	Ongoing	Damaser	Mechanisms of Incontinence Following Vaginal Distention	NIH	04/06-03/11	$200,000	$109,000	$309,000	$1,000,000
6.	Ongoing	Damaser	Patient-Oriented Models for Urinary Function in Women	NIH	07/06-06/09	$97,221 subcontract	$52,985	$150, 206	$450,619
7.	Ongoing	Garverick	SiC TAPS Sensors for Extreme Harsh Environments	DARPA	01/05-12/08	$616,439	$335,959	$952,398	$1,849,318
8.	Ongoing	Garverick	Neuromechanics of Multifunctionality in Aplysia	NIH	05/05-04/09	$471,500	$256,967	$728,467	$1,886,000
9.	Ongoing	Garverick	Diamond Neuro-Sensing and Stimulating Electrodes	NIH	07/06-06/11	$380,800	$207,536	$588,336	$1,904,000
10.	Complete	Garverick	Microprocessor-based Constant-Voltage Anemometer	Tao Systems, Inc.	07/06-05/07	$12,633	N/A	$12,633	$12,633
11.	Ongoing	Kirsch	Prosthetic Arm Control Device for Amputees [2]	TATRC	01/07-12/07	$1,151,250	$279,750	$1,431,000	$1,431,000
12.	Complete	Rowan	Development of Novel Organic/Inorganic Hybrid Oligomer Architectures	NSF-Career	06/02-05/07	$120,100	$65,400	$185,500	$600,500
13.	Ongoing	Rowan	Center for Layered Polymeric Systems	NSF S&T Center	06/05-05/10	$3,692,000	$2,012,140	$5,704,140	$18,460,000
14.	Ongoing	Triolo	Automatic Control of Standing Balance [2]	NIH	04/06-03/10	$345,785	$188,453	$534,238	$1,383,143

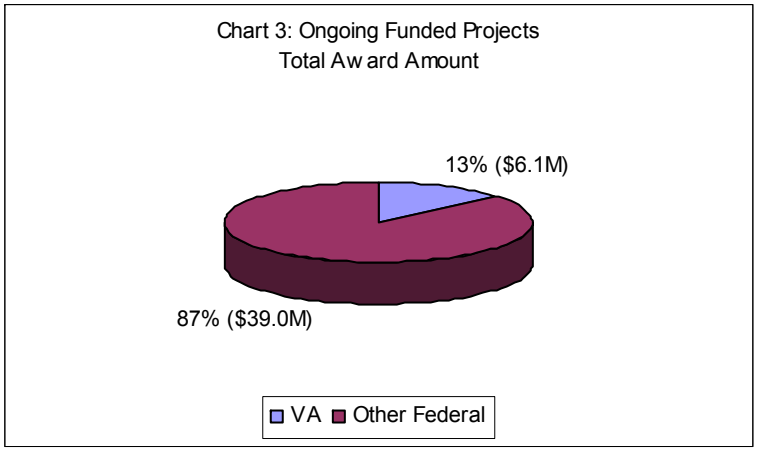
	Status	PI	Title	Sponsor	Period	2007 Direct Costs[1]	2007 Indirect Costs[1]	2007 Award	Total Award
15.	Ongoing	Triolo	A Hybrid Neuroprosthesis for Mobility	DOD	04/05-03/09	$436,383	$237,828	$674,211	$1,745,533
16.	Ongoing	Triolo	Center of Excellence, Advanced Platform Technology	VA RR&D	01/05-01/10	N/A	N/A	$850,000	$4,550,000
17.	Complete	Triolo	Enhancing Neuroprosthesis Performance with Nerve Cuff Electrodes	NIH	09/03-08/07	$117,554	$64,067	$181,621	$1,128,525
18.	Complete	Triolo	Research Career Scientist	VA RR&D	10/02-06/07	$61,250	N/A	$30,625	$306,250
19.	Ongoing	Tyler	Stimulus-Responsive, Mechanically-Dynamic Nanocomposite for Cortical Electrodes	NIH	06/06-05/08	$150,000	$81,750	$231,750	$424,875
20.	Ongoing	Tyler	Electrical Stimulation of the Bilaterally Paralyzed Larynx Paced with Respiration [2]	NIH	06/06-05/11	$118,180	$64,409	$182,589	$590,904
21.	Complete	Weder	Polymers with Integrated Deformation Sensors	NSF-DMI	09/04-08/07	$147,000	$79,933	$226,933	$1,056,000
22.	Complete	Weder	NSF Special Creativity Award	NSF-DMR	09/05-08/07	$80,000	$43,600	$123,600	$576,000
23.	Complete	Weder	Responsive Polymers for Cortical Electrodes	NIH	12/05-11/07	$184,341	$100,466	$284,807	$402,200
24.	Ongoing	Weder	Dynamic Inorganic/Organic Hybrid Photonic Crystals	NSF	07/06-05/09	$194,000	$105,730	$299,730	$582,000
25.	Complete	Weder	Single Molecule Conductors	CWRU PRI	04/04-04/07	$50,000	N/A	$50,000	$200,000
26.	Complete	Weder	Mechanochromic Polymers	Kimberly-Clark	01/05-06/07	$20,000	N/A	$20,000	$100,000
27.	Complete	Weder	Synthesis of High-Spin Conducting Polymers	EU Marie Curie Grant GKSS	07/05-06/07	$24,000	N/A	$24,000	$48,000
28.	Ongoing	Young	Intelligent Sensor Network for In-Vivo Real Time Biological Dynamic System	NSF	09/03-08/07	$65,211	35,540	$100,751	$675,000
29.	Ongoing	Young	RF Data Transmitter and Receiver Modules for MEMS	ARO	06/05-08/07	$61,473	33,502	$94,975	$150,000
30.	Ongoing	Young	Nerve Reshaping for Improved Selectivity	NIH	07/05-06/10	$300,000	$163,500	$300,000	$1,500,000

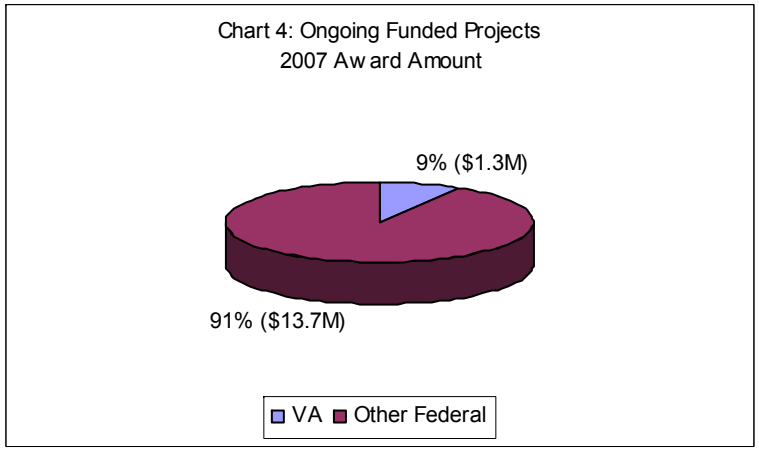
	Status	PI	Title	Sponsor	Period	2007 Direct Costs[1]	2007 Indirect Costs[1]	2007 Award	Total Award
31.	Ongoing	Zorman	Comprehensive Characterization of the Mechanical Properties and Hermetic/Chemical Inertness of Sputtered and PECVD SiC	NASA (GSRP Training Grant)	09/07-08/10	$30,000	$16,350	$30,000	$90,000
32.	Ongoing	Zorman	A Micro fabricated Neural Electrode Array Technology for Long-Term Implant Applications	NSF (Training Grant)	09/07-08/08	$31,075	$16,935	$48,010	$96,022
	Total VA			**5**				**$1,273,555**	**$6,074,860**
	Total Other Federal			24				$13,686,931	$39,006,639
	Industry			3				$56,633	$160,633
	Grand Total			**32**				**$15,017,119**	**$45,242,132**

[1] Calendar Year Non-VA grants only

[2] Joint Project with Cleveland FES Center

The APT Center exceeded the leveraged funding requirement for years 2005 and 2006 with a 27:1 match (Chart 3). In addition, greater than 91% of the leveraged funds were from sources other than VA RR&D (Chart 4).





3. Project Progress Notes

The APT Center investigators led or actively participated in numerous ongoing projects in 2007 and either initiated or assumed principal roles in the eleven projects described below. Detailed summaries of the status of each project, including plans for publication and future funding opportunities, are provided. These projects would be prohibitively difficult or impossible to pursue without the unique environment and contributions of the APT Center.

Project #1: Clinical Needs Assessment

Principal Investigators: Graham Creasey, M.D., and Suzana Iveljic, M.B.A.

Description

The APT Center places high priority on developing technology that is clinically relevant. This project consists of using systematic processes to determine the needs of veterans that may be addressed by advanced technologies. This information can be used by us and other researchers in focusing research in the direction most beneficial to the veteran. The project collects and examines information about needs and utilizes that data to determine priority goals, to develop a plan, and to allocate funds and resources. Veterans, researchers, rehabilitation clinicians, and representatives from the medical device industry, are included with APT Center Co-Investigators and Leadership in gathering data. Both structured and informal data gathering techniques are employed. Structured techniques include focus groups, surveys, and expert panels; informal techniques include user-engineer and clinician-engineer interaction, web-based methods, and unsolicited feedback obtained at conferences and scientific meetings.

Objectives

The main objective of this project is to identify and prioritize the needs of veterans that may be solvable by applying new and emerging technologies in the short, medium, and long-term. A secondary objective is to learn the most effective techniques for obtaining this data.

In particular, objectives for the needs assessment workshop regarding lower limb prosthetics were as follows:

a. Assess qualitatively and in detail, the needs, concerns and interests and perspectives of users about the performance of their prosthetics devices.
b. Assess the basic working hypothesis in research and design about different needs for the diabetic dysvascular and the traumatic groups.
c. Hold open-ended discussion of what issues and opportunities could shape the future directions of research and design across the different kinds of professionals attending as well as across the range of prosthesis users.

Research Plan

Surveys provide general impressions and direction but not enough detail to develop specific technological applications. Consumers have difficulty trying to define the "next step" technological device and it is rare that consumers can express their needs in a way that is translatable to technical specifications. Our best successes come from having those involved in technical design and development converse and interact directly with consumers during their regular activities. Interactions such as these enable critical design specifications that might otherwise go unnoticed be identified. Therefore, we plan to use focus groups, workshops, expert panels, and direct interaction with veterans at the foundation of our research plan. Once we obtain a relatively broad picture of the technological needs, we can follow-up and supplement this with surveys, web-based information gathering, and observation to fill in details, provide feedback, and complete our assessment.

Methodology

We have held several workshops using the Water Cooler Logic Methodology. This methodology driving the agenda of the workshops has been used in over 50 projects in 15 Veterans Integrated Service Networks (VISNs) encompassing 65 Veterans Affairs Medical Centers (VAMCs), Community Based Outpatient Clinics (CBOCs), the Veterans Benefit Administration (VBA) and National Cemetery Administration (NCA) organization, and within National Headquarters. It is a method of qualitative discovery, research, and social intervention that integrates the aims and principles of change management with organizational learning. It also recognizes and leverages the largely unrecognized contributions of informal work and learning.
The three phases of this methodology are:

a. "Discovery" – observing and talking with those who are potential users of the technology or who will be affected by it.

b. "Co-design" – initially using divergent thinking to scan a wide range of options, followed by convergent thinking to classify and group the resulting possibilities into practical solutions and products.

c. "Deep implementation" – evaluating prototypes while maintaining a willingness to revise, adjust, and amend the process. This recognizes the iterative nature of development whereby feedback refines the design and corrects misconceptions or unintended consequences.

Benefits of using a strict qualitative methodology include inviting the best participants and helping participants to conduct useful, focused discussions and related idea-development processes through plenary sessions and break-out groups. Participants also gain exceptional clarity of expression and then formal representation of the outcomes of their discussions, brainstorms, debates, etc — and help them move these ideas to actionable plans whenever it is appropriate and feasible to do so.
Finally, other proven supplemental methodologies such as surveys and web-based information gathering will be used to reaffirm our findings and provide for insight into other exploratory areas.

Milestones

We submitted grant applications to the DOD with the **Brain Rehabilitation Research Center at the Malcolm Randall VA Medical Center, Gainesville, Florida** for a technology needs assessment focusing on the clinical area of TBI and **University of Southern California Institute for Creative Technologies, Marina Del Rey, California,** for a technology needs assessment focusing on the clinical area of PTSD.

Figure 10: 10/30-31/07 Lower Limb Needs Assessment group picture.

We organized one Needs Assessment Workshops and two Specialty Tutorials this year. The first workshop occurred in October 2007, in collaboration with the Dr. Glenn Klute at **VA Center of Excellence in Limb Loss Prevention and Prosthetic Engineering** focusing on the needs of lower extremity amputees. As a result of this Needs Assessment, a publication is in progress and research grant applications are being explored.

The specialty tutorials focused on burns and areas of control and remote sensors, command conditioning and control strategies for wheelchair applications. The wheelchair tutorial was Dr. Richard Simpson from the **Pittsburgh VA Research Center of Excellence, Human Engineering Research Laboratories.** It was attended by over 10 individuals from the clinical, engineering, and scientific disciplines. A small group of attendees then participated in two additional site visits, with definitive plans for technology development in progress.

Figure 11: Dr. Simpson presenting at the Wheelchair Tutorial.

We held a specialty tutorial on burns with 14 clinical experts, scientists, and engineers. Dr. Charles Yowler was previously Chief of the Burn Study Branch in the U.S. Army Institute of Surgical Research at Fort Sam, Houston and key clinical speaker. It was determined that imaging could be used to determine burn depth and predict which skin graphs will heal after application. Next steps are to involve collaborators from the Case Western's School of Medicine and Biomedical Engineering departments.

Clinical Relevance

The entire purpose of this project is to insure the clinical relevance of the technologies developed by the APT Center. It is crucial for the APT Center to develop technologies that meet the clinical needs of veterans with disabilities and this project enables us to obtain information regarding important unmet needs. It also allows us the opportunity to formally solicit clinician leadership and participation in assessing needs, developing functional specifications, evaluating prototypes, and disseminating products for clinical testing.

Project #2: Career Development Award – Level 1 (CDA-1): "Stimulus- Responsive, Mechanically-Dynamic Nanocomposite for Cortical Electrodes"

Principal Investigator: Jeffrey Capadona, Ph.D.

