THE PROJECT

A Publication of The Miami Project To Cure Paralysis & The Buoniconti Fund To Cure Paralysis

The Miami Project To Cure Paralysis
Research Review
2016

THE MIAMI PROJECT TO CURE PARALYSIS

UHealth UNIVERSITY OF MIAMI HEALTH SYSTEM

UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

"This has been a most successful year in terms of testing new treatments for people living with the detrimental consequences of brain and spinal cord injury."

Drs. Barth A. Green, W. Dalton Dietrich and Allan D. Levi

This has been a most successful year in terms of testing new treatments for people living with the detrimental consequences of brain and spinal cord injury. The Miami Project to Cure Paralysis together with the Department of Neurological Surgery completed the first FDA approved Phase I dose escalation safety trial that tested human Schwann cell transplantation into subacute spinal cord injured subjects. These recently published findings show safety and evidence for this transplantation approach improving outcomes. Based on the safety record of this trial, permission has been received to extend this transplantation procedure into chronically injured subjects. This new trial for the first time is combining an extensive rehabilitation and exercise protocol with the Schwann cell transplantation to enhance recovery. Four subjects have already undergone the procedure and are showing no unwanted risk factors and small signs of improved neurologic function. In additional to Schwann cell transplantation, we also participated in an industry-sponsored, multi-center, Phase II trial using fetal neural stem cells to repair the injured cervical spinal cord. Follow-up assessments occurred through 12 months to evaluate safety and signs of functional improvement. Together, our cellular transplantation programs are demonstrating our ability to successfully translate innovative reparative therapies into people with the goal of improving the quality of life and function.

Clinical studies are also testing the benefits of different types of neurostimulation, including direct brain stimulation on spinal circuit reorganization and function. Neuropathic pain is a common consequence of SCI, and three subjects have successfully undergone this FDA approved deep brain stimulation experimental procedure. These types of investigative studies are helping to treat and clarify mechanisms underlying abnormal sensory function after SCI. The combination of our proven biological approaches, such as cell therapies and future approaches using state-of-the-art robotics, neuromodulation and brain stimulation strategies are an exciting direction for future research. To further promote this innovative research initiative, a new Neural Engineering Institute at the University of Miami has been approved that will complement the reparative strategies being tested in The Miami Project.

Basic neuroscience research, which continues to fuel our translational and clinical programs, is uncovering basic mechanisms of cell death and

axonal regeneration. Innovative screening strategies are identifying novel molecular targets to promote recovery, and our scientists are continuing to work with industry to help translate new reparative treatments. Drug discovery programs are characterizing novel compounds in translational models of trauma, stroke, and neurodegenerative diseases including muscular sclerosis. In addition to clarifying the mechanisms underlying cellular repair, the importance of inhibitory signals produced by the injured tissue that block successful regeneration are being identified. Together these studies are providing the necessary knowledge for understanding how best to utilize and possibly combine different treatment interventions to maximize protection and recovery mechanisms after injury.

Our Educational Outreach and Training Programs continue to contribute to the mission of The Miami Project. We are reaching out to individuals throughout the United States and abroad providing clinical information, resources, and news regarding progress in research and care. Over 3200 individuals living with SCI have volunteered to be in our research registry and in 2016 alone over 600 individuals participated in our active studies. With the completion of the Christine Lynn Rehabilitation Center for The Miami Project at the University of Miami and Jackson Memorial Hospital in the coming years, these programs will only continue to grow as we help individuals with acute, subacute, and chronic injuries.

We greatly appreciate the critical support from our friends and colleagues that are helping to move these investigations forward. The Miami Project to Cure Paralysis was established in 1985 to develop new therapies to improve function in paralyzed individuals. We are very enthusiastic about our current accomplishments and multi-disciplinary research programs. In addition, we are most eager about the future as we continue to move new treatments forward to treat paralysis.

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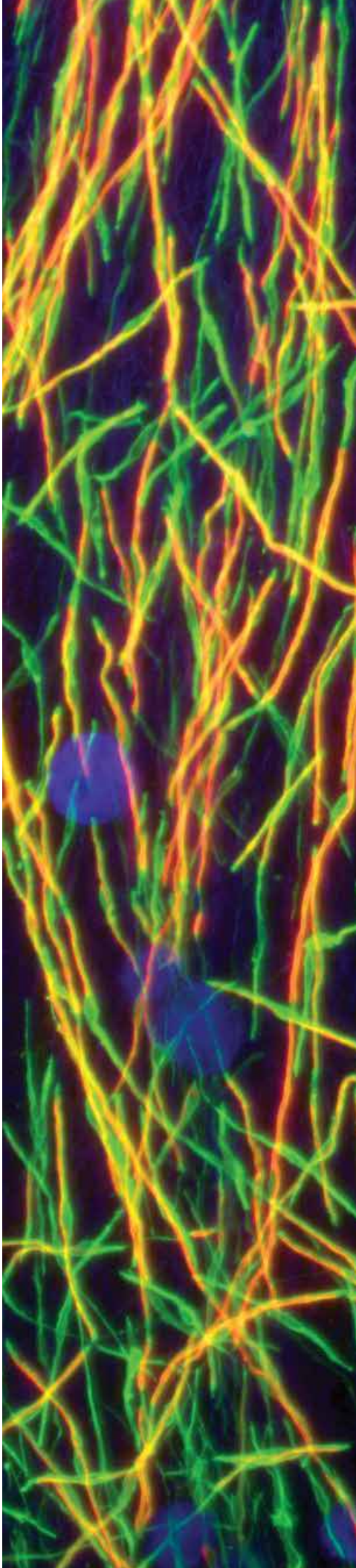
On the Cover
Myelinating co-cultures of purified Schwann cells and purified dissociated dorsal root ganglia neurons.



The Miami Project scientific team is grateful for the dedication and hard work of the the fundraising, administrative, and scientific support staff. This incredible group of people spend countless hours providing direct clerical and administrative support to the research staff, and raising the precious private funds to support Miami Project research endeavors.

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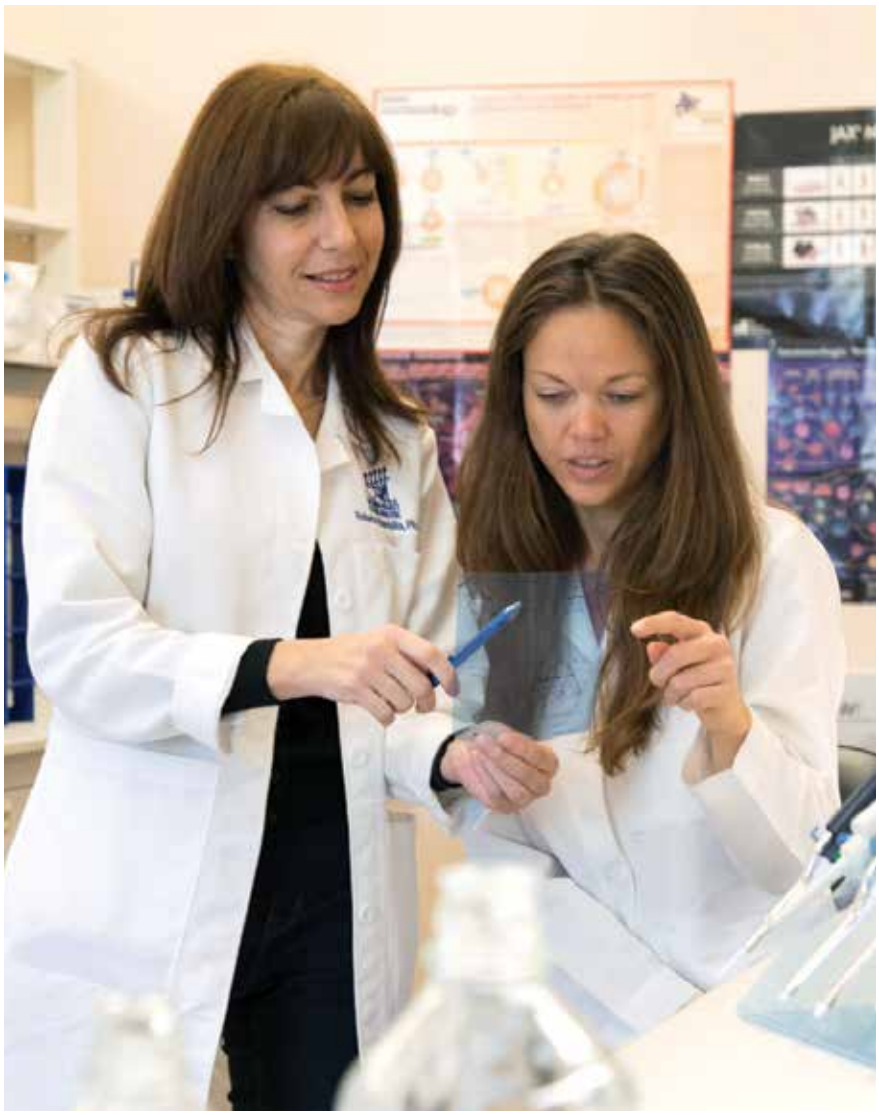
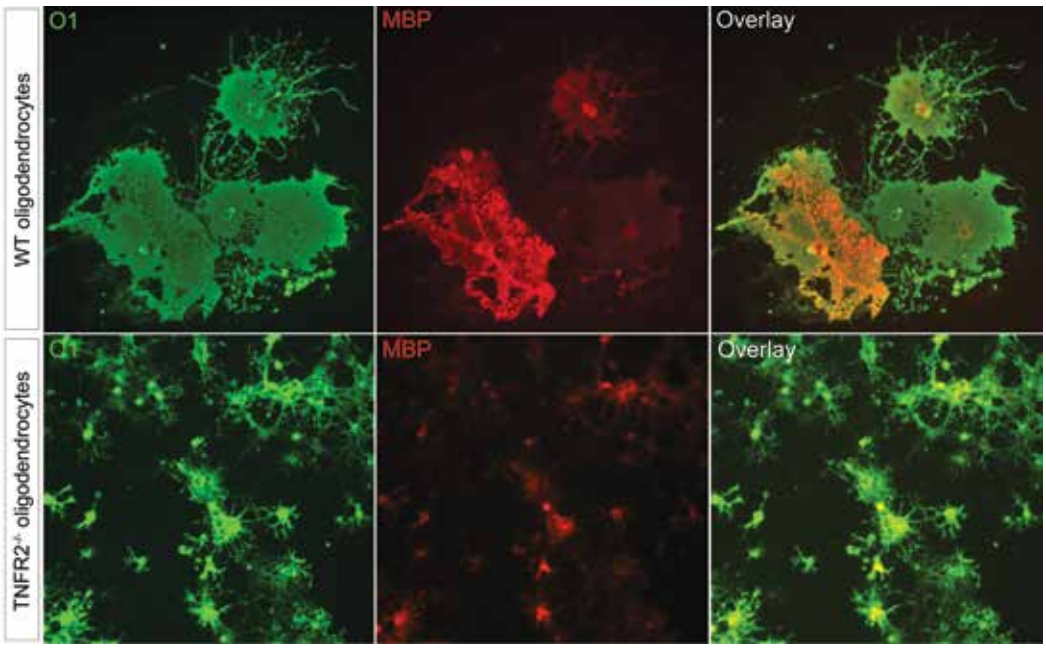
The Molecular Love Between TNFR2 and Oligodendrocytes

Although caused by different mechanisms, MS and spinal cord injury (SCI) both result in in damage to axons within the spinal cord, as well as a loss of insulation (demyelination). Any sort of therapeutic strategy that aims to protect myelin and encourage remyelination could be beneficial to both MS and SCI.



Multiple Sclerosis (MS) is a disease of the brain and spinal cord (the central nervous system) in which the body's immune system attacks the insulation (myelin) that protects nerve fibers (axons). Left uninsulated, the nerves aren't able to reliably transmit signals from the brain to the body. People often experience symptoms like muscle weakness, numbness, pain, and vision loss; in some forms of MS these symptoms recover for a period of time and in other forms of MS these symptoms continually get worse. Although caused by different mechanisms, MS and spinal cord injury (SCI) both result in damage to axons within the spinal cord, as well as a loss of insulation (demyelination). Any sort of therapeutic strategy that aims to protect myelin and encourage remyelination could be beneficial to both MS and SCI.



Primary oligodendrocyte cultures labeled for O1 (green), a marker for the oligodendrocyte lineage, and Myelin Basic Protein (MBP, red), a marker specific to mature oligodendrocytes. Normal "wild type" oligodendrocytes (WT) appear "differentiated" and express high levels of MBP, whereas oligodendrocytes lacking TNFR2 (TNFR2-/-) are small, non-ramified, and with low expression of MBP. This indicates that TNFR2 is important for oligodendrocyte differentiation.

Dr. Roberta Brambilla, Assistant Professor at The Miami Project, has been investigating potential targets for repairing damage to axons and myelin. For a few years now, her efforts have focused on an immune signaling molecule called tumor necrosis factor (TNF). TNF is present in different forms throughout the nervous system, and each form has different functions. One type, called transmembrane TNF (tmTNF), is attached to cells and promotes cell survival, reduces inflammation, and helps form myelin. This is the good form of TNF. Its beneficial functions are signaled by TNF receptor 1 (TNFR1) as well as TNF receptor 2 (TNFR2). Another type, soluble TNF (solTNF), signals only through TNFR1 and has detrimental effects, such as inflammation and cell death. We previously wrote (2012 Research Review) about a study in which Dr. Brambilla and her team selectively blocked the negative actions of solTNF, which resulted in improved outcomes. More axons were preserved and remyelination increased. This suggested that the activity of tmTNF is an important therapeutic target to continue pursuing.

It is important to understand the relationship between tmTNF and the receptor it interacts with primarily, called TNFR2. It is known that oligodendrocytes, the cells in the brain and spinal cord that produce myelin, express high levels of TNFR2. In a new study, Dr. Brambilla and her team, led by Ph.D. student Pernille Madsen, demonstrated that TNFR2 needs to be present specifically on oligodendrocytes in order for tmTNF to exert its good effects. They did this by breeding mice in a way that the action of TNFR2 was absent in oligodendrocytes and their precursor cells. This is called a conditional gene knock-out. A MS disease model was then induced in these mice that were missing TNFR2 on their oligodendrocyte cells. In this situation the disease came on much faster and the outcomes were much worse; oligodendrocytes could not become mature and as a result could not form new myelin. There were also more damaged axons.