Mentors: Dustin Tyler, Ph.D., Christoph Weder, Ph.D., Stuart Rowan, Ph.D., Ronald Triolo, Ph.D.

Description

The overall goal of this CDA-1 Award is to provide Dr. Capadona with the opportunity to continue to develop as an independent researcher under the mentorship of proven LSCDVAMC investigators. He will work as part of a research team to train in polymer materials development and fabrication, and in the *in vivo* assessment of the material's compatibility. He will also be attending regular seminar series related to the field, disseminate his research findings by publishing and presenting at national meetings, and attending graduate level courses pertaining to the development of polymeric materials for uses as biomedical materials in the Department of Macromolecular Science and Engineering and the Department of Biomedical Engineering at Case.

Preliminary Results

Dr. Capadona has rapidly assimilated into the research groups of his mentors, and has developed first generation polymer nanocomposites towards stimulus responsive cortical electrodes. He is currently training in the surgical techniques required for the *in vivo* evaluation of these materials.

Dr. Capadona's efforts have also lead to the submission of four co-authored papers, and presentations at multiple scientific meetings.

J.R. Capadona, K. Shanmuganathan, D.J. Tyler, S.J. Rowan, C. Weder. "Bio-inspired chemo-mechanical polymer nanocomposites that mimic the sea cucumber dermis." *Science*. 2008, (accepted).

J.R. Capadona, O. van den Berg, L.A. Capadona, M. Schroeter, S.J. Rowan, D.J. Tyler, C. Weder. "Self-assembled nanofiber templates for the preparation of well-dispersed polymer nanocomposites." *Nat. Nanotech.* 2007, 2(12); 765-769 (*Cover*).

O. van den Berg, M. Schroeter, **J.R. Capadona,** and C. Weder. "Nanocomposites based on cellulose whiskers and (semi)conducting conjugated polymers." *J. Mater. Chem.* 2007; 17(26); 2746-2753.

O. van den Berg, **J.R. Capadona,** and C. Weder. "Preparation of homogeneous dispersions of tunicate cellulose whiskers in organic solvents." *Biomacromolecules.* 2007, 8(4): 1353-1357.

Milestones

Dr. Capadona and his mentoring team published consecutive papers in high-profile, high-impact journals, Nature Nanotechnology (awarded front cover), and Science.

Dr. Capadona has been able to successfully develop dynamic materials that change their mechanical stiffness with response to two independent stimuli.

In 2007, we completed preliminary in-vivo testing and initiated full-scale animal trials.

Through his participation in the APT Center's Clinical Needs Assessment Series, Dr. Capadona has begun to develop collaboration with additional VA Investigators, and secured VA RR&D funding for an additional research program.

Future Grant & Publication Plans

Current funding for the CDA-1 Award is scheduled to continue through September 2008. A Level 2 Career Development Award (CDA-2) has been submitted for the continued mentored development under the guidance of VA Investigators.

The preliminary results obtained from Dr. Capadona's direct and contributed research efforts are in preparation for submission of multiple manuscripts:

1. *In Vitro Evaluation of the Cytotoxicity of Mechanically Dynamic Cortical Implant Materials*

   This paper will be a summary of the *in vitro assessment of the cytotoxicity* of the novel nanocomposite material, as well as the *in vitro* assessment of the electrode insertion into mimetic brain tissue (gelatin).

2. *In Vivo Evaluation of the Mechanically Dynamic Cortical Implant Materials*

   This paper will summarize the *in vivo* evaluation of the acute and chronic implant studies with electrodes fabricated from our nanocomposites.

3. *Water insoluble Cellulose Aerogels for Tissue Engineering Scaffolds*

   This paper will discuss findings related to the self-assembly of cellulose fibers into a rigid and porous network that can be chemically cross-linked into scaffolds for tissue engineering applications.

4. *Thermally Controlled Mechanically-Dynamic Polymer Nanocomposites*

   This paper will discuss the development of reinforced polymer nanocomposites that demonstrate changes in mechanical properties with heating and swelling in water.

Clinical Relevance

This development effort is highly significant as there is an unmet need for mechanically-dynamic material, which will enable development of a wide range of biomedical devices that will significantly and positively impact Veteran health care. Such applications could include dynamically compliant stress transducers, orthopaedic and prosthetic devices with controllable joint stiffness, conformal matching of prosthetic socket mechanical properties, neuromimetic electrodes for neural interfaces, obstructive sleep apnea (OSA) devices that dynamically stiffen the airway at night and are compliant during the day, implants for erectile dysfunction, vocal fold implants and biodynamic sensors. Further, this material will allow other investigators to devise many new and as yet unimagined applications.

Project #3: Modular Wound Therapy System (mWTS)

Principal Investigator: Kath Bogie, D.Phil.

Co-Investigators: Steven Garverick, Ph.D. & Christian Zorman, Ph.D.

Staff/Students: Jeremy Dunning, M.S.; B.S.; & Daniel Howe, B.S, Allison Hess

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Description

The overall goal of this project is to develop a wireless surface electrical stimulation system (mWTS) combining the use of advanced materials, fabrication techniques and design together with a simple, user-friendly communication interface in a novel medical device costing less than $100. It consists of a flexible substrate, battery, and custom integrated circuitry integrated into a conforming occlusive dressing. The device can be applied over a chronic wound as a bandage (for days or weeks at a time) and deliver therapeutic electrical currents to accelerate healing wirelessly. The device can then be simply removed, disposed of, and replaced to continue treatment. The mWTS will be a therapeutic electrical stimulation device that achieves high efficacy and safety *and* high acceptance by both clinicians and user.

This project will develop a reliable and effective disposable wound therapy stimulation system that will improve ease of use and acceptance by both users and clinicians. Multiple therapeutic applications in acute clinical care and rehabilitation would be positively affected by utilization of electrical stimulation (ES) as a platform modality. This project will thus provide the basis for the further development of a novel surface stimulation platform technology with the potential for widespread clinical utility both within the VA Health Care System and in other health care settings.

Objectives

a. To establish the proof of concept for the mWTS through the design and preliminary testing of a prototype device.

b. To implement use of the mWTS in the rat chronic ischemic wound model.

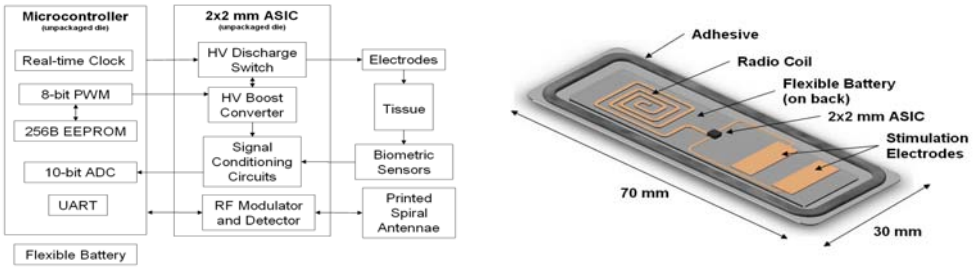


Figure 12: Concept drawing of the modular wound therapy system (mWTS).

Research Plan & Methodology

A preliminary mWTS has been developed by our team as a semi-flexible device (Figure 12). The electronics, communications components and lithium battery power supply are mounted on a rigid printed circuit board (PCB). The PCB is mounted on a 4x3cm flexible medical-grade polyimide substrate with sputter-plated platinum stimulating electrodes designed for use in our animal model. There is an infrared (IrDA®) bi-directional wireless communications interface to enable user command via an on-board microcontroller that can adjust stimulation variables. The electronic design employed an adaptable architecture that facilitates future functional adaptations. The on-board microcontroller is easily reprogrammed to communicate new clinical stimulation protocols. The capability for reprogrammable functions, including actuator timing, sensor data acquisition, sensor data storage, and communications host allows evaluation of the effects of varying ES conditions and can monitor device function in pre-clinical testing. In clinical use, the ability to vary stimulation protocols provides the potential for customized use of the mWTS.

Preliminary Results

Complete evaluation of the individual components of the mWTS and benchtop testing of a working prototype to determine electrical and mechanical functionality under simulated animal testing conditions has been completed. A prototype flexible mWTS was implemented in our rabbit ischemic wound model. The mWTS was attached to the animal with a medical grade pressure sensitive adhesive and preliminary device function and communication was tested. The external communications protocol allowed two-way communication to both control the stimulation variables and download information on wound status.

Milestones

Training in a new chronic ischemic wound animal model will commence in the 2nd quarter of 2008. A pilot series of animal testing using the prototype flexible mWTS will be carried out in the third quarter of 2008, which will result in information necessary to optimize the design of the integrated circuit by the end of the year. Preparation for production and qualification for human testing will follow.

Future Grant & Publication Plans

In addition to the VA Rehabilitation Research and Development grant application reported in **B1: Project Submissions/Approvals,** the following grant application is in preparation.

NAKFI Futures Grant:

Aging and healing of chronic wounds: development of a chronic ischemic wound animal model.

Submission is anticipated for February 2008.

Clinical Relevance

Electrical stimulation has been recommended for treatment of chronic wounds however this therapeutic modality is limited by the technology currently available. The mWTS will provide a major new tool in wound care because it will allow patients to receive continuous ES therapy within the optimal wound healing microenvironment without further restricting mobility. A communications interface will allow clinicians to control and monitor therapy using readily available devices, such a laptop or PDA.

The mWTS will apply leading-edge technology and design to significantly advance the field of wound care with a novel medical device that is well accepted by both clinicians and users. Furthermore, the mWTS will have the potential to improve clinical care for many conditions that may require short- to medium-term therapeutic electrical stimulation.

On completion of pre-clinical testing using the new animal model our goal is to carry out pilot clinical trials in collaboration with both the Spinal Cord Injury and Disability (SCI/D) and Podiatry Services of the Cleveland VAMC.

Project #4: Advances in Pressure Relief Technology Using Dynamic Materials

Principal Investigator: Kath Bogie, D.Phil.

Co-Investigators: Jeffrey Capadona, PhD. & Christoph Weder, PhD

Staff/Students: TBH

Description

The overall study objective is to develop a range of support surface devices, including wheelchair cushions and mattress overlays that will provide highly cost-effective pressure relief for individuals at increased risk of tissue breakdown.

The specific goal of this study was to develop and test a prototype cushion that utilizes advanced dynamic materials to create a modular support device. The unique modular design of this system will allow for low-cost customization for individual seating requirements and provide the capacity for the cushion to be repaired rather then replaced, thus increasing durability and decreasing overall costs. Within the scope of the study the aims were to:

Objectives

a) Characterize materials and develop designs for cost effective support surface device.

b) Design and fabricate prototype support surface devices for mechanical testing to investigate durability.

Research Plan & Methodology

Component materials for the proposed support device have been evaluated and prototype cushions assembled for qualitative evaluation of sitting comfort. Selected cushions will then be tested using standardized wheelchair cushion testing procedures.

Preliminary Results

The modular components of the proposed cushion were tested using Fourier Transform Infrared Radiation (FTIR) spectroscopy and Proton Nuclear Magnetic Resonance Spectroscopy (1H-NMR). It was found that the other layers of all the gel balls tested were composed of the same material, most likely to be polyethylene with considerable branching and/or side chains. Preliminary cushion layouts were tested and data analysis is in process.

Milestones

Testing of materials loading properties will be completed by the second quarter of 2008. Prototype cushions have been designed and will undergo comprehensive biomechanical testing by the third quarter of 2007.

Future Grant & Publication Plans

The findings from this pilot study will be used in the development of a Merit Review Application to the VA in late 2008.

Clinical Relevance

Chronic wounds, including pressure ulcers and venous ulcers, are a leading cause of re-hospitalization for many veterans and are often associated with prolonged periods of hospitalization. This major secondary complication is also among the most common cause of morbidity in the patient populations cared for by the VA.

Prevention of pressure ulcers in veterans at-risk for tissue breakdown is integral to the goal to provide the highest standards of care for veterans. Novel techniques to improve the efficacy of this intervention, in particular pressure relief systems, are integral to developing advanced programs of care for at-risk individuals.

Project #5: Wireless Implantable Pressure Monitor for Clinical Applications

Principal Investigator: Margot Damaser, Ph.D.

Co-Principal Investigators: Darrin Young, Ph.D. and Steve Garverick, Ph.D.

Co-Investigators: Wen Ko, Ph.D., Graham Creasey, M.D.,
Hui Zhu, M.D., Sc.D., Kenneth J. Gustafson, Ph.D.,

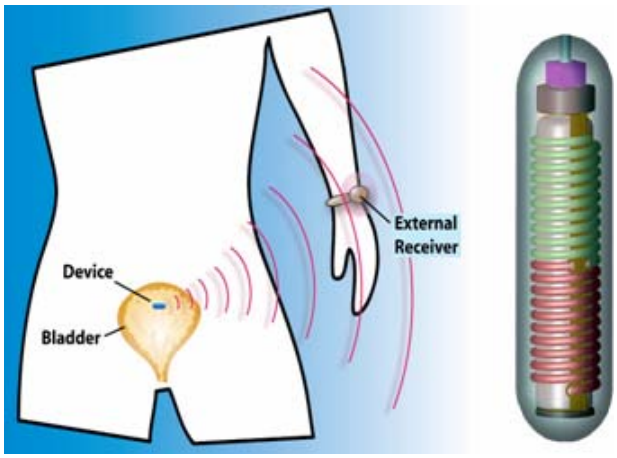
Staff: Paul Fletter, B.S., James Buckett, M.S., Brad Boggs, M.S.,
Paul Zaszczurynski, B.S.,

Students: Steve Majerus, Peng Cong

Description

Measurement of physiological pressures is fundamental to many forms of medical diagnosis and monitoring in cardiovascular, respiratory, gastrointestinal, urological and other systems. One example is urodynamics, the measurement of bladder pressure to diagnose incontinence. Pressure is usually measured via catheters, either connected to transducers outside the body or more recently by micro-transducers mounted on the tip of such catheters. However, this requires that the catheters be inserted and maintained without infection and that the patient be tethered to a recording device. It would be a great advantage to continuously measure pressure using a miniature device that transmits wirelessly to an external receiver (Figure 13). Existing monitors are either passive devices, with no onboard power source and required to be near their external power source, or active devices with a battery onboard that are too large for our primary application in the bladder. A miniaturized, active device, or one with a creative wireless powering method, could be implanted in internal organs. Such a device could either be inserted into an internal organ or could be implanted endoscopically. This device would have application for many purposes including

diagnostic, monitoring, biofeedback, and as a mechanism to improve control of rehabilitative systems, such as those using functional electrical stimulation or neuromodulation. Since no such systems currently exist, this technology development project will result in a novel medical device that clearly serves an important, but yet unmet, clinical need.



A) B)

Figure 13: A) Wireless signal is sent from the implanted sensor to an external reciever worn by the user. B) Conceptual representation of the implantable device.

Objectives

The objectives of this project are to design, fabricate, and test a wireless, implantable pressure monitor.

Research Plan & Methodology

Research Plan: We have created a large prototype using PC Board technology and have tested it in a pressure chamber. We have also tested methods and devices for insertion of the device into the bladder. We have determined that salt water (to simulate the body) does not degrade transmission of the signal. We have used these preliminary data to support a VA Merit Review proposal to build an appropriately sized prototype using integrated circuit technology. Experiments are being performed to further assess the attenuation of intravesical pressure signals as sensed through the mucosa and derive methods to compensate for any losses due to the this tissue layer. We are currently investigating the geometries and spatial relationships of internal and external coil designs to be used for wireless RF powering and data telemetry. Testing is currently underway on the first generation Application Specific Integrated Circuit (ASIC) and will lay the ground work toward on-board implant control circuitry.

Methodology: APT Center funding had enabled us to form an investigative team, formulate a research plan, and obtain the preliminary data needed to submit for external funding. We will continue to make progress toward the objectives above over the next three years. In addition, VA Merit review funding enables us to continue

pursuing methods of inserting and implanting the pressure sensor in the bladder (the initial target organ).

Milestones

This research project has been awarded VA Merit Review funding of $750,000 over three years, beginning October 2007.

We have determined that bladder pressure measured submucosally reflects lumen pressure by placing a catheter with a custom latex diaphragm under the mucosa in a pig bladder placed in our *in vitro* bladder testing apparatus. We have developed a large prototype using PC board technology and have tested in a pressure chamber. The results demonstrate high repeatability with low hysteresis. Fabrication of the device using an unpackaged pressure sensor, ASIC technology for the circuitry, and a different battery during the proposed project will significantly reduce the size of the device.

We have designed and tested an insertion tool to demonstrate implantation of a submucosal device into the bladder wall. We have demonstrated this concept in preliminary experiments inserting mock devices (i.e. steel pellets) into pig bladders *in vitro*.

We have fabricated the first generation ASIC to test the circuitry components that will be incorporated into the final design.

Clinical Relevance

The ability to *continuously* record pressures from within the body without catheters would have dramatic significance in many medical specialties. In intensive care units, besides eliminating inconveniences associated with tethering of patients by catheters, wireless implanted monitors have the potential to reduce catheter line infections and associated morbidity and mortality. Ambulatory monitoring, home monitoring, and telemedicine would be greatly enhanced by long term monitoring of pressure. In addition, pressure measurement could be used as feedback for biofeedback training and rehabilitation systems. This device would allow improved therapeutic control of many conditions such as urinary incontinence, pulmonary hypertension, chest pain of non-cardiac origin, and lack of bowel and bladder control due to spinal cord injury. The initial application to ambulatory urodynamics would have great significance for improving diagnosis and treatment of incontinence, which is endemic among the elderly.

The special features of the veteran population, such as traumatic injuries to the brain and spinal cord, increasing age, and prevalence of cardiovascular disease and diabetes suggest opportunities for improved monitoring and treatment of complications such as urinary and fecal incontinence, constipation, and pulmonary hypertension. As an example of relevance, 25% of the 250,000 people with spinal cord injuries in the U.S. are veterans and there are 10,000 people with new spinal cord injuries incurred each year. The aging veteran population includes many with disabilities as well as decreased bladder and bowel control, resulting in urinary and fecal incontinence.

Continence and pelvic health are especially important to the health and well being for these at-risk segments of the disabled veteran population. The proposed device will improve the health and quality of life for disabled veterans by enabling new treatment interventions and diagnostic modalities that will improve their standard of care.

Project # 6: Wireless Implantable EMG Microsystem

Principal Investigator: Darrin Young, Ph.D.

Co-Investigator: Ronald Triolo, Ph.D.

Staff/Students: Bradley Farnsworth, B.S.

Description

This project focuses on developing a subcutaneously implantable sensing and telemetry microsystem for electromyographic (EMG), or myoelectric signals (MES), which can be interfaced with an external transceiver module, housed in or on a prosthetic socket. The prototype system will sense EMG signals from the muscles in the residual limb and transmit them out of the body to the external receiver for analysis and adaptive control of a powered prosthetic limb (Figure 14). The external unit can also transmit RF power to the implanted system. Commercially available myoelectrically-controlled powered prostheses rely on EMG signals acquired from the surface of the skin via recording electrodes embedded in the socket and are prone to problems that can significantly degrade signal integrity and prosthesis performance. The microsystem configuration we are developing (tiny wireless sensing elements placed subcutaneously directly on the target muscles) should significantly reduce movement artifact and obviate other factors that are known to adversely impact the operation of myoelectric prostheses. In essence it will decouple the issues related to socket fit and alignment (including perspiration, variable contact with the skin surface, inability to utilize a liner, etc.) from issues related to EMG signal acquisition. The transcutaneous EMG sensing and telemetry microsystem is expected to substantially enhance the biomimetic performance of myoelectrically controlled powered prosthetic limbs for veteran amputees. The proposed prototype development can potentially be incorporated intoexisting upper and lower limb prosthetic systems.

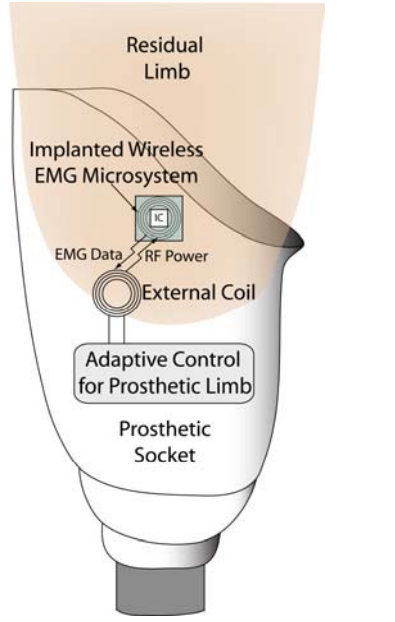


Figure 14: The implantable wireless EMG sensor will be powered by a radio-frequency signal transcutaneously from an external transceiver housed in a prosthetic socket as shown schematically in the figure.

Objectives

The objective of this project is to design and implement an implantable EMG sensing and telemetry microsystem, which can be interfaced with an external transceiver.

Research Plan & Methodology

The electronic building blocks required for the proposed implantable wireless EMG sensing microsystem will be first designed and optimized using a computer-based circuit simulation program. The finalized design will be fabricated using a commercial complementary metal oxide semiconductor (CMOS) process with an estimated chip dimension of 2 mm x 2 mm x 0.3 mm. The completed chips will initially be interfaced with existing implantable EMG electrodes. The electronic chip with an RF coil loop can be placed adjacent to the platinum electrodes to maintain flexibility in that region. Electrical connections will be formed by wire bonding of the IC and spot (or laser) welding of the stainless steel wires to electrically connected pads. The chip will be covered by epoxy and silicone before conducting animal implant studies. To eliminate the complexity associated with hand-made EMG electrodes and to improve the interconnect reliability between the electrodes and sensing electronics, microfabricated EMG electrodes will be made by using sputtered platinum thin film over flexible and biocompatible substrates such as polymer liquid crystal. The microfabricated EMG electrodes can be interfaced directly with the sensing electronics through flip-chip bonding of the IC, a technique well established and widely used in advanced semiconductor packaging. The packaged system will be protected by epoxy and silicone for further animal implant studies at the NEC at Case.

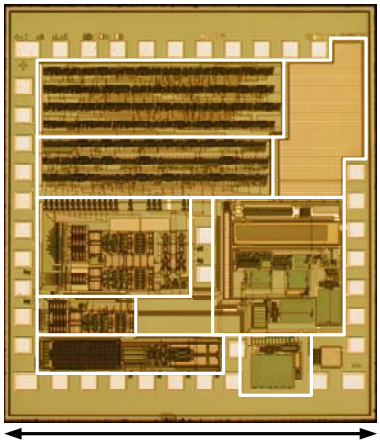


Figure 15: EMG sensing ASIC microphotograph.

Preliminary Results

A custom integrated circuit consisting of EMG interface electronics, analog to digital converter, wireless RF/DC power converter, wireless data telemetry circuits, and digital control circuitry was fabricated in the AMI 1.5 µm CMOS process in 2007 (Figure 15). Upon testing the chip, we discovered a layout problem which caused the RF/DC conversion block to be non-functional. However, we were otherwise able to perform a full circuit bench test characterization in wired operation. Overall, the microsystem performance was as designed. The chip is capable of amplifying and digitizing EMG waveforms. Additional issues affecting the performance of the ADC and the biasing of the front-end amplifier were also discovered during testing. These issues have been corrected in an updated version of the chip design which was submitted for fabrication in January, 2008. We previously characterized the wireless link for remote RF powering and data telemetry. RF power can be converted to achieve 2V/100 µA to supply the implantable electronics. Data telemetry with 2.5 Mbps has been demonstrated. These

capabilities far exceed the requirements for the control of existing myoelectric limb prostheses.

Milestones

We plan to develop a fully functional prototype wireless implantable EMG sensing microsystem within 6 months. Once performance of the prototype is verified, we will package the device for implantation and initiate *in vivo* animal testing. This will be followed by interfacing the prototype circuitry to an existing myoelectric prosthesis, essentially substituting the microsystem for the socket-based surface recording. Finally, issues related to fabrication and qualification for human use will be addressed. Initial proof-of-concept animal tests are planned for the spring of 2008.

Future Grant & Publication Plans

The research results will be published in BME conferences and related IEEE journals. Based on the research findings and developed electronics in this project, we plan to team up with another biomedical investigator to submit a research proposal to develop intelligent, wireless, implantable bio-potential signals sensing microsystem for neural prosthesis applications to funding agencies such as NIH and VA.

This microsystem will sense electroencephalogram (EEG) signals measured intracranially or under the scalp and transmit them out of the body for use as a control signal in neural prostheses such as brain-machine interfaces (BMI).

Clinical Relevance

The proposed implantable wireless EMG sensors can be used for obtaining long-term reliable myoelectrical signals for various clinical applications, including real-time adaptive human motor behavior control, wireless machinery control, and injured muscle activity and condition monitoring. The proposed study is expected to demonstrate and produce prototype fully functional wireless implantable EMG sensor units. The study results and prototype systems will be used to substantially enhance the biomimetic performance of myoelectrically controlled powered prosthetic limbs for veteran amputees. The developed technology also can potentially be incorporated into existing upper and lower limb prosthetic systems in the VA health care system.

Project # 7: Design, Development and Fabrication of Polymer Microstructures

Principal Investigators: Christian Zorman, Ph.D., & Dustin Tyler, Ph.D.

Staff/Students: Jeremy Dunning, M.S., Allison Hess, B.S.

Description

The APT Center is currently pursuing the design and development of innovative technologies that will yield advanced polymer materials for neural interfaces, microelectromechanical systems (MEMS) and implantable systems for biosignal acquisition and wireless transmission for the control of prostheses and other assistive devices. This particular effort proposes to merge two of these activities, namely advanced polymer materials and MEMS technology by developing polymer-based neurointerface devices made using MEMS-based fabrication techniques.

Objective

To develop baseline fabrication techniques for polymer micromachining using the tool set in the Microfabrication Laboratory (MFL), the Electronic Design Center (EDC), as well as the Emerging Materials Development and Evaluation Laboratory (EMDEL) in the Electrical Engineering and Computer Science (EECS) Department at Case Western Reserve University (CWRU) for the fabrication steps and mechanically flexible neural electrode array structures as the demonstration vehicles.

Research Plan & Methodology

The methodology used in this study follows procedures commonly used to evaluate new MEMS materials. For this project, the materials of interest include liquid crystal polymer (LCP) and polynorbornene (PNB). For the LCP devices, structures were fabricated from commercially-available LCP sheets. A CO_2 laser was used to pattern the periphery of the base structure of the electrode array. The LCP sheets were then mounted on silicon (Si) wafers. Platinum (Pt) electrodes with a titanium (Ti) adhesion layer were deposited and patterned on the base sheet. A PNB capping layer was spin coated and patterned on top of the metal and LCP. The electrode arrays were then released by stripping the Cu from the backside of the LCP to reveal the final structure. Process development involved using several wafers, some of which were extracted from the process sequence at various strategic points to evaluate key processing steps. Further, it involved choosing laser process parameters from an array in which the laser power, speed, and pulses per inch were systematically varied.

Results

During this reporting period (2007) development of mechanically flexible, polymeric neural electrode devices focused on the development of new nerve electrode design that would allow for both nerve stimulation and recording, as well as eliminate the need for molded silicone housing for the microfabricated electrode arrays. A schematic of an electrode array is shown in Figure 16. This device in particular is

composed of six thin film Pt electrodes, which are each connected to a contact pad by a long, flexible shaft. These long shafts are on each side of the structure to support of the long traces that link the electrodes to a standard Hirose FH-19 connector that enables interfacing to external electronics. This is in contrast to earlier electrode array designs, which required a silicone housing to secure two separate electrode arrays around a nerve. In the current design, a built-in strain relief accounts for roughly 20% of the shaft length. The array is folded along the centerline between the contact arrays, then positioned around the nerve, then closed and secured with sutures.

The electrodes are fabricated by laser cutting the base pattern into only the 50-µm thick LCP layer of a Cu-clad LCP sheet with a CO_2 laser. The laser was also used to cut the wafer shape out of the sheet by cutting through the LCP and perforating the Cu such that the wafer shape could be removed from the rest of the LCP sheet and adhered to a Si wafer. The contacts and traces are formed by negative tone photoresist, and sputter-deposition of 50nm Ti and 250nm Pt, prior to lift off in an ultrasonic bath. A PNB capping layer is then spin-cast and exposed to UV radiation, developed in methyl n-amyl ketone (MAK), and cured at 160ºC for 1 hour to create windows to the electrode and connector contacts. Finally, the Cu cladding on the backside of the LCP sheet is stripped in a sodium persulfate solution. Figure 17 shows one of the arrays after release.