Oligodendrocytes are normally wrapped around axons forming myelin and in essence are protecting the axons. Dr. Brambilla showed for the first time that TNFR2 is required to be present on oligodendrocytes in order for them to protect axons when MS disease is occurring and is also required for the oligodendrocytes to become mature and able to form myelin. Enhancing TNFR2 signaling in the central nervous system may provide a viable therapeutic option to boost remyelination and achieve neuroprotection of axons, which could halt or even reverse damage. This could be particularly important for the continually progressive forms of MS, for which there are no treatments.

How Important is Fitness after Spinal Cord Injury?

Each year on December 31st, many of us make New Year's resolutions. At the top of most of our lists is "get healthy", which ranked #1 amongst all resolutions made in 2017. Strategies to achieve this goal often include a mix of diet and exercise, which most of us have forgotten by January 15th. Yet, year after year, we keep making the same resolution to improve our fitness… but, why? Why is fitness so important to all of us? Well, studies have shown that fit people, in general, enjoy a better quality of life. For people living with a spinal cord injury (SCI), fitness is even more important.

Quality of life after SCI is highly dependent on participation, mobility, and personal care independence. Some tasks, like transfers, are critical to independence and require a certain amount of fitness to complete. Getting from a bed to a wheelchair, from a wheelchair to car, or ground to wheelchair are essential to daily life. Unfortunately, many people with SCI report that lack of fitness for certain tasks is a major barrier to achieving independence. In addition, age-related changes may further contribute to declines in fitness, resulting in even more dependence on family and caregivers.

Before any research study begins, there are 'practice' data collection sessions conducted. These 'practice' sessions are used to identify challenges, solutions, and develop a smooth workflow. In the above photo, UM Neuroscience Senior Andrew Mudreac is outfitted with a device that measures the amount of oxygen uses during fitness testing. On the opposite page, Andrew is serving as a 'practice' subject during a wheelchair based fitness test for Janiek van de Burgt, a Master's Student from the Netherlands

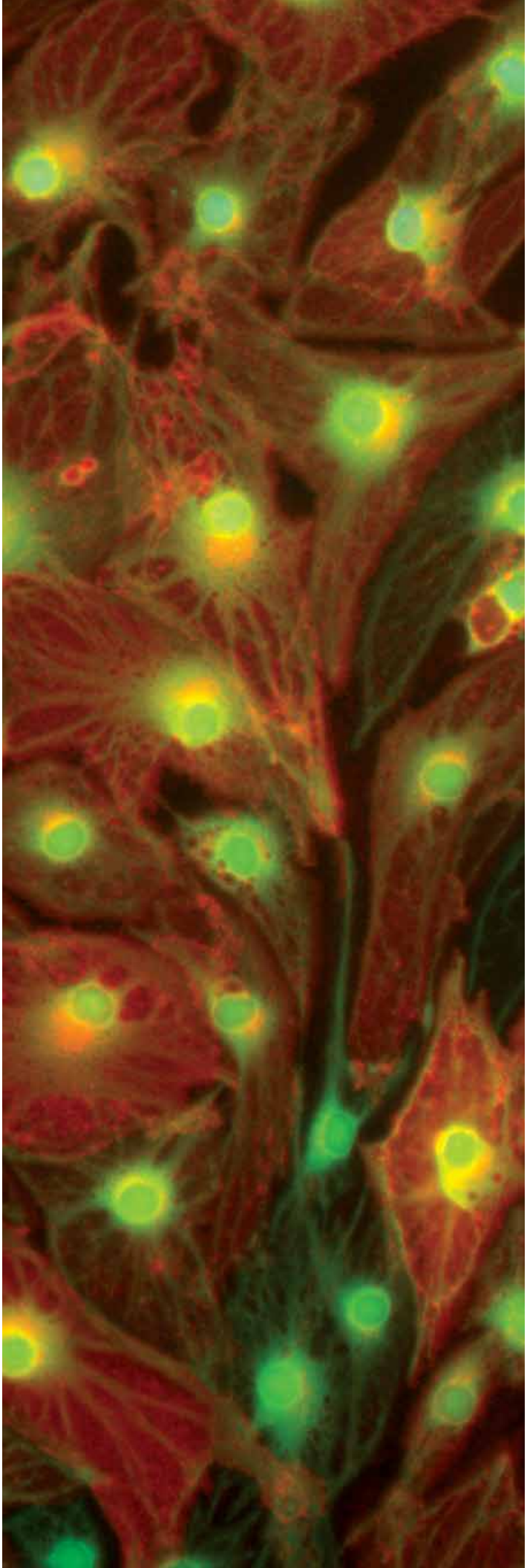
Although it has been well established that improvements in fitness can produce statistically significant changes in functional independence, the relationship has not been established. Dr. Rachel Cowan, a Research Assistant Professor with expertise in health and exercise science, has embarked on a mission to fill this knowledge gap. She was awarded a three-year grant from the Department of Defense to explore how fitness affects functional independence following SCI. After establishing this relationship, she hopes to use that information to estimate how much of a change in fitness is required to achieve a meaningful improvement in function. In the end, she hopes that this study will help develop "prescriptions" for people with SCI who have difficultly performing functional tasks.

This three-year multicenter study is a collaboration between the University of Miami Miller School of Medicine, MedStar National Rehabilitation Hospital (Washington DC), and George Mason University (Fairfax, VA). With a goal of enrolling over 300 people with SCI, this is the largest, most comprehensive examination of fitness and function in people with SCI.

Dr. Cowan and her team are currently enrolling individuals with SCI for this study. Non-ambulatory individuals who are at least 6 months post-injury are eligible to participate. After a quick questionnaire to establish participant safety, research subjects complete about 4 hours of testing to determine their current fitness and function. The assessments include tests of exercise, wheelchair propulsion, and balance, as well as questionnaires related to function, pain, and spasticity. Dr. Cowan will also be looking at the effect of neurological impairment and injury duration on the fitness-independence relationship.

In the future, people with SCI may have an easier time sticking to their New Year's resolution to "get healthy". From her work, Dr. Cowan hopes that better guidelines can be established that will help people with SCI reach their fitness goals. Ultimately, her mission is to help people with SCI achieve a higher quality of life due to improvements in functional independence.

If you are interested in participating in this research study, please contact Dr. Cowan's research associate, Christopher Fitzmaurice, at 305-243-6320 for more information.



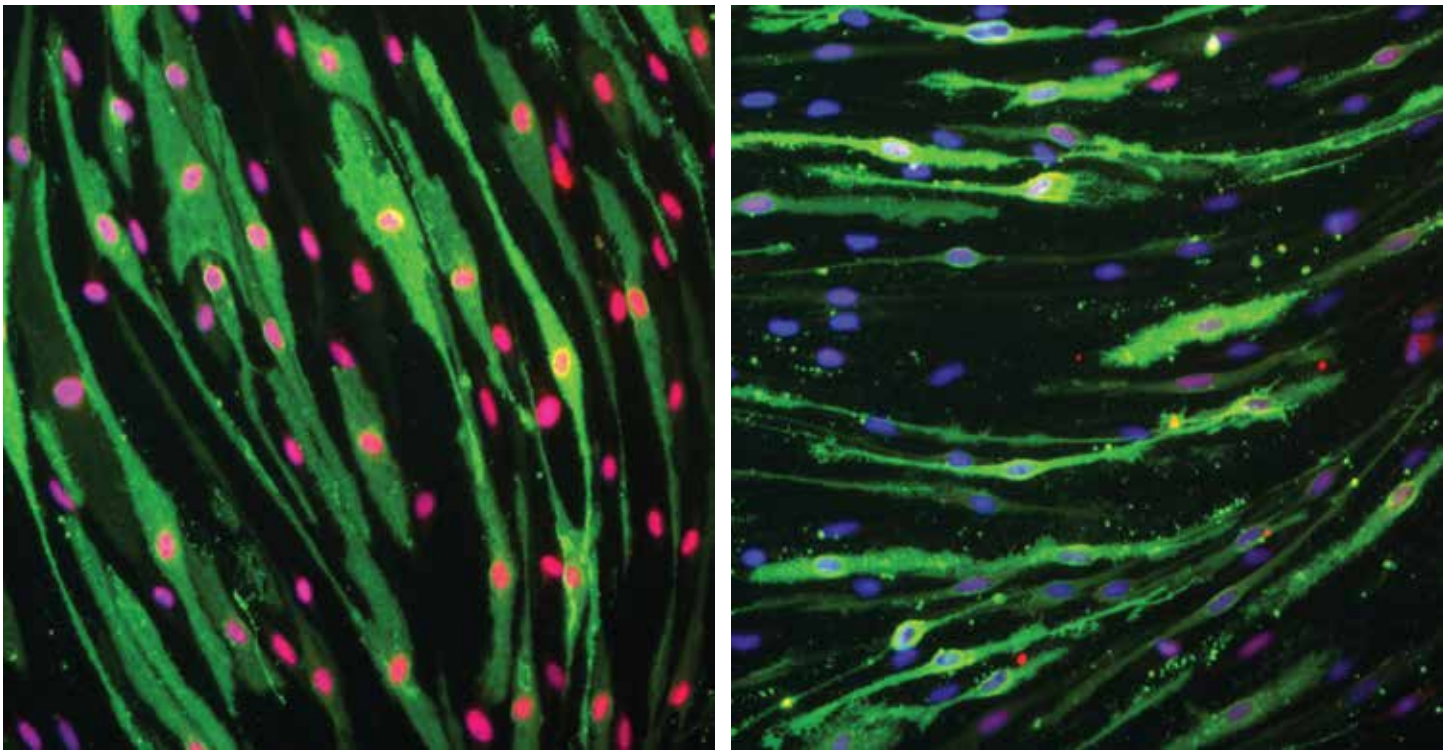
Controlling Schwann Cell Expansion and Maturation

The Miami Project is currently conducting FDA-approved Phase I clinical trials related to Schwann cell transplantation. Schwann cells are found in the peripheral nervous system and provide insulation to nerves by forming myelin. For over 40 years, Schwann cells have been evaluated in animal models of spinal cord injury (SCI), as well as peripheral nerve injuries. Transplantation of Schwann cells into the injured spinal cord has been shown to reinsulate some damaged nerve fibers and may lead to new growth and formation of new connections within the injured spinal cord. Clinical trials at The Miami Project have investigated the safety of transplanting Schwann cells after sub-acute SCI, as well as supplementation of Schwann cells for peripheral nerve injuries. We are now conducting a safety trial evaluating Schwann cell transplantation in individuals with chronic SCI.

With all of these studies, millions upon millions of Schwann cells are necessary. For a single transplant surgery in the chronic SCI trial, up to 200 million cells can be injected into the damaged spinal cord! Methods to prepare Schwann cells for transplantation are labor intensive and the steps needed to produce sufficient numbers of cells often require experimentation over the course of several weeks, not to mention the technical challenges associated with processing and purifying the final product.

Dr. Paula Monje, a Research Assistant Professor at The Miami Project, has been exploring methods of reducing the time required to produce purified Schwann cells in animal models. By introducing a series of novel changes to cell culture protocols, she and her team were able to

Mature Schwann cells: an in vitro model to study Schwann cell maturation



Inhibitory effect of lithium on Schwann cell maturation. Left panel: mature cells (control condition) expressing high levels of myelin proteins (red) and lipids (green). Right panel: immature cells treated with lithium.

both preserve the biological properties of Schwann cells and reduce the time required to produce purified cells from several weeks to only a few days. Their method consists of a series of easy-to-implement steps that, with the proper modifications, can be adapted for the manufacturing of Schwann cells from human nerves.

Her team has also been looking for new ways to manipulate Schwann cells in order to optimize their reparative benefits in transplantation studies. Dr. Monje's recent work has focused on examining the effects of lithium compounds on Schwann cell growth, survival, expansion, and specialization.

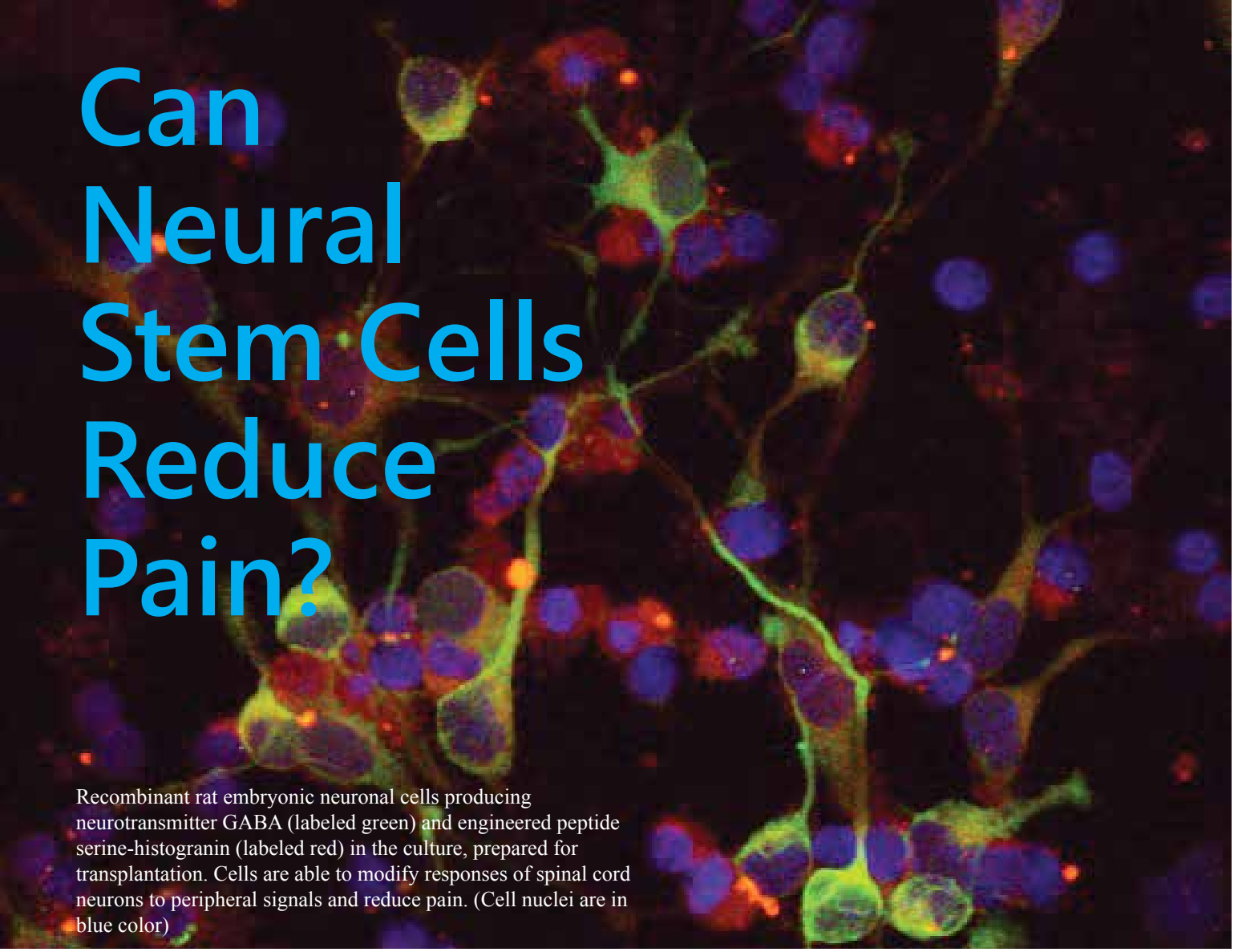
Lithium has been a conventional medical treatment for bipolar and major depressive disorders for over six decades. Lithium therapy has some additional neuroprotective and anti-inflammatory benefits, which have been exploited to treat central nervous system trauma and chronic neurodegenerative diseases, such as Huntington's disease, amyotrophic lateral sclerosis, and Parkinson's disease.