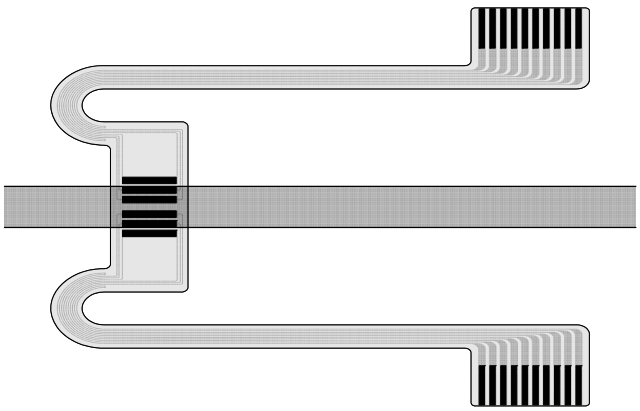


Figure 16: Schematic drawing of a LCP-based electrode array. The dark-grey region represents the

Conductivity from each of the electrode contacts to the connector contacts was evaluated prior to animal testing by submerging the business end of the device and a piece of stainless steel foil into a beaker with salt water. A multimeter was used to measure the resistance between the dry end of the foil and the connector end of the device. A resistance within the measurement range of the multimeter indicated that the Pt contacts and traces were continuous from the electrode contacts to the connector contacts.

Figure 17: Photograph of a completed and released LCP-PNB neural electrode array.

While this electrode array design has not yet been subjected to additional benchtop testing, a battery of tests was run to evaluate the electrical and mechanical viability of the earlier microfabricated FINE arrays. The earlier arrays were fabricated using a similar process sequence, with the exception of the way in which the LCP was patterned. For this earlier design, the effect of bending was examined by measuring the electrical resistance before and after wrapping the array around a 3.6 mm diameter rod. The average resistance of the flat electrode was 1107Ω while that for the curled electrode averaged 1112Ω ($p<<0.0001$, paired *t*-test). These numbers are comparable to the conventional Pt-foil/stainless steel wire based electrodes, which range from 600-2000Ω. The electrical resistance in solution was measured using a change-balanced, biphasic 1mA, 100μs current pulse applied by a standard stimulator to electrodes submerged in phosphate buffered saline (PBS). The voltage response was measured between the connector end and a strip of stainless steel foil placed at the opposite side of the container and indicated that the resistance of the electrodes in combination with the PBS is approximately 1kΩ.

The moisture absorption characteristics of the PNB capping layer on the LCP substrate were examined using interdigitated electrode (IDE) structures. Leakage current for a dry IDE was less that 20fA, and increased to 18pA over ten days of exposure to PBS.

The performance of the current array design was examined in trials in non-human primates to determine whether different channels on the same nerve could selectively produce different actions in the hand (Figure 18). Two different arrays were implanted on the median nerve in the upper extremity of a subject in locations chosen to target different muscles. The array was folded along the centerline between the contact arrays such that the array could be folded around the nerve, and the two halves of the array were secured around the nerve with a suture.

Figure 18: (left) No stimulation, (right) Stimulation of the proximal array, channel 1 (Grasping bar).

The functional response of the hand was recorded while each contact was stimulated individually with a multi-channel, square-wave, charge-balanced current generator.

For the distal array, it was found that stimulation of channel 1 resulted in the independent adduction of the thumb, while stimulation of channel 4 resulted in the independent movement of the long finger. On the proximal array, stimulation of channel 4 caused pronation of the forearm and stimulation of channel 1 caused flexion of the fingers into a fist.

Milestones

We are continuing with an extensive biocompatibility study of polynorbornene, the most comprehensive study of its type every conducted on PNB. The aforementioned fabrication work was completed by Allison Hess, a Ph.D. student in EECS at CWRU who is currently working on her MS thesis. Jeremy Dunning of the APT Center is assisting with many of the engineering aspects of this effort. An invention disclosure describing the design and fabrication of these electrodes was filed with CWRU and the VA in 2007. Ms. Hess has also completed the fabrication of PVAC-based cordical electrodes using material developed by APT investigators (Weder, Rowan, and Capadona) in the Department of Macromolecular Science at CWRU.

Future Grant & Publication Plans

Publication submissions in 2007 include a paper summarizing the in vitro assessment of the cytotoxcicity of *PNB* targeted to the Journal of Biomedical Materials Research and a paper detailing the use of polynorbornene as a bioMEMS material targeted for Biomedical Microdevices. An abstract was submitted for consideration by the program committee of the 2008 Solid-state Sensor, Actuator and Microsystems Workshop, better known as the Hilton Head Workshop. An invention disclosure is also in preparation.

Clinical Relevance

The work detailed in this report is clearly pre-clinical in nature as it involves new materials, methods and device designs that require rigorous evaluation at nearly all levels before they can be implemented at the clinical level. Nevertheless, the potential for such devices to make significant impact in the clinical setting in future systems is tremendous, since these devices offer the advantages of small size, mechanical flexibility, and high electrode density. The devices are created using a batch fabrication technology that offers a very high level of reproducibility and high throughput, which could lead to considerable cost savings over conventional devices as the device technology is moved towards commercialization. The devices should prove to benefit research at the pre-clinical level as components in systems designed to understand neural systems using animal models, which in turn, lead to improved clinical systems.

Project #8: Stimulus-Responsive, Mechanically-Dynamic Nanocomposite for Cortical Electrodes.

Principal Investigator: Dustin Tyler, Ph.D.

Co-Investigators: Jeffrey Capadona, Ph.D., Christoph Weder, Ph.D., Stuart Rowan, Ph.D., Christian Zorman, Ph.D.

Staff/Students: James Harris, M.S.

Description

The proposed project will develop the first examples of a new class of polymer nanocomposites that reversibly and dynamically alter their mechanical characteristics in response to an external stimulus. While many polymers alter their mechanical properties, the proposed materials are novel in that they change in direct proportion to the stimulus and are reversible, hence can be controlled. These advanced polymeric materials are scientifically novel and are expected to significantly contribute to the development of many advanced devices and applications in medical technology. The first application targeted here is a “smart” substrate for cortical electrodes. The proposed polymer nanocomposites will be engineered to exhibit a high Young’s modulus, or stiffness, and tensile strength to facilitate implantation of the electrodes into the cortex. Once the device is in place, the material will respond to the chemical environment of the cortex, changing the Young's modulus to match the surrounding tissue and thus becoming “mechanically invisible” to minimize chronic tissue response.

This will be the first demonstration of a mechanically dynamic and reversible, chemo-responsive synthetic material that can change its stiffness on a physiological time scale. We will establish the basic macromolecular engineering principles and demonstrate their feasibility in an important first application that represents an intriguing “prototype” because it only requires a single switching event under very well defined conditions. The general design principles established in this project can then be extended to other biomedical applications in which the mechanical properties can be changed in a controlled and reversible manner.

Cortical electrodes have demonstrated their potential for significant improvement in human health and quality of life, but have not yet achieved a satisfactory mechanical or molecular match with cortical tissue for long-term use. By matching tissue mechanical characteristics, we intend to investigate whether the tissue response to the electrode can be reduced, thus providing a stable long-term interface with cortical neurons. In this application, the material is only required to change mechanical properties once, demonstrating the feasibility of a mechanically-dynamic material in a relatively straightforward system, paving the way for future development of devices with substantial clinical impact.

Objectives

a. *To fabricate mechanically dynamic, nanocomposite polymers*

The focus of this effort is to establish the basic chemistry and processing methods to produce the polymer nanocomposite, and understand its material composition and behavior. The specifications of the prototype material will be guided by its targeted use as a neuromimetic cortical electrode. This will require a material that is initially stiff to allow for insertion of the electrode into the cortex and rapidly changes to match the compliance of the cortical tissue.

b. *To determine biocompatibility and tissue response to nanocomposite*

The objective is to demonstrate and understand the *in-vivo* behavior of the materials as they are developed. These studies will be performed in parallel to drive the development of the nanocomposite based on *in-vivo* behavior of the material. We will test the hypothesis that a mechanically matched material will minimize the astrocytic response and improve the interface between the cortical neurons and the electrode.

Research Plan & Methodology

To accomplish the first objective, high-aspect ratio, nanoscale cellulose "whiskers" are harvested from tunicates. These fibers are chemically functionalized and have been dispersed in polymer substrates of either polyethelene-oxide, polycaprolactone, or poly(vinyl acetate). As materials with varying mechanical properties are produced, these series of materials are characterized for their properties in the initial "stiff" configuration and "flexible" configuration after immersion in water or artificial cerebral spinal fluid (ACSF) at 37 $^{\circ}$C over extended periods. The effect of material composition and processing on the range of modulus change that can be realized will be compiled, resulting in a catalogue of the most promising formulations.

To accomplish the second objective, the most promising nanocomposites will be implanted chronically in the rat cortex. The tissue response will be characterized using fluorescent immunohistochemistry and light microscopy tools. The durability of the polymer will be assessed by mechanical testing of removed components. At the end of the proposed studies, we expect to have preliminary data to support further development of a cortical electrode with electrical contacts.

Preliminary Results

To date, significant research efforts have been made towards the first objective of fabricating mechanically dynamic nanocomposite polymers, and have recently begun towards the *in vivo* evaluation of first generation dynamic polymer nanocomposites.

Stimuli-Responsive Filler-Filler Interactions: Our group has already established the procedures to isolate gram-quantities of cellulose whiskers. In preliminary experiments in which the cellulose whiskers were decorated with sulfate groups, the feasibility of chemo-mechanical switching of the filler-filler interactions has been unequivocally demonstrated. Recently, we have further increased the mechanical contrast of these polymer nanocomposites through the introduction of a second,

synergistic switching mechanism based on the thermal transition of the polymer substrate.

Nanocomposite Fabrication: We have improved the mechanical reinforcement obtained in the polymer films containing cellulose whiskers since our last report, and now display approximately a 400-fold increase in modulus. The mechanism of modulus change in the nanocomposite is clearly related to coupling and decoupling of a whisker matrix, and results in a 40-fold, fully reversible mechanical contrast. The mechanism of switch mimics the natural defense mechanism of the sea cucumber, and has been accepted for publication in *Science,* (March 7th, 2008 issue).

The above systems demonstrated high contrast in "stiff" and "soft" states, but the overall modulus values were orders of magnitude below the mechanical requirements for our application. Therefore, based on the processing methods that we have recently developed, *Biomacromolecules 2007* and *Nature Nanotech* December 2008 (Cover), we were able to engineer a second generation chemoresponsive mechanically-dynamic material. This class of materials further increased the mechanical contrast of these polymer nanocomposites through the introduction of a second, synergistic switching mechanism based on the thermal transition of the polymer substrate.

Our most recent class of dynamic nanocomposites, demonstrating the multifaceted switching mechanism, utilizes the chemical environment of the body to alter the thermal properties of the polymer, in turn changing the mechanical properties at physiological temperatures. This most recently developed nanocomposite has proven to be "stiff" enough (5 GPa) for inserting into the cortex of a rat, unlike the "state of the art" in polymer electrodes. After applying both mechanisms for mechanical switching, the low end modulus fell to ~ 2 MPa, for a 2000-fold contrast in mechanical properties. This milestone was featured in the March 7th 2008 issue of *Science* Magazine.

Milestones

We have surpassed our anticipated milestones set on our last annual report. The second fabrication method that we developed for the production of polymer nanocomposites was featured on the cover of one of the world's most prestigious journals, *Nature Nanotechnology.* Additionally, the materials that we developed demonstrated a contrast in mechanical properties that successfully mimicked nature's design, and has been accepted for publication in another of the world's most prestigious scientific magazines, *Science*.

Preliminary *in-vivo* testing is underway utilizing advanced structures for cortical electrodes, which our fabrication team has developed from the novel materials. Working microelecrtodes have been utilized to record electrical potentials of cortical neurons, in an insect model. This work is currently being expanded to rodent models, which will also investigate the tissue response to the novel materials. These electrodes will be used for the full-scale animal trials to be conducted on second generation materials throughout 2008, and into the first quarter of 2009. These initial animal studies will demonstrate proof of concept, and will be the basis for design of next-generation dynamic materials.

The resources required to complete this work include a post-doc trainee and a graduate student to develop and explore the chemistry and synthesis of the nanocomposite material, constituent raw materials, testing instrumentation time. Additional resources are required for a second graduate student to characterize the materials *in vitro* an *in vivo*, and for the costs of animal trials, while a part of a third graduate student's time is required for developing the fabrication techniques to process the newly developed materials into relevant structures.

The resource required to complete this work are in place. The post-doc trainee working on this project has secured his own salary support in the form of a Level 1 Career Development Award. He is currently seeking the next phase in VA RR&D Career Development funding, in the form of a CDA-2. The research team has also been successful working under the awarded NIH R-21 Award, which covers operating costs, and salary/tuition support for two graduate students, and is not pursue an extension from the NIH in the form of a 4 year R-01 grant.

Future Grant & Publication Plans

An NIH - R21 proposal is currently funded. Upon successful completion of this APT Center pilot study, we will submit and R01 (Expected 03-08) for device development and animal trials using the new material. The CDA-2 Award is under review to investigate parallel aspects of the current projected. VA Merit Review funding and clinical trials are anticipated in 5-10 years.

These preliminary results will result in the preparation and submission of two manuscripts.

1. Journal TBD**,** *In Vitro Evaluation of the Cytotoxicity of Mechanically Dynamic Cortical Implant Materials*

   This paper will be a summary of the *in vitro assessment of the cytotoxicity* of the novel nanocomposite material, as well as the *in vitro* assessment of the electrode insertion into mimetic brain tissue (gelatin).

2. Journal TBD**,** *In Vivo Evaluation of the Mechanically Dynamic Cortical Implant Materials*

   This paper will summarize the *in vivo* evaluation of the acute and chronic implant studies with electrodes fabricated from our nanocomposites.

Clinical Relevance

This development effort is highly significant as there is an unmet need for mechanically-dynamic material, which will enable development of a wide range of biomedical devices that will significantly and positively impact Veteran care. Such applications could include dynamically compliant stress transducers, orthopaedic and prosthetic devices with controllable joint stiffness, conformal matching of socket mechanical properties, neuromimetic electrodes for neural interfaces, obstructive sleep apnea (OSA) devices that dynamically stiffen the airway at night and are compliant during the day, implants for erectile dysfunction, vocal fold implant to stiffen paralyzed folds for speaking and open the folds for breathing, dynamic loading

elements in implants, dynamic implantable connectors with minimal stiffness to connect and disconnect and rigid to prevent disconnect, and biodynamic sensors. Further, this material will allow other investigators to devise many new and as yet unimagined applications.

Project #9: Enhancing Neuroprosthesis Performance with Nerve Cuff Electrodes

Principal Investigator: Ronald J. Triolo, PhD.

Co-Investigators: Dustin Tyler, Ph.D.; Gilles Pinault, MD.

Staff/Students: Lee Fisher, Matthew Schiefer

Funding Agency: National Institutes of Health

Description

This project addresses the need for selective activation of peripheral nerves by optimizing the design of flat interface nerve electrodes (FINE) for application to the human femoral and sciatic nerves. The project builds upon earlier animal and human cadaveric studies to optimize the geometry and location of multiple contacts within the lumen of a FINE electrode to separate individual components of the femoral nerve to isolate knee extension from hip flexion, and the sciatic nerve to isolate ankle plantar/dorsiflexion with balanced inversion/eversion. The outcome will eventually improve the performance of neuroprostheses for standing and stepping after paralysis. The design and development process for these new neural interfaces progresses from a) quantitative neuroanatomical studies to b) computer modeling and simulation through c) intraoperative testing and d) device fabrication and chronic verification testing. This methodology was developed for the femoral nerve application and is being replicated for other neural targets, in this case the human sciatic nerve (tibial and fibular components).

Objectives

The primary technical objective of this development project is to optimize the design of stimulating nerve cuff electrodes to selectively activate desired fascicles within the human femoral and sciatic nerves. This is being accomplished by generating realistic models of cuff-nerve geometry and determining the fascicular selectivity of multi-contact cuff electrodes via computer simulation. This will result in an optimized cuff design that maximizes selectivity without detailed *a priori* knowledge of the fascicular structure of the nerve for any particular individual. The final goal of this project is to establish the chronic performance of resulting multi-contact cuff electrodes and evaluate their effectiveness in providing standing and stepping function in comparison to other electrode technologies.

Preliminary Results

We have completed quantitative anatomical studies of the structure of the human femoral and sciatic nerves. These studies documented the morphology of the nerve and defined the design space (nerve dimensions and variability) for FINEs intended for the neural targets. In short, we now know the ranges of cuff opening heights and widths appropriate

for the nerves and can manufacture devices customized for a specific nerve and its branches.

Serial cross sections of the femoral and sciatic nerves revealed their fascicular structures and have allowed the construction of finite element models that can be used to predict the fascicles (muscles) that can be activated by a stimulating current applied to a specific location within the lumen of the FINE. This powerful tool allowed us to optimize the selectivity of the devices by varying the placement of contacts within the electrode and simulating the responses of the nerves. Such computer simulation studies have been completed for the proximal femoral nerve and have resulted in the final specification of devices suitable for clinical use (Figure 19). FINEs configures specifically for the human femoral nerve have been fabricated and sterilized, and are currently undergoing intraoperative testing to verify their performance. Similar engineering analyses to design FINEs specifically for the distal sciatic nerve and its tibial and fibular branches are underway.

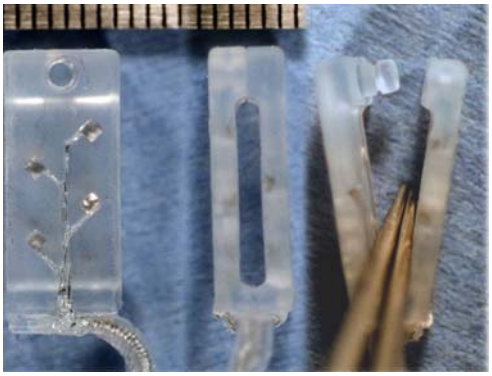


Figure 19: Clinical grade 8-contact FINE for the human femoral nerve.

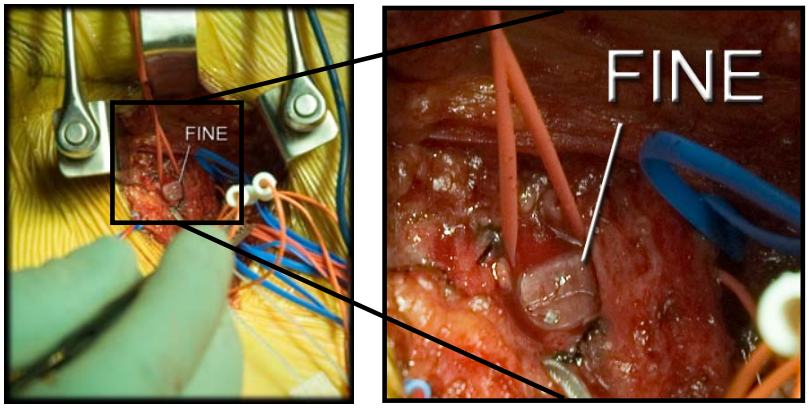


Figure 20: Intraoperative testing of the 8-contact FINE on a human femoral nerve.

Intraoperative testing of the clinical-grade 8-contact FINE based on the design parameters derived from our cadaver and computer simulation studies was initiated during the past year on the human femoral nerve (see Figure 20). Preliminary data on electrode selectivity coincide closely with predictions obtained from our modeling and simulation studies. Results to date indicate that a FINE of optimal design should allow both standing (knee extension without hip flexion) and walking (hip flexion without knee extension) from a single site on the proximal femoral nerve, rather than individual electrodes for each muscle, thus greatly improving surgical efficiency and neuroprosthesis functionality.

Milestones

Major project milestones accomplished this reporting period include: a) publication of the theoretical analysis optimizing electrode design for the femoral nerve, b) intraoperative verification of the performance of the resulting 8-contact femoral FINE, c) preparation and submission of a complete Device Master File for the FINE to the US FDA that completely specifies the design, d) successful renewal of R01 funding from the National Institutes of

Health to expand this work to include the sciatic nerve and complete development of the femoral FINE through chronic clinical testing.

Major project milestones for the coming year include: a) completing intraoperative testing of the 8-contact femoral FINE and publishing the results, b) filing an amendment to our existing IDE to include chronic human testing of the FINE in implanted neuroprostheses for standing and stepping after paralysis, c) first chronic human implantation of the femoral FINE, and d) modeling and simulation studies detailing the optimal configuration of contacts within the FINE specifically for the distal sciatic, tibial and fibular nerves.

Clinical Relevance

The design and fabrication of new neural interfaces like this one will extend the capabilities of systems for restoring lower extremity function after paralysis. The nerve-based approaches we are developing offer distinct advantages over current muscle-based electrodes used in neuroprosthetic systems, including the ability to completely recruit the target muscles and increase the forces and resulting joint moments available to move the extremities, support body weight, and resist disturbances. Careful design of these new neural interfaces to insure their selectivity will also significantly simplify implant surgery while expanding the repertoire of movement options available to neuroprosthesis users. Completion of this project will represent a significant advancement in the state-of-the-art of motor system neuroprostheses. The new neural interfaces and technology that will result should enable numerous neuroprosthetic interventions in spinal cord injury, stroke and other paralyzing conditions. Just as importantly, selective activation of individual muscles from a single multicontact cuff electrode around a proximal nerve trunk will simplify surgical installation of these systems.

Project #10: A Hybrid Neuroprosthesis

Principal Investigators: Ronald J. Triolo, PhD.

Co-Investigators: Roger Quinn, Ph.D., Rudi Kobetic, M.S.

Staff/Students: Thomas Bulea, John Schnellenberger, Curtis To, Nichole Kern

Funding Agency: Department of Defense

Description

The purpose of this ongoing project is to develop and evaluate a novel hybrid orthosis system consisting of an innovative trunk-hip-knee-ankle-foot orthosis (THKAFO). Design and development efforts focus on novel hip, knee and ankle joint mechanisms that can be locked and unlocked rapidly during the appropriate phases of the gait cycle. In particular, technical development concentrates on a new hydraulically actuated hip coupling mechanism that allows step length to vary with walking speed. Variable coupling between stance and swing limb hip angles is an innovation unique to this orthotic design. Secondarily, the project addresses trunk stability by exploring new configurations of

segmental joints within a thoracic jacket to allow the trunk to be stiffened during walking, and remain flexible while seated. Thirdly, new orthotic joints are being developed for the knees to allow the brace to lock and unlock smoothly without the backlash of conventional mechanical joints.

Preliminary Results

During this reporting period, the variable coupling hip reciprocating mechanism has been redesigned to be more space efficient (Figure 21). The current configuration minimizes interference with the arms during ambulation, facilitates sit-to-stand and stand-to-sit transitions and eases donning and doffing by reorienting the rack and pinion rotary actuator and hydraulic pistons. The mechanism has undergone a significant amount of testing with able-bodied volunteers to establish baseline performance and verify proper operation of the control algorithm for coupling and decoupling the joints during gait. Laboratory testing with volunteers with spinal cord injuries was also initiated during this period. For SCI testing, the knee joints were unlocked and controlled entirely with stimulation to the quadriceps, or replaced with solenoid actuated wrapped spring clutches. Testing of this component will continue throughout the coming year.

Figure 21: Mechanical design of the prototype hydraulic hip reciprocating orthosis with wrapped spring clutch knee mechanism.

Prototype knee joints based on shear mode operation of magneto-resistive fluids were fabricated during this period using our Rapid Prototyping facilities. The design incorporated a permanent magnet at the central axis of interdigitating plates within a closed system filled with magneto-resistive fluid. A coil wound around the magnets was designed to cancel the field generated by the permanent magnet when energized, thus allowing the joint to rotate. This both economized electrical power by locking the joint with the permanent magnet during stance and unlocking during brief periods of swing, and provided a degree of fail-safe operation. Bench testing of the mechanism resulted in locking moments that were less than predicted by our modeling and simulation work during the preliminary design and development phase. Failure to meet the input design specification indicates that the performance of the device would be inadequate to support a wearer of the device during the single limb stance phase of gait. Alternative designs based on valve mode operation of magneto-resistive fluids are being pursued. A new trunk corset has also been designed and preliminary prototypes fabricated.

Milestones

Project milestones accomplished this year include a) improving the performance of the hydraulically coupled hip reciprocating mechanism, b) completing able bodied testing, c) developing a control system to govern brace locking and coupling during locomotion, d) bench testing of the initial magneto-resistive fluid knee, and e) realization of a new conceptual design for the flexible trunk corset. During the coming year we plan to a) complete testing of the variable hip reciprocator with individuals with spinal cord injuries, b) produce and bench test a new valve-mode magneto-resistive knee mechanism, c) integrate hip, knee and trunk mechanisms and initiate laboratory testing, and d) begin the process of designing mechanisms to control the ankle joint.

Clinical Relevance

Immobility remains a major problem for disabled veterans. Current orthotic options hinder walking velocity and stair climbing and restrict reciprocal stepping to a single stride length. Components of the advanced orthoses being developed in this project have the potential to impact individuals with mobility impairments resulting from a wide variety of disorders. The trunk component is unique with the potential to help individuals with scoliosis, spinal instability or paralysis resulting from musculoskeletal or cerebrovascular insult.

Project #11: Prosthetic Arm Control for Amputees

Principal Investigator: Robert Kirsch, PhD.

Co-Investigators: R. Triolo, D. Tyler

Funding Agency: Department of Defense, Telemedicine and Advanced Technology Research Center (TATRC)

Description

This collaborative project was initiated on September 1, 2006 and focuses on improving the control interface between the user and his/her upper limb prosthetic device through the application of new platform technologies being developed by the APT Center. The purpose of the project is to evaluate the significance of interfacing with the intact nervous system to improve control of a powered prosthesis and provide sensory feedback to the user. It should result in more natural movements of existing myoelectric prostheses through a new high performance neural interface.

Objectives

This project intends to construct a prosthesis simulator to accurately represent the mechanical action of the prosthetic arm and the user's attempts to control it. It will also develop a percutaneous EMG-based controller and interface it with an existing myoelectric prosthesis. The system should be able to test selective peripheral nerve stimulation for sensory augmentation. We aim to design components of an advanced

prosthetic arm utilizing implanted neural interfaces. As well as deploying a permanently implanted system for sensory augmentation via selective peripheral nerve stimulation.

Research Plan & Methodology

A model-based arm simulator will be used to provide both a training system for prosthesis users, and to assess the improvement made by advanced control and feedback techniques. The first revision of this virtual reality software platform has been completed and is currently undergoing testing. In the coming year, we will adapt a fully implanted EMG recording and telemetry system that is being developed for neuroprosthesis applications for use in controlling upper extremity prostheses for transhumeral amputees. The use of implanted technology will greatly simplify system donning by the user and overcome the inherent limitations of surface EMG recordings. The use of four to eight EMG recordings and a more sophisticated pattern detection algorithm will provide a much more transparent and effortless control interface for the user that will allow at least three degrees of freedom to be controlled simultaneously.

We will integrate the new implanted EMG system into existing multi-DOF upper extremity prosthesis, provide this to a number of individuals with transhumeral amputations, and evaluate its performance. We will also adapt existing implantable stimulators and FINE electrode technology being developed by the APT Center to deliver relevant sensory information derived from an instrumented prosthesis to the nervous system through stimulation of the appropriate sensory components of peripheral nerves that once served the arm.

Clinical Relevance

The proposed effort is to develop a prosthesis system that would provide a more functional prosthesis for transhumeral amputees. The prosthesis would increase the chance of retention of active duty military for combat amputees, continued military career opportunities, and overall increased well being.

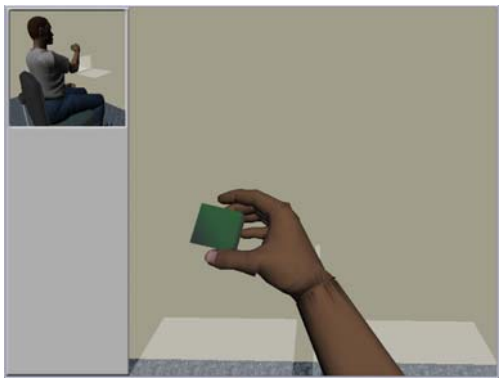


Figure 22: A screen capture from the Prosthesis Simulator, a virtual world to test various control algorithms and train eventual users.