A recent study by Dr. Monje revealed for the first time that lithium compounds can be used to safely control the expansion and maturation of cultured Schwann cells. These findings provide a rationale for the potential use of lithium therapy to treat the wide variety of diseases in which these processes are compromised, including diseases of the myelin and cancer of peripheral nerves. Similarly, lithium offers promise to improve the repair properties of Schwann cells used in cell therapy for the treatment of SCI and peripheral nerve injuries.

Andersen N, Srinivas S, Piñero G, Monje PV. A rapid and versatile method for the isolation, purification and cryogenic storage of Schwann cells from adult rodent nerves. *Scientific Reports* 6, 31781, 2016.

Piñero G, Berg R, Andersen N, Setton-Avruj P, Monje PV. Lithium reversibly inhibits Schwann cell proliferation and differentiation without inducing myelin loss. *Molecular Neurobiology*, 1-21, doi 10.1007/s12035-016-0262-z, 2016.

Can Neural Stem Cells Reduce Pain?



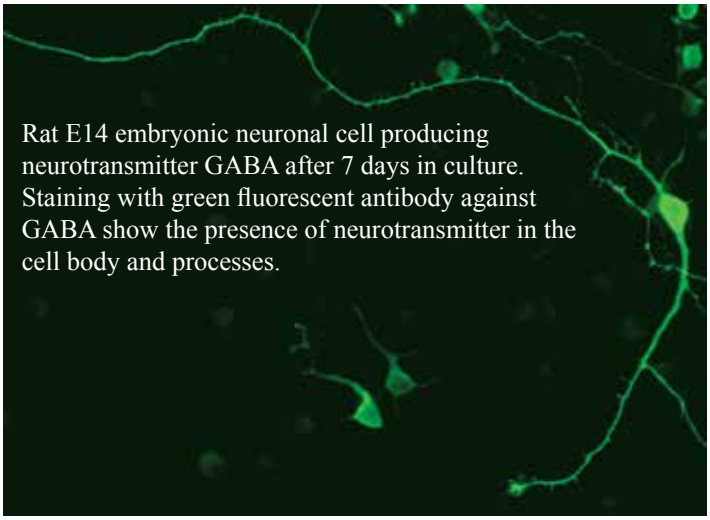
Recombinant rat embryonic neuronal cells producing neurotransmitter GABA (labeled green) and engineered peptide serine-histogranin (labeled red) in the culture, prepared for transplantation. Cells are able to modify responses of spinal cord neurons to peripheral signals and reduce pain. (Cell nuclei are in blue color)

For many people living with a spinal cord injury (SCI), pain is a constant and, sometimes, debilitating problem, which can interfere with activities of daily living and greatly reduce quality of life.

When you have a headache or muscle ache, you probably reach for a generic pain reliever from your medicine cabinet. Within 30 minutes, you typically start to feel a reduction in your pain, and by the next day, you've probably forgotten about the episode completely.

For many people living with a spinal cord injury (SCI), pain is a constant and, sometimes, debilitating problem which can interfere with activities of daily living and greatly reduce quality of life. The mechanisms underlying the development of chronic pain are very complex and currently there are few treatment options for the long-term control of chronic pain from nervous system injuries. Moreover, prolonged use of acute pain-killers may lead to undesirable side effects, such as tolerance and dependency.

Dr. Jacqueline Sagen, a Professor in the Department of Neurological Surgery, is working on developing experimental approaches aimed at improving the management of chronic pain after SCI. Her most recent research targets the delivery of pain-relieving agents directly to the regions of the central nervous system involved in pain signaling. But these aren't just any old pain-relievers from your grandmother's medicine cabinet...

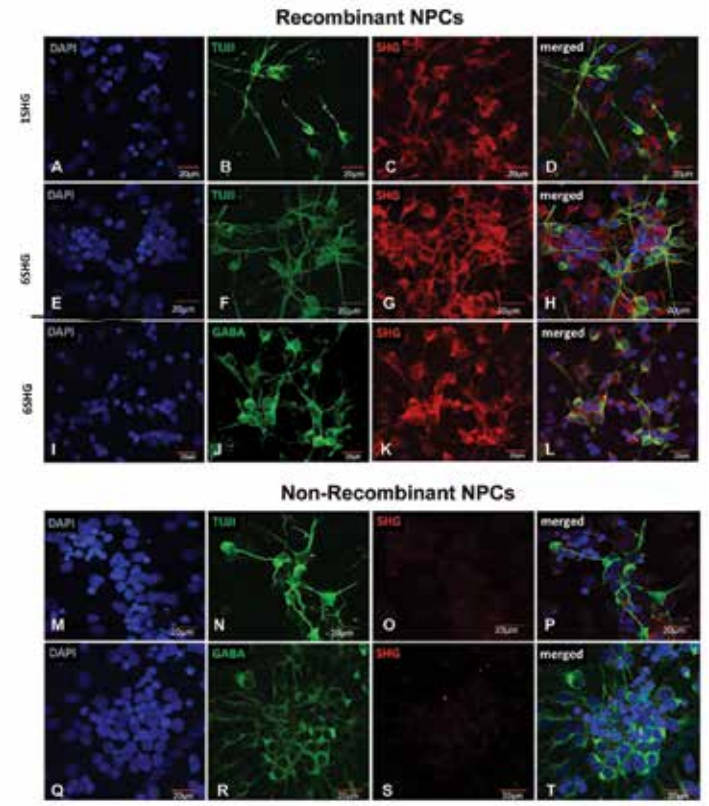


Rat E14 embryonic neuronal cell producing neurotransmitter GABA after 7 days in culture. Staining with green fluorescent antibody against GABA show the presence of neurotransmitter in the cell body and processes.

Previous research has shown that an imbalance of excitatory (positive) and inhibitory (negative) signals causes pain-processing neurons in the spinal cord to become overactive, which contributes to the development of chronic pain after SCI. In an attempt to counteract this hyperactivity, Dr. Sagen and her team injected specialized neural stem cells into the spinal cords of rodents 5 weeks after SCI. The neural stem cells expressing negative signals were transplanted below the level of injury, since many people with SCI report that below-level pain is the most severe and bothersome. Their findings show that the injection of these inhibitory cells helps to reduce the hyperactivity in pain-processing neurons, therefore reducing pain-like behavior.

To enhance the therapeutic potency of this approach, and to further target pain-processing pathways, Dr. Sagen then engineered the inhibitory neural stem cells to produce a pain-relieving molecule called serine-histogranin (SHG), which has an additional inhibitory effect on excitatory receptors in the spinal cord. This is an example of a combination therapy. The injection of such cells into the spinal cord may target both excitatory and inhibitory pathways simultaneously, to help restore a balance in the signaling of neurotransmitters. For this reason, they have also evaluated the effects of engineering the cells to produce multiple copies of SHG, to try to strengthen the pain-relieving activity.

The results from this work showed that injection of the modified cells into the spinal cord of rats with chronic pain reduced signs of pain-like behavior. The effect was stronger for cells that produced higher amounts of the pain-relieving molecule SHG. Dr. Sagen's findings support the potential for engineered neural cell transplants to alleviate neuropathic pain and further support the approach of combined therapy targeting several pain-signaling pathways in the treatment of chronic pain.



Rat recombinant (upper panel) and non-recombinant (lower panel) embryonic neuronal cells. Recombinant cells were genetically modified to produce analgesic peptide serine-histogranin. Immunohistochemical staining with neuronal marker TUJI and GABA antibody showed that both modified and naïve cells develop neuronal phenotype and preserve their ability to produce GABA. Recombinant cells are able to produce serine-histogranin (SHG, red) as an additional neuropeptide. (Cell nuclei are in blue color).

Stanislava Jergova with Dr. Jacqueline Sagen

Jergova S, Gajavelli S, Varghese MS, Shekane P, Sagen J. Analgesic effect of recombinant GABAergic cells in a model of peripheral neuropathic pain. *Cell Transplant.* 25(4):629-643, 2016.

Jergova S, Gajavelli S, Pathak N, Sagen J. Recombinant neural progenitor transplants in the spinal dorsal horn alleviate chronic central neuropathic pain. *Pain.* 157(4):977-989, 2016.

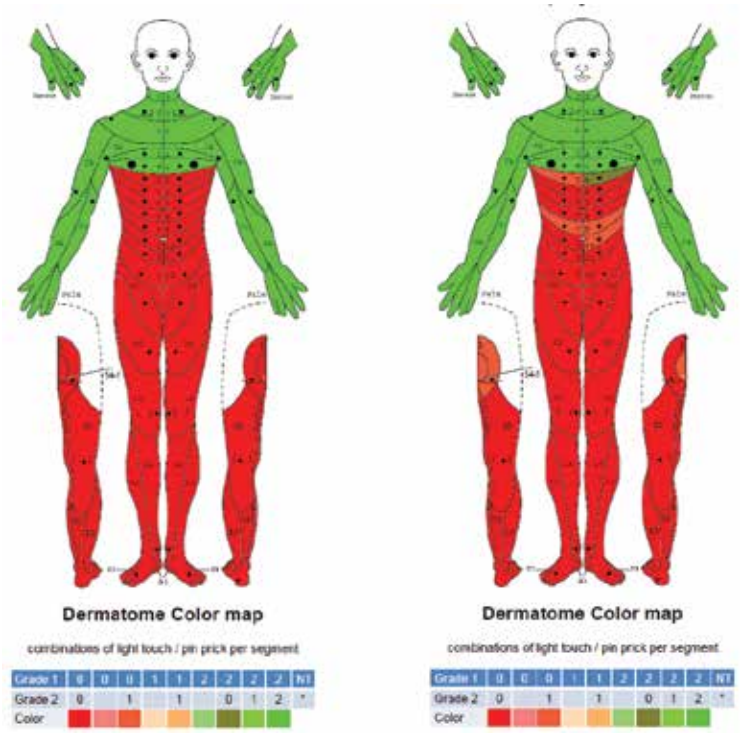
Safety Trial of Schwann Cell Transplantation in Subacute Spinal Cord Injury Completed Successfully

We are happy to announce that we have recently published the results of our FDA-approved Phase I clinical trial involving Schwann cell transplantation after a sub-acute spinal cord injury (SCI). The trial, performed at University of Miami / Jackson Memorial Hospital in Miami, is the first in a series designed to evaluate the safety and feasibility of transplanting autologous human Schwann cells to treat individuals with spinal cord injuries.

The trial enrolled subjects with the least chance of natural recovery in order to firstly establish the safety of the cell transplant procedure; specifically, it targeted people with new SCI, less than 30 days after injury, having sustained a trauma-induced lesion between thoracic levels T3-T11 and who were neurologically complete. This was a dose escalation treatment trial testing 3 different doses: 5 million, 10 million, and 15 million Schwann cells. There were a total of 39 people screened for eligibility, 9 were enrolled, and 6 participants were transplanted. The first two participants received the 5 million cell dose, the second two received the 10 million cell dose, and the final two received the 15 million cell dose. Each participant was followed intensively for one year after receiving the transplantation surgery, and their neurologic status, medical status, pain symptoms, and muscle spasticity were evaluated. All participants will continue to be monitored for a total of five years after the transplantation.

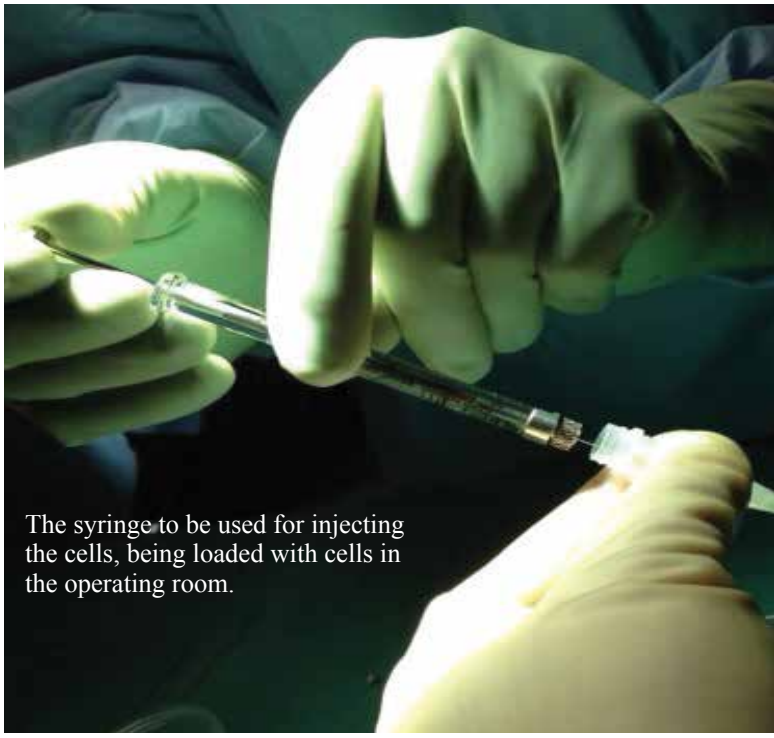
Because the Schwann cells, which reside in peripheral nerves, are obtained from a nerve biopsy from each participant, there is reduced concern of immune rejection and immunosuppressant medication is not required. Demonstrating the feasibility of a program involving an autologous cell therapy is critical, given the reduced risk associated with receiving your own versus someone else's cells. Once the cells are removed from the participant, they have to be handled in accordance to current Good Manufacturing Practices (GMP). Because the cells are eventually injected into the spinal cord, this process is required to ensure that the cells are prepared consistently and without contaminants.

Having now established the safety of Schwann cell transplantation in this initial group of subjects, it will be possible to combine other exciting therapies to amplify neurological recovery.



The results, recently published in the peer-reviewed Journal of Neurotrauma, provide preliminary evidence of safety in the six subjects followed out to one year post-transplanted.

- There were no surgical, medical, or neurological complications to indicate that the timing or procedure for the cell transplantation were unsafe.
- There were no negative events related to the Schwann cell therapy.
- There was no evidence of additional spinal cord damage, tumor, or syrinx formation.
- There were minor sensory changes, including one subject converting to neurologically incomplete status.



The syringe to be used for injecting the cells, being loaded with cells in the operating room.

Importantly, the trial successfully determined safety and feasibility for performing a peripheral nerve harvest within 5-30 days of injury followed by an intra-spinal transplantation of autologous cells within 4-7 weeks of injury, even in individuals having sustained severe spinal injury.

This first trial, using cells grown from the subject's own nerves is an important validation of decades of prior work and animal studies. It is a key milestone for The Miami Project's integrated program that studies spinal cord injury from multiple perspectives. Having now established the safety of Schwann cell transplantation in this initial group of subjects, it will be possible to combine other exciting therapies to amplify neurological recovery.

Kim D Anderson PhD, James D Guest MD PhD, W Dalton Dietrich PhD, Mary Bartlett Bunge PhD, Rosie Curiel PsyD, Marine Dididze MD PhD, Barth A Green MD, Aisha Khan MBA, Damien D Pearse PhD, Efrat Saraf-Lavi, MD, Eva Widerström-Noga DDS PhD, Patrick Wood PhD, Allan Levi MD PhD. (In press). Safety of Autologous Human Schwann Cell Transplantation in Subacute Thoracic Spinal Cord Injury. *Journal of Neurotrauma.* doi: 10.1089/neu.2016.4895

ACTIVE RESEARCH STUDIES

Investigators rely on individuals with SCI to serve as volunteers for specific clinical research studies and clinical trials. These studies are designed to answer questions about some aspect of SCI or the effectiveness of a particular treatment. Each study has specific inclusion/exclusion criteria, and a limited number of people will qualify and have the ability to make a commitment to participate. However, through the commitment of relatively few volunteers, the knowledge gained and communicated ultimately benefits many people with SCI. To be considered for current and future Miami Project research studies, please register via our website at themiamiproject.org.

Online Surveys	International SCI Basic Pain Dataset Survey www.surveymonkey.com/s/paindataset
Activity	Fitness and Independence after SCI
	Training Programs to Improve Outcomes
	Effects of Body Weight Support Treadmill Training and Intermittent Hypoxia
	Effects of Caregiver/Care-Receiver Relationships
	Energy Expenditure During and After Electrically Stimulated Cycling
Fertility	Fertility Evaluation
	Treatment for Infertility
Pain	Perspectives on Management of Severe Neuropathic Pain
	Biomarkers of Pain Phenotypes after Traumatic Brain Injury
Aging	Muscle Weakness and Fatigue after SCI
Sleep	Sleep Disordered Breathing in Chronic SCI
Motor Control and Plasticity	Bilateral Control of Arm Movement after SCI
	Synchronization of Corticospinal Volleys after SCI
	Bilateral Force Coupling after SCI
	Reorganization of Motor Cortical Representations after SCI
	Spike-timing Dependent Plasticity after SCI
	Relationship between Clinical and Physiological Outcomes

FDA-APPROVED CLINICAL TRIALS: CURRENTLY RECRUITING

Chronic (> 1 year post-injury) SCI

Autologous Schwann Cell Transplantation (Phase I)
- ASIA C5-T1, AIS B or C
- 18-65 years old
- Traumatic spinal cord injury
- Contact: Dr. Katie Gant (305-243-3056)

Deep Brain Stimulation (DBS) for Pain (Phase I)
- Level T12 or above
- 18-60 years old
- Neuropathic pain at or below level of injury
- Contact: Letitia Fisher (305-243-7108)

Brain-Machine Interface (BMI) for Hand Function (Phase I)
- ASIA C5 motor-complete
- 18-50 years old
- Contact: Letitia Fisher (305-243-7108)

Acute (at time of injury) SCI

Therapeutic Hypothermia

Riluzole (Phase II)

North American Clinical Trials Network (NACTN)

Biomarkers of SCI

Acute Traumatic Brain Injury (TBI)

Biomarkers of TBI

Track TBI

TBI Registry

Therapeutic Hypothermia

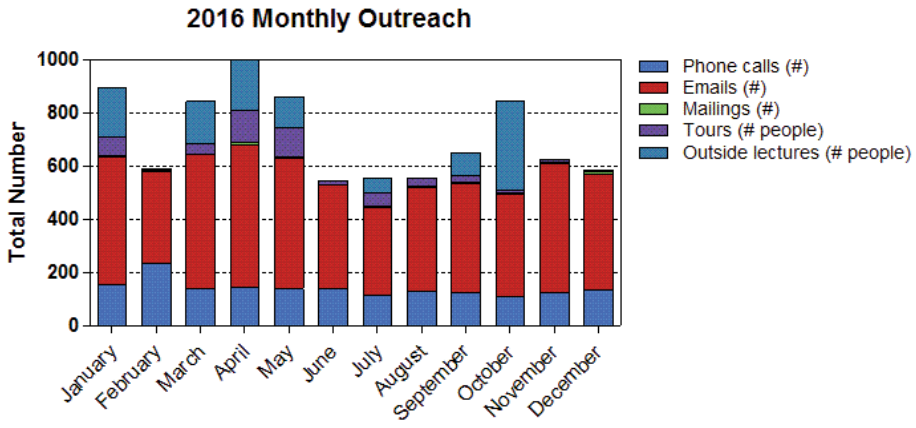
COMMUNITY

The Miami Project believes that an important component of developing treatments for paralysis involves communication with the community. The Education department, directed by Kim Anderson-Erisman, Ph.D., is responsible for helping thousands of our community members each year. The other valuable members of the department are Maria Chagoyen, Danielle Cilien, and Katie Gant. Each year the department answers thousands of phone calls and emails to provide people with information about all of our research programs and clinical studies as well as provide information about rehabilitation resources, clinical care referral, resources for living with paralysis, and advice about research from around the world. We also conduct numerous tours and lectures about our research.

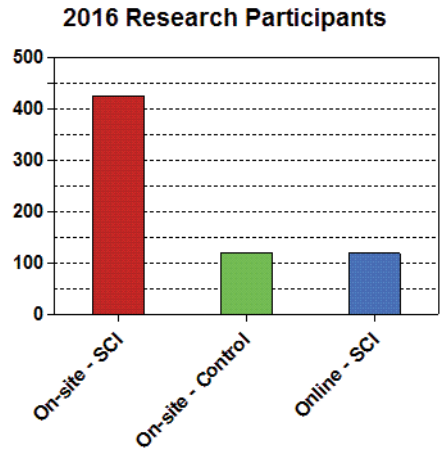
The Education department also assists all of The Miami Project clinical research faculty with recruitment for their clinical studies and trials. To participate in research studies, individuals must first complete an Intake form, which provides us with preliminary injury characteristics. Then you receive a phone call from us to discuss the studies that you pre-qualify for and determine whether you are interested in proceeding with any studies. If so, we set up an appointment for you to come to our research center for a neurologic exam ("ASIA") and introduction to the laboratories. A big thank you to the on-site participants at our research center and online participants in our surveys.

On April 9, 2016 the Education department hosted the 6th Annual Miami Project Community Open House. We enjoy this opportunity to open up our doors to the public to answer questions and share information, as well as to hear direct input from the community. The afternoon began with an informational session about the South Florida SCI Model Systems for spinal cord injury care and research, presented by Dr. Elizabeth Felix. This was followed by a Highlights on Clinical Trials session. Dr. Mark Nash spoke about exoskeleton devices, Dr. Nancy Brackett spoke about treatments for male infertility, and Dr. Allan Levi presented information about our Schwann cell and stem cell clinical trials. Videos of these presentations are available on our website. The final component of the day was Behind-the-Scenes demonstrations of four laboratories, including cells in culture, axons under microscopes, sensation and pain, and fitness and function. We also hosted a Clinician' Corner for the first time, with Dr. Alberto Martinez-Arizala.

If you have questions, don't hesitate to email us at mpinfo@med.miami.edu or call us at 305-243-7108.

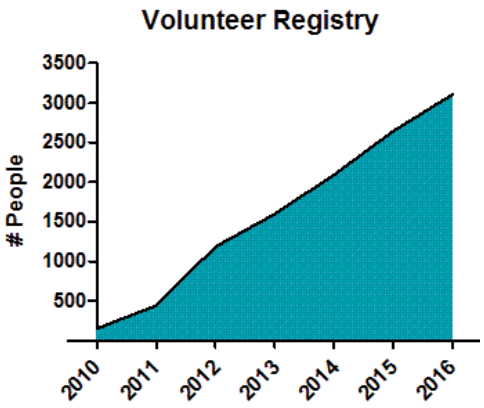


Total number of people interacted with each month during 2016 outreach activities.



Number of people that participated in our studies during 2016.

Cumulative number of individuals since 2010 that have volunteered to be contacted regarding research studies for which they may qualify.



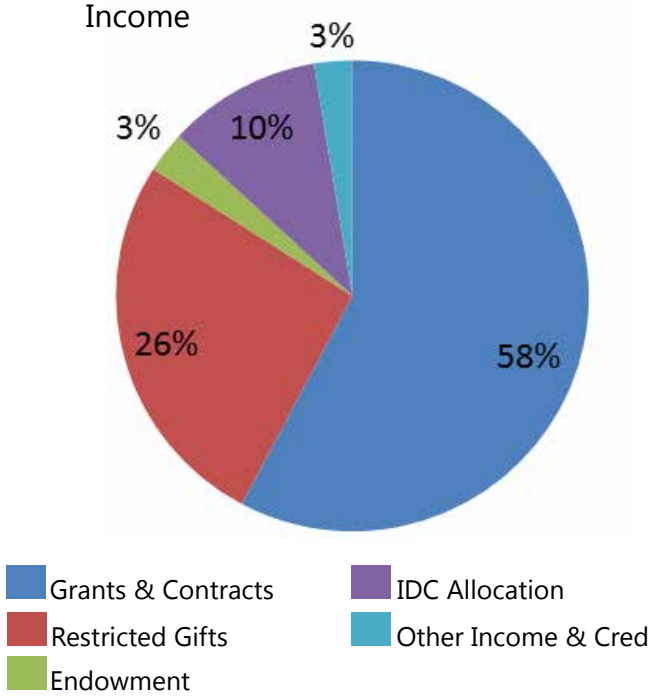
In 2017 we will be partnering with Unite 2 Fight Paralysis to host the Working 2 Walk Science and Advocacy Symposium in Miami.

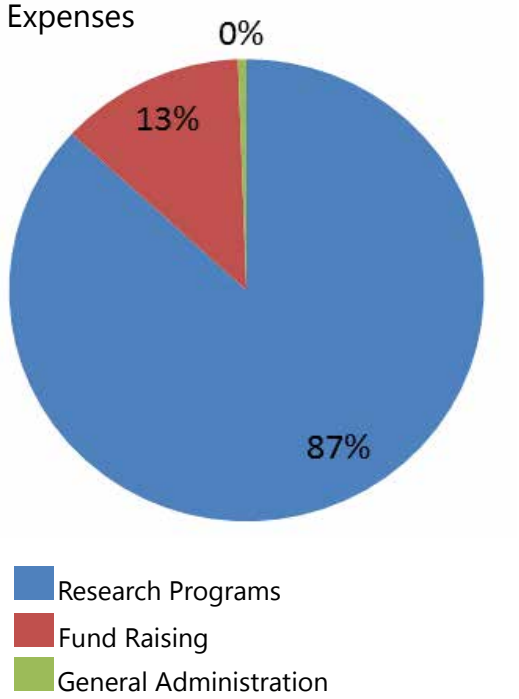
Photos to the left are of members of the community during the 6th Annual Miami Project Community Open House.

Research Funding

Each year, Miami Project scientists seek funding for their research by submitting proposals to the National Institutes of Health, the premier scientific body in the United States, as well as other funding agencies and foundations.

Their scientific peers rate the merits of these proposed experiments in a highly competitive process and only the best are funded. The agencies and organizations listed below supported the Principal Investigator(s) and the scientific project(s) indicated during 2016.





American Heart Association Scientific Development Grant
Dr. Juan Pablo De Rivero Vaccari (P.I.)
-Activation of Rig-like Receptor Signaling after Focal Cerebral Ischemia

BrainScope Company, Inc.
Dr. Gillian Hotz (Site-P.I.)
-EEG DEVICE for Concussion study

Bryon Reisch Foundation
Dr. Kim Anderson-Erisman (P.I.)
-The Safety of Autologous Human Schwann Cells in Subjects with Chronic SCI Receiving Rehabilitation – Screening

Christopher & Dana Reeve Foundation
Dr. James Guest (Center P.I.)
-North American Clinical Trials Network

Craig H. Neilsen Foundation
Dr. Kim Anderson-Erisman (P.I.)
-Miami Project Education Program

Dr. Nancy Brackett (P.I.), Dr. Kim Anderson-Erisman (Co-I.)
-Management of Infertility in Men with SCI: An Educational Program for Practitioners and Clients

Dr. Catherine Craven (P.I.), Dr. Mark Nash (Co-I.), Dr. Kim Anderson-Erisman (Co-I.)
-Statin Monotherapy for Treatment of Endocrine Metabolic Disease Risk

Dr. James Guest (P.I.)
-Neuroprotective Effects of Internal Decompression of the Spinal Cord

Dr. Paula Monje (P.I.)
-Identity-function Definitions for Transplantable Human Schwann Cells

Dr. Mark Nash (P.I.)
-A Time-Course Study of Experimental Cardiometabolic Risk/ Disease after SCI

Dr. Martin Oudega (P.I.)
-Role of Ang-1 in Vascular Stabilization in BMSC-mediated Spinal Cord Repair

Dr. Monica Perez (P.I.)
-Corticospinal Excitability of Leg Muscles After Spinal Cord Injury

Dr. Christine Thomas (P.I.)
-Weakness and Fatigue with Age after Spinal Cord Injury

Conquer Paralysis Now
Dr. Mary Bartlett Bunge (Co-P.I.), Dr. Christine Schmidt (Co-P.I.)
-A New Injectable Matrix to Maximize Schwann Cell Transplantation Efficacy Following Spinal Cord Injury

Danish Medical Research Council
Dr. Roberta Brambilla (Co-P.I.), Dr. Kate Lambertsen (Co-P.I.)
-Microglial-derived Transmembrane TNF Versus Soluble TNF: The Good and the Bad?