Milestones

Simulator development

- We have selected a commercial game engine to create custom virtual environments in order to provide realistic visual feedback to the user.
- The mechanical model of the prosthesis has been developed and has been demonstrated to perform reliably in real-time.
- Real-time motion capture of the residual limb and body has been successfully integrated into the simulator, allowing both the user's actual movements and the movements of the virtual prosthetic device to be displayed.

Controller development

- We have selected and purchased the Utah3 Arm and ProTouch Hand from Motion Control, Inc. (Salt Lake City, UT) in order to develop and test our control device. The ProTouch hand has embedded sensors that may simplify the sensory augmentation tasks described above.

Evaluation

- Human subject testing protocols and consent forms have been approved by local and TATRC IRBs.
- We have selected standardized measurement instruments for analyzing the advanced prosthesis and control algorithms.

4. Project Milestones

Project Milestones are incorporated into each project progress note above.

Figure 23: APT Center Members.

C. CAPACITY BUILDING

The APT Center has 51 total members, including 19 undergraduate, graduate, and post-doctoral trainees. Twelve (12) are APT researchers, 7 are researchers with joint appointments. Of our 19 researchers, 9 are in mentoring programs. The support staff totals 10. New members were added in all categories as this is our third year of operation.

1. Current APT Center Staff

Category	Last Name	First Name	Degree	Position
APT Investigators	1. Baskin	Jonathan	M.D.	Investigator
	2. Capadona	Jeffrey	Ph.D.	Associate Investigator
	3. Damaser	Margot	Ph.D.	Investigator
	4. Garverick	Steven	Ph.D.	Investigator
	5. Mohseni	Pedram	Ph.D.	Investigator
	6. Pinault	Gilles	M.D.	Investigator
	7. Potkay	Joseph	Ph.D.	Post-doctoral Fellow
	8. Quinn	Roger	Ph.D.	Investigator
	9. Rowan	Stuart	Ph.D.	Investigator
	10. Weder	Christoph	Ph.D.	Investigator
	11. Young	Darrin	Ph.D.	Investigator
	12. Zorman	Christian	Ph.D.	Investigator

Category	Last Name	First Name	Degree	Position
Joint Appointments	1. Bogie	Katherine	D. Phil.	Investigator
	2. Creasey	Graham	M.D.	Medical Director
	3. Kilgore	Kevin	Ph.D.	Associate Director
	4. Kirsch	Robert	Ph.D.	Investigator
	5. Kobetic	Rudolph	M.S.	Investigator
	6. Triolo	Ronald	Ph.D.	Center Director
	7. Tyler	Dustin	Ph.D.	Associate Director
Staff	1. Bartlett	Arden	M.S.	IT Specialist
	2. Boggs	Bradley	M.S.	Senior Engineering Manager
	3. Burger	James	B.S.	Quality Systems Manager
	4. Dunning	Jeremy	M.S.	Engineering Staff
	5. Fletter	Paul	B.S.	Engineering Staff
	6. Hounshell	Jessica	-	B.A. Student
	7. Iveljic	Suzana	M.B.A.	Director of Operations
	8. Lugo	Wildali	B.A.	Program Assistant
	9. Schnellenberger	John	M.S.	Engineering Staff
	10. Zaszczurynski	Paul	B.S.	Engineering Staff
Consultants	1. Yowler	Charles	M.D.	Medical Consultant
	2. Ho	Chester	M.D.	Medical Consultant
	3. Rimnac	Clare	Ph.D.	Consultant
Trainees	1. Arguello	Edward	B.S	M.S. Student
	2. Bulea	Thomas	B.S.	M.S. Student
	3. Cong	Peng	B.S.	M.S. Student
	4. Dutta	Anirban	M.S.	Ph.D. Student
	5. Farnsworth	Bradley	B.S.	M.S. Student
	6. Fetty	Eric	-	B. S. Student
	7. Gartman	Steven	M.S.	Ph.D. Student
	8. Grinberg	Yanina	B.S.	M.S./Ph.D. Student
	9. Harris	James	M.S.	Ph.D. Student
	10. Hess	Allison	B.S.	M.S./Ph.D. Student
	11. Howe	Daniel	B.S.	M.S./Ph.D. Student
	12. Lachut	Derek	-	B.S. Student
	13. Majerus	Steve	B.S.	M.S./Ph.D. Student
	14. Nataraj	Ravi	M.S.	Ph.D. Student
	15. Schiefer	Matthew	B.S.	Ph. D. Student
	16. Shanmuganathan	Kadhiravan	M.S.	Ph.D. Student
	17. To	Curtis	B.S.	Ph.D. Student
	18. Whitney	Adam	M.S.	Ph.D. Student
	19. Wu	Gary	M.S.	Ph.D. Student

2. *OOA Pre-Doctoral Fellows*

N/A

3. *Career Development Awardees*

Name: Tyler, Dustin J.
Dates: 2006 - 2010
Award: Nord Distinguished Assistant Professor, Case School of Engineering

Name: Rowan, Stuart J., Ph.D., NSF Career Award
Dates: 2002-2007
Award Amount: $600,500

4. *Research Career Scientists*

Name: Damaser, Margot S., Ph.D., Louis Stokes Cleveland VA Medical Center
Dates: 10/1/2004-9/30/2009
Award Amount: $306,250

Name: Triolo, Ronald J., Ph.D., Louis Stokes Cleveland VA Medical Center
Dates: 10/1/2002-9/30/2007
Award Amount: $306,250

5. *Senior Research Career Scientist*

Name: Triolo, Ronald J., Ph.D., Louis Stokes Cleveland VA Medical Center
Dates: 10/1/2007-9/30/2014
Award Amount: $586,515

6. *Other Research Fellow Programs*

A. Post-doctoral

(1) **Capadona**, Jeffrey Ph.D.
Mentor(s): Dustin J. Tyler, Ph.D.; Christoph Weder, Ph.D.; Stuart J. Rowan, Ph.D.; Ronald J. Triolo, Ph.D.
Project Title: Stimulus-responsive, mechanically-dynamic nanocomposite for cortical electrodes

(2) **Potkay**, Joseph
Mentor(s): Pedram Mohseni, Ph.D.; Christian Zorman, Ph.D.; Kevin Kilgore, Ph.D.; Ronald Triolo, Ph.D.
Project Title: A self-powered arterial cuff blood pressure monitor with energy harvesting

B. Pre-doctoral

(1) **Arguello**, Edward
Mentor: Dustin J. Tyler, Ph.D.
Project Title: Regeneration enabled FINE Electrodes

(2) **Bulea**, Thomas
Mentor: Ronald J. Triolo, Ph.D.
Project Title: A novel knee joint locking mechanism for a hybrid orthosis

(3) **Dutta**, Anirban
Mentor: Ronald J. Triolo, Ph.D.
Project Title: Myoelectric control of an implanted neuroprosthesis for ambulation after paralysis

(4) **Farnsworth**, Bradley
Mentor: Darrin Young, Ph.D.
Project Title: Wireless Implantable EMG Microsystem

(5) **Fetty,** Eric
Mentor: Dustin J. Tyler, Ph.D.
Project Title: Development of Rapid Prototype Processes for Fabrication of Implanted Devices

(6) **Fisher**, Lee
Mentor: Ronald J. Triolo Ph.D.; Dustin J. Tyler, Ph.D.
Project Title: Enhancing neuroprosthesis performance with spiral nerve cuff electrodes

(7) **Gartman**, Stephen
Mentor: Ronald J. Triolo Ph.D.
Project Title: Feedforward control of standing balance

(8) **Grinberg**, Yanina
Mentor: Dustin J. Tyler, Ph.D.
Project Title: Fascicular perineurium thickness, size, and position AFFECT model predictions of neural excitation

(9) **Harris**, James
Mentor: Dustin J. Tyler, Ph.D.
Project Title: Stimulus-responsive, mechanically-dynamic nanocomposite for cortical electrodes

(10) **Hess,** Allison
Mentor: Christian A. Zorman, Ph.D.
Project Title: Design, fabrication and evaluation of liquid crystal polymer and polynorbornene-based neural electrode arrays

(11) **Howe**, Daniel
Mentor(s): Kath Bogie, D.Phil, Steven Garverick PhD
Project Title: Integrated surface electrical stimulation device for therapeutic applications

(12) **Keesara,** Varun
Mentor: Christian A. Zorman, Ph.D.
Project Title: Design, development and fabrication of polymer microstructures

(13) **Lachut,** Derek
Mentor: Dustin J. Tyler, Ph.D.
Project Title: Development of Rapid Prototype Processes for Fabrication of Implanted Devices

(14) **Nataraj**, Ravi
Mentor: Ronald J. Triolo Ph.D.
Project Title: Automatic control of standing balance

(15) **Schiefer,** Matthew
Mentor(s): Dustin J. Tyler, Ph.D., Ronald J. Triolo, Ph.D.
Project Title(s): Enhancing neuroprosthesis performance with Flat Interface Nerve Electrodes.

(16) **Shanmuganathan,** Kadhiravan
Mentor: Christoph Weder, Dr. Sc. Nat.
Project Title: Stimulus-responsive, mechanically-dynamic nanocomposite for cortical electrodes

(17) **To,** Curtis
Mentor: Ronald J. Triolo, Ph.D
Project Title: Automated variable reciprocating hip mechanism for a hybrid orthosis

(18) **Whitney,** Adam
Mentor: Kath Bogie, D. Phil
Project Title: Development of an in-vitro model of electrical stimulation for wound healing

(19) **Wu,** Gary
Mentor: Kath Bogie, D. Phil
Project Title: Effects of weight shifting on pressure ulcer risk status

C. Faculty Fellowships

1. **Zorman,** Christian
   Fellowship: NASA Summer Faculty Fellow 2007, NASA Glenn Research Center

7. Advisory Board Members

Table 1. Members of the APT Executive Steering Committee.

Organization	Name	Position
Veterans Affairs Medical Center	Murray Altose, MD	Chief of Staff, Wade Park Division
	Neal Peachey, PhD	Assistant Chief of Staff – Research, Wade Park Division
	Robert Ruff, MD	Chief, Neurology Service National Director for Neurology
Case School of Medicine	Pamela Davis, MD, PhD	Dean, School of Medicine
	Randall Marcus, MD	Chair, Department of Orthopaedics
Case School of Engineering	Jeffrey Duerk, PhD	Chair, Department of Biomedical Engineering (BME)
	Meral Ozsoyoglu, PhD	Chair, Department of Electrical Engineering and Computer Science (EECS)
	Clare Rimnac, PhD	Chair, Mechanical and Aerospace Engineering (MAE)
	Norman Tien, PhD	Dean, School of Engineering
	Gary Wnek, PhD	Chair, Department of Macromolecular Science

D. INFORMATION DISSEMINATION –

APT Center investigators and staff contributed to 71 peer-reviewed journal articles which appeared or were accepted for publication in 2007. Twenty-six (26) additional manuscripts were submitted or were under revision during the same reporting period. The Center also produced 66 presentations, conference abstracts, posters or platform lectures in 2007, and Center investigators participated in the organization and conduct of 16 national and international workshops and scientific or clinical conferences. These activities complement our own efforts at sponsoring internal seminars and Neuroprosthesis Seminars for external speakers. Our investigators filed **7 new invention disclosures and 2 patents** during the reporting period for APT Center related technologies. Furthermore, APT Center members were active in 16 community activities and represented in 12 media releases. All of these activities are summarized below.

1. Presentations

1. **Bogie KM,** Nemunaitis G, Boggs L, Smith J, **Wu G**, **Triolo RJ**. Effects of trunk neuromuscular electrical stimulation on seated posture stability and function. North American Spinal Cord Injury Conference & Disability Expo 2007, Orlando, Florida August 2007

2. **Bogie KM**, Nemunaitis G, Boggs L, Smith J, **Wu G, Triolo RJ**, Boulet M. "Effects of Trunk Neuromuscular Electrical Stimulation on Seated Posture Stability and Function," American Paraplegia Society, 2007.

3. **Bogie KM,** Chronic wounds: prevention and treatment. National Academies Keck Futures Initiative "The Future of Human Healthspan", Newport Beach, CA. November, 2007.

4. **Bulea TC, Kobetic R, Triolo RJ**. "A Permanent Magnet Magnetorheological Fluid Knee Locking Mechanism for a Hybrid Orthosis System", Research ShowCase, CWRU, April 2007.

5. **Capadona JR,** van den Berg O, Capadona L, **Tyler D**, **Rowan SJ, Weder C.** Neuroengineering Circuits and Microsystems, IEEE Int. Symp. Circuits and Systems (ISCAS'07), New Orleans, LA, May 27-30, 2007 American Chemical Society, Polymer Division, April 2008. (podium).

6. **Capadona JR,** Department Seminar, Department of Biomedical Engineering, Case Western Reserve University, January 2008. (podium)

7. **Capadona JR, Harris JP, Shanmuganathan K, Rowan SJ, Weder CD**, **Tyler DJ**. Gordon Research Conference; Biomaterials: Biocompatibility / Tissue Engineering, Holderness School, RI, July 2007.

8. **Capadona JR, Harris JP, Rowan SJ, Weder C**, **Tyler DJ**. Neural Engineering and Rehabilitation Lectures, Department of Biomedical Engineering, Case Western Reserve University, June 2007. (podium)

9. **Capadona JR, Shanmuganathan K**, van den Berg O, **Rowan SJ, Weder C**, **Tyler DJ**. Research Showcase (Case Western Reserve University). Cleveland, OH. 2007.

10. **Capadona JR, Rowan SJ, Weder C, Tyler DJ.** Materials Research Society (MRS) Spring Meeting. San Francisco, CA. 2007. (podium)

11. **Dutta A, Kobetic R**, **Triolo RJ**. "Evaluation of Electromyogram-triggered Functional Electrical Stimulation-assisted Stand-to-Walk Transition," 12th Annual Conference of the International FES Society, November 2007, Philadelphia PA.