Department of Defense (DOD) Spinal Cord Injury Research Program of the Office of the Congressionally Directed Medical Research Programs
Dr. Treena Arinzeh (P.I.), Dr. Mary Bartlett Bunge (Site-P.I.)
-A Combination Tissue Engineering Strategy for Schwann Cell-Induced Spinal Cord Repair

Dr. Rachel Cowan (P.I.)
-Fitness and Independence After SCI: Defining meaningful Change and Thresholds

Dr. W. Dalton Dietrich (P.I.), Dr. Michael Wang (Partner P.I.)
-Biomarkers for Spinal Cord Injury-Related Medical Complications

Dr. Jonathan Jagid, (P.I.), Dr. Ian Hentall (Co-I.), Dr. Alberto Martinez-Arizala (Co-I.), Dr. Eva Widerström-Noga (Co-I.)
-Treatment of Pain and Autonomic Dysreflexia in Spinal Cord Injury with Deep Brain Stimulation

Dr. Allan Levi (P.I.)
-Systemic Hypothermia in Acute Cervical Spinal Cord Injury – A Prospective Case Controlled Study

Dr. Brian Noga (P.I.), Dr. James Guest (Co-I.)
-Gait Ignition Using DBS Following SCI

Dr. Damien Pearse (P.I.), Dr. Howard Levene (Partner P.I.)
-Translation of Novel PDE4 Inhibitors for the Treatment of Acute Spinal Cord Injury

Dr. Jacqueline Sagen (P.I.)
-Engineered Neural Progenitor Transplants in Combination with Exercise to Maximize Neuropathic Pain Reduction Following SCI

Dr. Shirin Shafazand (Co-P.I.), Dr. Mark S. Nash (Co-P.I.)
-Neuro-cognitive Decline and Sleep-Disordered Breathing After SCI

Dr. Eva Widerström-Noga (P.I.), Dr. Kim Anderson-Erisman (Co-I.), Dr. Alberto Martinez-Arizala (Co-I.)
-Perspectives in Management of Severe Neuropathic Pain After a Spinal Cord Injury

Department of Defense (DoD) Psychological Health and Traumatic Brain Injury Program of the Office of Congressionally Directed Medical Research Programs
Dr. M. Ross Bullock (P.I.)
-Preclinical Evaluation of FDA Approved Human Neural Stem Cells in a Rat Model of Severe Traumatic Brain Injury

Dr. W. Dalton Dietrich (P.I.), Dr. Helen Bramlett (Co-I.)
-Operation Brain Trauma Therapy
-The Importance of Temperature in the Pathophysiology of Mild Repetitive Brain Injury

Dr. W. Dalton Dietrich (P.I.), Dr. Helen Bramlett (Co-I.), Dr. Thomas Sick (Co-I.)
-The Use of Pro-Neurogenic Molecules to Promote Recovery of Function Following Acute and Chronic Traumatic Brain Injury

Dr. Eva Widerström-Noga (P.I.)
-Utility of MRS Brain Biomarkers of Pain Phenotypes after TBI

FISM Fondazione Italiana Sclerosi Multipla (Italian Multiple Sclerosis Foundation)
Dr. Roberta Brambilla (P.I.)
-Molecular Mechanisms of the Protective Function of Oligodendroglial TNFR2: A New Therapeutic Target in Neuro-immune Disease

Florida Department of Transportation
Dr. Gillian Hotz (P.I.)
-WalkSafe/Bikesafe Project, Public Service Announcement Marketing Campaign

GE/NFL Head Health Challenge
Dr. Gillian Hotz (P.I.)
-Advanced MRI Applications for Mild Traumatic Brain Injury

International Spinal Research Trust
Dr. James Guest (Center P.I.)
-Cellular Trials to Support Corticospinal Axon Regeneration in Non-Human Primates

Mazor Robotics
Dr. Michael Wang (Site P.I.)
-ADDRESS: Adult Deformity Robotic vs. Freehand Surgery to Correct Spinal Deformity
-MIS ReFRESH: Robotic vs. Freehand Minimally Invasive Spinal Surgeries

Medtronic Spinal and Biologics
Dr. Allan Levi (Site-P.I.), Dr. Barth Green (Co-I.)
-Study of the BRYAN Cervical Disc Prosthesis in the Treatment of Degenerative Disc Disease – Pivotal IDE Study

National Collegiate Athletic Association-Department of Defense Grand Alliance
Dr. Gillian Hotz (Site-P.I.)
Concussion Assessment Research & Education (CARE) Consortium - Longitudinal Clinical Study Core

National Eye Institute
Dr. Kevin K. Park (P.I.)
-Regeneration and Reconnection of Damaged Optic Nerve
-Development and Characterization of Guided Optic Nerve Regeneration

Dr. Kevin Park (Co-P.I.), Dr. Sanjoy Bhattacharya (Co-P.I.), Dr. Vance Lemmon (Co-P.I.)
-Novel Targets to Promote RGC Axon Regeneration: Insights from Unique RGC Cohorts

National Institute on Disability, Independent Living, and Rehabilitation Research
Dr. Michael Boninger (P.I.), Dr. Kevin Dalal (Site P.I.), Dr. Rachel Cowan (Site Co-P.I.)
-Collaboration on Mobility Training

Dr. Diana Cardenas (P.I.), Dr. Rachel Cowan (Co-I.), Dr. Mark Nash (Co-I.)
-South Florida Spinal Cord Injury Model Systems

Dr. Elizabeth Felix (Co-P.I.), Dr. Mark Nash (Co-P.I.), Dr. Eva Widerström-Noga (Co-I.)
-South Florida Spinal Cord Injury Model Systems

Dr. Suzanne Groah (P.I), Dr. Mark Nash (Co-I.)
-Rehabilitation Research and Training Center on Secondary Conditions in SCI

Dr. Mark Nash (P.I.), Dr. Kim Anderson-Erisman (Co-I.), Dr. Rachel Cowan (Co-I.), Dr. Eva Widerström-Noga (Co-I.)
-A Lifestyle Intervention Targeting Enhanced Health and Function for Persons with Chronic SCI in Caregiver/Care-Receiver Relationships: Effects of Caregiver Co-Treatment

Dr. Heather Taylor (P.I.), Dr. Eva Widerström-Noga (Co-I.)
-The Relations among Pain, Depression, and Resilience and their Prediction of Life Satisfaction in Men and Women with Spinal Cord Injury

National Institute of Neurological Disorders & Stroke
Dr. Kim Anderson-Erisman (Co-P.I.), Dr. W. Dalton Dietrich (Co-P.I.)
-NIH Neurotrauma Summer Research Experience Program

Dr. Coleen Atkins (P.I.)
-The Role of Phosphodiesterase 4B in Inflammation after Trauma (Fellowship)

Dr. Coleen Atkins (Co-P.I.), Dr. W. Dalton Dietrich (Co-P.I.)
-Cyclic Nucleotide Regulation in Traumatic Brain Injury

Dr. Coleen Atkins (P.I.), Dr. Thomas Sick (Co-I.)
-Rehabilitation Strategies for Memory Dysfunction after Traumatic Brain Injury

Dr. Mary Bartlett Bunge (Co-P.I.), Dr. John Bethea (Co-P.I.), Dr. Ian Hentall (Co-I.), Dr. Paula Monje (Co-I.), Dr. Kevin Park (Co-I.), Dr. Patrick Wood (Co-I.)
-Cytological Studies of Developing and Mature Neurons
Dr. Roberta Brambilla (P.I.), Dr. Juan Pablo De Rivero Vaccari (Co-I.)
-Molecular Mechanisms of the Protective Function of Oligodendroglial TNFR2: A New Therapeutic Target in Neuro-immune Disease

Dr. Helen Bramlett (P.I.)
-33rd Annual National Neurotrauma Society Symposium

Dr. Helen Bramlett (Co-P.I.), Dr. W. Dalton Dietrich (Co-P.I.), Dr. Daniel Liebl (Co-I.)
-A Novel Combination Strategy for Protection and Repair After TBI

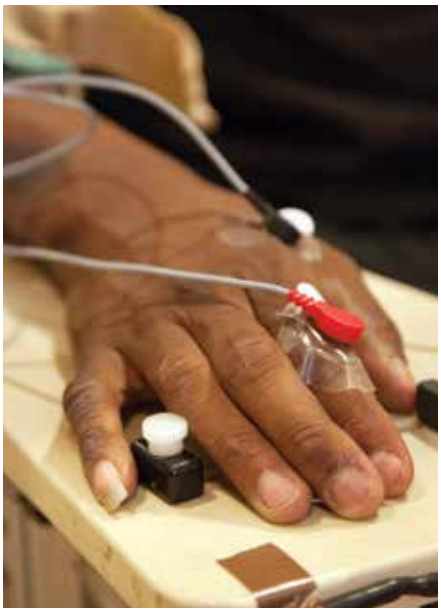
Dr. W. Dalton Dietrich (P.I.), Dr. Helen Bramlett (Co-I.), Dr. Juan Pablo De Rivero Vaccari (Co-I.)
-The Importance of Temperature on the Inflammatory and Microvascular Consequences of Mild TBI

Dr. W. Dalton Dietrich (Co-P.I.), Dr. Robert Keane (Co-P.I.), Dr. Juan Pablo De Rivero Vaccari (Co-I.)
-Therapeutic Neutralization of the Inflammasome after Spinal Cord Injury

Dr. Edelle Field-Fote (P.I.), Dr. Eva Widerström-Noga (Co-I.)
-Dose-response Effects of Whole Body Vibration on Spasticity and Walking in SCI

Dr. Mark Gurney (P.I.), Dr. Coleen Atkins (Subcontract-P.I.)
-PDE4B Inhibitors for Treating Brain Injury

Dr. Gillian Hotz (Site-P.I.), Dr. Ross Bullock (Site Co-P.I)
-Transforming Research and Clinical Knowledge in Traumatic Brain Injury



Dr. Jae Lee (P.I.)
-Role of Fibroblasts in Axon Regeneration After SCI
-Translational Profile of Perivascular Fibroblasts After Spinal Cord Injury

Dr. Vance Lemmon (Co-P.I.), Dr. John Bixby (Co-P.I.)
-Novel Gene Targets for CNS Axonal Regeneration

Dr. Vance Lemmon (Co-P.I.), Dr. John Bixby (Co-P.I.), Dr. Stephan Schürer (Co-P.I.)
-Regenbase: A Searchable Database to Organize Regeneration Knowledge via Ontologies

Dr. Daniel Liebl (P.I.)
-Ephrins Regulate Stem Cell Proliferation following Traumatic Brain Injury
-Modulating Post-Injury Gliotransmitter levels Leads to Improved Synaptic Function (Fellowship)

Dr. Paula Monje (P.I.)
-Phenotypic and Functional Analysis of Human Schwann Cells for Potency Assay Development

Dr. Brian Noga (P.I.), Dr. James Guest (Co-I.)
-Gait Induction After SCI

Dr. Michael Norenberg (P.I.), Dr. Helen Bramlett (Co-I.)
-Chronic Traumatic Encephalopathy: Role of Astrocytes

Dr. Monica Perez (P.I.)
-Neural Control of Bilateral Hand and Arm Movements After Spinal Cord Injury

Dr. Monica Perez (P.I.), Dr. Christine Thomas (Co-I.)
-Corticospinal Function After Human Spinal Cord Injury

Dr. Stephan Schürer (P.I.), Dr. Vance Lemmon (Co-I.), Dr. John Bixby (Co-I.)
-Data Coordination and Integration Center for LINCS-BD2K

Dr. Gaofeng Wang (P.I.), Dr. Mary Bartlett Bunge (Co-I.)
-Epigenetic Prevention of Diabetic Neuropathy by Vitamin C

Dr. Grace Zhai (P.I.), Dr. Pantelis Tsoulfas (Co-I.)
-Mechanisms of Neuronal Maintenance and Protection

National Multiple Sclerosis Society
Dr. Jae Lee (P.I.)
-Mechanisms of Fibrosis After Experimental Autoimmune Encephalomyelitis

National Scientific and Technical Research Council (CONICET, Argentina)
Dr. Paula Monje (Co-P.I.), Dr. Patricia Setton-Avruj (Co-P.I.)
-Signal Transduction Pathways Underlying the Pro-differentiating Effect of Iron in Schwann cells: A Comparison Between Rodent and Human Schwann Cells
-Transplantation of Bone Marrow Stromal Cells and Schwann Cells for Peripheral Nerve Repair

New Jersey Commission on Spinal Cord Injury
Dr. Treena Arinzeh (Co-PI.), Dr. Mary Bartlett Bunge (Co-P.I.)
-Testing Proteoglycan Subunits for Axon Growth Permissivity/ Inhibition

Pfizer, Inc.
Dr. Michael Wang (Site P.I.)
-STRIVE: Staphylococcus Vaccine Trial for Elective Spinal Surgery

SanBio, Inc.
Dr. Jonathan Jagid (Site-P.I.)
-A Double-Blind, Controlled Phase 2B Study of the Safety and Efficacy of Modified Stem Cells (SB623) in Patients With Chronic Motor Deficit From Ischemic Stroke.

Scythian Biosciences
Dr. Gillian Hotz (P.I.)
-The Effects of Cannabinoids on MTBI

State of Florida
Dr. Jacqueline Sagen (P.I.)
-Design of Inflammation-Driven Regulatable Gene Therapy for Management of Neuropathic SCI Pain

State of Florida Brain and Spinal Cord Injury Program, Department of Health, and Red Light Camera Fund
-These three state funds contribute to several research programs

within The Miami Project to Cure Paralysis

StemCells Inc.
Dr. Allan Levi (Site-P.I.), Dr. Kim Anderson-Erisman (Co-I.)
-A Single-Blind, Randomized, Parallel Arm, Phase II Proof-of-Concept Study of the Safety and Efficacy of HUCNS-SC Transplantation in Cervical Spinal Cord Injury

The Childhood Brain Tumor Foundation
Dr. Nagi Ayad (P.I.)
-A Novel CK1δ/Brd4 Pathway for the Treatment of Medulloblastoma

The Morton Cure Paralysis Fund
Dr. Martin Oudega (P.I.)
-Fibronectin for Enhancing BMSC-mediated Spinal Cord Repair

UM Dean's Bridge Funding Program
Dr. Daniel Liebl (P.I.)
-Molecular Mechanisms of Synaptic Dysfunction Following TBI

UM Scientific Advisory Council Award
Dr. Jae Lee (P.I.)
-BET Proteins as Epigenetic Regulators of Spinal Cord Injury Pathogenesis

Veterans Administration Rehabilitation Research and Development
Dr. Victor Arvanian (P.I.), Dr. Damien Pearse (Co-I.)
-Enhancing Plasticity in a Damaged Spinal Cord to Repair Transmission and Function

Dr. Martin Oudega (Co-P.I.), Dr. Monica Perez (Co-P.I.)
-Maximizing Spike Timing-Dependent Plasticity After Spinal Cord Injury

Dr. Damien Pearse (P.I.), Dr. Moushumi Ghosh (Co-I.)
-Enhancing the Reparative Efficacy of Schwann Cells Following Chronic SCI

Dr. Monica Perez (P.I.)
-Enhancement of Hand Motor Function After Cervical Spinal Cord Injury

Wallace H. Coulter Foundation
Dr. John L. Bixby (Co-P.I.), Dr. Vance P. Lemmon (Co-P.I.), Dr. Hassan Al-Ali, (Co-I.)
-Developing a Multi-Target Small-Molecule Drug for Treating CNS Injuries

Wings for Life
Dr. Martin Oudega (P.I.)
-ESHU for Optimizing BMSC Transplant Survival and Spinal Cord Repair Efficacy

Women's Cancer Association
Dr. Nagi Ayad (P.I.)
-Identifying Dual BET-FLT3 Inhibitors for Acute Myelogenous Leukemia

Meet our Faculty

The Miami Project To Cure Paralysis

The faculty of The Miami Project are a talented multidisciplinary team. In the following Profiles, each faculty member describes their specific research focus and highlights of recent progress.

W. DALTON DIETRICH, PH.D.
Scientific Director
Kinetic Concepts Distinguished Chair in Neurosurgery
Senior Associate Dean for Discovery Science
Professor, Departments of Neurological Surgery, Neurology, and Cell Biology

Neuroprotection and Improved Recovery of Function following CNS Trauma

My research interest is the pathobiology and treatment of CNS injury in both the acute and chronic setting. Animal models of spinal cord injury, traumatic brain injury, and stroke are utilized to investigate the cellular and molecular mechanisms of tissue injury. The ultimate goal is to target secondary injury processes for various interventions that may protect vulnerable cell types or promote reparative processes to enhance neuroprotection, circuit plasticity, and recovery of function. The use of therapeutic hypothermia and targeted temperature management in preclinical and clinical settings is currently a focus of discovery and clinical investigations in the laboratory.

ALLAN D. LEVI, M.D., PH.D., F.A.C.S.
Robert. Buck Distinguished Chair in Neurological Surgery
Professor, Departments of Neurological Surgery, Orthopedics, and Physical Medicine & Rehabilitation
Chairman, Department of Neurological Surgery
Chief of Neurosurgery, Jackson Memorial Hospital

Cellular Transplantation Strategies after SCI/Systemic Hypothermia after Acute SCI

My clinical research interests currently focus on developing cellular transplantation strategies to repair injuries within both the human central and peripheral nervous system. I am currently Co-PI on our clinical trial "Transplantation of Autologous Human Schwann Cells (SCs) to Repair the Injured Spinal Cord - Phase I - safety study". This represents a first-in-man dose escalation study of autologous human SCs for patients with sub-acute thoracic SCI (T3 to T11). We are also very interested in the use of SCs for peripheral nerve injuries with long segmental defects and have performed such transplantations in patients with acute sciatic nerve injuries. Hypothermia continues to show promise in a variety of acute central nervous system injuries. There are various factors that need to be considered with systemic cooling of the SCI patient, including methods of cooling, window from injury to initiation, duration and depth of hypothermia, rate of re-warming, etc. While profound levels of hypothermia (T <32°C) can be difficult to administer and are subject to increased complication rates, mild (modest) levels of hypothermia (T 32-34°C) have been shown to provide significant protection against traumatic and ischemic neuronal cell death. I am currently the PI of our institutional protocol as well as a multi-center Department of Defense funded randomized trial studying systemic hypothermia induced via an intravascular catheter and continued for 48 hours after acute cervical SCI.

BARTH A. GREEN, M.D., F.A.C.S.

Professor of Neurological Surgery, Neurology, Orthopaedics, and Rehabilitation
Co-Founder and Chairman, The Miami Project to Cure Paralysis
Executive Dean for Global Health and Community Service

Translational Interventions

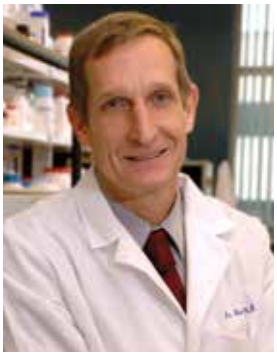
Over the recent years my research efforts have mainly involved taking the cutting edge basic neuroscience work product and data created by our Miami Project team from the bench to our UM affiliated clinics and hospitals. A good example of such translational research efforts has included the use of modest hypothermia for neuroprotection both in cases of acute spinal cord injury and for use in the operating room for patients undergoing high risk spinal cord surgery. I am also privileged to be able to collaborate with The Miami Project cellular transplantation programs and have been working on projects involving adult mesenchymal stem cells as well as being part of the major effort transforming our successful Schwann cell laboratory model into clinical trials. Other areas of research and clinical interest include the diagnosis and treatment of tethered cord syndrome, spinal cord cysts and Chiari I malformation.

MARY BARTLETT BUNGE, PH.D.

Christine E. Lynn Distinguished Professor in Neuroscience
Professor, Departments of Cell Biology, Neurological Surgery, and Neurology

Development of Combination Strategies with Schwann Cells to Repair the Injured Spinal Cord

The goal in my laboratory is to foster regeneration of axons across and beyond a spinal cord injury (SCI). To improve regeneration of axons, we are investigating reducing the accumulation of proteoglycans (molecules that inhibit axonal growth), improving survival of transplanted Schwann cells (SCs), genetically engineering SCs before transplantation to improve their growth factor-secretion capability or neurons to enhance their ability to regrow axons, and testing matrices (in which the SCs are transplanted) for efficacy after injury. We pay particular attention to the interfaces between the SC implant and the host spinal cord.



JOHN BIXBY, PH.D.

Professor, Departments of Molecular & Cellular Pharmacology and Neurological Surgery, Center for Computational Sciences, Institute for Human Genomics
Vice Provost for Research

VANCE LEMMON, PH.D.

Walter G. Ross Distinguished Chair in Developmental Neuroscience
Professor, Department of Neurological Surgery, Center for Computational Sciences, Institute for Human Genomics, Sylvester Cancer Center

High Content Screening and Functional Genomics of the Nervous System

Our laboratory has developed methods to test thousands of genes or chemicals in hundreds of thousands of neurons each week to obtain quantitative information about cell morphology and gene expression. This "high throughput" capability allows us to tackle questions about axon growth and regeneration using systems biology approaches, and to take them into animal models of injury. The Lemmon-Bixby lab has several ongoing projects related to axon regeneration. One project is to test the roles of known signaling proteins called protein kinases. In this screen we have tested >1600 kinase inhibitors, many of which strongly promote neurite growth in vitro. Using bioinformatics, biochemistry, and machine learning we can identify critical kinases and their signaling networks as well as potential lead therapeutic compounds, one of which has proven active in two different models of spinal cord injury. A second project is based on the observation that injured peripheral sensory neurons initiate a genetic program

appropriate for axonal regeneration. Our laboratory has combined next-generation sequencing with cell-based phenotypic screening to identify genes, especially transcription factors, and microRNAs that appear to regulate this genetic program, and is testing them in vitro and in vivo. Finally, in collaboration with Dr. S. Schürer, Dr. Ubbo Visser, and Drs. Nigam Shah and Alison Callahan (Stanford), we are developing RegenBase, an information system that includes an online tool for annotation of data and metadata, a knowledge base of diverse data on nerve regeneration, and an ontology that allows structured queries of the database.

HELEN M. BRAMLETT, PH.D.

Professor, Departments of Neurological Surgery and Psychology, Undergraduate Neuroscience Program Director, and Health Scientist Veterans Affairs

The Pathophysiology and Treatment of CNS Injury

The focus of my neurotrauma laboratory is to investigate both acute and long-term consequences of brain and spinal cord trauma. My current research interests are on the pathophysiology of traumatic brain and spinal cord injury with an emphasis on the pathogenesis of progressive white matter damage as well as the benefits of therapeutic hypothermia. My laboratory is also investigating mechanistic events leading to the development of posttraumatic epilepsy. Additionally, our current work is also focusing on complex traumatic brain injury models that mimic polytrauma as this type of injury has become more prevalent in combat areas.

M. ROSS BULLOCK, M.D., PH.D.

Professor, Department of Neurological Surgery

Director, Clinical Neurotrauma

Preclinical Mechanistic and Neuroprotection Research in Traumatic Brain Injury and Clinical Trials, and Neuromonitoring Techniques in the Injured Brain

We recently completed an extensive series of studies funded by the Department of Defense (DoD) to evaluate the neuroprotective effect of Perfluorocarbons in four rodent models of traumatic brain injury (penetrating brain injury, closed traumatic brain injury with secondary hypoxia, tissue culture with stretch injury, and mechanistic and safety studies). These oxygen carriers have shown benefit in previous studies involving fluid percussion injury and subdural hematoma models. Unfortunately, we could not demonstrate efficacy with 3 of the PFC's tested. We are also evaluating hypothermia neuroprotection, in humans and animals, using novel biomarkers. We are currently funded by the DoD to obtain efficacy and safety data with FDA approved human stem cells, transplanted into the rat brain, as therapy for Penetrating TBI.

ROBERT W. KEANE, PH.D.

Professor, Departments of Physiology & Biophysics, and Neurological Surgery

Regulation of Innate Immunity after CNS Trauma

Innate immunity is the first line of defense against pathogens and host-derived signals of cellular stress. My research focuses on investigating mechanisms that direct normal innate immunity and its dysregulation in central nervous system injury and disease, including (1) agonists and activation mechanisms of inflammasomes, (2) regulatory mechanisms that potentiate or limit inflammasome activation after injury, and (3) emerging data linking inflammasome proteins as biomarkers for CNS injury.

DANIEL J. LIEBL, PH.D.
Professor, Department of Neurological Surgery

Molecular Mechanisms that Regulate Cellular Dysfunction and Death Following CNS Injury, and Mechanisms to Promote Regeneration and Recovery

The goal of my laboratory is to identify the mechanisms that lead to CNS pathophysiology and its regenerative potential. We focus on a family of molecules, called eprhins and Eph receptors, which play important roles in the developing, regenerating, and injured nervous systems. Specifically, we are currently interested in areas of adult neurogenesis, neuroprotection, apoptotic cell death, synaptic plasticity, regeneration, and therapeutic strategies. Overall, our approach is to develop novel strategies to minimize CNS damage and maximize regeneration/tissue repair, which can be best achieved through a comprehensive mechanistic approach.

MARK S. NASH, PH.D., F.A.C.S.M.
Professor, Departments of Neurological Surgery, Physical Medicine & Rehabilitation, Physical Therapy, and Kinesiology & Sports Sciences

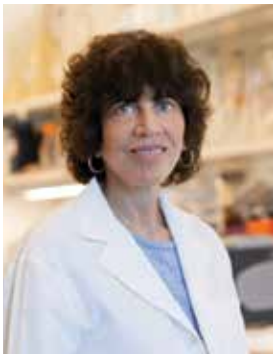
Physiological Assessment of Secondary Complications Following SCI: Electrical Stimulation, Cardiometabolic and Vascular Physiology, Cardioendocrine Pathology and Intervention, and Exercise and Nutritional Biochemistry

One of the enduring goals of The Miami Project has been to test and then translate strategies that optimize health of persons with SCI. A significant target for this strategy has focused on physical activity to lessen secondary risks of SCI associated with physical deconditioning. We also examine complementary themes to optimize exercise prescription after SCI, identify optimal nutritional intake, and use prescription and non-prescription agents that reduce hazards of fasting and postprandial lipid disorders, dysglycemia, and vascular inflammatory stress.

DAMIEN D. PEARSE, PH.D.
The John M. and Jocelyn H.K. Watkins Distinguished Chair in Cell Therapies
Professor, Department of Neurological Surgery

Exploration and Translation of Therapeutic Strategies to Repair the Injured Spinal Cord and Brain

My laboratory focuses on several key aspects of CNS injury repair, including (1) the utility and clinical translation of exogenous and endogenously harnessed cell therapeutics (particularly when used in combinatory approaches), (2) understanding the role of, and developing therapies for, altered cyclic AMP (adenylyl cyclase, phosphodiesterases, and PKA) and MAPK signaling in neurons and glia after CNS injury, (3) the use of nanotherapeutics for multifunctional and site-directed gene/drug targeting to the injured CNS, and (4) the application of methodologies for improved imaging of axonal regeneration and cell integration within the injured CNS such as 3D ultramicroscopy and diffusion tensor imaging.



JACQUELINE SAGEN, PH.D., M.B.A.
Professor, Department of Neurological Surgery

Cellular Implants and Gene Therapy for the Alleviation of Chronic Pain

Our laboratory is exploring novel and more effective strategies in the therapeutic management of chronic debilitating pain. Our recent research is focused on (1) identification of more effective analgesic agents and combinations for alleviating pain using SCI and peripheral neuropathic pain models and (2) development of emerging therapeutic interventions, including cell transplantation and gene therapy, which have the potential to provide long-term alleviation in people with intractable pain, overcoming the need for repeated pharmacologic administration.

THOMAS J. SICK, PH.D.
Professor of Neurology and Physiology & Biophysics

Cellular and Neuronal Circuit Alterations after Traumatic Brian Injury That Contribute to Cognitive Decline and Epilepsy

My laboratory is conducting electrophysiological assessments of neuron and brain circuit alterations that occur after traumatic brain injury. Long-term clinical consequences of brain injury include declines in cognitive function and in many cases the development of epilepsy. We are trying to understand how circuits in the brain change over time after injury and how these changes might lead to alterations of brain function and behavior.

CHRISTINE K. THOMAS, PH.D.
Professor, Department of Neurological Surgery, and Physiology & Biophysics

Neuromuscular Weakness, Fatigue, Spasms, and Regeneration

Our laboratory is currently asking two main questions regarding SCI. First, in studies on people with SCI, we want to understand how age at SCI and SCI duration impact muscle strength because injured people report new declines in physical function at 45-50 years of age. Second, in our animal studies, we are exploring how to protect neurons from death because of SCI. Neuron death is common at the injury site and results in severe muscle weakness.