12. **Dutta A, Kobetic R, Triolo RJ**. **"**Stability and Coordination of Functional Electrical Stimulation (FES)-Assisted Walking after Partial Paralysis," Research Showcase, CWRU, April 2007 **(Winner, 1st place student paper competition)**

13. **Farnsworth B, Triolo RJ**, **Young D**. "Wireless Implantable EMG Sensing Microsystem," Biomedical Engineering Society Meeting (BMES), Los Angeles CA, September 2007.

14. **Fisher LE,** Miller ME, **Tyler DJ, Triolo RJ**. "Stimulating Quadriceps with Four-Contact Nerve Cuff Electrodes to Improve Standing after Spinal Cord Injury," 12th Annual Conference of the International FES Society, November 2007, Philadelphia PA

15. **Gartman SJ,** Audu ML, **Kirsch RF**, **Triolo RJ**. "Selection of an Optimal Muscle Set for a 16-Channel Standing Functional Electrical Stimulation System," 12th Annual Conference of the International FES Society, November 2007, Philadelphia PA

16. **Hess A, Dunning J, Tyler DJ, Zorman CA**. "Development of FINE Electrode Structures Based on Micromachined Polymer Substrates", Research Showcase 2007, Case Western Reserve University, Cleveland, Ohio, April 11-12, 2007.

17. **Hess A, Dunning J, Tyler DJ, Zorman CA**. "A Polynorbornene-based Microelectrode Array for Neural Interfacing", Neural Engineering and Rehabilitation Lectures, Cleveland, Ohio, June 8, 2007.

18. **Mohseni P**. Technical Program Committee Member, Biomedical Circuits and Systems Technical Committee (BioCAS-TC) in IEEE Circuits and Systems (CAS) Society

19. **Mohseni P**. Technical Program Committee Member, Analog Signal Processing Technical Committee (ASP-TC) in IEEE Circuits and Systems (CAS) Society

20. **Mohseni P**. Technical Program Committee Member, Fourth Int. Conference on Networked Sensing Systems (INSS'07), Braunschweig, Germany, June 6-8, 2007

21. Audu M**, Nataraj R, Kirsch RF**, **Triolo RJ**. "Dynamic Computer Optimization for Standing Balance and Control of Postural Sway after SCI," 12th Annual Conference of the International FES Society, November 2007, Philadelphia PA.

22. **Nataraj R**, Audu ML, **Kirsch RF, Triolo RJ**. "Automatic Control of Standing Balance Using Functional Electrical Stimulation following Spinal Cord Injury," 12th Annual Conference of the International FES Society, November 2007, Philadelphia PA

23. **Nataraj R, Kirsch RF**, **Triolo RJ**. "Control System for Automatic Standing Balance using Functional Neuromuscular Stimulation (FNS) after Spinal Cord Injury (SCI)," American Society of Biomechanics, Stanford University, Palo Alto CA, 2007.

24. **Nataraj R, Triolo RJ**, **Kirsch RF**, Audu ML. "Strategy for Automatic Standing Balance Using Functional Neuromuscular Stimulation (FNS)," Research Showcase, CWRU, April 2007.

25. **Schiefer M, Triolo RJ**, **Pinault GC, Tyler DJ**. "Models of Selective Stimulation and Intraoperative Testing of a Flat Interface Nerve Electrode," Research Showcase, CWRU, April 2007 **(Honorable Mention student paper competition)**

26. **Schiefer MA,** Polasek KH, **Pinault GC**, **Triolo RJ**, **Tyler DJ**. "Intraoperative Evaluation of the First Flat Interface Nerve Electrode for a Standing Neuroprosthesis," 4th International IEEE/EMBS Conference on Neural Engineering, Kona Coast, Hawaii 2007.

27. Polasek KH, **Schiefer MA, Pinault GC**, **Triolo RJ**, **Tyler DJ**. "Intraoperative Evaluation of the Spiral Nerve Cuff Electrode for a Standing Neuroprosthetic," 4th International IEEE/EMBS Conference on Neural Engineering, Kona Coast, Hawaii 2007.

28. **To CS, Kobetic R, Triolo RJ**. "Variable Hip Constraint Mechanism for a Hybrid Orthosis System with Closed-Loop Control," Research Showcase, CWRU, April 2007.

29. Bailey SN, **Triolo RJ**, Hardin EC, Kobetic R, Boggs LM, Murray LR, Seitz BA, **Pinault GC**. "Neuroprosthetic and Neurotherapeutic Effects of Implanted Electrical Stimulation for Ambulation after Incomplete SCI," 12th Annual Conference of the International FES Society, November 2007, Philadelphia PA

30. **Triolo, RJ**. "Neuroprostheses for facilitating ambulation, postural control and balance after paralysis," Department of Biomedical Engineering, Rutgers University East Brunswick NJ, November 26, 2007. (invited lecture)

31. **Triolo, RJ**. "Advances in Neuroprostheses for Balance, Standing and Ambulation, Grand Rounds," CWRU Department of Orthopaedics, October 17, 2007. (invited lecture)

32. **Triolo, RJ**. "Restoration of Trunk Stability using FES" 46th International Spinal Cord Society Annual Scientific Meeting/10th Norwegian Spinal Cord Society Congress (ISCoS/NoSCoS), Reykjavik Iceland, June 27-July1, 2007. (invited lecture)

33. **Triolo, RJ**. "Restoration of Walking after Incomplete paralysis with FES", 46th International Spinal Cord Society Annual Scientific Meeting/10th Norwegian Spinal Cord Society Congress (ISCoS/NoSCoS), Reykjavik Iceland, June 27-July1, 2007. (invited lecture)

34. **Triolo, RJ**. "Implanted Neuroprostheses for Standing and Walking after Spinal Cord Injury: The Case Western Reserve University Approach," Centre for Neuroscience Seminar, University of Alberta, Edmonton Canada, April 24, 2007. (invited lecture)

35. **Triolo, RJ**. "Advanced Platform Technology Center: Overview and Examples of New Approaches to Rehabilitation," Electrical Engineering and Computer Science (EECS) Colloquium, Case Western Reserve University, March 29, 2007. (invited lecture)

36. **Triolo, RJ**. "Neuroprosthetic Interventions for Seated Balance and Bipedal Mobility after Spinal Cord Injury," Distinguised Speakers in Bioengineering Lecture Series, Institute for Biomaterials and Biomedical Engineering, University of Toronto, Toronto Canada, February 27, 2007. (invited lecture)

37. **Triolo RJ**, Boggs L, Bryden A, **Kirsch RF**, Memberg W, Miller M, Murray LM, Nemunaitis G, Nicolackis K, Bailey S, Smith J. "Implanted Electrical Stimulation of the Trunk for Seated Postural Stability and Functional Mobility after Cervical SCI," 12th Annual Conference of the International FES Society, November 2007, Philadelphia PA.

38. Yang Y, Koontz A, **Triolo RJ**, Cooper R, Boninger M. "Surface EMG Analysis on Shoulder Muscle during Prolonged Wheelchair Propulsion," International Society of Biomechanics, Taipei Taiwan, July 2007.

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61. **Zorman CA**. "Development of a Flat Interface Nerve Electrode Technology Using Mechanically-flexible Substrates and MEMS Fabrication Techniques", Neural Prosthetics Seminar, Department of Biomedical Engineering, Case Western Reserve University, March 9, 2007.

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2. Publications Published or Accepted for Publication

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2. **Bogie KM**, Wang X, Fei B, Sun J. A new technique for real-time interface pressure analysis: Getting more out of large image datasets. J. Rehabil. Res. Dev. (In press)

3. **Bogie KM**, Nemunaitis G, Boggs L, Smith J, Wu G, **Triolo RJ**. Effects of trunk neuromuscular electrical stimulation on seated posture stability and function. J. Spinal Cord Med., 30(4): 407, 2007 (abstract)

4. **Bogie KM**, Ho CH. Multidisciplinary approaches to the pressure ulcer problem. Ostomy Wound Manage. 53(10):26-32, October 2007.

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3. Publications Under Review or in Revision

1. **Bulea T, Kobetic R,** Audu M, **Triolo RJ**. "A variable compliance permanent magnet MR fluid braking mechanism", IEEE Robotics and Automation Magazine (submitted December 2007).

2. Spirka TA, **Damaser MS**. Modeling physiology of the urinary tract. J Endourol. March 2007; 21(3):294-299. (Review)

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15. Lambrecht J, Audu M, **Triolo RJ, Kirsch RF**. "A musculoskeletal model of the trunk and hips for the development of a seated posture-control neuroprosthesis," Journal of Rehabilitation Research & Development – (submitted August 2007)

16. **J. A. Potkay** and K. D. Wise, "A Hybrid Thermopneumatic and Electrostatic Microvalve with Closed-Loop Position Sensing," (manuscript in progress)

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22. **Young DJ**, P. Cong P, Ko WH. "Wireless Less-Invasive Blood Pressure Sensing Microsystem for Small Laboratory Animal Real-Time Monitoring", submitted to the Asia-Pacific Conference on Transducers and Micro-Nano Technology, Tainan, Taiwan, 2007.

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4. Sponsored Conferences and Workshops

Neural Prosthesis Seminar Series

The APT Center jointly hosted eight city-wide Neural Prosthesis Seminars. The program is a public educational forum on topics related to rehabilitation. Speakers are active in the national/international community of rehabilitation research and development of assistive technologies. Speakers invited to Cleveland to participate are provided with an excellent opportunity to experience our research environment, which often results in research collaborations. A complete list of the series speakers is below:

- January 19, 2007 – Steven C. Cramer, M.D., Associate Professor, Departments. of Neurology and Anatomy & Neurobiology, University of California – "Recovery from Stroke"

- February 9, 2007 – Stephen G. Waxman, M.D., Ph.D., Bridget Marie Flaherty Professor of Neurology, Neurobiology and Pharmacology; Chairman, Department of Neurology, Yale University School of Medicine, New Haven, CT; and Director, Center for Neuroscience & Regeneration Research, Veterans Affairs Medical Center, West Haven, CT – "Playing with Fire: Multiple Roles of Sodium Channels in Disorders of the Nervous System"

- March 9, 2007 – Christian A. Zorman, Ph.D., Associate Professor, Dept. of Electrical Engineering and computer Science, Case Western Reserve University – "Development of a Flat Interface Nerve Electrode Technology Using Mechanically-flexible Substrates and MEMS Fabrication Techniques"

- April 20, 2007 – William Craelius, Ph.D., Associate Professor, Biomedical Engineering, Rutgers, The State University of New Jersey – "Can neural codes for walking, reaching, and grasping be extracted from external muscle pressure?"

- May 11, 2007 – Richard F. Macko, M.D., Professor, Neurology, Medicine/Gerontology, Physical Therapy & Rehabilitation Science, University of Maryland School of Medicine & Baltimore VA Medical Center; Director, Academic Rehabilitation Program, UM-SOM; Director, Baltimore Veterans Affairs Center of Excellence in Exercise and Robotics & The VA Stroke Research Enhancement Program – "Task-Oriented Exercise after Stroke: Mechanisms of Neuromuscular Plasticity"

- September 14, 2007 – David C. Marin, Ph.D., Professor, Materials Science and Engineering, Macromolecular Science and Engineering and Biomedical Engineering; Founder and Chief Scientific Officer, Biotectix LLC, University of Michigan – "Direct Integration of Electronics with Neurons using Conducting Polymers"

- October 19, 2007 – Leigh R. Hochberg, M.D., Ph.D., Associate Investigator, Rehabilitation R&D, Department of Veterans Affairs, Acute Stroke and Neurocritical Care Service, Massachusetts General, Brigham and Women's, and Spaulding Rehabilitation Hospitals; Investigator in Neuroscience, Brown University – "Neurologists Listening to Neurons: Intracortical Recording for Restorative Neurotechnology"

- November 16, 2007 –Victor Pikov, Ph.D., Neuroscientist and Engineer, Neural Engineering Program, Huntington Medical Research Institute, Pasadena, CA - "The 'Virtual Stroke' Model of Spinal Hyperreflexia."

5. Transferred (Commercialized/Patented Technology)

- **Invention Disclosures Filed**
  - **Bogie, Kath –** Hi-tech, low-cost pressure relief cushion, 11/28/2007.
  - **Bogie, Kath –** Integrated surface stimulation device, 12/14/2007
  - **Capadona, Jeffrey –** Self-Assembled Nanofiber Templates: Versatile Approaches for Polymer Nanocomposites, 11/28/2007
  - **Damaser, Margot –** Wireless Implantable Pressure Monitor for Internal Organs, 7/18/2007.
  - **Kobetic, Rudi –** Split Collar Locking Mechanism for Use in Orthotics and Robotics, 8/31/2007.
  - **Potkay, Joseph –** Miniature, Flexible, Biocompatible Sensor Arrays, 7/3/2007.
  - **Potkay, Joseph –** A high-efficiency, micro machined artificial lung, 7/3/2007.

- **Issued Patents and Patent Applications**
  - Van den Berg, O.; Capadona, J. R.; **Weder**, C.; Self-Assemble Nanofiber Templates: A Versatile Approach for Polymer Nanocomposites; US Provisional Patent Application filed (2007).
  - Kinami, M.; Crenshaw, B.R.; **Weder,** C.; Time-Temperature Indicators; US Provisional Patent Application US 60/758,106 (1/11/2006);US Patent Application filed (2007).
- **Patents Filed**
  - **Baskin, Jonathan** – Biomaterial Implants, 4/13/2007, (PCT/US07/66614)
  - K. D. Wise and **J. A. Potkay**, "Thermopneumatic Microvalve," U.S. Patent 7,192,001, Mar 20, 2007

6. Community Activities

A. Conferences

1. **Japanese Delegation Visit -** January 28-29, 2007. An overview of the APT Center was provided to the Japanese Science and Technology Agency (JST) which is a major government funding agency in Japan. The goal of the visit was to gather information on the worldwide status and trends in brain machine/computer interface (BMI/BCI) related to R&D and design proposals to include international collaborative researchers.
2. **Health Services Research & Development (HSR&D) Annual Meeting –** Feb 21 – 23, 2007**.** Managing Recovery and Health through the Continuum of Care" was the theme of the 25th VA Health Services Research and Development Service (HSR&D) National Meeting that was held from February 21-23, 2007 in Arlington, VA. During the meeting, 552 researchers, clinicians, and policymakers participated in more than 90 paper sessions and workshops. In addition, HSR&D investigators viewed 128 posters on an array of veteran-related healthcare issues and several exhibits. This national forum provided many opportunities for discussion, collaboration, and the development of strategies that will improve the care of our diverse veteran population, including a new generation of veterans returning from Iraq and Afghanistan with unique healthcare needs. The APT Center sent a representative to this conference.
3. **Cleveland 2.0 –** March 16, 2007. Case Western Reserve University and a group of co-sponsors hosted a full day charette that focuses on community priorities and how the new and emerging next generation of internet services (know generically as Web 2.0) can be harvested to meaningfully attend to community priorities. Technologists can work together and support and collaborate in enabling cross-institutional initiatives to support various community priorities.
4. **Upper Limb Amputee State of the Science Conference** – March 30, 2007. Advances in upper extremity amputee surgical techniques and prosthetic

technologies have dramatically improved the potential functional capacity of the upper extremity amputee; however, it is the rehabilitative cares that will help the amputee realize his or her full functional potential. This Conference was designed to inform occupational and physical therapists about the current upper extremity amputee research and initiatives and to plan our future directions in upper extremity amputee rehabilitation.