MICHAEL Y. WANG, M.D., F.A.C.S.
Professor, Departments of Neurological Surgery and Physical Medicine & Rehabilitation
Director of Neurosurgery, University of Miami Hospital

Spinal Cord Injury Outcomes

My primary research has been in the investigation of SCI Outcomes. I work with Miami Project researchers Drs. Allan Levi and Barth Green in studying the clinical effects of Hypothermia. Currently, a multi-center randomized, prospective study on the effects of hypothermia in SCI is planned. In addition, I am studying the clinical application of SCI biomarkers to predict the effects of both injuries as well as therapeutic interventions with Drs. Dalton Dietrich and Ross Bullock.

NANCY L. BRACKETT, PH.D., H.C.L.D.
Research Professor, Departments of Neurological Surgery and Urology

Male Fertility following Spinal Cord Injury

Our research is focused on understanding and improving impairments to male fertility which occur following SCI. A major aim is to determine the cause of impaired semen quality in men with SCI. Our recent evidence indicates that the problem is related to the seminal plasma. Our current research is investigating inflammatory factors, including semen cytokine levels, as contributors to the problem. Our ultimate goal is to develop therapies to normalize semen quality in men with SCI, so that chances of biological fatherhood are increased.

JAMES D. GUEST, M.D., PH.D., F.A.C.S., F.R.C.S.(C)
Clinical Professor, Department of Neurological Surgery
The Preclinical to Clinical Spectrum in SCI: Path to Clinical Testing and Establishing Clinical Evidence

Our SCI research spans preclinical proof-of-concept (POC) studies of therapeutics into early Phase, and pivotal clinical trials of SCI. We are translational scientists using a variety of clinically-relevant tools within the complex process of determining which potential human therapeutics have a probability of success in clinical trial testing. We use our experience and expertise to test combinations of cellular, molecular, and neuromodulatory therapeutics in large animal models. The lab group has members and colleagues ranging from senior medical faculty to postdoctoral students, medical students, neurosurgery residents, and undergraduate students. This is a good setting for those trainees who aim for careers in neurologic therapeutics both in academia and industry with an interest in how medical evidence is developed. We are simultaneously conducting animal and human studies across the translational spectrum.

GILLIAN A. HOTZ, PH.D.
Research Professor, Department of Neurological Surgery
Director, KiDZ Neuroscience Center; Director, Concussion, WalkSafe™ & BikeSafe™Programs
Neurocognitive Deficits Associated with Brain Injury; Injury Prevention

As a behavioral neuroscientist my clinical interests have always been investigating the neurocognitive deficits of those individuals that have sustained a traumatic and acquired brain injury. I have co-authored two neurocognitive tests, The Brief Test of Head Injury for adults and the Pediatric Test of Brain Injury for children. My research has focused on developing evidenced based injury prevention programs in order to prevent brain and spinal cord injuries in children. In 2003, our team developed the WalkSafe program, which has been shown to decrease the number of elementary school age children that get hit by cars, and in 2009 we developed the BikeSafe program which educated middle school age children on bicycle safety skills. As the Director of the Concussion Program we have spent many year developing and implementing a comprehensive countywide high school sports concussion care program, which includes neurologic evaluation, neuroimaging, neuropharmacological management, neuropsychological testing, and baseline test with ImPACT, a computerized neurocognitive screening measure. We also have developed a Concussion Injury Surveillance system. Our program is multidisciplinary and assesses and treats athletes from all levels of play. I am also the PI on many local and federal grants: Safe Routes to School initiatives, Transportation Alternative Programs, GE/NFL MRI Phase 2 study, Brainscope EEG study, one of the TRACK TBI sites, and a new project that will study the Effects of Cannabinoids on Mild TBI.

ALBERTO MARTINEZ-ARIZALA, M.D., F.A.A.N.
Clinical Professor, Departments of Neurology, Neurological Surgery, and Physical Medicine & Rehabilitation
Chief, SCI Service Miami VA Medical Center
Pathophysiology and Treatment of Secondary Complications in Spinal Cord Injury

My research interests focus on common complications that are seen following spinal cord injury: pain, spasticity, syringomyelia, and tethered cord syndrome. My interests include investigating the basis for the development of the different spasticity and pain profiles in the spinal cord injured population and to study potential novel treatments for those conditions.

EVA WIDERSTRÖM-NOGA, D.D.S., PH.D.

Research Professor, Departments of Neurological Surgery, Physical Medicine & Rehabilitation, and Health Scientist Veterans Affairs

SCI-related Neuropathic Pain Phenotypes and Biomarkers

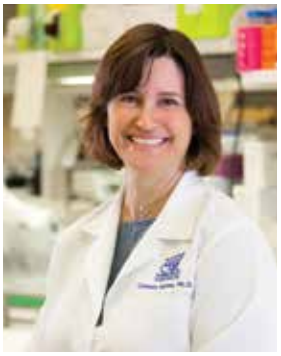
My research program is focused on the identification of clinical correlates of underlying mechanisms of neuropathic pain associated with neurological trauma in order to facilitate the translation of basic research findings to treatments tailored to specific mechanisms. We are also examining the personal experiences of people living with chronic pain and SCI to increase our understanding about factors that help or hinder obtaining optimal pain relief. My research program is highly collaborative and includes extensive interdisciplinary protocols for a multimodal evaluation of self-reported pain symptoms and its psychosocial impact, quantitative assessment of neurological function, and biomarkers including non-invasive brain imaging and genetic polymorphism.

PATRICK M. WOOD, PH.D.

Research Professor (Retired), Department of Neurological Surgery

Changes in the Molecular and Biological Properties of Human Schwann Cells

Schwann cells have shown promise in animal studies in promoting recovery from SCI. We have developed protocols that allow the generation, from a small biopsy of human peripheral nerve, of large numbers of a person's own Schwann cells that can be transplanted back into their injured spinal cord. Efficient growth of human Schwann cells in culture requires the addition of recombinant neuregulin and the cAMP enhancer forskolin. To better understand the effects of these reagents on Schwann cells, we are performing basic research to determine the mechanisms by which neuregulin and cAMP enhancers promote interaction between axons and Schwann cells, including axon-induced proliferation and the formation of myelin sheaths.



COLEEN ATKINS, PH.D.

Associate Professor, Department of Neurological Surgery

Developing Novel Therapies for Traumatic Brain Injury and Spinal Cord Injury

The research in my laboratory focuses on developing novel therapeutic interventions for traumatic brain injury (TBI) and spinal cord injury (SCI). The research goal of my laboratory is to enhance rehabilitation and recovery by manipulating synaptic plasticity at specific levels of the neuroaxis following TBI and SCI. We have found that specific synaptic plasticity signaling pathways are altered after TBI and we are currently using pharmacotherapies to target those pathways to improve behavioral recovery after TBI.

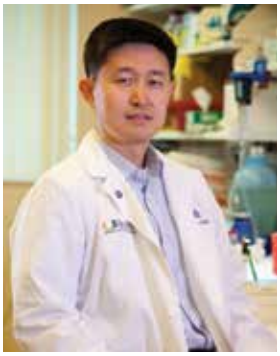
NAGI AYAD, PH.D.

Associate Professor, Department of Psychiatry and Behavioral Sciences

Cell Cycle Transitions in the Developing and Diseased Nervous Systems

The research in my laboratory focuses on cell cycle transitions in the developing nervous system. My laboratory identified essential proteins required for controlling mitotic entry and exit and also demonstrated that cell cycle proteins are present and active in the developing nervous system and fully differentiated neurons. Specifically, the research group uncovered the mechanism through which the Anaphase Promoting Complex/Cyclosome (APC/C) and other cell cycle regulators such as Wee 1 control cell proliferation, cycle exit, and differentiation. These neural progenitor cell cycle proteins are kinases, ubiquitin ligases, and epigenetic enzymes that may be targets in cancer, spinal cord injury, and traumatic brain injury. Thus, my laboratory is searching for novel

molecular pathways that control neural development and are targets in multiple human maladies. This is accomplished using a multi-disciplinary approach that utilizes whole genome, siRNA, cDNA, and small molecule cell-based screens to develop therapies.



JAE K. LEE, PH.D.
Associate Professor, Department of Neurological Surgery

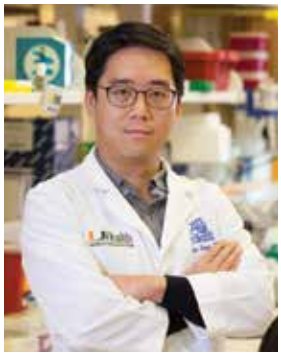
Promoting Proper CNS Wound Healing Response to Enhance Regeneration

The long term research goal in my laboratory is to elucidate the mechanisms of cellular interactions in the injured CNS that create an environment inhibitory to cellular regeneration. Similar to other tissue, injury to the CNS triggers a wound healing response characterized by inflammation, cellular proliferation, and matrix remodeling. Sometimes this wound healing response is incomplete and leads to tissue cavitation, while other times it is excessive and leads to scar formation (both gliotic and fibrotic). A better understanding of this scarring process will help identify novel therapeutic targets that can promote a more permissive environment for CNS regeneration.

KEVIN K. PARK, PH.D.
Associate Professor, Department of Neurological Surgery

Intrinsic Mechanisms of Axon Regeneration

My lab is interested in understanding the neuron's intrinsic mechanisms that account for failure of axon regeneration in the central nervous system (CNS). Previously, I and others have identified several key proteins that block axon regeneration, which are present in mature CNS neurons. In my current research, I will further extend my findings in order to better understand the mechanisms governing robust axon regeneration and also to explore the potential of developing therapeutic strategies for spinal cord injury and other neurodegenerative conditions.



MONICA A. PEREZ, P.T., PH.D.
Associate Professor, Departments of Neurological Surgery, Biomedical Engineering, Physical Therapy, Health Scientist Veterans Affairs

Motor Control in Humans With and Without Spinal Cord Injury

The focus of my research is on understanding how the brain and spinal cord contribute to the control of voluntary movements in healthy humans and in individuals with spinal cord injury. This theme is mainly investigated from a neurophysiological point of view, using a combination of transcranial magnetic stimulation (TMS), magnetic resonance imaging (MRI), and peripheral nerve stimulation techniques. The population of individuals with SCI is heterogeneous. The severity of impairments depends on the site and extent of the injury. We use electrophysiological outcomes to design neuroplasticity protocols aiming to enhance functional outcomes. Current research projects focus on topics such as studying (1) the contribution of the primary motor cortex, the corticospinal system, and subcortical pathways to the control grasping, (2) the organization of paired-pulse TMS-induced indirect (I) waves, and (3) the use of spike-timing dependent plasticity to enhance the activity of residual corticospinal projections after spinal cord injury.

PANTELIS TSOULFAS, M.D.

Associate Professor, Departments of Neurological Surgery and Cell Biology & Anatomy

Neurotrophins: Specificity of Action

My laboratory is interested in two areas of neurobiology that are significant for developing new strategies for spinal cord injury repair. Over the past years, we have worked to modify neurotrophins that are better suited for use in SCI. We are also interested in understanding the processes involved in maintaining and differentiating neural stem cells.

KIM ANDERSON-ERISMAN, PH.D.

Research Associate Professor, Department of Neurological Surgery

Director of Education, The Miami Project to Cure Paralysis

Translational Investigations for Chronic Spinal Cord Injury

My research focuses on translational investigations and bridging the gap between basic science, clinical science, and the public community living with SCI. My current projects focus on 1) SCI consumer engagement in research, 2) determining the minimum amount of exercise and locomotor training required for clinical trials targeting chronic SCI, and 3) identifying the facilitators and barriers to clinical trial participation from the SCI consumer perspective. In addition, I direct our entire Schwann cell clinical trial program (5 trials) in collaboration with Dr. Levi.

IAN D. HENTALL, PH.D.

Research Associate Professor, Department of Neurological Surgery

Brainstem Influences on Neurotrauma

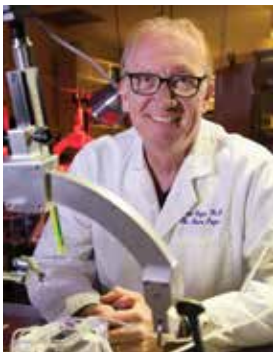
Our research is centered on the general idea that activity in brainstem neurons influences natural repair processes following brain or spinal cord injury, and indeed in many other neurodegenerative disorders, such as multiple sclerosis. Our main focus is to study in rodents how the prolonged electrical stimulation of these brainstem neurons influences functional and anatomical recovery in acute or chronic stages of neurodegeneration. This includes examining various molecular and cellular processes in damaged regions, and diverse types of impairment in visceral and behavioral functioning. Electrical deep brain stimulation in non-eloquent regions can potentially be used to promote long-lasting recovery in people with early or chronic injury.

JONATHAN R. JAGID, M.D.

Clinical Associate Professor, Department of Neurological Surgery

Device Interventions in SCI and TBI

My research includes projects investigating the use of Deep Brain Stimulation for spinal cord injury as well as hypothermia for traumatic brain injury. Presently, we are looking at the use of Deep Bain Stimulation of the periaqueductal gray to improve severe intractable neuropathic pain in spinal cord injured patients. In traumatic brain injury, a prospective multicenter study is underway looking at the effects of modest hypothermia on the surgical evacuation of subdural hematoma's (HOPES Trial). Shortly, we will embark on a study looking at a novel device to restore cortically controlled limb movement in spinal cord injury.



BRIAN R. NOGA, PH.D.
Research Associate Professor, Department of Neurological Surgery

Brain and Spinal Mechanisms Controlling Walking

Neuromodulation technologies are increasingly looked at as potential treatment options for paralysis associated with spinal cord injury (SCI). Deep brain stimulation is one such method that so far has had little or no application in persons with SCI even though most new and chronic injuries are incomplete. Recent work in our laboratory has pointed to a brain target for controlling walking. We are currently investigating the usefulness of stimulating this site to enhance walking in a translational large animal model of SCI.

MARTIN OUDEGA, PH.D.
Research Associate Professor, Department of Neurological Surgery, Health Scientist Veterans Affairs

Bioengineering Cell-based Spinal Cord Repair

We employ animal models to better our understanding of the neuroanatomical and functional consequences of spinal cord injury and to use this information to generate and guide cell-based strategies to maximize functional recovery. Bioengineering principles are tightly integrated in our studies; the versatility of natural and artificial biomaterials offers important possibilities to address questions related to the failed or limited repair by cell transplants. The overall goal of our scientific efforts is to develop repair approaches that lead to significant anatomical restoration resulting in functional restoration after spinal cord injury that can be translated into the clinic.