5. **Case Western Reserve University Research Showcase –** April 11-12, 2007.
   Research ShowCASE is a free public exhibit spotlighting the full range of faculty, postdoctoral, graduate, and undergraduate research being conducted at Case. From real-world applications to critical insights to creative and intellectual activities, Research ShowCASE provides evidence of how research brings value to Case, our community, and the world. The APT Center had a Center Exhibit Booth and 6 posters were presented (Figure 24).

Figure 24: Research Showcase at Case Western Reserve University.

6. **Materials Research Society Spring Meeting.** The meeting program focused on electronic and magnetic materials; polymers, hybrids and biomaterials; optical materials and phenomena; and nanoscale materials, properties, and applications.
7. **Institute for Electrical and Electronics Engineers - Engineering in Medicine and Biology Society (IEEE-EMBS)** May 2 – 5, 2007**.** The objective of this conference was to highlight the emerging field, Neural Engineering that unites engineering, physics, chemistry, mathematics, computer science with molecular, cellular, cognitive and behavioral neuroscience and encompasses such areas as replacing or restoring lost sensory and motor abilities, defining the organizing principles and underlying mechanisms of neural systems, neurorobotics, neuroelectronics, brain imaging and mapping, cognitive science and neuroscience. The APT Center had a display and poster at this conference.
8. **Medical Device Manufacturer's Association (MDMA) –** May 17 – 18, 2007. An APT representative attended their annual meeting. The MDMA Annual Meeting is a premier industry conference which brings executives from innovative medical technology companies together with healthcares most influential and respected decision makers. The program features speakers from industry, Congress, the Food & Drug Administration, and the Centers for Medicare & Medicaid Services. Attendees included high-level medical technology executives, attorneys, consultants, and others seeking to learn more about trends in the industry. The APT Center sent a representative to this conference.
9. **Louis Stokes Cleveland Veteran's Tea –** May 30, 2007. A light lunch was given in appreciation of the veterans involved in research studies. The APT Center had their display, literature, and representative at the Tea.
10. **Neural Engineering Research Lectures (NERL) Exhibit –** June 8, 2007.
    The Neural Engineering and Rehabilitation Day is presented annually by the members of

the APT and FES Centers, VA Research Centers of Excellence, and by the Neural Engineering Center (NEC) at Case Western Reserve University. The goal of NERL is to promote exchange of information among researchers, faculty, clinicians, and students working in the area of neural prostheses, neural engineering, and rehabilitation.

11. **Association for the Advancement of Medical Instrumentation (AAMI) Conference and Expo –** June 16 – 18, 2007**.** AAMI is a unique alliance of over 6,000 members united by the common goal of increasing the understanding and beneficial use of medical instrumentation. The APT Center presented a booth and device display, attendee registration approximately 700.

12. **2007 ISCoS (International Spinal Cord Society) Annual Scientific Meeting –** June 27–30, 2007. The scientific programme put focus on five main topics that represent some of the many faces of spinal cord injury that meet patients and clinicians every day. These topics were Late Complications, Metabolism, Nutrition and Obesity, Functional Electric Stimulation, Coping Strategies and Impact of SCI on the Family. The APT Center Medical Director attended.

13. **Ingenuity Cleveland – Cleveland's Annual Art & Technology Festival –** July 21-22, 2007. The APT Center had an exhibit at the Ingenuity Technology Hub. Ingenuity's Tech Hub is designed to showcase the various clusters of technological activity in which Northeast Ohio leads, and to connect professionals, businesses, researchers & developers, and students working in similar hi-tech fields across the region. The intent was to shift our audience's perception of our region, to celebrate and stimulate innovation, and support our region's growth. Attendees of Ingenuity's Technology Hub are toured through innovations coming from Northeast Ohio in the areas of bioscience & healthcare, design, hi-tech manufacturing, information technology, nanotechnology, polymers & advanced materials (including liquid crystals & smart fabrics), and space.

14. **American Paraplegia Society Annual Meeting** – August 27 – 29, 2007. American Paraplegia Society collaborates with researchers, physicians, and the entire spectrum of health care providers who serve persons with spinal cord injuries/disorders. The APT Center had a Display and Poster.

15. **2007 BMES Annual Fall Meeting** – September 26 – 29, 2007. Los Angeles 2007 "Engineering the Future of Biology and Medicine" underscored the ever expanding role engineering and technology has and will continue to have in the biomedical arena. Biomedical engineering and technology have increased our understanding and capabilities far beyond what had even been imagined as little as twenty years ago. The APT Center presented a poster.

16. **IEEE Workshop on Wearable Technology in Medicine –** October 22-23, 2007. The APT Center sent two representatives to this event. Meeting themes included applications of wearable technology in rehabilitation; body sensor networks in medicine, sports, and the arts; clinical applications of wireless sensor networks; home monitoring and just-in-time health applications; and others.

B. Media

1. **US Naval Institute Proceedings –** February 2007**.** Caring for the Wounded: Military Prosthetics, The Next Generation.
2. **US Naval Institute Proceedings –** February 2007**.** Caring for the Wounded: Military Prosthetics, The Next Generation.
3. **Case Engineering –** Spring 2007**.** Clips Ahoy! Capadona, Rowan, and Zorman
4. **Value of Research –** Fall 2007/Spring 2007**.** Connecting with the Nervous System: Integrated Engineered Devices into the Human Body.
5. **Radio Show –** August 2007**.** Dynamic Materials Project.
6. **VISN 10 Research Newsletter** – Spring 2007. Biomedical Engineering – D. Tyler.
7. **VISN 10 Research Newsletter –** Summer 2007. Veterans Affairs, Pennsylvania Medical Company developing Prosthetic Arm Control for Amputees.
8. **VISN 10 Research Newsletter –** Summer 2007. Capadona and Potkay awarded VISN 10 Research Initiative Programs.
9. **VA Research Currents –** June 2007. Engineers seek smoother, more natural control of prosthetic arms.
10. **Lines from Leimkeuhler –** Autumn 2007. Leimkuehler, Inc. displays prostheses at Veteran's Hospital.
11. **VISN 10 Research Newsletter –** Fall 2007. $750,000 awarded for the development of a Wireless Implantable Pressure Monitor for Clinical Applications: Setting the Stage for Improvements in the Care of Incontinence.
12. **VISN 10 Research Newsletter –** Fall 2007. $4.75 million awarded to Research Center on Spinal Cord Injury: Local Researcher to Lead Study in Effects of Weight-Shifting on Pressure Ulcers.
13. **VA Exhibit –** January 1 – December 31, 2007.
    APT Center Prosthetic Needs Assessment and Device Display (Figure 25).

Figure 25: VA Exhibit Jan1 – Dec 31, 2007.

C. Outreach

1. **Iveljic, SC –** VA Research Forum. The APT Center: A VA Research Center of Excellence.
2. **Triolo, RJ** – Board Member, **RePlay *for Kids*.**

   RePlay for *Kids* is a 501(c) (3) tax-exempt non-profit organization of volunteers who repair and adapt toys and assistive devices for children with disabilities in Northeast Ohio. **RePlay *for Kids*** provides these services at no cost for

non-profit organizations that provide medical, educational, or recreational resources for children with disabilities in the Northeast Ohio area. Most of these organizations have limited resources and often cannot afford to replace devices that have broken, and do not have the technical knowledge or time available to repair the devices. **RePlay *for Kids*** can provide these services, therefore increasing the number of functioning toys and assistive devices available for children with disabilities.

3. **Zorman, C** - *Program Committee*: SPIE Photonics West: MOEMS-MEMS 2007.

7. Other information Dissemination Activities

Information Dissemination			
Element	**Target**	**Purpose**	**Progress**
Annual report	Lay and consumer groups	Public relations and general education purposes	The VA annual report is completed and will be reformatted and revised for general educational purposes.
Investigator Minutes	Technical professionals and Center stakeholders	Update all Center Investigators and affiliates on program progress	Minutes are sent within one week of the meeting.
Center Website	Consumer & clinical or technical professionals	Information clearinghouse for all Center related activities	The Center Website is online.
Private list-serves and bulletin boards	Center Investigators and staff	Internal communication for ongoing project level management	We have established four list-serves. • The entire center • The investigators • The staff • The students
E-Newsletter	Stakeholders and Collaborators	Special Announcements and Requests	5 E-Newsletters were issued in 2007.
Professional society meetings	Rehabilitation & technical professionals	Transfer knowledge regarding Center discoveries, methods or products and solicit professional input and external advice	We presented at: Research Showcase April 11th and 12th, NERL Day June 8th, AAMI Conference June 16th-18th, Ingenuity Cleveland July 21st and 22nd, American Paraplegia Society August 27th-29th,
Special Issue of *JRRD*	Rehabilitation professionals, consumers	Contribute to scientific foundation of rehabilitation science and engineering.	A publication is planned.

E. RESEARCH COLLABORATIONS

1. Summary of Clinical Interface

The APT Center is fundamentally a technology center that designs, develops, and produces enabling technologies that are clinically relevant. We consciously strive to share our technology within and outside of the VA system. Examples of Clinical Interfaces include:

- Veteran population affected – The new and emerging technologies we are developing may potentially be used to positively affect a significant proportion of the veteran population. Veterans with sensory deficits or motor impairment as a result of spinal cord injury (SCI), stroke, and traumatic brain injury or other central nervous system damage or disease would benefit from clinical application of our technology. Veterans with limb loss would benefit from better mechanical and cybernetic interfacing of advanced prostheses. Veterans with impairment of special senses such as hearing and vision may benefit from further standardization of technology platforms.
- Active clinical participation in our leadership team – Graham Creasey, M.D., served as our Medical Director and a member of the leadership team which sets the direction and operational goals for the Center. Chester Ho, M.D.; and John Stahl, M.D.; are clinical advisors to the center.
- Multi-disciplinary research teams – Most of our research teams are lead by both a clinician and engineer. In addition to these team members, all teams have technical staff assigned.
- Work environment – Several of our laboratories are located immediately adjacent to clinical areas, allowing immediate contact between clinicians and engineers for discussion of issues such as needs definition, development and testing of prototypes, and definitive solution dissemination.
- Clinical Needs Assessment – The clinical needs assessment actively involves clinicians and consumers in identifying and prioritizing needs which then shape our research focus. These workshops also include leaders in the field of biotechnology which allow for a broader market perspective of the clinical applications.
- Investigator Meetings - To facilitate ongoing interactions between clinicians and affiliated APT Center scientists, we have established a quarterly Investigators Meeting that brings faculty and physicians together to discuss potential new projects and progress on existing projects. Part of each meeting is dedicated to a tutorial given by a clinician on a topic of particular relevance to the disabled veteran. Areas covered have included clinical issues related to organ, cavity or tissue pressure, prosthetics and orthotics, and telemedicine.
- Sponsored Conferences – We are in the process of organizing special sessions at clinical conferences (American Paraplegia Society, etc.) to identify barriers to deployment of existing technologies and acceptance by the medical community.
- LSCDVAMC – A center research staff member is a participant each week in the spinal cord injury rounds, and regular presentations are made to the clinical staff.

- Neural Prosthesis Seminar Series – This seminar series discussed in **D4: Sponsored Conferences and Workshops,** has both technical and clinical speakers with an opportunity for networking immediately following the event.
- Platform Advisory Board – An internal team consisting of investigators, senior engineers, and clinicians that triages potential solutions. The team allows for ongoing open discussion between those who are familiar with clinical needs and those who are familiar with capabilities of the technology.

2. Active Collaborations

- **University of Pittsburgh (DM Brienza, PhD and Yih-Kuen Jan, PhD):** "Effects of weight shifting on pressure ulcer risk status" is being carried out as a research project under the auspices of the Rehabilitation Engineering Research Center for Spinal Cord Injury (RERC on SCI). The U.S. Department of Education's National Institute on Disability and Rehabilitation Research awarded the five year grant to the University of Pittsburgh to create the Rehabilitation Engineering Research Center (RERC) on Spinal Cord Injury to address significant issues for people with spinal cord injury. The RERC team and collaborators include the department of rehabilitation science and technology, the department of physical medicine and rehabilitation, the McGowan Institute for Regenerative Medicine and the department of occupational therapy at the University of Pittsburgh, in addition to Case Western Reserve University, Northwestern University, Baylor College of Medicine, IBM and Immunetrics.
- **Vanderbilt University (Nashville, TN):** The central hypothesis of this proposal is that synchronization of stimulation of the posterior cricoarytenoid muscle for vocal fold abduction with the respiratory cycles will improve the performance of neuroprostheses for treating chronic fold medialization. The hypothesis of the sub-contract is that a flat interface nerve electrode (FINE) electrode can record the ENG activity of the phrenic nerve and adequately predict respiration. This will be the primary control source for the full system that is the subject of the studies in the parent proposal.

- **Other Rehabilitation R&D Centers of Excellence:** The APT Center is currently engaged in six joint projects being conducted in collaboration with the Cleveland FES Center. In these collaborative efforts, the APT Center has assumed responsibility for the design, development, and production of technical components for advanced neural prostheses, while FES Center has concentrated on clinical implementation and testing. One of these projects is described in detail in **Section B: Project Reports** ("Prosthetic Arm Control, Project #11") and illustrates the successful and productive synergy between these distinct Centers of Excellence that takes full advantage of their unique strengths.

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