ROBERTA BRAMBILLA, PH.D.
Assistant Professor, Department of Neurological Surgery

Modulation of the Neuro-Immune Response in Neurologic Disease

The main focus of my research is to understand the role of neuroinflammation in the pathophysiology of neurodegenerative disorders (e.g., multiple sclerosis, spinal cord injury and stroke), with a specific interest in the contribution of glial cells. We study astrocytes and microglia for their involvement in the neuro-inflammatory response to injury, and oligodendrocytes and oligodendrocyte precursor cells for their role in axon myelination, metabolic support of neurons and myelin repair. Currently, our primary lines of research in the area of neuroimmunology are centered on: (1) investigating the role of tumor necrosis factor and its receptors in the processes of neuroinflammation, demyelination and remyelination, and (2) understanding how mitochondrial dysfunction in oligodendrocytes may be involved in the etiopathology of multiple sclerosis.

Hassan Al-Ali, PH.D.
Research Assistant Professor, Department of Neurological Surgery

Drug Discovery for CNS Repair

As a chemical and computational biologist, my lab focuses on identifying pharmacological targets that can induce robust axon regeneration in the injured central nervous system. To accomplish this, I developed a unique drug discovery platform that combines phenotypic screening, target-based profiling, and sophisticated machine learning algorithms. The methodology identified a promising lead compound that is now in preclinical drug development. We continue to develop this methodology into a modular platform to advance drug discovery in spinal cord injury, as well as in other therapeutic areas, including cancer and kidney disease.

RACHEL E. COWAN, PH.D.
Research Assistant Professor, Department of Neurological Surgery

Enhancement and Preservation of Maximal Transfer and Wheelchair Propulsion Ability

Our first focus is defining what level of fitness and 'skill' are required to independently perform transfers to and from the bed, car, shower, and ground and if these are different for various levels of SCI. Our second focus is defining how changes in fitness and wheelchair configuration can meaningfully reduce the effort required to propel a manual wheelchair and how these changes may differ by level of SCI.

JUAN PABLO DE RIVERO VACCARI, PH.D.
Research Assistant Professor, Department of Neurological Surgery

Underlying Mechanisms of the Innate Immune Response and Contributions to Various CNS Diseases

My research focuses on understanding early inflammatory events in central nervous system (CNS) injury. Currently, my laboratory is studying the effects of pattern recognition receptor (PRR)-activation after spinal cord injury (SCI), traumatic brain injury (TBI), and stroke. In addition, my laboratory studies how natural-aging produces inflammation in the brain, a phenomenon known as brain inflammaging, which potentially precedes the onset of age-related neurodegenerative diseases.

MOUSUMI GHOSH, PH.D.
Research Assistant Professor, Department of Neurological Surgery

Altering Host Glial Responses following CNS Injury and Disease to Promote Repair

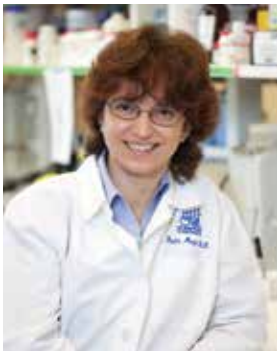
My research interests are focused on altering the hostile environment of the injured or diseased CNS to one that is conducive to repair through altering inflammation. Specifically our work focuses on delineating the intrinsic and extrinsic signals present after injury that antagonize the conversion of activated microglia and macrophages to a reparative phenotype in experimental models of CNS injury and disease. We are also interested in understanding how altering the immunophenotypical profile of macrophages and microglia can modulate spinal cord injury induced central neuropathic pain, affect host glial responses, including glial scar formation, as well as influence the ability of transplanted cells, such as Schwann cells and stem cells, to mediate neurorepair.

HOWARD B. LEVENE, M.D., PH.D., F.A.A.N.S.
Clinical Assistant Professor, Department of Neurological Surgery

Phosphodiesterase Inhibitors and Schwann Cell Transplantation after SCI

Secondary injury after spinal cord injury remains an active area for proposed therapy. With my co-PI Dr. Damien Pearse, we are investigating the effect of novel phosphodiesterase inhibitors after SCI. Phosphodiesterase inhibitors are proposed to sustain cAMP to abate cytotoxic processes during secondary injury, resulting in neuroprotection. Our work currently is transitioning from murine to porcine models. Another proposed therapy for spinal cord injury is to introduce cells to the injury site to help repair, restore, or support existing neurons. I worked with my colleagues on a large animal model to study the effect and behavior of transplanted autologous Schwann cells. I have been involved in the refinement of this animal model. This

approach allows for the scientific study of the behavior of implanted cells and generates the groundwork for clinical trials. Research utilizing this model is done in collaboration with clinicians and scientists at the Miami Project such as Drs. Guest, Solano, Pearse, Wood, Bunge, and many more.



PAULA V. MONJE, PH.D.

Research Assistant Professor, Department of Neurological Surgery

Molecular Mechanisms of Schwann cell Differentiation and Applications in Cell Therapy

Work in my laboratory combines signal transduction studies on mechanisms of Schwann cell differentiation and assay development studies on the use of Schwann cells in cell therapy. We are currently investigating the role of the second messenger cAMP in the reciprocal interactions between Schwann cells and neurons underlying the regulation of Schwann cell proliferation and myelination. We also work on the development of new in vitro systems for the growth and assessment of function of human and rodent Schwann cells. One important goal is to find reliable means to assess and improve the potency of the cells in culture prior to their use in cell transplantation strategies.

SummerStudentResearch

A major role of The Miami Project is to provide education and training for the next generation of neuroscientists

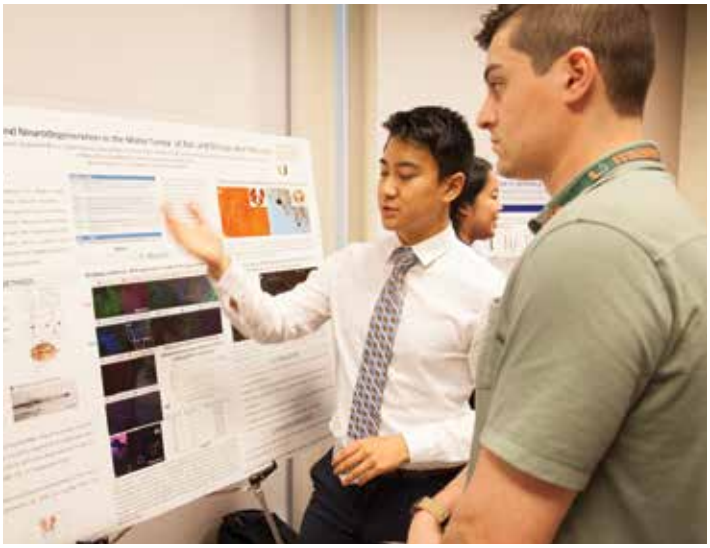
Our long-term educational goal is to increase the number of scientists and laboratories working on paralysis research and central nervous system disorders around the world. Students and young scientists beginning their careers gain skills from The Miami Project's state-of-the-art comprehensive research and academic environment.

In 2016, Drs. Anderson-Erisman and Dietrich embarked on year 4 of a 5-year NIH Summer Student Research Grant, which enables a handful of stellar undergraduate students the opportunity to work in the laboratory of a Miami Project faculty member for 10 weeks during the summer. Each week, the students attended 2 lectures and participated in 1 journal club, in addition to 37 hours of hands-on laboratory work (for a total of 40 hours each week). These 14 students wrote an abstract about their specific research project and presented a poster at the 6th Miami Project Summer Student Research Session on July 26, 2016.

Summer Students and their Research Projects:

Name	Summer mentor	Summer project
Bollepalli, Nagasantosha	Dr. Mary Bunge	"Investigation of Astrocyte Phenotype and Schwann Cell Migration after 6-AN Treatment"
Brothers, Stacey	Dr. Coleen Atkins	"Effect of Phosphodiesterase 4B Inhibition on Cortical and Hippocampal Atrophy Following TBI"
Cap, Caitlyn	Dr. Monica Perez	"Cortical Contributions during Tonic Voluntary Activity after SCI"
Di, Long	Dr. Ross Bullock	"Neurogenesis and Neurodegeneration in the Motor Cortex of Rats and Minipigs after CNS Injury"
Dumenigo, Alejandra	Dr. Damien Pearse	"Examining the Tolerability of Cell Transplant Doses in an Experimental Rodent Model of Chronic SCI"
Kuo, Blanche	Dr. Paula Monje	"Lack of Adhesion as an Underlying Cause of Premature Senescence in Primary Schwann Cell Cultures"
Lee-Hauser, Cecelia	Dr. Brian Noga	"Cholinergic Neuron Detection Within the Brainstem's Motor Pathways via Histological Analysis"

Lubarsky, Maya	Dr. Martin Oudega	"Integrins Involved in Superfibronectin Mediated Survival of Bone Marrow-Derived Mesenchymal Stem Cells"
Mudreac, Andrew	Dr. Rachel Cowan	"Effect of Changing Manual Wheelchair Configuration and Varying Propulsion Conditions on External Demand"
Rosewater, Jacob	Dr. Eva Widerström-Noga	"Psychometric Properties of Graphesthesia Measures in People with Neuropathic Pain after SCI"
Rumpf, Nathan	Dr. Vance Lemmon	"Stereo-3D Visualization of CNS Regeneration"
Shea, Samantha	Dr. Mark Nash	"Examining the Relationship between Self-Reported Versus Evaluator-Rated Level and Extent of Injury After SCI"
Rachel Auslander	Dr. Vance Lemmon	"Reported Activator of Stat3 in Cardiomyocytes Does Not Induce Phosphorylation of Stat3 in Neurons"
Nathaniel Cleri	Dr. Vance Lemmon	"Kinase Inhibition Alters Cell Shape of Human Cells *In Vitro*"



Gail F. Beach
Memorial Lecture Series

The Miami Project has brought many renowned neuroscientists from around the world to our campus as part of The Gail F. Beach Memorial Visiting Lectureship Series. The lectureship series is dedicated to Gail F. Beach, a schoolteacher and person with SCI, whose generosity and foresight provides outstanding educational opportunities for The Miami Project researchers and our neuroscience colleagues at the University of Miami.

October 5, 2016
Nicholas Theodore, MD
Johns Hopkins University – Baltimore, MD

November 2, 2016
David Fuller, PhD
University of Florida – Gainesville, FL

December 7, 2016
Ben Emery, PhD
Oregon Health and Science University – Portland, OR

January 4, 2017
Nanna Finnerup, MD, PhD
Danish Pain Research Center – Denmark

February 8, 2017
Frank Bradke, PhD
German Center for Neurodegenerative Diseases (DZNE) – Germany

March 1, 2017
Richard Andersen, PhD
California Institute of Technology – Pasadena, CA

April 5, 2017
Ron Harris-Warrick, PhD
Cornell University – Ithaca, NY

May 3, 2017
Adam Ferguson, PhD
University of California – San Francisco, CA

Scientific Publications

Published studies that have passed the test of peer review are the benchmark of scientific progress. Listed here are the 2016 research publications by Miami Project scientists and colleagues.

Ahmed AI, Bullock MR, Dietrich WD. (2016). Hypothermia in traumatic brain injury. *Neurosurgery Clinics of North America.* 27(4):489-497.

Ahmed AI, Gajavelli S, Spurlock MS, Chieng LO, Bullock MR. (2016). Stem cells for therapy in TBI. *Journal of the Royal Army Medical Corps.* 162(2):98-102.

Al-Ali H. (2016). The evolution of drug discovery: From phenotypes to targets, and back. *Medicinal Chemical Communications.* 7:788–798.

Al-Ali H, Beckerman S, Bixby JL, Lemmon VP. (2016). In vitro models of axon regeneration. *Experimental Neurology.* doi.org/10.1016.

Al-Ali H, Bixby JL, Lemmon VP. (2016). Exploiting kinase polypharmacology for nerve regeneration. *Neural Regeneration Research*. 11(1):71-72.

Al-Ali H, Lemmon VP, Bixby JL. (2016). Phenotypic screening of small-molecule inhibitors: Implications for therapeutic discovery and drug target development in traumatic brain injury. *Methods Molecular Biology.* 1462:677-688.

Alberga L, Menendez I, Landy HJ, Morcos JJ, Levi AD. (In press). Neurosurgery at the University of Miami. *Journal of Neurosurgery*.

Andersen ND, Srinivas S, Piñero G, Monje PV. (2016). A rapid and versatile method for the isolation, purification and cryogenic storage of Schwann cells from adult rodent nerves. *Scientific Reports*. 6:31781.

Anderson KD, Cowan RE, Horsewell J. (2016). Facilitators and barriers to spinal cord injury (SCI) clinical trial participation: Multi-national perspective of people living with SCI. *J. Neurotrauma*. 33(5):493-499.

Assis-Nascimento P, Umland O, Cepero ML, Liebl DJ. (2016). A flow cytometric approach to analyzing mature and progenitor endothelial cells following traumatic brain injury. *Journal of Neuroscience Methods*. 263:57-67.

Ayad NG, Lee JK, Lemmon VP. (2016). Casein kinase signaling in axon regeneration. *Neural Regeneration Research.* 11(2):210-211.

Batchelor P, Dietrich WD, Kochanek PM, Lundbye J. (2016). Secondary changes after injury and temperature. *Therapeutic Hypothermia and Temperature Management*. 6(2):58-62.

Benavides FD, Santamaria AJ, Bodoukhin N, Guada LG, Solano JP, Guest JD. (2016). Characterization of motor and somatosensory evoked potentials in the Yucatan micropig using transcranial and epidural Stimulation. *Journal of Neurotrauma*. doi 10.1089.

Bernardes D, Brambilla R, Bracchi-Ricard V, Karmally S, Dellarole A, Carvalho-Tavares J, Bethea JR. (2016). Prior regular exercise improves clinical outcome and reduces demyelination and axonal injury in experimental autoimmune encephalomyelitis. *Journal of Neurochemistry*. 136(Suppl 1):63-73.

Bloom L, Burks SS, Levi AD. (2016). Multiple recurrent postoperative spinal infections due to an unrecognized presacral abscess following placement of bicortical sacral screws: Case report. *Journal of Neurosurgery: Spine.* 24(3):502-505.

Bovis SE, Harden T, Hotz G. (2016). Pilot study: A pediatric pedestrian safety curriculum for preschool children. *Journal of Trauma Nursing*. 23(5):247-256.

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The Miami Project to Cure Paralysis was established in 1985 to develop new therapies to improve function in paralyzed individuals. We are very enthusiastic about our current accomplishments and multi-disciplinary research programs. In addition, we are most eager about the future as we continue to move new treatments forward to treat paralysis.

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